

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 forthcoming 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 is for further processing
 - 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 - Monitoring

- Facility must have written procedures, including the frequency they are to be performed, for monitoring the preventive controls (as appropriate to the nature of the preventive control)
- Monitoring must be documented in records subject to verification.

Food Safety Plan – Corrective Actions and Corrections

- Facility must have written procedures for steps to be taken when preventive controls are not properly implemented
 - Identify and correct a problem
 - Reduce likelihood of occurrence
 - Evaluate food for safety
 - Prevent adulterated food from entering commerce

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.

Responsibilities of a PC QI

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

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

- Farm mixed-type facilities are establishments that are farms that also conduct activities outside the farm definition that require registration.
- Certain low-risk manufacturing/processing, packing, and holding activities conducted on specific foods by small/very small businesses on farms are exempt from PCs

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.

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

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

Records

- § 117.9 - Records required for subpart A
- § 117.190 – Implementation records for subpart C (Document implementation of the food safety plan)
- Subpart F – Requirements applying to records (Retention, use of existing records...)
- § 117.475 – Records documenting the supply-chain program

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

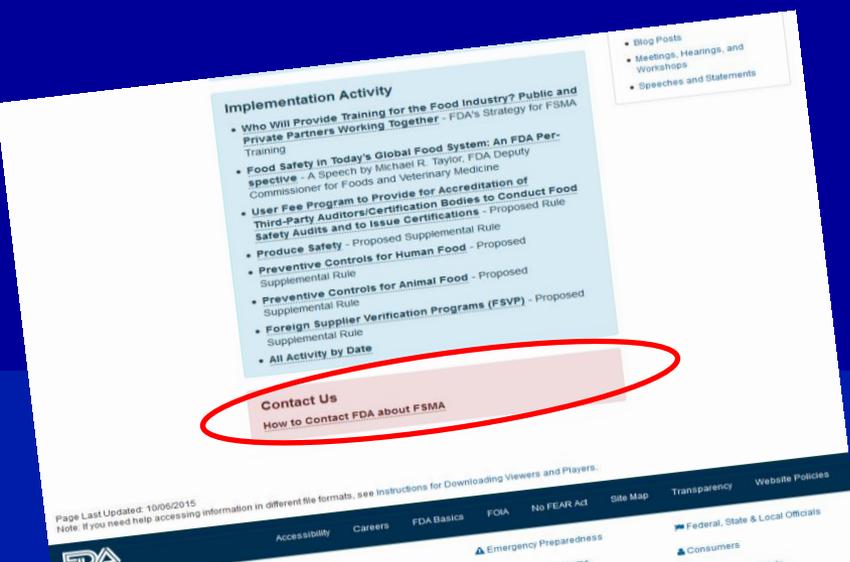
- *Very small businesses* (less than \$1 million in annual food sales): Three years
- Businesses subject to the Pasteurized Milk Ordinance: Three years
- *Small businesses* (a business with fewer than 500 full-time equivalent employees): Two years
- *All other businesses*: One year
- Separate compliance 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
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to [Contact Us](#)



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Food and Drug Administration
5100 Paint Branch Pkwy.