



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

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

Requirements for Additional Traceability Records for Certain Foods; Proposed Rule; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing three virtual public meetings entitled “Requirements for Additional Traceability Records for Certain Foods; Proposed Rule.” The purpose of the public meetings is to discuss the proposed rule entitled “Requirements for Additional Traceability Records for Certain Foods,” which was issued under the FDA Food Safety Modernization Act (FSMA). These public meetings are intended to facilitate and support the public’s evaluation and commenting process on the proposed rule.

DATES: The public meetings will be held on November 6, 2020, from 8:30 a.m. Eastern Time to 3:30 p.m. Eastern Time; November 18, 2020 from 9:30 a.m. Eastern Time to 4:30 p.m.

Eastern Time; and December 2, 2020 from 11:30 a.m. Eastern Time to 6:30 p.m. Eastern Time.

Submit either electronic or written comments on the notice by January 21, 2021. See “How to Participate in the Public Meetings” in the SUPPLEMENTARY INFORMATION section of this document for closing dates for advanced registration and other information regarding meeting participation.

ADDRESSES: Due to the impact of the COVID-19 pandemic, these meetings will be held virtually to help protect the public and limit the spread of the virus.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 21, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 21, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 “Requirements for Additional Traceability Records for Certain Foods.” Received comments, those filed in a timely manner (see ADDRESSES), 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.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: *For general questions about the public meetings or for special accommodations due to a disability:* Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1731, Juanita.Yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Pub. L. 111-353), enacted in 2011, modernized U.S. food safety law to better ensure the safety and security of the nation’s food supply. Section 204(d) of FSMA requires that FDA establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that the Agency designates as high risk, to facilitate the rapid and effective traceability of such foods. These recordkeeping requirements will be in addition to the food traceability

requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350c) (added to the FD&C Act in title III, subtitle A, section 306, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188)) and the implementing regulations in subpart J of part 1 of title 21 of the Code of Federal Regulations (21 CFR 1.326 to 1.368) (the subpart J regulations). Congress directed FDA to adopt the subpart J regulations recordkeeping requirements to allow the Agency to identify the immediate previous sources and immediate subsequent recipients of foods (commonly referred to as “one-up, one-back” recordkeeping) to address credible threats of serious adverse health consequences or death to humans or animals. In section 204(d)(1) of FSMA, Congress directed FDA to adopt additional recordkeeping requirements to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death to humans or animals resulting from foods being adulterated under section 402 of the FD&C Act (21 U.S.C. 342) or misbranded with respect to allergen labeling under section 403(w) of the FD&C Act (21 U.S.C. 343(w)).

In the *Federal Register* of September 23, 2020 (85 FR 59984), FDA published the proposed rule entitled “Requirements for Additional Traceability Records for Certain Foods” . The proposed additional recordkeeping requirements, when finalized, will fulfill Congress’s directive in section 204(d)(1) of FSMA and will help FDA follow the movement of listed food products and ingredients both backward and forward throughout the supply chain.

Section 204(d)(4) of FSMA states that, during the comment period for the proposed rule, FDA “shall conduct not less than 3 public meetings in diverse geographical areas of the United States to provide persons in different regions an opportunity to comment.” Due to the impact of

the COVID-19 pandemic, these meetings will be held virtually to help protect the public and limit the spread of the virus.

FDA is therefore announcing a series of virtual public meetings entitled “Requirements for Additional Traceability Records for Certain Foods; Proposed Rule” so that stakeholders can better evaluate and comment on the proposed rule. These meetings will be held during the formal comment period on the proposed rule. All three public meetings will cover the same agenda items and are intended to facilitate and support the public’s evaluation and commenting process.

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meetings, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket) for the proposed rule (Docket No. FDA-2014-N-0053). (See ADDRESSES).

II. Purpose and Format of the Public Meetings

The purpose of the public meetings is to provide information and facilitate comment so that stakeholders can better evaluate and provide input on the proposed rule. We invite interested parties to provide information and offer comments related to the proposed rule. During the public meetings we will present information on the various sections of the proposed rule: General Provisions; Traceability Program Records; Records of Growing, Receiving, Transforming, Creating, and Shipping Food; Special Requirements for Certain Persons and Foods; Procedures for Modified Requirements and Exemptions; Waivers; Records Maintenance and Availability; and Updating the Food Traceability List. Stakeholder panels will provide discussion on the various issues. There will be an opportunity for questions, as well as an opportunity for open public comment.

III. How to Participate in the Public Meetings

There will be a total of three virtual public meetings with different time frames, which will provide persons in different regions an opportunity to comment on the proposed rule.

Table 1 provides information on participation in the public meetings.

Table 1.--Information on Participating in the Public Meetings and on Submitting Comments to the Proposed Rule on Requirements for Additional Traceability Records for Certain Foods Docket

Activity	Date	Electronic address	Other information
First public meeting	November 6, 2020; 8:30 a.m.-3:30 p.m. EST	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by October 28, 2020	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation	by October 9, 2020	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements	---
Notice confirming opportunity to make oral presentation	by October 16, 2020	---	An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments	Submit comments by January 21, 2021	https://www.regulations.gov	See ADDRESSES for additional information on submitting comments.
Second public meeting	November 18, 2020; 9:30 a.m.-4:30 p.m. EST	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by November 6, 2020	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation	by October 16, 2020	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements	---
Notice confirming opportunity to make oral presentation	by October 23, 2020	---	An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments	Submit comments by January 21, 2021	https://www.regulations.gov	See ADDRESSES for additional information on submitting comments.

Third public meeting	December 2, 2020; 11:30 a.m.-6:30 p.m. EST	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by November 18, 2020	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation	by October 26, 2020	https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements	---
Notice confirming opportunity to make oral presentation	by November 9, 2020	---	An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments	Submit comments by January 21, 2021	https://www.regulations.gov	See ADDRESSES for additional information on submitting comments.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at:

<https://www.regulations.gov>. You may also view the transcript at the Dockets Management Staff (see ADDRESSES).

Dated: September 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy

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