CHAPTER 5
DEVELOPING THE SEVEN PRINCIPLES OF HACCP

I. INTRODUCTION

This chapter will present the last seven steps of HACCP applications. These last seven steps are also the principles of HACCP that are issued by CODEX Alimentarius Committee. The seven steps presented in this chapter are as follows.

Step 6 List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (Principle 1).
Step 7 Determine Critical Control Points (Principle 2).
Step 8 Establish Critical Limits for each CCP (Principle 3).
Step 9 Establish a Monitoring System for each CCP (Principle 4).
Step 10 Establish Corrective action for Deviation that may occur (Principle 5).
Step 11 Establish Verification Procedures (Principle 6).
Step 12 Establish Record keeping and Documentation (Principle 7).

II. CONDUCT HAZARD ANALYSIS (PRINCIPLE 1)

In this step, HACCP team must list all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards. Hazard analysis is the first principle of HACCP system. As the implication in the name HACCP, hazard analysis is one of the most important steps. A wrong hazard analysis would eventually lead to the development of an inadequate HACCP plan. Hazard analysis requires technical expertise and scientific background in various fields to properly identify all potential hazards. According the application of HACCP of CODEX (Source: Codex Alimentarius Committee, "Annex to CAC/RCP-1, 1996, Rev.3 (1997)), Hazard refers to "a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect".

Potential hazards in each company could be different, even though the products are the same due to differences of resources, ingredient, machines and equipment in the production process, arrangement and processes, production time, and storage condition, including knowledge and experience of the staffs. Therefore, hazard analysis should be carried out or revised when there is a change in raw materials, ingredients and other that mentioned earlier.

2.1 Potential Hazards

To identify biological, chemical, or physical hazards likely to occur, it is necessary to know about the chemical, physical, and microbiological characteristics of the product, and other

ingredients, as well as how various processes affect those characteristics. Consequently, we can evaluate each step in the process flow diagram to determine whether a biological, chemical and/or physical hazard may be introduced at that step and whether applicable preventive measures are available. Hazards, which are low risk and not likely to occur should be listed on the hazard analysis including with stated the reason that no further consideration is needed. These determinations should be based on rate of occurrence evaluation and/or scientific data.

2.3.1 Biological Hazards

Biological hazards refer to living organisms, including microorganisms that are dangerous for human health. Biological hazards include bacteria, parasites, protozoa, viruses, and others. Agricultural products can be contaminated with a wide range of bacteria. From a public health standpoint, most bacteria can be found in nature and, are harmless, while others--the pathogenic microorganisms--can cause illness or even death in humans. Any food may be exposed to bacterial contamination during production, processing, packaging, transportation, preparation, storage and service. Most pathogen can be destroyed during cooking. The most common biological hazards in a food product are microbiological.

The amount of microorganisms can be controlled by controlling hygienic and duration of transportation and storage. Causes of gastro-intestinal disease mostly come from food pathogen. Inappropriate storage and transportation may significantly increase the number of pathogen. Food that is already cooked is the best place for the growth of microorganisms if the conditions of storage and transportation are suitable. Virus may come along with raw materials, water or from human; however, virus cannot increase their numbers if they stay outside humans' bodies. Parasites usually live in some kinds of animal, but they can stay in human body for a while. The contamination of parasites usually occurs from uncooked meat or cross contamination in ready-to-eat product. Fungi including yeast is useful for producing some products such as chess and sauce; however, some types of fungi may create a toxic called "mycotoxin", which is harmful for human health.

2.3.2 Chemical Hazards

The contamination of chemical hazards can occur naturally or occur from adding some chemical substances during processing. Hazardous substances can cause severe illness if consume in high quantity. Chemical hazards can be separated into two categories as follows.

1) Naturally occurring poisons, chemicals, or harmful substances that are natural constituents of foods and are not the result of environmental, agricultural, industrial, or other contamination. The examples are mycotoxins, aflatoxins, and shellfish toxins.

2) Added poison chemicals or deletenous substances that are intentionally or unintentionally added to foods at some point in growing, harvesting, storage, processing, packing, or distribution. The examples of this group of chemicals are pesticides, fungicides, insecticides, fertilizers, drug residues, and antibiotics, as well as direct and indirect food additives. Moreover, this group can also include chemicals such as lubricants, cleaners, paints, and coatings.

2.3.3 Physical Hazards

A physical hazard refers to any physical material not usually found in a food, which causes illness or injury to the individual consuming the product. Physical hazards may be a result of contamination or improper works in steps of food chain from harvesting, manufacturing to consuming. Physical hazards contain a variety of foreign materials or objects, such as metal, glass, and plastic. However, foreign materials that cannot or do not cause illness or injury are not considered as hazards, even though they may effect the quality of the product. Many situations can result in physical hazards in finished products as following.

- Contaminated raw materials.
- Poorly designed or inadequate maintained facilities and equipment. For instance, grease and oil from motors or rollers falls onto exposed product or pieces of metal from worn or improperly maintained equipment entering product.
- Improper procedures or insufficient employee training and practices. For example, broken glass jars, by improper loading on the line by employees or improper or inadequate condition examination, glass pieces from broken or chipped jars could be included when filling product containers. Good Manufacturing Practices is very useful in this case.

2.2 Hazard Analysis

HACCP team should list all potential biological, chemical, and physical hazards that are possible to occur in each step of production process from raw materials, manufacturing, distribution to the end consumers. Next, the team must analyse every type of hazard in order to determine in the HACCP plan which hazard must be eliminated or controlled within the acceptable limits. This step is necessary for manufacturing safe products.

Occurrence of hazards or its potential for causing disease must be evaluated in term of frequency of occurrence and its seventy. Severity of a hazard refers to level of illness or injury if that hazard is not under control. Nevertheless, hazards that can be controlled by procedures of GMP are not considered in HACCP plan. Risk evaluation for potential hazards depends on experience and information of biological and technical data. The information can be gathered from several resources such as Internet sources, journal or educational document and etc.

2.3 How to Conduct a Hazard Analysis

A hazard analysis must be conducted for each product or process type and every time there is a new product. Consequently, the hazard analysis done for a product or process type must be reviewed and validated if there is any change in raw material, product ingredient, preparation, manufacturing, packaging, distribution and intended use of the product.
Hazards in food products may be different from one establishment to another because of the following reasons.

- Sources of ingredients
- Ingredient
- Equipment and layout
- Preparation/processing methods
- Duration of process/storage, and
- Experience/knowledge/attitude of personnel

For more simplicity, the Hazard Analysis procedure has been broken down into the five following steps. Applying them in a logical sequential manner will help to avoid any omissions.

2.3.1 Review Incoming Material

Review product description form to see the affect of the information to the analysis of production process. For example, ready-to-eat products must be free from pathogen, whereas the other types of products may be acceptable to find some bacteria in the end product if a further step can destroy them. For other products such as ingredient or packaging material the biological, chemical or physical hazard exists is identified on Hazard Identification Form. The information should be as specific as possible when describing the hazards.

In order to facilitate the identification of hazards, answer the following questions for each incoming material:

- Could pathogenic microorganisms, toxins, chemicals or physical objects possibly be present on/in this material? If so, note the hazard on the Hazard Identification Form.
- Are any returned/reworked products used as ingredients? If yes, is there a hazard linked to that practice?
- Are any preservatives used as ingredients for preventing the growth of microorganism or for increasing storage time?
- Is there any ingredient that is harmful when adding too much? For instance, nitrite could be a chemical hazard if use more than acceptable limits.

- Could any ingredients, if used in amounts lower than recommended or if left out, result in a hazard due to microbial vegetative or sporulated cells outgrowth? If yes, note this on the biological hazards form.
- Does the amount and type of acid ingredients, and resulting pH of the final product affect growth/survival of microorganisms?
- Does the amount of humidity and the A_w (water activity) of final product affect microbial growth? Do they affect the survival of pathogens? (Parasites, bacteria, fungi,...).
- Should adequate refrigeration be maintained for products during transit or in holding.

2.3.2 Evaluate Operations for Hazards

The objective of this step is to identify all potential hazards related to each processing step, the product flow and the employees traffic pattern. This is accomplished by:

1) Reviewing Process Flow Diagram Form and by:
   - Assigning a number to each processing step on the production flow diagram horizontally from receiving to distribution.
   - Examining each step on the process flow diagram and determining if a hazard exists for that step.
   - Coding "B" for biological hazards, "C" for chemical hazards and "P" for physical hazards to categorize the hazards in hazard identification form.
   - Fully describing on Hazard Identification Form, where such hazard has been found.
2) Reviewing Plant Schematic and Employees' Traffic Pattern:
   Review product flow and employees' traffic patterns, and identify all hazards in the same manner. To help in determining if a hazard exists, the following questions should be answered for each processing step:
   - Could contaminants reach the product during this processing step? Consider workers' hands, contaminated equipment/material, cross-contamination from raw materials, leaking valves/plates, dead ends (niches), splashing, etc.
   - Could any microorganisms of concern multiply during this processing step to the point where it becomes a hazard? Consider temperature, duration,...

