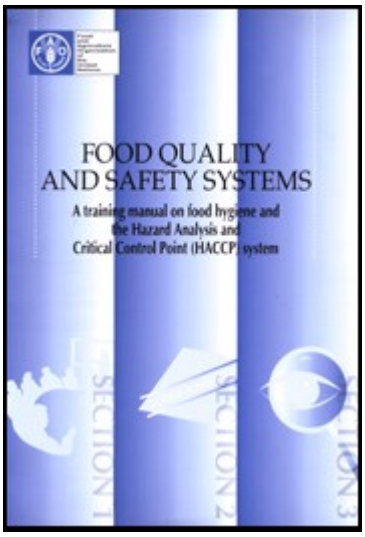
Food Quality and Safety Systems - A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System



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Food Quality and Standards Service Food and Nutrition Division
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 1998

Editing, design, graphics and desktop publishing:
Publishing Management Group, FAO Information Division

Reprinted with corrections 1998

M-83
ISBN 92-5-104115-6

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Foreword

The Food and Agriculture Organization of the United Nations (FAO) is the principal specialized UN agency dealing with all aspects of food quality and safety throughout each of the stages of food production, storage, transportation, processing and marketing. Work in this area is carried out by the Food Quality and Standards Service of the FAO Food and Nutrition Division. Activities include providing policy advice and executing food quality control and safety development projects, including the development of food standards and technical regulations; food quality and safety assurance

programmes for the food industry; establishing national export food certification programmes; monitoring programmes for food contaminants; and conducting regional and national seminars and workshops on food control issues.

One important element of FAO's work is building the capacity of food control personnel, including government authorities and food industry personnel carrying out food quality and safety assurance programmes. Such programmes should include specific food risk control procedures such as the Hazard Analysis and Critical Control Point (HACCP) system.

In December 1994, FAO held an expert consultation on HACCP principles in food control. The experts recommended that FAO should continue to emphasize high-quality and effective food industry and government HACCP training, based on the development of a core curriculum and the harmonized text and guidelines of the Codex Alimentarius Commission.

In February 1995, an ad hoc working group was formed and a core curriculum was developed for a training of trainers programme. The core curriculum recognizes the importance of the basic quality and safety controls included in the Codex General Principles of Food Hygiene and good manufacturing practices as embodied in the Codex Codes of Practice as a basis for effective implementation of the HACCP system. The training programme has been tested in Thailand, Brazil, Viet Nam and Slovakia. This training manual on food quality and safety systems is a direct result of that work.

The manual is structured to provide essential information in a standardized, logical and systematic manner while adhering to effective teaching and learning strategies. It is composed of three sections. Section 1 reviews principles and methods of training; Section 2 introduces and elucidates the Codex Alimentarius General Principles of Food Hygiene; and Section 3 explains the HACCP system and its implementation. Each section is made up of specific training modules which can be combined and customized to meet the specific needs of the students.

FAO has prepared this manual in an effort to harmonize the approach to training in the HACCP system based on the already harmonized texts and guidelines of the Codex Alimentarius Commission. It is clear that HACCP systems can only be effective when they are a part of a broader food quality and safety programme based on the General Principles of Food Hygiene and good manufacturing practices. Consequently, these aspects of quality and safety controls are incorporated in the training materials. We invite readers' comments and suggestions for improving this manual as part of our continuing effort to provide high-quality advice and reference materials to FAO member countries.

John R. Lupien
Director
FAO Food and Nutrition Division

Preface

All countries need adequate food control programmes to ensure that national food supplies are safe, of good quality and available in adequate amounts at affordable prices to ensure an acceptable nutritional and health status for all population groups. Food control includes all activities carried out to ensure the quality, safety and honest presentation of the food at all stages from primary production, through processing and storage, to marketing and consumption. The term has been used to describe a total national effort involving an integrated approach between government and all segments and sectors of the food industry. Food control is linked to improvement in the health of the population, potential for a country's economic development and reduction of spoilage and food losses.

The Codex Alimentarius General Principles of Food Hygiene lay a firm foundation for ensuring effective food control and food hygiene. The General Principles of Food Hygiene follow the food chain from primary production through to the consumer, highlighting the key hygiene controls at each stage. A Hazard Analysis and Critical Control Point (HACCP) approach is recommended wherever possible to

enhance food safety. The HACCP approach is internationally recognized as being effective in ensuring the safety and suitability of food for human consumption and in international trade.

Recognizing the importance of HACCP to food control, the twentieth session of the Codex Alimentarius Commission, held in Geneva, Switzerland from 28 June to 7 July 1993, adopted *Guidelines for the application of the Hazard Analysis Critical Control Point* (*HACCP*) *system* (ALINORM 93/13A, Appendix II). The revised version of the *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev. 3 (1997)], adopted during the twenty-second session of the Codex Alimentarius Commission, held in Geneva from 23 to 28 June 1997, incorporates the *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* as Annex.

The HACCP system, as it applies to food safety management, uses the approach of controlling critical points in food handling to prevent food safety problems. Besides enhancing food safety, other benefits of applying HACCP include effective use of resources and timely response to food safety problems. In addition, the application of the HACCP system can result in more focused risk management by food control regulatory authorities and can promote international trade by increasing buyer confidence in food safety.

The HACCP system identities specific hazards and control measures to ensure the safety of food. An HACCP plan is specific to the particular food and processing application. The HACCP system is capable of accommodating change, such as advances in equipment design, new information concerning health hazards or risks, new processing procedures or technological developments.

The successful application of HACCP requires the full commitment and involvement of management and the workforce. It also requires a team approach. The application of the HACCP system is compatible with the implementation of quality management systems, such as the ISO 9000 series, and HACCP is the system of choice for the management of food safety within such systems.

HACCP and trade

Significant implications for the Codex Alimentarius Commission arise from the Final Act of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT): the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). Codex standards, guidelines and other recommendations have become the specifically identified baseline for consumer protection under the SPS Agreement. In this environment they take on unprecedented importance with respect to consumer protection and international food trade. As a result, the work of the Codex Alimentarius Commission (including the *Hazard Analysis and Critical Control Point [HACCP] system and guidelines for its application*) has become the reference for international food safety requirements.

While the improved level of food safety associated with the implementation of HACCP and the leading role taken by the food industry are recognized, the application of HACCP as a public policy requires definition of the role of government in the utilization of the HACCP process and risk analysis. Individual countries need to address the issue of HACCP implementation so that their food export industry can meet the requirement recently adopted by some importing countries related to HACCP application to food products. The mandatory requirement to use HACCP and any subsequent barriers or other constraints to trade, particularly for developing countries, need to be considered and identified. The appropriate application of HACCP to different segments of the food chain and the impact of this application on small and medium-sized food industries also needs to be addressed.

Recent FAO activities

Recognizing the importance of HACCP in food control and the necessity and importance of improving the safety of food in international trade, and to address the issues identified above, FAO convened an expert technical meeting in Vancouver, Canada from 12 to 16 December 1994 to discuss the use of HACCP principles in food control.

The expert technical meeting noted that training in the application and implementation of the HACCP system was of utmost importance and recommended that FAO consider assuming the leadership role in conducting high-quality and effective industry and government HACCP training. In their report, the experts also recommended that FAO establish an inventory of available HACCP models and training reference material and prepare a core curriculum for practical HACCP training courses. It was recommended that the training be focused on developing skills and methods necessary for training government and industry representatives in the requirements of the Codex General

Principles of Food Hygiene and the principles and steps in implementation of HACCP. Further, the core curriculum should be modifiable to reflect cultural sensitivities and to address infrastructural problems in individual countries.

As follow-up to the training recommendations of the expert technical meeting, FAO convened a temporary technical working group which met in Rome from 13 to 17 February 1995 to plan a training of trainers course in HACCP for developing countries. The temporary technical working group consisted of representatives from the Centre of Export Inspection and Certification of Agricultural Products, Thailand Department of Agriculture; the Thai Food Industry; and international experts in food sanitation and hygiene, HACCP and training techniques. The working group prepared a tentative agenda for a course on training of trainers in the application of HACCP to be held in Thailand.

The meeting participants agreed that the objectives of the training should be to promote a common approach to the application of HACCP based on the Codex guidelines and to instil trainers where possible with sufficient skills in the theory and application of HACCP to train others. The training should establish agreed terminology and basic understanding of HACCP principles and impart to the trainees those skills necessary for the application of HACCP to food safety in both the public and private sectors.

Two pilot training courses were carried out in Cha Am, Thailand (31 July to 11 August 1995) and Sao Paulo/Brazil (12 to 23 August 1996). It was concluded that the course format achieved its objective of imparting a thorough understanding of the technical information and its application to the participants. Participants completing the course demonstrated practical knowledge of the General Principles of Food Hygiene and the application of the HACCP system and the ability to train other people.

The FAO approach to the HACCP system

There is a tremendous demand for training in the HACCP system and the development and assembly of reference materials to support this training, particularly in developing countries. It is a matter of urgency to provide the necessary clarification with regard to the application of the HACCP system.

The objective of the FAO HACCP training programme is to promote good manufacturing practices (GMPs) and the HACCP system through understanding and application of the Codex General Principles of Food Hygiene, including the Codex guidelines for the application of the HACCP system and other Codex codes of hygienic practice. FAO is working to enhance the role of science and risk analysis in the development of the HACCP system and to create a framework for determining equivalence of food safety control programmes for a harmonized approach to the application of HACCP.

The FAO training programme harmonizes the approach to GMPs and the application of the HACCP system and aims to provide an effective mechanism for delivering the appropriate core curriculum and knowledge to selected segments and sectors of the food industry, individuals involved to varying degrees in the preparation, monitoring, administration and verification of HACCP plans and food control regulators. Included in the FAO training programme is emphasis on training the trainers who are in a position to train others and to apply the knowledge gained and hence to contribute to self-reliance, particularly in developing countries.

To accomplish these objectives, FAO has embarked on a plan to develop further collaboration and partnerships with regional and national counterparts, where possible with other international organizations and with the food industry to review the needs of the developing countries regarding their HACCP system implementation plans and to establish workable strategies.

The training package

Training is not an objective in itself but is linked to improvement in a country's public health and economic development. It is in this context, and recognizing the need to standardize GMPs and HACCP training, that FAO has prepared the training package on the Codex Alimentarius General Principles of Food Hygiene and the application of the HACCP system. In order to harmonize or standardize the approach to training/Sections 2 and 3 of the training package are formatted around the *Codex Recommended International Code of Practice - General Principles of Food Hygiene* and the *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application.* The training manual consists of three sections:

- Section 1: Principles and methods of training
- Section 2: Recommended International Code of Practice - General Principles of Food Hygiene
- Section 3: The Hazard Analysis and Critical Control Point (HACCP) system

Each section is composed of training modules; this format allows for the training material to be combined and customized as appropriate to the specific trainees. Sections and/or modules can be selected by the instructor as appropriate to the level of knowledge, experience and specific responsibilities of the trainees in a given course.

An introductory section for each module outlines the objective, suggested methods of instruction, teaching aids and/or references, lesson content, presentation suggestions or exercises, anticipated time frame for instruction and anticipated learning outcome for the trainees.

The FAO training programme is not static; because of its modular approach it is sufficiently flexible to adapt to the evolution of food safety programmes and requirements. Modules can be added, deleted or amended as appropriate to remain current and to provide the appropriate training materials.

Content and material have been selected and structured to ensure that the training package provides essential information in a standardized, logical and systematic manner while adhering to effective teaching and learning strategies. The package is intended to standardize the training approach and to reduce the research and preparation time normally required by an instructor offering comprehensive courses of this nature. It should be noted, however, that the contribution of the individual instructor is essential to the success of the training. The instructor may add material as appropriate to the specific training. The instructor's personal experiences, elaboration and discussion of key points, anecdotes, review and questioning opportunities and involvement of the students are the means by which the material will be communicated, absorbed, enjoyed and understood.

Section 1 - PRINCIPLES AND METHODS OF TRAINING

Introduction

The objective of Section 1 is to address the basic elements necessary for the effective preparation, implementation and evaluation of training, with the aim of that training being "to get the message across".

To achieve that objective, the modules that follow are intended to provide guidance to trainers in the skills of conveying their message successfully and transferring related information.

Training is essentially the instructing of others in information new to them and its application. It may, and often does, involve the teaching of new skills, methods and procedures.

Very few people are born trainers, and most of those who wish to be trainers require training. Even those few who are born trainers benefit from training, and their effectiveness is enhanced as a result.

The most important element in a training situation is the trainer. The trainer who is enthusiastic, energetic and genuinely interested in both the subject and getting his or her message across will evoke the greatest response from the trainees. The trainer who lacks interest in training, who has little or no enthusiasm for the subject of the training and who merely goes through the motions of training is a failure. Such a trainer wastes not only his or her own time but also that of the trainees. The inept trainer is quickly identified by the trainees, who react with inattention, lassitude, undisciplined behaviour and absence from training sessions.

Successful training - that which produces the desired result - lies almost entirely in the hands of the trainer. In the trainer's hands lies the heavy responsibility for ensuring that the trainees achieve the maximum possible from the training.

A measure of the success of training is the relationship that develops between trainer and trainees. In a sound, productive training situation there is mutual respect and trust between them, with the trainer taking care to ensure that even the weakest trainee performs to the highest possible level, and the trainees feeling a desire within themselves to achieve. In this situation the trainer is the motivator and the trainees are the motivated.

It is intended that the modules that follow will be of assistance to those wishing to train and those already training.

The modules have been arranged as follows:

- Module 1: Principles of effective communication - "Getting the message across"
- Module 2: Effective oral communication
- Module 3: Why train? The trainer's role and responsibility
- Module 4: Methods of training - The right method
- Module 5: The art of questioning
- Module 6: Types of training aids - How to make and use them
- Module 7: Planning and delivering a presentation
- Module 8: Evaluating training
- Module 9: Testing trainee trainers - Individual presentations
- Module 10: Organizing and managing a training course

The above arrangement is systematic. Modules 1 and 2 deal with training theory. Module 3 is transitional in that it links the theory with the applied training methods covered by Modules 4 to 7. Modules 8 and 9 cover the important aspect of measuring and assessing the effectiveness of the training and the trainer. Module 10 is related to the management of training or, in other words, creating a favourable environment in which to train.

It is important that all members of a training team be familiar with the principles espoused in the training modules. This ensures that every presentation in a training course embodies the principles and in itself is a demonstration of the application of those principles: the trainees are not only told how to train, but see how it should be done.

It is stressed that the modules are not intended to constitute a textbook on training. Essentially, their contents are intended as memory joggers for those trained to train others. For this reason, and depending on the nature of the subject, some material is presented in point form while other material is covered by full text.

The training segment of this programme provides only the supports of training theory and practice. This places a heavier than normal responsibility on the trainer, who must in the span of ten hours make the deepest possible impression on the trainees if they are to be turned out as proficient trainers. This means not only that the trainer must be familiar with and skilled in presenting the training information and related methods, but that he or she must be at least familiar with many other aspects of training not covered by the modules, for example, motivation theory, the art of public speaking, conducting discussions, course planning, written communication and so on. A knowledge of these subjects enables the trainer to weave appropriate strands from them into the presentations of the modules, thus broadening the trainees' experience. There are many excellent texts on training as well as training manuals produced by training units in government ministries and departments, private companies and other organizations. Dedicated trainers make it an essential part of their continuing education as professionals to locate such publications in libraries or elsewhere, and by so doing keep abreast of theory and practice.

Module 1 - Principles of effective communication - "Getting the message across"

Objective

To familiarize the participants with the elementary principles of successful oral communication of information and to heighten awareness of the factors that interfere with communication and reduce its effectiveness

Suggested method of instruction

- Lecture/discussion with maximum trainee participation through questioning and relating of personal experience

Aids

- Overhead transparencies
- Handouts

Time frame

- One hour lecture/discussion

Content

- Effective communication
- Interference
- Ways of avoiding interference

Presentation suggestions

The foregoing module is easily adapted to discussion. The trainer should attempt to elicit from the trainees their experiences with transmission, interference and ways of avoiding interference, which are well within the purview of trainee experience.

Trainees should be asked to tell the course participants about good communicators and poor communicators they have known, describing why they are memorable. The reasons they give should be related to the types of interference and ways in which interference was or could have been avoided.

Such a discussion invariably brings out other indirectly related aspects of spoken communication which provide points of reference when subjects in later modules are being dealt with.

Learning outcome

Participants should be aware of effective communication principles.

EFFECTIVE COMMUNICATION

Communication specialists compare the way people communicate to the way a radio transmission takes place. That is to say:

Transmitter (Speaker/writer) → Message → Receiver (Listener/reader)

Three types of transmission are identified:

- Spoken
- Written
- Gesture/sometimes referred to as "body language"

Transmission is in code:

- Spoken language
- Written language
- Gestures

In spoken language the unit of code is the word, heavily supported by gestures. Some communication specialists believe that at least 40 percent of the full meaning of messages transmitted by speech is conveyed by body language (gestures). In written language the units of code are words and symbols (e.g. figures, punctuation). In the remainder of this module and the modules that follow reference to communication is to spoken communication only and assumes the transmitter can be seen by the receiver.

Successful communication depends on the message being received by the receiver intact and interpreted by the receiver to have the same meaning as when transmitted

INTERFERENCE

Frequently the message suffers from interference. That is, something interferes with the message between its transmission and reception and distorts it. The following are some types of interference.

Weak transmission

- Speaking too softly
- Speaking in a flat voice (monotone) without inflection
- Not speaking in a direct line with the receiver
- Insufficient volume of transmission to prevail over competing transmissions and localized noise (static)

Garbled transmission

The transmitter (speaker) often scrambles the contents of the message so that the facts it contains are not in logical order and often appear unrelated.

Wrong language

The transmitter may use words, terms and expressions unknown to the receiver.

Pitching message at the wrong level

The speaker may transmit information in a context beyond the experience of the receiver (this may involve the use of wrong language). This is sometimes called "transmitting or talking over the receiver's head". Examples are teaching food control procedures or HACCP to people who have no experience in food safety or food processing, or transmitting detailed and profound scientific messages to a receiver without a scientific background.

Receiver not receiving

- Receiver turned off (gone to sleep!)
- Tuned into another transmitter
- Transmission too weak
- Strength of receiver diminished (lack of interest - boredom)

- Receiver distracted by a competing focus of interest (an attractive person walks by)
- Receiver fatigued

Competing transmissions

The receiver may be unable to select between transmissions (too many people talking at once).

Overloading the message

The receiver does not possess the capacity to retain all of the information contained in the message. This frequently leads to receiver confusion/fatigue and anxiety.

WAYS OF AVOIDING INTERFERENCE

- Speak up and out
- Speak slowly and deliberately
- Use language that the receiver understands
- Do not talk over the receiver's head
- Ensure you have the attention of the receiver
- Only transmit your message in suitable surroundings where there is no, or little, competition
- Make the message succinct (as few words as possible) and transmit it in the simplest terms
- Plan the message in logical order

> **As a trainer it is essential that you get your message across-otherwise your effort to train will be wasted**

SUMMARY

To be a successful communicator

- Use your voice effectively
- Know your subject
- Know what you want to say
- Prepare your message carefully
- Arrange your points logically
- Display interest and enthusiasm
- Sound convincing and sincere

Module 2 - Effective oral communication

Objective

To assist the trainee-trainers to identify and become acquainted with the essential elements of getting the message across and becoming an effective oral communicator

Suggested method of instruction

- Lecture/discussion with maximum trainee participation through questioning
- An exercise in impromptu speaking to an audience

Aids

- Overhead transparencies
- Handouts

Time frame

- One hour lecture/discussion
- One hour of approximately three-minute impromptu speeches (time depends on the number of participants)

Content

- The importance of being an effective oral communicator
- Essential elements in transmitting a message
- Communication hazards

Presentation suggestions

The trainer should put much effort into preparing for presentation of this module.

The presentation should commence with a discussion based on a series of questions carefully devised by the trainer, for example:

- What makes a good communicator? (This question is a link to Module 1 and offers the opportunity for a few minutes revision of the previous module).

- What are the essential characteristics of effective oral communication?

It is important that the trainees identify the characteristics and convert them to elements by themselves. As each is identified it could be discussed in detail.

The trainer can project transparencies showing the elements to reinforce them in the minds of trainees, but only after they have been identified by the trainees.

Exercise

Each trainee is required to give a three- to four-minute impromptu talk. The following are examples of possible subjects:

- My reasons for attending the course
- The aspect of my work I enjoy the most
- Why I think HACCP (or food control) is important

In giving this talk the trainee will be expected to take into account the essential elements in transmitting a message.

A handout sheet may be helpful to assist the trainees with their short presentations. The following is an example:

- Describe your work.
- Why is it important to you?
- Which aspect of your work do you enjoy the most?
- Which aspect do you dislike the most?
- What do you think you are best at?
- What aspect of your work would you like to know more about?
- If you had a choice, which aspect of "Quality control" would you like to specialize in and why?

Learning outcome

The participants should be familiar with the essential elements of effective oral communication.

THE IMPORTANCE OF BEING AN EFFECTIVE ORAL COMMUNICATOR

As a trainer much of your effectiveness is measured by your ability to speak with clarity and conviction in getting your messages across.

Men and women in training positions are expected to be highly competent at presenting ideas, giving directions and explaining procedures. In fact, this quality of being an effective communicator is generally considered to be an essential element of the effective trainer's skills.

The information you communicate as a trainer is often critical to the people you train and to the workings of the organization as a whole. The way you explain procedures or give directions can make the difference between an employee being productive or frustrated. Sometimes clear information from you can make the difference between people doing a job safely or unsafely, working efficiently or inefficiently or doing things correctly or incorrectly.

How you present even an obviously brilliant idea can make the difference between whether or not anyone listens to you. The way in which you interpret and transmit information about agency policies, goals, values and procedures has significant influence on the way your staff or subordinates develop their perceptions and their commitments to the organization.

Communicating clearly - "getting your message across" - is not an inherited ability; people are not born with it. It is a learned skill developed through planning and practice.

ESSENTIAL ELEMENTS IN TRANSMITTING A MESSAGE

State the purpose and main point of your message

This encourages receivers (listeners) to focus on your information and be more receptive. They will not be distracted by trying to guess what your point is, but will be mentally prepared to follow along as you develop your discussion.

Stating your main point right away captures your listeners' attention and helps them remember the most important part of your message.

Introductory phrases like the following help to make your purpose clear at the start.

- My purpose in speaking to you is...
- It is important that I discuss with you...
- The subject of what I have to say to you is...
- As a result of new policies adopted by the organization you should know...

After the main point has been made, it can be highlighted with expressions like:

- Now, what this means in effect is...
- Put in another way, this means...
- You can expect that what will happen next will be...
- My main concern about this proposal is...
- The point that I wish to emphasize is...

Strengthen your main point with supporting points

Your explanations, instructions or ideas are more compelling when supported by clear facts and observations. Your objective is to gain respect and belief from your listeners and for them to gain insight into the details of the message you are communicating. The following guidelines will make the transmission of your message effective.

- Use simple language. Avoid technical jargon unless you are sure that everyone understands it.

- Keep your explanation short so you do not risk boring people. Do not swamp them with unnecessary detail (which is called "overloading").

- Choose reasoning that is natural and familiar to your listeners and your topic.

- Make your explanations as colourful as possible, using examples to illustrate your point.

- List all your supporting points first; then return to each point and fill in the details.

- Use visual aids, where possible, to illustrate your points.

Check to see whether you got your message across

You must find out whether you got your message across. Checking this may also introduce you to views of your listeners that were not apparent to you, or reveal misunderstandings that need to be quickly corrected. In addition, checking often helps listeners feel involved: they are being consulted. Their responses might uncover some problems not earlier apparent to you. The best way of checking is by questions. For example:

- Would somebody like to restate the steps of the new procedure?
- What do you think about...?
- What effect do you think the new arrangement will have?
- Is there anyone who disagrees with what is being proposed?
- Which of the points I have made do you think is the most important?

Respond to reactions to what you have presented

It is important that your trainees see you as somebody who is honest with them. A good part of this quality of openness is reflected in the way you respond to people when they question your statements, instructions or opinions.

Listeners question speakers because they have not received (not understood) the message, or because it is unclear, or because the details are vague. Generally, they are not challenging the speaker as a person; they are simply seeking clarification.

In answering questions, make sure you understand the question. If you do not understand the question, ask the questioner to repeat it. If you still do not understand it, start questioning the questioner. For example:

- Do you mean...?
- I understand that you are asking me...
- I am not sure that I understand you, but I think you are saying...

Sometimes you may understand the question or statement but feel that other listeners are having trouble with it. In such cases put the question or statement into your own words and restate it, ensuring that your restatement is correct by asking for confirmation from the person who has proposed the question or statement.

Never, never make fun of a questioner who has completely missed your message. Make light of the misunderstanding, and repeat the message to help him or her understand. You might introduce your statement as follows:

- I think there is a misunderstanding here. Let me repeat my main point again.
- This is a very complicated matter and difficult to understand fully. Let me repeat the main points.

Summarize your main point(s)

Your listeners will probably not be able to remember everything you have said, especially if you have presented several ideas. A short, simple restatement of the essential message(s) helps the listeners to remember and respond.

COMMUNICATION HAZARDS

Nervousness, forgetfulness and losing track

At one time or another all trainers (transmitters) experience these problems. Two ways to prevent these difficulties are:

- Use notes
- Rehearse the presentation of your message

Speakers familiar with their message seldom, if ever, suffer from severe interference.

Letting the audience get to you - becoming defensive

Do not get defensive when a trainee asks a question or makes a statement that is or appears to be a criticism of or an attack on you. As a trainer and communicator you must retain your objectivity. To become defensive and subjective quickly signals to the listeners that you are not sure of yourself or your facts, and they may assume that what you are saying is unreliable. This can lead to loss of your credibility.

Criticism of your presentation

Look upon critical statements or questions as a form of feedback. The information in them can tell you whether you are on the right track. However difficult it might be, handle yourself pleasantly and diplomatically, using responses such as:

- I'm glad you brought that up. It's an interesting question.
- Perhaps you could explain that a little more before we have a look at it.
- I can understand how you feel about the matter, but try and look at it this way.
- I understand your concerns. Let's try to come up with some alternatives.
- I can see that the matter is of great concern to you. Let's discuss it personally at the coffee break.

Module 3 - Why train? The trainer's role and responsibility

Objective

To introduce the participants to the basic principles of training in the simplest possible way and to establish fully the responsibility of the trainer

Suggested method of instruction

- Lecture/discussion
- An exercise in identifying the role of each of the senses in learning
- An exercise in planning a skill training session

Aids

- Overhead transparencies
- Handouts

Time frame

- One hour lecture/discussion

Content

- The process of learning
- Factors that hinder learning
- Obtaining and holding the learners' attention
- Facilitating understanding
- Steps in skill training

Approach

This module is important because it is essentially the introduction to the training modules that follow.

Discussion should play a major part in the presentation. Because of their life-experiences the trainees will be familiar with learning, even though they may never have analysed the process. Therefore the major task of the trainer is to plan a sequence of questions that will lead the trainees to an identification of the elements and steps in the learning process and the factors that hamper learning.

Trainees should be encouraged to recall the good trainers and teachers they have known and to identify the skills that made their training and teaching memorable.

The material in the lecture and overhead transparencies is in point form and requires explanation by the trainer.

Exercises

• Ask the participants to give a demonstration of a skill related to an industry or food control operation with which they are associated. Have the participants set down in logical order the steps in which they would present the demonstration.

• List ways in which each sense may be used by the trainer to make a sufficient impression to get the message across. For example:

SENSE	USE OF THE SENSE	APPLICATIONS
Sight	*Written word* etc.	*Textbooks* *Notes* *Handouts* *Blackboard summaries* etc.
Hearing		
Touch		
Smell		
Taste		

Learning outcome

The participants should be aware of and understand the trainer's role and responsibilities.

Why train?
To improve the trainee's knowledge and skill

What is the responsibility of the trainer?
To get the message across - that is, to ensure that the trainees have received and understood the message

Training is not easy
Training is hard work
Some trainers merely go through the motions of training
Some trainers are unsuccessful

THE PROCESS OF LEARNING

The successful trainer possesses insight into the process of learning. The learning process conforms to the following pattern: external sensations stimulate the sense organs - ears, eyes, body (touch), nose and tongue - and the nervous system conveys impressions to the relevant sections of the brain. The brain then transmits impulses to the muscles and organs of movement and speech, and the end result is a reaction.

Creating an impression

Receiving an impression is the first step in learning. Therefore, the trainer must ensure that the trainee receives strong impressions. The strength of the impression will depend on:

- The number of senses involved
- The vividness of the impression
- Whether the impression registers

Observing the learners

The only way the trainer can know if people have learned the material is by observing their behaviour:

- Their actions
- Their written impressions
- Their speech

FACTORS THAT HINDER LEARNING

- The learning plateau: at intervals the rate of learning flattens out as the brain rests
- Saturation: if the message is overloaded the receiver rejects the excess and learning stops
- Fatigue: a tired receiver is not as receptive as an alert one
- Inability to concentrate: the longer the message, the more concentration decreases from beginning to end

OBTAINING AND HOLDING THE LEARNERS' ATTENTION

Before people can learn any material they must focus their voluntary attention on it. The desire to learn comes from within; it is spontaneous.

The good trainer tries to gain and maintain voluntary attention in every session he or she presents.

- Relate what you aim to teach to those subjects in which you know the trainees are interested.

- Introduce the session in such a way that the trainees will not only see and become interested in this relationship, but will want to learn more about it.

- Begin with a good story to which the trainees can relate. An effective trainer makes it his or her business to know the background of the trainees.

- Having done these things, maintain the trainees' attention by doing all that is possible to facilitate their understanding and absorption of the material.

- Ensure that the trainee's learning is an active process in which the trainer and trainees are equal partners in terms of participation.

FACILITATING UNDERSTANDING

To facilitate understanding, the trainer proceeds from:

- Known to unknown
- Simple to complex
- Whole to part and back to whole
- Concrete to abstract
- Particular to general
- Observations to reasoning
- Point to point in logical order

To facilitate absorption, remember that trainees learn only by impressions received through their senses.

STEPS IN SKILL TRAINING

Having learned a skill, trainees must reinforce its acquisition by using it. Learning by doing is the basic principle underlying the acquisition of any skill.

When teaching skills, the trainer most often achieves the best results by keeping the talk short and by working through a set sequence of discrete steps, as follows:

- Show the trainees the actual skill they are to acquire.

• Demonstrate and explain, step by step, the operations involved (this requires an analysis of the total procedure by the trainer).

• Have trainees imitate the necessary actions.

• Have trainees practise performing the operations.

• Devote at least 50 percent of the session to trainee practice time.

SUMMARY
The first rules of training are:

• Make the best use of the most effective channels to the brain - the senses: sight, hearing, touch, taste and smell.

• Use a combination of the senses. For knowledge, use the trainees' eyes and ears. For manual skills, use the trainees' hands, eyes and ears.

• Make presentations as vivid as possible.

These are the basic principles of instruction - the means by which the instructor reaches and makes an impression on the brains of the trainees.

Module 4 - Methods of training - The right method

Objective
To inform participants of the methods of training available to them, with particular attention given to the lecture, the lecture/discussion, the skill lesson and the on-the-job session
Suggested methods of instruction

• Lecture
• Discussion
• Demonstration
• Exercise

Aids

• Overhead transparencies
• Demonstrations
• Handouts

Time frame

• One hour lecture/discussion
• One hour of five-minute mini-lectures

Content

• The different methods of training
• Selecting the right method
• The lecture

- The lecture/discussion
- The skill lesson
- On-the-job training (the four-step method of instruction)

Approach

This module lends itself to a lively presentation by the trainer. The trainer must be capable of demonstrating personally the methods of training selected for special attention. These methods are believed to be the most appropriate for use in training in food control practices including GMPs and HACCP. It is acknowledged that case studies also have their use, but considerable time is required in their preparation.

The trainer should spare no effort to make this module effective. The methods are the tools the trainees will use when they became trainers. It is essential that the presentation of the module provide them with a base for effective training, on which the trainees can build by practising to improve performance.

Exercise

Ask participants to give a five- to seven-minute mini-lecture on a subject of their own choice that is related to food quality control. Instruct the participants to prepare a point outline on the subject of their lecture for use during their presentation.

THE DIFFERENT METHODS OF TRAINING

You have a choice of the following methods to prepare for effective training:

- Lecture
- Lecture/discussion
- Skill lesson
- On-the-job training (the four-step method)

There are other methods of training, but their effective use is specific to special training situations and will not be discussed in this lecture. Some of those methods include:

- Role play
- Assignment
- Case study
- Training games
- Group exercises
- Programmed learning

SELECTING THE RIGHT METHOD

All the resources at your command must be used to make your instruction real and vital for your trainees. The number and types of training methods you use during any presentation depend on many factors, and you must therefore have answers to the following questions before you decide how you will present your material.

- What is the ability and level of knowledge of the group?
- How many trainees are in the group and why are they there?
- How much time do you have to prepare your material?
- Can you cover your topic fully in the time available?
- What aids do you require?
- Do you have the experience to use these aids with confidence?
- Are you aware of the limitations of aids?

Your method of presentation will depend on the answers to these questions.

THE LECTURE

Use

- When the group is large - say 30 or more
- When knowledge or understanding is to be imparted by an expert
- When a body of factual information has to be communicated in a short time
- When information is not readily available to group members

Delivery

Essentials of good delivery:

- Words must all be clear
- Words must be spoken at a suitable pace
- Pauses should occur at logical places
- Variety should be used: emphasizing important points in a deliberate manner, connecting parts and using illustrations in a conversational way

Preparation and lecture notes

Preparation is important. The lecturer's notes need to be designed to facilitate efficient delivery. Distinction is needed between lecture outlines (showing matter only) and lecture notes (showing method and matter).

Notes may be too brief. The lecturer may then improvise, and he or she may be vague or may forget important elements. On the other hand, notes may be too extensive. The lecturer will then read them, and this is undesirable.

Given an outline of the material, prepare the notes by asking these questions:

- What is it safe to assume that the listeners know?
- What are they likely to find difficult?
- Hence, what will require special care or illustration?
- What will the illustrations (in detail) be? Can they be misunderstood or misinterpreted?
- What demonstrations will be appropriate? Will everyone see clearly? (Demonstrations are used to illustrate really important points. The more important the point, the more spectacular the demonstration should be.)
- What new terms will be introduced? What unusual names? Mark these in the notes. They will need to be written on a blackboard, whiteboard, chart or overhead transparency.
- What precisely should everyone know at the end of the lecture? (This is really a re-examination of the outline and a restatement of the important points.)

Structure

Introduction:

- Statement of aims
- Relation of this lecture to those that came before and are to follow
- Establishment of goal (which gives purpose and direction) by linking aims with participant needs
- Outline of thoughts that are to be developed

Body of lecture:

- Step-by-step building up of subject matter
- Logical development
- A few well-developed steps, strongly made (more effective than many steps)
- Appropriate use of aids and questions to stimulate student interest and activity
- Appropriately spaced summaries of material covered

Conclusion:

- Summary of lecture material
- Restatement of the relationship of this lecture to others in the series
- Reference to additional material that should be read or seen
- Setting of any assignments

Disadvantages

- Lecturer bombards students with considerable information (saturation may occur)
- Participants sit passively without interaction

THE LECTURE/DISCUSSION
Use

- When the group is small - say 20 or less
- When the members know one another well enough to risk making errors
- When the material is of a kind that can be assimilated readily, at least in part, or when there is some prior knowledge of it

Lecture
Refer to preceding section.
Discussion
The most useful starting point for the discussion is the question. Some uses of questions:

- At beginning of lecture: to find out what trainees already know and to discover opinions
- During lecture: to find out whether the participants understand and are following the lecture
- End of lecture: to recapitulate and test the participants' knowledge and understanding

Desirable features of questions:

- They should be clear
- They should be brief
- They should lead to some constructive statement rather than to a nod or a grunt
- They should stimulate thinking, rather than suggest the answer

Pitfalls

- Repeating the answer (Do not repeat. Move on.)

- Holding a dialogue with a single answerer (Bring in the group, e.g. "Would anyone like to add to that?")

- Trampling the incorrect answerer

- Asking too many questions (Adults do not like to be cross-examined.)

- Letting the discussion take too long (Guide it carefully. Remember the objective of your discussion.)

Structure

- Introduction
- Body of lecture
- Discussion
- Conclusion

THE SKILL LESSON
Aims

- To teach correct and safe job methods
- To develop confidence in job performance
- To achieve accuracy and speed
- To encourage conscientious effort

Structure
Introduction

- Development (body of skill lesson)
- Demonstration by trainer (complete)
- Demonstration and trainee practice of each stage, in sequence
- Practice of demonstrated job skill Conclusion

ON-THE-JOB TRAINING (THE FOUR-STEP METHOD OF INSTRUCTION)
Step 1

- Prepare the worker
- Put the worker at ease
- State the job and find out what the worker already knows about it
- Stimulate the worker's interest in learning the job
- Place the worker in the correct position

Step 2

- Present the operations
- Tell, show and illustrate one important point at a time
- Stress each key point
- Instruct clearly, completely and patiently, but teach no more than the worker can master

Step 3

- Try out the worker's performance
- Have the worker do the job, and correct errors
- Have the worker explain each key point to you as he or she does the job again
- Make sure the worker understands, and continue until you are certain of this

Step 4

- Follow up
- Put the worker on his or her own
- Designate to whom he or she should go for help
- Check frequently
- Encourage questions
- Taper off extra coaching and reduce follow-up

Example of an on-the-job training session: training workers in the correct method of hand washing

Workers in fish processing units must maintain a high degree of personal cleanliness. In order to educate the workers in better hygienic practices, the correct hand washing method is one of the topics demonstrated in fish processing units.

The main objective of washing hands is to avoid contaminating the material with organisms from the hands. Unwashed hands transmit microorganisms. It is therefore essential that hands be washed thoroughly. The following procedure for washing hands is recommended:

- Wet palms and arms, from the elbow down, with fresh water
- Apply soap
- Work lather on and around fingers, nails and arms from the elbow down
- Rinse palms and hands with fresh water
- Wipe palms and hands dry using a clean towel

Module 5 - The art of questioning

Objective

To provide guidance to the trainee-trainers on how to ask questions, and to make them aware of the dos and don'ts of questioning

Suggested methods of instruction

- Lecture/discussion
- Discussion
- Handouts

Aids

- Overhead transparencies
- Handouts

Time frame

- One hour presentation

Content

- Importance of questioning
- Types of questions
- Purpose of questions
- How to ask questions
- Preparation of questions
- Dos and don'ts of questioning
- Questions asked by trainees

Approach

This module is of great importance, as skilful questioning is essential to a trainer's effectiveness.

Learning outcome

The participants should have the knowledge and ability to utilize questioning to support effective training.

IMPORTANCE OF QUESTIONING

To be effective, trainers must be skilled questioners. Carefully devised questions, skilfully asked, are the basis of the lecture/discussion method of training, and questions should also feature prominently in other methods of training. Few people question well, and to do so requires careful preparation and practice.

- Questioning is one of the essential skills for any good trainer.
- Unless you question properly you cannot hope to know how much (if any) of your message is getting across.

TYPES OF QUESTIONS

Rhetorical

A rhetorical question is a question to which no answer is expected. Examples:

- Now that is simple enough, isn't it?
- What could be clearer?
- Anybody could understand that, don't you agree? Do not overuse this type of question.

Direct

A direct question to a named person can be a useful management device in a class situation. Example:

- Prakash, what detergent would you use for washing fish crates?

Do not overuse direct questions.

Overhead

An overhead question is asked to the whole group, and then a person named to answer. Example:

- What detergent is used for washing fish crates? Prakash, do you know?

Leading

A leading question suggests the answer.
Example:

- If chlorine kills microorganisms in water, what is it likely to do to them elsewhere?

Leading questions are of limited use.

PURPOSE OF QUESTIONS

Questions are used for all sorts of purposes in training. Some of the more common purposes are:

- Getting trainees to participate
- Checking on a trainee's understanding
- Attracting a trainee's attention
- Testing a trainee's knowledge of the subject
- Breaking the ice and initiating a discussion
- Stimulating confidence in shy trainees
- Reviewing earlier work
- Changing the topic

HOW TO ASK QUESTIONS

- Ask the question in a friendly and natural way to the group. Pause, then name one individual to answer.

- Vary tempo with pauses.

- Spread questions throughout the group at random.

PREPARATION OF QUESTIONS

- Prepare questions before the lesson, but use them flexibly.
- Introduce questions with such words as: what, when, explain, compare, how, why, outline, contrast, define, trace, describe, illustrate.

An effective question

- **Is simple and direct**
- **Is clear and well expressed in a complete sentence**
- **Contains one main thought**
- **Has only one correct answer;**
- **Requires more than a "yes" or "no" answer**

DOS AND DON'TS OF QUESTIONING
Do

- State questions clearly, concisely and audibly

- Ask in a friendly and natural way

- Use questions carefully and time them appropriately - to create interest, lift attention and evaluate

- Involve the whole group

- Include one main thought in each question

- Know the answer

Don't

- Interrogate people
- Embarrass people

- Trick people
- Get sidetracked by answers
- Ask questions with more than one correct answer
- Answer your own questions
- Ask more than one question at a time
- Ask questions with a "yes" or "no" answer

QUESTIONS ASKED BY TRAINEES

Genuine

Answer if you can. Do not bluff. If you cannot answer, say so, but indicate that you will try to find out the answer.

Ulterior

A trainee may be trying to embarrass the trainer or someone in the group. The options are:

- Ignore the question
- Reply negatively: "Let's leave that. I don't think it's entirely relevant."
- Relay the question: "Would somebody in the group like to answer that?"
- Reverse to questioner: "What do you think the answer might be?"

Module 6 - Types of training aids - How to make and use them

Objective

To introduce participants to training aids and to instruct them in their correct and most effective use

Suggested methods of instruction

- Lecture
- Demonstrations
- Exercises
- Handouts

Time frame

- One hour presentation
- One hour making and showing aids

Content

- Why use training aids?
- Classification of instructional aids
- Selection of aids
- Principles to follow in adopting a visual approach
- Charts and diagrams
- Handouts
- Overhead transparencies
- The computer pallet
- Colour slides
- Videos

Exercises

- You are to give a training session to workers in a processing plant about one of the following:

- Plant hygiene
- Vermin control
- A processing technique
- Moisture control
- The life cycle of an insect
- Factors adversely affecting quality
- The importance of food control
- The application of HACCP

Prepare a chart that may be used in the session you elect to give, or alternatively, in your presentation during the conclusion of this course.

• Prepare a single-page handout on a topic of your own selection (perhaps for use as part of your presentation during the conclusion of the course) and for an audience you designate, e.g. quality control officers, factory workers, management, export inspectors.

• Prepare an overhead transparency on a topic of your choice (perhaps for use as part of your presentation during the conclusion of the course), keeping in mind the rules of overhead transparency preparation.

WHY USE TRAINING AIDS?

All learning is through the senses. The more senses are brought into use, the more effective is the learning; 97 percent of learning is achieved through simultaneous appeal to the eye and ear. It is because of this that we should make use of audiovisual aids in training.

Effective use of audiovisual aids can be included in any sort of presentation. Charts, slides, videos, overhead transparencies and films can be used to add interest as well as supplement verbal explanations.

Proper use of instructional aids saves time, adds interest, helps trainees learn and makes your job easier. But remember that aids to training are aids only. They are not substitutes for training.

Trainers should use training aids to supplement their training rather than to replace all or part of it.

> **The trainer who shows a chart or illustration without any explanation, or who shows slides, videos or films without preparing the trainees to receive them, is guilty of not doing his or her job**

CLASSIFICATION OF INSTRUCTIONAL AIDS

Projective

- Motion pictures
- Videos
- Colour slides
- Overhead projector transparencies
- Computer pallet

Non-projective

- Chalkboard
- Whiteboard
- Charts and diagrams
- Models
- Exhibits
- Handouts
- Tape recorder

SELECTION OF AIDS

In selecting aids, take into account the following:

- Practicability
- Attractiveness and interest; vividness
- Suitability
- Complexity
- Clarity
- Portability
- Serviceability
- Availability
- Location
- Preparation and presentation
- Time factor

PRINCIPLES TO FOLLOW IN ADOPTING A VISUAL APPROACH

- Anything that can be quantified or is factual can be presented visually

- Obtain and select the necessary data; confusing data and confusing information will result in confusing visuals

- Know clearly what you want to say in your visuals; write it down

- Plan your visuals; know what you want to include (Sketch an outline of ideas you think will work.)

- Try the visuals out on others before you use them

Tips to ensure the trainees do not go to sleep during presentation of your visuals

- Make your visuals visible
- Ensure that the trainees can see them
- Use colour for headings
- Take care with drawings; they can be misinterpreted
- Make them simple; eliminate details
- Ensure the key feature occupies a prominent part of the screen or display
- Minimize reflection
- Show all the key points (oral presentation includes everything necessary to sell the key points through the ears; visual presentation includes everything necessary to sell the key points through the eyes)

Whatever instructional aid(s) you choose to use as a trainer, it is important to remember practise....practise....practise

Preparation

- Plan carefully the use of instructional aids
- Make sure that the aids can be seen clearly from all areas of the room
- If you write, write clearly
- Use colour for emphasis

CHARTS AND DIAGRAMS

These fall in two main categories:

Bold and simple

These are for use during a training session. They should:

- Be large enough to be seen by all
- Not necessarily be self-explanatory
- Be functionally coloured
- Include only the essentials

Detailed
These are for close study at leisure. They should:

- Be more or less self-explanatory
- Be of medium or small size
- Be suitable for semi-permanent display
- Be artistically produced

HANDOUTS
Handouts are specially prepared sheets and notes. They are used:

- For reference purposes during the session or course
- To substitute for note taking
- To retain as a permanent record for reference after the course

A handout can:

- Introduce a topic
- Provide revision
- Provoke discussion

Handouts should:

- Be brief and sharp/containing only essential details
- Be accurate and complete
- Be designed clearly and attractively, with good use of white space
- Include diagrams if appropriate
- Always have a title
- Be planned
- Be of a standard size
- Be presented in a logical sequence
- Be pitched at a level appropriate to the audience

Why use handouts?

- They carry the stamp of authority
- They provide a record of important information
- They supply data to reflect the presentation
- They can provide background documentation (longer and more comprehensive)
- They can be studied at the reader's own pace
- They convey with certainty the same data to a number of people
- They appeal to the sense of sight

When should handouts be distributed?

- Before the presentation
- During the presentation
- At the end

OVERHEAD TRANSPARENCIES

The overhead projector is one of the most useful training aids. It can replace the need for chalkboards, whiteboards and charts. The overhead projector can be used for presentation to a group of any size.

All material for use on an overhead projector needs to be reproduced on to transparencies using either special pens or printers with either non-permanent or permanent ink (the latter if the trainer wants to keep and reuse the transparencies). It is also possible to make either black and white or colour transparencies using a specially designed photocopier. Computer-generated transparencies can be excellent.

Design of overhead transparencies

- Keep them simple
- Include only essentials
- Make sure lettering is of sufficient height (>5 mm)
- Use colour on colourless film or contrasting colours on coloured film
- Do not clutter (no more than seven principle points to a transparency)
- Illustrations can be useful

Using the overhead projector

- Make sure the projector is placed so that all can see
- Focus correctly
- Use masking technique: cover part of the transparency so only the material you are discussing is shown

The overhead projector is probably the most flexible of the aids available to the trainer. Used correctly, it will enhance trainee learning by making presentations more interesting and explanations clearer.

THE COMPUTER PALLET

The computer pallet is a device that replaces the computer screen. It is placed on top of an overhead projector, allowing the instructor to project material that has been prepared and stored on a computer disk.

The same basic principles that apply to the design of overhead transparencies also apply to the preparation of material on a computer for use on a computer pallet. The benefits of using a computer pallet include flexibility and the ability to amend material easily. Particular computer programs, if available to the instructor, can provide a large selection of graphic materials and presentation packages.

At present this technology is not widely available. An instructor who wishes to utilize a computer pallet should be trained and familiar with its use.

COLOUR SLIDES

Main features

- Slides are relatively inexpensive to procure
- They are easily used
- They facilitate study of a topic one step at a time
- All trainees get the same clear view
- Each frame can be studied and discussed at leisure during the screening
- They can be used in conjunction with a tape-recorder (tape/slide sequence)

How to use slides effectively

- Do not treat as entertainment
- Select slides that are relevant
- Plan your presentation
- Include an introduction and conclusion
- Do not prolong the presentation
- Ensure the equipment is sound and well set up before the presentation

VIDEOS

- Make sure videos are directly related to the subject; do not use them merely for entertainment or to give yourself a rest

- Make sure all trainees can see the monitor

- The video should be introduced; trainees should be told what it is about and what they should look for

- Review the video in a discussion after screening

SUMMARY: RECOMMENDATIONS FOR AN EFFECTIVE PRESENTATION

Always:

- Allow ample time for preparation: sufficient time to plan and construct and sufficient time to rehearse

- Make a file copy of your visuals

- Check on your worst seats, those on the extreme right and left

- Mount screen high enough for all to see

- Remove competing attractions; competition will reduce impact of your visuals

- Check all arrangements before you go on, even if it means going without your breakfast, lunch or dinner; make sure you have done everything possible for a smooth presentation

- Maintain constant contact with your audience; know your visuals well enough that you do not have to break your commentary to check points

- Time your visuals to coincide with your comments; mistiming is distracting

- Make your presentation straightforward; be sincere and win the confidence of your audience

- Keep your visuals moving; parallel the flow of your words with the flow of visuals

- Use only the required number of words; avoid excessive wordage

- Use only well-trained assistants who know the visuals as well as you do

- Keep your visuals; they may be needed again

Module 7 - Planning and delivering a presentation

Objective
To guide and advise participants in the skill of planning a presentation and delivering it
Suggested method of instruction

- Lecture/discussion

Aids

- Overhead transparencies
- Handouts

Time frame

- One hour presentation

Content

- Importance of planning
- Steps in planning a presentation
- Delivering a presentation

Learning outcome
Participants should be aware of the importance and methods of effective presentation planning and delivery.
IMPORTANCE OF PLANNING
Every presentation in a training programme should be planned. The trainers who do not plan their presentations are not doing their job properly Unless the trainer is particularly gifted, it is most unlikely that the presentation will be successful and effective if it is unplanned. All effective trainers plan their presentations. They know precisely how the presentation will flow before they begin. The trainer who does not plan presentations is attracting trouble. Trainees are quick to sense a lack of planning, and their response will reflect their disdain for the trainer.

- The most important part of the presentation is preparation
- The first step in preparation is to have a plan
- Take a sheet of paper and commence planning

STEPS IN PLANNING A PRESENTATION
Determine what the trainees need to learn
Examples:

- How to achieve a high level of personnel and plant hygiene
- How to peel a prawn correctly
- How to use a thermometer
- How to disinfest cashews correctly
- How to apply HACCP
- How to establish export/import food control

State objective

Select the objective to be reached in satisfying the trainees' needs. Select it on the basis of what you expect the trainees will know or be able to do at the end of the training session. Consider:

- Time available in which to conduct the session
- Facilities available
- Prior knowledge and abilities of the trainees
- Relationship to the needs of the trainees
- Are you concerned with knowledge, skills or attitudes?

Choose an appropriate training method

- Appropriate to objective: is the objective to solve problems? to change attitudes? to teach skills?

- Appropriate to the trainee

- Appropriate to you, the trainer

- Appropriate administratively

Organize your material

- Decide on what the trainees must know
- Decide on what the trainees should know
- Decide on what the trainees could know
- Select key ideas
- Arrange (sequence) key ideas in logical order, e.g. known to unknown, simple to complex, concrete to abstract

Write the session plan

- Needs

- Objectives

- Method of training

- Organization of material: introduction, body, conclusion (keeping in mind time, questions, subheadings, details)

- Aids to be used

- Questions to be asked

Prepare and check aids

- Overhead transparencies, chalkboard plan, prepared charts, film, slides, tapes
- Check readability sequence, volume levels, suitability
- Handouts: notes, supplements

Presentation checks

- Check session plan, particularly timing and trainee activities
- Check equipment, aids, ventilation, seating and lighting

Evaluation

- Obtain feedback on students' learning during the session; use test questions
- Self-evaluation (How can I improve the session?)
- Write down on the session plan any comments for future reference before you forget them

Presentation planning checklist

Use the above outline as a checklist to be sure you follow all the necessary steps.

Use a plan - you will be more confident and training will be more effective

DELIVERING A PRESENTATION

Remember that the trainer's job is to help the trainee learn and remember. This is hard work. The trainer must be fully committed to the job. Trainees quickly sense whether a trainer is positive about what he or she is doing or is simply going through the motions. The trainer must motivate the trainees and spark their desire to learn new ideas and skills.

How is this done through delivery? The personal variations in manner and style employed by trainers are important in that they make instruction animated and interesting. Good delivery requires practice!

Influence attitudes through your manner

- Project enthusiasm regarding the training - through use of voice (modulation), body language (gesticulation) and eye contact

- Be confident and positive (this comes from sound session planning and preparation and from sound knowledge of what you are doing)

- Be firm

- Be energetic and lively - do not stay glued to one spot, move around the trainees (but don't overdo it)

- Introduce humour, if you can do so effectively (forced humour may be counterproductive, and too much humour may be damaging)

- Be pleasant, relaxed, and sympathetic to trainees; do not talk down to them

- Involve trainees in the training process, taking them into your confidence

Desirable qualities of speech

- Clear
- Pleasant
- Fluent
- Varied
- Coordinated with gesture

Set an example

- Convey a sense of the importance of the subject
- Take the subject seriously

Avoid

- Distracting mannerisms
- Not giving your best at every presentation

Module 8 - Evaluating training

Objective

To introduce participants to both the need and methods for measuring the effectiveness of their and others' training, as well as evaluating their own personal performance as trainers

Suggested method of instruction

- Lecture/discussion

Aids

- Overhead transparencies
- Handouts
- Model course evaluation questionnaires

Time frame

- One hour presentation

Content

- The need for evaluation
- Guidelines for course evaluation
- Course evaluation questionnaires
- Trainer self-assessment questionnaire for use before the session
- Trainer self-assessment questionnaire for use after the session

Learning outcome

The participants should be aware of the importance of evaluation in training and of methods that can be used to evaluate the effectiveness of training.

THE NEED FOR EVALUATION

It is not good enough for a trainer to feel self-satisfied with his or her training performance without evaluating it. All effective trainers not only evaluate or measure the degree of success of their course, they also evaluate their personal performance at the conclusion of each session or at least at the end of each training day.

Neglecting to make any attempt at evaluation reflects disinterest and lack of professionalism and is symptomatic of a non-caring attitude. Evaluation is a must; it is an integral part of effective training.

Purpose

- To improve training by discovering which training processes are successful in achieving their objectives (to "sort out the good from the bad")

Evaluation affects learning

- If we set examinations at the end of a course we affect the nature of learning

- If we study trainees' job behaviour after a course we have generally changed their job behaviour

- Since testing affects learning we can use it as a training aid

Two aspects of evaluation

- Course evaluation
- Trainer evaluation (self-evaluation)

GUIDELINES FOR COURSE EVALUATION

Break evaluation into clear, achievable steps:

Evaluating reaction

How well did the trainees enjoy the session(s)/course?

- Find out how well the trainees liked a particular training session or sessions or the course as a whole

- Does not include measurement of learning

Evaluating learning

What principles, facts and techniques were learned?

- Written test questions, oral test questions, skill tests
- Avoid questions like "Have you learned anything?"

Evaluating behaviour

What changes in job behaviour resulted from the training?

- Best evaluated through appraisal by on-the-job supervisors
- Remember: good trainers have on-the-job experience; they know the best way of doing things

Evaluating results

What were the tangible results of the training in terms of improved job performance?

- Some types of training results are easily measured (e.g. typing)
- Others are not easily measured (where management and attitudes are involved)

COURSE EVALUATION QUESTIONNAIRES

- Determine what you want to find out
- Use a written comment sheet covering the steps above
- Obtain honest reactions by making the form anonymous
- Allow trainees to write additional comments not covered by questions

Two model course evaluation questionnaires are included at the end of this module. Model 1 is intended for evaluation of a complete training course. Model 2 can be used to evaluate either a specific training session or module or the overall training course.

TRAINER SELF-ASSESSMENT QUESTIONNAIRE FOR USE BEFORE THE SESSION

Preparation

- Do the notes show clearly the limited, definite scope of this training session?

- Is my session planned to enable my specific purpose to be fully accomplished?

- Have I allowed for an adequate introduction; a presentation with participant activity; and a recapitulation which will clinch the chief points?

- Have I arranged for all necessary equipment/materials and teaching aids?

Introduction

- Will this step excite the interest of the trainees from the start - is it original or linked strongly with an emotion-stirring activity, or some matter of topical or personal interest?

- Will it pave the way for what is to follow so that the presentation will not discourage or bore by excessive difficulty?

- Will it provoke curiosity and interest for what is to come, generating a need which will be satisfied?

- Does it provide adequate revision of what has gone before?

Body

- Is the instruction broken up into steps of reasonable length?

- Will each step offer maximum trainee participation and activity?

- Will each step win trainee interest and attention?

- Will each step offer some way of evaluating the trainees' comprehension before the next step is undertaken?

- If there is a written exercise to be done, have I something useful ready to occupy the quicker trainees so that slower ones may finish comfortably?

- Is there adequate provision for holding the interest of the strongest trainees and giving them worthwhile activity?

- Have I allowed for a period of relief for trainees and myself after a period of intense concentrated work?

Conclusion

- Will this step adequately recall and test the vital points of the session?
- Have I timed my session so that there is time for this important step?

Chalkboard summary

- Will my chalkboard or whiteboard summary show what I expect to appear on the chalkboard at the end of the session?

- Is the arrangement (use of colour, diagrams, etc.) attractive?

- Have I thought out ways of obtaining the maximum help from the chalkboard with a minimum loss of contact with my group during the session?

- Are there any parts of the chalkboard that I should not use because they are not clearly visible because of poor lighting, shining sun, etc.?

- How will arrangement of any other visual aids fit in with my use of the chalkboard?

General

- Are there any other aids that will assist me?

- What rabbits have I ready to pull out of a hat if interest flags?

- Have I taken into consideration the intellectual level of the group, the time of day the session will take place and interruptions?

- Have I thought out how this session will fit into the general syllabus for the group?

- Am I sure of the correct pronunciation of unusual words that I will be using during the lesson?

- Am I sure of my subject-matter and of the correctness of the questions I intend to use?

- Am I sufficiently familiar with my questions and steps to be able to carry on the session at maximum effective speed without allowing the thin edge of the wedge of inattention to be inserted?

TRAINER SELF-ASSESSMENT QUESTIONNAIRE FOR USE AFTER THE SESSION
Voice

- Was my voice clearly audible in all parts of room?
- Was it restrained enough not to irritate trainees or disturb other session leaders?
- Did I vary the speed, pitch, volume and tone so as to give maximum interest to whatever I said?

Manner

- Was my manner reasonable, brisk and alert?
- Did I sincerely convey a sense of earnestness and enthusiasm for what I was instructing?
- Was my manner reasonably pleasant and general without being affectedly so?

Group management

- Did I get off to a clean brisk start, stimulating the group from the beginning?

- Did I stand in such a position that I could be seen and heard by all trainees?

- Did I keep all trainees under my eye and control whenever necessary?

- Did I take steps to see that no trainee disturbed the work of the group or failed to take adequate part in the session?

- Did I see that at the beginning of the lesson the floor and chalkboards were clean, the desks in order, the windows open and the class settled and ready?

- Did I have the trainees pulling with or against me?

- Did I refuse to be sidetracked?

Questioning

- Were my questions audible to all trainees?

- Were most questions easy enough for all trainees to be able to attempt an answer?

- Were there some particularly stimulating questions?

- Where the response to a question was unsatisfactory, did I take measures to improve the response (e.g. reframing the question) rather than waste a good question by immediately giving an answer?

- Did my questions follow rapidly without hesitation and uncertainty?

- Did I insist on answers being given loudly and clearly?

- Did I refrain from unnecessarily repeating answers?

- Did I distribute questions widely, encouraging weak trainees?

General

- Did I cover the steps of my session adequately?
- Was my recapitulation or other final step unhurried?
- Did I maintain my aim throughout the session?
- Did I keep as far as possible to the plan of my lesson?
- Did my trainees and I enjoy the session?
- What did the trainees gain from this session?
- What have I learned by leading this session?

Model 1 - COURSE EVALUATION/REACTION QUESTIONNAIRE

To assist in the planning of future courses it would be of great value if you would complete the sections that follow. Please be frank with your responses. Remember, only your honest reactions will enable adjustments and improvements to be made. The questions asked may not cover all of the aspects about which you wish to comment. For that reason a space headed "General comments" has been provided, and it is hoped that you will use it if appropriate.

Conditions

Were you comfortable?
What improvements, if any, do you suggest for the accommodation of future courses?
Were the seating arrangements satisfactory?
Could you see and hear satisfactorily?
Were the morning and afternoon sessions well balanced?

Course content

Were the subjects covered the ones you expected would be?
Were there any surprises? Why?
Was the coverage sufficiently wide? If not, what subjects would you have liked included?
Was each subject covered in sufficient depth? Name any that you think were not.
Was the course sufficiently practical in the sense that you will be able to apply knowledge and skills taught?
Did the subjects sustain your interest?

What additional subjects would you suggest for future courses?
What subjects would you omit from future courses?

Presentation

Were all sessions presented in a clear and interesting way?
Were there any sessions that left you confused or uncertain? Please specify.
Do you think trainers could have done more to improve their presentations? If so, what?
Were the lengths of sessions satisfactory?
Did the aids used help sustain your interest and understanding? Name any particular aid that impressed you.

General comments

_____

_____

You are not required to identify yourself on this form unless you desire to do so.

Model 2 - TRAINING MODULE OR COURSE EVALUATION

Instructions

You have just completed the training. Now we would like you to tell us about your feelings on what has just been presented. This information is valuable in helping us make following training sessions more interesting and useful to you. Below you will find a number of questions dealing with the just completed training session. Most questions can be answered by circling a number on the scale to the right of the question. Where a written response is required, please write your reply clearly in the space provided. Please consider your responses carefully and answer truthfully. Everything you say will be held in strictest confidence. The information will be used only to help us make this training activity more responsive to your needs.

Topic discussed:_____

I. Content

1. Relevance of the topic to your job	Not relevant				Relevant
	1	2	3	4	5
2. Clarity of the module's objectives	Not clear				Very clear
	1	2	3	4	5
3. Level of instruction	Too basic				Too advanced
	1	2	3	4	5
4. Lecture coverage	Inadequate				Very comprehensive
	1	2	3	4	5
5. Time allotment	Too short				Too long
	1	2	3	4	5
6. Emphasis on details	Too brief				Too detailed
	1	2	3	4	5
7. Organization and direction	Disorganized				Well organized
	1	2	3	4	5
8. Treatment of the topic	Abstract				Practical
	1	2	3	4	5

9. Additional comments you may have on these or other aspects of the content of this training module/session

_____

_____

II. Training aids and handouts

1. Effectiveness of teaching aids	Not effective				Very effective
	1	2	3	4	5
2. Readability of	Not readable				Very readable

_____*	1	2	3	4	5
3. Clarity of message of	Not clear				Very clear
_____*	1	2	3	4	5
4. Appeal of	Not appealing				Very appealing
_____*	1	2	3	4	5
5. Usefulness of	Not useful				Useful
_____*	1	2	3	4	5

* Here you would insert the names of instructional aids used: handouts, slides, videos, overhead transparencies, etc.

6. Additional remarks you may have on these or other aspects of the teaching methods, aids, and handouts used in the training session

_____

_____

Instructor effectiveness

1. Mastery of the subject	Not knowledgeable				Knowledgeable
	1	2	3	4	5
2. Ability to transfer/communicate information and knowledge effectively	Very poor				Excellent
	1	2	3	4	5
3. Ability to arouse and sustain interest	Very poor				Excellent
	1	2	3	4	5
4. Openness to ideas of trainees	Not receptive				Receptive
	1	2	3	4	5
5. Encouragement of trainee participation	Did not encourage				Encouraged
	1	2	3	4	5
6. Time management	Very poor				Excellent
	1	2	3	4	5
7. Speed in talking	Too slow				Too fast
	1	2	3	4	5
8. Clarity of speech	Not clear				Clear
	1	2	3	4	5

9. Additional remarks on these or other aspects of the instructor's effectiveness

_____

_____

IV. General

1. Please state the three most important ideas or concepts that you have learned from this session

_____

_____

2. Suggestion(s) to improve the session

_____

_____

V. Training logistics/administration

1. Quality of the meals	Very poor				Very good
	1	2	3	4	5

2. Quality of accommodation	Very poor				Very good
	1	2	3	4	5
3. Quality of transportation	Very poor				Very good
	1	2	3	4	5
4. Contact with staff members	Very poor				Very good
	1	2	3	4	5
5. Quality of training facilities	Very poor				Very good
	1	2	3	4	5

6. Please use the space below to indicate any suggestions you might have that will help us to improve the facilities and administration

_____

_____

Module 9 - Testing trainee trainers - Individual presentations

Objective

To evaluate the training capability of trainees following their training

Suggested methods of instruction

- Clear instructions to trainees of what is expected of them - both orally and in writing
- Personal assistance with preparation of presentations

Aids

- Handouts

Time frame

- Presentations of 30 minutes each

Content

- Individual presentations as a means of testing trainees
- Notification of presentation requirements
- Discussion to aid in preparation of presentations

Learning outcome

Participants should demonstrate knowledge of the subject material and skills developed based on the foregoing training.

INDIVIDUAL PRESENTATIONS AS A MEANS OF TESTING TRAINEES

There are a number of ways of testing trainees: written and oral examinations, seeing how well they have mastered the skill taught, demonstrating the new on-the-job procedure. A proven method of testing trainees who are training to become trainers is to see how they perform in a training situation.

The material that follows is self-explanatory and is offered as a guide only. It is important that the trainee discuss his or her proposed presentation with the trainer to ensure that pitfalls that often confront novice trainers (e.g. inappropriate choice of subject, topic too broad for coverage in the time available, insufficient time in which to prepare suitable aids) are avoided. The trainer should be sure to be available at all times to assist and advise trainees on the preparation of their presentations.

NOTIFICATION OF PRESENTATION REQUIREMENTS

Trainees should first be advised of the presentations at the beginning of the course, and the following notification should be distributed halfway through the course.

Guidelines for individual presentations

During the concluding days of the course each trainee will present a 20-minute training session on a selected topic related to the HACCP system or another nominated area of food control. Topics will be chosen by the trainer (or trainees). As part of the presentation the trainee will:

- Produce a plan for the session
- Produce a handout for distribution to other course members following the presentation
- Prepare visual aids (charts, overhead transparencies, slides, etc.) for use in the presentation

The presentation may be pitched at any level, that is, plant employees, inspection staff, quality control personnel, plant management, interested organizations, etc.

In the presentation trainees will be expected to make use of training skills (including communication techniques, visual aids, questions, etc.) and technical knowledge learned during the course.

Presentations should be developed progressively by trainees during the course, and maximum guidance in their presentation should be available from the trainer.

Each presentation will be followed by a ten-minute evaluation by the group.

DISCUSSION TO AID IN PREPARATION OF PRESENTATIONS

Trainees should be requested to complete a form comprising the following questions for discussion with the trainer before preparing the presentation.

- What is your subject?
- Have you given thought to a plan for your presentation? (brainstorming)
- Have you jotted down thoughts, especially main points you wish to emphasize?
- Do you need assistance with information?
- Have you determined at what level you wish to pitch your presentation?
- How do you propose making the greatest impact?
- What aids do you propose to use?
- Do you propose giving a demonstration?
- Do you propose using handouts?
- Have you in mind to ask questions?
- Have you discussed your subject or its presentation with others? Do you intend to do so?

Module 10 - Organizing and managing a training course

Objective

To provide guidance and advice to participants about the issues to be considered in course planning and management

Suggested methods of instruction

- Lecture/discussion using the course of which this module is a part as a model

Aids

- Handout

Time frame

- One hour lecture/discussion

Content

- Organization and management checklists

Learning outcome

Participants should be aware of the considerations for the planning and management of a successful training course.

ORGANIZATION AND MANAGEMENT CHECKLISTS

The need for the trainer to be informed about course organization and management is self-evident. The details that follow amount to little more than a checklist. However, it is valuable for the trainer to go through each list item by item/stressing the relative importance of each and relating the whole to the course of which the module is a part.

Organization

- Establish whether the course is part or full time
- Establish duration
- Establish content
- Plan syllabus and timetable
- Identify and engage appropriate instructors
- Secure suitable training accommodation (well-lit, well-ventilated room)
- Select and notify trainees, through appropriate channels, of the dates, time and place
- Select and brief session leaders
- Select and review preliminary reading materials
- Prepare course documentation
- Arrange training equipment: lectern, microphone, chalkboard and chalk, writing materials, visual aids (slide projector, video equipment, screen, spare bulbs, etc.), other aids
- Arrange training room: seating arrangements, namecards, position of chalkboard, screen, etc.

Don't forget... to arrange coffee and lunch breaks

Management

- Remind session leaders
- Arrange transport for outside speakers/trainers
- Introduce and thank session leaders
- Meet emergencies (give session yourself or rearrange sessions)
- Check facilities and equipment (projectors, boards, charts, etc.)
- Ensure trainees receive documentation
- Introduce visitors
- Coordinate all aspects of the course
- Evaluate training (based on trainees', session leaders' and own observations)
- Leave room tidy; return equipment and aids to proper place
- Prepare thank-you letters

- Prepare reports on course
- Prepare any statistics
- Each day appoint a "Monitor for the day" from among the trainees to assist with the conduct of the course

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Section 2 - RECOMMENDED INTERNATIONAL CODE OF PRACTICE - GENERAL PRINCIPLES OF FOOD HYGIENE

Introduction

The objective of Section 2 is to review the Codex Alimentarius *Recommended International Code of Practice - General Principles of Food Hygiene* and to provide the trainees with a comprehensive understanding of the requirements contained in its various sections.

The General Principles of Food Hygiene provide the basis for food hygiene and lay a firm foundation for the development of an effective HACCP or equivalent system. The application of the general principles and of good manufacturing practices (GMPs) allows the producer to operate within environmental conditions favourable to the production of safe food.

The *Recommended International Code of Practice - General Principles of Food Hygiene* was originally adopted by the Codex Alimentarius Commission at its sixth session in 1969. Since then it has been revised three times, by the thirteenth session (1979), the sixteenth session (1985) and the twenty-second session (1997). The last revision [CAC/RCP 1-1969, Rev. 3 (1997)] constitutes the basis of this training package and the modules included therein. As the general principles have been developed and adopted through the Codex process, they have the input and agreement of all Codex member countries (158 countries as at 31 August 1997).

The General Principles of Food Hygiene follow the food chain from primary production through to final consumption, highlighting the key controls at each stage. In brief, they give guidance on the design and facilities of premises, in-process control, required support programmes of sanitation and personal hygiene and consideration of hygiene controls once the product has left the production premises. They recommend an HACCP-based approach wherever possible to enhance food safety, as described in the *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* [Annex to CAC/RCP 1-1969, Rev 3 (1997)].

The importance of programmes based on the general principles and GMPs cannot be overstated, as they are the foundation of the HACCP plan. Inadequate programmes may lead to additional critical control points that would have to be identified, monitored and maintained under the HACCP plan.

Section 2 contains the following training modules:

- Module 1: The Codex Alimentarius Commission
- Module 2: The Codex General Principles of Food Hygiene
- Module 3: Primary production
- Module 4: Establishment: design and facilities
- Module 5: Control of operation
- Module 6: Establishment: maintenance and sanitation
- Module 7: Establishment: personal hygiene
- Module 8: Transportation
- Module 9: Product information and consumer awareness
- Module 10: Training

Module 1 provides a general introduction to the Codex Alimentarius Commission and the agreements of the World Trade Organization relating to food safety. The General Principles of Food Hygiene and their specific provisions are then covered in Modules 2 to 10.

Each module contains the harmonized Codex language, which promotes a common understanding of the requirements. Shaded boxes give verbatim text from the most recent (third) revision of the *Recommended International Code of Practice - General Principles of Food Hygiene,* CAC/RCP 1-1969, Rev. 3 (1997). Modules contain, in addition to the Codex text, explanatory notes and additional remarks relevant to the implementation of food safety programmes. Each module follows the format of the Codex text, giving the objective, rationale and guidelines for the application of the general principles.

The controls described in the General Principles of Food Hygiene are internationally recognized as essential to ensuring the safety and suitability of food for consumption. The general principles are recommended to governments, industry (including individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike. All have a responsibility in ensuring safe food for the consumer and reducing the incidence of foodborne illness and food spoilage.

New challenges facing the food industry include new food production, preparation and distribution techniques, changing eating habits and increasing volumes of food being transported around the world. Furthermore, opportunities for international trade are enhanced where food is produced in a strictly hygienic environment, and a country that follows strict hygienic practices gains a reputation as a producer of safe food.

Module 1 - The Codex Alimentarius Commission

Objective

To familiarize the participants with the role and activities of the Codex Alimentarius Commission and the importance of the Codex codes of hygienic practice, standards, guidelines and other recommendations consequent to the Final Act of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) and in particular the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement), which recognize Codex standards, guidelines and other recommendations as the specifically identified baseline for consumer protection

Suggested methods of instruction

- Lecture
- Video presentation

Aids

- Overhead transparencies/slides
- Handout: list of final Codex texts
- Codex Alimentarius video

Reference

- *This is Codex Alimentarius*

Time frame

- One hour

Content

- Introduction to the Codex Alimentarius Commission
- The Uruguay Round agreements

Learning outcome

Participants should be familiar with the role and activities of the Codex Alimentarius Commission and the list of Codex texts and should be aware of their importance in light of the SPS and TBT Agreements.

INTRODUCTION TO THE CODEX ALIMENTARIUS COMMISSION

The Codex Alimentarius Commission (CAC) was established by FAO in 1961. Since 1962 it has been responsible for implementing the Joint FAO/WHO Food Standards Programme, whose primary aims are to protect the health of consumers and to ensure fair practices in the food trade. CAC is an intergovernmental body, with 158 Member Governments as at 31 August 1997. The *Codex Alimentarius* (meaning "Food Code" or "Food Law" in Latin) is a collection of food standards, codes of practice and other recommendations presented in a uniform way. Codex standards, guidelines and other recommendations ensure that food products are not harmful to the consumer and can be traded safely between countries.

Food safety standards are defined in the Agreement on the Application of Sanitary and Phytosanitary Measures (see below) as those relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice. Codex food safety standards are to be used as the reference point for the World Trade Organization in this area (see below).

There are more than 300 Codex standards, guidelines and other recommendations relating to food quality composition and safety. The *Codex Alimentarius* has resulted in evaluations of the safety of over 760 food additives and contaminants and the setting of more than 2 500 maximum limits for pesticide residues and more than 150 for veterinary drug residues. In addition, CAC has established guideline levels for a number of environmental and industrial contaminants (including radionuclides) in foods.

Food hygiene has been a major area of activity of CAC since the commission's establishment. The Codex Committee on Food Hygiene, hosted by the Government of the United States, was founded in 1963. Because food hygiene is best regulated at the production and processing stage in the exporting country, the committee's main outputs have been codes of hygienic practice rather than end-product microbiological standards.

Taking this philosophy a step further, CAC has adopted the *Guidelines for the application of the Hazard Analysis Critical Control Point* (*HACCP*) *system* through its Committee on Food Hygiene. In doing this, it has recognized HACCP as a tool to assess hazards and establish control systems that focus on preventive measures instead of relying primarily on end-product testing.

CAC has been actively revising much of its work in recent years to stress the so-called horizontal aspects of food regulation, including food hygiene. New considerations such as risk analysis and the determination of equivalence in different food control systems have an impact on the new approach to international food hygiene regulations.

THE URUGUAY ROUND AGREEMENTS

The Uruguay Round of Multilateral Trade Negotiations which concluded in 1994 established the World Trade Organization (WTO) to replace the General Agreement on Tariffs and Trade (GATT).

The Uruguay Round negotiations were the first to deal with the liberalization of trade in agricultural products, an area excluded from previous rounds of negotiations. The Uruguay Round also included negotiations on reducing non-tariff barriers to international trade in agricultural products and concluded with two binding agreements: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). The agreements will be applied by members of WTO, and the general terms are also applicable to countries that are not WTO members.

The Agreement on the Application of Sanitary and Phytosanitary Measures

The SPS Agreement confirms the right of WTO member countries to apply measures necessary to protect human, animal and plant life and health. This right was included in the original 1947 GATT as a general exclusion from the other provisions of the agreement provided that "such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade". Despite this general condition for the application of national measures to protect human, animal and plant life and health, it had become apparent that national sanitary and phytosanitary measures had become, whether by design or accident, effective trade barriers.

The SPS Agreement therefore sets new rules in an area previously excluded from GATT disciplines. The purpose of the SPS Agreement is to ensure that measures established by governments to protect human, animal and plant life and health, in the agricultural sector only, are consistent with obligations prohibiting arbitrary or unjustifiable discrimination on trade between countries where the same conditions prevail and are not disguised restrictions on international trade. It requires that, with regard to food safety measures, WTO members base their national measures on international standards, guidelines and other recommendations adopted by the FAO/WHO Codex Alimentarius Commission where they exist. This does not prevent a member country from adopting stricter measures if there is a scientific justification for doing so, or if the level of protection afforded by the Codex standard is inconsistent with the level of protection generally applied and deemed appropriate by the country concerned. The SPS Agreement covers all food hygiene measures and food safety measures such as the control of residues of veterinary drugs, pesticides and other chemicals used in meat production. In addition, it covers animal and plant quarantine measures.

The SPS Agreement states that any measures taken that conform to international Codex standards, guidelines or other recommendations are deemed to be appropriate, necessary and non-discriminatory. Furthermore, the SPS Agreement calls for a programme of harmonization of national requirements based on international standards. This work is guided by the WTO Committee on Sanitary and Phytosanitary Measures, to which representatives of CAC, the International Office of Epizootics (OIE) and the International Plant Protection Convention (IPPC) are invited.

The Agreement on Technical Barriers to Trade

The Agreement on Technical Barriers to Trade (TBT Agreement) is a revision of the agreement of the same name first developed under the Tokyo Round of GATT negotiations in the 1970s. Examples given in the TBT Agreement of legitimate TBT measures are those with the objective of national security or the prevention of deceptive practices.

The objective of the agreement is to prevent the use of national or regional technical requirements, or standards in general, as unjustified technical barriers to trade. The agreement covers standards relating to all types of products including industrial and agricultural products, with the exception of aspects of food standards related to sanitary and phytosanitary measures. It includes numerous measures designed to protect consumers against deception and economic fraud. Examples of food standards covered by the TBT Agreement are those related to quality and labelling.

The TBT Agreement basically provides that all technical standards and regulations must have a legitimate purpose and that the impact or cost of implementing the standard must be proportional to the purpose of the standard. It also says that if there are two or more ways of achieving the same objective, the least trade-restrictive alternative should be followed. The agreement also places emphasis on international standards, WTO members being obliged to use international standards or parts of them

except where the international standard would be ineffective or inappropriate in the national situation. The TBT Agreement does not include a programme of harmonizing national standards.

The work of the Codex Alimentarius Commission in the environment of the Uruguay Round agreements

In this environment. Codex standards, guidelines and other recommendations take on unprecedented importance with respect to consumer protection and international food trade. As a result, the work of the Codex Alimentarius Commission - including the *Guidelines for the application of the Hazard Analysis Critical Control Point* (*HACCP*) *system* - has become the reference for international food safety requirements. In view of this it is imperative that the Codex guidelines for the application of HACCP be unequivocal in their guidance; otherwise conflicts on food safety grounds may arise.

Module 2 - The Codex General Principles of Food Hygiene

Objective

To introduce the participants to the Codex General Principles of Food Hygiene as a firm foundation for ensuring food safety and to their prerequisite relationship to the development of effective HACCP or equivalent systems

Suggested method of instruction

- Lecture

Aids

- Overhead transparencies/slides
- Handout

Reference

- *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev. 3 (1997)], Sections I and II - reproduced below in shaded boxes

Time frame

- One hour

Content

- What are the General Principles of Food Hygiene?
- Objectives
- Scope, use and definitions
- Structure

Learning outcome

The trainees should be familiar with the Codex General Principles of Food Hygiene and their prerequisite relationship to the development of an HACCP-based system for ensuring food safety.

WHAT ARE THE GENERAL PRINCIPLES OF FOOD HYGIENE?

The Codex General Principles of Food Hygiene lay a firm foundation for ensuring food hygiene. They follow the food chain from primary production through to the final consumer, highlighting the key hygiene controls at each stage, and recommend an HACCP-based approach whenever possible to enhance food safety as described in the *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* [Annex to *the Recommended International Code of Practice - General Principles of Food Hygiene,* CAC/RCP 1-1969, Rev. 3 (1997)]. These controls are internationally

recognized as essential to ensure the safety and suitability of food consumption. The general principles are recommended to governments, industry and consumers alike.

The requirements of the General Principles of Food Hygiene are considered to be the foundation for the development of an HACCP-based system for ensuring food safety. The application of the General Principles of Food Hygiene and of good manufacturing practices (GMPs) allows the producer to operate within environmental conditions favourable to the production of safe food.

In implementing an HACCP system in an establishment, the first step is to review existing programmes for compliance with the General Principles of Food Hygiene and GMPs and to verify whether all the necessary controls and documentation (e.g. programme description, individual responsible and monitoring records) are in place.

The importance of these programmes cannot be overstated, as they are the foundation of the implementation of the HACCP plan. Inadequate programmes may lead to additional critical control points that would have to be identified, monitored and maintained under the HACCP plan. In summary, adherence to the General Principles of Food Hygiene and GMPs will simplify the implementation of HACCP plans and will ensure that the integrity of HACCP plans is maintained and that the manufactured product is safe.

In order to harmonize or standardize the approach, the training is formatted around the *Recommended International Code of Practice - General Principles of Food Hygiene.* The application of HACCP principles should be preceded by compliance with the Principles of Food Hygiene and appropriate Codex commodity codes of practice. These controls are internationally recognized as necessary to ensure the safety and suitability of food for consumption.

The term "this document" whenever used in the general principles refers to the *Recommended International Code of Practice-General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev. 3 (1997)], and any allusion to the Annex refers to the annex to that document. The term "contamination" in the General Principles of Food Hygiene refers to the contamination of food by microbial pathogens, chemicals, foreign bodies, spoilage agents, objectionable taints and unwanted or diseased matter, e.g. sawdust or decomposed material. The general principles also use the terms "food safety" and "suitability for consumption". The former is used in the context of ensuring that food does not cause illness or injury to consumers, the latter in the context of distinguishing if food is spoiled or otherwise not suitable for normal human consumption.

OBJECTIVES

SECTION I- OBJECTIVES

The Codex General Principles of Food Hygiene:

- identify the essential principles of food hygiene applicable throughout the food chain (including primary production through to the final consumer), to achieve the goal of ensuring that food is. safe and suitable for human consumption;

- recommend an HACCP-based approach as a means to enhance: food safety;

- indicate how to implement those principles; and

- provide a guidance for specific codes which may be needed for - sectors of the food chain; processes; or commodities; to amplify the hygiene requirements specific to those areas.

SCOPE, USE AND DEFINITIONS

SECTION II - SCOPE, USE AND DEFINITION

2.1 Scope:

2.1.1 The food chain

This document follows the food chain from primary production to the final consumer, setting out the necessary hygiene conditions for producing food which is safe and suitable for consumption. The

document provides a base-line structure for other, more specific, codes applicable to particular sectors. Such specific codes and guidelines should be read in conjunction with this document and *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* (Annex).

2.1.2 Roles of governments, industry and consumers

Governments can consider the contents of this document and decide how best they should encourage the implementation of these general principles to:

- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population;

- provide assurance that food is suitable for human consumption;

- maintain confidence in internationally traded food; and,

- provide health education programmes which effectively communicate the principles of food hygiene to industry and consumers.

Industry should apply the hygienic practices set out in this document to:

-provide food which is safe and suitable for consumption;

-ensure that consumers have clear and easily understood information, by way of labelling and other appropriate means, to enable them to protect their food from contamination and growth/survival of foodborne pathogens by storing, handling and preparing it correctly; and

- maintain confidence in internationally traded food.

Consumers should recognize their role by following relevant instructions and applying appropriate food hygiene measures.

2.2 Use

Each section of this document states both the objectives to be achieved and the rationale behind those objectives in terms of the safety and suitability of food.

(...)

There will inevitably be situations where some of the specific requirements contained in this document are not applicable. The fundamental question in every case is "what Is necessary and appropriate on the grounds of the safety and suitability of food for consumption?"

