HACCP
Principles and Practice

Teacher's Handbook

Developed by
Dr Yasmine Motarjemi
WHO

Prof Dr Mike van Schothorst
Nestlé

Edited by
Dr Susan Jongeneel
Nestlé

A WHO / ICD Training manual
in collaboration with FAO
Foreword

The Hazard Analysis and Critical Control Point (HACCP) system is a food safety management tool developed in the early 1970s by the food industry. Since it enhances the safety of food, it is of considerable public interest and, thus, some 20 years ago the World Health Organization (WHO) recognized HACCP as an important concept to prevent foodborne disease. Several publications and documents were issued to help disseminate this information (see list of Additional References). Together with the food industry and other relevant partners, including the Food and Agriculture Organization of the United Nations (FAO), the principal contribution of WHO was to promote the development, international harmonization, and facilitation of the HACCP system.

Appreciable progress in the recognition of HACCP as the "new" method of food safety assurance was made in 1993 when the Codex Alimentarius Commission (CAC) adopted the Guidelines for the Application of the Hazard Analysis and Critical Control Point (HACCP) System. This text was revised following a report of a WHO consultation, convened in close collaboration with the FAO and the Industry Council for Development (ICD), as a representative of the food industry. Consequently, in 1997 the CAC adopted a much improved document Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (Annex to CAC/RCP 1-1969, Rev. 3 (1997)), as the presently best available guidance on this system.

With the establishment of the World Trade Organization (WTO) and the introduction of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Codex text on HACCP and the General Principles of Food Hygiene have become the points of reference on these subjects.

As a consequence of the increasing application of HACCP in the food safety management of food industries, the traditional role of food control agencies is evolving. Today, food control measures must include new responsibilities such as assessing HACCP systems that have been designed and implemented by industry. Because different interpretations of the HACCP system have caused confusion, training materials are required to provide a clear and consistent application worldwide. In addition, there is a growing need to promote HACCP to governments and the food industry, particularly in developing countries.

These considerations have led WHO and ICD to develop this training package. It is intended as a general introduction to HACCP and as a practical guide in countries at all stages of development. Since we believe that the responsibility for food safety should be shared by governments, industry and consumers, this internationally available training material addresses food operators, inspectors and consumers. The knowledge acquired from the course can be applied to all situations where food is processed or prepared.

Dir. and Prof. Dr. F.K. Käferstein
Former Director,
Programme of Food Safety and Food Aid,
WHO

Prof. Dr. M. van Schothorst
Chairman
ICD
About This Manual

The purpose of this manual

Training of personnel from industry, government and academia in HACCP principles and applications is an essential element for the effective implementation of HACCP. The manual HACCP Principles and Practice has been developed to facilitate the training of food inspectors and food industry personnel, and to support the consistent interpretation and application of HACCP worldwide.

Objectives of this manual

The manual intends to:

• provide a basic understanding of the principles of the HACCP system and its advantages

• review and strengthen basic knowledge required in food hygiene (including hazards associated with foods and methods for their control) in order to apply the HACCP system

• impart skills for applying the HACCP system

• define the respective roles of governments and industry in HACCP implementation

Organization and usage of this manual

The preliminary pages show the structure of the training course listing the five modules, a proposed 4-day training programme, and the objectives of the course and content of the modules.

Then each module is presented as sets of overheads and corresponding notes for trainers. Four practical exercises are included as case studies. However, other case studies may also be used.

It is recommended that a minimum of four examples of HACCP be presented during a training course to illustrate the system. A video presentation and/or field visit (e.g. visits to industrial plants or pilot plants) should also be foreseen as a part of the course.
Various courses can be given:

*Introductory course* (module 1 and module 4–lecture 2): to introduce HACCP to policymakers and managers of food safety programmes and raise their awareness of the needs and benefits of the HACCP system and assure their commitment in implementing a HACCP programme (1 day).

*Standard course* (modules 1 to 4 and case studies): to train food inspectors and food safety assurance personnel in understanding and applying the HACCP system (4–5 days).

*Training the trainer course* (modules 1 to 5 and case studies): to introduce trainers to the HACCP manual and the approach taken to teach the HACCP system as well as the recommendations for organizing, conducting and evaluating HACCP training courses (4–5 days).

This manual contains a wealth of information and more material than can be covered in a 4–5 day period. Depending on the time available and the background of the participants, some lectures can be shortened as illustrated in module 4–lecture 3.

**CD-ROM**

The WHO/ICD HACCP CD-ROM contains the following folders and files:

- **HACCP pp4**
- **HACCP-off97**
- **HACCP-Word2**
- **Milkpict**
- **Readme.txt**

The most important entry is the *HACCP-off97* folder that contains all the presentation material and associated notes for the training course, including student versions of the case studies. These are saved as Microsoft Office 97 files.

In order to offer compatibility for sites with older versions of Microsoft PowerPoint and Word the same material has been saved in previous formats. The presentation material in PowerPoint 4 format is collected in the *HACCP pp4* folder and the notes are saved in Word 2 format in the folder *HACCP-Word2*. *Milkpict* is a folder containing optional diagrammatic material for Case Study 4 (Dried Milk Production) as bitmap files. Finally, the file *Readme.txt* contains complementary information.

**Tell us what you think**

WHO and ICD would appreciate receiving the comments and experiences of trainers who have used this course.
Acknowledgements

WHO and ICD acknowledge with thanks the contributions of the following persons in reviewing this manual:

John Crowther, Unilever Research, Sharnbrook, United Kingdom

Carlos A. Lima dos Santos, Fish Utilization and Marketing Service, FAO, Rome, Italy

Bertrand Gagnon, Food Inspection Directorate, Canadian Food Inspection Agency, Canada

Marco F.G. Jermini, European Centre for Environment and Health, Rome Division, Italy

Poonsri Jirathana, Department of Agriculture, Ministry of Agriculture and Cooperatives, Thailand

Jean-Louis Jouve, Ecole Nationale Vétérinaire de Nantes, Hygiène et Industrie des Denrées Alimentaires d’Origine Animale (HIDAOA), Département Santé des Elevages & Qualité des Produits, France

Su Leaper, Campden and Chorleywood Food Research Association, United Kingdom

Judith Lee, Ministry of Agriculture and Forestry (Meat & Seafood), New Zealand

Hector Lupin, Fish Utilization and Marketing Service, FAO, Rome, Italy

Tony Mayes, Unilever Research, Sharnbrook, United Kingdom

Gerry Moy, Food Safety Unit, WHO, Geneva

Paola Robiolio, Societa Generale dell’Immagine s.r.l. (S.G.I.), Italy

Ricardo Molins, Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture, Austria

Rudolf Schmitt, Ecole d’Ingénieurs du Valais (EIV), Switzerland

Bob Tanner, NSF International, Belgium

Anthony Whitehead, Food Quality and Standards Service, Food and Nutrition Division, FAO, Rome, Italy

WHO and ICD would like to thank Gerda Heeringa for having contributed extensively to the preparation and finalization of the manual.
Acknowledgement is also due to the following members of the ICD for their support during the preparation of this manual:

Barry-Callebaut, Bestfoods Europe, Danone, Fondation Nestlé Pro Gastronomia, Mars, Monsanto, Nestlé, NSF International, Unilever.

Addresses for correspondence:

Industry Council for Development
P.O. Box 160
Ramsgate, Kent CT12 4GB
United Kingdom
Fax: +44(0) 1843 822566

World Health Organization
Food Safety Programme
CH-1211 Geneva 27
Switzerland
Fax: +41(0) 22 7910476
WHO References


Reilly, A. & Käferstein, F. Food safety hazards and the application of the principles of the hazard analysis and critical control point (HACCP) system for their control in aquaculture production. *Aquaculture Research* (28) 735-752, 1997.


*The WHO Golden Rules for Safe Food Preparation.*


**Additional References**


A simple guide to understanding and applying the Hazard Analysis Critical Control Point Concept. ILSI Europe, Avenue E. Mounier 83, Box 6, B-1200 Brussels, Belgium.
Structure of the WHO / ICD training course on Hazard Analysis and Critical Control Point system

Introduction

Module 1
INTRODUCTION OF THE HACCP SYSTEM

M1L1 The need for the HACCP system
M1L2 HACCP in food hygiene
M1L3 History and status of HACCP
M1L4 Basic principles of the HACCP system
M1L5 Benefits and areas of application

Module 2
ESSENTIAL KNOWLEDGE

M2L1 Microbiological hazards
M2L2 Chemical and physical hazards in food
M2L3 Hazards in raw material
M2L4 Food Technologies to render and keep foods safe
M2L5 Cleaning and disinfection

Module 3
HACCP APPLICATION

M3L1 Good hygienic practices
M3L2 HACCP system and its application
M3L3 Hazard Analysis and CCP determination
M3L4 Monitoring
M3L5 Validation & verification

Module 4
IMPLEMENTATION OF HACCP PLANS

M4L1 Implementation of HACCP
M4L2 The role of governments.

Module 5
TRAINING IN HACCP
CASE STUDIES

Case 1: Fresh cream and jam gateau
       Example of HACCP plan

Case 2: Fresh cream and jam gateau
       Example of unapproved HACCP plan

Case 3: Flour fried chicken
        Interactive exercise

Case 4: Dried milk production
        Group exercise

ADDITIONAL AIDS

Video
Field visit
SUGGESTED 4-DAY PROGRAMME OF WHO / ICD
HACCP TRAINING COURSE

MONDAY

09.00 Opening (WHO and ICD representatives, local authorities,
course leader, local organizers)

09.15 Presentation of participants

09.45 Introduction to the course

10.00 Break

INTRODUCTION TO HACCP

10.30 The need for HACCP M1L1 (M1L5)¹

11.15 History and status of HACCP M1L3 (M1L2)

12.00 Lunch

13.30 Basic principles of the system M1L4

14.15 Presentation of example of HACCP plan (Case 1)

ESSENTIAL KNOWLEDGE AND UNDERSTANDING OF HACCP

15.00 Microbiological hazards M2L1

16.00 Break

16.30 HACCP system and its application M3L2

17.30 Adjourn

¹ Lectures mentioned between brackets contain additional material
TUESDAY

09.00 Chemical and physical hazards
09.45 Hazards in raw materials
10.15 Break
10.45 Exercise: Critical examination of unapproved HACCP plan (Case 2)
12.00 Lunch
13.30 Presentation of results
14.15 Food technologies to render and keep foods safe
15.45 Break
16.15 Good hygienic Practices
17.00 Video
17.30 Adjourn

WEDNESDAY

HACCP APPLICATION

09.00 Hazard Analysis and CCP determination
09.30 Use of decision trees, examples (Case 3)
10.00 Break
10.30 Monitoring  
11.00 Group exercise  

12.00 Lunch  

13.00 Group exercise  

15.45 Break  

16.15 Presentation of results  
17.30 Adjourn  

**THURSDAY**  

09.00 Validation and verification  

**HACCP IMPLEMENTATION AND ROLE OF GOVERNMENTS**  

09.45 HACCP implementation  

10.00 Break  

10.30 Role of governments  
11.15 Training in HACCP  
11.45 Closing session  

12.00 Lunch  

13.30 Factory visit
Note for trainers

This training package can be used for many different purposes.

We have suggested a “standard course” outline on the foregoing pages. This “standard course” is intended to provide a four-day training for food inspectors and people in industry during four days in the basics of HACCP, its application, implementation and assessment. This training package contains more material than can be dealt with in such a period of time.

We will suggest which lectures or parts of lectures should be used in a four-day course. However, depending on the group to be trained, certain lectures may need to be shortened, others extended. When more time is available all material can be used.
Training in HACCP

WHO / ICD course on training in
Hazard Analysis
and
Critical Control Point system

Welcome to this WHO/ICD training course on Training in HACCP. HACCP stands for Hazard Analysis and Critical Control Point system. Please note that in the past we used to say Hazard Analysis Critical Control Point, but after a proposal from a WHO Consultation (Geneva 1995), the Codex Alimentarius Commission adopted in 1997 the term Hazard Analysis and Critical Control Point in order to ease its translation into other languages.
The objective of this training course is to explain:

a) advantages of HACCP, whether employed by food industry or government

b) the 7 principles of HACCP and how they are applied

We will also try to show you how HACCP should be implemented in industry and how it fits into a governmental food control system.

We have included some suggestions on how to organize a training course.

*Note for trainers*

HACCP and its assessment are based on knowledge, we therefore have included in this training package examples of the type of knowledge we consider to be essential for HACCP. These modules can be used in total, or tailored to complement the background expertise of the participants.
Course content: module 1
Introduction of the HACCP system

➢ The need for the HACCP system
➢ HACCP in food hygiene
➢ History and status of HACCP
➢ Basic principles of the HACCP system
➢ Benefits and areas or application

This module contains five lectures.
In the first lecture we will describe the problems in the area of food safety which led to the development of HACCP.
We will present the basics of HACCP and relate the system to other well known food safety management tools such as Good Manufacturing Practices (GMP) / Good Hygienic Practices (GHP) and ISO 9000.
We will then give an overview of the history of HACCP, and its current status.
Finally we will explain the benefits of the system.
We hope that by the end of the first module, you will understand what HACCP is and appreciate its importance.

Note for trainers
In the "standard course" the Need and Benefit, and HACCP in food hygiene and History of HACCP are combined.
Course content: module 2
Essential knowledge

- Microbiological hazards
- Chemical and physical hazards in food
- Hazards in raw material
- Food technologies to render foods safe
- Cleaning and disinfection

The second module describes the knowledge needed to apply HACCP.

Note for trainers
We have made a selection of the Food technologies material to be used in the "standard course". Depending on background knowledge, other subjects or overheads could be chosen. We suggest to use all material on Hygiene, but if more emphasis has to be put on cleaning and disinfection, the lecture on this subject can be helpful.
Course content: module 3
HACCP application

- Good Hygienic Practices
- HACCP system and its application
- Hazard Analysis and Critical Control Point determination
- Monitoring
- Validation and verification

During this lecture you will learn how to do HACCP or how to use HACCP for your work in controlling safety. We will first go through GMP/GHP which is prerequisite for the application of HACCP. Then we will repeat the definitions and principles of HACCP as defined by the Codex Alimentarius Commission. We will also present the Codex Guidelines for the application of HACCP. Finally we will take you step by step through the different principles of HACCP and show you how to do it.
In this module we will explain how HACCP could be implemented by industry and what should be the responsibility of government agencies in assessment of HACCP.
This module is intended for those who are organizing a training course and/or are already trainers. The module presents experiences gained in organizing HACCP training courses and shows trainers how to perform HACCP training efficiently.
Exercises

- Example of HACCP plan (case 1)
- Example of unapproved HACCP plan (case 2)
- Interactive exercise (case 3)
- Video
- Group exercise (case 4)
- Field visit

During the course we will also go through a number of exercises of different nature, including a video film and field visit, to help you understand how to do HACCP. However, you will really learn HACCP only by doing it yourself.
Module 01 - lecture 01

The need for the HACCP system
In the 30 years since its conception, the HACCP system has grown to become the universally accepted method for food safety assurance.

Since its conception, the HACCP system has grown to become the universally accepted method for food safety assurance. The World Health Organization has promoted it for about 20 years.
The first questions to ask are why has HACCP become so important, what are its objectives, and why has the World Health Organization (WHO) shown interest in it?
The need for HACCP

To successfully implement HACCP in the food supply, authorities responsible for food safety must first be aware of the need to move to a system such as HACCP.

Until this need is acknowledged, it is unlikely that a commitment at any level can be expected.

Report of a WHO Consultation on HACCP: Concept and Application (June 1995)

In the report of a WHO Consultation on HACCP: Concept and Application, it was stated that To successfully implement HACCP ....... expected.

Therefore, the objective of this lecture is to acknowledge this need and explain why food and health authorities in many countries have adopted this system.

A recommendation to use HACCP is not merely a burden imposed by regulatory agencies, but rather a tool which may benefit both industry and society.
The need for an effective food safety assurance method

To understand the need for HACCP, we have to realize the tremendous problems that public health authorities have been facing during the last two decades.
First, public health authorities have come to realize that foodborne diseases are a much more widespread public health problem than previously believed.

The Joint FAO/WHO Expert Committee on Food Safety reported in 1983 that *Illness due to contaminated food is perhaps the most widespread health problem in the contemporary world and an important cause of reduced economic productivity.*
Foodborne diseases are a widespread public health problem

<table>
<thead>
<tr>
<th>Country</th>
<th>Prevalence</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden (1995)</td>
<td>7%</td>
<td>National survey</td>
</tr>
<tr>
<td>Netherlands (1991)</td>
<td>15%</td>
<td>Sentinel study</td>
</tr>
<tr>
<td>New Zealand (1993)</td>
<td>9%</td>
<td>National survey</td>
</tr>
<tr>
<td>UK (1995)</td>
<td>7%</td>
<td>National survey</td>
</tr>
<tr>
<td>Canada (1985)</td>
<td>8%</td>
<td>Estimation</td>
</tr>
<tr>
<td>USA (1985)</td>
<td>10%</td>
<td>Estimation</td>
</tr>
</tbody>
</table>

This statement was confirmed by the alarming figures which are reported from several countries. Data and surveys from many industrialized countries indicate that up to 15% of the population may be affected each year by a foodborne disease.
Incidence of infectious enteritis and typhoid fever in Germany

Incidence reports indicate that foodborne diseases are not only widespread but, despite the efforts made by the public health authorities, they are on the increase, at least in some countries. This trend indicates that efforts of public health authorities over the past two decades have not been effective in preventing foodborne diseases.
Increased incidence of foodborne diseases in UK

Laboratory reports of gastrointestinal infections in England and Wales

A trend similar to Germany and some other industrialized countries has been observed in the UK. Some diseases such as campylobacterioses and salmonellosis have dramatically increased.
A similar situation is observed in some developing countries, particularly those that are moving rapidly towards industrialization.
In 1991, cholera emerged in Latin America, increasing the number of countries and people affected by cholera.
In addition to the need for preventing foodborne diseases which are traditionally known, public health authorities have also been challenged by the emergence of new or newly recognized foodborne diseases such as ...[see slide].

These diseases are referred to as "emerging" either because they have been newly identified (e.g. infections due to *E. coli* O157;H7), or have acquired a new niche in the environment (e.g. salmonellosis due to *S. enteritidis*), or have acquired a new geographic region such as cholera which in 1991 reached the Latin American region.

Some diseases are increasing because production systems are changing. For example, foodborne trematodes is an emerging problem because, among others, aquaculture production (sometimes under unsanitary conditions) is increasing.
Emergence of foodborne diseases

On this figure we note the emergence of infections due to *E.coli* O157:H7 in the UK.
Increased knowledge and awareness of the serious and chronic health effects

<table>
<thead>
<tr>
<th>Reactive arthritis</th>
<th>Cancer (liver)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meningitis</td>
<td>Congenital blindness</td>
</tr>
<tr>
<td>Haemolytic uraemic syndrome (HUS)</td>
<td>Abortion</td>
</tr>
<tr>
<td>Septicaemia</td>
<td>Malnutrition</td>
</tr>
<tr>
<td></td>
<td>Death</td>
</tr>
</tbody>
</table>

While in the past, public health authorities perceived foodborne illnesses as mild and self-limiting, today there is greater awareness that these diseases can have crippling effects or even be fatal. These are just a few examples of the serious health consequences of foodborne diseases.

In view of this, public health authorities realized that they could not allow such foodborne disease outbreaks to occur and saw the need to adopt a method of food safety assurance which enhances food safety, and is based on prevention, rather than identification, of contamination.
New food technologies and processing methods

Need for predicting potential health risk associated with

- new technologies and their application
- consequences due to inappropriate handling during preparation

In the contemporary world, new food processing and handling techniques are emerging. This means that it is increasingly important to have techniques to predict potential health risks which may be associated with the technology itself as well as later appropriate food handling in households.
Increased awareness of the economic consequences of foodborne diseases

- medical care costs
- loss of productivity
- loss of food
- reduced food trade
- decrease in tourism

There are also economic costs associated with food contamination, for treatment and loss of productivity. The economic costs are also tremendous for the food industry because food contamination may lead to recalls and loss of contaminated food. It may also jeopardize the reputation of the company and lead to reduction in food trade. Finally, the tourism industry may also be affected.
Increase in the number of vulnerable people

- elderly
- immunocompromised individuals
- pregnant women
- infants and young children
- undernourished individuals

Public health authorities are also realizing that some groups of the population are more susceptible to foodborne diseases and may acquire the diseases more easily or may suffer more severely from the diseases.

Again, the traditional method of food safety assurance did not provide a mechanism to consider the increased risk or health consequence of foodborne diseases for this group of the population.
Industrialization and mass production, at the agricultural level, manufacturing and processing, or food preparation and mass catering, also contribute to the increased incidence of foodborne disease. Under these conditions, there is an increased likelihood of outbreaks affecting a growing number of people.

This figure shows how a single foodborne disease outbreak which occurred in Illinois in 1985 affecting some 170,000 to 200,000 people influenced the statistics. In the summer of 1996, another large foodborne disease outbreak of *E. coli* O157 occurred in Japan affecting over 9000 people, mainly school children as a result of contamination of school lunch.

Again, this trend in the production system underlined the need for a more effective system, because the smallest error in food production can endanger the lives of a large number of people.
Another factor contributing to foodborne disease outbreaks is the fact that the food chain has become longer and more complex.

Each of the steps from food production to consumption is an opportunity for contamination or growth of microorganisms. A large foodborne disease outbreak in the USA affecting over 224 000 people resulted from the contamination of ice cream during transport. An outbreak of *E. coli* O157:H7 which occurred in Scotland during December 1996, showed that the food chain can be even more complex than indicated here as the butcher was selling meat to other butchers.

The traditional method of control at various stages of the food chain is costly and ineffective. The application of HACCP from production to consumption provides a mechanism to examine the entire food chain and implement measures which are necessary for ensuring food safety.
Changing lifestyles

- increase in food service and mass catering establishments (including street food vendors)
- travel
- role of women
- migration

The change in lifestyle is another factor with an impact on foodborne illness. More meals are being eaten outside the home because of travel and change in the role of women. The dietary habits are also changing partly due to migration or travel. As a consequence restaurants, fast food, street food outlets etc. have increased significantly.

Traditional inspection and control methods are not only inefficient, but cannot provide the increased resources which are required for controlling the increasing number of food businesses.
Increased tourism and international trade in foodstuffs

- increase in travel-related foodborne diseases
- foodborne disease outbreaks due to contaminated foods

There is also increased tourism and international trade of food. It is estimated that 20-50% of travellers are at risk of foodborne diseases. The problem is so important that in some places such as Scandinavia it is estimated that 80-90% of cases of salmonellosis are imported cases.

Many countries where tourism is an important source of revenue have realized the importance of food safety and have taken steps to improve the safety of foods served in restaurants and hotels.

Numerous outbreaks have also occurred as a result of import of contaminated food. Traditional approaches to food control are no longer satisfactory to importing countries as a guarantee of food safety. As a result many countries, even in developing areas, are applying HACCP in the production of food destined for export. The cholera outbreak in Peru and the blockade of their food exports have, for instance, promoted the application of HACCP in the fishery industries of this country.
Increased consumer awareness of food safety

- education
- media
- consumer organizations

In addition to the increase in public health problems, consumers today are better educated, informed through media and interested in food safety and demand a greater assurance to food safety.
Lack of or decreasing resources for food safety

- insufficient awareness on the part of public health authorities
- competition with other health programmes

The increase in problems related to foodborne disease, and the demand of consumers for better control over the safety of the food supply comes at a time when resources are decreasing. In some countries, public health authorities do not appreciate the importance of food safety. As a consequence, other health programmes compete with food safety and receive priority, so that those responsible for food safety have to do more, often with lesser resources. This has led public health authorities to look for a more efficient system of food safety assurance.
However, it should not be overlooked that HACCP was first introduced by the food industries themselves to obtain greater assurance for food safety.

It is clear that it is in industry's best interest to produce safe food. If people become ill after eating a company's products, it may lose its customers and its good reputation as well as large amounts of money. Therefore, the HACCP system is not meant to be an additional regulatory burden, but rather a tool for ensuring safety and preventing foodborne illnesses.

Therefore, whether HACCP is applied on a voluntary or mandatory basis, its objective is to enhance assurance in food safety to prevent foodborne illnesses more efficiently. Additional benefits of using HACCP may be to reduce the costs of control and wasted food, as well as to protect the reputation of the food processor and its entire industry.
Recommended reading on module 1

Motarjem Y et al.
Importance of HACCP for public health and development.
The role of the World Health Organization.
*Food control*, 7(2):77-85, 1996.

HACCP/WHO
Introducing the Hazard Analysis and Critical Control Point system.
HACCP in food hygiene

The objective of this lecture is to place HACCP in its context and explain the role of HACCP, versus Good Manufacturing/Hygienic Practices and ISO 9000 standards, in food safety assurance systems.
Food hygiene

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

Before going further, let us see what the term Food Hygiene means. Food hygiene, as defined by the Codex Alimentarius Commission (CAC) is all the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.
We often speak of HACCP as a method of food safety assurance. So what do we mean by “food safety”? Food safety is defined by the CAC as assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use. Food safety is something that we try to achieve by ensuring food hygiene.
To achieve food safety, three levels of hygienic measures can be implemented. First, the General Principles of Food Hygiene, as stipulated by the Codex Code with this name, can be applied. These principles lay the foundation for food safety. Additional hygienic requirements for particular food sectors are described in specific Codes of Manufacturing or Hygienic Practices (GMP/GHP). These two types of requirements, often prescribed in codes by food law or regulations, form the basis for Good Manufacturing/Hygienic Practice. Usually, these codes also cover requirements for nutritional and other properties of food. Finally, HACCP can be applied to achieve a greater assurance that the produced, processed or manufactured food is safe.
HACCP is a method of food safety assurance that complements the Codes of General Principles of Food Hygiene.

Today, HACCP is part of food hygiene, or the food safety assurance system. Food hygiene can itself be placed in the context of food quality assurance programmes.

To understand this, let us define quality and food quality assurance programmes.
Quality

Definitions

- Peculiar or essential character
- Inherent feature
- Degree of excellence
  (English Oxf. Dict.)
- The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs
  (ISO / UNCTAD / GATT)

Quality can be defined as the essential character or distinguishing feature of a thing or a person. However, it cannot be measured by a single parameter. Therefore, from a commercial point of view, quality refers to a totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.
Quality

Several types of quality can be distinguished

- organoleptic quality
- functional quality (e.g. rheologic properties, convenience, shelf-life or “keepability”)
- nutritional quality
- hygienic quality (safety)

As applied to food, there are several types of food quality such as: organoleptic, functional, nutritional and hygienic quality.
### Quality

**From a consumer/industry point of view:**
- organoleptic quality
- functional properties
- keepability
- "freshness"
- nutritional quality
- safety
- value for money

**From a public health point of view:**
- hygienic quality (safety)
- nutritional quality
- compliance with regulations

From the consumer's point of view, all these features of the food as well as the price/quality relationship are important. Industry tries to meet the consumers' demands. However, from the public health point of view, the hygienic quality and nutritional quality of the food are of primary importance. Other qualities of food are important only to the extent that they affect acceptance of the food by consumers.
Among the different qualities, safety is most important for all parties i.e. industry, consumer and public health authorities. Nevertheless, it is this feature of the food which is most often overlooked. This is because one is aware of safety only when it is no longer there. It is only after a succession of important and sometimes fatal foodborne disease outbreaks in the industrialized countries, as well as a raising awareness campaign of the WHO during recent years, that food safety has gained importance among consumers, public health authorities and industry.
Quality assurance

All planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (ISO/UNCTAD/GATT)

To achieve the desired quality, many industries try to establish a quality assurance system. The system may include a wide range of actions. We see a similarity of this definition with the definition of food hygiene.

When the requirements in terms of quality relate to hygienic properties of the food, the programme is referred to as a food safety assurance programme.
The International Organization for Standardization (ISO) has formulated a series of standards on quality systems known as the ISO 9000 series. In view of globalization of trade, and the need for a uniform method for assessing quality assurance systems, these standards have gained importance in industry. Suppliers of goods and services use them to provide objective evidence that their quality assurance systems enable them to consistently meet their standards.

Some standards organizations use the ISO standards without modification; others have adopted their own numbering systems while keeping the text identical to those of the ISO standards. The European Community has decided to adopt quality systems based on the EN 29000 series.

The ISO 9000 series include 5 documents. Three of them, i.e. ISO 9001, ISO 9002 and ISO 9003, provide standards for quality assurance systems.
The most stringent quality assurance model, which is ISO 9001, has 20 requirements. The standard establishes requirements for what should constitute the "elements" of a quality assurance system. However, it does not establish what the desired quality is, or the technical aspects of achieving it.

The ISO 9001 and ISO 9002 and to some extent ISO 9003 stipulate the need for product safety and liability. Certain elements (e.g. verification) reinforce some aspects of HACCP. It should be mentioned here that some of the terminology used in the ISO 9000 series is different from the HACCP system, e.g. corrective action.
Quality system elements
ISO 9000 series (2)

- Control of measuring and test equipment
  (Inspection, measuring and test equipment)
- Nonconformity (Control of nonconforming product)
- Corrective action
- Handling and post-production functions
  (handling, storage, packaging and delivery)
- After-sales servicing
- Quality documentation and records
  (Document control)

Nevertheless, ISO 9000 standards are compatible with HACCP programmes, and many of their elements support or reinforce the implementation of HACCP. For instance, the clauses on quality in specification and design, procurement and in production (product control) are all compatible with the HACCP philosophy, which ensures that safety concerns are dealt with from the raw material to consumption.
In summary, the ISO 9000 standards are used to evaluate the food quality assurance programmes, but give no guidance on technical requirements to achieve the required quality. The objective of a quality assurance programme is to suggest appropriate actions and ensure that they are carried out. Food hygiene is part of the food quality assurance programme. Its objective is to ensure that the food which is produced, processed or manufactured is safe and fit for human consumption. HACCP should be considered as part of food hygiene and a method of food safety assurance which complements the general aspects of a Total Quality Management culture as well as specific principles of food hygiene, and ensures that essential safety measures are implemented.
In the past, the food safety assurance system relied on two types of measures:

a. actions undertaken during procurement of raw material, processing and manufacturing, transport and distribution including design, layout and cleaning of premises, to produce safe food. These actions were usually those prescribed in the Codes of Manufacturing or Hygienic Practice.

b. actions undertaken to ensure that food which was produced was indeed safe. For this purpose, industries tested the “end-product” for contamination, and food control authorities inspected the premises and carried out independent testing.
Food control authorities also inspected the premises for compliance with GHP/GMP and carried out an independent testing of the end-products.

The inspection system has many weaknesses. Among others it is based on snap-shot inspection, and not on what happened during a longer period of time.

End-product testing performed by the industry itself as a means of auto-control or by food inspectors is costly, time consuming and not reliable as a food safety assurance tool.
In recent decades, food industries and public health authorities realised the limitations of this approach. GMP and GHP provide necessary and basic guidance for producing safe food; but by themselves, they are not always sufficient.

First, the codes give only general guidelines, and cannot be specific to a food or process. Thus, there is a risk of leaving out measures essential for food safety. The provisions of the codes are based on past experience and do not accommodate new product or process development. They often provide guidance of qualitative nature only, making it difficult to monitor compliance.

Also, an approach based on compliance with a code does not provide a mechanism for identifying those control measures which were essential for product safety. In addition, the effectiveness of the quality assurance system depends heavily on the probability, often remote, that sampling for end-product analysis allows timely detection of a hazard in the food.
Today’s approach to food safety assurance is based on a combination of compliance with GMP/GHP and application of HACCP. GMP and GHP are the foundation of the food safety assurance system. HACCP is complementary to compliance with the GMP/GHP; its application ensures that all potential hazards have been systematically analysed and those that are significant for the food or process have been identified and controlled.
The Pillsbury Company in the USA first developed HACCP in 1959 to ensure the safety of space food for the NASA programme. It is already mandatory in some countries and for some foods, and in the future, an increasing number of countries may require its application.

This introduction to the concept will give a brief overview of what happened during these 25-30 years.
Traditional food production

- Shelf life ("keepability") and organoleptic quality oriented
- Production methods based on experience
- Safety taken for granted, later reliance on end - product testing

Early food production concentrated on keepability (shelf life) and organoleptic quality because preserving food was essential to survival. Production methods were based upon domestic experience; household methods were scaled up without any scientific experimentation to validate the safety of the product thus obtained. Safety was often taken for granted (cause and effect were not known, especially with regard to foodborne diseases caused by microorganisms).
Traditional regulatory measures
“Food Control”

- Based on:
  - observation and “testing” of samples
  - detection of spoilage ("unhealthy") and fraud

- The system was:
  - retroactive, and
  - provided little health protection, particularly regarding pathogenic organisms

Traditionally, governmental food inspectors checked samples on the market to determine if the goods were spoiled (regarded as "unhealthy"), and to detect fraud. The control system was usually retroactive. Often, foods were consumed before irregularities were detected. Punishment was regarded as an effective control measure, because it would prevent reoccurrence. In reality, this system offered little health protection, particularly in terms of preventing foodborne diseases.
Later, quality control was carried out by "snap-shot" inspection of food premises and end-product testing. End-product testing is reminiscent of the tasting by the joker of the court to provide evidence to the king that the food was not poisoned. This approach had many limitations.
Traditional food inspection

➢ “Flash” observation of hygiene
➢ Checking compliance with regulations
➢ Regulations on GMP used often vague terms such as: “as appropriate” “when necessary”
➢ Little distinction between trivial and important matters concerning safety

Inspection of premises was an important aspect of traditional food control. Such an inspection observed the hygiene status at a particular moment. No information could be obtained concerning the hygiene during other periods of food production or preparation. Often, the procedure checked only compliance with regulations. These regulations on Good Manufacturing Practices (GMP) or Good Hygienic Practices (GHP) frequently employed vague terms such as “as appropriate”, “when necessary”, etc. thus leaving many decisions to the judgement of the inspector. Another matter of concern for industries was that little distinction was made between trivial and important aspects of the production, especially those concerning safety.
Quality control

A system for maintaining standards
in production or in a product,
especially by inspecting samples
of the product

*Webster's Dictionary (1980)*

Until recently, quality and safety control depended on
testing or inspecting samples of the product. This is a
definition of quality control from Webster's dictionary of
1980.
End-product testing proved to be time consuming, costly and not reliable for identification of contaminated foods.
### Salmonella testing of milkpowder

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling scheme</td>
<td>60 units / lot</td>
</tr>
<tr>
<td>Examined</td>
<td>25g / unit of 250g</td>
</tr>
<tr>
<td>Lot size</td>
<td>10 tons</td>
</tr>
<tr>
<td>Assumption</td>
<td>homogeneous distribution of Salmonella</td>
</tr>
<tr>
<td>Confidence</td>
<td>Lots with 800 units containing Salmonella are</td>
</tr>
<tr>
<td></td>
<td>accepted with 30% probability</td>
</tr>
</tbody>
</table>

Testing foods for the presence of contaminants offers little protection even when large numbers of samples are examined. When a 10 ton lot or batch of milk powder is examined by taking 60 units, and 25 gram per unit of 250 gram is analysed, and if a negative result is obtained for all 60 samples, this still means that there is a 30% probability (one out of 3) of accepting a lot in which 800 units contain Salmonella. This interpretation assumes a homogeneous distribution of Salmonella through the lot, or a random sampling procedure, which is usually not the case.
This figure is based on the same sampling plan as in the preceding overhead, but it gives the probabilities of acceptance when fewer samples are taken, or when 2000 units contain Salmonella instead of 800.
Control in “space age”

- Preventative
- Having control over something
- Ensuring safety and quality of products by “building in” and “engineering out”
- Minimizing risks

Clearly, analytical examination of samples could not be relied upon when astronauts had to be fed in space. The risk of getting ill had to be minimized. Safety had to be “built in” during the development of the food product.

This is the reason that the space agency in the United States, together with food industry, worked out a system which would provide maximum food safety assurance, and where quality control took place during the process of production and or preparation. The resulting system was the basis of today’s HACCP system.
The HACCP concept was very simple:
It identified potential food safety problems
It determined how and where they could be controlled or prevented
To assure that measures were carried out as determined, all important actions were described and personnel was trained to carry them out
Actions had to be implemented without exception. To ensure that they were carried out correctly and to provide evidence of this, the results had to be recorded. The records also provided a basis for improvement.
HACCP

HACCP was:
An industrial food
processing - line - control
management tool

At first, HACCP was a management tool used in food industry to keep the processing line under control. Experience from the canning industry demonstrated that keeping control over processing conditions was much more efficient and reliable than end-product testing. The time and temperature employed guaranteed safety of the product; even significant under-processing can seldom be detected by end-product testing.
HACCP offers inspectors:

Evidence that essential process conditions were under control during a prolonged period of production time before inspection.

HACCP has been explained to food inspectors since the beginning of the 1970s. For inspectors, the advantage of HACCP is that it provides evidence that essential process conditions are under control during production. This minimizes the risk of producing a contaminated food and is clearly an advantage over traditional food inspection.
Importance of HACCP in food safety management

**HACCP ensures:**

- that decisions are based on reflection and best judgement
- accountability
- transparency and consistency
- continuous improvement
- partnership building
- free movement of products
- safety is designed and manufactured in the product

Therefore, the HACCP system became an important regulatory tool. HACCP also remains an important food safety management tool. The responsibility for the HACCP plan and its implementation lie with industry. Application facilitates international trade, because WTO/SPS measures, which will be discussed later, stipulate that Codex Standards and Guidelines should be used as the "yardstick" to measure food safety. The Codex Code of General Principles of Food Hygiene also recommends that HACCP be applied.
Even though the concept was presented in 1971 by industry in the USA to the food inspectors, it took many years before it got world-wide recognition and application. This schematic figure is just used to show growth and sudden increase in application of HACCP.
This overhead gives a historical overview of HACCP. There was little development after its first presentation in 1971. In 1980 the WHO asked the International Commission on Microbiological Specification for Foods to describe the system in more detail. Subsequently, other people and organizations examined the system and in 1983, WHO Europe recommended HACCP as a food inspection tool. In 1985 some ICMSF members participated in a Committee of National Research Council in the USA, and texts similar to the ones later published in ICMSF Book 4 on HACCP appear in the CS report. The NRC stated that HACCP provided more safety protection than end-product testing. In 1991 Codex adopted the concept and started to include HACCP in their codes; Codex issued the first HACCP guidelines in 1993. Several WHO and FAO consultations were also held since that date to provide guidance on the application and training in HACCP. Following the recommendations of a WHO consultation in 1995, the Codex guidelines on HACCP (including the term Hazard Analysis Critical Control Point system) were revised.
 Originally, HACCP was a tool used in food industries on a voluntary basis. However, over the years, it has proved to have many applications. In addition to its application in food industries and food service establishments, the system has also been used in health education, and in food safety programme management. In health education, the HACCP concept has been used to study food preparation practices, and to identify and assess hazardous behaviour which needs to be the focus of health education. In food safety program management, the HACCP concept is used to identify the problems along the food chain which are of greatest risk to public health, and measures which need to be implemented in priority.
Evolution of "Hazard"

