Memorandum

Date: January 7, 2020

To: Kelly Randolph, D.V.M., M.P.H., Consumer Safety Officer, Division of Food Contact Substances (HFS-275)
Through: Sarah C. Winfield, Biologist, Environmental Team, Office of Food Additive Safety, HFS-255

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2017: *bis* (hydrogenated palm-oil alkyl) hydroxy amines (CAS Reg. No. 1374859-51-4)

Notifier: BASF Corporation

Attached is the FONSI for FCN 2017, which is for the use of bis(hydrogenated palm-oil alkyl) hydroxy amines (CAS Reg. No. 1374859-51-4) for use as an antioxidant and/or stabilizer in olefin polymers complying with 21 CFR 177.1520(c); intended for single and repeat food contact use. 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 November 8, 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

Food Contact Substance (FCS) Notification (FCN) 2017, submitted by BASF Corporation for the use of *bis* (hydrogenated palm-oil alkyl) hydroxy amines (CAS Reg. No. 1374859-51-4) for use as an antioxidant and/or stabilizer in olefin polymers complying with 21 CFR 177.1520(c); intended for single and repeat food contact use.

The FCS is for use:

1. At levels not to exceed 0.1 percent by weight of polypropylene polymers complying with 21 CFR 177.1520(c), item 1.1, 1.2, 1.3, 3.1a (with density of 0.85- 0.91 gram per cubic centimeter), 3.2b, 3.4 and 3.5. The finished polymers may be used in contact with: (a) food types I, II, IV-B, VII-B and VIII described in Table 1, under Condition of Use A through H described in Table 2; (b) food types VI-A and VI-B described in Table 1, under Conditions of Use A through C described in Table 2; and food types III, IV-A, V, VI-C, VII-A, and IX described in Table 1, under Conditions of Use B through H described in Table 2
2. At levels not to exceed 0.1 percent by weight of high density polyethylene polymers and copolymers complying with 21 CFR 177.1520(c), item 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.6 (with a density not less than 0.94 gram per cubic centimeter) and 5. The finished polymers may be used in contact with food types I, II, IV-B, VI-A, VI-B, VII-B and VIII under Conditions of Use A through H as described in Tables 1 and 2, and with food types III, IV-A, V, VI-C, VII-A and IX under Conditions of Use B through H as described in Tables 1 and 2.
3. At levels not to exceed 0.1 percent by weight of polyethylene polymers and copolymers complying with 21 CFR 177.1520(c), item 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.4, 3.5, and 3.6 (with a density less than 0.94 gram per cubic centimeter). The finished polymers may be used under Conditions of Use B through H described in Table 2.

The FCS is not 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 November 8, 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 (FONSI) and is briefly summarized below.

The FCS is intended for use as an as an antioxidant and/or stabilizer in olefin polymers complying with 21 CFR 177.1520(c); intended for single and repeat food contact use. 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. We anticipate that finished food-packaging materials containing the FCS may be 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. Similarly, when combusted, there is nothing to suggest the FCS would threaten a violation of 40 CFR 60 (based on the composition of the FCS and the marginal amount of FCS compared to all combusted MSW). According to information in a confidential attachment to the EA, total annual emissions of greenhouse gases (GHG), represented as CO2-equivalent (CO2-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. Additionally, as the FCS is expected to replace similar antioxidants/stabilizers on the market and not change the manufacture and disposal pattern of the food contact articles manufactured with the FCS, we do not expect an impact to recycling. 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. Furthermore, as the use and disposal of the FCS is not expected to result in significant adverse environmental impacts; mitigation measures are not identified.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2017 will not significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 01-07-2020
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 01-07-2020
Sarah C. Winfield
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration