FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods Webinar July 10, 2025 | 12:30 - 2pm (eastern)

The webinar will begin shortly

This project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an award of \$148,000 in federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov







Welcome

Susan C. Winckler, RPh, Esq.

Chief Executive Officer Reagan-Udall Foundation for the FDA

Housekeeping



Due to the meeting size, your microphone and video will remain off during the meeting



Please share your questions using the Zoom Q&A function

- This webinar is being recorded
 - The slides, transcript, and video will be available at www.ReaganUdall.org

Today's Agenda



12:30 pm	Welcome & Opening Remarks Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA
12:35 pm	FDA Opening Remarks Donald A. Prater, DVM, Principal Deputy Director for Human Foods, FDA
12:40 pm	Conducting Outbreak Investigations Angela Fields, MPH, Senior Consumer Safety Officer for the CORE Network, FDA Adam Friedlander, MS, Policy Analyst, Coordinated Outbreak Response, Evaluation & Emergency Preparedness, FDA
1pm	Update on Implementation Activities Melinda Hayman, PhD, Consumer Safety Officer, Office of Compliance and Enforcement, FDA
1:10 pm	Pilot Panel Discussion Takashi Nakamura, PhD, MBA, VP, Corporate R&D and Food Safety, Del Monte Fresh Produce Company Charles Leftwich, MBA, Vice President of Food Safety and Quality Assurance, Sysco Michael Lookup, Traceability Lead, Wegmans Food Markets
2pm	Closing Remarks & Adjourn



Opening Remarks

Donald A. Prater, DVM

Principal Deputy Director for Human Foods U.S. Food and Drug Administration

Conducting Outbreak Investigations

Angela Fields, MPH

Senior Consumer Safety Officer for the CORE Network

U.S. Food and Drug Administration

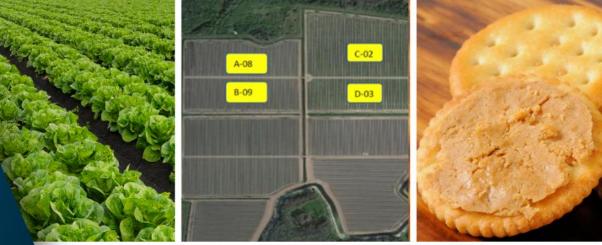
Adam Friedlander, MS

Policy Analyst, Coordinated Outbreak Response, Evaluation & Emergency Preparedness U.S. Food and Drug Administration









Overview of FDA Foodborne Outbreak Response Process

July 10, 2025 Reagan Udall Foundation Food Traceability Webinar

Angela Fields, MPH Adam Friedlander, MS Coordinated Outbreak Response Evaluation & Emergency Preparedness, Human Foods Program (HFP), FDA







Exemptions to the Food Traceability Ru

You are subject to the Food Traceability final rule, <u>unless</u> an exemption applies. To determine whether you may be exempt, please click on any of the following catego that may apply to you:

Farm	Certain types of processing
Commingled raw egnicalitanal commodities (PACs)	Personal consumption, holding face for specific consumers
Fishing vessels, notice can shellful	Oter
Retail lood establishments (RFEs),	

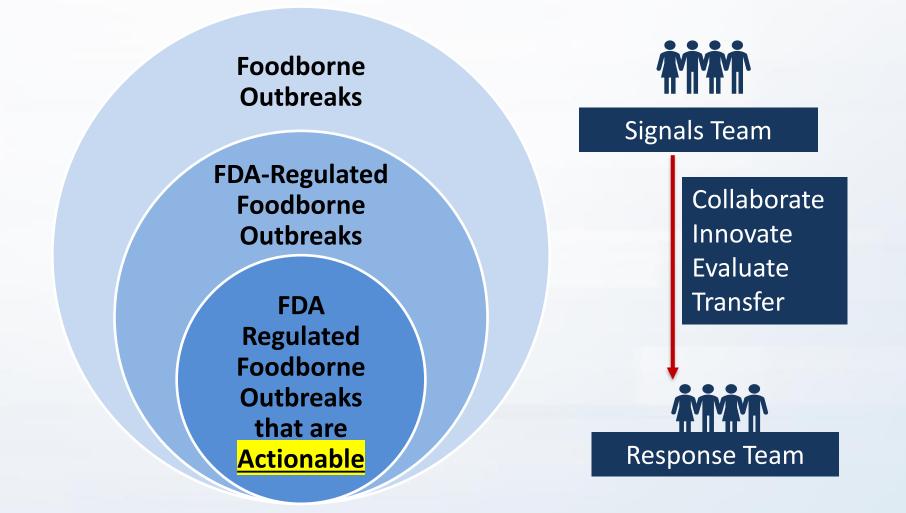




Identifying Outbreak Investigations



Detect and then determine if we can respond to them!



Purpose of Traceback Investigations



	Identify	Identify the vehicle (food) that made people sick
3-	Determine	Determine the supply chain and product source
ΔŢΛ	Regulate	Decide what regulatory actions are required
	Inform	Inform consumers
		10

Roles During a Multistate Outbreak



States/locals

- Collect epidemiological info from cases
 Food history/exposure; share with CDC
- Visit POS and obtain records, interview and observe
- Conduct trace intrastate
- Conduct joint investigations with FDA

CDC

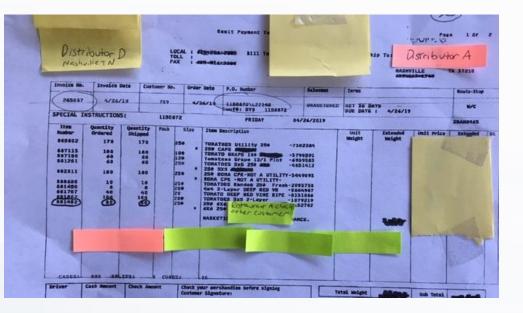
- Assist and coordinate state epidemiological info collection
- Maintain illness onset and food exposures (line lists)
- Assist with review of exposure data

FDA

- Determine whether to trace
- Select best clusters/cases to trace
- Possibly visit POS with state, interview, collect records
- Continue collection of info at each level of distribution
- Compile traceback info and analyze
- Conduct joint investigation with states

Current State









OrderNo	StoreNo	StoreName	ShipDate	SKU	Description	Units
10003491	555	Big Foodservice (St Louis)	4/6/2025	1275	Iceberg, 24ct, Heads (4061)	430
10003491	555	Big Foodservice (St Louis)	4/6/2025	1275	Iceberg, 24ct, Heads (4061)	210
10003508	555	Big Foodservice (St Louis)	4/10/2025	1275	Iceberg, 24ct, Heads (4061)	320
10003508	555	Big Foodservice (St Louis)	4/10/2025	1275	Iceberg, 24ct, Heads (4061)	320
10003535	555	Big Foodservice (St Louis)	4/15/2025	1275	Iceberg, 24ct, Heads (4061)	640
10003536	555	Big Foodservice (St Louis)	4/10/2025	1275	Iceberg CS (24-ct)	400
10003537	555	Big Foodservice (St Louis)	4/10/2025	1275	Iceberg CS (24-ct)	240
10003538	555	Big Foodservice (St Louis)	4/1/2025	1275	Iceberg/24Case	640
10003539	555	Big Foodservice (St Louis)	4/8/2025	1275	Iceberg/24Case	640

FDA Traceback Records Requests



Current Records Requests

- Date range or range of shipments/lot codes based on available exposure information
 - Can be broad if epi is limited
- Requires explanation of data contained on provided records
- May require confirming records and/or information with each supply chain entity

Future Records Requests

- Requests can focus on Traceability Lot Code(s) shipped and/or received
- Traceability Plan information would provide explanation of record information
- Will not necessarily need to request records and information from all supply chain partners



Exposure Line List

	Α	В	С	D	E	F	G	н	1	J	К	L	М	Ν	0
1	ey	Wgsid	State	Age	Sex	Isolationdate	Onsetdate	Hospitalized	Died	HUS	Grocerystores	Restaurants	Exposuresofnote	Comments	LTF
													bought iceberg lettuce head from Big Mart on on 4/10 (Store Address: 117 W Duval St,		
2 F	L_2222222	PNUS2222222	FL	56.00	F	2025-04-17	2025-04-15	No	No	No	[Big Mart, Gas N Groceries]	0	Jacksonville, FL 32202), ground beef purchased at Gas N Groceries for tacos at home	Shopper Card said PLU 4061	No
													ate BLT sandwich (w/ Iceberg lettuce) from Tasty Diner #08 on 4/19 (Restaurant		
3	_9876543	PNUS9876543	IL	28.00	M	2025-04-25	2025-04-21	No	No	No	0	[Tasty Diner, Bombay Best]	Address: 510 Green Bay Rd, Winnetka, IL 60093)		No
													bought iceberg lettuce head from Big Mart on 4/11 (Store Address: 360 S County Rd,		
4 F	L_3333333	PNUS3333333	FL	4.00	M	2025-04-22	2025-04-17	Yes	No	Yes	[Big Mart]	0	Palm Beach, FL 33480)	Shopper Card said PLU 4061	No
													ate coleslaw from facility (LTCF) kitchen on 4/23 (Address: 125 N Main St, Memphis, TN		
5 1	N_7979797	PNUS7979797	TN	78.00	F	2025-04-28	2025-04-26	Yes	No	No	0	[Silver Days Home]	38103)		No
													ate wedge salad from Tasty Diner #12 on 4/18 (Restaurant Address: 800 E Monroe St,		
6 I	_12345678	PNUS1234567	IL	65.00	F	2025-04-26	2025-04-23	No	No	No	0	[Tasty Diner]	Springfield, IL 62701)		No
7															
8															
9															
10															
11															

CORE RT3: Assignment # - Charlie Go-Go – S. Litchfield / Cantaloupe / Jan 2014

ATTN: OII OHFI East 3 (Atlanta District Office)

FDA's Coordinated Outbreak Response and Evaluation (CORE) Network is requesting traceback record collection from Santa Foods (Lakeland, GA; FEI:).

This traceback assignment (FACTS #, Operations ID #) is related to an outbreak of *Salmonella* Litchfield. To date, 13 states and Canada are reporting 51 culture-confirmed cases since December 10, 2013. The epidemiological investigation determined that illnesses appear to be associated with cantaloupe consumption. Two individuals reported eating fruit salad containing cantaloupe on the buffet. They also reportedly consumed honeydew from the same buffet. Both individuals consumed cantaloupe only once in the week prior to illness. The first case reportedly had consumption on 1/24/14 and illness on 1/30/14, while the second case consumed cantaloupe on 1/25/14 and became ill 2/2/14.

CORE Information Request

Based on the available epidemiologic exposure information, ill persons have reported purchasing cantaloupe from Charlie Go-Go prior to becoming ill. Santa Foods (Lakeland, GA) was identified as a supplier to Charlie Go-Go during the timeframe of interest.

CORE is requesting traceback record collection related to shipments of cantaloupe to Charlie Go-Go for the identified timeframe of interest, January 4, 2014 to January 25, 2014.

Follow-up Correspondence

Electronic spreadsheets containing the requested traceability data are preferred if available. Any paper records or electronic copies of paper records can be provided later. As requested, please provide information back to us <u>within 24 hours</u>.

Document and Information Collection

- Please provide complete traceability information (invoices, BoLs, etc.), to the best of your ability, for cantaloupe supplied to Charlie Go-Go by Santa Foods, from 1/4/14 – 1/25/14, respectively to include:
 - a. Please include delivery dates to the point of service.
 - Please include Best by dates/lot numbers that would have likely been available at Charlie Go-Go.
 - c. Is there any product manipulation prior to shipping to the point of service?
 - d. If available, for each best by date/lot number identified in part 1.b), provide processor and grower level information to the best of your ability, including:
 - i. Complete processor name, location, and address
 - ii. Harvest information including company, crew, and dates
 - iii. Growers, farms, and ranches with addresses as applicable
 - iv. GPS locations of each farm/ranch in decimal format

- An explanation of any brand, lot code, date, or other identifiable information used to determine traceability of the product.
- f. For each shipment of cantaloupe that was supplied to Charlie Go-Go from Santa Foods during the timeframe of interest, 1/4/14 – 1/25/14, please collect the following:



- Bills of Lading, Purchase Orders, Shipping/Receiving Documents, Invoices, internal documents connecting incoming shipments from the firm's cantaloupe supplier(s) with outgoing shipments to the point of service.
- ii. Please explain how incoming shipments are linked to outgoing shipments.
- Explain what the dates provided on the documents above stand for (for example shipping date, arrival date).
- iv. Please describe how the cantaloupes are received from the supplier(s).
- g. Explain the average turn-around time and whether the firm uses First-in-First-Out (FIFO).
- h. Obtain a list of other customers including institutions that received the same lots/shipments of cantaloupes during the respective timeframe of interest as Charlie Go-Go from Santa Foods.
- Please provide all brands and production descriptions of products supplied to the above point of service.
- j. What is the shelf life of the cantaloupes?

Please refer to the April 2001 traceback procedures, which can be found at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm075005.htm, for the investigation methodology and reporting requirements. In accordance with this guidance, please also cover: the firm's shipping and receiving practices, handling and storage practices, stock rotation practices, daily stock inventory, and order practices, as this information will be needed to determine which shipments were available and most likely consumed at the time the implicated meals were consumed.

All activities related to this outbreak response should be reported under PAC 03C001. Please send all information collected, and responses to the questions above, electronically to FDA.

As this outbreak is ongoing, we would appreciate your prompt attention to this **high priority** assignment. Please include your state partners, as appropriate. We would appreciate you notifying **CORE Response Team 3** when you initiate the assignment and provide an estimate as to when the information requested will be provided. If you have any questions or we can be of any assistance, please contact <u>CORE Response Team 3</u>.

Assignment Close Out

All activities related to this outbreak response should be reported under PAC 03C001.

Upon completion of the assignment by the division, the responsible division Branch Chief should notify your Field Emergency Response Coordinator (FERC) via eNSpect that the assignment is endorsed and completed via the drop-down notification listing in eNSpect, so the FERC receives an e-mail notification.

SANTA SANTA SANTA INSTRUCTIONS BOLD TO: 152241 Charlie - GoGo Ogien, GA Item & Ordered Shipped With Veraficture of Pactritice Brand Ogi999854 1 1 CE 02565 40/LB PARKON 90991919 1 1 1 CE 02565 40/LB PARKON	INVOICE INV	FDA
00991919 1<	.942/02 SQUASE, BANANA 17-22 LB AVERAG 80 15.68 24.03 17.40 .052/02 BROCCULI, CROWNS ICELSCONTRACT 90 .514/EA GRAPEPRUIT, STAR RUHY 80 18.5	BILL OF LADING 11.30 NOTCE OF DELNERY
00894418 1 1 C5/03103 50/128 993800F 00997999 1 1 05015190 15/CT PACKER 009990168 4 4 C5/02635 4/5 128 993800F	1,264/RA MELCUS, CANTALOUPES 9-15CT 10 18.9 1.264/RA MELCUS, CANTALOUPES 9-15CT 10 18.9 1.65/02 LETTUCE, SALAD MIX RSS 10 13.2	SANTA FOODS 495 50234
	574 152 CR5 192 (
		Identity: Demonsta TEMP = 36 PED F RUER & ETT 126 - TRUCKS 3 3POMMETEON CARAJER JONE JOINT UNIVERS LICA 9695 720
	un Hilton 121	DRIVER NUME: CLUB (1) SALA DRIVER CELLO (1) SALA DRIVER CELLO (1) SALA DRIVER CELLO (1) SALA DRIVER DRIVER CELLO (1) SALA DRI

Shipments for January 2014 to Santa Foods

Chin Data A	miscal Data	Canta DO#	Chinner	Chinnes Defi	Landler Landler	1.1.4				
Ship Date A	irrival Date	Santa PO#	Shipper	Shipper Ref#	Loading Location	Label	Quantity Pr	roduct	CHR lot # Arrival at KO	JLDHOLD
	. 1-Jan	50466	Luna	PU# 51037	Tampa, FL	Luna label	92 Ca	antaloupe 15ct.		
	4-Jan	50570	New Hunt	PU# 7032481	Boise, ID	New Hunt Label	112 Ca	antaloupe 15ct.		
3-Jan	7-Jan	50616	Alimentario	CHR OB Lot# 337718	Wilmington, CA	Mike's Melon Label		antaloupe 12ct.	CHR 001	1/3/2014
7-Jan	10-Jan	50651	Alimentario	CHR OB Lot# 337717	Wilmington, CA	Mike's Melon Label		antaloupe 9ct.	CHR 001	1/3/2014
11-Jan	14-Jan	50697	Alimentario	CHR OB Lot# 337986	Wilmington, CA	Mike's Melon Label		antaloupe 12ct.	CHR 003	1/10/2014
15-Jan	17-Jan	50749	Alimentario	CHR OB Lot# 340248	Wilmington, CA	Mike's Melon Label		antaloupe 12ct	CHR 011	1/15/2014
18-Jan	21-Jan	50807	Alimentario	CHR OB Lot# 340846	Wilmington, CA	Mike's Melon Label	192 Ca	antaloupe 12ct.	CHR 014	1/17/2014
22-Jan	24-Jan	50859	Alimentario	CHR OB Lot# 340918	Wilmington, CA	Mike's Melon Label	256 Ca	antaloupe 12ct.	CHR 023	1/22/2014
25-Jan	28-Jan	50927	Alimentario	CHR OB Lot# 3	· · · · · · · · · · · · · ·	. / .	,		R 027	1/24/2014
					Mimontaria	Num				

fimentano Naevo

*** PUT SHEET ***

Page: 2

2UT / RECEIPT # : 152798

Time: 3:44pm Date: Received From;

R.R. Cruspe

R. R. Crusce

A/C 09.66

Carr	ler: HOUSE AP	RU5757349		Shpment Pro/Way	Refę: Bill: APL MA	NACLIA VODS	
Line	Product	Description			Lot No.	SKU Uni	ts/Loc't
001	CAN 9/64 MH	CANTALOUPE	9/64	NIKB'S	4397	CAS	364
		1D: CRRDol4					
002	CRN 12/64 MM	CANTALOUPE	12/64	MIKR'S	4398	CAS	896
	_ C	1D: CBR0014					

17

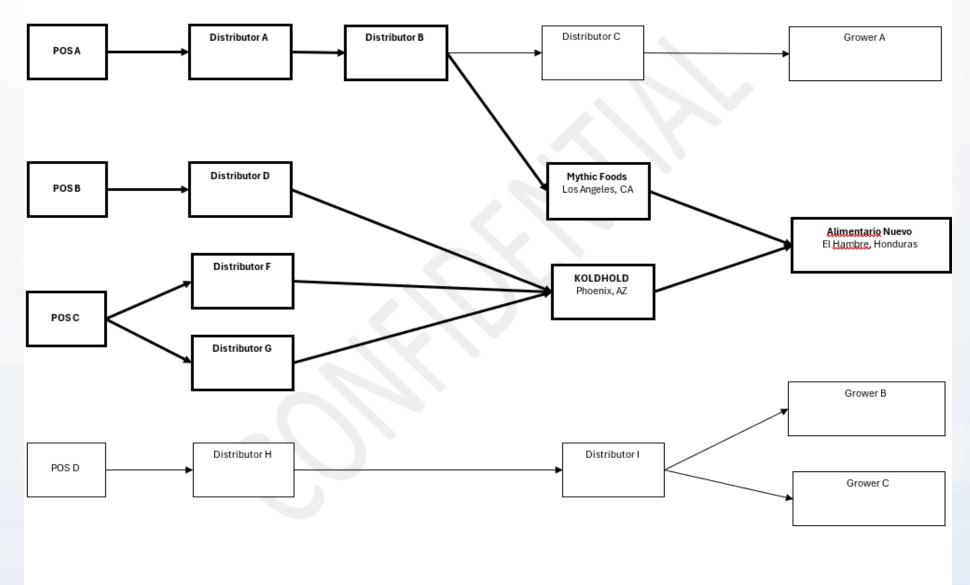
Salmonella Litchfield – Cantaloupes Multistate Outbreak, Jan – Mar 2014 Traceback Timeline

FDA

Receipt Date																	olded)					_
	F	Sa		M		W		F		100	М		W		F		S	M		W		F
DATE	1/4	1/5	1/6	1/7	1/8	1/9	1/10	1/11	1/12	1/13	1/14	1/15	1/16	1/17	1/18	1/19	1/20	1/21	1/22	1/23	1/24	1/25
At Charlie-GoGo, Ogden, GA										1		N										
m Santa Foods, Lakeland, GA (15 1)		2		1		2		1	2				2		1	2		2		1		
							1						1				1					
At Santa Foods, Lakeland, GA										-			-					_	/			
At KOLDHOLD, Phoenix, AZ thru R.R. Crusoe, Despair Isle, WI (12- count unless identified)				64 CHR			256 (9 ct)				320 CHR			128 CHR		To 1/21			\checkmark			
count unces reconnectly				001			CHR 001				003		/	011		ſ		192 CHR			256 CHR	-
Fm New Hunt Produce, Boise, ID	112 (15 ct)									7			/					014			023	
			1				V		Y					1								
At KOLDHOLD, Phoenix, AZ thru R.R. Crusoe, Despair Island, WI												/		1								
From Alimentario Nuevo, El Hambre, Honduras					5		640 CHR	/				768 CHR		896 CHR					896 CHR			
(12 ct fancy only)		1					003					011		014					023			
1				1																	15	
						1																
					1														1			_
				11																		
				111																		

Salmonella Litchfield Cantaloupe Jan 2014 Master Traceback Diagram

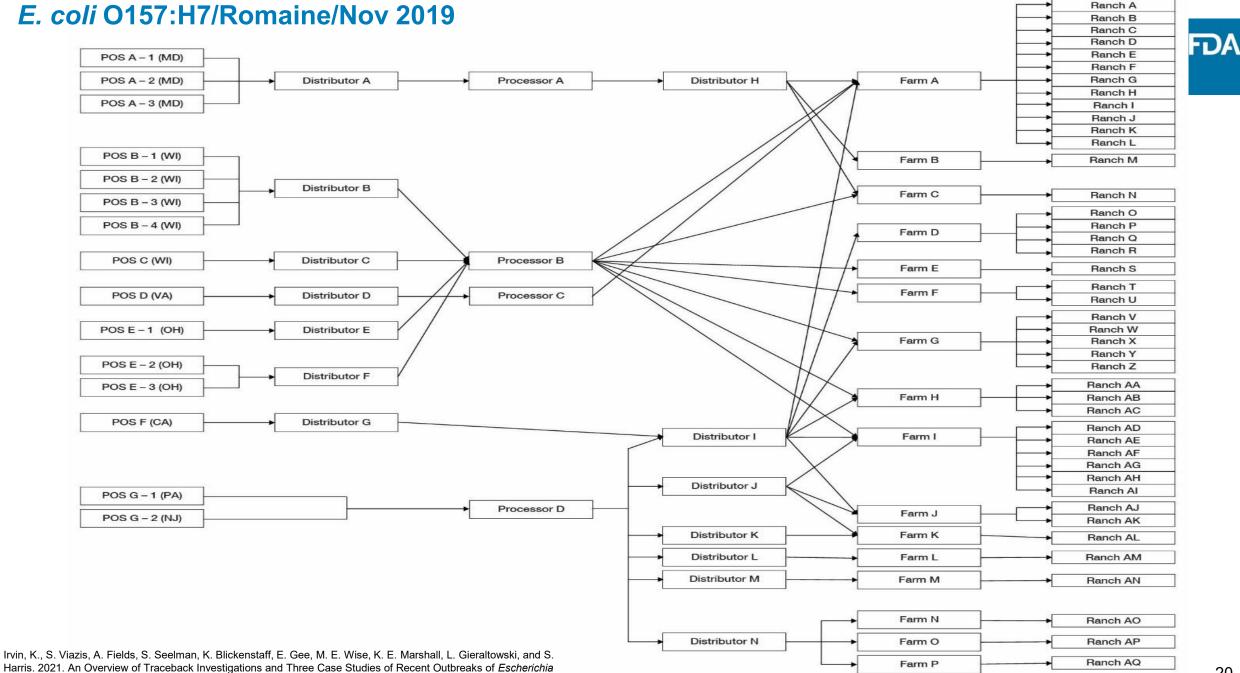




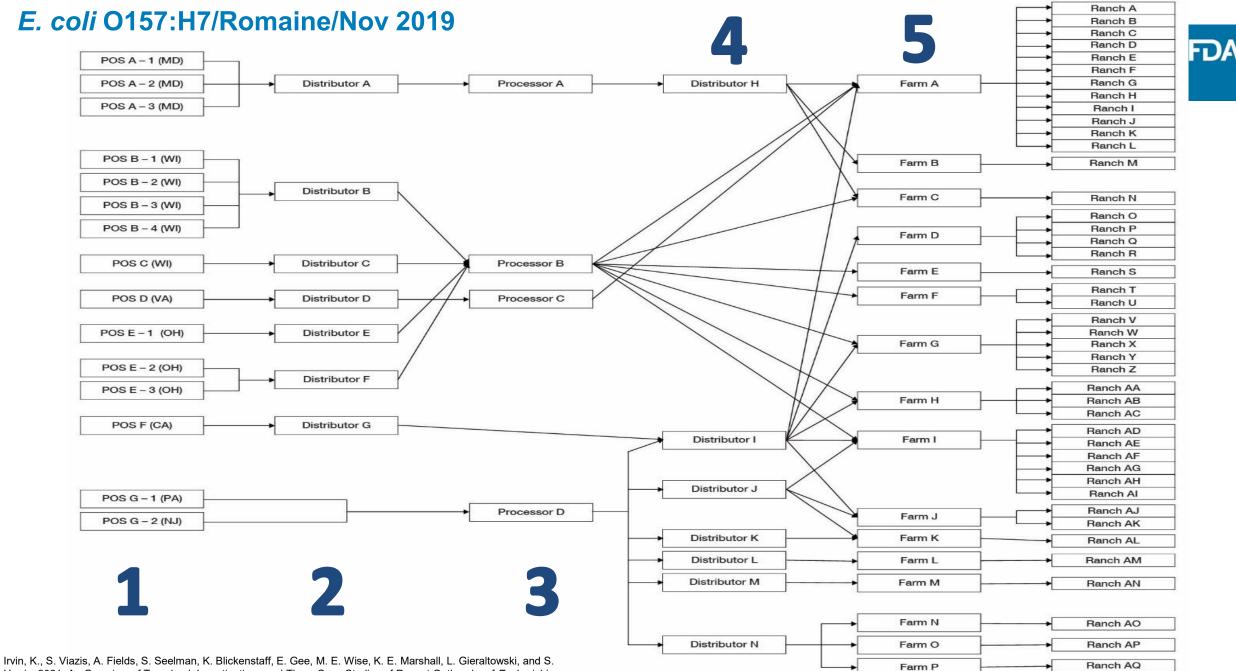
FDA's Coordinated Outbreak Response and Evaluation (CORE) Network

Created Date: 3/4/14; Updated: <u>4/14/14</u>

This report contains confidential/commercial information and may not be further distributed beyond its intended FDA audience without express permission from FDA



coli O157:H7 Infections Linked to Romaine Lettuce. Journal of Food Protection.



Irvin, K., S. Viazis, A. Fields, S. Seelman, K. Blickenstaff, E. Gee, M. E. Wise, K. E. Marshall, L. Gieraltowski, and S. Harris. 2021. An Overview of Traceback Investigations and Three Case Studies of Recent Outbreaks of *Escherichia coli* O157:H7 Infections Linked to Romaine Lettuce. *Journal of Food Protection*.

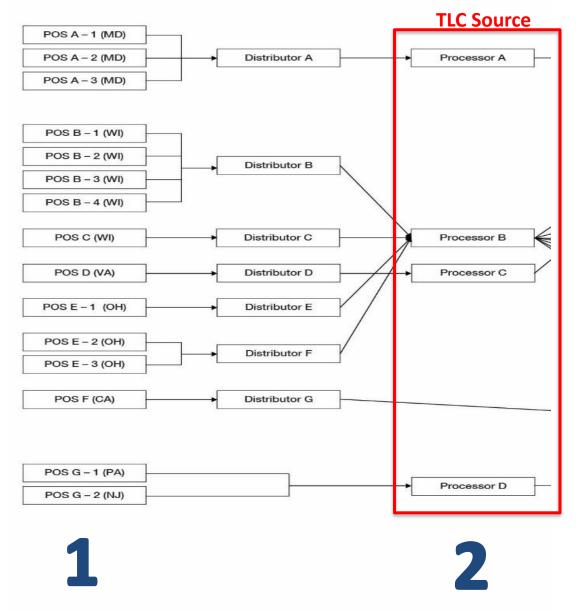
E. coli O157:H7/Romaine/Nov 2019

POS A - 1 (MD)		
SA-2 (MD)		
S A – 3 (MD)		
POS B - 1 (WI)		
POS B – 2 (WI)		
POS B – 3 (WI)		
OS B - 4 (WI)		
POS C (WI)		
POS D (VA)		
POS E - 1 (OH)		
POS E – 2 (OH)		
POSE-3(OH)		
POS F (CA)		
POS G – 1 (PA) – POS G – 2 (NJ) –		

Irvin, K., S. Viazis, A. Fields, S. Seelman, K. Blickenstaff, E. Gee, M. E. Wise, K. E. Marshall, L. Gieraltowski, and S. Harris. 2021. An Overview of Traceback Investigations and Three Case Studies of Recent Outbreaks of *Escherichia coli* O157:H7 Infections Linked to Romaine Lettuce. *Journal of Food Protection*.

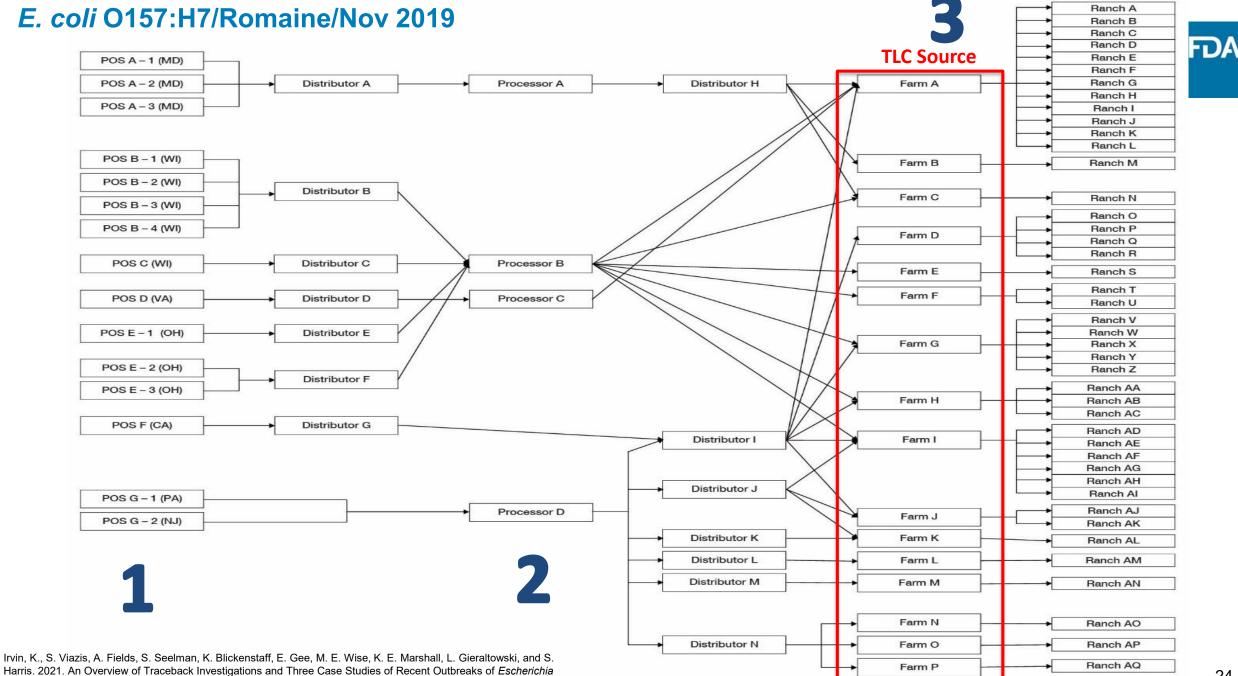
FDA

E. coli O157:H7/Romaine/Nov 2019



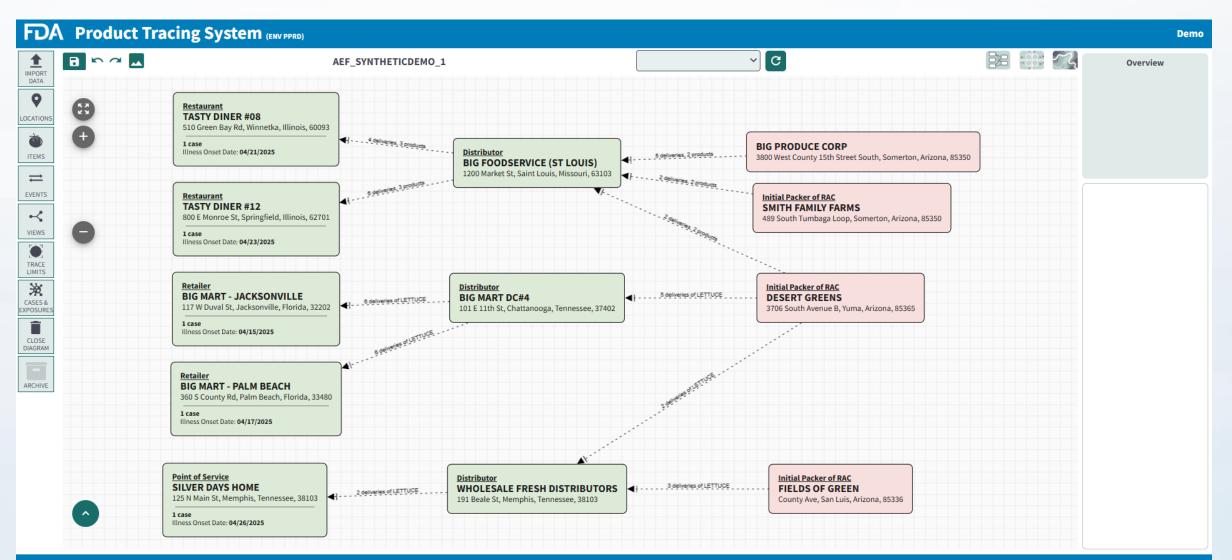
Irvin, K., S. Viazis, A. Fields, S. Seelman, K. Blickenstaff, E. Gee, M. E. Wise, K. E. Marshall, L. Gieraltowski, and S. Harris. 2021. An Overview of Traceback Investigations and Three Case Studies of Recent Outbreaks of *Escherichia coli* O157:H7 Infections Linked to Romaine Lettuce. *Journal of Food Protection*.

FDA



coli O157:H7 Infections Linked to Romaine Lettuce. Journal of Food Protection.

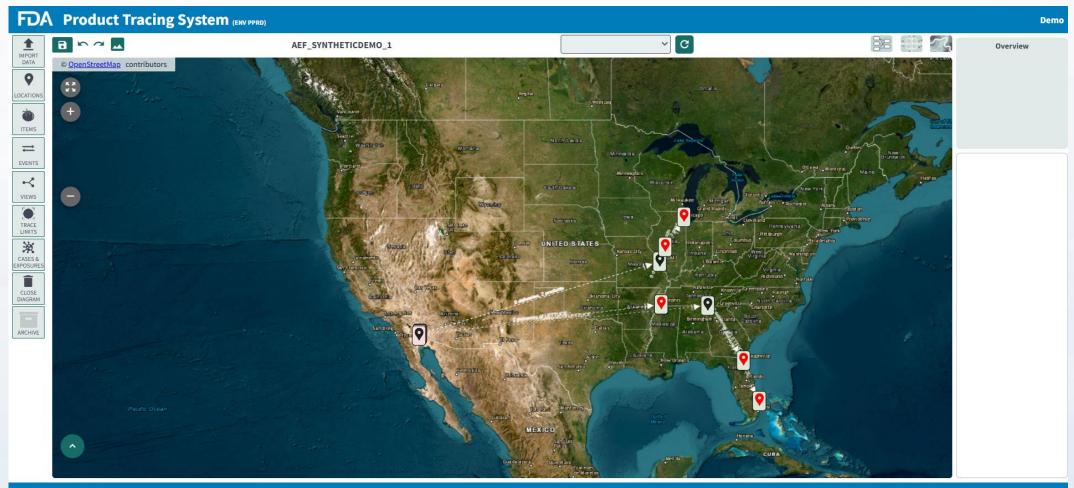
PTS Traceback Diagram



C Last Change: April 23, 2025 client version@1.3.0



PTS GIS Capabilities



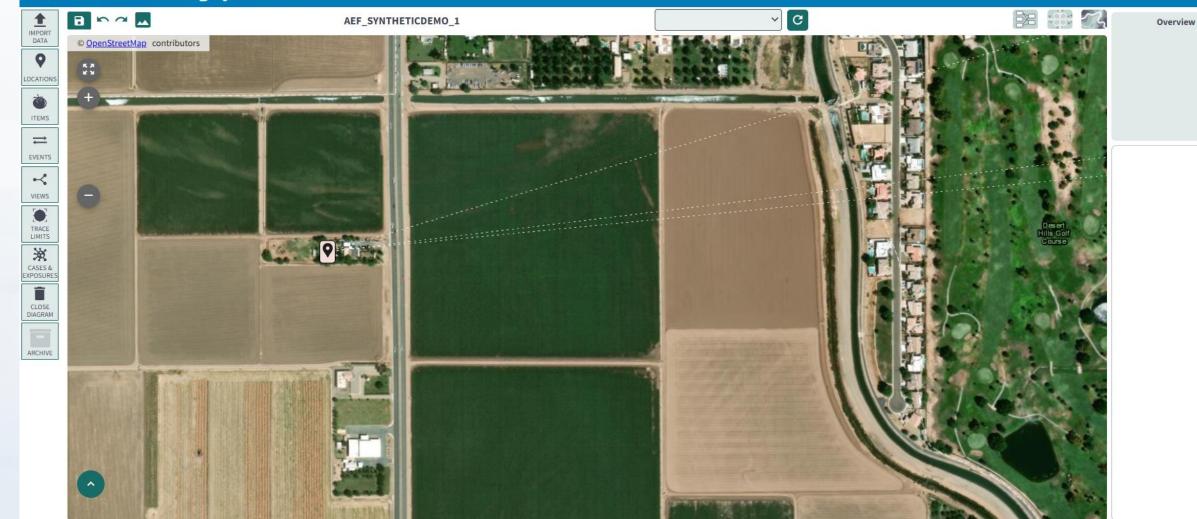
C Last Change: April 23, 2025 client version@1.3.0

PTS GIS Capabilities

FDA Product Tracing System (ENV PPRD)



Demo



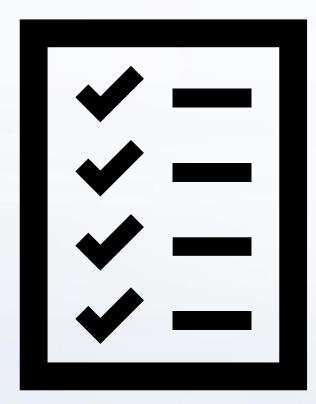


PTS Development Continues

- Based on peer-reviewed traceback methods and aligns with CIFOR guidelines
- Will be utilized for all foods, regardless of FTR compliance requirements
- Continuing to test PTS during active incidents
- Continued research into analytic capabilities

Using Traceability Data to Protect Public Health





- Public advisory
- Recall
- Root cause analysis
- Prevention activities

Thank you!







Update on Implementation Activities

Melinda Hayman, PhD

Consumer Safety Officer Office of Compliance and Enforcement U.S. Food and Drug Administration



Food Traceability Implementation Updates

July 10, 2025 Melinda Hayman, Ph.D. Office of Compliance and Enforcement FDA Human Foods Program









Exemptions to the Food Traceability Ru

You are subject to the Food Traceability final rule, <u>unless</u> an exemption applies. To determine whether you may be exempt, please click on any of the following catego that may apply to you:

Farms	Certain types of processing
Commingled new agricultural commodities (FACs)	Personal consumption, holding face for specific consumers
Pating vesses molescan shelling	Oter
Retail lood establisheends (RFEs), restaurants	





FTR Implementation Planning



FDA

Developing FTR Inspectional Approach

Collaborated with experts across FDA to develop inspectional approaches

Discussed with small group of state regulators, made adjustments Engaging more broadly with SLTT regulators to coordinate approach

FDA

FTR Regulator Training









Goals

- Provide an understanding of the rule
- Inspection considerations

Target Audience

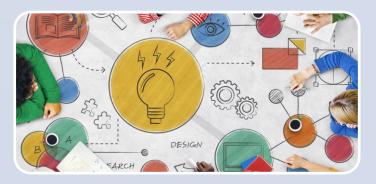
- FDA investigators
- SLTT regulators and investigators

Modality

- Web-based training course
- Modules on different topics/Self paced

FTR Industry Training – with FSPCA









Goals

- Provide an understanding of the rule
- Considerations for how to build a traceability program

Target Audience

• All persons covered by the rule

Modality

- Train-the-trainer model
- Lead Instructors will deliver the training
- In person and virtual offerings

More to come

- Development of an internal FDA system to facilitate <u>analysis of traceability information</u>.
- Development of system for <u>sending required</u> information to FDA.





FTR Resources



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

f Share 🔰 Tweet 🚺 Linkedin 🖾 Email 🖨 Print



Frequently Asked Questions on FSMA

FSMA Rules & Guidance for Industry

What's New in FSMA

FSMA Training

FSMA Technical Assistance Network (TAN)



<u>Español (Spanish) | Bahasa Indonesia | 中文 (Chinese, Simplified) | עטט'ואט (Thai) | Tiê´ng Việt (Vietnamese)</u>

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 regulations, for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). The final rule is a key component of FDA's New Fig. of Smarter Food Safety Blueprint and

	Federal Register Notice
•	Docket No. FDA-2014-N-
	0053
•	<u>eCFR Subpart S -</u>
	Additional Traceability
	Records for Certain Foods

Food Traceability Final Rule webpage

- Food Traceability Final Rule (Federal Register)
- eCFR <u>21 CFR, Part 1, Subpart S</u> (codified)

Translations



Available Resources



- Food Traceability List <u>webpage</u>
- Frequently Asked Questions (FAQs)
- Food Traceability Final Rule Webinar
- Small Entities Compliance <u>Guide</u>
- At-a-Glance <u>handout</u>
- Critical Tracking Events and Key Data Elements
 <u>document</u>
- Traceability Lot code <u>webpage</u>
- Exemptions tool

- Electronic Sortable Spreadsheet in Excel™
- Electronic Sortable Spreadsheet w/data in Excel™
- Risk Ranking Model Results tool
- Supply Chain Examples
- Resources for farms
- Resources for Retail Food Establishments and Restaurants

Thank you!



Pilot Panel Discussion





Charles Leftwich, MBA Sysco Corporation



Michael Lookup Wegmans Food Markets



Takashi Nakamura, PhD, MBA Fresh Del Monte

Virtual Public Meeting on FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods Webinar

Thank you for attending!



