

## CHAPTER 2

### THEORY OF HACCP

#### I. INTRODUCTION

This chapter will present the overview of HACCP system and its prerequisite program. For HACCP, it will describe the history and the reason why HACCP is very important for food manufacturing nowadays. The seven principles of HACCP will be briefly discussed as well as the applications of HACCP. However, HACCP cannot give all out of its benefits if its prerequisite program is not implemented. The prerequisite program of HACCP will also be overviewed in this chapter.

#### II. HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP)

##### ***2.1 HACCP: The Definition***

Hazard Analysis Critical Control Point (HACCP) is a preventive system for food safety, which is designed to minimize the risk of food-safety hazards. Moreover, it is a management tool used to protect the food supply chain and production process against microbiological, chemical and other physical hazard contamination.

According to "Guidebook For The Preparation Of HACCP Plans" United State Department of Agriculture, 1997, Hazard Analysis Critical Control Points (HACCP) system is a logical, scientific system that can control safety problems in food production. HACCP is now being adopted worldwide. It works with any type of food production system and with any food. It works by controlling food safety hazards throughout the process. The hazards can be biological, chemical, or physical.

##### ***2.2 History of HACCP***

Hazard Analysis Critical Control Point (HACCP) has been commonly known as a system for food safety. It is a worldwide recognized systematic and preventative approach that identifies and controls biological, chemical and physical hazards by anticipating and preventing, rather than by finished production inspection. The HACCP system for managing food safety concerns came from two major developments. The first breakthrough was involved with Dr. W.E. Deming, whose theories of quality management are widely regarded as a major factor in turning around the quality of Japanese products in the 1950's. Dr. Deming and his colleagues developed Total Quality Management (TQM) systems that emphasized a total system approach to manufacturing that could improve quality while deducting production costs.

The second major breakthrough was the development of the original HACCP concept in 1960's. The HACCP concept was initiated by the Pillsbury Company, the US Army and NASA as a collaborative development of the production of safe foods for the space program. NASA wanted a "zero defects" program to ensure that the foods that astronauts would be consuming in space are safe. At that time, Pillsbury was asked to design and manufacture the first space foods for Mercury flights. The problems were magnified as they moved onto Gemini with its more complex foods and longer flights. HACCP was developed by the time the Apollo program landed on the moon. Within two years of that first moon landing HACCP was in commercial use in the manufacture of consumer foods at Pillsbury. Pillsbury concluded, after extensive evaluation, that the only way they could succeed in having safe food would be to have control over the raw materials, the process, the environment and people, beginning as far upstream in the processing system as possible. In using this approach they developed the Hazard Analysis Critical Control Points concept for food safety by utilizing operator control and/or continuous monitoring techniques at critical control points. Pillsbury therefore introduced and adopted HACCP as a system that could provide the greatest safety while reducing dependence on finished product sampling and testing. Subsequently in 1971, Pillsbury presented the HACCP concept publicly in the meeting of National Conference on Food Protection. There are three principles included in that report as follows.

1. Determine and evaluate any hazard, which may occur from planting, harvesting, and preparing before consuming.
2. Identify critical point or points that should be controlled.
3. Establish a system to monitor control of that critical point/points.

Consequently, HACCP became more popular and was applied broadly since 1973. The use of HACCP principles in the promulgation of low acid canned food regulations was completed in 1974 by the U.S. Food and Drug Administration (FDA). In the early 80's, the HACCP approach was widely adopted by other major food companies. In 1980 WHO (World Health Organization) in cooperate with ICMSF (International Commission for Microbiological Standards for Foods) presented the report concerning the application of HACCP in food industry. The report indicated the advantages of HACCP comparing to traditional quality control processes. The main advantage is that it can help manufacturers to produce more standard products that are safe to consume. Moreover, it can create more profit to manufactures due to reduction of production cost.

