



January 2024

# FOOD SAFETY

## FDA Should Finalize Plans to Implement Its Rule to Help Trace Source of Outbreaks

# GAO Highlights

Highlights of [GAO-24-106563](#), a report to congressional committees

## Why GAO Did This Study

Foodborne illness remains a common and costly public health problem in the U.S. Being able to efficiently trace products linked to a foodborne illness outbreak can help government agencies and those who produce and sell food identify the source of the outbreak. FDA, within the U.S. Department of Health and Human Services (HHS), is responsible for developing and implementing several rules required by the FDA Food Safety Modernization Act, enacted in 2011. These include the food traceability rule.

The act also included a provision for GAO to report on the traceability rule. This report, among other things, (1) describes FDA's and selected stakeholders' views on the rule's recordkeeping requirements and (2) examines FDA's actions to implement the rule and challenges FDA and stakeholders may face in achieving compliance.

GAO reviewed FDA documentation and interviewed FDA officials and 20 selected stakeholders representing industry associations, consumer advocacy groups, and nonfederal regulators.

## What GAO Recommends

GAO recommends that FDA finalize and document an implementation plan for the traceability rule. HHS agreed with this recommendation.

View [GAO-24-106563](#). For more information, contact Steve D. Morris at (202) 512-3841 or [morriss@gao.gov](mailto:morriss@gao.gov).

January 2024

## FOOD SAFETY

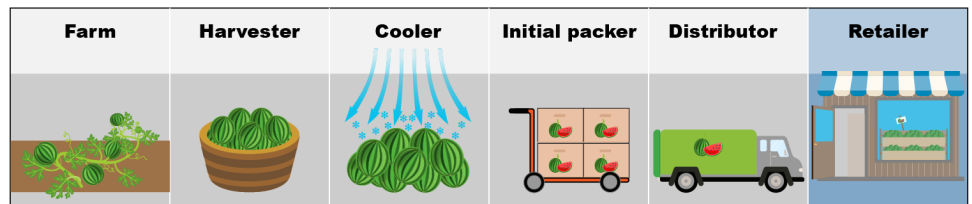
# FDA Should Finalize Plans to Implement Its Rule to Help Trace Source of Outbreaks

## What GAO Found

In November 2022, the Food and Drug Administration (FDA) promulgated a final rule on food traceability to help identify the source of outbreaks of foodborne illness. In developing the rule, the FDA established a list of certain foods for which enhanced recordkeeping is required, and set a compliance date of January 20, 2026. Entities handling an item on the list must maintain specific records, including a traceability plan, at certain points in the item's supply chain.

To identify foods for the list, FDA used an approach that incorporates statutorily mandated criteria, such as the history and severity of prior outbreaks involving the item. Several stakeholders GAO interviewed said FDA's methodology for identifying foods for the list was appropriate. Several other stakeholders disagreed with this assessment, stating that FDA's approach resulted in an overly inclusive list. In response to similar comments on the draft rule, FDA provided its rationale for considering foods at the commodity—or category—level, stating that foods in these groups had similar risk characteristics and associated hazards.

## Examples of Points in the Supply Chain Required to Maintain Traceability Records for a Produce Item on the Food Traceability List



Source: GAO analysis of U.S. Food and Drug Administration information; Kazakova Maryia/stock.adobe.com. | GAO-24-106563

FDA has taken some steps to help industry and nonfederal regulators prepare for compliance with and enforcement of the rule. Also, in late 2022, FDA began an iterative planning process for implementing the rule. However, as of October 2023, FDA had not finalized or documented an implementation plan, according to FDA officials.

Components of such a plan could help address challenges stakeholders identified in preparing for the compliance deadline. For example, the plan could include additional information on nonfederal regulators' roles in the inspection process and FDA's enforcement strategy and needed resources. It also could identify additional guidance, training, and tools for stakeholders. By finalizing and documenting an implementation plan, FDA will have better assurance it is well positioned to make progress toward its regulatory goals and address the various challenges that stakeholders identified to achieving compliance by the deadline.

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## Abbreviations

|      |  |
|------|--|
| CDC  | Centers for Disease Control and Prevention |
| FDA  | Food and Drug Administration               |
| FSMA | FDA Food Safety Modernization Act          |
| HHS  | Department of Health and Human Services    |
| KDE  | Key data element                           |
| USDA | U.S. Department of Agriculture             |

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January 18, 2024

### Congressional Committees

Although the U.S. food supply is generally considered safe, foodborne illness remains a common and costly public health problem. Being able to efficiently trace products linked to a foodborne illness outbreak can help government agencies and those who produce and sell food identify the source of the product and where contamination might have occurred, according to the Food and Drug Administration (FDA).<sup>1</sup> Certain foods such as fresh produce, seafood, and eggs are more frequently associated with foodborne illnesses than others, according to the Centers for Disease Control and Prevention (CDC). For example, from 2014 through 2021, foodborne disease outbreaks linked to leafy greens were associated with a total of 2,028 illnesses, 477 hospitalizations, and 18 deaths, according to CDC.

The FDA Food Safety Modernization Act (FSMA), signed into law in January 2011, expanded and overhauled U.S. food safety law. For example, it included requirements for FDA to establish additional recordkeeping requirements for facilities that manufacture, process, pack, or hold foods FDA designates as high risk to public health.<sup>2</sup> These additional requirements are intended to facilitate the rapid and effective

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<sup>1</sup>FDA, an agency within the Department of Health and Human Services, is responsible for ensuring the safety of more than 80 percent of the U.S. food supply. Specifically, FDA is to ensure that all domestic and imported foods—excluding meat, poultry, catfish, and processed egg products—are safe, wholesome, sanitary, and properly labeled. The federal food safety system is integrated with Tribes, states, localities, and territories, which may have their own laws and agencies to address the safety and quality of food. In all, more than 3,000 nonfederal regulatory partners perform the great majority of government food safety activities, including inspections. See GAO, *Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed*, [GAO-16-425](#) (Washington, D.C.: May 19, 2016). For the purposes of this report, we refer to these nonfederal agencies as “nonfederal regulatory partners.”

<sup>2</sup>Pub. L. No. 111-353, § 204(d)(1), 124 Stat. 3885, 3931 (2011). FDA previously promulgated 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. *Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, 69 Fed. Reg. 71,562 (Dec. 9, 2004). According to FDA, in the years following the adoption of those requirements, FDA learned that the one-up, one-back recordkeeping requirements did not capture all of the data elements necessary to effectively and rapidly link shipments of food through each point in the supply chain.

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identification of the recipients of these foods.<sup>3</sup> In response, FDA developed the rule *Requirements for Additional Traceability Records for Certain Foods*, widely referred to as the food traceability rule, which went into effect in January 2023.<sup>4</sup> The rule applies to domestic and foreign entities producing food for human consumption in the U.S., along the entire food supply chain, with some exemptions. For example, the traceability rule only pertains to foods regulated by FDA and does not apply to foods regulated by the U.S. Department of Agriculture (USDA).<sup>5</sup> The compliance date for all entities subject to the rule's recordkeeping requirements is January 20, 2026.

As directed by FSMA, FDA established a Food Traceability List to identify foods for which additional traceability records are required.<sup>6</sup> Foods on the list include, for example, fresh-cut fruit and vegetables, ready-made deli salads, and nut butters. Entities handling foods on the list must, among other things, maintain specific records at certain points in the food's supply chain, maintain a traceability plan, and provide FDA with specific traceability information within 24 hours of a request—or within a reasonable time to which FDA has agreed—to help FDA during an outbreak or other threat to public health.

FSMA includes a provision for us to report on the food traceability rule. This report (1) describes FDA and selected stakeholder views on the development of the rule's recordkeeping requirements, including benefits and costs; (2) describes FDA and selected stakeholder views on the exemptions from the rule requirements; and (3) examines FDA's actions

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<sup>3</sup>Food traceability relates to the ability to follow the movement of a food product and its ingredients backward and forward through all steps in the supply chain between the farm and the consumer. Traceability involves documenting and linking the production, processing, and distribution chain of food products and ingredients.

<sup>4</sup>87 Fed. Reg. 70,910 (Nov. 21, 2022) (codified at 21 C.F.R. pt. 1, subpt. S).

<sup>5</sup>USDA's Food Safety and Inspection Service is responsible for the safety of most domestic and imported meat, poultry, catfish, and processed egg products. As previously noted, FDA is responsible for the safety of virtually all other foods. USDA has traceability requirements for official establishments and retail stores that grind raw beef products. U.S. Department of Agriculture, *Records To Be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products*, 80 Fed. Reg. 79,231, 79,249, 79,250 (Dec. 21, 2015) (codified at 9 C.F.R. pt. 320).

<sup>6</sup>According to the final food traceability rule, as part of the agency's implementation of FSMA, FDA designated foods for which the rule's additional recordkeeping requirements are appropriate and necessary to protect public health. Those designated foods constitute the Food Traceability List.



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to prepare for implementation of the rule and challenges FDA and selected stakeholders may face in achieving compliance with the rule.

For all three objectives, we reviewed laws and regulations and FDA documents.<sup>7</sup> To describe FDA and stakeholder viewpoints on the development of the rule's recordkeeping requirements, the exemptions to the rule, and challenges industry and FDA may face in achieving compliance with the rule, we interviewed FDA officials and selected stakeholders. Specifically, we conducted 20 semi-structured interviews with stakeholders representing industry, consumers, and nonfederal regulatory partners.<sup>8</sup>

We identified stakeholders by reviewing previous GAO reports and asking interviewed stakeholders to recommend the names of other stakeholders. We then selected stakeholders for interviews to ensure our selection covered a range of the commodities included on the Food Traceability List and critical tracking events identified in the rule's requirements.<sup>9</sup> We synthesized the information that we gathered during each of the stakeholder interviews to identify relevant themes.<sup>10</sup> These interviews

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<sup>7</sup>*Methodological Approach to Developing a Risk-Ranking Model for Food Tracing* (Sept. 2022); *Memo on Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing* (Oct. 31, 2022); *Requirements for Additional Traceability Records for Certain Foods: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis*, Docket No. FDA-2014-N-0053 (Sept. 23, 2020); and *Requirements for Additional Traceability Records for Certain Foods: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis*, Docket No. FDA-2014-N-0053 (Nov. 21, 2022).

<sup>8</sup>We interviewed 16 industry associations: the American Frozen Food Institute; FMI, the Food Industry Association; Global Cold Chain Alliance; International Dairy Foods Association; International Foodservice Distributors Association; International Fresh Produce Association; Institute of Food Technologists; National Association of Convenience Stores; National Fisheries Institute; National Grocers Association; National Milk Producers Federation; National Restaurant Association; Peanut and Tree Nut Processors Association; Texas International Produce Association; United Egg Producers; and Western Growers. We also interviewed two consumer advocacy organizations, the Center for Science in the Public Interest and Stop Foodborne Illness, and two associations representing nonfederal regulatory partners, the Association of Food and Drug Officials and the National Association of State Departments of Agriculture.

<sup>9</sup>For the purposes of this report, we use the term selected stakeholders to represent the industry, consumer, and nonfederal regulatory partner groups we interviewed, unless otherwise specified. The stakeholders provided their perspectives from the viewpoint that the rule was finalized and promulgated by FDA, but the compliance period had not begun.

<sup>10</sup>Throughout this report, we use modifiers to characterize the views of the 20 stakeholders as follows: "some" represents two to three stakeholders, "several" represents four to nine, and "many" represents 10 or more.

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provide a range of views and are not generalizable to all industry, consumer advocacy, or nonfederal regulatory partner groups.

To examine actions FDA has taken to prepare for implementation of the rule, we reviewed FDA documents related to the rule, including guidance and outreach and education materials. We compared FDA's plans for implementation against criteria from GAO's Key Considerations for Regulatory Design and Compliance and leading practices for project management.<sup>11</sup> For further details on our objectives, scope, and methodology, see appendix I.

We conducted this performance audit from January 2023 to January 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

Prior to FSMA, FDA focused primarily on reacting to foodborne illnesses after they occurred, rather than on preventing outbreaks. FSMA required FDA to focus on prevention by, in part, requiring new rules that collectively provide a framework for preventing foodborne illness across the food supply chain. Some of these rules, such as those on produce safety and preventive controls for human food, focus only on specific stages of the food supply chain—the farms that grow food for human consumption and facilities that process the food.<sup>12</sup>

In contrast, the food traceability rule reaches all entities that manufacture, process, pack, or hold foods on the Food Traceability List and spans the food supply chain from the harvest of a food through transformation at food processing facilities, to food available for sale at a retail food establishment or restaurant.<sup>13</sup> The rule requires these entities to maintain

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<sup>11</sup>GAO, *Federal Regulations: Key Considerations for Agency Design and Enforcement Decisions*, [GAO-18-22](#) (Washington, D.C.: Oct. 19, 2017) and Project Management Institute, Inc., *A Guide to the Project Management Body of Knowledge (PMBOK® Guide)*, Seventh Edition (2021). PMBOK is a trademark of Project Management Institute, Inc. The Project Management Institute is a not-for-profit association that, among other things, provides standards for managing various aspects of projects, programs, and portfolios.

<sup>12</sup>In response to FSMA, FDA developed nine foundational rules, including a rule governing the growing, harvesting, packing, and holding of produce—widely referred to as the produce safety rule—and a rule governing the production of human food, widely referred to as the preventive controls rule for human food.

<sup>13</sup>According to the final rule, transformation involves manufacturing/processing a food or changing a food or its packaging.

and provide specific information, or key data elements, for certain events in the food’s supply chain, known as critical tracking events.<sup>14</sup>

Central to these requirements is the assignment, recording, and sharing of traceability lot codes for foods on the list, as well as linking traceability lot codes to other information that identifies foods as they move through the supply chain, according to the preamble to the final rule.<sup>15</sup> Table 1 provides information on the critical tracking events defined in the rule, examples of key data elements to be collected at each milestone, and when traceability lot codes are to be assigned. Figure 1 provides an example of the information collected throughout the supply chain for foods on the Food Traceability List.

**Table 1: Critical Tracking Events Established in the Food Traceability Rule and Examples of Required Key Data Elements**

| Critical tracking event   | Description   | Examples of key data elements required  |
|---------------------------|---|---|
| Harvesting                | Activities traditionally performed on farms for the purposes of removing foods in their raw or natural state—raw agricultural commodities—from the place they are grown or raised and preparing them for use as food. | Location description for where the food was harvested.<br>Date of harvesting.   |
| Cooling                   | Active temperature reductions of a raw agricultural commodity.  | Quantity and unit of measure of the food.<br>Date of cooling.   |
| Initial packing           | Packing a raw agricultural commodity for the first time.  | Date food was received.<br>Location description for the farm where the food was harvested.  |
| First land-based receiver | Person takes possession of a food for the first time on land directly from a fishing vessel.  | Species and/or acceptable market name for unpackaged food, or the product description for packaged food.<br>Harvest date range and locations for the trip during which the food was caught. |

<sup>14</sup>According to the preamble to the final rule, the information that entities must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to a listed food, from harvesting of the food through processing, distribution, and receipt at retail or other point of service.

<sup>15</sup>FDA defines a traceability lot code as a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the entity that assigned the traceability lot code. 21 C.F.R. § 1.1310.

|                |   |  |
|----------------|---|--|
| Shipping       | Food is arranged for transport (e.g., by truck or ship) from one location to another.                                     | Product description for the food.<br>Traceability lot code. <sup>a</sup>   |
| Receiving      | Food is received by someone other than a consumer after being transported (e.g., by truck or ship) from another location. | Date the food was received.<br>Traceability lot code. <sup>a</sup>   |
| Transformation | Involves manufacturing/ processing a food or changing a food or its packaging. <sup>b</sup>                               | For Food Traceability List foods used as ingredients, the incoming traceability lot code for the food. <sup>a</sup><br><br>For new foods produced, the product description for the food to which the new traceability lot code applies. <sup>a</sup> |

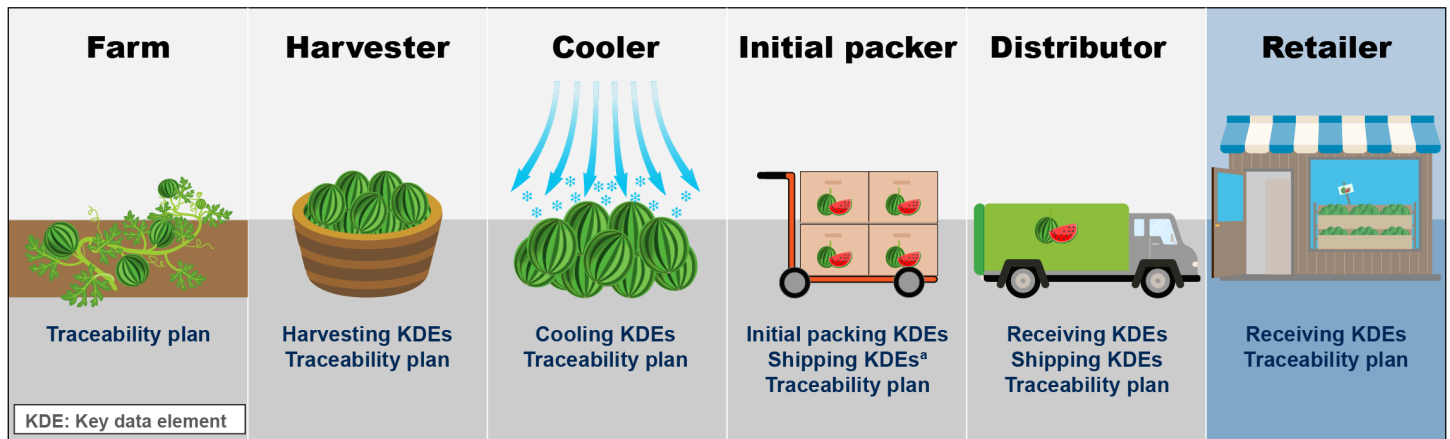
Source: 87 Fed. Reg. 70,910 (Nov. 21, 2022) (codified at 21 C.F.R. pt. 1, subpt. S). | GAO-24-106563

<sup>a</sup>A traceability lot code is a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the entity that assigned the traceability lot code. According to the final rule, the traceability lot code is assigned when an entity initially packs a raw agricultural commodity other than food obtained from a fishing vessel, performs the first land-based receiving of a food obtained from a fishing vessel, or transforms a food.

<sup>b</sup>According to the final rule, the transformation key data element requirements do not apply to retail food establishments and restaurants with respect to foods they do not ship (e.g., foods they sell or send directly to consumers).

**Figure 1: Examples of Points in the Supply Chain Required to Maintain Traceability Records for a Produce Item on the Food Traceability List**

The Food and Drug Administration’s (FDA) food traceability rule requires businesses handling items on the Food Traceability List, such as fresh melons, to maintain specific records—key data elements (KDEs)—at certain points in a food’s supply chain, as well as a traceability plan.



Source: GAO analysis of U.S. Food and Drug Administration information; Kazakova Maryia/stock.adobe.com. | GAO-24-106563

Note: FDA’s food traceability rule also requires entities handling items on the Food Traceability List to provide FDA with specific traceability information within 24 hours of a request. According to the preamble to the final rule, the assignment of a traceability lot code, and linking lot codes to other information that identifies foods as they move through the supply chain, is central to the rule’s recordkeeping requirements.

<sup>a</sup>In this example, the traceability lot code would be assigned during the initial packing stage and be included in the shipping KDEs, according to the final rule.

## FDA and Stakeholders Cited Various Benefits of the Rule’s Recordkeeping Requirements, while Stakeholder Concerns Included Compliance Costs

To identify items for the Food Traceability List, for which additional traceability records are required, FDA developed a model that incorporated statutory requirements and that ranked foods based in part on risks to public health. The agency plans to update the list approximately every 5 years, according to the preamble to the final rule. In our interviews with selected stakeholders about FDA’s development of the Food Traceability List, they made comments that reflected several key themes, such as the potential effects on businesses’ decisions about how to handle foods not on the list. Additionally, FDA identified health and non-health benefits of the rule, but stakeholders expressed concerns that, among other things, FDA underestimated the costs to industry of complying with the recordkeeping requirements.

## What foods are covered by the Food Traceability List?

The Food Traceability List identifies the commodities for which additional traceability records are required. The foods on the list fall into six broad categories: dairy, eggs, nuts and nut products, prepared food, produce, and seafood (see table 2). Foods that contain an item on the list are also covered by the food traceability rule's recordkeeping requirements if that ingredient remains in the form in which it appears on the list, according to FDA. For example, according to FDA, fresh lettuce used in a bagged salad mix, fresh cantaloupe in a commercially prepared smoothie, or a sandwich containing a fresh tomato would be covered by the rule's requirements. A frozen pizza with a spinach topping or trail mix with dried papaya would not be covered according to FDA, because frozen leafy greens and dried tropical tree fruits are not on the list.

**Table 2: Commodities Included on the Food Traceability List**

| Commodity category    | Commodity   |   |
|-----------------------|---|---|
| Dairy                 | Cheese (made from pasteurized milk), soft ripened or semi-soft<br>Cheese (made from pasteurized milk), fresh soft or soft unripened <sup>d</sup>  | Cheese (made from unpasteurized milk), other than hard cheese   |
| Eggs                  | Shell eggs  |   |
| Nuts and nut products | Nut butters   |   |
| Prepared food         | Ready-to-eat deli salads (refrigerated)   |   |
| Produce               | Cucumbers (fresh)<br>Fruits (fresh cut)<br>Sprouts (fresh)<br>Leafy greens (fresh and fresh cut)<br>Vegetables other than leafy greens (fresh cut)  | Herbs (fresh)<br>Peppers (fresh)<br>Tropical tree fruits (fresh)<br>Melons (fresh)<br>Tomatoes (fresh)  |
| Seafood               | Finfish, histamine-producing species <sup>a</sup> (fresh and frozen)<br>Finfish, species potentially contaminated with ciguatoxin <sup>b</sup> (fresh and frozen)<br>Smoked finfish (refrigerated and frozen)<br>Crustaceans (fresh and frozen) | Finfish, species not associated with histamine or ciguatoxin <sup>c</sup> (fresh and frozen)<br>Molluscan shellfish, bivalves (fresh and frozen) <sup>d</sup> |

Source: 87 Fed. Reg. 70,910 (Nov. 21, 2022) (codified at 21 C.F.R. pt. 1, subpt. S). | GAO-24-106563

<sup>a</sup>Some species of finfish are known to be capable of producing elevated levels of histamine if temperature controls are not followed. These species include, but are not limited to, tuna, mahi mahi, mackerel, swordfish, and yellowtail.

<sup>b</sup>Finfish species potentially contaminated with ciguatoxin include, but are not limited to, grouper, barracuda, and snapper.

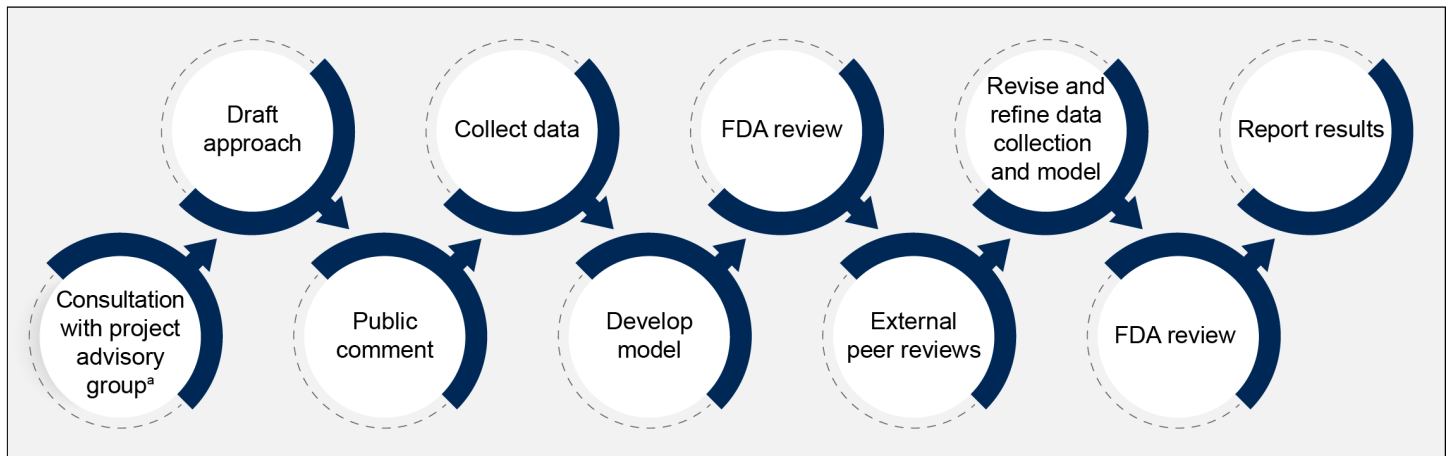
<sup>c</sup>All species of finfish not associated with histamine or ciguatoxin include, but are not limited to, cod, haddock, Alaska pollock, salmon, tilapia, and trout.

<sup>d</sup>Raw bivalve molluscan shellfish are exempt from the requirements of the food traceability rule if they are (1) covered by the requirements of the National Shellfish Sanitation Program; (2) subject to the requirements of 21 C.F.R. pt. 123, subpt. C, and 21 C.F.R. § 1240.60; or (3) covered by a final equivalence determination by FDA. Equivalence determinations recognize that another country's food safety requirements for these products, though different from FDA's, provide at least the same level of public health protection.

How did FDA develop the list, and what plans does FDA have to update it?

FDA developed a risk-ranking model to identify foods to include on the Food Traceability List, and the agency plans to update the list approximately every 5 years, subject to available resources. FDA officials told us they selected a risk-ranking model because it allowed them to weigh quantitative and qualitative data sources against statutorily mandated criteria.<sup>16</sup> FDA’s process for developing and implementing the model included creating a draft approach, collecting data and determining a risk score, and generating a ranked list of items to be added to the list, according to FDA documents and officials. FDA also incorporated public comment and peer review into its process (see fig. 2).

**Figure 2: The Food and Drug Administration’s (FDA) Process for Developing a Model to Identify Items to Include on the Food Traceability List**



Source: GAO analysis of U.S. Food and Drug Administration Information; maulaga/stock.adobe.com. | GAO-24-106563.

<sup>a</sup>According to FDA documents, FDA developed the risk-ranking model in consultation with a project advisory group that included members from its Center for Food Safety and Applied Nutrition; Office of Foods and Veterinary Medicine; Office of Food Policy and Response; Office of Policy, Legislation, and International Affairs; Center for Veterinary Medicine; and Office of Regulatory Affairs, as well as the Centers for Disease Control and Prevention, another agency within the Department of Health and Human Services.

According to FDA documents, the design of the risk-ranking model was guided by six specific statutory factors in FSMA, in addition to a requirement in FSMA that the food traceability rule could only apply to foods on the Food Traceability List. The six factors include the history and

<sup>16</sup>FDA described the approach used in its methodological document as a multicriteria-based model. FDA selected this approach following the review of a variety of methods and tools developed for identifying, ranking, comparing, and prioritizing food safety risks, including multicriteria decision analysis methodology and qualitative and quantitative risk assessment methods and tools. Food and Drug Administration, *Methodological Approach to Developing a Risk-Ranking Model* (Sept. 2022).

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severity of previous foodborne illness outbreaks.<sup>17</sup> FDA used these six factors to create seven criteria used in the model, according to an FDA document on the agency’s methodology.<sup>18</sup>

FDA used the risk-ranking model to evaluate all human foods regulated by the agency. These foods were represented in 211 commodities across 47 distinct commodity categories, according to FDA officials.<sup>19</sup> FDA determined that the “commodity” level was the appropriate level of granularity for foods in the model because items within the same commodity designation have similar characteristics, associated hazards, and production and supply-chain practices and conditions, according to agency documents.

In its model, FDA paired specific commodities with known or foreseeable hazards most often associated with these foods and then ranked each

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<sup>17</sup>These factors include the likelihood that a particular food has a high potential risk for contamination, the likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination, and the severity of a foodborne illness attributed to a particular food. See Pub. L. No. 111-353, § 204(d)(2)(A), 124 Stat. 3885, 3932 (2011) (codified at 21 U.S.C. § 2223(d)(2)(A)).

<sup>18</sup>The agency used seven criteria in the model because, according to FDA’s methodology document for the model, several of the factors required in FSMA included two types of information, and therefore were implemented in the model as two separate criteria. The seven criteria in the model are (1) frequency of outbreaks and occurrence of illnesses; (2) severity of illness, taking into account illness duration, hospitalization, and mortality; (3) likelihood of contamination; (4) potential growth of microbial pathogens; (5) manufacturing process contamination probability and industry-wide intervention; (6) consumption; and (7) cost of illness. Food and Drug Administration, *Methodological Approach to Developing a Risk-Ranking Model* (Sept. 2022).

<sup>19</sup>According to FDA, the commodities in the model are defined in a food classification scheme that consists of 47 commodity categories based on the FDA Reportable Food Registry commodity definitions and relevant Industry Codes in the FDA facility registration program, with consideration of product-specific categories, process-specific categories, and the role of processing and preventive controls. The Reportable Food Registry is an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. FDA requires food facilities to register with the FDA to carry out certain provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Pub. L. No. 107-188, § 305(a), 116 Stat. 594, 667 (codified as amended at 21 U.S.C. § 350d).



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food-hazard pair on the basis of the risk criteria.<sup>20</sup> For each criterion evaluated, FDA assigned a numeric score of 0, 1, 3, or 9, with 0 representing the lowest level and 9 representing the highest level for each of the seven criteria. FDA added a food to the list if any food-hazard pair for that food had an aggregated risk score of 330 or higher, which corresponded to those with a significant public health risk.<sup>21</sup> FDA officials stated that the agency selected 330 as a minimum score for adding foods to the list to strike a balance between identifying foods with significant public health risk and avoiding an overly broad list. Appendix II provides the list of commodities on the list and the risk score for each food.

FDA stated in the preamble to the final rule that it plans to update the list approximately every 5 years, subject to available resources.<sup>22</sup> According to FDA officials, for the initial update to the Food Traceability List following publication of the final rule, FDA will take into consideration the compliance date when deciding when to begin the update process. In updating the list, the agency plans to incorporate new data and information into the risk-ranking model based on the established criteria and approach outlined in its methodology document, according to officials.<sup>23</sup> FDA then plans to publish a notice of any changes to the list

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<sup>20</sup>The approximately 100 hazards in the model are classified within three hazard categories, according to FDA: microbial hazards, chemical hazards, and undeclared allergens. FDA determined that for the purposes of developing the Food Traceability List, it would only consider results from the model for microbial hazards and acute chemical toxins. FDA developed multiple food-hazard pairs for most commodities, depending on whether the item had more than one hazard to assess. For example, FDA assessed peppers against its seven criteria for four hazards—*Listeria monocytogenes*; *Salmonella enterica* – Serovar paratyphi; *Salmonella* spp.; and STEC non-O157. Because the food-hazard pair of peppers and *Salmonella* spp. had a risk score of 370, peppers were added to the Food Traceability List.

<sup>21</sup>This risk score corresponds to at least two of the criterion scores being “strong,” or a score of 9, and the remaining five criterion scores being “moderate,” or a score of 3, providing evidence of a significant public health risk, according to FDA documents. A commodity was also included on the Food Traceability List if the outbreaks and illnesses (criteria 1) and cost of illness (criteria 7) scores for one or more associated commodity-hazard pairs were “strong,” providing evidence of a significant public health risk. The risk score is calculated by summing equally weighted criteria scores across all seven criteria. Food and Drug Administration, *Methodological Approach to Developing a Risk-Ranking Model* (Sept. 2022) and *Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing* (Oct. 2022).

<sup>22</sup>87 Fed. Reg. 70,910, 70,916, 71,050, 71,088 (Nov. 21, 2022).

<sup>23</sup>Food and Drug Administration, *Methodological Approach to Developing a Risk-Ranking Model* (Sept. 2022). FDA officials stated that in the future, as additional data streams, risk assessment methods, and computational methods arise, the agency may decide to modify how the agency implements the factors in section 204(d)(2)(A) of FSMA into a risk-ranking model.

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and the reasons for these changes in the Federal Register and request public comments on the proposed changes before making a final determination and issuing a final notice in the *Federal Register*.<sup>24</sup>

In addition, FDA officials pointed to other routes through which FDA may provide exemptions, modifications, and waivers to covered foods or entities as described in the final rule.<sup>25</sup> For example, FDA stated in the preamble to the final rule that the agency is considering whether to exempt certain cottage cheese from the recordkeeping requirements.<sup>26</sup> Cottage cheese currently is included on the list under the category “cheese (made from pasteurized milk), fresh soft or soft unripened.”<sup>27</sup> According to FDA officials, the process that the agency would use to make this determination is described in the final rule under its procedures for modified requirements and exemptions. FDA officials did not provide us a time frame for making a determination about a potential cottage cheese exemption.

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What are selected stakeholders’ views on FDA’s development of the list?

The stakeholders we interviewed made comments that reflected several key themes regarding FDA’s development of the Food Traceability List. These themes were (1) how FDA assessed the risk of foods for inclusion on the list, (2) the clarity of the list, (3) the process for adding or removing foods from the list, and (4) potential effects on businesses’ decisions about how to handle foods not on the list.

FDA’s Assessment of Risk

Many stakeholders commented on FDA’s assessment of the risk of foods for inclusion on the list. Several stakeholders stated that FDA’s risk assessment methodology for developing the list was appropriate, or that the final list seemed reasonable based on the history of recalls. For

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<sup>24</sup>Any deletions from the list would become effective immediately, and any additions to the list would become effective 2 years after the date of the publication of a notice in the *Federal Register* announcing the revised list, unless otherwise noted by FDA.

<sup>25</sup>Waivers are described in the final rule as a process under which FDA may waive one or more of the rule’s requirements if they would (1) result in an economic hardship and (2) not impair FDA’s ability to identify recipients of a food to prevent or mitigate a foodborne illness outbreak, among other things. FDA also established procedures for making modifications to the rule’s requirements or exempting a food or type of entity from the rule’s requirements, if FDA determines that the requirements are not necessary to protect public health.

<sup>26</sup>87 Fed. Reg. 70,910, 70,932 (Nov. 21, 2022).

<sup>27</sup>FDA noted in the preamble to the final rule that it is considering initiating a process to determine whether cottage cheese should be exempted from the rule’s requirements, recognizing that much of the cottage cheese produced in the United States is regulated under the pasteurized milk ordinance—a federal program that includes specific requirements for processing and frequent testing and inspection by regulatory authorities.

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example, one industry association stated that the list was scientifically grounded, comprehensive, and balanced. Several other stakeholders disagreed with this assessment, stating that FDA's consideration of foods at the commodity level was not appropriate and resulted in an overly inclusive list.

As we noted above, FDA stated in the final food traceability rule and its methodological documents that the agency determined that the "commodity" level was an appropriate level of granularity for food items for the purposes of developing the list.<sup>28</sup> However, some stakeholders told us that the broadly defined commodities of certain finfish, cheeses, and fresh cut fruits and vegetables might include foods that are not as high risk as those of other foods in those commodities.

#### Clarity of the List

Several stakeholders commented that there was confusion about which foods are on the list. For example, officials from some stakeholders representing industry told us that it is difficult for their membership to identify which specific foods from broad-based categories—such as those containing soft cheeses and finfish—are on the list. Some stakeholders added that it is difficult for small and midsize businesses to understand the list and determine when the recordkeeping requirements apply. Some stakeholders also commented on the need for more information about foods not added to the list so they can better understand FDA's decision-making process. These stakeholders, for example, raised questions about why certain foods were not added to the list or said they did not understand how FDA developed its cutoff point for adding foods to the list.

In June 2023, FDA made the risk scores for foods not on the Food Traceability List available to the public on its website.<sup>29</sup> Additionally, in the preamble to the final rule and on its website, FDA responded to public comments about the list's clarity by providing examples of foods for many of the commodities. In addition, for some commodities, FDA identified foods not included in that commodity, such as specific types of tropical tree fruits.

#### Adding or Removing Foods

Several stakeholders commented on the process for adding and removing foods from the list and the amount of time it would take to make

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<sup>28</sup>87 Fed. Reg. 70,910, 70,920 (Nov. 21, 2022); FDA, *Methodological Approach to Developing a Risk-Ranking Model* (September 2022).

<sup>29</sup>Stakeholders raised this issue during interviews we held with them before FDA added this information to its website. Food and Drug Administration, *FDA Publishes New FAQs and Additional Tools for the Food Traceability Rule* (June 23, 2023), accessed June 26, 2023.

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## Businesses' Decisions about Non-listed Foods

these changes. For example, one stakeholder expressed concern about the amount of time it would take for FDA to assess foods for removal from the list, stating that FDA should have developed a more efficient process to make changes. As we noted above, according to FDA documents, the agency plans to update the list approximately every 5 years, subject to available resources. Furthermore, according to FDA officials, covered entities may request waivers, modified requirements, or exemptions, using the processes outlined in the final rule. Additionally, in its list of frequently asked questions about the rule, FDA provided a description of the information and process it plans to use to update the list.<sup>30</sup>

Many stakeholders also stated that, as a result of how FDA designed the list and because of the complexity and cost of having multiple recordkeeping systems, some businesses might choose to apply the recordkeeping requirements to all foods, not just those on the list. For example, one stakeholder group said it would be impractical and inefficient for its members to apply recordkeeping requirements for certain products—they want to have one system and set of records for all foods. FDA addressed comments related to this topic in the preamble to the final rule and its final regulatory impact analysis, noting that the agency believes applying the recordkeeping requirements to all foods would benefit both industry and American consumers by facilitating faster traceback and identification of contaminated food.<sup>31</sup>

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<sup>30</sup>Food and Drug Administration, *Frequently Asked Questions: FSMA Food Traceability Rule*, <https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule>, accessed Nov. 13, 2023.

<sup>31</sup>According to FDA officials, an external panel of industry experts interviewed by an FDA contractor expressed mixed expectations on whether and to what extent businesses would conform recordkeeping of non-Food Traceability List foods to the requirements for Food Traceability List foods. FDA further noted that it expects it will be possible for businesses to implement changes on an as-needed basis for compliance purposes, though some might voluntarily opt to enhance traceability more broadly.

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What are the benefits and costs of the rule's recordkeeping requirements, according to FDA and selected stakeholders?

FDA's Assessment of Benefits and Costs

FDA assessed the benefits and costs of the food traceability rule in its final regulatory impact analysis.<sup>32</sup> According to FDA's analysis, the rule provides two types of benefits—public health and non-health benefits. The primary public health benefits include fewer foodborne illnesses, hospitalizations, and deaths because better traceability records shorten the time a contaminated product covered by the rule remains in the food supply chain. Non-health benefits include the avoidance of costs associated with overly broad recalls, improvements in supply chain management and inventory control, and a more timely initiation and completion of recalls.<sup>33</sup> In its analysis, FDA calculated the benefits of the rule based on an estimate that the rule's recordkeeping requirements would result in about an 80 percent reduction in the time it takes FDA to trace a product to its origin.

FDA's analysis also assessed potential compliance costs for industry in adopting the rule. Specifically, FDA's analysis determined that such costs to industry would stem from the increased number of records required for covered food products and expenses to establish and maintain a traceability plan. FDA also determined that some entities might incur initial and recurring capital investment and training costs for systems to maintain their traceability records as well as one-time costs to read and understand the rule. Table 3 provides FDA's monetary economy-wide estimates for the rule's annual health and non-health benefits and

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<sup>32</sup>Food and Drug Administration, *Requirements for Additional Traceability Records for Certain Foods: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis*, Docket No. FDA-2014-N-0053 (Nov. 21, 2022).

<sup>33</sup>An overly broad recall occurs when a recall includes products that aren't genuinely affected or don't pose a risk, leading to unnecessary removal from the market. For example, FDA may have determined that a foodborne illness outbreak is likely attributed to tomatoes from a certain region of the country, but without adequate traceability, FDA may not know the specific farm that is responsible for the outbreak, which could lead to all tomatoes from that region of the country being recalled.

compliance costs over a 20-year period. Appendix III provides additional estimates developed by FDA on the compliance costs for small businesses, per firm, covered by the rule.

**Table 3: Food and Drug Administration (FDA) Estimates of Annualized Monetary Benefits and Compliance Costs of the Food Traceability Rule**

Dollars in millions

|                         |                         | Primary estimate | Low estimate | High estimate |
|-------------------------|-------------------------|------------------|--------------|---------------|
| <b>Benefits</b>         | <b>Health</b>           | 780              | 59           | 2,200         |
|                         | Non-health <sup>a</sup> | 575              | 233          | 1,800         |
| <b>Compliance costs</b> | Domestic                | 570              | 63           | 2,300         |
|                         | Foreign <sup>b</sup>    | 51               | 4            | 286           |

Source: Food and Drug Administration. | GAO-24-106563

Note: The estimate included above is for a 7 percent discount rate for 20-year annualized benefits and costs, according to FDA’s regulatory impact analysis for the food traceability rule. FDA’s estimates are considered rough because FDA did not have specific, tailored data sources to develop its regulatory impact analyses, according to FDA documents and officials. According to FDA officials, the agency relied on a variety of data sets and the viewpoints of experts to develop its conclusions in the proposed and final regulatory impact analyses. FDA officials further noted that in developing these estimates they followed Office of Management and Budget and Department of Health and Human Services’ guidelines. However, we did not assess the extent to which FDA followed these guidelines.

<sup>a</sup>According to agency documents, FDA estimated non-health benefits that could result from avoiding overly broad recalls and market withdrawals and discussed other non-health benefits qualitatively.

<sup>b</sup>A portion of foreign costs—up to \$50.5 million—could be passed on to domestic consumers, according to FDA’s analysis.

### Selected Stakeholders’ Perspectives on Benefits and Costs

The selected stakeholders that we interviewed made comments on the benefits of the food traceability rule that largely paralleled FDA’s perspectives, but many expressed concerns about compliance costs. Several stakeholders highlighted potential improvements to the recall process during foodborne illness outbreaks. In addition, some stakeholders said the enhanced traceability requirements could help minimize broad recalls or warnings and, hence, costs to industry. For example, one stakeholder cited a 2019 recall of Mexican papayas that, according to this stakeholder, resulted in an increase in the cost of papayas for industry due to decreased market supply.

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Many stakeholders cited concerns that the rule's recordkeeping requirements would create compliance costs for industry, including that FDA underestimated these costs. The stakeholders provided examples of the types of investments they expect to make to comply with the rule, including enhanced technology systems and IT capabilities. Several stakeholders also said they would need to hire more staff or train and educate current staff on the rule, leading to higher personnel costs.

Some stakeholders also said that FDA underestimated costs associated with the time it would take industry to understand the rule. For example, one stakeholder group told us that large businesses in its membership estimated that it would take up to a year to understand how to comply with the rule, how many of their products fall under the rule's requirements, and where these products are located, before they can start to implement the rule. Several stakeholders also stated that FDA did not appropriately weigh the costs or effects of the recordkeeping requirements on small businesses, which have fewer resources than larger entities.

FDA responded to public comments on how it assessed the compliance costs of the rule in its final regulatory impact analysis and in the final rule published in the Federal Register. In its final regulatory impact analysis, in response to comments that FDA substantially underestimated costs, FDA reported that it took steps to collect additional information about the rule's compliance costs for various covered entities and updated the agency's estimates for the number of entities covered by the rule, resulting in a revised final cost estimate. In response to comments on costs spent to read and understand the rule, FDA stated that it used methods consistent with previous FDA analyses of the economic impact of rulemaking and that in this final analysis, FDA accounted for multiple employees reading the rule at larger companies. In its regulatory impact analysis, FDA also estimated and assessed the impacts on small businesses.

Several stakeholders also highlighted concerns about the potential effects of the rule on consumers. For example, several stakeholders expressed concerns that potential costs associated with the recordkeeping requirements could result in changes to which foods a producer grows or a store stocks. A consumer advocacy group that we spoke to told us that some small retailers already struggle with maintaining access to fresh produce in their communities and that the rule's requirements could present disincentives to stocking foods that are on the Food Traceability List. Some stakeholders also said consumers might face increased prices if fewer businesses produce or offer foods on the list due to the burden of the recordkeeping requirements.

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In response to these stakeholder comments, FDA officials stated that it is possible that some producers and growers may change product offerings as a result of the traceability requirements, as FDA also noted in its regulatory impact analysis.<sup>34</sup> FDA officials also agreed that, as with many other rules, some producers might pass some of their compliance costs on to other entities in the supply chain, including to consumers through higher prices. However, according to these officials and FDA's regulatory impact analysis, the agency did not find evidence that would allow it to estimate the magnitude and distribution of these cost pass-throughs or their effect on consumers.<sup>35</sup>

Some stakeholders said that limiting recordkeeping requirements to foods on the list, rather than applying them to all foods, could create public health risks. For example, one stakeholder suggested that if a food not on the list is recalled, the traceability records for that item may not be available.<sup>36</sup> However, as noted above, FSMA prohibited FDA from applying the rule's traceability requirements to all foods.

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<sup>34</sup>According to FDA officials, FDA expects that this would occur when the additional traceability requirements cause some covered products to become unprofitable.

<sup>35</sup>According to the regulatory impact analysis, FDA retained a contractor to understand the anticipated effect of the final rule on costs and, therefore, on consumer prices. However, FDA found no evidence on the magnitude of the cost pass-through, the incidence of cost pass-through on items not on the Food Traceability List, substitution patterns of different segments of consumers, or price elasticity estimates for items on the Food Traceability List for different demographics. As a result, it was not able to assess the distributional effects of the final rule on various consumers. However, FDA acknowledged in the regulatory impact analysis that the costs and benefits of the rule might accrue unequally to various consumer segments.

<sup>36</sup>FDA's recordkeeping requirements for all foods, commonly referred to as "one-up, one-back," still remain in place. These requirements, according to FDA, allow the agency to identify the immediate previous sources and immediate subsequent recipients of foods. *Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, 69 Fed. Reg. 71,562 (Dec. 9, 2004). Certain entities are excluded from these requirements, including farms and restaurants. 21 C.F.R. § 1.327. The limitations of one-up, one-back recordkeeping are discussed in the preamble to the proposed food traceability rule. 85 Fed. Reg. 59,984, 59,990 (Sept. 23, 2020).



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## FDA and Stakeholders Identified Some Benefits of Exemptions from the Rule, but Industry Cited Several Concerns

FDA developed complete and partial exemptions from the food traceability rule's recordkeeping requirements for certain foods and entities. FDA based these exemptions on factors such as the type of food and size of the business. Selected stakeholders identified some advantages of the exemptions, such as relief for small businesses. However, they also expressed concerns about the exemptions' thresholds, complexity, and potential public health risks.

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## What are the exemptions, and how were they developed?

FDA developed complete and partial exemptions from the food traceability rule's recordkeeping requirements for certain foods and entities by considering requirements in FSMA and weighing public health risks with thresholds for coverage. FDA based these exemptions on factors such as the type of food and business size (see app. IV for a list of the exemptions).

- **Full exemptions.** Certain food categories and entities, such as certain produce farms and most shell egg producers, are fully exempt from the traceability rule's recordkeeping requirements.
- **Partial exemptions.** Certain entities and food categories that may not qualify for a full exemption can benefit from modified requirements, according to the rule. Specifically, modified requirements—or partial exemptions—may reduce the type of information entities are required to collect and the length of time they need to maintain the records. For example, certain retail food establishments or restaurants that purchase directly from a farm or another retail food establishment may get partial exemptions that reduce some of their recordkeeping requirements.

FDA developed the exemptions by considering requirements in FSMA, assessing the risk of excluding certain entities from the rule, and addressing public comments on the rule, according to agency documents and officials. In addition, FDA officials told us the agency coordinated with officials at USDA on the development of the partial exemptions for farm-to-school and farm-to-institution programs, to avoid placing undue

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burdens on these programs.<sup>37</sup> FDA officials stated that the agency aimed to strike a balance between its public health mission and identifying the appropriate number of small businesses that would benefit from the exemptions. Specifically, FDA officials said they considered the following in developing the exemptions:

- **Thresholds and sales coverage.** The agency evaluated different thresholds (cutoff limits) for sales revenue-based exemptions, according to agency officials. For example, for the exemption for small retail food establishments, FDA evaluated the public health risks and benefits of setting the threshold at certain monetary values ranging from \$100,000 to \$1 million. FDA ultimately set the threshold at \$250,000 because this limit would represent less than 5 percent of sales of covered foods. In its assessments, FDA also evaluated whether these limits would adequately cover a suitable number of small businesses and the percentage of sales for commodities included on the Food Traceability List, according to FDA officials and documents.
- **Consistency with existing food safety regulations.** FDA officials told us that the agency worked to maintain consistency in exemptions for small farms by mirroring other exemptions across various food safety regulations, particularly for produce and eggs. For example, one exemption for small produce farms was linked to the produce safety rule, so that if a farm qualified for exemption under that rule, it was also exempted from the food traceability rule. Similarly, the exemption for eggs was intended to align with FDA's shell egg regulations, according to the preamble to the final rule.<sup>38</sup>

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How many entities does FDA estimate will be covered by and exempted from the rule?

In its regulatory impact analysis for the food traceability rule, FDA estimated that the final rule would cover more than 323,800 domestic businesses operating more than 484,100 establishments, including over 11,000 farms (see table 4). FDA estimated that about 98 percent of

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<sup>37</sup>This coordination was required under FSMA. Pub. L. No. 111-353, § 204(d)(6)(A), 124 Stat. 3885, 3933 (2011). FDA officials stated that they coordinated with representatives from several USDA agencies, including the Food and Nutrition Service, the Agricultural Marketing Service, and the Food Safety and Inspection Service. We have previously reported on the need for coordination between FDA, USDA, and other agencies with food safety responsibilities. See GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas* (GAO-23-106203) (Washington, D.C.: Apr. 20, 2023).

<sup>38</sup>Food and Drug Administration, *Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation*, 74 Fed. Reg. 33,030 (July 9, 2009) (codified as amended at 21 C.F.R. pt. 118).

covered businesses would be considered small businesses, according to the Small Business Administration’s definition.<sup>39</sup>

**Table 4: Food and Drug Administration’s (FDA) Estimated Number of Domestic Businesses and Establishments Covered by the Food Traceability Rule**

| Entity type                | Number of businesses | Number of establishments |
|----------------------------|----------------------|--------------------------|
| Farms                      | 11,760               | 11,796                   |
| Manufacturers              | 7,991                | 8,650                    |
| Wholesalers                | 12,007               | 15,101                   |
| Warehouses                 | 2,504                | 5,176                    |
| Retail food establishments | 102,424              | 171,380                  |
| Restaurants                | 187,185              | 272,021                  |
| <b>Total</b>               | <b>323,871</b>       | <b>484,124</b>           |

Source: Food and Drug Administration. | GAO-24-106563

Note: According to FDA, values may not sum to the total due to rounding. FDA’s estimates are considered rough because FDA did not have specific, tailored data sources to develop its regulatory impact analyses, according to FDA documents and officials. According to FDA officials, the agency relied on a variety of data sets and the viewpoints of experts to develop its conclusions in the proposed and final regulatory impact analyses. FDA officials further noted that in developing these estimates they followed Office of Management and Budget and Department of Health and Human Services’ guidelines. However, we did not assess the extent to which FDA followed these guidelines.

FDA stated in the preamble to the final rule that, based on exemptions for certain small producers in the rule and the selected exemption thresholds, the following entities are estimated to be exempt from the food traceability rule:

- Produce farms: About 63 percent of produce farms representing approximately 1 percent of covered produce sales.
- Shell egg producers: Approximately 98 percent of shell egg producers representing approximately 1 percent of covered shell egg sales.

<sup>39</sup>The Small Business Administration publishes size standards for industry categories of firms. The Small Business Act defines a small business as one that is independently owned and operated and is not dominant in its field of operation. 15 U.S.C. § 632(a)(1). The act authorizes the Small Business Administration to establish standards for determining whether an entity is a small business. Such standards could utilize number of employees, dollar volume of business, net worth, net income, a combination thereof, or other appropriate factors. 15 U.S.C. § 632(a)(2). The Small Business Administration established standards in regulation. See 13 C.F.R. pt. 121.

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- Aquaculture operations: About 40 percent of aquaculture operations representing approximately 3 percent of covered aquaculture sales.
  - Retail food establishments: Approximately 19 percent of retail food establishments representing about 1 percent of retail food establishment sales.
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**What are selected stakeholders' and FDA views on the exemptions?**

While some selected stakeholders identified advantages of exemptions for small businesses from the traceability rule's recordkeeping requirements, several expressed concerns related to the exemptions. For example, one stakeholder said the exemptions provide some relief to industry members who would otherwise be burdened by the rule's requirements, while another said the exemptions allow them to invest time and money in other parts of their business. Others said the exemptions could enhance food access by reducing barriers that small retailers may face to selling fresh produce. However, several stakeholders expressed concern about the exemption thresholds, the complexity of the rule, and the risks to public health.

**Exemption thresholds**

Several stakeholders said they were concerned that FDA set too low a threshold for entities to qualify for an exemption. For example, several stakeholders said the threshold of \$250,000 in annual sales, averaged across 3 years, for retail food establishments and restaurants, was so low that only the smallest businesses, such as small food trucks, would qualify. An association representing grocery stores noted that grocery stores are high-volume businesses, so even the smallest grocery store might make \$20 million in revenue. According to this association, a \$250,000 limit is not reasonable for even the smallest of grocery stores, and with this threshold, it is uncertain if even convenience stores, which generally make less revenue than grocery stores, are exempted. Similarly, an association representing restaurants commented that few of its members make less than \$250,000 on a 3-year rolling basis; thus, even the smallest restaurants will not be eligible for the exemption.

FDA officials told us that they considered higher thresholds when developing the exemptions but concluded such thresholds were not appropriate because they would exempt a significant portion of the covered market from the recordkeeping requirements. Doing so would limit the government's ability to efficiently and thoroughly trace back products to protect public health, according to FDA.

**Complexity of Exemptions**

Several stakeholders discussed concerns about the various complexities of the exemptions, including the difficulty in maintaining the required recordkeeping and challenges associated with identifying businesses and

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products to which the exemptions apply. For example, one association said that the exemptions would add a layer of complexity to the rule's recordkeeping requirements because very small businesses that are suppliers for other businesses and are eligible for an exemption do not need to provide traceability information to the next step in the supply chain. According to another association, this raises the question of how to ensure that companies not exempt receive the required traceability information for listed foods from companies that are exempt.<sup>40</sup>

In another example, one stakeholder mentioned the complexity in understanding which foods are exempt because one category of foods may include some items that are exempt and others that are not. For example, some commingled raw agricultural commodities, such as eggs and seafood, are exempt while others, such as produce, are not.<sup>41</sup> Although FDA officials told us that they developed a web-based tool to help covered entities understand the exemptions, one stakeholder highlighted the need for a tool as an example of the overly complex nature of the exemptions.

## Public Health Risks

Many stakeholders discussed concerns about public health risks associated with the exemptions. For example, one stakeholder mentioned that creating exemptions based on a sales volume threshold does not necessarily make all consumers safer because pathogens and outbreaks can happen in any environment, regardless of an entity's size. A restaurant owner we interviewed stated similar concerns, noting that the smallest businesses may have the highest food safety risks because they do not have the resources for a sophisticated food safety system. Another stakeholder also expressed concern that implementing more exemptions could limit FDA's or businesses' ability to conduct a full traceback.

FDA officials disagreed with the potential public health risks of the exemptions, noting that exempted entities below the cutoff threshold do

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<sup>40</sup>According to FDA, this issue is addressed in the final rule under requirements for when entities receive a food from an exempt entity. See 21 C.F.R. § 1.1345(b).

<sup>41</sup>For the purposes of this rule, Congress directed FDA to create an exemption for commingled raw agricultural commodities and to define a commingled raw agricultural commodity as an item that is combined or mixed after harvesting but before processing. Pub. L. No. 111-353 § 204(d)(6)(D), 124 Stat. 3885, 3934 (2011). Congress further directed that the term "commingled raw agricultural commodity" shall not include fruits and vegetables that are subject to the produce safety rule. Pub. L. No. 111-353 § 204(d)(6)(D)(ii)(II), 124 Stat. 3885, 3934 (2011). According to FDA officials, of the foods currently covered by the food traceability rule, the only ones that are eligible for this exemption are seafood and shell eggs.

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not contribute significantly to the volume of listed foods in the marketplace that could become contaminated. Further, the officials stated that subsequent parties in the supply chain will be required to maintain records for the food they receive from farms exempted from the rule.

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## FDA Has Taken Some Actions to Prepare for the Rule's Implementation but Has Not Finalized an Implementation Plan

FDA has taken several actions to help its nonfederal regulatory partners and industry prepare for compliance with the food traceability rule by the January 20, 2026, deadline. However, selected stakeholders highlighted various challenges that industry and federal and nonfederal regulators could face as they prepare for compliance and enforcement. While FDA has begun an iterative planning process for implementing the rule, as of October 2023 it had not finalized or documented an implementation plan, which could hinder its ability to address these challenges.

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### What actions has FDA taken to help stakeholders prepare for compliance with the rule?

As part of its preparations for implementation of the rule, FDA took several actions to help industry and nonfederal regulatory partners prepare for compliance with the food traceability rule by the January 20, 2026, deadline. These actions included completing several FSMA requirements and providing education and technical assistance, according to FDA documents and officials.

- **FDA completed some FSMA requirements.** As required by FSMA, in 2011 FDA funded two traceability pilot projects to assess methods to improve product tracing and better identify recipients of foods, among other things. In 2016, FDA submitted a summary of the report on these pilots to Congress.<sup>42</sup> In May 2023, FDA released a small entity compliance guide to help small entities—such as farms and small businesses—comply with the requirements of the rule, according to FDA documentation.
- **FDA began providing education and outreach to industry.** FDA's actions in this area include the following:
  1. After the final rule was published in November 2022, FDA took steps to educate industry about the rule. Specifically, FDA provided trade associations and industry groups with presentations and webinars and held sector-specific meetings to explain the rule's requirements and expectations, according

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<sup>42</sup>For a summary of these findings, see Institute of Food Technologists, McEntire, J., *Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report* (Chicago, IL: Aug. 2012).

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to FDA officials.<sup>43</sup> FDA also produced materials to help industry understand the requirements of the rule, including online interactive tools, supply chain examples, frequently asked questions, a small entity compliance guide, and factsheets for farms and retail food establishments and restaurants. In addition, in September 2023, FDA announced that the agency would not begin routine inspections until 2027 to provide time to develop and provide training and other educational support to the agency’s nonfederal regulatory partners and industry.<sup>44</sup>

2. FDA also took steps to encourage innovation in software and tools that industry can use in their compliance efforts. For example, FDA sponsored a competition to encourage development of low- or no-cost traceability hardware, software, and data analysis tools to facilitate adoption of technology-enabled traceability systems throughout the supply chain, according to FDA documentation.
  3. To promote international compliance with the rule, FDA translated most of the existing traceability rule materials into key foreign languages to educate international businesses on requirements they face for exporting foods to the U.S., according to agency officials and the agency’s website.<sup>45</sup>
- **FDA began offering technical assistance.** FDA is using its Technical Assistance Network to provide answers to industry

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<sup>43</sup>According to FDA officials, as of January 4, 2024, the agency had provided over 90 presentations and webinars and held sector-specific meetings on the rule.

<sup>44</sup>FDA stated that it may conduct inspections on a for-cause basis, such as during an outbreak investigation, after the compliance date of January 20, 2026. In November 2023, FDA also updated its frequently asked questions and published additional tools and templates on its website. Food and Drug Administration, “Frequently Asked Questions: FSMA Food Traceability Rule” (Silver Spring, MD: Nov. 20, 2023), accessed Nov. 30, 2023, <https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule#TE1>.

<sup>45</sup>Businesses that produce foods on the Food Traceability List that are imported into the U.S. are required to follow the food traceability rule’s requirements.

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questions about the rule.<sup>46</sup> From November 2022 through July 2023, the network received nearly 150 inquiries on the traceability rule and resolved 95 percent of them within 3 weeks, according to data FDA provided. In addition, FDA plans to offer technical assistance to its nonfederal regulatory partners after inspections begin, according to FDA officials.

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What challenges could individual businesses face in implementing the rule, according to selected stakeholders?

Additional, Timely Education and Outreach

Stakeholders we interviewed highlighted various challenges that could affect individual businesses within a food's supply chain. Specifically, stakeholders identified three broad challenges: (1) obtaining additional, timely guidance, tools, templates, and education; (2) making operational changes; and (3) dedicating additional costs and resources.

Many stakeholders said that industry needs additional, timely guidance, tools, templates, education, and outreach to achieve compliance with the rule. Several stakeholders also expressed concerns about the assistance FDA has provided to date and indicated that a lack of detailed information is delaying their efforts to comply with the rule. For example, several stakeholders said that although FDA has provided some webinars and training, industry needs additional guidance. This guidance could include additional information on how to comply with the rule, what data are required, how to share information with FDA, and how FDA will use the data industry provides during an outbreak. Some stakeholders also told us that FDA's presentations and webinars often do not address industry-specific (e.g., fishery or farm) questions or concerns.

In addition, some stakeholders said industry needs more clarity on some terminology in the rule, such as definitions of specific terms or the format of a sortable spreadsheet. Some stakeholders also requested that FDA provide tools specific to individual sectors, similar to a tool farmers use in implementing FSMA's produce safety rule to assess if farms are ready to comply with the rule.<sup>47</sup> Other tools, such as a traceability plan template or

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<sup>46</sup>In September 2015, FDA launched a FSMA Technical Assistance Network, through which industry, regulators, and the public may submit questions to subject matter experts at FDA about the FSMA-mandated rules. Inquiries may be submitted to the network via an online web portal or mail. GAO, *Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed*, [GAO-16-425](#) (Washington, D.C.: May 19, 2016).

<sup>47</sup>According to FDA, on-farm readiness reviews are used to foster dialogue between farmers and regulators or educators about the requirements of FSMA's produce safety rule to enable farmers to come into compliance with the rule.



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sample sortable spreadsheet, could be used more broadly across industries.

Some stakeholders stated that responses they have received from FDA's Technical Assistance Network simply point to the rule without providing clarifying context or guidance that would enable industry to implement the rule's requirements. FDA officials stated that some questions requiring additional interpretation of the final rule must be responded to through agency guidance, which FDA is drafting. The officials said they expect to publish this guidance before the compliance date.

Stakeholders emphasized that this additional information could be used to show industry what successful compliance looks like and what FDA's specific expectations are. Some stakeholders said this guidance could allow businesses to avoid having to justify to inspectors how their traceability efforts are compliant when these efforts do not match precisely the guidance and training inspectors receive. However, several stakeholders stated that the longer it takes FDA to provide clarifying guidance, the more difficult it will be for industry to meet the compliance date of January 20, 2026.

In the preamble to the final rule, FDA responded to public comments about the need for additional guidance and other materials to help all sectors of the food industry come into compliance. Specifically, FDA stated that it would use the 3 years before the deadline for compliance to provide additional outreach and training, as well as guidance and other materials to industry. In addition, in their responses to frequently asked questions on the rule, FDA officials have provided updates clarifying certain aspects of the rule—such as how industry can share information with FDA. FDA officials also told us that they anticipate releasing a sortable spreadsheet template, and in November 2023 released some examples of a traceability plan.<sup>48</sup>

## Making Operational Changes

Many stakeholders stated that businesses would need to adjust their current traceability practices and operational procedures. For example, several stakeholders said that the rule would require changing current traceability practices such as assigning lot codes or using purchase records and financial accounting to aid in traceability. As previously noted, some stakeholders said these changes could lead to entities

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<sup>48</sup>FDA officials did not provide a timeline in which they anticipate releasing examples of a sortable spreadsheet template. These officials further noted that examples of a traceability plan and electronic sortable spreadsheet have been included in presentations and webinars provided by FDA and are included in the slides posted on FDA's website.

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applying traceability rule requirements to foods not included in the Food Traceability List.

Some stakeholders said businesses might begin collecting a large amount of data beyond what is required, which could be time-consuming and expensive. For example, businesses that prepare foods for sale direct to consumers—such as deli salads that include multiple ingredients on the Food Traceability List—may have to adapt their operations to continue producing and selling these foods. Some stakeholders also said it might be challenging for industry, including small businesses, to establish new systems or find service providers they can incorporate into their operations that will allow them to comply with the traceability rule.

In the preamble to the final rule, FDA responded to public comments by stating that the changes are justified considering the benefits associated with more efficient and effective tracing in the event of an outbreak. In addition, FDA stated that the final rule is flexible in how firms meet the requirements—for example, the rule does not specify how businesses are to maintain data or provide data to FDA in the case of an outbreak or recall.

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## Additional Costs and Resources

### Case Level Tracking



The FDA Food Safety Modernization Act prohibits the Food and Drug Administration (FDA) from requiring foods on the Food Traceability List to be tracked by individual cases of product. However, several selected industry stakeholders we interviewed commented to FDA that the rule would require tracking individual cases by default. For example, if a distributor receives a pallet with products that contain several lot codes, the distributor would need to track the lot codes at the case level when it is packing items for shipping to a customer.

Some stakeholders commented that tracking at the case level would be unnecessarily complex, decrease efficiency, and could result in slower recall efforts in the future. FDA clarified in the preamble to the final rule that industry has flexibility in how they address this challenge, depending on individual business practices.

Source: GAO analysis of FDA and selected stakeholder documents; kadmy/stock.adobe.com. | GAO-24-106563

Many stakeholders said the additional costs or resources needed to implement the rule would present a challenge. For example, businesses may need to hire additional staff, purchase technology systems, or hire providers to set up these systems and train staff on how to appropriately use them. Specifically, some stakeholders said distribution centers would need to hire and train additional staff to capture the required data for a large volume of products moving into and out of the centers. In contrast, small businesses, including some restaurants, may need to purchase additional technology or services to comply with the rule.

In the preamble to the final rule, FDA stated that it expected the public health benefits of the rule would outweigh the costs of compliance. In addition, FDA stated that in the final rule, it streamlined requirements that were in the proposed rule. For example, the final rule reduced information to be included in the traceability plan. FDA stated that these streamlined requirements and the exemptions should help minimize compliance costs and cost increases that food suppliers might pass on to their customers for foods on the Food Traceability List. FDA estimated that the rule would cost industry about \$570 million per year.

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## What challenges could businesses across a food's supply chain face in implementing the rule?

Stakeholders representing industry associations identified two broad categories of challenges that could affect multiple businesses operating across a food's supply chain and that would require coordination among those businesses to meet compliance goals.<sup>49</sup> These challenges are (1) interoperability, or ensuring data and technology systems can communicate with each other; and (2) meeting the established compliance timeline.

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<sup>49</sup>Stakeholder responses in this section were limited to those representing industry associations.

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## Ensuring Interoperability of Systems

Many stakeholders said that it is a challenge for industry to ensure data and technology systems—such as software and scanners used to read labels and populate a database—are interoperable along food supply chains. For example, several stakeholders noted that the rule lacks standardization with respect to some required data—such as units of measure and lot size—that may make tracking individual products difficult as a product moves along the food supply chain.

Related challenges include identifying which businesses in a food supply chain will lead development and deployment of the data and technology systems needed to comply with the rule. For example, several stakeholders said that businesses do not know if their customers will use different software or require different data formats and reporting that these businesses would need to adopt. In addition, several stakeholders said if businesses purchase products from suppliers that do not provide quality data, they may have difficulty developing, maintaining, and providing quality information to provide to others in a food's supply chain. Finally, some stakeholders mentioned challenges relating to the use of technology systems. For example, for businesses that bring in products from multiple suppliers, their traceability systems will be required to integrate the traceability data from each of those suppliers.

In the preamble to the final rule, FDA acknowledges that FSMA does not allow the agency to prescribe specific technologies for the maintenance of traceability records. FDA further explained that it considers the food traceability rule's key data elements and critical tracking event data elements necessary first steps in achieving interoperability throughout the food supply chain. However, they commented that food supply chain partners will need to work together to address data quality concerns and address how to share required information, much of which is typically captured on existing business records.

FDA officials also stated that they intend to explore ways to encourage firms to voluntarily adopt tracing technologies that are interoperable throughout the food supply chain. To accomplish this, FDA commissioned a report to evaluate food traceability trends focused on data and software interoperability, usability, and costs, among other things. The report highlighted the need for continued innovation and industry-wide action to make technology-enabled traceability functional.<sup>50</sup> In addition, FDA

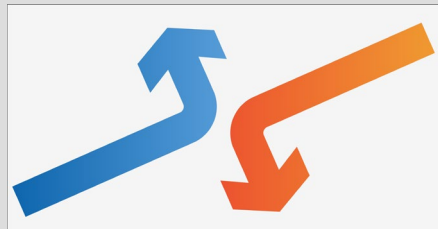
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<sup>50</sup>Institute of Food Technologists, Global Food Traceability Center, *IFT's Tech-Enabled Traceability Insights Based on the FDA's Low- or No-Cost Traceability Challenge Submissions* (Chicago, IL: 2023).

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## Meeting the Compliance Deadline

### Businesses Shared Different Views on the Traceability Rule



Business leaders shared contrasting views on the food traceability rule and its recordkeeping requirements during a site visit we made to Houston, Texas, in June 2023. For example, one business said it would not have to make significant changes from its current traceability practices to comply with the rule, while a similar business said its ability to comply with the rule would require changes to its existing practices and would depend on its suppliers' ability to provide quality data. Similarly, while one business (a distributor) stated that it would apply the rule's recordkeeping requirements to all food products it handles, another business said it did not plan to change any of its traceability practices until it is guided to do so by a state or local health inspector.

Source: GAO analysis of interviews with selected stakeholders; surfupvector/stock.adobe.com. | GAO-24-106563

officials told us that the agency is encouraging industry to take steps to promote data interoperability.<sup>51</sup>

Several stakeholders said it would be challenging for industry to meet the compliance deadline if they do not have quality data, as discussed above. Some of these stakeholders suggested changes FDA could make to facilitate compliance across food supply chains. For example, some stakeholders said producing quality traceability information depends on how individual businesses collect and share data across complex food supply chains. Some stakeholders suggested that FDA consider either (1) developing interim steps that lead industry to compliance over a longer time frame or (2) staggering implementation to allow some firms to achieve compliance before others. Specifically, staggered dates would allow time for earlier segments of the food supply chains to become compliant before later segments (i.e., farmers would become compliant before grocery stores).

In the preamble to the final rule, FDA stated that it considered requests to stagger the implementation period but determined a single compliance date was better, partly because staggering compliance would further complicate compliance and delay the benefits of the rule and would make collaboration across food supply chains more difficult. To address industry comments that the original time frame in the proposed rule was too short, in the final rule, FDA provided an additional year for industry to achieve compliance by changing the compliance date to January 20, 2026. As noted above, in September 2023, FDA announced that the agency would not begin routine inspections until 2027, to give covered entities more time to work together and ensure that traceability information is being maintained and shared within supply chains per the rule's requirements.

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<sup>51</sup>According to FDA officials, FDA is using the Electronic Product Code Information Services, which is an openly accessible data standard that is available for use by industry to promote interoperability across their supply chains. FDA officials stated that the use of this standard is not a requirement and FDA does not require traceability data in this format.

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What challenges could FDA and its nonfederal regulatory partners face in implementing and enforcing the rule, according to FDA and selected stakeholders?

FDA and stakeholders identified four broad challenges that FDA and its nonfederal regulatory partners could face as they implement and enforce the traceability rule.<sup>52</sup> These challenges are (1) identifying and obtaining the resources needed to implement and enforce the rule; (2) conducting outreach and education for sectors where FDA has limited experience; (3) clarifying the enforcement process, roles, and responsibilities; and (4) coordinating with nonfederal regulatory partners for consistent application. In addition, some stakeholders stated that FDA also faces the challenge of effectively managing data during an outbreak.

Resources for Implementation and Enforcement

FDA will need additional resources to implement the rule, particularly for staffing and funding, including resources to develop and test the new product tracing system required in FSMA, according to FDA officials.<sup>53</sup> According to FDA officials, this new system will more effectively and rapidly analyze food traceability data. They said that FDA is actively developing the system requirements and addressing its internal technology needs to implement this system. FDA officials stated that they expect to pilot the new system before the rule's compliance date. However, these officials also said that ensuring continued resource support for IT investments, program and contract support, among other things, is critical for implementation.<sup>54</sup>

In addition, during enforcement, inspector training and support will require resources, according to several stakeholders. Specifically, stakeholders expect that FDA will face challenges to its efforts to educate its own inspectors, as well as inspectors from its nonfederal regulatory partners, so that they enforce the rule uniformly. These efforts may require additional training and staffing resources and flexibility once the compliance date is reached, according to the stakeholders. For example, if FDA provides inspectors with guidance showing an example of how industry can comply with the rule, the agency will also need to ensure inspectors are trained to understand that industry may choose to comply with the rule in a different manner. These stakeholders suggested, among

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<sup>52</sup>FDA will work with its nonfederal regulatory partners from tribal, state, local, and territorial governments, which may end up conducting traceability inspections at certain businesses during the implementation of the food traceability rule.

<sup>53</sup>FSMA directed FDA to establish a product tracing system to receive information from industry that improves the agency's capacity to effectively and rapidly track and trace foods in the United States or offered for import into the United States.

<sup>54</sup>In addition, FDA officials stated that these resources are needed for training, development of the compliance program, and continued outreach and education to regulatory partners and industry.

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other things, that FDA establish a hotline to resolve real-time disagreements between inspectors and companies, such as over whether a food product is on the Food Traceability List.

FDA officials said they were planning to use a regulatory technical assistance network, similar to those the agency has employed in implementing other FSMA rules, to provide inspectors with prompt feedback on interpretation of the traceability rule or differing opinions during industry inspections. Inspectors can also seek resolution on disagreements that arise during inspections by using an established process that goes through FDA's regional field offices.

In the preamble to the final rule, FDA stated that it would build on existing collaboration efforts with nonfederal regulatory partners to develop tools and training for inspectors and investigators. FDA also stated that it would consider obtaining additional funds, such as through grants, for these nonfederal regulatory partners. FDA officials told us that they have been in contact with their nonfederal regulatory partners and the associations that represent them, such as the Association of Food and Drug Officials and the National Association of State Departments of Agriculture. However, these associations told us that neither they nor their members had had substantive conversations with FDA on the rule's implementation as of October 2023.

## Outreach and Education to Certain Sectors

FDA may face challenges with outreach and education to sectors with which it does not have extensive experience working, according to some stakeholders. Sector-specific outreach and education for entities such as small businesses, businesses that export food to the U.S., and farms, may be needed, these stakeholders said. They indicated that FDA may have to consider how to prepare these businesses for enforcement of the traceability rule. For example, small- to midsize farms trust and rely on agricultural extension services to understand complex issues, according to a stakeholder representing nonfederal regulatory partners with experience working with these groups.<sup>55</sup> In its planning for implementation and enforcement of the rule, FDA could include outreach and education through these trusted providers, according to some stakeholders.

Without targeted support, some stakeholders said, the rule could negatively affect these businesses. For example, one association representing state agriculture officials said that farmers could switch their

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<sup>55</sup>According to the USDA's National Institute of Food and Agriculture, the agricultural or cooperative extension services help farmers, ranchers, and others apply new knowledge to address their problems in food safety and nutrition, among other areas.

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production to grow foods not included on the Food Traceability List, or small farmers—particularly minority farmers who do not have resources to implement these measures—could find the requirements a barrier to starting to farm.

FDA officials told us that they expect to have both regulator and industry training available in 2025. However, these officials said they would need additional time to develop detailed aspects of the inspection strategy and other resources for some businesses—such as restaurants and farms—in part because nonfederal regulatory partners have primary responsibility for inspecting restaurants, retail food establishments, and farms in many states.

Uncertainty about Enforcement Process, Roles, and Responsibilities

Several stakeholders said they were uncertain how FDA will enforce the food traceability rule and that they would like clarity from FDA in specific areas. These areas include what compliance and enforcement tools FDA will use, when FDA intends to begin enforcement, what role nonfederal regulatory partners will play, and what FDA's enforcement plan is. One stakeholder representing nonfederal regulators told us that FDA would need to lay out these details, including the relationship between FDA and its nonfederal regulatory partners, in an enforcement strategy. In addition, a stakeholder that works with state regulators told us that, as of October 2023, FDA had not held preliminary conversations with the states on inspector training programs, among other aspects of the rule's enforcement.

In the preamble to the final rule, FDA stated that it would work with its regulatory partners to clarify oversight responsibilities, reduce redundancy, and consider tools to implement the rule. In addition, FDA officials told us that they expected to finalize their enforcement strategy by 2026, and that they expect this strategy to include efforts to educate industry before and during regulation.<sup>56</sup> FDA officials told us that the enforcement strategy will detail how FDA can best work with its regulatory partners to avoid duplication and ensure nonfederal regulatory partners have the resources they need to conduct traceability inspections. In September 2023, FDA publicly announced that it would begin routine inspections related to the rule in 2027.

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<sup>56</sup>FDA officials stated that when agency officials identify compliance issues in inspections, they give individuals and firms an opportunity to take prompt and voluntary corrective action before initiating an enforcement action.



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## Coordination with Nonfederal Regulatory Partners

Stakeholders representing nonfederal regulatory partners stressed that FDA needs to improve coordination with, and guidance to, nonfederal regulatory partners to ensure consistent enforcement of the food traceability rule across jurisdictions. Because nonfederal regulatory partners often conduct inspections under contract with FDA, successful and uniform implementation of the rule depends on the relationship between federal and state regulators and adequate training of inspectors, according to one association representing nonfederal regulators. Specifically, some stakeholders said that without a clear enforcement strategy, there is a risk that the 3,300 local health departments across the country could inconsistently apply the rule.

In addition, addressing coordination with states is important because, for example, some states and localities may have different budgetary resources for enforcement, according to stakeholders representing FDA's nonfederal regulatory partners. Variation in resources available may present a challenge to training inspectors and investigators; such training is necessary to ensure nonfederal regulatory partners consistently enforce the rule.

As of October 2023, FDA had not provided nonfederal regulatory partners with detailed information on how the rule will be enforced, what nonfederal regulatory partners' respective roles will be, or when additional guidance and training will be provided. However, FDA stated in the preamble to the final rule that consistent application of the rule is important because producers will share traceability information throughout the food supply chain. FDA officials also told us that they are considering the best approach for structuring and conducting compliance inspections. FDA officials said they expect to finalize regulator training in 2025 and their inspection strategy and enforcement policy before 2026.<sup>57</sup> FDA officials also stated that to address challenges in the implementation of the food traceability rule, including ensuring consistent application across states, they would leverage their experience from working with nonfederal regulatory partners to implement other regulations.

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<sup>57</sup>FDA officials told us that as part of developing an inspection and compliance approach, they are considering developing job aids or traceability data request templates, among other tools, that can be made available for nonfederal regulatory partners. However, FDA officials also stated that resource constraints and the complex nature of intra-agency and interagency activities could affect the overall inspection and compliance approach.

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## Data Management During an Outbreak

FDA's technology limitations, such as its existing data systems, could constrain FDA's ability to compile and analyze the significant amount of data it will receive during an outbreak, according to some stakeholders. These stakeholders noted that these technology limitations could hamper the agency's and industry's ability to respond effectively.

FDA officials told us that they began IT development for the product tracing system in late 2022. FDA will use this system to receive and analyze food traceability data from industry. These officials also stated that under the rule, industry traceability data will be carried through the supply chain for foods on the Food Traceability List. Doing so will allow data requests during outbreak investigations to be more focused, potentially reducing the need for FDA to request traceability data from all points in the supply chain. This could in turn reduce the amount of traceability data FDA receives. FDA also announced that industry stakeholders will have the option to upload electronic sortable spreadsheets or other traceability records into FDA's Safety Reporting Portal, which is a secure web-based portal that will be updated to include a traceability-specific landing page.<sup>58</sup>

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## To what extent is FDA planning for the rule's implementation?

FDA is in the early stages of planning for implementation of the rule and, as of October 2023, had not finalized and documented an overall implementation plan, according to FDA officials. These officials said that their planning involves developing the approaches, documents, tools, and other materials needed to implement the rule. FDA has made progress developing some high-level content for an implementation plan, according to agency officials. These officials noted that this content mirrors the structure of implementation plans FDA developed for other FSMA rules. In addition, officials said they have identified time frames for starting and completing planning activities.

FDA began some components of its implementation planning efforts in 2022 and expects related activities to continue past the 2026 compliance date, according to agency officials.<sup>59</sup> However, these officials told us they are preparing components of the implementation plan iteratively and expect certain components of the plan to be completed before 2026.<sup>60</sup>

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<sup>58</sup>Food and Drug Administration, *Safety Reporting Portal*, accessed Oct. 18, 2023, [www.safetyreporting.hhs.gov](http://www.safetyreporting.hhs.gov).

<sup>59</sup>FDA began its planning efforts in 2022 by starting development of the product tracing system, according to agency officials.

<sup>60</sup>FDA officials provided these dates in calendar years.

FDA officials described to us a list of the components of the implementation plan and a timeline for their development, as table 5 shows. For example, FDA officials stated that in 2027, they expect to finalize details of how they will manage the long-term implementation of the rule. In addition, FDA stated in its September 2023 announcement that it expects to start routine inspections in 2027. FDA plans to use the period between the compliance date and start of routine inspections to develop and provide training and other educational support to the agency’s nonfederal regulatory partners and industry.

**Table 5: The Food and Drug Administration’s (FDA) Planning Efforts for the Food Traceability Rule and Timeline**

| Components   | Activity status <sup>a</sup> | Expected completion date <sup>a</sup> |
|--|------------------------------|---------------------------------------|
| Training development – will include training modules for FDA investigators, nonfederal regulators, and industry  | In progress                  | 2025                                  |
| Inspection strategy – will detail procedures for conducting both routine inspections and “for cause” inspections—i.e., to address a specific cause, such as during an outbreak at a restaurant, retail food establishment, farm, or an FDA-registered food facility <sup>b</sup> | In progress                  | Before 2026                           |
| Compliance and enforcement strategy – will detail enforcement and compliance process, tools, and citation development for inspections, among other things  | Anticipated to begin in 2024 | Before 2026                           |
| Food traceability rule assignment and program development – will detail how FDA will manage the food traceability program over the long term, including issuance and frequency of field assignments  | Anticipated to begin in 2024 | 2027/ongoing <sup>c</sup>             |
| IT Development – Product Tracing System, food traceability rule-specific Safety Reporting Portal form for traceability data submission and other enhancements needed for inspectional data capture   | In progress                  | Before 2026                           |
| Performance measures and metrics –determine how and what types of data should be collected to evaluate how well the food traceability rule is being implemented and where there could be room for improvement  | In progress                  | Before 2026/ongoing <sup>c</sup>      |
| Stakeholder Outreach and Engagement – on rule requirements, updates to implementation; includes internal, domestic, and foreign stakeholders   | In progress                  | Before 2026/ongoing <sup>c</sup>      |

Source: GAO analysis of FDA officials’ statements. | GAO-24-106563

Note: According to FDA officials, planning involved in each component includes developing the approaches, documents, tools, and other materials needed to implement the rule.

<sup>a</sup>All dates are in calendar years.

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<sup>b</sup>In September 2023, FDA publicly announced that the agency expects to begin routine inspections related to the rule in 2027 but that inspections in cases of an outbreak or recall may begin after the compliance date of January 20, 2026.

<sup>c</sup>FDA officials also described certain activities as ongoing, meaning that certain components may be developed after 2026.

FDA officials stated they recognize the importance of outreach, training, and education to their nonfederal regulatory partners and industry. However, FDA has not finalized components of the plan or documented its inspection and compliance strategy, both of which are important to enable nonfederal regulatory partners and businesses to effectively implement or comply with the rule, respectively. These components include detailed information on the inspection process and enforcement strategy that nonfederal regulatory partners told us they need before they can begin conducting inspections and enforcing the rule. Such information, provided well ahead of the compliance date, could help nonfederal regulatory partners better prepare for enforcement of the rule. The plan's components also include additional outreach, education, and training on the rule that industry stakeholders told us they would need before they can fully comply with the rule's requirements by January 20, 2026.

GAO and project management leading practices provide a framework that agencies can use to manage time frames and reduce delays in achieving a regulatory goal—in FDA's case, ensuring entities comply with the traceability rule by January 20, 2026. Specifically, GAO has reported on key considerations that agencies can use for regulatory design and compliance to help them achieve their regulatory objectives.<sup>61</sup> For example, agencies should identify the optimal mix of compliance and enforcement tools they will use to implement a regulation.<sup>62</sup> Agencies can also manage time frames and reduce delays by using project management leading practices described by the Project Management Institute.<sup>63</sup>

According to FDA officials, as of October 2023, FDA had not finalized and documented an overall implementation plan for the traceability rule

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<sup>61</sup>GAO, *Federal Regulations: Key Considerations for Agency Design and Enforcement Decisions*, [GAO-18-22](#) (Washington, D.C.: Oct. 19, 2017).

<sup>62</sup>In addressing these considerations, agencies are to develop their regulatory approach to minimize burden on regulated entities, maximize efficiency, provide clarity, and coordinate to avoid duplication, among other things.

<sup>63</sup>These practices include identifying milestones, identifying and sequencing activities needed, and estimating the duration of the activities to develop the project schedule. Project Management Institute, Inc., *A Guide to the Project Management Body of Knowledge* (PMBOK® Guide), Seventh Edition, (2021).

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because agency efforts have focused on clarifying the Food Traceability List and providing an overview of the rule to industry and state partners.<sup>64</sup> It is understandable that FDA would prioritize these initial stages of implementing the rule's provisions. However, according to the framework we describe above, an agency should engage in this planning from the beginning of its regulatory compliance effort, to facilitate ongoing assessment of whether the effort is meeting the agency's regulatory goals—in this case, ensuring compliance with the traceability rule by January 20, 2026.<sup>65</sup> By finalizing and documenting an implementation plan, and communicating relevant information from this plan to stakeholders, as appropriate, FDA will have better assurance it is well positioned to make progress towards its regulatory goals. For example, FDA will have better assurance it can identify the resources it needs to implement the rule, define nonfederal regulatory partners' oversight roles, and provide additional education and training materials to industry, nonfederal regulatory partners, and FDA regulatory staff so that they are better prepared to comply with or enforce the rule by January 20, 2026. An implementation plan could also help FDA address some of the challenges stakeholders identified related to meeting the rule's requirements.

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## Conclusions

FDA's promulgation of the food traceability rule continues the agency's progress in developing the framework for a food safety system focused on preventing foodborne illness across the food supply chain. FDA has taken a number of steps to implement the rule in anticipation of the January 20, 2026, compliance date, including completing several actions required in FSMA and providing some education and outreach to entities covered by the rule. However, FDA's nonfederal regulatory partners told us they need additional information to clarify their enforcement roles, and industry stakeholders told us they need additional, timely guidance, education, and tools to comply with the rule.

While FDA has developed components of its implementation plan and general time frames for completing these planning efforts, it has not finalized components of the plan that are important for both nonfederal regulatory partners and industry to effectively implement or comply with the rule, nor has the agency documented its strategy. By finalizing and documenting its implementation plan, FDA will have better assurance it is

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<sup>64</sup>FDA officials also stated that the agency has not finalized and documented an overall implementation plan for the traceability rule because of the complexity of intra-agency and interagency activities involved.

<sup>65</sup>[GAO-18-22](#).

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well positioned to make progress toward its regulatory goal of achieving full industry compliance with the traceability rule by January 20, 2026.

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## Recommendation for Executive Action

The FDA Commissioner should direct the Center for Food Safety and Applied Nutrition to finalize and document an implementation plan to help the agency achieve its regulatory goal of compliance with the food traceability rule by January 20, 2026. Such a plan should include FDA's resource needs, strategies for facilitating compliance with the rule, and detailed plans for communicating with and educating regulated entities, nonfederal regulatory partners, and FDA regulatory staff about the rule's requirements. (Recommendation 1)

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## Agency Comments and Our Evaluation

We provided a draft of this report to the Department of Health and Human Services (HHS) for review and comment. In its written comments, reproduced in appendix V, HHS agreed with our recommendation. HHS also provided technical comments, which we incorporated as appropriate.

In its written comments, HHS recognized the importance of continued outreach, training, and education for regulatory partners and industry in advance of the January 20, 2026, compliance date. According to HHS, FDA's implementation planning for the food traceability rule is using the same project management framework used for the previous eight FSMA rules and continues to be documented, refined, and executed as FDA works towards the compliance date. FDA understands that the implementation of the food traceability rule will be challenging for some stakeholders and will continue to update and engage with industry and regulatory stakeholders as additional strategies and approaches are developed to facilitate compliance with the rule.

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We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or [morriss@gao.gov](mailto:morriss@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix VI.



Steve D. Morris  
Director, Natural Resources and Environment

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*List of Committees*

The Honorable Bernard Sanders  
Chair  
The Honorable Bill Cassidy  
Ranking Member  
Committee on Health, Education, Labor and Pensions  
United States Senate

The Honorable Jeanne Shaheen  
Chair  
The Honorable Joni Ernst  
Ranking Member  
Committee on Small Business and Entrepreneurship  
United States Senate

The Honorable Martin Heinrich  
Chair  
The Honorable John Hoeven  
Ranking Member  
Subcommittee on Agriculture, Rural Development, Food and Drug  
Administration, and Related Agencies  
Committee on Appropriations  
United States Senate

The Honorable Cathy McMorris Rodgers  
Chair  
The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Roger Williams  
Chair  
The Honorable Nydia Velázquez  
Ranking Member  
Committee on Small Business  
House of Representatives

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The Honorable Andy Harris  
Chair  
The Honorable Sanford Bishop, Jr.  
Ranking Member  
Subcommittee on Agriculture, Rural Development, Food and Drug  
Administration, and Related Agencies  
Committee on Appropriations  
House of Representatives



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# Appendix I: Objectives, Scope, and Methodology

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This report (1) describes the Food and Drug Administration (FDA) and selected stakeholder views on the development of the food traceability rule's recordkeeping requirements, including benefits and costs;<sup>1</sup> (2) describes FDA and selected stakeholder views on the exemptions from the rule requirements; and (3) examines FDA's actions to prepare for implementation of the rule and challenges FDA and selected stakeholders may face in achieving compliance with the rule. For all three objectives, we reviewed relevant laws and regulations. For example, we reviewed the FDA Food Safety Modernization Act, the food traceability rule, and other FDA rules related to food safety, such as *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, commonly referred to as the produce safety rule.<sup>2</sup>

To describe FDA's development of the food traceability rule's recordkeeping requirements, we reviewed FDA documents detailing its methodology for the development of the Food Traceability List.<sup>3</sup> We reviewed the results of FDA's risk-ranking model for food items added to the Food Traceability List and those not added to the list. We assessed the reliability of the model's results by interviewing agency officials knowledgeable about the data and reviewing related documentation, and determined that the data were sufficiently reliable to illustrate FDA's process for identifying foods added to the Food Traceability List. To describe the benefits and costs of the rulemaking requirements and the exemptions from the rule's requirements, we reviewed FDA's proposed and final analyses for the regulatory impact of the traceability rule.<sup>4</sup> We assessed the reliability of the estimates included in these documents by interviewing agency officials responsible for developing the estimates.

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<sup>1</sup>FDA promulgated its requirements for enhanced traceability in *Requirements for Additional Traceability Records for Certain Foods*, commonly referred to as the food traceability rule. 87 Fed. Reg. 70,910 (Nov. 21, 2022) (codified at 21 C.F.R. pt. 1, subpt. S).

<sup>2</sup>Pub. L. No. 111-353, 124 Stat. 3885 (2011). FDA, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, 80 Fed. Reg. 74,354 (codified at 21 C.F.R. pt. 112).

<sup>3</sup>Food and Drug Administration, *Methodological Approach to Developing a Risk-Ranking Model for Food Tracing* (Sept. 2022); and *Memo on Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing* (Oct. 31, 2022).

<sup>4</sup>Food and Drug Administration, *Requirements for Additional Traceability Records for Certain Foods: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis*, Docket No. FDA-2014-N-0053 (Sept. 23, 2020); and *Requirements for Additional Traceability Records for Certain Foods: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis*, Docket No. FDA-2014-N-0053 (Nov. 21, 2022).

While the estimates in FDA's analyses are considered rough, we determined that they were sufficiently reliable to broadly characterize the number of entities that FDA estimates will be covered by and exempted from the rule.<sup>5</sup>

To describe FDA and stakeholder viewpoints on the development of the rule's recordkeeping requirements, the exemptions to the rule, and challenges industry and FDA may face in achieving compliance with the rule, we interviewed FDA officials and selected stakeholders. To obtain FDA's viewpoints, we interviewed FDA officials from the Center for Food Safety and Applied Nutrition responsible for the design and implementation of the rule. We also reviewed FDA's response to public comments in the final food traceability rule and final regulatory impact analysis.

To obtain the perspectives of selected stakeholders, we conducted 20 semi-structured interviews with selected stakeholders representing industry, consumers, and nonfederal regulatory partners (see table 1).<sup>6</sup> We identified stakeholders by reviewing previous GAO reports and asking key stakeholders to recommend the names of other stakeholders. We then selected stakeholders for interviews to ensure our selection covered a range of the commodities included on the Food Traceability List and critical tracking events identified in the rule's requirements.<sup>7</sup> We used a semi-structured interview format to ask closed and open-ended questions about the rule's requirements, the exemptions, and challenges FDA and stakeholders face in achieving compliance with the rule. The stakeholders

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<sup>5</sup>FDA's estimates are considered rough because FDA did not have specific, tailored data sources to develop its regulatory impact analyses, according to FDA documents and officials. According to FDA officials, the agency relied on a variety of data sets and the viewpoints of experts to develop its conclusions, in the proposed and final regulatory impact analyses. FDA officials further noted that in developing these estimates they followed Office of Management and Budget and Department of Health and Human Services' guidelines. However, we did not assess the extent to which FDA followed these guidelines.

<sup>6</sup>The federal food safety system is integrated with Tribes, states, localities, and territories, which may have their own laws and agencies to address the safety and quality of food. In all, more than 3,000 nonfederal regulatory partners perform the great majority of government food safety activities, including inspections. See GAO, *Food Safety: FDA Coordinating with Stakeholders on New Rules but Challenges Remain and Greater Tribal Consultation Needed*, [GAO-16-425](#) (Washington, D.C.: May 19, 2016). For the purposes of this report, we refer to these nonfederal agencies as "nonfederal regulatory partners."

<sup>7</sup>For the purposes of this report, we use the term selected stakeholders to represent the industry, consumer, and nonfederal partner regulatory groups we interviewed, unless otherwise specified.

provided their perspectives from the viewpoint that the rule was finalized and promulgated by FDA, but the compliance period had not begun.

**Table 6: Selected Stakeholder Groups GAO Interviewed**

| <b>Industry associations</b>                                   |  |
|--|--|
| American Frozen Food Institute                                 | National Fisheries Institute                             |
| FMI, the Food Industry Association                             | National Grocers Association                             |
| Global Cold Chain Alliance                                     | National Milk Producers Federation                       |
| International Dairy Foods Association                          | National Restaurant Association                          |
| International Foodservice Distributors Association             | Peanut and Tree Nut Processors Association               |
| International Fresh Produce Association                        | Texas International Produce Association                  |
| Institute of Food Technologists                                | United Egg Producers                                     |
| National Association of Convenience Stores                     | Western Growers  |
| <b>Consumer advocacy organizations</b>                         |  |
| Center for Science in the Public Interest                      | Stop Foodborne Illness                                   |
| <b>Nonfederal regulatory partner organizations<sup>a</sup></b> |  |
| Association of Food and Drug Officials                         | National Association of State Departments of Agriculture |

Source: GAO. | GAO-24-106563

<sup>a</sup>The federal food safety system is integrated with Tribes, states, localities, and territories, which may have their own laws and agencies to address the safety and quality of food. For the purposes of our report, we refer to these nonfederal agencies as “nonfederal regulatory partners.”

We conducted a content analysis of the written summaries of the selected stakeholder interviews to identify categories of key themes related to FDA’s development of the recordkeeping requirements, the exemptions, and implementation challenges. To develop the categories of key themes, two analysts independently reviewed a sample of the written summaries and developed an initial list of categories and subcategories. These analysts then compared and reconciled their lists to develop one agreed-upon list of categories and subcategories. To code, one analyst applied the list of categories to each of the 20 interview discussion summaries. A second analyst reviewed the coding results for agreement. When there was a difference in coding, the two analysts discussed the categories to reach a resolution, and if they could not come to a resolution, then a third analyst served as the final decision-maker.

After identifying key themes and conducting the content analysis, we synthesized perspectives from the 20 semi-structured interviews to summarize the range of viewpoints. One analyst developed a summary statement of each theme, and a second analyst reviewed the summary

for agreement. These statements from the selected stakeholders are not generalizable to all industry groups, consumer advocacy organizations, or nonfederal regulatory partners.

Throughout this report, we used modifiers to characterize the selected stakeholders' views, which we define as follows:

- “some” stakeholders represents two to three stakeholders,
- “several” stakeholders represents four to nine stakeholders, and
- “many” stakeholders represents ten or more stakeholders.

We also conducted site visits to a food service distribution center, a cold storage warehouse, a restaurant, and a convenience store to obtain perspectives on the design of the recordkeeping requirements and exemptions and to observe how these entities were considering or starting implementation of the rule.<sup>8</sup> We selected these businesses based on recommendations from the industry stakeholder groups we interviewed. We developed written summaries from the site visits and used these visits to enhance our understanding of how the traceability rule will affect businesses and as illustrative examples in the report. These site visits provide examples of views and are not generalizable to all stakeholders, businesses, or others affected by the food traceability rule.

To examine actions FDA has taken to prepare for implementation of the rule, we reviewed FDA documents related to the rule, including guidance and outreach and education materials. We reviewed data on FDA's Technical Assistance Network to identify the number of inquiries submitted to the network about the traceability rule and FDA's average response time. We assessed the reliability of this information by interviewing knowledgeable agency officials and determined the data were sufficiently reliable for our report. We also interviewed officials from FDA's Center for Food Safety and Applied Nutrition responsible for the implementation of the rule. We compared FDA's plans for implementation

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<sup>8</sup>Foodservice distributors supply food and related products to restaurants, colleges and universities, hospitals and care facilities, hotels and resorts, and other foodservice operations. Cold storage refers to the management of temperature for perishable products.

against GAO's key considerations that agencies can use for regulatory design and compliance and leading practices for project management.<sup>9</sup>

We conducted this performance audit from January 2023 to January 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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<sup>9</sup>GAO, *Federal Regulations: Key Considerations for Agency Design and Enforcement Decisions*, [GAO-18-22](#) (Washington, D.C.: Oct. 19, 2017) and Project Management Institute, Inc., *A Guide to the Project Management Body of Knowledge (PMBOK® Guide)*, Seventh Edition (2021). PMBOK is a trademark of Project Management Institute, Inc. The Project Management Institute is a not-for-profit association that, among other things, provides standards for managing various aspects of projects, programs, and portfolios.

# Appendix II: Foods Added to the Food Traceability List and Associated Commodity Risk Scores

The Food and Drug Administration (FDA) established a Food Traceability List to identify foods for which additional traceability records are required (see table 7).<sup>1</sup> To identify foods for the list, FDA used a risk-ranking model based on criteria established by FDA in response to factors included in the FDA Food Safety Modernization Act. For each criterion evaluated, FDA assigned a numeric score of 0, 1, 3, or 9, with 0 representing the lowest level of public health risk and 9 representing the highest level of public health risk. Foods were added to the list if any food-hazard pair for that item had an aggregated risk score of 330 or higher.<sup>2</sup>

**Table 7: Items Added to the Food Traceability List and Associated Commodity Risk Scores**

| Food Traceability List items   | Description  | Risk-ranking model commodity risk score <sup>a</sup> |
|--|--|--|
| <b>Dairy products</b>  |  |  |
| Cheese (made from pasteurized milk), soft ripened or semi-soft             | Soft ripened/semi-soft cheeses. Examples include, but are not limited to, brie, camembert, feta, mozzarella, blue, Monterey jack, and muenster. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged. <sup>b</sup> | 490  |
| Cheese (made from pasteurized milk), fresh soft or soft unripened          | Soft unripened/fresh soft cheeses. Examples include, but are not limited to, cottage cheese, chevre, cream cheese, ricotta, and queso fresco. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged. <sup>b</sup>   | 430  |
| Cheese (made from unpasteurized milk), other than hard cheese <sup>c</sup> | All cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged. <sup>b</sup>  | 410  |
| <b>Eggs</b>  |  |  |
| Shell eggs   | The egg of the domesticated chicken.   | 450  |
| <b>Nuts and nut products</b>   |  |  |

<sup>1</sup>FDA established the Food Traceability List in response to the FDA Food Safety Modernization Act. Pub. L. No. 111-353, § 204(d)(2), 124 Stat. 3885, 3932 (2011) (codified at 21 U.S.C. § 2223(d)(2)).

<sup>2</sup>A commodity was also included on the list if the outbreaks and illnesses (criteria 1) and cost of illness (criteria 7) criterion scores for one or more associated commodity-hazard pairs were “strong,” providing evidence of a significant public health risk.

**Appendix II: Foods Added to the Food  
Traceability List and Associated Commodity  
Risk Scores**

|   |  |      |
|---|--|------|
| Nut butters   | All types and forms of tree nut and peanut butters, including shelf stable, refrigerated, and frozen products. Examples include, but are not limited to, almond, cashew, coconut, hazelnut, peanut, and walnut butters. Does not include soy or seed butters.  | 420  |
| <b>Prepared food</b>  |  |      |
| Ready-to-eat deli salads (refrigerated)                     | All types of refrigerated ready-to-eat deli salads. Examples include, but are not limited to, egg salad, potato salad, pasta salad, and seafood salad. Does not include meat salads.   | 330  |
| <b>Produce</b>  |  |      |
| Cucumbers (fresh)   | All varieties of fresh cucumbers.  | 430  |
| Leafy greens (fresh)  | All types of fresh leafy greens. Examples include, but are not limited to, arugula, chard, iceberg lettuce, kale, Romaine lettuce, and spinach. Does not include whole head cabbages, such as green cabbage, and banana leaves, grape leaves, and leaves that are grown on trees. Leafy greens exempt from the produce safety rule, such as collards, are exempt from the requirements of the food traceability rule. <sup>d</sup> | 430  |
| Melons (fresh)  | All types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, and watermelon.   | 430  |
| Tomatoes (fresh)  | All varieties of fresh tomatoes.   | 430  |
| Vegetables other than leafy greens (fresh cut) <sup>e</sup> | All types of fresh cut vegetables other than leafy greens. Vegetables exempt from the produce safety rule, such as asparagus, are exempt from the requirements of the food traceability rule. <sup>d</sup>   | 430  |
| Sprouts (fresh)   | All varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts. Examples include, but are not limited to, alfalfa sprouts, bean sprouts, broccoli sprouts, and other fresh sprouted grains, nuts, and seeds.   | 420  |
| Leafy greens (fresh cut) <sup>e</sup>                       | All types of fresh cut leafy greens, including single and mixed greens.  | 390  |
| Peppers (fresh)   | All varieties of fresh peppers.  | 370  |
| Tropical tree fruits (fresh)                                | All types of fresh tropical tree fruit. Examples include, but are not limited to, mango, papaya, and guava. Does not include non-tree fruits such as bananas, tree nuts such as coconut, pit fruits such as avocado, and citrus, such as orange.   | 370  |
| Fruits (fresh cut) <sup>e</sup>                             | All types of fresh cut fruits. Fruits exempt from the produce safety rule, such as figs, are exempt from the requirements of the food traceability rule. <sup>d</sup>  | 370  |
| Herbs (fresh)   | All types of fresh herbs. Examples include, but are not limited to, parsley, cilantro, and basil. Herbs exempt from the produce safety rule, such as dill, are exempt from the requirements of the food traceability rule. <sup>f</sup>  | 240f |

**Appendix II: Foods Added to the Food Traceability List and Associated Commodity Risk Scores**

| <b>Seafood</b>  |  |     |
|---|--|-----|
| Finfish, histamine-producing species (fresh and frozen)                         | All histamine-producing species of finfish. Examples include, but are not limited to, tuna, mahi mahi, mackerel, swordfish, and yellowtail.  | 430 |
| Crustaceans (fresh and frozen)  | All crustacean species. Examples include, but are not limited to, shrimp, crab, lobster, and crayfish.   | 430 |
| Molluscan shellfish, bivalves (fresh and frozen)                                | Includes all species of bivalve mollusks. Examples include, but are not limited to, oysters, clams, and mussels. Does not include scallop adductor muscle. Raw bivalve molluscan shellfish that are (1) covered by the requirements of the National Shellfish Sanitation Program; (2) subject to the requirements of 21 C.F.R. part 123, subpart C, and 21 C.F.R. § 1240.60; or (3) covered by a final equivalence determination by FDA are exempt from the requirements of the food traceability rule. <sup>g</sup> | 380 |
| Finfish, species not associated with histamine or ciguatoxin (fresh and frozen) | All species of finfish not associated with histamine or ciguatoxin. Examples include, but are not limited to, cod, haddock, Alaska pollock, salmon, tilapia, and trout. Siluriformes fish, such as catfish, are not included, because they are subject to U.S. Department of Agriculture regulations.  | 370 |
| Smoked finfish (refrigerated and frozen)  | All types of smoked finfish, including cold smoked finfish and hot smoked finfish.   | 360 |
| Finfish, species potentially contaminated with ciguatoxin (fresh and frozen)    | All finfish species potentially contaminated with ciguatoxin. Examples include, but are not limited to, grouper, barracuda, and snapper.   | 330 |

Source: Food and Drug Administration. | GAO-24-106563

<sup>a</sup>To identify foods for the list, FDA used a risk-ranking model based on six criteria established in the FDA Food Safety Modernization Act. For each criterion evaluated, FDA assigned a numeric score of 0, 1, 3, or 9, with 0 representing the lowest level of public health risk and 9 representing the highest level of public health risk. Foods were added to the list if any food-hazard pair for that item had an aggregated risk score of 330 or higher. The risk score is calculated by summing equally weighted criteria scores across all seven criteria.

<sup>b</sup>Aseptic processing and packaging means the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.

<sup>c</sup>Examples of hard cheese include, but are not limited to, cheddar, Romano, and Parmesan.

<sup>d</sup>21 C.F.R. pt. 112.

<sup>e</sup>Examples of fresh cut items include those that have been cut, shredded, sliced, chopped, or torn.

<sup>f</sup>A commodity was also included on the list if the outbreaks and illnesses (criteria 1) and cost of illness (criteria 7) criterion scores for one or more associated commodity-hazard pairs were "strong," providing evidence of a significant public health risk.

<sup>g</sup>Equivalence determinations recognize that another country's food safety requirements for these products, though different from FDA's, provide at least the same level of public health protection.



# Appendix III: The Food and Drug Administration’s Estimates of Small Business Compliance Costs per Firm

The Food and Drug Administration (FDA) assessed the benefits and costs of the food traceability rule, including the compliance costs for small businesses as defined by the Small Business Administration.<sup>1</sup> Tables 8 and 9 provide information on the estimated annualized compliance costs per small firm and the compliance costs as a percentage of annual revenue.

**Table 8: The Food and Drug Administration’s (FDA) Estimates of Annualized Small Firm Compliance Costs, by Firm, of the Final Food Traceability Rule**

Dollars

|   | Primary estimate | Low estimate | High estimate |
|---|------------------|--------------|---------------|
| Farms/growers (produce, non-sprouts)            | 849              | 144          | 5,700         |
| Farms/growers (sprouts)                         | 4,295            | 581          | 29,950        |
| Farms (shell eggs)                              | 3,801            | 674          | 22,007        |
| Fishing/aquaculture                             | 3,941            | 684          | 14,197        |
| Manufacturing/processing                        | 4,625            | 314          | 20,668        |
| Wholesalers/distributors/warehouses and storage | 8,027            | 349          | 26,751        |
| Retail – non-restaurants                        | 402              | 61           | 1,636         |
| Restaurants                                     | 180              | 61           | 729           |

Source: Food and Drug Administration. | GAO-24-106563

Note: These estimates are annualized over 20 years at a 7 percent discount rate, according to FDA’s analysis. FDA’s estimates are considered rough because FDA did not have specific, tailored data sources to develop its regulatory impact and regulatory flexibility analyses, according to FDA documents and officials. According to FDA officials, the agency relied on a variety of data sets and the viewpoints of experts to develop its conclusions in the proposed and final regulatory impact analyses and regulatory flexibility analyses. FDA officials further noted that in developing these estimates they followed Small Business Administration, Office of Management and Budget, and Department of Health and Human Services’ guidelines. However, we did not assess the extent to which FDA followed these guidelines.

<sup>1</sup>Food and Drug Administration, *Requirements for Additional Traceability Records for Certain Foods: Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis*, Docket No. FDA-2014-N-0053 (Nov. 21, 2022).

**Appendix III: The Food and Drug  
Administration's Estimates of Small Business  
Compliance Costs per Firm**

**Table 9: The Food and Drug Administration's (FDA) Estimates of Annualized Small Firm Compliance Costs, by Firm, as a Percentage of Annual Revenue**

|   | <b>Primary estimate</b> | <b>Low estimate</b> | <b>High estimate</b> |
|---|-------------------------|---------------------|----------------------|
| Farms/growers (produce, non-sprouts)            | 0.38%                   | 0.06%               | 2.56%                |
| Farms/growers (sprouts)                         | 0.79%                   | 0.11%               | 5.52%                |
| Farms (shell eggs)                              | 0.12%                   | 0.02%               | 0.71%                |
| Fishing/aquaculture                             | 0.75%                   | 0.13%               | 2.69%                |
| Manufacturing/processing                        | 0.06%                   | 0.00%               | 0.25%                |
| Wholesalers/distributors/warehouses and storage | 0.10%                   | 0.00%               | 0.32%                |
| Retail – non-restaurants                        | 0.02%                   | 0.00%               | 0.10%                |
| Restaurants                                     | 0.02%                   | 0.01%               | 0.06%                |

Source: Food and Drug Administration. | GAO-24-106563

Note: These estimates are annualized over 20 years at a 7 percent discount rate, according to FDA's analysis. FDA's estimates are considered rough because FDA did not have specific, tailored data sources to develop its regulatory impact and regulatory flexibility analyses, according to FDA documents and officials. According to FDA officials, the agency relied on a variety of data sets and the viewpoints of experts to develop its conclusions in the proposed and final regulatory impact analyses and regulatory flexibility analyses. FDA officials further noted that in developing these estimates they followed Small Business Administration, Office of Management and Budget, and Department of Health and Human Services' guidelines. However, we did not assess the extent to which FDA followed these guidelines.

# Appendix IV: Full and Partial Exemptions to the Food Traceability Rule

**Table 10: Full and Partial Exemptions to the Food Traceability Rule**

| Exempted entity or item                           | Description   | Exemption type    |                      |
|---|---|-------------------|----------------------|
|   |   | Full <sup>a</sup> | Partial <sup>b</sup> |
| Certain produce farms                             | <p>Farms or the farm activities of farm mixed-type facilities with respect to the produce they grow, when the farm is not a covered farm under the produce safety regulation.</p> <p>Farms whose average annual sum of the monetary value of their sales of produce and the market value of produce they manufacture, process, pack, or hold without sale over the previous 3-year period is no more than \$25,000.<sup>c</sup></p> | ●                 |                      |
| Certain shell egg producers                       | Shell egg producers with less than 3,000 laying hens at a particular farm.  | ●                 |                      |
| Certain producers of raw agricultural commodities | Producers of raw agricultural commodities, other than produce or shell eggs, with an average annual sum of the monetary value of the sale of raw agricultural commodities and the market value of raw agricultural commodities they manufacture, process, pack, or hold without sale is not greater than \$25,000 over the previous 3-year period. <sup>c</sup>   | ●                 |                      |
| Farms who sell or donate directly to consumers    | Farms with respect to food produced on the farm (including food that is also packaged on the farm) that is sold or donated directly to a consumer by the owner, operator, or agent in charge of the farm.   | ●                 |                      |
| Certain foods produced or packaged on a farm      | Foods produced on a farm where the packaging of the food remains in place until the food reaches the consumer, provided that: (1) the packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and (2) the labeling of the food that reaches the consumer includes certain contact and locating information for the farm in which the food was produced and packaged.   | ●                 |                      |

**Appendix IV: Full and Partial Exemptions to the Food Traceability Rule**

|  |  |   |
|--|--|---|
| Foods that receive certain types of processing                             | Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance. <sup>d</sup>   | ● |
|  | Shell eggs when all eggs produced at the particular farm receive a treatment. <sup>e</sup>   | ● |
|  | Food that is subject to a kill step. <sup>f</sup>  | ● |
|  | Food that is changed such that the food is no longer on the Food Traceability List. <sup>g</sup>   | ● |
|  | Food received that has previously been subjected to a kill step or that has previously been changed such that the food is no longer on the Food Traceability List.   | ● |
|  | Food that will be subjected to a kill step, or changed, such that the food will no longer be on the Food Traceability List, unless the kill step or the change will be done by a retail food establishment, restaurant, or consumer. <sup>h</sup>                          | ● |
| Produce that is rarely consumed raw  | Applies to produce that is listed as rarely consumed raw. <sup>i</sup>   | ● |
| Certain shellfish  | Raw bivalve molluscan shellfish. <sup>j</sup>  | ● |
| Certain foods that are regulated by the U.S. Department of Agriculture     | Persons who manufacture, process, pack, or hold food on the Food Traceability List during or after the time when the food is within the exclusive jurisdiction of the U.S. Department of Agriculture. <sup>k</sup>   | ● |
| Commingled raw agricultural commodities                                    | Commingled raw agricultural commodities that are not subject to the produce safety rule, such as seafood and eggs. <sup>l</sup>  | ● |
|  | Raw agricultural commodities that will become a commingled raw agriculture commodity in the future. <sup>h</sup>   | ● |
| Small retail food establishments and small restaurants                     | Small retail food establishments and small restaurants with a 3-year average annual value of foods sold or provided of no more than \$250,000. <sup>c</sup>  | ● |
| Retail food establishments and restaurants purchasing directly from a farm | Retail food establishments and restaurants partially exempt with respect to food that is produced on a farm (including food produced and packaged on the farm) and both sold and shipped directly to the retail food establishment or restaurant by the farm. <sup>m</sup> | ● |

**Appendix IV: Full and Partial Exemptions to the Food Traceability Rule**

|  |   |   |
|--|---|---|
| Retail food establishments and restaurants making certain purchases from another retail food establishment or restaurant | Retail food establishments and restaurants partially exempt with respect to purchases made by a retail food establishment or restaurant from another retail food establishment or restaurant, and the purchase occurs on an ad hoc basis outside of the buyer's usual purchasing practice.                                | ● |
| Farm-to-school and farm-to-institution programs  | Institution operating certain child nutrition programs with respect to food that is produced on a farm (including food produced and packaged on the farm) and sold or donated to the school or institution. <sup>n</sup>  | ● |
| Fishing vessels  | Owner, operator, or agent in charge of a fishing vessel with respect to food that is obtained from the fishing vessel. This does not apply to persons who manufacture, process, pack, or hold the food until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel. <sup>o</sup> | ● |
| Food transporters  |   | ● |
| Nonprofit food establishments  |   | ● |
| Persons who manufacture, process, pack, or hold food for personal consumption  |   | ● |
| Certain persons who hold food on behalf of individual consumers  | Persons who hold food on behalf of specific consumers and are not parties to the transaction regarding the food they hold and are not in the business of distributing food.   | ● |
| Food for research or evaluation  | Food for research or evaluation use that is not intended for retail sales and not sold or distributed to the public and is accompanied by the statement "food for research or evaluation use."  | ● |

Source: 87 Fed. Reg. 70,910 (Nov. 21, 2022) (codified at 21 C.F.R. pt. 1, subpt. S). | GAO-24-106563

Note: Exemptions are listed in the order in which they appear in the final rule.

<sup>a</sup>Full exemptions exempt an establishment from all requirements of the proposed rule.

<sup>b</sup>Partial exemptions are for those foods or entities that do not qualify for a full exemption but have modified traceability requirements.

<sup>c</sup>On a rolling basis, adjusted for inflation, using 2020 as the baseline year for calculating the adjustment.

<sup>d</sup>Provided the conditions in 21 C.F.R. § 112.2(b) of the produce safety rule are met.

<sup>e</sup>As defined in 21 C.F.R. § 118.3, in accordance with 21 C.F.R. § 118.1(a)(2) of the shell egg regulation.

<sup>f</sup>Provided that businesses keep (1) receiving records under § 1.1345 of the food traceability rule and (2) a record of the application of the kill step.

<sup>g</sup>Provided that businesses keep receiving records under § 1.1345 of the food traceability rule.

<sup>h</sup>Provided that certain conditions are met regarding written agreements between shipper of food and receiver.

<sup>i</sup>As listed at 21 C.F.R. § 112.2(a)(1) of the produce safety regulation.

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**Appendix IV: Full and Partial Exemptions to  
the Food Traceability Rule**

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<sup>j</sup>Applies to shellfish that are covered by the requirements of the National Shellfish Sanitation Program subject to other regulations or covered by a final equivalence determination.

<sup>k</sup>This applies to U.S. Department of Agriculture exclusive jurisdiction under regulations the Federal Meat Inspection Act, The Poultry Products Inspection Act, or the Egg Products Inspection Act.

<sup>l</sup>These standards are for growing, harvesting, packing, and holding of produce for human consumption.

<sup>m</sup>Provided certain records are maintained containing information about the farm for 180 days.

<sup>n</sup>Applies to institutions operating child nutrition programs under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966 or any other entity conducting a farm-to-school or farm-to-institution program. The school food authority or relevant food procurement entity must maintain a record documenting the name and address of the farm that was the source of the food and such records shall be maintained for 180 days.

<sup>o</sup>Provided that in some situations certain records must be maintained for a period of 2 years.

# Appendix V: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

January 4, 2024

Steve D. Morris  
Director, Natural Resources and Environment  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"Food Safety: FDA Should Finalize Plans to Implement Its Rule to Help Trace Source of Outbreaks"** (GAO-24-106563).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

*Melanie Anne Egorin*

Melanie Anne Egorin, PhD  
Assistant Secretary for Legislation

Attachment

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**Appendix V: Comments from the Department  
of Health and Human Services**

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**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – FOOD SAFETY: FDA SHOULD FINALIZE PLANS TO IMPLEMENT ITS RULE TO HELP TRACE SOURCE OF OUTBREAKS (GAO-24-106563)**

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and provide comments on the Government Accountability Office's (GAO) draft report.

**GAO Recommendation**

The FDA Commissioner should direct the Center for Food Safety and Applied Nutrition to finalize and document an implementation plan to help the agency achieve its regulatory goal of compliance with the food traceability rule by January 20, 2026. Such a plan should include FDA's resource needs, strategies for facilitating compliance with the rule, and detailed plans for communicating with and educating regulated entities, nonfederal regulatory partners, and FDA regulatory staff about the rule's requirements.

**HHS Response**

HHS concurs with this recommendation.

Implementation for the Food Traceability Rule (FTR) was initiated using the same project management framework utilized for the previous eight FSMA rules and continues to be documented, refined and executed as the Agency works towards the compliance date. We recognize the importance of continued outreach, training, and education for regulatory partners and industry in advance of the January 20, 2026, compliance date. As additional strategies and approaches are developed to facilitate compliance with the requirements of the rule, FDA will continue to update and engage with industry and regulatory stakeholders.

Since the publication of the proposed rule on September 23, 2020, final rule publication on November 22, 2022, and the conclusion of GAO's study in October 2023, FDA has worked to provide additional outreach, educational materials, tools and clarification on the rule requirements to both industry and regulatory partners to keep stakeholders informed and help covered entities come into compliance. In September 2023, FDA announced that routine inspections under the FTR will not begin until 2027 to give covered entities additional time to work together and ensure that traceability information is being maintained and shared within supply chains per the requirements of the rule. The Agency understands that implementation of the FTR could be challenging for some stakeholders and remains responsive and committed to addressing stakeholder concerns related to potential barriers related to complying with rule requirements as well as the need for a cohesive and uniform compliance and enforcement strategy that can also be leveraged by regulatory partners.



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# Appendix VI: GAO Contact and Staff Acknowledgements

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## GAO Contact

Steve D. Morris, (202) 512-3841 or [morriss@gao.gov](mailto:morriss@gao.gov)

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## Staff Acknowledgements

In addition to the contact named above, Anne K. Johnson (Assistant Director), Emily Ryan (Analyst in Charge), Adrian Apodaca, Matthew Bond, Kevin Bray, Mark Braza, Tara Congdon, Amanda Nelsen, and Josie Ostrander made key contributions to this report.

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