

Authority: 15 U.S.C. 1124, 1125, 1127; 17 U.S.C. 101, 601, 602, 603; 19 U.S.C. 66, 1202, 1499, 1526, 1624; 31 U.S.C. 9701.

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Section 133.61 also issued under Sec. 308(d), Pub. L. 114–125; Sec. 507, Pub. L. 108–90; Sec. 2, Pub. L. 114–279.

Subpart G—[Reserved].

- 2. Add and reserve subpart G.
- 3. Add subpart H, consisting of § 133.61, to read as follows:

Subpart H—Donations of Intellectual Property Rights Technology and Support Services.

§ 133.61 Donations of intellectual property rights technology and support services.

(a) *Scope.* The Commissioner of U.S. Customs and Border Protection (CBP) is authorized to accept donations of hardware, software, equipment, and similar technologies, as well as donated support services and training, from private sector entities, for the purpose of assisting CBP in enforcing intellectual property rights. Such acceptance must be consistent with the conditions set forth in this section and section 308(d) of the Trade Facilitation and Trade Enforcement Act of 2015, as well as either section 482 of the Homeland Security Act of 2002 or section 507 of the DHS Appropriations Act of 2004.

(b) *Donation offer.* A donation offer must be submitted to CBP either via email, to IPRdonations@cbp.dhs.gov, or mailed to the attention of the Executive Assistant Commissioner, Office of Field Operations, or his/her designee. The donation offer must describe the proposed donation in sufficient detail to enable CBP to determine its compatibility with existing CBP technologies, networks, and facilities (e.g. operating system or similar requirements, power supply requirements, item size and weight, etc.). The donation offer must also include information pertaining to the donation's scope, purpose, expected benefits, intended use, costs, and attached conditions, as applicable, that is sufficient to enable CBP to evaluate the donation and make a determination as to whether to accept it. CBP will notify the donor, in writing, if additional information is requested or if CBP has determined that it will not accept the donation.

(c) *Agreement to accept donation.* If CBP accepts a donation of hardware, software, equipment, technologies, or to accept training and other support services, for the purpose of enforcing intellectual property rights, CBP will enter into a signed, written agreement with an authorized representative of the

donor. The agreement must contain all applicable terms and conditions of the donation. An agreement to accept training and other support services must provide that the services or training are offered without the expectation of payment, and that the service provider expressly waives any future claims against the government.

R. Gil Kerlikowske,
Commissioner.

Approved: January 09, 2017.

Timothy E. Skud,
Deputy Assistant Secretary of the Treasury.
[FR Doc. 2017–00653 Filed 1–13–17; 8:45 am]

BILLING CODE 9111–14–P

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 July 26, 2017.

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.

[FR Doc. 2017–00819 Filed 1–13–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 143

[EPA–HQ–OW–2015–0680; FRL–9958–23–OW]

RIN 2040–AF55

Use of Lead Free Pipes, Fittings, Fixtures, Solder and Flux for Drinking Water

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to make conforming changes to existing drinking water regulations based on the Reduction of Lead in Drinking Water Act of 2011 (RLDWA) and the Community Fire Safety Act of 2013 (CFSA). Section 1417 of the Safe Drinking Water Act (SDWA) prohibits the use and introduction into commerce of certain plumbing products that are not lead free. The RLDWA revised the definition of lead free to lower the allowable maximum lead content from 8.0 percent to a weighted average of 0.25

percent of the wetted surfaces of plumbing products and established a statutory method for calculating lead content. In addition, the RLDWA created exemptions from the lead free requirements for plumbing products that are used exclusively for nonpotable services as well as for other specified products. The CFSA further amended section 1417 to exempt fire hydrants from these requirements.

EPA proposes to establish new requirements to assure that individuals purchasing, installing or inspecting potable water systems can identify lead free plumbing materials. Specifically, EPA proposes to establish labeling requirements to differentiate plumbing products that meet the lead free requirements from those that are exempt from the lead free requirements and to require manufacturers to certify compliance with the lead free requirements. These proposed requirements would reduce inadvertent use of non-lead free plumbing products in potable use applications and, consequently, reduce exposure to lead in drinking water and associated adverse health effects.

DATES: Comments must be received on or before April 17, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2015–0680, to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system).

For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Russ Perkinson, telephone number: 202–564–4901; email address: perkinson.russ@epa.gov, Office of Ground Water and Drinking Water, Standards and Risk