



## Consumer Federation of America

June 24, 2013

Docket Clerk, Food Safety and Inspection Service,  
U.S. Department of Agriculture  
Patriots Plaza 3, 1400 Independence Avenue SW.  
Mailstop 3782, Room 8-163A,  
Washington, DC 20250-3700

**Re: Docket No. FSIS- 2013-0005**

To Whom It May Concern:

The Consumer Federation of America (CFA) appreciates the opportunity to comment on the Draft Interagency Risk Assessment--*Listeria monocytogenes* in Retail Delicatessens (**Docket No. FSIS-2013-0005**). The Risk Assessment provides useful information that can help inform supermarkets, delis, regulators, and industry about opportunities to prevent the growth of *Listeria monocytogenes* on food products. It also raises important issues about how the federal food safety agencies approach Listeria control and the need to alert consumers to Listeria risks in deli products.

The Centers for Disease Control and Prevention (CDC) has estimated that *L. monocytogenes* causes approximately 1,600 illnesses, 1,500 hospitalizations, and 255 deaths annually. While listeriosis is rare, the fatality rate is very high (nearly 16%). Pregnant women are at particular risk. The CDC notes that pregnant women are about 20 times more likely than other healthy adults to get listeriosis, and approximately one-third of listeriosis cases happen during pregnancy. Infection creates serious risk to an unborn fetus, frequently leading to miscarriage, stillbirth or serious health problems.

### **Increased Cross-Contamination under Disjointed Food Safety Regulation**

Listeria risk in retail delis is a particular concern. The University of Florida ranked Listeria in deli meats as third in terms of annual disease burden in the United States.<sup>1</sup> As noted in the Risk Assessment, surveillance studies have shown that the prevalence of *L. monocytogenes* is approximately seven times higher in deli meats sliced at retail, compared to those sliced and packaged at federally inspected facilities.<sup>2</sup> The surveys have also found higher levels of *L. monocytogenes* on RTE meats sliced or packaged at retail. Further, a Food Safety and Inspection Service (FSIS) comparative risk assessment indicated that approximately 83% of the listeriosis cases attributed to deli meat were associated with deli meats sliced at retail.<sup>3</sup>

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<sup>1</sup> Batz MB, Hoffmann S, Morris Jr. JG, "Ranking the Risks: The 10 Pathogen-Food Combinations With the Greatest Burden on Public Health." University of Florida Emerging Pathogens Institute, 2011.

<sup>2</sup> Gombas, D.E., Chen, Y., Clavero, R.S., and Scott, V.N., Survey of *Listeria monocytogenes* in ready-to-eat foods. *Journal of Food Protection*, 2003. **66**(4): p. 559-69. Draughon, A.F. A collaborative analysis/risk assessment of *Listeria monocytogenes* in ready-to-eat processed meat and poultry collected in four FoodNet states. in *International Association for Food Protection 93rd Annual Meeting*. 2006. Calgary, Alberta, Canada.

<sup>3</sup> Endrikat, S., Gallagher, D., Pouillot, R., Hicks Quesenberry, H., Labarre, D., Schroeder, C.M., and Kause, J., A Comparative Risk Assessment for *Listeria monocytogenes* in Prepackaged versus Retail-Sliced Deli Meat. *Journal*

Product in delis comes into contact with hands, utensils, slicers and other product, providing ample opportunity for cross-contamination. The Risk Assessment notes that “[c]ross contamination of *L. monocytogenes* in the retail environment dramatically increases the predicted risk of listeriosis. Cross contamination during the routine operation of the retail deli is not amenable to a simple solution.”<sup>4</sup> This is especially important considering the differences in how the Food and Drug Administration (FDA) and FSIS regulate products that may be contaminated with *Listeria*.

In 2008, FDA issued a Compliance Policy Guide Sec. 555.320 *Listeria monocytogenes* to provide guidance on the agency’s enforcement policy for *Listeria* in ready-to-eat foods. The proposal stated that for Ready-to-Eat (RTE) foods that do not support the growth of *Listeria*, FDA would regard the food as adulterated when *Listeria* is present at or above 100 cfu/g of food. This is in contrast to FSIS’ policy, which maintains a zero tolerance for *Listeria* in RTE foods.<sup>5</sup>

