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The Food Safety People

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Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland.20852

00-048N
00-048N-1
Rhona Applebaum, Ph.D.

[Docket No. 99N-1168] Relative Risk tu Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-To-Eat Foods; Draft Risk Assessment Document and Risk Management Action Plan

Dear Sir or Madam:

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food *safety,* nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and *crisis* management support for the Association's U.S. and international members- NFPA's members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, *snacks,* drinks, and juices, or provide supplies and services to food manufacturers.

On January 19,2001, the Food and *Drug* Administration (FDA) and the Food Safety and Inspection Service (FSIS) announced the availability of a draft risk assessment on the relationship between foodborne *Listeria monocytogenes* and human health and a risk *management* action plan based on the *L. monocytogenes* risk assessment. The agencies' requested public comment of a technical nature on *the* draft risk assessment and on the risk management strategies reflected *in* the action plan.

The draft risk assessment is an extensive document (approximately 350 pages) of highly technical information. The agencies' goal *is* the use the best science available to develop the risk assessment and for this reason is seeking public comments. In particular, comments *are* requested *on* the assumptions and surrogate dah sources used when specific data were unavailable; the modeling

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approaches and techniques used in developing the exposure assessment, hazard characterization and *risk* characterization; the adequacy of the data sets used in developing exposure assessments; and the transparency *of* the risk assessment document There are also a number of additional specific questions, many of these related to the availability of additional data to address areas where there were gaps.

The risk assessment *is* a significant advance in our efforts to develop risk-based approaches to controlling foodborne illness. This risk assessment provides government and industry with important information that car. be used to target our food safety efforts at those areas where they will be most effective. However, in order to do so, it is critical that we ensure that the best data and most appropriate assumptions are used in this risk assessment. Because of the large volume of *technical* information and the amount of data in the risk assessment, we believe it will take substantially more than 60-days to critically review the report and develop substantive comments. Industry will also be examining the data that were used and determining whether there are additional data that could be provided to the agencies to enhance the risk assessment. For these reasons we are requesting a 60-day extension on the comment period. We are dso requesting that the comment period for the Risk Management Action Plan be extended by the same amount of time. We believe *that* the *Listeria* Risk Assessment and Action Plan are of such importance that this additional time is warranted to obtain the best possible input from the public.

Thank you for your consideration.

Sincerely,

Rhona Applebaum, Ph.D.
Executive Vice President
Scientific and Regulatory Affairs