12 – Background Material

12 Textbook: Hazard Analysis and Critical Control Points (HACCP)

12.1 Introduction

12.1.1 What is HACCP

What is HACCP?

The concept of Hazard Analysis and Critical Control Points (HACCP) is a preventive system to guarantee the safety of food for the consumer. It focuses on the prevention of physical, chemical and biological hazards rather than on carrying out inspection of the finished products.

The HACCP approach was developed in 1959, when NASA commissioned the Pillsbury Company to produce food for astronauts. The food had to be absolutely safe to exclude any risk to the health of the astronauts, who would be cut off from medical care for weeks. The company applied the FMEA method (Failure Mode and Effect Analysis) to the production of food. Later on this approach was further developed, and was first released in 1971. Since 1993 the application of HACCP has been recommended by the Codex Alimentarius published by FAO (Food and Agriculture Organization of the United Nations).

The HACCP concept requires a company:

- To analyse all risks within its control related to the safety of its products;
- To identify critical points for control of the quality of food;
- To define critical limits for relevant parameters at the critical points;
- To establish procedures for continuous control of food safety;
- To define corrective measures for deviations;
- To regularly check whether this system is appropriate and effective;
- To document all measures taken.

The European regulation 178/2002 requires all companies which produce, package and sell food in Europe to apply this concept. From 1st January 2006 only food, that complied with the HACCP-requirements could be imported and traded within the European Union. Companies intending to supply food to EU member states are required to have a documented HACCP system.

12.1.2 The principles of HACCP

Application of good hygiene practices

The application of HACCP starts with the application of good hygiene practices.

The Codex Alimentarius and a general description of good hygiene practices can be found on the FAO web page (www.fao.org). It also includes also Codex codes for hygienic practices in the following sectors:

- Meat;
- Fish and fishery products;
- Milk and milk products;
- Fresh fruits and vegetables;
- Egg products;
- Coffee production.

The following text is a summary of the general description of good hygiene practices as recommended by FAO. The full text is accessible at http://www.fao.org/docrep/006/y5307e/y5307e00.htm).

Good hygienic practices include the following measures:

- **Environmental hygiene**

Food production must not be carried out where potentially harmful substances would lead to an unacceptable level of such substances in food.

- **Hygienic production of food sources**

Points where a high probability of contamination may exist should be identified and specific measures should be taken to minimize the probability of contamination.

Producers need to implement measures to:

- Minimize contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;
- Control plant and animal health so that it does not pose a threat to human health through food consumption;
- Protect food sources from faecal and other contamination;
- Manage waste and store harmful substances appropriately.

- **Handling, storage and transport**

Procedures should be in place to:

- Sort food and food ingredients to segregate material which is evidently unfit for human consumption;
- Dispose of any rejected material in a hygienic manner; and
- Protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport. This may include controlling temperature, humidity, and/or other controls.

- **Cleaning, maintenance and personnel hygiene at primary production**

Appropriate facilities and procedures should be in place to ensure that:

- Any necessary cleaning and maintenance is carried out effectively;
- An appropriate degree of personal hygiene is maintained.

- **Establishments and equipment**

Establishments should normally be located away from:

- Environmentally polluted areas and industrial activities which pose a serious threat of contaminating food;
- Areas subject to flooding unless sufficient safeguards are provided;
- Areas prone to pest infestations;
- Areas where waste, either solid or liquid, cannot be removed effectively.

Structures within food establishments should be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected. In particular the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- The surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use;
- Walls and partitions should have a smooth surface up to a height appropriate to the operation;
- Floors should be constructed to allow adequate drainage and cleaning;
- Ceilings and overhead fixtures should be constructed and finished to minimize the build-up of dirt and condensation, and the shedding of particles;

- Windows should be easy to clean, be constructed to minimize the build-up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed;
- Doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect;
- Working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions.

Premises and structures covered here include market stalls, mobile sales and street vending vehicles, temporary premises in which food is handled such as tents and marquees. Such premises and structures should be sited, designed and constructed to avoid, as far as reasonably practicable, contaminating food and harbouring pests.

Equipment and containers (other than once-only use containers and packaging) coming into contact with food, should be designed and constructed so that they can be adequately cleaned, disinfected and maintained to avoid the contamination of food. Equipment and containers should be made of materials with no toxic effect in intended use.

Equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Such equipment should also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of food. These requirements are intended to ensure that:

- Harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels or their survival and growth is effectively controlled;
- Where appropriate, critical limits established in HACCP-based plans can be monitored;
- Temperatures and other conditions necessary for food safety and suitability can be rapidly achieved and maintained.

Containers for waste, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Containers used to hold dangerous substances should be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food.

- **Facilities – water supply, waste disposal, cleaning, personal hygiene**

Drinking water should conform to the requirements specified in the latest edition of the WHO Guidelines for Drinking Water Quality, or be of a higher standard. Non-drinking water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system. Non-drinking water systems shall be clearly identified and shall not connect with, or allow reflux into, drinking water systems.

The drainage and waste disposal systems and facilities should be designed and constructed so that the risk of contaminating food or the drinking water supply is avoided.

Adequate facilities, suitably designated, should be provided for cleaning food, utensils and equipment. Such facilities should have an adequate supply of hot and cold drinking water where appropriate.

Personnel hygiene facilities should include:

- Adequate means of hygienically washing and drying hands, including wash basins and a supply of hot and cold (or suitably temperature controlled) water;
- Lavatories of appropriate hygienic design; and
- Adequate changing facilities for personnel.

Such facilities should be suitably located and designated.

Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, monitoring food temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

- **Facilities – air quality, lighting**

Adequate means of natural or mechanical ventilation should be provided, in particular to:

- Minimize air-borne contamination of food, for example, from aerosols and condensation droplets;
- Control ambient temperatures;
- Control odours which might affect the suitability of food; and
- Control humidity, where necessary, to ensure the safety and suitability of food.

Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas and, where necessary, it has to be ensured that they can be adequately maintained and cleaned.

Adequate natural or artificial lighting should be provided to enable the company to operate in a hygienic manner. Where necessary, lighting should not be such that the resulting colour is misleading. The intensity should be adequate to the nature of the operation. Lighting fixtures should, where appropriate, be protected to ensure that food is not contaminated by breakages.

- **Facilities – storage**

Where necessary, adequate facilities for the storage of food, ingredients and non-food chemicals (e.g. cleaning materials, lubricants, fuels) should be provided.

Where appropriate, food storage facilities should be designed and constructed to:

- Permit adequate maintenance and cleaning;
- Avoid pest access and harbourage;
- Enable food to be effectively protected from contamination during storage; and
- Where necessary, provide an environment which minimizes the deterioration of food (e.g. by temperature and humidity control).

The type of storage facilities required will depend on the nature of the food. Where necessary, separate, secure storage facilities for cleaning materials and hazardous substances should be provided.

FAO's official training manual can be viewed at: http://www.fao.org/docrep/W8088E/W8088E00.htm or ordered this website.

After establishing Good hygienic practices, an HACCP system should be established to minimize the potential impact of the remaining risks.

HACCP is based on seven established principles, as defined by FAO:

7 principles of HACCP

Principle 1: Conduct a hazard analysis. The Codex defines a hazard as "A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect". The hazard analysis identifies which hazards need to be controlled to prevent the contamination of food.

Principle 2: Identify critical control points. According to the Codex a critical control point (CCP) is a point, step, or procedure in a food process at which control should be applied so that a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.

Principle 3: Establish critical limits for each critical control point. A critical limit represents the boundaries that are used to ensure that a process step produces safe products. Critical limits are set for factors such as temperature, exposure time, physical product dimensions, water quality, moisture level, etc.

Principle 4: Establish requirements for monitoring critical control points. Monitoring activities are necessary to ensure that the process is under control at each critical control point. Therefore, it is important to specify fully how, when and by whom monitoring is to be performed.

Principle 5: Establish corrective actions. The Codex defines corrective action as "any action to be taken when the results of monitoring at the CCP indicate a loss of control". Loss of control is considered as a deviation from a critical limit for a CCP. All deviations must be controlled by taking action(s) to control the non-compliant product and to correct the cause of non-compliance.

Principle 6: Establish verification procedures. The Codex guidelines define verification as "the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan". Verification and auditing methods, procedures and tests, can be used to determine if the HACCP system is functioning correctly.

Principle 7: Establish documentation and record keeping. A record shows the process history, the monitoring, the deviations and the corrective actions (including disposition of product) that occurred at the identified CCP. It is imperative that the manufacturer maintain complete, current, properly filed and accurate records.

The following flow diagram shows the sequence of application of these seven principles of HACCP to the food industry. The HACCP programme can be adapted to other industries as well.

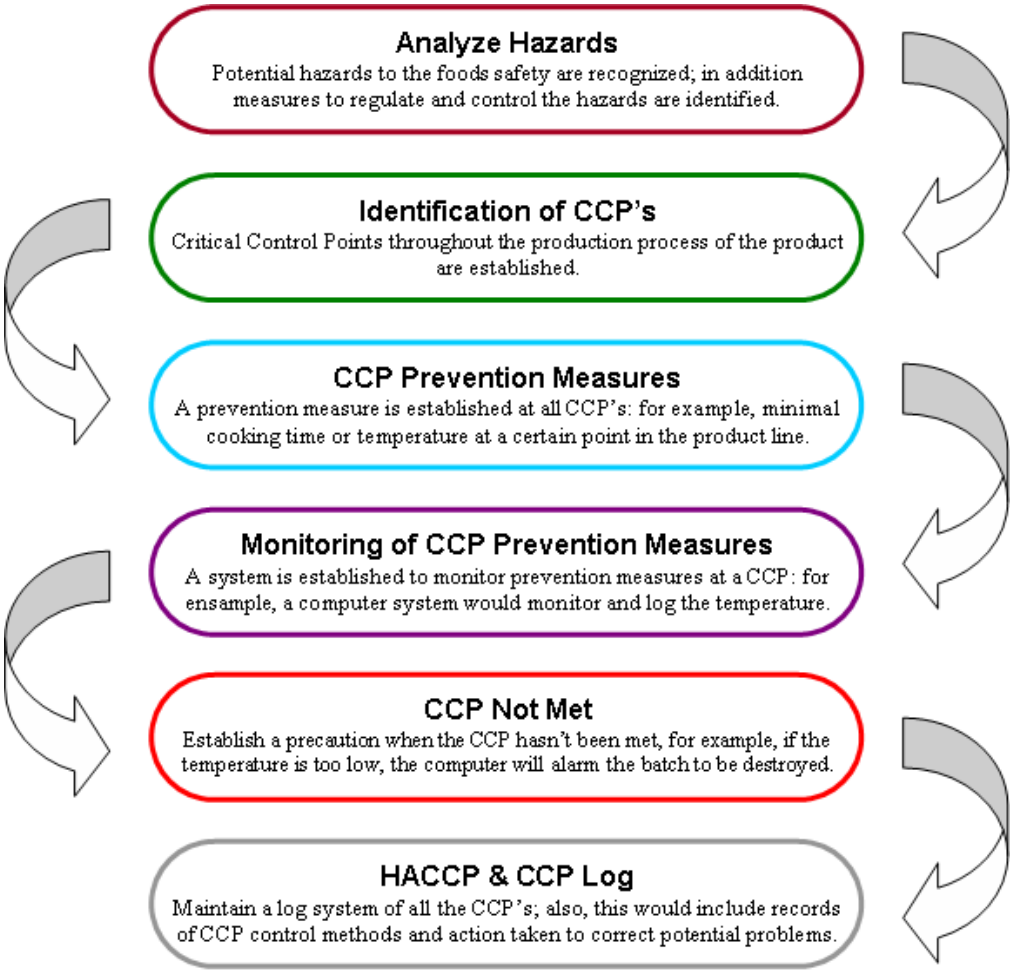

Figure 1: The seven principles of HACCP
(Source: American Meat Institute Foundation)

12.2 ISO 22000

The standard ISO 22000

The international standard ISO 22000:2005 (available from: http://www.iso.org/iso/catalogue_detail?csnumber=35466) specifies the requirements for a food safety management system as follows:

- To plan, implement, operate, maintain and update a food safety management system aimed at providing products that, according to their intended use, are safe for the consumer.
- To demonstrate compliance with applicable statutory and regulatory food safety requirements;
- To evaluate and assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety, in order to enhance customer satisfaction;
- To effectively communicate food safety issues to their suppliers, customers and relevant interested parties in the food chain;
- To ensure that the organization conforms to its stated food safety policy;
- To demonstrate such conformity to relevant interested parties; and
- To seek certification or registration of its food safety management system by an external organization, or make a self-assessment or self-declaration of conformity to ISO 22000:2005.

ISO 22000 can either be applied independently of other management system standards or be integrated into existing management system requirements.

ISO 22000 integrates the principles of the Hazard Analysis and Critical Control Point (HACCP) system and application steps developed by the Codex Alimentarius Commission to identify, prevent and control food safety hazards. HACCP systems apply a methodology with seven steps (7 HACCP principles) which are used to develop an HACCP plan. This document describes how an organization can plan the management and control of its food safety hazards. ISO 22000 gives instructions on how to combine the HACCP plan and prerequisite programs (PRPs) into a single integrated food safety management strategy. PRPs are conditions that must be established throughout the food chain (all the stages and operations involved in the production and consumption of foods) and activities and practices that must be conducted to allow a hygienic framework. PRPs must be feasible in order to provide safe food for human consumption. PRPs are what is referred to as "good practices" in hygiene, production, manufacturing, etc.

The International Organization for Standardization is currently developing additional standards that are related to ISO 22000. Currently, the following standards are operational:

- ISO 22000 - Food safety management systems - Requirements for any organization in the food chain.
- ISO 22001 - Guidelines on the application of ISO 9001:2000 for the food and drink industry.
- ISO TS 22003 - Food safety management systems for bodies providing audit and certification of food safety management systems.
- ISO TS 22004 - Food safety management systems - Guidance on the application of ISO 22000:2005.
- ISO 22005 - Traceability in the feed and food chain - General principles and basic requirements for system design and implementation.
- ISO 22006 - Quality management systems - Guidance on the application of ISO 9002:2000 for crop production.

12.3 Preparatory steps for the introduction of an HACCP system

Steps to prepare the introduction of an HACCP system

The preparation of an HACCP plan includes the following steps (according to FAO recommendations):

1. Assemble an HACCP team
2. Describe the relevant food products, and method of production and distribution; identify intended use and consumers of the products.
3. Develop and verify process flow diagram(s).
4. Decide whether products can be grouped together.

12.3.1 Assemble the HACCP team

The HACCP team

Prior to selecting the members of the HACCP team, it is extremely important to ensure the full commitment of management at all levels. Preferrably the development of an HACCP system should be carried out by more than one person, even in a small or very small enterprise. Analysing the entire food production process requires a variety of different kinds of knowledge and experience. The team could include personnel from production, cleaning, quality assurance, the laboratory, engineering and inspection.

It is essential that the team members are trained on the Codex General Principles of Food Hygiene and the fundamentals of the HACCP system to ensure that the team will work together with a common focus and use the same approach and terminology.

12.3.2 Describe the product

Description of products, their methods of production and distribution

In the next step the HACCP team describes the product and its method of production and distribution, as well as intended use and consumers. **Worksheet 12-1** shall assist in this task (source: American Meat Institute Foundation).

The following questions should be answered during the description phase:

1. What is the common name of the product?
2. How is the product to be used?
3. What type of packaging is used for the product?
4. What is the shelf life of the product and at what temperature?
5. Where will the product be sold? Who is the intended consumer and what is the intended use?
6. What labelling instructions are needed?
7. Is special distribution control needed?

12.3.3 Develop and verify a process flow diagram

Draw a process flow diagram

Draw a process flow diagram as described in Volume 3 of the UNIDO CP Toolkit using Worksheet 12-2. The best way to draw the company's process flow diagram is by walking through the plant and making sure that all the steps in the process are included in the flow diagram.

12.3.4 Decide whether products can be grouped using process categories

Product categories

One way to reduce paperwork that is a part of an HACCP system is to control all products in the same process category using a single HACCP plan. This is especially advantageous for very small establishments which may produce many different products.

If given products differ only in properties that would not affect safety, e.g. the amount or kind of seasoning used (hot vs. mild), they are clearly in the same process category and may be covered by the same HACCP plan (source: American Meat Institute Foundation).

Examples of process categories, into which products can be grouped, are shown below:

- Slaughter – all species: beef, swine and poultry;
- Raw product – ground: e.g. ground beef, ground pork, ground turkey;
- Raw product – not ground: boneless cuts, steaks;
- Thermally processed – commercially sterile: e.g. canned beef stew, pasta with meat;
- Not heat treated – shelf stable: summer sausage, dry salami;
- Heat treated – shelf stable: meat and poultry jerky, snack sticks, cooked vegetables and fruits;
- Fully cooked – not shelf stable: hot dogs, roast beef, ham;
- Heat-treated but not fully cooked – not shelf stable: partially cooked patties, bacon;
- Product with secondary inhibitors: corned beef.

Thus the preparatory steps for the development of an HACCP system have been completed. The next steps involve applying the seven principles of HACCP and developing the HACCP plan.

The following section provides a detailed description of this process.

12.4 The seven principles of HACCP

12.4.1 Principle I: Conduct a hazard analysis

Conduct a hazard analysis

The first principle of HACCP is to conduct a hazard analysis. The hazard analysis is necessary to identify hazards whose elimination or reduction to acceptable levels is essential to the production of a safe food. All biological, chemical and physical hazards should be considered.

Biological hazards

Biological hazards

Biological hazards are living organisms that can make food unsafe to eat. Biological hazards may be bacterial, parasitical, or viral. They can be associated with the raw materials from which meat and poultry products are made.

Biological hazards may also be introduced during the processing of meat and poultry products from people who are involved in the processing, from the environment in which the foods are processed, or from other ingredients in the products.

Identifying the biological hazards to which the production processes might be subjected is clearly a difficult and important task that requires all the expertise that the HACCP team can bring to it.

Examples of biological hazards are (source: FAO, Food quality and safety systems training manual):

Bacteria (spore-forming):

- Clostridium botulinum;
- Clostridium perfringens;
- Bacillus cereus;

Bacteria (non-spore-forming):

- Brucella abortis;
- Brucella suis;
- Campylobacter spp.;
- Pathogenic Escherichia coli (E. coli 0157:1-17, EHEC, EIEC, ETEC, EPEC);
- Listeria monocytogenes;
- Salmonella spp. (S. typhimurium, S. enteriditis);
- Shigella (S. dysenteriae);
- Staphylococcus aureus;

- Streptococcus pyogenes;
- Vibrio cholerae;
- Vibrio parahaemolyitcus;
- Vibrio vulnificus;
- Yersinia enterocolitica.

Viruses:

- Hepatitis A and E;
- Norwalk virus group;
- Rotavirus.

Protozoa and parasites:

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

Chemical hazards

Chemical hazards

Chemical hazards may be the result of compounds naturally occurring in foods or added during the processing of foods. Naturally occurring chemical hazards include aflatoxins, mycotoxins and shellfish toxins.

Added chemical hazards are those which are intentionally or sometimes unintentionally added to food during the growing, harvesting, storage, processing, packaging or distribution phases of production. This group of chemical hazards is very broad and might include components of animal food or drinking water, animal drugs, pesticides, food ingredients, or chemicals used in the processing establishment such as lubricants, cleaners, paints and coatings.

Examples of chemical hazards are given below (source: FAO, Food quality and safety systems training manual):

Naturally occurring chemicals:

- Allergens;
- Mycotoxins (e.g. aflatoxin);
- Scombrotoxin (histamine);
- Ciguatoxin;
- Mushroom toxins;
- Shellfish toxins:
    - Paralytic shellfish poisoning (PSP);
    - Diarrhoeic shellfish poisoning (DSP);
    - Neurotoxic shellfish poisoning (NSP);
    - Amnesic shellfish poisoning (ASP);
    - Pyrrolizidine alkaloids;
    - Phytohaemagglutinin.

Added chemicals:

- Polychlorinated biphenyls (PCBs);
- Agricultural chemicals:
    - Pesticides;
    - Fertilizers;
    - Antibiotics;
    - Growth hormones;
- Prohibited substances:
    - Direct;
    - Indirect;
- Toxic elements and compounds:
    - Lead;
    - Zinc;
    - Cadmium;
    - Mercury;
    - Arsenic;
    - Cyanide;
- Food additives;
- Vitamins and minerals;

- Contaminants:
  - Lubricants;
  - Cleaners;
  - Sanitizers;
  - Coatings;
  - Paints;
  - Refrigerants;
  - Water or steam treatment chemicals;
  - Pest control chemicals.

From packaging materials:

- Plasticizers;
- Vinyl chloride;
- Printing/coding inks;
- Adhesives;
- Lead;
- Tin.

Physical hazards

Physical Hazards

Foreign materials such as glass, metal or plastic are physical hazards in food that can cause illness and injury to consumers. These physical hazards can result from contamination and/or poor practices at many points in the food chain from harvest to consumer, including points within the food establishment.

Examples of physical hazards are (source: FAO, Food quality and safety systems training manual):

Material	Injury potential	Sources
Glass	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, light fixtures, utensils, gauge covers, etc.
Wood	Cuts, infection, choking; may require surgery to remove	Field sources, pallets, boxes, building materials
Stones	Choking, broken teeth	Fields, buildings
Metal	Cuts, infection; may require surgery to remove	Machinery, fields, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking	Improper processing
Plastic	Choking, cuts, infection; may require surgery to remove	Packaging, pallets, equipment
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

Worksheet 12-3 is a checklist of questions which might help the team to be as thorough as possible in considering the hazards associated with the company's process.

The second step in performing a hazard analysis is to identify preventive measures that could be used to control each hazard. **Worksheet 12-4** can be used to go through the process systematically, identify the hazards which might occur at each step in the process and the measures which can be used to prevent, eliminate or reduce each hazard to an acceptable level. The worksheet can be used together with the checklist.

12.4.2 Principle II: Identify the critical control points

Identify the critical control points

For each food safety hazard that is likely to occur, a preventive measure must be identified at a point or points in the process where these preventive measures should be applied.

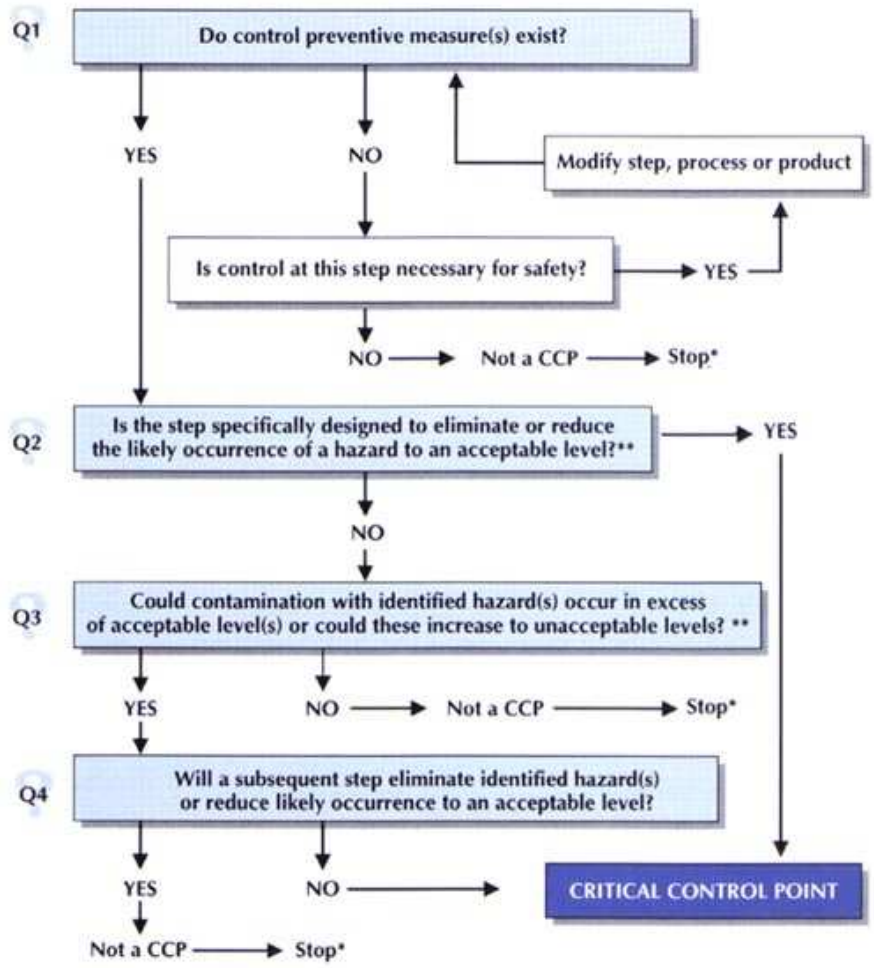

Figure 2: Decision tree to identify critical control points (source: Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application)

Some critical points where control can be applied in the process include (source: American Meat Institute Foundation):

- Chilling to exact temperatures;
- Cooking to specific temperatures with exact times;
- Product formulations, such as the addition of cultures or adjustment of pH or water quality;
- Processing procedures such as filling and sealing cans;
- Etc.

12.4.3 Principle III: Establish critical limits for each critical control point

Establish critical limits for each critical control point

Principle III requires the HACCP team to establish critical limits at each CCP. Critical limits are defined as criteria that separate acceptability from unacceptability (source: FAO, Food quality and safety systems training manual).

The critical limits should meet requirements of government regulations and/or company standards and/or be supported by other scientific data. In some cases, food control regulatory authorities provide information with which to establish the critical limits based on known food hazards and the results of risk analysis.

Examples of critical limits are:

- The time and temperature requirements for thermal processes such as pasteurization, cooking, retorting;
- The minimum internal temperature to which products must be cooked;
- The time which may elapse while a product is being cooled to a specific temperature;
- The maximum number and size of physical contaminants and, chemical residues.

There are two types of critical limits (source: American Meat Institute Foundation):

A critical limit can be an *upper limit* where a set amount or level cannot be exceeded.

A critical limit can also be a *lower limit* where a minimum amount is required to produce the safe effect.

To address the hazard of metal fragments from the grinding equipment ending up in the ground product the *upper* critical limit for the preventive measure could be no sharp metal fragments more than 1 mm should be part of the grinding equipment.

A grinding room temperature of 18 °C to help control pathogen growth, is another kind of *upper* critical limit. An example of a *lower* critical limit would be the addition of an acidifier with a given minimum concentration to inhibit bacterial growth. **Worksheet 12-5** can be used for the hazard analysis.

12.4.4 Principle IV: Establish monitoring procedures

Establish monitoring procedures

The purposes of monitoring include the following (source: FAO, Food quality and safety systems training manual):

- To measure the performance level of the system's operation at the CCP (trend analysis);
- To determine when the performance level of the system results in a loss of control at the CCP, e.g. when there is deviation from a critical limit;
- To establish records that reflect the performance level of the system's operation at the CCP to comply with the HACCP plan

Monitoring procedures are carried out routinely, either by employees or mechanically. They include monitoring by employees such as checking documentation accompanying incoming materials and records from equipment, such as recording thermometers. Continuous monitoring is always preferred when it is feasible.

Examples of monitoring equipment include:

- Thermometers;
- Clocks;
- Scales;
- pH-meters;
- Water activity meters;
- Chemical analytical equipment.

Equipment should undergo periodic calibration as necessary to ensure accuracy. However, the variability of the equipment should be considered when setting the critical limits.

Monitoring procedures need to be well planned and effective because of the potentially serious consequences of loss of control. Employees monitoring HACCPs should be trained in the technique to be used to monitor each preventive measure or control. They should fully understand the purpose and importance of monitoring and accurately report monitoring activities and results. They must have complete access to the CCP being monitored and to the process-monitoring equipment in use (source: American Meat Institute Foundation).

The team can use **Worksheet 12-6** to help them decide on monitoring procedures and their frequency.

12.4.5 Principle V: Establish corrective actions

Establish corrective actions

The Codex guidelines for application of the HACCP system define deviation as "failure to meet a critical limit". Procedures should be put in place to identify, isolate and evaluate products whose critical limits are exceeded.

As deviations from critical limits will occur, the company needs to have a plan to make sure these deviations do not result in unsafe products. The manufacturer's corrective action programme should include the following:

- Investigation to determine the cause of the deviation;
- Effective measures to prevent recurrence of the deviation;
- Verification of the effectiveness of the corrective action taken.

The HACCP team needs to devise a standardized set of actions that company employees will follow when there is a deviation from a critical limit. The following questions will help in developing effective corrective actions (source: American Meat Institute foundation):

- How will people be informed when the deviation occurs? If a person is performing the monitoring procedure, who will that person contact?
- Who will be responsible for controlling the product that may have been affected by the deviation? How should that person decide how much product needs to be controlled?
- Who will be involved in deciding what to do about the product which might have been affected by the deviation?
- Once it has been figured out what was the cause of the deviation, who will be involved in deciding how to get the process back in control and prevent recurrence of the deviation?
- Who will be responsible for keeping the records of everything the company does in response to a deviation from a critical limit at this CCP?
- If any person who has a responsibility in the corrective action plan is not available, who will be the back-up?

Worksheet 12-7 helps the HACCP team make sure they have developed appropriate corrective actions for each CCP.

12.4.6 Principle VI: Establish verification procedures

Establish verification procedures

The Codex guidelines define verification as "the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan". Validation, verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine whether the HACCP system is working properly.

Verification uses methods, procedures or tests in addition to those used in monitoring to establish whether the HACCP system is in compliance with the HACCP plan or whether the HACCP plan needs modification. There are three types of verification (source: American Meat Institute Foundation):

Validation is the initial phase in which the plan is tested and reviewed. The selected monitoring measures must be tested and their suitability for preventing or controlling identified hazards under real process conditions must be demonstrated.

In this phase, microbial or residue testing can be used effectively to verify by cross checking that the process is in control and is producing acceptable product. Such testing provides clear evidence that the techniques and methods adopted by the plant to control hazards are not just effective in theory but will work in *this* specific plant.

Ongoing verification ensures that the HACCP plan is working effectively on a day-to-day basis. This includes tasks like calibrating monitoring instruments, observing monitoring activities and reviewing HACCP records.

Auditing is an overall review of the plan that must be performed at least annually, or whenever any changes occur that could affect the hazard analysis or alter the HACCP plan.

12.4.7 Principles VII: Establish record keeping procedures

Establish record keeping procedures

Effective records help to document the measures of the HACCP plan and the effectiveness of the system.

The best record keeping system is usually the simplest one that can be easily integrated into the existing operation. One way to approach development of the record keeping requirements of the HACCP system is to review the records the company already keeps and see if they are suitable, in their present form or with minor modifications, to serve the purposes of the HACCP system.

The following list shows the records a company will have to develop (source: FAO, Food quality and safety systems training manual):

RECORDS GENERATED BY THE HACCP SYSTEM

Monitoring records for all Critical control points:

All HACCP monitoring records should be kept on forms that include the following information:

- Form title;
- Time and date;
- Product identification (including product type, package size, processing line and product code);
- Critical limits;
- Monitoring observation or measurement;
- Operator's signature or initials;
- Corrective action taken, where applicable;
- Reviewer's signature or initials;
- Date of review.

Deviation and corrective action records:

- Identification of the deviant lot/product;
- Amount of affected product in the deviant lot;
- Nature of the deviation;
- Information on the disposition of the lot;
- Description of the corrective action.

Verification/validation records

- In-house on-site inspection;
- Equipment testing and evaluation;
- Accuracy and calibration of monitoring equipment;
- Results of verification activities, including methods, date, individuals and/or organizations responsible, results or findings and action taken.

DOCUMENTATION OF METHODS AND PROCEDURES USED:

The manufacturer should maintain records of the methods and procedures used in the HACCP system. Examples include:

- Description of the monitoring system for the critical limit of each CCP, including the methods and equipment used for monitoring, the frequency of monitoring and the person performing the monitoring;
- Plans for corrective actions for critical limit violations or situations resulting in potential hazards;
- Description of record keeping procedures, including copies of all record forms;
- Description of verification and validation procedures.

RECORDS OF EMPLOYEE TRAINING PROGRAMMES:

- Records of all employee trainings

Review of records can be instrumental in identifying trends and in making operational adjustments. Timely corrective action can be taken if a critical limit is violated.

Records do not need to be in any particular format. **Worksheet 12-8** is an example of a blank HACCP plan form. **Worksheet 12-9** is a list of some typical records of an HACCP system in operation.

12.5 HACCP and cleaner production

The increasing globalization of trade in the food sector requires that food safety standards (e.g. HACCP), quality and environmental standards (e.g. ISO standards) be met in order to compete in the world marketplace. There is increasing pressure to make the necessary changes to comply with these standards or risk losing access to export markets, and face further economic decline. On the whole all these standards are beneficial to the environment.

HACCP as a safety system should operate in partnership with quality systems and cleaner production. HACCP contributes to understanding risks to the quality of food products and prevention of damage by corresponding measures. Quality management, food safety and cleaner production systems can work synergistically to identify options for improvement in all three areas. Principle 1 of HACCP corresponds with a cleaner production audit procedure (identification of risks in HACCP and identification of areas of loss in CP), the principles 2 to 7 have a strong similarity with the establishment of the plan-do-check-act cycle of an environmental management system according to ISO 14001.

Cleaner production can help industries to comply with food standards such as HACCP by providing tools to optimize the performance of cleaning steps, refrigeration or heating. Tendencies in the health sector are to consider CP approaches in order to minimize vector-borne diseases. CP strategies are also being considered in the search for sustainable solutions to the growing problem of waste volumes, the acute water problem, high post harvest losses and increasing volumes of construction waste.

12.6 Literature and links

American Meat Institute Foundation. HACCP: The Hazard Analysis and Critical Control Point System in the Meat and Poultry Industry. Washington, D.C., 1994.

Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application [Annex to CAC/RCP 1-1969, Rev 3 (1997)]

Notermans, S., et al. The HACCP Concept: Identification of Potentially Hazardous Microorganisms. Food Microbiol. 11:203-214, 1994.

Pierson, M.D. and Corlett, D.A., Jr. Editors. HACCP Principles and Applications.

Stevenson, K.E. and Bernard, D.T. Editors. HACCP: A Systematic Approach to Food Safety. 3rd Edition. The Food Processors Institute, Washington, D.C., 1999.

Van Nostrand Reinhold, New York, 1992.

FAOs official training manual:
http://www.fao.org/docrep/W8088E/W8088E00.htm

good hygiene practices:
http://www.fao.org/docrep/006/y5307e/y5307e00.htm