Reducing the Risk of *Listeria monocytogenes* FDA/CDC 2003 Update of the Listeria Action Plan

Center for Food Safety and Applied Nutrition
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EXECUTIVE SUMMARY

Listeria monocytogenes (*L. monocytogenes*) is a harmful bacterium that can be found in a variety of foods. In pregnant women, *L. monocytogenes* caused illness can result in miscarriage, fetal death, or severe illness in or death of a newborn infant. The elderly and those with weakened immune systems are also at risk for severe illness or death from *L. monocytogenes* contaminated food.

The Healthy People 2010 goals for national health promotion and disease prevention called on federal food safety agencies to reduce foodborne listeriosis by 50% by the end of the year 2005. Preliminary FoodNet data on the incidence of foodborne illness for the United States in 2001 indicated that the incidence of infection from *L. monocytogenes* decreased between 1996 and 2001 from 0.5 to 0.3 cases per 100,000 people per year. The level then reached a plateau. It became evident that, in order to reduce further the incidence to a level of 0.25 cases per 100,000 people by the end of 2005, additional targeted measures were needed. The *L. monocytogenes* Risk Assessment was initiated as an evaluation tool in support of this goal. The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have reviewed ongoing *L. monocytogenes* prevention and control activities and have developed an action plan, which includes activities targeted at the serious problem of *L. monocytogenes* caused illness.

For more than 15 years, the Department of Health and Human Services (HHS), FDA, CDC, along with other Federal, State, and local agencies, has been working toward preventing *L. monocytogenes* illness and controlling this pathogen. In recent years, HHS, along with the United States Department of Agriculture (USDA), conducted a risk assessment of *L. monocytogenes* (Quantitative Assessment of The Relative Risk to Public Health from Foodborne *L. monocytogenes* Among Selected Categories of Ready-to-Eat Foods) in order to understand better both the health risk posed by the bacterium and the associated food vehicles that can transmit the pathogen. Results from the Risk Assessment support the need for additional targeted public health action.

This Action Plan complements the work of the Risk Assessment, focusing on certain ready-to-eat foods that can potentially become contaminated with *L. monocytogenes*. This revised plan updates the FDA and CDC components of the Action Plan (Joint Response to the President: Reducing the Risk of *L. monocytogenes*) that was previously released in January 2001. The modifications in the plan have been undertaken, in part, to reflect the 2003 updating of the Risk Assessment. This plan seeks to reduce significantly the risk of illness and death caused by *L. monocytogenes* in ready-to-eat foods with consideration of control measures for at-risk foods.

FDA and CDC have identified six areas for action:

1. Develop and revise guidance for processors that manufacture or prepare ready-to-eat foods and develop or revise guidance for retail and food service and institutional establishments.
2. Develop and deliver training and technical assistance for industry and food safety regulatory employees.
3. Enhance consumer and health care provider information and education efforts.
4. Review, redirect, and revise enforcement and regulatory strategies, including microbial product sampling.
5. Enhance disease surveillance and outbreak response.
6. Coordinate research activities to refine the Risk Assessment, enhance preventive controls, and support regulatory, enforcement, and educational activities.

The attached report provides further detail on the action items.

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I. Background

American consumers enjoy one of the safest food supplies in the world. Nevertheless, each year millions of Americans become ill, some with potentially fatal illnesses, from eating contaminated food. To address this serious public health problem, the Federal agencies responsible for food safety have repeatedly taken action to enhance the safety of the U.S. food supply and reduce foodborne illness.

Listeria monocytogenes (*L. monocytogenes*), is a harmful bacterium that can be found in a variety of foods. In pregnant women illness caused by *L. monocytogenes* can result in miscarriage, fetal death, or severe illness in or death of a newborn infant. The elderly and those with weakened immune systems are also at risk for severe illness or death from *L. monocytogenes* -contaminated food. Pregnant women, newborns, the elderly, and those with compromised immune systems are at highest risk of infection and complications of illness. But many of these illnesses can be prevented.

