Issued on July 29, 2025.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2025–15039 Filed 8–6–25; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2014–N–0053]

RIN 0910–ZC21

Requirements for Additional Traceability Records for Certain Foods: Compliance Date Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration is proposing to extend the compliance date for the final rule, ''Requirements for Additional Traceability Records for Certain Foods,'' due to concerns about the amount of time affected entities will need to implement the requirements of the rule. If finalized, this rule would extend the compliance date by 30 months from January 20, 2026, to July 20, 2028.

DATES: Either electronic or written comments on the proposed rule must be submitted by September 8, 2025.

ADDRESSES: You may submit comments on the extension of the compliance date 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 September 8, 2025. 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 ''Requirements for Additional Traceability Records for Certain Foods: Compliance Date Extension.'' 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, the plain language summary of the proposed rule of not more than 100 words as required by the ''Providing Accountability Through Transparency Act,'' 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:

Table of Contents

I. Background
  A. The Food Traceability Rule
  B. Proposed Compliance Date
II. Legal Authority
III. Description of Proposed Rule
IV. Preliminary Economic Analysis of Impacts
V. Analysis of Environmental Impact
VI. Paperwork Reduction Act of 1995
VII. Federalism
VIII. Consultation and Coordination With Indian Tribal Governments
IX. References

I. Background

A. The Food Traceability Rule

The Food and Drug Administration (FDA, the Agency, or we) published the final rule, ''Requirements for Additional Traceability Records for Certain Foods'' (87 FR 70910) (Food Traceability Rule), on November 21, 2022. The final rule 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) based on risk. The final rule requires these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods (FTL foods), such as initial packing, shipping, receiving, and transforming these foods. The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death. The requirements will reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving the ability to quickly and efficiently trace the movement through the supply chain of FTL foods identified as causing illness, identify and remove contaminated foods from the marketplace, and develop mitigation strategies to prevent future contamination. The final rule had an effective date of January 20, 2023 (60 days after publication of the final rule), and a compliance date of January 20, 2026 (3 years after the effective date).

The Food Traceability Rule establishes first of its kind national standards for supply chain traceability from farm to restaurant/retail, for certain foods based on risk. The rule requires covered entities to maintain and share specific data elements for FTL foods throughout supply chains (and with FDA upon request). Entities along a supply chain must therefore coordinate to share relevant data elements with subsequent entities in the chain, in a compatible and timely manner.

Since issuing the Food Traceability Rule in 2022, 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. As the regulated industry has worked to comply with the rule's requirements, entities from across the supply chain have voiced strong concerns with the initial 3-year implementation timeframe, stating that they need more time to come into compliance. Specifically, FDA has heard concerns from industry that some of the required data elements are not routinely maintained or shared throughout supply chains, nor are many data systems currently interoperable throughout supply chains. Industry has also expressed concerns about the volume of data certain entities in the supply chain (particularly distributors and retailers) would be required to manage and challenges with implementing the requirements, including implementing technology to manage and share the data required. Technology solutions to assist industry in managing the data are still being developed, piloted, and evaluated for interoperability. In addition to the technology challenges, distributors are struggling to obtain lot codes from their suppliers and experiencing challenges transmitting them to retailers in a cost-effective manner.

At FDA's request, the Reagan-Udall Foundation for the Food and Drug Administration (the Foundation) held a series of roundtables over the summer of 2024 to hear from industry about challenges with implementation and to help facilitate cross-sector dialogue on potential solutions. The Foundation issued a summary of feedback received via the roundtables (Ref. 1). On October 7, 2024, the Foundation held a public meeting to allow all interested parties to comment on the feedback gleaned via the roundtables (Ref. 2). The Foundation also accepted public feedback in writing (Ref. 3).

The feedback received during the roundtables, the public meeting, and the comments submitted to the Foundation was consistent with what FDA has been hearing in our other interactions with stakeholders. While members of industry have expressed a range of views on the challenges of implementation, very few of them have indicated that they expect to be able to comply with the Food Traceability Rule by the January 2026 deadline. Even the entities that have been able to devote significant efforts to compliance have expressed concern about the timeline, in part because they rely on receiving accurate data from their supply chain partners, who might not be similarly situated. Moreover, although the rule does not require electronic recordkeeping or any specific technologies for records maintenance or supply chain communications, many industry members using or intending to use electronic data systems have expressed that they need additional time to develop interoperable systems for maintaining and sharing traceability data. However, some consumer group representatives have expressed concern with postponing implementation of the rule as that would delay the benefits of enhanced foodborne illness outbreak response.

