

Requirements for Additional Traceability Records for Certain Foods: Proposed Requirements

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Proposed Codified Provisions

- Traceability Program Records (Proposed §§ 1.1315 to 1.1320)
- Records of Growing, Receiving, Transforming, Creating, and Shipping Food (Proposed §§ 1.1325 to 1.1350)
- Requesting Exemptions and Waivers (Proposed §§ 1.1360 to 1.1450)
- Records Maintenance and Availability (Proposed § 1.1455)

§1.1315: Traceability Program Records



- Records related to a firm’s internal traceability program
- Intended to help us more quickly review and understand the information provided by a firm during an investigation into a foodborne illness outbreak involving a food on the FTL
- Traceability Program Records must be maintained for 2 years after discontinuance



§1.1315: Traceability Program Records



- Description of reference records in which you maintain the required information
 - Explanation of where on the records the required information appears
 - Description of how reference records for different tracing events for a food (e.g., receipt, transformation, shipment) are linked (if applicable)
- List of foods on the FTL that you ship, including traceability product identifier and description for each food
- Description of how you establish and assign traceability lot codes, if applicable
- Other relevant information needed to understand the data provided



§1.1320: Establishing and Assigning Traceability Lot Codes



- Traceability Lot Code (TLC) is proposed to be a descriptor, often alphanumeric, used to identify a traceability lot and would be assigned by the TLC generator
 - Entity that assigns the TLC would be known as the *TLC Generator*
- Proposed rule offers flexibility on how TLCs are created
 - Proposed rule does **NOT** specify how TLCs should be created
 - Proposed rule does **NOT** identify any specific KDEs that would have to be included in the TLC



§1.1320: Establishing and Assigning Traceability

Lot Codes



- Traceability lot codes (TLC) would be established and assigned if:
 - Originate, transform, or create food on the FTL
 - You are the First Receiver of a food on the FTL and originator did not assign a TLC
- New traceability lot codes **CANNOT** be established or assigned when other activities in the supply chain are conducted
 - E.g. shipping, receiving



CTE/KDE Framework



Critical Tracking Events

Growing, receiving, transforming, creating, and shipping are Critical Tracking Events (CTEs) for which records would be required.

Key Data Elements

Required records would need to contain specific Key Data Elements (KDEs). The KDEs would depend on the CTE being performed.

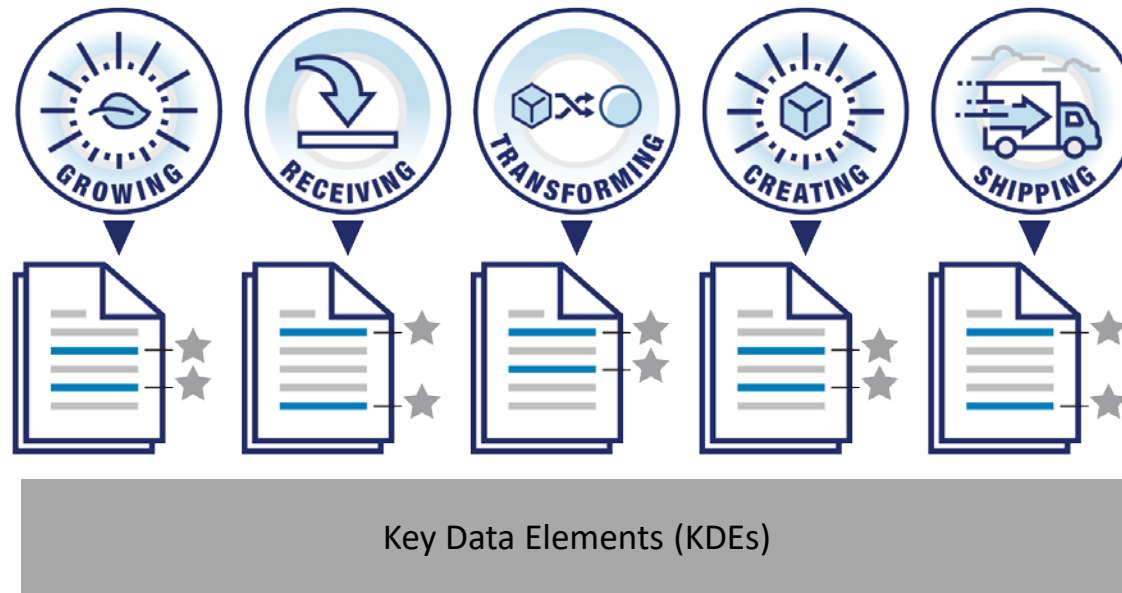


Key Data Elements (KDEs)



CTE/KDE Framework

- The record requirements would apply to all foods on the FTL
 - Includes foods that contain foods on the list as ingredients
- Must be established, maintained and sent (in some cases)
- Must be linked to the traceability lot code of the food



§1.1325: Grower KDEs



Traceability lot code linked to:

- Growing area coordinates

**Additional KDEs required for sprout growers*

**Growers must also keep and send Shipping KDEs and Additional Send KDEs for Farms*



§1.1325 – Required Grower KDEs (Sprouts)



Traceability lot code of the sprouts linked to:

- Location identifier and location description of the grower of seeds for sprouting, and the associated seed lot code assigned by the seed grower, and date of seed harvesting
- Location identifier and location description of the seed conditioner or processor, the associated seed lot code they assigned, and date of conditioning or processing
- Location identifier and location description of the seed packinghouse (including any repackers), associated seed lot codes, and date of packing/repacking
- Location identifier and location description of the seed supplier
- Description of the seeds, including type or taxonomic name, growing specifications, volume, type of packaging, and antimicrobial treatment
- Seed lot code assigned by the seed supplier, including master lot and sub-lot codes, and any new seed lot code assigned by the sprouter
- Date of receipt of the seeds by the sprouter
- Date(s) of production and sprout traceability lot code(s) associated with the seed lot code



§1.1350: Shipping KDEs



(Keep and send unless otherwise indicated)

- Traceability lot code(s) for the food
- Entry number(s) (if imported)
- Quantity and unit of measure of the food
- Traceability product identifier and product description
- Traceability lot code generator location identifier, description and POC
- Immediate subsequent recipient location identifier and location description
- Shipping location identifier and description
- Shipment date and time
- Reference record type(s) and #(s) containing Shipping KDEs (keep but do not send)
- Transporter name (keep but do not send)



§1.1350: Shipping + Sending KDEs



Additional Send KDEs for Farms

- A statement that you are a farm
- Originator Information (if not you)
 - Originator location identifier
 - Originator location description
- Harvester Information (if not you)
 - Business name
 - Point of contact
 - Phone number
- Date(s) and time(s) of harvesting
- Cooler Information (if not you)
 - Location identifier where food cooled
 - Location description where food cooled
- Date and time of cooling
- Packer Information (if not you)
 - Location identifier where packed
 - Location description where packed
- Date and time of packing



§1.1335: Receiving KDEs



Traceability lot code linked to:

- Immediate previous source location identifier and description
- Entry number (if imported)
- Receiver location identifier and description
- Receipt date and time
- Quantity received and unit of measure
- Traceability product identifier and description of product received
- Traceability lot code generator location identifier, description and POC
- Reference record type(s) and #(s) for documents containing Receiving KDEs
- Transporter name



§1.1330: First Receiver KDEs



- Created to account for variances across commodity types with different growing and production practices or associated business relationships for FTL foods
- First person (other than a farm) who **purchases** and takes physical possession of a listed food
 - Examples could include manufacturers, processors, buyers of seafood from fishing vessels, and distribution centers
- Only applies to foods that are originated (i.e., grown, harvested (for a non-produce commodity), raised, or caught)



§1.1330: First Receiver KDEs



Traceability lot code linked to:

- Originator location identifier and description
- Name/phone #/ POC of harvester
- Date/time of harvest
- Location identifier and description of cooler
- Date/time of cooling
- Location identifier and description of packer
- Date/time packing

+ RECEIVING KDEs



§1.1330: First Receiver KDEs



(Seafood Obtained from a Fishing Vessel)

