



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 106 and 117

[Docket No. FDA-2024-D-2604]

### Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, Department of Health and Human Services (HHS).

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled “Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event.” The draft guidance, when finalized, will explain FDA’s current thinking on establishing a routine sanitation program for low-moisture ready-to-eat human foods (LMRTE foods) that can help prevent contamination of food or a food-contact surface with a pathogen and will explain our current thinking for corrective actions, including corrective actions to remediate contamination of food-contact surfaces, if prevention fails.

**DATES:** Submit either electronic or written comments on the draft guidance by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.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-2024-D-2604 for "Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event." 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, 240-402-7500.

- 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.” We will review this copy, including the claimed confidential information, in our 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.govinfo.gov/content/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, 240-402-7500.

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 draft guidance to the Office of Microbiological Food Safety, Human Foods Program, Food and Drug Administration, 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 draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Benjamin Warren, Office of Microbiological Food Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-645-7004, Benjamin.Warren@fda.hhs.gov; or Linda S. Kahl, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2784, Linda.Kahl@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**

I. Background

We are announcing the availability of a draft guidance for industry entitled “Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event.” We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The 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.

We are issuing this draft guidance to help manufacturers/processors of LMRTE foods comply with 21 CFR part 117 and, for powdered infant formula, 21 CFR part 106. Examples of LMRTE foods are powdered infant formula, peanut butter, nut butters, powdered drink mixes, chocolate, medical foods in powdered and paste forms, processed tree nuts, milk powders, powdered spices, snack foods such as chips and crackers, granola bars, and dry cereal. When finalized, the recommendations in this guidance can help manufacturers/processors of LMRTE foods consider and take actions to help ensure a safe and sanitary food supply through current good manufacturing practices and to establish and implement hazard analysis and risk-based preventive controls for these foods. The draft guidance, when finalized, will explain our current

thinking on establishing a routine sanitation program for LMRTE foods that can help prevent contamination of food or a food-contact surface with a pathogen and will explain our current thinking on recommendations for corrective actions, including corrective actions to remediate contamination of food-contact surfaces, if prevention fails.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in 21 CFR part 106 have been approved under OMB control number 0910-0256. The collections of information in 21 CFR part 117 have been approved under OMB control number 0910-0751.

## III. Electronic Access

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

Dated: December 27, 2024.

**Kimberlee Trzeciak,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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