



Traceability: Fact, Fiction & Future



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Founder, Food Safety Strategy

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Traceability: Fact, Fiction & Future

Jennifer McEntire, Ph.D.

Founder

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About me



Native Long Islander, no food/ ag background



Ph.D. Food microbiology (with no intention of staying in a lab)



20+ yrs in Washington DC

Institute of Food Technologists
The Acheson Group
Grocery Manufacturers Assn
United Fresh/ IFPA



Expertise: FDA regulations, outbreaks/recalls/crises, traceability, environmental monitoring,... jack of all trades

Key Points

01

Trace BACK is
challenging
Recalls are easier

02

Don't
overcomplicate
things.

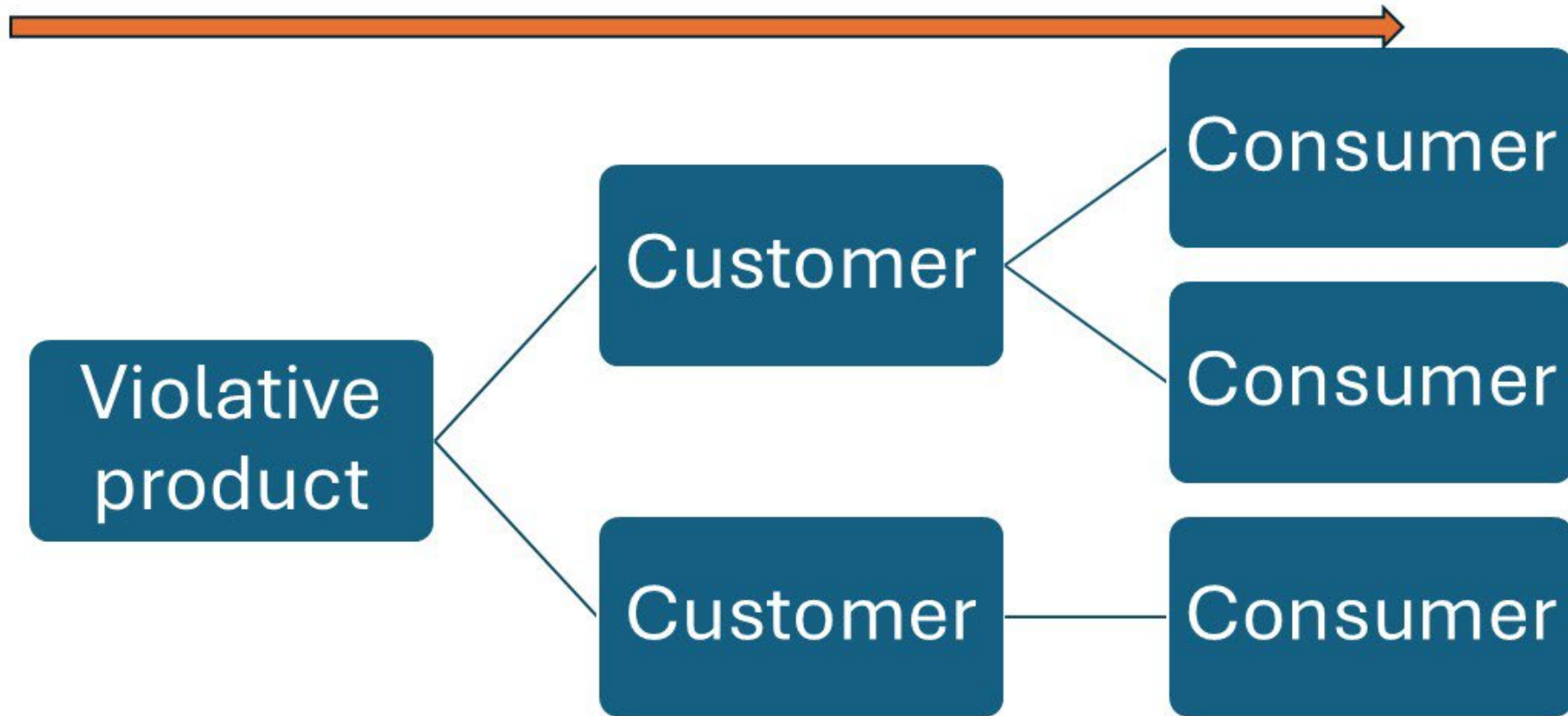
03

Traceability is a
team sport

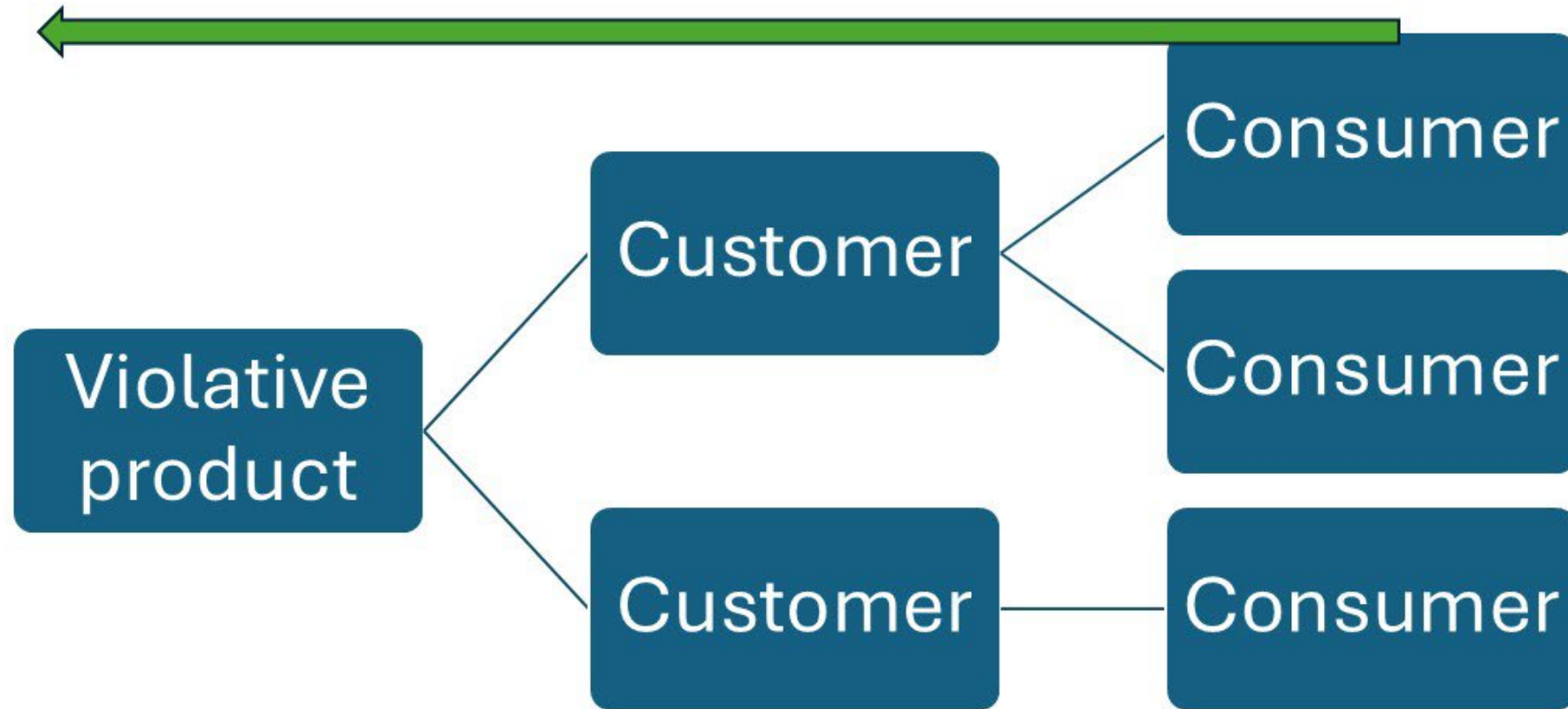
How we got here

- Recall
 - Removal of **violative** product
 - Class I- most serious; requires press release
 - Class II
 - Class III
 - May or may not be associated with illness or injury
 - May be “voluntary” or “mandatory”, but never “optional”
- Outbreaks
 - People are ill
 - Source may or may not be discovered
 - If it is, there’s generally a recall

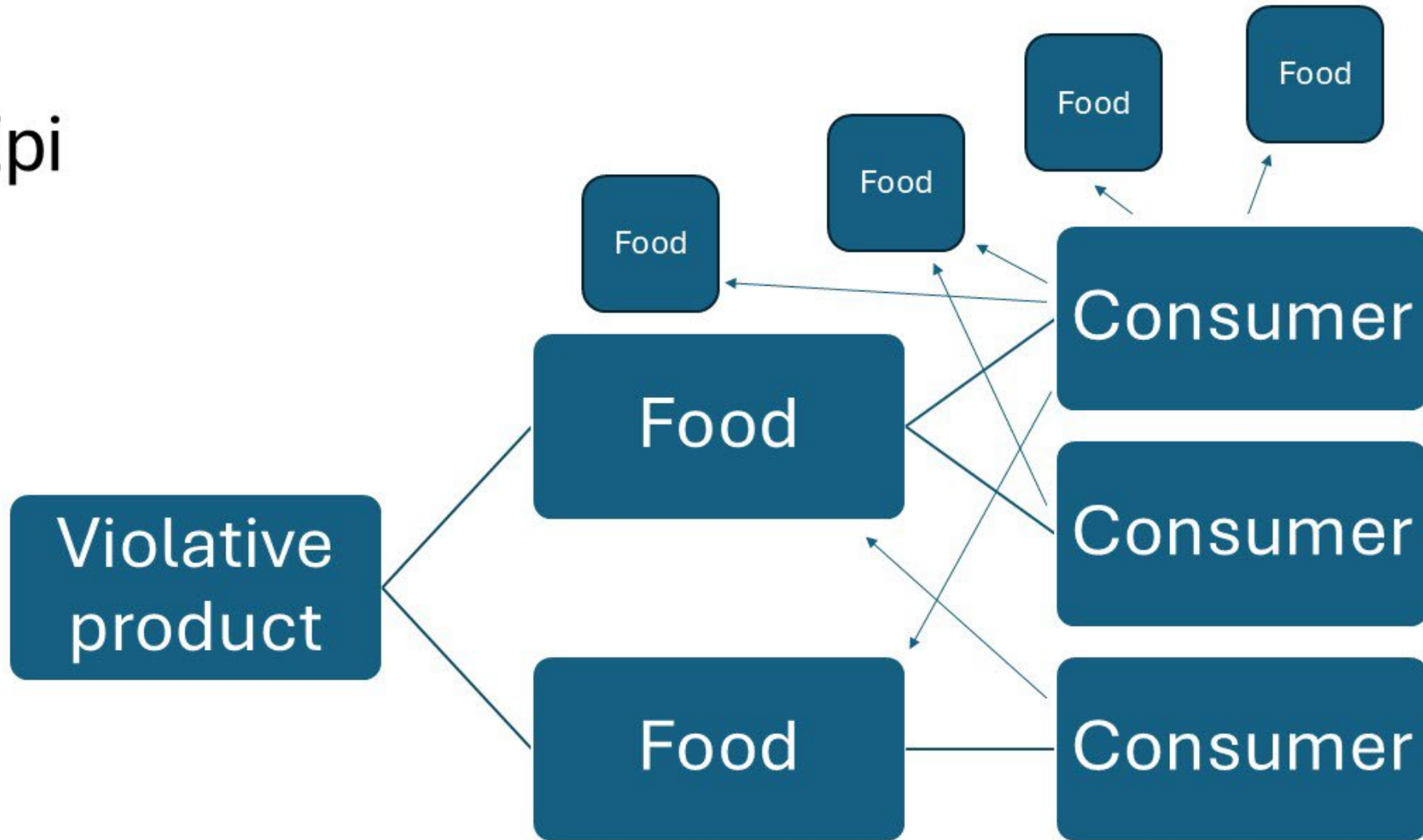
Recall

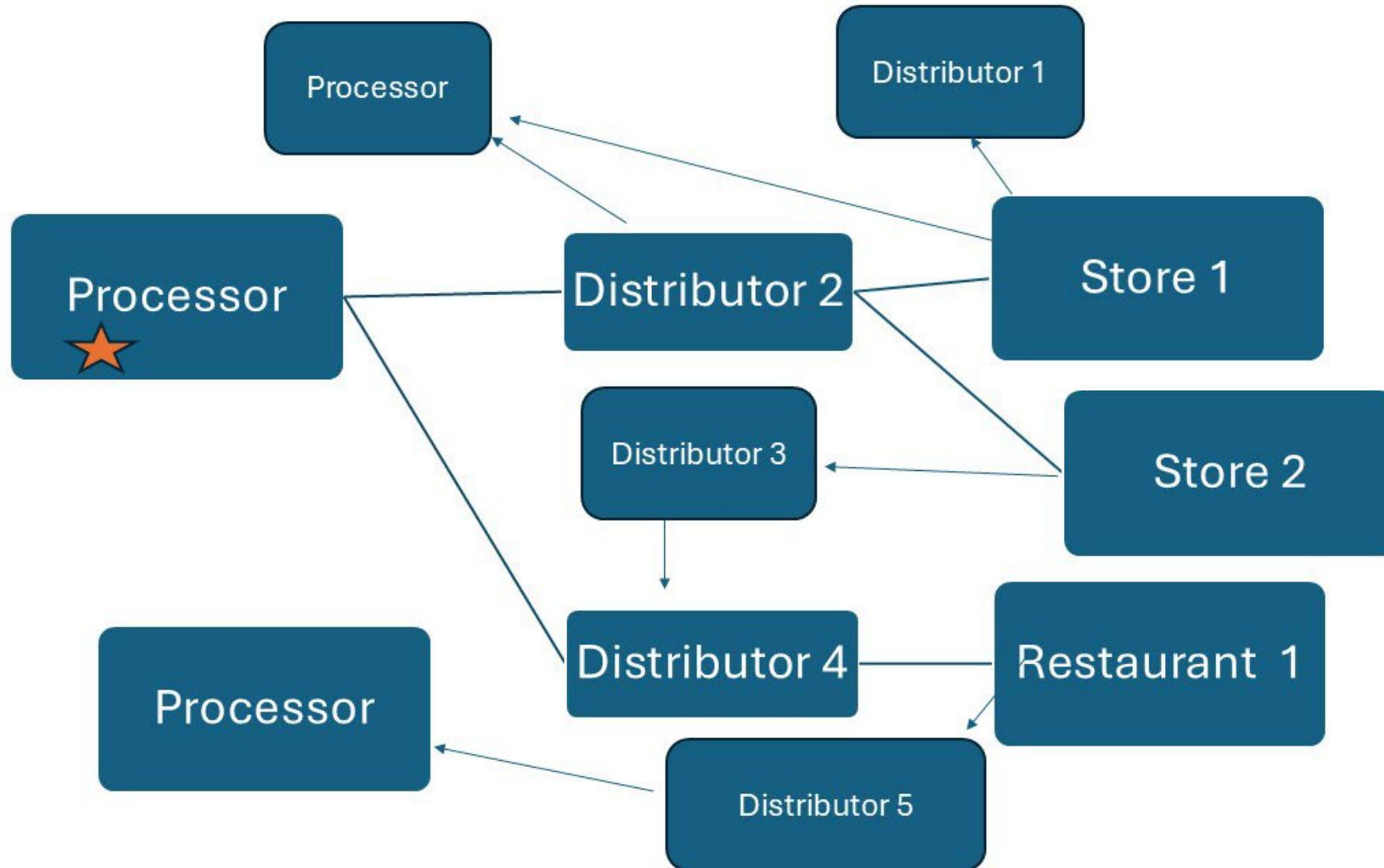


Outbreak



Epi







Recalls Vs Outbreaks

Recalls	Outbreaks
Issue is “known”	Issue is unknown
Goal: remove product May or may not be associated with illness/ injury	Goal: determine product associated with illness or injury
Industry driven	Regulator driven
Conservative approach is helpful: ensure the signal is removed, even if some noise is removed too	Conservative approach hurts: too many “it could be” create noise and the signal is lost

Outbreaks often, but don’t always, lead to recalls

Not all recalls are related to outbreaks

You can have a food safety issue that never results in a recall

Regulator Challenges

Volume of possibilities

Paper-based systems

Lack of standardized naming

Missing or incorrect data



Distributor D
Nashville TN

Remit Payment To

LOCAL : 615-284-2805 Bill To
TOLL :
FAX : 615-284-2806

Page 1 of 2

Ship To: **Distributor A**
NASHVILLE TN 37210
615-284-2805

Invoice No.	Invoice Date	Customer No.	Order Date	P.O. Number	Salesman	Terms	Route-Stop
265037	4/26/19	709	4/26/19	1150872/L22140 Conf: SYB 1150872	UNASSIGNED	NET 30 DAYS DUE DATE : 4/26/19	W/C

SPECIAL INSTRUCTIONS: 1150872 FRIDAY 04/26/2019 DBAN8465

Item Number	Quantity Ordered	Quantity Shipped	Pack	Size	Item Description	Unit Weight	Extended Weight	Unit Price	Extended	St
885802	170	170		25#	TOMATOES Utility 25# -7302204					
887113	180	180		10#	25# CAFE -					
887100	60	60		12#	TOMATO GRAPE 10# -3790591					
881201	60	60		25#	Tomatoes Grape 12/1 Pint -6939383					
882311	180	180		25#	TOMATOES 5x5 25# -4851412					
880600	10	10		25#	25# 5X5 -					
881450	8	8		25#	25# ROMA CPK-NOT A UTILITY-3449093					
881707	40	40		20#	ROMA CPK -NOT A UTILITY-					
881802	100	100		20#	TOMATOES Random 25# Fresh-2093730					
881482	80	80		20#	4x4 2-Layer DEEP RED VR -0864967					
				20#	TOMATO DEEP RED VINE RIPE -0131088					
				25#	TOMATOES 5x5 2-Layer -1079219					
				25#	25# 6X6 Restaurant Aching -132702					
				25#	6X6 25# other customer					
					MARKETPLACE VANCE.					

CASES: 892 SPLITS: 0 CUBES: 0.00

Driver	Cash Amount	Check Amount	Check your merchandise before signing Customer Signature:	Total Weight	Sub Total

ST=Status Code	S=Sub	Tax
PS=Partial Ship	O=Out	Other
		Total

The Perishable agricultural commodities listed on this invoice are sold subject to the statutory trust authorized by section 5(c) of the Perishable Agricultural Commodities Act, 1930 (7 U.S.C. 409(c)). The seller of these commodities retains a trust claim over these commodities, all inventories of food or other products derived from these commodities, and any receivables or proceeds from the sales of these commodities until full payment is received. Interest at 1.5% per month added to unpaid balance. Buyer agrees to pay interest and attorney's fees incurred to collect any balance due hereunder. Interest and attorney's fees necessary to collect and balance due hereunder shall be considered sums owing in connection with this transaction under the PACA trust. All accounts due and payable within stated terms. Customer's obligation cannot be assigned or transferred without the prior written consent of the supplier.



= Traceability Rule

- Timing:
 - January 2026/ routine enforcement 2027
- Certain Foods (Food Traceability List)
 - And foods containing FTL ingredients
 - Only FDA regulated products
- Capture/share Key Data Elements at various Critical Tracking Events
 - Traceability lot code
- Provide an electronic sortable spreadsheet within ~24 hrs of an FDA request
- Maintain a food traceability plan

Food Traceability List: FDA regulated foods

Produce Items



Cucumbers
(fresh)



Sprouts
(fresh)



Herbs (fresh)



Tomatoes
(fresh)



Leafy greens
(fresh),
including
fresh cut
leafy greens



Tropical tree
fruit (fresh)



Melons
(fresh)



Fruits and
vegetables
(fresh cut)



Peppers
(fresh)



Ready to eat
deli salads
(refrigerated)

Non-Produce Items



Cheeses, other
than hard
cheeses



Finfish,
including
smoked fish



Shell eggs



Crustaceans
(fresh and
frozen)



Nut butter
(does not
include soy or
seed butters)



Mollusks, bi-
valves (fresh
and frozen)

Includes foods that CONTAIN FTL foods
Will be updated ~every 5 years

FTL possibilities

- FTL ingredients form new food (no kill step) = FTL (e.g. bagged salad)
- FTL ingredients form new food (kill step) = NOT FTL (e.g., pasta sauce, cooked shrimp)
- FTL ingredients form new food (new form) = NOT FTL (e.g. veggie lasagna)
- Non FTL ingredients form FTL food (e.g., nut butter, sliced apples) = FTL food





New Concepts: Traceability Rule (Jan 2026)

- Requires a farm map
- Requires the harvester to capture Key Data Elements
- Requires the “initial packer” to assign a Traceability Lot Code
- “Transformation” requires associating the raw material TLC with the finished product TLC- **but not if done in the retail store** (usually)
 - The “Traceability Lot Code Source” must be communicated through the supply chain (to the retail store or restaurant) so FDA can quickly figure out who made the product



Critical Tracking Events & Key Data Elements

- CTEs
 - Receiving
 - Shipping
 - Harvesting, cooling, packing
 - First land-based receiver
 - Transformation





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



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).

Common Questions

- What are our requirements if we are self-distributing?
 - *The rule applies to each location, whether it has the same ownership or not*
 - *You can lean on another entity to keep your traceability data*
- Our stores do receive some product potentially on the FTL directly from a manufacturer/local farm.
 - *Manufacturer: rule applies (unless exempt)*
 - *Farm: rule applies (unless exempt) OR unless the farm packages the food for consumers and includes the farm contact info etc.*

- Do we really need to track all the ingredients that are used in items produced in the stores?
 - No, not as long as they will be sold to the end consumer
- We have some stores that transform produce into cut produce and ship to another store.
 - *These are transformations, shipping, and receiving CTEs*
- What about commissaries/ central kitchens?
 - *These are transformations, shipping and receiving CTEs*

- What information are we required to track for items cross-docked at our DC's, but never "received" into the inventory of the DC?
 - *Cross-docking is not a CTE; it's a part of transportation*
 - *(FDA FAQ "To determine whether the food was received at point X (and then subsequently shipped to point B), we would consider factors such as how long the food was held at point X, whether it was held there under temperature-controlled conditions that differ from transportation conditions, and whether it was taken into inventory at point X.")*

- What is the difference of the Traceability Lot Code and a “Lot code” of product?
 - *FMI and others are proposing GTIN + Lot Code*
- TLC’s do not have to be on package, so we have no way of verifying at any point in our process.
 - *The rule is silent on how information is shared- nothing is required on packages cases, etc.*
- Does the rule require case level tracking?
 - *No. Although people claim this, case level tracking is a very specific thing, where you need to know where case #1 went vs case #2. The rule requires lot level tracking– it just so happens they are usually packaged in cases. But if they are pallets or “eaches” you need to track those too.*

- If a supplier claims they are not covered under FSMA 204, what is our responsibility to ensure that is correct?
 - *Good lawyer question.*
- If a supplier refuses to provide the information, what is our level of responsibility?
 - *Good lawyer question.*

The Future

- January 2026 Compliance date
- 2027 for routine inspection
- FDA has held industry roundtables
- Legislation has been introduced
- FSPCA is developing training
~summer 2025



Things to Do

1

See what you already have

- Foods on the list
- Physical processes
- Software system

2

Identify gaps

- Prioritize!
- Try to meet the intent of the rule

3

Ask for help

- Align with industry approaches
- Upgrade systems only if needed

Thank you!



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