

Food and Drug Administration's Final Food Traceability Rule: What It Says and What It Means for the Future

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In this article, the authors discuss the long-awaited final Food Traceability Rule issued recently by the Food and Drug Administration, and explain why industry should be paying attention.

The Food Safety Modernization Act (FSMA) may have been passed more than a decade ago, but it is anything but old news. While the Food and Drug Administration (FDA) has issued many of the “foundational” rules that set forth safety standards for the food industry, the agency continues to issue rules with new requirements and guidance documents to assist industry with compliance.

On November 21, the FDA published the long-awaited final Food Traceability Rule (or final rule), which establishes additional traceability recordkeeping requirements for those that manufacture, process, pack, or hold certain foods.¹ While the final rule is limited in scope by statute, industry should be paying attention because it sets the stage for the agency's ultimate vision of end-to-end traceability.

The ability to track and trace foods is important for a number of reasons. First, it can protect public health by identifying recipients of unsafe foods more quickly and efficiently, allowing for more rapid recalls and warnings to consumers. Second, and as a consequence to the first, the ability to identify and remove unsafe food quickly can help to reduce a company's risk of liability when food safety events occur. Third, enhanced food system traceability might help anticipate disruptions in the food supply chain and improve inventory control. This could avoid the kind of problems seen with the recent infant formula crisis and during the early days of the COVID-19 pandemic, when foods and other consumer items were not necessarily scarce overall, but in the wrong place at the wrong time (e.g., restaurants and hotels had food that retail stores were lacking, leading to food waste). Finally, being able to quickly

identify the source of foodborne illness outbreaks and other contamination events can also help prevent food producers from being unfairly affected by recalls and advisories about contaminated foods that have nothing to do with them.²

The FDA's final Food Traceability Rule is the first step to achieving end-to-end traceability throughout the supply chain. While many companies have established tracing systems, the systems are not always interoperable, thus hindering the ability to trace foods from farm to table. This final rule creates the foundational components that will allow the food system to speak the same traceability language and can be used by the technology sector to develop software for this rapidly growing market.

The Final Rule

The final rule establishes additional traceability recordkeeping requirements for those that manufacture, process, pack, or hold certain foods on the FDA's Food Traceability List (FTL). The final rule identifies key activities or Critical Tracking Events (CTEs) along the supply chain where records containing Key Data Elements (KDEs) will have to be created, maintained, and shared for these foods.

Food Traceability List

Let us begin by understanding what foods are covered by the Food Traceability Rule. Section 204(d)(2) of the FSMA required the FDA to designate high-risk foods for which additional recordkeeping would be required. After soliciting public comments on an approach for developing a list of high-risk food in 2014,³ the agency developed a risk-ranking model that was used to develop the FTL.⁴ The model was designed to be flexible and to consider a wide range of contaminants in FDA-regulated human foods. The agency looked at data associating these contaminants with different commodities and used the model to rank commodity-hazard pairs to develop a proposed FTL in conjunction with the proposed rule.⁵

After receiving public comment on the proposed FTL, the FDA has now issued the final FTL. The final FTL includes:

- All fresh-cut fruits and vegetables;
- Certain other fresh produce: leafy greens, cucumbers, peppers, tomatoes, tropical tree fruits, sprouts, herbs, melons;

- Certain fresh and frozen finfish;
- Fresh and frozen smoked finfish;
- Fresh and frozen crustaceans;
- Fresh and frozen molluscan shellfish, bivalves;
- Certain cheeses;
- Shell eggs;
- Nut butters; and
- Ready-to-eat deli salads.⁶

The Food Traceability Rule's additional recordkeeping requirements will apply not only to foods specifically listed on the FTL but also to foods that contain FTL foods as ingredients, provided the form of the food (e.g., fresh) has not changed. While the FDA considered comments regarding the contents of the FTL, the FTL did not change between the proposed and final rules. In response to stakeholder feedback, however, the FDA added additional descriptions to help industry understand the categories, as well as examples for further clarification.

The FDA recognizes that the FTL may evolve over time and has established a process for updates that includes public input. Based on recommendations in public comments, the agency intends to update the FTL every five years, based on available resources.⁷ The agency will review new scientific data or other information that is relevant to the list, as well as the risk-ranking model. The agency may also provide updates sooner than five years, if warranted.⁸ When the agency concludes that an update is necessary, it will publish a notice in the Federal Register for comment. After considering additional feedback and information, the agency will publish a second notice in the Federal Register identifying and explaining any changes. Any additions to the list would become effective two years after the date of the second notice, while any deletions would become effective immediately.

Critical Tracking Events

The Food Traceability Rule focuses on key activities along the supply chain for which KDEs must be established, maintained, and/or shared. The final rule identifies the following CTEs for which records would be required:

- *Harvesting*: Activities that are traditionally performed on farms for the purpose of removing raw agricultural

commodities from the place they were grown or raised and preparing them for use as food.

