

FSMA’S PREVENTIVE CONTROLS RULE FACTS and FAQs

What is the FSMA Preventive Controls for Human Food (PCHF) rule and does it apply to my facility?

Subpart C of *Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food*, the Preventive Controls for Human Food Rule, has been called “HACCP on steroids” by many industry insiders. What they mean is that while the rule uses HACCP principles to identify hazards and control them in your process, it incorporates controls beyond those within the HACCP framework. If your facility is required to register with FDA under section 415 of the FD & C Act, then your facility is likely covered under this rule. However, there are exceptions (see below).

How are the Preventive Controls rules different from the Hazard Analysis and Critical Control Points (HACCP) system?

Element	HACCP Plan	Food Safety Plan
Hazard Analysis	Biological, chemical, physical hazards	Radiological hazards included with chemical; consideration of economically motivated adulteration (21 CFR 117.130(b)(1)(ii))
Preventive Controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs (21 CFR 117.135(a)(2))
Parameters and values	Critical limits at CCPs	Parameters and minimum/maximum values (equivalent to critical limits for process controls) (21 CFR 117.135(c)(1))
Monitoring	Required for CCPs	Required as appropriate for preventive controls (21 CFR 117.145)
Corrective actions and Corrections	Corrective actions	Corrective actions or corrections as appropriate (21 CFR 117.150(a))
Verification (including validation)	For process controls	Verification as appropriate for all preventive controls; validation for process controls; supplier verification required when supplier controls a hazard (21 CFR 117.155, 117.160)
Records	For process controls	As appropriate for all preventive controls (21 CFR 117.190)
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified (21 CFR 117.139)

What are the FSMA-PCHF training requirements?

- A designated Preventive Controls Qualified Individual (PCQI) – like your HACCP Team Leader - must have successfully completed training in risk-based preventive controls at least equivalent to a standardized curriculum recognized as adequate by FDA (the *Food Safety Preventive Controls Alliance's Preventive Controls for Human Food Training* is currently the only training recognized by FDA) or be qualified through experience (although FDA does not specify what that means).
- All employees must be trained in food safety and food hygiene (GMPs, GDPs, GAPs, etc.)

What are the Key Requirements for the Preventive Controls for Human Foods Rule?

Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. The rule sets requirements for a written food safety plan that includes:

- **Hazard analysis:** Hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards.
- **Preventive controls:** These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. In addition to having a Recall Plan in place, preventive controls must be in place for the following:
 1. Process controls
 2. Allergen controls
 3. Sanitation control
 4. Supply-chain controls
 - **Oversight and management of preventive controls:** The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and can correct problems that may arise.
 - **Monitoring:** Monitoring is conducted as appropriate to the preventive control.
 - **Corrective actions and corrections:** Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during food production. Corrective actions include actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering commerce. Corrective actions must be documented with records.
 - **Verification:** As with traditional HACCP these activities are required to ensure that preventive controls are consistently implemented and effective. They include validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of

process monitoring equipment and verification instruments and reviewing records to ensure that monitoring and corrective actions (if necessary) are being conducted.

Product testing and environmental monitoring are possible verification activities but are only required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. Environmental monitoring generally would be required if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control.

What firms are exempt from the Preventive Controls Rule (Subpart C)

- Facilities operating under Juice and Seafood HACCP programs*
- Activities within the definition of a "farm" (Produce Safety Rule may apply)
- Low acid canned foods
- Alcoholic beverage processing
- Dietary supplement manufacture, processing or holding
- Storing raw agricultural commodities (RAC) such as wheat, soybeans to be used in food manufacturing, other than fruits and vegetables
- Storing unexposed packaged food at ambient temperatures
- "Qualified" facilities**
 - Business with average annual sales of <\$500,000 per year during that last three years, and sales to consumers or local retailers or restaurants (within the same state or within 275 miles) must exceed sales to others, OR
 - Very small (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale.

*Foods regulated by USDA, (meat, poultry and egg products) are not covered.

**Qualified facilities may be eligible for an exemption from the hazard analysis, risk based preventive controls requirements (Subpart "C" of the rule) and supply-chain preventive control requirements (Subpart "G"). Qualified facilities must register and submit documentation to FDA to verify their status. They must comply with cGMPs and other parts of the rule.

What is the compliance date for covered facilities: September 19, 2016

There are multiple dates based on many factors. Many small companies have an additional year.

For detailed information on the requirements of the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food Rule:

<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM461834.pdf>

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