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SUMMARY

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The Food and Drug Administration's Food Traceability Rule: Overview and Issues for Congress

Foodborne illness outbreaks and subsequent recalls have garnered broad public attention to the safety of the U.S. food supply. The Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA; P.L. 111-353), enacted in 2011, aimed to improve food safety, among other objectives. In Section 204 of FSMA, Congress directed FDA to improve the tracking and tracing of food through the supply chain by establishing additional recordkeeping requirements for facilities handling certain foods frequently associated with foodborne illness outbreaks. The additional recordkeeping requirements were intended to enable more efficient removal of products from the market in the case of an outbreak leading to a recall. FDA has established these recordkeeping requirements in the Food Traceability Rule, as described below.

Prior to FSMA, some entities that handled, manufactured, packed, transported, or distributed food were required to keep records to trace food one step forward and one step back in the supply chain. Notably, farms and restaurants were *not* required to keep such records. Through FSMA, §204, Congress directed FDA to conduct pilot projects, collect and assess data, establish a list of high-risk foods, and issue regulation establishing additional recordkeeping requirements for foods on the high-risk list. Congress directed the agency to require certain records from entities that "manufacture, process, pack, or hold" foods on the list, including some previously exempt food establishments. FDA was to ensure the requirements were science-based and proportionate to risks associated with the food; that the public health benefits would outweigh the compliance costs; and that the burden on subject entities would be minimized whenever possible.

FDA has implemented many of the Section 204 requirements. Some implementation has occurred after the deadlines set by Congress. On September 23, 2020, FDA published the proposed rule, "Requirements for Additional Traceability Records for Certain Foods" (the "Food Traceability Rule"), and requested comments on the rule and its accompanying list of high-risk foods (the "Food Traceability List"). FDA published the final Food Traceability Rule, as well as the Food Traceability List, on November 21, 2022. The Food Traceability List includes some fresh-cut produce, some soft cheeses, shell eggs, nut butters, and some seafood. The Food Traceability Rule requires facilities that perform certain activities with these products to keep specific records to facilitate faster identification of the source of a foodborne illness outbreak. Enforcement of the rule spans across the supply chain: from harvest to transformation or processing, through distributors of the food product, to the final product sold at a restaurant or grocery store. Subject entities handling a food on the Food Traceability List are to maintain specific records for certain points in the item's supply chain. In addition, subject entities are to provide FDA with specific 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 public health threat. FDA estimated that the final rule would cover more than 323,000 domestic businesses operating more than 484,100 establishments and set the initial compliance date for January 20, 2026.

In January 2024, the Government Accountability Office recommended that FDA finalize and document an implementation plan for the Food Traceability Rule to meet the 2026 compliance date. In September 2024, a stakeholder roundtable report published by the Reagan-Udall Foundation for the FDA indicated that industry stakeholders may not be aware of or prepared to be in compliance with the rule by January 2026. In March 2025, FDA announced its intention to extend the compliance date by 30 months and, in August 2025, published a notice of proposed rulemaking to provide additional time to covered entities to coordinate across the supply chain to fully implement the rule. In the FY2026 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act (P.L. 119-37, Division B), Congress further directed that "no funds appropriated by this act may be used to administer or enforce the [Food Traceability Rule] ... prior to July 20, 2028." Congress directed FDA to provide guidance and engage with stakeholders and to report on its implementation plan and the status of its product tracing system.

Congress has provided direction to FDA on its implementation of FSMA and may use oversight mechanisms to continue to evaluate whether FDA activities to implement Section 204 are accomplishing the law's intended goals. Congress may also consider whether or not additional legislation may be necessary to direct FDA's actions and rule enforcement. Such legislation may include directing FDA to conduct additional pilot projects or tabletop exercises, to finalize an implementation plan, and to exempt certain entities from being subject to the rule. Congress may also consider whether further action is needed to achieve the goal of improving food safety through increased food traceability.

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Introduction

The Food and Drug Administration (FDA) regulates about 80% of the U.S. food supply, covering more than 220,000 domestic and foreign registered facilities (such as food manufacturing plants, packers, and distributors) and nonregistered facilities (such as restaurants, food banks, fishing vessels, and other entities in the food supply chain).[1] FDA-regulated foods include produce, seafood, shell eggs, packaged foods, and processed foods, among others.[2]

Since 2024, FDA has investigated more than 50 foodborne illness outbreaks responsible for causing at least 2,592 illnesses, 357 hospitalizations, and 27 deaths.[3] The U.S. Department of Agriculture (USDA) Economic Research Service (ERS) has estimated the annual economic burden of foodborne illnesses acquired domestically to be $75 billion in 2023 dollars.[4]

FDA investigations identified the microbial contaminants causing some of the illnesses, including *E. coli* in carrots, raw cheddar cheese, onions, romaine lettuce, and walnuts; *Salmonella* in cucumbers, basil, mangoes, and eggs; and *Listeria* in soft cheeses, bagged salads, and packaged sandwiches.[5] In at least 10 investigations—covering at least 300 of the people who have fallen ill—the contaminated food product has not been identified.[6] Studies conducted by federal public health agencies have shown that certain foods—such as fresh produce, meats, and dairy—are more frequently associated with foodborne illnesses than others.[7]

During an outbreak investigation, public health investigators attempt to identify contributing factors that led to people becoming ill. Contributing factors include "food preparation practices, behaviors, and environmental conditions that lead to pathogens getting into food [i.e.,

[1] Facilities that manufacture, process, pack, or hold food for consumption are to be registered with the Food and Drug Administration (FDA; 21 U.S.C. §350d). Food facilities not required to be registered with FDA include farms, fishing vessels, and restaurants (21 C.F.R. Part 1, Subpart J). The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) regulates the rest of the U.S. food supply, including most meat and poultry and some egg products. FDA, "FDA at a Glance," https://www.fda.gov/economics-staff/fda-glance. For more information about FSIS, see CRS In Focus IF12784, *Federal Inspection of Meat, Poultry, and Egg Products*.

[2] FDA regulates the production, transportation, and storage of shell eggs, which are eggs in the shell from the domesticated chicken, turkey, duck, goose, or guinea. For the purposes of FDA's Food Traceability Rule, only eggs from the domesticated chicken are considered shell eggs. FDA, "Egg Guidance, Regulation, and Other Information," https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/egg-guidance-regulation-and-other-information; and FDA, "Food Traceability List," https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list.

[3] FDA, "Investigations of Foodborne Illness Outbreaks," https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks (hereinafter FDA, "Investigations of Foodborne Illness Outbreaks").

[4] The Economic Research Service (ERS) under USDA estimates included costs incurred because of severity and duration of illness, resulting chronic health problems, medical treatment costs, value of time, and the value of preventing premature death. Sandra Hoffman et al., "Economic Burden of Foodborne Illnesses Acquired in the United States," *Foodborne Pathogens and Disease*, vol. 22, no. 1 (2025), p. 7.

[5] FDA, "Investigations of Foodborne Illness Outbreaks."

[6] When the food associated with the outbreak is unknown, other tools, such as genetic sequencing of the microbe, can be used to link illnesses to the food. FDA, "Investigations of Foodborne Illness Outbreaks."

[7] According to the most recent Interagency Food Safety Analytics Collaboration (IFSAC) report, which uses outbreak data from 1998 through 2022, foodborne *E. coli* O157:H7 and *Listeria* illnesses were most frequently attributed to the FDA-regulated food categories vegetable row crops (e.g., lettuce, broccoli, celery, etc.) and dairy, respectively. In this study, more than 75% of *Salmonella* illnesses were attributed to categories such as chicken, pork, beef, turkey, fruits, seeded vegetables, and other produce. IFSAC, "Foodborne Illness Source Attribution Estimates – United States, 2022," https://www.cdc.gov/ifsac/php/data-research/annual-report-2022.html.

contamination], growing on food, or surviving in food."[8] For example, contamination may come from the environment where the food was grown, a crew of sick employees, water or ice that comes into contact with food, or poor sanitation on a packing line. Incorrect temperature controls, or other processing errors, may lead to survival or continued growth of pathogens on food.

According to FDA, the ability to efficiently trace food products linked to a foodborne illness outbreak can help government agencies and those who produce and sell food identify where the product came from and where contributing factors might have occurred.[9] *Food traceability* generally refers to the ability to trace the movement of food and ingredients through each stage of production, processing, and distribution.[10] Effective food traceability often requires information collection, recordkeeping, and planning among supply chain partners, as well as mechanisms to link this information as the food moves from one step to the next.[11]

Traceability enables regulators and entities throughout the supply chain (e.g., producers, processors, distributors, and retail establishments) to remove foods from the market when necessary.[12] When a foodborne illness outbreak is linked to a specific product in a grocery store or other food retailer, the contaminated product is often pulled from the market in what is known as a *food recall*.[13] Food recalls are implemented as a measure to reduce foodborne illnesses associated with a known or suspected contamination of a food on the market.[14] Academic researchers estimated the cost of the November 2018-2019 *E. coli* outbreak in romaine lettuce to range from $276 to $343 million.[15]

The FDA Food Safety Modernization Act

Congress has passed legislation to improve food safety in the United States. The FDA Food Safety Modernization Act (FSMA; P.L. 111-353) amended the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§301 et seq.) and directed FDA to issue regulations focused on

[8] To identify contributing factors, public health investigators review data from epidemiologic, laboratory, environmental, and interview sources. Meghan M. Holst et al., *Contributing Factors of Foodborne Illness Outbreaks—National Outbreak Reporting System, United States, 2014-2022*, U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC), MMWR vol. 74, no. 1, March 13, 2025, p. 2, https://pmc.ncbi.nlm.nih.gov/articles/PMC11908744/pdf/ss7401a1.pdf.

[9] FDA, "Tracking and Tracing of Food," accessed January 13, 2026, https://www.fda.gov/food/new-era-smarter-food-safety/tracking-and-tracing-food (hereinafter FDA, "Tracking and Tracing of Food").

[10] Neither Congress nor FDA provide an explicit definition for food traceability. FDA refers to food traceability generally as a way to "effectively and rapidly link shipments of food through each point in the supply chain." The Codex Alimentarius Commission, an international food safety standards organization, defines traceability as "the ability to follow the movement of a food through specified stage(s) of production, processing and distribution." FDA, "Requirements for Additional Traceability Records for Certain Foods," 87 *Federal Register* 70910, 70912-70913, November 21, 2022; and Food and Agriculture Organization of the United Nations, "Traceability and Recalls," https://www.fao.org/food-safety/food-control-systems/traceability---recalls/en.

[11] Claudina Padilla Quiñonez et al., "Traceability in the United States Food Supply," *Oklahoma State Extension*, August 2024.

[12] FDA, "Requirements for Additional Traceability Records for Certain Foods," 87 *Federal Register* 70910, 70912, November 21, 2022.

[13] FDA, "Recalls, Outbreaks, and Emergencies," October 4, 2024, https://www.fda.gov/food/recalls-outbreaks-emergencies.

[14] CDC, "How CDC Investigates Foodborne Outbreaks," November 21, 2025, https://www.cdc.gov/foodborne-outbreaks/outbreak-basics/index.html.

[15] This estimated cost includes factors such as total value of product that was unable to be sold, losses to supply chain entities, loss of sales or employment due to the outbreak, among others. Ashley Spalding et al., "Economic Impacts of Food Safety Incidents in a Modern Supply Chain: *E. coli* in the Romaine Lettuce Industry," *American Journal of Agricultural Economics*, vol. 105, no. 2 (March 2023), pp. 597-623.

preventing contamination that causes foodborne illness across the food supply chain. Before FSMA, for many foods, FDA's regulatory approach toward foodborne illness was reactive (i.e., requesting a voluntary food recall in response to a foodborne illness outbreak).[16] FSMA also provided FDA with additional inspection authorities and mandatory recall authority if the agency deemed or suspected regulated foods to be adulterated, or unsafe.