- *Cooling (Before Initial Packing)*: Active temperature reduction of a raw agricultural commodity using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process.
- *Initial Packing of a Raw Agricultural Commodity Other Than a Food Obtained from a Fishing Vessel*: Packing a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time.
- *First Land-Based Receiving of a Food Obtained from a Fishing Vessel*: Taking possession of a food for the first time on land directly from a fishing vessel.
- *Shipping*: An event in a food's supply chain in which a food is arranged for transport (e.g., by truck or ship) from one location to another location.
- *Receiving*: An event in a food's supply chain in which a food is received by someone other than a consumer after being transported (e.g., by truck or ship) from another location.
- *Transformation*: An event in a food's supply chain that involves manufacturing/processing a food or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the FTL.⁹

In response to comments, the FDA revised the final CTEs significantly from the proposed rule to better align with industry practices and terminology. Among other things, "growing" was removed in favor of more the descriptive "harvesting" and "cooling." Similarly, "first receiver" was replaced with "initial packing" of a raw agricultural commodity (other than food obtained from a fishing vessel) and "first land-based receiver" for food obtained from a fishing vessel. In addition, "creating" was removed in the final rule because "transforming" already adequately captured activities that fell under it.

Key Data Elements

As discussed above, KDEs are information associated with a CTE for which a record must be established, maintained and, at

times, passed on. The KDEs will vary at each CTE but the records will contain information necessary to effectively trace back a product based on the CTEs a firm performs. Not all KDEs are relevant for each CTE; however, firms that perform multiple CTEs would be required to maintain all the applicable KDEs to the CTEs they perform. The KDEs will link the traceability lot code of the food to the relevant KDE, allowing a food to be traced along the supply chain. This will assist regulators and industry in the case of a food safety event. The agency adopts an approach for maintaining and sharing specific KDEs that it believes aligns with consensus standards for traceability currently used by industry.¹⁰ What follows is a summary of the KDE requirements; not all specific situations are addressed in this table (e.g., sprouts).

CTE	KDE
Harvesting	<ul style="list-style-type: none"> • Location description for the immediate subsequent recipient (other than a transporter) of the food • Commodity and, if applicable, variety of the food • Quantity and unit of measure of the food • Location description for the farm where the food was harvested • For produce: <ul style="list-style-type: none"> • Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or • Other information identifying the harvest location at least as precisely as field or growing area name • For aquacultured food: <ul style="list-style-type: none"> • Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or • Other information identifying the harvest location at least as precisely as the container name • Date of harvesting • Reference document type and reference document number

CTE	KDE
Harvesting (continued)	<ul style="list-style-type: none"> • Provide to the initial packer: <ul style="list-style-type: none"> • Business name • Phone number • Harvesting KDEs (except the reference document type and reference document number)
Cooling	<ul style="list-style-type: none"> • Location description for the immediate subsequent recipient (other than a transporter) of the food • Commodity and, if applicable, variety of the food • Quantity and unit of measure of the food • Location description for where you cooled the food • Date of cooling • Location description for the farm where the food was harvested • Reference document type and reference document number • Provide to the initial packer: <ul style="list-style-type: none"> • Cooling KDEs (except the reference document type and reference document number)
Initial Packaging	<ul style="list-style-type: none"> • Traceability lot code you assign • Commodity and, if applicable, variety of the food received • Date you received the food • Quantity and unit of measure of the food received • Location description for the farm where the food was harvested • For produce: <ul style="list-style-type: none"> • Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or • Other information identifying the harvest location at least as precisely as field or growing area name • For aquacultured food: <ul style="list-style-type: none"> • Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or

CTE	KDE
Initial Packaging (<i>continued</i>)	<ul style="list-style-type: none"> • Other information identifying the harvest location at least as precisely as the container name • Business name and phone number for the harvester of the food • Date of harvesting • Location description for where the food was cooled (if applicable) • Traceability lot code you assigned • Product description of the packed food • Quantity and unit of measure of the packed food • Location description for where you initially packed the food (i.e., traceability lot code source), and (if applicable) the traceability lot code source reference • Date of initial packing • Reference document type and reference document number
First Land-Based Receiver of Food Obtained from a Fishing Vessel	<ul style="list-style-type: none"> • Traceability lot code you assign • Species and/or acceptable market name for unpackaged food, or the product description for packaged food • Quantity and unit of measure of the food • Harvest date range and locations for the trip during which the food was caught • Location description for the first land-based receiver (i.e., traceability lot code source), and (if applicable) traceability lot code source reference • Date the food was landed • Reference document type and reference document number
Shipping	<ul style="list-style-type: none"> • Traceability lot code for the food • Quantity and unit of measure of the food • Product description for the food • Location description for the immediate subsequent recipient (other than a transporter) of the food • Location description for the location from which you shipped the food

