June 8, 2009

Docket Clerk
U.S. Department of Agriculture, FSIS
1400 Independence Avenue, SW
Room 2534
South Agriculture Building
Washington, DC 20250-3700

RE: Comments on Draft FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Deli Meats (Docket No. FSIS-2009-0003)

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the results enumerated in the U.S. Department of Agriculture's Draft FSIS Comparative Risk Assessment for *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Deli Meats (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

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.⁴ 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.⁵

In 2008, CSPI surveyed over 600 consumers—both CSPI activists and those that frequent internet message boards for pregnant women—about *Listeria* in an effort to uncover what consumers know about the pathogen.⁶ The results indicate that even highly informed consumers do not recognize those foods that carry an increased risk of *Listeria.* Further, respondents indicated that healthcare providers are not informing pregnant women of

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³ *Listeria Recalls in the United States, 2008.* Safe Tables Our Priority.
⁵ Id.
their particular risks and the steps to avoid them. These results clearly demonstrate that consumers are largely unaware of the risks of contracting listeriosis.

CPSI is pleased that FSIS has undertaken a risk assessment to further clarify the findings based on the 2003 FDA-FSIS risk assessment. Those findings indicated that the risk of Listeria is much greater in deli meats sliced at retail (when compared to deli meat sliced and packaged at processing establishments). This latest risk assessment solidifies those findings, and indicates the need for greater controls of this dangerous pathogen in the retail environment.

We urge FSIS to use the data from this risk assessment to maintain robust Listeria controls over FSIS-regulated products, including refuting FDA’s call for weaker tolerances on FDA-regulated products entering the retail environment.

II. The Risk Assessment Clarifies Significant Risks at Retail

This risk assessment, using current retail contamination data and consumer behavior data, confirms that the retail environment represents a very real risk of increased Listeria contamination. Approximately 83% of all Listeria cases attributed to deli meats are associated with deli meats sliced at retail.7 This result clearly indicates that controls in the retail environment must be strengthened—not just on FSIS-regulated products, but also on those FDA-regulated products that may enhance the risk at retail, such as deli-prepared salads, cheeses, and smoked seafood. Because Listeria can continue to live on food contact surfaces and then migrate to foods, it is vitally important that the entire retail environment is kept from contamination. This risk assessment shows why: FSIS-products entering the retail environment can easily be contaminated by Listeria already existing in deli cases and on food contact surfaces.

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. This

risk assessment provides even more evidence that this proposal is fatally flawed. We have asked FDA to design their own risk assessment with an eye toward this premise, including requesting that the data analyzed come from countries where zero tolerance is not the standard. Data that has been generated 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 100cfu/g is tolerated.

**III. FSIS’s Risk Assessment Shows that FDA’s Proposed Regulatory Limit Will Create Chaos and Put Consumers At Risk**

FDA’s proposal to allow 100 cfu/g of *Listeria* in products entering the retail environment would create conflicting regulatory schemes between the FDA and FSIS at a time when the U.S. food safety system is already fragmented and ineffective. FSIS has repeatedly and publicly opposed this proposal. In 2005, FSIS rejected an industry position for the regulatory limit now being considered by FDA, and in 2008, then-Undersecretary Richard Raymond reiterated FSIS’ opposition to the proposal in a strongly-worded letter to FDA. It is clear that dual regulatory limits for FDA and FSIS-regulated products will create chaos among the regulated industries, and foster frustration between the agencies—all while confusing consumers and endangering public health. We strongly urge FSIS to maintain its historic opposition to this relaxed standard, particularly in light of this risk assessment.

FSIS has repeatedly expressed a concern—shared by CSPI and other consumer groups—that allowing higher levels of *Listeria* in FDA products will exacerbate dangerous cross-contamination among FDA and FSIS products at retail. This concern is supported by the data from the European Union, which allows the weaker standard. The 0.04 cfu/g standard currently required of FSIS-regulated products has made significant strides in controlling the pathogen in those items. However, since many FSIS products do promote the growth of *Listeria*, allowing them to become seeded by FDA products carrying higher loads of the pathogen into retail could be disastrous. FDA has failed to explain how it will ensure that those products carrying a load of 100 cfu/g will not contaminate FSIS-regulated foods.
CSPI urges FSIS to demand that FDA fully address the capacity for cross-contamination, and to announce a comprehensive prevention strategy if one exists, before moving forward with this proposal.

Allowing FDA products to carry greater quantities of the pathogen into the retail setting will only heighten the risk to consumers at home. A recent 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 improperly refrigerated and seldom sanitized—FDA must recognize the danger of seeding consumer refrigerators with increased levels of Listeria brought home from retail stores.

Further, a dual regulatory scheme imposes additional requirements on already overburdened FDA and FSIS inspection forces, who will be required to spend significant time and resources upholding this relaxed standard in the retail setting. While the current 0.04 cfu/g standard provides some measure of reassurance that levels of Listeria will not reach hazardous levels at retail, the relaxed standard offers no such comfort. Seeding the environment with the pathogen will require both agencies to expend precious dollars on increased retail inspections, at a time when agency budgets are already stretched dangerously thin.

III. Conclusion

CSPI is encouraged that FSIS is continuing to seek clarification of the scope of the Listeria problem in the retail environment. We concur with the conclusion of the risk assessment that further studies are needed to determine how contamination occurs, and to design effective mitigation strategies. We strongly believe that, in the interim, FSIS should resist FDA’s efforts to weaken existing Listeria controls, and should instead urge the agency to craft its own comprehensive risk assessment to identify the real risks of FDA-regulated products. Agreeing to a change in the current 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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