The Healthy People 2010 goals for national health promotion and disease prevention called on Federal food safety agencies to reduce foodborne listeriosis by 50% by the end of the year 2005. Preliminary FoodNet data on the incidence of foodborne illnesses for the United States in 2001 indicated that the incidence of infection from *L. monocytogenes* decreased between 1996 and 2001 from 0.5 to 0.3 cases per 100,000 people per year. The level then reached a plateau. In order to reduce the incidence to a level of 0.25 cases per 100,000 people by the end of 2005 it became evident that additional targeted measures were needed. The *L. monocytogenes* risk assessment was initiated as an evaluation tool in support of this goal. The purpose of the assessment was to systematically examine available scientific data and information to estimate the relative risks of serious illness and death associated with consumption of different types of ready-to-eat (RTE) foods that may be contaminated with *L. monocytogenes*. The risk assessment, which was published in draft form in 2001 and published in final form in 2003, provides analyses and models that (1) estimate the potential level of exposure of three age-based population groups and the total United States population to *L. monocytogenes* contaminated foods for 23 food categories and (2) relate this exposure to public health consequences. The food categories consist of foods with a documented history of *L. monocytogenes* contamination. This examination of the current science and the models developed from it are among the tools that food safety regulatory agencies may use to evaluate the effectiveness of current and future policies, programs and regulatory practices to minimize the public health impact of this pathogen and is the foundation of this response.

In 2001, the Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) reviewed ongoing *L. monocytogenes* prevention and control activities and developed an action plan, published in 2001, which included activities targeted at the serious problem of *L. monocytogenes* caused illness. The 2001 Action Plan included 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. This 2003 Action Plan is an update of the FDA/CDC components of the 2001 Action Plan.

Taken together, the activities in the action plan are designed to achieve the Healthy People 2010 goal of reducing *L. monocytogenes* caused illness by 50 percent by 2005.

II. This Updated Action Plan

This revised and updated Action Plan outlines the steps FDA and CDC will take to reduce *L. monocytogenes* illnesses associated with consumption of ready-to-eat foods within the regulatory purview of the Food and Drug Administration (FDA). The plan focuses on those food categories identified in the FDA/USDA risk assessment as either warranting additional measures to reduce *L. monocytogenes* contamination or warranting collection of additional data.

The actions will be undertaken in consultation with other Federal agencies, State and local health officials, consumers, industry, and academia. In planning and implementing the actions listed below, FDA also plans to hold public meetings to receive stakeholder input.

This Action Plan will be posted on the interagency web site, www.foodsafety.gov, and the FDA web site, www.cfsan.fda.gov.

To address risks from *L. monocytogenes*, FDA and CDC plan to:

1. Develop and revise guidance for processors that manufacture or prepare ready-to-eat foods and develop or revise guidance for retail and food service and institutional establishments.
2. Develop and deliver training and technical assistance for industry and food safety regulatory employees.
3. Enhance consumer and health care provider information and education efforts.
4. Review, redirect, and revise enforcement and regulatory strategies, including microbial product sampling.
5. Enhance disease surveillance and outbreak response.
6. Coordinate research activities to refine the Risk Assessment, enhance preventive controls, and support regulatory, enforcement, and educational activities.

III. Participants

FDA and the CDC have the primary responsibility for implementation of this action plan. FDA and CDC will continue to work in partnership with other agencies to achieve the target of a 50 percent reduction in *L. monocytogenes* illnesses by 2005.

IV. Action Areas

Objective 1:
Develop and revise guidance for processors that manufacture or prepare ready-to-eat foods and develop or revise guidance for retail and food service and institutional establishments.

