This lecture will highlight some aspects of Good Manufacturing Practices, which are prerequisites for the establishment and implementation of a HACCP plan. The basic document is the Codex text General Principles of Food Hygiene.

As it is impossible to deal with all aspects of Good Manufacturing Practice in a single lecture, a visit to a food production or service establishment is highly recommended.

Although the term "GMP" is often used to describe "Good Hygienic Practices", GMP also deals with other practices that have a bearing on a product's safety and suitability.
Good Manufacturing Practices (GMP)

That combination of manufacturing and quality control procedures aimed at ensuring that products are consistently manufactured to their specifications

IFST (UK)

Many codes of GMP include hygiene-related rules for manufacturing a certain type of product, known as codes of Good Hygienic Practices. They may contain specifications related to the safety of food, such as recommended or prescribed time/temperature relationships of pasteurization, sterilization etc.

GMP codes are often branch-specific: for example, for the production of chocolate bars, milk powder, chilled food.
Good Hygienic Practices (GHP)

All practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain

(Based on the Codex definition of Food Hygiene)

This definition is based on the Codex definition for food hygiene (General Principles of Food Hygiene), and includes the words "safety" and "suitability." These concepts will be discussed in more detail.

The expression "all stages of the food chain" is important. GHP must be applied from “farm to fork”, “from stable to table”, “from plough to plate” to be effective.
The Codex General Principles of Food Hygiene spells out the principles which are essential for food safety and suitability.

Clearly, many things are done in the manufacturing or preparation of food which will not be found in any code. Codes can be viewed as a listing of minimum requirements which food operators have to apply to achieve defined goals and to assure fair trade.
Food safety

Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use

Codex 1997

This definition acknowledges that the consumer has a role to play in assuring the food safety. The word "harm" refers to foodborne diseases caused by microorganisms or adverse effects caused by chemicals; it also includes injury caused by bones, stones and other objects in the food.
A food is suitable for consumption if people can eat it without having an adverse reaction. Eating a spoiled food does not always result in food poisoning. Some people regard certain spoiled foods -- e.g. cheeses, hung birds, fermented fishes -- as a delicacy, and consider them to be suitable for consumption.

The introduction of the term "suitability for consumption" has widened the use of the word "hygiene."
Contaminant

Any biological or chemical agent, foreign matter, or substances not intentionally added to food which may compromise food safety or suitability

Codex 1997

Codes often use the word "contamination." A contaminant is an agent, foreign matter or substance not intentionally added to food. Thus, starters used in fermentation are not contaminants. A holding stick added to a piece of ice-cream is not a contaminant; a wood splinter accidentally fallen into a piece of ice cream is.
Contamination

The introduction or occurrence of a contaminant in a food or food environment

"Contamination" refers to the presence of an agent in a food or food environment, and to the act of introducing a contaminant to a food or food environment.

Good Hygienic Practices prevent the introduction of contaminants. Codes should describe where or when contaminations can occur, and how they can be prevented or controlled.

Good Hygienic Practices should also ensure the elimination, or reduction to acceptable levels, of contaminants in the raw materials, intermediate foods or line and line environments. Often, such points will be singled out and incorporated in HACCP plans, as will be later discussed.
Cleaning

The removal of
soil, food residue, dirt, grease
or other objectionable matter

Codex 1997

Cleaning is a very important aspect of GHP. Soil, food residues, dirt, dust, waste, used packaging material etc. may harbour microorganisms and, left uncontrolled, the conditions in the food environment may allow unacceptable growth.

Grease, lubricants, insects, loose objects and other objectionable matter must be kept out of the food to prevent it from becoming unsuitable for consumption.

There are many cleaning methods; all involve the removal of unacceptable matter.
Disinfection

The reduction, by means of chemical agents and/or physical methods, of the number of microorganisms in the environment, to a level that does not compromise food safety or suitability.

Once a surface has been cleaned it may be disinfected, using chemical disinfectants, heat or other physical means such as ultra-violet radiation.

Since some microorganisms remain even after disinfection, this definition uses the words "reduction to a level that is acceptable", the level at which neither food safety nor suitability is compromised.
The Codex document is very general. The hygienic provisions described apply from farm to fork. Many details are specific to the food industry but the wording is general so they can also be applied to catering establishments, institutional kitchens etc.

In an attempt to make the text more meaningful, branch specific codes have been developed. These codes are still limited to general statements; the reason for this is that regulations or codes should not be prescriptive, and Codex serves as an example to national governments on preparing simple, clear and uncomplicated, non-prescriptive rules and regulations.

The specific details, particularly those referring to the safety aspects of the production or preparation of food, must be prescribed in the HACCP plan.
Areas examined under GHP

1. Primary production
2. Establishment: design and facilities
3. Control of operation
4. Establishment: maintenance and sanitation
5. Establishment: personal hygiene
6. Transportation
7. Product information and consumer awareness
8. Training

The Codex document discusses the areas listed above. These are discussed in more detail in the following slides.
Primary production

Hygienic practices should reduce the likelihood of introducing hazards that may be difficult or impossible to control at later stages of the food chain.

Examples: pesticides, antibiotics, mycotoxins, microorganisms in foods eaten raw or fresh.

Precautions to prevent contamination should begin at the farm, the pond, the sea or wherever the food is produced or gathered.

Man-made chemicals are used to increase production yield, to keep the animals or the crop healthy, or to improve their quality. The residue levels depend on the choice of chemicals, how they are used, and on the length of time between the application of the chemical and harvesting, collecting, milking, slaughtering etc.

The environment in which the food is produced is often crucial. Shellfish grown in polluted estuaries may contain harmful microorganisms, which may not be removed during subsequent treatments, resulting in a potential hazard when eaten raw. Organic fertilizers used on crops for human consumption may be a source of microbiological hazards such as *Salmonella* and *E. coli* O157:H7.
Establishment: design (1)

Premises, equipment, surfaces and facilities should be located, designed and constructed to ensure:

- minimum contamination
- proper maintenance, cleaning, disinfection
- protection against pests

Clearly, establishments should be designed to prevent contamination of the final product. The same is true for equipment, surfaces coming in contact with food etc.

Since pests are important sources of microbiological contamination, pest control must be taken into account in the design and layout of the factory and other premises.

Establishments should be properly maintained, and design, construction and layout should allow easy cleaning.
Establishment: design (2)

Evaluation of the premises takes into account:

- Location
- Equipment
- Facilities: water
  - air
  - lighting
  - storage

Establishments should not be located in environmentally polluted areas, areas subject to flooding, prone to infestations, or where wastes cannot be removed effectively.

Water should be of potable quality, personnel facilities and toilets should ensure adequate hygiene levels, and have adequate drainage and waste disposal.

Temperature control should be adequate. Air quality and ventilation should control humidity and prevent product contamination.
This slide shows two examples of good and bad hygienic design of equipment.

They demonstrate that hygienic design does not need to be ingenious; it has to do with hazard anticipation. The design should allow easy access and minimize the build-up of hard-to-remove residues.
It is not uncommon that tanks have been installed in an incorrect manner.

1) Unsatisfactory location of pump and motor resulting in restricted access to pump face-plate for cleaning and maintenance.

2) Insufficient ground clearance to allow easy cleaning under pump and motor base plate.

3) Siting of the pump motor and its electrical terminal housing may result in a hazard from contamination with spillage of product, water or condensation running down the tank wall.

Better solutions exist such as shown here. Sufficient clearance and accessibility are the key to efficient and effective cleaning.
Establishment: practice

- "Good housekeeping" applies to the surroundings and the roof of the establishment
- Pest control starts at the boundaries of the premises
- Water management deals with incoming and used water
- Windows are closed or screened
- Internal surfaces are smooth and easy to clean
- Floors have rounded corners
- Ceilings and ducts are accessible for cleaning

This overhead and the next one mention a few practical aspects of hygiene of establishments.

Many more Good Hygienic Practices could be mentioned here, but time does not allow us to go into more detail.
Establishment: practice (cont.)

- Dry zones are designed to remain dry
- Drains can be cleaned
- Cable trays carry cables, not dirt or dust
- Insectocuters are effective
- Only potable water is in contact with food
- Air handling systems deliver the required air quality (and not contaminants)
- Doors are closed when not used
Control of operation

- Control of food hazards through HACCP
- Hygiene control:
  - Time & temperature
  - Humidity
  - (Cross) contamination
  - Microbiological specifications
- Incoming materials (incl. packaging materials)
- Water, air, steam
- Management, documentation, recall procedures

No operation can be considered to be under control if there is not a proper management system and if operations are not documented and recorded.
Control : practice

➢ Keep potentially contaminated materials separated from uncontaminated ones
➢ Assure effectiveness of treatments
➢ Assure effectiveness of cleaning
➢ Assure reliability of measurements, tests and recording
➢ Perform hazard analysis when changes occur
➢ Assure updating of HACCP plan

These are a few practical suggestions.
Establishment: maintenance & sanitation

**Objective**
to control possible sources of food contamination through:

- Maintenance and cleaning
- Pest control systems
- Waste management
- Monitoring

This overhead shows the objective of maintenance and sanitation and the subjects covered in this section. Some details are given in the next slides.
Maintenance

Establishments and equipment should be kept in condition to:

- facilitate sanitation procedures
- function as intended, particularly at Critical Control Points (CCPs)
- prevent contamination of food e.g. metal shards, flaking plaster, debris, chemicals, pests, dust etc.

In practice, a very important aspect of maintenance is to assure the continued effectiveness of the operations. A pasteurizer may create hazards rather than prevent them if improperly maintained. Leaking valves may lead to product contamination etc.

Preventive maintenance is thus an important aspect of Good Manufacturing Practices.
Cleaning procedures involve:

- removing gross debris from surfaces
- applying a detergent solution
- rinsing with water
- disinfection where necessary
- dry cleaning

Cleaning has already been discussed. Industrial experience has shown that in many situations dry cleaning is preferable to wet cleaning. As long as no water is available, microorganisms do not multiply. Dust itself is not a hazard if it does not carry pathogenic microorganisms. In many instances, vacuum cleaning is a much more hygienic operation than the use of water.

Cleaning is a prerequisite for proper disinfection.
Pest control

Good hygienic practices should:

- prevent pests from entering the premises
- protect food from pests
- eradicate infestations immediately
- include regular inspections

Pests are all animals that may carry contaminants into a factory environment, line environment or food, e.g. dogs, cats, birds, lizards, rats, mice and insects.

Pest control involves activities such as barrier design and maintenance, prevention of infestation and eradication programmes.

Regular inspections of production areas, warehouses, waste disposal sites etc. are necessary.
Establishment: personal hygiene

To prevent food from being contaminated by the people who come in contact with it, personnel must receive clear instruction on the following:

➤ Health status
➤ Illness and injuries
➤ Personal cleanliness
➤ Personal behaviour

Personal hygiene is also an important aspect of GMP. Personnel should be instructed on when to wash their hands, and should be taught to avoid unhygienic behaviour such as smoking, spitting, chewing and sneezing or coughing over unprotected food. Jewelry should not be worn if it could drop into the food.

Medical examination of a food handler should be carried out only if it is clinically or epidemiologically indicated. However, any person who may be suffering from a disease or illness, or visibly infected skin lesions (boils, cuts etc.) should not be allowed to enter any food handling area.
Transportation

Measures should be taken to:

➢ protect food from:
  i) contamination sources
  ii) damage likely to render the food unsuitable for consumption

➢ provide an environment which controls the growth of pathogenic or spoilage microorganisms and the production of toxins in food

This slide outlines the requirements for hygienic transport. In addition, where appropriate, particularly in bulk transport, containers and conveyances should be designated and marked for food use only.
Product information and consumer awareness

- Lot identification
- Product information
- Labelling
- Consumer education

Products should bear appropriate information to ensure that adequate and accessible information is available to enable the next person in the food chain to handle, store, process, prepare and display the product safely and correctly, and that the lot or batch can easily be identified and recalled if necessary.

The label is an important source of information to the consumer. However, to allow him to make the appropriate choices and to make or keep his food safe, the consumer should get more information than is normally found on the label.
Consumers should know enough about food hygiene to be able to:

- understand the importance of product information
- make informed choices appropriate to the individual
- prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using it correctly

Insufficient product information, and/or inadequate knowledge of general food hygiene can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness, or in a product becoming unsuitable for consumption, even where adequate hygiene control measures have been taken earlier in the food chain.
Training

➢ Awareness and responsibilities
➢ Training programmes
➢ Instruction and supervision
➢ Refresher training

Training is fundamental to any food hygiene system, and should extend to all people involved in food related activities.
Key messages

- Good Manufacturing Practices are the basis of the production and preparation of safe food
- Good Hygienic Practices deal with safety and suitability requirements to be followed world-wide
- Each food operation should adapt existing codes to their specific set of conditions
- They should also decide which practices are critical for the safety of a product and thus have to be included in the HACCP plan

In conclusion, here are a few key reminders related to Good Hygienic Practices.
This lecture discusses the HACCP system and its application as presented by Codex Alimentarius.
Codex HACCP system and guidelines for its application

> HACCP can (should) be applied from the primary producer to the final consumer

> HACCP enhances food safety, makes better use of resources, enables more timely response to problems

> HACCP can aid official inspection and promote international trade by increasing confidence in food safety

    > Codex Alimentarius 1995

The Codex has accepted the HACCP system as the primary tool to ensure the safety of foods. It recognizes that HACCP can be applied from the primary producer to the final consumer. It will become clear, however, that HACCP should be applied from farm to fork to be effective.

Hazards are only food safety hazards, and only control points that are critical to assure the safety of a food should be called Critical Control Points.

Codex recognizes that HACCP is an important tool in the international trade in food and that it will help official inspectors to do their job.
Codex HACCP principles and guidelines

The "Principles" set the basis for the minimum requirements for the application of HACCP. The "Guidelines" provide general guidance.

Codex differentiates between the principles of HACCP and the guidelines for their application. The principles should be considered as fundamental requirements; the guidelines suggest ways to apply these principles. This allows sufficient flexibility to apply HACCP principles at all levels of the food chain (from farm to fork), and in food establishments of various sizes and sophistication.
Codex HACCP principles

1. Conduct a hazard analysis
2. Determine the CCPs
3. Establish critical limit(s)
4. Establish a monitoring system
5. Establish corrective actions
6. Establish verification procedures
7. Establish documentation

(Definitions are given for all important terms)

This overhead shows the 7 HACCP principles. The Codex definitions of important terms will be given in the course of this lecture. The language used in the description of the principles indicates that the application of the HACCP concept needs a careful study of the production or preparation of food and that a number of decisions have to be made.

Monitoring, taking corrective actions, verification and recording are the real "shop floor" activities which are carried out in practice in order to achieve food safety.
How to do HACCP (1)

- HACCP study
- HACCP plan
- Training the personnel
- Implementation of the plan
- Verifying and improving

The 5 stages in developing and implementing HACCP are:
1. Perform a HACCP study during which the elements of the HACCP system in line with the 7 principles of HACCP are established
2. Develop a HACCP plan. This is a document that reflects the results of the study
3. Train personnel in their functions as determined by the HACCP plan
4. Implement the HACCP plan i.e. monitoring, taking corrective actions and verification
5. Verify the HACCP plan

How to do HACCP (2)

* Commitment of management
* Training in HACCP
* Resources expertise, equipment, etc.