1970s
Something we do not want to happen

1990s
A biological, chemical or physical agent with the potential to cause an adverse health effect when present at an unacceptable level

(WHO, 1995)

This overhead, by comparing definitions of "hazard" in the 1970s and in the 1990s, demonstrates how the concept has evolved. The WHO definition of 1995 has been changed for Codex purposes. The Codex definition will be presented later.
For a number of years HACCP has been applied on a voluntary basis in food industries. Recognizing its importance, food and public health authorities worldwide have promoted it and some countries now require its application to certain foods, including those which are imported.
This overhead gives some information concerning the current regulatory status of HACCP. It is likely that HACCP will become mandatory in many countries. Already in Europe, the Food Hygiene Directives (EC Directive 93/43) include 5 principles of HACCP in the requirements for Food Hygiene. The Directive on fish and fishery products also explicitly requires application of HACCP. In the USA the FDA regulations regarding HACCP are also far advanced and presently the application of HACCP is mandatory for both locally produced and imported fish and fishery products and meat and poultry products, regulated by USDA.
Similarly the Codex Alimentarius Commission recognized the importance of HACCP and in 1993 adopted guidelines for its application. These guidelines were revised in 1997. The Codex Code of General Principles of Food Hygiene, also revised in 1997, recommends a HACCP-based approach to food operations as a means to enhance food safety. Other specific codes are in the process of revision to take a HACCP-based approach in their recommendations.
Until April 1995, acceptance of the work of Codex by the member governments was voluntary: governments were free to adopt or not adopt Codex recommendations, standards and guidelines in their national legislation. However, with the finalization of the Uruguay Round of Multilateral Trade Negotiations and the establishment of the World Trade Organization in April 1995, the situation has changed. According to two of the Agreements of the WTO (the Agreement on Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barrier to Trade (TBT)), the work of Codex is recognized as the reference for international food safety requirements. This implies that in future, Member States of WTO cannot reject foods which meet Codex recommendations, standards and guidelines without providing justification based on risk assessment. Since the application of HACCP is recommended by the Codex Code of General Principles on Food Hygiene and other specific codes, this means that HACCP has become the international reference system for food safety assurance.
Food safety assurance starts at the "farm", the primary agricultural or fishery level.

At all steps of the food chain, particular attention is given to potential food safety problems and how they could be prevented or controlled.

To control microbiological hazards a heat treatment of raw materials is often required, either at production level or during preparation before consumption. In the overhead we used the word bactericidal, but treatment should also kill viruses, moulds and parasites when possible.

The use of a product may also influence its safety; thus, HACCP has to be applied "from farm to fork".
In the new concept of "food control", government inspectors do less "policing" and more "advising" and "discussing". They should apply the "farm to fork" principle in assessing HACCP.

The emphasis is on shared responsibility: responsibility for the production and preparation of safe food is in the hands of professional food handlers and regulation of food safety is in the hands of governments.

International standards are in the process of being worked out by Codex Alimentarius.
Module 01 - lecture 04

Basic principles of the HACCP system

This lecture is an introduction to the HACCP concept.
HACCP is the methodology to provide safe food for consumers all over the world. HACCP is a dynamic, versatile system which can be applied everywhere. This lecture will demonstrate that the principles behind the system are logical and easy to understand. Later on, we will discuss HACCP in more detail using definitions given by Codex Alimentarius.
First, we have to understand what "safe food" means. A safe food does not cause harm when it is prepared and/or eaten according to its intended use. This definition implies that the consumer has an active role in food safety. Sometimes the food has to be made safe during preparation; sometimes it is important to understand the intended use of a food. Mishandling and misuse can make even the safest food unsuitable for consumption. We will come back later to what harm means in the context of food safety. We will also explain how food should be handled and prepared to keep it safe.
The traditional system of food safety assurance in industry was based on applying codes of GMP/GHP in food production and processing. Confirmation of safety and identification of potential problems were obtained by end-product testing.

Inspectors in food control agencies checked for compliance with GMP/GHP codes and also analysed the food for compliance with regulations and identification of unsafe food.

Since GMP and GHP are the bases of food hygiene, it was possible to achieve a great degree of assurance in food safety with this approach.
If this is so, why is HACCP needed? There were many weaknesses in food safety assurance systems based on Codes:

a) Codes provide general requirements without considering the specificity of the food or process in question and its related potential hazards

b) Codes do not provide a mechanism for identifying those measures which are essential for safety

c) Codes do not provide for monitoring mechanisms to ensure that measures necessary for safety are implemented and are carried out correctly

d) The system does not make provision for corrective measures if the process gets out of control

e) Finally, the system does not provide proof that the products were prepared according to the established requirements

There are also problems related to relying on end-product testing for the detection of unsafe food.
Food safety assurance

- Product and process design
- Selection of raw material
- Process control
- Good Manufacturing Practices (GMP)
- Good Hygienic Practices (GHP)
- Good Commercialization and Use Practices
- HACCP

There was a need to have a system where "safety" was designed and manufactured into the product (ISO/UNCTAD/GATT). HACCP starts already at the drawing board, potential hazards are anticipated and "designed and engineered out", and safety has to be "built in". It continues with the selection of appropriate raw materials. Then, the processes need to be fully controlled. All these have to be performed in hygienic conditions ensuring minimum contamination of the food and opportunities for survival and growth of microorganisms.
HACCP concept

- Identification of potential food safety problems
- Determination of how and where these can be prevented
- Description of what to do and training of the personnel
- Implementation and recording

In its simplest form, HACCP consists of identifying potential food safety problems, and determining the most efficient way to prevent, reduce or eliminate them. To assure that these preventive measures or control measures are executed regularly and consistently, they have to be described and the people who execute them have to be trained. HACCP involves careful record keeping, to document how the system was developed and to demonstrate that the process was under control during a given period of time. The results are also used to improve the system.
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

HACCP consists of 7 principles; the minimum requirements in the mandatory application of the HACCP system. We will now review the meanings of the essential terms used in these principles.

A few important terms must be explained to assure a good understanding of what is meant by certain words or expressions. Some of the terms are not the official Codex definitions. The definitions as described in the Codex text will be given later, when this text is discussed in detail.
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 HACCP. 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.
This overhead gives examples of hazardous agents. Examples of bacteria are: Salmonella, Campylobacter, Staphylococcus aureus and Clostridium botulinum. Viruses include Hepatitis A, Norwalk viruses etc. Many moulds can produce mycotoxins such as aflatoxins, ochratoxins, patulin, T2 toxins. Well known parasites are Trichinella, Taenia, Toxoplasma etc. Recently, fishborne parasites have received attention. Besides the toxins produced by bacteria or fungi, some foods contain “natural” toxins. Examples are the toxins from the puffer fish, cassava, potatoes. The word “chemicals” refers to man-made substances which are used in animal husbandry (antibiotics, hormones, tranquilizers) or in crop farming (pesticides). Other chemicals are used in food processing as cleaning agents, lubricants etc. All of them can be hazardous only when they are above a certain level. Examples of foreign material are stones, plastic material, glass, pieces of bone.
Examples of adverse health effects

Acute illness:
- choking
- vomiting
- abdominal cramps
- diarrhoea
- nausea
- fever

Chronic illness:
- chronic infections
- damage of various organs
- cancer

Death

Objects in the food (physical hazards) may cause choking.
Bacteria and some viruses may cause acute illnesses with symptoms such as vomiting, abdominal pain, diarrhoea, nausea and fever.
Some bacterial toxins provoke vomiting, while most fungal toxins can provoke chronic illnesses. In experimental animals it has been shown that the latter may cause kidney or liver damage and some may cause cancer.
Some bacteria and parasites may provoke chronic infections.
Both man-made chemicals and natural toxins can cause chronic diseases when high levels are ingested regularly.
These infections and diseases can sometimes be fatal.
Acceptable levels

Not all levels (or sizes) of all agents are harmful to all individuals under all conditions.

Agents (contaminants) are acceptable as long as their levels remain below a certain maximum.

It is crucial to recognize that "hazardous" is related to levels, sizes or doses of the agent. The effect of the agent varies with the food in which it is found and the susceptibility of the person ingesting it. Some agents are more dangerous than others, and there is a great variety in the severity of the effect. However, there is always a level below which the presence of an agent is considered to be acceptable. For many bacterial pathogens, the level may be less than one per gram or per portion. For most chemicals, a maximum residue level has been established. For the establishment of acceptable levels for chemicals, risk assessment protocols have been in use; for microbes these are under development.
Increase or decrease in level

If an agent is present in a food at a

- low, acceptable, level, *its increase to an unacceptable level should be prevented*

- high, unacceptable, level, *its reduction to an acceptable level should be assured*

Potentially harmful agents are present in many raw materials, usually in very low levels. They become dangerous when their level, or the level of the toxins they produce, increases to a point where they may cause disease. Viruses and parasites do not multiply in food; the same is true for many natural toxins and chemicals. However, there are also situations where chemical reactions may continue to occur; for example, nitrosamine formation. To prevent this the conditions leading to increase should be kept under control. If an agent is at a high level and processing is meant to decrease the level to an acceptable one, the conditions during processing should assure that the acceptable level is actually reached.
Control

Noun: Having things under control

Verb: To direct, regulate, command

It does not mean: to check, to test

The word "control" is used in the HACCP concept both as a noun and a verb. It means "having things under control;" for instance, as it is used in the expression "traffic control". As a verb it means "to direct", "to regulate", "to command" etc. It does not mean "to check", "to test", "to verify" etc. Other terms are used for testing, measuring and observing, which play an important role in HACCP.
Hazard control

- Prevention of contamination
- Prevention of increase in level
- Assurance of adequate reduction
- Prevention of recontamination
- Prevention of dissemination (spread)

Control measures should focus on several aspects of food production or preparation. Contamination of foods has to be prevented, and if this is not possible, measures should be taken to ensure its reduction. Measures should also be in place to keep pathogens from increasing to unacceptable levels. Separation of raw (untreated materials) from treated (rendered safe) material is an important control measure. Prevention of dissemination or spread of pathogens is also a very important aspect of good hygienic practice, as is the prevention of recontamination of "safe" products. The effectiveness of HACCP is based on the success of these 5 types of control measures.
The concept of acceptable levels of potentially hazardous agents means that other levels may be unacceptable. The critical limit is the value which separates acceptability from unacceptability. It may refer to a temperature, a time, a pH, an $a_w$, a level of cleanliness, but also to a level of the hazard of concern.
Microbiological process control

Having control over conditions which may lead to unacceptable or growth, survival, spread contamination with / of undesirable microorganism

HACCP was developed in the food processing industry because it was known that controlling processing conditions gives a better assurance of the product's safety than testing the final product. For example, it is more effective to control retorting time and temperature in canning, because even serious under-processing cannot normally be detected by microbiological testing of the end-product. Microbiological process control means having control over conditions which may lead to unacceptable events. Such events are unacceptable growth, survival, spread or contamination of/with undesirable microorganisms. The word “unacceptable” is important because some growth, survival and even spread or contamination can always occur.
Example of processing for safety

Pasteurization

- Safety assured by adequate heating time & temperature
- Reliance on monitoring to detect deviations
- Timely adjustments and corrective actions

Pasteurization is a good example of processing for safety. When a product such as milk is heated for a sufficiently long period of time at a high enough temperature, levels of pathogens such as Salmonella and Mycobacterium bovis are reduced by a factor of more than $10^6$. This assures the safety of the product. Heating time and temperature are monitored and when a deviation occurs, the milk is automatically returned to the raw milk section by a flow diversion valve. When controls are in place to prevent recontamination, no safety problem will occur. If the temperature shows a tendency to drop, timely adjustments have to be made and corrective actions should ensure that this situation does not repeat itself.
Critical Control Point

A step in the food chain where activities are carried out, or conditions prevail which can have an influence on the safety of the product, and where
control can be exercised over
one or more factors to
prevent or eliminate a food safety hazard
or reduce it to an acceptable level

Critical Control Points (CCPs) are crucial to ensuring product safety. A CCP can be related to raw materials, processes and practices applied along the food chain. CCPs govern all factors which are basic to the prevention of foodborne diseases.
Monitoring

Checking, by testing, measuring or observing, whether a Critical Control Point (CCP) is under control.

"Monitoring" is checking, by testing, measuring, observing etc., whether a Critical Control Point is under control. Whenever possible, the monitoring results should be available in real time, so that corrective actions can be taken before the situation is "out of control". Microbiological tests are often not usable for monitoring, because it takes too long for the result to become available. Target values are used in monitoring. Even if the value is slightly higher or lower than the target value, it is still acceptable as long as it remains within critical limits; otherwise, the product is considered unacceptable and cannot be released.
Verification

Checking the implementation and effectiveness of the HACCP system

Although there is not yet international agreement on what verification should encompass, it means checking whether HACCP is correctly implemented and effective.
Factors contributing to foodborne illness

- Contamination
  - Unclean equipment
  - Raw materials
  - Insects / rodents
  - Aerosols / condensation
  - Infected handlers

- Survival
  - Inadequate cooking / reheating

- Growth
  - Insufficient cooling / hot holding

Data obtained during investigation of foodborne diseases show that a few factors are responsible for the majority of outbreaks, which were mostly caused by mistakes in the food service business. In some cases, the outbreak is due to contamination of food with pathogens. Unclean equipment is often the source of foodborne pathogens. Raw materials, which are eaten fresh or insufficiently cooked, are another source. In other cases, pathogens find their way into food through insects, rodents or other pests. Aerosols (minute water droplets) originating from drains or cleaning dirty surfaces with jet sprays etc., carry pathogens from unclean areas into foods. Condensation droplets falling down from cold pipes etc. do the same. Also, infected food handlers contaminate foods via their hands, noses etc.

Outbreaks can be caused by pathogen survival: foods carrying pathogens are insufficiently cooked or leftovers are insufficiently reheated.

Lastly, foods that are often insufficiently cooled or not held at hot enough temperatures, so that pathogens are allowed to multiply, are at the source of many epidemics of foodborne disease.
HACCP was based on preventing contamination by survival and growth of pathogens. Nowadays it includes also prevention of illness caused by chemical or physical objects. The following overheads are used to explain the basics of prevention of microbiological problems. It is not meant to explain in any detail processing techniques which can be used to control these microbiological hazards. It is a structured system, based on the principle that prevention is better than cure.
Prevention of foodborne diseases

Prevent, eliminate or reduce

unacceptable

• growth
• survival of pathogens
• spread
• contamination with

Not all growth, survival, spread, and contamination lead to foodborne disease. The presence of a few pathogens in a food does not always lead to disease. It is important to distinguish between what is acceptable and what is unacceptable. The HACCP concept is based on preventing unacceptable events, eliminating the conditions leading to these events, or reducing growth, survival, spread and contamination to acceptable levels.
Controlling growth of microbes

<table>
<thead>
<tr>
<th>Needed for growth</th>
<th>Control measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrients</td>
<td>Clean surfaces</td>
</tr>
<tr>
<td>Water</td>
<td>Dry surfaces</td>
</tr>
<tr>
<td>Temperature</td>
<td>Food kept hot or cold</td>
</tr>
<tr>
<td>Time</td>
<td>Short holding time</td>
</tr>
</tbody>
</table>

To understand how growth can be prevented or reduced, it should be remembered that to multiply, microbes need nutrients, water, an appropriate temperature and time.

