



FSMA Year One

Advancing and Building
The 21st Century Food Safety System

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EAS Consulting Group

Food Safety: The Old-Fashioned Way



FSMA: Redirecting the Focus Toward *Prevention*

- Under FSMA, a food is now adulterated unless it is made in an FDA-registered facility with a food safety plan providing for:
 - Analysis of the significant human health hazards that could affect the food
 - Preventive controls to avoid or minimize their occurrence
 - Corrective action procedures
 - Monitoring to assure effectiveness
 - Verification and recordkeeping
 - Periodic re-analysis of hazards
- “Preventive Controls” should include measures that a prudent food safety professional would employ:
 - Process controls
 - Sanitation procedures
 - Training in food safety and personal hygiene for all employees
 - Environmental monitoring where necessary (RTE)
 - Food allergen program
 - Recall plan
 - cGMPs
 - Supplier verification activities relating to food safety

Swinging Into Action...

- FDA saw early on that implementing FSMA was going to require a multi-pronged approach:
 - Extensive outreach to inform manufacturers, distributors and importers of what FSMA requires
 - Ongoing efforts to educate industry, especially small and medium-sized companies
 - Many such firms are becoming an increasingly important part of the emerging the food economy
 - Collaboration with industry to achieve these objectives

A New Challenge for FDA

“Food safety success requires a comprehensive systems approach that considers all possible pathways for contamination and in which everyone in the system understands their role and does their part.

“[FDA] will have our greatest positive impact on food safety by thinking about our role in a more expansive way. We are the federal regulator, of course, but we are also an educator, a collaborator and even a partner with those who share the food safety goals now embodied in FSMA.”

*Michael R. Taylor
FDA Deputy Commissioner
Harvey Wiley Lecture
Food and Drug Law Institute
April 20, 2015*



A “New Chapter...”

“We know that this is new territory for food companies; it’s new territory for us too. For years we’ve been talking about the FSMA rulemakings and our implementation plans. Now, an important compliance date is here for some companies.

“As we enter this new chapter, the FDA’s primary focus will continue to be on education, training and technical assistance to help companies comply with the new requirements.

“We intend to continue this dialogue and collaboration with regulated industry to ensure that everyone understands and engages in their respective roles in food safety.”



Joann Givens, FDA Office of Regulatory Affairs

“What to Expect Now that the First Big FSMA Compliance Dates
Are Here”

September 2016

FSVP: Educating Importers



“We have done a lot of outreach already to help importers understand the regulations and what they have to do. However, we understand that this is new to a lot of importers, so our approach will be to educate while we regulate to create a culture of compliance.”

“Importers can expect interactive FDA inspections with opportunities to explain how their programs meet our requirements and how they will take corrective actions if we observe deficiencies. Good communication is key.”

From www.fda.gov Q&A:

“FSVP: What Do Importers Need to Know?”

Conversation with Sharon Mayl

FDA Senior Policy Advisor

FDA Implementation Activities

- Provide technical assistance, *i.e.*, the framework for implementing preventive controls
 - Draft guidance on cGMP requirements, 21 CFR, part 117
 - Chapters 1-5 and App. 1 (issued 8/16)
 - Ch. 6 on Heat Treatments recently issued
 - Two dozen more guidance documents planned over the coming months
- Promote education and training, collaborating with industry, academia
 - Key role of **Food Safety Preventive Controls Alliance (“FSPCA”)**
 - FSPCA training in FSMA for both industry and FDA inspectors
- Conduct inspections that “educate while we regulate”
 - Provide fact sheets and Q&As
 - Especially to importers, who were not subject to regulation prior to FSMA implementation date of 5/30/17
 - Inform facility / importer of FSPCA training and technical resources



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



- Initiated in September 2011, composed of members from the FDA, state regulatory agencies, industry, and academia
- Created under an FDA grant to the Illinois Institute of Technology's Institute for Food Safety and Health
- Developing training and information specifically designed to help industry, especially small and medium-sized companies, comply with FSMA



Alliance Agenda



- Develop a standardized hazard analysis and preventive controls training course and distance education modules for food industry and regulatory personnel
 - State-of-the-art distance learning training portal at the IIT IFSH Moffett Campus in Bedford Park, Ill.
 - “Train-the-trainer” materials and student education delivery systems
- Technical assistance network, with information that can be used for commodity/industry sector-specific guidelines for preventive controls
- Assess knowledge gaps and research needs for further enhancement of preventive controls measures
- Identify and prioritize the need for, and compile, minimum/maximum values (e.g. critical limits) for parameters for widely used process controls

Standard Texts for FSMA Training

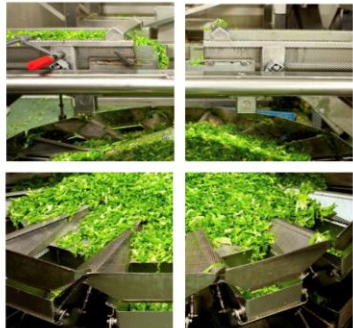


FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

**Preventive Controls
for Human Food**

First Edition - 2016



Participant Manual



FSPCA

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

**Foreign Supplier
Verification Programs**

First Edition - 2017

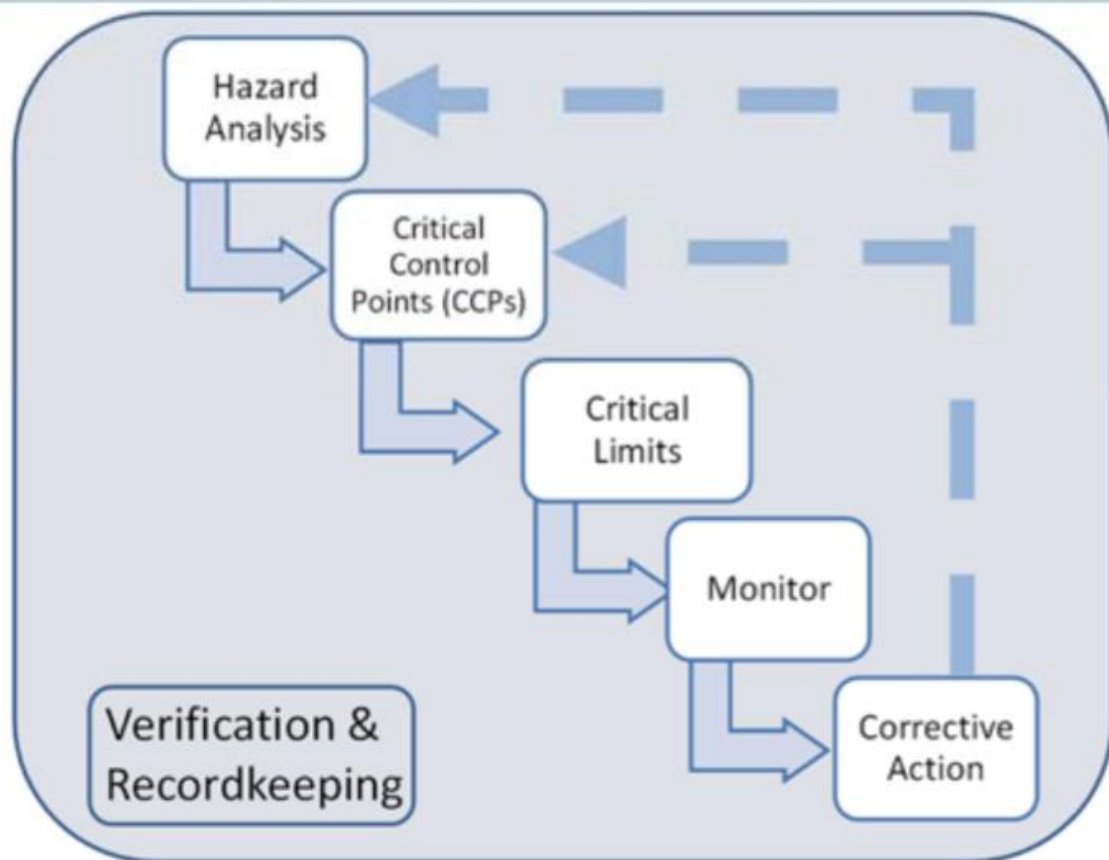


Participant Manual

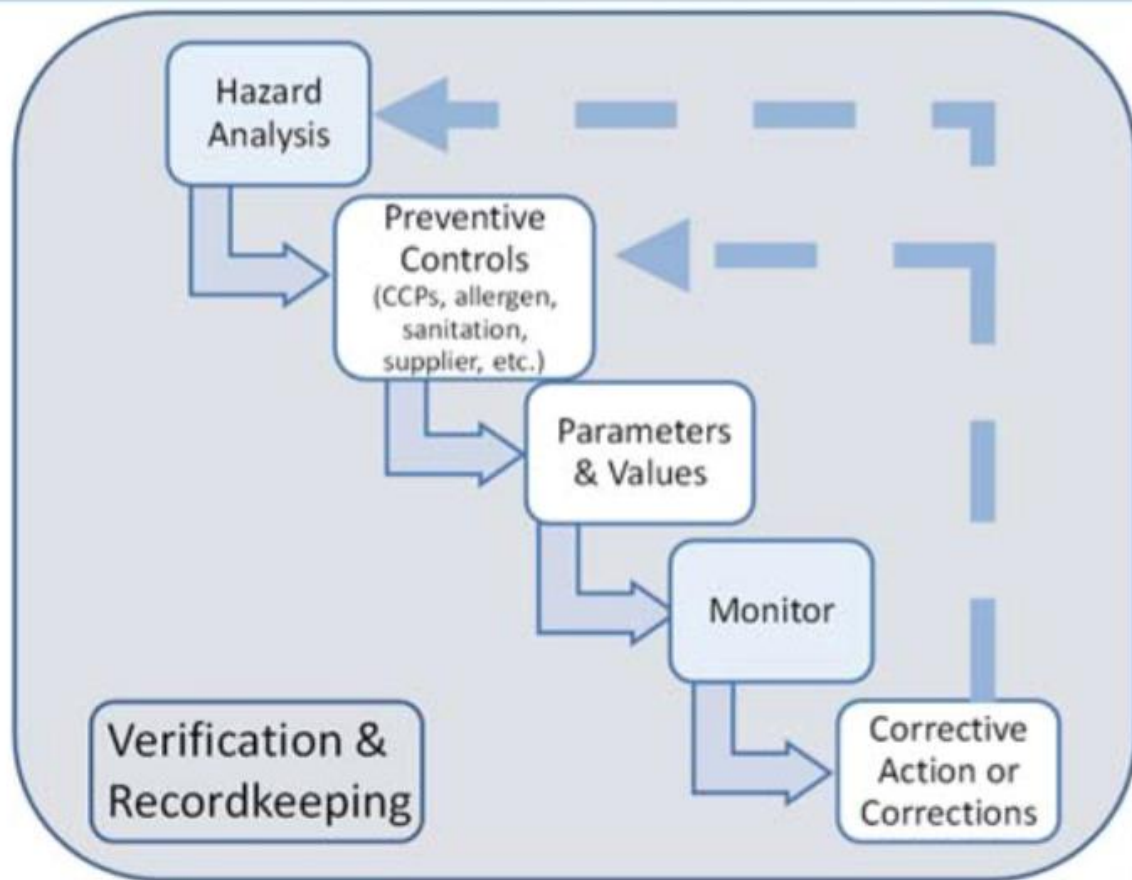
The Heart of the Matter...

- The FSPCA materials waste no time in explaining the kind of approach that FSMA requires
- A key point, made early on:
 - Don't confuse HACCP with HARPC, *i.e.*, the risk-based hazard analysis and preventive controls for human or animal food now required by FSMA
 - Understanding the difference is key to understanding how to comply with FSMA

Historically HACCP Focuses on the Process

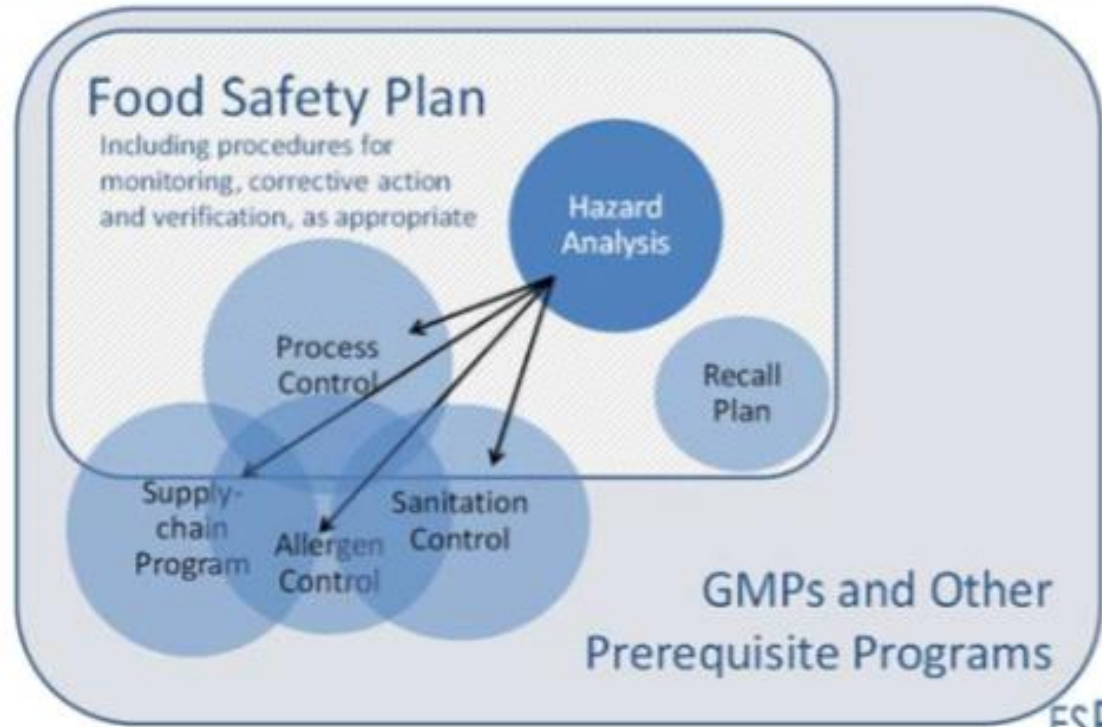


Preventive Controls Include More Than HACCP



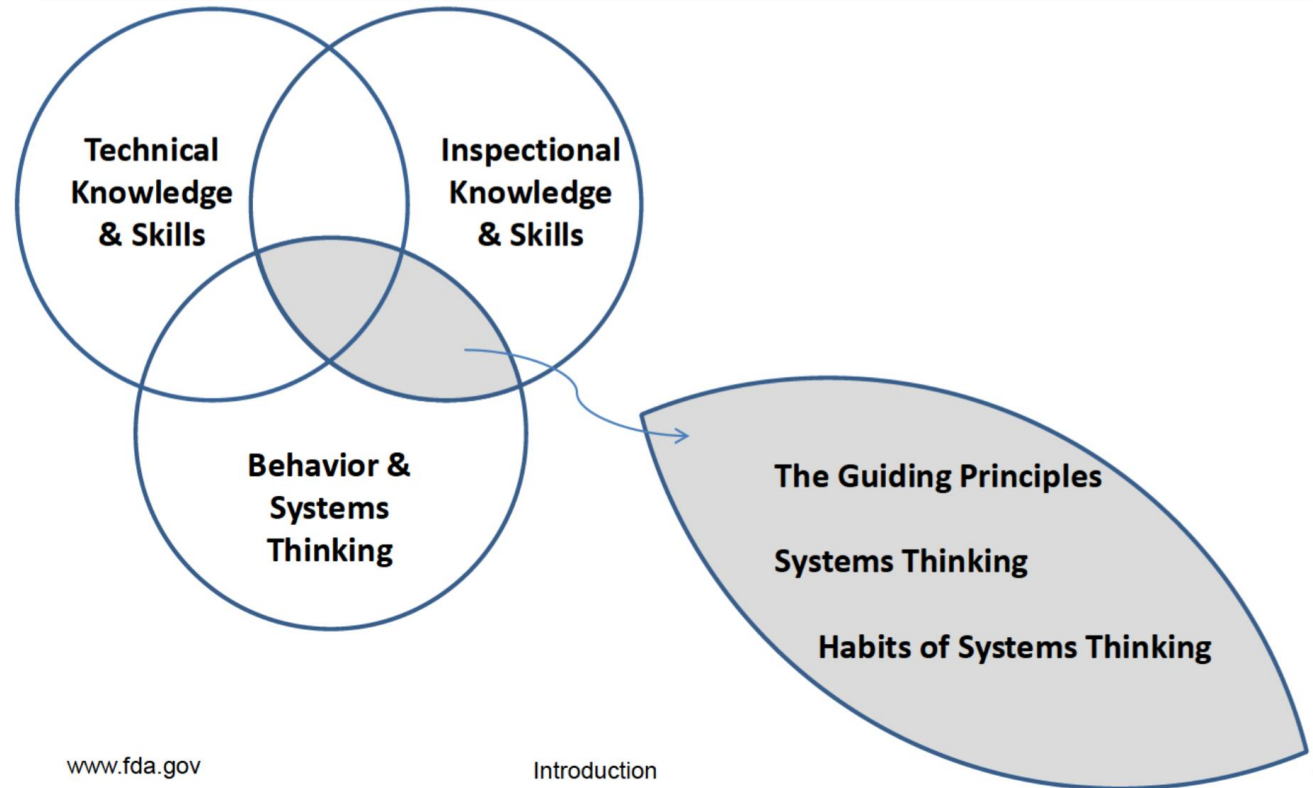
A Network
Of Systems
Designed
To Work
Together

Preventive Food Safety Systems



The FSMA CONTEXT

FSMA Training for
Inspectors:
Emphasis on
“Systems Thinking”

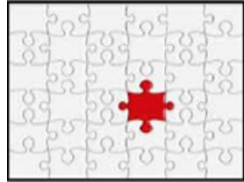


GUIDING PRINCIPLES OF A SYSTEMS-BASED FOOD SAFETY REGULATORY PROGRAM

Food safety
systems should be
open, interactive,
collaborative and
grounded in trust

- 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”



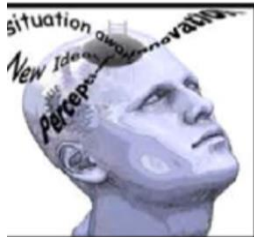
Looking at the Big Picture – stepping back to examine the dynamics of a system and the interrelationships among its parts.

- Systems Thinker balances their focus between the forest and the details of any tree.
- 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?”



Recognizing Interdependencies – recognizing the cause and effect relationships from the parts of the system.

- Systems Thinker sees the interdependencies in a system and uncovers the connections.
- Question: “How do the parts affect one another, and depend on one another?”



Making Connections –connect new information to what has already been observed by adding, modifying, transferring, and synthesizing the information

- Systems Thinker sees how concepts, facts, and ideas link together, which can lead to new learning, discoveries and innovations.
- Question: “How does this new information change/affect my understanding? Should I re-think my next steps?

More Habits of “Systems Thinking”



Considering Assumptions and Internal Representations – thinking through how past experiences influence the development of personal theories, views, filters, biases and mental models (pictures in the mind)

- A systems thinker is aware of how their beliefs and attitudes, and personal mental pictures influence perspectives and actions
- Question: “What are my biases, assumptions, expectations, past experiences and mental pictures about the firm, and how can I get think differently?”



Assessing from Many Perspectives – considering the system from a variety of different angles and from differing points of view, in collaboration with others

- A systems thinker increases understanding by changing the ways he or she looks at the system.
- Question: “Am/are I/we open to other points of view?”



Seeing Issues Fully: be patient and resist the urge to come to a quick conclusion

- 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
- Question: “What questions could I ask to deepen my understanding of the issues before I take action?”

Seeing the Big Picture?

- FDA is clearly making the effort to reach out to industry – and to its own consumer safety inspectors
 - A new, holistic approach to evaluating food safety systems
- Continued efforts will be necessary all around to ensure that FDA inspectors have visibility to where and how food safety programs are managed
 - At food facilities themselves, *e.g.*, process controls, allergen programs, environmental monitoring
 - At a firm's central offices, *e.g.*, supplier management, technical support, standard setting
 - At the importer's office, warehouse, the foreign facility and its supply chain
- In any event, the inspection experience under FSMA, should be quite different, if FDA's training materials are any indication...

Introductory
page from a
current course
for FSVP
investigators!

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.