

DEVELOPING A FOOD SAFETY PLAN:

AN OVERVIEW



Introduction

The Food Safety Modernization Act (FSMA) Preventive Controls for Human Food (PCHF) rule was introduced to enhance the food safety system and ensure the safety of food products directed to consumers. The FSMA-PCHF focuses on identifying hazards associated with food production and the application of appropriate preventive controls to minimize or eliminate these hazards (Ganjyal and Coles 2017).

All food manufacturers covered under the FSMA-PCHF rule must prepare a Food Safety Plan, which is defined as “a set of written documents that is based on food safety principles; incorporates hazard analysis, preventive controls, supply-chain programs, and a recall plan; and delineates the procedures to be followed for monitoring, corrective actions and verification” (FSPCA 2016).

Steps in Developing a Food Safety Plan

Developing a strong Food Safety Plan involves several steps, as shown in Figure 1. Preliminary steps, including assembling the food safety team, development of the overview of the processing facility, description of the product(s), development and verification of a flow diagram, and detailed description of the process, are not required by the PCHF regulation but are highly recommended (Figure 1). These steps are crucial in providing comprehensive information about the company, product(s), and production process needed to successfully develop and implement the Food Safety Plan.

Each step in developing a Food Safety Plan has been described in this publication, with special emphasis on the most critical activities.

Assemble the Food Safety Team

The Food Safety Plan should be created by the food safety team led by a *preventive controls qualified individual* (PCQI) (Pietrysiak et al. 2019). A strong food safety team will include individuals from different areas of expertise including management, maintenance, production, cleaning and sanitation, quality control, and the laboratory (if applicable). Including people from different areas of expertise within the facility ensures that as many hazards are identified as possible throughout all points of production.

Develop an Overview of the Processing Facility

Overview of the processing facility should include information about the company, number of employees, types of products manufactured, work schedule, source of water (if applicable), and basic information about cleaning and sanitation systems used.

Thoroughly Describe the Product(s)

Describing the food product or products helps everyone on the food safety team become familiar with the product(s) manufactured in the facility, the end uses, intended consumers, and storage requirements. The product description should include the product name(s), relevant food safety characteristics (e.g., pH, moisture content, water activity), ingredients list, packaging type, shelf life, and directions for storage and distribution. Describing the product end uses and intended consumers will enable the food safety team to identify potential or reasonably foreseeable hazards. All of this information will help the food safety team to implement appropriate controls in manufacturing as well as to define necessary conditions for storage and distribution.



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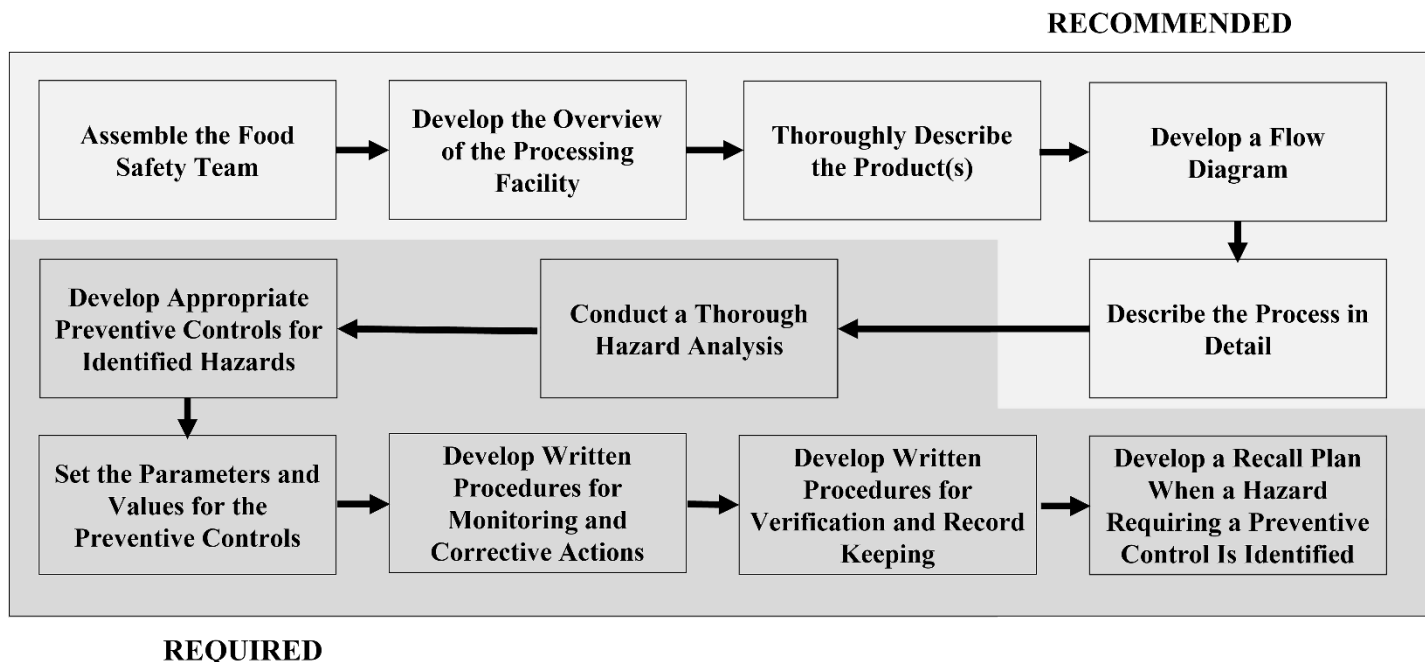


