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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
[Docket No. FDA-2001-N-0092]

Docket Clerk
US Department of Agriculture
Food Safety and Inspection Service
George Washington Carver Center
5601 Sunnyside Avenue, Mailstop 5474
Beltsville, MD 20705-5464
[Docket No. FSIS-2010-0035]

Re: Update of the 2003 Interagency Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* among Selected Categories of Ready-to-Eat Foods; Request for Comments, Scientific Data and Information

The Center for Science in the Public Interest (CSPI)¹ appreciates the opportunity to comment on the Food and Drug Administration's (FDA) and Food Safety and Inspection Service's (FSIS) update of the 2003 Interagency Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* among Selected Categories of Ready-to-Eat (RTE) Foods (hereinafter "Risk Assessment").

FDA and FSIS have requested comments in order to (1) update estimates of the relative risk of listeriosis associated with the consumption of different types of RTE foods that may be contaminated with *L. monocytogenes* and to (2) evaluate the relative effectiveness of strategies to reduce or prevent exposure to *L. monocytogenes* from consumption of RTE foods.

In 2009, CSPI commented on a 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. As many of our previous comments resonate with this 2011 Risk Assessment update, we will state them again here.

1. Background

¹ CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 850,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

Listeria monocytogenes is one of the most lethal foodborne pathogens. While it causes fewer cases of illness each year than *Salmonella*, nearly 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.²

Rates of *Listeria* contamination are rising in the U.S., despite a national health objective to reduce incidence, articulated in *Healthy People 2020 Food Safety Objectives*.³ In fact, neither the *Healthy People 2005* nor *Healthy People 2010* health objectives for *Listeria* were met. Since the 2003 Risk Assessment, CSPI has documented 11 *Listeria* outbreaks responsible for 72 illnesses, 58 hospitalizations, and 9 deaths.⁴ This data indicates that the problem of *Listeria* contamination is far from contained.

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 knew about the pathogen.⁵ 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 risk of contracting listeriosis.

This Risk Assessment update must be approached with careful consideration to ensure that any resulting policy changes do not increase risk to consumers. We urge FDA and FSIS to update this Risk Assessment in a way that provides clear and accurate data so that sound policy decisions can be made.

2. The Risk Assessment Must Accurately Identify the Risk

² Centers for Disease Control and Prevention. “Listeriosis.”
<http://www.cdc.gov/nczved/divisions/dfbmd/diseases/listeriosis/>

³ Centers for Disease Control and Prevention. “Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly through Food – 10 States, 2009.” *Morbidity and Mortality Weekly Report*. April 16, 2010. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5914a2.htm#tab1>

Healthy People 2020. Food Safety Objectives.
<http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/FoodSafety.pdf>

⁴ Data available until 2008 only

⁵ Center for Science in the Public Interest Survey, *Foodborne Hazards for Pregnant Women*, conducted March 19-27, 2008

In 2008, FDA proposed to allow certain FDA-regulated products (“food that does not support the growth of *L. monocytogenes*”) to carry *Listeria* at rates of 100 cfu/gram.⁶ CSPI, along with FSIS, opposed this proposal, as it necessarily increases the likelihood of contamination of products at retail. While we do not support this proposal, we urge that updates to the Risk Assessment focus data-gathering on the increased public health risk as a result of this proposed standard. 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 collected under a zero 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 100 cfu/gram 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/gram standard is applied to foods coming into the retail environment.⁷ Notably, just as the rates of *Listeria* in the U.S. have not fallen despite the objectives articulated in *Healthy People 2020*, rates of *Listeria* in Europe have been increasing since the year 2000 as well, following the European adoption of the 100 cfu/gram standard. The March 2008 Eurosurveillance report *Human Listeria monocytogenes Infections in Europe* indicated “statistically significant and increasing trends” in a least six European Union member states in the last 8 years.⁸ 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.⁹

In addition, FDA and FSIS 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*.¹⁰ 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

⁶ Foods with a pH less than or equal to 4.4; water activity less than or equal to 0.92; or formulated to contain one or more inhibitory substances that, alone or in combination, inhibit the growth of *L. monocytogenes*

FDA Guidance for Industry; Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-to-Eat Foods; Draft Guidance. February 2008

⁷ A 2007 report by the European Food Safety Authority, for example, for 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, p12

⁸ Denny, J. and McLauchlin, J, Eurosurveillance: *Human Listeria monocytogenes infection sin Europe – an opportunity for improved European surveillance*, March 2008.

⁹ Id.

¹⁰ Center for Science in the Public Interest Survey, *Foodborne Hazards for Pregnant Women*, conducted March 19-27, 2008

seldom sanitized – FDA and FSIS must recognize the danger of seeding consumer refrigerators with increased levels of *Listeria* brought home from retail stores.

Of particular concern is the distinction made in the 2003 Risk Assessment between “frankfurters, not reheated” as high risk and “frankfurters, reheated” as low risk. All frankfurters should be considered high risk products, even if they are reheated, because *Listeria*-contaminated frankfurters can introduce this hazard into the consumer refrigerator. Once present, the pathogen can spread through hand-to-mouth transmission, when consumers don’t wash their hands after touching the frankfurters, or through cross-contamination, when any content from the hot dog package comes into contact with other ready-to-eat foods. Reheating of the frankfurters will not prevent illness from in-home cross-contamination; therefore, all hot dogs should be considered high risk and new approaches should be identified for reducing potential contamination.

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.

3. The Risk Assessment Should Include Labeling As a New Strategy

In 2000, CSPI petitioned FSIS to include a safe-handling label on ready-to-eat meat and poultry products as an interim measure pending adoption of a final rule requiring microbial testing in all processing plants and end products. As no such final rule was adopted, CSPI urges both agencies to consider labeling of ready-to-eat products as a means to alert high-risk consumers about the potential risks of *Listeria* contamination and to reduce or prevent exposure. Ready-to-eat foods are not truly ready-to-eat for people who are especially vulnerable to foodborne illness. A safe-handling statement indicating that RTE foods could be contaminated with *Listeria* and therefore pose a potential health threat to infants, pregnant women, the elderly, and those with weakened immune systems gives consumers important information both at the point-of-purchase and when preparing the food. Such labels could serve as an effective strategy to prevent life-threatening listeriosis cases in high-risk consumers when government regulations are unable to ensure that foods are not adulterated.

4. Conclusion

CSPI is encouraged that FDA and FSIS are seeking additional scientific data and information to update the 2003 Risk Assessment in order to better protect public health by reducing *Listeria* contamination. We urge the agency to use this risk assessment to gather additional data from other countries that utilize different risk management strategies and to study that data in considering changes to U.S. policy. An assessment that fails to include data from countries that have already adopted a more relaxed standard – many of which have seen the corresponding rise in illness – would represent only a partial picture of the risk.



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In addition, we urge FDA and FSIS not to suspend risk management decision making while the final Risk Assessment document is being prepared. 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 illnesses and deaths for many vulnerable consumers, including pregnant women, young children, older consumers, and the immune-compromised.

Respectfully submitted,

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