

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1168]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00-048N]

Relative Risk to Public Health from Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods; Draft Risk Assessment Document and Risk Management Action Plan; Availability

AGENCY: Food and Drug Administration, HHS., and Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) are announcing the availability of two documents: A draft risk assessment on the relationship between foodborne *Listeria monocytogenes* and human health that considers 20 ready-to-eat food categories, and a risk management action plan based on the *L. monocytogenes* risk assessment. We are making these documents available, and we are seeking public comment of a technical nature on the draft risk assessment. The risk management action plan identifies immediate actions as well as short-term and long-term activities targeted to reduce *L. monocytogenes* associated illnesses. This plan is intended to respond to the President's directive to reduce *L. monocytogenes* associated illnesses by 50 percent by the year 2005. HHS and USDA invite comments on the risk management strategies reflected in the action plan. A public meeting to discuss the draft risk assessment and the risk management plan will be announced in a future issue of the **Federal Register**.

DATES: Comments on the draft risk assessment and the HHS/USDA risk management action plan must be submitted by March 20, 2001.

ADDRESSES: Printed copies of the draft risk assessment and the risk management action plan may be requested by faxing your name and mailing address with the names of the documents you are requesting by faxing your name and mailing address with the names of the documents you are requesting to the CFSAN Outreach and Information Center at 1-877-366-3322. The documents may be reviewed at the FDA Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, and at the FSIS Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

Submit written comments to the Dockets Management Branch (HFA-305), Docket No. 99N-1168, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of comments are to be submitted, except that individuals may submit one copy.

or

Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 00-048N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th St. SW., Washington, DC 20250-3700. All comments submitted in response to this notice will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday. For electronic access to these documents see section III of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

For information concerning the draft risk assessment document: Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS-032), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-260-3984, FAX 202-260-9653, or e-mail: sdennis@cfsan.fda.gov.

For information concerning the risk management action plan: Kathy Gombas, Center for Food Safety and Applied Nutrition (HFS-615), Food and Drug Administration, 200 C St. SW.,

Washington, DC 20204; 202-205-4231; FAX 202-260-0136, e-mail:

Kathy.Gombas@cfsan.fda.gov or Charles Edwards, Food Safety and Inspection Service,
U.S. Department of Agriculture, rm. 405, Cotton Annex, 300 12th St. SW., Washington,
DC 20250-3700; 202-205-0675; FAX 202-205-0080.

SUPPLEMENTARY INFORMATION:

I. Draft Risk Assessment

A. Background

The draft risk assessment was written by FDA's Center for Food Safety and Applied Nutrition (CFSAN) and USDA/FSIS, in consultation with the Centers for Disease Control and Prevention (CDC). These agencies began this comprehensive quantitative microbial risk assessment (QMRA) in 1999, and have held two public meetings to present the framework of the assessment, the assumptions, and the modeling procedures.

In the **Federal Register** of May 7, 1999 (64 FR 24661), FDA, in collaboration with USDA/FSIS, announced plans to conduct a risk assessment to determine the extent of consumer exposure to foodborne *L. monocytogenes*. In the **Federal Registers** of May 7, 1999 (64 FR 24663), and August 13, 1999 (64 FR 44225), the agencies announced public meetings to discuss issues related to the risk models under development. You may refer to these notices for further background information.

B. The Listeria monocytogenes QMRA

The goal of this QMRA is to provide FDA and USDA/FSIS with information that will assist the agencies with the review of current programs and the development of new programs relating to the regulation of *L. monocytogenes* contamination in foods to ensure that such programs protect the public health. QMRA is a structured and systematic process of collecting and evaluating data and information to establish the risks to human health from consumption of pathogenic microorganisms. The draft risk assessment evaluates the available data on food consumption,

contamination of various foods within 20 ready-to-eat food product categories by *L. monocytogenes*, growth of the pathogen in such foods, and the infectious dose. The draft risk assessment follows the framework recommended by both the National Academy of Sciences and the Codex Alimentarius Commission. This structured framework involves the following steps:

(1) *Hazard identification*. The collection and critical review of data and information on *L. monocytogenes*.

(2) *Exposure assessment*. The determination of total exposure to *L. monocytogenes* from consumption of various foods using prevalence and food consumption data.

(3) *Hazard characterization/Dose-response*. The assessment of the potential for *L. monocytogenes* to cause illness in human populations using epidemiological investigations and data from animal studies.

(4) *Risk characterization*. The integration of the exposure and dose-response data into a complex model to estimate both the risk to the public health and the uncertainty associated with this estimate.

The risk assessment process also includes the identification of data gaps and the development of, and the reliance on, reasonable assumptions when data are unavailable.

As part of a peer evaluation of the draft risk assessment, FDA and USDA/FSIS are seeking comments that can be used to improve:

- (1) The assumptions made,
- (2) the modeling technique,
- (3) the data used, and
- (4) the transparency of the draft risk assessment document.

It is our intent to review and evaluate all public comments and make modifications to the assessment, as appropriate. As noted previously, the draft risk assessment is available electronically on websites listed in section III of the Supplementary Information section of this document and

may be reviewed at the FDA's Dockets Management Branch and FSIS's Docket Clerk's Office (addresses above).

II. HHS/USDA Risk Management Action Plan

A. Background

On May 5, 2000, the President directed the Secretary of HHS and the Secretary of Agriculture to identify aggressive steps to reduce significantly the risk of illness and death from *L. monocytogenes* in ready-to-eat foods. The President called for action to reduce the number of *L. monocytogenes* illnesses by 50 percent by the year 2005—5 years ahead of the previously established Healthy People 2010 target.

The President directed the Secretary of HHS to develop an action plan identifying additional steps necessary to reduce *L. monocytogenes* contamination. He specifically directed that the HHS plan include consideration of control measures for at-risk foods, publication of guidance for processors, retailers, and food service facilities, and consideration of enhanced labeling to provide additional safeguards for consumers. The President also directed the Secretary of Agriculture to report back on the actions that would reduce significantly the risk of illness and death from *L. monocytogenes* in ready-to-eat foods. The President in particular directed the Secretary of Agriculture to “complete proposed regulations that include any appropriate microbiological testing and other industry measures” to prevent cross-contamination in the processing environment; ensure that the processing of ready-to-eat products meets appropriate standards; and ensure that such products are safe throughout their shelf-life. Taken together, these actions are designed to reduce *L. monocytogenes*-related illnesses by 50 percent by 2005.

B. The *L. Monocytogenes* Action Plan

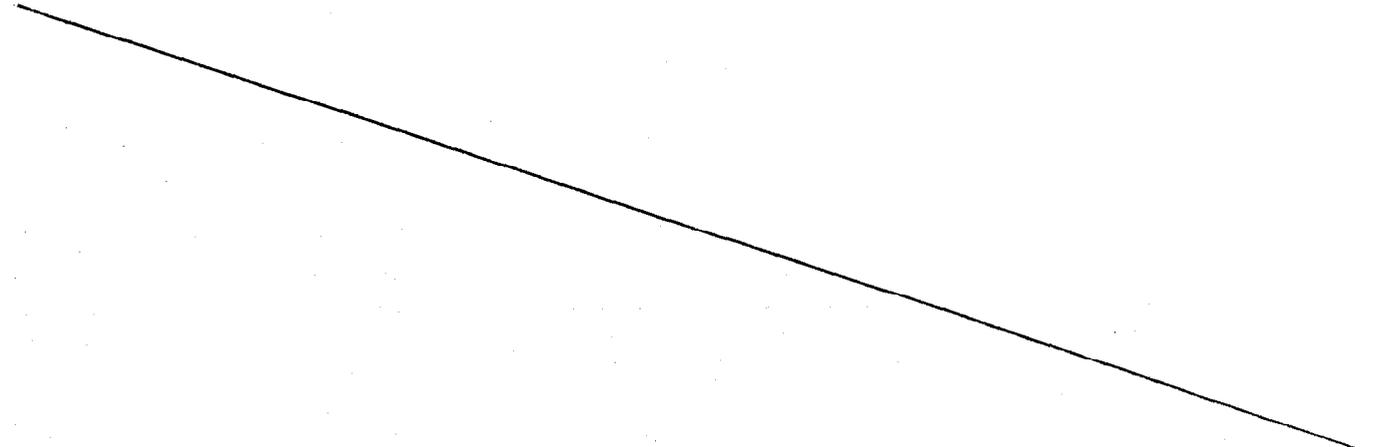
The action plan outlines the actions HHS and USDA intend to undertake to reduce *L. monocytogenes* illnesses from ready-to-eat foods. The plan focuses on those food categories identified in the draft risk assessment as either warranting additional measures to reduce *L.*

monocytogenes contamination or warranting collection of additional data. Within HHS, FDA and CDC have the primary responsibility for implementation of this action plan. Within USDA, FSIS has the primary responsibility for implementation of this plan, working in concert with other USDA agencies through the Office of Food Safety.

The action plan contains the following eight action areas:

- (1) Enhance consumer and health care provider information and education efforts;
- (2) Develop and revise guidance for processors, retailers, and food service/institutional establishments that manufacture or prepare ready-to-eat foods;
- (3) Develop and deliver training/technical assistance to the regulated industry and food safety regulatory employees;
- (4) Review and redirect enforcement and regulatory strategies including microbial product sampling;
- (5) Propose new regulations and revisions to existing regulations as needed;
- (6) Enhance disease surveillance and outbreak response;
- (7) Initiate projects with retail operations such as delicatessens and salad bars to pilot new *L. monocytogenes* control measures including employee practices; and
- (8) Coordinate research activities to refine the risk assessment, enhance preventive controls, and support regulatory, enforcement, and educational activities.

As noted, the draft risk assessment will be available, along with other information, to assist HHS and USDA as they consider the specific means to implement the elements of the action plan.



III. Electronic Access

The draft risk assessment document and the risk management plan are available electronically as follows:

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| Draft Risk Assessment Document | www.cfsan.fda.gov www.fsis.usda.gov www.foodsafety.gov www.foodriskclearinghouse.umd.edu |
| The Risk Management Action Plan | www.cfsan.fda.gov www.foodsafety.gov www.fsis.usda.gov |

Dated: January 11, 2001

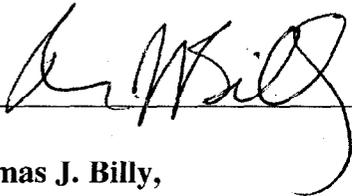
CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation, Food and Drug Administration,

HHS.



Thomas J. Billy,

Administrator, Food Safety Inspection Service, USDA.

[FR Doc. 00-¹???? Filed ??-??-00¹; 8:45 am]

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