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

Moderator: Allen Sayler, EAS Consulting Group, LLC, USA

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Webinar Housekeeping

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• This webinar is being recorded and will be available for access by IAFP members at www.foodprotection.org within one week.
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 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 GSFI 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
Conducting Inspections, Investigations, Sample Collections and State Program Evaluations During the COVID-19 Pandemic

• 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.
Assignment Process:

• Pre-Assignment:

• During Assignment:

• Close Out and Post Assignment:
Challenges
Challenges
FY 20 Accomplishments
FY 20 Accomplishments
New Tools
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

Respected • Experts • Ethical • with Integrity
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

<table>
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<th>$ in Thousands</th>
<th>FY 2019 Enacted</th>
<th>FY 2019 Actuals</th>
<th>FY 2020 Enacted</th>
<th>FY 2021 President's Budget</th>
<th>FY 2021 President's Budget +/- From FY 2020</th>
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COVID-19 Impact on FDA Food Safety Enforcement

- **February 14, 2020** - FDA Inspections and Monitoring Compliance of FDA Products Manufactured Overseas: Any travel to China which is deemed to be mission-critical is being assessed on a case-by-case basis in close coordination with HHS and the State Department. For the month of February, the FDA identified all scheduled inspections in China, and they were either postponed or the agency was able to utilize other information to inform decisions allowing the products to enter our U.S. market. Of these inspections, approximately 90% were routine surveillance inspections in China and the remaining for-cause inspections scheduled for February were able to be postponed after reviewing all available information and analyzing on a case-by-case basis.

- **March 18, 2020** - FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections

- **May 11, 2020** - FDA updates on surveillance inspections during COVID-19: FDA will continue to utilize and implement additional alternative inspection tools and approaches while postponing domestic and foreign routine surveillance inspections. This will continue as local, national and international conditions warrant, with the exception of certain mission critical inspections. Mission critical inspections are identified on a case-by-case basis and conducted with appropriate safety measures in place.
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.
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 propose 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
Seafood was the second highest category recalled by pounds, accounting for 22.6% of recalled pounds.
FDA Enforcement Actions

**Compliance Actions:**
- Warning Letters: 2,552
- Injunctions: 90
- Seizures: 40
- All Actions: 2,682

**Warning Letters by Fiscal Year**
- Fiscal Years: 2009 - 2020
- 2011: 220
- 2012: 213
- 2013: 200
- 2014: 192
- 2015: 203
- 2016: 251
- 2017: 288
- 2018: 281
- 2019: 87
- 2020: 67

**Injunctions and Seizures by Fiscal Year**
- Fiscal Years: 2009 - 2020
- Action Type Count:
  - Injunction: 6, 4, 6, 15, 12, 9, 5, 5, 2
  - Seizure: 4, 6, 10, 11, 11, 5, 5, 5, 2

**Actions by Product Type:**
- Strangers: 0
- Devices: 0
- Drugs: 0
- Food / Cosmetics: 2,682
- Tobacco: 0
- Veterinary: 0
- All Actions: 2,682

**Warning Letters by Product Type**
- Fiscal Years: 2009 - 2020
- Food / Cosmetics: 2,682

**Injunctions and Seizures by Product Type**
- Fiscal Years: 2009 - 2020
- Action Type Count:
  - Injunction:
    - Food / Cosmetics: 90
  - Seizure:
    - Food / Cosmetics: 40
FDA Enforcement Actions

Foreign and Domestic Inspections
Fiscal Years: 2009 - 2020

Inspections Region
- Domestic
- Foreign

Inspections Classification by Fiscal Year
Fiscal Years: 2009 - 2020

Classification
- NAI
- OAI
- VAI

Inspections Classification by Product Type
Fiscal Years: 2009 - 2020

Classification
- NAI
- OAI
- VAI

Domestic Inspections
Total: 112,807

EAS Consulting Group, LLC
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.
### US SOURCE OF FOOD Imports

#### Top 5 Manufacturing Countries - Import Lines by Fiscal Year

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Country/Area</th>
<th>Sum of Import Lines</th>
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</thead>
<tbody>
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<td>2019</td>
<td>Canada</td>
<td>9.66M</td>
</tr>
<tr>
<td>2018</td>
<td>Canada</td>
<td>9.14M</td>
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<tr>
<td>2017</td>
<td>Italy</td>
<td>8.74M</td>
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<td>2016</td>
<td>Mexico</td>
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FDA Food Import Refusals by Country – FY 2020

Human Foods - 182,286
TOTAL FOOD PRODUCT REFUSALS BY US GOVERNMENT FISCAL YEAR
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?
Measuring the Value of FSPCA Training Efforts: Challenges and Lessons Learned

Loralyn Ledenbach
IAFP 2020
About Kraft Heinz

A Global Food Powerhouse

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

$25 billion in net sales (2019)
5th largest food company in the world
40+ countries with dedicated Kraft Heinz employees
8 1-billion + brands in retail and foodservice sales
3.2 million meals packaged by KHC employees with our partner Rise Against Hunger (2019)
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

- Full Scope: 51%
- Full Scope + LACF: 5%
- Full Scope + Swabbing: 10%
- Full Scope + LACF + Swabbing: 1%
- Limited Scope: 23%
- Full Scope switched to Acidified/Juice/Seafood HACCP: 3%
- FSVP: 2%
- IA Quick Check: 5%
### FSMA Inspections and Kraft Heinz (since 2016)

<table>
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<th># FDA Personnel:</th>
<th>Average of 1-2 investigators: typically 1 trainer, 1 trainee (less often in 2019), increasing State involvement</th>
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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
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

- **Strict Liability**
  - Are you a manufacturer?
  - Was the product unsafe?
  - Did product cause injury?

- **Negligence**
  - Are you a product seller?
  - Did you act “reasonably”?

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

- Allen Sayler  
  EAS Consulting Group, LLC  
  asayler@easconsultinggroup.com

- Loralyn H. Ledenbach  
  The Kraft Heinz Company  
  lharris@kraftheinz.com

- William D. Marler, Esq.  
  Marler Clark LLP PS  
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This webinar is being recorded and will be available for access by **IAFP members** at [www.foodprotection.org](http://www.foodprotection.org) within one week.

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