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May 25, 2005

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Risk Assessment of the Public Health Impact from Foodborne Listeria Monocytogenes in Smoked Finfish; and Evaluation of Food Code Provisions that Address Preventive controls for Listeria Monocytogenes in Retail and Foodservice Establishments; Request for Comments and for Scientific Data and Information; 70 Fed. Reg. 10650 (March 4, 2005)**

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) appreciates this opportunity to provide comments as the Food and Drug Administration (FDA) makes plans to conduct a risk assessment for *Listeria monocytogenes* (Lm) in smoked finfish (smoked finfish risk assessment), and to evaluate the provisions of the 2001 Food Code that address preventive controls for Lm in retail and foodservice establishments. AFFI strongly urges FDA to review the benefits of freezing as a food safety vehicle to enhance the safety of smoked finfish in retail and food service establishments and reduce the potential for foodborne listeriosis.

AFFI is the national trade association representing frozen food manufacturers, their marketers, and suppliers. AFFI's 520 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationally and internationally.

Smoked finfish have been implicated in outbreaks of foodborne disease of microbial etiology including listeriosis; however, the number of reported outbreaks of listeriosis is low. In 1995, there were nine cases of listeriosis associated with smoked rainbow trout.<sup>1</sup> The prevalence of *Lm* in cold smoked fish can range from 0 percent to 60+ percent.<sup>2</sup> Importantly, it is the potential for smoked finish to support growth of *L. monocytogenes* during refrigerated storage that is the critical issue that must be addressed; freezing, however, inhibits growth of the organism.

### **Freezing is an Effective Means of Pathogen Control**

Freezing represents a significant means of food preservation that has long been used to prevent food spoilage and to control foodborne pathogens. The physical and biochemical effects of freezing on microorganisms have been well described.<sup>3,4,5</sup> Freezing is known to have a bacteriostatic effect. Most recently, a review paper cited the benefits of freezing in regard to prevention of listeriosis, stating in part that "It should not be overlooked that freezing prevents the growth of *L. monocytogenes*, and this fact alone makes freezing an important public health barrier with regards to *L. monocytogenes* and other pathogens as well."<sup>6</sup>

*L. monocytogenes* is considered to be a psychrotrophic bacterium, with the minimum growth temperature identified as  $-0.4^{\circ}\text{C}$ .<sup>7</sup> In food matrices, very slow growth of the organism has been observed in chicken broth at  $-0.4^{\circ}\text{C}$  and in pasteurized milk at  $-0.2^{\circ}\text{C}$ .<sup>8</sup> Studies examining butter, minced meat, and culture media held at temperatures of  $-18^{\circ}\text{C}$  have demonstrated no growth of the pathogen to occur at this temperature.<sup>9</sup> These reports establish that *L. monocytogenes* does not grow at temperatures below  $-0.4^{\circ}\text{C}$ . Thus, *L. monocytogenes* will not grow under commercial freezer conditions.

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<sup>1</sup> J. Clin. Microbiol. 35:2904 - 2907.

<sup>2</sup> Int. J. Fd. Microbiol. 42:127 -131.

<sup>3</sup> El-Kest, S.E. 1991. Fate of *Listeria monocytogenes* during freezing and frozen storage. J. Food Sci. 56:1068-1071.

<sup>4</sup> El-Kest, S.E. 1992. Freezing of *Listeria monocytogenes* and other microorganisms: A review. J. Food Prot. 55:639-648.

<sup>5</sup> Lund, B.M. 2000. Freezing. In The Microbiological Safety and Quality of Food, Volume I, pp. 122-145 (B.M. Lund, T.C. Baird-Parker, and G.W. Gould, editors).

<sup>6</sup> Archer, D.L. 2004. Freezing: an underutilized food safety technology? Int. J. of Fd. Microbiol. 90: 127 - 138.

<sup>7</sup> International Commission on Microbiological Specifications for Foods (ICMSF) 1996. Microorganisms in Foods 5 – Microbiological Characteristics of Food Pathogens, p. 148.

<sup>8</sup> Walker, S.J., et al. 1990. Growth of *Listeria monocytogenes* at refrigeration temperatures. J. Appl. Bacteriol. 68:157-162.

<sup>9</sup> International Commission on Microbiological Specifications for Foods (ICMSF) 1996. Microorganisms in Foods 5 – Microbiological Characteristics of Food Pathogens, p. 148.

### **Government and International Studies Show a Food Safety Benefit Associated with Freezing Food**

The Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes*, conducted by FDA and the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA), cited ice cream and frozen desserts as an example of a food category that does not support the growth of *L. monocytogenes*, and the predicted cases of listeriosis associated with ice cream and frozen desserts at  $6.3 \times 10^{-12}$  per serving.<sup>10</sup>

The agencies have acknowledged that the pathogen cannot grow in a frozen medium, although it is able to survive. Because the levels of *L. monocytogenes* found in retail surveys were low, and would not increase during distribution, the risk assessment characterized ice cream as the product category with one of the lowest relative risk ranking.

Other studies show the effectiveness of utilizing freezing to reduce or eliminate pathogens. FDA's Draft Risk Assessment on the Public Health Impact of *Vibrio parahaemolyticus* in Raw Molluscan Shellfish found "Freezing combined with frozen storage, which causes a 1 to 3 log decrease substantially reduces the probability of illness." Also, the Risk Assessment of *Campylobacter* spp. in Broiler Chickens conducted by the Food and Agricultural Organization and World Health Organization (FAO/WHO) in 2002 found "frozen chicken posed a lower risk via consumption than fresh chicken," and the Danish Veterinary & Food Administration showed 25-fold reduction in human illness through freezing rather than refrigerating chickens.<sup>11</sup>

Freezing is an underutilized food safety technology. AFFI believes FDA has the opportunity to promote the use of freezing more effectively during the production, distribution and retailing of smoked finfish and limit the potential for growth of *Lm*. The freezing process can lower the relative risk of consuming smoke finfish.

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<sup>10</sup>Food and Drug Administration and Food Safety and Inspection Service (FDA/FSIS). 2003. Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods, pp. 119

<sup>11</sup> FAO/WHO, 2002. Sugarcane, chicken and radish sprouts: a sample of country safe food experiences. Global Forum of Food Safety Regulators (29/01/2002)

AFFI Comments  
Docket No. 2005N - 0065  
May 25, 2005

AFFI appreciates the opportunity to comment on FDA's request for comment on the public health impact from foodborne *Listeria monocytogenes* in smoked finfish. We would be pleased to discuss this issue further with the agency. Thank you for your consideration.

Sincerely,

Leslie G. Sarasin, CAE  
President and  
Chief Executive Officer