



2000 Corporate Ridge Suite 1000, McLean Virginia 22102
Telephone (703) 821-0770 E-mail: rgarfield@affi.com

August 5, 2004

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

RE: Docket 2003P-0574 – Regulatory Limit For *Listeria monocytogenes*

Dear Sir or Madam:

The National Frozen Pizza Institute (NFPI) respectfully submits these comments **in support** of the Citizen Petition requesting the establishment of a regulatory limit for *Listeria monocytogenes* (*L.m*) in certain cases. More specifically, the petition requests that the Food and Drug Administration (FDA) adopt a regulatory limit of 100 cfu/gram for those ready-to-eat foods which do not support growth of the organism.

NFPI is the national trade association representing the majority of frozen pizza manufacturers and allied suppliers. Frozen pizzas are not ready-to-eat products and hence are not even subject to the current zero tolerance for *L.m*. Although frozen pizzas are not subject to the zero tolerance, NFPI will always support the use of science-based standards by government regulators and submits the above petition is consistent with the use of science to guide public health regulation.

In the case of *L.m*, the scientific evidence demonstrates that it is the *level* of *L.m* in the product, not its mere presence, which 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.m* will not pose a public health risk. Indeed, in the joint FDA/Food Safety and Inspection Service “Qualitative Assessment of Relative Risk to Public Health from Foodborne *Listeria 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 makes little sense for FDA to dedicate its limited resources on products which do not pose a health risk. Rather, as FDA has recognized, it needs to target its resources where there will be demonstrable health benefits.

We hope that FDA will move promptly to propose and then finalize the regulatory limit requested. Moreover, we hope that such action will be the first of similar actions by FDA, basing regulatory health policy on science and allocating resources where they will be most effective.

We appreciate the opportunity to comment in support of the Citizen Petition and look forward to working with FDA on this and other initiatives to enhance food safety.

Respectfully submitted,

Robert L. Garfield
Executive Director