FSPCA 2025 ANNUAL CONFERENCE

STRENGTHENING THE FOOD SUPPLY CHAIN
THROUGH EDUCATION, TRAINING AND OUTREACH

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
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WELCOME

JASON WAN, PHD
INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

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OPENING REMARKS & IFSH UPDATES

BRIAN SCHANEBERG, PHD
INSTITUTE FOR FOOD SAFETY & HEALTH (IFSH)

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WELCOME
2025 IFSH FSPCA Annual Meeting

November 18-19, 2025

Rockville, MD

Agenda

- Meeting Highlights
- Year-in-Review
- Forward Looking

Meeting Highlights

SPEAKERS

RADM Kis Robertson Hale, DVM, MPH, DACVPM

U.S. FDA HFP

Director for the Office of Laboratory Operations and Applied Science (OLOAS)

2025 FSPCA Lifetime Achievement Award Winner

David Fairfield

Retired

2025 FSPCA Volunteer of the Year Award Winner

Juan Silva, PhD

Professor

Mississippi State University

TOPICS

- Food Traceability Rule
- Hazard Analysis 2.0
- Chemical Hazards
- Regional Centers
- Breakout Sessions

Thank You Annual Meeting Support Team

Annual Meeting
Planning Committee

IFSH Staff

IFSH Year-in-Review

Facilities / Equipment

- High Pressure Processing system repaired
- 91E
  - Repaired EDS
  - Certified air flow systems
  - Suite shower repaired
  - CDC inspection completed
    - Working towards BSL3 (HPAI H5N1 avian influenza research needs)
  - External certification expected by end of November

Research Highlights

- HPAI H5N1 avian influenza
  - Survival in raw milk yogurt
  - Inactivation studies using HPP
- Powdered Infant Formula
  - Microbiome evaluation and assessment of *C. sakazakii* to desiccation and sanitizer stress
  - Assessment of population dynamics of *C. sakazakii* and *S. enterica* in powdered and reconstituted infant formula during storage
  - Sanitizing procedures in controlling *C. sakazakii*

Research Highlights

- Dry cleaning efficacy for removal of microbial hazards
- Risk of *C. botulinum* and toxin production in plant-based meat products
- Reducing *Salmonella* and *E. coli* in sprout seeds
- Cold crew coffee challenge studies
- Allergen cross contact risk and washing treatments (nut/peanut products, seed butters and pastes, seafood, and gluten)
- Post-consumer recycled plastics, nanostructured materials
- Absorption and intestinal bioaccessibility of vitamins and minerals from plant-based milk alternatives

Forward Looking

Future Planning

- Chicagoland is a global food hub generating $9.1B annually in output.
- Illinois Tech has a long history developing students and lifelong learners, including in the food sector.
- Since 1988, IFSH has been an FDA Center of Excellence working collaboratively with the Division of Food Processing Science and Technology.
- Although the Moffett Campus is fully operational, the age and design of the buildings are past their prime and would require significant funding to renovate.
- Bedford Park location has benefit, but the negatives carry greater headwinds.

Current Activities

- IFSH Strategic Planning document drafted defining approach, objectives and key results.

Implementation Steps

- Develop specific Objectives and Key Results aligned with vision statement by end of 2025.
- Establish working groups for each objective to create detailed implementation plans, identifying requirements for both the institute and the university by January 2026.
- Working groups will present findings to the Executive Director, Dean, Provost, and selected Board members, who will develop a three-year plan and action commitments by end of March 2026.

Draft Strategic Objectives

- Reclaim Position as Premier Research Institute
- Increase Faculty Involvement from Across the University
- Increase Student and Lifelong Learner Engagement
- Increase Number and Depth of Partnerships with Food and Food-Adjacent Industries
- Reframe and Broaden Partnership with Government Agencies
- Increase Role and Impact in the Chicago Community

Thank You

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KEYNOTE SPEAKER

REAR ADMIRAL KIS ROBERTSON HALE
U.S. FOOD AND DRUG ADMINISTRATION (FDA)

FSPCA Annual Conference | November 18-19, 2025

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FSPCA OPERATIONAL HIGHLIGHTS

JASON WAN, PHD
INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

KATHY GOMBAS
FSMA SOLUTIONS, FSPCA EAB CHAIR

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FSPCA Operational Plan

PLAN + **DEDICATION** = **CELEBRATION**

FSPCA Strategic Plan

Vision: Be an internationally recognized trusted source for training programs and outreach for the prevention-oriented standards of the US Food Safety Modernization Act (FSMA).

Mission: Assist the human and animal food industry and related entities in building food safety capacity through education, training and outreach with an emphasis on small and medium-sized businesses.

Core Values:

People: We foster a community that values respect, inclusivity, & transparency.

Collaboration: We develop trusted & strategic relationships with stakeholders worldwide.

Excellence: We deliver the highest quality curricula recognized by FDA, with personal & professional integrity.

Evolve: We innovate to proactively & continually adapt to stakeholder needs.

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FSPCA EAB Members

DEDICATION

First Name	Last Name	Organization
Martin	Bucknavage	Penn State Department of Food Science
Claudia	Coles	Seafood Products Association
Berit	Foss	National Grain and Feed Association
Kathy	Gombas (Chair)	FSMA Solutions
Chris	Lincecum	Cooperative Farmers Elevator
Modestar	Liyokho	IRCA Group
Tania	Martinez	Demos Global Group, Inc.
Juan	Silva	Mississippi State University
Katherine	Simon	Minnesota Department of Agriculture
Jennifer	Thomas	Human Foods Program - FDA EX Officio Member

FSPCA Management

DEDICATION

- Brian Schaneberg – IFSH Executive Director
- Jason Wan – FSPCA Director
- Jerry Wojtala – IFPTI Executive Director
- Steve Mandernach – AFDO Executive Director
- Dawn Johnson – FSPCA Program Manager

Committees

DEDICATION

Curriculum

- Identify FSPCA curricula development and update needs
- Ensure curricula remain current and relevant to meet stakeholder's needs
- Establish a qualified training force to deploy the curriculum in coordination with implementation committee

Implementation

- Certificate and records maintenance
- Oversee lead instructor training courses
- Support lead instructors through communications and educational forums to promote quality of lead instructor instruction
- Monitor lead instructor course registrations, performance, LI course advertising
- Oversee new curricula rollouts

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Committees

DEDICATION

International

- Develop and disseminate international outreach materials via technical assistance networks
- Exchange information with the international trainer community
- Oversee translations of FSPCA curricula

Marketing & Communications

- Promote the FSPCA brand, products, and services
- Plan and implement the Annual Conference
- Maintain and enhance FSPCA website
- Publish communication notifications to FSPCA lead instructors and external stakeholders

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Trainers-of-Trainers

DEDICATION

- Delivering Lead Instructor courses and mentoring our future Lead Instructors

Human Food

1. Claudia Coles
2. Kathy Gombas
3. Lynette Johnson
4. Lori Ledenbach
5. Tania Martinez
6. Juan Silva
7. Katherine Simon
8. Warren Stone
9. Jason Wan

Animal Food

1. Jennifer Abrahamzon
2. Adam Fahrenholz
3. Cassie Jones

FSVP

1. Bob Bauer
2. Claudia Coles
3. Kathy Gombas
4. Juan Silva
5. Warren Stone
6. Hilary Thesmar

IAVA

1. Jennifer van de Ligt
2. Jon Woody
3. John Collier
4. Caitlin Hickey
5. Ned Mitenius

FTR

1. Neil Aeschliman
2. Asma Madad
3. Jennifer McEntire
4. Juan Silva
5. Chris Waldrop
6. Jason Wan
7. Lisa Weddig
8. Angela Fields
9. Adam Friedlander
10. Bob Gravani
11. Melinda Hayman

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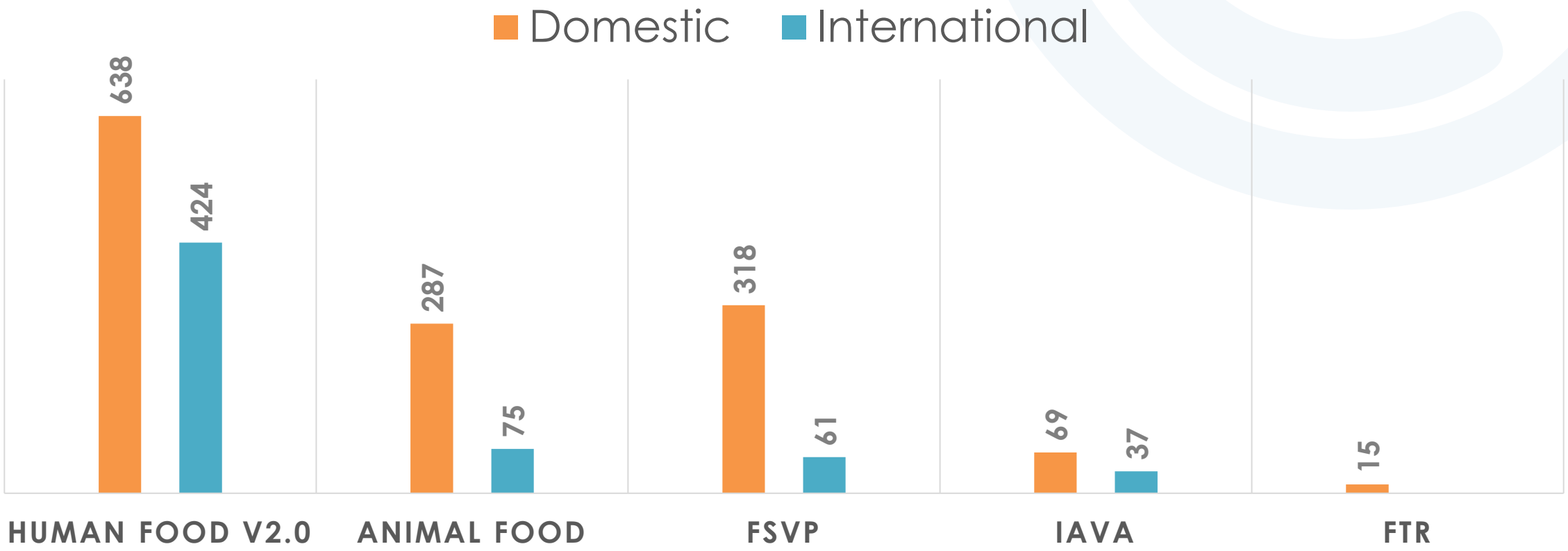
FSPCA LEAD INSTRUCTORS (AS OF NOV 5, 2025)



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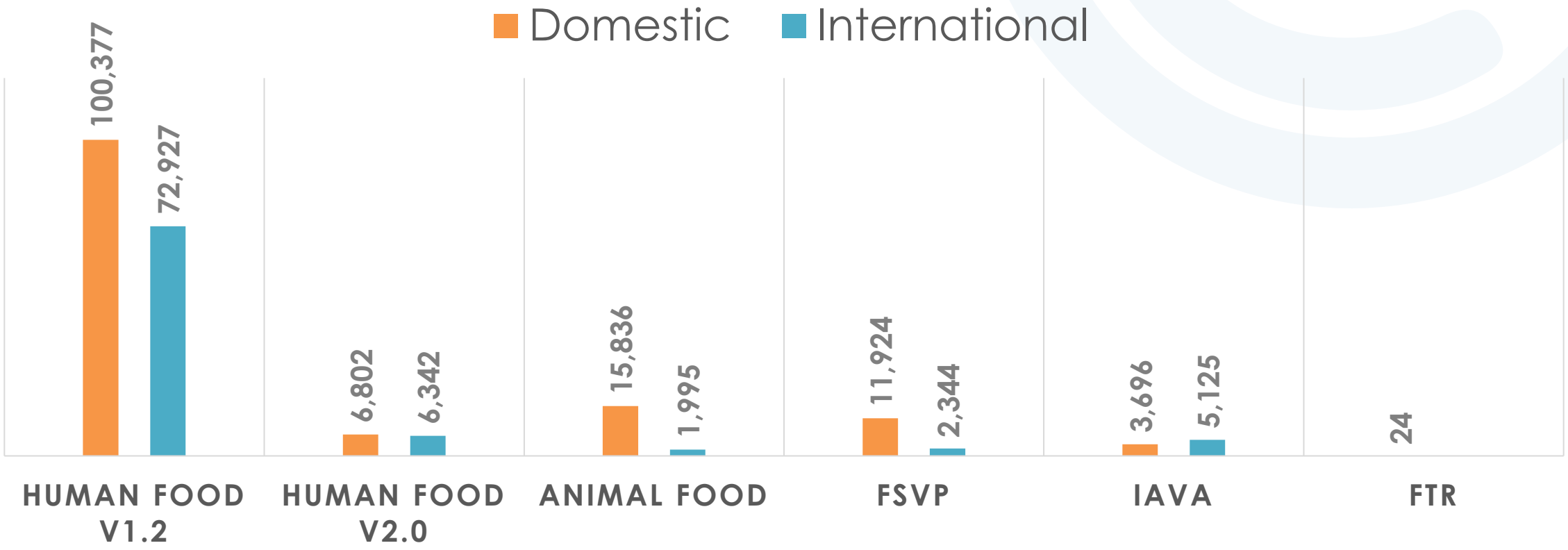
PARTICIPANT CERTIFICATES ISSUED (AS OF NOV 5, 2025)



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Technical Assistance Network

DEDICATION

V2.0 TAN

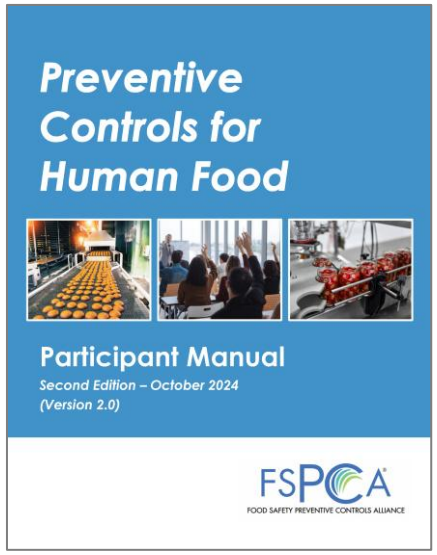
1. Kathy Gombas
2. Claudia Coles
3. Martin Bucknavage
4. Katherine Simon
5. Jason Wan

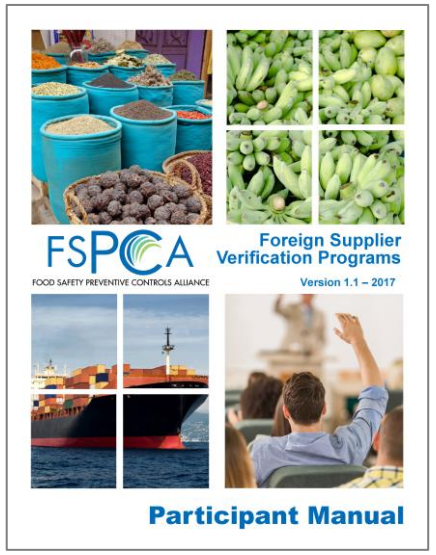
University Extension Specialists

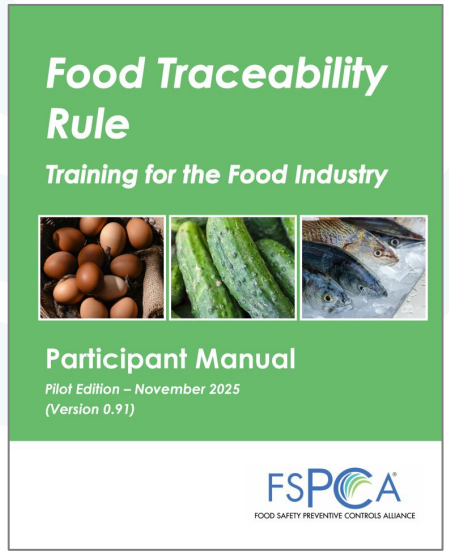
1. AK
2. CO
3. FL
4. GA
5. ID
6. IA
7. KY
8. LA
9. ME
10. MD
11. MI
12. MS
13. NE
14. NJ
15. NY
16. NC
17. OK
18. OR
19. PA
20. SC
21. TX
22. VA
23. WA
24. WV
25. WI

FSPCA Standardized/Core Curricula

CELEBRATION







FSPCA Participants Manuals are publicly available on the FSPCA website

Coming Soon: Food Traceability Rule – Training for the Food Industry

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FSPCA Food Traceability Rule – Training for the Food Industry

CELEBRATION

- **October 2023:** FTR curriculum editorial team established
- **July 2024:** First draft curriculum completed
- **July 29-Aug 2, 2024:** FTR curriculum walkthrough at FDA Rockville MD
- **Feb 18-21, 2025:** FTR curriculum Editorial Team pilot at FDA White Oak MD
- **June 12-13, 2025:** FTR curriculum Target Audience pilot at FDA College Park MD
- **Sept 2025 - Continuing:** FDA review
- **Nov 2025:** FTR Pilot Lead Instructor Combo courses
- **Jan & Feb 2026 (TBC):** FTR Lead Instructor Combo courses

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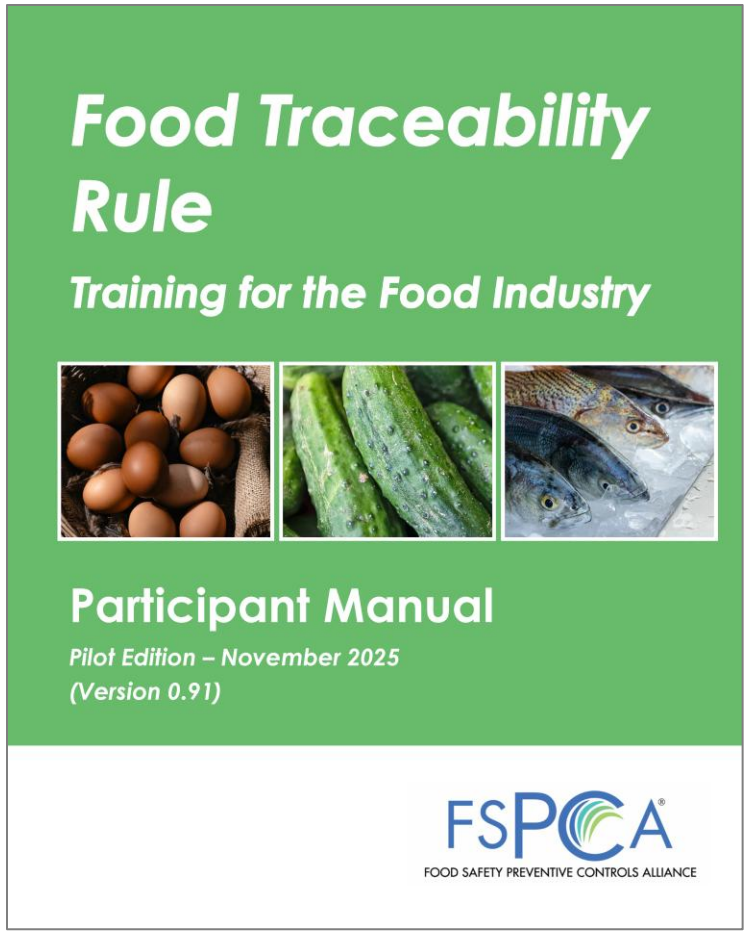
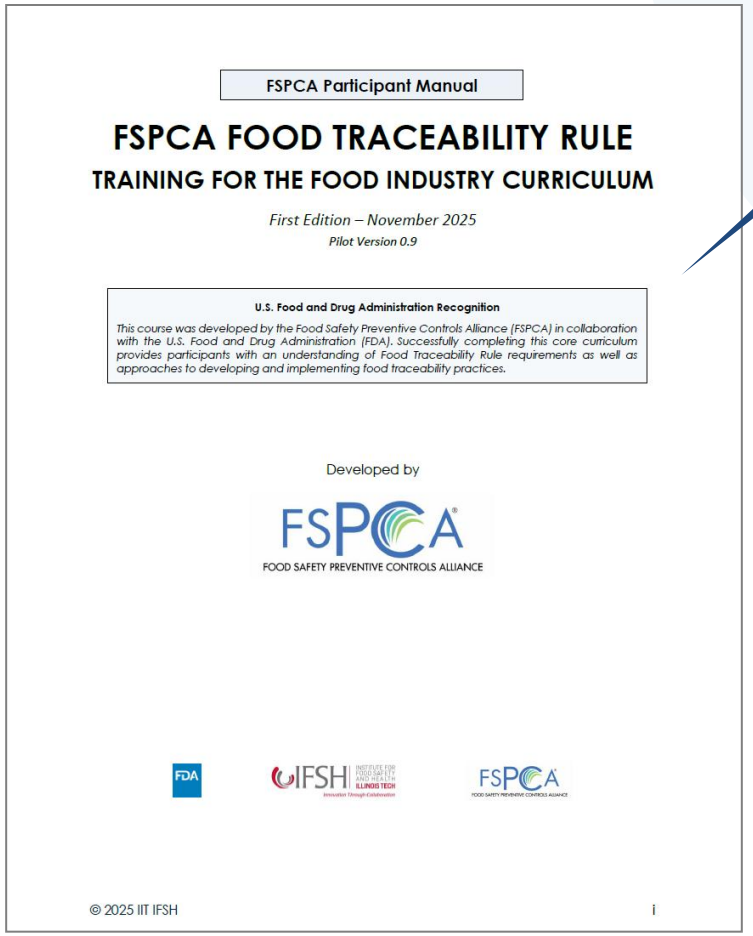
FTR Training for the Food Industry
Recognized by FDA as a Core Curriculum

CELEBRATION





FDA Recognition
"…Successfully completing this core curriculum provides participants with an understanding of Food Traceability Rule requirements as well as approaches to developing and implementing food traceability practices"

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PCHF V2.0 Rollout - Accomplishments

CELEBRATION

- Launched the V2.0 Participant courses on January 1, 2025
  - V1.2 curriculum retired June 30, 2025
- Published Spanish translation of V2.0
- Developed and launched V2.0 Blended Course Part 1 and Part 2
- Updated and published V2.0 Food Safety Plan Teaching Examples
- Launched V2.0 Technical Assistance Network
- Received USDA NIFA grant for LIRT training of FSMA Regional Center/Extension Network Lead Instructors
- Launched V2.0 Lead Instructor Courses
- Delivered Lead Instructor Refresher Training (LIRT) courses
  - Future LIRT courses are in planning for 2026

PCHF V2.0 Rollout – LIRT and LI Courses

CELEBRATION

- 59 Lead Instructor Refresher Training (LIRT) courses completed resulting in **1,018 Lead Instructors** trained
- 3 V2.0 Lead Instructor courses resulting in **44 Lead Instructors** trained
  - April 14-17, 2025
  - June 3-6, 2025
  - Sept 2-5, 2025
- Upcoming Lead Instructor Courses
  - December 9-12, 2025 (Sold Out)
  - March 30 – April 2, 2026
  - June 15-18, 2026
  - September 8-11, 2026

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Animal Food, FSVP & IA VA

CELEBRATION

- **Animal Food Lead Instructor Courses**
  - Held October 6-10, 2025, resulting in 5 Lead Instructors trained
  - Upcoming: TBD - Curriculum Updates In Progress
- **FSVP Lead Instructor Courses**
  - Developed and launched Lead Instructor course format vs. Combination Course
  - Upcoming Lead Instructor Courses
    - December 17-19, 2025
    - August 11-13, 2026
- **IA VA Combination Courses**
  - Held August 5-6 & August 11-12, 2025, resulting in 8 Lead Instructors trained
  - Upcoming: June 2-3 & June 9-10, 2026

FSPCA Annual Conferences

CELEBRATION

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CELEBRATION

Metrics

(as of November 5, 2025)

159

FSPCA Lead Instructor courses completed

3204

Successfully trained Lead Instructors from 80 countries

21406

FSPCA participant courses delivered by FSPCA Lead Instructors

238615

Personnel from 152 countries have been trained on FSMA regulations

ALL METRICS

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Mahalo
Grazi
THANK
YOU
Danke
Shukran

FOOD TRACEABILITY RULE

PANELIST
MELINDA HAYMAN

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

PANELIST
MICHAEL ROBERSON

PUBLIX

PANELIST
JENNIFER McENTIRE

FOOD SAFETY STRATEGY, LLC

PANELIST
BENJAMIN MILLER

THE ACHESON GROUP (TAG)

MODERATOR
HILARY THESMAR

THE FOOD INDUSTRY ASSOCIATION (FMI)

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Traceability & FSMA 204: Origins of the Rule

Ben Miller, PhD, MPH – COO & EVP of Scientific and Regulatory Affairs

THE ACHESON GROUP

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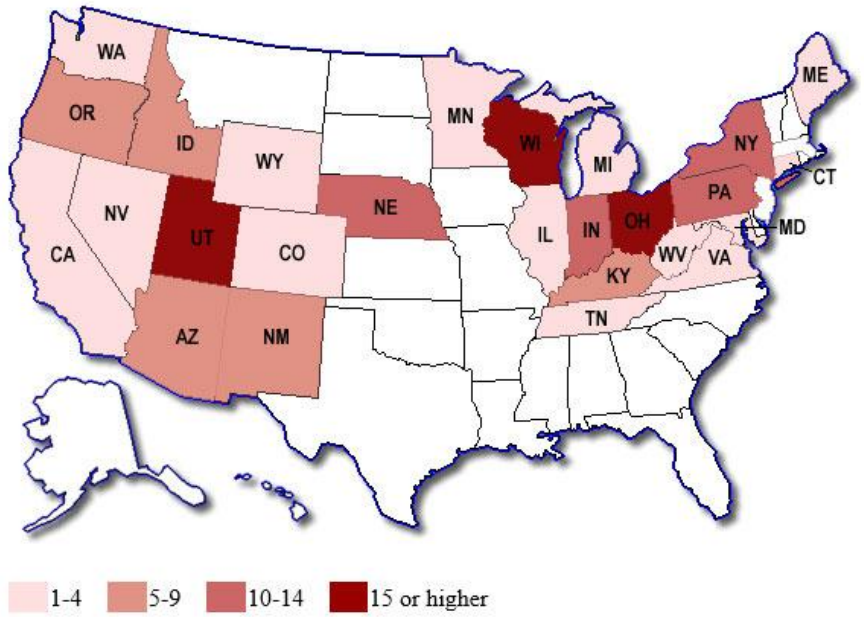
November 18, 2025

Why are we here?

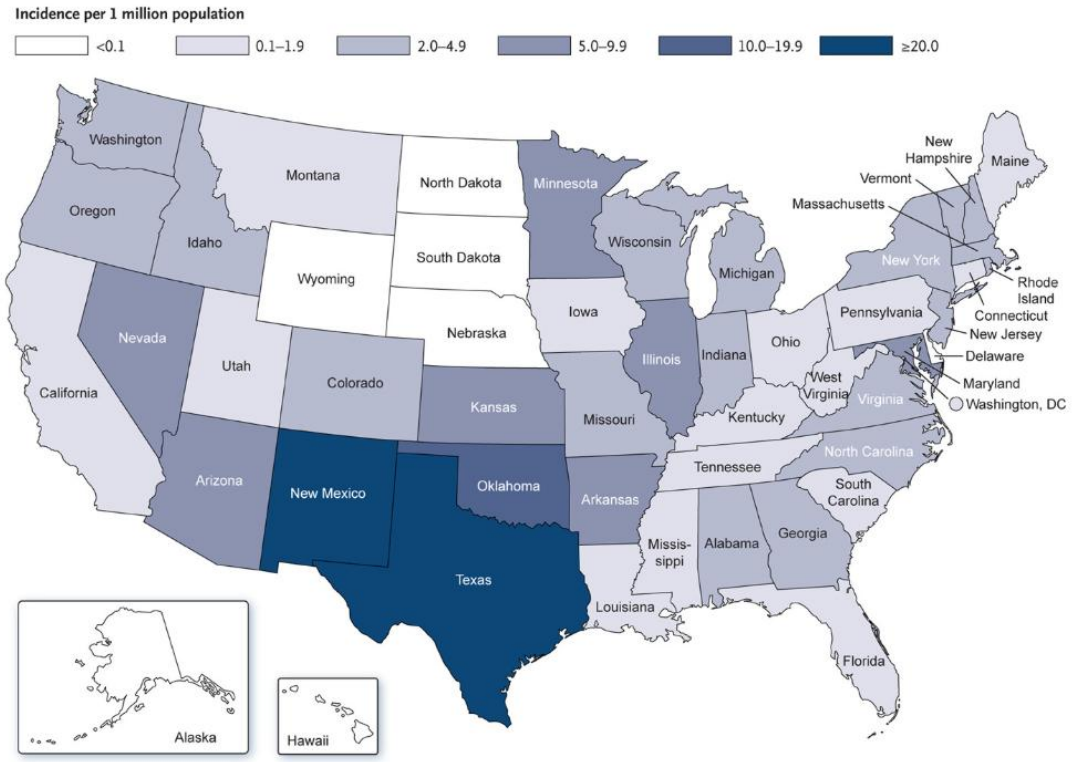
Guess that outbreak:



Answer: 2006 *E. coli* Outbreak Linked to Fresh Spinach

Why are we here?

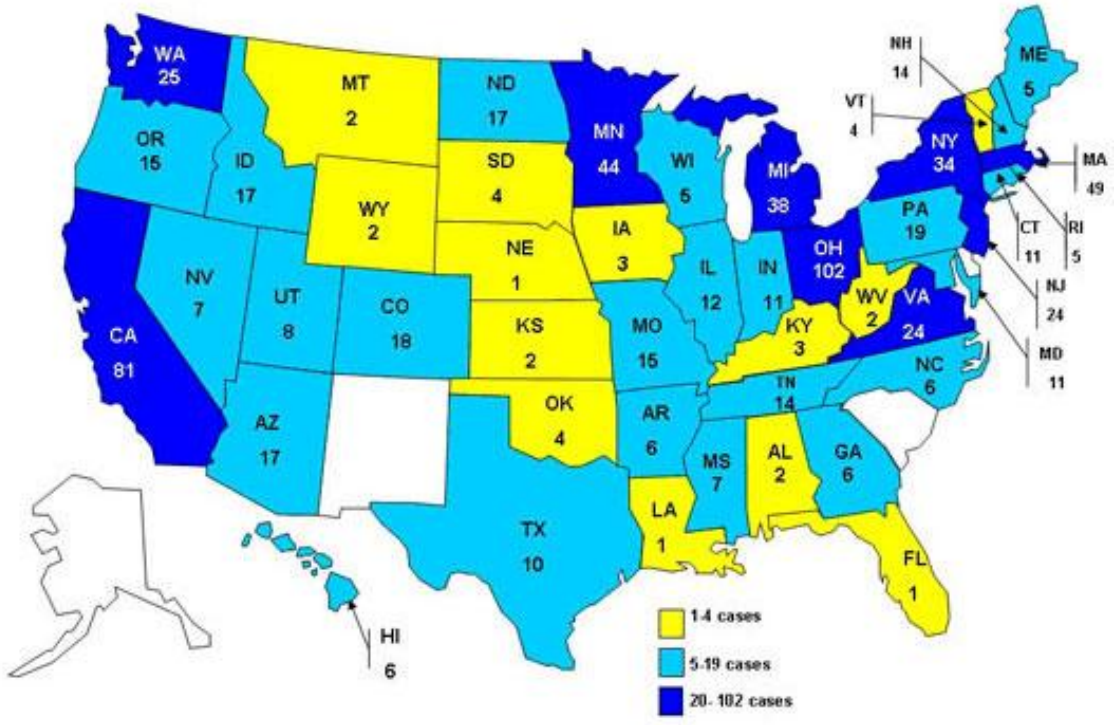
Guess that outbreak:



Answer: 2008 Outbreak of Salmonella Saintpaul Infections Associated with Raw Produce

Why are we here?

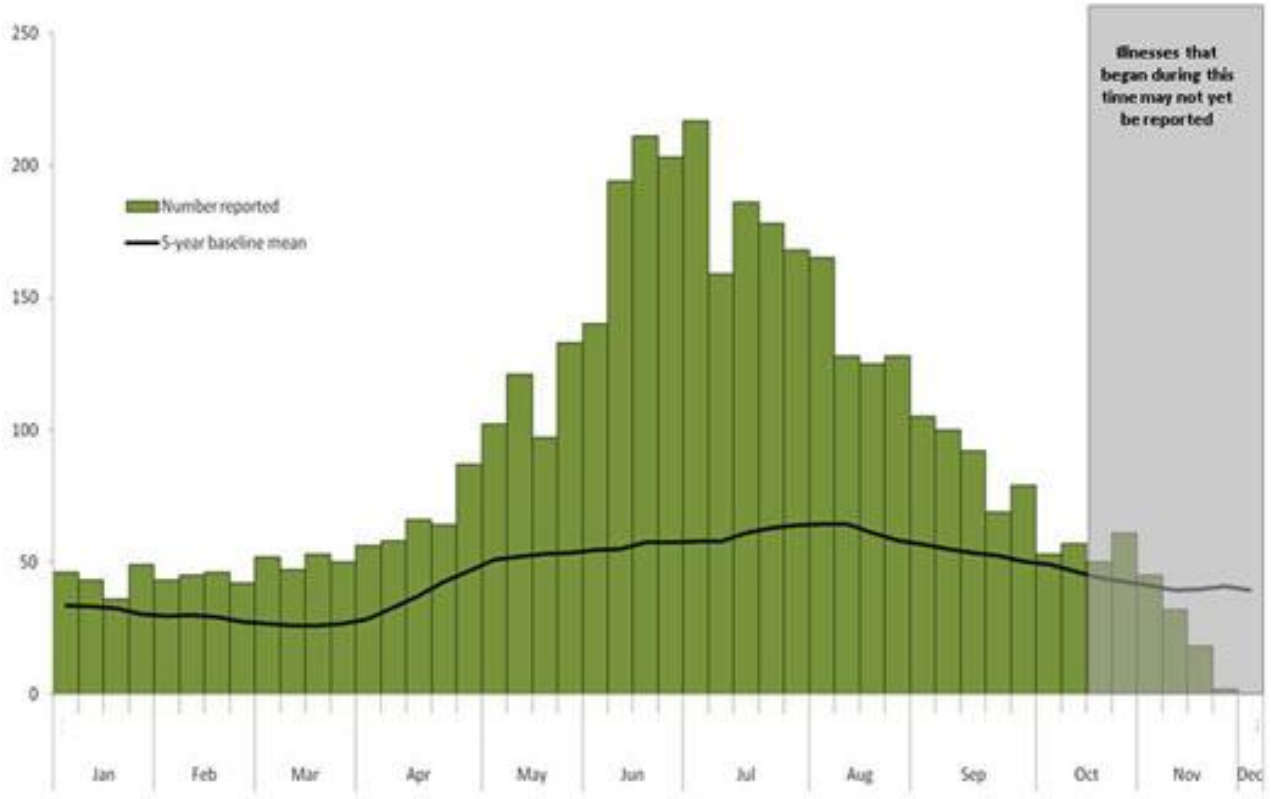
Guess that outbreak:



Answer: 2008-2009 Salmonella Outbreak Linked to Peanut Butter

Why are we here?

Guess that outbreak:



Answer: 2010 *Salmonella* Outbreak Associated with Shell Eggs

Food Safety Modernization Act – Section 204

President Obama signing FSMA - January 4, 2011

SEC. 204. > ENHANCING TRACKING AND TRACING OF FOOD AND RECORDKEEPING.

(a) Pilot Projects.--

(1) In general.--Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), taking into account recommendations from the Secretary of Agriculture and representatives of State departments of health and agriculture, shall establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) or misbranded under section 403(w) of such Act (21 U.S.C. 343(w)).

FTL Foods

- Food Traceability List Foods
- Risk Ranking Model for Food Tracing (RRM-FT)
  - Finalized in 2022
  - Based off expert panel and peer-reviewed processes
  - Seven Criteria for a final “score”
- Foods can be added or dropped from the list when the agency revises the model
- ~ every 5 years

TABLE 1—FOOD TRACEABILITY LIST

Food traceability list	Description
Cheeses, other than hard cheeses, specifically:	
• Cheese (made from pasteurized milk), fresh soft or soft unripened.	Includes soft unripened/fresh soft cheeses. Examples include, but are not limited to, cottage, chevre, cream cheese, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
• Cheese (made from pasteurized milk), soft ripened or semi-soft.	Includes soft ripened/semi-soft cheeses. Examples include, but are not limited to, brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
• Cheese (made from unpasteurized milk), other than hard cheese [1].	Includes all cheeses made with unpasteurized milk, other than hard cheeses. Does not include cheeses that are frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
Shell eggs	Shell egg means the egg of the domesticated chicken.
Nut butters	Includes all types of tree nut and peanut butters. Examples include, but are not limited to, almond, cashew, chestnut, coconut, hazelnut, peanut, pistachio, and walnut butters. Does not include soy or seed butters.
Cucumbers (fresh)	Includes all varieties of fresh cucumbers.
Herbs (fresh)	Includes all types of fresh herbs. Examples include, but are not limited to, parsley, cilantro, and basil. Herbs listed in 21 CFR 112.2(a)(1), such as dill, are exempt from the requirements of the rule under 21 CFR 1.1305(e).
Leafy greens (fresh)	Includes all types of fresh leafy greens. Examples include, but are not limited to, arugula, baby leaf, butter lettuce, chard, chicory, endive, escarole, green leaf, iceberg lettuce, kale, red leaf, pak choi, Romaine, sorrel, spinach, and watercress. Does not include whole head cabbages such as green cabbage, red cabbage, or savoy cabbage. Does not include banana leaf, grape leaf, and leaves that are grown on trees. Leafy greens listed in § 112.2(a)(1), such as collards, are exempt from the requirements of the rule under § 1.1305(e).
Leafy greens (fresh-cut)	Includes all types of fresh-cut leafy greens, including single and mixed greens.
Melons (fresh)	Includes all types of fresh melons. Examples include, but are not limited to, cantaloupe, honeydew, muskmelon, and watermelon.
Peppers (fresh)	Includes all varieties of fresh peppers.
Sprouts (fresh)	Includes all varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts. Examples include, but are not limited to, alfalfa sprouts, allium sprouts, bean sprouts, broccoli sprouts, clover sprouts, radish sprouts, alfalfa & radish sprouts, and other fresh sprouted grains, nuts, and seeds.
Tomatoes (fresh)	Includes all varieties of fresh tomatoes.
Tropical tree fruits (fresh)	Includes all types of fresh tropical tree fruit. Examples include, but are not limited to, mango, papaya, mamey, guava, lychee, jackfruit, and starfruit. Does not include non-tree fruits such as bananas, pineapple, dates, soursop, jujube, passionfruit, Loquat, pomegranate, sapodilla, and figs. Does not include tree nuts such as coconut. Does not include pit fruits such as avocado. Does not include citrus, such as orange, clementine, tangerine, mandarins, lemon, lime, citron, grapefruit, kumquat, and pomelo.
Fruits (fresh-cut)	Includes all types of fresh-cut fruits. Fruits listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Vegetables other than leafy greens (fresh-cut).	Includes all types of fresh-cut vegetables other than leafy greens. Vegetables listed in § 112.2(a)(1) are exempt from the requirements of the rule under § 1.1305(e).
Finfish (fresh and frozen), specifically:	
• Finfish, histamine-producing species.	Includes all histamine-producing species of finfish. Examples include, but are not limited to, tuna, mahi mahi, mackerel, amberjack, jack, swordfish, and yellowtail.
• Finfish, species potentially contaminated with ciguatoxin.	Includes all finfish species potentially contaminated with ciguatoxin. Examples include, but are not limited to, grouper, barracuda, and snapper.
• Finfish, species not associated with histamine or ciguatoxin.	Includes all species of finfish not associated with histamine or ciguatoxin. Examples include, but are not limited to, cod, haddock, Alaska pollock, salmon, tilapia, and trout.[2] Siluriformes fish, such as catfish, are not included.[3]

RRM-FT Criteria

Table 1. Moderate and strong score definitions for each of the seven criteria in the model

Criteria	Moderate (criteria score=3)	Strong (criteria score=9)
Outbreaks and illnesses (C1)[a]	• >1-10 outbreaks and hundreds of cases since 1999; OR • ≥10 outbreaks and tens of cases since 1999; OR • ≤1 outbreak and thousands of cases since 1999	• ≥10 outbreaks and hundreds or thousands of cases since 1999; OR • >1-10 outbreaks and thousands of cases since 1999
Severity of illness (C2)	• Hospitalization rate >10-20% and mortality rate 0%; OR • Hospitalization rate ≤20% and mortality rate >0% to ≤0.5%	• Hospitalization rate >20% OR mortality rate >0.5%
Likelihood of contamination (C3)[b]	• Contamination rate >0.1-1%; OR • >1-10 RFR[c] reports/year; OR • >5-10 recalls/year	• Contamination rate >1%; OR • >10 RFR reports/year; OR • >10 recalls/year
Growth potential with consideration of shelf life (C4)	• 1-3 $\log_{10}$ CFU (colony forming unit) increase given customary shelf life	• ≥3 $\log_{10}$ CFU increase given customary shelf life

RRM-FT Criteria

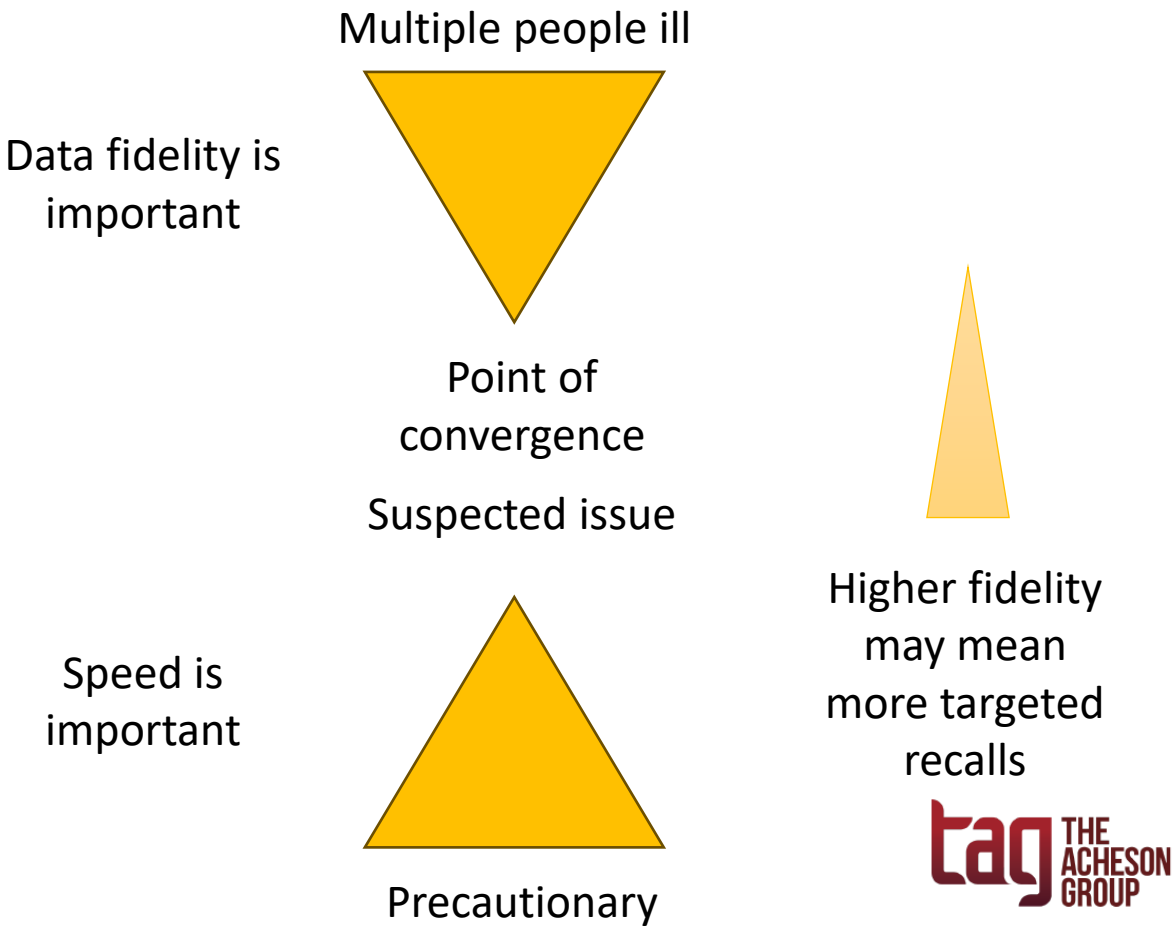
Manufacturing process contamination probability and industry-wide intervention (C5)	• Recurring or frequent detection of contamination; control measures available and adequate, evidence for consistent implementation in industry; OR • Known history of contamination; control measures available but lack of an adequate kill step, lack of evidence for consistent implementation, or evidence for inconsistent implementation in industry; OR • Infrequent detection of contamination; lack of adequate control measures, or evidence of poor implementation of control measures in industry	• Recurring or frequent detection of contamination; lack of adequate control measures, or evidence of poor implementation of control measures in industry; OR • Recurring or frequent detection of contamination; control measures available but lack of an adequate kill step, lack of evidence for consistent implementation, or evidence for inconsistent implementation in industry; OR • Known history of contamination; lack of adequate control measures, or evidence of poor implementation of control measures in industry
Consumption (C6)	• >10% consumers and >0-10 g/serving; OR • >5-10% consumers and >10-100 g/serving; OR • 1-5% consumers and > 100 g/serving	• >10% consumers and >10 g/serving; OR • >5-10% consumers and >100 g/serving
Cost of illness (C7)	• >$1M to 10M/year	• >$10M/year

[a] Weighted by year of outbreak; [b] Weighted by number of samples, geographic location and year; [c] Reportable Food Registry

Traceability vs Recall

Traceability = Investigation

Recall = Corrective Action



Retail/Restaurant
- Receiving CTEs

Distribution, supplier steps
- Shipping CTEs
- Receiving CTEs

Manufacturers
- Transformation CTEs
- Shipping CTEs
- Receiving CTEs

First Land-based Receiver, Harvesting
- Harvest CTEs
- TLC creation
- Shipping CTEs

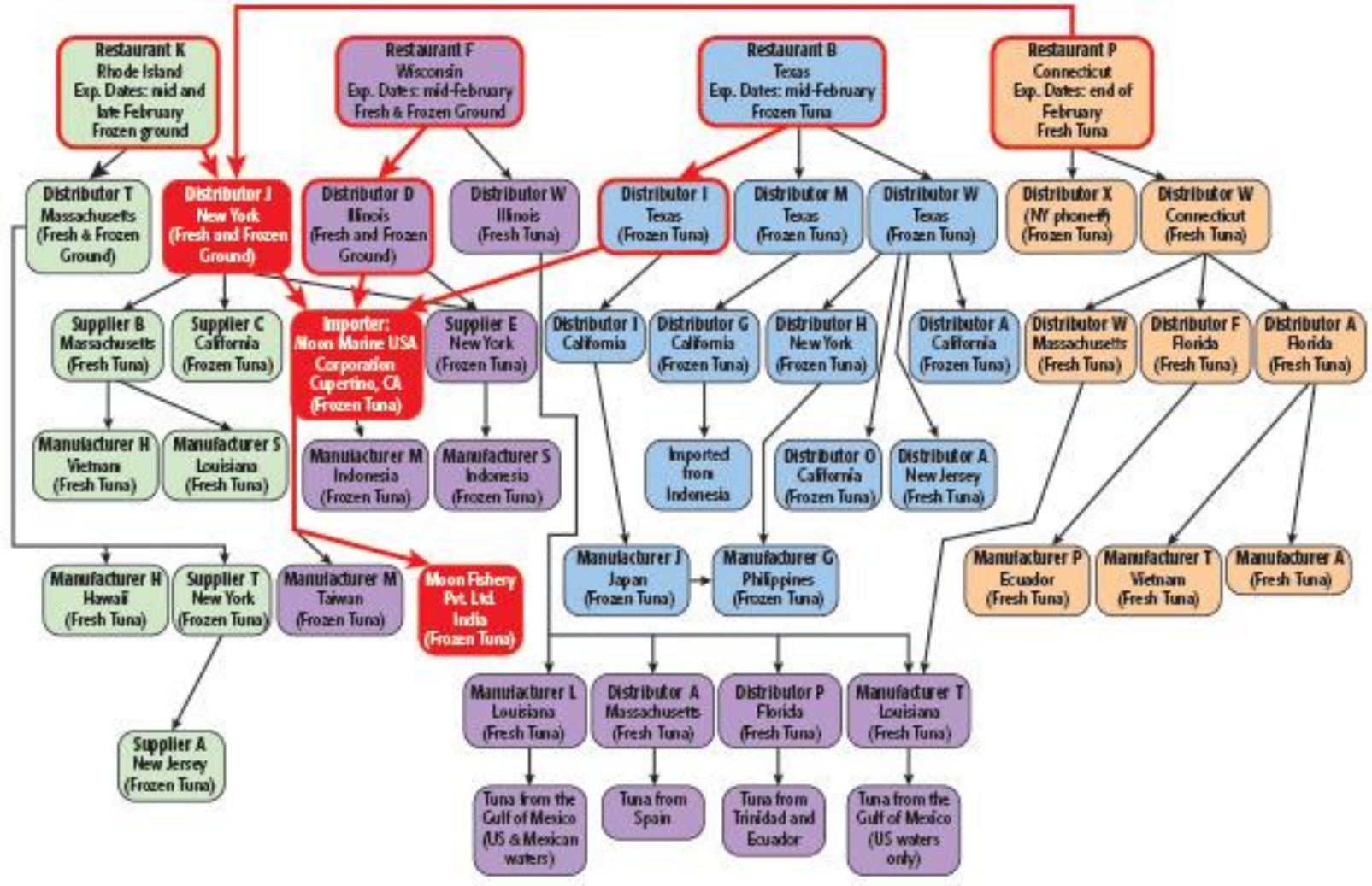


Figure 2: Salmonella Bareilly Traceback (The distribution of the contaminated tuna is outlined in red.)

https://www.foodsafetynews.com/2014/10/traceback-investigations-mapping-the-maze/

The Traceability Lot Code

One data field to rule them all, and in the supply chain, bind them.

