U.S. FOOD & DRUG ADMINISTRATION

Key Facts about Preventive Controls for Human Food

Preventive controls are steps that you, a domestic or foreign food facility, must take to reduce or eliminate food safety hazards. The rule on Preventive Controls for Human Food is mandated by the 2011 FDA Food Safety Modernization Act. The rule also incorporates the Current Good Manufacturing Practice (CGMP) requirements, which have been updated.

- **DO THE REQUIREMENTS FOR PREVENTIVE CONTROLS FOR HUMAN FOOD APPLY TO ME?**
- **DO THE REQUIREMENTS FOR CURRENT GOOD MANUFACTURING PRACTICES (CGMPS) APPLY TO ME?**
- **WHEN DO I HAVE TO BE IN COMPLIANCE WITH THE RULE?**
- **WHAT CURRENT GOOD MANUFACTURING PRACTICES WERE UPDATED UNDER THIS RULE?**
- **WHAT ARE THE REQUIREMENTS REGARDING FOOD SAFETY PLANS?**
- **WHAT DO I DO IF A HAZARD COULD FIT UNDER DIFFERENT PREVENTIVE CONTROLS?**
- **WHAT IS THE FOOD SAFETY PLAN BUILDER? HOW DO I USE IT?**
- **ARE THERE ANY OTHER RESOURCES TO HELP ME FOLLOW THIS RULE?**

DO THE REQUIREMENTS FOR PREVENTIVE CONTROLS FOR HUMAN FOOD APPLY TO ME?

In general, the requirements apply to you if you manufacture, process, pack, or hold human food for consumption in the United States, whether your facility is domestic or foreign. The requirements apply to you if you are required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic (FD&C) Act. Entities defined as "farms," retail food establishments, and restaurants are some of the entities that are not subject to the preventive control requirements because they are not required to register. In addition, there are several exemptions or modified requirements that may apply.

DO THE REQUIREMENTS FOR CURRENT GOOD MANUFACTURING PRACTICES (CGMPS) APPLY TO ME?

In general, the requirements apply to you if you manufacture, process, pack or hold human food. As with the preventive controls requirements, there are exemptions and modified requirements, but they are not identical.

WHEN DO I HAVE TO BE IN COMPLIANCE WITH THE RULE?

September 18, 2017: Small businesses (businesses with fewer than 500 full-time equivalent employees)

September 17, 2018: Very small businesses (averaging less than $1 million per year (adjusted for inflation) in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale)

September 17, 2018: Facilities subject to the Pasteurized Milk Ordinance (PMO) (for their Grade "A" milk and milk products); compliance date was extended to allow time for changes to the PMO to incorporate the requirements of this preventive controls rule)

* *All other businesses (also known as "large" businesses) were required to be in compliance on September 19, 2016. Note that compliance dates for some facilities and activities have been extended.*

> SEE ALL FSMA COMPLIANCE DATES
> https://www.fda.gov/food/guidanceregulation/fsma/ucm540944.htm

■ WHAT CURRENT GOOD MANUFACTURING PRACTICES (CGMPS) WERE UPDATED UNDER THIS RULE?

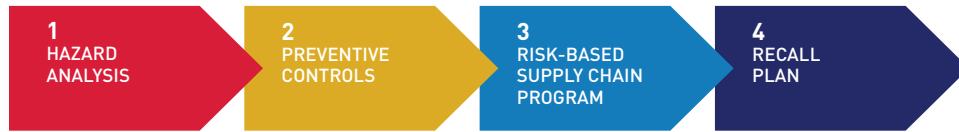Now you are required to be in compliance with some provisions that were optional before.

■ **Training:** Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties. The employees must be trained in the principles of food hygiene and food safety, including the importance of employee health and hygiene as appropriate to the food, the facility, and the individual's assigned duties. Records of training must be maintained.

■ **Allergen cross-contact:** FDA's longstanding position that CGMPs address allergen cross-contact is now explicit in the regulatory text. You are required to employ practices and procedures to control allergen cross-contact.

■ **Human food by-products used for animal foods:** The updated CGMPs contain provisions for holding and distributing human food by-products that are used for animal food.

Human Food By-Products for Use as Animal Food (Guidance for Industry - Draft)
https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdfhttps://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf

■ WHAT ARE THE REQUIREMENTS REGARDING FOOD SAFETY PLANS?

You, a domestic or foreign food facility, must (1) have and implement a written food safety plan that identifies food safety hazards that require a preventive control and (2) implement preventive controls to significantly minimize or prevent the hazard. The plan is required to include the following:

| 1 HAZARD ANALYSIS | 2 PREVENTIVE CONTROLS | 3 RISK-BASED SUPPLY CHAIN PROGRAM | 4 RECALL PLAN |

1 ▶ HAZARD ANALYSIS: You are required to identify any known or reasonably foreseeable (i.e., potential) biological, chemical, and physical hazards, and determine if any of those hazards require a preventive control.

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

https://www.federalregister.gov/documents/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human
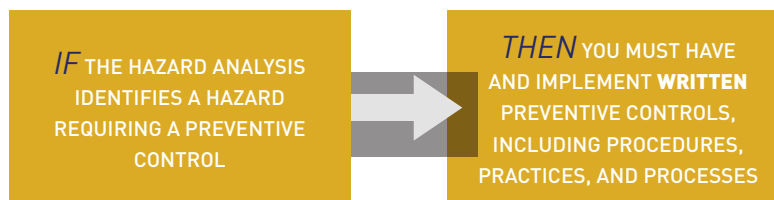
Hazard Analysis and Risk-Based Preventive Controls for Human Food

https://www.federalregister.gov/documents/2017/08/31/2017-18464/hazard-analysis-and-risk-based-preventive-controls-for-human-food-guidance-for-industry-availability

Hazard analysis and risk-based preventive controls for human food [Draft Guidance for Industry]

https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517394.pdfhttps://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM517394.pdf

2 ▶ PREVENTIVE CONTROLS: If the hazard analysis identifies a hazard that requires a preventive control, you are required to develop and implement a control to significantly minimize or prevent the hazard.

IF THE HAZARD ANALYSIS IDENTIFIES A HAZARD REQUIRING A PREVENTIVE CONTROL ➡ *THEN* YOU MUST HAVE AND IMPLEMENT **WRITTEN** PREVENTIVE CONTROLS, INCLUDING PROCEDURES, PRACTICES, AND PROCESSES

The rule outlines preventive controls and associated requirements that could include:

- **process controls**

- **food allergen controls**

- **sanitation controls**

- **other controls**

■ **Process controls:** procedures, practices, and processes to control parameters during operations. Examples of process controls are cooking and refrigeration, and product formulation.

- Associated requirements for process controls include, as appropriate, parameters (and minimum or maximum values) associated with the control of the hazard, monitoring, corrective actions, verification including validation as necessary, records

■ **Food allergen controls:** procedures, practices, and processes to control allergen cross-contact within a facility and procedures to ensure all food allergens are correctly labeled.

- Associated requirements for food allergen controls include, as appropriate, monitoring, corrective actions, verification, and records

■ **Sanitation Controls:** procedures, practices, and processes to make sure the facility is maintained in a sanitary manner to control hazards such as environmental pathogens. Environmental monitoring is required if contamination of a ready-to-eat food with an environmental pathogen such as *Listeria monocytogenes* is a hazard requiring a preventive control.

- Associated requirements for sanitation controls include, as appropriate, monitoring, corrective actions, verification (including environmental monitoring for an environmental pathogen or appropriate indicator organism as necessary), and records

See Control of Listeria monocytogenes in Ready-to-Eat Foods (Draft Guidance for Industry)
https://www.fda.gov/RegulatoryInformation/Guidances/ucm073110.htm

■ **Other Controls:** preventive control procedures that are not process, food allergen, or sanitation controls, but are necessary to ensure that a hazard requiring a preventive control will be significantly minimized or prevented.