Timeline: Present through 2005

Action:
To achieve this objective, the following steps are planned:

- FDA will finalize guidance for processors identifying preventive controls for *L. monocytogenes*, with an emphasis on post-process contamination controls and measures including sanitation practices and environmental sampling for ready-to-eat foods
- FDA will, in consultation with the industry, design a project with smoked seafood operations to pilot *L. monocytogenes* preventative control measures and modify the Fish and Fisheries Products Hazards and Controls Guide, as appropriate.
- FDA will develop and issue guidance on enhancing the safety of the production of fresh-cut produce.
- FDA will develop and issue guidance specifically on enhancing the safety of the production of milk and milk products. FDA will also review current recommendations in the Pasteurized Milk Ordinance (PMO) based on the findings of the *L. monocytogenes* risk assessment, in conjunction with the National Conference on Interstate Milk Shipments.
- FDA will, in cooperation with Michigan State University, continue to examine the levels of *L. monocytogenes* transferred in retail food establishments. Specifically, the project will study transfer rates between foods contaminated with *L. monocytogenes* and food contact surfaces (i.e., slicing machines, knives, spoons, etc.).
- FDA will review the Model Food Code to determine if provisions that address preventive controls, such as approved source, date marking, and cold holding times and temperatures, warrant revision.
- FDA will issue guidance, in conjunction with the Conference for Food Protection, to the retail and food service industry and state and local regulatory professionals on the use of HACCP principles to identify and control risk factors contributing to foodborne illness. This guidance will discuss intervention strategies that can be used to control *L. monocytogenes* and other pathogens.
- FDA will promote the inclusion of *L. monocytogenes* control strategies in future guidance documents that address food processing at retail operations (e.g., smoked seafood, specialty meats).
- FDA will continue to work with the Codex Alimentarius Commission on the "Proposed Draft Guidelines for the Control of *L. monocytogenes* in Foods."
- FDA will cooperate with USDA/FSIS and the states on activities directed toward improved *L. monocytogenes* control measures at the retail level.

Objective 2:
Develop and deliver training and technical assistance for industry and food safety regulatory employees.

Timeline: Present through 2005

Action:
FDA and CDC plan to take the following steps toward enhanced training and technical assistance:

- Review existing FDA training and technical assistance programs for regulatory and industry employees and revise, as needed, based on the findings of the *L. monocytogenes* Risk Assessment. Revise existing training, based on the findings of the *L. monocytogenes* Risk Assessment to include a segment on *L. monocytogenes* and preventive and post-process contamination controls and a segment on auditing the effectiveness of these controls.
- FDA will provide technical assistance to small and very small dairy facilities.
- In addition to its ongoing training programs for inspectors and state, local and foreign government officials, FDA and CDC will utilize public and private partnership training groups, internet and software-based programming and curricula; and the land-grant university and extension based network, as appropriate, to deliver training.
- Develop or revise training modules on *L. monocytogenes* and preventive and post-process contamination controls and a segment on auditing the effectiveness of these controls available for long distance training; e.g. satellite-based training, computer-based training with an interactive web site.

Objective 3:
Enhance consumer and health care provider information and education efforts.

Timeline: Present through 2005

Action:
FDA and CDC will collaborate with their public health counterparts to develop further and disseminate to consumers and health care providers appropriate information and educational messages about the prevention of *L. monocytogenes* caused illness. Educational efforts will be revised, as appropriate, based on the findings of the *L. monocytogenes* Risk Assessment. FDA and CDC plan to undertake educational initiatives to achieve the following:

- Focus consumer messages on safely selecting, storing, and handling foods with special emphasis on keeping storage temperatures as cold as necessary (target temperature not exceeding 40°F).
- Focus consumer messages on short storage times in combination with storage temperatures.
- Collaborate with manufacturers of refrigeration equipment to maximize design enhancements that facilitate consumer efforts to keep foods appropriately cold.

- Tailor information to target populations (for example, specific recommendations tailored for higher-risk groups such as pregnant women and immune-compromised individuals);
- Continue to inform, educate, and develop medical guidance for health care professionals about the diagnosis, treatment, and prevention of *L. monocytogenes* caused illness.
- Achieve maximum outreach to women and women's health care professionals by coordinating education efforts with the DHHS Office of Women's Health and other agencies within HHS.
- Target education campaigns to Hispanic women of child-bearing age about the importance of eating only fresh soft cheeses that are made with pasteurized milk.
- Collaborate with other public and private organizations (such as the Cooperative State Research, Education and Extension Service (CSREES), the Food and Nutrition Service (FNS), the Partnership for Food Safety Education, consumer groups, professional associations, providers, and health care organizations) to maximize the effectiveness of outreach efforts.