2.3.3 Observe Actual Operating Practices

HACCP team must familiarize with details of the operation under the investigation. All identified hazards must be recorded in an appropriate form. HACCP team must:

- Observe the operation long enough to ensure that it is normally done.
- Observe the operations of employees whether they can create cross contamination of raw materials or products from gloves, hands, or equipment to finished goods.
- Observe the hygienic practices and record hazards that are possible to occur.

- Find out whether there is any process step that can kill microorganism in the production process. If there is, that process step must be seriously taken in account because it can also create the contamination.

2.3.4 *Take Measurements*

It is necessary to take measurements all significant parameters of production process to confirm actual operating conditions. The examples of parameters that need to be taken measurement are as follows.

- The temperature of the product. Consider all heating and chilling process by measuring the highest temperature of chilling process, and the lowest temperature of heating process.
- Measure duration and temperature for cooking.
- Measure the size of packaging and quantity of the product.
- Measure pressure, headspace, venting procedure, and adequacy of container closure, initial temperatures, and any other important parameters to the successful delivery of a scheduled process.
- Measure pH of the product during processing and also the pH of the finished product at room temperature whenever possible.
- Measure water activity (a_w) of the product at least two times to reduce variations. Make corrections for room temperatures if necessary.
- When information on hazards is not otherwise available for new products, it is necessary to sample collections, and carry out inoculated-pack studies, and microbial challenge studies. Moreover, the samples must be kept for assessing the expected shelf life.

2.3.5 *Analyse the Measurements*

A qualified individual who has a proper scientific background analyzes the measurement in order to interpret the collected data correctly. During the review and interpretation of the data, identified hazards will be fully described on the hazard identification form.
For example:

- Plot relationship between time and temperature measurements on a computer printout or on graph paper.
- Compare controlled data Vs optimal growth temperatures of microorganisms and temperature ranges at which they can multiply.
- Estimate and evaluate probable cooling rate of the product. Interpret measured value and compare the measured temperatures with temperature ranges within which bacteria of concern multiply rapidly Vs temperature at which growth begins, slows and ceases. Determine whether covers applied on containers can cool down foods because the covers

may delay the cooling but may also prevent contamination or in the case that containers are stacked against each other. An evaluation of its impact must be done.

- Compare a_w and pH values to ranges at which pathogens multiply or are eliminated.
- Evaluate the product's shelf life.

2.4 Control Measures

After conduct the hazard analysis, HACCP team must determine the preventing methods that can be used to control each identified hazard. A control measure refers to any method or operation which can prevent or eliminate hazards or reduce the occurrence of hazards to the acceptable limits. It may be necessary to use many control measures to control one hazard, or only one control measure can control more than one hazard. Risk assessment is very useful to determine the level of control measures. Food manufacturers should consider three objectives for HACCP program that involve biological hazards as follows.

- Significantly reduce or eliminate hazards.
- Prevent or control the growth or multiplication of microorganisms.
- Control the contamination.

Biological hazards can be eliminated or controlled by heating and chilling process, or preservatives. Moreover, they can be controlled by the control of factors that is necessary for the living, growth, and multiplication of microorganisms. The examples of control measures of biological, chemical, and physical hazards are as followings.

2.4.1 Biological Hazards

Bacteria

- Time and temperature control such as the control of chilling process and storage time.
- Heating process in suitable time and temperature in order to eliminate or reduce the number of microorganisms within acceptable limits.
- Frozen process.
- Fermentation and the control of pH. For instance, bacteria in yogurts that release lactic acid can stop the multiplication of other microorganisms that cannot stand with the acid conditions.
- Additives or preservatives. For example, adding salt can stop the growth of microorganisms.
- Dry the product to control temperature and water activity. Drying process may use enough temperature to eliminate microorganisms. If we use lower temperature for drying, which can reduce water activity, it can constrain the growth of some types of microorganisms.

- Conditions of packaging. Vacuum packing can stop the growth of microorganisms that need air for their livings.
- The control of sources of raw material. Buy materials from approved suppliers who can control the condition and microorganisms in raw materials.
- Cleaning and pasteurizing can reduce the growth of microorganisms.
- Personal Hygienic Practices.

Virus

- Process that use high temperature such as cooking may destroy most virus.
- Personal Hygiene and separate employees who catch virus.

2.4.2 Chemical Hazards

- The control of sources of raw materials: Determine the characteristics of materials, and ask the suppliers for a certification that there is no dangerous chemical substance in the materials.
- The control of production process: The control of product's ingredient and additives. Separate the storage of non-food chemical substances.
- The control of contamination of grease and oil.
- Label control: The product must have a label that describes food ingredient and allergic substances.

2.4.3 Physical Hazards

- The control of sources of raw material: Determine characteristics of raw materials or food ingredient including with supplier's certificate that physical hazards are controlled within acceptable limits.
- The control of production process; for instance, using magnets, metal detector, sieves or mesh.
- Environmental control: Follows the GMPs' procedures to ensure that no physical hazard comes from the environmental factors such as premises, facilities, and equipment.

2.5 Hazards' Assessment

All information from the hazard analysis will be used to determine:

- The severity of hazard
- Risk of identified hazard in each process step
- Step or method that can be applied to control, prevent, or eliminate hazards into acceptable limits.

2.5.1 *Severity*

Severity refers to the significance of a hazard or the level of consequent result from that hazard. Severity can be separated into three categories as follows.

- High Severity: Hazards in this category can cause to mortality.
  The examples are illnesses from Clostridium botulinum, Salmonella typhi, Listeria monocytogenes, Escherichia coli 0157:H7 Vibrio cholerae, Vibro vulnificus, toxic from shellfish such as Paralytic Shellfish Poison and Amnesic Shellfish Poison and etc.
- Medium Seventy
  The examples are illnesses from Brucella, Campylobacter, Salmonella, Shigella, Streptococcus type A, Yersinia entercolitica, Mycotoxin, Ciquatera toxin and etc.
- Low Severity
  The examples are illnesses from Bacillus spp., Clostridium perfringens, Staphylococcus aureus, Norwalk virus, most parasites, Histamine-like substances, and other solid metals that cause suddenly illness.

2.5.2 *Risk of Hazard*

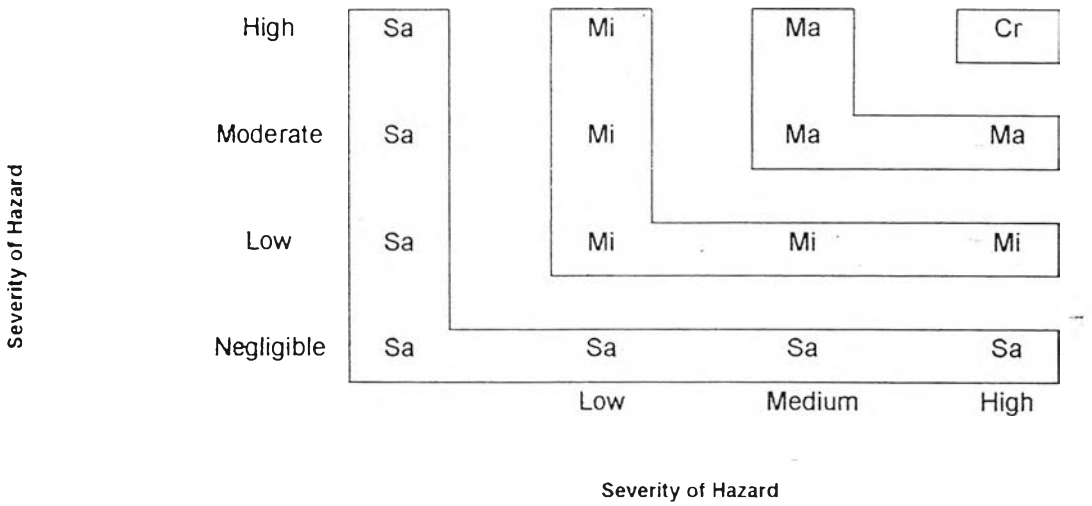
Risk refers to the probability that hazards will significantly occur including consequent result. Level of risk can divide into High (H), Moderate (M), Low (L), and Negligible (N).

2.5.3 *Identification of points, steps, procedures*

This sort of information can be used to determine critical control points, and determine any change in production process or product ingredient that can significantly reduce hazards.

Figure 4.1 illustrates the hazards' assessment from the relationship of severity and risk of hazard. Therefore, a hazard can be categorized into four categories: Satisfactory (Sa), Minor (Mi), Major (Ma), and Critical (Cr).

FIGURE 5.1 HAZARDS' ASSESSMENT (SOURCE: NATIONAL FOOD INSTITUTE AND BIOTEC OF THAILAND, " HACCP FOR FOOD INDUSTRY", ATTHASIT PUBLISHING, 1999)



The Case Study

In the case study, the company decides to consider insects that come along with raw materials as a biological hazard. Actually, eating these insects does not create any danger to consumers but they are the most frequent reason that customers reject the products. Therefore, insects such as weevils are included in biological hazard, but these will exclude the insects that do not come along with raw materials since they will be controlled and eliminate by the pest control procedure of GMP. For the analysis of biological hazards, microorganisms hardly effect safe consuming of rice since rice must be cooked before eating. Therefore, most of microorganisms will be eliminated due to the heat from cooking. As shown in Table 5.1, all kinds of microorganisms need water activity at least 0.9 to use for their growth and multiplication, while water activity of rice is not more than 0.6. Furthermore, according to the past 20 years of the company's history, there is no complaint about microbiological hazards. Thus, we can conclude that microbiological hazards that come along with raw materials can be controlled and eliminated by the end consumers and by the nature of the product.

It is very important to let every member of HACCP team involving in the identification of hazard because one may understand some processes in detail more than the others. However, the comments from other members that scarcely involve are still very useful because it may create some aspects that are overlooked. Table 5.2 illustrates the hazard identification of incoming materials and production process of the case company.

TABLE 5.1 MAXIMUM AND MINIMUM VALUES OF FACTORS THAT CAN EFFECT THE GROWTH OF PATHOGEN (SOURCE: SIWAPORN SIWAVECH, "SANITARY IN A FOOD FACTORY", KASETSART UNIVERSITY, FIFTH EDITION, 1999)

Pathogen	Min. aw	Min. pH	Max. pH	Max. % Salt	Min. Temp.	Max. Temp.	Oxygen requirement
Bacillus cereus	0.92	4.3	9.3	18	39.2 °F 4 °C	°F °C	aerobe
Campylobacter jejuni	0.987	4.9	9.5	1.5	86 °F 30 °C	°F °C	Micro-aerophilic*
Clostridium botulinum, type E, and proteolytic B and F	0.935	4.6	9	10	50 °F 10 °C	°F °C	Anaerobe**
Clostridium botulinum, type E, and nonproteolytic B and F	0.97	5	9	5	37.9 °F 3.3 °C	°F °C	Anaerobe**
Clostridium perfringens	0.93	5	9	7	50 °F 10 °C	°F °C	Anaerobe**
Pathogenic strains of Escherichia coli	0.95	4	9	6.5	44.6 °F 7.0 °C	°F °C	Facultative anaerobe***
Listeria monocytogenes	0.92	4.4	9.4	10	31.3 °F -0.4 °C	°F °C	Facultative anaerobe***
Salmonella spp.	0.94	3.7	9.5	8	41.4 °F 5.2 °C	°F °C	Facultative anaerobe***
Shigella ssp	0.96	4.8	9.3	5.2	43 °F 6.1 °C	°F °C	Facultative anaerobe***
Staphylccoccus aureus-growth	0.83	4	10	25	44.6 °F 7 °C	°F °C	Facultative anaerobe***
Staphylococcus aureus-toxin	0.85	4	9.8	10	50 °F 10 °C	°F °C	
Vibrio cholerae	0.97	5	10	6	50 °F 10 °C	°F °C	Facultative anaerobe***
Vibrio parahaemolytcus	0.94	4.8	11	10	41 °F 5 °C	°F °C	Facultative anaerobe***
Vibrio vulnificus	0.96	5	10	5	46.4 °F 8 °C	°F °C	Facultative anaerobe***
Yersinia enterocolitica	0.945	4.2	10	7	29.7 °F -1.3 °C	°F °C	Facultative anaerobe***

* requires limited levels of oxygen ** requires the absence of oxygen *** grows either with or without oxygen

TABLE 5.2 HAZARD IDENTIFICATION OF THE CASE FACTORY

No.	Process Step	Potential Hazards	Cause	Control Procedure
0	Raw material	B Insects C Pesticides P wood, metals, stones, and rubbers	From raw material Come along with material. Wood from trucks, stones from raw material, rubber from rice milling.	Insects: Fumigation Pesticides: Buy raw material from Approved Supplier to ensure that all used pesticides are approved by FDA. Rubber: Drum sieve and Color Sorting Woods: Pre-cleaner machine Stone: Pre-cleaner, De-stoner Metals: Pre-cleaner, De-stoner, Magnet
1	Unloading raw material	B microorganisms C P glass	From workers From light bulbs	Personal Hygiene Procedure Glass Control Procedure
2	Bucket Elevator	B C grease P metal	 From bearing From bolts at buckets	 Use food-grade grease Magnet1
3	Drum sieve	B C grease P metal	 From motor From mesh of Drum sieve	 Use food-grade grease Magnet1
4	Conveyor	B C grease, oil P	From bearing and motor	Use food-grade grease and Preventive Maintenance Program
5	Tripper			

No.	Process Step	Potential Hazards	Cause	Control Procedure
6	Storage tank			
7	Fumigation	B Survive of insects C P	From the deviation of fumigation process	Check time of fumigation, and the number of chemical substance
8	Conveyor	B C grease, oil P	From bearing and motor	Use food-grade grease and Preventive Maintenance Program
9	Magnet1	B C P leakage of metals	Deviation of magnet	Clean magnet1 as scheduled Magnet2
10	Bucket Elevator	B C grease P metal	From bearing From bolts at buckets	Use food-grade grease Magnet2
11	Hopper			
12	Pre-cleaner	B C P leakage of woods, rubbers and stones.	Deviation from this process step	Preventive Maintenance Program Check condition of mesh, and clear foreign materials from the mesh as scheduled De-stoner, Color Sorter
13	Bucket Elevator	B C grease P metal	From bearing From bolts at buckets	Use food-grade grease Magnet2
14	Hopper	B		

No.	Process Step	Potential Hazards	Cause	Control Procedure
		C P metal	From inner supports	Magnet2
15	De-stoner	B C P leakage of woods and stones	Deviation of de-stoner machine	Stone Work Instruction of De-stoner Metals Magnet2
16	Hopper	B C P metal	From inner supports	Magnet2
17	Magnet2	B C P leakage of metals		Clean magnet2 as scheduled Magnet3
18	Filter	B microorganisms C P	water	Microorganism Water Control Procedure
19	Polishing machine	B C P metals	from mesh of the machine	Metal Check condition of mesh and Magnet3
20	Conveyor			
21	Bucket Elevator	B C grease	From bearing	Use food-grade grease

No.	Process Step	Potential Hazards	Cause	Control Procedure
		P metal	From bolts at buckets	Magnet3
22	Hopper	B C P metal	 From inner supports	 Magnet3
23	Sieving machine	B C P metals	 From sieves	Check condition of mesh Preventive Maintenance Program Magnet 3
24	Bucket Elevator	B C grease P metal	 From bearing From bolts at buckets	 Use food-grade grease Magnet3
25	Airleg Aspirator	B C P metal	 From bolts at valves	 Magnet3
26	Grading machine	B C oil P	 from Bearing	 Preventive Maintenance Program
27	Hopper	B C P metal	 From inner supports	 Magnet3
28	Conveyor			

No.	Process Step	Potential Hazards	Cause	Control Procedure
29	Magnet3	B C P leakage of metals	 Deviation of magnet3	 Clean magnet3 as scheduled Plate Magnet
30	Bucket Elevator	B C grease P metal	 From bearing From bolts at buckets	 Use food-grade grease Plate Magnet
31	Color Sorter	B C P leakage of wood and rubber	 Deviation of color sorter	 Check conditions of the machine
32	Bucket Elevator	B C grease P metal	 From bearing From bolts at buckets	 Use food-grade grease Plate Magnet
33	Conveyor			
34	Tripper			
35	Finished Product Storage Tank	B C P		
36	Conveyor			
37	Plate Magnet	B C		

No.	Process Step	Potential Hazards	Cause	Control Procedure
		P leakage of metals		Work Instruction for cleaning Magnet
38	Bucket Elevator	B C grease P	From bearing	Use food-grade grease
39	Packing Hoppers			
40	Rice bags			
41	Storage of bags			
42	Sending to Packing line			
43	Bags Preparation	B microorganism C P	From workers	Personal Hygiene Procedure
44	Weighing machine	B C oil P	From air pipe	Set air pip away from the machine
45	Conveyor			
46	Sewing and Packaging	B germs C P needle	From workers From sewing machine	Germs Personal Hygiene Procedure Work instruction when needle is broken or lost.
47	Placing on pallets			
48	Loading to containers			

III. DETERMINE CRITICAL CONTROL POINTS (PRINCIPLE 2)

The determination of critical control points (CCPs) is the second HACCP principle. According to the definition of Codes, a CCP is defined as any 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. If there is an identified hazard in any step, it is necessary to control that hazard for food safety. Nevertheless, if there is no control measure in that step or in subsequent steps, the production process should be improved for enough control measures.