Through FSMA, Congress also directed FDA and other agencies to improve the federal capacity to detect and respond to foodborne illness outbreaks.[17] Specifically, FSMA required FDA to promulgate a rule establishing additional recordkeeping requirements to better track foods associated with foodborne illness throughout the supply chain, and to take certain actions to inform the development of the rule.[18] Before FSMA, entities that "manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States" (not including farms, restaurants, certain fishing vessels, and nonprofit food organizations) were required to keep records identifying one step forward and one step back in the supply chain (P.L. 107-188, Title III, §306).[19]

FDA published the final rule "Requirements for Additional Traceability Records for Certain Foods" (the "Food Traceability Rule") on November 21, 2022, with an initial compliance date of January 20, 2026.[20] In August 2025, FDA announced an extension of the compliance deadline to July 20, 2028.[21] Subsequently, in November 2025, Congress restricted FDA from using appropriated funds to administer or enforce the rule before FDA's delayed compliance date.[22]

This report summarizes Section 204 of FSMA and its implementation, including FDA's promulgation of the Food Traceability Rule, FDA's plans to develop an internal product tracing system, and recent developments regarding the rule's compliance date.[23] The report also discusses issues of potential interest to Congress, such as existing oversight efforts and additional policy options regarding FDA's implementation of FSMA, Section 204.

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[16] Before FSMA, certain entities, including restaurants and farms, were excluded from food facility registration and subsequent recordkeeping requirements. FDA, "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," 69 *Federal Register* 71562, December 9, 2004; and FDA, *Report to Congress: On Enhancing Tracking and Tracing of Food and Recordkeeping, Submitted Pursuant to Section 204 of the FDA Food Safety Modernization Act*, P.L. 111-353, November 16, 2016, https://www.fda.gov/media/102784/download?attachment (hereinafter FDA, *Report to Congress: On Enhancing Tracking and Tracing of Food and Recordkeeping*).

[17] FSMA, §205.

[18] Section 204 of the FDA Food Safety Modernization Act (FSMA; P.L. 111-353) directed the HHS Secretary to issue additional recordkeeping requirements for certain foods. The recordkeeping requirements were to be in addition to the existing regulations that required the identification of the immediate previous sources and immediate subsequent recipients of food. FDA, "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," 69 *Federal Register* 71562, December 9, 2004. The HHS Secretary has delegated some of HHS's regulation authority pertaining to the FFDCA to FDA. HHS, "FDA; Delegation of Authority," 86 *Federal Register* 49337, September 2, 2021.

[19] The recordkeeping regulations established before FSMA for registered food facilities are at 21 C.F.R. Part 1, Subpart J (21 C.F.R. §1.326). In 2016, FDA noted that this recordkeeping was not sufficient to efficiently trace and track food in the case of a foodborne illness outbreak. FDA, *Report to Congress: On Enhancing Tracking and Tracing of Food and Recordkeeping*, p. 10.

[20] FDA, "Requirements for Additional Traceability Records for Certain Foods," 87 *Federal Register* 70910, November 21, 2022.

[21] FDA, "Requirements for Additional Traceability Records for Certain Foods: Compliance Date Extension," 90 *Federal Register* 38084, August 7, 2025.

[22] Section 780, Division B of the FY2026 Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act (P.L. 119-37).

[23] This report does not discuss any other FSMA provisions or regulations in detail.

Selected Events Since Congress Enacted the Food Safety Modernization Act

2011-2012	On behalf of the Food and Drug Administration (FDA), the Institute of Food Technologists conducted required pilot projects and submitted its report to the agency.
2014	FDA requested comments, information, and scientific data to inform its development of the Food Traceability List of high-risk foods.
2016	FDA submitted a report to Congress that included the results of the pilot projects, additional information received by stakeholders, and difficulties experienced in conducting successful traceback investigations.
2018	Advocacy groups Center for Food Safety and Center for Environmental Health sued FDA for failure to meet statutory requirements such as issuing the proposed Food Traceability Rule by the congressional deadline in Section 204 of FSMA.
2020	FDA published the proposed Food Traceability Rule and a draft of the Food Traceability list and requested public comments.
2022	FDA finalized the Food Traceability Rule and Food Traceability List and set the compliance date for January 20, 2026.
2024	The Government Accountability Office published its evaluation of the Food Traceability Rule and recommended that FDA finalize its implementation plans.
2024	The Reagan-Udall Foundation held public meetings and roundtable discussions with industry regarding the Food Traceability Rule.
2025	FDA announced a 30-month compliance date delay for the Food Traceability Rule.
2025	Congress enacted the FY2026 appropriations law, which included provisions prohibiting rule enforcement before July 2028 and directing FDA action during the delay.
2026	FDA issued draft guidance for industry and announced quarterly listening sessions in conjunction with the Partnership for Food Traceability.

FSMA Section 204: Enhancing Tracking and Tracing of Food and Recordkeeping

In passing FSMA, Congress directed the Secretary of Health and Human Services (HHS) to improve the safety of the food supply through a prevention-based framework and to more effectively respond to foodborne illness outbreaks. Specifically, Section 204 of FSMA required FDA to promulgate a rule, as informed by pilot projects and data gathering, to improve the government's ability to determine the source of foodborne illness outbreaks through additional recordkeeping.[24]

Pilot Projects and Data Gathering

FSMA, Section 204, directed the HHS Secretary to conduct pilot studies.[25] The objective of these studies was to evaluate methods to rapidly identify food recipients so that foodborne illness outbreaks could be prevented or mitigated, and to address any credible threat of adulterated or

[24] Section 204 of FSMA is codified at 21 U.S.C. §2223. In this report, referenced sections refer to the provisions of the act.

[25] FSMA, §204(a).

misbranded foods that may cause serious health consequences.[26] The Secretary was to consider recommendations from the Secretary of Agriculture and state health and agriculture departments, and to conduct the studies, called pilot projects, in coordination with the food industry.[27]

FSMA required the Secretary to coordinate at least one project with the processed food sector and at least one with processors or distributors of fruits and vegetables that are raw agricultural commodities.[28] Additionally, the projects were to include at least three different types of foods that had been the subject of significant outbreaks during the preceding five-year period.[29] The pilot projects were to begin no later than 270 days after FSMA's enactment, with a report due to Congress by 18 months after enactment providing the findings of the pilot projects and recommendations for improving the tracing of food.[30]

Congress also directed the HHS Secretary, in coordination with the Secretary of Agriculture and state public health and agricultural departments, to gather additional data to inform the rulemaking process and assess the adoption and use of several product tracing technologies.[31] This assessment was required to include methods and technologies used in the pilot projects, as well as other commercially available product tracing strategies. The assessment was also to evaluate the costs and benefits of adopting these to track food throughout the supply chain. The assessment required FDA to evaluate whether the food industry, including small businesses, could adopt these strategies to comply with the requirements set by Congress.[32] FSMA required the HHS Secretary to consider possible integration and compatibility of the technologies with existing global tracing systems and to consult with a range of experts and stakeholders from the agricultural community, the food industry, and consumer organizations.[33]

Further, Congress directed the HHS Secretary, in consultation with the Secretary of Agriculture, to establish a product tracing system within FDA.[34] The tracing system was intended to improve federal capacity to effectively and rapidly track and trace food that was domestically produced or imported by receiving and organizing traceability data from subject entities. The HHS Secretary was to consider the results of the pilot projects and additional data gathering to ensure that the development of the product tracing system was well informed.

Additional Recordkeeping Requirements for High-Risk Foods

Congress directed the HHS Secretary to establish recordkeeping requirements—beyond those required under previously existing laws and regulations—for entities that manufacture, process,

[26] FSMA, §204(a). Under the Federal Food, Drug, and Cosmetic Act (FFDCA), a food may be deemed adulterated (21 U.S.C. §342) or misbranded (21 U.S.C. §343) for any of the various reasons provided in statute. Examples include "if it bears or contains any poisonous or deleterious substance which may render it injurious to health" or "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food."

[27] FSMA, §§204(a)(1)-(3).

[28] FSMA, §204(a)(2). The term "raw agricultural commodity" refers to any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing (21 U.S.C. §321).

[29] FSMA, §204(a)(2).

[30] FSMA, §204(a)(1) and (3).

[31] FSMA, §204(b).

[32] FSMA, §204(b)(1).

[33] FSMA, §204(b)(2).

[34] FSMA, §204(c).

pack, or hold foods designated as high risk by the Secretary.[35] Before FSMA, food entities were required to maintain records identifying one step forward in the supply chain and one step back.[36]

Congress directed the new requirements to be risk-based, to minimize the recordkeeping burden whenever possible, and to provide sufficient flexibility so that food entities of different types, sizes, and resource-availability could comply.[37] The recordkeeping requirements were to be science-based and proportionate to known food safety risks, to require only reasonably available information, and to ensure that the public health benefits would outweigh the cost of compliance with the requirements.[38]

Furthermore, the Secretary was to minimize the number of different requirements that would apply to facilities handling multiple high-risk foods. The rule was not to require facilities to change business systems or use specific recordkeeping technologies. The rule was to include a process for the Secretary to waive requirements, if deemed necessary, for individual facilities or types of facilities due to economic hardship. Lastly, Congress directed that when determining how long a facility would be required to retain records, the Secretary should consider the shelf life of the food; Congress set the time frame for records retention as not to exceed two years.[39]

Designation of High-Risk Foods

Congress directed the HHS Secretary to designate high-risk foods that would be subject to additional recordkeeping requirements.[40] In determining which foods to designate as high risk, the Secretary was to consider the known (historical) or likely severity of health and economic impacts from foodborne illness attributed to particular foods; known safety risks of particular foods; the likelihood that a food has a high potential risk for pathogens to grow or for contamination to occur and for a person to become ill after consumption of the food; and foodborne illness data collected by CDC.[41]

For example, considerations that may inform the high-risk designation include the likelihood of contamination during different manufacturing steps before a food product reaches the consumer or whether there are controls in place to reduce the likelihood of contamination or of causing foodborne illness (e.g., cooking process that kills microbes, low moisture reduces the likelihood that microbes can grow) before the product reaches the consumer.[42]

[35] FSMA, §204(d).

[36] Previously existing regulations required entities to keep records necessary to identify the immediate previous source and immediate subsequent recipients of food (i.e., one step forward and one step back in the supply chain; 21 C.F.R. Part 1, Subpart J). These recordkeeping requirements were for "persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food" (21 U.S.C. §350c(b)).

[37] FSMA, §204(d)(1).

[38] FSMA, §204(d)(3). Congress directed the HHS Secretary to take measures to ensure that no confidential information or trade secrets are reproduced or accessed without authorization and that access records are maintained.

[39] FSMA, §204(d)(5).

[40] FSMA, §204(d)(2)(A). For non-high-risk foods, no additional records were required to be kept beyond those already required by law (FSMA, §204(d)(7)).

[41] Some pathogens can cause a larger proportion of sickened people to have severe illness, cause a larger share of those affected to develop long-term conditions, or lead to more fatalities than other pathogens.

[42] For example, if the food undergoes a high-temperature step (e.g., cooking, pasteurization) during manufacturing or has a low moisture content (e.g., dried fruits, cured meats), microbes that can cause foodborne illness are less likely to reach the consumer.

The HHS Secretary was to designate the high-risk foods no later than one year after enactment of FSMA.[43] The Secretary was also to publish the list of high-risk foods on an FDA web page at the same time the final rule was issued.[44] Congress authorized the Secretary to update the list to designate new high-risk foods or remove those no longer deemed high risk, provided that the notice of list updates is published in the *Federal Register*.

Exemptions, Limitations, and Waivers

Congress established specific or partial exemptions, limitations, or waivers for the recordkeeping requirements for certain types of foods and entities. Foods that were not designated as high risk by the HHS Secretary would not be subject to the additional recordkeeping requirements.[45] Congress specifically identified fishing vessels and entities that commingle certain raw agricultural commodities as subject to more limited requirements, only requiring records identifying one step forward and one step back in the supply chain.[46] A food that is produced and packaged on a farm and that retains its packaging with all necessary labeling requirements is exempt by the statute.[47]

Congress also provided that the HHS Secretary may exempt or partially exempt other foods and entities and their compliance requirements, if compliance was not deemed necessary to protect public health, such as for commingled ingredients that will be processed to reduce pathogens before reaching the consumer.[48] Congress directed the Secretary to not require any distribution records for farms selling directly to consumers, and to limit the required records and time period to keep records for grocery stores that purchase directly from farms, as long as the food was sold by the owner and produced on the farm selling the food.[49]

Deadlines

The HHS Secretary was to publish a notice of proposed rulemaking to establish these recordkeeping requirements no later than two years after enactment of FSMA.[50] The Secretary was then to set an appropriate effective date for these additional requirements after publication of the final rule.[51] Congress directed the Secretary to take additional actions to support small business compliance with the regulation.[52] FSMA amended the FFDCA's section on enforcement

[43] FSMA, §204(d)(2)(A).

[44] FSMA, §204(d)(2)(B).

[45] FSMA, §204(d)(7).

[46] Food produced through the use of a fishing vessel (as defined in 16 U.S.C. §1802(18)), commingled raw agricultural commodities (as defined in 21 U.S.C. §2223(d)(6)(D)(ii)), and other exempted foods and facilities would still be required to keep records identifying one step forward and one step back in the supply chain, if applicable. FSMA, §§204(d)(6)(C)-(D).

[47] FSMA, §204(d)(6)(B).

[48] FSMA, §204(d)(6)(E).

[49] Grocery stores purchasing directly from farms are not required to keep records about the source farm beyond 180 days. FSMA, §§204(d)(6)(G)-(I).

[50] FSMA, §204(d)(1).

[51] FSMA, §204(d)(1). Congress authorized extended compliance dates for entities defined by the HHS Secretary as "small and very small businesses." FSMA, §204(i).

[52] The HHS Secretary was to issue a guide communicating the regulatory requirements in plain language, no later than 180 days after the regulation was finalized, to support small entities (e.g., farms, businesses) with compliance. FSMA, §204(h).

to include provisions prohibiting the violation of recordkeeping requirements for domestic and imported foods, once the rule went into effect.[53]

In addition, Congress directed the Comptroller General to submit an evaluation of the public health benefits and costs of implementing the rule one year after its effective date; this evaluation was required to consider if limiting the additional recordkeeping information, including not requiring restaurants to keep additional records, would have an impact on FDA's ability to trace food through the supply chain.[54]

FDA Implementation of FSMA Section 204

FDA has implemented many of the requirements established in Section 204 of FSMA, with some implementation occurring after the deadlines established by Congress.[55] The following sections further describe FDA's progress on implementing Section 204 of FSMA, including conducting pilot projects, developing an internal product tracing system (not yet implemented), publishing the Food Traceability List to designate high-risk foods, and finalizing the Food Traceability Rule.

Report to Congress on Pilot Projects

In 2011, FDA asked the Institute of Food Technologists (IFT) to execute food tracing pilot projects as described in Section 204(a) of FSMA (see "Pilot Projects and Data Gathering").[56] IFT completed traceability pilot projects and also evaluated the costs and benefits of improved product tracing. IFT submitted a final report on these efforts to FDA in 2012.[57] In March 2013, FDA subsequently released the project report and published a notice requesting comments and information expanding on the report results.[58] FDA submitted its statutorily required report to Congress in 2016; FDA's report summarized the IFT report and additional information-gathering

[53] FSMA, §204 amended 21 U.S.C. §331(e) and 21 U.S.C. §381(a) to add the violation of these recordkeeping requirements as a prohibited act under the FFDCA (except when the violation is committed by a farm) and to authorize food imports to be refused if the importer is in violation of these requirements, respectively.

[54] Congress also directed the Comptroller General to consider how compliance may impact small businesses, considering factors such as simultaneous compliance with other food safety and traceability requirements. The Comptroller General's evaluation was published as a Government Accountability Office (GAO) report in January 2024. FSMA, §204(e); and see summary table at GAO, "Food Safety: FDA Should Finalize Plans to Implement Its Rule to Help Trace Source of Outbreaks," January 2024, https://www.gao.gov/products/gao-24-106563.

[55] GAO, *Food Safety: FDA Should Finalize Plans to Implement Its Rule to Help Trace Source of Outbreaks*, GAO-24-106563, January 18, 2024, https://www.gao.gov/products/gao-24-106563, p. 16 (hereinafter GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563). GAO, *Food Safety: Further Action Needed to Implement Foodborne Illness Prevention Law and Assess Its Results*, GAO-26-107394, January 7, 2026, https://www.gao.gov/assets/gao-26-107394.pdf (hereinafter GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394).

[56] FSMA, §204(a) required the pilot projects to be conducted in collaboration with the food industry and other regulatory partners in order to evaluate different ways to identify recipients of food in the case of a food safety emergency, accounting for the range of operations in the food sector and utilizing then-currently available traceability technology. FDA, "Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA to Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food; Request for Comments and Information," 78 *Federal Register* 14309, March 5, 2013.

[57] Jennifer McEntire and Tejas Bhatt, *Pilot Projects for Improving Product Tracing Along the Food Supply System – Final Report*, Institute of Food Technologists (IFT), https://www.ift.org/siteassets/1-page-sections-media-blocks/4-policy-and-advocacy/docs/ift_fda_producttracingpilotsfinalreport.pdf (hereinafter McEntire and Bhatt, *Pilot Projects for Improving Product Tracing Along the Food Supply System – Final Report*).

[58] FDA, "Implementation of the FDA Food Safety Modernization Act Provision Requiring FDA to Establish Pilot Projects and Submit a Report to Congress for the Improvement of Tracking and Tracing of Food; Request for Comments and Information," 78 *Federal Register* 14309, March 5, 2013.

efforts, included the agency's recommendations for improving the tracking and tracing of food, listed next steps for developing the rule, and identified potential hurdles.[59]

IFT conducted two product tracing pilot projects with food products (or ingredients of products) that had been implicated in foodborne illness outbreaks between 2005 and 2010.[60] The two studies conducted were on (1) three ingredients (chicken, peanuts, and crushed red pepper) used in the production of four multi-ingredient processed food products, and (2) whole and sliced tomatoes.[61]

IFT reported working with representatives from more than 100 organizations—comprising a variety of stakeholders, including state departments of agriculture and public health, as well as specific subject matter experts—for the produce and processed foods pilot projects. During the pilot projects, a key goal for IFT was to recreate a mock supply chain traceability investigation to identify a common source in the supply chain (i.e., producer of food) starting at multiple points of sale (i.e., final retailers of food).[62] **Figure 1** illustrates a simplified traceability investigation with an example supply chain used to trace food during an outbreak investigation.

In **Figure 1**, the consumer illnesses are linked to one of three retail food establishments: Restaurant A, Grocery Store B, or Restaurant C. The retail food establishments were supplied by a total of 15 different supply chain entities, including distributors, packers, repackers, and growers. The goal of this traceback investigation was to find a common supplier for all three retail food establishments by utilizing records kept by each of the entities in the supply chain. For example, Restaurant C's records show that it received product from Distributor E and Distributor F. Distributor E's records show that it received product from Grower/Packer C. Distributor F received its product from Repacker B, which received product from Packer B. Packer B's records show that it received product from Grower D. In also reviewing Restaurant A's, Grocery Store B's, and their suppliers' records, Grower/Packer C was the common entity growing and packing food that supplied to the restaurants and grocery store.

In the report, FDA noted that the existing recordkeeping requirements (one step forward and one step back) were not always sufficient to connect retail food establishments to a common supplier.[63] FDA reported that IFT's findings were consistent with previous studies and known limitations of tracing food during outbreak investigations; it also reported that the findings brought a greater understanding of the required information and potential strategies to improve FDA's abilities to trace food throughout the supply chain.[64]

The pilot projects revealed that many collaborative platforms that were in use by industry at the time were easily able to support some degree of traceability through the supply chain. Gaps in communication, lack of common vocabulary, and lack of a standardized system of recordkeeping

[59] FDA, *Report to Congress: On Enhancing Tracking and Tracing of Food and Recordkeeping*.

[60] McEntire and Bhatt, *Pilot Projects for Improving Product Tracing Along the Food Supply System – Final Report*, p. 14.

[61] The processed foods pilot also included jarred peanut butter and two dry packaged spice packets due to the limited number of manufacturers of "Kung Pao" frozen chicken products initially chosen for the study.

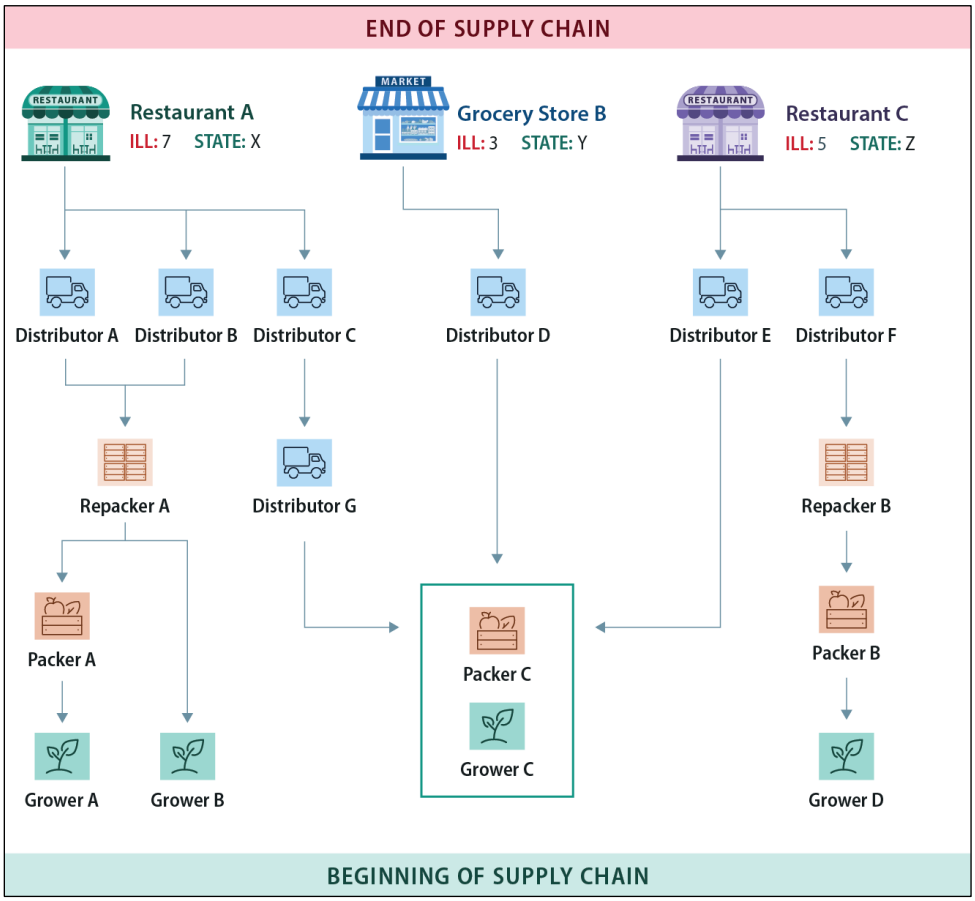
[62] FDA, *Report to Congress: On Enhancing Tracking and Tracing of Food and Recordkeeping*, pp. 9, 17.

[63] FDA listed other factors that contributed to the agency's difficulty conducting successful traceback investigations such as "lack of coverage of all sectors involved in food production, distribution, and sale," "lack of uniform data collection," and the inability to link incoming with outgoing product within a firm and between supply chain entities. FDA, "Requirements for Additional Traceability Records for Certain Foods: Final Rule," 87 *Federal Register* 70910, 70913, November 21, 2022.

[64] FDA, *Report to Congress: On Enhancing Tracking and Tracing of Food and Recordkeeping*, p. 4.

requirements all posed difficulties in identifying the common source of food during the pilot projects.[65]

Figure 1. Example of a Traceability Investigation During a Foodborne Illness Outbreak



Source: CRS adapted from Food and Drug Administration (FDA), Report to Congress: On Enhancing Tracking and Tracing of Food and Recordkeeping, Submitted Pursuant to Section 204 of the FDA Food Safety Modernization Act, P.L. 111-353, November 16, 2016, p. 9, https://www.fda.gov/media/102784/download?attachment.

Notes: In this simulation of a foodborne illness outbreak, sickened individuals consumed food from Restaurant A, Grocery Store B, or Restaurant C. By using records kept by the restaurants and grocery store, investigators would begin to follow food items backward through the supply chain, eventually linking to additional supply chain entities (e.g., distributor, repacker, packer, grower) involved in handling the implicated food item. In a successful traceback investigation, public health officials will be able to identify a common supplier to the establishments that were linked to the outbreak illnesses. The figure identifies Grower/Packer C as the common supplier to the two restaurants and grocery store.

FDA provided 17 different recommendations on enhancing tracking and tracing of food and related records in its report to Congress regarding uniform data elements, collaborations and capacity building, and other items.[66] These recommendations were aimed at FDA, the food industry generally, and government public health partner agencies. These included recommendations that FDA "identify a uniform set of data elements to be collected, recorded, and

[65] FDA, *Report to Congress: On Enhancing Tracking and Tracing of Food and Recordkeeping*, p. 19.

[66] FDA, *Report to Congress: On Enhancing Tracking and Tracing of Food and Recordkeeping*, pp. 23-25.

systematically maintained by firms for the purpose of product tracing" and that firms have "a written description of their process for tracking and tracing ingredients and finished products within their establishment that covers at least one step forward and back in the supply chain."[67] FDA also acknowledged a need for additional information gathering, particularly with regard to small and medium-sized firms and their current practices in tracing products and potential needs or limitations.

FDA's Food Traceability Rule

In 2018, the advocacy groups Center for Food Safety (CFS) and Center for Environmental Health (CEH) sued FDA for not meeting statutory requirements, such as promulgating final regulations by the congressional deadlines specified in Section 204 of FSMA.[68] The parties eventually reached a settlement in the lawsuit, agreeing to a consent decree that required FDA to submit the proposed and final rules to the *Federal Register* by September 8, 2020, and November 7, 2022, respectively.[69]

On September 23, 2020, FDA published the proposed Food Traceability Rule and requested comments from stakeholders for the rule and the Food Traceability List.[70] FDA also hosted three virtual public meetings and subsequently extended the comment period following requests from stakeholders.[71] FDA received 1,100 comments from stakeholders such as "consumers, consumer groups, trade organizations, farmers, industry (e.g., food manufacturers, processors, distributors), public health organizations, State and local governments, foreign governments and organizations."[72] The comments varied and were on topics related to almost all the provisions in the Food Traceability Rule.[73]

FDA published the final Food Traceability Rule on November 21, 2022.[74] In the *Federal Register*, FDA acknowledged the various comments to the proposed rule and outlined changes made in the final rule, including providing an additional year for subject entities to comply with the rule.[75] In

[67] FDA, *Report to Congress: On Enhancing Tracking and Tracing of Food and Recordkeeping*, p. 23.

[68] Complaint, Center for Food Safety (CFS) v. Azar, Case No. 4:18-cv-06299 (D.D.C. Oct. 15, 2018).

[69] Consent Decree, Center for Food Safety (CFS) v. Azar, Case No. 4:18-cv-06299 (D.D.C. June 11, 2019). The consent order also included procedures for FDA to request an extension from the court in the event that the agency believed an extension was necessary and the parties were unable to reach an agreement regarding extended deadlines. The order required FDA to show exceptional circumstances or good cause that would warrant a delay.

[70] FDA, "Requirements for Additional Traceability Records for Certain Foods: Proposed Rule," 85 *Federal Register* 59984, September 23, 2020.

[71] FDA received comments up until February 22, 2021. FDA, "Requirements for Additional Traceability Records for Certain Foods; Extension of Comment Period; Reopening of the Comment Period," 85 *Federal Register* 82393, December 18, 2020.

[72] FDA, "Requirements for Additional Traceability Records for Certain Foods: Final Rule," 87 *Federal Register* 70910, 70915, November 21, 2022.

[73] FDA responses to comments are organized by topic in Sections V.B through V.U. FDA, "Requirements for Additional Traceability Records for Certain Foods: Final Rule," 87 *Federal Register* 70910, 70915-71067, November 21, 2022.

[74] FDA, "Requirements for Additional Traceability Records for Certain Foods: Final Rule," 87 *Federal Register* 70910, November 21, 2022.

[75] FDA stated that the agency incorporated information learned from the required pilot projects, previously conducted pilot studies, and previously collected information from stakeholders through public meetings, as well as information learned through the agency's experience in conducting foodborne illness outbreak investigations.

its regulatory impact analysis, FDA estimated that the final rule would cover more than 323,000 domestic businesses operating more than 484,100 establishments.[76]

FDA asserts that the rule will improve its ability to "quickly and efficiently trace the movement of covered foods through the supply chain" and "identify and remove contaminated food from the marketplace during an outbreak."[77] The former commissioner for human foods also stated that the rule will "prevent the tremendous waste that results from recalls that are overly broad."[78] FDA's Food Traceability Rule spans across the supply chain: from harvest to processing or manufacturing (transformation), through food product distribution channels, to the final product sold at a restaurant or grocery store.[79]

The Food Traceability Rule requires domestic and foreign subject entities (e.g., farms, processing facilities, distributors) that "manufacture, process, pack, or hold" high-risk foods on the Food Traceability List to maintain additional records.[80] Subject entities handling a food on the Food Traceability List are to maintain specific records and information for certain points in the item's supply chain.[81] In addition, subject entities are to 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.[82]

Noncompliance with FDA recordkeeping requirements is prohibited (unless the violation is committed by a farm) and, for imported foods, failure to comply may result in refusal of admission.[83]

Food Traceability List

In 2014, FDA published a request in the *Federal Register* for comments, scientific data, and additional information as part of developing the Food Traceability List of high-risk foods.[84] In the notice, FDA described a draft multicriteria decision analysis approach to identify those foods to be designated as high risk, and requested feedback on the approach.[85] FDA stated that the approach would take into account the statutorily mandated criteria for high-risk food designation, such as the history and severity of prior outbreaks involving the item and whether the item had an

[76] FDA Economics Staff, *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, 2022, p. 64, https://www.regulations.gov/document/FDA-2014-N-0053-1302 (hereinafter FDA Economics Staff, *Requirements for Additional Traceability Records for Certain Foods*).

[77] FDA Economics Staff, *Requirements for Additional Traceability Records for Certain Foods*, p. 70.

[78] Reagan-Udall Foundation, "Virtual Public Meeting on FDA's Final Rule Requirements for Additional Traceability Records for Certain Foods," October 7, 2024, https://reaganudall.org/news-and-events/events/virtual-public-meeting-fdas-final-rule-requirements-additional-traceability.

[79] FDA, "Requirements for Additional Traceability Records for Certain Foods: Final Rule," 87 *Federal Register* 70910, November 21, 2022.

[80] 21 C.F.R. §1.1300.

[81] 21 C.F.R. §§1.1325-1.1350.

[82] 21 C.F.R. §1.1455(c)(1).

[83] 21 C.F.R. §1.1460.

[84] FDA, "Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information," 79 *Federal Register* 6596, February 4, 2014.

[85] FDA, "FDA's Draft Approach for Designating High-Risk Foods as Required by Section 204 of FSMA," February 2014, https://www.fda.gov/media/124152/download?attachment.

elevated potential for contamination and characteristics that would support the growth of pathogens.[86]

Subsequently, FDA developed the Risk-Ranking Model for Food Tracing.[87] In developing the model, FDA used the statutory requirements and a decision analysis methodology to define mandatory criteria and scoring criteria. The model determined a "total risk score" for FDA-regulated food.[88] Examples of data used in the model included FDA recall data, USDA Microbiological Data Program data, surveillance data of pathogens in different food types, manufacturing process and control data, peer-reviewed literature, and subject matter expertise.[89] The model used criteria determined by Congress to weigh the "risk score" of each food. For example, the model used parameters such as severity of illness, growth potential of pathogens, cost of illness, probability of contamination during the manufacturing process offset by industry-wide strategies to mitigate risk, and historical frequency of outbreaks to assist in the final ranking.[90] Using the results of the model, FDA identified foods to be designated as high risk and placed on the Food Traceability List.[91] FDA published the Food Traceability List on its website when the proposed rule was issued and included clarification for the food products on the list when the rule was finalized in 2022.[92]

In the published Food Traceability List, FDA included both pasteurized and unpasteurized types of cheeses; shell eggs; nut butters; fresh produce, such as cucumbers, herbs, leafy greens, melons, sprouts, and tomatoes; finfish; crustaceans; shellfish; and ready-to-eat deli salads (see **Figure 2**). The Food Traceability Rule also applies to foods containing an ingredient on the Food Traceability List, as long as the ingredient remains in the same form in which it appears on the list (e.g., fresh, fresh-cut).[93]

[86] FSMA, §204(d)(2)(A)(i).

[87] FDA's model was reviewed by separate, peer-review panels of external experts. FDA, *Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223)*, September 2022, https://www.fda.gov/media/142247/download (hereinafter FDA, *Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204*); and FDA, "FDA's Response to External Peer Review—Model Review on FDA's 'Draft Report for Peer Review: Risk-Ranking Model for Product Tracing as Required by Section 204 of FSMA' (September 2015)," August 2020, https://www.fda.gov/media/142280/download.

[88] FDA made the risk scores for the foods not on the Food Traceability List available on its website. FDA Memorandum, "Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing (2022 version)," October 31, 2022, https://www.fda.gov/media/142282/download?attachment; and FDA, "Risk-Ranking Model for Food Tracing," https://hfpappexternal.fda.gov/scripts/FDARiskRankingModelforFoodTracingfinalrule/.

[89] FDA, *Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204*, pp. 28-30.

[90] FDA, *Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204*, pp. 14, 21, 22. The severity of illness scoring included historical mortality and hospitalization rates as well as severity of symptoms associated with illness (p. 14). Probability of contamination and industry-wide strategies to mitigate risk takes into account which part of the manufacturing process is most likely to be associated with the risk of contamination, ability to control contamination, and how effective industry control strategies are (e.g., pressure and/or heat treatment such as pasteurization) and how frequently these strategies are implemented by industry (p. 21). Cost of illness scoring utilized incidence data (how frequently illnesses occurred) and estimates of costs of diagnosis, medical treatment, and value associated with prevention of death and chronic illness (p. 22).

