

# FSMA Update

Jennifer Thomas  
Interim Director for FSMA Operations  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
May 2018

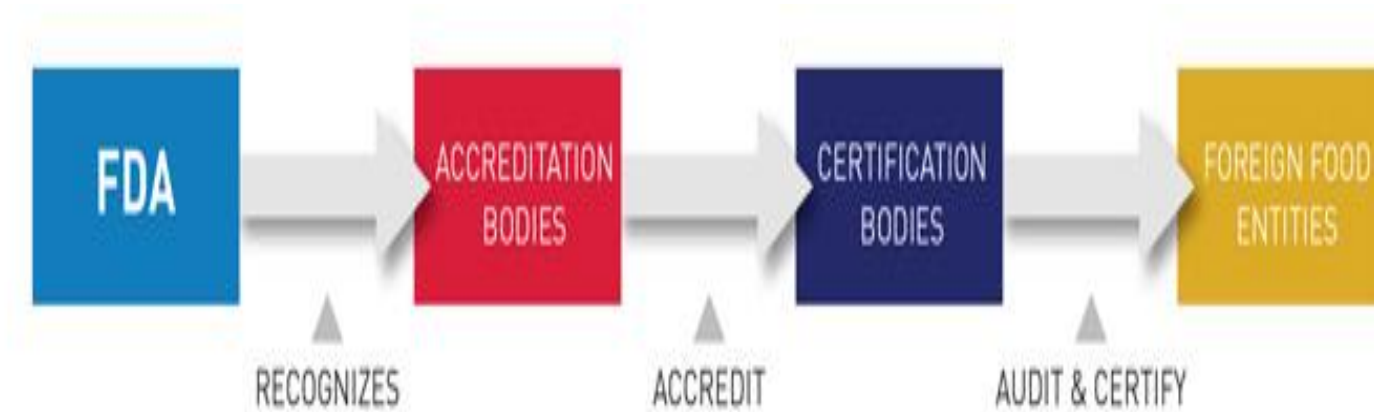
# Foundational Rules

Regulation	Final Rule Published
Preventive Controls - Human Food	September 17, 2015
Preventive Controls - Animal Food	September 17, 2015
Produce Safety	November 27, 2015
Foreign Supplier Verification Programs	November 27, 2015
Third Party Accreditation	November 27, 2015
Sanitary Transport	April 6, 2016
Intentional Adulteration	May 27, 2016

# Initial Compliance Dates

- Preventive Controls – Human Food: September 2016
- Preventive Controls – Animal Food
  - GMPs: September 2016
  - PC: September 2017
- Produce Safety
  - Sprouts: January 2017
  - Produce other than sprouts: January 2018
- Sanitary Transportation: April 2017
- Foreign Supplier Verification Programs: May 2017
- Intentional Adulteration: July 2019

# Accredited Third Party Certification Program



# Key Recent Guidance Documents

- Hazard Analysis and Risk-Based Preventive Controls for Human Food
  - Chapter 15: Supply-Chain Program for Human Food Products
- FSVP
  - Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
  - Small entities compliance guide

