

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. 2003P-0574]

~~21 CFR Part 109~~

D. Battle, OFR 5-19-04  
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**Listeria Monocytogenes; Petition to Establish a Regulatory Limit**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a petition has been filed that requests that the agency establish a regulatory limit of 100 colony forming units per gram for *Listeria monocytogenes* in foods that do not support the growth of the microorganism. The agency is requesting comment on the petition. The agency is also requesting the submission of relevant data and information to assist it in evaluating and responding to the petition.

**DATES:** Submit written or electronic comments by *[insertdate 75 days after date of publication in the Federal Register]*.

**ADDRESSES:** You may submit comments, identified by Docket No. 2003P-0574, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

- E-mail: [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov). Include Docket No. 2003P–0574 in the subject line of your e-mail message.

- FAX: 301–827–6870.

- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:  
Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the agency name and Docket No. 2003P–0574 for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/dockets/ecomments>, including any personal information provided. For detailed instructions on submitting comments and additional information on the petition, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/dockets/ecomments> and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** John Kvenberg, Office of Compliance (HFS–600), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436–2359.

**SUPPLEMENTARY INFORMATION:**

**I. The Petition**

Fifteen trade associations (the American Bakers Association, the American Frozen Food Institute, the American Meat Institute, the Grocery Manufacturers of America, the International Ice Cream Association, the Midwest Food Processors Association, the National Cheese Institute, the National Chicken Council, the National Fisheries Institute, the National Food Processors

Association, the National Milk Producers Federation, the National Turkey Federation, the Northwest Food Processors Association, the Snack Food Association, and the United Fresh Fruit and Vegetable Association) (the petitioners) submitted a citizen petition on December 24, 2003, requesting that FDA amend the regulations in part 109 *Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Material* (21 CFR part 109) to establish a regulatory limit for *L. monocytogenes* of 100 colony forming units per gram in foods that do not support growth of the microorganism.

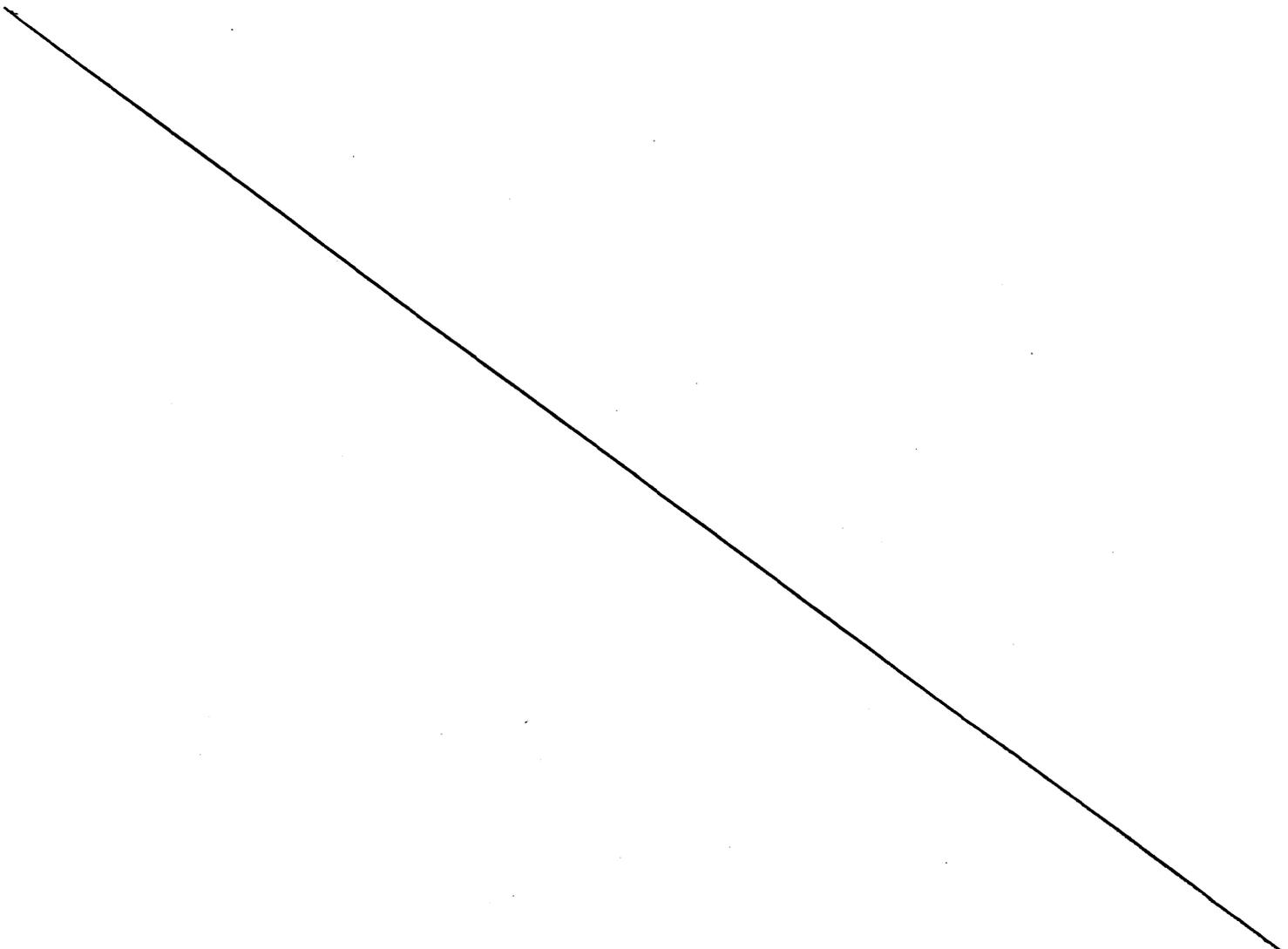
Petitioners assert that the requested regulatory limit would establish a science-based standard for the presence of *L. monocytogenes* in such foods, noting that their request is based on new and emerging evidence that consumer protection is a function of the organism's cell numbers in food, and not its mere presence. Petitioners further assert that a regulatory limit will permit **FDA** and the food industry to distinguish products for which increased scrutiny is prudent from those for which greater attention will not yield a corresponding benefit to public health. Petitioners state that a risk-based approach to *L. monocytogenes* is consistent with the comprehensive risk assessment undertaken by FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service, in which the agencies concluded that "targeted initiation of new or enhanced controls may be needed to achieve further reductions in the incidence of listeriosis." In addition, petitioners assert that there is general scientific agreement that low levels of *L. monocytogenes* are not uncommon in the food supply and that such low levels are regularly consumed without **apparent** harm.

For over 15 years, FDA has been working with its Federal, State, and local food safety counterparts to reduce the incidence of foodborne illness in the

United States, including illness caused by *L. monocytogenes*. The action requested in the petition directly bears on the safety of the food supply and FDA's longstanding effort. Accordingly, FDA is requesting public comment on the petition as well the submission of any relevant data or information that could assist the agency's evaluation of or its response to the petition.

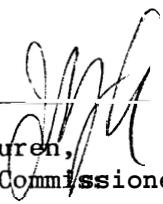
## 11. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the petition. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. If your comments are based on scientific data or other evidence,



please submit copies of such information with your comments. The petition and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/7/04  
May 7, 2004.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

