Memorandum

Date: April 9, 2020

To: Kelly Randolph, D.V.M, M.P.H., Division of Food Contact Substances (HFS-275)
Through: Mariellen Pfeil, Lead Biologist, Environmental Team, Office of Food Additive Safety (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) 2050: Copolymer of acrylamide, 2-methacryloxyethyltrimethyl ammonium chloride, itaconic acid, and N, N'- methylenebis(acrylamide) (CAS Reg. No 214495-32-6)

Notifier: Harima Chemicals, Inc./Plasmine Technology Inc.

Attached is the FONSI for FCN 2050, which is for the use of copolymer of acrylamide, 2-methacryloxyethyltrimethyl ammonium chloride, itaconic acid, and N, N'- methylenebis(acrylamide) (CAS Reg. No 214495-32-6) as a wet and dry strength agent, as a retention and/or drainage aid added prior to the sheet forming process in the manufacture of paper and paperboard, and as a pitch control agent added prior to the sheet forming process/or to pulp in the pulping process immediately prior to sheet forming. 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, and the notifier's environmental assessment (EA), dated March 31, 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.

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

Food Contact Substance Notification (FCN) 2050, submitted by Harima Chemicals, Inc./Plasmine Technology, Inc. for the use of copolymer of acrylamide, 2-methacryloxyethyltrimethyl ammonium chloride, itaconic acid, and N, N'-methylenebis(acrylamide) (CAS Reg. No 214495-32-6) as a wet and dry strength agent, as a retention and/or drainage aid added prior to the sheet forming process in the manufacture of paper and paperboard, and as a pitch control agent added prior to the sheet forming process/or to pulp in the pulping process immediately prior to sheet forming. The FCS should not exceed 30 lbs/ton dry weight of the finished paper and paperboard in food-contact paper and paperboard. The FCS may be used in contact with all types of food, including powdered infant formula under Conditions of Use A through H, 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 4/9/20).

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 March 31, 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 for use as a wet and dry strength agent, as a retention and/or drainage aid added prior to the sheet forming process in the manufacture of paper and paperboard, and as a pitch control agent added prior to the sheet forming process/or to pulp in the pulping process immediately prior to sheet forming. The FCS is expected to remain with the paper/paperboard fiber and, therefore, environmental introduction via wastewater is not expected. 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. 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. The low use level of the FCS in paper and paperboard will not impact the disposal patterns of the products in which the FCS is used. 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 CO_2-equivalent (CO_2-e) in metric tons (mT), are well 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 MWCs. Thus, the use of the FCS as proposed is not expected to result in significant environmental impacts.

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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2050 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 04-09-2020
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 04-09-2020
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