CHAPTER 6
Hazard Analysis

6.1 Identifying Various Hazards and Determining Level of Acceptance

All food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities shall be identified and recorded. The identification shall be based on
a) the preliminary information and data collected according to preliminary steps,
b) experience,
c) external information including, to the extent possible, epidemiological and other historical data,
d) 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.

The step(s) (from raw materials, processing and distribution) at which each food safety hazard may be introduced shall be indicated.

When identifying the hazards, consideration shall be given to:
a) the steps preceding and following the specified operation,
b) the process equipment, utilities/services and surroundings, and
c) the preceding and following links in the food chain.

For each of the food safety hazards identified, the acceptable level of the food safety hazard in the end product shall be determined whenever possible. The determined level shall take into account established statutory and regulatory requirements, customer food safety requirements, the intended use by the customer and other relevant data. The justification for, and the result of, the determination shall be recorded.

The HACCP team conducts a hazard analysis and identifies appropriate control measures. 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. Hazards that are not reasonably likely to occur would not require further consideration within a 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. A hazard is defined as a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. Thus, the word hazard as used in this document is limited to safety.

A thorough hazard analysis is the key to preparing an effective HACCP plan. If the hazard analysis is not done correctly and the hazards warranting control within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed.

The hazard analysis and identification of associated control measures accomplish three objectives: Those hazards and associated control measures are identified. The analysis may identify needed modifications to a process or product so that product safety is further assured or improved. The analysis provides a basis for determining CCPs in Principle 2.

The process of conducting a hazard analysis involves **two stages**. The **first,** hazard identification, can be regarded as a brain storming session. During this stage, the HACCP team reviews the ingredients used in the product, the activities conducted at each step in the process and the

equipment used, the final product and its method of storage and distribution, and the intended use and consumers of the product. Based on this review, the team develops a list of potential biological, chemical or physical hazards which may be introduced, increased, or controlled at each step in the production process. **Example 1 at the end of the chapter** lists examples of questions that may be helpful to consider when identifying potential hazards. Hazard identification focuses on developing a list of potential hazards associated with each process step under direct control of the food operation. A knowledge of any adverse health-related events historically associated with the product will be of value in this exercise.

After the list of potential hazards is assembled, **stage two**, the hazard evaluation, is conducted. In stage two of the hazard analysis, the HACCP team decides which potential hazards must be addressed in the HACCP plan. During this stage, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence. Severity is the seriousness of the consequences of exposure to the hazard. Considerations of severity (e.g., impact of sequelae, and magnitude and duration of illness or injury) can be helpful in understanding the public health impact of the hazard. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature. When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and severity of the potential consequences if the hazard is not properly controlled. In addition, consideration should be given to the effects of short term as well as long term exposure to the potential hazard. Such considerations do not include common dietary choices which lie outside of HACCP. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage and persons likely to consume the product should be considered to determine how each of these factors may influence the likely occurrence and severity of the hazard being controlled. The team must consider the influence of likely procedures for food preparation and storage and whether the intended consumers are susceptible to a potential hazard. However, there may be differences of opinion, even among experts, as to the likely occurrence and severity of a hazard. The HACCP team may have to rely upon the opinion of experts who assist in the development of the HACCP plan.

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. A summary of the HACCP team deliberations and the rationale developed during the hazard analysis should be kept for future reference. This information will be useful during future reviews and updates of the hazard analysis and the HACCP plan.

Example 2 at the end of the chapter gives three examples of using a logic sequence in conducting a hazard analysis. While these examples relate to biological hazards, chemical and physical hazards are equally important to consider. This is for illustration purposes to further explain the stages of hazard analysis for identifying hazards. Hazard identification and evaluation as outlined in this example may eventually be assisted by biological risk assessments as they become available.

Upon completion of the hazard analysis, the hazards associated with each step in the production of the food should be listed along with any measure(s) that are used to control the hazard(s). The term control measure is used because not all hazards can be prevented, but virtually all can be controlled. More than one control measure may be required for a specific hazard. On the other hand, more than one hazard may be addressed by a specific control measure (e.g. pasteurization of milk).