The next indicates where such questions are likely to arise by using the phrases "where necessary" and "where appropriate". In practice this means that, although the requirement is generally appropriate and reasonable, there will nevertheless be some situations where it is neither necessary nor appropriate on the grounds of food safety and suitability. In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made, preferably within the framework of the HACCP approach. This approach allows the requirements in this document to be flexibly and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the wide diversity of activities and varying degrees of risk involved in producing food. Additional guidance Is available in specific food codes.

2.3 Definitions

For the purpose of this Code, the following expressions have the meaning stated:

Cleaning - the removal of soil, food residue, dirt, grease or other objectionable matter.

Contaminant - any biological or chemical agent, foreign matter, or other substances not intentionally added to food which may compromise food safety or suitability.

Contamination - the introduction or occurrence of a contaminant in food or food environment.

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.

Establishment - any building or area in which food is handled and the surroundings under the control of the same management.

Food hygiene - all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

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

HACCP - A system which identifies, evaluates, and controls hazards which are significant for food safety.

Food handler - any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements.

Food safety - assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food suitability - assurance that food is acceptable for human consumption according to its intended use.

Primary production - those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing.

STRUCTURE

The Codex Alimentarius General Principles of Food Hygiene include an Introduction, an Annex [*Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application*] and ten sections as follows:

- Section I - Objectives of the general principles of food hygiene
- Section II - Scope and use of the document
- Section III - Primary production
- Section IV - Establishment: design and facilities
- Section V - Control of operation
- Section VI - Establishment: maintenance and sanitation
- Section VII - Establishment: personal hygiene
- Section VIII-Transportation
- Section IX - Product information and consumer awareness
- Section X - Training

Sections III to X are addressed individually in the remaining modules (3 to 10) of this section of the manual.

Module 3 - Primary production

Objective

To introduce the trainees to the importance of identifying potential food safety hazards at the primary production stage of the food chain and the necessity of controlling or minimizing hazards at this stage in order to reduce the likelihood of introducing a hazard that may adversely affect the safety of food, or its suitability for consumption, at later stages of the food chain; to review the role of government and the importance of the Codex Alimentarius with respect to the control of pesticide residues, residues of veterinary drugs and contaminants in foods

Suggested method of instruction

- Lecture

Aids

- Overhead transparencies/slides
- Handout

References

- *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev 3 (1997)], Section III - reproduced below in shaded boxes

- *Codex Alimentarius,* Volume 1A, *General requirements.* Section 6, Contaminants in Foods. Rome, FAO/WHO, 1995.2nd ed. (Revised 1995)

- *Codex Alimentarius,* Volume 2, *Pesticide residues in foods.* Rome, FAO/WHO, 1993.2nd ed.

- *Codex Alimentarius,* Volume 2B, *Pesticide residues in foods - Maximum Residue Limits.* Rome, FAO/WHO, 1996. 2nd ed. (Revised 1996)

- *Codex Alimentarius,* Volume 3, *Residues of veterinary drugs in foods.* Rome, FAO/WHO, 1995. 2nd ed. (Revised 1995)

Time frame

- 30 minutes lecture
- 90 minutes exercise

Content

- Objectives and rationale
- Environmental hygiene
- Hygienic production of food sources
- Handling, storage and transport
- Cleaning, maintenance and personnel hygiene
- Role of government

Exercise

Break trainees into three groups and have each group prepare a list of chemical, physical and microbiological hazards that may be associated with the primary production of meat, fruits and vegetables and marine products (fish). Identify control programmes that may reduce or eliminate these hazards. Both the role of the primary producers and the role of governments should be considered. Each group should then report its findings using flipcharts or overhead transparencies.

Learning outcome

Trainees should be able to identify potential hazards associated with the primary production of agricultural products including meat, poultry, eggs, milk, grains, fruits and vegetables and seafood and should be able to identify the role of the primary producers and of governments in controlling these hazards.

OBJECTIVES AND RATIONALE

SECTION III - PRIMARY PRODUCTION

Objectives:

Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include:

- avoiding the use of areas where the environment poses a threat to the safety of food;

- controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety;

- adopting practices and measures to ensure food is produced under appropriately hygienic conditions.

Rationale:

To reduce the likelihood of introducing a hazard which may adversely affect the safety of food, or its suitability for consumption, at later stages of the food chain.

The major challenge in encouraging the management of primary production is the integration of the role of government with the role of the primary producer. There is a need for governments to participate in the control of hazards associated with primary production through the regulation of pesticides and veterinary drugs, the identification and control of environmental hazards and the development of "good practices" documents.

Education and training programmes at the primary production level should be developed to facilitate the management of primary production.

ENVIRONMENTAL HYGIENE

3.1 Environmental hygiene

Potential sources of contamination from the environment should be considered. In particular, primary food production should not be carried on in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food.

HYGIENIC PRODUCTION OF FOOD SOURCES

3.2 Hygienic production of food sources

The potential effects of, primary production activities on the safety and suitability of food should be considered at all times. In particular this includes identifying any specific points in such activities where a high probability of contamination may exist and taking specific measures to minimize that probability. The HACCP-based approach may assist in the taking of such measures - see *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* (Annex);

Producers should as far as practicable implement measures to:

- control contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;

- control plant and animal health so that it does not pose a threat to human health through food,

consumption, or adversely affect the suitability of the product; and

- protect food sources from faecal and other contamination.

In particular, care should be taken to manage wastes, and store harmful substances appropriately. On-farm programmes which achieve specific food safety goals are becoming an important pact of primary production and should be encouraged.

HANDLING, STORAGE AND TRANSPORT

3.3 Handling, storage and transport

Procedures should be in place to:

- sort food and food ingredients to segregate material which is evidently unfit for human consumption;

- dispose of any rejected material in a hygienic manner; and

- protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

Care should be taken to prevent, so far as reasonably practicable, deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

CLEANING, MAINTENANCE AND PERSONNEL HYGIENE

3.4 Cleaning, maintenance and personnel hygiene at primary production

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

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

In considering the appropriate controls for primary production the following Codex references should be considered:

- *Codex Alimentarius,* Volume 1A, *General requirements.* Section 6, Contaminants in Foods. Rome, FAO/WHO/1995. 2nd ed. (Revised 1995)

- *Codex Alimentarius,* Volume 2, *Pesticide residues in foods. Rome,* FAO/WHO, 1993. 2nd ed.

- *Codex Alimentarius,* Volume 2B, *Pesticide residues in foods -Maximum Residue Limits.* Rome, FAO/WHO, 1996. 2nd ed. (Revised 1996)

- *Codex Alimentarius,* Volume 3, *Residues of veterinary drugs in foods.* Rome, FAO/WHO, 1995. 2nd ed. (Revised 1995)

ROLE OF GOVERNMENT

Governments need to provide guidance to primary producers and to establish regulatory control programmes to ensure food safety and wholesomeness at the primary production level. Hazards associated with primary production may or may not be eliminated or reduced to acceptable levels depending on the subsequent processing and handling of the primary food products.

Possible health risk may occur because of primary products excessively contaminated with microorganisms or toxins that could affect the health of consumers. An understanding of how pathogens are introduced during primary production is essential in the development of appropriate interventions and effective control mechanisms. In many cases, however, primary production control measures have not yet been defined that will provide a means to control certain hazards. More

research is needed to establish the ecology of pathogenic microorganisms so that appropriate intervention strategies can be devised for the reduction of pathogens at the beginning of the food chain.

Other programmes, such as good husbandry practices, could be used to reduce the incidence of pathogens, thereby reducing risk at later stages of the food chain. Simple changes such as minimizing the amount of moisture, mud and faeces buildup on animal hide, hair, feathers or skin would be expected to reduce microbial levels. This type of approach would be particularly important prior to shipment for slaughter. A number of other factors, such as reduction of animal stress and reduction of feed and water contamination, when combined with other practices would result in overall pathogen reduction and minimization of risk.

Similar control strategies may be developed for plant food sources. Interventions might include avoidance of fertilization with manures containing viable pathogens and avoidance of sewage-contaminated growing areas.

Another type of health risk can occur if primary products are contaminated as a result of improper use of pesticides or veterinary drugs or because of environmental contamination. The improper use of pesticides or veterinary drugs in primary production can result in unsafe residues of these substances in the food.

In addition to providing the health protection benefits, effective pesticide and veterinary drug use and residue control programmes and environmental control programmes enable a country to participate in international food trade with greater confidence; an effective residue control programme can serve as the foundation for certifying the safety of the country's exported food products, as well as providing assurance of the safety of food products imported into the country.

In establishing effective residue control programmes, a country should first establish a comprehensive system for determining the safety of pesticides and veterinary drugs. This may be accomplished, for example, through an organization or organizations with suitable technical expertise and administrative authority. Approval of pesticides and veterinary drugs may take into consideration several relevant criteria, among which will be the safety evaluation of pesticides or veterinary drugs intended for primary food products. Scientific evaluation of the safety of pesticides or veterinary drugs and the acceptable levels for human consumption is a long and rigorous task which may not need to be performed in each country, especially among developing countries. In such evaluations the interested country could use the technical expertise of international organizations such as the Joint FAO/WHO Expert Committee on Food Additives (for veterinary drugs) or the Codex Committee on Pesticide Residues (for maximum residue limits for pesticides in foods and animal feeds).

The elements in establishing an effective national programme for the control of pesticide or veterinary drug residues in food should include but not necessarily be limited to the following:

- Establishing the regulatory authority/authorities for implementing inspection programmes and laboratory analysis

- Establishing an integrated inspection programme, including a residue control programme for the inspection of foods (The organization responsible for implementing the inspection programme should be granted the authority to take all the steps necessary to control products when residues exceed the maximum residue limits established for a food commodity or when non-permitted residues are found)

- Compiling registers of veterinary drugs and pesticides used in the country, including products manufactured in the country and products imported into the country

- Elaborating regulations concerning the distribution of veterinary drugs and pesticides, providing procedures for authorized sale, manufacture, import, distribution and use of such products

- Elaborating procedures for determining the safety and efficacy of veterinary drugs and pesticide residues (This should include description of procedures for determining maximum residue limits for pesticides and veterinary drugs in food)

• Establishing procedures for monitoring through sampling of food products for pesticide residues and veterinary drugs

• Selecting the methods of analysis to be used for pesticide and veterinary drug residues

• Implementing a laboratory quality assurance programme to ensure the highest quality of analytical results

• Developing educational programmes for primary producers and veterinarians, instructing on the proper use of pesticides and veterinary drugs and encouraging the use of preventive measures to reduce the occurrence of residues in food

HACCP plans may not need to be developed on an individual basis for primary producers but may be developed by experts and recommended to primary producers as "good practice recommendations". Education and training programmes should be relied upon to introduce practices that, in effect, may represent a change in the manner in which farms and other primary food production operations are managed.

Module 4 - Establishment: design and facilities

Objective

To introduce the participants to Section IV of the Codex General Principles of Food Hygiene and to examine the importance and requirements of good hygienic design and construction, including appropriate siting, design and construction of premises, equipment and facilities to control risks of contamination

Suggested method of instruction

• Lecture

Aids

• Overhead transparencies/slides
• Handout
• Slides or videos that the instructor may have available

Reference

• *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev. 3 (1997)], Section IV - reproduced below in shaded boxes

Time frame

• One hour

Content

• Objectives and rationale
• Location
• Premises and rooms
• Equipment
• Facilities

Learning outcome

Participants should understand the importance and relationship of the establishment design and facilities to food hygiene and the control of hazards.

OBJECTIVES AND RATIONALE

SECTION IV-ESTABLISHMENT: DESIGN AND FACILITIES

Objectives:

Depending on the nature of the operations, and the risks associated with them, premises, equipment and facilities should be located, designed and constructed to ensure that:

- contamination is minimized;

- design and layout permit appropriate maintenance, cleaning and disinfections and minimize airborne contamination;

- surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable, and easy to maintain and clean;

- where appropriate, suitable facilities are available for temperature, humidity and other controls; and

- there is effective protection against pest access and harbourage.

Rationale:

Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities, is necessary to enable hazards to be effectively controlled.

LOCATION

4.1 Location:

4.1.1 Establishments

Potential sources of contamination need to be considered when deciding where to locate food establishments, as well as the effectiveness of any reasonable measures that might be taken to protect food. Establishments should not be located anywhere where, after considering such protective measures, it is clear that there will remain a threat to food safety or suitability. In particular, establishments should normally be located away from:

- environmentally polluted areas and industrial activities which pose a serious threat of contaminating food;

- areas subject to flooding unless sufficient safeguards are provided;

- areas prone to infestations of pests;

- areas where wastes, either solid or liquid, cannot be removed effectively.

4.1.2 Equipment

Equipment should be sited so that it:

- permits adequate maintenance and cleaning;
- functions in accordance with its intended use; and
- facilitates good hygiene practices, including monitoring.

PREMISES AND ROOMS

4.2 Premises and rooms

4.2.1 Design and layout

Where appropriate, the internal design and layout of food establishments should permit good food hygiene practices, including protection against cross-contamination between and during operations by foodstuffs.

The following should be considered in providing protection against cross-contamination:

- Activities should be adequately separated by physical or other effective means where cross-contamination may result.

- Buildings and facilities should be designed to facilitate hygienic operations by means of a regulated flow in the process from the arrival of the raw material at the premises to the finished product. Where appropriate, blueprints and/or process flow diagrams should be available.

4.2.2 Internal structures and fittings

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

- the surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use;

- walls and partitions should have a smooth surface up to a height appropriate to the operation;

- floors should be constructed to at low adequate drainage and cleaning;

- ceilings and overhead fixtures should be constructed and finished to minimize the build up of dirt and condensation, and the shedding of particles;

- windows should be easy to clean, be constructed to minimize the build up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed;

- doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect;

- working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions.

Additional points to consider

- The building exterior should be designed, constructed and maintained to prevent entry of contaminants and pests. For example, there should be no unprotected openings, air intakes should be appropriately located, and the roof, walls and foundation should be maintained to prevent leakage.

- Drainage and sewage systems should be equipped with appropriate traps and vents.

- Establishments should be designed and constructed so that there is no cross-connection between the sewage system and any other waste effluent system in the establishment.

• Effluent or sewage lines should not pass directly over or through production areas unless they are controlled to prevent contamination.

• Coatings, paints, chemicals, lubricants and other materials used for surfaces or equipment that may have contact with food should be such that they will not contribute to unacceptable contamination of the food.

4.2.3 Temporary/mobile premises and vending machines

Premises and structures covered here include market stalls, mobile sales and street vending vehicles, temporary premises in which food is handled such as tents and marquees.

Such premises and structures should be sited, designed and constructed to avoid, as far as reasonably practicable, contaminating food and harbouring pests.

In applying these specific conditions and requirements, any food hygiene hazards associated with such facilities should be adequately controlled to ensure the safety and suitability of food.

EQUIPMENT

4.3 Equipment

4.3.1 General

Equipment and containers (other than once-only use containers and packaging) coming into contact with food, should be designed and constructed to ensure that, where necessary, they can be || adequately cleaned, disinfected and maintained to avoid the contamination of food. Equipment and containers should be made of materials with no toxic effect in intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection, monitoring and, for example, to facilitate inspection for pests.

The manufacturer should have an effective written preventive maintenance programme to ensure that equipment that may affect food is maintained in proper working order. This should include:

• A list of equipment requiring regular maintenance
• The procedures and frequencies of maintenance (e.g. equipment inspection, adjustments and part replacements) are based on the equipment manufacturer's manual or equivalent or on operating conditions that could affect the condition of the equipment

The preventive maintenance programme should be adhered to. Equipment should be maintained to ensure the absence of any physical or chemical hazard potentials, e.g. inappropriate repairs, flaking paint and rust, excessive lubrication.

4.3.2 Food control and monitoring equipment

In addition to the general requirements in paragraph 4.3.1, equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. Such equipment should also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment should have effective means of controlling and monitoring humidify, air-flow and any other characteristic likely to have a detrimental effect on the safety or suitability of food. These requirements are intended to ensure that:

- harmful or undesirable microorganisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled;

- where appropriate, critical limits established in HACCP-based plans can be monitored; and

- temperatures and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.

Additional points to consider

• Written protocols, including calibration methods and frequencies, should be established by the manufacturer for equipment monitoring and/or controlling devices that may have an impact on food safety.

• Maintenance and calibration of equipment should be performed by appropriately trained personnel.

4.3.3 Containers for waste and inedible substances

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

FACILITIES

4.4 Facilities

4.4.1 Water supply

Art adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food.

Potable water should be as specified in the latest edition of WHO guidelines for drinking water quality, or water of a higher standard. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food) shall halve a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.

Additional points to consider

• There should be no cross-connections between potable and non-potable water supplies. All hoses, taps and other similar possible sources of contamination should be designed to prevent back-flow or back-siphonage.

• Where it is necessary to store water, storage facilities should be adequately designed, constructed and maintained (e.g. covered) to prevent contamination.

• The volume, temperature and pressure of the potable water should be adequate for all operational and clean-up demands.

• Water treatment chemicals, where used, should not cause chemical contamination of the water.

• Chemical treatment should be monitored and controlled to deliver the desired concentration and to prevent contamination.

• Recirculated water should be treated, monitored and maintained as appropriate to the intended purpose. Recirculated water should have a separate distribution system which is clearly identified.

• Ice used as an ingredient or in direct contact with food should be made from potable water and protected from contamination.

4.4.2 Drainage and waste disposal

Adequate drainage and waste disposal systems and facilities should be provided. They should be designed and constructed so that the risk of contaminating food or the potable water supply is avoided.

4.4.3 Cleaning

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

Additional points to consider

• Facilities should be constructed of corrosion-resistant materials that can be easily cleaned and should be provided with potable water at temperatures appropriate for the cleaning chemicals used.

• Equipment cleaning and sanitizing facilities should be adequately separated from food storage, processing and packaging areas to prevent contamination.

4.4.4 Personnel hygiene facilities and toilets

Personnel hygiene facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Where appropriate, facilities should include:

- adequate means of hygienically washing and drying hands, including wash basins and a supply:! of hot and cold (or suitably temperature controlled) water;

- lavatories of appropriate hygienic design; and

- adequate changing facilities for personnel.

Such facilities should be suitably located and designated.

4.4.5 Temperature control

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

4.4.6 Air quality and ventilation

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

- minimize air-borne contamination of food, for example, from aerosols and condensation droplets;

- control ambient temperatures; and

- control odours which might affect the suitability of food; and

- control humidity, where necessary, to ensure the safety and suitability of food.

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

4.4.7 Lighting

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

Additional points to consider

Lighting should be appropriate such that the intended production or inspection activity can be effectively conducted. The lighting should not alter food colour and should not be less than the following:

- 540 lux (50 foot-candles) in inspection areas
- 220 lux (20 foot-candles) in work areas
- 110 lux (10 foot-candles) in other areas

Inspection areas are defined as any point where the food product or container is visually inspected or instruments are monitored, e.g. the place where empty containers are evaluated or where products are sorted and inspected.

4.4.8 Storage

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

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

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

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

Additional points to consider

- Ingredients requiring refrigeration should be stored at 4°C or less and should be appropriately monitored. Frozen ingredients should be stored at temperatures that do not permit thawing.

- Ingredients and packaging materials should be handled and stored in such a manner as to prevent damage and/or contamination.

- Rotation of ingredients and where appropriate packaging materials should be controlled to prevent deterioration and spoilage.

- Humidity-sensitive ingredients and packaging materials should be stored under appropriate conditions to prevent deterioration.

- Non-food chemicals should be received and stored in a dry/well-ventilated area.

- Non-food chemicals should be stored in designated areas such that there is no possibility for cross-contamination of food or food contact surfaces.

- Where required for ongoing use in food handling areas, these chemicals should be stored in a manner that prevents contamination of food/food contact surfaces or packaging materials.

- Chemicals should be stored and mixed in clean, correctly labelled containers.

- Chemicals should be dispensed and handled only by authorized and properly trained personnel.

- Finished product should be stored and handled under conditions that prevent deterioration.

- Stock rotation should be controlled to prevent deterioration that could present a health hazard.

- Returned defective or suspect product should be clearly identified and isolated in a designated area for appropriate disposition.

- Finished product should be stored and handled in a manner to prevent damage. For example, stacking heights should be controlled and forklift damage avoided.

Module 5 - Control of operation

Objective

To introduce the trainees to Chapter 5 of the Codex General Principles of Food Hygiene and to examine the considerations regarding the key aspects of control systems, incoming material requirements, packaging, water, management, documentation and records and recall systems (excluding the HACCP system, as this is covered in Section 3 of the training manual)

Suggested methods of instruction

- Lecture
- Exercise: food additive calculations
- Homework exercises

Aids

- Overhead transparencies/slides
- Handout

Reference

- *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev. 3 (1997)], Section V - reproduced below in shaded boxes

Time frame

- Two hours lecture
- One hour exercises

Content

- Objectives and rationale
- Control of food hazards
- Examples of general control procedures
- Key aspects of hygiene control systems
- Incoming material requirements
- Packaging
- Water
- Management and supervision
- Documentation and records
- General record requirements
- Recall procedures

Exercise: food additive calculation

1. A food manufacturer wants to prepare 1 000 litres of fruit drink containing 100 parts per million (ppm) sodium benzoate.

How much sodium benzoate should be used?

Answer:

100 ppm = 100/1 000 000
100/1 000 000 x 1 000 litres = **0.1 kg** or **100 g**

2. A food manufacturer has added 500 g of a salt containing 5% sodium nitrite to 30 kg of a ground meat product.

What is the resultant concentration of the sodium nitrite in the meat?

Answer:

5% sodium nitrite = 5/100 x 1 000 000 ppm = 50 000 ppm
Ground meat + salt = 30 kg + 500 g (0.5 kg) = 30.5 kg
Therefore 0.5 kg/30.5 kg x 50 000 ppm = **819.6 ppm**

3. A food additive preparation contains 7% sodium metabisulfite.

If a food manufacturer wants to prepare 500 litres of wine containing 100 ppm sodium metabisulfite, how much of the food additive preparation should be used?

Answer:

7% sodium metabisulfite = 7/100 x 1 000 000 ppm = 70 000 ppm
Therefore 100 ppm/70 000 ppm x 500 litres = **0.71 litres** or **710 ml**

4. An inspector finds that a food manufacturer has added 1 kg of an additive preparation containing 10% saccharin to 150 kg of a dry beverage base product. What is the level of saccharin in the product?

Answer:

10% = 100 000 ppm
Therefore 1 kg/151 kg x 100 000 ppm = **662 ppm**

Learning outcome

Participants should understand the factors affecting the control of microorganisms and other hazards, the importance of incoming material requirements, packaging, water, management and supervision, documentation and records and recall procedures in the control of operations.

OBJECTIVES AND RATIONALE

SECTION V - CONTROL OF OPERATION

Objectives:

To produce food which is safe and suitable for human consumption by:

- formulating design requirements with respect to raw materials, composition, processing, distribution, and consumer use to be met in the manufacture and handling of specific food items; and

- designing, implementing, monitoring and reviewing effective control systems.

Rationale:

To reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards.

CONTROL OF FOOD HAZARDS

5.1 Control of food hazards

Food business operators should control food hazards through the use of systems such as HACCP. They should:

- identify any steps in their operations which are critical to the safety of food;

- implement effective control procedures at those steps;

- monitor control procedures to ensure their continuing effectiveness; and

- review control procedures periodically, and whenever the operations change.

These systems should be applied throughout the food chain to control food hygiene throughout the shelf-life of the product through proper product and process design.

Control procedures may be simple, such as checking stock rotation, calibrating equipment, or correctly loading refrigerated display units. In some cases a system based on expert advice, and involving documentation, may be appropriate. A model of such a food safety system is described in *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* (Annex).

EXAMPLES OF GENERAL CONTROL PROCEDURES

Product formulae

Current written formulae provide a basis for assessment of food additives, nutritional requirements, food allergens and the scheduled process. The processor should consider the following:

- Written master formulae should be available.

- The formulae should contain all details of the formulation, including identification of specific ingredients and additives (e.g. concentration, type) and amounts of additives and ingredients.

- The master formulae should be current for the products being processed.

Food additives

Inadequate control of food additives could result in chemical or biological hazards.

- The manufacturer should ensure that all food additives used are permitted for use in the particular food and meet all requirements of the food law.

- The manufacturer should have specifications for all food additives.

- The manufacturer should require that all food additives have the identity and purity required to meet food grade quality.

- The manufacturer should obtain certification/verification from the supplier that each lot of food additives meets the requirements of the food law, e.g. specification sheets and clear identification of the grade on the additive package.

- The manufacturer should verify and demonstrate through calculations that food additives are used within the maximum level specified in the food law.

The manufacturer should have controls in place during preparation or blending to ensure that food additives are permitted and are used within allowable levels. These include:

- Clear identification of additives
- Accurate measurement
- Adequate blending for homogeneity

Nutritional requirements

The manufacturer should have control over the product formulation to ensure that all nutritional requirements and claims are met. Formulation controls are necessary to prevent hazards that could result from excesses, inadequacies and omissions of nutrients, for example in the case of special dietary foods, infant formulae, meal replacements, fortified foods and foods for which nutritional claims have been made (e.g. reduced-calorie and low-sodium foods).

- Nutrients used should be permitted in accordance with the food law.

- The nutrient content of the product should be accurately reflected on the label.

- The manufacturer should have specifications for nutrients.

- The manufacturer should receive from the supplier a certificate of analysis accompanying each lot of nutrient; for nutrients used in foods that are the sole source of nutrition, each certificate should be verified through analysis.

- The manufacturer should verify and demonstrate through calculations that nutrients are used within the limits specified in the food law.

The manufacturer should have controls in place for nutrient addition during preparation or blending to ensure that the levels comply with regulatory and label requirements. These controls should include:

- Clear identification of nutrient
- Proper storage and handling to maintain nutrient stability
- Accurate measurement
- Adequate blending for homogeneity

Label accuracy

The manufacturer should have procedures in place to ensure that label information accurately represents the composition and formulation of the product. Controls are necessary to prevent the presence of undeclared ingredients or misinformation concerning product composition. The manufacturer should ensure that the label information provides the public with accurate information related to net contents; manufacturer's, packer's and/or distributor's names; and instructions for proper handling and preparation at home.

The following controls should be included:

- New label review
- Incoming label review for accuracy/correctness
- Formulation changes/substitutions

Allergens

The manufacturer should have controls in place to prevent the presence of undeclared allergens in the product. Allergens are those ingredients that will elicit an allergic response in sensitive individuals. Areas that may require control include:

- Misdirection of ingredients
- Rework
- Contamination by undeclared ingredients
- Ingredient carryover
- Ingredient substitutions
- Carryover from equipment, e.g. from product changeovers

Product preparation/blending

Critical factors specified in the formulation should be controlled during preparation and blending to prevent physical, chemical, nutritional and biological hazards. Inadequate control of critical factors associated with product preparation or blending could result in underprocessing, formation of toxins, presence of undeclared allergens, violative levels of food additives or nutritional hazards.

In thermal processing, the manufacturer should have controls for critical factors identified in the validated process. Examples of critical factors are:

- Size, e.g. dicing, grinding, slicing
- Temperature treatment, e.g. heating, blanching, defrosting, cooling (textural changes)
- Moisture, e.g. rehydration, concentration (viscosity, brix)
- Proportioning, e.g. weight, volume (weighing, volumetric control, metering)
- pH/acidity (pH measurement, titratable acidity)

For microbial control, the manufacturer should control time and temperature during preparation, blending, and holding of in-process materials to prevent conditions that could result in excessive microbial growth or in the production of enterotoxin by *Staphylococcus aureus.*

KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2 Key aspects of hygiene control systems

5.2.1 Time and temperature control

Inadequate food temperature control is one of the most common causes of foodborne illness or food spoilage. Such controls include time and temperature of cooking, cooling, processing and storage. Systems should be in place to ensure that temperature is controlled effectively where it is critical to the safety and suitability of food.

Temperature control systems should take into account:

- the nature of the food, e.g. its water activity, pH, and likely initial level arid types of microorganisms;

- the intended shelf-life of the product;

- the method of packaging and processing; and!-how the product is intended to be used, e.g. further cooking/processing or ready-to-eat.

Such systems should also specify tolerable limits for time and temperature variations.

Temperature recording devices should be checked at regular intervals and tested for accuracy.

5.2.2 Specific process steps

Other steps which contribute to food hygiene may include, for example:

- chilling
- thermal processing
- irradiation

- drying
- chemical preservation
- vacuum or modified atmospheric packaging

5.2.3 Microbiological and other specifications

Management systems described in paragraph 5.1 offer an effective way of ensuring the safety and suitability of food. Where microbiological, chemical or physical specifications are used in any food control system, such specifications should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and action limits.

