

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0065]

Risk Assessment of the Public Health Impact From Foodborne Listeria Monocytogenes in Smoked Finfish; and Evaluation of Food Code Provisions That Address Preventive Controls for Listeria Monocytogenes in Retail and Foodservice Establishments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 5, 2005, the comment period for the notice that appeared in the **Federal Register** of March 4, 2005 (70 FR 10650). In the notice, FDA requested comments and scientific data and information to assist the agency in its plans to conduct a risk assessment for *Listeria monocytogenes* in smoked finfish and to evaluate the provisions of the 2001 Food Code that address preventive controls for *L. monocytogenes* in retail and foodservice establishments. The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments and scientific data and information.

DATES: Submit written and electronic comments and scientific data and information by July 5, 2005.

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 <http://www.fda.gov.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Sherri B. Dennis, Center for Food Safety and Applied Nutrition (HFS-06), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1903.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 4, 2005 (70 FR 10650), FDA published a notice with a 60-day comment period to request comments and scientific data and information to assist the agency in its plans to conduct a risk assessment for *L. monocytogenes* in smoked finfish (smoked finfish risk assessment) and to evaluate the provisions of the 2001 Food Code that address preventive controls for *L. monocytogenes* in retail and foodservice establishments.

For the smoked finfish risk assessment, the agency specifically requested information on the following topics:

1. *L. monocytogenes* levels in raw fish, smoked fish, and finished product,
2. Effect of mitigation measures (e.g., ozonation, acidified sodium chlorite) to reduce *L. monocytogenes* levels in raw and finished product,
3. Potential for transfer of *L. monocytogenes* to food from contaminated food contact and noncontact surfaces during manufacturing and/or processing (e.g., equipment, workers, floor drains, etc.),
4. Potential for transfer of *L. monocytogenes* from the slicer to cold-smoked fish,

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5. Impact of adding inhibitors (e.g., bacteriocins and bacteriocins-producing bacterial strains or sodium lactate) to smoked finfish to reduce or prevent *L. monocytogenes* growth,

6. Impact of frozen versus refrigerated storage conditions on levels of *L. monocytogenes*,

7. Impact of time and temperature on levels of *L. monocytogenes* for commercial and home storage conditions of finished product, and

8. Effect of training regarding sanitation and hygienic practices on reducing the levels of *L. monocytogenes* in smoked finfish.

For evaluating the Food Code provisions for preventive controls for *L. monocytogenes* in retail and foodservice establishments, the agency specifically requested the following data and information:

1. *L. monocytogenes* levels in products stored in retail and foodservice establishments,

2. Levels of environmental contamination and harborage of *L. monocytogenes* on food contact and nonfood contact surfaces in retail and foodservice establishments (e.g., equipment, workers, floor drains, etc.),

3. Effects of short- and long-term refrigerated storage on levels of *L. monocytogenes* in retail and foodservice establishments,

4. Impact of time and temperature on levels of *L. monocytogenes* in products stored in retail and foodservice establishments,

5. Efficacy of cleaning procedures and sanitizing agents on environmental surfaces and utensils,

6. Frequency of use and impact of adding inhibitors to food products in retail and foodservice establishments to reduce or prevent *L. monocytogenes* growth, and

7. Effect of training regarding hygienic practices and sanitation on levels of *L. monocytogenes* in products in retail and foodservice establishments.

Interested persons were given until May 3, 2005, to submit comments and scientific data and information.

The agency has received a request for a 60-day extension of the comment period for the notice. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful response to the notice.

FDA has considered the request and is extending the comment period for the notice for an additional 60 days, until July 5, 2005. However, the agency does not anticipate granting any further extensions of the comment period.

II. Request for Comments and for Scientific Data and Information

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments, scientific data, and information on this document. Submit a single copy of electronic comments, scientific data, and information 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.

Dated: April 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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