



FoodIndustry

COUNSEL LLC

“GOING **ALL-IN** FOR FOOD AND **ALL-OUT** FOR THOSE WHO PRODUCE IT”

Shawn Stevens

stevens@foodindustrycounsel.com

920.698.2561

TRACEABILITY CHANGES EVERYTHING

Are the Legal Threats Worse Than You Think?



TRACEABILITY CHANGES EVERYTHING

Are the Legal Threats Worse Than You Think?

1

Years

10

Months

26

Days

7

Hours

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November 15, 2022

November 15, 2023

November 15, 2024

December 31, 2025

January 20, 2026

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TRACEABILITY CHANGES EVERYTHING

Are the Legal Threats Worse Than You Think?



“Yeah ... I did that.”



THE FOOD SAFETY MODERNIZATION ACT

“MAKE FOODBORNE ILLNBESS STOP”



FOOD PRODUCT RECALLS SINCE 2003

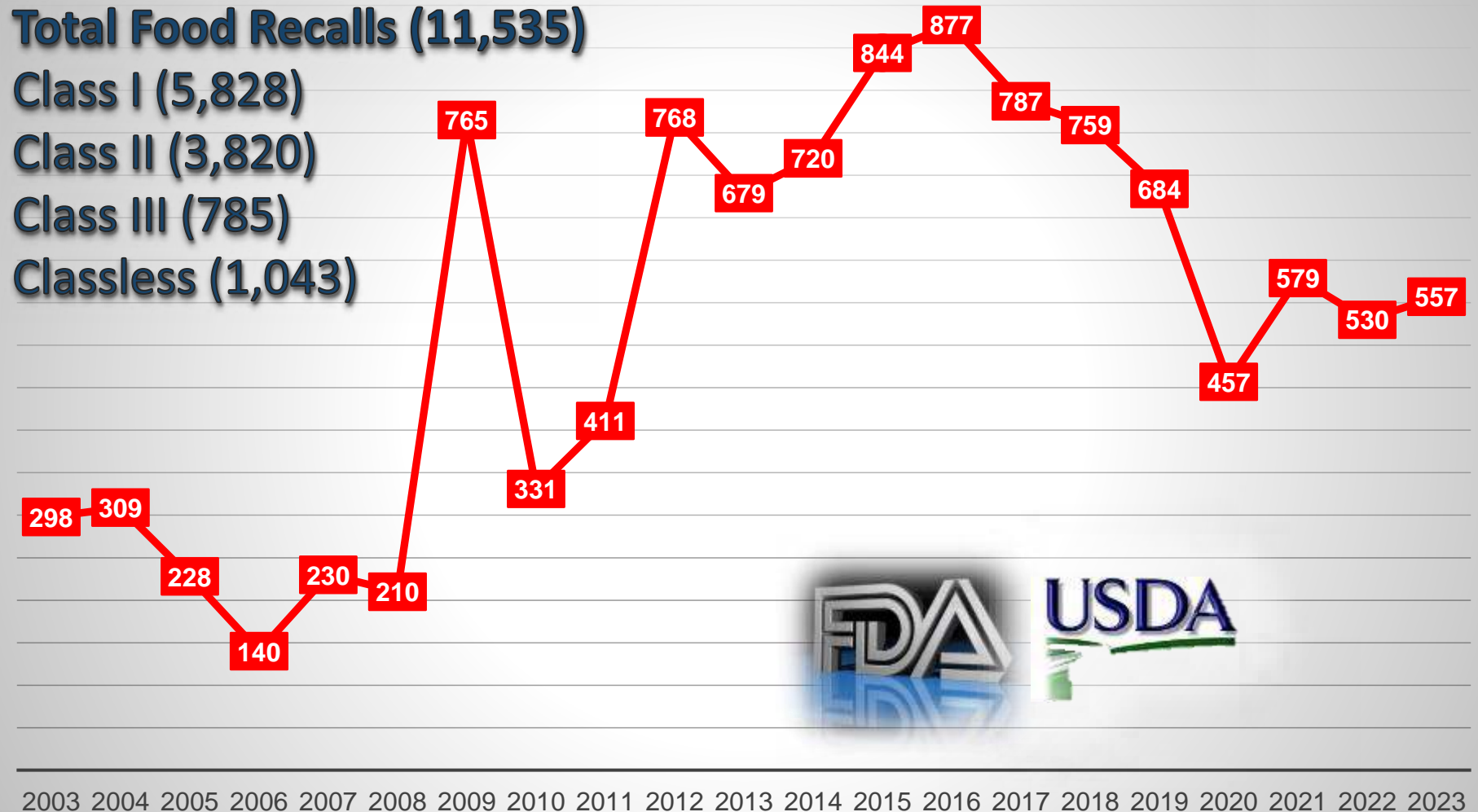
Total Food Recalls (11,535)

Class I (5,828)

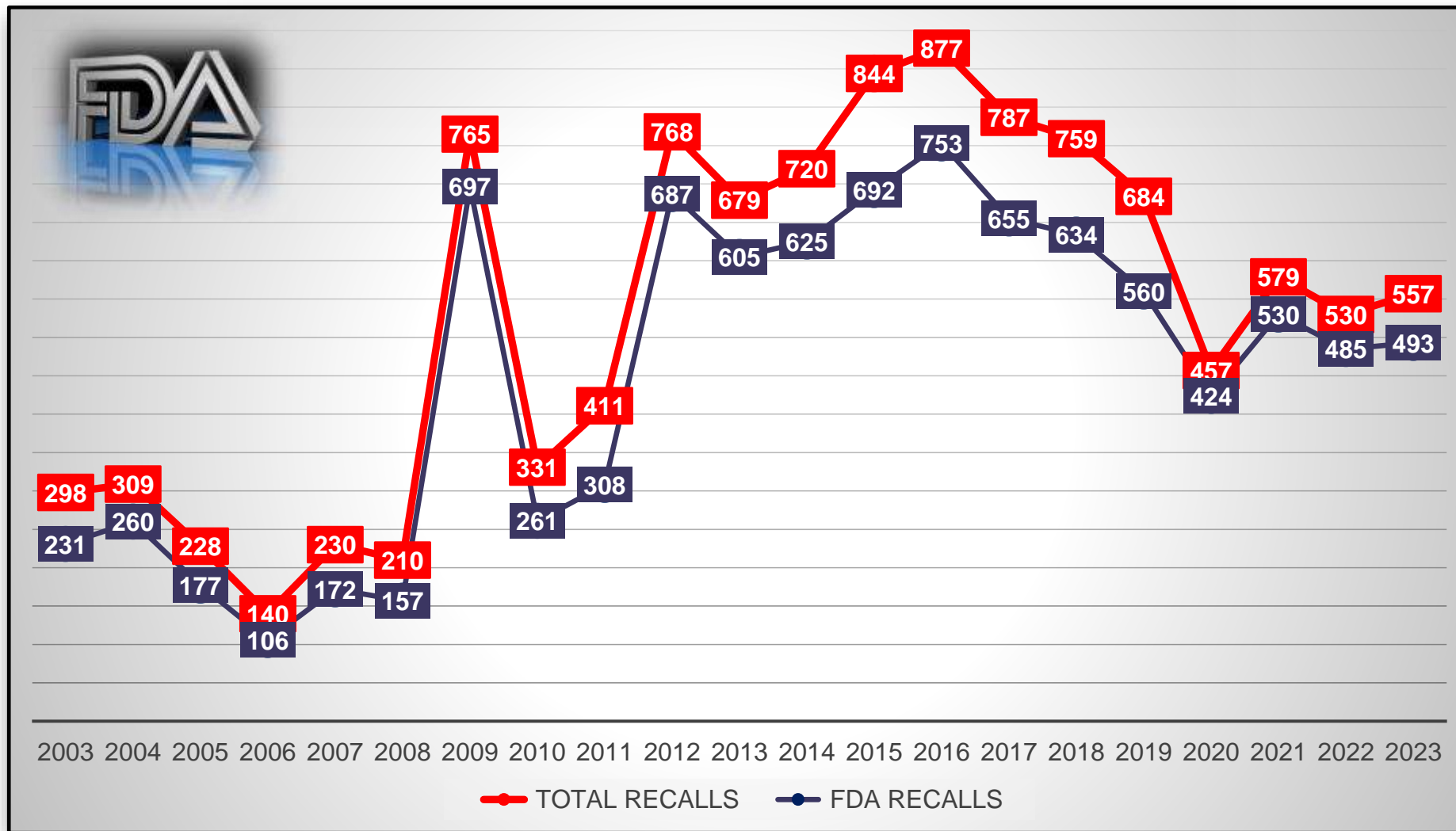
Class II (3,820)

Class III (785)

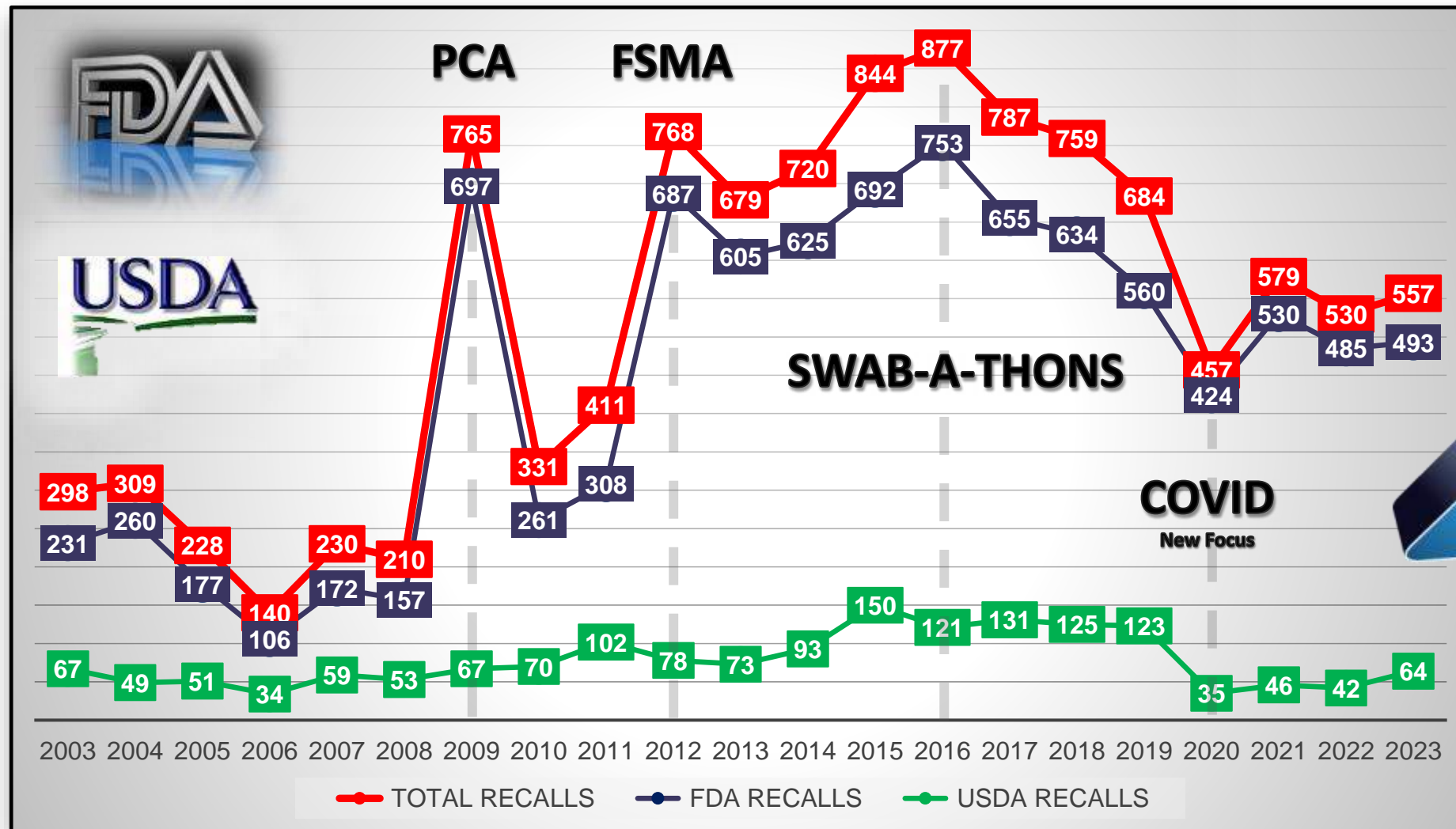
Classless (1,043)



FOOD PRODUCT RECALLS SINCE 2003



FOOD PRODUCT RECALLS SINCE 2003



2015-2023

RECALL STATISTICS

(HUMAN FOOD AND BEVERAGES ONLY – EXCLUDES DIETARY SUPPLEMENTS, ANIMAL FEED, AND PET FOOD)

CAUSES BY YEAR	2015	2016	2017	2018	2019	2020	2021	2022	2023	AVERAGES
All Causes	746	801	714	656	619	403	489	476	497	600
UNDECLARED ALLERGENS										
Allergens (Big 8)	410 (55%)	388 (48%)	410 (57%)	336 (51%)	235 (38%)	145 (36%)	250 (51%)	249 (52%)	301 (61%)	303 (51%)
PATHOGENS										
<i>Listeria monocytogenes</i>	63 (8%)	144 (18%)	125 (18%)	87 (13%)	92 (15%)	31 (8%)	54 (11%)	47 (10%)	43 (9%)	76 (13%)
<i>Salmonella</i>	69 (9%)	101 (13%)	34 (5%)	95 (14%)	43 (7%)	44 (11%)	52 (11%)	54 (11%)	31 (6%)	58 (10%)
<i>E. coli</i> (All Varieties)	13 (2%)	46 (6%)	22 (3%)	18 (3%)	18 (3%)	6 (1%)	5 (1%)	6 (1%)	10 (2%)	16 (3%)
Total Pathogens ("Big 3")	145 (19%)	291 (36%)	182 (25%)	200 (30%)	153 (25%)	81 (20%)	111 (23%)	107 (22%)	97 (20%)	152 (25%)
FOREIGN MATERIALS										
Foreign Materials (All Varieties)	69 (9%)	80 (10%)	80 (11%)	67 (10%)	106 (17%)	50 (12%)	68 (14%)	66 (14%)	61 (12%)	72 (12%)

FOOD RECALL SEARCH

FOOD RECALL REPORTER

www.foodrecallreporter.com



RECALLS BY YEAR

2024	2019	2006
2023	2014	2005
2022	2013	2004
2021	2012	2003
2020	2011	2002
2019	2010	2001
2018	2009	2000
2017	2008	
2016	2007	

BIG 9 ALLERGENS

- ☐ Milk 68
- ☐ Soy 58
- ☐ Tree Nuts 44
- ☐ Wheat/Gluten 36
- ☐ Egg 31
- ☐ Peanuts 29
- ☐ Sesame 27
- ☐ Fish 8
- ☐ Shellfish 4

FOREIGN MATERIALS

- ☐ Plastic 24
- ☐ Metal 16
- ☐ Glass 6
- ☐ Unknown Foreign Material 4
- ☐ Bone 3
- ☐ Insects 3
- ☐ Rodent Activity 3
- ☐ Rock 2
- ☐ Rubber 2

PATHOGENS

- ☐ Listeria monocytogenes 43
- ☐ Salmonella 37
- ☐ Hepatitis A 7
- ☐ E. coli 5
- ☐ Cronobacter sakazakii 4
- ☐ Clostridium botulinum 3
- ☐ E. coli O103 3
- ☐ E. coli O157:H7 2
- ☐ E. coli O45 1
- ☐ Norovirus 1

FDA's New Era of Smarter Food Safety

Retail Modernization

Food Safety Culture



**Tech Enabled
Traceability**

Outbreak Response

FDA's New Era of Smarter Food Safety

Retail Modernization

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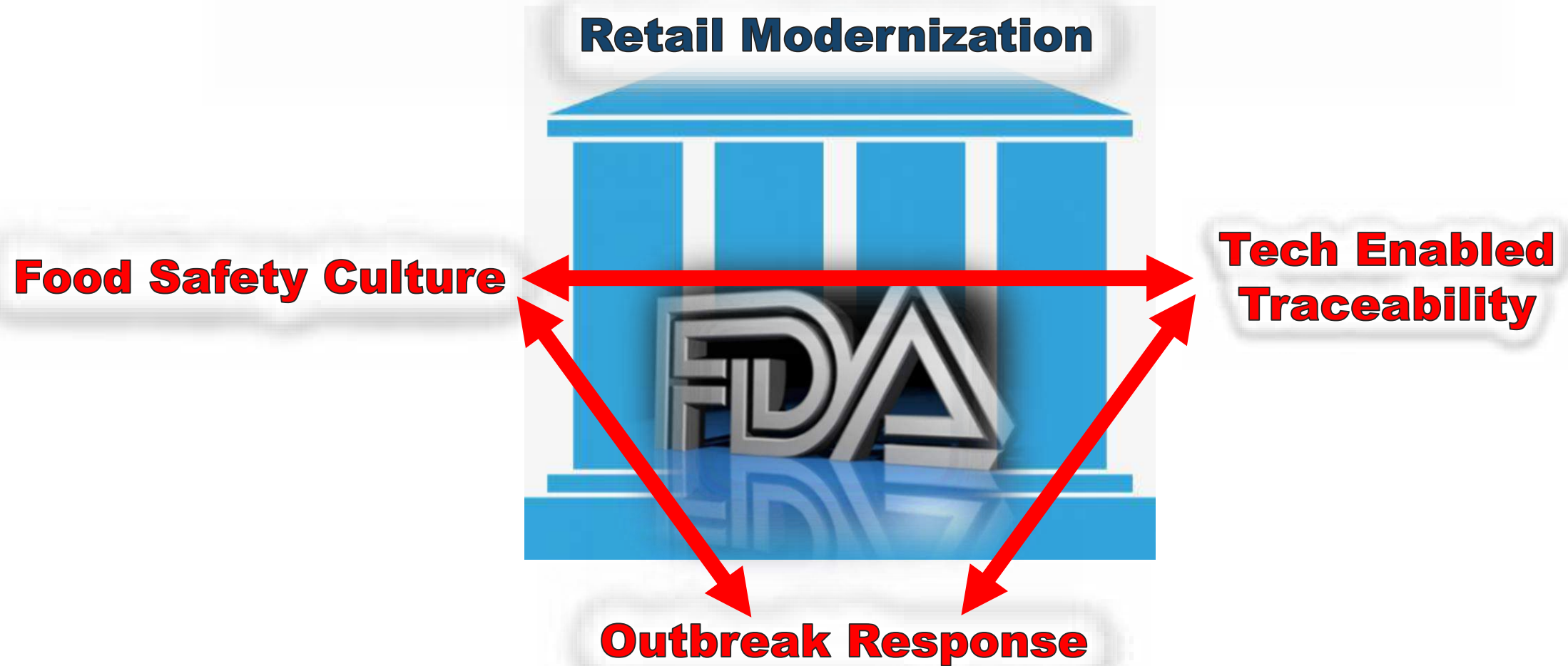
Food Safety Culture



**Tech Enabled
Traceability**

Outbreak Response

FDA's New Era of Smarter Food Safety



FDA's New Era of Smarter Food Safety

**Tech-enabled Traceability
Outbreak Response**

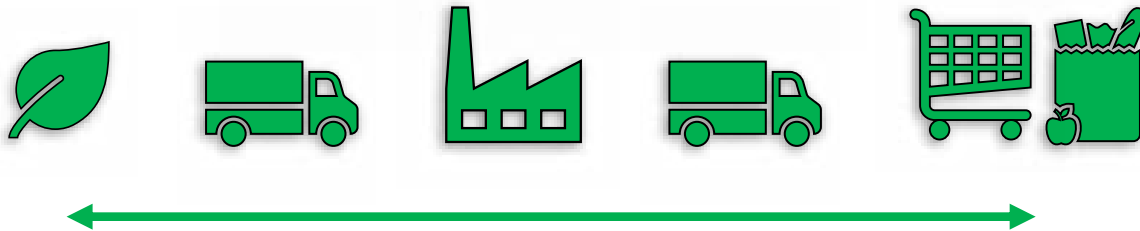
ONE FORWARD, AND ONE BACK



FDA's New Era of Smarter Food Safety

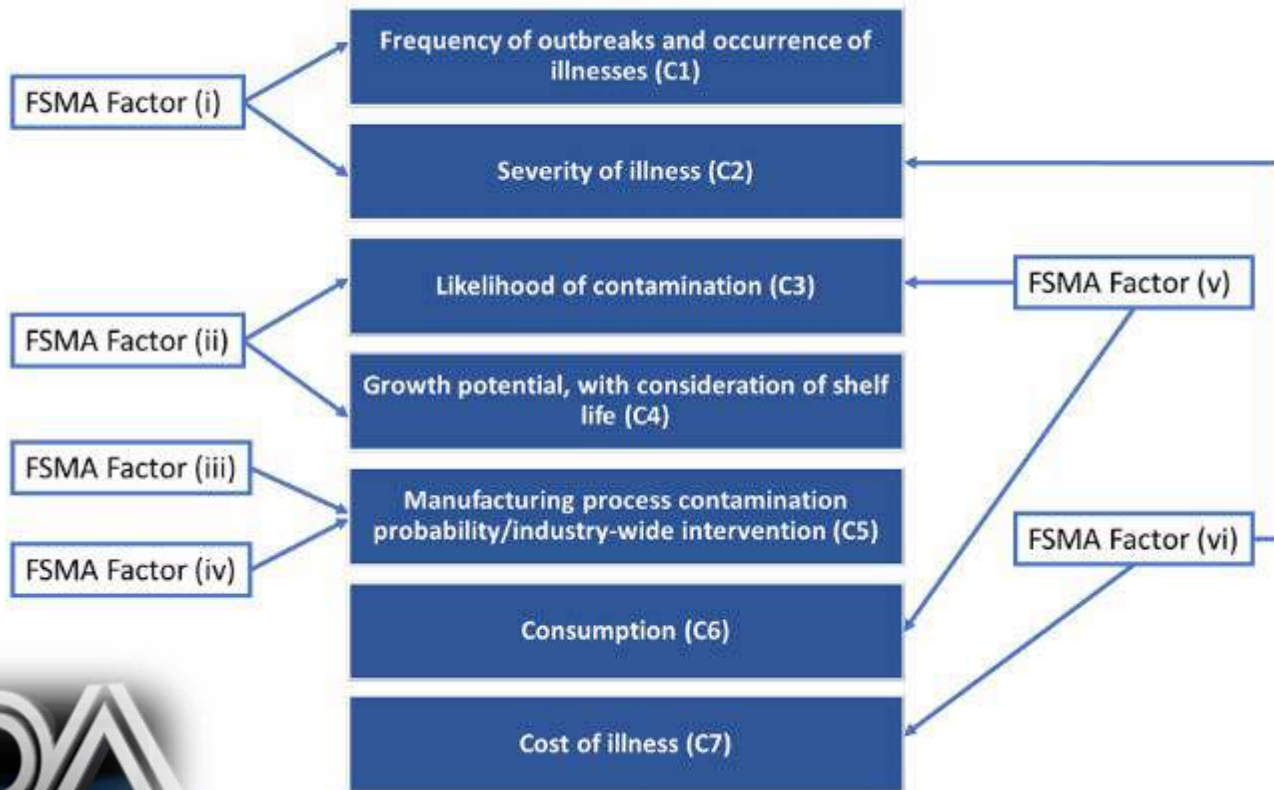
**Tech-enabled Traceability
Outbreak Response**

FARM TO RETAIL FRIDGE



WHAT FOODS DOES THE RULE APPLY TO?

FOODS ON THE TRACEABILITY LIST (FTL)



WHAT FOODS DOES THE RULE APPLY TO?

FOODS ON THE TRACEABILITY LIST (FTL)

Cheese (other than hard cheeses)

Shell eggs

Nut Butter

Cucumbers

Herbs (fresh)

Leafy Greens (including fresh-cut)

Melons (fresh)

Peppers (fresh)

Sprouts (fresh)

Tomatoes (fresh)

Tropical tree fruits (fresh)

Fruits and vegetables (fresh-cut)

Smoked Finfish

Crustaceans

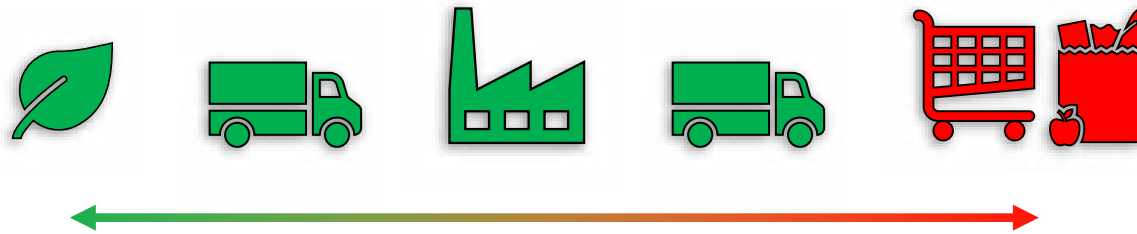
Molluscan shellfish, Bivalves

Ready-to-eat deli salads



WHO DOES THE RULE APPLY TO?

Persons who manufacture, process, pack, or hold foods that appear on the FTL



WHAT NEEDS TO BE DONE?

LOT TRACEABILITY CODE

Must be assigned by: (1) the initial packer;
(2) the FLBR (fishing vessel); or (3) any transformer

Examples of traceability lot codes	
(01)04562135785133 (17)140704 (10) DE-456 GS1-128 Example	1147M2023213 1. 2. 3.
475123C 6-digit code + letter to represent grower/manufacturing location	1. Product code 2. Facility 3. Julian date
BFCA179A152023213 1. 2. 3. 4. 5.	134AD5607 Randomized alphanumeric code generated by firm's traceability system
1. Company name 2. Production location 3. Product 4. Grower 5. Julian date	



WHO DOES THE RULE APPLY TO?

Persons who manufacture, process, pack, or hold foods that appear on the FTL

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

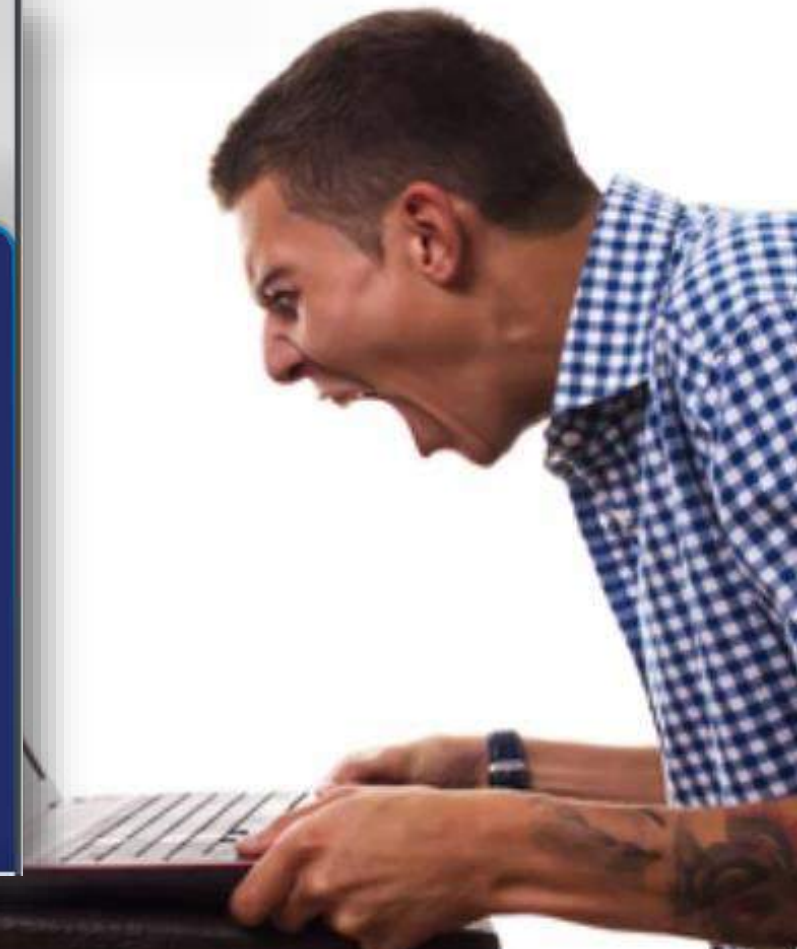

FDA U.S. FOOD & DRUG ADMINISTRATION

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



WHAT NEEDS TO BE DONE?

CRITICAL TRACKING EVENTS (CTEs)

Harvesting
Cooling
Initial packing
FLBR (Fishing vessel)
Shipping
Receiving; and
Transforming

(when the finished product is still a product on the FTL)



WHAT NEEDS TO BE DONE?

KEY DATA ELEMENTS (KDEs)

Traceability Lot Code Source (TLCS)

[Place assigning Lot Code (Location description)]

Traceability Lot Code Source Reference (TLCSR)

[i.e., FDA Registration Number]

Product Description

[Brand name, commodity, and variety]



WHAT NEEDS TO BE DONE?

Traceability Plan

Description of the procedures you use to maintain the required records, including the format and location of the records

Description of the procedures you use to identify foods on the FTL that you manufacture, process, pack or hold

Description of how you assign traceability lot codes to foods on the FTL, if applicable

Statement identifying a point of contact for questions regarding your traceability plan and records



WHAT NEEDS TO BE DONE?



WHAT TYPES OF EXPOSURE EXIST FOR NONCOMPLIANCE?

Regulatory, Civil, and Criminal



*** Between 2000 and 2020, at least 41 cucumber-associated outbreaks were reported to CDC's National Outbreak Reporting System (NORS), causing 2,401 illnesses, 323 hospitalizations, and 7 deaths**

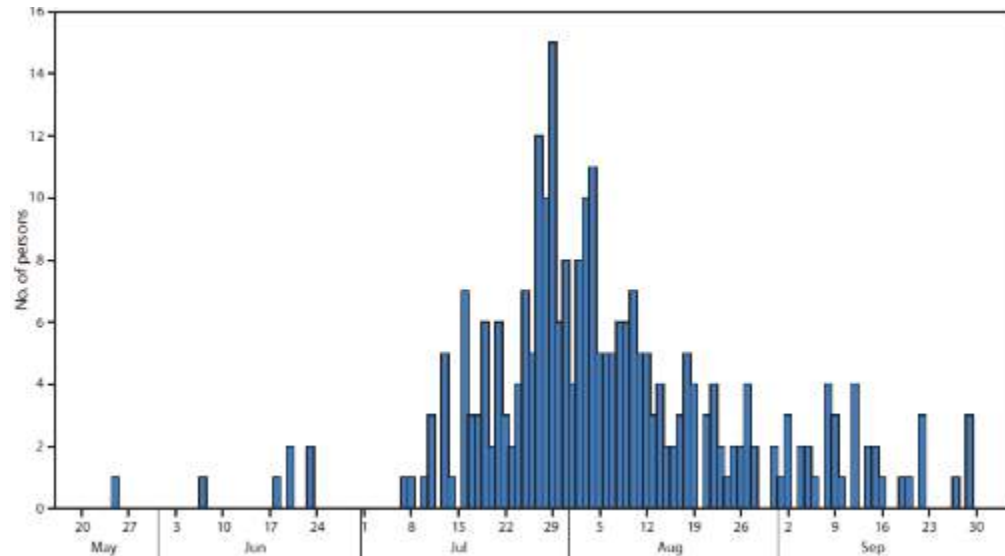
WHAT TYPES OF EXPOSURE EXIST FOR NONCOMPLIANCE?

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WHAT TYPES OF EXPOSURE EXIST FOR NONCOMPLIANCE?

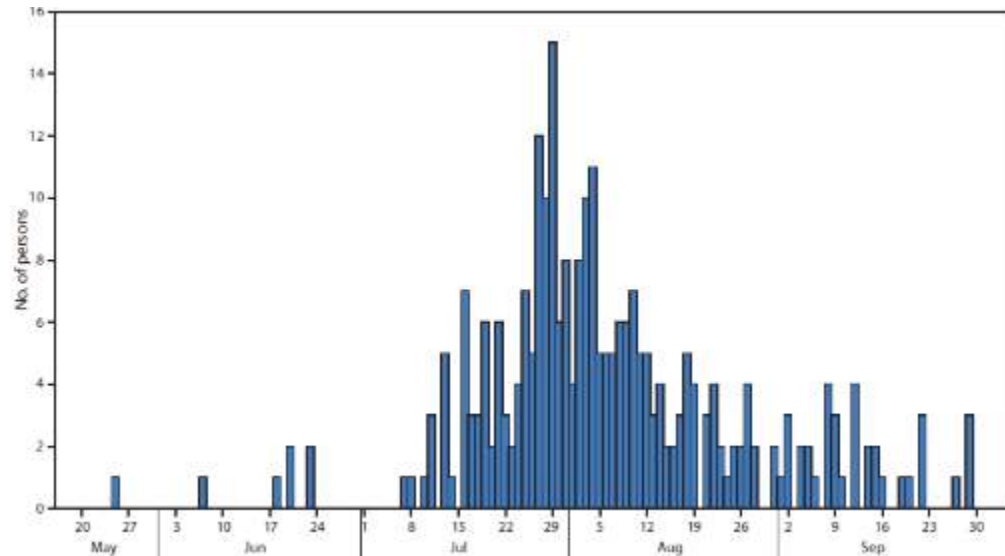
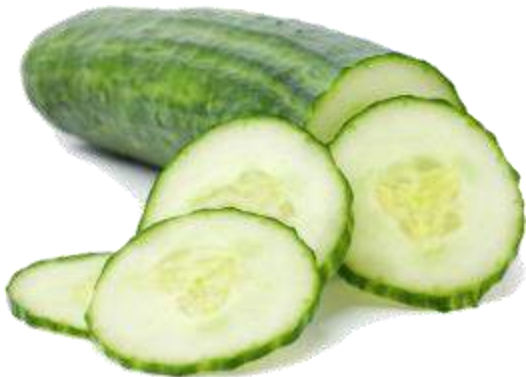
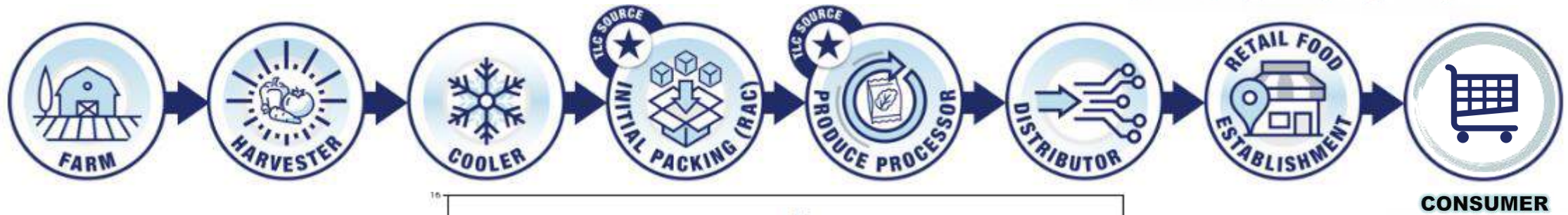
Regulatory, Civil, and Criminal



WHAT TYPES OF EXPOSURE EXIST FOR NONCOMPLIANCE?

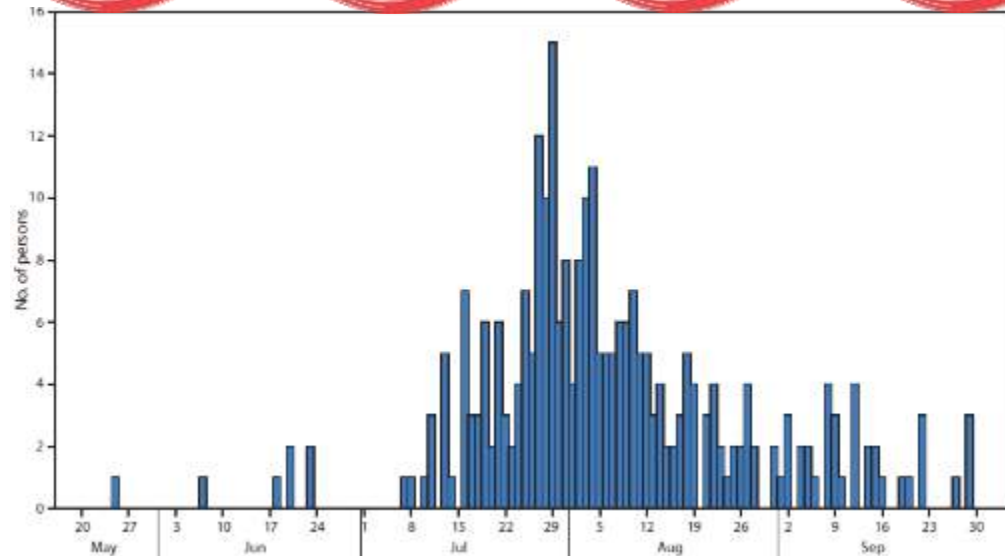
Regulatory, Civil, and Criminal

~~BFCA179A152023213~~



WHAT TYPES OF EXPOSURE EXIST FOR NONCOMPLIANCE?

Regulatory, Civil, and Criminal



WHAT TYPES OF EXPOSURE EXIST FOR NONCOMPLIANCE?

CIVIL



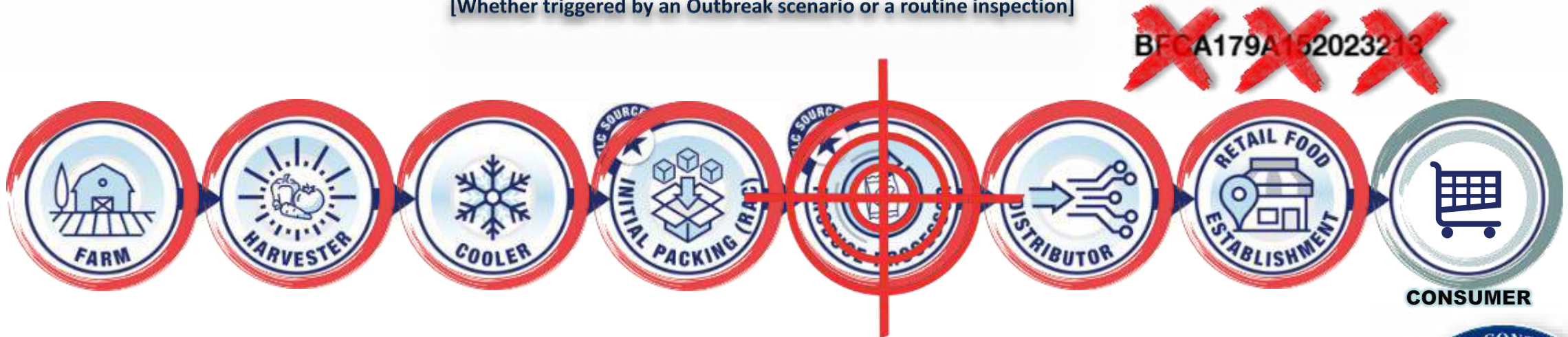
PUNITIVE DAMAGES



WHAT TYPES OF EXPOSURE EXIST FOR NONCOMPLIANCE?

REGULATORY

[Whether triggered by an Outbreak scenario or a routine inspection]



FORM 483s
WARNING LETTERS

DEBARMENT / DISQUALIFICATION
SUSPENSION OF FOOD FACILITY REGISTRATION



WHAT TYPES OF EXPOSURE EXIST FOR NONCOMPLIANCE?

CRIMINAL PARK DOCTRINE LIABILITY



WHAT TYPES OF EXPOSURE EXIST FOR NONCOMPLIANCE?

CRIMINAL PARK DOCTRINE LIABILITY



A corporate official with authority and responsibility for supervising subordinates may be held criminally liable—without a showing of affirmative wrongful action or intent—for a subordinate's violation of a public welfare statute that contains no requirement of intent and carries only misdemeanor penalties. The principle has become known as the RCO doctrine



WHAT TYPES OF EXPOSURE EXIST FOR NONCOMPLIANCE?

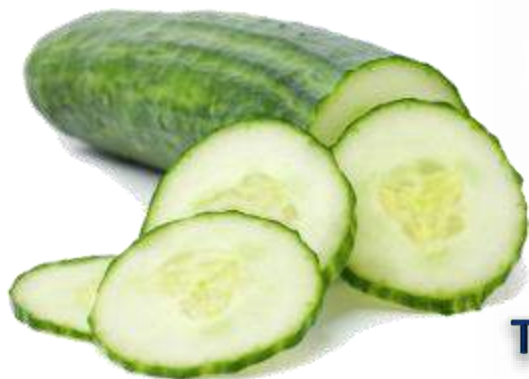
CRIMINAL PARK DOCTRINE LIABILITY



THE DEFENDANT IS AWARE OF A CONDITION
THAT COULD LEAD TO PRODUCT CONTAMINATION

THE DEFENDANT IS IN A POSITION
TO ELIMINATE THE CONDITION

THE DEFENDANT FAILS TO ELIMINATE THE CONDITION



MOCK TRACEABILITY CRIMINAL TRIAL



MOCK TRACEABILITY CRIMINAL TRIAL



MOCK TRACEABILITY CRIMINAL TRIAL



Bill Garrett
MAGGIE'S
CEO



Lynn White
MAGGIE'S
VP of Food Safety



Mark Grantly
EARTHLY GLOW
VP of Food Safety



Courtney Ryan
August 3, 2019 – December 20, 2023

MOCK TRACEABILITY CRIMINAL TRIAL

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHER DISTRICT OF GEORGIA	
UNITED STATES of AMERICA,	
vs.	Case No.: 23 CR 12597
Plaintiff,	

As to Counts 1-40 of the Criminal Complaint, we, the Jury, find Defendant LYNN WHITE

Guilty

Not Guilty

the product contamination, then you must render a verdict of Guilty.

If the United States has failed to prove any of the above elements, you must find the Defendant not guilty.

As to Counts 1-40 of the Criminal Complaint, we, the Jury, find Defendant LYNN WHITE

Guilty

Not Guilty

DATED this 30th day of January, 2024.



TRACEABILITY CHANGES EVERYTHING

The Legal Threats Are Worse Than You Think

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