

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry¹

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Chapter 1: The Food Safety Plan

Table of Contents

- 1.1 Purpose of this Chapter
- 1.2 What is a Food Safety Plan?
- 1.3 Who Develops the Food Safety Plan for a Facility?
- 1.4 What are the Differences Between a HACCP Plan and a Food Safety Plan?
 - 1.4.1 Hazard Analysis and Controls to Address the Hazards
 - 1.4.2 Monitoring
 - 1.4.3 Corrective Actions and Corrections
 - 1.4.4 Verification
 - 1.4.5 Validation
 - 1.4.6 Recall plan
- 1.5 What if a Facility Already Has a HACCP Plan?
- 1.6 What Format Is Required for a Food Safety Plan?

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Chapter 1 that we issued for public comment in August 2016.

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1.7 When Are Changes Needed for a Food Safety Plan?

1.8 References

1.1 Purpose of this Chapter

The guidance provided in this chapter is intended to help you understand what a food safety plan is and how it differs from a HACCP plan. The PCHF requirements specify that a facility must prepare, or have prepared, and implement a written food safety plan. See 21 CFR 117.126.

1.2 What is a Food Safety Plan?

A Food Safety Plan (FSP) consists of the primary documents in a preventive controls food safety system that provides a systematic approach to the identification of food safety hazards that must be controlled to prevent or minimize the likelihood of foodborne illness or injury. It contains a collection of written documents that describes activities that ensure the safety of food during manufacturing, processing, packing, and holding. See 21 CFR 117.126.

Below, we describe the written documents that make up the FSP (see 21 CFR 117.126(b)).

- Hazard analysis to identify whether there are hazards requiring a preventive control. This hazard analysis must be written, regardless of whether any hazards requiring a preventive control are identified. (Some facilities may not identify any hazards requiring a preventive control.)
- When the hazard analysis identifies hazards requiring a preventive control, the FSP also includes the following written documents:
 - Preventive controls (see 21 CFR 117.135), as appropriate to the facility and the food, to ensure safe food is produced, including:
 - Process controls
 - Food allergen controls
 - Sanitation controls
 - Supply-chain controls
 - Recall plan
 - Other controls
 - Procedures for monitoring the implementation of the preventive controls, as appropriate to the nature of the preventive control and its role in the facility's food safety system
 - Corrective action procedures, as appropriate to the nature of the hazard and the nature of the preventive control
 - Verification procedures, as appropriate to the nature of the preventive control and its role in the facility's food safety system

This written FSP is a record that you must maintain. See 21 CFR **117.126(c)** and 21 CFR part 117, subpart F, particularly 21 CFR 117.310. In addition, you must maintain records to document that you are implementing the FSP. (See 21 CFR 117.190.)

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The FSP starts with a hazard analysis of all ingredients and process or manufacturing steps (see Chapter 2 of this guidance). A “hazard” is any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. It is important to understand that for the purposes of food safety, the term “hazard” refers only to the conditions or contaminants in food that are capable of causing illness or injury to people. These include hazards that occur naturally, that are unintentionally added or that may be intentionally added to a food for purposes of economic gain (i.e., economic adulteration). Many conditions are highly undesirable in food, such as the presence of insects, hair, filth or spoilage, and violations of regulatory food standards. All of these defects should be controlled in food processing; often, however, these defects do not directly affect the safety of the product. Unless these conditions directly affect food safety, documents addressing these issues are not included in an FSP. If the hazard analysis does not identify any hazards requiring a preventive control, the only document in the FSP would be the hazard analysis.

1.3 Who Develops the Food Safety Plan for a Facility?

A “preventive controls qualified individual” (PCQI) must develop (or oversee the development of) the FSP. 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 FDA (e.g., the Food Safety Preventive Controls Alliance (FSPCA) training). The PCQI does not need to be an employee of the facility. See 21 CFR 117.126(a) and the definition of PCQI in 21 CFR 117.3.

The FSP must be signed and dated by the owner, operator or agent in charge of the facility when it is first completed and whenever the plan is modified (See 21 CFR 117.310.). See section 1.6 of this document for information on signing an FSP that consists of multiple components such as HACCP plans, prerequisite programs, a recall plan and a variety of procedures.

1.4 What are the Differences Between a HACCP Plan and a Food Safety Plan?

Hazard Analysis and Critical Control Points (HACCP) is a preventive food safety strategy that is a systematic approach to the identification and assessment of the risk of hazards from a particular food or food production process or practice and the control of those hazards that are reasonably likely to occur. HACCP systems have been mandated by U.S. Federal regulations issued by the Food and Drug Administration (FDA) for seafood and juice and by the Food Safety and Inspection Service (FSIS) for meat and poultry.

The preventive controls approach to controlling hazards used in an FSP incorporates the use of risk-based HACCP principles in its development. (See the HACCP principles and their application as described by the National Advisory Committee on Microbiological Criteria for Foods.) Although an FSP and a HACCP plan are similar, they are not identical. Table 1-1 compares what is required for the elements of each type of plan. In the following paragraphs, we briefly discuss each of these elements.

