

ReposiTrak

OnTrak Webinar Series

*July 20, 2021*

# FDA & Food Safety: New Rules & New Risks



Shawn Stevens, ESQ.

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REPOSITRAK.COM

# World's Largest Network of Supply Chain Partners Sharing Documents and Data

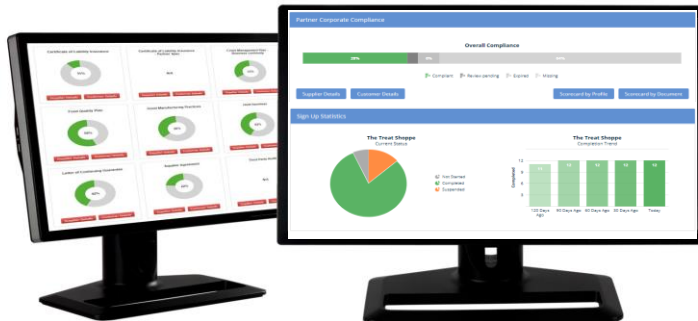
*Improve Product Safety, Reduce Cost & Risk*

More than **100,000+**  
**connections**  
in the ReposiTrak network  
used in **100+ countries**



ReposiTrak

Many of you and your suppliers are likely already using ReposiTrak to share documents with customers



# Exclusively Endorsed in the Industry



“ReposiTrak augments our food and drug safety efforts...with a **proven, comprehensive and easy-to-implement solution** that **doesn't require systems changes** and is extremely cost effective.”

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“We see the ReposiTrak system becoming an **industry standard** for the retail supply chain, helping all trading partners **meet the new federal food safety requirements**, reducing unsalable products and keeping the end consumer healthy.”

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“We were looking for a technology partner to help us **raise the bar** not only with our data management and reporting, but also with upgrades to all of our user interfaces. It made perfect sense to partner with ReposiTrak because of their **experience in the industry** and technical capabilities.”

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“ReposiTrak is a **pioneering innovator** in delivering robust retail management software solutions for our rapidly changing industry. This technology will equip our members with a toolbox for success in a constantly evolving marketplace. We are thrilled to partner with ReposiTrak as we continue to advance and expand our ecosystem.”



# We Know You're Busy, So Our Team Does the Heavy Lifting for You

## Cloud-based system

- Nothing to install, you just need an internet browser

## Set-up is easy

- We just need your supplier list and document requirements to get started

## We do all the supplier follow-up for you!

- It takes up to 20 “touches” by phone, e-mail and mail on average to get and keep a supplier compliant
- We have a full-time, U.S. based, multi-lingual Customer Success Team who follow-up with your vendors to ensure adoption and compliance with your requirements



# ReposiTrak is Now the Most Complete Compliance & Quality Management Solution

World's largest document sharing network  
100,000+ locations in 100+ countries  
Customer success team handles  
supplier follow-up

Supplier  
Compliance  
Management

Automate internal forms & quality records  
Improve quality management  
Save time & money  
Reduce audit prep time

Active QMS  
Quality  
Management

COA  
Management  
Automation

Audit  
Management  
Automation

Collect COAs via email  
Track COAs to batch/lot  
Auto-validation of COAs to specs

Automate internal &  
supplier audits for  
efficiency and consistency



# Food Traceability Leadership Consortium

*Leadership in traceability*



Created a methodology



Adopted principles of an optimal solution

Minimal Cost

Easy to adopt, use and verify

Meet or exceed FDA proposed regulation

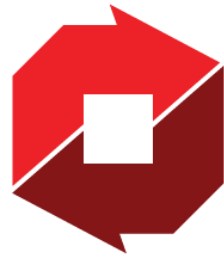


Create a Framework



Review possible solution





ReposiTrak

OnTrak Webinar Series

*July 27, 2021*

# FDA & Food Safety: New Rules & New Risks



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# FoodIndustry

COUNSEL LLC

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

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# FDA AND FOOD SAFETY NEW RULES AND NEW RISKS



# **FDA AND FOOD SAFETY NEW RULES AND NEW RISKS**

**Fun with Recalls**

**3 Strikes**

**3 C's**

**Far Fetched Audits**

**Trace = ability (to Trace)**

**A Stroll Down Sesame Street**

**And Other Stuff**

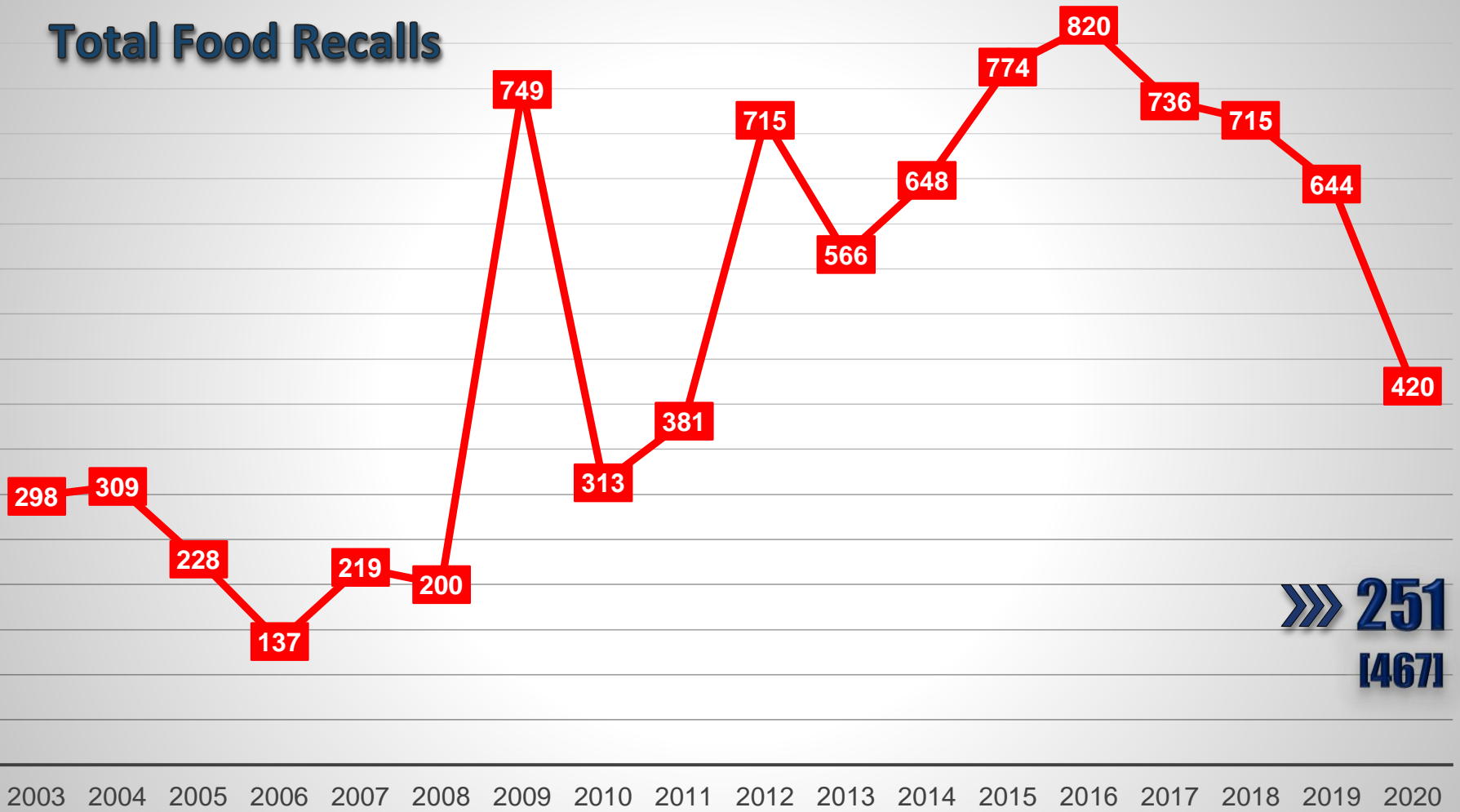
# Fun With Recalls



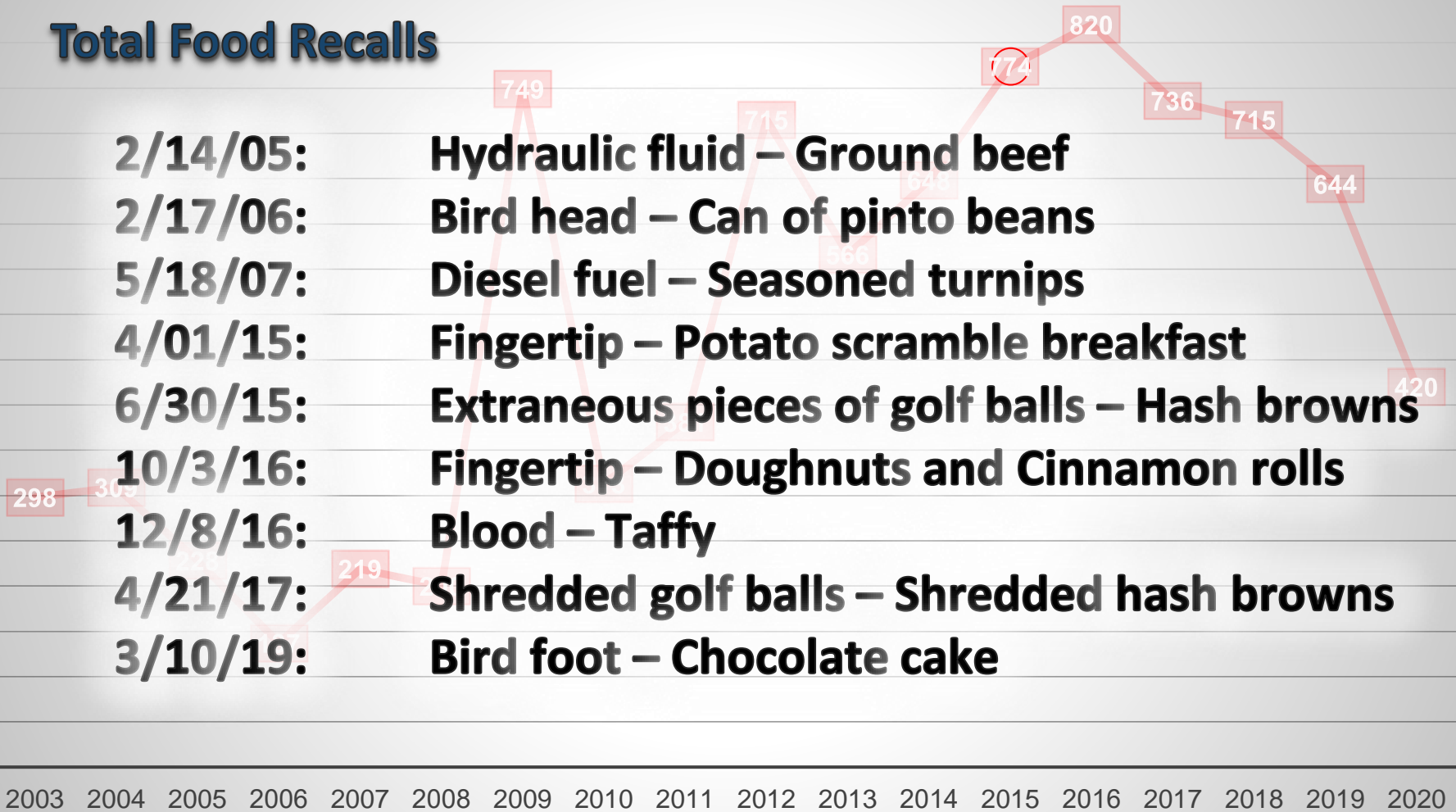
251  
467



# Total Food Recalls



## Total Food Recalls



**2/14/05:**

**Hydraulic fluid – Ground beef**

**2/17/06:**

**Bird head – Can of pinto beans**

**5/18/07:**

**Diesel fuel – Seasoned turnips**

**4/01/15:**

**Fingertip – Potato scramble breakfast**

**6/30/15:**

**Extraneous pieces of golf balls – Hash browns**

**10/3/16:**

**Fingertip – Doughnuts and Cinnamon rolls**

**12/8/16:**

**Blood – Taffy**

**4/21/17:**

**Shredded golf balls – Shredded hash browns**

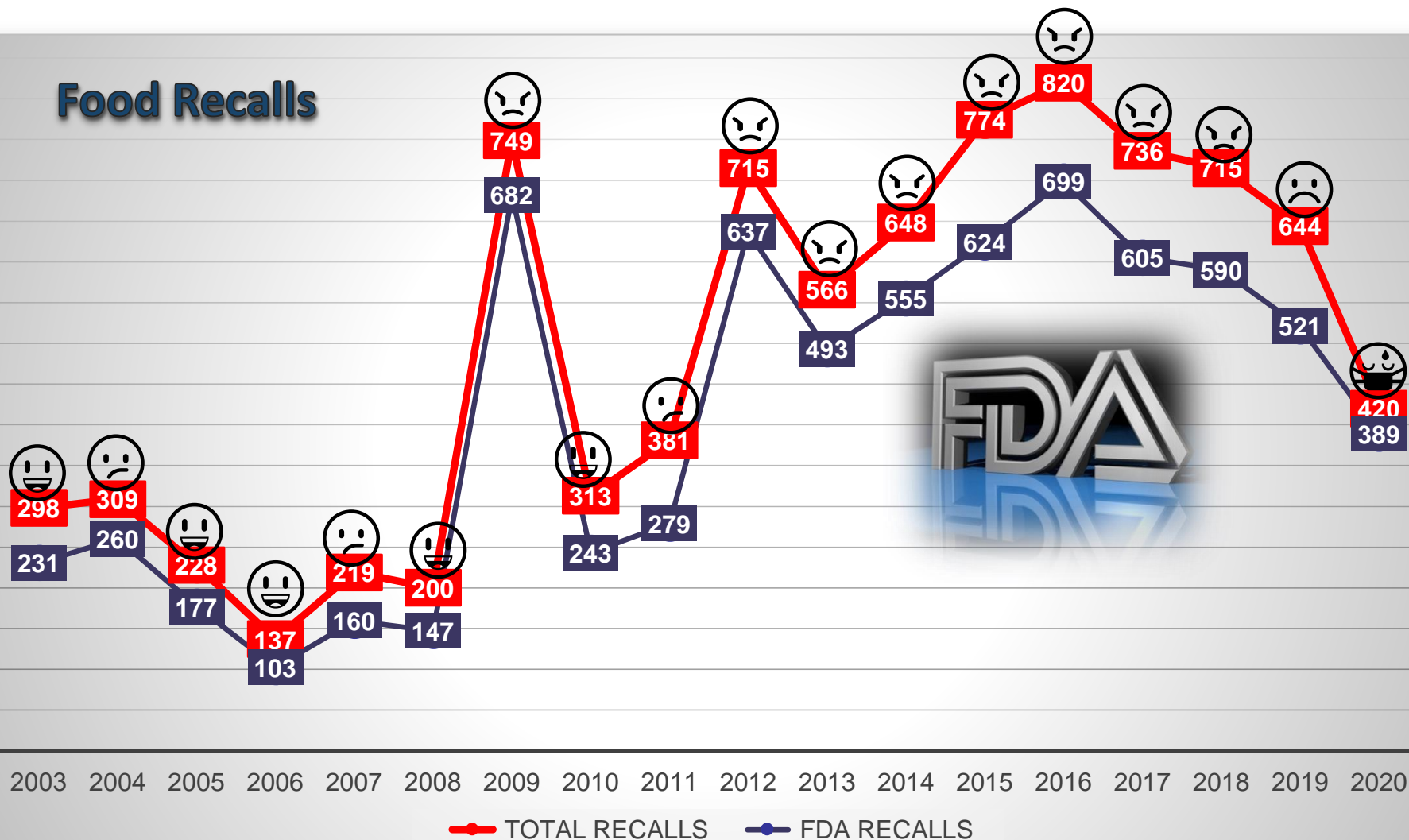
**3/10/19:**

**Bird foot – Chocolate cake**



**Bird foot – Chocolate cake**

# Food Recalls



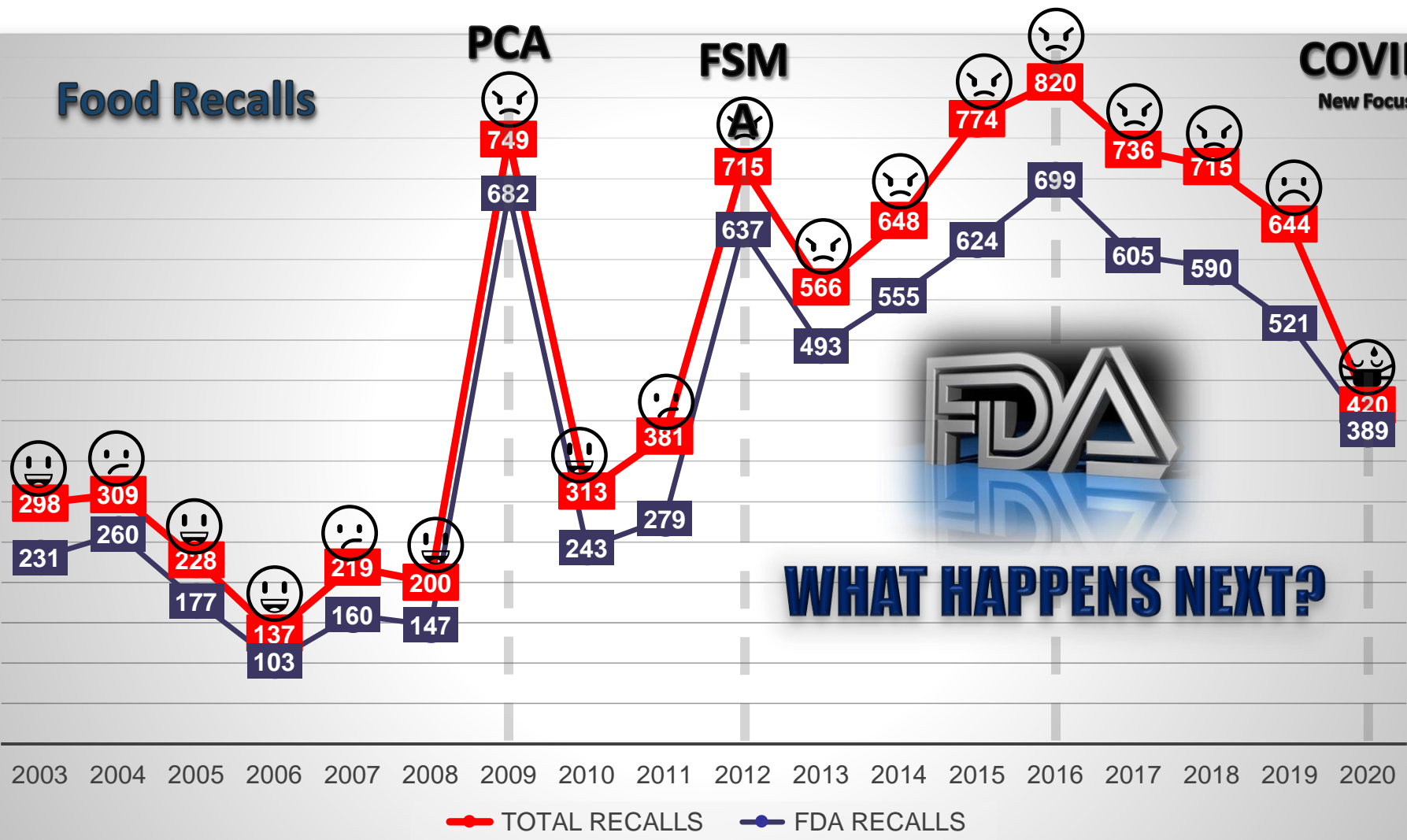
# SWAB-A-THONS

## Food Recalls

PCA

FSM

COVID  
New Focus



WHAT HAPPENS NEXT?





# FOOD RECALL SEARCH

## FOOD RECALL REPORTER

www.foodindustrycounsel.com/recalls



RECALLS BY YEAR		
2021	2013	2005
2020	2012	2004
2019	2011	2003
2018	2010	2002
2017	2009	2001
2016	2008	2000
2015	2007	
2014	2006	

**COVID**  
New Focus



644

521

### RECALL CLASS

- II 1
- III 1

Q finger tip X

Limit search to:  Company  Brand  Product

2 results found in 1ms

Items per page 25

### RECALL AGENCY

- FDA 2

### FOOD TYPE

- Human 2

Date	Company	Brand	Details	Product
10/03/2016	Mel-O Cream Donuts International. Inc.	Arrowhead, Hy-Vee, Mel-O	Finger Tip	Cinnamon Rolls, Shells, Ring Donut
04/01/2005	G.A. Food Service, Inc.	G.A. Food Service	Finger Tip	Potato Scramble Breakfast

### BIG 8 ALLERGENS

- Milk 1,167
- Soy 634
- Wheat/Gluten 579
- Tree Nuts 550
- Egg 506

### LLC

06/29/2021	Manna Pro Products, LLC	Flock Party	Salmonella	Quack Snacks Duck Treats
06/28/2021	Bazzini, LLC	Trader Joe's	Peanuts	Dark Chocolate Almond Butter Cups

# SWAB-A-THONS

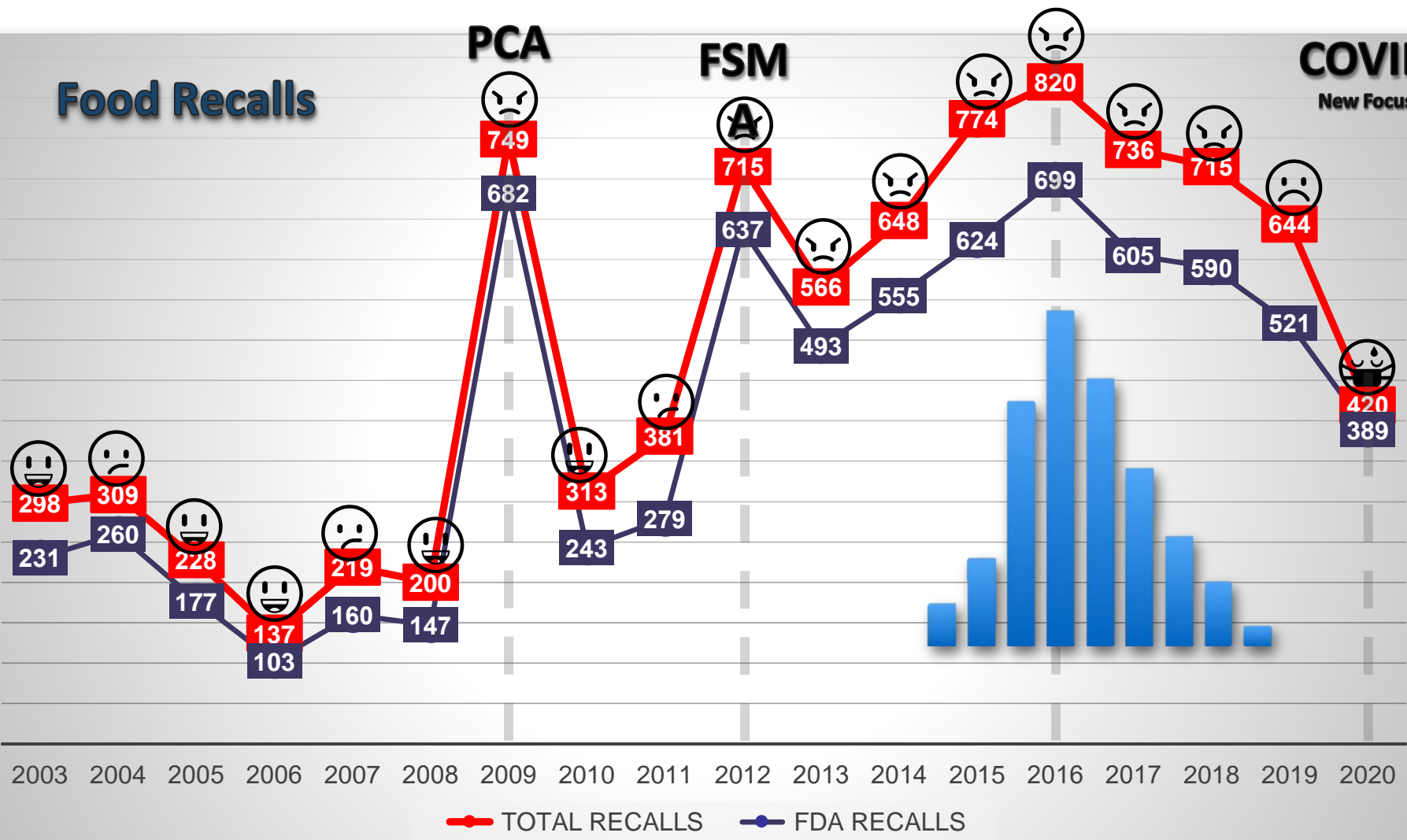
## Food Recalls

PCA

FSM

COVID

New Focus



# NEW RECALL / OUTBREAK PROFILE



# NEW RECALL / OUTBREAK PROFILE



July 2019

April 2021

**NEW RECALL / OUTBREAK PROFILE**

**PLAY FDA FOR A DAY**



**FDA AND PERSISTENCE**

**THREE STRIKES**



**AND YOUR OUT!!!**

# Food Safety Culture

**2020**  
**179 Class I Recalls**



# Food Safety Culture

**16,500,000 safe flights – and only 179 crashes**





# Food Safety Culture

## Safe Handling Instructions

*This product was prepared from inspected and passed meat and/or poultry. Some food products **may contain bacteria that could cause illness** if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.*



Keep refrigerated or frozen.  
Thaw in refrigerator or microwave.



Keep raw meat and poultry separate from other foods.  
Wash working surfaces (including cutting boards),  
utensils, and hands after touching raw meat or poultry.



Cook thoroughly.



Keep hot foods hot. Refrigerate leftovers  
immediately or discard.

# Food Safety Culture

As discussed in section II.C, *L. monocytogenes* is widespread in the environment, has been isolated from food packing and processing environments, and has been shown to persist in equipment and the processing environment in harborage sites. As a result, you should expect to detect the presence of *Listeria* spp. or *L. monocytogenes* on an occasional basis in environmental samples collected from your plant. As discussed in section XIII.A, the goals of an environmental monitoring program include finding *L. monocytogenes* and harborage sites if present in your plant and ensuring that corrective actions have eliminated *L. monocytogenes* and harborage sites when found in your plant. If you consistently see negative test results in environmental samples collected from your plant, we recommend that you revise your environmental monitoring procedures to add, substitute, or both add and substitute other surfaces in your plant for sample collection and testing to ensure you are not missing a source of contamination.

# Food Safety Culture



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# Food Safety Culture

YOU NEVER GET A  
**BE REAL**  
IMPRESSION.

# FOOD SAFETY CULTURE

## THREE “Cs”

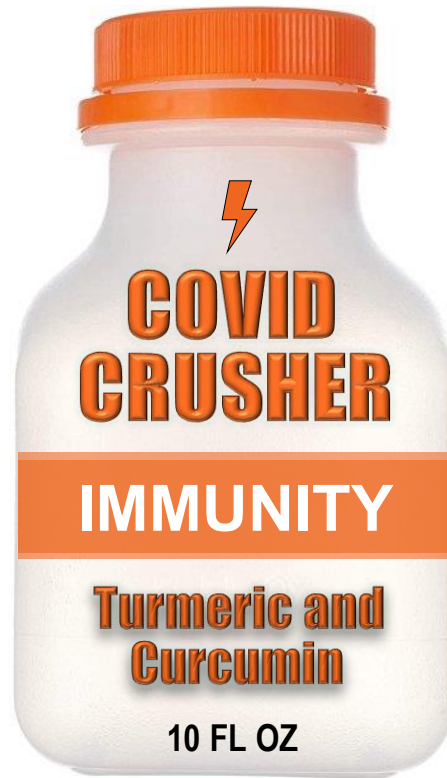


# FDA and CULTURE

Compassion  
Commitment  
Communication



# FDA AND LABELING



# FDA AND LABELING





# TRACEABILITY

**Affected Products**  
**CTEs and KTEs**  
**Requirements**

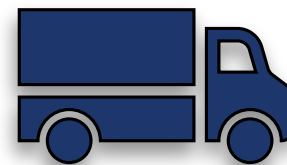
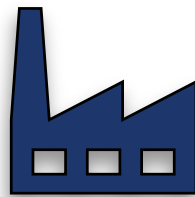
# TRACEABILITY

Foods	Description
Cheeses, other than hard cheeses	Includes all cheeses made with either pasteurized or unpasteurized milk, other than hard cheeses. Includes soft ripened/semi-soft cheeses (e.g., brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster) and soft unripened/fresh soft cheeses (e.g., cottage, chevre/goat, cream, mascarpone, ricotta, puna).
Shell eggs	Shell egg means the egg of the domestic fowl.
Nut butter	Includes all types of tree nut and peanut butter.
Cucumbers (fresh)	Includes all varieties of cucumbers.
Herbs (fresh)	Includes all types of herbs, such as parsley, basil, dill, and cilantro.
Leafy greens (fresh), including fresh-cut leafy greens	Includes all types of leafy greens, such as spinach, kale, collard greens, chicory, watercress, chard, arugula, and spring mix.
Melons (fresh)	Includes all types of melons, such as cantaloupe, honeydew, and watermelon.

Peppers (fresh)	Includes all varieties of peppers.
Sprouts (fresh)	Includes all varieties of sprouts.
Tomatoes (fresh)	Includes all varieties of tomatoes.
Tropical tree fruits (fresh)	Includes all types of tropical tree fruit, such as mango, papaya, mamey, guava, lychee, jackfruit, starfruit, etc.
Fruits and Vegetables (fresh-cut)	Includes all types of fresh-cut fruits and vegetables.
Finfish, including smoked finfish	Includes all finfish species, such as cod, haddock, Alaska pollock, tuna, mahi mahi, mackerel, grouper, barracuda, salmon, etc.; except does not include siluriformes fish, such as catfish [1]
Crustaceans	Includes all crustacean species, such as shrimp, crab, lobster, crayfish, etc.
Mollusks, bivalves	Includes all species of bivalve mollusks, such as oysters, clams, mussels, etc.; does not include scallop adductor muscle.
Ready-to-eat deli salads	Includes all types of ready-to-eat deli salads, such as egg salad, potato salad, pasta salad, seafood salad, etc.; does not include meat salads.

# TRACEABILITY

## CRITICAL TRACKING EVENT

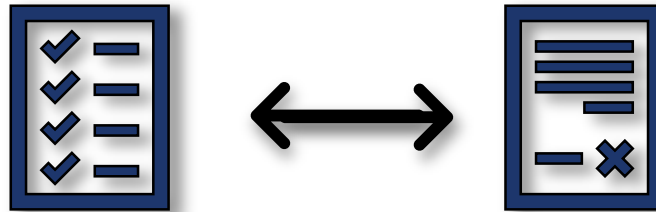


## KEY DATA ELEMENT

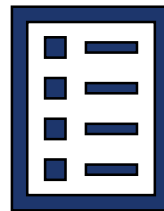


# TRACEABILITY

## REFERENCE RECORD



## TRACEABILITY LOT CODE/DESCRIPTION



# TRACEABILITY

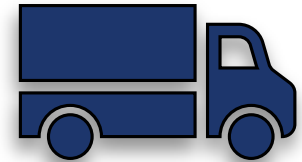
**Grower**



**Receiver**



**First Receiver**



**Transformer**

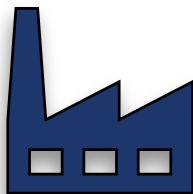
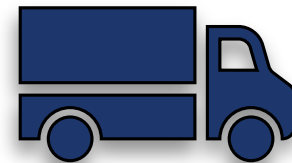
**[USING INGREDIENTS ON LIST]**

**Creator**

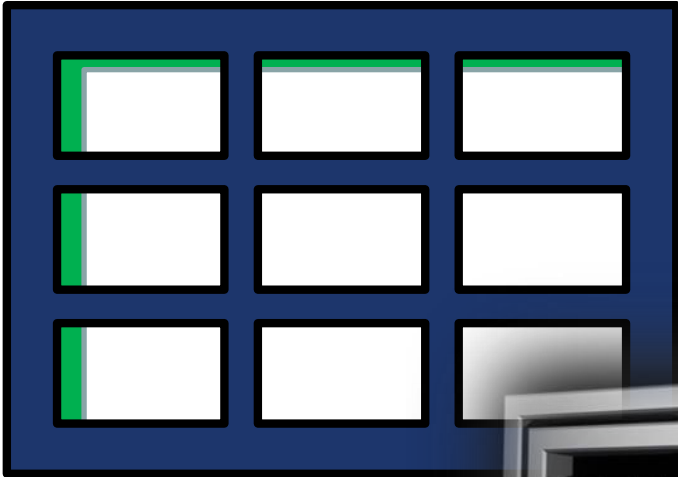
**[CREATING A PRODUCT ON LIST]**



**Shipper**



# TRACEABILITY



# FDA and INSPECTIONS

# REMOTE AUDITS



# REMOTE AUDITS





# SESAME STREET



# What Would 12 Jurors Think





# FoodIndustry

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