

DEPARTMENT OF AGRICULTURE**Food Safety and Inspection Service**

[Docket No. FSIS-2010-0035]

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2011-N-0092]

Update of the 2003 Interagency Quantitative Assessment of the Relative Risk to Public Health From Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods; Request for Comments, Scientific Data and Information**AGENCY:** Food Safety and Inspection Service, USDA; Food and Drug Administration, HHS.**ACTION:** Notice; request for comments and for scientific data and information.

SUMMARY: The Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) are requesting comments and scientific data and information that would assist the agencies in their plan to update a risk assessment on the relationship between foodborne *Listeria monocytogenes* in selected categories of ready-to-eat (RTE) foods and human health. The purpose of the risk assessment is to incorporate newly available scientific data and information into the risk assessment in order to update estimates of the relative risk of illness and death associated with the consumption of different types of RTE foods that may be contaminated with *L. monocytogenes* and to evaluate the relative effectiveness of strategies to reduce or prevent exposure to *L. monocytogenes* from the consumption of RTE foods, including, for example, the impact of changing refrigerated time and temperature storage prior to consumption.

DATES: Submit electronic or written comments and scientific data and information by July 6, 2011.**ADDRESSES:** FSIS: Submit electronic comments and scientific data and information to <http://www.regulations.gov>. Submit written comments and scientific data and information to the Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, George Washington Carver Center, 5601 Sunnyside Ave., Mailstop 5474, Beltsville, MD 20705-5464. All submissions must include the Agency name and docket number FSIS-2010-0035.

FDA: Submit electronic comments and scientific data and information to <http://www.regulations.gov>. 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. All submissions must include the Agency name and docket number FDA-2011-N-0092.

FOR FURTHER INFORMATION CONTACT:

FSIS: Janell Kause, Office of Public Health Science, Food Safety and Inspection Service, United States Department of Agriculture, 1400 Independence Ave., Aerospace Maildrop 344, Washington, DC 20250, 202-690-0286; or

FDA: Sherri Dennis, Center for Food Safety and Applied Nutrition (HFS-06), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1914.

SUPPLEMENTARY INFORMATION:**I. Background**

Listeria monocytogenes is a bacterium that is commonly found in the human environment, including food processing environments. After ingesting *L. monocytogenes*, humans can develop listeriosis, a severe foodborne disease with a high case-fatality rate. Listeriosis occurs predominantly in high-risk population subgroups, including pregnant women and their fetuses or neonates, immune-compromised individuals, and the elderly population (defined for the purpose of the risk assessment discussed in this notice as individuals who are 60 years of age or older). Due to the high proportion of serious illnesses and the high case-fatality rate associated with listeriosis, the "Healthy People 2010" goals for national disease prevention and health promotion specified a reduction in the prevalence of foodborne listeriosis by 50 percent as an important objective (Ref. 1). ("Healthy People" is a national health promotion and disease prevention initiative that brings together national, State, and local government agencies; nonprofit, voluntary, and professional organizations; and businesses, communities, and individuals to improve the health and quality of life of all Americans, eliminate disparities in health, and promote good health and quality of life across all life stages (Ref. 2).) However, despite considerable efforts to reduce the number of listeriosis cases during the past decade, the listeriosis prevalence still exceeds the "Healthy People 2010" target of 0.25 cases per 100,000 population (Ref. 3). (Note that then President Clinton's

Council on Food Safety, established by Executive Order 13100, August 25, 1998, developed a strategic plan that set public health goals including, by 2005, reducing foodborne illness by 25 percent for some pathogens and for others to the quantitative targets established in "Healthy People 2010." In 2005, FoodNet data showed 0.30 *L. monocytogenes* cases per 100,000 population; the "Healthy People 2005" target was 0.25 *L. monocytogenes* cases per 100,000 population.) In 2009, the prevalence of listeriosis had decreased by only 26 percent compared to the baseline period (1996 to 1998) rate, and reducing the prevalence of listeriosis was retained in the "Healthy People 2020" objectives, with a target of 0.2 cases per 100,000 population (Refs. 3 and 4).

In 2003, FDA and FSIS published a quantitative assessment of the relative risk to public health from foodborne *L. monocytogenes* among 23 selected categories of RTE foods (the 2003 risk assessment) (Ref. 5). This 2003 risk assessment provided estimates for the median number of listeriosis cases attributable to each of 23 RTE food categories on a per-annum and per-serving basis. This allowed for a relative ranking of the 23 food categories based on the associated public health risk and permitted the evaluation of the likely impact of several "what-if" mitigation scenarios.

Since publication of the 2003 risk assessment, the food industry has changed some practices, including by adding growth inhibitors to RTE products. *L. monocytogenes* prevalence in some RTE foods has decreased over the past decade, and a substantial amount of new scientific data has become available for potential inclusion in risk assessments (Refs. 6, 7, and 8). These changes could potentially affect the outcomes of the risk assessment and alter the relative risk rankings of the RTE food categories evaluated in the 2003 risk assessment.

Risk assessments can be used to evaluate potential risk mitigation strategies and can guide, support, and enhance an Agency's risk management policies, outreach efforts, data collection initiatives, and research priorities. To help ensure that risk mitigation strategies, risk management policies, outreach efforts, data collection initiatives, and research priorities aimed at controlling *L. monocytogenes* in RTE foods are directed to those RTE foods that pose the greatest risk, FDA and FSIS have initiated an update to the 2003 risk assessment. The purpose of updating the risk assessment is to incorporate newly available scientific

data and information that reflect changes in *L. monocytogenes* prevalence and industry practices into the risk assessment in order to: (1) Update estimates of the relative risk of listeriosis associated with the consumption of different types of RTE foods that may be contaminated with *L. monocytogenes* and (2) evaluate the relative effectiveness of strategies to reduce or prevent exposure to *L. monocytogenes* from the consumption of RTE foods, including by modeling the effect of changing refrigerated storage times and temperatures. To fill critical data gaps, FDA and FSIS have initiated collaborative efforts with the USDA Agricultural Research Service, academic partners, and private laboratories to survey the presence and quantity of *L. monocytogenes* in selected categories of RTE foods. RTE foods chosen for this survey include: Leafy green vegetables, low-acid cut fruits, smoked seafood, seafood and deli-type salads, soft ripened and semi-soft cheeses, sandwiches, raw milk, deli meats, hot dogs, pâté, and meat spreads. Estimates for other RTE foods to be included in the risk assessment will be updated using scientific data newly available in the literature (if applicable) and information provided in response to this notice.

II. Request for Comments and Scientific Data and Information

FSIS and FDA are requesting technical comments on the approach outlined previously for updating the 2003 risk assessment. FDA and FSIS are also requesting the submission of new data and information relevant to this risk assessment that was not available for inclusion in the previous risk assessment and that may reflect changes in *L. monocytogenes* prevalence and industry practices that have occurred since the previous risk assessment.

The agencies specifically request new data and information concerning, but not limited to, the following factors that may affect the relative risk of listeriosis associated with consumption of the types of RTE foods that were considered in the 2003 risk assessment:

1. *L. monocytogenes* contamination in different RTE foods sampled at retail or in the processing plant, including:
 - The frequency of detecting the presence of *L. monocytogenes* in RTE foods (including sample size, number of positives, total number tested for a specified time period, and test method); and
 - The number of *L. monocytogenes* cells present per amount (unit volume or weight) of contaminated RTE food (including method used).

2. *L. monocytogenes* survival and growth dynamics in RTE foods, including:
 - Data or models on survival and growth of *L. monocytogenes* in specific RTE food matrices, including the potential effects of commensal microflora;
 - Data or models on survival and growth of *L. monocytogenes* in the presence or absence of substances that inhibit or retard growth; and
 - Data or models on survival and growth of *L. monocytogenes* at different storage temperatures and over different storage times.

3. The relationship between the dose of *L. monocytogenes* ingested with food and the frequency of listeriosis, including:
 - The effect of age, health status, or other characteristics of the consumer on the dose-response relationship;
 - The effect of food matrix and product formulation on the dose-response relationship;
 - The effect of genetic characteristics of the *L. monocytogenes* strain on the dose-response relationship; and
 - Any other data pertinent to *L. monocytogenes* dose-response relationships.

4. Current food consumption practices in the United States, including:
 - The frequency with which different RTE foods (e.g., deli meats or cheeses manufactured with growth inhibitors) are consumed by population subgroups (e.g., general adult population, pregnant women, the elderly); and
 - Serving sizes for different RTE foods.

5. Food production practices in the United States that may impact *L. monocytogenes* prevalence, concentration, survival, or growth in RTE foods, including:
 - The absolute or relative frequency of manufacturing different RTE foods with substances that inhibit the growth of *L. monocytogenes* and the types and concentrations of growth inhibitor used;
 - The absolute or relative amount of specific types of RTE foods that are prepared, sliced, cut, or repackaged in retail operations as opposed to being sold pre-sliced/pre-cut;
 - The absolute or relative amount of different RTE foods manufactured without growth inhibitors that are prepared, sliced, or repackaged at retail;
 - The average shelf life of foods that were identified in the 2003 risk assessment (Ref. 4) as supporting *L. monocytogenes* growth;
 - The average shelf life of RTE foods that were not explicitly identified in the 2003 risk assessment but that may conceivably support *L. monocytogenes* growth;

6. Storage times and temperatures that may affect *L. monocytogenes* growth during transport and storage of foods in the consumer's home.

7. Other comments, including the RTE food categories that should be evaluated in the risk assessment.

• The ability of current production practices to prevent or reduce *L. monocytogenes* contamination in finished product;

• The ability of current operational practices in retail operations to prevent or reduce *L. monocytogenes* contamination in the final product at the time of sale; and

• The ability of current post-processing practices to prevent *L. monocytogenes* cross-contamination after processing.

6. Storage times and temperatures that may affect *L. monocytogenes* growth during transport and storage of foods in the consumer's home.

7. Other comments, including the RTE food categories that should be evaluated in the risk assessment.

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6. Storage times and temperatures that may affect *L. monocytogenes* growth during transport and storage of foods in the consumer's home.

7. Other comments, including the RTE food categories that should be evaluated in the risk assessment.

III. Request for Comments, Scientific Data and Information

FSIS: Interested persons may submit to FSIS's Docket Clerk (*see ADDRESSES*) either electronic or written comments regarding this document. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FDA: Interested persons may submit to FDA's Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

IV. 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. We have verified all addresses, but we are 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," Chapter 10, Food Safety, Washington, DC, 2000, <http://www.healthypeople.gov/2010/Document/pdf/Volume1/10Food.pdf>.
2. U.S. Department of Health and Human Services, "Healthy People 2020," HP 2020 Framework, Washington, DC, 2010, available at <http://www.healthy>

people.gov/2020/Consortium/HP2020Framework.pdf.

3. Anonymous, 2010, "Preliminary FoodNet Data on the Incidence of Infection With Pathogens Transmitted Commonly Through Food—10 States, 2009," *Morbidity and Mortality Weekly Report*, 59: 418–422, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5914a2.htm>.

4. U.S. Department of Health and Human Services, "Healthy People 2020," HP 2020 FS–1.3, Washington, DC, 2010, available at <http://www.healthypeople.gov/2020/topicsobjectives2020/pdfs/HP2020objectives.pdf>.

5. 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 *L. monocytogenes* Among Selected Categories of RTE Foods," September 2003, available in Docket No. FDA–1999–N–0134 (formerly Docket No. 1999N–1168), vols. 23 through 28, available at <http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm>.