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Table 1-1 Comparison of Elements of a HACCP Plan and a Food Safety Plan

| Element | HACCP Plan | Different in Food Safety Plan |
|-------------------------------------|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard Analysis | Biological, chemical, physical hazards | Chemical hazards include radiological hazards, consideration of economically motivated adulteration (21 CFR 117.130(b)(1)(ii)) |
| Preventive Controls | CCPs for processes | Process CCPs + controls at other points that are not CCPs (21 CFR 117.135(a)(2)) |
| Parameters and values | Critical limits at CCPs | Parameters and minimum/maximum values (equivalent to critical limits for process controls) (21 CFR 117.135(c)(1)) |
| Monitoring | Required for CCPs | Required as appropriate for preventive controls (21 CFR 117.145) |
| Corrective actions and Corrections | Corrective actions | Corrective actions or corrections as appropriate (21 CFR 117.150(a)) |
| Verification (including validation) | For process controls | Verification as appropriate for all preventive controls; validation for process controls; supplier verification required when supplier controls a hazard (21 CFR 117.155, 117.160) |
| Records | For process controls | As appropriate for all preventive controls (21 CFR 117.190) |
| Recall plan | Not required in the plan | Required when a hazard requiring a preventive control is identified (21 CFR 117.139) |

1.4.1 Hazard Analysis and Controls to Address the Hazards

In developing a HACCP plan, the hazard analysis leads to the identification of critical control points (CCPs) where essential process controls are needed to prevent a foodborne hazard from causing illness or injury. Once CCPs are identified, critical limits are established that define the operating conditions in the process that must be effectively managed and monitored to control the hazard. When critical limits are not met, predefined corrective actions are taken. All of the steps in a HACCP plan are recorded and verified to ensure the system is operating as intended.

The FSP also begins with a hazard analysis, which includes consideration of radiological hazards as chemical hazards, as well as hazards due to economically motivated adulteration, such as addition of dyes containing lead to spices to enhance color. The outcome of the hazard

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analysis is the facility's determination of whether there are any known or reasonably foreseeable hazards that require a preventive control. In an FSP, preventive controls may be applied at CCPs, but also at points other than at CCPs. The FSP includes control measures that, under the HACCP approach, may have been included in prerequisite programs or CGMPs. For example, supplier controls and food allergen controls have often been addressed through prerequisite programs, and sanitation controls have often been addressed through CGMPs. Process controls in an FSP will have parameters with minimum or maximum values, which are equivalent to the critical limits for HACCP CCPs. The use of preventive controls in an FSP may expand beyond CCPs by identifying and providing controls that may not be process-related, but are still important in the control of a hazard. Critical limits (minimum or maximum values) may not be practical or needed for non-process-related preventive controls, such as using hygienic zoning controls to prevent cross-contact and cross-contamination or ensuring that suppliers have adequately controlled hazards in the foods they are providing a manufacturer/processor.

1.4.2 Monitoring

In a HACCP plan, the CCPs are always monitored. In an FSP, preventive controls are only monitored as appropriate to the nature of the preventive control and its role in the facility's food safety system, and some preventive controls that are not applied at CCPs may not be monitored.

1.4.3 Corrective Actions and Corrections

In a HACCP plan, corrective actions are taken for deviations from a critical limit at a CCP. An FSP also provides for facilities to take corrective actions. However, immediate corrections (e.g., re-cleaning and sanitizing a line before start-up of production when food residue remains after cleaning) may be more appropriate for some preventive controls than a specific corrective action involving product risk evaluations of product safety for some preventive controls. The requirements for an FSP provide this flexibility.

1.4.4 Verification

In a HACCP plan, verification activities take place for process controls to ensure the process can control the hazards and the HACCP plan is being followed. In an FSP, verification activities will also be applied to preventive controls, but because preventive controls are not just process controls, there is flexibility to conduct verification activities as appropriate to the food, the facility and the nature of the preventive control and its role in the food safety system.

1.4.5 Validation

Some HACCP systems (e.g., for juice, and for meat and poultry products) require validation of the HACCP plan as a whole. In an FSP, validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards. The extent of validation activities may be less rigorous for some preventive controls than others, or may not be required (e.g., sanitation controls).

1.4.6 Recall plan

In a HACCP plan, recall plans have not been included. In an FSP, a Recall Plan must be prepared for each product for which a hazard requiring a preventive control has been identified.

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1.5 What if a Facility Already Has a HACCP Plan?

If you have an existing HACCP plan, you should determine if it satisfies all the PCHF requirements in part 117. You can use existing programs, procedures, and records and supplement these with any additional information required, such as a supply-chain program.

1.6 What Format Is Required for a Food Safety Plan?

There is no standardized or required format for an FSP. This guidance provides flexibility in its approach to guide you in identifying and establishing preventive controls for different types of hazards identified in your hazard analysis. You can use whatever format works best for your facility, provided that the FSP includes all the required information. The formats shown in this guidance are for illustrative purposes only and may not be complete. The FSPCA training materials have FSP worksheets and teaching example model FSPs that may be helpful.

The FSP may consist of one or more existing HACCP plans, one or more prerequisite programs that include food safety controls, a recall plan, a written supply-chain program, written verification procedures such as environmental monitoring, and any other components specified in the PCHF requirements. You have flexibility in how to organize these documents within your FSP. One approach for organizing the FSP to allow for signing and dating it is to collect all these documents in a single location (e.g., a binder or folder) with a cover page containing the signature of the owner, operator, or agent in charge of the facility and the date on which the cover page was signed. However, because the FSP also could be a set of documents kept in different locations within the facility, another approach is for the owner, operator, or agent in charge of the facility to sign and date a list of the relevant documents (e.g., as in a Table of Contents).

1.7 When Are Changes Needed for a Food Safety Plan?

The FSP is a dynamic document that reflects your current hazard analysis, preventive controls, and applicable procedures. The FSP as a whole must be reanalyzed at least every 3 years. The reanalysis may be limited to the applicable portion of the FSP when you make changes to your system or equipment, when you become aware of new information about potential hazards associated with the food or your facility, when there is an unanticipated food safety problem, or when you find that a preventive control, combination of preventive controls, or the FSP itself is ineffective. See 21 CFR 117.170.

1.8 References

National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 1998. "Hazard Analysis and Critical Control Point Principles and Application Guidelines." *J Food Protect* 61: 1246-1259.