

# Association *for* Healthcare Foodservice



# AHF NATIONAL CONFERENCE

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# Session Title: The Food Traceability Rule is Coming – Is Your Team Prepared?

## Presenters

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# FSMA 204 Background

- The FSMA 204 Traceability law was passed as part of the Food Modernization Act of 2011 (FSMA, 2011).
- FSMA 204 is intended to:
  - Enhance Detection and
  - Speed Response to foodborne illness outbreaks
- Law Published – November 21, 2012
- Compliance Date – January 20, 2016

# Overview of the Law

## Who does it affect?

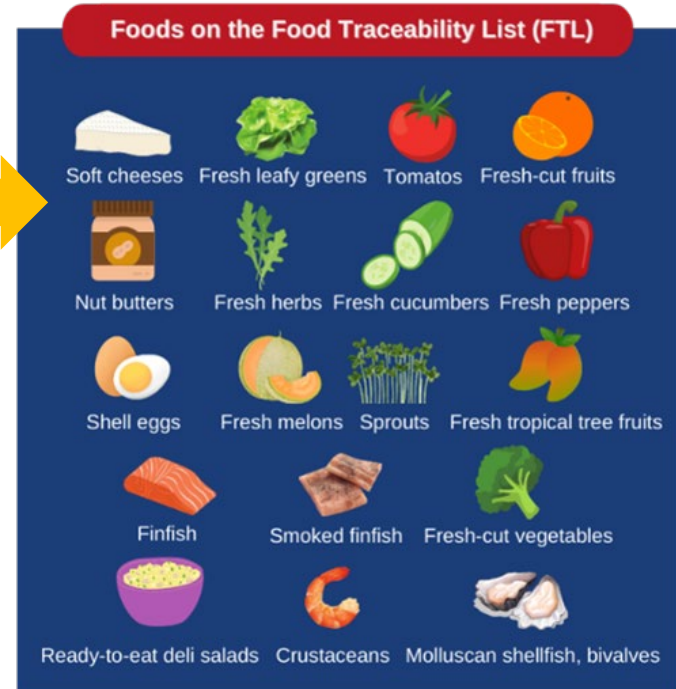
- Manufacture
- Pack
- Process
- Hold Foods

## What does it entail?

- Key Data Elements (KDEs) & Critical Tracking Events (CTEs)
- Traceability Lot Codes (TLCs) & Food Traceability List (FTLs)
- Traceability Plans

# FDA's Food Traceability List (for reference)

Foods and Foods that contain, in same form



## Exemptions:

Meat, poultry, pork (USDA)

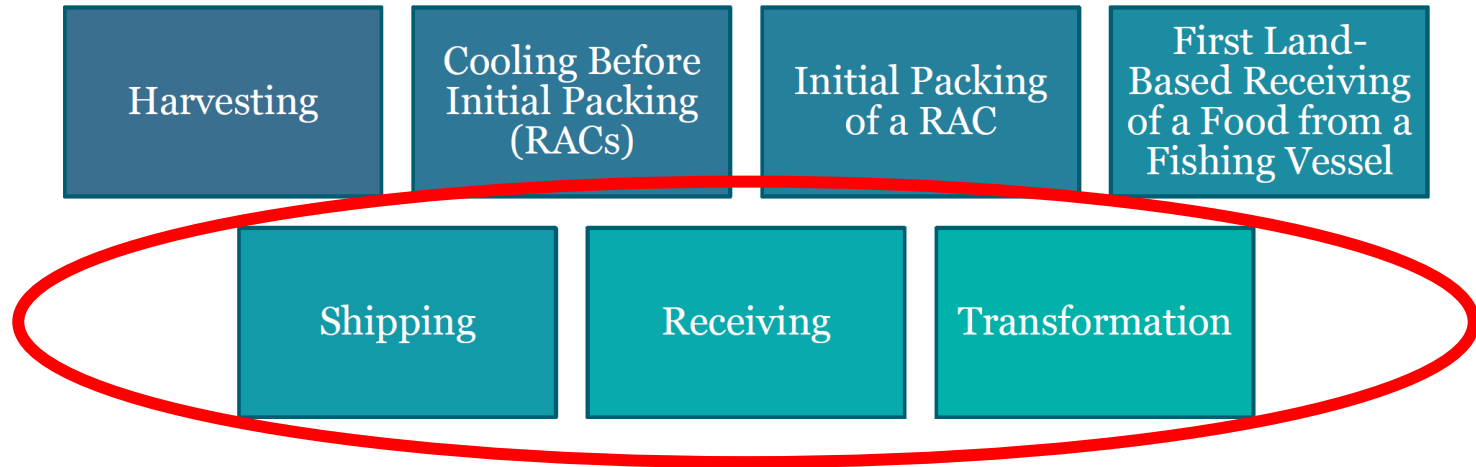
Cooked / kill-step

Field packed produce

FTL items NOT in same form

# CTE = Critical Tracking Events

At each CTE, entities must link KDEs to the food's TLC.



# Key data elements - Shipping

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



Harvesting

Cooling  
(before Initial  
Packing)

Initial  
Packing  
(RAC)

First Land-Based  
Receiver

Shipping

Receiving

Transformation

Traceability  
Plan

## Shipping KDEs (maintain and provide)

*KDEs must be linked to the traceability lot for the food*

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Location description for the location from which you shipped the food
- Date you shipped the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number (maintain only)

\*This section does not apply to the shipment of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel).



# Key data elements - Receiving

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



## Receiving KDEs

*KDEs must be linked to the traceability lot for the food*

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received
- Date you received the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number

## Receiving KDEs

*For food you receive from a person who is exempt from the rule*

*KDEs must be linked to the traceability lot for the food*

- Traceability lot code for the food, which you must assign if one has not already been assigned (does not apply to RFEs or restaurants)
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received (i.e., traceability lot code source) and (if applicable) traceability lot code source reference
- Date you received the food
- Reference document type and reference document number

\*This section does not apply to receipt of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).



# Key data elements - Transformation

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



## Transformation KDEs

### *FTL food(s) used as Ingredient(s)*

*KDEs must be linked to the new traceability lot for the food*

- Traceability lot code for the food
- Product description for the food to which the traceability lot code applies
- For each traceability lot used, the quantity and unit of measure of the food used from that lot

## Transformation KDEs

### *New food produced*

*KDEs must be linked to the new traceability lot for the food*

- New traceability lot code for the food
- Location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference
- Date transformation was completed
- Product description for the food
- Quantity and unit of measure of the food
- Reference document type and reference document number

For RACs (other than a food obtained from a fishing vessel) that were not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c).

For sprouts that were not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c), and also § 1.1330(b).

\*This section does not apply to retail food establishments and restaurants with respect to foods they do not ship (e.g., foods they sell or send directly to consumers).

# Traceability Plan Checklist

- Written Traceability Plan
- Recall Team and Recall Coordinator
- Product Identification and Traceability
- Recall Strategy
- Notification
- Disposition of Product
- Documentation and Record Keeping
- Root Cause Analysis
- Post Recall Procedures
- Effectiveness Checks

# Elements of a Traceability Plan

- Identify CTEs/KDEs
  - Identify food on FTL
  - Identify how TLC is generated
  - Identify & Maintain Records - Need to receive and record this information on a daily, transactional basis
  - Identify point of Contact
- Resource Investments?
- Must be able to send records to FDA via an electronic sortable spreadsheet within 24 hours

## Traceability Plan Example for Restaurants (§ 1.1315)



The purpose of this document is to help restaurants establish a traceability plan as required in § 1.1315 of the Food Traceability Rule.

This example incorporates the information that is required by FDA's Food Traceability Rule and is one example of how a traceability plan can be established. There is no specific format required for the traceability plan, but the information in the traceability plan must meet the requirements as described in § 1.1315 of the Food Traceability Rule and reflect the current practices specific to the covered entity.

### Requirements under § 1.1315 of the Food Traceability Rule:

If you are subject to the requirements of the final rule, you must establish and maintain a traceability plan containing the following information:

1. A description of the procedures you use to maintain the records you are required to keep under this rule, including the format and location of these records;
2. A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold;
3. A description of how you assign traceability lot codes to foods on the Food Traceability List, if applicable;
4. A statement identifying a point of contact for questions regarding your traceability plan and records; and
5. If you grow or raise a food on the Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods.
  - The farm map must show the location and name of each field (or other growing area) in which you grow a food on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each field or growing area.
  - For aquaculture farms, the farm map instead must show the location and name of each container (e.g., pond, pool, tank, cage) in which you raise seafood on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each container.
6. You must update your traceability plan as needed to ensure that the information provided reflects your current practices and to ensure that you are in compliance with the requirements of the rule. You must retain your previous traceability plan for 2 years after you update the plan.

# Records and Reporting Requirements

- Consist of original paperwork or electronic records
- Must be kept back to traceability lot level
- 2 year record retention
- Available to FDA within 24 hours
- Must provide electronic spreadsheet to FDA (for recalls and outbreak investigations)

# References:

- FDA: FSMA 204
- FDA: Guidance for Industry: Product Recalls, Including Removals and Corrections
- USDA FSIS: Guidance for Industry: Product Recall Procedures

# Thank You!



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