In a food environment, nutrients are nearly always found on surfaces which are not cleaned and disinfected. Keeping surfaces clean helps control growth. Whenever possible, prep line surfaces or line-environments should be dry, to deprive the pathogens of water. Foods should be kept either hot or cold, because these temperatures hamper growth. When these conditions cannot be fulfilled, food should be consumed immediately after preparation, to limit growth time.
The survival of microorganisms depends on the substrate in which they are found, the heating time and temperature, and the number present before any treatment was applied. The number of microorganisms killed is a direct function of time and temperature of the heat treatment. The quantity of food to be heated has to be taken into account when designing the equipment, and time and temperature required to obtain a safe food. Moreover, in a large quantity of food, there may always be some microorganisms surviving; this is why the notion of unacceptable survival has been introduced.
This slide presents an example of insufficient control. A pathogenic strain of *E. coli* was in hamburger. Many Americans eat their hamburgers rare and heat the meat only for a short time. Moreover, fat protects the microorganism from heat applied during frying. In this case, some *E. coli* survived. Only small numbers of this particular pathogen are necessary to produce illness, particularly in children. Many children became ill, a few died and several had long-lasting after-effects. In one case, the parents of a child claimed 13 million dollars as compensation. This outbreak could have been prevented because these facts were known. Irradiation of meat for control of *E. coli* in products such as hamburger patties at a point in the processing chain before preparation for consumption (i.e. in the processing plant) was recently approved in the USA.
The Codex Alimentarius has summarized the HACCP concept with these seven principal activities. All seven should be applied in all circumstances. How they should be applied and implemented may vary with the situation. Codex has also provided definitions for all important terms. This will prevent misunderstanding when foods are in international trade, because foods everywhere should be produced while applying the same HACCP system.

The next series of overheads will give a simple example of how these steps can be applied, even in a household.
Milk is used as an example of a raw material because the hazards it may contain can be controlled by the dairy industry as well as at home.

The following example can also be applied to coconut milk, which is widely used in tropical countries.
The raw material may contain a number of microbiological hazards such as *Salmonella* and *Campylobacter.*
These microbiological organisms are destroyed by heat; this means that they can be eliminated or reduced to acceptable levels by heating the milk.
In the home, milk is heated by boiling it in a pan, so this is the Critical Control Point.
Reaching the boiling point assures that potential hazards which we have identified in the milk have been eliminated. Milk starts foaming at the boiling point. Thus, the critical limit is the formation of foam.
Monitoring is easy: we observe the formation of foam. This allows us to monitor whether the critical limit has been met.
Even if the pan is emptied, we can still observe whether the milk was sufficiently heated by looking for traces of foam on the inside of the pan. This is an example of verification. It comes after the fact.
HACCP looks also at the use of food. If the boiled milk is not consumed while it is still hot, it may become recontaminated. Pathogens may multiply, and provoke a foodborne illness.

In such a case, potential hazards of recontamination and growth have not been kept under control.
Effectiveness of HACCP

Shared responsibility:

Farmers  Manufacturers  Consumers

One very important aspect of HACCP has not yet been mentioned. HACCP is effective at assuring product safety only when it is applied at all levels of the food chain, from "farm to fork". Food safety is a shared responsibility of farmers, manufacturers and consumers.
Key messages

- Safe food is obtained by applying HACCP "from farm to fork"
- Hazards are all kinds of agents when present at unacceptable levels
- Control means "having things under control"
- Good Manufacturing Practice (GMP) and Good Hygienic Practice (GHP) are the basis of HACCP
- Anticipating hazards is the key to their prevention
Module 01 - lecture 05

HACCP system

Benefits and areas of application
Benefits of the HACCP system (1)

The HACCP system overcomes many of the limitations of traditional approaches to food safety control:

- collecting and examining sufficient number of samples
- high cost
- time
- identification of problems without understanding the causes
- limitations of “snap-shot” inspection

As explained during previous lectures, HACCP overcame many of the limitations, inherent to traditional approaches of food safety assurance.
The HACCP system has the potential to identify all conceivable, reasonably expected hazards, even where failures have not previously been experienced. It is therefore particularly useful for new operations.

One of the major advantages of HACCP is that it has the potential to anticipate problems. It is therefore a powerful tool in preventing foodborne illnesses.
Benefits of the HACCP system (3)

The HACCP system is capable of accommodating changes introduced, such as progress in equipment design, improvements in processing procedures and technological developments related to the product.

HACCP is also very flexible and can be quickly adapted to new situations.
Benefits of the HACCP system (4)

The HACCP system will help to target or manage resources to the most critical part of the food operation.

HACCP helps to draw attention to and manage resources to the most critical part of the food operation.
Benefits of the HACCP system (5)

With the HACCP system one can expect an improvement in the relationship between food processors and food inspectors & food processors and consumers.

Industries applying HACCP show their concern for food safety and express their willingness to do what reasonably can be done to achieve the highest possible level of food safety.
Benefits of the HACCP system (6)

The available documentation facilitates the
inspection activities
of food inspectors

The documentation demonstrates the measures taken to ensure food safety and facilitate the work of industries.
Benefits of the HACCP system (7)

Application of HACCP systems can promote international trade by equalizing food safety control systems everywhere in the world, by the resulting decrease in detentions, confiscation and even destruction of contaminated food shipments and by increasing confidence in food safety.

As HACCP enhances food safety, it also promotes food trade.
Benefits of the HACCP system (8)

The HACCP system is applicable to the whole food chain, from the production of raw materials to the end-product, i.e. growing, harvesting, processing, manufacturing, transport and distribution, preparation and consumption.

HACCP can be applied to the whole food chain (from "farm to fork"). At each step the application of HACCP leads to the analysis of hazards at earlier or later stages. In this way it ensures an integrated approach to food safety and promotes the concept of shared responsibility.
Benefits of the HACCP system (9)

The HACCP system can be easily integrated into quality management systems, such as ISO 9000

As seen in lecture 2, HACCP can be integrated in ISO 9000 and complement these standards by providing guidance on how to achieve food safety.
Areas of application (1)

In food control

- as an inspection tool to channel the resources to critical issues
- assessment of the HACCP plan and confirmation that it is properly designed and operating effectively

HACCP is a method of food safety assurance which was initially developed in food industries for production, processing and manufacturing.
Areas of application (2)

As method of food safety assurance
in food production
processing, manufacturing
& preparation

However, it can also be used for the preparation of food in food service and catering establishments as well as in street food operations and in homes.
Areas of application (3)

In education on health interventions

➢ to study food preparation practices
➢ to identify and assess hazardous behaviour, which should be the focus of health education

It can also be used for health education programmes. Food handlers should be trained to adopt a HACCP-based approach in their efforts for hygienic handling of food. With regard to traditional foods, they could be trained in the correct implementation of the Critical Control Points, and foreseeing what they could do if failure occurs.
Areas of application (4)

In the investigation of foodborne disease outbreaks

to identify the cause of the outbreak

A HACCP-based approach can be taken during investigation of foodborne disease outbreaks to identify the cause of the outbreak.
Areas of application (5)

* In the management of food safety programmes *

- to identify those problems which are of greatest risk to public health
- to identify and prioritize interventions which may have the greatest impact on the prevention of the problem

A HACCP system is designed to enhance a food safety system of hygiene that is already in place.
HACCP should **enhance** food safety, but it requires that a minimum of hygiene is already in place before it is implemented.
HACCP is important both for health as well as for food trade. In future, foods which are not manufactured according to the HACCP approach may be excluded from national or international markets.