

Introduction to FSMA 204 Traceability Rule

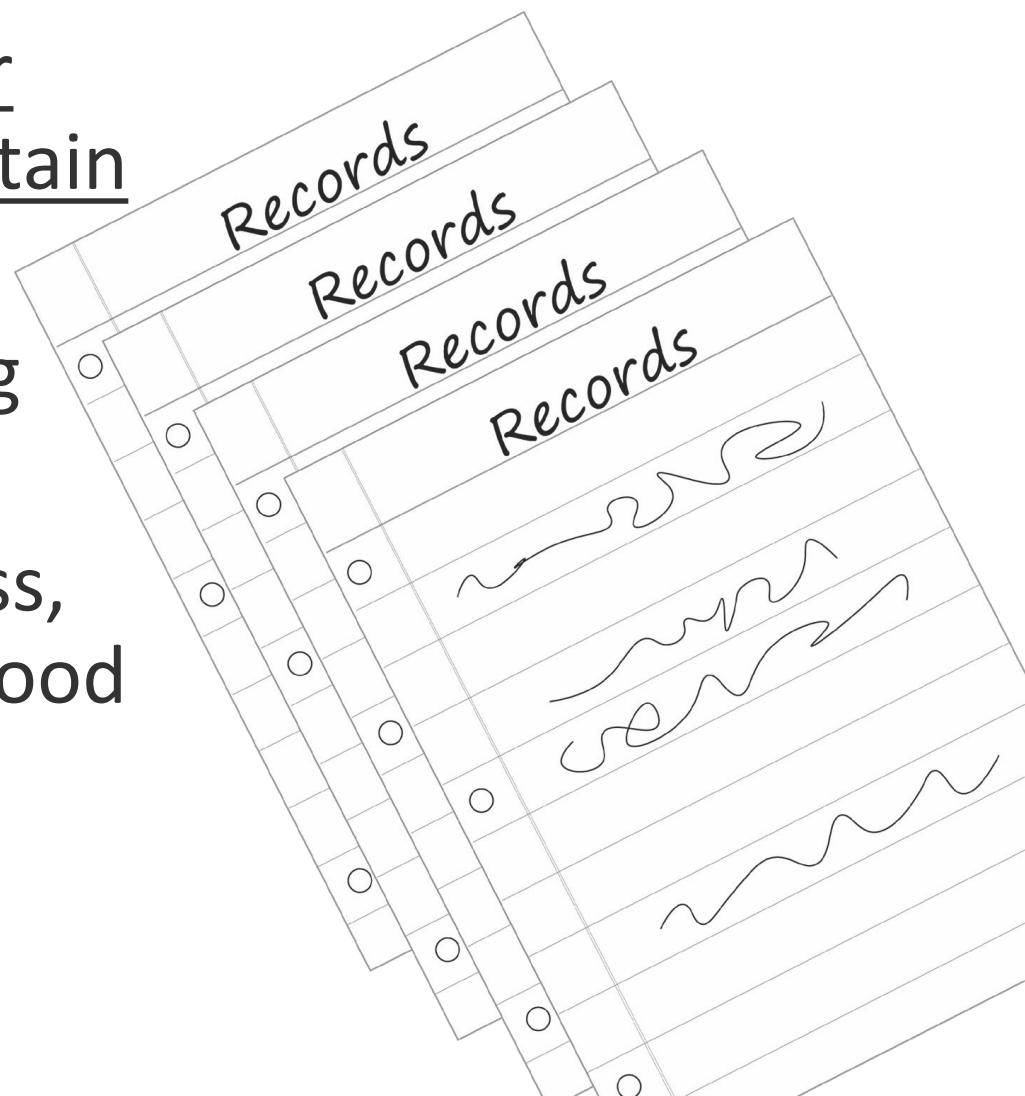
Background, Compliance, Food Traceability List, Definitions, and Exemptions

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Introduction

The FDA final rule on Requirements for Additional Traceability Records for Certain Foods

- establishes traceability recordkeeping requirements
- for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL).



