



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA-2016-D-2343]

Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of another draft chapter of a multichapter guidance for industry entitled “Hazard Analysis and Risk-Based Preventive Controls for Human Food.” This multichapter draft guidance is intended to explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under our rule entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.” The newly available draft chapter is entitled “Chapter 14--Recall Plan.”

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2016-D-2343 for "Hazard Analysis and Risk-Based Preventive Controls for Human Food." 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 Dockets Management Staff 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 Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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

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

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production.

Section 103 of FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), by adding section 418 (21 U.S.C. 350g) with requirements for hazard analysis and risk-based preventive controls for establishments that are required to register as food facilities under our regulations in 21 CFR part 1, subpart H, in accordance with section 415 of the FD&C Act (21

U.S.C. 350d). We have established regulations to implement these requirements within part 117 (21 CFR part 117).

In the *Federal Register* of August 24, 2016 (81 FR 57816), we announced the availability of several chapters (Chapters 1-5) of a multichapter draft guidance for industry entitled “Hazard Analysis and Risk-Based Preventive Controls for Human Food.” In the *Federal Register* of August 31, 2017 (82 FR 41364), and January 25, 2018 (83 FR 3449), we announced the availability of additional chapters (Chapter 6 and Chapter 15, respectively). We now are announcing the availability of an additional draft chapter of this multichapter guidance for industry.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

The multichapter draft guidance for industry is intended to explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under part 117, principally in subparts C and G. The chapter that we are announcing in this document is entitled “Chapter 14--Recall Plan.” We intend to announce the availability for public comment of additional chapters of the draft guidance as we complete them.

III. Paperwork Reduction Act of 1995

This 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 (44 U.S.C. 3501-3520). The collections of information in part 117 have been approved under OMB control number 0910-0751.

IV. Electronic Access

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

Dated: September 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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