

GUIDE TO FDA FSMA 204 TRACEABILITY RULE

INTRODUCTION AND OVERVIEW

On November 21, 2022, the FDA published the final rule for additional traceability records for certain foods. This became effective on January 20, 2023, and affected parties must comply by January 20, 2026.

The FDA created this rule to assist in quickly identifying the food source of a foodborne illness outbreak and subsequently where the product was distributed. The information required in the rule is to help with identifying the root cause of the contamination and, hopefully, prevent further outbreaks.

Currently, not all foods are included in this rule. The FDA wanted to focus on foods that have been subject to foodborne illnesses over the past few years. This includes but is not limited to leafy green vegetables, shell eggs, nut butters, semi-soft and soft cheeses, and fresh and frozen seafood. The complete list can be found on the Food Traceability List (FTL). A link for this can be found in the references and links section.

The rule applies to any farm, food facility, restaurant, or retailer that manufactures, processes, packs, or holds foods on the FTL; even farms and food facilities in countries other than the United States. There are exemptions and partial exemptions, some of which are explained below.

EXEMPTIONS AND PARTIAL EXEMPTIONS

1. *Who is Exempt or Partially Exempt from FDA's 204 Traceability Rule?*
 - a. Small farms (produce and aquaculture) with sales of no more than \$25,000 annual average during the previous three years on a rolling basis, adjusted for inflation using 2020 as the baseline.
 - b. Restaurants and retail food establishments (AKA retail food stores) selling no more than \$250,000 annual average of food during the previous 3-year period (adjusted for inflation using 2020 as the baseline).
 - c. Fishing Vessel owners, operators, or agents in charge.
 - i. Seafood sourced from a fishing vessel is also exempt until it is sold by the owner, operator, or agent in charge of the vessel.
 - ii. Fishing vessels that are also FDA registered facilities must keep records identifying the immediate previous source and immediate subsequent recipient of the food (*i.e.*, one-step forward, one-step back records).
 - iii. NOTE: a fishing vessel *could* establish and maintain the required records on behalf of the first land-based receiver (see #3c. below).
 - d. Persons who manufacture, process, pack, or hold FTL foods during or after the time when the food is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA).
 - e. Transporters (ocean, air, rail, road)
 - f. Nonprofit food establishments
 - g. Certain smaller entities are exempt from the requirement to provide information in an electronic sortable spreadsheet, though they must still provide the information in other electronic or paper forms.

2. *What Foods are Exempt or Partially Exempt from FDA's 204 Traceability Rule?*
- a. Any food not on the Food Traceability List
 - i. Catfish and other siluriformes (fish and fish products) which are under USDA FSIS jurisdiction are not on the Food Traceability List.
 - b. Food produced on a farm and sold or donated directly to consumers from the farm.
 - c. Food produced and packaged on a farm provided the packaging:
 - i. prevents contamination or alteration of the product;
 - ii. remains in place until the food reaches the consumer;
 - iii. has labeling that includes the name, complete physical address, and business phone number of the farm from which the food was produced and packaged.
 - d. Commercially processed seafood and produce given a kill step to minimize pathogens.
 - i. FSMA 204 Key Data Elements (KDE) records required until kill step is applied.
 - ii. Record of kill step required.
 - iii. Once food is given a kill step, FSMA 204 shipping or receiving records are no longer required in subsequent steps in the supply chain.
 - e. Food that is changed (*i.e.*, transformed) so that the food is no longer on the FTL.
 - i. FSMA 204 KDE records required until the food is no longer on the FTL.
 - ii. Once a food is no longer on the FTL, FSMA 204 shipping or receiving records are no longer required in subsequent steps in the supply chain.
 - f. Food that will be subjected to a kill step or transformation into a food that is no longer on the FTL, by an entity other than a retail food establishment, restaurant, or consumer provided that:
 - i. there is a written agreement between the shipper of the food and the receiver stating that the receiver or another entity in the supply chain after the receiver will:
 - 1. apply a kill step to the food or change the food such that it is no longer on the FTL; or
 - 2. enter into a similar written agreement with a subsequent receiver stating that a kill step will be applied to the food or that the food will be changed such that it is no longer on the FTL;
 - ii. the written agreements include effective date, printed names and signatures of persons entering the agreement, and substance of the agreement;
 - iii. the written agreements must be renewed at least once every 3 years and maintained for as long as in effect.
 - g. Raw (fresh and frozen) bivalve molluscan shellfish that are:
 - i. covered by the National Shellfish Sanitation Program (NSSP),
 - ii. covered under 21 CFR 123, subpart C and 21 CFR 1240.60, or
 - iii. covered by final equivalence determination by FDA for raw bivalve molluscan shellfish.
 - h. Food for research or evaluation purposes provided:
 - i. the food is not sold or distributed to the public; and
 - ii. the food is accompanied by the statement "Food for research or evaluation use."
 - i. Food purchased by a restaurant or food retailer from another restaurant or food retailer on an ad hoc basis provided:
 - i. the purchaser keeps records of the name of the product, date of purchase and name and address of where the food was purchased.
 - j. Food sold and shipped directly from a farm to a restaurant or retail food establishment provided:

- i. the purchaser keeps records of the name and address of the farm and keep the records for 180 days.
- k. Commingled raw agricultural commodities (RACs), other than fruits and vegetables provided that:
 - i. commingling occurs prior to processing,
 - ii. commingling of farmed products (i.e., aquaculture) occurs with product from different farms under different management,
 - iii. commingling of seafood from a fishing vessel occurs with seafood from different vessels after landing.
 - iv. NOTE: if commingling of RACs occurs later in the supply chain, the RAC is exempt *if* there is a written agreement between entities in the supply chain that the RAC will be included as part of a commingled RAC.
- l. The rule establishes procedures under which persons may request *modified* requirements or an *exemption* from the new traceability recordkeeping requirements for a specific food or a type of entity on the grounds that application of the requirements to that food or type of entity is not necessary to protect the public health.
- m. The rule also establishes procedures for requesting a waiver of one or more of the requirements for an individual entity or a type of entity on the grounds that having to meet the requirements would result in an economic hardship due to the unique circumstances of that entity or type of entity.

REQUIREMENTS – BY BUSINESS TYPE

1. All businesses required to comply with the regulation must:
 - a. Develop and implement a Traceability Plan that includes the following:
 - i. description of:
 1. records kept including format and location;
 2. process used to determine the covered foods items on the Food Traceability List;
 3. Traceability Lot Codes and how they are assigned (if applicable).
 - ii. point of contact(s) within the organization who is knowledgeable about the Traceability Plan.
 - iii. Farms, including aquaculture operations, must also include a map showing the areas where food is raised including:
 1. the geolocations of the growing areas (FDA refers to aquaculture growing areas as “containers” which includes pond, pool, tank, cage);
 2. unique name of each growing area;
 3. other information necessary to identify the location of each growing area.
 - b. Update Traceability Plan as needed and keep previous plans for 2 years after plan is updated.
 - c. Provide required records to FDA when requested.
 - i. Most businesses will be required to provide FDA with an electronic sortable spreadsheet containing the requested information within 24 hours of request.
 - ii. Required records are to be retained for 2 years from the date you created or obtained the record.
2. Harvesters of raw agricultural commodities from farms (e.g., aquaculture seafood, produce, eggs) must:
 - a. Keep harvest records that include:

- i. document name/type and reference number;
 - ii. farm name, physical address, and phone number;
 - iii. species or acceptable market name of seafood commodity and, if applicable, variety;
 - 1. commodity and, if applicable, variety for non-seafood raw agricultural commodities;
 - iv. quantity and unit of measurement of food harvested;
 - v. the name of the container (i.e., pond, pool, tank, cage) or other information identifying the harvest location;
 - 1. field name or other information identifying the harvest location for non-seafood raw agricultural commodities;
 - vi. harvest date;
 - vii. company name, physical address and phone number for the immediate subsequent receiver (other than a transporter).
 - b. Provide harvester name and phone number plus all of the above listed information, except document name/type and reference number, to the initial packer of the harvested food.
- 3. First Processor (also known as the Primary Processor):
 - a. In most situations the first processor will assign the Traceability Lot Code (TLC).
 - b. Initial packer of farmed products (this includes aquaculture, produce and eggs) must generate records to include:
 - i. company name, physical address, and phone number where the food is being packed;
 - ii. document name/type and reference number;
 - iii. species and/or acceptable market name of seafood commodity and, if applicable, variety of product received;
 - 1. commodity and, if applicable, variety for non-seafood raw agricultural commodities;
 - iv. dates of harvesting, receiving, and packing;
 - v. quantity and unit of measurement of food received;
 - vi. farm name, physical address, and phone number;
 - vii. name of the container (i.e., pond, pool, tank, cage) or other information identifying the harvest location;
 - 1. field name or other information identifying the harvest location for non-seafood raw agricultural commodities;
 - viii. name and phone number of the harvester;
 - ix. product description of the packed food;
 - x. quantity and unit of measure of the packed food;
 - xi. Traceability Lot Code assigned;
 - xii. Traceability Lot Code reference (if used).
 - c. First Land-based Receiver of fish from a fishing vessel must generate records to include:
 - i. company name, physical address, and phone number where the food is being received;
 - ii. document name/type and reference number;
 - iii. species and/or acceptable market name of seafood commodity and, if applicable, variety of product received;
 - 1. product description for seafood that is packaged on fishing vessel;
 - iv. quantity and unit of measurement of food receiving;
 - v. harvest date range;
 - vi. harvest location(s) (FAO zone or NMFS Geographic Code);

