



May 20, 2014

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

RE: Food Contact Substance Notification (FCN) 001419
Final Letter

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

Notifier

Enviro Tech Chemical Services, Inc.

Manufacturer/Supplier

Enviro Tech Chemical Services, Inc.

Intended Use

The FCS will be used as an antimicrobial additive in process water (processing aid) for poultry products such as:

- a. Post-main chiller (air or water) secondary processing of whole birds, parts and pieces, skin on or off and organs, in the washing, rinsing, cooling and processing of poultry products; and,
- b. Use in pre-air chiller dip tanks and post-main water chiller systems as finishing chillers

Limitations/ Specifications

The FCS would be intermittently or continuously introduced to the wash water and be limited to a maximum dose of 2000 parts per million (ppm) as peroxyacetic acid, 770 ppm as hydrogen peroxide, and 100 ppm as HEDP.

This is to inform you that on May 23, 2014, FCN 001419 will become effective. It will be added to the list of effective notifications which is available in the Food Ingredients and Packaging section under the Food topic on the Agency's internet site at <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 the subject FCS 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 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 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(ll) 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(ll)(1)-(4) applies. In our review of this notification, FDA did not consider whether section 301(ll) 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(ll).

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,



Vivian Gilliam

Consumer Safety Officer
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition