



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA-2008-D-0096 (formerly Docket No. 2007D-0494)]

Control of Listeria monocytogenes in Ready-To-Eat Foods: Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a revised draft guidance for industry entitled “Control of Listeria monocytogenes in Ready-To-Eat Foods.” The revised draft guidance is intended for any person who is subject to our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” and who manufactures, processes, packs, or holds ready-to-eat (RTE) foods. The revised draft guidance is intended to help such persons comply with the requirements of that regulation with respect to measures that can significantly minimize or prevent the contamination of RTE food with L. monocytogenes whenever a RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to L. monocytogenes) that would significantly minimize L. monocytogenes.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft guidance before we issue the final version of

the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 180 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2008-D-0096 for “Control of Listeria monocytogenes in Ready-To-Eat Foods.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the revised draft guidance to the Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-300), 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the revised draft guidance.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2166.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a revised draft guidance for industry entitled "Control of Listeria monocytogenes in Ready-To-Eat Foods." We are issuing the revised draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does

not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

In the Federal Register of February 7, 2008 (73 FR 7293), we made available a draft guidance for industry entitled “Control of Listeria monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods” (the 2008 draft Listeria guidance). The recommendations in the 2008 draft Listeria guidance were intended to complement the requirements in a regulation entitled “Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food,” which had been established in part 110 (21 CFR part 110). The recommendations in the 2008 draft Listeria guidance also were intended to assist processors of refrigerated and frozen RTE foods in meeting the requirements in part 110 with respect to the control of L. monocytogenes. We gave interested parties an opportunity to submit comments by April 7, 2008, for us to consider before beginning work on the final version of the guidance. We received several comments on the 2008 draft Listeria guidance.

Since issuing the 2008 draft Listeria guidance, we conducted rulemaking to amend the current good manufacturing practice (CGMP) requirements in part 110 to modernize them and establish them in new part 117 (21 CFR part 117), subparts A, B, and F (80 FR 55908, September 17, 2015). Part 117 (entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food”) also includes new requirements (in subparts A, C, D, E, F, and G) for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) to establish and implement hazard analysis and risk-based preventive controls for human food (the human food preventive controls requirements). The new human food preventive controls requirements are part of our implementation of the FDA Food Safety

Modernization Act (FSMA; Pub. L. 111-353). We also discussed certain recommendations in the 2008 draft Listeria guidance with our Food Advisory Committee during a meeting held on December 7 and 8, 2015 (80 FR 69229, November 9, 2015 and Ref. 1).

We have revised the 2008 draft Listeria guidance to reflect the comments we received on that draft guidance, the amended CGMP requirements now established in part 117, the new human food preventive controls requirements established in part 117, and the recommendations of our Food Advisory Committee (Ref. 2). The revised draft guidance is intended to explain our current thinking on procedures and practices to help food establishments that are subject to part 117 to: (1) Comply with the CGMP requirements of part 117 (e.g., for personnel, buildings and facilities, equipment and utensils, and production and process controls) during the production of an RTE food that is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to L. monocytogenes) that would significantly minimize L. monocytogenes; and (2) comply with certain human food preventive controls requirements regarding environmental pathogens in such RTE foods.

Part 117 defines “environmental pathogen” to mean a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen (21 CFR 117.3). Within that definition, L. monocytogenes is listed as an example of an environmental pathogen. The hazard analysis required by part 117 must include an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the

pathogen) that would significantly minimize the pathogen (§ 117.130(c)(1)(ii)). If the hazard analysis identifies L. monocytogenes as a hazard requiring a preventive control, the facility must identify one or more preventive controls to provide assurances that L. monocytogenes will be significantly minimized or prevented in the facility's food products and the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act (§ 117.135(a)). In addition, the human food preventive controls requirements specify that, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system, the facility must conduct activities that include environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an RTE food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples (§ 117.165(a)(3)). The revised draft guidance includes recommendations for controls to significantly minimize or prevent L. monocytogenes in RTE foods, for sanitation controls to eliminate L. monocytogenes from the food production environment, and for environmental monitoring as verification of sanitation controls.

II. Paperwork Reduction Act of 1995

The revised draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in part 117 have been approved under OMB Control No. 0910-0751.

FDA tentatively concludes that the revised draft guidance also contains proposed information collection provisions that are subject to review by OMB under the PRA but are not

included in the information collection approved under OMB Control No. 0910-0751.

“Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we will publish a 60-day notice on the proposed collection of information in a future issue of the Federal Register.

III. Electronic Access

Persons with access to the Internet may obtain the revised draft guidance at either <http://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

IV. References

The following references are on display at the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. FDA. 2015. Food Advisory Committee Meeting, Charge and Questions. Topic: Addressing Listeria monocytogenes in Ready-To-Eat Foods, December 7-8, 2015. Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM472842.pdf>.

2. FDA. 2015. Food Advisory Committee (FAC) Recommendations. Topic: Addressing Listeria monocytogenes in Ready-To-Eat Foods, December 7-8, 2015. Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM476521.pdf>.

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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