# Enforcement Discretion

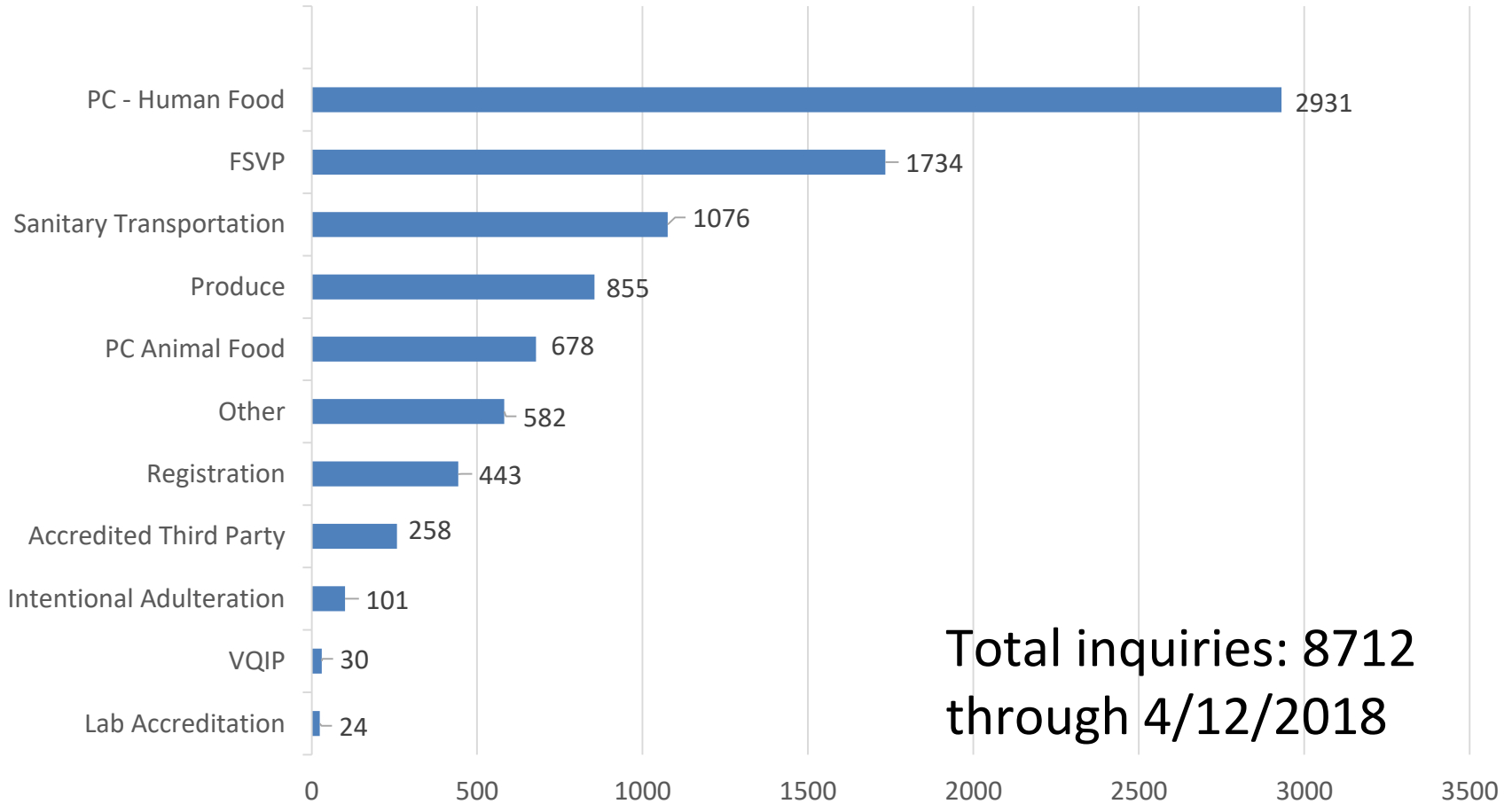
- FDA issued several guidance documents granting enforcement discretion for:
  - Facilities that would be farms except for certain factors
  - Written assurance requirements in the FSVP, PC Human, PC Animal, and Produce rules
  - Animal PC requirements for certain human by-products use as animal food
  - FSVP requirements for importers of food contact substances
  - FSVP requirements for importers of grain Raw Agricultural Commodities and live animals
  - Certain supply chain requirements for co-manufacturers

# Industry Education, Outreach, Technical Assistance

- Key Implementation Principle: Facilitate industry compliance with prevention-oriented standards through guidance; developing tools/resources for education, outreach and technical assistance
  - Website
  - Guidance Documents
  - Alliances
  - Technical Assistance Networks



# Technical Assistance Network





# Industry training - Alliances



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



# Compliance/Enforcement

- Key Implementation Principles:
  - Develop and implement inspection/enforcement strategies that facilitate consistent decision making by regulators
  - Encourage industry to comply and make corrections on its own
  - Recognition that not all observations are equal relative to risk and potential for public health impact
  - Regulatory strategy that is dynamic

# Training for Regulators

- Key Implementation Principle: Invest in regulator training/continuing education, on-going calibration of regulators to promote consistent inspections and decision making
  - FSMA Rule Readiness: Industry Best Practices
  - Alliance Courses with Industry
  - Regulator Specific Training
  - Technical Assistance Network / Resources

# Inspections

- Initiated inspections for:
  - Modernized GMPs – human food
  - Preventive controls – human food
  - GMPs – animal food
  - Sprouts
  - FSVP
  - Sanitary transportation
- Upcoming
  - Preventive controls – animal food
  - Produce safety
  - Intentional adulteration



(c) ClipArtIllustration.com

# Inspection findings: PCHF

- Significant observations:
  - Hazard analysis – identification of hazard
  - Sanitation controls verification procedures – establish and implement
  - Plant construction and design
  - Pest control
  - Sanitation of food contact surfaces – frequency
  - Food safety plan
  - Hazard analysis – written
  - Allergen control procedures
  - Supply chain program – establish and implement

# Inspection findings: FSVP

- Significant observations:
  - Failure to have any FSVP
  - Failure to establish written procedures to ensure that foods are imported only from approved foreign suppliers
  - Failure to have a written analysis to identify and evaluate known or reasonable foreseeable hazards.
  - Failure to document the approval of foreign suppliers
  - Incorrect entry data

# FSMA Enforcement Tools

- Mandatory recall
- Suspension of registration

# FDA Food Safety Modernization Act (FSMA)

## [Sign-Up for FSMA Email Updates](#)

About 48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.



Spotlight

- [FDA Takes Important New Steps to Strengthen Oversight of Food Imports](#)  
January 2018
- [FDA Issues Guidance Documents to help Importers and Food Producers meet FSMA Requirements](#)  
January 2018

[The FDA Food Safety Modernization Act \(FSMA\)](#) is transforming the nation's food safety system by shifting the focus from responding to foodborne illness to preventing it. Congress enacted FSMA in response to dramatic changes in the global food system and in our understanding of foodborne illness and its consequences, including the realization that preventable foodborne illness is both a significant public health problem and a threat to the economic well-being of the food system.

FDA has finalized seven major rules to implement FSMA, recognizing that ensuring the safety of the food supply is a shared responsibility among many different points in the global supply chain for both human and animal food. The FSMA rules are designed to make clear specific actions that must be taken at each of these points to prevent contamination.

## [Rules and Related Programs](#)

### [Guidance Documents](#)

### [Training and Technical Assistance](#)

### [Compliance and Implementation Tools](#)

### [FSMA Background](#)

### [FSMA's Impact on Public Health](#)





# FSMA Enforcement Update

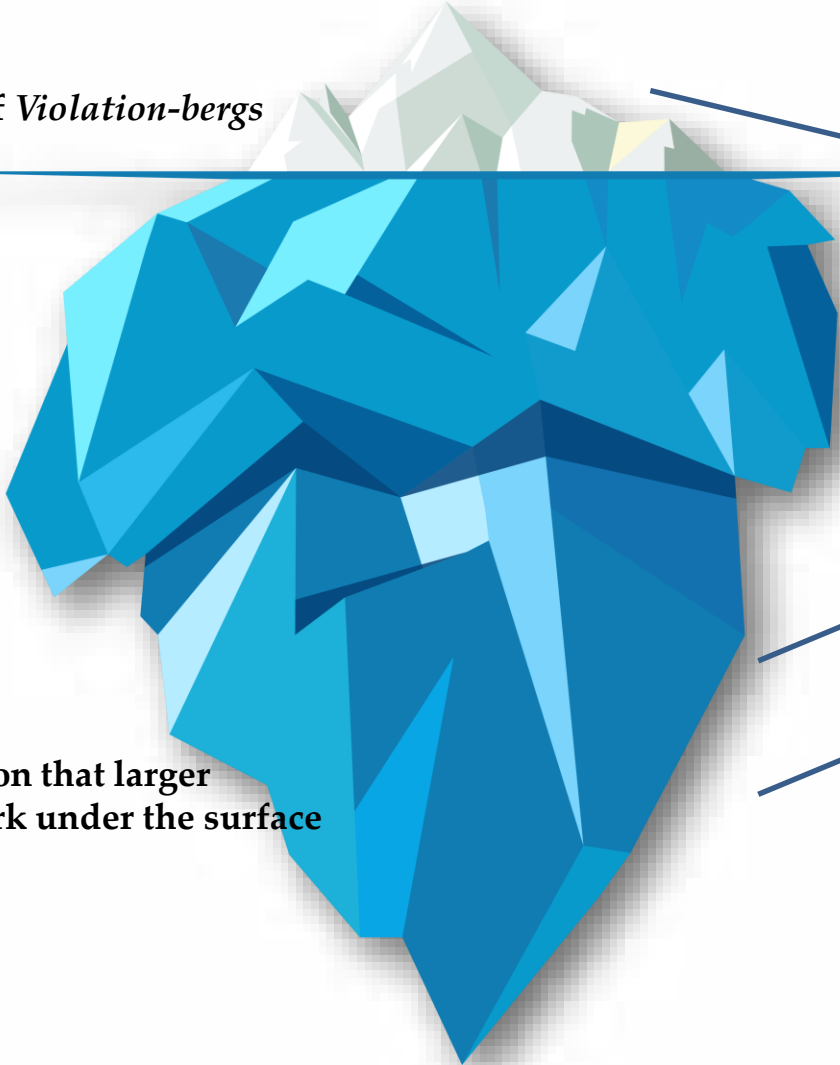
*Don't Abandon the Basics*

*Marc C. Sanchez, Esq.*

# Inspections Before FSMA

- Focus solely on GMPs (Part 110, 111, etc.) unless mandatory HACCP applied or other regulations like LACF.
- At the end of each fiscal year a full list of Observations reported in 483s published.
- Top 10 in the published list were remarkably consistent.

**Tips of Violation-bergs**



*Inspection Occurs Here*

*BUT, inspection is looking for evidence of compliance culture and approach to compliance*

---

*Unlike USDA/FSIS inspections, FDA inspections are infrequent and random*

**Suggestion that larger issues lurk under the surface**

# Inspections After FSMA

- Twin goals – traditional GMP inspection plus educational review and check-in on FSMA implementation.
- Eventually inspections will look at GMP and FSMA compliance.
- Remember PC rule for human food moved GMPs to Part 117.
- Top 10 in the published list will remain consistent, for now, meaning:
  - Don't abandon the basics; and
  - Look at the bottom of the list for Part 117 citations.



