



How to Read the FDA FSMA 204(d) Final Food Traceability Rule

FSMA 204 Key Sections

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At New Era Partners, we commonly hear feedback that the text of Rule 204 is too long to read; in fact, the full PDF of the rule is one hundred and seventy-nine pages in nine-point font containing over two-hundred thousand words. To make it easier to understand the rule, we recommend reading it as it appears in the Code of Federal Regulations (CFR), without the preamble, comment responses, economic analysis, etc. The most important sections to read first are:

- Who is subject to this subpart
- Definitions
- Traceability Plan
- Records of Critical Tracking Events
- Records Maintenance and Availability

Once you have this context, the remaining sections will make more sense: Consequences of Failure to Comply, Updating the Food Traceability List, Waivers, and Procedures for Modified Requirements and Exemptions.

In an effort to simplify the Food Traceability Rule, we have created an interactive guide with links to the Code of Federal Regulations website. Click on the hyperlinked text ([in blue](#)) on the sections you want to learn more about and **you will automatically be taken to that section of the rule.**





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Who Has to Comply With Rule 204?

Anyone who manufactures, processes, packs, or holds foods on the [Food Traceability List \(FTL\)](#) must comply with the requirements found in FSMA Rule 204 under Subpart S—Additional Traceability Records for Certain Foods. We've included a list of definitions for your reference. Click on each term below to see the FDA's full definitions.

Subpart S—Additional Traceability Records for Certain Foods

General Provisions

§ 1.1300 Who is subject to this subpart?

§ 1.1310 What definitions apply to this subpart?

- [Commingled raw agricultural commodity](#)
- [Cooling](#)
- [Critical tracking event](#)
- [Farm](#)
- [First land-based receiver](#)
- [Fishing vessel](#)
- [Food Traceability List](#)
- [Harvesting](#)
- [Holding](#)
- [Initial Packing](#)
- [Key data element](#)
- [Kill step](#)
- [Location description](#)
- [Manufacturing/processing](#)
- [Mixed-type facility](#)
- [Nonprofit food establishment](#)
- [Packing](#)
- [Person](#)
- [Point of contact](#)
- [Produce](#)
- [Product description](#)
- [Raw agricultural commodity](#)
- [Receiving](#)
- [Reference document](#)
- [Reference document number](#)
- [Restaurant](#)
- [Retail food establishment](#)
- [Shipping](#)
- [Traceability lot](#)
- [Traceability lot code](#)
- [Traceability lot code source](#)
- [Traceability lot code source reference](#)
- [Transformation](#)
- [Transporter](#)
- [You](#)



Traceability Plan

Under FSMA 204, you need to maintain a Traceability Plan that includes important information such as recordkeeping procedures, point of contact for questions regarding your plan, a farm map, and Traceability Lot Code assignment.

§ 1.1315 What traceability plan must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold?

§ 1.1320 When must I assign traceability lot codes to foods on the Food Traceability List?



What are Critical Tracking Events (CTEs)?

The FDA requires you to collect Key Data Elements (KDEs) if you are performing certain actions in the supply chain called Critical Tracking Events (CTEs). For a clickable PDF that summarizes the CTEs, see the FDA's [Learn the CTEs document](#).

Record of Critical Tracking Events (CTEs)

§ 1.1325 What records must I keep and provide when I [harvest or cool](#) a raw agricultural commodity on the Food Traceability List?

- a. [Harvesting](#)
- b. [Cooling before initial packing](#)

§ 1.1330 What records must I keep when I am performing the [initial packing](#) of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List?

- a. Except as specified in paragraph (c) of this section, [for each traceability lot of a raw agricultural commodity \(other than a food obtained from a fishing vessel\) on the Food Traceability List you initially pack](#), you must maintain records containing the following information and linking this information to the traceability lot:
- b. For each traceability lot of [sprouts](#) (except soil- or substrate-grown sprouts harvested without their roots) you initially pack, you must also maintain records containing the following information and linking this information to the traceability lot:
- c. For each traceability lot of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List you initially pack that you receive [from a person to whom this subpart does not apply](#), you must maintain records containing the following information and linking this information to the traceability lot:



§ 1.1335 What records must I keep when I am the **first land-based** receiver of a food on the Food Traceability List that was obtained from a fishing vessel?

§ 1.1340 What records must I keep and provide when I **ship** a food on the Food Traceability List?

