USDA

United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

Stephen Sundlof, D.V.M., Ph.D.
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration, Room 4B064
Harvey W. Wiley Building
5100 Paint Branch Parkway
College Park, MD 20740

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Dear Dr. Sundlof:

We would like to take this opportunity to express our significant concerns about the Food and Drug Administration's (FDA) draft Compliance Policy Guide, Section 555.320, and accompanying draft guidance to industry on control of *Listeria monocytogenes* (*L. monocytogenes*) in ready-to-eat (RTE) foods. The draft documents were published in the February 7, 2008, *Federal Register* (73 FR 7293, 7298). We are troubled, in particular, about the basis and potential effects of the draft policy guidance in respect to foods that do not support growth of *L. monocytogenes*. We plan to submit extensive and technical comments before the end of the comment period.

In the past two years, officials of our two agencies have met on several occasions to discuss the issue of *L. monocytogenes* in the so-called "no-growth" RTE products. We are disappointed that we did not have the opportunity to weigh in on the draft documents before FDA published them. We regard the policy that the documents embody as opposite and adverse to our efforts to ensure the safety of the foods that the Food Safety and Inspection Service (FSIS) regulates.

Regarding the FDA documents, although neither the draft compliance policy nor the guidance to industry is precisely in the nature of a regulatory standard, the documents suggest that FDA might permit a dangerous pathogen in some RTE foods and, hence, in the environment in which they are prepared and held. This policy introduces an inconsistency in the way our two agencies approach the regulation of RTE foods. As you know, under FSIS regulations, any detectable level of *L. monocytogenes* in any RTE meat or poultry product adulterates the product. Also, any RTE product that, after a lethality process, comes into contact with a surface contaminated with *L. monocytogenes*, is adulterated (9 CFR 430.4(a)). Our focus has been on ensuring that this environmental contaminant is controlled, thus preventing contamination of the product, and foodborne illness.

The FSIS policy of "zero tolerance" – currently measured by the absence of a detectable level of *L. monocytogenes* in a 25-gram sample or swab sample – along with risk-based testing, has been effective in reducing *L. monocytogenes* risk in RTE meat and poultry products. FSIS microbiological testing data since the early 1990s shows that FSIS' policy has led to reduced *L. monocytogenes* prevalence in RTE meat and poultry products at FSIS-inspected facilities.

As you are aware, in September 2005, FSIS rejected an industry petition for a regulatory limit (100 cfu/g) for *L. monocytogenes* in RTE products that do not support its growth. A similar petition had been filed with FDA in 2004. FSIS would have rejected a second, revised petition, just on scientific grounds, had the industry not withdrawn it. We have some of the same misgivings regarding the policy represented in your draft documents as we had about the industry petition.

FSIS believes that a policy that permits *L. monocytogenes* in products that do not support its growth provides an increased opportunity for the pathogen to spread in the environment and cross-contaminate products that do support growth of the pathogen. By allowing *L. monocytogenes* in the environment, rather than controlling it, the organism can form biofilms in processing establishments subject to FSIS and FDA jurisdiction and be a source of product adulteration, and human illness, over time – for years, in fact.

We are also concerned about the possible effects that adoption of the FDA policy could have in retail establishments. FSIS believes 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.

Thus, we believe that the policy represented in FDA's draft guidance documents could weaken efforts to control cross-contamination in dual-jurisdiction (FDA-FSIS) and retail establishments. For these reasons, we urge FDA to abandon the policy it is considering with regard to *L. monocytogenes* in RTE foods that do not support growth of the pathogen.

Sincerely,

Richard A. Raymond, M.D.
Under Secretary
Office of Food Safety