

May 6, 2011

Mr. Robert Hibbert  
K&L Gates  
1601 K Street, N.W.  
Washington, DC 20006-1600

Dear Mr. Hibbert:

This letter is in response to your December 17, 2010, notification on behalf of EBI Food Safety requesting the Food Safety and Inspection Service's (FSIS) reconsideration of its previous processing aid determination that required labeling of their bacteriophage product. Specifically, you requested that FSIS consider EBI Food Safety's (EFS) bacteriophage product, marketed under the trade name, Listex P100, as a processing aid to reduce *Listeria monocytogenes* (LM) in ready-to-eat (RTE) meat and poultry products and not require labeling.

Previously, FSIS and the Food and Drug Administration (FDA) had reviewed EBI Food Safety's bacteriophage preparation information (GRAS Notice 000218). FDA had determined that Listex P100 was safe and FSIS had determined that it was suitable as an antimicrobial in ready-to-eat (RTE) meat and poultry products to reduce LM. However, the data submitted did not support the request for a processing aid determination as defined in 21 CFR 101.100(a)(3)(ii)(c), i.e., substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food. This required that the bacteriophage preparation be labeled.

However, you submitted additional information<sup>1</sup> with your December 17, 2011, notification to support your claim that the bacteriophage preparation should be considered a processing aid. This additional information showed that Listex P100 only provides a momentary antimicrobial effect on treated product, is present in the finished food at insignificant levels, and that there was no residual activity even when the products are recontaminated with LM. Thus, Listex P100 meets the processing aid definition as defined in 21 CFR 101.100(a)(3)(ii)(c).

Therefore, FSIS has no objection to the use of EBI Food Safety's (EFS) bacteriophage product, marketed under the trade name, Listex P100, as a processing aid to reduce *Listeria monocytogenes* (LM) in ready-to-eat (RTE) meat and poultry products without requiring labeling when applied to the surface of the product to achieve a level of  $1 \times 10^7$  to  $1 \times 10^9$  plaque forming units (pfu) per gram of product. However, standardized

meat and poultry products that do not permit the use of any safe and suitable antimicrobial agent must be descriptively labeled.

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

The use of this ingredient, as described in your notification, will need to be incorporated into a hazard analysis addressing the biological food safety hazard *Listeria monocytogenes*. Where appropriate based on the decisions made in the hazard analysis, the ingredient application must be incorporated into a Hazard Analysis and Critical Control Point (HACCP) plan or written Sanitation Standard Operating Procedures (SSOPs) or other prerequisite program. The ingredient's application procedure must be validated under in-plant conditions 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.

Any future changes or revisions to your December 17, 2010, notification are to be submitted to the Risk, Innovations, and Management Division (RIMD) as a revised notification prior to implementation. A copy of this letter should be provided to each establishment and made available for the FSIS inspector's review prior to its use.

If you have any questions, please contact Dr. David Zeitz at (321) 327-2576 or by e-mail at [David.Zeitz@fsis.usda.gov](mailto:David.Zeitz@fsis.usda.gov).

Sincerely,

  
for

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

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<sup>1</sup> Guenther, S., Huwyler, D., Richard, S. & Loessner, M.J. (2009). Virulent bacteriophage for efficient biocontrol of *Listeria monocytogenes* in ready-to-eat foods. *Appl Environ Microbiol* 75, 93-100.

Holck, A. & Berg, J. (2009). Inhibition of *Listeria monocytogenes* in cooked ham by virulent bacteriophages and protective cultures. *Appl Environ Microbiol* 75, 6944-6.

Soni, K.A., Nannapaneni, R. & Hagens, S. Reduction of *Listeria monocytogenes* on the surface of fresh channel catfish fillets by bacteriophage Listex P100. *Foodborne Pathog Dis* 7, 427-34.

MSU statement on the efficacy of Listex (2010).

DMRI- Summary Report – Efficacy Listex P100 on meat (April 7, 2010).

Denis, C. & Lemonnier S. (2010) Application de bacteriophages pour le controle de *Listeria monocytogenes* dan le saumon fume.

Statement of the Dutch ministry of health on the status of Listex (translated version) (2009).

Swiss BAG statement on the use of Listex in cheese (2007).

Health Canada letter of no objection (2010).

TNO (Netherlands) expert opinion (2010).

Organics Material Review Institute (OMRI) Certificate of listing.