# Memorandum

**Date:** March 20, 2018

**To:** Vanee Komolprasert, Ph.D., Consumer Safety Officer, Division of Food Contact Notification (HFS-275)
**Through:** Mariellen Pfeil, Biologist, Acting Environmental Team Lead, 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) 1865: Isophthalic acid (CAS Reg. No. 121-91-5) for use as a monomer in the manufacture of ethylene terephthalate-isophthalate copolymers. The finished copolymers must contain from 3 to 17 weight percent ethylene isophthalate units. The finished copolymers must also meet specifications in 21 C.F.R. §177.1630(f) - (j) appropriate to their intended use. The FCS is not for use in contact with infant formula and human milk.

**Notifier:** Indorama Ventures USA Inc. and its stewarded affiliates around the world

Attached is the FONSI for FCN 1865.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated February 15, 2018, 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) 1865, submitted by Indorama Ventures USA Inc. and its stewarded affiliates around the world to provide for the safe use of Isophthalic acid (CAS Reg. No. 121-91-5) for use as a monomer in the manufacture of ethylene terephthalate-isophthalate copolymers. The finished copolymers must contain from 3 to 17 weight percent ethylene isophthalate units. The finished copolymers must also meet specifications in 21 C.F.R. §177.1630(f) - (j) appropriate to their intended use. 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 1865 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 15, 2018. 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 monomer in the manufacture of ethylene terephthalate-isophthalate copolymers; therefore, food-contact articles containing the FCS will be widely distributed across the country. Post-consumer disposal of the articles which contain the FCS will be to landfills or municipal solid waste (MSW) combustors complying with 40 CFR Parts 258 and 60, respectively. Recycling of articles manufactured with the FCS will not be impacted as the subject FCS is similar to other dimethyl terephthalate (or terephthalic acid)-ethylene glycol-isophthalic acid copolymers (i.e., PET) polymers currently registered for use. 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 of the FCS or its components as a result of land disposal of articles manufactured with the FCS is not anticipated. The FCS is comprised of carbon, hydrogen, and oxygen, and will not significantly alter the emissions from properly operating MSW combustion facilities. Further, incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60, regulations for mandatory emissions reporting at 40 CFR Part 98, and/or other relevant state and local laws. Based upon an analysis using market volume information provided in the confidential attachment to the EA there are no significant impacts with respect to greenhouse gas emissions resulting from incineration of materials containing 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 similar materials now on the market for use in food-contact articles. Use of the FCS will consume energy and resources in amounts comparable to the manufacture and use of other polymers. As such, replacement by the FCS is not expected to have any significant impact on the use of energy and resources. As polymer resins are typically added to PET, use of the FCS in food-contact applications is not expected to have a negative impact on recyclability.

**Mitigation Measures**

No significant environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the FCS. Therefore, mitigation measures are not required.

**Alternatives to the Proposed Action**

No significant environmental impacts 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 materials 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 1865 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 03-20-2018
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 03-20-2018
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