

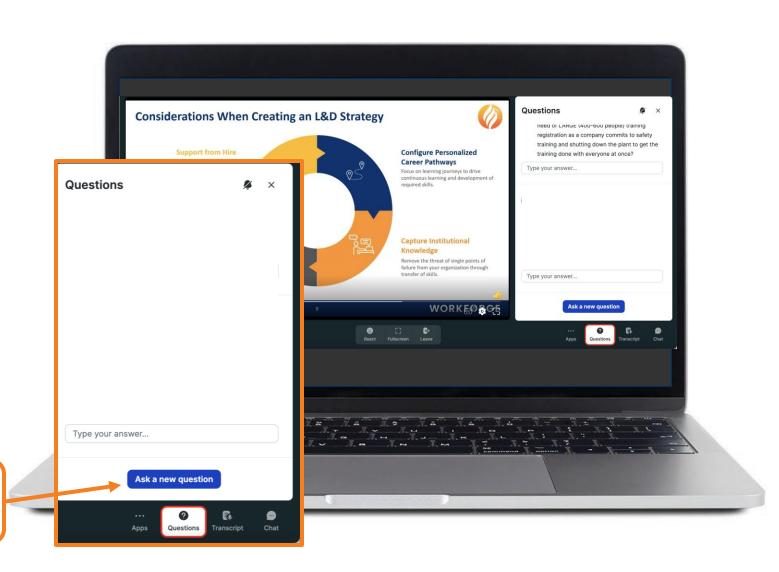
WORKFØRGE

Is your operation prepared and able to meet the FDA's food traceability requirements?

Housekeeping

- Everyone is muted by default
- Use Q&A tab to post questions
- Recording and slides will be shared immediately following event

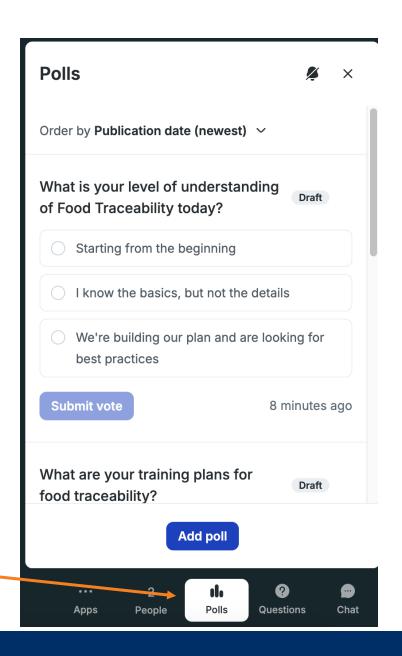
We will do our best to answer as many questions as possible during the presentation using the Q&A tab.



Poll Questions

1. What is your level of understanding of Food Traceability today?

Click the Polls icon on the right to answer the questions.





Today's presenter



Erik Kurdelak
Food Safety and Industry Expert

- Over 25 years in food safety
- State of Indiana subject matter expert for Food Protection Division
- Has done extensive work with Purdue University Food Science
- Founding Board Member of The Central Indiana
 Food Hub & Sustainability Center

Agenda

- Critical Definitions
- General Overview
- Outline specific actions to take for compliance
- Discuss various approaches to the required actions
- What the FDA's approach to FTR suggests for the future
- Actions you can take to prepare

Food Traceability List



List of foods for which additional traceability <u>records are required</u> to be maintained, as designated in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act. The term "Food Traceability List" includes both the <u>foods</u> <u>specifically listed</u> and <u>foods that</u> <u>contain listed foods</u> as ingredients.

- Includes many soft cheeses, most produce, finfish, nut butters, shell eggs, mollusks, crustaceans, RTE deli salads
- Rule also applies to manufactured foods containing FTL foods as an ingredient
 - Quiche
 - o Pie
 - o Etc.

Critical Tracking Event (CTE)



An event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.

- Tracking is required as product flows through the facility
- Primary CTEs are:
 - Receiving
 - Holding
 - Transforming
 - Packing
 - Shipping
- CTEs are the point in the flow of food where Key Data Elements (KDE) are recorded

Key Data Element (KDE)



Information associated with a critical tracking event for which a record must be maintained and/or provided in accordance with this subpart.

- KDEs are the specific data required to be captured at each CTE
- Not all CTEs require the same KDEs
- Different people will collect different KDEs as the product moves through the facility

CTE & KDE: Example



CTE & KDEs are sometimes regarded in three stages



- Transforming may have 14 KDE
- Packaging may have 9 KDE
- Expect duplicate data capture across the various processes

Traceability Lot



A batch or lot of food that has been initially packed (for raw agricultural commodities other than food obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.

- Traceability Lot describes on set or batch of a given ingredient or product
- Lot size is determined by the operation, not the government
- Large lots vs. Small lots

Determining your lot size strategy

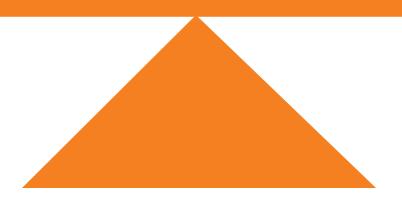


Large Lots

- Less data capture
- Larger recalls
- More complicated recalls

Small Lots

- More data capture
- Smaller recalls
- Less complex recalls



Traceability Lot Code



A descriptor, often alphanumeric, <u>used to</u> <u>uniquely identify a traceability lot</u> within the records of the traceability lot code source.

- This is the specific code assigned by an operation to describe a Lot.
- When product moves on to the next location or the next user it is expected that they be provided an explanation of the lot code.

Traceability Lot Code Source



The <u>organization that assigned</u> a traceability lot code to the food product.

- The lot code source tells who came up with the Lot Code for a product or ingredient
- The Lot Code Source decided what string of numbers and letters to use as the Lot Code
- It tells WHO assigned the traceability lot code

Traceability Lot Code Source Reference



An <u>alternative method for providing</u> FDA with <u>access to the location description for</u> <u>the traceability lot code source</u> as required under this subpart.

- Lot Code Source Reference provides a way to be sure that the Lot Code Source can be contacted
- Often this is a facility address. It tells WHERE the traceability lot code was assigned.
- Traceability Lot Code Source may also be a company's website in certain cases

Every operation under FTR must



Have a plan



Be prepared to share their plan with the FDA

Every plan requires



5 Key Elements

- 1. A description of the procedures you use to maintain the records you are required to keep under this subpart, 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 in accordance with § 1.1320.
- 4. A statement identifying a point of contact for questions regarding your traceability plan and records.
- 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.

Traceability plan expectations



- You must update the traceability plan as needed to keep information & practices current.
 - You must retain any previous versions of your traceability plan for 2 years after making updates to the plan.
 - No Exceptions: You must assign a Traceability Lot Code whenever you transform a food.

Once a Lot Code is established by your operation your operation cannot change it during a later CTE!

Required records for receiving



- ✓ The traceability lot code for the food
- ✓ The quantity and unit of measure of the food
- ✓ The product description for the food
- ✓ The location description for the immediate previous source of the food

- ✓ The location description for where the food was received
- ✓ The date you received the food
- ✓ The location description for the traceability lot code source, or the traceability lot code source reference
- ✓ The reference document type and reference document number

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RECEIVING		ENHANCED TRACEABILITY REQUIREMTN FOR FTR								
					Ingredient Lot Code					
Traceability Lot Code		Ingredient Unit of		Ingredient	Source Location	Ingredient Lot Code	Ingredient Supplier		Receiving	Reference
of ingredient	Ingredient Quantity	Measure	Date Received	Description	Description	Source	Location Description	Ingredient Supplier	Location Description	Document Type
A259ZA	120	50# cs	5/17/2024	Peanut Butter	1 Peanut Butter Way, Kansas City, MO	Really Good Peanut Butter Company	1 Peanut Butter Way, Kansas City, MO 66214	Really Good Peanut Butter Company	Peanut Butter Cookie Company 1 Peanut Butter Cookie Way, Kansas City, MO 66214	Trailer Check Shee
A259ZA	150	50# cs	5/18/2024	Peanut Butter	1 Peanut Butter Way, Kansas City, MO	Really Good Peanut Butter Company	1 Peanut Butter Way, Kansas City, MO 66214	Really Good Peanut Butter Company	Company 1 Peanut Butter Cookie Way, Kansas City, MO 66214	Trailer Check Shee
A259ZA	145	50# cs	5/19/2024	Peanut Butter	1 Peanut Butter Way, Kansas City, MO	Really Good Peanut Butter Company	1 Peanut Butter Way, Kansas City, MO 66214	Really Good Peanut Butter Company	Company 1 Peanut Butter Cookie Way, Kansas City, MO 66214	Trailer Check Shee

Required records for transforming



For the food on the Food Traceability List used in transformation (if applicable), the following information:

- ✓ The traceability lot code for the food
- ✓ The product description for the food to which the traceability lot code applies

						Ingredient Lot
				Ingredient		Code Source
Date of	Ingredient	Ingredient	Ingredient Unit of	Traceability Lot	Ingredient Lot	Location
Transform	Description	Quantity Used	Measure	Code	Code Source	Description

✓ For each traceability lot used, the quantity and unit of measure of the food used from that lot

Required records for transforming



For the food produced through transformation, the following information:

- ✓ The new traceability lot code for the food
- ✓ The location description for where you transformed the food

Transforming				Product Lot Code		Reference
Location	Product	Product Quantity	Product	Assigned by	Reference	Document
Description	Description	Made	Unit of Measure	company	Document Type	Number

- ✓ The date transformation was complete
- ✓ The product description for the food
- ✓ The quantity and unit of measure of the
- ✓ The reference document type and reference document number

Required records for shipping



- ✓ The traceability lot code for the food
- ✓ The quantity and unit of measure of the food
- ✓ The product description for the food
- ✓ The location description for the immediate subsequent recipient of the food

- ✓ The location description for the location from which the food shipped
- ✓ The date you shipped the food
- ✓ The location description for the traceability lot code source, or the traceability lot code source reference
- ✓ The reference document type and reference document number

General requirements

Records

- You must keep original paper or electronic records
- All records must be legible
- Securely and safely stored to prevent damage or theft



General requirements

Record Availability

- All records required to be available to an authorized FDA representative, upon request, within 24 hours
- Offsite storage is permitted, as long as they can be retrieved in 24 hours
- 24 hours starts at phone request, not written
- Must provide in a sortable spreadsheet

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RECEIVING		ENHANCED TRACEABILITY REQUIREMTN FOR FTR								
					Ingredient Lot Code					
Traceability Lot Code		Ingredient Unit of		Ingredient	Source Location	Ingredient Lot Code	Ingredient Supplier		Receiving	Reference
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									Peanut Butter Cookie Company 1 Peanut Butter Cookie	
A259ZA	120	50# cs	5/17/2024	Peanut Butter	1 Peanut Butter Way, Kansas City, MO	Really Good Peanut Butter Company	1 Peanut Butter Way, Kansas City, MO 66214	Really Good Peanut Butter Company	Way, Kansas City, MO 66214	Trailer Check Sheet
A259ZA	150	50# cs	5/18/2024	Peanut Butter	1 Peanut Butter Way, Kansas City, MO	Really Good Peanut Butter Company	1 Peanut Butter Way, Kansas City, MO 66214	Really Good Peanut Butter Company	Company 1 Peanut Butter Cookie Way, Kansas City, MO 66214	Trailer Check Sheet
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A259ZA	145	50# cs	5/19/2024	Peanut Butter	Kansas City, MO	Company	Kansas City, MO 66214	Company	66214	Trailer Check Sheet

General requirements

Record retention

You must maintain records for 2 years from the date you created or obtained the records.

Use of existing records

- You do not need to duplicate existing records
- You may supplement any such existing records as necessary to include all of the information required by this subpart.

Paper data capture



- Is paper and clipboards even possible?
- Paper must be transferred into a searchable spreadsheet
- Originals must be organized, secured and stored for 2 years

Electronic data capture

- Multiple barcodes?
- Can you add new data to existing codes?
- Will you need one code for supplier data and another for your operations?
- Is the data secure?



Personnel considerations



- Are tasks assigned to a specific team?
- How will you train the front lines to complete tasks?
- How will you train the front lines why FTR is done?
 - Auditors will ask



External considerations and future plans

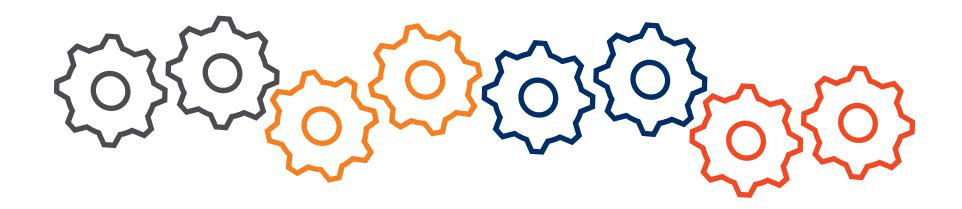


- What is the net impact mock recalls and audit readiness?
- How will you handle customer demands to use their tracking platform?
- How will you handle others passing their increased compliance on you?
- Should you apply traceability to all items?
- How long until more items are added to the Food Traceability List?



Most common





Interdepartmental with electronic data capture



What to expect





Digital Records

Will paper and excel tracking become too hard or even permitted?



24-Hour Turnarounds

Will all record request become a 24-hour turnaround?



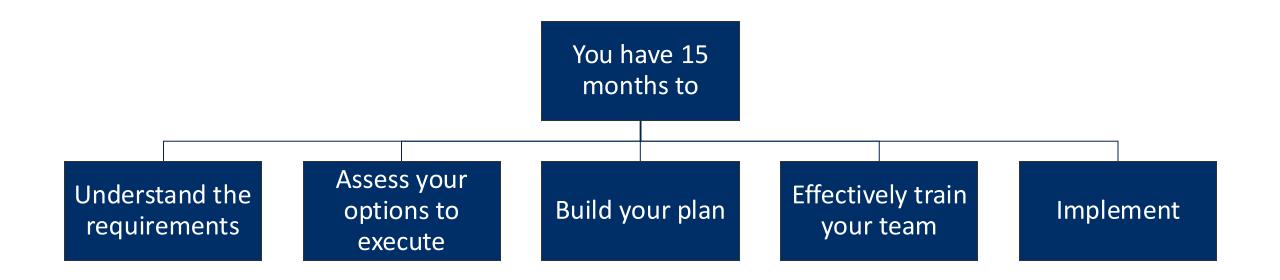
Other governing bodies

Will digital records and 24-hour turnarounds become the norm across all governing bodies?



FTR is coming...Are you ready?







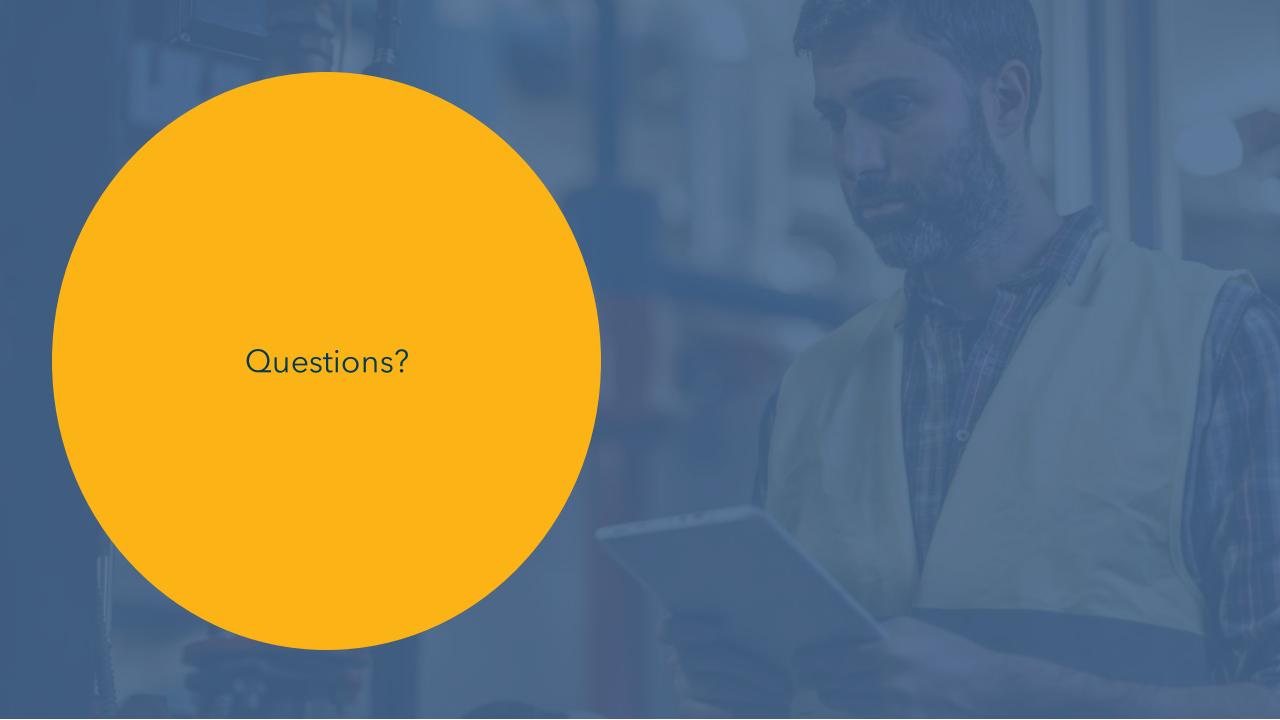
Employee Retention Food Traceability e-learning modules

How WorkForge Can Help

Custom training modules for your unique SOPS

Operational efficiency

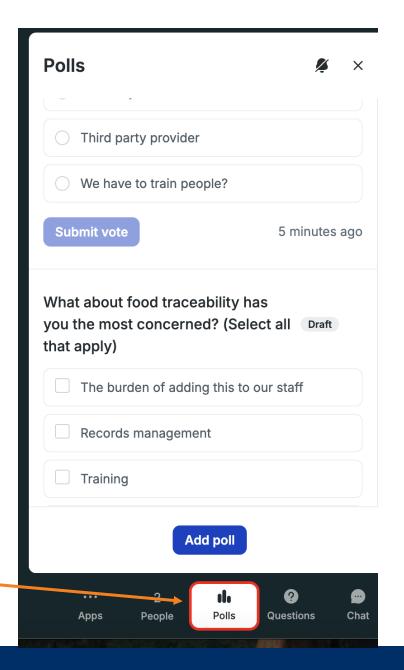
Digital training records



Poll Questions

- 1. What are your training plans for food traceability?
- 2. What about food traceability has you the most concerned? (Select all that apply)

Click the Polls icon on the right to answer the questions.



Resources and references



- 1. Food Traceability Rule
- 2. Subpart S
- 3. When to assign traceability lot codes