Figure 1. Process flow of developing a Food Safety Plan. Squares marked in white indicate recommended (optional) steps, whereas squares marked in gray indicate the steps that are required. Adapted from [Preventive Controls for Human Food: An Overview](#) (Ganjyal and Coles 2017).

Develop a Flow Diagram and Verify It On-site

A flow diagram is a visual representation of all the ingredient processing steps in a sequence, from receiving through the final product packaging and storage. Once the food safety team develops the flow diagram, it is critical for the team to walk the actual production line to ensure that they captured all the critical steps in the flow diagram. It is very important to consider the rework or waste streams coming from the processes.

Describe the Process in Detail

A written process description provides detailed information about the processes and conditions at each of the processing steps. It is critical to focus on information that is relevant to food safety in the description, such as process temperatures, exposure times to the temperatures, temperature of rooms, and internal product temperature before and at the end of the process. A deeper understanding of the whole production process will aid the food safety team in performing effective hazard analysis by evaluating the risks at each step.

Conduct a Thorough Hazard Analysis

The first required step (Figure 1) is a written hazard analysis assessment. Food safety hazards are agents that can adversely affect human health and are classified into three groups: biological, chemical (including radiological), and physical (FSPCA 2016). The hazards are identified based on experiences,

illness data, scientific reports, the FDA food hazard guide, and other relevant information (CFR Title 21 Part 117.130). Once identified, hazards are assessed to determine the probability of occurrence and severity of potential illness or injury. This information is then used to determine if a preventive control is needed to address the hazard or if it can be addressed by the CGMPs (Current Good Manufacturing Practices) or prerequisite programs. A written hazard analysis is required even if there are no identified hazards or if the facility has determined there is no need for preventive controls.

Develop Appropriate Preventive Controls for the Identified Hazards

The next step is to identify and implement preventive controls as necessary to address the identified hazards. Preventive control is a risk-based, reasonably appropriate intervention that is applied to minimize or prevent the hazards identified under the hazard analysis (CFR Title 21 Part 117.3). The PCHF rule includes the following preventive controls:

- Process controls (similar to critical control points [CCP] under Hazard Analysis Critical Control Point [HACCP]), are applied to monitor the production process and ensure that the critical steps are kept within identified parameters;
- Allergen controls including methods or labeling procedures are applied to prevent cross-contamination or improper labeling of allergens;
- Sanitation controls to ensure that sanitary conditions are maintained in the processing environment;

- Supply chain controls to verify if hazards related to ingredients or raw materials have been controlled by the supplier.

