5 Key Elements of FSMA

- Preventive Controls
- Inspection and Compliance
- Enhanced Relationships
- Imported Food Safety
- Response
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
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%

Source: 5th Annual Reportable Foods Registry (2014)
## RFR - Summary for 2009 to 2014

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella</td>
<td>86 (37.6%)</td>
<td>86 (38.2%)</td>
<td>63 (28.1%)</td>
<td>58 (28.7%)</td>
<td>50 (24.9%)</td>
<td>343 (36.1%)</td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
<td>33 (14.4%)</td>
<td>40 (17.8%)</td>
<td>48 (21.4%)</td>
<td>35 (17.3%)</td>
<td>38 (19.0%)</td>
<td>194 (20.4%)</td>
</tr>
<tr>
<td>Undeclared Allergens</td>
<td>69 (30.1%)</td>
<td>75 (38.3%)</td>
<td>85 (37.9%)</td>
<td>88 (43.6%)</td>
<td>95 (47.0%)</td>
<td>412 (43.4%)</td>
</tr>
</tbody>
</table>

### Commodity (Whole and Milled Grain/Flours)

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole and Milled Grain/Flours</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>7 - (2%)</td>
</tr>
<tr>
<td>Total Salmonella</td>
<td>86</td>
<td>86</td>
<td>63</td>
<td>58</td>
<td>50</td>
<td>343</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole and Milled Grain/Flours</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4 - (1%)</td>
</tr>
<tr>
<td>Total Allergens</td>
<td>69</td>
<td>75</td>
<td>85</td>
<td>88</td>
<td>95</td>
<td>412</td>
</tr>
</tbody>
</table>
• 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
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.

source 2016 FDA database
# FDA Inspections

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

*Conducted by cadre; includes On-the-Job Experience*
Summary of 12 Categories of Hazards

**Biological**
- Parasites

**Chemical**
- Natural Toxins
- Drug Residue
- Decomposition
- Pesticides
- Allergens (human food)
- 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 in 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

- Grower
- Elevators
- Flour mill
- Premix producer
- Bakery
- Retailer
- Wholesaler
- Mycotoxins?
- Allergens?
- Labeling?
- Foreign matter?
- Allergens?
- Pathogen?
- Labeling?
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

- 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](https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm)
Other resources: FDA Fact sheet – Preventive Controls for Human Food

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)
International 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

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The Alliance
Committees, Subcommittees, Work Groups

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FSPCA Advertising Recommendations for Lead Instructors (Animal Food)
FSPCA Advertising Recommendations for Lead Instructors (FSVP)
FSPCA Animal Food Bookstore
FSPCA Community
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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
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Produce Safety Alliance
Sprout Safety Alliance
FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD BLENDED COURSE

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

Thanks to AIB International and FSCPA for material shared

Tom.black@ardentmills.com