In conducting its educational activities, FDA and CDC will expand their use of new technologies such as satellite video conferencing and computer-based and interactive web training.

Objective 4:
Review, redirect, and revise enforcement and regulatory strategies including microbial product sampling.

Timeline: Present through 2005

Action:
Toward this objective, the following steps are planned:

- FDA will increase inspections of regulated food processing facilities that produce ready-to- eat foods identified in the risk assessment as warranting additional measures to reduce *L. monocytogenes* contamination or warranting collection of additional data. Also, FDA will modify these inspection programs to focus additional efforts on post-process contamination potential, sanitation practices, and environmental testing programs.
- FDA will focus *L. monocytogenes* inspectional resources away from those food categories that the Risk Assessment showed to be very low to low risk and increase *L. monocytogenes* inspection to those food categories that were deemed moderate to high risk.
- FDA will develop an action plan to address the unlawful importation of raw milk soft cheeses from other countries.
- FDA will work with the states to eliminate the unlawful production and sale of raw milk soft cheeses.
- FDA will undertake surveillance sampling and *L. monocytogenes* testing of ready-to-eat domestically produced products that are identified in the Risk Assessment as either warranting additional measures to reduce *L. monocytogenes* contamination or warranting collection of additional data. For imported foods, the agency will increase the frequency of ready-to-eat product sampling and *L. monocytogenes* testing of similar ready-to-eat foods. The agency will use inspection guides, the FDA web page, and/or FDA

memoranda to communicate product sampling criteria and analytical methodology to Federal and state regulators.

- Consistent with guidance announced in the Federal Register of Jan. 5, 1999 (64 FR 517-518), FDA will continue to expedite the review of food additive petitions for *L. monocytogenes* control interventions. FDA may consider revising the standards of identity for dairy products to allow for the use of bacteriocins to control *L. monocytogenes*.
- FDA will continue to seek advice from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) on the scientific basis for establishing safety-based "use by" shelf life date labeling for refrigerated, ready-to-eat foods. FDA will evaluate the need for a new regulation requiring processors and retailers to label packages of certain foods with a validated safety-based "use by" date. In addition, FDA will evaluate the need for a regulation requiring safety-based "keep refrigerated" labeling for certain refrigerated, ready-to-eat foods that are identified in the Risk Assessment as warranting additional measures for reducing *L. monocytogenes* contamination and for foods that support the growth of *L. monocytogenes*.
- FDA will continue to seek advice from NACMCF on the scientific basis for the redefining of the term "pasteurized" as dictated by the Farm Bill (Public Law 107-171).
- FDA will review its current Good Manufacturing Practice (21 CFR Part 110) regulations and will evaluate whether to revise these regulations based on the findings in the Risk Assessment.
- FDA will review the adequacy of *L. monocytogenes* controls in existing regulations and standards of identity for those products identified in the Risk Assessment as either warranting additional measures for reducing *L. monocytogenes* contamination or warranting collection of additional data.
- FDA will develop a model statute that will prohibit the sale of raw milk for dissemination to those states which still permit the sale of raw milk.
- Utilizing *L. monocytogenes* data gathered through FDA's regulatory product surveillance testing, in combination with data generated from exposure assessment studies, FDA will revise its regulations and enforcement policies as necessary to maximize public health protection.

Objective 5:
Enhance Disease Surveillance and Outbreak Response

Timeline: Present through 2005

Action:
The following steps will enhance the effectiveness of *L. monocytogenes* surveillance and outbreak response:

- To detect illness outbreaks more quickly and accurately, continue to increase and enhance the number of laboratories capable of *L. monocytogenes* analysis through CDC's "PulseNet" laboratory network. CDC also is developing a centralized, computerized library of *L. monocytogenes* DNA "fingerprints" for cross-matching bacterial samples, and will examine additional methods for rapid subtyping of pathogenic *L. monocytogenes*

strains. FDA will continue to improve the ability and speed with which positive *L. monocytogenes* isolates taken from ready-to-eat food products and environmental samples are submitted to PulseNet for cross matching with human isolates. These enhancements will enable the Federal regulatory agencies and state and local public health officials to investigate illness outbreaks more quickly and trace implicated foods to their sources to limit more effectively the spread of illness.

