Section 3-3: Principle 1: Conduct a Hazard Analysis

Asia-Pacific Economic Cooperation
FSCF Food Safety Cooperation Forum
PTIN Partnership Training Institute Network
THE WORLD BANK
MICHIGAN STATE UNIVERSITY

Principle 1: Hazard Analysis

Section Overview

The first principle of HACCP is to conduct a hazard analysis. Conducting a complete and accurate hazard analysis is the most important step in developing a valid HACCP plan, so the HACCP team must approach this step in a systematic, thorough manner.

The following topics will be discussed in this section:

- Definition and considerations
- Importance of conducting a thorough hazard analysis
- Food safety hazards
- Hazard analysis process
- Hazard identification
- Determination of acceptable levels
- Hazard evaluation
- Control measures
- Summarize the hazard analysis
- Final considerations

Learning Objectives

At the conclusion of this section, the learner will be able to:

- discuss the purpose of a hazard analysis and describe the overall approach to hazard analysis in HACCP systems,
- list examples of biological, chemical and physical food safety hazards that are common in food products,
- discuss factors the HACCP team should consider when conducting hazard identification,
- discuss considerations when determining acceptable levels of food safety hazards,
- describe the process used to evaluate hazards and describe factors which influence severity and likelihood of occurrence of hazards,
- define and provide examples of control measures, and
- describe the required elements of a hazard analysis summary.

Principle 1: Hazard Analysis

Definition and Considerations

HACCP Principle 1 states:

- Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe control measures.

Hazard analysis is the process used by the HACCP team to determine which potential hazards present a significant health risk to consumers.

The purpose of the hazard analysis is to develop a list of hazards which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. Only those hazards that pose significant risk to the health of consumers should be included in the HACCP plan.

It is important to consider in the hazard analysis the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer.

When conducting a hazard analysis, safety concerns must be differentiated from quality concerns. HACCP applies to food safety only, not food quality.

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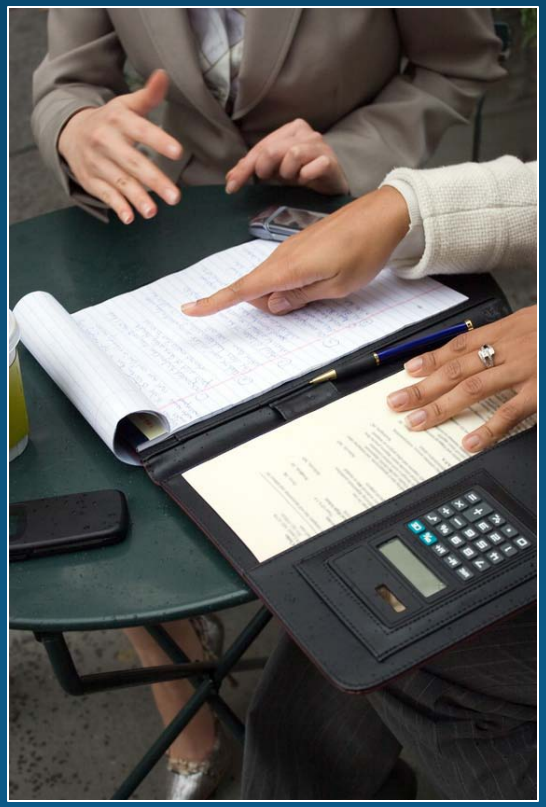
Importance of Conducting a Thorough Hazard Analysis

Completing a comprehensive and valid hazard analysis is critical to the potential success of the overall HACCP system. Successful application of HACCP principles 2-7 depends on a high-quality hazard analysis.

An improper hazard analysis may result in a HACCP plan that is not effective in protecting consumers regardless of how well it is followed.

It also is important to note that operations in the food establishment may need to be modified based on the findings from a thorough hazard analysis. If the hazard analysis determines that a significant hazard is potentially present, without corresponding control measures to manage this hazard, then the product formulation, processing steps or other plant operations must be modified to enable control of this hazard.



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Food Safety Hazards

As stated earlier, a food safety hazard is defined by the Codex Alimentarius as "a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect."

