

August 15, 2011

Mr. Mike Harvey  
Regulatory Manager  
Enviro Tech Chemical Services, Inc.  
500 Winmoore Way  
CA, 95358

Dear Mr. Harvey:

This letter is in response to your revised May 12, 2011, notification, requesting a letter of no objection from the Food Safety and Inspection Service (FSIS) for use of FCN 908; a mixture of peroxyacetic acid, hydrogen peroxide, 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP), sulfuric acid and acetic acid as an antimicrobial agent (Log No.10-ING-0693-N-A).

Specifically, Enviro Tech Chemical Services, Inc. is requesting permission to use FCN 908; an aqueous mixture of peroxyacetic acid at a level not to exceed 220 ppm, hydrogen peroxide at a level not to exceed 85 ppm, 1-hydroxyethylidene -1, 1-diphosphonic acid (HEDP) at a level not to exceed 11 ppm, sulfuric acid and acetic acid. The mixture would be used as an antimicrobial agent in process water or ice used for washing, rinsing, storing or cooling of processed and preformed meat and poultry products as described in 21CFR 170.3 (n)(29) and (34).

Under the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA) and the Egg Products Inspection Act (EPIA), FSIS is responsible for determining the efficacy and suitability of food ingredients in meat, poultry, and egg products. Suitability relates to the effectiveness of the ingredient in performing the intended purpose of use and the assurance that the conditions of use will not result in an adulterated product or one that misleads the consumer.

In reviewing your submitted information, it was discovered that the Food and Drug Administration (FDA) received a Food Contact Notification from your company and issued their decision regarding FCN 908 effective September 24, 2009. FDA concluded that there were no safety issues regarding the use of FCN 908 as an antimicrobial agent in process water or ice used for washing, rinsing, storing or cooling of processed and preformed meat and poultry products.

FSIS agrees with FDA's conclusion that the technical effect of the peroxyacetic mixture as an antimicrobial agent at the concentrations specified in FCN 908 has been adequately demonstrated in previous submissions to FDA and FSIS.

Thus regarding suitability, FSIS has no objection to the use of an aqueous solution of peroxyacetic acid at a level not to exceed 220 ppm, hydrogen peroxide at a level not to exceed 85, 1-hydroxyethylidene -1, 1- diphosphonic acid (HEDP) at a level not to exceed 11 ppm, acetic acid and sulfuric acid. The mixture would be used as an antimicrobial agent in process water or ice used for washing, rinsing, storing or cooling of processed and preformed meat and poultry products as described in 21CFR 170.3 (n)(29) and (34).

The use of this ingredient, as described in your notification, will need to be addressed in the establishment's hazard analysis as appropriate, incorporated into a Hazard Analysis and Critical Control Point (HACCP) plan or written Standard Operating Procedures for Sanitation (Sanitation SOPs) or other prerequisite program, validated for its application, and verified on an "on-going" basis for its effectiveness. If the establishment does not address the effects of using this ingredient in its hazard analysis, FSIS would be unable to determine that product processed using this ingredient is not adulterated, and therefore the product would not be eligible to bear the mark of inspection.

This letter should not be considered as validation that your chemical or process would be effective in any particular official establishment.

Any future changes or revisions to your May 12, 2011, notification are to be submitted to the Risk, Innovations, and Management Division (RIMD) as a revised notification prior to implementation. Enviro Tech Chemical Services, Inc. should provide a copy of this letter to each establishment and make it available for the FSIS inspector's review prior to its use.

If you have any further questions, please contact Dr. Liza Murray at (301) 504-0845 or Liza.Murray@fsis.usda.gov

Sincerely,

A handwritten signature in blue ink that reads "William K. Shaw, Jr." with a stylized flourish at the end.

William K. Shaw, Jr., Ph.D.  
Director,  
Risk, Innovations, and Management Division  
Office of Policy and Program Development