



# FoodIndustry

COUNSEL LLC

**“GOING ALL-IN FOR FOOD AND ALL-OUT FOR THOSE WHO PRODUCE IT”**

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# **FSMA 204 FOOD TRACEABILITY**

**- WE'RE PAST THE POINT OF WAITING -**



# FSMA 204 FOOD TRACEABILITY

## - WE'RE PAST THE POINT OF WAITING -



January 20, 2026

November 2022

November 28, 2023

December 1, 2024

December 31, 2025



# **FSMA 204 FOOD TRACEABILITY**

**- WE'RE PAST THE POINT OF WAITING -**



**APPLIES TO ALL**  
*(i.e., RETAIL)*

# **24 MONTHS**

# WHY??????????



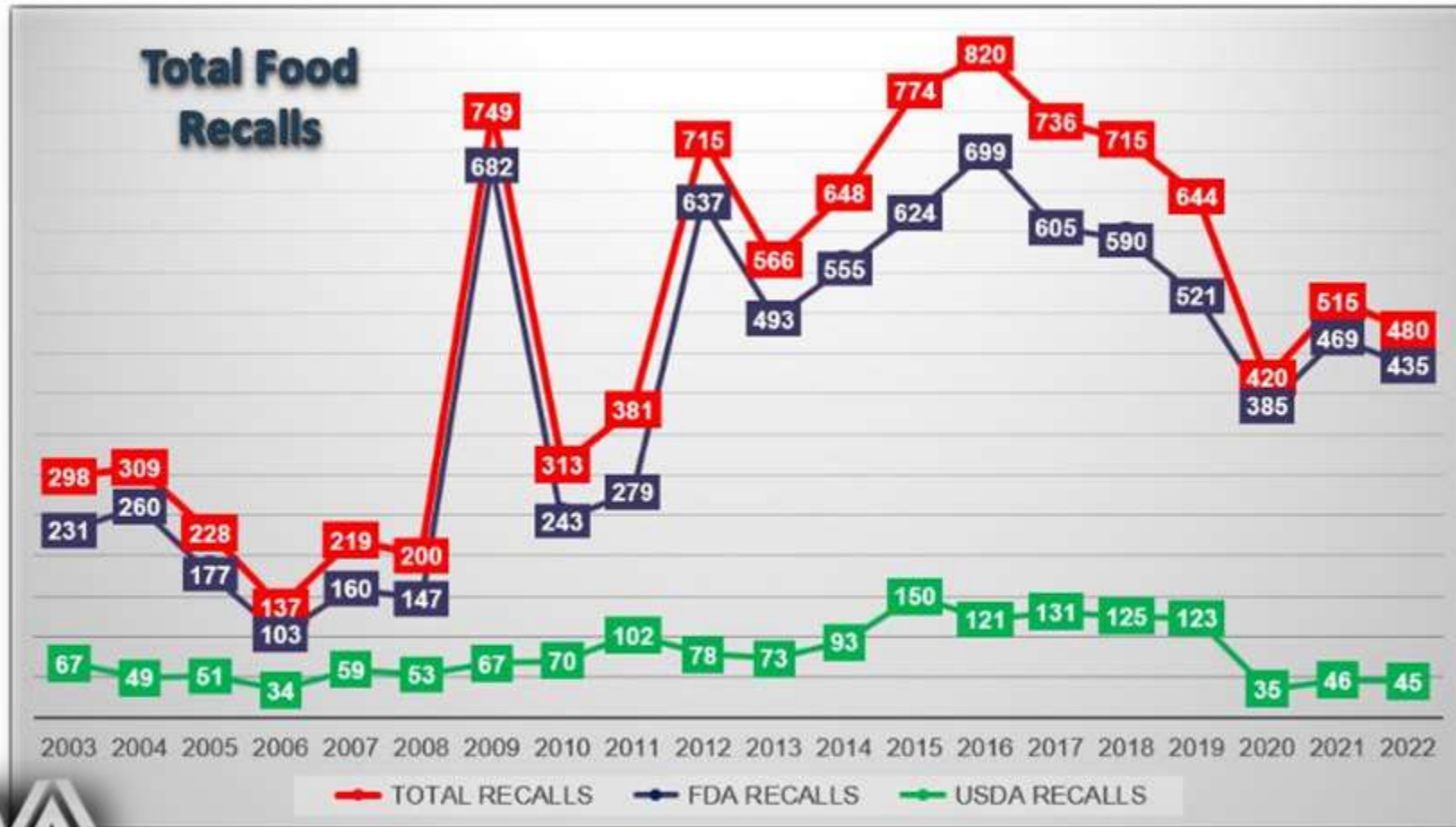
# FDA's New Era of Smarter Food Safety



**"Yeah ... I did that."**



# FDA's New Era of Smarter Food Safety



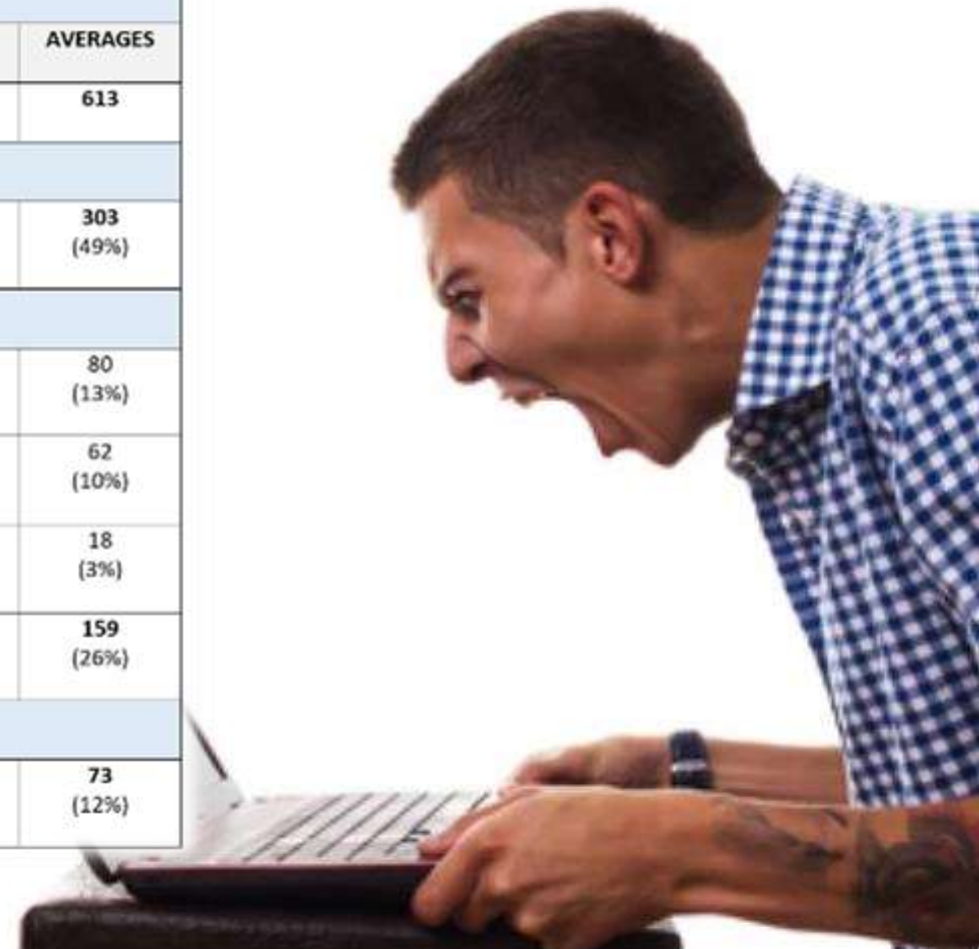
[www.foodrecallreporter.com](http://www.foodrecallreporter.com)



# FDA's New Era of Smarter Food Safety

2015-2022 RECALL STATISTICS (HUMAN FOOD AND BEVERAGES ONLY – EXCLUDES DIETARY SUPPLEMENTS AND ANIMAL FOOD)									
CAUSES	2015	2016	2017	2018	2019	2020	2021	2022	AVERAGES
All Causes	746	801	714	656	619	403	489	476	613
<b>UNDECLARED ALLERGENS</b>									
Allergens (Big 8)	410 (55%)	388 (48%)	410 (57%)	336 (51%)	235 (38%)	145 (36%)	250 (51%)	249 (52%)	303 (49%)
<b>PATHOGENS</b>									
<i>Listeria monocytogenes</i>	63 (8%)	144 (18%)	125 (18%)	87 (13%)	92 (15%)	31 (8%)	54 (11%)	47 (10%)	80 (13%)
<i>Salmonella</i>	69 (9%)	101 (13%)	34 (5%)	95 (14%)	43 (7%)	44 (11%)	52 (11%)	54 (11%)	62 (10%)
<i>E. coli</i> (All Varieties)	13 (2%)	46 (6%)	22 (3%)	18 (3%)	18 (3%)	6 (1%)	5 (1%)	6 (1%)	18 (3%)
<b>Total Pathogens</b> ("Big 3")	<b>145</b> (19%)	<b>291</b> (36%)	<b>182</b> (25%)	<b>200</b> (30%)	<b>153</b> (25%)	<b>81</b> (20%)	<b>111</b> (23%)	<b>107</b> (22%)	<b>159</b> (26%)
<b>FOREIGN MATERIALS</b>									
Foreign Materials (All Varieties)	69 (9%)	80 (10%)	80 (11%)	67 (10%)	106 (17%)	50 (12%)	68 (14%)	66 (14%)	73 (12%)

[www.foodrecallreporter.com](http://www.foodrecallreporter.com)





# FDA's New Era of Smarter Food Safety

**Tech-enabled Traceability**

**Smarter Tools and Approaches  
for Prevention and Outbreak Response**

**New Business Models and Retail Modernization**

**Food Safety Culture**



# FDA's New Era of Smarter Food Safety

**Tech-enabled Traceability**

**Smarter Tools and Approaches  
for Prevention and Outbreak Response**

**New Business Models and Retail Modernization**

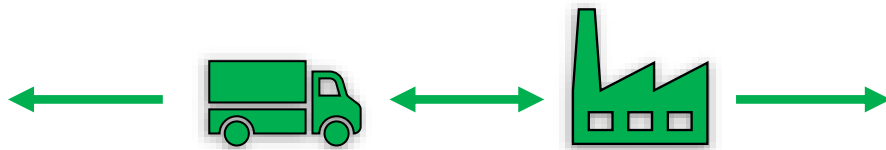
**Food Safety Culture**



# FDA's New Era of Smarter Food Safety

**Tech-enabled Traceability  
Outbreak Response**

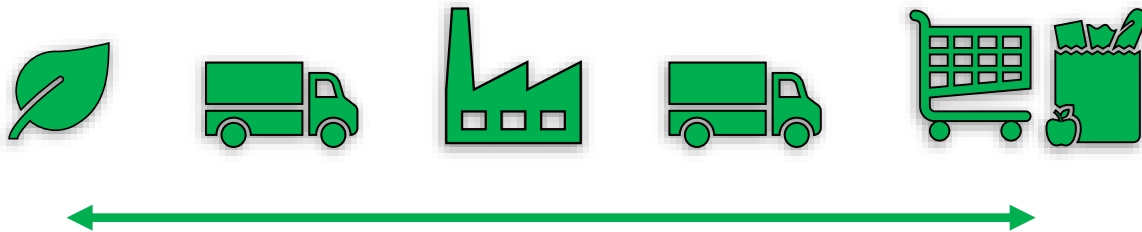
**ONE FORWARD, AND ONE BACK**



# FDA's New Era of Smarter Food Safety

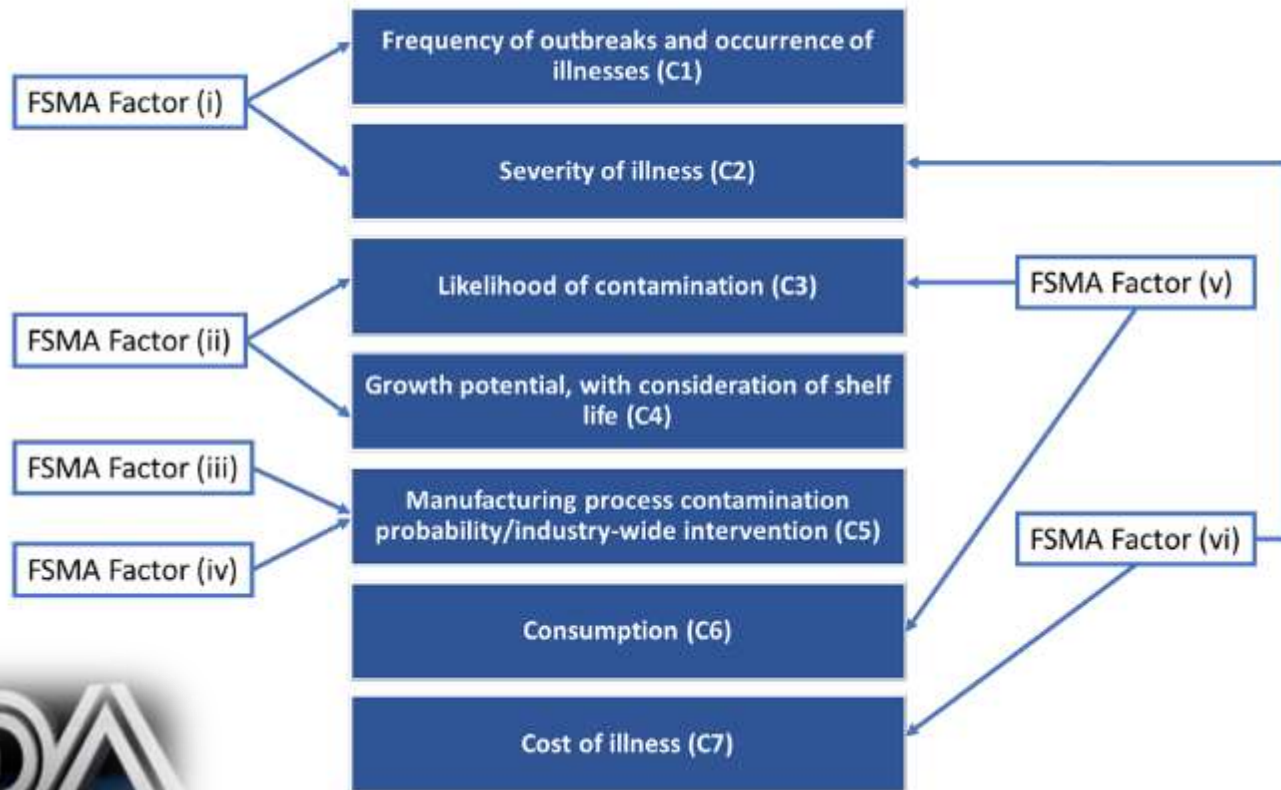
**Tech-enabled Traceability  
Outbreak Response**

**FARM TO RETAIL FRIDGE**



# WHAT FOODS DOES THE RULE APPLY TO?

## FOODS ON THE TRACEABILITY LIST (FTL)



# WHAT FOODS DOES THE RULE APPLY TO?

## FOODS ON THE TRACEABILITY LIST (FTL)

### FOOD RECALL SEARCH

#### FOOD RECALL REPORTER



RECALLS BY YEAR

2023	2015	2007
2022	2014	2006
2021	2013	2005
2020	2012	2004
2019	2011	2003
2018	2010	2002
2017	2009	2001
2016	2008	2000

Food Industry Counsel is proud to offer the **Food Recall Reporter**, the only searchable food recall database that allows users to conduct a food recall search for FDA and USDA food product recalls. Search food and beverage recalls, the types of food products, the reasons for the recalls, and the names of the companies recalling the products.

#### RECALL CLASS

- 5,777
- 5,786
- 11,395
- Not Published: 1,000

Limit search for:  Company  Brand  Details  Product

11,433 results found in 5ms

Items per page:

Date	Company	Brand	Details	Product
11/24/2023	Pacific Trellis Fruit, LLC dba Dulcinea	Malichisa	Salmonella	Whole Cantaloupe
11/24/2023	Wine Country Gift Baskets	Acorn Baking Company	Tree Nuts	Raspberry Creme Filled Cookies



# WHAT FOODS DOES THE RULE APPLY TO?

## FOODS ON THE TRACEABILITY LIST (FTL)

**Cheese (other than hard cheeses)**

**Shell eggs**

**Nut Butter**

**Cucumbers**

**Herbs (fresh)**

**Leafy Greens (including fresh-cut)**

**Melons (fresh)**

**Peppers (fresh)**

**Sprouts (fresh)**

**Tomatoes (fresh)**

**Tropical tree fruits (fresh)**

**Fruits and vegetables (fresh-cut)**

**Smoked Finfish**

**Crustaceans**

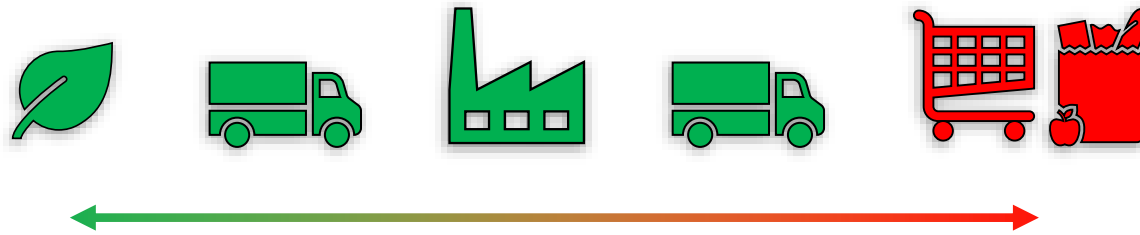
**Molluscan shellfish, Bivalves**

**Ready-to-eat deli salads**



# WHO DOES THE RULE APPLY TO?

Persons who manufacture, process, pack, or hold foods that appear on the FTL



January 20, 2026





# WHO DOES THE RULE APPLY TO?

## EXEMPTIONS

FDA Traceability Final Rule website

- Getting Started with the Food Traceability Rule
- Food Traceability List (FTL)
- Key Features
- Full and Partial Exemptions**
- Modified Requirements, Exemptions, and Waivers
- Critical Tracking Events and Key Data Elements
- Supply Chain Examples



# WHO DOES THE RULE APPLY TO?

## EXEMPTIONS

FDA Traceability Final Rule website

Exemptions to the Food Traceability Rule

Exemptions to the Food Traceability Rule

Start Here



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# WHO DOES THE RULE APPLY TO?

## EXEMPTIONS

FDA Traceability Final Rule website

### 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

Commingled raw agricultural commodities (RACs)

Fishing vessels, molluscan shellfish

Retail food establishments (RFEs), restaurants

Certain types of processing

Personal consumption, holding food for specific consumers

Other

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# WHO DOES THE RULE APPLY TO?

## EXEMPTIONS

Produce that is rarely consumed raw

Foods regulated by USDA

Small retail food establishments

Restaurants that purchase directly from the farm

Transporters

Food for personal consumption

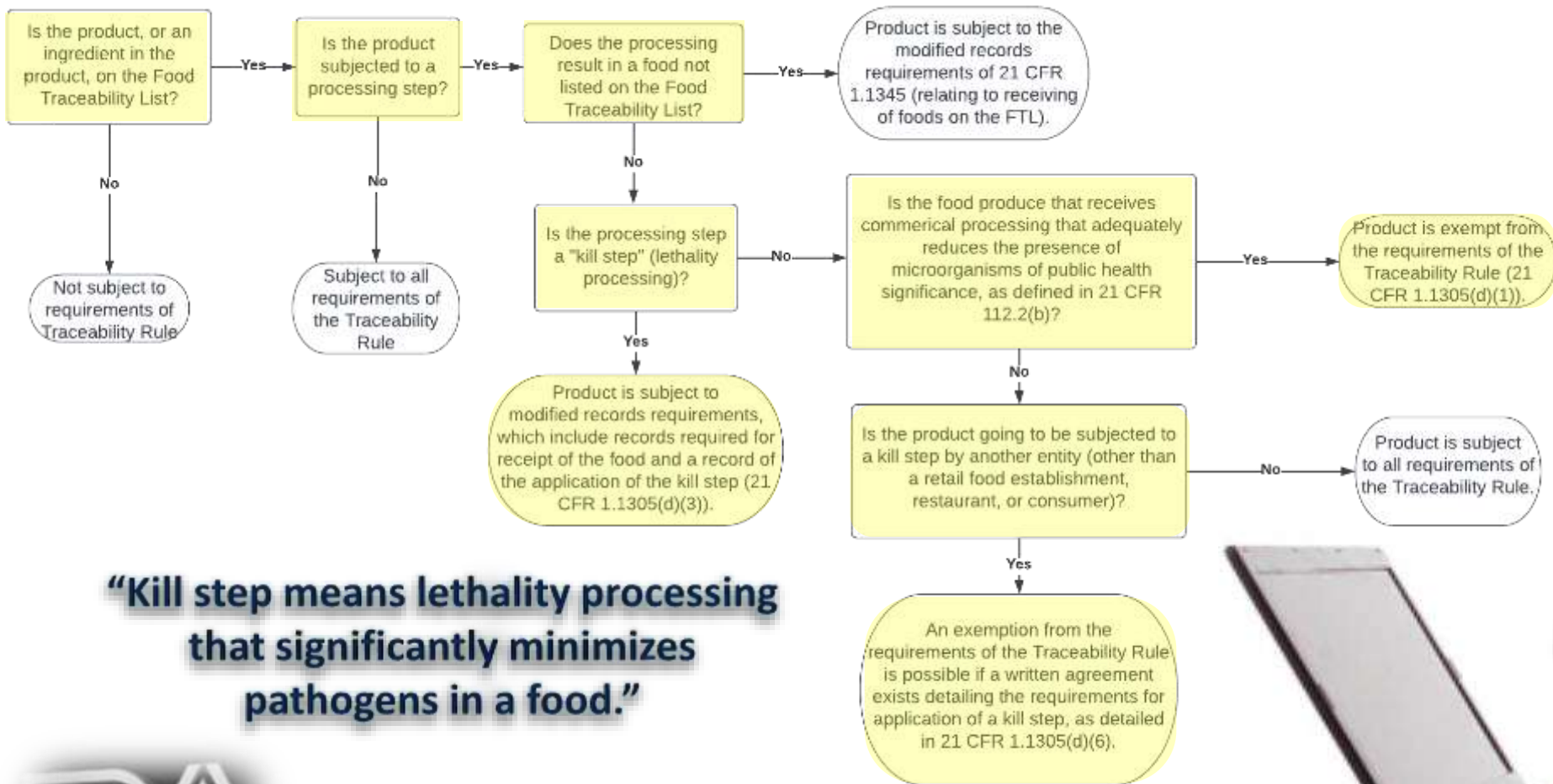
Research and development

Food that receives a “kill step”

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# WHO DOES THE RULE APPLY TO?



**“Kill step means lethality processing that significantly minimizes pathogens in a food.”**

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# WHAT NEEDS TO BE DONE?

## LOT TRACEABILITY CODE

Must be assigned by: (1) the initial packer;  
(2) the FLBR (fishing vessel); or (3) any transformer

### Examples of traceability lot codes

**(01)04562135785133**  
**(17)140704 (10) DE-456**

GS1-128 Example

**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

**1147M2023213**

              
1. 2. 3.

1. Product code
2. Facility
3. Julian date

**134AD5607**

Randomized  
alphanumeric  
code generated  
by firm's  
traceability  
system

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# WHAT NEEDS TO BE DONE?

## CRITICAL TRACKING EVENTS (CTEs)

Harvesting  
Cooling  
Initial packing  
FLBR (Fishing vessel)  
Shipping  
Receiving; and  
Transforming

(when the finished product is still a product on the FTL)



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# WHAT NEEDS TO BE DONE?

## KEY DATA ELEMENTS (KDEs)

### Traceability Lot Code Source (TLCS)

[Place assigning Lot Code (Location description)]

### Traceability Lot Code Source Reference (TLCSR)

[i.e., FDA Registration Number]

### Product Description

[Brand name, commodity, and variety]



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# WHAT NEEDS TO BE DONE?

## HARVESTING KDEs

Location Description (farm)

Name or description of field/growing area

Harvest date

Brand, commodity, and variety

Quantity

Location description for  
immediate subsequent recipient

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# WHAT NEEDS TO BE DONE?

## HARVESTING KDEs

### Location Description

The key contact information for the location where a food is handled, specifically the business name, phone number, physical location address or geographic coordinates, the city, State, and Zip code for domestic locations and comparable information for foreign locations including country.” This information could also be maintained through a reference to this information (such as a database code that then refers to the specific information within a database.



# WHAT NEEDS TO BE DONE?

## Cooling KDEs

**Location Description (farm)**

[Name or description of field/growing area]

**Harvest date**

**Brand, commodity, and variety**

**Quantity**

**Cooling location**

**Cooling date**

**Location description for  
immediate subsequent recipient**



# WHAT NEEDS TO BE DONE?

## Initial Packing KDEs

**Location Description (farm)**

[Name or description of field/growing area]

**Harvest Date**

**Brand, Commodity, Variety**

**Quantity**

**Date Received**

**Cooling Location**

**Cooling Date**

**Location description of where food packed**

(TLC Source/TLC source Reference)

**Traceability Lot Code you assigned**

**Date of initial packing**

**Location Description for immediate subsequent recipient**

**Reference document type and reference document number**



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# WHAT NEEDS TO BE DONE?

## Initial Packing KDEs

### Reference document type and reference document number

Reference document is defined as “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 food.” These could include purchase orders, work orders, invoices, and similar documents; the reference document could be created by the tracking company or another organization in the supply chain.



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# WHAT NEEDS TO BE DONE?

## Shipping KDEs

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



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# WHAT NEEDS TO BE DONE?

## **Transformation KDEs** (If a new food is produced)

**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**



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# WHAT NEEDS TO BE DONE?

## 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

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.



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# WHAT NEEDS TO BE DONE?

## Traceability Plan

Description of the procedures you use to maintain the required records, including the format and location of the records

Description of the procedures you use to identify foods on the FTL that you manufacture, process, pack or hold

Description of how you assign traceability lot codes to foods on the FTL, if applicable

Statement identifying a point of contact for questions regarding your traceability plan and records



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# WHAT NEEDS TO BE DONE?

## Examples

FDA

### Supply Chain Example: Cucumbers

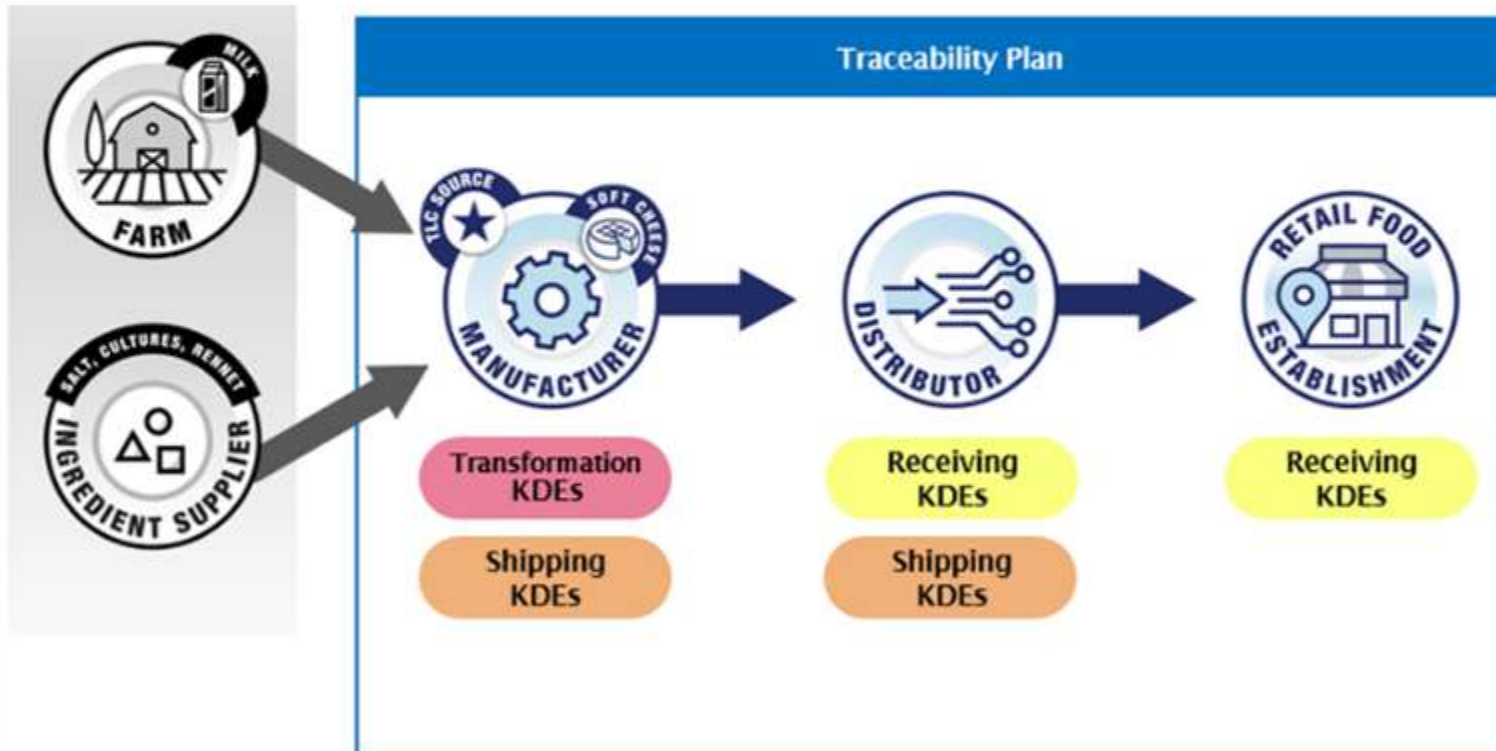


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# WHAT NEEDS TO BE DONE?

## Examples

### Supply Chain Example: Soft Cheese



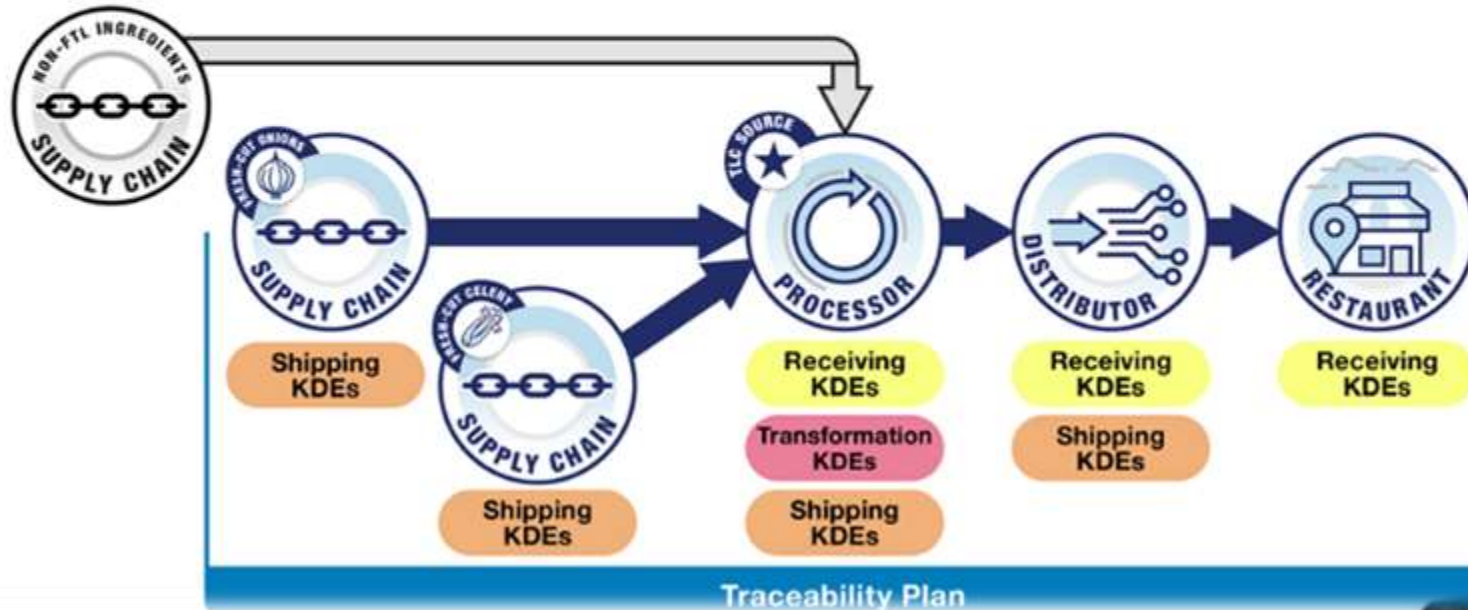
# WHAT NEEDS TO BE DONE?

