

Overview of the FSMA Rules

U.S. Food and Drug Administration

<http://www.fda.gov/fsma>

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FDA FOOD SAFETY
MODERNIZATION ACT

THE FUTURE IS NOW



Agenda

- Introduction to FSMA
- The FSMA Produce Rule
- The FSMA Preventive Controls for Human Food Rule
- The Foreign Supplier Verification Programs (FSVP) Rule
- Questions and Answers

Why is FSMA needed?

- Foodborne illness is a significant burden.
 - About 48 million (1 in 6 Americans) get sick each year;
 - 128,000 are hospitalized; and
 - 3,000 die.
- Globalization
 - 15 percent of U.S. food supply is imported.
- Food supply is more high-tech and complex.
 - More foods in the marketplace
 - New hazards in foods not previously seen
- Shifting demographics
 - Growing population (about 30%) of individuals are especially “at risk” for foodborne illness.



The 7 Major FSMA Rules

- Produce Safety Standards
- Preventive Controls for Human Food (PCHF)
- Foreign Supplier Verification Program
- Preventive Controls (Animal Food)
- Third Party Accreditation
- Sanitary Transport
- Intentional Adulteration

Implementation Approach

- Implementation already underway
- Coalition needed
- Transparency a priority
- Focus on public health protection
- Engage with stakeholders to help determine reasonable and practical ways to implement provisions

Produce
Final

Final Rule on Produce Safety

<http://www.fda.gov/fsma>



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Coverage of Produce Safety Rule

(published November 27, 2015)

Produce
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Covers

- Domestic and imported produce
- Produce for human consumption

Does not cover

- Produce for personal or on-farm consumption
- Produce not a “raw agricultural commodity”
- Certain specified produce rarely consumed raw
- Farms with produce sales of \leq \$25,000 per year

Eligible for exemption (with modified requirements)

- Produce that will receive commercial processing (“kill-step” or other process that adequately minimizes hazards)
- Qualified exemption



Farms

- “Farm” definition revised to:
 - clarify that the relevant entity is the farm business
 - reflect modern farming practices
- Manufacturing/processing that goes beyond activities within the farm definition do not fall under “farm”; for example:
 - Chopping herbs;
 - Roasting peanuts or tree nuts

Standards for Produce Safety

Produce
Final

Focus on conditions and practices identified as potential contributing factors for microbial contamination

- Agricultural water
- Biological soil amendments of animal origin
- Worker health and hygiene
- Equipment, tools, buildings and sanitation
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities
- Sprouts requirements

Variations - Flexibility

- A state, tribe, or foreign country may petition FDA for a variance from some or all provisions
 - if necessary in light of local growing conditions
 - Practices under the variance need to provide the same level of public health protection as the rule and not increase the risk that produce is adulterated

Applicability to Spices

- “Produce” includes crops often thought of as “spices” such as peppercorns, saffron and cumin.
- Such crops are potentially subject to the produce rule, but some key limits include:
 - Commercial processing exemption (disclosure and records requirements apply) (§ 112.2(b))
 - Other exemptions or limitations may be relevant (e.g., based on farm size) (§§ 112.4, 112.5)

Applicability to Spices (cont'd)

- Making spice products that are processed foods such as ground spices and spice mixes is not within the farm definition
 - Making such products may be subject to the cGMPs and/or Preventive Controls requirements in Part 117 (as applicable)

Supply chain example

- Peppercorns grown, harvested, and packed by “A”
 - Black pepper dried on site by A (for moisture control only; does not create distinct commodity – still a RAC)
- Peppercorns sold to “B” who aggregates and stores peppercorns from multiple growers
 - Drying continues at B’s location – still a RAC
- Peppercorns sold to “C” who treats for pathogens, grinds some peppercorns into ground pepper, and packages pepper (as whole peppercorns and as ground pepper) for retail sale to consumers
 - C’s pathogen control treatment uses a validated process that adequately reduces pathogens

Supply chain example (cont'd)

Produce
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- “A” is a **farm** and may be subject to the produce rule
 - “A” may not be covered, or may be exempt, based on factors such as business size (e.g., A would not be covered if A’s average annual value of produce sold is \$25,000 US or less (§ 112.4))
 - IF “A” is a covered farm, peppercorns that receive commercial processing that adequately reduces pathogens (in this example, performed by “C”) are eligible for exemption (§ 112.2(b)). “A” would need to comply with certain records and disclosure requirements.
- “**B**” and “**C**” are facilities:
 - May be required to register (see Part 1, Subpart H)
 - May be subject to cGMP requirements (Part 117, Subpart B)
 - May be subject to Hazard Analysis and Preventive Controls requirements (Part 117, Subparts C and G)
 - May be subject to Foreign Supplier Verification Program requirements (Part 1, Subpart L)

Final Rules Preventive Controls for Human Food Preventive Controls for Animal Food

<http://www.fda.gov/fsma>

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FSMA Preventive Controls Human Food (PCHF) published Sept. 17, 2015

Human PC
Final

- Requires facilities that must register (with some exceptions such as seafood) to
 - Conduct a hazard analysis
 - Implement preventive controls (PCs) for hazards
 - Monitor PCs, verify PCs, take corrective actions, keep records

The facilities are domestic and foreign facilities producing food for consumption in the U.S.



Farms

- A farm is exempt from FDA's food facility registration requirement.
- Facilities that do not have to register with FDA are not subject to the preventive controls requirements.
 - Depending on certain factors, farms may be subject to the FSMA Produce Safety rule.
- PCHF revises the farm definition to reflect modern farming practices.

FSMA PC Food Safety Plan

§ 117.126

- Hazard analysis
- Preventive controls
- Supply-chain program
- Recall plan
- Procedures for monitoring
- Corrective action procedures
- Verification procedures

FSMA Food Safety Plan vs. HACCP Plan

Food Safety Plan	HACCP Plan
Hazard analysis	Hazard analysis
Preventive controls (PCs)	CCPs to control food hazards
*	Critical limits
Monitoring**	Monitoring
Corrective actions**	Corrective actions
Verification**	Verification
Records	Records

*Process controls have, as appropriate, parameters and min./max. values

**As appropriate to ensure the effectiveness of the PCs, taking into account the nature of the PC

Food Safety Plan – Hazard Analysis

- Hazard identification must consider known or reasonably foreseeable biological, chemical and physical hazards.
 - These could occur naturally, be unintentionally introduced, or be intentionally introduced for economic gain.

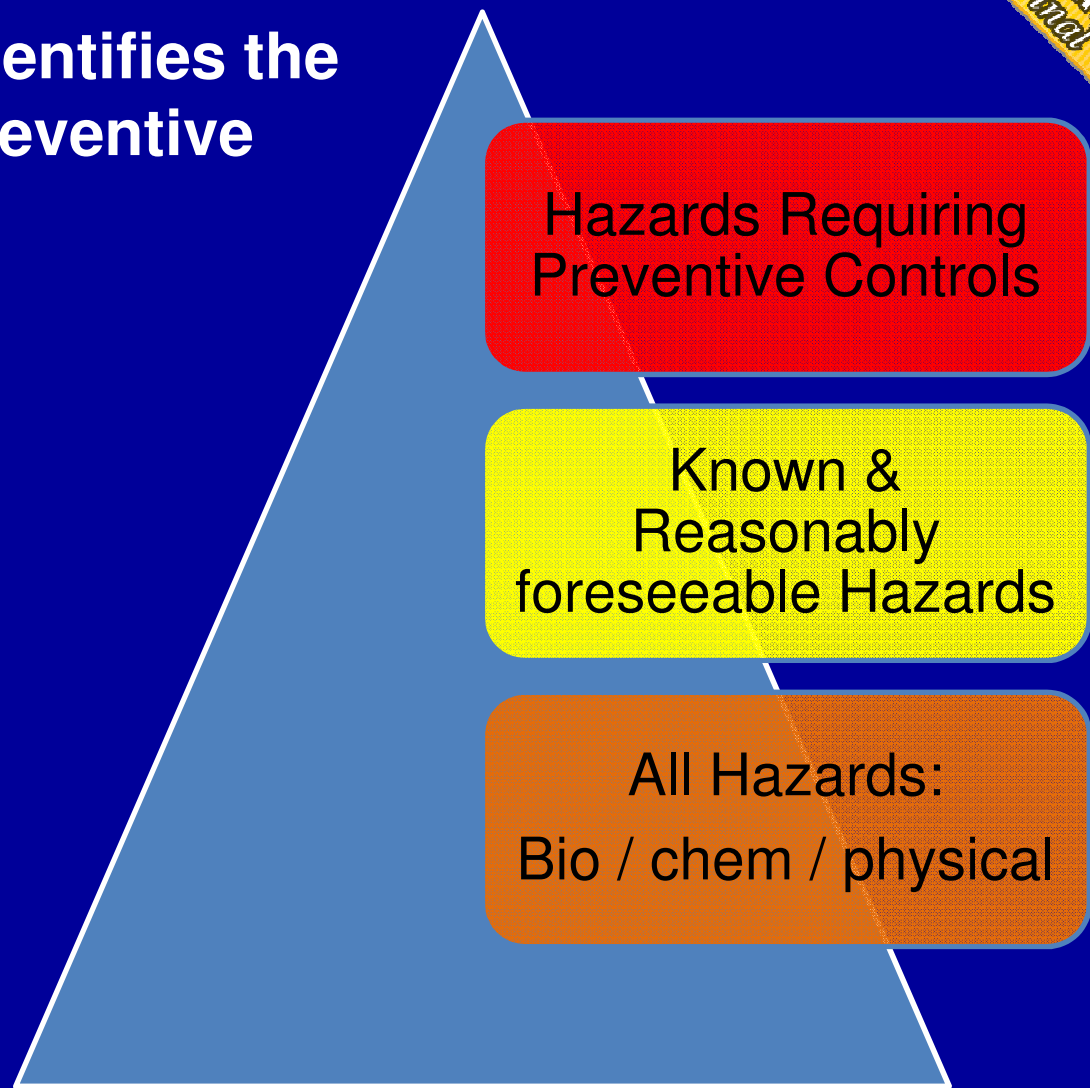
Hazard evaluation identifies the hazards requiring preventive controls

§ 117.130 Hazard Analysis includes:

Hazard Identification to list “known and reasonably foreseeable hazards”

Hazard Evaluation

Assesses the *severity* of illness... and the *probability* that the hazard will occur in the absence of preventive controls.



Not all hazards require a preventive control

- § 117.3 Definition: *Hazard requiring a preventive control*
- A hazard for which a knowledgeable person would, based on the outcome of a hazard analysis assessing the severity and probability ... would establish one or more preventive controls...as appropriate to the food and facility... to significantly minimize or prevent the hazard in a food

What are Preventive Controls?

- Measures required to ensure that hazards are **significantly minimized or prevented (SMOP)**. In § 117.135, these include:
 - Process controls
 - Food allergen controls
 - Sanitation controls
 - Supply-chain controls
 - Recall plan

Flexibility for Preventive Controls

Required Preventive Controls Include:

(i) controls at critical control points (CCPs), if any, and

(ii) **controls other than those at CCPs** that are appropriate for food safety, (e.g., some “prerequisite programs” or CGMPs)

117.135 (a)(2)

When are Preventive Controls not required? § 117.136

- Not required if type of food could not be consumed without application of an appropriate control (e.g., cocoa beans, coffee beans)
- Not required when hazard is controlled by another entity later in the distribution chain
 - Disclose that food is for further processing
 - Obtain assurances hazard will be controlled

Preventive Control Management Components

§ 117.140

- Monitoring
- Corrective Actions
- Verification

As appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system

Food Safety Plan - Verification

- Includes (as appropriate to the facility, food and nature of the preventive control):
 - **Validation** of preventive controls
 - **Verification** of monitoring and corrective actions
 - Calibration of process monitoring and verification instruments
 - Product testing, environmental monitoring
 - Records review and reanalysis

PC Qualified Individual

- A qualified individual who has 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 or is otherwise qualified through job experience to develop and apply a food safety system.

Responsibilities of a Preventive Controls Qualified Individual

- Preparation of the food safety plan
- Validation of preventive controls
- Review of records
- Reanalysis

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

FSPCA Website

- Lead Instructor Application
- Task Timeline
- Draft Training Curriculum Outline
- FSPCA One Page Flyer
- FSPCA Pilot Sessions
- FSPCA Presentations
- FSMA Proposed & Supplemental Rules
- Webinar Events
- Committees & Meeting Summaries
- FAQs

The screenshot shows the homepage of the Food Safety Preventive Controls Alliance (FSPCA) website. At the top, there is a navigation bar with the Illinois Institute of Technology logo, a search bar, and a 'Quick Links' dropdown. Below the navigation bar is a banner image featuring the IFSH logo and a collage of food safety-related images. The main content area is divided into a left sidebar and a main content area. The sidebar contains links for 'IFSH Home', 'FSPCA Home', 'The Alliance', 'Upcoming Events', 'Committees', 'FAQ', and 'Resources'. The main content area features a 'Welcome to FSPCA Online' message, a paragraph describing the alliance's mission, and a 'NEWS' section with three columns of updates. The first column includes 'New! FSPCA Downloads' with links to a task timeline and a draft training curriculum outline. The second column covers 'FSPCA Pilot Sessions', detailing an April pilot session. The third column lists 'FSPCA Committees, Subcommittees and Working Groups', including the Executive, Steering, Editorial, and Continuation subcommittees, each with a meeting date and summary link. At the bottom, there are links for 'FSPCA Presentations' and 'Supplemental Rules'.

ILLINOIS INSTITUTE OF TECHNOLOGY

Quick Links

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LEAD INSTRUCTOR

FSPCA Home

Welcome to FSPCA Online

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).

NEWS

New! FSPCA Downloads

[FSPCA Task Timeline \(gif\)](#)

[FSPCA Hazard Analysis and Preventive Controls for Human Food - Draft Training Curriculum Outline \(pdf\)](#)

[FSPCA One Page Flyer \(pdf\)](#)

FSPCA Pilot Sessions

April Pilot Session

Over 30 guests from academia, state and federal government, industry and industry associations attended the first FSPCA Pilot session held at DHRD in Rockville, MD. The course was deemed well organized and the content was clear. Based on feedback and flow, the agenda and materials will be adjusted for the second Pilot session, being held May.

FSPCA Presentations

April 2015

FSPCA Committees, Subcommittees and Working Groups

Executive Committee

The Executive Committee met April 21, 2015. [Meeting summaries.](#)

Steering Committee

The Steering Committee met April 15, 2015. [Meeting summaries.](#)

Editorial Subcommittee

The Editorial Subcommittee met April 2, 2015. [Meeting summaries.](#)

Continuation Subcommittee

The Continuation Subcommittee met March 27, 2015. [Meeting summaries.](#)

FSMA

Supplemental Rules

Redline versions of the codified text of the four recently released proposed supplemental rules are now available.

PC Supply-Chain Program

(General requirements § 117.410)

- Use of approved suppliers
- Determine appropriate supplier verification activities
- Conduct and document supplier verification activities
- When applicable, obtain documentation of verification by another entity



Flexibility

Supplier Verification Activities

§ 117.410(b)

- Onsite audits (default for most serious hazards) see also: § 117.430(b)
- Sampling and testing
- Review of relevant food safety records
- Other as appropriate

Activity and frequency based on nature of hazard, where it is controlled, and supplier performance

For More Information

- Web site:
<http://www.fda.gov/fsma>
- Subscription feature available
- To contact FDA about FSMA and find the new online form for submitting questions:
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>