



March 8, 2017

Michael Harvey
Enviro Tech Chemical Services, Inc.
500 Winmoore Way
Modesto, CA 95358
mharvey@envirotech.com

RE: Food Contact Substance Notification (FCN) 001738
Final Letter
Replaces FCN000447

Dear Mr. Harvey:

This letter is in reference to the notification for the food contact substance and use described as follows:

Food Contact Substance (FCS)

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), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP; CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9).

Notifier

Enviro Tech Chemical Services, Inc.

Manufacturer/Supplier

Enviro Tech Chemical Services, Inc.

Intended Use

As an antimicrobial agent in process water or ice used in the production, processing and preparation of meat, fruits, and vegetables.

Limitations/ Specifications

The components of the FCS mixture will not exceed: (1) 1200 ppm PAA, 275 ppm hydrogen peroxide, and 33 ppm HEDP in process water or ice used for washing, rinsing, or cooling whole or cut meat, including hides, carcasses, parts, trim and organs; (2) 500 ppm PAA, 115 ppm hydrogen peroxide, and 14 ppm HEDP in process water or ice used for washing or chilling fruits and vegetables in food processing facilities.

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740

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This is to inform you that as of March 28, 2017, FCN001738 will become effective. It will be added to the list of effective notifications for FCNs which is available on our website: <http://www.fda.gov>.

The agency has determined that allowing this notification to become effective will not have a significant impact on the quality of the human environment and therefore an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the notification.

This effective notification is applicable only to 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), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP; CAS Reg. No. 2809-21-4), and optionally sulfuric acid (CAS Reg. No. 7664-93-9) manufactured by Enviro Tech Chemical Services, Inc., and is limited to the use identified above. You should inform the Agency of any modification to the FCS, the limitations/specifications given in the notification, or of any alteration in the manufacturing process that would result in a change in the impurities or impurity level in the FCS. Such changes may require the submission of a new notification.

FDA's review of this notification was limited to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The existence of an effective notification for a FCS does not relieve use of the subject substance from compliance with any other provision of the Act or with §174.5 (General provisions applicable to indirect food additives). For example, in accordance with section 402(a)(3) of the Act (21 U.S.C. 342), use of the FCS should not impart odor or taste to food rendering it unfit for human consumption.

Section 301(l) of the FFDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FFDCA, a biological product licensed under section 351 of the Public Health Service Act or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(l)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(l) or any of its exemptions apply to the intended use of the FCS. Accordingly, allowing this FCN to become effective should not be construed as a statement that the intended use of the FCS would not violate section 301(l).

If new data or information becomes available to FDA demonstrating that the intended use of the FCS is no longer safe, the Agency will inform you of its determination that the intended use of the FCS is unsafe. In addition, if you become aware of data that raise questions about the safety of the intended use of the FCS, you should notify the Agency immediately and be prepared to supply the necessary data to resolve any questions.

Food Safety and Inspection Service's Risk, Innovations, and Management Division

Antimicrobial washes intended to be used on meat and poultry are also regulated by the US Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS). Since an effective

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FCN is required by USDA/FSIS to complete their authorization process, forwarding a copy of this Effective Letter will assist in completing their review. If you have previously requested concurrent review at USDA/FSIS by sending them copies of your Acknowledgement Letter and Food Contact Notification, please forward this Effective Letter to USDA/FSIS for their records at the following address:

For US Mail:

William K. Shaw, Jr.
USDA/FSIS/OPPD/RIMD
Stop Code 3782, Patriots Plaza III, Cubicle 8-163A
1400 Independence Ave. SW
Washington, DC 20250-3700

For Courier Services

William K. Shaw, Jr.
USDA/FSIS/OPPD/RIMD
Patriots Plaza III, Rm. 8-142
355 E St. SW
Washington, DC 20024-3221

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Elizabeth S.
Furukawa -S

Digitally signed by Elizabeth S.
Furukawa -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
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Furukawa -S
Date: 2017.03.08 11:31:30 -05'00'

Elizabeth S. Furukawa, Ph.D.
Consumer Safety Officer
Division of Food Contact Notifications HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition