



**International Dairy Foods Association**  
Milk Industry Foundation  
National Cheese Institute  
International Ice Cream Association

August 3, 2004

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

**Re: Docket No. 2003P-0574; *Listeria Monocytogenes*; Petition to Establish a Regulatory Limit; 69 Fed. Reg. 29564 (May 24, 2004)**

Dear Sir or Madam:

The International Dairy Foods Association (IDFA) appreciates this opportunity to offer comments concerning the December 24, 2003 Citizen Petition seeking a regulatory limit of 100 colony forming units per gram (cfu/g) for *Listeria monocytogenes* in ready-to-eat foods that do not support its growth. IDFA and its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association and the National Cheese Institute, represent nearly 500 companies that process, manufacture, distribute and market about 85 percent of the dairy products consumed in the United States.

IDFA is a member of the Alliance for Listeriosis Prevention and its constituent organization the National Cheese Institute (NCI) and International Ice Cream Association (IICA) were co-petitioners seeking the proposed regulatory limit. The members of the NCI and IICA fully

support adoption of the proposed regulatory limit and urge the Food and Drug Administration (FDA) to move forward as soon as possible.

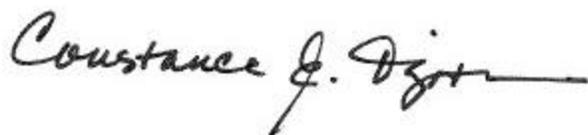
Significantly, there is now agreement that the public health impact of *L. monocytogenes* is almost exclusively a function of foods that contain high numbers of the organism, well in excess of the proposed limit of 100 cfu/g. Low levels of *L. monocytogenes* in foods that do not support its growth present a minimal risk of harm. Control measures that prevent high cell numbers of *L. monocytogenes* in food at the point of consumption will therefore be most effective in reducing the incidence of listeriosis. The proposed regulatory limit will facilitate adoption of targeted, science-based measures by permitting FDA and the dairy industry to focus resources and attention on cell numbers of public health significance. Accordingly, as a result of the risk assessment and other data and information described in the Petition, there is now a compelling scientific basis upon which FDA policies on *L. monocytogenes* may be reexamined.

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.

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To establish a science-based standard for the control of *L. monocytogenes* in food and prevention of listeriosis, IDFA urges FDA to adopt the proposed regulatory limit as soon as possible. IDFA looks forward to working with the agency and would be pleased to discuss with CFSAN any of the points made in these comments.

Sincerely,

A handwritten signature in black ink that reads "Constance E. Tipton". The signature is written in a cursive style with a horizontal line at the end.

Constance E. Tipton  
President and CEO

cc: C. Frye  
C. Hough