5.2.4 Microbiological cross-contamination

Pathogens can be transferred from one food to another, either by direct contact or by food handlers, contact surfaces or the air. Raw, unprocessed food should be effectively separated, either physically or by time, from ready-to-eat foods, with effective intermediate cleaning and, where appropriate, disinfection,

Access to processing areas may need to be restricted or controlled. Where risks are particularly high, access to processing areas should be only via a changing facility. Personnel may need to be required to put on clean protective clothing including footwear and wash their hands before entering.

Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food, particularly meat and poultry, has been handled or processed.

5.2.5 Physical and chemical contamination

Systems should be in place to prevent contamination of foods by foreign bodies such as glass or metal shards from machinery, dust, harmful fumes and unwanted chemicals. In manufacturing and processing, suitable detection or screening devices should be used where necessary.

INCOMING MATERIAL REQUIREMENTS

5.3 Incoming material requirements

No raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing. Where appropriate, specifications for raw materials should be identified and applied.

Raw materials or ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests should be made to establish fitness for use. Only sound, suitable raw materials or ingredients should be used.

Stocks of raw materials and ingredients should be subject to effective stock rotation.

Prevention of health hazards begins with control of incoming materials. Inadequate incoming ingredient controls could result in product contamination and/or underprocessing. The degree of control exercised over incoming ingredients is appropriate to the risk.

The manufacturer should control incoming ingredients through one of the following programmes or equivalent. The first three options apply to ingredients that may be critical factors where further processing is not likely to eliminate a hazard. The fourth option applies to ingredients that are not likely to have an impact on the safety of the food.

Periodic evaluation of incoming ingredients

- The manufacturer should have written specifications for ingredients.

- Purchasing specifications should include a provision for compliance with the food law.

- The manufacturer should maintain a documented history of adherence to specifications for each supplier, e.g. analytical results.

- The manufacturer should obtain a certificate of analysis for each lot (code).

- A statistically representative sample should be taken to verify the accuracy of the certificates of analysis at a scheduled frequency.

- A new history of adherence to specifications should be established when a firm changes suppliers, purchases ingredients from a new supplier or purchases a new ingredient from an existing supplier or when spot checks do not agree with the certificate of analysis.

One hundred percent lots inspected

- The manufacturer should have written specifications for ingredients.
- The manufacturer should obtain a certificate of analysis for each lot (code).
- Each incoming lot should be sampled according to a predetermined sampling plan and analysed for adherence to specifications.

Vendor certification

When the manufacturer relies on vendor certification the following minimum requirements should be in place:

- The manufacturer should have written specifications for ingredients.

- The manufacturer should have documentation to demonstrate adequate knowledge of the vendor's process, e.g. process flow charts, on-site evaluations, identification of critical control points, specifications, control limits, monitoring programmes and frequencies, corrective action and verification procedures.

- The manufacturer should have data to demonstrate the capability of the vendor's process to manufacture consistently within specifications.

- Prior to implementation of a periodic monitoring programme the firm should analyse an appropriate number of consecutive lots to establish a historical database and confirm adherence to specifications.

- The manufacturer should conduct periodic monitoring to verify adherence to specifications.

- The manufacturer should conduct vendor audits to validate the status of the vendor certification programme.

Specification requirements

Where incoming ingredients are not likely to impact on the safety of the food:

- The manufacturer should have written specifications for these ingredients.
- Purchasing specifications should include a provision for compliance with the food law.
- The supplier should provide assurance that the ingredients meet specifications.

When ingredients are found not to meet specifications, the manufacturer investigates and identifies the root cause. If the ingredients do not meet specifications but have not been used, the case

is not considered a deviation; however, if it is possible that ingredients that do not meet specifications have been used, the manufacturer should initiate deviation/correction control procedures.

PACKAGING

> **5.4 Packaging**
>
> Packaging design and materials should provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling. Packaging materials or gases where used must be non-toxic and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Where appropriate, reusable packaging should be suitably durable, easy to clean and, where necessary; disinfect.

Where appropriate, the manufacturer should control incoming packaging materials from the supplier using an approach similar to the options suggested for incoming ingredients.

WATER

> **5.5 Water**
>
> **5.5.1 In contact with food**
>
> Only potable water should be used In food handling and processing, with the following exceptions:
>
> - for steam production, fire control and other similar purposes not connected with food; and
>
> - in certain food processes, e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean seawater).
>
> Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored. Recirculated water which has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

Additional points to consider

- Water should meet the requirements of the regulations. Water should be analysed by the manufacturer or municipality at a frequency adequate to confirm its potability. Water from sources other than municipal supplies must be treated as necessary and tested to ensure potability.

- There should be no cross-connections between potable and non-potable water supplies. All hoses, taps and other similar possible sources of contamination should be designed to prevent back-flow or back-siphonage.

- Where it is necessary to store water, storage facilities should be adequately designed, constructed and maintained (e.g. covered) to prevent contamination.

- The volume, temperature and pressure of the potable water should be adequate for all operational and clean-up demands.

- Water treatment chemicals, where used, should not result in unacceptable chemical residues in the water.

- Chemical treatment should be monitored and controlled to deliver the desired concentration and to prevent contamination.

- Recirculated water should be treated, monitored and maintained as appropriate to the intended purpose. Recirculated water should have a separate distribution system which is clearly identified.

5.5.2 As an ingredient

Potable water should be used wherever necessary to avoid food contamination.

5.5.3 Ice and steam

Ice should be made from water that complies with section 4.4.1. Ice and steam should be produced, handled and stored to protect them from contamination.

Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food.

Additional points to consider

- Ice used as an ingredient or in direct contact with food should be made from potable water and protected from contamination.

- Boiler treatment chemicals used should be acceptable to the regulator and should not result in unacceptable residues.

- Boiler feed water should be tested regularly, and its chemical treatment should be controlled to prevent contamination.

- The steam supply should be generated from potable water and should be adequate to meet operational requirements.

- Traps should be provided as necessary to ensure adequate condensate removal and elimination of foreign materials.

MANAGEMENT AND SUPERVISION

5.6 Management and supervision

The type of control and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers and supervisors should have enough knowledge of food hygiene principles and practices to be able to judge potential risks, take appropriate preventive and corrective action, and ensure that effective monitoring and supervision takes place.

DOCUMENTATION AND RECORDS

5.7 Documentation and records

Where necessary, appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product. Documentation can enhance the credibility and effectiveness of the food safety control system.

GENERAL RECORD REQUIREMENTS

The following are requirements for all record-keeping activities:

- Records should be legible and permanent and should accurately reflect the actual event, condition or activity.

- Errors or changes should be identified in a manner such that the original record is clear, e.g. struck out with a single stroke and initialed near the correction or change.

- Each entry on a record should be made by the responsible person at the time the event occurs. The completed records should be signed and dated by the responsible person.

• Critical records, e.g. records related to the adequacy of the thermal process and the achievement of a hermetic seal, should be signed and dated by a qualified individual designated by management prior to distribution of the product. All other records should be reviewed at an appropriate frequency to provide an early indication of potentially serious deficiencies.

• Records should be retained for one year after the expiry date on the label or container or, if there is no expiry date, for two years after the date of sale.

• Records should be maintained at the manufacturing plant and should be available upon request.

RECALL PROCEDURES

5.8 Recall procedures

Managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market. Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions, and which may present a similar hazard to public; health, should be evaluated for safety and may need to be withdrawn. The need for public warnings should be considered.

Recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

There should be a written procedure for recall, which should include:

• The person or persons responsible, e.g. recall coordinator(s)

• The roles and responsibilities for coordination and implementation of a recall

• Methods to identify, locate and control recalled product

• A requirement to investigate other products that may be affected by the hazard and that should be included in the recall

• A procedure for monitoring the effectiveness of the recall to the appropriate level of distribution specified in the recall notice

Recall information should include the following:

• Amount of product produced, in inventory and distributed

• Name, size, code or lot numbers of food recalled

• Area of distribution of product, e.g. local, national, international

• Reason for the recall

Product code identification

• Each pre-packaged food should have permanent, legible code marks or lot numbers and where required expiry or "best before" dates on the packages.

• Code marks used and the exact meaning of the codes should be available.

Recall capability

The manufacturer should be capable of producing accurate information on a timely basis to verify that all affected product can be rapidly identified and removed from the marketplace. This can be demonstrated by the manufacturer as follows:

- Records of customer names, addresses and telephone numbers available for the lot tested
- Records of production, inventory and distribution by lot available for the lot tested
- Periodic testing to verify the capability of the procedure for rapid identification and control of a code lot of potentially affected product and for reconciling the amount of product produced, in inventory and in distribution; identification and correction of any deficiencies in the recall procedure

Distribution records

Distribution records should contain sufficient information to permit traceability to a particular code or lot number. The following minimum information should be required for distribution records:

- Product identification and size
- Lot number or code
- Quantity
- Customers' names, addresses and telephone numbers to the initial level of product distribution

Module 6 - Establishment: maintenance and sanitation

Objective

To introduce the participants to Chapter 6 of the Codex General Principles of Food Hygiene and to examine the importance and requirements of maintenance and sanitation

Suggested methods of instruction

- Lecture
- Exercise: calculation of sanitizer concentration
- Homework: cleaning and sanitizing

Aids

- Overhead transparencies/slides
- Handout

References

- *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev. 3 (1997)], Section VI - reproduced below in shaded boxes

Time frame

- Two hours lecture

Content

- Objectives and rationale
- Maintenance and cleaning
- Cleaning programmes
- Pest control systems

- Waste management
- Monitoring effectiveness

Learning outcome

Participants should understand the importance and relationship of sanitation and maintenance to food safety and hygiene.

OBJECTIVES AND RATIONALE

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

Objectives:

To establish effective systems to:

- ensure adequate and appropriate maintenance and cleaning;
- control pests;
- manage waste; and
- monitor effectiveness of maintenance and sanitation procedures.

Rationale:

To facilitate the continuing effective control of food hazards, pests, and other agents likely to contaminate food.

MAINTENANCE AND CLEANING

6.1 Maintenance and cleaning

6.1.1 General

Establishments and equipment should be kept in an appropriate state of repair and condition to:

- facilitate all sanitation procedures;
- function as intended, particularly at critical steps (see paragraph 5.1);
- prevent contamination of food, e.g. from metal shards, flaking plaster, debris and chemicals.

Cleaning should remove food residues and dirt which may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the food business. Disinfection may be necessary after cleaning.

Cleaning chemicals should be handled and used carefully and in accordance with manufacturers' instructions and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.

6.1.2 Cleaning procedures and methods

Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water, and chemical methods using detergents, alkalis or acids.

Cleaning procedures will involve, where appropriate:

- removing gross debris from surfaces;

- applying a detergent solution to loosen soil and bacterial film and hold them in solution or suspension;

- rinsing with water which: complies with section 4, to remove loosened soil and residues of

detergent;

- dry cleaning or other appropriate methods for removing and collecting residues and debris; and

- where necessary, disinfection.

Additional points to consider

• Cleaning and sanitizing equipment should be designed for its intended use and properly maintained.

• The sanitation programme should be carried out in such a manner that food or packaging materials are not contaminated (e.g. by aerosols or chemical residues) during or subsequent to cleaning and sanitizing.

• Operations should only begin after sanitation requirements have been met.

CLEANING PROGRAMMES

6.2 Cleaning programmes

Cleaning and disinfection programmes should ensure that all parts of the establishment are appropriately clean, and should include the cleaning of cleaning equipment.

Cleaning and disinfection programmes should be continually and effectively monitored for their suitability and effectiveness and where necessary, documented.

Where written cleaning programmes are used, they should specify:

- areas, items of equipment and utensils to be cleaned;
- responsibility for particular tasks;
- method and frequency of cleaning; and
- monitoring arrangements.

Where appropriate, programmes should be drawn up in consultation with relevant specialist expert advisors.

Additional points to consider: cleaning of equipment

The manufacturer should have a written cleaning and sanitation programme for all equipment which includes:

• The name of responsible person
• The frequency of the activity
• Chemicals and concentration used
• Temperature requirements
• Procedures for cleaning and sanitizing

The procedures for cleaning and sanitizing are different depending on whether the equipment is cleaned out of place (COP), e.g. hand-cleaned, or cleaned in place (CIP).

For COP equipment, the procedures should be specified as follows:

• Identification of equipment and utensils
• Disassembly/reassembly instructions as required for cleaning and inspection
• Identification of areas on equipment requiring special attention
• Method of cleaning, sanitizing and rinsing

For CIP equipment, the procedures should be specified as follows:

- Identification of lines and/or equipment
- CIP set-up instructions
- Method of cleaning, sanitizing and rinsing
- Disassembly/reassembly instructions as required for cleaning and inspection

Additional points to consider: cleaning of premises

The manufacturer should have a written cleaning and disinfection programme for premises (preparation, processing and storage areas) which specifies areas to be cleaned, method of cleaning, person responsible and frequency of the activity. Special sanitation and housekeeping procedures required during processing should be specified within the document, e.g. removal of product residues during breaks.

PEST CONTROL SYSTEMS

6.3 Pest control systems

6.3.1 General

Pests pose a major threat to the safety and suitability of food; Pest infestations can occur where there are breeding sites and a supply of food. Good hygiene practices should be employed to avoid creating an environment conducive to pests. Good sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

6.3.2 Preventing access

Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

6.3.3 Harbourage and infestation

The availability of food and water encourages pest harbourage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises should be kept clean. Where appropriate, refuse should be stored in covered, pest-proof containers.

6.3.4 Monitoring and detection

Establishments and surrounding areas should be regularly examined for evidence of infestation.

6.3.5 Eradication

Pest infestations should be dealt with immediately and without adversely affecting food safety or suitability. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food.

Additional points to consider

There should be an effective written pest control programme for the premises and equipment that includes:

- The name of the person and the operator assigned responsibility for pest control

- Where applicable, the name of the pest control company or the name of the person contracted for the pest control programme

• The list of chemicals used, the concentration, the location where applied, method and frequency of application

• A map of trap locations

• The type and frequency of inspection to verify the effectiveness of the programme

In addition, the following should be considered:

• Pesticides used should be acceptable to the food control regulatory authorities and should be used in accordance with the label instructions.

• Treatment of equipment, premises or ingredients for pest control should be conducted in such a manner as to ensure that the permitted maximum residue limit is not exceeded, e.g. by limiting the number of fumigation treatments per lot.

• Birds and animals, other than those intended for slaughter, should be excluded from establishments.

WASTE MANAGEMENT

6.4 Waste management

Suitable provision must be made for the removal and storage of waste. Waste must not be allowed to accumulate in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business.

Waste stores must be kept appropriately clean.

Additional points to consider

• Adequate facilities and equipment should be provided and maintained for the storage of waste and inedible material prior to removal from the establishment. These facilities should be designed to prevent contamination.

• Containers used for waste should be clearly identified, leakproof and, where appropriate, kept covered.

• Waste should be removed and containers cleaned and sanitized at an appropriate frequency to minimize contamination potential.

MONITORING EFFECTIVENESS

6.5 Monitoring effectiveness

Sanitation systems should be monitored for effectiveness, periodically verified by means such as audit pre-operational inspections or, where appropriate, microbiological sampling of environment and food contact surfaces and regularly reviewed and adapted to reflect changed circumstances.

Module 7 - Establishment: personal hygiene

Objective

To introduce the participants to Chapter 7 of the Codex General Principles of Food Hygiene and to examine the importance and requirements of personal hygiene in preventing contamination of food and in food safety

Suggested method of instruction

- Lecture

Aids

- Overhead transparencies/slides
- Handout
- Video: *Germ busters -A guide to good hygiene*

References

- *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev. 3 (1997)], Section VII - reproduced below in shaded boxes

Time frame

- One hour

Content

- Objectives and rationale
- Health status
- Illness and injuries
- Personal cleanliness
- Personal behaviour
- Visitors

Learning outcome

Participants should understand the importance and relationship of personal hygiene to food safety and to the prevention of food contamination.

OBJECTIVES AND RATIONALE

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

Objectives:

To ensure that those who come directly or indirectly into contact with food are not likely to contaminate food by:

- maintaining an appropriate degree of personal cleanliness;
- behaving and operating in an appropriate manner.

Rationale:

People who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers.

HEALTH STATUS

7.1 Health status

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, should not be allowed to enter any food handling area if there is a likelihood of

their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.

Medical examination of a food handler should be carried out if clinically or epidemiologically indicated.

Additional points to consider

• The manufacturer should have and enforce a policy to prevent personnel known to be suffering from or known to be carriers of a disease transmissible through food from working in food handling areas.

• The manufacturer should require that employees advise management when they are suffering from a communicable disease likely to be transmitted through food.

• Employees having open cuts or wounds should not handle food or food contact surfaces unless the injury is completely protected by a secure waterproof covering, e.g. rubber gloves.

ILLNESS AND INJURIES

7.2 Illness and injuries

Conditions which should be reported to management so that the need for medical examination and/of possible exclusion from food handling can be considered, include:

- jaundice
- diarrhoea
- vomiting
- fever
- sore throat with fever
- visibly infected skin lesions (boils, cuts, etc.)
- discharges from the ear, eye or nose;

PERSONAL CLEANLINESS

7.3 Personal cleanliness.

Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering and footwear. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof dressings.

Personnel should always wash their hands when personal cleanliness may affect food safety, for example:

- at the start of food handling activities;
- immediately after using the toilet; and
- after handling raw food or any contaminated material, where this could result in contamination of other food items; they should avoid handling ready-to-eat food, where appropriate.

Additional points to consider

• All persons should wash their hands upon entering food handling areas, before starting work, after handling contaminated materials, after break and after using toilet facilities. Where necessary to minimize microbiological contamination, employees should use disinfectant hand dips.

• Protective clothing, hair covering, footwear and/or gloves appropriate to the operation that the employee is engaged in, e.g. effective hair coverings for employees in production areas, should be worn and maintained in a sanitary manner.

PERSONAL BEHAVIOUR

7.4 Personal behaviour

People engaged in food handling activities should refrain from behaviour which could result in contamination of food, for example:

- smoking;
- spitting;
- chewing creating;
- sneezing or coughing over unprotected food.

Personal effects such as jewellery, watches, pins or other items should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

Additional points to consider

• Any behaviour that could result in contamination of food, such as eating, use of tobacco or chewing gum or unhygienic practices such as spitting, should be prohibited in food handling areas.

• All persons entering food handling areas should remove jewellery and other objects that could fall into or otherwise contaminate food. Jewellery that cannot be removed, such as wedding bands and medical alerts, should be covered.

• Personal effects and street clothing should not be kept in food handling areas and should be stored in such a manner as to prevent contamination.

VISITORS

7.5 Visitors

Visitors to food manufacturing, processing or handling areas should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.

Additional points to consider

• Access of personnel and visitors should be controlled to prevent contamination. The traffic pattern of employees should not result in cross-contamination of the product.

Module 8 - Transportation

Objective

To introduce the participants to Chapter 8 of the Codex General Principles of Food Hygiene and to examine the importance and requirements of transportation and good transportation practices in preventing contamination of the food and in food safety

Suggested methods of instruction

• Lecture
• Exercise

Aids

• Overhead transparencies/slides
• Handout

Reference

• *Recommended International Code of Practice-General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev. 3 (1997)]/Section VIII - reproduced below in shaded boxes

Time frame

• One hour lecture
• One hour exercise

Content

• Objectives and rationale
• General considerations
• Requirements
• Use and maintenance
• Transportation and distribution

Exercise

Break the trainees into groups and have each group identify potential hazards and controls associated with transportation of a specific product/e.g. fish in ships, milk in tanker trucks and peanuts during storage and distribution (30 minutes to prepare and 30 minutes to present findings).

Learning outcome

Participants should understand the importance and relationship of transportation and good transportation practices in preventing contamination of food and in food safety.

OBJECTIVES AND RATIONALE

SECTION VIII-TRANSPORTATION

Objectives:

Measures should be taken where necessary to:

- protect food from potential sources of contamination;
- protect food from damage likely to render the food unsuitable for consumption; and
- provide an environment which effectively controls the growth of pathogenic or spoilage microorganisms and the production of toxins in food.

Rationale:

Food may become contaminated, or may not reach its destination in a suitable condition for consumption, unless effective control measures are taken during transport, even where adequate hygiene control measures have been taken earlier in the food chain.

GENERAL CONSIDERATIONS

8.1 General

Food must be adequately protected during transport. The type of conveyances or containers required depends on the nature of the food and the conditions under which it has to be transported.

REQUIREMENTS

8.2 Requirements

Where necessary, conveyances and bulk containers should be designed and constructed so that they:

- do not contaminate foods or packaging;

- can be effectively cleaned and, where necessary, disinfected;

- permit effective separation of different foods or foods from non-food items where necessary during transport;

- provide effective protection from contamination, including dust and fumes;

- can effectively maintain any temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsuitable for consumption; and

- allow any necessary temperature, humidity and other conditions to be checked.

Additional points to consider

• Ingredients requiring refrigeration should be transported at 4°C or less and should be appropriately monitored. Frozen ingredients should be transported at temperatures that do not permit thawing.

• Food products should be transported under conditions that prevent microbiological, physical and chemical hazards.

USE AND MAINTENANCE

8.3 Use and maintenance

Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection should take place between loads.

Where appropriate, particularly in bulk transport, containers and conveyances should be designated and marked for food use only and be used only for that purpose.

Additional points to consider

The manufacturer should verify that carriers are suitable for the transportation of food. For example:

• Carriers should be inspected by the manufacturer on receipt and prior to loading to ensure they are free from contamination and suitable for the transportation of food.

• The manufacturer should have a programme in place to demonstrate the adequacy of cleaning and sanitizing. For example, for bulk carriers a written cleaning and sanitizing procedure should be available.

• Where the same carriers are used for food and non-food loads (e.g. dual use), procedures should be in place to restrict the type of non-food loads to those that do not pose a risk to subsequent food loads after an acceptable cleaning or to food loads in the same shipment. For example/the manufacturer may require a cleaning certificate and a record of the previous material transported prior to loading or unloading of dual-use tankers, or may have a programme in place to verify the adequacy of cleaning, e.g. tanker inspection, sensory evaluation of ingredients and/or analysis, as appropriate.

• Carriers should be loaded, arranged and unloaded in a manner that prevents damage and contamination of the food.

- Bulk tanks should be designed and constructed to permit complete drainage and to prevent contamination.

- Where appropriate, materials used in carrier construction should be suitable for food contact.

TRANSPORTATION AND DISTRIBUTION

The transportation and distribution segments are very diverse. In many cases, transportation firms may be handling a variety of products in addition to food, which adds to the complexity of the situation.

The first step is to identify those circumstances that pose a significant health risk, such as improper handling of sensitive products or ineffective cleaning or sanitizing of transportation vehicles. For example, inadequate control of temperatures during transportation and distribution can contribute to microbial growth, formation of mycotoxins, spoilage and/or deterioration of certain products.

A recent example of improper practice has served to underscore needs in this area. An outbreak of salmonellosis in the United States was caused by the hauling of pasteurized ice-cream mix in a tanker truck that had previously carried raw eggs. This example illustrates the importance of preventing cross-contamination.

HACCP plans developed by the food industry must consider the control of temperatures and contamination during the transport of foods. A food business operator may require an HACCP plan as a condition of doing business with a particular transportation firm.

Properly designed HACCP-based good transportation practices for the transportation and distribution sector may be a more appropriate approach than HACCP plans. General education programmes are needed to alert food transporters to the potential hazards that can be associated with the transportation and distribution (including storage) of food products. Requirements for handling and distribution of food products or ingredients must be developed by food manufacturers, and these requirements must be communicated to transportation and distribution businesses. Transporters or storage facilities should be required to take proper hygienic measures to protect the food and should be required to keep and retain records that will document their adherence to food safety plans.

Module 9 - Product information and consumer awareness

Objective

To provide the participants with knowledge of the importance of product information in ensuring that consumers have adequate information to avoid mishandling food and to make informed choices regarding food

Suggested methods of instruction

- Lecture
- Exercise

Aids

- Overhead transparencies/slides
- Handout

References

- *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev 3 (1997)], Section IX - reproduced below in shaded boxes

- *Codex General Standard for the Labelling of Prepackaged Foods* (*World-wide Standard*) [Codex Stan 1-1985 (Rev 1-1991)]

- *Codex General Guidelines on Claims* [CAC/GL 1-1979 (Rev. 1-1991)]

- *Codex Guidelines on Nutrition Labelling* [CAC/GL 2-1985 (Rev 1-1993)]

Time frame

- 30 minutes lecture
- 30 minutes exercise

Content

- Objectives and rationale
- Lot identification
- Product information
- Labelling
- Consumer education

Exercise

The instructor should have the trainees identify the type of information that should be available on product labels and the type of information that should be provided to consumers regarding the safe handling of foods.

Learning outcome

Participants should understand the importance of product information in ensuring that consumers have adequate information to prevent mishandling of food and can make informed choices regarding food. Participants should also be aware of the Codex standards regarding labelling.

OBJECTIVES AND RATIONALE

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

Objectives:

Products should bear appropriate information to ensure that:

- adequate and accessible information is available to the next person in the food chain to enable them to handle, store, process, prepare and display the product safely and correctly;

- the lot or batch can be easily identified and recalled if necessary.

Consumers should have enough knowledge of food hygiene to enable them to:

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

Information for industry or trade users should be clearly distinguishable from consumer information, particularly on food labels.

Rationale:

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 products becoming unsuitable for consumption, even where adequate hygiene control measures have been taken earlier in the food chain.

LOT IDENTIFICATION

9.1 Lot identification

Lot identification is essential in product recall and also helps effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) applies.

PRODUCT INFORMATION

9.2 Product Information

All food products should be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly.

LABELLING

9.3 Labelling

Prepackaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display store and use the product safely: Codex General Standard for the Labelling 1 of Prepackaged Foods (CODEX STAN 1-1985) applies.

CONSUMER EDUCATION

9.4 Consumer education

Health education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product information and to follow any instructions accompanying products, and make informed choices. In particular consumers should be informed of the relationship between time/temperature control and foodborne illness.

Module 10 - Training

Objective

To introduce the participants to Chapter 10 of the Codex General Principles of Food Hygiene and to examine the importance of training those engaged in food business operations who come directly or indirectly into contact with food to a level appropriate to the operations they are to perform

Suggested method of instruction

- Lecture

Aids

- Overhead transparencies/slides
- Handout

References

- *Recommended International Code of Practice-General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev. 3 (1997)], Section X - reproduced below in shaded boxes

- Section 1 of this training manual

Time frame

- 30 minutes lecture

Content

- Objective and rationale
- Awareness and responsibilities
- Training programmes
- Instruction and supervision
- Refresher training

Learning outcome

Participants should understand the importance of training those engaged in food business operations to a level appropriate to the operations they are to perform.

OBJECTIVE AND RATIONALE

SECTION X - TRAINING

Objective:

Those engaged in food operations who come directly or indirectly into contact with food should be trained, and/or instructed in food hygiene to a level appropriate to the operations they are to perform.

Rationale:

Training is fundamentally important to any food hygiene system.

Inadequate hygiene training, and/or instruction and supervision of all people involved in food elated activities pose a potential threat to the safety of food and its suitability for consumption.

AWARENESS AND RESPONSIBILITIES

10.1 Awareness and responsibilities

Food hygiene training is fundamentally important. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle a strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

TRAINING PROGRAMMES

10.2 Training programmes

Factors to take into account in assessing the level of training required include:

- the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage microorganisms;

- the manner in which the food is handled and packed, including the probability of contamination;

- the extent and nature of processing or further preparation before final consumption;

- the conditions under which the food will be stored; and

- the expected length of time before consumption.

Additional points to consider

- Training should be appropriate to the complexity of the manufacturing process and the tasks assigned.

• Personnel should be trained to understand the importance of the critical control points for which they are responsible, the critical limits, the procedures for monitoring, the action to be taken if the limits are not met and the records to be kept.

• Personnel responsible for maintenance of equipment having an impact on food safety should be appropriately trained to identify deficiencies that could affect product safety and to take appropriate corrective action, e.g. in-house repairs, contract repairs. Individuals performing maintenance on specific equipment, e.g. closing machines, recorders, etc., should be appropriately trained.

• Personnel and supervisors responsible for the sanitation programme should be appropriately trained to understand the principles and methods of effective cleaning and sanitizing.

