
Memorandum

Date: April 10, 2019

To: Kenneth McAdams, Consumer Safety Officer, Division of Food Contact Notifications, HFS-275

Through: Leah Proffitt, Biologist, Environmental Review Team, Office of Food Additive Safety (HFS-255)

From: Biologist, Environmental Review Team, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 1953 (trimethylolpropane; CAS Reg. No. 77-99-6)

Notifier: Tronox LLC

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1953, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

The Food Contact Substance (FCS) that is the subject of FCN 1953 is trimethylolpropane (CAS Reg. No. 77-99-6). The FCS is intended for use as a milling aid and dispersant for pigments used as components of food-contact articles, at levels not to exceed 0.45 percent by weight of pigment. The pigmented article may contact all food types under Conditions of Use A through H. 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.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated February 6, 2019, may be made available to the public. We will post digital transcriptions of the FONSI and the environmental assessment 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.

Sarah C. Winfield

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1953, submitted by Tronox LLC for the use of trimethylolpropane (CAS Reg. No. 77-99-6) as a milling aid and dispersant for pigments used as components of food-contact articles. The FCS will be used at levels not to exceed 0.45 percent by weight of pigment. The pigmented article may contact all food types under Conditions of Use A through H, as described in Table 2.¹ 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 February 6, 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 a milling aid and dispersant for pigments used as components of food-contact articles. Once the FCS-containing food contact articles are made, they will be used and then disposed (landfilled or combusted). Based on confidential estimated market volume information provided in an attachment to the EA, the FCS will make up a very small portion of the total municipal solid waste (MSW) landfilled and combusted. Because of the Environmental Protection Agency's (EPA's) regulations governing landfills (40 CFR Part 258) and the marginal amount of the FCS that would be landfilled, the FCS is not expected to be introduced to land or water when disposed via landfill. Similarly, when combusted, there is nothing to suggest the FCS would threaten a violation of 40 CFR 60, the regulations governing MSW combustion facilities (based on the composition of the FCS and the marginal amount of FCS compared to all combusted MSW). The EA and confidential attachment to the EA also considered the impact of greenhouse gas (GHG) emissions. The confidential attachment estimates the total annual emissions of GHGs, represented as carbon dioxide-equivalents (CO₂-e) in metric tons (mT). The GHG estimate is 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 MSW combustion facilities.

The EA also considered the FCS migrating into food, being consumed, excreted and then introduced into the environment. Although the FCS may be metabolized in the body, as well as diluted (first when mixed with household water and second when mixed with water at Publicly Owned Treatment Works, POTW); the EA conservatively assumes the environmental introduction concentration is the same as the estimated dietary concentration in food (a ppb estimate), which is orders of magnitude below the lowest acute ecotoxicity endpoint identified for the FCS (5 ppm, 24 hour LC₅₀ for sea lamprey). In sum, we do not expect a significant impact to the environment from the use of the FCS as specified in FCN 1953.

As indicated in the EA, we do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect adverse environmental effects, which would necessitate alternative actions to that proposed in this FCN. The alternative of not approving the action proposed herein would result in the continued use of the materials which the FCS would otherwise replace; such action would have no environmental impact. Furthermore, as the use, disposal and excretion of the FCS is not expected to result in significant adverse environmental impacts; mitigation measures are not identified.

¹ <https://www.fda.gov/food/ingredientpackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm>, accessed 4/1/19

As evaluated in the EA, the use of the FCS, as described in FCN 1953, as a milling aid and dispersant for pigments used as components of food-contact articles, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: see electronic signature

Sarah C. Winfield

Biologist

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: see electronic signature

Leah Proffitt

Biologist, Environmental Review Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration