



How Can a Farmer Prepare for the FDA Traceability Rule, FSMA 204

Produce Safety Educators'

Call #69

February 21, 2024



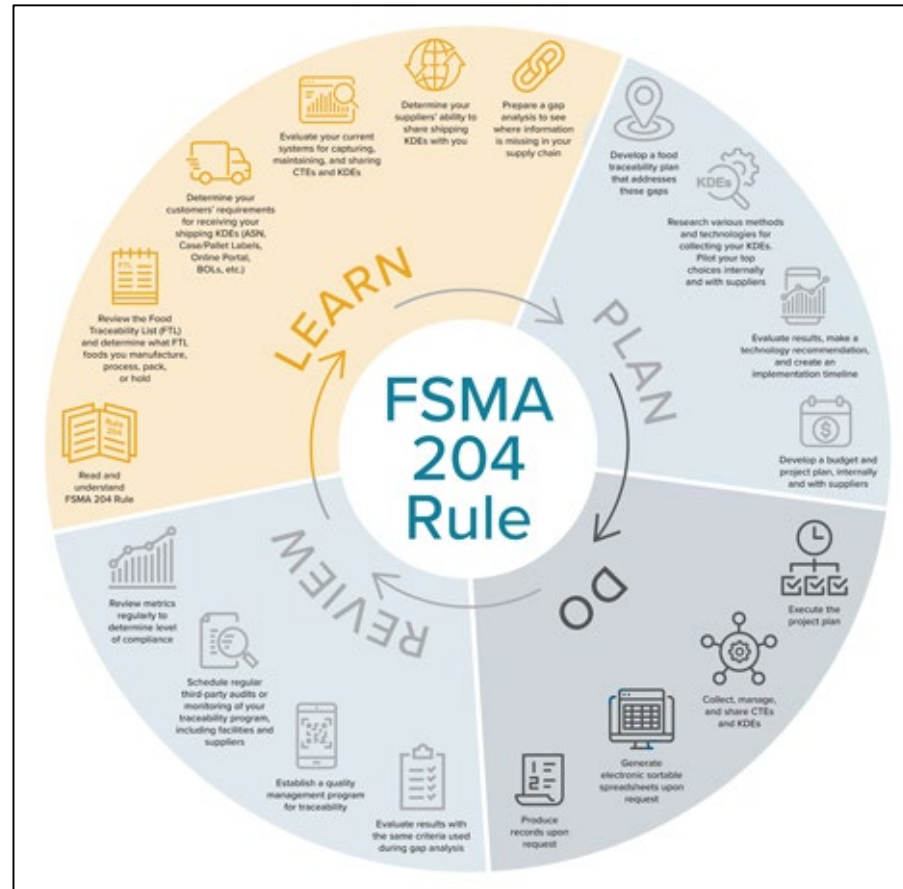
Instructions

- All participants are muted.
- There will be time for questions and discussion at the end of the meeting.
- Feel free to use the chat box to ask questions as well!
- This session will be recorded and the presentation will be shared via the listserv and on our website after the call.
- The views and opinions expressed in this presentation are those of the speakers and do not necessarily reflect legal advice, views or positions of the PSA and its members, nor any entities they represent.



Introduction

- Matt Regusci,
New Era Partners
- Johnna Hepner
iFoodDS



www.ifoodds.com/fsma-rule-for-food-traceability/



Topics

- New acronyms: What they mean and why they are relevant (FTL, KDE, CTE, TLC, etc.)
- Who is exempted from this new FSMA 204 rule?
- What does a covered farmer need to do to comply with FSMA 204?
- What are the expectations for all farms from covered buyers (Packers, Processors, Distributers, Retailers, Restaurants)?
- What tools can assist with compliance with regulatory or market expectations?



New Era
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Workshop

FDA Food Traceability Rule

Regusci | Feb 21, 2024

Matthew Regusci

Principal Compliance Advisor

New Era Partners



Matt has extensive experience building businesses in the Testing, Inspection, and Certification (TIC) industry. Early in his career, Matt co-founded of Azzule Supply Chain Program & PrimusGFS Certification & Training. Following this formative experience, he led BSI's business development in the Americas, where they became the largest GLOBALG.A.P. Certification Body in the U.S.

With Matt's help, BSI sold BSI Food Verification Services, Inc. to WQS, an international Certification Body with over 400 subcontractors, where he became a co-owner. Together with the co-owner of WQS, he successfully launched a training company which was sold with WQS to Qima, a global TIC company based in Hong Kong.

Farming runs in the family - in High School and College he assisted his grandfather in dairy nutrition studies. Matt has created, managed, and consulted the full gamut of the TIC industry from Labs, Inspections, Certifications to Supply Chain Software, Training Software, and Traceability tools.

Matt holds a B.A. Organized Leadership from Chapman University and a Doctorate of Entrepreneurship from the School of Hard Knocks.



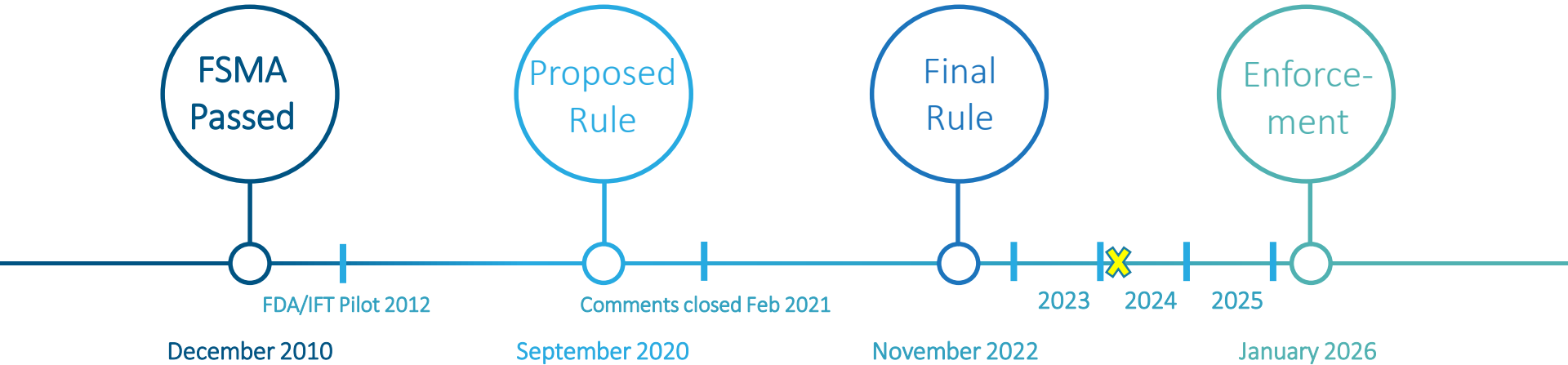
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FSMA 204 Timeline

Yellow "X" Indicates Current Date



Key Concepts of the Final Rule

- Framework of CTEs and KDEs
- Standard language
- Linking information by lot code
- Electronic and/or paper records
- Records provided to FDA within 24 hours
- Faster product identification and removal

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CTE and KDE Framework

The role of the entity in the supply chain defines the data it must keep and share

Critical Tracking Events

- Harvesting, Cooling, Initial Packing, First Land-based Receiving, Shipping, Receiving, and Transforming are Critical Tracking Events (CTEs) for which records would be required.

Key Data Elements

- Required records would need to contain specific Key Data Elements (KDEs). The KDEs would depend on the CTE being performed.

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The KDEs required would vary depending on the CTE that is being performed.

- The records required at each CTE would need to contain and link the KDEs to the traceability lot.

Definitions

- **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.



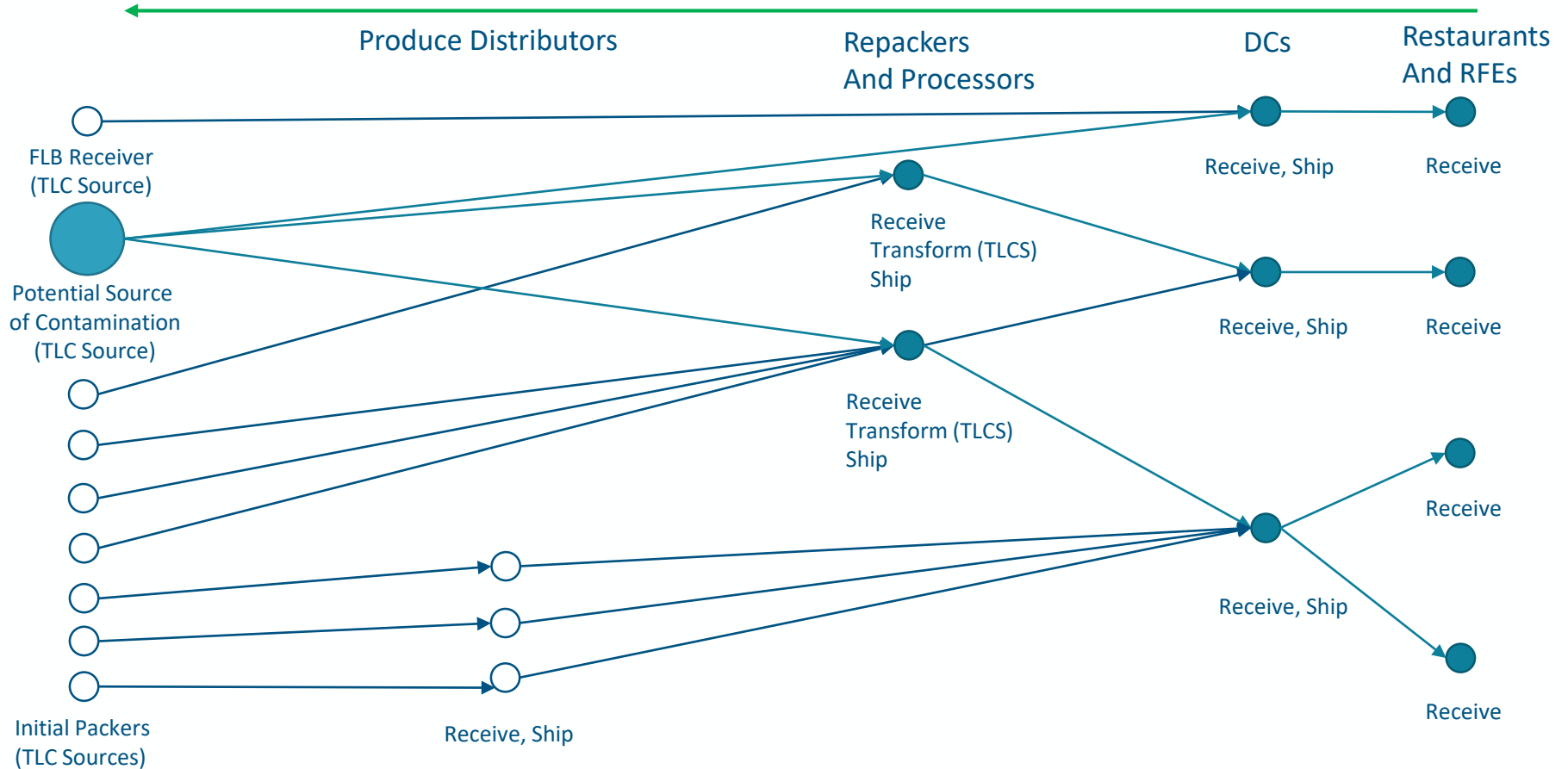
§1.1320: Establishing and Assigning Traceability Lot Codes

- Traceability lot codes (TLC) would be established and assigned if:
 - You initially pack a RAC, perform the first land-based receiving of a food obtained from a fishing vessel, or transform a food on the FTL
- New traceability lot codes **CANNOT** be established or assigned when other activities in the supply chain are conducted
 - E.g., shipping, receiving



Future state – Speeding Outbreak Investigations

FDA Traceback during Outbreak Investigation



Who is exempted from FSMA 204

FSMA 204 applies to all food facilities except meat, poultry, and certain egg producers.

Some exemptions to FSMA 204 include:

- Small farms (produce and aquaculture) with sales of no more than \$25,000 annual average during the previous three years
- Small retail food establishments
- Farms selling food directly to consumers
- Certain food produced and packaged on a farm
- Food that receives certain types of processing
- Transporters of food
- Foods not listed on the FTL or that have gone through a kill step
- Restaurants, RFES, or distributors that do not manufacture, process, pack, or hold foods on the FTL

FSMA regulations only apply to commercially grown, packed, and processed food or feed. Home gardeners or home food preservers are not covered under the law.

Exemptions to the Food Traceability Rule

Exemptions to the Food Traceability Rule

[Start Here](#)

FDA Food Traceability List



Cheeses, other than
hard cheeses



Shell eggs
(from chickens)



Nut butters



Cucumbers
(fresh)



Herbs
(fresh)



Leafy greens
(fresh & fresh-cut)



Melons
(fresh)



Peppers
(fresh)



Sprouts
(fresh)



Tomatoes
(fresh)



Tropical tree fruits
(fresh)



Fruits & Vegetables
(fresh-cut)



Finfish
(fresh, frozen, smoked)



Crustaceans
(fresh, frozen)



Molluscan
shellfish, bivalves
(fresh and frozen)



Ready-to-eat
deli salads
(refrigerated)

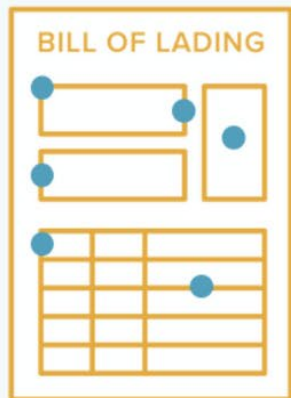


Foods that contain
listed foods as
ingredients

2 New KDEs for FDA new Food Traceability Rule, FSMA 204

THE 8 KDES OF FSMA 204'S SHIPPING AND RECEIVING CTEs

Where to Find Them in the Records You Already Have



1 Ship-To Location



4 Reference Document Type & Number (e.g. BOL)



2 Ship-From Location



5 Product Description



3 Shipment Date or Receive Date



6 Quantity and Unit of Measure

6 KDEs typically found in existing systems.

2 new KDEs that require additional data capture efforts.



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Traceability Lot Code

- Used to uniquely identify a traceability lot within the records of the TLC Source.
- Best practice is GS1 GTIN + Batch/Lot
- Can be found in GTIN on GS1-128 case label



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Traceability Lot Code Source or Reference

- TLC Source = location where a food was assigned a TLC.
- TLC Source Reference = alternative to providing FDA with TLC Source (e.g., GS1 GLN, FDA FFRN, web URL).
- Both can be found in the GLN with location description on a BOL

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Total Shipping and Receiving KDEs

-

6

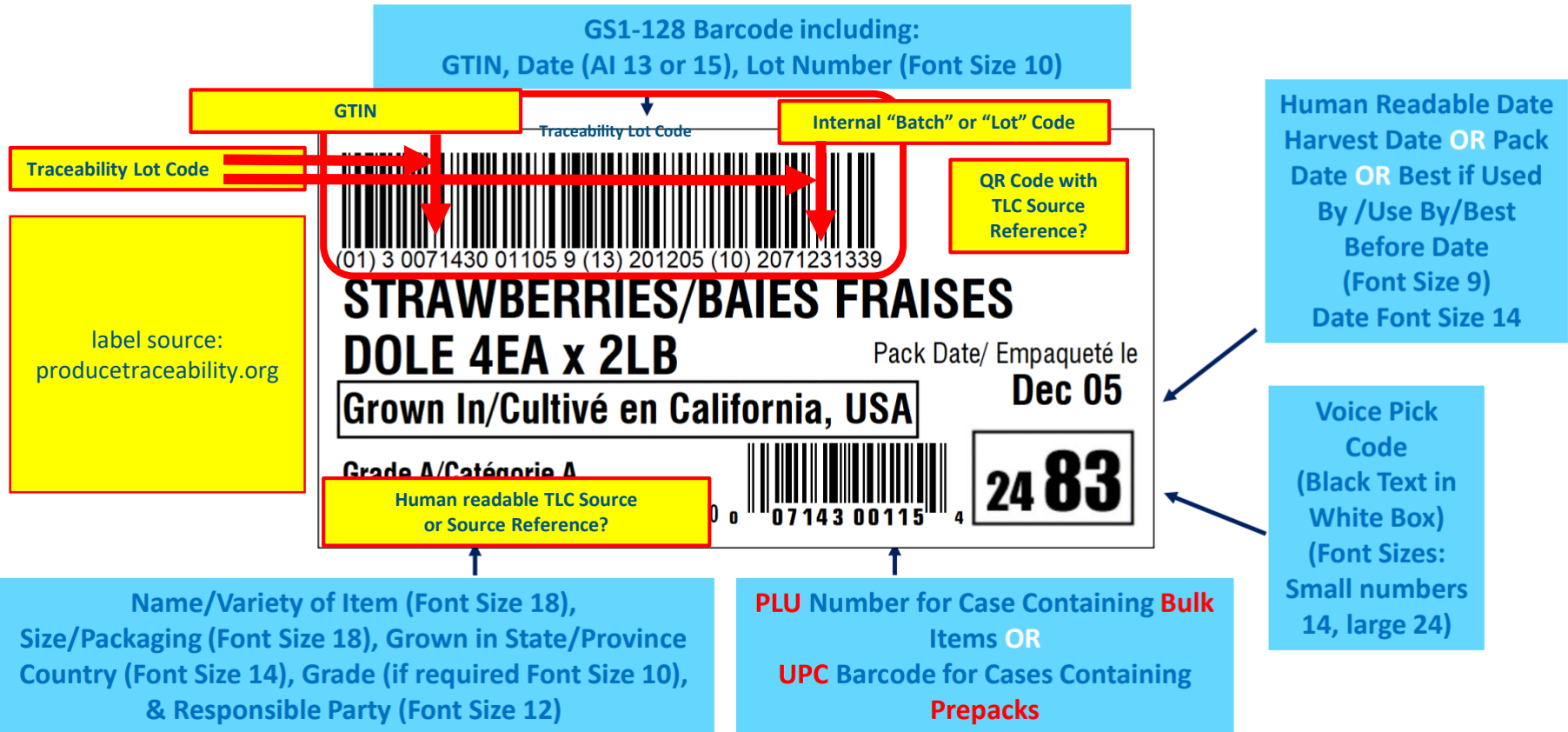
KDEs commonly found on Bills of Ladings & EDI messages

=

2

Remaining KDEs easily captured & shared with proven technology systems

What is the difference between a batch/lot code and a Traceability Lot Code?
Will the PTI Label Change?



Application of GS1 System of Standards to Support FSMA 204

Retail Grocery and Foodservice

How do GS1 Standards fit in?

“Traceability Lot Code” in Section 3.2.2 is:

- GTIN (GS1 AI(01))
- batch/lot (GS1 AI(10))

GS1 Standards Supporting Item-Level Traceability			
Identification Standards	Trade Items	Global Trade Item Number (GTIN)	
	Locations & Trading Partners	Global Location Number (GLN)	
	Logistics Units	Serial Shipping Container Code (SSCC)	
AIDC Standards	GS1 Barcodes	GS1-128 GS1 DataMatrix QR Code with GS1 Digital Link URI Data Matrix) with GS1 Digital Link URI	
	GS1 EPC/RFID	RAIN RFID	
Data Standards	Master Data: Global Data Dictionary (GDD) Item Business Messaging Standard Party Business Messaging Standard	Transactional Data: eCom/EDI	Event Data: EPCIS Schema EPCIS Core Business Vocabulary
Sharing & Communication Standards	Master Data: Global Data Sharing Network (GDSN) GS1 US Data Hub Location EPCIS Master Data	Transactional Data: AS2	Event Data: EPCIS Capture EPCIS Query Discovery Services



Food Traceability Rule Electronic Sortable Spreadsheet (example of existing data sources)

For covered foods and entities, the FDA may request and receive a sortable spreadsheet within 24 hours. The sheet must include the Traceability Lot Code and Traceability Lot Code Source. Utilizing this information, the FDA can quickly “skip” multiple entities in the supply chain and thus proceed directly to the entity that produced the food (e.g., Initial Packers).

This represents an electronic sortable spreadsheet generated by a distribution center when FDA requested records for all FTL foods received from 9/18/2020 through 9/23/2020.

TLC	Quantity and UOM	Product Description	Immediate Previous Source Location Description*	Receiving Location Description*	Receive Date	TLC Source Location Description*/TLC Source Reference	Reference Document Type and Number
GTIN(01): 1234567890123 Mfg Date Code(13): 12-22-12 Mfg Lot Code(10): ABCD123	85 CS	PB Co., Peanut Butter Spread, Reduced Fat, 12ea x 18oz	PB Co. Mfg 1 100 1 st Street Everett, MA 02149	Distributor 1 202 2 nd St Newburgh, NY 12551	1/10/12	Peanut Butter Co., Manufacturer 1 100 1st Street Everett, MA 02149 +1.999.999.9999	Customer Order 573366
(01)11411411411404(10)FPP16-092220		Sales Order - Shipping Department					55441 PO 456213
		Peanut Butter Manufacturer 1 Everett, MA 02149		Distributor 1 Customer Order: 573366 Due Date: 01/10/12		Freight: Prepaid Trucker: None selected	/10/FPP16- BOL 11401
		Distributor 1 Newburgh, NY 12551		Sold To: Distributor 1 Vendor #322 Bratt'sboro, VT 05302		Terms: 2/10 Net/30 Broker Order: Broker: Cancel Date: Date Entered: 12/20/11 Customer: 10108	/10/FPP16- BOL 11401
(01)22322322322302(10)FFI2020-09-20							/10/FFI2020- BOL 22302
	85	85	1615	Retail	12/18 OZ REDUCE FAT P/SPREAD	12-22-12	

PB Co.
Peanut Butter Spread,
Reduced Fat, 12ea x 18oz CS

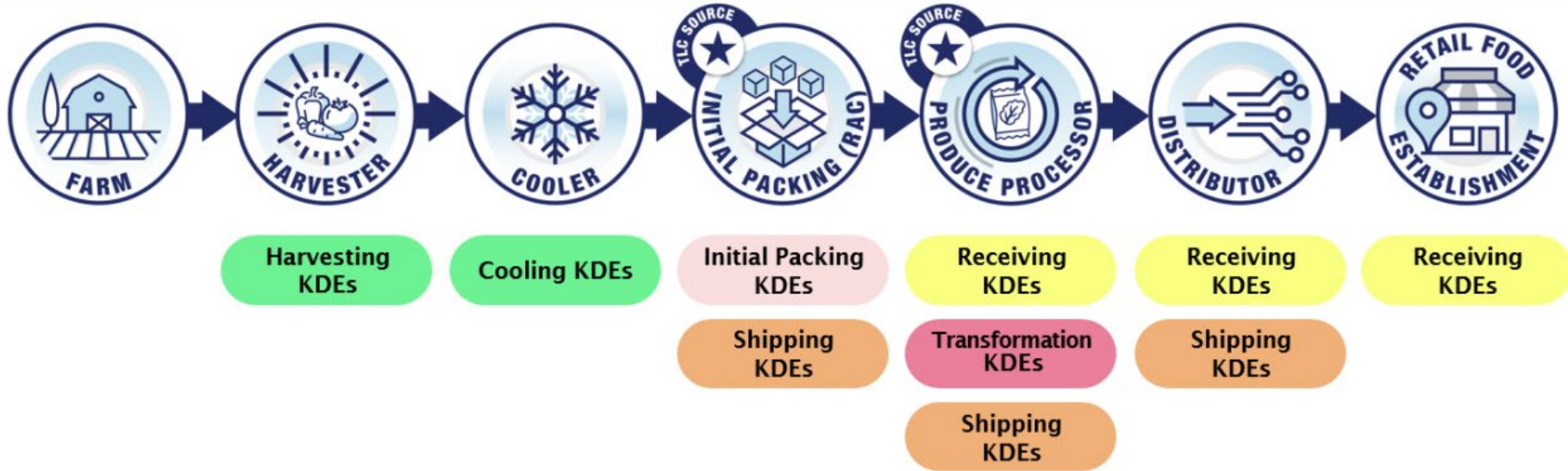
Pallet or Case Label

(01)1234567890123(13)122212(10)ABCD123

*See Master Data Spreadsheet for full location

Supply Chain Example: Cucumbers

Traceability Plan



How do I populate the CTE Records?

Farm Name	Lizzie's Farm
Address Line 1	113 Farm St
Address Line 2	
City	Farms
State (Region)	CA
Zip (Postal Code)	11311
Country	US
Telephone	999.999.9999
GLN {optional}	1234567890123

Field Name {GLN.GLN Extension}	Field Geographic Coordinates
1234567890123.A-08	-24.5000145, -11.107417
1234567890123.D-03	-24.5000144, -11.107418
1234567890123.C-02	-24.5000146, -11.107419
1234567890123.B-09	-24.5000147, -11.107416



How do I populate the CTE Records?

§ 1.1325(a) Harvest KDEs	Notes	Value
(1)(i) Immediate subsequent recipient location description	Initial Packing location name or GLN	Packing Shed 102
(1)(ii) Commodity		Lettuce
(1)(ii) Variety		Romaine
(1)(iii) Quantity & UOM		1000 Cases
(1)(iv) Farm where food was harvested	Could be Farm Name or GLN	1234567890123
(1)(v) Field where food was harvested	Could be Field Name or GLN Extension	A-08
(1)(vii) Harvest date		7/24/2023
(1)(viii) Reference doc type and number		Harvest Rec 93495
Enter your initials and today's date		AK, 7/27/2023

FDA FSMA 204 Final Food Traceability Rule

Common Challenges and Questions

- The rule is 600 pages! How can I read and understand that much information?
- When is the enforcement date, and what happens if I am not in compliance 100%? What will FDA do?
- Am I covered by the rule? Are my suppliers all covered?
- What do I do if I am covered by the rule and some of my suppliers are not?
- What is the difference between a batch/lot code and a traceability lot code?
- How do GS1 Standards fit in? Will the PTI label change?
- How are my peers meeting the requirements of the rule?
- Are my systems capable of meeting the requirements of the rule as-is, or do I need to do something?
- What will this all cost?



Food Traceability Rule Landing Page

FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

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Food Safety Modernization Act (FSMA)

[Frequently Asked Questions on FSMA](#)

[FSMA Rules & Guidance for Industry](#)

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[FSMA Training](#)

[FSMA Technical Assistance Network \(TAN\)](#)



Content current as of:
11/17/2022

Regulated Product(s)
Food & Beverages

The FDA final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) establishes traceability recordkeeping requirements, beyond those in existing

- [Federal Register Notice](#)
- [Docket No. FDA-2014-N-](#)

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Traceability Rule FAQ Page

Traceability

Traceability Topics

- [The Food Traceability List \(FTL\)](#)
- [Risk-Ranking Model for Food Tracing \(RRM-FT\)](#)
- [Initial Packer](#)
- [First Land-Based Receiver](#)
- [Transformation](#)
- [Intracompany Shipments and Cross-Docking](#)
- [Farms](#)
- [Retail Food Establishments \(RFEs\)](#)
- [Comingled Raw Agricultural Commodities \(RACs\)](#)
- [Traceability Lot Code \(TLC\)](#)
- [Implementation](#)
- [Kill Step](#)
- [General](#)

The Food Traceability List (FTL)

T.1 How did FDA determine which foods are included on the Food Traceability List (FTL)?

To determine which foods should be included on the FTL, the FDA developed a risk-ranking model for food tracing (“the Model”) based on factors that Congress identified in Section 204(d)(2) of the Food Safety Modernization Act (FSMA). The Model scores commodity-hazard pairs (e.g., Shiga toxin-producing *E.coli* O157 (STEC O157) in Leafy Greens) according to data and information relevant to seven criteria described in the report [Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204](#):

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FSMA 204 Final Traceability Rule† in Brief

Beginning January 20, 2006, the Food Traceability Rule requires covered entities ([§ 1.1300](#)) who manufacture, process, pack, or hold foods on the Food Traceability List ([FTL](#)), to:

- Develop a Traceability Plan ([§ 1.1315](#))
- Assign Traceability Lot Codes ([§1.1320](#))
- Maintain Records of Critical Tracking Events
 - Harvesting & Cooling ([§1.1325](#))
 - Initial Packing of Raw Agricultural Commodities ([§1.1330](#))
 - First Land-Based Receiver of an FTL Food from a Fishing Vessel ([§1.1335](#))
 - Shipping ([§1.1340](#))
 - Receiving ([§1.1345](#))
 - Transformation ([§1.1350](#))
- Requirements for Records Maintenance and Availability ([§1.1455](#))
- In cases where a covered entity fails to comply, consequences are outlined in [§1.1460](#)
- The rule includes procedures for [Modified Requirements and Exemptions](#), and [Waivers](#).
- Existing exemptions are listed in ([§ 1.1305](#)).
- Foods not covered by this rule are covered by the Bioterrorism Act of 2002 ([Subpart J](#)).

The rule is 600 pages! How can I read and understand that much information?

FDA Resources for the Traceability Rule

The following are important resources from FDA for better understanding the rule and answering frequently asked questions:

When is the enforcement date, and what happens if I am not in compliance 100%? What will FDA do? Am I covered by the rule? Are my suppliers all covered?

Resources	Select FAQs
Food Traceability List	Are dried or frozen versions of FTL foods covered?
Exemption Tool	Are foods that contain FTL foods covered?
Supply Chain Examples	Is frozen cheese (on a pizza) covered? (no)
Webinar on the Food Traceability Rule	Food that will be subjected to a kill step, exemption
Technical Assistance Network (TAN)	Intracompany shipments
Translations of Rule and Resources	Cross Docking
Retail Food Establishments and Restaurants What Records Do I Need to Keep? What Do I Need to Know about the Rule? What Should I Know about the Traceability Plan?	When will FDA request records? When will FDA request sortable spreadsheets? What is the penalty for non-compliance? Will FDA provide a portal for submitting data?
Frequently Asked Questions	Kill step applied to nuts before making nut butter
How did FDA determine which foods are on FTL?	Does rule apply to importers?

PTI Resources and FSMA 204 Templates



Guides

PTI FSMA 204 Implementation Guidance (2024)

This implementation guideline was prepared by the PTI FSMA Working Group to assist with the implementation of the FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods.

[FSMA 204 IMPLEMENTATION GUIDANCE](#)

PTI FSMA 204 TLC Source and Reference Guidance (2024)

This guidance was prepared by the PTI FSMA Working Group to assist with the understanding of the Traceability Lot Code (TLC) Source and (TLC) Source Reference.

[TLC SOURCE AND REFERENCE GUIDANCE](#)

PTI FSMA 204 Electronic Sortable Spreadsheet Templates (2024)

- [Harvester/Cooler/Initial Packer/Transformer](#)
- [Receiver](#)
- [Shipper](#)
- [Final Distributor](#)
- [Retail Store](#)
- [Foodservice Operation/Restaurant](#)

GS1 US Application of GS1 System of Standards to Support FSMA 204 Guideline (2023)

This implementation guideline was prepared by the GS1 US FSMA 204 Workgroup to assist the United States' food industry with implementing GS1 Standards for traceability and specifically to help meet the requirements outlined in the Final Rule.

[DOWNLOAD GUIDANCE \(ON GS1US.ORG\)](#)

<https://producttraceability.org/resources/>



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ARTICLE

How to Get Started Creating Your Own

Your company already has a traceability or recall plan as part of your Good Manufacturing Practices (GMPs), but you are now covered by...

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ARTICLE

Going Beyond Compliance: Getting ROI Out of Food

Many in the industry consider compliance with FDA's new Food Traceability Rule, FSMA 204, another cost their organization will incur. Whil...

[Read more >](#)

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ARTICLE

How to Budget for FSMA 204 Compliance

In January of 2023, the New Era Partners team hit the road. We met with many large retail, food service, and distribution companies over the...

[Read more >](#)



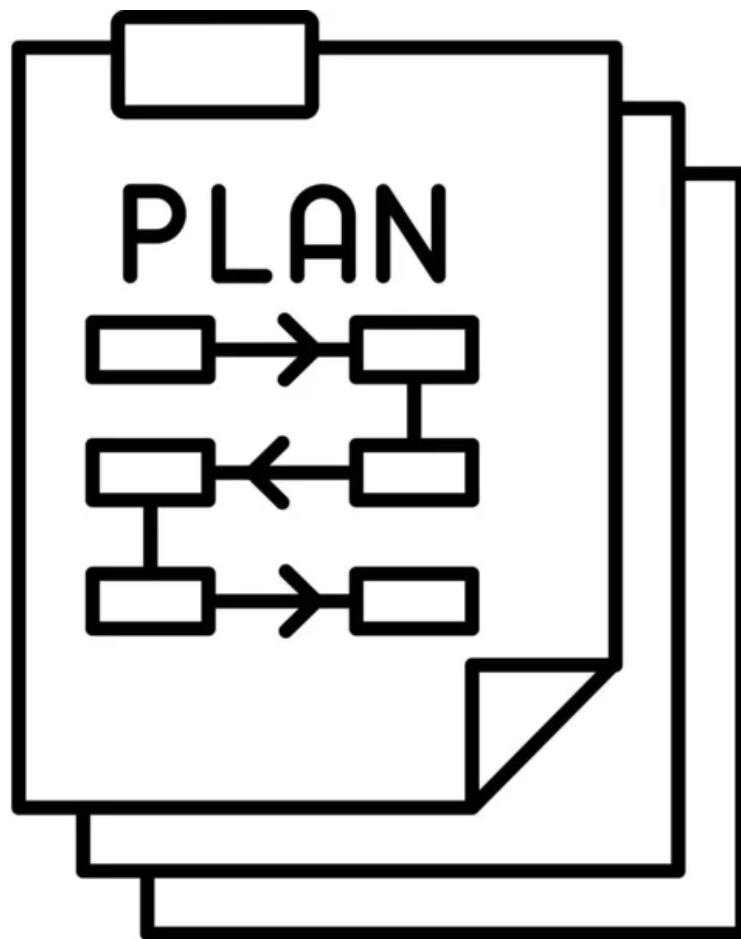


THANK YOU

Matt and Andy



Discussion





FDA Resources

[← Home](#) / [Food](#) / [Guidance & Regulation \(Food and Dietary Supplements\)](#) / [Food Safety Modernization Act \(FSMA\)](#)
/ [FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods](#)

FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods

Getting Started with the Food Traceability Rule



Food Traceability List (FTL)



Key Features



Full and Partial Exemptions



Modified Requirements, Exemptions, and Waivers



Critical Tracking Events and Key Data Elements



Supply Chain Examples



Traceability Lot Code



Guidance for Industry



Traceability Plan



Frequently Asked Questions about the Food Traceability Final Rule



Stakeholder Calls, Webinars, and Meetings



Contact Us



Translations



Additional Information





Spotlighted FDA Resource

- This one is less easy to find, targeted at farms

Exemptions Relevant to Produce Farms Under the Produce Safety Rule and the Food Traceability Rule

- Under the “Additional Information” drop down
- Exemption-by-exemption comparison between Produce Safety Rule and Food Traceability Rule exemptions and exclusions



Next Educators' Call

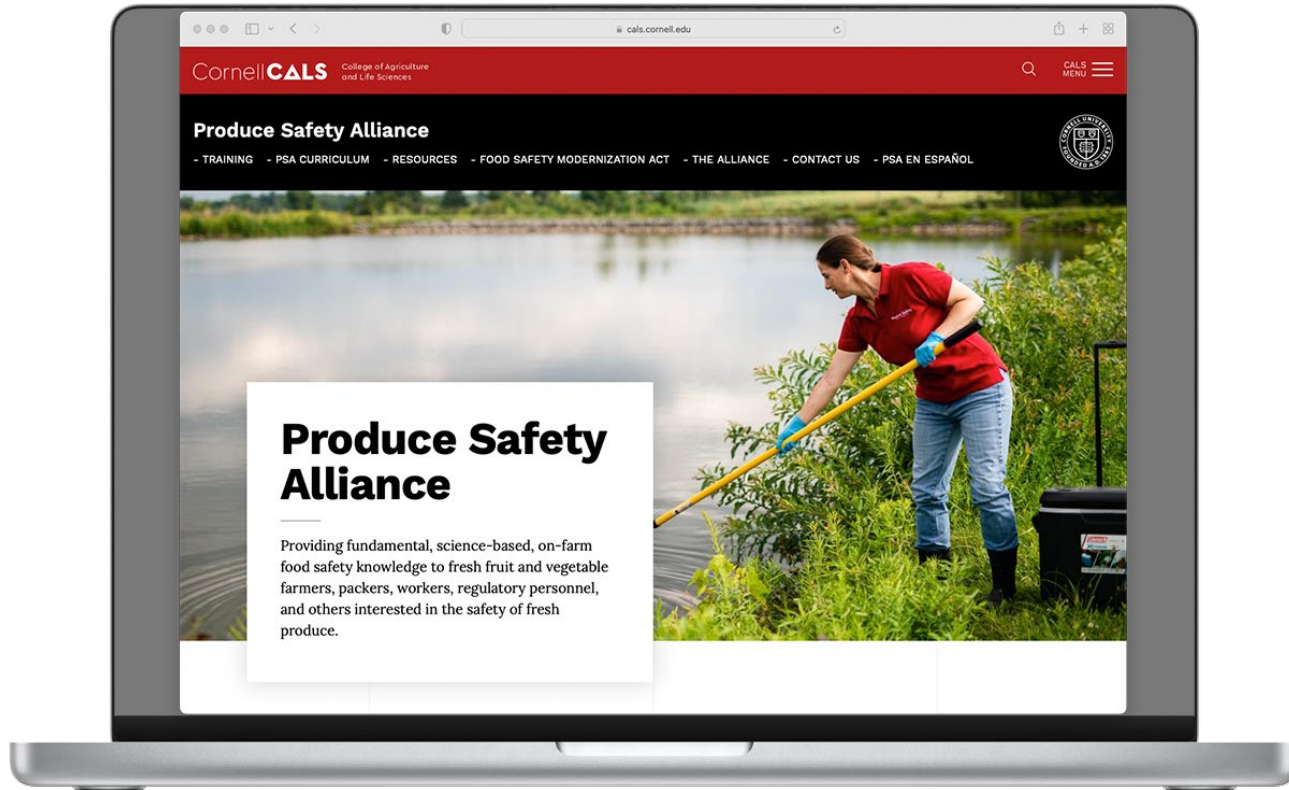
- Next PSA Educators' Group call: *PSA Sanitizer Tool Updates and Lessons Learned*
 - Date: TBD
 - Speaker: Donna Clements
- Registration link will be shared by email through the Educators' Group Call mailing list



The PSA Website

English: producesafetyalliance.cornell.edu

Spanish: es.producesafetyalliance.cornell.edu





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