6. Endrikat, S., D. Gallagher, R. Pouillot, H. Hicks Quesenberry, D. Labarre, C. M. Schroeder, and J. Kause, "A Comparative Risk Assessment for *L. monocytogenes* in Prepackaged Versus Retail-Sliced Deli Meat," *Journal of Food Protection*, 73:612–9.

7. U.S. Department of Agriculture, Food Safety and Inspection Service, 2003, 9 CFR part 430, "Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products," final rule. **Federal Register**, 68 FR 34208 to 34254.

8. U.S. Department of Agriculture/Food Safety and Inspection Service, "The FSIS Microbiological Testing Program for Ready-to-Eat (RTE) Meat and Poultry Products, 1990–2009," September 2010, available at http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp.

Dated: March 25, 2011.

Alfred V. Almanza,
Administrator, FSIS.

Dated: March 31, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

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DEPARTMENT OF AGRICULTURE

Forest Service

Chequamegon-Nicolet National Forest, Wisconsin, Lakewood Southeast Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service will prepare an environmental impact statement (EIS) to document the analysis and disclose the environmental impacts of proposed land management activities and corresponding alternatives within the Lakewood Southeast Project. The purpose of the Lakewood Southeast Project is to implement land management activities that are consistent with direction in the Chequamegon-Nicolet National Forest 2004 Land and Resource Management Plan and respond to the specific needs identified in the project area. The project-specific needs include: Reintroduction of natural regimes, wildlife habitat and stream bank improvement, forest age, forest composition, and stocking.

DATES: Comments concerning the scope of the analysis must be received by May 9, 2011 in order to be useful in preparation of the draft statement. The draft environmental impact statement is expected in May 2011 and the final environmental impact statement is expected August 2011.

ADDRESSES: Send written comments concerning this proposal to Marilee Houtler, *Attn:* Lakewood Southeast Project, Lakewood-Laona Ranger District, 15085 State Road 32, Lakewood, WI 54138. Comments may also be sent via e-mail to comments-eastern-chequamegon-nicolet-lakewood@fs.fed.us, or via facsimile to 715–276–3594. Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered; however, anonymous comments will not provide the Agency with the ability to provide the respondent with subsequent environmental documents.

FOR FURTHER INFORMATION CONTACT: Marilee Houtler, NEPA Coordinator at the above address or by phone at 715–276–6333.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339

between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The information presented in this notice is included to help the reviewer determine if they are interested in or potentially affected by the proposed land management activities. The information presented in this notice is summarized. Those who wish to provide comments, or are otherwise interested in or affected by the project, are encouraged to obtain additional information from the contact listed above.

Purpose and Need for Action

The current conditions of many forest stands in the project area vary from desired conditions in the Chequamegon-Nicolet National Forest 2004 Land and Resource Management Plan (forest plan). Our information shows some of the more notable gaps between the existing and desired future conditions by management area. Of primary importance is the need for change in: (1) Loss of natural regimes (2) wildlife habitat (3) stream improvement (4) species age structure (5) species composition and (6) stocking densities. The dominant habitat in the Lakewood Southeast Project area is upland conifer forests mixed with other forest communities.

Preliminary analysis of the project area indicates that there are certain conditions that warrant action to accomplish the direction and desired conditions identified in the forest plan.

Proposed Action

Projected project implementation would be spring of 2012. Lakewood Southeast Project is located on National Forest System lands, administered by the Lakewood-Laona Ranger District, east of Mountain, WI. The legal description of the project is Township 31–32 North, Range 17 East. The Forest Service proposes to reintroduce natural regimes in the Northern dry forests and Pine Barrens (mainly fire), improve wildlife habitat (manage openings, improve habitat for Regional Forester Sensitive Species) and stream corridors (adding long lived species), and use timber harvest (selection, clearcut, shelterwood, and thinning) to move toward desired conditions in the forest plan.

Responsible Official

The responsible official for this project is Lakewood-Laona District Ranger, Chequamegon-Nicolet National Forest.