

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

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**FDA FOOD SAFETY  
MODERNIZATION ACT**

THE FUTURE IS NOW

# Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human [Animal] Food

# Who is Covered?

- Facilities that manufacture, process, pack or hold human food
- In general facilities required to register with FDA under sec. 415 of the FD&C Act
  - Not farms or retail food establishments
- Applies to domestic and imported food
- Some exemptions and modified requirements apply

# Exemptions and Modified Requirements

- Qualified facilities (very small businesses)
- Foods subject to low-acid canned food regulations (microbiological hazards only)
- Foods subject to HACCP (seafood and juice)
- Dietary supplements
- Alcoholic beverages

# Qualified Facilities

- Very small businesses are qualified facilities exempt from the full requirements for hazard analysis and risk-based preventive controls (but have some modified requirements).
  - Average less than \$1M per year (\$2.5M animal food) in both sales of human food plus the market value of human food manufactured, processed, packed or held without sale

# Food Safety Plan

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

# 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.

# Food Safety Plan – Hazard Analysis

- Evaluation of hazards must include
  - consideration of severity of illness/injury and probability of occurrence in absence of preventive controls
  - evaluation of environmental pathogens for ready-to-eat foods exposed to the environment
  - consideration of effect of factors such as formulation and processing of food, facility, equipment, ingredients, intended use



# Food Safety Plan – Preventive Controls

- Measures required to ensure that hazards are significantly minimized or prevented. These include:
  - Process controls
  - Food allergen controls
  - Sanitation controls
  - Supply-chain controls
  - Recall plan

# Food Safety Plan – Preventive Controls

- Include controls at critical control points (CCPs), if any, and controls other than those at CCPs that are appropriate for food safety
- 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

- 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

# Food Safety Plan vs. HACCP Plan

Food Safety Plan	HACCP Plan
Hazard analysis	Hazard analysis
Preventive controls (PCs)	CCPs to control food hazards
Process controls*	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

# Supply-Chain Program

- Manufacturing/processing facilities must have a risk-based supply-chain program to ensure control of hazards in raw materials and other ingredients when the control is applied before receipt (“supply-chain applied control”).

# Supply-Chain Program

- Use of approved suppliers
- Determine , conduct and document appropriate supplier verification activities
- When applicable, obtain documentation of verification by another entity
- Compliance with FSVP requirements meets the PC supplier verification requirements



## Flexibility

# Supplier Verification Activities

- Onsite audits (default for most serious hazards)
- 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



# Planned Guidances

- Hazard analysis and preventive controls
- Environmental monitoring
- Food allergen controls
- Validation of process controls
- Supply-chain program
- A Small Entity Compliance Guide

# Planned Guidances

- Current Good Manufacturing Practices
- Human Food By-Products for Use as Animal Food
- Hazard Analysis and Preventive Controls
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule

# Public Information

- Web site: [www.fda.gov/fsma](http://www.fda.gov/fsma)
- Subscription feature available
- To submit a question about FSMA, visit [www.fda.gov/fsma](http://www.fda.gov/fsma) and go to Contact Us

