



# FSMA Full Enforcement Impact on Food Safety - Data Analysis, Stats, Trends, Challenges

**Moderator:** Allen Saylor, EAS Consulting Group, LLC, USA

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# Today's Presenters



**Glenn Bass**

*Deputy Director, Human and Animal Food Operations - West*  
**Office of Regulatory Affairs (ORA) at the Food and Drug Administration (FDA)**

In his current position, Glenn oversees and manages human and animal food programs regulated by the agency on behalf of the associate commissioner of operations. He serves as the central point within the agency through which directorates and other headquarters offices obtain field support services for food and feed activities and serves as the agency focal point in coordinating, directing, and assisting the field and headquarters offices with investigative food and feed activities. . He received his Bachelor of Arts in Biology from the College of Charleston, Master of Science in Administration from Central Michigan, and Bachelor of Science in Nursing from the University of Maryland. Glenn joined FDA in 200.



**Allen Saylor**

*Senior Director for Food Consulting Services*  
**EAS Consulting Group, LLC**

Allen has expertise in the areas of food processing, particularly in the area of dairy processing, infant formula, bakery products, food additives, botanical products and food packaging as well as GFSI Third-Party Certification programs such as Safe Quality Foods (SQF). With more than 35 years as a food processing and regulatory expert, including representing the US food processing industry at the Codex Committees on Food Additives, Food Labeling, Food Hygiene and Milk & Milk Products, Allen has held prestigious positions such as Vice President of Regulatory Affairs and International Standards at the International Dairy Foods Association as well acting chief for FDA's Milk Safety Branch and Assistant Dairy Commissioner for the North Dakota Department of Agriculture.

# Today's Presenters



**Loralyn H. Ledenbach**

*Principal Scientist in the Food Safety & Regulatory department*  
**Kraft Heinz Company**

Loralyn has worked for Kraft Heinz for 40 years and currently leads the company's HACCP and food safety programs. Much of her career has been spent working with product developers assessing microbial safety and stability for new products in the salad dressing, frozen entrée, pizza, natural cheese, and process cheese categories. She helped create the training curriculum for Better Process Control School for LACF Process Cheese, is a Lead Instructor and Trainer of Trainers for FSPCA Preventive Controls for Human Foods, and a Lead Instructor for FSPCA Foreign Supplier Verification Program and Intentional Adulteration Vulnerability Assessment courses. She received the IAFP Harold Barnum Industry Award in 2013 and the IAFP Fellow Award in 2018.



**William Marler, Esq**

**Marler Clark, The Food Safety Law Firm**

An accomplished attorney and national expert in food safety, William (Bill) Marler has become the most prominent foodborne illness lawyer in America and a major force in food policy in the U.S. and around the world. Marler Clark, The Food Safety Law Firm, has represented thousands of individuals in claims against food companies whose contaminated products have caused life altering injury and even death.



# U.S. Food and Drug Administration

Glenn Bass, Deputy

Office of Human and Animal Food  
Operations-West

Office of Regulatory Affairs

U.S. Food & Drug Administration | FDA

**IAFP:** Conducting Inspections, Investigations, Sample  
Collections During the COVID-19 Pandemic

September 29, 2020



## Conducting Inspections, Investigations, Sample Collections During the COVID-19 Pandemic

- Mission Critical Inspections
- Prioritized Domestic Surveillance Inspections
- State Contract Inspections



- Week of March 16, 2020; Suspended all **surveillance** inspections ( domestic & Foreign)
- June 17, 2020: Lifted Stop Work Order- for state contracts
- Week of July 10, 2020 – FDA resumed **prioritized surveillance domestic** inspections



## Conducting Inspections, Investigations, Sample Collections and State Program Evaluations During the COVID-19 Pandemic

### COVID-19 Advisory Matrix

1. Red
2. Yellow
3. Green



## Conducting Inspections, Investigations, Sample Collections and State Program Evaluations During the COVID-19 Pandemic

### ***ORA Field Instructions:***

- *You are FDA's greatest resource.*
- *Take care of yourself first.*
- *If you feel you are at risk, get out and get safe.*
- *Afterwards and as soon as you can, contact your supervisor.*



## Conducting Inspections, Investigations, Sample Collections and State Program Evaluations During the COVID-19 Pandemic

### **Assignment Process:**

- Pre-Assignment:
- During Assignment:
- Close Out and Post Assignment:

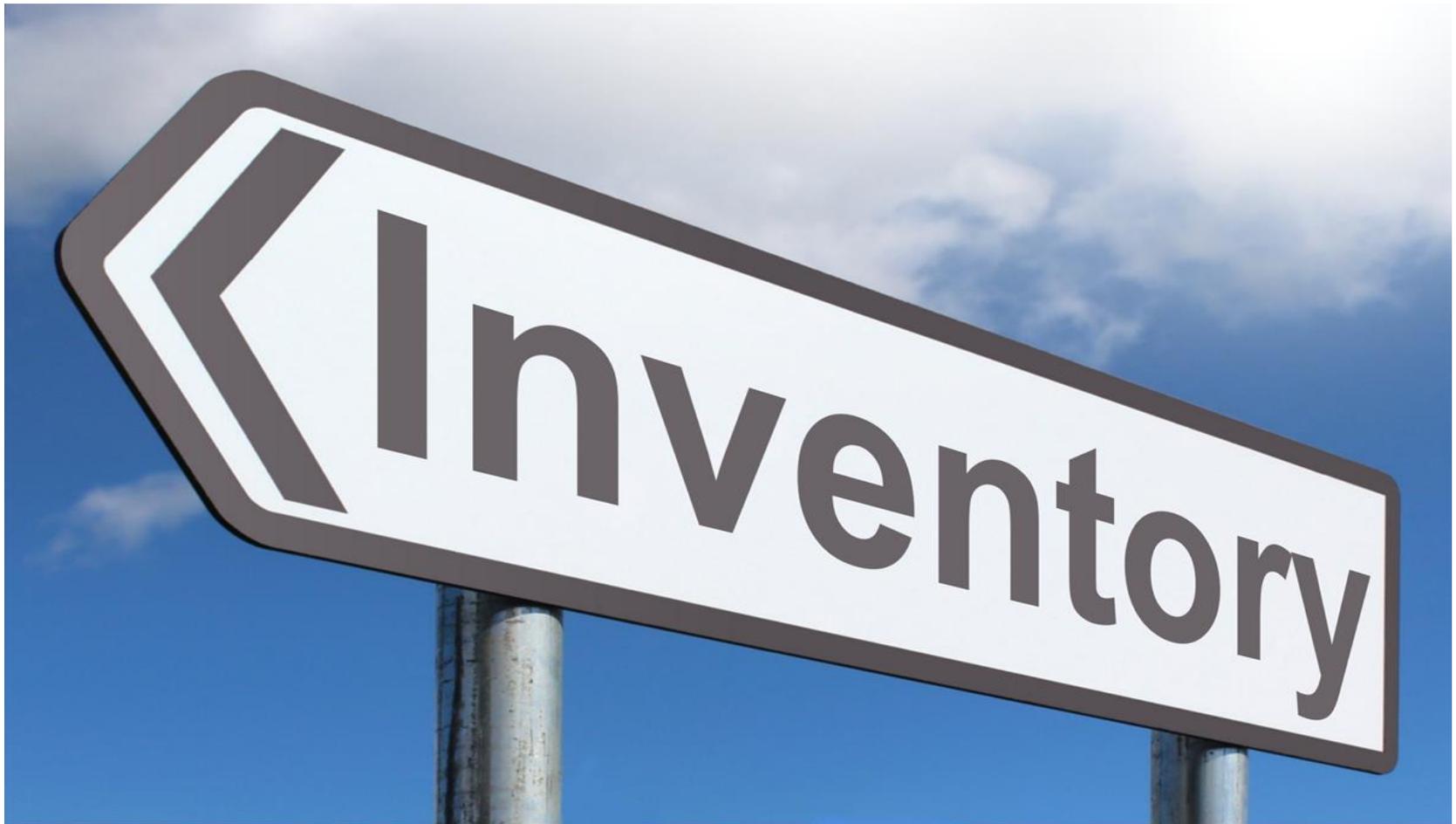
# Challenges



# Challenges



# FY 20 Accomplishments



# FY 20 Accomplishments



# New Tools







# EAS Consulting Group

## Full Enforcement Trends Driven by FSMA

**Allen R. Sayler, Senior Director of Food Consulting Services**  
**EAS Consulting Group, Alexandria, Virginia**  
**571-447-5509    [asayler@easconsultinggroup.com](mailto:asayler@easconsultinggroup.com)**

*Respected • Experts • Ethical • with Integrity*

# Allen Saylor

## EAS Senior Director for Food Consulting Services



### Career History:

- 16 years of state, FDA and USDA food safety & food processing regulatory experience
- 21 years working as a regulatory advisor and consultant to the food manufacturing industry.
  - 12 years as VP of Regulatory Affairs and International Standards at the International Dairy Foods Association
  - 5 years running my own regulatory consulting company – CFSRS
  - 3 years with EAS
- Served in leadership positions at IAFP, 3-A SSI, Dairy Practices Council, IDF, etc.
- Numerous professional awards while at FDA, USDA and from professional organizations

# 2021 FDA Fiscal Year Food Budget

\$ in Thousands	FY 2019 Enacted		FY 2019 Actuals		FY 2020 Enacted		FY 2021 President's Budget		FY 2021 President's Budget +/- From FY 2020	
	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000
<b>Foods</b>	3,758	1,077,612	3,758	1,059,926	3,863	1,099,970	3,934	1,127,941	71	27,971
<b>Budget Authority</b>	3,758	1,066,741	3,758	1,059,926	3,819	1,088,881	3,838	1,090,530	19	1,649
<b>User Fees</b>	---	10,871	---	---	44	11,089	96	37,411	52	26,322
<b>Center</b>	1,097	335,244	1,097	327,462	1,144	342,815	1,209	371,490	65	28,675
<b>Budget Authority</b>	1,097	334,412	1,097	327,462	1,141	341,966	1,154	344,524	13	2,558
<b>User Fees</b>	---	832	---	---	3	849	55	26,966	52	26,117
<b>Food and Feed Recall</b>	---	243	---	---	1	248	1	253	---	5
<b>VQIP</b>	---	243	---	---	1	248	1	253	---	5
<b>Third Party Auditor Program</b>	---	346	---	---	1	353	1	360	---	7
<b>Innovative Food Products (Proposed)</b>	---	---	---	---	---	---	52	26,100	52	26,100
<b>Field</b>	2,661	742,368	2,661	732,464	2,719	757,155	2,725	756,451	6	-704
<b>Budget Authority</b>	2,661	732,329	2,661	732,464	2,678	746,915	2,684	746,006	6	-909
<b>User Fees</b>	---	10,039	---	---	41	10,240	41	10,445	---	205
<b>Food and Feed Recall</b>	---	1,000	---	---	4	1,020	4	1,040	---	20
<b>Food Reinspection</b>	---	4,575	---	---	19	4,667	19	4,760	---	93
<b>Voluntary Qualified Importer Program</b>	---	4,320	---	---	18	4,406	18	4,495	---	89
<b>3<sup>rd</sup> Party Auditor Program</b>	---	144	---	---	---	147	---	150	---	3



## June 2, 2020 Pandemic Challenges Highlight the Importance of the New Era of Smarter Food Safety



New Era of Smarter Food Safety Blueprint - The FDA will release the blueprint in the coming weeks, outlining our plans over the next decade to create a more digital, traceable, and safer food system. The challenges that have arisen during the pandemic have made it clear that the actions called for in the blueprint will strengthen how we approach the safety and security of the food supply, not just in the normal course of events but especially in times of crisis.

Emerging technologies, such as blockchain, make it easier to track and trace products through the supply chain – from the time that they are grown or manufactured, until purchased by a consumer, and back through the supply chain. When the agency originally developed the blueprint, we knew that these new technologies could be game changers in facilitating a more rapid traceback of a contaminated food to its source in the event of a foodborne outbreak. In other words, we believe a digitized food system is likely to be a stronger, more agile, and resilient food system.

## June 2, 2020 Pandemic Challenges Highlight the Importance of the New Era of Smarter Food Safety



The blueprint calls for the use of smarter tools, such as root cause analyses to understand how a food became contaminated and predictive analytics that use data to anticipate the likelihood of contamination. And it also calls for other new tools to be explored, such as virtual or remote inspections (which we started as a result of the pandemic), which would have been invaluable in the current public health emergency.

Partnership is a theme woven throughout the New Era Blueprint – and our partners stepped up in a big way during this crisis. The collaboration between government and industry especially was raised by many magnitudes. . . . positive impact of partnerships between the FDA and our local and state regulatory and public health counterparts, and the strength of relationships between federal partners – including the Centers for Disease Control and Prevention, the U.S. Department of Agriculture, and the Occupational Safety and Health Administration – and the food industry. We all have the same goals: to ensure that consumers have access to the foods they need and to protect the food industry workers who have made that possible.

## September 23, 2020 – Publication of the FDA Requirements for Additional Traceability Records for Certain Foods



Today, the U.S. Food and Drug Administration (FDA) announced a proposed rule “Requirements for Additional Traceability Records for Certain Foods” which mandates traceability recordkeeping requirements for certain foods. The Traceability Regulation will be the final component of FSMA and a key component of the FDA “New Era of Smarter Food Safety Blueprint”, when finalized. The proposed rule would implement Section 204(d) of the FDA Food Safety Modernization Act (FSMA). The “Food Traceability List,” describes foods that would be subject to the proposed requirements with the option of FDA adding to or deleting from this list.

FDA’s proposed rule lays the foundation for a standardized approach to traceability recordkeeping, paving the way for industry to adopt, harmonize, and leverage digital traceability systems in the future. With improved traceability, the source of contaminated products and foodborne illnesses would be identified more quickly, reducing FDA’s and the industry’s resource investment, time investment and hopefully, lower the foodborne illness risk to the American consumer. It could also provide more timely root-cause investigations and more certainty to the source and circumstances of the contamination to prevent future outbreaks.

## September 23, 2020 –Traceability Records - Certain Foods List



- Cheeses, other than hard cheeses and Includes all soft ripened or semi-soft cheeses, and fresh soft cheeses that are made with pasteurized or unpasteurized milk
- Shell eggs
- Nut butter Includes all types of tree nut and peanut butters; does not include soy or seed butters
- Cucumbers Includes all varieties of cucumbers
- Herbs (fresh) Includes all types of herbs, such as parsley, cilantro, basil
- Leafy greens, including freshcut leafy greens including lettuce, (e.g., iceberg, leaf and Romaine lettuces), kale, chicory, watercress, chard, arugula, spinach, pak choi, sorrel, collards, and endive
- Melons Includes all types of melons, such as cantaloupe, honeydew, and watermelon
- Peppers Includes all varieties of peppers
- Sprouts Includes all varieties of sprouts
- Tomatoes Includes all varieties of tomatoes
- Tropical tree fruits such as mango, papaya, mamey, guava, lychee, jackfruit, and starfruit
- Fruits and Vegetables (fresh-cut)
- Finfish, including smoked finfish such as cod, haddock, Alaska pollack, tuna, mahi mahi, mackerel, grouper, barracuda, and salmon; except does not include siluriformes fish, such as catfish
- Crustaceans Includes all crustacean species, such as shrimp, crab, lobster, and crayfish
- Mollusks, bivalves such as oysters, clams, and mussels; does not include scallop adductor muscle.
- Ready-to-eat deli salads

# FDA Food Recalls 2012 - 2020

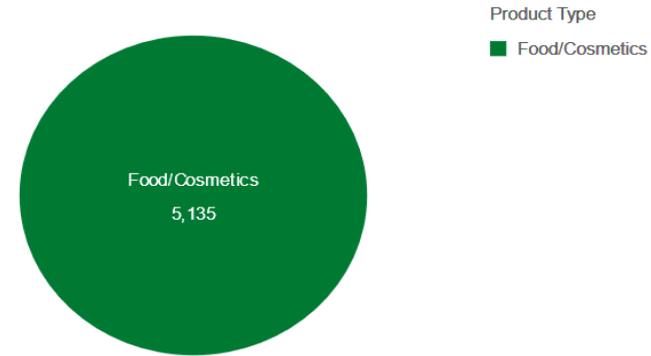
**Recall Events by Fiscal Year**

Fiscal Years: 2012 - 2020



**Recall Events by Product Type**

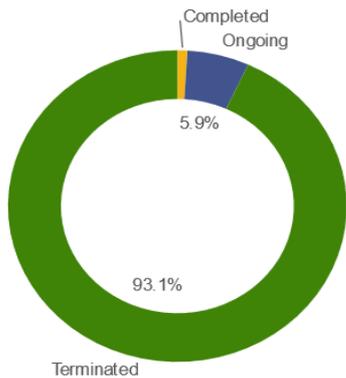
Fiscal Years: 2012 - 2020



Export

**Recall Events by Status**

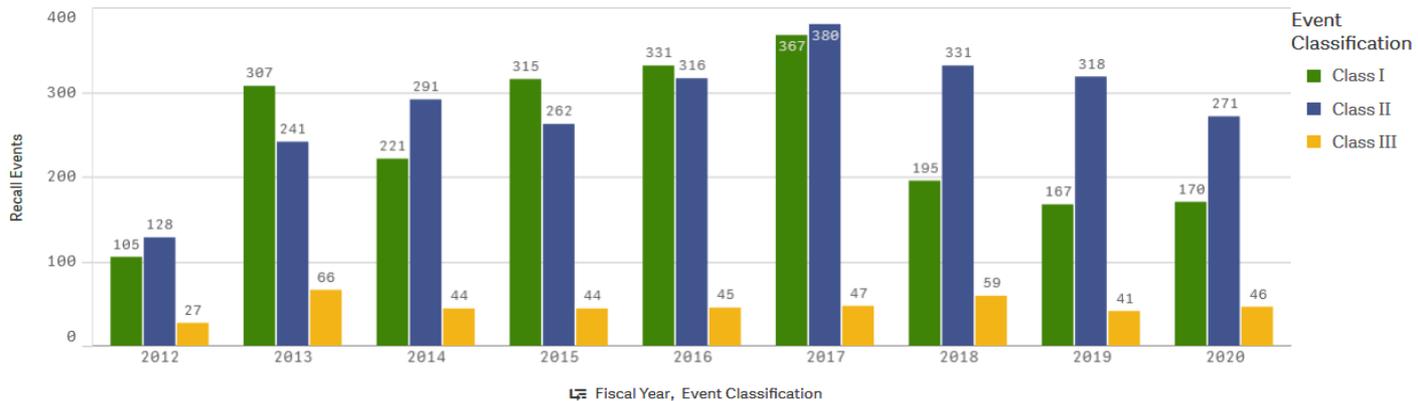
Fiscal Years: 2012 - 2020



Export

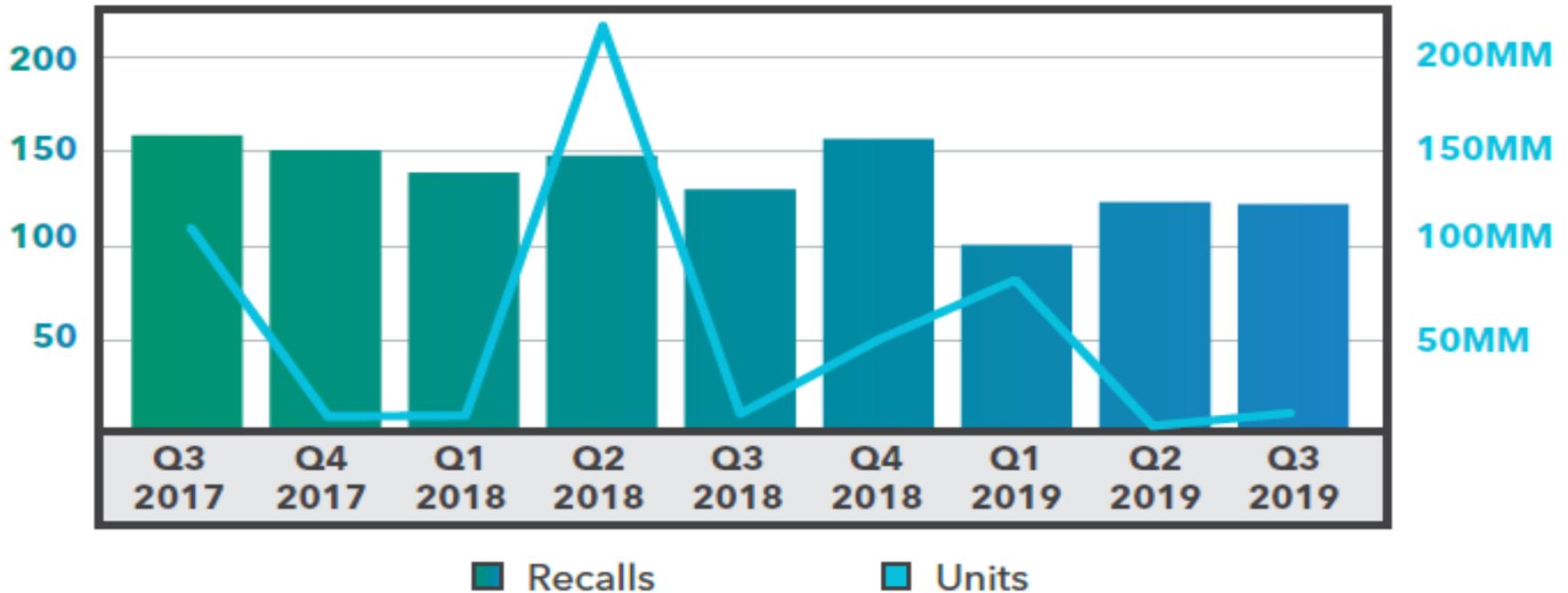
**Recall Events by Classification**

Fiscal Years: 2012 - 2020



# FDA Food Recalls By Product Classification 2018 – 2019 (Source – Stericycle)

## FDA FOOD RECALLS & UNITS



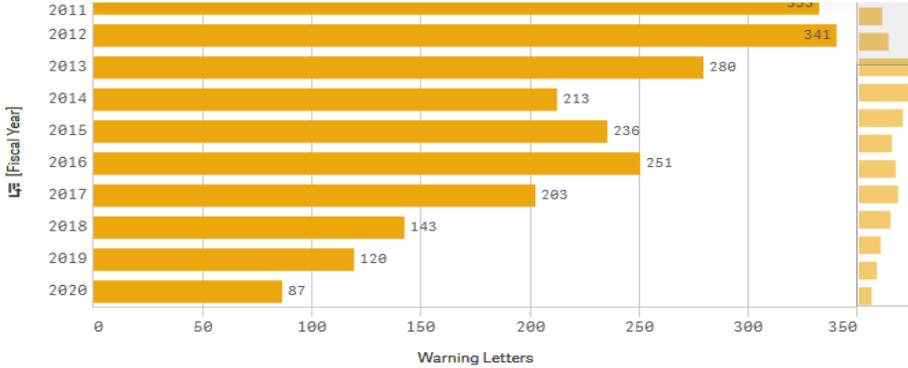
Seafood was the second highest category recalled by pounds, accounting for **22.6%** of recalled pounds.

# FDA Enforcement Actions

<b>Compliance Actions:</b>	Warning Letters 2,552	+	Injunctions 90	+	Seizures 40	<b>All Actions 2,682</b>
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**Warning Letters by Fiscal Year**

Fiscal Years: 2009 - 2020



**Injunctions and Seizures by Fiscal Year**

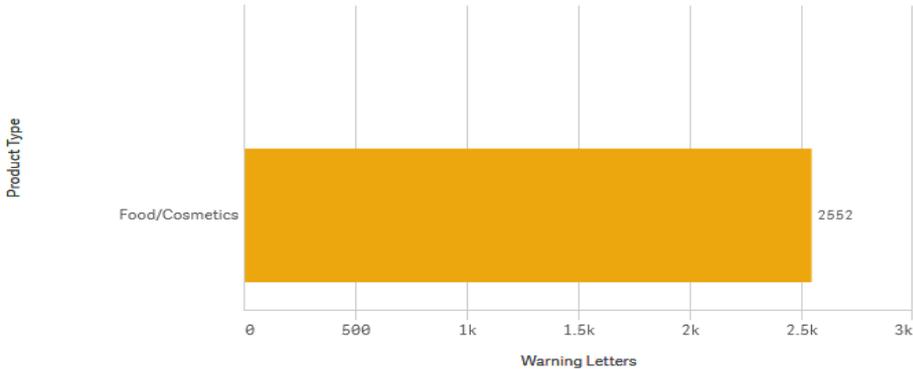
Fiscal Years: 2009 - 2020



<b>Actions by Product Type:</b>	Biologics 0	+	Devices 0	+	Drugs 0	+	Food / Cosmetics 2,682	+	Tobacco 0	+	Veterinary 0	<b>All Actions 2,682</b>
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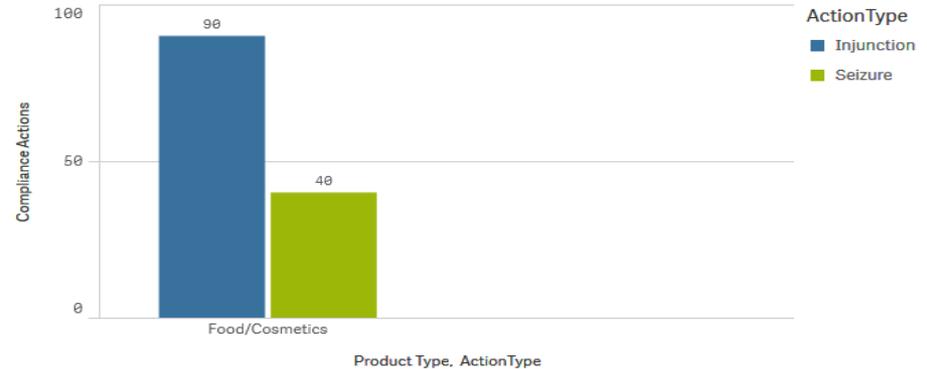
**Warning Letters by Product Type**

Fiscal Years: 2009 - 2020



**Injunctions and Seizures by Product Type**

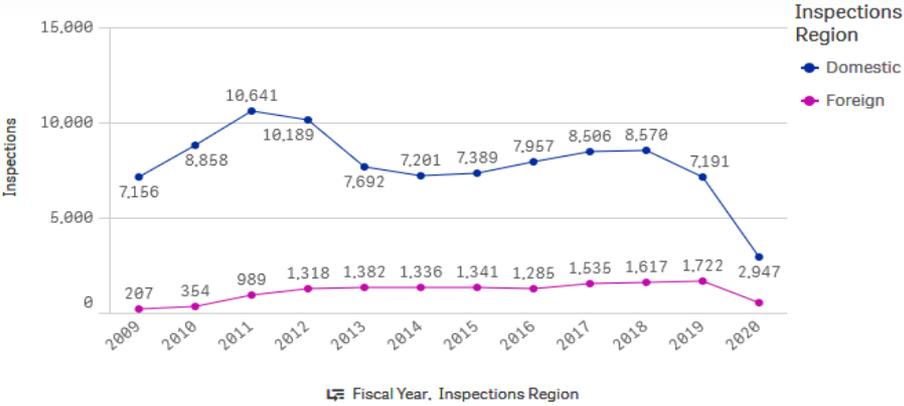
Fiscal Years: 2009 - 2020



# FDA Enforcement Actions

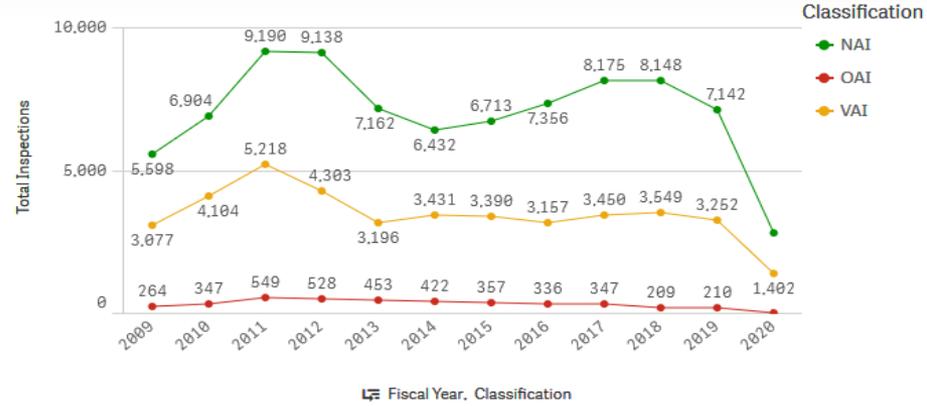
**Foreign and Domestic Inspections**

Fiscal Years: 2009 - 2020



**Inspections Classification by Fiscal Year**

Fiscal Years: 2009 - 2020



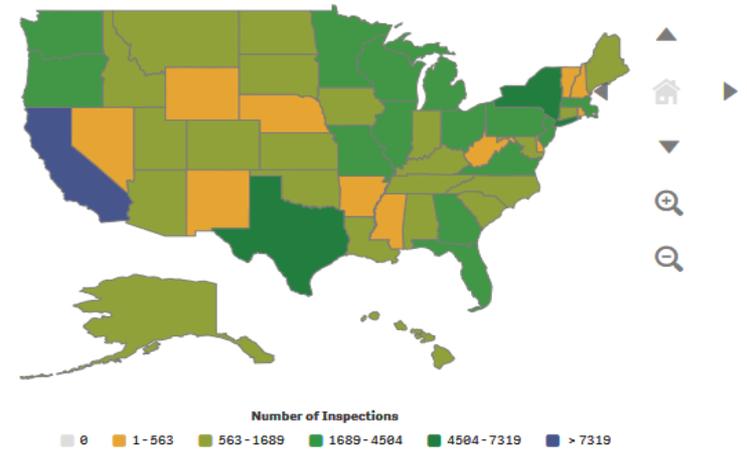
**Inspections Classification by Product Type**

Fiscal Years: 2009 - 2020



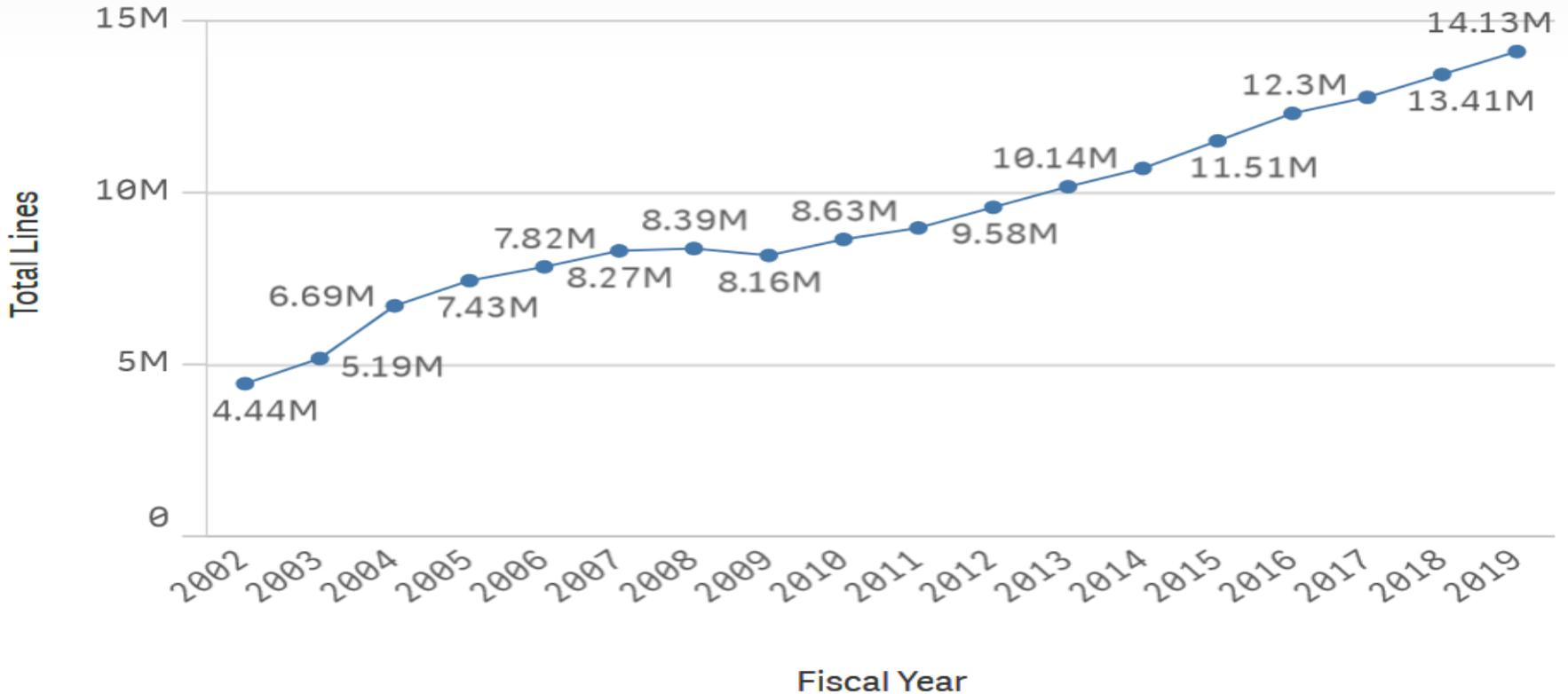
**Domestic Inspections**

Total: 112,607



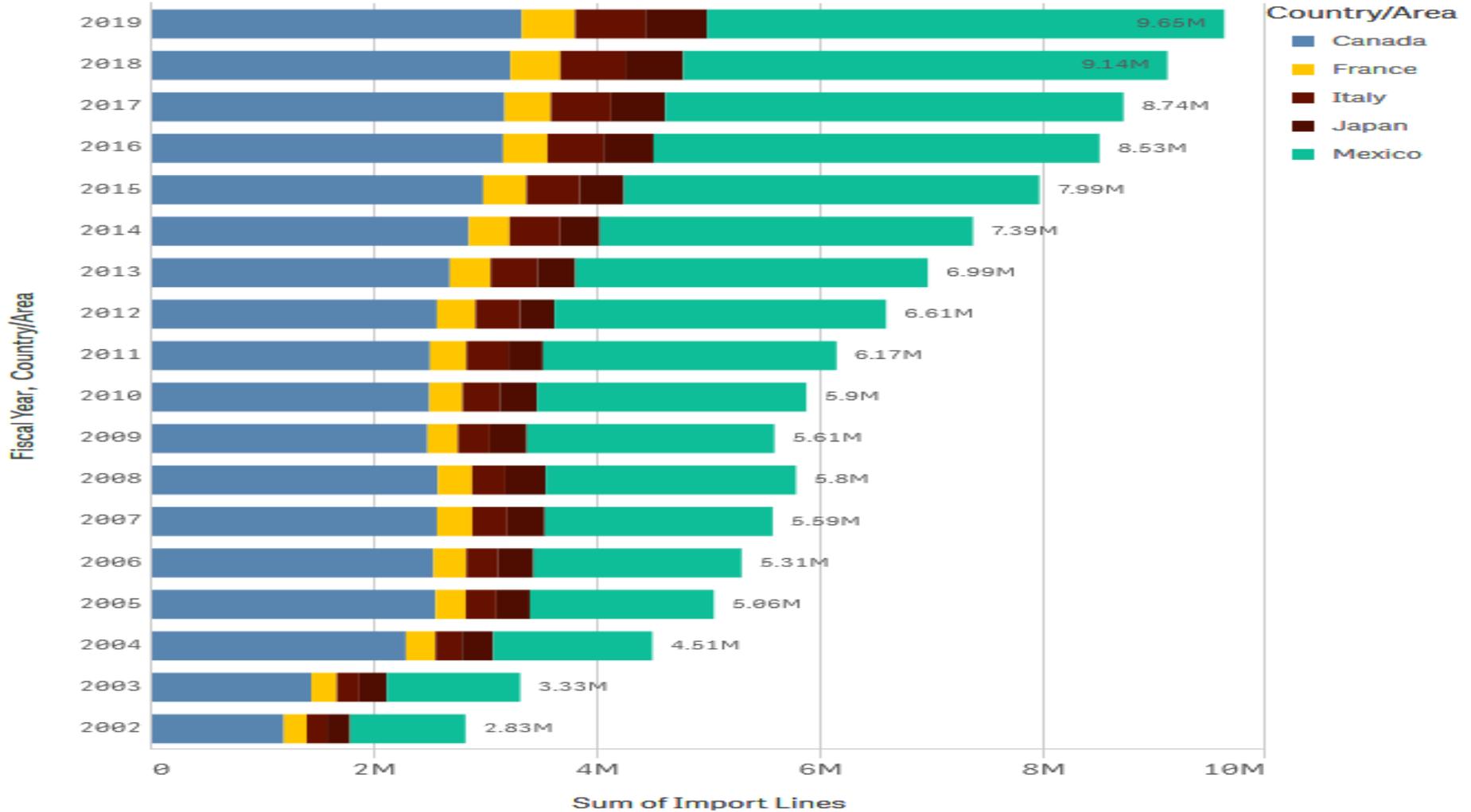
## Total Lines\* of Products Imported by Fiscal Year

Fiscal Years: 2002 - 2019



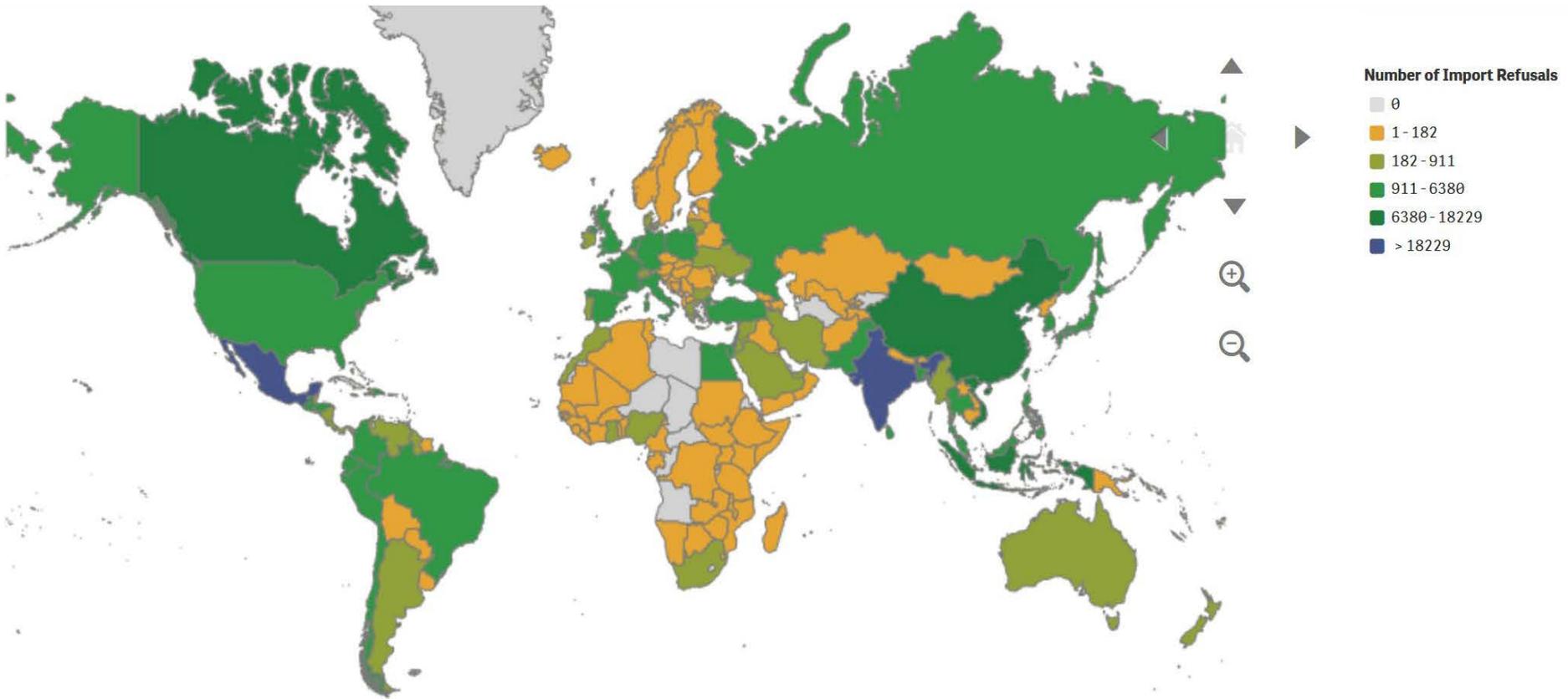
\*A line is a distinct product within a shipment. A single shipment may include multiple lines.

**Top 5 Manufacturing Countries - Import Lines by Fiscal Year**  
Fiscal Years: 2002 - 2019

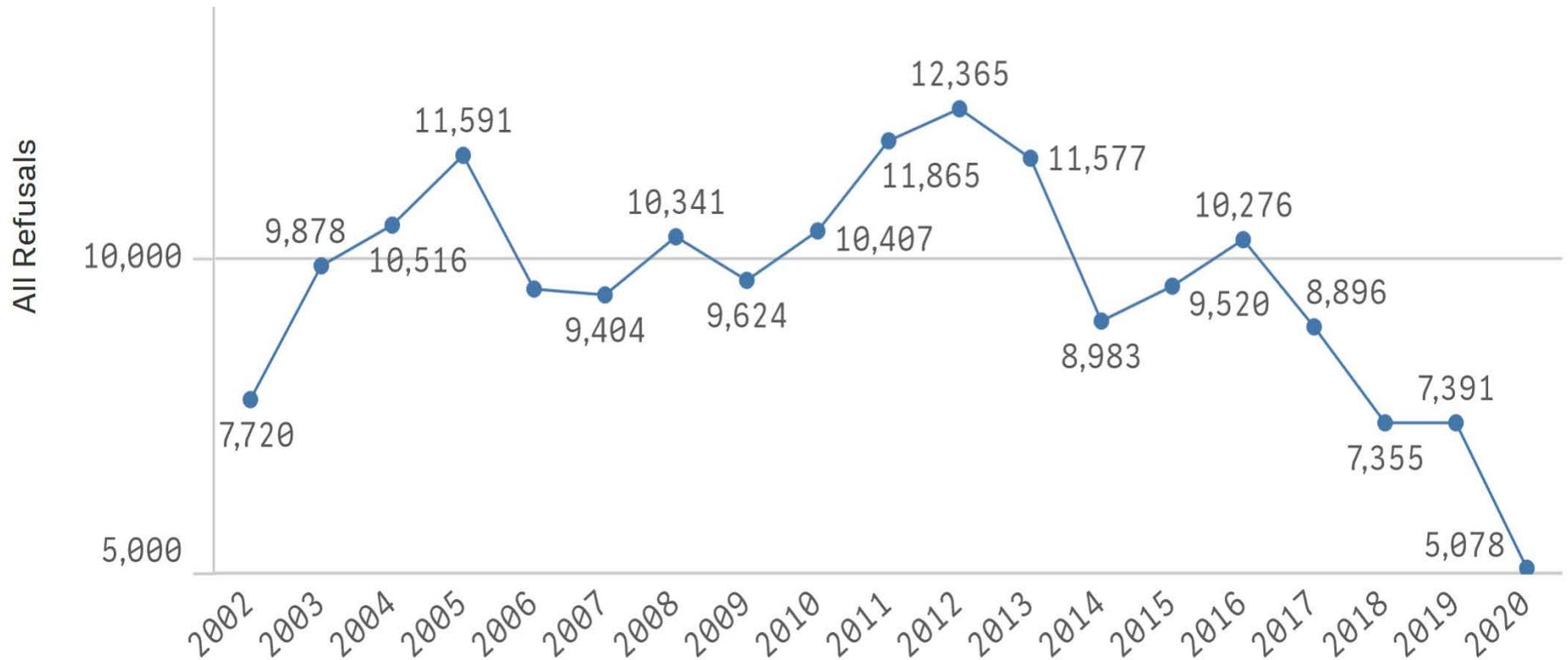


# FDA Food Import Refusals by Country – FY 2020

## Human Foods - 182,286



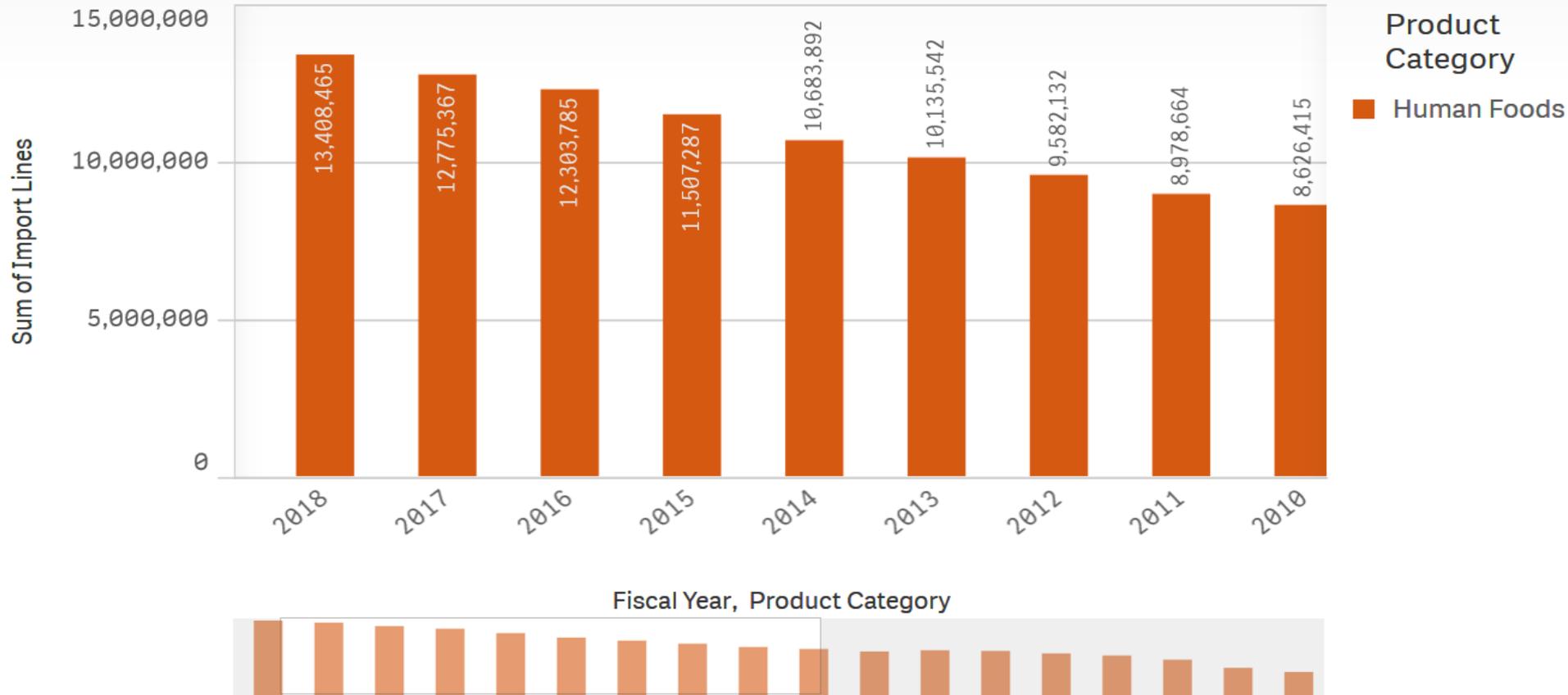
## TOTAL FOOD PRODUCT REFUSALS BY US GOVERNMENT FISCAL YEAR



# FDA Food Import Enforcement Actions – 2010 – 2019

## Total Import Lines by Product Category

Fiscal Years: 2002 - 2019

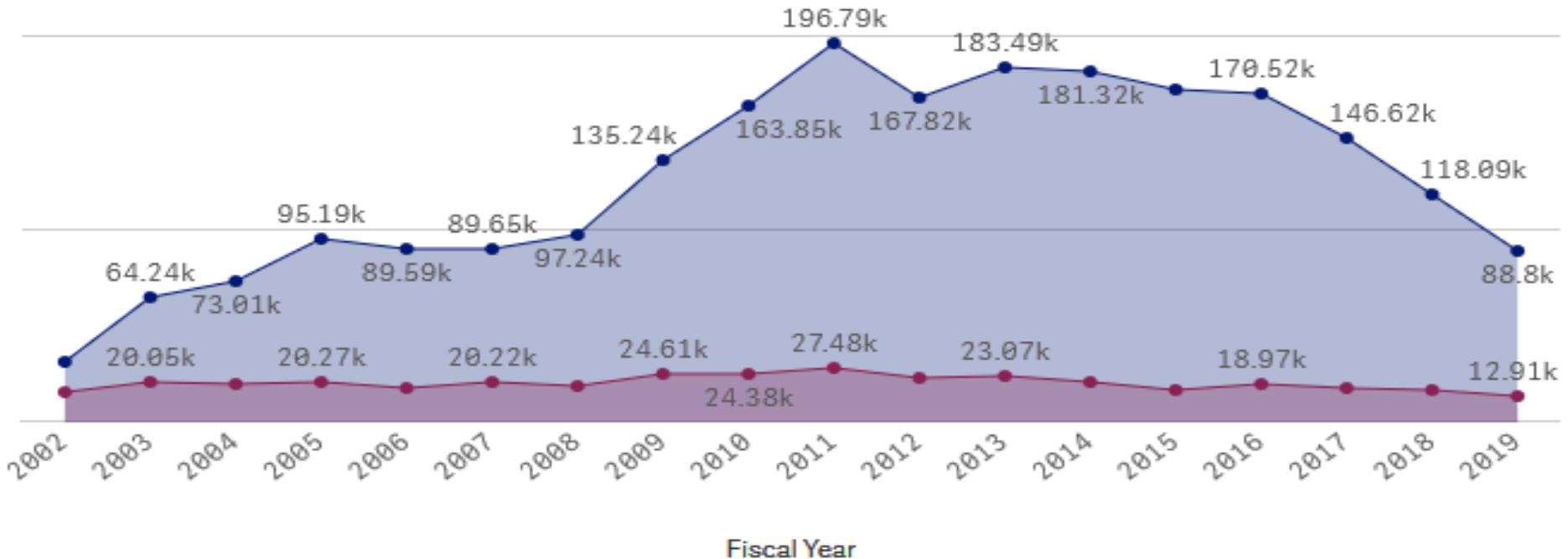


# FDA Food Import Enforcement Action

## Examined and Sampled Line Totals by Fiscal Year

Fiscal Years: 2002 - 2019

Measures ● ExaminedLines ● SampledLines

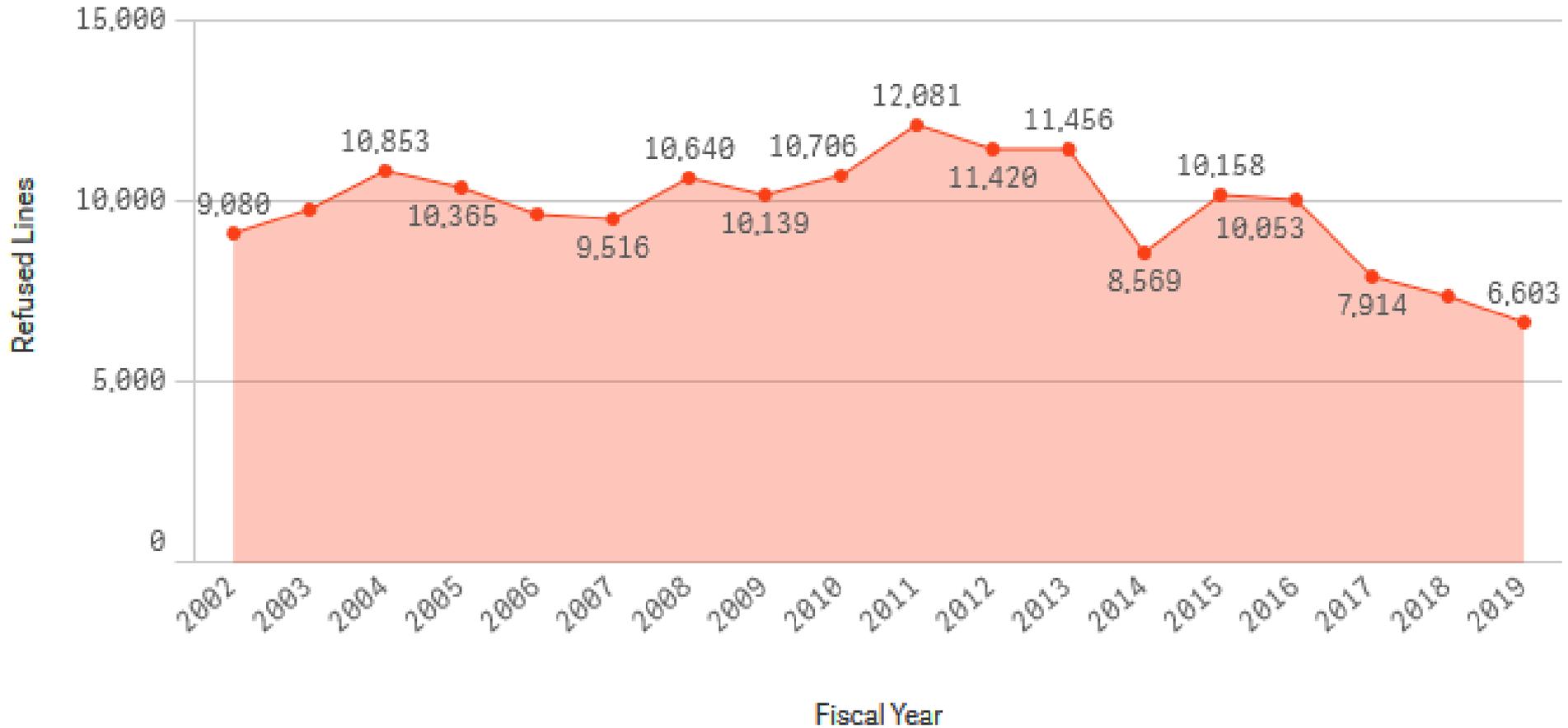


## Refused Line Totals by Fiscal Year

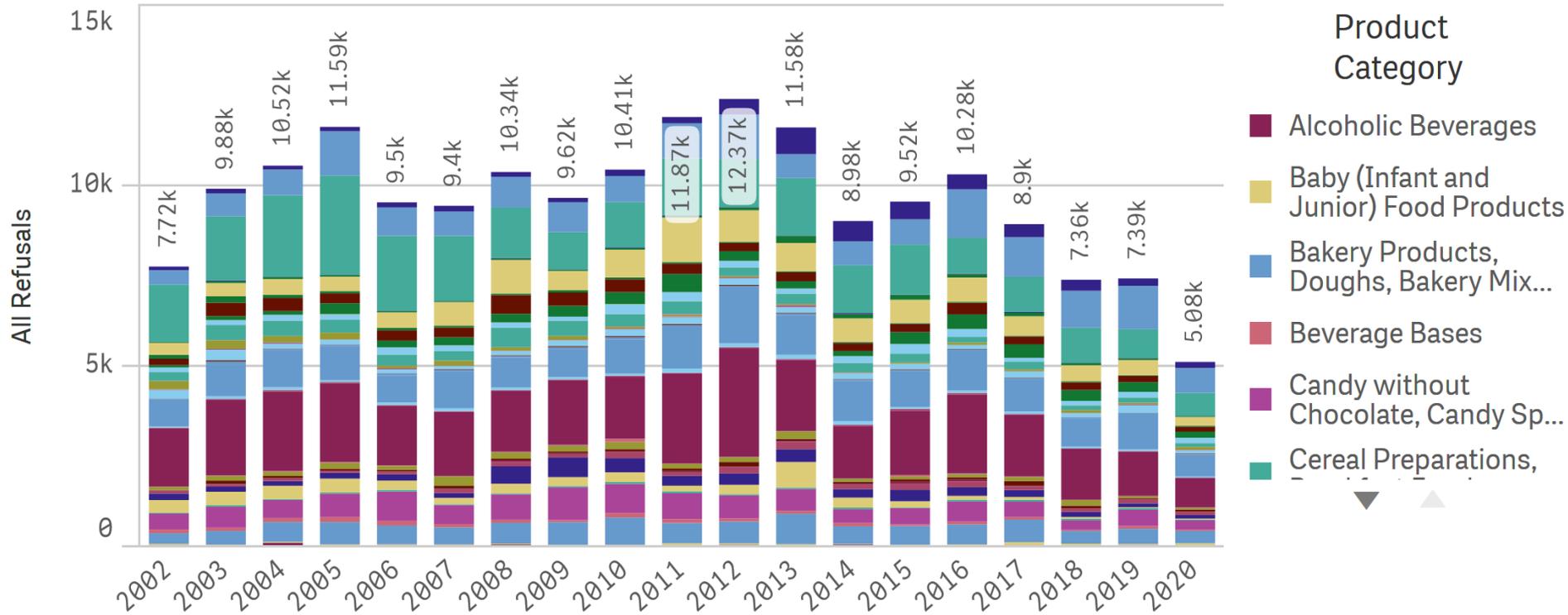
Fiscal Years: 2002 - 2019

### Refused Line Totals by Fiscal Year

Fiscal Years: 2002 - 2019



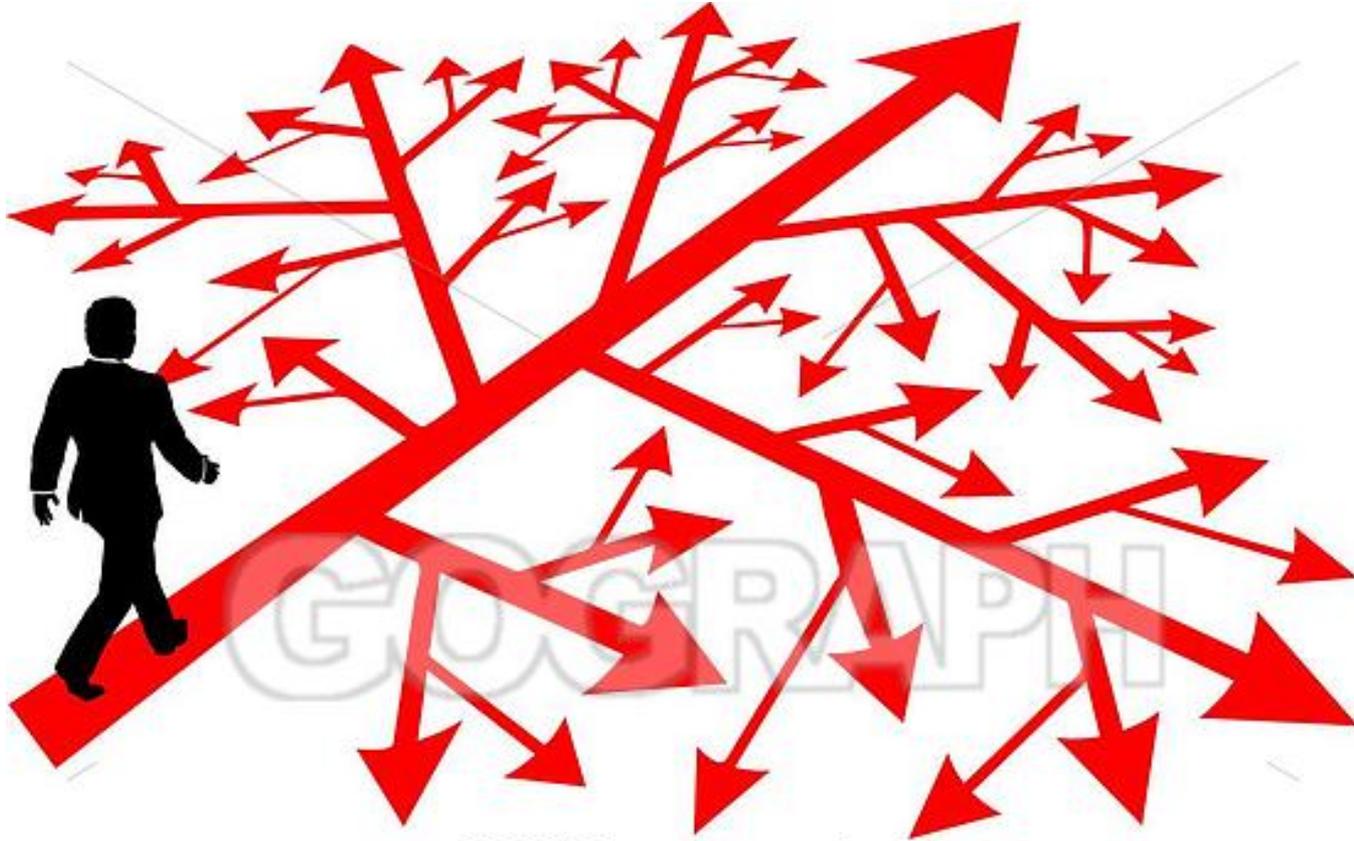
# FDA Food Import Refusals by Product



## Highest Food Category Import Refusals:

- Vit., Min., Protein & Diet. Suppl. (light blue)
- Vegetable Products (green)
- Fruit Products (middle blue grey)
- Seafood (red)
- Candy (no chocolate) & Chewing Gum (bottom pink)
- Bakery doughs, mixes & icings (bottom blue-grey)

## What Does This Data Mean for the Future?





THE KRAFT HEINZ COMPANY

## **Measuring the Value of FSPCA Training Efforts: Challenges and Lessons Learned**

Loralyn Ledenbach

IAFP 2020

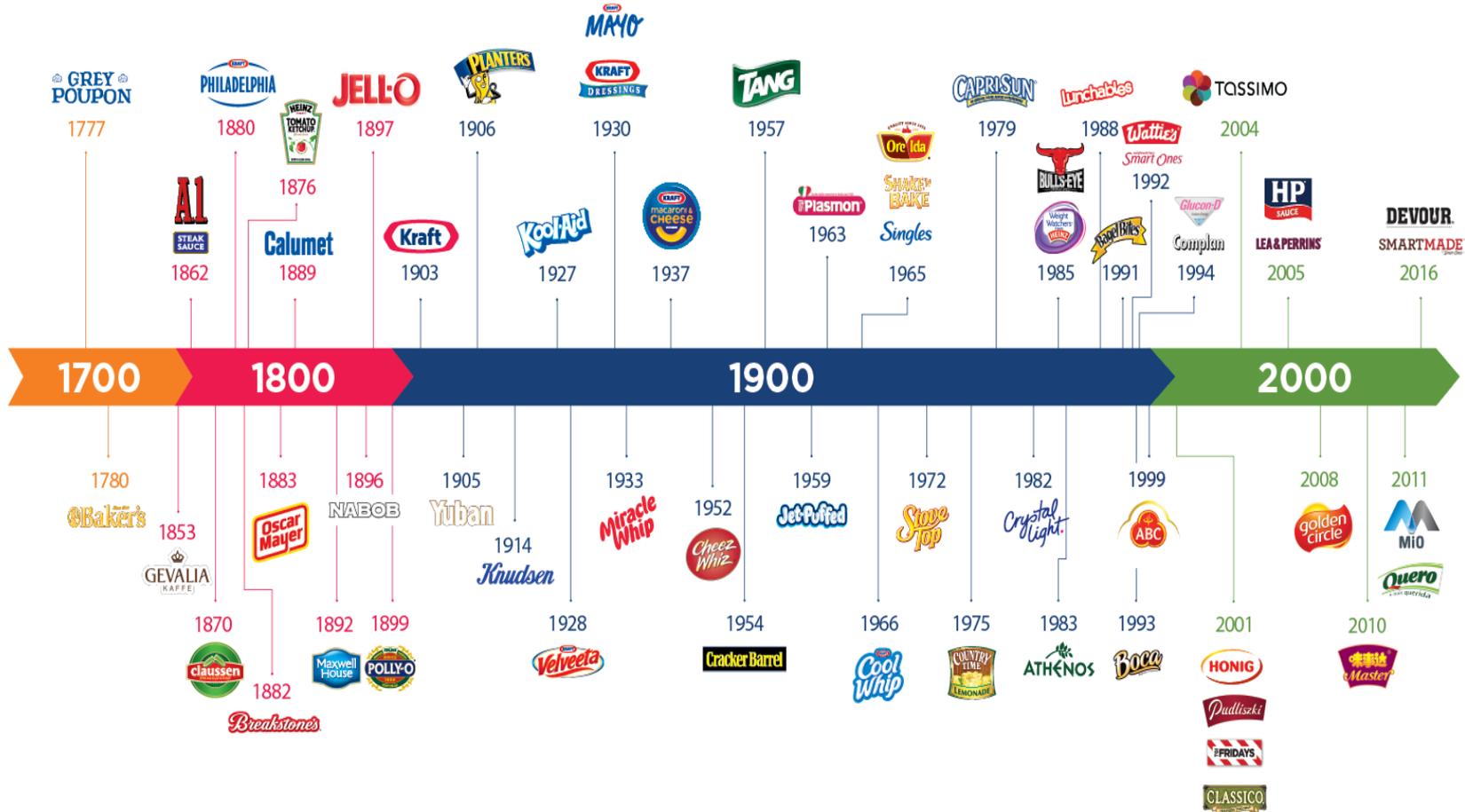
## About Kraft Heinz

### A Global Food Powerhouse

- 3<sup>rd</sup> largest North American food and beverage company
- #1 Food Service company in North America



# About Kraft Heinz



## About Me: Lori Ledenbach

- Principal Scientist
- 40 years at Kraft Heinz in Food Safety and Microbiology
- FSPCA lead instructor for PCHF, FSVP, and IAVA

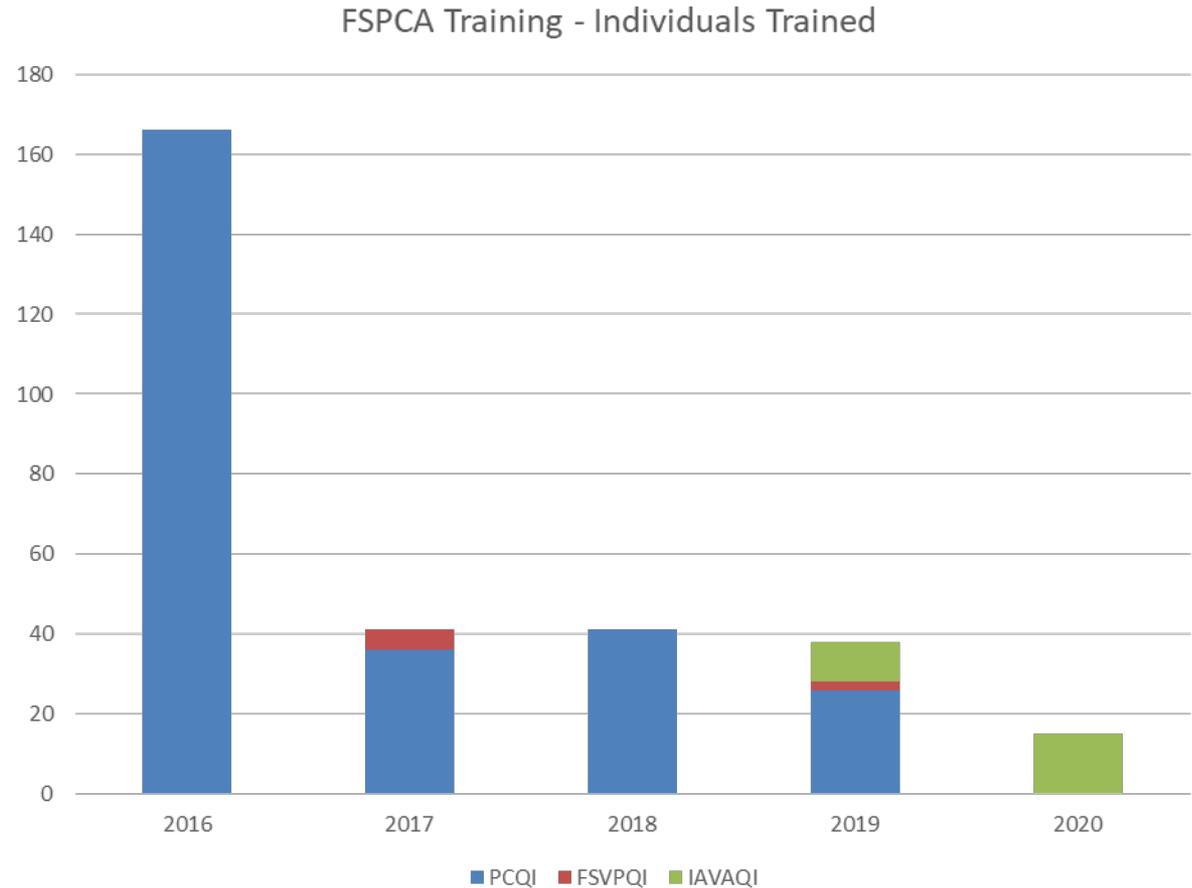


## FSPCA Training Efforts



# FSPCA Internal Training

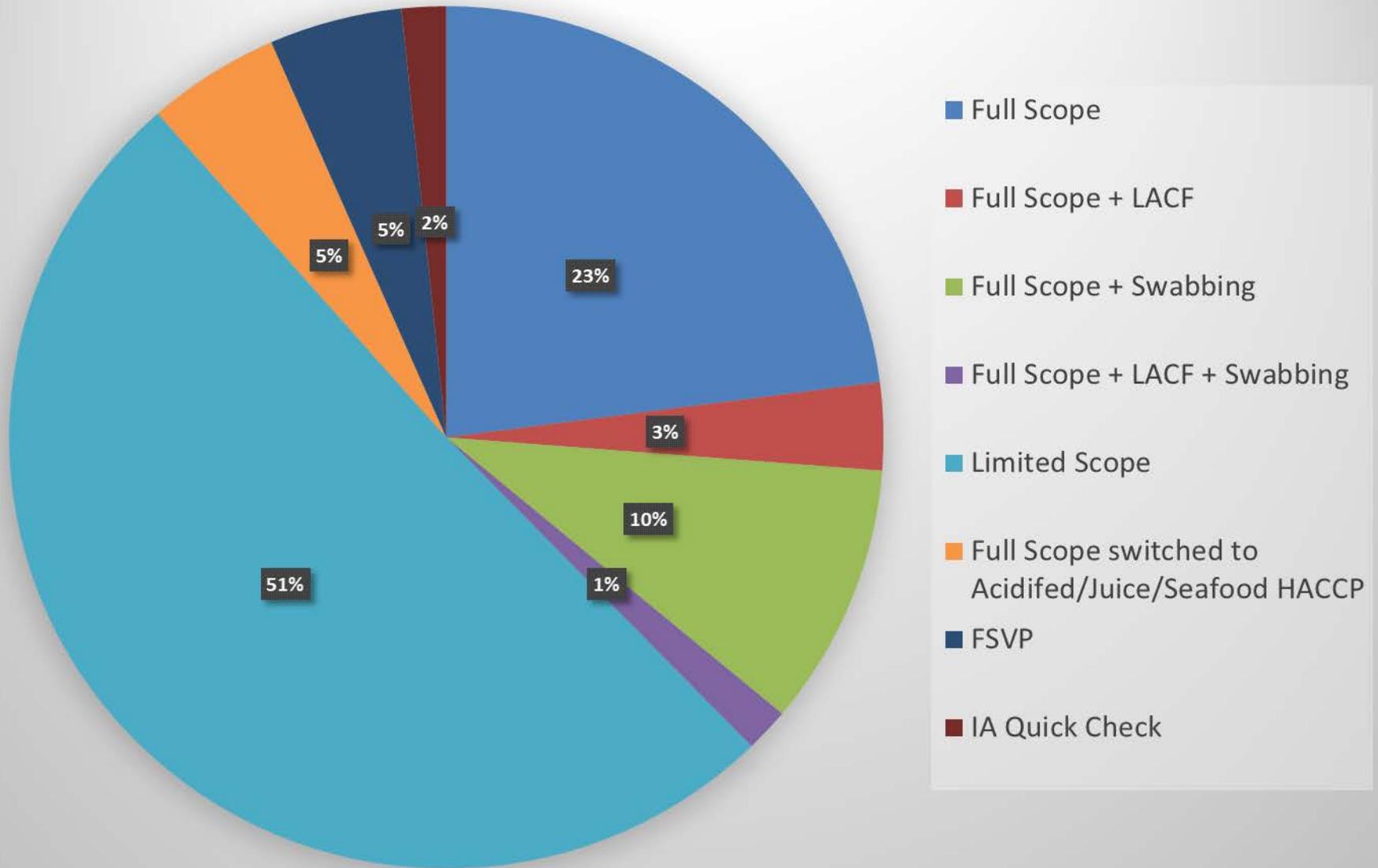
- Lead Instructors:
  - Two LI's for PCHF
  - One LI for FSVP
  - Two LI's for IAVA
  - One ToT for PCHF
- External Sessions:
  - 4 PCAFQI
- Cover full FSPCA curriculum, model plan examples, and how they work within KHC policy



## FSMA Impact: What Investigations (Inspections) Look Like



## FSMA Investigations (Inspections): Total = 49



## FSMA Inspections and Kraft Heinz (since 2016)

<b># FDA Personnel:</b>	Average of 1-2 investigators: typically 1 trainer, 1 trainee (less often in 2019), increasing State involvement
<b>Length:</b>	1-5 days
<b>Products:</b>	Whipped Topping, Meal Kits, Cream Cheese, Process Cheese, Natural Cheese, Spice Blends, Boxed Pasta Products, Bagel Bites, Grated Parmesan, RTD Juice, Frozen Meals, Potatoes, Pickles, Nuts, Sauces/Condiments, Ketchup, Cultures

# FSVP Inspections and Kraft Heinz

## FSVP Inspections

- We have had three at our corporate office: Dec 2017, Nov 2018, and Nov 2019
- Two for same product: frozen drink concentrate, 2019 one for ingredients that we manage under Subpart G
- Told we were chosen due to risk: type of product and amount imported
- FDA reached out via email both time to set up investigation, 2018 and 2019 requests came from import oversight office (rather than ORA)
- 1 day office visit

## Lessons Learned/Challenges

# Kraft Heinz Lessons Learned/Challenges

## Know the regulation and be prepared

- High level of investigator expertise
  - Corporate site for frequently asked questions and answers
- Sufficient availability of personnel for multiple inspection types (PCHF, LACF, swabbing)
- Supply chain policy summary and talking points
- FDA draft guidance Appendix 1 differences and rationales
- Chemical Hazards Management talking points
- Company ways of working for requests: photographs/copies of records
- Scientific basis for preventive controls and validation information
- Products under Acidified Foods or Preventive Controls for Human Foods regulations

# Kraft Heinz Lessons Learned

## Engage with FDA

- Investigator level
  - Educate and regulate
- District/Division level
  - Meet and greet
- CFSAN or ORA level
  - Technical exchanges
  - Reconnects
  - Sharing opportunities



# Legal & Food Industry Liability Challenges Created by FSMA

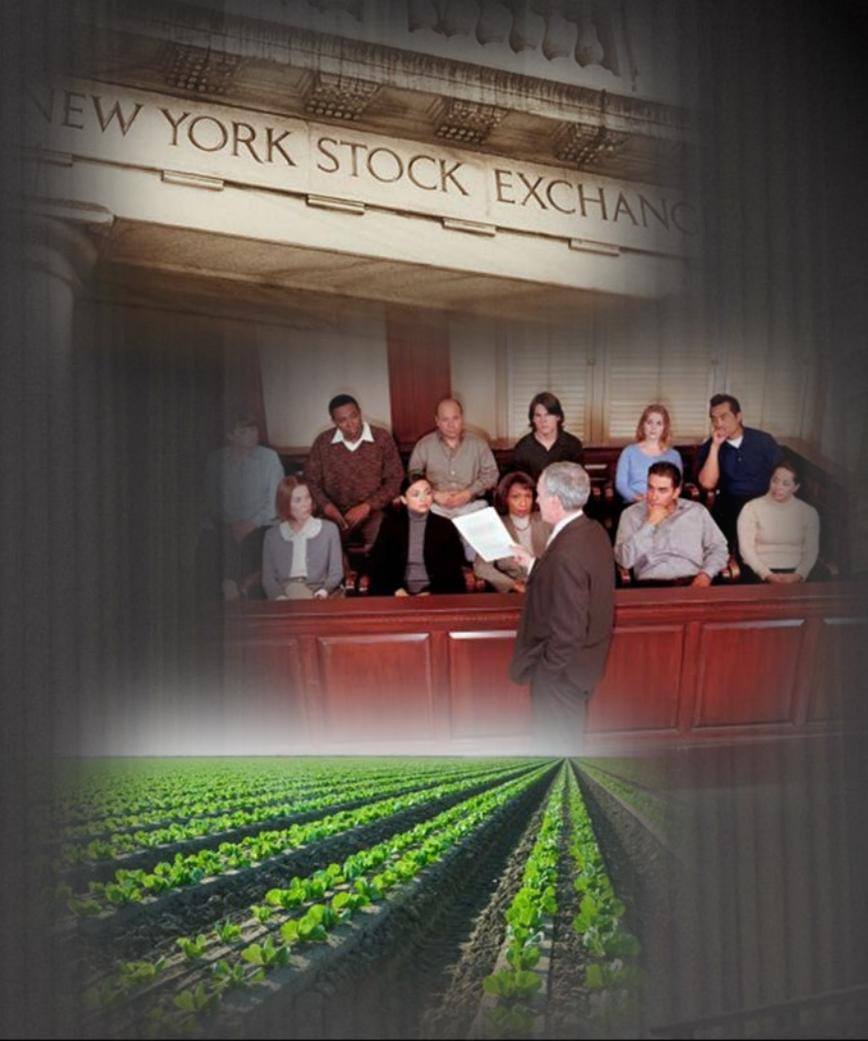
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**MARLER CLARK**  
THE FOOD SAFETY LAW FIRM

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# Food Production is a Risky Business

- Competitive Markets
- Wall Street and Stockholder Pressures for Increasing Profits
- Lack of Clear Reward For Marketing and Practicing Food Safety
- Risk of Litigation



# It is a Global Food Economy



# Strict Product Liability



- Punitive Damages /Criminal Liability
  - Did you act with conscious disregard of a known safety risk?

- Strict Liability
  - Are you a manufacturer?
  - Was the product unsafe?
  - Did product cause injury?
- Negligence
  - Are you a product seller?
  - Did you act "reasonably"?

# Planning AGAINST Litigation – What Is Really Important

- Identify Hazards
  - HACCP
  - Do they have qualified and committed people?
- What is the Culture?
- Involve Vendors and Suppliers
  - Do they really have a plan?
  - Ever visit them?



# Lessons Learned From Litigation

They can insure the brand's and the company's reputation

1. Be armed with good, current information
2. There is a choice between doing nothing or being proactive - be proactive
3. Make food safety part of everything they, their suppliers and customers do



# Questions?

Questions should be submitted via  
the **Questions section** at the right of  
the screen.

# Contact information for presenters

- Glenn Bass                      Food and Drug Administration    [gbass@fda.hhs.gov](mailto:gbass@fda.hhs.gov)
- Allen Sayler                     EAS Consulting Group, LLC        [asayler@easconsultinggroup.com](mailto:asayler@easconsultinggroup.com)
- Loralyn H. Ledenbach        The Kraft Heinz Company         [lharris@kraftheinz.com](mailto:lharris@kraftheinz.com)
- William D. Marler, Esq.       Marler Clark LLP PS                [bmarler@marlerclark.com](mailto:bmarler@marlerclark.com)



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