



Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2025-D-6952]

Requirements for Additional Traceability Records for Certain Foods: Enforcement Policy for Certain Retail Food Establishments and Restaurants; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing the availability of a draft guidance for industry titled “Requirements for Additional Traceability Records for Certain Foods: Enforcement Policy for Certain Retail Food Establishments and Restaurants.” The draft guidance states that, at this time and based on our current understanding of the risks, FDA does not intend to enforce certain regulatory requirements as they apply to certain entities and/or activities. The applicable requirements are established in our regulation titled “Requirements for Additional Traceability Records for Certain Foods.”

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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 FDA 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-2025-D-6952 for "Requirements for Additional Traceability Records for Certain Foods: Enforcement Policy for Certain Retail Food Establishments and Restaurants: Draft Guidance for Industry." 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.” 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, 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 guidance to the Office of Strategy and Risk Prioritization, 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 requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Vierk, Office of Strategy and Risk

Prioritization, Human Foods Program Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2122, Katherine.Vierk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry titled “Requirements for Additional Traceability Records for Certain Foods: Enforcement Policy for Certain Retail Food Establishments and Restaurants: Guidance for Industry.” We are issuing this 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 implementing the final rule titled “Requirements for Additional Traceability Records for Certain Foods” (see 21 CFR Part 1, Subpart S). 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 November 21, 2022, we published a final rule titled “Requirements for Additional Traceability Records for Certain Foods” (87 FR 70910) (Food Traceability Rule) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). The purpose of this draft guidance for industry is to state that FDA, at this time and based on our current understanding of the risk, does not intend to enforce certain regulatory requirements as they apply to certain entities subject to the Food Traceability Rule.

The Food Traceability Rule has a full exemption for small retail food establishments (RFEs) and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than \$250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment (21 CFR 1.1305(i)) (“small retail and restaurant exemption”). Since the issuance of the final rule, regulated entities from the RFE and restaurant industries have brought to light challenges associated with complying with the rule for small businesses that are not small enough to be eligible for the small retail and

restaurant exemption. Therefore, FDA intends to exercise enforcement discretion for all requirements in the Food Traceability Rule for RFEs and restaurants that have an average annual monetary value of food sold or provided during the previous 3-year period of greater than \$250,000 but no more than \$1,000,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

The draft guidance represents the current thinking of FDA on implementing the Food Traceability Rule. It does not establish any rights for any person and is not binding on FDA or the public.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this draft 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 part 21 have been approved under OMB control number 0910-0560.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