The contrasting approaches to *Listeria* by the two federal food safety agencies is particularly concerning with respect to establishments that handle both FDA and FSIS regulated products, such as retail delis. CFA remains concerned about the likelihood of cross contamination of RTE foods that do not promote the growth of *Listeria* and that are permitted to maintain a level of 100 cfu/g (as regulated by FDA) and RTE foods that do promote the growth of *Listeria* and are under a zero tolerance standard (as regulated by FSIS). The Risk Assessment notes that “Increasing *L. monocytogenes* concentration in incoming product increased the predicted risk of listeriosis whether or not the contaminated RTE product itself supported growth. The increase in predicted risk was greater when the equivalent contamination occurred on product that supported the growth of *L. monocytogenes*.” Since the FSIS-regulated product promotes the growth of *Listeria*, the pathogen could continue to multiply on the product, and consumers would be at greater risk of *Listeria* from that contaminated product. Introducing increased levels of *Listeria* via FDA-regulated products into these environments could increase the risk of contamination of retail deli products and food contact surfaces.

FSIS has previously urged FDA to abandon its policy weakening the zero tolerance standard for *Listeria*, outlining a number of important concerns that a change in FDA policy would present for FSIS-regulated products. In particular, FSIS raised concerns about the effects in retail establishments. FSIS stated that it believed that “controlling the presence and level of *L. monocytogenes* in retail-sliced deli meat products will be much more difficult if they are handled and held at retail with products that while not supporting growth, are contaminated with the pathogen.”<sup>6</sup>

Considering the issues identified in the Risk Assessment, CFA urges FDA to reinstate a zero tolerance standard for *Listeria* for all products the agency regulates. This is particularly important to reduce cross contamination risks in retail delis.

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of Food Protection, 2010. 73(4): p. 612-9. FSIS, FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-eat Meat and Poultry Deli Meats, 2010: Washington, DC. p. 58. Available from: [http://www.fsis.usda.gov/PDF/Comparative\\_RA\\_Lm\\_Report\\_May2010.pdf](http://www.fsis.usda.gov/PDF/Comparative_RA_Lm_Report_May2010.pdf).

<sup>4</sup> The Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup, Draft Interagency Risk Assessment--*Listeria monocytogenes* in Retail Delicatessens, May 2013.

<sup>5</sup> Measured as the absence of a detectable level of *Listeria* in a 25-gram sample.

<sup>6</sup> Letter to Steven Sundlof, Director, Center for Food Safety and Applied Nutrition from Richard Raymond, Under Secretary, Food Safety and Inspection Service, dated March 27, 2008.

## **FDA and FSIS Should Require Labeling for RTE Products**

Delis sell a variety of foods that consumers assume are safe to eat directly from the package. These foods typically state that they are “ready-to-eat” and may also have “use-by” date labeling which suggests the product is safe to consume if eaten before that date. However, consuming these foods directly from the package is not safe for many consumers, particularly pregnant women, the elderly and immune-compromised persons who are at greater risk for *Listeria* food poisoning. Further, the Risk Assessment states that “for any given dose of ingested *L. monocytogenes*, individuals from the susceptible population are predicted to have a higher probability of illness, compared to the general population.”<sup>7</sup>

The federal government, in its food safety education materials, advises pregnant women to thoroughly reheat certain RTE foods such as hot dogs and deli meats. It also advises pregnant women to avoid soft cheeses, pate, smoked fish and unpasteurized milk.<sup>8</sup> These are important messages for susceptible populations, but could be reinforced through messaging at the point of purchase.

In light of the Risk Assessment, FDA and FSIS should require delis and food processors to label RTE product packages with safe food handling messages targeted to susceptible populations. Retail delis could affix stickers or labels on food containers and/or packaging that would carry the appropriate messaging. The labels could include the same language used in federal government food safety education materials, such as: “If you are pregnant or immune suppressed, reheat this product to steaming hot or 165° F before eating.” Placing this message on the package would assure that the information was immediately available at the time of purchase as well as consumption, and would help remind susceptible individuals that the product is not “ready-to-eat” and should be handled appropriately.

CFA appreciates the opportunity to provide these comments.

Sincerely,



Chris Waldrop  
Director, Food Policy Institute

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<sup>7</sup> The Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup, Draft Interagency Risk Assessment--*Listeria monocytogenes* in Retail Delicatessens, May 2013.

<sup>8</sup> Checklist of Foods to Avoid During Pregnancy, available at [http://www.foodsafety.gov/poisoning/risk/pregnant/chklist\\_pregnancy.html](http://www.foodsafety.gov/poisoning/risk/pregnant/chklist_pregnancy.html).