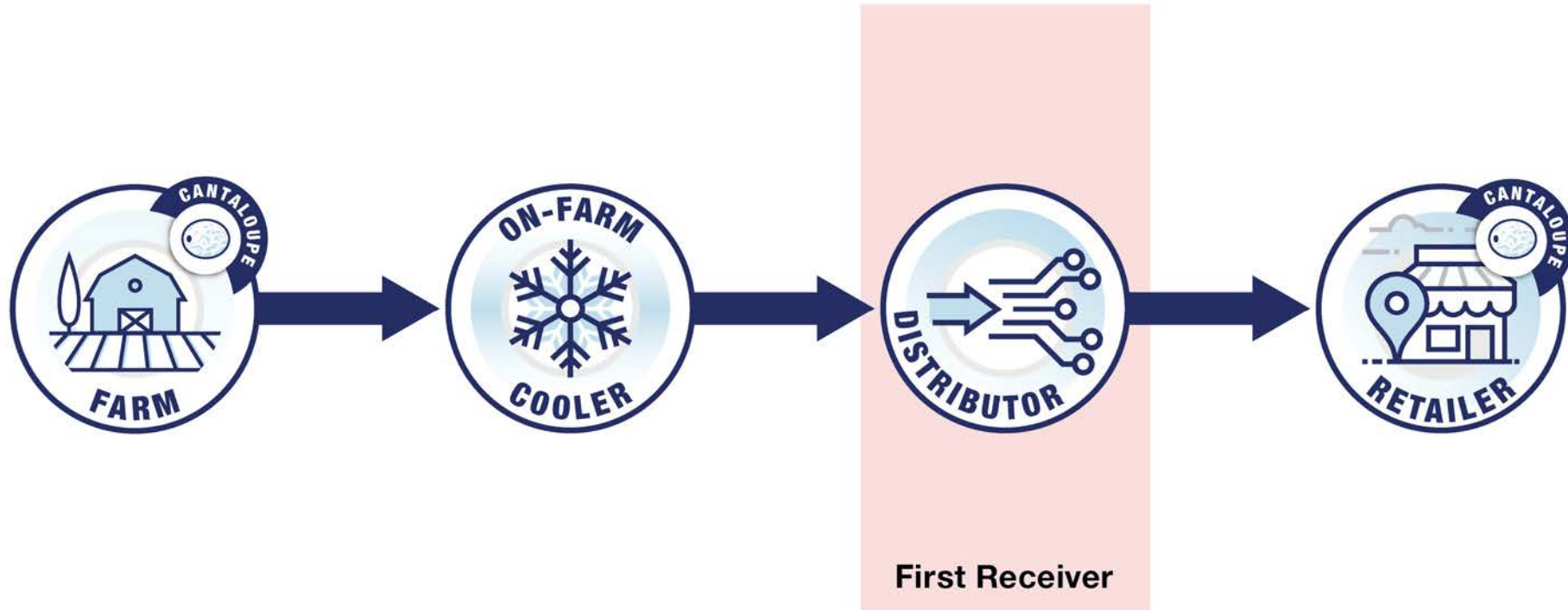
Traceability lot code linked to:

- Harvest Date Range
- Harvest locations (NMFS Ocean Geo Code or geographical coordinates) for trip when seafood was caught

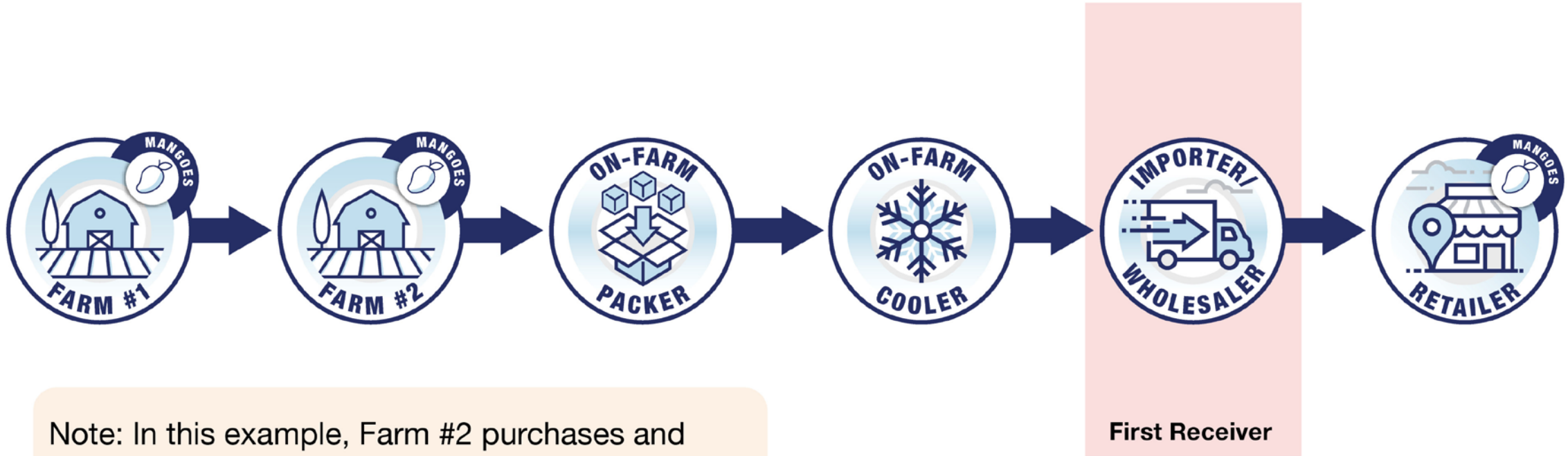
+ RECEIVING KDEs



First Receiver Example: Cantaloupe



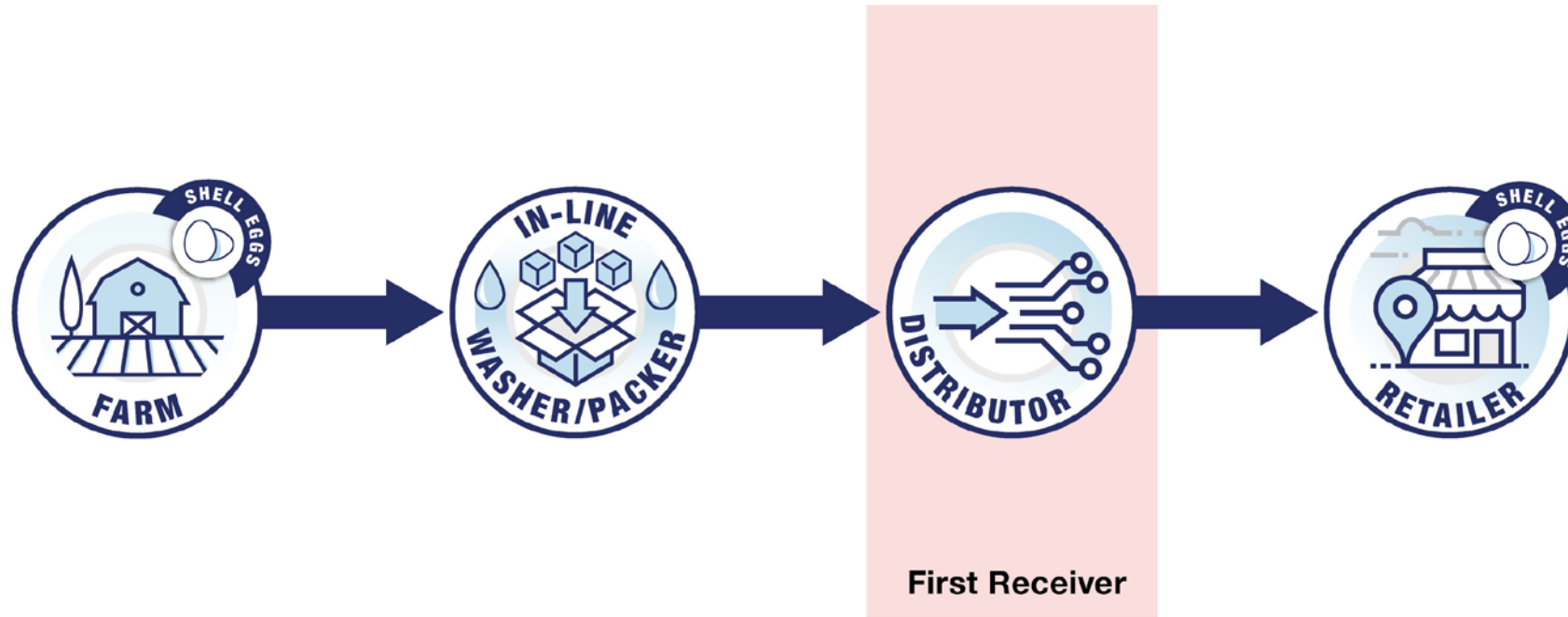
First Receiver Example: Mango

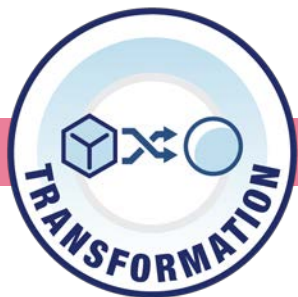


Note: In this example, Farm #2 purchases and takes physical possession of the mangoes from Farm #1. However the Importer/Wholesaler would be considered the First Receiver, since that is the first non-farm entity who receives the food.



First Receiver Example: Shell Eggs





§1.1340: Transformation KDEs



Traceability lot code of the food produced through transformation linked to:

- Traceability lot code, product identifier and description of food used
- Quantity of each traceability lot of food used
- Transformation location identifier and description
- Transformation completion date
- New traceability product identifier and description
- Quantity and unit of measure of the food produced
- Reference record type(s) and #(s) containing Transformation KDEs





