U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Memorandum

Date: January 25, 2025

From: Biologist, Office of Pre-Market Additive Safety, Environmental Review Team

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2414

Notifier: LANXESS Corporation

To: Kenneth McAdams,
Office of Pre-Market Additive Safety, Division of Food Contact Substances

Through: Mariellen Pfeil, Lead Biologist,
Office of Pre-Market Additive Safety, Environmental Review Team

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Attached is the FONSI for FCN 2414, which is for the use of dimethyl dicarbonate (CAS Reg. No. 4525-33-1) as a microbial control agent in ready-to-drink 1) hard seltzer and shandy with no more than 8% alcohol by volume (ABV) and 2) cocktails, i.e., distilled spirit-based mixed alcoholic beverages, with no more than 15% ABV. This FONSI explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated December 19, 2024, 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.

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Date: 2025.01.25 07:16:20 -05'00'

Denis Wafula, Ph.D.

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 2414, submitted by LANXESS Corporation for the use of dimethyl dicarbonate (CAS Reg. No. 4525-33-1) as a microbial control agent in ready-to-drink 1) hard seltzer and shandy with no more than 8% alcohol by volume (ABV) and 2) cocktails, i.e., distilled spirit-based mixed alcoholic beverages, with no more than 15% ABV. The FCS may be used at a maximum level of 250 ppm (0.025%) by weight of the beverage. The FCS will also comply with the requirements listed in 21 CFR 172.133(a) and (c). The beverages must be produced under good manufacturing conditions and their microbial load must first be reduced by current technologies such as heat treatment, filtration, etc. prior to the addition of the FCS.

The Office of Pre-Market and 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 December 19, 2024. 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 components of the FCS may be used at a maximum level of 250 ppm (0.025%) by weight of the beverage. The FCS is intended to be used as an antimicrobial agent added to beverages prior to their packaging for consumption. The FCS reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present in the beverage and increases the shelf-life of the packaged beverages.

The FCS will be directly added to beverages. There, the FCS will completely breakdown within hours and thus will not be present in final product consumed. However, some of its breakdown products will remain in the beverage until ingestion by consumers and will be subsequently excreted to wastewater. The breakdown products are methanol (48%), carbon dioxide (48%), ethyl methyl carbonate (4%), dimethyl carbonate (0.2%), and methyl carbamate (0.01%). Carbon dioxide produced during the breakdown of the FCS will eventually vent to the atmosphere and will contribute an insignificant volume to the annual carbon dioxide emissions in the USA. The other breakdown products are either digested and/or metabolized to other substances or excreted largely intact into publicly owned treatment works or private sewage systems.

Due to their high solubility in water and high partition coefficients, when excreted into wastewater, methanol, ethyl methyl carbonate, dimethyl carbonate, and methyl carbamate will almost exclusively partition to the water column and not to sludge. Although they degrade at relatively different rates, methanol, ethyl methyl carbonate, and dimethyl carbonate are readily biodegradable under aerobic conditions. Therefore, they are expected to be rapidly removed during treatment of wastewater and negligible amounts are expected to be introduced into the environment. The EA states that although when compared to the other metabolites methyl carbamate has a relatively slower rate of biodegradation under aerobic conditions, it is still biodegradable. Further, because, it is a negligible product of the dissociation of the FCS, it reasonably expected that insignificant amounts of the substance will be introduced into the environment.

As discussed above, none, or only insignificant amounts of the FCS and its degradation products are reasonably expected to be released into the environment. Based on this conclusion, no significant adverse environment effects are expected as a result of the use of the FCS. This is further reinforced by the available ecotoxicological data for the breakdown products of the FCS. The lowest short term toxicity endpoint for methanol is >10000 mg/L 48h EC_{50} for *Daphnia magna*. Because methanol is rapidly metabolized in the environment, no reliable long term ecotoxicological data is available. However, based on the Environmental Protection Agency's (EPA's) Ecological Structure Activity Relationships (ECOSAR) Class Program, the estimated long-term no observed effect

concentrations (NOECs) in fish and invertebrates are 444 and 208 mg/L, respectively. Although methanol is not expected to adsorb to sediments or end up in biosolids used as soil amendments, if it ended up in sediments, we do not expect any adverse environmental impact. This is because the expected toxicity towards organisms in sediments is low as shown by the available ecotoxicological endpoints; an EC_{50} of 71700 mg/L and LC_{50} of 54890 mg/L for *Tubifex tubifex*. Additionally, if biosolids are used as soil amendments, we do not expect any toxicity towards terrestrial organisms because methanol has shown no toxicity to terrestrial organisms at up to 1000 mg/Kg of dry soil. The lowest short term ecotoxicity endpoint for ethyl methyl carbonate is >62 mg/L 72h EC_{50} for *Desmodesmus subspicatus*. However, because of its rapid biodegradation, no reliable long-term ecotoxicological data exists. The lowest short term toxicity endpoint for dimethyl carbonate is >57.29 mg/L 96h EC_{50} for *Raphidocelis subcapitata*. The long-term invertebrate ecotoxicity endpoint for invertebrates is for *Daphnia magna*, a NOEC of 25.0 mg/L. For methyl carbamate, the lowest short-term ecotoxicological end point is 598 mg/L 96h EC_{50} for *Raphidocelis subcapitata*.

The EA further uses the EPA's Exposure and Fate Assessment Screening Tool (E-FAST 2014)[1] to estimate the worst-case concentrations for the FCS when released to surface waters. The estimates assume are no chemical or biological removal of the FCS during wastewater treatment. The modelled values for methanol (1.8×10^{-1} µg/L), ethyl methyl carbonate (1.6×10^{-2} µg/L), dimethyl carbonate (7.6×10^{-4} µg/L), and methyl carbamate (3.8×10^{-5} µg/L) are orders of magnitude below the previously discussed ecotoxicological endpoints. Therefore, the use and disposal of the FCS and its breakdown products is not expected to have toxic effects.

No significant environmental impacts are expected from use and disposal of the FCS; therefore, mitigation measures have not been identified. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

[1] US EPA (United States Environmental Protection Agency). 2014. Exposure and Fate Assessment Screening Tool (E-FAST) 2014. E-FAST-Exposure and Fate Assessment Screening Tool Version 2014 | US EPA

Consequently, we find that use of the FCS as a microbial control agent in select alcoholic beverages will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Prepared by

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