

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 Food

- Hazard Analysis and Risk-Based Preventive Controls
 - Each facility is required to implement a written food safety plan that focuses on preventing hazards in foods.
- Updated Good Manufacturing Practices
- Revised Definition of a 'Farm'

Who is Covered by PCHF?

- 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

Expanding the Farm Definition

- The final Preventive Controls for Human Food rule clarified the definition and expanded it to cover two kinds of farming operations:
 - Primary production farm
 - Secondary activities farm

Primary Production Farm

- An operation under one management in one general, but not necessarily contiguous, location
- Devoted to the growing of crops, the harvesting of crops, the raising of animals, or any combination of these activities
 - The definition has been expanded to include operations that just grow crops and operations that just harvest crops.

Primary Production Farm

- In addition to these activities, a primary production farm can:
 - Pack or hold RACs (regardless of who grew or raised them)
 - Manufacture/process, pack, or hold processed foods so long as:
 - all such food is consumed on that farm or another farm under the same management; or
 - the manufacturing/processing falls into limited categories

On-farm Manufacturing/Processing

- Drying/dehydrating RACs to create a distinct commodity (e.g., drying grapes to produce raisins)
- Treatment to manipulate the ripening of RACs (e.g., treating produce with ethylene gas)
- Packaging and labeling RACs

Secondary Activities Farm

- An operation not located on a primary production farm that is devoted to harvesting, packing, and/or holding RACs.
- The primary production farm(s) that grow, harvest, and/or raise the majority of those RACs must own or jointly own a majority interest in the secondary activities farm.
- Can do the same manufacturing/processing as a primary production farm

Exemptions and Modified Requirements for Preventive Controls

- 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

Exemptions and Modified Requirements

- Certain low-risk manufacturing/processing, packing and holding activities conducted by small/very small businesses on farms for specific foods
 - Making jams/jellies/preserves from acid fruit
 - Milling grains
 - Extracting oils from grains (e.g., sunflower seeds) and fruits/vegetables (e.g., olives)

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

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”).

Supplier

- The establishment that manufactures/ processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

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

Onsite Audits

- Must be performed by a qualified auditor
 - Government employee
 - Third-party (e.g., agent of a certification body)
 - Employee of receiving facility
 - Another entity in the supply chain
- Inspection may substitute for audit in certain cases

What's New in a Food Safety Plan

Element	HACCP Plan	Added in Food Safety Plan
Hazard analysis	Biological, chemical, physical	Chemical hazards to include radiological; consider econ. motivated adulteration
Preventive controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs
Parameters and values	Critical limits	Parameters and minimum/maximum values (= Critical limits for process controls)
Monitoring	Required for CCPs	Required as appropriate for preventive controls
Corrective actions or Corrections	Corrective actions	Corrective actions or corrections, as appropriate
Verification	For process controls	As appropriate for all preventive controls; supplier verification required when supplier controls a hazard
Records	For process controls	As appropriate for all preventive controls
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified

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

Compliance Dates for Businesses

- **Very small businesses** (less than \$1 million in annual food sales): Three years (except for certain records).
- **Small businesses** (a business with fewer than 500 full-time equivalent employees): Two years
- **All other businesses:** One year
- Separate compliance dates for the supply chain program

Compliance Dates – Supply-Chain Program

- Separate compliance dates have been established for the supply-chain program provisions to accommodate compliance dates for suppliers of different sizes and subject to different rules (e.g., Produce Safety Standards).

Planned Guidances

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

Training and Information - International

- Plans include
 - Collaborating with the Food Safety Preventive Controls Alliance on capacity building through its International Subcommittee
 - Working with regulatory counterparts and multinational organizations
 - Developing and disseminating outreach, education, and technical materials
 - Developing guidance documents
 - Establishing network call center to provide information

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

- Originally proposed: October 29, 2013
- Supplemental proposal: September 29, 2014
- Public comments: More than 2,400 for the original proposal; more than 140 for the supplemental proposal
- Final rule: September 17, 2015

Who is Covered?

- In general, facilities that manufacture, process, pack or hold animal food
 - Facilities required to register with FDA under sec. 415 of the FD&C Act
 - Not farms
- Applies to domestic and imported food
- There are some exemptions and modified requirements for certain facilities

Key Areas Addressed

- Establish Current Good Manufacturing Practices (CGMPs)
- Hazard Analysis and Risk-Based Preventive Controls
 - Each facility is required to implement a written food safety plan that focuses on preventing hazards in animal foods
- Revised Definition of a ‘Farm’

Good Manufacturing Practices

- Personnel
- Plant and grounds
- Sanitation
- Water supply and plumbing
- Equipment and utensils
- Plant operations
- Holding and distribution
- Holding and distribution of human food by-products for use as animal food

Compliance Dates

Business Size	CGMP Compliance	PC Compliance
Other Businesses	1 year	2 years
Small Business*	2 years	3 years
Very Small Business◇	3 years	4 years

*Small Business – business with fewer than 500 full-time equivalent employees

◇ Very Small Business – Average less than \$2.5M per year in sales of animal food plus the market value of animal food manufactured, processed, packed or held without sale

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
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us