- a. For **each traceability lot of a food on the Food Traceability List you ship**, you must maintain records containing the following information and linking this information to the traceability lot:
- b. You **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 you ship.
- c. 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).

§ 1.1345 What records must I keep when I **receive** a food on the Food Traceability List?

- a. Except as specified in paragraphs (b) and (c) of this section, **for each traceability lot of a food on the Food Traceability List you receive**, you must maintain records containing the following information and linking this information to the traceability lot:
- b. For each traceability lot of a food on the Food Traceability List you receive **from a person to whom this subpart does not apply**, you must maintain records containing the following information and linking this information to the traceability lot:
- c. **This section does not apply to receipt 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) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).



§ 1.1350 What records must I keep when I **transform** a food on the Food Traceability List?

- a. Except as specified in paragraphs (b) and (c) of this section, **for each new traceability lot of food you produce through transformation**, you must maintain records containing the following information and linking this information to the new traceability lot:
- b. For each traceability lot produced through transformation of a **raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List that was not initially packed** prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c), and, if the raw agricultural commodity is sprouts, the information specified in § 1.1330(b)
- c. Paragraphs (a) and (b) of this section **do not apply to retail food establishments and restaurants with respect to foods they do not ship** (e.g., foods they sell or send directly to consumers).



Records Maintenance and Availability

This section details how you can store your traceability records and how to share them with the FDA. It's important to note that the Key Data Elements for each Critical Tracking Event must be shared in an electronic sortable spreadsheet within 24 hours of a request, with some exceptions.

§ 1.1455 How must records required by this subpart be maintained and made available?

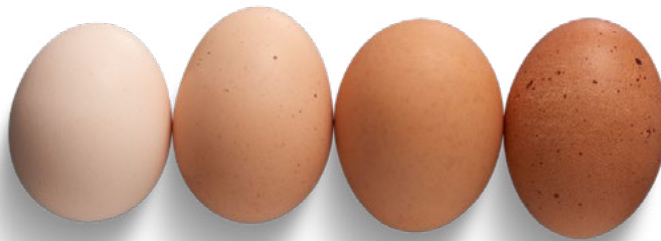
- General requirements for records
- Establishment and maintenance of records by another entity
- Record availability
- Record retention
- Electronic records
- Use of existing records
- Use of multiple sets of records
- Public disclosure



Consequences of Failure to Comply

Failing to comply with the requirements of FSMA Rule 204 is prohibited under section 301(e) of the Federal Food, Drug, and Cosmetic Act, and violators will be subject to the penalties outlined there. Additionally, your products may be subject to refusal of admission.

§ 1.1460 What consequences could result from failing to comply with the requirements of this subpart?



Updating the Food Traceability List

The FDA has outlined a process for updating the Food Traceability List. Any deletions will be effective immediately, but any additions will become effective 2 years after the revised list has been published in the Federal Register.

§ 1.1465 How will FDA update the Food Traceability List?



Procedures for Modified Requirements and Exemptions

The FDA has created formal processes to grant exemptions and waivers, as well as modify the requirements of Rule 204. There are also many exemptions outlined in the rule.

§ 1.1305 What foods and persons are exempt from this subpart?

Procedures for Modified Requirements and Exemptions

Waivers

The [Food Traceability List](#) details foods covered under Subpart S. For foods not covered by this rule, see [Subpart J](#).

There are a lot of exemptions, so [FDA provided an online tool](#) for determining if you are covered.

- Exemptions for certain small producers
- Exemption for farms when food is sold or donated directly to consumers
- Inapplicability to certain food produced and packaged on a farm
- Exemptions and partial exemptions for foods that receive certain types of processing
- Exemption for produce that is rarely consumed raw
- Exemption for raw bivalve molluscan shellfish
- Exemption for persons who manufacture, process, pack, or hold certain foods subject to regulation by the U.S. Department of Agriculture (USDA)
- Partial exemption for commingled raw agricultural commodities
- Exemption for small retail food establishments and small restaurants
- Partial exemption for retail food establishments and restaurants purchasing directly from a farm
- Partial exemption for retail food establishments and restaurants making certain purchases from another retail food establishment or restaurant
- Partial exemption for farm to school and farm to institution programs
- Partial exemption for owners, operators, or agents in charge of fishing vessels
- Exemption for transporters.
- Exemption for nonprofit food establishments.
- Exemption for persons who manufacture, process, pack, or hold food for personal consumption
- Exemption for certain persons who hold food on behalf of individual consumers
- Exemption for food for research or evaluation





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