



FDA-Enforced Food Traceability is Here: Are You Ready?



ReposiTrak

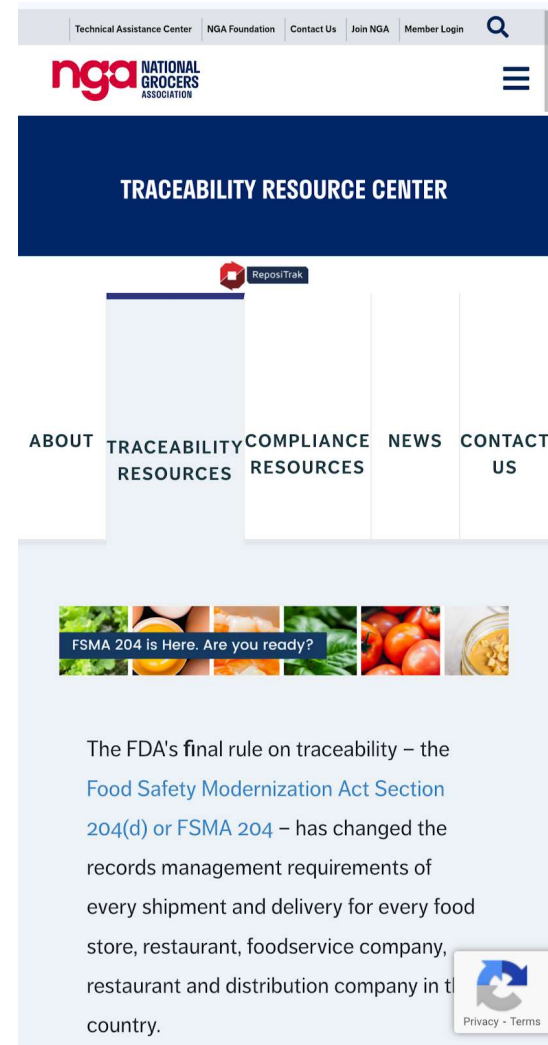
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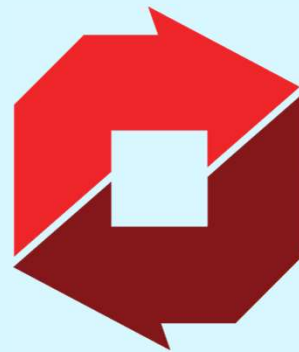
NGA/ReposiTrak Traceability Resource Center

ReposiTrak is the **official compliance
and traceability partner** of the
National Grocers Association

[https://www.nationalgrocers.org/
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Presenter



RepoSiTrak

Derek Hannum

Chief Customer Officer
RepoSiTrak



The ReposiTrak Traceability Network®

FDA Traceability is Here

Understanding the regs, the questions to ask and steps to take in preparation for FSMA 204.

December 2023

REPOSITRAK.COM

What we will cover...

- Introduction to FSMA 204 traceability requirements
- The current state of the supply chain...the big challenge to achieve FDA traceability
- Questions you should be asking & steps you can take to get started

This is where we are...

Your company is now part of the largest supply chain data collaboration in history

1.5 to 2 million stores, restaurants, DCs, production facilities, packing houses need to create and manage food traceability records...most are not equipped to do it

This is not a food safety project, this is a supply chain data management project.

Who is required to do traceability?

In the words of the FDA...


“...At the core of the final rule is a requirement **that persons who manufacture, process, pack or hold food on the FTL** maintain records including Key Data Elements (KDEs) related to Critical Tracking Events (CTEs)...

...Covered firms and farms, retail food establishments and restaurants will be required to provide information to the FDA within 24 hours... in an electronic sortable spreadsheet...

...all records must be retained for 2 years.”

What categories of products need to be tracked?

FDA Food Traceability List (FTL)

	Soft Cheeses		Shell Eggs		Nut butter		Cucumbers
	Herbs (fresh)		Leafy greens (including fresh-cut)		Melons		Peppers
	Sprouts		Tomatoes		Tropical tree fruits		Fresh-cut Fruits and Vegetables
	Finfish		Crustaceans		Mollusks (bivalves)		Ready-to-eat deli salads

What store departments are impacted?

