

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. 2007N-0432]

**Risk Assessment of the Public Health Impact from Foodborne Listeria  
Monocytogenes in Soft-Ripened Cheese: Request for Comments and for  
Scientific Data and Information**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments and for scientific data and information.

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**SUMMARY:** The Food and Drug Administration (FDA) is requesting comments and scientific data and information that would assist the agency in its plans to conduct a risk assessment for *Listeria monocytogenes* in soft-ripened cheese. The purpose of the risk assessment is to ascertain the impact on public health from the reduction and/or prevention of *L. monocytogenes* growth and recontamination during the manufacturing and/or processing of soft-ripened cheese.

**DATES:** Submit comments and scientific data and information by [*insert date 60 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written comments and scientific data and information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>.

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**2007N-0432**

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**FOR FURTHER INFORMATION CONTACT:** Steven M. Gendel, Center for Food Safety and Applied Nutrition (HFS-06), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2290.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Department of Health and Human Services' *Healthy People 2010* is a comprehensive set of disease prevention and health promotion objectives for the Nation to achieve over the first decade of the new century. Created by scientists both inside and outside of Government, it identifies a wide range of public health priorities and specific, measurable objectives. One of these objectives calls on Federal food safety agencies to reduce foodborne listeriosis (Ref. 1). In support of this goal, in 2003, FDA issued an assessment of the relative risk to the public health from foodborne *L. monocytogenes* among selected categories of ready-to-eat (RTE) foods (*Listeria* risk assessment) (Ref. 2). The *Listeria* risk assessment formed the basis of the 2003 FDA/Centers for Disease Control and Prevention (CDC) *Listeria* Action Plan (Ref. 3), which identifies prevention and control activities that FDA and CDC will take to reduce the incidence of foodborne listeriosis in the United States. The Public Health Risk Assessment: *Listeria monocytogenes* in Soft-Ripened Cheese supports the agency's commitment to fulfilling the *Listeria* Action Plan.

The 2003 *Listeria* risk assessment provided the first quantitative estimate of the relative risk of listeriosis from consumption of a variety of RTE foods. Among the dairy foods, soft unripened cheese was considered to present a high risk, and fresh soft cheese, semi-soft cheese, and soft-ripened cheese was considered to present a moderate risk of listeriosis. This risk assessment estimated that the risk of listeriosis from the consumption of fresh soft cheese

made using unpasteurized (raw) milk could be as much as 40-fold higher than the risk from consumption of these cheeses made from pasteurized milk.

The United States (U.S.) and Canada have experienced sporadic illnesses and outbreaks of listeriosis associated with the consumption of cheese. In both countries, there is a strong epidemiological correlation between consumption of soft cheese and listeriosis. For example, a 1985 outbreak of listeriosis associated with the consumption of a Mexican-style soft cheese resulted in 142 illnesses in Los Angeles (Ref. 4), a similar outbreak in 2000 in North Carolina resulted in 12 illnesses, and a 2002 soft cheese-associated outbreak in Quebec resulted in 17 illnesses including 2 premature births (Ref. 5). Both FDA and Health Canada (HC) continue to evaluate the safety of soft cheese, particularly soft cheese made from unpasteurized milk.

As a followup to the *Listeria* risk assessment, FDA and HC have agreed to collaborate on the development of a model for the production of soft-ripened cheese that will evaluate the public health impact of factors such as the microbiological status of milk used in cheese production, the impact of various cheese manufacturing steps, conditions during distribution and storage, and cross contamination during processing and handling. The risk assessment model also will be used to evaluate the effectiveness of various process changes and intervention strategies in reducing human illness.

Specifically, the objectives of the *Listeria* in soft-ripened cheese risk assessment model are to quantitatively evaluate the impact on public health of the following: (1) Variations in *L. monocytogenes* levels in the raw materials used to produce cheese; (2) changes in *L. monocytogenes* levels as a result of growth, inactivation, or re-contamination at each step of the manufacturing

process, between final packaging and sale at retail, and between retail sale and consumption; and (3) the impact of various intervention and control strategies.

