Food and Nutrition Service
U.S. DEPARTMENT OF AGRICULTURE

OVERVIEW: HAZARD ANALYSIS RISK-BASED PREVENTIVE CONTROL FOOD SAFETY PLAN (HARPC) AND HAZARD ANALYSIS CRITICAL CONTROL POINT PLAN (HACCP)

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The Food Safety Modernization Act (FSMA) protects public health by taking a proactive approach to strengthening the nation's food safety system. The FSMA was signed into law in 2011 and is implemented by the **U.S. Food and Drug Administration (FDA)**.[1] It allows the FDA to focus on reducing and preventing food safety problems at each point of the supply chain, rather than responding after they happen.

The FSMA has **seven rules** including **Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food**, which is widely known as the Preventive Controls for Human Food Rule (PCHF).[2] This rule became effective in November 2015 and requires food facilities to have a written **Hazard Analysis Risk-Based Preventive Control (HARPC) food safety plan** in place that includes preventive controls to minimize or prevent identified hazards from occurring.

The requirements within the PCHF apply to commercial food operations that manufacture, process, pack, or hold human food for consumption in the United States that are already required to register with FDA under section 415 of the **Food, Drug, and Cosmetic Act (FD&C Act)**. The rule also applies to businesses in other countries that export food to the United States. Operations defined as farms, retail food establishments, and restaurants are some of the businesses that are not subject to the PCHF requirements because they are not required to register with the FDA under this Act.

There are several exemptions or modified requirements that may apply even if some food products are covered under the PCHF, including:

- Qualified facilities (very small businesses)
- Food businesses subject to low-acid canned food regulations
- Foods subject to the Hazard Analysis Critical Control Point (HACCP) regulation (such as seafood and juice)
- Dietary supplements
- Alcoholic beverages
- Certain low-risk manufacturing/processing, packing, and holding activities conducted by small/very small businesses on farms for specific foods (e.g., making jams, jellies, and preserves from acidic fruit and extracting oils from grains)

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Visit the FDA webpage for more information about key requirements, including applicable PCHF compliance dates.[2]

HACCP is an internationally recognized and universally accepted risk-based system, which addresses food safety through the analysis and control of biological, chemical, and physical hazards. HACCP is used in many segments of the food industry and encompasses **seven principles** to identify and assess the risk of hazards, and control the identified hazards. HACCP systems have been mandated by U.S. Federal regulations issued by the FDA for seafood and juice, and by the **USDA Food Safety and Inspection Service (FSIS)** for meat and poultry.

The Seven HACCP Principles

1: Conduct a Hazard Analysis

2: Determine Critical Control Points (CCPs)

3: Establish Critical Limits

4: Establish Monitoring Procedures

5: Establish Corrective Actions

6: Establish Verification Procedures

7: Establish Record-Keeping and Documentation Procedures

A **HARPC food safety plan** is developed using HACCP principles, but all components are not identical. Based on scientific data, both plans use a proactive approach to identify and assess process-specific food safety hazards and to utilize appropriate, effective, and verifiable control measures. In HACCP plans, **critical control points (CCPs)** are steps where a control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. CCPs are measurable and include critical limits, which specify a maximum and/or minimum value, or combination of values.

In HACCP plans, controls are applied at critical control points (CCPs), whereas the HARPC food safety plans may include preventive controls at CCPs, along with controls at other steps, to ensure food safety. In HARPC food safety plans, there are **five main preventive controls**, which include **Process Controls, Food Allergen Controls, Sanitation Controls, Supply Chain Controls, Other Controls,** and **Recall Plan.** The majority of CCPs in a HACCP plan fall under the Process Controls section in a HARPC food safety plan.

A **preventive controls qualified individual (PCQI)** must develop or oversee the development of the written HARPC food safety plan [21 CFR 117.126[a]].[3] A PCQI is a person with the education, training, or experience (or a combination of these) to develop and apply a food safety system. A PCQI can be qualified through job experience or by completing training equivalent to the standardized curriculum recognized as adequate by the FDA and does not need to be an employee of the facility [21 CFR 117.3].[4]

Components of HARPC

1: Hazard Analysis (Risk Assessment)

