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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:

The following comments are submitted 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).

L. monocytogenes of 100 cfu/g, as opposed to the zero-tolerance approach, is consistent with the scientific approach toward food safety. Recent innovative process control measures have resulted in substantial pathogens in ready-to-eat (RTE) foods. Most perishable food products are formulated/processed under process control methods such as antimicrobial agents, low pH values, and processing control (freezing) that inhibit the growth of *Listeria monocytogenes*. The University of Wisconsin reported in a study commissioned by the Refrigerated Food Association (1993) that "Overall, *L. monocytogenes* (*L.m*) did not survive well in the salads, even in control samples with no barrier chemicals added." Also, where antimicrobial agents (e.g., sodium lactate, sodium diacetate, organic acids) are used, any increase in *L. monocytogenes* is prohibited during refrigerated storage. Work by the Food Processors Institute has indicated that low numbers of *L. monocytogenes* in RTE refrigerated foods are unlikely to be a problem, even for the immune compromised.

Therefore, it seems inappropriate for risk-based food safety programs to allow some tolerance in the standards for RTE foods. Such a program should be regulated by specifically defining the parameters for standards. Therefore, I concur with the petition that the FDA establish a regulatory limit of 100 cfu/g for *Listeria monocytogenes* in foods that do not support the growth of the microorganism.

If you have questions or need clarification on any of these comments, please contact me at the email address above or Donna Moore at dsmoore@starfoodproducts.com (336/227-4079).

Sincerely,

Neil B. Webb, Ph.D.

President, Neil Webb Consulting & Adjunct Professor, Dept. of Food Science, NCSU

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