April 20, 2009

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

RE: Comments on the Risk Assessment of the Public Health Impact from Foodborne Listeria Monocytogenes in Some Ready-to-Eat Foods Sliced, prepared, and/or Packaged in Retail Facilities; Request for Comments and for Scientific Data and Information (Docket No. FDA-2008-N-0658)

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the goals set forth for the Food and Drug Administration (FDA) Risk Assessment of the Public Health Impact from Foodborne Listeria Monocytogenes in Some Ready-to-Eat Foods Sliced, prepared, and/or Packaged in Retail Facilities (hereinafter “Risk Assessment”). CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by 900,000 subscribers to its Nutrition Action Healthletter and by foundation grants.

I. Background

Listeria monocytogenes is one of the most lethal foodborne pathogens. While it causes fewer cases of illness each year than Salmonella, 20% of those stricken die, and many more are hospitalized—some with severe and lasting consequences. Many of those made ill are pregnant women who can suffer miscarriage or stillbirth even after a relatively mild exposure. Other groups at increased risk of severe illness and death include newborns, persons with weakened immune systems, persons with cancer, diabetes, or kidney disease, persons with AIDS, persons who take glucocorticosteroid medications, and older consumers.1

Rates of *Listeria* contamination are rising around the world, after declining in the 1990s. Here in the U.S., rates are not falling despite a national health objective to reduce incidence articulated in *Healthy People 2010 Food Safety Objectives*. In fact, the *Healthy People 2010* objectives have failed since 2005, the target date imposed by the Clinton Administration. The lowest rate of *Listeria*, reported in 2002, has not been repeated and rates have increased since 2004.\(^2\) Twenty-nine products were recalled in the U.S. in 2008 due to *Listeria* contamination, an indication that the problem is far from contained.\(^3\)

In 2008, CSPI surveyed over 600 consumers—both CSPI activists and those that frequent internet message boards for pregnant women—about *Listeria monocytogenes* in an effort to uncover what consumers know about the pathogen.\(^4\) The results indicate that even highly informed consumers do not recognize those foods that carry an increased risk of *Listeria monocytogenes*. Further, respondents indicated that healthcare providers are not informing pregnant women of their particular risks and the steps to avoid them. These results clearly demonstrate that consumers are largely unaware of the risks of contracting listeriosis.

Thus, a risk assessment intended to underpin regulatory action regarding *Listeria* must be approached with careful consideration to ensure that any resulting policy changes do not increase the risk to consumers. We urge FDA to design this Risk Assessment in a way that provides clear and accurate data so that sound policy decisions can be made.

**II. The Risk Assessment Must Accurately Identify the Risk**

FDA’s 2008 proposal to allow certain FDA-regulated products to carry *Listeria* at rates of 100 cfu/g necessarily increases the likelihood of contamination of products at retail. The proposed Risk Assessment must focus data-gathering on the increased risk as a result of this change. **It is critically important to the accuracy of the Risk Assessment that the data analyzed comes from countries where zero tolerance is not the standard.** Data that has been generated under a zero

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\(^3\) *Listeria Recalls in the United States, 2008*. Safe Tables Our Priority.

\(^4\) Center for Science in the Public Interest Survey, *Foodborne Hazards for Pregnant Women*, conducted March 19-March 27, 2008.
tolerance enforcement policy will reflect less risk, and will skew the resulting data toward underestimating the resulting levels of *Listeria* in the retail environment. Specifically, data should be requested on the prevalence and levels of *Listeria* entering the retail environment in countries where a level of 100cfu/g is tolerated.

To accurately understand the risk created by this more relaxed standard, FDA must gather comparative data from other countries and the European Union, where a 100 cfu/g standard is applied to foods coming into the retail environment. Notably, just as rates of *Listeria* in the U.S. have not fallen despite the objectives articulated in *Healthy People 2010*, rates of *Listeria* in Europe have been increasing since the year 2000 as well, following the European adoption of the 100 cfu/g standard. The March 2008 Eurosurveillance report *Human Listeria monocytogenes Infections in Europe* indicated “statistically significant and increasing trends” in at least six European Union member states in the last 8 years. The report states that it is likely that this represents a “true change” in the incidence of *Listeria* in Europe, and recommends additional investigation to determine the scope of the problem.

In addition, FDA should request data on the prevalence and levels of *Listeria* in the post-retail environment (i.e., consumer homes). A 2008 consumer survey indicated that over 70% of consumers clean their refrigerators less than twice a year. In addition, nearly 40% of consumers are unaware that their refrigerator must be set at 40 degrees F or below in order to restrict the growth of harmful bacteria. Since *Listeria* can continue to grow in a refrigerated environment—particularly if that environment is seldom sanitized—FDA must recognize the danger of seeding consumer refrigerators with increased levels of *Listeria* brought home from retail stores. It is critically important to any future policy decisions that the risk of *Listeria* in the post-retail environment—under a zero tolerance policy and under a more relaxed standard—is fully recognized.

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5 A 2007 report by the European Food Safety Authority, for example, found that 13.3% - 77.8% of smoked fish sampled at retail contained *Listeria*. *Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission of Request for updating the former SCVPH opinion on Listeria monocytogenes risk related to ready-to-eat foods and scientific advice on different levels of LM in ready-to-eat foods and the related risk for human illness. The EFSA Journal* (2007) 599, 1-42, p.12.

6 Id. at p.1.


8 Id.

III. Conclusion

CSPI is encouraged that FDA is seeking additional data on rates of *Listeria* before moving forward on any change in the accepted tolerances of the pathogen. We urge the agency to use this Risk Assessment to gather additional data from regions that utilize different risk management strategies and to study that data in light of the proposed relaxed standard of 100 cfu/g. An assessment that fails to include data from countries that have already adopted this standard—many of which have seen the corresponding rise in illnesses—would represent only a partial picture of the risk. Changing the risk management approach should be done only with great caution to avoid a rise in deaths and illnesses linked to *Listeria*. To do otherwise could increase the risk of severe illness for pregnant women, young children, older consumers, and the immune-compromised.

Respectively submitted,

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