April 7, 2008

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

RE: Comments on Draft Compliance Guide Sec. 555.320—*Listeria Monocytogenes*; Availability. (Docket No. FDA-2008-D-0058)

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food and Drug Administration (FDA) draft Compliance Policy Guide (CPG) for *Listeria monocytogenes* in ready-to-eat foods that do support the growth of the organism and ready-to-eat foods that do not support the growth of the organism. 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. Introduction

*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 the elderly.¹

CSPI recently 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.² 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 unaware of the risks of contracting listeriosis. Thus, any regulatory action that exposes consumers to an increased risk—such as allowing higher levels of the pathogen to contaminate product—is inappropriate. Until such time that FDA can demonstrate both that the risk is contained and that consumers are sufficiently educated, the consideration of a more relaxed standard is foolhardy and premature.

## II. A Lower Standard Will Not Improve Public Health

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 incidents 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 2004.³

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² Center for Science in the Public Interest Survey, *Foodborne Hazards for Pregnant Women*, conducted March 19-March 27, 2008.
Listeria illnesses are most frequently associated with a variety of mostly ready-to-eat foods that support the growth of the pathogen. Surveys of these foods have not only looked at the food types themselves, but also in the food environment—i.e., food packaging, preparation practices (e.g., the use of slicing machines), storage temperatures, the lack of effective HACCP systems, and education and training of food handlers. It is abundantly clear that the growth of Listeria is dependent not only on the food item, but on numerous additional environmental factors as well.

Traditionally, discussions of Listeria use the phrase “foods that do/do not support growth.” However, given the reality that the holistic environment of the product is of similar importance when determining the likelihood of Listeria contamination, we recommend that the phrase “conditions which do/do not support growth” be considered in addition to “foods which do/do not support growth.” This change would reflect the importance of the food environment when assessing the risk of Listeria growth, rather than focusing narrowly on the food item alone. Limiting discussion to specific foods undermines the critical understanding that the entire environment must be considered when assessing the risk of bacterial growth and cross-contamination in Listeria control. FDA should consider and evaluate “conditions which do/do not support growth” when promulgating effective regulatory limits for Listeria.

III. Dual Regulatory Limits Will Create Chaos and Put Consumers At Risk

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4 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.

5 Examples of conditions that do not support growth might include continuously frozen products like ice cream. Examples of conditions that do support growth might include meats requiring retail slicing, even if they are formulated to reduce growth in the product itself.
FDA’s proposal 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, for many of the same reasons outlined herein, including significant concerns regarding cross-contamination. Last week, 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.

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. 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. For example, a recent National Alliance for Food Safety and Security Report noted that while *Listeria* has decreased in FSIS-regulated deli meats since 2003, the levels in those meats sliced at the deli are 7 times higher than in unopened packages. This suggests that products that are exposed to cross-contamination in retail do in fact become contaminated, and the result is more *Listeria* in consumers’ homes.

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6 Letter to Stephen Sundlof, Director, CFSAN, from Undersecretary, Office of Food Safety, USDA, dated March 27, 2008.
Allowing FDA products to carry greater quantities of the pathogen into that 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.\(^7\) 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.

In addition, a European Food Safety Authority report on *Listeria* released in December 2007 stated that “it is impossible to predict with high degree of certainty that the level [of *Listeria*] will or will not exceed 100 cfu/g during the shelf life” of products that do support the growth of the bacteria.\(^8\) Although FDA has stated that its proposal only applies the 100 cfu/g standard to products that do not support growth, FDA has failed to explain how it will ensure that those products carrying a load of 100 cfu/g will not contaminate those foods that do promote the growth of *Listeria*. CSPI urges FDA to fully address the capacity for cross-contamination thoroughly, and to announce a comprehensive prevention strategy if one exists, before moving forward with this proposal.

Further, a dual regulatory scheme imposes additional requirements on already over-burdened FDA and FSIS inspection forces, who will be required to spend significant time and resources

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\(^7\) Center for Science in the Public Interest Survey, *Foodborne Hazards for Pregnant Women*, conducted March 19-March 27, 2008.

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.

IV. FDA Should Not Attempt to Harmonize with Ineffective International Standards

The attempt to harmonize U.S. regulatory limits for Listeria with those of the European Union are misguided, particularly since there is significant evidence that those standards are not effective in protecting consumers. 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 standard now being considered by FDA.9

The scientific evidence does not support FDA’s proposal for a relaxed standard, and in fact highlights the folly of such a proposal. 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.10 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.11 CSPI believes this assessment, points to the failure of the Listeria standard in Europe, and urges FDA to refrain from weakening

11 Id.
the comparatively robust U.S. standard until it can be proven that the rise in *Listeria* seen in the E.U. will not be repeated here.

Based on the rising rates of *Listeria* in Europe, it seems clear that the standard is not effective in preventing human illness. Until the 100 cfu/g standard can be shown to be effective in controlling the rate of *Listeria* in those countries in which it has been accepted, it should not be expanded to the U.S. To do so would be to ignore available data and could increase the risk of severe illness for pregnant women, young children, and the immune-compromised.

Respectively submitted,

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