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Myron D. Nicholson

FSIS Docket Clerk
Docket No. 03-005N
Room 102, Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700
Fax No. 202-690-0486

[Docket No. 03-005N] *Listeria* Risk Assessment Technical Meeting; 68 *Federal Register* 6109; February 6, 2003

Dear Ms. Riley:

Viskase Corporation, a world-wide leader in the manufacturing and sale of cellulose and plastic casing, has a rich 75 year history of sourcing the needs of the processed meat and poultry industry. At the core of Viskase's heritage is an undying pursuit of innovation for the benefit of its customer base---be it new product opportunities, process improvements , in-plant efficiency and though-put gains, and product/process cost reductions.

Of present concern and interest to Viskase are Food Safety Initiatives that will effectively control the quality and wholesomeness of processed meats, and ensure a vibrant and growing process meat industry for Viskase and our customers. With over 10 years of relevant Research and Development activity in the area of pathogen control, Viskase has remained very current of the industry, scientific, and regulatory landscape surrounding the Listeria monocytogenes issues in processed meats.

In keeping with Viskase's commitment to food safety, we support science-based policy making and we would like to congratulate FSIS and FDA on the development of the *Listeria* Risk Assessment Model that was presented at the February 26, 2003 meeting. We can all agree that this risk assessment is a valuable beginning of what should be an ongoing process to improve and utilize the model to guide policy decisions. We also appreciate the opportunity to participate in the improvement process by commenting on aspects of the ***Draft FSIS Risk Assessment for Listeria in Ready-to-eat Meat and Poultry Products;*** Februay 26, 2003.

In gerneral, the Risk Assessment Model does not address the product risk categories as identified in the New Directive (10, 240.3) published December 9, 2002. We concur,

the Risk Assessment precludes any categorization of products, and suggest that clarification be made as a part of the Final Risk Assessment Model publication.

More specifically, we address our comments to the model component which assesses the impact of post-processing technologies on *Listeria monocytogenes* (LM) occurrence and subsequent risk. Model iterations presented in Table 14 of the *Draft FSIS Risk Assessment* predict dramatic improvement in terms of lives saved when a combination of post-processing LM reduction/bacteriocidal technologies (PP) in combination with growth inhibitory/bacteriostatic technologies (GIP) are employed on RTE deli meats. In fact, we believe the projections under-estimate the potential impact of post-processing technologies on risk reduction. Viskase further urges that the Post Processing technologies be made part of the science based Final Rule targeted for 2003.

As pointed out in the meeting of February 26, PP impact was modeled based on assumed efficiencies of 95% or 99% reduction of LM, however, 99% reduction does not accurately reflect the state of the art in terms of post-processing LM reduction available to food processors today. We will not comment on physical process (heat, pressure, etc.) efficiencies, but will speak to the efficiency of ingredient technologies that reduce LM in the product vs. those designated as GIP/formula modifications which only maintain the number of LM at given levels. In order to express the full range of technologies we would urge that the model be run at efficiencies of 90% - 99.9% inclusive. We are confident that this model iteration will show that using such technologies can yield significant improvements in predicted risk reduction. Likewise, we will not be surprised if the benefit is greater than that shown for the iteration of the model utilizing the combination of PP95% + GIP.

The substantial risk reduction in terms of illness and death that are predicted from widespread adoption of post processing listeriocidal technologies can be quantified using this model and, as employment of these technologies are predicted to yield considerable public health benefit. Viskase urges FSIS to move the process forward rapidly from Risk Assessment to Risk Management in the form of the final rule on RTE meat and poultry, and that post processing lethality be incorporated in the corresponding directives and guidelines for implementation.

Thank you for the opportunity to comment on this important draft risk assessment.

Sincerely,

Myron D. Nicholson
Director, Research/Technology and Regulatory Affairs
Viskase Corporation