6.2 Assessment of Hazard

A hazard assessment shall be conducted to determine, for each food safety hazard identified in the earlier step, whether its elimination or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met.

Each food safety hazard shall be evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence. The methodology used shall be described, and the results of the food safety hazard assessment shall be recorded.

For example, if a HACCP team were to conduct a hazard analysis for the production of frozen cooked beef patties (Example 2 & 3), enteric pathogens (e.g., *Salmonella* and verotoxin-producing *Escherichia coli*) in the raw meat would be identified as hazards. Cooking is a control measure which can be used to eliminate these hazards. The following is an excerpt from a hazard analysis summary table for this product.

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

The hazard analysis summary could be presented in several different ways. One format is a table such as the one given above. Another could be a narrative summary of the HACCP team's hazard analysis considerations and a summary table listing only the hazards and associated control measures.

6.3 Selection and Assessment Control measure

Based on the hazard assessment of hazard, an appropriate combination of control measures shall be selected which is capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels.

In this selection, each of the control measures as described in process steps shall be reviewed with respect to its effectiveness against the identified food safety hazards.

The control measures selected shall be categorized as to whether they need to be managed through operational PRP(s) or by the HACCP plan.

The selection and categorization shall be carried out using a logical approach that includes assessments with regard to the following:
a) its effect on identified food safety hazards relative to the strictness applied;
b) its feasibility for monitoring (e.g. ability to be monitored in a timely manner to enable immediate corrections);
c) its place within the system relative to other control measures;

d) the likelihood of failure in the functioning of a control measure or significant processing variability;
e) the severity of the consequence(s) in the case of failure in its functioning;
f) whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s);
g) synergistic effects (i.e. interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects).

Control measures categorized as belonging to the HACCP plan shall be implemented in accordance with HACCP plan. Other control measures shall be implemented as operational PRPs according to PRP's.

The methodology and parameters used for this categorization shall be described in documents, and the results of the assessment shall be recorded.

6.4 Establishing Operational Prerequisite Programmes (PRP's)

The operational PRPs shall be documented and shall include the following information for each programme:

a) food safety hazard(s) to be controlled by the programme;
b) control measure(s);
c) monitoring procedures that demonstrate that the operational PRPs are implemented;
d) corrections and corrective actions to be taken if monitoring shows that the operational PRPs are not in control (seen in correction & corrective action, respectively);
e) responsibilities and authorities;
f) record(s) of monitoring.

Example 1

Questions to be Considered When Conducting a Hazard Analysis

The hazard analysis consists of asking a series of questions which are appropriate to the process under consideration. The purpose of the questions is to assist in identifying potential hazards.

A. Ingredients
    1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., Salmonella, Staphylococcus aureus); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
    2. Are potable water, ice and steam used in formulating or in handling the food?
    3. What are the sources (e.g., geographical region, specific supplier)

B. Intrinsic Factors - Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing.
    1. What hazards may result if the food composition is not controlled?
    2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
    3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
    4. Are there other similar products in the market place? What has been the safety record for these products? What hazards have been associated with the products?

C. Procedures used for processing
    1. Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider both vegetative cells and spores.
    2. If the product is subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging which biological, chemical or physical hazards are likely to occur?

D. Microbial content of the food
    1. What is the normal microbial content of the food?
    2. Does the microbial population change during the normal time the food is stored prior to consumption?
    3. Does the subsequent change in microbial population alter the safety of the food?
    4. Do the answers to the above questions indicate a high likelihood of certain biological hazards?

E. Facility design
    1. Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat (RTE) foods if this is important to food safety? If not, what hazards should be considered as possible contaminants of the RTE products?
    2. Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
    3. Is the traffic pattern for people and moving equipment a significant source of contamination?

F. Equipment design and use
    1. Will the equipment provide the time-temperature control that is necessary for safe food?
    2. Is the equipment properly sized for the volume of food that will be processed?
    3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
    4. Is the equipment reliable or is it prone to frequent breakdowns?
    5. Is the equipment designed so that it can be easily cleaned and sanitized?

6. Is there a chance for product contamination with hazardous substances; e.g., glass?
7. What product safety devices are used to enhance consumer safety?
    - metal detectors
    - magnets
    - sifters
    - filters
    - screens
    - thermometers
    - bone removal devices
    - dud detectors
8. To what degree will normal equipment wear affect the likely occurrence of a physical hazard (e.g., metal) in the product?
9. Are allergen protocols needed in using equipment for different products?

G. Packaging
1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
2. Is the package clearly labeled "Keep Refrigerated" if this is required for safety?
3. Does the package include instructions for the safe handling and preparation of the food by the end user?
4. Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?
5. Are tamper-evident packaging features used?
6. Is each package and case legibly and accurately coded?
7. Does each package contain the proper label?
8. Are potential allergens in the ingredients included in the list of ingredients on the label?

H. Sanitation
1. Can sanitation have an impact upon the safety of the food that is being processed?
2. Can the facility and equipment be easily cleaned and sanitized to permit the safe handling of food?
3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

I. Employee health, hygiene and education
1. Can employee health or personal hygiene practices impact upon the safety of the food being processed?
2. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?
3. Will the employees inform management of a problem which could impact upon safety of food?

J. Conditions of storage between packaging and the end user
1. What is the likelihood that the food will be improperly stored at the wrong temperature?
2. Would an error in improper storage lead to a microbiologically unsafe food?

K. Intended use
1. Will the food be heated by the consumer?
2. Will there likely be leftovers?

L. Intended consumer
1. Is the food intended for the general public?
2. Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immunocompromised individuals)?
3. Is the food to be used for institutional feeding or the home?

Example 2

How the Stages of Hazard Analysis are used to Identify and Evaluate Hazards*

		1	2	3
Hazard Analysis Stage		**Frozen cooked beef patties produced in a manufacturing plant**	**Product containing eggs prepared for foodservice**	**Commercial frozen pre-cooked, boned chicken for further processing**
Stage 1*Determine potential* Hazard *hazards associated* **Identification *with product***		Enteric pathogens (i.e., E. coli O157:H7 and Salmonella)	Salmonella in finished product.	Staphylococcus aureus in finished product.
Stage 2 Hazard Evaluation	*Assess severity ofhealth consequencesif potential hazard is notproperly controlled.*	Epidemiological evidence indicates that these pathogens cause severe health effects including death among children and elderly. Undercooked beef patties have been linked to disease from these pathogens.	Salmonellosis is a food borne infection causing a moderate to severe illness that can be caused by ingestion of only a few cells of Salmonella.	Certain strains of S. aureus produce an enterotoxin which can cause a moderate foodborne illness.
	Determine likelihood of occurrence of potential hazard if not properly controlled.	E. coli O157:H7 is of very low probability and salmonellae is of moderate probability in raw meat.	Product is made with liquid eggs which have been associated with past outbreaks of salmonellosis. Recent problems with Salmonella serotype Enteritidis in eggs cause increased concern. Probability of Salmonella in raw eggs cannot be ruled out. If not effectively controlled, some consumers are likely to be exposed to Salmonella from this food.	Product may be contaminated with S. aureus due to human handling during boning of cooked chicken. Enterotoxin capable of causing illness will only occur as S. aureus multiplies to about 1,000,000/g. Operating procedures during boning and subsequent freezing prevent growth of S. aureus, thus the potential for enterotoxin formation is very low.
	Using information above, determine if this potential hazard is to be addressed in the HACCP plan.	The HACCP team decides that enteric pathogens are hazards for this product. **Hazards must be addressed in the plan.**	HACCP team determines that if the potential hazard is not properly controlled, consumption of product is likely to result in an	The HACCP team determines that the potential for enterotoxin formation is very low. However, it is still desirable to keep the initial number of S. aureus organisms low.

			unacceptable health risk. **Hazard must be addressed in the plan.**	Employee practices that minimize contamination, rapid carbon dioxide freezing and handling instructions have been adequate to control this potential hazard. **Potential hazard does not need to be addressed in plan.**

* The potential hazards identified may not be the only hazards associated with the products listed. The responses may be different for different establishments.

Example 3