



United States Department of Agriculture

Food Safety and
Inspection Service

July 5, 2016

Office of Policy and
Program Development

Risk, Innovations, &
Management Staff
Patriot Plaza III

1400 Independence
Avenue, SW,
Washington, D.C.
20250-3700

Joseph E. Donabed III
R&D Chemist/Microbiologist
Enviro Tech Chemical Services Inc.
500 Winmoore Way
Modesto, CA 95358

Dear Mr. Donabed:

This letter is in response to your April 29, 2016 notification. Enviro Tech Chemical Services, Inc. requested an acceptability determination from the Food Safety and Inspection Service (FSIS) for the use of FCN 1654, an aqueous mixture of peroxyacetic acid, hydrogen peroxide, acetic acid, and 1-hydroxyethylidene, 1,1-diphosphonic acid (HEDP); FSIS Log No. 16-ING-2026-N-A).

FSIS has completed its review of your request and has no objection to the use of FCN 1654 as an antimicrobial agent in brines, sauces and marinades at a level not to exceed 50 ppm as peroxyacetic acid, 18 ppm as hydrogen peroxide, and 6.0 ppm as HEDP. Please contact Ms. Rosalyn Murphy-Jenkins at (301) 504-0879 or via email at rosalyn.murphy-jenkins@fsis.usda.gov, if you have questions on labeling.

The use of this antimicrobial, as described in your notification, will need to be addressed in an establishment's hazard analysis and, as appropriate, incorporated into a Hazard Analysis and Critical Control Point (HACCP) plan, Sanitation Standard Operating Procedures (SSOPs), 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 FCN 1654 in its hazard analysis, FSIS would be unable to determine that product produced using FCN 1654 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.

As described in the FR Notice Vol. 70, No. 201, Pages 60784-60786, dated October 19, 2005, a summary description on your new ingredient will be posted on the Food Safety and Inspection Service New Technology Information Table. If you do not object within five business days from the date that you receive this letter, the Agency will post the included description of the technology on the Web site. If you do object to the description, you should state in writing that you object to the description, explain the basis for your objection (for example, proprietary agreement, confidential commercial information, etc.), and provide an alternate description. FSIS will post the alternate description, unless the Agency concludes that the description does not fairly describe the technology. In such a case, FSIS will post the

description that it has prepared and will notify the company of its decision. The FSIS will post the following summary of your new ingredient:

Log Number	Company Name	Summary of the Notification/Protocol	Regulatory Waiver
16-ING-2026-N-A	Enviro Tech Chemical Services Inc.	An aqueous solution of peroxyacetic acid (PAA), hydrogen peroxide, acetic acid, optional sulfuric acid and 1-hydroxyethylidene, 1,1-diphosponic acid (HEDP). FCN 1654	N/A

FSIS Directive 7120.1, "Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products," will be amended to include the use of FCN 1569 in poultry products as shown below. The amendment will be included in the next scheduled revision of FSIS Directive 7120.1.

SUBSTANCE	PRODUCT	AMOUNT	REFERENCE	LABELING REQUIREMENTS
Antimicrobials				
An aqueous solution of peroxyacetic acid (PAA), hydrogen peroxide, acetic acid, optional sulfuric acid and 1-hydroxyethylidene, 1,1-diphosponic acid (HEDP)	As an antimicrobial agent in: (1) brines, sauces, and marinades to be applied on the surface or injected into processed or unprocessed, cooked or uncooked whole or cut poultry or parts and pieces and (2) surface sauces and marinades applied on processed and preformed meat and poultry products as described in 21 CFR 170.3(n) (29) and (34).	A blend of PAA [50 PPM or less], hydrogen peroxide [18 PPM or less], acetic acid, optional sulfuric acid and HEDP [6 PPM or less].	Food Contact Substance Notification No. FCN 1654	None under the accepted conditions of use (6)
6) Food Contact Substance (FCS) subject to food contact notifications (FCN) is defined as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.				

Sincerely,

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