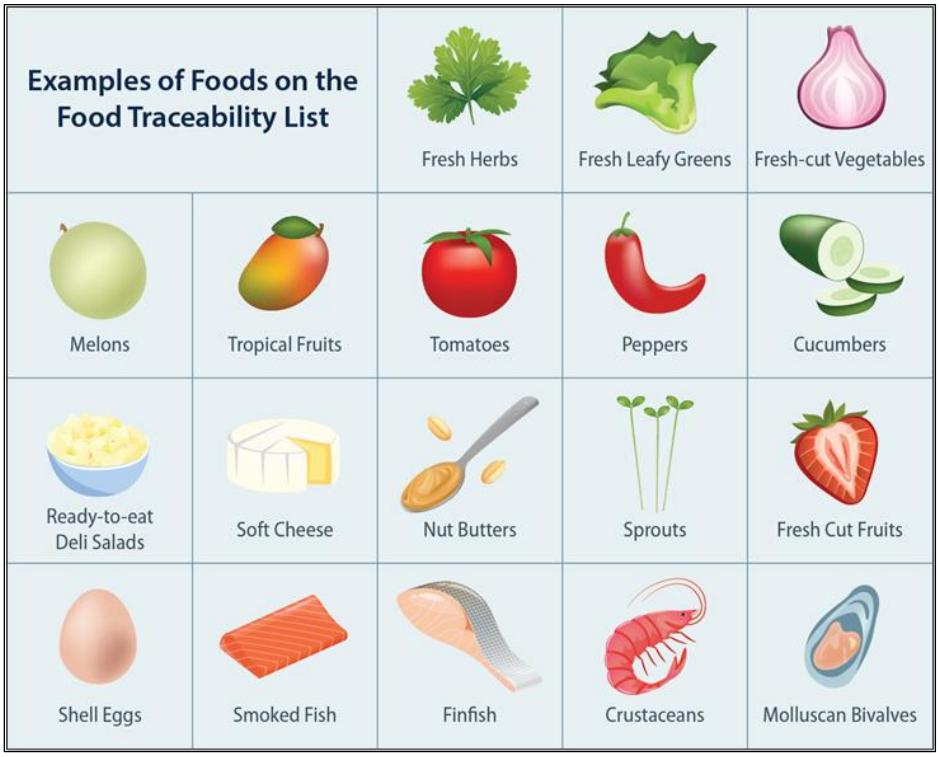
[91] FDA Memorandum, "Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing (2022 Version)," October 31, 2022, https://www.fda.gov/media/142282/download.

[92] FDA, "Requirements for Additional Traceability Records for Certain Foods," 87 *Federal Register* 70910, 70916, November 21, 2022.

[93] FDA, "Food Traceability List," https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list.

The agency reports that it will use the notice-and-comment process to solicit feedback from stakeholders on proposed changes to the list and publish final revisions.[94] Any deletions from the list would be effective immediately, and any additions to the list would be effective two years after the final notice is published.[95] In the final rule, FDA stated its intention to update the Food Traceability List approximately every five years, subject to available resources and taking into consideration time for industry to comply before updating the Food Traceability List.[96]

Figure 2. Examples of Foods on the Food Traceability List



Source: CRS adapted from Food and Drug Administration (FDA), "Food Traceability List," https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list.

Notes: These foods are examples of those listed on the Food Traceability List and would be subject to additional recordkeeping requirements. FDA provides additional guidance for the foods specifically listed on the Food Traceability List, and for foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list. For example, foods

[94] For example, in June 2024, FDA published a notice announcing that it would consider whether exempting Grade "A" cottage cheese that appears on the Interstate Milk Shippers List would be appropriate. FDA, "Requirements for Additional Traceability Records for Certain Foods; Proposed Exemption for Cottage Cheese Regulated by the National Conference on Interstate Milk Shipments Grade 'A' Pasteurized Milk Ordinance," 89 *Federal Register* 51281, June 17, 2024.

[95] 21 C.F.R. §1.1465.

[96] As reported by GAO, FDA officials stated that as additional information, risk assessments, and computational methods emerge, the agency may decide to modify its risk-ranking model. Appendix C in FDA's methodological approach document contains additional considerations for identifying a new food-hazard pair for the risk-ranking model. Food-hazard pairs are based on data such as historical food and hazard associations (i.e., association between a certain food and a pathogen or chemical that makes someone sick when that food is consumed) and hazard identification in foodborne illness outbreaks. FDA, "Requirements for Additional Traceability Records for Certain Foods: Final Rule," 87 *Federal Register* 70910, November 21, 2022. GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563, p. 12; and FDA, *Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204*, pp. 24, 62-63.

containing ingredients appearing on the Food Traceability List in the same form—such as a fruit smoothie, bagged salad mix, or peanut butter crackers—may be subject to the Food Traceability Rule.

Subject Entities

Entities subject to FDA's Food Traceability Rule are those that "manufacture, process, pack, or hold" foods found on the Food Traceability List, or foods that have ingredients on the list.[97] **Figure 3** depicts examples of subject entities throughout the supply chain that may be covered by the rule, such as farms, handlers, processors, distributors, grocery stores, food hubs, and restaurants.[98] FDA estimated in its regulatory impact analysis that nearly 485,000 establishments—including approximately 12,000 farms/aquaculture operations/growers and 443,000 retail food establishments and restaurants—will be affected by the final rule.[99] To help entities determine whether or not they are subject to the Food Traceability Rule, FDA developed an online tool.[100]

Traceability Plan

Entities subject to the Food Traceability Rule are to establish and maintain a food traceability plan.[101] The traceability plan is to include, among other things, procedures for record maintenance, identification of Food Traceability List foods handled by the entity, assignment of traceability lot codes to those foods, a point of contact for the plan and records, and farm or facility maps, if applicable.[102] The final rule requires entities to keep their plans updated with current practices, and to retain previous plans for at least two years after updating.[103]

Maintaining Records

Subject entities are required to adhere to certain recordkeeping requirements for foods on the Food Traceability List by establishing tracking information, recording data, and maintaining and sharing records.[104] These records are to include information regarding origin of food, how the entity handled the food, and any repackaging or processing performed by the entity. The precise information required to be maintained depends on the activities of the subject entity.

Entities that initially pack subject food are to assign it a traceability lot code, a unique identifier that is maintained throughout the supply chain.[105] The traceability lot code—also known as the

[97] This includes any foods that contain ingredients found on the Food Traceability List in the same form in which they're listed. For example, fresh herbs and leafy greens used in a prepared salad mix, fresh/raw tomato salsa, and fresh fruit tart would be covered by the rule's requirements. Frozen spinach, tomato and basil pasta sauce, and a breakfast cereal with freeze-dried strawberries would not be covered because frozen leafy greens, cooked tomatoes and herbs, and freeze-dried fruit are not on the list.

[98] These entities would be subject to the rule if they handled food items on the Food Traceability List, such as seafood, fresh-cut tomatoes, and onions. Other entities who may be subject include farms, "first land-based receivers" of seafood, and grocery stores. FDA, "Food Safety Modernization Act (FSMA) Food Traceability Rule: Supply Chain Examples," June 2023, https://www.fda.gov/media/169511/download?attachment.

[99] FDA Economics Staff, *Requirements for Additional Traceability Records for Certain Foods*, p. 215.

[100] FDA, "Exemptions to the Food Traceability Rule," online tool, March 10, 2025, https://collaboration.fda.gov/tefcv13.

[101] 21 C.F.R. §1.1315.

[102] 21 C.F.R. §1.1315.

[103] 21 C.F.R. §1.1315(b).

[104] 21 C.F.R. §§1.1325-1.1350.

[105] Examples of initial packing include packing activities in the field, a packing house, or a refrigerated facility. Additionally, the first land-based receiver of seafood from a fishing vessel is to assign a traceability lot code.

"lot" or "lot code" by industry—can be a string of numbers or letters or a combination of both. Lot codes can be used to link important information collected at each step. Entities that "transform" subject food through processing or repackaging are also to assign a traceability lot code that can be linked to previous steps in the supply chain.[106] A subject entity is *not* to create a new traceability lot code if conducting activities other than initial packing or transforming of a subject food.[107] The process of assigning, recording, and sharing a food's traceability lot code is deemed an essential aspect of the rule.

Additional information required to be kept by subject entities, referred to as "key data elements," include data such as dates, locations, and supplier details associated with specific steps in the supply chain where established "critical tracking events" occur.[108] As required by statute, FDA identified certain places throughout the supply chain as points in the manufacturing process where contamination is most likely to occur and named them "critical tracking events."[109] Critical tracking events listed by FDA are harvesting, cooling, initial packing, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, and transformation (**Figure 3**).[110]

FDA asserts that the information each subject entity is required to collect is necessary and sufficient to perform traceability investigations.[111] Upon FDA's request, usually during outbreak investigations, entities are to provide an electronic sortable spreadsheet with traceability information within 24 hours.[112]

[106] The meaning of "transform" is defined by the regulations (21 C.F.R. §1.1310). Transforming a food involves manufacturing or processing or otherwise changing the food or its packaging (e.g., by commingling, repacking, or relabeling). Entities that transform a subject food to a nonsubject food—for example, processing fresh-cut tomatoes into canned tomatoes—may have different recordkeeping requirements.

[107] 21 C.F.R. §1.1320.

[108] 21 C.F.R. §§1.1310, 1.1325-1.1350.

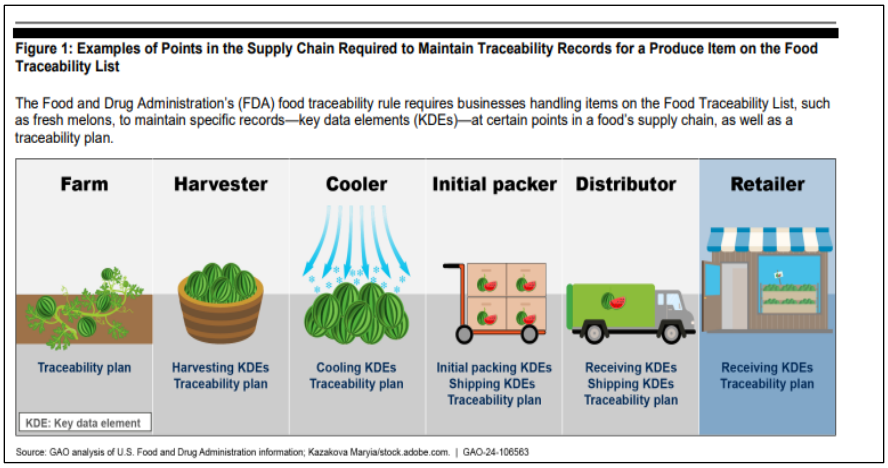
[109] FSMA, §204(d)(2)(A)(iii).

[110] 21 C.F.R. §1.1310.

[111] FDA, "Requirements for Additional Traceability Records for Certain Foods," 87 *Federal Register* 70910, 70910-70911, November 11, 2022.

[112] FDA specified exemptions from the electronic format requirement for very small entities or for religious purposes, but clarified that subject entities would still have to comply by providing paper copies of traceability records. FDA, "Requirements for Additional Traceability Records for Certain Foods," 87 *Federal Register* 70910, 70911, November 11, 2022.