Naturally, before attempting to do HACCP, management support and commitment are needed. In addition to the final costs necessary for training there may be also additional costs for acquiring necessary expertise, or equipment and material. It is important that such resources are available.
Codex HACCP guidelines

1. Assemble HACCP team
2. Describe product
3. Identify intended use
4. Construct flow diagram
5. Confirm on-site flow diagram
6. List all potential hazards, conduct a hazard analysis and consider control measures
7 - 12. Apply principles 2 - 7

The Codex guidelines describe how a HACCP study could be performed. These guidelines give a certain universal structure to a study, which will make it more likely to be accepted by other parties (food inspectors and trade partners). However, the 7 principles should be applied taking specific conditions of size, sophistication of the processes and the level of the food safety management system into account.
To perform a HACCP study, a HACCP team has to be assembled. A leader knowledgeable in HACCP should be appointed as well as a secretary. Documenting the HACCP study is a very important aspect of the exercise. Experts in quality assurance, microbiology, chemistry, food technology etc. will be needed in complicated food production or preparation lines. Often, other experts, e.g. on logistics, agricultural practices etc., may be needed to complete the study. To keep the study manageable, it is important to define its scope and set priorities.
(2) Describe product

- Formulation and composition
  Raw materials & ingredients
  Parameters influencing safety
- Processing
- Packaging
- Distribution

One of the first activities of the study team is to describe the product. Which raw materials and ingredients are used, and who are the suppliers. Which parameters influence safety (pH, $a_w$, modified atmosphere packaging, storage temperature and time etc.)? What are the processing conditions, temperature treatments etc.? How is the packaging performed, and what are the characteristics of the packaging material? What are the real conditions during distribution, warehousing and sales?
(3) Identify intended use

- Food service establishments
- Caterers
- Hospitals
- General population
- Specific groups of the population
- Preparation practices
- Exportation

Next, the intended use of the product has to be defined, because this may influence the level of safety to be assured, or the risks which can be taken. If the product is to be sold to hospitals or groups of the population with high susceptibility to certain microbes, more safety has to be built in and critical limits need to be more strict.

The use and preparation practices may also influence the safety of a product. HACCP is successful only if applied from farm to fork. For certain products such as hamburgers, the preparation practices determine the final safety for the consumer. For certain bacteria, such as *Salmonella*, contamination of the raw material (i.e. meat) at the agricultural level cannot be prevented. Thus, if the processing does not include any killing step, the only CCP which can render the product safe is the adequate heat treatment during preparation.
(4) Construct flow diagram

Cover all steps which might have an influence on the safety of the product

- Include important data such as time & temperature
- Indicate hygiene level of areas and barriers

To understand how a product is manufactured, and to have a disciplined approach in the study, it is important to construct a flow diagram covering all steps where product safety could be affected. In order to do this all information which should be looked at, should be gathered. Temperatures in heat treatments should be mentioned as well as time; time and temperature should also be mentioned for holding the product in buffer tanks, holding vats etc.

In many food production and preparation establishments, different areas or rooms have different hygiene levels, and barriers, such as walls or air curtains separate them. For instance, all Good Manufacturing Practices require a clear separation between raw materials and prepared foods. For the same reason, it is important to indicate on the diagram or factory layout sheet, the personnel movements.
(5) On-site confirmation of flow diagram

- Check correctness of information
- Check whether important information was not overlooked
- Check during all periods of operation and cleaning, but also during idle hours
- Discuss practices with operators

Up to this point, the study is a paper exercise. Clearly, what has been put on paper should be confirmed by an on-site inspection. This should check the correctness of the information and ensure that nothing crucial was overlooked. It is important to inspect the site and the practices applied during all hours (night shifts, weekends etc.) of operation, as well as the idle hours. Inspection of the cleaning procedures and validation of their efficacy are very important. Operators often are better informed than Chief Engineers or Production Managers about practices and the problems encountered during the operation, and may have information about problems that were not considered in the study.
(6) List all hazards associated with each step, conduct a Hazard Analysis, consider any measures to control identified hazards

This activity will be described in detail during the next lecture.
Hazard

A biological, chemical, or physical
agent in, or condition of, food
with the potential
to cause an adverse health effect

Codex alimentarius, 1997

The word "hazard" has a particular meaning in the HACCP concept. It refers to something which is unacceptable because it may cause harm to the consumer. This "something" can be a biological, chemical or physical agent in a food. It can also be a feature or condition of a food. For instance, if a food permits the growth of an infectious agent (a "pathogen"), and if the food is not refrigerated properly, such a condition is a hazard.

Examples of hazards are certain microorganisms or their toxins, carcinogens, pesticides, hormones, antibiotics, heavy metals and other harmful agents when present in unsafe levels, stones, bones, glass etc. The notion that not all levels (or sizes) are unsafe is very important.
Hazard Analysis

The process of collecting and interpreting information on hazards and conditions leading to their presence to decide which are significant for food safety and should be addressed in the HACCP plan.

This overhead gives the Codex definition of Hazard Analysis.
Control measures

Actions and activities
that can be used
to prevent or eliminate
a food safety hazard
or reduce it to an acceptable level

After hazards have been identified, control measures have to be envisaged. The Codex definition presented here speaks for itself.
Control

To take all necessary actions
to ensure and maintain compliance with
established criteria established in the HACCP
plan *(verb)*

The state wherein correct procedures are
being followed and criteria are being met
*(noun)*

It is important to understand that the word "control" is used both as a verb and a noun. As was already explained, it never is used in the sense of testing or checking. It always refers to having things under control, or to bringing things under control.
When to perform a Hazard Analysis

- during product development
- during industrialization of new product
- when new hazards emerge
- when new raw materials are used
- when formulation or use is changed
- when equipment is changed
- with new (layout of) production area
  etc.

The HACCP system is very dynamic. During a HACCP study, only the existing situation, or the situation as it is expected to exist can be taken into account. Every change can introduce a new hazard; thus, every change has to induce the "hazard analysis reflex". It should be understood that once a HACCP Plan has been established, it needs continuous "maintenance". Every new raw material may bring a new hazard. A change in pH, due to the introduction of a new ingredient may create a new hazard. Using the line for which the HACCP plan was developed for the production of another product may introduce hazards. Hazard analysis has to be performed when epidemiological evidence becomes available concerning new, emerging, hazards.

Many differences exist between a pilot plant and the actual production unit. Potential new hazards have to be analysed during and directly after industrialization.

This continuous adaptation of the HACCP plan is one reason for not recommending HACCP certification.
(7) Determine CCPs

*Critical Control Points (CCPs)*

*can be related to:*

- Raw materials,
- Locations,
- Processes,
- Procedures,
- Practices,
- Product formulations etc.

Hazards are controlled at CCPs. CCPs can be raw materials, locations, processes, procedures, practices, product formulations etc. This again will become clear from the explanations given in the next lecture.
A Critical Control Point is a step at which control can be applied, and is essential to prevent or eliminate a hazard. In this definition the word "step" is used, a term which is defined in the next overhead.
This definition makes clear that the Codex recognizes that HACCP has to be applied from farm to fork. For instance, veterinary drug residues can be controlled only at the farm. Salmonellae in meat can presently not be adequately controlled at farm level, and have to be controlled either by irradiation and/or by food handlers during preparation.
(8) Establish critical limits for each CCP

Critical limits can be:

- Values of: pH, a_w, temperature, time
- Maximum residue limits
- Maximum levels (of contaminants)
- Limits in microbiological criteria
- Level of cleanliness
- Levels of chlorine, overpressure etc.

To assure that hazards are properly controlled, critical limits have to be defined. These limits set the levels at which certain agents become unacceptable. Sometimes critical limits are set by the operator, sometimes they are fixed by health authorities.
Critical limit

A criterion which separates
acceptability
from
unacceptability

The correct definition leaves no room for misinterpretation. Somewhere, there is a level at which things are unacceptable. The definition is simple, the decision concerning what is acceptable and unacceptable is usually not simple at all.
(9) Establish a monitoring system for each CCP

* the method or equipment to be used
* the moment and / or frequency of checking
* the interpretation of the results and the actions to be taken

Clearly, the effectiveness of control measures has to be checked or, in HACCP terminology, to be monitored. At each CCP, a monitoring system has to be defined. This includes the method or equipment to be used, the moment when control has to be checked (for instance at the start up of production or at the end of production); often, the frequency of the checking also has to be defined. The operators in the line should not be allowed to make their own interpretation of the results. The interpretation has to be clearly described, as well as the actions to be taken.
Monitor

The act of conducting a planned sequence
of observations or measurements
of control parameters
to assess whether a CCP
is under control

Again the Codex definition leaves no room for misunderstanding.
(10) Establish corrective actions

Corrective actions should ensure

that only safe products

reach the consumer

Various corrective actions may be necessary. There is still some ambiguity in the use of the terminology "corrective actions," but the final result should be that only safe products reach the consumer.
Corrective actions

Actions to be taken when
the results of monitoring at the CCP
indicate a loss of control

For completeness; the Codex definition is given in this overhead.
(11) Establish verification procedures

Verification procedures are intended to check the effectiveness of the HACCP system

Obviously, it is necessary to obtain evidence that the HACCP system is really working. For this purpose, verification procedures have to be established.
Verification

The application of methods, procedures, tests and other evaluations in addition to monitoring, to determine compliance with the HACCP plan.

This overhead shows the Codex definition of verification. This subject will be discussed in another lecture.
(12) Establish record keeping and documentation

- Minutes of HACCP study meetings, decisions made and their reasons
- Records of monitoring
- Records of verification
- Records of deviations and corrective actions
- Records of modifications to the HACCP plan

An important difference between GMP requirements and HACCP is that the HACCP system requires extensive documentation. Examples are given in this overhead. Usually, the documentation of GMP and its application is not this detailed.
The term "HACCP plan" has been used several times. The Codex definition describes what a HACCP plan is. It indicates what needs to be done, when and where. It is the basis of documentation which can be shown to food inspectors and auditors. Normally, a flow sheet with CCPs is attached. It is the result of a HACCP study, it is specific to a production site and product, and must be rigorously implemented. Since the HACCP plan is specific, each change, and its potential impact on safety, should be studied and the HACCP plan modified when necessary. The results of a HACCP study are also presented in a condensed form in a HACCP data sheet.
### HACCP data sheet

<table>
<thead>
<tr>
<th>Raw Materials</th>
<th>Hazards</th>
<th>Control Measures</th>
<th>CCP Parameters</th>
<th>Critical Limits</th>
<th>Target Values</th>
<th>Monitoring Procedures</th>
<th>Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process step</td>
<td>Hazards</td>
<td>Control Measures</td>
<td>CCP Parameters</td>
<td>Critical Limits</td>
<td>Target Values</td>
<td>Monitoring Procedures</td>
<td>Corrective Actions</td>
</tr>
</tbody>
</table>

This sheet lists all CCPs and their associated hazards, the control measures, the parameters assuring the control, the critical limits and target values which need to be monitored, as well as the monitoring procedures and the corrective actions. This data sheet gives auditors and inspectors a quick insight into the decisions made during the HACCP study. The monitoring data can be used to evaluate the control exercised over the hazards during a longer period of time. This provides the evidence that safe products were consistently produced. Checking the list of deviations and corrective actions taken will provide evidence that only safe products reached the customer or consumer.

The Codex data sheet is not used here because it is rather meant for governmental use, whereas this HACCP data sheet is a tool for industry.
Finally, a few useful tips are given here.

* Use disciplined approach
* Don’t make assumptions
* Challenge beliefs
* Discuss non-hierarchical
* Don’t rush
* Set deadlines for comments
* Keep accurate records
* Teamleader should moderate, not dominate
Key messages

➢ The HACCP system consists of 7 Principles
➢ The Codex terminology should be used to prevent misunderstanding
➢ The Guidelines provide an optional framework for HACCP studies
➢ Hazard Analysis should be performed when significant changes are made
➢ Records should be kept to demonstrate correctness of application and implementation
This lecture will discuss some of the most difficult aspects of HACCP.
Hazard Analysis

The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and should be addressed in the HACC P plan

(Codex Alimentarius 1997)

In the context of HACCP, the term Hazard Analysis means to collect and evaluate information on hazards. We have already explained that to prevent hazards, the conditions leading to their presence have to be evaluated. Hazards can originate from the raw materials, the line and line environment, and the personnel handling the food, but even if they enter the final product, this does not mean that their levels are dangerous. Therefore, hazard analysis is also the process of deciding whether potential hazards are significant and if they need to be controlled. Hazards and control measures are elements which are described in the HACCP plan, which will be discussed later.
Requirements of Hazard Analysis

Information needed for hazard analysis:

- the agents that could be present in the food under study
- the severity of the effects and the likelihood of their occurrence
- the levels that could cause adverse health effects
- the conditions that could lead to unacceptable levels

For instance, hazard analysis determines which agents could be present in the food under study. Epidemiological data have linked foods with particular foodborne pathogens, chemicals or physical hazards, for example: canned foods and *C. botulinum*, eggs and *Salmonella*, milk and the *Mycobacterium bovis* responsible for tuberculosis. These agents may be present in the raw material, but their levels may not be high enough to cause disease. To decide whether the presence of an agent in the raw material is a significant hazard, we have to know the levels at which it may cause disease. We also have to know which conditions can cause a pathogen to increase to an unacceptable level, the severity or magnitude of a health effect, and the likelihood of its occurrence.
Areas to consider in Hazard Analysis

- Raw materials and ingredients
- Product formulation
- Processing conditions
- Packaging
- Storage and distribution
- Preparation and use
- Target groups

Potential hazards can be present in raw materials and in ingredients, or may be introduced or increase during processing. A product formulation may allow a pathogen to multiply to unacceptable levels, i.e. to become a significant hazard. Packaging may prevent a food from recontamination but may also create conditions favouring pathogen growth. Storage and distribution of perishable foods may create hazards; the growth of pathogens increases significantly at temperatures above 5-10°C. Foodborne illness sometimes results from improper preparation and use. Finally, the consumer's susceptibility influences the severity and the probability of occurrence of a foodborne disease. When a food product is targeted at the very young, the very old or people with certain diseases, potential hazards often become significant hazards. For instance, a healthy person normally can consume low levels of *Listeria monocytogenes* without becoming ill; for immuno-suppressed persons, these doses may be dangerous.
This decision tree can be used to determine hazards during a HACCP study. If an agent is not present in a raw material or in the line or line environment, it is not a hazard. If it is in the environment but cannot contaminate the product, it is still not a hazard. If it can contaminate the product and survive, persist or increase, it may become a hazard. This depends on whether an adequate reduction will take place later in the process or during preparation of the food prior to consumption.

These questions have to be asked at each step of the food chain, and for each agent or potential hazard. This hazard determination is very important because the results of this exercise will determine the safety of the final product. All possible hazards must be considered.
Hazard Analysis
Assessment of risk

Choice of words

- possible
- probable
- likely
- reasonably expected to occur
- acceptable / unacceptable

Evaluating the likelihood of occurrence of the hazard is the most difficult aspect of Hazard Analysis. For many raw materials it is possible that Salmonella is present, but is the presence probable or likely or reasonably expected to occur? The choice of the words is reflecting an assessment of the likelihood of occurrence which is one of the elements of the assessment of risks. Another part is the assessment of whether the reduction of a hazard is adequate, acceptable or unacceptable.
Once we have established a list of hazards and the conditions leading to them, control measures are taken at "Critical Control Points," which are identified by using decision trees. In this course, we are using the decision tree proposed by the International Life Science Institute. Other trees can be found in other texts, such as the Codex document. The questions in such trees are helpful because they bring a systematic approach to the study. Additional questions may be necessary.

The first question deals with raw materials. If the answer to question 1 is NO, then the raw material is not a Critical Control Point (no hazards have to be kept under control). If the answer is YES, the next question must be answered.

If the hazard is eliminated or reduced by a later process step, the raw material is not a CCP; for instance, if milk is pasteurized or boiled, the raw material (milk) is not a critical control point. If it is not heated before consumption, it must be considered to be a CCP. This means that measures to prevent it from becoming contaminated are necessary before using it as a raw material.
HACCP Decision Tree
Questions for each hazard and each process step (1)

Q 3. Is the formulation / composition of the intermediate or final product essential to prevent unacceptable increase of the hazard?