For identifying CCPs in HACCP system, it can be done by the use of CCP decision tree (see Figure 2.2), which illustrates the logical thinking of separating CCPs from other controls such as SSOP's, GMP's or other operating procedures.

3.1 Reviewing Identified Hazards

Prior to determine critical control points, it is necessary to review all identified hazards to ensure that all of them are under control by the use of GMP procedures. In addition, HACCP team must verify all hazards in the real production process. Hazards that are not controlled by GMPs should be analyse to determine whether it they are CCPs or not. CCP decision tree is a system consisting of four questions, which are designed to analyse whether it is necessary to determine that process step, should be considered as a critical control point.

Table 4.2 illustrates the CCP identification form, which is used to determine CCPs in every process step of the production line by following the four questions of CCP decision tree.

3.2 Question # 1

"Could a Control Measure(s) be used by the operator at any process step?"

The meaning of question 1 is whether the manufacturer could use any control measure at this step or anywhere else in the food establishment to control the identified hazard such as temperature control, visual examination, use of metal detector, etc.

- If the answer to Question 1 is yes, clearly describe in that column what the control measure is that the manufacturer could use and proceed to the next question in the decision tree.
- If there is no known control measure, identify how the identified hazard will be controlled before or after the manufacturing process and then proceed to the next identified hazard in the process.

3.3 Question # 2

"Is this process step specifically designed to eliminate or reduce the likely occurrence of this identified hazard to an acceptable level?"

The word "Specifically Designed" refers to any procedure or step in a production process that is designed specifically for the identified hazard. The examples of these specifically designed process step are: the retorting operation in a canning plant, a pasteurization step, the chlorination of cooling water, metal detector, a particular hygiene procedure performed by the operator to clean contact surfaces without which the product would be contaminated. Acceptable and unacceptable limits must be determined, including the objectives for identifying CCPs in HACCP plan.

- If the process step is specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable limit, answer yes and it automatically becomes a CCP.
- If the process step is not specifically designed, answer no and proceed to the next question.

This question must be used for processing steps only. This question is not available for incoming materials, for not applicable and proceed to Question 3.

3.4 Question # 3

"Is it likely that contamination with the identified hazard could occur in excess of the acceptable level or could increase to an unacceptable level?"

This question is used to find out whether this hazard could possibly impact on the safety of the product? Question 3 refers both to the probability of occurrence and the severity: Risk assessment is very useful for decision making and must be based on all of the information that has been gathered. When answering "yes" or "no", it may be useful to explain the reason of the answers, for future reference. This would be useful especially when dealing with some hazards that may be controversial.

- If there is any customers' complaint, or scientific literature suggest that the contamination with the identified hazard may increase to an unacceptable level and result in an unacceptable health hazard, answer yes and proceed to question 4 in the decision tree.
- If it is not found that the contamination to impact on the safety of the product or is not likely to occur, answer no and proceed to the next identified hazard in the process.

3.5 Question # 4

"Will a subsequent step eliminate the identified hazard or reduce its likely occurrence to an acceptable level?"

This question is designed for eliminate those hazards which are harmful to a human health or could increase to an unacceptable level, and for which a subsequent process step will control the identified hazard.

- If there is subsequent step later in the process that will eliminate the identified hazard or reduce it to an acceptable level, answer yes and this step is not a CCP and proceed to the next identified hazard in the process.
- If no subsequent step is scheduled in the process to control this identified hazard, answer no and this particular process step becomes a CCP.

The Case Study

For determining CCPs, we list all process steps in the CCP determination form and follow all 4 questions in CCP decision tree. Some hazards can be cut out of this step because of the improvement of the factory and Good Manufacturing Practice. For example, a chemical hazard such as grease can be cut because the company decides to change type of grease to food grade grease. Therefore, grease will become no more harmful when it contaminates to the product. Moreover, environmental factor such as water and microorganisms from workers can be controlled by the use of GMP procedures (Water Control Procedure and Personal Hygiene Procedure). All members of HACCP team must carry out the determination of CCPs. All comments and different points of view will lead to the discussion and conclusion for answering in CCP decision tree. After performing through decision tree, there are four process steps that are determined as CCPs as followings.

- Fumigation ⇒ The survive of insects (Biological)
- De-stoner ⇒ Leakage of stone (Physical)
- Color Sorter ⇒ Leakage of wood and rubber (Physical)
- Plate Magnet ⇒ Leakage of metal (Physical)

TABLE 5.3 CCP DETERMINATION OF THE CASE FACTORY

No.	Process Step	Hazards	DECISION TREE				CCP (Y/N)	Subsequent Step
			Q1	Q2	Q3	Q4		
1	Unloading raw materials	B microorganisms (GMP) P glass (GMP)						
2	Bucket Elevator	P metal	√	X	√	√	N	9
3	Drum sieve	P metal	√	X	√	√	N	9
4	Conveyor							
5	Tripper							
6	Storage tank							
7	Fumigation	B Survive of insects	√	√	N/A	N/A	Y	
8	Conveyor							
9	Magnet 1	P leakage of metals	√	X	N/A	N/A	N	17
10	Bucket Elevator	P metal	√	X	√	√	N	17
11	Hopper							
12	Pre-cleaner machine	P leakage of wood	√	X	√	√	N	31
		P leakage of rubber	√	X	√	√	N	31
		P leakage of stone	√	X	√	√	N	15
13	Bucket Elevator	P metal	√	X	√	√	N	17
14	Hopper							
15	De-stoner machine	P leakage of stone P metal	√	√	N/A	N/A	Y	
16	Hopper							
17	Magnet 2	P leakage of metal	√	X	√	√	N	29
18	Filter	B germ from water (GMP)						
19	Rice polisher	C metal	√	X	√	√	N	29
20	Conveyor							
21	Bucket Elevator	P metal	√	X	√	√	N	29
22	Hopper	P metal	√	X	√	√	N	29
23	Sieving machine	P metal	√	X	√	√	N	29

No.	Process Step	Hazards	DECISION TREE				CCP (Y/N)	Subsequent Step
			Q1	Q2	Q3	Q4		
24	Bucket Elevator	P metal	√	X	√	√	N	29
25	Airleg Aspirator	P metal	√	X	√	√	N	29
26	Grading							
27	Hopper							
28	Conveyor							
29	Magnet 3	P leakage of metals	√	X	√	√	N	37
30	Bucket Elevator	P metal	√	X	√	√	N	37
31	Color Sorter	P leakage of wood P leakage of rubber	√ √	√ √	N/A N/A	N/A N/A	Y Y	
32	Bucket Elevator	P metal	√	X	√	√	N	37
33	Conveyor							
34	Tripper							
35	Finished-product storage tanks							
36	Conveyor							
37	Plate Magnet	P leakage of metals	√	√	N/A	N/A	Y	
38	Bucket Elevator							
39	Packing tanks							
40	Bags receiving							
41	Inspect & store bags							
42	Sending bags to packing line							
43	Preparing rice bags	B microorganisms (GMP)						
44	Weighing machine							

No.	Process Step	Hazards	DECISION TREE				CCP (Y/N)	Subsequent Step
			Q1	Q2	Q3	Q4		
45	Conveyor							
46	Sewing and Packaging	B microorganisms (GMP) P needle	√	X	X	N/A	N	
47	Placing on pallet							
48	Loading to containers							

IV. ESTABLISH CRITICAL LIMITS FOR EACH CCP (PRINCIPLE 3)

In this step, critical limits will be established at each critical control point (CCP). Critical limits are defined as a criterion which separates acceptability from unacceptability. If these parameters are maintained within boundaries, it will confirm the safety of the product. Critical limits may be determined as related factors such as temperature, time, appearance, water activity, moisture content, and etc. The critical limits should at least conform to or exceed government regulations, company standards or other scientific data. In some cases, some governmental organizations such as Food and Drug Administration may give the basic information for determining critical limits according to characteristics of hazards and risk assessment. The examples are time and temperature for heating process such as pasteurization and steaming process, and the amount of the allowed contamination. For establishing critical limits, it is necessary to in depth understand production process, government regulations, and standards of the product. Sources of information for establishing critical limits are as follows.

- Scientific publishing or information of researches
- Government regulations
- Experts such as an expert of thermal process, consultants, food scientist, suppliers of equipment or machines, and sanitary engineers
- Experiments such as experiments in the factory and in laboratory

If there is not enough information to formulate critical limits, the existing standard or registration should be applied instead. After establishing the critical limits, they will be written on HACCP plan form with the description of the process step, the CCP number and hazard description.