Examples of potential biological hazards include the following:

Bacteria (non-spore forming)

Campylobacter spp.
Pathogenic *Escherichia coli* (*E. coli* 0157:H7 and other enterohemorrhagic *E. coli*)
Listeria monocytogenes
Salmonella spp. (*S. typhimurium, S. enteritidis*)
Shigella (*S. dysenteriae*)
Staphylococcus aureus
Streptococcus pyogenes
Vibrio cholerae
Vibrio parahaemolyiticus
Vibrio vulnificus
Yersinia enterocolitica

Bacteria (spore forming)

Clostridium botulinum
Clostridium perfringens
Bacillus cereus

Viruses

Hepatitis A Virus
Noroviruses
Rotavirus

Protozoa and Parasites

Cryptosporidium parvum
Diphyllobothrium latum
Entamoeba histolytica
Giardia lamblia
Ascaris lumbricoides
Taenia solium
Taenia saginata
Trichinella spiralis

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Food Safety Hazards

Examples of potential chemical hazards include the following:

Naturally occurring chemicals

Allergens
Mycotoxins (e.g. aflatoxin)
Scombrotoxin (histamine)
Ciguatoxin
Pyrrolizidine alkaloids
Phytohemagglutinin
Mushroom toxins

Shellfish toxins
- Paralytic shellfish poisoning
- Diarrhoeic shellfish poisoning
- Neurotoxic shellfish poisoning
- Amnesic shellfish poisoning

Added Chemicals

Polychlorinated biphenyls
Agricultural chemicals
- Pesticides
- Fertilizers
- Antibiotics
- Growth hormones

Prohibited substances
- Direct
- Indirect

Toxic elements and compounds
- Lead
- Zinc
- Cadmium
- Mercury
- Arsenic
- Cyanide

Added Chemicals (cont.)

Food additives
Vitamins and minerals
Contaminants
- Lubricants
- Cleaners
- Sanitizers
- Coatings
- Paints
- Refrigerants
- Water or steam treatment chemicals
- Pest control chemicals

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Food Safety Hazards

Additional examples of potential chemical and physical hazards include the following:

Chemicals from Packaging Materials

Plasticizers
Vinyl chloride
Printing/coding inks
Adhesives
Lead
Tin

Physical Hazards

Metal
Glass
Wood
Stones
Bone (when not expected)
Plastics

Hazard Analysis Process

The process of conducting a hazard analysis involves two stages. These are:

1. Hazard Identification and Determination of Acceptable Levels
   - First, the HACCP team develops a list of potential hazards that may be associated with a food.
   - Following the identification of hazards, the team then determines the acceptable level for each identified food safety hazard.
2. Hazard Evaluation
   - The HACCP team evaluates each identified hazard based on its likelihood of occurrence in that particular food product and the severity of effects of the specific hazard.
   - Using this information, as well as information on acceptable levels for identified hazards, the HACCP team identifies which of the potential hazards pose a significant risk to the consumer.

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Hazard Identification

This is essentially a “brainstorming” exercise wherein the team generates a list of potential biological, chemical, and physical hazards that may be introduced, increased, or controlled at each step described on the product flow diagram.

The process of hazard identification should consider the following items.

- The preliminary information collected while developing the product description.
- Experience. For example, the establishment probably has considerable information on the likelihood of hazards being present in finished products based on results of product testing or information from consumer complaints.
- External information including, when possible, epidemiological and other historical data.
- Information from the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products, and the food at consumption.

Appendix C in the document “Hazard Analysis and Critical Control Point Principles and Application Guidelines” which was published in 1997 by the U.S. National Advisory Committee On Microbiological Criteria For Foods (NACMCF) contains a thorough set of questions the HACCP team should consider when conducting hazard identification. This document is available at:

http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm

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Determination of Acceptable Levels

After conducting the "brainstorming" exercise to identify which food safety hazards may be associated with the product and process, the HACCP team must then determine the acceptable levels of each of these hazards. This determination typically can be completed by consideration of the following factors:

- Regulatory requirements
- Customer requirements
- Intended use by the customer
- Other relevant data

For those products that will be exported to other countries, it is vitally important that the HACCP team be cognizant of regulatory and customer requirements in the destination countries.

The HACCP team should record the result of these determinations and their justifications, and maintain these with other HACCP records.

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Hazard Evaluation

Following identification of hazards and determination of acceptable levels, the next step in the hazard analysis is to determine which hazards are sufficiently significant that they must be addressed by the HACCP plan.

The HACCP team decides which of the potential hazards listed during hazard identification stage present a significant risk to consumers.

Each potential hazard should be evaluated based on two factors:

1. Severity of the potential illness or injury
2. Likelihood of occurrence

We will consider each of these factors in sequence.

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Evaluating Severity

Evaluation of the severity of a food safety hazard requires consideration of various factors, including:

- the magnitude and duration of the illness or injury,
- the possible impact of secondary problems (chronic sequelae), and
- the susceptibility of intended customers to foodborne illness (e.g. children versus adults).

The illnesses or injuries caused by foodborne hazards differ considerably in their magnitude and duration. For example, some foodborne pathogens can be deadly either due to the infection itself (e.g. *Listeria monocytogenes*), due to the actions of toxins formed by the pathogens after their consumption and outgrowth in the gastrointestinal tract (e.g. *E. coli* O157:H7), or due to the actions of toxins formed prior to ingestion of the food (e.g. *Clostridium botulinum*). Depending upon the hazard and its concentration, chemical hazards may cause acute intoxications or may only represent a hazard through chronic ingestion. Physical hazards commonly are associated with relatively minor injuries to the teeth and oral cavity, although some may represent choking hazards.

Some foodborne hazards have long-term adverse consequences, which are referred to as sequelae. For example, Campylobacter jejuni infection is associated with increased incidence of Guillain-Barré syndrome, a chronic inflammatory neuropathy. Several pathogenic bacteria, such as pathogenic *E. coli* and *Salmonella* spp., are known to initiate reactive arthritis.

We already have discussed the increased susceptibility of certain sensitive populations. It is also important to note that children typically consume greater quantities of food on a relative basis, so their exposure to foodborne hazards can be greater than that of adults.

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Estimating Likelihood of Occurrence

The other factor the HACCP team must evaluate is the likelihood of occurrence of the foodborne hazard. Assessment of this factor can be complex and requires consideration of several factors, including the following.

1. Experience – The HACCP team should have considerable experience with the products the firm produces and the likelihood of occurrence of specific food safety hazards in these products.
2. Data from past foodborne illness outbreaks – Past outbreaks are tremendous learning opportunities, and the HACCP team must take into account lessons learned from these prior events.
3. Information in the scientific literature – Peer-reviewed scientific journals and other sources of technical literature contain a wealth of information on foodborne hazards, their occurrence, potential amplification in foods (in the case of biological hazards) and their control.
4. Historical information gathered by the establishment – The establishment likely has considerable information on the likelihood of occurrence of hazards in their food products. This information can be gleaned from previous laboratory tests on finished products, ingredients, or in-process materials. Consumer complaint records can be an outstanding source of information on physical hazards.

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Factors Influencing Likelihood of Occurrence

The HACCP team also should consider various other factors which can influence the likelihood of occurrence of food safety hazards. These factors include:

- Effectiveness of prerequisite programs
- Frequency of association of the potential hazard with the food or ingredient
- Method of preparation
- Conditions during transportation
- Expected storage conditions
- Likely preparation steps before consumption

Hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product. For example, due to differences in equipment and/or an effective maintenance program, the probability of metal contamination may be significant in one facility but not in another.

Photo: kuma.kigurumi / Flickr

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Evaluating Hazards

The diagram to the right illustrates a conceptualization of the manner in which the HACCP team may evaluate severity and likelihood of occurrence of food hazards.

Hazards that are severe and have relatively high likelihood of occurrence (upper right corner) represent high risk and must be controlled by the HACCP plan.

Conversely, hazards that don't have severe consequences and are relatively unlikely to occur (lower left corner) are low risk and need not be controlled by the HACCP plan.

Hazards that fall in other areas of the diagram should be carefully considered. Whether or not these hazards must be controlled by the HACCP plan will depend upon several factors, including compliance with regulatory and customer requirements.

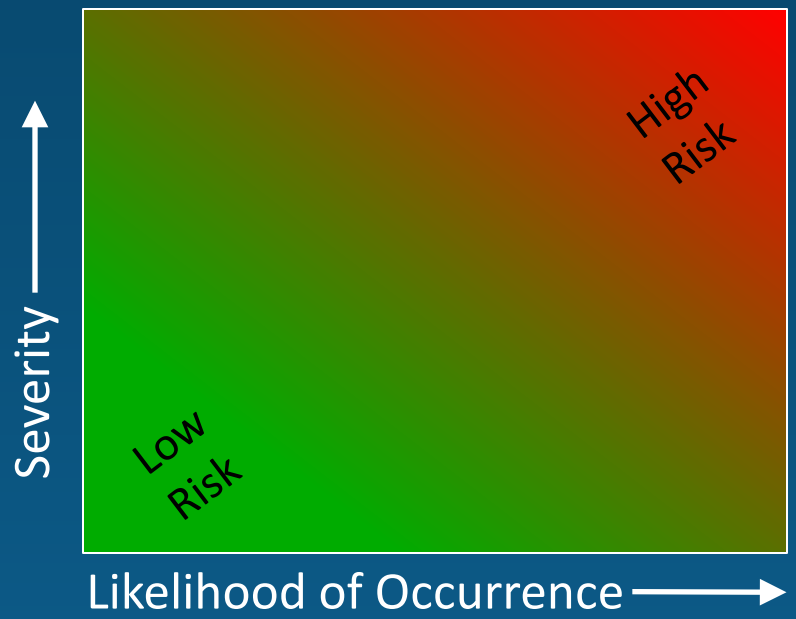

Illustration: Leslie Bourquin

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Control Measures

Hazards that represent a significant risk based upon an assessment of their severity and likelihood of occurrence must be addressed in the HACCP plan.