## Examples

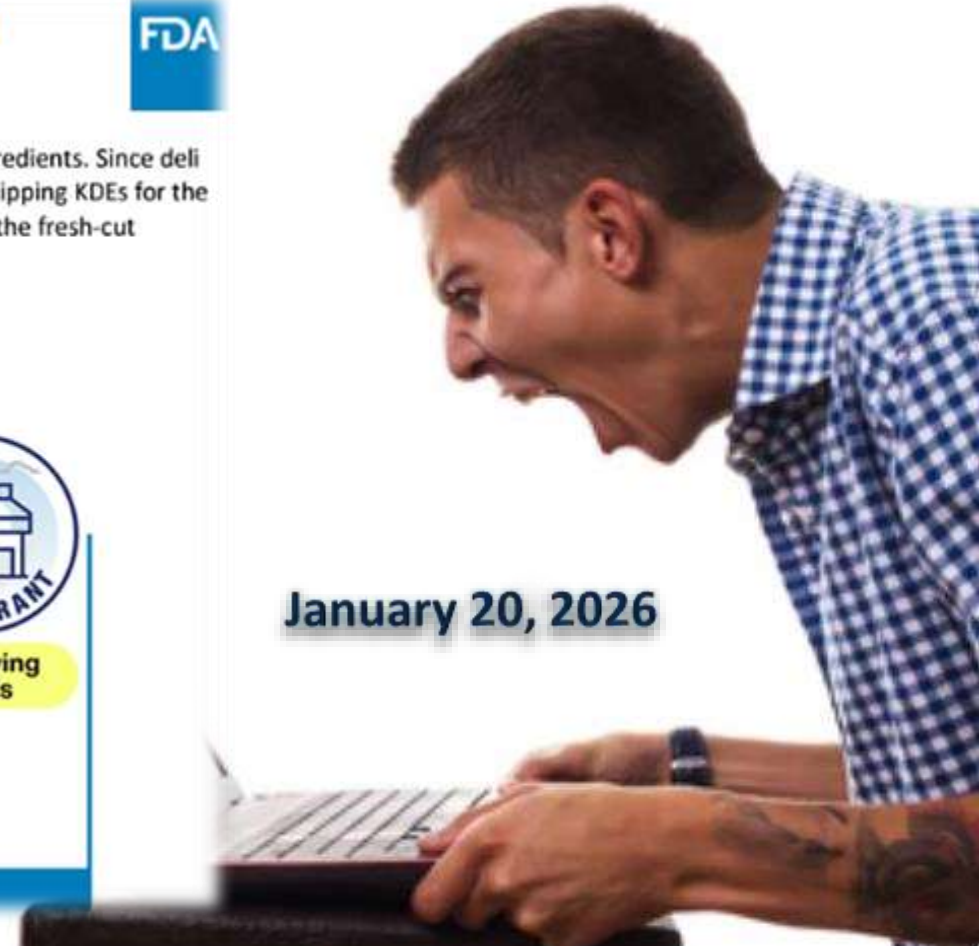
### Supply Chain Example: Deli salad using FTL ingredients and non-FTL ingredients



In this scenario, a deli salad is made with fresh-cut celery and fresh-cut onions, both of which are on the FTL, as well as other non-FTL ingredients. Since deli salads are on the FTL, the processor would need to maintain receiving KDEs for the FTL ingredients, as well as transformation KDEs and shipping KDEs for the deli salad. All entities in blue are covered by the final rule and must maintain a Traceability Plan, in addition to the KDEs. The suppliers of the fresh-cut onions and fresh-cut celery may be required to maintain other KDEs (in addition to shipping), depending on their role in the supply chain.



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# FSMA 204 FOOD TRACEABILITY

## - WE'RE PAST THE POINT OF WAITING -



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