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## Memorandum

**Date:** April 29, 2020

**To:** Kenneth McAdams, Division of Food Contact Substances, HFS-275

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

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

**Subject:** Finding of No Significant Impact for Food Contact Substance Notification (FCN) 2029 for an aqueous mixture of hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1) stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4).

**Notifier:** Agri Neo, Inc.

Attached is the Finding of No Significant Impact (FONSI) for FCN 2029 which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2029 is for the use of an aqueous mixture of HP stabilized with HEDP as an antimicrobial agent for use as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, hulled millet, pumpkin, sesame, sunflower kernel, and quinoa) and nuts (almond, cashew, walnut, Brazil nut, hazelnut, macadamia nut, and pecan), except for use in contact with components of infant formula.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated January 24, 2020, 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.

Leah D. Proffitt

Attachment: Finding of No Significant Impact

## FINDING OF NO SIGNIFICANT IMPACT

**Food Contact Substance (FCS) Notification (FCN) 2029:** submitted by AgriNeo, Inc., for the safe use of an aqueous mixture of hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), stabilized with 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), as an antimicrobial agent for use as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, hulled millet, pumpkin, sesame, sunflower kernel, and quinoa) and nuts (almond, cashew, walnut, Brazil nut, hazelnut, macadamia nut, and pecan), except for use in contact with components of infant formula.

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), at a level not to exceed 7.9 g hydrogen peroxide per kg of seeds or nuts. The concentration of HEDP in the FCS will not exceed 60 ppm.

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 will not be prepared. This finding is based on information submitted by the notifier in an environmental assessment (EA) dated January 24, 2020. The EA was prepared in accordance with 21 CFR 25.40. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below.

The antimicrobial agent is needed to reduce or inhibit the growth of pathogenic and non-pathogenic microorganism that may be present on and in food to provide safer foods for consumers.

Waste water from the above-described uses will be either discharged ultimately to a publicly-owned treatment works (POTW), or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters after onsite pre-treatment.

The FCS solution is diluted to 12 ppm HEDP at the time of use. The HP is expected to degrade rapidly into oxygen and water in the presence of organic material or after wastewater treatment at the latest; thus, the focus of the environmental analysis is on HEDP. HEDP is a chelating agent and exhibits unique partitioning behavior such that 80% adsorbs to wastewater treatment sludge, while the remaining 20% stays in the water.

The HEDP use level of 12 ppm is used to estimate environmental introduction concentrations. Application of the 80:20 sludge:water adsorption ratio and 10-fold factor dilution upon discharge to surface waters yields an effective environmental concentration (EEC) of 9.6 ppm for sludge, and 0.24 ppm for water. These concentrations are well below the toxicity endpoints for soil (1000 mg/kg NOEC red worms—*Eisenia foetida*) and water (10 mg/L NOEC *Daphnia magna*). Therefore, there is no toxicity expected from land application of sludge containing 9.6 ppm HEDP. Similarly, discharge to surface waters of effluent containing 0.24 ppm HEDP is not expected to have toxic effects.

Use of the FCS is not expected to cause a significant impact on resources or energy. No mitigation measures are needed since no significant adverse impacts are expected from use of the FCS. The alternative to not allowing the FCN to become effective would be continued use of currently approved antimicrobial agents; such action would have no significant environmental impact.

As evaluated in the EA, the use of the FCS as described in FCN 2029 is not expected to significantly affect the human environment, and, therefore an environmental impact statement will not be prepared.

Prepared by \_\_\_\_\_ Date: digitally signed 04-29-2020

Leah D. Proffitt

Biologist, Environmental Team

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Approved by \_\_\_\_\_ Date: digitally signed 04-29-2020

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