



FDA FSMA 204: Traceability Requirements for Seafood Appendix

Global Food Traceability Center

Definitions

The following is a list of full definitions that could apply to this category. Note: The term "First Land-Based Receiver" was added; the terms "First Receiver" and "Vessel Identification Number" have been deleted from the list of definitions and CTE/KDE requirements.

- **Commingled Raw Agricultural Commodity:** any commodity that is combined or mixed after harvesting but before processing. 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
- **Cooling:** active temperature reduction of an RAC before initial packing using hydrocooling, icing, forced air cooling, vacuum cooling, or a similar process. This definition excludes the icing of seafood
- **Critical Tracking Event:** an event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a RAC 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
- **Farm:** an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood such as aquaculture and oyster leaseholds), or any combination of these activities
 - Both persons who harvest and persons who initially pack must keep location identifying information
- **First Land-Based Receiver (Wild Caught):** the person taking possession of a food for the first time on land directly from a fishing vessel
- **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
- **Food Traceability List:** the list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d)(2) of FSMA, including both the foods specifically listed and foods that contain listed foods as ingredients (provided that the listed food used as an ingredient remains in the same form in which it appears on the list)
- **Initial Packing (Aquaculture):** packing a RAC (other than food obtained from a fishing vessel) for the first time
 - This include produce packinghouses or any entity that initially packs a RAC (not obtained from a fishing vessel) and must assign a traceability lot code and maintain harvest and (when applicable) KDEs linked to the traceability lot code
- **Harvesting (Aquaculture):** activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food.
 - Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots, or stems). Examples of harvesting also include cooling*, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm

Definitions

- **Holding:** storage of food in warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks; and includes activities performed incidental to the storage of a food such as fumigating and drying/dehydrating, and activities performed as a practical necessity for the distribution of that food
- **Key Data Element:** information associated with a CTE for which a record must be maintained “and/or provided” in accordance with subpart S
- **Kill Step:** lethality processing that significantly minimizes pathogens in a food
- **Location Description:** key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, state, and zip code for domestic locations and comparable information for foreign locations, including country. If a person is the first land-based receiver of a food that was obtained from a fishing vessel, the only location description record the person must maintain is the location description for itself, which also serves as the traceability lot code source for the food; and must maintain a record of the harvest date range and location for the trip during which the food was harvested
- **Manufacturing/Processing:** making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients; including baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating RACs to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing
- **Mix-Type Facilities:** an establishment that engages in both activities that are exempt from registration under section 415 of the FD&C Act and activities that require the establishment to be registered. This includes an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered
- **Nonprofit Food Establishment:** a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States including central food banks, soup kitchens, and nonprofit delivery services.
- **Packing:** placing food into a container other than packaging the food including re-packing and activities performed incidental to packing or re-packing a food such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing
- **Point of Contact:** an individual having familiarity with an entity’s procedures for traceability, including their name and/or job title, and phone number
- **Product Description:** a description of a food product, which includes the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style. The product name may include the species and/or acceptable market name.
- **Raw Agricultural Commodity:** 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; as defined in section 201(r) of the FD&C Act

Definitions

- **Receiving:** an event in a food's supply chain in which a food is received by someone other than a consumer after being transported (e.g., by truck or ship) from another location. Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm
- **Reference Document:** a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the KDEs for a CTE in the supply chain of a food.
- **Reference Document Number:** the identification number assigned to a specific reference document
- **Restaurant:** a facility that prepares and sells food directly to consumers for immediate consumption including entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens; and pet shelters, kennels, and veterinary facilities in which food is provided to animals
- **Retail Food Establishment:** an establishment that sells food products directly to consumers as its primary function including facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food; grocery stores, convenience stores, and vending machine locations, certain farm- operated businesses selling food directly to consumers as their primary function, roadside stand, farmers' market, CSA program, door-to-door sales; mail, catalog, and internet order; religious or other organization bazaars; and state and local fairs
- **Shipping:** an event in a food's supply chain in which a food is arranged for transport (e.g., by truck or ship) from one location to another location. Shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food. Shipping includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.
- **Traceability Lot:** a batch or lot of food that has been initially packed (for RACs other than food obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed
- **Traceability Lot Code:** a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source
- **Traceability Lot Code Source:** the place where a food was assigned a traceability lot code
- **Traceability Lot Code Source Reference:** an alternative method for providing FDA with access to the location description for the traceability lot code source as required under subpart S
- **Transformation:** an event in a food's supply chain that involves manufacturing/processing a food or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List
- **Transporter:** a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air

KDE Descriptions & Examples

Color Key	
	No FDA definitions or specific guidance provided.