YES

Formulation or composition is CCP

NO
Not a CCP

This question deals with the formulation or composition of the product. It is clear that in certain products, pathogen multiplication is prevented by the pH, in others by the $a_w$ and in others by the "sterility". Fermentation of foods to make and keep them safe becomes a Critical Control Point if the fermented food is not heated before consumption. The composition can be an important aspect of a product's safety, for instance if a raw ingredient is added to a heat treated product.
Contamination or recontamination may occur at several points; control measures are needed to prevent this. If pathogen levels can increase at a certain step in the food chain, this has to be controlled at that step. However, if the hazard is reduced during further processing or preparation, (re)contamination or increase is of lower concern, i.e. the step is not a CCP for these hazards.

If the answer to question 4 is NO, then question 6 has to be answered.

If the answer to question 4 is YES, question 5 asks whether a later step of the process will render the product safe. If it will, then this step is not a Critical Control Point. But if the answer is NO (the hazard will not be removed), then recontamination and growth have to be prevented at this step.

Measures to limit recontamination and pathogen growth are needed at each process stage, but they are often not critical for product safety.
If an agent is likely to be present, and a treatment is meant to reduce it to acceptable levels, it is important that the reduction actually occurs. If the reduction is insufficient, the product can still be hazardous. Clearly, a point where such a treatment is applied is a Critical Control Point.

Question 6 refers to a process step which is designed to keep hazards under control; for example, pasteurization and sterilization, or any other treatment such as irradiation meant to kill pathogens.

The time and temperature or the radiation dose, needed to kill the bacteria should be clearly specified and applied. If the temperature is not reached or the time is too short, or the absorbed radiation dose is too low, i.e. the critical limits are not met, then the safety of the product is not ensured.
Normally, foods produced under GMP are safe

When foodborne diseases occurred, this was due to deviations from GMP, or incidents that were not detected in time

One of the problems in a HACCP study is to distinguish between a Critical Control Point and a "Normal" Control Point. Normally, foods produced according to what is called "Good Manufacturing Practices" (GMP) are safe. If this were not the case, we would simply not call those manufacturing practices "good"; furthermore, we would be ill most of the time. In most cases where foods have been incriminated in foodborne diseases, deviations from GMP occurred, or incidents happened, that where not detected in time. This means that many aspects of food production are covered by measures and controls which form part of GMP. HACCP underscores those practices, which are critical in ensuring a product's safety. It may also play a complementary role to GMP as during the HACCP study, some control measures specific to the food and line of production may additionally be identified. The documentation and record keeping concerning a CCP are more demanding than for a normal control point. Personnel should be better trained in how to detect deviations from normality and how to correct the situation promptly.
Questions for each CCP and Hazard (1)

When is deviation from normality unacceptable?
(i.e. establishment of Critical Limits)

Once we have identified the CCPs, we have to establish the parameters and the critical limits attached to them. Assuming that under normal conditions, a safe product is manufactured, the next question is to determine the extent to which deviations from normality can be allowed before the product is considered unsafe. We do this by asking for each CCP and hazard: "At what point does a deviation become unacceptable?"

We first have to define the normal procedure and identify the consequences of deviations from it. If a hazard could emerge, then we have to define when the deviation becomes unacceptable.

If a chicken is thoroughly heated, *Salmonella* and *Campylobacter* are killed. This means that the temperature inside a chicken must reach 70°C. Thus, this is the critical limit. This aspect of the HACCP study will be discussed further in the following lecture.
The next question is: How can a deviation be identified?
The internal temperature of chicken can be measured with a thermometer, or the colour of the meat can be observed. This is monitoring.

We also must determine the monitoring frequency. For chicken, monitoring starts only after it has been cooking for a while. However, in a continuous process such as milk pasteurization, monitoring is needed from beginning to end. It can be continuous; if the equipment does not allow this, the frequency must be sufficient to ensure that everything is under control.

We have to record the results in a simple and understandable form. Recording is necessary for inspection purposes and, if there are complaints, to demonstrate that everything was under control.

If no monitoring procedure exists to check control over the hazard at a CCP, such a point should not be called a CCP.
Questions for each CCP and hazard (3)

*What is the appropriate reaction to deviations?*

(i.e. description of corrective actions)

If an unacceptable deviation occurs, or if the monitoring procedures indicate that the situation is getting out of control, we need to know how to react. If the chicken meat is pink, reheating or continued heating is the corrective action. If temperature recorders indicate that the temperature in a pasteurizer is too low, the heating system should be adjusted. Any product produced while the system was out of control should be reprocessed or disposed of in another way.

Corrective actions should be described in the HACCP plan so that quick and effective action can be taken if necessary. These actions should deal not only with bringing the situation under control, but also with preventing a product produced under abnormal conditions from reaching the consumer.
Key messages

➤ Hazard analysis should be done in a systematic manner, to prevent hazards from being overlooked
➤ CCPs may be identified with the help of decision trees
➤ Existing lines normally produce safe products, based on GMP, deviations from normality have to be prevented
➤ Hazards associated with changes must be anticipated and controlled
In this lecture, we will discuss monitoring. To monitor, we need to set critical limits and determine which methods can be used to check whether a CCP is under control. If critical limits are exceeded, corrective actions have to be taken; these must be described in the HACCP plan. Monitoring is an essential element of “controlling hazards”. It has to be carried out by the person (operator) in charge of the control measure at the CCP. Review of monitoring data is to be carried out by supervisors as part of verification (to be discussed later).
Monitor

The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Monitoring means regular measuring and recording of values at predetermined intervals. These values are the parameters used to assure that a situation is under control. This means that a hazard is reduced to an acceptable level, that no unacceptable growth occurs and that unacceptable contamination is prevented.
Ideally, measurement and testing should be done continuously. An example is the continuous measurement and recording of the acidity or pH obtained during fermentation. Such a recording shows that small fluctuations always occur. This reflects the normal treatment variations. In process control terminology, we call the arithmetic mean of the values the **target level**, and two or more standard deviations determine the upper and lower control level. Under optimal conditions, there should be sufficient distance between the upper (or lower) control level and the critical limit, to ensure that the critical limit is not surpassed in normal operational conditions. This figure shows that for $a_w$ or pH in milk pasteurization, the critical limit should be lower than the lower control level.
Critical limit

A criterion which separates
acceptability
from
unacceptability

The critical limit should not be exceeded; if it is, the safety of the product cannot be assured. By definition, the critical limit separates acceptability from unacceptability in terms of risks for the consumer wherever possible.

In the future, when Food Safety Objectives (which are not going to be discussed here) are established, the Critical Limit should ensure that the products are in compliance with them.
Critical limits can be all kind of parameters. Physical parameters such as pH, a_w, temperature and time are usually preferred as they can be measured continuously and “in line”. Critical limits may also be established for other process parameters such as absorbed radiation dose, level of disinfectant or antimicrobial agents, over-pressure in heat exchanger, or over-pressure of air in a clean room. However, critical limits can also be Maximum Residue Levels for pesticides or Maximum Levels of chemicals set by Public Health Authorities and Codex Alimentarius. Also, limits in microbiological criteria of pathogens or indicators may be taken as critical limit, although they are often of little practical use.

The selection of parameters for which critical limits have to be established requires in-depth understanding of the technologies used for controlling the hazards and the processing. For instance, for chlorination of water, it is important to monitor not only the residual chlorine but also the contact time, pH and turbidity of the water.
Questions for each CCP and hazard (1)

When is deviation from normality unacceptable?

(i.e. establishment of Critical Limits)

We assume that normally a safe product is manufactured; thus, we have to establish a point at which deviation from normality is unacceptable.
Let us take the example of pasteurization of milk. Normally, the milk is heated at 73°C for 15 seconds. This temperature treatment assures that levels of pathogens such as *Mycobacterium bovis, Salmonella, Listeria monocytogenes* and *Campylobacter* are reduced sufficiently to guarantee that the product is safe. When the temperature drops a few tenths of a degree, the number of microorganisms will still be reduced sufficiently; there is a safety margin. But at a certain point, the deviation becomes too large and safety is not assured. This unacceptable deviation determines the critical limit. Milk produced with a temperature lower than the critical limit should not reach the consumer. This is an easy example because it deals with thermal treatments of known bacteria in an easy to control situation. Many other situations are less easy to control (for instance re-contamination) and determining a deviation from "normality" is much more difficult.
Corrective actions

Actions to be taken when
the results of monitoring at the CCP
indicate a loss of control

When a deviation occurs, corrective actions have to be taken. In the latest text of Codex Alimentarius, corrective actions are only those actions which are taken when a CCP is out of control; thus, when a critical limit is exceeded. In this course we will use the term "corrective action" to apply also to situations where critical limits were not exceeded, and where the corrective action was used only to make minor readjustments.
Deviation

Failure to meet a critical limit

According to the Codex terminology, deviation means an unacceptable deviation, or loss of control. To understand this, the following 3 pictures may be helpful. For the purposes of this lecture, however, the word deviation will be used for any situation which is not "normal".
The value measured here varies in a normal way around the mean or target level. The process remains in control, because neither the acidity nor the pH level reaches the upper control level.
The process is still in control, but an adjustment was needed because the pH reached too high a level, i.e. reached the upper control level.
In this case, the pH increased to exceed the critical limit. The adjustment was not made in time; this led to an unacceptable deviation and corrective action was necessary. In this case, the corrective action was not only a readjustment, but the product produced during the time that control was lost, had to be reprocessed or disposed of to prevent it from reaching the consumer.
Questions for each CCP and hazard (2)

How can this be identified?
How frequently should it be checked?
How should results be recorded?

( i.e. establishment of monitoring procedures )

With a parameter such as temperature or pH, which can be measured and recorded automatically and continuously, the questions mentioned in this overhead are easy to answer. For other situations, for instance recontamination problems, this may be quite difficult. However, HACCP requires that decisions have to be made regarding monitoring methods, frequencies and recording.
One of the most frequently used methods for monitoring is observation. Microbiological methods are often too slow to be useful. Rapid tests can sometimes be used if no other means of monitoring are available. In many situations however, physico-chemical tests are preferred. Monitoring the correct operation of a pasteurizer is done by recording the temperature and the product flow. Observation of the time at a CCP is often important. Pressure gauges, pH meters etc. can give a quick result, which makes timely adjustments possible. Clearly such quick adjustments prevent situations from getting out of control, and are thus the best monitoring methods.
Questions for each CCP and hazard (3)

What is the appropriate reaction to deviations?

(i.e. description of corrective actions)

The last question to be asked for each CCP and each hazard is what the appropriate reaction to a deviation should be. This will help to define corrective actions.
Corrective actions

- should readjust deviations before the situation is out of control
- should prevent hazardous products reaching the consumer
- should prevent recurrence of the event

Ideally, corrective actions should readjust deviations before they become unacceptable. They should ensure that the product produced during a situation that is out of control does not reach the consumer, and they should also prevent reoccurrence of the event. This may mean that the process has to be redesigned, or that a monitoring frequency method or a target level has to be changed; in other words, the HACCP plan should be improved.
Key messages

- Monitoring should ensure that the "process" at a CCP is kept under control.
- Procedures should give early warnings which enable adjustments to be made before the "process" is out of control.
- When Critical Limits have been surpassed, corrective actions should ensure that the defective product does not reach the consumer.
In this lecture, we will discuss validation and verification. Verification is one of the seven principles of HACCP, and the associated activities are established during the HACCP study.

Validation is mentioned in the Codex guidelines on the application of the seven HACCP principles, but it is not described how to do it. The words "validation" and "verification" are often misused to cover activities which should not be called validation or verification. In this lecture these terms, as well as terms such as auditing, will be defined.
Validation

Obtaining evidence
that the elements
of the HACCP plan
are effective

Codex 1996

A HACCP plan contains a list of hazards, CCPs, critical limits, monitoring and verification procedures etc. All these elements were decided upon during the HACCP study. At a certain CCP specified hazards are controlled with specific control measures, for instance a heat treatment to achieve a certain effect (which should ideally be specified, i.e. a process criterion should be set). Validation means ensuring that e.g. a heat treatment at 72° C for 12 seconds really reduces Salmonella a million fold (6D) on the equipment and in the food under consideration. If a food product should not contain more than a certain level of a hazard at the moment of consumption, challenge studies may need to be performed to validate that under the marketing conditions, and even under slight abuse situations, the hazard levels remain below a specified level. Validation deals with product formulation, processes, storage conditions, preparation and use. Validation is performed before the results of the HACCP study are approved and implemented. Validation may require highly professional skills and may be costly and time consuming. Validation is the responsibility of the producer.
Validation

Obtaining evidence that the elements of the HACCP plan are effective

*It is the responsibility of the industry and should be undertaken initially and as needed thereafter*

FAO/WHO consultation June 1998

Whenever a change occurs, a new hazard analysis has to be carried out, because a change might induce a new hazard, or eliminate an existing one (or reduce it to an acceptable level). Clearly the results of this hazard analysis as well as the effectiveness of new control measures (if any) have to be validated. Validation is thus part of the maintenance of the system.
Verification refers to activities undertaken to check compliance with the plan and its implementation. These activities should be planned ahead, because they should be approved by the responsible person in the establishment at the same time as all other results of the HACCP study.

Originally verification was done by the producer to check the effectiveness of the HACCP system. However, since HACCP has been incorporated into legislation and recommended by Codex Alimentarius, regulators have seen verification as their task. This is not correct, as will be explained in the lecture on regulatory assessment.

Internationally accepted definitions of the tasks of regulators or law enforcement officers have not been established yet, but the recommendations of a FAO/WHO consultation on the subject (June 1998) will be followed in this lecture. We will use the word verification to refer to: verification as done by the food handler, in accordance with the HACCP plan.
Verification

The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine conformity with the HACCP plan.

This is primarily the responsibility of the industry, however some verification activities can be undertaken during regulatory assessments.

FAO/WHO consultation June 1998

Verification is done by the food handler, to determine conformity with the HACCP plan. The word conformity is used when it relates to "compliance" with internal requirements. The word compliance is reserved for an assessment carried out by regulatory authorities (see next overheads).

When regulatory agencies test samples of the end-products, this could be seen as verification if the results are also used by the industry. When during a regulatory assessment books and records are reviewed, this again can be seen as verification as long as the results are used by the industry. If results of assessment activities by regulatory authorities are not communicated to and used by the industry these activities should not be called verification.
Conformity

Activities are carried out according to the established procedures e.g. the HACCP plan and prerequisites

FAO/WHO consultation June 1998

The word conformity is used in reference to industrial activities, the word "confirmation" refers to a regulatory situation.
Compliance

The HACCP plan and prerequisites, and their implementation, meet regulatory requirements

FAO/WHO consultation June 1998

In definitions both of conformity and compliance, it is mentioned that they refer not only to HACCP, but also to its prerequisites. Foods in international trade have to be produced according to General Principles of Hygiene and HACCP. Even for foods which are intended for domestic use, GHP should be the basis, HACCP is complementary to the system, but cannot stand alone. For this reason the word "prerequisites" has been introduced.
Prerequisites to HACCP

Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety, as described in the Codex General Principles of Food Hygiene and other Codes of Practice

FAO/WHO consultation June 1998

This is the definition of prerequisites which is self-explanatory.
Food safety confirmation

* * * * *

* Industries perform various activities to ascertain that safe foods have been produced.
* They check that:
  * the things are done
  * the things are done right
  * the right things are done
  * the right results are obtained

This lecture attempts to clarify validation and verification activities.
A number of activities are carried out by industry to ascertain the safety of a product.
We will see which of them can be called validation and which verification.
The word confirmation is used in the sense of Webster’s Dictionary: established as true.
To illustrate this, we take the example of milk pasteurization. We can check whether milk was pasteurized by testing a sample for phosphatase activity.

The heat treatment can be checked by looking at the thermograph and the flow meter (pump speed).

The objective of the treatment is to kill a sufficient number of vegetative forms of pathogens. We can check with challenge tests or data from models or literature, whether the applied time/temperature combination should achieve this.

Finally the milk can be tested for surviving pathogens, but it is more appropriate to test for coliforms or other indicators of a correct heat treatment.
Food safety confirmation

Checking that:

- things are done verification
- things are done right monitoring
- the right things are done validation/verification
- the right results are obtained validation

Clearly the first activity is verification; the activity is done after the milk is produced.

The next activity is monitoring. When things are getting out of control, adjustments can still be made in time.

The third activity is validation as well as verification, depending on the timing. When it is done after the production run it is verification; if it is done before production starts it is validation.

The last activity is clearly validation, it is certainly not correct to bring products on the market when results of the control measures have not been shown to meet objectives.
At a CCP a hazard should be controlled. The effectiveness of this control depends on many factors and parameters, some of them are listed in this overhead.

First of all the identified hazard should be the right one, and the CCP should be appropriate in dealing with this hazard. If *Listeria* can grow in a drain next to an open line, controlling the drain is more effective than prevention of contamination of the product in the adjacent line. Cleaning the drain frequently, and drying directly afterwards if possible, would be an adequate control measure.

Time and temperature as critical limits were already discussed.

It is clear that a monitoring method should detect a deviation in time, i.e. before a product reaches the consumer, but preferably as soon as a change from normality indicates that adjustments should be made.
The safety of foods is achieved by "safety by design". The activities listed in this overhead may need to be carried out before production starts. Challenge and storage tests may be used for validation. Process parameters and cleaning and disinfection systems may need to be validated. Validation is an integral part of product development and process design.
Verification comprises checking system conformity:

- the seven principles have been correctly applied
- the resulting HACCP plan is correctly and consistently implemented

Effectiveness confirmation:

- the system delivers what is expected

Verification comprises checking system **conformity** and confirmation of **effectiveness** of the system.

System **conformity** means that the seven principles have been correctly applied and that the HACCP plan is correctly and consistently implemented. It is not an approval of the system, i.e. that all the hazards have been correctly identified, that critical limits have been correctly chosen etc. It only means that the system was understood and the resulting activities put into action.

Effectiveness **confirmation** means that evidence is sought to confirm that the system delivers what is expected.
Verification activities

- Review of HACCP system and records
  - Review of unacceptable deviations and their follow up
  - Confirmation that CCPs are controlled
- Review of consumer complaints
- End-product testing
- Review of validation data

These activities are mentioned in the Codex text as examples of verification. "Review" means a retrospective view or survey of past events, experiences etc.

A review should show whether unacceptable deviations were followed up and/or whether CCPs were kept under control. The review of consumer complaints can demonstrate that deviations were not detected, and thus that things have to be changed: the system did not deliver what was expected. If the review shows that CCPs were not always monitored as foreseen, or that instruments used for monitoring were not accurate, the system or its implementation has to be improved.

End-product testing may provide some evidence that the plan was effective, and that objectives were achieved, but especially as regards control of pathogens it is a poor verification tool, as will be explained later.

Validation itself is not the same as verification as was explained before, however review of validation data can certainly be regarded as a verification activity.
Verification

verification is an ongoing activity

Whenever a change from the existing situation is made a new Hazard Analysis needs to be carried out, the outcome verified and the effectiveness of changes in the HACCP plan, if any, validated. Monitoring records, deviation files, raw material & end-product test results, customer complaints etc. need to be reviewed regularly. Records should be kept of all activities.

Verification is an ongoing activity. A new hazard analysis is necessary after changes in raw materials, processing conditions, line lay-out, distribution conditions, preparation and use etc. The outcome of such an analysis may need to be validated and verified.

As a consequence of trends detected in monitoring results, results of raw material and end product testing etc., changes may be made which need to be verified.

Records of all these verification activities should be kept for examination by external auditors or government inspectors.
In this overhead two examples are given concerning verification activities, and how established verification activities could be summarized for implementation.
Questions to be asked in verification before approval

Is there evidence that:

1. hazards have been correctly identified?
2. control measures eliminate or reduce significant hazards to acceptable levels?
3. corrective actions restore control?
4. deviating products will not reach the consumer?

In summary these questions cover the essence of verification. They speak for themselves and do not need to be further explained. If they are however, not well understood, some of the foregoing overheads may need to be explained or discussed again.
Audit

A systematic and functionally independent examination to determine whether activities and related results comply with planned objectives

Codex 1997

The term audit is used for a variety of activities. Normally, an audit is performed by independent auditors; it involves an in-depth examination of the production site and of how the HACCP plan was established and implemented. This definition is given because the word audit is frequently used in the context of verification or regulatory assessment.
Audits

- Should ideally be carried out by a multidisciplinary team of experts
- Should validate and review all decisions taken during HACCP study and during HACCP plan implementation
- Should, if necessary, recommend improvements in order to satisfy internal or external needs

It is good practice to let “another pair of eyes” scrutinize the HACCP study and the implementation of a HACCP plan.

This scrutiny or audit can be performed by people employed at the factory or industry to which the factory belongs, or by professional auditors working for an independent accredited auditing organization.

Most processing lines are quite complicated, and thus not only HACCP teams, but also audit teams should have members with different types of expertise.

The auditors may have some expertise which the HACCP team did not have, the HACCP team may have overlooked certain things because of a well known “familiarity blindness”.

Sometimes auditors are acting on behalf of a customer who has specific requirements, and they may recommend improvements to satisfy their specific needs.
Key messages

- Validation and verification are activities carried out by, or under responsibility of, industry.
- Validation is principally done before implementation of the HACCP plan and before changes are introduced.
- Verification activities are very diverse, and have different purposes, but the final goal is to obtain evidence that the system is working, i.e. that safe food is consistently produced.
- Regulatory assessments may provide data which can be used for verification by industry.
In this lecture some aspects of the implementation of HACCP will be presented. The Codex text does not give guidance on how to put the results of the HACCP study into practice. Therefore some industrial practices are provided.
Implement (verb)

To carry into effect

*Webster's Dictionary*

The word "implementation" is used for activities carried out by industry as a follow-up of the recommendations of the HACCP team.
Application of the seven HACCP principles means in practice that a HACCP study is performed by a HACCP team. This overhead summarizes some of the activities carried out by the team. Note that during the study certain points are singled out as CCPs others as CPs. These CPs refer to control measures which are considered by the team to be sufficiently covered by prerequisites to HACCP. Note also that validation is considered to be an activity carried out during the HACCP study, but that verification refers to listing verification activities carried out during and after implementation.
Approve (verb)

To give one's consent to,

sanction,

confirm

Webster's Dictionary

The HACCP study results in a number of recommendations which have to be approved by the responsible manager. This can be the factory manager (often the one who is legally accountable) or anyone else who has been given this responsibility. It is advisable to have the HACCP plan and other recommendations (for instance those dealing with modifications) approved by someone who did not act as the HACCP team leader.
Before the plan is implemented, it should be approved by the food business operator. It covers often not only the plan, but also the prerequisites. As a special point modifications are mentioned here. Often it becomes clear during a study that certain points can be improved to enhance safety, and sometimes points must be improved or modified to assure safety. Due to budgetary constraints and other considerations, not all proposed modifications can be immediately executed. A plan should be made and approved concerning the priorities of the improvements, if possible a timetable as well, but a plan should not be approved if certain modifications are essential to achieve the required level of safety.
It is essential that line operators and everyone else concerned are properly trained to carry out prerequisites, control measures, monitoring, corrective actions and recording. Of course, all activities which are mentioned in the HACCP plan, should indeed be executed. In the list of this overhead, the word “awareness” is also included. This underlines that HACCP touches almost everyone in the business and thus they all should be made aware of HACCP and its importance for the company, suppliers, customers and consumers.
This summarizes what has been discussed already in detail in the lecture on this subject. Several of these activities can be scheduled, others, such as external and internal information gathering, are continuous and activities such as review of changes and validation are triggered by the events.
In this overhead you find all elements present, but it demonstrates also to those who are familiar with the Demming circle, and the concept of continuous improvement, that HACCP falls completely in line with these Quality Assurance tools used for more than 30 years in industry.
Responsibility of industry

To ensure proper application of HACCP principles and implementation of the HACCP plan

To provide evidence of this to government authorities when requested

It is unanimously accepted that responsibility for producing safe food is in the hands of producers or providers. It is thus the responsibility of industry to ensure proper application of the seven HACCP principles and implementation of the HACCP plan. The Codex text distinguishes principles, which are essential, from guidelines for their application, which are advisory. Application may differ according to the product, the size and sophistication of the industry, the country etc., but it is the responsibility of industry to ensure that the essentials of HACCP are put into practice and, when requested, to provide evidence that this was done.
One very important aspect of HACCP has to be repeated here. Each step of the food chain has its own responsibility. HACCP is effective at ensuring safety only when it is applied at all steps, from farm to fork. Food safety is a shared responsibility of farmers, manufacturers and consumers.

Governments have also a role to play, this will be the subject of the next lecture.
Although HACCP is a food safety management tool used by industry, governments can or have to play several roles in its use. Many of the following recommendations, definitions and explanations are taken from two FAO/WHO consultations where these roles were discussed.

HACCP was developed in the early seventies as a means to improve the safety of processed foods and to increase efficiency of governmental inspections. These aspects of HACCP have gained in importance since the signing of the WTO/SPS agreements in 1994. Free trade will in future be only possible when governments can rely on industry's performance, and when one government can rely on another government's inspection efficiency.

It is therefore very important that industries understand the role governments have to play in HACCP, and that governments understand the intricacies of industrial implementation of HACCP.
Role of government authorities

As facilitators:
Clarify the goals and scope of HACCP,
provide expertise when requested

As enforcers:
Assess correct application and
implementation of the HACCP principles

As trainers:
Assist in or provide training programmes

Government authorities can play three roles: they can act as facilitators, enforcers and trainers.

As facilitators, they can help industries understand the goals and scope of HACCP, and provide expertise during the establishment of a HACCP plan or its verification.

As enforcers, their task is to assess the correct application and implementation of the seven HACCP principles.

Government authorities can participate in training courses organized by or for industry, as well as provide training programmes for use in such courses.
Responsibilities of governments

Strategic
effective implementation of HACCP

Operative
effective and on-going assessment
of HACCP

Strategy means having a plan of how to do certain things or to achieve a preset goal. Before governments are going to implement a mandatory or even a voluntary HACCP programme, they should have worked out how to do it, foreseen the necessary training, allocated sufficient resources and communicated this programme to the industry.

Once the programme started it becomes operational and many activities have to be executed, several on an on-going basis. A few of these will be explained in this lecture.
Strategic responsibilities

➤ Development of an overall strategy
➤ Providing leadership
➤ Providing the necessary infrastructure (expertise, legislation, training, etc.)
➤ Formulating an overall programme to assess HACCP systems

A few of these strategic responsibilities which were already touched upon are summarized in this overhead. Since this training manual is meant to inform governmental inspectors and industrial Quality Assurance managers etc. what HACCP is all about, these strategies will not be further dealt with. The strategies are developed by the managerial level of the government rather than the operational level, the target group of this training package.
Operative responsibilities

- Enforcing relevant legislation and regulations
- Applying sanctions in case of non-compliance
- Engaging in international relations
- Conducting research, risk assessment
- Publicizing requirements
- Providing technical assistance
- Training (governmental and industrial people)
- Regulatory assessment

The mentioned responsibilities are self explanatory. It is evident that governmental inspectors have to enforce the legislation, and that sanctions have to be applied in case of non-compliance. Governments have always had certain relations with other governments, but their responsibilities as exporters towards importing countries have been enlarged as a consequence of the WTO/SPS agreement. Another consequence of this agreement is that food safety criteria such as FSO’s, performance criteria and microbiological end-product criteria have to be based on scientific evidence and where appropriate, risk assessment. Conducting scientific research is therefore an operative responsibility. Results of these studies have to be published and communicated to interested bodies as part of the transparency policy required by WTO/SPS. Having scientific knowledge also means that technical assistance can be provided, which is also part of the training to be given to governmental inspectors and industrial operators. Regulatory assessment will be discussed in more detail.
The Codex Committee dealing with import and export regulations has defined the term **inspection**. HACCP assessment is one of the aspects of inspection. According to this definition it is very important for importing and exporting countries to agree on the "requirements". It should be realized that this definition should serve all kinds of inspection activities, not only those to assure the safety of food.

An example is the use of the verb "verify" which might lead to the use of the word "verification" by inspection services for their activities in relation to HACCP; this is incorrect.
Although "verification of the HACCP plan" has been used in various countries as the term to deal with governmental assessment of HACCP, in this training course the word "verification" is reserved for activities carried out by industry. The results of governmental activities such as document review and end-product testing can be used for verification by industries. It is part of their information gathering. A governmental assessment report is certainly the type of information which will be examined in detail and improvements will be made in the HACCP plan, if necessary.
Regulatory assessment (definition)

Regulatory assessment refers to governmental activities carried out with the objective of obtaining evidence that the seven principles have been effectively applied and the HACCP plan and prerequisites to HACCP correctly implemented and that the system has been maintained.

This definition expresses clearly the responsibility of a governmental inspector in assessing HACCP. This definition was the result of the FAO/WHO consultation of June 1998. An important aspect of this definition is the mention of prerequisites to HACCP. It was the unanimous opinion of the experts that HACCP can only be based on having effective GHPs and other prerequisites in place.

The assessment should not only cover the development and implementation of a HACCP plan, but also its maintenance. HACCP is an on-going and dynamic system. It has to respond to changes, it has to be improved whenever data indicate that such an improvement is necessary or that the system can be more efficient or more effective by making certain changes.
Prerequisites to HACCP

Practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety, as described in Codex Alimentarius Commission’s General Principles of Food Hygiene and other Codes of Practices.

Safe food was produced already a long time before HACCP was developed. If food caused a case or an outbreak of foodborne illness the causative factors were analysed and practices put in place to prevent recurrence. The practices thus developed were called Good Manufacturing Practices (GMP) as has been explained in previous lectures. Many activities are carried out in the production and preparation of food to prevent foodborne diseases. Examples are pest control, preventive maintenance, training of the personnel, etc. All these activities are described in general terms in the Codex document on the Principles of Food Hygiene and product specific codes based on this general text. HACCP deals not only with assuring that critical aspects or GHP are indeed carried out, but also anticipates potential problems and tries to prevent or control these. Application of HACCP alone is not enough to ensure food safety, prerequisites should be in place as well.
Purpose of regulatory assessment

The purpose of assessment is to establish whether the food business has the ability to consistently manufacture, and/or distribute safe food, i.e., to ascertain that the HACCP system is effective.

Although it is the responsibility of food industry to assure the safety of food on the market, history has shown that overseeing is necessary. Adulteration of food is still taking place, food laws and regulations have a long history and enforcement of these is necessary. Even if governments accept that development of a HACCP plan is the industry’s responsibility, they still have to ascertain that those HACCP plans lead to the manufacture and distribution of safe food. Assessment of establishments in the food chain responsible herefor is called “regulatory assessment”.
Regulatory assessment should determine

➢ whether all required elements of HACCP are present in the plan and that they are addressed adequately
➢ whether the system will satisfactorily maintain food safety
➢ whether the actual events comply with the documented procedures described in the plan

Reg 11

Regulatory assessment should cover various aspects of HACCP.
First of all it should be determined whether hazards have been correctly identified, adequate CCPs determined, correct control measures were put in place etc.
Then evidence should be sought to assess whether the production of safe food is consistently assured. This includes reviewing the documentation in order to assess whether the plan was indeed executed.
An assessment of the application and implementation of HACCP alone is not enough. The evaluation of the adequacy of prerequisites is an integral part of regulatory assessment. Finally we should not forget that enforcers are bound by their legislation to check compliance with any (other) regulatory requirement.
Competencies of assessors (1)

➢ Knowledge of and experience with HACCP and its application
➢ Knowledge and experience in assessing prerequisites to HACCP
➢ Ability to assess the effectiveness of methodologies for controlling hazards and of HACCP plan verification

Small businesses can often be assessed by a single assessor, who is familiar with the business, knows the basic principles of HACCP and has the ability to judge the appropriateness of the control measures.

In more sophisticated industries these skills can often not be found in one person. For the assessment multi-disciplinary teams may be required, who have together the competencies mentioned in this and the next slide.
Competencies of assessors (2)

- Knowledge of auditing methodologies
- Knowledge of relevant industrial processes
- Knowledge of relevant industrial codes of practice, legal requirements, guidelines and standards
- Recognized qualifications in food science or equivalent disciplines are desirable for the assessor or the assessing team
Elements of regulatory assessment

Assessed should be:

- HACCP management
- HACCP plan development
- Hazard Analysis
- control measures
- verification procedures
- documentation
- implementation

In this overhead a number of elements of the regulatory assessment are summarized. What the assessment of these elements means in practice will be explained hereafter.
Assessing the HACCP management

*an indication of management’s commitment to food safety can be obtained by checking:*

- the compliance history of the business
- the level of food hygiene training and its application
- the technical knowledge within or available to the company
- the existence of satisfactory documented procedures and food safety management systems

The commitment of management to apply, implement and maintain HACCP is of utmost importance. Obtaining indications concerning this commitment is therefore one of the first elements of assessment. In this overhead a few hints are given concerning how such indications can be obtained. If the business never had food safety problems, if all personnel are well trained to do their jobs, if the overall knowledge of hygiene is adequate, this shows already that management feels that these things are important. If the establishment has technical skills and expertise or when these are readily available, this shows again that management understands that this is necessary to assure the safety of its products. In smaller enterprises documentation may not be really necessary, because personnel “knows everything by heart”. When HACCP plans and their execution are still well documented, this again is an indication of management’s commitment.
Assessing the HACCP plan development

This involves an evaluation of

• accuracy of the product and process description
• accuracy of the flow diagram
• expertise used in the HACCP plan development
• adequacy of the prerequisites to HACCP

The efficiency of the HACCP plan depends on the expertise used during its development, and the correctness of the data used. Assessment therefore starts with an evaluation of these two points. As has been mentioned before, not only should HACCP be assessed, but also the prerequisites. The accuracy of several data, such as the correctness of the flow diagram, can only be checked during on-site inspection mentioned later in this lecture.
Assessing the Hazard Analysis

**Adequacy of the hazard analysis**
- all significant hazards have been identified
- hazard analysis has been undertaken for all products and processes to which the assessment is directed

**Assessors may require access to supporting evidence**
- records of validation
- sample results
- history of the safety of the product
- generic plans
- relevant and appropriate predictive models

In order to be effective, significant hazards which are inherent to the product or production line, should not be overlooked. Furthermore products and the way they are produced may seem similar, but details may be different and a small difference may have an influence on the outcome of a hazard analysis. For instance botulism was caused by a hazelnut yogurt when the hazelnut paste was produced with an artificial sweetener instead of sugar. The water activity of the sugar-free paste permitted growth and toxin formation, the sugar in the original formula prevented this. The outcome of a hazard analysis is as good as its input. Sometimes it may be necessary to ask for access to supporting data. A few of the sources of such data are mentioned in this overhead. A very important point to be looked at is the history of the product. When the product under scrutiny has been produced and consumed during a long period of time, not much more evidence is needed to assess its safety.
Assessing the effectiveness of control measures

- Adequacy of Critical Control Points (CCPs)
- Appropriateness of critical limits
  - are they realistic, do they ensure the required safety level?
  - how were they determined and validated?
- Adequacy of monitoring methods and frequency
- Adequacy of corrective actions to restore control and to prevent that deviating product reaches the consumer

This overhead is self explanatory. Effective control is only achieved if indeed the CCP is adequate, critical limits ensure the required safety level, monitoring procedures assure that the system remains under control, and that if a deviation occurred adequate corrective actions were taken.
Assessing the verification procedures

First should be assessed what was verified, how, when and by whom, and whether these activities are adequate and effective

Then the adequacy of actions taken as a result of
  • new emerging hazards
  • changes or deficiencies in the HACCP plan or prerequisites to HACCP
  • other non-conformities
should be assessed

The term “verification” is used for a number of different activities as has been explained in the lecture on the subject. These actions can be summarized as obtaining evidence that safety of the product was assured. Many of these activities and their results can easily be reviewed. It may be more difficult to find out whether actions were taken in time as a result of new emerging hazards (and the other reasons mentioned under the bullet points), and whether these actions were adequate. Assessing these aspects of HACCP is very important because they give a good indication whether verification is indeed an ongoing activity.
Assessing the documentation

The following documents should be assessed

- description of the product and its intended use
- flow diagram, location of CCPs and important parameters
- HACCP worksheet
- list of verification activities
- results of monitoring and verification
- records necessary to demonstrate the adequacy of prerequisites to HACCP

This overhead lists the kind of documentation that should be assessed. This is mainly a paper activity, which can be carried out before an on-site assessment is performed.
Assessing the implementation

This means checking whether

- the HACCP plan and prerequisites have been adequately implemented
- the plan is adequately maintained and functioning correctly
- operators are sufficiently trained
- records are in order (monitoring and verification executed as planned and corrective actions, if any, taken)

Many of the foregoing points had to do with an assessment of adequateness of the HACCP plan. It is of equal importance to assess whether HACCP was adequately implemented. A few of the points to be checked are mentioned in this overhead. What is mentioned in the second and third bullet point should receive particular attention. Even if a plan is correctly developed and implemented it will not function correctly, if it is not adequately maintained. If operators are not sufficiently trained to keep their CCPs under control, HACCP will not be effective, regardless of whether everything on paper is well looked after.
Frequency of assessment

- Classification scheme
  - potential hazards associated with the product or process
  - history of previous compliance
  - food safety management system
- Food safety incident
- Other factors

Classification schemes may be helpful to target resources effectively, more frequent visits can be planned to premises where high risk foods are produced, to premises where HACCP is not yet fully operative, or where apparently a number of problems still have to be solved.

Apart from adhering to a fixed scheme of assessments it may be necessary to assess a company after a food safety incident. Other reasons for assessment may be the emergence of new hazards or changes in requirements, for instance by importing countries.
Assessment in practice

An assessment includes the following stages

- Planning
- On-site assessment
- Evaluation

Regulatory assessors follow normally the above-mentioned stages, which will be explained in the next overheads.
Planning

*Information required for planning includes*

- relevant company documentation
- previous file records, data on premises and products
- results from previous visits or assessments

Planning often takes place before visiting the premises of food producers. It allows the assessor to familiarize him/herself with the product, the processes, the HACCP plan etc. and it reduces the time that the assessor has to stay at the site. In short it can improve the efficiency of an assessment.
On-site assessment

The purpose of on-site assessment is to confirm, based on observations, interviews and record reviews, that the HACCP plan and its prerequisites are, according to the assessor's expertise, acceptable.

Normally an on-site assessment is planned beforehand with the manager of the operation, in order to have everything ready for the assessment, and also to have those responsible available for questioning.

The on-site inspection of the premises is a very important aspect of assessment, practices and procedures can be observed and the correctness of certain aspects questioned. Observing the behaviour of the operators, inspecting toilets and canteens as indicators of the hygiene attitude of management etc., may be part of the assessment. Such observations can only be carried out on the spot, reviewing documentation will not reveal information which can thus be obtained.
Checklist (1)

- A list that contains points / elements that may be considered during assessment.
- A checklist is an assessment tool for the entire HACCP application including prerequisites, design, implementation, maintenance of the plan

Checklists may be helpful in assessment. However, the use of checklists alone will never be sufficient to perform an appropriate assessment. In the next two slides some advantages and some potential problems are mentioned, they speak for themselves.
Checklist (2)

Advantages

- aide-memoir
- helps to maintain focus and objectivity
- helps to ensure completeness of assessment
- acts as a record of assessment
- helps to evaluate comparability of different assessments, companies or assessors
- ensures transparency of the assessment process
Checklist (3)

Potential problems

If improperly designed and / or used

- it may contain irrelevant or unnecessary items but critical ones may have been overlooked
- restricts the initiative and judgment of the assessor and discourages critical evaluation
Evaluation

- Analyse information and evaluate deficiencies
  - impact of deficiencies on food safety
  - regulatory compliance
  - trade concerns
- Formulate proposals for improvements or remedial actions
- Discuss findings and proposals with management and agree on follow-up

Assessment should result in an evaluation during which the findings are discussed with the management of the enterprise. The assessor should analyse the information and evaluate whether the deficiencies, if any, have an impact on the safety of the food, whether the findings indicate that some of the regulatory requirements were not met, or whether the product may lead to problems in trade.

It is recommended that the assessor also formulates proposals for improvements or remedial actions which, again, should be discussed with management. It should be made very clear to management that they have to make the decisions and to implement some of the proposals. The assessor has only the right to demand the follow-up of a proposal when it is clearly based on the regulatory requirement.
Key messages

➢ Regulatory assessment may become increasingly important as a consequence of the WTO requirements
➢ The scope and purpose of an assessment should be well defined
➢ Assessor should have the necessary skills
➢ Assessor should determine the correct application and implementation of the seven HACCP principles and prerequisites to HACCP
➢ The evaluation of results of the assessment should be discussed with the responsible management
The best HACCP plan in the world will not work if the people who implement it are not properly trained. People responsible for the development of the HACCP plan, as well as people who have to assess its implementation and maintenance, also need training.

This lecture deals with several aspects of training in HACCP.
There are a number of tasks associated with organizing and running a training course. It is helpful to have an action checklist for noting the planned date and execution date for each task.

Planning should start 4-6 months in advance, and activities related to the course may continue even after the teaching sessions are finished.

Note that not all of the activities discussed in this lecture may be appropriate for your course.
Initial planning (2)

- Define objectives
- Determine sources for funds and identify sponsors
- Decide on place and date

The first step is to define the course objectives. The objectives defined in the training package may have to be modified to take into account local conditions.

Sponsors and sources of funds have to be identified.

A date and place for the course should be chosen.
Before the course (1)

Select

- organizers
- speakers
- participants

The first stage of course planning is to decide who will be responsible for organizing the course, who will make the presentations, and who will participate.
Select the organizers

Organizing Committee

- have both an organizer and an assistant organizer
- have representatives both from the institution carrying out the course, and from external organizations

The organizing committee may include members of the institution carrying out the course and other related organizations, or local universities. A principal organizer and an assistant organizer should be appointed.
Select the speakers

> Send invitations well in advance

> Include in the invitation letter:
  * details of course organization
  * description of material to be covered

> Send course material when the invitation is accepted

Speakers should be invited well in advance. The invitation should specify the subject, the expected lecture time and date, fees payable (if applicable) and any additional information or data to be presented. A copy of lecture materials from the module should be sent once the speaker accepts the invitation. Speakers are allowed to supplement course materials with their own materials.
Recommended skills for trainers

- Knowledge of local language OR assistance by a qualified interpreter
- Good communication skills and experience conducting interactive exercises
- Technical background
- Expert knowledge of: hazards, hazard analysis, HACCP plans OR access to a qualified resource person
- Flexibility and responsiveness

Training means communication; thus, it is recommended that trainers know the local language or are provided with interpreters who understand the subject.

The trainer should have a suitable technical background, and be able to add his own experiences to the lectures.

If the trainer or trainers assigned to a course do not have all the knowledge covered by a training package, they should assure that particular expertise is available.

Often the background of the students is not known until the course begins. Trainers should be sufficiently flexible to adapt their lectures and exercises to the real needs of their trainees.
Trainees’ qualifications

- Good reading and comprehension skills, and an understanding of technical language
- Basic knowledge of:
  - the commodity or process
  - food safety requirements, including government requirements
  - general principles of food hygiene
  - biological, chemical and physical hazards to food and measures for their control

Ideally, a course should have 10-25 participants from a variety of backgrounds. Participants should include personnel in food industry and government inspectors. When people in industry and government are trained together, they can share their knowledge and experiences, thus establishing a common understanding.

Invitations should be sent in advance so sponsors can be found. Information on the course can be forwarded at this time.

As minimum qualifications, students should be able to understand the language of the course, including technical language. They should have a basic knowledge of the product and processes, of food safety requirements, of the general principles of food hygiene, and of hazards and their control.
After identifying and notifying the people who will be involved with the course, it is necessary to prepare the materials, equipment and other resources that will be used. Materials should include information that is relevant to the local situation.

If site visits or other special activities are planned, these should be arranged well in advance.
Teaching material

- Teacher's manual
- Course schedule
- Transparencies
- Handouts

The material in the package should be supplemented with material relevant to the local situation

Teaching materials to prepare include: teacher's manual, transparencies, course schedule, additional lecture notes, student handouts, and supplementary reading. Background documents and other reading materials should be requested well in advance to allow for shipping time. It is a good idea to have additional training materials adapted to local needs. Presentations are often improved if speakers add current examples or data.
When preparing the training room, verify that the overhead projector, video tape recorder and slide projector (if needed) are present. Check the room’s arrangement (seating, lighting, tables). Make sure that you have the necessary writing materials.

Make sure the room is available throughout the course. Try to avoid using a room that is near a disrupting activity such as construction or maintenance work.
Equipment

Questions to ask

- does everything work?
- are the slides in order?
- are all the presentation tools available?
- is there enough writing material for all participants?
- is the video compatible with the equipment?

Check all equipment one day in advance.

If you are using slides, make sure that they are in order. Other tools such as the whiteboard, transparency sheets, markers, flipchart, pinboard should be prepared according to the type of activities and the number of participants.

For the video recorder, check the television monitor, volume, colours and placement. If possible, make the video recorder available throughout the course so participants can use it. Verify that the video cassette format is compatible with the local equipment (NTSC or PAL or SECAM etc.). The person presenting audio-visual material should view it beforehand.
Other preparations

- Schedules
- Site visits
- Other resources

The speakers should set up and agree upon course schedules, although the organizer should allow adjustment or modification. It is an advantage to have one or two “backup” people with a good general knowledge of the subject who can be contacted in case of last-minute cancellations.

Field visits are useful to illustrate the principles discussed in the classroom. These should be planned well in advance. Field observation of small restaurants or street vendors is a good comparison to big industry.

Additional preparations and contacts may be needed depending on the activities selected.
During the course

- Introductory exercise
- Guest speakers
- Visits
- Teaching tips
- Exam
- Evaluation

We now turn to the practical aspects of running the course.
**Introductory exercise**

**Purpose**

to allow organizers, lecturers and participants to get to know each other.

On the first day of the course, conduct an introductory exercise to allow the organizers, lecturers, and participants to get to know each other. Organizational representatives may be asked to specify their expectations from the course.

Participants should be given a folder containing the following information: list and description of materials, name and institution of attending participants, evaluation sheet, time schedule and institutional background material (for outside participants).

The teacher’s manual and transparencies should be left in the training room so that all lecturers have easy access to them.
Guest speakers

Can be from:
- government
- food industry
- consumer organization
- academia

Guest speakers with special expertise can be invited to present certain subjects. The choice depends on the course objectives and the background of the participants.
Field observations are an important part of this course. A HACCP exercise can be part of the visit to a local food establishment or of the street vendor observation. Specific questionnaires or checklists may have to be developed.
What is effective in teaching HACCP?

- Case studies appropriate to the country
- Low (1:5) instructor / participant ratio during exercises
- Participatory training approach
- Teachers who are flexible, good communicators and have experience in successful HACCP implementation
- Outside experts used as resource persons
- Use of examples of actual HACCP plans to illustrate points made in the lectures

The course contents is laid out in the teacher’s manual; however, the way this is presented depends very much on the teacher’s personal style, the class composition, and the place where the course is being taught. This slide and the next one list some practices that have been shown to work, and not to work, when teaching HACCP.
**Sources of problems**

- Poor advance planning
- Poor balance of lecture / theory / exercises
- Distractions (e.g. telephone calls)
- Long days
- Pace not adapted to students' capacities
- Unmotivated students
- Students who dominate the course
- Students from widely diverse backgrounds

These are some of the most frequently encountered sources of problems.
Exam

➤ Can be made up of multiple choice questions, short answer questions, essay questions, or a combination
➤ Grading depends on the regulations of the institution
➤ Give the participants time to study!