The National Academy of Science (USA) recommended in 1985 ("The Green Book") that the HACCP approach be adopted in food processing establishments to ensure food safety. More recently there have been recommendations for the broad application of HACCP to food safety from numerous groups (e.g., International Commission for Microbiological Standards for Foods (ICMSF), International Association of Milk, Food and Environmental Sanitarians

(IAMFES)). The Codex Alimentarius (FAO/WHO) Food Hygiene Committee mandated a working group in 1991 that has developed guidelines for HACCP application. This document has been well received and is getting wide international acceptance.

Canada, the European Economic Community (EEC), the United States and other countries are being guided with regard to the HACCP approach by the deliberations taking place at the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations and the pertinent Codex Alimentarius Committees. Codex has initiated a working group to formalize a worldwide approach and application of HACCP principles. The concepts incorporated in the Canadian model, FSEP, are consistent with the Codex approach towards HACCP.

### III. CONSUMER BEHAVIOR

Nowadays consumer behavior has changed gradually from the past. We are now entering a new era of consumer awareness and concern. People pay more attention to their health and welfare; thus, they are looking for high quality or value-added products. Therefore, companies which appreciate and react these concerns will reap the most benefits in this consumer oriented era.

What is tolerated and acceptable today will not necessarily be acceptable in the future. As consumer become better educated, made more aware through improved communication and become more affluent. Thus, their perceptions and buying patterns will change. The new consumer mentality can be described as follows.

- Ecological concerns: for example, environment, food safety, organic.
- Preference for quality not quantity
- Increase appetite for conformation such as Where it from?, How it grows?
- Social concerns
  - Animal welfare "Freedom Food"
  - Occupational health and safety
- Life styles change
  - ready to service, convenience.

### IV. THE NEED FOR HACCP

According to the trend of globalization nowadays, the world economic has been changed considerably. Import tax in Europe and America tends to be reduced continuously in accordance with the announcement of WTO (World Trade Organization). However, a new kind of trade barrier is occurred in form of the requirement of standard such as ISO and HACCP (especially in food industry) because of consumer awareness and concern about the quality of product. The needs for HACCP came from following reasons.

- *Legislation and Regulatory organisations recommend or demand it.* In food industry, some kinds of food manufacturers, such as fish sauce, canned food, and seafood must have HACCP certificates according to laws and regulations controlled by Food and Drug Administration. Nevertheless, there is no regulation on rice industry to achieve HACCP certification but it has more or less tendency to force all parts of food industry to have quality system for food safety. Furthermore, product liability law in western countries is very important and may cause severe problems and costs if there is any suing case for damages from products. Therefore, it is necessary for rice exporters to prepare themselves for this legislation.
- *Consumers expect for safe food.* As mentioned earlier, new consumer mentality expects for safe food. Obviously, it will change customer requirements (referring to rice importers or distributors) to require more food safety. Thus, they will force rice exporters to conform to their requirements by implementing HACCP in factories.
- *HACCP system provides manufacturers with self-confidence, assurance, and brand protection.* Although there is no external factors such as laws forcing food manufacturers applying HACCP in their processes, some companies would like to use HACCP for self-confidence, assurance, and brand protection. Thus, they can run business with confidence that their food products are safe for consumers.

In order to earn profit and simultaneously provide standard quality product to consumer in reasonable price, food manufacturers must analyze and inspect raw material before processing. In addition, every process must be controlled up to storage and distribution points. If there is any point that has high probability to be adulterated, that point must be markedly controlled. This control process will make food product good quality and safe to be consumed. Besides, it can reduce production cost due to the reduction of loss from low-quality products. This kind of quality control that has been developed to be appropriate and efficient for international admittance and widely used in quality assurance of food products is HACCP (Hazard Analysis Critical Control Point).

## V. THE SEVEN PRINCIPLES OF HACCP

The following seven principles of HACCP were adopted by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF, 1992):

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

Three types of hazards:

Biological (B)— primarily concerned with pathogenic bacteria, such as *Salmonella*, *Staphylococcus aureus*, *Campylobacter jejuni*, *Clostridium perfringens*, *Clostridium botulinum*, *Listeria monocytogenes*, and *Escherichia coli* O157:H7; also should consider *Trichinella spiralis*, and other parasites, as well as potential pathological concerns.