2: Risk-based Preventive Controls

3: Effectiveness Monitoring

4: Corrective Actions

5: Compliance Verification

6: Recordkeeping and Documentation

7: Reanalysis

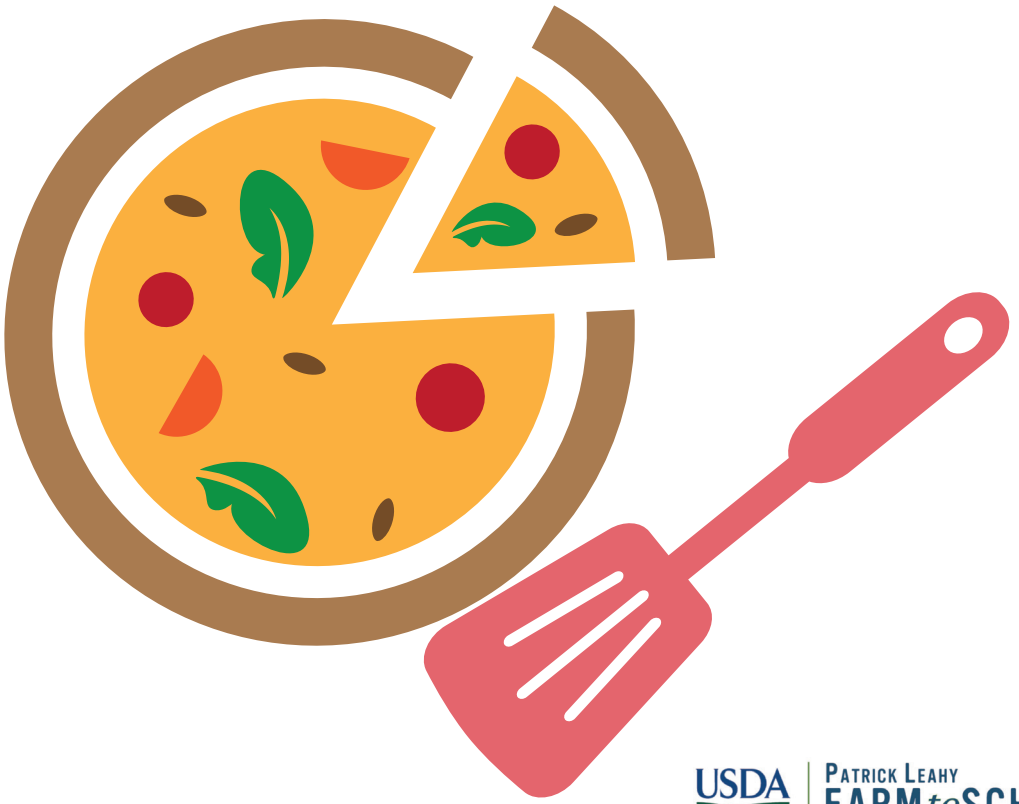
For Receiving Facilities: Supply-Chain Program

For All Facilities: Recall Plan

A HARPC food safety plan must be reanalyzed at least every three years. The reanalysis may focus on an applicable portion of the plan when there are changes to a system or equipment, when there is new information available about potential hazards associated with the food or facility, when there is an unanticipated food safety problem, or when a preventive control, a combination of preventive controls, or the food safety plan is ineffective. The following records must be kept to comply with the PCHF:[5]

- The hazard analysis
- Preventive controls for each identified hazard and verification that they effectively control the hazards
- Monitoring records to ensure preventive controls are consistently performed
- Documentation of any corrective actions taken
- The supplier approval and verification program
- The recall plan
- All testing and auditing results
- The results of the food safety plan reanalysis

As a producer, understanding differences and similarities between HARPC food safety plans and HACCP plans can help you to determine which elements of each plan may apply to your business and what requirements you need to follow. The FDA has a free **Food Safety Plan Builder (FSPB)** software program to assist owners/operators of food facilities with the development of food safety plans that are specific to their facilities and meet the requirements of the PCHF.[6]



References

(1) *Full Text of the Food Safety Modernization Act (FSMA)*
www.fda.gov/food/food-safety-modernization-act-fsma/full-text-food-safety-modernization-act-fsma

(2) *FSMA Final Rule on Preventive Controls for Human Food*
www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food

(3) *Code of Federal Regulations 21 CFR 117.126: Hazard Analysis and Risk-Based Preventive Controls, Food Safety Plan*
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=117.126

(4) *Code of Federal Regulations 21 CFR 117.3: Definitions*
www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117/subpart-A/section-117.3

(5) *Penn State University (PSU): Understanding FSMA: HACCP, HARPC and the Preventive Controls for Human Food Rule*
extension.psu.edu/understanding-fsma-haccp-harpc-and-the-preventive-controls-for-human-food-rule

(6) *FDA Food Safety Plan Builder (FSPB)*
www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-plan-builder

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For more information and to sign up for The Dirt, the e-newsletter from the Patrick Leahy Farm to School Program, visit www.fns.usda.gov/f2s/e-letter-archive.
Questions? Email us at SM.FN.FarmToSchool@usda.gov.

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