## II. Request for Comment and for Scientific Data and Information

FDA requests comments on the risk assessment approach outlined previously in this document and the submission of data and information relevant to the risk assessment. The agency specifically requests information for the following:

(1) Characteristics of the manufacturing and marketing processes for soft-ripened cheese including:

- The number of large and small (artisan) facilities producing soft-ripened cheese in the U.S. and Canada, and
- The amount of soft-ripened cheese produced each year in the U.S. and Canada by large and small facilities including information on different sizes of cheese that are produced and the relative production volumes for these sizes.

(2) Factors that influence the levels of *L. monocytogenes* in milk used for cheese manufacturing including:

- On-farm practices that influence the frequency and level of *L. monocytogenes* in raw milk used for cheese making,
- *L. monocytogenes* levels and/or frequencies in raw milk in the U.S. and Canada,
- Bulk tank sizes and mixing practices used by large and small manufacturers,
- Growth of *L. monocytogenes* in raw milk,
- Conditions of storage (temperatures and times) encountered by milk prior to cheese manufacture, and

- The identity and effectiveness of processes other than pasteurization used to treat raw milk prior to cheese making.

(3) Factors that influence the levels of *L. monocytogenes* in products during cheese manufacturing including:

- Changes in *L. monocytogenes* levels and frequency (i.e., growth, inactivation, or re-contamination) at each step in cheese manufacturing (i.e., during curd formation, ripening, packaging, aging);
- Conditions of storage (temperatures and times) encountered during post-production holding at the producer; and
- Pathways for transfer of *L. monocytogenes* to soft-ripened cheese from environmental sources during packaging, cutting, transport, and handling at retail, including data on frequencies or amounts of transfer.

(4) Factors that influence the levels of *L. monocytogenes* in cheese post-production including:

- Levels and/or frequencies of *L. monocytogenes* that occur in cheese at retail; and
- The conditions (temperature and time) encountered during transport and storage throughout the distribution process, including at retail, in the U.S. and Canada.

(5) Factors that influence the levels of *L. monocytogenes* in cheese at consumption including:

- Storage conditions (temperature and times) encountered in consumers' homes, and
- Consumption patterns for soft cheese (including serving size and frequency) in the U.S. and Canada.

(6) The identity and effectiveness of control measures or interventions to reduce levels and frequency of *L. monocytogenes* in cheese during processing, manufacturing, packaging, storage, and transportation prior to retail sale.

(7) Any other data related to the occurrence, growth, and control of *L. monocytogenes* in soft-ripened cheese.

Interested persons should submit comments, scientific data, and information to the Division of Dockets Management (see **ADDRESSES**). Three copies of all comments, scientific data, and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered, except by petition under 21 CFR 10.30.

### **III. References**

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

1. U.S. Department of Health and Human Services, *Healthy People 2010*, vol. 1, Washington, DC, 2000, <http://www.healthypeople.gov>.