# 13

*Citations for “Modernized GMPs”*

*Part 117 in 2017*

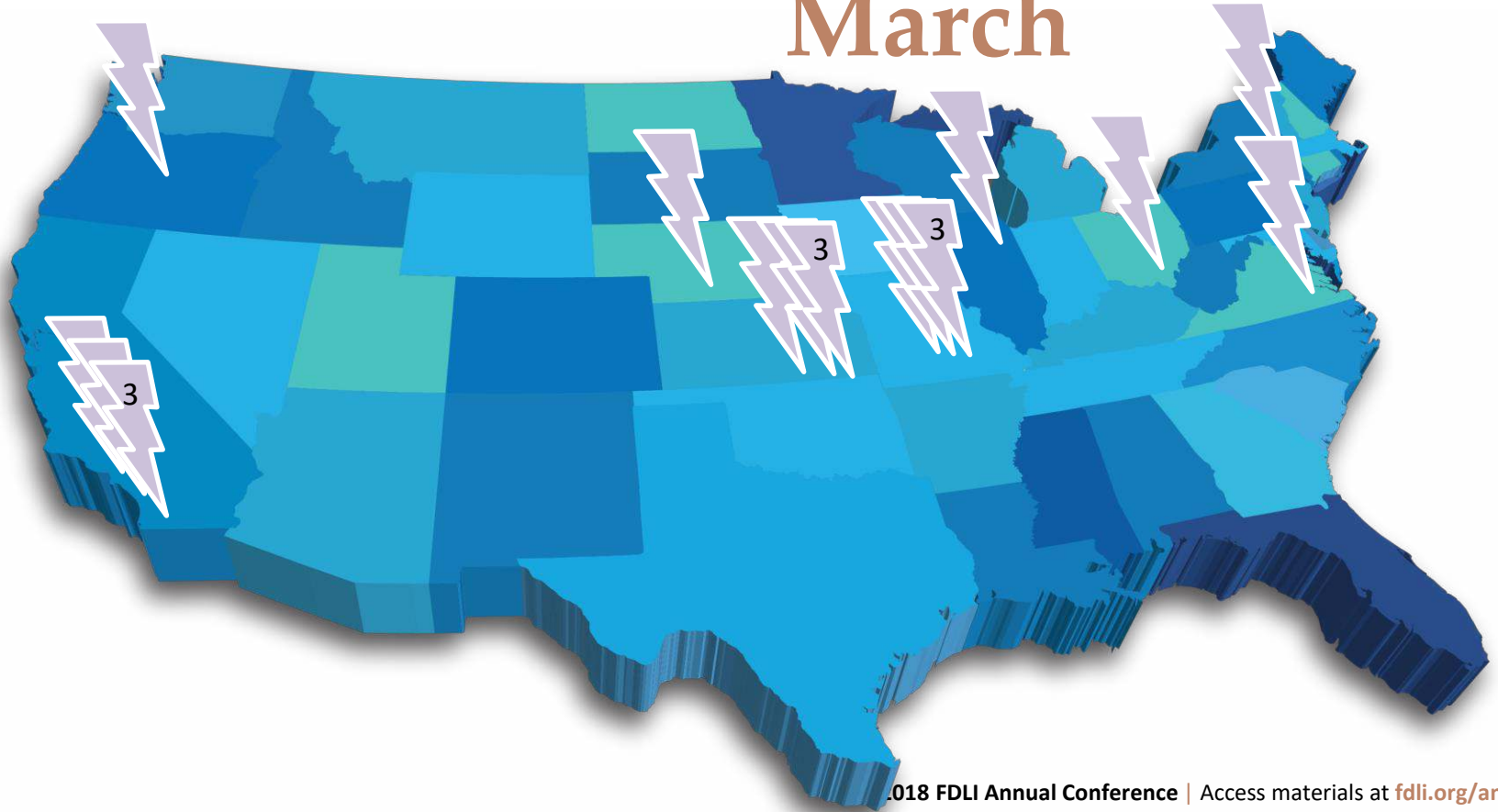
# FSMA Enforcement in 2017

Districts Responding	
San Francisco	3
Cincinnati	1
Dallas	5
Seattle	1
New Orleans	1
Chicago	1
Baltimore	1
New York	1



Types of Facilities	
(Conventional Food) Manufacturer	9
Acidified Foods Manufacturer	1
Seafood Manufacturer	1
RTE Manufacturer	1
Warehouse	1

# FSMA Enforcement Sept. – March



# 1

## *HARPC Citation*

Failure to identify a known or reasonably foreseeable hazard during the hazard analysis...



# 1

## HARPC Citation

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 913-495-5100	11/29,30/2016; 12/2,6,7,8,9/2016
Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	FBI NUMBER
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	3002660788
TO: Mr. Jeffrey M. Gaddy, General Manager	
FIRM NAME	STREET ADDRESS
J&J Snack Foods Corp	1070 Industrial Court

You did not identify during your hazard analysis a known or foreseeable hazard (chemical) requiring a preventive control.

Specifically, you did not identify the chemical hazard for allergen cross-contact in your HACCP Product Category Description Wire Cut Cookies. Furthermore, you did not identify and implement a preventative control to control allergen cross-contact in your dairy free cookies. (b) (4) are used as an ingredient in the manufacture of (b) (4) which is formulated and labeled not to contain any dairy ingredients.

ected  
Cookies, Breakfast Bars  
FACILITY. THEY ARE INSPECTION  
AN OBJECTION REGARDING  
TION, YOU MAY DISCUSS TH  
A AT THE ADDRESS ABOVE.  
requiring a preventive  
CCP Product Category  
ive control to contro  
are used as an  
d and labeled not to  
aled dairy  
nalysis confirmed  
Lot Numbers:  
at not limited to the

# Inspections After FSMA

- Remember HACCP is now voluntary (except juice and seafood) and HACCP plans may have gaps; and
- Hazard analysis includes physical, chemical and microbiological, but don't forget how FSMA focuses on allergens.



# FSMA Perspectives

## Industry and Regulators Adjust to a New Paradigm

Steve Armstrong  
Independent Advisor, EAS Consulting  
May 3, 2018

# New Tools, New Methods

“FSMA is intended to offer a new public health paradigm for the FDA’s food safety program – the shifting of the food safety focus from reaction to prevention – by providing new tools to the government and industry. [While] the food safety focus has long been oriented toward prevention, FSMA certainly promotes the systematic building of preventive measures across the food system... With a special focus on regulating the increasing volume of imported foods.”

From *Food Law in the United States*

Michael T. Roberts, UCLA School of Law

# Learning Phase

- Both industry and FDA are adjusting to the new paradigm
  - Many producers are unfamiliar and somewhat uncomfortable with agency's new authority to inspect food safety records; differences over photography continue
  - FDA investigators are being encouraged to approach inspectional oversight in "system-oriented" terms
    - Focus inspectional visits on a particular program, e.g., supply chain, allergen program, FSVP, environmental monitoring
    - Observations alone are not the only mark of a successful inspection
- Industry must keep in mind that FDA, while educating, remains ready to protect public health with its new enforcement tools, e.g., facility suspension, mandatory recall



## Preventive Food Safety Systems

Compliance with FSMA requires a coordinated network of food safety programs, all designed to work together; important to think in terms of “systems,” which are all interlinked



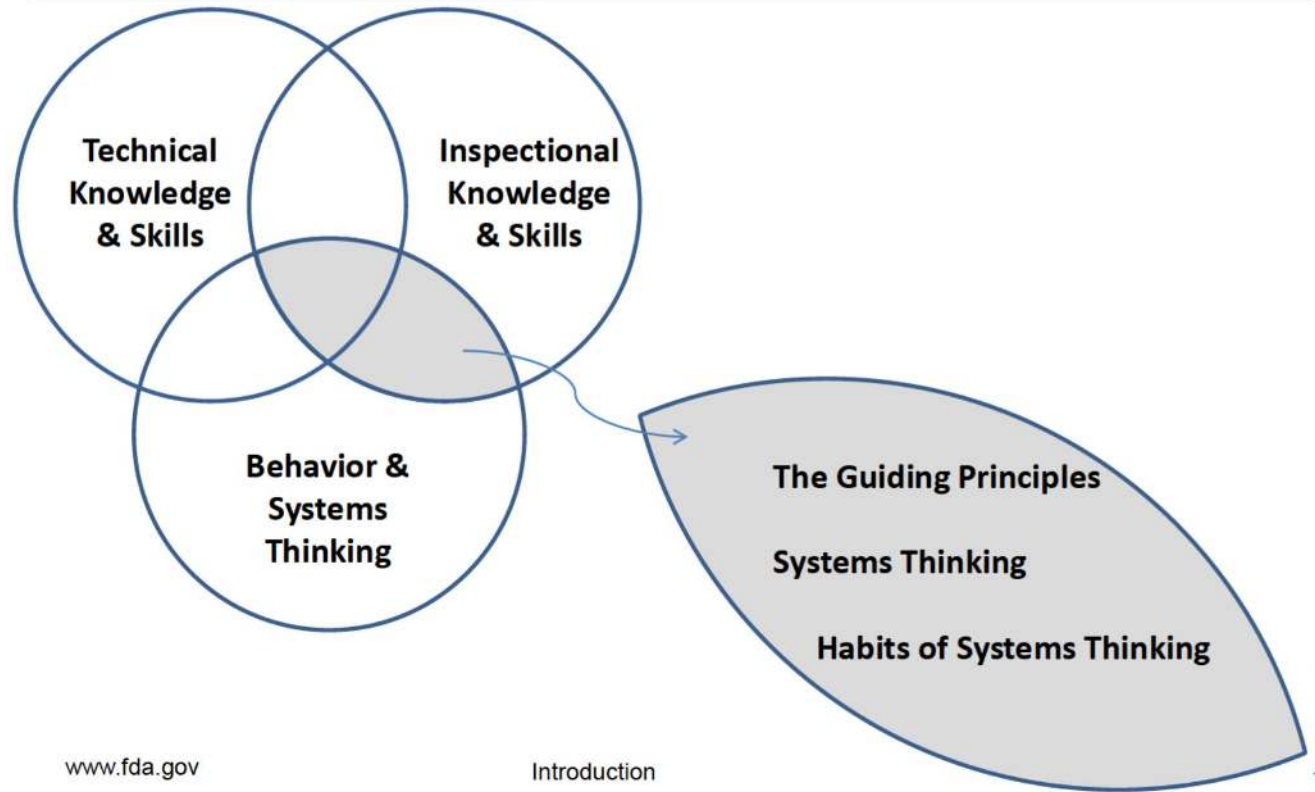
# Training FSVP Investigators

Instructional memo issued to field offices:

- Investigators conducting an FSVP inspection must first complete FSPCA course to become PCQIs
- A “Regulators Course” is also required
  - Stressing that food safety programs should be open, interactive and accountable
  - Introducing investigators to “Habits of A Systems-Thinking Mindset”

# The FSMA CONTEXT

Training for FSVP inspectors:  
Emphasis on “Systems Thinking”





# GUIDING PRINCIPLES OF A SYSTEMS-BASED FOOD SAFETY REGULATORY PROGRAM









Instructions to the  
Field:  
Approach FSVP  
Inspections with a  
“Systems  
Mindset”

- Build trust and accountability
- Promote open communication to enhance mutual understanding of food safety systems
- Utilize all tools to achieve compliance with relevant regulations
- Accomplish a common goal—produce safe food products and protect public health



## Key Habits for a Systems Thinking Mindset

	<p><b>Looking at the Big Picture</b> – stepping back to examine the dynamics of a system and the interrelationships among its parts.</p> <ul style="list-style-type: none"> <li>• Systems Thinker balances their focus between the forest and the details of any tree.</li> <li>• Question: “When we look at the firm, what does the big picture (the larger context) look like and how do the parts (other systems) fit together?”</li> </ul>
	<p><b>Recognizing Interdependencies</b> – recognizing the cause and effect relationships from the parts of the system.</p> <ul style="list-style-type: none"> <li>• Systems Thinker sees the interdependencies in a system and uncovers the connections.</li> <li>• Question: “How do the parts affect one another, and depend on one another?”</li> </ul>
	<p><b>Making Connections</b> – connect new information to what has already been observed by adding, modifying, transferring, and synthesizing the information</p> <ul style="list-style-type: none"> <li>• Systems Thinker sees how concepts, facts, and ideas link together, which can lead to new learning, discoveries and innovations.</li> <li>• Question: “How does this new information change/affect my understanding? Should I re-think my next steps?”</li> </ul>
	<p><b>Considering Assumptions and Internal Representations</b> – thinking through how past experiences influence the development of personal theories, views, filters, biases and mental models (pictures in the mind)</p> <ul style="list-style-type: none"> <li>• A systems thinker is aware of how their beliefs and attitudes, and personal mental pictures influence perspectives and actions</li> <li>• Question: “What are my biases, assumptions, expectations, past experiences and mental pictures about the firm, and how can I get think differently?”</li> </ul>
	<p><b>Assessing from Many Perspectives</b> – considering the system from a variety of different angles and from differing points of view, in collaboration with others</p> <ul style="list-style-type: none"> <li>• A systems thinker increases understanding by changing the ways he or she looks at the system.</li> <li>• Question: “Am/are I/we open to other points of view?”</li> </ul>
	<p><b>Seeing Issues Fully:</b> be patient and resist the urge to come to a quick conclusion</p> <ul style="list-style-type: none"> <li>• A Systems Thinker takes time to understand the system’s structure and its behaviors before making judgement while a deeper understanding of the system is developed</li> <li>• Question: “What questions could I ask to deepen my understanding of the issues before I take action?”</li> </ul>

# SOFT SKILLS



Along with systems thinking, the course will integrate behaviors and skills needed to effectively:

- build rapport
- get information from others
- develop good working relationships
- diffuse difficult situations

These soft skills are very important to your success as an investigator to conduct an effective inspection.

# Seeing the Big Picture

- FDA is clearly making the effort to reach out to industry
  - and to its investigators
    - A new, holistic approach to evaluating food safety systems
- Continued efforts will be necessary all around to ensure that inspectors have visibility to where and how food safety programs are managed
  - At food facilities themselves, e.g., HACCP and environmental monitoring
  - At central offices, e.g., supplier management, technical support, standard setting

# Period of Adjustment

- Adjusting to the FSMA paradigm will still take some time
  - Industry will continue to feel uneasy about sharing detailed processing and testing records, since they have not had to share a lot before now
  - Regulators, trained to verify everything, may be reluctant to accept freely offered information at face value
- Ultimately, the framework set up by FSMA should encourage information sharing and collaboration
- And promote transparency, trust and collaboration toward the shared goal of safeguarding public health