

Memorandum

Date: November 5, 2018

To: Elizabeth Furukawa, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275

Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Food Additive Safety (HFS-255)

From: Staff Fellow, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 1928: Fatty acids, C18-unsatd., dimers, polymers with caprolactam and hexamethylenediamine [Nylon 6/6.36] (CAS Reg. No 2068097-08-3)

Notifier: BASF SE

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1928, which is for the use of Fatty acids, C18-unsatd., dimers, polymers with caprolactam and hexamethylenediamine in the manufacture of food contact films. Films containing the FCS may contact all food types under Conditions of Use A through H. The film layer containing the FCS should not exceed a maximum thickness of 2 mil (0.002 inch). The FCS is not for use in contact with infant formula and human milk.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment, dated October 8, 2018, may be made available to the public. We will post digital transcriptions of the FONSI, the revision sheet 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.

Denis Wafula

Attachments:

Finding of No Significant Impact

Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1928, submitted by BASF SE which is for the use of Fatty acids, C18-unsatd., dimers, polymers with caprolactam and hexamethylenediamine in the manufacture of food contact films. Films containing the FCS may contact all food types under Conditions of Use A through H. The film layer containing the FCS should not exceed a maximum thickness of 2 mil (0.002 inch). The FCS is not for use in contact with infant formula and human milk.

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 8, 2018. 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 in the manufacture of food-contact films. Manufacture of the FCS and FCS-containing food-contact articles is not expected to result in adverse environmental impact. After manufacture, the FCS-containing food contact articles will be used and disposed of by conventional municipal solid waste (MSW) disposal and are not expected to be recycled. Consequently, based on the disposal trends for municipal solid waste (MSW) as reported by the U.S. Environmental Protection Agency (EPA)¹, 80% of the FCS is expected to be disposed in landfills while 20% will be incinerated. Market volume information provided in a confidential attachment to the EA shows that the FCS will make up a very small portion of the total MSW landfilled and incinerated.

Because of EPA's regulations governing landfills (40 CFR Part 258) and the comparatively small amounts 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, the EA explains there is nothing to suggest the FCS would threaten a violation of the regulations governing MSW combustion facilities (40 CFR 60). This conclusion is based on the composition of the FCS and the comparatively small amounts of FCS that will be incinerated compared to the total volume of combusted MSW. The EA also considered the impact of greenhouse gas (GHG) emissions in a confidential attachment. According to information, total annual emissions of GHGs represented as carbon dioxide-equivalents (CO₂-e) in metric tons (mT), would not cause any MSW incinerator to exceed 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. In sum, we do not expect a significant impact to the environment from the use of the FCS as specified in FCN 1928.

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 those 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 and disposal of the FCS is not expected to result in significant adverse environmental impacts; mitigation measures are not identified.

¹ EPA 2018. Advancing Sustainable Materials Management: 2015 Fact Sheet. Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States July 2018.

As evaluated in the EA, the use of the FCS, as described in FCN 1928, as a component in multi-layer films used to make food-contact articles, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____ Date: digitally signed 11-05-2018

Denis Wafula

Staff Fellow

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by _____ Date: digitally signed 11-05-2018

Mariellen Pfeil

Supervisory Biologist, Environmental Review 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 8, 2018 EA for FCN 1928

Dated: November 5, 2018

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of October 8, 2018 for food contact notification (FCN) 1928 concluded that the action will not constitute a significant impact. The 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:

- Footnote 2 states that year of publication of the reference is 2017. The correct year is 2016.
- The EA was submitted with a blank page 3. Information found on page 2 continues without interruption on page 4.