

FSMA FACT SHEET

What Do “Facilities” Need to Do to Comply with the FSMA Preventive Controls Rule?

Overview

If your operation is a “facility” registered with the FDA you are required to comply with the FSMA Preventive Controls (PC) for Human Food rule. (See the FSMA fact sheet entitled “Is My Operation a “Farm” Covered by the Produce Safety Rule?” if you aren’t certain whether your operation is a farm or a facility.) Covered facilities must establish and implement a food safety system that includes an analysis of hazards and implementation of risk-based preventive controls (21 CFR Part 117, Subpart C). The FDA’s Current Good Manufacturing Practice (CGMP) requirements (21 CFR Part 117, Subpart B) also apply to registered facilities (and are not summarized here).

Key Requirements

- Develop and implement a written Food Safety Plan that includes:
 - A hazard analysis
 - Preventive controls
 - Monitoring procedures
 - Corrective action procedures
 - Verification procedures
 - A supply-chain program, if appropriate
 - A recall plan
- Document your implementation of your food safety plan in records that you keep and make available to the FDA for review and copying.
- Have your food safety plan prepared (or its preparation overseen) by a Preventive Controls Qualified Individual
- Meet updated CGMP requirements

Hazard Analysis

The purpose of the hazard analysis is to identify any “hazards requiring a preventive control” (HRPCs). The first step is to conduct a hazard identification, where you consider known or reasonably foreseeable biological, chemical (radiological hazards, substances such as pesticide and drug residues, natural toxins [such as mycotoxins], decomposition, unapproved food or color additives, and food allergens) and physical hazards. These hazards could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).

Then you must evaluate these identified hazards by assessing the severity of illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. You must consider the potential for environmental pathogens whenever you have a ready-to-eat food that is exposed to the environment prior to packaging. Identified hazards requiring a preventive control may include things such as pathogenic E. Coli, Salmonella, mycotoxins, undeclared allergens, environmental pathogens post-pasteurization, and/or metal.

Preventive Controls

Preventive controls means “those risk-based, reasonably appropriate procedures, practices and processes that a person knowledgeable about the safe manufacturing, processing, packing or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing or holding at the time of the analysis.” There are several different types of preventive controls: process controls (e.g., roasting, metal detection), food allergen controls, sanitation controls, supply chain controls, recall plans and “other” controls. Preventive controls are similar to “critical control points” (CCPs) in HACCP plans, but can include procedures and processes that are not CCPs. For example, a sanitation procedure used to control for allergen cross-contamination or environmental pathogens may be a preventive control, but not a CCP.

You do not have to implement a preventive control if the HRPC will be controlled further down the supply chain, such as by your customer. In these cases, you must disclose that the food is “not processed to control Salmonella” and obtain written assurance from your customer regarding certain actions the customer agrees to take to ensure the hazard is controlled. (There are corresponding regulations that require the customer to provide a written assurance to you that it is indeed controlling for those hazards, but FDA is not enforcing those requirements until at least September 2018 because they are reconsidering this requirement.)

Management of Preventive Controls

Once you've implemented your preventive controls, the regulation requires you to take additional steps to ensure that the preventive controls are effective and to correct problems that may arise. These steps are often referred to as the "management components" of preventive controls.

- **Monitoring:** These procedures are designed to provide assurance that preventive controls are consistently performed and are operating as intended. Monitoring is conducted "as appropriate" to the preventive control. For example, monitoring of a heat process to kill pathogens would include actual temperature values and be more frequent than monitoring preventive maintenance activities used to minimize metal hazards, which could be a simple record of the date on which the activity took place.
- **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:** 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 and verification instruments such as thermometers, and reviewing records to verify 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 expected for ready-to-eat almonds.

Supply Chain Program

If you have a manufacturing/processing facility, you need to have a supply chain program for any raw materials and other ingredients you receive where a HRPC is controlled earlier in the supply chain. You must take certain required steps to ensure that these foods are received only from suppliers who are approved after a consideration of factors that include a hazard analysis of the food, the entity that will be controlling that hazard, supplier performance, and the results of appropriate supplier verification activities (e.g., audits, testing).

Another entity in the supply chain, such as a broker or distributor, can conduct supplier verification activities on your behalf, but you must review and assess that entity's documentation of the verification of control of the hazard.

Recall Plan

If your facility has any foods with HRPCs, you must establish a written recall plan that addresses the steps to be taken in the event of a recall and assigns responsibility for taking those steps. Your recall plan must address: notifying your direct customers; notifying the public, if necessary; checking the effectiveness of the recall; and disposing of the food appropriately.

Documentation

Activities required under the PC regulation must be documented. These records must be maintained for at least two years after the document is created or use of the document is discontinued. The FDA has legal authority to review these records during facility inspections.

Exemptions and Modified Requirements

There are a few important exemptions and modified requirements to take note of:

- If a facility is a stand-alone huller and sheller, it is not required to comply with the CGMP regulations.
- If a facility is solely engaged in packing and/or holding almonds, without additional processing, it is not required to comply with the CGMP regulations.
- If a facility is solely engaged in the storage of unexposed packaged food (so long as the food does not require time/temperature control for safety), it is not required to comply with the PC regulations.
- If a facility has under \$1 million in annual sales of human food, it is subject to modified requirements as a "qualified facility" (which are not summarized on this FSMA fact sheet).
- If an operation is a "farm mixed-type facility" (i.e., an operation that falls under both the Produce Safety and PC rules) and has under 500 full-time equivalent employees, the PC requirements will not apply if the operation only conducts certain specified activities under the regulations (which are not summarized on this FSMA fact sheet).

Compliance Dates

The following compliance dates apply for the modernized CGMPs and PC rule:

FSMA Rule	Compliance Date	Notes/Explanations
Modernized CGMPs and Preventive Controls for Human Food >500 full-time equivalent (FTE) employees	September 19, 2016	General compliance date is one year after publication of the final rule, except as detailed below
	March 17, 2017	Supply Chain Program general compliance date is March 17, 2017, OR six months after a supplier is required to comply with the applicable PC or Produce safety rule
	September 19, 2018	For compliance with the written customer assurance requirement in 21 CFR 117.136 only; compliance with the written disclosure provision and the remainder of the rule is required by Sept. 19, 2016
	January 26, 2018	For “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells” ¹
	January 26, 2018	For facilities that meet the definition of “secondary activities farms” except for the ownership criterion ²
Modernized CGMPs and Preventive Controls for Human Food <500 FTE employees	September 18, 2017	General compliance date is two years after publication of the final rule, except as detailed below
	September 18, 2017	Supply Chain Program general compliance date is Sept. 18, 2017, OR six months after a supplier is required to comply with the applicable PC or Produce safety rule
	September 18, 2019	For compliance with the written customer assurance requirement in 21 CFR 117.136 only; compliance with the written disclosure provision and the remainder of the rule is required by Sept. 18, 2017
	January 28, 2019	For “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells” ¹
	January 28, 2019	For facilities that meet the definition of “secondary activities farms” except for the ownership criterion ²
FSMA Rule	Compliance Date	Notes/Explanations
Modernized CGMPs and Preventive Controls for Human Food <\$1 million in sales + market value of food manufactured/ processed/ packed/ held without sale	September 17, 2018	The compliance date for qualified facilities to retain records to support their status as a qualified facility is Jan. 1, 2016
	January 27, 2020	For “facilities solely engaged in packing and/or holding activities conducted on produce RACs and/or nut hulls and shells” ¹
	January 27, 2020	For facilities that meet the definition of “secondary activities farms” except for the ownership criterion ²

¹This extension covers almond brown skin facilities that only size, sort, grade or pack almonds, as well as facilities that only hull and shell almonds, as long as the facility does not engage in manufacturing or processing activities (i.e., chopping, grinding, mixing, roasting, pasteurizing, salting).

² Facilities that meet the definition of “secondary activities farms” except for the ownership criterion can take advantage of an extension for compliance with the PC rule if: (1) The operation is not located on the primary production farm; (2) The operation is devoted to harvesting, packing, and/or holding of RACs (including operations that hull, shell and/or dry nuts without additional manufacturing); and (3) The operation is under common ownership with the primary production farm that grows, harvests and/or raises the majority of the RACs harvested, packed and/or held by the operation.