§1.1345: Creation KDEs

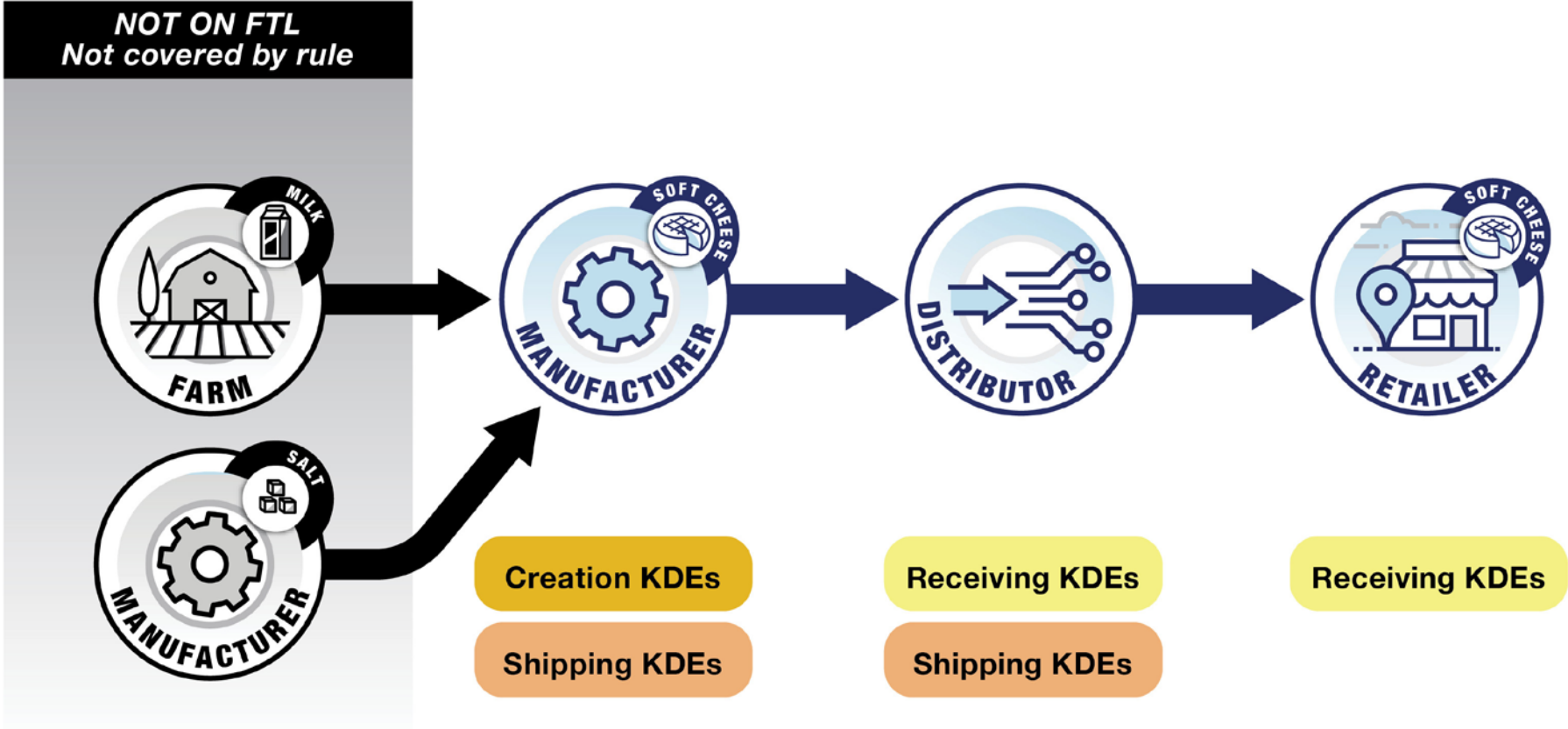


Traceability lot code of the food created linked to:

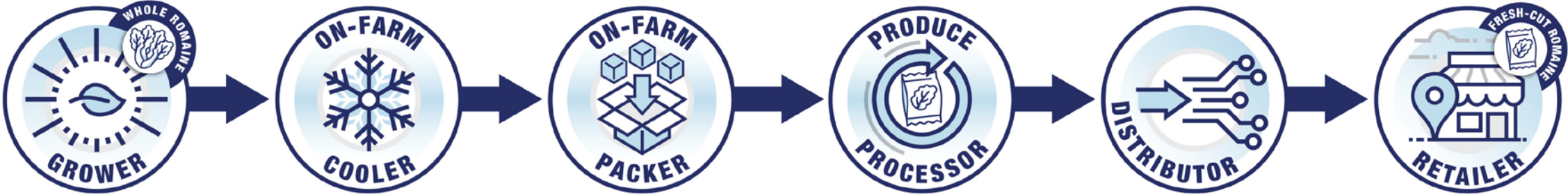
- Creation location identifier and description
- Creation completion date
- Traceability product identifier and product description
- Quantity and unit of measure
- Reference record type(s) and #(s) containing Creation KDEs