CTE	KDE
Shipping (continued)	<ul style="list-style-type: none"> • Date you shipped the food • Location description for the traceability lot code source or the traceability lot code source reference • Reference document type and reference document number (maintain only)
Receiving ¹¹	<ul style="list-style-type: none"> • Traceability lot code for the food • Quantity and unit of measure of the food • Product description for the food • Location description for the immediate previous source (other than a transporter) for the food • Location description for where the food was received • Date you received the food • Location description for the traceability lot code source or the traceability lot code source reference • Reference document type and reference document number
Transformation when FTL food is used as an ingredient	<ul style="list-style-type: none"> • Traceability lot code you assigned • Product description for the food to which the traceability lot code applies • For each traceability lot used, the quantity and unit of measure of the food used from that lot
Transformation when a new food is produced	<ul style="list-style-type: none"> • New traceability lot code for the food • Location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference • Date transformation was completed • Product description for the food • Quantity and unit of measure of the food • Reference document type and reference document number

Like with the CTEs, the FDA made revisions to the originally proposed KDEs in response to stakeholder feedback. These revisions not only reflected changes to the associated CTEs but also simplified terminology and better aligned the KDEs with industry practices to foster compliance. For example, the final rule allows covered entities to define “lot” according to their business practices rather than creating a universal definition. Several changes

were made in response to comments expressing privacy concerns about information that would need to be shared with others in the supply chain. For example, the agency changed the proposed KDE of a “traceability lot code generator,” which would have revealed personal information about an employee, to including in the final KDE for the location description a “traceability lot code source,” which will only reveal the place the lot code was assigned. Similarly, the final rule removed “point of contact” as a required KDE and now only requires firms to identify a point of contact in their traceability plan, and that point of contact can be identified as a job title and phone number.

Traceability Program Records

In addition to requiring records of KDEs, the final rule also requires anyone subject to the rule to establish and maintain a traceability plan. The plan must contain descriptions of how a firm maintains traceability program records (including relevant reference records for the KDEs), lists of food on the FTL that are shipped, description of how traceability lot codes are assigned, a statement identifying a point of contact regarding traceability plans and records, and other information needed to understand data provided within the required records. The traceability plan requirements also include farm maps showing locations and names of fields (or containers for aquaculture farms) where food on the FTL is grown (including geographic coordinates and other location information).

The final rule does not require that records be kept electronically or to communicate electronically, other than to provide an electronic, sortable spreadsheet with relevant tracing information when the FDA is investigating an outbreak, recall, or other threat to public health. Nevertheless, the agency encourages all those subject to the Food Traceability Rule to incorporate electronic recordkeeping and communication procedures into their traceability programs to facilitate and expedite the analysis of data and completion of traceback and traceforward operations.

Exemptions

The final Food Traceability Rule includes a number of full and partial exemptions based on the type of entity and the type of food.

These exemptions can get complicated to interpret but include exemptions based on the size of the entity and whether or not the food will be further processed to include a “kill step” to control the potential hazard. While the final rule applies to restaurants and retail establishments, there are some exemptions for restaurants and retail establishments to accommodate business practices. The agency provides a tool to assist businesses in determining whether an exemption applies.¹²

Providing Records to the FDA

Those subject to the final rule are required to keep records, as original paper or electronic records (or true copies). Records must be provided to the FDA within 24 hours of the agency’s request, unless the FDA agrees to additional time.¹³ Such a request can be written or by phone. When needed to assist the FDA in the event of an outbreak, recall, or other serious threat to public health, records must be provided to the FDA in an electronic, sortable spreadsheet, unless the firm is subject to a partial exemption from that requirement. Moreover, while the firm can keep its records in any language, they must be translated upon request within a reasonable time, as agreed to by the FDA.¹⁴

Oversight and Enforcement

As with other FSMA rules the FDA is taking the “educate before and while it regulates” approach to enforcing this rule. The agency is still developing its compliance program and will work with its state and local regulatory partners to determine the best approach to conducting routine records inspections to ensure compliance. Violation of this rule is a prohibited act under the Federal Food, Drug, and Cosmetic Act and the agency can bring a civil or criminal action against one or more violative firms.¹⁵ The agency can also enforce the rule by refusing entry of imported shipments of food.¹⁶

Compliance Dates

The final compliance date for all persons subject to these recordkeeping requirements is January 20, 2026, three years after

the effective date of the final regulation.¹⁷ While Congress directed the FDA to adopt staggered compliance dates based on size, the FDA determined that, because smaller firms and larger firms will potentially have to interact in the event of traceback and traceforward events, having different compliance dates would diminish the rule's effectiveness.¹⁸ While the FDA had initially proposed a two-year compliance date for all firms, the agency added an extra year in the final rule to give industry more time to coordinate information sharing and make any needed changes to tracing systems. The extra year will also provide the FDA with additional time for outreach and training to industry to assist with these efforts.¹⁹

The Future of Traceability

FDA Deputy Commissioner Frank Yiannis calls the lack of end-to-end traceability the “Achilles’ heel” of the food system, and it is clearly his goal to help industry achieve this through regulatory and voluntary measures.²⁰ While the FSMA restricted the traceability requirements to certain foods and prevented the agency from prescribing specific technologies for maintaining records, the final rule establishes a framework for data that can be utilized throughout industry beyond the confines of the final rule.