Control Measures are "any action or activity that can be used to prevent or eliminate a food safety hazard, or reduce it to an acceptable level."

In older HACCP documents, control measures are often termed "preventive measures." The term control measure is now used in recognition of the fact that not all hazards can be prevented, but virtually all can be controlled.

For each significant hazard identified by the HACCP team, control measures must be described that will prevent, eliminate, or reduce the hazard to an acceptable level. As noted previously, significant hazards may be different for the same product produced at different facilities.

Photo: http://www.vatpasteurizer.com

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Control Measures

More than one hazard may be addressed by a specific control measure. For example, thermal processing is a control measure to kill vegetative cells of pathogenic microorganisms. Application of specific time and temperature combinations in a process (such as pasteurization of milk) is very effective in controlling all of the microbial hazards that might be present.

Conversely, more than one control measure may be required for a specific hazard. One example of this is the control of *Clostridium botulinum* in fermented meats such as salami, wherein combinations of control measures (e.g. sodium nitrite and high acidity arising from fermentation) are commonly used to control the outgrowth of this spore-forming bacterium.

Photo: ahunxue-er / Flickr

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Control Measures

On the right is a partial list of possible control measures. These are provided as examples of the wide variety of methods which can be used to control the different hazards which may be present in foods.

For microbiological hazards, common control measures include those which either directly kill the microorganism (e.g. different types of thermal processing, irradiation) or prevent its germination and/or growth (e.g. acidification, fermentation, refrigeration, freezing, drying).

Control measures for chemical hazards include a variety of approaches such as testing and rejection of ingredients which contain excess concentrations of natural or artificial chemical hazards, following proper formulation procedures, correct application of GMPs in the facility, monitoring for allergens, and end product testing.

Likewise, physical hazards can be controlled by methods such as using equipment for straining or aspirating, mechanical separation, metal detection, or use of x-ray or other detection equipment.

- Cooking
- Pasteurization
- Thermal processing
- Irradiation
- Acidification
- Fermentation
- Disinfection
- Refrigeration
- Freezing
- Drying
- Filtering
- Metal detectors
- X-ray devices

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Control Measures

The HACCP team must consider many factors when identifying potential control measures for the significant hazards in the process. In addition to the considerations on the previous pages, selection and categorization of control measures should also include assessments with regard to:

- its effect on identified food safety hazards,
- its feasibility for monitoring,
- its place in the system relative to other control measures,
- the likelihood of failure of a control measure or significant processing variability,
- the severity of consequences in case of a failure,
- whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazards, and
- synergistic effects between control measures.

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Summarize the Hazard Analysis

At the completion of the hazard analysis, the HACCP team must prepare a written summary of the hazard analysis. This summary must :

- Identify potential hazards for each step in the process flow diagram.
- Determine significance of identified hazards, and justify this decision.
- Identify control measures that can be applied at each step to control the identified hazards.

This written summary of the hazard analysis is an important record which must be retained. An example of a format for this written report is provided below. Note that this example only depicts one hazard at one step in the process. The final hazard analysis must include all hazards identified at each step of the process.

Step	Potential Hazard(s)	Justification	Hazard to be addressed in plan? Y/N	Control Measure(s)
5. Cooking	Enteric pathogens: e.g., Salmonella, verotoxigenic-E. coli	enteric pathogens have been associated with outbreaks of foodborne illness from undercooked ground beef	Y	Cooking

Table: NACMCF 1997

Final Considerations

Remember that the hazard analysis, and subsequent HACCP plan, is specific to a product and process. However, it is reasonable to use a common hazard analysis for classes of products that are similar in formulation, have similar processing steps, and are otherwise prepared and packaged in a similar manner. An example of where products might be grouped together for a hazard analysis and subsequent HACCP plan might be for the production of different juice drink products that are produced on the same processing line in a single facility. It is important to note, however, that different formulations can have a dramatic impact on product characteristics (e.g. pH), and these factors must be carefully considered in the hazard analysis.

For reasons discussed previously, the hazard analysis and HACCP plan will likely be different for the same product produced in different facilities. The HACCP team must take into account the unique characteristics, equipment and procedures used at their establishment when preparing the HACCP plan specific for their firm. However, it is perfectly reasonable for the HACCP team to refer to generic HACCP models to help guide their deliberations. Excellent sources of generic HACCP plans are available at the following web sites:

http://haccpalliance.org/alliance/haccpmodels.html

http://seafood.ucdavis.edu/haccp/plans.htm

Generic HACCP models from many other reputable sources also are available.

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