Produce

Cucumbers (fresh)
Herbs (fresh)
Any Leafy greens (fresh)
Any Leafy greens (fresh-cut)
Vegetables other than leafy greens (fresh-cut)
Peppers (fresh)
Sprouts (fresh)
Tomatoes (fresh)
Melons (fresh)
Tropical tree fruits (fresh)
Any Fruit (fresh-cut)

Dairy

Shell Eggs

Cheese

Seafood

Smoked Finfish (refrigerated & frozen)

Crustaceans (fresh & frozen)

Molluscan shellfish, bivalves (fresh & frozen)

Finfish (fresh and frozen)

Deli / Prepared Foods

Ready-to-eat deli salads

Center store / Frozen

Nut butters, as an ingredient where no kill-step has been applied*

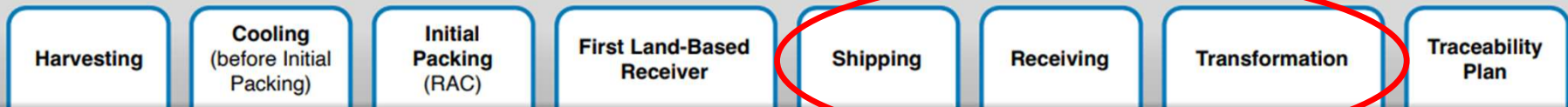
When does FSMA 204 enforcement start?

“...The final rule...**is effective January 20, 2023**... it aligns with current industry best practices and covers domestic, as well as foreign firms producing food for U.S. consumption, along the entire food supply chain in the farm-to-table continuum.

...come into **compliance date** for all persons subject to the recordkeeping requirements is Tuesday, **January 20, 2026.**”

525
Business Days
from Today

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



Every Critical Tracking Event (CTE) has a set of Key Data Elements (KDEs) that must be collected and saved as an easily retrievable record.

The CTEs that impact wholesalers/ distributors and retailers are Shipping, Receiving, and in some cases Transformation.



Understanding the Transformation CTE

- **Transformation** is taking one or more items from the FTL and transforming them to create a new item that is on the FTL
- Example: Tomatoes and peppers used in a deli salad...the tomatoes and the peppers, as well as the deli salad are all on the FTL
- The lot codes of FTL ingredients and the quantities used must be tracked and associated with the lot code of the new FTL food produced, in addition to location data and other KDEs
- Repacking is considered transformation
- **IMPORTANT:** This only applies if the transformation happens in a facility that does not sell the product directly to consumers, such as a processing facility or a central kitchen

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

FDA U.S. FOOD & DRUG ADMINISTRATION

Harvesting	Cooling (before Initial Packing)	Initial Packing (RAC)	First Land-Based Receiver	Shipping	Receiving	Transformation	Traceability Plan
<div><div>Transformation KDEs <i>FTL food(s) used as ingredient(s)</i> KDEs must be linked to the new traceability lot for the food</div><div><ul style="list-style-type: none">Traceability lot code for the foodProduct description for the food to which the traceability lot code appliesFor each traceability lot used, the quantity and unit of measure of the food used from that lot</div></div> <div><div>Transformation KDEs <i>New food produced</i> KDEs must be linked to the new traceability lot for the food</div><div><ul style="list-style-type: none">New traceability lot code for the foodLocation description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source referenceDate transformation was completedProduct description for the foodQuantity and unit of measure of the foodReference document type and reference document number<p>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).</p><p>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).</p></div></div>							

<https://www.fda.gov/media/163132/download?attachment>

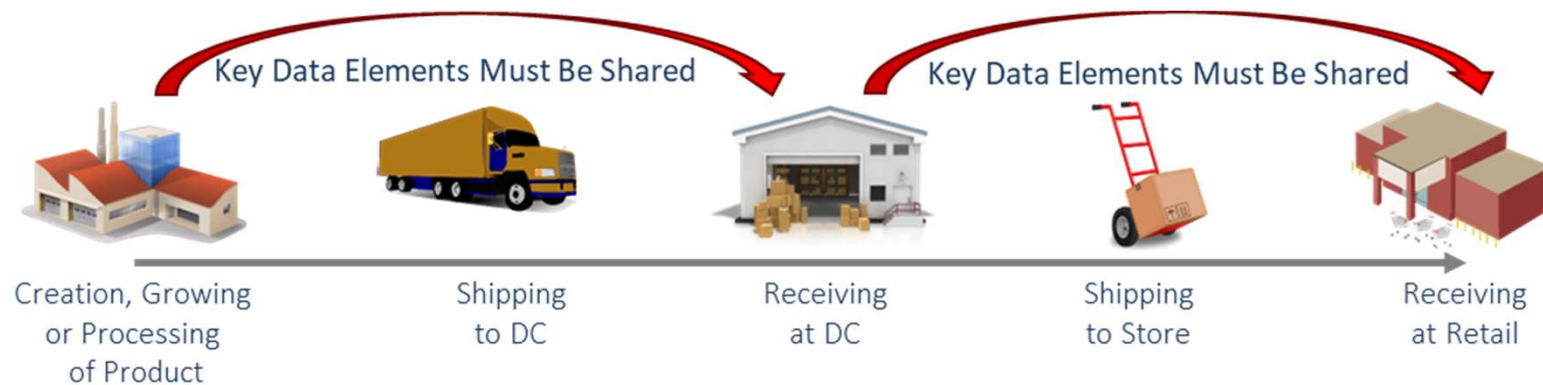
ReposiTrak Food Safety Partner – The Acheson Group

- If you need an expert assessment of how FSMA 204 impacts your specific operation as a product supplier, distributor or retailer
- TAG provides a written assessment report of your FSMA 204 impact – only \$500
- ReposiTrak can make the introduction to TAG



What records are required for Shipping & Receiving CTEs?

...At the DC/warehouse when product is received
...From the DC/warehouse when product is shipped
...At stores when product is received



Requirements at DC/Warehouse Receiving

The receiving record combines product data with receiving/transaction data. A label, importantly, can only contain the product (static) information.

Product
data that
stays the
same

1. The traceability lot code for the food
2. The product description for the food
3. The location description for the traceability lot code source, or the traceability lot code source reference

Shipment
data that
changes as
the product
moves

4. The location description for where the food was received
5. The location description for the immediate previous source (other than a transporter) for the food
6. The reference document type and reference document number
7. The quantity and unit of measure of the food (e.g. 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds)
8. The date the food was received

Requirements at DC/Warehouse Shipping

The shipping record combines product data with shipment/transaction data. A label, importantly, can only contain the product (static) information.

Product
data that
stays the
same

1. The traceability lot code for the food
2. The product description for the food
3. The location description for the traceability lot code source, or the traceability lot code source reference

Shipment
data that
changes as
the product
moves

4. The location description for the location from which the food was shipped
5. The reference document type and reference document number
6. The location description for the immediate subsequent recipient (other than a transporter) of the food
7. The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds)
8. The date the food was shipped

Requirements at Retail Store Receiving

The receiving record combines product data with receiving/transaction data. A label, importantly, can only contain the product (static) information.

Product
data that
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1. The traceability lot code for the food
2. The product description for the food
3. The location description for the traceability lot code source, or the traceability lot code source reference

Shipment
data that
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4. The location description for where the food was received
5. The location description for the immediate previous source (other than a transporter) for the food
6. The reference document type and reference document number
7. The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds)
8. The date the food was received

The big challenges

At the Supplier Shipping Location

- Your customers need to receive Traceability Lot Code Data and Lot Code Source Reference data from you.
- If you don't track these today, and include the lot code on your shipping units, you need to start.
- Your biggest risk is that all your customers choose to do traceability data collection differently, creating more work and cost for you.

At the Distribution Center

- Lot codes are not tracked in wholesaler and retailer DCs today.
- Instituting the systems and processes to track lot codes is expensive and takes months or even years to implement.
- DCs can't create KDE records if they don't have a way to collect and track lot codes.

At the Retail Store

- As a retailer, you **MUST** have a KDE receiving record for products received at the store, warehouse and DSD items.
- This is not optional...the store KDE receiving record needs to be created by someone.
- As a receiver, you likely know the shipment data, so how do you collect the lot code data?

Labels are required, but NOT the complete solution

- All cases/shipping units need to have identifying lot code information.
- If you don't have labels or Traceability Lot Code case identification, you should address this ASAP...it will be required by your customers.
- Adopt the GS1 standard.
- IMPORTANT: Labels only carry the **product** Key Data Elements, not the **shipment data**...so labels alone can't be used to generate the required KDE record.

1. The traceability lot code for the food
 2. The product description for the food
 3. The location description for the traceability lot code source, or the traceability lot code source reference
-
4. The location description for where the food was received
 5. The location description for the immediate previous source (other than a transporter) for the food
 6. The reference document type and reference document number
 7. The quantity and unit of measure of the food (e.g. 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds)
 8. The date the food was received

**Steps to take & questions to ask so you
know what to do, and when to start**

Steps to take now to get ready – retailers/wholesalers

1. Identify the products and suppliers requiring traceability under FSMA 204.
2. Identify the DC/warehouse systems and processes that need to change.
3. Understand the requirements of retail stores and what systems and processes need to change.
4. Identify and establish the human and technology infrastructure required to support traceability.



1. Identify the products and suppliers requiring traceability under FSMA 204.

- Identifying some FTL foods might be easy, including fresh-cut fruits and vegetables, melons, peppers, cucumbers, herbs and leafy greens.
- You should consider tracking all seafood.
- Identifying other FTL foods might be difficult, for example nut butters alone may be found as an ingredient in as many as 2,000-3,000 products on your shelves in addition to packaged nut butters.
- Will you need to collect ingredient statements to determine what's covered under FSMA 204?
- How will Key Data Elements (KDEs) be retrieved for products purchased from a distributor?
- How will new requirements, processes and methodologies be communicated to suppliers?

How long will it take to identify the items/suppliers, and contact them to understand what's necessary to get them onboard with your traceability plan?

2. Identify DC/warehouse systems and processes that need to change.

The DC/Warehouse Management System

- Does the current warehouse system collect, create and store the KDEs necessary for traceability?
- How long will it take to replace or modify the warehouse system?
- What system will store and manage the millions of records required?

The Receiving Process

- How will trucks and pallets containing FTL products be identified?
- Will every single case coming into the DC need to be “scanned”?
- How will scanning systems recognize a TLC on a case, given that there are no standards?
- How and where will training and change management take place?

The Shipping Process

- How will cases and items containing FTL products be identified?
- Will every single case leaving the DC need to be scanned?
- How will scanning systems recognize a TLC on a case, given that there are no standards?
- How and where will training and change management take place?

How long will it take for the budget, technology and process changes at the DC/warehouse to be determined and completed?

3. Identify the requirements of retail stores and what systems and processes need to change.

- Do stores require KDEs to be exchanged in a specific format or method?
- How do retailer systems collect, create and store the KDEs necessary for traceability?
- How long will it take to replace or modify systems to accommodate new requirements?
- How will stores deal with shipments from wholesaler DCs, their own DCs and DSD suppliers?
- How and where will training and change management take place?

How long will it take for the budget, technology and process changes at the store to be determined and completed?

4. Identify and establish the infrastructure required to support traceability.

- How will an end-to-end technology be established that will contain and retain all required KDE records?
- How will errors be detected and corrected?
 - Millions of records will be created per year, so even a small error rate will create 100,000 or more errors.
 - How will missing or incorrect information be detected?
 - How will errors be corrected?
 - Who will be contact suppliers to correct errors?
- How and where will training and change management take place for merchants, operations, DC/warehouse and store personnel?
- How will a “Help Desk” be established and maintained for suppliers who are onboarding, and for ongoing traceability support?

How long will it take to identify the infrastructure requirements and establish what is needed?

ReposiTrak's findings:
**The amount of time and effort required to
develop and implement a traceability program
is far greater than most people think**

Steps to take NOW

Product Suppliers

1. Evaluate your labeling, standardize to GS1 labels.
2. Don't be surprised if customers require you to do traceability even if you don't have products on the FSMA 204 list.
3. Make sure your management team understands the risk of customer fragmentation and look for technical solutions that require little to no new work or cost for you or your customers.

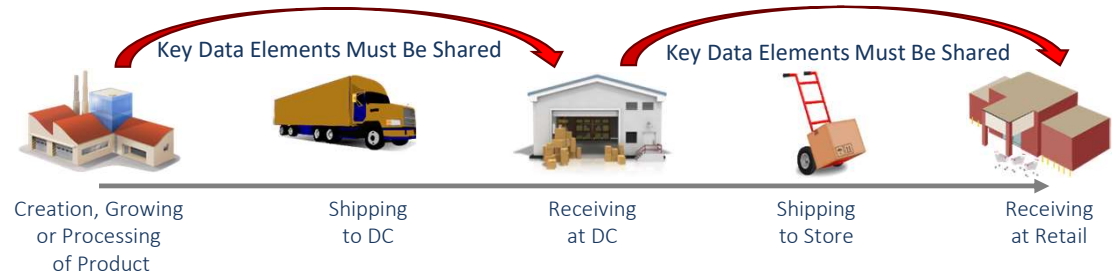
Wholesalers/Distributors/Retailers

1. Identify the products and suppliers you need to track/trace...this is not easy!
2. Identify the DC/warehouse systems and processes that need to change.
3. Understand the requirements of retail stores and what systems and processes need to change.
4. Identify and establish the human and technology infrastructure required to support traceability.

Summary

- Traceability is the law and time is running out to get in compliance
- Every retailer, wholesaler and the producers of covered items need to collect and retain traceability data
- This is not a food safety project...don't expect your food safety pro to do it on their own
- The traceability data you collect must be saved for 24 months, and sent to the FDA within 24 hours of a request
- This involves the collaboration of trading partners...you can't go it alone
- The work and time involved is even greater than you realize

How will
Traceability Data
get shared
between the
trading partners
as product moves
through the
supply chain?



ReposiTrak
automates KDE
records inbound
into the DC

Receiving at stores
is simplified using
the ReposiTrak
mobile app on a
phone or tablet



Capturing the Case Label

Using a mobile device pre-loaded with location

As easy as taking a picture





Questions

Derek Hannum
Chief Customer Officer
dhannum@repositrak.com
(407) 558-9829 Mobile
(435) 645-2230 Office

ReposiTrak is DOING traceability, while
others are simply talking about it.
Talk to us to find out why.

REPOSITRAK.COM

Questions?



ReposiTrak

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GROCERS
ASSOCIATION

Thank You