After carefully considering the public comments, feedback, and other information gathered since issuing the rule, including from the Foundation-led efforts, meetings with stakeholders, onsite visits to covered entities, and other outreach, we have tentatively concluded that additional time is needed for covered entities to prepare, including working with their supply chain partners, to help ensure successful implementation. As stated in the preamble to the final rule (87 FR 70910 at 71067), because the traceability requirements operate via a chain of information being maintained and passed forward through covered entities in the supply chain, if entities in the supply chain fail to provide required information to their supply chain partners, the chain would be broken. This means that even if most of the entities in that particular supply chain were prepared to comply with the rule, accurate traceability data would still not reach the retail location, which is where FDA generally must begin its outbreak investigations. Therefore, the possibility that a significant number of supply chain entities may have great difficulty coming into compliance by the current compliance date (January 20, 2026) could substantially diminish the rule's effectiveness.

We have tentatively concluded that a partial or phased approach to compliance is not feasible. For the reasons described above, any break in the chain of information would affect the availability of traceability data if FDA needed to investigate an outbreak. Moreover, the complex, interconnected nature of supply chains (with many entities both sending and receiving required traceability information) makes extending the compliance date for all covered entities more operationally feasible than a phased approach that would require compliance by different types of entities according to different schedules. Implementing a phased approach would likely require FDA to describe and classify different steps in the supply chain, which would be difficult in light of the varied and complicated supply chains that exist for different types of products. More generally, the focus of both FDA and industry would be likely to shift to the logistics of describing and implementing a partial or phased approach to compliance. We think the public health benefits will be greater if the compliance date is delayed by 30 months for all of industry, allowing time to focus on successful implementation of the entire rule throughout the full supply chain. During the additional time for achieving compliance that the proposed rule would allow, FDA would continue to support industry by providing education and other forms of

engagement to help facilitate the implementation process.

This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 deregulatory action.

B. Proposed Compliance Date

The current compliance date for the Food Traceability Rule is January 20, 2026. FDA is proposing to extend the compliance date deadline by 30 months to July 20, 2028. This proposed rule is limited in scope to the Food Traceability Rule compliance date; therefore, comments should address the proposed compliance date extension. This compliance date extension does not amend, nor do we intend to amend, the requirements of the final rule, which will improve food safety and protect public health.

II. Legal Authority

The Food Traceability Rule was promulgated under section 204(d)(1) of the FDA Food Safety Modernization Act (FSMA) (21 U.S.C. 2223(d)(1)), which directed FDA to establish recordkeeping requirements, in addition to the requirements under section 414 of the FD&C Act (21 U.S.C. 350c) and FDA regulations in 21 CFR part 1, subpart J (the subpart J regulation), for facilities that manufacture, process, pack, or hold foods that FDA designates under section 204(d)(2) of FSMA as high-risk foods. The proposed compliance date discussed in this document is consistent with our authority under section 204(d) of FSMA. We discuss our legal authority in greater detail in the Final Rule on the Requirements for Additional Traceability Records for Certain Foods (87 FR 70910 at 70915).

III. Description of the Proposed Rule

This proposed rule proposes to extend the compliance date for the Food Traceability Rule to address concerns about the amount of time affected entities will need to implement the requirements. If finalized, this rule would extend the compliance date by 30 months from January 20, 2026, to July 20, 2028. FDA anticipates that this additional time is sufficient for affected entities to implement the requirements of the Food Traceability Rule—including coordinating with their supply chain partners as needed—so that the anticipated public health benefits of the rule can be fully realized.

IV. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct us to assess all benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are economically significant under Executive Order 12866 if they have an annual effect on the economy of $100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is an economically significant regulatory action under section 3(f)(1) of Executive Order 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant regulatory actions ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.'' This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 deregulatory action.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule will reduce the burden on covered food entities by extending the compliance date of the final rule titled ''Requirements for Additional Traceability Records for Certain Foods'' (the Food Traceability Rule), we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (Section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current threshold after adjustment for inflation is $187 million, using the most current (2024) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The benefits of this proposed rule comprise the foregone benefits associated with extending the compliance date of the Food Traceability Rule by 2.5 years. We estimate that the present value of the benefits of the proposed rule over 20 years ranges from −$3,866 million to −$102 million, with a primary estimate of −$1,348 million, using a 3 percent discount rate and from −$3,408 million to −$90 million, with a primary estimate of −$1,188 million, using a 7 percent discount rate. The annualized benefits of the proposed rule range from −$260 million per year to −$7 million per year, with a primary estimate of −$91 million per year, using a 3 percent discount rate and from −$322 million per year to −$8 million per year, with a primary estimate of −$112 million per year, using a 7 percent discount rate.