KDE	Description	Data Point(s)	Example	
Location Description	<p>Key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates) and city, state, zip code for domestic locations and comparable information for foreign locations.</p> <p>Location identifiers (e.g. store number, GLN, FDA Establishment Number) can be added to or used in place of the location description elements, provided a glossary or key is maintained to indicate the physical address and other required elements for the specific location.</p> <p>Does not apply to fishing vessels.</p>	<p>Option 1 (Domestic Entities): Business Name Phone Number Address or Geographic Coordinates City State Zip Code</p> <p>Option 2 (Foreign Entities): Country level equivalent of Option 1</p> <p>Option 3 (All Entities): Location identifier (e.g. GLN, FDA est. #) that can be linked to a physical address</p>	Option 1 Example	
			Business Name	Institute of Food Technologists
			Phone Number	+1 312-782-8424
			Address	525 W Van Buren St STE 1000
			City	Chicago
			State	IL
			Zip Code	60607
			Option 2 Example	
			Business Name	Fresas Mexicanas
			Phone Number	+52 12-3456-7890
			Street Name/Type	Privada Union
			Building/House #	10
			Neighborhood/Quarter	Col. Agricola Pantitlan
			Municipality	Itzacalco
			Postal Code	8100
			City	Ciudad De Mexico
			State	CDMEX
			Country	Mexico
			Option 3 Example	
			FDA Est Number	12347568493
Quantity	Quantity of food associated with event	Numerical Quantity	100	
Unit of Measure	Unit of measure associated with quantity	Categorical Unit	Cases	

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KDE	Description	Data Point(s)	Example
Reference Document Type	<p>A business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food.</p> <p>A reference document may be established by you or obtained from another person. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.</p>	Categorical description of document	Bill of Lading
Reference Document Number	ID number assigned to a specific reference document. (e.g. PO number, BOL number, WO number, etc.)	ID number assigned to a specific reference document.	AB123
Harvester Business Name	Business name of firm that harvested the food. Harvester can be the farm from which the food originates or a third-party entity that performs the harvest event.	Business Name	Sara's Sprouts
Harvester Phone Number	Contact phone number of firm that harvested the food. Harvester can be the farm from which the food originates or a third-party entity that performs the harvest event.	Phone Number	+1 123-456-7890
RAC Commodity & Variety	Common name for food item and type/variety descriptor (e.g. commodity = melon, variety = honeydew)	Commodity Name	Lettuce
		Variety Name	Iceberg
Field/Growing Area Name or Equivalent Identifier	<p>Name of the field or growing area from which food is harvested - must correspond to the name used by the grower. If a "name" is not used by the grower, other equivalent identifying information may be used.</p> <p>Applies only to Produce.</p>	Field Name or Equivalent Identifier	Iceberg Field 1

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KDE	Description	Data Point(s)	Example
Container Name or Equivalent Identifier	Name of the container (e.g. pond, pool, tank, cage, etc) from which food is harvested - must correspond to the name used by the aquaculture farmer. If a "name" is not used by the farmer, other equivalent identifying information may be used. Applies only to Aquaculture	Container Name or Equivalent Identifier	Tank 3
Event Date	Date on which CTE took place.	Date	12/1/2022
Receive Date	Date on which food was received. Applies only to Initial Packers.	Date	12/1/2022
Traceability Lot Code	Any descriptor used to uniquely identify a traceability lot within the records of the firm that assigned the traceability lot. TLC must be included in the records required at each CTE. All KDEs must be linked to the TLC once assigned. No specific format, length, info to capture like a barcode, etc. Just any code that links to CTEs/KDEs associated with a food product.	Lot Code (usually alphanumeric)	GKR011222
Species and/or Acceptable Market Name or Product Description for Packaged Food	Description of food obtained from a fishing vessel. Applies only to First Land-Based Recievers.	Species Name, Market Name, or Product Description Elements (See Above)	Sockeye Salmon
Harvest Date Range for Trip	Range of dates for the trip during which the food was caught. Applies only to First Land-Based Recievers.	Harvest Start Date	Start Date 12/1/2022
		Harvest End Date	End Date 1/10/2023

KDE Descriptions & Examples

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KDE	Description	Data Point(s)	Example	
Product Description	<p>A description of a food product that includes the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style.</p> <p>For seafood, the product name may include the species and/or acceptable market name. For mixed-commodity products (e.g. packaged mixed veggies) commodity and variety will not be applicable.</p> <p>A single unique identifier (e.g. GTIN) can be used in place of product description KDEs provided that a glossary or key is maintained to indicate the complete product description requirements.</p>	<p>Required: Product Name Packaging Style Packaging Size</p> <p>If Applicable: Brand Name Commodity Variety</p>	Example 1:	
			Product Name	Little Tomatoes
			Packaging Style	Carton
			Packaging Size	10 LB
			Brand Name	Tom's Produce
			Commodity	Tomatoes
			Variety	Cherry
			Example 2:	
			Product Name	Garden Salad Kit 10x12oz
			Packaging Style	Carton
Packaging Size	8 LB			
Brand Name	Best Fresh			
Commodity	NA			
Variety	NA			
Example 3:				
GTIN	19827393847592			
Harvest Locations for Trip	<p>Location(s) for the trip during which the food was caught.</p> <p>Applies only to First Land-Based Recievers.</p>	Geocoordinates? FAO Major Fishing Area or Sub-Area? EEZ? RFMO? Ocean Name?	FAO Fishing Area 71	
Traceability Lot Code Source	The place where a food was assigned a traceability lot code	Location Description (see above)	See above Location Description Examples	
Traceability Lot Code Source Reference	An alternative method for providing FDA with access to the location description for the traceability lot code source as required under this subpart. Examples of a traceability lot code source reference include, but are not limited to, the FDA Food Facility Registration Number for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source.	TLC Source Reference Identifier	Web Address www.mytlcsourcereference.net	