- vii. landing date;
 - viii. Traceability Lot Code assigned;
 - ix. Traceability Lot Code source reference (if used).
4. Shipper (any business after initial packing or receiving from fishing vessel) must:
- a. generate records to include:
 - i. company name, physical address, and phone number from where the food shipped;
 - ii. document name/type and reference number;
 - iii. quantity and unit of measurement of food being shipped;
 - iv. product description (species and/or acceptable market name, brand (if applicable), variety, packaging size, and style);
 - v. company name, physical address, and phone number for where the food is going;
 - vi. date food was shipped;
 - vii. Traceability Lot Code and source location or source reference.
 - b. provide the above listed information (other than the document name and reference number) to the receiver;
 - i. information can be provided in electronic or paper form.
5. Secondary Processor/Warehouse/Distributor receiving packed foods (any business after initial packing or receiving from fishing vessel) must:
- a. generate and keep records to include:
 - i. Traceability Lot Code (as received) and source location or source reference;
 - ii. document name/type and reference number;
 - iii. quantity and unit of measurement of food being received;
 - iv. product description (species and/or acceptable market name, brand (if applicable), variety, packaging size, and style);
 - v. company name, physical address, and phone number for the shipper and the receiver;
 - vi. date of receipt;
 - b. link receiving records to the Traceability Lot Code;
 - c. when shipping foods follow the requirements outlined in #4 above.
6. Secondary Processor changing the food (also known as “transformation”) after receiving must:
- a. generate and keep records of the ingredients/raw materials used to include:
 - i. Traceability Lot Code(s) (as received);
 - ii. product description (species and/or acceptable market name, brand (if applicable), variety, packaging size, and style);
 - iii. quantity and unit of measure of the ingredients/raw materials for each Traceability Lot Code used;
 - b. generate and keep records of the new finished product being made:
 - i. newly assigned Traceability Lot Code;
 - ii. company name, physical address, and phone number for where the new food was processed;
 - iii. product description (species and/or acceptable market name, brand (if applicable), variety, packaging size and style) of the new food;
 - iv. Traceability Lot Code source location or source reference (the source location will be the same as ii);
 - v. date of transformation was completed;
 - vi. quantity and unit of measure for the new food;
 - vii. document name/type and reference number.

RESOURCES AND REFERENCES

DEFINITIONS

1. Raw Agricultural Commodity (RAC) – 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. <https://www.ecfr.gov/current/title-7/subtitle-B/chapter-I/subchapter-C/part-66/subpart-A/section-66.1>
2. Commingled RAC – Any commodity that is combined or mixed after harvesting but before processing. For food obtained from a fishing vessel, a commodity is “combined or mixed” only when the combination or mixing involves food from different landing vessels and occurs after the vessels have landed. Similarly, for food not obtained from a fishing vessel, a commodity is “combined or mixed” only when the combination or mixing involves food from different farms under different company management. <https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule#TRAC1>
3. Food – (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. <https://www.govinfo.gov/content/pkg/COMPS-973/pdf/COMPS-973.pdf>
4. Fishing vessel – any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing, as set forth in in the Magnuson-Stevens Fisher Conservation and Management Act (16 U.S.C 1802(18)). <https://www.ecfr.gov/current/title-50/chapter-III/part-300/subpart-N/section-300.201>
5. Mixed-type facility – an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-121/subpart-A/section-121.3>
6. Packing – Placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-121/subpart-A/section-121.3>

USEFUL LINKS

1. [Food Traceability List](#)
2. [Exemption Tool](#)
3. [Supply Chain Examples](#)
4. [Webinar on the Food Traceability Rule](#)
5. [GS1 US FSMA 204 Readiness Checklist](#)