An exam may be needed if this course is part of a specific training programme. A two hour exam containing a combination of multiple choice, short answer, and essay questions is suggested.

Participants are also graded on their involvement in class activities.

A certificate of attendance may be given.
Time allocation

- Basic principles 25%
- Hazard identification & determination of CCPs 63%
- Remaining topics, including assessment 12%

These are recommendations based on current experience; however in certain situations the contents of the course may need to deviate significantly from the outline presented in this overhead.
Evaluation

Three types of evaluation can be useful:

- an evaluation of individual participants and their needs, prior to the course
- an evaluation of the course by individual participants
- an evaluation of participants once they have completed the course

There are three aspects to course evaluation, which will be discussed in detail in the following overheads.
Evaluation before the course

Evaluation of participants and their needs prior to the course:

- education and background
- knowledge of food safety
- current position and responsibilities
- individual expectations from the course

Before the course, if possible, the background and qualifications of the participants should be evaluated. This makes it possible to tailor the course to the needs of the participants.
Evaluation during the course

- Communication between instructor(s) and participants
- Communication between participants
- Feasibility of recommendations developed during the course
- Correspondence between course material and participants’ needs

During the course, trainers can evaluate whether the course improves communication between the participants, and the effectiveness of the course instructors in communicating with participants.

The quality and feasibility of recommendations developed during the course can also be evaluated.

Finally, throughout the course, it is necessary to evaluate how well it meets the needs of the participants.
Evaluation after the course

- What worked and what did not; how should the course be changed; were participants able to implement HACCP after the course as planned?
- Evaluate attitude and commitment to change for industry and food control authorities
- Find out if the trainees have a better focus on enhancing food safety
- Determine the degree of acceptance of their changing role by food control authorities

Evaluations 6-9 months after the course are very valuable. By then, trainees have had ample opportunities to find out what worked and what did not work, and whether HACCP could be implemented as planned.

Changes in attitude in the industry as well as the food control authorities should also be apparent after such a period of time.
HACCP

case study no. 1

(teacher's version)

Fresh cream and jam gateau

WHO / ICD
HACCP STUDY  (CASE 1)

EXAMPLE OF HACCP PLAN
FRESH CREAM AND JAM GATEAU¹

a.  FACILITY
    The purpose-built factory produces a variety of decorated gateaux for sale to the retail industry. The factory is based on a large new industrial estate and produces both chilled and frozen products.

b.  PRODUCT
    The product has a fresh cream and jam filling between two sponges. It is a chilled product and must be kept below 5 °C through the distribution chain. The shelf life is 3 days from date of manufacture.

c.  MANUFACTURE
    Sponge batters are baked at 150-170 °C through a travelling oven for 18.5 minutes. They are then cooled to ambient, automatically sliced and filled. There are a wide variety of fillings for the sponges. The sponges are flow-wrapped and put into cartons.

d.  PRINCIPAL HAZARDS AND CONTROL MEASURES
    Principal biological hazards are the potential presence of pathogens in various ingredients and cross-contamination during processing. Control measures include approved suppliers and certificates of conformance, sensitive ingredient testing, baking and segregation.

e.  INTENDED USE
    The product is targeted at the general public and may therefore be consumed by high-risk individuals. Salmonella and Listeria control is therefore critical.

¹ This study was partly reproduced and adapted from Sara Mortimer and Carol Wallace, HACCP, a practical approach, Chapman & Hall, 1994
NOTE FOR TRAINERS

This example should be used to clarify the type of data resulting from a HACCP study. Trainees should start to understand that decisions have to be made concerning the types of hazards to identify, the important raw materials to mention and the control measures to be included in the HACCP plan. At this step it is not important to discuss whether decisions were right or wrong. This will be dealt with in the example of case 2.
Fresh cream and jam gateau

- Flour
- Milk powder
- Pasteurized liquid egg
- Water
- Ingredients

Mixer

Put batter in tins

< 1 hr.

Bake sponge

150 – 170 °C for 18.5 min.

Depan and cool

Fill

Pack

Chill

Dispatch < 5 °C

Cream
Jam
Packaging material

High care area

< 5 °C

0-5 °C
### Example of HACCP data sheet

<table>
<thead>
<tr>
<th>Process step</th>
<th>CCP No.</th>
<th>Hazard to be controlled</th>
<th>Control measures</th>
<th>Critical limits</th>
<th>Monitoring</th>
<th>Corrective actions</th>
<th>Responsible person(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incoming raw material</td>
<td>1.1</td>
<td>Aflatoxin</td>
<td>Obtain Certificates of Analysis from suppliers</td>
<td>Aflatoxin: &lt; 10 mg/kg</td>
<td>Inspect Certificate of Analysis</td>
<td>Every batch</td>
<td>Reject batch</td>
</tr>
<tr>
<td>Flour</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mains water</td>
<td>1.2</td>
<td>Chemical contamination</td>
<td>Carry out on-site micro checks and obtain Certificate of Analysis of local sample-</td>
<td>Chemical contamination (see spec.) Regulatory Compliance</td>
<td>Testing to include toxic substances Giardia/ Cryptosporidium Inspect Certificates of Analysis from Water Authority</td>
<td>Weekly</td>
<td>Contact Water Authority</td>
</tr>
<tr>
<td>Jam</td>
<td>1.3</td>
<td>Pesticide residues</td>
<td>Certificates of Analysis from approved supplier</td>
<td>Within legal limits</td>
<td>Inspect Certificate SQA Audit</td>
<td>Annually</td>
<td>Contact Purchasing Manager</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cream</td>
<td>1.4</td>
<td>Salmonella and Listeria</td>
<td>Supplier Quality Assurance System Approved supplier</td>
<td>Laboratory tests Salmonella, Listeria, Procedure Nos xxx</td>
<td>Inform purchasing SQA audit</td>
<td>Every delivery 6-monthly</td>
<td>Reject batch QA Manager</td>
</tr>
</tbody>
</table>
### Example of HACCP data sheet (cont.)

<table>
<thead>
<tr>
<th>Process step</th>
<th>CCP No.</th>
<th>Hazard to be controlled</th>
<th>Control measures</th>
<th>Critical limits</th>
<th>Monitoring</th>
<th>Corrective actions</th>
<th>Responsible person(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage of raw material</td>
<td>2</td>
<td>Physical contamination, biological growth</td>
<td>Store as specified, i.e. cream &lt; 5°C, egg for specified max. time. Keep covered</td>
<td>No physical, chemical contamination. Maintain temp. &lt; 5°C</td>
<td>Automatic temperature recorder. Visually inspect label to ensure stock rotation</td>
<td>Daily checks – continue during use. Every batch</td>
<td>Hold and inform QA Manager</td>
</tr>
<tr>
<td>Bake sponge through oven</td>
<td>3</td>
<td>Survival of vegetative pathogens</td>
<td>Bake sponge at specified time/ temperature</td>
<td>Bake at 70°C for 2 min. minimum core temperature</td>
<td>Automatic chart recorder</td>
<td>Continuous</td>
<td>Stop production. Reject faulty product, Adjust oven temp/time</td>
</tr>
<tr>
<td>Metal detect</td>
<td>4</td>
<td>Metal contamination</td>
<td>Metal detector</td>
<td>Absent – ferrous 2.0 mg, non-ferrous 2.5 mg</td>
<td>Metal detection check using test pieces. Calibrate metal detector</td>
<td>Every 30 min.</td>
<td>Stop line, recalibrate, notify QAM. Hold stock manufactured since previous check</td>
</tr>
<tr>
<td>Dispatch</td>
<td>5</td>
<td>Growth of pathogens</td>
<td>Low temperature during storage and distribution</td>
<td>0-5°C</td>
<td>Continuous chart recorder – warehouse and distribution vehicle. Check recorder calibration</td>
<td>Daily review</td>
<td>Hold, inform QAM, Sample and test product</td>
</tr>
</tbody>
</table>

**Case 1**
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Finished product</td>
<td>Check conformity with criterion</td>
<td>1/week</td>
<td>ISO method</td>
<td>Find cause, Improve HACCP plan</td>
</tr>
<tr>
<td>Listeria testing</td>
<td>Absence in 5 x 10g</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring records</td>
<td>Check adherence to HACCP plan</td>
<td>1/week</td>
<td>Inspection</td>
<td>Correct, Train, Improve</td>
</tr>
<tr>
<td>review</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
HACCP

case study no. 1
(student’s version)

Fresh cream and jam gateau

WHO / ICD
HACCP STUDY (CASE 1)

EXAMPLE OF HACCP PLAN
FRESH CREAM AND JAM GATEAU

a. FACILITY
   The purpose-built factory produces a variety of decorated gateaux for sale to the retail industry. The factory is based on a large new industrial estate and produces both chilled and frozen products.

b. PRODUCT
   The product has a fresh cream and jam filling between two sponges. It is a chilled product and must be kept below 5 °C through the distribution chain. The shelf life is 3 days from date of manufacture.

c. MANUFACTURE
   Sponge batters are baked at 150-170 °C through a travelling oven for 18.5 minutes. They are then cooled to ambient, automatically sliced and filled. There are a wide variety of fillings for the sponges. The sponges are flow-wrapped and put into cartons.

d. PRINCIPAL HAZARDS AND CONTROL MEASURES
   Principal biological hazards are the potential presence of pathogens in various ingredients and cross-contamination during processing. Control measures include approved suppliers and certificates of conformance, sensitive ingredient testing, baking and segregation.

e. INTENDED USE
   The product is targeted at the general public and may therefore be consumed by high-risk individuals. Salmonella and Listeria control is therefore critical.

---

1 This study was partly reproduced and adapted from Sara Mortimer and Carol Wallace; HACCP, a practical approach, Chapman & Hall, 1994
Fresh cream and jam gateau

- Flour
- Milk powder
- Pasteurized liquid egg
- Water
- Ingredients

Mixer

Put batter in tins

Bake sponge
150 - 170 °C for 18.5 min.

Depan and cool

Fill

Pack

Chill

Dispatch

< 5 °C

- Cream
- Jam
- Packaging material

High care area
## Example of HACCP data sheet

<table>
<thead>
<tr>
<th>Process step</th>
<th>CCP No.</th>
<th>Hazard to be controlled</th>
<th>Control measures</th>
<th>Critical limits</th>
<th>Monitoring</th>
<th>Corrective actions</th>
<th>Responsible person(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incoming raw material Flour</td>
<td>1.1</td>
<td>Aflatoxin</td>
<td>Obtain Certificates of Analysis from suppliers</td>
<td>Aflatoxin: &lt; 10 mg/kg</td>
<td>Inspect Certificate of Analysis</td>
<td>Every batch</td>
<td>Reject batch</td>
</tr>
<tr>
<td>Mains water</td>
<td>1.2</td>
<td>Chemical contamination</td>
<td>Carry out on-site micro checks and obtain Certificate of Analysis of local sample-Water Authority</td>
<td>Chemical contamination (see spec.) Regulatory Compliance</td>
<td>Testing to include toxic substances <em>Glianda</em>/<em>Cryptosporidium</em> Inspect Certificates of Analysis from Water Authority</td>
<td>Weekly</td>
<td>Contact Water Authority</td>
</tr>
<tr>
<td>Jam</td>
<td>1.3</td>
<td>Pesticide residues</td>
<td>Certificates of Analysis from approved supplier</td>
<td>Within legal limits</td>
<td>Inspect Certificate SQA Audit</td>
<td>Annually</td>
<td>Contact Purchasing Manager</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Salmonella and Listeria</em></td>
<td>Supplier Quality Assurance System Approved supplier</td>
<td>Laboratory tests <em>Listeria, Salmonella</em>, Procedure No s xxx</td>
<td>SQA audit SQA Audit</td>
<td>Annually</td>
<td>Contact Purchasing Manager</td>
</tr>
<tr>
<td>Cream</td>
<td>1.4</td>
<td></td>
<td>Supplier Quality Assurance System Approved supplier</td>
<td>Absent/25 g</td>
<td>Laboratory tests <em>Listeria, Salmonella</em>, Procedure No s xxx</td>
<td>Every delivery</td>
<td>Reject batch</td>
</tr>
</tbody>
</table>

SQA Manager
### Example of HACCP data sheet (cont.)

<table>
<thead>
<tr>
<th>Process step</th>
<th>CCP No.</th>
<th>Hazard to be controlled</th>
<th>Control measures</th>
<th>Critical limits</th>
<th>Monitoring</th>
<th>Corrective actions</th>
<th>Responsible person(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage of raw material</td>
<td>2</td>
<td>Physical contamination, biological growth</td>
<td>Store as specified, i.e. cream &lt; 5°C, egg for specified max. time. Keep covered</td>
<td>No physical, chemical contamination. Maintain temp. &lt; 5°C</td>
<td>Automatic temperature recorder. Visually inspect label to ensure stock</td>
<td>Daily checks – continue during use. Every batch</td>
<td>Hold and inform QA Manager</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>rotation</td>
<td></td>
<td>Warehouse Manager and Operator</td>
</tr>
<tr>
<td>Bake sponge through oven</td>
<td>3</td>
<td>Survival of vegetative pathogens</td>
<td>Bake sponge at specified time/temperature</td>
<td>Bake at 70°C for 2 min. minimum core temperature</td>
<td>Automatic chart recorder</td>
<td>Continuous</td>
<td>Stop production. Reject faulty product. Adjust oven temp/time</td>
</tr>
<tr>
<td>Metal detect</td>
<td>4</td>
<td>Metal contamination</td>
<td>Metal detector</td>
<td>Absent – ferrous 2.0 mg, non-ferrous 2.5 mg</td>
<td>Metal detection check using test pieces. Calibrate metal detector</td>
<td>Every 30 min.</td>
<td>Stop line, recalibrate, notify QAM. Hold stock manufactured</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>since previous check</td>
</tr>
<tr>
<td>Dispatch</td>
<td>5</td>
<td>Growth of pathogens</td>
<td>Low temperature during storage and distribution</td>
<td>0-5°C</td>
<td>Continuous chart recorder – warehouse and distribution vehicle. Check recorder calibration</td>
<td>Daily review</td>
<td>Hold, inform QAM, Sample and test product</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Warehouse Manager</td>
</tr>
</tbody>
</table>

Case 1
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Finished product <em>Listeria</em> testing</td>
<td>Check conformity with criterion Absence in 5 x 10g</td>
<td>1/week</td>
<td>ISO method</td>
<td>Find cause, Improve HACCP plan</td>
</tr>
<tr>
<td>Monitoring records review</td>
<td>Check adherence to HACCP plan</td>
<td>1/week</td>
<td>Inspection</td>
<td>Correct, Train, Improve</td>
</tr>
</tbody>
</table>
case study no. 2

(teacher's version)

Fresh cream and jam gateau

WHO / ICD
HACCP STUDY  (CASE 2)

EXAMPLE OF UNAPPROVED HACCP PLAN
FRESH CREAM AND JAM GATEAU\(^1\)

a. FACILITY
   The purpose-built factory produces a variety of decorated gateaux for sale to the retail industry. The factory is based on a large new industrial estate and produces both chilled and frozen products.

b. PRODUCT
   The product has a fresh cream and jam filling between two sponges. It is a chilled product and must be kept below 5 °C through the distribution chain. The shelf life is 3 days from date of manufacture.

c. MANUFACTURE
   Sponge batters are baked at 150-170 °C through a travelling oven for 18.5 minutes. They are then cooled to ambient, automatically sliced and filled. There are a wide variety of fillings for the sponges. The sponges are flow-wrapped and put into cartons.

d. INTENDED USE
   The product is a treat for everyone at all times at all places.

---

\(^1\) The original study was published by: Sara Mortimer and Carol Wallace; HACCP, a practical approach, Chapman & Hall, 1994

- It has been changed on purpose to include errors. It should not be used as a "good" example
NOTES FOR TRAINERS

CCP 1

It is unlikely that insects are a food safety problem. Since removing insects from flour could be regarded as a Good Hygienic Practice, sieving is not a CCP.

CCP 2

It is possible, but highly unlikely, that B. cereus in this product will cause food poisoning, nor is there epidemiological evidence that B. cereus would reach sufficient numbers in a few days at refrigeration temperatures to cause illness. Even a few hours at high temperatures (for example, if the gateaux are packed in a picnic basket, or served at a party) will probably not cause harm. (The description of “intended use” mentions that the product is a treat at all times and all places.) B. cereus is thus not a significant hazard, and flour not a CCP for this microorganism.

CCP 3 and 4

In principle, the supplier controls the mycotoxin hazard. Testing for aflatoxin and coliforms can be regarded as verification of the supplier’s conformance with a specification, rather than monitoring. However, when deviations from specifications are found, the incoming material is rejected, i.e. the results of testing are used to control a hazard, and as such, testing can be regarded as monitoring.

CCP 5

The listed hazard is chemical contamination, without specifying which chemicals the HACCP team had in mind. Micro checks are mentioned as control measures but the critical limits refer to chemical contamination. Under monitoring, Giardia and Cryptosporidium are mentioned. These are microbes, and not chemicals, and testing for them is a specialized activity, normally not performed in factory laboratories. The water is used to make batter for the cakes, which are then heated sufficiently to kill vegetative bacteria and parasites. For this reason such microbes are not significant hazards and need not be addressed in the HACCP plan. It is questionable whether weekly monitoring would be sufficient to prevent unacceptable chemicals from reaching the consumer. Filtration and chlorination would correct unacceptable contamination with microbes, but would not rectify chemical pollution.

CCP 6

It takes at least two days to test for the absence of Listeria with the ISO method. Pasteurized cream has a shelf-life of several days, but the product has a
shelf-life of only three days; manufacturers will be unwilling to lose two days on testing. In any case testing is not a good method to assure absence of pathogens in a product. It would be better to rely on the supplier's quality assurance. Thus, monitoring for *Listeria* makes no sense. Cream is a very critical material because it supports the growth of *Listeria* and it does not receive a heat treatment during manufacturing. Optimal hygiene and time/temperature control along the food chain are therefore required rather than testing the incoming lots.

CCP 7

Auditing the supplier once a year cannot be regarded as monitoring.

CCP 8

Moulds could indeed be a problem in this product. However, it would be a quality problem, not a safety problem. Thus, testing would not be a control measure, and this step would not be a CCP.

CCP 9

The sheet does not mention which biological growth the HACCP team had in mind. Biological growth does not necessarily lead to a safety problem. Often it is just a spoilage one, but in fermentation bacterial growth is even needed. Bacteria should therefore be specified. In this example, sensitive material is kept at refrigeration temperatures for short periods of time, so there probably is not a safety problem. Therefore, storage of raw materials should be covered by GHP. If physical contamination takes place, it is unlikely to cause a problem, because some materials are sieved and there is a metal detector at the end of the line.

CCP 10

Too much salt is a quality problem, not a safety one.

CCP 11

The pathogens should be specified. *Bacillus cereus* and *Clostridium perfringens* will survive this baking process, but *Salmonella, Listeria* and many other non-sporeforming microbes should be killed by the intended time/temperature. This is certainly a CCP for vegetative pathogens.

CCP 12, 13 and 14

Cooling, filling and probably cream whipping take place in a high hygiene area. Since there are no further possibilities to kill microorganisms such as *Listeria* and *Salmonella*, it is important to prevent product contamination. Air quality is important as well as cleanliness of lines and line environment. It is unlikely that *Salmonella* is a hazard in this product. Salmonellae can grow only in the whipped cream (cake and jam have too low a water activity); the product is
kept at low temperatures and has a shelf-life of only a few days. If the cakes are kept at too high temperatures for a longer period of time, which would allow the growth of *Salmonella*, the cream would probably spoil (become rancid) and the cake would not be eaten. However, it is possible that few salmonellae in a fatty material such as cream, eaten by a susceptible person, could cause illness. As such, the filling would be a CCP, but not only for *Salmonella*, also for *Listeria*.

**CCP 15 and 16**

The pathogens that are regarded as hazards should be mentioned.

**CCP 17**

Two mg of ferrous metal or 2.5 mg of a non-ferrous metal in the form of a ball would not really be a physical hazard. In the form of a needle of a certain size metal is a harmful physical object. Therefore, the metal detector should be programmed to detect a needle of a certain size, rather than metal of a certain weight. A standard needle should be used for calibration.
Fresh cream and jam gateau

Ingredients:
- Milk powder
- Water
- Pasteurized liquid egg
- Flour

Steps:
1. Dispatch
2. Chill
3. Pack
4. Fill
5. Depan and cool
6. Bake sponge
   - 750-770°C for 16.5 min.
7. Put batter in tins
8. <1 hr.
9. Packaging material
10. Jam
11. Cream
12. <5°C
Example of *unapproved* HACCP data sheet

<table>
<thead>
<tr>
<th>Raw material</th>
<th>CCP No.</th>
<th>Hazard to be controlled</th>
<th>Control measures</th>
<th>CCP parameters</th>
<th>Critical limits</th>
<th>Monitoring</th>
<th>Corrective actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flour</td>
<td>1</td>
<td>Insects</td>
<td>Sieving</td>
<td>Pore size</td>
<td>2 by 2 mm</td>
<td>Inspection</td>
<td>Re-sieve</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td><em>B. cereus</em></td>
<td>Testing</td>
<td>No./g</td>
<td>&lt; 1000/g</td>
<td>ISO method</td>
<td>Rejection</td>
</tr>
<tr>
<td>Milk powder</td>
<td>3</td>
<td>Aflatoxin</td>
<td>Supplier QA</td>
<td>Aflatoxin M&lt;sub&gt;x&lt;/sub&gt;</td>
<td>&lt; 10mg/kg</td>
<td>ISO method</td>
<td>Rejection</td>
</tr>
<tr>
<td>Liquid egg</td>
<td>4</td>
<td><em>Salmonella</em></td>
<td>Supplier QA</td>
<td>Coliforms count</td>
<td>&lt; 10/g</td>
<td>ISO method</td>
<td>Rejection</td>
</tr>
<tr>
<td>Water</td>
<td>5</td>
<td>Chemical contamination</td>
<td>Carry out on-site</td>
<td>Regulatory requirements</td>
<td>Chemical contamination (see spec.)</td>
<td>Testing to include toxic substances</td>
<td>Weekly</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>micro checks and obtain Certificate of Analysis of local sample</td>
<td>Regulatory compliance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>of Water Authority</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cream</td>
<td>6</td>
<td><em>Listeria</em></td>
<td>Testing</td>
<td>Absence in 10 g</td>
<td>5 samples of 10 g negative</td>
<td>ISO method</td>
<td>Daily</td>
</tr>
<tr>
<td>Jam</td>
<td>7</td>
<td>Pesticides</td>
<td>Supplier QA</td>
<td>Regulatory requirements</td>
<td>Regulatory requirements</td>
<td>Supplier audit</td>
<td>Yearly</td>
</tr>
<tr>
<td>Packing material</td>
<td>8</td>
<td>Moulds</td>
<td>Testing</td>
<td>Aerobic count</td>
<td>&lt; 100/cm&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Rodac plate</td>
<td>Every delivery</td>
</tr>
</tbody>
</table>
### Example of unapproved HACCP data sheet (cont.)

<table>
<thead>
<tr>
<th>Process step</th>
<th>CCP No.</th>
<th>Hazard to be controlled</th>
<th>Control measures</th>
<th>CCP parameters</th>
<th>Critical limits</th>
<th>Monitoring</th>
<th>Corrective actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage of raw material</td>
<td>9</td>
<td>Physical contamination, biological growth</td>
<td>Store as specified, i.e. cream &lt; 5°C, egg for specified max. time, Keep covered</td>
<td>Various</td>
<td>No physical, chemical contamination. Maintain temperature &lt; 5°C</td>
<td>Automatic temperature recorder. Visually inspect label to ensure stock rotation</td>
<td>Hold and inform QA Manager</td>
</tr>
<tr>
<td>Ingredient weighing</td>
<td>10</td>
<td>Too much salt</td>
<td>Weighing</td>
<td>Weight/batch</td>
<td>0.2%</td>
<td>Sartorius</td>
<td>Each batch</td>
</tr>
<tr>
<td>Sponge baking</td>
<td>11</td>
<td>Survival of pathogens</td>
<td>Bake sponge at specified time/ temperature</td>
<td>Time/temperature</td>
<td>Bake at 70°C for 2 min. minimum core temperature</td>
<td>Automatic chart recorder</td>
<td>Continuous</td>
</tr>
<tr>
<td>Cooling</td>
<td>12</td>
<td>Listeria</td>
<td>Keep cooling area clean</td>
<td>Visible residues</td>
<td>No residues visible</td>
<td>Observation</td>
<td>After every cleaning</td>
</tr>
<tr>
<td>Cream whipping</td>
<td>13</td>
<td>Listeria</td>
<td>Clean machine</td>
<td>Visible residues</td>
<td>No residues visible</td>
<td>Observation</td>
<td>After every cleaning</td>
</tr>
<tr>
<td>Filling</td>
<td>14</td>
<td>Salmonella</td>
<td>Keep line clean</td>
<td>Visible residues</td>
<td>No residues visible</td>
<td>Observation</td>
<td>After every cleaning</td>
</tr>
</tbody>
</table>
### Example of *unapproved* HACCP data sheet (cont.)

<table>
<thead>
<tr>
<th>Process step</th>
<th>CCP No.</th>
<th>Hazard to be controlled</th>
<th>Control measures</th>
<th>CCP parameters</th>
<th>Critical limits</th>
<th>Monitoring</th>
<th>Corrective actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flow wrapping</td>
<td>15</td>
<td>Biological contamination</td>
<td>Hermetic seal</td>
<td>No holes</td>
<td>Intact seal</td>
<td>Visual inspection</td>
<td>Re-sealing</td>
</tr>
<tr>
<td>Chilling</td>
<td>16</td>
<td>Growth of pathogens</td>
<td>Blast chilling</td>
<td>Time/temperature</td>
<td>½ hr./ 5 °C</td>
<td>Temperature recorder</td>
<td>Rework</td>
</tr>
<tr>
<td>Metal detect</td>
<td>17</td>
<td>Metal contamination</td>
<td>Metal detector</td>
<td>Metal size</td>
<td>Absent – ferrous 2.0 mg, non-ferrous 2.5 mg</td>
<td>Metal detection check using test pieces. Calibrate metal detector</td>
<td>Every 30 min. Stop line, recalibrate, notify QAM. Hold stock manufactured since previous check</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------------------------</td>
<td>-----------</td>
<td>------------</td>
<td>----------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cream taste testing</td>
<td>Acceptance</td>
<td>Every batch</td>
<td>Triangle test</td>
<td>Reject</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finished product B. cereus testing</td>
<td>Check safety, &lt; 100/g</td>
<td>Every batch</td>
<td>ISO method</td>
<td>Rework</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finished product Listeria testing</td>
<td>Check conformity with criterion Absence in 5 x 10g</td>
<td>1/week</td>
<td>ISO method</td>
<td>Find cause, Improve HACCP plan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring records review</td>
<td>Check adherence to HACCP plan</td>
<td>1/week</td>
<td>Inspection</td>
<td>Correct, Train, Improve</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
HACCP

case study no. 2
(student's version)

Fresh cream and jam gateau

WHO / ICD
HACCP STUDY  (CASE 2) 

EXAMPLE OF UNAPPROVED HACCP PLAN 
FRESH CREAM AND JAM GATEAU

a. FACILITY 
The purpose-built factory produces a variety of decorated gateaux for sale to the retail industry. The factory is based on a large new industrial estate and produces both chilled and frozen products.

b. PRODUCT 
The product has a fresh cream and jam filling between two sponges. It is a chilled product and must be kept below 5 °C through the distribution chain. The shelf life is 3 days from date of manufacture.

C. MANUFACTURE 
Sponge batters are baked at 150-170 °C through a travelling oven for 18.5 minutes. They are then cooled to ambient, automatically sliced and filled. There are a wide variety of fillings for the sponges. The sponges are flow-wrapped and put into cartons.

d. INTENDED USE 
The product is a treat for everyone at all times at all places.

---

1 The original study was published by: Sara Mortimer and Carol Wallace; HACCP, a practical approach, Chapman & Hall, 1994
♦ It has been changed on purpose to include errors. It should not be used as a "good" example.
Fresh cream and jam gateau

- Flour
- Milk powder
- Pasteurized liquid egg
- Water
- Ingredients

Mixer

Put batter in tins

Bake sponge

Depan and cool

Fill

Pack

Chill

Dispatch

< 5 °C

< 1 hr.

150 – 170 °C for 18.5 min.