• Additional training, e.g. specific technical training, apprenticeship programmes, etc., should be provided as necessary to ensure current knowledge of equipment and process technology.

INSTRUCTION AND SUPERVISION

10.3 Instruction and supervision

Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively.

Managers and supervisors of food processes should have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

REFRESHER TRAINING

10.4 Refresher training

Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

Additional points to consider

The manufacturer should have a written training programme for employees which should be delivered as follows:

• Appropriate training in personal hygiene and hygienic handling of food should be provided to all food handlers at the beginning of their employment.

• The original food hygiene training should be reinforced and updated at appropriate intervals.

Section 3 - THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

Introduction

The objective of Section 3 is to review the tasks in the application of the HACCP system and to provide trainees with the knowledge and background necessary to establish HACCP plans and/or verify the acceptability of existing HACCP plans and systems.

Section 3 reviews the 12 tasks in the application of HACCP, including the seven HACCP principles. It emphasizes the importance of the Codex General Principles of Food Hygiene and the appropriate commodity codes of practice, standards and guidelines as a basis for developing the HACCP plan.

Section 3 of the training manual is based on Revision 1 (current) of the *Hazard Analysis and Critical Control* (*HACCP*) *system and guidelines for its application,* which was adopted during the twenty-second session of the Codex Alimentarius Commission in 1997 and included as Annex to the *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev. 3 (1997)]. A previous draft of the *Hazard Analysis and Critical Control* (*HACCP*) *system and guidelines for its application* was included as Appendix II to ALINORM 97/13 and was adopted by the twentieth session of the Codex Alimentarius Commission in 1993.

Section 3 contains the following training modules:

- Module 1: History and background of the HACCP system
- Module 2: The Codex guidelines for the application of the HACCP system
- Module 3: Assemble the HACCP team - Task 1
- Module 4: Describe product and identify intended use - Tasks 2 and 3
- Module 5: Construct flow diagram and on-site confirmation of flow diagram -Tasks 4 and 5
- Module 6: List all potential hazards associated with each step, conduct a hazard analysis and consider any measures to control identified hazards - Task 6/Principle 1
- Module 7: Determine critical control points - Task 7/Principle 2
- Module 8: Establish critical limits for each critical control point - Task 8/Principle 3
- Module 9: Establish a monitoring system for each critical control point - Task 9/Principle 4
- Module 10: Establish corrective actions - Task 10/Principle 5

- Module 11: Establish verification procedures - Task 11/Principle 6

- Module 12: Establish documentation and record keeping - Task 12/Principle 7

Module 1 provides a general introduction and background information on the HACCP system. It discusses the history and application of HACCP and looks at the increasingly important role of HACCP in international trade. Module 2 gives the Codex text and definitions of the Hazard Analysis and Critical Control Point as approved by the twenty-second session of the Codex Alimentarius Commission (Geneva, Switzerland, June 1997). Modules 3 to 12 follow the logical sequence for application of HACCP recommended by the Codex Alimentarius Commission, which consists of 12 tasks.

Section 3 uses lecture and traditional training aids such as slides and videos to relay the information. In addition, an important component of the training is the development of an HACCP plan by the trainees divided into working groups. The plan is developed step by step by addressing each of the 12 tasks and completing the appropriate forms elaborated in each module. These forms record the information and data necessary to document the HACCP implementation process and capture monitoring and verification information for evaluating the effectiveness of the HACCP system. A complete set of blank forms is attached in Annex 1 of the manual.

At the end of each module, an example of the completed form is provided. The example case (canned mushroom) is based on a training example used by government agencies. This example can be used during training or replaced with a different food product depending on local food production methods, product types, etc.

The forms have been prepared for training purposes only and may not be suitable for direct application by the food industry. Instead, the industry may develop or design its own forms for development of its specific HACCP plan. Furthermore, trainers may wish to redesign the demonstration forms to enhance the effectiveness of the message during classroom sessions, including the basic information and data given in the forms along with other information and data considered necessary or desirable for actual use.

Module 1 - History and background of the HACCP system

Objective

To introduce the trainees to the history and background of the Hazard Analysis and Critical Control Point (HACCP) system and its importance as a food safety management system in identifying and controlling food safety hazards

Suggested method of instruction

- Lecture

Aids

- Overhead transparencies
- Handout
- HACCP videos

Reference

- *The use of hazard analysis critical control point* (*HACCP*) *principles in food control.* Report of an FAO Expert Technical Meeting, Vancouver, Canada, 12-16 December 1994. FAO Food and Nutrition Paper No. 58. Rome, FAO/1995.

Time frame

- One hour lecture

Content

- History of HACCP
- The Codex Alimentarius General Principles of Food Hygiene
- Advantages of HACCP
- Application of HACCP
- HACCP and trade
- Training
- Objectives of the FAO approach to HACCP

Learning outcome

Participants should be familiar with the history of HACCP, its importance as a programme for food safety and its importance in international trade.

HISTORY OF HACCP

HACCP has become synonymous with food safety. It is a worldwide-recognized systematic and preventive approach that addresses biological, chemical and physical hazards through anticipation and prevention, rather than through end-product inspection and testing.

The HACCP system for managing food safety concerns grew from two major developments. The first breakthrough was associated with W.E. Deming, whose theories of quality management are widely regarded as a major factor in turning around the quality of Japanese products in the 1950s. Dr Deming and others developed total quality management (TQM) systems which emphasized a total systems approach to manufacturing that could improve quality while lowering costs.

The second major breakthrough was the development of the HACCP concept itself. The HACCP concept was pioneered in the 1960s by the Pillsbury Company, the United States Army and the United States National Aeronautics and Space Administration (NASA) as a collaborative development for the production of safe foods for the United States space programme. NASA wanted a "zero defects" programme to guarantee the safety of the foods that astronauts would consume in space. Pillsbury therefore introduced and adopted HACCP as the system that could provide the greatest safety while reducing dependence on end-product inspection and testing. HACCP emphasized control of the process as far upstream in the processing system as possible by utilizing operator control and/or continuous monitoring techniques at critical control points. Pillsbury presented the HACCP concept publicly at a conference for food protection in 1971. The use of HACCP principles in the promulgation of regulations for low-acid canned food was completed in 1974 by the United States Food and Drug Administration (FDA). In the early 1980s, the HACCP approach was adopted by other major food companies.

The United States National Academy of Science recommended in 1985 that the HACCP approach be adopted in food processing establishments to ensure food safety. More recently, numerous groups, including for example the International Commission on Microbiological Specifications for Foods (ICMSF) and the International Association of Milk, Food and Environmental Sanitarians (IAMFES), have recommended the broad application of HACCP to food safety.

THE CODEX ALIMENTARIUS GENERAL PRINCIPLES OF FOOD HYGIENE

Recognizing the importance of HACCP to food control, the twentieth session of the Codex Alimentarius Commission, held in Geneva, Switzerland from 28 June to 7 July 1993, adopted *Guidelines for the application of the Hazard Analysis Critical Control Point* (*HACCP*) *system* (ALINORM 93/13A, Appendix II). The commission was also informed that the draft revised General Principles of Food Hygiene would incorporate the HACCP approach.

The revised *Recommended International Code of Practice - General Principles of Food Hygiene* [CAC/RCP 1-1969, Rev 3 (1997)] was adopted by the Codex Alimentarius Commission during its twenty-second session in June 1997. *The Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* is included as its Annex.

The Codex General Principles of Food Hygiene lay a firm foundation for ensuring food hygiene. They follow the food chain from primary production through to the consumer, highlighting the key hygiene controls at each stage and recommending an HACCP approach wherever possible to enhance

food safety. These controls are internationally recognized as essential to ensuring the safety and suitability of food for human consumption and international trade.

ADVANTAGES OF HACCP

The HACCP system, as it applies to food safety management, uses the approach of controlling critical points in food handling to prevent food safety problems. The system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is based on prevention and reduces the reliance on end-product inspection and testing.

The HACCP system can be applied throughout the food chain from the primary producer to the consumer. Besides enhancing food safety, other benefits of applying HACCP include more effective use of resources, savings to the food industry and more timely response to food safety problems.

HACCP enhances the responsibility and degree of control at the level of the food industry. A properly implemented HACCP system leads to greater involvement of food handlers in understanding and ensuring food safety, thus providing them with renewed motivation in their work. Implementing HACCP does not mean undoing quality assurance procedures or good manufacturing practices already established by a company; it does, however, require a revision of these procedures as part of the systematic approach and for their appropriate integration into the HACCP plan.

The application of the HACCP system can aid inspection by food control regulatory authorities and promote international trade by increasing buyers' confidence.

Any HACCP system should be capable of accommodating change, such as advances in equipment design, changes in processing procedures or technological developments.

APPLICATION OF HACCP

While the application of HACCP to all segments and sectors of the food chain is possible, it is assumed that all sectors should be operating according to good manufacturing practices (GMPs) and the Codex General Principles of Food Hygiene. The ability of an industry segment or sector to support or implement the HACCP system depends on the degree of its adherence to these practices.

The successful application of HACCP requires the full commitment and involvement of management and the workforce. It requires a multidisciplinary approach which should include, as appropriate, expertise in agronomy, veterinary health, microbiology, public health, food technology, environmental health, chemistry, engineering, etc. according to the particular situation. The application of the HACCP system is compatible with the implementation of TQM systems such as the ISO 9000 series. However, HACCP is the system of choice in the management of food safety within such systems.

HACCP AND TRADE

The Final Act of the Uruguay Round of multilateral trade negotiations, which began in Punta del Este, Uruguay in September 1986 and concluded in Marrakesh, Morocco in April 1994, established the World Trade Organization (WTO) to succeed the General Agreement on Tariffs and Trade (GATT). The Uruguay Round negotiations were the first to deal with the liberalization of trade in agricultural products, an area excluded from previous rounds of negotiations.

Significant implications for the Codex Alimentarius Commission arise from the Final Act of the Uruguay Round: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement).

The purpose of the SPS Agreement is to ensure that measures established by governments to protect human, animal and plant life and health, in the agricultural sector only, are consistent with obligations prohibiting arbitrary or unjustifiable discrimination on trade between countries where the same conditions prevail and are not disguised restrictions on international trade.

The SPS Agreement is particularly relevant to food safety, providing a framework for the formulation and harmonization of sanitary and phytosanitary measures. It requires that such measures be based on science and implemented in an equivalent and transparent manner. They cannot be used as an unjustifiable barrier to trade by discriminating among foreign sources of supply or providing an unfair advantage to domestic producers.

To facilitate safe food production for domestic and international markets, the SPS Agreement encourages governments to harmonize their national measures or base them on international standards, guidelines and recommendations developed by international standard-setting bodies.

The purpose of the TBT Agreement is to prevent the use of national or regional technical requirements, or standards in general, as unjustified technical barriers to trade. The agreement covers

all types of standards including quality requirements for foods (except requirements related to sanitary and phytosanitary measures), and it includes numerous measures designed to protect the consumer against deception and economic fraud.

The TBT Agreement also places emphasis on international standards. WTO members are obliged to use international standards or parts of them except where the international standard would be ineffective or inappropriate in the national situation.

Codex standards, guidelines and other recommendations have become the specifically identified baseline for safe food production and consumer protection under the SPS Agreement. In this environment. Codex standards, guidelines and other recommendations take on unprecedented importance with respect to consumer protection and international food trade. As a result, the work of the Codex Alimentarius Commission, including the *Guidelines for the application of the Hazard Analysis Critical Control Point* (*HACCP*) *system,* has become the reference for international food safety requirements. In this light it is imperative that the Codex guidelines for the application of the HACCP system be unequivocal in their guidance; otherwise conflicts on food safety grounds could arise.

The application of HACCP as a public policy requires definition of the role of government in the utilization of the HACCP process. Food-exporting countries may require additional resources to enhance their food industries to meet the requirements. Adequate steps should be taken to facilitate food trade, such as assessment of food safety, training of personnel, technology transfer and strengthening of the national food control system.

TRAINING

Food industries and food control regulatory agencies worldwide have shown interest in implementing the HACCP system. A common understanding about terminology and approaches for application will greatly enhance its adoption and will lead to a harmonized approach to food safety among countries all over the world. Many countries have integrated or are in the process of integrating the HACCP system into their regulatory mechanisms. In many countries, application of the HACCP system to foods may become mandatory. As a result, there is a tremendous demand, particularly in developing countries, for training in the HACCP system and for the development and assembly of reference materials to support this training.

It is in this context that FAO has prepared this training package on the Codex General Principles of Food Hygiene and the guidelines for the application of the HACCP system.

OBJECTIVES OF THE FAO APPROACH TO HACCP

The objectives of the FAO approach to HACCP include:

- Promotion of the implementation of the HACCP system based on the harmonized Codex General Principles of Food Hygiene and GMPs

- Development of a programme to train trainers who are in a position to train others who can apply the knowledge gained

- Identification and provision of appropriate reference and training materials on the application of HACCP to support the training

- Provision of training to individuals involved to varying degrees with the preparation, monitoring, administration and verification of HACCP plans

- Enhancement of the role of science and risk assessment in the development of HACCP systems

- Creation of a framework for determining the equivalence of food safety control programmes through a harmonized approach to the application of HACCP

Module 2 - The Codex guidelines for the application of the HACCP system

Objective

To introduce the trainees to the Codex guidelines for the application of the Hazard Analysis and Critical Control Point (HACCP) system; to provide an overview of the system, the definitions and the internationally accepted approach on which the subsequent HACCP training modules are based

Suggested method of instruction

- Lecture

Aids

- Overhead transparencies/slides
- Handout
- HACCP videos

References

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

- *HACCP in microbiological safety and quality.* International Commission on Microbiological Specifications for Foods (ICMSF). Oxford Mead, UK, Blackwell Scientific Publications, 1988.

Time frame

- One hour lecture
- 30 minutes video

Content

- The HACCP system
- Definitions
- Principles of the HACCP system
- Guidelines for the application of the HACCP system
- Application of the HACCP principles
- Training

Learning outcome

Participants should be familiar with the Codex guidelines for the application of the HACCP system and the definitions and approach in these guidelines. This module provides a foundation for the more in-depth HACCP training to follow.

THE HACCP SYSTEM

[Excerpt from Preamble]

The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing and inspection. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

DEFINITIONS

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

Control* (*noun*)*: To state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: Any action to betaken when the results of monitoring at the CCP indicate a loss of control.

Critical Control Point* (*CCP*)*: A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit: A criterion which separates acceptability from unacceptability.

Deviation: Failure to meet a critical limit.

Plow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an averse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions loading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

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

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

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

PRINCIPLES OF THE HACCP SYSTEM

The HACCP system consists of the following seven principles:

Principle 1

Conduct a hazard analysis.

Identify the potential hazard(s) associated with food production at all stages, from primary production, processing, manufacture and distribution until the point of consumption. Assess the likelihood of occurrence of the hazard(s) and identify the measures for their control.

Principle 2

Determine the Critical Control Points (CCPs).

Determine the points, procedures or operational steps that can be controlled to eliminate the hazard(s) or minimize its (their) likelihood of occurrence.

A "step" means any stage in food production and/or manufacture including the receipt and/or production of raw materials, harvesting, transport, formulation, processing, storage, etc.

Principle 3

Establish critical limit(s).

Establish critical limit(s) which must be met to ensure the CCP is under control.

Principle 4

Establish a system to monitor control of the CCP.

Establish a system to monitor control of the CCP by scheduled testing or observations.

Principle 5

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

Principle 6

Establish procedures for verification to confirm that the HACCP system is working effectively.

Principle 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

Prior to application of HACCP to any sector of the food chain, that sector should be operating according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practise, and appropriate food safety legislation. Management commitment is necessary for implementation of an effective HACCP system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found.

HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature.

The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

It is important when applying HACCP to be flexible where appropriate, given the context of the application, taking into account the nature and the size of the operation.

APPLICATION OF THE HACCP PRINCIPLES

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP [see Figure].

Logic sequence for application of HACCP

1. Assemble HACCP team

The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other Sources. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

2. Describe product

A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including A_w, pH, etc.), packaging, durability and storage conditions and method of distribution.

3. Identify intended use

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

4. Construct flow diagram

The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

5. On-site verification of flow diagram

The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.

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

The HACCP team should list all hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption.

The HACCP team should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of microorganisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents; and
- conditions leading to the above.

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

More then one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

7. Determine Critical Control Points (see Principle 2)[1]

[1] Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g. slaughter, and

therefore it should be used in conjunction with professional judgement, and modified in some cases.

There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree [see Figure] which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations, Other approaches may be used. Training in the application of the decision tree is recommended.

Example of decision tree to identify critical control points

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

8. Establish critical limits for each CCP (see Principle 3)

Optical limits must be specified and validated if possible for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, A_w, available chlorine, and sensory parameters such as visual appearance and texture.

9. Establish a monitoring system for each CCP (see Principle 4)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect toss of control at the CCP. Further, monitoring should ideally provide this Information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carryout corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP d in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

10. Establish corrective actions (see Principle 5)

Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

The actions must ensure that the CCP has been brought under control, Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

11. Establish verification procedures (see Principle 6)

Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include:

- Review of the HACCP system and its records;
- Review of deviations and product dispositions;
- Confirmation that CCPs are kept under control.

Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

12. Establish documentation and record keeping (see Principle 7)

Efficient and accurate record keeping is essential to the application of an HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation.

Documentation examples are:

- Hazard analysis;
- CCP determination;
- Critical limit determination.

Record examples are:

- CCP monitoring activities;
- Deviations and associated corrective actions;
- Modifications to the HACCP system.

TRAINING

Training of personnel in industry, government and academia in HACCP principles and applications, and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support an HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each Critical Control Point.

Cooperation between primary producer, industry, trade groups, consumer organizations and responsible authorities is of vital importance. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

The International Commission on Microbiological Specifications for Foods (ICMSF) monograph *HACCP in microbiological safety and quality,* which describes the type of training required for various target groups, is an example of a general approach to training. Its section on training (Chapter 8) is equally applicable for training regarding other hazards besides those of a microbiological nature.

Module 3 - Assemble the HACCP team - Task 1

Objective

To familiarize the trainees with the appropriate composition and knowledge required for an effective HACCP team

Suggested methods of instruction

- Lecture
- Exercise

Aids

- Overhead transparencies/slides
- Handout

Time frame

- 30 minutes lecture
- One hour exercise

Content

- The HACCP team
- Training requirements
- Resources

Approach

The instructor should identify three to four "HACCP teams" from among the participants to complete the exercises in the following modules.

Exercise

The instructor should have the trainees consider and identify the appropriate composition and areas of knowledge of an HACCP team and list these on flip charts or overhead transparencies.

Learning outcome

Participants should be able to identify the appropriate composition and knowledge required of an HACCP team.

THE HACCP TEAM

Prior to proceeding to HACCP team selection, it is extremely important to have full commitment to the HACCP initiative from management at all levels. Without a firm commitment, it may be difficult or impossible to implement the HACCP plan. Before the study is begun, management should inform all staff of the intention to implement HACCP. Both the company and the personnel involved in the development of the HACCP plan must be totally committed to its implementation.

The first task in the application of HACCP is to assemble a team having the knowledge and expertise to develop an HACCP plan. The team should be multidisciplinary and could include plant personnel from production/sanitation, quality assurance, laboratory, engineering and inspection. It is essential to assemble the right blend of expertise and experience, as the team will collect, collate and evaluate technical data and identify hazards and critical control points. In smaller establishments, one person may fulfil several roles or even constitute the whole team. In the latter case the use of external consultants or advice may be necessary.

The team should also include personnel who are directly involved in daily processing activities, as they are more familiar with the specific variability and limitations of the operations. Their representation will foster a sense of ownership among those who will have to implement the plan. The HACCP team may require independent outside experts to advise on identified issues or problem areas; for example, an expert in public health risks associated with the product or process may be hired. However, complete reliance on outside sources is not recommended in developing the HACCP plan, as such an approach may lack the support of the plant personnel.

Ideally the team should not be larger than six, although for some stages of the study it may be necessary to enlarge the team temporarily with personnel from other departments, e.g. marketing, research and development or purchasing and finance.

Team composition

When selecting the team, the coordinator should focus on:

- Those who will be involved in hazard identification
- Those who will be involved in determination of critical control points
- Those who will monitor critical control points
- Those who will verify operations at critical control points
- Those who will examine samples and perform verification procedures

Knowledge required

Selected personnel should have a basic understanding of:

- Technology and equipment used on the processing lines
- Practical aspects of the food operations
- The flow and technology of the process
- Applied aspects of food microbiology
- HACCP principles and techniques

Scope

One of the first tasks of the HACCP team should be to identify the scope of the HACCP plan. The team should:

- Limit the study to a specific product and process
- Define the type(s) of hazards to be included (e.g. biological, chemical, physical)
- Define the part of the food chain to be studied

Coordinator

The team must include a coordinator (chairperson) whose role is to:

- Ensure that the composition of the team meets the needs of the study
- Suggest changes to the team if necessary
- Coordinate the team's work
- Ensure that the agreed established plan is followed
- Share the work and responsibilities
- Ensure that a systematic approach is used
- Ensure that the scope of the study is met
- Chair meetings so that team members can freely express their ideas
- Represent the team before management
- Provide management with an estimate of the time, money and labour required for the study

TRAINING REQUIREMENTS

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

RESOURCES

The number of meetings will depend on the scope of the study and the complexity of the operation. For efficiency, each meeting should have a specific objective, a planned agenda and a limited duration. Meetings should be of sufficient frequency to maintain momentum, but spaced out enough so there will be time between meetings for the gathering of any necessary information. It is advantageous to keep the study proceeding at a reasonable pace to maintain the enthusiasm of the team. A time-line should be developed and goals set for the accomplishment of team and individual assignments.

To ensure success and demonstrate commitment, it is important for senior management to allocate the necessary resources for the HACCP study. These may include:

- Time for team meetings and administration
- Costs of initial training
- Necessary documents
- Access to analytical laboratories
- Access to information sources to answer questions raised by the team (e.g. universities, public and private research authorities, government and public authorities, scientific and technical literature, databases)

Module 4 - Describe product and identify intended use - Tasks 2 and 3

Objective

To introduce the trainees to the importance and considerations of a complete product description and the identification of product ingredients and packaging materials

Suggested methods of instruction

- Lecture
- Exercise

Aids

- Overhead transparencies/slides

Reference

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

Time frame

- 30 minutes lecture
- Two hours exercise and review

Content

- Product description
- Identification of intended use
- Examples/Forms 1 and 2

Exercise

The instructor should have each of the "HACCP teams" formed in Module 3 select a product and describe all of the appropriate characteristics of the product/the ingredients and the packaging materials using Forms 1 and 2. Each team should then present its findings using flip charts or overhead transparencies.

Learning outcome

Trainees should be aware of the importance and considerations of a complete product description and of the identification of product ingredients and packaging materials as a basis for understanding the product and for identifying possible hazards.

PRODUCT DESCRIPTION

The HACCP team must make a complete description of each food product - including all ingredients/processing methods/packaging materials/etc. used in the formulation of the product - to assist in the identification of all possible hazards associated with the product. In brief, the product description should include the name of the product, ingredients and composition, potential to support microbial growth (water activity [A_w], pH, etc.), brief details of the process and technology used in production, appropriate packaging and intended use, including target population.

To complete this description as accurately as possible it is important that the team be familiar with the properties, destination and use of the product. It is important, for example, to take into consideration whether sensitive segments of the population may consume the product.

The HACCP team needs to have as complete an understanding of the product as possible. All details of the product's composition and processing should be known and understood. This information will be essential particularly for microbiological hazards because the product's composition needs to be assessed in relation to the ability of different pathogens to grow.

The product to which the HACCP plan applies should be described on Forms 1 and 2.[1]

[1] All of the forms to be used for the development of the HACCP plan can be found in Annex 1.

Before arriving at the specific details of the product description to be included in the forms, the HACCP team should address the questions outlined below.

Formulation of product

- What raw materials or ingredients are used?

- Are microorganisms of concern likely to be present in or on these materials, and if so what are they?

- If food additives or preservatives are used, are they used at acceptable levels, and at those levels do they accomplish their technical objective?

- Will the pH of the product prevent microbial growth or inactivate particular pathogens?

- Will the A_w of the product prevent microbial growth?

- What is the oxidation/reduction potential (Eh) of the product?

Processing and preparation checklist

- Can a contaminant reach the product during preparation, processing or storage?

- Will microorganisms or toxic substances of concern be inactivated during cooking, reheating or other processing?

- Could any microorganisms or toxins of concern contaminate food after it has been heated?

- Would more severe processing be acceptable or desirable?

- Is the processing based on scientific data?

- How does the package or container affect survival and/or growth of microorganisms?

- How much time is taken for each step of processing, preparation, storage and display?

- What are the conditions of distribution?

Form 1 - Product description

See example.

1. Product name (common name) or group of product names (the grouping of like products is acceptable as long as all hazards are addressed)

2. Important end-product characteristics: properties or characteristics of the food under review that are required to ensure its safety (e.g. A_w, pH/preservatives)

3. How the product is to be used (i.e. ready-to-eat/further processing required, heated prior to consumption)

4. Type of package, including packaging material and packaging conditions (e.g. modified atmosphere)

5. Shelf-life, including storage temperature and humidity if applicable

6. Where the product will be sold (e.g. retail, institutions, further processing)

7. Labelling instructions (e.g. handling and usage instructions)

8. Special distribution control (e.g. shipping conditions)

Form 2 - Product ingredients and incoming material

See example.

List the product ingredients and incoming materials (including raw materials, product ingredients, processing aids, packaging materials) that are used during the manufacturing process. This exhaustive listing is required for proper identification of all potential hazards that could apply.

IDENTIFICATION OF INTENDED USE

The intended use of the product refers to its normal use by end-users or consumers. The HACCP team must specify where the product will be sold, as well as the target group, especially if it happens to be a sensitive portion of the population (i.e. elderly, immune-suppressed, pregnant women and infants). The intended use of the product should be described in Form 1.

Example

FORM 1

PRODUCT DESCRIPTION

1. Product name(s)	*Canned mushroom*
2. Important product characteristics of end product (e.g. A_w, pH, etc.)	*pH 4.8 to 6.5* (*low acid*) *A_w > 0.85* (*high moisture*)
3. How the product is to be used	*Normally heated before serving* (*casseroles, garnishes, etc.*) *or sometimes served unheated* (*salads, appetizers, etc.*)
4. Packaging	*Hermetically sealed metal container*
5. Shelf-life	*Two years plus, at normal retail shelf temperatures*
6. Where the product will be sold	*Retail, institutions and food service. Could be consumed by high-risk groups* (*infirm, immunocompromised, elderly*)
7. Labelling instructions	*None required to ensure product safety*
8. Special distribution control	*No physical damage, excess humidity or temperature extremes*

DATE: _____ APPROVED BY: _____

Example

FORM 2

PRODUCT INGREDIENTS AND INCOMING MATERIAL

PRODUCT NAME(S): *Canned mushroom*

RAW MATERIAL	***PACKAGING MATERIAL***	***DRY INGREDIENTS***
Mushrooms (*domestic, white*)	*Cans* *Ends*	*Salt* *Ascorbic acid* *Citric acid*
OTHER		
Water (*municipal*)		

DATE:_____ APPROVED BY:_____

Module 5 - Construct flow diagram and on-site confirmation of flow diagram - Tasks 4 and 5

Objective

To introduce trainees to the construction of an accurate and complete flow diagram and plant schematic and to its importance in understanding the specific processing operation and in identifying potential hazards associated with the flow of raw materials from the point at which they enter the plant, through processing to departure

Suggested methods of instruction

- Lecture
- Exercise

Aids

- Overhead transparencies/slides
- Handout

Reference

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

Time frame

- 45 minutes lecture
- Two hours exercise and report

Content

- Flow diagram
- Plant schematic
- On-site confirmation of flow diagram and plant schematic
- Examples, Forms 3 and 4

Exercise

The instructor should have each of the "HACCP teams" select a specific product with which the trainees are familiar and prepare a theoretical flow diagram for the product using Form 3. Each team should select a different product, and where possible the different products should represent different sectors of the food industry in the country or region of training.

Learning outcome

Trainees should understand the importance of the construction of an accurate and complete flow diagram and plant schematic in understanding the specific processing operation and in identifying potential hazards associated with the flow of raw materials from the point at which they enter the plant, through processing to departure. The trainees should be able to construct a complete flow diagram and plant schematic.

FLOW DIAGRAM (Task 4)

It is easier to identify routes of potential contamination, to suggest methods of control and to discuss these among the HACCP team if there is a flow diagram. The review of the flow of raw materials from the point at which they enter the plant, through processing to departure is the feature that makes HACCP a specific and important tool for the identification and control of potential hazards.

A process flow diagram must be constructed, using Form 3, following interviews, observation of operations and other sources of information such as blueprints. The process flow diagram will identify the important process steps (from receiving to final shipping) used in the production of the specific product being assessed. There should be enough detail to be useful in hazard identification, but not so much as to overburden the plan with less important points.

The example of Form 3 given at the end of the module shows a summary flow diagram. This example is an indication of the process only and should not be taken as an attempt to give the complete detail required. Remember to include all inputs such as water, steam and other process aids.

Each process step should be considered in detail and the information expanded to include all relevant process data. Data may include but is not restricted to:

- All ingredients and packaging used (biological, chemical, physical data)
- Sequence of all process operations (including raw material addition)
- Time/temperature history of all raw materials and intermediate and final products, including the potential for delay
- Flow conditions for liquids and solids
- Product recycle/rework loops
- Equipment design features

PLANT SCHEMATIC

A plant schematic must be developed, using Form 4, to show product flow and employee traffic patterns within the plant for the specific product. The diagram should include the flow of all ingredients and packaging materials from the moment they are received at the plant, through storage, preparation, processing, packaging, finished product holding and shipping. The personnel flow should indicate employee movement through the plant, including changing rooms, washrooms and lunchrooms. The location of hand-washing facilities and footpaths (if applicable) should also be noted.

This plan should aid in the identification of any areas of potential cross-contamination within the establishment.

The plant schematic/floor and equipment layout should be considered in detail and assessed. Data may include but is not restricted to:

- Personnel routes
- Routes of potential cross-contamination
- Area segregation
- Flow of ingredients and packaging materials
- Location of changing rooms, washrooms, lunchrooms and hand-washing stations

ON-SITE CONFIRMATION OF FLOW DIAGRAM AND PLANT SCHEMATIC (Task 5)

Once the process flow diagram and plant schematic have been drafted, they must be confirmed by an on-site inspection for accuracy and completeness. This will ensure that all the major process operations have been identified. It will also confirm the assumptions made with respect to the movement of product and employees on the premises.

The draft flow diagram should be compared with the operation it represents on site. The process should be reviewed at various times throughout the hours of operation to verify that the flow diagram is valid throughout all operational periods. All members of the HACCP team should be involved in the flow diagram confirmation. Adjustments should be made to the flow diagram, as necessary based on the actual operations observed.

Example

FORM 3

FLOW DIAGRAM

PRODUCT NAME(S): *Canned mushroom*

***MUSHROOM* (*Raw*)**	***EMPTY CANS/ENDS***	***DRY INGREDIENTS***	***WATER* (*municipal*)**
1. Receiving	*2. Receiving*	*3. Receiving*	*4. Intaking*
5. Storing	*6. Storing*	*7. Storing*	
8. Dumping/Washing	*9. Inspecting/Depalletizing*	*10. Dumping*	
11. Blanching	*12. Conveying*	*13. Mixing*	
14. Conveying/Inspecting	*15. Washing*		
16. Slicing/Dicing	*17. Brine injecting*		
18. Foreign object removing	*19. Filling*		
	20. Weighing		
	21. Water filling		
	22. Head-spacing		
	23. End feeding/Closing/ Inspecting		*24. Chlorinating*
	25. Thermal processing		
	26. Cooling		
	27. Conveying/Drying		
	28. Labelling/Storing		
	29. Shipping		

DATE: _____ **APPROVED BY:** _____

Example

FORM 4

PLANT SCHEMATIC/FLOOR PLAN

PRODUCT NAME(S): *Canned mushroom*

The diagram should show the product flow and employee traffic patterns in each individual plant to identify and eliminate cross-contamination potentials

DATE:_____ APPROVED BY:_____

Module 6 - List all potential hazards associated with each step, conduct a hazard analysis and consider any measures to control identified hazards - Task 6/Principle 1

Objective

To provide the trainees with the necessary knowledge and abilities to identify all potential hazards in a process and to consider the appropriate control measures

Suggested methods of instruction

- Lecture
- Exercises

Aids

- Overhead transparencies/slides

Reference

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

Time frame

- One hour lecture
- 30 minutes Exercise 1
- Two hours Exercise 2

Content

- Hazard analysis
- Potential hazards
- Sources of information for hazard analysis
- How to conduct a hazard analysis
- Control measures
- Hazard assessment
- Examples, Forms 2,3 and 5 to 7

Exercises

- The instructor should lead a brainstorming session to prepare a list of potential biological, chemical and physical hazards. Flip charts or overhead transparencies should be prepared showing all biological, chemical and physical hazards identified.

- The instructor should have each "HACCP team" identify the potential hazards associated with all aspects of their selected products and their manufacture. The teams should then present their results on Forms 5, 6 and 7 using flip charts or overhead transparencies.

Learning outcome

The trainees should have the necessary knowledge and abilities to identify all potential hazards in a process and to consider the appropriate control measures.

HAZARD ANALYSIS

Hazard analysis is the first HACCP principle. As the name HACCP implies, hazard analysis is one of the most important tasks. An inaccurate hazard analysis would inevitably lead to the development of an inadequate HACCP plan. Hazard analysis requires technical expertise and scientific background in various domains for proper identification of all potential hazards. Knowledge of food science and HACCP is necessary for the performance of a satisfactory hazard analysis.

The Codex *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* [Annex to CAC/RCP 1-1969, Rev. 3 (1997)] defines a hazard as "A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect". The hazard analysis is necessary to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

Hazards will vary among firms making the same products because of differences in:

- Sources of ingredients
- Formulations
- Processing equipment
- Processing and preparation methods
- Duration of processes

- Storage conditions
- The experience, knowledge and attitudes of personnel

Therefore hazard analysis must be done on all existing and new products. Changes in raw materials, product formulations, processing or preparation procedures, packaging, distribution and/or use of the product will require review of the original hazard analysis.

The first step in the development of an HACCP plan for a food operation is the identification of all potential hazards associated with the product at all stages from raw materials to consumption. All biological, chemical and physical hazards should be considered.

POTENTIAL HAZARDS

Examples of potential biological, chemical and physical hazards are given in the accompanying boxes. These lists can be used for assistance in the identification of potential hazards.

Biological hazards

Foodborne biological hazards include microbiological organisms such as bacteria, viruses, fungi and parasites. These organisms are commonly associated with humans and with raw products entering the food establishment. Many of-these microorganisms occur naturally in the environment where foods are grown. Most are killed or inactivated by cooking, and numbers can be minimized by adequate control of handling and storage practices (hygiene, temperature and time).

EXAMPLES OF BIOLOGICAL HAZARDS

Bacteria (spore-forming)

Clostridium botulinum
Clostridium perfringens
Bacillus cereus

Bacteria (non-spore-forming)

Brucella abortis
Brucella suis
Campylobacter spp.
Pathogenic *Escherichia coli* (*E. coli* 0157:1-17, EHEC, EIEC, ETEC, EPEC)
Listeria monocytogenes
Salmonella spp. (*S. typhimurium, S. enteriditis*)
Shigella (*S. dysenteriae*)
Staphylococcus aureus
Streptococcus pyogenes
Vibrio cholerae
Vibrio parahaemolyitcus
Vibrio vulnificus
Yersinia enterocolitica

Viruses

Hepatitis A and E
Norwalk virus group
Rotavirus

Protozoa and parasites

Cryptosporidium parvum
Diphyllobothrium latum
Entamoeba histolytica
Giardia lamblia
Ascaris lumbricoides
Taenia solium

Taenia saginata *Trichinella spiralis*

The majority of reported foodborne disease outbreaks and cases are caused by pathogenic bacteria. A certain level of these microorganisms can be expected with some raw foods. Improper storage or handling of these foods can contribute to a significant increase in the level of these microorganisms. Cooked foods often provide fertile media for rapid growth of microorganisms if they are not properly handled and stored.

Viruses can be foodborne/water-borne or transmitted to food by human, animal or other contact. Unlike bacteria, viruses are unable to reproduce outside a living cell. They cannot therefore replicate in food, and can only be carried by it.

Parasites are most often animal host-specific and can include humans in their life cycles. Parasitic infections are commonly associated with undercooked meat products or contaminated ready-to-eat food. Parasites in products that are intended to be eaten raw, marinated or partially cooked can be killed by effective freezing techniques.

Fungi include moulds and yeasts. Fungi can be beneficial, as they can be used in the production of certain foods (e.g. cheese). However, some fungi produce toxic substances (mycotoxins) which are toxic for humans and animals.

Chemical hazards

Chemical contaminants in food may be naturally occurring or may be added during the processing of food. Harmful chemicals at high levels have been associated with acute cases of foodborne illnesses and can be responsible for chronic illness at lower levels.

EXAMPLES OF CHEMICAL HAZARDS
Naturally occurring chemicals
Allergens
Mycotoxins (e.g. aflatoxin)
Scombrotoxin (histamine)
Ciguatoxin
Mushroom toxins
Shellfish toxins
• Paralytic shellfish poisoning (PSP)
• Diarrhoeic shellfish poisoning (DSP)
• Neurotoxic shellfish poisoning (NSP)
• Amnesic shellfish poisoning (ASP)
• Pyrrolizidine alkaloids
• Phytohaemagglutinin
Added chemicals
Polychlorinated biphenyls (PCBs)
Agricultural chemicals
• Pesticides
• Fertilizers
• Antibiotics
• Growth hormones
Prohibited substances
• Direct
• Indirect
Toxic elements and compounds
• Lead
• Zinc
• Cadmium
• Mercury
• Arsenic

- Cyanide

Food additives
Vitamins and minerals
Contaminants

- Lubricants
- Cleaners
- Sanitizers
- Coatings
- Paints
- Refrigerants
- Water or steam treatment chemicals
- Pest control chemicals

From packaging materials

Plasticizers
Vinyl chloride
Printing/coding inks
Adhesives
Lead
Tin

Physical hazards

Illness and injury can result from hard foreign objects in food. These physical hazards can result from contamination and/or poor practices at many points in the food chain from harvest to consumer, including those within the food establishment.

SOURCES OF INFORMATION FOR HAZARD ANALYSIS

The information required concerning potential hazards associated with a specific food can be obtained from a variety of sources including the following.

Reference texts

Depending on the experience and knowledge of the team, review of texts on HACCP, food microbiology, food processing and plant sanitation may be useful. Such texts include:

- *Procedures to implement the HACCP system.* International Association of Milk, Food and Environmental Sanitarians (IAMFES), 1991. Ames, Iowa, USA

- *HACCP in microbiological safety and quality.* International Commission on Microbiological Specifications for Foods (ICMSF), 1989. Boston, Massachusetts, USA, Blackwell Scientific Publications

- *An evaluation of the role of microbiological criteria for foods and food ingredients.* National Research Council (NRC) Committee on Food Protection, 1985. Washington, DC, USA, National Academy Press

- *Microorganisms in foods 1 - Their significance and methods of enumeration.* ICMSF/1978. Toronto, Ontario, Canada, University of Toronto Press

- *Microorganisms in foods 2 - Sampling for microbiological analysis: principles and specific applications.* ICMSF, 1986. Toronto, Ontario, Canada, University of Toronto Press (second edition)

- *Microbial ecology of foods.* Volume 1, *Factors affecting life and death of microorganisms;* Volume 2, *Food commodities.* ICMSF, 1980. Orlando, Florida, USA/Academic Press

EXAMPLES OF PHYSICAL HAZARDS

Material	Injury potential	Sources

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

Texts with more specific information on particular food products and food processes are of course available, depending on the product being considered. However, the best places to obtain access to these texts would be universities and research institutions.

Company complaints file

This file should be thoroughly examined. The causes of complaints should be reviewed to assist in hazard identification.

Scientific research and review papers

These papers can be a good source of specific and up-to-date information. They are published in the many food journals from around the world. University librarians can help search their library indexes as well as international data network systems for pertinent information on specific food products, ingredients, processes and packages. Abstracts can be reviewed and the papers obtained, if appropriate.

Epidemiological data on foodborne illness or disease

Where available, the HACCP team should review epidemiological data on foodborne illness or disease in the country or region of concern.

The World Wide Web - homepages on Internet

Use of the Internet may provide additional information related to hazards in foods useful to the analysis.

HOW TO CONDUCT A HAZARD ANALYSIS

After listing all the hazards (biological, chemical or physical) that may be reasonably expected at each step from primary production, processing, manufacturing and distribution until the point of consumption, the HACCP team should assess the potential significance or risk of each hazard by considering its likelihood of occurrence and severity. The estimate of the risk of a hazard occurring is based upon a combination of experience, epidemiological data and information in the technical literature. Severity is the degree of seriousness of the consequences of a hazard if the hazard is not controlled. There may be differences of opinion even among experts as to the risk of a hazard.

Hazards addressed under the HACCP system must be of such a nature that their prevention, elimination or reduction to acceptable levels is essential to the production of safe foods. Hazards of a low probability of occurrence and a low severity should not be addressed under the HACCP system but may be addressed through the good manufacturing practices (GMPs) contained in the Codex General Principles of Food Hygiene.

A hazard analysis must be conducted for each existing product or process type and for each new product. In addition, the hazard analysis done for a product or process type must be reviewed if any changes are made in raw material, product formulation, preparation, processing, packaging, distribution or intended use of the product.

For simplicity, the hazard analysis procedure has been broken down into the five following activities. Applying them in a logical sequential manner will help to avoid any omissions. Once these five activities have been completed, the HACCP team will have an extensive list of realistic potential hazards on Forms 5 (biological hazards), 6 (chemical hazards) and 7 (physical hazards).

1. Review incoming material

In order to complete this activity, use the product description form (Form 1) and the list of product ingredients and incoming material (Form 2).

Review the information on the product description form (Form 1) and determine how it could influence your interpretation during the analysis of the process. For example, a ready-to-eat product must not contain pathogens in amounts that may harm the consumer. On the other hand, if the end-product is not a ready-to-eat product, some microorganisms may be acceptable in the end-product if a further operation (e.g. cooking at home) will eliminate or reduce them to an acceptable level.

For each incoming material (ingredient or packaging material), write B, C or P directly on Form 2 (see example) to indicate the potential of a biological, chemical or physical hazard, using the sources of information described above. Each time a hazard is identified on Form 2, fully describe the hazard on Form 5 if it is a biological hazard, on Form 6 if it is a chemical hazard and on Form 7 if it is a physical hazard (see examples). Be specific when describing the hazards. For example, instead of writing "bacteria in incoming ingredient", write *"C. botulinum* in incoming mushroom".

To facilitate the identification of potential hazards, answer the following questions for each incoming material:

- Could pathogenic microorganisms, toxins, chemicals or physical objects possibly be present on/in this material?

- Are any returned or reworked products used as ingredients? If yes, is there a hazard linked to that practice?

- Are preservatives or additives used in the formulation to kill microorganisms or inhibit their growth or to extend shelf-life?

- Are any ingredients hazardous if used in excessive amounts? (for example, nitrites could be a chemical hazard if used excessively)

- Could any ingredients, if used in amounts lower than recommended or if omitted altogether, result in a hazard because of microbial vegetative or sporulated cell outgrowth?

- Does the amount and type of acid ingredients and the resulting pH of the final product affect growth or survival of microorganisms?

- Do the moisture content and the water activity (A_w) of the final product affect microbial growth? Do they affect the survival of pathogens (parasites, bacteria, fungi)?

- Should adequate refrigeration be maintained for products during transit or in holding?

2. Evaluate processing operations for hazards

The objective of this activity is to identify all realistic potential hazards related to each processing operation, the product flow and the employee traffic pattern. This can be accomplished by reviewing the process flow diagram (Form 3) and the plant schematic (Form 4) and modifying them as follows.

- Assign a number to each processing step on the process flow diagram (Form 3) horizontally from receiving to shipping (see example)

- Examine each step on the process flow diagram and determine if a hazard (biological, chemical or physical) exists for that operation

- Write B for biological, C for chemical and P for physical beside each operation where such a hazard has been identified (see example)

- Review the plant schematic and employee traffic pattern on Form 4 in the same manner

The hazards identified on Forms 3 and 4 should be fully described on the hazard analysis forms (Forms 5,6 and 7). The hazards should be related to the process. For example, if a biological hazard is identified at storing, a letter B is placed close to the storing operation on the process flow diagram (Form 3). Then "Improper storage temperature and humidity could result in increase of bacterial load" should be written on the biological hazards form (Form 5).

To help in determining if a hazard exists, the following questions should be answered for each processing step:

- Could contaminants reach the product during this processing operation? (consider personnel hygiene, contaminated equipment or material, cross-contamination from raw materials, leaking valves or plates, dead ends [niches], splashing, etc.)

- Could any microorganisms of concern multiply during this processing operation to the point where they constitute a hazard? (consider temperature, time)

3. Observe actual operating practices

The HACCP team must be very familiar with every detail of the operation under investigation. Any identified hazard must be recorded on the appropriate forms. The HACCP team shall:

- Observe the operation long enough to be confident that it comprises the usual process or practices

- Observe the employees (e.g. could raw or contaminated product cross-contaminate workers' hands, gloves or equipment used for finished or post-process product?)

- Observe hygienic practices and note the hazards

- Analyse if there is a kill step (process which destroys all microorganisms) during the process (if so, attention should be focused on potential cross-contamination after this processing operation)

4. Take measurements

It may be necessary to take measurements of important processing parameters to confirm actual operating conditions. Before measuring, make sure all devices are accurate and correctly calibrated.

The following are examples of some of the measurements that may be done, depending on the product or process type:

- Measure product temperatures, considering heat processing and cooling or chilling operations: take measurements at the coldest point of the product when heat processing is evaluated and at the warmest point of the product when cooling or chilling is evaluated (frequently at the centre of the largest piece)

- Measure time/temperature for cooking, pasteurizing, canning cooling (rates), storing, thawing, reconstituting, etc.

- Measure the dimension of the containers used to hold foods being cooled and the depth of the food mass

- Measure pressure, headspace, venting procedure, adequacy of container closure, initial temperatures and any other factors critical to the successful delivery of a scheduled process

- Measure the pH of the product during processing and also of the finished product, measuring pH at room temperature whenever possible

- Measure A_w of the product, running duplicate samples whenever possible (because of variations) and remembering to make corrections for ambient temperatures, as necessary

Sample collections, inoculated-pack studies and microbial challenge studies could be necessary when information on hazards is not otherwise available, for new products or for assessing expected shelf-life.

5. Analyse the measurements

A qualified individual (with proper scientific background) must analyse the measurements to interpret correctly the data collected. During the review and interpretation of the data, identified hazards are fully described on Forms 5,6 and 7.

For example:

- Plot time/temperature measurements using a computer or on graph paper

- Interpret controlled data versus optimal growth temperatures of microorganisms and temperature ranges at which they can multiply

- Estimate and evaluate probable cooling rates; interpret cooling rates and compare the measured temperatures with temperature ranges within which bacteria of concern multiply rapidly versus temperature at which growth begins, slows and ceases (see reference material); determine whether covers are used on containers to cool down foods (which may delay cooling but may also prevent contamination); if containers are stacked against each other in a manner affecting cooling or heating time/evaluate the impact

- Compare A_w and pH values to ranges at which pathogens multiply or are eliminated

- Evaluate the shelf stability of the product

CONTROL MEASURES

After the hazard analysis is completed, the team must then consider what control measures, if any, exist which can be applied for the control of each hazard. Control measures are any actions and activities that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. More than one measure may be required to control a specific hazard and more than one hazard may be controlled by a specified measure.

Risk analysis methods can help to determine the level of control that should be implemented to control a hazard.

Controlling biological hazards

Biological hazards can be controlled by limiting, removing or altering the growth kinetics microorganisms need to survive, grow and reproduce. They can be destroyed, eliminated or controlled by thermal processing (heating or cooking), freezing or drying.

Food growers or processors should have three objectives for their HACCP programmes with regard to biological hazards:

- To eliminate or significantly reduce the hazard
- To prevent or minimize microbial growth and toxin production
- To control contamination

The following are examples of control measures for biological hazards. For bacteria, control measures include:

- Temperature/time control (proper control of refrigeration and storage time, for example, minimizes the proliferation of microorganisms)

- Heating and cooking (thermal processing) for an adequate time and at an adequate temperature to eliminate microorganisms or reduce them to acceptable levels

- Cooling and freezing

- Fermentation and/or pH control (for example, lactic acid-producing bacteria in yoghurt inhibit the growth of other microorganisms that do not tolerate the acidic conditions and competition)

- Addition of salt or other preservatives, which at acceptable levels may inhibit growth of microorganisms

- Drying, which may use enough heat to kill microorganisms or may remove enough water from the food to prevent certain microorganisms from growing even when drying is conducted at lower temperatures

- Packaging conditions (vacuum packaging, for example, can be used to inhibit microorganisms that require air to grow)

- Source control, i.e. control of the presence and level of microorganisms by obtaining ingredients from suppliers who can demonstrate adequate controls over the ingredients (e.g. suppliers that follow an HACCP programme)

- Cleaning and sanitizing, which can eliminate or reduce the levels of microbiological contamination

- Personal and hygienic practices, which can reduce the levels of microbiological contamination

For viruses, control measures include:

- Thermal processing - heating or cooking methods such as steaming, frying or baking - which may destroy many but not all viruses (the type of virus determines the appropriate controls)

- Personal hygienic practices, including the exclusion of workers affected by certain viral diseases, e.g. hepatitis

For parasites (worms and protozoa), control measures include:

- Dietary control (infection from *Trichinella spiralis* in pork, for example, has decreased as a result of better control of the pigs' diet and environment) - a method not always practical, however, for all species of animals used for food (the diet and environment of wild fish, for example, cannot be controlled)

- Heating, drying or freezing

- Salting or brining

- Visual examination, which can be used in some foods to detect parasites (e.g. a procedure called "candling" can be used for certain fish)

• Good personal hygiene practices by food handlers, proper disposal of human faeces and proper sewage treatment

Controlling chemical hazards

The following are examples of control measures for chemical hazards:

• Source control, i.e. specifications for raw materials and ingredients and vendor certification that harmful chemicals or levels are not present

• Processing control, i.e. formulation control and the proper use and control of food additives and their levels

• Proper segregation of non-food chemicals during storage and handling

• Control of incidental contamination from chemicals (e.g. greases, lubricants, water and steam treatment chemicals, paints)

• Labelling control, i.e. ascertaining that the finished product is accurately labelled with ingredients and known allergens

Controlling physical hazards

The following are examples of control measures for physical hazards:

• Source control, i.e. specifications for raw materials and ingredients and vendor certification that unacceptable physical hazards or levels are not present

• Processing control, e.g. use of magnets, metal detectors, sifter screens, de-stoners, clarifiers, air tumblers

• Environmental control, i.e. ensuring that good manufacturing practices are followed and that no physical contamination occurs to the food through the building, facilities, work surfaces or equipment

HAZARD ASSESSMENT

The information gathered from the hazard analysis can be used to determine:

• The severity of the hazard(s)
• Risks associated with hazards identified at various stages of the operation
• The points, steps or procedures at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to an acceptable level, i.e. critical control points (CCPs)

Severity

Severity is the magnitude of a hazard or the degree of consequences that can result when a hazard exists. Disease-causing hazards can be categorized according to their severity. One system uses the categories of:

• High (life-threatening) - examples include illnesses caused by *Clostridium botulinum, Salmonella typhi, Listeria monocytogenes, Escherichia coli* 0157:H7, *Vibrio cholerae, Vibrio vulnificus,* paralytic shellfish poisoning, amnesic shellfish poisoning

• Moderate (severe or chronic) - examples include illnesses caused by *Brucella* spp., *Campylobacter* spp.. *Salmonella* spp., *Shigella* spp.. *Streptococcus* type A, *Yersinia entercolitica,* hepatitis A virus, mycotoxins, ciquatera toxin

• Low (moderate or mild) - examples include illnesses caused by *Bacillus* spp., *Clostridium perfringens, Staphylococcus aureus,* Norwalk virus, most parasites, histamine-like substances and most heavy metals that cause mild acute illnesses

Risk of hazard

Risk is a function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food. Degrees of risk can be categorized as high (H), moderate (M), low (L) and negligible (N).

Identification of points, steps and procedures

The above data can then be used to ascertain the appropriate locations to establish critical control points, the degree of monitoring required and any changes in the process or ingredients that would reduce the magnitude of the hazards that exist.

The Figure illustrates one method of assessing the significance of the hazard. By taking into account the probability of occurrence (inverse to the degree of control) and the severity of consequences, the significance of the hazard can be differentiated as satisfactory (Sa), minor (Mi), major (Ma) or critical (Cr).

Two-dimensional health risk assessment model

Note: Likelihood of occurrence is inversely proportional; to the degree of control.

Example

FORM 2

PRODUCT INGREDIENTS AND INCOMING MATERIAL

PRODUCT NAME(S): *Canned mushroom*

RAW MATERIAL	***PACKAGING MATERIAL***	***DRY INGREDIENTS***
Mushrooms (domestic, white) B, C, P	*Cans B, C, P Ends B, C*	*Salt B, C Ascorbic acid B, C Citric acid B, C*
OTHER		
Water (municipal) B, C		

DATE:_____ APPROVED BY:_____

Example

FORM 3

FLOW DIAGRAM

PRODUCT NAME(S): *Canned mushroom*

MUSHROOM (Raw)	***EMPTY CANS/ENDS***	***DRY INGREDIENTS***	***WATER (municipal)***
*1. Receiving **P***	*2. Receiving **P***	*3. Receiving **P***	*4. Intaking*
*5. Storing **BP***	*6. Storing **BCP***	*7. Storing **BCP***	
8. Dumping/Washing	*9. Inspecting/Depalletizing BP*	*10. Dumping*	
*11. Blanching **BC***	*12. Conveying **BP***	*13. Mixing*	
14. Conveying/Inspecting CP	*15. Washing*		
*16. Slicing/Dicing **CP***	*17. Brine injecting*		
18. Foreign object removing	*19. Filling **CP***		

	*20. Weighing **B***		
	*21. Water filling **B***		
	*22. Head-spacing **B***		
	*23. End feeding/Closing/ Inspecting **BC***		*24. Chlorinating*
	*25. Thermal processing **B***		
	*26. Cooling **B***		
	*2 7. Conveying/Drying **B***		
	*28. Labelling/Storing **B***		
	*29. Shipping **B***		

DATE: _____ APPROVED BY: _____

Example

FORM 5

HAZARD IDENTIFICATION: BIOLOGICAL HAZARDS

PRODUCT NAME(S): *Canned mushroom*

List all biological hazards related to ingredients, incoming material, processing, product flow, etc.