Set the Parameters and Values for the Preventive Controls

Parameters and values of operating conditions (critical limits) need to be established for identified preventive controls. Critical limits are the operating conditions selected to mitigate the hazard effectively (FSPCA 2016). For example, pasteurization of milk at 161°F for 15 seconds will ensure its safety from biological hazards such as the presence of pathogenic bacteria (FDA 2019). The critical limit values are set based on scientific data and the understanding of the specific process parameters.

Develop Written Procedures for Monitoring and Corrective Actions

Monitoring is “to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended” (CFR Title 21 Part 117.3). For example, the monitoring of a pasteurization process to inactivate pathogens should consist of recording temperature and time at predetermined time intervals. There are requirements for calibrating the instruments used to measure these parameters. Measurements must be documented and verified. Corrective actions describe what to do when process preventive controls are not correctly applied.

Develop Written Procedures for Validation, Verification, and Record Keeping

Validation of Preventive Controls

All identified process preventive controls must be validated to ensure they are effective once implemented. Validation includes the use of scientific principles and data, expert opinions, in-plant observations and testing, end-product testing, and challenging the limits of process controls to ensure the hazards can be controlled through proper implementation of the preventive controls (FSPCA 2016).

Verification of Preventive Controls

As a part of the validation procedure, it is important to verify the preventive controls are effective and are controlling the hazards. This is done through the review of processing records, equipment calibration, and end-product testing. Verification and validation go hand in hand and must be performed or overseen by the PCQI.

Record Keeping

The FSMA-PCHF rule requires record keeping of information relevant to the food safety of the product. Records required in the PCHF rule include implementation of the Food Safety Plan, exceptions for not establishing a preventive control, monitoring of preventive controls and corrective actions when needed, records of verification and validation, employee training, supply chain control, reanalysis of the Food Safety Plan, and records of the record review (FSPCA 2016).

Record Review

- All monitoring and corrective action records must be reviewed within seven working days from when the record is created.
- Verification and validation records including calibration, product testing, environmental testing, and supplier program records must be reviewed in a reasonable amount of time.
- Review of records must be performed by or overseen by the PCQI (CFR Title 21 Part 117.130).

Develop a Recall Plan When a Hazard Requiring a Preventive Control Is Identified

A recall plan describes what to do when the safety of the food product is compromised and the product is already in commerce. It is mandatory to have a written recall plan if the hazard analysis determines at least one hazard that requires the implementation of a preventive control. The recall plan assigns responsibility for performing all the procedures such as notifying customers and the public, conducting effectiveness checks, and executing a proper disposition of recalled food. It is also recommended that facilities practice mock recalls to keep themselves ready and that they continuously check the system.

Conclusion

Food processors covered under the FSMA-PCHF rule are required to develop and implement a Food Safety Plan. A Food Safety Plan describes all the aspects of the production process and production environment related to food safety and identifies food safety hazards and appropriate controls to prevent those hazards. If there is a change in the process, formulation, equipment, end use, or if new products are added, the Food Safety Plan must be revised. An effective Food Safety Plan will help to ensure that food products are manufactured and distributed safely to consumers.

Acknowledgments

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References

CFR (Code of Federal Regulations). Title 21 Part 117.130. [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food—Hazard Analysis](#).

CFR (Code of Federal Regulations). Title 21 Part 117.3. [Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food—Definitions](#).

FDA (U.S. Food and Drug Administration). 2019. [Grade “A” Pasteurized Milk Ordinance](#).

FSPCA (Food Safety Preventive Controls Alliance). 2016. Training Manual for the FSMA Preventive Control for Human Food Rule Training Course Version 1.2. <https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>.

Ganjyal, G.M., and C. Coles. 2017. [Preventive Controls for Human Food: An Overview](#). Washington State University Extension Publication FS282E. Washington State University.

Pietrysiak, E., B. Rasco, and G.M. Ganjyal. 2019. Preventive Controls Qualified Individual: Roles and Responsibilities. *Cereal Foods World* 64(2).

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