

Food Safety Modernization Act (FSMA) 204 Rule

Sections and Regulations Applicable to Distributors

Source: FDA Website Landing Page for FSMA 204 Rule: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods>

Background: The [Food Safety Modernization Act \(FSMA\)](#) was enacted into law in 2011 and contains measures to improve U.S. food safety regulations.

Section 204(d) of the FSMA directs the Food and Drug Administration to institute recordkeeping and safety requirements for high-risk foods. While this section has been part of the FSMA from the beginning, businesses must take proactive steps to comply before Section 204(d) goes into effect on January 20, 2026.

On November 21, 2022, FDA published the final rule entitled, “Requirements for Additional Traceability Records for Certain Foods” (Food Traceability Rule) (87 FR 70910). The regulation can be found at 21 CFR part 1, subpart S (§§ 1.1300-1.1465).

Monitoring Critical Tracking Events (CTEs) and Key Data Elements (KDEs)

Critical Tracking Events (CTEs) refer to points in the food supply chain where products are handled, transformed, or moved. Each point represents a potential opportunity for contamination and an opportunity to mitigate such outcomes. By monitoring CTEs, each movement or transformation within the food supply chain can be traced.

Key Data Elements (KDEs)—such as source, transformation, and transportation information—represent data points that could be tied to safety-related issues, such as temperature deviations during transit or processing delays.

Under FSMA Section 204, KDEs must be logged as food items pass through CTEs. That means, however, that businesses need to carefully evaluate their data management systems and packaging solutions to determine whether they can support rapid, reliable data retrieval in case of FDA audits.

CTEs and KDEs Applicable to Distributors

Critical Tracking Event (CTE)	Key Data Elements (KDEs) for Each CTE
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. Shipping does not include the sale or shipment of a food directly to a consumer	Shipping KDEs <ul style="list-style-type: none">• Traceability lot code for the food• Quantity and unit of measure of the food

<p>or the donation of surplus food. Shipping does include sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.</p>	<ul style="list-style-type: none"> • 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 the food is shipped • Date the food is shipped • Location description for the traceability lot code source or the traceability lot code source reference • Reference document type and reference document number (maintain only)
<p>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. Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location of the firm at a different street address.</p>	<p>Receiving KDEs</p> <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 food is received • Location description for the traceability lot code source or the traceability lot code source reference • Reference document type and reference document
<p>Transformation: an event in a food's supply chain that involves manufacturing/processing or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List (FTL). Transformation does not include the initial packing of a food or activities preceding that event (e.g., harvesting, cooling).</p>	<p>Transformation KDEs [FTL food(s) used as ingredient(s)]</p> <ul style="list-style-type: none"> • Traceability lot code for the food • 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

<p>Transformation: an event in a food's supply chain that involves manufacturing/processing or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List (FTL). Transformation does not include the initial packing of a food or activities preceding that event (e.g., harvesting, cooling).</p>	<p>Transformation KDEs [New food produced]</p> <ul style="list-style-type: none"> • New traceability lot code for the food • Location description for where the food is transformed (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 • RACs (other than a food obtained from a fishing vessel) that were not initially packed prior to transformation of the food, and records must be maintained containing the information specified in § 1.1330(a) or (c). • For sprouts that were not initially packed prior to transformation of the food, records must be maintained containing the information specified in § 1.1330(a) or (c), and also § 1.1330(b).
<p>Traceability Plan</p>	<ul style="list-style-type: none"> • Description of the procedures used to maintain the required records, including the format and location of the records • Description of the procedures used to identify foods on the FTL that you manufacture, process, pack or hold • Description of how traceability lot codes are assigned to foods on the FTL, if applicable • Statement identifying a point of contact for questions regarding traceability plan and records • If a food grown or raised is on the FTL (other than eggs), a farm map showing the areas in which you grow or raise such foods - The farm map must show the location and name of each field (or other growing area) in which food is grown on the FTL, including geographic coordinates and any other

	<p>information needed to identify the location of each field or growing area</p> <ul style="list-style-type: none"> - For aquaculture farms, the farm map must show the location and name of each container (e.g., pond, pool, tank, cage) in which you raise seafood on the FTL, including the geographic coordinates and any other information needed to identify the location of each container • Update traceability plan as needed to ensure that the information reflects your current practices and to ensure you are in compliance with the rule • Retain previous traceability plan for 2 years after an update to the plan
--	---

Exemption from the Food Traceability Rule (§ 1.1305)

Certain companies and foods are fully exempt from the requirements of the Food Traceability Rule, while others may be eligible for partial exemptions. FDA has developed a software flow chart tool to determine whether an exemption may apply (<https://collaboration.fda.gov/tefcv13/>).

Examples of Exemptions (That May Apply to Distributors)

Exempt: Food produced and packaged on a farm that meets certain packaging and labeling criteria. The packaging of the food remains in place until the food reaches the consumer, and such packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and the labeling of the food that reaches the consumer includes the name, complete address (street address, town, State, country, and zip or other postal code for a domestic farm and comparable information for a foreign farm), and business phone number of the farm on which the food was produced and packaged. Cite: § 1.1305(c).

Exempt: A transporter of food who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air. Cite: § 1.1305(n).

Exempt: Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Conditions set forth in 21 CFR 112.2(b), which is part of the produce safety regulation, must be met for the produce. Cite: § 1.1305(d)(1).

Exempt: Shell eggs when all eggs produced at the particular farm receive a treatment (as defined in 21 CFR 118.3) in accordance with 21 CFR 118.1(a)(2), which is part of the shell egg regulation. Cite: § 1.1305(d)(2).

Waivers of One or More of the Requirements of the Food Traceability Rule for an Individual Entity or a Type of Entity (Cite § 1.1405)

The FDA will waive one or more of the requirements of the Food Traceability Rule when the agency determines that:

- (1) Application of the requirements would result in an economic hardship for an individual entity or a type of entity, due to the unique circumstances of the individual entity or type of entity;
- (2) The waiver will not significantly impair the FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act; and
- (3) The waiver will not otherwise be contrary to the public interest.

Assignment of Traceability Lot Codes for FTL Foods (Cite §§1.1320 and 1.1345(b)(1))

For foods on the FTL, a traceability lot code is assigned when:

- Initially pack a raw agricultural commodity other than a food obtained from a fishing vessel;
- Perform the first land-based receiving of a food obtained from a fishing vessel;
- A food is transform a food; or
- Receive a food from a person to whom the Food Traceability Rule does not apply, provided you are not a retail food establishment or restaurant.
- Do **not** establish a new traceability lot code when you conduct other activities for a food on the FTL. For example, you must not establish a new traceability lot code when you ship a food on the FTL.

Recordkeeping Responsibilities

Covered entities must maintain records describing their traceability program, including:

- A description of relevant reference records
- A list of foods on the FTL that they handle
- A description of how traceability lot codes are assigned
- Other procedures used to maintain required records

Similarly, required records must be electronically stored in sortable formats by January 2025. This mandate requires food businesses to have a digital infrastructure that allows data to be easily retrieved, sorted, and analyzed.

Under Section 204(d), businesses must be able to produce FDA-requested records within 24 hours. Records must be maintained for at least two years and stored in original paper, electronic, or copies to prevent deterioration or loss.

Records Required When a Food on the FTL is Shipped (Cite § 1.1340)

For each traceability lot of a food on the FTL that is shipped, maintain records containing the following information and linking this information to the traceability lot:

- (1) The traceability lot code for the food;
- (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
- (3) The product description for the food;
- (4) The location description for the immediate subsequent recipient (other than a transporter) of the food;
- (5) The location description for the location from which the food was shipped;
- (6) The date the food was shipped;
- (7) The location description for the traceability lot code source, or the traceability lot code source reference; and
- (8) The reference document type and reference document number.

A distributor must provide (in electronic, paper, or other written form) the information in paragraphs (a)(1) through (7) of this section to the immediate subsequent recipient (other than a transporter) of each traceability lot that is shipped.

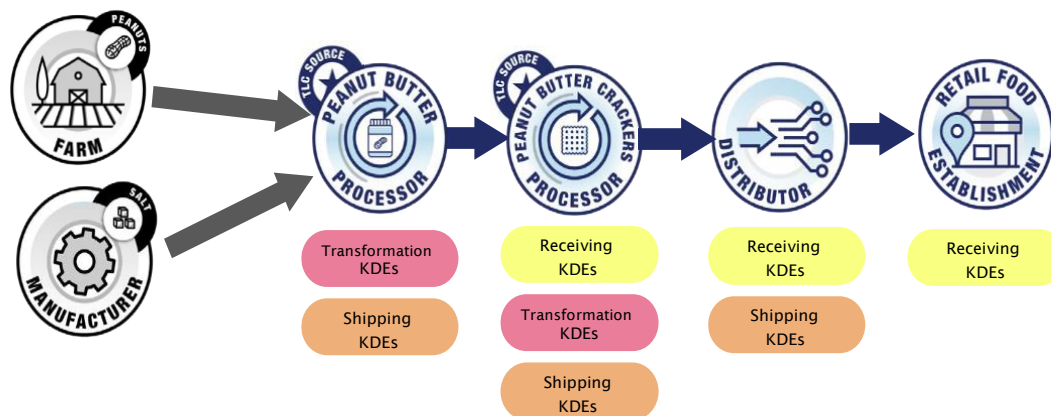
This section does not apply to the shipment of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel).

Records Required When a Food on the FTL Is Received (Cite § 1.1345(a), (c))

For each traceability lot of a food on the FTL that is received by a distributor, maintain records containing the following information and linking this information to the traceability lot:

- (1) The traceability lot code for the food;
- (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
- (3) The product description for the food;
- (4) The location description for the immediate previous source (other than a transporter) for the food;
- (5) The location description for where the food was received;
- (6) The date the food was received;
- (7) The location description for the traceability lot code source, or the traceability lot code source reference; and
- (8) The reference document type and reference document number.

Supply Chain Example: Peanut Butter Crackers (Source: FDA)



Monitoring Food Temperatures in Transit

Under FSMA Section 204(d), distributors must monitor temperature-sensitive items in real time. Temperature-tracking RFID (Radio Frequency Identification Technology) tags, allow food distributors to continuously monitor and record temperature data while products are in transit, providing an audit-ready trail for compliance.

Enforcement and Consequences of Failure to Comply with FSMA Section 204(d)

Where appropriate, regulatory actions the FDA will take in response to violations of subpart S, whether by distributors or any other type of entity subject to the rule, will be aimed at gaining compliance through voluntary corrective actions, as has been the case with the FDA implementation of other FSMA regulations. As previously stated, the FDA plans to educate industry before and while the agency assists firms in understanding the rule. The agency intends to use the FDA standard regulatory inspection tools, including discussing violations at the time the FDA reviews records, to inform covered entities of violations of the rule as they are observed and to provide firms with a reasonable opportunity to comply.

The violation of any recordkeeping requirement under section 204 of the FSMA, including the violation of any requirement of the Food Traceability Rule, is prohibited under section 301(e) of the FD&C Act, except when such violation is committed by a farm. An article of food is subject to refusal of admission under section 801(a)(4) of the FD&C Act if it appears that the recordkeeping requirements under section 204 of the FSMA (other than the requirements under subsection (f) of that section), including the requirements of the Food Traceability Rule, have not been complied with regarding such article.