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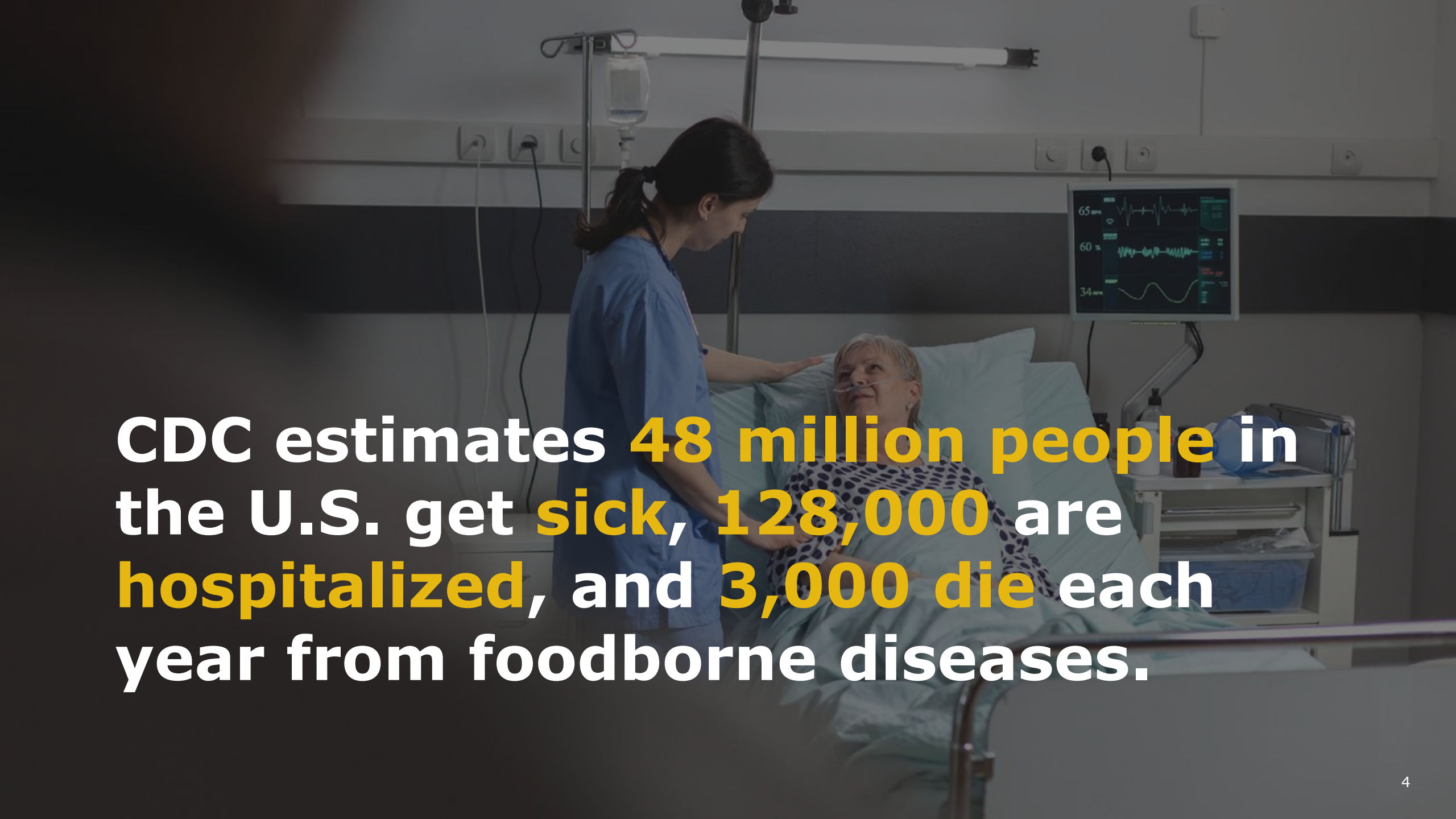
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*If applicable



CDC estimates **48 million people** in the U.S. get **sick**, **128,000** are **hospitalized**, and **3,000** die each year from foodborne diseases.

Leveraging GS1 Standards for FSMA 204



GS1 US Supporting the Food Industry



Traceability Plan

Farm Map

TLC Source Reference

FTL

Harvester

Cooler

TLC

TLC

CTE

CTE

TLC Source

KDE

TLC Source Reference

Geo-Coordinates

FTL

Cooler

KDE

Geo-Coordinates

Farm Map

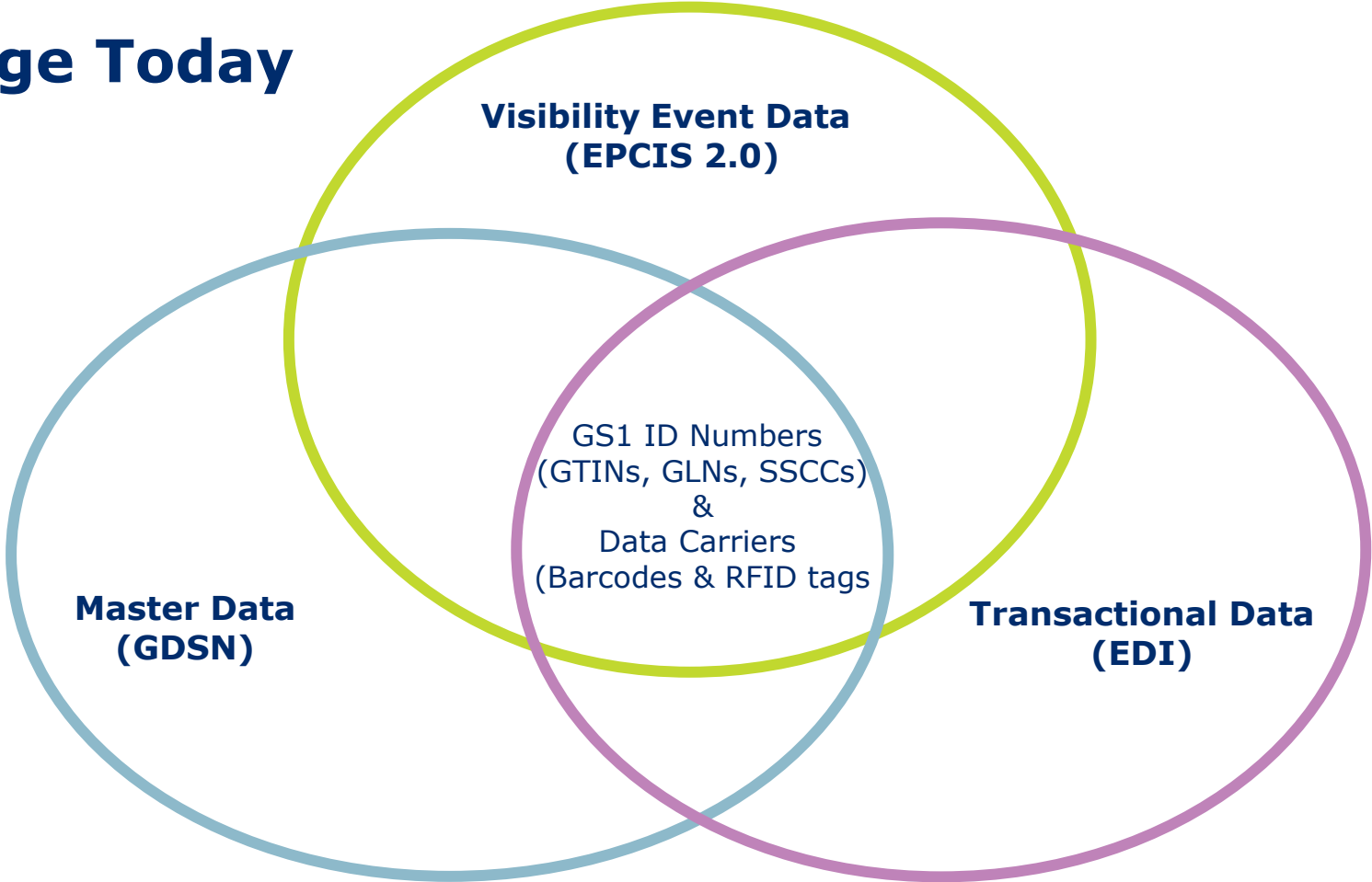
Traceability Plan

TLC Source

Harvester

GS1 US Supporting the Food Industry

Data Exchange Today



Industry Partnerships



Everything You Need To Know For FSMA 204



Webinar 1
Wednesday, August 2, 12:00 PM - 1:00 PM ET
The What: Understanding the Basics of FSMA Rule 204



Webinar 2
Wednesday, August 9, 12:00 PM - 1:00 PM ET
The How: Industry-Defined Guidance to Help Meet FSMA 204 Recordkeeping Requirements



Webinar 3
Wednesday, August 16, 12:00 PM - 1:00 PM ET
The Why: Driving Business Value Beyond FSMA 204 Regulatory Compliance



Webinar 4
Wednesday, August 23, 12:00 PM - 1:00 PM ET
The What's Next: Preparing to Meet FSMA 204 Requirements—Tools and Resources



FSMA 204 Detailed CTEs-KDEs

1. Harvesting
2. Cooling
3. Initial Packing
4. First Land-Based Receiver (*Seafood*)
5. Shipping
6. Receiving
7. Transformation

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

FDA U.S. FOOD & DRUG ADMINISTRATION

Harvesting Cooling (before Initial Packing) Initial Packing (RAC) First Land-Based Receiver Shipping Receiving Transformation Traceability Plan

Receiving KDEs
KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received
- Date you received the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number

Receiving KDEs
For food you receive from a person who is exempt from the rule
KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food, which you must assign if one has not already been assigned (does not apply to RFEs or restaurants)
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received (i.e, traceability lot code source) and (if applicable) traceability lot code source reference
- Date you received the food
- Reference document type and reference document number

*This section does not apply to receipt of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

Source: [FDA.gov](https://www.fda.gov)

Master Data & Event Data

Master Data

Additional Identifier: GTIN®*

- Product Name
- Brand Name
- Commodity
- Variety
- Packaging Size
- Packaging Style
- Species (seafood)
- Market Name (seafood)

GDSN®

Additional Identifier: GLN*

- Business Name
- Primary Phone Number
- Physical Location Name
- Physical Location Address
- Growing-Area Coordinates (farm)
- Company Contact
- Phone
- City
- State
- Postal Code

GS1 US Data Hub | Location*

Transactional/Event Data

Additional Identifier: GTIN, GLN, SSCC*

- Event Date
- Quantity & Unit of Measure
- Reference Records
- Product & Location Descriptions
- Traceability Lot Codes
- Assignment Method
- Point of Contact
- Reference Record Type & Identifier

EPCIS/EDI*

* Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards.
For more information refer to x12.org/products/transaction-sets

GS1 US FSMA 204 Guideline

- Outlines Food Industry best practice to adopt GS1 Standards and meet FSMA 204 Requirements
- Includes FDAs comments and direct links as well as other foundational resources



FSMA Rule 204 and Applicable Standards

REQUIREMENTS

Identify FTL Items & Product Description KDEs

Parties & Locations Description KDEs

Shipping KDEs

All Other CTEs/KDEs

Capture TLC (Traceability Lot Code) & TLC Source Throughout Supply Chain

SOLUTIONS

GTIN and GDSN▶

GLN and GS1 US Data Hub▶

ASN (EDI 856)*▶

EPCIS▶

Data Carriers, ASNs, EPCIS▶

Connecting Master Data to Transactional and Event Data ▶

**Source: All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards. For more information refer to x12.org/products/transaction-sets*

Real World Example

How it all Comes together!

Following the Food Supply Chain



Supplier

- Salad order placed at supplier



Supplier's Manufacturing Plant

- Supplier makes and packs salad
- **EPCIS:** Salad transformation
- **Case GS1-128 label: with GTIN, Date and Lot**



- Cases are packed into pallets
- **Pallet GS1-128 label with SSCC**

Following the Food Supply Chain



Retailer/Restaurant
Distribution Center



- **ASN contains shipping info:** Qty of GTIN+Lot (TLC) per pallet, Ship From, Ship To, TLC Source, etc.

- Distributor scans **SSCC**
- Matches to **ASN** in system

- Individual cases shipped to final food outlet (**GLN**)

Following the Food Supply Chain



Retail Store/Restaurant

- **Case GS1-128s** scanned at each location identified with GLN
- **GTIN+Lot** combination ties back to ASN info

GS1 Standards at Work

- Meet regulatory requirements
- Conduct rapid, targeted recalls
- Customer Trust
- Transparency
- End to End Supply Chain Visibility
- Improved Inventory Management

More than Meeting Regulation



64,794 restaurants were contacted during **11** quality incidents

Traceability enables annual potential savings



9,259 hours of labor

more than **\$110K**

\$1.3 Million in annual cost avoidance from Master Data cleanup with GDSN

[GS1 US Case Study: IPC/Subway Delivering the Promise of End-to-End Traceability Throughout the Subway System](#)

Eliminating pain for more than 24,000 restaurants using GS1 Standards
\$72 million/year in cost avoidance



[Inventory Management Solution Helps Eliminate Pain for More Than 24,000 Restaurants Across North America Using GS1 Standards](#)

Challenges & How to Overcome!

Regulation focuses on the “what” and not the “how.”

Understanding impact to my organization and my network.

Interoperability Challenge

Initial Investment/ Implementation Costs

“Quick Fix” Mentality

A Strategic Shift in Thinking

Data-Flow-Centric Approach

Leading organizations are focusing more on how traceability data moves end to end and where breakdowns occur before choosing technology.

Process and Partner Emphasis

Emphasizing process, ownership, and partner interaction helps identify critical points and high-risk products.

Strategic Technology Selection

Selecting technology aligned with operations ensures interoperability, scalability, and avoids overinvestment in isolated tools.

ROI

Information

- Accurate information drives sales
- Clean data saves time, money, and resources

Product

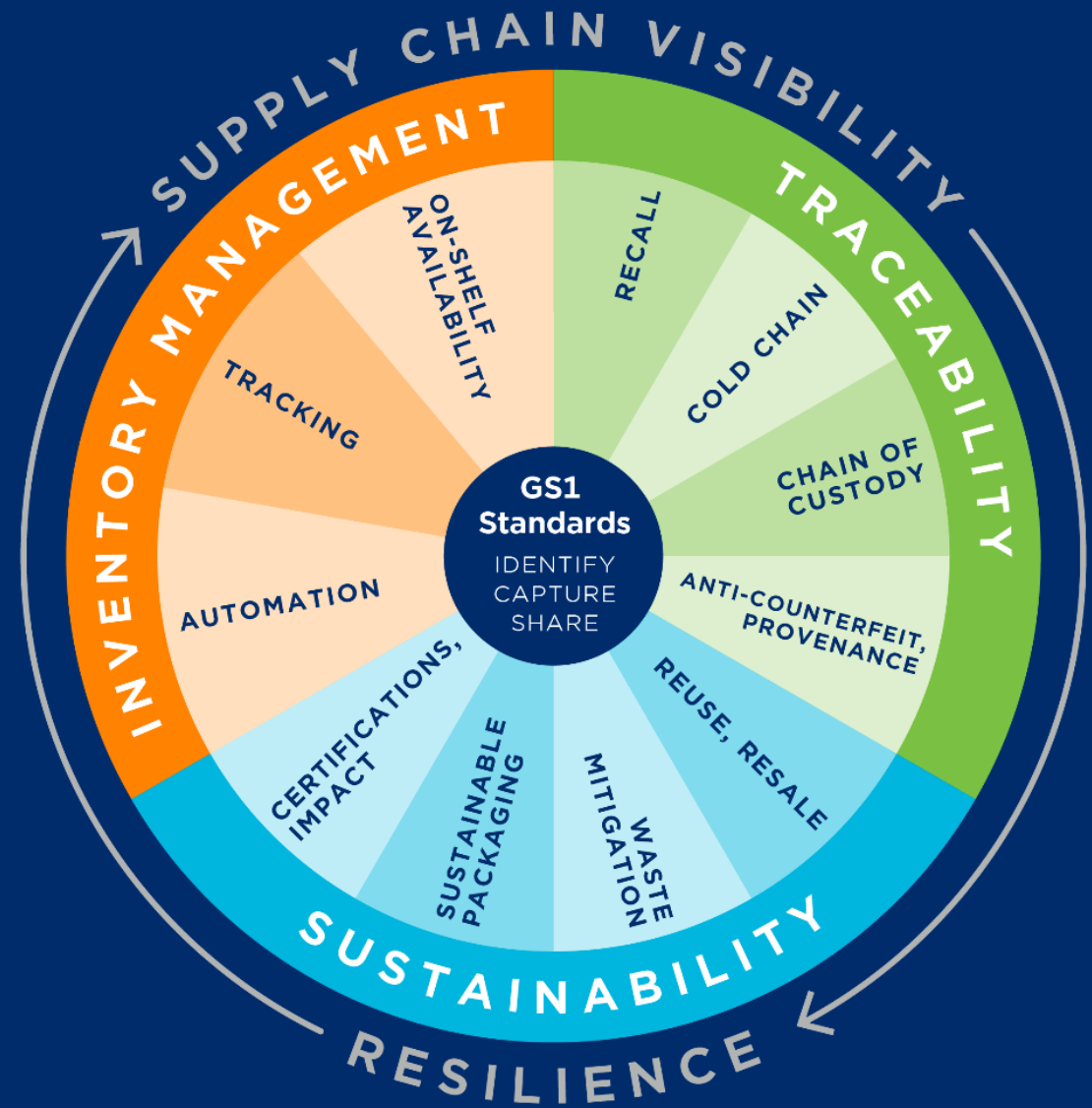
- Less product waste
- Ability to better identify affected lots for recall
- Better freshness management

Process

- Greater efficiency/transparency via automation
- Enhanced consumer safety

Consumer Engagement

- Brand loyalty
- Additional safety



Key Takeaways

- Don't wait
- Leverage what others have already done, collaborate with your partners
- Understand the details of FSMA 204:
 - Take advantage of fda.gov and **GS1 US Resources:**
www.gs1us.org/fsma
- Map out your processes, understand your systems, figure out what you are missing, and look at your master data
- Prioritize- highest volume, highest criticality and PILOT
- Don't get bogged down with exceptions



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Why Food Traceability Matters

May 13, 2026
Traceability – Practical FSMA 204 Applications
2026 Food Safety Summit

Asma Madad, Biologist
Human Foods Program
U.S. Food and Drug Administration



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	



Purpose of Traceback Investigations



Identify

Identify the vehicle (food) that made people sick



Determine

Determine the supply chain and product source



Regulate

Decide what regulatory actions are required



Inform

Inform consumers

Current State

Realit Payment to Page 1 of 2

Distributor D
Nashville TN

LOCAL : 615-284-2800 BILL TO
TOLL :
FAX : 615-284-2800

Ship To: Distributor A
NASHVILLE TN 37210

Invoice No.	Invoice Date	Customer No.	Order Date	P.O. Number	Salesman	Terms	Route/Stop
265037	4/26/19	719	4/26/19	1150872/L22140 CONF: SY3 1150872	UNASSIGNED	NET 30 DAYS DUE DATE: 4/26/19	N/C

SPECIAL INSTRUCTIONS: 1150872 FRIDAY 04/26/2019 DBA00465

Item Number	Quantity Ordered	Quantity Shipped	Pack	Size	Item Description	Unit Weight	Extended Weight	Unit Price	Extended
885822	170	170	250	250	TOMATOES UTILITY 250	-7302204			
807113	100	100	100	100	250 CAPE	-3790291			
807180	60	60	120	120	TOMATO GRAPE 12/1 Pint	-4959583			
801291	60	60	250	250	TOMATOES 5X5 250	-4051412			
882311	180	180	250	250	250 ROMA CPE -HOT A UTILITY-3449893				
886688	10	10	250	250	ROMA CPE -HOT A UTILITY-				
841400	8	8	250	250	TOMATOES Random 250 Fresh-2093730				
881707	40	40	20	20	40x 2-Layer DEEP RED V8	-2064987			
881802	100	100	20	20	TOMATO DEEP RED VINE RIPE	-2331008			
881482	100	100	200	200	TOMATOES 5X5 2-Layer	-1079219			
			250	250	250 4X4 250	-132762			

MARKETS: AMNC.

Driver: [Redacted] Cash Amount: [Redacted] Check Amount: [Redacted] Total Weight: [Redacted] Sub Total: [Redacted]

Receiving for Distr. A

Tomato Door 3

NASHVILLE, TN 37210 PHONE: 615-284-2800

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

UPC NUMBER	ITEM DESCRIPTION	CL	ITEM	SLOT	LOC	ORDER	REC'D	AVG WGT	WGT REC
9500	TOMATO CAPE CT USB T1/H1 10/4 Shelf Life 0	9500	22553	C	01C075A	170	170	4590.00	
	Quality: TOMATO GRAPE 10LB T1/H1 8/7 Shelf Life 0	9500	22542	C	01C064A	180	180	1980.00	
	Quality: TOMATO GRAPE 12PT T1/H1 12/12 Shelf Life 0	9500	22533	C	01C073A	60	60	660.00	
	Quality: TOMATO LARGE ROUNDS 25LB T1/H1 8/10 Shelf Life 0	9500	22531	C	01C088A	60	60	1560.00	
	Quality: TOMATO ROMA 25LB T1/H1 10/5 Shelf Life 0	9500	22490	C	01C072A	180	180	4860.00	
	Quality: TOMATO SELECT 25LB USB T1/H1 10/4 Shelf Life 0	9500	22556	C	01C079A	10	10	270.00	
	Quality: TOMATO 4X4 T1/H1 8/6 Shelf Life 0	9500	22500	C	01C078A	8	8	176.00	
	Quality: TOMATO 4X5 CCP T1/H1 8/6 Shelf Life 0	9500	22507	C	01C077A	40	40	880.00	
	Quality: TOMATO 5X5 20LB LAYER T1/H1 8/6 Shelf Life 0	9500	22511	C	01C076A	104	104	1976.00	
	Quality: TOMATO 5X5 20LB LAYER T1/H1 8/6 Shelf Life 0	9500	22561	C	01C074A	80	80	2160.00	

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

Distributor A Nashville TN

RECEIVING PURCHASE ORDER

SHIP DELIVERY DATE: 4/25/2019

OPTION	QTY	UNIT	PRICE	TOTAL
0 CAPE CT USB	170	US		
0 GRAPE 10LB	180	US		
0 GRAPE 12PT	60	US		
0 LARGE ROUNDS 25LB	60	US		
0 ROMA 25LB	180	US		
0 SELECT 25LB USB	10	US		
0 4X4	8	US		
0 4X5 CCP	40	US		
0 5X5 20LB LAYER	104	US		
0 6X6 25 LB	80	US		

Distributor D Nashville TN

Farm A

2453 CHOPIN FRESH LINE LLC

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

Quality: good color 1/2-4

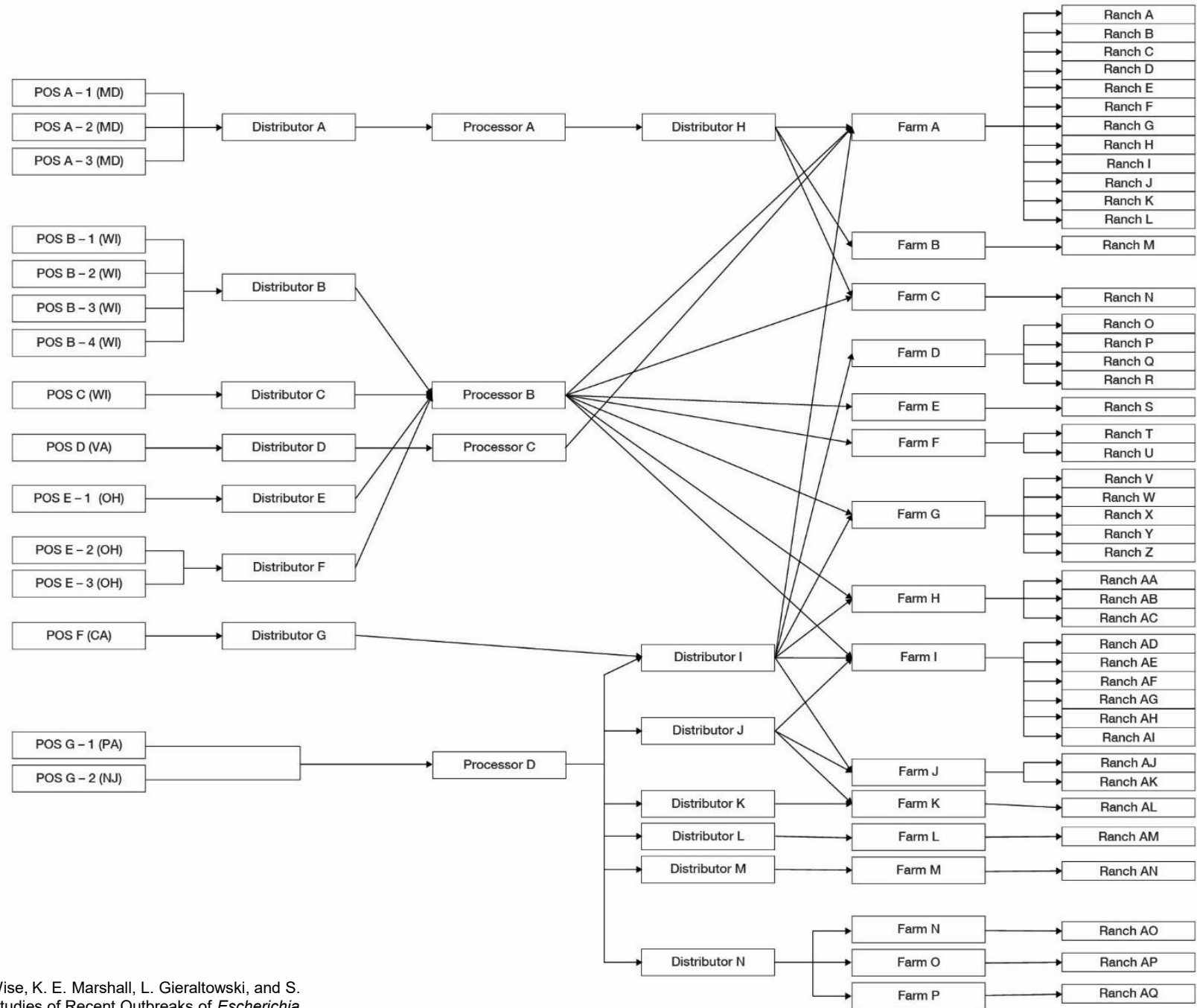
QTY	UNIT	PRICE	TOTAL
75	2	54.0	
72	2		
78	3	52.0	
72	2		
70	3	53.0	

TOTALS: 1600 4800.00

DATE RCVD 04/23/19 TRAILER TEND So TOTAL UNITS 1600

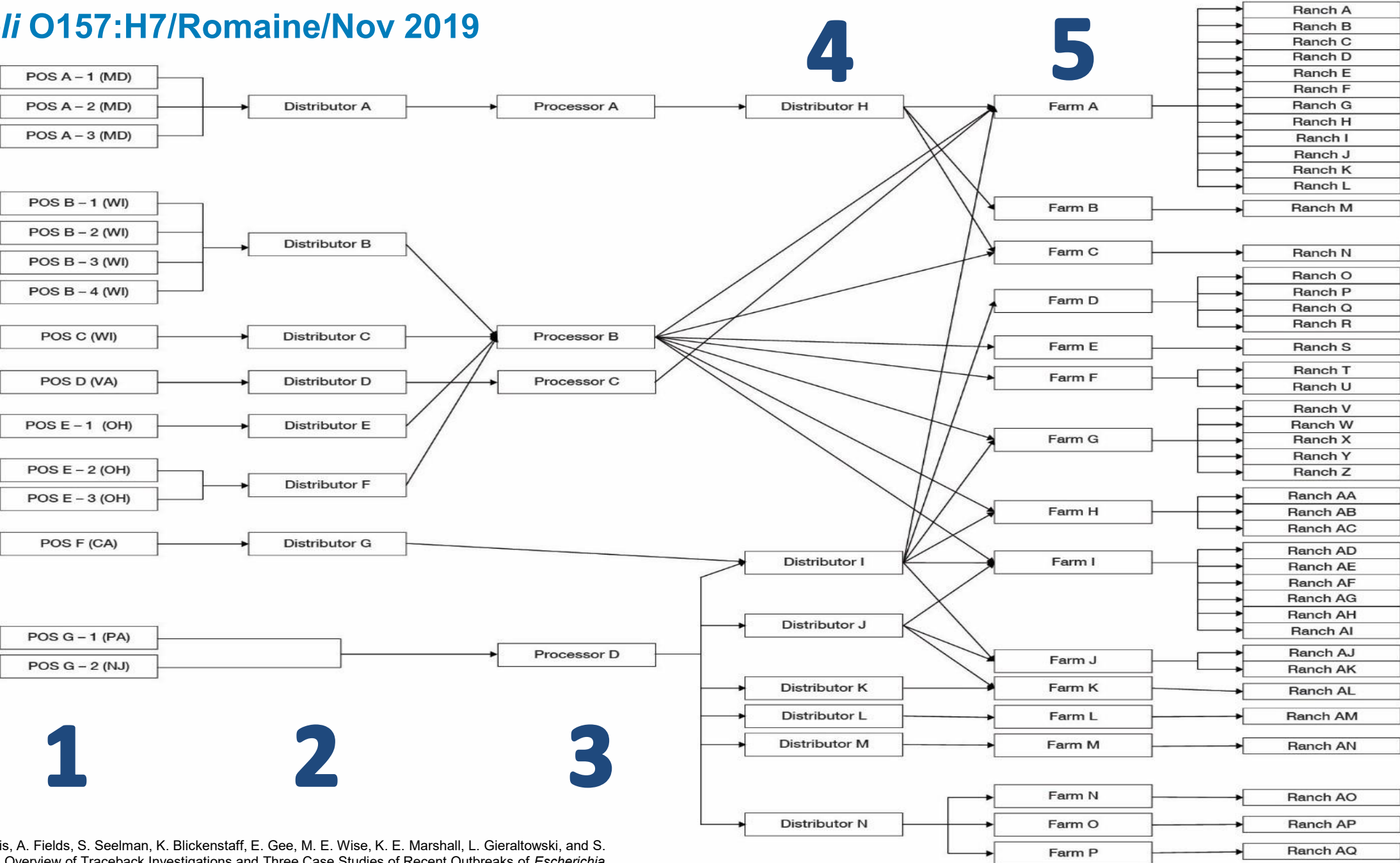
TIME RCVD 7:00 PM VISIBLE DAMAGE TO TRUCK DEBRIS 1/2

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



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



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)

POS A - 2 (MD)

POS A - 3 (MD)

POS B - 1 (WI)

POS B - 2 (WI)

POS B - 3 (WI)

POS B - 4 (WI)

POS C (WI)

POS D (VA)

POS E - 1 (OH)

POS E - 2 (OH)

POS E - 3 (OH)

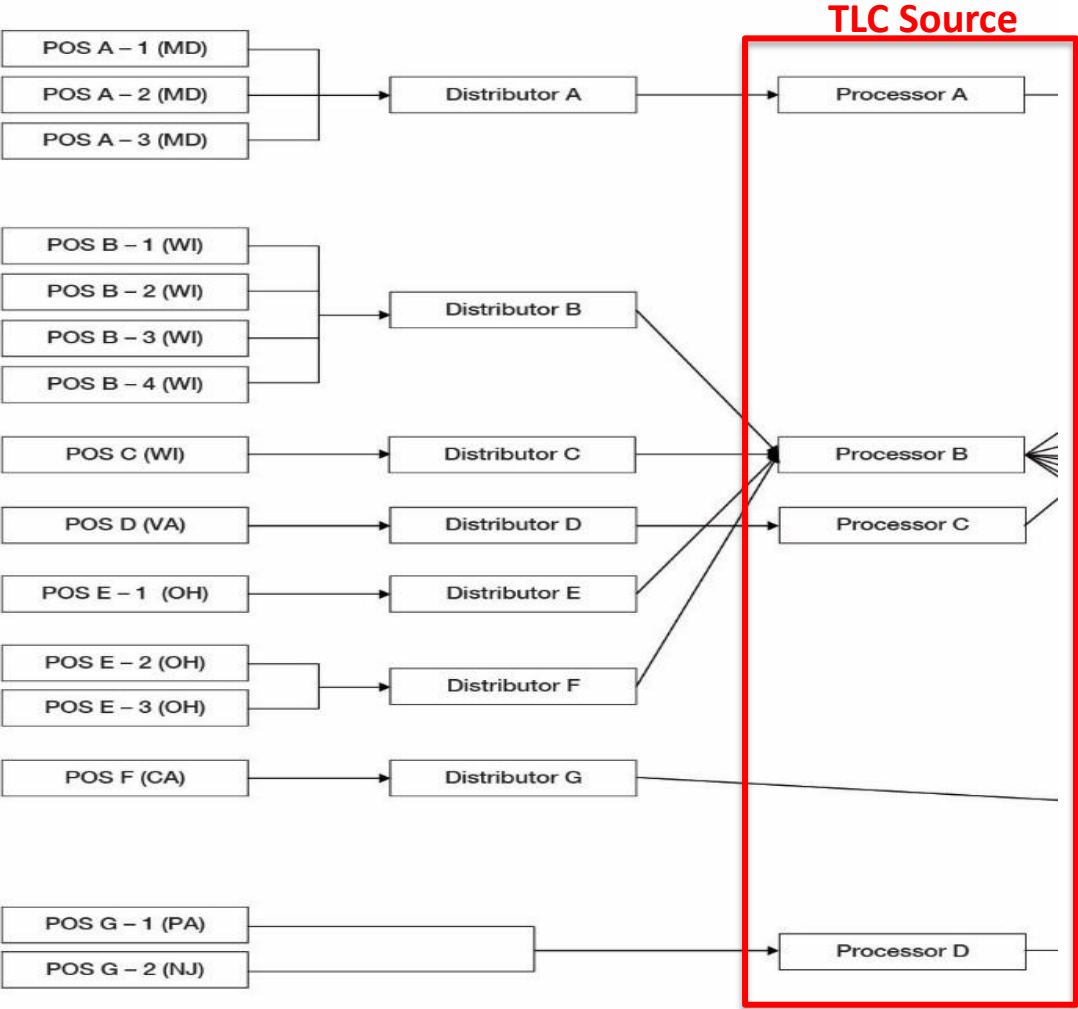
POS F (CA)

POS G - 1 (PA)

POS G - 2 (NJ)

1

E. coli O157:H7/Romaine/Nov 2019



1

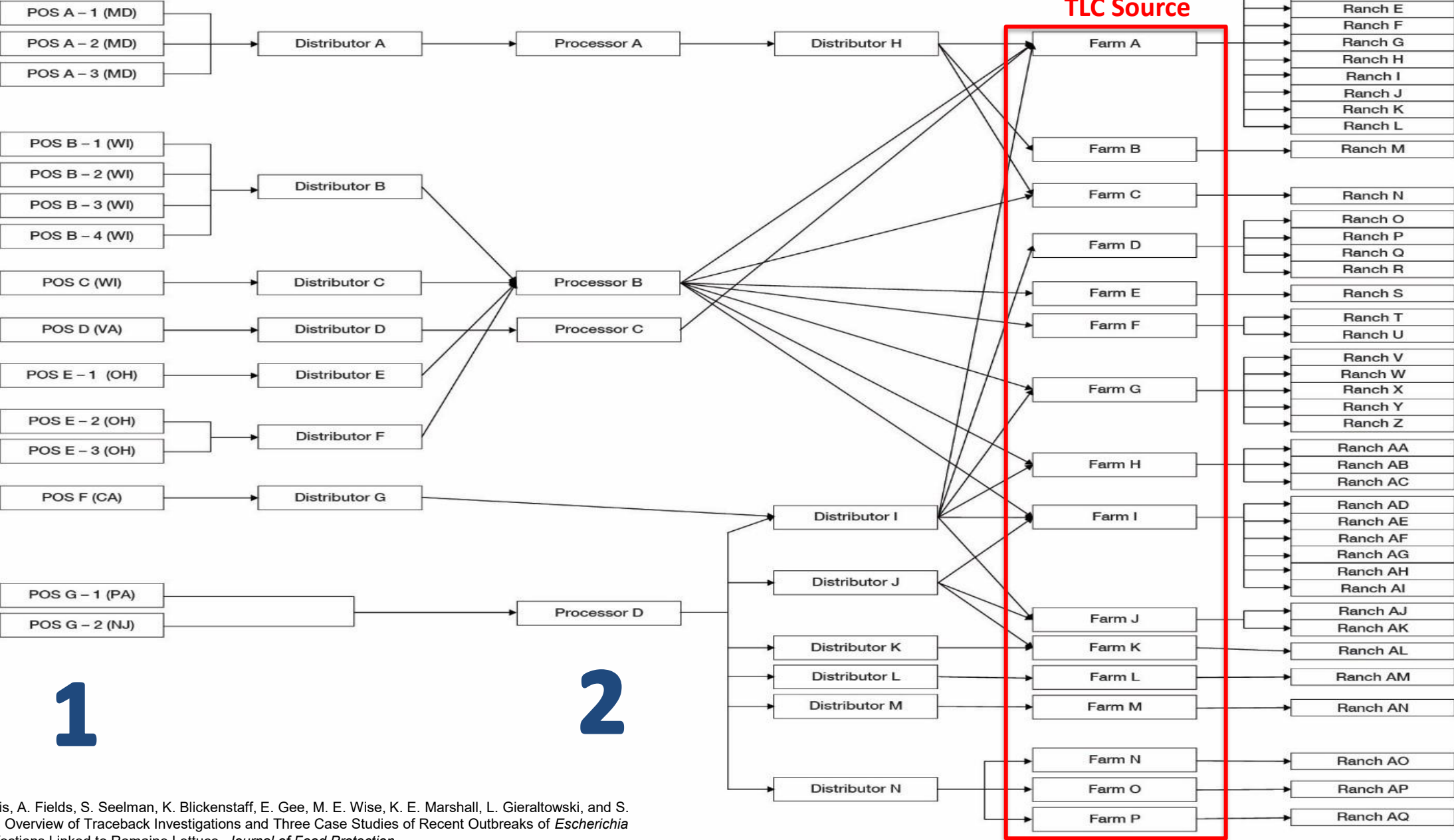
2

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

3

TLC Source



1

2

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 Traceback 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

Thank you!

