DEPARTM

Food and Drug Administration

[Docket No. FDA-2025-D-2837]

Questions and Answers About Requirements for Additional Traceability Records for Certain Foods; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing the availability of a draft guidance for industry entitled "Questions and Answers About Requirements for Additional Traceability Records for Certain Foods." The draft guidance answers questions about the final rule entitled "Requirements for Additional Traceability Records for Certain Foods," which established additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List. The draft guidance is intended to answer questions to facilitate industry's understanding of the final rule.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2025-D-2837 for "Questions and Answers About Requirements for Additional Traceability Records for Certain Foods: 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 draft guidance to the Office of Surveillance 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Vierk, Office of Surveillance

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 entitled "Questions and Answers About Requirements for Additional Traceability Records for Certain Foods: Guidance for Industry." The FDA final rule entitled "Requirements for Additional Traceability Records for Certain Foods" (Food Traceability Rule) (87 FR 70910, November 21, 2022) was issued under section 204(d)(1) of the FDA Food Safety Modernization Act (FSMA), which directed FDA to establish recordkeeping requirements, in addition to the requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350c) and FDA regulations in 21 CFR part 1, subpart J, for persons who manufacture, process, pack, or hold foods that FDA designates under section 204(d)(2) of FSMA as high-risk foods. FDA identifies such designated foods on the Food Traceability List (FTL). The new requirements established by the final rule will allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and deaths.

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 Food Traceability Rule. 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.

At the core of the Food Traceability Rule is a requirement that persons subject to the rule who manufacture, process, pack, or hold foods on the FTL maintain records containing key data elements associated with specific critical tracking events. The rule also requires covered entities to maintain a traceability plan, which describes a firm's traceability procedures and how they

identify the FTL foods that they handle. The final rule covers domestic firms as well as foreign firms producing food for U.S. consumption, along the entire food supply chain.

This draft guidance includes questions and answers to assist industry in understanding the scope of the Food Traceability Rule and meeting applicable requirements. Topics covered in this draft guidance include additional information on requirements for farms, food obtained from fishing vessels, raw molluscan shellfish, retail food establishments and restaurants, commingling, initial packing of a food, transformation of a food, the traceability plan, recordkeeping, and the FTL.

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 21 CFR Part 1, Subpart S, have been approved under OMB control number 0910-0560.

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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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