Intent

The new requirements identified in the final rule will allow for faster identification and **rapid removal of potentially contaminated food** from the market, resulting in fewer foodborne illnesses and/or deaths.

35 days without lot code to ID Source

6 days with lot code to ID Source





Food Traceability List

Cheese (made from pasteurized milk), fresh soft or soft unripened	Tomatoes (fresh)
Cheese (made from pasteurized milk), soft ripened or semi-soft	Tropical tree fruits (fresh)
Cheese (made from unpasteurized milk), other than hard cheese	Fruits (fresh-cut)
Shell eggs	Vegetables (fresh-cut)
Nut butters	Finfish, histamine-producing species (fresh, frozen, and previously frozen)
Cucumbers (fresh)	Finfish, species potentially contaminated with ciguatoxin (fresh, frozen, and previously frozen)
Herbs (fresh)	Finfish, species not associated with histamine or ciguatoxin (fresh, frozen, and previously frozen)
Leafy greens (fresh)	Smoked finfish (refrigerated, frozen, and previously frozen)
Leafy greens (fresh-cut)	Crustaceans (fresh, frozen, and previously frozen)
Melons (fresh)	Molluscan shellfish, bivalves (fresh, frozen, and previously frozen)
Peppers (fresh)	
Sprouts (fresh)	Ready-to-eat deli salads (refrigerated)

Food Traceability List

Exemptions

Farms

- Certain small produce farms
- Certain small shell egg producers
- Certain other small RAC producers
- Certain food produced + packaged on farm
- Farms selling food directly to consumers

Commingled raw agricultural commodities (RACs)

- Certain commingled RACs (not fruits & vegetables)
- Certain RACs that will be commingled

Fishing vessels, molluscan shellfish

- Owner/operator/agent in charge of a fishing vessel
- Raw bivalve molluscan shellfish

Retail food establishments (RFEs), restaurants

- Certain small RFEs + restaurants
- RFEs or restaurants purchasing food directly from a farm
- RFEs or restaurants purchasing food from another RFE or restaurant on ad hoc basis

Certain types of processing

- Produce and shell eggs that receive certain processing
- Exemptions related to a kill step
- Exemptions related to changing a food to a form not on the list

Personal consumption, holding food for individual consumers

- Personal consumption
- Holding food for individual consumers

Other

- Produce listed as “rarely consumed raw”
- Farm-to-school/farm-to-institution programs
- Foods regulated by USDA
- Transporters of food
- Non-profit food establishments
- Food for research or evaluation

Other Exemptions

Sized-based Exemptions

Type of Entity	Exemption Cut-off
Produce Farms	Sales $\leq$ \$25,000
Shell Egg Producers	< 3,000 layers
Other RAC Producers	Sales $\leq$ \$25,000
RFEs & Restaurants	Sales $\leq$ \$250,000

Electronic Sortable Spreadsheet Exemptions

Type of Entity	Electronic Spreadsheet Exemption
Farms	Sale $\leq$ \$250,000
RFEs & Restaurants	Sales $\leq$ \$1 Million
Person other than a farm, RFE, or restaurant	Sales $\leq$ \$1 Million

[Example Spreadsheets](#)

Compliance

Compliance Date: **January 20, 2026**, with routine enforcement starting one year later.

FDA Constituent Update: March 20, 2025 – FDA Announces **extension of compliance date 30 months**.

~July 20, 2028

Basic Requirements

Facilities must:

- establish and maintain a traceability plan;
- maintain records containing **Key Data Elements (KDEs)** associated with specific **Critical Tracking Events (CTEs)**;
- and provide information to the FDA, upon request, within 24 hours or within some reasonable time to which the FDA has agreed.

[Electronic Sortable Spreadsheet](#)

Traceability Plan

Any facility/operation subject to the Food Traceability Rule must establish and maintain a traceability plan containing:

1. Record keeping procedures;
2. Process for identifying foods on the FTL;
3. How you assign traceability lot codes, if applicable;
4. Point of contact for your traceability plan; and
5. A farm map showing the areas in which you grow or raise foods, if applicable.

7 Critical Tracking Events (CTEs)

Harvesting

Cooling (before
Initial Packing)

Initial Packing
(RAC) ★

First Land-Based
Receiver ★

Shipping

Receiving

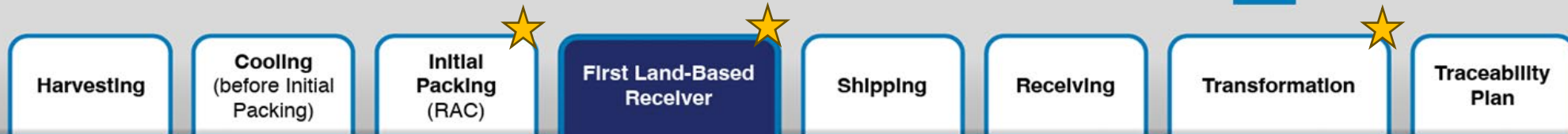
Transformation ★

Scan the QR code to view
FDA's guide to CTEs and KDEs.
Or visit
bit.ly/CTEs-KDEs



Critical Tracking Events and Key Data Elements

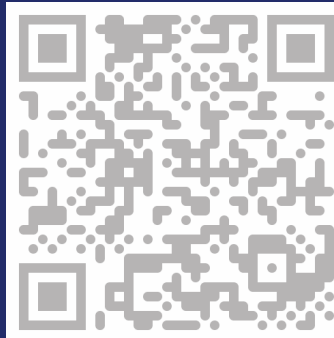
Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



First Land-Based Receiver KDEs (food obtained from a fishing vessel)

KDEs must be linked to the traceability lot for the food

- 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), and (if applicable) traceability lot code source reference
- Date the food was landed
- Reference document type and reference document number



Traceability Lot Code (TLC)

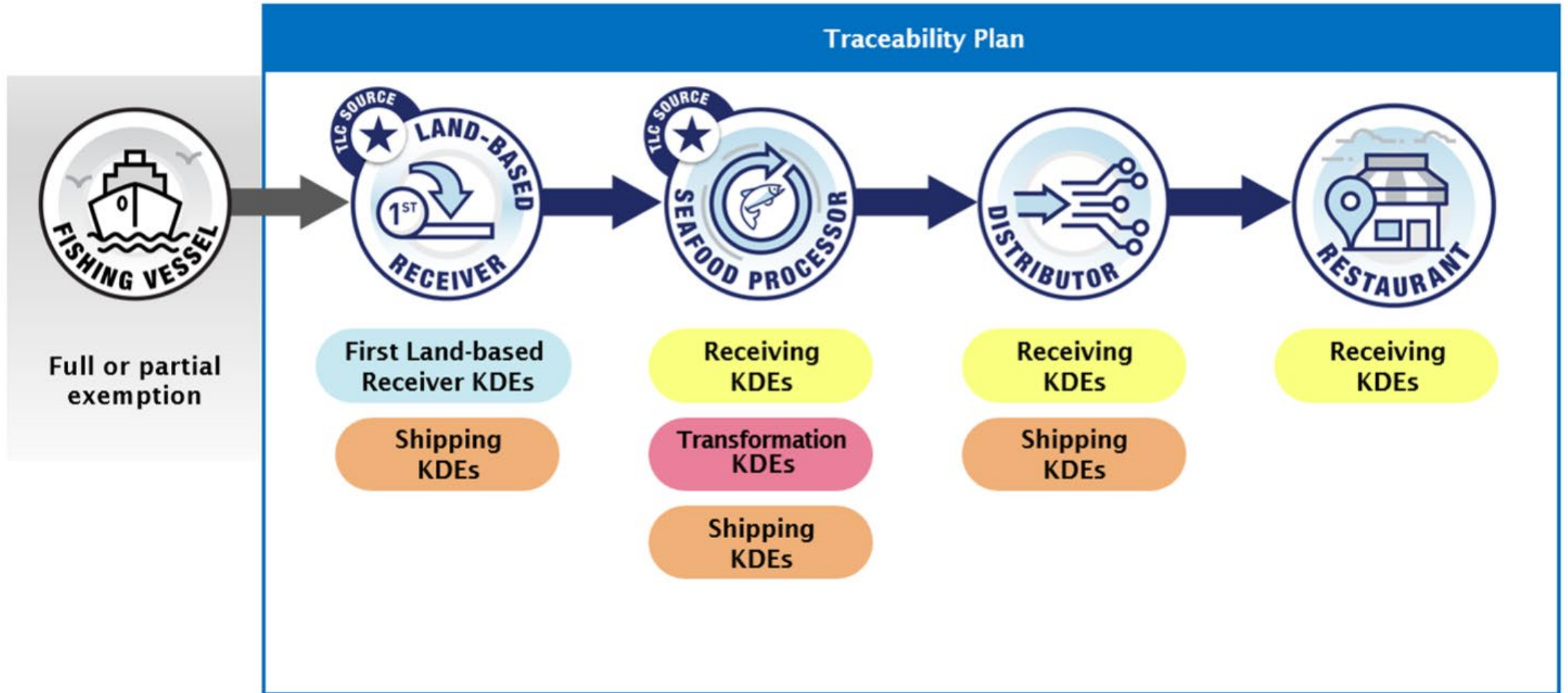
A traceability lot code means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records

Traceability lot code source
Traceability lot code source
reference

Examples of traceability lot codes	
(01)04562135785133 (17)140704 (10) DE-456 GS1-128 Example	1147M2023213 1. 2. 3. 1. Product code 2. Facility 3. Julian date
475123C 6-digit code + letter to represent grower/manufacturing location	
BFCA179A152023213 1. 2. 3. 4. 5. 1. Company name 2. Production location 3. Product 4. Grower 5. Julian date	134AD5607 Randomized alphanumeric code generated by firm's traceability system

[More TLC Examples](#)

Supply Chain Example: Wild Caught Tuna



Receiving KDE's

Traceability Lot Code: unique identifier for batch of food

Quantity and Unit of Measure: Amount of food received (e.g. lbs, cases)

Product Description: a clear description of what is received

Location Description of the Previous Source: name and address where the food was shipped from

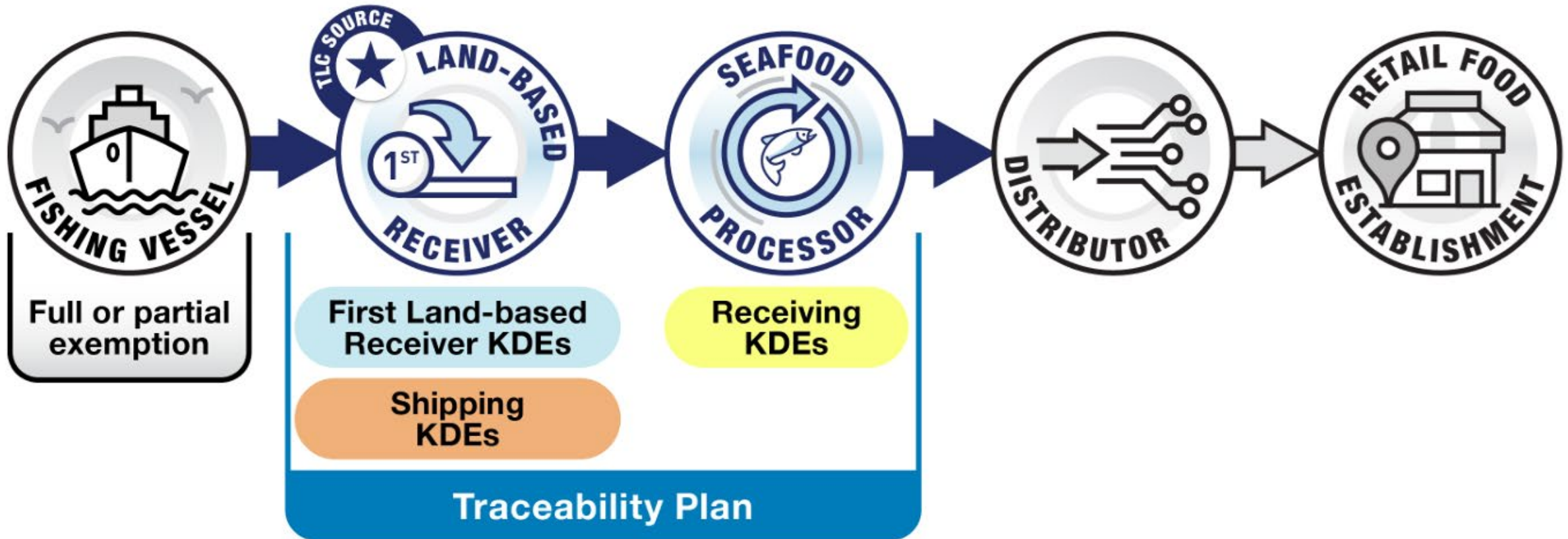
Location Description for Receipt: Where the food is received (e.g. restaurant)

Date Received: the date the restaurant received the food

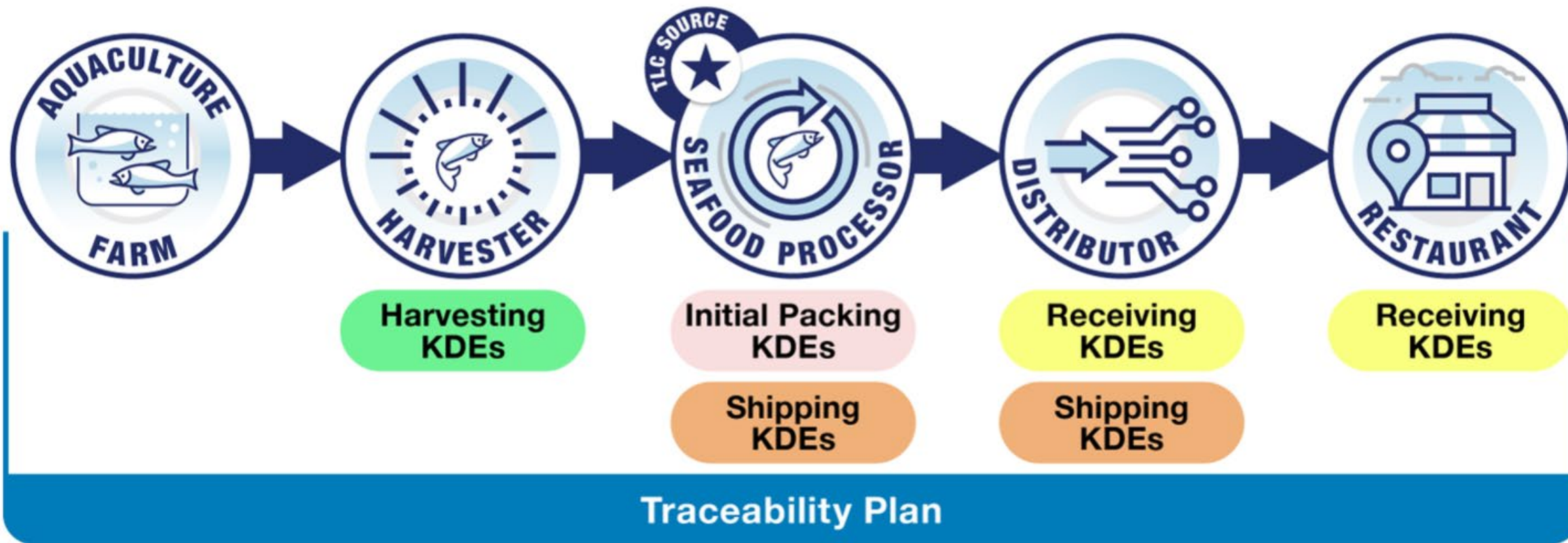
TLC Source or Reference: name and location of entity that created the TLC

Reference Document: Type/title of document housing this information

Supply Chain Example: Canned Salmon



Supply Chain Example: Tilapia



FSMA 204 Preparations

Preparing for Compliance

1. Foods on the [Food Traceability List](#)
2. Determine if you are exempt ([Exemption Tool](#))
3. Identify [CTE's](#) you conduct
4. Determine what [KDE's](#) you need to track
5. Develop and implement a **traceability plan**
6. Communicate with supply chain partners

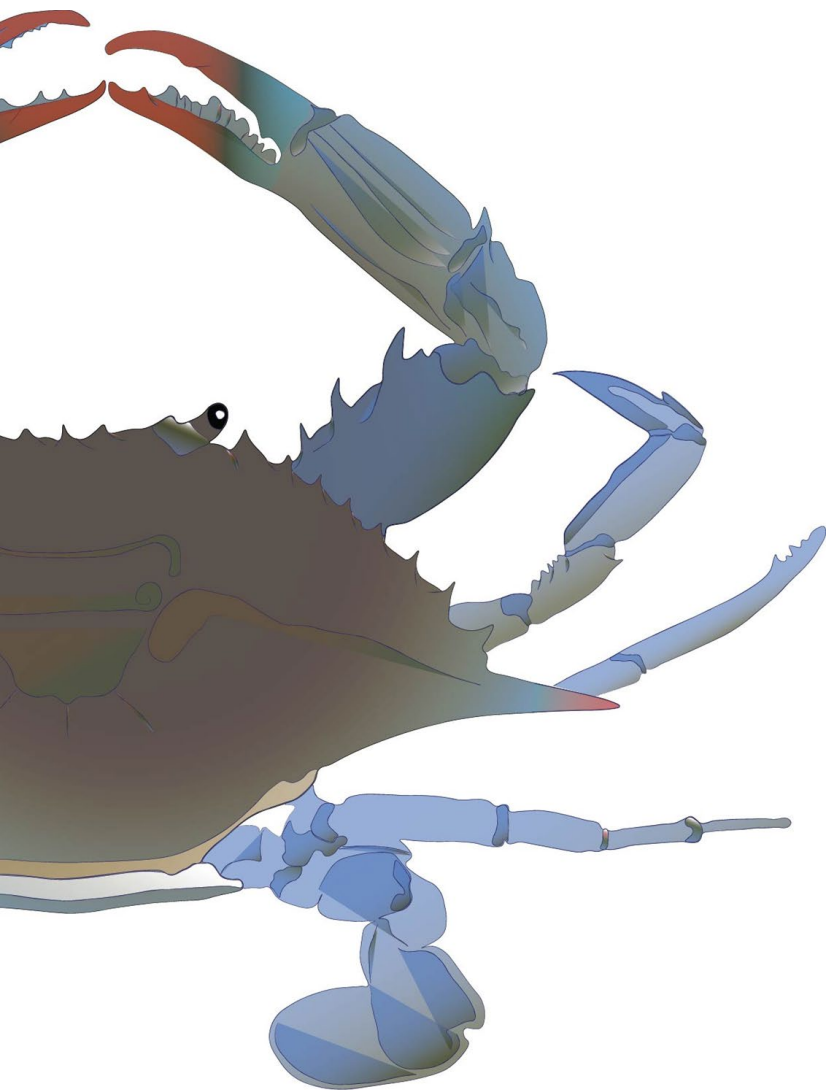
Communication and collaboration across the supply chain is key!

Additional Resources

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

- [Traceability Rule at a Glance \(FDA\)](#)
- [Food Traceability Rule Exemption Tool](#)
- [Small Entity Compliance Guide](#)
- [FSMA Technical Assistance Network \(TAN\)](#)
- [Frequently Asked Questions: FSMA Food Traceability Rule](#)
- [National Fisheries Institute FSMA 204 Resources](#)

Questions?



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