4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0053]

Challenges and Solutions in Lot-Level Food Traceability; Public Meeting and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting titled "Challenges and Solutions in Lot-Level Food Traceability." The purpose of the meeting is to provide a forum for the public to share information on continued implementation of the Food Traceability Rule and areas of concern, especially as they relate to lot-level tracking, and identify potential flexibilities to support compliance. In addition, FDA has developed a discussion paper titled "Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement" that includes potential flexibilities for lot-level food traceability and questions we have regarding those flexibilities. This discussion paper may be helpful to speakers as they develop remarks for the public meeting. We are also providing an opportunity for all stakeholders to submit feedback on the discussion paper.

DATES: The public meeting will be held on June 15, 2026, from 12:00 - 3:30 p.m. Eastern Time. Either electronic or written comments on this public meeting or discussion paper must be submitted by July 15, 2026. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held virtually, and login instructions will be provided at registration.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept

comments until 11:59 p.m. Eastern Time at the end of July 15, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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-2014-N-0053 for "Challenges and Solutions in Lot-Level Food Traceability: Public Meeting." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," will be 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.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.

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; or Alissa Van Wie, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-654-7524, Alissa.Vanwie@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA final rule, "Requirements for Additional Traceability Records for Certain Foods" (87 FR 70910, November 21, 2022) (Food Traceability Rule), establishes enhanced recordkeeping requirements for those who manufacture, process, pack, or hold foods on FDA's Food Traceability List. The Food Traceability Rule requires lot-level tracking for foods on the Food Traceability List. Businesses that perform specific activities are required to assign unique codes, known as Traceability Lot Codes, that must be passed along unchanged (unless the food is transformed) as the food moves through the supply chain. Entities that handle foods on the Food Traceability List are required to record Key Data Elements (KDEs), such as the Traceability Lot Code, when they perform specific Critical Tracking Events (CTEs) like initial packing, transformation, and shipping. Lot-level tracking enables rapid tracing of contaminated foods during recall events, allowing FDA to find the source of the food faster, narrowing the scope of recalls, and removing affected product from the supply chain quickly, resulting in fewer foodborne illnesses and deaths.

The original compliance date for all persons subject to the recordkeeping requirements of the Food Traceability Rule was January 20, 2026. FDA proposed to extend the compliance date for the rule by 30 months to July 20, 2028 (90 FR 38084, August 7, 2025). Subsequently,

the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act of 2026 (Pub. L. 119-37) (Continuing Appropriations Act) directed FDA not to enforce the Food Traceability Rule prior to that same date of July 20, 2028. FDA intends to comply with this Congressional directive.

Section 780 of the Continuing Appropriations Act also directed FDA to engage quarterly with regulated entities to identify and implement, as appropriate, additional flexibilities for satisfying the Food Traceability Rule's lot-level tracking requirement. This public meeting is part of a series of engagements being held to fulfill that directive. Congress further stated that within 180 days of the Continuing Appropriations Act's enactment, FDA should provide industry stakeholders with recommendations for these additional flexibilities. At present, with most of the quarterly engagements still ahead of us, we have not made a decision about the scope of flexibilities that would best address the challenges being faced by regulated entities while still protecting public health and maintaining the benefits of the Food Traceability Rule. However, we recognize Congress's desire for FDA to be transparent with stakeholders about this process, and specifically about where things stand approximately 180 days after enactment of the Continuing Appropriations Act. One goal of the discussion paper, "Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement," is to provide that transparency.

II. Topics for Discussion at the Public Meeting

The goal of this public meeting is for FDA to hear stakeholder feedback on lot-level food traceability efforts and implementation challenges facing industry. FDA is interested in hearing about the challenges and potential solutions for satisfying the Food Traceability Rule's lot-level tracking requirements.

We are also making available a discussion paper, "Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement," that includes potential flexibilities and questions we have around those flexibilities (Ref. 1). We intend for

this discussion paper to further dialogue with regulated entities and other stakeholders, including at this public meeting, and help advance progress toward successful implementation of the Food Traceability Rule. We encourage those participating in this public meeting to consider the questions in this discussion paper as you develop your remarks for this meeting.

We want to provide all stakeholders with an opportunity to actively engage with FDA on this topic. We therefore invite and encourage all interested parties to submit feedback on the discussion paper to https://www.regulations.gov, Docket No. FDA-2014-N-0053. Comments do not need to cover every question that is asked in the document; you are encouraged to focus on whichever aspects of the discussion paper are of the most interest to you. To ensure that we can fully consider your feedback as we work to expeditiously identify flexibilities to implement, please submit your comments no later than July 15, 2026.

Please note that the discussion paper does not reflect an exhaustive list of options that FDA plans to consider. New ideas may emerge as a result of this public meeting and our other upcoming engagements with stakeholders. The document is meant to capture the areas where we currently have the most questions, or where we think further dialogue would be especially helpful. Please also note that the order in which the topics are listed is not meant to represent a prioritization or a preference for any topic.

III. Participating in the Public Meeting

Registration: Please visit the following website for additional information and to register for the public meeting: https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/fda-public-meeting-challenges-and-solutions-lot-level-food-traceability-06152026?utm_medium=email&utm_source=govdelivery.

The virtual public meeting is free and open to the public, but registration is necessary to attend. General registration will remain open until June 14, 2026. Individuals who want to speak during the public comment period must register by June 5, 2026. Same-day registration is not allowed. Individuals that have already registered through the Partnership for Food Traceability

website do not need to register again. Instructions for joining the virtual meeting will be provided upon registration.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session. We will do our best to accommodate all requests to make public comments. Following the close of registration, we will determine the amount of time allotted to each presenter and will notify participants in advance. All requests to make oral presentations must be received by the close of registration on June 5, 2026. All presentations must be given orally; slides or visuals will not be able to be accommodated on the virtual platform. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

IV. References

1. Food and Drug Administration, "Discussion Paper: Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement". 2026.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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