Chemical (C)— toxic substances or compounds that may be unsafe for consumption; i.e., cleaners, sanitizers, pesticides, insecticides, rodenticides, paint, lubricants, etc.

Physical (P)— foreign objects which may injure the consumer; i.e., rocks, stones, wood, metal, glass, nuts, bolts, screws, plastic, knife blades, etc.

2. Determine the critical control points (CCPs) in the process. A critical control point is defined as a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to an acceptable level.
3. Establish critical limits for preventive measures associated with each identified CCP. A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to assure prevention, elimination or reduction of hazards to acceptable levels. Each preventive measure has associated with it critical limits that serve as boundaries of safety for each CCP.
4. Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.
5. Establish the corrective action to taken when monitoring indicates that a particular CCP is not under control.
6. Establish procedures for verification that the HACCP system is working correctly.
7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

## VI. THE APPLICATION OF HACCP

The application of HACCP in a food factory should be done

### 1. *Assembly the HACCP team.*

The appropriate product specific knowledge and expertise is necessary for the development of an effective HACCP plan. Optimally, this may be succeeded by assembling a multi-disciplinary team. Expert advice should be obtained from external sources if such expertise is not available on site. The scope of the HACCP plan should be identified, and it should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. whether it cover all classes of hazards or only particular classes). A multi-disciplinary HACCP team needs to include knowledge of the following aspects of the business:

- Raw materials
- Process

- Specialist (technical)
- Operational activities
- Engineer
- Finished product
- Hazard expertise

2. *Describe the product.*

Each kind of product has its own specific product description. Types and amount of additives and storage time can be different depending on composition, manufacturing processes, and storage condition and methods. Therefore, HACCP plan will be different when applying to each particular product. It is necessary to drawn up a full product description, including the following information:

- Product Name
- Composition
- End Product Characteristics
- Method of Preservation
- Packaging-Primary
- Customer Preparation
- Packaging-Shipping
- Storage Conditions
- Distribution Method
- Shelf Life
- Specific Labeling

3. *Identify the Intended use.*

The intended use should be identified to ensure that the HACCP plan will consider the correct target consumer since some groups of consumers need special care. There are five sensitive groups in the population:

- Elderly
- Infants
- Pregnant
- Sick
- Immunocompromised

4. *Construct a Process Flow Diagram.*

The HACCP team should construct the flow diagram which covers all steps in the operation from incoming materials, processing, packaging, storage, to distribution. When applying HACCP to a given operation, consideration should be given to steps former and later the specified operation.

5. *On-site Verification of the Process Flow Diagram.*

The HACCP team should confirm the constructed flow diagram during all stages and hours of operation due to reliable and accurate analysis.

6. *List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (Principle 1).*

The HACCP team must consider all possible hazards which can occur in each process from primary production, processing, manufacture, and distribution until the point of consumption. Possible hazards could be physical, chemical or biological hazards.

Subsequently, HACCP team will conduct a hazard analysis to identify whether the elimination or reduction of each hazard is significant to the production of a safe food. A significant hazard must be controlled if it is:

- Reasonably likely to occur
- Likely to result in an unacceptable risk to consumers

Moreover, the team must then consider what control measures, if any, exist which can be applied for each hazard.

7. *Determine Critical Control Points (Principle 2).*

Critical Control Point (CCP) is a point, step, or procedure at which control can be applied and a food-safety hazard can be prevented, eliminated or reduced to acceptable levels. Decision tree in Figure 2.2 is then used to determine CCP.

8. *Establish Critical Limits for each CCP (Principle 3).*

Critical Limit is ⇒ A criterion which separates acceptable from unacceptable  
⇒ The absolute tolerance for safety  
⇒ The boundaries of control

Therefore, critical limits should be established by a person who have experience and knowledge about that process, related standard and specification of the product. Parameters that are often used as critical limits must be easy to observe and measure such as temperature, time, pH and appearance.

9. *Establish a Monitoring System for each CCP (Principle 4).*

Monitoring is a planned sequence of observations or measurements to assess whether a critical control point is under control. To develop HACCP effectively, it is necessary to monitor each procedure and make adjustments to ensure control of the process to prevent violating the critical limits.

10. *Establish Corrective action for Deviation that may occur (Principle 5).*

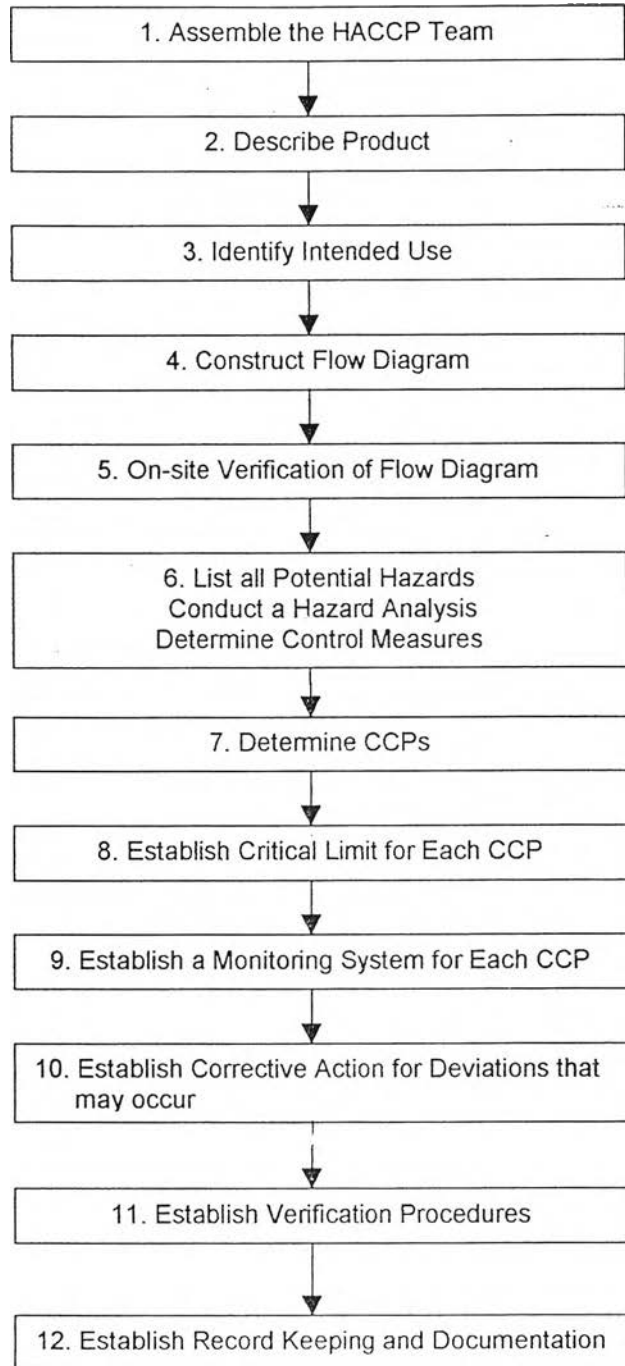
Corrective action is any action to be taken when the results of monitoring at a critical control point indicate a loss of control. The actions are used to bring CCP under control and include proper disposition of the affected product.

11. *Establish Verification Procedures (Principle 6).*

Verification is the application of methods procedures, test and other evaluation, in addition to monitoring to determine compliance with the HACCP plan. Verification must be done frequently enough to ensure that HACCP system is developed effectively.

12. Establish Record keeping and Documentation (Principle 7).

Record are written evidence that an act has taken place. A form is the template on which the results of acts are recorded. Hence, a completed form becomes a record. This can ease working procedure and tracking down the record.



See CCP Decision Tree (Figure 2.2)

FIGURE 2.1 LOGIC SEQUENCE FOR APPLICATION OF HACCP (SOURCE: CODEX ALIMENTARIUS SUPPLEMENT TO VOLUME 1B, 1997; ANNEX TO CAC/RCP-1 (1969), REV.3 (1997))



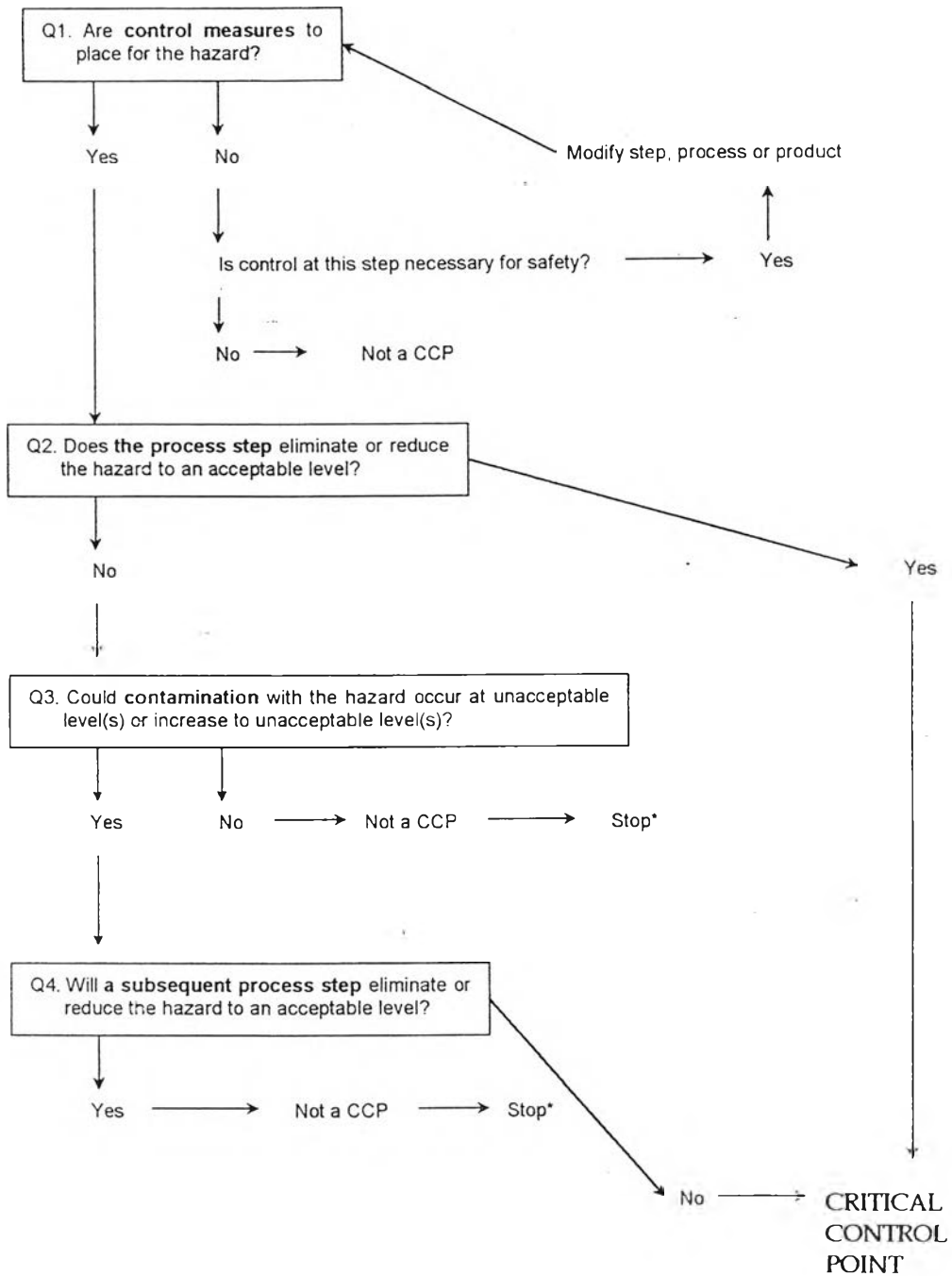


FIGURE 2.2 DECISION TREE TO IDENTIFY CCPs (SOURCE: CODEX ALIMENTARIUS SUPPLEMENT TO VOLUME 1B, 1997; ANNEX TO CAC/RCP-1 (1969), REV.3 (1997))

