



The SCHWAN FOOD COMPANY™

August 9, 2004

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852.

RE: Docket 2003P-0574 – *Listeria monocytogenes*; Petition to Establish a Regulatory Limit

Dear Sir or Madam:

The Schwan Food Company (Schwan) respectfully submits these comments **in support** of the Citizen Petition requesting the establishment of a **regulatory limit** of 100 cfu/gram of *Listeria monocytogenes* for those ready-to-eat foods which do not support growth of the organism.

By way of introduction, Schwan is one of the largest branded frozen food companies in the world. The company employs more than 25,000 people in the processing, manufacturing, transportation, distribution and sales of frozen foods nationally, and internationally.

Food safety has always been a priority for the company. Schwan supports the use of science-based standards by government regulators and believes the above-captioned petition is consistent with the use of science to address public health regulation.

Scientific evidence demonstrates that it is the level of *L. monocytogenes* in the product that determines whether a product may be harmful. Accordingly, if a product contains a low initial level of contamination (less than 100 cfu/g) and this level will not increase given the nature of the product (e.g., frozen), *L. monocytogenes* will not pose a public health risk. In the joint FDA/Food Safety and Inspection Service Qualitative Assessment of Relative Risk to Public Health from Foodborne *L. monocytogenes*, the agencies concluded that foods with a low level of contamination and no growth were "highly unlikely to be a source of foodborne listeriosis."

In light of the scientific support contained in both the Citizen Petition and the FDA/FSIS Risk Assessment, it is reasonable for FDA to dedicate its limited resources on products which actually do pose a health risk. As FDA has recognized, it needs to target its resources where there will be demonstrable health benefits.

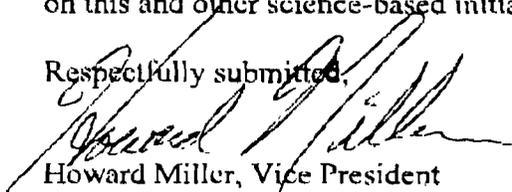
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Schwan supports FDA acting promptly to propose and finalize the regulatory limit requested. The company hopes that such action will be the first of many actions that bases policy on science and that allocates resources most effectively.

FDA consideration of these comments in support of the Citizen Petition is appreciated. Schwan looks forward to the continuing cooperation between the food industry and FDA on this and other science-based initiatives to enhance food safety.

Respectfully submitted,



Howard Miller, Vice President
Vice President of Corporate Relations