4.1 Examples of Critical Limits

These following examples present that a critical control point may be controlled by several critical limits.

- An acidified beverage that needs a hot fill and hold as the process may have acid addition as the CCP. If inadequate acid is added or if the temperature of the hot fill is not enough, the product would be under processed with potential for the growth of pathogenic spore-forming bacteria. In this case, the critical limits would be pH and fill temperature.
- Beef patties are cooked in a continuous oven. More than one critical limit is set to control the hazard of heat-resistant pathogen survival. The critical limits could be; minimum internal temperature of the patty; oven temperature; time in the oven determined by the belt speed in rpm; patty thickness.

4.2 Operating Limits

If the monitoring system shows that it tends to lose the control at CCP, the operator can proceed anything for preventing CCP exceeding the control point. The point that the operator starts to proceed is called a "operating limit". Many people are often confused between operation limits and critical limits. Generally, operating limits are determined to be stricter than critical limits. In other words, operating limits are used to prevent the deviation from critical limits.

When operating limits exceed the setting points, it might be necessary to adjust the production process. This is called "process adjustment", which manufacturer must use this process to prevent the lack of control that may lead to throw the product away. In order to avoid the rework or recall of the product, operators must observe the tendency of lacking control and carry out corrective action. For instance, if the boiler cannot generate the consistent temperature control at designed level and the deviation of the temperature exceed the critical limits, the company may change to use operating limits in order to reduce the chance that the temperature exceed the critical limits. Therefore, many manufacturers prefer to use operating limits due to the following reasons.

- Quality reasons such as the use of higher temperature during cooking for making better taste and smell of the product.
- To avoid the excess of critical limits; for example, the operating limits will be set up more strictly than critical limits in order to warn the operator to adjust the equipment when the temperature drop from setting point.
- To cover the boundary of the deviation; for example, when the deviation of boiler is $\pm$ 2°C, it is suggested to determine temperature at least 2°C more than the critical limit to prevent the excess of critical limit.

Table 5.4 illustrates the examples of critical limits and operating limits.

Process Step	Critical Limits	Operating Limits
Acidification	pH < 4.6	pH < 4.3
Dryer	water activity < 0.84	water activity < 0.80
Thermal Packing	> 80°C	> 85°C

TABLE 5.4 THE EXAMPLES OF CRITICAL LIMITS AND OPERATING LIMITS

4.3 The Case Study

In the case factory, critical limits of all four critical point are determined as follows.

4.3.1 Fumigation

To establish critical limits for this step, we consider two factors involving fumigation process. The first is the amount of fumigating pills used for this process step. The number of pills depends on the volume of rice in the storage tank. According to the instruction of fumigation, it is suggested to apply two fumigating pills per one ton of products. If we apply inadequate pills for the fumigation process, it is possible that some insects may survive and may contaminate in the finished product. The second parameter is the time for fumigation. Time used for fumigation must be at least three days or forty-eight hours to ensure that all fumigating pills evaporate.

4.3.2 De-stoner

Prior to establish critical limits for this machine, it is necessary to understand its function. The objective of this machine is to separate stones from rice. Figure 5.2 illustrates how the machine works. From the figure, raw materials will be released from a hopper. Then, the machine will use air pressure to blow up the rice through the sieve. Then, rice will be go upward, while stones that are heavier still are on the sieve. Subsequently, the stones will be carried forward by the vibration system of the machine toward and stuck at the end of the sieve. Finally, the operator (rice technician) will manually press the button to open the valve; thus, the stones will fall into the stone tray. The rice that is cleared of stone will be carried to the bucket elevator in order to transport to another process step. According to the function of this machine, there are several parameters that can be defined as critical limits as follows.

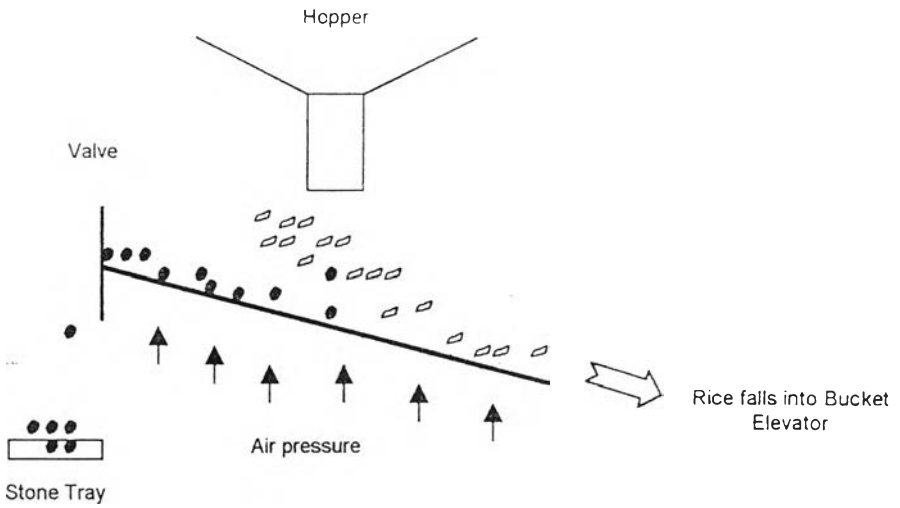


FIGURE 5.2 THE FUNCTION OF DE-STONER MACHINE

Static pressure: According to the specification of the machine, the static pressure of the machine must be between 90 to 100 millimeter of water. If the static pressure is too high (more than 100), the pressure will blow the stone with the rice. Therefore, stone will not be eliminated from this process step. If the pressure is too low, air pressure will not be able to blow rice from the stone and rice will come out in the stone tray in high volume which will lead to over weight of the sieve. So the vibration system cannot separate stone from rice and cannot bring the left over on the sieve to the higher side. It may lead to the contamination of stone. However, the critical limit of this parameter is that the static pressure must be between 90 and 100.

Time to eject stones: To prevent the contamination of stones, it is necessary to eject stones at the end of the sieve in time before they accumulate too much. When the accumulation of stones reaches the point that raw materials come out, it is possible that the excess of stones may go along with the product. Therefore, we must ensure that the ejection of stones must be frequent enough to prevent the contamination of stones. On the contrary, if the operator ejects stones too frequently, production loss will be higher due to the increase of proportion of rice in the stone tray. Thus, the test of stone ejection must be carried out to determine this critical limit. In this case, the operator was told to release stones every four hours of production, and inspect the product every ten minute to find the contamination of stone. If stones are found in the product, the duration will be reduced. Finally, the conclusion from the test is that the operator must release stones into the stone tray at least every two hours during production time.

Slope of the sieve: The slope of the sieve affects the chance of contamination. If the slope is too steep, stones can easily roll to the other side of the sieve and go along with the product. According the information from the supplier, it is suggested to set the slope of the sieve at 11.5 degree. Therefore, we decide to set up the slop of the sieve permanently and do not allow adjusting its slope.

Production capacity: Production capacity is another factor we should concern. According to the specification of the machine, de-stoner machine can not operate effectively if the flow of raw materials is more than 3 metric tons per hour. The air pressure generated by the machine cannot lift such a thick layer of rice; therefore, the flow of rice may bring stones along with the product. However, according to the company's records, the production capacity of every production line, which contains three de-stoner machines never exceed 8 metric tons per hour. Thus, it is articulate that the production capacity should not possibly be considered as a critical limit.

After looking at all parameters involving the de-stoner machine, time to release stones and the static pressure seem to be critical factors for this process step. This limit must be monitored, which will be described in the later section. The slope of sieve is not considered because it is already set at 11.5 degree and all operators are not allowed to adjust this parameter. The overflow of raw materials is not be concerned also because a hopper cannot feed the product more than 3 metric tons per hour. Therefore, the critical limits for this process step is that the rice technician must release the stuck stones into the stone tray at least every two hours, and the static pressure of the air must be less than $50N/m^2$.

4.3.3 Color Sorter

Color sorter machine is the latest technology the company brought to improve the product's quality. This machine will detect the other materials by generating UV light through incoming materials. Then, it will distinguish physical hazards from rice according to color that it detects. Consequently, hazards will be blown away by the air injectors. Parameters that we should consider for determining the critical limits for this process step are as follows.

- Flow rate: To ensure that all woods and rubbers will be eliminated in this process, flow rate of incoming materials must be slow enough to create a thin layer of them; thus, detectors can find every piece of hazards. If rice is in line of sight of the detectors, it is possible that some hazards may remain in the product. This machine will adjust flow rate through vibrator feeders installed on the top of it. Through a touch screen, the operator can adjust the flow rate from 0 to 100 percent. 100 percent of flow rate equals to 12 metric tons per hour.

