

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

Draft Guidance

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**U.S. Department of Health and Human Services
Food and Drug Administration
Human Foods Program**

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Requirements for Additional Traceability Records for Certain Foods: Enforcement Policy for Certain Retail Food Establishments and Restaurants: Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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 alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this document is to state that the Food and Drug Administration (FDA, we, or the Agency), at this time and based on our current understanding of the risks, 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 entitled “Requirements for Additional Traceability Records for Certain Foods” (21 CFR Part 1, Subpart S).

FDA’s guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

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 or FTR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L.

¹ This draft guidance has been prepared by the U.S. Food and Drug Administration, Human Food Program’s Office of Surveillance Strategy and Risk Prioritization, Office of Coordinated Outbreak Response, Evaluation, and Emergency Preparedness, and Office of Policy and International Engagement.

111-353).² The purpose of this document is to state that FDA, at this time, does not intend to enforce certain regulatory requirements for certain entities subject to the FTR.³

The FTR establishes additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL). Persons subject to the rule must maintain records containing key data elements associated with specific critical tracking events for FTL foods. Covered entities must maintain records required by the rule for 2 years, provide records requested by FDA within 24 hours of a request (or within a reasonable time to which FDA has agreed), and provide required records in an electronic sortable spreadsheet when necessary to help FDA prevent or mitigate a foodborne illness outbreak, assist in the implementation of a recall, or otherwise address a threat to the public health. They also must establish and maintain a traceability plan that, among other things, describes their procedures for maintenance of records under these requirements, identification of FTL foods handled, and assignment of traceability lot codes to FTL foods, as applicable. The goal of the FTR is to facilitate more efficient and effective tracing to prevent or mitigate foodborne illness outbreaks while providing firms considerable flexibility in how they structure their traceability operations.

The FTR provides exemptions and partial exemptions to certain persons. Among other exemptions, 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, are fully exempt from the requirements of the FTR (21 CFR 1.1305(i)) (“small retail and restaurant exemption”). Additionally, RFEs and restaurants that are otherwise subject to the rule but 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, are exempt from the electronic sortable spreadsheet requirement and can provide required information to FDA in an alternate format (21 CFR 1.1455(c)(3)(iii)(B)).

² The Food Traceability Rule was promulgated under FSMA section 204(d)(1), which directed FDA to establish recordkeeping requirements, in addition to the requirements under section 414 of the Federal Food, Drug, and Cosmetic Act (FD&C 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 has designated such foods on the Food Traceability List.

³ The original compliance date for the FTR was January 20, 2026. On August 7, 2025, FDA proposed to extend the compliance date to July 20, 2028, for all persons subject to the rule (90 FR 38084). Subsequently, the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act of 2026 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. We anticipate that the enforcement discretion policy described in this draft guidance will be in effect when the compliance date is reached, and will continue thereafter as we consider possible solutions to address the concerns described in this document.

III. Discussion

Since the issuance of the final rule, FDA has conducted extensive stakeholder outreach and education on the rule, in addition to providing technical assistance, tools, and other resources to assist industry with implementation.⁴ Through this stakeholder engagement on implementation, regulated entities from the RFE and restaurant industries have brought to light challenges associated with complying with the rule for certain small RFEs and restaurants that are not small enough to be eligible for the small retail and restaurant exemption. We understand that many of these entities, despite exceeding the \$250,000 threshold for exemption, are nonetheless small enough that they struggle to stay in business and can only employ a very small staff. Such entities often lack the resources to engage in the types of training protocols, technological investments, or staffing improvements that would assist them in being able to comply with the rule. Although the exemption from the requirement to provide required information in an electronic sortable spreadsheet provides some relief to many of these entities, the Agency recognizes the challenges that small RFEs and restaurants face in trying to meet all applicable requirements of the FTR. Therefore, FDA intends to exercise enforcement discretion for all requirements in the FTR 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. RFEs and restaurants with annual sales under \$1,000,000 represent about 6% of all RFE and restaurant sales on an annual basis, and 50% of all RFE and restaurant establishments (see 87 FR 70910 at 70973). These numbers are comparable to the percentage of produce farms (62%) and percentage of produce (9%) that are exempted from the FTR under 21 CFR 1.1305(a)(1).

We anticipate continuing the enforcement discretion policy while advancing Agency efforts to better understand the challenges faced by these entities and to consider possible solutions to address these concerns while minimizing the impact on effective and efficient traceback.

⁴ For example see the Stakeholder Calls, Webinars, and Meetings section at: [FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods | FDA](#)