

Memorandum

Date: December 18, 2023

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2322

Notifier: Agri-Neo Inc.

To: Elizabeth Furukawa, 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)

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Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2322, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN.

FCN 2322 is for the use of an aqueous solution of peroxyacetic acid (CAS Reg. No. 79-21-0), hydrogen peroxide (CAS Reg. No. 7722-84-1), acetic acid (CAS Reg. No. 64-19-7), sulfuric acid (CAS Reg. No. 7664-93-9) and 1-hydroxyethylidene-1,1-disphosphonic acid (HEDP, CAS Reg. No. 2809-21-4), as an antimicrobial agent for use as a spray on (1) seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, millet hulled, pumpkin, sesame, sunflower kernel, and quinoa), and nuts (almond, cashew, walnut, Brazil nuts, hazelnuts, macadamia and pecans) and (2) pulses (peas, beans, lentils, and chickpeas), soybeans, and all herbs and spices.

The components of the FCS on (1) seeds and nuts will not exceed 229 parts per million (ppm) peroxyacetic acid, 1043 ppm hydrogen peroxide, 388 ppm acetic acid, 48 ppm sulfuric acid, and 25 ppm HEDP; and (2) pulses (peas, beans, lentils, and chickpeas), soybeans, and all herbs and spices will not exceed 459 parts per million (ppm) peroxyacetic acid, 2459 ppm hydrogen peroxide, 1117 ppm acetic acid, 99 ppm sulfuric acid, and 59 ppm HEDP. The FCS is also not intended for contact with infant formula and human milk; such uses were not included as part of the intended use of the substance in the FCN. The FCS will be applied in the preparing, packing, or holding of the food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i). The treated seeds for sprouting are intended to be consumed as sprouts. The treated edible seeds may be consumed directly or further processed into flour, protein, or oil. The treated edible nuts are intended to be consumed as nuts. The treated pulses may be consumed directly. The treated soybeans may be consumed directly or further processed into flour, isolate, meal, or oil. The treated herbs and spices may be consumed directly.

After this notification becomes effective, copies of this FONSI, and the notifier's environmental assessment (EA), with revision sheet, dated October 17, 2023 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

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Attachment: Finding of No Significant Impact (FONSI)

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2322, submitted by Agri-Neo, Inc. for the use of peroxyacetic acid, hydrogen peroxide, acetic acid, sulfuric acid and 1-hydroxyethylidene-1,1-disphosphonic acid (HEDP), as an antimicrobial agent for use as a spray on (1) seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, millet hulled, pumpkin, sesame, sunflower kernel, and quinoa), and nuts (almond, cashew, walnut, Brazil nuts, hazelnuts, macadamia and pecans) and (2) pulses (peas, beans, lentils, and chickpeas), soybeans, and all herbs and spices, excluding infant formula and human milk, 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 October 17, 2023. 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.

No significant environmental release is expected upon the use of the subject FCS. This FCS will be used in processing plants throughout the United States, and wastewater containing the FCS subsequently generated at these facilities is expected to enter the wastewater treatment unit at the plants. It is assumed that treated wastewater will be discharged directly to surface waters in accordance with each plant's National Pollutant Discharge Elimination System (NPDES) permit.

Treatment of the process water is expected to result in complete degradation of peroxyacetic acid, hydrogen peroxide, and acetic acid. Additionally, 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.

Introduction of the HEDP into the environment will mainly result from disposal of wastewater into the processing plant wastewater treatment facility (either on-site or at a publicly owned treatment works plant). Through treatment of the wastewater, approximately 80% of the HEDP will be absorbed into the sewage treatment sludge, as determined from data generated by the HERA project (Human & Environment Risk Assessment on Ingredients of European Household Cleaning Products: Phosphonates)¹. Additionally, a 10-fold dilution factor is assumed for wastewater discharged to surface waters. As such, the final concentrations of HEDP 26.4 ppm. This value is below the aquatic toxicity endpoints for the most sensitive species. Therefore, no significant environmental impacts from HEDP are anticipated.

Terrestrial introduction of HEDP will mainly result from sludge that ends up landfilled or land-applied. If the latter, HEDP is known to degrade in soil with a half-life of 373 days. Additionally, if the HEDP-containing sludge is disposed of in a landfill, HEDP would be expected to be controlled by the relevant EPA regulations, as well as state and/or local guidelines. When the HEDP is introduced to the environment, terrestrial and aquatic toxicity studies done also in the HERA project show that there would be no adverse effect on wildlife as a result of the maximum concentrations predicted for use of this FCS.

¹ HERA. (2004). Human & Environmental Risk Assessment (HERA) on ingredients of European household cleaning products: phosphonates. Accessed June 1, 2023. Available at: <https://www.heraproject.com/files/30-f-04-%20hera%20phosphonates%20full%20web%20wd.pdf>

Use of the FCS is not expected to result in a net increase in the use of energy and resources, because it is expected to replace, to a certain extent, other substances already in use. Manufacture of the FCS and its use as an antimicrobial agent applied to foods will consume energy and resources in amounts comparable to the manufacture and use of materials already in use.

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.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2322 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by

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