

**INSTITUTE OF FOOD TECHNOLOGISTS**

THE SOCIETY FOR FOOD SCIENCE AND TECHNOLOGY

BARBARA BYRD KEENAN, CAE / *Executive Vice President*

August 9, 2004

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

Re: Docket No. 2003P-0574

Dear Sir or Madame:

The Institute of Food Technologists (IFT) appreciates the opportunity to offer comments to the Food and Drug Administration (FDA) as the agency considers the petition requesting that a regulatory limit of 100 colony forming units per gram (cfu/g) be established for *Listeria monocytogenes* in foods that do not support the growth of the microorganism. As the international, not-for-profit society for food science and technology with 26,000 members working throughout academia, government, and the food industry, IFT offers the following comments that it is hoped will be helpful to the agency.

IFT agrees with the petitioners that a regulatory limit of 100 cfu/g in foods that do not support the growth of the microorganism, specifically prepared foods held at or below – 1°C, prepared foods with pH values less than 4.4, and prepared foods with water activity ( $a_w$ ) less than 0.92, will not jeopardize public health, and supports amendment of 21 CFR, Part 109, subpart C to establish a regulatory limit for *L. monocytogenes*.

As the petitioners point out, the “zero tolerance” approach to dealing with the microorganism was a “cautious enforcement policy based on the state of the science during the 1980’s,” a time when there was no understanding of the ubiquity of the microorganism nor effective methods for finding it in any environment, including foods and food processing environments, outside humans or animals. As noted in a forthcoming IFT authoritative report, “While there is no way to provide absolute safety in food products, management of risk to an appropriate level is possible and achievable. Through information provided by risk assessors, the food industry, and consumers, it is possible to determine a maximum frequency or concentration of a microbiological hazard in food that would be considered appropriate in terms of consumer protection.” (IFT, 2004). Now it is generally understood that levels of *L. monocytogenes* must considerably

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exceed 100 cfu/g to result in listeriosis, even in immunocompromised subpopulations. In Table IV-12 of the FDA/FSIS Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* among Selected Categories of Ready-to-Eat Foods, the probability of mortality at the 5<sup>th</sup> percentile for the neonatal population (worst case scenario) was 1 in  $1.7 \times 10^{-8}$ . Additionally, Appendix 9 shows that in the vast majority of sporadic and outbreak cases, the contamination levels exceeded 100 cfu/g by several orders of magnitude.

Moreover, studies question whether all subspecies of *L. monocytogenes* are virulent or of equal virulence (Wiedmann et al., 1997); some subtypes of *L. monocytogenes* found in or on foods have not been associated with illness (IFT, 2002). Thus, IFT agrees with the petitioners that there is now a credible scientific basis for reexamining U.S. regulatory policies on *L. monocytogenes*.

IFT agrees with the petitioners' assertion that consumer protection is a function of the number of *L. monocytogenes* cells in a food and that this has a greater impact on the likelihood of illness than the mere presence of the microorganism. The petitioners cite Chen et al. (2003) to demonstrate that when the number of *L. monocytogenes* in foods is limited to 100 cfu/g, the number of listeriosis cases is expected to decrease by more than 99.9%; in contrast, reducing the overall prevalence of the organism by 50% would only decrease the number of cases by 50%. IFT finds that the study and conclusions drawn provide adequate support for focusing efforts on limiting the opportunity for high concentrations of *L. monocytogenes* in foods.

IFT's forthcoming authoritative report on performance standards notes that "Sampling ... inherently assumes that the attribute being measured has relatively stable variation in the lot, i.e., homogeneous distribution of measurable amounts. Acceptance sampling cannot detect pathogens or toxins that are concentrated in a very small portion of the lot nor hazards that are present at very low levels. ....As more effective control measures are adopted by industry and the prevalence of contamination decreases, a point is reached where product testing is no longer practical or justifiable. At that stage, greater benefit can be achieved by shifting verification procedures to comprehensive analysis of control systems that have been validated to control the pathogens of concern." (IFT, 2004).

In addition to supporting the effort to achieve the lowest possible levels of *L. monocytogenes* in foods that do not support the growth of the organism, IFT also supports the petitioners' notion that eliminating the zero tolerance policy for foods that do not support the growth of the microorganism will allow efforts and resources to be focused on areas that may have a greater health benefit. The FDA/FSIS risk assessment (FDA/FSIS, 2003) clearly showed that not all foods represent an equal risk. Effective

removal of a small amount of product containing high levels of *L. monocytogenes* will undoubtedly have a greater positive impact on public health than removing greater amounts of product containing levels of the microorganism so low as to present virtually no public health risk.

The proposed regulatory limit would also offer several additional public health benefits that may facilitate a reduction in listeriosis. The proposed limit would, for example, provide a strong incentive for development of products that do not support growth of *L. monocytogenes*, encourage aggressive sampling programs, and facilitate collection of better quantitative data on *L. monocytogenes*. These positive consequences should be taken into account as FDA considers the petition.

As IFT reported in 2002 in its Expert Report "Emerging Microbiological Food Safety Issues: Implications for Control in the 21st Century," the zero tolerance policy has acted as a disincentive for the application of quantitative (enumerative) methods for *L. monocytogenes*. Food manufacturers concerned with *L. monocytogenes* are hesitant to test for the microorganism below the genus level because finding the microorganism in a finished, ready-to-eat food would result in regulatory action under the current policy of both FDA and the USDA. Knowing how the presence of *Listeria* species other than *L. monocytogenes* in foods and food processing environments relates to the possible presence of *L. monocytogenes* is, therefore, currently not achievable. Further speciation and sub-typing, however, could yield useful data. If the mere presence of *L. monocytogenes* did not necessarily mean that a food is potentially harmful, food manufacturers may then have an incentive to speciate further and apply methods capable of determining virulence. A true farm-to-table food safety system would consider downstream handling and consumption patterns and epidemiologic characteristics of listeriosis cases; such a system would not destroy foods that are unlikely to cause illness in the general population (IFT, 2002).

IFT appreciates the opportunity to provide input on the agency's consideration of its regulatory policy on *L. monocytogenes* and the citizen's petition to establish a regulatory limit for *L. monocytogenes* in foods that do not support its growth. Thank you for considering our comments on this matter.

References:

Chen, Y.H., Ross, E.H., Scott, V.N., and Gombas, D.E., 2003. *Listeria monocytogenes*: Low levels equal low risk. *J. Food Protect.* 66: 570-577.

FDA/FSIS Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* among Selected Categories of Ready-to-Eat Foods. Department of Health and Human Services Food and Drug Administration/ United States Department of Agriculture Food Safety Inspection Service. <http://www.cfsan.fda.gov/~dms/lmr2-toc.html>

IFT. 2004. *Managing Food Safety: Use of Performance Standards and Other Criteria in Food Inspection Systems*. Institute of Food Technologists, Chicago, Ill. (in press).

IFT. 2002. *Emerging Microbiological Food Safety Issues: Implications for Control in the 21st Century. An Expert Report of the Institute of Food Technologists, Chicago, Ill.* <http://www.ift.org/govtrelations/microfs>

Wiedmann, M., Bruce, J.L., Keating, C., Johnson, A.E., McDonough, P.L., and Batt, C.A. 1997. Ribotypes and virulence gene polymorphisms suggest three distinct *Listeria monocytogenes* lineages with differences in pathogenic potential *Infect. Immun.* 65: 2707-2716.

Sincerely,



C. Ann Hollingsworth, Ph.D.  
President