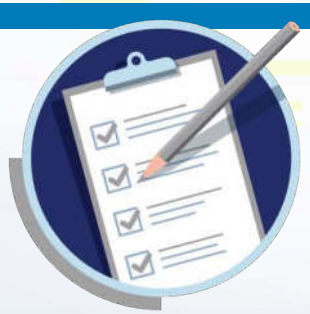
Regulatory News & Updates

What will the Food Traceability Rule require?



- New recordkeeping requirements.
  - Persons who manufacture, process, pack, or hold foods on the Food Traceability List.
- Covers the entire food supply chain.
- Includes both foreign and domestic entities.
- Full and partial exemptions may apply.

Compliance date

January 20, 2028

- Applies to all firms.
- Provides 3 years for covered entities to work with supply chain.
- We will educate before and while we regulate.

- Routine inspections under the rule will start in 2029.
- For-cause inspections will start at onset of compliance date.

Key Requirements of the Food Traceability Rule

- Traceability Plan
- Records of Critical Tracking Events (CTEs)
  - Specific Key Data Elements (KDEs) for each CTE
- Traceability lot code (TLC) and TLC source
- Records provided to FDA within 24 hours
- Records maintained for 2 years
- Electronic Sortable Spreadsheet (ESS) for outbreaks and recalls

FTR Implementation

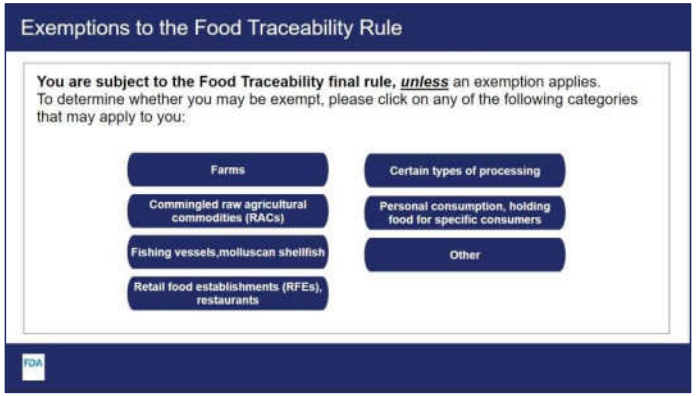
Implementation Updates

- Developing of an internal FDA system to facilitate analysis of traceability information
- Developing approach/program for routine and for-cause inspections and overall compliance strategy
- Collaborating with State, Local, Tribal and Territorial partners
- Developing of regulator and industry training

Food Traceability List

Cheese (made from pasteurized milk), fresh soft or soft unripened	Tomatoes (fresh)
Cheese (made from pasteurized milk), soft ripened or semi-soft	Tropical tree fruits (fresh)
Cheese (made from unpasteurized milk), other than hard cheese	Fruits (fresh-cut)
Shell eggs	Vegetables (fresh-cut)
Nut butters	Finfish (histamine-producing species) (fresh, frozen, and previously frozen)
Cucumbers (fresh)	Finfish (species potentially contaminated with ciguatoxin) (fresh, frozen, and previously frozen)
Herbs (fresh)	Finfish, species not associated with histamine or ciguatoxin (fresh, frozen, and previously frozen)
Leafy greens (fresh)	Smoked finfish (refrigerated, frozen, and previously frozen)
Leafy greens (fresh-cut)	Crustaceans (fresh, frozen, and previously frozen)
Melons (fresh)	Molluscan shellfish, bivalves (fresh, frozen, and previously frozen)
Peppers (fresh)	Ready-to-eat deli salads (refrigerated)
Sprouts (fresh)	

Exemptions Tool



https://collaboration.fda.gov/tefcv13/

Traceability Plan Example

Traceability Plan Example for Restaurants (continued)

Traceability Plan		Page 1 of 1
BUSINESS NAME: Sammy's Sandwich Shoppe	ISSUE DATE	01/01/2028
ADDRESS: 123 Main Street, Anytown, CA 12345	SUPERSEDES	01/20/2026

Procedures to Maintain the Records

Hard copies of Invoices and Bills of Lading are scanned and stored in an electronic filing system located on our local computer system. Digital advance shipment notices that have been received are also maintained in an electronic filing system located on our local computer system. Records are maintained for two years.

Procedures to Identify FTL Foods

All suppliers to Sammy's Sandwich Shoppe are obligated by contract to identify FTL Foods on the records provided when shipments are received (either paper copies provided at receiving or electronically sent ahead of shipment receipt).

Assigning Traceability Lot Codes

We do not assign TLCs.

Point of Contact

Steve McGee, Manager, 456-789-1233

Traceability Plan Updates

This plan is reviewed annually as part of our management review of our food safety program, as well as whenever something changes in our traceability procedures. Each previous traceability plan is kept in a folder on our local computer system for at least two years after it is updated.

Supply Chain Example: Fresh Produce

Traceability Plan

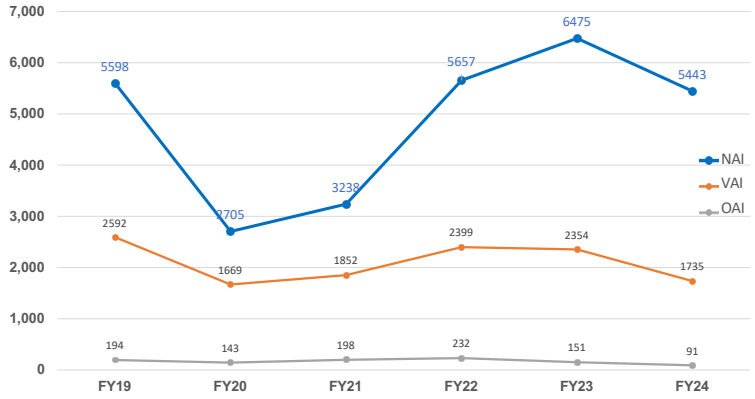
Electronic Sortable Spreadsheet Example

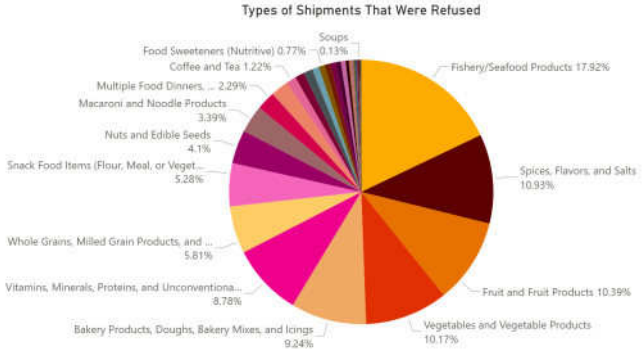
Location Description for the Immediate Subsequent Recipient (other than a transporter) - Business Name (Name of the Company Operating the Location Receiving the Food)	Location Description for the Immediate Subsequent Recipient (other than a transporter) - Phone Number (Phone Number to Call the Location Receiving the Food)	Location Description for the Immediate Subsequent Recipient (other than a transporter) - Street Address or Geographic Coordinates (Street Address or Geographic Coordinates of the Actual Location Where the Food is Received)
Cathy's Cooler	+1.123.123.1231	123 Park Ave
Cathy's Cooler	+1.123.123.1231	123 Park Ave
Fresh Processor Plant #16	+1.114.114.1141	114 Hill St
Ca Mau Shrimp Farm - Cooling Shed	+84 99 999 88 33	123 Nguyen

What can industry do to get started?

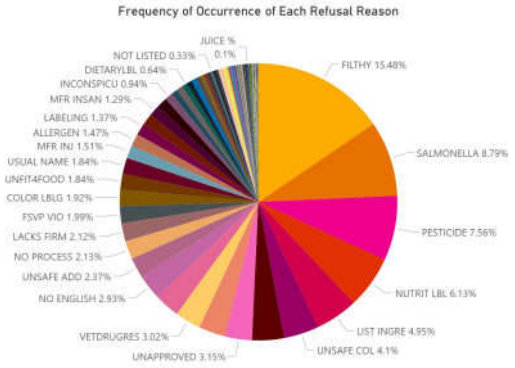
1. Do you manufacture, process, pack or hold a food on the Food Traceability List?
2. Do any exemptions apply to your situation?
3. What Critical Tracking Events (CTEs) do you conduct?
4. What Key Data Elements (KDEs) do you already maintain? What additional KDEs do you need to maintain to be in compliance with the final rule?
5. Develop a traceability plan.
6. Talk with your supply chain partners.
   - Understand the record keeping practices in your supply chains
   - Determine how best to communicate required information
   - Discuss potential solutions

Food Inspections, FY19 – FY24





Source modified from FSPCA Annual Conference Nov 20-21, 2024, Chicago, IL, USA



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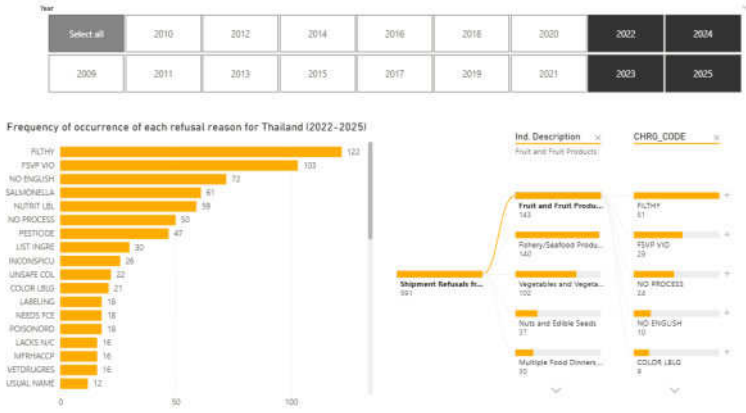

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10 Reasons Products from Thailand Are Refused Entry Into the U.S.

FILTHY	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the article appears to consist in whole or in part of a filthy, putrid, or decomposed substance or be otherwise unfit for food.
SALMONELLA	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain Salmonella, a poisonous and deleterious substance which may render it injurious to health.
PESTICIDE	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a pesticide chemical residue, which causes the article to be adulterated within the meaning of section 402(a)(2)(B) of the FD&C Act.
NO ENGLISH	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(f) of the FD&C Act in that any word, statement, or other information required by or under the authority of the FD&C Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary terms of purchase and use (for example, label contains information in two or more languages but fails to repeat all required information in both languages in accordance with 21 CFR 101.15(c)(2), or label fails to include all required information in English in accordance with 21 CFR 101.15(c)(1), except in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English)).
NUTRIT LBL	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be misbranded in that the label or labeling fails to bear the required nutrition information.

10 Reasons Products from Thailand Are Refused Entry Into the U.S.

NO PROCESS	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the manufacturer's failure to file a scheduled process demonstrates that the product is not being manufactured under the mandatory provisions of 21 CFR Part 108 and therefore appears to have been manufactured, processed, or packed, under insanitary conditions whereby it may have been rendered injurious to health.
LIST INGRE	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(i)(2) of the FD&C Act in that it is fabricated from two or more ingredients and the label fails to bear the common or usual name of each such ingredient and/or the article purports to be a beverage containing vegetable or fruit juice, but does not bear a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food.
UNSAFE COL	The article appears to be, or to bear or contain a color additive which is unsafe within the meaning of Section 721(a).
FSVP VIO	The article is subject to refusal of admission pursuant to section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) in that it appears that the importer (as defined in section 805 of the FD&C Act) is in violation of section 805.
LACKS N/C	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(e)(2) of the FD&C Act in that the food is in package form and the label fails to bear an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count in accordance with Section 403(e)(2) of the FD&C Act.

10 Reasons Products Are Refused Entry Into the U.S.

No.	Refusal Charge	Refusal Charge Description	FSMA Preventive Controls
1	**FILTHY**	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the article appears to consist in whole or in part of a filthy, putrid, or decomposed substance or be otherwise unfit for food.	CGMPs and Sanitation PCs
2	**SALMONELLA**	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain Salmonella, a poisonous and deleterious substance which may render it injurious to health.	CGMPs, Sanitation PCs, and Process PCs
3	**PESTICIDE**	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a pesticide chemical residue, which causes the article to be adulterated within the meaning of section 402(a)(2)(B) of the FD&C Act.	Supply Chain PCs
4	**NUTRIT LBL**	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be misbranded in that the label or labeling fails to bear the required nutrition information.	CGMPs
5	**LIST INGRE**	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(i)(2) of the FD&C Act in that it is fabricated from two or more ingredients and the label fails to bear the common or usual name of each such ingredient and/or the article purports to be a beverage containing vegetable or fruit juice, but does not bear a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food.	CGMPs

10 Reasons Products Are Refused Entry Into the U.S.

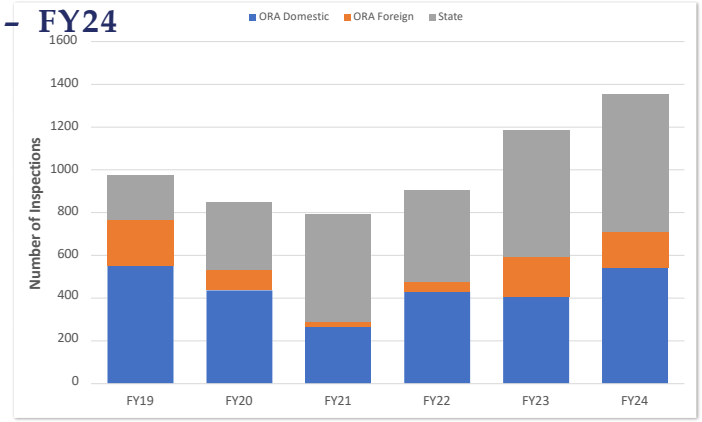
No.	Refusal Charge	Refusal Charge Description	FSMA Preventive Controls
6	**UNSAFE COL**	The article appears to be, or to bear or contain a color additive which is unsafe within the meaning of Section 721(a).	Supply Chain PCs
7	**MELAMINE**	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to bear or contain a food additive, namely melamine and/or a melamine analog, that is unsafe within the meaning of section 409.	Supply Chain PCs
8	**UNAPPROVED**	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a new drug within the meaning of Section 201(p) without an approved New Drug Application (NDA).	Supply Chain PCs
9	**POISONOUS**	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a poisonous or deleterious substance which may render the article injurious to health.	Supply Chain PCs, Process PCs, and Sanitation PCs
10	**VETDRUGRES**	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain a new animal drug (or conversion product thereof) that is unsafe within the meaning of Section 512.	Supply Chain PCs

Discussion

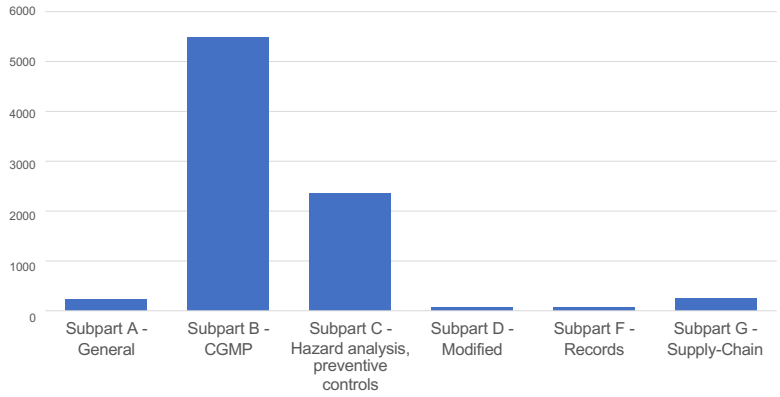
Implications:

- Preventive controls directly map to FDA refusal codes
- Stronger implementation = lower refusal rates
- Exporters with weaker sanitation/label systems face higher risks
- Verification strength (FSVP) critical for imported foods

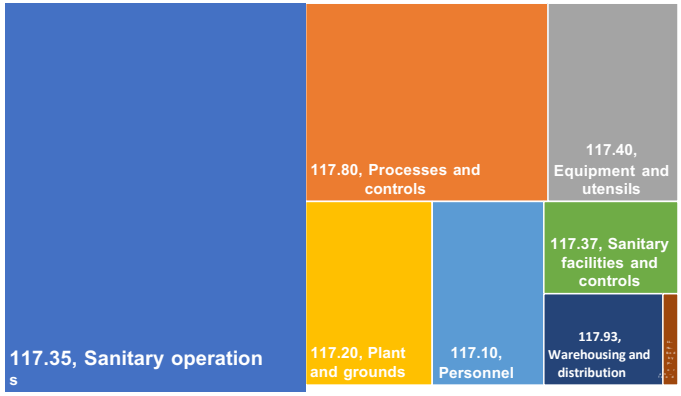
Preventive Controls Human Food, 21 CFR 117 FY19 – FY24



Preventive Controls HF, 21 CFR 117 Observations, FY19 – FY24



Preventive Controls HF, 21 CFR 117 Subpart B Observations, FY19 – FY24



Inspection Observations – Subpart B
(GMP)

117.35 – Sanitary Operations

- Plastic container without label
- Extensive dough residues
- Significant rusting of metal
- Cleaned brush placed on floor, brush still heavily soiled
- Pest control live cats, cat excrement; live birds and bird feathers near uncovered tanks

Inspection Observations – Subpart B
(GMP)

117.40 – Equipment and utensils

- Flaking and peeling paint exposed to food
- Shredder plate had pressure of metal-on-metal contact
- Not clean or sanitize to protect against allergen cross-contact (low sanitizer concentration)

Inspection Observations – Subpart B
(GMP)

117.80 – Manufacturing, Processing, Packing Controls

- Apparent rodent excreta
- Environmental samples tested positive for *Listeria monocytogenes*
- Rust, corrosion, peeling paint above in-process, RTE product
- Did not maintain cold room or cooler to prevent condensation with in-progress products
- Repeat observations, exposed concrete throughout manufacturing area; liquid pooling on floor and equipment near in-process foods

Inspection Observations – Subpart C
(Hazard analysis and preventive controls)

117.130 – Hazard Analysis

- Repeat observation, hazard analysis did not identify a known or reasonable hazard that required a preventive control.
- Did not identify pathogen (listeria monocytogenes) as a hazard requiring a preventive control.
- Did not identify pathogens or recontamination with environmental pathogens as hazards requiring a preventive control.

Inspection Observations – Subpart C
(Hazard analysis and preventive controls)

117.135 – Preventive Controls

- Did not implement your process preventive control and verification procedures. (temperatures, metal detection)

Inspection Observations – Subpart C
(Hazard analysis and preventive controls)

117.145 – Monitoring

- Repeat observation, did not establish and implement adequate written procedures for monitoring process controls. (metal, labeling – undeclared allergens, environmental pathogens).

Inspection Observations
Egregious Findings

Repeat observations, plant construction, sanitary operations, pest control (holes/cracks in equipment, building, gaps), pest harborage, accumulation of product, presence of live larvae, beetles, insects in product, presence of birds, feathers, bird carcass, rodent activity.

Examples of Voluntary Corrections

- Training of personnel.
- No longer handling product.
- Repaired or maintained equipment.
- Recall plan contained required elements.
- Monitoring records of calibrated devices.

Examples of Voluntary Corrections

- Environmental swabs negative of pathogens.
- Sanitation records and frequency of cleaning.
- Floors repaved and repaired that water could drain.
- Replaced previous equipment; designed to be cleaned and maintained.

What is Required for IA Rule

- Food Defense Plan
  - Vulnerability assessment
  - Mitigation strategies
  - Food defense monitoring procedures
  - Food defense corrective action procedures
  - Food defense verification procedures
- Reanalysis
- Records
- Training

Training

- All people performing activities for this rule must be qualified individuals
- Individuals working at actionable process steps and their supervisors must also complete
  - Food defense awareness training
  - Training on the proper implementation of mitigation strategies at their actionable process steps

Training (cont)

- Individuals performing the following activities:
  - Food defense plan development
  - Performing vulnerability assessment
  - Identifying and explaining mitigation strategies
  - Performing reanalysis of the food defense plan
- Must also:
  - Complete training at least equivalent to standardized curriculum recognized as adequate by FDA
  - Or be otherwise qualified through job experience

FSPCA Training Offerings

FSPCA IA Rule Training Courses	Delivery Method	Intended Audience	Cost
Food Defense Awareness[1]	Available now ONLINE TRAINING	• Workers at Actionable Process Steps (e.g., front line food workers) • Supervisors of Workers at Actionable Process Steps • Satisfies requirement in § 121.4(b)(2)	Free
Overview of IA Rule	Available now ONLINE TRAINING	• Any stakeholder interested in learning more about the IA rule requirements • This course is not associated with any IA rule training requirement	Free

FSPCA IA Rule Standardized Curriculum Recognized by FDA[2]	Delivery Method	Intended Audience	Cost
Conducting Vulnerability Assessments using Key Activity Types	Available now ONLINE TRAINING	• Food professionals who conduct VAs using the KAT Method only • This course is strongly recommended before taking the Conducting Vulnerability Assessments course	$169.00 USD
Identification and Explanation of Mitigation Strategies	Available now ONLINE TRAINING	• Food professionals who identify Mitigation Strategies to implement at Actionable Process Steps	$179.00 USD
Conducting Vulnerability Assessments	Available now 1-Day Course	• Food professionals who conduct VAs using the 3 Fundamental Elements • This 1-day course must be taught by FSPCA VA Lead Instructors • The VA/KATs online course is strongly recommended before taking this course	Varies – price set by independent IAVA Lead Instructors
Food Defense Plan Preparation and Reanalysis	Available now ONLINE TRAINING	• Food professionals who prepare the Food Defense Plan and/or who conduct Reanalysis activities	$109.00 USD

Inspectional Framework for IA Rule

- Two-level inspectional approach
  1. Food Defense Plan Quick Check
     - Conducted on covered facilities during food safety inspections
     - High level review of Food Defense Plan (FDP)
  2. Food Defense Comprehensive Inspections
     - Conducted only at limited number of prioritized facilities during food safety inspection
     - Conducted by specially trained investigators
     - Critical evaluation of FDP, conclusions, rationale

Schedule of Inspections

- Food Defense Plan Quick Checks: Fall 2020
  - Started slow due to COVID
  - Add-on to other program inspections
  - Validating our inventory information and coverage
  - Will continue now that comprehensive inspections have begun
- Comprehensive Food Defense Inspections: August 2024

Food Defense Plan Quick Check Process

- Quick Check is conducted through short inspectional protocol that is relevant to the requirements of a food defense plan
  - 21 CFR 121.126 *Food Defense Plan*
- Visual, on-site inspection of the Plan
- No records collected
- Investigator can provide informational materials/additional resources
  - IA rule guidance fact sheets, FSPCA training

Food Defense Plan Quick Check Inspections

- What are we seeing?
  - Industry is developing food defense plans as required
  - Use of IA rule guidance is beneficial
  - KATs are showing significant utilization by industry
    - Key Activity Types and Hybrid are widespread for VA methodology

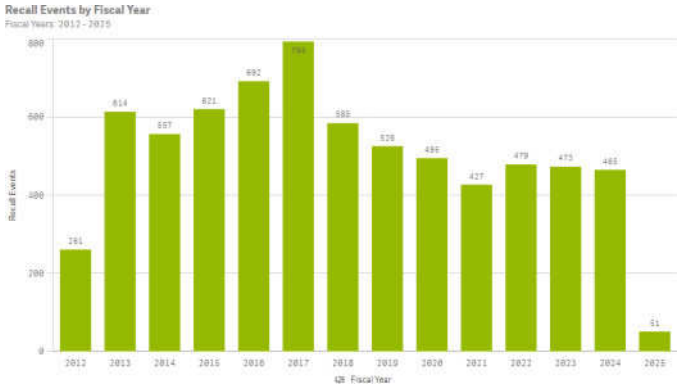
Comprehensive Food Defense Inspections

- Detailed review of food defense plan and inspection to determine status of plan implementation in the facility
  - Determine adequacy of plan components
  - Assess implementation status
- Conducted by Food Defense Inspection Team (FDIT) members
  - Specialized food defense training
  - Food Defense Team SMEs available for real-time consultation & technical support

Comprehensive Food Defense Inspections

- What are we seeing?
  - Firms are aware of IA rule and have FD plans
  - Interested in getting feedback and improving FD plans
  - Firms that use FDPB tend to be more organized and have addressed the requirements of the IA rule
  - Many questions firms have can be answered directly from guidance
  - Training is not a mitigation strategy
  - Cameras facilitate human observation

Recall Events FY 2012 to 2025
(Food and Cosmetics)



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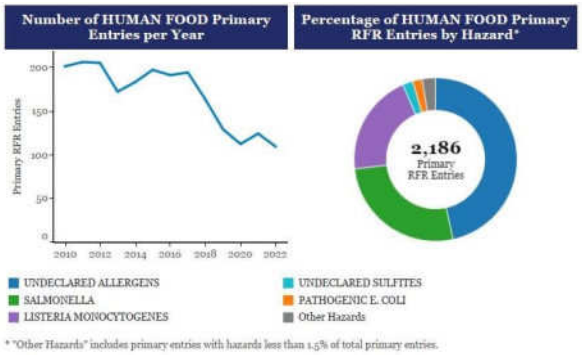
Reportable Food Registry (thru FY 2022)



Source modified from FSPCA Annual Conference Nov 20-21, 2024, Chicago, IL, USA

Is the US Food Supply Less Safe?

- There is no indication, based upon recall data or outbreaks, to indicate our food supply is getting worse.
- Potential impact by amplification in media due to highly visible outbreaks (E. coli O157:H7 in slivered onions, Listeria in deli meat), and recalls (waffles and RTE chicken, both Listeria) in an election year
- Social media creates an echo effect

Identifying Issus in Food Supply

- Investigate more recent recalls
  - Published retrospective studies lag too far in the past and/or take too much time into account
  - Allows one to identify issues where gaps still exist
  - Provides educators fodder to reinforce learning objectives

Methodology

- Evaluated about 148 posted recalls from January 1, 2024 to September 30, 2024
  - Type of Hazard
  - Source / Cause
  - How issue was identified
- Where possible, assessed size of company and any related factors
  - While FDA identifies 'small business' as less than 500, I will define it as less than $25 million in sales.

Limitations

- Limited to posted recalls versus the all that are listed on Enforcement Report
  - May be the source of some bias
- Limited by the amount of information shared on the recall notice
- Did not include seafood or animal feed / pet food

FDA Recalls – January to September, 2024

Issue		Number	
Allergens		58	
Listeria	(assoc with cheese outbreak)	35	(19)
Salmonella		20	
Lead		12	
Sulfites		6	
Foreign Material		3	
E. Coli (STEC)		2	
C. botulinum		2	
Mold growth		2	

Undeclared Allergens

- Label Application – Mislabeling (22/58)
  - Often found by down-stream entity
  - Normally involves limited quantities of product
  - One common issue is misapplication of back ingredient label
- Label Design (19/58)
  - Small firms or imported product
- Formulation (9/58)
- Cross-contact (6/58)
  - Often found through customer complaint

The majority of recalls are associated with small firms

Listeria monocytogenes

Queso fresco and cotija cheeses manufactured by Rizo Lopez Foods, Inc., of Modesto, California

- Total Illnesses: 26
- Hospitalizations: 23
- Deaths: 2

- In January 2024, the Hawaii DOH tested product made by Rizo-López Foods and found the outbreak strain in the product.
- FDA conducted inspections at the Rizo-López Foods facility and found the outbreak strain from two environmental samples that were collected at the facility.
- Product was used by other firms resulting in multiple secondary recalls – demonstrates the need for Supplier Preventive Controls.

Listeria monocytogenes

Outside of the cheese recall, *Listeria* related recalls are primary due to sample testing.

- State or Federal agencies
- Internal testing
- Customer testing
- Supplier-related testing

Salmonella

Imported basil from Columbia recalled after being involved in outbreak.

- Total Illnesses: 12 and Hospitalizations: 1

Confectionary product - liquid coating supplier notified customers that there was a potential for contamination with *Salmonella* from an ingredient that was potentially contaminated from one of their suppliers

Sample testing primary reason for recalls

- Seven imported products – recalls issued after testing

E. coli (STEC)

E. coli outbreak linked to raw milk cheese from Raw Farm Brand.

- Illnesses: 11
- Hospitalizations: 5 (2 HUS)

Recalled organic walnut halves and pieces were sold in bulk bins at natural food and co-op stores

- Total Illnesses: 13
- Hospitalizations: 7
- Deaths: 0

Lead in Cinnamon Apple Sauce

- Foreign supplier of apple sauce used a cinnamon source that had lead chromate added to it as part economic adulteration
- FDA reported 90 confirmed cases of lead poisoning in children
- Put additional attention on supplier's supplier relationship

Following this issue, FDA conducted a sampling of cinnamon in the US and found additional cases of elevated lead in cinnamon which resulted in recalls. These cases were not as high as those found in the applesauce.

Other Types of Recalls

- Sulfites – dried fruit, especially if imported
- Foreign material – there has been improvement over the past several years
- Issues related to process – mold growth, C. botulinum, and under-processing

Identification of How Issues are Discovered – Trigger Elements

- Customer feedback systems
- Increased testing by various entities (Gov agencies, customers, etc)
- Improved microbiological analysis

Need for Improvement

Reinforces the need to utilize Preventive Controls approach.

Allergens PCs

- Cannot take allergen control for granted.
- PCs at label design and application, but also formulation and areas where cross-contact is a risk

Sanitation PC for environmental hazards including Listeria

- Product may be subject to sample testing of the product

Supply chain preventive controls

- Allergen labeling (although may be more FSVP)
- Biological and chemical hazards

Outreach to small and very small firms

Utilizing Published Recall Data

- Instructors should keep abreast of food safety issues and utilize worthy examples to reinforce learning objectives
- Drill down to gain the best understanding of root cause
- Refrain from guessing at potential causes or sources, or clearly indicate that it is a just speculation