Memorandum

Date: December 9, 2020

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)

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2106: aqueous solution of hydrogen peroxide, stabilized with 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP), to be used as a microbial agent for use as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, millet hulled, pumpkin, sesame, sunflower, kernel, and quinoa), nuts (almond, cashew, walnut, brazil nuts, hazelnuts, macadamia and pecans), and all spices.

Notifier: Agri-Neo, Inc.

Attached is the Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2106, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2106 is for the use of an aqueous solution of hydrogen peroxide, stabilized with 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP), to be used as a microbial agent for use as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, millet hulled, pumpkin, sesame, sunflower, kernel, and quinoa), nuts (almond, cashew, walnut, brazil nuts, hazelnuts, macadamia and pecans), and all spices.

After this notification becomes effective, copies of this FONSI, an environmental assessment (EA) Revision Sheet, and the notifier's environmental assessment (EA) dated November 11, 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.

Brittany Ott

Attachments: Finding of No Significant Impact (FONSI), EA Revision Sheet

FINDING OF NO SIGNIFICANT IMPACT

Proposed Action: Food Contact Substance Notification (FCN) 2106, submitted by Agri-Neo, Inc. for the use of an aqueous solution of hydrogen peroxide, stabilized with 1-hydroxyethylidine-1,1-diphosphonic acid (HEDP), to be used as a microbial agent for use as a spray on seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, millet hulled, pumpkin, sesame, sunflower, kernel, and quinoa), nuts (almond, cashew, walnut, brazil nuts, hazelnuts, macadamia and pecans), and all spices.

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 11, 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 (FONSI) and is briefly summarized below.

This FCS is for use as an antimicrobial agent spray on seeds, nuts and spices. 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, nuts, or spices. The concentration of HEDP in the FCS will not exceed 60 ppm. 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 seeds for sprouting are intended to be consumed as sprouts. The treated spices may be consumed directly.

No significant environmental release is expected upon the use of the subject FCS. In these applications, the primary pathway of introduction to the environment will be through the plant processing wastewater treated on-site or at local Publicly Owned Treatment Works (POTWs) and subsequently discharged into surface waters. Following wastewater treatment, HP is expected to break down into molecular oxygen and water, and thus have limited to no environmental impact within aquatic, terrestrial, or atmospheric environments.

The stabilizer, HEDP, is the only chemical component of the FCS that is anticipated to reach the environment to any significant extent following wastewater treatment. Based on a maximum concentration of 60 ppm HEDP in the FCS, the maximum concentration in the diluted FCS (20 L FCS plus 80 L water) is 12 ppm. According to the HERA report of 2004, 80% of HEDP is expected to be absorbed into sludge (Expected Environmental Concentration, EEC = 9.6 ppm), leaving a maximum of 2.4 ppm HEDP in the effluent before considering the 10-fold dilution factor typically associated with wastewater treatment (EEC = 0.24 ppm). The sludge resulting from wastewater treatment may end up landfilled or land-applied. If the latter, the HERA (2004) report shows degradation in soil, with a half-life of 373 days. These estimated EECs for HEDP are below the toxicity endpoints for soils (1000 ppm No Observed Effect Concentration [NOEC] for earthworms) and water (10 ppm chronic NOEC for *Daphnia magna*). Therefore, there is no toxicity expected from land application of sludge or from discharge to surface waters of effluent containing the FCS. Additionally, land applications related to the proposed use will result in soil phosphorus and phosphonate concentrations that are an insignificant fraction of the total concentrations introduced to the environment as fertilizers. Finally, no significant effect on the concentration of and exposure to HEDP in the atmosphere is anticipated due to the proposed use of this FCS.

As with most FCSs, production, transportation, use, and disposal of wastes from this FCS will involve the use of natural resources and energy. Although the actual amount of such resources and energy is dependent on market penetration and demand, the anticipated limited use of this FCS, as well as the precursors used to produce the product, is expected to be minimal.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2106 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 12-09-2020
Brittany Ott, Ph. D
Biologist, Environmental Team
Office of Food Additive Safety,
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 12-17-2020
Mariellen Pfeil
Lead Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

U.S. Food and Drug Administration
Revision Sheet for the August 25, 2020 EA for FCN 2082

December 9, 2020

U.S. Food and Drug Administration (FDA) in its review of the Environmental Assessment (EA) of November 11, 2020 for food contact notification (FCN) 2106 concluded that the action will not constitute a significant impact. This revision is issued to make a minor correction that should be acknowledged, while not making any substantive changes to the EA. This revision does not impact our Finding of No Significant Impact (FONSI).

The revision is necessary to remove implied use of this FCS solely on specific spices (i.e. dehydrated onion, garlic, and peppercorns), and instead indicate that this FCS may be used for all spices and to incorporate the FCS use on seeds and nuts as described in prior authorized Food Contact Notification 2029 for which this FCN now replaces.

These revisions are as follows:

Revision Under Item 4 a), first paragraph –

The text, "*The action requested in this submission is to permit the use of the food contact substance (FCS), 33-35% hydrogen peroxide (HP) as an antimicrobial agent for use as a spray on spices (dehydrated onion, garlic, and peppercorns).*

Is revised to, "*The action requested in this submission is to permit the use of the food contact substance (FCS), 33-35% hydrogen peroxide (HP) as an antimicrobial agent for use as a spray on* ***seeds for sprouting (alfalfa, clover, broccoli, flax, and chia), edible seeds (chia, flax, hemp, millet hulled, pumpkin, sesame, sunflower, kernel, and quinoa), nuts (almond, cashew, walnut, brazil nuts, hazelnuts, macadamia and pecans), and all spices***.

Revision Under Item 4 a), third paragraph –

In addition to the above described revision, calculations performed by the review team for this FCN indicate that the maximum concentration of HP on the spices would be 7,900 ppm (or mg HP per kg of spices) using a density of 1.1259 g/mL. Therefore, the text, "*[…] HP on spices will not exceed 7,700 ppm (i.e., 7,700 mg HP per kg of spices).*

Is revised to, "*[…] HP on* ***seeds, nuts and*** *spices will not exceed* ***7,900*** *ppm (i.e.,* ***7,900*** *mg HP per kg of* ***seeds, nuts and*** *spices).*

Revisions resulting from the change in the scope of use for this FCS (i.e., from "specific spices" to "seeds, nuts and all spices") are revised as follows:

The text …
"[…] spices (dehydrated onion, garlic and peppercorns) […]", or *"[…] spices […]"*

Is revised to …
"[…] ***seeds, nuts and spices*** *[…]"*

These revisions (21 in total) are present in the following locations in the EA:
Item 4 a), third paragraph (3 incidents), **fourth paragraph** (2 incidents), **fifth paragraph** (3 incidents), **sixth paragraph** (2 incidents)
Item 4 b) (1 incident)
Item 4 c), first paragraph (1 incident)

Item 5 b), first paragraph (1 incident), **third paragraph** (2 incidents), **fifth paragraph** (1 incident)
Item 6 b), page 6, first paragraph (1 incident), **Table 2 – Use description** (1 incident)**, page 7, first paragraph** (1 incident)**, third paragraph** (1 incident)
Item 7 page 10, Table 4 – Use description (1 incident)