# Food Traceability Final Rule: Impacts on Shell Eggs

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National Egg Regulatory Organization

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# What will the Food Traceability Rule require?

- Persons who manufacture, process, pack, or hold foods on the Food Traceability List

- Covers the entire food supply chain

- Includes both foreign and domestic entities

- Full and partial exemptions may apply

# Exemptions

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

**Commingled raw agricultural commodities (RACs)**
- <mark>Certain commingled RACs</mark> (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**
- <mark>Produce and shell eggs that receive certain processing</mark>
- <mark>Exemptions related to a kill step</mark>
- 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

# Exemptions Tool

## Exemptions to the Food Traceability Rule

**You are subject to the Food Traceability final rule, _unless_** an exemption applies.
To determine whether you may be exempt, please click on any of the following categories that may apply to you:

| Farms | Certain types of processing |
| --- | --- |
| Commingled raw agricultural commodities (RACs) | Personal consumption, holding food for specific consumers |
| Fishing vessels, molluscan shellfish | Other |
| Retail food establishments (RFEs), restaurants | |

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https://collaboration.fda.gov/tefcv13/

# 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 and frozen) |
| Cucumbers (fresh) | Finfish (species potentially contaminated with ciguatoxin) (fresh and frozen) |
| Herbs (fresh) | Finfish, species not associated with histamine or ciguatoxin (fresh and frozen) |
| Leafy greens (fresh) | Smoked finfish (refrigerated and frozen) |
| Leafy greens (fresh-cut) | Crustaceans (fresh and frozen) |
| Melons (fresh) | Molluscan shellfish, bivalves (fresh and frozen) |
| Peppers (fresh) | Ready-to-eat deli salads (refrigerated) |
| Sprouts (fresh) | |

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# CTE and KDE Framework

## The role of the entity in the supply chain defines the data it must keep and share

### Critical Tracking Events

Harvesting, Cooling, Initial Packing, First Land-based Receiving, Shipping, Receiving, and Transforming are Critical Tracking Events (CTEs) for which records would be required.
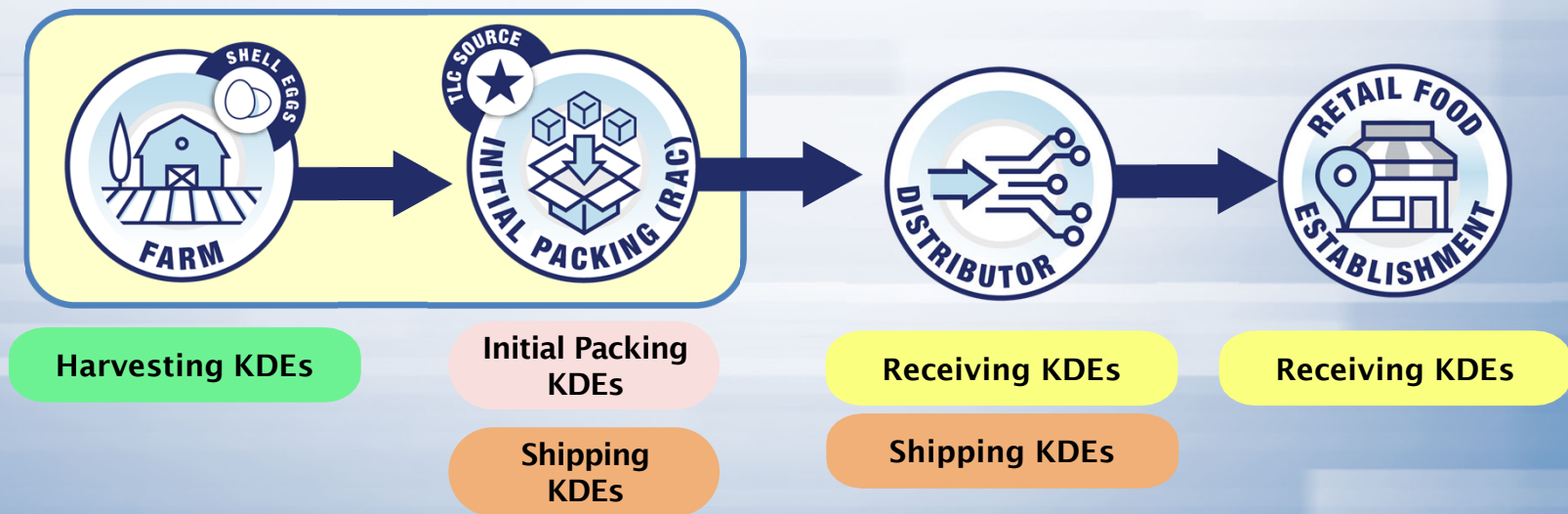
### Key Data Elements

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

### The KDEs required would vary depending on the CTE that is being performed.

The records required at each CTE would need to contain and link the KDEs to the traceability lot.

# Example: In-line shell egg production operation that ships to a distributor



Harvesting KDEs

Initial Packing KDEs

Shipping KDEs

Receiving KDEs

Shipping KDEs

Receiving KDEs

**Traceability Plan**

In this example, the farm is an in-line (represented by the yellow box) shell egg production operation which does not commingle its eggs with eggs from other farms. The farm ships its eggs to a distributor.

# Initial Packer Example

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**KDEs for Incoming**

- **For each incoming RAC, the following KDEs should be linked to each traceability lot that gets packed:**

- What you received*
- How much you received*
- Date you received it
- Where it came from*
- Information about harvesting and/or cooling*
- Reference document information

**Packing KDEs**

- **For each traceability lot of a RAC that you pack, the following KDEs should be linked to the traceability lot:**

- TLC you assigned
- Date you packed it
- What you packed
- How much you packed
- When you packed it
- Where you packed it
- Reference document information

**Shipping KDEs**

- **For each traceability lot of a RAC that you ship after packing, the following KDEs should be linked to the traceability lot:**

- TLC
- How much you shipped
- What you shipped
- Where you shipped it
- Where you shipped it from
- Date you shipped it
- Traceability lot code source information (i.e., where you packed it)
- Reference document information

* indicates KDEs you receive

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

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| Harvesting | Cooling (before Initial Packing) | Initial Packing (RAC) | First Land-Based Receiver | Shipping | Receiving | Transformation | Traceability Plan |

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. This framework forms the foundation for effective and efficient tracing and clearly communicates the information that FDA needs to perform such tracing.

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.

Graphics on the subsequent pages provide readers with a list of KDEs required for each CTE performed.

https://www.fda.gov/media/163132/download

# Key Concepts of the Final Rule

- Framework of CTEs and KDEs

- Standard language

- Linking information by lot code

- Records provided to FDA within 24 hours

- Faster product identification and removal

FDA

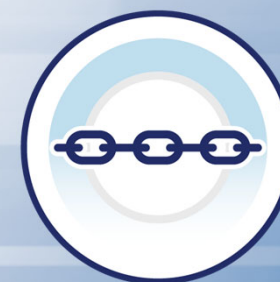# Emphasis on…

**FDA**

**Keeping and sharing KDEs**

**Traceability Lot Code (TLC)**

**Traceability Lot Code Source (TLC Source)**

**Traceability Plan**

**Working with supply chain partners**

# Records Maintenance and Availability

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Legible **original paper, electronic**, or true copies. Stored to prevent deterioration or loss. May **include electronic links.**

Records must be **kept for 2 years.**

Available **within 24 hours (or reasonable time if FDA agrees).** May be stored **offsite or by another entity** .

During an outbreak - **electronic sortable spreadsheet** within 24 hours of a request (including a **phone request**).

# Compliance date

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## January 20, 2026

- Applies to all firms
- Provides 3 years for covered entities to work with supply chain
- We will educate before and while we regulate

# More to come

- Outreach, education, technical assistance
- Additional communications materials
- Development of system for sending required information to FDA

# Implementation and Enforcement

**FDA**

- Currently considering best approach for conducting inspections under this rule

- Developing compliance strategy and plan to work with State, Local, Tribal, Territorial and other regulatory partners to enforce rule

# Available Resources

**FDA**

- **Food Traceability Final Rule (Federal Register)**

  - **Link directly to codified (Bookmark this!):** https://www.federalregister.gov/d/2022-24417/p-amd-1

  - CTRL + F

- **Food Traceability Final Rule webpage**

  - NEW translations!

- **Frequently Asked Questions (FAQs)**

  - NEW search feature!

- **Food Traceability Final Rule Webinar**

- **Critical Tracking Events and Key Data Elements document**

- **Exemptions tool**

- **Food Traceability List webpage**

- **Risk Ranking Model Results tool**

# Available Resources (cont.)

- **Supply Chain Examples:**
  - Produce Supply Chain Example
    - Video Presentation
    - Transcript
    - Slides
  - Seafood Supply Chain Example
    - Video Presentation
    - Transcript
    - Slides
  - Cheese Supply Chain Example
    - Video Presentation
    - Transcript
    - Slides

**Retail Food Establishments and Restaurants**

- Retail Food Establishments (RFEs) and Restaurants: What Records Do I Need to Keep for the Food Traceability Rule?

- Retail Food Establishments (RFEs) and Restaurants: What You Need to Know About the Food Traceability Rule

- Retail Food Establishments (RFEs) and Restaurants: What You Need to Know About Establishing and Maintaining a Traceability Plan for the Food Traceability Rule

**Questions?**

- FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

# Thank you!