



New Era
Partners™

FSMA 204 What is it? What does it mean for Fresh Produce?

Southern Region Integrated Produce Safety Conference

Andrew Kennedy Background

- Co-Founder, New Era Partners (div of iFoodDS)
- PTI and GS1 Standards Leadership since 2010
- Co-led FDA Tech-Enabled Traceability and No-Cost/Low-Cost Challenge
- Expert on FDA FSMA 204 Working Group
- Product lead for FDA 21 Forward
- PMA Board Member 2016-2019
- Interim Director for IFT GFTC
- Co-founder of FoodLogiQ

THE PRODUCE
TRACEABILITY
INITIATIVE





FDA's Food Traceability Rule

FSMA 204(d)

What is FSMA 204?

The FDA's Food Traceability Rule requires persons who **manufacture, process, pack, or hold** foods on the **Food Traceability List (FTL)** to maintain and provide to their supply chain partners **key data elements (KDEs)** for certain **critical tracking events (CTEs)** in the food's supply chain.

Firms must **keep and send forward information** under the rule 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**.

FSMA 204 imposes new record keeping requirements



Legible original paper, electronic, or true copies. May include electronic links.



Records must be kept for 2 years



Available within 24 hours



Electronic sortable spreadsheet within 24 hours

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

PTI FSMA 204 Guidance Released!

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

(01) 3 0071430 01105 9 (13) 201205 (10) 2071231339
STRAWBERRIES/BAIES FRAISES
DOLE 4EA x 2LB Pack Date/ Empaqueté le
Grown In/Cultivé en California, USA Dec 05
Grade A/Catégorie A
Dole Fresh Vegetables, Monterey, CA 93940 0 07143 00115 4 **2483**



<https://producetraceability.org/resources/#guides>

Traceability Lot Code (TLC)

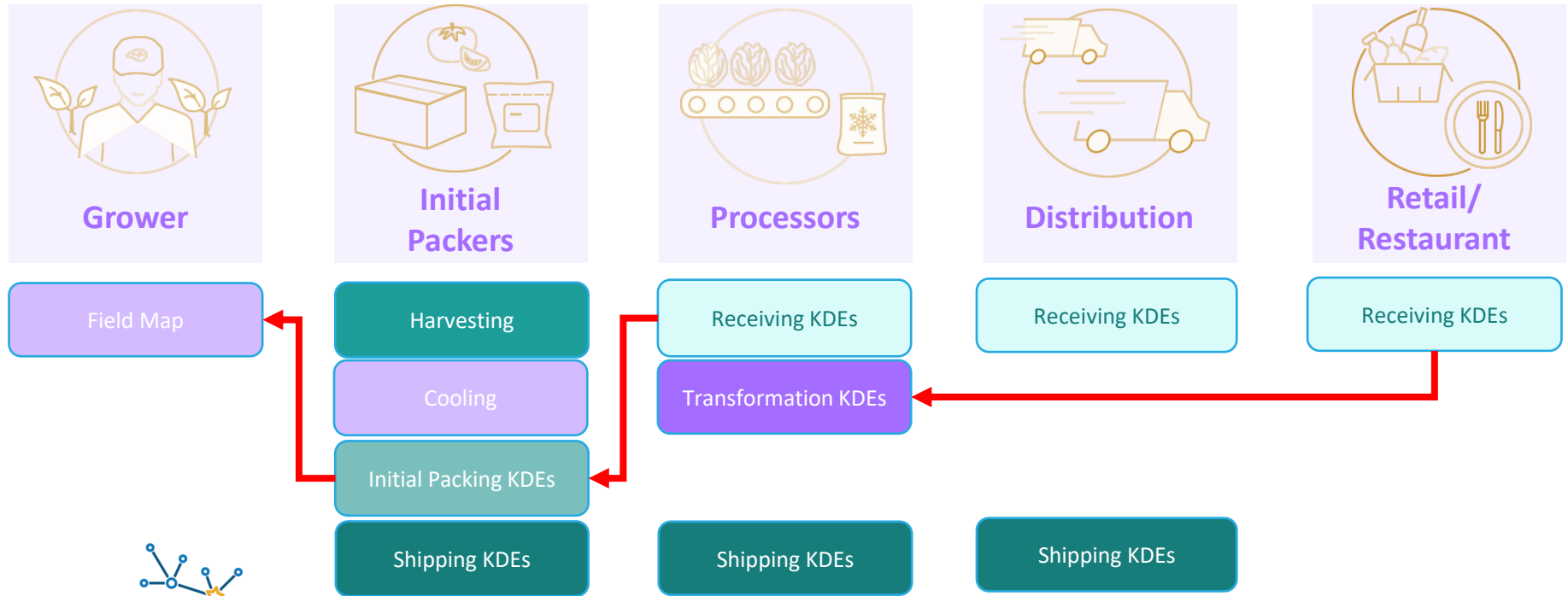
GTIN + Lot Code

(01) 14865239852157 + FL094529JL



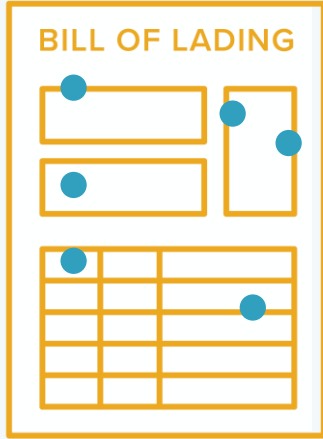
Produce supply chain traceback investigation example

FDA uses Critical Tracking Events, Key Data Elements, and the Traceability Lot Code to trace back to farm



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

6 KDEs typically found in existing systems.



1 Ship-To Location



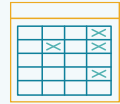
4 Reference Document Type & Number (e.g. BOL)



2 Ship-From Location



5 Product Description



3 Shipment Date or Receive Date



6 Quantity and Unit of Measure

2 **new** KDEs that require additional data capture efforts.



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



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).

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Total Shipping and Receiving KDEs

6

KDEs commonly found on Bill of Ladings & EDI messages

=

2

Remaining KDEs are new for industry

Example Receiving Record at Restaurant

§ 1.1345 Receiving Key Data Elements (KDEs)	Notes	Value
(a)(1) Traceability Lot Code for the food you received	(01) GTIN + (10) Lot	(01)30071430011062 (10) ABC123
(a)(2) Quantity & UOM of the food you received		3 Cases
(a)(3) Product description for the food you received		Ed's Chopped Salad Kit
(a)(4) The location description for the immediate previous source of the food	Ship-From Location	Fresh Foods DC #17
(a)(5) The location description from for where the food was received	Ship-To Location	Quality QSR Store #203
(a)(6) Received Date		7/28/2023
(a)(7) Location description for the traceability lot code source, or the traceability lot code source reference	TLC Source or method for looking up source.	Ed's Salad Processing Co.
(a)(8) Reference doc type and number	Purchase order, bill of lading, invoice, etc.	PO 456233-03
User ID and entry date		AKENNEDY, 7/28/2023

Receiving KDEs

Example Transformation Record at Salad Co.

§ 1.1350 Transformation KDEs	Notes	Value
<i>(1) For the food on the Food Traceability List used in transformation (if applicable), the following information</i>		
(1)(i) The traceability lot code for the food	(01) GTIN + (10) Lot	(01)30071430011059(10)2071231339
(1)(ii) Product description for each traceability lot code		Romaine Lettuce Hearts
(1)(iii) Quantity and unit of measure for each traceability lot code		100 Cases
<i>(2) For the food produced through transformation, the following information:</i>		
(2)(i) The new traceability lot code for the food;	(01) GTIN + (10) Lot	(01)30071430011062(10)ABC123
(2)(ii) The location description for where you transformed the food		Ed's Salad Processing Co.
(2)(iii) The date transformation was completed;		7/26/23
(2)(iv) The product description for the food;		Ed's Chopped Salad Kit
(2)(v) The quantity and unit of measure of the food		200 Cases
(2)(vi) The reference document type and reference document number	Work Order	WO-23923
User ID and entry date		MREGUSCI, 7/26/2023

Example Receiving Record at Salad Co.

§ 1.1345 Receiving Key Data Elements (KDEs)	Notes	Value
(a)(1) Traceability Lot Code for the food you received	(01) GTIN + (10) Lot	(01)30071430011059 (10)2071231339
(a)(2) Quantity & UOM of the food you received		100 Cases
(a)(3) Product description for the food you received		Romaine Lettuce Hearts
(a)(4) The location description for the immediate previous source of the food	Ship-From Location	Lizzie's Packing Shed
(a)(5) The location description from for where the food was received	Ship-To Location	Ed's Salad Processing Co.
(a)(6) Received Date		7/25/2023
(a)(7) Location description for the traceability lot code source, or the traceability lot code source reference	TLC Source or method for looking up source.	Lizzie's Packing Shed
(a)(8) Reference doc type and number	Purchase order, bill of lading, invoice, etc.	PO 82349
User ID and entry date		FTAYLOR, 7/25/2023

Receiving KDEs

Example Initial Packing Record at Grower, Packer, Shipper

§ 1.1330 Initial Packing KDEs	Notes	Value
(a)(1) Commodity and, if applicable, variety of the food received		Lettuce, Romaine
(a)(2) Date you received the food		7/22/23
(a)(3) The quantity and unit of measure of the food received		1000 Cases
(a)(4) Farm location description where the food was harvested		Lizzie's Farm
(a)(5) For produce, field name from which the food was harvested		1234567890123.A-08
(a)(6) For aquaculture, container name where food was harvested		n/a
(a)(7) The business name and phone number for the harvester		Harvest Co., 999-888-7777
(a)(8) The date of harvesting		7/22/23
(a)(9) The location description for where the food was cooled		n/a
(a)(10) The date of cooling (if applicable)		n/a
(a)(11) The traceability lot code you assigned;	(01) GTIN + (10) Lot	(01)30071430011059(10)2071231339
(a)(12) The product description of the packed food;		Romaine Lettuce Hearts
(a)(13) The quantity and unit of measure of the packed food		1000 Cases
(a)(14) The location description for where you initially packed the food		Lizzie's Packing Shed
(a)(15) The date of initial packing		7/22/23
(a)(16) The reference document type and reference document number.		Prod Order 12345
User ID and entry date		JJONES, 7/22/2023

Example Farm Location and Field Map

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



Field Map

FSMA 204 requires an electronic sortable spreadsheet

An [electronic sortable spreadsheet](#) containing relevant traceability information must be provided to the FDA within **24 hours** of a request to assist the FDA during an outbreak, recall, or other threat to public health.

FSMA compliance {Keeps an audit trail of data exports}

FSMA records Recent exports

Product information: Start date: End date:

Receiving **Farm activities** Shipping Transformation Product details Location details

{Produce Sortable Spreadsheets with required Master Data, CTEs and KDEs Upon Request}

Product	Product ID	Lot code	Quantity	Activity	Farm	Area	Date	Business name	Business p
Green Bell Peppers	8618846241652.Ojih	ABC-123	50 CS	HARVESTED	iFood Farms Pack House #1	--	6/29/2023, 11:51 AM	iFoodDS	+12062193
Green Bell Peppers	8618846241652.Ojih	ABC-123	5 CS	HARVESTED	iFood Grocery Store #2302	--	6/29/2023, 3:20 AM	iFoodDS	+12062193
Green Bell Peppers	8618846241652.Ojih	ABC-123	500 CS	INITIAL_PACKED	iFood Farms Pack House #1	--	6/28/2023, 3:08 PM	iFoodDS	+12062193
Green Bell Peppers	8618846241652.Ojih	ABC-123	6000 LBR	HARVESTED	iFood Farm Field #1015	Field 1015 Section 14-16	6/28/2023, 12:08 PM	iFoodDS	+12062193

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NEW ERA PARTNERS

Services include:



Supply Chain X-Ray

Readiness evaluation of enterprise and supplier operations for FSMA 204 Food Traceability Rule. Extract existing CTEs and KDEs, generation of sortable spreadsheets, diagrams, and compliance heat map.



On-Call Retainer

Our experts join traceability teams and projects to provide ongoing assistance with education, communication, implementation assurance, trace plan development, etc.



Workshops

Educate stakeholders with tailored presentations, and hands-on exercises using client products, documents, procedures, and facilities. Primarily an in-person activity.



Executive Briefings

Tailored presentations on FSMA 204 Traceability Rule and GS1 US Application Guidance for the rule from former co-leader of FDA Tech-Enabled Traceability and member of FSMA 204 rule writing team



ANDREW KENNEDY

Andrew worked with the FDA Office of Food Policy and Response on the New Era of Smarter Food Safety, with a focus on Tech-Enabled Traceability, and served on the FDA Food Traceability Rule working group.



MATT REGUSCI

Matt Regusci is one of the leading entrepreneurs in the Testing, Inspection, and Compliance marketplace. Over the past decade, he co-founded Azzule | Primus GFS, co-owned WQS, and co-founded TrainToComply. Check out Matt's podcast "[Don't Eat Poop!](#)"



NATALIE HUNTER

Natalie brings a wealth of experience in sustainable supply chain, traceability technology and business development. Most recently, Natalie held a leadership role in innovation at The Marine Stewardship Council.



ERIK LARSEN

Erik is a veteran in the agriculture industry, starting his ag career at Gargiulo, Inc in 1994. Since then, he has led the IT Departments for such well-known companies as Naturipe Farms, L&M Companies, and most recently, A. Duda & Sons.

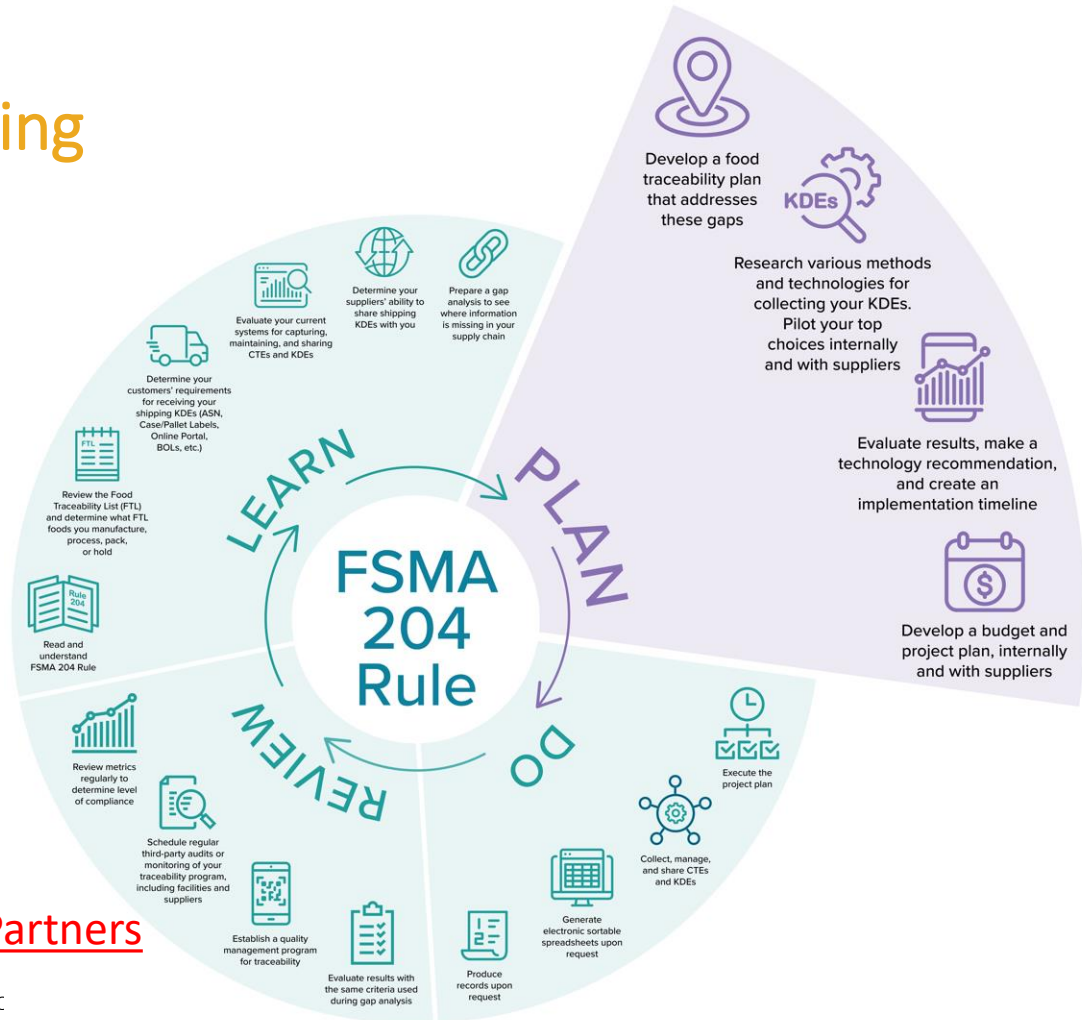
What you should be doing now

The FSMA 204 compliance deadline is January 20, 2026 – just 100 weeks away!



Insights - New Era Partners

CC



FSMA 204 Final Traceability Rule† in Brief

Beginning January 20, 2026, 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](#)).

[GS1 US FSMA 204 Standards](#)



THANK YOU

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