Figure 3. Examples of Subject Entities and Required Key Data Elements



Source: Government Accountability Office (GAO), *FDA Should Finalize Plans to Implement Its Rule to Help Trace Source of Outbreaks*, GAO-24-106563, January 2024, p. 4, https://www.gao.gov/products/gao-24-106563. 21 C.F.R. §1.1310.

Notes: Key data elements (KDEs) are the specific types of data that each subject entity are to maintain. Key data elements are collected when a critical tracking event occurs. A critical tracking event is an event in the supply chain of a food involving harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.

Exemptions and Modified Requirements

The final rule provides exemptions or allows modified requirements for certain supply chain entities or types of food. Congress specified the parameters for some of these (see "Exemptions, Limitations, and Waivers") and provided FDA with the authority to include additional exemptions or modified requirements in regulation.

Selected Exemptions from FDA's Food Traceability Rule

- Certain small producers, such as produce farms or other producers of raw agricultural commodities with sales of no more than $25,000 annual average during the previous three years, and for shell egg producers with fewer than 3,000 laying hens at a particular farm (21 C.F.R. §1.1305(a))
- Small retail food establishments and restaurants with no more than $250,000 in average monetary value of food sold or provided during the previous three years (21 C.F.R. §1.1305(i))
- Farms, when food is sold or donated directly to consumers (21 C.F.R. §1.1305(b))
- Food produced and packaged on a farm whose packaging maintains product integrity and prevents subsequent contamination, as long as it is labeled with specific contact information for the farm (21 C.F.R. §1.1305(c))
- Any foods transformed or changed such that they are no longer on the Food Traceability List and foods that receive types of processing or treatment that reduce the likelihood of pathogen growth, if specific documentation is kept (21 C.F.R. §1.1305(d))
- Produce that is considered "rarely consumed raw" (21 C.F.R. §1.1305(e))
- Certain raw bivalve molluscan shellfish (21 C.F.R. §1.1305(f))
- Persons who manufacture, process, pack, or hold foods 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 (21 C.F.R. §1.1305(g))
- Nonprofit food establishments (21 C.F.R. §1.1305(o))

The final rule exempts some small producers, including certain produce farms and most shell egg producers and, at the other end of the supply chain, certain small retail food establishments and restaurants (see the **textbox** titled "Selected Exemptions for the FDA Traceability Rule," above).[113] In determining the cutoff limits for sales-based exemptions, FDA weighed the public health risks against the burden the rule would impose on small entities or specific food entities.[114] FDA additionally included exemptions in the final rule for foods that pose a lower food safety risk, such as those that undergo commercial processing that reduces pathogens, foods rarely consumed raw, and raw molluscan bivalves that are subject to the requirements of the National Shellfish Sanitation Program.[115] FDA officials reported to the Government Accountability Office (GAO) that the agency worked to maintain consistency in these exemptions with those of other FDA regulations, such as the Produce Safety Rule and the Shell Egg Rule.[116]

FDA asserts that the agency considered the costs of compliance and the proportion of products on the Food Traceability List in the food supply chain in determining exemptions.[117] For example, FDA estimated that 40% of aquaculture operations account for approximately 3% of subject aquaculture sales, and 19% of retail food establishments represent approximately 1% of retail food establishment sales. Similarly, FDA estimated that 63% of produce farms account for 1% of

[113] 21 C.F.R. §1.1305.

[114] GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563, p. 19.

[115] 21 C.F.R. §1.1305(d), (e), (f), and (r). The purpose of the National Shellfish Sanitation Program is to promote public health and standardize the sanitary control of shellfish produced and sold for human consumption. For more information about this program, see FDA, "National Shellfish Sanitation Program (NSSP)," https://www.fda.gov/food/federal-state-local-tribal-and-territorial-cooperative-human-food-programs/national-shellfish-sanitation-program-nssp.

[116] The Produce Safety Rule and Shell Egg Rule contain exemptions for small entities and for products that undergo specific pathogen-reducing processing. GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563, p. 20; 21 C.F.R. Part 112 – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule); and 21 C.F.R. Part 118 – Production, Storage, and Transportation of Shell Eggs (Shell Egg Rule).

[117] 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. FDA Economics Staff, *Requirements for Additional Traceability Records for Certain Foods*.

covered produce sales and that 98% of shell egg producers account for 1% of shell egg sales. These FDA estimates indicate that a small proportion of food entities may be contributing to a significant portion of the regulated market. In its assessment of the final rule, FDA estimated 40% of aquaculture operations, 19% of retail food establishments, 63% of produce farms, and 98% of shell egg producers would be exempt.[118] Subsequently, FDA asserted that the exemptions would not limit the government's ability to trace food throughout the supply chain.

Certain entities and food categories that do not qualify for a full exemption may benefit from modified requirements (i.e., partial exemptions).[119] For example, the final rule allows certain small entities to record data on paper rather than electronically.[120] Commingled raw agricultural commodities and owners, operators, or agents in charge of fishing vessels may receive a partial exemption.[121] Partial exemptions are also provided for grocery stores and restaurants that purchase directly from grocery stores and restaurants, from farms, or from farm-to-school and farm-to-institution programs.[122]

Additionally, FDA may waive, exempt, or modify recordkeeping requirements for a food or specific entity on request, depending on public health considerations or if meeting the requirements would result in an economic hardship due to unique circumstances.[123] The rule establishes procedures for either submitting a petition or requesting a waiver that affirms that FDA's ability to track and trace food would not be significantly hindered by granting such exceptions and, in the case of a waiver request, that complying with the requirements would pose an economic hardship.[124] FDA's procedures include a notice-and-comment period in which the submitted waiver information will be available to the public for feedback.

FDA Product Tracing System

In Section 204, Congress also directed the HHS Secretary to establish a system *within* FDA that could receive information to improve its capacity for food tracing. According to a January 2026 GAO report, FDA has not established an internal product tracing system, but FDA began developing the system in 2022.[125]

FDA's website, last updated in March 2024, states that FDA is "currently developing" an internal product tracing system that will "enhance existing foodborne illness outbreak response processes."[126] On the website, FDA describes how the product tracing system will integrate with existing reporting portals and data visualization platforms, while maintaining data and network security. FDA has indicated that it may make use of an existing supply chain visibility standard, a way of organizing traceability information, called the Electronic Product Code Information Services (EPCIS). FDA states that subject entities are not required to use EPCIS, but that EPCIS

[118] FDA Economics Staff, *Requirements for Additional Traceability Records for Certain Foods*.

[119] 21 C.F.R. §§1.1360-1.1400.

[120] 21 C.F.R. §1.1455(c)(3)(iii).

[121] 21 C.F.R. §1.1305(h) and 21 C.F.R. §1.1305(m).

[122] 21 C.F.R. §1.1305(j)-(l).

[123] 21 C.F.R. §§1.1360-1.1400, 1.1405-1.1450.

[124] 21 C.F.R. §§1.1360-1.1400, 1.1405-1.1450.

[125] GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394, p. 36.

[126] One such existing process is FDA's Coordinated Outbreak Response and Evaluation (CORE) Network. FDA, "Product Tracing System," March 5, 2024, https://www.fda.gov/food/new-era-smarter-food-safety/product-tracing-system; and FDA, "About the CORE Network," January 8, 2024, https://www.fda.gov/food/outbreaks-foodborne-illness/about-core-network.

provides an option "to promote interoperability across [] supply chains."[127] Additionally, FDA is proposing that authorized government users utilize an open-source data visualization platform called FoodChain-Lab to create supply chain diagrams with submitted food traceability data.[128]

In its 2026 report, GAO recommended that FDA develop a plan with specific milestones and timelines for establishing the product tracing system.[129] GAO asserted that the development of the system is important because "it is intended to allow FDA to analyze food traceability data more effectively and rapidly."[130] In March 2025, FDA told GAO that the product tracing system was anticipated to be complete by the initial Food Traceability Rule compliance date of January 2026.[131] After announcing its intention to delay the compliance date to July 2028, FDA then informed GAO that the agency expected the system to be complete by July 2028 and that the additional time would allow FDA to test the system with industry partners.[132]

Delayed Compliance Date for FDA's Food Traceability Rule

FSMA required the HHS Secretary to set an appropriate effective date for compliance with FDA's Food Traceability Rule. In establishing the date, the Secretary was to take into consideration the time necessary for covered entities to comply with the additional requirements for foods designated as high risk.[133] The proposed Food Traceability Rule set a compliance date for two years after the effective date of the final rule.[134] FDA published the final Food Traceability Rule on November 21, 2022, with an effective date of January 20, 2023, and an initial compliance date of January 20, 2026, thus extending compliance until three years after the rule's effective date.[135] FDA agreed with comments requesting this extension, stating that the three-year time frame "appropriately balances the public health gains" with providing sufficient time for covered supply chain partners to work together toward compliance; the agency disagreed with requests to extend

[127] Electronic Product Code Information Services (EPCIS) is a standard developed by GS1, a nonprofit organization best known for developing the barcode, to allow for "disparate applications to create and share visibility event data, both within and across enterprises." GS1, "EPCIS Standard," version 2.0, https://ref.gs1.org/standards/epcis/.

[128] FDA, "Product Tracing System," March 5, 2024, https://www.fda.gov/food/new-era-smarter-food-safety/product-tracing-system; and Armin A. Weiser et al., "FoodChain-Lab: A Trace-Back and Trace-Forward Tool Developed and Applied during Food-Borne Disease Outbreak Investigations in Germany and Europe," *PLoS One*, vol. 11, no. 3 (eCollection 2016).

[129] GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394, p. 27.

[130] GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394, p. 16.

[131] GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394, p. 17.

[132] GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394, p. 17.

[133] FSMA, §204(d)(1).

[134] Congress specified that the compliance date for the smallest businesses would be two years after promulgation of the final rule (FSMA, §204(i)). In order to avoid a staggered compliance approach, FDA proposed that the compliance date for *all* subject entities be set to two years after the rule's effective date. FDA, "Requirements for Additional Traceability Records for Certain Foods: Proposed Rule," 85 *Federal Register* 59984, 60020, September 23, 2020.

[135] The effective date of January 20, 2023, was 60 days after the final rule was published in the *Federal Register*. FDA, "Requirements for Additional Traceability Records for Certain Foods," 87 *Federal Register* 70910, 71067, November 21, 2022.

it beyond that time frame.[136] In September 2023, FDA announced that the agency would not begin routine inspections until 2027, to give covered entities more time to prepare for compliance.[137]

In January 2024, GAO recommended that FDA finalize and document an implementation plan for the Food Traceability Rule in order to meet the original 2026 compliance date after interviewing stakeholders.[138] The implementation plan was to include the agency's resource needs, strategies for facilitating compliance, and detailed plans for communicating with subject entities and nonfederal regulatory partners (i.e., state inspectors, local and state public health agencies) about inspections. FDA agreed with the recommendation;[139] FDA did not provide a timeline for finalizing the implementation plan but indicated that it had made progress in drafting the plan.[140] While some stakeholders concurred with the recommendation, others expressed concern about the feasibility of compliance within the proposed time frame. For example, in September 2024, the Reagan-Udall Foundation for the FDA, a nonprofit established by Congress to advance the mission of FDA, conducted a series of industry roundtables about the final Food Traceability Rule.[141] Some stakeholders exhibited low awareness of the rule and its requirements, such as certain industry sectors, small and medium-sized suppliers, foreign suppliers, nonchain restaurants, and companies not part of a trade association.[142] Some stakeholders observed that the rule requirements would be easier to implement for some entities than others, with some operations needing to make large changes to their current practices that may require additional resource investment.[143] Some stakeholders also stated their uncertainty regarding the accuracy of data and the feasibility of ensuring the data properly follow the intended food products in what they describe as an increasingly complex supply chain.[144] GAO reported that several stakeholders

[136] In the interim, FDA stated its intention to provide outreach and training, guidance, and additional materials to support industry compliance across sectors. FDA, "Requirements for Additional Traceability Records for Certain Foods," 87 *Federal Register* 70910, 70912, 71068, November 21, 2022.

