



Information Paper: FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

On January 20, 2023, the U.S. Food and Drug Administration (FDA) final rule establishing additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods became effective. The rule, “Requirements for Additional Traceability Records for Certain Foods” (Food Traceability Rule) is one of the last remaining elements of the FDA’s Food Safety Modernization Act (FSMA) and lays the foundation for end-to-end food traceability across the food industry. It is a key component of the FDA’s New Era of Smarter Food Safety Blueprint which outlines several key elements, including enhanced traceability.

FDA’s Deputy Commissioner for Food Policy and Response, Frank Yiannas, has stated that “This standardized, data-driven approach to traceability recordkeeping helps create a harmonized, universal language of food traceability that will help pave the way for industry to adopt and leverage more digital, interoperable and tech-enabled traceability systems both in the near term and the future.”

Existing traceability requirements

Existing FDA regulations require much of the food industry to establish and maintain records to identify immediate recipients (i.e. customers) and previous suppliers of foods. This is commonly known as ‘one-up and one-back’ traceability.

“When we look at the current state of traceability across the food supply, we find that even though some food producers, manufacturers and retailers have adopted modern, effective traceability systems, rarely are these systems compatible with each other. And still, many other food companies have not adopted traceability systems at all. Simply put, we lack a harmonized system of traceability from farm to fork that is universally understood and utilized,” adds Yiannas.

“This means that during an outbreak investigation, our ability to rapidly track and trace specific food products through the supply chain is often impeded by a lack of data. The result can be millions of dollars in avoidable product loss by necessitating overly broad recalls and consumer advisories, a loss of consumer trust, and prolonged outbreaks of consumer illnesses and deaths.”

Foods covered by the proposed rule

While subject to review and updating, the rule identifies eighteen (18) food types and listed them on the Food Traceability List (FTL). These foods include:



- Cheeses, other than hard cheeses
- Shell eggs
- Nut butters
- Cucumbers (fresh)
- Herbs (fresh)
- Leafy greens, including fresh and fresh-cut
- Melons (fresh)
- Peppers (fresh)
- Sprouts (fresh)
- Tomatoes (fresh)
- Tropical tree fruits (fresh)
- Fruits (fresh-cut)
- Vegetables other than leafy greens (fresh-cut)
- Finfish (fresh and frozen)
- Smoked finfish (refrigerated and frozen)
- Crustaceans (fresh and frozen)
- Molluscan shellfish, bivalves (fresh and frozen)
- Ready-to-eat deli salads (refrigerated)

It is worth noting that the “Food Traceability List” (FTL) refers not only to the foods specifically listed, but also to any foods that contain listed foods as ingredients. Each requirement described in the Food Traceability Rule therefore pertains to all such foods unless an exemption applies.

While the regulations only apply to foods on the FTL, they were designed to be suitable for all FDA-regulated food products. FDA is encouraging the voluntary adoption of these practices industrywide.

Impact on BRCGS product categories

Based on the product categories outlined in BRCGS Global Standard Food Safety Issue 9, the following categories may be impacted by this Rule:

- 2 - Raw poultry
- 3 - Raw prepared products (meat and vegetarian)
- 4 - Raw fish products
- 5 - Fruit, vegetables and nuts
- 6 - Prepared fruit, vegetables and nuts
- 7 - Dairy, liquid egg
- 8 - Cooked meat/fish products
- 9 - Raw cured and/or fermented meat and fish



If any products contain listed foods as ingredients, category 10 - Ready meals and sandwiches, ready-to-eat desserts may also be affected.

All BRCGS certified sites are encouraged to use the FDA decision calculator to help determine if the Rule specifically applies or not.

Risk-Ranking Model for Food Tracing

How did the FDA decide which foods would be included on the Food Traceability List? Foods on the FTL have been selected based on a Risk-Ranking Model for Food Tracing.

The Model scores commodity-hazard pairs according to data and information relevant for seven criteria: (C1) frequency of outbreaks and occurrence of illnesses, (C2) severity of illness, (C3) likelihood of contamination, (C4) growth potential, with consideration of shelf life, (C5) manufacturing process contamination probability and industrywide intervention, (C6) consumption, and (C7) cost of illness.

You can read more about the Risk-Ranking Model for Food Tracing by [clicking here](#)

Requirement to maintain traceability records

The Food Traceability Rule seeks to standardize the data elements and information firms must establish and maintain, and the information they would need to send to the next entity in the supply chain to facilitate rapid and accurate traceability.

At the core of this rule is a requirement for those who manufacture, process, pack or hold foods on the Food Traceability List (FTL) to establish and maintain records containing Key Data Elements (KDEs) associated with different Critical Tracking Events (CTEs).

Critical Tracking Events (CTEs)

Critical tracking events are defined in the rule as “an event in the supply chain of a food involving the 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.”

If your business engages in any of these processes for foods listed in the Food Traceability List, compliance is required unless exempted.

By way of example, CTEs may be related to harvesters, on-farm cool storage, on-farm packing, processors, manufacturers, distributors, or retailers.



Key Data Elements (KDEs)

In the context of the traceability rule, Key Data Elements can be seen as pieces of information that support and help to verify the traceability system within a business. It is data that critical to the success of tracing food from farm to fork. This information must be maintained and provided to supply chain partners.

Given the different circumstances, products and capacities of food businesses, a 'one size fits all' KDE list is not possible. However, examples of KDEs could include:

- Contact details of the produce harvester
- Harvest date/time, locations, growing geographical coordinates
- Traceability lot codes
- Transporter name
- Quantity and unit of measure of the food produced
- Creation location identifier, description, completion date

You can access other examples by [clicking here](#).

BRCGS certified sites should be currently addressing this requirement through compliance with traceability and record keeping requirements outlined in applicable BRCGS standards.

Traceability Plan

If you are subject to the requirements of the Food Traceability Final Rule, you must establish and maintain a traceability plan. This traceability plan is to outline how your business will comply with the rule. Other requirements include:

1. A description of the procedures you use to maintain the records you are required to keep under this rule, including the format and location of these records.
2. A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold;
3. A description of how you assign traceability lot codes to foods on the Food Traceability List, if applicable;
4. A statement identifying a point of contact for questions regarding your traceability plan and records; and
5. If you grow or raise a food on the Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods.

You must update your traceability plan as needed to ensure that the information reflects your current practices and to ensure you are in compliance with the rule. You must also retain your previous traceability plan for two years after you update the plan.



BRCGS Traceability requirements

BRCGS defines traceability as the “ability to trace and follow raw materials, components and products, through all stages of receipt, production, processing and distribution both forwards and backwards”.

Clause 3.9 Traceability outlined in BRCGS Global Standard Food Safety Issue 9 requires the traceability system to meet the legal requirements in the country of sale or intended use. In its current form, clause 3.9 partially supports compliance with the traceability plan requirements mandated by the Food Traceability Rule.

An exception to this is the requirement to specifically identify a point of contact for questions regarding your traceability plan and records. To meet this requirement, BRCGS suggests that this function be allocated to your nominated contact and the responsibility documented within relevant job descriptions.

The requirement for farm maps to indicate areas where food is grown or raised closely aligns to clauses 2.3.2 and 4.3.2. Additionally, reviewing the food traceability plan should be achieved through the internal audit function outlined in clause 3.4.

Sites may need to amend record retention procedures to ensure that previous traceability plans are retained for two years after they are updated.

Traceability Records

Under the rule, the FDA allows either paper or electronic records. However, it’s worth noting that the FDA has made it clear that there is a preference for electronic records. An ‘electronic sortable spreadsheet’ containing relevant traceability information will be required to be provided to the FDA within 24 hours of a request (or within a reasonable time to which the FDA has agreed).

Am I subject to the rule?

The final rule aligns with current industry best practices and covers domestic firms, retail food establishments, restaurants, and farms, as well as foreign firms and farms producing food for U.S. consumption.

If you are unsure if your business is subject to the final rule, the FDA has published an easy-to-follow decision tree calculator to help with this determination. You can access this tool by [clicking here](#).



Timeframe for Implementation

Because the Food Traceability Final Rule requires entities to share information with other entities in their supply chain, the most effective and efficient way to implement the rule is to have all persons subject to the requirements come into compliance by the same date. The compliance date for all persons subject to the recordkeeping requirements is Tuesday, January 20, 2026.

Impact for BRCGS certificated sites

If your business is currently certificated by BRCGS and you are located within the USA, we highly recommend that you use the [decision tree calculator](#) to determine if you are subject to the rule. While the Food Traceability Final Rule applies to US importers of food, importers may request traceability information from BRCGS certified sites that export to the USA. BRCGS also encourages exporters to work with their importers to ensure they are keeping records of information that may be required by their importers.

If you are required to comply with the rule, we also recommend completing a gap analysis to determine if your business currently records relevant KDEs. Performing traceability and mass balance activities on each of your product may also help with this determination.

For more information about BRCGS Standards, please visit the [BRCGS website](#) or email enquiries@brcgs.com.