The TLC is new and essentially does not exist in today's supply chain

Key Concept – cannot aggregate or change lots codes at will

The Traceability Lot Code Source

The place on the earth where the traceability lot code was assigned

Also a new concept which allows for "shortcuts" in a traceback investigation

Key Concept – allows investigators to potentially find points of convergence more quickly

Thank you

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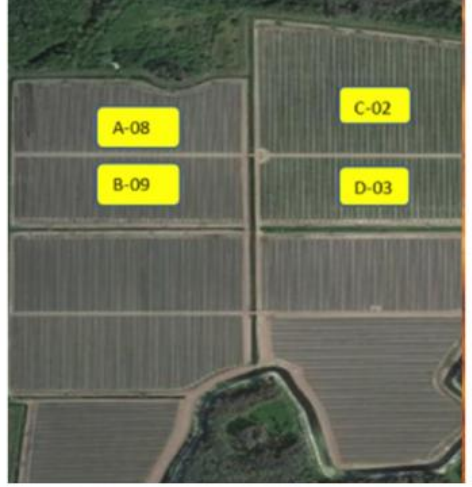
Food Traceability Rule Implementation and Resource Updates



November 18, 2025

FSPCA Annual Meeting

What will the Food Traceability Rule Require?

- Establishes 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

Exemptions*

Farms
- Certain small produce farms
- Certain small shell egg producers
- Certain other small RAC producers
- Certain food produced + packaged on farm
- Farms selling food directly to consumers

Commingled raw agricultural commodities (RACs)
- Certain commingled RACs (not fruits & vegetables)
- Certain RACs that will be commingled

Fishing vessels, molluscan shellfish
- Owner/operator/agent in charge of a fishing vessel
- Raw bivalve molluscan shellfish

Retail food establishments (RFEs), restaurants
- Certain small RFEs + restaurants
- RFEs or restaurants purchasing food directly from a farm
- RFEs or restaurants purchasing food from another RFE or restaurant on ad hoc basis

Certain types of processing
- Produce and shell eggs that receive certain processing
- Exemptions related to a kill step
- Exemptions related to changing a food to a form not on the list

Personal consumption, holding food for individual consumers
- Personal consumption
- Holding food for individual consumers

Other
- Produce listed as “rarely consumed raw”
- Farm-to-school/farm-to-institution programs
- Foods regulated by USDA
- Transporters of food
- Non-profit food establishments
- Food for research or evaluation

*Full list of exemptions in § 1.1305 of the final rule

Compliance Date

~~January 20, 2026~~

- On August 7, 2025 we announced our intention to extend the FTR compliance date by 30 months.
- Would apply to all firms/farms subject to the FTR.

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)	

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

CTE and KDE Framework

The role of the entity in the supply chain defines the data it must keep and share

Critical Tracking Events

Harvesting, Cooling, Initial Packing, First Land-based Receiving, Shipping, Receiving, and Transforming are Critical Tracking Events (CTEs) for which records would be required.

Key Data Elements

Required records would need to contain specific Key Data Elements (KDEs). The KDEs would depend on the CTE being performed.

The KDEs required would vary depending on the CTE that is being performed.

The records required at each CTE would need to contain and link the KDEs to the traceability lot.

FTR Implementation

FTR Inspectional Approach

Collaborated with experts across FDA to develop inspectional approaches

Discussed with small group of state regulators, made adjustments

Engaging more broadly with SLTT regulators to coordinate approach

Impacts on Outbreak/Traceback Investigations

- It will be mandatory for covered entities handling foods on the FTL to provide records
- Create standard nomenclature for traceability information
- Traceability Lot Code could help skip steps in supply chain investigations
- Outbreaks – Electronic Sortable Spreadsheet

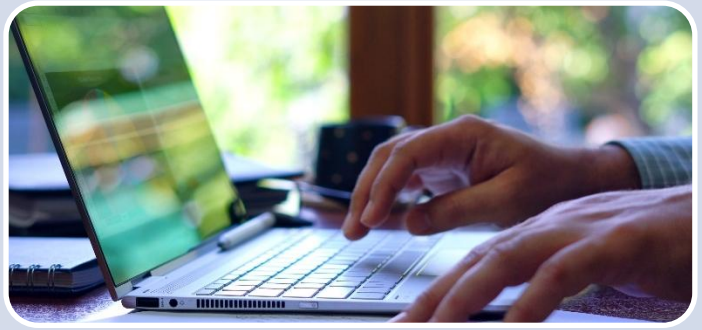
FTR Regulator Training

Goals

- Provide an understanding of the rule
- Inspection considerations

Target Audience

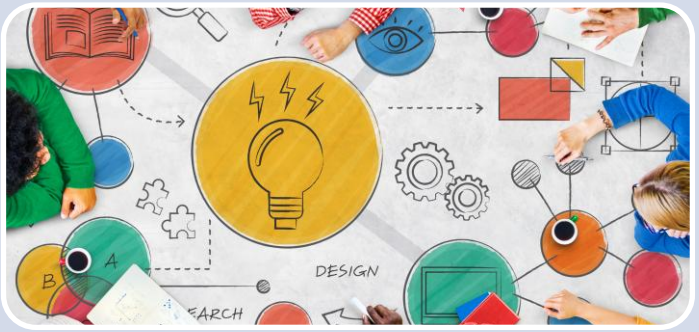
- FDA investigators
- SLTT regulators and investigators

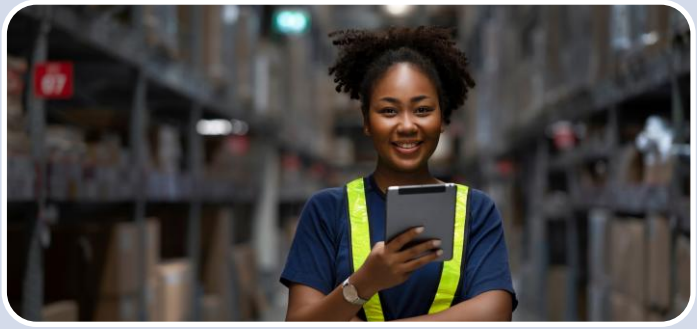


Modality

- Web-based training course
- Modules on different topics/Self paced

FTR Industry Training – with FSPCA





Goals

- Provide an understanding of the rule
- Considerations for how to build a traceability program

Target Audience

- All persons covered by the rule

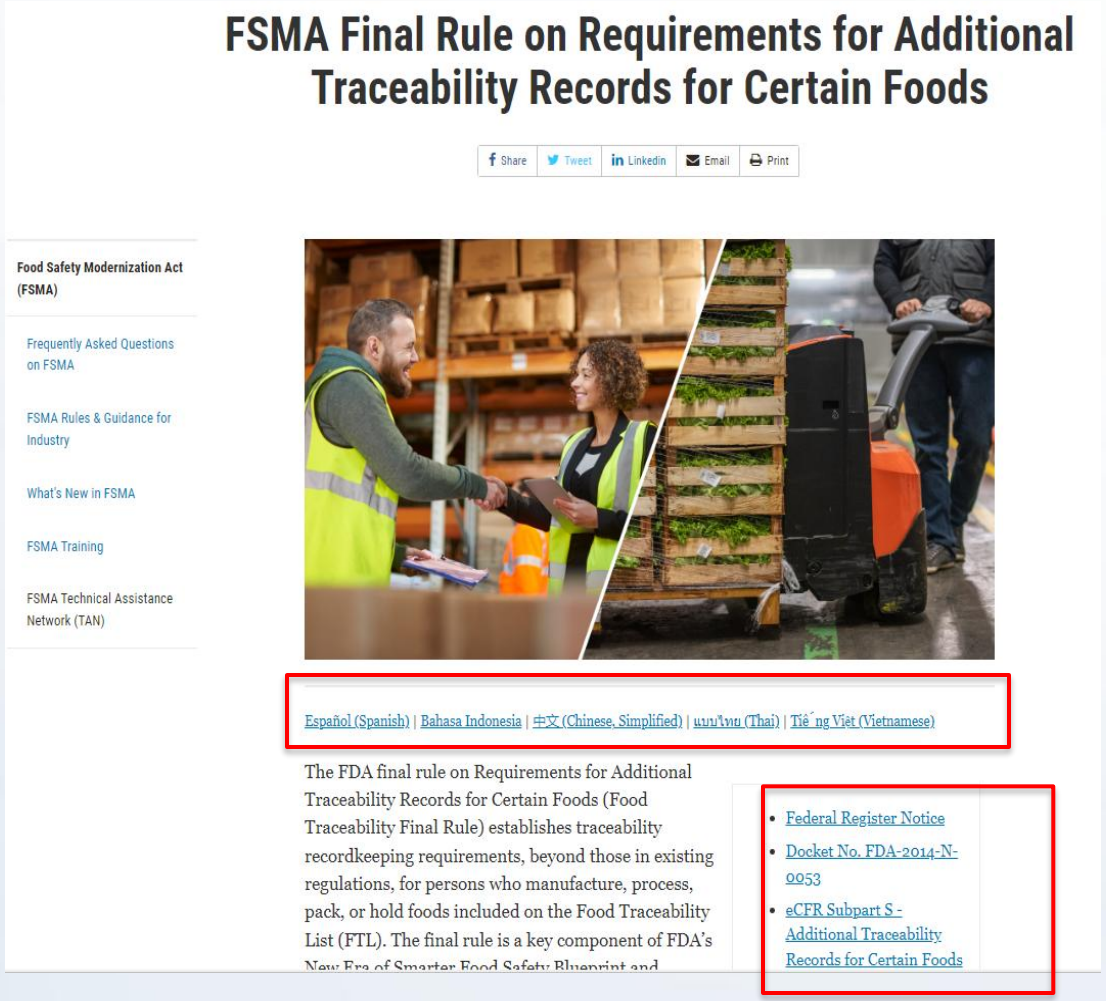
Modality

- Train-the-trainer model
- Lead Instructors will deliver the training
- In person and virtual offerings

Receipt and Analysis of Traceability Data

- Development of an internal FDA system to facilitate analysis of traceability information.
- Development of system for sending required information to FDA.

Available Resources



Food Traceability Final Rule webpage

- Food Traceability Final Rule (Federal Register)
- eCFR - 21 CFR, Part 1, Subpart S (codified)
- Translations

Available Resources cont'd

- Food Traceability List webpage
- Frequently Asked Questions (FAQs)
- Food Traceability Final Rule Webinar
- Small Entities Compliance Guide
- At-a-Glance handout
- Critical Tracking Events and Key Data Elements document
- Traceability Lot code webpage
- Exemptions tool
- Electronic Sortable Spreadsheet w/data in Excel™
- Risk Ranking Model Results tool
- Traceability Plan Examples
- Supply Chain Examples
- Resources for Farms and RFEs/restaurants
- Questions?
  - FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

Thank you!

BREAKOUT SESSIONS

Have a burning question? This is your chance to get answers to your questions and learn from questions that others ask.

FOOD SAFETY PRIORITIES AND POLICIES - AN EXPERT PANEL DISCUSSION

MAIN CONFERENCE ROOM

ASK AN EXPERT: ANIMAL FOOD

STRATHMORE A & B

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

IFSH | INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
Innovation Through Collaboration

FOOD SAFETY PRIORITIES AND POLICIES - AN EXPERT PANEL DISCUSSION

EXPERT
DONNA GARREN
American Frozen Food Institute (AFFI)

EXPERT
STEVEN MANDERNACH
Association of Food and Drug Officials (AFDO)

EXPERT
JENNIFER McENTIRE
Food Safety Strategy, LLC

EXPERT
BRIAN RONHOLM, M.A.
Consumer Reports

MODERATOR
JERRY WOJTALA
International Food Protection Training Institute

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IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
Innovation Through Collaboration

ASK THE EXPERTS: ANIMAL FOOD

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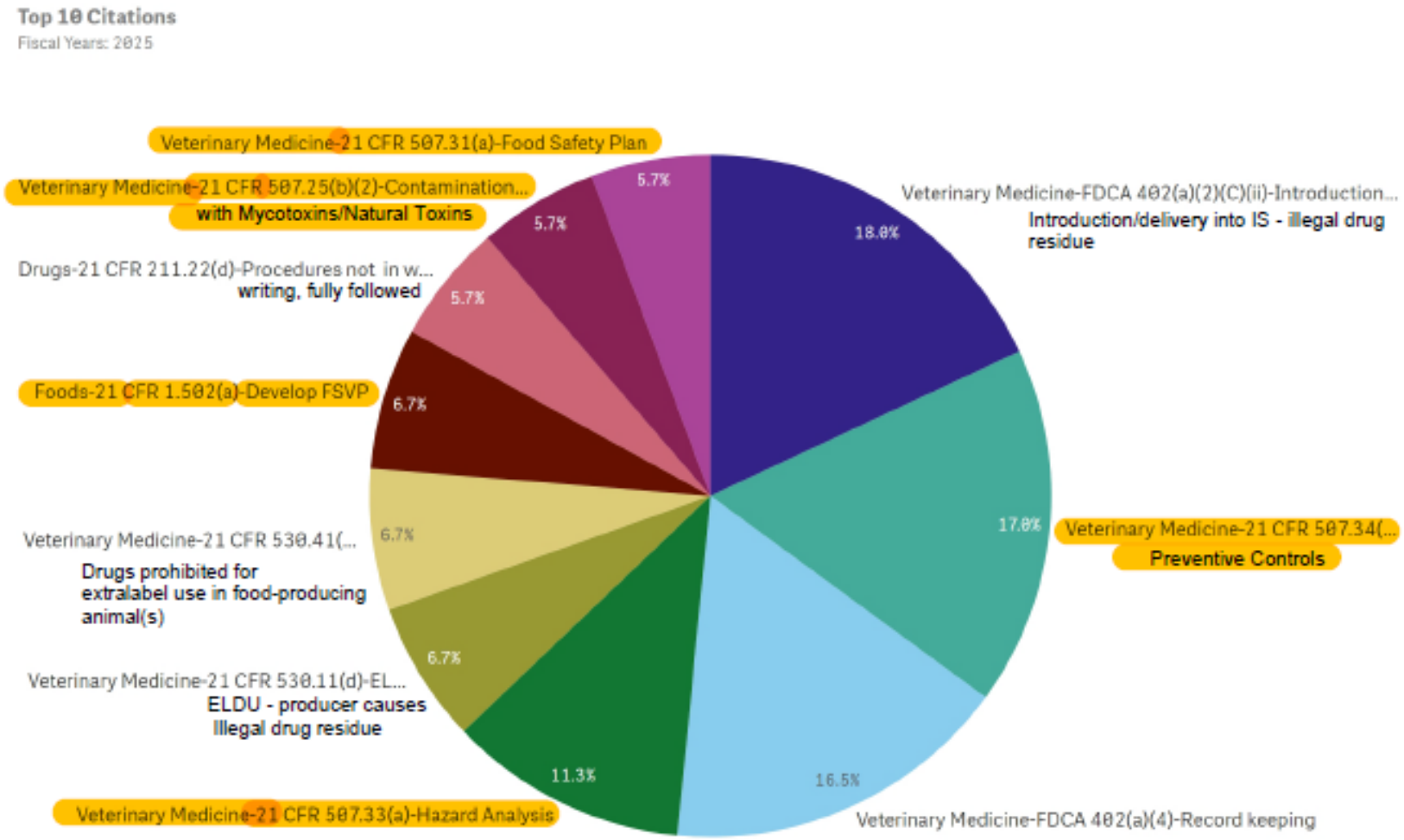
FDA CVM INSPECTION TRENDS

FDA CVM: FY2025



FSPCA CURRICULUM UPDATES

ANIMAL FOOD BREAKOUT SESSION

Case Studies:

EXPERTS:

Marissa Cohen, PhD, North Carolina State University

Berit Foss, PhD, National Grain and Feed Association

Breakout Objective

Explore the critical role of ingredients in building and maintaining a robust food safety plan.

Background Information

1. Review required components of a food safety plan.
2. Review Reanalysis under Part 507 regulations.

Case Studies

1. Highly Pathogenic Avian Influenza: How raw ingredients introduced unexpected hazards and prompted FDA action.
2. GRAS Reform: Current focus on ingredient transparency.

21 CFR 507.31 Food Safety Plan

- *(c) The written food safety plan must include:*
  - *(1) The written hazard analysis as required by § 507.33(a)(2);*
  - *(2) The written preventive controls as required by § 507.34(b);*
  - *(3) The written supply-chain program as required by subpart E of this part;*
  - *(4) The written recall plan as required by § 507.38(a)(1);*
  - *(5) The written procedures for monitoring the implementation of the preventive controls as required by § 507.40(a)(1);*
  - *(6) The written corrective action procedures as required by § 507.42(a)(1); and*
  - *(7) The written verification procedures as required by § 507.49(b).*
- *(d) The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.*

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Components of a Food Safety Plan

Required Components

- Hazard Analysis
- Preventive Controls*
  - Supply-Chain Applied Controls*
  - Process Controls*
  - Sanitation Controls*
  - Other Controls*
- PC Management Components*
  - Monitoring*
  - Corrective Actions and Corrections*
  - Verification*
    - Validation*
    - Verification of Implementation and Effectiveness*
  - Recall Plan*
- Reanalysis
- Implementation Records

Other Useful Components

- Background Information
  - Food Safety Team
  - Facility Overview
  - Flow Diagram

Required, when appropriate, if hazard analysis identifies a *hazard requiring a preventive control

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FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

4-6

Components of a Food Safety Plan

Required Components

- Hazard Analysis
- Preventive Controls*
  - Supply-Chain Applied Controls*
  - Process Controls*
  - Sanitation Controls*
  - Other Controls*
- PC Management Components*
  - Monitoring*
  - Corrective Actions and Corrections*
  - Verification*
    - Validation*
    - Verification of Implementation and Effectiveness*
  - Recall Plan*
- Reanalysis
- Implementation Records

Other Useful Components

- Background Information
  - Food Safety Team
  - Facility Overview
  - Flow Diagram

Update to Curriculum under other useful components:

- Ingredient List

Required, when appropriate, if hazard analysis identifies a *hazard requiring a preventive control

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4-6

Reanalysis of the Food Safety Plan

21 CFR 507.50 Reanalysis

- *(a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years.*
- *(b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:*
  - *(1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;*
  - *(2) Whenever you become aware of new information about potential hazards associated with the animal food;*
  - *(3) Whenever appropriate after an unanticipated animal food safety problem in accordance with § 507.42(b); and*
  - *(4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.*

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4-17

Reanalysis Timeframe

21 CFR 507.50 Reanalysis

- *(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified;*
  - *(1) Before any change in activities (including any change in preventive control) at the facility is operative; or,*
  - *(2) When necessary to demonstrate the control measures can be implemented as designed:*
    - *(i) Within 90 calendar days after production of the applicable animal food first begins; or*
    - *(ii) Within a reasonable timeframe, provided that the Preventive Controls Qualified Individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable animal food first begins.*

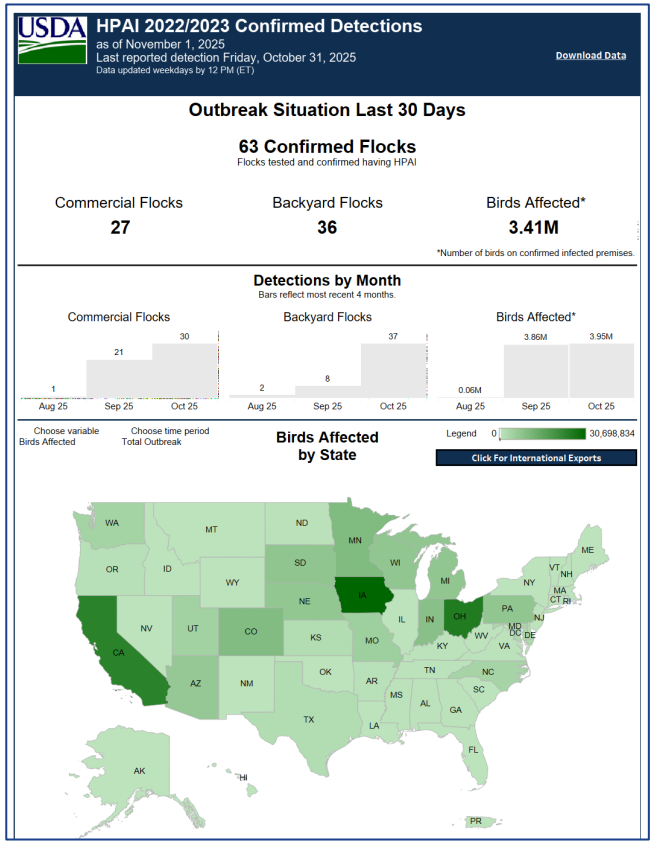
4-18

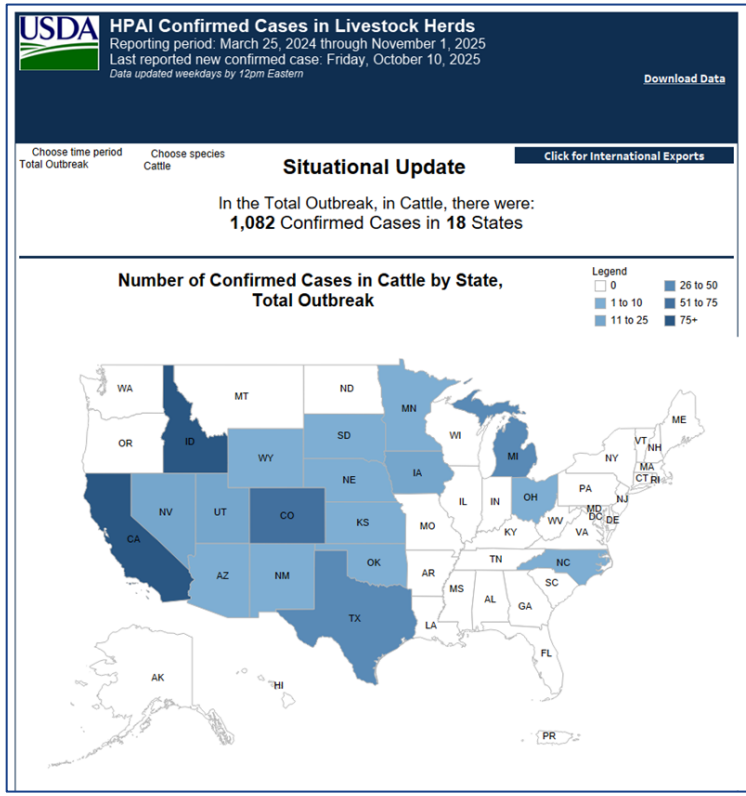
FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

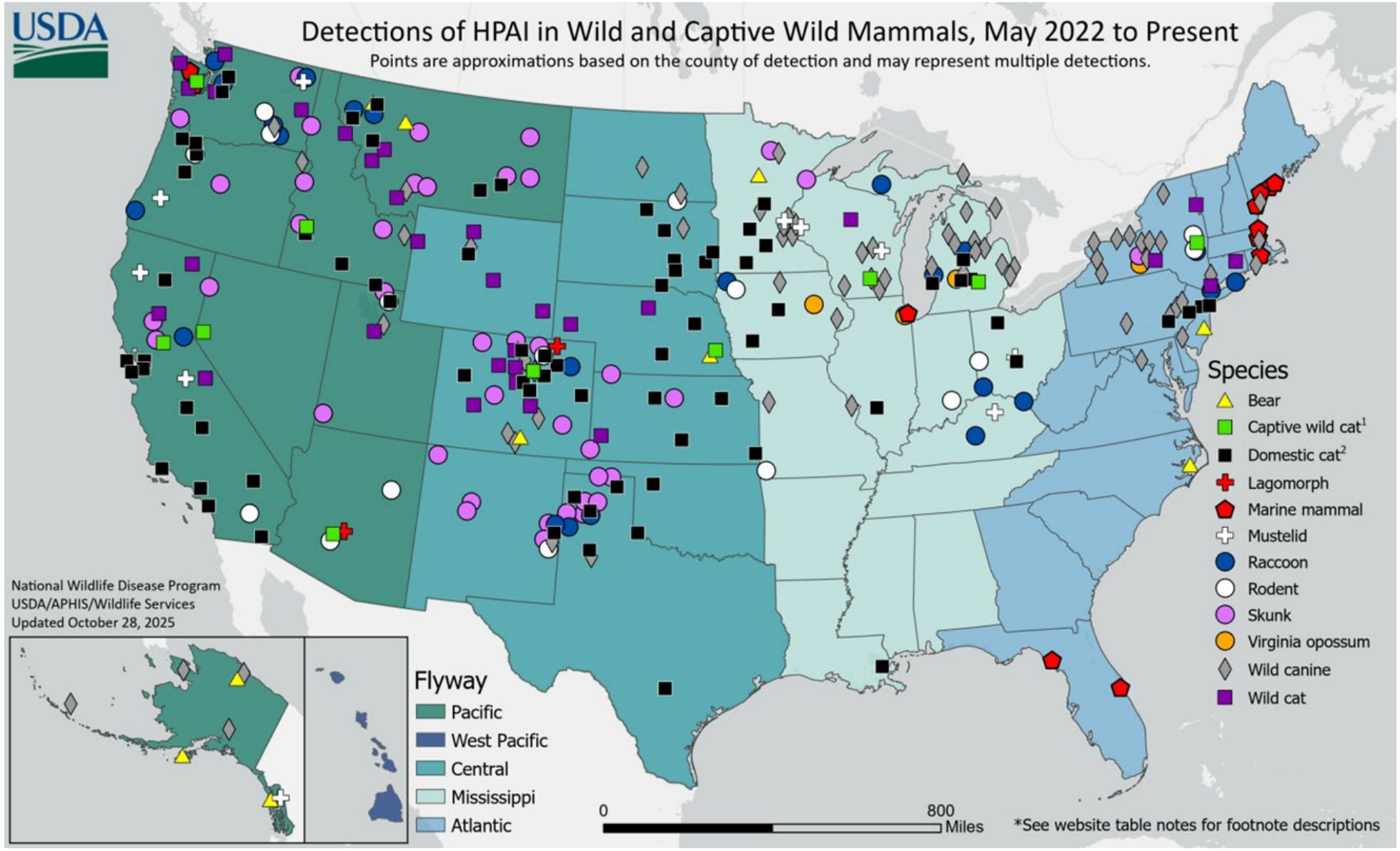
CASE STUDY: HPAI

Highly Pathogenic Avian Influenza

- HPAI is a highly contagious virus that primarily affects wild and domestic birds and is carried by migratory waterfowl.
- Around the country, the virus has been detected in various species of wild carnivorous mammals







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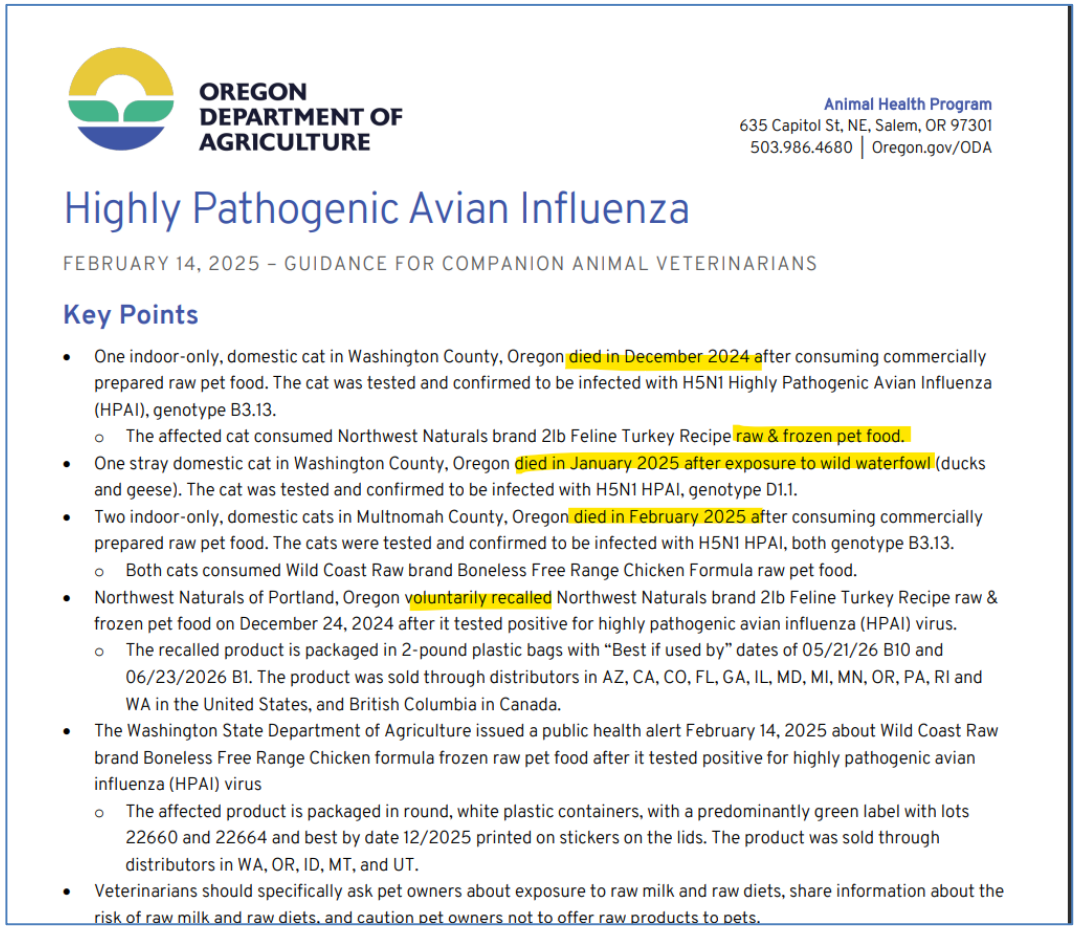
State Notifications of Pet Deaths



OREGON DEPARTMENT OF AGRICULTURE

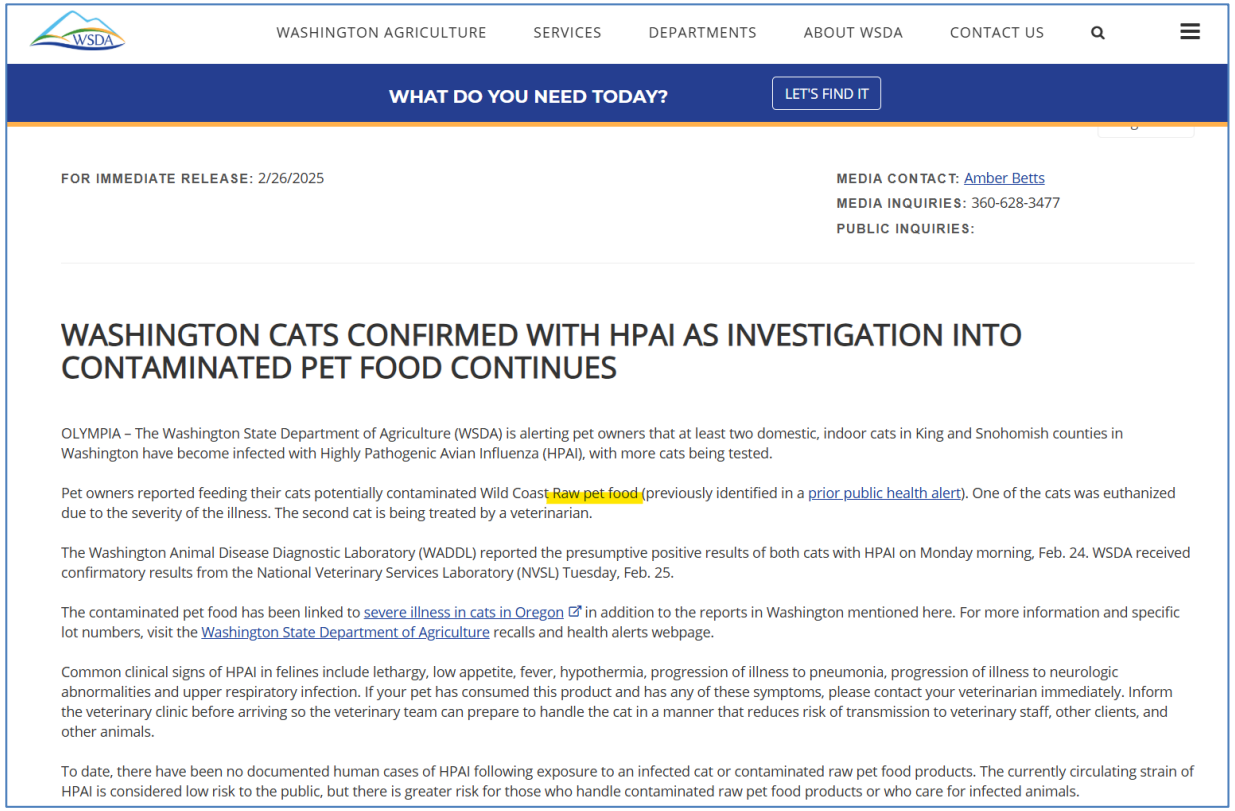
Animal Health Program
635 Capitol St, NE, Salem, OR 97301
503.986.4680 | Oregon.gov/ODA

Highly Pathogenic Avian Influenza

FEBRUARY 14, 2025 – GUIDANCE FOR COMPANION ANIMAL VETERINARIANS

Key Points

- One indoor-only, domestic cat in Washington County, Oregon died in December 2024 after consuming commercially prepared raw pet food. The cat was tested and confirmed to be infected with H5N1 Highly Pathogenic Avian Influenza (HPAI), genotype B3.13.
  - The affected cat consumed Northwest Naturals brand 2lb Feline Turkey Recipe raw & frozen pet food.
- One stray domestic cat in Washington County, Oregon died in January 2025 after exposure to wild waterfowl (ducks and geese). The cat was tested and confirmed to be infected with H5N1 HPAI, genotype D1.1.
- Two indoor-only, domestic cats in Multnomah County, Oregon died in February 2025 after consuming commercially prepared raw pet food. The cats were tested and confirmed to be infected with H5N1 HPAI, both genotype B3.13.
  - Both cats consumed Wild Coast Raw brand Boneless Free Range Chicken Formula raw pet food.
- Northwest Naturals of Portland, Oregon voluntarily recalled Northwest Naturals brand 2lb Feline Turkey Recipe raw & frozen pet food on December 24, 2024 after it tested positive for highly pathogenic avian influenza (HPAI) virus.
  - The recalled product is packaged in 2-pound plastic bags with "Best if used by" dates of 05/21/26 B10 and 06/23/2026 B1. The product was sold through distributors in AZ, CA, CO, FL, GA, IL, MD, MI, MN, OR, PA, RI and WA in the United States, and British Columbia in Canada.
- The Washington State Department of Agriculture issued a public health alert February 14, 2025 about Wild Coast Raw brand Boneless Free Range Chicken formula frozen raw pet food after it tested positive for highly pathogenic avian influenza (HPAI) virus
  - The affected product is packaged in round, white plastic containers, with a predominantly green label with lots 22660 and 22664 and best by date 12/2025 printed on stickers on the lids. The product was sold through distributors in WA, OR, ID, MT, and UT.
- Veterinarians should specifically ask pet owners about exposure to raw milk and raw diets, share information about the risk of raw milk and raw diets, and caution pet owners not to offer raw products to pets.



WSDA

WASHINGTON AGRICULTURE SERVICES DEPARTMENTS ABOUT WSDA CONTACT US

WHAT DO YOU NEED TODAY? LET'S FIND IT

FOR IMMEDIATE RELEASE: 2/26/2025

MEDIA CONTACT: Amber Betts
MEDIA INQUIRIES: 360-628-3477
PUBLIC INQUIRIES:

WASHINGTON CATS CONFIRMED WITH HPAI AS INVESTIGATION INTO CONTAMINATED PET FOOD CONTINUES

OLYMPIA – The Washington State Department of Agriculture (WSDA) is alerting pet owners that at least two domestic, indoor cats in King and Snohomish counties in Washington have become infected with Highly Pathogenic Avian Influenza (HPAI), with more cats being tested.

Pet owners reported feeding their cats potentially contaminated Wild Coast Raw pet food (previously identified in a prior public health alert). One of the cats was euthanized due to the severity of the illness. The second cat is being treated by a veterinarian.

The Washington Animal Disease Diagnostic Laboratory (WADDL) reported the presumptive positive results of both cats with HPAI on Monday morning, Feb. 24. WSDA received confirmatory results from the National Veterinary Services Laboratory (NVSL) Tuesday, Feb. 25.

The contaminated pet food has been linked to severe illness in cats in Oregon in addition to the reports in Washington mentioned here. For more information and specific lot numbers, visit the Washington State Department of Agriculture recalls and health alerts webpage.

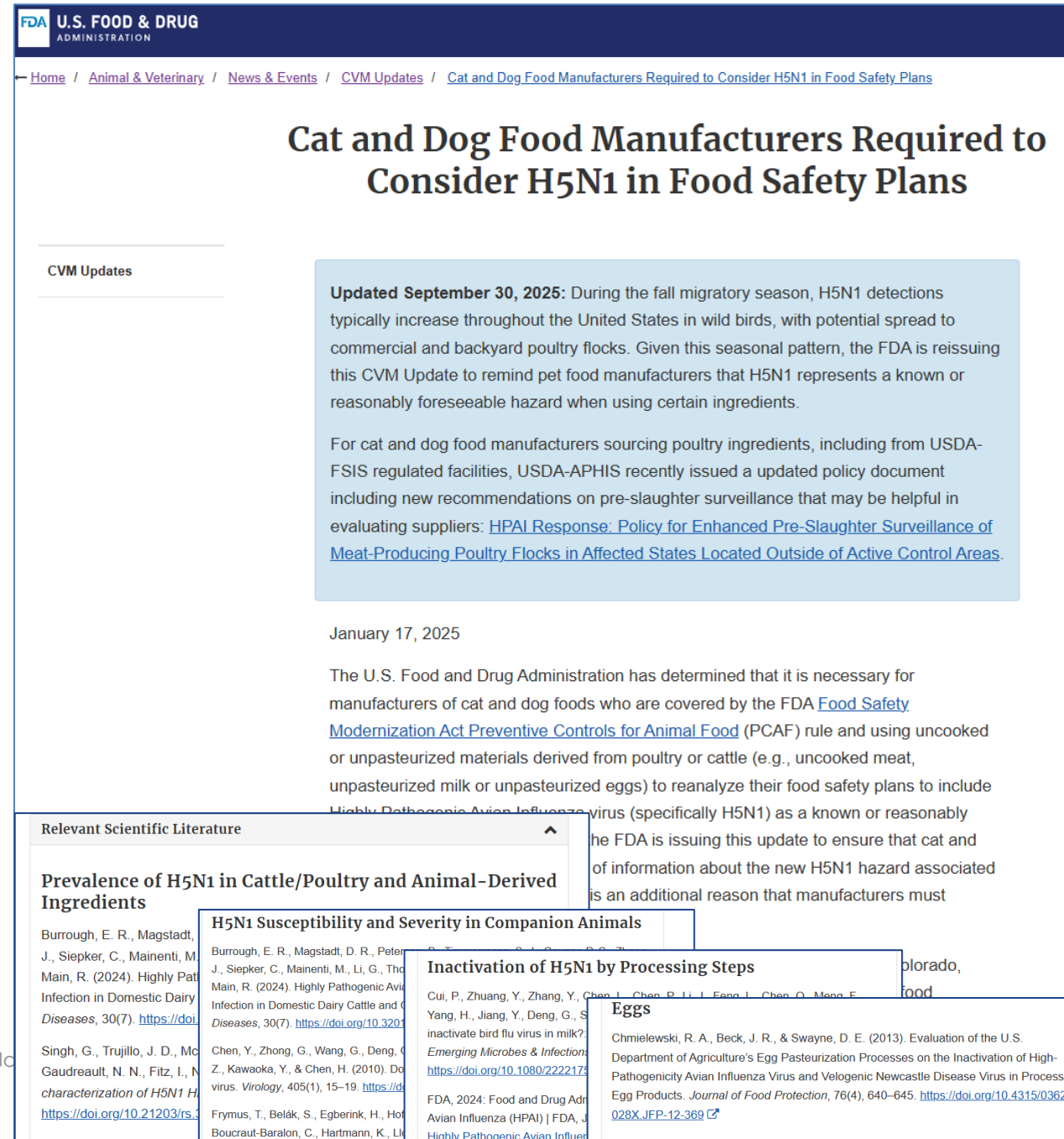
Common clinical signs of HPAI in felines include lethargy, low appetite, fever, hypothermia, progression of illness to pneumonia, progression of illness to neurologic abnormalities and upper respiratory infection. If your pet has consumed this product and has any of these symptoms, please contact your veterinarian immediately. Inform the veterinary clinic before arriving so the veterinary team can prepare to handle the cat in a manner that reduces risk of transmission to veterinary staff, other clients, and other animals.

To date, there have been no documented human cases of HPAI following exposure to an infected cat or contaminated raw pet food products. The currently circulating strain of HPAI is considered low risk to the public, but there is greater risk for those who handle contaminated raw pet food products or who care for infected animals.

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FDA CVM Update: Reanalysis

- Reanalyze food safety plans to include HPAI (specifically H5N1) as a known or reasonably foreseeable hazard.
- This applies to manufacturers using uncooked or unpasteurized materials derived from poultry or cattle (e.g., raw meat, unpasteurized milk, or eggs).
- The reanalysis must assess the severity and likelihood of illness from HPAI and determine if preventive controls (e.g., cooking, pasteurization, sourcing protocols) are needed.



U.S. FOOD & DRUG ADMINISTRATION

Home / Animal & Veterinary / News & Events / CVM Updates / Cat and Dog Food Manufacturers Required to Consider H5N1 in Food Safety Plans

Cat and Dog Food Manufacturers Required to Consider H5N1 in Food Safety Plans

CVM Updates

Updated September 30, 2025: During the fall migratory season, H5N1 detections typically increase throughout the United States in wild birds, with potential spread to commercial and backyard poultry flocks. Given this seasonal pattern, the FDA is reissuing this CVM Update to remind pet food manufacturers that H5N1 represents a known or reasonably foreseeable hazard when using certain ingredients.

For cat and dog food manufacturers sourcing poultry ingredients, including from USDA-FSIS regulated facilities, USDA-APHIS recently issued a updated policy document including new recommendations on pre-slaughter surveillance that may be helpful in evaluating suppliers: HPAI Response: Policy for Enhanced Pre-Slaughter Surveillance of Meat-Producing Poultry Flocks in Affected States Located Outside of Active Control Areas.

January 17, 2025

The U.S. Food and Drug Administration has determined that it is necessary for manufacturers of cat and dog foods who are covered by the FDA Food Safety Modernization Act Preventive Controls for Animal Food (PCAF) rule and using uncooked or unpasteurized materials derived from poultry or cattle (e.g., uncooked meat, unpasteurized milk or unpasteurized eggs) to reanalyze their food safety plans to include

virus (specifically H5N1) as a known or reasonably

he FDA is issuing this update to ensure that cat and

of information about the new H5N1 hazard associated

is an additional reason that manufacturers must

Relevant Scientific Literature

Prevalence of H5N1 in Cattle/Poultry and Animal-Derived Ingredients

Burrough, E. R., Magstadt, J., Siepker, C., Mainenti, M. Main, R. (2024). Highly Pat Infection in Domestic Dairy *Diseases*, 30(7). https://doi.

Singh, G., Trujillo, J. D., Mc Gaudreault, N. N., Fitz, I., N *characterization of H5N1 H* https://doi.org/10.21203/rs.

H5N1 Susceptibility and Severity in Companion Animals

Burrough, E. R., Magstadt, D. R., Peter J., Siepker, C., Mainenti, M., Li, G., Tho Main, R. (2024). Highly Pathogenic Avia Infection in Domestic Dairy Cattle and *Diseases*, 30(7). https://doi.org/10.320

Chen, Y., Zhong, G., Wang, G., Deng, Z., Kawaoka, Y., & Chen, H. (2010). Do virus. *Virology*, 405(1), 15–19. https://d

Frymus, T., Belák, S., Egberink, H., Hot Boucraut-Baralon, C., Hartmann, K., Lic

Inactivation of H5N1 by Processing Steps

Cui, P., Zhuang, Y., Zhang, Y., Chen, J., Chen, R., Li, J., Feng, J., Chen, Q., Meng, F. Yang, H., Jiang, Y., Deng, G., S inactivate bird flu virus in milk? *Emerging Microbes & Infections* https://doi.org/10.1080/2222175

FDA, 2024: Food and Drug Adr Avian Influenza (HPAI) | FDA, J Highly Pathogenic Avian Influe

Eggs

Chmielewski, R. A., Beck, J. R., & Swayne, D. E. (2013). Evaluation of the U.S. Department of Agriculture's Egg Pasteurization Processes on the Inactivation of High-Pathogenicity Avian Influenza Virus and Velogenic Newcastle Disease Virus in Process Egg Products. *Journal of Food Protection*, 76(4), 640–645. https://doi.org/10.4315/0362 028X.JFP-12-369

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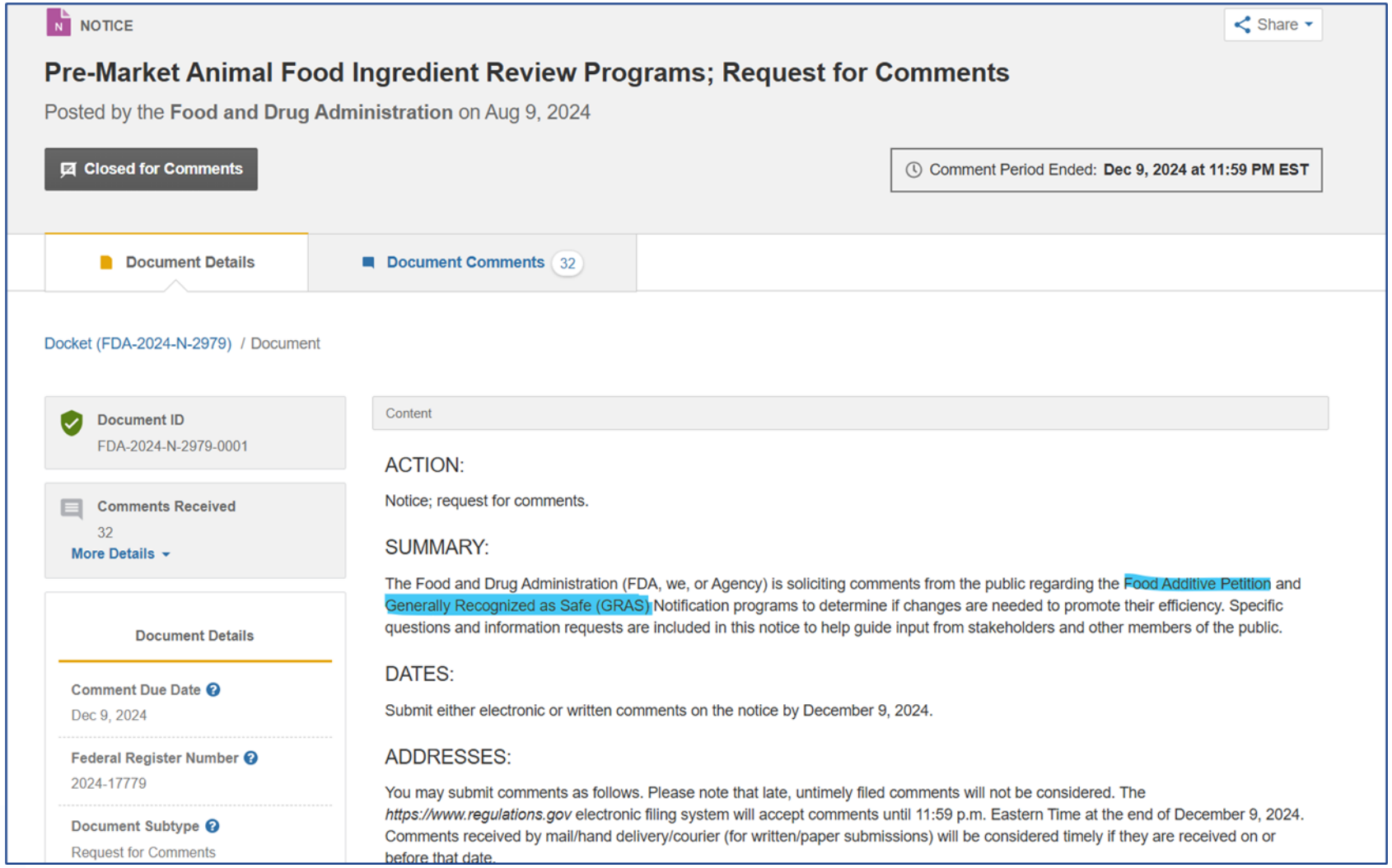
FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

GRAS REFORM

GRAS Reform: 2024 FDA CVM Request for Comments



NOTICE

Share

Pre-Market Animal Food Ingredient Review Programs; Request for Comments

Posted by the **Food and Drug Administration** on Aug 9, 2024

Closed for Comments

Comment Period Ended: **Dec 9, 2024 at 11:59 PM EST**

Document Details | Document Comments 32

Docket (FDA-2024-N-2979) / Document

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Comments Received
32
More Details

Document Details

Comment Due Date
Dec 9, 2024

Federal Register Number
2024-17779

Document Subtype
Request for Comments

Content

ACTION:

Notice; request for comments.

SUMMARY:

The Food and Drug Administration (FDA, we, or Agency) is soliciting comments from the public regarding the Food Additive Petition and Generally Recognized as Safe (GRAS) Notification programs to determine if changes are needed to promote their efficiency. Specific questions and information requests are included in this notice to help guide input from stakeholders and other members of the public.

DATES:

Submit either electronic or written comments on the notice by December 9, 2024.

ADDRESSES:

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 9, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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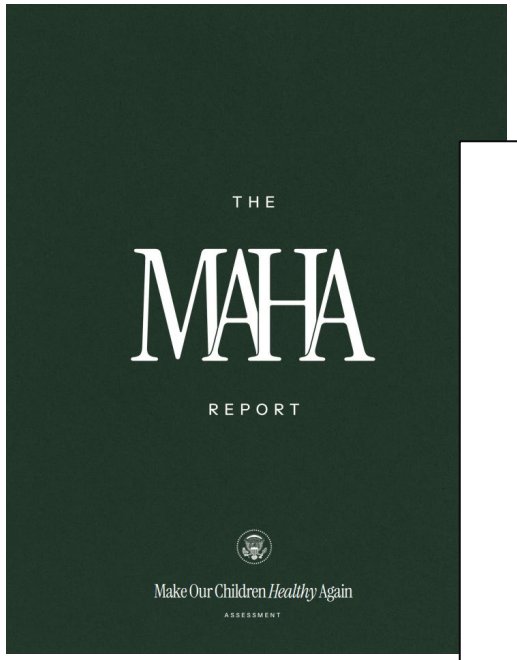
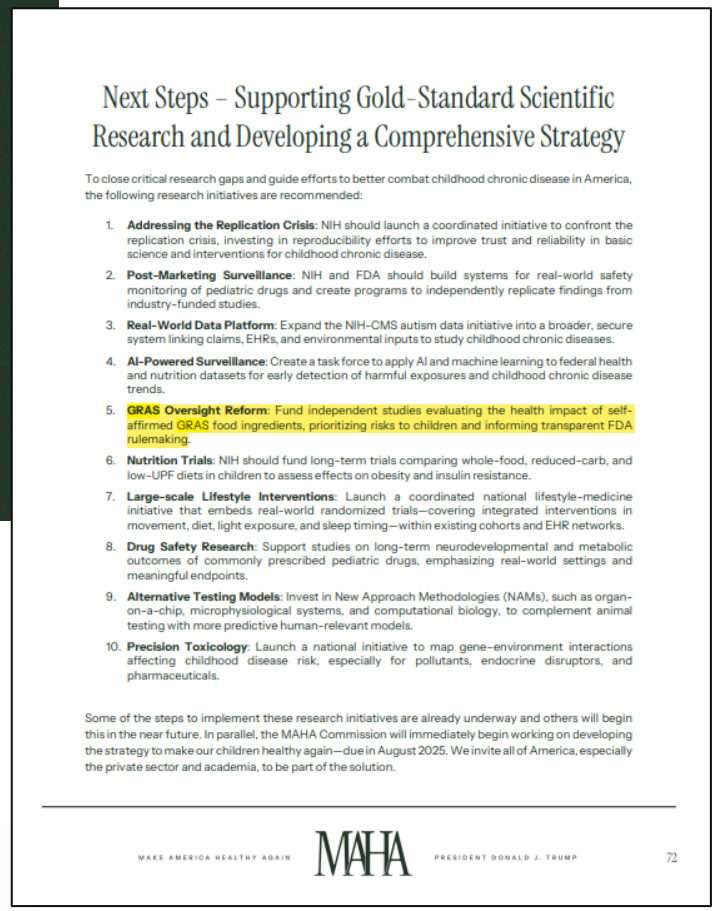
MAHA Assessment and Strategy Reports



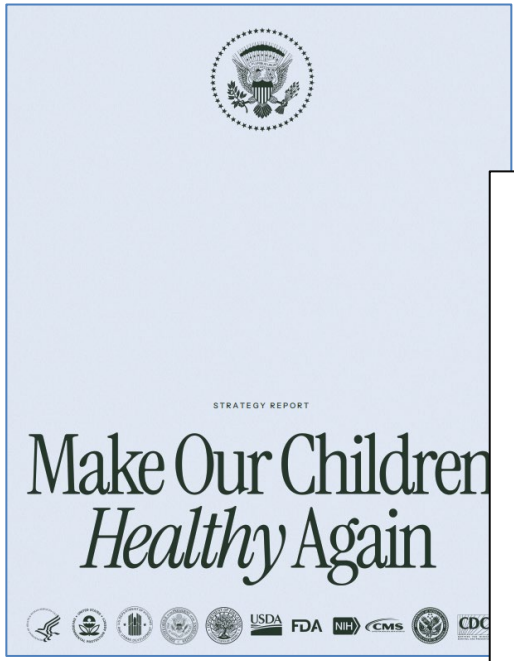


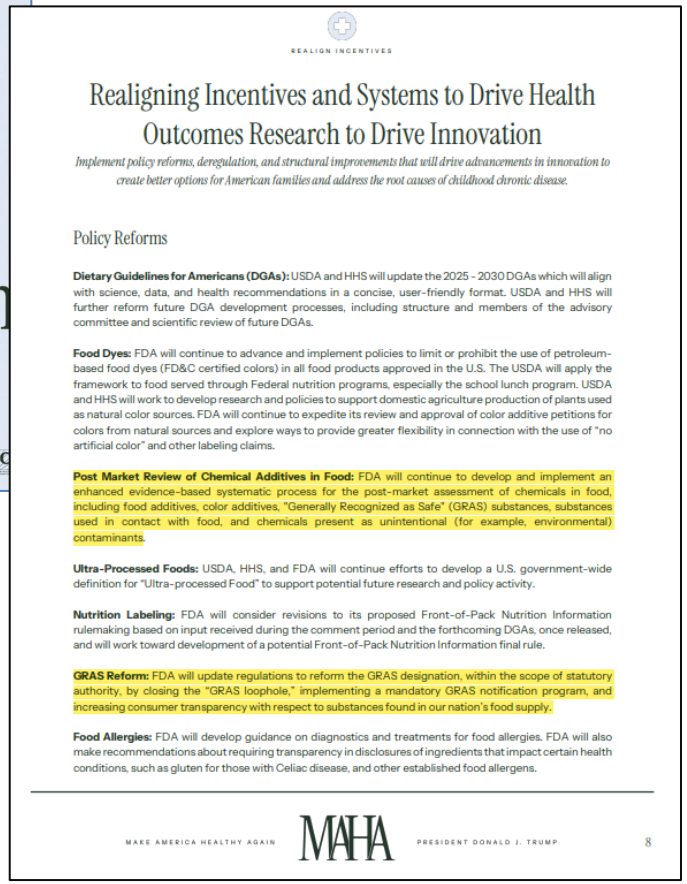
Next Steps – Supporting Gold-Standard Scientific Research and Developing a Comprehensive Strategy

To close critical research gaps and guide efforts to better combat childhood chronic disease in America, the following research initiatives are recommended:

1. **Addressing the Replication Crisis**: NIH should launch a coordinated initiative to confront the replication crisis, investing in reproducibility efforts to improve trust and reliability in basic science and interventions for childhood chronic disease.
2. **Post-Marketing Surveillance**: NIH and FDA should build systems for real-world safety monitoring of pediatric drugs and create programs to independently replicate findings from industry-funded studies.
3. **Real-World Data Platform**: Expand the NIH-CMS autism data initiative into a broader, secure system linking claims, EHRs, and environmental inputs to study childhood chronic diseases.
4. **AI-Powered Surveillance**: Create a task force to apply AI and machine learning to federal health and nutrition datasets for early detection of harmful exposures and childhood chronic disease trends.
5. **GRAS Oversight Reform**: Fund independent studies evaluating the health impact of self-affirmed GRAS food ingredients, prioritizing risks to children and informing transparent FDA rulemaking.
6. **Nutrition Trials**: NIH should fund long-term trials comparing whole-food, reduced-carb, and low-UPF diets in children to assess effects on obesity and insulin resistance.
7. **Large-scale Lifestyle Interventions**: Launch a coordinated national lifestyle-medicine initiative that embeds real-world randomized trials—covering integrated interventions in movement, diet, light exposure, and sleep timing—within existing cohorts and EHR networks.
8. **Drug Safety Research**: Support studies on long-term neurodevelopmental and metabolic outcomes of commonly prescribed pediatric drugs, emphasizing real-world settings and meaningful endpoints.
9. **Alternative Testing Models**: Invest in New Approach Methodologies (NAMs), such as organ-on-a-chip, microphysiological systems, and computational biology, to complement animal testing with more predictive human-relevant models.
10. **Precision Toxicology**: Launch a national initiative to map gene–environment interactions affecting childhood disease risk, especially for pollutants, endocrine disruptors, and pharmaceuticals.

Some of the steps to implement these research initiatives are already underway and others will begin this in the near future. In parallel, the MAHA Commission will immediately begin working on developing the strategy to make our children healthy again—due in August 2025. We invite all of America, especially the private sector and academia, to be part of the solution.





REALIGN INCENTIVES

Realigning Incentives and Systems to Drive Health Outcomes Research to Drive Innovation

Implement policy reforms, deregulation, and structural improvements that will drive advancements in innovation to create better options for American families and address the root causes of childhood chronic disease.

Policy Reforms

Dietary Guidelines for Americans (DGAs): USDA and HHS will update the 2025 - 2030 DGAs which will align with science, data, and health recommendations in a concise, user-friendly format. USDA and HHS will further reform future DGA development processes, including structure and members of the advisory committee and scientific review of future DGAs.

Food Dyes: FDA will continue to advance and implement policies to limit or prohibit the use of petroleum-based food dyes (FD&C certified colors) in all food products approved in the U.S. The USDA will apply the framework to food served through Federal nutrition programs, especially the school lunch program. USDA and HHS will work to develop research and policies to support domestic agriculture production of plants used as natural color sources. FDA will continue to expedite its review and approval of color additive petitions for colors from natural sources and explore ways to provide greater flexibility in connection with the use of "no artificial color" and other labeling claims.

Post Market Review of Chemical Additives in Food: FDA will continue to develop and implement an enhanced evidence-based systematic process for the post-market assessment of chemicals in food, including food additives, color additives, "Generally Recognized as Safe" (GRAS) substances, substances used in contact with food, and chemicals present as unintentional (for example, environmental) contaminants.

Ultra-Processed Foods: USDA, HHS, and FDA will continue efforts to develop a U.S. government-wide definition for "Ultra-processed Food" to support potential future research and policy activity.

Nutrition Labeling: FDA will consider revisions to its proposed Front-of-Pack Nutrition Information rulemaking based on input received during the comment period and the forthcoming DGAs, once released, and will work toward development of a potential Front-of-Pack Nutrition Information final rule.

GRAS Reform: FDA will update regulations to reform the GRAS designation, within the scope of statutory authority, by closing the "GRAS loophole," implementing a mandatory GRAS notification program, and increasing consumer transparency with respect to substances found in our nation's food supply.

Food Allergies: FDA will develop guidance on diagnostics and treatments for food allergies. FDA will also make recommendations about requiring transparency in disclosures of ingredients that impact certain health conditions, such as gluten for those with Celiac disease, and other established food allergens.

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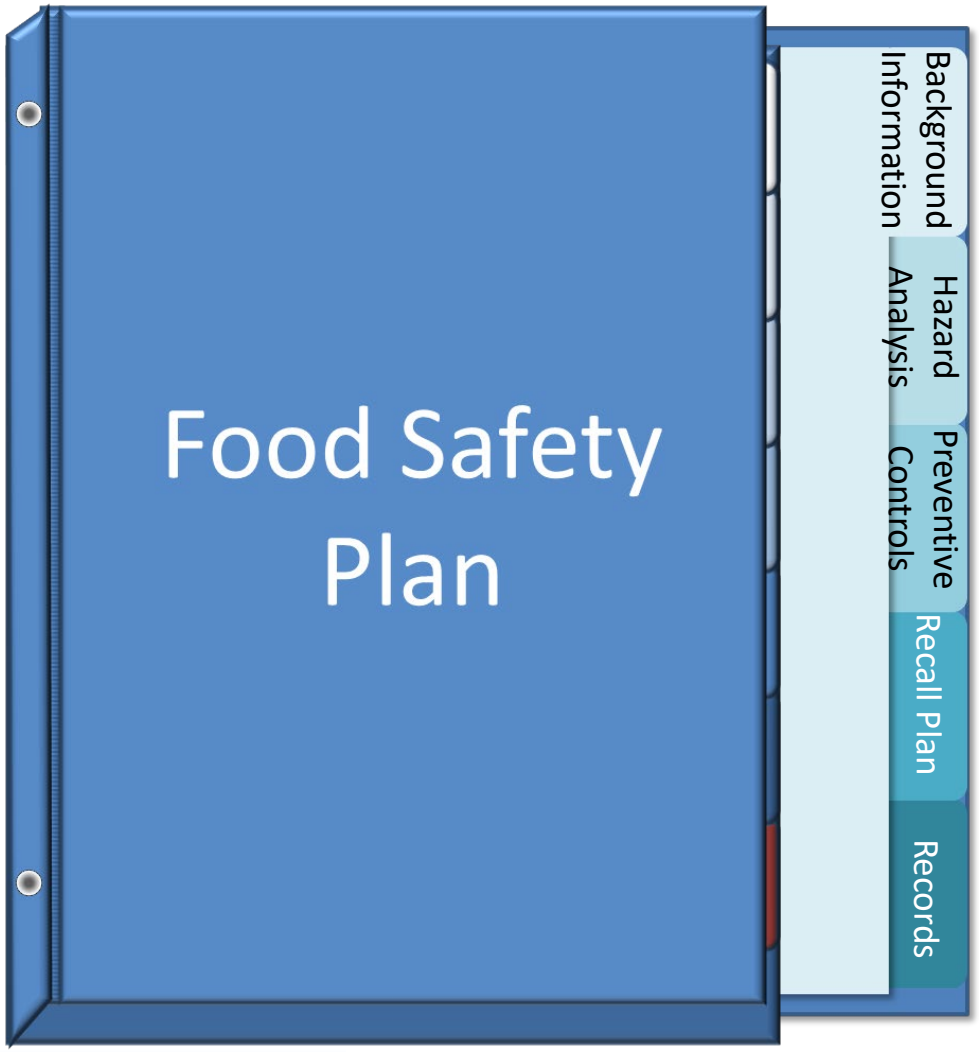
Components of a Food Safety Plan



<u>Other Useful Components:</u>

- Ingredient List

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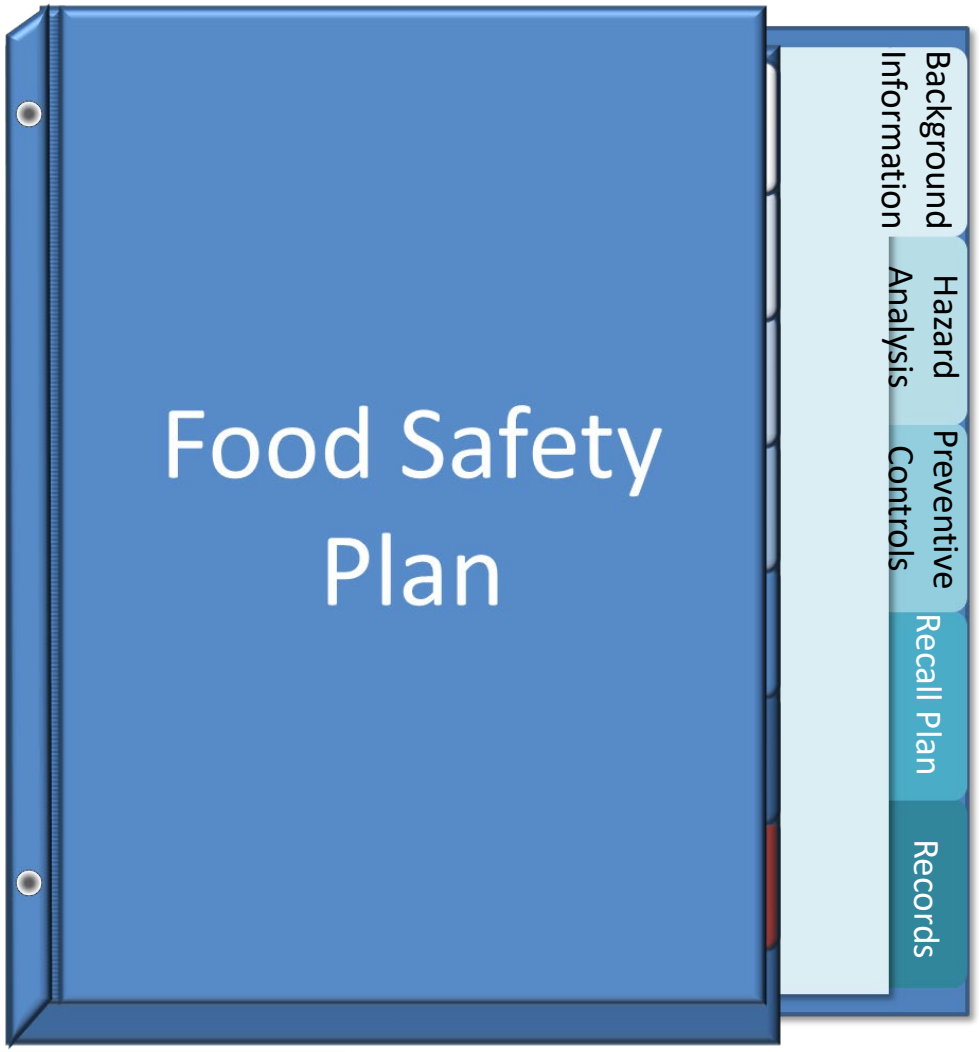
Components of a Food Safety Plan



Other Useful Components:

- Ingredient List
  - Food Additive Petition
  - GRAS
    - Self-Affirmed?
    - FDA Notified?
  - AAFCO Ingredient Definition: 2024 OP

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Takeaways

1. Ingredients are a critical component of food safety planning—they can introduce hazards if not properly managed.
2. Upcoming curriculum updates will include “Ingredient Lists” as an optional but valuable tool for strengthening food safety programs.
3. For the first time, FDA triggered a mandatory reanalysis of a food safety plan due to a hazard introduced through raw ingredients—highlighting the importance of ingredient oversight.
4. Policy reforms are increasingly focused on ingredient transparency, and maintaining a detailed ingredient list will help you assess your current risk and compliance impact.

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Government Shutdown: Animal Food

SEC. 785. The Commissioner of the Food and Drug Administration shall develop a report to determine the cost and any implications associated with efforts to issue a proposed rule and implement FDA guidance and enforcement for setting standards for pet and animal food labeling and ingredient regulation: Provided, That the report shall—

(1) cover intent for harmonization across state and Federal regulatory bodies for pet and animal food labeling and ingredients;

(2) include timelines for developing guidelines, proposed regulations, resource and personnel needs to implement such standards, and where FDA would need additional authority to implement any proposed changes; and

be submitted to the House and Senate Committees on Appropriations within 120 days of enactment of this Act.

Section 785 directs the FDA to prepare a report on:

- **Harmonizing pet and animal food labeling and ingredient standards across state and federal regulations.**
- **Timelines for developing guidelines and proposed regulations.**
- **Resource and personnel needs for implementation.**
- **Identifying areas where FDA may need additional authority.**
- **The report must be submitted to Congress within 120 days of enactment.**

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CLOSING

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UNDERSTANDING THE NEW APPROACH TO HAZARD ANALYSIS 2.0 – FAQS

KATHY GOMBAS
FSMA SOLUTIONS; FSPCA EAB CHAIR

CLAUDIA COLES
SEAFOOD PRODUCTS ASSOCIATION (SPA)

MODERATOR: JASON WAN

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
Innovation Through Collaboration

New Hazard Analysis Approach

HAZARD IDENTIFICATION

- **Ingredients:**
  - **Ingredient inherent hazards**
  - **Ingredient supplier's process- and facility-related hazards**

- **Product Process Steps:**
  - identification of process- and facility-related hazards

Hazard Identification

FDA's Hazard Guide Appendix 1 Tables

Ingredient-Related Hazards (Inherent hazards)

Contains Non-binding Recommendations
Draft-Not for Implementation

Table 1A: Known or reasonably foreseeable ("potential") food-related biological hazards for Bakery Items

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Bread, Biscuits, Rolls, Brownies, Cookies, Pizza, Pie Crust	1	- Unbaked Bakery Items - Ready-To-Bake (RTB) Dough - RTB Crust - With or Without Inclusions[1]	Refrigerated or Frozen						X	X	X				Includes bagels, croissants, puff pastry, phyllo
Bread, Whole/Pre-sliced	2a	- Fully-Baked - With or without Pre-Bake Added Filling or Inclusions[1] - Without Post-Bake Added Frosting/Topping	Ambient, Refrigerated or Frozen						X	X	X				Includes biscuits, bagels, rolls, croissants
Bread, Whole/Pre-sliced	2b	- Fully-Baked - With or without Pre-Bake Added Filling or Inclusions[1] - With Post-Bake Added Filling, Frosting, and/or Topping	Ambient, Refrigerated or Frozen						X	X	X	X			Includes bread with drizzles/ frosting

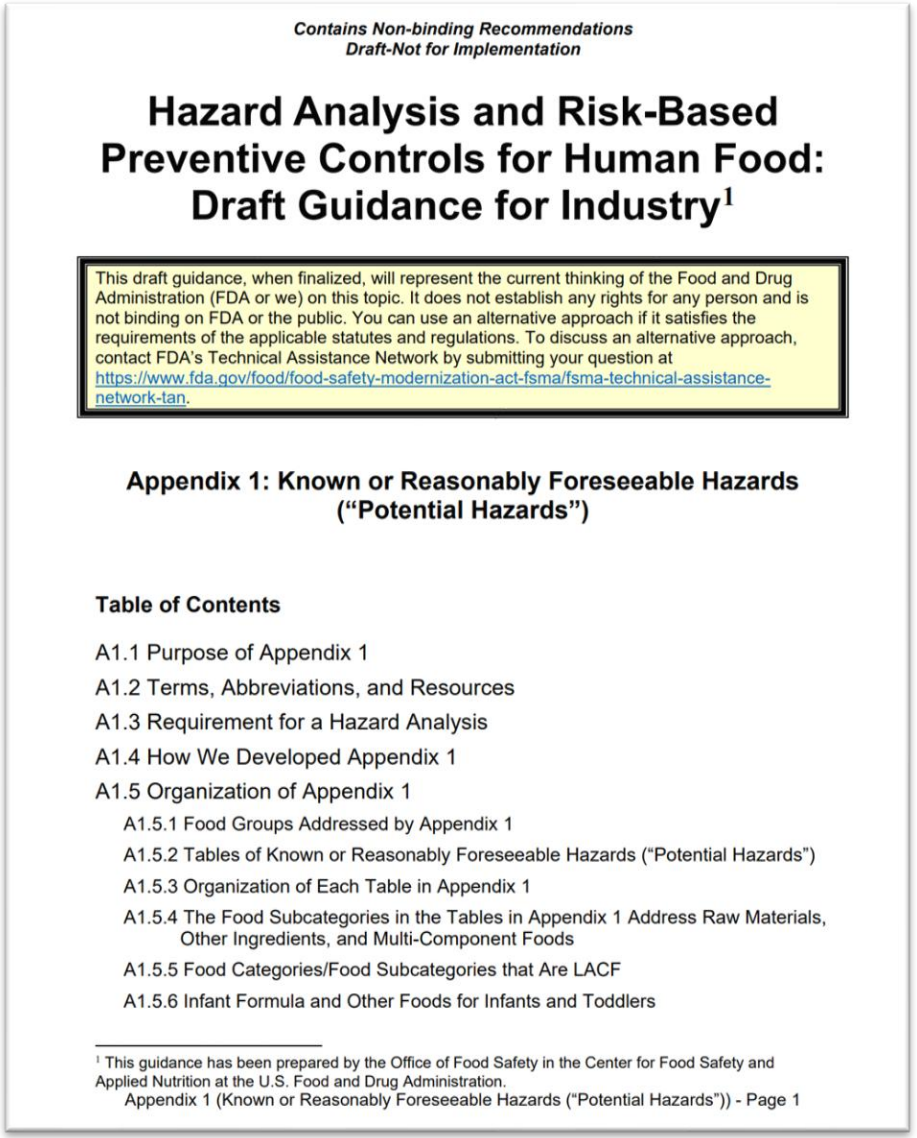
FSPCA's Form 0231- Common Process- & Facility-Related Hazards

Supplier's Process-Related and Facility-Related Hazards

Process-Related and Facility-Related Hazards

BIOLOGICAL HAZARDS A1.7.1	**Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment** *For example, a heat treatment that is not properly delivered (e.g., the temperature is too low, or the heating time is insufficient) could allow a pathogen to survive; in some cases, the surviving pathogens could subsequently grow and produce toxin.*
	Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control *For example, a cooling mechanism that does not function as intended could allow a small number of microbial pathogens to increase in number.*
	Bacterial pathogens – Growth and/or toxin production due to poor formulation control *For example, if insufficient acid is added to reduce the pH sufficiently in an acidified food, pathogenic sporeformers could grow and produce toxin.*
	Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging *For example, reduced oxygen packaging that is used to increase shelf life could create an environment that supports the growth of C. botulinum.*
	Bacterial pathogens – Presence due to ingredients added after process controls
	Bacterial pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity *For example, if a container is not properly sealed and it is cooled in water, water containing pathogens can be drawn into the container.*
	Environmental pathogens – presence due to recontamination from the processing environment *For example, equipment that is difficult to clean or is prone to damage could increase the risk for environmental pathogens to contaminate the product post-processing.*
CHEMICAL HAZARDS A1.7.2	**Undeclared food allergens – incorrect label** *Examples include: a label printed incorrectly, labels are not changed after product formulation changes, and when a label is applied to the wrong product.*
	Unintended food allergen presence – allergen cross-contact *Shared equipment is not properly cleaned after running a product containing a food allergen, unintentional addition of the wrong ingredient [that contains a food allergen].*
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5) *Examples include: misformulation can occur when some products are manufactured/processed with added sulfites and other products without sulfites, and sulfites are unintentionally added to a product that does not include sulfites in the product recipe or when ingredients with a maximum use level for safety, e.g., preservatives, are added over the allowed maximum usage level.*
	Process-contamination hazards in certain plant-based foods (e.g., acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils) *For example, some chemical hazards (such as acrylamide in certain plant-based foods and 3-monochloropropane-1,2-diol esters (3-MCPDEs) and glycidyl esters (GEs) [developed in some refined oils]) have the potential to form during food production, particularly at high temperature.*
PHYSICAL HAZARDS A1.7.3	**Metal** *For example, a process that uses a metal chopping blade could introduce metal fragments if the blade breaks.*
	Glass (when product packed in glass) *For example, a product packaged in glass containers could introduce glass fragments if a container breaks.*
	Hard Plastic *For example, hard plastic can be introduced into food when tools and equipment such as scoops, paddles, buckets, or other containers develop fatigue, crack, and break as they wear, or when plastic sieves and screens deteriorate.*

FDA's "Food Hazards and Controls" Guidance: Appendix 1



Contains Non-binding Recommendations
Draft-Not for Implementation

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Appendix 1: Known or Reasonably Foreseeable Hazards ("Potential Hazards")

Table of Contents

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

- FDA issued Appendix 1 as revised draft on January 30, 2024
- Provides "most relevant" food-related hazards for specific Food Groups, Categories, Subcategories
- To help the facility identify potential biological, chemical and physical hazards for their ingredients

FDA Hazard Guide – Appendix 1 – 16 Food Groups

Each Food Group has Food Categories and Subcategories	
Food Group A: Bakery Items	**Food Group I:** Game Meat Products
Food Group B: Beverage Items	**Food Group J:** Grains, Pulses, Flours, and Starches
Food Group C: Food Additives, Color Additives, and GRAS Substances	**Food Group K:** Nuts and Seeds
Food Group D: Chocolate and Candy	**Food Group L:** Oils and Oil Products
Food Group E: Dairy	**Food Group M:** Snack Foods
Food Group F: Dressings, Condiments, and Dips	**Food Group N:** Soups and Sauces
Food Group G: Egg and Egg Products	**Food Group O:** Spices and Herbs
Food Group H: Fruits and Vegetables	**Food Group P:** Food Sweeteners (Nutritive and Non-Nutritive)

FDA Hazard Guide – Appendix 1 – Potential Food-Related Hazards Tables

Most Relevant Food-Related Hazards:

Appendix 1 includes two set of tables identifying the potential food-related hazards for each Food Group/Category/Subcategory:

- Food-related **biological** hazards: Tables 1A – 1P
- Food-related **chemical** hazards: Tables 2B – 2E; 2G – 2L; and 2O – 2P
  - Chemical hazard tables are not available for four of the Food Groups: 2A (Bakery), 2F (Dressing, Condiments, and Dips), 2M (Snack Foods), & 2N (Soups and Sauces)
    - For these four categories, use the Table(s) associated with the ingredients in the food item, e.g. for Bakery item that contains flour; leavening agent; and shortening, review hazards for: flour (2J); leavening agent (2C); and shortening (2L)
- There are no tables for potential food-related **physical hazards** – these are considered process-related or facility-related hazards

FAQs

- Where do I find the potential hazards for the garlic powder, an ingredient used in the Fettuccini Teaching Example?

GARLIC POWDER

Table 1O: Known or reasonably foreseeable ("potential") food-related biological hazards for Spices and Herbs

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Spices	1	Dried, Ground, Cracked, or Whole	Ambient	X[1]	X[1]	X[1]				X[2]					Includes cinnamon, cardamom, turmeric, paprika, pepper (black, white, red), cayenne powder, paprika, chili powder, cumin, coriander, mustard, fenugreek, horseradish, fennel seeds, caraway, allspice, nutmeg, ginger, garlic (minced or powder), onion (minced or powder), oregano, celery seed
Herbs	2a	Dried	Ambient	X[1]	X[1]	X[1]				X[2]					Includes basil, oregano, thyme, sage, parsley, bay leaf, dill, rosemary, cilantro, mint, kaffir lime, chives, peppermint
Herbs	2b	Fresh	Ambient or Refrigerated							X[2]			X[3]		Includes basil, oregano, thyme, sage, parsley, bay leaf, dill, rosemary, cilantro, mint, kaffir lime, chives, peppermint

FOOTNOTES

[1] FDA identified these as a "potential" biological hazards applicable only when these products are rehydrated and/or used as an ingredient in a high-moisture food

[2] FDA identified Salmonella spp., but not pathogenic E. coli…based on a 2022 FAO/WHO report.

RAW GARLIC

Table 2H: Known or reasonably foreseeable ("potential") food-related chemical hazards for Fruits and Vegetables[1]

Category	#[1]	Subcategory	Storage Conditions	Drug residues	Arsenic	Cadmium	Lead	Mycotoxins/ Natural toxins	Pesticides	Comments
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated						X	All fruits and vegetables
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated			X				Includes spinach, lettuce, potatoes, beets
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated				X			Includes sweet potatoes, carrots, spinach, dried plums (prunes), potatoes, mushrooms, garlic
Fruits and vegetables	All	Whole RAC or processed	Ambient or Refrigerated					X[2]		Includes apple products, dried fruits, dried beans and peas

[1] Known or reasonably foreseeable ("potential") chemical hazards generally apply to a raw agricultural commodity regardless of whether and how it is processed. Therefore, each row in **Table 2H** applies to "fruits and vegetables," regardless of whether they are whole RACs or processed as described in **Table 1H** regarding known or reasonably foreseeable ("potential") biological hazards. The difference between each row is the chemical hazard that is listed as a known or reasonably foreseeable ("potential") chemical hazard.

Hazard Identification Columns 1 & 2

Ingredient Hazard Identification

Record Potential Biological and Chemical Ingredient-Related Hazards on the Hazard Analysis Form for Garlic Powder used in Fettuccini Marinara

(1) Ingredient **Garlic Powder**	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Ingredient-related hazards (inherent hazards)	B	*Salmonella*						
	B	Sporeforming pathogens: *(C. botulinum, C. perfringens, B. cereus)*						
	C	Pesticides						
	C	Lead						

FAQs

Is there a tool for Lead Instructors to use to help them identify the correct potential hazards in the other ingredients used in all the FSPCA's Teaching Example?

FAQs

YES! a new **Food Safety Plan Teaching Examples User Guide** is now available in the FSPCA HF LI Portal

This Lead Instructor User Guide:

- Lists the ingredient(s) used in the teaching example and the page numbers in FDA's Hazard Guide Appendix 1 for the respective biological and chemical hazard tables
- Includes details about the Table number, Category, and Subcategory to ensure the correct potential hazard is identified for the appropriate food category

Potential Ingredient-related Hazards (inherent hazards) per FDA Hazard Guide Appendix 1

Available in the HF LI Portal

FETTUCCINI MARINARA WITH BROCCOLI

Ingredient	Potential Biological Hazards (Tables 1)	Potential Chemical Hazards (Tables 2)
Dry Wheat Pasta	***Salmonella*** P. 65 ***B. cereus, Clostridium botulinum, Clostridium perfringens:*** see footnote P. 65 only applicable when food becomes hydrated to an A_w that allows growth. **Table 1J:** Grains, Pulses, Flours, and Starches **Category (4c)**: Grain-based Pasta Products **Subcategory:** Dried Pasta	**Mycotoxins and Pesticides** in wheat used to make flour used in pasta. P. 89. **see footnote[1] for applicable mycotoxins.** **Table 2J:** Grains, Pulses, Flours, and Starches **Category (1):** Grains, Non-Rice **Subcategory:** Whole and milled grains (e.g., flour and bran)
Marinara Sauce (#10 Cans)	***B. cereus, Clostridium botulinum,*** **Pathogenic *E. coli, Salmonella, L. mono*.** P. 59 **Table 1H:** Fruits and Vegetables **Category (4d)**: Processed Vegetables **Subcategory:** Acidified Products	**Pesticides** in tomatoes used to make marinara sauce. P. 87 **Table 2H:** Fruits and Vegetables **Category (All):** Fruits and Vegetables **Subcategory:** Whole RAC or processed
Romano Cheese (shredded)	**Pathogenic *E. coli; Salmonella; L. mono; S. aureus.*** P. 53 **Table 1E:** Dairy **Category (5a)**: Cheese and Cheese Products – Sliced, Shredded, or Grated **Subcategory:** Hard and Extra Hard Cheese	**Drug residues** P. 84 **Table 2E:** Dairy **Category (1-5):** All **Subcategory:** All

Potential Ingredient-related Hazards (inherent hazards) per FDA Hazard Guide Appendix 1

Available in the HF LI Portal

FETTUCCINI MARINARA WITH BROCCOLI

Ingredient	Potential Biological Hazards (Tables 1)	Potential Chemical Hazards (Tables 2)
Salt	None P. 45 **Table 1C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category (6a)**: Other Chemical Ingredients **Subcategory:** Processing Chemicals	None P. 82 **Table 2C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category:** None for Processing Chemicals only Nutrients
Garlic Powder	***Salmonella.*** P 74. ***B. cereus, Clostridium botulinum, Clostridium perfringens,*** see footnote P. 75 only applicable when these products becomes hydrated or used as ingredient in-high moisture food. **Table 1O:** Spices and Herbs **Category (1)**: Spices **Subcategory:** Dried, Ground, Cracked, or Whole	**Pesticides** in garlic used to make garlic powder. P. 87 **Table 2H:** Fruits and Vegetables **Category (All):** Fruits and Vegetables **Subcategory:** Whole RAC or processed **Lead** in garlic used to make garlic powder P. 87 *Note: FDA discusses in various other guidance that lead is a potential issue for foods intended for babies and young children.*
IQF Broccoli	**Pathogenic *E. coli; Salmonella, L. mono*** p. 59 **Table 1H:** Fruits and Vegetables **Category (4b)**: Processed Vegetables **Subcategory:** Whole or Cut	**Pesticides** P. 87 **Table 2H:** Fruits and Vegetables **Category (All):** Fruits and Vegetables **Subcategory:** Whole RAC or processed

Potential Ingredient-related Hazards (inherent hazards) per FDA Hazard Guide Appendix 1

PEANUT BUTTER

Available in the HF LI Portal

Ingredient	Potential Biological Hazards (Tables 1)	Potential Chemical Hazards (Tables 2)
Sugar	None P. 76 **Table 1P:** Food Sweeteners (Nutritive and Non-Nutritive) **Category (1a)**: Food Sweeteners (Nutritive and Non-Nutritive) **Subcategory:** Sugars (Dry)	None P. 82 **Table 2C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category:** None for Processing Chemicals only Nutrients
Salt	None P. 45 **Table 1C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category (6a)**: Other Chemical Ingredients **Subcategory:** Processing Chemicals	None P. 82 **Table 2C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category:** None listed for Processing Chemicals only Nutrients
Hydrogenated Vegetable Oil	None P. 68 **Table 1L:** Oils and Oil Products **Category (1c)**: Oil Products **Subcategory:** Shortening	None P. 92 **Table 2L:** Oils and Oil Products **Category**: None listed for Shortening Products

Potential Ingredient-related Hazards (inherent hazards) per FDA Hazard Guide Appendix 1

PEANUT BUTTER

Available in the HF LI Portal

Ingredient	Potential Biological Hazards (Tables 1)	Potential Chemical Hazards (Tables 2)
Nitrogen	None P. 46 **Table 1C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category (6e)**: Other Chemical Ingredients **Subcategory:** Processing Aid Gases	None P. 82 **Table 2C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category:** None listed for Other Chemical Ingredients only Nutrients
Raw, shelled peanuts	Pathogenic *E. coli, Salmonella, L. mono*. P. 66 **Table 1K:** Nuts and Seeds **Category (1a)**: Nuts **Subcategory:** Peanuts, Raw	Mycotoxins and Pesticides P. 91. see footnote[1] for applicable mycotoxin (Aflatoxin). **Table 2K:** Nuts and Seeds **Category (1a):** Nuts **Subcategory:** Peanuts, Raw and treated

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Potential Ingredient-related Hazards (inherent hazards) per FDA Hazard Guide Appendix 1

BLACK PEPPER

Available in the HF LI Portal

Ingredient	Potential Biological Hazards (Tables 1)	Potential Chemical Hazards (Tables 2)
Black Peppercorns	***Salmonella.*** P 74. ***B. cereus, Clostridium botulinum, Clostridium perfringens,*** see footnote P. 75 only applicable when these products becomes hydrated or used as ingredient in-high moisture food. **Table 1O:** Spices and Herbs **Category (1)**: Spices **Subcategory:** Dried, Ground, Cracked, or Whole	**Pesticides**. P. 95. **Table 2O:** Spices and Herbs **Category (1):** Spices **Subcategory:** Dried, Ground, Cracked, or Whole

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Hazard Identification Columns 1 & 2

Ingredient Hazard Identification

Record Potential Biological and Chemical Ingredient-Related Hazards on the Hazard Analysis form

(1) Ingredient GARLIC POWDER	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Ingredient-related hazards (inherent hazards)	B	*Salmonella*						
	B	Sporeforming pathogens: *(C. botulinum, C. perfringens, B. cereus)*						
	C	Pesticides						
	C	Lead						
Supplier process-related and facility-related hazards	B	?						
	C	?						
	P	?						

Ingredient-Related Hazards (Inherent Hazards) ✓

AND

Supplier's Process-Related and Facility-Related Hazards

FDA Hazard Guide – Appendix 1

Most Relevant Process-Related and Facility-Related Hazards:

- The Food Safety Team must consider those potential hazards originating from **processes** (process-related hazards), and the **food-production environment** (facility-related hazards)

FDA Hazard Guide – Examples of Common Process-Related and Facility-Related Hazards

Appendix 1 – A1.7	Common Process-Related and Facility-Related Hazards
BIOLOGICAL HAZARDS A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to **survival of a lethal treatment**
	Bacterial pathogens – Growth and/or toxin production due to **poor time/temperature control**
	Bacterial pathogens – Growth and/or toxin production due to **poor formulation control**
	Bacterial pathogens – Growth and/or toxin production due to **reduced oxygen packaging**
	Bacterial pathogens – Presence due to **ingredients added after process controls**
	Bacterial pathogens – Presence, growth, or growth with toxin production due to **recontamination due to lack of container integrity**
	Environmental pathogens – presence due to **recontamination from the processing environment**
CHEMICAL HAZARDS A1.7.2	Undeclared food allergens – incorrect label
	Unintended food allergen presence – allergen cross-contact
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)
	Process-contamination hazards in certain plant-based foods (e.g. acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils)
PHYSICAL HAZARDS A1.7.3	Metal
	Glass (when product packed in glass)
	Hard Plastic

FSPCA Form 0231 – Tool to use to rule out process- & facility-hazards that are not relevant (not “potential” hazards)

FDA Hazard Guide – Appendix 1

Most Relevant Process-Related and Facility-Related Hazards:

- Each facility must identify potential process-related or facility-related hazards based on their knowledge, experience, and history of hazards associated with:
  - their own operations, AND
  - their ingredient supplier's operations

SUPPLIER INFO CHALLENGES

Obtaining info about supplier's process

- Visit the supplier's facility
- Pre-assessment questionnaires
- Request:
  - Food safety plans
  - Plant diagrams (assess if and when product is exposed to environment)
  - Environmental monitoring program / results
  - Grower records, e.g. pesticide usage & application records
  - FSVP records

Do you know the garlic powder supplier's process?

- The U.S. based supplier dries and grinds raw garlic into powder which has a_w 0.52
- The raw garlic is sourced from a U.S. grower
- The garlic powder supplier verifies proper use of pesticides on the raw whole garlic by the U.S. grower
- The garlic powder supplier uses a "microbial reduction treatment":
  - validated irradiation process, after packaging
  - Irradiation process conducted by supplier's commercial sterilizers for vegetative pathogens
- The garlic supplier does not handle allergens in their facility
- No glass or hard plastic is used by the supplier
- Grinding process has potential for metal-to-metal contact
- Garlic powder packaged in 25 lb. paper bags with plastic liners

FDA Appendix 1 – A1.7	Common Process-Related and Facility-Related Hazards	Potential? Yes/No
BIOLOGICAL HAZARDS A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to **survival of a lethal treatment**	**Yes –** Potential (if not properly irradiated)
	Bacterial pathogens – Growth and/or toxin production due to **poor time/temperature control**	**No** – Shelf stable
	Bacterial pathogens – Growth and/or toxin production due to **poor formulation control**	**Not applicable** – Not formulated for safety
	Bacterial pathogens – Growth and/or toxin production due to **reduced oxygen packaging (ROP)**	**Not applicable** – Not packaged in ROP
	Bacterial pathogens – Presence due to **ingredients added after process controls**	**Not applicable** – No ingredients added after irradiation
	Bacterial pathogens – Presence, growth, or growth with toxin production due to **recontamination due to lack of container integrity**	**Not applicable** – Not packaged in hermetically sealed container
	Environmental pathogens – presence due to **recontamination from the processing environment**	**No** - Garlic powder is irradiated in the package - no exposure to the environment
CHEMICAL HAZARDS A1.7.2	Undeclared food allergens – incorrect label	**Not applicable –** no allergens present in garlic powder
	Unintended food allergen presence – allergen cross-contact	**Not applicable** – The garlic supplier does not handle any allergens
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)	**Not applicable** – Does not contain ingredients with a maximum use level for safety
	Process-contamination hazards in certain plant-based foods (e.g. acrylamide in certain plant-based foods, & 3-MCPDEs and glycidyl esters in refined oils)	**Not applicable**
PHYSICAL HAZARDS A1.7.3	Metal	**Yes** – Supplier's grinding of garlic may result in metal contamination
	Glass (when product packed in glass)	**Not applicable** – Not packed in glass
	Hard Plastic	**Not applicable** – Hard plastic not used by supplier

Ingredient Hazard Identification

Hazard Identification Columns 1 & 2

Record Potential Biological and Chemical Ingredient-Related Hazards on the Hazard Analysis form

(1) Ingredient GARLIC POWDER	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Ingredient-related hazards (inherent hazards)	B	*Salmonella*						
	B	Sporeforming pathogens: *(C. botulinum, C. perfringens, B. cereus)*						
	C	Pesticides						
	C	Lead						
Supplier process-related and facility-related hazards	B	Recontamination with environmental pathogens *Salmonella*						
	P	Metal						

Ingredient-Related Hazards (Inherent Hazards) ✓

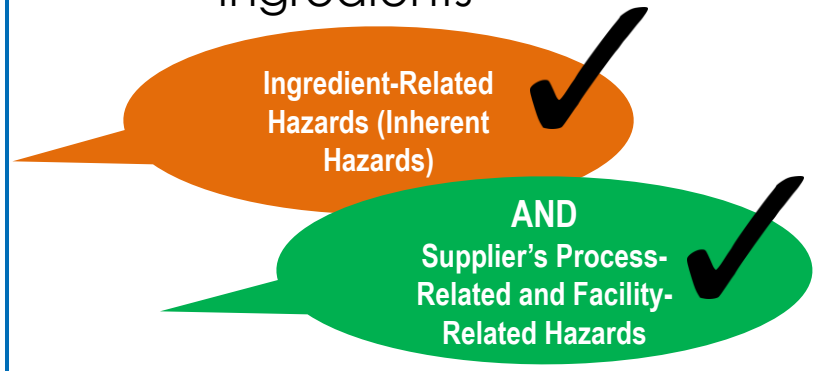
AND

Supplier's Process-Related and Facility-Related Hazards ✓

Hazard Analysis – Two Step Process

Step 1: Hazard Identification

- Brainstorm to generate a list of potential biological, chemical, and physical hazards
- List all potential hazards for:
  1. raw materials and other ingredients



  2. each manufacturing process step

Step 2: Hazard Evaluation

- Determine whether the potential hazard identified poses a significant risk to the consumer **in the absence of a preventive control** based on:
  - severity of the illness or injury
  - likelihood of occurrence
- Recognize that those hazards evaluated to be significant require a preventive control

Ingredient Hazard Evaluation

(1) **Ingredient** **GARLIC POWDER**	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Ingredient-related hazards (inherent hazards)	B	*Salmonella*	X		*Salmonella* has been known to occasionally contaminate garlic. Supplier provides lethal treatment of the garlic powder in the package (a validated irradiation process).			
	B	Sporeforming pathogens: *(C. botulinum, C. perfringens, B. cereus)*		X	*C. botulinum, C. perfringens* and *B. cereus* spores may be in garlic powder, but low water activity (a_w 0.52) prevents growth in the dry spice and in the Marinara sauce during processing time, especially given the acid pH <4.6 of the Marinara sauce.			
	C	Pesticides in garlic used to make garlic powder		X	Raw whole garlic is US-sourced and FDA data show that unapproved pesticide use of residues above EPA tolerance levels are rare in garlic grown in the US.			
	C	Lead			Garlic powder is not a food intended for babies and young children.			
Supplier process-related and facility-related hazards	B	Recontamination with environmental pathogens *Salmonella*		X	Environmental contamination is not likely to occur since garlic powder is irradiated in the package and therefore there is no exposure to the environment.			
	P	Metal	X		Supplier's grinding of garlic can result in metal contamination			

FAQs

What processes are considered “Exceptionally Lethal”?

Processes: Exceptionally Lethal

- Some thermal processes might not necessarily be a process preventive control
  - When process parameters necessary for palatability/sensory properties far exceed what is necessary to destroy vegetative pathogens

Examples include:
- frying potato chips
- baking snack crackers
- popping popcorn
- making highly refined oil

Review Tables 1 in Appendix 1 for more examples

Exceptionally Lethal – FDA Hazard Guide

Category	#	Subcategory	Storage Conditions	*Bacillus cereus*	*Clostridium botulinum*	*C. perfringens*	*Brucella* spp.	*Campylobacter* spp.	Pathogenic *E. coli*	*Salmonella* spp.	*L. monocytogenes*	*S. aureus*	Parasites	Viruses	Comments
Beverage Concentrates/ Base Mixes	10b	Dry Powdered	Ambient												Includes powdered flavors
Adult Beverage Mixers[2]	11	Mixes intended for alcoholic beverages (liquid and powders)	Ambient[3] or Refrigerated	X[1]	X[1]					X					All varieties
Ground Coffee Substitutes	12	Dry Powdered	Ambient						X[4]	X[4]					Includes chicory root powder, roasted grains

[1] The SMEs noted that whether these pathogenic sporeformers are known or reasonably foreseeable ("potential") biological hazards that could require time/temperature controls depends on the product (e.g., pH, water activity) and the process used to make the product.

[2] Depending on the ingredients there could be other hazards. Refer to other tables for the ingredients.

[3] There may not be any known or reasonably foreseeable ("potential") biological hazard applicable to shelf-stable products. Shelf-stable products that are LACF products are not subject to the requirements for biological hazards in 21 CFR Part 117. Shelf-stable non-LACF products generally are produced using an exceptionally lethal process. (See the discussion of exceptionally lethal processes in section A1.6.1.3.)

[4] The SMEs identified this as a known or reasonably foreseeable ("potential") biological hazard applicable only when the beverage includes an herb.

[5] See **Table 1J** for the known or reasonably foreseeable ("potential") biological hazards associated with the applicable roasted grain.

Exceptionally Lethal – FDA Hazard Guide

A1.6.1.3 Note about biological hazards in food subcategories manufactured using exceptionally lethal processes

- Some food products can only be produced using exceptionally lethal processes that adequately control biological hazards.
- If the processing is not conducted in a way that adequately controls biological hazards, the product would not be suitable for distribution.
- Due to the exceptional lethality of the processes used to manufacture these food products, in some instances the SMEs did not identify any known or reasonably foreseeable ("potential") biological hazards for these foods **(e.g., sugar confections in Table 1D and crackers in Table 1M).**
- In other instances, the tables indicate known or reasonably foreseeable ("potential") biological hazards, but a facility could determine these are not hazards requiring a preventive control because they are produced using an exceptionally lethal process (**e.g., soups, sauces and gravies**, where some of the products receive an exceptionally lethal process but other products do not).

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DAVID FAIRFIELD

David began his career in the animal food industry in 1981 after graduating from Kansas State University's Department of Grain Science. He spent the next 20 years within the industry managing operations for Cargill, Inc., Continental Grain Company, and Ridley, Inc.

In 2001, David joined the National Grain and Feed Association (NGFA) – a Washington, DC-based trade association – to address animal food safety and industry issues that impacted its members.

Over the course of the next 24 years, David served as a subject matter expert within a variety of animal food safety forums, including the Association of American Feed Control Officials, Global Food Safety Initiative, and the International Organization for Standardization (ISO).

In addition, David was selected to serve as an inaugural member of the Food Safety Preventive Controls Alliance Organizing Committee that conducted its first meeting in December of 2011. He subsequently served as a member of FSPCA Steering Committee and Executive Advisory Board and chaired the Animal Food Work Group.

After a career in the animal food industry that spanned almost 45 years, David retired at the end of 2024.

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Dr. Juan Silva is a Professor, Researcher and Extension Specialist at Mississippi State University. He holds a B.S. and M.S. in Chemical Engineering and a Ph.D. in Food Science and Technology. He is a consultant and trainer for the food and related industries. He served on Institute of Food Technologists' Board of Directors and currently serves on the Food Safety Preventive Controls Alliance (FSPCA) Executive Advisory Board, providing professional and strategic advice regarding FSPCA offerings and services to the food industry worldwide.

Dr. Silva's emphasis is to train and inform instructors in FSMA and HACCP rule requirements so they can conduct quality training to the industry worldwide. He started international outreach and training in 1995, with HACCP systems. In 2005, he started working on train-the-trainer courses in Good Agricultural Practices for Latin America and other parts of the world. He also was part of five teams conducting Seafood HACCP/Good Aquaculture Practices train-the-trainer courses in the U.S., Latin America, and Asia. He has led many train-the-trainer courses for the Produce Safety Alliance targeted to U.S. farms that are covered under FDA's Produce Safety Rule. He also led an effort to train growers in the Produce Safety Rule in Mexico, Honduras, Argentina, and Peru during the COVID pandemic. This led to working with Argentinian industry and government groups in developing their cadre of Lead Trainers who have conducted over 12 grower courses over the past few years.

In addition to conducting FSPCA Lead Instructor courses in the U.S., Juan has led teams that conducted Lead Instructor trainings in Latin America, Bangkok, Thailand, Tanzania -East Africa, and most recently in Egypt. Other international efforts have included educating foreign suppliers and exporters on FDA's Foreign Supplier Verification Programs regulation and Better Process Control Schools.

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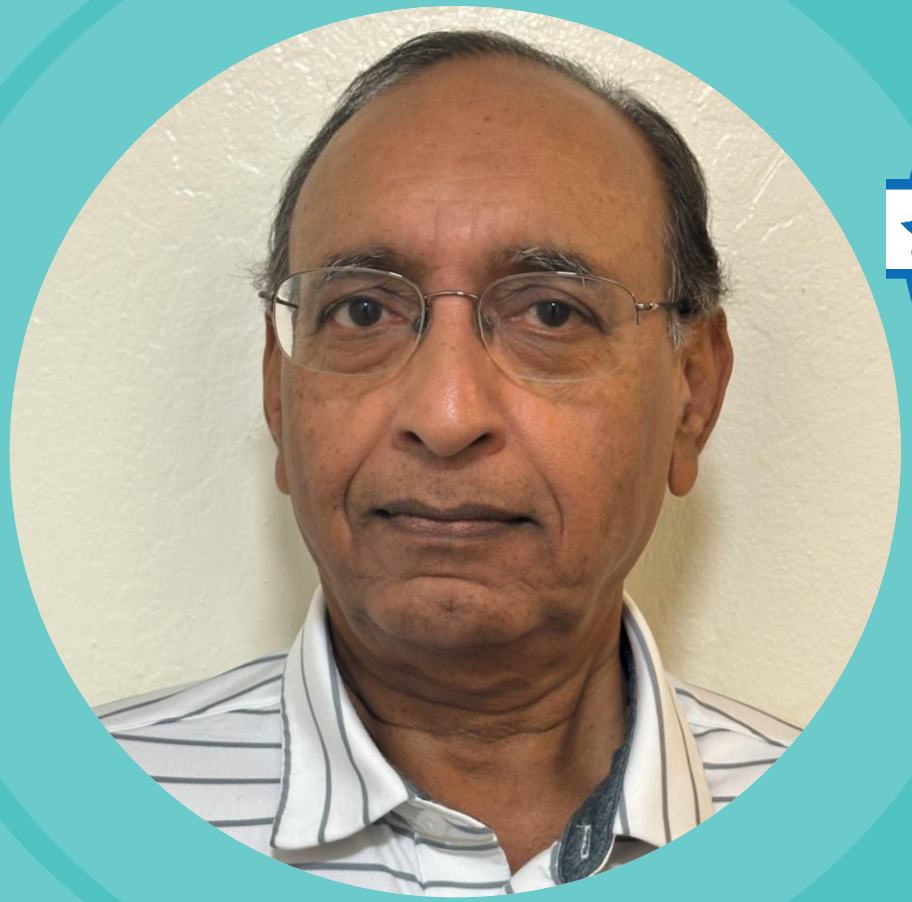

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IA VA

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LANCE ROBERIE

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JEDSADA TIPMONTIAN

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CLOSING REMARKS

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INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

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FSPCA 2025 ANNUAL CONFERENCE

STRENGTHENING THE FOOD SUPPLY CHAIN
THROUGH EDUCATION, TRAINING AND OUTREACH

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WELCOME BACK

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INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

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MATTHEW J. BOTOS TRIBUTE

JASON WAN, PHD
INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

KATHY GOMBAS
FSMA SOLUTIONS, FSPCA EAB CHAIR

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https://www.beidelmankunschfh.com/obituaries/Matthew-J-Botos?obId=34260590

Matthew J. Botos

- Chair of the FSPCA Annual Conference Work Group: 2019 – 2024
- FSPCA Lead Instructor for PCHF, FSVP, trained over 360 individuals
- Editorial Committee for Juice HACCP Training Curriculum
- Former staff member at the National Center for Food Safety and Technology (NCFST)
- Served as an Adjunct Industry Professor in the Department of Food Science and Nutrition (FDSN) at Illinois Tech

Chicago Section IFT Suppliers Day Expo Workshop Panel, November 2019 on "The Digital Transformation of the Food Industry"

Courtesy Armand Paradis

https://www.tributearchive.com/obituaries/34260590/matthew-j-botos

Courtesy Alan Reed

https://www.biggertable.org/mattbotosscholarship/

Matthew J. Botos

June 5, 1974 - December 23, 2024

The Dash

I read of a woman who stood to speak at a funeral of a friend. She referred to the dates on his tombstone from the beginning to the end.

She noted that first came his date of birth and spoke the following date with tears, but she said what mattered most of all was the dash between those years.

For that dash represents all the time that he spent alive on earth, and now only those who loved him know what that little line is worth.

For it matters not, how much we own; the cars…the house…the cash, what matters is how we live and love and how we spend our dash.

So, think about this long and hard are there things you'd like to change? For you never know how much time is left that can still be rearranged.

If we could just slow down enough to consider what's true and real. And always try to understand the way other people feel.

And be less quick to anger and show appreciation more. And love the people in our lives like we've never loved before.

If we treat each other with respect, and more often wear a smile, remembering that this special dash might only last a little while.

So, when your eulogy is being read with your life's actions to rehash, would you be proud of the things they say about how you spent your dash?

ADDRESSING CHEMICAL HAZARDS

PANELIST
BENJAMIN MILLER
THE ACHESON GROUP (TAG)

PANELIST
KATHERINE SIMON
MINNESOTA DEPARTMENT OF AGRICULTURE

PANELIST
TYLER DIXON
MEAD JOHNSON NUTRITION

MODERATOR
KATHY GOMBAS
FSMA SOLUTIONS
FSPCA EAB CHAIR

Reducing Toxic Element Exposure: Contaminant Overview

Industry approaches to minimize harmful contaminants in food manufacturing

Tyler Dixon, November 2025

FDA's Closer to Zero Initiative

Purpose of Closer to Zero

HEALTHIER FAMILIES

REDUCING RISK

FDA Initiative Goal

The initiative aims to minimize children's exposure to harmful toxic elements in foods.

Toxic Elements Overview

Arsenic, lead, cadmium, and mercury are key contaminants of concern in children's food.

Health Risks to Children

These metals cause serious health issues including neurological, kidney, and developmental damage.

Commitment to Safety

The FDA is dedicated to protecting vulnerable children through this focused safety effort.

FDA's Four-Stage Approach

Scientific Evaluation

FDA reviews current scientific studies to set interim contaminant reference levels.

Proposing Action Levels

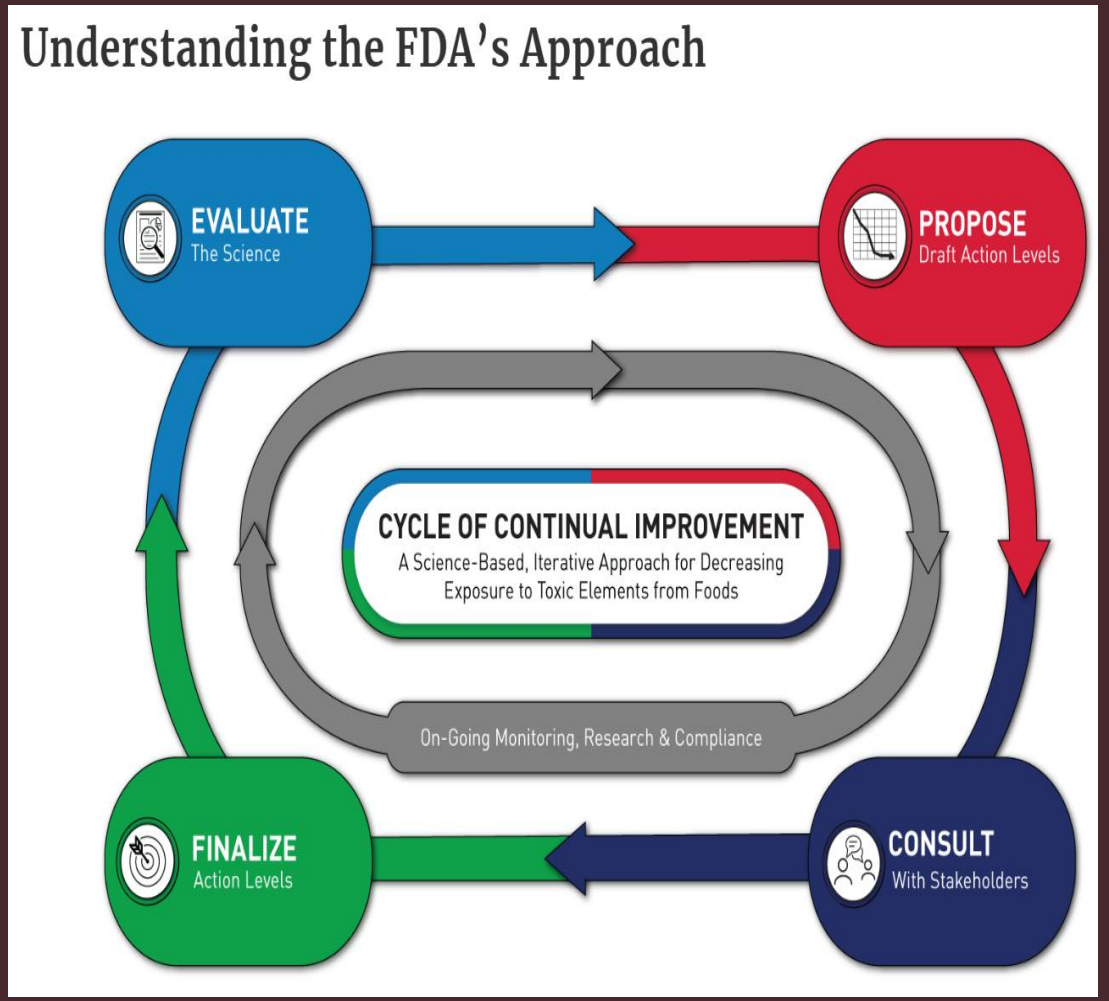
Draft guidance is created for food categories with proposed contaminant limits.

Stakeholder Consultation

FDA engages industry and experts to ensure proposed levels are feasible.

Finalization and Enforcement

Action levels finalized, and compliance is enforced to protect consumer health.



Focuses around Closer to Zero

Transparency in Labeling

- Front of Packaging
- Updated clarity

Health Prioritization and Risk Management

What is Being Considered?

Heavy Metal Contaminants

Arsenic - Oral toxicity leading to gastrointestinal damage, nervous disorder, skin abnormalities

Lead - Neural and cognitive development impairments with higher levels of susceptibility in children

Cadmium - Metabolic poison with long half-life (10-30 years) in kidneys. Often asymptomatic until kidney damage is identified.

Mercury - Kidney and gastrointestinal toxicity and altered nervous system development in babies.

Why Prioritize Contaminants in Younger Populations?

Heightened Susceptibility

Children have greater vulnerability to toxic elements due to smaller body size and faster metabolism.

Long-term Health Consequences

Early exposure to contaminants can cause developmental delays and chronic illnesses.

Safeguarding Future Generations

Focus on children promotes lifelong health through early Intervention strategies.

Preventive Controls Importance

FDA stresses preventive measures to reduce chemical hazards even without full risk data.

Industry Engagement and Action

Call to Action for Industry

Industry Data Contribution

Urged to share data on food contaminant levels for assessment.

Collaborative Effort Importance

Collaboration for practical action levels and effective regulatory decisions.

Leadership in Food Safety

Engaging in research and influencing food safety best practices

Shaping Future Regulations

Active input ensures regulations are feasible and demonstrate commitment to health.

WE CANNOT CONTROL WHAT WE CANNOT MEASURE

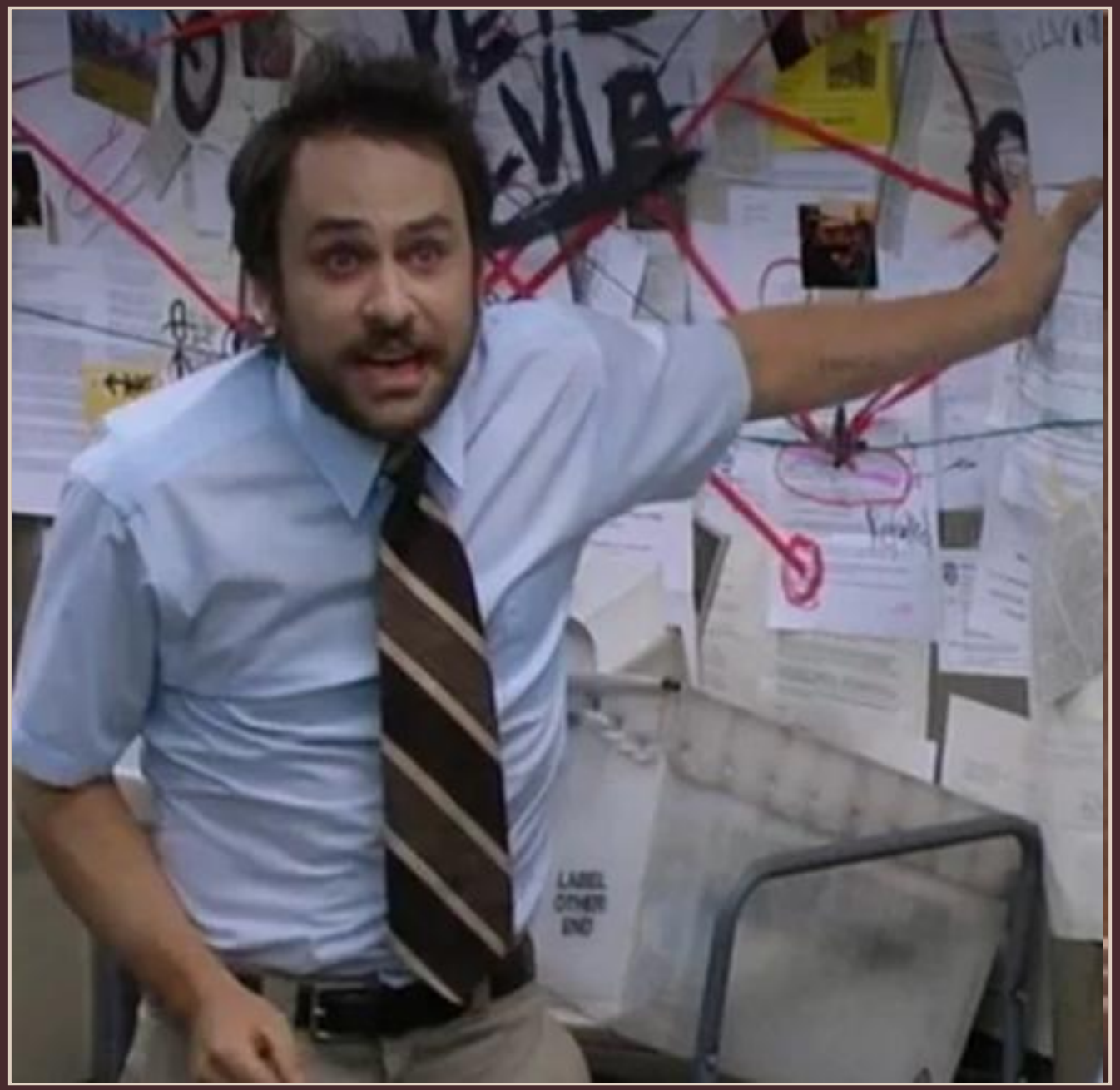
FOOD SAFETY IS NOT PROPRIETARY!

Sharing learnings, data, science can help reduce risk levels

Encouragement to push towards As Low As Reasonably Achievable (ALARA) levels'

Proactive Measures
Proactive actions based on shared research minimize exposure and enhance public health outcomes.

We should strive to protect the next generation by being proactive.



Food Safety by Design (FSbD)

Standardized Review Approach

FSbD uses a consistent preventive methodology considering standards, sources, manufacturing, and scientific data for product safety.

Global Regulatory Integration

Annual reviews use data from international organizations to ensure global food safety standards.

Key Safety Actions

Vendor audits, toxicological assessments, and conservative safety standards are key FSbD actions.

Continuous Improvement

FSbD fosters ongoing accountability and enhancement of food safety and contaminant risk reduction.

Food Safety by Design Elements

- Designed as a Project, with Purpose, Scope, and intended study design
- Project team of 6-8 with functional experts in relevant fields
- Microbiological and Product Specifications determined by review of regulatory, in-house, and source methodologies
- Testing of individual components against Heavy Metals, Chlorates, special concerns – in triplicate
    - 100+ potential hazards considered
- Sum of total individual components and review of potential worst-case combinations
- Testing of finished product to understand potential load add from processing, including furan, acrylamide

Working in tandem with HACCP and Project Workstreams

Knowledge Sharing and Promoting Good Science

EXAMPLES!

Chlorate and Perchlorate Prevalence

Higher levels of chlorates and perchlorates are found in US and ASEAN food products than in the EU.

Elevated Lead Levels

Certain US-sourced materials show increased lead levels compared to Imported materials.

Targeted Intervention Strategy

Next steps include mapping ingredient matrices to identify high-risk contaminants and areas.

Improving Food Safety

Implementing focused strategies reduces exposure and enhances overall product quality.

Practical Next Steps for the Industry

Identify and Understand Risks

Industry stakeholders should identify risks in ingredients and processing stages to improve food safety.

- Invest in risk detection- Train your team

Review Chemical and Cleaning Programs

Regularly review chemical use and cleaning protocols to reduce contamination potentials

- Focus on QAC/BAC, chlorates, and perchlorates due to their potential health impacts on endocrine and thyroid systems. Hurdle technology

Test for Processing Toxins

Test acrylamide and furan levels before and after high-temperature processing to ensure product safety.

THANK YOU

DEPARTMENT OF AGRICULTURE

Chemical Hazard Assessments – Regulators' Approach

Katherine Simon | Food & Feed Safety Director

Regulatory Assessment

- Business
- Product characteristics
- Handling practices
- Customers and use

Food Safety Plan Review

- Use of FDA Hazard Guide
- Inquiry and dialogue
- Importance of available data

Compliance and Enforcement

- Sampling
- Inspection
- Investigation and traceback
- Correction orders
- Warning letters
- Product Interventions –

  embargos, C/D, seizure

Recommendations

FAMILIAR WITH COMMON RESOURCES

KNOW YOUR PROCESS AND CONTROLS

SPEAKING TO YOUR DECISIONS

Thank You!

Katherine Simon

Katherine.Simon@state.mn.us

952-452-4107

Addressing Chemical Hazards: Approaches and Resources

Ben Miller, PhD, MPH – COO & EVP of Scientific and Regulatory Affairs

THE ACHESON GROUP

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

November 19, 2025

Where Chemical Hazards Show Up in Your Plan

- Ingredients – contaminants such as heavy metals, pesticides, mycotoxins, PFAS, radiological hazards.
- Processing steps – reaction products like acrylamide, 3-MCPD (3-monochloropropane-1,2-diol) and GE (glycidyl esters), PAHs (Polycyclic Aromatic Hydrocarbons), nitrosamines.
- Contact surfaces and packaging – migration from equipment, containers, and distribution systems.
- Environment and water – legacy or natural contamination, sanitizers, and utilities.
- All of these need to be considered in a preventive controls or HACCP-style hazard analysis.

Ingredient and Process Hazard Analyses

1. Map the product and process – ingredients, processing steps, and contact materials.
2. Screen each ingredient and process step against priority hazard lists and guidance.
3. Ask an exposure-based question: could a consumer realistically be exposed at a level of concern?
4. Decide and document – not reasonably foreseeable vs. reasonably foreseeable and needing controls or further assessment.
5. Revisit when formulations, suppliers, processes, or regulations change.

FDA Hazard Guide – Examples of Common Process-Related and Facility-Related Hazards

Appendix 1 – A1.7	Common Process-Related and Facility-Related Hazards
BIOLOGICAL HAZARDS A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment
	Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control
	Bacterial pathogens – Growth and/or toxin production due to poor formulation control
	Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging
	Bacterial pathogens – Presence due to ingredients added after process controls
	Bacterial pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity
	Environmental pathogens – presence due to recontamination from the processing environment
CHEMICAL HAZARDS A1.7.2	Undeclared food allergens – incorrect label
	Unintended food allergen presence – allergen cross-contact
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)
	Process-contamination hazards in certain plant-based foods (e.g. acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils)
PHYSICAL HAZARDS A1.7.3	Metal
	Glass (when product packed in glass)
	Hard Plastic

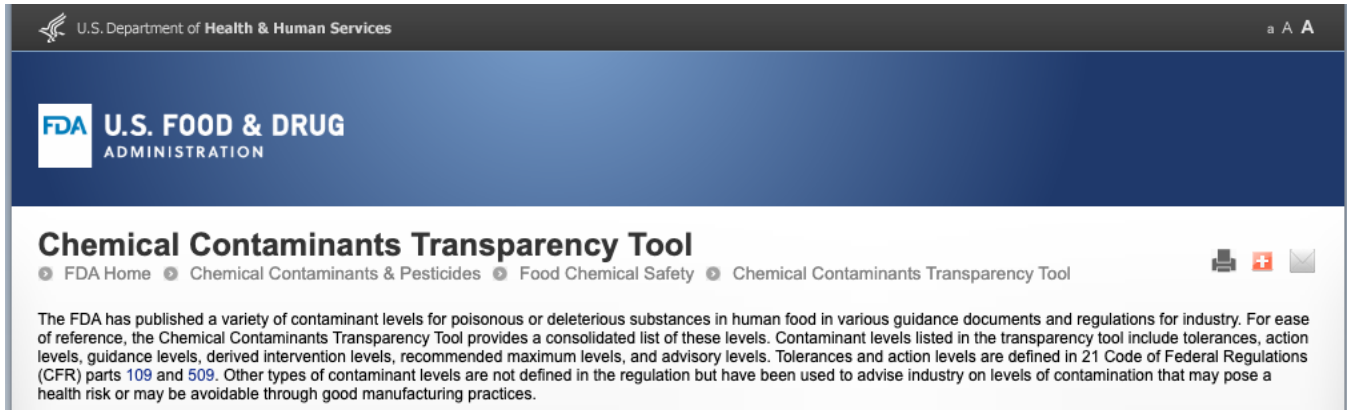
Online Resources – Ingredient and Contaminant Focus

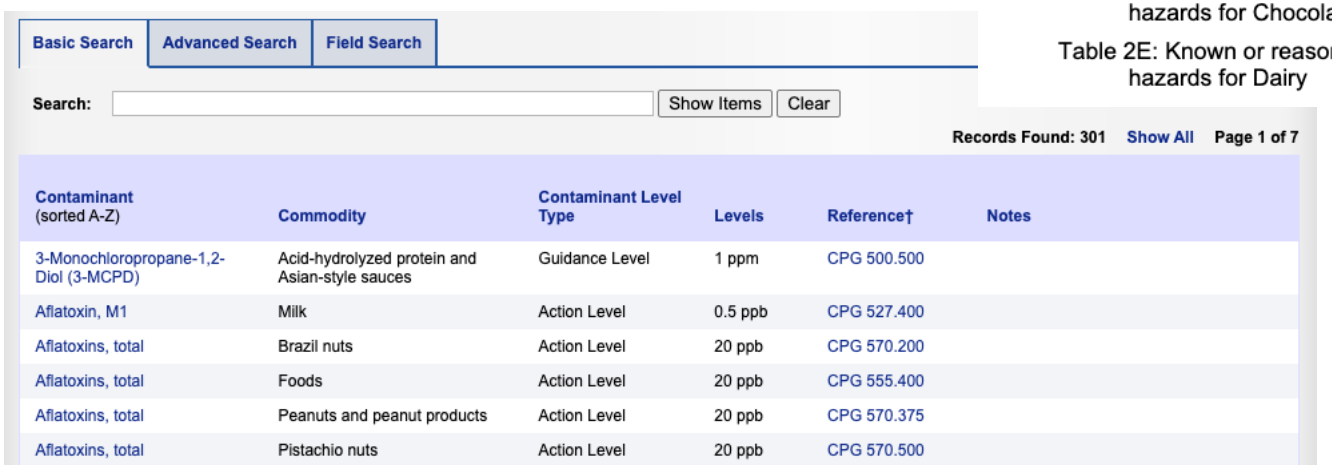
- FDA Appendix 1

  https://www.fda.gov/media/99581/download

- FDA Chemical Contaminants & Pesticides page – overview and links to programs and limits: https://www.fda.gov/food/chemical-contaminants-pesticides
- FDA Chemical Contaminants Transparency Tool – searchable database of contaminant tolerances, action levels, and guidance levels by chemical and commodity: https://hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=contaminant-levels
- Codex General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995) – Codex MLs: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/fr/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS+193-1995%252FCXS_193e.pdf
- USDA Pesticide Data Program (PDP) – monitoring data for pesticide residues in U.S. foods: https://www.ams.usda.gov/datasets/pdp

Online Resources – Ingredient and Contaminant Focus





Contains Non-binding Recommendations
Draft-Not for Implementation

Table 1P: Known or reasonably foreseeable ("potential") food-related biological hazards for Food Sweeteners (Nutritive and Non-Nutritive)

A1.11 Tables of Potential Food-Related Chemical Hazards

Food Group 2A: Known or reasonably foreseeable ("potential") food-related chemical hazards for Bakery Items

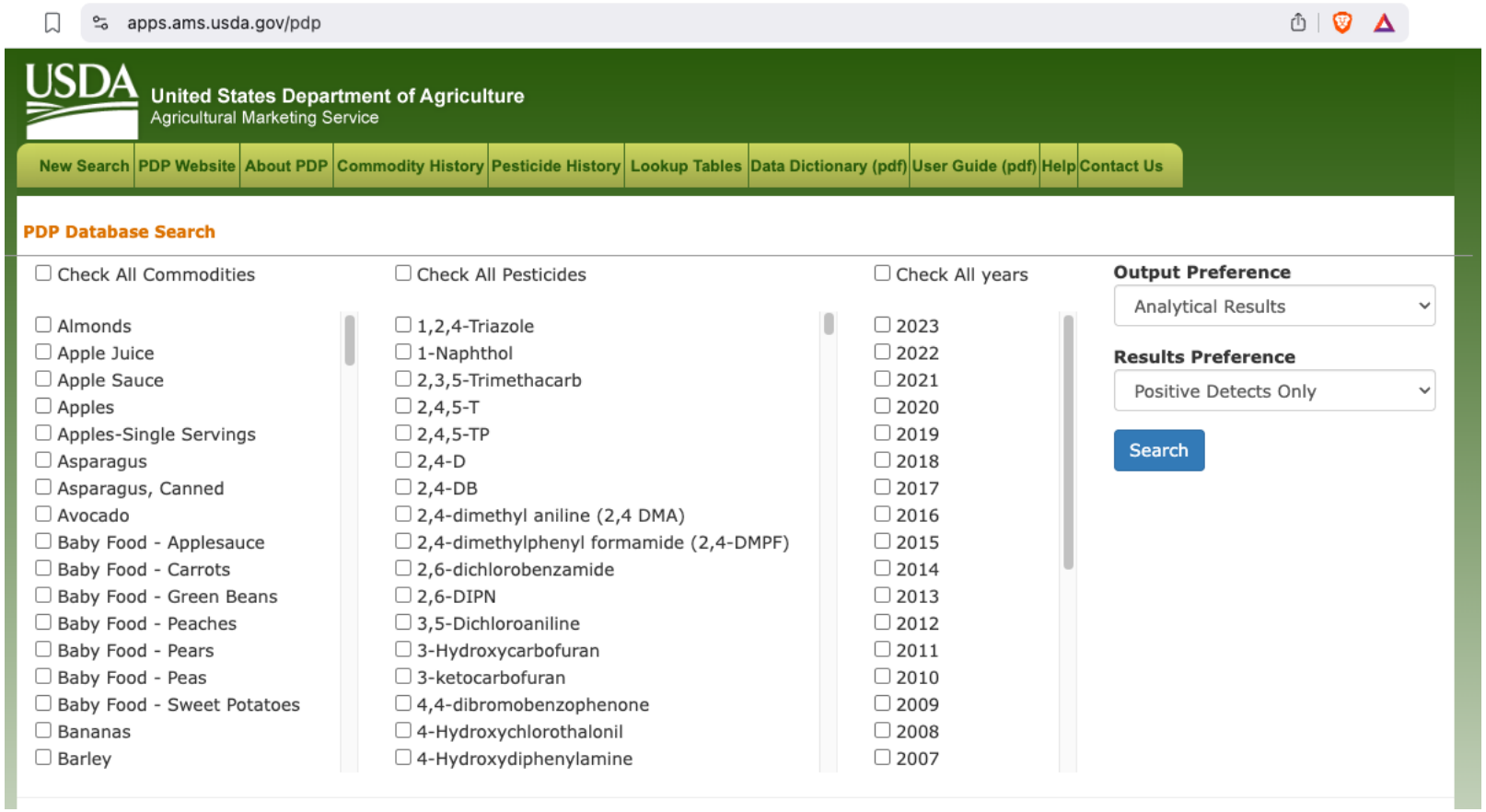
Table 2B: Known or reasonably foreseeable ("potential") food-related chemical hazards for Beverage Items

Table 2C: Food Additives, Color Additives, and GRAS Substances

Table 2D: Known or reasonably foreseeable ("potential") food-related chemical hazards for Chocolate and Candy

Table 2E: Known or reasonably foreseeable ("potential") food-related chemical hazards for Dairy

Online Resources – Ingredient and Contaminant Focus



Online Resources – Toxicology and Reference Values

- JECFA Evaluations Database – ADIs/TDI and monographs for additives, contaminants, and residues:
  https://apps.who.int/food-additives-contaminants-jecfa-database/
- EFSA OpenFoodTox – hazard data, critical endpoints, and reference values for chemicals:
  https://www.efsa.europa.eu/en/data-report/chemical-hazards-database-openfoodtox
- EPA Integrated Risk Information System (IRIS) – human health assessments and reference doses:
  https://www.epa.gov/iris
- FDA Guidance on Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed:
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed

Online Resources – Toxicology and Reference Values

World Health Organization

Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

This searchable database contains the summaries of all the evaluations of flavours, food additives, contaminants, toxicants and veterinary drugs JECFA has performed. Each summary contains basic chemical information, ADIs/TDIs, links to the most recent reports and monographs as well as to the specification database, and a history of JECFA evaluations. The database is searchable by partial name or CAS number, by first character (letter or symbol), or by functional class.

Includes all updates up to the 101st JECFA meeting (October 2025).

Partial name or CAS number

FEMA or JECFA number

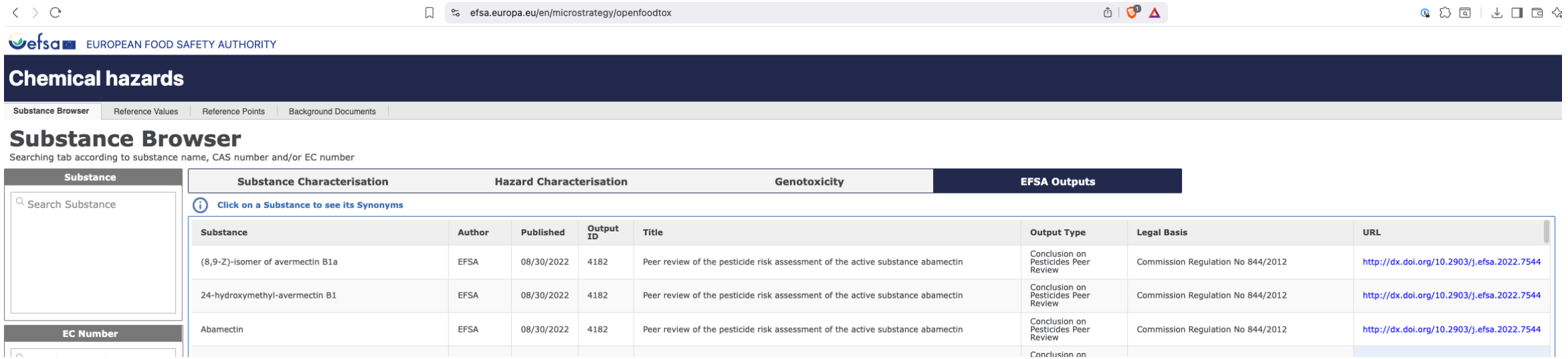
First Character

food_additive

List of chemicals in functional class **food_additive** (34 results):

CALCIUM METABISULFITE
POLYETHYLENIMINE
SULFITES

Online Resources – Toxicology and Reference Values



Online Resources – Process and Packaging Hazards

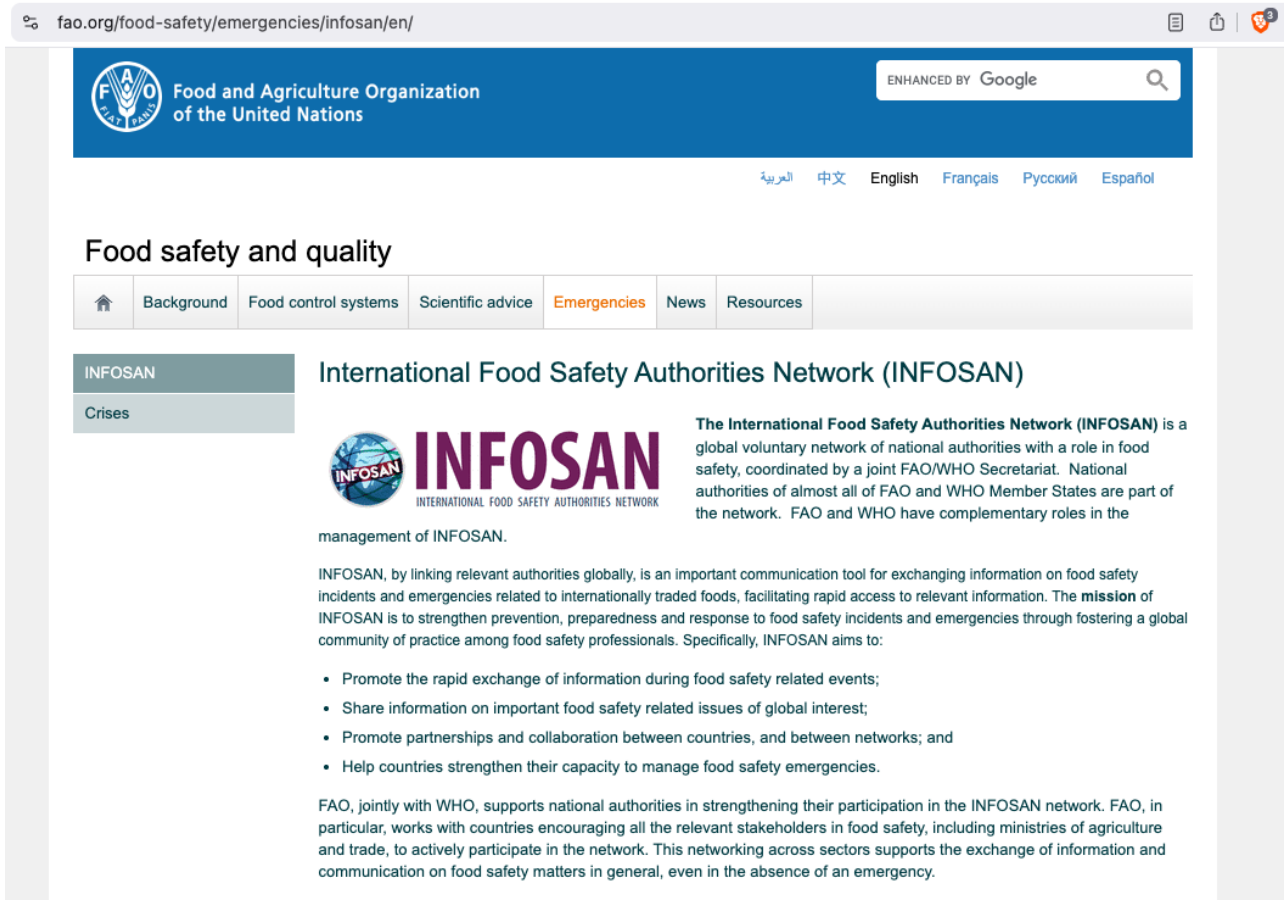
- FDA Chemical, Metals, Natural Toxins & Pesticides guidance page – links to guidance on acrylamide, 3-MCPD/GE, PAHs, and other process contaminants:
  - https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations
- Food contact materials and packaging – check national positive lists and guidance, for example:
  - EU food contact and plastics regulations, and PFAS/FCM guidance from FDA and other authorities.
- Sector-specific guidance – trade and commodity groups often translate these hazards into practical controls for categories like baby foods, dairy, confections, and snacks (time/temperature, formulation, packaging choices).

Online Resources – Process and Packaging Hazards

Surveillance and Horizon-Scanning Tools

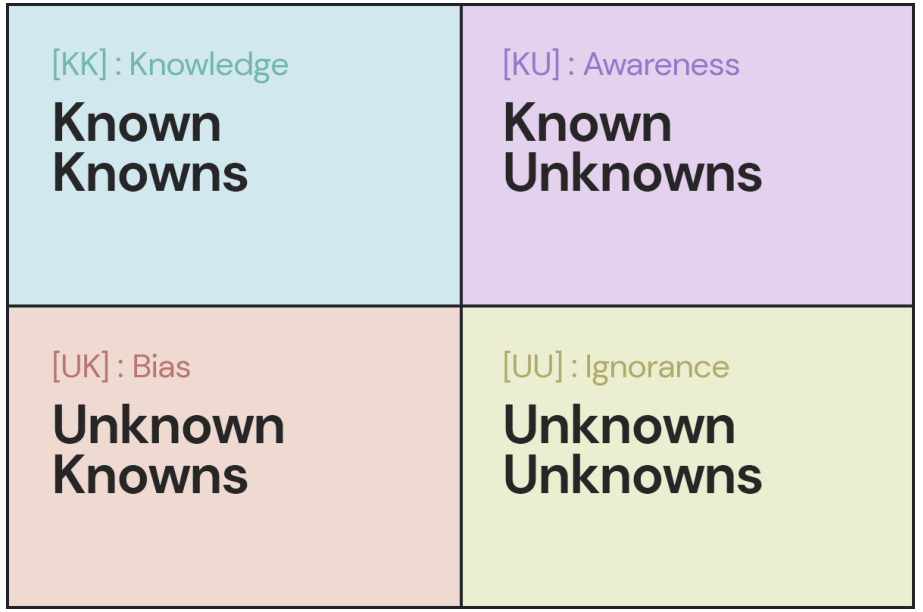
- FDA recall, warning letter, and enforcement databases – to see real-world contaminants driving actions.
- USDA Pesticide Data Program (PDP) – annual summaries and searchable data on pesticide residues:
  https://www.ams.usda.gov/datasets/pdp
- RASFF (EU Rapid Alert System for Food and Feed) – searchable notifications on chemical hazards in trade:
  https://food.ec.europa.eu/food-safety/rasff_en
- INFOSAN summaries – WHO/FAO International Food Safety Authorities Network incident reports and quarterly summaries highlighting chemical incidents:
  https://www.fao.org/food-safety/emergencies/infosan/en/

Surveillance and Horizon-Scanning Tools



Practical Application

- Prioritize – begin with the highest concern product categories and ingredients rather than trying to solve everything at once.
- Build a living references library – save key guidance documents and tool links for your key commodities and processes in a shared folder or internal site.
- Use a consistent screening template – the same set of questions and core tools for every ingredient or process step, so decisions are transparent and repeatable.
- Escalate when needed – when you identify a potential issue with significant uncertainty or high impact bring in toxicology or regulatory expertise rather than ignoring the signal.



https://fairing.co/blog/the-known-unknowns-matrix-in-ecommerce

Thank you!

Questions
and
Discussion

Ben.Miller@AchesonGroup.com
www.achesongroup.com
info@achesongroup.com
800-401-2239

BREAKOUT SESSIONS

Have a burning question? This is your chance to get answers to your questions and learn from questions that others ask.

FDA's Use of AI to Inform Food Safety Oversight

MAIN CONFERENCE ROOM

FSVP: Compliance, Training and Lessons Learned

STRATHMORE A&B

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FDA'S USE OF AI TO INFORM FOOD SAFETY OVERSIGHT

JOHN (CHUCK) HASSENPLUG
U.S. FOOD AND DRUG ADMINISTRATION (FDA)

MODERATOR: TANIA MARTINEZ

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
Innovation Through Collaboration

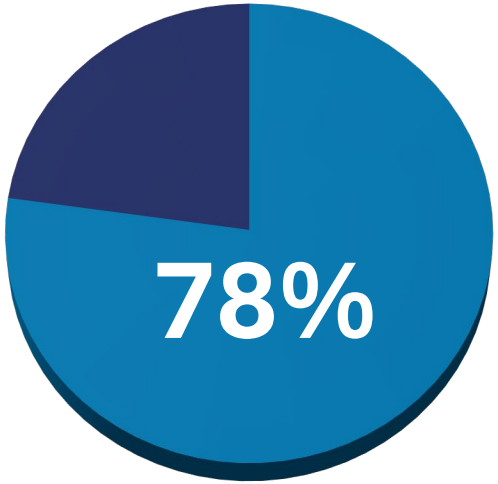
Needle in a Haystack:

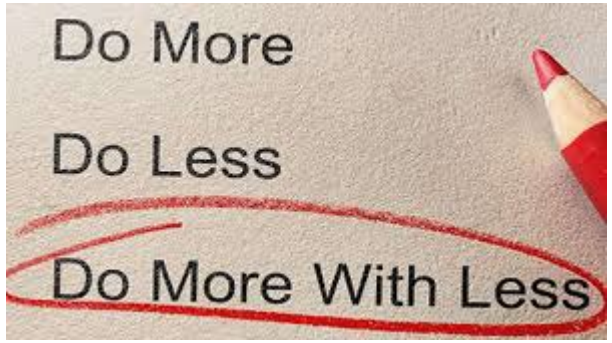
How artificial intelligence and machine learning are being used to enhance food safety.

FDA's Human Food Program,
Office of Surveillance Strategy and Risk Prioritization (OSSRP)
11/19/2025

FDA Human Food Key Facts

- HFP's mission is protecting and promoting the health and wellness of all people through science-based approaches to prevent foodborne illness, reduce diet related chronic disease, and ensure chemicals in food are safe.
- FDA protects about 78% of the U.S. food supply, with a significant amount coming from abroad (e.g., seafood (95%), fresh produce (50%), spices (60%))
- Food regulations cover more than 236,000 registered food facilities (more than ½ are overseas); 35,000 domestic farms; and 12 million import shipments. This is over 10 times more facilities than overseen by the medical product centers combined.
- FDA's foods program is 17% of the agency's budget but is tasked with overseeing 80% of its active establishments
- As HFP is largely post-market, 76% of OII's field activities is spent on human food.
- With such a huge budget and limited resecures, the use of AI is critical to help FDA more efficiently and efficiently protect public health

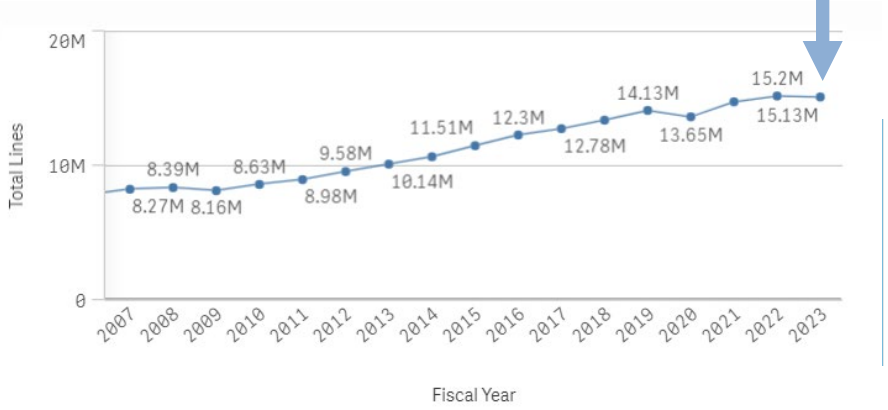




Which container would you pick?

74% increase last decade

to 15M shipment lines in 2023



Percent of commodity imported (examples)

94%
Seafood

55%
Fresh Fruit

32%
Fresh Vegetables

***Source:** FDA Data Dashboard (https://datadashboard.fda.gov/ora/cd/impsummary.htm)

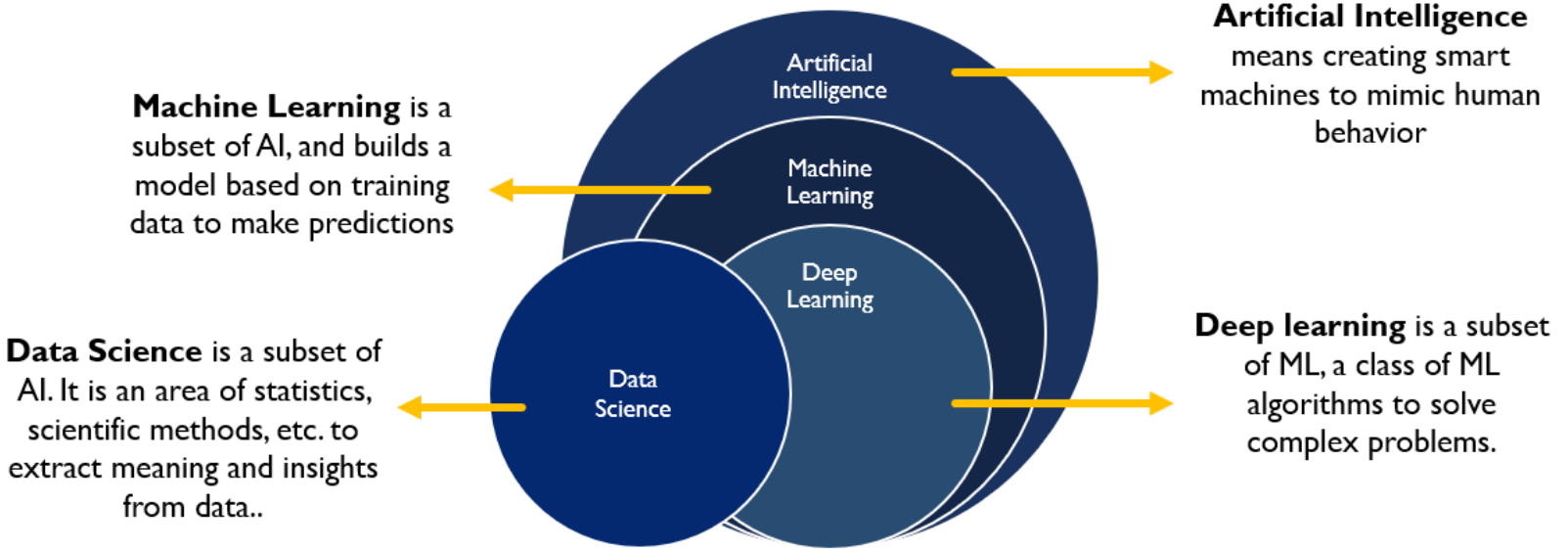
11/19/2025

AI Landscape at FDA

- Historically, each Center was doing its own exploration, some further along/advanced than others
- Clear line dividing internal AI use vs. external AI use by industry (e.g. drug development)
- Many cross-agency workgroups, but more “brown bag” than “control board”
- Currently there is a large focus on AI and ensuring rapid enterprise development and sharing across Centers (e.g. Elsa)
- The Human Food Program has pioneered applying AI to food safety issues and has been actively sharing its insights with stakeholders

What is machine learning (ML)?

- The use of computational, statistical, and mathematical models to **learn patterns from historical data** and then use that to subsequently **predict an outcome for a new instance**.
- Real-life applications: Email spam detectors, credit/debit card fraud detection, etc.
- Within the Food Program, our traditional ML models are currently deployed to **enhance (not replace) risk-based targeting** of food products and supply chains likely to be violative of microbiological and chemical hazards.



While deep learning is often more accurate, that comes at a cost of complexity and explainability. Neural Nets are examples here and include LLMs.

https://medium.com/@mishrasubhendu147/ai-vs-ml-vs-dl-vs-data-science-854d79bb1833

Criticality of AI Technology to Support FDA Human Food Mission

Generative AI

Satellite and GIS

FDA protects about 78% of the U.S. food supply

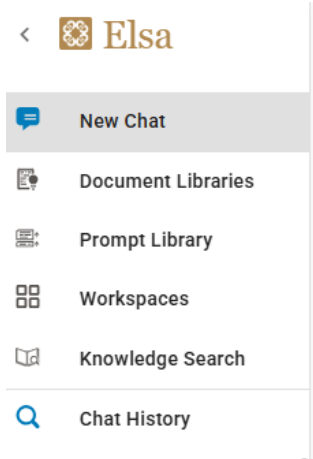
Largely post-market

Computer Vision

Machine Learning

Generative AI

Elsa



How many food safety recalls were there last year and in which commodities. Make a bar chart.

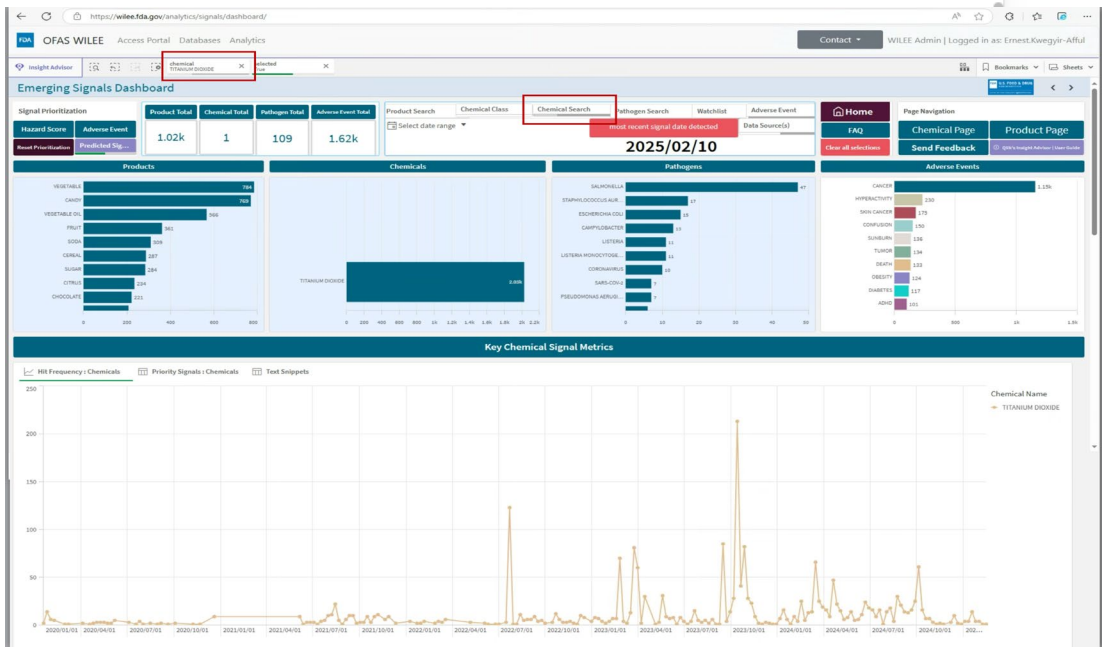
Other (Supplements, Additives, etc.)	18
Total	**466**

Bar Chart: 2024 Food Recalls

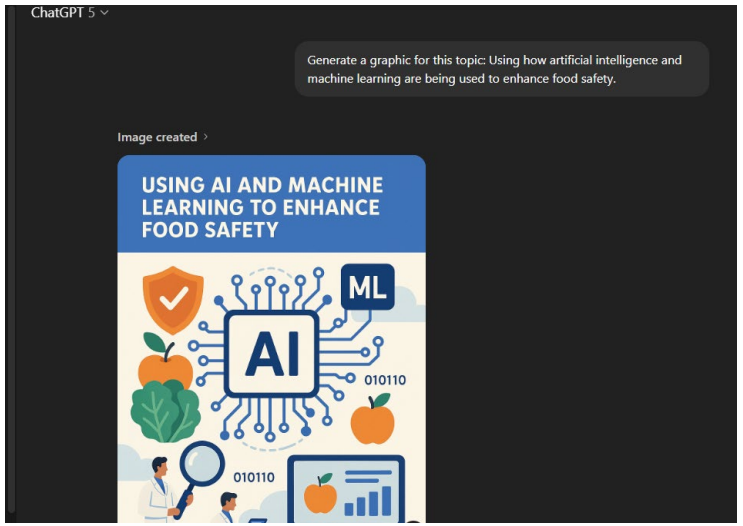
This chart visually represents the number of recalls for each commodity category.

```
Commodity Category          | Number of Recalls
-----------------------------------------------------------------------------
Produce                     | ■■■■■■■■■■■■■■■■ (85)
Prepared Foods              | ■■■■■■■■■■■■■■ (72)
Bakery & Grains             | ■■■■■■■■■■■■■ (65)
Meat & Poultry              | ■■■■■■■■■■■ (58)
Seafood                     | ■■■■■■■■ (45)
Dairy & Eggs                | ■■■■■■■ (41)
Spices, Flavors, & Salts    | ■■■■■■ (33)
Beverages                   | ■■■■ (27)
Confectionery/Sweets        | ■■■■ (22)
Other                       | ■■■ (18)
```

(Each ■ represents approximately 5 recalls)



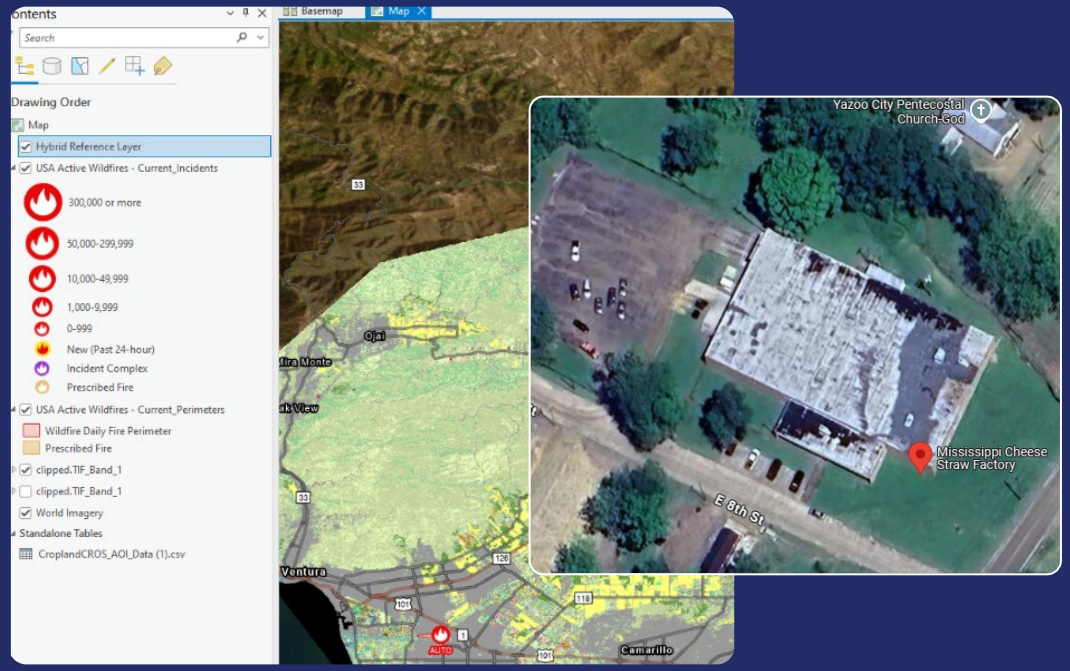
WILEE (Warp Intelligent Learning Engine)

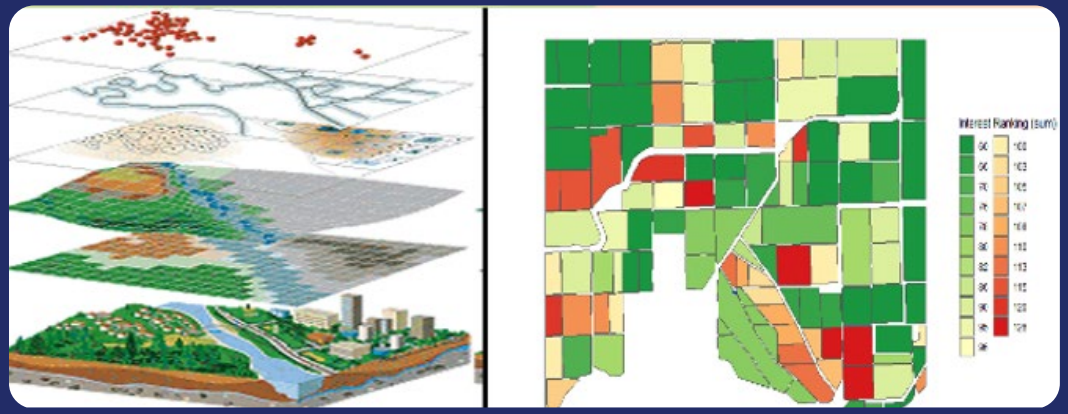


HHS ChatGPT

HFP Use Case: Satellite and GIS Intelligence

Satellite and GIS





The Problem: Contaminated fresh produce causes most food outbreaks in the U.S., but farms don't have to register with FDA, making it hard to track where problems might occur.

The Solution: Using computer technology to analyze satellite images (like Google Maps) to automatically identify farms, what they grow, and potential contamination risks.

Current Progress: FDA is already using satellite data to map crop types and farm boundaries, identify potential sources of contamination, and avoid wasting time inspecting closed facilities.

Benefits: Faster outbreak response saves lives and reduces economic damage, while avoiding unnecessary inspections could save $25,000 per operation for more important work.

Future Plans: The system works now on a case-by-case basis, but could be automated to run continuously with better real-time data access.

Who Benefits: FDA staff primarily, with potential to share insights with industry and other countries for prevention and training.

Computer Vision

The Challenge: FDA manually examines 59,000 food import labels annually, requiring 20 full-time staff members to check for safety violations and compliance issues.

The Solution: Computer vision technology that can automatically scan food labels and predict which ones are likely to have violations, making the review process faster and more efficient.

Early Results: After just one month of testing, the new system performs 6 times better than traditional methods at identifying problematic labels.

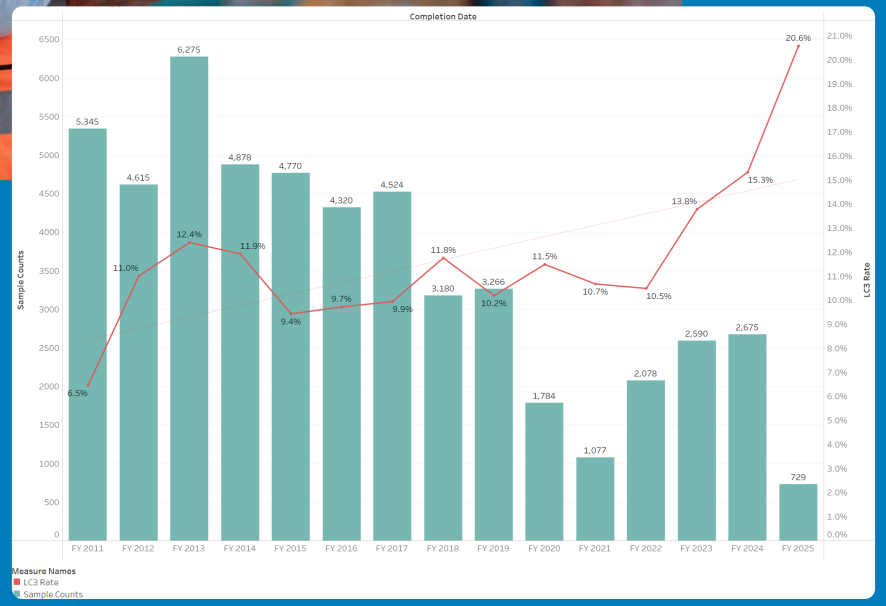
Cost Benefits: The technology allows FDA to focus staff time on the 5% of labels most likely to have problems, while automatically processing the majority that are likely compliant.

Future Plans: FDA aims to fully deploy the system in 2025 and is considering developing a public app that would let consumers scan food labels to make informed purchasing decisions.

Additional Impact: The system is building a comprehensive database of food labels that supports ongoing research into unsafe chemicals and food safety trends.

HFP Use Case: Food AI Decision Engine (FAIDE)

Machine Learning



The Challenge: Millions of food shipments enter the U.S. annually, but FDA has only a small number of field staff at each port to inspect them for safety violations.

The Solution: Machine learning technology that analyzes FDA data to predict which food shipments are most likely to have safety problems before they're inspected.

Performance Results: The system is 2-6 times better at catching violations than traditional methods and correctly identifies safe shipments 95% of the time.

Cost Savings: FDA cut the cost of finding each violation in half (from $24,000 to $12,000), meaning they can provide twice the public health protection with the same budget.

Staff Efficiency: In just three months, the equivalent of 5 full-time employees were redirected from routine work to focus on high-risk shipments that pose greater safety concerns.

Current Status: The system is actively being used but requires manual maintenance; FDA plans to upgrade to an automated, real-time platform to make it even more efficient.

Broader Impact: The technology has significantly improved detection rates for specific hazards like pesticide contamination in imported foods.

Compliance ML Model Objectives

- The objective of the ML models we have developed is to **predict** the probability of being violative. For samples that means the presence of a hazard being found in the product (Lab Class 3 result), and for inspections that means serious violation that indicate official action needed (OAI)

- This prediction comes in **two forms**; 1) the probability between 0 and 100% of being violative, and 2) whether that probability is above an threshold that optimizes sensitivity (finding all violations) and specificity (not targeting those that are in compliance)
  - This threshold can either be chosen by the model based on the training dataset or set manually by FDA staff. It varies depending on the hazard and resource capacity when deployed.

- We assess model performance in several ways:
  - Better at predicting a violation (positive predictive value or PPV)
  - Overall accuracy (how often is the model prediction right)
  - Statistical significance (using confusion matrix and other statistical tests)
  - FDA staff feedback; are predictions helping FDA staff in their complex targeting work and the execution of the annual work plan
  - Public health impact in terms of volume of violative food removed from commerce and illness/harm avoided

ML Models Portfolio

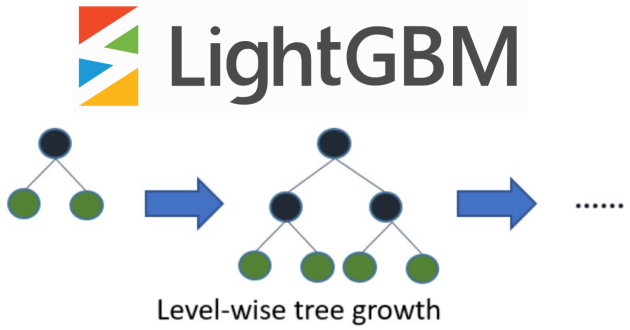
Hazard Code	Hazard Description	Hazard Examples	Target Feature	Commodities of Interest	Domestic / Import?	Deployment Status
MIC	Microbiological (pathogenic bacteria)	*E. coli, Salmonella, Listeria*, etc.	Presence of pathogen	All Human Food	Imports and domestic	Updated Quarterly
DEC	Decomposition (toxic compounds from spoilage)	Histamines, scrombotoxins, etc.	Detection of decomposition in sensory test	Seafood only	Imports only	Updated Quarterly
ANT	Unapproved Antibiotics	Tetracyclines, florfenicol sulfonamides, etc.	Antibiotic concentration above safe threshold	Seafood only	Imports only	Updated Quarterly
PES	Pesticides	carbendazim, glyphosate, chlorpyrifos, etc.	Element concentration above safe threshold or acceptable trace amount	All Human Food, focus on raw produce and whole grains	Imports only	Updated Quarterly
ELE	Toxic elements	Lead, arsenic, mercury, etc.	Element concentration above safe threshold	All Human Food	Imports and domestic	Updated Quarterly
LEX	Label Exam	Undeclared allergen, banned ingredient, not in English	Violative label (Lab Class 3)	All Human Food	Imports only	Deployment planned in FY26 Q2
OAI	Violative Inspection (Initial or final)	N/A	Initial or final OAI classification (domestic), 483 (foreign)	All Human Food	Domestic (all, FSMA 201 Only, FSVP) and Foreign	Monitor Results Retrospectively

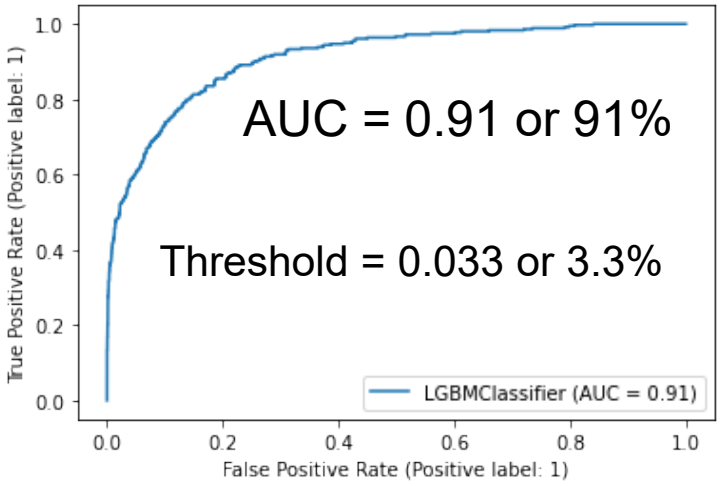
ML Model Development Pipeline (IMP MIC example)

Data

- 10+ years of import sampling data (~60k samples)
- Past oversight and compliance information
- Demographic data from FDA and DUNS (location, sales, employees)

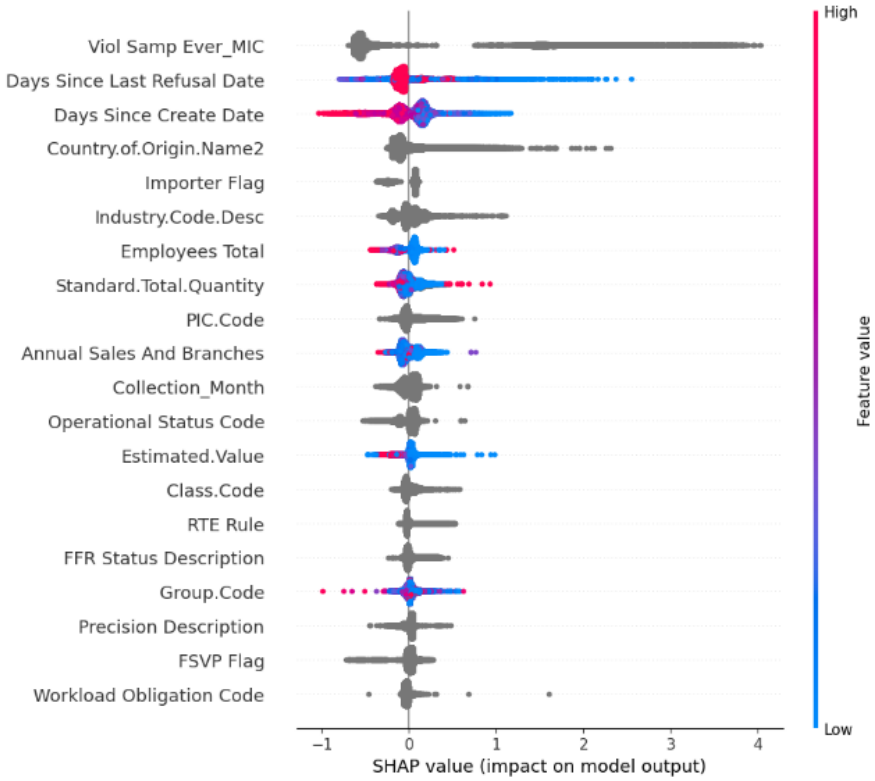
Model Training



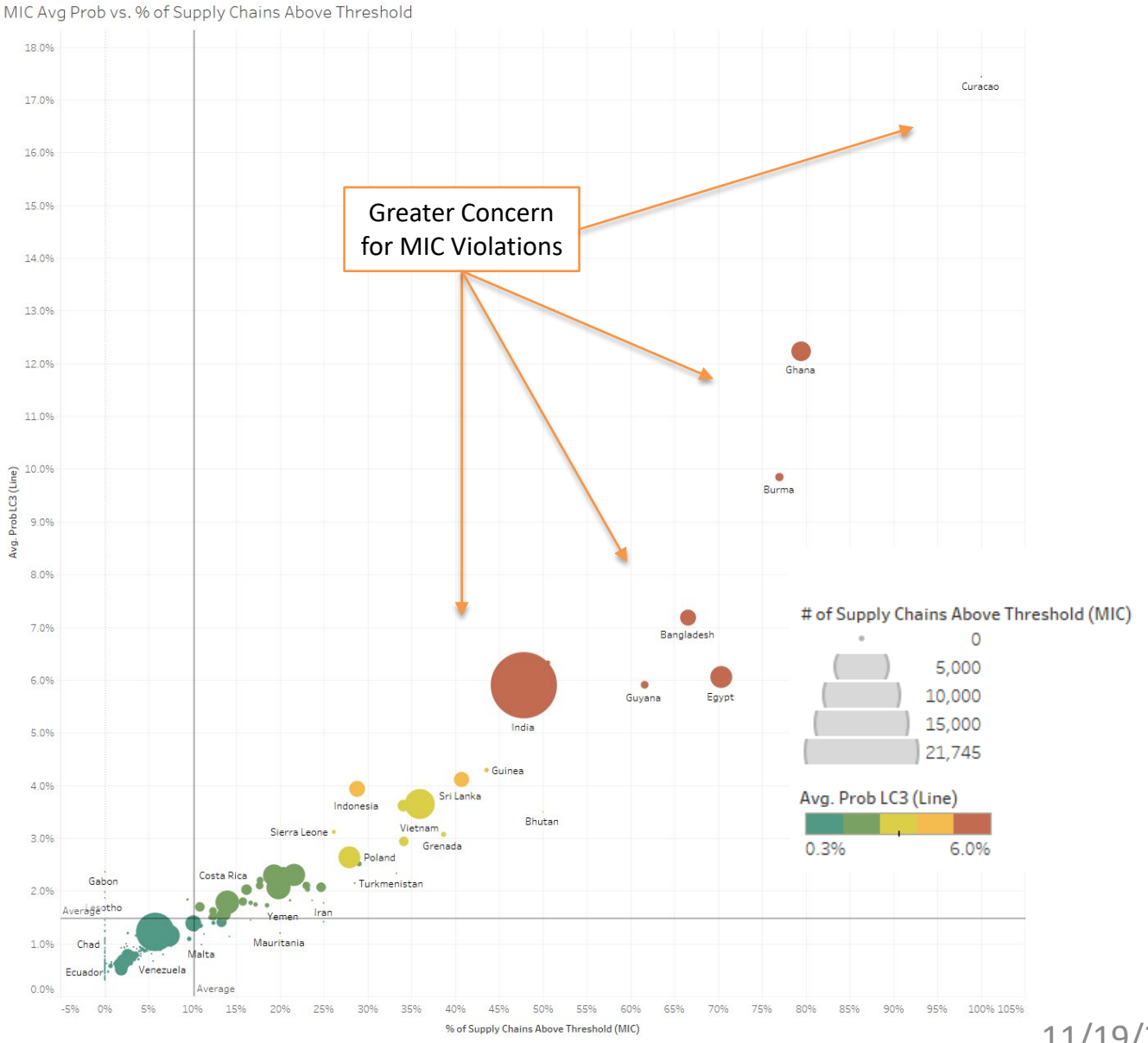


Feature Evaluation

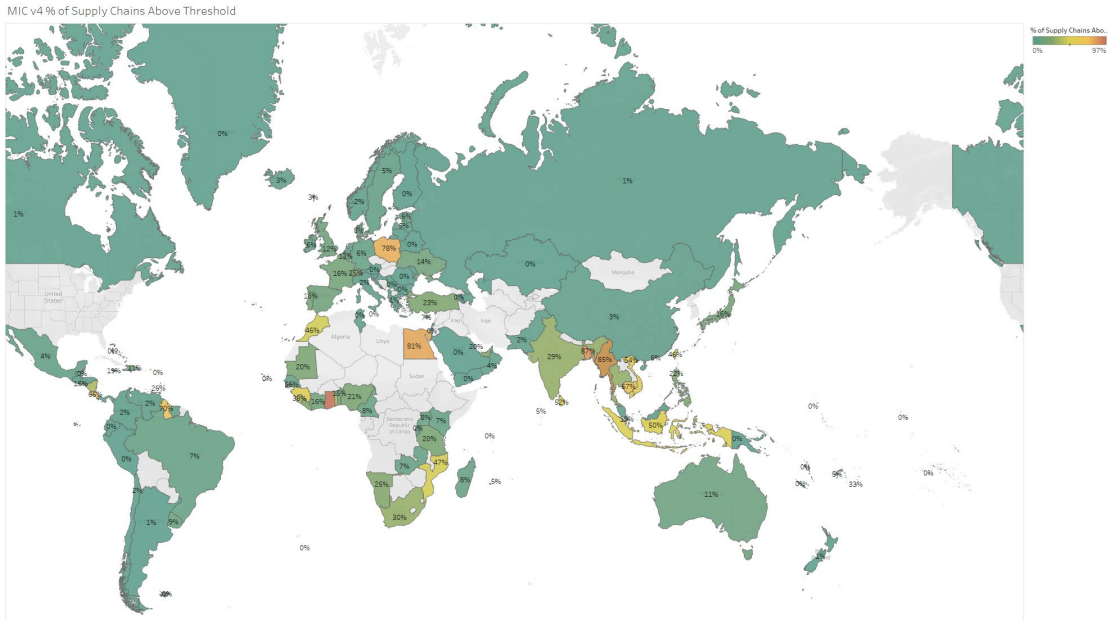
Shap values help explain results



Exploring Model Output by Country of Origin (Seafood example)

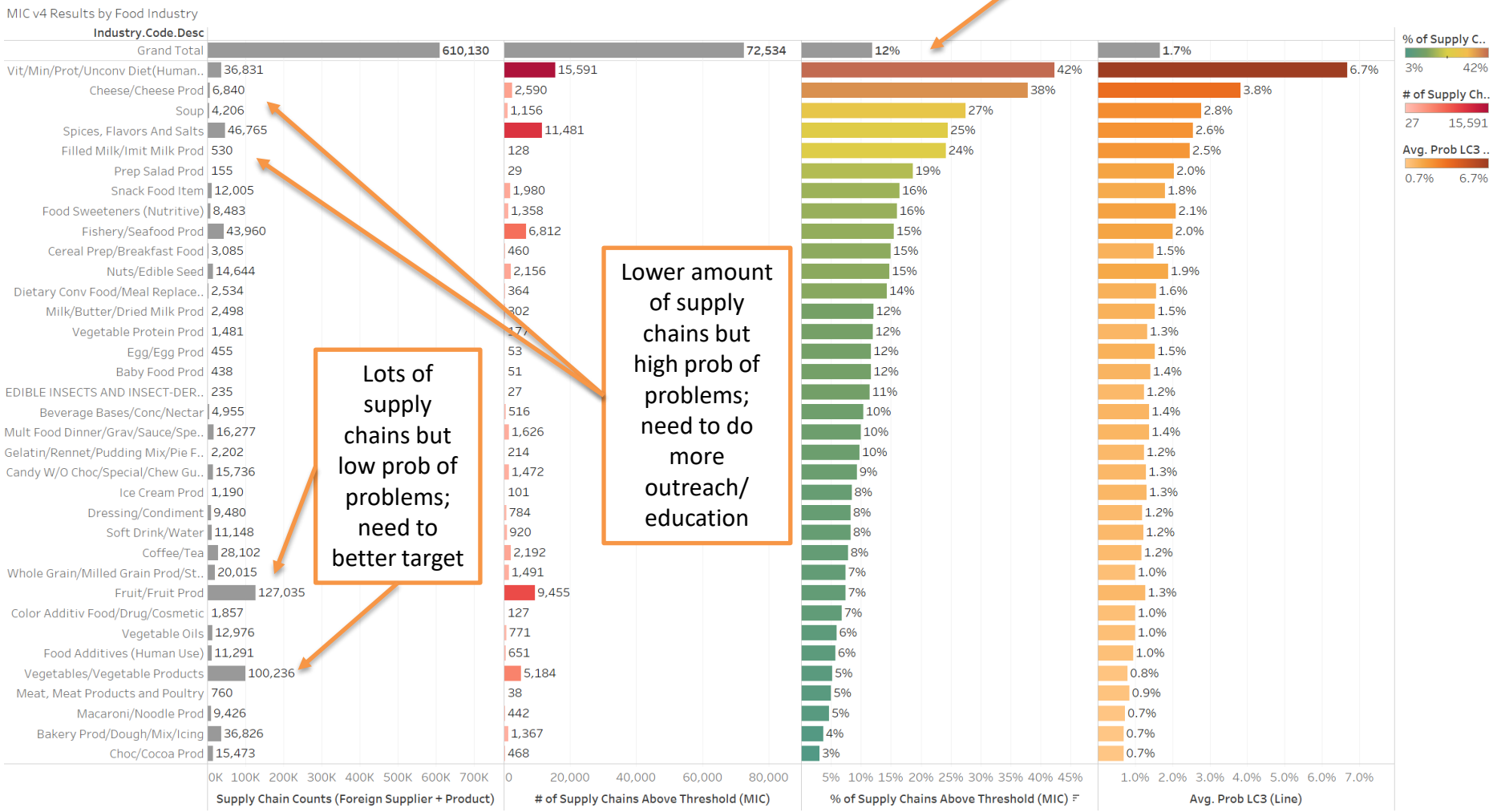


- The average probability of being violative (y axis) and the % of all seafood supply chains above threshold (x-axis) vary by country
- This information may also help inform outreach efforts by country or region to improve compliance.



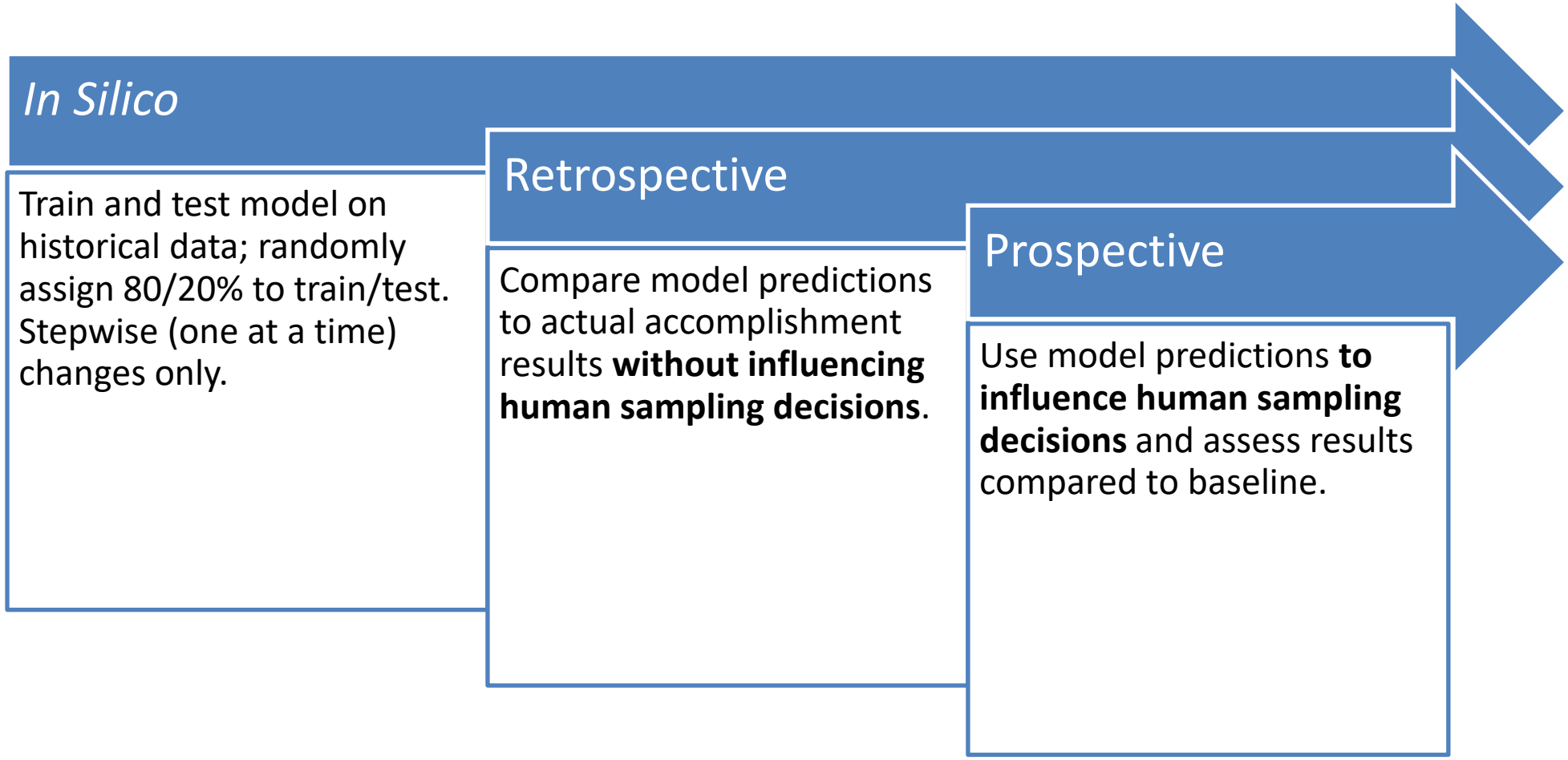
Exploring ML Output by Industry

Only 12% of the active 600k supply chains are predicted violative by the model, allowing us to focus precious resources and facilitate trade



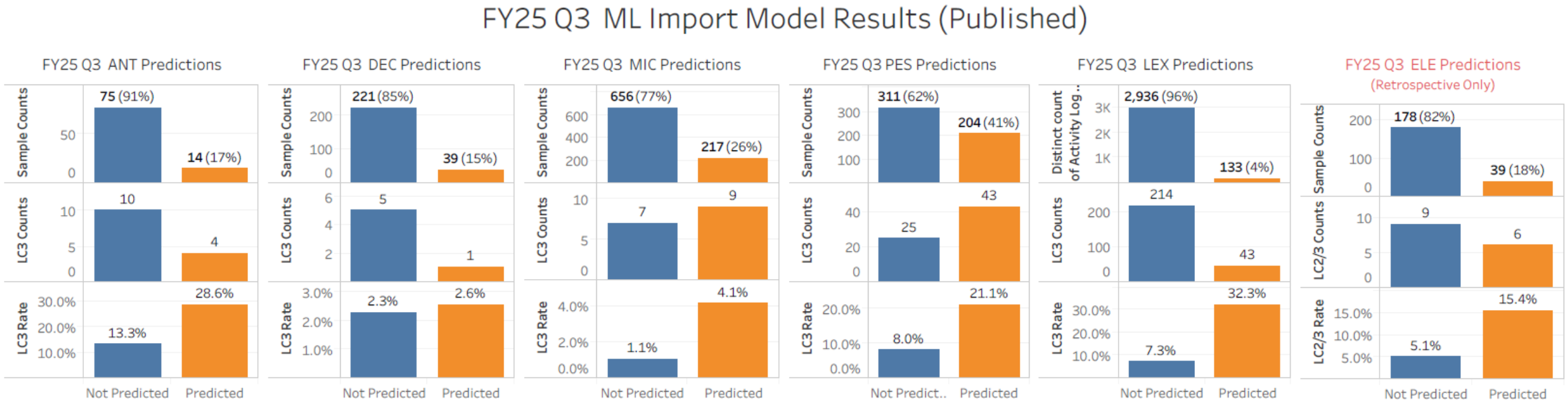
- Produce, Spices, Seafood, Dietary Supplements, and Bakery Products had the greatest number of assessed supply chains
- The model was most concerned with dietary supplements, cheese, soup, and spices for MIC contamination

How we assess our models



Confidence

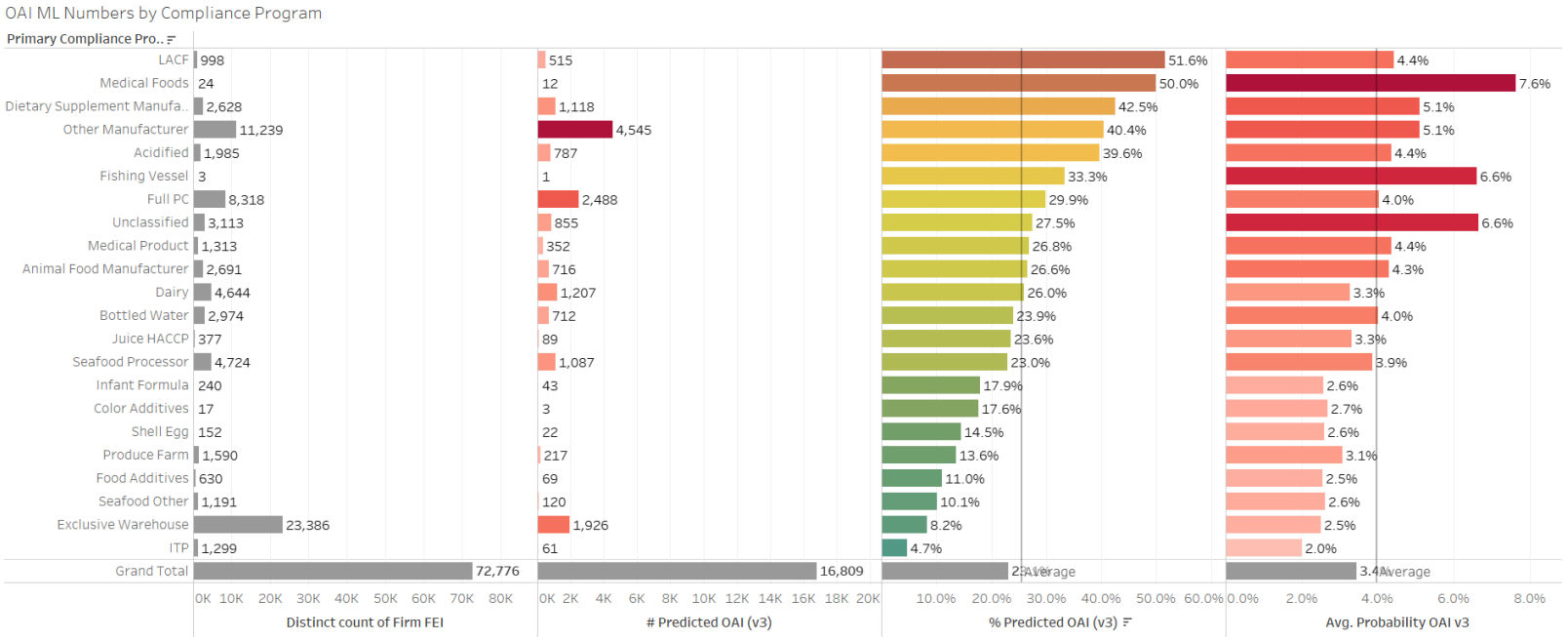
Import Model Prospective Performance FY25 Q3*

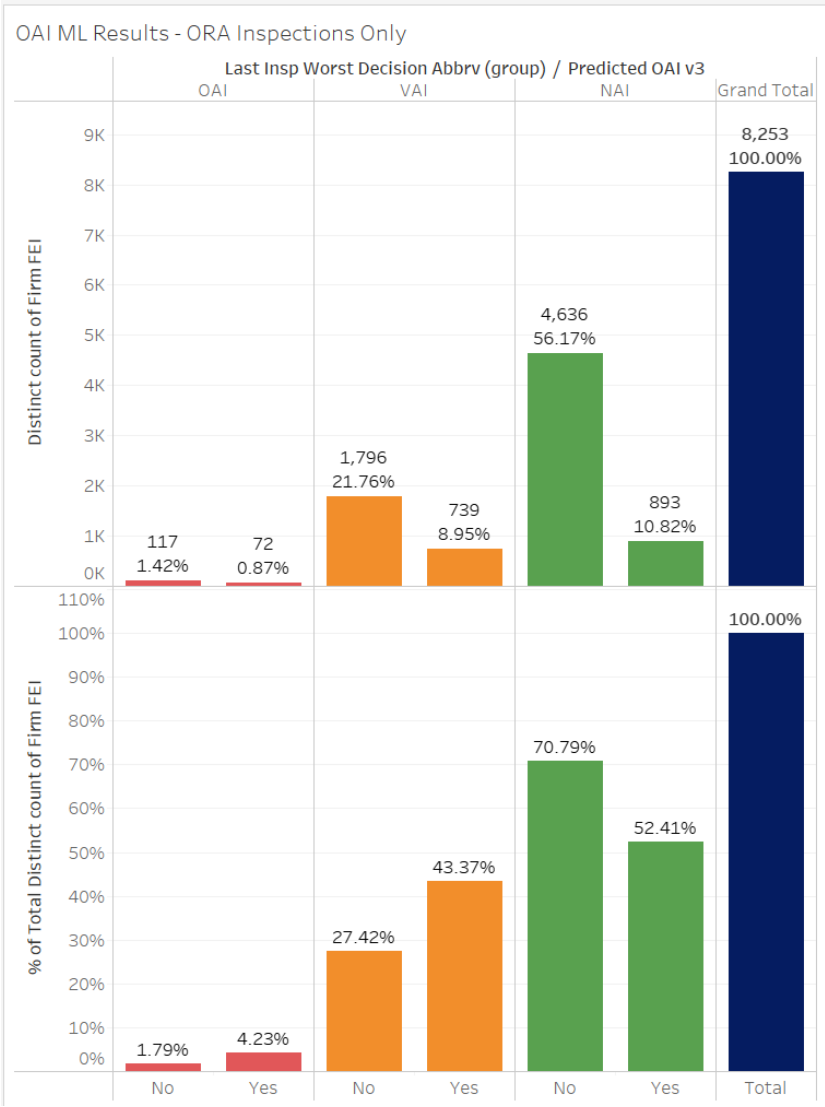


- So far in Q3, we have found 106 violations, many of which would not have been reviewed by humans and recommended for sampling without AI intervention.
- Across all hazards, AI/ML is doing a better job at finding violations than baseline

*As of 7/21/25

Results from Domestic OAI Model





What is Predicted? (Above)

- 23% of the domestic inventory is predicted OAI by the model, meaning the model is VERY sensitive
- However, that % varies significantly by establishment type, division, and compliance program (shown above)

What were the Results? (Right)

- There have been almost 8,253 ORA inspections since we first ran v3 of our OAI ML model in March of 2023
- The OAI rate is more than 2x higher among those FEIs predicted OAI
- The VAI rate is also higher among the OAI-predicted FEIs

Model Results “In the Wild”

Retrospective

- Accuracy ranges from 70-92%
- Positive predictive value (PPV) is 2-5x greater than baseline, aka “hit rates”
- All models are statistically significant at 95% CI

Prospective

- Predictions shared with field staff to help inform sampling decisions (% of samples recommended by model increased)
- Results consistent or better than retrospective results (human knowledge helps)

Public Health Impact

- Through FY25, of **530** violative samples, primarily based on model recommendation.
- This represented **138M** KG of food, with a declared value of **$36M**
- *Assuming* 1/2 KG serving size and 10% illness rate, **27.6M** people did not get harmed because of our ML implementation

Key Lessons Learned

1. **Data quality is essential:** Current and accurate registration, product codes, name and address of manufacturer help the model more accurately makes its predictions; missing, inconsistent, or unexpected (outliers) data are red flags.

2. **Shrinking the Haystack:** With only ~17% of active supply chains (and only 8% of total lines) predicted violative by the ML models, it greatly helps FDA focus on riskier shipments and facilities trade of the rest (win/win)

3. **Surveillance vs. Compliance:** 35% of the predicted supply chains have never been sampled ever, helping FDA address its surveillance needs while also prioritizing potential compliance violations (another win/win)

4. **Reactive vs. Proactive:** Using the ML results at the supply chain level helps us identify problem shipments and remove from the market before an outbreak or recall; at the industry/country level, it could help inform training and outreach efforts and prevent violations in the first place.

Implications of ML Results

- Better protecting public health (higher detection rate)
- Better using limited resources (focusing on subset of inventory)
- Identifying emerging trends (correcting blind spots)
- Complementing/codifying human intelligence
- Facilitating trade (not sampling those in compliance)

Moving more towards “smart” regulation

How to Move Forward Together?

FDA seeks and values input from public, academia, and industry:

- Suggestions on how to **improve models** to include additional data or features (e.g. food safety culture, weather data)
- How would external stakeholders **benefit from having access to protected, aggregated model results**?
  - Could it be used for training/outreach? Prompt preventative changes?
  - Would it improve compliance, impact purchase decisions, reduce food safety events?
- How could FDA **collaborate** with other stakeholders to share/exchange data and/or develop joint models?
  - Does industry use AI/ML to evaluate their suppliers?

Questions or Feedback?

Contact Info:

John (Chuck) Hassenplug,
Senior Policy Analyst

john.hassenplug@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

STRATHMORE
A&B

FSVP: COMPLIANCE, TRAINING AND LESSONS LEARNED

HILARY THESMAR
THE FOOD INDUSTRY ASSOCIATION (FMI)

BOB BAUER
ASSOCIATION OF FOOD INDUSTRIES (AFI)

MODERATOR: KATHY GOMBAS

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Background and Key Requirements

FSVP Rule

- Final Rule published on November 27, 2015 in the *Federal Register*
- *Section 301 of FSMA*
- *FD&C Act Section 805*

- Requires importers to complete risk based verification activities to assure that foods have the same level of public health protection as foods produced in the US

Rule Basics

- Requires foreign suppliers to meet the same level of public health protection as firms in the US
- Considers known or reasonably foreseeable food safety hazards
- Supplier approval program
- Hazard analysis
- Evaluation of supplier's performance and the risk posed by the food
- Verification Activities

FSVP Importer

- The US owner or consignee of an article of food that is being offered for import into the US. If there is no US owner or consignee of an article of food at the time of US entry, the importer is the US agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the importer under this subpart.

What does the Importer need to do?

- CBP Importer – Designate a FSVP Importer
- FSVP Importer – Comply with FSVP

If there is no US owner or consignee of an article of food at the time of US entry, ***the importer is the US agent or representative of the foreign owner or consignee at the time of entry****, as* ***confirmed in a signed statement of consent*** *to serve as the importer under this subpart.*

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Records to be Kept by the Importer

1. Signed statement of consent from the US Agent or representative if there is no US owner or consignee of the product
2. Written procedures for the supplier approval program
3. Hazard analysis of the food or documentation of review of the HA
4. Documentation of the evaluation of the foreign supplier's performance (food safety procedures, compliance with regulations, food safety history)
5. Hazard disclosures and assurances
6. Verification activities
7. Reevaluations – when needed or every 3 years
8. Corrective actions

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Not an exhaustive list

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Who is responsible for the FSVP and Verification Activities

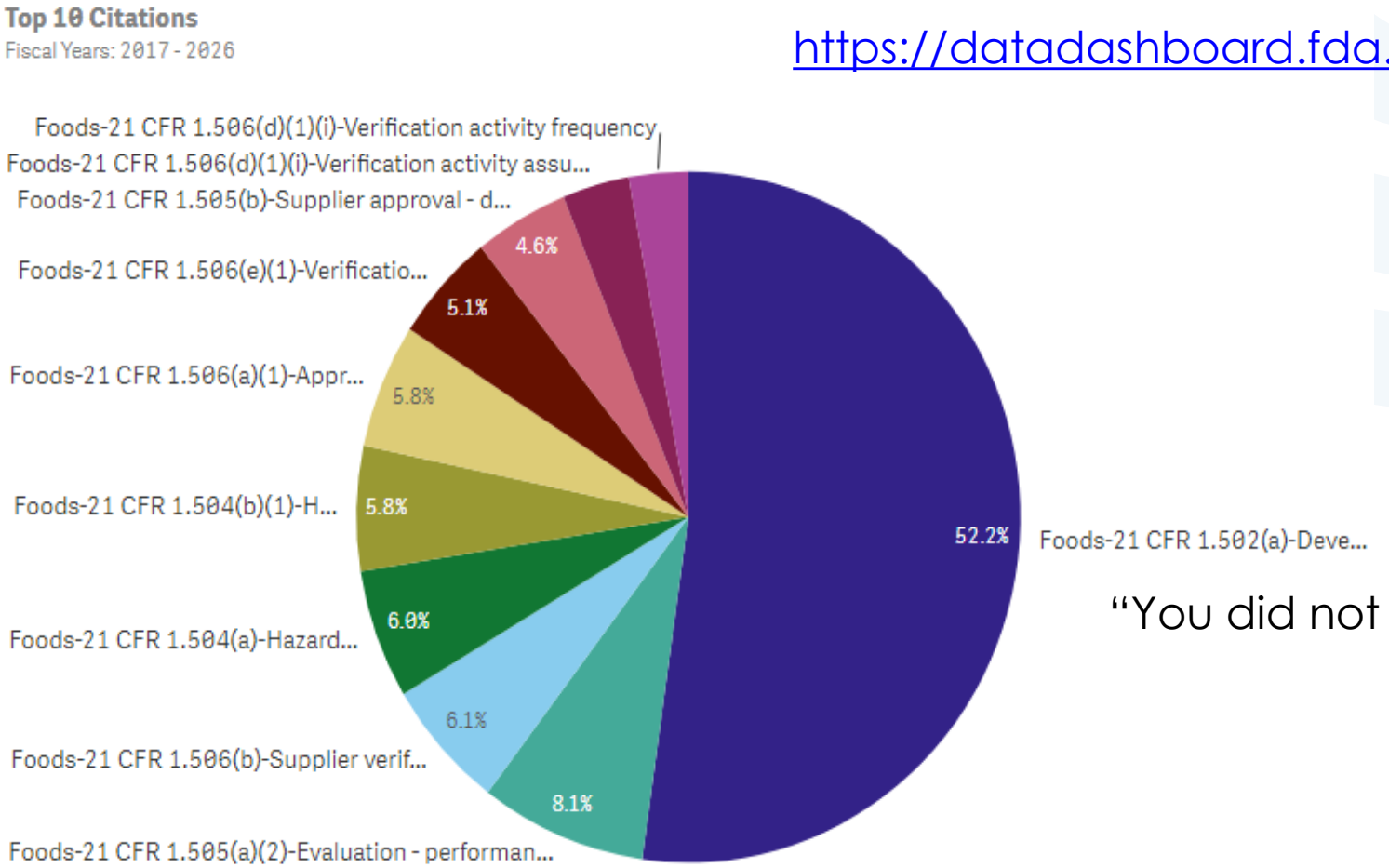
- Importer
- Qualified Individual – develop FSVP and perform each of the required activities
  - Must have the education, training or experience to perform assigned duties
- Qualified auditor – responsible for audits as verification activities
  - Must have technical expertise obtained through education, training, or experience to perform the auditing function

What is not covered?

- Juice
- Seafood
- Meat, poultry and egg products under USDA jurisdiction
- Food imported for research or evaluation
- Food imported for personal consumption
- Alcoholic beverages
- Food transshipped or imported for processing and export

Compliance Insights

FSVP Top 10 Citations



https://datadashboard.fda.gov/oii/index.htm

"You did not develop an FSVP"

Top Citations 2017-2025

1.	52.2%	4300	Develop FSVP
2.	8.1%	677	Evaluation – performance, risk
3.	6.1%	510	Supplier verification – establish written procedures
4.	6.0%	505	Hazard Analysis – written
5.	5.8%	488	Hazard Analysis – biological, chemical, physical
6.	5.8%	488	Approved Supplier Procedures – importer established
7.	5.1%	430	Verification Activity before Import
8.	4.6%	384	Supplier Approval Document
9.	3.3%	272	Verification Activity – assurance
10.	2.9%	242	Verification Activity - frequency

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https://datadashboard.fda.gov/oii/index.htm

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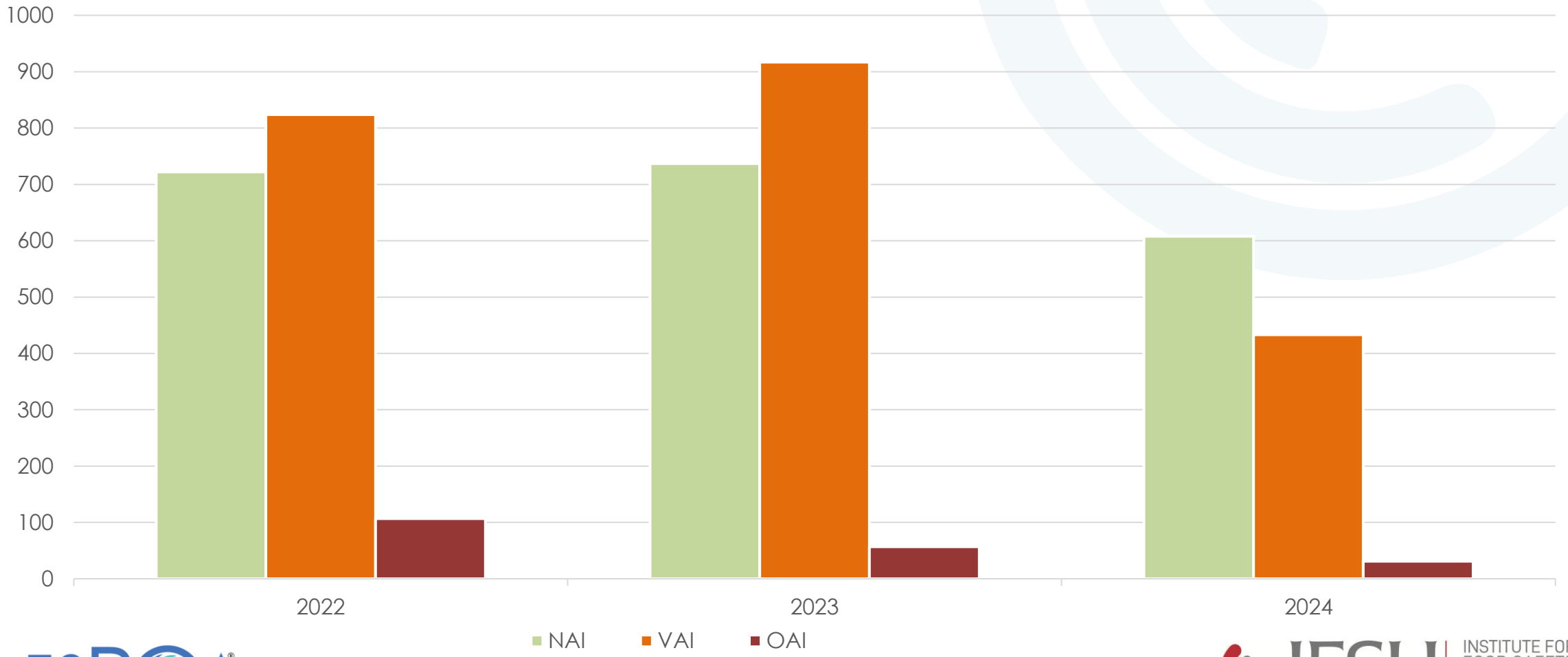
Narratives in compliance reports

- Failure to develop an FSVP: Importers have not created a written Foreign Supplier Verification Program plan, which is a mandatory requirement under the Food Safety Modernization Act (FSMA) for most food imports.
- Inadequate supplier evaluation: Importers are failing to adequately assess the risk and performance of their foreign suppliers based on factors like their compliance history and food safety practices.
- Incomplete hazard analysis: The hazard analysis, which identifies potential biological, chemical, or physical hazards in a food, is often found to be incomplete or not written down.
- Lack of periodic verification activities: Importers are not performing or documenting regular verification activities, such as audits, record reviews, or testing, to ensure their suppliers remain compliant.
- Failure to establish written procedures: Importers have not created and followed written procedures for supplier verification activities.
- Failure to identify FSVP importer at customs entry: Importers are not correctly identifying themselves as the FSVP importer when food enters the U.S..

Common Violations

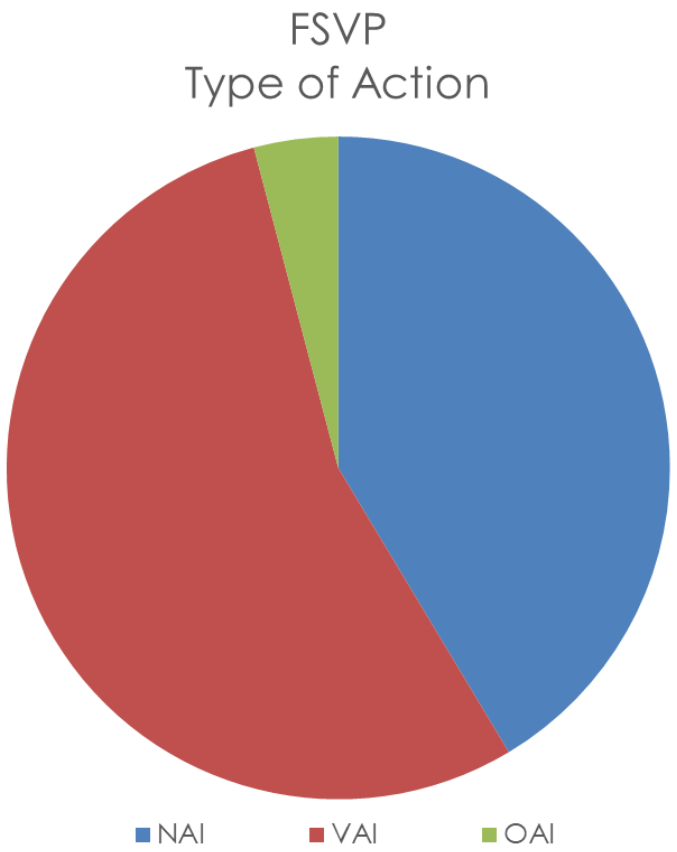
- "You did not develop an FSVP"
- "Your hazard analysis did not identify a hazard that requires a control"
- "You did not document that you conducted an evaluation or reviewed and assessed an evaluation conducted by another entity to determine a foreign supplier's performance and the risk posed by a food"

FSVP Inspection Classification



Data from FDA-TRACK

FSVP Inspection Classifications

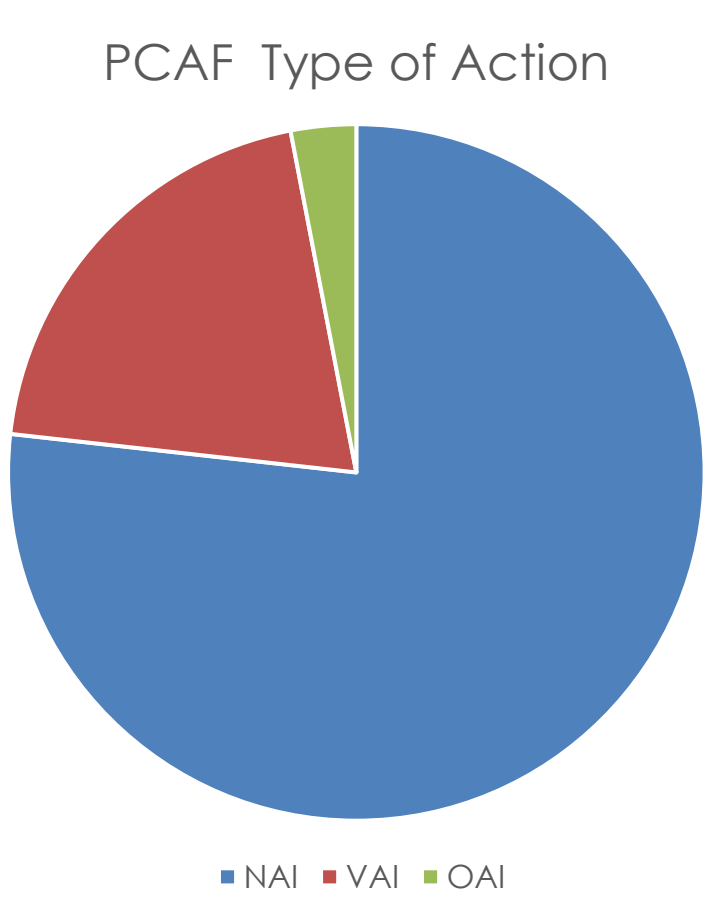


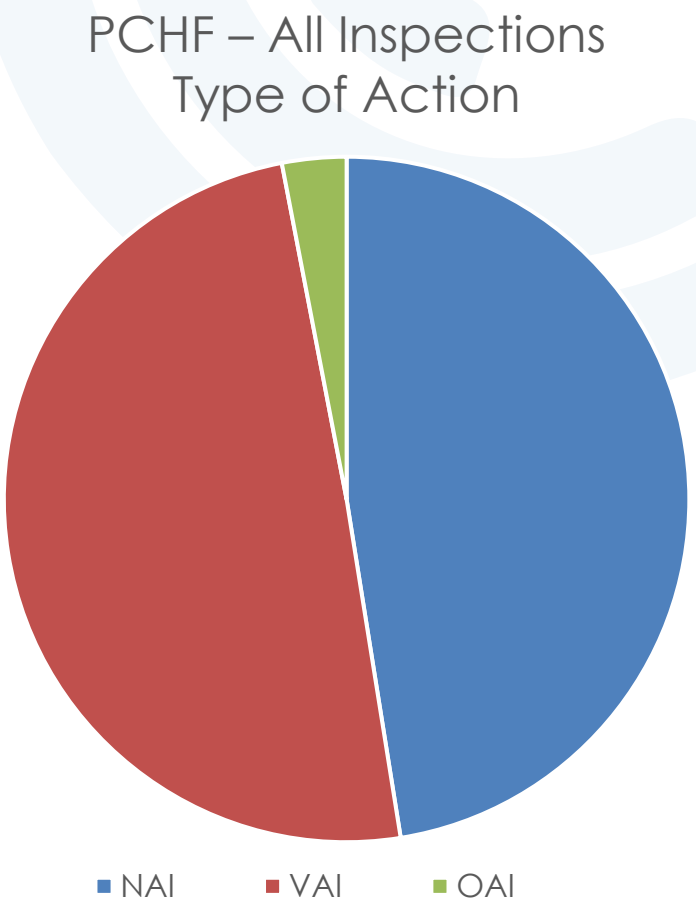
NAI 41.4%

VAI 54.5%

OAI 4.1%

Noncompliance Rates





Training Opportunities and Best Practices

Importance of Training

Best Option – FSPCA

- FSVP Instructors: Form #33 from Instructor Portal Especially Useful

Obvious Candidates – Importers

Not-As-Obvious – Foreign Suppliers, Customs Brokers

Other "Training" Options

- FDA Updates at Industry Events
- FDA Data Dashboard
- Associations

Best Practices for FSVP

Communication

- With ALL Partners in Supply Chain – Early and Often!
  - Docs with Each?

Standard Operating Procedure Document

- Brief Description of Regulation
- Outline of Firm's Program
- Specific Details on Items Such As:
  - What Records are Needed & Where They Are
  - Who Has Access to the Records
  - Who Interacts with FDA
  - Use of Approved Foreign Suppliers

Best Practices for FSVP

FDA RESOURCES

Import Alert Subscription

Warning Letter Subscription

FDA Data Dashboard

Inspections Database

REGIONAL FSMA CENTERS

PANELIST
ALEXIS HAMILTON
VIRGINIA TECH

PANELIST
ANNIE FITZGERALD
NORTHEAST CENTER TO ADVANCE FOOD SAFETY (NECAFS)

PANELIST
QINGYANG WANG
OREGON STATE UNIVERSITY

MODERATOR
JERRY WOJTALA
INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE (IFPTI)

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KING MONGKUT'S INSTITUTE OF TECHNOLOGY LADKRABANG

PANELIST

KYOTA MURAI

GLOVALUTION LLC

PANELIST

ADRIANA CAMACHO

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Lightning Rounds: Food Safety in a Flash

FSPCA Annual Conference
November 19, 2025

BREAKOUT SESSION:
NEW FSPCA FOOD SAFETY PLAN TEACHING EXAMPLES

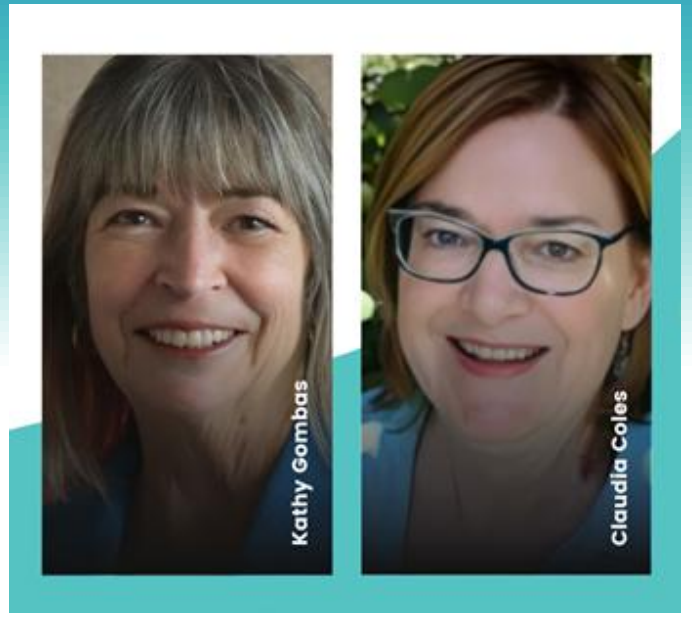
PRESENTER
CLAUDIA COLES
SEAFOOD PRODUCTS ASSOCIATION (SPA)

PRESENTER
KATHY GOMBAS
FSMA SOLUTIONS

MODERATOR
JERRY WOJTALA
INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE (IFPTI)

New FSPCA Food Safety Plan Teaching Examples

November 19, 2025



FSPCA PCHF V2.0
Food Safety Plan Teaching Examples

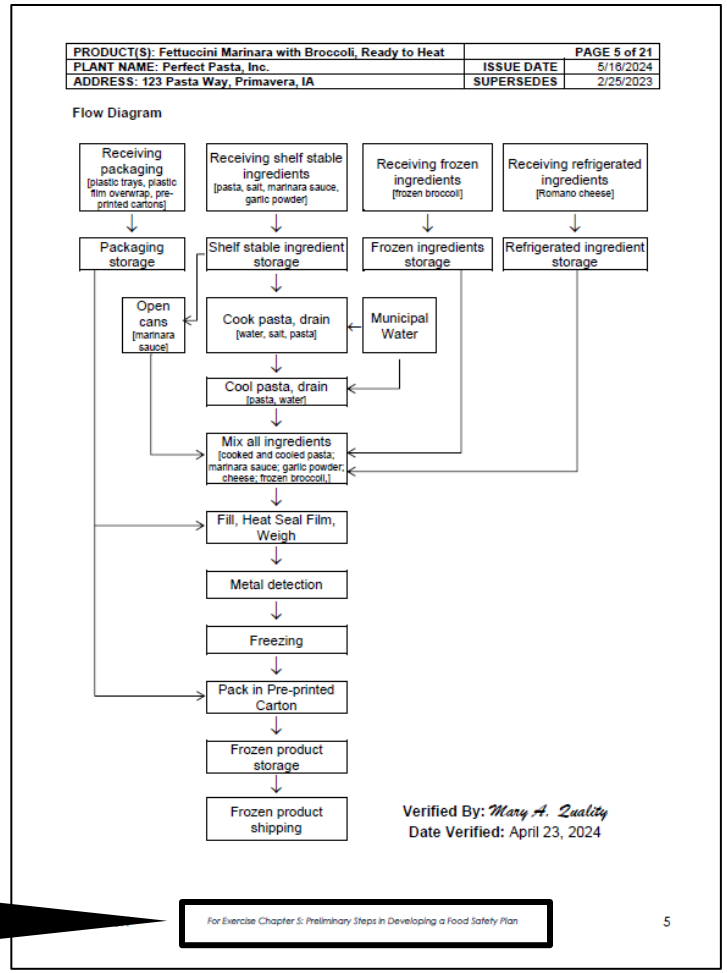
- **Objective:** Support learning by providing the opportunity to practice **developing a Food Safety Plan** for a model food

- Lead Instructor **use with the Exercise Workbook** for V2.0 PCHF Participant Course Exercises
  - **Exercises in chapters 5, 7, 10, 11, 12, and 13**

- **Divide in groups** – 2 to 5 participants
  - use one or more FSPCA Teaching Examples depending on course audience

FSPCA PCHF V2.0
Food Safety Plan Teaching Examples

- **Use during the exercises in chapters 5, 7, 10, 11, 12, & 13**
  - Teaching examples **footer** designates which pages should be used for each of the chapter exercises



For Exercise Chapter 5: Preliminary Steps in Developing a Food Safety Plan

FSPCA PCHF V2.0
Food Safety Plan Teaching Examples

- **AVAILABLE NOW**
  - Fettuccini Marinara with Broccoli
  - Peanut Butter
  - Black Pepper

- **FDA REVIEWED**
  - Cold Pressed Energy Bars

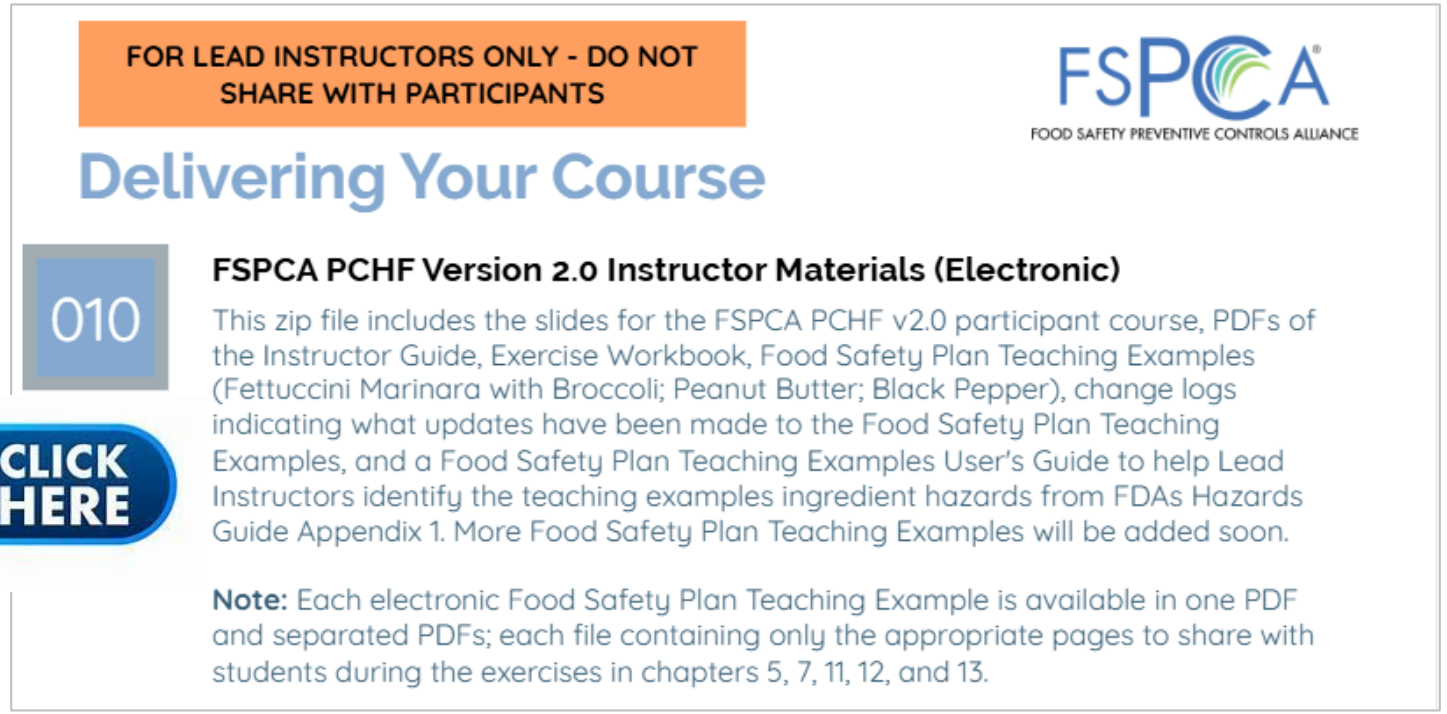
- **SUBMIT TO FDA**
  - Pepper Jack Cheese
  - Broccoli, Carrot, Pecan Salad

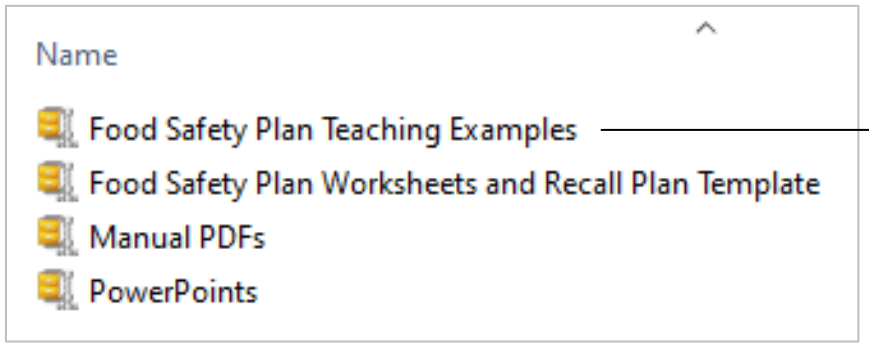
Obtaining PCHF V2.0 Course Materials – Options

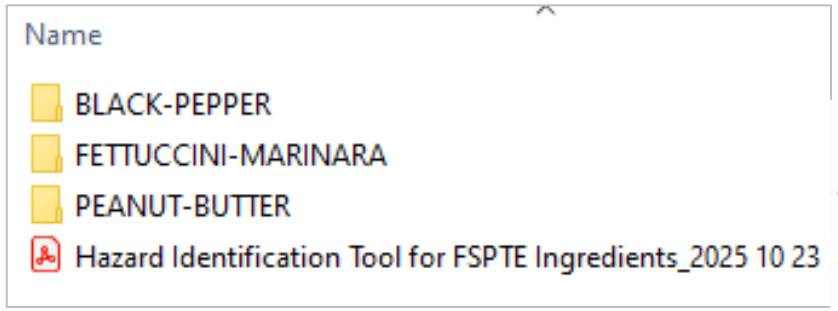
MATERIALS	LEAD INSTRUCTORS	PARTICIPANTS
Exercise Workbook: $10.00 USD	• **Download** an electronic copy from the FSPCA Instructor Resource Portal • **Purchase** hardcopies from the FSPCA Lead Instructor Bookstore or Amazon	• **Purchase** a hardcopy from the FSPCA Public Bookstore or Amazon • Electronic copy provided by the Lead Instructor
Teaching Examples: $30.00 USD (for 5 Participants)	• **Download** electronic copies from the FSPCA Instructor Resource Portal • **Purchase** hardcopies from the FSPCA Lead Instructor Bookstore **(NOW AVAILABLE)**	• **NOT available for purchase or download** • Can only be supplied by the Lead Instructor

FSPCA PCHF V2.0
Food Safety Plan Teaching Examples

- **Electronic** copies are available in the FSPCA Instructor Resource Portal





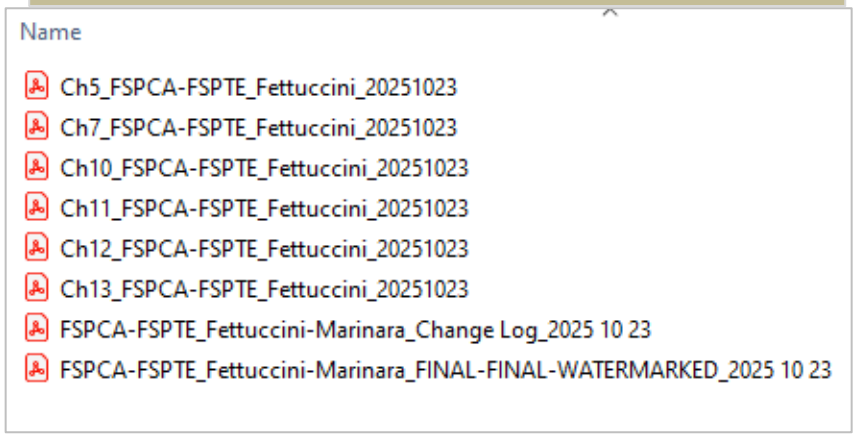


FSPCA PCHF V2.0
Food Safety Plan Teaching Examples

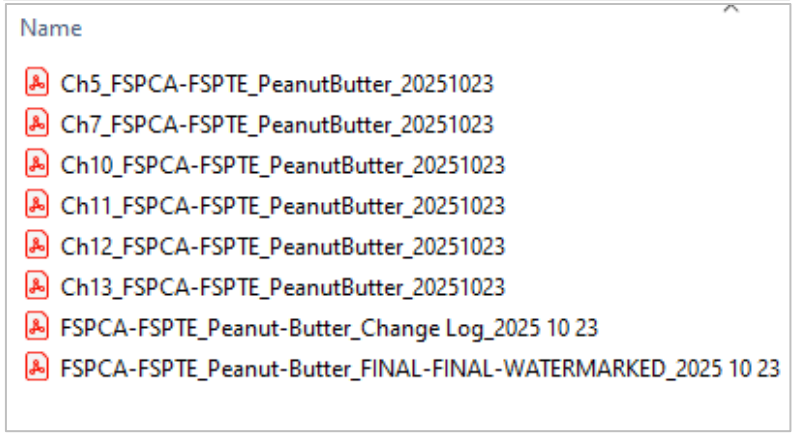
Teaching Examples were REVISED on October 23, 2025 – download the current version!

- Each electronic Food Safety Plan Teaching Example is separated in several files;
- Each file contains only the appropriate pages to share with students during the exercises in chapters 5, 7, 10, 11, 12, and 13;
- Files includes the full Teaching Example (PDF);
- Revision Change Log

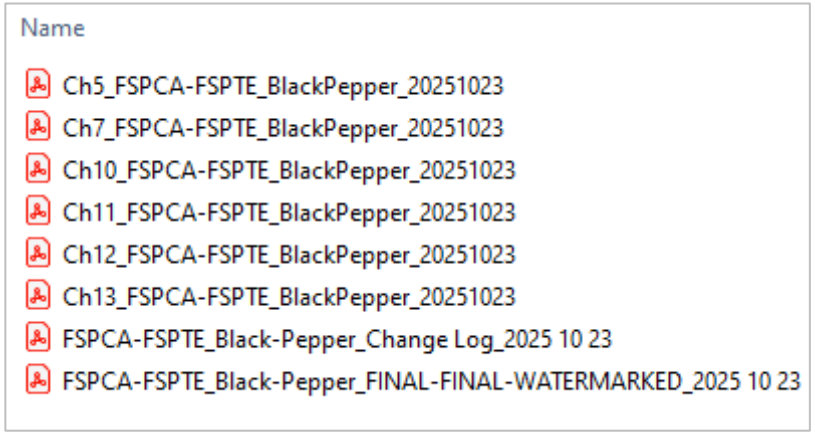
Fettuccini Marinara with Broccoli Zip File Contents



Peanut Butter Zip File Contents



Peanut Butter Zip File Contents

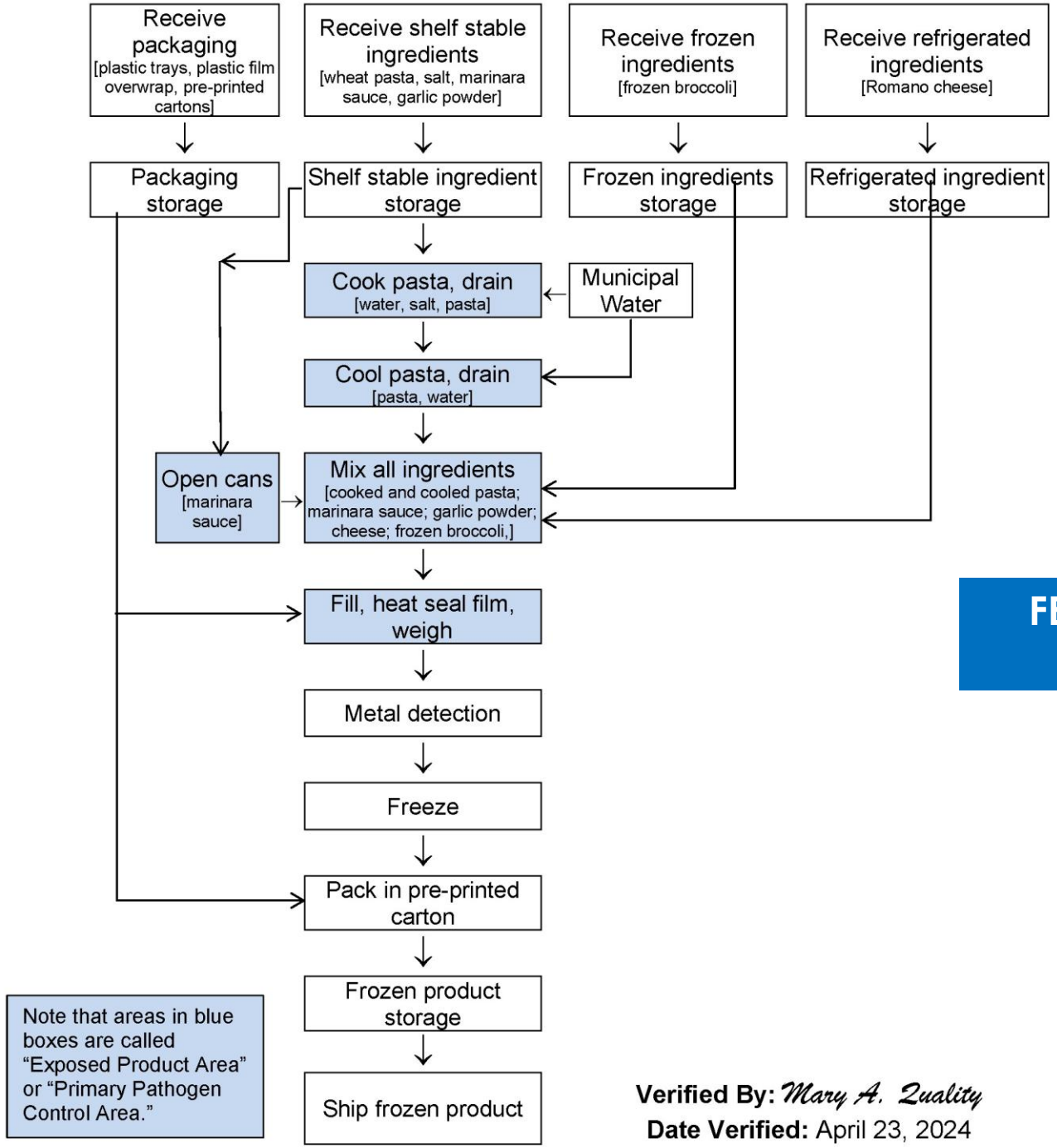


REVISIONS
Food Safety Plan Teaching Examples

- Revised October 2025 – download version dated 10.23.2025

Change log available in the HF Lead Instructor Portal

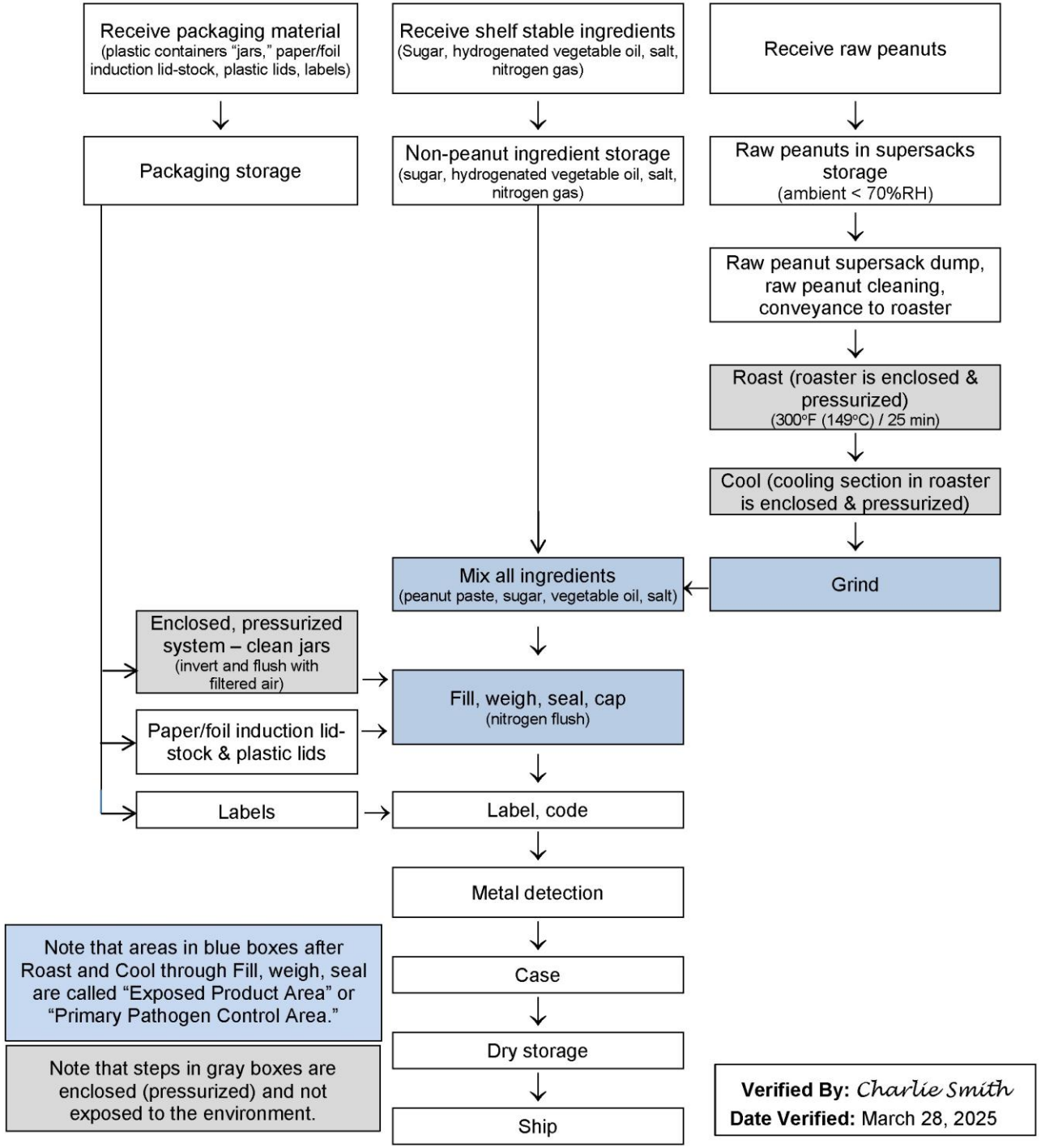
	Fettuccini Marinara	Peanut Butter	Black Pepper
Company Overview	clarified "wheat" pasta		
Flow Diagrams:			
– highlighted **"Exposed Product Area"** or **"Primary Pathogen Control Area"**	X	X	X
- changed process steps to **nouns** ("receiving" to "receive"; freezing to freeze)	X	X	X



FETTUCCINI MARINARA WITH BROCCOLI

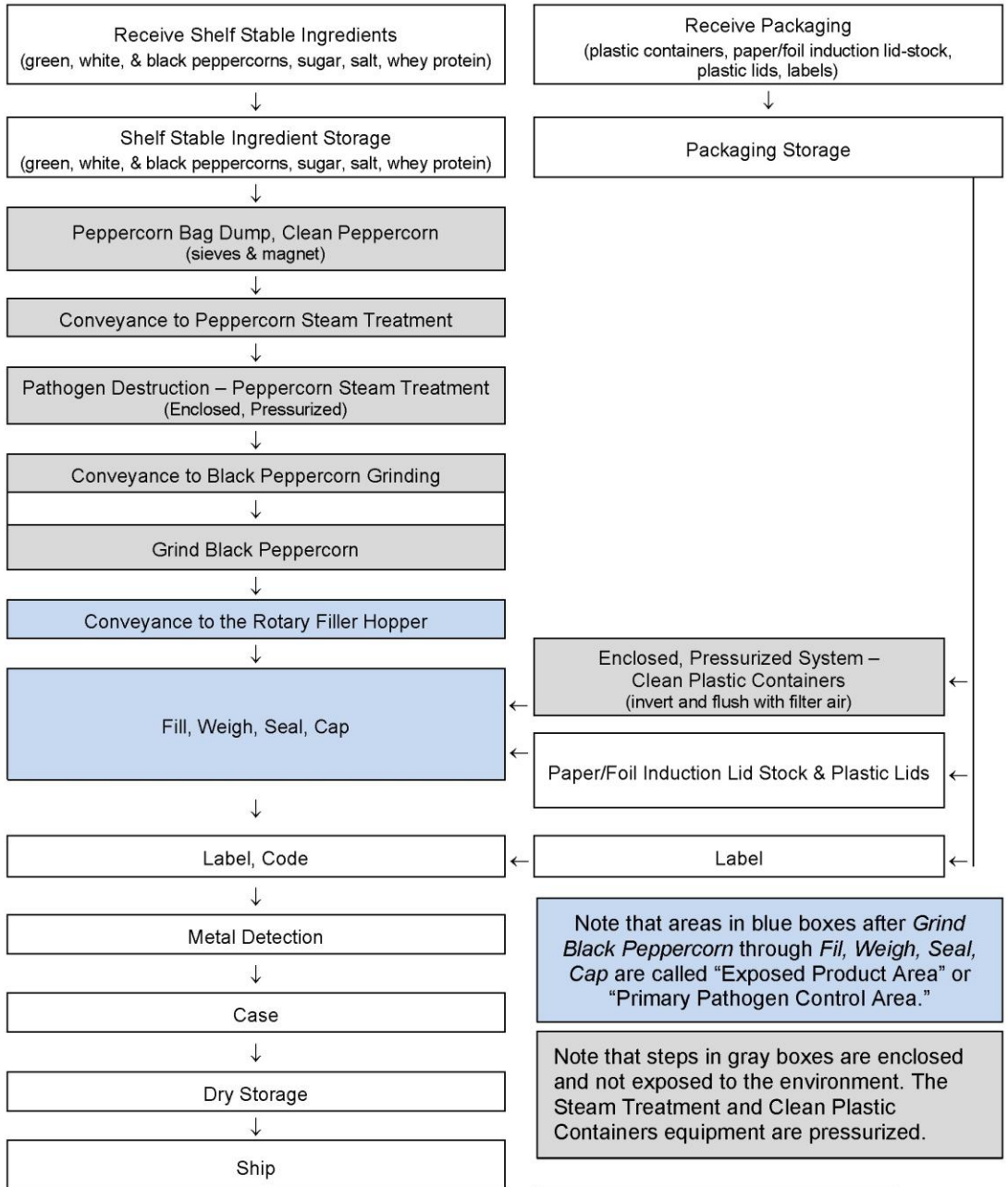
Verified By: *Mary A. Quality*
Date Verified: April 23, 2024

PEANUT BUTTER



Verified By: *Charlie Smith*
Date Verified: March 28, 2025

BLACK PEPPER



Note that areas in blue boxes after *Grind Black Peppercorn* through *Fil, Weigh, Seal, Cap* are called "Exposed Product Area" or "Primary Pathogen Control Area."

Note that steps in gray boxes are enclosed and not exposed to the environment. The Steam Treatment and Clean Plastic Containers equipment are pressurized.

Verified By: Lynn Cumin
Date Verified: April 7, 2025

REVISIONS
Food Safety Plan Teaching Examples

- Revised October 2025 – download version dated 10.23.2025

	Fettuccini Marinara	Peanut Butter	Black Pepper
Process Description	**Salt:** added *"Supplier only processes salt (no food allergens). No glass or hard plastic is used in the supplier's manufacturing or packaging processes."*	**Raw peanut supersack dump, raw peanut cleaning, conveyance to roaster step**: added "Raw peanuts are conveyed from the supersack dump station through the wall directly into the enclosed, pressurized roaster"	**Label, code** step: added "Immediately after the capping, the filled plastic containers are conveyed through an opening in the wall to the label area"
	Garlic powder: revised to say *"Supplier dries and grinds* ***raw*** *garlic…"*	**Label, code** step: added "Immediately after the capping, the jars are conveyed through an opening in the wall to the label area."	

REVISIONS
Food Safety Plan Teaching Examples

- Revised October 2025 – download version dated 10.23.2025

	Fettuccini Marinara	Peanut Butter	Black Pepper
Process Description	• Moved "Open cans [Marinara sauce]" step before "Mix all ingredients" • Designated cans are opened in "mixing area"		
	• Designated cook pasta is in "kettle room"		
	• Designated cooled pasta bins are stainless steel and wheeled into "mixing area"		
	• At "Fill, Heat Seal Film, Weigh" step, designated sealed trays are conveyed to the metal detector (in same room)		
	• At "Freeze" step, stated freezer tunnel is enclosed		

FETTUCCINI MARINARA WITH BROCCOLI - INGREDIENTS

Need to understand supplier's process & facility related hazards

WHEAT PASTA

PASTA SUPPLIER

- Flour sourced from grain grown in US
- Flour supplier's grain supplier monitors for mycotoxin – data below regulatory limits for 5 years.
- Pasta extruded & cut prior to drying.
- Packed in 50 lb. paper bags with plastic liners.
- Only handles wheat allergen.
- No glass or hard plastic used.

SALT

SALT SUPPLIER

- Food grade salt.
- Packed in 10 lb. paper bags with plastic liners.
- Only processes salt - no allergens
- No glass or hard plastic used.

MARINARA SAUCE

MARINARA SUPPLIER

- Shelf-stable, thermally processed (pH 4.6).
- FDA acidified food filed process.
- Packed in 10# cans.
- Source tomatoes from US growers who control pesticides.
- Tomatoes pureed & mixed with other ingredients in ribbon blender.
- No allergens handled in facility.
- No glass or hard plastic used.

ROMANO CHEESE SHREDDED, REFRIGERATED

CHEESE SUPPLIER

- Uses Grade A milk in compliance with PMO pasteurization & drug residue requirements.
- Cheese contains lactic starter culture, rennet, salt, and anti-caking agent powdered cellulose.
- Cheese aged 5 months then shredded (exposed to environment).
- Packaged in 20 lb. oxygen permeable plastic bags.
- Cheese pH 5.3, Aw 0.92 – does not require refrigeration.
- Only milk used in facility.
- No glass or hard plastic.

FROZEN BROCCOLI

FROZEN BROCCOLI SUPPLIER

- Sources broccoli from US growers in compliance with FDA's Produce Safety Rule – supplier obtains annual audit to verify compliance with rule.
- Broccoli florets are cut into pieces.
- Broccoli is blanched & individually quick frozen.
- Packed into 40 lb. corrugated cases lined with plastic.
- No allergens handled
- No glass or hard plastic used.

GARLIC POWDER

GARLIC POWDER SUPPLIER

- Sources raw garlic from US supplier who sources garlic from US grower & verifies proper use of pesticides.
- Dries & grinds raw garlic into powder Aw 0.52.
- Fill into 25 lb. paper bags with plastic liners.
- Powder in paper bags are irradiated by commercial sterilizer using validated process.
- No allergens used at supplier.
- No glass or hard plastic used.

PEANUT BUTTER- INGREDIENTS

Need to understand supplier's process & facility related hazards

RAW, SHELLED PEANUTS

SALT

SUGAR

HYDROGENATED VEGETABLE OIL (CANOLA & SOYBEAN)

NITROGEN (PROCESSING AID)

PEANUT SUPPLIER

- Nuts sourced from 2 US grower/sheller locations.
- Supplier use sorting process for extraneous removal.
- Nuts packed in 2,000 lb. super sacks.
- Suppliers monitor for aflatoxin quarterly – submit COAs (<20 PPB).
- Only handles peanuts
- No glass or hard plastic used.

SALT SUPPLIER

- Food grade salt.
- Packed in 10 lb. paper bags with plastic liners.
- Only processes salt - no allergens.
- No glass or hard plastic used.

SUGAR SUPPLIER

- Packed in 50 lb. paper bags with plastic liners.
- No allergens handled in facility.
- No glass or hard plastic used.
- Grinding with metal-on-metal contact occurs in the sugar refining process.

OIL SUPPLIER

- Filled in 5-gal plastic jugs
- Crush seeds and use solvent extract.
- Oils are highly refined.
- Process is fully enclosed.
- No allergens handled in facility.
- No glass or hard plastic used.
- There is no metal-to-metal contact in the supplier's process.

NITROGEN SUPPLIER

- Filled in cylinders.
- Food grade Nitrogen gas – receive COA each shipment.

BLACK PEPPER- INGREDIENTS

Need to understand supplier's process & facility related hazards

UNTREATED BLACK PEPPERCORNS

PEPPERCORN SUPPLIER

- Peppercorns are sourced from a **grower in Vietnam**, ABC Pepper Farms, and imported into the US via a U.S. distributor (Spice4U Co., Port, USA) which maintains a Foreign Supplier Verification Program.
- Peppercorns are not treated and label on the product states ***"Not treated to control for pathogens"*.**
- Untreated black peppercorns are filled in 50 lb. bags with plastic liners.
- Supplier uses sorting process to remove extraneous material.
- ABC Pepper Farms follows Good Agricultural Practices and applies only approved pesticides.
- Monthly pesticide screening on peppercorns is conducted by the supplier and submits COAs.
- ABC Pepper Farms only grows green, white, and black peppercorns.
- No glass or hard plastic.

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

REVISIONS
Food Safety Plan Teaching Examples

- Revised October 2025 – download version dated 10.23.2025

	Fettuccini Marinara	Peanut Butter	Black Pepper
Hazard Analysis – Revised column 5 to say *"Supply-chain Preventive Control* ~~***at receiving step***~~*"*	X	X	X
	• Deleted "Allergen Cross-contact" as <u>potential</u> hazard for wheat pasta and Romano cheese		For Receiving Black Peppercorns, <u>corrected</u> potential hazard as "none" vs "metal"
	• Added **Lead** as potential chemical hazard for Garlic Powder per FDA Hazard Guide Appendix 1. Marked "no" in column 3 and in column 4 state *"Garlic powder is not a food intended for babies and young children"*		
	• **Metal detection step**: revised column 4 to say: Metal may be introduced from the ribbon blender **(at mix all ingredients step), and from incoming wheat pasta, Marinara sauce, garlic powder, Romano cheese,** and IQF broccoli.		

REVISIONS
Food Safety Plan Teaching Examples

- Revised October 2025 – download version dated 10.23.2025

	Fettuccini Marinara	Peanut Butter	Black Pepper
Process Preventive Controls – Metal detection:			
- Corrected Monitoring Table Header for "How" (typo- said frequency and "Frequency (typo- said how)	X		
- Changed monitoring frequency to **"Continuous"** instead of **"Each rejection"**	X	X	X
Allergen Assessments - Allergens listed in top column are now in Alphabetical order.	X	X	X

REVISIONS
Food Safety Plan Teaching Examples

- Revised October 2025 – download version dated 10.23.2025

	Fettuccini Marinara	Peanut Butter	Black Pepper
Sanitation Preventive Controls #1: • Revised Procedure to say ABC **"detergent"** (not "cleaning solution") mixed with **"potable"** water	X	X	
• Revised Monitoring and Corrections to add ABC detergent (only listed sanitizer)	X	X	
• Revised Corrective Action to include 2) Determine root cause and 4) retrain or correct as appropriate	X		

REVISIONS
Food Safety Plan Teaching Examples

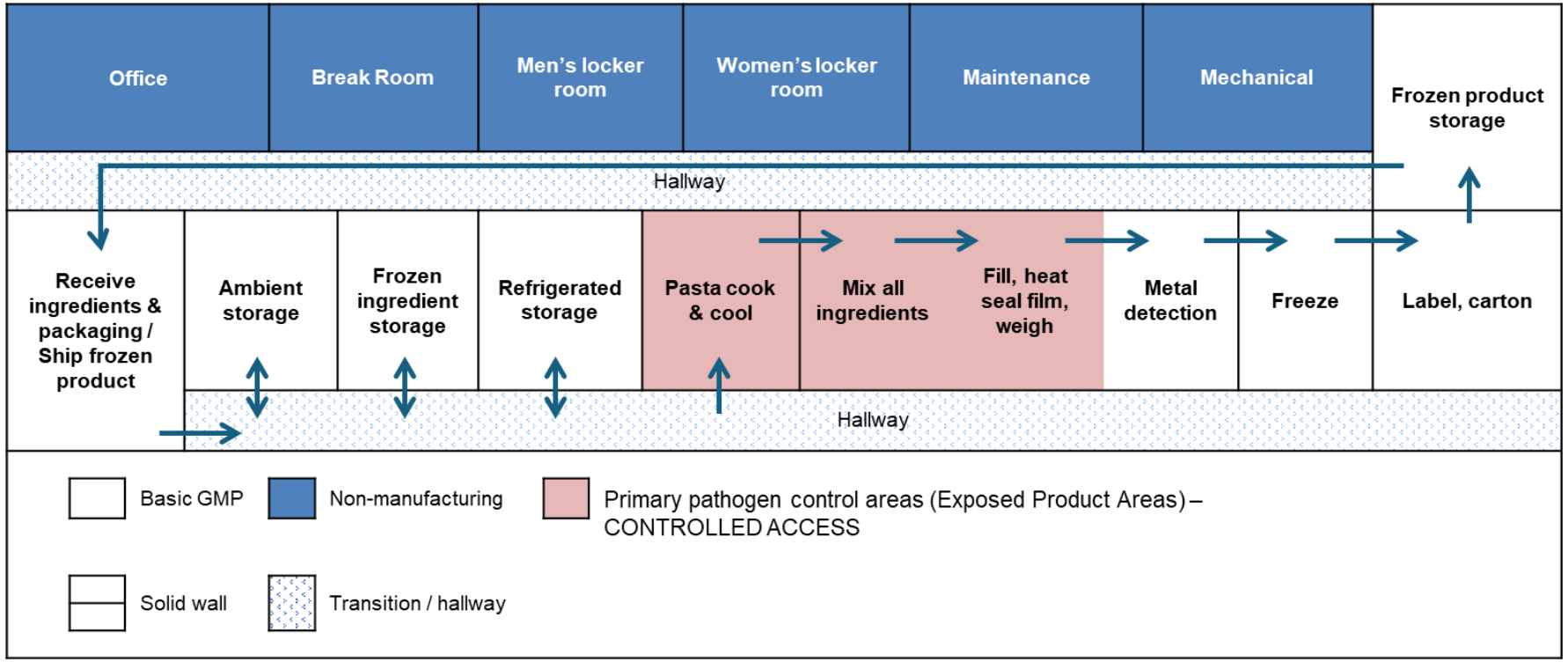
- Revised October 2025 – download version dated 10.23.2025

	Fettuccini Marinara	Peanut Butter	Black Pepper
Sanitation Preventive Control #2: - Added environmental pathogen of concern to Objective		X	
- Revised Verification to say …Hygienic Zoning Sanitation Preventive Control #3	X	X	X
- Revised Monitoring and Corrections to include ABC detergent.	X		
- Monitoring revised to say at each cleaning/sanitizing time.	X		
Sanitation Preventive Control #3: Revised frequency to say "During production and sanitation".	X	X	X

Plant Diagrams – Sanitation PC #3

FETTUCCINI MARINARA WITH BROCCOLI

Sanitation Preventive Control #3 Hygienic Zoning (Kettle, Mixer, & Filler)



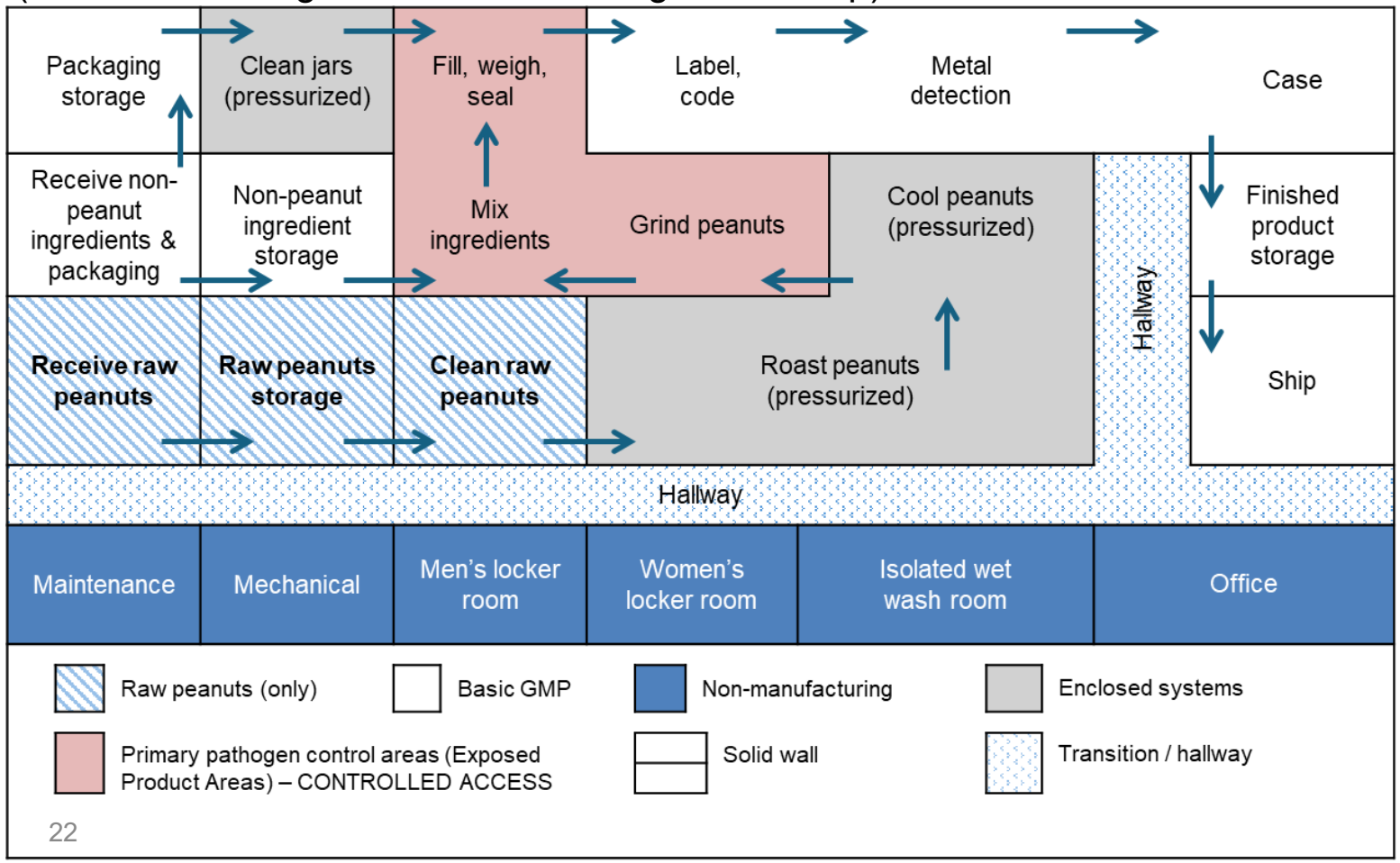
Plant Diagram revised:

1) to say "Receive ingredients & packaging / Ship frozen product" and changed to white Basic GMP area (versus Transition);
2) Added a legend for "Solid Wall";
3) Removed wall lines between "Mix All Ingredients; Fill, Heat Seal Film Weigh; and Metal Detection";
4) Extended arrow from Frozen Storage to "Receive ingredients & packaging / Ship frozen product".

Plant Diagrams – Sanitation PC #3

PEANUT BUTTER

Sanitation Preventive Control #3 Hygienic Zoning: Exposed Product Areas (Grind; Mix all Ingredients; & Fill, Weigh, Seal Cap)



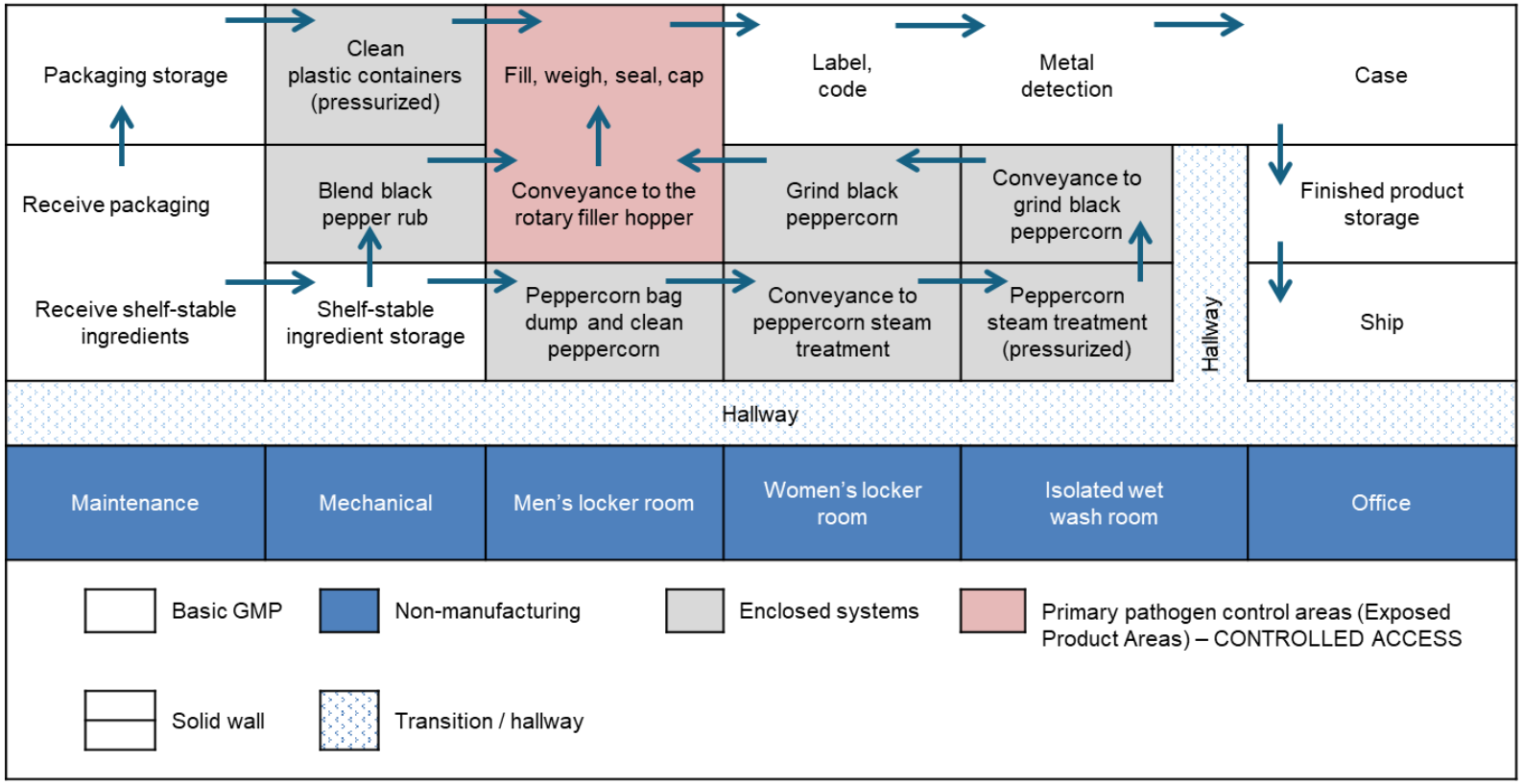
Plant Diagram revised:

1) Changed legend to say "Non-manufacturing" (vs "Non-GMP area)
2) Changed legend to say "Raw peanuts (only)"
3) Added legend for "Transition"
4) Revised gray legend to say "Enclosed systems" AND noted equipment that is "pressurized"
5) Added arrows from "Receive non-peanut ingredients & packaging" going to "Packaging storage" and "Non-peanut ingredient storage"
6) Added solid wall BETWEEN:
   - "Fill, weigh, seal" AND "Label, code;
   - "Clean jars" AND ""Fill, weigh, seal";
   - "Cool peanuts" AND "Grind"

Plant Diagrams – Sanitation PC #3

BLACK PEPPER

Sanitation Preventive Control #3 Hygienic Zoning: Exposed Product Areas (Conveyance to Rotary Filler Hopper and Fill, Weigh, Seal, Cap)



Plant Diagram revised:

1) Changed legend to say "Non-manufacturing" (vs "Non-GMP area)
2) Remove line between Receiving Packaging and Receiving shelf-stable ingredients
3) Remove wall line between Conveyance to the Rotary Filler Hopper and Fill, weigh, seal, cap
4) Added solid wall end of Hallway (next room with metal detector)

REVISIONS
Food Safety Plan Teaching Examples

- Revised October 2025 – download version dated 10.23.2025

	Fettuccini Marinara	Peanut Butter	Black Pepper
Receiving Procedure for Ingredients Requiring a Supply-chain PC	Revised procedure to include: *"If the product is not from an approved supplier, reject the shipment at time of receipt."*		

Tips for using the V2.0 Human Food Food Safety Plan Teaching Example

REMINDER:
View the April 22, 2025 LI Webinar
How to use the Fettuccini Teaching Example

FUTURE WEBINARS IN 2026
How to use the other Teaching Examples

Chapter 5 – Preliminary Steps Exercise

1. The Instructor will provide the **Preliminary Steps section of the Food Safety Plan Teaching Example** assigned to each group.
   a. Preliminary Steps include product description, flow diagram, and process narrative.

2. **Individually or as a group**, read the product description, the flow diagram, and the process narrative.

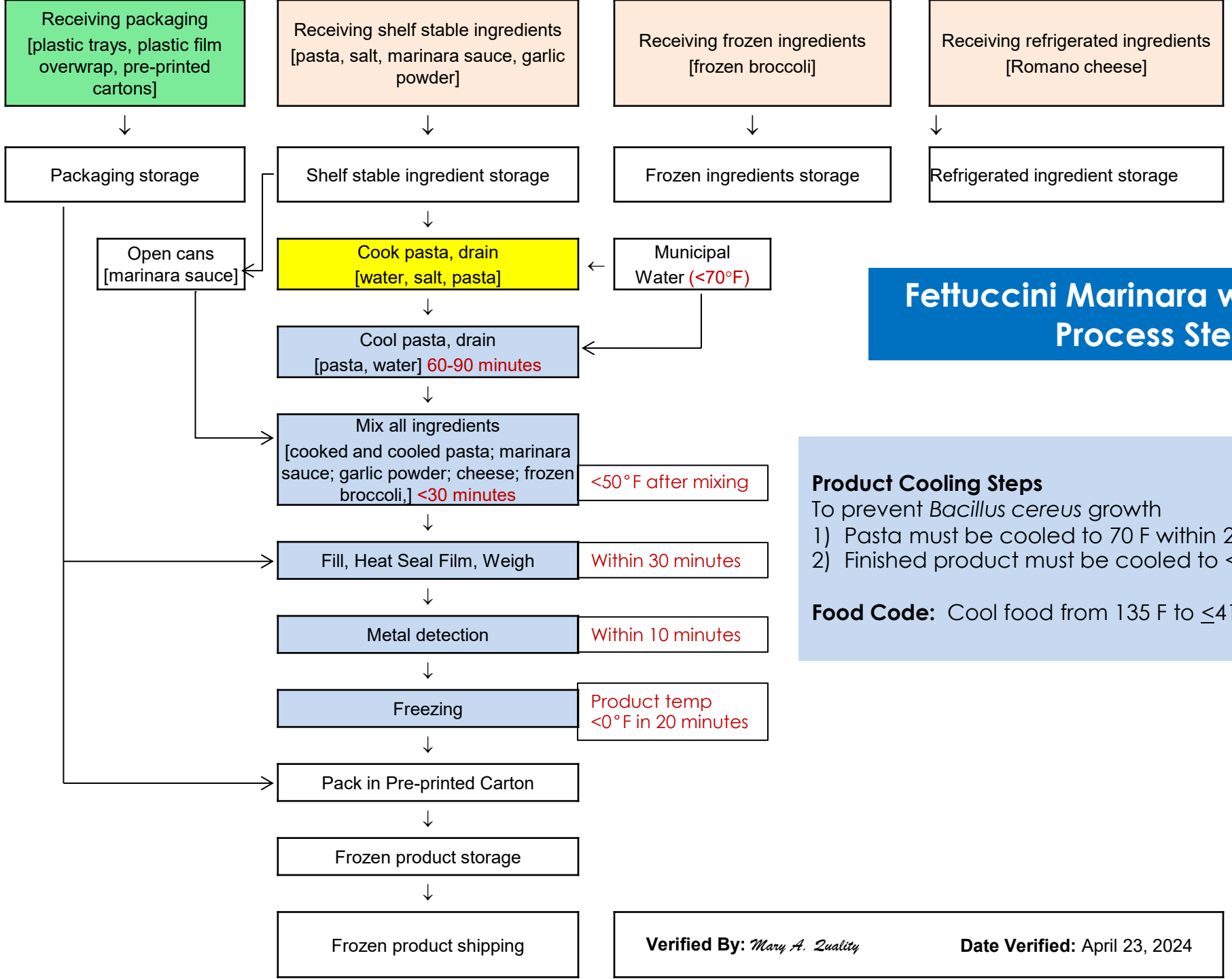
3. **As a group**, discuss and respond to the following questions:
   a. What are the key details or unique aspects of the product description?
   b. Would you choose to group or separate products in the Food Safety Plan?
   c. Is there anything in the Food Safety Plan product description, flow diagram, and process narrative that doesn't make sense to you or that you have questions about?

4. Groups are to pick a spokesperson to summarize the group's discussion and responses to the class.

Fettuccini Marinara with Broccoli Process Steps

Product Contact Packaging (food grade materials)
Plastic trays received in bulk. Clear oxygen permeable plastic film overwrap received in bulk. Pre-printed cartons are received in bulk and are reviewed for conformance with product allergen requirements and ingredients.

Cook pasta is an exceptionally lethal process. Validation data demonstrated that for pasta temperatures achieved during cooking process to achieve a palatable texture far exceed those needed to destroy vegetative pathogens.



Product Cooling Steps
To prevent *Bacillus cereus* growth
1) Pasta must be cooled to 70 F within 2 hours
2) Finished product must be cooled to <41°F within 4 hours

Food Code: Cool food from 135 F to ≤41°F in 6 hours

Verified By: *Mary A. Quality* **Date Verified:** April 23, 2024

Chapter 7 Hazard Analysis Exercise – **Part 1**

Using your Food Safety Plan Teaching Example from the Preliminary Steps Exercise and the FDA Hazard Guide:

1. In your group, complete the hazard analysis form in the Exercise Workbook (Columns 1 – 4)
2. For "a." identify potential hazards **for two ingredients**, and for "b." identify potential hazards **for three process steps** (complete Columns 1 and 2)
   a. **Ingredients inherent hazards AND Supplier's process- and facility-related hazards**

   b. **Food Safety Plan Teaching Example manufacturing facility's process- and facility-related hazards**

3. Evaluate potential hazards to determine hazards requiring a preventive control (complete Columns 3 and 4)

Chapter 7 Preventive Controls Exercise – **Part 2**

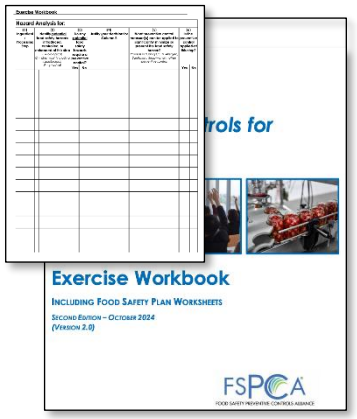
1. In your group, continue conducting a hazard analysis **using the assigned Food Safety Plan Teaching Example.**
2. Record on the Hazard Analysis Form (pages 7-9):
   a. If Column 3 was marked "yes", identify the preventive control (in Column 5) (e.g., process, allergen, sanitation, supply-chain, or other).
   b. In Column 6, designate if a preventive control will be applied at this process step (yes/no).
3. Respond to the following questions:
   - What hazard, ingredient, or process step posed the greatest challenge and why?
   - How did your hazard analysis compare to the FSPCA's Food Safety Plan Teaching Example?
4. Pick a spokesperson to summarize the group's response to the questions to the rest of the class.

Chapter 7 Exercise - Materials

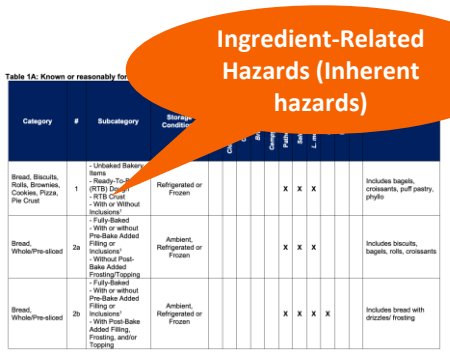
- Download the following exercise materials from chat box <u>if needed</u>:

Fettuccini Marinara
Model Plan Preliminary Steps ONLY

Exercise Workbook
(Page 7- 10)



FDA Hazard Guide
Appendix 1 Tables



FSPCA Form 0231 - Common Process-Related & Facility Related Hazards

Other useful resources:

- FDA Hazard Guide – Chapter 2
- FDA Hazard Guide – Chapter 3
- FDA Hazard Guide – Appendix 1 Narrative

GROUP EXERCISE ≈ 90 minutes
Hazard Analysis and PC Determination

Instructions

After Ch 7 - Complete Hazard Analysis.

Resources:

1. Page 7 - 10 Exercise Workbook
2. FDA's Hazard Guide Appendix 1 Tables
3. FSPCA Form 0231 – Common Process-Related & Facility Related Hazards
4. Model Plan

(group member names) *Group 1*	(group member names) *Group 2*	(group member names) *Group 3*
1. Wheat Pasta (shelf-stable) 2. Salt (shelf-stable) 3. Receive packaging 4. Cook pasta in water, drain 5. Cool pasta, drain	1. Marinara Sauce #10 can 2. Refrigerated Romano Cheese [shredded] 3. Refrigerated ingredient storage [Romano Cheese] 4. Open cans [Marinara sauce] 5. Fill, heat seal film, weigh	1. Garlic powder 2. Individually Quick Frozen (IQF) broccoli 3. Frozen ingredient storage [IQF broccoli] 4. Mix all ingredients 5. Metal detection

Chapter 7 Exercise TAKE-UP

- Once you complete your hazard analysis form for your assigned steps, answer:
  1. What hazard, ingredient, or process step posed the greatest challenge and why?
  2. How did your hazard analysis compare to the FSPCA's Food Safety Plan Teaching Example?
- Pick a spokesperson to summarize the group's response to the questions to the rest of the class.

(group member names) ***Group 1***	**(group member names)** ***Group 2***	**(group member names)** ***Group 3***
1. Wheat Pasta (shelf-stable) 2. Salt (shelf-stable) 3. Receive packaging 4. Cook pasta in water, drain 5. Cool pasta, drain	1. Marinara Sauce #10 can 2. Refrigerated Romano Cheese [shredded] 3. Refrigerated ingredient storage [Romano Cheese] 4. Open cans [Marinara sauce] 5. Fill, heat seal film, weigh	1. Garlic powder 2. Individually Quick Frozen (IQF) broccoli 3. Frozen ingredient storage [IQF broccoli] 4. Mix all ingredients 5. Metal detection

Distribute the FSPCA Fettuccini with Marinara Model Plan with answers to students **AFTER** the students complete the exercise.

Potential Ingredient-related Hazards per FDA Hazard Guide Appendix 1

Available in the HF LI Portal

FETTUCCINI MARINARA WITH BROCCOLI – HAZARD ID TOOL

Ingredient	Potential Biological Hazards (Tables 1)	Potential Chemical Hazards (Tables 2)
Dry Wheat Pasta	***Salmonella*** P. 65 ***B. cereus, Clostridium botulinum, Clostridium perfringens:*** see footnote P. 65 only applicable when food becomes hydrated to an A_w that allows growth. **Table 1J:** Grains, Pulses, Flours, and Starches **Category (4c)**: Grain-based Pasta Products **Subcategory:** Dried Pasta	**Mycotoxins and Pesticides** in wheat used to make flour used in pasta. P. 89. **see footnote[1] for applicable mycotoxins.** **Table 2J:** Grains, Pulses, Flours, and Starches **Category (1):** Grains, Non-Rice **Subcategory:** Whole and milled grains (e.g., flour and bran)
Marinara Sauce (#10 Cans)	***B. cereus, Clostridium botulinum,*** **Pathogenic *E. coli, Salmonella, L. mono*.** P. 59 **Table 1H:** Fruits and Vegetables **Category (4d)**: Processed Vegetables **Subcategory:** Acidified Products	**Pesticides** in tomatoes used to make marinara sauce. P. 87 **Table 2H:** Fruits and Vegetables **Category (All):** Fruits and Vegetables **Subcategory:** Whole RAC or processed
Romano Cheese (shredded)	**Pathogenic *E. coli; Salmonella; L. mono; S. aureus.*** P. 53 **Table 1E:** Dairy **Category (5a)**: Cheese and Cheese Products – Sliced, Shredded, or Grated **Subcategory:** Hard and Extra Hard Cheese	**Drug residues** P. 84 **Table 2E:** Dairy **Category (1-5):** All **Subcategory:** All

Potential Ingredient-related Hazards per FDA Hazard Guide Appendix 1

Available in the HF LI Portal

FETTUCCINI MARINARA WITH BROCCOLI – HAZARD ID TOOL

Ingredient	Potential Biological Hazards (Tables 1)	Potential Chemical Hazards (Tables 2)
Salt	None P. 45 **Table 1C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category (6a)**: Other Chemical Ingredients **Subcategory:** Processing Chemicals	None P. 82 **Table 2C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category:** None for Processing Chemicals only Nutrients
Garlic Powder	***Salmonella.*** P 74. ***B. cereus, Clostridium botulinum, Clostridium perfringens,*** see footnote P. 75 only applicable when these products becomes hydrated or used as ingredient in-high moisture food. **Table 1O:** Spices and Herbs **Category (1)**: Spices **Subcategory:** Dried, Ground, Cracked, or Whole	**Pesticides** in garlic used to make garlic powder. P. 87 **Table 2H:** Fruits and Vegetables **Category (All):** Fruits and Vegetables **Subcategory:** Whole RAC or processed **Lead** in garlic used to make garlic powder P. 87 *Note: FDA discusses in various other guidance that lead is a potential issue for foods intended for babies and young children.*
IQF Broccoli	**Pathogenic *E. coli; Salmonella, L. mono*** p. 59 **Table 1H:** Fruits and Vegetables **Category (4b)**: Processed Vegetables **Subcategory:** Whole or Cut	**Pesticides** P. 87 **Table 2H:** Fruits and Vegetables **Category (All):** Fruits and Vegetables **Subcategory:** Whole RAC or processed

Potential Ingredient-related Hazards per FDA Hazard Guide Appendix 1

PEANUT BUTTER – HAZARD ID TOOL

Available in the HF LI Portal

Ingredient	Potential Biological Hazards (Tables 1)	Potential Chemical Hazards (Tables 2)
Sugar	**None** P. 76 **Table 1P:** Food Sweeteners (Nutritive and Non-Nutritive) **Category (1a)**: Food Sweeteners (Nutritive and Non-Nutritive) **Subcategory:** Sugars (Dry)	**None** P. 82 **Table 2C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category:** None for Processing Chemicals only Nutrients
Salt	**None** P. 45 **Table 1C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category (6a)**: Other Chemical Ingredients **Subcategory:** Processing Chemicals	**None** P. 82 **Table 2C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category:** None listed for Processing Chemicals only Nutrients
Hydrogenated Vegetable Oil	**None** P. 68 **Table 1L:** Oils and Oil Products **Category (1c)**: Oil Products **Subcategory:** Shortening	**None** P. 92 **Table 2L:** Oils and Oil Products **Category**: None listed for Shortening Products

Potential Ingredient-related Hazards per FDA Hazard Guide Appendix 1

PEANUT BUTTER – HAZARD ID TOOL

Available in the HF LI Portal

Ingredient	Potential Biological Hazards (Tables 1)	Potential Chemical Hazards (Tables 2)
Nitrogen	None P. 46 **Table 1C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category (6e)**: Other Chemical Ingredients **Subcategory:** Processing Aid Gases	None P. 82 **Table 2C:** Misc. Food Additives, Color Additives, and GRAS Substances **Category:** None listed for Other Chemical Ingredients only Nutrients
Raw, shelled peanuts	Pathogenic *E. coli, Salmonella, L. mono*. P. 66 **Table 1K:** Nuts and Seeds **Category (1a)**: Nuts **Subcategory:** Peanuts, Raw	Mycotoxins and Pesticides P. 91. see footnote[1] for applicable mycotoxin (Aflatoxin). **Table 2K:** Nuts and Seeds **Category (1a):** Nuts **Subcategory:** Peanuts, Raw and treated

Potential Ingredient-related Hazards per FDA Hazard Guide Appendix 1

BLACK PEPPER – HAZARD ID TOOL

Available in the HF LI Portal

Ingredient	Potential Biological Hazards (Tables 1)	Potential Chemical Hazards (Tables 2)
Black Peppercorns	***Salmonella.*** P 74. ***B. cereus, Clostridium botulinum, Clostridium perfringens,*** see footnote P. 75 only applicable when these products becomes hydrated or used as ingredient in-high moisture food. **Table 1O:** Spices and Herbs **Category (1)**: Spices **Subcategory:** Dried, Ground, Cracked, or Whole	**Pesticides**. P. 95. **Table 2O:** Spices and Herbs **Category (1):** Spices **Subcategory:** Dried, Ground, Cracked, or Whole

FSPCA Form 0231 – Examples of Common Process-Related and Facility-Related Hazards

Use tool to assess both the ingredient supplier's process/facility related hazards AND the Fettuccini Marinara with Broccoli process steps

FDA Appendix 1 – A1.7	Common Process-Related and Facility-Related Hazards	Potential? Yes/No
BIOLOGICAL HAZARDS A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment	**Yes– Cook Pasta**
	Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control	**Yes – potential temperature abuse (*B. cereus* growth) at the following steps: 1) receiving frozen broccoli and Romano cheese; 2) refrigerated storage of Romano; 3) cool pasta; 4) mixer; 5) fill; 6) metal detection; 7) freezer tunnel; 8) frozen product storage; and 9) frozen product shipping.**
	Bacterial pathogens – Growth and/or toxin production due to poor formulation control	**N/A** – Not formulated for safety
	Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP)	**N/A** – Not packaged in ROP
	Bacterial pathogens – Presence due to ingredients added after process controls	**Yes– The ingredients garlic powder, Romano cheese, and frozen broccoli added after pasta cook biological hazards already identified in the ingredient hazard analysis (inherent hazards)**
	Bacterial pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity	**N/A** – Not packaged in hermetically sealed container
	Environmental pathogens – presence due to recontamination from the processing environment	**Yes – Ingredients and finished Fettuccine Marinara product are ready-to-eat, exposed to environment during 1) cool pasta, drain; 2) mix all ingredients; 3) fill prior to packaging**
CHEMICAL HAZARDS A1.7.2	Undeclared food allergens – incorrect label	**Yes – Romano cheese contains milk and dry pasta contains wheat which are major food allergens**
	Unintended food allergen presence – allergen cross-contact	**Yes – Shrimp Alfredo Pasta contains shrimp (a major food allergen) which could be unintentionally incorporated into the other pasta finished products that do not contain shrimp (at mixer and filler).**
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)	**N/A** – Does not contain ingredients with a maximum use level for safety
	Process-contamination hazards in certain plant-based foods (e.g. acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils)	**N/A** – Not Applicable (not a plant-based food)
PHYSICAL HAZARDS A1.7.3	Metal	**Yes –Metal from suppliers: garlic powder grinding; Romano cheese shredding; dry pasta cutting. Metal from ribbon blender. (NOT from metal shavings opening Marinara Sauce cans – not significant.)**
	Glass (when product packed in glass)	**N/A** – Not packed in glass
	Hard Plastic	**N/A** – Hard plastic not used by supplier and Fettuccini company

Fettuccini Marinara with Broccoli Preventive Controls

Process Preventive Controls:

1. Cool pasta, drain (70°F within 2 hours)
2. Timing interval for mix all ingredients; fill, heat seal film, weigh; metal detection; freezing (<41°F within 4 hours)
3. Metal detection

Allergen Preventive Controls:

1. Receipt of Packaging (pre-labeled carton)
2. Finished Product Labeling – Pack in Pre-printed carton

Sanitation Preventive Controls:

1. Kettle, Mixer, and Filler Sanitation (food-contact surfaces to prevent recontamination from environmental pathogens). NOTE: allergen cleaning for mixer & filler to prevent allergen cross-contact.
2. Kettle, Mixer, and Filler Areas Environmental Sanitation (non-food-contact surfaces)
3. Kettle, Mixer, and Filler Hygienic Zoning

Supply-Chain Preventive Controls:

1. Garlic Powder
2. Romano Cheese
3. Frozen Broccoli

Chapter 10 Process Preventive Controls Exercise

Use the hazard analysis from Chapter 7 exercise to complete the following:

1. Was a hazard requiring a process preventive control identified in the hazard analysis?
2. **Select one process preventive control and complete all of the columns on the Process Preventive Control Form**:
    a. What do you do to control the step?
    b. What considerations did you take into account?
3. Potential resources:
    a. Chapter 6: Hazard Analysis
    b. Chapter 7: Preventive Controls Determination
    c. Appendix 4: Foodborne Pathogen Supplementary Information
    d. FDA Hazard Guide, Chapters 4 and 6
4. Pick a spokesperson to summarize the process to the rest of the class.

Ch 10: Process Preventive Controls Exercise @ 30 minutes

Instructions

After Ch 10 – Complete Process Preventive Controls form in Exercise Workbook page 12 for your ASSIGNED Process Preventive Controls for Fettuccini Marinara with Broccoli (see below)

Needed Resources:

1. Pages 11-12 Exercise Workbook
2. Chapter 7 (HA & PC) Completed Exercise for your Model Plan

Potential Resources:

1. FSPCA Chapters 6 & 7 and Appendix 4
2. FDA Hazard Guide Chapters 4 & 6

(group member names) *Group 1*	(group member names) *Group 2*	(group member names) *Group 3*
Cool pasta, drain (70°F within 2 hours)	Timing interval for mix all ingredients; fill, heat seal film, weigh; metal detection; freezing (<41°F within 4 hours)	Metal detection

Distribute the FSPCA Fettuccini with Marinara Model Plan with answers to students **AFTER** the students complete the exercise.

FSMA Solutions

Chapter 11 Allergen Preventive Controls Exercise

Use the hazard analysis from the Chapter 7 exercise to complete the following:

1. Did you identify the need for allergen preventive control?
2. **Complete allergen forms to manage this hazard.** Useful questions to guide discussion:
   a. What allergens are present in the facility?
   b. Do all products contain the same allergens?
   c. If not, what do you do to control these allergens?
   d. What considerations did you take into account?
3. Potential resources:
   a. Chapter 4 of the Participant Manual (allergen section)
   b. FDA Hazard Guide, Chapter 11: Food Allergen Program
4. Pick a spokesperson to summarize the process to the rest of the class

BACKGROUND INFORMATION – COMPANY OVERVIEW
Page 3 of the Fettuccini Marinara with Broccoli Model Plan

This example company is a firm that makes a variety of fully cooked, ready-to-heat frozen entrees that are intended to be re-heated prior to consumption. Products which are made on the same production line include:

- Fettuccini Marinara with Broccoli – pasta, Marinara sauce, garlic powder, salt, Romano cheese, IQF broccoli (contains allergens: wheat, milk)
- Shrimp Alfredo with Pasta – shrimp, alfredo sauce, pasta (contains allergens: wheat, milk, shrimp)
- Pasta Primavera – IQF mix of peppers, zucchini, carrots, pasta, Parmesan cheese (contains allergens: wheat, milk) ….

This Food Safety Plan covers production of Fettuccini Marinara with Broccoli, but some activities included (e.g., pasta cooking, mixing, filling, pack in pre-printed cartons, freezing, etc.) apply to the two other products produced on the same production line.

Ch 11: Allergen Preventive Controls Exercise @ 30 minutes

Instructions

After Ch 11 – Complete the forms in the Exercise Workbook pages 13-15:

1. Ingredient Food Allergen Identification Table
2. Production Line Food Allergen Assessment Table
3. Production Scheduling Implications
4. Allergen Cleaning Implications
5. Allergen Labeling Implications
6. Allergen Preventive Controls form for your ASSIGNED Allergen Preventive Controls for Fettuccini Marinara with Broccoli (see below)

Needed Resources:

1. Pages 13-15 Exercise Workbook
2. Chapter 7 (HA & PC) Completed Exercise for your Model Plan

Potential Resources:

1. FSPCA Chapter 4 (allergen section)
2. FDA Hazard Guide Chapter 11: Food Allergen Program

Distribute the FSPCA Fettuccini with Marinara Model Plan with answers to students **AFTER** the students complete the exercise.

(group member names) ***Group 1***	**(group member names)** ***Group 2***	**(group member names)** ***Group 3***
Receipt of Packaging (pre-labeled cartons)	Finished Product Labeling – Pack in Pre-printed carton	Receipt of Packaging (pre-labeled cartons)

Chapter 12 Sanitation Preventive Controls Exercise

1. Did you identify the need for a sanitation preventive control within the hazard analysis, and if so, which one?
2. **Complete sanitation summary form to detail how the sanitation preventive control** will manage the hazard for where you identified a sanitation preventive control. Useful questions to guide discussion:
   a. What conditions exist in the facility that warrant a sanitation preventive control?
   b. What hazards are being controlled by the sanitation preventive control?
   c. What considerations did you take into account for the design of the sanitation preventive control?
3. Potential resources:
   a. Chapter 3 and Chapter 4 of the Participant Manual (environmental pathogens and allergen sections respectfully)
   ~~b. The FDA Hazard Guide,~~ Chapter 12: Sanitation Preventive controls of the Participant Manual
4. Pick a spokesperson to summarize the process to the rest of the class.

THREE (3) Sanitation Preventive Controls

#1: Clean and sanitize food-contact surfaces

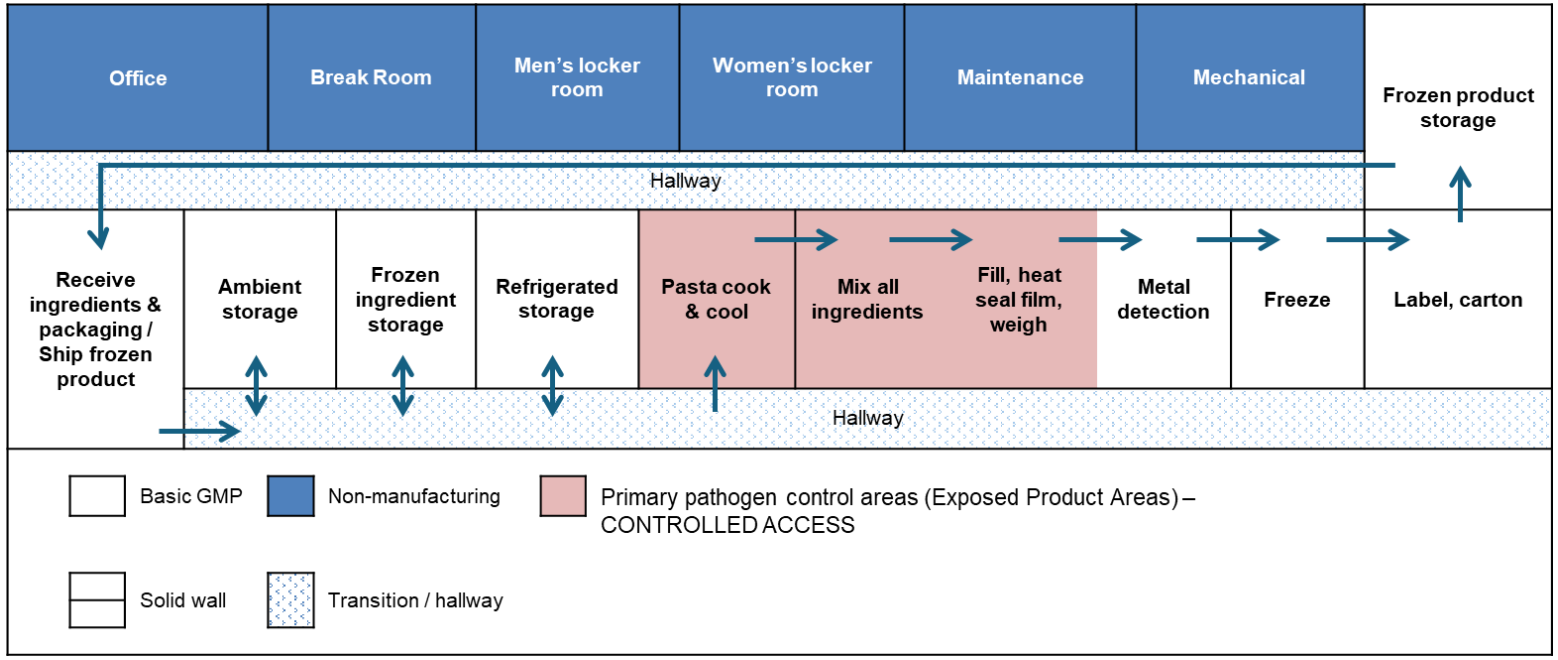
- Prevent Cross-contact (full clean after Shrimp Alfredo) - Mixer & Filler
- Prevent Recontamination with Environmental Pathogens – Kettles (pasta cool); Mixer; & Filler

#2: Clean and sanitize non-food-contact surfaces

- Prevent Recontamination with Environmental Pathogens – Clean areas around Kettles (pasta cool); Mixer; & Filler

#3: Hygienic Zoning

- Prevent cross-contamination with Environmental Pathogens via personnel



Ch 12: Sanitation Preventive Controls Exercise @ 30 minutes

Instructions

After Ch 12 – Complete Process Preventive Controls form in Exercise Workbook page 16-17 for your ASSIGNED Process Preventive Controls for Fettuccini Marinara with Broccoli (see below)

Resources:

1. Pages 16-17 Exercise Workbook
2. Chapter 7 (HA & PC) Completed Exercise for your Model Plan
3. FSPCA Chapters 3 & 4, 12

(group member names) *Group 1*	(group member names) *Group 2*	(group member names) *Group 3*
#1: Clean and sanitize food-contact surfaces Prevent Recontamination with Environmental Pathogens – Kettles (pasta cool); Mixer; & Filler	**#2: Clean and sanitize non-food-contact surfaces** Prevent Recontamination with Environmental Pathogens – Clean areas around Kettles (pasta cool); Mixer; & Filler	**#3: Hygienic Zoning** Prevent cross-contamination with Environmental Pathogens via personnel

Distribute the FSPCA Fettuccini with Marinara Model Plan with answers to students **AFTER** the students complete the exercise.

FSMA Solutions

Chapter 13 Supply-chain Preventive Controls Exercise

Using the hazard analysis from the Chapter 7 exercise:

1. **Identify at least one ingredient and one hazard requiring a supply-chain-applied control for your Food Safety Plan Teaching Example;**
2. Identify the preventive control(s) to be applied by the supplier;
3. Identify at least one supplier verification activity;
4. Outline the elements the procedure would require;
5. Identify required records;
6. Identify receiving procedures; and
7. Pick a spokesperson to bring up questions or insights discovered.

Ch 13: Supply-chain Preventive Controls Exercise @ 20 minutes

Instructions

After Ch 13 – Complete Supply-chain Preventive Controls form in Exercise Workbook page 18 for your ASSIGNED one ingredient and one hazard (see below)

Needed Resources:

1. Pages 17-18 Exercise Workbook
2. Chapter 7 Exercise for your Model Plan

(group member names) ***Group 1***	(group member names) ***Group 2***	(group member names) ***Group 3***
Ingredient: Garlic Powder Hazard requiring a supply-chain-applied control: *Salmonella*	Ingredient: Romano Cheese Hazard requiring a supply-chain-applied control: Recontamination with environmental pathogens *L. mono*	Ingredient: Frozen Broccoli Hazard requiring a supply-chain-applied control: Pathogenic *E. coli, L. mono,* and *Salmonella* **OR** Recontamination with environmental pathogens *L. mono* but group 2 is already doing

Distribute the FSPCA Fettuccini with Marinara Model Plan with answers to students **AFTER** the students complete the exercise.

Chapter 13 Supply-chain Preventive Controls Example

PRODUCT(S): Fettuccini Marinara with Broccoli, Ready to Heat		PAGE 41 of 42
PLANT NAME: Perfect Pasta, Inc.	ISSUE DATE	5/16/2024
ADDRESS: 123 Pasta Way, Primavera, IA	SUPERSEDES	2/25/2023

Supply-Chain Preventive Controls Determination of Verification Procedures and Corrective Actions – Frozen Broccoli

Raw Material or Other Ingredient	Approved Supplier Name and Location	Date of Approval	Hazard(s) Requiring a Supply-chain-Preventive Control	Preventive Control(s) Applied by Supplier	Verification Activities	Verification Procedures	Corrective Actions	Records
Frozen Broccoli	US Grown Co., Farm Valley, USA	2/22/2024	Pathogenic *E. coli, L. mono, and Salmonella* AND Recontamination with environmental pathogens *L. mono*	Broccoli produced under Produce Safety Rule Standards AND Sanitation Control verified by environmental monitoring program	A third-party annual audit by a qualified auditor is used to verify the supplier's preventive controls for the identified hazards.	A copy of a third-party audit is requested from the supplier annually. The audit date, auditor qualifications, audit procedures and audit results are reviewed by the QA manager. Follow-up with the supplier takes place, as necessary, to verify that any corrective actions mentioned in the report have been completed, with records maintained for this activity.	Follow up with the supplier to verify corrective actions taken in response to significant audit deficiencies. If it is determined that the supplier is not controlling identified hazards as requiring a supply-chain-applied control, take and document prompt action, as appropriate, to include: • Dispose of any ingredient(s) from the supplier, as well as products made using the impacted ingredient(s), that are still under our control. • Discontinue use of the supplier until the cause or causes of non-conformance, are adequately addressed. • Notify the supplier of the problem and request documentation of corrective actions taken by the supplier. • Assist the supplier's efforts to correct and prevent recurrence of the problem. • Revise the supply-chain program. • Conduct, or work with the supplier to conduct, a recall of any adulterated food.	Copy of audit report kept in the Supplier Verification File. Supplier Verification and Corrective Action Documentation

Don't forget to complete the receiving procedure

PRODUCT(S): Fettuccini Marinara with Broccoli, Ready to Heat		PAGE 42 of 42
PLANT NAME: Perfect Pasta, Inc.	ISSUE DATE	5/16/2024
ADDRESS: 123 Pasta Way, Primavera, IA	SUPERSEDES	2/25/2023

Receiving Procedure for Ingredients Requiring a Supply-chain Preventive Control

Purpose: Ensure that all ingredients requiring a supply-chain-applied preventive control are received from approved suppliers (see list of raw materials and respective approved suppliers) with appropriate preventive controls in place.

Frequency: Each delivery before accepting for use.

Who: Receiving clerk

Procedure:

1. Verify that each load of:
   a. Garlic Powder was produced by Spicetown Co., Gilroy, USA by checking the bill of lading and manufacturer name on the cases upon receipt.
   b. Romano Cheese was produced by Big Cheese Co., Cheesytown, USA by checking the bill of lading and manufacturer name on the cases upon receipt.
   c. Frozen Broccoli was produced by US Grown Co., Farm Valley, USA by checking the bill of lading and manufacturer name on the cases upon receipt.
2. If the product is not from an approved supplier, reject the shipment at time of receipt.
3. Document on receiving log.

Corrections: Contact the plant manager to notify procurement of rejection of shipment of ingredients from an unapproved supplier.

Verification: Receiving records review within 7 working days.

Records: Receiving Log, Bill of Lading, Correction Records, Verification Record

THANK YOU!

TODAY – During the Lightening Round Sessions

Raffle Packets of Teaching Examples (3 full sets)

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

STRATHMORE
A&B

BREAKOUT SESSION: DATA DASHBOARD

ROBERT E. BUGHMAN
U.S. FOOD AND DRUG ADMINISTRATION (FDA)

MODERATOR: JUAN L. SILVA

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
Innovation Through Collaboration

U.S. FOOD & DRUG ADMINISTRATION

FDA Data Dashboard

Robert Bughman, OII/OBISM, Project Manager

19 November 2025

Office of Inspections & Investigations

History

The FDA created the Data Dashboard to increase transparency and accountability by displaying and allowing the analysis of public FDA data through easy to use, visually accessible, customizable, and understandable graphics.

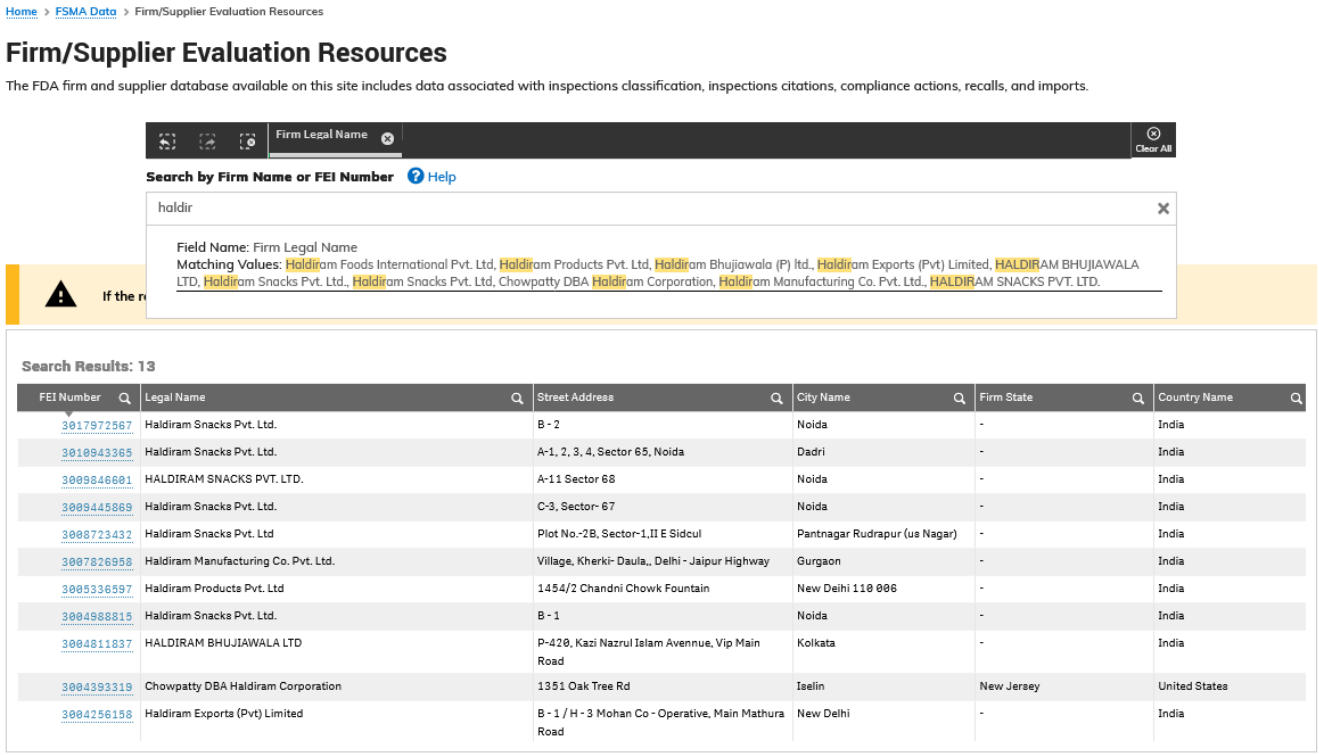
Origin and Initial Dashboard

- Presidential Transparency Initiative.
- First dashboard (FDA GovDashboard) went live in September 2014.
- Dashboard with a mix of static and interactive graphs and tables.

New FDA Data Dashboard

- Went live December 2017.
- Initially contained Compliance (Compliance Actions, Recalls, and Inspections) and Imports (Refusals and Summary) data.
- COTS system (Qlik) hosted in AWS Cloud
- Dashboard displays data in multiple interactive visualizations (graph, charts, maps, and tables).
- Allows easy analysis of data using multiple filters and search functions

Link & Consolidate Data



FEI Number	Legal Name	Street Address	City Name	Firm State	Country Name
3017972567	Haldiram Snacks Pvt. Ltd.	B - 2	Noida	-	India
3010943365	Haldiram Snacks Pvt. Ltd.	A-1, 2, 3, 4, Sector 65, Noida	Dadri	-	India
3009846601	HALDIRAM SNACKS PVT. LTD.	A-11 Sector 68	Noida	-	India
3009445869	Haldiram Snacks Pvt. Ltd.	C-3, Sector- 67	Noida	-	India
3008723432	Haldiram Snacks Pvt. Ltd	Plot No.-2B, Sector-1,II E Sidcul	Pantnagar Rudrapur (us Nagar)	-	India
3007826958	Haldiram Manufacturing Co. Pvt. Ltd.	Village, Kherki- Daula,, Delhi - Jaipur Highway	Gurgaon	-	India
3005336597	Haldiram Products Pvt. Ltd	1454/2 Chandni Chowk Fountain	New Delhi 110 006	-	India
3004988815	Haldiram Snacks Pvt. Ltd.	B - 1	Noida	-	India
3004811837	HALDIRAM BHUJIAWALA LTD	P-420, Kazi Nazrul Islam Avennue, Vip Main Road	Kolkata	-	India
3004393319	Chowpatty DBA Haldiram Corporation	1351 Oak Tree Rd	Iselin	New Jersey	United States
3004256158	Haldiram Exports (Pvt) Limited	B - 1 / H - 3 Mohan Co - Operative, Main Mathura Road	New Delhi	-	India

Firm/Supplier Evaluation Resources

- Supplier evaluation requirements under the Food Safety Modernization Act (FSMA) and Firm Supplier Verification Program.
- Information was spread across seven different datasets on FDA.gov
- Linked all Dashboard datasets using the FDA Establishment Identifier (FEI) number in one central location.
- Used web tools to search and display other FDA datasets (Import Alerts, Warning Letters, and published 483s).
- Created the Firm Profile pages to combine and display all available data associated to each firm.
- Timeline on Firm Profile provides comprehensive view of the Firm's compliance history overtime.

Other Key Features

New Data

- Inspections Citations
- Imports Entry
- FSMA Programs
- Published 483s
- Link to other FDA.gov data

System

- Automated weekly data refresh
- Cloud hosted solution (AWS)
- Customizable COTS product (Qlik)
- Dashboard APIs
- Quick search for millions of rows (Imports Entry)
- Multiple ways to analyze and view the data.

Flexible Solution

- OII Unified Logon (OUL) Integration

Future Enhancements

Data Access

- Dashboard's data source move to GovCloud
- Increased data refresh frequency
- More APIs (Imports Entry, Published 483s)

New Data

- Expand Current Datasets (State Inspections)
- Improved Warning Letter and Import Alert results
- New Datasets

Demonstration

https://datadashboard.fda.gov

Questions & Answers

https://datadashboard.fda.gov

Thank You!

https://datadashboard.fda.gov

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FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

BREAKOUT SESSIONS REPORT OUT

CLAUDIA COLES

SEAFOOD PRODUCTS ASSOCIATION (SPA)

MODERATOR: RON TANNER

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH

Innovation Through Collaboration

Breakout Session Summary: Food Safety Priorities & Policies

- Experts from diverse associations have been promoting improvements to FDA and USDA policies, funding, culture, and structure.
- These experts have been meeting regularly as the "Breakfast Club"
- Current leaders at the agencies seem to be engaged and listen to stakeholders
- However, stakeholders have identified areas that need improvement such as the dichotomy between a public health focus and a regulatory focus
- Many examples were provided that showed more work is needed to overcome issues around communication, information sharing (such as distribution lists), and using resources effectively
- The experts were skeptical that we will see a single food safety agency
- While the current funding outlook for the agencies seems positive, it is still not enough to support a food safety mission

Breakout Session Summary: Animal Food

- Great discussions amongst group in all topic areas

Topics

- FDA inspection trends based on FDA Inspection Dashboard
  - Facilities without Food Safety Plans, hazards not identified
  - These are training gaps that may be able to be addressed
- Curriculum update (version1.2)
  - Updates to RFR data, better chapter flow, addition of HPAI as a hazard
  - The group discussed the benefits of having LI best practice forums
- Case Studies
  - HPAI as a required hazard
    - FDA announces reanalysis requirement for pet food producers
  - GRAS Reform (impacts to animal food)
    - Knowing how ingredients are regulated
- Other key takeaways
  - Inclusion of animal food in the CR
  - Discussion participants mentioned resources currently used in the HF curriculum that might be beneficial to AF participants

Breakout Session Summary: Animal Food

Q&A

1. When do we anticipate the new curriculum will be published?
   - While we can't share an exact date, the target timeframe is Fall 2026
2. Is there information in the curriculum for human food producers that generate by-products for use in animal food?
   - Yes, there is a slide that illustrates how human food by-products can be used in animal food. This is something that we may be able to share with Human Food LIs to use as a supplemental slide in their curricula.
3. In the food safety plan, is it okay to name "pathogens" as the hazard, but not to specify the bacteria or viruses?
   - The group discussed best practices for how to delineate the specific pathogens or viruses

Breakout Session Summary: New FSPTEs

- Three revised plans are now available!
- Updated with the revised Appendix 1 guide
- Formatted for better alignment with V2.0
- More details on ingredients, supplier, and processor
- .pdf's are available for the exercises
- Two more to go (cold pressed bar, carrot broccoli salad)
- New LI user guides for the Teaching Examples are available in the Inst Portal
- Webinars upcoming!

Breakout Session Summary: FDA Data Dashboard

- History and future additions to the FDA Data Dashboard
- Demonstration of the Dashboard and limitations
- Questions/suggestions:
  - Be able to discriminate between foods and cosmetics
  - Be able to search different food categories

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CLOSING REMARKS

JASON WAN, PHD
INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

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