FDA U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: September 20, 2019

To: Laura Dye, Ph.D., Division of Food Contact Substances (HFS-275)
Through: Sarah Winfield, Biologist, Environmental Team, Office of Food Additive Safety (HFS-255)

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

Subject: Finding of No Significant Impact (FONSI) for Food Contact Substance Notification (FCN) 2009 –An aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), acetic acid (AA) (CAS Reg. No. 64-19-7), and, optionally, sulfuric acid (SA) (CAS Reg. No. 7664-93-9).

Notifier: Hydrite Chemical Co.

Attached is the FONSI for FCN 2009, which explains how the Food and Drug Administration (FDA) has met the requirements under the National Environmental Policy Act (NEPA) for this FCN. FCN 2009 is for the use of an aqueous mixture of PAA, HP, AA, and, optionally, SA for use as an antimicrobial agent used as a spray on seeds for sprouting and on edible seeds and nuts.

After this FCN becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated August 16, 2019 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.

Antonetta Thompson-Wood

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A Food Contact Substance Notification (FCN 2009), submitted by Hydrite Chemical Co. to provide for the safe use of an aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), acetic acid (AA) (CAS Reg. No. 64-19-7), and optionally sulfuric acid (SA) (CAS Reg. No. 7664-93-9) for use as an antimicrobial agent used as a spray on seeds for sprouting and on edible seeds and nuts. The components of the FCS will not exceed 229 parts-per-million (ppm) PAA and 1067 ppm HP 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 Federal Food, Drug, and Cosmetic Act (FD&C Act) section 201(q)(1)(B)(i). 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 by the notifier in an environmental assessment (EA), dated August 16, 2019. 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 antimicrobial agent is needed to inhibit the growth of undesirable or pathogenic micro-organisms on edible seeds and nuts, and on seeds for sprouting.

When used in food processing plants, the waste process water containing the FCS is expected to be disposed of through the processing plant wastewater treatment facilities, through a local publicly owned treatment works (POTW) or disposed of to surface waters in accordance with the plants' National Pollutant Discharge Elimination System (NPDES) permit.

Treatment of the process water at an on-site wastewater treatment plant or POTW is expected to result in the complete degradation of PAA, HP, and AA. Specifically, the PAA will breakdown into oxygen, and AA, while HP will break down into oxygen and water. AA is rapidly metabolized by ambient aerobic microorganisms to carbon dioxide and water. Sulfuric acid dissociates readily in water to sulfate ions and hydrated protons. As part of the sulfur cycle, sulfate is either incorporated into living organisms, reduced via anaerobic biodegradation to sulfides, deposited as sulfur, or re-oxidized to sulfur dioxide and sulfate.

Use of the FCS is not expected to cause a significant impact on resources and energy. No mitigation measures are needed since no 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 proposed use of the FCS as an antimicrobial agent as described in FCN 2009 is not expected to significantly affect the human environment; therefore, an EIS will not be prepared.

Prepared by _____Date: digitally signed 09-20-2019
Antonetta Thompson-Wood
Physical Scientist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by _____Date: digitally signed 09-25-2019
Sarah Winfield
Biologist, Environmental Team
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration