

Memorandum

Date: June 25, 2024

To: Katherine Wilkening, Ph.D., Division of Food Contact Substances, HFS-275

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

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2024.06.26 13:08:36 -04'00'

From: Leah Proffitt, Biologist, Environmental Team, Division of Science and Technology, HFS-255

Subject: Finding of No Significant Impact for food-contact notification (FCN) 2367

Notifier: Safe Foods Chemical Innovations and LPR Technologies

Attached is the Finding of No Significant Impact (FONSI) for FCN 2367 for use of an aqueous solution of hydrogen peroxide (CAS Reg. No. 7722-84-1), as an antimicrobial agent in process water for whole poultry carcasses. Hydrogen peroxide concentration will not exceed 2000 ppm in process water applied as scald water to whole poultry carcasses.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment (EA), dated April 26, 2024, 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.

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Leah D. Proffitt

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 2367), submitted by Safe Foods Chemical Innovations and LPR Technologies, to provide for the safe use of an aqueous solution of hydrogen peroxide (CAS Reg. No. 7722-84-1), as an antimicrobial agent in process water for whole poultry carcasses.

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, dated April 26, 2024. The EA is incorporated by reference in this Finding of No Significant Impact and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

Hydrogen peroxide concentration will not exceed 2000 ppm in process water applied as scald water to whole poultry carcasses. During commercial synthesis of hydrogen peroxide (HP), phosphate stabilizers may be present as phosphate salts in the FCS. The Food Chemicals Codex provides the specification for the maximum phosphate content as no more than 0.005% (50 ppm) in hydrogen peroxide (HP) suitable for food use.

The food-contact substance (FCS) is intended to inhibit the growth of undesirable or pathogenic microorganisms and will be used in food processing facilities throughout the United States. Wastewater from the proposed 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 HP is expected to degrade rapidly in the presence of organic material; thus, the focus of the environmental analysis is on the phosphate stabilizer. Phosphate exhibits a unique characteristic in that adsorbs at a 90:10 sludge:water ratio to wastewater treatment sludge. By multiplying the phosphate use levels by 0.9 and 0.1, the notifier arrives at the following EICs/EECs:

$$\text{EEC}_{\text{sludge}}: 0.286 \times 0.9 = 0.257 \ll 1000 \text{ mg/kg NOEC } \textit{Eisenia foetida}$$

$$\text{EIC}_{\text{water}}: 0.286 \times 0.1 = 0.028 = 0.0028 \text{ EEC}$$

If applied as a soil amendment, the sludge will be mixed with other soil and its concentration further diluted. The aquatic EEC of 0.0028 ppm is four orders of magnitude below the nominal concentrations of greater than 100 mg/L for all three organisms tested (fish, daphnia and alga). Therefore, discharge to surface waters is not expected to have toxic effects.

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.

Consequently, we find that use of the FCS as an antimicrobial agent in process water for whole poultry carcasses will not cause significant adverse impacts on the human environment. Therefore, an environmental impact statement will not be prepared.

Leah D. Proffitt -S Digitally signed by Leah D. Proffitt -S
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Prepared by _____

Leah D. Proffitt
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Food and Drug Administration

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