

HACCP Job Aid

Instructions: Review this Job Aid and policy documents, regulations, and inspection methodologies with a mentor.

Acronyms/Definitions

- Hazard Analysis and Critical Control Point (HACCP) – A systematic approach to the identification, evaluation, and control of food safety hazards.
- Critical Control Point (CCP) – Point or step in a process at which control can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.
- Critical Limit (CL) – A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.
- Food Safety Hazard – Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
- Hazard Analysis (HA) – The process of determining the food safety hazards that are "reasonably likely to occur" during a food production process.
- Reasonably Likely to Occur (RLTO) Food Safety Hazard – A hazard for which a prudent establishment would establish controls because it has historically occurred, or because there is a reasonable possibility that it will occur in the product being processed, in absence of those controls.
- Prerequisite Program (PRP) – A procedure or set of procedures designed to provide basic environmental or operating conditions necessary to produce safe product.

Overview

- The HACCP regulations are found in [9 CFR Part 417](#).
- FSIS requires establishments to design and operate a validated **HACCP system** to prevent, eliminate, reduce to an acceptable level, or control identified food safety hazards in the products it produces ([FSIS Directive 5000.1](#), Ch. III., Pt. I., I.).
 - The HACCP system, also called a food safety system, is defined as the "HACCP plan in operation" which includes the Hazard Analysis, HACCP plan, supporting documentation (including PRPs), and HACCP records generated on an ongoing basis.
- The establishment first develops a **flow chart** that identifies all steps in the production process. ([FSIS Directive 5000.6](#), Sec. V., Step 1).
 - **Note:** A step is a point or activity within the operation that is critical to the proper production of the product. Each step is to be included on the flow chart. However, multiple activities can be incorporated into one step.
- Then the establishment **conducts a Hazard Analysis** to consider and identify all potential **biological, chemical, and physical hazards** at each step in the process. They determine if each hazard is **reasonably likely to occur (RLTO)**, or **not reasonably likely to occur (NRLTO)** ([FSIS Directive 5000.1](#), Ch. III., Pt. I., II.; [FSIS Directive 5000.6](#), Sec. V., Step 2).

- If the establishment does not identify hazards at a step in the hazard analysis, they are not required to include a justification for no hazards identified. However, IPP may question any determination in the hazard analysis if, for example, historically a food safety hazard has occurred, or new information becomes available regarding a particular process having a potential food safety hazard.
- Examples of food safety hazards:
 - Biological: *E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, *Campylobacter*, Specified Risk Materials
 - Chemical: allergens, drug residues, curing agents
 - Physical: metal, plastic, wood, glass
- **Note:** The establishment is required to develop a **HACCP plan** whenever a hazard analysis reveals one or more food safety hazards that are RLTO. The contents of the HACCP plan, which lists the CCPs, are described in [9 CFR 417.2\(c\)](#).
- If the establishment **determines a hazard is RLTO**, they are required to **develop a CCP** to address the hazard at that step or later in the process to prevent, eliminate, or reduce the hazard to acceptable levels. Examples of CCPs: cooking, chilling, antimicrobial intervention application ([FSIS Directive 5000.6](#), Sec. V., Step 3).
 - Each CCP is to **list the critical limit**, a maximum and/or minimum measurable or quantifiable value, that must be met to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. Examples of critical limits: Cooking temperature - achieve 165°F or more internal temperature, Chilling target - achieve 40°F or less in 10 hours or less.
 - For each CCP, the establishment is required to:
 - Establish **Monitoring Procedures** – to assess whether a CCP is under control.
 - Establish **Verification Procedures** – validation, ongoing verification, and reassessment.
 - Establish **Corrective Actions** – that they will take in response to a deviation from the critical limit.
 - Establish **Recordkeeping and Documentation Procedures** – a system of recordkeeping to demonstrate its effective operation of the system.
- If the establishment **determines a hazard is NRLTO**, they are required to provide justification or support for this decision. PRPs are commonly used as supporting documentation that serve as a basis for why a hazard is NRLTO. Examples of PRPs: Allergen Control Program, Temperature Control Program, Sanitation SOPs, Written Specified Risk Material Program ([FSIS Directive 5000.6](#), Sec. V., Steps 4-5).
 - The establishment is required to maintain copies of all the documents referenced in the hazard analysis that are designated as support for the decisions that hazards are NRLTO. This may include PRPs, scientific documents, or historical records.
- The establishment is to validate the adequacy of its HACCP system ([FSIS Directive 5000.6](#), Sec. V., Step 6).

- The establishment is to reassess its HACCP system under the conditions described in the regulations ([FSIS Directive 5000.6](#), Sec. V., Step 7).

Basic Procedure

- IPP perform two HACCP inspection tasks to verify establishments are complying with [9 CFR Part 417 \(FSIS Directive 5000.1, Ch. III., Pt. I., III.\)](#):
 1. Hazard Analysis Verification (HAV) task – focuses on the design and support of the HACCP system, including the overall effectiveness of the system. IPP conduct the HAV task quarterly and review the hazard analysis for one HACCP plan, the HACCP plan itself, and any PRPs or other supporting documentation used to support decisions in the hazard analysis.
 2. HACCP Verification task – focuses on the implementation of the establishment's HACCP plans, PRPs and other supporting programs (HACCP system). IPP perform HACCP Verification tasks for each of the HACCP process categories listed in the establishment's profile, at the frequency assigned in PHIS.

Discussion Points

- Discuss the differences between the hazard analysis, the HACCP plan, and prerequisite programs.
- Discuss the differences between prerequisite programs and any other procedures performed by the establishment not used to support the hazard analysis decisions.
- Discuss how to evaluate supporting documentation.
- Discuss access to establishment records ([FSIS Directive 5000.1](#), Ch. III., Pt. I., Sec. III., D.).

Knowledge Check

- When conducting a hazard analysis, if the establishment determines that a hazard is RLTO, what are they required to develop to address the hazard?
- When conducting a hazard analysis, if the establishment determines a hazard is NRLTO, what are they required to provide for this decision?

Resources

- [FSIS Directive 5000.1](#) – *Verifying an Establishment's Food Safety System*
- [FSIS Directive 5000.6](#) – *Performance of the Hazard Analysis Verification Task*
- [Meat and Poultry Hazards and Controls Guide](#)
- IM Workbook – HACCP Seven Principles