Background: Background is a value presenting the brightness of UV light from fluorescent bulbs. This machine will measure the difference of the brightness after the light has been through incoming materials. Therefore, the more the brightness of fluorescent bulbs, the more the efficiency of the machine. Background also can be adjusted from 0 to 100 percent, and it will represent the sensitivity of the machine. The percent of background is calculated from the percentage of the adjusted brightness over the maximum brightness generated by UV bulb.

From the two parameters discussed above, we decide to use background as a critical limit. Thus, a test was set up by fixing flow rate at 100 percent which is the worst case for possible contamination. Next, we set the value of background at 100. Consequently, twenty pieces of woods and rubbers are added to incoming materials at the vibrator feeders, and the amount of the physical hazards will be recorded. Then, the operator will gradually reduce background and record the results until any wood or rubber is found in the finished product. From the test, we can conclude that the background must be more than 82 in order to ensure full prevention of physical hazards.

4.3.4 Plate Magnet

Plate magnet is the last process step that can eliminate metals from the product. Obviously, the hazard for this process is the leakage of metals. As illustrated in Figure 5.3 plate magnet will attract metals during the product transported on the conveyor. To ensure that finished product is free from metal, there are two significant factors the manufacturer should concern as follows.

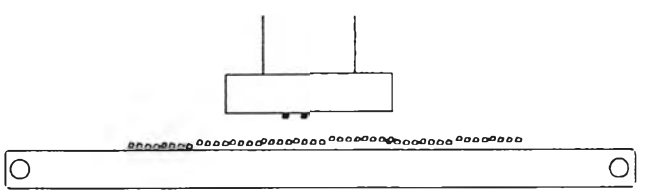


FIGURE 5.3 PLATE MAGNET

Frequency of cleaning: When the magnet has operated for a while, it is necessary to clear metals because the accumulation of metals may cover and reduce the section area of the magnet. Moreover, if there are too many metals, they may fall onto the conveyor since the magnetic force cannot hold such a heavy weight. Thus, we should create a cleaning schedule to avoid this problem. To establish a critical limit for this parameter, the cleaning schedule for this magnet must be done at least twice a week. After performing this schedule for a while, it is never found that there are only a few metals collected from the magnet. Therefore, this will be the critical limit.

Distance from the conveyor: The distance between the magnet and the conveyor is another factor to make this process step effectively works. The magnet must be close enough to the conveyor in order to create sufficient magnetic force. For determining the limit, the test was carried out by putting metals covered with rice, and let them pass the plate magnet. Then, the observation will take on the maximum distance that the magnet can fully magnetize the metals. According to the result of the test, the minimum distance equals to 22 cm when the specimen is a nail. However, we will set this limit at 10 cm because metals that are smaller than nails may require shorter distance to be drawn by the magnet. This limit is an operating limit. Nevertheless, there is no record of customers' complaint about the contamination of metals. Therefore, 10 cm will be acceptable to be used as a critical limit for this process step.

After examining all CCPs and establishing critical limits for all CCPs, the conclusion of critical limits will be added in HACCP plan.

V. ESTABLISH A MONITORING SYSTEM FOR EACH CCP (PRINCIPLE 4)

5.1 Monitoring

According to the definition of CODEX, monitoring refers to "the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control". Monitoring is a plan for measuring and observing the relationship between CCP and critical limit. Monitoring tracks the system's operation and allows for action to be taken in the event of a loss of control or if there is a trend toward the loss of control. Thus, it is necessary to determine who will monitor, how to monitor, and when to monitor. The objectives of monitoring are as follows.

- To track the system's operation at CCPs. In other words, it is an trend analysis of system's operation.
- To identify whether CCPs are under control.
- To be an evident showing the operation at CCPs still conforming to HACCP plan.

Monitoring should provide information in time in order to correct, change, or prevent the loss of control in the production process. The monitoring procedures will be established at CCPs, and will generally relate to on-line processes. Monitoring may be continuous or non-continuous. Continuous monitoring at a CCP usually is done with measuring equipment, such as automatic time-temperature equipment used at a cooking step. Continuous monitoring is better because it results in a permanent record that can be reviewed and evaluated to ensure that the CCP is under control.

When continuous monitoring is not feasible, non-continuous monitoring procedures are preferable. The examples of non-continuous monitoring are visual examinations; monitoring of ingredient specifications; measurements of pH, water activity (Aw), and product temperatures; attribute sampling; and etc. When non-continuous monitoring is applied, it is necessary to ensure that the frequency of monitoring is enough to ensure that the hazard is under control and that the monitoring is performed at random times. For instance, each plant needs to set its own times and frequency for checking the cooking time/temperature of products. This may vary from one establishment to another because of differences in plant size, plant layout, the type of product, the length of time for processing, and the product flow.

Time of inspection is another factor should be concerned. Most of monitoring process must be done in short time because it must relate to the actual operation in the production process. Therefore, it has not enough time for the test that spends relatively long time. Consequently, the physical and chemical inspections are very popular and more preferable than the microbiological test. The examples of the physical and chemical measurement are temperature, time, pH, water activity and moisture. In addition, the measuring equipment or devices must be calibrated for accuracy.

The results of monitoring must be recorded in a form of document, which will be used as reference presenting the condition of production. Monitoring record should provide the information of the production, and corrective action when it tends to lose the control of the production. All operational records and documents that are associated with CCP monitoring must be properly filled in and signed by the person doing the monitoring and verified/signed by a responsible official of the company.

If any one of the critical limits is out of control as determined by the monitoring procedures, the CCP will be out of control. Lack of control at a CCP is defined as being a critical defect or a deviation. Deviations will result in the production of a hazardous or unsafe product. Therefore, adequate and effective monitoring procedures are essential due to the serious consequences arising from deviations.

5.2 Design for Monitoring System

The monitoring system is then used to check whether the control procedures are in action. To ensure that there is no deviation from critical limits, monitoring system should consist of:

1) What to monitor?
2) How to monitor critical limits and control procedures?
3) Frequency of monitoring.
4) Who will be responsible for monitoring?

5.2.1 *What to monitor?*

Monitoring may refer to the inspection of the product's characteristics or processes in order to check whether they still conform and are under the control limits. The examples of this type of measurement are:

- The measurement of time and temperature of pasteurization.
- The measurement of temperature at storage.
- The measurement of pH.
- The measurement of water activity.

Monitoring may refer to the process that observes whether the control procedure at CCPs still works such as:

- The eye inspection of sealed cans.
- The verification of certificates from suppliers.

The very important thing to be concerned in monitoring is that operating limits should be used instead of critical limits so the operate will have enough time to take the corrective action.

5.2.2 *How to monitor?*

Deviation should be detected as early as possible in order to provide enough time for corrective action and reduce the loss of production. In this case, microbiological tests are not suitable for monitoring CCPs. Moreover, these tests need a lot of samples to test microorganisms that can cause illness. Physical and chemical tests such as pH, water activity, time, and temperature are preferable since the test can be done quickly and also present the control of microorganisms in the production process.

The effectiveness of monitoring depends on the selection of appropriate devices. The calibration of these devices is very important also. Tools that used for monitoring will be different according to the types of measurement as follows.

- Thermometer
- Watch
- Scale
- Equipment and device for chemical analysis

These tools and devices must be timely calibrated to ensure the accuracy; however, the determination of critical limits must concern about the deviation of these devices. Operators must be sufficiently trained for the use of devices and the measurement methods, including

with the adequate information about how to monitor. For instance, the measurement of temperature for pasteurization must be done at the last point that is heated.

5.2.3 *Frequency of Monitoring*

Monitoring could be done continuously or non-continuously. If applicable, the continuous monitoring system should be created. This can be done in both physical and chemical tests such as:

- Temperature and time in pasteurization process
- The use of metal detector in packaging line

The record of monitoring must be verified frequently to enhance the system. When the non-continuous monitoring system is used, the frequency of monitoring can be determined from the past record of the product and production process. When a problem is found, it is necessary to increase the frequency. Frequency of monitoring may be determined from:

- The deviation of production process
- The gap between operating limit and critical limit
- The risk that the manufacturer can handle

5.2.4 *Who will monitor?*

For developing HACCP plan, it is important to assign the responsibility for monitoring CCPs. The examples of people who are responsible for monitoring CCPs are as follows.

- Operators in packing line
- Technician
- Supervisor
- Q.C.

Person who responsible for monitoring CCPs must:

- Be sufficiently trained about the monitoring technique.
- Understand the importance of monitoring system.
- Perform a proper method of monitoring.
- Report the result of monitoring properly.
- Be authorized to take action as mentioned in HACCP plan.
- Immediately report when a deviation from critical limit is found.

The important thing is that assigned person must suddenly report any deviation in order to take action in time. Monitoring person must record the results including the evidence during monitoring process.

