U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: April 17, 2019

To: Sharon Koh-Fallet, Ph.D., Consumer Safety Officer, Division of Food Contact Notification (HFS-275)
Through: Leah Proffitt, Biologist, Environmental Review Team, Office of Food Additive Safety, HFS-255

From: Physical Scientist, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1966: 1,4-Benzenedicarboxylic acid, polymer with 2-methyl-1,8-octanediamine and 1,9-nonanediamine, reaction products with benzoic acid (CAS Reg. No. 1310362-57-2) for use as a base polymer in the production of food- contact articles. The FCS is not for use in contact with infant formula and human milk.

Notifier: Kuraray Company, Ltd.

Attached is the FONSI for FCN 1966.

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

Antonetta Thompson-Wood

Attachment: FONSI

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN) 1966, submitted by Kurary Company, Ltd. for the use of 1,4-Benzenedicarboxylic acid, polymer with 2-methyl-1,8-octanediamine and 1,9-nonanediamine, reaction products with benzoic acid (CAS Reg. No. 1310362-57-2) for use as a base polymer in the production of food contact articles. The finished food-contact article may contact all food types and may be used under conditions of use A through H, as described in FDA Tables 1 and 2. The FCS is not for use in contact with infant formula and human milk.

The Office of Food Additive Safety has determined that allowing FCN 1966 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 25, 2019. The EA is incorporated by reference in this Finding of No Significant Impact (FONSI) and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

Impacts to the Environment as a Result of Use and Disposal
The FCS is intended for use as a base polymer in the production of food-contact articles. Food-contact articles containing the FCS will be widely distributed across the country. Post-consumer disposal of food-contact articles containing the FCS will be to landfills or municipal solid waste (MSW) combustors complying with 40 CFR Parts 258 and 60, respectively. No significant effect 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. Based upon an analysis using market volume information there are no significant impacts with respect to greenhouse gas emissions resulting from food-contact articles manufactured with the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts.

Use of Resources and Energy
The FCS will replace other conventional polyamides such as Nylon6,6 and Nylon 6T, which is widely used as food packaging. Use of the FCS will consume energy and resources in amounts comparable to the manufacture and use of other, conventional polyamides. As such, replacement by the FCS is not expected to have any significant impact on the use of energy and resources. Food-contact materials manufactured from the FCS are not expected to be collected for recycling.

Mitigation Measures
No significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles manufactured from the FCS. Therefore, mitigation measures are not required.

Alternatives to the Proposed Action
No significant adverse environmental effects were identified in the EA that would necessitate alternative actions for the proposed use in this Food Contact Notification. If the proposed action is not approved, the result would be the continued use of the articles that the FCS would replace. Such action would have no significant environmental impacts.

As evaluated in the EA, the proposed use of the FCS as described in FCN 1966 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed on 04-17-2019
Antonetta Thompson-Wood
Physical Scientist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed on 04-19-2019
Leah Proffitt
Biologist, Environmental Review Team, Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration