

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



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.



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.

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

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 the FSPCA logo. 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. The 'NEWS' section includes links for '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', 'FSPCA Presentations', 'FSPCA Committees, Subcommittees and Working Groups', 'Executive Committee', 'Steering Committee', 'Editorial Subcommittee', and 'Continuation Subcommittee'. There are also buttons for 'SIGN UP FOR IIT IFSH FSPCA NEWS' and 'APPLY TO BECOME AN FSPCA LEAD INSTRUCTOR'.

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>