Examples: CTEs for a Soft Cheese Supply Chain



Example: CTEs for Fresh-Cut Romaine Supply Chain



Grower KDEs

Receiving KDEs

Receiving KDEs

1st Receiver KDEs

Receiving KDEs

Receiving KDEs

Shipping KDEs

Shipping KDEs

Shipping KDEs

Receiving KDEs

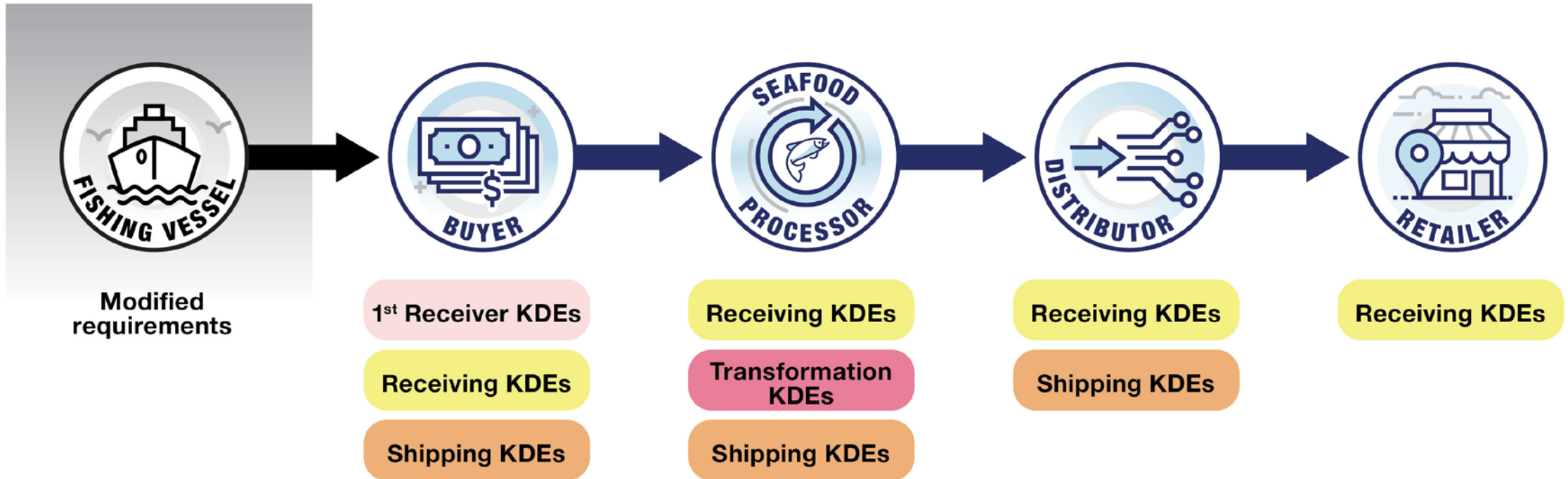
Shipping KDEs

Transformation KDEs

Shipping KDEs



Examples: CTEs for a Seafood Supply Chain



§§ 1.1360 – 1.1400: Procedures for Modified Requirements and Exemptions

- Modified requirements or an exemption
- For a food or type of entity
- If FDA determines that application of the requirements is not necessary to protect the public health
- FDA will consider whether to modify requirements or grant exemption on our initiative or
- Citizen petition by any interested party



§§ 1.1405 – 1.1450: Waivers



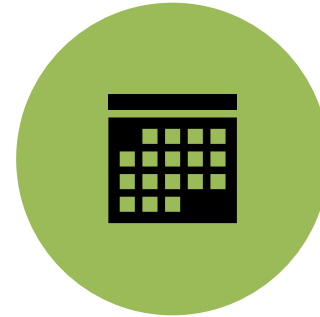
- Waiver for one or more of the requirements in the rule
 - For an individual entity or type of entity
 - If we determine that application of the requirements would result in an economic hardship due to the unique circumstances of the individual entity or type of entity; and
 - The waiver will not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate an outbreak or address credible threats of serious adverse health consequences or death; and
 - The waiver will not otherwise be contrary to the public interest
 - FDA will consider whether to issue a waiver on our initiative or
 - Written request for an individual entity
 - Citizen petition for a type of entity



§1.1455: Records Maintenance and Availability



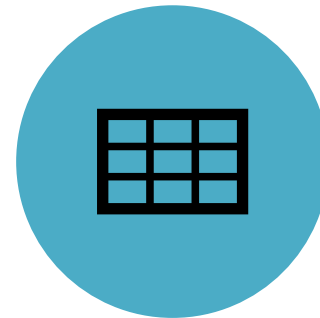
Legible records maintained as either **original paper records**, **electronic records**, or true copies and stored to prevent deterioration or loss.



In general records must be **kept for 2 years** from the date you created the record



Records would have to be made available to FDA as soon as possible, but **no later than 24 hours after a request** is made.



If requested to assist FDA during an outbreak or other threat to public health, records would need to be provided to FDA in an **electronic sortable spreadsheet**



Review of Proposed Rule Key Concepts



- Traceability Lot Codes should carry through the supply chain and can only be established and assigned when origination, transformation, or creation occurs
- All proposed KDEs would be required to be linked to the TLC
- Where possible, firms can reuse KDEs provided by the immediate previous source to meet proposed requirements (e.g., traceability product identifiers, etc.)
- Traceability Program Records would be required to explain terminology used in a firm's internal traceability system that may differ from the terminology of the proposed rule



Review of Proposed Rule Key Concepts



- Records required by the rule would have to be provided to FDA within 24 hours of the record request regardless of where records are stored
 - Records can be maintained by a 3rd party (or other firm in the supply chain)
- Any firm can be a receiver; first receiver is more specific
 - Dependent on the structure of a product's supply chain
 - First receiver is the first non-farm that purchases and takes physical possession; created foods don't have first receivers
- Transformation includes repacking



Review of Proposed Rule Key Concepts



- Goal of the proposed rule is to ensure KDEs (especially TLC) can be maintained across the supply chain for more efficient and effective tracing while providing firms flexibility within their existing tracing systems
- We are seeking comments that:
 - Provide examples of business models that may not be compatible with the proposed rule, with an explanation of why
 - Identify and explain if there is confusion within the proposed rule





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