FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

Foodservice Distributor Supplier Expectations





Food Traceability Rule – Foodservice Distributor Supplier Expectations



The US Food and Drug Administration's (FDA's) <u>Final Rule on Requirements for Additional Traceability Records</u> for <u>Certain Foods</u> will take effect on **January 20, 2026**. The rule requires entities to maintain records containing specific "key data elements" (KDEs) when they engage in "critical tracking events" (CTEs) regarding foods listed on FDA's <u>Food Traceability List</u> (FTL) or foods that contain FTL foods as ingredients (collectively, FTL foods). Entities engaging in certain activities at specified points in the supply chain will be required to assign a unique "traceability lot code" (TLC) to each FTL food, and subsequent entities in the supply chain will need to link KDE records to the food using the food's TLC.

As a supplier, you will be required to pass forward the following "shipping" KDEs to your foodservice distributor customers for each FTL food you supply:

- The product's TLC.
- The quantity and unit of measure.
- The product description.
- The location description for the immediate subsequent recipient, for where the food was shipped, and for the TLC source or TLC source reference.
- The date of shipment.

To fulfill these requirements, and to ensure that foodservice distributors can fulfill their own regulatory obligations, we expect you to comply with the following:

 You must determine whether your operations are exempt from the Traceability Rule, and you must notify your foodservice distributor customers of this determination before the January 20, 2026, compliance date, and then as necessary on an ongoing basis (e.g., with each shipment or as part of your master data). If you conclude that your operations are exempt, then you must notify your foodservice distributor customers of that conclusion and identify the basis for that conclusion in writing. We will presume that any suppliers who do not provide such notifications are subject to the rule. If you are subject to the rule, you must develop a written traceability plan and take other necessary measures to ensure compliance with the rule. You should take these steps well in advance of the January 20, 2026 compliance date.

- 2. You must identify which foods you send to your foodservice distributor customers are FTL foods. You should provide this information to your foodservice distributor customers before the January 20, 2026, compliance date, and then as necessary on an ongoing basis, preferably as part of the product's master data. If you determine that any of the FTL foods you supply are exempt from the rule, you must inform your foodservice distributor customers of that conclusion and identify the applicable exemption in writing.
- **3. You must pass forward shipping KDE records for each FTL food you supply.** In doing so, you must comply with the following expectations:
 - a. Provide the shipping KDEs in electronic format via advanced ship notice (ASN), electronic product code information services (EPCIS) standard, or other electronic data exchange (EDI) transactions *before* the delivery date.
 - b. In addition to (a), provide any hard copy paper records along with the bill of lading (BOL) at the time of delivery.
 - c. Ensure that all shipping KDE records are complete and accurate.
 - d. Clearly identify the TLC for each FTL food and use a standardized TLC format across shipments.
 - e. Clearly identify each individual KDE and use a standardized format for KDEs across shipments.

4. To the extent possible, you should also comply with the following best practices:

- a. Use a FSMA 204 attribute to identify which foods in a shipment are FTL foods and convey this information as part of your master data during item setup (e.g., using a Global Data Synchronization Network (GDSN) or Product Lifecycle Management (PLM) FSMA 204 attribute).
- b. Place data carriers that encode to the TLC and the TLC source or TLC source reference (e.g., barcodes, QR codes, RFID tags, etc.) on two adjacent sides of all packages, unless otherwise agreed upon.
- c. Include pallet tags that reference all TLCs in a pallet (e.g., GS1 Serial Shipping Container Code (SSCC)) and identify all mixed pallets (*i.e.* pallets with multiple TLC lots).

We recommend consulting with legal counsel if you have additional questions about your obligations under the rule.

