
Memorandum

Date: February 6, 2017

From: Mariellen Pfeil, Supervisory Biologist, Division of Science & Technology, Office of Food Additive Safety, HFS-255

Subject: Finding of No Significant Impact for Food Contact Notification (FCN) 2352.

Notifier: Clean Chemistry Inc.

To: Sean Fischer, Ph.D., Consumer Safety Officer, Division of Food Contact Substances, Office of Food Additive Safety, HFS-275

Attached is the Finding of No Significant Impact (FONSI) for FCN 2352. This FCN was submitted by TSG Consulting on behalf of Clean Chemistry Inc. and is for use of an aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), sodium acetate (CAS Reg. No. 127-09-3), and glycerol (CAS Reg. No. 56-81-5) as an antimicrobial agent in the production and preparation of whole or cut meat and poultry, processed and pre-formed poultry and meat, fruits and vegetables, fish and seafood, shell and hard boiled, peeled eggs, aseptic glass, plastic, and polymeric packaging, liquid, pasteurized whey used in the production of whey protein concentrate, and lactose manufacture.

After this notification becomes effective, copies of this FONSI and the notifier's environmental assessment, dated February 1, 2024 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.

Mariellen Pfeil  Digitally signed by Mariellen Pfeil -S
Date: 2024.02.06 15:13:47 -05'00'

Mariellen Pfeil

Attachment: Finding of No Significant Impact

FINDING OF NO SIGNIFICANT IMPACT

A food-contact notification (FCN No. 2352), submitted by TSG Consulting on behalf of Clean Chemistry Inc. for use of an aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), sodium acetate (CAS Reg. No. 127-09-3), and glycerol (CAS Reg. No. 56-81-5) as an antimicrobial agent in the production and preparation of whole or cut meat and poultry, processed and pre-formed poultry and meat, fruits and vegetables, fish and seafood, shell and hard boiled, peeled eggs, aseptic glass, plastic, and polymeric packaging, liquid, pasteurized whey used in the production of whey protein concentrate, and lactose manufacture.

The Office of Food Additive Safety has determined that allowing this food contact notification (FCN) to become effective will not significantly affect the quality of the human environment and, therefore, will not require the preparation of an environmental impact statement. This finding is based on information submitted by the notifier in an environmental assessment dated February 1, 2024. The environmental assessment (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.

The food contact substance (FCS) is intended for use as an antimicrobial agent in process water and ice used as described above. The specified use rate of the FCS varies according to the regulatory limitations / specifications of the notification' described uses.¹ The highest use rate is when the FCS is used as a an antimicrobial agent applied during the tempering and before milling of grains of wheat, corn, and rice applied at a level not to exceed 3% by weight of the grain at a maximum use level of 6000 ppm peracetic acid and 133.3 ppm hydrogen peroxide. The FCS is intended for use in processing facilities throughout the United States. The need for the FCS is to reduce or eliminate pathogenic and non-pathogenic microorganisms that may be present on food during production activities.

Introduction of Substances into the Environment as a Result of Use

It is expected that wastewater from an on-site wastewater treatment facility will discharge to a publically-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.

The EA describes the process by which PAA is generated from hydrogen peroxide, sodium hydroxide and triacetin using an on-site / on-demand generator. It describes the production and process fate of several residual substances – monoacetin, sodium acetate and glycerol. The EA provides adequate analysis to support that PAA, hydrogen peroxide, sodium hydroxide and monoacetin will not be environmentally released and thus will not have a significant environmental impact. Specifically, PAA, acetic acid, and hydrogen peroxide are rapidly degraded on contact with organic matter, transition metals, and upon exposure to sunlight. PAA will break down into oxygen, water, and acetic acid. Rapid degradation of acetic acid is expected in wastewater and sludges. Residual hydrogen peroxide remaining in the FCS will break down into oxygen and water. Rapid degradation of residual triacetin and monoacetin to sodium acetate and glycerin (glycerol) is also expected during use and wastewater treatment.

¹ The Notified Uses and Specified Limitations are provided as an endnote to this FONSI.

With respect to these remaining components/residues, the EA appropriately describes their environmental fate and impacts and shows that expected surface water release concentrations of these substances are well below published ecotoxicity endpoints for sensitive species. We note further, that these estimates are based conservatively upon the highest notified FCS use rate.