[137] The agency published additional educational resources in November 2023. FDA, "Constituent Update: FDA Rolls Out Third Wave of New FAQs and Tools for the Food Traceability Rule to Assist Stakeholders," November 30, 2023, https://www.fda.gov/food/hfp-constituent-updates/fda-rolls-out-third-wave-new-faqs-and-tools-food-traceability-rule-assist-stakeholders.

[138] GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394, p. 40.

[139] The agency agreed with this recommendation and reported expected completion before 2026. The recommendation remains open on the GAO website for this report. GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563, p. 37.

[140] In March 2025, FDA reportedly was taking steps to draft its implementation plan, which included an initial assessment of resource needs and progress toward an inspectional framework. See table containing recommendations for agency action. GAO, "Food Safety: FDA Should Finalize Plans to Implement Its Rule to Help Trace Source of Outbreaks," January 2024, https://www.gao.gov/products/gao-24-106563.

[141] 21 U.S.C. §379dd(b). Reagan-Udall Foundation for the FDA, *Industry Roundtable Series on the FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods: Top-Line Learnings Summary*, September 2024, https://reaganudall.org/sites/default/files/2024-09/Food%20Traceability%20Top-Line%20Summary%20090424_0.pdf (hereinafter Reagan-Udall Foundation, *Industry Roundtable Summary*).

[142] Nathan Strout, "Seafood Sector Unprepared for Food Safety Modernization Act, Trade Experts Warn," *Seafood Source: Supply & Trade*, May 2, 2024, https://www.seafoodsource.com/news/supply-trade/trade-expert-seafood-sector-unprepared-for-food-safety-modernization-act; and Reagan-Udall Foundation, *Industry Roundtable Summary*, p. 3.

[143] In contrast, some operations due to size or position in the supply chain will need only relatively small modifications to their current practices to fully comply. FDA reported that large firms with vertically integrated supply chains have shown progress in adopting successful traceability systems. Reagan-Udall Foundation, *Industry Roundtable Summary*. FDA, "Requirements for Additional Traceability Records for Certain Foods," 87 *Federal Register* 70910, 70914, November 21, 2022.

[144] Reagan-Udall Foundation, *Industry Roundtable Summary*.

indicated difficulty meeting the compliance date without additional clarifying guidance from FDA.[145]

In March 2025, FDA announced its intention to extend the compliance date for its Food Traceability Rule an additional 30 months.[146] In the announcement, FDA stated that "the compliance date extension affords covered entities the additional time necessary to ensure complete coordination across the supply chain in order to fully implement the final rule's requirements."[147] FDA reported that subject entities, such as retailers, distributors, and suppliers, have had difficulty obtaining accurate information from and transmitting it to supply chain partners in a timely and cost-effective manner.[148] On August 7, 2025, FDA published a notice of proposed rulemaking to extend the compliance date to July 20, 2028.[149]

In November 2025, the FY2026 Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act (P.L. 119-37) directed that "no funds appropriated by this Act may be used to administer or enforce the [Food Traceability Rule] ... prior to July 20, 2028."[150]Additionally, Congress directed FDA to engage quarterly during the interim period with regulated entities such as farms, restaurants, retail food establishments, and warehouses distributing to retail food establishments and restaurants.[151] Congress directed FDA to provide guidance to these stakeholders on how to navigate certain situations common for the food industry—such as food waste recovery, reclamation, intra-company transfers, and customer returns—under the rule. With regard to FDA's development of an internal product tracing system, Congress directed the agency to test the system with a series of hypothetical data intake exercises to support any necessary troubleshooting before the compliance date.[152]

FDA subsequently stated its intention to comply with congressional directives.[153] On February 19, 2026, FDA published a constituent update announcing availability of a finalized exemption for certain cottage cheese products, new draft guidance, and a series of stakeholder engagement sessions.[154] The draft guidance document addresses questions about specific subject entities, such

[145] GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394, p. 27.

[146] FDA, "Constituent Update: FDA Intends to Extend Compliance Date for Food Traceability Rule," March 20, 2025, https://www.fda.gov/food/hfp-constituent-updates/fda-intends-extend-compliance-date-food-traceability-rule (hereinafter, FDA, "FDA Intends to Extend Compliance Date for Food Traceability Rule").

[147] An FDA official working on the rule stated, "It requires coordination, not just compliance." Kristen Hampshire, "Closing the Gap: FSMA, Traceability and the Road Ahead," *Quality Assurance,* January 22, 2026, https://www.qualityassurancemag.com/article/closing-the-gap/ (hereinafter, Hampshire, "FSMA, Traceability, and the Road Ahead"). FDA, "FDA Intends to Extend Compliance Date for Food Traceability Rule."

[148] FDA, "Requirements for Additional Traceability Records for Certain Foods: Compliance Date Extension," 90 *Federal Register* 38084, 38085, August 7, 2025.

[149] FDA, "Requirements for Additional Traceability Records for Certain Foods: Compliance Date Extension," 90 *Federal Register* 38084, August 7, 2025.

[150] Section 780 of Division B, P.L. 119-37.

[151] Congress directed FDA to consider additional flexibilities for specific subject entities in order for those entities to satisfy the rule's lot-level tracking requirement without being required to track product to the case level, given that the latter requirement is prohibited by FSMA, §204(d)(1)(L)(iii).

[152] Congress directed that, if resources allow, FDA conduct these hypothetical data intake exercises with covered entity traceability systems upon request.

[153] FDA, "FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods," accessed January 23, 2026, https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods.

[154] FDA, "Constituent Update: FDA Takes Several Actions Related to the Food Traceability Rule," February 19, 2026, https://www.fda.gov/food/hfp-constituent-updates/fda-takes-several-actions-related-food-traceability-rule (hereinafter FDA, "Constituent Update: FDA Takes Several Actions Related to the Food Traceability Rule"). FDA, "Requirements (continued...)

as farms, fishing vessels, retail food establishments, and restaurants; several exemptions related to raw molluscan shellfish and commingling; and additional clarification for critical tracking events and rule recordkeeping requirements.[155] Stakeholder engagement sessions reportedly will be held quarterly in conjunction with the Partnership for Food Traceability (PFT); the first listening session, in March 2026, was limited to PFT members and the following sessions will reportedly be open to the public.[156] PFT has announced virtual town halls in June and November 2026 to identify and discuss challenges and solutions for lot-level traceability.[157] FDA asserted that the planned listening sessions will provide an opportunity to engage with stakeholders on topics that may be unclear or with which regulated entities may have compliance challenges.[158]

Issues for Congress

Congress passed FSMA in order to improve the safety of the U.S. food supply. In Section 204 of FSMA, Congress directed FDA to improve the tracking and tracing of food through the supply chain by establishing additional recordkeeping requirements for facilities handling foods frequently associated with foodborne illness outbreaks. FDA's implementation of Section 204 of FSMA and regulation of food traceability may be of continued interest to Congress. As of 2024, FDA reportedly was developing training modules; inspection, compliance, and enforcement strategies; its internal product tracing system; and an overall plan for its food traceability program management.[159] Previously, Congress has provided direction to FDA on its implementation of FSMA and may wish to continue to evaluate through oversight mechanisms whether FDA activities to implement Section 204 are accomplishing the intended goals of the statute and, if not, whether further congressional action is necessary. Congress may also consider whether additional legislation may be necessary to direct FDA's actions and rule enforcement or whether the agency's implementation and enforcement plans are sufficient.

Inspector Training and Product Tracing System

Some stakeholders have concerns about variable interpretations and enforcement of the rule across the supply chain that may depend on the regulatory personnel conducting the inspections and regulator familiarity with the industry.[160] Similarly, GAO reported that nonfederal regulatory

for Additional Traceability Records for Certain Foods; Exemption for Cottage Cheese Regulated by the National Conference on Interstate Milk Shipments Grade 'A' Pasteurized Milk Ordinance," 91 *Federal Register* 8256, February 20, 2026.

[155] FDA is accepting comments on the draft guidance until May 21, 2026, at Docket no. FDA-2025-D-2837. FDA, "Questions and Answers About Requirements for Additional Traceability Records for Certain Foods; Draft Guidance for Industry; Availability," 91 *Federal Register* 8243, February 20, 2026.

[156] Division B, §780, of the FY2026 Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act (P.L. 119-37). FDA, "Constituent Update: FDA Takes Several Actions Related to the Food Traceability Rule." See more about Partnership for Food Traceability (PFT) at https://pftraceability.org/.

[157] PFT, "2026 PFT-FDA Town Halls: Lot-Level Traceability," https://pftraceability.org/town-halls/.

[158] FDA, "Constituent Update: FDA Takes Several Actions Related to the Food Traceability Rule."

[159] GAO reported that FDA expected to complete much of the initial development of these materials and strategies in preparation for the 2026 compliance date. The food traceability rule assignment and program development were reportedly expected to be initially complete by 2027. In its 2026 report, GAO reported that FDA expects to have the product tracing system complete by July 2028. GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563, p. 37. GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394, p. 27.

[160] Industry roundtable participants expressed interest in ensuring adequate education and communication between (continued...)

partners expressed a need for clear guidance and coordination with FDA to ensure consistent enforcement of the rule.[161] GAO asserted the importance of an operational internal product tracing system within FDA to allow the agency to analyze food traceability data submitted by industry and collected during inspections.[162]

Congress prohibited FDA from utilizing FY2026 appropriations to administer or enforce the Food Traceability Rule and instructed it to take certain steps toward rule implementation and preparedness.[163] In P.L. 119-37, Congress directed FDA to conduct a series of hypothetical traceability data intake exercises to test the capabilities of its internal product tracing system and, if resources allow, test and identify technical difficulties in subject entities' traceability systems on request. In the joint explanatory statement accompanying P.L. 119-37, Congress requested a report on expected timelines and strategies planned to ensure FDA implementation of the final rule by July 20, 2028.[164] In addition, Congress directed that the report include an inspections and compliance road map, include a status update for the statutorily required internal product tracing system, and be submitted within 60 days of enactment. In S.Rept. 119-37, the Senate Committee on Appropriations directed that FDA may not use funds to delay enforcement of the Food Traceability Rule beyond July 20, 2028, and that full compliance and enforcement begin by then.[165] The language set forth in S.Rept. 119-37—which accompanies S. 2256, the Senate-passed appropriations bill—carries the same weight as the joint explanatory statement unless explicitly noted otherwise.[166]

Upon reviewing FDA's plans, Congress may consider the sufficiency of the agency's plan for implementation and enforcement ahead of the July 20, 2028, compliance deadline. If Congress deems the plan insufficient, it may consider providing further direction or oversight. Congress may also evaluate whether any further action or funding is warranted as it receives agency updates regarding FDA's compliance and enforcement strategy and product tracing system.

Supporting Industry Compliance

FDA officials have acknowledged the complexity of the rule and the potential effort from industry to communicate and collaborate with supply chain partners to ensure compliance.[167] Factors such as sector, supply chain, and size may have an impact on ease of compliance.[168]

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subject entities, FDA, and nonfederal regulatory personnel, some of which may be responsible for enforcing the Food Traceability Rule. Reagan-Udall Foundation, *Industry Roundtable Summary*, p. 4.

