Human PC
Final

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.
- PCHF revises the farm definition to reflect modern farming practices.

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

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- 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

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- 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

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

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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.

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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)

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

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

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").

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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.

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

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.

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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