

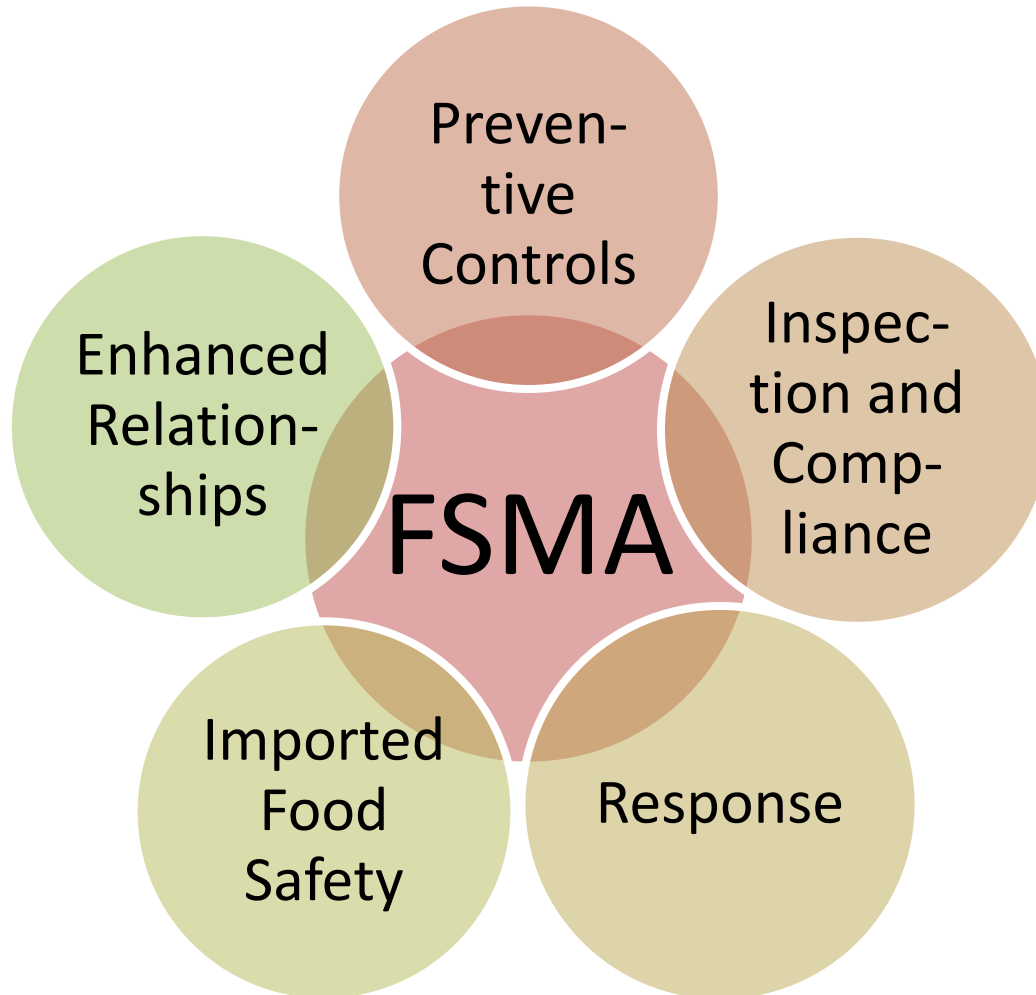


**International  
Association of  
Operative Millers**

**FSMA**

**Tom Black  
Western District IAOM  
August 17, 2017**

# 5 Key Elements of FSMA



# From Reaction to Prevention

- FSMA is the most significant change in US food laws since the Food, Drug and Cosmetic Act of 1938.
  - A lot has changed in the past 75+ years
- 402(a)(3) reflects the past:
  - Product considered adulterated after the failure has already occurred
- 402(a)(4) is the future:
  - Emphasis is on prevention by managing sanitary conditions



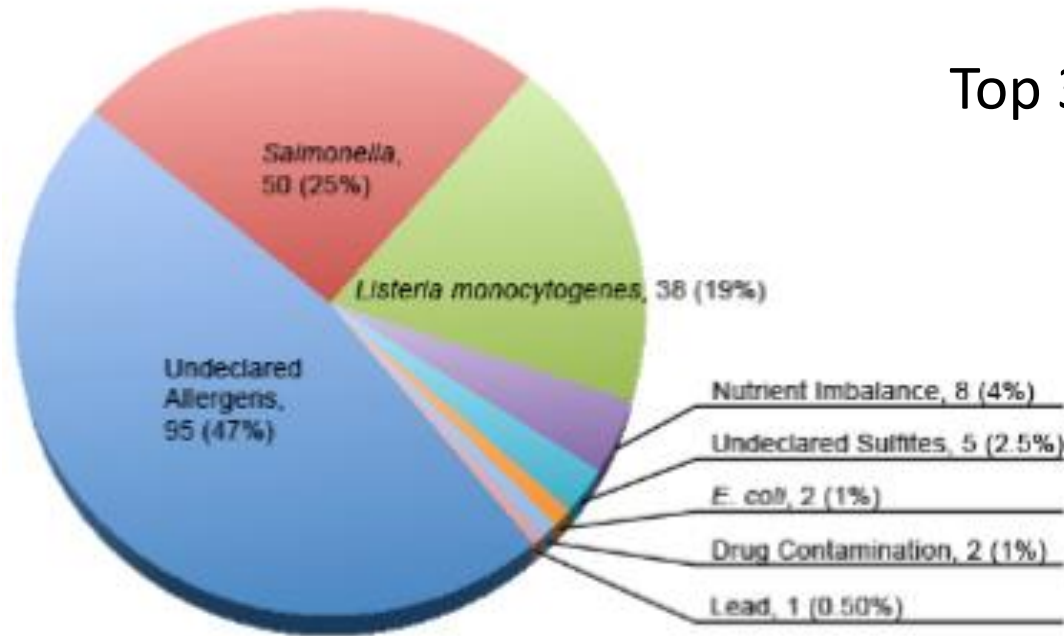
Prevention

*REACTION*

# Recalls by the Numbers

- Recalled products typically numbered in the hundreds in the past decade
- By 2009, thousands of products were being recalled annually
- Possible reasons?
  - Increased imports
  - Growing complexity of the supply chain
  - Better detection and recognition of food safety problems
  - Better reporting by manufacturers, i.e., RFR

# Recalls by the Numbers, continued



Top 3 > 90%

## RFR - Summary for 2009 to 2014

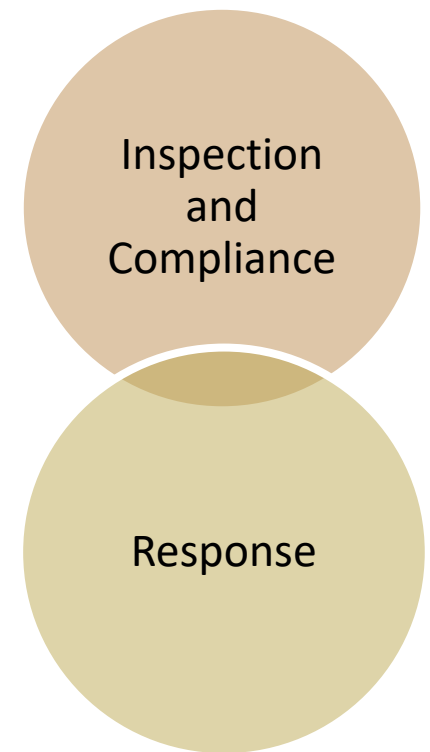
Hazard	Year 1	Year 2	Year 3	Year 4	Year 5	Total
<i>Salmonella</i>	86 (37.6%)	86 (38.2%)	63 (28.1%)	58 (28.7%)	50 (24.9%)	343 (36.1%)
<i>Listeria monocytogenes</i>	33 (14.4%)	40 (17.8%)	48 (21.4%)	35 (17.3%)	38 (19.0%)	194 (20.4%)
Undeclared Allergens	69 (30.1%)	75 (38.3%)	85 (37.9%)	88 (43.6%)	95 (47.0%)	412 (43.4%)
<b>No. of entries (percentage)</b>	<b>188 (82.1%)</b>	<b>201 (94.3%)</b>	<b>196 (87.4%)</b>	<b>181 (89.6%)</b>	<b>183 (90.6%)</b>	<b>949 (100%)</b>

Commodity	Yr-1	Yr-2	Yr-3	Yr-4	Yr-5	Total
Whole and Milled grain/flours	3	1	1	1	1	7 - (2%)
Total - Salmonella	86	86	63	58	50	343

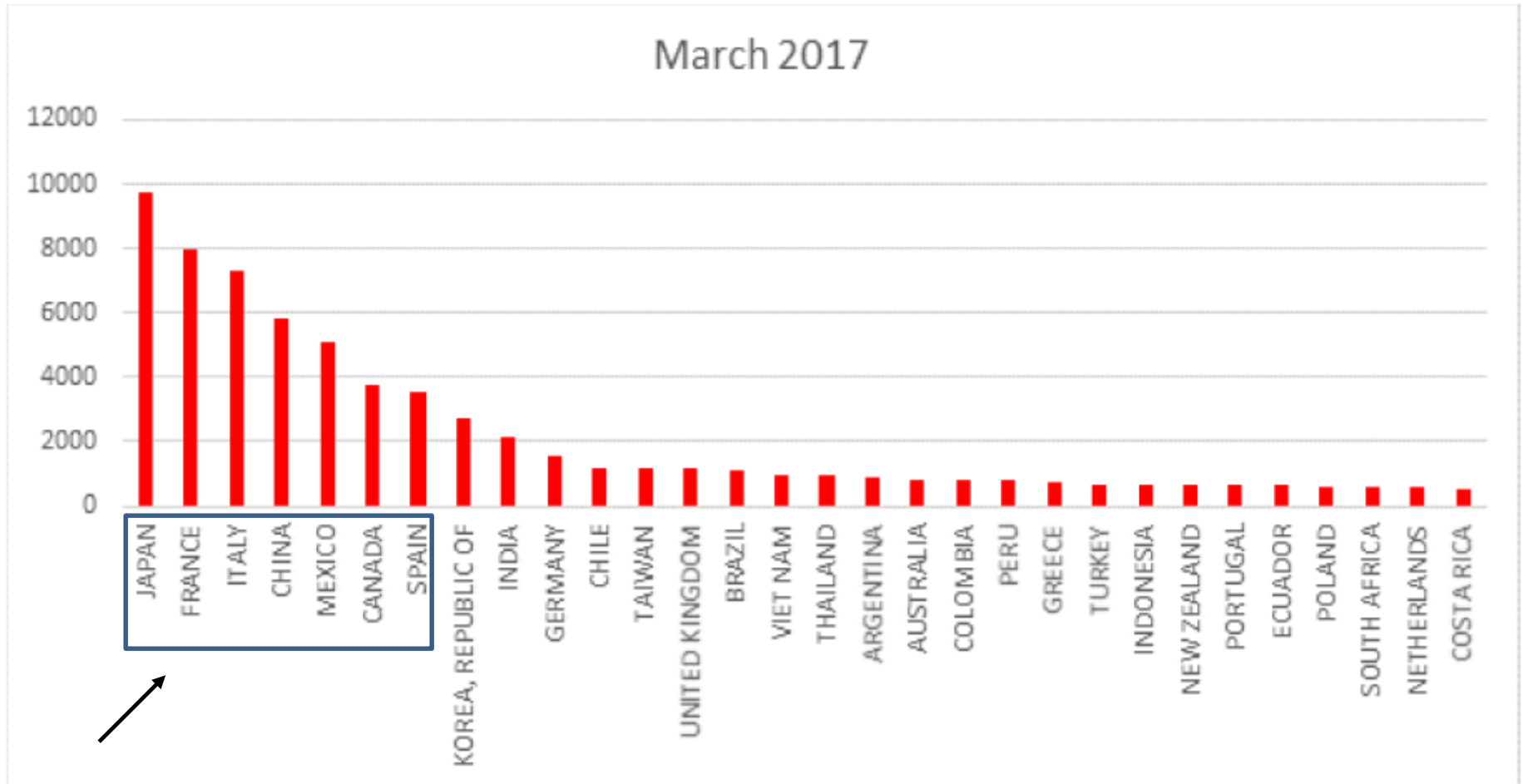
Commodity	Yr-1	Yr-2	Yr-3	Yr-4	Yr-5	Total
Whole and Milled grain/flours	0	1	0	0	0	4 - (1%)
Total - Allergens	69	75	85	88	95	412

# Inspection, Compliance, and Response

- 402(a)(3) — Adulteration is determined by “credible and verifiable information”
- 402(a)(4) — Now, “reason to believe” is the equivalent to unsanitary conditions that could lead to adulteration
  - Emphasis is now on *prevention*.
- Major implications for food safety programs *and* FDA inspections
- FDA’s focus is on sanitary conditions and supporting documentation



# FDA Facility Registration Data (Human Food)





# Intent, Scope and Implications of FSMA

- From correction to prevention
  - Reducing the number of failures (recalls)
- Back to the basics
  - 402 (a) (4)
- Food Safety from “Farm to Fork”
  - Supply-chain applied control
- Global Imports of food
  - Import and Foreign Supplier Verification
- Responsibility and accountability
  - Private sector supply chain

# Current GMPs, Hazard Analysis and Risk-Based Preventive Controls (HARPC)

- Subpart A - General Provisions
- Subpart B - Current Good Manufacturing Practice
- Subpart C - Hazard Analysis and Risk-Based Preventive Controls (HARPC)
- Subpart D - Modified Requirements
- Subpart E - Withdrawal of Qualified Facility Exemption
- Subpart F – Requirements Applying to Records that must be Established and Maintained
- Subpart G – Supply-Chain Program

# GMP's- Addressing Allergen Cross-Contact

Revises several provisions of the cGMPs, Part 110 and now Part 117, to address and control potential allergen cross-contact, including:

- Personnel, clothing, traffic and practices
- Building structure/separation of processes
- Cleaning product zones (equip, bulk and utensils)
  - Cleaning non-product zones (equip/structure)
  - Methods of cleaning (CIP, COP, air or other)
  - Equipment design (cleanability)

# Top Five FDA Violations (Form 483)

- **Lack of Effective Pest Exclusion** – Effective measures were not taken to exclude pests from processing areas and/or protect against the contamination of food on the premises by pests
- **Sanitation Monitoring** – Sanitation conditions and practices were not monitored closely enough to assure conformance with current Good Manufacturing Practices (cGMP) to prevent unsanitary conditions
- **Screening** – The facility lacked adequate screening and protection against pests
- **Floors, Walls, and Ceiling** – The facility's construction prevented adequate cleaning and repairs of the floors, walls, and ceilings resulting in unsanitary conditions
- **Critical Limits** – The facility's HACCP plan did not list a critical limit or listed a critical limit that did not ensure control of one or more hazards

# FDA Inspections

	Planned	Accomplished
<b>Human Food modernized GMP</b>	<b>450</b>	<b>307</b>
<b>Full PC</b>	<b>240 (domestic) 60 (foreign)</b>	<b>45* (OJE) 5 6-OAI:</b>
<b>Animal Food cGMP</b>	<b>250</b>	<b>47</b>
<b>FSVP</b>	<b>325</b>	<b>6/19/17-9/30/17</b>
<b>Sprout Facilities</b>	<b>30</b>	<b>5/19/17-9/30/17</b>

*\*Conducted by cadre; includes On-the-Job Experience*

# Summary of 12 Categories of Hazards

## Biological

Parasites

## Chemical

Natural Toxins

Pesticides

Drug Residue

Allergens (human food)

Decomposition

Unapproved Additives

## Physical

Hazards not covered  
under HACCP  
Radiological  
Intentional  
+  
EMA

# Economically Motivated Adulteration

## Guidance documentation

- Will be forthcoming with the Food Defense Rule
- Examples of significant food fraud
  - Melamine in infant formulae and pet food
  - Horse meat in ground beef products
  - Recently, peanut residue in cumin
  - Use of sweeteners in processed honey
  - Deliberate fish speciation for higher value

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm>

# Understanding RTE Foods

- *Ready-to-eat food (RTE food)* means any food that is normally eaten in its **raw state** or any other food, **including a processed food**, for which it is reasonably foreseeable that the food will be eaten **without further processing** that would **significantly minimize** biological hazards.

Does this criteria apply to flour?



# Environmental Risk Assessment

- The hazard evaluation to include an assessment
  - of environmental pathogens whenever a ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a pathogen reduction treatment
  - or otherwise includes a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

# Environmental Risk Guidance

- Product is eaten in its raw state
- Product is unprotected prior to packaging
- Formulation does not inhibit pathogens (processed products)
- Maintain **appropriate** sanitary conditions for the physical facility, the process and personnel
  - Zone 1
  - Zone 2 -Example
  - Zone 3
  - Zone 4

# Environmental monitoring – Zone #2

- Equipment framework
- Drip shields and housing
- Control panels and buttons
- Computer screens
- Overhead pipes directly over Zone 1 surfaces
- Maintenance tools



# Role of Environmental Monitoring

- Verifies PCs are preventing unsanitary condition(s)
  - Roof leaks, standing water, condensate, pathogen harborage in building structure (floors, walls) or equipment, utensils & equipment (contact & noncontact ), cleaning not effective, unsanitary plant conditions, etc.
- Done “as appropriate” for RTE foods
- The goal is to know where the problems are and correct them.

# Preventative Control (PC) Management Components

- Monitoring
- Corrections and corrective action
- Verification
- Validation
- Supply chain program
- Record review for all the above
- Reanalysis of Food Safety Plan
- Recall plan

# PC Management Components

- Validation
  - For PCs as appropriate by PCQI
  - Prior to implementation of Food Safety Plan, or
  - Implemented within 90 days after production begins
  - Don't need to validate:
    - Food allergen controls
    - Sanitation controls
    - Recall plan
    - Supply chain program
    - Other PC if written justification is provided

# PC Management Components

All Preventive Controls **will not** be managed the same

- Not all PCs will need documented records for monitoring, corrective action, verification and validation.
- However, all PCs will get documented corrective action if the hazard is considered to be “significant”

# Managing Preventive Controls

*... allow flexibility for the application of management elements for preventive controls so that such controls are managed with a level of rigor commensurate to the nature of the risk and the type of control employed..*

*“Levels of oversight should align with the risk and type of Preventive Control”*



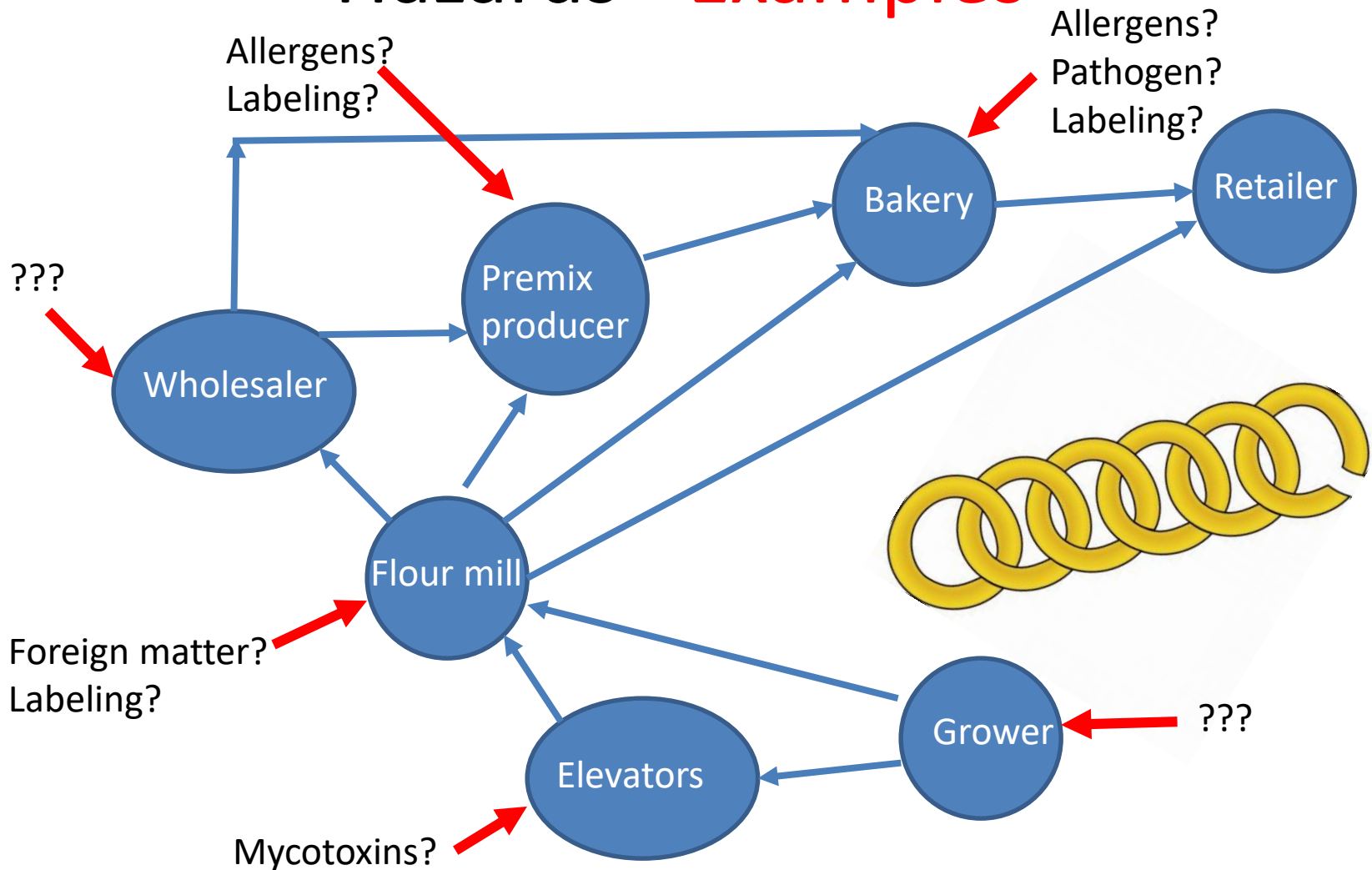
# Recall Plan

- For food with a hazard requiring a preventive control:
  - You must establish a written recall plan
  - Documented procedures describe the steps to be taken, responsibilities for taking those steps to perform the following actions:
    - Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food
    - Notify the public about any hazard presented by the food when appropriate to protect public health
    - Conduct effectiveness checks to verify that the recall is carried out; and
    - Appropriately dispose of recalled food—*e.g.*, through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food

# Supply Chain Program

- Supplier verification for raw materials may include-
  - Onsite audits
  - Sampling and testing of the raw material or other ingredient;
  - Review of the supplier's relevant food safety records
  - Supplier performance review
    - Supplier's regulatory history
    - Audit results, actions taken, product testing, COAs, etc.

# Supply Chain Program for Identified Hazards - Examples



# Supply Chain Program

- The receiving facility must apply a written supply-chain control program if raw materials and other ingredients require a control
  - Upstream: Prior to receipt of raw materials, ingredients and direct contact packaging materials
  - Downstream: If customer or other entities after first customer are going to control the hazard.
- Importers need to comply with the Foreign Supplier Verification Program (FSVP) for foreign suppliers controlling the hazard.

# Guidance Documents

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- Preventive Controls Human Food:
  - Hazard Analysis and Preventive Controls: Draft Published 8/16
  - Listeria in RTE Food: Draft Published 1/17
  - Classification of Activities for Farms and Facilities: Draft published 8/16
  - Small Entity Compliance Guide: Published 10/16
  - Planned Guidances include: Supplier Controls, Validation of Process controls, Food Allergens

# Introduction to FDA's FSMA website

- Hyperlink: [www.fda.gov/fsma](http://www.fda.gov/fsma)
- <https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

U.S. Department of Health and Human Services  
**FDA U.S. FOOD & DRUG ADMINISTRATION**

Home > Food > Guidance & Regulation > Food Safety Modernization Act (FSMA)

## Food Safety Modernization Act (FSMA)

The Law, Rules & Guidance

Fact Sheets & Presentations

Frequently Asked Questions on FSMA

FDA Actions and Meetings

FSMA Training

FSMA Technical Assistance Network (TAN)

### FDA Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

#### Featured Announcements

- At FDA, a Long-term Commitment to Engaging Stakeholders  
June 26, 2017
- FDA Launches Accredited Third-Party Certification Site  
June 21, 2017
- FDA Intends to Extend Compliance Dates for Agricultural Water

#### Most Popular

- Full Text of the Law
- Rules and Guidance for Industry
- Public Meetings
- Information by Topic
- FSMA Technical Assistance Network (TAN)

#### Rules

- Final Rule for Preventive Controls for Human Food
- Final Rule for Produce Safety
- Final Rule on Accredited Third-Party Certification
- Final Rule for Foreign Supplier Verification Programs

## Food Safety Modernization Act (FSMA)

The Law, Rules & Guidance

Fact Sheets & Presentations

Frequently Asked Questions on FSMA

FDA Actions and Meetings

FSMA Training

FSMA Technical Assistance Network (TAN)

# Other resources: FDA Fact sheet – Preventive Controls for Human Food

## FDA AT A GLANCE

FDA FOOD SAFETY  
MODERNIZATION ACT  
THE FUTURE IS NOW

### KEY REQUIREMENTS:

#### Final Rule on Preventive Controls for Human Food

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule is now final, and compliance dates for some businesses begin in September 2016.

This final rule is the product of an unprecedented level of outreach by the FDA to industry, consumer groups, the agency's federal, state, local and tribal regulatory counterparts, academia and other stakeholders. This outreach began before the rule was proposed in January 2013.

In response to input received during the comment period and during hundreds of engagements that included public meetings, webinars, listening sessions, and visits to farms and food facilities across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the

because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).

- **Preventive controls:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. They include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan.
- **Oversight and management of preventive controls.** The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.
  - **Monitoring:** These procedures are designed to provide assurance that preventive controls are consistently performed.  
Monitoring is conducted as appropriate to the

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM461834.pdf>





FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



Menu ▾

FSPCA.net

## FSPCA Home

The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public private alliance consisting of key industry, academic and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training and outreach programs to assist companies producing human and animal food in complying with the preventive controls regulations that will be part of the Food Safety Modernization Act (FSMA).

### Training

- [List of FSPCA Participant Courses](#)
- [FSPCA Preventive Controls for Human Food](#)
- [FSPCA Preventive Controls for Animal Food](#)
- [Foreign Supplier Verification Programs \(FSVP\)](#)
- [Intentional Adulteration](#)

### Technical Assistance Networks

- [FSPCA Technical Assistance Network](#)
- [FDA FSMA Technical Assistance Network](#)

### Food Safety Modernization Act (FSMA)

- [Supplier Evaluation Resources](#)
- [FDA Update! FDA Extends Certain FSMA Compliance Dates; Issues Draft Guidance](#)
- [FDA Food Safety Modernization Act Homepage](#)
- [FSMA Final Rule for Preventive Controls for Human Food](#)
- [FSMA Final Rule for Preventive Controls for Animal Food](#)
- [FSMA Final Rule on Foreign Supplier Verification Programs \(FSVP\) for Importers of Food for Humans and Animals](#)
- [FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration](#)

[Sign up for the FDA's e-mail updates](#)

### The Alliance

- [Committees, Subcommittees, Work Groups](#)

### Quick Links

- [Apply to Become a Lead Instructor](#)
- [FSPCA Advertising Recommendations for Lead Instructors \(Human Food\)](#)
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- [FSPCA Advertising Recommendations for Lead Instructors \(FSVP\)](#)
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- [FSPCA FSVP Bookstore](#)
- [FSPCA Human Food Bookstore](#)
- [FSPCA Lead Instructor Listing](#)
- [FSPCA Materials](#)
- [FSPCA Metrics](#)
- [FSPCA Trainers of Trainers for Animal Food](#)
- [FSPCA Trainers of Trainers for Foreign Supplier Verification Programs \(FSVP\)](#)
- [FSPCA Trainers of Trainers for Human Food](#)
- [Register for a Course \(for Lead Instructors only\)](#)

### Stay Connected

- [FSPCA Webinars](#)
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### Sister Alliances

- [Produce Safety Alliance](#)
- [Sprout Safety Alliance](#)





## FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD BLENDED COURSE

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*January 12, 2017*

### FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD BLENDED COURSE

This Food Safety Preventive Controls Alliance (FSPCA) Blended Training course was developed to provide an alternative way for individuals to complete the FSPCA Preventive Controls for Human Food course. The Blended course consists of 2 parts. Part 1 is online and Part 2 is instructor-led. Both parts must be completed in order to obtain the certificate. Any Lead Instructor can provide a one-day Part 2: Instructor-Led course, and you can search for upcoming courses and Lead Instructors on the [FSPCA Community website](#).

#### **IMPORTANT**

**Once you begin the process, you have up to six months to complete the Part 1: Online course. Upon completion, you have six months to complete a Part 2: Instructor-Led course. We recommend you have a Part 2: Instructor-Led course identified before enrolling in Part 1: Online.**

# Questions



[Tom.black@ardentmills.com](mailto:Tom.black@ardentmills.com)

*Thanks to AIB International and FSCPA for material shared*