The costs of this proposed rule comprise the cost savings associated with extending the compliance date of the Food Traceability Rule by 2.5 years. The present value of the costs of the proposed rule over 20 years ranges from −$3,381 million to −$46 million, with a primary estimate of −$797 million, using a 3 percent discount rate and from −$3,258 million to −$56 million, with a primary estimate of −$775 million, using a 7 percent discount rate. Annualized, the costs of the proposed rule range from −$227 million per year to −$3 million per year, with a primary estimate of −$54 million per year, using a 3 percent discount rate and from −$308 million per year to −$5 million per year, with a primary estimate of −$73 million per year, using a 7 percent discount rate.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE
[Millions of 2024 dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $millions/year	−$112	−$322	−$8	2024	7	2024–2043	Foregone benefits associated with extending the compliance date of the Food Traceability Rule by 2.5 years.
	−91	−260	−7	2024	3	2024–2043	
Annualized Quantified					7		
					3		
Qualitative							
Costs:							
Annualized Monetized $millions/year	−73	−308	−5	2024	7	2024–2043	The costs of this proposed rule comprise the cost savings associated with extending the compliance date of the Food Traceability Rule by 2.5 years. A portion of foreign cost savings could be passed on to domestic consumers. We estimate that between 0% and 100% of $5 million in annualized costs savings (7%, 20 years) to foreign facilities could be passed on to domestic consumers. This estimate is not included in total cost savings reported in this table.
	−54	−227	−3	2024	3	2024–2043	
Annualized Quantified					7		
					3		
Qualitative	Farming-, manufacturing- or cooking-related actions form a necessary link between direct compliance activities and changing risks of foodborne illness; thus, negative benefits estimates imply cost savings in this unquantified category.						
Transfers:							
Federal Annualized Monetized $millions/year.					7		
					3		
From/To	From:			To:			
Other Annualized Monetized $millions/year.					7		
					3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government: None.
Small Business: We estimate that small, covered food entities will experience a collective *cost savings* of between $16 million and $22 million annually.
Wages: None.
Growth: None.

In line with Executive Order 14192, in Table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 deregulatory action. We estimate that this proposed rule would generate $54 million in annualized net cost savings at a 7 percent discount rate, discounted relative to year 2024 over a perpetual time horizon.

TABLE 2—EXECUTIVE ORDER 14192 SUMMARY TABLE
[Millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate]

	Primary estimate	Low estimate	High estimate
Present Value of Costs	$0	$0	$0
Present Value of Cost Savings	771	3,239	56
Present Value of Net Costs	−771	−3,239	−56
Annualized Costs	0	0	0
Annualized Cost Savings	54	227	4
Annualized Net Costs	−54	−227	−4

We have developed a Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 4).

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively

have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This proposed rule contains no new or revised collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

VIII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175.We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

IX. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Reagan-Udall Foundation for the FDA, ''Industry Roundtable Series on the FSMA Final Rule of Requirements for Additional Traceability Records for Certain Foods Top-Line Learnings Summary''. September 2024. Available at: *https://reaganudall.org/sites/default/files/2024-09/Food%20Traceability%20Top-Line%20Summary%20090424_0.pdf.*
2. Reagan-Udall Foundation for the FDA, ''Virtual Public Meeting on FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods''. October 7, 2024. Available at: *https://reaganudall.org/news-and-events/events/virtual-public-meeting-fdas-final-rule-requirements-additional-traceability.*
3. Reagan-Udall Foundation for the FDA, ''FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods (Written Comments)''. Available at: *https://reaganudall.org/sites/default/files/2024-11/FDA%27s%20Final%20Rule%20on%20Requirements%20for%20Additional%20Traceability%20Records%20for%20Certain%20Foods%20%28Written%20Comments%29.pdf.*
4. FDA, ''Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Requirements for Additional Traceability Records for Certain Foods: Compliance Date Extension,'' 2025. Available at: *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–14967 Filed 8–6–25; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2024–0468; FRL–12884–01–R8]

Air Plan Approval; Colorado; Inspection and Maintenance Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Colorado through the Colorado Department of Public Health and Environment (CDPHE) on May 16, 2022. The revision includes changes to the Colorado Air Quality Control Commission's Regulation Number 11, ''Motor Vehicle Emissions Inspection Program.'' The submitted changes constitute a revision to Colorado's vehicle inspection and maintenance (I/M) SIP. Colorado's I/M SIP revision includes several minor clerical and typographical revisions. The I/M SIP revision also streamlines the visual inspection procedures used on subject vehicles in obtaining I/M program emissions certification compliance and vehicle registration renewal. CDPHE also submitted revisions to its I/M program regulations which were marked as ''state only'' revisions and not meant for EPA consideration. The EPA is not acting upon these state-only changes in this action.

DATES: Written comments must be received on or before September 8, 2025.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2024–0468, to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *https://www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: All documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically in *https://www.regulations.gov.* Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

FOR FURTHER INFORMATION CONTACT: Gregory Lohrke, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado 80202–1129,