U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: March 1, 2018

To: Anita Chang, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications, HFS-275
Through: Leah Proffitt, Acting Supervisor, Environmental Review Team, Office of Food Additive Safety (HFS- 255)

From: Biologist, Environmental Review Team, Division of Biotechnology and GRAS Notice Review, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification 1850 (an aqueous mixture 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-hydroxyethylidine-1,1- diphosphonic acid, CAS Reg. No. 2809-21-4)

Notifier: Agri-Neo Inc.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 1850, which is for the use of an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, sulfuric acid and 1-hydroxyethylidine-1,1-disphosphonic acid as an antimicrobial agent for use as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia) as well as select edible seeds (chia, flax, and hemp) and nuts (almond, cashew, and walnut).

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated November 22, 2017, may be made available to the public. We will post digital transcriptions of the FONSI and the environmental assessment 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.

Sarah C. Winfield

Attachments: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance (FCS) Notification (FCN) 1850, submitted by Agri-Neo Inc. for the use of an aqueous mixture 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-hydroxyethylidine-1,1-diphosphonic acid (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) as well as select edible seeds (chia, flax, and hemp) and nuts (almond, cashew, and walnut). The components of the FCS application mixture will not exceed 229 parts per million (ppm) peroxyacetic acid (PAA), 1043 ppm hydrogen peroxide (HP), and 25 ppm 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) on treated seeds and nuts. 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) but not applied for use under 201(q)(1)(B)(i)(I), 201(q)(1)(B)(i)(II), or 201(q)(1)(B)(i)(III). The treated edible seeds can be consumed directly or further processed into flour, protein, or oil. The treated edible nuts are intended to be consumed as nuts. The treated seeds for sprouting are intended to be consumed as sprouts.

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 November 22, 2017. 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.

Manufacture of the FCS is not expected to result in environmental introduction, nor adverse environmental impact. When the FCS is used as an antimicrobial on seeds and nuts, environmental introduction could occur via wastewater. It is expected that wastewater from an on-site wastewater treatment facility will discharge to a Publicly Owned Treatment Works (POTW) or, if in possession of a National Pollutant Discharge Elimination System (NPDES) permit, directly to surface waters. Land application of sewage treatment sludge could result in terrestrial introduction of the FCS.

Complete degradation of the FCS components (except HEDP) is expected to occur during treatment at the on-site wastewater treatment plant or POTW. Specifically, peroxyacetic acid will breakdown into oxygen, water and acetic acid, while hydrogen peroxide will break down into oxygen and water. Acetic acid is expected to dissociate in wastewater and degrade at the wastewater treatment facility/POTW. Sulfuric acid will completely dissociate into sulfate ions and hydrated protons, neither of which are a toxicological or environmental concern at the proposed use levels. As such, the environmental impacts of these FCS components are not considered in further detail in the EA. The FCS can optionally be mixed with ethanol. Ethanol is expected to degrade rapidly in air and water, and is expected to have no environmental impact. The EA focuses on the environmental fate and effects of HEDP.

Assuming, as a worst-case, that the FCS goes directly into wastewater, the maximum concentration of HEDP in wastewater would be equal to the concentration of HEDP in the solution sprayed on seeds and nuts, or 540 ppm. Environmental Introduction Concentrations (EICs) were calculated assuming 80 percent of the HEDP partitions to sludge during on-site wastewater treatment (and 20 percent of the HEDP remains in the water). Expected Environmental Concentrations (EECs) were calculated assuming a ten-fold dilution when the disposed wastewater mixes with surface waters. Therefore, the terrestrial EEC for HEDP is 432 ppm (540 ppm * 0.80) and the aquatic EEC for HEDP is 10.8 ppm ([540 ppm * 0.20] / 10).

Terrestrial toxicity studies with HEDP demonstrated no effects on seed germination up to 100 ppm through no effects to earthworms at levels up to 1,000 ppm soil dry weight. The terrestrial HEDP EEC is 432 ppm, a worst case concentration that assumes no dilution from mixing nor degradation of HEDP. As the terrestrial HEDP EEC in sludge is conservative and within the range of concentrations where no effects were observed in terrestrial toxicity studies, there is no toxicity expected from land application of sludge that contains HEDP from the proposed use of the FCS. In evaluation of the aquatic toxicity of the FCS, the lowest relevant HEDP concentration for aquatic toxicity was determined to be the chronic No Observed Effect Concentration (NOEC) of 10 ppm for *Daphnia magna*. The calculated aquatic HEDP EEC of 10.8 ppm is a conservative estimate, as it assumes the concentration of HEDP in wastewater is the same as in the solution applied to seeds and nuts. The aquatic HEDP EEC is just above the 10 ppm chronic NOEC for *Daphnia magna*. Because the aquatic HEDP EEC is conservative, and no effects were observed at 10 ppm, the proposed use of the FCS is not expected to have an adverse effect on aquatic organisms.

We do not expect a net increase in the use of energy and resources from the use of the FCS, nor do we expect adverse environmental effects, which would necessitate alternative actions to those proposed in this FCN. The alternative of not approving the action proposed herein would result in the continued use of materials which the FCS would otherwise replace (*i.e.*, similar antimicrobial agents already on the market); such action would have no significant environmental impact. Furthermore, as the use and disposal of the FCS is not expected to result in significant adverse environmental impacts, mitigation measures are not identified.
The use of the FCS, as described in FCN 1850, as an antimicrobial agent for use as a spray on seeds and nuts, will not significantly affect the quality of the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 03-01-2018
Sarah C. Winfield
Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 03-01-2018
Leah Proffitt
Acting Supervisor, Environmental Review Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration