



# FSPCA 2025 ANNUAL CONFERENCE

STRENGTHENING THE FOOD SUPPLY CHAIN  
THROUGH EDUCATION, TRAINING AND OUTREACH



# WELCOME

JASON WAN, PHD

INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

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GOLD



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# OPENING REMARKS & IFSH UPDATES

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

# **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 brew 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**



# KEYNOTE SPEAKER

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



# FSPCA OPERATIONAL HIGHLIGHTS

**JASON WAN, PHD**

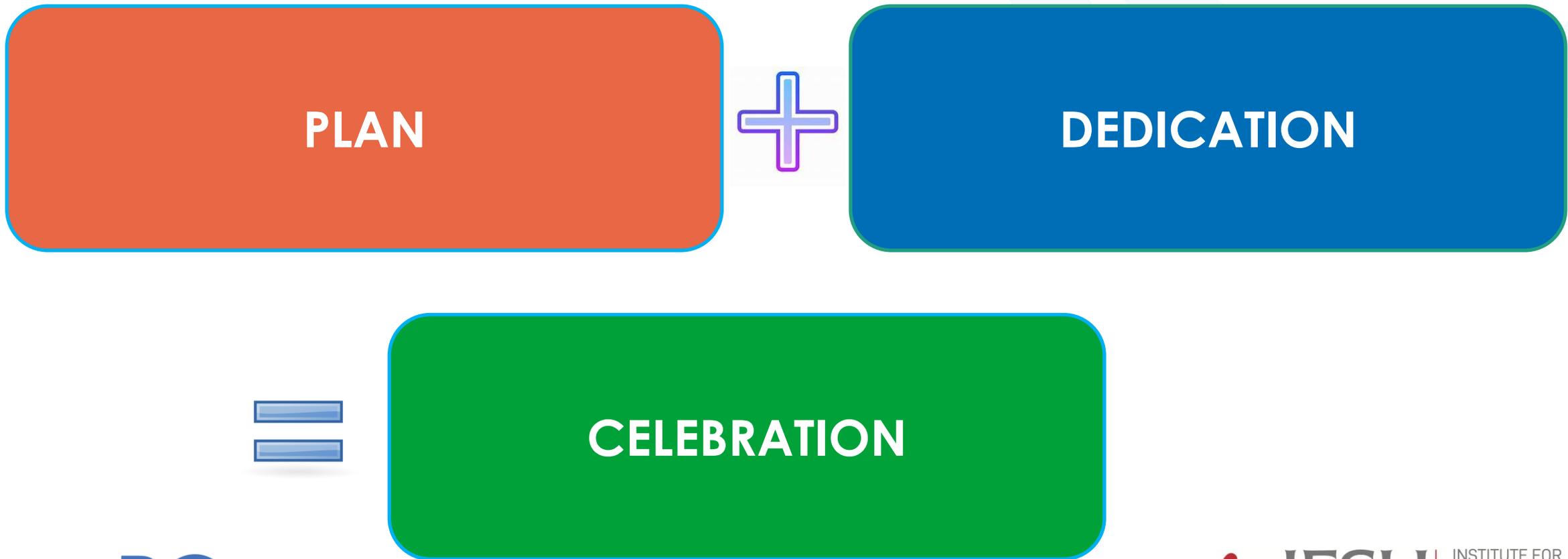
INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)

**KATHY GOMBAS**

FSMA SOLUTIONS, FSPCA EAB CHAIR



# FSPCA Operational Plan



# 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.

# 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

### 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

### 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

# 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

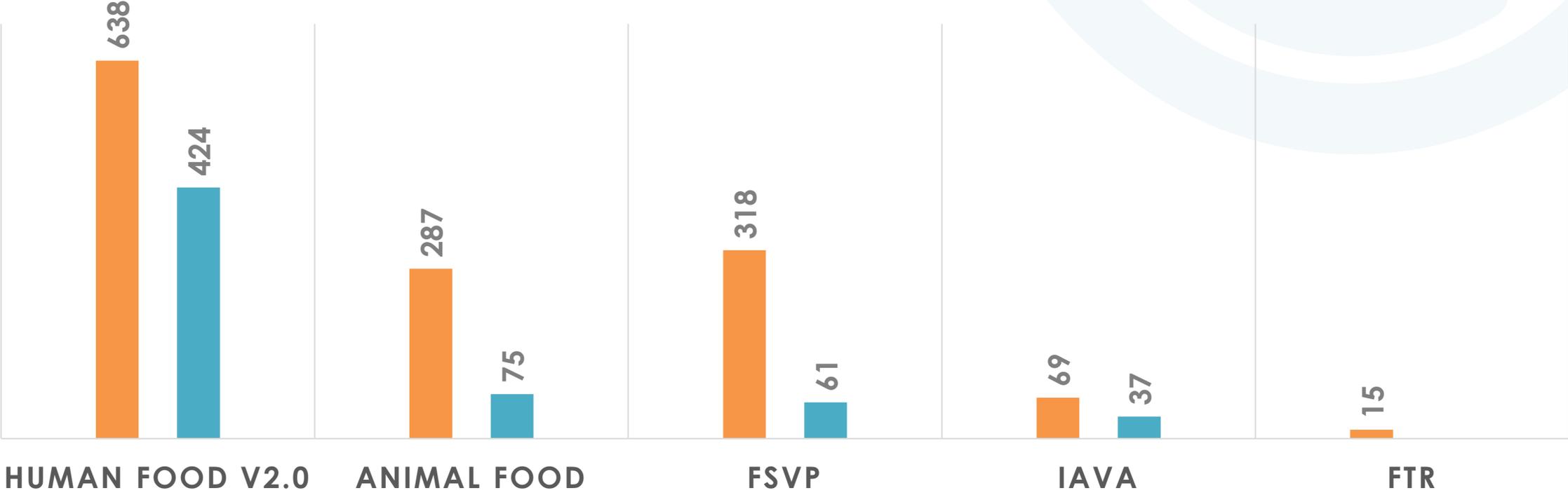
### FTR

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

# DEDICATION

## FSPCA LEAD INSTRUCTORS (AS OF NOV 5, 2025)

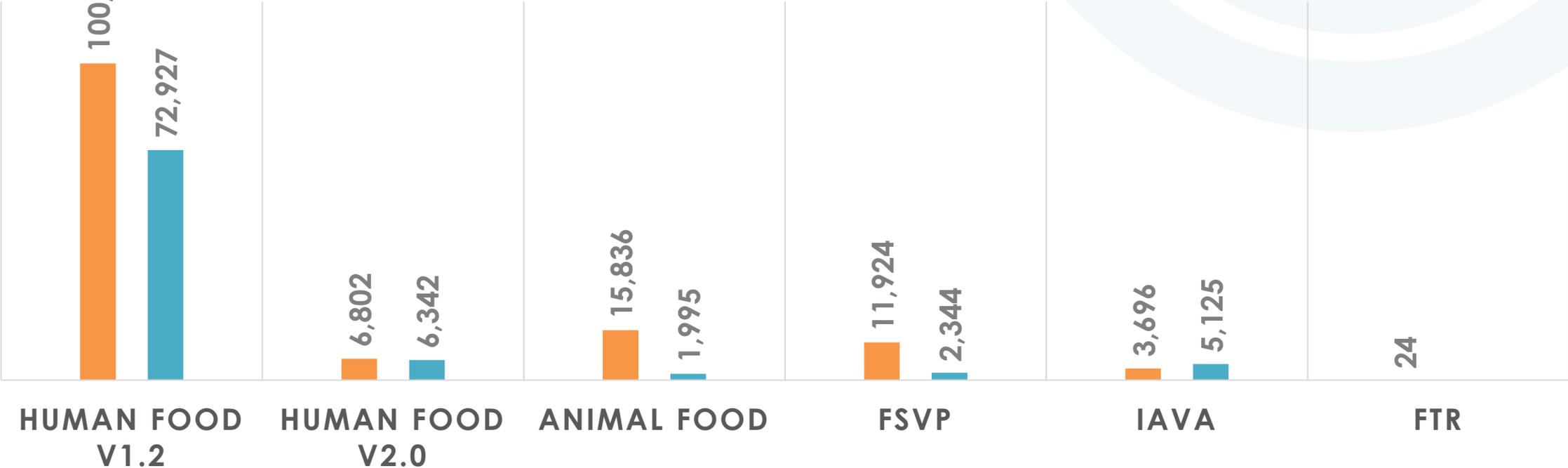
Domestic International



# DEDICATION

## PARTICIPANT CERTIFICATES ISSUED (AS OF NOV 5, 2025)

Domestic International



# Technical Assistance Network

## DEDICATION

### V2.0 TAN

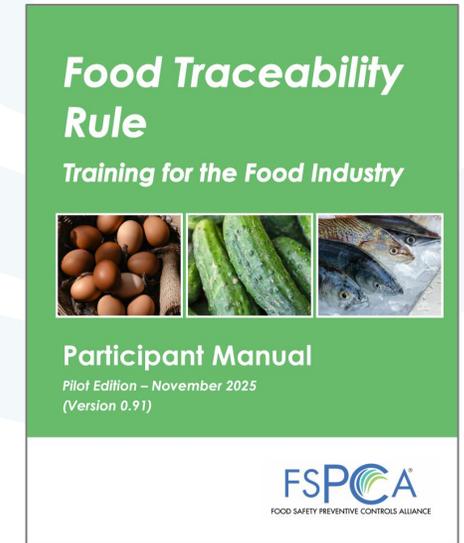
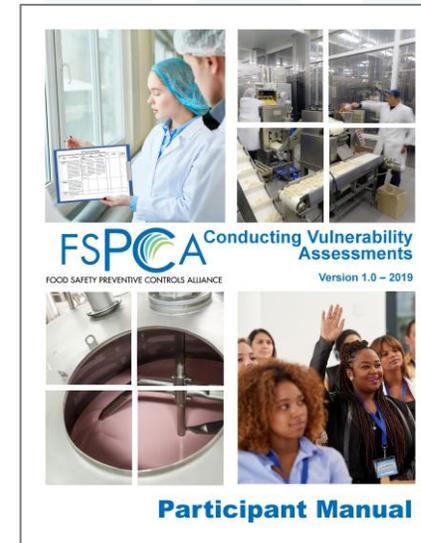
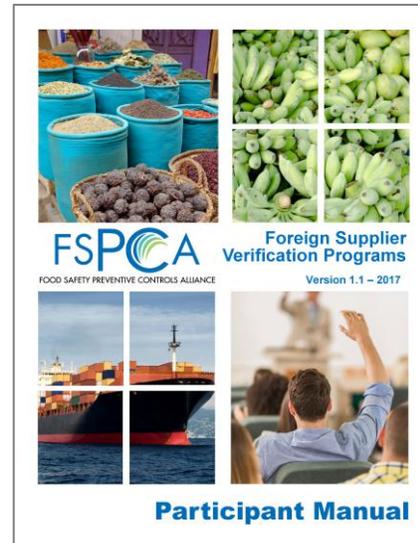
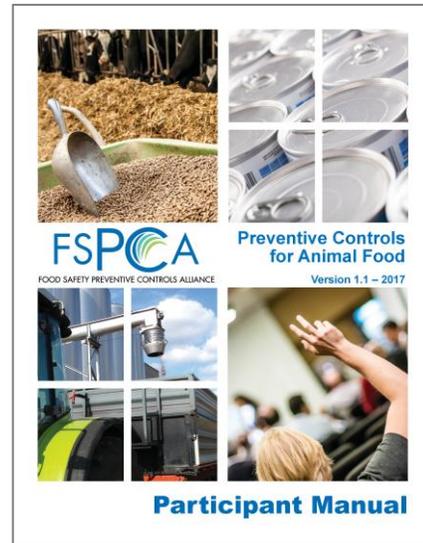
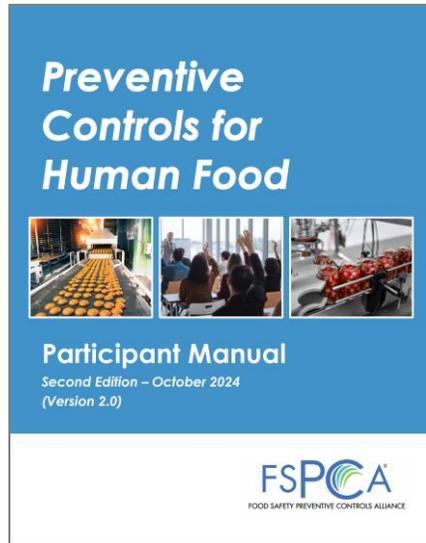
1. Kathy Gombas
2. Claudia Coles
3. Martin Bucknavage
4. Katherine Simon
5. Jason Wan

### University Extension Specialists

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

# 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

# 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



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

## CELEBRATION

## Food Traceability Rule

Training for the Food Industry



## Participant Manual

Pilot Edition – November 2025  
(Version 0.91)



FSPCA Participant Manual

### FSPCA FOOD TRACEABILITY RULE TRAINING FOR THE FOOD INDUSTRY CURRICULUM

First Edition – November 2025  
Pilot Version 0.9

#### U.S. Food and Drug Administration Recognition

This course was developed by the Food Safety Preventive Controls Alliance (FSPCA) in collaboration with the U.S. Food and Drug Administration (FDA). 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.

Developed by



© 2025 IIT IFSH

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## 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”



# 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

- **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

ANNUAL CONFERENCE  
Immediately following the IAFP Annual Conference  
**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

July 13th-14th  
Thur: 8:00 a.m.- 5:00 p.m.  
Fri: 8:00 a.m.- Noon

Tampa Convention Center 333 S. Franklin St, Tampa, FL 33602

Social Event | Join us on Thursday Evening for the Cocktail Reception  
Registration | [fspca-annual-conference.eventbrite.com](http://fspca-annual-conference.eventbrite.com)

**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE  
ANNUAL CONFERENCE

JULY 18-19  
Immediately following the IFT Annual Conference

DAY 1 1:00 PM - 5:00 PM  
DAY 2 8:00 AM - 5:00 PM

DAY 1 NETWORKING RECEPTION 5:30 PM - 7:00 PM

CHICAGO NAVY PIER  
600 EAST GRAND AVE.  
CHICAGO, IL 60611

**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

2019 ANNUAL CONFERENCE  
Advancing Food Safety Collaboration

CHICAGO MARRIOTT SOUTHWEST  
OCTOBER 22 - 23, 2019

**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

2020 VIRTUAL ANNUAL CONFERENCE  
Advancing Food Safety Collaboration

DECEMBER 8-9, 2020

**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

2021 VIRTUAL ANNUAL CONFERENCE  
OCTOBER 20-21

OPERATING AT THE CROSSROADS OF PRE- AND POST-COVID

**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

2022 ANNUAL CONFERENCE  
**Keeping Food Safe**  
In an Increasingly Challenging Business Environment

OCTOBER 19-20 VIRTUAL

**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FSPCA 2023 ANNUAL CONFERENCE  
BUILDING GLOBAL FOOD SAFETY CAPACITY THROUGH EDUCATION, TRAINING AND OUTREACH

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

FSPCA Annual Conference | October 17-18, 2023

**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

2024 ANNUAL CONFERENCE  
A Global Community Navigating a Changing Landscape

OCT 19-20

**FSPCA**  
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

**FSPCA**  
9th ANNUAL CONFERENCE

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

# 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



# 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)

# Traceability & FSMA 204: Origins of the Rule

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

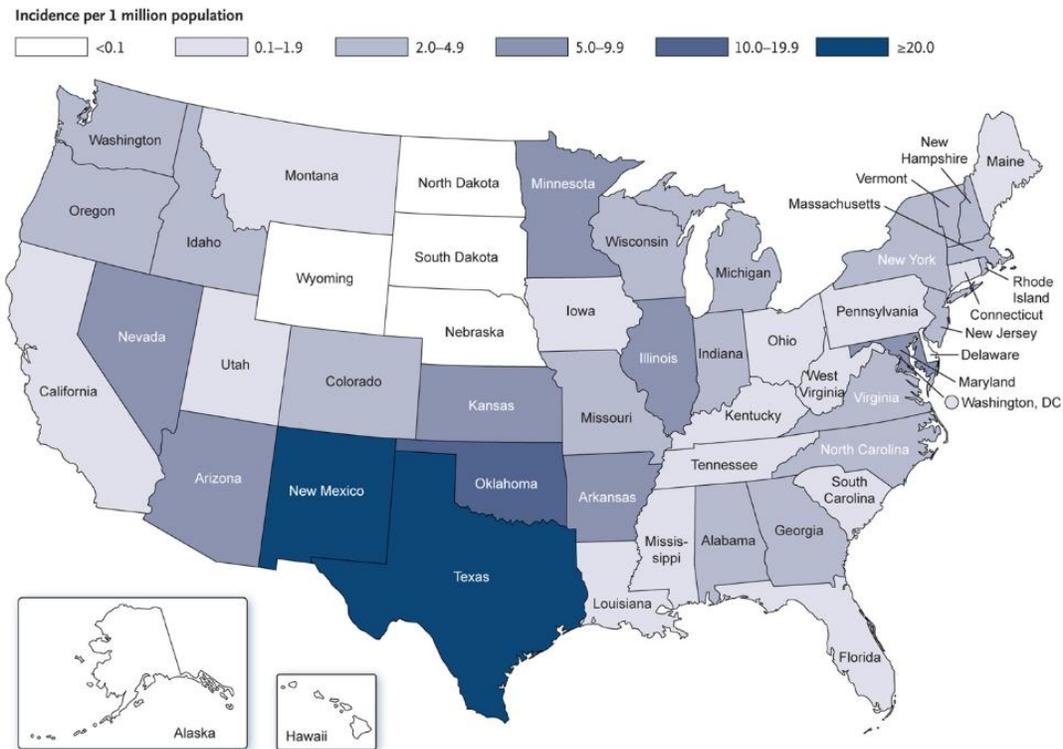


November 18, 2025



# Why are we here?

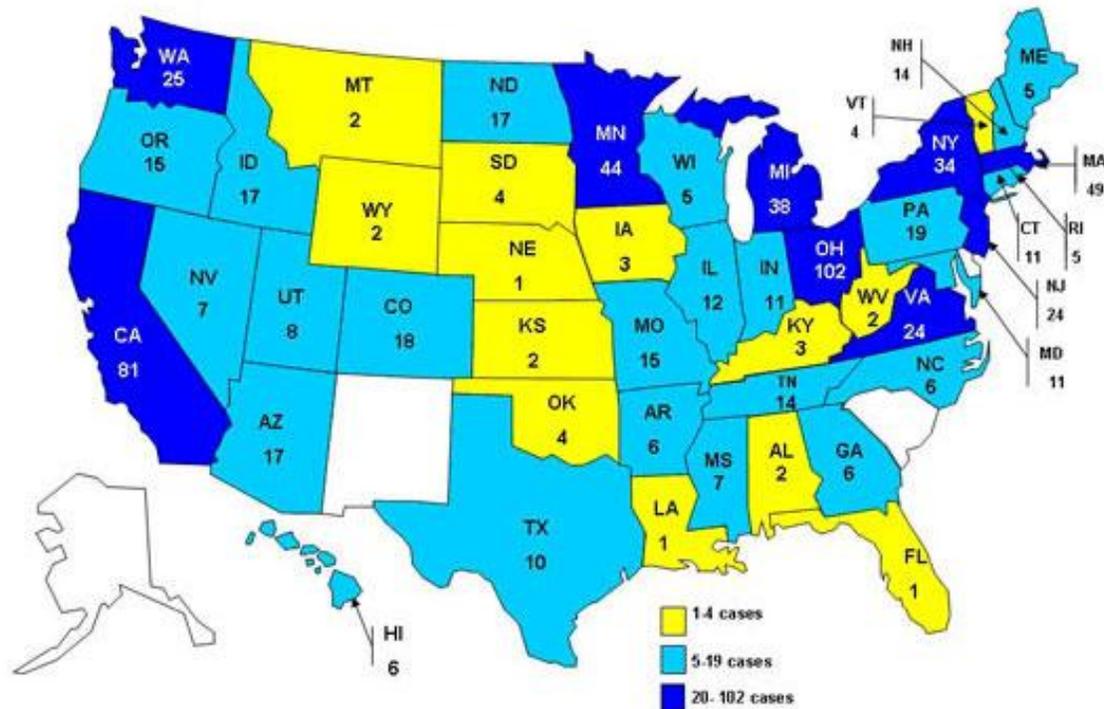
Guess that outbreak:



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

# Why are we here?

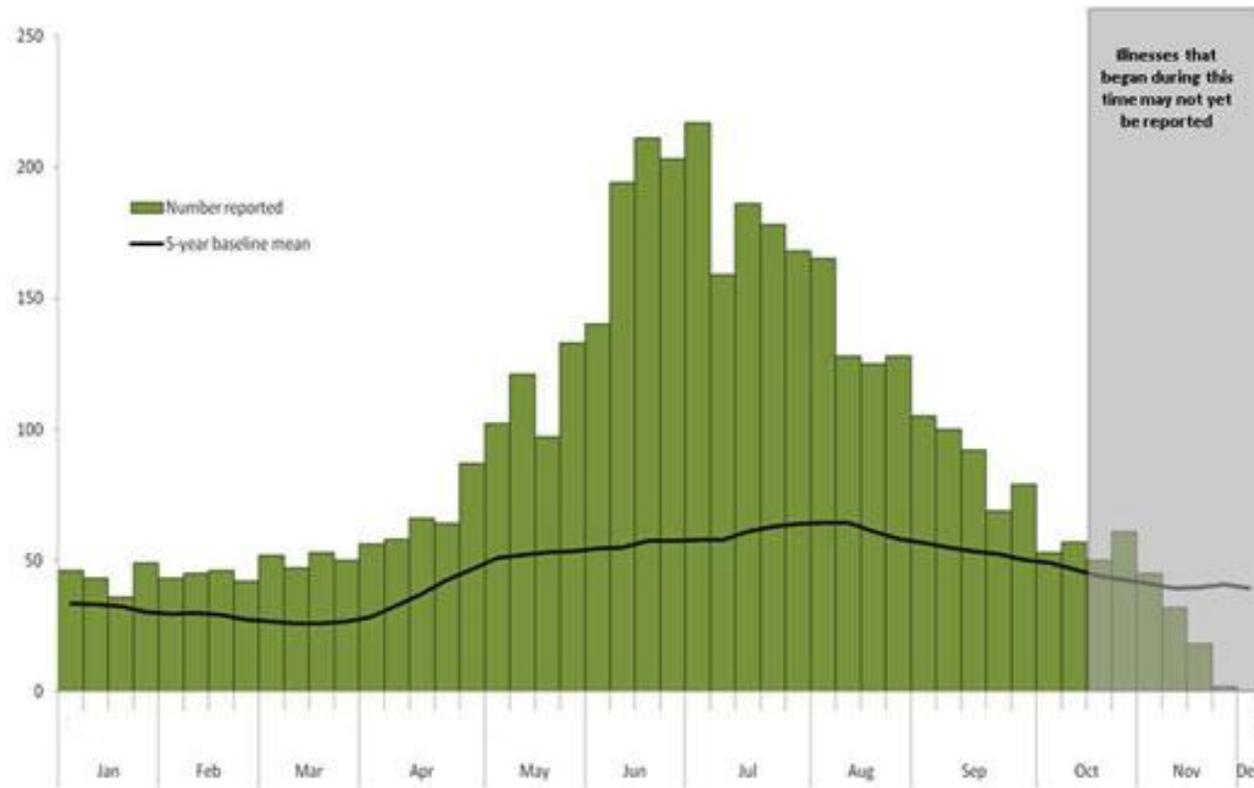
Guess that outbreak:



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: <ul style="list-style-type: none"> <li>• Cheese (made from pasteurized milk), fresh soft or soft unripened.</li> <li>• Cheese (made from pasteurized milk), soft ripened or semi-soft.</li> <li>• Cheese (made from unpasteurized milk), other than hard cheese<sup>1</sup>.</li> </ul>	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.  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.  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: <ul style="list-style-type: none"> <li>• Finfish, histamine-producing species.</li> <li>• Finfish, species potentially contaminated with ciguatoxin.</li> <li>• Finfish, species not associated with histamine or ciguatoxin.</li> </ul>	Includes all histamine-producing species of finfish. Examples include, but are not limited to, tuna, mahi mahi, mackerel, amberjack, jack, swordfish, and yellowtail.  Includes all finfish species potentially contaminated with ciguatoxin. Examples include, but are not limited to, grouper, barracuda, and snapper.  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. <sup>2</sup> Siluriformes fish, such as catfish, are not included. <sup>3</sup>

# RRM-FT Criteria

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

<b>Criteria</b>	<b>Moderate (criteria score=3)</b>	<b>Strong (criteria score=9)</b>
Outbreaks and illnesses (C1) <sup>a</sup>	<ul style="list-style-type: none"> <li>• &gt;1-10 outbreaks and hundreds of cases since 1999; OR</li> <li>• ≥10 outbreaks and tens of cases since 1999; OR</li> <li>• ≤1 outbreak and thousands of cases since 1999</li> </ul>	<ul style="list-style-type: none"> <li>• ≥10 outbreaks and hundreds or thousands of cases since 1999; OR</li> <li>• &gt;1-10 outbreaks and thousands of cases since 1999</li> </ul>
Severity of illness (C2)	<ul style="list-style-type: none"> <li>• Hospitalization rate &gt;10-20% and mortality rate 0%; OR</li> <li>• Hospitalization rate ≤20% and mortality rate &gt;0% to ≤0.5%</li> </ul>	<ul style="list-style-type: none"> <li>• Hospitalization rate &gt;20% OR mortality rate &gt;0.5%</li> </ul>
Likelihood of contamination (C3) <sup>b</sup>	<ul style="list-style-type: none"> <li>• Contamination rate &gt;0.1-1%; OR</li> <li>• &gt;1-10 RFR<sup>c</sup> reports/year; OR</li> <li>• &gt;5-10 recalls/year</li> </ul>	<ul style="list-style-type: none"> <li>• Contamination rate &gt;1%; OR</li> <li>• &gt;10 RFR reports/year; OR</li> <li>• &gt;10 recalls/year</li> </ul>
Growth potential with consideration of shelf life (C4)	<ul style="list-style-type: none"> <li>• 1-3 log<sub>10</sub> CFU (colony forming unit) increase given customary shelf life</li> </ul>	<ul style="list-style-type: none"> <li>• ≥3 log<sub>10</sub> CFU increase given customary shelf life</li> </ul>

# RRM-FT Criteria

<p>Manufacturing process contamination probability and industry-wide intervention (C5)</p>	<ul style="list-style-type: none"> <li>• Recurring or frequent detection of contamination; control measures available and adequate, evidence for consistent implementation in industry; OR</li> <li>• 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</li> <li>• Infrequent detection of contamination; lack of adequate control measures, or evidence of poor implementation of control measures in industry</li> </ul>	<ul style="list-style-type: none"> <li>• Recurring or frequent detection of contamination; lack of adequate control measures, or evidence of poor implementation of control measures in industry; OR</li> <li>• 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</li> <li>• Known history of contamination; lack of adequate control measures, or evidence of poor implementation of control measures in industry</li> </ul>
<p>Consumption (C6)</p>	<ul style="list-style-type: none"> <li>• &gt;10% consumers and &gt;0-10 g/serving; OR</li> <li>• &gt;5-10% consumers and &gt;10-100 g/serving; OR</li> <li>• 1-5% consumers and &gt; 100 g/serving</li> </ul>	<ul style="list-style-type: none"> <li>• &gt;10% consumers and &gt;10 g/serving; OR</li> <li>• &gt;5-10% consumers and &gt;100 g/serving</li> </ul>
<p>Cost of illness (C7)</p>	<ul style="list-style-type: none"> <li>• &gt;\$1M to 10M/year</li> </ul>	<ul style="list-style-type: none"> <li>• &gt;\$10M/year</li> </ul>

<sup>a</sup> Weighted by year of outbreak; <sup>b</sup> Weighted by number of samples, geographic location and year;

<sup>c</sup> Reportable Food Registry

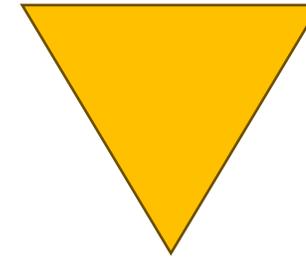
# Traceability vs Recall

Traceability =  
Investigation

Recall = Corrective Action

Data fidelity is  
important

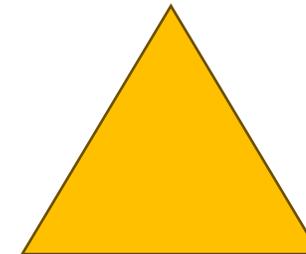
Multiple people ill



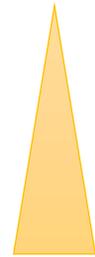
Point of  
convergence

Suspected issue

Speed is  
important



Precautionary



Higher fidelity  
may mean  
more targeted  
recalls



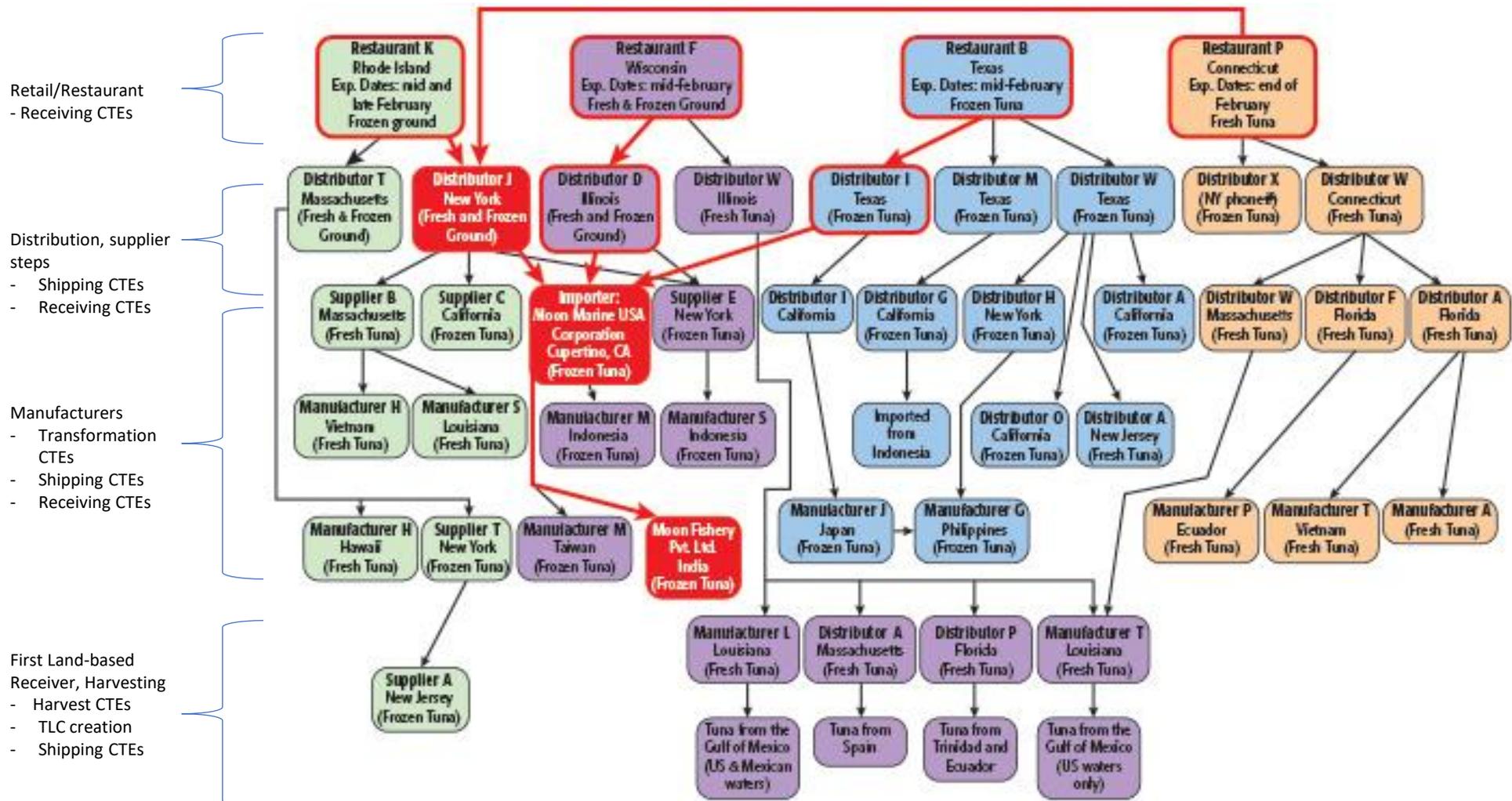


Figure 2: Salmonella Bareilly Traceback (The distribution of the contaminated tuna is outlined in red.)

<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

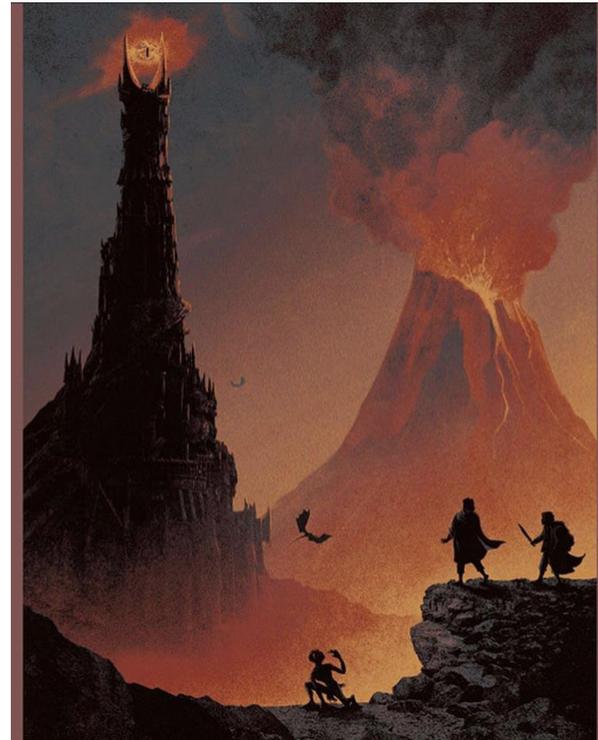


# The Traceability Lot Code Source

*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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[Ben.Miller@AchesonGroup.com](mailto:Ben.Miller@AchesonGroup.com)

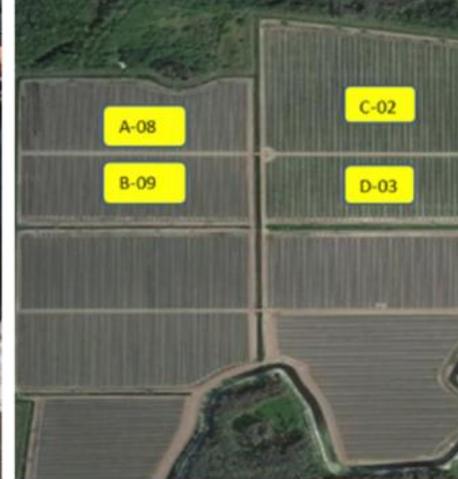
[www.achesongroup.com](http://www.achesongroup.com)

[info@achesongroup.com](mailto:info@achesongroup.com)

800-401-2239

# Food Traceability Rule Implementation and Resource Updates

November 18, 2025  
FSPCA Annual Meeting



**Exemptions to the Food Traceability Rule**

You are subject to the Food Traceability final rule, unless an exemption applies. To determine whether you may be exempt, please click on any of the following categories that may apply to you:

<a href="#">Farms</a>	<a href="#">Certain types of processing</a>
<a href="#">Commingled raw agricultural commodities (RACs)</a>	<a href="#">Personal consumption, holding, food for specific consumers</a>
<a href="#">Fishing vessels, public health risks</a>	<a href="#">Other</a>
<a href="#">Retail food establishments (RFEs), restaurants</a>	



# 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

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

# 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

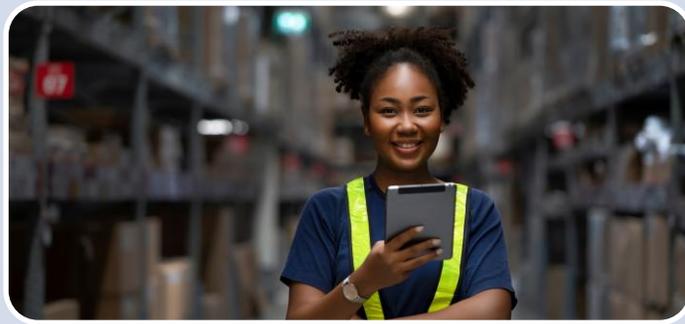
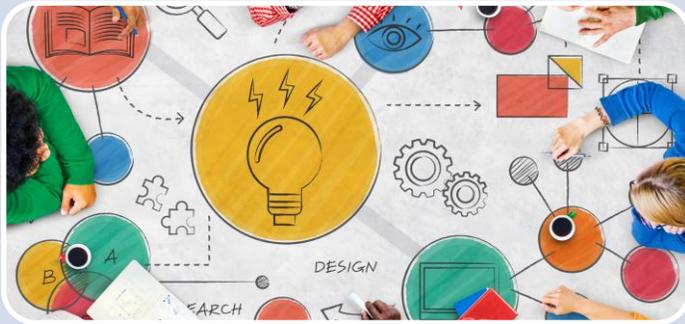
## Target Audience

- 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

## FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods



Food Safety Modernization Act (FSMA)

Frequently Asked Questions on FSMA

FSMA Rules & Guidance for Industry

What's New in FSMA

FSMA Training

FSMA Technical Assistance Network (TAN)



[Español \(Spanish\)](#) | [Bahasa Indonesia](#) | [中文 \(Chinese, Simplified\)](#) | [ภาษาไทย \(Thai\)](#) | [Tiếng Việt \(Vietnamese\)](#)

The FDA final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) establishes traceability recordkeeping requirements, beyond those in existing regulations, for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL). The final rule is a key component of FDA's New Era of Smarter Food Safety Blueprint and

- [Federal Register Notice](#)
- [Docket No. FDA-2014-N-0053](#)
- [eCFR Subpart S - Additional Traceability Records for Certain Foods](#)

## 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

# 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

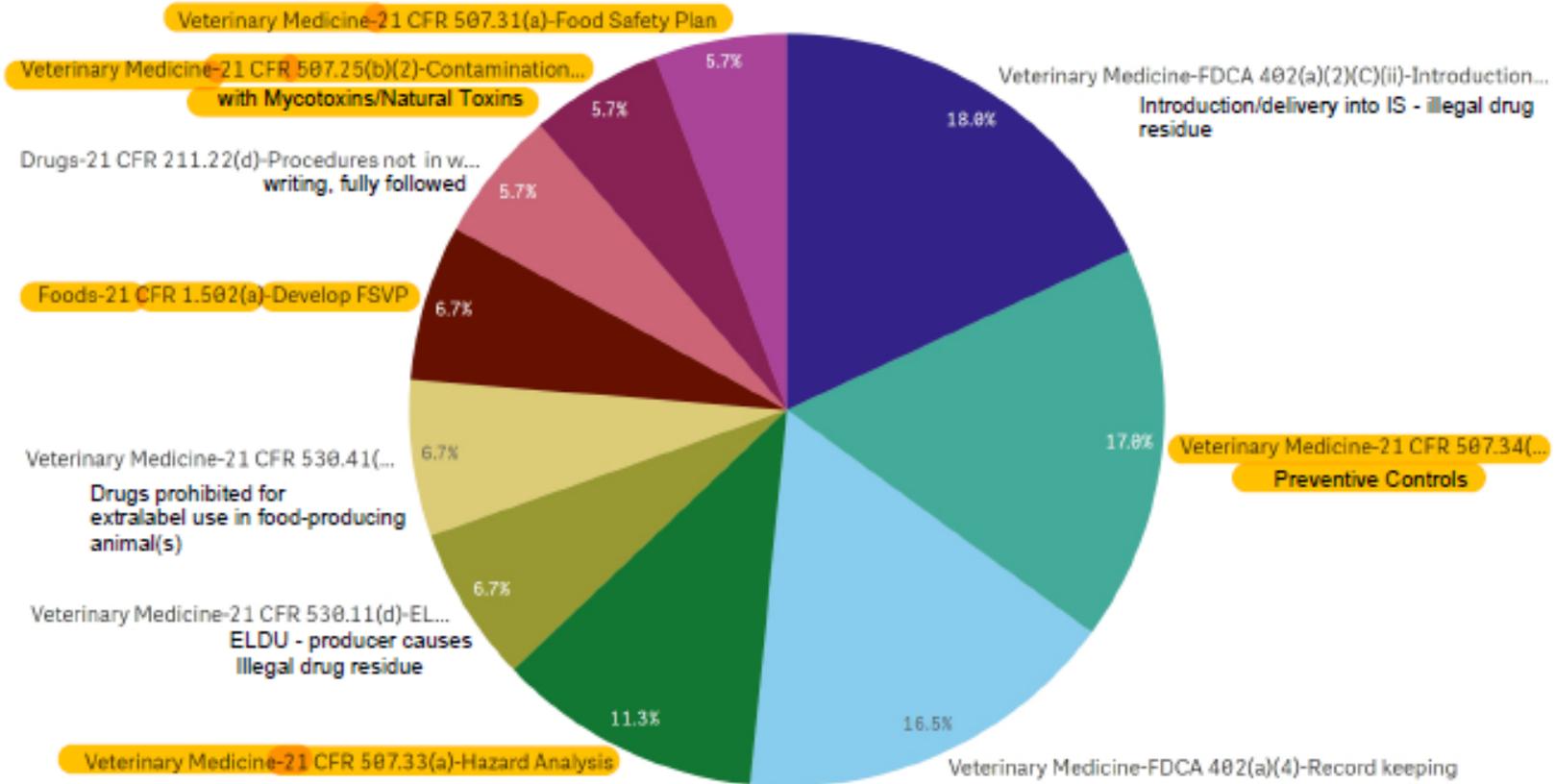
# ASK THE EXPERTS: ANIMAL FOOD

# FDA CVM INSPECTION TRENDS

# FDA CVM: FY2025

## Top 10 Citations

Fiscal Years: 2025



# 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.*

# 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**

# Components of a Food Safety Plan

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  - 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**

# 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.*

# Reanalysis Timeframe

## 21 CFR 507.50 Reanalysis

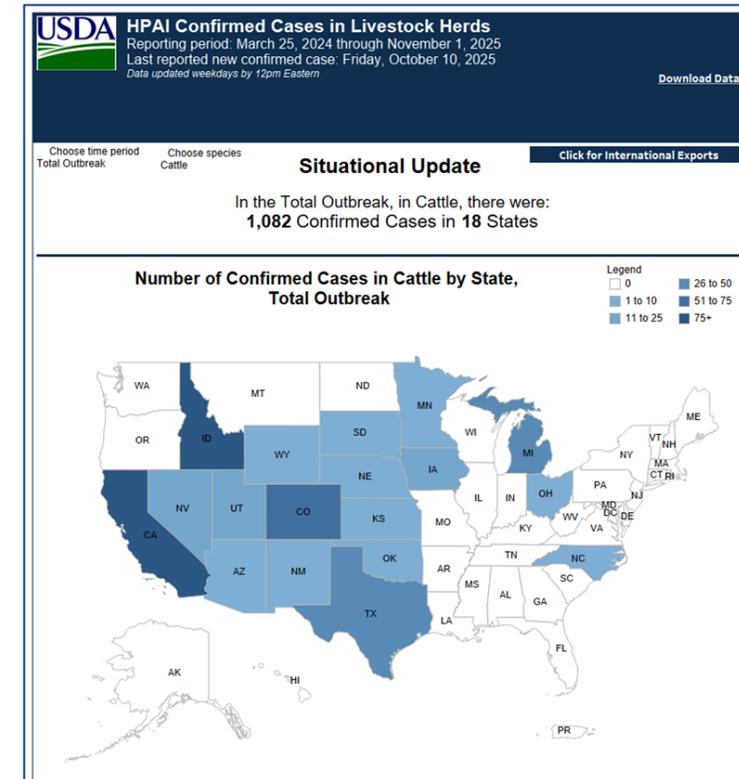
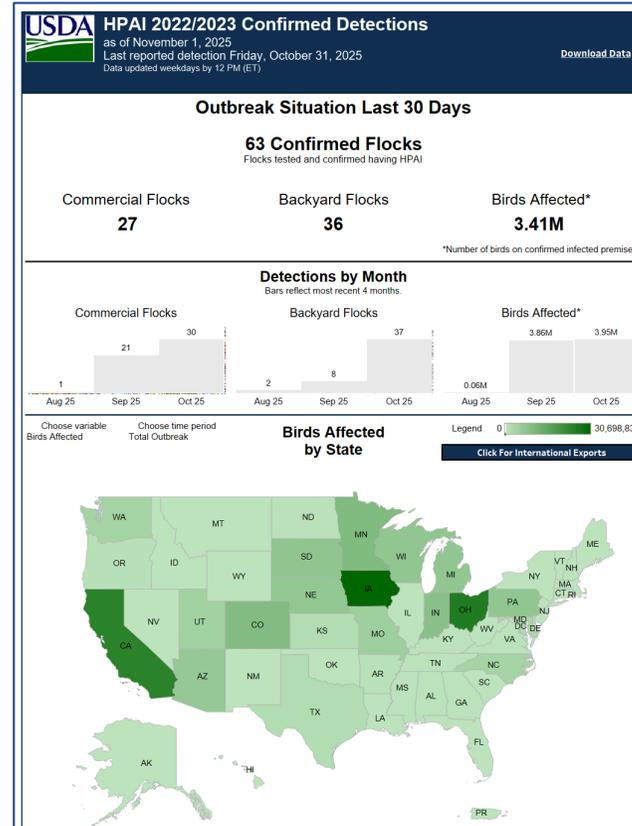
- *(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified;*
  - *(1) Before 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

# CASE STUDY: HPAI

# Highly Pathogenic Avian Influenza

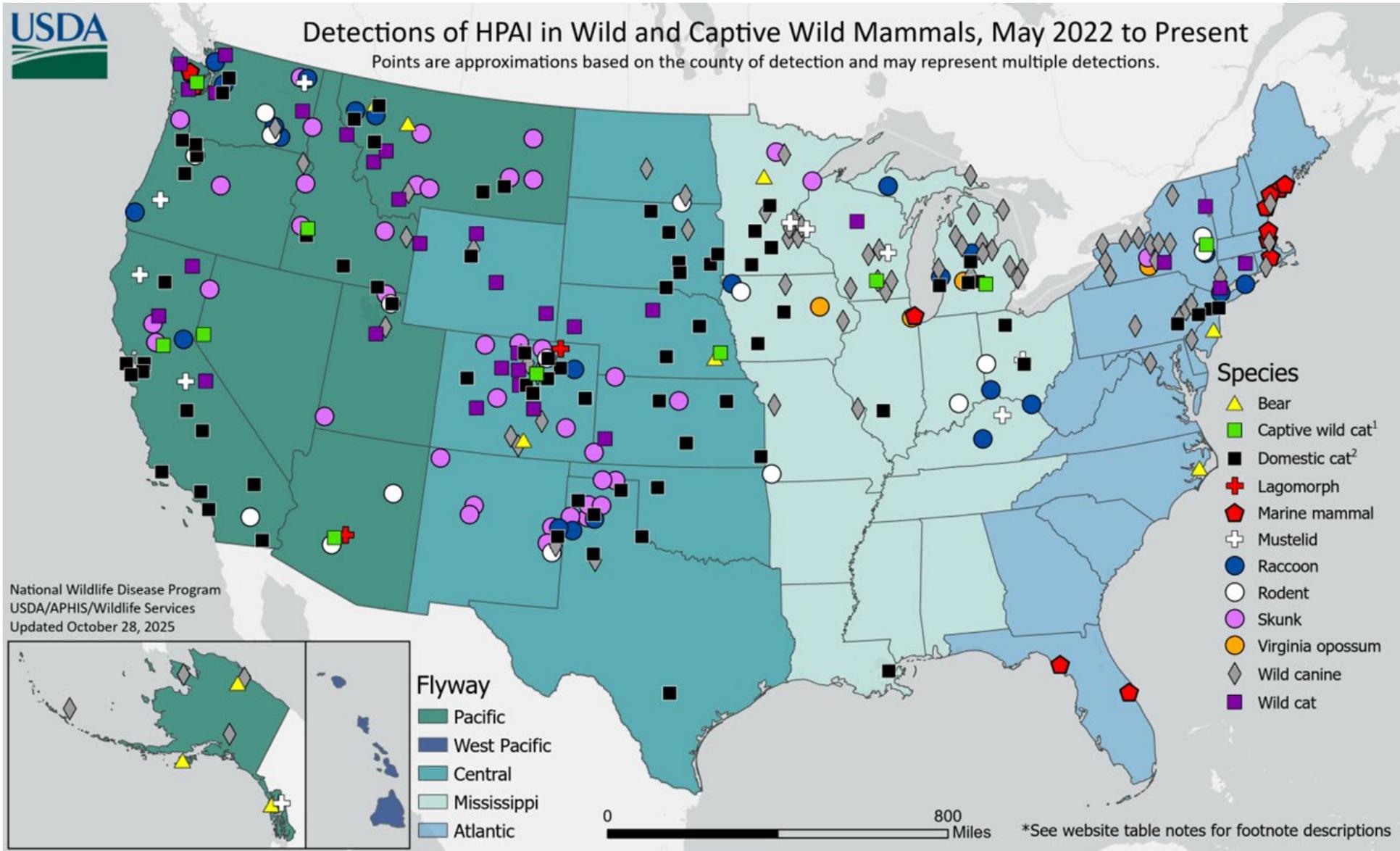
- HPAI is a highly contagious virus that primarily affects wild and domestic birds and is carried by migratory waterfowl.
- Around the country, the virus has been detected in various species of wild carnivorous mammals





# Detections of HPAI in Wild and Captive Wild Mammals, May 2022 to Present

Points are approximations based on the county of detection and may represent multiple detections.



National Wildlife Disease Program  
USDA/APHIS/Wildlife Services  
Updated October 28, 2025

### Flyway

- Pacific
- West Pacific
- Central
- Mississippi
- Atlantic

### Species

- Bear
- Captive wild cat<sup>1</sup>
- Domestic cat<sup>2</sup>
- Lagomorph
- Marine mammal
- Mustelid
- Raccoon
- Rodent
- Skunk
- Virginia opossum
- Wild canine
- Wild cat

# State Notifications of Pet Deaths



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.**

The screenshot shows the Washington State Department of Agriculture (WSDA) website. The header includes navigation links for WASHINGTON AGRICULTURE, SERVICES, DEPARTMENTS, ABOUT WSDA, and CONTACT US, along with a search icon and a menu icon. A blue banner below the header contains the text "WHAT DO YOU NEED TODAY?" and a "LET'S FIND IT" button. The main content area features a news article titled "WASHINGTON CATS CONFIRMED WITH HPAI AS INVESTIGATION INTO CONTAMINATED PET FOOD CONTINUES". The article includes a release date of 2/26/2025, media contact information for Amber Betts (360-628-3477), and a public inquiries section. The article text describes the confirmation of HPAI in cats in Washington, the recall of contaminated pet food by Northwest Naturals, and the WSDA's investigation and public health alert.



# 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

**Document ID**  
FDA-2024-N-2979-0001

**Comments Received**  
32  
[More Details](#)

**Document Details**

**Comment Due Date**  
Dec 9, 2024

**Federal Register Number**  
2024-17779

**Document Subtype**  
Request for Comments

**Content**

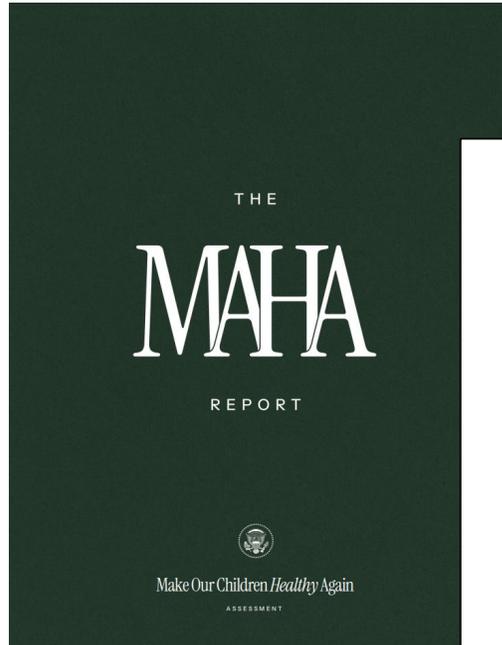
**ACTION:**  
Notice; request for comments.

**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.

# MAHA Assessment and Strategy Reports



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

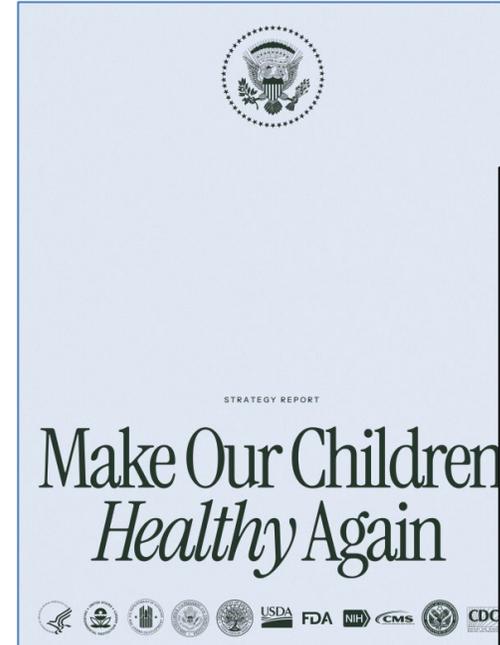
To close critical research gaps and guide efforts to better combat childhood chronic disease in America, the following research initiatives are recommended:

- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- Drug Safety Research:** Support studies on long-term neurodevelopmental and metabolic outcomes of commonly prescribed pediatric drugs, emphasizing real-world settings and meaningful endpoints.
- 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.
- 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.

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MAKE AMERICA HEALTHY AGAIN **MAHA** PRESIDENT DONALD J. TRUMP 72



## 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.

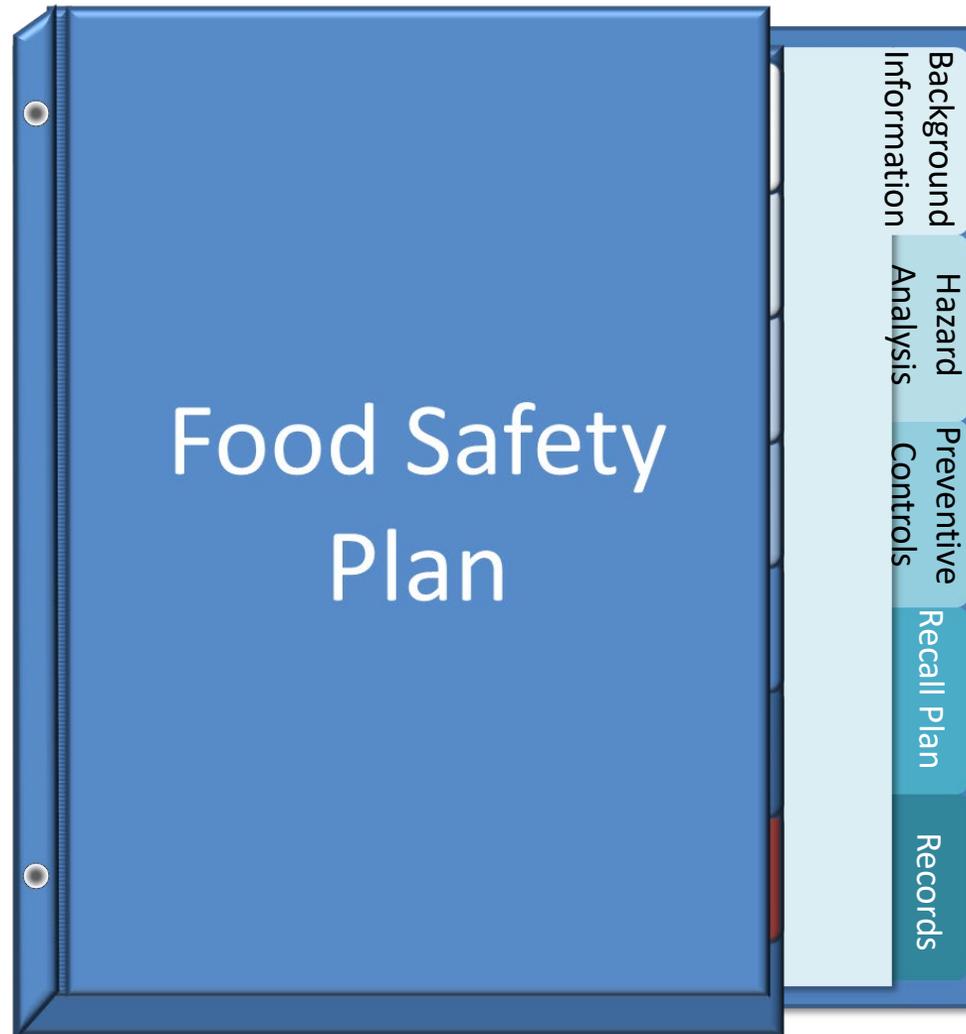
**GRAS Reform:** FDA will update regulations to reform the GRAS designation, within the scope of statutory authority, by closing the "GRAS loophole," implementing a mandatory GRAS notification program, and increasing consumer transparency with respect to substances found in our nation's food supply.

**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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MAKE AMERICA HEALTHY AGAIN **MAHA** PRESIDENT DONALD J. TRUMP 8

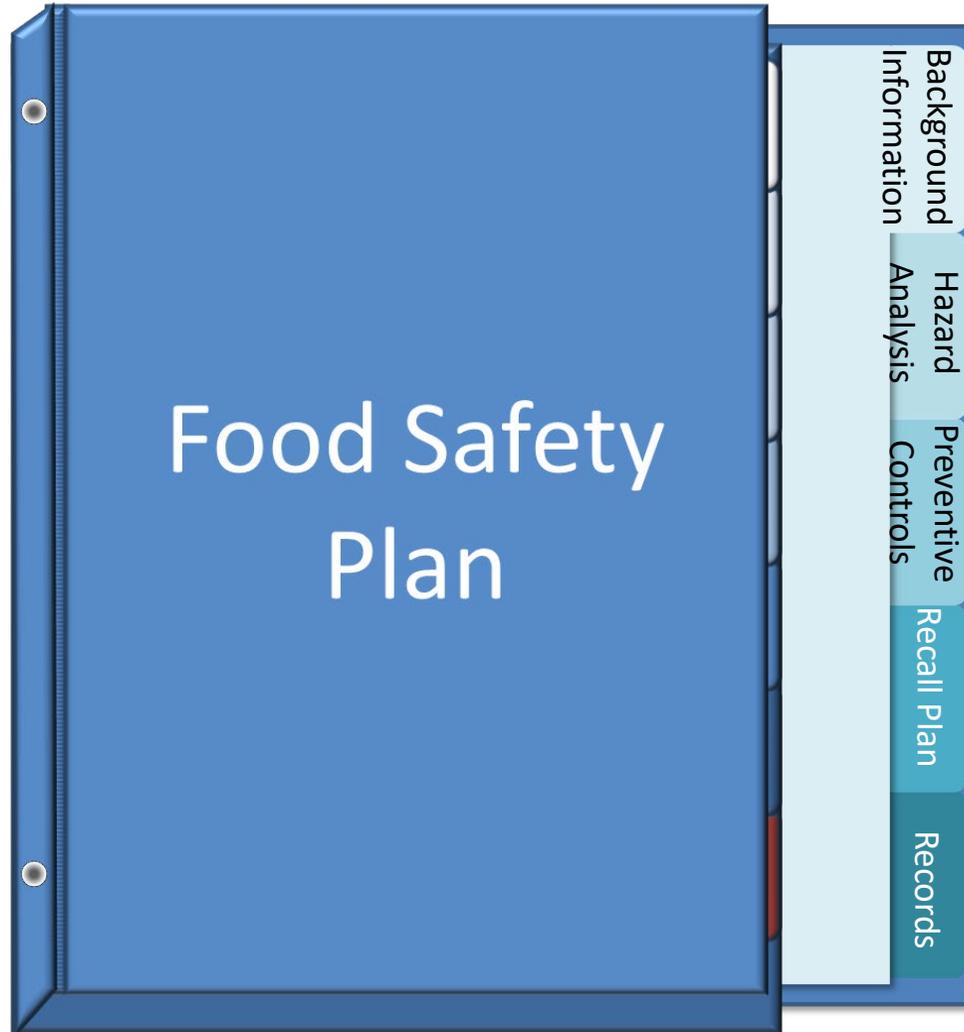
# Components of a Food Safety Plan



## Other Useful Components:

- Ingredient List

# Components of a Food Safety Plan



## Other Useful Components:

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

# 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.

# Government Shutdown: Animal Food

6        *SEC. 785. The Commissioner of the Food and Drug*  
7        *Administration shall develop a report to determine the cost*  
8        *and any implications associated with efforts to issue a pro-*  
9        *posed rule and implement FDA guidance and enforcement*  
10       *for setting standards for pet and animal food labeling and*  
11       *ingredient regulation: Provided, That the report shall—*  
12                *(1) cover intent for harmonization across state*  
13        *and Federal regulatory bodies for pet and animal*  
14        *food labeling and ingredients;*  
15                *(2) include timelines for developing guidelines,*  
16        *proposed regulations, resource and personnel needs to*  
17        *implement such standards, and where FDA would*  
18        *need additional authority to implement any proposed*  
19        *changes; and*  
20        *be submitted to the House and Senate Committees on Ap-*  
21        *propriations 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.**