Use of Resources and Energy

The notified uses of the FCS mixture is not expected to result in a net increase in the use of energy and resources, because it is expected to utilize substances already in use and because the components readily degrade.

Alternatives to the Proposed Action

No potential adverse environmental effects were identified in the EA that would require evaluation of reasonable alternatives for the proposed use in this FCN. If the proposed action is not approved, the result would be the continued use of the currently marketed antimicrobial agents that the subject FCS would replace. Such action would not have a significant environmental impact.

As evaluated in the EA, the proposed use of the FCS as described in FCN 2352 is not expected to have a significant environmental impact; therefore, an environmental impact statement will not be prepared.

Mariellen Pfeil -S Digitally signed by Mariellen Pfeil -S
Date: 2024.02.06 15:14:35 -05'00'

Prepared by
Mariellen Pfeil
Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Endnote:

Intended Use: As an antimicrobial agent used:

1. in process water, ice or brine used in washing, rinsing, scalding, or cooling whole or cut meat and poultry carcasses, parts, trim, and organs;
2. in process water, ice, or brine used in washing, rinsing, or cooling processed and preformed meat and poultry products;
3. in process water or ice for washing, rinsing, chilling or processing fruits and vegetables in food processing facilities;
4. in process water and ice used to commercially prepare fish and seafood;
5. during the tempering and before milling of grains of wheat, corn, and rice;
6. in water for washing shell eggs;
7. in spray, wash, dip, rinse, mist, or chiller water for hard boiled, peeled eggs;
8. in liquid, pasteurized whey used in the production of whey protein concentrate;
9. in wash water used to manufacture lactose;
10. in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts or pieces;
11. in surface sauces and in marinades applied on processed and preformed meat and poultry products;
12. alone or in combination with other processes in the commercial sterilization of aseptic filling systems and glass and plastic food packaging and their closures prior to filling,
13. except for use in contact with infant formula and human milk, on food packaging used in contact with infant formula and human milk, or aseptic filling equipment used to fill food packaging used in contact with infant formula and human milk (see Limitations/Specifications).

Limitations/Specifications: The components of the FCS will not exceed:

1. 2000 ppm PAA and 44.4 ppm HP in spray, wash, rinse, dip, chill, and scald process water, ice, or brine used in the production, processing, and preparation of whole or cut meat and poultry carcasses, parts, trim, and organs;
2. 495 ppm PAA and 11 ppm HP in process water, ice, or brine used for washing, rinsing, or cooling of processed and preformed meat and poultry;
3. 600 ppm PAA and 13.3 ppm HP in process water or ice for washing, rinsing, chilling or processing fruits and vegetables in food processing facilities;
4. 230 ppm PAA and 5.1 ppm HP in process water and ice used to commercially prepare fish and seafood;
5. 6000 ppm PAA and 133.3 ppm HP when applied during the tempering and before milling of grains of wheat, corn, and rice applied at a level not to exceed 3% by weight of the grain;
6. 2000 ppm PAA and 44.4 ppm HP in water for washing shell eggs;
7. 2000 ppm PAA and 44.4 ppm HP in spray, wash, dip, rinse, mist, or chiller water for hard boiled, peeled eggs;
8. 15 ppm PAA and 0.33 ppm HP in liquid, pasteurized whey used in the production of whey protein concentrate;
9. 30 ppm PAA and 0.67 ppm HP in wash water used to manufacture lactose;
10. 50 ppm PAA and 1.1 ppm HP in brines, sauces, and marinades applied either on the surface or injected into processed or unprocessed, cooked, or uncooked, whole or cut poultry parts or pieces;
11. 50 ppm PAA and 1.1 ppm HP in surface sauces and in marinades applied on processed and preformed meat and poultry products;
12. 4500 ppm PAA and 100 ppm HP when applied to aseptic filling systems and glass and plastic food packaging and their closures prior to filling.

The FCS is not for use in contact with infant formula and human milk. The FCS is also not for use on food packaging used in contact with infant formula and human milk or on aseptic filling equipment used to fill such packaging. Such uses were not included as part of the intended use of the substance in the FCN.