## VII. PREREQUISITE PROGRAM OF HACCP

In order to develop HACCP system, companies should pass prerequisite programs of HACCP. Prior to the development of HACCP plans under the Food Safety Enhancement Program (FSEP), there is a requirement for establishments to have developed, documented and implemented programs to control factors that may not be directly related to manufacturing controls but support the HACCP plans. These programs are called prerequisite programs and need to be effectively monitored and controlled before implementing HACCP plans.

Prerequisite programs are defined as universal steps or procedures that control the operational environmental factors within a food establishment allowing for environmental conditions that are favorable to the production of safe food. When implementing HACCP in an establishment, the first step is to review existing programs to verify if all the prerequisite requirements are met and if all the necessary controls and documentation (for example program description, individual responsible and monitoring records) are in place. Prerequisite programs are evaluated for their conformance to the requirements and the effectiveness of the programs is monitored and the required records are properly maintained.

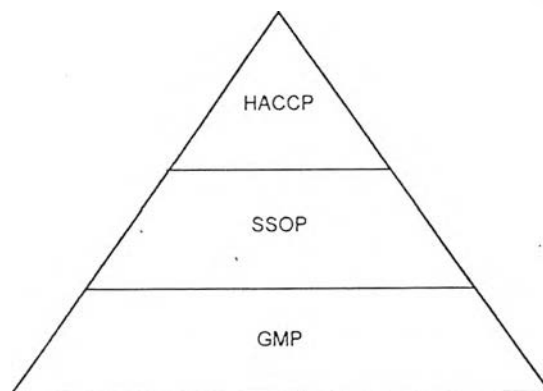


FIGURE 2.3 THE BASIC FOUNDATION FOR THE DEVELOPMENT OF A HACCP SYSTEM.

### 7.1 SSOP: Sanitation Standard Operating Procedures

Eight Keys Areas for SSOP:

- i. Safety of water
- ii. Condition/cleanliness of food contact surfaces
- iii. Prevention of cross-contamination
- iv. Handwashing, sanitizing facilities
- v. Protection of food adulteration
- vi. Proper labeling and storage

- vii. Control of employee health conditions
- viii. Exclusion of pest

## **7.2 Good Manufacturing Practices (GMP)**

Good Manufacturing Practices (GMPs) are minimum common sense sanitary and processing requirements which should apply to all food processing establishment. GMP generally relates to good house keeping practices concerning food safety and quality. The major difference between GMP and HACCP is that GMP focuses on improving working environment and condition while HACCP concentrates on process control. Consequently, GMP consists of working procedures in food factories, and concentrates on preventing products from both direct and indirect contamination. There are two kinds of GMP as followings.

*Umbrella GMP:* Umbrella GMP is general sanitary procedure for most industries. There are eight basic procedures

- i. Personal Hygiene Procedure
- ii. Pest Control Procedure
- iii. Water Control Procedure
- iv. Glass Control Procedure
- v. Cleaning Procedure
- vi. Identification and Traceability Procedure
- vii. Hold/Release Procedure
- viii. Recall Procedure

*Specific GMP:* Specific GMP is developed for particular food industries since some types of food manufacturing have their own particular working conditions. For example, the control procedures of high-risk products such as low-acid food must be stricter than those of low-risk products. Specific GMP in Thailand is used in following manufacturers.

- i. Can food
- ii. Drinking water
- iii. Beverage
- iv. Fish sauce
- v. Soy sauce
- vi. Milk
- vii. Frozen food
- viii. Noodle
- ix. Ice cream