# CLOSING

# UNDERSTANDING THE NEW APPROACH TO HAZARD ANALYSIS 2.0 – FAQS

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FSMA SOLUTIONS; FSPCA EAB CHAIR

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SEAFOOD PRODUCTS ASSOCIATION (SPA)

**MODERATOR: JASON WAN**



# New Hazard Analysis Approach

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## 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

Contains Non-binding Recommendations  
Draft-Not for Implementation

Ingredient-Related Hazards (Inherent hazards)

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 <sup>1</sup>	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 <sup>1</sup> - 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 <sup>1</sup> - 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

<b>BIOLOGICAL HAZARDS</b> A1.7.1	<p><b>Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment</b> 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.</p> <p><b>Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control</b> For example, a cooling mechanism that does not function as intended could allow a small number of microbial pathogens to increase in number.</p> <p><b>Bacterial pathogens – Growth and/or toxin production due to poor formulation control</b> For example, if insufficient acid is added to reduce the pH sufficiently in an acidified food, pathogenic sporeformers could grow and produce toxin.</p> <p><b>Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging</b> For example, reduced oxygen packaging that is used to increase shelf life could create an environment that supports the growth of <i>C. botulinum</i>.</p> <p><b>Bacterial pathogens – Presence due to ingredients added after process controls</b></p> <p><b>Bacterial pathogens – Presence, growth, or toxin production due to recontamination due to lack of container integrity</b> For example, if a container is not properly sealed and it is cooled in water, water containing pathogens can be drawn into the container.</p> <p><b>Environmental pathogens – presence due to recontamination from the processing environment</b> 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.</p>
<b>CHEMICAL HAZARDS</b> A1.7.2	<p><b>Undeclared food allergens – Incorrect label</b> Examples include: a label printed incorrectly, labels are not changed after product formulation changes, and when a label is applied to the wrong product.</p> <p><b>Unintended food allergen presence – allergen cross-contact</b> 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).</p> <p><b>Chemical hazards due to misformulation (e.g., sulfites, yellow #5)</b> 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.</p> <p><b>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)</b> 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.</p>
<b>PHYSICAL HAZARDS</b> A1.7.3	<p><b>Metal</b> For example, a process that uses a metal chopping blade could introduce metal fragments if the blade breaks.</p> <p><b>Glass (when product packed in glass)</b> For example, a product packaged in glass containers could introduce glass fragments if a container breaks.</p> <p><b>Hard Plastic</b> 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.</p>

Supplier's Process-Related and Facility-Related Hazards

Process-Related and Facility-Related Hazards

# 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<sup>1</sup>

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

- A1.1 Purpose of Appendix 1
- A1.2 Terms, Abbreviations, and Resources
- A1.3 Requirement for a Hazard Analysis
- A1.4 How We Developed Appendix 1
- A1.5 Organization of Appendix 1
  - A1.5.1 Food Groups Addressed by Appendix 1
  - A1.5.2 Tables of Known or Reasonably Foreseeable Hazards ("Potential Hazards")
  - A1.5.3 Organization of Each Table in Appendix 1
  - A1.5.4 The Food Subcategories in the Tables in Appendix 1 Address Raw Materials, Other Ingredients, and Multi-Component Foods
  - A1.5.5 Food Categories/Food Subcategories that Are LACF
  - A1.5.6 Infant Formula and Other Foods for Infants and Toddlers

<sup>1</sup> 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.  
Appendix 1 (Known or Reasonably Foreseeable Hazards ("Potential Hazards")) - Page 1

- 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

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

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

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## 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

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

# GARLIC POWDER

Table 10: Known or reasonably foreseeable (“potential”) food-related biological hazards for Spices and Herbs

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>S. aureus</i>	Parasites	Viruses	Comments
Spices	1	Dried, Ground, Cracked, or Whole	Ambient	X <sup>1</sup>	X <sup>1</sup>	X <sup>1</sup>				X <sup>2</sup>					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 <sup>1</sup>	X <sup>1</sup>	X <sup>1</sup>				X <sup>2</sup>					Includes basil, oregano, thyme, sage, parsley, bay leaf, dill, rosemary, cilantro, mint, kaffir lime, chives, peppermint
Herbs	2b	Fresh	Ambient or Refrigerated							X <sup>2</sup>			X <sup>3</sup>		Includes basil, oregano, thyme, sage, parsley, bay leaf, dill, rosemary, cilantro, mint, kaffir lime, chives, peppermint

## FOOTNOTES

<sup>1</sup> 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

<sup>2</sup> FDA identified *Salmonella* spp., but not pathogenic *E. coli*...based on a 2022 FAO/WHO report.

# RAW GARLIC

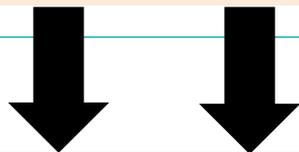
Table 2H: Known or reasonably foreseeable (“potential”) food-related chemical hazards for Fruits and Vegetables<sup>1</sup>

Category	# <sup>1</sup>	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 <sup>2</sup>		Includes apple products, dried fruits, dried beans and peas

<sup>1</sup> 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  <b>Garlic Powder</b>	(2) Identify <u>potential</u> food safety hazards introduced, controlled, or enhanced at this step		(3) Do any <u>potential</u> 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? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
 <b>Ingredient-related hazards (inherent hazards)</b>	B	<i>Salmonella</i>						
	B	Sporeforming pathogens: <i>(C. botulinum, C. perfringens, B. cereus)</i>						
	C	Pesticides						
	C	Lead						

## FAQs

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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?

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

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

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

# 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)
<b>Nitrogen</b>	<p><b>None</b> P. 46  <b>Table 1C:</b> Misc. Food Additives, Color Additives, and GRAS Substances  <b>Category (6e):</b> Other Chemical Ingredients  <b>Subcategory:</b> Processing Aid Gases</p>	<p><b>None</b> P. 82  <b>Table 2C:</b> Misc. Food Additives, Color Additives, and GRAS Substances  <b>Category:</b> None listed for Other Chemical Ingredients only Nutrients</p>
<b>Raw, shelled peanuts</b>	<p><b>Pathogenic <i>E. coli</i>, <i>Salmonella</i>, <i>L. mono.</i></b> P. 66  <b>Table 1K:</b> Nuts and Seeds  <b>Category (1a):</b> Nuts  <b>Subcategory:</b> Peanuts, Raw</p>	<p><b>Mycotoxins and Pesticides</b> P. 91. <b>see footnote<sup>1</sup> for applicable mycotoxin (Aflatoxin).</b>  <b>Table 2K:</b> Nuts and Seeds  <b>Category (1a):</b> Nuts  <b>Subcategory:</b> Peanuts, Raw and treated</p>

# 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	<p><i>Salmonella</i>. P 74.</p> <p><i>B. cereus, Clostridium botulinum, Clostridium perfringens</i>, see footnote P. 75 only applicable when these products becomes hydrated or used as ingredient in-high moisture food.</p> <p><b>Table 10:</b> Spices and Herbs <b>Category (1):</b> Spices <b>Subcategory:</b> Dried, Ground, Cracked, or Whole</p>	<p><b>Pesticides.</b> P. 95. <b>Table 20:</b> Spices and Herbs <b>Category (1):</b> Spices <b>Subcategory:</b> Dried, Ground, Cracked, or Whole</p>

**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 <u>potential</u> food safety hazards introduced, controlled, or enhanced at this step		(3) Do any <u>potential</u> 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? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Ingredient-related hazards (inherent hazards)	B	Salmonella			<div data-bbox="1039 692 1549 873" data-label="Text"> <p>Ingredient-Related Hazards (Inherent Hazards) ✓</p> </div>			
	B	Sporeforming pathogens: ( <i>C. botulinum</i> , <i>C. perfringens</i> , <i>B. cereus</i> )						
	C	Pesticides						
	C	Lead						
Supplier process-related and facility-related hazards	B	?			<div data-bbox="988 968 1523 1149" data-label="Text"> <p>AND Supplier's Process-Related and Facility-Related Hazards</p> </div>			
	C	?						
	P	?						



# 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
<b>BIOLOGICAL HAZARDS</b> <b>A1.7.1</b>	Bacterial pathogens – Presence, growth, or toxin production due to <b>survival of a lethal treatment</b>
	Bacterial pathogens – Growth and/or toxin production due to <b>poor time/temperature control</b>
	Bacterial pathogens – Growth and/or toxin production due to <b>poor formulation control</b>
	Bacterial pathogens – Growth and/or toxin production due to <b>reduced oxygen packaging</b>
	Bacterial pathogens – Presence due to <b>ingredients added after process controls</b>
	Bacterial pathogens – Presence, growth, or growth with toxin production due to <b>recontamination due to lack of container integrity</b>
	Environmental pathogens – presence due to <b>recontamination from the processing environment</b>
<b>CHEMICAL HAZARDS</b> <b>A1.7.2</b>	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)
<b>PHYSICAL HAZARDS</b> <b>A1.7.3</b>	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?



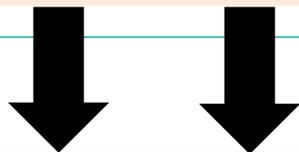
- The U.S. based supplier dries and grinds raw garlic into powder which has  $a_w$  0.52
- The raw garlic is sourced from a U.S. grower
- The garlic powder supplier verifies proper use of pesticides on the raw whole garlic by the U.S. grower
- The garlic powder supplier uses a “microbial reduction treatment”:
  - 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
<b>BIOLOGICAL HAZARDS</b> A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to <b>survival of a lethal treatment</b>	<b>Yes</b> – Potential (if not properly irradiated)
	Bacterial pathogens – Growth and/or toxin production due to <b>poor time/temperature control</b>	<b>No</b> – Shelf stable
	Bacterial pathogens – Growth and/or toxin production due to <b>poor formulation control</b>	<b>Not applicable</b> – Not formulated for safety
	Bacterial pathogens – Growth and/or toxin production due to <b>reduced oxygen packaging (ROP)</b>	<b>Not applicable</b> – Not packaged in ROP
	Bacterial pathogens – Presence due to <b>ingredients added after process controls</b>	<b>Not applicable</b> – No ingredients added after irradiation
	Bacterial pathogens – Presence, growth, or growth with toxin production due to <b>recontamination due to lack of container integrity</b>	<b>Not applicable</b> – Not packaged in hermetically sealed container
	Environmental pathogens – presence due to <b>recontamination from the processing environment</b>	<b>No</b> - Garlic powder is irradiated in the package - no exposure to the environment
<b>CHEMICAL HAZARDS</b> A1.7.2	Undeclared food allergens – incorrect label	<b>Not applicable</b> – no allergens present in garlic powder
	Unintended food allergen presence – allergen cross-contact	<b>Not applicable</b> – The garlic supplier does not handle any allergens
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)	<b>Not applicable</b> – 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)	<b>Not applicable</b>
<b>PHYSICAL HAZARDS</b> A1.7.3	Metal	<b>Yes</b> – Supplier’s grinding of garlic may result in metal contamination
	Glass (when product packed in glass)	<b>Not applicable</b> – Not packed in glass
	Hard Plastic	<b>Not applicable</b> – Hard plastic not used by supplier



**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 <u>potential</u> food safety hazards introduced, controlled, or enhanced at this step		(3) Do any <u>potential</u> 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? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Ingredient-related hazards (inherent hazards)	B	<i>Salmonella</i>			<p style="text-align: center;">Ingredient-Related Hazards (Inherent Hazards) ✓</p>			
	B	Sporeforming pathogens: ( <i>C. botulinum</i> , <i>C. perfringens</i> , <i>B. cereus</i> )						
	C	Pesticides						
	C	Lead						
Supplier process-related and facility-related hazards	B	Recontamination with environmental pathogens <i>Salmonella</i>			<p style="text-align: center;">AND Supplier's Process-Related and Facility-Related Hazards ✓</p>			
	P	Metal						



# 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

Ingredient-Related Hazards (Inherent Hazards) ✓

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

2. each manufacturing process step

Manufacturing Facility Process-Related and Facility-Related Hazards

## 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? <i>Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control</i>	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Ingredient-related hazards (inherent hazards)	B	<i>Salmonella</i>	X		<i>Salmonella</i> 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: ( <i>C. botulinum</i> , <i>C. perfringens</i> , <i>B. cereus</i> )		X	<i>C. botulinum</i> , <i>C. perfringens</i> and <i>B. cereus</i> 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 <i>Salmonella</i>		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

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

<sup>1</sup> 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.

<sup>2</sup> Depending on the ingredients there could be other hazards. Refer to other tables for the ingredients.

<sup>3</sup> 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.)

<sup>4</sup> The SMEs identified this as a known or reasonably foreseeable (“potential”) biological hazard applicable only when the beverage includes an herb.

<sup>5</sup> See **Table 1J** for the known or reasonably foreseeable (“potential”) biological hazards associated with the applicable roasted grain.

# Exceptionally Lethal – FDA Hazard Guide

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## **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).

# A NEW PARADIGM FOR DOMESTIC FOOD SAFETY INSPECTIONS



PANELIST  
**ERIK METTLER**

U.S. FOOD AND DRUG  
ADMINISTRATION  
(FDA)



PANELIST  
**STEVEN MANDERNACH**

ASSOCIATION OF  
FOOD AND DRUG  
OFFICIALS (AFDO)



PANELIST  
**KATHERINE SIMON**

MINNESOTA  
DEPARTMENT OF  
AGRICULTURE



MODERATOR  
**JERRY WOJTALA**

INTERNATIONAL FOOD  
PROTECTION TRAINING  
INSTITUTE (IFPTI)



# AWARDS PRESENTATION

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

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

**KATHY GOMBAS**  
FSMA SOLUTIONS, FSPCA EAB CHAIR

# LIFETIME ACHIEVEMENT AWARD

In recognition of contributions and support to FSPCA  
and a lasting impact on Global Food Safety



DAVID  
FAIRFIELD

# 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.



# VOLUNTEER OF THE YEAR AWARD

In recognition and appreciation for exceptional dedication and service to FSPCA.



JUAN L.  
SILVA

# JUAN SILVA

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.





## 1000 CLUB

IN RECOGNITION OF TRAINING 1000 OR MORE PARTICIPANTS, CUMULATIVELY IN THE FOUR FSPCA TRAINING CURRICULA, WITH FSPCA CERTIFICATES ISSUED.

## 2025 1000 Club Members

---

- Gary Huddleston
- Nancy Johnson
- Yukio Kaizawa
- Jenifer Kane
- Kathy Knutson
- Cathy Martin
- Edna Negrón
- Mauricio Rousselon
- Jeffrey Strout



# GARY HUDDLESTON

1000 CLUB



# KATHY KNUTSON

1000 CLUB



# CATHY MARTIN

1000 CLUB



# EDNA NEGRÓN

1000 CLUB



# MAURICIO ROUSSELON

1000 CLUB



# JEFFREY STROUT

1000 CLUB



# TOP TEN FSPCA LEAD INSTRUCTORS

IN RECOGNITION OF THE NUMBER OF PARTICIPANTS TRAINED (INSTRUCTOR-LED) WITH FSPCA CERTIFICATES ISSUED BETWEEN AUGUST 15, 2024, AND AUGUST 15, 2025.

# 2025 Top Ten Lead Instructors – Animal Food

---

- David Fairfield
- Gary Huddleston
- Teerانات Limpichotikul
- Chris Lincecum
- Rachel Montgomery
- Alicia Moore
- Jose Sabal
- Christopher Snabes
- Charles Starkey
- Jedsada Tipmontian



# GARY HUDDLESTON

ANIMAL FOOD



# CHRIS LINCECUM

ANIMAL FOOD



**JOSE SABAL**

ANIMAL FOOD



# CHRISTOPHER SNABES

ANIMAL FOOD



# JEDSADA TIPMONTIAN

ANIMAL FOOD

# 2025 Top Ten Lead Instructors – FSVP

---

- Bob Bauer
- Lindsey Bowen
- Bartosz Dobek
- Jin Kim
- Eduardo Lecea
- Rachel Montgomery
- Nari Nayini
- Jose Sabal
- Bitu Saidi
- Martin Torres



# BOB BAUER

FSVP



# BARTOSZ DOBEK

FSVP



**JIN KIM**

FSVP



# EDUARDO LECEA

FSVP



**NARI NAYINI**

FSVP



**JOSE SABAL**

FSVP

# 2025 Top Ten Lead Instructors – Human Food

---

- Jeanne Alba Luna
- Marisol Alejandra Acuña Canales
- Jeff Chilton
- Kathy Knutson
- Eduardo Lecea
- Hipolito Nava Cruz
- Nari Nayini
- Derrick Lee Payne
- Leonard Steed
- Jedsada Tipmontian



# JEANNE ALBA LUNA

HUMAN FOOD



# MARISOL ALEJANDRA ACUÑA CANALES

HUMAN FOOD



**JEFF CHILTON**

HUMAN FOOD



# KATHY KNUTSON

HUMAN FOOD



**EDUARDO LECEA**

HUMAN FOOD



# HIPOLITO NAVA CRUZ

HUMAN FOOD



**NARI NAYINI**

HUMAN FOOD



# JEDSADA TIPMONTIAN

HUMAN FOOD

# 2025 Top Ten Lead Instructors – Intentional Adulteration

---

- Maria Cecilia Cascabelo
- Jorge Descalzo
- Satoshi Imanari
- Tania Martinez
- Kyota Murai
- Wonjun Oh
- Jirakorn Prasertcheeva
- Lance Roberie
- Jedsada Tipmontian
- David Wankowski



## JORGE DESCALZO

IA VA



**SATOSHI IMANARI**

IA VA



**TANIA MARTINEZ**

IA VA



**KYOTA MURAI**

IA VA



## LANCE ROBERIE

IA VA



## JEDSADA TIPMONTIAN

IA VA



# CLOSING REMARKS

**JASON WAN, PHD**

INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)



# FSPCA 2025 ANNUAL CONFERENCE

STRENGTHENING THE FOOD SUPPLY CHAIN  
THROUGH EDUCATION, TRAINING AND OUTREACH



# WELCOME BACK

JASON WAN, PHD

INSTITUTE FOR FOOD SAFETY AND HEALTH (IFSH)



# MATTHEW J. BOTOS TRIBUTE

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

**KATHY GOMBAS**  
FSMA SOLUTIONS, FSPCA EAB CHAIR





Official Obituary of

# Matthew J. Botos

June 5, 1974 - December 23, 2024

Obituary & Events

Tribute Wall

<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>



## Matt Botos Memorial Scholarship

Remembering Matt Botos:  
Investing in the Future of Food Safety

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

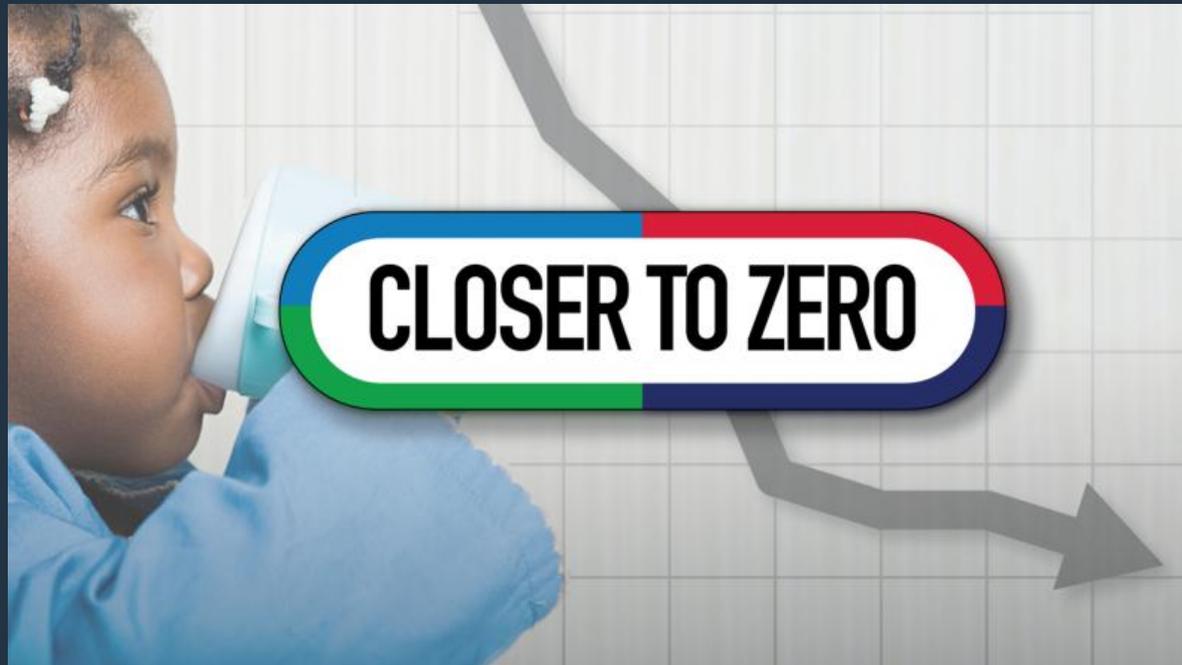
# Reducing Toxic Element Exposure: Contaminant Overview

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

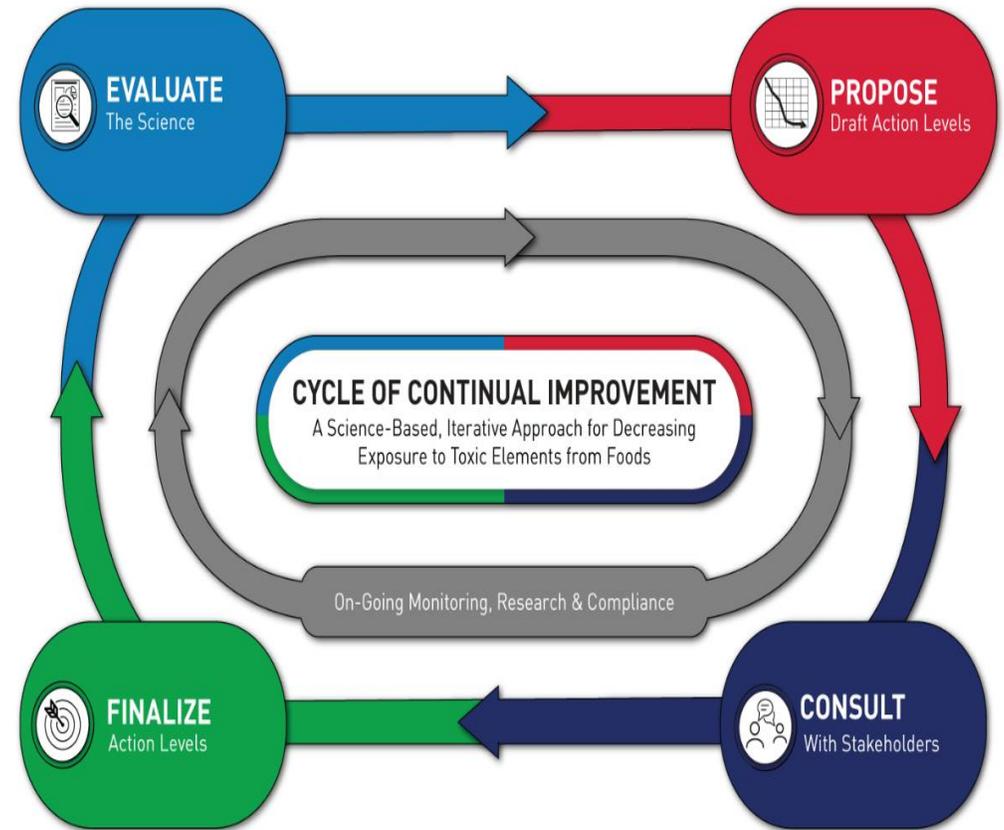
FDA engages industry and experts to ensure proposed levels are feasible.

## Finalization and Enforcement

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



## Understanding the FDA's Approach



## 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

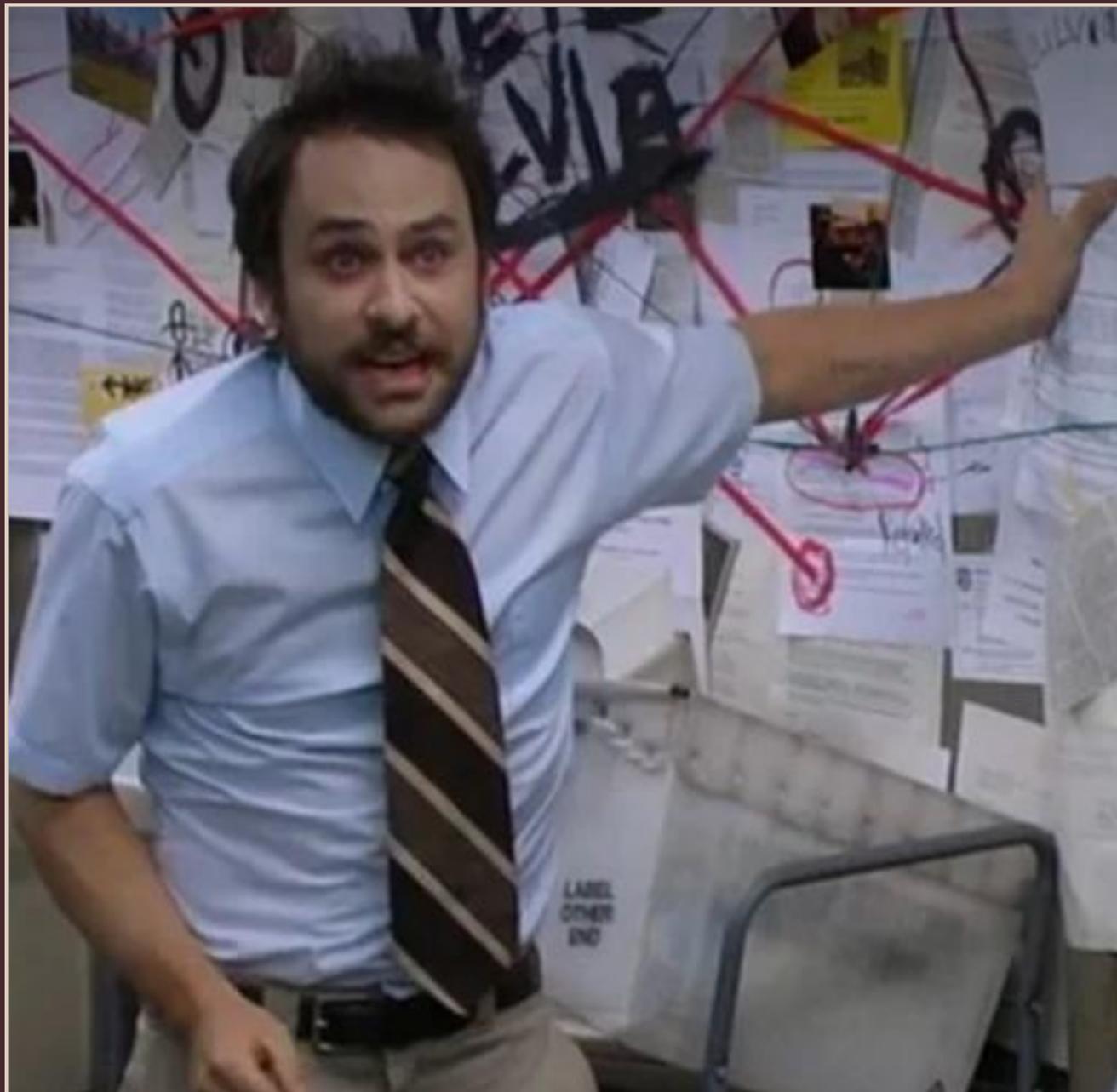
Encouragement to push towards As Low As Reasonably Achievable (ALARA) levels'

## 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



# 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**

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# Addressing Chemical Hazards: Approaches and Resources

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



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
<b>BIOLOGICAL HAZARDS</b> <b>A1.7.1</b>	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
<b>CHEMICAL HAZARDS</b> <b>A1.7.2</b>	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)
<b>PHYSICAL HAZARDS</b> <b>A1.7.3</b>	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/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS+193-1995%252FCXS\\_193e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/fr/?Ink=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

U.S. Department of Health & Human Services

**FDA U.S. FOOD & DRUG ADMINISTRATION**

## Chemical Contaminants Transparency Tool

[FDA Home](#)
[Chemical Contaminants & Pesticides](#)
[Food Chemical Safety](#)
[Chemical Contaminants Transparency Tool](#)

The FDA has published a variety of contaminant levels for poisonous or deleterious substances in human food in various guidance documents and regulations for industry. For ease of reference, the Chemical Contaminants Transparency Tool provides a consolidated list of these levels. Contaminant levels listed in the transparency tool include tolerances, action levels, guidance levels, derived intervention levels, recommended maximum levels, and advisory levels. Tolerances and action levels are defined in 21 Code of Federal Regulations (CFR) parts 109 and 509. Other types of contaminant levels are not defined in the regulation but have been used to advise industry on levels of contamination that may pose a health risk or may be avoidable through good manufacturing practices.

Basic Search **Advanced Search** Field Search

Search:  Show Items Clear

Records Found: 301 Show All Page 1 of 7

Contaminant (sorted A-Z)	Commodity	Contaminant Level Type	Levels	Reference†	Notes
3-Monochloropropane-1,2-Diol (3-MCPD)	Acid-hydrolyzed protein and Asian-style sauces	Guidance Level	1 ppm	CPG 500.500	
Aflatoxin, M1	Milk	Action Level	0.5 ppb	CPG 527.400	
Aflatoxins, total	Brazil nuts	Action Level	20 ppb	CPG 570.200	
Aflatoxins, total	Foods	Action Level	20 ppb	CPG 555.400	
Aflatoxins, total	Peanuts and peanut products	Action Level	20 ppb	CPG 570.375	
Aflatoxins, total	Pistachio nuts	Action Level	20 ppb	CPG 570.500	

### 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

apps.ams.usda.gov/pdp

**USDA** United States Department of Agriculture  
Agricultural Marketing Service

[New Search](#) [PDP Website](#) [About PDP](#) [Commodity History](#) [Pesticide History](#) [Lookup Tables](#) [Data Dictionary \(pdf\)](#) [User Guide \(pdf\)](#) [Help](#) [Contact Us](#)

### PDP Database Search

<input type="checkbox"/> Check All Commodities	<input type="checkbox"/> Check All Pesticides	<input type="checkbox"/> Check All years	<b>Output Preference</b> Analytical Results
<input type="checkbox"/> Almonds	<input type="checkbox"/> 1,2,4-Triazole	<input type="checkbox"/> 2023	<b>Results Preference</b> Positive Detects Only  <input type="button" value="Search"/>
<input type="checkbox"/> Apple Juice	<input type="checkbox"/> 1-Naphthol	<input type="checkbox"/> 2022	
<input type="checkbox"/> Apple Sauce	<input type="checkbox"/> 2,3,5-Trimethacarb	<input type="checkbox"/> 2021	
<input type="checkbox"/> Apples	<input type="checkbox"/> 2,4,5-T	<input type="checkbox"/> 2020	
<input type="checkbox"/> Apples-Single Servings	<input type="checkbox"/> 2,4,5-TP	<input type="checkbox"/> 2019	
<input type="checkbox"/> Asparagus	<input type="checkbox"/> 2,4-D	<input type="checkbox"/> 2018	
<input type="checkbox"/> Asparagus, Canned	<input type="checkbox"/> 2,4-DB	<input type="checkbox"/> 2017	
<input type="checkbox"/> Avocado	<input type="checkbox"/> 2,4-dimethyl aniline (2,4 DMA)	<input type="checkbox"/> 2016	
<input type="checkbox"/> Baby Food - Applesauce	<input type="checkbox"/> 2,4-dimethylphenyl formamide (2,4-DMPF)	<input type="checkbox"/> 2015	
<input type="checkbox"/> Baby Food - Carrots	<input type="checkbox"/> 2,6-dichlorobenzamide	<input type="checkbox"/> 2014	
<input type="checkbox"/> Baby Food - Green Beans	<input type="checkbox"/> 2,6-DIPN	<input type="checkbox"/> 2013	
<input type="checkbox"/> Baby Food - Peaches	<input type="checkbox"/> 3,5-Dichloroaniline	<input type="checkbox"/> 2012	
<input type="checkbox"/> Baby Food - Pears	<input type="checkbox"/> 3-Hydroxycarbofuran	<input type="checkbox"/> 2011	
<input type="checkbox"/> Baby Food - Peas	<input type="checkbox"/> 3-ketocarbofuran	<input type="checkbox"/> 2010	
<input type="checkbox"/> Baby Food - Sweet Potatoes	<input type="checkbox"/> 4,4-dibromobenzophenone	<input type="checkbox"/> 2009	
<input type="checkbox"/> Bananas	<input type="checkbox"/> 4-Hydroxychlorothalonil	<input type="checkbox"/> 2008	
<input type="checkbox"/> Barley	<input type="checkbox"/> 4-Hydroxydiphenylamine	<input type="checkbox"/> 2007	



# 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



## 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

efsa EUROPEAN FOOD SAFETY AUTHORITY

## Chemical hazards

Substance Browser | Reference Values | Reference Points | Background Documents

### Substance Browser

Searching tab according to substance name, CAS number and/or EC number

Substance	Substance Characterisation	Hazard Characterisation	Genotoxicity	EFSA Outputs			
<input type="text" value="Search Substance"/>	<i>Click on a Substance to see its Synonyms</i>						
Substance	Author	Published	Output ID	Title	Output Type	Legal Basis	URL
(8,9-Z)-isomer of avermectin B1a	EFSA	08/30/2022	4182	Peer review of the pesticide risk assessment of the active substance abamectin	Conclusion on Pesticides Peer Review	Commission Regulation No 844/2012	<a href="http://dx.doi.org/10.2903/j.efsa.2022.7544">http://dx.doi.org/10.2903/j.efsa.2022.7544</a>
24-hydroxymethyl-avermectin B1	EFSA	08/30/2022	4182	Peer review of the pesticide risk assessment of the active substance abamectin	Conclusion on Pesticides Peer Review	Commission Regulation No 844/2012	<a href="http://dx.doi.org/10.2903/j.efsa.2022.7544">http://dx.doi.org/10.2903/j.efsa.2022.7544</a>
Abamectin	EFSA	08/30/2022	4182	Peer review of the pesticide risk assessment of the active substance abamectin	Conclusion on Pesticides Peer Review	Commission Regulation No 844/2012	<a href="http://dx.doi.org/10.2903/j.efsa.2022.7544">http://dx.doi.org/10.2903/j.efsa.2022.7544</a>
					Conclusion on		

# 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



[Guidance Documents & Regulatory Information by Topic \(Food and Dietary Supplements\)](#) / [Chemical, Metals, Natural Toxins & Pesticides Guidance Documents & Regulations](#)

## Chemical, Metals, Natural Toxins & Pesticides Guidance Documents & Regulations

Chemical, Metals, Natural  
Toxins & Pesticides  
Guidance Documents &  
Regulations

*Guidance documents contain nonbinding recommendations.*

For additional information, see the [Chemicals, Metals & Pesticides in Food](#) section.

Content current as of:  
01/06/2025

Regulated Product(s)  
Food & Beverages

### Chemical

- **Acrylamide:** [Guidance for Industry: Acrylamide in Foods](#) (March 2016)
- **Dioxins & PCBs:** [Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products \(PDF - 7.7KB\)](#) (August 1999)
- **Melamine:** ["Dear Colleague" Letter to the United States Food Manufacturing Industry, Regarding Melamine](#) [↗](#) (October 10, 2008)



# 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](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



The screenshot shows the FAO website page for the International Food Safety Authorities Network (INFOSAN). The page header includes the FAO logo and the text "Food and Agriculture Organization of the United Nations". A search bar is present with the text "ENHANCED BY Google". Below the header, there are language options: العربية, 中文, English, Français, Русский, and Español. The main content area is titled "Food safety and quality" and has a navigation menu with options: Home, Background, Food control systems, Scientific advice, Emergencies (highlighted), News, and Resources. On the left side, there is a sidebar with "INFOSAN" and "Crises" options. The main content area features the INFOSAN logo and the following text:

## International Food Safety Authorities Network (INFOSAN)

The International Food Safety Authorities Network (INFOSAN) is a global voluntary network of national authorities with a role in food safety, coordinated by a joint FAO/WHO Secretariat. National authorities of almost all of FAO and WHO Member States are part of the network. FAO and WHO have complementary roles in the management of INFOSAN.

INFOSAN, by linking relevant authorities globally, is an important communication tool for exchanging information on food safety incidents and emergencies related to internationally traded foods, facilitating rapid access to relevant information. The mission of INFOSAN is to strengthen prevention, preparedness and response to food safety incidents and emergencies through fostering a global community of practice among food safety professionals. Specifically, INFOSAN aims to:

- Promote the rapid exchange of information during food safety related events;
- Share information on important food safety related issues of global interest;
- Promote partnerships and collaboration between countries, and between networks; and
- Help countries strengthen their capacity to manage food safety emergencies.

FAO, jointly with WHO, supports national authorities in strengthening their participation in the INFOSAN network. FAO, in particular, works with countries encouraging all the relevant stakeholders in food safety, including ministries of agriculture and trade, to actively participate in the network. This networking across sectors supports the exchange of information and communication on food safety matters in general, even in the absence of an emergency.

# 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.

[KK] : Knowledge <b>Known Knowns</b>	[KU] : Awareness <b>Known Unknowns</b>
[UK] : Bias <b>Unknown Knowns</b>	[UU] : Ignorance <b>Unknown Unknowns</b>

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

Thank you!

---

Questions  
and  
Discussion



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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

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**



# Background and Key Requirements

# FSVP Rule

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- 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

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- 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.*

# Records to be Kept by the Importer

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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

# 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?

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- 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

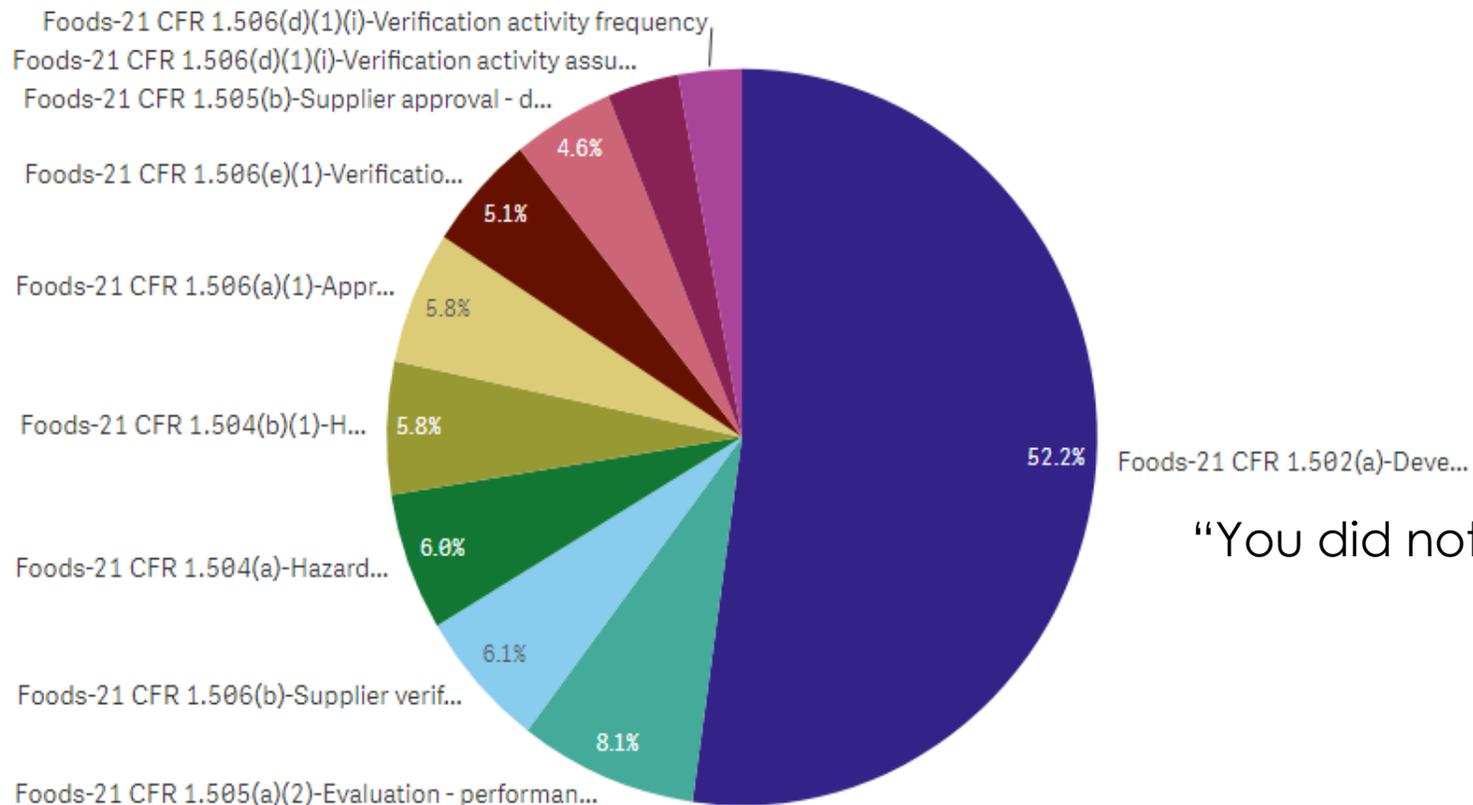
# Compliance Insights

# FSVP Top 10 Citations

## Top 10 Citations

Fiscal Years: 2017 - 2026

<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

# Narratives in compliance reports

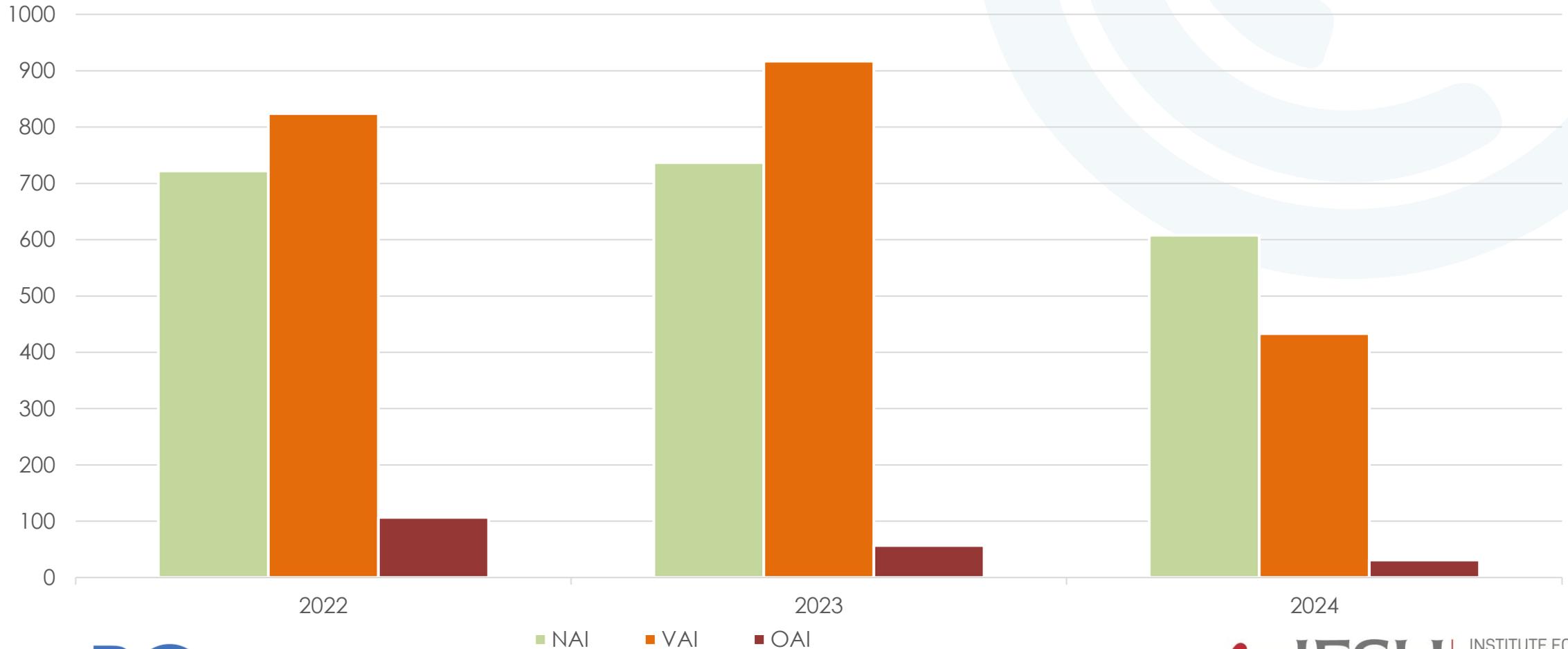
- Failure to develop an FSVP: Importers have not created a written Foreign Supplier Verification Program plan, which is a mandatory requirement under the Food Safety Modernization Act (FSMA) for most food imports.
- Inadequate supplier evaluation: Importers are failing to adequately assess the risk and 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

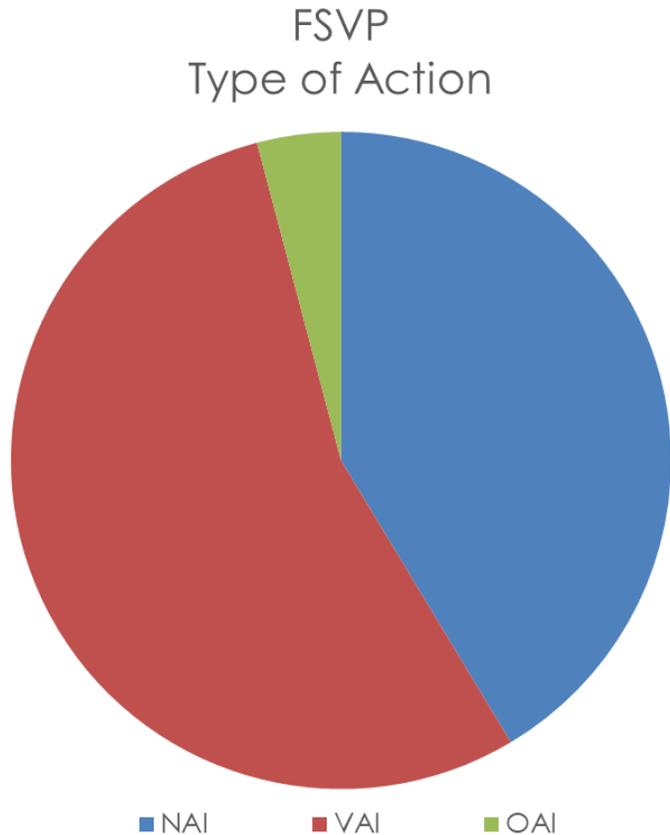
---

- “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



# FSVP Inspection Classifications



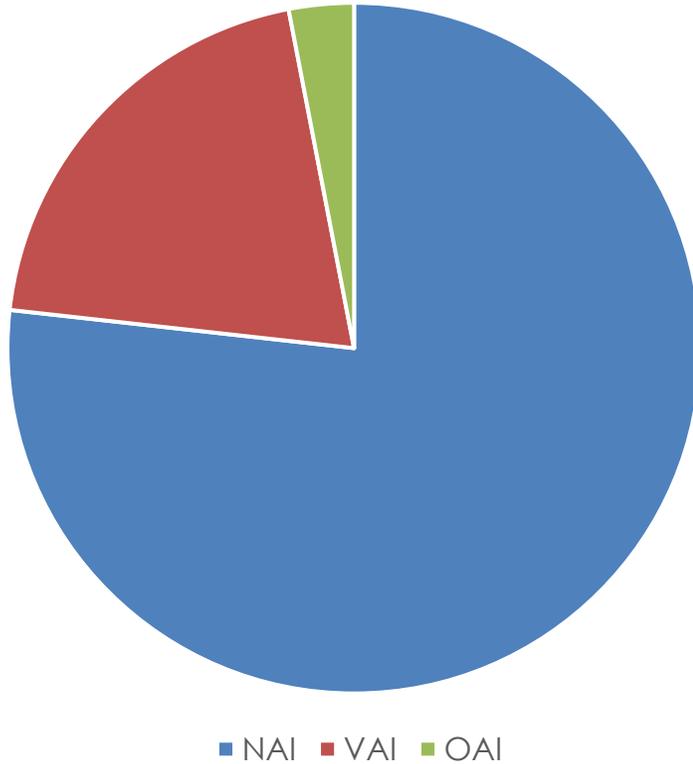
NAI 41.4%

VAI 54.5%

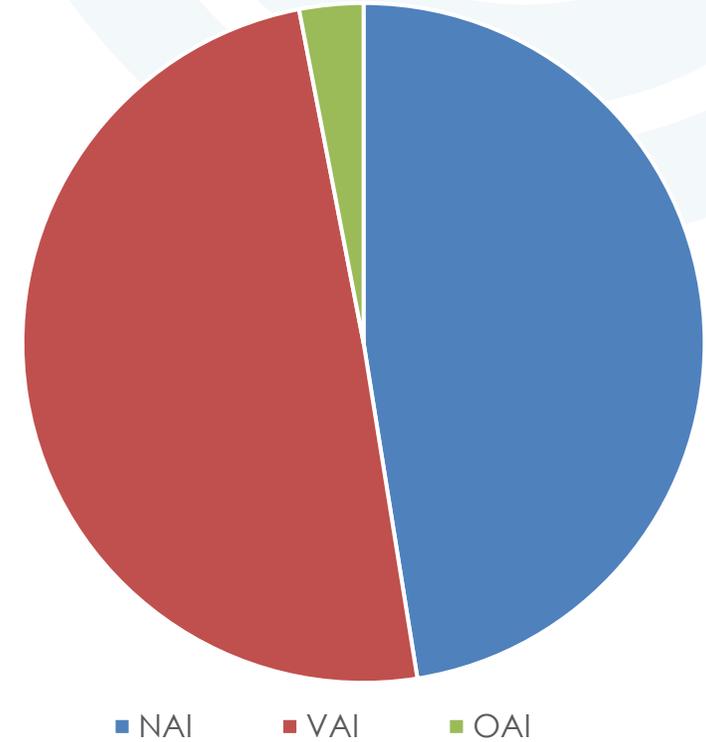
OAI 4.1%

# Noncompliance Rates

PCAF Type of Action



PCHF – All Inspections  
Type of Action



# 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)

# NAVIGATING FSPCA COURSE CHALLENGES: AN INTERNATIONAL PANEL



PANELIST  
**JEDSADA  
TIMPONTIAN**

KING MONGKUT'S  
INSTITUTE OF  
TECHNOLOGY  
LADKRABANG



PANELIST  
**KYOTA MURAI**

GLOVALUTION  
LLC



PANELIST  
**ADRIANA  
CAMACHO**

AZZULE SYSTEMS



PANELIST  
**ANA MARISA  
CORDERO PEÑA**

INTER-AMERICAN  
INSTITUTE FOR  
COOPERATION ON  
AGRICULTURE (IICA)



PANELIST  
**NOEMI  
ZUNIGA-THIMEOS**

INTER-AMERICAN  
INSTITUTE FOR  
COOPERATION ON  
AGRICULTURE (IICA)



MODERATOR  
**JUAN L. SILVA**

MISSISSIPPI STATE  
UNIVERSITY

# 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

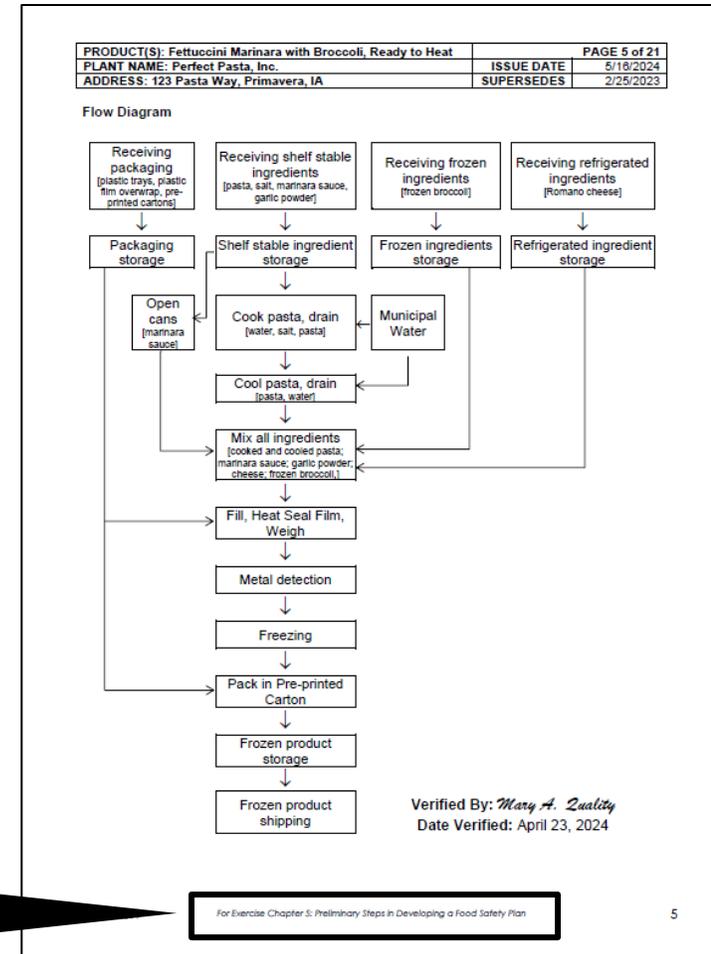
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- **Objective:** Support learning by providing the opportunity to practice **developing a Food Safety Plan** for a model food
- Lead Instructor **use with the Exercise Workbook** for V2.0 PCHF Participant Course Exercises
  - **Exercises in chapters 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

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

5

# 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
<p><b>Exercise Workbook: \$10.00 USD</b></p>	<ul style="list-style-type: none"> <li>• <b>Download</b> an electronic copy from the FSPCA Instructor Resource Portal</li> <li>• <b>Purchase</b> hardcopies from the FSPCA Lead Instructor Bookstore or Amazon</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Purchase</b> a hardcopy from the FSPCA Public Bookstore or Amazon</li> <li>• Electronic copy provided by the Lead Instructor</li> </ul>
<p><b>Teaching Examples: \$30.00 USD (for 5 Participants)</b></p> 	<ul style="list-style-type: none"> <li>• <b>Download</b> electronic copies from the FSPCA Instructor Resource Portal</li> <li>• <b>Purchase</b> hardcopies from the FSPCA Lead Instructor Bookstore <b>(NOW AVAILABLE)</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>NOT available for purchase or download</b> <ul style="list-style-type: none"> <li>• Can only be supplied by the Lead Instructor</li> </ul> </li> </ul>

# FSPCA PCHF V2.0

## Food Safety Plan Teaching Examples

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

FOR LEAD INSTRUCTORS ONLY - DO NOT  
SHARE WITH PARTICIPANTS



### Delivering Your Course

010

#### FSPCA PCHF Version 2.0 Instructor Materials (Electronic)

This zip file includes the slides for the FSPCA PCHF v2.0 participant course, PDFs of the Instructor Guide, Exercise Workbook, Food Safety Plan Teaching Examples (Fettuccini Marinara with Broccoli; Peanut Butter; Black Pepper), change logs indicating what updates have been made to the Food Safety Plan Teaching Examples, and a Food Safety Plan Teaching Examples User's Guide to help Lead Instructors identify the teaching examples ingredient hazards from FDAs Hazards Guide Appendix 1. More Food Safety Plan Teaching Examples will be added soon.

**Note:** Each electronic Food Safety Plan Teaching Example is available in one PDF and separated PDFs; each file containing only the appropriate pages to share with students during the exercises in chapters 5, 7, 11, 12, and 13.



Name

- Food Safety Plan Teaching Examples
- Food Safety Plan Worksheets and Recall Plan Template
- Manual PDFs
- PowerPoints

Name

- BLACK-PEPPER
- FETTUCCINI-MARINARA
- PEANUT-BUTTER
- Hazard Identification Tool for FSPTE Ingredients\_2025 10 23



# 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

Name
 Ch5_FSPCA-FSPTE_Fettuccini_20251023
 Ch7_FSPCA-FSPTE_Fettuccini_20251023
 Ch10_FSPCA-FSPTE_Fettuccini_20251023
 Ch11_FSPCA-FSPTE_Fettuccini_20251023
 Ch12_FSPCA-FSPTE_Fettuccini_20251023
 Ch13_FSPCA-FSPTE_Fettuccini_20251023
 FSPCA-FSPTE_Fettuccini-Marinara_Change Log_2025 10 23
 FSPCA-FSPTE_Fettuccini-Marinara_FINAL-FINAL-WATERMARKED_2025 10 23

### Peanut Butter Zip File Contents

Name
 Ch5_FSPCA-FSPTE_PeanutButter_20251023
 Ch7_FSPCA-FSPTE_PeanutButter_20251023
 Ch10_FSPCA-FSPTE_PeanutButter_20251023
 Ch11_FSPCA-FSPTE_PeanutButter_20251023
 Ch12_FSPCA-FSPTE_PeanutButter_20251023
 Ch13_FSPCA-FSPTE_PeanutButter_20251023
 FSPCA-FSPTE_Peanut-Butter_Change Log_2025 10 23
 FSPCA-FSPTE_Peanut-Butter_FINAL-FINAL-WATERMARKED_2025 10 23

### Peanut Butter Zip File Contents

Name
 Ch5_FSPCA-FSPTE_BlackPepper_20251023
 Ch7_FSPCA-FSPTE_BlackPepper_20251023
 Ch10_FSPCA-FSPTE_BlackPepper_20251023
 Ch11_FSPCA-FSPTE_BlackPepper_20251023
 Ch12_FSPCA-FSPTE_BlackPepper_20251023
 Ch13_FSPCA-FSPTE_BlackPepper_20251023
 FSPCA-FSPTE_Black-Pepper_Change Log_2025 10 23
 FSPCA-FSPTE_Black-Pepper_FINAL-FINAL-WATERMARKED_2025 10 23

# REVISIONS

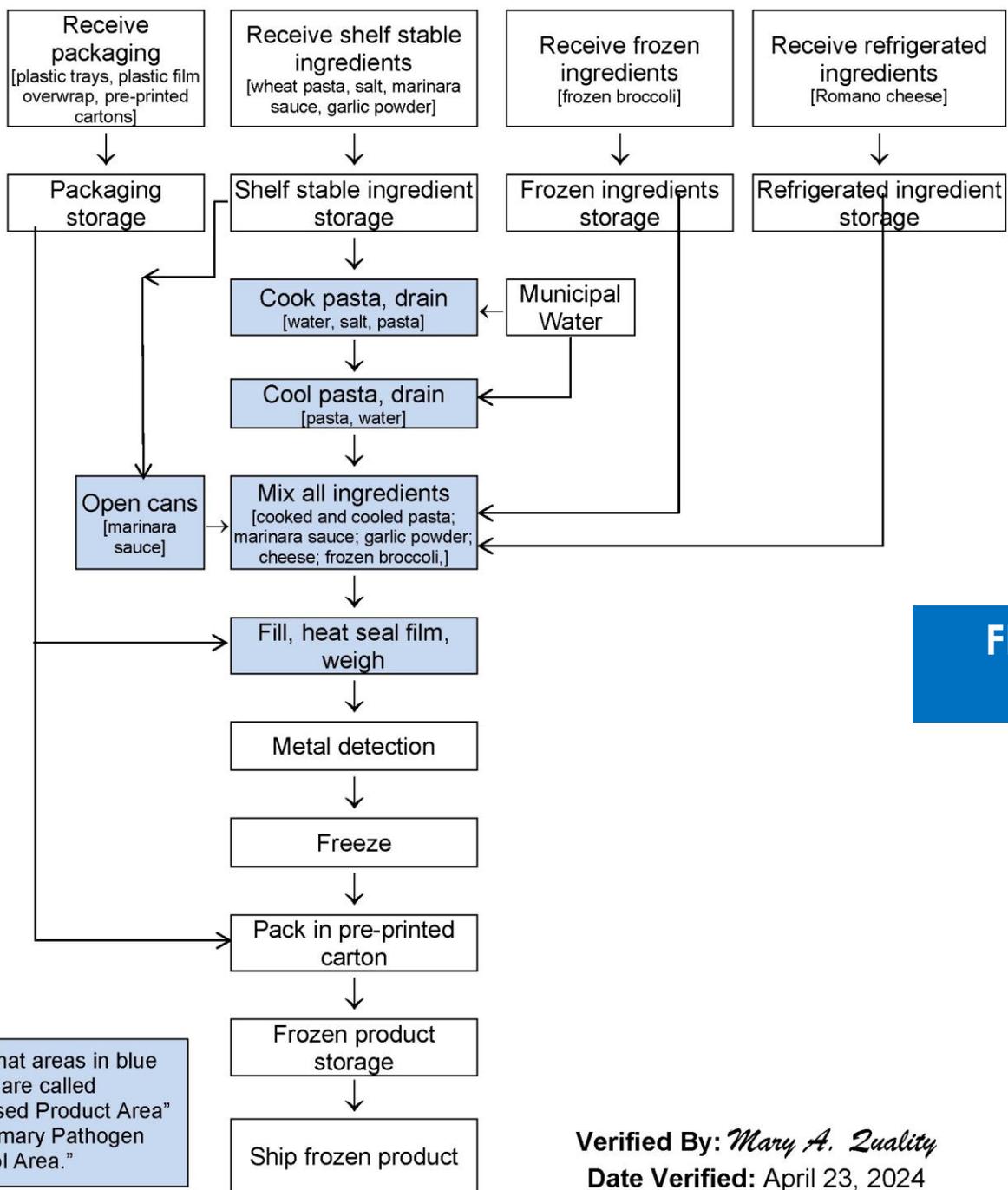
## Food Safety Plan Teaching Examples

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- Revised October 2025 – download version dated 10.23.2025

Change log available in the HF Lead Instructor Portal

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

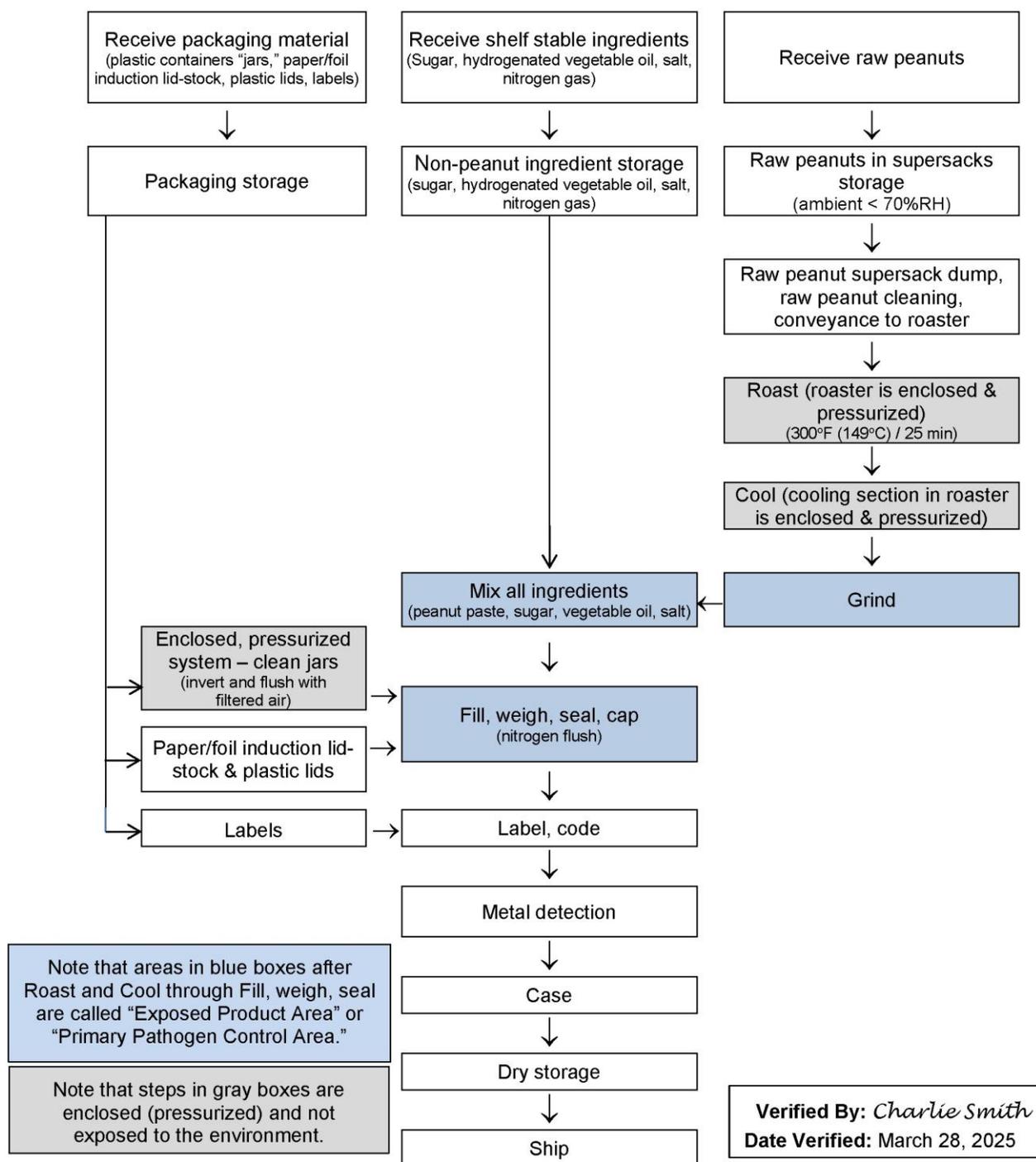


## FETTUCCINI MARINARA WITH BROCCOLI

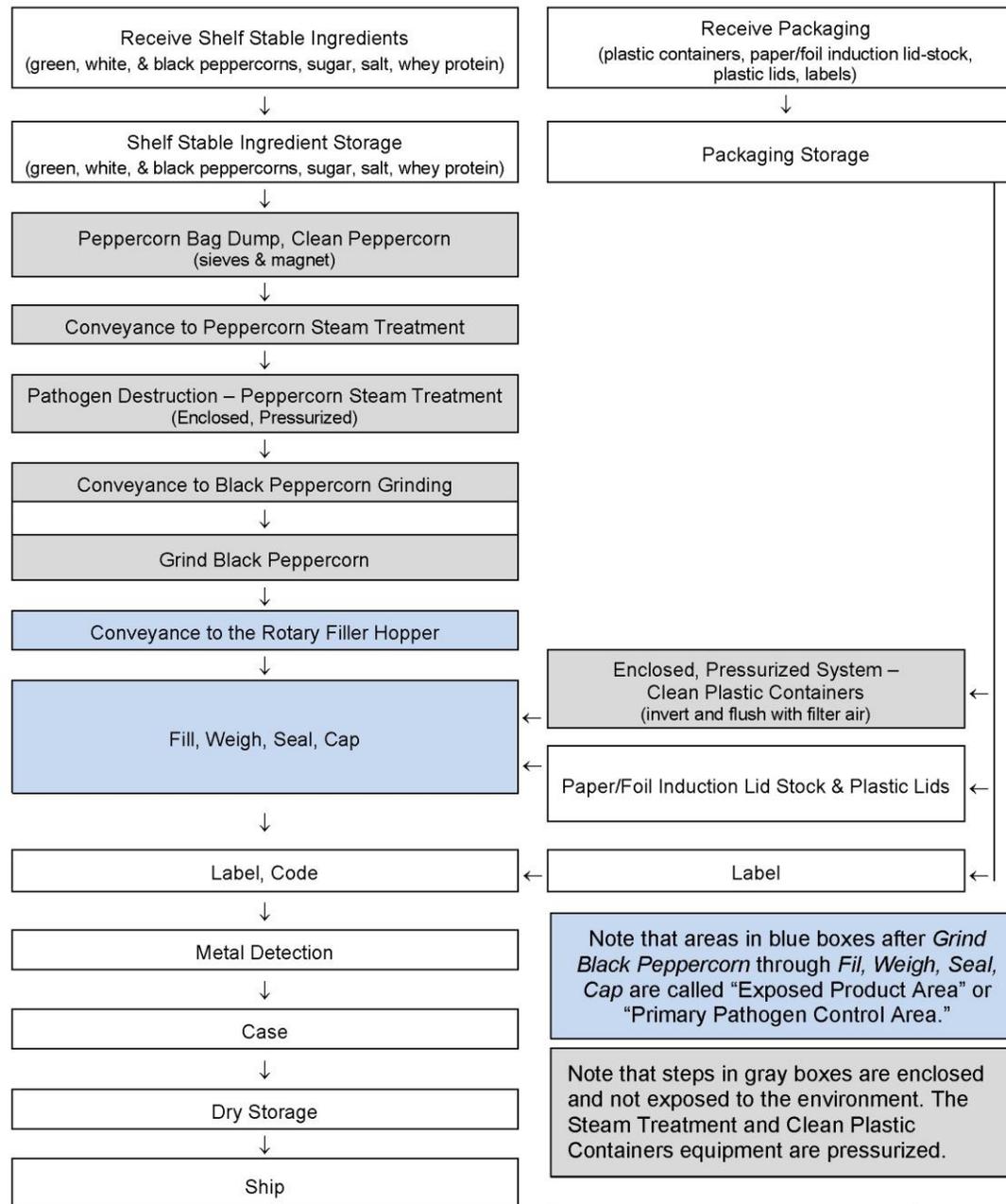
Note that areas in blue boxes are called "Exposed Product Area" or "Primary Pathogen Control Area."

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

# PEANUT BUTTER



# BLACK PEPPER



Verified By: Lynn Cumín  
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
<b>Process Description</b>	<b>Salt:</b> added <i>“Supplier only processes salt (no food allergens). No glass or hard plastic is used in the supplier’s manufacturing or packaging processes.”</i>	<b>Raw peanut supersack dump, raw peanut cleaning, conveyance to roaster step:</b> added “Raw peanuts are conveyed from the supersack dump station <b>through the wall directly into the enclosed, pressurized</b> roaster”	<b>Label, code</b> step: added “Immediately after the capping, <b>the filled plastic containers are conveyed through an opening in the wall to the label area”</b> ”
	<b>Garlic powder:</b> revised to say <i>“Supplier dries and grinds <b>raw</b> garlic...”</i>	<b>Label, code</b> step: added “Immediately after the capping, <b>the jars are conveyed through an opening in the wall to the label area.”</b> ”	

# REVISIONS

## Food Safety Plan Teaching Examples

- Revised October 2025 – download version dated 10.23.2025

	Fettuccini Marinara	Peanut Butter	Black Pepper
<b>Process Description</b>	<ul style="list-style-type: none"> <li>Moved “Open cans [Marinara sauce]” step <u>before</u> “Mix all ingredients”</li> <li>Designated cans are opened in “mixing area”</li> <li>Designated cook pasta is in “kettle room”</li> <li>Designated cooled pasta bins are stainless steel and wheeled into “mixing area”</li> <li>At “Fill, Heat Seal Film, Weigh” step, designated sealed trays are conveyed to the metal detector (in same room)</li> <li>At “Freeze” step, stated freezer tunnel is enclosed</li> </ul>		

# 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.

# REVISIONS

## Food Safety Plan Teaching Examples

- Revised October 2025 – download version dated 10.23.2025

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

# REVISIONS

## Food Safety Plan Teaching Examples

- Revised October 2025 – download version dated 10.23.2025

	Fettuccini Marinara	Peanut Butter	Black Pepper
<b>Process Preventive Controls – Metal detection:</b>			
- Corrected Monitoring Table Header for “How” (typo- said frequency and “Frequency (typo- said how)	X		
- Changed monitoring frequency to <b>“Continuous”</b> instead of <b>“Each rejection”</b>	X	X	X
<b>Allergen Assessments -</b> 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
<b>Sanitation Preventive Controls #1:</b> <ul style="list-style-type: none"> <li>Revised Procedure to say ABC <b>“detergent”</b> (not “cleaning solution”) mixed with <b>“potable”</b> water</li> </ul>	X	X	
<ul style="list-style-type: none"> <li>Revised Monitoring and Corrections to <u>add</u> ABC detergent (only listed sanitizer)</li> </ul>	X	X	
<ul style="list-style-type: none"> <li>Revised Corrective Action to <b>include 2) Determine root cause and 4) retrain or correct as appropriate</b></li> </ul>	X		

# REVISIONS

## Food Safety Plan Teaching Examples

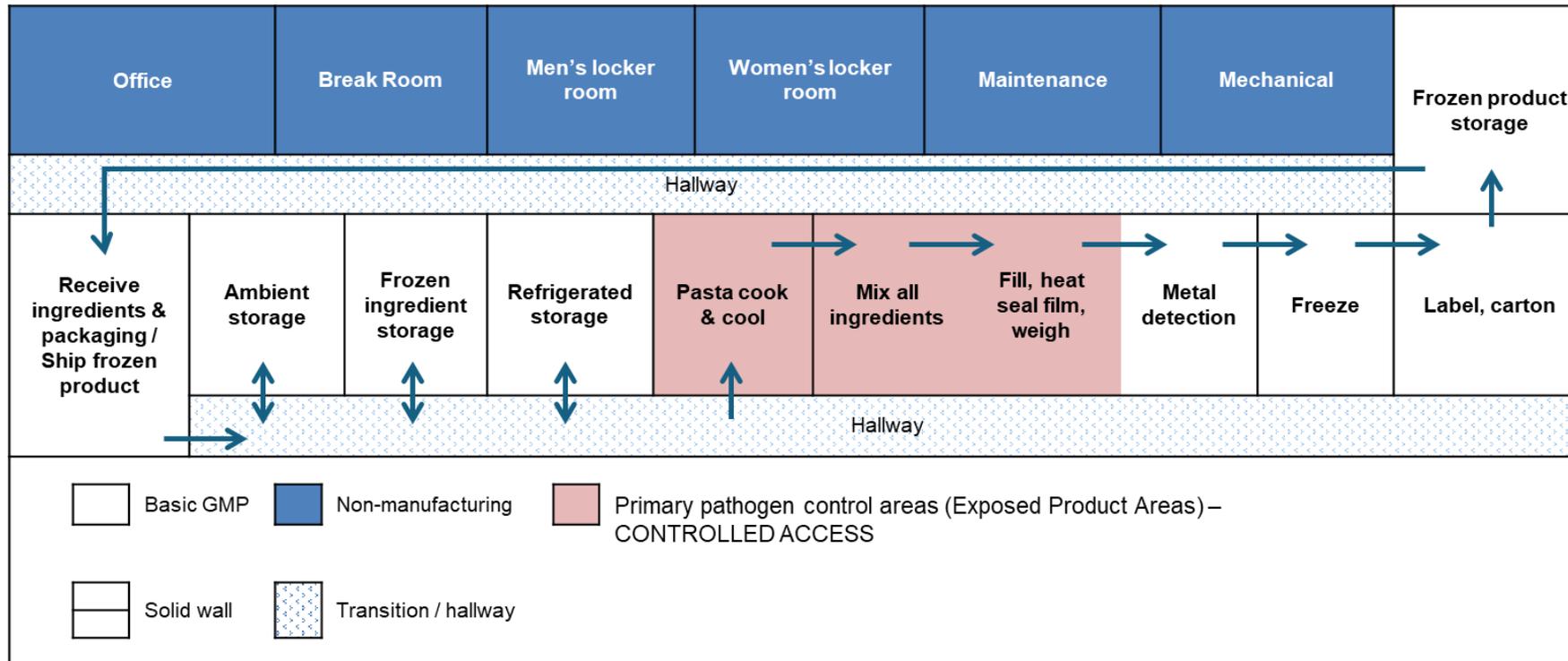
- Revised October 2025 – download version dated 10.23.2025

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

# Plant Diagrams – Sanitation PC #3

## FETTUCCINI MARINARA WITH BROCCOLI

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

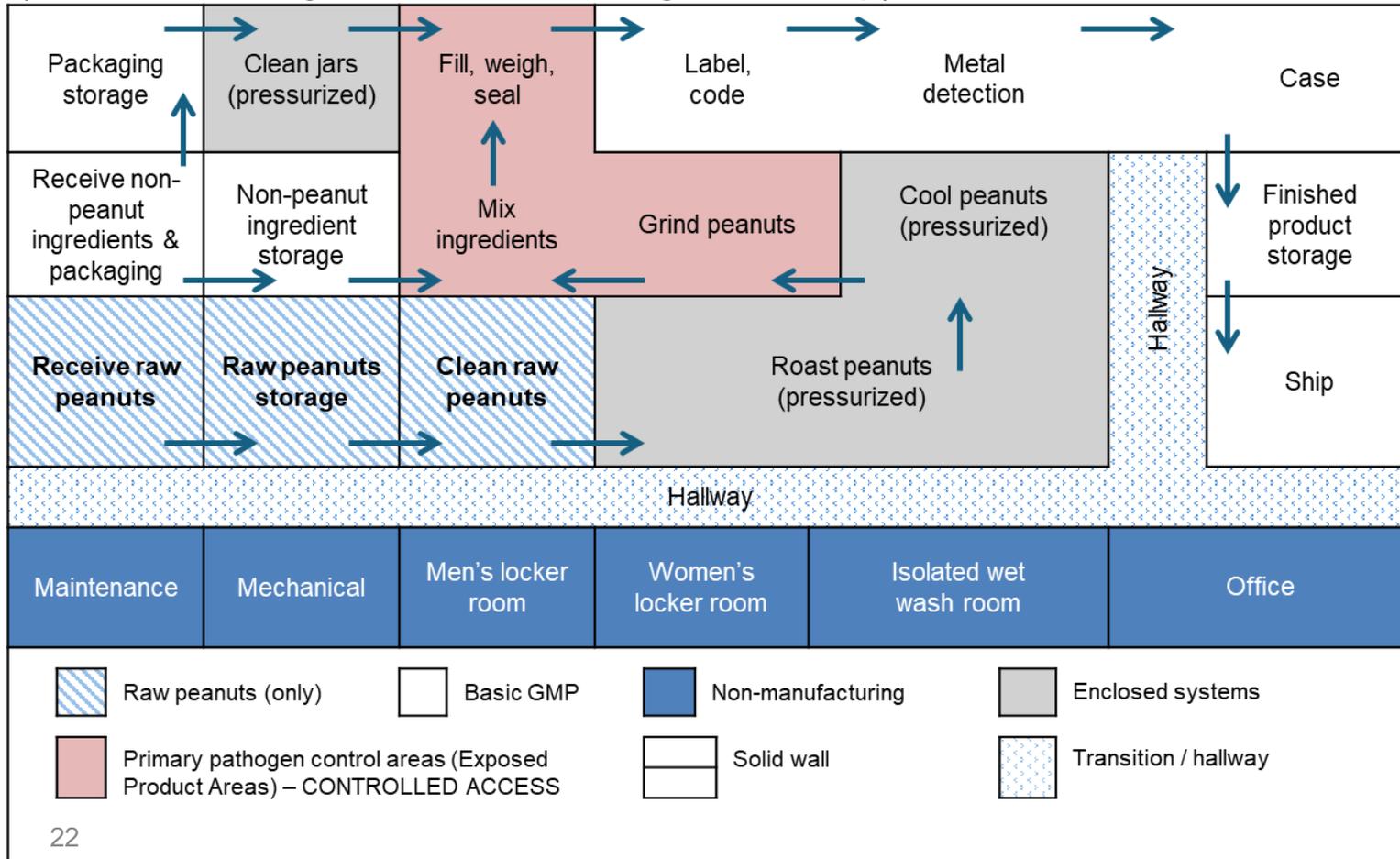


- Plant Diagram revised:
- 1) to say “Receive ingredients & packaging / Ship frozen product” and changed to white Basic GMP area (versus Transition);
  - 2) Added a legend for “Solid Wall”;
  - 3) Removed wall lines between “Mix All Ingredients; Fill, Heat Seal Film Weigh; and Metal Detection”;
  - 4) 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)



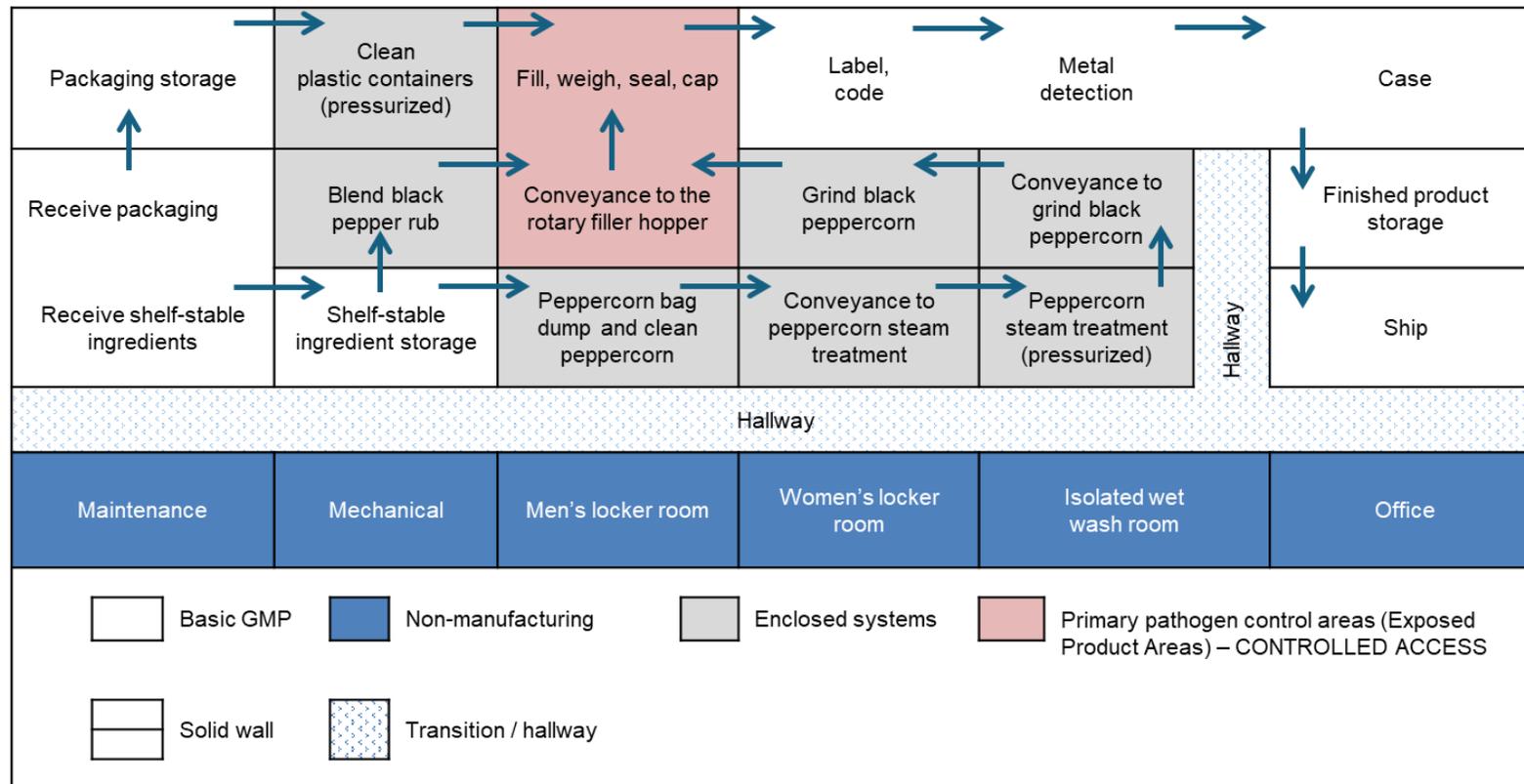
### Plant Diagram revised:

- 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

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- 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: <i>“If the product is not from an approved supplier, reject the shipment at time of receipt.”</i>		

# 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

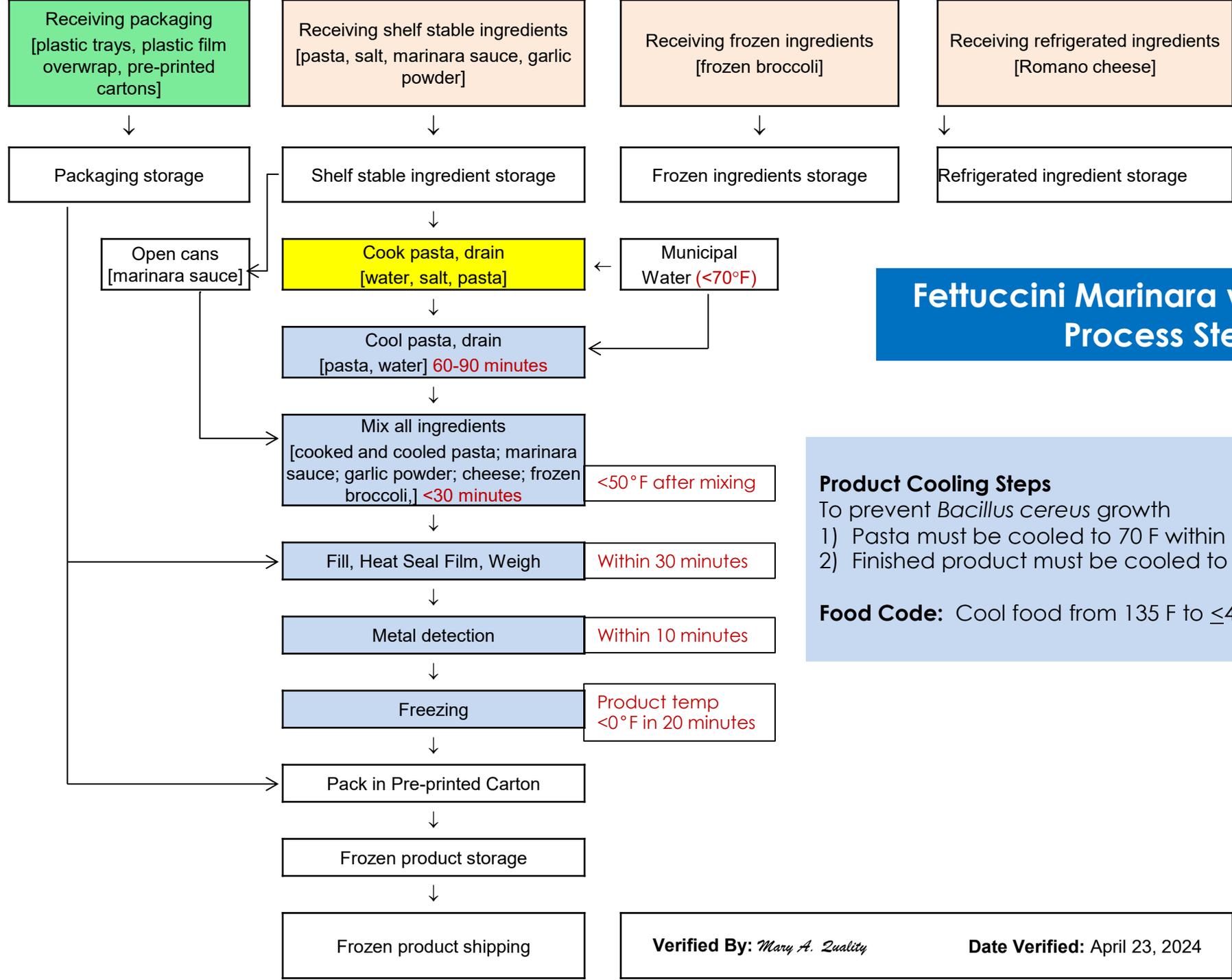
# Chapter 5 – Preliminary Steps Exercise

---

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.

**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.



## Fettuccini Marinara with Broccoli Process Steps

**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**



Ingredient-Related Hazards (Inherent Hazards)



Supplier’s Process-Related and Facility-Related Hazards

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



Process-Related 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 if needed:

## Fettuccini Marinara Model Plan Preliminary Steps ONLY

**Food Safety Plan for Fettuccini Marinara with Broccoli Ready to Host**  
Teaching Example

**Fettuccini Marinara**

## Exercise Workbook (Page 7- 10)

**Exercise Workbook**  
INCLUDING FOOD SAFETY PLAN WORKSHEETS  
SECOND EDITION - OCTOBER 2024  
(VERSION 2.0)

**FSPCA**  
FOOD SAFETY PROMOTION CENTER ASSOCIATION

## FDA Hazard Guide Appendix 1 Tables

Table 1A: Known or reasonably likely to occur hazards

Category	#	Subcategory	Storage Condition	Biological	Chemical	Physical	Other	Control	Prevention	Control	Prevention	Control	Prevention
Bread, Biscuits, Rolls, Biscuits, Cookies, Pizza, Pie Crust	1	Unbaked Bakery Items - Ready-To-Bake (RTB) Crust - With or without Inclusions	Refrigerated or Frozen						X	X			
	2a	Fully Baked - With or without Pre-Slice Added - Without Post-Slice Added - Frosting/Topping	Ambient, Refrigerated or Frozen						X	X			
Bread, Whole/Pre-sliced	2b	Fully Baked - With or without Pre-Slice Added - Frosting, and/or Topping	Ambient, Refrigerated or Frozen						X	X	X		

Ingredient-Related Hazards (Inherent hazards)

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

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

**Process-Related and 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 member names)	(group member names)
<i>Group 1</i>	<i>Group 2</i>	<i>Group 3</i>
<ol style="list-style-type: none"> <li>1. Wheat Pasta (shelf-stable)</li> <li>2. Salt (shelf-stable)</li> <li>3. Receive packaging</li> <li>4. Cook pasta in water, drain</li> <li>5. Cool pasta, drain</li> </ol>	<ol style="list-style-type: none"> <li>1. Marinara Sauce #10 can</li> <li>2. Refrigerated Romano Cheese [shredded]</li> <li>3. Refrigerated ingredient storage [Romano Cheese]</li> <li>4. Open cans [Marinara sauce]</li> <li>5. Fill, heat seal film, weigh</li> </ol>	<ol style="list-style-type: none"> <li>1. Garlic powder</li> <li>2. Individually Quick Frozen (IQF) broccoli</li> <li>3. Frozen ingredient storage [IQF broccoli]</li> <li>4. Mix all ingredients</li> <li>5. Metal detection</li> </ol>

# 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) <i>Group 1</i>	(group member names) <i>Group 2</i>	(group member names) <i>Group 3</i>
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

## FETTUCINI MARINARA WITH BROCCOLI – HAZARD ID TOOL

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

# Potential Ingredient-related Hazards per FDA Hazard Guide Appendix 1

Available in the  
HF LI Portal

## FETTUCCHINI MARINARA WITH BROCCOLI – HAZARD ID TOOL

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

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

# 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)
<b>Nitrogen</b>	<p><b>None</b> P. 46  <b>Table 1C:</b> Misc. Food Additives, Color Additives, and GRAS Substances  <b>Category (6e):</b> Other Chemical Ingredients  <b>Subcategory:</b> Processing Aid Gases</p>	<p><b>None</b> P. 82  <b>Table 2C:</b> Misc. Food Additives, Color Additives, and GRAS Substances  <b>Category:</b> None listed for Other Chemical Ingredients only Nutrients</p>
<b>Raw, shelled peanuts</b>	<p><b>Pathogenic <i>E. coli</i>, <i>Salmonella</i>, <i>L. mono.</i></b> P. 66  <b>Table 1K:</b> Nuts and Seeds  <b>Category (1a):</b> Nuts  <b>Subcategory:</b> Peanuts, Raw</p>	<p><b>Mycotoxins and Pesticides</b> P. 91. <b>see footnote<sup>1</sup> for applicable mycotoxin (Aflatoxin).</b>  <b>Table 2K:</b> Nuts and Seeds  <b>Category (1a):</b> Nuts  <b>Subcategory:</b> Peanuts, Raw and treated</p>

# 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	<p><i>Salmonella</i>. P 74.</p> <p><i>B. cereus, Clostridium botulinum, Clostridium perfringens</i>, see footnote P. 75 only applicable when these products becomes hydrated or used as ingredient in-high moisture food.</p> <p><b>Table 10:</b> Spices and Herbs <b>Category (1):</b> Spices <b>Subcategory:</b> Dried, Ground, Cracked, or Whole</p>	<p><b>Pesticides.</b> P. 95. <b>Table 20:</b> Spices and Herbs <b>Category (1):</b> Spices <b>Subcategory:</b> Dried, Ground, Cracked, or Whole</p>

# 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
<b>BIOLOGICAL HAZARDS A1.7.1</b>	Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment	<b>Yes– Cook Pasta</b>
	Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control	<b>Yes – potential temperature abuse (<i>B. cereus</i> 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.</b>
	Bacterial pathogens – Growth and/or toxin production due to poor formulation control	<b>N/A</b> – Not formulated for safety
	Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP)	<b>N/A</b> – Not packaged in ROP
	Bacterial pathogens – Presence due to ingredients added after process controls	<b>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)</b>
	Bacterial pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity	<b>N/A</b> – Not packaged in hermetically sealed container
	Environmental pathogens – presence due to recontamination from the processing environment	<b>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</b>
<b>CHEMICAL HAZARDS A1.7.2</b>	Undeclared food allergens – incorrect label	<b>Yes – Romano cheese contains milk and dry pasta contains wheat which are major food allergens</b>
	Unintended food allergen presence – allergen cross-contact	<b>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).</b>
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)	<b>N/A</b> – 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)	<b>N/A</b> – Not Applicable (not a plant-based food)
<b>PHYSICAL HAZARDS A1.7.3</b>	Metal	<b>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.)</b>
	Glass (when product packed in glass)	<b>N/A</b> – Not packed in glass
	Hard Plastic	<b>N/A</b> – Hard plastic not used by supplier and Fettuccini company

# Fettuccini Marinara with Broccoli Preventive Controls

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

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



# 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 member names)	(group member names)
<i>Group 1</i>	<i>Group 2</i>	<i>Group 3</i>
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

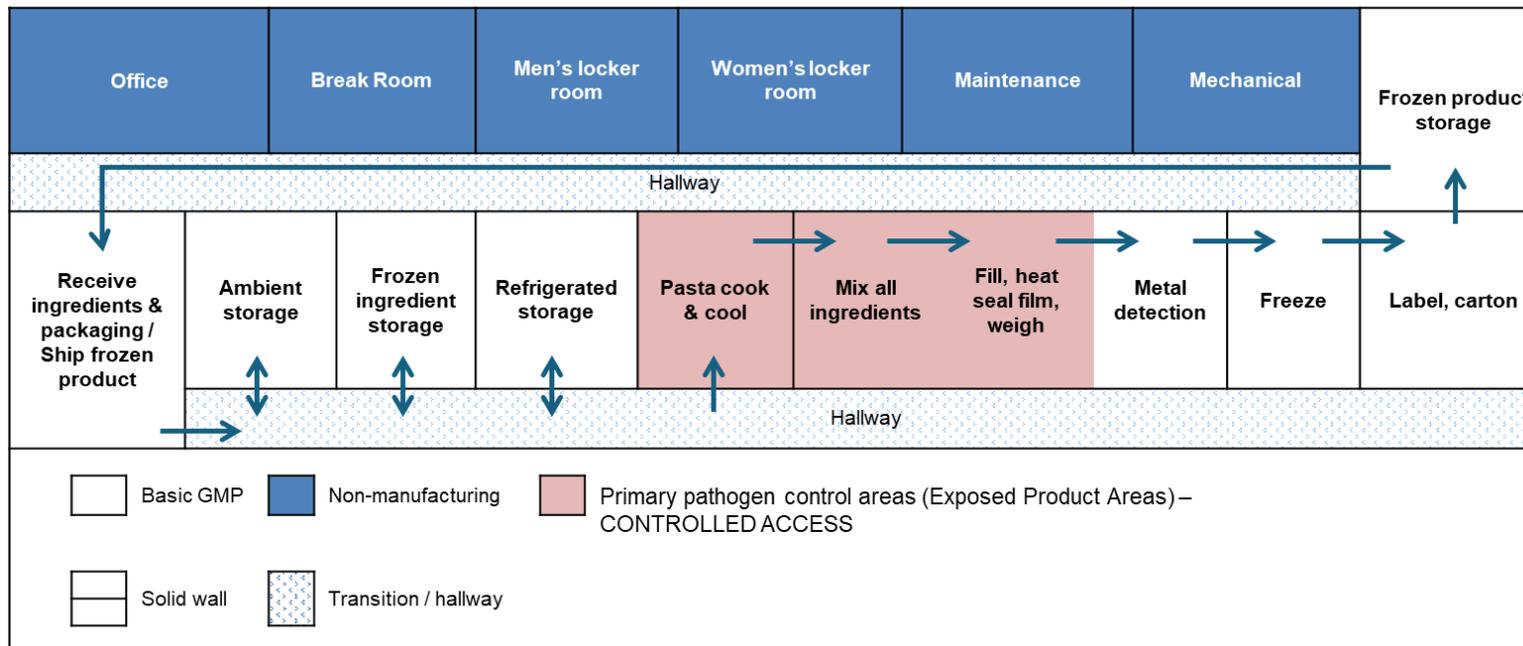
- Prevent Cross-contact (full clean after Shrimp Alfredo) - Mixer & Filler
- Prevent Recontamination with Environmental Pathogens – Kettles (pasta cool); Mixer; & Filler

### #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 member names)	(group member names)
<i>Group 1</i>	<i>Group 2</i>	<i>Group 3</i>
<b>#1: Clean and sanitize food-contact surfaces</b> Prevent Recontamination with Environmental Pathogens – Kettles (pasta cool); Mixer; & Filler	<b>#2: Clean and sanitize non-food-contact surfaces</b> Prevent Recontamination with Environmental Pathogens – Clean areas around Kettles (pasta cool); Mixer; & Filler	<b>#3: Hygienic Zoning</b> 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.



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

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



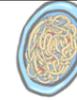
# Chapter 13 Supply-chain Preventive Controls Example

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 <i>E. coli</i> , <i>L. mono</i> , and <i>Salmonella</i> <b>AND</b> Recontamination with environmental pathogens <i>L. mono</i>	Broccoli produced under Produce Safety Rule Standards <b>AND</b> 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: <ul style="list-style-type: none"> <li>Dispose of any ingredient(s) from the supplier, as well as products made using the impacted ingredient(s), that are still under our control.</li> <li>Discontinue use of the supplier until the cause or causes of non-conformance, are adequately addressed.</li> <li>Notify the supplier of the problem and request documentation of corrective actions taken by the supplier.</li> <li>Assist the supplier's efforts to correct and prevent recurrence of the problem.</li> <li>Revise the supply-chain program.</li> <li>Conduct, or work with the supplier to conduct, a recall of any adulterated food.</li> </ul>	Copy of audit report kept in the Supplier Verification File.  Supplier Verification and Corrective Action Documentation

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

## 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:**

- Verify that each load of:
  - Garlic Powder was produced by Spicetown Co., Gilroy, USA by checking the bill of lading and manufacturer name on the cases upon receipt.
  - Romano Cheese was produced by Big Cheese Co., Cheesytown, USA by checking the bill of lading and manufacturer name on the cases upon receipt.
  - 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.
- If the product is not from an approved supplier, reject the shipment at time of receipt.
- 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 Lightning Round Sessions  
Raffle Packets of Teaching Examples (3 full sets)



STRATHMORE  
A&B

# BREAKOUT SESSION: DATA DASHBOARD

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

**MODERATOR: JUAN L. SILVA**

# 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

[Home](#) > [FSMA Data](#) > Firm/Supplier Evaluation Resources

## Firm/Supplier Evaluation Resources

The FDA firm and supplier database available on this site includes data associated with inspections classification, inspections citations, compliance actions, recalls, and imports.

Search Results: 13

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

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## New Data

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

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## 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.

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## Flexible Solution

- OII Unified Logon (OUL) Integration

# Future Enhancements

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## Data Access

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

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## New Data

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

# Demonstration

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<https://datadashboard.fda.gov>



# Questions & Answers

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<https://datadashboard.fda.gov>

**Thank You!**

**<https://datadashboard.fda.gov>**  
**[Robert.Bughman@fda.hhs.gov](mailto:Robert.Bughman@fda.hhs.gov)**  
**[FDADataDashboard@fda.hhs.gov](mailto:FDADataDashboard@fda.hhs.gov)**



# BREAKOUT SESSIONS REPORT OUT

**CLAUDIA COLES**

SEAFOOD PRODUCTS ASSOCIATION (SPA)

**MODERATOR: RON TANNER**

# Breakout Session Summary: Food Safety Priorities & Policies

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- 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 (version 1.2)
  - 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

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## 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 IIs 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

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- 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

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- 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



# CLOSING REMARKS

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