FSMA Proposed Rule for Food Traceability: Guidance for Sites

Summary

On September 21, 2020, the U.S. Food and Drug Administration (FDA) announced that they are proposing to establish additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods.

The proposed rule, "Requirements for Additional Traceability Records for Certain Foods" (Food Traceability Proposed 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 "While limited to certain foods, this proposed rule would create a first-of-its-kind, standardized approach to traceability recordkeeping, paving the way for industry to adopt and leverage more digital, 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 proposed rule has tentatively identified sixteen (16) food types and listed them on the Food Traceability List (FTL). These foods include:

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

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 Proposed Rule therefore pertains to all such foods unless an exemption applies.

While the proposed regulations would 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.

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: https://www.fda.gov/media/142282/download

Requirement to maintain traceability records

The Food Traceability Proposed 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 proposal 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).

What are Critical Tracking Events (CTEs)?

FDA proposes growing, receiving, transforming, creating, and shipping activities as Critical Tracking Events. If your business engages in any of these processes for foods listed in the Food Traceability List, compliance will be required unless exempted.

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

What are Key Data Elements KDEs?

In the context of the proposed 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 is critical to the success of tracing food from farm to fork.

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: https://www.fda.gov/food/food-safety-modernization-act-fsma/which-key-data-elements-would-apply-me

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.

Am I subject to the rule?

If you are unsure if your business is subject to the proposed rule, the FDA has published an easy to follow decision tree to help with this determination. You can access this tool by clicking here: https://www.fda.gov/media/143516/download?utm_medium=email&utm_source=govdelivery

Timeframe for Implementation

At this stage, the proposed rule and draft FTL are available for public comment until January 1, 2021. You can submit your comments to docket FDA-2014-N-0053 by clicking here regulations.gov.

The FDA proposes that any final rule on additional traceability recordkeeping requirements for foods on the FTL would become effective 60 days after it is published in the *Federal Register*.

Because an effective traceability system requires all entities in a supply chain to maintain traceability records, the FDA has stated that all persons subject to the rule should come into compliance by the same date. It is proposed that the compliance date for all persons subject to the recordkeeping requirements would be 2 years after the effective date of the final regulation.

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 follow the decision tree to determine if you are subject to the proposed rule. There may also be compliance obligations if you export your product to the USA. You can access the decision tree by clicking here: https://www.fda.gov/media/143516/download

If you are required to comply with the proposed 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 products may also help with this determination.