- Associated requirements for other controls include, as appropriate, monitoring, corrective actions, verification, and records

Explaining the Oversight and Management of Preventive Controls: Once a facility has identified a preventive control for a hazard, the facility must make sure that the controls are being met using the following actions:
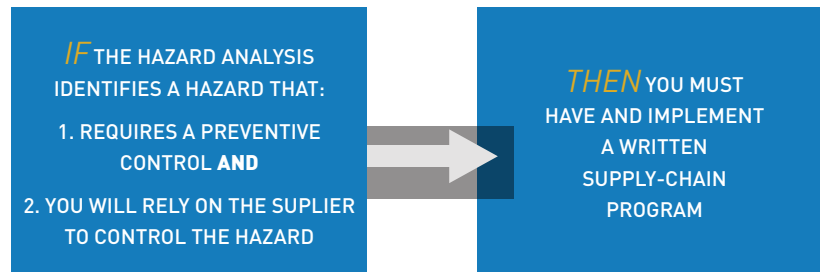
■ MONITORING: These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include recording temperature values. Monitoring must be documented.

■ CORRECTIONS: These are steps taken, in a timely manner, to identify and correct a minor, isolated problem that occurs during food production.

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■ **CORRECTIVE ACTIONS:** These include actions to identify and correct a problem implementing a preventive control, reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent that food from entering commerce if you cannot ensure that the affected food is not adulterated. Corrective actions must be documented with records.

■ **VERIFICATION:** These activities are required to ensure that preventive controls are consistently implemented and effective in minimizing hazards. Examples of verification activities include scientifically validating process preventive controls to ensure that the control measure is capable of effectively controlling an identified hazard and calibrating (or checking the accuracy of) process monitoring and verification instruments such as thermometers. Verification activities also include reviewing records to ensure that monitoring and corrective actions (if necessary) are being conducted. Verification activities must be documented.

■ Product testing and environmental monitoring are also possible verification activities, 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 is required if the contamination of a ready-to-eat food with an environmental pathogen is a hazard the facility identified as requiring a preventive control.

3 ▶ **Risk-Based Supply Chain Program:** If you are a manufacturer and identify a hazard related to ingredients you receive from a supplier and will depend on the supplier to control that hazard, you must have and implement a supply- chain program with appropriate verification activities.

| *IF* THE HAZARD ANALYSIS IDENTIFIES A HAZARD THAT:

1. REQUIRES A PREVENTIVE CONTROL **AND**

2. YOU WILL RELY ON THE SUPLIER TO CONTROL THE HAZARD | ➡ | *THEN* YOU MUST HAVE AND IMPLEMENT A WRITTEN SUPPLY-CHAIN PROGRAM |

Supply chain program must include:

■ Using approved suppliers

■ Determining appropriate supplier verification activities and frequency of those activities. They may include:

  • On-site audit

  • Sampling and testing of raw material

  • Review of suppliers' relevant food safety records

  • Other appropriate verification activities

■ Conducting supplier verification activities

■ Documenting supplier verification activities

When do I NOT need a supply-chain program?

■ If you control the hazard at your own facility OR

■ If the hazard will be controlled by a subsequent entity (such as another processor). Certain requirements are specific to this situation.

4 ▶ **Recall Plan:** If the hazard analysis identifies a hazard that requires a preventive control, you must have a written recall plan that includes the procedures that describe the steps to perform the recall and at minimum assigns responsibility for:

■ Notifying the direct consignees of the food being recalled, including how to return or dispose of the affected food;

■ Notifying the public about hazards in the food;

■ Conducting effectiveness checks; and

■ Appropriately disposing of the recalled product.

■ **WHAT IS THE FOOD SAFETY PLAN BUILDER? HOW DO I USE IT?**

The Food Safety Plan Builder is a software program that can help you develop a customized food safety plan for your facility. The program can be downloaded for free.

■ **Food Safety Plan Builder Resources:**

Download the **Food Safety Plan Builder**
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm

Read the **User Guide**
https://www.accessdata.fda.gov/scripts/foodSafetyPlanBuilder/FoodSafetyPlanBuilderUserGuide_v1.0.pdf

How to use the Food Safety Plan Builder **(videos)**
https://www.youtube.com/playlist?list=PLey4Qe-Uxcxb9AGNwFj-oGlquHDZ-tkqo

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■ **ARE THERE ANY OTHER RESOURCES TO HELP ME FOLLOW THIS RULE?**

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies.
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

You can also use the **FSMA TAN Popular Topics**
https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM551983.pdf

FSMA Rules & Guidance for Industry
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm

Training & Materials on Preventive Controls for Human Food (FSPCA)
https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food