

LM WORKING GROUP

2000 CORPORATE RIDGE
TELEPHONE 703-821-0770

MCLEAN VIRGINIA
FACSIMILE 703-821-1350

April 11, 2001

00-048N
00-048N-4
American Frozen Foods
Institute, American Meat
Institute, Food Marketing

Docket Clerk
Docket No. 99N-1168
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

6630 01 APR 11 P2

RE: Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods 'Draft Risk Assessment Document and Risk Management Action Plan; (FDA Docket No. 99N-1168), Request to Extend Comment Period.

In addendum to our letter of March 11, 2001 the *Listeria monocytogenes* (LM) Working Group would like to provide additional information to support a request for extension of the comment period. The LM Working Group is a coalition of trade associations and companies representing the food industry, including the 20 food categories referred to in the *Listeria* risk assessment. Since 1994, the LM Working Group has advocated, in cooperation with the federal government, responsible and appropriate risk management strategies and policy concerning the regulation of *Listeria monocytogenes* in domestic and international trade.

The recently released draft *Listeria* Risk Assessment and the FDA / USDA Action Plan will have a major impact on all segments of the food industry including processors, retailers and food service providers, as well as the public. Since the January 19, 2001 *Federal Register* release of the draft risk assessment and the action plan the LM Working Group has met several times to discuss and analyze the document. Collectively, we have determined that the 60-day extension that was initially granted by FDA will be inadequate to allow us to effectively review, analyze and constructively respond to the comprehensive risk assessment and action plan.

Specifically, there is an effort underway to collect and evaluate additional data and modified assumptions that may improve the assessment and reduce the uncertainty attendant with some of the food categories. The LM Working Group has contracted with a third party skilled in risk assessment and familiar with FDA's model to assist in the evaluation of the models and the appropriateness of new data. However, FDA should recognize that with so many food products involved, it will take time to compile data, run

analyses and assess the results. The LM Working Group appreciates FDA's goal to expeditiously "use the best science available to develop this risk assessment," and is confident that the agency aspires to produce a document, based on the most current information, that will be most useful to the agency and food industry. The LM Working Group, therefore, requests that FDA provide an additional extension to the comment period on the *Draft Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods, and the Risk Management Action Plan* (FDA Docket No. 99N-1168) for 60 days until July 18, 2001.

The LM Working Group looks forward to working with the agency on this issue. We believe that the efforts we have underway will serve to enhance the draft *Listeria monocytogenes* risk assessment and the proposed action plan.

Respectfully,

American Frozen Foods Institute
American ~~Meat~~ Institute
Food Marketing Institute
Grocery Manufacturers Association
International Dairy Foods Association
National Chicken Council
National Fisheries Institute
National Food Processors Association
National Turkey Federation

cc: Joseph Levitt
Janice Oliver
Robert Buchanan