High care area

Cream

Jam

Packaging material
Example of *unapproved* HACCP data sheet

<table>
<thead>
<tr>
<th>Raw material</th>
<th>CCP No.</th>
<th>Hazard to be controlled</th>
<th>Control measures</th>
<th>CCP parameters</th>
<th>Critical limits</th>
<th>Monitoring</th>
<th>Corrective actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flour</td>
<td>1</td>
<td>Insects</td>
<td>Sieving</td>
<td>Pore size</td>
<td>2 by 2 mm</td>
<td>Inspection</td>
<td>Re-sieve</td>
</tr>
<tr>
<td>Flour</td>
<td>2</td>
<td><em>B. cereus</em></td>
<td>Testing</td>
<td>No./g</td>
<td>&lt; 1000/g</td>
<td>ISO method</td>
<td>Rejection</td>
</tr>
<tr>
<td>Milk powder</td>
<td>3</td>
<td>Aflatoxin</td>
<td>Supplier QA</td>
<td>Aflatoxin Mt.</td>
<td>&lt; 10mg/kg</td>
<td>ISO method</td>
<td>Rejection</td>
</tr>
<tr>
<td>Liquid egg</td>
<td>4</td>
<td><em>Salmonella</em></td>
<td>Supplier QA</td>
<td>Coliforms count</td>
<td>&lt; 10/g</td>
<td>ISO method</td>
<td>Rejection</td>
</tr>
<tr>
<td>Water</td>
<td>5</td>
<td>Chemical contamination</td>
<td>Carry out on-site micro checks and obtain Certificate of Analysis of local sample-Water Authority</td>
<td>Regulatory requirements</td>
<td>Chemical contamination (see spec.) Regulatory compliance</td>
<td>Testing to include toxic substances Giardia/Cryptosporidium Inspect Certificates of Analysis from Water Authority</td>
<td>Weekly</td>
</tr>
<tr>
<td>Cream</td>
<td>6</td>
<td><em>Listeria</em></td>
<td>Testing</td>
<td>Absence in 10 g</td>
<td>5 samples of 10 g negative</td>
<td>ISO method</td>
<td>Rejection</td>
</tr>
<tr>
<td>Jam</td>
<td>7</td>
<td>Pesticides</td>
<td>Supplier QA</td>
<td>Regulatory requirements</td>
<td>Regulatory requirements</td>
<td>Supplier audit</td>
<td>Yearly</td>
</tr>
<tr>
<td>Packing material</td>
<td>8</td>
<td>Moulds</td>
<td>Testing</td>
<td>Aerobic count</td>
<td>&lt; 100/cm²</td>
<td>Rodac plate</td>
<td>Rejection</td>
</tr>
<tr>
<td>Process step</td>
<td>CCP No.</td>
<td>Hazard to be controlled</td>
<td>Control measures</td>
<td>CCP parameters</td>
<td>Critical limits</td>
<td>Monitoring</td>
<td>Corrective actions</td>
</tr>
<tr>
<td>-------------------</td>
<td>---------</td>
<td>-------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>----------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>Storage of raw material</td>
<td>9</td>
<td>Physical contamination, biological growth</td>
<td>Store as specified, i.e. cream &lt; 5°C, egg for specified max. time. Keep covered</td>
<td>Various</td>
<td>No physical, chemical contamination. Maintain temperature &lt; 6°C</td>
<td>Automatic temperature recorder. Visually inspect label to ensure stock rotation</td>
<td>Daily checks – continue during use. Every batch. Hold and inform QA Manager</td>
</tr>
<tr>
<td>Ingredient weighing</td>
<td>10</td>
<td>Too much salt</td>
<td>Weighing</td>
<td>Weight/batch</td>
<td>0.2%</td>
<td>Sarforius</td>
<td>Each batch Reprocess</td>
</tr>
<tr>
<td>Sponge baking</td>
<td>11</td>
<td>Survival of pathogens</td>
<td>Bake sponge at specified time/temperature</td>
<td>Time/temperature</td>
<td>Bake at 70°C for 2 min. minimum core temperature</td>
<td>Automatic chart recorder</td>
<td>Continuous Stop production. Reject faulty product. Adjust oven temperature/time</td>
</tr>
<tr>
<td>Cooling</td>
<td>12</td>
<td>Listeria</td>
<td>Keep cooling area clean</td>
<td>Visible residues</td>
<td>No residues visible</td>
<td>Observation</td>
<td>Clean again before start</td>
</tr>
<tr>
<td>Cream whipping</td>
<td>13</td>
<td>Listeria</td>
<td>Clean machine</td>
<td>Visible residues</td>
<td>No residues visible</td>
<td>Observation</td>
<td>Clean again before start</td>
</tr>
<tr>
<td>Filling</td>
<td>14</td>
<td>Salmonella</td>
<td>Keep line clean</td>
<td>Visible residues</td>
<td>No residues visible</td>
<td>Observation</td>
<td>Clean again before start</td>
</tr>
<tr>
<td>Process step</td>
<td>CCP No.</td>
<td>Hazard to be controlled</td>
<td>Control measures</td>
<td>CCP parameters</td>
<td>Critical limits</td>
<td>Monitoring Procedure</td>
<td>Frequency</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------</td>
<td>-------------------------------</td>
<td>------------------</td>
<td>---------------</td>
<td>----------------</td>
<td>-------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Flow wrapping</td>
<td>15</td>
<td>Biological contamination</td>
<td>Hermetic seal</td>
<td>No holes</td>
<td>Intact seal</td>
<td>Visual inspection</td>
<td>Every 15 min.</td>
</tr>
<tr>
<td>Chilling</td>
<td>16</td>
<td>Growth of pathogens</td>
<td>Blast chilling</td>
<td>Time/temperature</td>
<td>½ hr./ 5 °C</td>
<td>Temperature recorder</td>
<td>Each batch</td>
</tr>
<tr>
<td>Metal detect</td>
<td>17</td>
<td>Metal contamination</td>
<td>Metal detector</td>
<td>Metal size</td>
<td>Absent – ferrous 2.0 mg, non-ferrous 2.5 mg</td>
<td>Metal detection check using test pieces, Calibrate metal detector</td>
<td>Every 30 min. Daily</td>
</tr>
</tbody>
</table>
## VERIFICATION

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cream taste testing</td>
<td>Acceptance</td>
<td>Every batch</td>
<td>Triangle test</td>
<td>Reject</td>
</tr>
<tr>
<td>Finished product</td>
<td>Check safety, &lt; 100/g</td>
<td>Every batch</td>
<td>ISO method</td>
<td>Rework</td>
</tr>
<tr>
<td><em>B. cereus</em> testing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finished product</td>
<td>Check conformity</td>
<td>1/week</td>
<td>ISO method</td>
<td>Find cause, Improve HACCP plan</td>
</tr>
<tr>
<td><em>Listeria</em> testing</td>
<td>with criterion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring records review</td>
<td>Check adherence to HACCP plan</td>
<td>1/week</td>
<td>Inspection</td>
<td>Correct, Train, Improve</td>
</tr>
<tr>
<td></td>
<td>Absence in 5 x 10g</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
case study no. 3

Flour Fried Chicken

WHO / ICD
HACCP Interactive exercise

During this exercise the trainer and trainees are together conducting a HACCP study of Flour Fried Chicken. The trainer should stimulate the questions which need to be asked, he should try to prevent as much as possible to elaborate the HACCP plan himself. The trainees are the experts, the trainer only the moderator.

Preparation of Flour Fried Chicken

A chef prepares a flour-fried chicken for a group of people according to the following recipe:

a. Chicken preparation.

Take 3 lbs. of chicken meat, wash it, and cut into several pieces.

b. Cooking

Pour ½ inch (1.25 cm) cooking oil in an electric skillet set at 350 °F (175 °C). Beat two eggs in a flat dish.

Combine ¼ cup (125 ml) flour with salt, pepper and two cloves of chopped garlic in a flat dish. Add enough cold water to make a stiff paste.

Dip chicken pieces in the egg mixture, then roll them in the flour mixture to coat all sides. Drop the chicken into hot oil, cover (leave vent in lid open) and cook for about 15 minutes or until dark golden brown. Turn chicken pieces. Reduce the temperature to 300 °F (150 °C) and continue cooking, uncovered, until golden on all sides and tender, about 15 minutes more. Serve immediately.

Interactive exercise

Carry out a HACCP analysis on this recipe. The teacher and the trainees have to design the flow diagram, including the raw materials and processing steps. In the preparation of the fried chicken the time and temperature necessary to render the chicken safe, is very critical. The heat penetration curve is provided but should only be shown when students ask for it. They should themselves find out that such a curve is necessary to determine the critical limits at the frying process as a CCP. They may also need to determine during which time and at which temperature the chicken could be kept before serving. At the end of the exercise the complete flow diagram, the heat penetration curve and the examples of the two HACCP data sheets can be shown and further explained.
DIAGRAM FLOW OF FLOUR FRIED CHICKEN

Pepper
Salt
Water
Flour
Garlic
Chopping
Egg
Whisk
Holding
Chicken
Washing
Cutting
Holding
Cooking Oil

Mixing
Holding
Covering
Deep Frying
Holding
Serve
Rolling
Temperature/Time chart for chicken

HEATING CURVE OF CHICKEN MEAT IN ELECTRIC SKILLET
SET AT 175 °C

Centre Temperature (°C)

Time (minutes)
## Microbiological Study

### HACCP Data Sheet

<table>
<thead>
<tr>
<th>Point of control (raw material or process step)</th>
<th>Hazards</th>
<th>Control measures</th>
<th>CCP parameters</th>
<th>Critical limit</th>
<th>Target values</th>
<th>Monitoring procedures</th>
<th>Corrective action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep frying</td>
<td>Survival of or recontamination with microbial pathogen (<em>E. coli, C. jejuni, Salmonella spp.</em>)</td>
<td>Correct design and operation of deep frying</td>
<td>Temperature and time</td>
<td>70 °C all parts of chicken meat within 2 minutes</td>
<td>175 °C 15 minutes and 150 °C 15 minutes</td>
<td>Record the temperature and time at centre of meat</td>
<td>Adjust the temperature</td>
</tr>
<tr>
<td>Holding (or as GMP, can be avoided if it is consumed immediately)</td>
<td>Growth of and recontamination with microbial pathogen</td>
<td>Time of holding</td>
<td>Time of storage</td>
<td>less than 4 hours</td>
<td>Eat immediately while still hot/warm</td>
<td>Record the time</td>
<td>Reheating</td>
</tr>
<tr>
<td></td>
<td>Storage condition</td>
<td>Storage condition of cooked chicken</td>
<td>No flies, cooked food should be covered</td>
<td>No flies, cooked food should be covered</td>
<td>Observe the flies and cover of cooked food</td>
<td></td>
<td>Reheating</td>
</tr>
<tr>
<td>Point of control (raw material or process step)</td>
<td>Hazards</td>
<td>Control measures</td>
<td>CCP parameters</td>
<td>Critical limit</td>
<td>Target values</td>
<td>Monitoring procedures</td>
<td>Corrective action</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>---------</td>
<td>-----------------</td>
<td>----------------</td>
<td>----------------</td>
<td>---------------</td>
<td>----------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Pepper and onion (can be ignored since they are used in small amounts only)</td>
<td>Presence of Pesticide</td>
<td>Supplier's quality assurance</td>
<td>Absence of pesticide</td>
<td>0.1 mg/kg (Aldrin &amp; Dieldrin in onion) 0.5 mg/kg (Chlorpyrifos in onion) 1 mg/kg (Dimethoate in onion &amp; peppers) (Codex Vol 2,93)</td>
<td>No target value</td>
<td>Inspection, chemical testing</td>
<td>Rejection of suspected lots</td>
</tr>
<tr>
<td>Chicken meat</td>
<td>Presence of hormone and antibiotic</td>
<td>Supplier's quality assurance</td>
<td>Absence of hormone or antibiotic</td>
<td>Oxytetracycline MRL 100 ppb or 0.3ppb/kg body weight</td>
<td>No target value</td>
<td>Supplier record inspection, chemical testing</td>
<td>Reject</td>
</tr>
</tbody>
</table>
NOTES FOR DISCUSSION

Microbiological study

From the earlier lectures we have learned that we must assume that raw chicken will always be contaminated with infectious pathogens. The CCP is the temperature at the centre of the chicken while it is cooking. This must reach the equivalent of 70°C for 2 minutes at the center. Other time-temperature equivalents are given in the Manual.

After cooking, the next CCP is to prevent recontamination, which will occur if the kitchen hygiene is poor. It is important to teach that the layout of a kitchen (or any food operation) may be crucial in the prevention of cross-contamination.

Holding time and temperature may not be critical when the chickens are served within four hours after preparation (surviving microorganisms will still be in the lag phase, and the temperature may be still too high for multiplication of pathogens). In this case it is covered by Good Hygienic Practice (GHP) and not a CCP.

The key piece of information which is missing is the chart of temperatures/times reached in the middle of the chicken.

Chemical study

While the limits for pesticides and antibiotics are correct, they are of no practical value to caterers and fast food outlets. These limits are used by regulatory authorities to ascertain the levels of agricultural chemicals in the food chain and to take action when the levels exceed the critical limits. The message for caterers and fast food restaurants is to use a reputable supplier who is aware of these hazards in the raw materials.
HACCP

case study no. 4

Dried milk production

WHO / ICD
HACCP STUDY

DRIED MILK PRODUCTION

1 INTRODUCTION

In order to provide the consumer with safe milk powder, the conditions under which it is produced should be well chosen and critical steps kept adequately under control.

The factory manager of a certain dairy plan has asked its quality assurance manager to carry out a HACCP study of a newly installed milk powder production line in order to revise the HACCP plan. The local food inspector has never been involved in the production of milk powder and has asked the plant manager to participate in the study in order to assure that certain aspects of food safety and legislative compliance are adequately addressed.

The quality assurance manager has selected several well-motivated people to carry out the HACCP study with him. The food inspector participates in the discussions but the final responsibility for making the decisions is in the hands of the other members of the team.

2 THE PRODUCT

The product is a simple full-cream milk powder. It is intended for use by people of all ages who live in a country where refrigeration facilities for fresh milk are sparse. Its preparation requires only the reconstitution of the powder in warm water. Once reconstituted, the milk should be consumed immediately or, at most, within two hours after preparation.

3 RAW MATERIALS

Milk is obtained from a farmers cooperative that operates a milk collection and chilling operation. The chilled milk is transported by tankers to the factory. The plant is located in a country with a moderate climate, the farms are of moderate size, and cows are normally quite healthy, although mastitis problems do sometimes occur. Pests may bother the cows and certain feed ingredients may come from tropical countries. The powder is packed in tins which are obtained from a nearby factory.
4 THE FACTORY

The plant recently switched from the production of sweetened condensed milk to the production of milk powder. The employees have been trained by the production manager and have sufficient technical skills to produce a product of the required quality. Unfortunately, the factory is located quite close to a waste treatment plant; however, odour problems occur very infrequently.

5 THE LINE

The actual processing line is newly installed but everything except the drying tower had to be installed in an existing building which was formerly used for the production of sweetened condensed milk (for the lay-out see the enclosed plan). The line consists of milk reception, skimming, standardising, clarifying, pasteurising, condensing, homogenising, spray-drying, cooling, filling and packaging. Some details concerning some of the processing steps are given in the Annex.

N.B.
The study team is under time pressure and decides to deal only with hazards of the highest priority.
ANNEX

A SHORT DESCRIPTION OF THE PRODUCTION
OF SPRAY - DRIED MILK POWDER

Raw milk is received, either in tanks or churns, in the milk reception area (Fig. 1).

Part of the milk is skimmed i.e. the fat is removed (Fig. 2). This skimmed milk is added to unskimmed milk in a standardization tank in order to obtain the required fat content.

The standardized milk is then clarified, normally at a temperature of around 40°C, in a kind of centrifuge to remove undesirable matter before pasteurization (Fig. 3).

Pasteurization is usually carried out in tubular or plate heat exchangers of various types (Fig. 4).

Prior to drying, the milk is concentrated in evaporators where it is indirectly heated, and where the vapour is separated from the condensed milk (Fig. 5).

In order to obtain the correct size and distribution of fat globules the concentrated milk is homogenised by compressing and decompressing the milk in so-called homogenizers (Fig. 6).

In the spray-drying process, the concentrated milk is dispersed by a nozzle or other means in the spray tower (Fig. 7). The fine droplets are exposed to a stream of air, the water evaporates and is extracted with the air from the drying tower. The powder falls down and is removed at the base of the tower. Cyclones are attached to the tower to separate milk powder fines from the outgoing air. The hot powder is cooled with air before it is filled in tins or other packaging material.
Notes for the teacher

The participants should be divided over working groups of ca. 6-8 persons. The course leader has to explain that each group has to simulate a real situation, i.e. they have to act as a HACCP team.

The task is to fill in the HACCP data sheet, and to present to all participants the outcome of their efforts.

As background information they get:

A description of the factory, the milk supply and the product
A simple flow (block) diagram
A lay-out of the factory
A short description of the process
Some figures illustrating some of the equipment
A HACCP data sheet

The working groups have to use their imagination to fill in all the missing elements, and consequently each working group may come up with other hazards, CCPs, critical limits etc. There is not one good HACCP data sheet!

The study will normally take at least half a day. The groups are only helped by the "experts" (the course leader and some technical helpers) when critical information is lacking, or when a group gets lost in details.

During the presentation of the results of the HACCP study, the leader should only indicate where mistakes in the procedure were made. For instance when it is clear that a group did not use the decision trees, when CPs (non-critical control points, covered by GHP) are listed as CCPs, when hazards are mentioned which are not causing safety concerns etc..

The purpose of the exercise is that the participants get a better understanding of the system, and how HACCP forces people to make decisions. The exercise is what counts, not the results.
MILK POWDER PRODUCTION
(BLOCK DIAGRAM)

1. MILK RECEPTION

2. SKIMMING

3. CLARIFYING

4. PASTEURISING

5. EVAPORATION

6. HOMOGENISING

7. SPRAY DRYING

TO FILLING
FIG 4. PASTEURISING

Plate pasteurizer with regenerative sections and booster pump

1 Cooling section
2 Regenerative section
3 Regenerative section
4 Holding section
5 Heating section
6 Booster pump

Plate heat exchanger with connecting plate between two sections
FIG 5. EVAPORATION

Two-stage falling-film evaporator with thermocompressor

FIG 6. HOMOGENISING

Cutaway view of a homogeniser
FIG 7. SPRAY DRYING

ROOF

EXHAUST AIR

MILK

HOT AIR

TOP FLOOR

COLD AIR

GROUND FLOOR

POWDER
HAZARD ANALYSIS ASPECTS

RAW MATERIAL PACKAGING

PRODUCT AND USAGE

PEOPLE

ENVIRONMENTS

buildings

equipments

treatment

line

hygiene

training