

Food Traceability Rule

Training for the Food Industry



Participant Manual

*First Edition – March 2026
(Version 1.0)*



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Public Version

FSPCA FOOD TRACEABILITY RULE TRAINING FOR THE FOOD INDUSTRY CURRICULUM

First Edition – March 2026

Version 1.0

U.S. Food and Drug Administration Recognition

This course was developed by the Food Safety Preventive Controls Alliance (FSPCA) in collaboration with the U.S. Food and Drug Administration (FDA). Successfully completing this core curriculum provides participants with an understanding of Food Traceability Rule requirements as well as approaches to developing and implementing food traceability practices.

Developed by



Copyright Notice

The Food Traceability Rule (FTR) Training for the Food Industry curriculum was developed by the Food Safety Preventive Controls Alliance (FSPCA).

The FSPCA is a broad-based public-private alliance of key industry, academia and government stakeholders.

It was established in late 2011 by grants from U.S. Food and Drug Administration (FDA) to Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH) (U01FD003801, U19FD005322, U01FD005661).

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FSPCA Participant Manual

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Disclaimer

The information provided by the Food Safety Preventive Controls Alliance (FSPCA) is for training purposes only. The FSPCA is not your attorney and cannot provide you with legal advice. The FSPCA curriculum is intended as a training tool to assist companies in complying with the FDA Food Safety Modernization Act (FSMA) Final Rule on Requirements for Additional Traceability Records for Certain Foods; however, following this curriculum does not ensure compliance with the law or FDA's regulations. For advice regarding the legal compliance with FSMA, please consult your legal counsel.

The information provided by the FSPCA will vary in applicability to each food manufacturer, processor, packer, or holder. It is not possible for the FSPCA training curriculum to address every situation. Companies should implement the practices and programs that will function best to produce safe foods based on the nature of their individual operations. FSPCA materials do not outline the only approach to developing and implementing Traceability Practices. Companies can follow any approach that satisfies the requirements of the applicable statutes and regulations related to FSMA. The information provided by FSPCA does not create binding obligations for the Food and Drug Administration or industry.

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Food Traceability Rule Training

The Food Safety Preventive Controls Alliance developed this training curriculum for segments of the food industry that must comply with the Food Traceability Rule. This curriculum provides participants with the knowledge on the Food Traceability Rule and approaches to developing and implementing food traceability practices. For the most current course information, please consult the FSPCA website (www.fspca.net).

This publication was developed by the Food Safety Preventive Controls Alliance (FSPCA) and was supported, in part, by a grant from the U.S. Food and Drug Administration (FDA) to the Illinois Institute of Technology's Institute for Food Safety and Health (IFSH). The views expressed herein do not necessarily reflect the views of these organizations.

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TABLE OF CONTENTS

FSPCA Food Traceability Rule Training Curriculum Recognition	i
FSPCA Food Traceability Rule Training Curriculum Disclaimer	ii
2026 FSPCA Executive Advisory Board (EAB)	iii
2026 FSPCA Management	iii
2026 FSPCA Food Traceability Rule Curriculum Development Team.....	iii
2026 FSPCA Food Traceability Rule Curriculum Review Team (FDA)	iii
Food Traceability Rule Training	iii
Course Description	vii
Target Audience	vii
Course Overview	vii
Purpose	vii
Course Goal	vii
Chapter Learning Objectives.....	viii
Course Completion Requirements	x
Participant Expectations.....	xii

Course Content

Preface: Overview of the FSPCA Food Traceability Rule Participant Course	0-1
Chapter 1: Introduction and Background	1-1
Chapter 2: Application of the Food Traceability Rule	2-1
Chapter 3: Critical Tracking Events and Key Data Elements.....	3-1
Chapter 4: Traceability Plan Requirements.....	4-1
Chapter 5: Recordkeeping Requirements	5-1
Chapter 6: Implementation of Food Traceability Programs and Procedures	6-1
Final Activity	F-1

Appendices

Appendix 1: 21 CFR Part 1 Subpart S Full Text.....	A1-1
Appendix 2: Other Regulations that Impact Traceability.....	A2-1
Appendix 3: Critical Tracking Events and Key Data Elements.....	A3-1
Appendix 4: Sample Farm Map	A4-1
Appendix 5: Procedures to Implement a Traceability Program.....	A5-1
Appendix 6: Barcodes and Their Role in Traceability	A6-1
Appendix 7: Common Food Industry Data Systems	A7-1
Appendix 8: Data Systems Questions	A8-1
Appendix 9: Supply Chain Scenarios.....	A9-1
Appendix 10: Glossary and Terminology	A10-1

Course Description

The FDA Final Rule on Requirements for Additional Traceability Records for Certain Foods, also known as the Food Traceability Rule (FTR), was the final rule promulgated under the Food Safety Modernization Act (FSMA). The FTR established additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). The FTL includes a broad variety of commodities and manufactured products. Industry compliance with the requirements in the FTR will allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths. This course was developed by the FSPCA for segments of the food industry that must comply with the FTR. This curriculum provides participants with knowledge on the FTR and approaches to developing and implementing food traceability practices.

Target Audience

The target audience for the FSPCA Food Traceability Rule Training for the Food Industry curriculum is firms that manufacture, process, pack, or hold FTL foods and must comply with the Food Traceability Rule, including domestic and foreign firms along the farm-to-table continuum for foods produced for U.S. consumption. This includes farms (produce, aquaculture, eggs), distribution, manufacturing, retail food establishments, and restaurants.

Individuals in academia, government, or service providers to the food industry, may also find this course useful.

Course Overview

The FSPCA Food Traceability Rule Training for the Food Industry participant course is a core, industry-oriented training that provides participants with the knowledge that is needed to understand and comply with the FTR. The participant course content is focused on providing the participant with an understanding of FTR record keeping requirements, how to recognize the requirements applicable to them based on the supply chain activities they perform, how traceability data is transmitted through the supply chain, and what is required in a Traceability Plan. The training also covers how companies may approach establishing food traceability programs and procedures, including supply chain and data considerations.

The FSPCA training materials include the training manual with slides, explanations of key terms and concepts, exercises, and reference materials.

Purpose

The training will address the regulatory requirements of the FDA Food Traceability Rule (FTR) and discuss considerations for implementing food traceability programs and procedures.

Course Goal

- Recognize the importance of, and need for, the Food Traceability Rule
- Describe what is required under the Food Traceability Rule

Food Traceability Rule – Training for the Food Industry

- Identify what actions need to be taken to be compliant with the Food Traceability Rule
- Demonstrate how to develop a Traceability Plan

Chapter Learning Objectives

Terminal Learning Objectives (TLOs)	Enabling Learning Objectives (ELOs)
Chapter 0: Preface: Overview of the FSPCA Food Traceability Rule Participant Course	
Upon completion of this chapter, participants will be able to describe FSPCA and FSPCA Food Traceability Rule curriculum.	Upon completion of this chapter, participants will specifically be able to: 1. Describe FSPCA. 2. Describe FSPCA Food Traceability Rule Curriculum. 3. Describe the course materials and format.
Chapter 1: Introduction and Background	
Upon completion of this chapter, participants will be able to articulate how the Food Traceability Rule addresses challenges in tracing food.	Upon completion of this chapter, participants will specifically be able to: 1. Recognize the importance of traceability to public health. 2. Distinguish between the application of traceability in outbreaks and recalls. 3. Describe the main components of the Food Traceability Rule. 4. Explain how the Food Traceability Rule addresses current challenges in tracing food.
Chapter 2: Application of the Food Traceability Rule	
Upon completion of this chapter, participants will be able to discuss the applicability of the Food Traceability Rule.	Upon completion of this chapter participants will specifically be able to: 1. Identify the foods on the Food Traceability List. 2. Indicate the importance of the Food Traceability List in complying with the rule. 3. Recognize steps of the food supply chain impacted by the Food Traceability Rule. 4. Point out if exemptions are applicable to your situation.

Chapter 3: Critical Tracking Events and Key Data Elements

Upon completion of this chapter, participants will be able to explain the significance of Critical Tracking Events (CTEs) and Key Data Elements (KDEs) in food traceability.

Upon completion of this chapter participants will specifically be able to:

1. Describe CTEs in the supply chain.
2. Recognize that KDEs are dependent on the CTE.
3. Compare KDEs that are shared with KDEs that are not shared.
4. Identify actions to take when exemptions to the FTR affect KDEs received.
5. Show how records at each CTE facilitate traceability.

Chapter 4: Traceability Plan Requirements

Upon completion of this chapter, participants will be able to identify the components of a written Traceability Plan.

Upon completion of this chapter participants will specifically be able to:

1. Describe the identification of foods handled on the FTL.
2. Describe the assignment of Traceability Lot Codes to food on the FTL.
3. Recognize the requirements of a farm map for each growing area for foods on the FTL.
4. Describe how Traceability Plans are updated.
5. Describe how required records are maintained.
6. Identify a point of contact for questions on the Traceability Plan and associated records.

Chapter 5: Recordkeeping Requirements

Upon completion of this chapter, participants will be able to explain the recordkeeping requirements of the rule.

Upon completion of this chapter participants will specifically be able to:

1. State how long records must be maintained.
2. Recognize that firms may use existing records to meet the requirements of the rule.
3. Examine ways to leverage existing traceability information.
4. Describe the situations in which FDA will request an electronic sortable spreadsheet.
5. Explain what elements are required on electronic sortable spreadsheets.
6. Explain the process to submit records to FDA.

Chapter 6: Implementation of Food Traceability Programs and Procedures

Upon completion of this chapter, participants will be able to implement food traceability programs and procedures to support compliance with the Food Traceability Rule (FTR).

Upon completion of this chapter participants will specifically be able to:

1. Formulate procedures to implement a traceability program.
2. Explore types of data systems used to manage traceability data.
3. Understand the value of interoperability and the role that data standards play in supporting it.
4. Describe how TLC information can be traced throughout the supply chain.

Appendices

Upon review of the appendices, participants will be able to recognize the resources available in the curriculum to assist in gaining knowledge on FTR and developing traceability practices.

Upon review of the appendices, participants will specifically gain knowledge of:

1. 21 CFR Part 1 Subpart S Full Text
2. Other Regulations that Impact Traceability
3. Critical Tracking Events and Key Data Elements
4. Sample Farm Maps
5. Procedures to Implement a Traceability Program
6. Barcodes and Their Role in Traceability
7. Common Food Industry Data Systems
8. Data Systems Questions
9. Supply Chain Scenarios
10. Glossary and Terminology

Course Completion Requirements

To successfully complete this course and receive a course certificate, each participant is required to:

- Be on time and attend the entire course.
- Participate in the class discussions and exercises.

Participant Expectations

- To successfully complete the course, each participant is expected to attend each session and participate in each group exercise.
- To assess participation, instructors will observe participants as they contribute to group discussions. Participation is evidenced by asking questions, offering opinions, and/or debating opinions and answers, and specific criteria contained in each activity's rubric.
- Proficiency (demonstration of knowledge, skill, or abilities) for each activity will be assessed by the instructors. Constructive feedback will be provided by both the instructors and the other participants.

Notes:

Lined area for notes.

Preface: Overview of the FSPCA Food Traceability Rule Participant Course

Slide 1: Preface: Overview of the FSPCA Food Traceability Rule Participant Course



Preface

OVERVIEW OF THE FSPCA FOOD TRACEABILITY RULE PARTICIPANT COURSE



Slide 2: Food Safety Preventive Controls Alliance (FSPCA) (1 of 2)



The Food Safety Preventive Controls Alliance (FSPCA) was established in 2011 as part of a federal grant from FDA to the Institute for Food Safety and Health at the Illinois Institute of Technology. The purpose of this broad-based alliance is to develop and maintain a cost-effective education and training program to assist the food industry with understanding the Preventive Controls regulation requirements applicable to their facilities.

FSPCA is a public-private alliance with representation from industry, academia, and government, and is based on collaboration among federal and state regulatory officials, academic food safety researchers and educators, and food industry.

Slide 3: Food Safety Preventive Controls Alliance (FSPCA) (2 of 2)

Food Safety Preventive Controls Alliance (FSPCA)



Vision: Be an internationally recognized trusted source for training programs and outreach for the prevention-oriented standards of the Food Safety Modernization Act (FSMA).



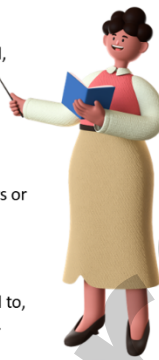
Mission: Assist the human and animal food industry and related entities in building food safety capacity through education, training, and outreach with an emphasis on small- and medium-sized businesses.



FSPCA's Vision is to be an internationally recognized trusted source for training programs and outreach for the prevention-oriented standards of the Food Safety Modernization Act (FSMA).

FSPCA's Mission is to assist the human and animal food industry and related entities in building food safety capacity through education, training, and outreach with an emphasis on small- and medium-sized businesses.

Slide 4: FSPCA Lead Instructor Disclosure



FSPCA Lead Instructor Disclosure

Although I attended the FSPCA Lead Instructor training:

- a) Lead Instructors are not certified, licensed, accredited, qualified, registered, sanctioned, authorized, recognized, endorsed, or approved by the FSPCA;
- b) I do not represent, speak for, or act on behalf of the FSPCA;
- c) The FSPCA cannot provide legal advice;
- d) The FSPCA does not guarantee the accuracy, adequacy, completeness or availability of any information provided and is not responsible for any errors or omissions or for any results obtained from the use of such information;
- e) Following the FSPCA curriculum does not ensure compliance with FDA's regulations or any other law or legal requirement; and
- f) The FSPCA gives no express or implied warranties, including but not limited to, any warranties of merchantability or fitness for a particular purpose or use.

Slide 5: FSPCA Food Traceability Curriculum



FSPCA Food Traceability Rule Curriculum

The FSPCA **Food Traceability Rule; Training for the Food Industry** course is a core curriculum recognized by FDA.

This curriculum serves to provide education and training to assist the food industry in understanding the requirements of FDA's regulation – Requirements for Additional Traceability Records for Certain Foods (21 CFR Part 1 Subpart S).

This course, developed by FSPCA, is a training curriculum that will provide participants with an understanding of the requirements of the Food Traceability Rule (FTR) and how to implement its provisions.

The Food Traceability Rule does not require you to attend a training program following a "standardized curriculum" recognized by FDA. Therefore, completing this course is **NOT** mandatory. Attending this course, however, will help you understand the Food Traceability Rule requirements and how those requirements can be met in your particular circumstance.

Slide 6: FSPCA Food Traceability Rule Course Audience

FSPCA Food Traceability Rule Course Audience

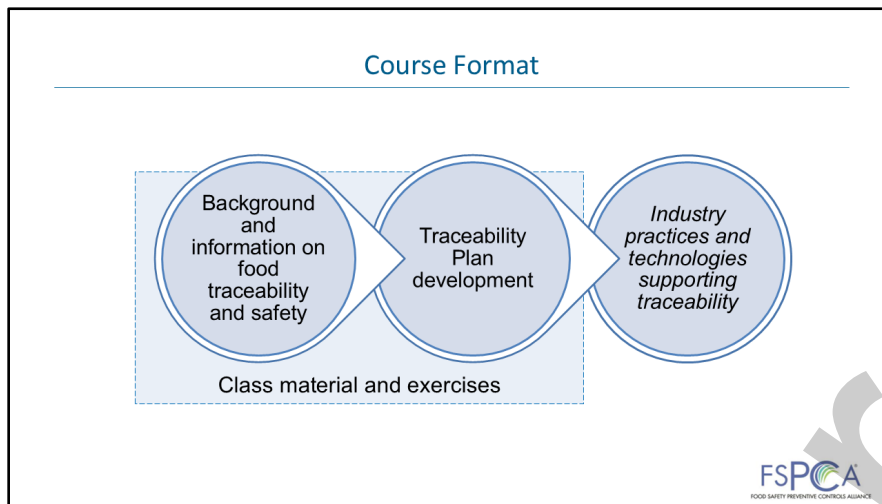


The audience for FSPCA's Food Traceability Rule Course consists of **all** domestic and foreign entities that manufacture, process, pack, and hold foods that are covered by the Food Traceability Rule.



The audience for FSPCA's Food Traceability Rule course consists of **all** domestic (including Retail Food Establishments and restaurants) and foreign entities that manufacture, process, pack, and hold foods that are covered by the Food Traceability Rule. This includes supply chain professionals, and anyone else involved in the industry for foods covered by the rule.

Slide 7: Course Format

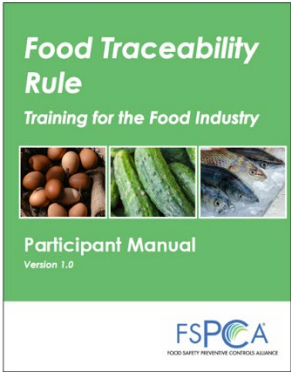


The FSPCA Food Traceability Rule Course is divided into 3 parts:

1. The first part provides background information on food traceability and safety, articulates how the Food Traceability Rule (FTR) addresses challenges in tracing food, applicability of the FTR, and recognizes the significance of Critical Tracking Events (CTEs) and Key Data Elements (KDEs) in food traceability. This is found in Chapters 1, 2, and 3.
 2. The second part, Chapters 4 and 5, focuses on Traceability Plan development and recordkeeping requirements.
 3. The third part addresses implementation of food traceability programs and procedures and provides examples of technologies and industry practices supporting food traceability. This is found in Chapter 6.
-

Slide 8: Course Materials

Course Materials



- Agenda
- FSPCA Food Traceability Rule Participant Manual
 - Chapters 1 through 6
 - Appendices 1 through 10

The course participant manual includes six chapters with presentation slides, supporting text, explanations of key terms and concepts, credible references, and appendices.

Become familiar with the participant manual and use it as a reference. The participant manual contains forms and activities that can help participants develop a knowledge base of food traceability, its importance and impact on business, and how to develop a Traceability Plan.

Slide 9: Course Chapters

Course Chapters	
Chapter #	Title
1	Introduction and Background
2	Application of the Food Traceability Rule
3	Critical Tracking Events and Key Data Elements
4	Traceability Plan Requirements
5	Recordkeeping Requirements
6	Implementation of Food Traceability Programs and Procedures



There are six chapters in this course to go through the Food Traceability Rule and implementation of food traceability programs and procedures:

1. Introduction and Background
2. Application of the Food Traceability Rule
3. Critical Tracking Events and Key Data Elements
4. Traceability Plan Requirements
5. Recordkeeping Requirements
6. Implementation of Food Traceability Programs and Procedures

Slide 10: Appendices

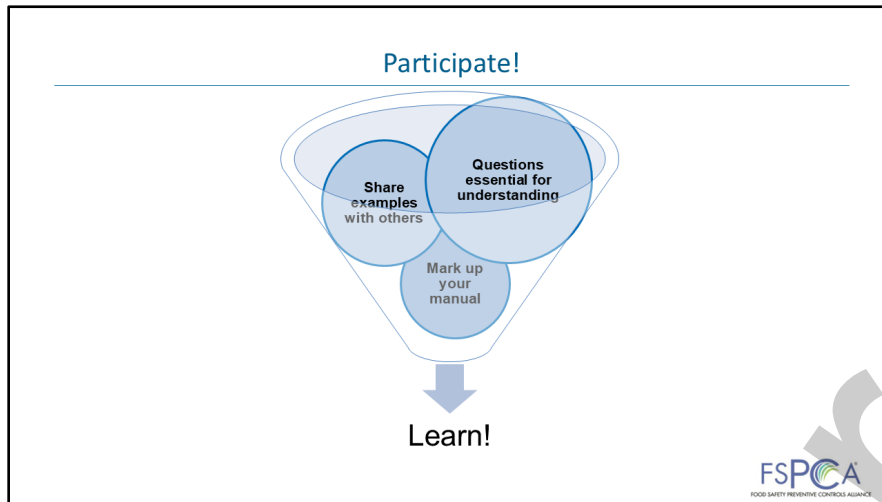
Appendices	
Appendix	Title
1	21 CFR Part 1 Subpart S Full Text
2	Other Regulations that Impact Traceability
3	Critical Tracking Events and Key Data Elements
4	Farm Map Examples
5	Procedures to Implement a Traceability Program
6	Barcodes and Their Role in Traceability
7	Common Food Industry Data Systems
8	Data Systems Questions
9	Supply Chain Scenarios
10	Glossary and Terminology



There are ten appendices in the participant manual that will be used throughout the course. These provide additional context for the subject matter for your own research or for activities here in class.

1. 21 CFR Part 1 Subpart S Full Text
2. Other Regulations that Impact Traceability
3. Critical Tracking Events and Key Data Elements
4. Farm Map Examples
5. Procedures to Implement a Traceability Program
6. Barcodes and their Role in Traceability
7. Common Food Industry Data Systems
8. Data Systems Questions
9. Supply Chain Scenarios
10. Glossary and Terminology

Slide 11: Participate!



Traceability principles and protocols can be integrated into your organization's food supply chain; however, this can seem daunting until the basic concepts are understood.

Asking questions and contributing first-hand experiences during course discussions can help everyone better understand and apply the concepts. This course includes class engagement and exercises. The more the course participants contribute to these exercises, the easier it will be for them to develop and implement an effective Traceability Plan.

Slide 12: FSPCA Contact Information

FSPCA Contact Information

If you have any questions, please contact
FSPCA at fspca@illinoistech.edu

or visit the [FSPCA website](https://www.fspca.net) where you can find resources
on food traceability and information on FSPCA
activities.

<https://www.fspca.net/>



FSPCA Website

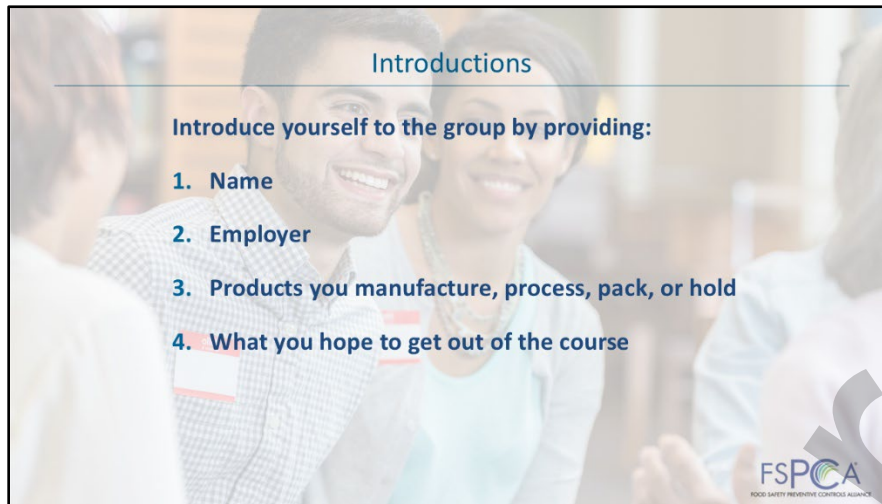


The QR Code provided will access the FSPCA Website.

The following are the URLs of some general websites for your reference:

- FDA Food Traceability Rule Website: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods>
- FDA Draft Question and Answer Guidance for Food Traceability Rule: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/questions-and-answers-about-requirements-additional-traceability-records-certain-foods>
- FDA FSMA Technical Assistance Network (TAN): <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>
- FSPCA Website: <https://www.fspca.net/>
- FSPCA Technical Assistance Network (TAN): <https://www.fspca.net/fspca-technical-assistance-network>

Slide 13: Introductions

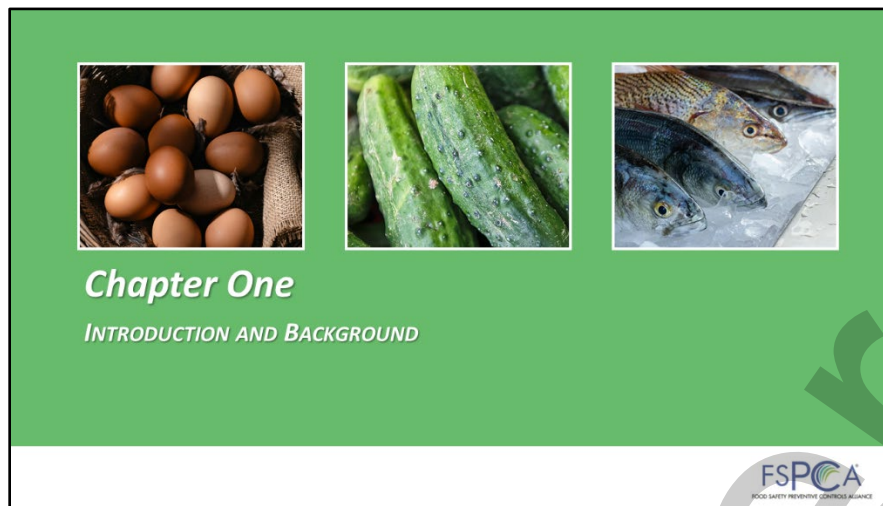


Introduce yourself to the group by providing:

1. Name
 2. Employer
 3. What food products you manufacture, process, pack, or hold
 4. What you hope to get out of the course
-

Chapter 1: Introduction and Background

Slide 1: Chapter One



Slide 2: Goals and Learning Objectives

Chapter 1: Introduction and Background

Goal: Articulate how the Food Traceability Rule addresses challenges in tracing food.

Learning Objectives:

By the end of this chapter, participants will be able to:

- Recognize the importance of traceability to public health.
- Distinguish between the application of traceability in outbreaks and recalls.
- Describe main components of the Food Traceability Rule.
- Explain how the Food Traceability Rule addresses current challenges in tracing food.

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Chapter One introduces the basic concepts, including the meaning and usefulness of traceability and traceability challenges in the food industry. It also addresses outbreaks and recalls to provide the context in which traceability becomes critical.

Chapter 1

Goal: Articulate how the Food Traceability Rule addresses challenges in tracing food.

Learning Objectives:

By the end of this chapter, participants will be able to:

- Recognize the importance of traceability to public health.
 - Distinguish between the application of traceability in outbreaks and recalls.
 - Describe the main components of the Food Traceability Rule.
 - Explain how the Food Traceability Rule addresses current challenges in tracing food.
-

Slide 3: Section One



Slide 4: What Is Food Traceability?

What is Food Traceability?

- Tracking the movement of food products through various stages of production, processing, and distribution within the supply chain
- Documenting and recording key information about a food product at specific points along the supply chain
- Tracing the journey of a food item from its source to the consumer OR from the consumer back to its source



Stakeholders: Parties that have an interest in the food supply chain, such as producers, processors, distributors, retailers, and consumers.

Supply Chain: The interconnected system of individuals, organizations, resources, activities and technologies involved in the manufacture and sale of a food product from supplier to consumer.

Let's begin by defining the big, important word for this course. In the context of food, what is traceability?

- Food traceability is the process of tracking the movement of food products through various stages of production, processing, and distribution within the supply chain.
- It involves documenting and recording key information about a food product at specific points along the supply chain.
- This information enables stakeholders to quickly trace the journey of a food item from its source to the consumer OR from consumer back to its source, even if the food is no longer available.

Better traceability data allows for a more efficient food tracing process.

Slide 5: Food Traceability Prevents Foodborne Illnesses

Food Traceability Prevents Foodborne Illnesses

Traceability

- Enables rapid response to food safety incidents
- Facilitates identification of potentially contaminated food
- Tracks source of contamination back to its origin
- Allows for prompt removal of unsafe products from the marketplace



Food safety incidents are safety issues with food or drink and can be caused by biological or chemical contamination or physical hazards (examples: outbreaks, contaminated food, improper handling, or hygiene).

How does traceability prevent foodborne illnesses?

- Traceability information allows for a swift response to food safety incidents, minimizing the duration and scope of potential health risks.
- Traceability enables rapid identification and containment of potentially contaminated food products, reducing the spread of contamination.
- By tracing the suspected product back to its origin, authorities and food companies can implement targeted interventions to prevent further contamination and protect public health.
- Effective traceability processes enable the timely removal of potentially unsafe products from the market to prevent additional consumer exposure.

It is important to note that we can't control how fast people go to the doctor and get tested for an illness, but we can control how fast we respond after a food exposure has been determined.

Slide 6: Other Benefits of Food Traceability

The Importance of Food Traceability

Other Benefits of Enhanced Traceability

- Enhances inventory management and supply chain transparency
- Provides the ability to track food, which may also help industry reduce food fraud
- Helps reduce food waste and promotes food sustainability
- Facilitates improved operational efficiencies
- Generates timely and accurate data
- Improves decision making



What other benefits might we see from enhanced traceability?

Note: The “other benefits” are beyond the scope of the rule but apply to business operations or consumer confidence.

- Enhances inventory management and supply chain transparency.
- Provides the ability to track food, which may also help industry reduce food fraud.
- Helps reduce food waste and promotes food sustainability.
- Facilitates improved operational efficiencies.
- Generates timely and accurate data.
- Improves decision making.

How does traceability build consumer confidence?

- Transparent traceability processes build consumer trust by providing assurance regarding the safety and quality of food products.

Slide 7: Notable Foodborne Outbreaks

Notable Foodborne Outbreaks



An outbreak involving peanut butter (2009)



An outbreak involving frozen tuna (2012)



An outbreak involving romaine lettuce (fall 2018)

- ❓ What was the impact on food safety and confidence in the US food system?
- ❓ How could this have been prevented?
- ❓ What role does traceability, as well as you understand it, play in these stories?


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Outbreaks: Instances where two or more people get the same illness from the same source (for example, contaminated food or drink).

Recalls: Actions taken to remove a food product from the market because it is adulterated or misbranded.

Three significant U.S.-based food safety scenarios affected public health and highlighted issues with food safety. Story one helped shape FSMA; stories two and three reinforce the need for better traceability.

Story One: Peanut Butter Products

In 2009, a peanut butter outbreak was caused by *Salmonella* contamination in peanut butter and products. The outbreak led to the largest food recall in U.S. history at the time, with over 3,900 different peanut-containing products from 200 companies impacted.

The outbreak affected 46 U.S. states and resulted in 714 illnesses and 9 deaths.

Story Two: Frozen Tuna

In 2012, a *Salmonella* outbreak occurred caused by imported frozen tuna. The investigation experienced delays due to discrepant information in the supply chain, such as incorrect country of origin, changes in product description, and lack of product labeling.

The outbreak affected 28 U.S. states and resulted in over 420 illnesses.

Story Three: Romaine Lettuce

In the fall of 2018, a romaine lettuce outbreak was caused by Shiga toxin-producing *Escherichia coli* (STEC) O157:H7. The investigation experienced delays in identifying the farm source, limited product-identifying information throughout the supply chain, and a lack of communication between recordkeeping systems. The best FDA could do was ask the public not to consume romaine lettuce generally to keep them safe.

The outbreak affected 16 U.S. states and 4 Canadian provinces and resulted in over 90 illnesses.

How might these stories have gone differently if they had good traceability?

These outbreaks could have been contained faster (meaning the potentially contaminated food could have been removed from the market more quickly) and affected fewer people if effective traceability had been implemented in each of the involved supply chains.

Slide 8: Traceback Challenges

Traceback Challenges



Traceback investigations can feel like finding a **needle in a haystack**. The FTR addresses several significant challenges in tracing food within the supply chain.

? What examples of traceability challenges can you cite from your own experience?

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The FDA has sometimes been unable to confirm links between illnesses and specific product distribution due to inconsistent, unstandardized recordkeeping, inability to connect records from different points in the supply chain, and lot codes not being consistently carried through the supply chain. The FTR addresses several significant challenges in tracing food within the supply chain, aiming to enhance food safety and improve capabilities for responding to foodborne illness outbreaks.

Slide 9: Common Challenges

Common Challenges



- Unavailability of Records
- Unavailability of Data across the Supply Chain
- Absence of Recordkeeping Practices
- Nonstandard Recordkeeping Practices
- Lack of Knowledge or skills
- Lack of food safety culture

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Traceability challenges can also be overcome with the right procedures and processes. The FTR addresses this with specific requirements for foods on the FTL; other tools that go beyond the scope of the FTR are discussed in Chapter 6.

Current challenges in tracing food:

- Unavailability of records
- Unavailability of data across the supply chain
- Absence of recordkeeping practices
- Nonstandard recordkeeping practices
- Lack of knowledge or skills
- Lack of food safety culture

Slide 10: Section Two

Section 2

OUTBREAKS AND RECALLS



Slide 11: An Outbreak Story

An Outbreak Story

This is a true story, but the names of the organizations have been changed.

Listen to the story and be prepared to discuss any part of it you found noteworthy, or any questions that arise from hearing this story.



Listen to the story and think about any situations like this you have experienced in your industry, and how it went differently. Be prepared to answer any questions the instructor asks.

Follow along with this story:

A *Salmonella* Enteritidis outbreak linked to shell eggs was identified after ill people reported eating restaurant dishes made with shell eggs.

The FDA worked with federal, state, and local officials in conducting a traceback investigation. The restaurants kept traceability data about their suppliers, enabling FDA to identify Cool Chicks Egg Farms in Alabama as a source of the outbreak.

The FDA and the Alabama Department of Agriculture and Industries began an inspection at Cool Chicks Egg Farms and collected environmental samples from poultry houses for laboratory testing. Results confirmed that *Salmonella* Enteritidis isolates collected from the farm's environment were genetically related to isolates obtained from ill people.

As a result of the investigation, Cool Chicks Egg Farms recalled cage-free, large eggs and removed the eggs from grocery stores, restaurants, and other retail locations. The company cooperated with the FDA and ceased distribution of the eggs while they worked to investigate the cause of the problem.

Once we begin to discuss the requirements of the FTR, we will see how they will provide essential and timely data to allow us to more rapidly remove potentially contaminated products from the market and protect public health.

Slide 12: Distinctions between Outbreaks and Recalls

Distinctions between Outbreaks and Recalls		
Outbreaks		Recalls
Identify contamination source Prevent further spread of illness	Focus	Remove potentially contaminated products from commerce
Investigate and contain a specific incident of foodborne illness	Scope	Product safety Consumer protection
May not result in product actions	Results	Specifically related to product actions

Note that mock recalls are not the same as a traceback investigation.

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A **foodborne illness outbreak** is when two or more people get sick from eating or drinking the same contaminated food or drink. The FDA investigates outbreaks to prevent more people from getting sick and to learn how to prevent future outbreaks.

A **recall** is a procedure for removing or correcting a product that violates FDA regulations. Recalls can be voluntary or mandated by the FDA. A recall does not include market withdrawal or stock recovery. (See 21 CFR 7.3(g))

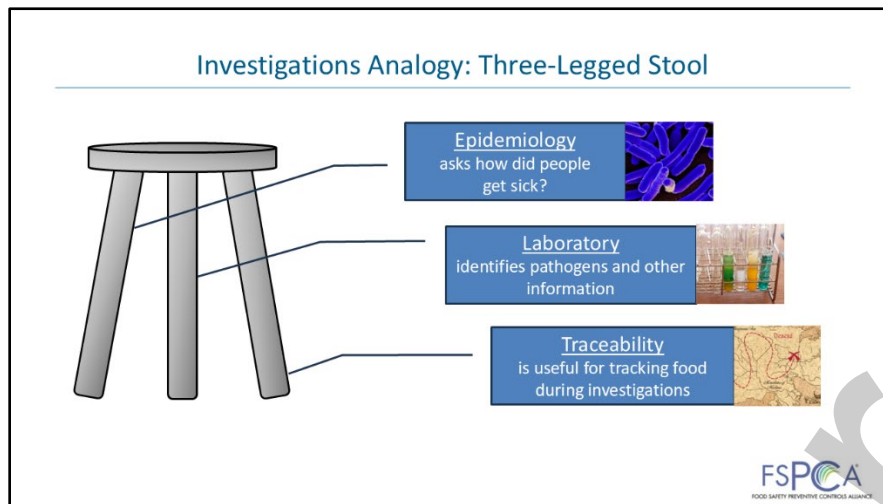
Outbreaks and recalls are not mutually exclusive and could be concurrent (meaning that a recall could be the result of an outbreak), or they could be separate situations. A food may be recalled because of something as simple as a labeling issue.

Distinctions between Outbreaks and Recalls:

- In outbreaks, traceability focuses on identifying the source of contamination and preventing further spread of illness; while in recalls, it focuses on removing potentially unsafe products from commerce.
- Outbreaks involve investigating and containing a specific incident of foodborne illness, while recalls can address broader issues of product safety and consumer protection; sometimes recalls are a result of outbreaks.
- In non-outbreak-related recalls, a recall may be initiated voluntarily by the food company or at the request of a regulatory agency; often there are no associated human illnesses.
- Not all outbreak investigations will necessarily result in product actions for a variety of reasons (e.g., because the growing season is over, no common/specific food was identified, etc.). In order to protect public health, the FDA can disseminate advisories based on available information including a product in an outbreak or a recall even if a source of contamination may not have been fully identified.

Notes:

Slide 13: Investigation Analogy: The Three-Legged Stool



Note that the Three-Legged Stool and outbreak example below follow typical processes in U.S. investigations.

Imagine that you are a local public health official investigating complaints of foodborne illness associated with three local restaurants. Most of the ill people seemed to consume the same food. How can you, as an investigator, find out exactly where it came from?

Traceability is part of a wider set of tools useful in helping FDA staff identify a potential source or point of contamination.

FDA uses the **three-legged stool** analogy to describe the outbreak investigation process. The first two legs are **epidemiology, and laboratory**.

An investigation begins with epidemiology, which is the responsibility of state and local health departments and the Centers for Disease Control and Prevention (CDC). Epidemiologists ask: Where did people get ill? How many people were affected? What did they consume? When did they consume it?

Laboratory testing may occur at retail or at other points in the supply chain where product or environmental samples are collected. If the FDA lacks clarity as to which products to trace, laboratory results can shed light on this.

The third leg of the stool is **traceability**. FDA or state regulatory staff begin the traceback investigation, asking where foods were purchased, what the distribution patterns look like for those foods, and compare the information to determine a point of commonality.

Any or all of these steps may happen simultaneously.

Slide 14: Section Three

Section 3

**THE MAIN COMPONENTS OF THE
FOOD TRACEABILITY RULE**



Slide 15: The Food Traceability Rule

The Food Traceability Rule

- The purpose of the rule is to identify the **information** required by FDA at different points along the supply chain for effective and efficient tracing of food.
- The rule also helps standardize traceability **terminology** across the food industry.



Food Safety Modernization Act (FSMA): A United States federal law that aims to ensure the U.S. food supply is safe by shifting the focus from responding to foodborne illness to preventing it. The Food Traceability Rule is one of the regulations required by FSMA.

The purpose of the rule is to identify the information required by FDA at different points along the supply chain to assist with effective and efficient tracing of food.

Through **FSMA**, Congress gave the FDA a specific mandate to create the Food Traceability Rule (FTR). The FTR, which was finalized in 2022, establishes requirements for certain foods, focusing on additional traceability data collection across the food supply chain. The official name of this rule is "Requirements for Additional Traceability Records for Certain Foods" and can be found in 21 CFR Part 1 Subpart S.

The rule also helps standardize traceability terminology across the food industry.

Slide 16: Main Components of the Food Traceability Rule

Main Components of the Food Traceability Rule

The Food Traceability Rule is located in 21 CFR Part 1 Subpart S. It is made up of the codified rule, which is the regulation and requirements, and the preamble, which provides additional context and information about the provisions of the rule.

The main components of the Rule are:

- Food Traceability List (FTL)
- Critical Tracking Events (CTEs)
- Key Data Elements (KDEs)
- Traceability Lot Codes (TLCs)
- Traceability Plan
- Record maintenance requirements
- Records requests
- Electronic sortable spreadsheet



Note: This is a generalized list of requirements because we will go into detail later. The purpose of this slide is to provide a simple overview of the requirements of the rule at this early stage of the course.

The Food Traceability Rule is made up of the codified rule, which is the regulation and requirements, and the preamble, which provides additional context and information about the provisions of the rule.

The main components of the Rule are:

- Food Traceability List (FTL)
- Critical Tracking Events (CTEs)
- Key Data Elements (KDEs)
- Traceability Lot Codes (TLCs)
- Traceability Plan
- Record maintenance requirements
- Records requests
- Electronic sortable spreadsheet

Traceability is a concept touched on by other regulations as well. For additional reading, see Appendix 2: Other Regulations that Impact Traceability.

Slide 17: How the Food Traceability Rule Addresses Traceback Challenges

How the Food Traceability Rule Addresses Traceback Challenges



The FTR allows for faster product identification and removal during threats to public health by:

- Establishing a framework of CTEs and associated KDEs
- Standardizing traceability information
- Linking information by lot code
- Requiring that records be provided to FDA within 24 hours

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Compliance: adherence to the requirements set forth in a regulation (for example, the Food Traceability Rule).

The FTR addresses common traceback challenges.

Industry compliance with the FTR will allow FDA to more **quickly** identify products of concern within the supply chain during food safety incidents. This will result in rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and deaths.

This is achieved through the following:

- Establishing a framework of CTEs and KDEs, which standardizes the information that the food industry maintains, and in some cases, shares across the supply chain.
- Requiring traceability lot codes to be kept and shared along the supply chain, which is critical to track the movement of food by lot code. This can help enable FDA to avoid issuing overly-broad recalls as has sometimes been done in the past, which can help limit the adverse impacts on industry sectors affected by these outbreaks.
- Requiring FTR records be provided to FDA within 24 hours of a request (or within some reasonable time to which FDA has agreed).
- Identifying the traceability lot code source early on in an investigation, which would allow FDA to potentially 'skip' steps in a supply chain investigation, also increasing the speed of a traceback investigation.

Slide 18: Summary

Chapter 1: Summary

- Traceability, and the Food Traceability Rule, matter during outbreaks and recalls
- Food traceability assists in efforts to:
 - Respond to food safety incidents to protect public health
 - Increase consumer confidence
- Multiple challenges with food safety investigations are addressed through the FTR



Slide 19: Questions

**Thank you for your
participation!**

What questions
do you have?



Chapter 1

Notes:

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Chapter 2: Application of the Food Traceability Rule

Slide 1: Chapter Two



Slide 2: Goals and Learning Objectives

Chapter 2: Goal and Objectives

Goal: Discuss the applicability of the Food Traceability Rule.

Learning Objectives:

- Identify the foods on the Food Traceability List.
- Indicate the importance of the Food Traceability List in complying with the rule.
- Recognize steps of the food supply chain impacted by the Food Traceability Rule.
- Point out if exemptions are applicable to your situation.

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Chapter Two examines the information that will need to be reviewed to determine whether the FTR is applicable to your situation. Specifically, Chapter Two addresses how the participants will understand, interpret, and analyze the Food Traceability List to determine if a food is covered by the rule. Chapter Two also presents exemptions from the requirements of the rule.

Chapter 2

Goal: Discuss the applicability of the Food Traceability Rule.

Learning Objectives:

- Identify the foods on the Food Traceability List.
 - Indicate the importance of the Food Traceability List in complying with the rule.
 - Recognize steps of the food supply chain impacted by the Food Traceability Rule.
 - Point out if exemptions are applicable to your situation.
-

Slide 3: Section One



Slide 4: The Food Traceability List (FTL)

The Food Traceability List (FTL)

• Cheeses (other than hard) • Shell eggs • Nut butters • Cucumbers (fresh) • Herbs (fresh) • Leafy greens (fresh) • Leafy greens (fresh-cut) • Melons (fresh) • Peppers (fresh) • Sprouts (fresh) • Tomatoes (fresh) • Tropical tree fruits (fresh)	• Fruits (fresh-cut) • Vegetables (fresh-cut) • Ready-to-eat deli salads (refrigerated) The following are on the FTL if they are fresh, frozen, or previously frozen: • Finfish • Smoked finfish • Crustaceans • Molluscan shellfish, bivalves
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A simplified version of the Food Traceability List (FTL) is shown on this slide. Note that for many foods the form of the food is also listed (e.g. fresh, frozen, previously frozen). The FTL includes both foods specifically listed and foods that contain any of those specifically listed foods as ingredients, provided that an FTL food used as an ingredient is in the same form as it appears on the list.

The FTR applies to entities which manufacture, process, pack, or hold foods on the FTL. It does not cover all foods; only those specific foods on the list.

The FTL is not static. It is updated approximately every five years through a public process. Foods might be added to, or removed from, the list. If a food is removed from the FTL, the removal would be effective immediately; if a food is added to the FTL, there is a 2-year period before that new food is subject to the additional recordkeeping requirements.

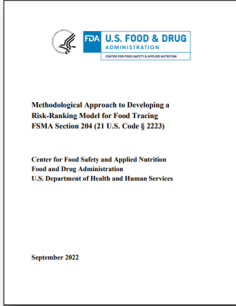
Slide 5: The Risk-Ranking Model for Food Traceability

 **The Risk-Ranking Model for Food Traceability**

FDA developed the Risk-Ranking Model to assess commodity/hazard pairs for:

- Frequency of outbreaks and occurrences of illnesses
- Severity of illness
- Likelihood of contamination
- The potential for pathogen growth, with consideration of shelf life
- Manufacturing process contamination probability and industry-wide intervention
- Consumption rate and amount consumed
- Cost of illness

<https://hfpappexternal.fda.gov/scripts/FDARiskRankingModel/foodTracingfinalrule/>



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To develop the FTL, FDA assessed over 200 food commodities using its Risk-Ranking Model for Food Tracing (RRM-FT) that was created based on criteria outlined by Congress in FSMA Section 204(d)(2). The resulting list are those foods that “present an immediate public health risk and for which traceability recordkeeping would be necessary to rapidly identify the source of contamination and prevent additional illnesses.”

Per FDA: “The Model is designed to be flexible and to consider a wide range of known and reasonably foreseeable contaminants in FDA-regulated human foods. It evaluates and ranks a comprehensive list of commodity-hazard pairs and the associated commodities to inform the Food Traceability List.”

Slide 6: Food Traceability List Descriptions



Food Traceability List	Description
Cheeses, other than hard cheeses, specifically:	
Cheese (made from pasteurized milk), fresh soft or soft unripened	Includes soft unripened/fresh soft cheeses. Examples include, but are not limited to, cottage, chevre, cream cheese, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna. Does not include cheeses that are frozen or previously frozen, shelf stable at ambient temperature, or aseptically processed and packaged.



The full FTL is available on FDA's website and contains additional details about each food that is included on the FTL. These additional details will help identify foods that are on the FTL, as well as those that are not. Reviewing the descriptions in detail may help address questions that you have about whether your foods are covered by the FTR.

Cheese is an example of a food where it is important to review the description in the FTL. All cheeses are covered except hard cheeses (hard cheese is defined in a footnote on the FDA's FTL webpage). Some examples are given of types of cheeses that are included in this category. However, as noted in the descriptive language, cheeses that are frozen or previously frozen, shelf stable at ambient temperature, or aseptically processed and packaged are not included on the FTL.

Slide 7: Your FTL Foods



Your FTL Foods

- Individual activity
- Review the FTL
- Note foods you work with and what details you can find on the FTL
- Be prepared to share your thoughts with the class





The FTR applies to entities which manufacture, process, pack, or hold foods on the FTL. It does not cover all foods; only those specific foods on the list.

Table 2-1: Think of three foods your organization works with (if you don't work for/with a food company, choose your favorite foods). Identify whether these foods are on the FTL.

Your Food	Is it on the FTL? Yes/No

Notes:

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Slide 8: Complexities to Be Aware of

Complexities to be Aware of

-  What form of the food is covered by the FTR?
-  Is the FTL food used as an ingredient of another food?
-  Has this food been changed to a food not on the FTL?

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Note: Foods regulated solely by USDA's Food Safety and Inspection Service (FSIS) are not covered by the rule.

For the FTR, a 'kill step' means lethality processing that significantly minimizes pathogens in a food.

There are some points of complexity to be aware of when you are determining whether a food is covered by the FTR.

1. The form of the food

For most foods, the form is specified in the FTL. These include fresh, fresh-cut, refrigerated, frozen, and previously frozen. Only the form(s) listed on the FTL is/are covered by the FTR; other forms are not. Where the form is not specified on the FTL, all forms are covered (e.g., nut butters).

Example of specified forms on the FTL:

- Fresh melons, fresh herbs.
- Fresh-cut fruits, fresh-cut leafy greens.
- Fresh (or refrigerated for smoked finfish), frozen, and previously frozen finfish.
- Refrigerated, ready-to-eat deli salads; this also includes ready-to-eat deli salads that are frozen at some point in the supply chain prior to retail (see description column in FTL).

Example of forms NOT on the FTL:

- Frozen or previously frozen cheese (see description column in FTL).

2. FTL foods used as ingredients

If a food designated on the FTL is used as an ingredient in a new food in the same form, then **the new food product is covered by the FTR.**

Examples:

- Fresh bagged salad mix containing fresh lettuce or a prepared sandwich containing fresh tomatoes would be covered.
- A peanut butter sandwich cracker, for which no kill step is applied (to either the finished peanut butter or the peanut butter sandwich cracker) is covered.

3. Changing the form of the food

If the food is changed to a form that is not on the FTL, it is **no longer covered by the FTR**.

Examples:

- Drying or freezing fresh spinach, fresh peppers, and fresh herbs.
- Pickling fresh cucumbers.

For finfish, crustaceans, bivalve molluscan shellfish, and smoked finfish, the form encompasses fresh (or refrigerated for smoked finfish), frozen, and previously frozen (meaning it was thawed out and appears to be fresh). Therefore, freezing does not change these products to a form that is no longer on the FTL.

Slide 9: Is It a Multi-Ingredient FTL Food?

Is It a Multi-Ingredient FTL Food?

Food One



Food Two



Food Three





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	Is It a Multi-ingredient FTL Food?
Activity	Collaboratively review the images and descriptions to determine which multi-ingredient food is on the FTL and which is not.
Objectives	Participants will become familiar with the FTL as they take a closer look at it.
Time	10 minutes
Materials	Participant Manual
Directions to Participants	- Review the images and descriptions provided for Food One, Food Two, and Food Three. - Discuss which food would be on the FTL with your team. Be aware of the complexities we've discussed. - Write your answers. Be prepared to share with the class.
Breakout	Groups of 3-5 participants
Summary	Some foods are a little challenging, but the FTL is clear enough that you can still make a certain determination, even for complex or tricky situations.
Key Learnings	- How to use the FTL - How to determine whether a multi-ingredient food is on the FTL - Application of the discussion about complexities

Application of the Food Traceability Rule

Table 2-2: Determine which of the following multi-ingredient foods are on the FTL:

	Image/Description	Is it on the FTL?
Food One	Frozen pizza with peppers 	
Food Two	Pickled Cucumbers 	
Food Three	Ravioli with ricotta cheese 	

Images: [This Photo](#) by Unknown Author is licensed under [CC BY](#)

Chapter 2

Notes:

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Slide 10: Section Two

Section 2

**STEPS OF THE FOOD SUPPLY CHAIN AFFECTED BY THE
TRACEABILITY RULE**



Slide 11: Who Must Comply with the Rule?

Who Must Comply with the Rule?

- Persons who manufacture, process, pack, or hold foods on the Food Traceability List
 - Entities anywhere along the food supply chain
 - Foreign as well as domestic entities are included

Note that full or partial exemptions may apply.



From the FTR: Person includes an individual, partnership, corporation, and association.

Exemptions: Specific situations or entities to which the requirements of the FTR may not fully apply. These can be based on the type of entity or the specific food product.

Who Must Comply with the Rule?

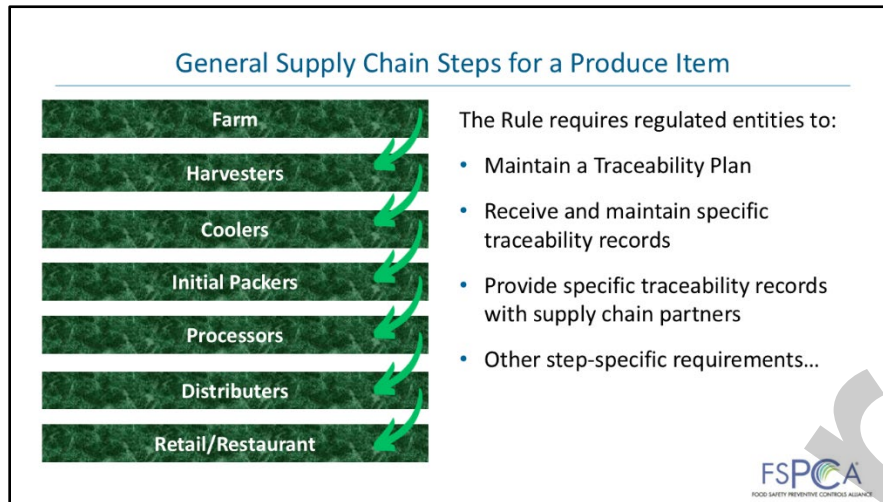
Persons who manufacture, process, pack, or hold foods on the Food Traceability List (i.e., covered foods)

- Entities anywhere along the food supply chain; this starts from farms all the way to Retail Food Establishments and restaurants.
- Foreign as well as domestic entities are covered

A covered food is any item on the FTR, including foods or products containing listed ingredients in their specified forms.

In considering who must comply with the rule, keep in mind that **full or partial exemptions** may apply.

Slide 12: General Supply Chain Steps for a Produce Item



The Rule requires all regulated entities in the food supply chain to do the following:

- Maintain a Traceability Plan
- Receive and maintain specific traceability records
- Provide specific traceability records to supply chain partners

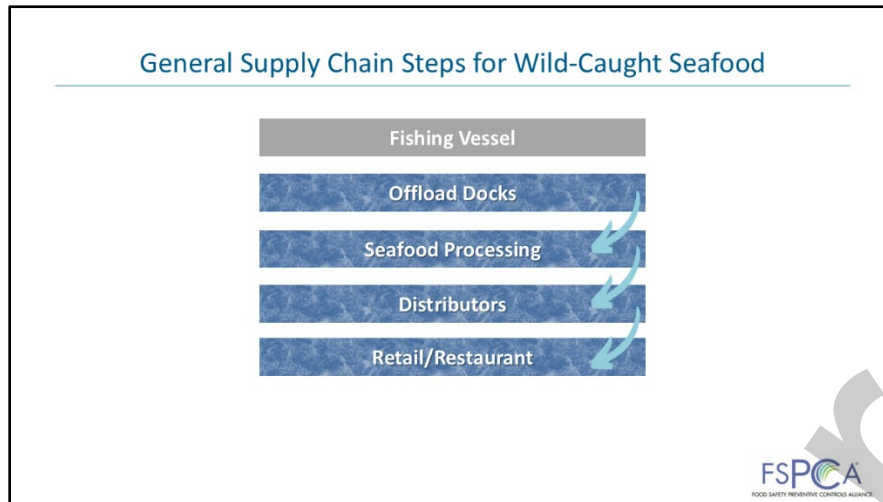
There are additional requirements that are specific to a particular supply chain step, which we will discuss in Chapter 3.

Slide 13: General Supply Chain Steps for Sprouts



The supply chain for sprouts looks different than that of other FTL foods. Seeds are not on the FTL, so the seed grower, seed conditioner, and seed supplier are not covered by the FTR. In this case, the FTR requirements start from the sprout grower, then apply to all subsequent covered entities in the food supply chain. We will discuss sprout-specific FTR requirements later in the course.

Slide 14: General Supply Chain Steps for Wild-Caught Seafood



Fishing Vessel: means any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing, as set forth in the Magnuson-Stevens Fishery Conservation and Management Act.

The supply chain for wild-caught fish looks different than that of other FTL foods. The entity who takes possession of wild-caught fish for the first time on land directly from a **fishing vessel** is referred to as the “first land-based receiver.”

In this case, the FTR requirements start with the first person who receives the food on land (offload docks), then apply to all subsequent covered entities in the food supply chain. We will discuss the seafood-specific FTR requirements later in the course.

Slide 15: Importers and Brokers

Importers and Brokers

- Remember that entities are covered by the FTR if they manufacture, process, pack, or hold a regulated food, even if the food is produced in a foreign country for export to the US.
- Brokers often do not manufacture, process, pack, or hold food, so the FTR may not apply to them.



Importer: The U.S. owner or consignee of an article of food that is being offered for import into the United States.

Broker/Customs Broker: Licensed representative hired by importers to facilitate the entry of products into the U.S. They submit necessary information and appropriate payments to Customs and Border Protection (CBP) on behalf of the importer.

If **importers** bringing food into the U.S. do not take physical possession of the product, they have no requirements under the FTR. If they manufacture, process, pack, or hold food on the FTL, they must keep required records, such as receiving and shipping.

A facility in another country that exports food to the U.S. is covered by the FTR if it manufactures, processes, packs, or holds the covered food.

Even if a particular entity is not covered by the rule, such as importers or brokers who do not take physical possession of the food, they may play a role in helping supply chain partners be in compliance with the rule by agreeing to hold required records.

Slide 16: Exporting FTL Foods from the United States

Exporting FTL Foods from the United States

- If an entity in the US exports food to another country, that food is not covered by the FTR after export, unless it comes back to the U.S.
- Exported food might be subject to another country's traceability requirements.
- Food sold in the US must have no breaks in the chain of records, even if its journey takes it out of the country for a time.



If an entity in the U.S. exports food to another country, that food is not covered by the FTR after export, unless it comes back to the U.S. Exported food might be subject to another country's traceability requirements.

Food exported to another country is only exempt when it does not return to the U.S. for consumption. If a food is exported and then imported back into the U.S., there must be records documenting the entire time it was out of the country. That helps ensure there are no breaks in the chain of records.

Slide 17: Section Three

Section 3

DO EXEMPTIONS APPLY TO YOUR FIRM OR THE FOODS YOU HANDLE?



Slide 18: Exemptions and Partial Exemptions



Exemptions and Partial Exemptions

- If you are fully exempt, then no requirements of the rule apply to you.
- If you are partially exempt, the FTR will tell you what requirements apply.
- In some cases, the entity is exempt; in other cases, the specific food is exempt.



If you are *fully* exempt, no requirements of the FTR apply to you.

If you are *partially* exempt, the FTR will tell you which requirements apply.

In some cases, an entity is exempt; in others, a specific food is exempt. Take note that just because your food is exempt from the FTL does not mean you are exempt from traceability requirements for other rules, such as Subpart J. See Appendix 2: Other Regulations that Impact Traceability for more information about other rules.

Slide 19: Exemptions Video



Exemptions video transcript:

There are many full and partial exemptions in the Food Traceability Rule. In this video, we will cover some of the most common exemptions so you know what to expect and so you can ask questions as they come up.

Let's look at some examples of foods that are exempt from the rule.

Raw bivalve molluscan shellfish are on the list, but they are exempt if they are covered by the National Shellfish Sanitation Program. That said, the businesses that handle raw molluscan shellfish may not be exempt if they handle other products on the FTL.

There is a partial exemption when food is sold directly from a farm to a restaurant; the restaurant is still required to keep records of the name and address of the farm. A farm could sell the same produce to a packer or processor in which case that food would be covered by the rule.

In other cases, specific entities are exempt from the rule.

Size of the Business

Restaurants and retail food establishments with an average annual food sale of less than \$250,000 (adjusted for inflation) are exempt from the rule.

Small produce farms that make less than \$25,000 annually (adjusted for inflation) are exempt. Egg producers with fewer than 3,000 laying hens are exempt from the rule.

Other producers of raw agricultural commodities, such as aquaculture farms, that make less than \$25,000 annually (adjusted for inflation) are exempt.

Farmers' Markets

Food products sold directly to consumers, such as at farmers' markets, roadside stands, and similar venues, are exempt from the traceability requirements of the FTR.

Fishing vessels

The owner of the fishing vessel is exempt. Additionally:

- There is a partial exemption if the owner also processes fish on the vessel; they must maintain limited records specific to who they send the product to, also known as “one up one back” records.
- The fish is exempt until it is sold by the owner of the fishing vessel. For example, the owner of a fishing vessel may also own a processing facility on land and as well as a warehouse. So even though the fish is being processed and held in the owner's facilities, it would be exempt until it was sold by the owner of the fishing vessel.

There are some other exemptions and partial exemptions related to processing the food. It's important to understand some of the nuances of the rule, so you can identify when a food is covered by the rule and/or when it is no longer covered.

Partial Exemption for a Kill Step

If you apply a kill step to a food on the FTL, the requirements of the rule do not apply to your subsequent shipping of the food, or to anyone else who handles the food after you ship it. You must maintain a record of your application of the kill step. An example is roasted peppers, which come into a processing facility as fresh peppers, which is a food on the FTL, but after they have been roasted, they are no longer covered by the rule because a kill step was applied.

Partial Exemption for Changing the form of a food

Freezing fresh produce changes its form so the food is no longer covered by the rule. Note that seafood is covered regardless of whether it is fresh, frozen, or previously frozen so this exemption does not apply to seafood.

If you dry a food, that is also a change in the form of the food such that it is no longer on the list.

Partial Exemption for Commingling

The rule includes a partial exemption for commingled raw agricultural commodities such as eggs or fish. This exemption does not apply to any produce items on the list. This exemption only applies when the products are combined or mixed after harvesting but before processing of the food. For eggs or aquacultured seafood, the commingling can only involve the same product from different farms under different company management.

For wild-captured seafood the commingling has to occur after landing with fish from different vessels.

Written Agreements

In these cases, the partial exemption requires supply chain partners to have a written agreement that at some point in the supply chain, a kill step will be applied, the form of the food will be changed, or that the food will be commingled.

Example 1

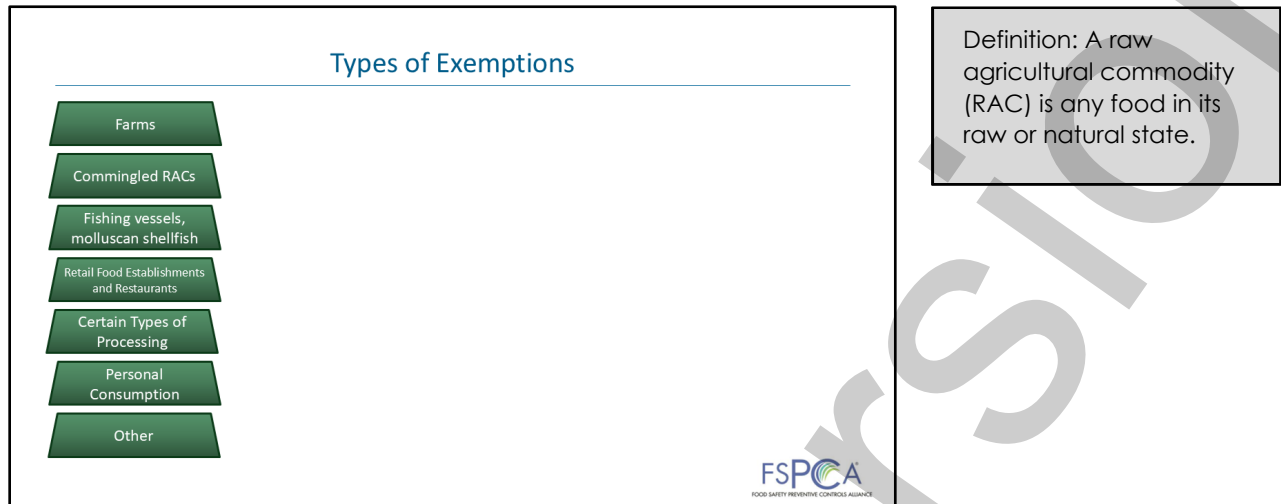
A farmer grows herbs, but they know three steps down the supply chain, someone will dry the herbs, which is a change in the form of the FTL food. This can be a situation where members of the supply chain may wish to use written agreements to indicate that the food will be changed. So, the farmer and his buyer could have a written agreement stating the buyer will send the herbs to a processor who will dry the herbs. Then the buyer could have a written agreement with the processor that the herbs will be dried. In this case, the farmer, buyer, and processor do not have to maintain any other records under the FTR as long as they have the written agreements.

Example 2

Crabs are wild-caught, but they are going to a processor to be cooked, picked, and pasteurized.

Since it is known at the point the crabs are landed that they will eventually receive a kill step, if there are written agreements between supply chain partners in that supply chain that the facility will pasteurize the product, the entities that maintain the written agreements do not have to maintain any other records under the rule. However, the processor would still need to maintain a record of the application of the kill step.

Slide 20: Types of Exemptions



Look over the following exemptions, with some broken down by the type of entity that would be subject to these exemptions. Refer to the FTR for more detailed information (including whether these are full or partial exemptions).

Farms

- Certain small produce farms
- Certain small shell egg producers
- Certain other small Raw Agricultural Commodity (RAC) producers (such as aquaculture)
- Certain food produced and packaged on a farm
- Farms selling food directly to consumers

Commingled RACs

- Certain commingled RACs (not fruits and 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) and restaurants

- Certain small RFEs and restaurants
- RFEs or restaurants purchasing food directly from a farm
- RFEs or restaurants purchasing food from another RFE or restaurant on an ad hoc basis

Certain types of processing

- Produce and shell eggs that receive certain processing
- Exemptions related to a kill step
- 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
-

Slide 21: Exemptions across Rules

Exemptions across Rules

Many of the exemptions in the Food Traceability Rule largely mirror the exemptions present in other FDA food safety rules, including:

- Produce rarely consumed raw
- Processing or kill step
- Farms with sales of less than \$25,000
- Egg producers with fewer than 3,000 hens



Many of the exemptions in the FTR mirror the exemptions present in other FDA food safety rules.

The Produce Safety Rule (PSR) (21 CFR Part 112) and the FTR share similar exemptions including those for produce rarely consumed raw, food that receives commercial processing/a kill step, and farms with sales of \$25,000 or less. Similarly, shell egg producers with fewer than 3,000 laying hens are not subject to either the Egg Safety Rule (21 CFR Part 118) or the FTR. Additionally, there is an exemption for shell eggs when all eggs produced at the particular farm receive a treatment.

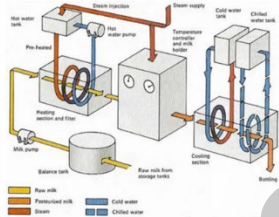
There are some differences between FTR exemptions and those found in other regulations. Notably, the Qualified Facility exemption in the Preventive Controls for Human Food Rule (21 CFR Part 117) does not apply to the FTR, and neither does the PSR Qualified Exemption for farms. A fishing vessel that also processes and packages the fish on board (also known as a factory vessel or at-sea processor) is not exempt from FDA's Seafood HACCP regulation (21 CFR Part 123) but has a partial exemption from the FTR requirements.

Slide 22: Exemptions: Kill Step

Exemptions: Kill Step

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

- Cooking
- Pasteurization
- Other heat treatments
- High-pressure
- Irradiation

A food manufacturing facility that performs a kill step. Photo credit: <https://microbenotes.com/>

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The following processing methods would most likely not be considered kill steps because they do not significantly minimize pathogens:

- Freezing
- Drying
- Ozonated water
- UV light

Other steps may be used to prevent the growth of pathogens but do not minimize pathogens in food, therefore they would not be considered kill steps, such as:

- Acidification
- Lowering water activity
- Use of certain preservatives

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

Note: If you want to know if your process is a kill step, you can submit a question to the FDA FSMA Technical Assistance Network (TAN) for more information.

Examples of kill steps include cooking, pasteurization, other heat treatments, high-pressure processing, and irradiation, as long as those processes are conducted in a manner that results in a lethality treatment that significantly minimizes the pertinent pathogen.

If you apply the kill step and want to receive the partial exemption for a kill step in § 1.1305(d)(3)(ii) you must maintain a record of your application of the kill step.

- The FTR provides flexibility regarding the type of documentation used to fulfill this requirement and allows firms to use records they keep in accordance with other regulations or for any other purpose to meet their recordkeeping requirements under the FTR (see § 1.1455(f)).
- Examples of existing records of a kill step that could be maintained to fulfil this exemption include monitoring of a preventive control (21 CFR 117.190(a)(2)) or documentation of thermal processing of low-acid canned foods (LACF) (21 CFR 113.100).

The citation for the partial exemption for foods which undergo a kill step is:

Citation: § 1.1305(d)

(d) Exemptions and partial exemptions for foods that receive certain types of processing. This part does not apply to the following foods that receive certain types of processing:

(3) Food that you subject to a kill step, provided that you maintain records containing:

- (i) The information specified in § 1.1345 for your receipt of the food to which you apply the kill step (unless you have entered into a written agreement concerning your application of a kill step to the food in accordance with § 1.1305(d)(6)); and
- (ii) A record of your application of the kill step.

Slide 23: Exemptions: Changing the Form of an FTL Food

Exemptions: Changing the Form of an FTL Food	
Form on the FTL	Form NOT on the FTL
Fresh herbs	Dried herbs
Fresh tomatoes	Sun-dried tomatoes
Fresh herring	Pickled herring
Fresh mangos	Frozen mangos
Fresh cucumbers	Pickled cucumbers



Another partial exemption provided in the rule is when an FTL food has been changed to a form that is no longer on the FTL.

Note: If you want to know if the form of your specific food is no longer on the FTL, you can submit a question to the FDA FSMA Technical Assistance Network (TAN) for more information.

As previously discussed, many foods on the FTL include reference to a specific form; for example **fresh** tomatoes, **fresh** herbs, **fresh, frozen or previously frozen** finfish. Examples of changing the form of a food include creating dried herbs from fresh herbs, freezing fresh green pepper strips, pickling cucumbers, and salting and drying raw fish.

In order to receive the exemption for changing the form of the food as provided in § 1.1305(d)(4), you must maintain records of receiving the FTL food.

The citation for the partial exemption for foods which have been changed to a form no longer on the FTL is:

Citation: § 1.1305(d)

(d) Exemptions and partial exemptions for foods that receive certain types of processing. This part does not apply to the following foods that receive certain types of processing:

(4) Food that you change such that the food is no longer on the Food Traceability List, provided that you maintain records containing the information specified in § 1.1345 for your receipt of the food you change (unless you have entered into a written agreement concerning your changing of the food such that the food is no longer on the Food Traceability List in accordance with paragraph (d)(6) of this section);

(5) Food that you receive that has previously been subjected to a kill step or that has previously been changed such that the food is no longer on the FTL.

Slide 24: Written Agreements

Exemptions: Written Agreements

Written agreements are between the shipper and receiver of a food and must state that:

- A kill step will be applied OR
- There will be a change in the form of the food so it is no longer on the FTL

Note that written agreements:

- Have no required format
- May apply on a per-lot, per-shipment, or any other basis
- Must be updated to reflect a current understanding of the partnership
- Are not filed with or sent to the FDA unless requested



Please note that a written agreement itself is NOT considered an exemption, but a requirement if you want to take advantage of the exemption for FTL foods subject to a kill step or change in the form of the FTL food applied by someone else in your supply chain. There is no required format for written agreements. Written agreements can be entered into in a variety of ways, depending on the business practices of the supply chain partners. The written agreement can be a new agreement developed for the purposes of this regulation, or it can be written into existing contracts or other documents between the shipper and receiver. The written agreement can be written to cover the FTL food on a per-lot, per-shipment, or other basis (for example, all products the shipper provides to the receiver will receive a kill step), depending on what makes the most sense for the shipper and receiver.

Written agreements do not have to be shared with every shipment. They can be drafted one time with each person keeping a copy of the agreement. The written agreement must represent the current understanding of the parties. If circumstances change such that the substance of the written agreement is no longer accurate, the agreement must be updated.

Written agreements do not have to be filed with or sent to FDA. However, as with all records required under subpart S, written agreements must be provided to FDA upon request in accordance with § 1.1455(c).

Additional details:

Citation: § 1.1305(d)(6)

- (i) There is a written agreement between the shipper of the food and the receiver stating that the receiver will apply a kill step to the food or change the food such that it is no longer on the FTL; or
- (ii) There is a written agreement between the shipper of the food and the receiver stating that an entity in the supply chain subsequent to the receiver will apply a kill step to the food or change the food such that it is no longer on the FTL and that the receiver will only ship the food to another entity that agrees, in writing, it will:
 - (A) Apply a kill step to the food or change the food such that it is no longer on the FTL; or
 - (B) Enter into a similar written agreement with a subsequent receiver stating that a kill step will be applied to the food or that the food will be changed such that it is no longer on the FTL.
- (iii) Any such written agreement must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement; and
- (iv) Such written agreement must be maintained by both parties for as long as it is in effect and must be renewed at least once every 3 years.

Slide 25: Exemptions Tool



Exemptions Tool

- Individual activity
- Open the exemptions tool
- Look at scenarios 1 through 3 and use the tool to decide if they are on the FTL



[link to tool](#)



Chapter 2

Open the FDA Exemptions tool to identify which exemptions apply in the scenarios found in table 2-3.

Table 2-3 Use the Exemptions tool to identify which exemptions apply in the scenarios.

Scenario	What Exemptions Apply? Full or Partial?
One: You work in a restaurant that gets an FTL food directly from Uncle Joe's Farm.	
Two: A processor freezes fresh-cut vegetables. Would this product be covered by the rule?	
Three: A grocery store sells shell eggs purchased from a distributor that were obtained from a farm where all eggs received an in-shell treatment that provides a 5-log reduction of <i>Salmonella</i> Enteritidis. Do any exemptions apply?	

Slide 26: Summary

Chapter 2: Summary

- The Food Traceability List shows what foods, and what form of the food, are subject to additional traceability requirements
- There are requirements throughout the food supply chain for FTL foods to comply with the FTR
- Exemptions may apply to specific entities or foods



Slide 27: Questions

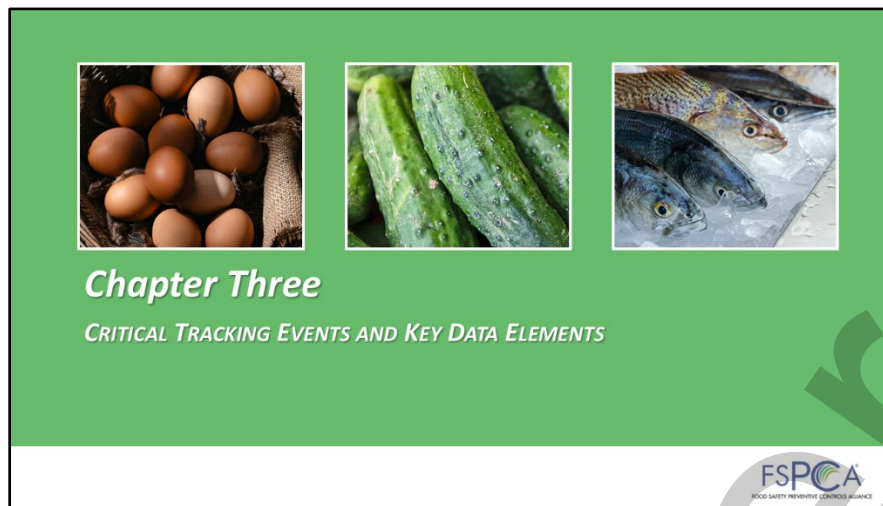
**Thank you for your
participation!**

**What questions
do you have?**



Chapter 3: Critical Tracking Events and Key Data Elements

Slide 1: Chapter 3



Slide 2: Goals and Learning Objectives

Chapter 3: Goal and Objectives

Goal: Explain the significance of Critical Tracking Events (CTEs) and Key Data Elements (KDEs) in traceability.

Learning Objectives:

By the end of this chapter, participants will be able to:

- Describe CTEs in the supply chain.
- Recognize that KDEs are dependent on the CTE.
- Compare KDEs that are shared with KDEs that are not shared.
- Identify actions to take when exemptions to the FTR affect KDEs received.
- Show how records at each CTE facilitate traceability.



Chapter Three introduces two major concepts in the Food Traceability Rule (FTR): Critical Tracking Events and Key Data Elements.

Chapter 3

Goal: Recognize the significance of Critical Tracking Events (CTEs) and Key Data Elements (KDEs) in food traceability.

Learning Objectives:

By the end of this chapter, participants will be able to:

- Describe CTEs in the supply chain.
- Recognize that KDEs are dependent on the CTE.
- Compare KDEs that are shared with KDEs that are not shared.
- Identify actions to take when exemptions to the FTR affect KDEs received.
- Show how records at each CTE facilitate traceability.

Slide 3: Definitions

Definitions

Definition of CTE from the FTR

Critical Tracking Events (CTEs) means 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.

Definition of KDE from the FTR

Key Data Elements (KDEs) means information associated with a critical tracking event for which a record must be maintained and/or provided in accordance with this subpart.



The FTR defines CTE and KDE as follows:

Critical Tracking Events (CTEs) means an event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity (RAC) 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.

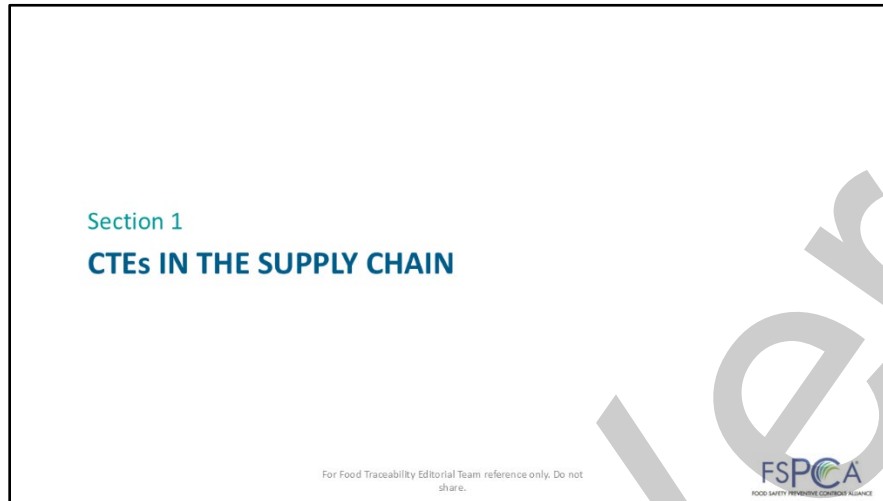
Key Data Elements (KDEs) means information associated with a CTE for which a record must be maintained and/or provided in accordance with this subpart.

CTEs are key activities in the movement and handling of food products throughout the supply chain and represent critical junctures where data, specifically KDEs, must be documented.

Many types of information are considered KDEs in traceability systems; KDEs designated by the FTR include product description, or date a product was received. The KDEs you maintain are the basis of your electronic sortable spreadsheet.

Maintaining KDEs for the CTEs defined in the FTR is critical for accurately tracking the movement of food products throughout the supply chain and facilitating rapid traceback or traceforward in the event of food safety incidents or recalls.

Slide 4: Section One



Slide 5: The Food Supply Chain

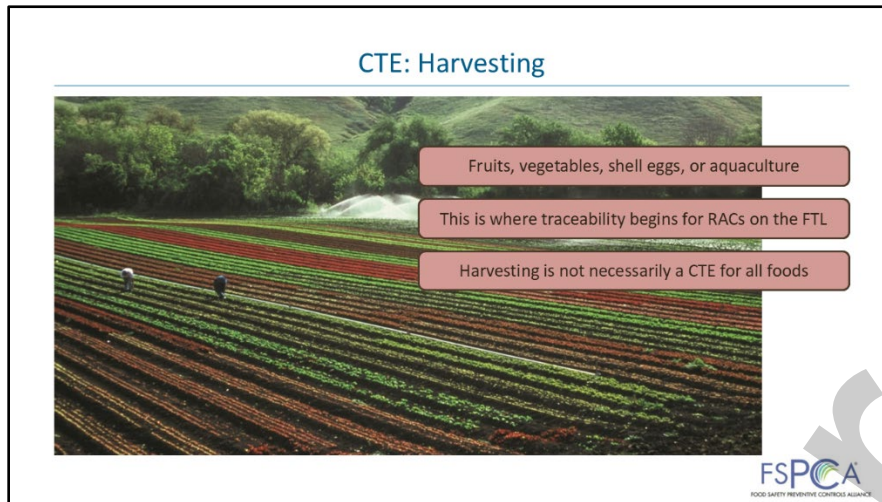
The Food Supply Chain

- Each physical destination in a product's journey is likely associated with one or more CTE. Let's identify the list of CTEs in the supply chain required by the FTR.



Each physical destination in a product's journey is likely associated with one or more CTE. Let's identify the list of CTEs in the supply chain required by the FTR.

Slide 6: CTE: Harvesting

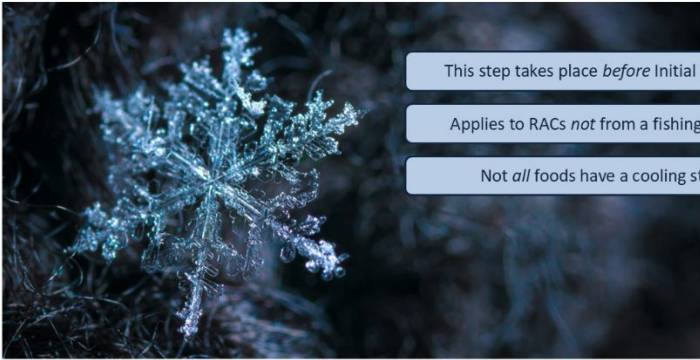


Harvesting

- This can be the harvesting of fresh fruits and vegetables included on the Food Traceability List (FTL), as well as shell eggs, which are considered raw agricultural commodities (RACs). Harvesting also applies to aquacultured food harvested from a pond, tank, etc.
- Relevance to the FTR: Harvesting represents the origination of a product. It is the beginning of the “life” of an FTL product required to be traced through the supply chain and is the first point in this journey. Harvesting only happens once during a product life cycle.
- In some cases, harvesting is *not* a CTE for an FTL food. For example, nut butter is an FTL food, but nuts and nut butter ingredients are not. The rule does not require traceability of the nuts (which are the harvested product); therefore, there is no harvesting CTE for nut butter.

Slide 7: CTE: Cooling (before Initial Packing)

CTE: Cooling (before Initial Packing)



This step takes place *before* Initial Packing

Applies to RACs *not* from a fishing vessel

Not *all* foods have a cooling step

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Cooling is a Critical Tracking Event (CTE) that means active temperature reduction of a raw agricultural commodity using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process.

Traceability Lot Code (TLC) means a description, often alphanumeric, used to uniquely identify a traceability lot.

The next CTE is **cooling**.

Note that cooling only counts as a CTE if it occurs *before* Initial Packing.

- A Cooling CTE applies to RACs *not* obtained from a fishing vessel. This could include some of the produce RACs on the FTL, as well as shell eggs and aquacultured FTL products. Not all foods on the FTL receive a cooling step. If they do, however, Cooling that occurs before Initial Packing is considered a CTE.
- Relevance to the FTR: Cooling is a handling step where contamination can occur. Therefore, traceability information in the form of KDEs is needed to understand the product's physical path. For the FTR, cooling is only considered a CTE *before* Initial Packing. This is because the product, once packed, is assigned a Traceability Lot Code (TLC).
- Icing seafood is not considered a Cooling CTE.

Slide 8: CTE: Initial Packing

CTE: Initial Packing



- Limited to specific RACs
- Foods are assigned a Traceability Lot Code
- Initial Packing only happens *once*

CTE: Initial Packing (Sprouts)



- Specific KDEs apply only to sprout growers

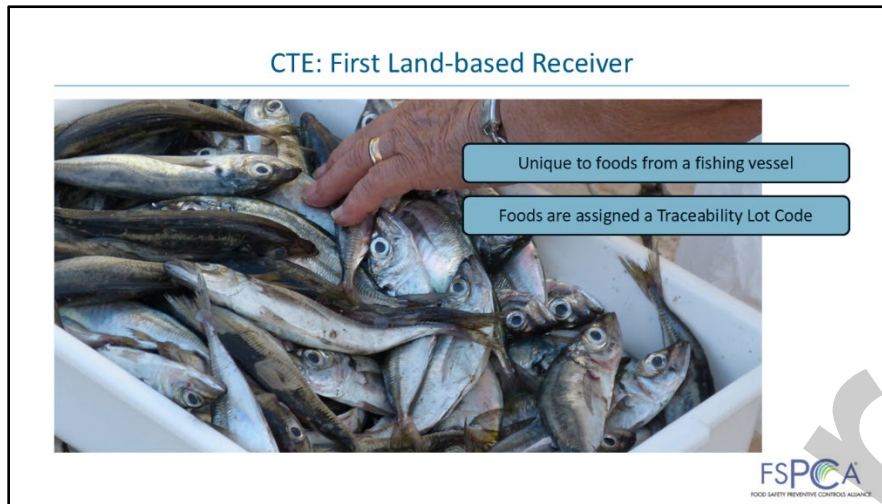
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The next CTE is Initial Packing.

Note that Initial Packing only counts as a CTE for RACs.

- Initial Packing is a CTE limited only to RACs such as produce on the FTL, shell eggs, and aquacultured FTL products. Initial Packing means the packing of RACs for the first time.
- Relevance to the FTR: Initial Packing is another point where microbial contamination can occur. It also represents the first time that RACs other than those obtained from a fishing vessel are assigned TLCs. Initial Packing only happens once during a product's life cycle. The FTR does not consider that any packing or packaging performed after Initial Packing corresponds to this CTE.
- Not all foods on the FTL have an Initial Packing CTE.
- Note: Generally, Initial Packing, First Land-Based Receiver, and Transformation, discussed below, are the only CTEs for which a TLC may be assigned to an FTL product.

Slide 9: CTE: First Land-based Receiver



The following applies to the First Land-Based Receiver:

- This CTE is unique to food on the FTL obtained from a fishing vessel. The First Land-Based Receiver is the person taking possession of a food for the first time on land directly from a fishing vessel.
- Relevance to the FTR: Similar in concept to Initial Packing, the First Land-Based Receiver is the point in the supply chain where a food on the FTL receives a TLC. Each covered food will have only one First Land-Based Receiver.

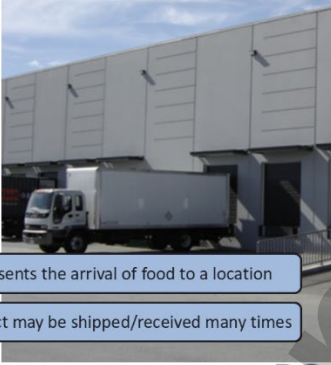
Slide 10: CTE: Shipping | CTE: Receiving

CTE: Shipping



- Change in address location of the food
- Each location needs to be known to establish traceability
- Not if a product moves around the same facility

CTE: Receiving



- Represents the arrival of food to a location
- A product may be shipped/received many times

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Cross-docking is a logistics strategy where products are unloaded from an incoming vehicle and then loaded onto an outgoing vehicle with little or no storage time in between.

Shipping:

- Most foods on the FTL will have Shipping CTEs when a product is transported from one physical location to another location. In fact, a single food may be shipped several times before being sold to the end-consumer. After Initial Packing, each shipping event is considered a unique CTE for which KDEs must be documented.
- Relevance to the FTR: Shipping CTEs represent changes in a food's physical location. To establish a product's traceability, each location must be known. The Shipping CTE is critical to establishing the supply chain pathway.
- **Prior to Initial Packing/First Land-Based Receiving, Shipping CTEs do not apply.**

Notes:

- Moving product within the same facility is not considered a Shipping CTE; however, product moved from one facility to another owned by the same company is considered a Shipping CTE.
- Shipping and Receiving CTEs are generally in pairs; one location ships a food, and another receives it.

Receiving:

- Receiving means food is received by someone other than a consumer after being transported. Like Shipping CTEs, most foods on the FTL will have a Receiving CTE. Again, a single food may be received several times along its journey. In most cases, Receiving CTEs only exist after a food is assigned a TLC.
- Relevance to the FTR: Similar to Shipping, Receiving represents changes in a food's physical location. To establish a product's traceability, each location must be known.

Slide 11: CTE: Transformation

CTE: Transformation



- A non-FTL food becomes an FTL food
- An FTL food transforms but is still an FTL food
- An FTL food becomes the same FTL food

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Transformation is a complex topic, therefore this CTE is described across multiple slides.

Note that a kill step is not considered Transformation.

The next CTE is Transformation.

- The Transformation CTE represents an event in the supply chain when the final product is an FTL food. Transformation results from applying a manufacturing or processing step or by changing the food or its packaging.
 - Relevance to the FTR: Transformation will result in a new traceability lot, and most transformation events will result in a new TLC.
 - Transformation does NOT apply to RFEs and restaurants with respect to prepared foods they sell directly to consumers.
- A new traceability lot of food can be produced through transformation in a few different ways. A non-FTL food is processed and becomes an FTL food.
Example: nuts are not on the FTL, but when they are processed into nut butter, that is an FTL food.
- An FTL food undergoes a manufacturing or processing step and the result is an FTL food.
Example: Lettuce combined with other foods in a salad kit.

- An FTL food goes through a processing step, and the outcome is the same FTL food. This could happen by commingling, repacking, or relabeling.
Example: Red, green, and yellow peppers, each type from a different farm, are repacked and commingled into a “stoplight” product that contains peppers of each color.

Note that application of a kill step is not considered Transformation. Neither is when an FTL food is processed and the outcome is a non-FTL food. An example would be fresh herbs (an FTL food) that are dried to make spices (a non-FTL food).

Slide 12: CTE: Transformation (Repacking)

The TLC Source means the place where a food was assigned a Traceability Lot Code. TLC Source will be covered in more detail later in this chapter.

As noted, repacking an FTL food is a type of transformation.

Repacking an FTL food is always a transformation event, and it **often (but not always) requires a new traceability lot code.**

Repacked product can retain the traceability lot code from the original traceability lot if the food is repacked within the same traceability lot (repacking “like into like”). In this situation, the repacker would keep the required transformation records under § 1.1350, with the lot codes in § 1.1350(a)(1)(i) and (2)(i) being the same. **The traceability lot code source would be changed to reflect the place where the repacking occurred.**

Slide 13: CTE: Transformation (TLC Assignment)



As noted, Transformation is one of the few CTEs where TLCs can be assigned. Let us consider how this impacts TLC recordkeeping.

- Transformation when ingredients of that food are not on the FTL.
 - Examples could include:
 - Milk used for cheese
 - Pasta used in a deli salad
 - Apples used to make sliced apples
 - In this case, the non-FTL ingredients are not required to have TLCs or other KDEs captured before the transformation event. When the FTL food is created through Transformation, a TLC is then assigned to it.
- Transformation when ingredients of that food are on the FTL.
 - Examples could include:
 - Bean sprouts used in a mixed salad.
 - A bagel including smoked salmon.
 - In this case, both the newly created food, as well as one or more of its ingredients, are on the FTL. The specific KDEs that need to be captured as part of Transformation are discussed in the next section, but it is important to recognize that in this kind of Transformation, the TLCs of both FTL ingredients and the transformed FTL food need to be captured and linked to each other.

Reminder: When restaurants and RFEs prepare FTL foods onsite that will be sold directly to consumers, this is NOT considered a transformation event. The restaurant/RFE does NOT need to assign a TLC to the prepared food, nor keep Shipping KDEs. However, they do need to record the Receiving KDEs of the FTL ingredients used in the prepared foods.

Notes:

Lined area for notes.

Slide 14: Transformation or Not?

Transformation or Not?	
Read the seven situations	Yes, it is a transformation event.
Determine if it would count as a transformation CTE based on the language of the Rule	
Discuss	No, it is NOT a transformation event.

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Look over the following situations and determine if it would be considered a transformation event according to the FTR. You may also take notes on any discussion that follows when the correct answer is revealed. Be sure to ask any questions that come up, so you are well equipped to identify transformation events in your supply chain.

Table 3-1: Is it Transformation or Not?

#	Situation (notes)	My Response (Yes/No)	Explanation	Additional Information
1	Commingled live crabs are cooked, sectioned, frozen, and bagged.			Raw crabs are exempt as a commingled RAC, so Receiving CTEs are not needed. After the kill step, the cooked crab sections are exempt from the FTR so subsequent records are not required.
2	Commingled whole shrimp have heads removed and are frozen raw.			The raw whole shrimp is a commingled RAC and is exempt from the FTR, therefore Receiving CTEs do not apply. The shrimp is no longer a RAC after processing steps such as removing the head and freezing (i.e., the commingled RAC exemption no longer applies).
3	Peanut butter is warmed and incorporated into vanilla ice cream to make peanut butter swirl ice cream.			Warming is not a kill step. Peanut butter is on the FTL, therefore Receiving CTEs are also needed.

Chapter 3

#	Situation (notes)	My Response (Yes/No)	Explanation	Additional Information
4	Shell eggs are pasteurized in-shell.			The kill step must be documented. Shell eggs are on the FTL, so Receiving CTEs are also needed.
5	Tomatoes that have already been washed are received from the Initial Packer at various stages of maturity and are various sizes. Every few days, the tomatoes are sorted and those tomatoes at the desired ripeness and of the same size are repacked into cases and shipped to retail customers.			Receiving the tomatoes from the Initial Packer will require a Receiving CTE.
6	A company makes salads that are sold at convenience stores. The company receives cut lettuce and shredded carrots from their sister facility located across the street. Other ingredients such as assorted cheeses, dressings, and toppings are received from a local distributor.			The cut lettuce and shredded carrots are both fresh-cut produce items which are FTL foods; Receiving CTEs are required, even though they are being produced by the sister facility across the street. The company must check the styles of cheeses to see if any are on the FTL and require a Receiving CTE.

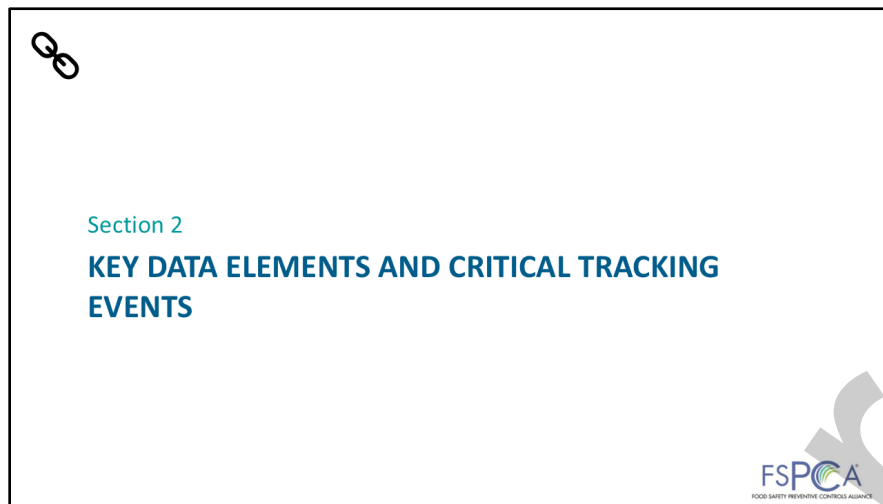
#	Situation (notes)	My Response (Yes/No)	Explanation	Additional Information
7	A restaurant makes tableside guacamole using avocados, cilantro, tomatoes, onions and jalapenos.			Because the cilantro, tomatoes, and jalapenos are FTL foods, the restaurant needs Receiving CTEs for these foods.

Chapter 3

Notes:

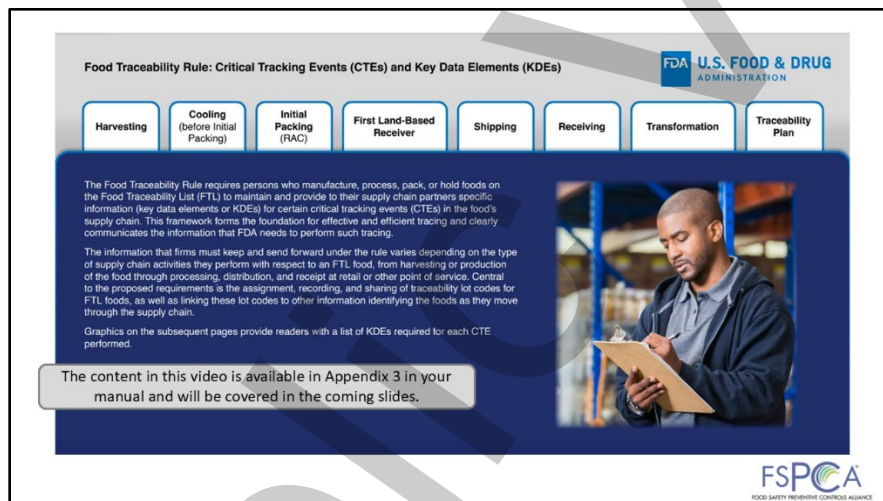
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Slide 15: Section Two



Appendix 3: Critical Tracking Events and Key Data Elements shows what KDEs are required to be captured at which specific CTEs.

Slide 16: CTEs and KDEs



The content in this video is available in Appendix 3 in your manual and will be covered in the next slides.

The FTR identifies a set of specific KDEs that must be documented for each CTE. KDEs are dependent on the CTE, so that for each CTE you conduct, you will need to refer to the regulation to ensure you are capturing all the required data.

While each CTE has a set of KDEs associated with it, there may be some overlap; for example, the Product Description KDE is required for both the Shipping CTE and the Receiving CTE.

You are only responsible for capturing and sharing the KDEs for the CTEs performed by your operation.

Slide 17: What KDEs Would a Harvester Document?

The slide features a title "What KDEs Would a Harvester Document?" in blue text. On the left, there is a vertical orange bar with the text "Harvesting KDEs" and a circular logo above it that says "HARVESTER" and shows a sun and a field. To the right of the bar, a blue-bordered box contains a list of requirements. At the bottom right of the slide is the FSPCA logo, which stands for Food Safety Preventive Controls Alliance.

What KDEs Would a Harvester Document?

Harvesting KDEs

- For each raw agricultural commodity on the FTL that you harvest, you must maintain records containing the following information:
 - Where you sent it to
 - What you harvested
 - How much you harvested
 - Where the food was harvested
 - Name of the field or growing area (produce)
 - Name of the container (aquaculture)
 - When it was harvested
 - Reference document information
- You must also provide these KDEs, and your business name and phone number, with the Initial Packer of the food, either directly or through the supply chain

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We will start with the Harvesting CTE, with the applicable KDEs listed on the slide.

- You can see here that a harvester will only need to maintain Harvesting KDEs.
- However, if the harvester is conducting other CTEs such as Cooling and/or Initial Packing, then KDEs associated with Cooling and/or Initial Packing would also be maintained.
- If the firm only performs harvesting, the Shipping CTE is not required. However, the Harvesting KDEs as well as the Harvester's business name and phone number must be provided to the Initial Packer.

A reference document is a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the KDEs for a CTE. Reference Documents will be covered in more detail in Chapter 5.

Slide 18: What KDEs would a Cooler Document?

What KDEs Would a Cooler Document?

Cooling KDEs



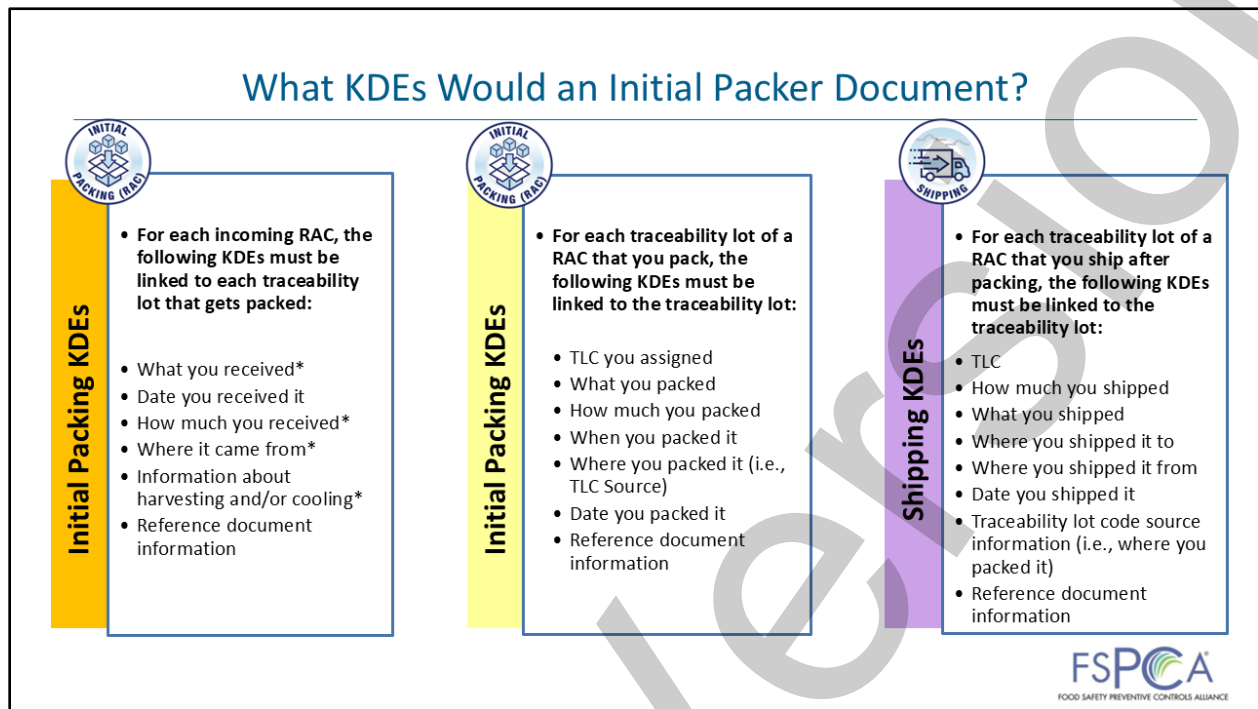
- For each raw agricultural commodity on the FTL that you cool before it is initially packed, you must maintain records containing the following information:
- Where you sent it to
- What you cooled
- How much you cooled
- Where the food was cooled
- When it was cooled
- Where it was harvested
- Reference document information
- You must also provide these KDEs, and your business name and phone number, with the Initial Packer of the food, either directly or through the supply chain



We next review the Cooling CTE, with applicable KDEs listed on the slide.

- You can see here that a cooler will only need to maintain Cooling KDEs.
- However, if the cooler is conducting other CTEs such as Initial Packing, then KDEs associated with Initial Packing would also be maintained.
- If the firm only performs Cooling, the Shipping CTE is not required. However, the Cooling KDEs as well as the Cooler's business name and phone number must be provided to the Initial Packer.

Slide 19: What KDEs Would an Initial Packer Document?



The Initial Packer will be responsible for maintaining both Initial Packing AND Shipping KDEs.

- The Initial Packing KDEs include information about the incoming FTL food, as well as information about packing, including the TLC that is assigned by the Initial Packer.
- Shipping KDEs are required and need to be linked to the TLC.
- Subsequent steps in the supply chain will also need to maintain their own Shipping KDEs, based on the FTL food they are shipping.
- After initial packing, the TLC and TLC Source should only be changed if the food undergoes Transformation. Otherwise, the TLC and TLC Source remain the same and are passed along as part of the Shipping KDEs.

Although Initial Packing does not apply to food obtained from a fishing vessel, it does apply to aquacultured seafood.

In addition to maintaining Initial Packing KDEs, there are specific requirements for Initial Packing of Sprouts, namely:

- Location description for the seed grower and date of seed harvesting (if either is available).
- Location description for the seed conditioner or processor, associated seed lot code, and date of conditioning or processing.
- Location description for the seed packinghouse, date of packing/repacking, and any associated seed lot code.
- Location description for the seed supplier, any seed lot code assigned by the seed supplier, and any new seed lot code assigned by the sprout grower.

- Description of the seeds, including seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment.
 - Date of receipt of the seeds by the sprout grower.
-

Slide 20: What KDEs Would a First Land-Based Receiver Document?

What KDEs Would a First Land-Based Receiver Document?

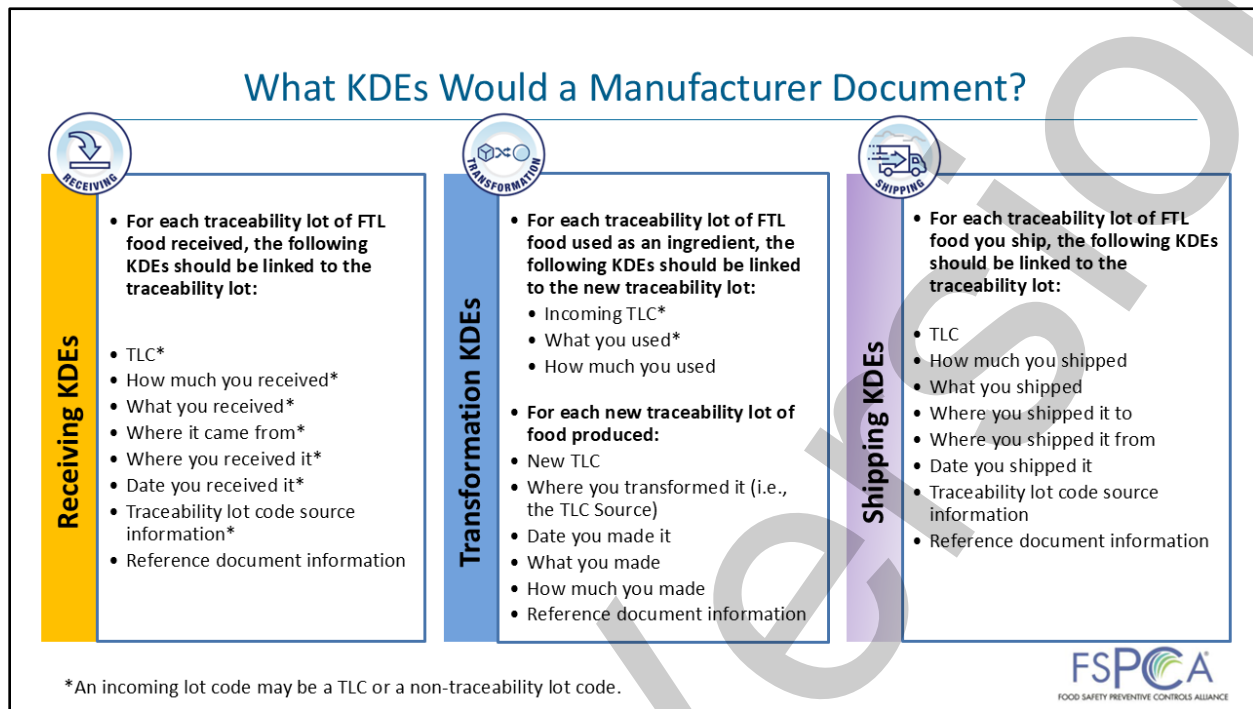
 First Land-Based Receiver KDEs	 Shipping KDEs
• For each FTL food obtained from a fishing vessel, the following KDEs should be linked to each traceability lot: • TLC you assigned • What you obtained • How much you obtained • Harvest date range and locations for the trip during which it was caught • Traceability lot code source information (i.e., your location description) • Date the food was landed • Reference document information	• For each traceability lot of FTL food you ship, the following KDEs should be linked to the traceability lot: • TLC • How much you shipped • What you shipped • Where you shipped it to • Where you shipped it from • Date you shipped it • Traceability lot code source information (i.e., your location) • Reference document information


FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

The First Land-based Receiver will be responsible for maintaining both First Land-Based Receiver AND Shipping KDEs.

- The First Land-Based Receiver KDEs include information about the incoming FTL food as well as the TLC that is assigned by the First Land-Based Receiver.
- Shipping KDEs are required and need to be linked to the TLC.
- Subsequent steps in the supply chain will also need to maintain their own Shipping KDEs, based on the FTL food they are shipping.
- After first land-based receiving, the TLC and TLC Source should only be changed if the food undergoes Transformation. Otherwise, the TLC and TLC Source remain the same and are passed along as part of the Shipping KDEs.

Slide 21: What KDEs Would a Manufacturer Document?



Finally, we will review the CTEs a manufacturer performs.

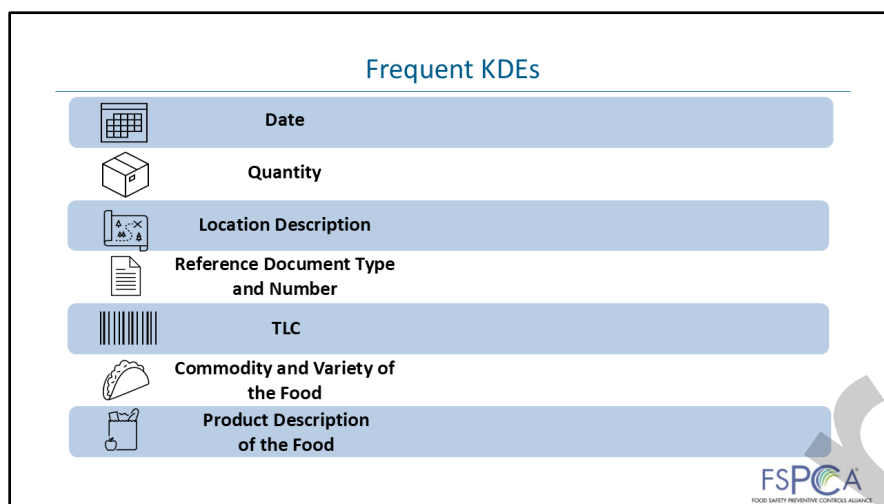
- A manufacturer that receives FTL foods needs to document the requirements for the Receiving CTE.
- If they transform FTL foods, they will need to document the requirements for the Transformation CTE including assigning a TLC.
- Shipping KDEs apply and need to be linked to the TLC.
- Subsequent steps in the supply chain will also need to maintain their own Shipping KDEs, based on the FTL food they are shipping.
- After transformation, the TLC and TLC Source should only be changed if the food undergoes Transformation again. Otherwise, the TLC and TLC Source remain the same and are passed along as part of the Shipping KDEs.

Now let's consider:

Which KDEs would a warehouse or distribution center need to maintain?

Which KDEs would an RFE or restaurant need to maintain?

Slide 22: Frequent KDEs



Let's look at the most frequent KDEs, or the KDEs that are required across the most CTEs. Feel free to use Appendix 3: Critical Tracking Events and Key Data Elements to help you complete the CTE column in Table 3-2 below.

Table 3-2: Which CTEs include the following KDEs?

KDE	CTEs	Notes (if applicable)
Date		- Each CTE may have a date relevant to its own operations. For example, Harvesting will have Date of Harvest and Cooling will have Date of Cooling. - On some documents commonly exchanged in the supply chain, the date listed may not be the date the food was physically handled; it may be the date of the transaction or the date the information was entered into the system. - The date KDE requires the dates when the activities actually occurred, not when they might have been reported or recorded in a document or in a digital system.
Quantity		

KDE	CTEs	Notes (if applicable)
Location Description		
Reference Document Type and Number		While each CTE has the KDE requirement of a reference document type and number, each company will have its own organization-specific reference document type and number.
Traceability Lot Code		The TLC is documented at all subsequent CTEs in the supply chain.
Commodity and Variety of the Food		- The FTR uses the term “commodity” to identify the food before it is in a package; afterward, it uses “product description.” - Once a RAC is packaged, it requires more detailed descriptions. Commodity is a sub-component of product description after packing.
Product Description of the Food		- Applies to all CTEs except Harvesting and Cooling. - For a first land-based receiver, unpacked food requires a species and/or acceptable market names; when a product is packaged on a fishing vessel, the first land-based receiver will capture the product description.

Notes:

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Notes:

Lined area for notes.

Slide 23: What is a “Compound KDE?”

What is a “Compound KDE?”

"Compound KDEs" refer to Key Data Elements (KDEs) that are composed of **multiple sub-elements or components**. Instead of representing a single piece of information, compound KDEs consist of a combination of data fields or attributes that together provide a more comprehensive understanding of a particular aspect of the product or process.

Location Description

Product Description



“Compound KDE” is NOT an official term found in the Rule. The Rule says “some KDEs contain multiple pieces of data.” We distinguish “compound KDEs” this way simply so it is easy to understand.

"Compound KDEs" refer to KDEs composed of *multiple sub-elements or components*. Instead of representing a single piece of information, compound KDEs consist of a combination of data fields or attributes that together provide a more comprehensive understanding of a particular aspect of the product or process.

Slide 24: Compound KDEs

Compound KDEs

Location Description	Product Description
📍 Business name	📦 Product name
📍 Phone number	📦 Brand name
📍 Physical location address or geographic coordinates	📦 Commodity
📍 City state and zip code for domestic locations	📦 Variety
📍 Comparable information for foreign locations including country	📦 Packaging size
	📦 Packaging style
	📦 Species and/or market name (for seafood)



The full requirements for the Location Description and Product Description are in the definitions found in the Rule.

There are two compound KDEs:

- Location Description
 - *Location description* means key contact information for the location where a food is handled; specifically, the business name, phone number, physical location address (or geographic coordinates), city, state, and zip code for domestic locations and comparable information for foreign locations, including country.

- *Note: Regulated entities should take care to ensure they are describing the physical location where a food was packed or held rather than a company's corporate location that may have had an ownership relationship to the food but was not the physical location of the food.*
- Product Description
 - *Product description means a description of a food product and includes the product name (if applicable, the brand name, commodity, and variety), packaging size, and packaging style. For seafood, the product name may include the species and/or acceptable market names.*

By requiring the information captured in these compound KDEs to be collected, the FDA can obtain a more accurate description of the location and product, which can speed up a traceback investigation.

Story: During an outbreak investigation in 2017 that FDA responded to involving tomatoes, some people with illness reported consuming salsa. During the traceback investigation, it was found that some businesses were describing the ingredients as "tomatoes" and others were describing them as "Roma tomatoes." Knowing the variety of tomatoes helped to narrow the traceback investigation.

Slide 25: Compound KDE Evaluation

Compound KDE Evaluation

- Small group activity
- Read each compound KDE example
- Evaluate whether the compound KDE meets the requirements or if it is missing any information



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	Compound KDE Evaluation
Activity	Within a small group, determine if a given compound KDE meets the FTR requirements or not.
Objectives	Evaluate compound KDE examples against the requirements.
Time	10 minutes

Chapter 3

	Compound KDE Evaluation
Materials	Participant Manual
Directions to Participants	- Read through example compound KDEs - Compare them against KDE requirements - Collaboratively make a determination as to whether it is complete or if it is lacking some details
Breakout	3-5 participants
Summary	Look at several example compound KDEs and determine if they are complete or if they are missing some required details
Key Learnings	The requirements of compound KDEs

Evaluate these compound KDE examples and identify what, if anything, is missing. What needs to be added to these examples to make them complete product/location descriptions?

Location description: Is this data complete? If not, what is missing?

- Sophia's Specialty Soft Cheeses
- PO Box 56, Winchester MD 21921
- 240-567-9876

Product description: Is this data complete? If not, what is missing?

- Roma tomatoes
- Clamshell
- Melly's Tomatoes brand

Location description: Is this data complete? If not, what is missing?

- Tim's Tilapia Processor
- Quito, Pichincha Province, Ecuador 170156

Product description: Is this data complete? If not, what is missing (assume this product is not wild-caught)?

- 16-20 Count Frozen shrimp
 - 2-pound package
-

Notes:

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Slide 26: Traceability Lot Codes



Traceability Lot Codes

The TLC is one more data element that helps identify the product, providing a link to the **records** showing where the food is coming from and where it is going. The TLC is the link for each of the steps in the supply chain and the paperwork.

The benefit of the TLC is that it can be used to **differentiate** the same product produced by the same manufacturer but for different shipments or different production days.

Unless the entity is exempt, the TLC is **assigned** when the food is initially packed (for RACs not obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.

Once a TLC is assigned, it must **stay the same** as the food moves through the supply chain; it can only be changed if the food is transformed.



Advance Shipping Notices (ASNs):
Electronic documents sent by a shipper to a receiver in advance of a shipment, often containing details about the contents and expected arrival.

Maintaining TLCs help ensure accurate identification of the food as it moves through the supply chain.

TLC Definition:

The **Traceability lot code (TLC)** means a description, often alphanumeric, used to uniquely identify a traceability lot within the records of a traceability lot code source.

Description:

The TLC is one more data element that helps identify the product, providing a link to the **records** showing where the food is coming from and where it is going. *The TLC is the link for each of the steps in the supply chain and the paperwork.*

The benefit of the TLC is that it can be used to **differentiate** the same product produced by the same manufacturer but for different shipments or different production days.

Unless the entity is exempt, the TLC is **assigned** when the food is initially packed (for RACs not obtained from a fishing vessel), received by the first land-based receiver (for food obtained from a fishing vessel), or transformed.

Once a TLC is assigned, it must **stay the same** as the food moves through the supply chain; it can only be changed if the food is transformed.

Relevance to the FTR:

Requiring documentation of TLCs and TLC Sources to be carried through the supply chain enables the FDA to more quickly identify the source of a food by being able to skip some steps in the supply chain, leading back to the food's source during an outbreak investigation.

Supplemental information:

Does the TLC Need to Be on the Packaging?

"No, the final rule does not require that the TLC be included on food labeling or food packaging. The TLC can be sent to the next recipient of the food in a variety of ways, such as via a bill of lading, an advance shipment notice (ASN), in a separate email, or by embedding the information in a QR code that appears on the packaging of the food or on a related document. The information does not have to physically accompany the food sent to the recipient but must be provided in a way that permits the receiver of the food to keep the records it is required to maintain under the rule."

Slide 27: Impact of Traceability Lot Codes

Impact of Traceability Lot Codes

- Read the memorandum from an outbreak investigation.
- Review Table 3-3 and discuss the impact availability (and unavailability) of lot codes had on this outbreak investigation.



Read the following memorandum from an outbreak investigation:

In the fall of 2019, FDA, CDC, and state health authorities investigated an outbreak of *E. coli* O157:H7 in the U.S. linked to romaine lettuce. The traceback investigation was initiated on 11/18/2019 in conjunction with state partners to analyze 15 points-of-sale (POS) where ill persons shopped. Of the 15 POS traced, lot code information was obtained for two POS where ill persons purchased the implicated lettuce product. Due to lack of available lot codes to trace for the remaining 13 POS, FDA requested tracing data to identify all growers who supplied any romaine lettuce used in products reported by consumers and available for sale during the time period of 9/15/2019 to 11/18/2019. It took approximately one month to collect and analyze the requested distribution data to identify the growers who supplied the lettuce (Table 3-3). In contrast, a narrower scope of data was requested for the two POS where lot codes were available, resulting in identification of growers within 24 hours or less.

Chapter 3

Review Table 3-3 and discuss the impact availability (and unavailability) of lot codes had on this outbreak investigation.

Table 3-3: Traceback initiation dates for POS with and without available lot code data associated with *E. coli* O157:H7 outbreak linked to romaine lettuce.

	Traceback Initiation Date	Grower Identification Date
POS locations with no lot code data	11/18/2019	12/13/2019
MD POS location with lot code data	11/18/2019	11/18/2019
WI POS location with lot code data	12/4/2019	12/5/2019

Slide 28: TLC Source

TLC Source

- TLC Source means the location where a food was assigned a traceability lot code. Both the TLC and the TLC Source will improve the FDA's ability to identify the specific food and location involved in a contamination event and determine the appropriate scope of a recall event.



As a reminder, TLC Source means the location where a food was assigned a traceability lot code. Both the TLC and the TLC Source will improve the FDA's ability to identify the specific food and location involved in a contamination event and determine the appropriate scope of a recall.

The TLC Source is a new concept that comes from the FTR. It did not exist before this rule.

Slide 29: TLC Source Reference

TLC Source Reference

- A TLC Source Reference is a method for giving FDA access to the TLC Source location description required by the FTR without providing the TLC Source location information directly to subsequent recipients.



Traceability Lot Code Source Reference means an alternative method for providing FDA with access to the location description for the Traceability Lot Code Source as required under the rule.

The use of a TLC Source Reference may be appropriate for those entities concerned about sharing TLC Source information through the supply chain. A brand owner who doesn't produce their own products, or a contractor for a large national brand, could use a TLC Source Reference to protect information their company may not want to be public knowledge.

The TLC Source Reference can help streamline information if the TLC Source Reference turns a string of data elements into a small number or a code.

Slide 30: Examples of TLC Source Reference Types

Examples of TLC Source Reference Types

 FDA Food Facility Registration number	 GS1 Digital Link
 Web address	 Shell Egg Producers Registration Module

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Examples of TLC Source Reference types include but are not limited to:

- The FDA Food Facility Registration Number (referred to as FFRN) assigned to the TLC Source
- A web address that provides the FDA with the location description for the TLC Source
- A web address in a GS1 Digital Link. Such a web address may employ reasonable security measures, such as only being accessible to a government email address, provided the FDA has access to the information at no cost and without delay.

Slide 31: Section Three

Section 3

KDEs THAT ARE SHARED vs. KDEs THAT ARE NOT SHARED

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Slide 32: Which KDEs Are Shared and with Whom?

Which KDEs Are Shared and with Whom?

The rule facilitates traceback by requiring that **traceability information is maintained and shared along the supply chain**. It is important to understand what data you should receive from your suppliers, as well as pass along to your customers.

There is a misconception that you have to pass along all the information you receive, from the farm to the grocery store. That is NOT true. Each point in the supply chain only needs to focus on all the information related to that food as it passes through the supply chain.

CTEs Required to Maintain KDEs

CTEs Required to Provide KDEs

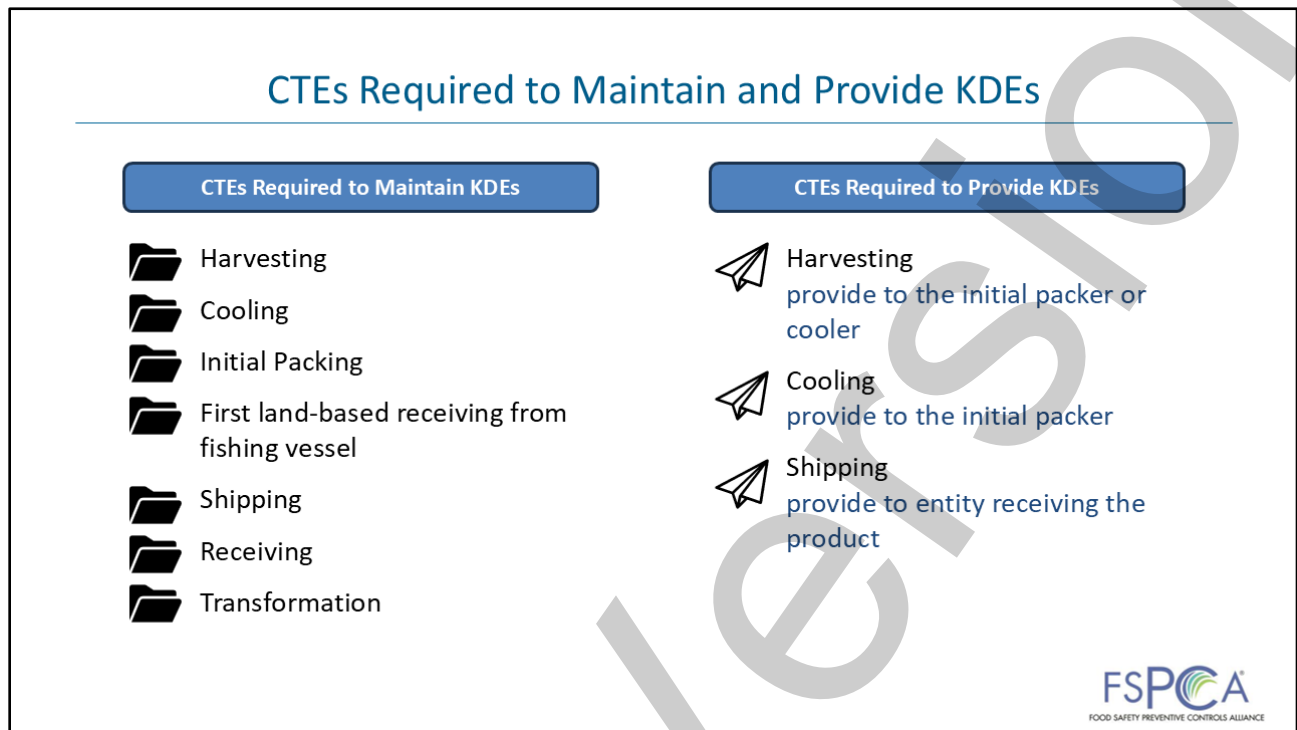


The FTR facilitates traceback by requiring that traceability information is maintained and provided along the supply chain. You must keep records of KDEs for each of the CTEs you perform. Some of these CTEs will also require you to receive KDEs from your suppliers, or to pass along to your customers.

There is a misconception that you have to pass along all the information you receive, from the farm to the grocery store. That is NOT true. Each point in the supply chain only needs to focus on the required information.

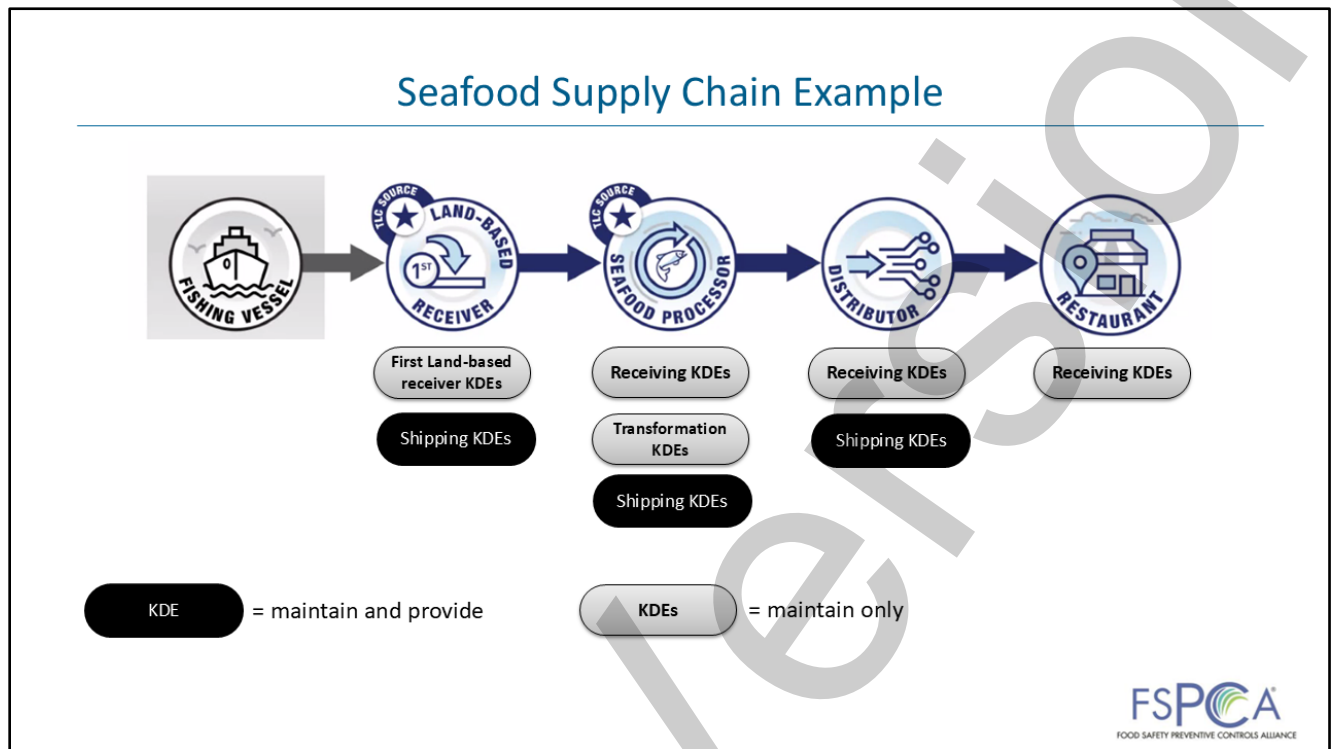
While trading partners need to exchange data, the data flow does not need to follow the product flow in all cases.

Slide 33: CTEs Required to Maintain and Provide KDEs



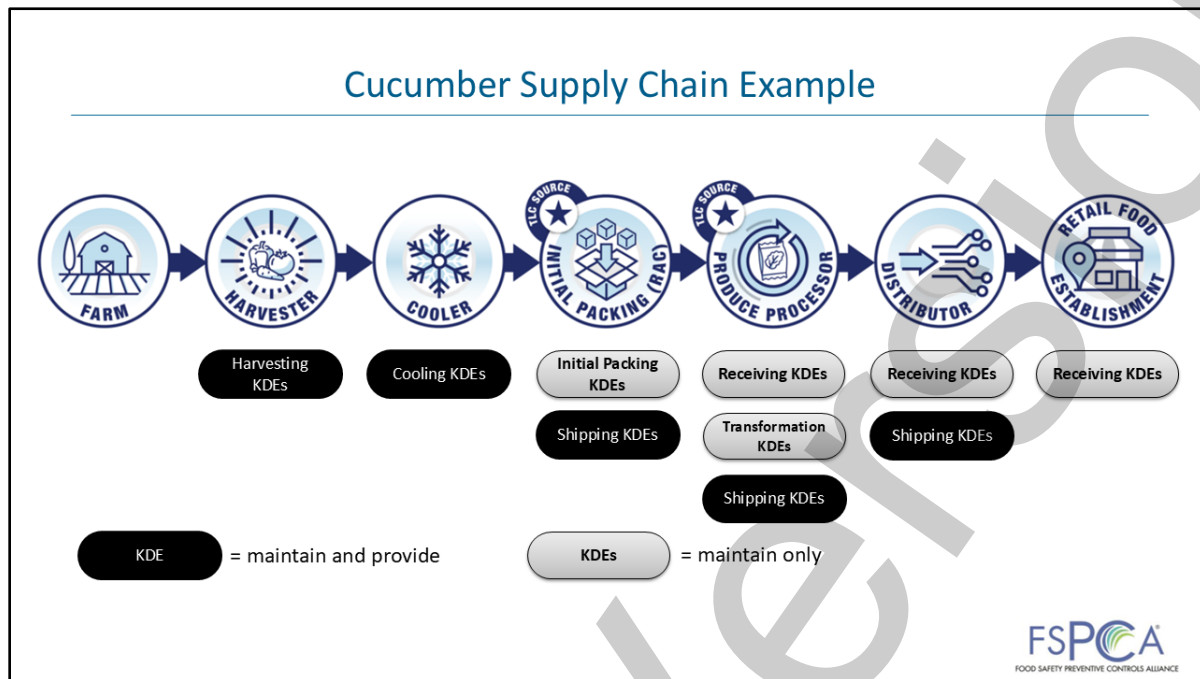
If you are performing Harvesting, Cooling, or Shipping CTEs, you are required to provide your KDEs to the next point in the supply chain. All CTEs are required to maintain required KDEs.

Slide 34: Seafood Supply Chain Example



Review the seafood supply chain example and note the CTEs that occur at each step in this supply chain. The black shapes denote steps in the supply chain where KDEs need to be maintained and provided, and the grey shapes are KDEs that only need to be maintained.

Slide 35: Cucumber Supply Chain Example



Review this cucumber supply chain and discuss your observations during the class discussion.

A few things to note about this supply chain example:

- In contrast to the seafood example, produce commodities on the FTL will require Harvesting and Cooling KDEs to be both maintained and provided. Harvesting and Cooling KDEs must be shared with the entity doing the initial packing, but the rule provides flexibility in how that is done.
- Harvesters and coolers can provide the required KDEs to the initial packer either directly or have another entity in the supply chain, such as the farm where the RAC was grown, a third-party entity directing the movement of the RAC, or a supply chain partner who will handle the food before it reaches the initial packer, provide the information to the initial packer.
- Since Harvesting and Cooling happen before the TLC is assigned, the initial packer is not required to maintain Receiving KDEs.

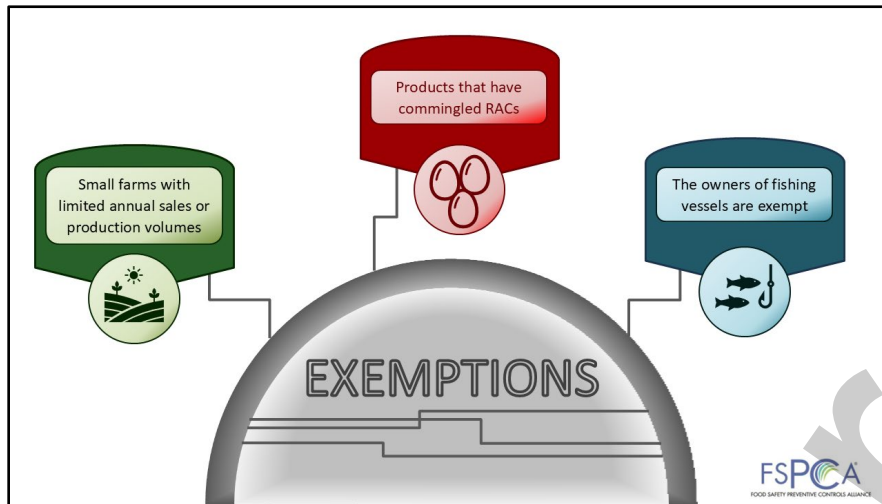
Slide 36: Section Four

Section 4

WHAT ACTIONS TO TAKE WHEN EXEMPTIONS TO THE RULE AFFECT KDEs RECEIVED?



Slide 37: Exemptions That May Impact KDEs Received



Exemptions to the FTR may vary depending on the specific regulations and requirements applicable to different segments of the food industry. However, exemptions that may impact KDEs received include:

1. Small farms with limited annual sales or production volumes
2. Products that have commingled RACs (this exemption does not apply to produce covered under 21 CFR Part 112)
3. Owners of fishing vessels

Slide 38: Additional Exemptions

Additional Exemptions	
Exemption	Action
If the entity who ships a product is exempt	The food will not have Shipping KDEs, including the TLC. The receiver assigns the TLC (plus maintains other receiving KDEs).
If the food is exempt	The food remains exempt and no KDEs need to be maintained/assigned.
Commingled RACs (seafood and eggs)	The receiver maintains records identifying the source of the RACs and the subsequent KDEs
Fishing vessels	The receiver maintains records identifying the source of the RACs and the subsequent KDEs



If the **entity** is exempt from the FTR, they are not required to provide KDEs for food they ship; this includes the TLC. In this case, the receiver must assign the TLC and maintain other Receiving KDEs. The required KDEs start at this point, and the receiver is not required to get additional information from their exempt supplier.

Note: Normally only Initial Packing, Transformation and First Land-Based Receiver (of food obtained from a fishing vessel) CTEs assign a TLC but if there are entity exemptions, then a receiver must assign a TLC.

If the **food** is exempt from the FTR, then the food remains exempt and no KDEs need to be maintained/assigned unless the food is transformed back into an FTL food.

Another exemption that impacts KDEs is the partial exemption for certain commingled RACs. In this instance, the entity must maintain records identifying the immediate previous source of the RAC and the immediate subsequent recipient. This exemption applies to eggs and seafood and **does not** apply to produce that is covered by the Produce Safety Rule.

Supplemental information on commingled RACs and fishing vessels:

With respect to a commingled RAC that qualifies for either of the exemptions set forth in § 1.1305 (h)(1) and (2) of the FTR, "if a person who manufactures, processes, packs, or holds such commodity is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable raw agricultural commodity, such person must maintain records identifying the immediate previous source of such raw agricultural commodity and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345."

Slide 39: Entity- and Product-Related Exemption Examples

Entity- and Product-Related Exemption Examples

Example One
(entity-related)

A fishing vessel catches Alaska pollock



This Photo by Unknown Author is licensed under CC BY

Example Two
(product related)

A seafood processor receives a batch of commingled fish



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Entity-related:

Example: A fishing vessel catches Alaska pollock. As long as the fishing vessel owner also owns the pollock, the fish stays exempt. Once they sell it, however, they no longer own the fish and the next step in the supply chain is responsible for the KDEs. The receiver must assign a TLC but is NOT required to find out where and when the fish was harvested.

Product-related:

Example: A seafood processor receives a batch of fish from various fishing vessels (a commingled RAC – a partial exemption). When they start processing the fish, it is no longer a RAC and the FTR applies. After processing the fish into fillets (Transformation), the seafood processor would maintain the Transformation KDEs.

Slide 40: Why Didn't You Receive KDEs?

Why Didn't You Receive KDEs?

- Class discussion
- You did not receive KDEs from your supplier for a food on the FTL
- Think of three reasons for not receiving KDEs
- Share your thoughts with the class



What do you do when your company does not receive KDEs from your supplier for a food on the FTL?

- Your supplier did not send the KDEs you were expecting. What are possible reasons for this?
- What do you do if your supplier does not provide KDEs (when they are supposed to)?

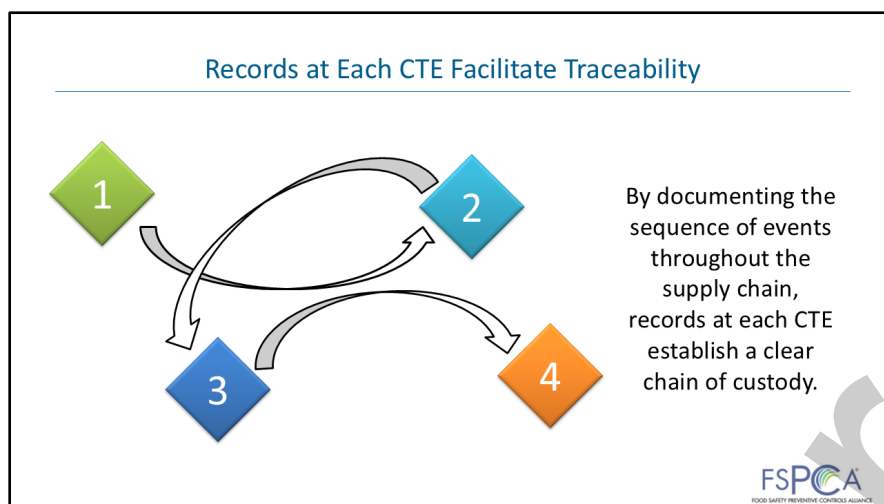
Slide 41: Section Five

Section 5

RECORDS AT EACH CTE FACILITATE TRACEABILITY



Slide 42: Records at Each CTE Facilitate Traceability



Records associated with CTEs play a fundamental role in facilitating traceability throughout the food supply chain. One function they play is to establish the chain of custody of a FTL product.

We are using the phrase “chain of custody” to refer to the sequence of possession of food and associated records through the supply chain.

By documenting the sequence of events from the point of origin for food products to the final destination, records at each CTE can be used to establish a clear chain of custody. This chain of custody provides a chronological record of product movement, enabling the FDA to trace food through the supply chain when needed. Note that traceability is based on physical location, not just ownership.

Overall, records (i.e., KDEs) at each CTE serve as the foundation for an effective traceability system in the food supply chain. Documenting key information and establishing chain of custody enable rapid information retrieval, supports regulatory compliance, facilitates recall management, enhances supply chain visibility, and supports quality assurance. These records play vital roles in safeguarding public health and maintaining consumer trust in the safety and integrity of the food supply chain.

Slide 43: The Snack Box

The Snack Box

- Small group activity
- Read the journey of each ingredient in the snack box
- Identify what CTEs were performed for each item



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The purpose of this activity is to pull all the discussion about CTEs and KDEs together and to think critically about how they interact with each other. The context is a complex snack box that contains multiple FTL foods as ingredients. Note that not all ingredients in the snack box are on the FTL, so we need to correctly identify which are.

	The Snack Box
Activity	Small group reading and analysis activity.
Objectives	Correlate FTL foods and CTEs.
Time	20 min
Materials	• Participant Manual
Directions to Participants	• Read through the given situation for your assigned food and its path to the snack box. • Collaboratively determine what foods are on the FTL, and what CTEs apply to each point in the supply chain for your assigned food. • Write out your answers and be prepared to share with the class.
Breakout	Groups of 3-5 participants
Summary	Review assigned foods in the snack box product and identify what CTEs are associated with that food.
Key Learnings	• Identify what foods are on the FTL and what associated CTEs are performed before they reach the customer.

EG Foods is expanding its product line to a refrigerated, multi-component snack box that will be available in retail stores and airport restaurants. The box has an egg salad sandwich (including celery, lettuce, and sprouts) and soft cheese cubes.

Work collaboratively with your team. For each assigned ingredient in the snack box, read its journey and identify what CTEs were performed between the time a TLC was initially assigned and the time it reached its customer.

Table 3-4: Snack box activity. For each assigned ingredient in the snack box identify what CTEs were performed.

If you need any further detail to make a decision, consult the FTL.

Food in the Snack Box	FTL?	CTEs in the Supply Chain
Shredded lettuce: Supply chain: Whole-head iceberg lettuce is grown and harvested by Acme Farms and is cooled and packed at Pick-A-Name Cooling, LLC. The lettuce is sent to Leticia's Lettuce Processing where it is shredded, packaged, and sent to Jen's Distribution Center. From there, it is sent to restaurants, retail stores, and EG Foods.	Yes	- Acme Farms: harvesting - Pick-A-Name: cooling, initial packing, shipping - Leticia's Lettuce: receiving, transformation, shipping - Jen's Distribution: receiving, shipping - EG Foods: receiving
Egg: Supply chain: Hilary's Egg Farm has a flock of laying hens. It collects, washes, packs, and then cools the eggs before shipping them to EG Foods via cross-docking at Jen's Distribution Center. Note that Hilary's Egg Farm has more than 3,000 laying hens.		
Biscuit: Supply chain: Flaky Co. manufacturers buttermilk biscuits and ships them directly to the EG Food Company.		
Celery: Supply chain: Celery is grown and harvested by Acme Farms and is cooled at Pick-A-Name Cooling, LLC. It is sent to Chad's Chopping, where it is chopped, packaged, and sent to Jen's Distribution Center. From there, it is sent to restaurants, retail stores, and EG Foods.		

Chapter 3

Sprouts Sprouts are grown at Happy Sprouts, a local company that mainly sells at Farmers Markets, with annual revenue of \$80,000. They ship directly to EG Foods.		
Mayonnaise: Supply chain: Myers Mayonnaise manufactures the mayonnaise product using eggs, vinegar, and oil, and packages it in jars. It ships to EG Foods via a broker.		
Monterrey Jack and Muenster Cheese: Supply chain: Rockwell Dairy Farm produces milk that is shipped to Porter Cheese Company, where it is used in producing both Monterrey Jack and Muenster cheeses. After the cheeses are produced, they are cut into cubes, placed in bags, and shipped to EG Foods.		
Snack box: Supply chain: EG Foods boils, cools, shells, and chops the eggs, and immediately combines the eggs with celery, sprouts, mayonnaise, and seasonings to produce the egg salad. Egg salad is refrigerated for up to 24 hours. The egg salad sandwich is made by combining the prepared egg salad with the biscuit and topping it with the shredded lettuce. The sandwich is placed in the snack box with the cheese cubes and sealed. It is sent to a retail distribution center that ships directly to its retail stores, and to a food service distributor that delivers the snack boxes to one airport location and three convenience stores.		

Notes:

Lined area for notes.

Chapter 3

Notes:

Public Version

Notes:

Lined area for notes.

Slide 44: Summary

Chapter 3: Summary

- There are various Critical Tracking Events (CTEs) in the supply chain, and Key Data Elements (KDEs) must be recorded for each CTE
- KDEs are dependent on the CTE
- Of the KDEs that are maintained, some are provided to the next step in the supply chain
- Exemptions that apply to one supply chain member may impact the requirements on another
- Records at each CTE facilitate traceability



Slide 45: Questions

**Thank you for your
participation!**

What questions
do you have?



Chapter 4: Traceability Plan Requirements

Slide 1: Chapter Four



Slide 2: Goals and Learning Objectives

Chapter 4: Goal and Objectives

Goal: Identify the components of a written Traceability Plan.

Learning Objectives:

By the end of this chapter, participants will be able to:

- Describe the identification of foods handled on the FTL.
- Describe the assignment of Traceability Lot Codes to foods on the FTL.
- Recognize the requirements of a farm map for each growing area for foods on the FTL.
- Describe how Traceability Plans are updated.
- Describe how required records are maintained.
- Identify a point of contact for questions on the Traceability Plan and associated records.

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The FTR requires each covered entity to keep and maintain a Traceability Plan, so in this chapter, we look at what the Traceability Plan is, and what the required elements are.

Chapter 4

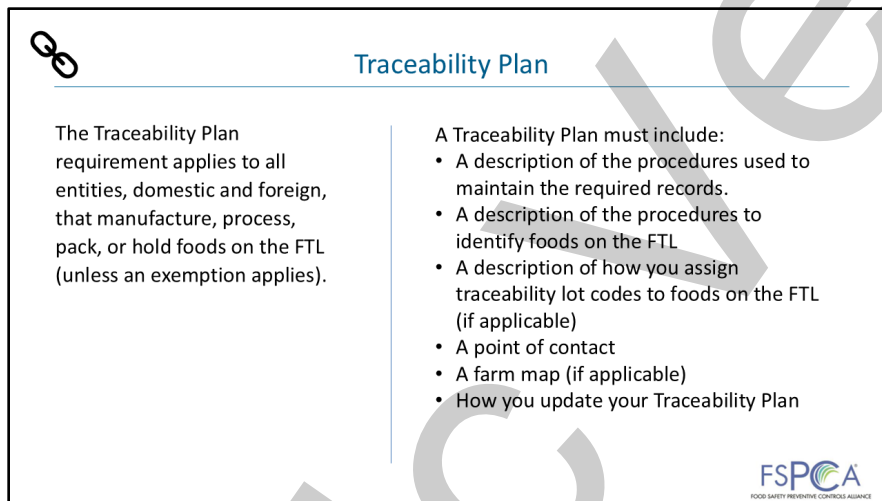
Goal: Identify the components of a written Traceability Plan.

Learning Objectives:

By the end of this chapter, participants will be able to:

- Describe the identification of foods handled on the FTL.
- Describe the assignment of Traceability Lot Codes to foods on the FTL.
- Recognize the requirements of a farm map for each growing area for foods on the FTL.
- Describe how Traceability Plans are updated.
- Describe how required records are maintained.
- Identify a point of contact for questions on the Traceability Plan and associated records.

Slide 3: Traceability Plan



Traceability Plan

The Traceability Plan requirement applies to all entities, domestic and foreign, that manufacture, process, pack, or hold foods on the FTL (unless an exemption applies).

A Traceability Plan must include:

- A description of the procedures used to maintain the required records.
- A description of the procedures to identify foods on the FTL
- A description of how you assign traceability lot codes to foods on the FTL (if applicable)
- A point of contact
- A farm map (if applicable)
- How you update your Traceability Plan

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Point of Contact: A designated individual or role included in a firm's traceability plan for questions regarding the plan and records from FDA or state regulators.

The Traceability Plan serves as an operational guide for the FDA about a firm's procedures for complying with the FTR.

The Traceability Plan requirement applies to all entities, domestic and foreign, that manufacture, process, pack, or hold foods on the FTL (unless an exemption applies). Thus, foreign exporters and other firms that manufacture, process, pack, or hold FTL foods would be required to maintain a traceability plan for food imported to the U.S.

A firm with a *partial exemption* from the FTR must maintain a Traceability Plan.

The FTR requires that the Traceability Plan must contain:

- A description of the **procedures you use to maintain the required records**, including the format and location of the records
- A description of the **procedures you use to identify foods on the FTL** that you manufacture, process, pack or hold
- A description of **how you assign Traceability Lot Codes** to foods on the FTL, if applicable
- A statement identifying a **point of contact** for questions regarding your traceability plan and records

- If you grow or raise a food on the FTL, **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 FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area
- A procedure to **update your Traceability Plan** as needed

Entities subject to the FTR are not required to have separate plans for each FTL food they handle; instead, they can have a single plan that covers all FTL foods they handle, provided that the plan describes the procedures used to maintain the records required to be kept for all such foods.

This also applies to entities with multiple locations (for example, a restaurant chain). If the required information is consistent across all locations, a chain could maintain a single Traceability Plan that applies to some or all locations, as long as the application of the plan to multiple locations is made clear. Even if some of the required information differs by location, the single document could clarify the information applying to a particular location. For example, if a different statement for identifying the point of contact is necessary for each location, the statements could be included in a single Traceability Plan used across the chain, or a customized Traceability Plan could be created for each location.

Slide 4: Section One

Section 1

IDENTIFY FTL FOODS



Slide 5: The Food Traceability List

The Food Traceability List (FTL)

-  The FTL is a specific **list of foods** the FDA designates as requiring additional recordkeeping under the FTR.
-  You are **responsible** for identifying foods on the FTL that you manufacture, process, pack, or hold.
-  You need to look at your **foods and ingredients** to determine which are on the FTL and must be compliant with the FTR.

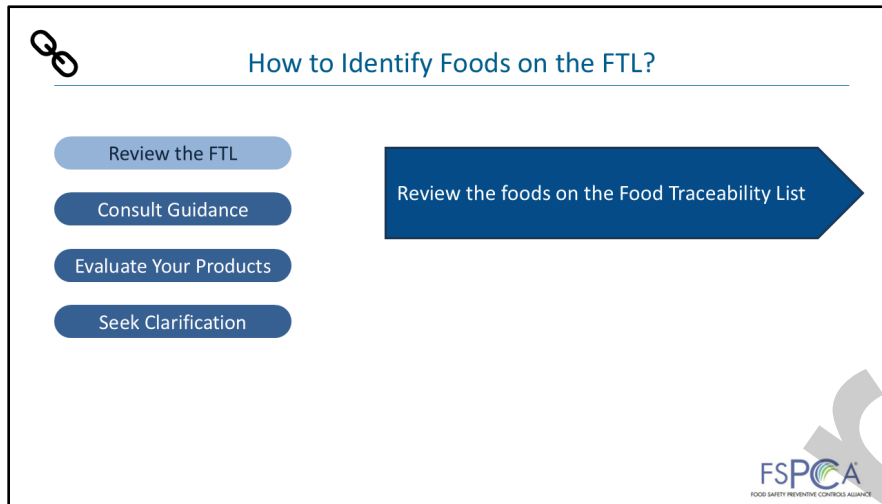


Part of complying with the FTR is familiarity with the FTL. As a reminder, the FTL is a specific list of foods the FDA designates as requiring additional recordkeeping under the FTR.

The FDA used established criteria to designate foods that have additional traceability requirements. You are responsible for identifying foods on the FTL that you manufacture, process, pack, or hold.

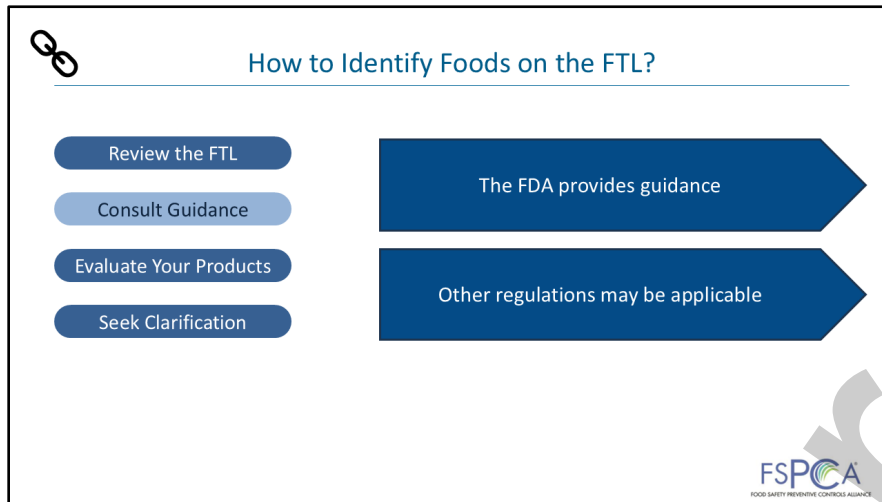
Covered entities need to look at their foods and the ingredients in those foods to determine which are on the FTL and must be compliant with the FTR. For example, both peanut butter and a granola bar that *contains* peanut butter (where no kill step is applied), would be on the FTL.

Slide 6: How to Identify Foods on the FTL? (Review the FTL)



Review the FDA Food Traceability List. If you have questions about whether your foods are on the FTL, you can consult guidance or the FDA Technical Assistance Network (TAN).

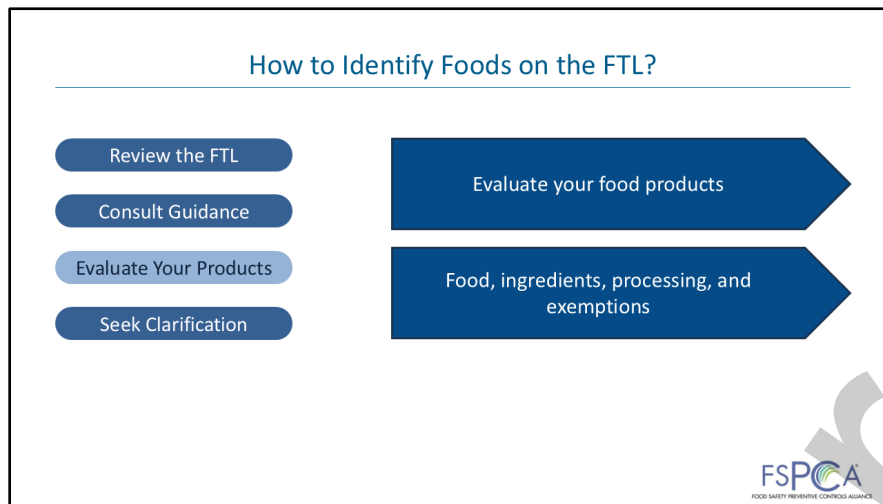
Slide 7: How to Identify Foods on the FTL? (Consult Guidance)



Consult Guidance Documents:

- The FDA guidance documents and resources may help industry stakeholders determine whether their products are within the scope of the FTR. Two examples of guidance documents are:
 - Fish and Fishery Products Hazards and Controls Guidance (Chapter 3)
 - Draft Guidance for Industry: Classification of Activities for Farms and Facilities

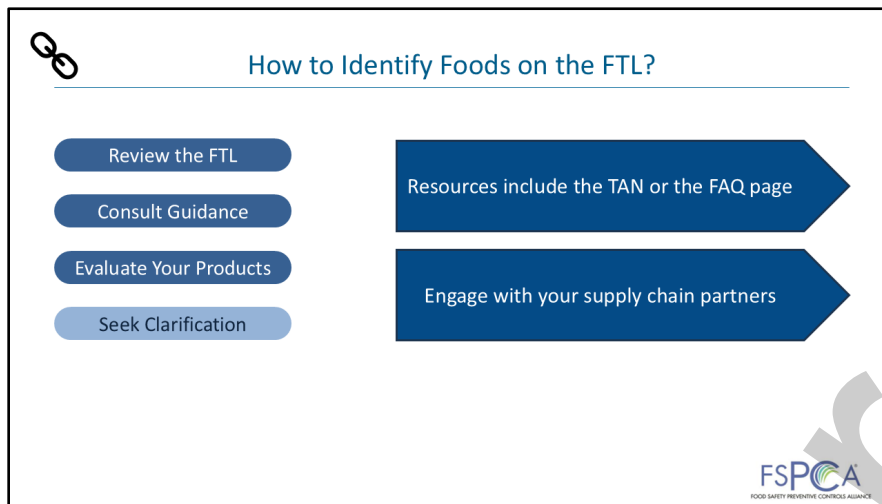
Slide 8: How to Identify Foods on the FTL? (Evaluate Your Products)



Evaluate Your Products:

- Evaluate or determine whether the products your operation manufactures, processes, packs, or holds are on the FTL.
- Consider the type of food product, its ingredients, and processing methods:
 - Does processing change the form of the food?
 - Is a kill step applied?
Remember our example of peanut butter being in granola bars? If the peanut butter were processed such that it was cooked into the granola bars, this would be considered a kill step, and this food would no longer be on the FTL. This is different from just adding peanut butter to the top of the granola bar, in which case the food is still on the FTL.
- Determine if an exemption applies (as discussed in Chapter 2).

Slide 9: How to Identify Foods on the FTL? (Seek Clarification)



Seek Clarification if Needed:

- If you're unsure whether your products are on the FTL, consider asking industry experts, consultants, or upstream suppliers who have handled or transformed them; or consider reaching out to the FDA for clarification.
 - Reach out to the FSMA TAN (Food Safety Modernization Act Technical Assistance Network). Use the form to submit questions.
 - Refer to the FTR FAQ page for responses to common questions.
- It is important to engage with your supplier to determine whether the product is on the FTL. Suppliers are experts in the products they produce, and as such are well equipped to address specific questions.

Slide 10: How to Identify Foods on the FTL? (Summary)

How to Identify Foods on the FTL?

- Review the FTL
- Consult Guidance
- Evaluate Your Products
- Seek Clarification

To oversimplify, look at the FTL. If your food is there, you are covered.

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The Traceability Plan needs to explain how you determine what is on the FTL but it does not need to list all FTL foods that are handled.

To put it simply, Check the FTL. If your food is there, it is covered by the FTR.

In some cases, simply looking at the FTL may not be sufficient. A retail grocery store, for example, may handle 10,000 food items on the FTL. While single-ingredient foods are easy to identify, multi-ingredient foods are not. The latter requires in-depth review and evaluation of each food and its ingredients.

Overall, there are many options to find out what is on the FTL. Your Traceability Plan needs to explain which of these you use and how you use them.

Slide 11: FoodDistro Co. Case Study

FoodDistro Co. Case Study

- Individual activity
- Look at the FoodDistro case study in the context of how they identify foods on the FTL
- Describe the process of identifying foods on the FTL as if you were FoodDistro Co.
- Be prepared to discuss your process with the class



Read the FoodDistro Co. case study:

FoodDistro Co. is a leading food distribution company specializing in supplying fresh produce and perishable goods to grocery retailers and restaurants across the United States.

FoodDistro consults the FTL on FDA's website to identify which food products they distribute are covered by the FTR. FoodDistro regularly reviews the FTL to ensure they are aware of any changes to the foods included on the FTL; they also review the FTL when they introduce any new food products.

FoodDistro works with their supply chain partners so they can identify foods on the FTL. They have thousands of items shipping to their customers' stores that may be on the FTL. By working with their suppliers, they are better able to identify foods that come into their facilities. They are able to verify what foods are on the FTL and have traceability requirements under the FTR.

Question: If you were FoodDistro, and you were tasked with writing the Traceability Plan for your company, what description would you include of HOW you identify which foods you handle on the FTL?

Answer:

Slide 12: Section Two



Slide 13: Traceability Lot Codes



Traceability Lot Codes

- Traceability Lot Code (TLC) means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the Traceability Lot Code source.
- The FTR requires regulated entities to document Traceability Lot Codes but does not stipulate *how* Traceability Lot Codes are created or assigned.
- Note that *smaller* traceability lots might lead to less food being affected in the event of a recall or other regulatory action.

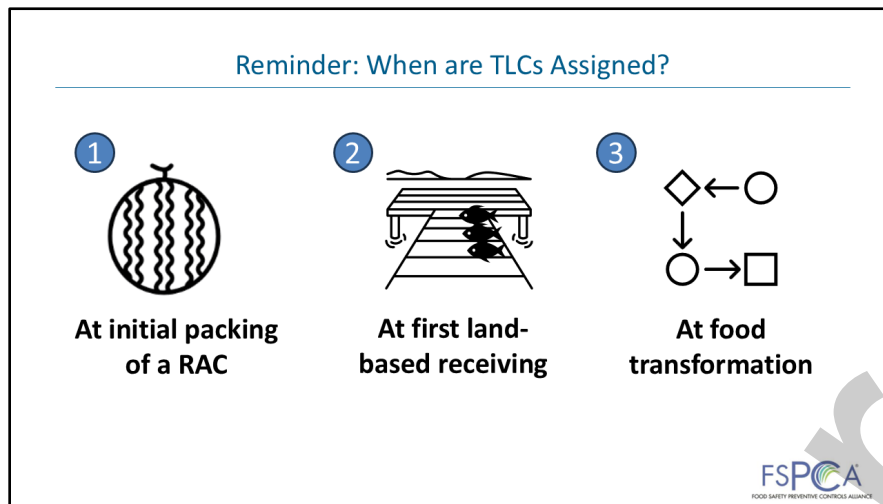


A TLC is a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the TLC source.

The FTR does not prescribe a specific way regulated entities must define a traceability lot; rather, it provides covered entities with flexibility in how they determine what constitutes one. We note that traceability lots with smaller product quantities per lot might lead to less food being affected in a recall or other regulatory action.

The FTR requires covered entities to document TLCs but does not stipulate **how** TLCs are created or assigned.

Slide 14: Reminder: When are TLCs Assigned



If you receive a shipment of FTL food from an exempt entity that does not already have a TLC, you are responsible for assigning a TLC yourself. This does not apply to RFEs, such as grocery stores, convenience stores, or to restaurants.

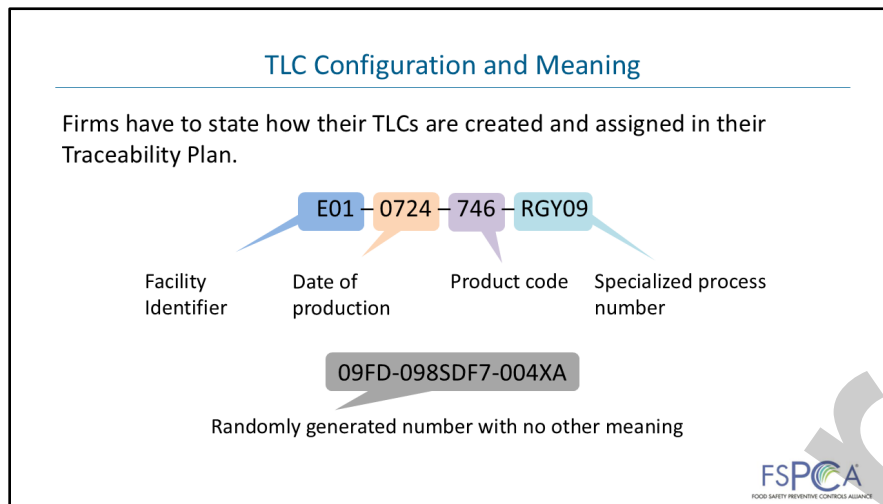
As a reminder, you must assign a TLC when you do any of the following:

- Initially pack a raw agricultural commodity (RAC) other than a food obtained from a fishing vessel
- Perform the first land-based receiving of a food obtained from a fishing vessel
- Transform a food

When shipping the food, the entity must send, either in writing or electronically, the TLC assigned by the TLC Source.

In addition to a TLC, some entities assign their own internal lot codes to track food products within their systems. Internal lot codes may have the TLC embedded in them. In such a case, an entity would maintain its internal lot code as well as the TLC assigned by the TLC Source. You may still keep internal lot codes, but you still have to maintain and provide the assigned TLC to your customer.

Slide 15: TLC Configuration and Meaning



TLCs may contain helpful information such as production information or production dates. Some entities use those as their lot codes. The FDA uses that information in its food safety investigations.

An entity's Traceability Plan must state how their TLCs are created and assigned, if applicable. The Traceability Plan should describe how any information is encoded in a TLC so the FDA can understand it. A Traceability Plan should describe what the numbers mean and how unique numbers are differentiated. If TLCs contain no encoded information, a Traceability Plan should indicate it.

More examples:

Lot code: 001-1225-65: 001 is the facility number for the location in Ohio, 1225 is the production date of December 2025, and 65 is company code for that product.

OR

Lot code: 788g0gghbre: a random number with no meaning. This is perfectly acceptable as long as it is a unique TLC and differentiates this lot from all others.

Ask yourself these questions as you create your organization's Traceability Plan and describe your TLCs:

- Are my lot codes issued differently based on the location?
- Do my lot codes include a date and/or time of manufacture? Or issued based on different dates and/or times?
- Do my lot codes include references to the type of food/product?
- Do my lot codes include a best-by, sell-by, expiration, or other shelf-life date?
- Do my lot codes include any other descriptive information?

Slide 16: Section Three



Slide 17: Farm Map Requirements

Farm Map Requirements

- A farm's Traceability Plan must include a farm map
- A farm map can be a one-time action or a continuous effort
- A farm map helps FDA investigators during investigations



The FTR specifies that if an entity grows or raises a food on the FTL (other than eggs), its Traceability Plan must include a farm map showing the area in which the food is grown or raised. Only a farm has to keep a farm map; this does not apply to other CTEs.

Additional information, such as adjacent road names or other landmarks, can help position the farm in its geographic area and provide a better understanding of the farm and where foods are grown or raised than its physical location alone. That said, for small farms with only a few adjacent fields or containers, only one set of geographic coordinates may be sufficient.

Creating the farm map could be a one-time action unless the locations or names of fields or growing areas change.

During outbreak investigations, a farm map helps FDA investigators visualize how and where the food is grown, as well as identify geographic correlations when a single farm or field cannot be identified based on traceback analysis.

Farm maps can be digital or hand-drawn, as long as they contain the required information.

Slide 18: Specific Requirements

Specific requirements



For farms growing RACs (raw agricultural commodities) other than eggs, the farm map must show:

- The location and name of each field (or other growing area) in which you grow a food on the FTL, including geographic coordinates
- Any other information needed to identify the location of each field or growing area



For aquaculture farms, the farm map must show:

- The location and name of each container (e.g., pond, pool, tank, or cage) in which you raise seafood on the FTL, including geographic coordinates
- Any other information needed to identify the location of each container



For examples of farm maps, see Appendix 4: Farm Map Examples.

Specific requirements for different types of farms:

Farm maps must show the location and name of each field or other growing area for foods on the FTL. A farm may extend over a large area and each field may not have an address, so the map must show geographic coordinates and any other information needed to identify the locations.

“Other growing area” describes instances where a growing location is not a field; examples include indoor or outdoor growing operations such as sprouting operations, greenhouses, or hydroponic farms, and aquaculture harvest area. These types of operations may consist of multiple growing areas.

For farms growing RACs (other than eggs), the farm map must show:

- Location and name of each field (or other growing area) in which you grow a food on the FTL, including geographic coordinates
- Any other information needed to identify the location of each field or growing area

For aquaculture farms, the farm map must show:

- Location and name of each container (such as a pond, pool, tank, or cage) in which you raise seafood on the FTL, including geographic coordinates
- Any other information needed to identify the location of each container

Chapter 4

Presenting this information as a map versus a single set of geographic coordinates provides a greater level of specificity and visual perspective for each container on the farm, as well as a fuller context for understanding their sizes and locations.

Field or container names used by the grower or aquaculture farm should correspond to the KDEs maintained by the initial packer. The initial packer must use the farm's naming conventions for fields or containers.

Slide 19: Farm Map

Farm Map

- Small group activity
- Analyze the farm maps
- Compare them with the requirements for a farm map
- Determine which have any noncompliant details and identify what they are
- Be prepared to share your discoveries with the class



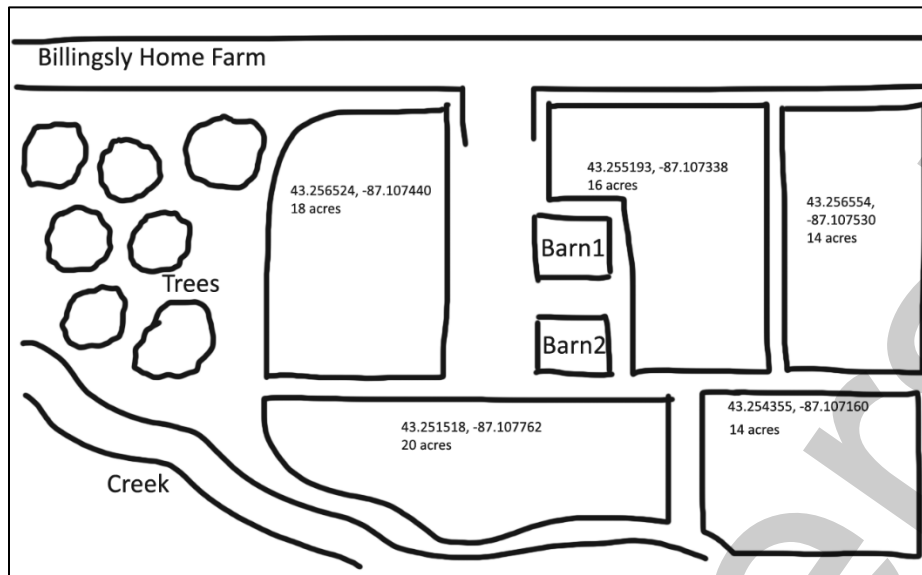
	Farm Map
Activity	Small group activity: evaluate sample farm maps and determine if they meet the requirements and if not, what they lack.
Objectives	To practice evaluating farm maps with regards to FTR requirements.
Time	Small group activity: 5 minutes Discussion/questions: 5 minutes
Materials	• Participant Manual
Directions to Participants	• Collaboratively review the two farm maps provided. • Determine which of them are compliant and identify what requirements are not met in those maps that are not compliant. • Be prepared to share your responses with the class.
Breakout	Teams of 3-5 participants

Traceability Plan Requirements

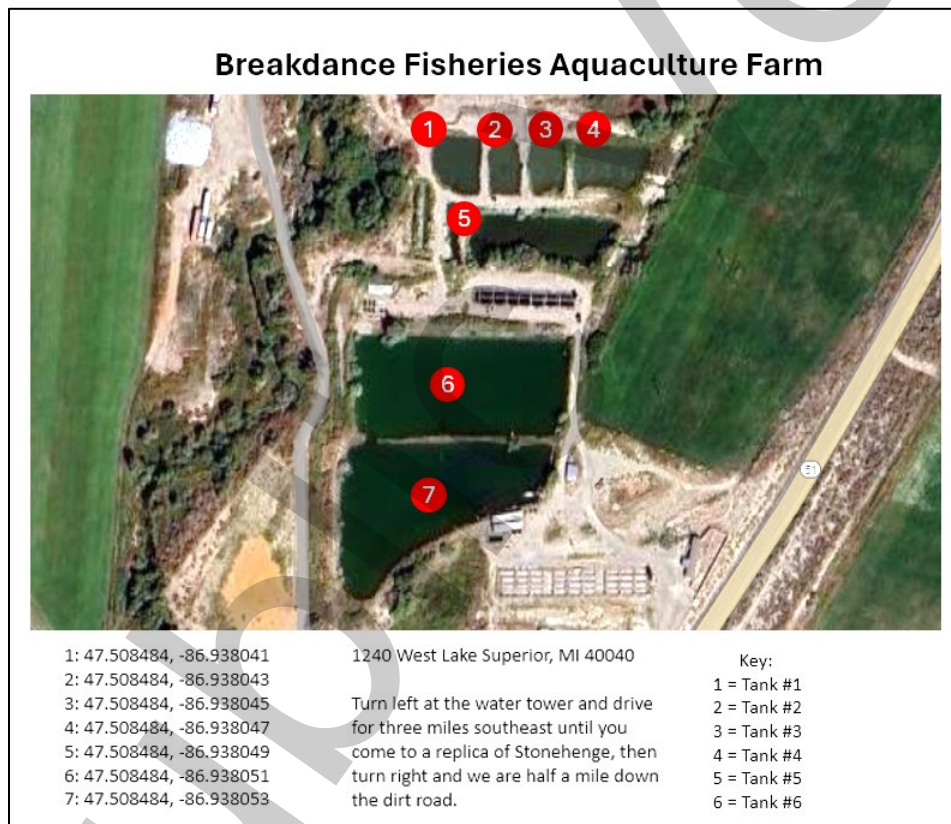
	Farm Map
Summary	Evaluate a set of farm maps to reinforce the principles of a compliant farm map.
Key Learnings	• The requirements of a farm map

Chapter 4

Map 1



Map 2



Slide 20: Section Four

Section 4

HOW TO MAINTAIN REQUIRED RECORDS



Slide 21: Record Maintenance

Record Maintenance

- Describe general recordkeeping procedures
- Describe receipt and storage of all relevant business documents



A covered entity's Traceability Plan must describe the general recordkeeping procedures it follows in meeting the FTR requirements, including the following:

- The **format** and **location** of the files, whether electronic or physical
- A description of the electronic process used to store files (if FTR records are electronic)
- A description of the receipt and storage of business documents as FTR records

Slide 22: Records Maintenance Examples

Records Maintenance Examples

- Harket Market uses a third-party administrator to maintain the records in a cloud-based database for electronic documents.
- Hamily Family Distribution uses a heavy metal filing cabinet with manilla folders marked with permanent marker labels to keep paper records.



Following are two acceptable ways of maintaining records:

- Harket Market uses a third-party administrator to maintain the records in a cloud-based database of electronic documents.
- Hamily Family Distribution uses a heavy metal filing cabinet with manila folders marked with permanent marker to keep paper records.

In addition to these requirements, you could include other records maintenance information in your Traceability Plan; for instance, some covered entities include abbreviations or master data. Such information may be helpful in meeting your traceability needs.

Slide 23: Master Data and Data Keys

Master Data and Data Keys

Some companies store data about transactions such as dates, quantities, units of measure, product IDs, and location IDs separate from the data that describes the products and locations

Transactional Data

Electronic Invoice #4505	
Location # 314	
<u>Product</u>	<u>Quantity</u>
Peanut butter	45
Fish	14
Sprouts	95
Chopped celery	112
Fresh salsa	54

Master Data

Loc. #	Location Name	Address	State
313	Monopoly Farms	123 Main Street	Iowa
314	F&Q Warehouse	456 Center Road	Nevada
315	Processing Plant #36	789 Peak Way	Florida



If your organization maintains traceability data using master data or abbreviations, it is important to provide those descriptions to FDA in the event of a request to help decipher your information.

21 CFR 1.1455 in the Rule.

Many firms maintain "master data" separately from their records of supply chain activities. This data describes products, companies, and locations which are repeatedly mentioned in other records. Some KDEs, such as location description, could be considered master data. Using a consistent code, such as a number, to represent master data is a way to avoid needing to write or enter the same address or product description countless times.

The example on this slide shows a foodservice distributor that uses a location number of #314 to represent a particular supplier on an invoice (a transactional record). The distributor's master data database would need to be consulted to determine that #314 corresponds to the address for F&Q Warehouse in Nevada.

Maintaining master data separately from transactional data is an acceptable method for FTR record maintenance. Providing master data and any associated data keys describing codes used in your documents and records is necessary to assist FDA in understanding the information captured in these documents during an investigation.

The information on how the codes used in master data are generated and what they mean could be kept in your Traceability Plan or provided in a separate document to FDA upon a records request.

Slide 24: Section Five

Section 5

**A POINT OF CONTACT FOR QUESTIONS ON THE
TRACEABILITY PLAN AND ASSOCIATED RECORDS**

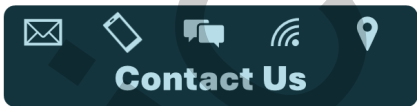


Slide 25: Point of Contact Requirements

Point of Contact Requirements

The FTR requires that a firm establishes a designated point of contact for FTR questions from FDA or state regulators in their Traceability Plan.

The plan could give a specific name, in which case the plan would need to be updated if that person were to take on different responsibilities; or it could be a job title or role along with a phone number.



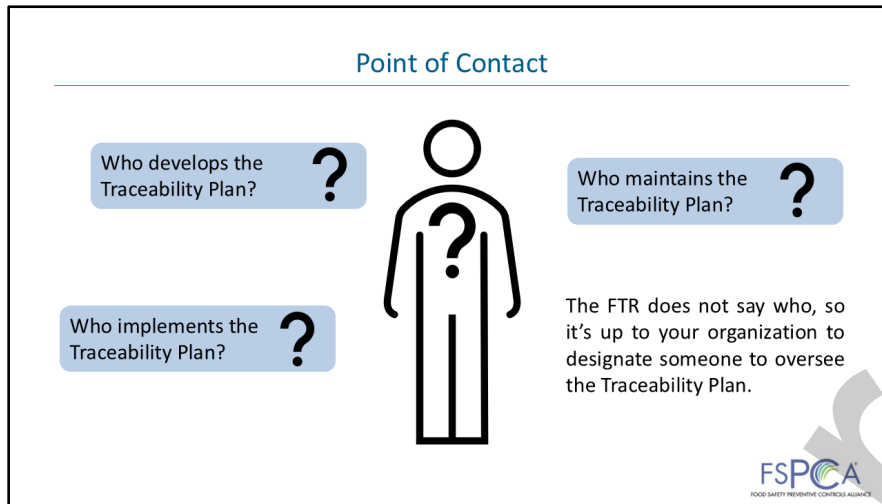
Contact Us



The FTR requires that a firm include in its Traceability Plan a designated point of contact for FTR questions from FDA or other regulators. The plan could mention the person by name; in which case it would need to be updated if that person were to take on different responsibilities or provide a job title or role along with a phone number.

Note: a generic number such as a corporate 1-800 number could be acceptable as long as FDA can call that number and be forwarded directly to the point of contact.

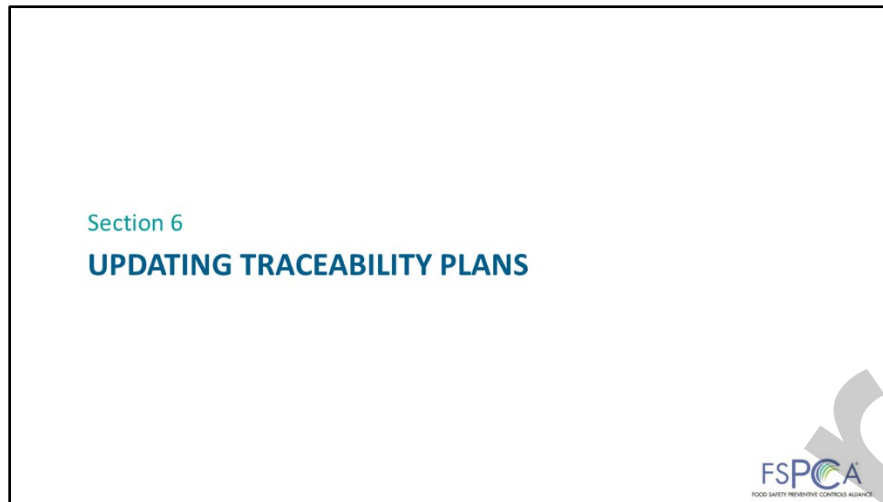
Slide 26: Point of Contact



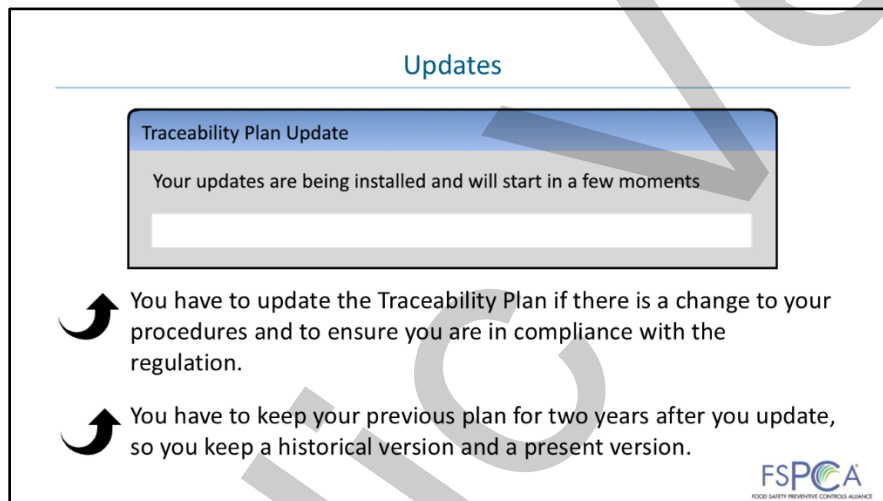
The FTR does not specify which members of an organization have responsibility for maintaining a Traceability Plan. However, within the organization, specific individuals or roles may be assigned to oversee the development, implementation, and maintenance of the Traceability Plan. These may include quality assurance personnel, food safety managers, or designated traceability coordinators responsible for ensuring the plan is up to date, effectively implemented, and followed throughout the organization.

Note that in the case of a food safety incident or other public health threat, the Traceability Plan point of contact must be able to be contacted outside of normal business hours.

Slide 27: Section Six



Slide 28: Updates



Update the Traceability Plan if your firm implements changes to its procedures and/or to ensure it is in compliance with the FTR.

Keep your previous plan for two years after any update, so you have both historical and current versions available.

Note that every version of the Traceability Plan must be kept for 2 years (even if there are multiple versions over two years).

The Traceability Plan may also include a description of how you update your plan.

Slide 29: Version Control

Version Control

Traceability Plan Example for Farms (continued)

Traceability Plan		Page 1 of 2
BUSINESS NAME:	Lizzie's Lettuce	ISSUE DATE: 01/01/2028
ADDRESS:	331 Laurel St, Carthage, CA 93313	SUPERSEDES: 01/20/2026

Procedures to Maintain the Records

Records of all required KDEs are captured and stored in our commercial software solution. Records are maintained for two years.

Hard copies of Bills of Lading are provided to subsequent recipients containing all KDEs except TLC/ TLC Source Reference, which is barcoded on product case labels. Some companies also receive digital advanced shipment notices containing all required KDEs.

Procedures to Identify FTL Foods

All products packed at this facility are on the FTL.

Assigning Traceability Lot Codes

Unique products/pack sizes are assigned a 14-digit case GS1 GTIN. Internal lot codes are assigned using date (MMDDYY) and packing line ("AAA" - "ZZZ"). Together the case GTIN and Internal Lot code represent our traceability lot code.


FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Version Control: A system for managing changes to a document, such as a traceability plan, over time, often including issued and supersedes dates to track the current and previous versions.

Note the Issue Date and Supersedes Date in the example plan on the slide. In this example, the newest version was issued in January of 2028 and replaces the previous version from January of 2026.

These dates help you determine that you have the most current or most relevant version and they let you know when two years have elapsed.

Slide 30: Traceability Plan Evaluation



Traceability Plan Evaluation

- Small group activity
- Look at the examples of Traceability Plans in your participant guide
- Determine if they are compliant and if not, what error is present?





	Traceability Plan Evaluation
Activity	Evaluate the two Traceability Plans for compliance with FTR requirements.
Objectives	Identify any noncompliant features of the sample Traceability Plans.
Time	10 minutes
Materials	Participant Manual
Directions to Participants	- Review the details of the provided sample Traceability Plans. - Collaborate on what you think is missing and what is adequate. - Be prepared to share your findings with the class.
Breakout	Breakout groups of 3-5 participants.
Summary	Evaluation activity where participants review two sample Traceability Plans and determine what is compliant and what is not.
Key Learnings	The specific requirements of an organization's Traceability Plan.

Review each sample Traceability Plan shown below and determine if the plan is compliant with the FTR or if the plan needs to be corrected.

Example 1: A farm that is a Grower and Initial Packer of an FTL commodity

Traceability Plan Example for Farms (§ 1.1315)



The purpose of this document is to help farms 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. Please note that for purposes of illustration, we have provided two examples of what a farm map could look like; however, the rule only requires one farm map (if applicable).

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.

Traceability Plan Example for Farms (continued)

Traceability Plan		Page 1 of 2	
BUSINESS NAME: Lizzie's Lettuce		ISSUE DATE	01/01/2028
ADDRESS: 331 Laurel St, Carthage, CA 33133		SUPERSEDES	01/20/2026

Procedures to Maintain the Records

Digital records of all required KDEs are captured and stored in our commercial software solution. Records are maintained for two years.

Hard copies of Bills of Lading are provided to subsequent recipients containing all KDEs except TLC/ TLC Source Reference, which is barcoded on product case labels. Some companies also receive digital advanced shipment notices containing all required KDEs.

Procedures to Identify FTL Foods

All products packed at this facility are on the FTL.

Assigning Traceability Lot Codes

Unique products/pack sizes are assigned a 14-digit case GS1 GTIN. Internal lot codes are assigned using date (MMDDYY) and packing line ("AAA" – "ZZZ"). Together the case GTIN and Internal Lot code represent our traceability lot code.

Point of Contact

Sarah Tree, Traceability Manager, 123-456-7899

Farm Map

See Appendix.

Traceability Plan Updates

This plan is reviewed annually as part of our management review of our food safety system, as well as whenever something changes in our traceability procedures. Each previous traceability plan is kept in a folder on SharePoint for at least two years after it is updated.

Example 2: Restaurant**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.

Chapter 4

Traceability Plan Example for Restaurants (continued)

Traceability Plan		Page 1 of 1
BUSINESS NAME: Sammy's Sandwich Shoppe	ISSUE DATE	01/01/2028
ADDRESS: 123 Main Street, Anytown, CA 12345	SUPERSEDES	01/20/2026

Procedures to Maintain the Records

Hard copies of Invoices and Bills of Lading are scanned and stored in an electronic filing system located on our local computer system. Digital advance shipment notices that have been received are also maintained in an electronic filing system located on our local computer system. Records are maintained for two years.

Assigning Traceability Lot Codes

We do not assign TLCs.

Point of Contact

Steve McGee, Manager, 456-789-1233

Traceability Plan Updates

This plan is reviewed annually as part of our management review of our food safety program, as well as whenever something changes in our traceability procedures. Each previous traceability plan is kept in a folder on our local computer system for at least two years after it is updated.

Public Version

Slide 31: Summary

Chapter 4: Summary

- The Traceability Plan indicates how foods on the FTL are identified
- The Traceability Plan communicates how Traceability Lot Codes are assigned to foods on the FTL, as applicable
- Farm maps are required in the Traceability Plan for farms growing FTL foods
- The Traceability Plan describes how required records are identified and maintained
- A point of contact for questions on the Traceability Plan and associated records must be identified
- The Traceability Plan must be current and available
 - Historical versions must be retained for 2 years



Slide 32: Questions

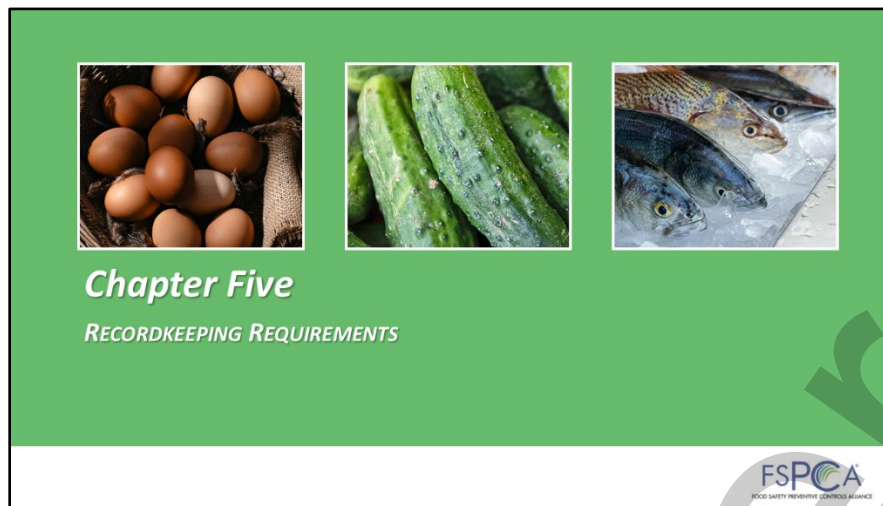
**Thank you for your
participation!**

**What questions
do you have?**



Chapter 5: Recordkeeping Requirements

Slide 1: Chapter 5



Slide 2: Goals and Learning Objectives

Chapter 5: Goal and Objectives

Goal: Explain the recordkeeping requirements of the rule.

Learning Objectives:

By the end of this chapter, participants will be able to:

- State how long records must be maintained
- Recognize that firms may use existing records to meet the requirements of the rule
- Examine ways to leverage existing traceability information
- Describe the situations in which FDA will request an electronic sortable spreadsheet
- Explain what elements are required on electronic sortable spreadsheets
- Explain the process to submit records to FDA

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Chapter Five discusses the recordkeeping requirements of the FTR and how a covered entity can fulfill them. Records are a major component of traceability, and your organization must get them right to be in compliance with the FTR.

Chapter 5

Goal: Explain the recordkeeping requirements of the rule.

Learning Objectives:

By the end of this chapter, participants will be able to:

- State how long records must be maintained
 - Recognize that firms may use existing records to meet the requirements of the rule
 - Examine ways to leverage existing traceability information
 - Describe the situations in which FDA will request an electronic sortable spreadsheet
 - Explain what elements are required on electronic sortable spreadsheets
 - Explain the process to submit records to FDA
-

Slide 3: Section One



Slide 4: Record Retention

Record Retention



How long should traceability records to be kept according to the FTR requirements?

TWO YEARS

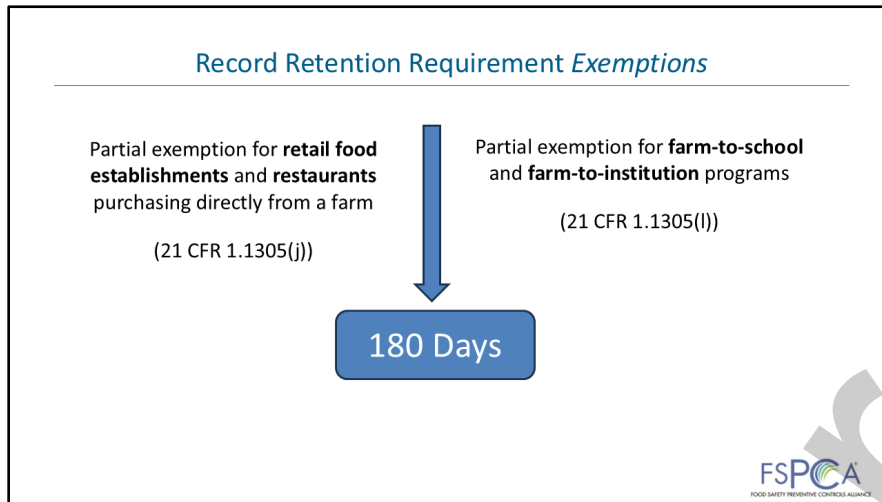


The FTR requires entities to keep various types of records.

All records must be maintained for two years, unless a partial exemption applies.

The recordkeeping requirement is 2 years from the date the CTE occurred.

Slide 5: Record Retention Requirement Exemptions



There are two partial exemptions in the rule that have a different timeframe for maintaining records.

- The first is a partial exemption for retail food establishments and restaurants purchasing directly from a farm (21 CFR 1.1305(j)).
- The second is a partial exemption for farm-to-school and farm-to-institution programs (21 CFR 1.1305(l)).

In both cases, the purchasing entity must maintain a record documenting the name and address of the farm that was the source of the food for 180 days.

Slide 6: Record Retention Justification



Record Retention Justification

Although a highly perishable food might pose a risk to consumers for only a few weeks, illnesses caused by a contaminated food can be linked retrospectively to past illnesses through whole genome sequencing (WGS) and other evidence months or even years after the food was sold.

Having access to traceability records for the food for up to 2 years after the records were created could greatly aid the FDA's investigation into an illness outbreak involving the food.

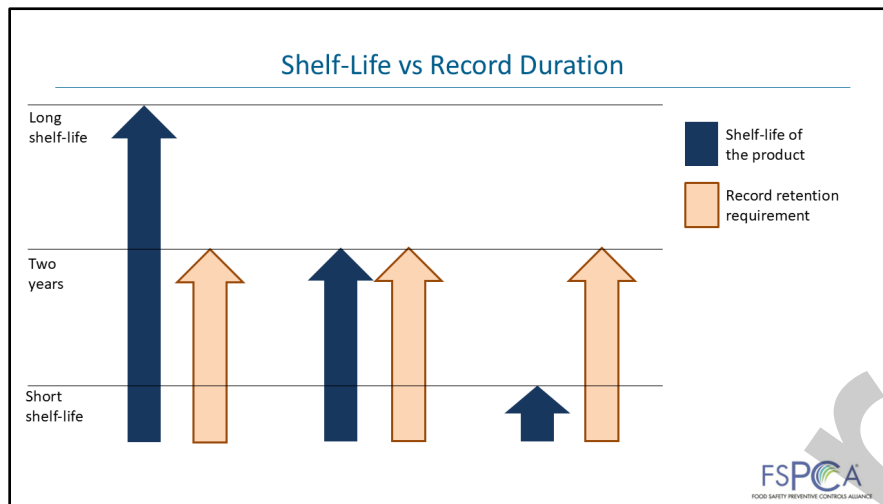
In particular, it could help the FDA determine whether a current foodborne illness outbreak was part of a long-standing contamination problem with a food or firm.



The text on the slide comes directly from the preamble to the FTR and addresses record retention duration.

Some foods, such as fresh produce or fresh seafood, have short shelf lives. Other products, such as peanut butter or frozen seafood, have longer shelf lives. The FTR requires establishments to maintain records for two years regardless of the type of FTL foods they produce or handle.

Slide 7: Shelf-Life vs Record Duration



This slide shows the shelf-life of a product in blue and the record retention duration in orange to demonstrate that while shelf-life may vary, the record retention duration is always the same, except in the case of a few exemptions.

Having access to traceability records for foods up to 2 years after the records were created could greatly aid outbreak investigations.

Although a highly perishable food might pose a risk to consumers for only a few weeks, current illnesses caused by a contaminated food can be linked to past illnesses through whole genome sequencing (WGS) and other evidence months or even years after that food was sold.

Access to these records could help determine whether a current foodborne illness outbreak was part of a long-standing contamination problem with a food or firm.

Slide 8: Section Two



Slide 9: Using Existing Records to Comply with the FTR

Using Existing Records to Comply with the FTR

-  Persons subject to the rule do not need to duplicate existing records
-  If a record contains the information required by the FTR, a covered person may supplement any such existing records
-  Persons do not have to keep all the information required by the FTR in one set of records
-  **The Traceability Plan** must indicate the format and location of the records the person is required to keep



Emphasize that regulated entities are not required to create unique records to meet the requirements of the FTR unless no such record currently exists. They may identify how the records they currently keep can be leveraged to meet those requirements.

Unlike other FSMA rules you may be familiar with, the FTR does not specify what records to keep, only what data to keep, so your company can use records that best match your company's needs and functions as long as the required information is there.

Companies may already have traceability systems in place, or have documents kept for other purposes that contain the required KDES. If records based on existing recordkeeping practices maintain the information required by the FTR, companies do not need to develop a new system or maintain duplicate records.

There is no requirement that the records be kept together as one set. Your Traceability Plan just needs to identify where the information is stored, so FDA can understand how your records are maintained.

Slide 10: Assessing Existing Records

Assessing Existing Records

The FTR says you can use records kept in the “ordinary course of business.”

- What records or documents used in the “ordinary course of business” may contain required KDEs?
- What KDEs would be found in such documents?

Companies should perform an assessment to identify which KDEs are being captured, where and any gaps.



For each CTE a company conducts, staff should map out what is required by the FTR and the records they currently use in their operations containing that information. Your company should perform an assessment of these records to identify which KDEs are being captured and in what documents. For KDEs that are not currently being captured, a procedure for maintaining these records will need to be implemented.

Write your answers to these questions and take notes on the class discussion:

What records or documents used in the “ordinary course of business” may contain required KDEs?

What KDEs would be found in such documents?

Public Version

Slide 11: Overlap with Other Regulations



Overlap with Other Regulations

The FTR requires covered firms to keep records on their application of a kill step. Kill steps must be documented in other regulations such as:

- Seafood HACCP (21 CFR Part 123)
- Preventive Controls for Human Food (21 CFR Part 117)
- LACF regulations (21 CFR Part 113)



The records covered entities already keep for other regulations may be used to meet the requirements of the FTR.

The FTR requires firms to keep records on their application of a kill step for purposes of the exemption in 21 CFR 1.1305(d)(3). Other regulations that may require a kill step include:

- Seafood HACCP (21 CFR Part 123)
- Preventive Controls for Human Food (21 CFR Part 117)
- LACF regulations (21 CFR Part 113)

Note that this is not an exhaustive list of regulations that could apply to FTL foods.

The regulations listed above require a record that a kill step has been applied. That same record can be used for the purpose of the FTR to show that the kill step was applied to take advantage of this exemption.

Examples of kill step records include:

- Cook log
- Pasteurization record
- Hot fill/hold record

Slide 12: Example

Example

Crock-o-Crackers

They keep a record of a kill step for Preventive Controls for Human Food. This same record could be used to comply with the FTR.





A simple example:

Crock-o-Crackers is applying a kill step to peanut butter by cooking it at a high temperature in their peanut butter cracker product. As part of its requirements under regulations related to Preventive Controls for Human Food, it keeps a production record that shows the kill step was applied. This same record could demonstrate the application of the kill step to satisfy requirements of the FTR for the exemption.

Slide 13: Keeping Records on Behalf of Someone Else



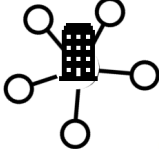
Keeping Records on Behalf of Someone Else

- The rule allows another entity to establish and maintain records on behalf of the covered entity
- The responsibility for ensuring the records can be retrieved and provided to FDA remains with the covered entity

Example One



Example Two





21 CFR 1.1455(b) enables another entity to establish and maintain records on your behalf; however, you are still responsible for getting those to the FDA within 24 hours.

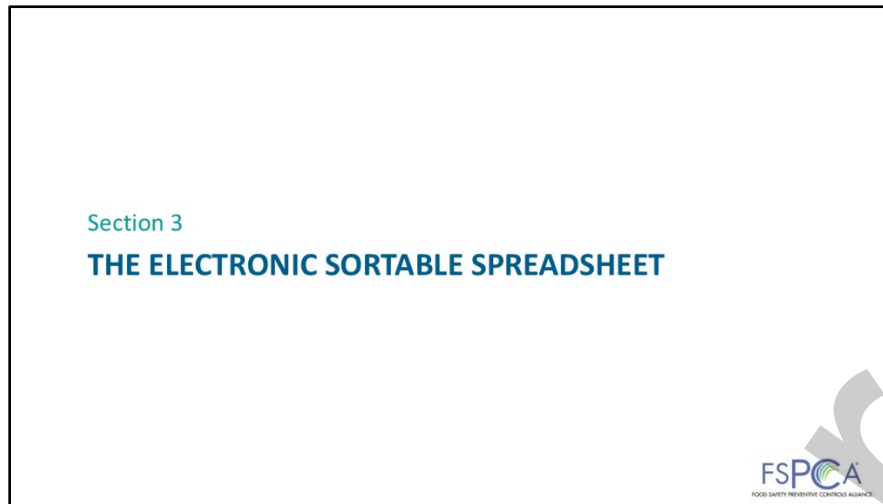
Example 1:

If a restaurant wanted a food service distributor to maintain its records, they would need to clearly discuss that expectation with the food service distributor. If a regulator requests records from the restaurant, the restaurant must be able to contact the distributor to get those records and provide them within 24 hours or another reasonable timeframe.

Example 2:

A centralized corporate headquarters could maintain records on behalf of its franchises or retail outlets, but the physical location (such as an individual franchise) is responsible for complying with a records request.

Slide 14: Section Three



Slide 15: Firm Records



During an outbreak investigation, FDA must review a firm's traceability records. When firms provide paper records, scanned PDFs, or photocopies, FDA personnel must manually review those records, which takes significant time. During a time-sensitive investigation, that may prolong the time it takes to identify and remove potentially contaminated products from the market.

Story:

Isaac, an investigator with a public health agency, is working on an ongoing *Salmonella* outbreak linked to almond butter. The owner of the grocery stores that sold the almond butter gives him a large volume of scanned PDFs that require a lot of time to review and interpret. Isaac must manually enter the information into a spreadsheet in order to effectively analyze the information. Even though Isaac creates an electronic sortable spreadsheet with the information as fast as he possibly

can, by the time he has a working document, more people could have been exposed to potentially contaminated almond butter that was still on the market.

This could have been prevented if he had immediate access to an electronic sortable spreadsheet. Under the FTR, the grocery store is required to compile the data requested into an electronic sortable spreadsheet within 24 hours (or a reasonable timeframe agreed upon by FDA) unless an exemption applies. This reduces the time the FDA must spend analyzing the information, which is critical during an outbreak investigation.

Electronic sortable spreadsheets can be more quickly analyzed than other documents or non-sortable spreadsheets, saving valuable time during an investigation.

Slide 16: When Will the FDA Request an Electronic Sortable Spreadsheet?

When Will the FDA Request an Electronic Sortable Spreadsheet?

- To help FDA prevent or mitigate a foodborne illness outbreak
- To aid FDA in the implementation of a recall
- To otherwise address a threat to the public health, such as:
 - Intentional adulteration
 - Bioterrorism events
 - Natural disaster
- FDA won't ask for an Electronic Sortable Spreadsheet during a routine inspection.



When will the FDA or another regulator request an electronic sortable spreadsheet? Per 21 CFR 1.1455(c)(3), situations in which an electronic sortable spreadsheet may be requested are:

- To help FDA prevent or mitigate a foodborne illness outbreak
- To aid FDA in the implementation of a recall
- To otherwise address a threat to public health

In these situations, the FDA will request records for the specific FTL foods that may be associated with the outbreak, recall, or other threat to public health. The FDA will not request all your traceability records for every food you handle.

Note: The FDA won't ask for an electronic sortable spreadsheet during a routine inspection.

Slide 17: Required Elements of the Electronic Sortable Spreadsheet

Required Elements of the Electronic Sortable Spreadsheet

- Must include ALL KDEs for the CTEs you perform based on FDA's request.
- FDA will provide parameters such as:
 - Specific food(s)
 - Specific lot code(s)
 - Specific timeframe(s)
 - Specific location(s)



The electronic sortable spreadsheet must include all relevant KDEs for the CTEs you perform based on FDA's request.

The FDA's request will be as specific as possible and would include:

- The specific lot code and/or a specific food
- The specific timeframe
- The specific location
- CTEs of interest

The FDA's request will be as narrow as possible, but it will need to cover the products and timeframe of interest for the entire investigation.

Slide 18: Electronic Sortable Spreadsheet Template



Electronic Sortable Spreadsheet Template

- The FDA Electronic Sortable Spreadsheet template is available on the FDA website.
 - An Electronic Sortable Spreadsheet template, including synthetic data, is also available
- It is not mandatory to use this template.

What questions do you have about this template?



The FDA electronic sortable spreadsheet template can be used to fulfill FTR-related traceability data requests made by the FDA, but use of this template is not mandatory.

Each tab represents a CTE and contains all of the corresponding KDEs for that CTE. Within each tab, each column header represents a required KDE and has a hyperlink to the corresponding provision for your reference. For convenience, the definitions are listed on an accompanying tab with hyperlinks to the corresponding provisions. The template includes a tab for each CTE listed in the FTR, but you do not have to complete every tab when fulfilling a data request for FDA. You should only complete the relevant tab(s) based on the CTE(s) you perform according to the data request provided by FDA.

Some of the KDEs within the rule contain multiple pieces of data (i.e., compound KDEs). Within this template, the compound KDEs have been separated into multiple columns. For example, the location description KDE spans multiple columns to individually capture all of the information required under that KDE.

Slide 19: Electronic Sortable Spreadsheet - Receiving Example

Electronic Sortable Spreadsheet – Receiving Example

Traceability Lot Code	Quantity (e.g., 6, 25, 100, 200)	Unit of Measure (e.g., cases, reusable plastic containers, tanks, pounds)	Product Description - Product Name
PLU: 4062 Lot: GS-WCA-02-27-260	24	Cases	Gulf Sunrise Green Cucumber
PLU: 4062 Lot: GS-WCA-02-27-261	24	Cases	Gulf Sunrise Green Cucumber
UPC: 614141025251 LOT: BHMXXB23309	150	Cases	Johnny's English Cucumber
UPC: 614141025251 LOT: BHMXXB23310	150	Cases	Johnny's English Cucumber

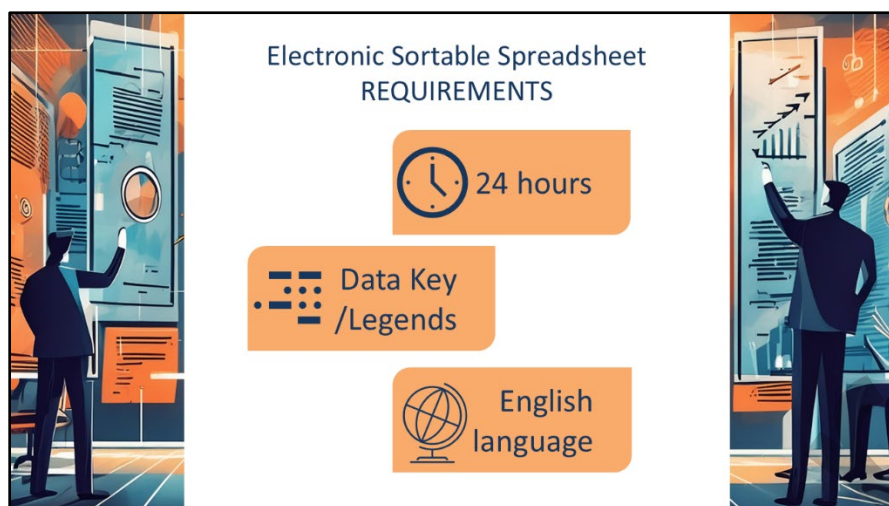
 FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

This example shows three of the KDEs that would be required for the Receiving CTE; see the FDA electronic sortable spreadsheet template for all KDEs required for each CTE.

On the slide, we see an example of an electronic sortable spreadsheet with a subset of Receiving KDEs. As you can see, each column of the spreadsheet represents a KDE that must be kept as part of the Receiving CTE.

This example includes information related to two different cucumber products (each with distinct TLCs) that the firm provided based upon a request. Please note that this screenshot only displays a few of the required KDEs, but the electronic sortable spreadsheet contains more KDEs as the view scrolls to the right.

Slide 20: Additional Electronic Sortable Spreadsheet Requirements



Firms are required to provide the electronic sortable spreadsheet within **24 hours** of a request, or another timeframe agreed to by the FDA.

- In some circumstances, the FDA may agree that it is appropriate to provide a firm with additional time to provide the electronic sortable spreadsheet.
Note: If a regulator's request for the information is made by phone, it will also be provided in writing if requested; however, the firm must provide the requested information within 24 hours of receiving the phone request.
- The FDA may also require information needed to understand the electronic sortable spreadsheet and other traceability records, such as internal or external coding systems, glossaries, abbreviations, and a description of how the information provided corresponds to requirements. This information could be included in your Traceability Plan or provided in another document, but does not need to be part of the electronic sortable spreadsheet itself.
- Both the electronic sortable spreadsheet (and any other traceability records if applicable) must be provided in English to the regulator. Some firms maintain their records in a language other than English. In this case a firm must provide an English translation of such records.

Slide 21: Section Four

Section 4:

ELECTRONIC SORTABLE SPREADSHEET EXEMPTIONS



Slide 22: Electronic Sortable Spreadsheet Exemptions (1 of 4)



Electronic Sortable Spreadsheet Exemptions (1 of 4)



An exemption may be made to accommodate a religious belief of a person asked to provide such a spreadsheet (example: Plain sect).



An exemption may be made to accommodate the religious beliefs of a person asked to provide an electronic sortable spreadsheet.

Example: a member of a Plain sect.

Slide 23: Electronic Sortable Spreadsheet Exemptions (2 of 4)

Electronic Sortable Spreadsheet Exemptions (2 of 4)



A farm whose average annual sales is below the threshold is exempt from generating this format.



Also, entities meeting the requirements of 21 CFR 1.1455(c)(3)(iii) may provide the information requested by FDA in a form other than an electronic sortable spreadsheet. These include the next three exemptions:

A farm whose average annual sales do not exceed \$250,000 (adjusted for inflation). All dollar amounts are adjusted for inflation from 2020.

Slide 24: Electronic Sortable Spreadsheet Exemptions (3 of 4)

Electronic Sortable Spreadsheet Exemptions (3 of 4)



A retail food establishment or restaurant with average annual sales below the threshold is exempt from generating this format.



Another exemption:

A retail food establishment or restaurant with average annual sales not exceeding \$1 million (adjusted for inflation) may provide the information requested by FDA in a form other than an electronic sortable spreadsheet.

Slide 25: Electronic Sortable Spreadsheet Exemptions (4 of 4)

Electronic Sortable Spreadsheet Exemptions (4 of 4)



A covered entity (such as a distribution center or a manufacturer) whose average annual sales is below the threshold is exempt from generating this format.



The last exemption:

A covered entity (such as a distribution center or a manufacturer) whose business is not a farm, retail food establishment, or restaurant, and whose average annual sales do not exceed \$1 million (adjusted for inflation) may provide the information requested by FDA in a form other than an electronic sortable spreadsheet.

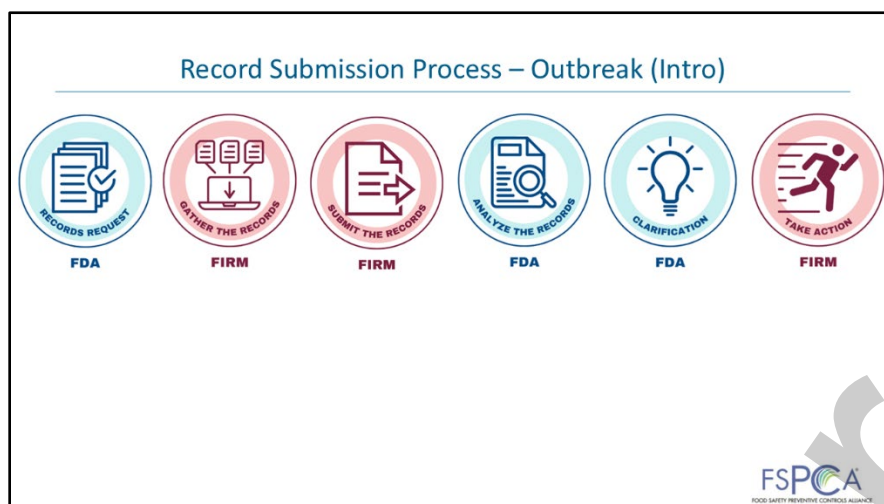
Slide 26: Section Five

Section 5

THE PROCESS TO SUBMIT RECORDS TO FDA



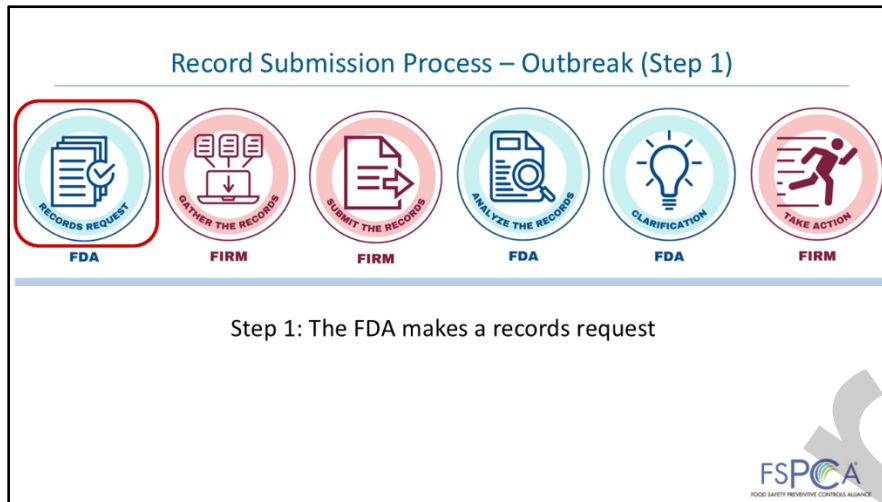
Slide 27: Record Submission Process – Outbreak (Intro)



Note: In addition to a recall plan being a separate process from a traceability plan, the exercise of gathering traceability records is a **different** process from when a company conducts a mock recall exercise.

Here is an example of steps for submitting requested records during an outbreak. The steps may be slightly **different** for a recall or other food safety incident.

Slide 28: Record Submission Process – Outbreak (Step 1)



Step 1: The FDA makes a records request.

In an outbreak, investigators will make specific requests **via phone call or email**. They will request records that correspond with the investigation and involve specific lot codes or foods and specific time frames. They would not request all records kept by a firm.

Note that not all requests come from the FDA. They could also come from a state or local regulator.

Slide 29: Record Submission Process – Outbreak (Step 2)

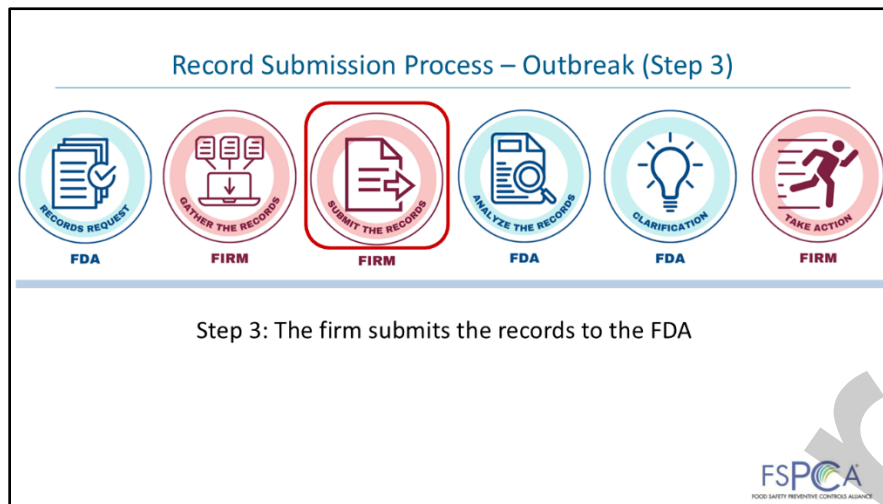


Step 2: The firm gathers their records.

Under the FTR, how long do firms have to submit records after a records request?

24 hours (or within some reasonable timeframe agreed to by the FDA) to provide the data in electronic sortable spreadsheet format (unless an exemption applies).

Slide 30: Record Submission Process – Outbreak (Step 3)

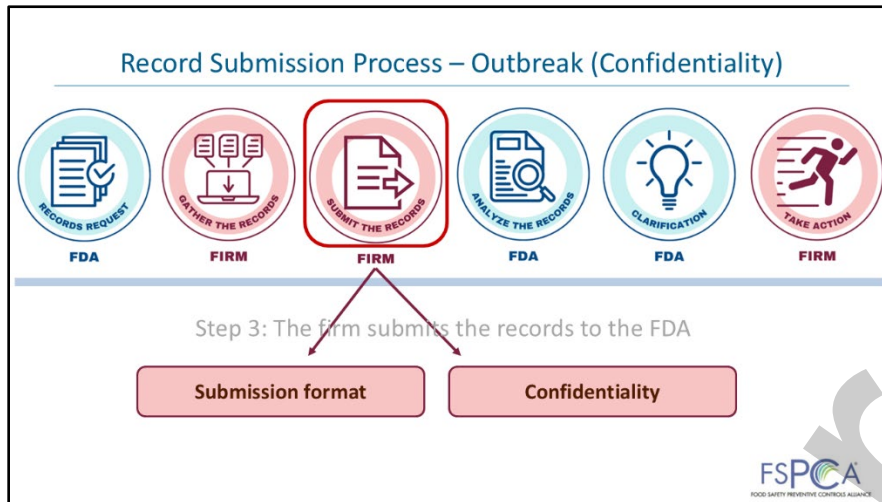


Step 3: The firm submits the records to the FDA.

As a reminder, you don't have to have keep your records in a specific format - there are no mandatory requirements for data formatting. FDA does not tell you how to keep or maintain the data, just what data to provide.

Records submitted in response to an FDA request can be in electronic or paper format. Requested information must be provided in an electronic sortable spreadsheet format unless an exemption applies. An industry submission portal specific to traceability data submission is being explored. Records can be emailed to the FDA; the email address is included in the records request.

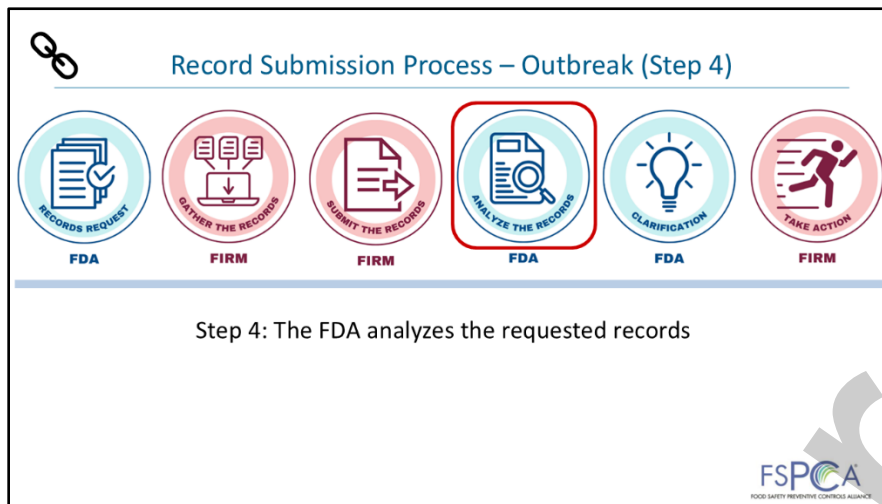
Paper records are often handed directly to an investigator on-site.

Slide 31: Record Submission Process – Outbreak (Confidentiality)**Confidentiality:**

The FDA protects all submitted commercial confidential and trade secret information (CCI and TS) from disclosure in accordance with all applicable statutes and regulations. This includes all requested traceability records. There are no changes to existing process in that traceability information can be subject to Freedom of Information Act (FOIA) requests but would be redacted to protect CCI and TS.

The FDA has very strict data and network security protocols. Only permissioned government users can access the data.

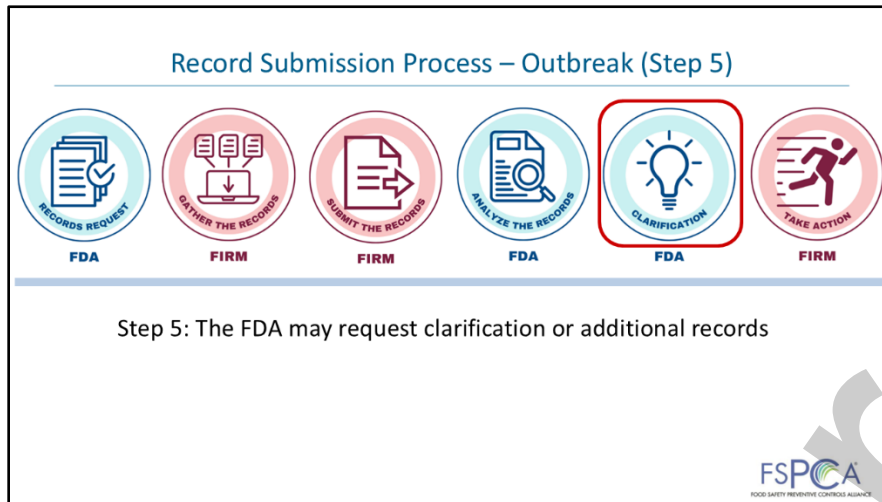
Slide 32: Record Submission Process – Outbreak (Step 4)



Step 4: The FDA will analyze the requested information to inform their investigation.

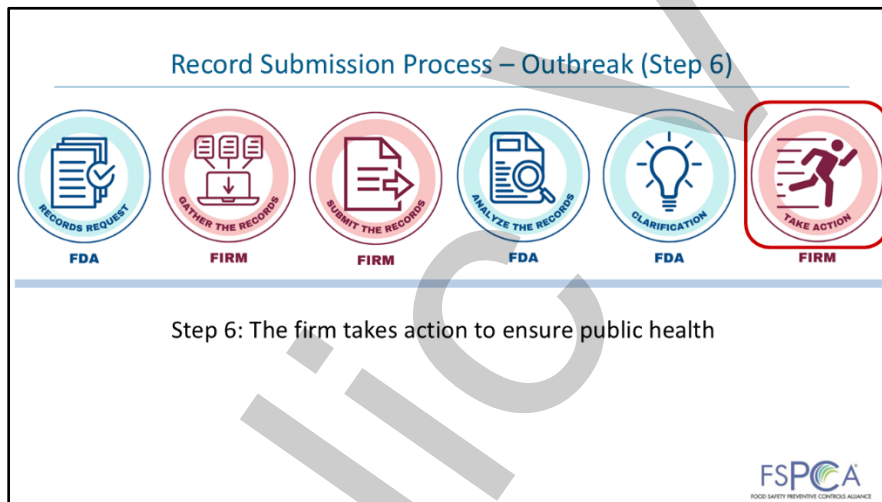
The Product Tracing System (PTS) is an internal tool FDA is developing to support more rapid outbreak-related traceback and traceforward analyses.

Slide 33: Record Submission Process – Outbreak (Step 5)



Step 5: The FDA may contact the firm for clarification or for additional records.

Slide 34: Record Submission Process – Outbreak (Step 6)



Step 6: Based on the investigation, the firm may need to take action to remove potentially contaminated products from the market.

Slide 35: Summary

Chapter 5: Summary

- Records must be maintained for two years, with a few exemptions
- Firms may use existing records to meet the requirements of the rule
- Upon FDA request and unless an exemption applies, be prepared to populate and submit an electronic sortable spreadsheet when the FDA requests it



Slide 36: Questions

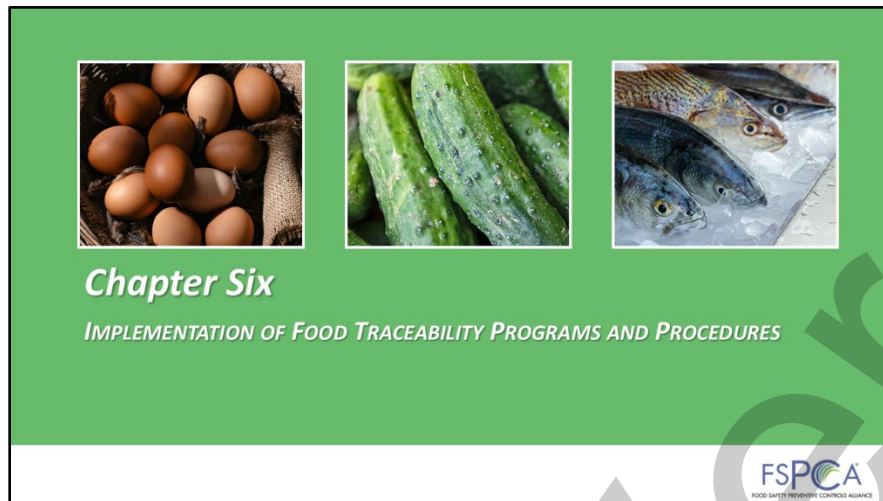
**Thank you for your
participation!**

**What questions
do you have?**



Chapter 6: Implementation of Food Traceability Programs and Procedures

Slide 1: Chapter Six



Slide 2: Goals and Learning Objectives

Chapter 6: Goal and Objectives

Goal: Implement a food traceability program and procedures to support compliance with the Food Traceability Rule (FTR).

Learning Objectives:

By the end of this chapter, participants will be able to:

- Formulate procedures to implement a traceability program.
- Explore types of data systems used to manage traceability data.
- Understand the value of interoperability and the role that data standards play in supporting it.
- Describe how TLC information can be traced throughout the supply chain.

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Chapter Six looks at best practices beyond the scope of the FTR itself and identifies ways in which a company could establish a food traceability program and procedures that will assist in being compliant with FTR requirements.

In addition, this chapter explores data systems that support traceability and their potential relevance to your organization along with important considerations such as interoperability and the role of data standards.

Chapter 6

Finally, the last part of the chapter takes a practical look at traceability by providing scenarios that describe the different ways that lot code (or TLC) information can be provided from one organization to another throughout the supply chain.

Goal: Implement a food traceability program and procedures to support compliance with the FTR.

Learning Objectives:

By the end of this chapter, participants will be able to:

- Formulate procedures to implement a traceability program.
 - Explore types of data systems used to manage traceability data.
 - Understand the value of interoperability and the role that data standards play in supporting it.
 - Describe how TLC information can be traced throughout the supply chain.
-

Slide 3: Section One

Section 1

BUILDING A TRACEABILITY PROGRAM

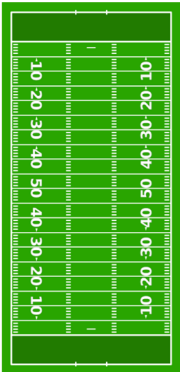


Slide 4: Traceability Plan vs Traceability Program

Traceability Plan vs Traceability Program

Traceability Plan

The traceability PLAN is the “football playbook” or “game plan.” It describes what the company does to meet requirements.



The PROGRAM is the “football game.” It is the execution of the plan. It defines HOW everything works together to meet the requirements.

Traceability Program

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The visual metaphor here is that the Traceability Plan describes what is going to be done, like a winning football play the coach has described, while the program is the actual performance. Both must be excellent in order to succeed.

A Traceability Plan is required by the FTR; a traceability program is not required by the FTR. A traceability program can describe how a covered entity combines the different required elements into an integrated system.

The plan is the company's written intent that describes how they will carry out activities that meet the FTR's requirements. The program defines how these activities work together to implement the plan. Many companies' traceability programs are unique to their operations.

Slide 5: The Purpose of the Program

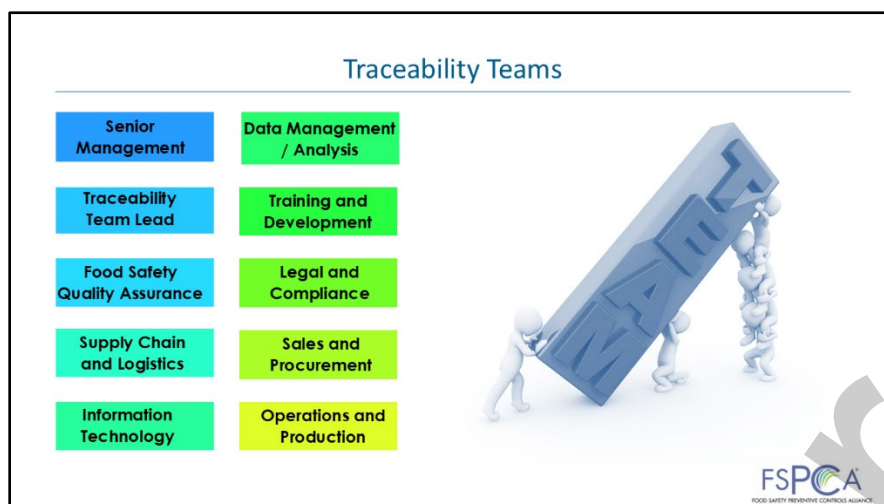


A traceability program has the following characteristics:

- It sets the overarching **vision and goals** for traceability within the organization, aligning with its overall business objectives and values.
- It is often tailored to the **unique characteristics and needs** of the organization, accounting for such factors as the nature of the food products, the complexity of the supply chain, and applicable regulations, and industry standards or guidelines.
- It is a broader framework that encompasses the overall approach, policies, and practices adopted by a food business to **ensure effective traceability** throughout its operations.
- It goes beyond the tactical aspects covered in the Traceability Plan and covers **strategic elements**, including organizational culture, leadership commitment, continuous improvement, and stakeholder engagement.

A traceability program may enhance transparency, collaboration, and information sharing across the food supply chain, as well as efforts to leverage technology and innovation to improve traceability capabilities.

Slide 6: Traceability Teams



There is no requirement to assemble a traceability team in the FTR.

A traceability team is a group of individuals within an organization with responsibilities related to the development, implementation, and maintenance of the Traceability program and Plan. By assembling a *multidisciplinary traceability team* with diverse expertise and skills, organizations can effectively build, implement, and manage their food traceability programs.

Each entity's traceability needs will be unique, so their teams must reflect their specific business needs and scopes. The specific responsibilities for each role may vary between companies.

For small businesses, the same person might fill multiple roles. Roles can be consolidated depending on business needs. Some roles are more critical to a company's traceability program and need to be at every meeting; others may be as-needed consultants and are only involved from time to time. Table 6-1 includes examples of traceability team roles and the skills and knowledge they can bring to a traceability team. Based on the company's needs, other roles might be added to the team.

Table 6-1 Traceability Team Roles

Senior Management	
Responsibilities Provide management support, buy-in, and resources	Skills/Knowledge High-level understanding and vision of the components of a traceability program

Implementation of Food Traceability Programs and Procedures

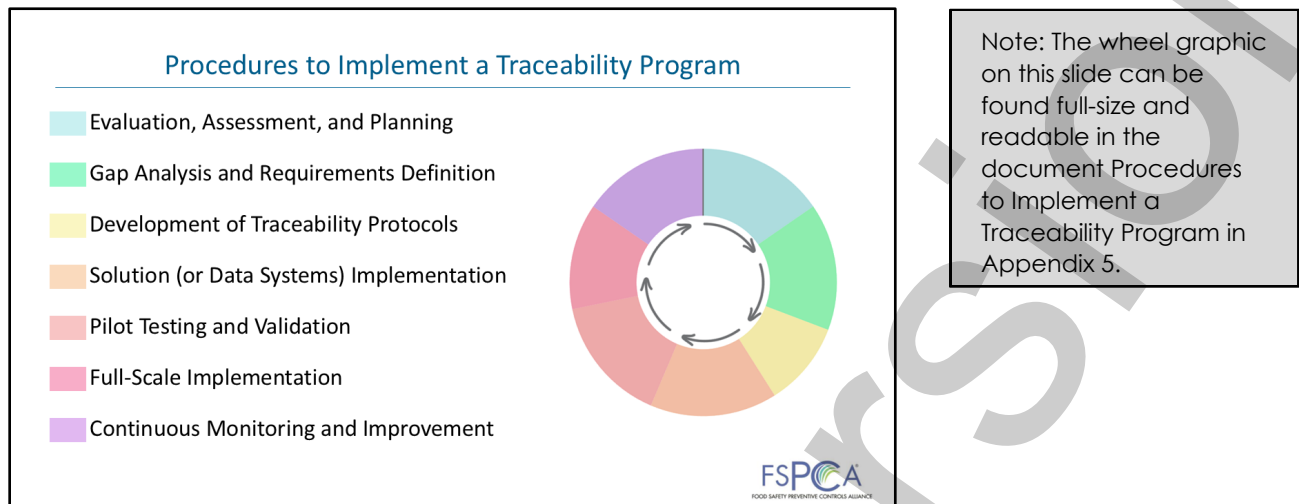
Traceability Team Lead	
Responsibilities - Serves as the primary point of contact for traceability-related activities and initiatives and as the company's primary lead - Empowered by senior management with authority and resources - Oversees the development, implementation, and maintenance of the food traceability program - Coordinates communication and collaboration between internal departments and external stakeholders - Assigns data capture to the appropriate department(s)	Skills/Knowledge - Understanding of traceability principles, regulations, and industry best practices - Strong project management and organizational skills - Effective communication and interpersonal abilities - Knowledge of supply chain logistics and IT systems
Food Safety Quality Assurance (FSQA)	
Responsibilities - Understands that the FTR requirements protect public health and reduce the time needed for foodborne illness investigations - Ensures that the traceability program aligns with supplier, customer, and regulatory requirements - Conducts assessment activities to ensure compliance with FTR requirements; this is best practice, not a FTR requirement	Skills/Knowledge - Expertise in FSQA and regulatory requirements - Knowledge of food safety regulations and industry standards - Attention to detail and analytical skills
Supply Chain/Logistics	
Responsibilities - Manages the flow of products and information throughout the supply chain to enable effective traceability - Engages with suppliers, distributors, and logistics partners to ensure FTR requirements are met - Identifies opportunities to optimize supply chain processes, enhance traceability capabilities, and integrate systems for efficiencies	Skills/Knowledge - Comprehensive understanding of supply chain management principles and logistics operations - Proficiency in data analysis and supply chain technologies

Information Technology (IT)	
Responsibilities • Develops, implements, and maintains traceability systems, databases, and IT infrastructure • Provides technical support and troubleshooting for traceability software and hardware • Implements data security measures to protect traceability-related information • Ensures the IT systems are integrated and communicating with each other (this responsibility overlaps with the logistics role)	Skills/Knowledge • Proficiency in database management, software development, and system integration • Knowledge of traceability technologies and systems to identify, capture, share, and store data • Problem-solving and critical thinking skills
Data Management/Data Analyst	
Responsibilities • Creates an electronic sortable spreadsheet upon request • Analyzes traceability data to identify trends, patterns, and areas for improvement • Generates reports and insights to support decision-making and continuous improvement efforts • Develops data visualization tools and dashboards to communicate traceability-related information effectively	Skills/Knowledge • Proficiency in data analysis tools and statistical software • Strong quantitative and analytical skills • Ability to translate data into actionable insights • Understanding of database querying languages and data visualization techniques
Training and Talent Development	
Responsibilities • Develops and delivers training programs to educate employees on traceability policies, procedures, and best practices • Identifies appropriate training for each role in the business • Ensures that all team members are adequately trained and knowledgeable about their roles and responsibilities in the traceability program • Monitors and evaluates training effectiveness and identifies opportunities for continuous improvement Note: While the FTR does not have a training requirement, training is essential to ensure all personnel involved know their roles and how to facilitate compliance	Skills/Knowledge • Instructional design skills and experience developing and repurposing training materials • Strong presentation and facilitation skills • Knowledge of adult learning principles and training evaluation methods • Ability to communicate complex concepts in a clear and engaging manner

Implementation of Food Traceability Programs and Procedures

Legal/Compliance	
Responsibilities - Assures that the program as implemented meets regulatory requirements - Verifies that the content of the electronic sortable spreadsheet meets regulatory requirements - Reviews supplier and customer communications related to the FTR	Skills/Knowledge Knowledge of the FTR
Category Management/Sales/Buyers/Procurement	
Responsibilities - Communicates the expected compliance information to company staff and supply chain partners - Controls both incoming and outgoing product specifications for each item on the FTL - Collaborates with suppliers and customers to assure information is correct and in compliance with the FTR - Manages supplier and customer contact information - Able to implement supplier-compliance programs across the enterprise	Skills/Knowledge Excellent communication, collaboration, and negotiation skills
Operations/Production	
Responsibilities Records traceability data as per company protocols	Skills/Knowledge Proficiency in following company-defined traceability procedures

Slide 7: Procedures to Implement a Traceability Program

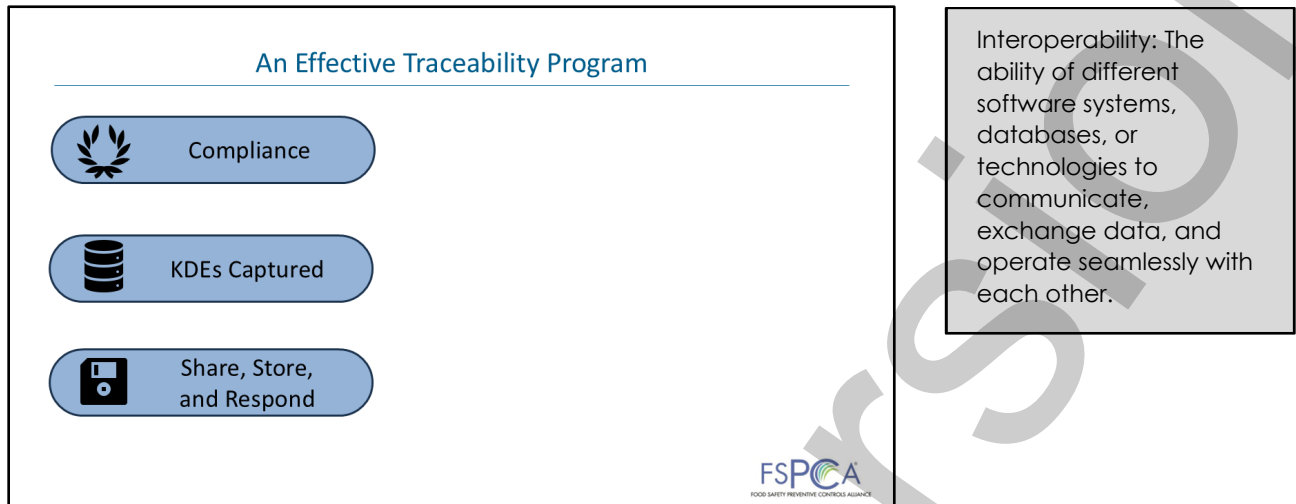


Before you begin implementing a traceability program, the traceability team should be familiar with the components of such a program. Following is a procedure for implementing a traceability program:

1. Evaluation, Assessment, and Planning
2. Gap Analysis and Requirements Definition
3. Development of Traceability Protocols
4. Solution (or Data Systems) Implementation
5. Pilot Testing and Validation
6. Full-Scale Implementation
7. Continuous Monitoring and Improvement

For additional reading, see Appendix 5: Procedures to Implement a Traceability Program.

Slide 8: An Effective Traceability Program



We will look at three elements of an effective traceability program: compliance, an organization's ability to capture the required KDEs, and its capacity to share and store records as well as respond to record requests.

For a covered entity handling foods on the FTL, compliance with the FTR will be the primary objective of the traceability program.

There are three main components needed to be compliant with the FTR:

- A Traceability Plan
- Records (KDEs for each CTE the entity performs)
- An electronic sortable spreadsheet (when requested by the FDA, unless an exemption applies)

Next, your company will need procedures to capture KDEs. The FTR has no requirements regarding the type of system your organization should have. We will review potential options in the next section.

In addition to capturing KDEs, you will also need to effectively share and store traceability data and respond to data requests.

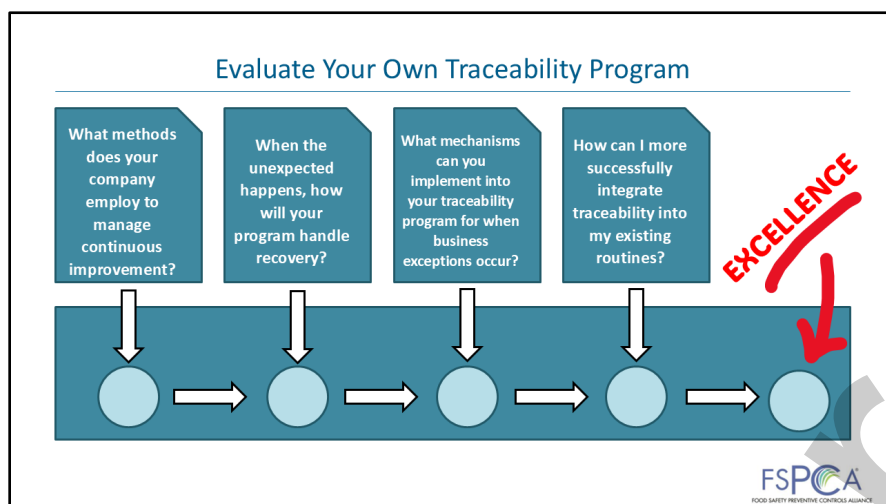
- Store: For each CTE your company performs, every KDE must be kept for two years (unless an exemption applies).
- Share: Companies need to share KDEs during shipping of FTL foods.
- Respond: When there is an outbreak, recall, or other food safety incident, the FDA will request an electronic sortable spreadsheet.

Systems performing these tasks should be able to "talk" to other systems and share information with supply chain partners and the FDA. This is referred to as **interoperability**. We will discuss this later in this chapter.

Notes:

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Slide 9: Evaluate Your Own Traceability Program



Consider the following as you evaluate your own traceability program:

- What methods does your company employ to manage continuous improvement?
- When the unexpected happens, how will your program handle recovery?
- What mechanisms can you implement into your traceability program when business exceptions occur?
- How can I more successfully integrate traceability into my existing routines?

Slide 10: Section Two

Section 2

TYPES OF DATA SYSTEMS USED TO MANAGE TRACEABILITY DATA



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Slide 11: Main Activities of a Data System

Main Activities of a Data System

- ? Identify product info
- ? Capture product info
- ? Storage
- ? Retrieval
- ? Share data

Follow data system management principles



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Data systems are a tool for managing data. The main activities of a traceability data system include identifying the product, capturing the product information, sharing the data, data storage, and data retrieval.

Important considerations for any data management system include data validation, or the process of ensuring accuracy, completeness and integrity of the data as well as establishing policies to ensure effective management and quality of data, or data governance.

Slide 12: Capturing Traceability Data

Capturing Traceability Data

- Data carriers are used to track product and product information.
- Data carriers come in a variety of forms: QR codes, barcodes, etc.
- Data carriers facilitate records or data shared electronically between trading partners.



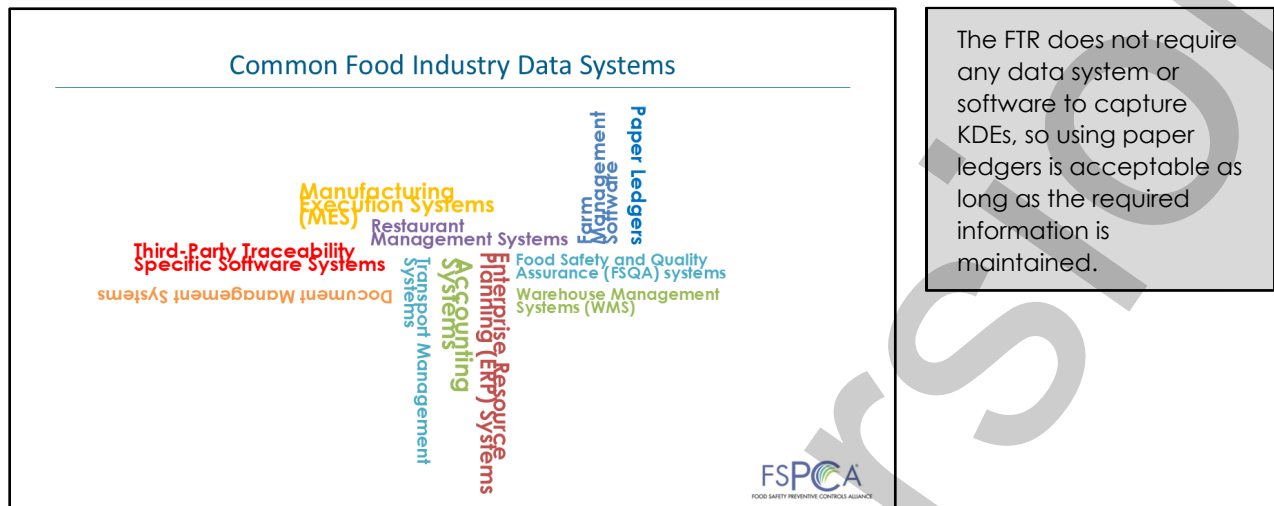
Data carriers are used to track product and product information. Barcodes, 2-dimensional symbols (such as QR codes), and Radio-Frequency Identification (RFID) tags are all examples of data carriers. They might simply support price lookup at checkout, or they might be used to capture and share more complex traceability data such as KDEs.

Data carriers are typically affixed to food packaging at various levels, which could include inner package, outer package, pallet, or the consumer unit. They can come with a variety of machine-readable data encoded in them and are read by scanners.

Data carriers provide an identity as well as other relevant information which can be captured by downstream recipients in the supply chain and associated with records or data shared electronically between trading partners. Often, they are used in conjunction with other electronic records to exchange data with supply chain partners. Interoperability is critical here (we will discuss that next).

For more information, please see Appendix 6: Barcodes and their Role in Traceability.

Slide 13: Common Food Industry Data Systems



There is a cornucopia of data systems employed by food companies to track their business operations. Companies may already record many of the required KDEs in one, or several, data management system(s).

In addition to using data systems to capture data, firms may still manually capture data in paper ledgers

Consult Appendix 7: Common Food Industry Data Systems on your own time to learn about the below systems currently used in the food industry, and how they can help manage traceability data:

- Warehouse Management Systems (WMS)
- Enterprise Resource Planning (ERP) Systems
- Third-Party Traceability Specific Software Systems
- Accounting Systems
- Food Safety and Quality Assurance (FSQA) systems
- Farm Management Software
- Manufacturing Execution Systems (MES)
- Transport Management Systems
- Document Management Systems
- Restaurant Management Systems

Each data management system, software or not, has its own set of advantages, limitations, and primary focus areas. Organizations may need to evaluate their specific requirements, budget constraints, and integration needs when selecting the most suitable software or other solution for managing traceability data within their supply chain operations.

Appendix 8: Data Systems Questions presents a list of questions that you can use to evaluate a data system. You can explore this outside of class time.

Implementation of Food Traceability Programs and Procedures

As you review Appendix 8, ask yourself what your customers and supply chain partners need. Your agreements and contracts may also inform what kind of system(s) you choose to use.

Slide 14: Section Three

Section 3

INTEROPERABILITY AND DATA STANDARDS



Slide 15: Interoperability



Interoperability



The ability of different software systems, databases, or technologies to communicate, exchange data, and operate seamlessly with each other.



In the context of a traceability system, "interoperability" refers to the ability of different software systems, databases, or technologies to **communicate, exchange data, and operate seamlessly with each other**. Interoperability ensures that disparate systems can work together effectively to share information, track products, and facilitate end-to-end traceability across the supply chain.

Interoperable systems enable the seamless exchange of data between various stakeholders, including suppliers, manufacturers, distributors, retailers, and regulatory agencies. This facilitates the sharing of critical information such as product origin, processing details, shipping records, and quality control data. If you have multiple supply chain partners and they all use different systems, interoperability allows those different systems to share data.

Implementation of Food Traceability Programs and Procedures

See the following information regarding interoperability adapted from the Institute of Food Technology's report on FDA's Low- or No-cost Traceability Challenge:

What is interoperability?

Interoperability is the ability of software systems to exchange and interpret data without the need for human intervention.

Why is interoperability important?

Businesses in the food industry vary based on commodities, size, and position in the supply chain. Therefore, different systems are selected to meet the varying needs of each entity. A single traceability solution meeting the needs of every business is impractical, but with interoperability, different businesses can communicate effectively while utilizing solutions tailored to their individual needs. Interoperability also reduces system-wide costs by:

- Eliminating the need for custom integration between software solutions
- Reducing the administrative burden and input errors associated with manually inputting shared data

How is interoperability achieved?

Seamless data exchange and interpretation require three levels of standardization:

- Standardization of the data that is collected
 - Standardization of the data format
 - Standardization of the communications protocol that allows software to transfer information between them
-

Slide 16: Spreadsheet Discussion

A	B	C	D	E	F	G	H	I	J	K	L	M
1	Date	Grower	Field	Color/Grade	Cases	Temp	Harvester	Packaging				
2	03/01/26	Red Maters Farms	Northwest-1	U.S. No. 1	562	69	Goetz Harvesting LLC	20lb				
3	03/02/26	Red Maters Farms	East	U.S. No. 2	520	72	Goetz Harvesting LLC	25lb				
4	03/02/26	Red Maters Farms	Northwest-2	U.S. Combination	1,265	68	Goetz Harvesting LLC	20lb				
5	03/02/26	Red Maters Farms	Northwest-2	U.S. No. 2	554	77	Goetz Harvesting LLC	20lb				
6	03/05/26	Red Maters Farms	Southeast	U.S. No. 3	1,445	73	Goetz Harvesting LLC	25lb				
7	03/02/26	FL Best Growers	A-2	U.S. No. 3	1,425	76	Goetz Harvesting LLC	15lb Tray				
8	03/02/26	FL Best Growers	B-1	U.S. Combination	774	69	Goetz Harvesting LLC	15lb Tray				
9	03/03/26	FL Best Growers	A-1	U.S. No. 1	580	72	Goetz Harvesting LLC	20lb				
10	03/04/26	FL Best Growers	C-3	U.S. Combination	1,300	72	Goetz Harvesting LLC	15lb Tray				
11	03/02/26	Montgomery Fields	Noah	U.S. No. 2	664	75	Goetz Harvesting LLC	25lb				
12	03/03/26	Montgomery Fields	Ann	U.S. No. 3	520	74	Goetz Harvesting LLC	25lb				
13	03/04/26	Montgomery Fields	Joshua	U.S. No. 3	264	71	Goetz Harvesting LLC	25lb				
14	03/05/26	Montgomery Fields	James	U.S. No. 2	500	76	Goetz Harvesting LLC	20lb				

A	B	C	D	E	F	G
1	Quantity	Use	Harvest	Farm Field	Crew	Pack Size
2	71,500	Lbs	Beefsteaks	FL Wilmark Family Farms - Field#1	Lennox Ag Inc.	25#
3	30,470	Lbs	Beefsteaks	FL Wilmark Family Farms - Field#1	Lennox Ag Inc.	25#
4	30,910	Lbs	Beefsteaks	FL Wilmark Family Farms - Field#2	Lennox Ag Inc.	20#
5	14,520	Lbs	Beefsteaks	Broadbent Vines - Orange	Lennox Ag Inc.	15Tray
6	79,475	Lbs	Beefsteaks	Broadbent Vines - Purple	Lennox Ag Inc.	20#
7	31,900	Lbs	Beefsteaks	Broadbent Vines - Orange	Lennox Ag Inc.	15Tray
8	42,570	Lbs	Beefsteaks	Broadbent Vines - Green	Lennox Ag Inc.	15Tray
9	28,600	Lbs	Beefsteaks	Broadbent Vines - Blue	Lennox Ag Inc.	15Tray
10	28,600	Lbs	Beefsteaks	Broadbent Vines - Black	Lennox Ag Inc.	15Tray
11	47,520	Lbs	Beefsteaks	Left Pines - North 1	Lennox Ag Inc.	20#
12	27,500	Lbs	Beefsteaks	Left Pines - North 2	Lennox Ag Inc.	20#
13	69,575	Lbs	Beefsteaks	Left Pines - South	Lennox Ag Inc.	25#



In this example, an Initial Packer receives two spreadsheets, each with information from a different tomato harvester.

What differences do you see between the two harvesters' spreadsheets?

Slide 17: Spreadsheet Discussion Continued

A	B	C	D	E	F	G	H	I	J	K	L	M
1	Date	Grower	Field	Color/Grade	Cases	Temp	Harvester	Packaging				
2	03/01/26	Red 'Maters Farms	Northwest-1	U.S. No. 1	562	69	Goetz Harvesting LLC	20lb				
3	03/02/26	Red 'Maters Farms	East	U.S. No. 2	520	72	Goetz Harvesting LLC	25lb				
4	03/02/26	Red 'Maters Farms	Northwest-2	U.S. Combination	1,265	68	Goetz Harvesting LLC	20lb				
5	03/02/26	Red 'Maters Farms	Northwest-2	U.S. No. 2	554	77	Goetz Harvesting LLC	20lb				
6	03/05/26	Red 'Maters Farms	Southeast	U.S. No. 3	1,445	73	Goetz Harvesting LLC	25lb				
7	03/02/26	FL Best Growers	A-2	U.S. No. 3	1,425	76	Goetz Harvesting LLC	15lb Tray				
8	03/02/26	FL Best Growers	B-1	U.S. Combination	74	69	Goetz Harvesting LLC	15lb Tray				
9	03/03/26	FL Best Growers	A-1	U.S. No. 1	580	72	Goetz Harvesting LLC	20lb				
10	03/04/26	FL Best Growers	C-3	U.S. Combination	1,300	72	Goetz Harvesting LLC	15lb Tray				
11	03/02/26	Montgomery Fields	Noah	U.S. No. 2	864	75	Goetz Harvesting LLC	25lb				
12	03/03/26	Montgomery Fields	Ava	U.S. No. 3	520	74	Goetz Harvesting LLC	25lb				
13	03/04/26	Montgomery Fields	Joshua	U.S. No. 3	264	71	Goetz Harvesting LLC	25lb				
14	03/05/26	Montgomery Fields	James	U.S. No. 2	500	76	Goetz Harvesting LLC	20lb				

A	B	C	D	E	F	G
1	Quantity	UoM	Harvest	Farm Field	Crew	Pack Size
2	71,500	Lbs	Beefsteaks	FL Wilmark Family Farms - Field#1	Lennox Ag Inc.	25#
3	30,470	Lbs	Beefsteaks	FL Wilmark Family Farms - Field#4	Lennox Ag Inc.	25#
4	30,910	Lbs	Beefsteaks	FL Wilmark Family Farms - Field#2	Lennox Ag Inc.	20#
5	14,520	Lbs	Beefsteaks	Broadbent Vines - Orange	Lennox Ag Inc.	15Tray
6	79,475	Lbs	Beefsteaks	Broadbent Vines - Purple	Lennox Ag Inc.	20#
7	31,900	Lbs	Beefsteaks	Broadbent Vines - Orange	Lennox Ag Inc.	15Tray
8	42,570	Lbs	Beefsteaks	Broadbent Vines - Green	Lennox Ag Inc.	15Tray
9	28,600	Lbs	Beefsteaks	Broadbent Vines - Blue	Lennox Ag Inc.	15Tray
10	28,600	Lbs	Beefsteaks	Broadbent Vines - Black	Lennox Ag Inc.	15Tray
11	47,520	Lbs	Beefsteaks	Left Pines - North 1	Lennox Ag Inc.	20#
12	27,500	Lbs	Beefsteaks	Left Pines - North 2	Lennox Ag Inc.	20#
13	69,575	Lbs	Beefsteaks	Left Pines - South	Lennox Ag Inc.	25#

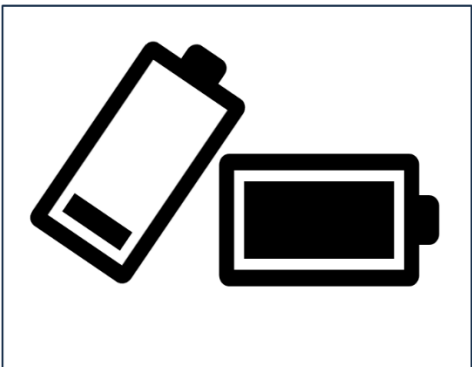
Note the differences between the two spreadsheets. Think about how this relates to interoperability and what that might mean for you and your supply chain partners.

Notes:

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Slide 18: Standards and Batteries

Standards and Batteries



How do household batteries illustrate interoperability and standards?

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Household batteries like AAs or AAAs have consistent dimensions, voltage, and connectors.

The American National Standards Institute (ANSI) publishes a standard defining what constitutes an AA or AAA battery.

By following that standard, manufacturers of batteries and electronics enable you to choose batteries from various brands and trust they will power your various electronics.

Slide 19: Data Standards

Data Standards

- An agreement among multiple parties
- Enables connectivity
- The FTR does not define or require standards



A data standard is a technical specification that describes how data should be stored or exchanged for the consistent collection and interoperability of that data across different systems, sources, and users.

Data standards play a critical role in enabling interoperability, data exchange, and collaboration within traceability systems.

Data standards act as an agreement among multiple parties who wish to connect. These agreed-upon formats and protocols provide consistency in the exchange of data between different systems or organizations, hence facilitating interoperability.

The FTR does not define standards, nor does it require following standards as a condition of compliance. However, if an industry wants to come together and agree to leverage standards, that decision could play a part in that industry's thinking about how they want to comply with the FTR.

Consider how standards allow for scanning grocery items at the point of sale. UPC barcodes used at any scanner follow a standard and facilitate purchasing. UPC barcodes are not mandated by any regulation; they are voluntary, and the industry has aligned around this approach. If a product used a propriety barcode, it would make it more difficult to make a purchase.

Slide 20: Examples of Industry Data Standards for Traceability



Examples of Industry Data Standards for Traceability

- GS1
- Global Dialogue on Seafood Traceability
- X12
- PTI

Interoperability depends on data standards!



There are various industry traceability standards designed to support interoperability: GS1, GDST, X12, and PTI to name a few. Choosing a data standard can be made in collaboration with your supply chain partners.

Slide 21: Consult Available Guides and Technical Resources



Consult Available Guides and Technical Resources

- Industry Guides
- Technical resources from FDA
- FDA's electronic sortable spreadsheet template



There are also various industry guides designed to help companies ready themselves for FTR compliance: GS1, PTI, FMI, GDST, and NGA to name a few. Trade associations have guides specific to their sectors.

The FDA has technical resources about the FTR's requirements, including an FAQ page.

The FDA's FTR website also has an electronic sortable spreadsheet template including synthetic data.

Slide 22: Comparison of Data Systems

Comparison of Data Systems

- Small group activity
- Read each of the scenarios:
 - Morty's Melon Farm
 - Marvelous Melon Patch
 - Momma Mabel's Melons
- Discuss the pros and cons of each data system solution
- Record your ideas in the table provided





Note that as we look at pros and cons of these solutions and technologies, we're not trying to identify one as superior over another, but rather we want to highlight the differences between them and the trade-offs between these systems.

There is no one way to comply with the rule, nor is there a silver bullet - even the most sophisticated ways will have some weaknesses. One trade-off is upfront investment versus on-going costs for compliance.

	Comparison of Data Systems
Activity	Read the assigned scenario and discuss your group's assessment with the class. Use the table provided to compare the scenarios.
Objectives	Apply what you have learned in a real-world scenario.
Time	20 min
Materials	Participant Manual
Directions to Participants	- Read through the description of your assigned melon farm. - Discuss pros, cons, and any unique features of the farm's data system approach.
Breakout	3-5 participants
Summary	Read and analyze the given scenario with respect to their data systems.
Key Learnings	Compare given data solutions for covered entities.

Compare the data system approaches each company takes to comply with the rule by filling out the table below the scenarios (one during your group's analysis of your assigned scenario and the other two during class discussion).



At **Morty's Melon Farm**, melons are harvested and sent to the Initial Packer.

Refer to Appendix 6 for more information on GS1 standards if needed. The Initial Packer applies a label with a GS1-128 barcode with a GTIN and a lot number and sends the melons to a distributor.

The food service distributor receives the cases of melons, and by scanning the barcode, can receive/read the GTIN and the lot number, which make up the TLC.

The food service distributor selects items, including melons, to fulfill an order from one of their customers, a restaurant. They assemble pallets to be delivered there and to others along the same truck route.

After the pallet is assembled, the distributor assigns and prints an SSCC barcode label to associate its contents with that specific pallet. The distributor sends an Advance Shipping Notice (ASN) to the customer indicating the specific lots and product IDs that will be on the pallet delivered to them.

Compare and contrast the pros and cons of this approach.

Scenario	Pros	Cons	Unique Features
Morty's Melon Farm			



At **Marvelous Melon Patch**, melons are harvested and sent to another Initial Packer.

The Initial Packer sends out whole melons to a manufacturer. On the cases the PLU number and a production date are handwritten in black marker. The Initial Packer considers this the TLC and they are the TLC Source. Its packing list for the manufacturer includes the PLU and production date.

The manufacturer receives cases with the PLU and the production date. Its staff manually enter that data into their systems. They cut the melons into chunks and put them in a melon bowl and record a new TLC because of the transformation step. The manufacturer is considered the new TLC Source. Next, the bowls are packed into a master case and only the case label is applied. They are then sent to a grocery chain with an emailed spreadsheet that includes the TLCs of the melon bowls.

The grocery chain has cut off external email for data security purposes. All they have is a shipping manifest with an invoice that comes in with the melon bowls delivered physically by the trucker to the distribution center.

Compare and contrast the pros and cons of this approach.

Scenario	Pros	Cons	Unique Features
Marvelous Melon Patch			



At **Momma Mabel's Melons**, melons are harvested and sent to another Initial Packer.

The Initial Packer sends out whole melons to a distribution warehouse. It uses M-Trace Technology that incorporates advanced tags. The case packaging includes a microtracker that reports humidity, temperature, GPS location, and relevant traceability information for these melons via wireless communication. M-Trace microtrackers allow anyone with the M-Trace phone app to access most information by scanning the tracker; special permissions are required to see all the information remotely as it is shipped, including its history.

The distribution warehouse receives the shipment. The M-Trace microtracker shows the time the shipment arrived at this warehouse. The warehouse accesses M-Trace's third-party system and makes a record in its own on-site system. The data is verified against the purchase order. It is shipped from there to a grocery store.

Compare and contrast the pros and cons of this approach.

Scenario	Pros	Cons	Unique Features
Momma Mabel's Melons			

Slide 23: Section Four

Section 4

TRACKING TLCs IN SUPPLY CHAINS



Slide 24: Tracking TLCs in Supply Chains

Tracking TLCs in Supply Chains

- Scenario 1: Warehouse Slotting and Picking
- Scenario 2: Key Drop
- Scenario 3: Field-Packed Produce
- Scenario 4: Transformation
- Scenario 5: Import Customers
- Scenario 6: Hub and Spoke



For Food Traceability Editorial Team reference only. Do not share.

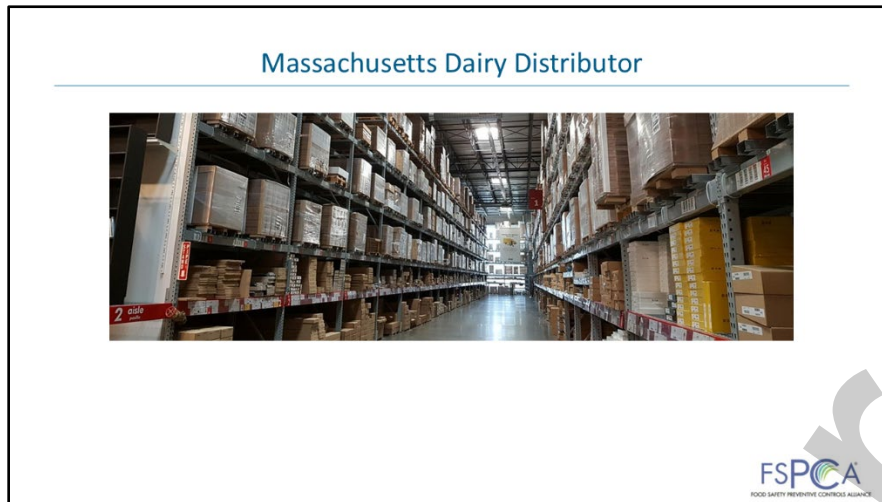
We will review one or two scenarios to demonstrate how TLC information associated with FTL products can be traced throughout the supply chain. There are six scenarios included in Appendix 9 for your reference.

	Tracking TLCs in Supply Chains
Activity	Class activity
Objectives	Identify or assess a traceability solution(s) for a given supply chain scenario to ensure TLCs are passed between steps in the supply chain.
Time	Review the scenario(s): 10 minutes

Implementation of Food Traceability Programs and Procedures

	Class discussion: 10 minutes
Materials	• Participant Manual, Appendix 9
Directions to Participants	• Read through the selected scenario(s). • Collaboratively come up with or assess a traceability solution(s) (as applicable) and answer the questions. • Be prepared to discuss your ideas with the class.
Summary	Read the scenario(s) and assess or identify a traceability solution to ensure TLCs are passed between steps in the given supply chain.
Key Learnings	• Critically analyze a supply chain scenario and its traceability needs. • Identify or assess a realistic solution(s) that meets these needs.

Slide 25: Scenario 1 – Massachusetts Dairy Distributor



This is an example of warehouse slotting and picking, which is a process of organizing inventory at determined locations in the warehouse to increase efficiency and maintain accurate data that can help with traceability.

After reviewing the story, answer the following questions:

1. What are the pros and cons of each idea?
2. How would each solution affect traceability?

Slide 26: Scenario 2 – Farmer in the Dale Distributing



A key-drop delivery is a delivery made to a business after hours, when the business is closed. The delivery person uses a key to access the business and store the delivery in the correct place. The business receives the delivery and inspects it when it opens.

After reading the scenario, consider the following questions:

1. What did you notice in this scenario that is unique to a key-drop arrangement?
2. How was TLC information communicated/transferred?
3. What do you think is important in making Farmer in the Dale Distributing's approach successful?

Notes:

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Slide 27: Scenario 3 – Huge Produce Brand, Inc.



In this scenario, cantaloupes are grown by Huge Produce Brand, Inc. They are harvested and packed in the field under contract by Moon Harvest. Both Harvesting and Initial Packing CTEs are applicable; there is no cooling prior to Initial Packing, therefore it is not a CTE. Some customers require that a GS1-128 barcode (containing the TLC) be placed on the cases in accordance with PTI.

After reading Section 1 of the scenario consider:

1. Who is responsible for maintaining Harvesting and Initial Packing KDEs?
2. What are some of the challenges related to recording KDEs for field-packed produce?
3. How could the problems with printing a PTI label be addressed?

Chapter 6

Read Section 2 of the field-packed produce story. After completing reading the scenario, consider the following questions:

1. How can the TLC be communicated to supply chain partners?
 2. Can "00123B" be used as the TLC Source reference?
-

Slide 28: Scenario 4 – Fred's Good Stuff

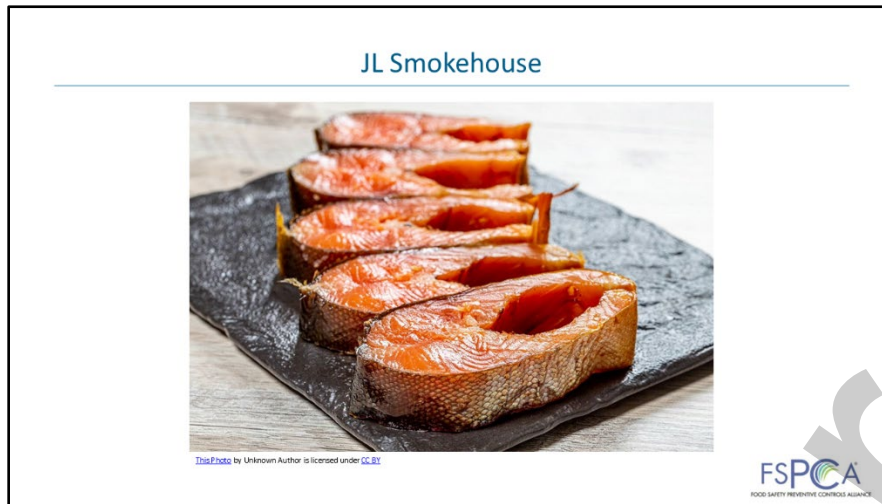


In this scenario, Fred's Good Stuff produces deli salad, an FTL food. Their deli salad is made from ingredients that are on the FTL, as well as non-FTL foods.

After reading, consider the following questions:

1. Which of these foods are on the FTL?
2. What challenges does Fred's Good Stuff face in complying with the FTR?
3. Is Fred's Good Stuff's solution sufficient for their traceability needs?
4. What other probable issues do you foresee Fred's Good Stuff needing to address?

Slide 29: Scenario 5 – JL Smokehouse



In this scenario, note that the rule does not supersede other rules you have to follow, such as Seafood HACCP (21 CFR 123).

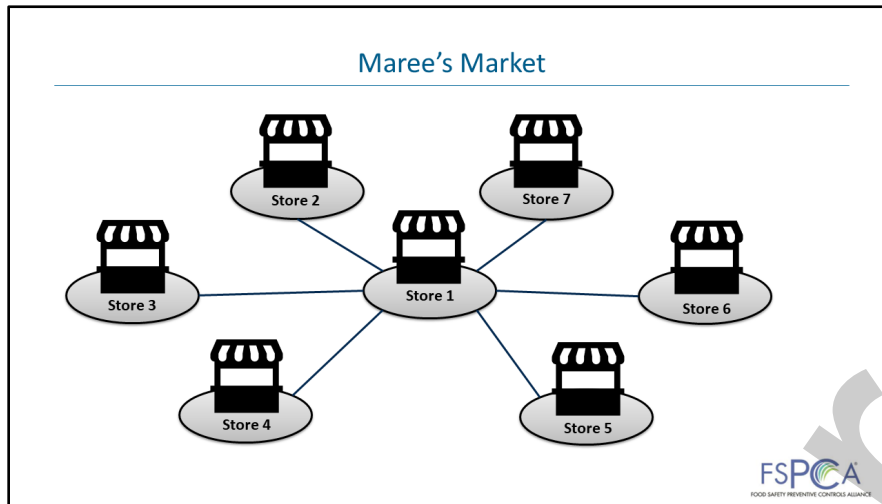
In this scenario, JL Smokehouse (a manufacturer outside the U.S.) produces smoked salmon (an FTL food) for Customers A and B (U.S.-based customers).

After reading, consider the following questions:

1. How are Customers A and B different?
2. Did JL Smokehouse assign TLCs appropriately?
3. What suggestions for improvement or other comments do you have about JL Smokehouse and how they handle TLCs?

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Slide 30: Scenario 6 – Maree's Market



The hub and spoke is a distribution model that resembles a bicycle wheel. In the middle of a wire-spoked wheel is what is known as the hub. This concept is used in multiple industries, such as retail – where food and consumer products are often loaded into a single truck at a distribution hub, then sent to individual satellite stores.

After reading the story consider the following questions:

1. If Store 1 doesn't ship sushi to other stores, what FTR records must they maintain?
2. How does Store 1's recordkeeping requirements change when they adopt the hub and spoke model?
3. Can Store 1 maintain FTR records for the other Maree's Market locations?

Slide 31: Summary

Chapter 6: Summary

- An organization should formulate procedures to implement a traceability program
- A range of data systems are available to manage traceability data
- Interoperability is vital for data systems to be able to communicate with each other
- Data standards are important for interoperability
- TLCs can be maintained in a variety of ways depending on the needs of the supply chain



Slide 32: Questions

**Thank you for your
participation!**

**What questions
do you have?**



Final Activity

Slide 1: Final Activity



Final Activity

WHAT ARE YOU BRINGING BACK TO YOUR ORGANIZATION?



Slide 2: To-Do List

To-Do List

- Individual activity
- Read through the to-do list
- For each line item, determine **how** it will be accomplished and **who** should be responsible
- For any details that require collaboration, be prepared to share and discuss this list with your coworkers





	To-Do List
Activity	Individual activity
Objectives	Fill out the to-do list for traceability in the context of your own organization

Final Activity

	To-Do List
Time	10 minutes
Materials	Participant Manual
Directions to Participants	- Read the to-do list - Draw on what you have learned - Fill it out - Note what aspects of this list require collaboration from your organization's stakeholders to complete
Breakout	Individual
Summary	Fill out the to-do list to the best of your abilities and be prepared to discuss with your team
Key Learnings	Implement traceability in your organization

The goal for this activity is to use the knowledge gained throughout the course and apply it towards implementation in your own organization.

Fill out the following to-do list, with specific emphasis on HOW these items will be accomplished and WHO is responsible for accomplishing them. Some items or details may require collaboration with your team at your company, so note those and be prepared to discuss this list and these steps with your coworkers.

10 Steps to Compliance

	Step	Make notes on how and who will accomplish this step
1	Create a cross functional team	
2	Determine which of your products are on the Food Traceability List	

	Step	Make notes on how and who will accomplish this step
3	Understand the rule and exemptions	
4	Understand where you are in the supply chain to focus on your CTEs and KDEs	
5	Map out what traceability practices, data elements, and records you currently have in place	
6	Identify and update current paper and/or digital information transfer systems to include the necessary fields to capture and pass on the required KDEs	
7	Clean up your master data quality	
8	Collaborate with each of your suppliers and customers on how to receive/transfer the required KDEs	

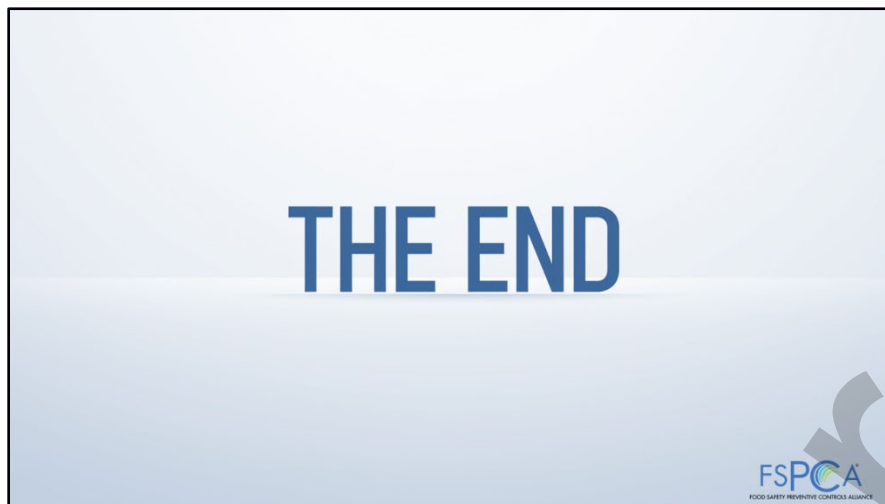
Final Activity

	Step	Make notes on how and who will accomplish this step
9	Budget for system upgrades	
10	Develop your Traceability Plan	

Additional Notes:

Public View

Slide 3: Conclusion of Training



Public Version

This content is from the eCFR and is authoritative but unofficial.

Subpart S—Additional Traceability Records for Certain Foods

Source:87 FR 71077, Nov. 21, 2022, unless otherwise noted.

General Provisions

§ 1.1300 Who is subject to this subpart?

Except as otherwise specified in this subpart, the requirements in this subpart apply to persons who manufacture, process, pack, or hold foods that appear on the list of foods for which additional traceability records are required in accordance with section 204(d) of the FDA Food Safety Modernization Act (Food Traceability List). FDA will publish the Food Traceability List on its website, www.fda.gov., in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act.

§ 1.1305 What foods and persons are exempt from this subpart?

- (a) Exemptions for certain small producers.
 - (1) Certain produce farms.
 - (i) This subpart does not apply to farms or the farm activities of farm mixed-type facilities with respect to the produce they grow, when the farm is not a covered farm under part 112 of this chapter in accordance with § 112.4 of this chapter,
 - (ii) This subpart does not apply to produce farms when the average annual sum of the monetary value of their sales of produce and the market value of produce they manufacture, process, pack, or hold without sale (e.g., held for a fee) during the previous 3-year period is no more than \$25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.
 - (2) Certain shell egg producers. This subpart does not apply to shell egg producers with fewer than 3,000 laying hens at a particular farm, with respect to the shell eggs they produce at that farm.
 - (3) Certain other producers of raw agricultural commodities. This subpart does not apply to producers of raw agricultural commodities other than produce

or shell eggs (e.g., aquaculture operations) when the average annual sum of the monetary value of their sales of raw agricultural commodities and the market value of the raw agricultural commodities they manufacture, process, pack, or hold without sale (e.g., held for a fee) during the previous 3-year period is no more than \$25,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.

- (b) Exemption for farms when food is sold or donated directly to consumers. This subpart does not apply to a farm with respect to food produced on the farm (including food that is also packaged on the farm) that is sold or donated directly to a consumer by the owner, operator, or agent in charge of the farm.
- (c) Inapplicability to certain food produced and packaged on a farm. This subpart does not apply to food produced and packaged on a farm, provided that:
 - (1) The packaging of the food remains in place until the food reaches the consumer, and such packaging maintains the integrity of the product and prevents subsequent contamination or alteration of the product; and
 - (2) The labeling of the food that reaches the consumer includes the name, complete address (street address, town, State, country, and zip or other postal code for a domestic farm and comparable information for a foreign farm), and business phone number of the farm on which the food was produced and packaged. FDA will waive the requirement to include a business phone number, as appropriate, to accommodate a religious belief of the individual in charge of the farm.
- (d) Exemptions and partial exemptions for foods that receive certain types of processing. This subpart does not apply to the following foods that receive certain types of processing:
 - (1) Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions set forth in § 112.2 of this chapter are met for the produce;
 - (2) Shell eggs when all eggs produced at the particular farm receive a treatment (as defined in § 118.3 of this chapter) in accordance with § 118.1(a) of this chapter;
 - (3) Food that you subject to a kill step, provided that you maintain records containing:
 - (i) The information specified in § 1.1345 for your receipt of the food to which you apply the kill step (unless you have entered into a written agreement concerning your application of a kill step to the food in accordance with paragraph (d) of this section); and
 - (ii) A record of your application of the kill step;
 - (4) Food that you change such that the food is no longer on the Food Traceability List, provided that you maintain records containing the information specified in § 1.1345 for your receipt of the food you change

- (unless you have entered into a written agreement concerning your changing of the food such that the food is no longer on the Food Traceability List in accordance with paragraph (d) of this section);
- (5) Food that you receive that has previously been subjected to a kill step or that has previously been changed such that the food is no longer on the Food Traceability List;
 - (6) Food that will be subjected to a kill step by an entity other than a retail food establishment, restaurant, or consumer; or that will be changed by an entity other than a retail food establishment, restaurant, or consumer, such that the food will no longer be on the Food Traceability List, provided that:
 - (i) There is a written agreement between the shipper of the food and the receiver stating that the receiver will apply a kill step to the food or change the food such that it is no longer on the Food Traceability List; or
 - (ii) There is a written agreement between the shipper of the food and the receiver stating that an entity in the supply chain subsequent to the receiver will apply a kill step to the food or change the food such that it is no longer on the Food Traceability List and that the receiver will only ship the food to another entity that agrees, in writing, it will:
 - (A) Apply a kill step to the food or change the food such that it is no longer on the Food Traceability List; or
 - (B) Enter into a similar written agreement with a subsequent receiver stating that a kill step will be applied to the food or that the food will be changed such that it is no longer on the Food Traceability List.
 - (iii) A written agreement entered into in accordance with paragraph (d)(6) or of this section must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement; and
 - (iv) A written agreement entered into in accordance with paragraph (d)(6) or must be maintained by both parties for as long as it is in effect and must be renewed at least once every 3 years.
 - (e) Exemption for produce that is rarely consumed raw. This subpart does not apply to produce that is listed as rarely consumed raw in § 112.2(a) of this chapter.
 - (f) Exemption for raw bivalve molluscan shellfish. This subpart does not apply to raw bivalve molluscan shellfish that are covered by the requirements of the National Shellfish Sanitation Program, subject to the requirements of part 123, subpart C, and § 1240.60 of this chapter, or covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish.
 - (g) Exemption for persons who manufacture, process, pack, or hold certain foods subject to regulation by the U.S. Department of Agriculture (USDA). This subpart does not apply to persons who manufacture, process, pack, or hold food on the Food Traceability List during or after the time when the food is within the

exclusive jurisdiction of the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

- (h) Partial exemption for commingled raw agricultural commodities.
- (1) Except as specified in paragraph (h) of this section, this subpart does not apply to commingled raw agricultural commodities (which, as defined in § 1.1310, do not include types of fruits and vegetables to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in part 112 of this chapter apply).
 - (2) Except as specified in paragraph (h) of this section, this subpart does not apply to a raw agricultural commodity that will become a commingled raw agricultural commodity, provided that:
 - (i) There is a written agreement between the shipper of the raw agricultural commodity and the receiver stating that the receiver will include the commodity as part of a commingled raw agricultural commodity; or
 - (ii) There is a written agreement between the shipper of the raw agricultural commodity and the receiver stating that an entity in the supply chain subsequent to the receiver will include the commodity as part of a commingled raw agricultural commodity and that the receiver will only ship the raw agricultural commodity to another entity that agrees, in writing, it will either:
 - (A) Include the raw agricultural commodity as part of a commingled raw agricultural commodity; or
 - (B) Enter into a similar written agreement with a subsequent receiver stating that the raw agricultural commodity will become part of a commingled raw agricultural commodity;
 - (iii) A written agreement entered into in accordance with paragraph (h)(2) or of this section must include the effective date, printed names and signatures of the persons entering into the agreement, and the substance of the agreement; and
 - (iv) A written agreement entered into in accordance with paragraph (h)(2) or must be maintained by both parties for as long as it is in effect and must be renewed at least once every 3 years;
 - (3) With respect to a commingled raw agricultural commodity that qualifies for either of the exemptions set forth in paragraphs (h) and of this section, if a person who manufactures, processes, packs, or holds such commodity is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable raw agricultural commodity, such person must maintain records identifying the immediate previous source of such raw agricultural commodity and the immediate subsequent recipient of such

food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.

- (i) Exemption for small retail food establishments and small restaurants. This subpart does not apply to retail food establishments and restaurants with an average annual monetary value of food sold or provided during the previous 3-year period of no more than \$250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.
- (j) Partial exemption for retail food establishments and restaurants purchasing directly from a farm.
 - (1) Except as specified in paragraph (j) of this section, this subpart does not apply to a retail food establishment or restaurant with respect to a food that is produced on a farm (including food produced and packaged on the farm) and both sold and shipped directly to the retail food establishment or restaurant by the owner, operator, or agent in charge of that farm.
 - (2) When a retail food establishment or restaurant purchases a food directly from a farm in accordance with paragraph (j) of this section, the retail food establishment or restaurant must maintain a record documenting the name and address of the farm that was the source of the food. The retail food establishment or restaurant must maintain such a record for 180 days.
- (k) Partial exemption for retail food establishments and restaurants making certain purchases from another retail food establishment or restaurant.
 - (1) Except as specified in paragraph (k) of this section, this subpart does not apply to either entity when a purchase is made by a retail food establishment or restaurant from another retail food establishment or restaurant, and the purchase occurs on an ad hoc basis outside of the buyer's usual purchasing practice (e.g., not pursuant to a contractual agreement to purchase food from the seller).
 - (2) When a retail food establishment or restaurant purchases a food on the Food Traceability List from another retail food establishment or restaurant in accordance with paragraph (k) of this section, the retail food establishment or restaurant that makes the purchase must maintain a record (e.g., a sales receipt) documenting the name of the product purchased, the date of purchase, and the name and address of the place of purchase.
- (l) Partial exemption for farm to school and farm to institution programs.
 - (1) Except as specified in paragraph (l) of this section, this subpart does not apply to an institution operating a child nutrition program authorized under the Richard B. Russell National School Lunch Act or Section 4 of the Child Nutrition Act of 1966, or any other entity conducting a farm to school or farm to institution program, with respect to a food that is produced on a farm (including food produced and packaged on the farm) and sold or donated to the school or institution.

Appendix 1

- (2) When a school or institution conducting a farm to school or farm to institution program obtains a food from a farm in accordance with paragraph (l) of this section, the school food authority or relevant food procurement entity must maintain a record documenting the name and address of the farm that was the source of the food. The school food authority or relevant food procurement entity must maintain such record for 180 days.
- (m) Partial exemption for owners, operators, or agents in charge of fishing vessels.
 - (1) Except as specified in paragraph (m) of this section, with respect to a food that is obtained from a fishing vessel, this subpart does not apply to the owner, operator, or agent in charge of the fishing vessel, and this subpart also does not apply to persons who manufacture, process, pack, or hold the food until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel.
 - (2) With respect to any person who receives the partial exemption set forth in paragraph (m) of this section, if such person is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.
- (n) Exemption for transporters. This subpart does not apply to transporters of food.
- (o) Exemption for nonprofit food establishments. This subpart does not apply to nonprofit food establishments.
- (p) Exemption for persons who manufacture, process, pack, or hold food for personal consumption. This subpart does not apply to persons who manufacture, process, pack, or hold food for personal consumption.
- (q) Exemption for certain persons who hold food on behalf of individual consumers. This subpart does not apply to persons who hold food on behalf of specific individual consumers, provided that these persons:
 - (1) Are not parties to the transaction involving the food they hold; and
 - (2) Are not in the business of distributing food.
- (r) Exemption for food for research or evaluation. This subpart does not apply to food for research or evaluation use, provided that such food:
 - (1) Is not intended for retail sale and is not sold or distributed to the public; and
 - (2) Is accompanied by the statement "Food for research or evaluation use."

[87 FR 71077, Nov. 21, 2022, as amended at 88 FR 65815, Sept. 26, 2023]

§ 1.1310 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this subpart. In addition, the following definitions apply to words and phrases as they are used in this subpart:

Commingled raw agricultural commodity means any commodity that is combined or mixed after harvesting but before processing, except that the term “commingled raw agricultural commodity” does not include types of fruits and vegetables that are raw agricultural commodities to which the standards for the growing, harvesting, packing, and holding of produce for human consumption in part 112 of this chapter apply. For the purpose of this definition, a commodity is “combined or mixed” only when the combination or mixing involves food from different farms under different company management; except that for food obtained from a fishing vessel, a commodity is “combined or mixed” only when the combination or mixing involves food from different landing vessels and occurs after the vessels have landed. Also, for the purpose of this definition, the term “processing” means operations that alter the general state of the commodity, such as canning, cooking, freezing, dehydration, milling, grinding, pasteurization, or homogenization.

Cooling means active temperature reduction of a raw agricultural commodity using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process.

Critical tracking event means 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.

Farm means farm as defined in § 1.328. For producers of shell eggs, “farm” means all poultry houses and grounds immediately surrounding the poultry houses covered under a single biosecurity program, as set forth in § 118.3 of this chapter.

First land-based receiver means the person taking possession of a food for the first time on land directly from a fishing vessel.

Fishing vessel means any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration,

transportation, or processing, as set forth in the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(18)).

Food Traceability List means the list of foods for which additional traceability records are required to be maintained, as designated in accordance with section 204(d) of the FDA Food Safety Modernization Act. The term "Food Traceability List" includes both the foods specifically listed and foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list.

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots, or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Initial packing means packing a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time.

Key data element means information associated with a critical tracking event for which a record must be maintained and/or provided in accordance with this subpart.

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

Location description means key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Person includes an individual, partnership, corporation, and association.

Appendix 1

Point of contact means an individual having familiarity with an entity's procedures for traceability, including their name and/or job title, and their phone number.

Produce means produce as defined in § 112.3 of this chapter.

Product description means a description of a food product and includes the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style. For seafood, the product name may include the species and/or acceptable market name.

Raw agricultural commodity means "raw agricultural commodity" as defined in section 201 of the Federal Food, Drug, and Cosmetic Act.

Receiving means an event in a food's supply chain in which a food is received by someone other than a consumer after being transported (e.g., by truck or ship) from another location. Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

Reference document means 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 a food. A reference document may be established by you or obtained from another person. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.

Reference document number means the identification number assigned to a specific reference document.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. "Restaurant" does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

- (1) Entities in which food is provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants; and
- (2) Pet shelters, kennels, and veterinary facilities in which food is provided to animals are restaurants.

Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term "retail food establishment" includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it

manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. A "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function.

- 1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:
 - (i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);
 - (ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and
 - (iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.
- 2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:
 - (i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);
 - (ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

- (iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and internet order, including online farmers' markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.
- 3) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

Shipping means an event in a food's supply chain in which a food is arranged for transport (e.g., by truck or ship) from one location to another location. Shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food. Shipping includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

Traceability lot means 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 code means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.

Traceability lot code source means the place where a food was assigned a traceability lot code.

Traceability lot code source reference means an alternative method for providing FDA with access to the location description for the traceability lot code source as required under this subpart. Examples of a traceability lot code source reference include, but are not limited to, the FDA Food Facility Registration Number for the traceability lot code source or a web address that provides FDA with the location description for the traceability lot code source.

Transformation means an event in a food's supply chain that involves manufacturing/processing a food or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List. Transformation does not include the initial packing of a food or activities preceding that event (e.g., harvesting, cooling).

Transporter means a person who has possession, custody, or control of an article of food for the sole purpose of transporting the food, whether by road, rail, water, or air.

You means a person subject to this subpart under § 1.1300.

Traceability Plan

§ 1.1315 What traceability plan must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold?

- (a) If you are subject to the requirements in this subpart, 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 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, 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.
 - (i) Except as specified in paragraph (a)(5) of this section, 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.
 - (ii) For aquaculture farms, the farm map 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.
- (b) 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 this subpart. You must retain your previous traceability plan for 2 years after you update the plan.

§ 1.1320 When must I assign traceability lot codes to foods on the Food Traceability List?

- (a) You must assign a traceability lot code when you do any of the following: Initially pack a raw agricultural commodity other than a food obtained from a fishing vessel; perform the first land-based receiving of a food obtained from a fishing vessel; or transform a food.
- (b) Except as otherwise specified in this subpart, you must not establish a new traceability lot code when you conduct other activities (e.g., shipping) for a food on the Food Traceability List.

Records of Critical Tracking Events

§ 1.1325 What records must I keep and provide when I harvest or cool a raw agricultural commodity on the Food Traceability List?

- (a) Harvesting.
- (1) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you harvest, you must maintain records containing the following information:
 - (i) The location description for the immediate subsequent recipient (other than a transporter) of the food;
 - (ii) The commodity and, if applicable, variety of the food;
 - (iii) The quantity and unit of measure of the food (e.g., 75 bins, 200 pounds);
 - (iv) The location description for the farm where the food was harvested;
 - (v) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;
 - (vi) For aquacultured food, the name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name;
 - (vii) The date of harvesting; and
 - (viii) The reference document type and reference document number.
 - (2) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you harvest, you must provide (in electronic, paper, or other written form) your business name, phone number, and the information in paragraphs (a)(1) through of this section to the initial packer of the raw agricultural commodity you harvest, either directly or through the supply chain.
- (b) Cooling before initial packing.
- (1) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you cool before it is initially packed, you must maintain records containing the following information:
 - (i) The location description for the immediate subsequent recipient (other than a transporter) of the food;
 - (ii) The commodity and, if applicable, variety of the food;
 - (iii) The quantity and unit of measure of the food (e.g., 75 bins, 200 pounds);
 - (iv) The location description for where you cooled the food;
 - (v) The date of cooling;

- (vi) The location description for the farm where the food was harvested; and
 - (vii) The reference document type and reference document number.
- (2) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you cool before it is initially packed, you must provide (in electronic, paper, or other written form) the information in paragraphs (b)(1) through of this section to the initial packer of the raw agricultural commodity you cool, either directly or through the supply chain.

§ 1.1330 What records must I keep when I am performing the initial packing of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List?

- (a) Except as specified in paragraph of this section, for each traceability lot of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List you initially pack, you must maintain records containing the following information and linking this information to the traceability lot:
- (1) The commodity and, if applicable, variety of the food received;
 - (2) The date you received the food;
 - (3) The quantity and unit of measure of the food received (e.g., 75 bins, 200 pounds);
 - (4) The location description for the farm where the food was harvested;
 - (5) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;
 - (6) For aquacultured food, the name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name;
 - (7) The business name and phone number for the harvester of the food;
 - (8) The date of harvesting;
 - (9) The location description for where the food was cooled (if applicable);
 - (10) The date of cooling (if applicable);
 - (11) The traceability lot code you assigned;
 - (12) The product description of the packed food;
 - (13) The quantity and unit of measure of the packed food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
 - (14) The location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
 - (15) The date of initial packing; and

- (16) The reference document type and reference document number.
- (b) For each traceability lot of sprouts (except soil- or substrate-grown sprouts harvested without their roots) you initially pack, you must also maintain records containing the following information and linking this information to the traceability lot:
 - (1) The location description for the grower of seeds for sprouting and the date of seed harvesting, if either is available;
 - (2) The location description for the seed conditioner or processor, the associated seed lot code, and the date of conditioning or processing;
 - (3) The location description for the seed packinghouse (including any repackers), the date of packing (and of repacking, if applicable), and any associated seed lot code assigned by the seed packinghouse;
 - (4) The location description for the seed supplier, any seed lot code assigned by the seed supplier (including the master lot and sub-lot codes), and any new seed lot code assigned by the sprouter;
 - (5) A description of the seeds, including the seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment;
 - (6) The date of receipt of the seeds by the sprouter; and
 - (7) The reference document type and reference document number.
- (c) For each traceability lot of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List you initially pack that you receive from a person to whom this subpart does not apply, you must maintain records containing the following information and linking this information to the traceability lot:
 - (1) The commodity and, if applicable, variety of the food received;
 - (2) The date you received the food;
 - (3) The quantity and unit of measure of the food received (e.g., 75 bins, 200 pounds);
 - (4) The location description for the person from whom you received the food;
 - (5) The traceability lot code you assigned;
 - (6) The product description of the packed food;
 - (7) The quantity and unit of measure of the packed food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
 - (8) The location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
 - (9) The date of initial packing; and
 - (10) The reference document type and reference document number.

§ 1.1335 What records must I keep when I am the first land-based receiver of a food on the Food Traceability List that was obtained from a fishing vessel?

For each traceability lot of a food obtained from a fishing vessel for which you are the first land-based receiver, you must maintain records containing the following information and linking this information to the traceability lot:

- (a) The traceability lot code you assigned;
- (b) The species and/or acceptable market name for unpackaged food, or the product description for packaged food;
- (c) The quantity and unit of measure of the food (e.g., 300 kg);
- (d) The harvest date range and locations (as identified under the National Marine Fisheries Service Ocean Geographic Code, the United Nations Food and Agriculture Organization Major Fishing Area list, or any other widely recognized geographical location standard) for the trip during which the food was caught;
- (e) The location description for the first land-based receiver (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
- (f) The date the food was landed; and
- (g) The reference document type and reference document number.

§ 1.1340 What records must I keep and provide when I ship a food on the Food Traceability List?

- (a) For each traceability lot of a food on the Food Traceability List you ship, you must maintain records containing the following information and linking this information to the traceability lot:
 - (1) The traceability lot code for the food;
 - (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
 - (3) The product description for the food;
 - (4) The location description for the immediate subsequent recipient (other than a transporter) of the food;
 - (5) The location description for the location from which you shipped the food;
 - (6) The date you shipped the food;
 - (7) The location description for the traceability lot code source, or the traceability lot code source reference; and
 - (8) The reference document type and reference document number.
- (b) You must provide (in electronic, paper, or other written form) the information in paragraphs (a) through (8) of this section to the immediate subsequent recipient (other than a transporter) of each traceability lot that you ship.

- (c) 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).

§ 1.1345 What records must I keep when I receive a food on the Food Traceability List?

- (a) Except as specified in paragraphs and of this section, for each traceability lot of a food on the Food Traceability List you receive, you must maintain records containing the following information and linking this information to the traceability lot:
 - (1) The traceability lot code for the food;
 - (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
 - (3) The product description for the food;
 - (4) The location description for the immediate previous source (other than a transporter) for the food;
 - (5) The location description for where the food was received;
 - (6) The date you received the food;
 - (7) The location description for the traceability lot code source, or the traceability lot code source reference; and
 - (8) The reference document type and reference document number.
- (b) For each traceability lot of a food on the Food Traceability List you receive from a person to whom this subpart does not apply, you must maintain records containing the following information and linking this information to the traceability lot:
 - (1) The traceability lot code for the food, which you must assign if one has not already been assigned (except that this paragraph does not apply if you are a retail food establishment or restaurant);
 - (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
 - (3) The product description for the food;
 - (4) The location description for the immediate previous source (other than a transporter) for the food;
 - (5) The location description for where the food was received (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
 - (6) The date you received the food; and
 - (7) The reference document type and reference document number.
- (c) 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).

§ 1.1350 What records must I keep when I transform a food on the Food Traceability List?

- (a) Except as specified in paragraphs and of this section, for each new traceability lot of food you produce through transformation, you must maintain records containing the following information and linking this information to the new traceability lot:
 - (1) For the food on the Food Traceability List used in transformation (if applicable), the following information:
 - (i) The traceability lot code for the food;
 - (ii) The product description for the food to which the traceability lot code applies; and
 - (iii) For each traceability lot used, the quantity and unit of measure of the food used from that lot.
 - (2) For the food produced through transformation, the following information:
 - (i) The new traceability lot code for the food;
 - (ii) The location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
 - (iii) The date transformation was completed;
 - (iv) The product description for the food;
 - (v) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds); and
 - (vi) The reference document type and reference document number for the transformation event.
- (b) For each traceability lot produced through transformation of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List that was not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330 or (c), and, if the raw agricultural commodity is sprouts, the information specified in § 1.1330(b).
- (c) Paragraphs (a) and (b) of this section do 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).

Procedures for Modified Requirements and Exemptions

§ 1.1360 Under what circumstances will FDA modify the requirements in this subpart that apply to a food or type of entity or exempt a food or type of entity from the requirements of this subpart?

- (a) **General.** Except as specified in paragraph (b) of this section, FDA will modify the requirements of this subpart applicable to a food or type of entity, or exempt a food or type of entity from the requirements of this subpart, when we determine that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health.
- (b) **Registered facilities.** If a person to whom modified requirements or an exemption applies under paragraph (a) of this section (including a person who manufactures, processes, packs, or holds a food to which modified requirements or an exemption applies under paragraph (a) of this section) is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (and in accordance with the requirements of subpart H of this part) with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.

§ 1.1365 When will FDA consider whether to adopt modified requirements or grant an exemption from the requirements of this subpart?

FDA will consider modifying the requirements of this subpart applicable to a food or type of entity, or exempting a food or type of entity from the requirements of this subpart, on our own initiative or in response to a citizen petition submitted under § 10.30 of this chapter by any interested party.

§ 1.1370 What must be included in a petition requesting modified requirements or an exemption from the requirements?

In addition to meeting the requirements on the content and format of a citizen petition in § 10.30 of this chapter, a petition requesting modified requirements or an exemption from the requirements of this subpart must:

- (a) Specify the food or type of entity to which the modified requirements or exemption would apply;
- (b) If the petition requests modified requirements, specify the proposed modifications to the requirements of this subpart; and

- (c) Present information demonstrating why application of the requirements requested to be modified or from which exemption is requested is not necessary to protect the public health.

§ 1.1375 What information submitted in a petition requesting modified requirements or an exemption, or information in comments on such a petition, is publicly available?

FDA will presume that information submitted in a petition requesting modified requirements or an exemption, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with the petition.

§ 1.1380 What process applies to a petition requesting modified requirements or an exemption?

- (a) In general, the procedures set forth in § 10.30 of this chapter govern FDA's response to a petition requesting modified requirements or an exemption. An interested person may submit comments on such a petition in accordance with § 10.30(d) of this chapter.
- (b) Under § 10.30(h)(3) of this chapter, FDA will publish a notice in the Federal Register requesting information and views on a submitted petition, including information and views from persons who could be affected by the modified requirements or exemption if we granted the petition.
- (c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing, as follows:
 - (1) If we grant the petition either in whole or in part, we will publish a notice in the Federal Register setting forth any modified requirements or exemptions and the reasons for them.
 - (2) If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial.
- (d) We will make readily accessible to the public, and periodically update, a list of petitions requesting modified requirements or exemptions, including the status of each petition (for example, pending, granted, or denied).

§ 1.1385 What process will FDA follow when adopting modified requirements or granting an exemption on our own initiative?

- (a) If FDA, on our own initiative, determines that adopting modified requirements or granting an exemption from the requirements for a food or type of entity is appropriate, we will publish a notice in the Federal Register setting forth the proposed modified requirements or exemption and the reasons for the proposal. The notice will establish a public docket so that interested persons may submit written comments on the proposal.
- (b) After considering any comments timely submitted, we will publish a notice in the Federal Register stating whether we are adopting modified requirements or granting an exemption, and the reasons for our decision.

§ 1.1390 When will modified requirements that we adopt or an exemption that we grant become effective?

Any modified requirements that FDA adopts or exemption that we grant will become effective on the date that notice of the modified requirements or exemption is published in the Federal Register , unless otherwise stated in the notice.

§ 1.1395 Under what circumstances may FDA revise or revoke modified requirements or an exemption?

FDA may revise or revoke modified requirements or an exemption if we determine that such revision or revocation is necessary to protect the public health.

§ 1.1400 What procedures apply if FDA tentatively determines that modified requirements or an exemption should be revised or revoked?

- (a) If FDA tentatively determines that we should revise or revoke modified requirements or an exemption, we will provide the following notifications:
 - (1) We will notify the person that originally requested the modified requirements or exemption (if we adopted modified requirements or granted an exemption in response to a petition) in writing at the address identified in the petition; and
 - (2) We will publish a notice in the Federal Register of our tentative determination that the modified requirements or exemption should be revised or revoked and the reasons for our tentative decision. The notice will establish a public docket so that interested persons may submit written comments on our tentative determination.

- (b) After considering any comments timely submitted, we will publish a notice in the Federal Register of our decision whether to revise or revoke the modified requirements or exemption and the reasons for the decision. If we do revise or revoke the modified requirements or exemption, the effective date of the decision will be 1 year after the date of publication of the notice, unless otherwise stated in the notice.

Waivers

§ 1.1405 Under what circumstances will FDA waive one or more of the requirements of this subpart for an individual entity or a type of entity?

FDA will waive one or more of the requirements of this subpart when we determine that:

- (a) Application of the requirements would result in an economic hardship for an individual entity or a type of entity, due to the unique circumstances of the individual entity or type of entity;
- (b) The waiver will not significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and
- (c) The waiver will not otherwise be contrary to the public interest.

§ 1.1410 When will FDA consider whether to waive a requirement of this subpart?

FDA will consider whether to waive a requirement of this subpart on our own initiative or in response to the following:

- (a) A written request for a waiver for an individual entity; or
- (b) A citizen petition requesting a waiver for a type of entity submitted under § 10.30 of this chapter by any person subject to the requirements of this subpart.

§ 1.1415 How may I request a waiver for an individual entity?

You may request a waiver of one or more requirements of this subpart for an individual entity by submitting a written request to the Food and Drug Administration as described at www.fda.gov. The request for a waiver must include the following:

- (a) The name, address, and point of contact of the individual entity to which the waiver would apply;
- (b) The requirements of this subpart to which the waiver would apply;
- (c) Information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the entity, including information about the unique circumstances faced by the entity that result in unusual economic hardship from the application of these requirements;
- (d) Information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and
- (e) Information demonstrating why the waiver would not otherwise be contrary to the public interest.

§ 1.1420 What process applies to a request for a waiver for an individual entity?

- (a) After considering the information submitted in a request for a waiver for an individual entity, we will respond in writing to the person that submitted the waiver request stating whether we are granting the waiver (in whole or in part) and the reasons for the decision.
- (b) Any waiver for an individual entity that FDA grants will become effective on the date we issue our response to the waiver request, unless otherwise stated in the response.

§ 1.1425 What must be included in a petition requesting a waiver for a type of entity?

In addition to meeting the requirements on the content and format of a citizen petition in § 10.30 of this chapter, a petition requesting a waiver for a type of entity must:

- (a) Specify the type of entity to which the waiver would apply and the requirements of this subpart to which the waiver would apply;
- (b) Present information demonstrating why application of the requirements requested to be waived would result in an economic hardship for the type of entity, including information about the unique circumstances faced by the type of entity that result in unusual economic hardship from the application of these requirements;

- (c) Present information demonstrating why the waiver will not significantly impair FDA's ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; and
- (d) Present information demonstrating why the waiver would not otherwise be contrary to the public interest.

§ 1.1430 What information submitted in a petition requesting a waiver for a type of entity, or information in comments on such a petition, is publicly available?

FDA will presume that information submitted in a petition requesting a waiver for a type of entity, as well as information in comments submitted on such a petition, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with the petition.

§ 1.1435 What process applies to a petition requesting a waiver for a type of entity?

- (a) In general, the procedures set forth in § 10.30 of this chapter govern FDA's response to a petition requesting a waiver. An interested person may submit comments on such a petition in accordance with § 10.30(d) of this chapter.
- (b) Under § 10.30(h) of this chapter, FDA will publish a notice in the Federal Register requesting information and views on a submitted petition requesting a waiver for a type of entity, including information and views from persons who could be affected by the waiver if we granted the petition.
- (c) Under § 10.30(e) of this chapter, we will respond to the petitioner in writing, as follows:
 - (1) If we grant the petition either in whole or in part, we will publish a notice in the Federal Register setting forth any requirements we have waived and the reasons for the waiver.
 - (2) If we deny the petition (including a partial denial), our written response to the petitioner will explain the reasons for the denial.
- (d) We will make readily accessible to the public, and periodically update, a list of petitions requesting waivers for types of entities, including the status of each petition (for example, pending, granted, or denied).

§ 1.1440 What process will FDA follow when waiving a requirement of this subpart on our own initiative?

- (a) If FDA, on our own initiative, determines that a waiver of one or more requirements for an individual entity or type of entity is appropriate, we will publish a notice in the Federal Register setting forth the proposed waiver and the reasons for such waiver. The notice will establish a public docket so that interested persons may submit written comments on the proposal.
- (b) After considering any comments timely submitted, we will publish a notice in the Federal Register stating whether we are granting the waiver (in whole or in part) and the reasons for our decision.
- (c) Any waiver for a type of entity that FDA grants will become effective on the date that notice of the waiver is published in the Federal Register, unless otherwise stated in the notice.

§ 1.1445 Under what circumstances may FDA modify or revoke a waiver?

FDA may modify or revoke a waiver if we determine that:

- (a) Compliance with the waived requirements would no longer impose a unique economic hardship on the individual entity or type of entity to which the waiver applies;
- (b) The waiver could significantly impair our ability to rapidly and effectively identify recipients of a food to prevent or mitigate a foodborne illness outbreak or to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act; or
- (c) The waiver is otherwise contrary to the public interest.

§ 1.1450 What procedures apply if FDA tentatively determines that a waiver should be modified or revoked?

- (a) Waiver for an individual entity.
 - (1) If FDA tentatively determines that we should modify or revoke a waiver for an individual entity, we will notify the person that had received the waiver in writing of our tentative determination that the waiver should be modified or revoked. The notice will provide the waiver recipient 60 days in which to submit information stating why the waiver should not be modified or revoked.
 - (2) Upon consideration of any information submitted by the waiver recipient, we will respond in writing stating our decision whether to modify or revoke the

- waiver and the reasons for the decision. If we modify or revoke the waiver, the effective date of the decision will be 1 year after the date of our response to the waiver recipient, unless otherwise stated in the response.
- (b) Waiver for a type of entity.
- (1) If FDA tentatively determines that we should modify or revoke a waiver for a type of entity, we will provide the following notifications:
- (i) We will notify the person that originally requested the waiver (if we granted the waiver in response to a petition) in writing at the address identified in the petition.
- (ii) We will publish a notice in the Federal Register of our tentative determination that the waiver should be modified or revoked and the reasons for our tentative decision. The notice will establish a public docket so that interested persons may submit written comments on our tentative determination.
- (2) After considering any comments timely submitted, we will publish a notice in the Federal Register of our decision whether to modify or revoke the waiver and the reasons for the decision. If we do modify or revoke the waiver, the effective date of the decision will be 1 year after the date of publication of the notice, unless otherwise stated in the notice.

Records Maintenance and Availability

§ 1.1455 How must records required by this subpart be maintained and made available?

- (a) **General requirements for records.**
- (1) You must keep records as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records). Electronic records may include valid, working electronic links to the information required to be maintained under this subpart.
- (2) All records must be legible and stored to prevent deterioration or loss.
- (b) **Establishment and maintenance of records by another entity.** You may have another entity establish and maintain records required under this subpart on your behalf, but you are responsible for ensuring that such records can be retrieved and provided onsite within 24 hours of request for official review.
- (c) **Record availability.**
- (1) You must make all records required under this subpart available to an authorized FDA representative, upon request, within 24 hours (or within some reasonable time to which FDA has agreed) after the request, along with any information needed to understand these records, such as internal or external

- coding systems, glossaries, abbreviations, and a description of how the records you provide correspond to the information required under this subpart.
- (2) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.
 - (3) When necessary to help FDA prevent or mitigate a foodborne illness outbreak, or to assist in the implementation of a recall, or to otherwise address a threat to the public health, including but not limited to situations where FDA has a reasonable belief that an article of food (and any other article of food that FDA reasonably believes is likely to be affected in a similar manner) presents a threat of serious adverse health consequences or death to humans or animals as a result of the food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act, you must make available, within 24 hours (or within some reasonable time to which FDA has agreed) of a request made in-person or remotely (e.g., by phone) by an authorized FDA representative, the information you are required to maintain under this subpart, for the foods and date ranges or traceability lot codes specified in the request.
 - (i) If FDA's request for the information specified in paragraph (c)(3) of this section is made by phone, we will also provide the request to you in writing upon your request; however, you must provide the requested information within 24 hours (or within some reasonable time to which FDA has agreed) of the phone request.
 - (ii) Except as specified in paragraph (c)(3)(iii) and of this section, when the information requested by FDA under paragraph (c)(3) of this section is information you are required to maintain under §§ 1.1325 through 1.1350, you must provide such information in an electronic sortable spreadsheet, along with any other information needed to understand the information in the spreadsheet.
 - (iii) You may provide the information requested by FDA under paragraph (c)(3) of this section in a form other than an electronic sortable spreadsheet if you are:
 - (A) A farm whose average annual sum of the monetary value of their sales of raw agricultural commodities and the market value of raw agricultural commodities they manufacture, process, pack, or hold without sale (e.g., held for a fee) during the previous 3-year period is no more than \$250,000 (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment;

- (B) A retail food establishment or restaurant with an average annual monetary value of food sold or provided during the previous 3-year period of no more than \$1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment; or
- (C) A person (other than a farm, retail food establishment, or restaurant) whose average annual sum of the monetary value of their sales of food and the market value of food they manufacture, process, pack, or hold without sale (e.g., held for a fee) during the previous 3-year period is no more than \$1 million (on a rolling basis), adjusted for inflation using 2020 as the baseline year for calculating the adjustment.
- (iv) FDA will withdraw a request for an electronic sortable spreadsheet under paragraph (c)(3)(ii) of this section, as appropriate, to accommodate a religious belief of a person asked to provide such a spreadsheet.
- (4) Upon FDA request, you must provide within a reasonable time an English translation of records required under this subpart maintained in a language other than English.
- (d) **Record retention.** Except as specified otherwise in this subpart, you must maintain records containing the information required by this subpart for 2 years from the date you created or obtained the records.
- (e) **Electronic records.** Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter, if not otherwise exempt.
- (f) **Use of existing records.** You do not need to duplicate existing records you have (e.g., records that you keep in the ordinary course of business or that you maintain to comply with other Federal, State, Tribal, territorial, or local regulations) if they contain the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.
- (g) **Use of multiple sets of records.** You do not have to keep all of the information required by this subpart in a single set of records. However, your traceability plan must indicate the format and location of the records you are required to keep under this subpart, in accordance with § 1.1315(a)(1).
- (h) **Public disclosure.** Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

Consequences of Failure To Comply

§ 1.1460 What consequences could result from failing to comply with the requirements of this subpart?

- (a) Prohibited act. The violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act, including the violation of any requirement of this subpart, is prohibited under section 301(e) of the Federal Food, Drug, and Cosmetic Act, except when such violation is committed by a farm.
- (b) Refusal of admission. An article of food is subject to refusal of admission under section 801(a)(4) of the Federal Food, Drug, and Cosmetic Act if it appears that the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection of that section), including the requirements of this subpart, have not been complied with regarding such article.

Updating the Food Traceability List

§ 1.1465 How will FDA update the Food Traceability List?

- (a) When FDA tentatively concludes, in accordance with section 204(d) of the FDA Food Safety Modernization Act, that it is appropriate to revise the Food Traceability List, we will publish a notice in the Federal Register stating the proposed changes to the list and the reasons for these changes and requesting information and views on the proposed changes.
- (b) After considering any information and views submitted on the proposed changes to the Food Traceability List, FDA will publish a notice in the Federal Register stating whether we are making any changes to the list and the reasons for the decision. If FDA revises the list, we will also publish the revised list on our website.
- (c) When FDA updates the Food Traceability List in accordance with this section, any deletions from the list will become effective immediately. Any additions to the list will become effective 2 years after the date of publication of the Federal Register notice announcing the revised list, unless otherwise stated in the notice.

Appendix 2: Other Regulations that Impact Traceability

There is a long history of traceability requirements for various foods in order to protect public health. The following standards and regulations, along with others, can be viewed as precursors to the Food Traceability Rule (FTR). Information maintained to fulfil requirements for these regulations and programs could also be used to comply with the FTR.

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Let's look at a few examples.

The Pasteurized Milk Ordinance

This regulation began as the Standard Milk Ordinance (SMO). Through its 100-year history, this federal/state cooperative program developed standard food safety and sanitation practices for the interstate sales of milk. Traceability elements of the program include requiring that packaged milk products processed under the PMO be labeled to include information about the processing facility and for certain products include a code or lot numbers to identify product date.

Low-Acid Canned Foods

Regulations for the production of low-acid canned foods (LACF) and acidified foods, which have been in place since the 1970s, require processors to assign codes to production lots. A key traceability element of this regulation is that each container is marked with a code that identifies the product, the facility where the product was manufactured, and the specific production period which can be correlated to relevant manufacturing records. Processors are also required to maintain records identifying the initial distribution of the finished product.

National Shellfish Sanitation Program

The NSSP is a federal/state cooperative program that established oversight on the growing, harvesting, processing and repacking of interstate sales of raw molluscan shellfish such as oysters, clams, mussels and whole or roe-on scallops. A key traceability element of the program includes maintaining information about the date of harvest, identity of harvest location and harvester with the shellstock throughout distribution chain.



Subpart J ("One-Up One-Back")

Subpart J - Establishment, Maintenance, and Availability of Records, was mandated by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The purpose of this 2005 rule is to allow FDA to identify the immediate previous sources and immediate subsequent recipients of foods (including ingredients and packaging used in manufacturing foods) when necessary to address credible threats of serious adverse health consequences or death. Certain sectors of the food supply chain are required to maintain records of this information. This rule is often referred to as "One Up One Back."

Appendix 3: CTEs and KDEs

On the following pages you will find a document called Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs). This document shows each CTE and their required KDEs.

This same document is available online and your instructor will provide you with a link. Online, the tabs are interactive and it is easy to navigate.

Refer to this document when you need to identify which KDEs and which CTEs are required in a given scenario.

Cooling (before Initial Packing)

Initial Packing (RAC)

First Land-Based Receiver

Shipping

Receiving

Transformation

Traceability Plan

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.



Harvesting

Cooling
(before Initial Packing)

Initial Packing
(RAC)

First Land-Based Receiver

Shipping

Receiving

Transformation

Traceability Plan

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

Harvesting KDEs (Raw agricultural commodities (RACs) not obtained from a fishing vessel)

- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for the farm where the food was harvested
- For produce:
 - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or
 - Other information identifying the harvest location at least as precisely as field or growing area name
- For aquacultured food:
 - Name of the container (e.g., pond, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or
 - Other information identifying the harvest location at least as precisely as the container name
- Date of harvesting
- Reference document type and reference document number

Provide to the Initial Packer

- Business name
- Phone number
- Harvesting KDEs (except the reference document type and reference document number)

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2

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

Cooling KDEs (RACs not obtained from a fishing vessel)

- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for where you cooled the food
- Date of cooling
- Location description for the farm where the food was harvested
- Reference document type and reference document number

Provide to the Initial Packer

- Cooling KDEs (except the reference document type and reference document number)



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



Initial Packing KDEs of RACs (other than a food obtained from a fishing vessel)
KDEs must be linked to the traceability lot you assign for the food that you pack

- Commodity and, if applicable, variety of the food received
- Date you received the food
- Quantity and unit of measure of the food received
- Location description for the farm where the food was harvested
- For produce:
 - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or
 - Other information identifying the harvest location at least as precisely as field or growing area name
- For aquacultured food:
 - Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or
 - Other information identifying the harvest location at least as precisely as the container name
- Business name and phone number for the harvester of the food
- Date of harvesting
- Location description for where the food was cooled (if applicable)
- Date of cooling (if applicable)
- Traceability lot code you assigned
- Product description of the packed food
- Quantity and unit of measure of the packed food
- Location description for where you initially packed the food (i.e., traceability lot code source), and (if applicable), the traceability lot code source reference
- Date of initial packing
- Reference document type and reference document number

Harvesting

Cooling
(before Initial Packing)

Initial Packing
(FAC)

First Land-Based Receiver

Shipping

Receiving

Transformation

Traceability Plan

FDA

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

Initial Packing KDEs (Sprouts)

KDEs must be linked to the traceability lot for the food

All KDEs on previous slide **AND** :

- Location description for the grower of seeds for sprouting and date of seed harvesting, if either is available
- Location description for the seed conditioner or processor, associated seed lot code, and date of conditioning or processing
- Location description for the seed packinghouse (including any repackers), date of packing (and repacking, if applicable), and any associated seed lot code assigned by the seed packinghouse
- Location description for the seed supplier, any seed lot code assigned by the seed supplier (including master lot and sub-lot codes), and any new seed lot code assigned by the sprouter
- Description of the seeds, including seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment
- Date of receipt of the seeds by the sprouter
- Reference document type and reference document number



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5

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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

Initial Packing KDEs of RACs (other than a food obtained from a fishing vessel)
For food you receive from a person who is exempt from the rule KDEs must be linked to the traceability lot for the food

- Commodity and, if applicable, variety of the food received
- Date you received the food
- Quantity and unit of measure of the food received
- Location description for the person from whom you received the food
- Traceability lot code you assigned
- Product description of the packed food
- Quantity and unit of measure of the packed food
- Location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference
- Date of initial packing
- Reference document type and reference document number



Harvesting

Cooling
(before Initial Packing)

Initial Packing
(RAC)

First Land-Based Receiver

Shipping

Receiving

Transformation

Traceability Plan

FDA

U.S. FOOD & DRUG
ADMINISTRATION

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

First Land-Based Receiver KDEs (food obtained from a fishing vessel)
KDEs must be linked to the traceability lot for the food

- Traceability lot code you assigned
- Species and/or acceptable market name for unpackaged food, or the product description for packaged food
- Quantity and unit of measure of the food
- Harvest date range and locations for the trip during which the food was caught
- Location description for the first land-based receiver (i.e., traceability lot code source), and (if applicable) traceability lot code source reference
- Date the food was landed
- Reference document type and reference document number



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7

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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

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).

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8

Harvesting

Cooling
(before Initial Packing)

Initial Packing
(IAC)

First Land-Based Receiver

Shipping

Receiving

Transformation

Traceability Plan

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ADMINISTRATION

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).

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9

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

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).

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10



Traceability Plan

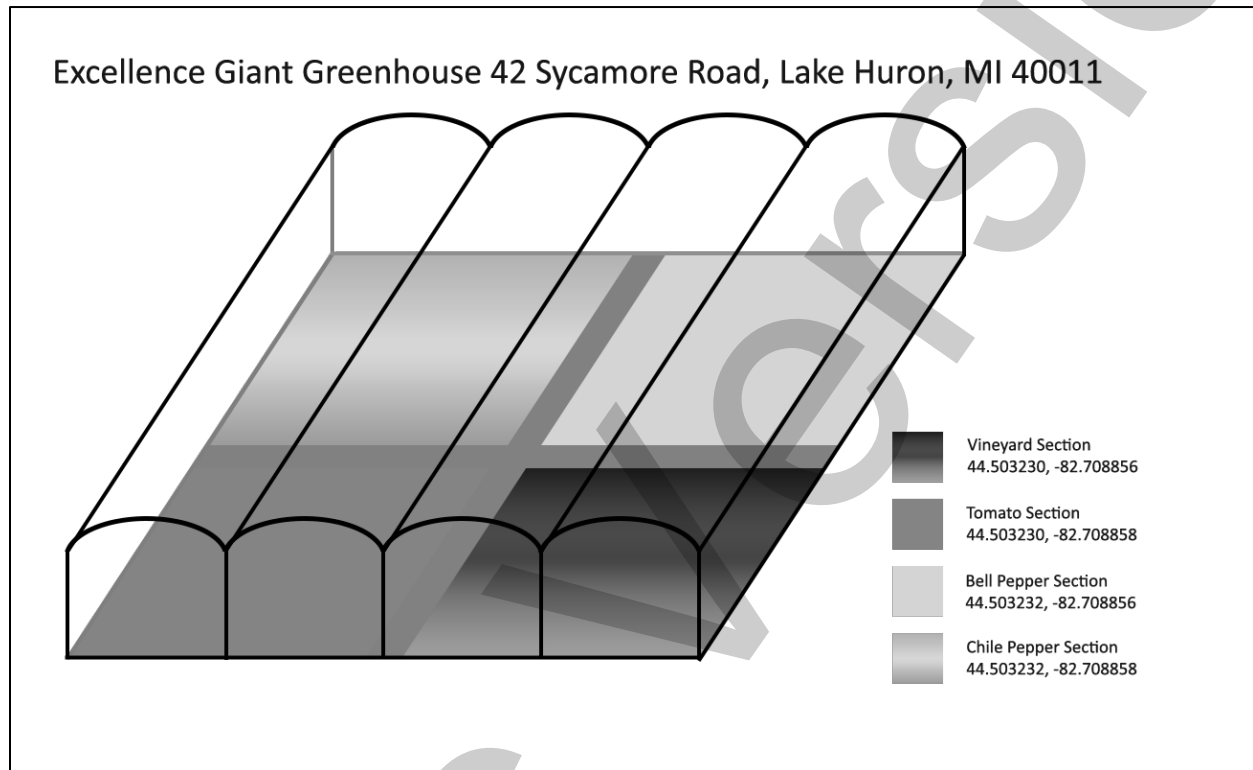
Required for all persons covered by the rule

- 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
 - If you grow or raise a food on the FTL (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 FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area
 - For aquaculture farms, the farm map must show the location and name of each container (e.g., pond, pool, tank, cage) in which you raise seafood on the FTL, including the geographic coordinates and any other information needed to identify the location of each container
 - You must update your traceability plan as needed to ensure that the information reflects your current practices and to ensure you are in compliance with the rule
- You must retain your previous traceability plan for 2 years after you update the plan

Appendix 4: Sample Farm Maps

This appendix contains several farm maps for you to reference. They show different formats, all of which are acceptable as farm maps.

Sample Farm Map 1



Appendix 4

Sample Farm Map 2

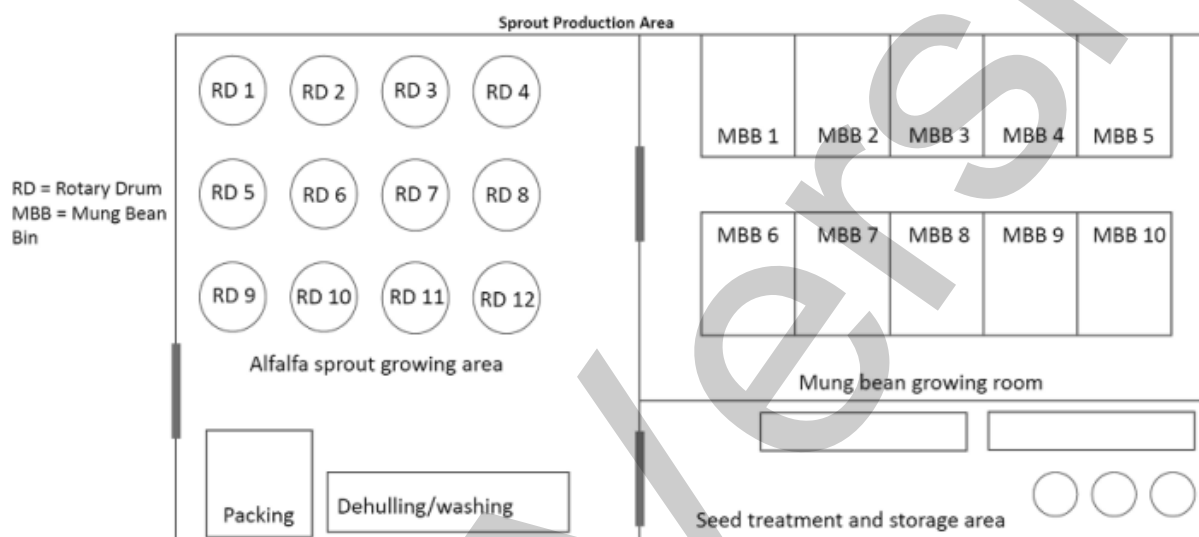
Lizzie's Lettuce: 331 Laurel St, Carthage, CA 33133

Farm Name	Field Name	Field Geographic Coordinates
Lizzie's Lettuce	Field A-08	26.35145, -81.45909
Lizzie's Lettuce	Field B-09	26.35008, -81.45906
Lizzie's Lettuce	Field C-02	26.34812, -81.45893
Lizzie's Lettuce	Field D-03	26.34647, -81.45913



Sample Farm Map 3

Growing Green
123 Alfalfa lane
Minneapolis, MN 55401
GPS coordinates: 39.289661, -76.580203



Public Version

Appendix 5: Procedures to Implement a Traceability Program

Note: These are best practices but not regulatory requirements.

Step 1: Evaluation, Assessment, and Planning

- Conduct a thorough assessment of current traceability practices, systems, and capabilities within the organization. Evaluate what you have now.
- Define the scope and objectives of the traceability program, considering such factors as product types, supply chain complexity, regulatory requirements, and organizational goals.
- Identify key internal and external stakeholders. These could include suppliers, customers, technology providers, consultants, and software companies (such as warehouse management and Enterprise Resource Planning (ERP) systems).

Step 2: Gap Analysis and Requirements Definition

- Perform a gap analysis to identify discrepancies between existing practices and desired traceability objectives. Evaluate your current capabilities and determine what is needed to comply with the FTR.
- Define the specific requirements and components of the traceability plan, including Critical Tracking Events (CTEs), Key Data Elements (KDEs), recordkeeping protocols, and technology solutions.



Step 3: Develop Traceability Protocols

- Develop processes and procedures to identify, capture, and share traceability data throughout the supply chain, determine if industry standards exist, and if supply chain members expect alignment around industry standards.
- Define roles and responsibilities for personnel involved in traceability activities, ensuring clarity and accountability at each stage of the process.
- Establish or determine appropriate formats, templates, and documentation requirements for traceability records to ensure consistency and compliance. These may be built in-house or found in external resources.

Part of the protocol will enable you to format your data in an electronic sortable spreadsheet. KDEs might be found in business records or in a database. Companies with databases must be able to query them to retrieve KDEs, and store KDEs in such a manner that they can easily populate an electronic sortable spreadsheet upon FDA request.

Companies should prepare for FDA information requests. This is different from a mock recall. Traceability team members could practice how they will pull the requested information together in 24 hours.



Step 4: Solution (or Data Systems) Implementation

- Identify and implement appropriate data management solutions to support traceability efforts, such as traceability software, tools, and technologies.
- If appropriate, integrate data management systems or your solutions with existing enterprise systems and supply chain partners' systems to enable seamless data exchange and interoperability.
- If resources allow, provide personnel with training and support for technology tools and systems to ensure effective adoption and utilization.

Note: the FTR does not require this.

Step 5: Pilot Testing and Validation

- Conduct pilot tests or simulations of the traceability program to assess its effectiveness, feasibility, and scalability.
- Identify and address any issues, challenges, or gaps during pilot testing, including feedback from internal and external stakeholders.
- Make necessary adjustments and refinements to the program as needed.



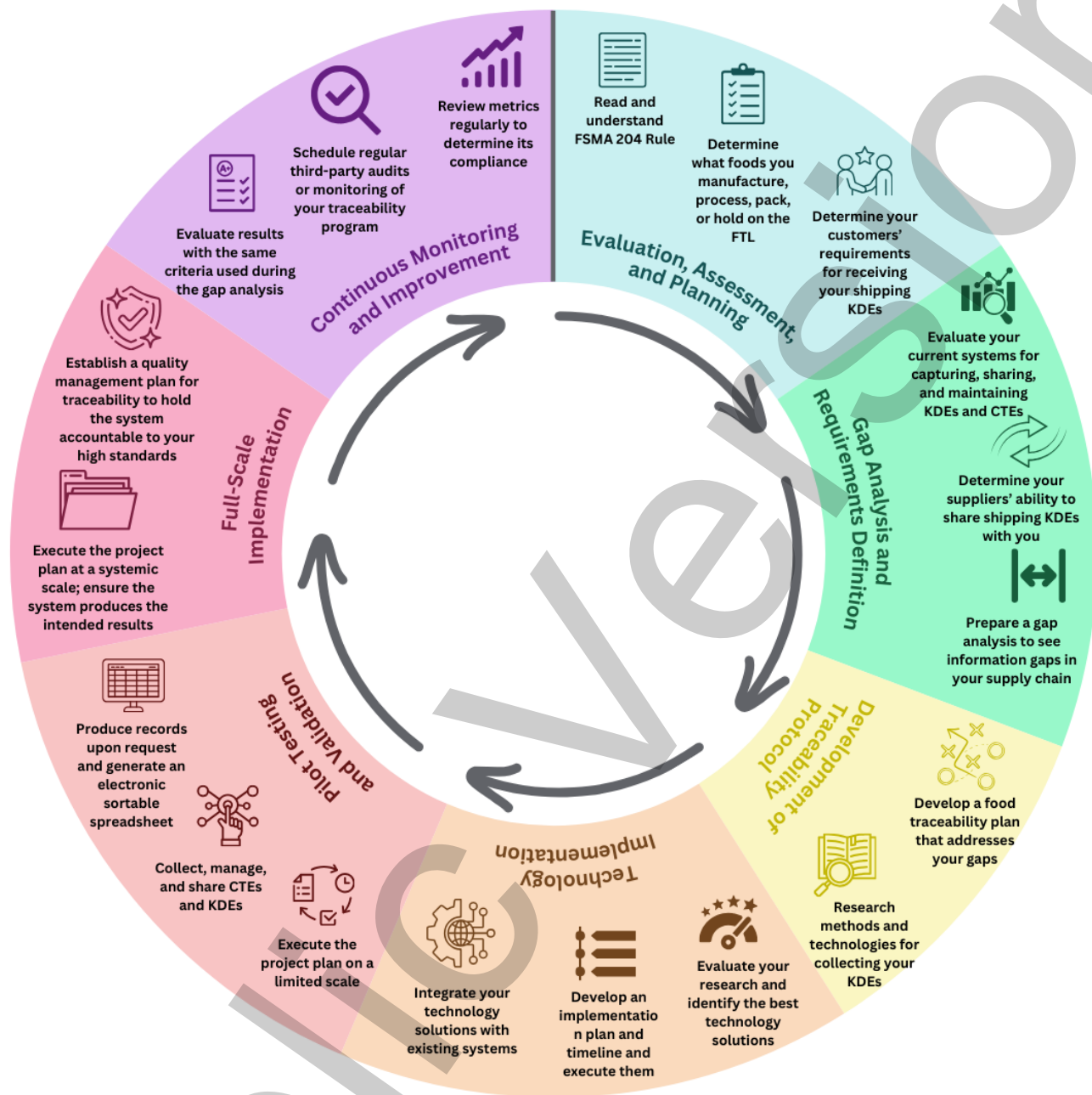
Step 6: Full-Scale Implementation

- Develop a rollout plan that fits the size and complexity of your organization.
- Roll out the traceability program across the organization and its supply chain partners, ensuring clear communication and coordination.
- Monitor and assess the implementation. Modify it as needed.
- Identify and address any challenges through proactive communication, training, and support mechanisms.

Step 7: Continuous Monitoring and Improvement

- Establish mechanisms for ongoing monitoring, evaluation, and improvement of traceability practices and systems.
- Regularly review and update the traceability plan in response to changing regulatory requirements, industry standards, technological advancements, and business needs.
- Foster a culture of continuous improvement and learning, encouraging collaboration, innovation, and knowledge sharing among stakeholders involved in traceability efforts.

Procedures to Implement a Traceability Plan



Public Version

Appendix 6: Barcodes and Their Role in Traceability

Barcodes are a fundamental tool used throughout the food supply chain for product identification. Barcodes can play a significant role in facilitating traceability, although it's important to understand the distinction between regulatory requirements and industry best practices. While the Food Traceability Rule (FTR) does not mandate the use of barcodes, understanding their application can enhance your traceability program.

Types of Barcodes Used in the Food Supply Chain

Different types of barcodes are used at various levels of the supply chain to convey different kinds of information.

- **UPC (Universal Product Code):** This is the barcode commonly found on **consumer-level units** and is primarily used for point-of-sale scanning and inventory management at the retail level. You can find more information about GS1 UPC barcodes at: <https://www.gs1us.org/upcs-barcodes-prefixes/barcode-types>
- **GS1-128 Barcode:** This barcode is often used at the **case or logistics unit level** and can carry more complex information, including **tracking details and lot codes**. As seen in the example below (provided by Publix), the lot number can be incorporated after the GTIN:

Figure 3-10 A GS1-128 Barcode Encoding a GTIN, Expiration Date and Batch/Lot



- **Voice Pick Code:** In the produce industry, a simple **4-digit hash code**, known as the Voice Pick Code, can be generated from the GTIN, lot number, and date code. This allows for **easier voice-directed picking** in warehouses instead of requiring scanning.
- **SSCC (Serial Shipping Container Code):** This is an **18-digit GS1 Identification Key** used to identify a **logistic unit**, such as a pallet. It acts as a "license plate" to track shipments through the supply chain and is often linked to an **advanced shipping notice (ASN)**, which can contain detailed information about the contents, including lot codes.
- **ITF-14 Barcode:** This barcode is commonly used for labeling outer cartons or cases or products in supply chains. It is designed for high durability in printing on corrugated packaging. In addition, it encodes a GTIN which identifies products during shipping, warehousing, and receiving. ITF-14 barcodes are not scanned at the retail level but

are common in distribution centers and logistics operations. While the ITF-14 itself does not carry item-specific data like batch/lot numbers or expiration dates, it plays a supporting role in traceability.

An ITF-14 barcode example:



- **2-Dimensional Barcode (e.g., QR Codes):** This group of codes use **light and dark squares** instead of bars and spaces. With ample storage capacity, these codes can record item-specific data in the same form as a GS1-128 barcode or as a web address. More common with consumer and healthcare applications, these codes are **increasingly seen in supply chain applications** in places where image scanners are in-use.

A QR Code example:



- **RFID Tag:** These data carriers can record a GTIN plus a serial number and other item-specific data with certain tags. Instead of using scanners, RFID tags **transmit data over radio frequencies** which can improve automation and accuracy. Commonly used for inventory management with apparel, **increasingly seen with food products** in the supply chain.

An RFID example:



GS1 Standards and Traceability

GS1 is an industry organization that develops and maintains global standards for business communication, including barcodes. Adhering to GS1 standards can enable interoperability and the ability to track products and lot codes consistently across different trading partners.

- **GTIN (Global Trade Item Number):** This is a **unique identifier for trade items** and can be encoded in barcodes like the UPC and GS1-128.

ITF-14



1 00 12345 67890 2

GS1-128



(01) 1 0012345 67890 2

INDICATOR DIGIT

The indicator digit denotes the level of packaging for a particular carton.

GS1 COMPANY PREFIX

The GS1 Company Prefix is a 7-10 digit number assigned by GS1 to uniquely identify ownership of a particular brand.

ITEM REFERENCE

For cartons that contain the same item, the item reference is the same as that of the item contained within. A new item reference number is assigned for cartons containing an assortment

CHECK DIGIT

The check digit is calculated using a MOD10 check digit algorithm.

- **SSCC (Serial Shipping Container Code):** As mentioned earlier, this identifies **logistics units** like pallets.
- **GLN (Global Location Number):** This is a **unique identifier for physical locations or legal entities** within the supply chain.

While the FTR does not mandate the use of GS1 standards, members of the food industry have adopted these standards to help facilitate more efficient and comprehensive traceability. By using common standards, a lot code can be tracked from the manufacturer, through the distribution “network” to the retail outlet or restaurant.

Implementing GS1 Standards

For food industry companies looking to implement GS1 standards, the following guideline may be helpful:

- **Application of GS1 System of Standards to Support FSMA 204:**
<https://www.gs1us.org/content/dam/gs1us/documents/industries-insights/by-industry/food/guideline-toolkit/GS1-US-Application-of-GS1-System-of-Standards-to-Support-FSMA-204-Guideline.pdf>

Relationship to the Food Traceability Rule (FTR)

While barcodes and GS1 standards can greatly assist in traceability efforts, they are **not required by the FTR**. The FTR focuses on the **Key Data Elements (KDEs) that need to be recorded and the Critical Tracking Events (CTEs) at which they must be captured**.

Industry can use barcodes as a **tool to efficiently capture and communicate some of these KDEs**, such as product identification (potentially through GTINs linked to product descriptions) and potentially traceability lot codes (TLCs).

For example, a GS1-128 barcode on a case of produce could encode the GTIN and batch/lot to use as a TLC. When this case is received by another entity in the supply chain, scanning the barcode can automatically input this information into their traceability system, reducing manual data entry and improving accuracy. **A TLC may even incorporate a GTIN as part of its overall format.**

Appendix 7: Common Food Industry Data Systems

Warehouse Management System	Description: Software applications designed to manage and optimize warehouse operations, including inventory management and order fulfillment. Primary Focus: Record the receiving, storage, and shipping of inventory related to a specific warehouse facility. Relevance to Traceability: Could capture Receiving and Shipping KDEs. In particular, they could help store inbound as well as outbound TLCs. May also capture additional CTEs if a warehouse performs additional operations, such as Transformation. May also capture other data, such as when a distribution operation breaks down pallets or cases into smaller quantities.
Enterprise Resource Planning System	Description: Software solutions that integrate core business processes, including finance, human resources, procurement, manufacturing, and supply chain management. Record transactions such as purchase orders, sales orders, work orders, and often interface with a firm's other software systems. They also facilitate data sharing and collaboration across departments. Primary Focus: Record the financial picture of the firm, including transactions such as buying, receiving, manufacturing, shipping, and selling materials. Relevance to Traceability: Could be used to record Receiving, Transformation, and Shipping KDEs including TLCs, product descriptions, or location descriptions of the firm.

Third-Party Traceability Solutions	Description: Specialized software solutions, often tailored to existing regulations, designed specifically for traceability in the food industry. Interface with a food company's existing systems. Primary Focus: Features may include connecting to your Electronic Data Interchange systems and to your barcode readers, printers, portals for suppliers to share traceability data, and more. Enables easier sharing of data across supply chain partners. Relevance to Traceability: Can record CTEs and associated KDEs for food companies along with possibly aiding in data exchange with their trading partners. Note: Electronic Data Interchange (EDI) is a messaging format used by many warehouses to communicate with customers, partners, and retailers. For example, if Facility 1 has a purchase order and wants to submit it to Facility 2, EDI enables their two systems to communicate.
Accounting Systems	Description: Systems, such as financial management software, primarily used for managing financial transactions, budgeting, invoicing, financial reporting, and possibly inventory management. Primary Focus: Serve as primary repositories of transactions between business partners. Record the current balance sheet, income, and cash flows of a firm related to day-to-day operations. Relevance to Traceability: May record purchase and receipt of materials as well as sales and shipments of goods which could include relevant Receiving and Shipping KDEs.
Food Safety and Quality Assurance Systems	Description: Software that focuses on managing food safety and quality processes, including quality control, quality assurance, compliance management, and corrective and preventive actions (CAPA). Primary Focus: Help manage a firm's day-to-day quality management and food safety functions. Relevance to Traceability: May include traceability features as part of their quality control and compliance management capabilities. These systems can support kill step documentation, for example.

Farm Management Software	Description: Software that collects and stores information related to farm operations. This data can be related to land use, pesticide use, weather and climate, product price, etc. Primary Focus: Keep records of farm activities for financial management and optimizing operations. Relevance to Traceability: Keeps track of the field or container a food is grown in, which is useful for outbreak traceback investigation purposes. Helps in managing and storing records for a food business's Traceability Plan, including farm map and geographic coordinates. When appropriate, these systems can be used to document Harvesting and/or Cooling KDEs.
Manufacturing Execution System	Description: Systems that monitor the production of foods and the consumption of ingredients and materials (such as packaging) associated with those foods. Keep records of bills of materials for different foods, capture yield, line speed, tracking, downtime, rework, changeover, and other indicators of manufacturing efficiency. Primary Focus: Monitor the manufacture of foods. Relevance to Traceability: It could be suitable for recording the Transformation KDEs since it captures both the inputs and the outputs from a manufacturing process.
Transport Management Systems	Description: System that helps companies manage logistics associated with the movement of physical goods. Helps ensure timely delivery of goods by optimizing loads and delivery routes, tracking freight across local and global routes, and automating previously time-consuming tasks. Primary Focus: Manage and monitor the transportation of foods between immediate previous sources and immediate subsequent recipients. Relevance to Traceability: Could help provide the linkage of foods and their TLCs between two supply chain partners. May be general about what is being shipped but is very specific about the location it shipped from and to.

Document Management Systems	Description: Systems used to store, manage, and track electronic documents and electronic images of paper-based information captured via a document scanner. Primary Focus: Enterprise-wide document storage and organization. Relevance to Traceability: May be suitable for keeping Reference documents. May assign a record number to different documents and/or store the original record number of that document.
Restaurant Management Systems	Description: Business tool primarily for restaurants but also suitable for other food preparation sites such as in-store delis and central kitchens. Designed to track individual restaurant operations including ordering, deliveries, accounting, food preparation, and more. Primary Focus: Tracks restaurant operations including preparing foods for consumption. Relevance to Traceability: Could be used to record Receiving, Shipping, and Transformation KDEs for food preparation sites that supply other restaurant/retail locations.

Appendix 8: Data Systems Questions

Interacting with data requires cooperation between the businesses and entities involved in the food supply chain. This is why we have standards and common practices.

The purpose of this appendix is to encourage the participants to evaluate the data position of their organization by answering and considering questions related to the main activities of a data system. This is a reflection exercise; there are no right or wrong answers.

Fill out the following tables.

Identify

Question	Response
Do you identify products and locations with a numbering system?	
What is the format of your identifiers for products and locations? Is it numbers alone or a combination of numbers, letters, and special characters?	
Are the numbers you use specific to your firm, to one of your systems, or are they shared with your trading partners?	
Are they part of a globally unique numbering scheme, e.g., GTINs, GLNs, DUNs, SSCCs?	
Are these numbers stored in your systems? Are they referenced in data shared with your trading partners?	

Appendix 8

Capturing Product

Are you marking/labeling the physical product?

Question	Response
Are you using barcodes or RFID tags?	
How are the products identified in the barcodes/RFID? Which barcodes do you use and what data is contained in your barcode of choice?	
Are you using a barcode that only includes the product ID? For example, ITF-14, EAN/UPC?	
OR does your barcode or RFID tag contain a product ID plus additional data such as a lot code/TLC or serial number?	
What syntax does your barcode or RFID tag use? Does it follow a standard and can your trading partners' systems read it?	
Do you use a manual method, such as writing with grease pens or markers on the case packaging?	
If so, is it legible for your trading partners for your operations?	
Does it have necessary information for appropriately identifying the food product?	

Question	Response
Can your trading partners accept these markings/labels?	
Do you have a process for scanning damaged (ripped or wet) barcodes?	
Do you have printing quality control processes to ensure barcodes are scannable by others in the supply chain?	
Are your printing and packaging processes ready for incorporating a TLC and are you one of the entities to assign one?	
What objects are you marking and labeling?	
Are they packed cases or reusable plastic containers or pallets, or bins/totes?	
Do you use different markings/labels/data carriers among these objects?	

Appendix 8

Share data with other companies in the supply chain.

Your system will need to perform data exchange with trading partners. Consider the following:

Question	Response
Are you using data standards to enable interoperability?	
Product description data	
Does your company define what the product is, or is it defined by one of your trading partners?	
Do you need more information from your trading partners?	
Do you have all the product description elements in your system or in your trading partners' systems?	
Do your trading partners use a network or system for exchanging this kind of data? (Possible example: GDSN.)	

Data Systems Questions

Question	Response
Location descriptions data	
How do you define and store information about locations within your firm?	
Does your firm use third-party locations, and if so, how do you store the data elements of those third-party firms?	
For the locations of your trading partners that you receive product from, or that you send product to, how do you receive location description data?	
Transactional data/documents exchange	
How do you receive purchase orders, invoices, bills of lading, advanced shipping notices or CTE/KDE data from your trading partners?	
Are the companies that ship products to you including all the KDEs you need under the FTR? If not, how are you reconciling the lack of that information?	
Are you and your trading partners using data exchange standards such as EDI, EPCIS, or others?	

Appendix 8

Storage

Storage of your firm's data:

Question	Response
Is your system able to store data for the two-year required period?	
Do you use cloud storage, on-premises storage, local digital storage, or paper storage for your data?	
Can your data storage solution hold the volume of data your records will take up?	

Retrieval

Question	Response
Is the data aggregated in one system or in more than one system, and do the data from multiple systems need to be combined?	
Who is assigned to retrieve and collate the data, when needed?	
Do you have procedures to retrieve data when your firm needs to populate an electronic sortable spreadsheet?	

Scenario 1: Massachusetts Dairy Distributor

Warehouse slotting and picking refers to a process of organizing inventory at determined locations in the warehouse to increase efficiency and maintain accurate data that can help with traceability. This process is done to move fast-moving product quickly and segregate slow-moving products.

Let's look at a story involving warehouse slotting and picking.

Massachusetts Dairy Distributor (MADD) specializes in distributing a wide variety of cheeses. MADD has created procedures to speedily fulfil orders. Implementing these procedures required the collaboration of **Wanda** (Food Safety & Quality Assurance Manager), **Mike** (Warehouse Manager), and **Natalie** (IT Business Analyst).

Restaurants rely on MADD to deliver the cheese they specified, which doesn't just mean mozzarella versus Manchego. It means giving each cheese a separate Stock Keeping Unit (**SKU**) number to distinguish the brand, packaging size, flavor, and other attributes from all other cheeses in the warehouse.

Wanda, Mike, and Natalie learned that MADD will need to start including Shipping KDEs as part of the information they provide to each restaurant. Their existing procedures would not be able to accommodate this requirement. Accordingly, they scheduled a meeting where each of them would present ideas that could help.

Natalie outlined three technological approaches they could consider. The first was to request suppliers include KDEs on the Advanced Shipping Notices (ASNs) which they already sent to MADD via Electronic Data Interchange (EDI). The second was to begin employing fixed position barcode scanners on conveyor belts to automate the reading of lot codes (or KDEs) for each case of cheese. The third was for order pickers to use Voice Pick Codes marked on cases when receiving instructions from the Warehouse Management System (WMS) voice picking system.

Mike talked about having suppliers declare whether pallets of inbound cheeses would include more than one lot per pallet. He also suggested that maybe MADD's delivery drivers could record and provide relevant KDEs as they were delivering the product to each restaurant.

Wanda suggested outfitting order pickers with finger barcode scanners to record the barcodes on cases as they grabbed cases from the pick slots. Finally, she suggested that when suppliers send pallets with more than one lot, they can stack the cases into separate layers based on each lot and separate the layers with pallet sheets so order pickers would know when they were switching to a new lot.

Natalie, Mike, and Wanda all had very different ideas. They also knew there were pros and cons to each suggestion. At the end of their meeting, they realized that they may need more than a single solution. Although they did not agree on an approach after one meeting, they felt that by continuing to leverage their joint expertise they could find an approach after further research and discussion.

Scenario 2: Farmer in the Dale Distributing

A key-drop delivery is a delivery made to a business after hours, when the business is closed. Items are delivered on dates and times as agreed upon in the contract. The delivery person uses a key to access the business and store the delivery in the correct place, then leaves immediately after. The business receives the delivery and inspects it when it opens.

Let's look at a scenario illustrating the concept of a key-drop delivery.



Joe, who works for Farmer in the Dale Distributing, arrives at the restaurant after hours to do a key-drop delivery. Joe uses the key he was given to access the restaurant and make the delivery.



Joe delivers the food and places it in refrigeration units, freezers, and dry storage areas. Joe follows the written procedures for monitoring the foods' delivery temperatures, condition, and corrective actions that must be taken if they are found to be out of compliance with the food service establishment's requirements.



Joe has a checklist/log or electronic device/system that allows him to document the following information:

- ☒ Date of delivery (receive date) including the time of arrival and the time the delivery is complete.
- ☒ Specific restaurant receiving area.



- ☒ Evaluation of condition of food. If anything is damaged or spoiled, it will be noted. (Joe takes photos to document the condition. Damaged/spoiled items are placed to the side and labeled "do not use").



- ☒ Quantities/measurements of foods are verified, and any discrepancies are noted. Joe confirms that this matches the information on the invoice.
- ☒ TLCs for FTL foods are verified to be legible on the packaging and that they match the TLCs on the invoice (Reminder – the FTR does not require the TLC to be on the packaging).
- ☒ Confirmation that the invoice has a number that can be used as a Reference document number.

Appendix 9

- ☒ Confirmation that the invoice identifies the supplier/distributor name and location and the TLC Source's name and location (or this information can be accessed on the supplier/distributor website).



When the restaurant staff arrive, they check and confirm the information on the log/checklist/system, take product temperature and verify that invoice information is accurate. Any discrepancies are reported to the supplier/distributor and agreed upon resolution is documented.

Note: Restaurants will provide written documents related to this process to the FDA upon request.

Scenario 3: Huge Produce Brand, Inc.

In this scenario, cantaloupes are grown by Huge Produce Brand, Inc. They are harvested and packed in the field under contract by Moon Harvest. Both Harvesting and Initial Packing CTEs are applicable; there is no cooling prior to Initial Packing, therefore it is not a CTE. Some customers require that a PTI label with a GS1-128 barcode (containing the TLC) be placed on the cases.

Section 1:

Cantaloupe grown by Huge Produce Brand, Inc. is then harvested and packed into cardboard cases in the field by Moon Harvest. The cardboard cases are then sent to a cooler by Huge Produce Brand, Inc. before moving through the distribution chain to consumers at retail stores. Each evening, a Moon Harvest crew (in this example, crew #03) is assigned a field to harvest (in this case field #02), and this corresponds to the farm map that Huge Produce Brand, Inc. has developed.

The crew begins harvest the next morning, recording that date as when harvest began.

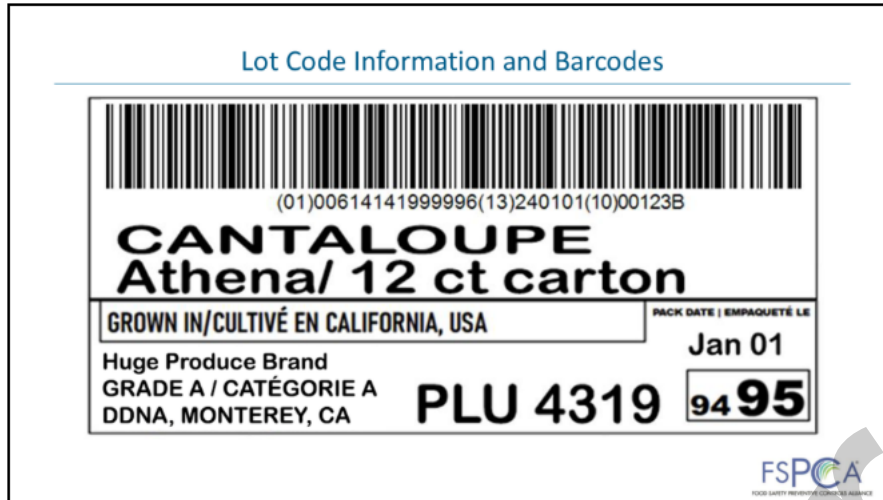
Some smaller growers in the area use a mobile printing device to PTI labels in the field. However, the scale and throughput at the Huge Produce Brand, Inc. farm, as well as unreliable cell services, makes this challenging. The number of stickers in a roll exceeds the number of cases typically harvested, and the waste created by the stickers was financially undesirable. They had also tried pre-printing and applying labels prior to harvest, but the melons vary in size and it's difficult to know how many cases of each size will be harvested.

Section 2:

After discussion with Huge Produce Brand, Inc., Harvest Moon uses a price gun to apply a small sticker to each case after it has been packed. This sticker includes the date of harvest, field code, crew number, and machine number. They have found this method to be more reliable than a roller stamp that used to print this information on cases as they moved via conveyor to the trailer.

The trucks drive the boxed melons to the cooling facility where the field ticket is retained as its receiving record.

Some retail customers require the information on the case to be provided in a GS1-128 barcode in accordance with PTI. Therefore, upon receipt of the cases at the facility, prior to cooling, 5-6 people work to transfer the information from the price gun sticker into PTI labels, which are then applied to each case.



In this example the barcode is (01)00614141999996(13)240101(10)00123B and includes the following information:

After "(01)"	"00" two filler values "614141999996" the GTIN "614141" company prefix for Huge Produce Brand, Inc. "99999" item number for Athena cantaloupes packed in 12 counts "6" check digit
After "(13)"	"240101" pack date of January 1, 2024
After "(10)" is the lot # 00123B	"001" the Julian date for January 1 "2" harvest field #2 "3" harvest crew #3 "B" harvest machine B

According to produce industry recommendations, the TLC is the combination of the GTIN and the lot code. As noted above, these encode a wealth of additional information. The GTIN can be deciphered to reveal the company prefix and the item number that relates to the product description. The lot number can be deciphered to reveal the date of harvest, field, crew number, and harvest machine.

Scenario 4: Fred's Good Stuff

The following story illustrates the impact of the FTR on recordkeeping for a complex food item such as a potato salad.

Joaquin is the manager at Fred's Good Stuff, and his team makes potato salads and sells them to a large grocery store chain. The potato salad contains mayonnaise, mustard, spices, potatoes, fresh-cut onions, and fresh-cut celery. Joaquin needs to maintain and track the lot codes (or TLC) for any FTL ingredients as they are making the deli salad.

Since whole potatoes, mayonnaise, mustard and spices are not on the FTL, Receiving KDEs are not applicable for those ingredients (although records may need to be maintained under 21 CFR Part 1, subpart J). Fred's Good Stuff receives KDEs for the fresh-cut onions on the invoice from Onions R Us. They receive KDEs for the fresh-cut celery on the bill of lading from Pete's Produce.

Fred's Good Stuff makes 5-gallon tubs of potato salad for retail delis, as well as eight-, sixteen-, and thirty-two-ounce containers for consumer sales. When Fred's Good Stuff makes the potato salad, they use their Manufacturing Execution System (MES) to keep track of the TLCs for the fresh-cut celery and onions as well as the product description and amount of product used in each lot of potato salad. The MES also keeps track of the new TLC and other KDEs for each lot of potato salad produced.

While the lot of potato salad is the same for all the different size containers they make, the TLC is different depending on the container size. This helps Fred's Good Stuff better track the different sizes in the event of an outbreak or recall.

Fred's Good Stuff packs their potato salads into cases with labels indicating the TLC information. They send the potato salads to the distribution centers for the grocery store chain, using an Advance Shipping Notice (ASN) to transmit the Shipping KDEs to the distribution centers.

Scenario 5: JL Smokehouse

Foods imported into the U.S. can go directly to the buyer, or to a third-party warehouse or storage facility. In many cases the information needed to satisfy traceability requirements is sent by the exporter, but in some cases, is managed by importer or other party.

Let's consider a scenario involving imported products.

Salmon is farmed outside of the U.S. Multiple farms send whole, raw salmon to a consolidator. These are commingled RACs and therefore are partially exempt from the rule until the point of processing.

Chad, the owner of JL Smokehouse, also outside the U.S., receives the salmon from the consolidator, then stores and processes the fish into fillets to be smoked (by them). JL Smokehouse keeps separate production runs. They clear out the smokehouse before they make another batch, so everything in the smokehouse at one time is the same lot. They mark the lot numbers on the cases and products (inkjet or encoded in barcodes), and this information is also in his manufacturing tracking system.

JL Smokehouse has two customers, both importers in the U.S.

Customer A does not physically hold product in the U.S. The imported smoked fish is stored in a third-party cold storage warehouse. Customer A orders a container load of smoked fish. It takes JL Smokehouse one week to produce enough smoked salmon to fill the container, so multiple lots are shipped in the container. JL Smokehouse uses a TLC scheme that has been provided by Customer A.

The third-party warehouse holds the smoked salmon and is therefore covered by the FTR; since Customer A does not hold the smoked salmon, they are not a covered entity. However, the third-party warehouse and Customer A have an agreement that Customer A will maintain the Receiving and subsequent Shipping KDEs on behalf of the warehouse. Customer A stores the Receiving KDEs for the warehouse in purchase orders. When Customer A sells the product, they notify the third-party warehouse what product to ship. The warehouse has a WMS that would tell them which TLC is in a specific location. Customer A prepares the shipping documents and transmits the Shipping KDEs via their shipping documents for the warehouse to pass forward to the receiver.

Customer B stores the smoked fish in their refrigerated storage warehouse for distribution to their retail stores. For Customer B, JL Smokehouse assigns lot codes based on their own production date/lot system. JL Smokehouse provides the Shipping KDEs directly to Customer B's warehouse, which captures them as part of their Receiving KDEs. Customer B's warehouse then provides Shipping KDEs to their retail stores.

Scenario 6: Maree's Market

The hub and spoke is a distribution model that resembles a bicycle wheel. In the middle of a wire-spoked wheel is what is known as the hub. This concept is used in multiple industries, such as retail – where food and consumer products are often loaded into a single truck at a distribution hub, then sent to individual satellite stores.

Let's look at a scenario involving hub and spoke distribution:

Maree's Market Store 1 is a retail food establishment located in Rockhurst that produces sushi onsite.

Initially, Store 1 produces sushi and sells it directly to consumers at the Rockhurst location.

The sushi is so popular that Maree decides to sell it at an additional six of their retail locations. Store 1 will produce sushi for these locations, and it will be shipped from Store 1 to the other six stores.

Public Version

Appendix 10: Glossary and Terminology

Accounting Systems: Software used to manage a company's financial data, which may contain some information relevant to traceability such as invoice details.

Advance Shipping Notices (ASNs): Electronic documents sent by a shipper to a receiver in advance of a shipment, often containing details about the contents and expected arrival.

Broker/Customs Broker: Licensed representative hired by importers to facilitate the entry of products into the U.S. They submit necessary information and appropriate payments to Customs and Border Protection (CBP) on behalf of the importer.

Covered Foods: Foods that fall under the scope of the FTR included on the Food Traceability List (FTL).

Compliance: Adherence to the requirements set forth in a regulation, for example, the Food Traceability Rule.

Cooling: A Critical Tracking Event (CTE) that means active temperature reduction of a raw agricultural commodity using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process.

Critical Tracking Events (CTEs): 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.

Cross-docking: A logistics strategy where products are unloaded from an incoming vehicle and then loaded onto an outgoing vehicle with little or no storage time in between.

Data Standards: A data standard is a technical specification that describes how data should be stored or exchanged for the consistent collection and interoperability of that data across different systems, sources, and users.

Direct Store Delivery (DSD): A retail distribution model where a manufacturer or supplier delivers products directly to a retail store, instead of to a warehouse or distribution center.

Electronic Data Interchange (EDI): EDI is a digital communication system that enables the automated exchange of business documents—such as shipping notices, invoices, and traceability records—between organizations in a standardized format.

Enterprise Resource Planning (ERP) Systems: Integrated software systems that manage a company's core business processes, potentially including modules relevant to traceability such as supply chain management and inventory.

Exemptions: Specific situations or entities to which the requirements of the FTR may not fully apply. These can be based on the type of entity or the specific food product.

Farm Map: A map showing the areas in which food is grown or raised, including geographic coordinates.

FDA (U.S. Food and Drug Administration): A federal agency responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; the safety of our nation's food supply,

cosmetics, and products that emit electronic radiation; and for regulating tobacco products.

First Land-based Receiver: A Critical Tracking Event (CTE) that means the person taking possession of a food for the first time on land directly from a fishing vessel.

Fishing Vessel: Means any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing, as set forth in the Magnuson-Stevens Fishery Conservation and Management Act.

Food Safety and Quality Assurance (FSQA) systems: Systems that help manage a firm's day-to-day quality management and food safety functions, which can support traceability policies.

Food Traceability: The process of tracking the movement of food products through various stages of production, processing, and distribution within the supply chain.

Food Traceability List (FTL): A list of foods designated by the FDA that require additional recordkeeping under the FTR. This includes both foods specifically listed and foods that contain any of those specifically listed foods as ingredients, provided that a listed food used as an ingredient is in the same form as it appears on the list.

Food Traceability Rule (FTR): A regulation finalized in 2022 that establishes additional recordkeeping requirements for certain foods, allowing for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths.

FSMA (Food Safety Modernization Act): A United States federal law that aims to ensure the U.S. food supply is safe by shifting the focus from responding to foodborne illness to preventing it. The Food Traceability Rule is one of the regulations required by FSMA.

GSIN (Global Shipment Identification Number): The GSIN is a unique global identifier assigned by the seller or shipper to a shipment consisting of one or more logistic units intended to be delivered together. It helps trace the shipment across the supply chain and is used to link traceability data to specific shipments.

GTIN (Global Trade Item Number): A unique identifier for trade items (products or services) that can be part of the GS1 system.

GLN (Global Location Number): A unique identifier for physical locations or legal entities within the GS1 system.

Harvesting: A Critical Tracking Event (CTE) that represents the origination of fresh fruits, vegetables, shell eggs, and aquacultured food included on the FTL. See § 1.1310 of the FTR to see the full definition of harvesting.

Holding: Storage of food; also includes activities performed incidental to storage of a food (for example, activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Importer: The U.S. owner or consignee of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee of an article of food at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry.

Initial Packing: A Critical Tracking Event (CTE) that involves the packing of a raw agricultural commodity (other than a food obtained from a fishing vessel) for the first time.

Interoperability: The ability of different software systems, databases, or technologies to communicate, exchange data, and operate seamlessly with each other.

Inventory Control Systems: Systems used to manage and track the quantities of products and ingredients held in inventory, which can help maintain accurate lot code information.

Key Data Elements (KDEs): Information associated with a Critical Tracking Event (CTE) for which a record must be maintained and/or provided in accordance with the FTR.

Kill Step: Lethality processing that significantly minimizes pathogens in food.

Location Description: A Key Data Element (KDE) that means key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country.

Master Data: Descriptive data that describes the foods, locations, and entities that are referenced in other records; can be thought of as static data such as an address.

Outbreaks: Instances where two or more people get the same illness from the same source (for example, contaminated food or drink).

Point of Contact: A designated individual or role included in a firm's traceability plan for questions regarding the plan and records from FDA or state regulators.

Product Description: A Key Data Element (KDE) that means a description of a food product and includes the product name (including, if applicable, the brand name, commodity, and variety), packaging size, and packaging style. For seafood, the product name may include the species and/or acceptable market name.

Recalls: Actions taken to remove a food product from the market because it is adulterated or misbranded.

Receiving: A Critical Tracking Event (CTE) that means an event in a food supply chain in which a food is received by someone other than a consumer after being transported (for example, by truck or ship) from another location. Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm.

Record Maintenance: The procedures a regulated entity follows for keeping records that meet the FTR requirements, including format and location of files.

Shipping: A Critical Tracking Event (CTE) in which a food is arranged for transport (for example, by truck or ship) from one location to another location. Shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food. Shipping includes sending an intracompany shipment of food from one

location at a particular street address of a firm to another location at a different street address of the firm.

SKU (Stock Keeping Unit): A unique code used by retailers to identify and track their inventory.

SSCC (Series Shipping Container Code): The SSCC is a unique identifier used to track logistic units—such as pallets, cases, or containers—throughout the supply chain. It enables companies to associate traceability data with specific containers and is often encoded in barcodes on shipping labels.

Stakeholders: Parties that have an interest in the food supply chain, such as producers, processors, distributors, retailers, and consumers.

Supply Chain: The interconnected system of individuals, organizations, resources, activities and technologies involved in the manufacture and sale of a food product from supplier to consumer.

Third-Party Traceability Software Systems: Specialized software solutions designed specifically for traceability in the food industry.

Traceability Lot Codes (TLCs): Descriptors, often alphanumeric, used to uniquely identify a traceability lot within the records of the TLC source.

Traceability Lot Code (TLC) Source: The physical location where a food was assigned a traceability lot code.

Traceability Lot Code (TLC) Source Reference: An alternate method for providing FDA with access to the location description for the traceability lot code source.

Traceability Plan: A description of internal procedures used to maintain records under the Food Traceability Rule, intended to help FDA more quickly review and understand the traceability information provided by a firm involving a food on the Food Traceability List.

Traceability Program: The overarching vision and goals and operations for traceability within an organization, aligning with its overall business objectives and values, and often tailored to the organization's unique characteristics.

Traceability Team: A group of individuals within an organization with responsibilities related to the development, implementation, and maintenance of the traceability program and plan.

Transformation: A Critical Tracking Event (CTE) that means an event in a food's supply chain that involves manufacturing/processing a food or changing a food (for example, by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List. Transformation does not include the initial packing of a food or activities preceding that event (for example, harvesting, cooling).

Version Control: A system for managing changes to a document, such as a traceability plan, over time, often including issued and supersedes dates to track the current and previous versions.

Warehouse Management Systems (WMS): Software applications designed to manage and optimize warehouse operations, including inventory management and order fulfillment.

Public Version

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