5.3 The Case Study

In the case study, the monitoring system will be determined according to the above basis. All of these monitoring system will be written in HACCP plan form.

5.3.1 Fumigation

The first critical limit of this process step is the duration of fumigation. To eliminate all insects in raw materials, fumigation must take at 48 hours to make all substances evaporate. In this case, technical supervisor will be responsible for checking time of fumigation. This is done by measuring time from the start of this process to issuing raw materials to the next step. Technical supervisor must record time and number of storage tank when he start fumigation. Then, he will calculate time when the raw materials are allowed to go to the next process. Frequency of this monitoring is every time when this process step starts.

The second critical limit is the amount of fumigating pills that relate to the volume of raw materials. The amount of incoming materials must be checked before applying fumigating pills. Technical supervisor will calculate the volume of raw materials from the information of incoming materials, which are received by production assistant. This checking procedure must be done every time previous to the fumigation process.

5.3.2 De-stoner

As mentioned earlier, there are two critical limits for this process step, which are time to release stone and the static pressure. These two limits will be monitored as follows.

First, static pressure must be between 90 and 100 millimeter of water. In this case the mechanical and electrical technicians are responsible for measuring this parameter by the observing a manometer attached to the machine. The frequency of this monitoring task is set at one time per week, and this task will include in the preventive maintenance program of this machine.

Secondly, the frequency to release stone is another point we should concern. This task will be done by rice technician who controls the production line. Rice technician has to release the stone by pressing the release button at the machine. This limit must be done every two hours of production time.

5.3.3 Color Sorter

The only one critical limit of this machine is the background value of the fluorescent bulbs. This value can be adjusted at the touch screen of the machine. In this case, rice technicians who control the production line will be responsible for monitoring the background. They are not allowed to adjust the background less than 82. Therefore, every time they operate this machine, they must check and record the background value at the logbook of rice technicians.

5.3.4 Plate Magnet

There are two critical limits to monitor in this process step. First is the frequency of magnet cleaning. This procedure is to clear the metals in order to avoid accumulation of them. Technical assistants whose jobs are to clean the machine and production line will be responsible for this task. According to the schedule of cleaning, they have to clear metals twice a week.

The second critical limit is the gap between the conveyor and the magnet. To ensure that the magnet is close enough to the product, rice technician must measure this gap by using a ruler. This monitoring action must be done every time before the rice technician feed the product from any finished product storage tank to the conveyor.

VI. ESTABLISH CORRECTIVE ACTION (PRINCIPLE 5)

According to guidelines for HACCP application of CODEX, corrective action is defined as "any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level". Deviation procedures including set of corrective actions that are implemented when a deviation occurs are previously determined and documented. Taking appropriate corrective actions will control all deviations in order to control the defected product and to correct the cause of the problem. All corrective actions taken must be recorded and filed as references.

Since the deviation at each CCP may come from several causes, more than one corrective action may be necessary at each CCP. Product control includes proper identification and elimination of the defected products. Corrective actions are prescribed and formalized so that operators who responsible for monitoring CCP understand and are able to properly perform the corrective action when a deviation occurs. When a deviation occurs, it will most likely be noticed during the routine monitoring of a CCP when the pre-determined critical limit for a CCP is out of compliance. If the corrective action is not taken properly, the deviation may result in an unacceptable health risk.

6.1 Deviation

A deviation is defined as failure to meet the specified critical limits. When the deviation from critical limits occurs, it is necessary to identify, separate, and assess risk of the product. If the correction action is taken improperly, it may create unsafe products and may cause more severe deviation. The corrective action should be done as follows.

1) Identification of deviation: Manufacturers should develop a system for identifying the affected product when there is a deviation.
2) Product separation: Manufacturers should have working procedure to separate and control the affected product.
    - All affected products must be separated from the last time CCP is under control.
    - Separated products must be distinctly marked in order to show the condition of those products such as labeling including lot number, type and amount of products, date of retention, reasons of holding, and responsibility person.
    - Manufacturers should hold the products from date of retention until their conditions are changed such as bringing to destroy, rework and etc.
3) Assessment of affected product: The assessment must be carried out by experts. In order to analyze the probability of the occurrence of hazards, product assessment must be carried out in a proper way. Decision making will be done on the basis of scientific principle. Affected products must ensure that they are safe before releasing to other processes.

6.2 Corrective action

The main reason of developing HACCP is to prevent the problem before occurrence, which must be immediately corrected to prevent deviation at CCP. It is necessary to take action after deviation for food safety and prevention of the next deviation. Method of correction is necessary for analyzing the problem and finding the way to prevent this problem. Monitoring is very useful to create an effective corrective action. If the action taken does not identify the cause of deviation, the deviation may occur again. Furthermore, the consideration of hazard analysis and the improvement of HACCP plan may be necessary for preventing future deviation. To create correction program, manufacturer should consider:

- The survey for evaluating cause of the deviation
- Effective way to prevent repetition
- Verification procedure

6.3 Record

Records are used to present the control of affected product and the performed corrective action. Complete records will help in verification procedure for showing that manufacturer has a control of deviation and also effective corrective action. The following data should be included in the record.

6.3.1 Deviation and Retention

- Product's name and lot number
- Date of production/hold/release
- Reason for retention
- Volume of hold products
- Result of evaluation
- Signature of responsibility person
- Methods to destroy affected products

6.3.2 Correction

- Causes of deviation
- Method of correction
- Monitoring of efficiency of corrective action
- Date of correction
- Signature of responsibility person

6.4 The Case Study

The corrective action or the deviation procedure of the case factory will be described according to each CCP. The deviation procedures at each CCP are written on HACCP plan (Table 5.6)

6.4.1 Fumigation

Deviations in this process step can be occurred in two ways. The first deviation is that the fumigation time is less than 48 hours. The other is the inadequate amount of fumigating pills. In this case, technical supervisor will stop the production process as soon as possible and that lot of product (according to the storage tank) will be hold and sent to rework. This procedure will carried out as determining in the hold/release procedure of GMP procedures.

6.4.2 *De-stoner*

Deviations of the de-stoner machine come from the lack of stone release as scheduled and insufficient air pressure. When a rice technician does not release the stone as scheduled (every 2 hours), he must stop the production and open the de-stoner machine to looking at the stones that remain on the sieve. If the accumulation of the stones does not exceed the entrance of incoming materials, the production process can continue. Consequently, if the accumulation of the stones exceed the point that raw materials enter, it is necessary to separate and hold the product from the last time when the stones are released. The procedures to trace back and hold the product are described in product identification and traceability, and hold/release procedures of GMP.

Moreover, the other deviation can occur when the air pressure is found that it does not conform to the requirement (between 90 and 100). If the pressure exceed 100 or below 90 mm. of water, then technicians must hold the production process to fix the error by adjusting the static pressure through a damper. The products that already passed after the previous observation must be hold and inspected by Q.C. Then, if the contamination of stone is unacceptable, the affected product must be released to rework.

6.4.3 *Color Sorter*

The background of the light is a deviation in this process step. When the value of background is less than 82 percent, rice technician will suddenly inform technical supervisor and report the cause of the problem. Technical supervisor is responsible to hold and separate all of the products that are produced from that production lot. This is counted from the last time when rice technician has set up the color sorter machine. All procedures of holding product should be in conformance with the GMP procedures.

6.4.4 *Plate Magnet*

The plate magnet is the last CCP in the production process; there are two critical limits to determine the corrective action. First is when the gap between the magnet and the conveyor is too far. Although the monitoring must be done every time before releasing the products from finished product storage tanks to packing tanks, the deviation may occur from the forgetfulness of the employees or due to the too high flow rate of the product flow. Therefore, when it is found that the gap is too long, the product in that packing tank must be called back to rework.

The second deviation is when too many metals are found at the plate magnet. Technical assistant must inform technical supervisor for analyzing whether the cleaning schedule could

be adjusted to become more frequent. In another case, when technical assistants do not clear metals as scheduled, the magnet must be checked for the metals. If the accumulation of metals is possible to obstruct the capability of the magnet, it is necessary to trace the product from the last time of clearing metals, and send them to rework.

VII. ESTABLISH VERIFICATION PROCEDURES (PRINCIPLE 6)

According to the definition of CODEX, verification activities refer to "methods, procedures and tests that are used to determine if the HACCP plan for that establishment is valid and is operating properly". Verification activities may include analytical testing. Carrying out the verification activities may assist manufacturer to find that some hazards were overlooked or they may discover new or unexpected hazards. In this case, the plan needs to be modified appropriately. The verification procedures at each CCP are added on the form of HACCP plan. Verification activities are different to monitoring activities. Results from verification activities are unintentional to make decisions on the acceptability of lots of affected product. Verification activities consist of analytical testing or auditing of the monitoring procedures, product sampling, audits of monitoring and verification records, plant inspection audits, environmental sampling or any other appropriate activities. Verification activities must be done by appropriate person who is enable to find the faults of an existing plan. Verification activities should proceed:

- After studying HACCP plan.
- When there is a change in products, ingredient, production process, and etc.
- When deviation is found due to the identification of a new hazard.
- As scheduled.

