DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

September 28, 2011

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

Re: Food Contact Substance Notification (FCN) 001098

Dear Mr. Harvey:

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

Food Contact Substance (FCS)
Hypobromous acid (CAS Reg. No. 13517-11-8) generated on-site from an aqueous mixture of hydrogen bromide (CAS Reg. No. 10035-10-6) and sodium, potassium or calcium hypochlorite (CAS Reg. Nos. 7681-52-9, 7778-66-7 or 7778-54-3)

Notifier
Enviro Tech Chemical Services, Inc.

Manufacturer/Supplier
Enviro Tech Chemical Services, Inc.

Intended Use
As an antimicrobial in water or ice used for processing poultry products.

Limitations/Specifications
For use at a level not to exceed that needed to provide 450 ppm available bromine or 200 ppm available chlorine in water or ice applied to poultry products.

This is to inform you that as of October 4, 2011, FCN 001098 will become effective. It will be added to the list of effective notifications for FCNs, which can be accessed from the Internet in the Food Ingredients and Packaging section under the Food Topic of 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.

This effective notification is applicable only to the subject FCS manufactured by the listed manufacturer/supplier and is limited to the use of the FCS identified above. 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 in the FCS. Such changes may require 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 21 CFR § 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 food-contact substance. Accordingly, allowing this food-contact substance notification to become effective should not be construed as a statement that the intended use of the food-contact substance 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 no longer safe. 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 data necessary to resolve the questions.

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

Sincerely,

Vanee Komolprasert

Vanee Komolprasert, Ph.D., P.E.
Consumer Safety Officer
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
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