

# Final Rule for Preventive Controls for Human Food

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FDA FOOD SAFETY  
MODERNIZATION ACT

THE FUTURE IS NOW



# Background

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

- Originally proposed: January 16, 2013
- Supplemental proposal: September 29, 2014
- Public comments: More than 8,000 for the original proposal; more than 1,300 for the supplemental proposal
- Final rule: published September 17, 2015

# What does PCHF do?

- Revises the farm definition
- Modernizes longstanding current good manufacturing practice (CGMP) requirements
- Establishes new requirements for hazard analysis and risk-based preventive controls

# 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

# 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 Produce Safety rule.
- PCHF revises the farm definition to reflect modern farming practices.

# 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

# Activities that Do or Do Not Fall Under Farm Definition

- FDA expects to issue guidance on activities that fall within the farm definition and activities that do not in the near future.

# Updated Current Good Manufacturing Practices

- Protection against allergen cross-contact
- Certain provisions containing recommendations have been deleted
- Previously nonbinding provisions, such as education and training, are now binding.

# Qualifications of Individuals

- Must have the education/ training/ experience necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties
- Must receive training in the principles of food hygiene and food safety, as appropriate to the food, the facility and the individual's assigned duties

# 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.
- Hazard evaluation must consider severity of illness/injury and probability of occurrence in absence of preventive controls

# 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
- Flexibility for how preventive controls are managed

# Food Safety Plan – Preventive Controls

- Not required if the type of food could not be consumed without application of an appropriate control (e.g., cocoa beans, coffee beans, grains)
- Not required when hazard is controlled by another entity later in the distribution chain
  - Disclose that food has not been processed to control the [“identified hazard”]
  - Obtain assurances hazard will be controlled

# Assurances Regarding PCs

- Must include:
  - Name, date, signature
  - The specific assurance required
  - Acknowledgement that the facility that provides the assurance assumes legal responsibility to act consistent with the assurance and document actions taken to satisfy the assurance
  - Provision regarding termination

# 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

# Reanalysis of Food Safety Plan

- At least every three years
- Whenever there is a significant change that creates the potential for a new hazard or a significant increase in one previously identified
- When there is new information about potential hazards associated with a food
- When a preventive control is ineffective

# 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.

# Exemptions

- Foods subject to Hazard Analysis & Critical Control Points (HACCP) regulations (i.e., seafood and juice)
- Dietary supplements
- Alcoholic beverages
- Food subject to low-acid canned food regulations (microbiological hazards only)

# Exemptions

- Certain storage facilities such as grain elevators and warehouses that store only raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing
- “Holding” includes activities performed for the safe or effective storage of RACs (e.g., drying, screening, fumigating)

# Exemptions

- Small/very small businesses only conducting certain low-risk manufacturing/processing, packing, and holding activities on farms on specific foods are exempt from PCs
  - Making sugars and syrups from saps (e.g., maple syrup)
  - Making candy from saps (e.g., maple candy, maple cream)

# Facilities Storing Unexposed Packaged Food

- Exempt from the requirements for hazard analysis and risk-based preventive controls
- Modified requirements apply if the food requires time/temperature control for safety
  - Monitoring, corrective actions, and verification for temperature controls

# Produce Packing Houses

- Produce packing houses that fall under the new farm definition → produce safety rule
- Produce packing houses that do not fall under the new farm definition → PCHF
- Specific steps necessary to ensure the safety of produce would generally be the same

# Off-farm Produce Packing House

- Food safety plan would focus on a few key preventive controls, generally with counterparts in the produce safety rule
  - Maintaining and monitoring water temperature
  - Sanitation controls
- PC management components
  - Product testing: unlikely
  - Environmental monitoring: some facilities may choose as a verification activity

# 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 appropriate supplier verification activities
- Conduct and document supplier verification activities
- When applicable, obtain documentation of verification by another entity



Flexibility

# Supplier Verification Activities

- Onsite audits
- 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

- Annual audits are the appropriate verification activity for hazards that may cause serious adverse health consequences/death
- Other verification activities or less frequent auditing may provide adequate assurance that hazards are controlled.

# Qualified Facilities

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

# Modified Requirements for a Qualified Facility

- Attestation the facility is a qualified facility;  
AND
- Attestation that hazards have been identified and that preventive controls have been implemented and are being monitored; OR
- Attestation facility is in compliance with an applicable non-Federal food safety law

# Human Food By-products for Use as Animal Food

- Human food by-products are not subject to animal food rule (except for provisions for holding and distribution) if:
  - Human food is produced in compliance with human food CGMPs and all applicable food safety requirements
  - Not further processed

# Holding and Distribution of Human Food By-Products

- Must be held in a manner that protects against contamination
  - Containers cleaned as necessary
  - Must be accurately identified during holding
  - Labeling that identifies common or usual name must be affixed to or accompany when distributed
- Shipping containers examined before use

# Compliance Dates for Businesses

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

# Planned Guidances

- Hazard analysis and preventive controls
- Environmental monitoring
- Food allergen controls
- Validation of process 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](#)

