



Food Safety and  
Inspection Service

December 19, 2018

Office of Policy and  
Program Development

Risk Management and  
Innovations Staff  
Patriot Plaza III

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

Dr. Scott Hartnett  
CMO and Partner  
IET, Inc. dba EcoloxTech  
102 NW 22nd Ave  
Miami, FL 33125

Dear Dr. Hartnett

This letter is in response to your submission, dated April 20, 2018, requesting an acceptability determination for food contact substance notification (FCN) 1811, an aqueous solution of hypochlorous acid, as an antimicrobial in the production of whole or cut meat and poultry and processed and preformed meat and poultry (Log No. 18-ING-2202-N-A).

Specifically, you are requesting the use FCN 1811 as described below:

1. Free chlorine not to exceed 50 ppm in process water or ice which comes into contact with food as a spray, wash, rinse, dip, chiller water, and scalding water for whole or cut meat and poultry, including carcasses, parts, trim, and organs;
  - pH range for all applications is 4.0 – 9.0;
  - Contact/dwell time for spray, wash, rinse, dip: 1 – 120 seconds;
  - Dwell time chiller water: 10 seconds to 120 minutes; and
  - Pressure for spray: 5-100 psi.
2. Free chlorine not to exceed 50 ppm in process water, ice, or brine used for washing, rinsing, or cooling of processed and pre-formed meat and poultry products as defined in 21 CFR 170.3(n)(29) and 21 CFR 170.3(n)(34), respectively;
  - pH range for all applications is 4.0 – 9.0;
  - Contact/dwell time for spray, wash, rinse, dip: 1 – 120 seconds;
  - Pressure for spray: 5-100 psi.
3. Free chlorine not to exceed 60 ppm in process water for washing or rinsing shell eggs;
  - pH range is 4.0 – 9.0;
  - Contact/dwell time for spray, wash, rinse, dip: 1 – 120 seconds;
  - Pressure for spray: 5-100 psi.

Under the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), the Food Safety and Inspection Service (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.

FSIS has completed its review and has no objection to the use of FCN 1811 (an aqueous solution of hypochlorous acid) as described above. Food contact substances intended for use in the production of FSIS-regulated meat, poultry, and egg products are subject to the Food and Drug Administration (FDA) regulations. FCN 1811 became effective with FDA on October 13, 2017.

The use of this aqueous solution of hypochlorous acid (FCN 1811), 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 this ingredient application 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.

All manufacturers, suppliers and establishments are to comply with the Occupational Safety and Health Administration (OSHA) regulations to ensure that the use of this substance will not jeopardize the safety of Federal inspection program personnel (IPP). This includes compliance with Safety Data Sheets (SDS), hazard communication, employee safety information and training, hazard assessments for personal protective equipment (PPE) selection and air sampling data for substances with Permissible Exposure Limits (PELs). The use of this technology will need to be addressed in the establishment's hazard communication program to ensure adequate controls are in place to protect IPP from the associated safety and health hazards. For questions regarding OSHA standards, visit [www.osha.gov](http://www.osha.gov) or call OSHA at 1-800-321-OSHA (6742), TTY 1-877-889-5627.

As described in the October 19, 2005 [Federal Register Notice, Vol. 70, No. 201, pages 60784-60786](#), a summary description on your new technologies will be posted on the FSIS 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 prepared and will notify the company of its decision. FSIS will post the following summary description of your technology:

Case Number	Company Name	Summary of the Notification/Protocol
18-ING-2202-N-A	EcoloxTech	An aqueous solution of hypochlorous acid, as an antimicrobial in the production of whole or cut meat and poultry and processed and preformed meat and poultry.

This change will become effective when listed in FSIS Directive 7120.1, “Safe and Suitable Ingredients in Meat, Poultry, and Egg Products”. The tables in FSIS Directive 7120.1 will be updated to include the following changes:

Substance	Intended use of Product	Amount	Reference	Labeling Requirements
<b>Antimicrobials</b>				
An aqueous solution of hypochlorous acid	(1) in process water or ice which comes into contact with food as a spray, wash, rinse, dip, chiller water, and scalding water for whole or cut meat and poultry, including carcasses, parts, trim, and organs; (2) in process water, ice, or brine used for washing, rinsing, or cooling of processed and pre-formed meat and poultry products as defined in 21 CFR 170.3(n)(29) and 21 CFR 170.3(n)(34), respectively; (3) in process water for washing or rinsing shell eggs.	(1), (2) Free chlorine not to exceed 50 ppm. pH range is 4.0 – 9.0; spray, rinse, wash, dip contact/dwell time: 1-120 seconds; spray pressure: 5-100 psi; chiller water dwell time: 10 seconds-120 minutes.  (3) Free chlorine not to exceed 60 ppm. pH range 4.0 – 9.0; contact time for spray, rinse, wash, dip: 1-120 seconds; spray pressure: 5-100 psi	Food Contact Notification (FCN 1811)	None under the accepted conditions of use (1)

Any questions regarding regulatory guidance from FSIS should be directed to:  
Jennifer E. Green, Ph.D., by email at [Jennifer.Green@usda.gov](mailto:Jennifer.Green@usda.gov) or by phone at 202-649-1520.

Sincerely,

Melanie Abley, Ph.D.  
Acting Director  
Risk Management and Innovations Staff  
Office of Policy and Program Development