

May 10, 2011

Dr. Elis Owens
Research & Development
Birko Corporation
9152 Yosemite Street
Henderson, Colorado 80640-8027

Dear Dr. Owens:

This letter is in response to your April 19, 2011, revised notification requesting the use of the ingredient mixtures identified as Beefxide™, Porkxide™, and Lambxide™ without labeling. Specifically, you requested the use of Beefxide™ as an antimicrobial processing aid on raw beef carcasses, Porkxide™ as an antimicrobial processing aid on raw pork carcasses, and Lambxide™ as an antimicrobial processing aid on raw lamb carcasses. Furthermore, you intend on using all three mixtures on additional parts of the carcasses that include unskinned livers, tongues, tails, primal cuts, sub-primal-cuts, cuts and trimmings (Log Numbers: 09-NT-0384-N-A, 09-NT-0422-N-A, 09-NT-0455-N-A).

You describe Beefxide™, Porkxide™, and Lambxide™ as a mixture of lactic acid (45-60%), citric acid (20-35%), and potassium hydroxide (>1%) applied as a spray at a level not to exceed 2.5% solution by weight.

As part of the revised notification a study entitled "Evaluation of 2.5% Beefxide and 5.0% Lactic acid as a Surface Decontaminate for Chilled Beef Surfaces" dated March 26, 2009, was submitted. The report data showed that indicator microorganisms (APC counts) exhibited recovery and growth after initial application demonstrating an immediate effect of the treatment. This supports your claim of processing aid status and request for not requiring labeling.

Therefore, the Food Safety and Inspection Service (FSIS) has no objection to the use of Beefxide™, Porkxide™, and Lambxide™ applied on carcasses as a spray at a level not to exceed 2.5% solution by weight including the use on unskinned livers, tongues, tails, primal cuts, sub-primal cuts, cuts and trimmings without requiring labeling. However, before organ meat products are packaged, they must be drained for a minimum of 1 - 2 minutes after the application of the antimicrobial mixture.

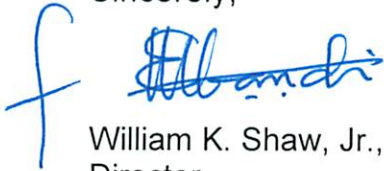
This letter should not be considered as validation that your chemical or process would be effective in any particular official establishment.

The use of this ingredient on raw product, as described in your notification, will need to be incorporated into a hazard analysis. 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 April 19, 2011, 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 Mr. Doug Palo at (301) 504-0847, or by e-mail him at DougPalo@fsis.usda.gov or Dr. David Zeitz at (321) 327-2576 or by e-mail at David.Zeitz@fsis.usda.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "W. Shaw, Jr.", with a large, stylized initial "f" to the left.

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