

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0658]

Risk Assessment of the Public Health Impact From Foodborne *Listeria monocytogenes* in Some Ready-to-Eat Foods Sliced, Prepared, and/or Packaged in Retail Facilities; 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.

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 of the public health impact of foodborne *Listeria monocytogenes* in some ready-to-eat foods sliced, prepared, and/or packaged in retail facilities. The purpose of the risk assessment is to ascertain the impact on public health of current practices and potential interventions that reduce or prevent *L. monocytogenes* contamination in ready-to-eat food.

DATES: Submit comments and scientific data and information by [insert date 90 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, scientific data, and information to <http://www.regulations.gov>.

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NRD

FOR FURTHER INFORMATION CONTACT: Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS-005), Food and Drug Administration, 5100 Paint Branch Pkwy, College Park, MD 20740, 301-436-2355, e-mail: sherri.dennis@fda.hhs.gov.

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 and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) issued an assessment of the relative risk to public health from foodborne *Listeria 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 and 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 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 RTE foods evaluated in the 2003 risk assessment, deli meats (e.g., luncheon meats) were considered to present the highest risk per serving and the highest risk per annum. This rank was the result of a moderate

contamination frequency, a high number of servings consumed and high growth rates of *L. monocytogenes*. Additional data obtained in California and Maryland showed that *L. monocytogenes* prevalence and levels in luncheon meats, deli-style salads, and seafood salads were higher for in-store-packaged than for manufacturer-packaged foods (Ref. 4). This observation was confirmed for meat and poultry products in a study by the National Alliance for Food Safety and Security performed in northern California, Georgia, Minnesota, and Tennessee in 2008 (Ref. 5). Using these latter results, it was estimated that most of the listeriosis cases attributed to ready-to-eat meat and poultry deli meats are from products sliced and packaged at retail (FSIS/USDA, unpublished results).

Little is known about how *Listeria* contamination occurs in retail facilities. Retail practices may result in either cross-contamination from one product to another or through contamination from the retail environment. There is thus a need to identify potential sources and practices that may increase *L. monocytogenes* contamination in retail settings and practices or interventions that could reduce or eliminate *L. monocytogenes* contamination of food products (sold to consumers at the retail level) and resulting human illness.

FDA is engaged in a risk assessment that will evaluate the dynamics of *L. monocytogenes* contamination in retail facilities contributing to listeriosis. It will evaluate how specific practices could affect the overall level and frequency of contamination, and the relative effectiveness of various process changes and intervention strategies intended to reduce human illness. The project will address FDA and USDA regulated RTE foods. It will focus on RTE foods that are sliced, prepared, and/or packaged for the consumer in the retail

environment and consumed in the home. Cheeses, deli meats, and deli-type salads (as defined in Ref. 2) will be studied as representative examples.

This risk assessment of the public health impact of *L. monocytogenes* in RTE foods sliced, prepared, and/or packaged in retail facilities supports the agency's commitment to fulfilling the *Listeria* Action Plan (Ref. 3).

II. Request for Comments and for Scientific Data and Information

FDA requests comments on the risk assessment goals outlined in this document and the submission of scientific data and information relevant to the risk assessment. Specifically, we request data and information about the following:

1. Characteristics of ready-to-eat food markets in the United States, including:
 - a. Volumes of cheeses and deli meats sliced by manufacturers and the volumes sliced in retail facilities,
 - b. Volumes of deli-type salads prepared by manufacturers and the volumes prepared in retail facilities, and
 - c. Volumes of ready-to-eat food sold in delicatessen departments of major grocery chains (i.e., large supermarket facilities) and the volumes sold in other groceries (i.e., multipurpose independent small or local facilities).
2. Characteristics of deli departments in groceries, including the proportion of separated seafood/meat/dairy deli departments in groceries.
3. Product contamination data, including:
 - a. *L. monocytogenes* levels and/or frequencies in wholesale products (deli meats (chubs), cheeses, fresh produce, seafood) arriving at retail facilities; and
 - b. *L. monocytogenes* levels and/or frequencies in cheeses, deli meats, and deli-type salads sold by retail facilities.

4. Factors that influence the growth of *L. monocytogenes* in cheeses, deli meats, and deli-type salads, including:

a. Growth rates of *L. monocytogenes* in cheeses, deli meats, and deli-type salads and the effects of different ingredients in and compositions of those products;

b. Chemical characteristics of cheeses, deli meats, and deli-type salads that could influence *L. monocytogenes*, including pH and water activity;

c. Proportions of deli meats treated with growth inhibitors, the inhibitors used, the level of growth inhibitors, and their efficiency;

d. Data on the temperatures to which cheeses, deli meats, and deli-type salads are exposed at retail, including time and temperature for walk-in coolers or refrigerators, display cabinets, and ambient displays; and

e. Data on the use of advisory “use-by” or “best by” labels for ready-to-eat food sold by retail facilities.

5. Environmental contamination data, including:

a. Data and information on the prevalence and levels of *L. monocytogenes* in the retail environment including, e.g., drains, countertops, walls, and equipment; and

b. Data on the growth of *L. monocytogenes* on non-food surfaces including environmental biofilm growth.

6. Factors that influence the environmental contamination and the cross-contamination of food by *L. monocytogenes* in retail facilities, including:

a. Data and information on the potential transfer of *L. monocytogenes* to food from the retail environment, e.g., experimental studies on the transfer to food from drains, slicers, food contact surfaces, and non-food contact surfaces; and

b. Data and information on food handlers' activities, e.g., observations of food handlers' practices and monitoring of specific food safety actions in retail facilities (e.g., glove usage, hand hygiene practices, and cleaning practices).

7. Identity and effectiveness of control measures or interventions intended to reduce levels and frequency of *L. monocytogenes* in the retail environment, including:

a. Environmental sanitation procedures including the sanitizers and protocols used, frequency of application, and efficiency; and

b. Worker sanitation procedures including frequencies, protocols, and efficiency.

8. Any other data related to the occurrence, growth, and control of *L. monocytogenes* in retail facilities.

As the project progresses, additional data needs may be identified.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

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 FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. U.S. Department of Health and Human Services, *Healthy People 2010*, v. 1. Washington, DC, 2000, <http://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. Gombas, D.E., Chen, Y., Clavero, R.S., and Scott, V.N. (2003). Survey of *Listeria monocytogenes* in ready-to-eat foods. *Journal of Food Protection*, 66(4), 559–569.
5. Draughon, A.F. (2006). A collaborative analysis/risk assessment of *Listeria monocytogenes* in ready-to-eat processed meat and poultry collected in four FoodNet states. Symposium S–16: Contamination of ready-to-eat foods: transfer and risk: *Listeria monocytogenes* and other microorganisms. International Association for Food Protection 93rd Annual Meeting, Calgary, Alberta. August 13–16.

JAN 12 2009

Dated: _____

January 12, 2009.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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