[161] According to FDA officials, the agency will need additional resources for staffing and funding implementation activities (e.g., test product tracing system). GAO reported that in March 2025, FDA provided information on steps taken toward drafting its implementation plan, but no time frame was provided. GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563, p. 33; and GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394, p. 2.

[162] GAO, *Action Needed to Implement Foodborne Illness Prevention Law*, GAO-26-107394, p. 16.

[163] Division B, §780, of P.L. 119-37.

[164] Sen. Susan Collins, "Joint Explanatory Statement Accompanying Div. B of FY2026 Continuing Appropriations Act," *Congressional Record*, vol. 171, part 189 (November 9, 2025), p. S8051.

[165] S.Rept. 119-37 included similar language for the report requirements and deadlines established by Congress. Sen. Collins, "Joint Explanatory Statement Accompanying Div. B of FY2026 Continuing Appropriations Act," p. S8051.

[166] Sen. Collins, "Joint Explanatory Statement Accompanying Div. B of FY2026 Continuing Appropriations Act," p. S8051.

[167] Reagan-Udall Foundation, "Virtual Public Meeting on FDA's Final Rule Requirements for Additional Traceability Records for Certain Foods," October 7, 2024, https://reaganudall.org/news-and-events/events/virtual-public-meeting-fdas-final-rule-requirements-additional-traceability.

[168] For example, stakeholders closer to the end of the supply chain, such as distributors, may carry thousands of (continued...)

Among other requirements, Congress directed FDA's Food Traceability Rule to minimize the recordkeeping burden whenever possible and provide sufficient flexibility so that food entities of different types, sizes, and resource availability could comply while prohibiting the agency from requiring product tracking to the case level.[169] In previously held appropriations hearings, Congress expressed interest in additional collaboration between FDA and industry to address challenges in successful rule compliance.[170] In enacted FY2026 appropriations law, Congress directed the agency to conduct certain activities to support industry compliance and consider providing flexibilities for entities facing compliance challenges.

Requirement Modifications and Exemptions

Congress has provided FDA with direction and considerations, such as additional flexibilities or exemptions for certain subject entities, as the agency works toward supporting industry compliance. Congress has expressed interest in additional pilot projects to inform the sufficiency of the rule in tracing products in the case of foodborne illness outbreaks if such exemptions were implemented. Stakeholders have mixed views regarding changes or increased exemptions for entities throughout the supply chain. Some stakeholders are interested in revisiting rule requirements for increased flexibility; others assert that reducing requirements for entities at the end of the supply chain would undercut the value of the rule.[171] FDA asserts that the required records are necessary to perform traceability investigations and that the full public health benefits of the final rule would not be achievable unless all subject entities are in compliance.[172]

In P.L. 119-37, Congress directed FDA to consider whether additional flexibilities may be warranted for specific entities for satisfying the rule's lot-level tracking requirement in order to be in compliance by July 20, 2028. The House Committee on Appropriations provided further detail through H.Rept. 119-172, which directed FDA to conduct four pilot projects to evaluate the feasibility of traceback investigations without entities (e.g., restaurants, retail food establishments, and warehouses) recording lot code information and to report its findings on completion of the projects. S.Rept. 119-37 (accompanying the Senate-passed FY2026 appropriations bill S. 2256) directs FDA to engage with subject entities to identify and implement, as appropriate, additional flexibilities for satisfying the rule's lot-level tracking requirement. In the 119th Congress, H.R. 4121, as reported in the House, would have required FDA to establish a panel of experts, which would have included stakeholders, to assess the

different items on the food traceability list. In 2024, Reagan-Udall reported that most warehouse management systems may not be capable of capturing all required information without significant upgrades. Reagan-Udall Foundation, *Industry Roundtable Summary*, p. 4.

[169] Some have said that the flexibility required to avoid burdening small businesses has given rise to a rule that lacks a specific design. Hampshire, "FSMA, Traceability, and the Road Ahead."

[170] During congressional appropriations hearings in the 118th Congress, some Members expressed interest in additional collaboration between FDA and industry in order to implement the Food Traceability Rule. U.S. Congress, Senate Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, *A Review of the President's Fiscal Year 2025 Budget Request for the Food and Drug Administration*, 118th Cong., 2nd sess., May 8, 2024 (GPO, 2025), p. 76.

[171] Some industry associations have asserted that the recordkeeping is burdensome and that the exemptions provided in the final rule are not sufficient. Some consumer advocacy groups assert that lot code information exemptions for retailers "would effectively lay waste to FDA's efforts," and the efforts of suppliers who have developed and maintained such information. Reagan-Udall Foundation, *Industry Roundtable Summary*, p. 4; GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563, pp. 32-35; and Safe Food Coalition, "Food Safety Coalition letter to Congress about FDA traceability rule," June 25, 2024, https://www.cspi.org/resource/food-safety-coalition-letter-congress-about-fda-traceability-rule.

[172] FDA, "FDA Intends to Extend Compliance Date for Food Traceability Rule."

agency's traceback investigation process and pilot projects and to publish a subsequent report on the findings.

Upon reviewing FDA's reports, summaries, and progress updates, if deemed necessary, Congress may consider previously introduced legislation or may choose to develop legislation aimed at improving subject entities' rule compliance.

Rule Interpretation and Technical Assistance

Stakeholders throughout the supply chain have reported difficulty complying with the rule, and some have requested additional education, "prescriptive direction on implementation requirements,"[173] and clarity around varying interpretations of the rule's requirements.[174] Some stakeholders indicated that the lack of detailed information from FDA has delayed their efforts to comply with the rule, as they did not find that the agency's presentations and webinars answered industry-specific questions or concerns.[175] Some stakeholders have stated that businesses may begin to collect much more data, beyond what the rule requires, such as by requesting suppliers to provide records for all foods, not just those on the Food Traceability List.[176] Some stakeholders are also concerned that the rule will require them to adopt new technologies, potentially leading to unnecessary investment of resources.[177] Some stakeholders have indicated that partnerships within industry, state regulatory officials, and trusted education providers may support compliance and education to sectors for which FDA has less experience working with.[178] Some stakeholders believe that testing existing technology, widely recognized communication standards, and industry best practices with a variety of food products across industry sectors along the supply chain may be an avenue to support compliance, especially if the results are shared publicly.[179]

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[173] Reagan-Udall Foundation, *Industry Roundtable Summary*, p. 3.

[174] For example, some stakeholders believe that the rule's lot level tracking requirement is fundamentally at odds with the FSMA provision prohibiting FDA from requesting subject entities to track product at the case level. In the preamble of the final rule, FDA disagreed with comments asserting that the rule requires case level tracking, stating "the final rule provides adequate flexibility for firms to decide how to manage these situations, depending on their individual practices." Reagan-Udall Foundation, *Industry Roundtable Summary*, p. 3; GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563, p. 29; and FDA, "Requirements for Additional Traceability Records for Certain Foods," 87 *Federal Register* 70910, 71007, November 21, 2022.

[175] GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563, p. 26.

[176] For example, some large grocery retailers have begun to require traceability records that go beyond what is required in regulation, not just those considered high-risk. Catherine Douglas Moran, "How grocers are taking charge of food traceability requirements," *GroceryDive*, January 29, 2026, https://www.grocerydive.com/news/food-traceability-regulations-grocery-fda/810737/; and Elizabeth Crawford, "Food Traceability Rule compliance threatened by too much tech, over-eager retailers, *Food Navigator*, October 22, 2024, https://www.foodnavigator-usa.com/Article/2024/10/22/over-eager-retailers-excessive-tech-threaten-food-traceability-rule-compliance/.

[177] Stakeholders report that such interpretations "potentially require significant increases in labor, equipment, and space." Reagan-Udall Foundation, *Industry Roundtable Summary*, p. 4.

[178] For example, universities in North Carolina and Ohio have partnered to offer a free training course for small and medium operators in the retail food service sector to comply with the Food Traceability Rule. Additionally, 10 food industry organizations, including a few representing nonfederal regulatory agencies, have partnered to "enhance industry-wide awareness" of FDA's Food Traceability Rule. North Carolina State University Extension, "Food Traceability Rule in Retail Food Establishments," January 30, 2026, https://foodsafety.ces.ncsu.edu/retail-food-safety-programs/traceability-rule-in-retail-food-establishments/; Institute of Food Technologists, "Food Industry FSMA 204 Collaboration," https://info.ift.org/global-food-traceability-center-fsma-collab; Reagan-Udall Foundation, *Industry Roundtable Summary*, p. 5; and GAO, *FDA Should Finalize Plans to Implement Its Source of Outbreaks Rule*, GAO-24-106563, p. 33.

[179] Some subject entities have reported success in collecting and sharing required information by adopting GS1 (continued...)

Congress directed FDA to conduct and report on certain activities that are intended to support industry compliance. In P.L. 119-37, Congress directed FDA to provide assistance to industry on how to comply with the rule under certain circumstances, such as food waste recovery, reclamation, intracompany transfers, and customer returns. The joint explanatory statement accompanying P.L. 119-37 directed FDA to report on expected timelines and strategies the agency plans to use to support industry in achieving compliance along with progress updates every 90 days until the rule is in effect.[180] It also directed FDA to convene a tabletop traceability information exercise with participation and recordkeeping data from subject entities, such as processors, distributors, and retailers, as well as technology providers and related stakeholders; FDA is to publicly release summaries of these exercises no later than 90 days after their completion.[181] House appropriators directed FDA, through report language accompanying the House-passed FY2026 funding bill (H.R. 4121), to identify low-cost food traceability technologies and evaluate their feasibility and effectiveness.[182] H.R. 4121, as reported in the House, would have required FDA to assess industry standards and establish a model data format with reusable templates that would allow entities across the supply chain to communicate, share, and use traceability data effectively.[183]

Congress may review the agency's actions and may consider whether FDA's actions are sufficient to provide stakeholders with technical assistance or if further action might be needed.

standards, as an example. Reagan-Udall Foundation, *Industry Roundtable Summary*, p. 5; and Frank Yiannas, "Better Food Traceability Can't Wait," *Food Safety News*, July 2024, https://digitaledition.food-safety.com/june-july-2024/feature-supply-chain/.

[180] The language set forth in S.Rept. 119-37 and H.Rept. 119-172 carries the same weight as the language included in the explanatory statement unless explicitly noted to the contrary. These two reports accompany the Senate- and House-passed appropriations bills, S. 2256 and H.R. 4121, respectively. Sen. Collins, "Joint Explanatory Statement Accompanying Div. B of FY2026 Continuing Appropriations Act," p. S8051.

[181] Sen. Collins, "Joint Explanatory Statement Accompanying Div. B of FY2026 Continuing Appropriations Act," p. S8051.

[182] House appropriators, through language in H.Rept. 119-172, urged USDA's National Institute of Food and Agriculture to coordinate blockchain research as it may apply to improving food traceability and encourages coordination with FDA on the topic. FDA held a low- or no-cost tech-enabled traceability challenge in June 2021 that received 90 submissions. FDA stated that the main goal of the challenge was to "encourage stakeholders, including technology providers, public health advocates, entrepreneurs, and innovators from all disciplines to develop traceability hardware, software, or data analytics platforms that are low-cost or no-cost to the end user." Winners were announced in September 2021 and included teams representing over 10 countries. FDA, "Low- or No-Cost Food Traceability," updated January 24, 2024, https://www.fda.gov/food/new-era-smarter-food-safety/low-or-no-cost-food-traceability.

[183] In June 2024, FDA published a downloadable electronic sortable spreadsheet (available in Excel and PDF formats) that contained sample traceability data and an empty document that could be used as a template. See "Electronic Sortable Spreadsheet," at FDA, "FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods," https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods.

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