Memorandum

Date: November 10, 2020

To: Jessica Urbelis, Ph.D. Division of Food Contact Substances (HFS-275)
Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Division of Science and Technology (HFS-255)

From: Antonetta Thompson-Wood, Physical Scientist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2095: Bicyclo[2.2.1]heptane-2, 3-dicarboxylic acid, calcium salt (1:1), (1R, 2R, 3S, 4S)-rel- (CAS Reg. No. 839683-04-4) as a nucleating agent in the manufacture of polyolefin food contact articles.

Notifier: Milliken Chemical, Division of Milliken & Co

Attached is the FONSI for FCN 2095, which is for the use of bicyclo[2.2.1]heptane-2, 3-dicarboxylic acid, calcium salt (1:1), (1R, 2R, 3S, 4S)-rel- (CAS Reg. No. 839683-04-4) as a nucleating agent in the manufacture of polyolefin food contact articles, except for use in contact with infant formula or human milk. The FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this FCN becomes effective, copies of this FONSI, the notifier's environmental assessment (EA), dated October 16, 2020, and the EA Revision Sheet 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.

Antonetta Thompson-Wood

Attachment: FONSI; EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2095, submitted by Milliken Chemical, Division of Milliken & Co for the use of bicyclo[2.2.1]heptane-2, 3-dicarboxylic acid, calcium salt (1:1), (1R, 2R, 3S, 4S)-rel- (CAS Reg. No. 839683-04-4) as a nucleating agent in the manufacture of polyolefin food contact articles. The FCS may be used at a level up to 0.25 weight percent in:

1. high-density polyethylene and polypropylene in contact with all foods under Conditions of Use A-H, as described in Tables 1 and 2, respectively;
2. low-density polyethylene and linear low-density polyethylene in contact with acidic foods under Conditions of Use A through H; and low-density polyethylene and linear low-density polyethylene in contact with aqueous,
3. alcoholic and fatty foods under Conditions of Use B through H.

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 October 16, 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 is intended to be used as a component of finished food contact articles. The FCS reduces cycle processing time and improves the physical properties of the polyolefin article. The food contact articles manufactured with the FCS include food packaging and repeat-use articles, as well as articles such as utensils, plastic cups and plastic plates. Food-contact articles containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Disposal, recycling and combustion rates of food contact articles manufactured with the FCS will correspond with The United States Environmental Protection Agency (US EPA) Advancing Sustainable Materials Management: 2017 Fact Sheet.[1] Post-consumer disposal of food-contact articles containing the FCS will be to landfills, municipal waste combustors (MWC) complying with 40 CFR Parts 258 and 60, respectively and recycled. 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. Therefore, no significant impacts are expected from incineration of the FCS at MWCs. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

The EA also considered the impact of greenhouse gas (GHG) emissions. Based on estimated market volume information provided in a confidential attachment to the EA, the total estimated GHG emissions resulting from the combustion of food-contact articles manufactured with the FCS in this notification is below 25,000 metric tons CO2-e, the US EPA threshold for mandatory reporting of GHG emissions (40 CFR 98.2). Therefore, no significant environmental impacts are anticipated.

We do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect significant environmental impacts, which would necessitate alternative actions to those proposed in this FCN. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

[1] https://www.epa.gov/sites/production/files/2019-11/documents/2017_facts_and_figures_fact_sheet_final.pdf

As evaluated in the EA, the proposed use of the FCS as described in FCN 2095 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 11-10-2020
Antonetta Thompson-Wood
Physical Scientist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 11-10-2020
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 October 16, 2020 EA for FCN 2095

Revision Sheet Dated: November 10, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) dated October 16, 2020 for food contact notification (FCN) 2095 concluded that the action will not constitute a significant impact. This revision is issued to make a minor change and update of an editorial nature that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to explain the following:

Page 2 of the EA states: "The action identified in this Food Contact Notification (FCN) is to provide for the use of the food contact substance (FCS) identified as bicyclo[2.2.1] heptane- 2,3- dicarboxylic acid, calcium salt (1:1), (1R, 2R, 3S, 4S) - rel-, (CASRN 839683-04-4), as a nucleating agent, at a maximum level of 0.25 weight percent in all polyolefins in contact with all food types, under Conditions of Use A through H."

To reflect the final language for this notification, this statement should state:
"The action identified in this Food Contact Notification (FCN) is to provide for the use of the food contact substance (FCS) identified as bicyclo[2.2.1] heptane- 2,3- dicarboxylic acid, calcium salt (1:1), (1R, 2R, 3S, 4S) - rel-, (CASRN 839683-04-4), as a nucleating agent in the manufacture of polyolefin food contact articles. The FCS may be used at a level up to 0.25 weight percent in:

1. high-density polyethylene and polypropylene in contact with all foods under Conditions of Use A-H, as described in Tables 1 and 2, respectively;
2. low-density polyethylene and linear low-density polyethylene in contact with acidic foods under Conditions of Use A through H; and
3. low-density polyethylene and linear low-density polyethylene in contact with aqueous, alcoholic and fatty foods under Conditions of Use B through H.