

Memorandum

Date: May 9, 2022

From: Biologist, Environmental Team, Division of Science and Technology (HFS-255)

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2224: An aqueous mixture containing peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-disphosphonic acid (CAS Reg. No. 2809-21-4), and, optionally, sulfuric acid (CAS Reg. No. 7664-93-9).

Notifier: AFCO

To: Huichen Chang, Ph.D., Consumer Safety Officer, Division of Food Contact Notification (HFS-275)

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2224, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2224 is for the use of an aqueous mixture containing peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-disphosphonic acid, and, optionally, sulfuric acid as an antimicrobial agent in spray, wash, dip, rinse, mist, or chiller water, used in the process of hard-boiled, peeled eggs. The components of the FCS mixture will not exceed 2000 ppm peroxyacetic acid (PAA), 1447 ppm hydrogen peroxide (HP), and 85 ppm 1-hydroxyethylidene-1,1-disphonic acid (HEDP) in the spray, wash, dip, rinse, mist, or chiller water used in the process of hard-boiled, peeled eggs.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA) dated February 25, 2022 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.

Brittany Ott -S Digitally signed by Brittany Ott -
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Brittany Ott

Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2224, submitted by AFCO for the use of an aqueous mixture containing peroxyacetic acid, hydrogen peroxide, acetic acid, 1-hydroxyethylidene-1,1-disphosphonic acid, and, optionally, sulfuric acid as an antimicrobial agent in spray, wash, dip, rinse, mist, or chiller water, used in the process of hard-boiled, peeled eggs, as specified below.

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 February 25, 2022. 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 as an antimicrobial agent in spray, wash, dip, rinse, mist, or chiller water, used in the process of hard-boiled, peeled eggs. The components of the FCS mixture will not exceed 2000 ppm peroxyacetic acid (PAA), 1447 ppm hydrogen peroxide (HP), and 85 ppm 1-hydroxyethylidene-1,1-disphosphonic acid (HEDP) in the spray, wash, dip, rinse, mist, or chiller water used in the process of hard-boiled, peeled eggs. Following the appropriate use of this FCS, any waste process water containing the diluted FCS solution will be disposed of and processed in industrial wastewater treatment facilities established at processing plant use sites, in combination with publicly owned treatment works (POTWs), or privately own treatment plants. As such, the primary pathway by which the FCS is anticipated to be introduced to the environment is through the treatment and disposal of the plant processing wastewater. The total amount of the FCS used at any given food processing facility will depend on the volume of peeled, hard-boiled eggs processed within that facility, and the microbial stress level specific to that site. Therefore, the expected introduction concentration (EIC) was calculated according to an intentionally conservative, worst-case assumption that all of the diluted FCS solution used at a given site is discharged to surface waters.

Due to the high rate of decomposition of PAA, acetic acid, and HP, we do not have a concern regarding environmental release of these components. Additionally, the sulfuric acid dissociates readily in water, and so at environmentally relevant concentrations, sulfuric acid is practically totally dissociated. HEDP is the only chemical component of the FCS that is anticipated to reach the environment to any extent post-wastewater treatment. However, available data^{1,2} indicates that 80% of HEDP is removed from the water due to absorption in sludge, followed by a 10-fold dilution factor applied to the aquatic Expected Introduction Concentration (EIC)³. The final, worst-case scenario for the Expected Environmental Concentration (EEC) for the white water is 1.7 ppm, which is below the standard “acceptable” ecotoxicity concentration within waterways. Due to the half-life in the soil and the ultimate fate of sludge from treatment plants within landfills, as well as the projected HEDP levels

¹ HERA. (2004). Human & Environmental Risk Assessment (HERA) on ingredients of European household cleaning products: phosphonates. Available at: <https://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf>

² Jaworska J, Van Genderen-Takken H, Hanstveit A, van de Plassche E, Feijtel T. (2002). Environmental risk assessment of phosphonates, used in domestic laundry and cleaning agents in the Netherlands. *Chemosphere* 47, 655-665. Abstract available online at: <https://www.sciencedirect.com/science/article/pii/S0045653501003289>

³ Rapaport RA. (1988). Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. *Environmental Toxicology and Chemistry* 7(2): 107-115. Abstract available online at: <https://setac.onlinelibrary.wiley.com/doi/abs/10.1002/etc.5620070204>

provided in a confidential attachment to the EA, the environmental impacts of the HEDP from use of this FCS are not expected to be significant.

We do not expect a net increase in the use of energy and resources from the use of the FCS as notified here as this use will be substitutional to the same and similar materials already on the market. Nor do we expect significant environmental impacts, which would necessitate mitigative actions. The alternative to not allowing the FCN to become effective would be continued use of materials that the FCS would otherwise replace; therefore, this action would have no significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2224 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by **Brittany Ott -S** Digitally signed by Brittany Ott -S
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