To move toward this goal, the FDA launched the New Era of Smarter Food Safety initiative in July 2020.²¹ This initiative seeks to build on the foundational requirements of the FSMA by leveraging technology and other tools and approaches to create a safer and more digital, traceable food system.²² One component of this initiative specifically focuses on tech-enabled traceability. The Food Traceability Rule is the first step toward this end because it facilitates electronic data sharing by creating common terminology and a standard structure or format for traceability information that can be used by industry and regulatory partners.

Beyond the Food Traceability Rule, the New Era of Smarter Food Safety initiative encourages firms to voluntarily adopt tracing technologies and ways to harmonize tracing activities that will support end-to-end traceability throughout the food system. More specifically, the FDA seeks to create financial models that will enable human and animal food firms of all sizes to participate in a scalable, cost-effective way, focusing not on any particular technology but rather on interoperability across a variety of technology

solutions. This has resulted in the agency interacting with a wider range of stakeholders beyond the food industry itself. One noteworthy example is the FDA's "Low- or No-Cost Tech-Enabled Traceability Challenge" in June of 2021, the goal of which was to encourage participation from new types of stakeholders, including technology providers, entrepreneurs, and innovators to develop traceability hardware, software, or data analytics platforms that can be utilized by small and medium firms.²³

Looking ahead, the agency will continue to work with all stakeholders, not only to ensure compliance with the Food Traceability Rule (we can expect additional tools for industry assistance) but also to find ways to encourage all stakeholders to embrace the foundational components of that rule to achieve end-to-end traceability. This includes working with international stakeholders to create a global traceability system with common standards and mechanisms for exchanging data that work through complicated supply chains. While this goal will not be reached in the short term, the food industry has a significant economic stake in the long term, as do consumers, who will be better protected if outbreaks and other food safety threats can be identified and contained more quickly.

Notes

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1. See Final Rule 87 FR 70910.

2. Kiesel et al., *E. Coli in the Romaine Lettuce Industry: Economic Impacts from the November 2018 Outbreak (July 2021)* (estimating total societal losses of \$280-\$250 million as a result of the outbreak), <https://kiesel.ucdavis.edu/Full%20Report.pdf>.

3. Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information, 79 FR 6596 (Feb. 4, 2014).

4. FDA Report: Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223) (Aug. 2020), <https://www.fda.gov/media/142247/download>.

5. See Proposed Rule: Requirements for Additional Traceability Records for Certain Foods, 85 FR 59984, 59993 (Sept. 23, 2020).

6. 87 FR 70910, 70916-70917.

7. 87 FR 70910, 71050-71051.

8. See *id.*

9. See 21 CFR § 1.1310.

10. 87 FR 70910, 70913.

11. There are different KDEs for entities receiving FTL foods from suppliers that are exempt from the Food Traceability Rule, including assignment of a traceability lot code. 21 CFR 1.1345(b).

12. Traceability Exemptions Flow Chart, <https://collaboration.fda.gov/tefcv13/>.

13. 21 CFR § 1.1455(c)(1).

14. 21 CFR § 1.1455(c)(4).

15. 21 CFR § 1.1460(a).

16. 21 CFR § 1.1460(b) (citing FSMA § 801(a)).

17. 87 FR 70910, 70915.

18. 85 FR 60020.

19. 87 FR 70910, 71067.

20. Remarks by Frank Yiannas at the International Association for Food Protection 2020 Annual Meeting, Speech Transcript (Oct. 27, 2020), <https://www.fda.gov/news-events/speeches-fda-officials/remarks-frank-yiannas-international-association-food-protection-2020-annual-meeting-10272020>.

21. FDA web page: New Era of Smarter Food Safety, <https://www.fda.gov/food/new-era-smarter-food-safety>.

22. See FDA Report: New Era of Smarter Food Safety: FDA's Blueprint for the Future at 2 (July 2020), <https://www.fda.gov/media/139868/download>.

23. See FDA web page "Meet the Winners of FDA's Low- or No-Cost Food Traceability Challenge," <https://www.fda.gov/food/new-era-smarter-food-safety/meet-winners-fdas-low-or-no-cost-food-traceability-challenge>.