



Star Food Products, Inc.

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November 8, 2004

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

Re: Docket No. 2003P-0574, Listeria Monocytogenes; Petition to Establish a Regulatory Limit

To Whom It May Concern:

Star Food Products Inc. is a 50 year old family owned business that produces a variety of ready-to-eat deli salads (meat and non-meat), brunswick stew, chili and pork barbecue products. Star Food Products Inc. is submitting the following comments in response to the Citizen Petition to establish a regulatory limit of 100 colony forming units per gram (cfu/g) of *Listeria monocytogenes* in foods that do not support its growth (69 Fed. Reg. 29564 May 24, 2004).

A risk based approach to *L. monocytogenes* of 100 cfu/g as opposed to the zero-tolerance approach is more consistent with the scientific approach toward food safety as is HACCP. Because *L. monocytogenes* occurs naturally in the environment from various sources, the battle to completely eradicate it from a facility environment is constant and one that can be won and lost on a daily basis.

Star's products are formulated/processed with proven control methods including antimicrobial agents, low pH values, and processing controls (freezing) that inhibit the growth of *Listeria monocytogenes*. Dr. Eric Johnson of the University of Wisconsin found in a study *Control of Listeria Monocytogenes in Fresh Salad Products* commissioned by the Refrigerated Food Association (1993) of which Star Foods is a member that "Overall, *L. monocytogenes* (L.m.) did not survive well in the salads, even in control samples with no barrier chemicals added."

Based upon an FDA study *Quantitative Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods (September 2003)*, deli salads are classified as "moderate risk". "The risks associated with these products appear to be primarily associated with product recontamination, which in turn, is dependent on continued vigilant application of proven control measures". As previously stated Star currently applies barrier products and utilizes processing control methods to reduce the risk by the inhibition of growth during

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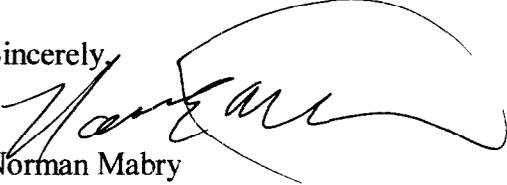
refrigerated storage. As newer processing technologies, more effective antimicrobials agents and improved formulations are introduced, the risk will be reduced further.

The zero tolerance approach to *Listeria monocytogenes* invokes a negative response from food processors due to the regulatory scrutiny of positive results in either the environment or product. Despite vigilant and sincere efforts by processors to manufacture listeria free products and maintain a listeria free environment, listeria can be introduced post processing and even post sale with the same consequences of liability to the processor. Therefore in conjunction with the efforts of food processors, an educated consumer would go a long way in helping to reduce the risk of listeria contamination as well as other foodborne illnesses. In addition, the most susceptible populations should be heavily targeted concerning their high risk.

In conclusion, Star stands in support of the Petition that FDA establish a regulatory limit of 100cfu/g for *Listeria monocytogenes* in foods that do not support the growth of the microorganism.

I may be reached at the following if you have questions on any of these comments
or 336-227-4079.

Sincerely,



Norman Mabry
President