

Alliance for Listeriosis Prevention

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August 6, 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 Alliance for Listeriosis Prevention (Alliance) 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. Members of the Alliance are organizations with an interest in strategic approaches to the prevention of listeriosis, and include the Petitioners seeking the proposed regulatory limit. A list of Alliance members is attached including descriptions of each organization.

The Alliance applauds the Food and Drug Administration's (FDA's) decision to solicit public comment concerning the Petition and proposed regulatory limit. To facilitate adoption of targeted control measures that will best achieve the public health goals for listeriosis prevention identified in *Healthy People 2010*, FDA is urged to grant the requested regulatory limit as expeditiously as possible following closure of the comment period.

A REGULATORY LIMIT WOULD ALLOW FOR TARGETED MEASURES TO PREVENT CELL NUMBERS OF PUBLIC HEALTH SIGNIFICANCE

Healthy People 2010, which presents national goals for health promotion and disease prevention, calls for a 50 percent reduction in listeriosis by the end of 2005. To achieve this goal and pursue further reductions in the incidence of listeriosis, targeted, science-based measures are required. Underlying the need for a targeted approach are three important considerations:

- 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. The relationship between high numbers of *L. monocytogenes* and listeriosis is characterized by numerous risk assessments, including the risk assessments cited in the Petition and the recently completed World Health Organization/Food and Agriculture Organization (WHO/FAO) risk assessments of *L. monocytogenes* in ready-to-eat foods.¹
- Conversely, numerous risk assessments, including the recent WHO/FAO assessment, indicate that a low probability of illness is associated with consumption of low levels of *L. monocytogenes* in foods that do not support its growth. One notable risk assessment estimated a 1-in-100 million chance of illness from consuming *L. monocytogenes* at a level of 100 cfu/g.²
- In light of the available risk assessments, there is substantial scientific agreement that control measures that prevent high levels of *L. monocytogenes* in food at the point of consumption will be most effective in reducing rates of listeriosis.³

The proposed regulatory limit would permit FDA and industry to focus on prevention of cell numbers of public health significance, which would facilitate use of targeted control measures capable of effecting meaningful reductions in listeriosis. Foods subject to the regulatory limit would continue to be safe and wholesome, through continued industry vigilance and adherence to current good manufacturing practice (CGMP) requirements in the production of these products.

PROPOSED LIMIT CONFORMS WITH FDA-FSIS RISK ASSESSMENT AND LISTERIA ACTION PLAN

The proposed regulatory limit is also fully consistent with the findings of the 2003 FDA-Food Safety and Inspection Service (FSIS) risk assessment and

¹ WHO/FAO Microbiological Risk Assessment Series, Risk assessments of Listeria monocytogenes in ready-to-eat foods (Interpretive Summary 16 Jan. 2004) (Advance proof copy).

² Chen, Y., et al. 2003. *Listeria monocytogenes*: Low level equals low risk. J. Food Prot. 66:570-577.

³ See, e.g., WHO/FAO Risk Assessment, *supra* note 1.

the agency's Listeria Action Plan objectives. A primary factor driving preparation of the 2003 risk assessment was a need to better understand the relative risk presented by categories of ready-to-eat foods, and to use this improved understanding to evaluate the adequacy and focus of current agency programs. In furtherance of this general objective, the Listeria Action Plan identifies as its focus foods identified in the risk assessment as warranting additional measures to reduce *L. monocytogenes* contamination or warranting collection of additional data. The foods that would be eligible for the proposed regulatory limit do not fall into these high priority categories.

The proposed regulatory limit also would offer several additional public health benefits that may facilitate a reduction in listeriosis. The proposed limit of 100 cfu/gram, for example, would promote development of products that do not support growth of *L. monocytogenes*, encourage aggressive sampling programs, and facilitate collection of better quantitative data. These positive consequences should be taken into account as FDA considers the Petition.

The Alliance for Listeriosis Prevention is committed to the development of science-based standards for the control of *L. monocytogenes* and prevention of listeriosis. The Alliance looks forward to working with the agency and would be pleased to discuss with the Center for Safety and Applied Nutrition (CFSAN) any of the points made in these comments.

Sincerely,

American Bakers Association
American Frozen Food Institute
American Meat Institute
Grocery Manufacturers of America
International Ice Cream Association
Midwest Food Processors Association
National Cheese Institute
National Chicken Council
National Fisheries Institute
National Food Processors Association
National Milk Producers Federation
National Turkey Federation
Northwest Food Processors Association
Snack Food Association
United Fresh Fruit and Vegetable Association