FSMA , PREVENTIVE CONTROLS & FSPCA : AN UPDATE

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Citrus Packinghouse day
Lake Alfred, FL
August 27 2015

1

Objective

- To review major provisions of FSMA and FDA expectations
- To discuss Food Safety Preventive Controls Alliance (FSPCA)
  - training, outreach and Technical assistance

Agenda

- Introduction
- FSMA – Major provisions and FDA expectations
- Preventive Controls – Changing paradigm
- Supply chain management, Imports and Foreign Supplier Verification Programs (FSVPs)
- Food Safety Preventive Controls Alliance (FSPCA)
- Summary

Introduction

- Professor Emeritus University of Wisconsin – River Falls
- PCV & Associates, LLC
- FDA-ORISE Fellow/Food Safety Preventive Controls Alliance (FSPCA)
- Emerging Pathogens and Rapid Methods and Automation in Food Microbiology
- Food Safety and Microbiology Specialist- UW Extension
- Professor of Food Science

Food Safety Modernization Act (FSMA)

" . . . the most important change to food safety in over 70 years . . ."

- Focus on prevention
- Broad prevention mandate and accountability
- Emphasizes farm-to-table responsibility
- Applies to domestic as well as Imports

5

FSMA – Main Themes

I. Prevention
II. Inspection, Compliance, and Response
III. Import Safety
IV. Enhanced Partnerships

- Confirms industry's primary role on food safety
- Risk-based
- Prevention of hazards

FDA FOOD SAFETY MODERNIZATION ACT

6

FSMA Foundational Proposed Rules

Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)*	January 16, 2013	August 30, 2015
Preventive Controls (Animal Food)*	October 29, 2013	August 30, 2015
Produce Safety*	January 16, 2013	October 31, 2015
Foreign Supplier Verification Program*	July 29, 2013	October 31, 2015
Third Party Accreditation	July 29, 2013	October 31, 2015
Sanitary Transport	February 5, 2014	March 31, 2016
Intentional Adulteration	December 24, 2013	May 31, 2016
Traceability	(Pending)	

**Supplemental proposals published September 2014*

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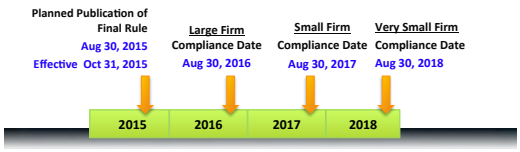
Preventive Controls Human and Animal Food Regulations Implementation Timeline



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8

FSMA- Who is covered?

- FDA has oversight of more than 166,000 registered domestic food facilities
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
- Applies to domestic and imported food
- Some exemptions and modified requirements

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Exemptions

- "Qualified" facilities:
  - Very small businesses (< $1 million in total annual sales)
- Foods subject to low-acid canned food regulations (microbiological hazards only)
- Foods subject to HACCP (seafood and juice)
- Dietary supplements
- Alcoholic beverages
- Farm related exemptions
- Certain storage facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables)

Exemptions

- Facilities such as warehouses that store raw agricultural commodities that are fruits and vegetables are NOT exempt from hazard analysis and risk-based preventive controls
- Facilities, such as warehouses, that only store packaged foods that are not exposed to the environment
  - Certain packaged food for which refrigeration is required for safety must have temperature controls, monitoring, verification and records

Who is Covered by FSMA?

- According to current proposed rule, most (if not all) citrus packinghouses are going to fall under the PC rule, not the produce rule
- Must comply with FSMA-Preventive Control rule
  - Written Food Safety Plan
  - Hazard Analysis
  - Preventive Controls

FDA Expectations

- FSMA Preventive Controls –
- Have a written food safety plan (FSP)
- Conduct Risk-based Hazard analysis (identify "significant" hazards)
- Put in place controls to significantly reduce or prevent hazards (Preventive Controls)
- Monitor the controls, establish corrective actions, and verify that the plan is working
- Keep records on implementation of FSP
- Reanalyze the FSP
- Importers are expected to comply with PC supplier program provisions

FDA Expectations

- Qualified Individual
- Responsible for:
  - Preparation of the food safety plan
  - Validation of the preventive controls
  - Review of records
  - Reanalysis of the food safety plan
- Must have successfully completed training in the development and application of risk-based preventive controls (At least equivalent to that received under a standardized curriculum recognized as adequate by FDA)
- be otherwise qualified through job experience to develop and apply a food safety system.

Preventive Controls: Changing paradigm

Preventive Controls - Definition

- "Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understand of safe food manufacturing, processing, packaging, or holding a the time of the analysis."
  - 21 CFR 117.3 Definitions

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Preventive Controls Many Include:

- Process preventive controls (CCP?)
- Food allergen preventive controls
  - Accurate labeling
  - Cross-contact prevention
- Sanitation preventive controls
  - Environmental pathogens
  - Cross-contamination, cross-contact
- Supplier preventive controls
- Other preventive controls
  - If needed

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FDA's Strategy of Creating Alliances

- Public private partnership
- Three alliances established by FDA based on previously successful model of Seafood and Juice HACCP Alliance
- Produce Safety Alliance (2010)
- Food Safety Preventive Controls Alliance (2011)
- Sprout Safety Alliance (2012)

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Food Safety Preventive Controls Alliance

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

- What is it?
- How does FSPCA relate to FSMA?
- Structure and organization
- Curriculum, Outreach and Technical assistance
- FSPCA webpage

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19

FSPCA: What is it and How does it relate to FSMA?

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH

- Public –private partnership following the Seafood HACCP Alliance model.
- FSPCA followed similar format, but with different structure to account to various commodities included in FSMA
- FDA recognized the need to provide food industry, particularly small and medium companies, education, training and assistance in understanding the technical elements of regulations and compliance with FSMA
- Continuing grant managed by IFSH

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FSPCA - Public-Private Partnership

FSPCA Structure and Organization

FSPCA Curriculum

- FSPCA Standardized course
  - Course for Preventive Controls for human foods
  - Course for Preventive Controls for animal foods
- 3 Pilots and one Small business focus group have been concluded
- Feedback on content, organization, exercises, timing, etc.
- Course cannot be finalized until the final regulation is published on August 30, 2015
- Finalization in September

FSPCA Curriculum

Introduction to Preventive Controls	Sanitation Preventive Controls
Prerequisite Programs and GMPs	Supplier program
Food Safety Hazards	Recall Plan
Preliminary Steps	Verification Validation Procedures
Food Safety Plan Overview	Record-keeping Procedures
Hazard Analysis and Preventive Control Determination	Regulation Overview – cGMPs and Hazard Analysis and risk-based Preventive Controls for Human Foods
Process Preventive Controls	Resources for Food Safety Plan
Food Allergen Preventive Controls	Preventive Controls for Human Foods Review
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Appendices -	

Food Safety Plan vs. HACCP

- Is Food Safety Plan (FSP) ≠ the same as HACCP we know it.
- Some aspects are similar but also key differences
- ***HACCP plan:*** A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration (Codex Alimentarius).
- ***Food Safety Plan:*** A set of written documents that is based upon food safety principles; incorporates hazard analysis, preventive controls, and a recall plan; and delineates the procedures for monitoring, corrective actions and verification to be followed.

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Food Safety Plan vs. HACCP

- Applicable sections of FD&C Act
  - Section 418(b) - hazard analysis
  - Section 418(c) - preventive controls
  - Section 418(d) the monitoring procedures
  - Section 418(e) the corrective action procedures
  - Section 418(f) - verification procedure, and
  - Section 418(o)(3)(E) - the recall plan

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How Does GMPs, PRPs, HACCP and Food Safety Plan Related?

- HACCP → Food Safety Plan (FSP)
- Some PRPs → Preventive Controls (PC)
- CCP → Critical Limit of Preventive Control
- Cross-contamination(allergen) → Cross-contact
- Cross-contamination(microbiological) →Cross-contamination

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What about HACCP and HARPC?

- Both involve Hazard analysis
- Both involve consideration of biological, Chemical and Physical hazards, HARPC include consideration of radiological hazard as a part of chemical hazards
- HACCP involves GMPs and Prerequisite programs (PPs) and addresses hazards controlled by/at CCPs
- HARPC involves control of "significant" hazard by Preventive Controls.
- HACCP involves establishing of "Critical limits". Some preventive Controls may not have "critical limits" and are controlled by "parameters and values"
- Both involve monitoring, Verification/Validation and Record keeping

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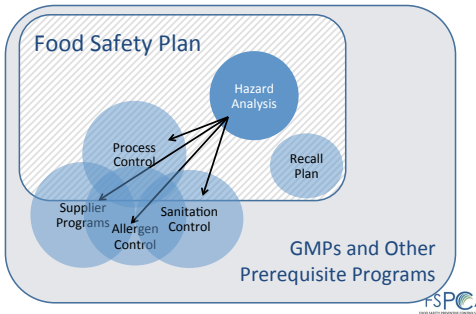
Food Safety Plan Includes More Than HACCP



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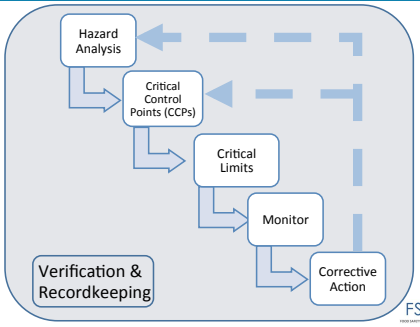
HACCP Focuses on the Process



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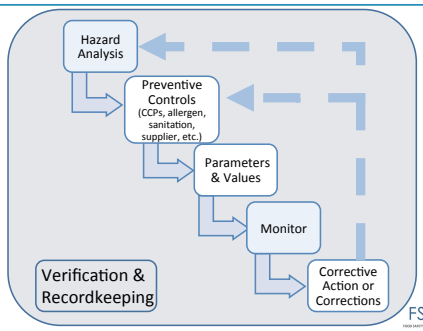
Preventive Controls Enhance HACCP



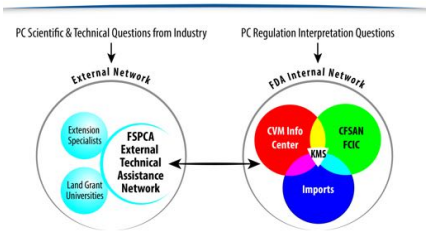
FSPCA Curriculum, Outreach and Technical Assistance Network

- FSPCA curriculum will include
  - Participants Manual & Exercise Workbook
  - Instructors Manual with select explanatory text
  - Instructor's Exercise Workbook
  - Electronic Resource and support material
  - Access to Technical Assistance Portal information for FSPCA Lead Instructors
- Lead Instructor recruitment
- Train-the-Trainer follows completion
- Intense roll out plan
- Hybrid course- Segment I (on line)) and one-day practicum (Segment II) in lieu of 2.5-day course

FSPCA Outreach & Technical Assistance

- Outreach-
  - Informational sessions and updates at Professional meetings
  - Quarterly webinars
- Lead Instructor recruitment (criteria and application on FSPCA website
  - University & Extension Specialists, State Regulators, consultants and private training providers, Professional Associations, Contract Laboratories, Third Party Audit Companies, International Partners, Others
- Technical Assistance Network – Domestic
  - FAQ and other helpful information resources

FDA Food/Feed Internal and External Technical Assistance Networks



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34

FSPCA Quarterly Webinars

2015 Webinars

- March 12
- June 24
- September 3
- December 17

FSPCA Webinars

The Food Safety Preventive Controls Alliance (FSPCA), in collaboration with the Food and Drug Administration (FDA), hosts quarterly webinars to update stakeholders on the progress of the Alliance. 2015 webinars are scheduled for **March 12, June 24, September 3 and December 17.** Click here to register.

June 24, 2015

With publication of the final rules expected this August, the FSPCA Quarterly Update Webinars are filling up quickly. Early registration is encouraged. If you were unable to register for the June 24th webinar, you can download the recording here.

Download past webinar recordings:
August 24, 2014 | May 12, 2014 | March 12, 2015

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35

What to Expect in the Final Preventive Controls Rule and How Might it Affect the Citrus Industry?

- Very similar to Supplemental Proposed Rules
  - > 90-95% rules will be the same
  - Clarification on training requirement
  - Testing and monitoring
  - Verification and Validation
- Know if you are affected and how?
- Does Animal Food Rule applies to you?
- Review Hazards, Risks and prepare FSP
- Have a Qualified individual(s)
- PSA / FSPCA Training or equivalent
- FDA External and Internal Technical Assistance network

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Take Home

- FSMA is focused on FDA's Prevention mandate and Farm-to-table responsibility and accountability for food industry, including Domestic as well as imported foods
- Final rules to be published on August 30, 2015 (> 90-95% rules will be the same)
- FSPCA and PSA training course will be available to help FSMA implementation
- Industry assistance through the FDA Outreach as well as through Food Safety Preventive Control Alliance (FSPCA), Produce Safety Alliance (PSA) and Sprout Safety Alliance(SSA).
- National Coordinating Center and 4 regional centers to help training, outreach and technical assistance

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Thank you!!

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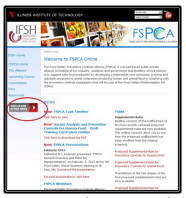
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

- Committees and meeting summaries
- Task Timeline
- Draft Training Curriculum Outline
- FSPCA Presentations
- FSMA Proposed & Supplemental Rules
- Webinar events
- Lead Instructor criteria and Application
- Quarterly webinars
- FAQs

FSPCA Website:
www.iit.edu/ifsh/alliance



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http://www.iit.edu/ifsh/allianceindex.shtml

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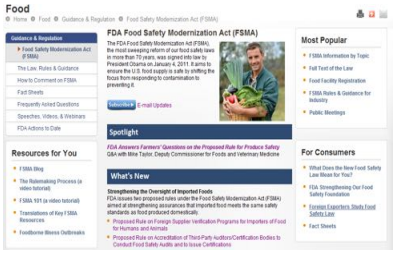
Information and updates on FDA's FSMA website

http://www.fda.gov/fsma
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm



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39