



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Office of Policy
and Program
Development

George Washington Carver Center
5601 Sunnyside Ave, STOP 5217
Beltsville, MD 20705-5217

October 23, 2009

Mr. James Tretheway
Mr. Russell Schlager
BioIonix Inc.
4603 Triangle Street
McFarland, WI 53558

Dear Mr. Tretheway and Mr. Schlager:

This letter is in response to your revised notification dated August 21, 2009, for the use of a technology that *“disinfects recycled cold brine and recycled chilled water streams by applying a low voltage electrochemical process to generate free chlorine that destroys bacteria and other pathogens and is applied on raw and ready-to-eat products (RTE)”* (FSIS Log Number 08-NT-0393-NA).

The BioIonix disinfection system is designed for use in meat and poultry establishments for application on raw and RTE. The system operates at low voltage, contains no moving parts, no chemical storage, and is clean-in-place (CIP) capable. The system continuously monitors flow rate, energy per stream volume to apply consistent disinfection performance at levels not to exceed 5ppm free chlorine in recycled cold brine and recycled cold water chillers for the same purpose or product.

The Food Safety and Inspection Service (FSIS), Risk and Innovations Management Division (RIMD), has completed its review of the data and information you submitted on this new technology. We have determined an in-plant trial is not necessary and have no objection for BioIonix, Inc.’s use of this technology in meat and poultry establishments, provided that this technology is used as outlined in the notification and supporting information you submitted.

This letter should not be considered as validation that the application of the technology will be effective in any particular official establishment. The use of this technology for meat and poultry, as described in your notification, will need to be factored into a hazard analysis, and if appropriate, incorporated into a Hazard Analysis and Critical Control Point (HACCP) plan or written Standard Operating Procedures for Sanitation (SSOP) or other prerequisite program, validated for its application, and verified on an “on-going” basis for its effectiveness.

Prior to an establishment using this technology, BioIonix, Inc. will need to assess the operation of the system specific to that particular establishment for revisions to its notification. Future changes or revisions are to be submitted to the RIMD as a revised notification prior to implementation.

BioIonix, Inc. should provide a copy of the notification and supporting information on the system to each establishment and make available for the FSIS inspector's review.

As described in the Federal Register (FR) Notice Vol. 70, Number 201: Pages 60784-60786, dated October 19, 2005, <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/05-014N.htm>, a summary description on your new technology will be posted on the FSIS New Technology Web site. If you do not object within five (5) working days from the date that you receive this letter, the Agency will post the description (see below) of the technology on the Web site. If you object to the description, you should state in writing that you object to the description, explain the basis for your objection (e.g., 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 BioIonix, Inc. of its decision. FSIS intends to post the following summary description of your new technology:

Case Number	Company Name	Summary of the Notification/ Protocol
08-NT-0393-NA	BioIonix, Inc.	A low voltage electrochemical process that disinfects recycled cold brine and recycled chilled water streams by generating free chlorine that destroys bacteria and other pathogens and is applied on raw and ready-to-eat products.

If you have further questions, please contact Mr. Doug Palo at (301) 504-0847 or e-mail Doug.Palo@fsis.usda.gov.

Sincerely,



John M. Hicks, Jr., Director
 Risk & Innovation Management Division
 Office of Policy and Program Development