

FDA's Food Traceability Final Rule

Moderators: Kari Irvin, FDA and Adam Friedlander, FDA

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- All attendees are muted. Questions should be submitted to the presenters during the presentation via the Questions section at the right of the screen. Questions will be answered at the end of the presentations.
- This webinar is being recorded and will be available for access by IAFP members at www.foodprotection.org within one week.

Today's Moderators

Kari Irvin, FDA

CAPT Kari Irvin is currently the Deputy Director of FDA's Coordinated Outbreak Response and Evaluation (CORE) Network in College Park, MD. CAPT Irvin joined FDA in 2008 as a microbiologist and has been a member of FDA CORE since 2011, where she serves to coordinate the FDA's role in detecting, responding to, and learning from foodborne illness outbreaks.

Adam Friedlander

Adam Friedlander is a Policy Analyst in the U.S. Food and Drug Administration's (FDA's) Coordinated Outbreak Response and Evaluation (CORE) Network where he helps lead the agency's efforts to advance strategic tech-enabled traceability initiatives and engage with a variety of stakeholders on the requirements of the FDA Food Traceability Rule. Adam graduated from Cornell University with a Bachelor of Science (BS) in Food Science and Operations Management and a minor in Music. He received his Master of Science (MS) in Regulatory Affairs of Food and Food Industries from Northeastern University.

Today's Panelists

Angela Fields, FDA

Angela Fields is a Senior Consumer Safety Officer for the Coordinated Outbreak Response and Evaluation Network (CORE). As a member of CORE Response, she provides epidemiologic and traceback expertise and evaluation of data related to outbreaks in support of FDA's response activities. Additionally, she serves as one of CORE's traceability subject matter experts participating in Agency initiatives and providing internal and external trainings on traceability and outbreak response.

Asma Madad, FDA

Asma Madad is a Senior Biologist who has been a part of Response Team 2 in the FDA/CFSAN Office of Coordinated Outbreak Response and Evaluation (CORE) Network since 2015. In her role on CORE Response, she leads the management of FDA's response to multistate outbreaks related to foods, dietary supplements and/or cosmetics, including, but not limited to, determining investigational strategy/objectives and traceback analysis. Asma is one of four FDA co-leads for implementation efforts related to the Food Traceability rule. Asma received her Master of Science in Biology from Hofstra University and earned her Master of Public Health in Epidemiology from University of Albany School of Public Health.

Tim York, LGMA, California

Tim York is the CEO of California Leafy Greens Marketing Agreement. The LGMA was formed in 2007 to protect public health. Mr. York joined the LGMA on December 1, 2020. Prior to the LGMA, Mr. York worked with Markon, starting in 1985 as Purchasing Director and President 1990-2020. Mr. York has been instrumental in the industry addressing food safety and was instrumental in the formation of the Center for Produce Safety in 2007, serving as its Chairman from 2007-2012.

FDA's Food Traceability Final Rule

Session 1:

Overview of the Food Traceability

Angela Fields

Food Traceability Final Rule: Requirements for Additional Traceability Records for Certain Foods (FSMA Section 204)

September 18, 2023

IAFP Webinar

Angela Fields



Exemptions to the Food Traceability Rule

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

Farms	Certain types of processing
Domestic raw agricultural commodities (DRAC)	Personal consumption, holding, food for specific consumers
Fishing vessels, public health risks	Other
Animal food establishments (AFEs), restaurants	



What will the Food Traceability Rule require?



- Persons who manufacture, process, pack, or hold foods on the Food Traceability List
- Covers the entire food supply chain
- Includes both foreign and domestic entities
- Full and partial exemptions may apply

Exemptions

Farms

- Certain small produce farms
- Certain small shell egg producers
- Certain other small RAC producers
- Certain food produced + packaged on farm
- Farms selling food directly to consumers

Commingled raw agricultural commodities (RACs)

- Certain commingled RACs (not fruits & 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), restaurants

- Certain small RFEs + restaurants
- RFEs or restaurants purchasing food directly from a farm
- RFEs or restaurants purchasing food from another RFE or restaurant on 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

Exemptions Tool

Exemptions to the Food Traceability Rule

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Farms

Certain types of processing

Commingled raw agricultural commodities (RACs)

Personal consumption, holding food for specific consumers

Fishing vessels, molluscan shellfish

Other

Retail food establishments (RFEs), restaurants



Food Traceability List

Cheese (made from pasteurized milk), fresh soft or soft unripened	Tomatoes (fresh)
Cheese (made from pasteurized milk), soft ripened or semi-soft	Tropical tree fruits (fresh)
Cheese (made from unpasteurized milk), other than hard cheese	Fruits (fresh-cut)
Shell eggs	Vegetables (fresh-cut)
Nut butters	Finfish (histamine-producing species) (fresh and frozen)
Cucumbers (fresh)	Finfish (species potentially contaminated with ciguatoxin) (fresh and frozen)
Herbs (fresh)	Finfish, species not associated with histamine or ciguatoxin (fresh and frozen)
Leafy greens (fresh)	Smoked finfish (refrigerated and frozen)
Leafy greens (fresh-cut)	Crustaceans (fresh and frozen)
Melons (fresh)	Molluscan shellfish, bivalves (fresh and frozen)
Peppers (fresh)	Ready-to-eat deli salads (refrigerated)
Sprouts (fresh)	



Food Traceability List

- Foods specified as “fresh” on the FTL
- Fresh FTL foods used in multi-ingredient foods
- Changing the form of the food
- Foods not specified as “fresh” used in multi-ingredient foods
- Applying a kill step to the food

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.

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.



§1.1320: Establishing and Assigning Traceability Lot Codes



- Traceability Lot Code (TLC) is a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source
- Traceability Plan must include a description of how you assign TLCs
- All KDEs must be linked to the traceability lot for the food
- Final rule offers flexibility on how TLCs are created and assigned



§1.1320: Establishing and Assigning Traceability Lot Codes



- TLC Source is the place where a food was assigned a TLC
 - This KDE helps FDA to more quickly identify this location and prioritize where we need to collect tracing data
- TLC Source Reference is an alternative method to provide TLC source information, examples include:
 - 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

Supply Chain Example: Fresh Produce



Initial Packer Example



KDEs for Incoming

- For each incoming RAC, the following KDEs must be linked to each traceability lot that gets packed:
- What you received*
- How much you received*
- Date you received it
- Where it came from*
- Information about harvesting and/or cooling*
- Reference document information



Packing KDEs

- For each traceability lot of a RAC that you pack, the following KDEs must be linked to the traceability lot:
- TLC you assigned
- Date you packed it
- What you packed
- How much you packed
- When you packed it
- Where you packed it
- Reference document information



Shipping KDEs

- For each traceability lot of a RAC that you ship after packing, the following KDEs must be linked to the traceability lot:
- TLC
- How much you shipped
- What you shipped
- Where you shipped it
- Where you shipped it from
- Date you shipped it
- Traceability lot code source information (i.e., where you packed it)
- Reference document information

* indicates KDEs you receive

Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



The 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 specific information (key data elements or KDEs) for certain critical tracking events (CTEs) in the food's supply chain. This framework forms the foundation for effective and efficient tracing and clearly communicates the information that FDA needs to perform such tracing.

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.



Key Concepts of the Final Rule

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

Emphasis on...



Keeping and sharing KDEs



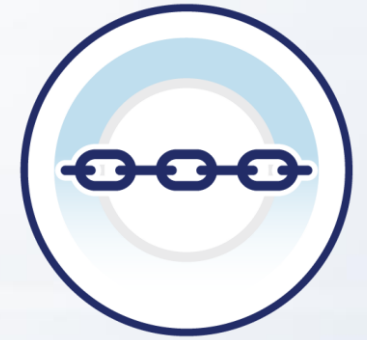
Traceability Lot Code (TLC)



Traceability Lot Code Source (TLC Source)



Traceability Plan



Working with supply chain partners

Records Maintenance and Availability



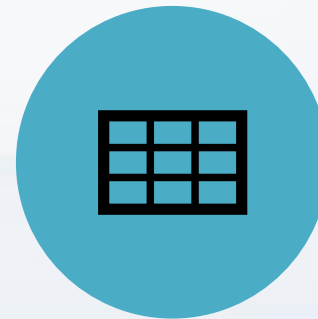
Legible **original paper, electronic**, or true copies. Stored to prevent deterioration or loss. May **include electronic links**.



Records must be **kept for 2 years**.



Available **within 24 hours (or reasonable time if FDA agrees)**. May be stored **offsite or by another entity**.



During an outbreak - **electronic sortable spreadsheet** within 24 hours of a request (including a **phone request**).

Compliance date

January 20, 2026

- Applies to all firms
- Provides 3 years for covered entities to work with supply chain
- We will educate before and while we regulate

More to come

- Outreach, education, technical assistance
- Additional communications materials to be posted
- Development of an internal FDA system to facilitate analysis of traceability information
- Development of system for sending required information to FDA



Implementation



- Currently considering best approach for conducting inspections under this rule
- Developing enforcement strategy and plan to work with State, Local, Tribal, Territorial and other regulatory partners to enforce rule
- Working with FSPCA to develop industry training

What can industry do to get started?

1. Do you manufacture, process, pack or hold a food on the [Food Traceability List](#)?
2. Do [any exemptions apply](#) to your situation?
3. What [Critical Tracking Events \(CTEs\)](#) do you conduct?
4. What [Key Data Elements \(KDEs\)](#) do you already maintain? What additional KDEs do you need to maintain to be in compliance with the final rule?
5. Develop a [traceability plan](#).
6. Talk with your supply chain partners.
 - Understand the record keeping practices in your supply chains
 - Determine how best to communicate required information
 - Discuss potential solutions
7. More resources available [here](#).



Available Resources

- **Food Traceability Final Rule ([Federal Register](#))**
 - Link directly to codified (Bookmark this!): <https://www.federalregister.gov/d/2022-24417/p-amd-1> (CTRL + F)
- **Food Traceability Final Rule [webpage](#)**
 - NEW translations!
- **Food Traceability List [webpage](#)**
- **Frequently Asked Questions ([FAQs](#))**
- **Food Traceability Final Rule [Webinar](#)**
- **Critical Tracking Events and Key Data Elements [document](#)**
- **Exemptions [tool](#)**
- **Risk Ranking Model Results [tool](#)**
- **Farms**
 - [What you need to know about the Food Traceability Rule: Coverage and Exemptions for Produce Farms](#)
 - [What you need to know about the Food Traceability Rule: Recordkeeping Information for Produce Farms](#)

Available Resources (cont.)

- **Supply Chain Examples:**

- Produce Supply Chain Example
 - [Video Presentation](#)
 - [Transcript](#)
 - [Slides](#)
- Seafood Supply Chain Example
 - [Video Presentation](#)
 - [Transcript](#)
 - [Slides](#)
- Cheese Supply Chain Example
 - [Video Presentation](#)
 - [Transcript](#)
 - [Slides](#)
- Additional Supply Chain Examples
 - [Slides](#)

Retail Food Establishments and Restaurants

- Retail Food Establishments (RFEs) and Restaurants: [What Records Do I Need to Keep for the Food Traceability Rule?](#)
- Retail Food Establishments (RFEs) and Restaurants: [What You Need to Know About the Food Traceability Rule](#)
- Retail Food Establishments (RFEs) and Restaurants: [What You Need to Know About Establishing and Maintaining a Traceability Plan for the Food Traceability Rule](#)

Questions?

- FSMA Technical Assistance Network (TAN): <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>

Thank you!



FDA's Food Traceability Final Rule

Session 2:

Traceability in Action:

How the Rule Could Impact Future Outbreak Investigations

Asma Madad

Traceability in Action: How the Food Traceability Rule Could Impact Future Outbreak Investigations

9/18/2023
IAFP

Asma Madad, Senior Biologist,
CFSAN/Office of Coordinated Outbreak
Response and Evaluation (CORE) Network



Exemptions to the Food Traceability Rule

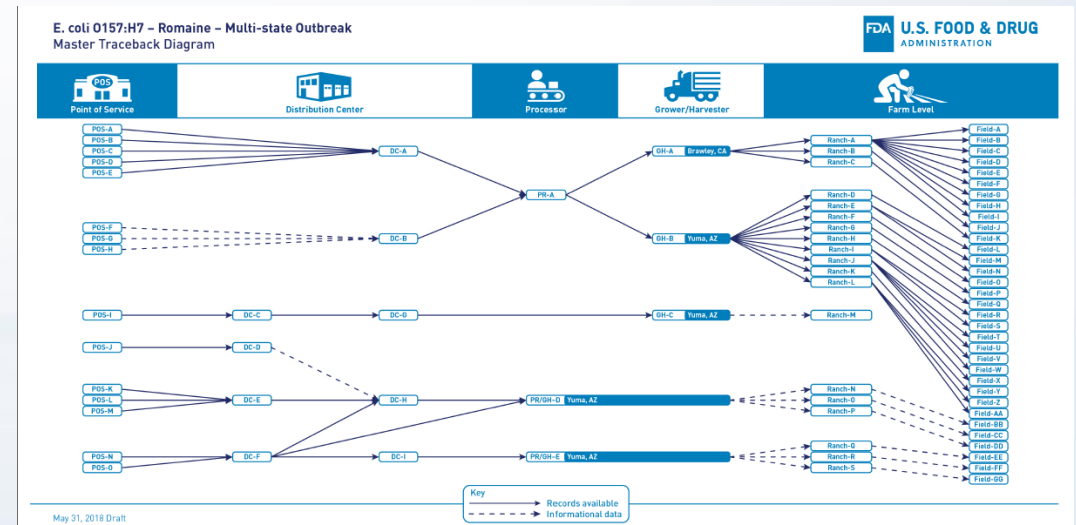
You are subject to the Food Traceability final rule, unless an exemption applies. To determine whether you may be exempt, please click on any of the following categories that may apply to you:

<input type="checkbox"/> Farms	<input type="checkbox"/> Certain types of processing
<input type="checkbox"/> Commingled raw agricultural commodities (RACs)	<input type="checkbox"/> Personal consumption, holding, used for specific consumer
<input type="checkbox"/> Fishing vessels, public health risks	<input type="checkbox"/> Other
<input type="checkbox"/> Small food establishments (SFEs), restaurants	



Traceback Investigations – Purpose

- Identify source(s) and distribution of food product of interest and remove from commerce
- Distinguish between two or more suspected food products
- Assist in determining potential route(s) and/or source(s) of contamination and prevent future illnesses/outbreaks



Traceback Investigations – Key Steps



Hypothesis Generating Questionnaire for Enter Pathogen (e.g., Salmonella) Form approved 08/16/10 (04/09) Expires 10/31/2016

PulseNet Cluster Code

Section 1: Interviewer Information (Questions 1-3 to be completed by interviewer prior to questionnaire administration)

1. PulseNet ID # 2. State/Local/Other ID #

3. Date of interview (your enter M8CDDYYYY)

4. Interviewer Information: Name Contact Phone Number

Agency or Organization

5. Before this interview how many times has the case been interviewed about their illness? None Once Twice Three Times

6. Respondent role: Self Parent Spouse Other (Specify)

Section 2: Demographic Data To be completed by asking a few questions about yourself (your OHNS) and your household.

1. What are your state, county, and zip code? State County Zip Code

2. Birth month (your enter 1-12) Birth year (your enter YYYY) 3. Sex Male Female Unknown

4. Hispanic or Latino origin: Yes No Unknown

5. How would you describe your race? White Black/African American American Indian/Alaska Native Asian Native Hawaiian/Other Pacific Islander Other (Specify)

Section 3: Clinical Information Now I have a few questions about your (your child's) illness.

1. What date did you first feel sick? (your enter M8CDDYYYY)

YES **NO** **Don't know**

2. Did you (your child) have any diarrhea (defined as at least 3 loose stools in 24 hours)

2a. What day did it start? (your enter M8CDDYYYY)

3. Hospitalized overnight?

4. Have any close contact with anyone with diarrhea or vomiting?

4a. When was this person? less than 24 hours before you 2-24 hours before you Unknown

5. How many days total were you sick? or Don't know

Section 4: Travel Next I have a couple of questions about any travel you (your child) might have done, either as part of your work or for pleasure.

YES **NO** **Don't know**

1. Did you (your child) travel to any of the 7 days before you were ill outside your home state?

1a. List all US states where you might have purchased or eaten foods. Enter 2-letter postal abbreviations. This should include foods eaten at airports, bus or train stations.

1b. List all countries outside the US where you might have purchased or eaten foods. List countries & travel dates.

1c. Did not travel outside the US

2. Did you (your child) travel to any of the 7 days before you were ill outside your home state?

2a. List all US states where you might have purchased or eaten foods. Enter 2-letter postal abbreviations. This should include foods eaten at airports, bus or train stations.

2b. List all countries outside the US where you might have purchased or eaten foods. List countries & travel dates.

2c. Did not travel outside the US

© 2010 CDC. All rights reserved. This questionnaire is for internal use only. It is not to be distributed outside the CDC. For more information, please contact the CDC. This questionnaire is for internal use only. It is not to be distributed outside the CDC. For more information, please contact the CDC. This questionnaire is for internal use only. It is not to be distributed outside the CDC. For more information, please contact the CDC.

Page 1 of 11



Current State of Traceback Records

Exit Payment To _____ Page 1 of 2

LOCAL : 615-286-2888 8111 TN
TOLL : 800-828-3388
FAX : 615-286-2888

Ship To: **Distributor A**
NASHVILLE TN 37210
489668-8760

Distributor D
NASHVILLE TN

Invoice No.	Invoice Date	Customer No.	Order Date	P.O. Number	Salesman	Terms	Route-Stop
265837	4/26/19	739	4/26/19	1150872/L22140 CONF: 573 1150872	UNASSIGNED	NET 30 DAYS DUE DATE: 4/26/19	WVC

SPECIAL INSTRUCTIONS: 1150872 FRIDAY 04/26/2019 5284965

Item Number	Quantity Ordered	Quantity Shipped	Pack Size	Item Description	Unit Weight	Extended Weight	Unit Price	Extended	ST
885802	170	170	250	TOMATOES UTILITY 250	-7382264				
887113	180	180	100	250 CAPE					
887186	60	60	120	TOMATO GRAPE 120	-3798291				
881281	60	60	250	Tomatoes Grape 12/1 Pint	-4959383				
882311	180	180	250	TOMATOES 5x5 250	-4851412				
886688	10	10	250	250 ROMA CPE-NOT A UTILITY-3449693					
881450	8	8	200	ROMA CPE - NOT A UTILITY-					
881707	40	40	200	TOMATOES Sanded 250 - Fresh -2093730					
881822	180	180	20	4x4 2-Layer DEEP RED V8	-3064987				
881483	10	10	20	TOMATO DEEP RED VINE RIPE	-8331086				
			200	TOMATOES 5x5 2-Layer	-1079219				
			250	250 4x6 250	-132782				

MARKETPLACE PRICE.

Driver: _____ Cash Amount: _____ Check Amount: _____
Check your merchandise before signing
Customer Signature: _____

Total weight: _____ Sub Total: _____

Receiving for Distr. A

Tomato

Row 3

NASHVILLE, TN 37210
PHONE: 615- [REDACTED]

TERMS: N/ LEAD: DAYS FRT: _____

BROKER BUYER: AM

R.R. CARB: _____
R.R. SEAL#: _____

SHIP DATE: 4/25/2019
DELIVERY DATE: 4/26/2019

UPC NUMBER	ITEM DESCRIPTION	CL	ITEM	SLOT	LOC	ORDER	RECD	AVG WGT	WGT REC
9500	TOMATO CAPE CT UBU	0	22553	C	01C075A	170	170	4590.00	
	T1/H1 10/4	Shelf Life							
			US						
	Quality:								
	TOMATO GRAPE 16LB		9500	22542	C	01C064A	180	180	1980.00
	T1/H1 8/7	Shelf Life							
			US						
	Quality:								
	TOMATO GRAPE 12PT		9500	22533	C	01C073A	60	60	660.00
	T1/H1 12/12	Shelf Life							
			US						
	Quality:								
	TOMATO LARGE ROUNDS 25LB		9500	22531	C	01C069A	60	60	1560.00
	T1/H1 8/10	Shelf Life							
			US						
	Quality:								
	TOMATO ROMA 25LB		9500	22490	C	01C072A	180	180	4860.00
	T1/H1 10/5	Shelf Life							
			US						
	Quality:								
	TOMATO SELECT 25LB UBU		9500	22556	C	01C079A	10	10	270.00
	T1/H1 10/4	Shelf Life							
			US						
	Quality:								
	TOMATO 4X4		9500	22500	C	01C078A	8	8	176.00
	T1/H1 8/6	Shelf Life							
			US						
	Quality:								
	TOMATO 4X5 CCF		9500	22507	C	01C077A	40	40	880.00
	T1/H1 8/6	Shelf Life							
			US						
	Quality:								
	TOMATO 5x5 20LB LAYER		9500	22511	C	01C076A	164	164	1976.00
	T1/H1 8/6	Shelf Life							
			US						
	Quality:								
			9500	22561	C	01C074A	80	80	2160.00

Handwritten notes on form: 60x60-50, 90x90, 53.5, 60x60-60, 53.5, 8, 8, 59.5, 104, 48x56, 80.

Distributor A
Nashville TN

RECEIVING PURCHASE ORDER

TERMS: N/ LEAD: DAYS FRT: _____

CBO BROKER: _____
BUYER: AM

R.R. CARB: _____
R.R. SEAL#: _____

SHIP / DELIVERY DATE: 4/25/2019

ITEM	QTY	UNIT	COOL	RYAN	S/C	FREIGHT	ICE	BLK	CH
0 CAPE CT UBU	170	170							
0 GRAPE 16LB	180	180							
0 GRAPE 12PT	60	60							
0 LARGE ROUNDS 25LB	60	60							
0 ROMA 25LB	180	180							
0 SELECT 25LB UBU	10	10							
0 4X4	8	8							
0 4X5 CCF	40	40							
0 5x5 20LB LAYER	164	164							
0 6x6 25 LB	80	80							

187529 QTY: 892 15061.22
COOL: RYAN S/C FREIGHT: ICE BLK CH

892 892 14061.22

Clauses of 41 CFR 60-1.4(a), 41 CFR 60-250.5(a), and 41 CFR 60-741.5 (e) as well as 29 CFR 1910.101-101.101 are incorporated by reference in all contracts and subcontracts, as applicable.

Distributor D
Nashville TN

Form A

2453 CHOPPING FRONT LANE LLC

SHIP DATE: 4/22/2019
DELIVERY DATE: 4/23/2019

SHIP TO: _____
BUYER: CH

SHIP DATE: 04/23/19 TRAILER TEMP: 50 TOTAL UNITS: 1600

TEMPERATURE: Quality: good color 3 1/2-4

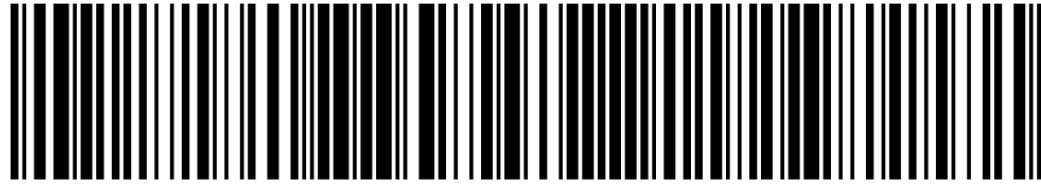
ITEM	QTY	UNIT	COOL	RYAN	S/C	FREIGHT	ICE	BLK	CH
75	2	SDA Decal							
72	2								
78	3								
72	2								
70	3								

54.0
52.4
53.0

Key Concepts of the Food Traceability Rule

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

ELECTRONIC SORTABLE SPREADSHEET



(01)11411411411401(10)FPP16-092120

Garden / Salad Kit

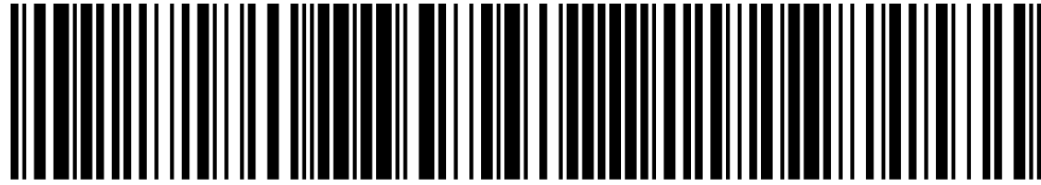
10x12oz, Bags
USA

Pack Date

Nov 01

14 **80**

Fresh Processor Brand
Springfield, MA
+1.800.999.9999



(01)11411411411401(10)FPP16-092120

Garden / Salad Kit

10x12oz, Bags
USA

Pack Date

Nov 01

14 80

Fresh Processor Brand
Springfield, MA
+1.800.999.9999



Traceability Lot Code:

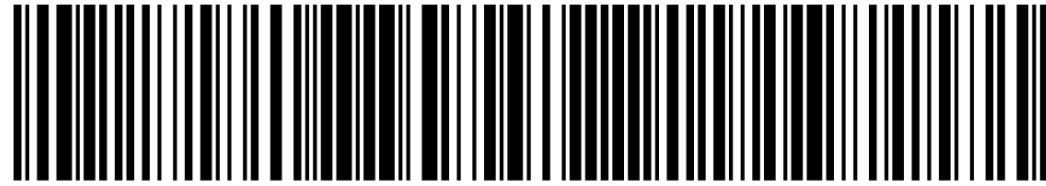
“(01)11411411411401(10)FPP16-092120”

Note: (01) = Global Trade Item Number (GTIN)
(10) = Lot Code

Traceability Lot Code:

“(01)11411411411401(10)FPP16-092120”

Note: (01) = Global Trade Item Number (GTIN)
(10) = Lot Code



(01)11411411411401(10)FPP16-092120

Garden / Salad Kit
10x12oz, Bags
USA

Pack Date

Nov 01

14 80

Fresh Processor Brand
Springfield, MA
+1.800.999.9999



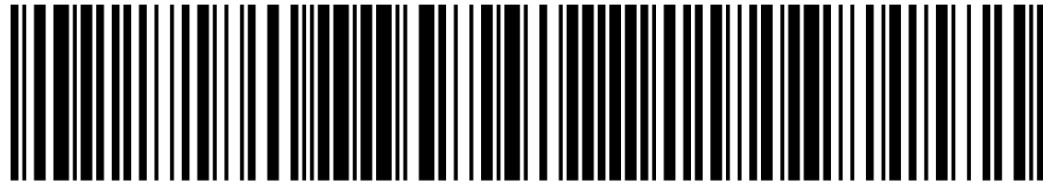
Electronic Sortable Spreadsheet (provided by Retail Food Establishment to FDA representative upon request):

Traceability Lot Code	Location Description for the immediate previous source	Location Description for where food was received	Receipt Date, Ref Rec	Quantity and Unit of Measure (Product Info)	Product Description (Product Info)	Traceability Lot Code Source Reference
(01) 11411411411401 (10)FPP16-091920	Distro Foodservice, DC #45 100 Main St., Anytown, GA 99999 +1.999.999.9999	Retailer Inc., Store #1052 222 Stone St., Anytown, SC 99999 +1.333.333.3333	09/21/2020 ASN 35467	5 Cases	Garden Salad Kit, Fresh Processor Brand, 10 X 12 OZ Bags	

Traceability Lot Code:

“(01)11411411411401(10)FPP16-092120”

Note: (01) = Global Trade Item Number (GTIN)
(10) = Lot Code



(01)11411411411401(10)FPP16-092120

Garden / Salad Kit
10x12oz, Bags
USA

Pack Date

Nov 01

14 80

Fresh Processor Brand
Springfield, MA
+1.800.999.9999

Electronic Sortable Spreadsheet (provided by Retail Food Establishment to FDA representative upon request):

Traceability Lot Code	Location Description for the immediate previous source	Location Description for where food was received	Receipt Date, Ref Rec	Quantity and Unit of Measure (Product Info)	Product Description (Product Info)	Traceability Lot Code Source Reference
(01) 11411411411401 (10)FPP16-091920	Distro Foodservice, DC #45 100 Main St., Anytown, GA 99999 +1.999.999.9999	Retailer Inc., Store #1052 222 Stone St., Anytown, SC 99999 +1.333.333.3333	09/21/2020 ASN 35467	5 Cases	Garden Salad Kit, Fresh Processor Brand, 10 X 12 OZ Bags	http://id.gs1.org/01/11411411411401/10/FPP16-091920

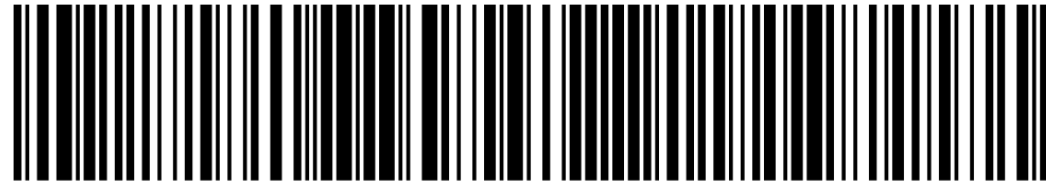
Traceability Lot Code:

“(01)11411411411401(10)FPP16-092120”

Note: (01) = Global Trade Item Number (GTIN)
(10) = Lot Code

Traceability Lot Code Source (shown on web page):

Fresh Processor Plant #16
60 Elm Street
Tomato City, FL 12345
+1.818.818.8181



(01)11411411411401(10)FPP16-092120

Garden / Salad Kit
10x12oz, Bags
USA

Pack Date

Nov 01

14 80

Fresh Processor Brand
Springfield, MA
+1.800.999.9999

Traceability Lot Code Source Reference (links to web page, displays TLCS info shown):

<http://id.gs1.org/01/11411411411401/10/FPP16-091920>

Calculated in spreadsheet from scanned TLC

Electronic Sortable Spreadsheet (provided by Retail Food Establishment to FDA representative upon request):

Traceability Lot Code	Location Description for the immediate previous source	Location Description for where food was received	Receipt Date, Ref Rec	Quantity and Unit of Measure (Product Info)	Product Description (Product Info)	Traceability Lot Code Source Reference
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Traceability Plan Example

The following is the Traceability Plan for Lizzie's Lettuce. **This is an example of a Traceability Plan. Please refer to §1.1315 of the Final Rule for the information that should be included in a Traceability Plan.*

Procedures to Maintain the Records

Digital records of all required KDEs are captured and stored in our commercial software solution.

Hard copies of Bills of Ladings 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 procedure. Each previous traceability plan is kept in a [folder on SharePoint](#) for at least two years after it is updated.



Farm Map Example



Appendix: Lizzie's Lettuce Field Map

Lizzie's Farm

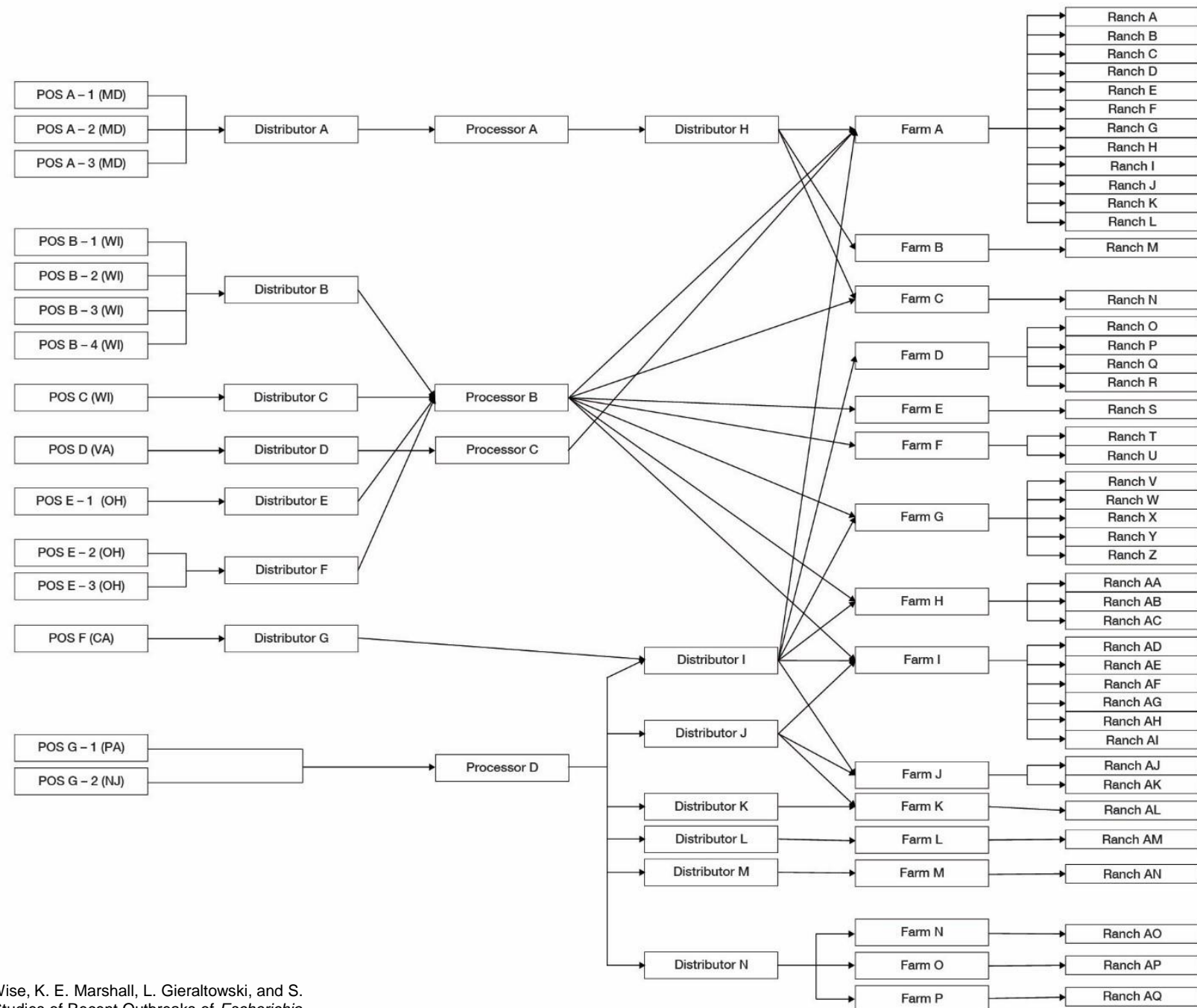
Address: 113 Farm St, Farms, CA 11311

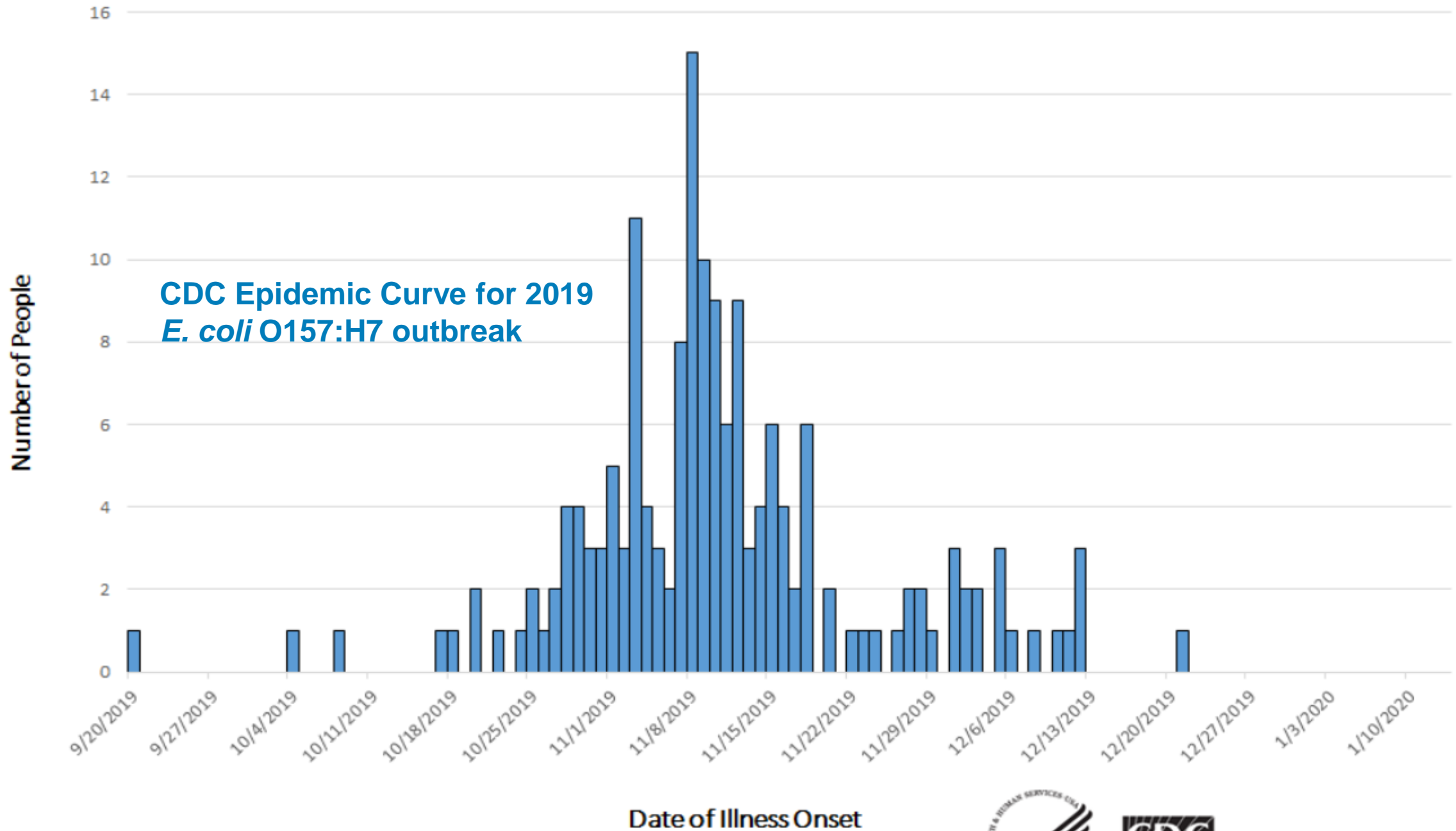
Field Name	Field Geographic Coordinates
Field A-08	-24.500145, -11.107417
Field D-03	-24.500144, -11.107418
Field C-02	-24.500146, -11.107419
Field B-09	-24.500147, -11.107416

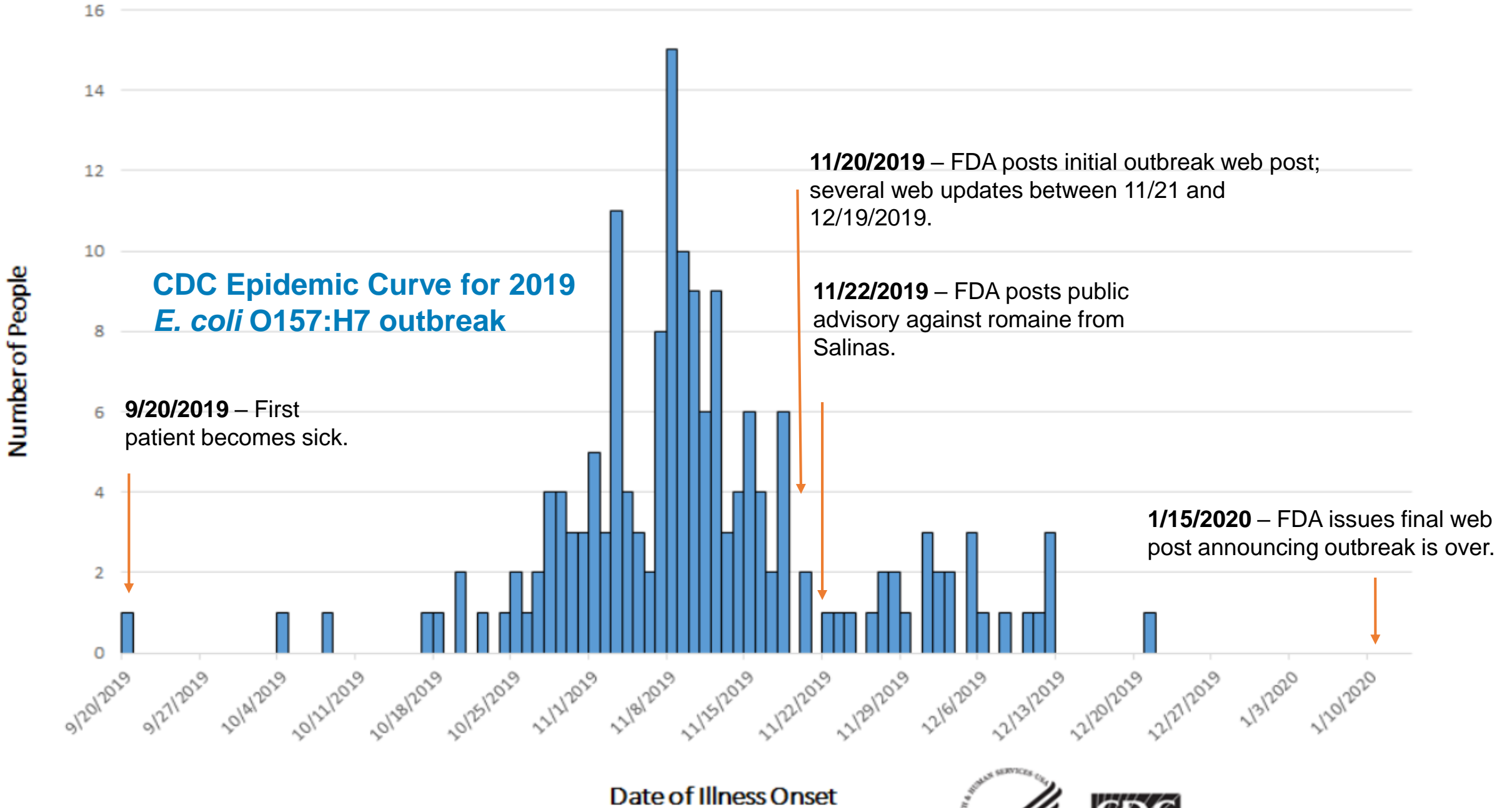


2019 E.COLI O157:H7 ROMAINE LETTUCE OUTBREAK

FDA Traceback for 2019 *E. coli* O157:H7 outbreak

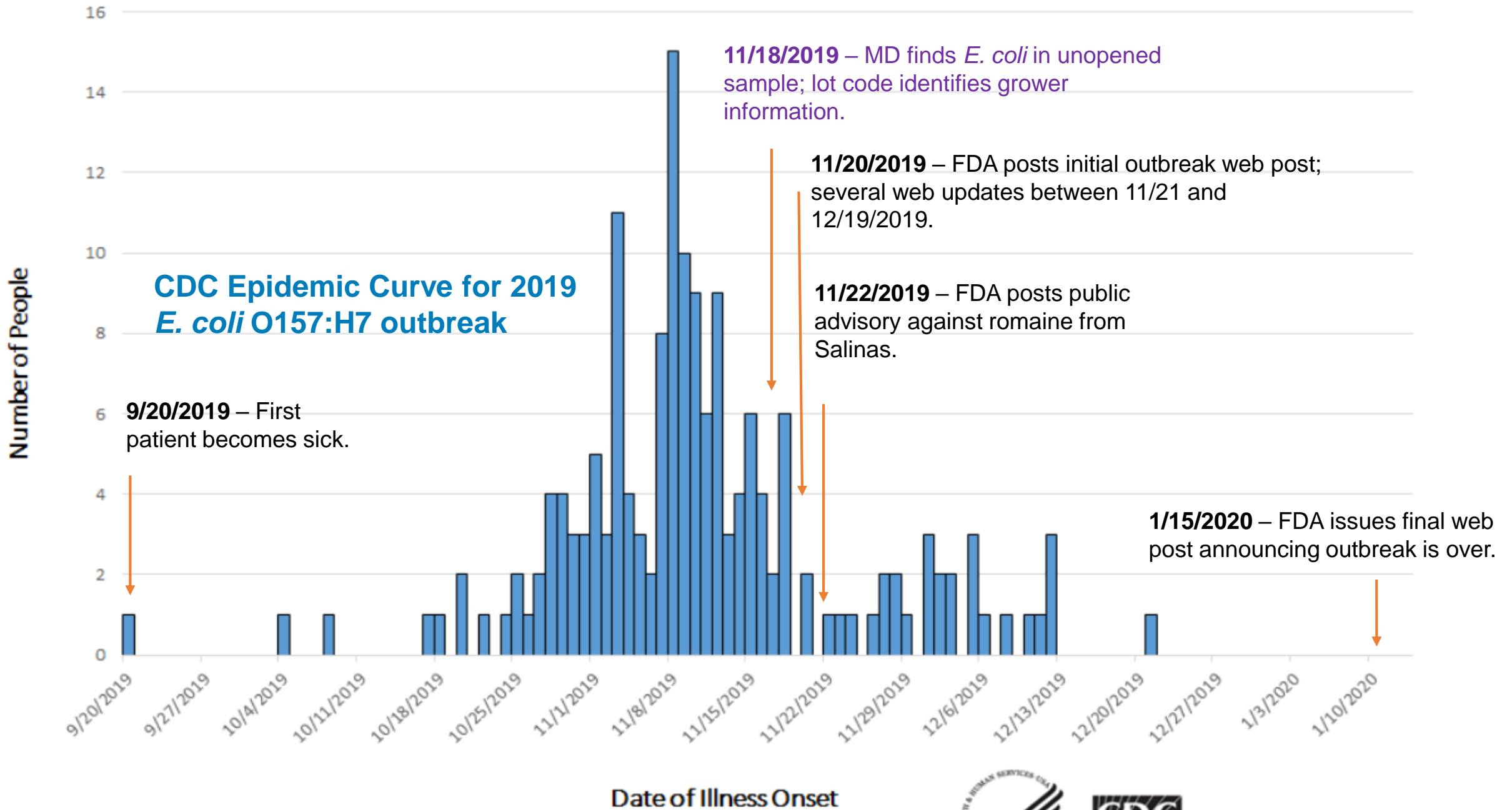


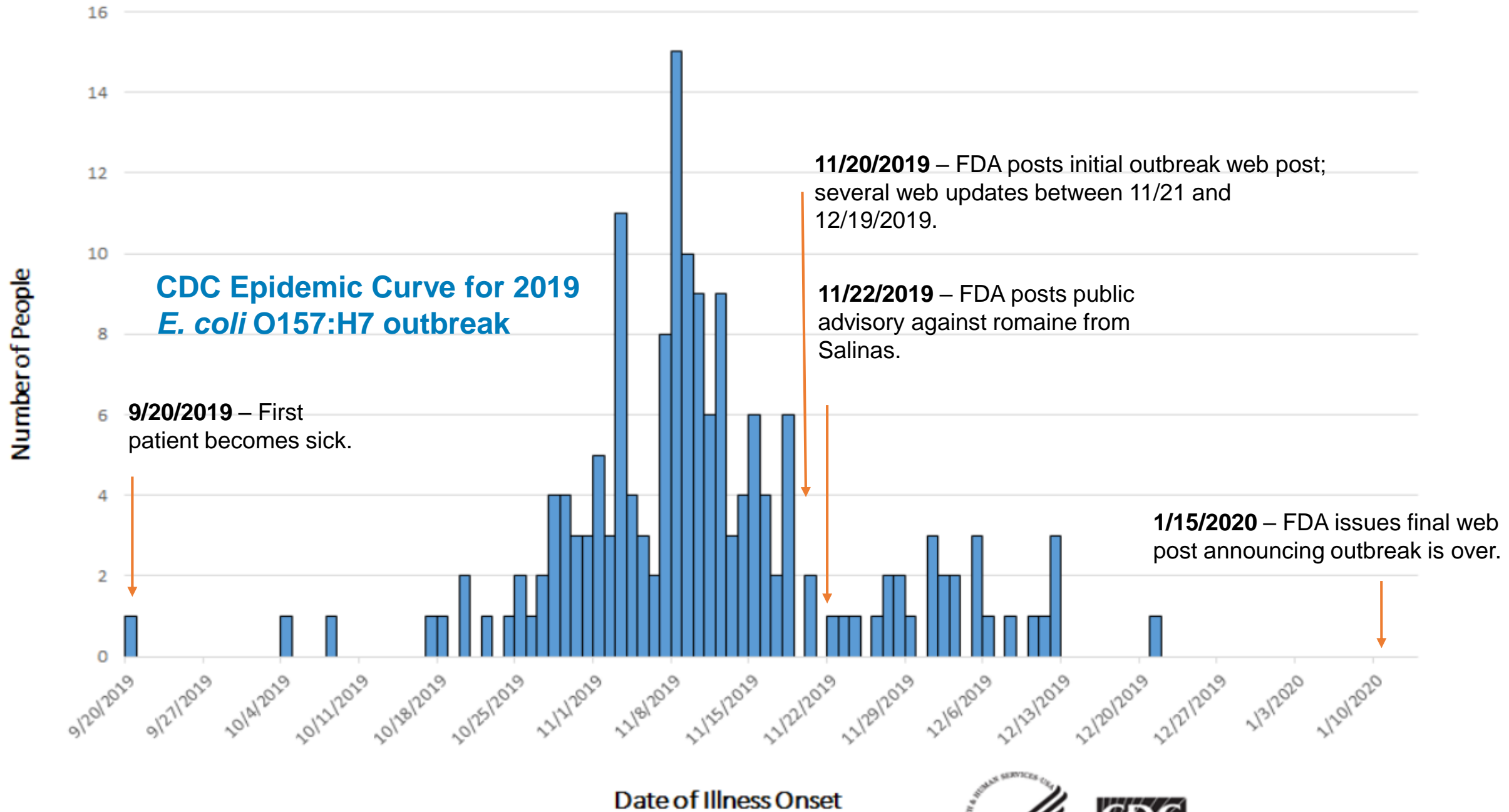


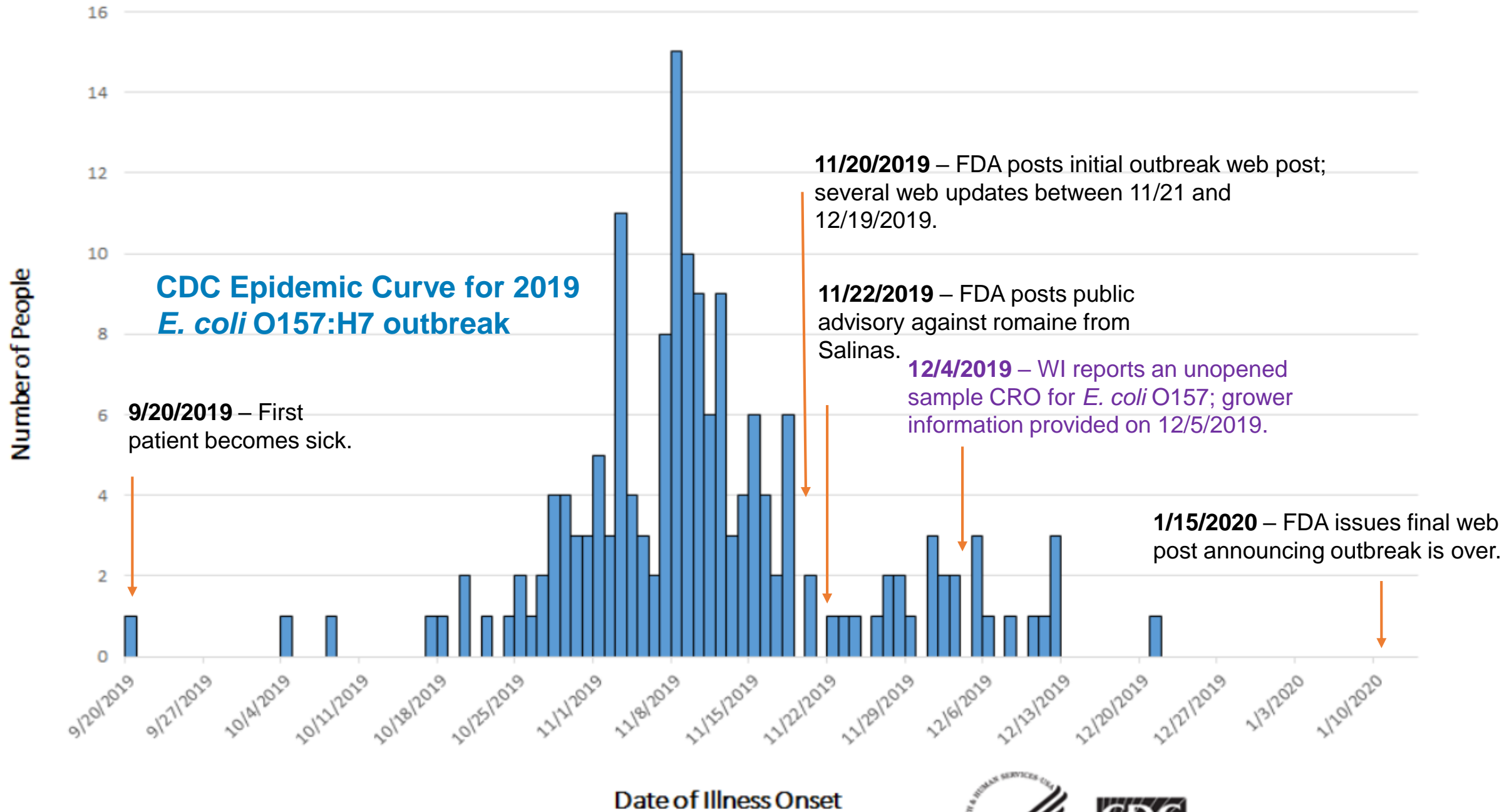


<https://www.cdc.gov/ecoli/2019/o157h7-11-19/index.html>









Impact of FTR on Records Requests



Current Records Requests

- Date range or range of shipments/lot codes based on available exposure information
 - Can be broad if purchase information or exact exposure dates are not available
- Requires explanation of what dates and other record information signifies
- 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

Remaining Challenges

Reporting Lag for Cases/Availability of Epi Information

- Takes time for cases to be reported, exposures of interest to be identified, available consumer purchase information to be obtained

Consumption Patterns

- Some foods are widely and frequently consumed, often eaten raw, and/or have a short shelf-life

Commingling

- Single production lots can contain product sourced from multiple suppliers, farms and/or fields

Exemptions to FTR

- May require additional follow up to obtain supply chain information needed for traceback

More to come

- Development of an internal FDA system to facilitate analysis of traceability information
- Development of system for sending required information to FDA
- Development of FTR compliance strategy and how we will collaborate with State, Local, Tribal and Territorial partners
- Development of regulator and industry training



References

- 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*. <https://doi.org/10.4315/jfp-21-112>
- <https://www.cdc.gov/ecoli/2019/o157h7-11-19/index.html>
- <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-romaine-salinas-california-november-2019>
- <https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-romaine-lettuce-implicated-three-outbreaks-e-coli>
- <https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/requirements-additional-traceability-records-certain-foods-final-rule-regulatory-impact-analysis>

Thank you!



FDA's Food Traceability Final Rule

Session 3:

Industry Perspective: Getting Ready for the Food Traceability

Tim York

Produce Traceability Initiative and FSMA 204



What is PTI?

The Produce Traceability Initiative is a voluntary, industry-wide effort designed to help the industry maximize the effectiveness of current track and trace procedures, while developing a standardized industry approach to enhance the speed and efficiency of traceability systems for the future. Industry participants cover every segment of the produce supply chain. The PTI is an industry-led, supply chain-wide Initiative governed by a 24-member Leadership Council



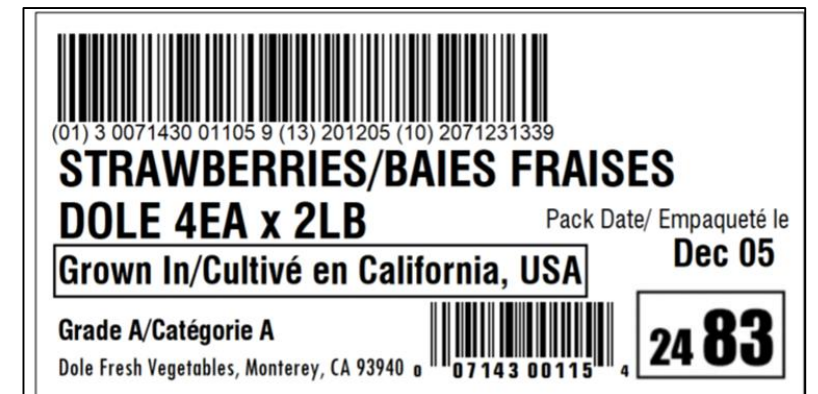
What is PTI?

The work of PTI is carried out by volunteer-led working groups in the areas of Implementation, Master Data, Technology, Communications and is administered by Canadian Produce Marketing Association (CPMA), GS1 US, GS1 Canada and International Fresh Produce Association (IFPA).



How does PTI align with FSMA 204 Final Rule?

- PTI is 90 – 95% aligned with FSMA 204.
 - PTI has kept FDA updated regularly for the last 13 years.
- PTI implementation requires case labeling at time of packing.
 - Global Trade Item Number (GTIN), Lot Code and Date are encoded in the GS1-128 barcode
- PTI coined the usage of Key Data Elements at the Critical Tracking Events



How does PTI differ from FSMA 204 Final Rule?

- Traceability Lot Code Source is new.
- Traceability Lot Code Source Reference is new.

PTI FSMA 204 Working Group

- Output is the PTI FSMA 204 Implementation guidance document
- 5 Working Groups
 - Initial Packing and Transformation
 - Receiver/Shipper
 - Distributor to retail stores or foodservice operations
 - Retail Stores
 - Foodservice Operations
- 108 volunteers
- 60 industry companies
- 9 trade associations

PTI FSMA 204 Working Group Companies

Aaniko Biosciences

Authentitrace

Avery Dennison

AWG

Braga Farms

CA LGMA

Cairnstack Software LLC

Carbon Robotics

Chic Fil A

CPMA

Del Fresco Produce Ltd

Del Monte Fresh Produce, N.A Inc.

Delta Trak

Denny's

Domex Superfresh

Ecogistix

Erie James

Famous Software

Four Seasons

Giumarra

Grimmway

iFoodDS

Interfresh, Inc.

iTradeNetwork

Kroger

L&M

LK Packaging

Lofredo/Produce Innovations

Markon

Naturipe Farms

Nunes

OpsSmart Global

Optel Group

Performance Food Group

Procurant

Provision Analytics

Red Sun Farms

Redline Solutions

ReposiTrak

RMS US

RSM US LLP

Sam's Club

Sato Global

Shareify

Silo

Silver Creek Software

Star Produce Ltd.

Syndigo

Tanimura & Antle

The Fresh Market

The Nunes Company, Inc.

The Oppenheimer Group

Top 10 Produce

Trustwell

US Foods

Walmart

WaudWare

Wegmans

Whole Foods

Wholesale Produce Supply Company

FFVA

FMI

GS1 Canada

GS1 Global

GS1 US

IDDBA

IFPA

IFT

Western Growers

Additional FSMA 204 guidance

- EDI 856 Advance Ship Notice/Manifest Transaction
 - Will be updated by November 2023
- Guidance for GLN Assignment
 - Will be updated by November 2023
- Traceability Lot Code Source Reference guidance
 - Will be created by November 2023

Recommendations for Implementation

- Start yesterday!
- Implement PTI
- Review PTI guidance documents being created for FSMA 204 implementation.
- Start with the Electronic Sortable Spreadsheet
 - Assume the FDA request is at 4:30 pm on a Friday
 - Determine the sources for data elements required in the electronic sortable spreadsheet.
 - Determine how you will identify the items to be traced that you received and sold/shipped

Recommendations for Implementation

- Determine how you will accurately track and share the Traceability Lot Code (GTIN/lot) for each shipment.
- Determine if and how you will share Traceability Lot Code Source or Alternate TLC Source for every lot shipped.
- Update or create your Traceability Plan.
- Consider implementing electronic Advanced Shipment Notifications (ASN's)
- Pilot with your customers and suppliers.

Recommendations for Implementation

- For Packers:
 - Determine how you will gather and store the pre-packing information
 - Harvest who/what/when/how much
 - Pre-cooling what/when/how much
 - Storage what/when/how much
 - Communicate to your growers and or harvesters they must share their data.
 - Communicate to your cooling companies they must share their data.
 - Communicate to your storage companies they must share their data.

Recommendations for Implementation

- For Buy Side:
 - Form a cross functional team. This is not a Produce project!
 - Store Operations
 - Distribution Management
 - Distribution Systems
 - Regulatory
 - Food Safety
 - Update or create your Traceability Plan
 - D.C.'s
 - Stores

Recommendations for Implementation

- For Buy Side:
 - Communicate to your suppliers that they will have to adopt PTI.
 - FTL items
 - Non FTL items
 - Implement usage of electronic Advanced Shipment Notifications (ASNs) into your distribution centers.
 - FTL items
 - Non FTL items

Recommendations for Implementation

- For Buy Side:
 - Determine the sources for data elements required in the electronic sortable spreadsheet.
 - At stores:
 - How will the stores be able to determine the list of items received that contain the FTL item being traced back by FDA?
 - How will the stores know who shipped them these items?
 - Corporate DC
 - Wholesaler
 - Direct to store (local programs)
 - Other (i.e. store to store transfer)

Recommendations for Implementation

- For Buy Side:
 - Determine the sources for data elements required in the electronic sortable spreadsheet.
 - At Distribution Centers:
 - Maintain a list of DC items for each commodity on the FTL list.
 - Whole
 - Fresh-Cut
 - Prepacks (i.e. fresh shish kebob with peppers)
 - Other

Recommendations for Implementation

- For Buy Side:
 - Determine who will be responsible to create the electronic sortable spreadsheet when FDA asks for it within 24 hours at 4:30 pm on Friday.
 - At stores
 - At DC's

Questions?

Contact Info

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Adam.Friedlander@fda.hhs.gov

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October 24, 2023

Managing Meat Shelf Life and Spoilage to Ensure Food Security

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