



# FDA FSMA 204: Traceability Requirements for Shell Eggs Appendix

Global Food Traceability Center

## Definitions

The following is a list of full definitions that could apply to this category.

- **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 farms under different company management
  - "Processing" means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.
- **Cooling:** active temperature reduction of an RAC before initial packing using hydrocooling, icing, forced air cooling, vacuum cooling, or a similar process
  - Re-cooling is considered "cooling" if the food is still a RAC, and if the other elements of the definition are met
- **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. Shell egg producers; "farm" means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program, as set forth in § 118.3
  - Both persons who harvest and persons who initially pack must keep location identifying information
- **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:** 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:** 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
  - Excludes activities that transform a raw agricultural commodity into a processed food

## Definitions

- **Holding:** storage of food including 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
  - Excludes activities that transform a RAC into a processed 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
- **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
  - Excludes activities that are a part of harvesting, packing, or holding (for farms and farm mix-type facilities)
- **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
  - Excludes activities that transform a raw agricultural commodity into a processed food
- **Point of Contact:** an individual having familiarity with an entity’s procedures for traceability, including their name and/or job title, and phone number

## Definitions

- **Produce:** means any fruit or vegetable (including mixes of intact fruits and vegetables); as it as it is defined in § 112.3 in the produce safety regulation
- **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
- **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
- **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
  - Excludes moving received foods from the loading dock to the warehouse; moving ingredients from storage to processing; and moving foods from processing to the warehouse or shipping dock
- **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 including BOLs, POs, ASNs, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts
- **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
  - Excludes: facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers

## Definitions

- **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
  - A RFE's primary function is to sell food directly to consumers\* if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers
- **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, including 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.
  - Excludes the sale or shipment of a food directly to a consumer or the donation of surplus food
- **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
  - Excludes the initial packing of a food or activities preceding that event (e.g. harvesting, cooling)
- **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	
<b>Location Description</b>	<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
<b>Quantity</b>	Quantity of food associated with event	Numerical Quantity	100	
<b>Unit of Measure</b>	Unit of measure associated with quantity	Categorical Unit	Cases	

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KDE	Description	Data Point(s)	Example
<b>Reference Document Type</b>	<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
<b>Reference Document Number</b>	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
<b>Harvester Business Name</b>	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
<b>Harvester Phone Number</b>	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
<b>RAC Commodity &amp; Variety</b>	Common name for food item and type/variety descriptor (e.g. commodity = melon, variety = honeydew)	Commodity Name	Lettuce
		Variety Name	Iceberg
<b>Field/Growing Area Name or Equivalent Identifier</b>	<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><b>Applies only to Produce.</b></p>	Field Name or Equivalent Identifier	Iceberg Field 1

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KDE	Description	Data Point(s)	Example
<b>Container Name or Equivalent Identifier</b>	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.  <b>Applies only to Aquaculture</b>	Container Name or Equivalent Identifier	Tank 3
<b>Event Date</b>	Date on which CTE took place.	Date	12/1/2022
<b>Receive Date</b>	Date on which food was received.  <b>Applies only to Initial Packers.</b>	Date	12/1/2022
<b>Traceability Lot Code</b>	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
<b>Species and/or Acceptable Market Name or Product Description for Packaged Food</b>	Description of food obtained from a fishing vessel.  <b>Applies only to First Land-Based Recievers.</b>	Species Name, Market Name, or Product Description Elements (See Above)	Sockeye Salmon
<b>Harvest Date Range for Trip</b>	Range of dates for the trip during which the food was caught.  <b>Applies only to First Land-Based Recievers.</b>	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	
<b>Product Description</b>	<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			
<b>Harvest Locations for Trip</b>	<p>Location(s) for the trip during which the food was caught.</p> <p><b>Applies only to First Land-Based Recievers.</b></p>	Geocoordinates? FAO Major Fishing Area or Sub-Area? EEZ? RFMO? Ocean Name?	FAO Fishing Area 71	
<b>Traceability Lot Code Source</b>	The place where a food was assigned a traceability lot code	Location Description (see above)	See above Location Description Examples	
<b>Traceability Lot Code Source Reference</b>	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 <a href="http://www.mytlcsourcereference.net">www.mytlcsourcereference.net</a>	