



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

February 29, 2012

Michael S. Harvey, President  
Enviro Tech Chemical Services, Inc.  
500 Winmoore Way  
Modesto, CA 95358

**Re: Food Contact Substance Notification (FCN) 001132  
Effective Letter**

Dear Mr. Harvey:

This letter is in reference to your notification we designated as FCN 001132, which was received on October 13, 2011 (original) and including amendments received on December 6, 2011, January 4, 2012, January 17, 2012, and January 31, 2012, for the food contact substance (FCS) and use described as follows:

**FCS:**

An aqueous mixture of peroxyacetic acid (CASRN: 79-21-0), hydrogen peroxide (CASRN: 7722-84-1), acetic acid (CASRN: 64-19-7), sulfuric acid (CASRN: 7664-93-9, optional ingredient), and 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP, CASRN: 2809-21-4).

**Notifier:**

Enviro Tech Chemical Services, Inc.

**Manufacturer/Supplier:**

Enviro Tech Chemical Services, Inc.

**Intended Use:**

As an antimicrobial agent for use in process water used for washing, rinsing, or cooling whole or cut meat or poultry including carcasses, parts, trim, and organs.

**Limitations/Specifications:**

The final process water will not exceed:

**For poultry:** 1000 ppm peroxyacetic acid, 385 ppm hydrogen peroxide, and 50 ppm HEDP.

**For meat (primarily as a spray):** 400 ppm peroxyacetic acid, 155 ppm hydrogen peroxide, and 20 ppm HEDP.

This is to inform you that as of February 10, 2012, FCN 001132 became effective. It will be added to the list of effective notifications available on the agency's internet site. This list can be accessed from the Internet in the Food Ingredients and Packaging section under the Food topic of [www.fda.gov](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 (FONSI) and the evidence supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the notification.

The effective notification is applicable only to the subject FCS manufactured by Enviro Tech Chemical Services, Inc. You should inform the Agency of any modification in the FCS 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.

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 Federal Food, Drug, and Cosmetic Act or with §174.5 (General provisions applicable to indirect food additives). For example, in accordance with section 402(a)(3) of the Act, use of the FCS should not impart odor or taste to food rendering it unfit for human consumption.

Section 301(ii) 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(ii)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(ii) 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(ii).

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.

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

Sincerely,



Thomas C. Zebovitz, PhD  
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and Applied Nutrition  
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