

How your suppliers can share electronic records with you:

- Use a traceability application
- Send ASNs via EDI
- Transfer flat files, such as a CSV extracted from their ERP, through a secure file transfer service
- Transfer data between platforms using an API

KDEs tracked at each Critical Tracking Event

(Harvesting, Cooling, Initial Packing, First Land-Based Receiver, Shipping, Receiving, Transformation)

As a retailer, distributor, or processor, it is critical to:

- Get all shipping information, including Key Data Elements (KDEs), from your suppliers electronically.
- Ensure your suppliers are labeling all cases and pallets with labels that contain GS1-128 barcodes so you can match physical goods to the electronic records.
- Work with a partner who can:
 - Accept electronic records in various formats and store them in the cloud.
 - Make KDEs visible to you so that you can track supplier compliance and traceback and forward across your supply chain.

The Food Traceability Rule requires persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) to maintain and provide to their supply chain partners specific information (Key Data Elements or KDEs) for certain Critical Tracking Events (CTEs) in the food's supply chain.

The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through processing, distribution, and receipt at retail or other point of service. Central to the proposed requirements is the assignment, recording, and sharing of traceability lot codes for FTL foods, as well as linking these lot codes to other information identifying the foods as they move through the supply chain.

Key Data Elements (KDEs) as outlined in FSMA Rule 204 for each Critical Tracking Event (CTE)

Shipping KDEs directly correspond to Receiving KDEs*

SHIPPING

SHIPPING KDEs (maintain and provide):

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Location description for the location from which you shipped the food.
- Date you shipped the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number (maintain only)

KDEs must be linked to the traceability lot for the food.

RECEIVING

RECEIVING KDEs:

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received
- Date you received the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number

KDEs must be linked to the traceability lot code for the food. Visit the FDA website for KDEs you must capture for food you receive from a person or entity who is exempt from the rule.

Additional KDEs

HARVESTING

HARVESTING KDEs (Raw agricultural commodities (RACs) not obtained from a fishing vessel):

- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for the farm where the food was harvested
- For produce:
 - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or
 - Other information identifying the harvest location at least as precisely as field or growing area name
- For aquacultured food:
 - Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or
 - Other information identifying the harvest location at least as precisely as the container name
- Date of harvesting
- Reference document type and reference document number

Additional KDEs that must be provided to the Initial Packer: Business name, phone number, Harvesting KDEs (with some exclusions)

TRANSFORMATION

TRANSFORMATION KDEs:

- FTL food(s) used as ingredients:
 - Traceability lot code for the food
 - Product description for the food to which the traceability lot code applies
- For each traceability lot used, the quantity and unit of measure of the food used from that lot

New food produced:

- New traceability lot code for the food
- Location description for where you transformed the food (i.e., the traceability lot code source, and (if applicable) the traceability lot code source reference
- Date transformation was completed
- Product description for the food
- Quantity and unit of measure of the food
- Reference document type and reference document number

KDEs must be linked to the new traceability lot for the food. Visit the FDA website for exceptions.

COOLING

COOLING KDEs (Before Initial Packing, for RACs not obtained from a fishing vessel):

- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for where you cooled the food
- Date of cooling
- Location description for the farm where the food was harvested
- Reference document type and reference document number

Cooling KDEs must be provided to the Initial Packer.

FIRST LAND-BASED RECEIVER

FIRST LAND-BASED RECEIVER KDEs (food obtained from a fishing vessel):

- Traceability lot code you assigned
- Species and/or acceptable market name for unpackaged food, or the product description for packaged food
- Quantity and unit of measure of the food
- Harvest date range and locations for the trip during which the food was caught
- Location description for the first land-based receiver (i.e., traceability lot code source reference
- Date the food was landed
- Reference document type and reference document number

KDEs must be linked to the new traceability lot for the food.

TRACEABILITY PLAN

Required for all persons covered by the rule:

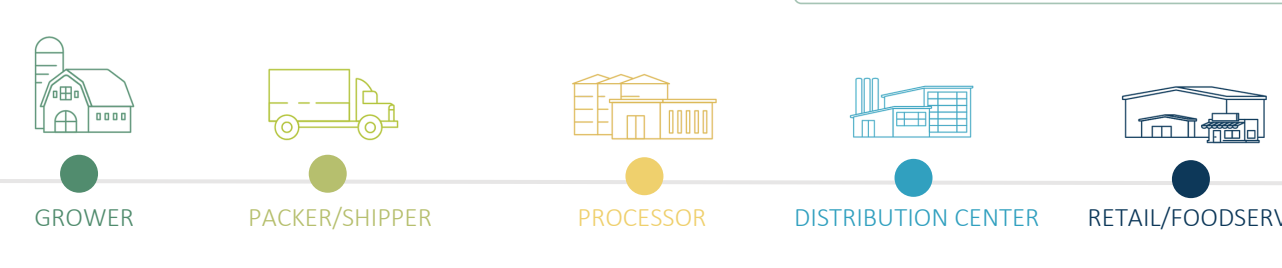
- Description of the procedures you use to maintain the required records, including the format and location of the records
- Description of the procedures you use to identify foods on the FTL that you manufacture, process, pack or hold
- Description of how you assign traceability lot codes to the FTL, if applicable
- Statement identifying a point of contact for questions regarding your traceability plan and records
- If you grow or raise a food on the FTL (other than eggs), a farm map showing the areas in which you grow or raise such foods
 - The farm map must show the location and name of each field (or other growing area) in which you grow a food on the FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area
 - For aquaculture farms, the farm map must show the location and name of each container (e.g., pond, pool, tank, cage) in which you raise seafood on the FTL, including the geographic coordinates and any other information needed to identify the location of each container
- 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 retain your previous traceability plan for 2 years after you update the plan

INITIAL PACKING

INITIAL PACKING KDEs (other than a food obtained from a fishing vessel):

- Commodity and, if applicable, variety of the food received
- Date you received the food
- Quantity and unit of measure of the food received
- Location description for the farm where the food was harvested
- For produce:
 - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or
 - Other information identifying the harvest location at least as precisely as field or growing area name
- For aquacultured food:
 - Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or
 - Other information identifying the harvest location at least as precisely as the container name
- Business name and phone number for the harvester of the food
- Date of harvesting
- Location description for where the food was cooled (if applicable)
- Date of cooling (if applicable)
- Traceability lot code you assigned
- Product description of the packed food
- Quantity and unit of measure of the packed food
- Location description for where you initially packed the food (i.e., traceability lot code source), and (if applicable), the traceability lot code source reference
- Date of initial packing
- Reference document type and reference document number

KDEs must be linked to the traceability lot you assign for the food that you pack.



Source: <https://www.fda.gov/media/163132/download>