7.1 Description of Verification Activities

Every HACCP plan should have verification activities for each CCP and for the whole HACCP plan. HACCP should be constructed and adjusted according to experience and the latest information. Thus, timely verification is very helpful for the improvement of HACCP plan because it will discover and correct the weakness of the system and also eliminate unnecessary control procedures. Verification activities should include:

1) HACCP plan validation
2) HACCP system audits
3) Calibration
4) Targeted Sampling and Testing

7.2 Verification Frequency

Verification activities should be carried out as scheduled in HACCP plan or when there is a tendency of unsafe product. This tendency comes from:

- The observation in production process where a deviation occurs.
- Verification activities found that the monitoring was not timely done.
- Verification activities found that the operation at CCP always deviates from critical limit.
- Customers' complaint, or unapproved reports from customers.

Verification procedure should determine the appropriate frequency to make HACCP plan proceed constantly and remain the accurate measurement methods. Therefore, the interval of verification should be suitable for the level of confidence to the conformance of HACCP plan. Frequency of verification may be changed; for instance, when the verification shows that production process is stable enough, the frequency may be reduced.

7.3 Records of Verification

Verification activities should determine the records of verification, which affect all verification activities, including with methods, date, responsibility, results, and the corrective action when a problem is found.

7.4 The Case Study

Verification procedures will be shown in table 5.6. To ensure that all activities of monitoring conform to the requirement and operate properly, it is necessary to have verification procedures at each CCP. Q.C. department will verify all CCP by sampling and visually inspect the samples of product. In this case, Q.C. will collect samples from all four CCPs every two hours. Then, Q.C. will visually inspect for the remaining of insects, stones, woods and rubbers, and metals. Moreover, for the color sorter machine, the machine will receive yearly check for the background from the supplier. The calibration of the background value will be done by the use of oscilloscope.

VIII. ESTABLISH DOCUMENTATION AND RECORD KEEPING (PRINCIPLE 7)

The HACCP records refer to the in plant record keeping that is done at each CCP and that contain the information required to ensure that the HACCP plan is followed. Records are very useful to determine the compliance of the establishment in following the agreed-upon HACCP plan. HACCP records are required at each CCP and are written on the HACCP plan form. A record can be presented in any form such as processing chart, written record, computerized record, and illustrates the past record of the process, the monitoring, the deviations and the

corrective actions (including disposition of product) that occurred at the identified CCP. The records contain information that is used to establish the product's processing profile. This would be used when there is any subsequent problem. Accurate records facilitate the trace back of the actual manufacturing conditions. The establishment must be maintained up-to-date, properly filed, and accurate records. There are four kinds of records that we should consider as follows.

1) Support document
2) Records in HACCP system
3) Work instruction
4) Training record

8.1 Supporting Document

Supporting document includes details and support information for developing HACCP plan such as hazard analysis, scientific data of CCPs, and critical limits such as:

- Information for constructing procedure to prevent the growth of microorganisms
- Information for determining product's life if it affected the safe
- Information for determining critical limits

Other examples of supporting are:

- Name lists of HACCP team and their responsibilities
- All forms used during developing HACCP plan such as form of:

  - Product description and intended uses
  - Flow diagram
  - Hazard analysis
  - Determination of CCP

8.2 Records in HACCP system

Records that are created from HACCP system are listed in the following table. Failure of establishing document for CCP can lead to the non-conformance of HACCP plan. Furthermore, records that are necessary for HACCP system are illustrated in the HACCP plan.

Monitoring at CCP	Deviation and Correction	Verification
All records of HACCP will be done in a form that consists of the following details. • Form Name • Date and Time • Product's type • Critical limits • Monitoring by observation or measurement • Signature of responsibility person • Record of corrective action • Signature of verification person • Verified date	• Product identification • Amount of affected products in that lot • Characteristics of deviation • Information of product elimination	• Detail of corrective action • Calibration of measuring devices • Records of verification results consisting of ➢ Method ➢ Date ➢ Responsibility person/department ➢ Result

TABLE 5.5 RECORDS FROM HACCP SYSTEM

8.3 Establishing Work Instruction

Manufacturers should establish work instruction used in HACCP system. The examples are:

- Monitoring system for each CCP including
  - ➢ Methods and equipment used for monitoring
  - ➢ Frequency of monitoring
  - ➢ Responsibility person
- Correction plan for deviation from critical limits or for situation that is possible to have the occurrence of hazards.
- Description of record keeping including their copies
- Description of verification

8.4 Record of Training Program

All documents involving training program should be systematically kept. This will be useful for related employees in monitoring critical limits at each CCP, and involving corrective action and verification. These employees must be trained to deeply understand to the appropriate procedures and methods for controlling CCP.

8.5 The Case Study

From the case study, the documents, records, procedures and schedules in the HACCP system must be defined as control documents. All of this document will be kept by the document control center, which is the responsibility of administration supervisor. The correction of document is prohibited, unless the plant manager approves. The records of each CCP can be described as follows.

8.5.1 Fumigation

Record of incoming materials: When unloading raw materials into the storage tanks, the production assistant is responsible for recording the volume of rice, time, type of product, supplier, and etc. This is very useful for calculating the right amount of fumigation substances.
Record of fumigation: This record will be written by technical supervisor. The record includes date, time, volume of raw materials in the storage tank, and amount of chemical substances used, and the time that allows releasing raw material to the production line.
Rice technician's log: This book contains the assigned task of rice technician, the time to start the production process, production capacity, and the problems and all action taken.

8.5.2 De-stoner and Color Sorter

Record of preventive maintenance program: The history card contains all information of the machine such as supplier, repair record, spare parts and etc.
QC inspection report: This report is the result of visual inspection of the product.

8.5.3 Plate Magnet

QC inspection report: This report is the result of visual inspection of the product.
Technical assistant's log: This logbook is the record of cleaning tasks of technical assistants as scheduled.
Record of releasing product from finished product tanks: The record is used to control the distance between the conveyor and magnet. It contains date, time, gap between conveyor and magnet, and packing tank number.

TABLE 5.6 HACCP PLAN OF THE CASE FACTORY

Process Step	Hazard Description	Critical Limits	Monitoring Procedures	Deviation Procedures	Verification Procedures	HACCP records
7. Fumigation	B-The survive of insects	Fumigation time must be more than 48 hours	Technical supervisor checks duration from the starting of fumigation to the releasing raw materials	Technical supervisor stops the production and holdss the product and send to rework.	Visual inspection by QC every 2 hours	Rice technician's log Record of incoming materials Record of fumigation
		The amount of fumigating pills.	Technical supervisor calculates from the amount of substances by comparing with incoming materials	Technical supervisor stops the production and holds the product and send to rework.	Visual inspection by QC every 2 hours	Rice technician's log Record of incoming materials Record of fumigation
15. De-stone	P-The leakage of stone	Static pressure between 90 and 100 millimeter of water.	Technicians use a pressure gauge to measure the static pressure	Closing machine. Technicians adjust the pressure QC inspects the affected product. Rework the product.	Visual inspection by QC every 2 hours	Machine's history card QC inspection report
		Time of releasing stone to the stone tray < 2 hr.	Rice technician releases the stones into the stone tray.	Closing machine. Rice technician inspects the stones in the machine. QC inspects the affected product. Rework the product if necessary.	Visual inspection by QC every 2 hours	Machine's history card Record of releasing stone QC inspection report

Process Step	Hazard Description	Critical Limits `	Monitoring Procedures	Deviation Procedures	Verification Procedures	HACCP records
31. Color Sorter	P-The leakage of wood and rubber	Background > 82 percent	Rice technician checks background of the machine before operation	Closing machine. Rice technician adjusts the background value QC inspects the affected product. Rework the product.	Visual inspection by QC every 2 hours Calibrate background value by the supplier.	Rice technician's log QC inspection report
37. Plate Magnet	P-The leakage of metal	Cleaning schedule (2 time per week)	Technical assistants clear metals from the plate magnet	Technical assistants wipe out remaining metals/ QC inspects the affected product. Rework the product if necessary.	Visual inspection by QC every 2 hours	Technical assistant's log QC inspection report
		Gap between magnet and conveyor < 10 cm.	Rice technician measures the gap by the ruler	Stop the conveyor. Rice technician adjusts the gap. QC inspects the affected product. Rework the product if necessary.	Visual inspection by QC every 2 hours	Rice technician's log QC inspection report