



FOOD TECHNOLOGY FACT SHEET

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405-744-6071 • www.fapc.biz • fapc@okstate.edu

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FSMA and Facilities Solely Engaged in the Storage of Unexposed Packaged Human Food

Ravi Jadeja

FAPC Food Safety Specialist

The Food Safety Modernization Act (FSMA), the largest food safety law reform in last 70 years, was enacted in 2011. One of the seven rules of FSMA is Preventive Controls for Human Food (PCHF), which specifically affects facilities engaged in the storage of unexposed packaged human food. This fact sheet summarizes the major compliance requirements listed in PCHF for a facility solely engaged in the storage of exposed packaged food.

Applicability of Subparts:

A facility solely engaged in the storage of unexposed packaged food product is exempt from subparts C (hazard analysis and risk-based preventive controls) and G (supply-chain program), but subjected to subpart D (modified requirements) section 117.206.

Major Requirements:

If a facility stores any food products that requires time/temperature control to minimize or prevent pathogen growth or toxin production significantly, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls:

- (1) **Establish:** Establish and implement adequate temperature controls to significantly minimize or prevent the growth of or toxin production by pathogens.

- (2) **Monitor:** Monitor the temperature controls with adequate frequency.

- (3) **Corrective action:** If there is a loss of temperature control, the following steps must be performed:

- (i) Correct the problem and reduce the likelihood the problem will recur.
- (ii) Evaluate affected food for safety.
- (iii) Prevent the food in question from entering commerce.

- (4) **Verify:** Verify temperature controls are consistently implemented by:

- (i) Calibrating temperature monitoring and recording devices (or checking them for accuracy).
- (ii) Reviewing records of calibration within a reasonable time after the records are created.
- (iii) Reviewing records of monitoring and corrective actions taken to rectify a problem with the control of temperature within seven working days after the records are created or the frequency determined by a preventive control qualified individual (PCQI).

Required Records:

- (1) **Temperature monitoring records:** Temperature logs, charts, etc.
- (2) **Corrective action records:** Nature of problem, how problem was fixed, root-cause analysis, identification of affected food and how affected food was dealt with.
- (3) **Verification activity records:** Temperature measuring device calibration and/or accuracy check, record review for calibration and accuracy check results on a pre-determined frequency, and monitoring and corrective action record review within seven days of creation or frequency determined by PCQI.

For more information, please contact Ravi Jadeja, FAPC food safety specialist, by calling 405-744-6071 or emailing ravi.jadeja@okstate.edu.

Disclaimer: The information provided is of a general nature and is intended to help you become familiar with general requirements of PCHF for a facility solely engaged in the storage of unexposed packaged human food. The complete version of rule can be found at <https://www.gpo.gov/fdsys/pkg/FR-2015-09-17/pdf/2015-21920.pdf>.

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