U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: December 12, 2017

To: Kenneth McAdams, 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) 1835: Use of poly((R)-3-hydroxybutyric acid-co-(R)-3-hydroxyhexanoic acid) (CAS Reg. No. 198007-37-3) in the manufacture of food contact materials, except for use in contact with infant formula and human milk.

Notifier: Kaneka North America LLC

Attached is the FONSI for FCN 1835.

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated August 30, 2017, 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) 1835, submitted by Kaneka North America LLC to provide for the safe use of poly((R)-3-hydroxybutyric acid-co-(R)-3-hydroxyhexanoic acid). The food contact substance (FCS) is intended for use in the manufacture of food contact materials, except for use in contact with infant formula and human milk.

The Office of Food Additive Safety has determined that allowing FCN 1835 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 August 30, 2017. 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.

Articles composed of the FCS may be used in contact with food type's I-V, VIA, VIB, and VII-IX under FDA Conditions of Use B 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.

Impacts to the Environment as a Result of Use and Disposal

The FCS is a "biopolymer" and is intended for use as an alternative to traditional petroleum based polymers that are currently used in the market. The properties of the FCS are expected to be similar to existing polyhydroxyalkanoate (PHA) polymers for use in food-contact applications. The FCS is intended for use in a wide variety of food-contact applications (e.g., single-use utensils and clamshells); 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 is not anticipated. Food-contact articles produced from the FCS may ultimately be subject to composting because PHA polymers are biodegradable. However, composting programs for items such as plastic cutlery and the like are not yet available nationwide in the U.S. 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 Parts 60, regulations for mandatory emissions reporting at 40 CFR 98, and/or 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 packaging applications. 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.

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 1835 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____Date: digitally signed 12-13-2017
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 12-13-2017
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