

Memorandum

Date: November 7, 2018

To: Vanee Komolprasert, Ph.D., P.E., Consumer Safety Officer, Division of Food Contact Notification (HFS-275)

Through: Mariellen Pfeil, Supervisory Biologist, Environmental Review Team, Office of Food Additive Safety, HFS-255
Attached is the FONSI for FCN 1926.

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) 1926: (3R,6R)-3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione (aka polylactide (PLA) polymers), optionally containing up to 16 weight percent D-lactic acid polymer units (CAS Reg. No. 9051-89-2) for use as components of food-contact articles. The finished polymers are intended to contact all types of food under FDA Conditions of Use B through H. The FCS is not for use in contact with infant formula and human milk.

Notifier: Total Corbion PLA bv

Attached is the FONSI for FCN 1926

After this FCN becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), dated October 12, 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) 1926, submitted by Total Corbion PLA bv for the use of (3R,6R)-3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione (aka polylactide (PLA) polymers), optionally containing up to 16 weight percent D-lactic acid polymer units (CAS Reg. No. 9051-89-2) for use as components of food-contact articles. The finished polymers are intended to contact all types of food under FDA Conditions of Use B through H. 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 1926 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 12, 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 components of food-contact articles. The thermal and mechanical properties of this polymer are useful in flexible packaging and in certain rigid packaging applications. Food-contact articles containing the FCS will be widely distributed across the country. Post-consumer disposal of food-contact articles containing the FCS will be to landfills or municipal solid waste (MSW) combustors complying with 40 CFR Parts 258 and 60, respectively. According to U. S. Environmental Agency's (US EPA) 2015, food-contact articles manufactured from PLA are not expected to be collected for recycling.¹ Additionally, even though the FCS is compostable, these articles are not likely to be recovered for composting given that commercial composting (i.e., at monitored sites operating at elevated temperatures, with mixing and aeration, etc.) is not a widely-used disposal option in the United States. 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 by food-contact articles manufactured with the FCS is not anticipated. Under aerobic conditions, PLA decomposes to lactic acid and other smaller compounds, ultimately to carbon dioxide and water. Under anaerobic conditions and in aqueous medium, PLA will hydrolyze to lactic acid.² Additionally, the hydrolysis kinetics of lactide indicates that the hydrolysis half-life of lactide at 25°C is 3.3 hours in neutral and aqueous media.³ 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 there are no significant impacts with respect to greenhouse gas emissions resulting from food-contact articles manufactured with the FCS. Thus, the use of the FCS as proposed is not reasonably expected to result in significant environmental impacts.

¹ US EPA Report: Advancing Sustainable Articles Management: Tables and Figures 2015, Assessing Trends in Articles Generation, Recycling Composting, Combustion with Energy Recovery and Landfilling in the United States. July 2018, Table 8, Plastics in Products in MSW, https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf

² Henton, D.E., et al, "Polylactic Acid Technology," in Natural Fibers, Biopolymers, and Biocomposites, Mohanty AK et al, eds. (2005).

³ Report, Hydrolysis of Lactide in Aqueous and Acidic Media, included as an Attachment to the EA.

Use of Resources and Energy

The FCS will replace similar articles 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, similar food-contact substances. As such, replacement by the FCS is not expected to have any significant impact on the use of energy and resources. Food-contact materials manufactured from PLA are not expected to be collected for recycling. Additionally, even though the FCS is compostable, these materials are not likely to be recovered for composting given that commercial composting (i.e., at monitoring sites operated at the elevated temperatures, with mixing and aeration, etc.) is not a widely-used disposal option in the United States.

Mitigation Measures

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

Alternatives to the Proposed Action

No significant adverse environmental effects 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 articles that the FCS would replace (e.g., other competitive PLA polymers currently on the market to manufacture food packaging). Such action would have no significant environmental impacts.

As evaluated in the EA, the proposed use of the FCS as described in FCN 1926 is not expected to significantly affect the human environment; therefore, an environmental impact statement will not be prepared.

Prepared by _____ Date: digitally signed 11-07-2018

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 11-08-2018

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