- CDC will continue working with state and local health departments and health professionals to improve the detection and reporting of *L. monocytogenes* illnesses in order to learn more about the frequency and severity of *L. monocytogenes* illness. CDC, in collaboration with the Council for State and Territorial Epidemiologists, will complete development of a national listeriosis case surveillance form that collects high risk food consumption histories on all cases on an ongoing basis; data will be available for immediate analysis upon outbreak detection to identify contaminated foods.
- CDC will continue enhanced monitoring of *L. monocytogenes* illnesses to identify and evaluate trends in disease occurrence and help measure the impact of the agencies' prevention activities.
- CDC will complete a comprehensive case-control study to gather additional information about *L. monocytogenes* illnesses, risk factors for acquiring infection, and opportunities for prevention. In this study, CDC is collaborating with FDA, FSIS, and many state health departments, particularly through the joint Foodborne Diseases Active Surveillance Network (FoodNet) project. These efforts are intended to provide better information about special risks to vulnerable populations (such as pregnant women, newborns, and the elderly) and help to identify additional high-risk foods.
- CDC will work with FDA to develop improved methods for the use of surveillance data in assessing the public health impact of regulatory and outreach programs by Federal agencies.
- CDC and FoodNet will continue work on two related projects to attribute the percentage of foodborne illness cases from various agents including *L. monocytogenes* to various vehicles based on epidemiologic data. These findings will further focus FDA efforts to prevent the spread of *L. monocytogenes* by the vehicles that are identified.
- CDC will continue to develop methods to identify and improve food purchasing, handling, and consumption behaviors at nursing homes and institutions with residents at high risk for listeriosis and among pregnant Hispanic women in the United States.

Objective 6:
Coordinate research activities to refine the Risk Assessment, enhance preventive controls, and support regulatory, enforcement, and educational activities.

Timeline: Present through 2005

Action:
Coordinating such research efforts will entail the following steps:

- FDA will continue to coordinate, conduct and support research to evaluate the effectiveness of existing commercial treatments (e.g., post-packaging pasteurization, bacteriocins, irradiation, high pressure processing, and inhibitory compounds) and

develop new technologies that can eliminate or prevent the growth of *L. monocytogenes* in ready-to-eat foods.

- FDA will initiate research to determine the growth rate of *L. monocytogenes* in specific foods to provide information and guidance on (a) the establishment of scientifically based safety-related date marking and (b) practical means for consumers to more effectively control *L. monocytogenes* in ready-to-eat foods after purchase.
- FDA will continue to conduct, coordinate, and support research on methods for the detection of *L. monocytogenes* in various ready-to-eat foods, with a particular emphasis on the quantitative evaluation of food samples.
- FDA will support research that provides rapid and accurate means for assessing the virulence of foodborne *L. monocytogenes* isolates that can be used to better estimate the potential of individual strains to cause disease, and thus lead to better estimates of the microorganism's dose-response relations.
- FDA and CDC will seek means for readily and objectively assessing the immune status of susceptible populations with the goal of better identifying the subpopulations of consumers that are more susceptible to *L. monocytogenes*.
- FDA will continue to seek data on the frequency and concentration of *L. monocytogenes* in a variety of ready-to-eat foods as a means of enhancing the existing exposure assessment databases and determining the impact that various control programs are having on attributable risk.
- FDA will perform additional *L. monocytogenes* product pathway simulation studies that can be appended to the existing risk assessment in order to provide guidance on how specific control strategies are likely to reduce the risk of foodborne listeriosis.
- CDC and FDA will conduct research on the development of methods for conducting enhanced case control studies, outbreak investigations, and related epidemiological tools for better identifying the foods, conditions, and practices that are associated with foodborne listeriosis.

VI. Conclusion

By undertaking the actions contained in this action plan, FDA and CDC, working with USDA, intend to meet the Healthy People 2010 goal to reduce *L. monocytogenes* caused illness by 50 percent by the year 2005.