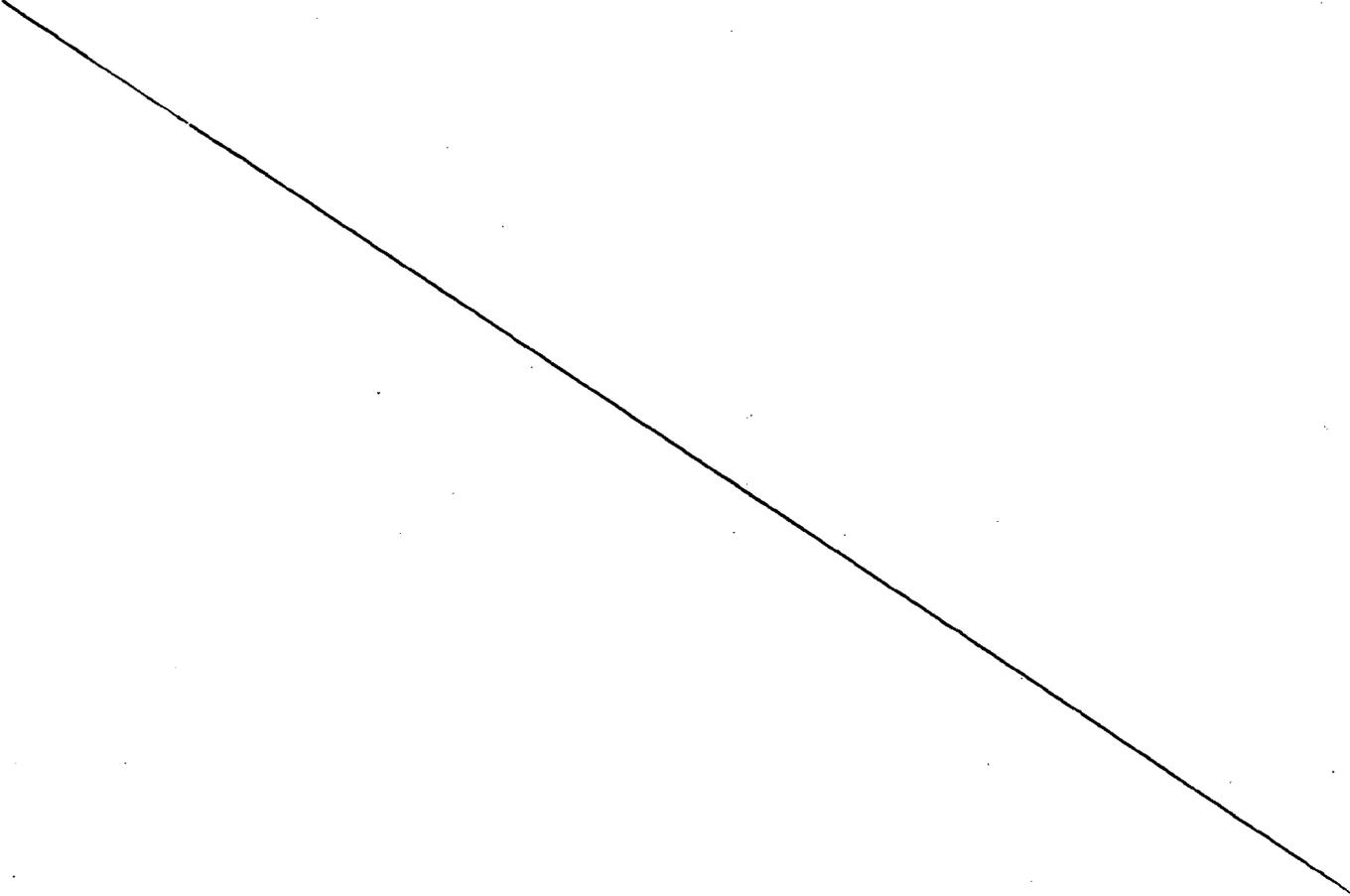
2. U.S. Department of Health and Human Services and U.S. Department of Agriculture/Food Safety and Inspection Service, "Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected

Categories of Ready-to-Eat Foods,” September 2003, <http://www.foodsafety.gov/~dms/lmr2-toc.html>.

3. U.S. Department of Health and Human Services, Food and Drug Administration/Centers for Disease Control and Prevention, “Reducing the Risk of *Listeria monocytogenes* FDA/CDC 2003 Update of the *Listeria* Action Plan,” November 2003, <http://www.cfsan.fda.gov/~dms/lmr2plan.html>.

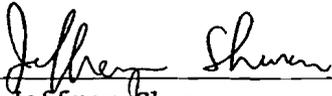
4. Linnan et al., “Epidemic Listeriosis Associated With Mexican-Style Cheese,” *New England Journal of Medicine*, 319 (13):823–8, 1988.

5. Gaulin et al., “First Documented Outbreak of *Listeria monocytogenes* in Quebec, 2002,” *Canada Communicable Disease Report*, 29 (21):181–6, 2003.



Dated: 11-20-07  
November 20, 2007.

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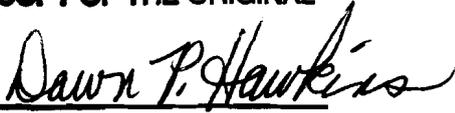


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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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Dawn P. Hawkins