Identified biological hazards	**Controlled at**
INGREDIENTS/MATERIALS	
Mushrooms *- could contain C. botulinum or other pathogenic organisms, yeast or moulds*	
Dry ingredients *- could contain bacterial spores - could contain rodent excrement*	
Water *- could contain coliform or spore-forming bacteria or other microorganisms*	
Empty cans/ends *- could arrive with serious internal double seam or body plate defects which could result in leakage causing post-process contamination - could arrive with serious external double seam, body plate, lacquer/coating defects or damage which could result in leakage causing post-process contamination*	
PROCESS STEPS	
5. Refrigerated mushroom storing *- improper storage temperature and humidity could result in increase of bacterial load*	
6. Can/end storing *- physical damage could result in serious double seam defects which could result in post-process contamination with pathogenic bacteria* *- could be contaminated with rodent excrement*	
7. Dry ingredient storing *- could be contaminated with rodent excrement*	
9. Can depalletizing/inspection *- incorrect cans, physical damage or serious visible defects could result in leakage and post-process contamination with pathogenic bacteria*	
11. Mushroom blanching *- improper cleaning of the blancher could result in the growth of thermophilic bacteria in mushrooms* *- inadequate blanching could result in insufficient removal of gases which could cause stress on double seams and perforations and lead to post-process contamination with pathogenic bacteria* *- excessive blanching could result in textural changes to the mushrooms which could result in inadequate thermal processing*	
12. Can conveying	

- physical damage could result in the formation of defective double seams which could lead to post-process contamination with pathogenic bacteria	
20. Weighing *- overfilled cans not properly rejected for overweight could be underprocessed*	
21. Water filling *- inadequate temperature could result in low initial temperature and subsequent underprocessing*	
22. Headspacing *- insufficient headspace could result in excessive internal pressure during processing causing distorted seams and leakage contamination*	
23. End feeding/closing/inspecting *- ends with damaged curls or other serious defects could result in leakage and contamination with pathogenic bacteria* *- improperly formed double seams could result in leakage and contamination with pathogenic bacteria*	
25. Thermal processing *- non-validated process or vent schedule could result in underprocessing and survival of pathogenic bacteria* *- improper flow patterns in processing area could result in heat-processed cans being contaminated with unclean water from unprocessed baskets of cans* *- improper flew design in processing area could result in retort baskets missing the retort, allowing growth of pathogenic bacteria* *- excessive time lapse between closing and retorting could result in excessive buildup of bacteria, some of which could survive the thermal process* *- lack of adherence to time, temperature and other critical factors of the scheduled process or vent schedule could result in inadequate heat treatment, allowing the survival of pathogenic bacteria*	
26. Cooling *- insufficient chlorinated cooling water could result in contamination of product during contraction of cans* *- excess chlorine in cooling water could result in corrosion and subsequent leakage and contamination of product* *- insufficient contact time between the chlorine and water could result in contamination of product during contraction of the cans* *- insufficient or excessive cooling could result in thermophilic spoilage or post-process contamination because of leakage of corroded cans*	
27. Conveying/drying *- contaminated water from wet and unclean post-process equipment could contaminate product*	
28. Labelling/storing *- physical damage to cans could result in leakage and contamination of product* *- high temperatures could result in growth of thermophilic bacteria*	
29. Shipping *- physical damage to cans could result in leakage and contamination of product*	

DATE: _____ APPROVED BY: _____

Example

FORM 6

HAZARD IDENTIFICATION: CHEMICAL HAZARDS

PRODUCT NAME(S): *Canned mushroom*

List all chemical hazards related to ingredients, incoming material, processing, product flow, etc.

Identified chemical hazards	**Controlled at**
INGREDIENTS/MATERIALS	
Mushrooms	

- could contain pesticide residues *- could contain heat-stable staphylococcal enterotoxin from improper handling*	
Water *- could be contaminated with dissolved heavy metals or toxic substances*	
Empty cans/ends *- cans/ends could be contaminated with greases/oils or cleaning chemicals*	
PROCESS STEPS	
6. Can/end storing *- cans/ends could become contaminated with non-food chemicals as a result of improper storage*	
7. Dry ingredient storing *- food ingredients could become contaminated with non-food chemicals if improperly stored*	
11. Mushroom blanching *- cleaning-chemical residues could contaminate the mushrooms* *- if live steam is used, boiler water additives could carry over and contaminate the product*	
14, 16, 19, 23. Mushroom conveying, mushroom slicing/dicing, filling, end feeding/closing *- cleaning-chemical residues or lubrificants could contaminate the mushrooms*	

DATE:_____ APPROVED BY:_____

Example

FORM 7

HAZARD IDENTIFICATION: PHYSICAL HAZARDS

PRODUCT NAME(S): *Canned mushroom*

List all physical hazards related to ingredients, incoming material, processing, product flow, etc.

Identified physical hazards	**Controlled at**
INGREDIENTS/MATERIALS	
Mushrooms *- could be contaminated with harmful extraneous materials, e.g. glass, metal, plastic, wood*	
Empty cans *- could contain metal fragments, etc.*	
Dry ingredients *- could be contaminated with harmful extraneous materials*	
INGREDIENTS/MATERIALS	
1. Mushroom receiving *- inadequate protection against harmful extraneous material could result in contamination of mushrooms*	
2. Can/end receiving *- inadequate protection against harmful extraneous material could result in contamination of cans and ends*	
3. Dry ingredient receiving *- inadequate protection against harmful extraneous material could result in contamination of ingredients*	
5. Mushroom storing *- inadequate protection against harmful extraneous material could result in contamination of raw mushrooms*	
6. Can/end storing *- inadequate protection against harmful extraneous material could result in contamination*	

7. Dry ingredient storing *- inadequate protection against harmful extraneous material could result in contamination of food ingredients*	
9. Can inspection/depalletizing *- empty cans coming from storage could contain harmful extraneous material which could result in contamination of food product*	
12. Can conveying *- inappropriate design and protection against harmful extraneous material could result in contamination of food product*	
14. Mushroom convening/inspection *- inappropriate design and protection against harmful extraneous material could result in contamination of the mushrooms*	
16. Mushrooms slicing/dicing *- product could become contaminated with metal fragments from plant machinery*	
18. Foreign object removal *- inadequate monitoring of foreign object removal could allow foreign objects to contaminate the product*	
19. Filling *- filled cans of mushrooms could become contaminated with metal fragments from the filling equipment*	

DATE:_____ APPROVED BY:_____

Module 7 - Determine critical control points - Task 7/Principle 2

Objective

To provide the trainees with the necessary knowledge and abilities to determine critical control points in the HACCP system

Suggested methods of instruction

- Lecture
- Exercises

Aids

- Overhead transparencies/slides
- Handout

Reference

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

Time frame

- One hour lecture
- 90 minutes exercise
- 60 minutes reports on exercise

Content

- Critical control points
- Review of identified hazards

- Identification of CCPs
- Parameters attached to CCPs
- Examples, Forms 5 to 9

Exercise

The instructor should have each "HACCP team" complete Form 8 and identify the critical control points in their selected operation. Each team will then present a report using overhead transparencies of the completed Form 8, explaining the team's rationale for answering the associated questions and the determination of CCPs.

Learning outcome

The trainees should have the necessary knowledge and abilities to determine critical control points, which should be demonstrated during their reports on the exercise of using the Codex decision tree to determine critical control points for their selected operations.

CRITICAL CONTROL POINTS

The determination of critical control points (Task 7) is the second principle of HACCP. The Codex guidelines define a critical control point (CCP) as "a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level".

If a hazard has been identified at a step where control is necessary for safety/and if no control measure exists at that step or at any other, then the product or process should be modified at that step, or at an earlier or later stage, to include a control measure.

The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree such as that included in the Codex *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* (see Figure) which indicates a logical reasoning approach. The application of the decision tree should be flexible according to the type of operation (production, slaughter, processing, storage, distribution or other). The decision tree proposed by Codex may not be applicable to all situations. Other approaches based on risk analysis may be used (see Annex 2).

REVIEW OF IDENTIFIED HAZARDS

Prior to determining CCPs, Forms 5, 6 and 7 should be reviewed to verify if any of the identified hazards are fully controlled by the application of the Codex General Principles of Food Hygiene, good manufacturing practices (GMPs) or good hygienic practices (GHPs). Furthermore, an on-site verification must be carried out by the HACCP team to verify if those hazards are in fact controlled by the application of GMP/GHP measures. If these hazards are controlled. Forms 5, 6 and 7 should be filled in accordingly.

Hazards that are not fully controlled by GMPs should be analysed to determine whether they are CCPs or not.

The decision tree consists of a systematic series of four questions designed to assess objectively whether a CCP is required to control the identified hazard at a specific operation of the process.

Form 8 was developed from the decision tree and records all the appropriate information. This form will serve as a reference document as it is the only document in which all the ingredients and all the process operations are recorded together with the identified hazards. The form can be used for reference in re-evaluating why a certain process operation was or was not designated as a CCP.

Question 1: Do control measure(s) exist?

Question 1 should be interpreted as asking whether or not the operator could use a control measure at this operation or anywhere else in the food establishment to control the identified hazard. Control measures could include, for example, temperature control, visual examination or use of a metal detector.

If the response to Question 1 is "yes", in the Question 1 column on Form 8 clearly describe the control measure(s) that the operator could use and proceed to Question 2 in the decision tree.

If the response is "no", i.e. a control measure does not exist, indicate how the identified hazard will be controlled before or after the manufacturing process (outside the control of the operator). For example, salmonella in raw poultry is controlled by the end-user. Alternatively, modify the operation, process or product so that a control measure exists, and then proceed to the next identified hazard in the process.

Example of decision tree to identify critical control points

Question 2: Is the step specifically designed to eliminate or reduce the likely occurrence of the identified hazard to an acceptable level?

Examples of procedures or operations in a food process that are designed specifically to identified hazard include:

- The retorting operation in a canning plant
- Pasteurization
- Chlorination of cooling water
- The addition of a metal detector to a process line
- A particular sanitation procedure performed by the operator to clean contact surfaces without which the line would be stopped and the product would be contaminated

Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of the HACCP plan.

If the process or operation is specifically designed to eliminate or reduce the likely occurrence of the hazard to an acceptable level, answer "yes" under Question 2 on Form 8; such a step automatically becomes a CCP and it should be identified as such in the last column of Form 8.

If the step is not specifically designed, answer "no" and proceed to the next question. Note that Question 2 applies to processing operations only. For incoming materials as delivered, write "no" and proceed to Question 3.

Question 3: Could contamination with the identified hazard occur in excess of acceptable levels or increase to unacceptable levels?

In other words, is it likely that the hazard could have an impact on the safety of the product? Question 3 refers to both probability (likelihood) and seriousness. The response is a judgement call involving risk assessment which must be based on all of the information that has been gathered. When answering "yes" or "no", it may be useful to explain in the Question 3 column the basis of the response, for future reference. This would be especially useful in dealing with some hazards that may be controversial.

If searches in the company's complaint files or scientific literature suggest that contamination with the identified hazard may increase to an unacceptable level and result in an unacceptable health hazard, answer "yes" and proceed to the next question in the decision tree.

If the contamination is not known to represent a substantial threat to human health or is not likely to occur, answer "no" (not a CCP) and proceed to the next identified hazard in the process.

Question 4: Will a subsequent step eliminate the identified hazard or reduce likely occurrence to an acceptable level?

This question is designed to identify those hazards that are known to represent a human health threat or that could increase to an unacceptable level, and that will be controlled by a subsequent process operation.

If no subsequent operation is scheduled in the process to control this identified hazard, answer "no". This particular process step becomes a CCP and should be identified as such in the last column of Form 8.

If there is a subsequent operation or operations later in the process that will eliminate the identified hazard or reduce it to an acceptable level, answer "yes". This step is not a CCP. However, you will need to identify the subsequent step(s) that control(s) the hazard, thus proceeding to the next identified hazard.

IDENTIFICATION OF CCPs

The last column in Form 8 is where CCPs are identified. CCPs should be identified numerically with a category qualifier B, P or C for biological, physical or chemical. For example, if the first CCP identified will control a biological hazard, it is recorded as CCP-1 (B). If the second CCP identified will control a chemical hazard, it is recorded as CCP-2 (C). If the fifth CCP will control both a biological and a chemical hazard at the same processing operation, it is recorded as CCP-5 (BC). This identification protocol was developed to identify CCPs sequentially, independent of process operation numbering, and to indicate readily to the user of the HACCP plan which type(s) of hazard need(s) to be controlled at a particular process operation.

Once all hazards related to incoming materials and process operations have been analysed in Form 8 to determine where and how they can be controlled, the right-hand column ("Controlled at") of Forms 5,6 and 7 is completed to identify where each hazard is controlled (see examples).

For hazards fully controlled by application of the Codex General Principles of Food Hygiene, write "GMP/GHP" on Forms 5,6 and 7 and specify the applicable programme. For hazards for which the answer to Question 3 is "no", write "not applicable" in the right-hand column on Forms 5,6 and 7.

Hazards identified on Forms 5, 6 and 7 are either controlled at some point in the food establishment or cannot be controlled by the food operator. Each hazard not controlled by the operator should be re-examined to determine whether or not a control measure could be established by the operator.

- If yes, then the appropriate control measure should be identified and Form 8 should be reviewed accordingly

- If no, then report these hazards on Form 9 and indicate how these hazards could be addressed outside the operator's manufacturing process

PARAMETERS ATTACHED TO CCPs

Once the CCPs have been established, the next step is to report the CCPs on Form 10 and to document on the same form the parameters that will be monitored and controlled.

HACCP Principles 3 to 7 will lead to the development of the establishment's HACCP plan which will be described on Form 10 (described in Modules 8 to 12). The critical limits, monitoring procedures, deviation procedures, verification procedures and record keeping will be described in the HACCP plan. This HACCP plan will provide the written guidelines that will be followed in the establishment.

Example

FORM 5

HAZARD IDENTIFICATION: BIOLOGICAL HAZARDS

PRODUCT NAME(S): *Canned mushroom*

List all biological hazards related to ingredients, incoming material, processing, product flow, etc.

Identified biological hazards	Controlled at
INGREDIENTS/MATERIALS	
<u>Mushrooms</u> *- could contain C. botulinum or other pathogenic organisms, yeast or moulds*	*- CCP5B*
<u>Dry ingredients</u> *- could contain bacterial spores* *- could contain rodent excrement*	*- CCP5B* *- GMP/GHP* (*Sanitation*)
<u>Water</u> *- could contain coliform or spore-forming bacteria or other microorganisms*	*- GMP/GHP* (*Premises*)
<u>Empty cans/ends</u> *- could arrive with serious internal double seam or body plate defects which could result in leakage causing post-process contamination* *- could arrive with serious external double seam, body plate, lacquer/coating defects or damage which could result in leakage causing post-process contamination*	*- CCP4B* *- CCP1B/CCP4B*
PROCESS STEPS	
5. <u>Refrigerated mushroom storing</u> *- improper storage temperature and humidity could result in increase of bacterial load*	*- GMP/GHP* (*Equipment*)
6. <u>Can/end storing</u> *- physical damage could result in serious double seam defects which could result in post-process contamination with pathogenic bacteria* *- could be contaminated with rodent excrement*	*- CCP1B* *- GMP/GHP* (*Sanitation*)
7. <u>Dry ingredient storms</u>	*- GMP/GHP*

- could be contaminated with rodent excrement	(*Sanitation*)
9. Can depalletizing/inspection *- incorrect cans, physical damage or serious visible defects could result in leakage and post-process contamination with pathogenic bacteria*	*- CCP1B*
11. Mushroom blanching *- improper cleaning of the blancher could result in the growth of thermophilic bacteria in mushrooms* *- inadequate blanching could result in insufficient removal of gases which could cause stress on double seams and perforations and lead to post-process contamination with pathogenic bacteria* *- excessive blanching could result in textural changes to the mushrooms which could result in inadequate thermal processing*	*- GMP/GHP* (*Sanitation*) *- GMP/GHP* (*Equipment*)
12. Can conveying *- physical damage could result in the formation of defective double seams which could lead to post-process contamination with pathogenic bacteria*	*- GMP/GHP* (*Equipment*)
20. Weighing *- overfilled cans not properly rejected for overweight could be underprocessed*	*- CCP2B*
21. Water filling *- inadequate temperature could result in low initial temperature and subsequent underprocessing*	*- CCP5B*
22. Headspacing *- insufficient headspace could result in excessive internal pressure during processing causing distorted seams and leakage contamination*	*- CCP3B*
23. End feeding/closing/inspecting *- ends with damaged curls or other serious defects could result in leakage and contamination with pathogenic bacteria* *- improperly formed double seams could result in leakage and contamination with pathogenic bacteria*	*- CCP4B* *- CCP4B*
25. Thermal processing *- non-validated process or vent schedule could result in underprocessing and survival of pathogenic bacteria* *- improper flow patterns in processing area could result in heat-processed cans being contaminated with unclean water from unprocessed baskets of cans* *- improper flow design in processing area could result in retort baskets missing the retort, allowing growth of pathogenic bacteria* *- excessive time lapse between closing and retorting could result in excessive buildup of bacteria, some of which could survive the thermal process* *- lack of adherence to time, temperature and other critical factors of the scheduled process or vent schedule could result in inadequate heat treatment, allowing the survival of pathogenic bacteria*	*- GMP/GHP* (*Records*) *- GMP/GHP* (*Personnel*) *- CCP5B* *- CCP5B* *- CCP5B*
26. Cooling *- insufficient chlorinated cooling water could result in contamination of product during contraction of cans* *- excess chlorine in cooling water could result in corrosion and subsequent leakage and contamination of product* *- insufficient contact time between the chlorine and water could result in contamination of product during contraction of the cans* *- insufficient or excessive cooling could result in thermophilic spoilage or post-process contamination because of leakage of corroded cans*	*- CCP6B* *- CCP6B* *- GMP/GHP* (*Sanitation, Personnel* *- GMP/GHP* (*Sanitation, Personnel*)
27. Conveying/drying *- contaminated -water from wet and unclean post-process equipment could contaminate product*	*- GMP/GHP* (*Sanitation*)
28. Labelling/storing *- physical damage to cans could result in leakage and contamination of product* *- high temperatures could result in growth of thermophilic bacteria*	*- GMP/GHP* (*Equipment, Personnel*) *- GMP/GHP* (*Personnel*)

29. Shipping *- physical damage to cans could result in leakage and contamination of product*	*- GMP/GHP* (*Personnel Training*)

DATE: _____ APPROVED BY: _____

Example

FORM 6

HAZARD IDENTIFICATION: CHEMICAL HAZARDS

PRODUCT NAME(S): *Canned mushroom*

List all chemical hazards related to ingredients, incoming material, processing, product flow, etc.

Identified chemical hazards	Controlled at
INGREDIENTS/MATERIALS	
Mushrooms *- could contain pesticide residues* *- could contain heat-stable staphylococcal enterotoxin from improper handling*	*See Form 9* *See Form 9*
Water *- could be contaminated with dissolved heavy metals or toxic substances*	*- GMP/GHP* (*Premises*)
Empty cans/ends *- cans/ends could be contaminated with greases/oils or cleaning chemicals*	*- GMP/GHP* (*Receiving, Storage & Transport*)
PROCESS STEPS	
6. Can/end storing *- cans/ends could become contaminated with non-food chemicals as a result of improper storage*	*- GMP/GHP* (*Sanitation*)
7. Dry ingredient storing *- food ingredients could become contaminated with non-food chemicals if improperly stored*	*- GMP/GHP* (*Sanitation*)
11. Mushroom blanching *- cleaning-chemical residues could contaminate the mushrooms* *- if live steam is used, boiler water additives could carry over and contaminate the product*	*- GMP/GHP* (*Sanitation*) *- GMP/GHP* (*Sanitation*)
14, 16, 19, 23. Mushroom conveying, mushroom slicing/dicing, filling, end feeding/closing *- cleaning-chemical residues or lubricants could contaminate the mushrooms*	*- GMP/GHP* (*Sanitation*)

DATE:_____ APPROVED BY:_____

Example

FORM 7

HAZARD IDENTIFICATION: PHYSICAL HAZARDS

PRODUCT NAME(S): *Canned mushroom*

List all physical hazards related to ingredients, incoming material, processing, product flow, etc.

Identified physical hazards	Controlled at
INGREDIENTS/MATERIALS	
Mushrooms *- could be contaminated with harmful extraneous materials, e.g. glass, metal, plastic, wood*	*Not applicable* (*not likely to get through equipment and inspection belt*)
Empty cans *- could contain metal fragments, etc.*	*- GMP/GHP* (*Receiving, Storing & Transport*)
Dry ingredients *- could be contaminated with harmful extraneous materials*	*- GMP/GHP* (*Receiving, Storing & Transport*)
INGREDIENTS/MATERIALS	

1. Mushroom receiving *- inadequate protection against harmful extraneous material could result in contamination of mushrooms*	*- GMP/GHP (Premises)*
2. Can/end receiving *- inadequate protection against harmful extraneous material could result in contamination of cans and ends*	*- GMP/GHP (Premises)*
3. Dry ingredient receiving *- inadequate protection against harmful extraneous material could result in contamination of ingredients*	*- GMP/GHP (Premises)*
5. Mushroom storing *- inadequate protection against harmful extraneous material could result in contamination of raw mushrooms*	*- GMP/GHP (Premises, Receiving, Storage & Transport)*
6. Can/end storing *- inadequate protection against harmful extraneous material could result in contamination*	*- GMP/GHP (Premises, Receiving, Storage & Transport)*
7. Dry ingredient storing *- inadequate protection against harmful extraneous material could result in contamination of food ingredients*	*- GMP/GHP (Premises, Receiving, Storage & Transport)*
9. Can inspection/depalletizing *- empty cans coming from storage could contain harmful extraneous material which could result in contamination of food product*	*- CC1P*
12. Can conveying *- inappropriate design and protection against harmful extraneous material could result in contamination of food product*	*- GMP/GHP (Equipment)*
14. Mushroom conveying/inspection *- inappropriate design and protection against harmful extraneous material could result in contamination of the mushrooms*	*- GMP/GHP (Premises, Equipment, Personnel)*
16. Mushrooms slicing/dicing *- product could become contaminated with metal fragments from plant machinery*	*- GMP/GHP (Equipment)*
18. Foreign object removal *- inadequate monitoring of foreign object removal could allow foreign objects to contaminate the product*	*- GMP/GHP (Equipment)*
19. Filling *- filled cans of mushrooms could become contaminated with metal fragments from the filling equipment*	*- GMP/GHP (Equipment)*

DATE:_____ APPROVED BY:_____

Example

FORM 8

CCP DETERMINATION

Process step/ incoming material	**Category and identified hazard**	**Question 1**	**Question 2**	**Question 3**	**Question 4**	**C numbe**
Mushrooms as delivered	***B** - pathogens*	***Yes** heat treatment*	*N/A*	***Yes***	***Yes** thermal processing (25)*	
	***C** - pesticides* ***C** - heat-stable toxins*	***No** control is at farms/growers* ***No** control is at farms/growers, storage*				

	P *- harmful extraneous material (HEM)*	***Yes*** *visual inspection and foreign object removal*	***Yes***	***No***		
Empty cans as delivered	***B*** *-post-process contamination from serious internal seam defects*	***Yes*** *can tear-down and inspection*	*N/A*	***Yes***	***Yes*** *closing and inspecting (23)*	
	B *- post-process contamination from serious external visible can defects*	***Yes*** *visual can inspection*	*N/A*	***Yes***	***Yes*** *inspecting/ depalletizing (9)*	
	C *- cleaning chemicals (GMPs)* ***P****-HEM*		*N/A*	***Yes***	***Yes*** *inspecting/ depalletizing (9)*	
Dry ingredients as delivered	***B*** *- bacterial spores*	***Yes*** *heat treatment*	*N/A*	***Yes***	***Yes*** *thermal processing (25)*	
	B *- rodent excrement (GMPs)*					
	P *- HEM (GMPs)*					
Water at intake	***B*** *- faecal coliform (GMPs)*					
	C *- heavy metals and other toxic chemicals (GMPs)*					
1. Mushroom receiving	***P*** *- HEM (GMPs)*					
2. Can/end receiving	***P*** *- HEM (GMPs)*					
3. Dry ingredient receiving	***P*** *- HEM (GMPs)*					
5. Mushrooms at receiving	***B*** *- growth of pathogens (GMPs)*					
	P *- HEM (GMPs)*					
6. Can/end storing	***B*** *- post-process contamination because of damaged cans/ends*	***Yes*** *visual Inspection*	***No***	***Yes***	***Yes*** *inspecting/ depalletizing (9)*	
	B *- rodent excrement*					

	(*GMPs*)					
	C *- cleaning chemicals* (*GMPs*)					
	P *- HEM* (*GMPs*)					
7. Dry ingredient storing	***B*** *- rodent excrement* (*GMPs*)					
	C *- cleaning chemicals* (*GMPs*)					
	P *- HEM* (*GMPs*)					
9. Can inspecting/ depalletizing	***B*** *- post-process contamination because of incorrect cans or serious can defects*	***Yes*** *visual inspection*	***Yes***	***Yes***		***C 1 (BP)***
	P*-HEM*	***Yes*** *visual inspection*	***Yes***	***Yes***		
11. Mushroom blanching	***B*** *- growth of thermophiles, textural changes affecting thermal process* (*GMPs*)					
	B *- inadequate removal of gases* (*GMPs*)					
	C *- cleaning chemicals* (*GMPs*)					
12. Can conveying	***B*** *- post-process contamination because of damage* (*GMPs*)					
	P *- HEM* (*GMPs*)					
14. Mushroom conveying/inspecting	***C*** *- cleaning chemicals* (*GMPs*)					
	P *- HEM* (*GMPs*)					
16. Mushroom slicing/dicing	***C*** *- cleaning chemicals, lubrificants* (*GMPs*)					
	P *- HEM* (*GMPs*)					
18. Foreign object removal	***P*** *- metal fragments* (*GMPs*)					
19. Filling	***C*** *- cleaning*					

	chemicals, lubrificants (*GMPs*)					
	***P** - metal-fragments* (*GMPs*)					
20. Weighing	***B** - product heavier than maximum fill weight in scheduled process*	***Yes** weighing*	***Yes***	***Yes***	***No***	***C 2 (B)***
21. Water filling	***B** - inadequate temperature resulting in low initial temperature* (*IT*) *for process*	***Yes** take IT just prior to thermal process*	***No***	***Yes***	***Yes** thermal processing* (*25*)	
22. Head-spacing	***B** - insufficient headspace resulting in distorted, potentially leaking seams*	*Yes*	***Yes***	***Yes***	***No***	***C 3 (B)***
23. End feeding/ closing/inspection	***B** - post-process contamination because of damaged ends*	***Yes** visual inspection*	***Yes***	***Yes***	***No***	***C 4 (B)***
	***B** - post-process contamination because of improperly formed seams*	***Yes** visual and teardown can inspection*	***Yes***	***Yes***	***No***	
	***C** - cleaning chemicals, lubrificants* (*GMPs*)					
25. *Thermal processing*	***B** - non-validated process or vent schedule could result in underprocessing and survival of pathogenic bacteria* (*GMPs*)					
	***B** - improper flow patterns for process could result in cross-contamination* (*GMPs*)					
	***B** - improper flow patterns for process could allow bypass of*	***Yes** use of heat-sensitive indicator*	***Yes***	***Yes***	***No***	***C 5 (B)***

	thermal process					
	***B** - excessive delays between closing and retorting could result in excessive growth of pathogenic bacteria*	***Yes** monitor time lapse between the two operations*	***Yes***	***Yes***	***No***	
	***B** - lack of adherence to time, temperature and. other critical factors of scheduled process or vent schedule could result in inadequate heat treatment and growth of pathogens*	***Yes** control critical factors of scheduled process and vent schedule*	***Yes***	***Yes***	***No***	
26. Cooling	***B** - post-process contamination during cooling/contracting of cans because of insufficiently chlorinated cooling water*	***Yes** control chlorine level in cooling water*	***Yes***	***Yes***	***No***	***C 6 (B)***
	***B** - post-process contamination because of leakage resulting from corrosion from excessive chlorine cleaning chemicals*	***Yes** control chlorine level in cooling water*	***Yes***	***Yes***	***No***	
	***B** - insufficient chlorine contact time could lead to contamination (GMPs)*					
	***B** - insufficient or excessive cooling could result in thermophilic spoilage or contamination because of corrosion leakage (GMPs)*					
27. Conveying/drying	***B** - unclean wet equipment*					

	could lead to contamination (*GMPs*)					
28. Labelling/storing	***B** - post-process contamination because of damaged cans* (*GMPs*)					
	***B** - growth of thermopiles* (*GMPs*)					
29. Shipping	***B** - post-process contamination because of damaged cans* (*GMPs*)					

Instructions:

• **Category and identified hazard:** Determine if hazard is fully controlled by adherence to Codex General Principles of Food Hygiene. If **Yes**, indicate "GMPs", describe and proceed to next identified hazard. If **No**, proceed to Question 1.

• **Question 1: Do control preventive measure(s) exist?** If **No**, this is not a CCP. Identify how the hazard can be controlled before or after the process and proceed to the next identified hazard. If **Yes,** describe and proceed to the next question.

• **Question 2: Is the operation specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level?** If **No**, proceed to Question 3. If **Yes,** this is a CCP; identify it as such in the last column.

• **Question 3: Could contamination with identified hazard(s) occur in** excess **of acceptable level(s) or could these increase to unacceptable levels?** If **No**, this is not a CCP; proceed to the next identified hazard. If **Yes**, proceed to Question 4.

• **Question 4: Will a subsequent operation eliminate identified hazard(s) or reduce likely occurrence to an acceptable level?** If **No**, this is a CCP; identify it as such in the last column. If **Yes**, this is not a CCP; identify the subsequent step and proceed to the next identified hazard.

Example
FORM 9
UNADDRESSED HAZARDS
PRODUCT NAME(S): *Canned mushrooms* List any biological, chemical and/or physical hazards that are not controlled at the establishment.

Unaddressed hazard from previous list	**Identified methods of addressing the hazard (e.g. cooking instructions, public education, use by date, etc.)**
***C** - raw mushrooms could contain pesticide residues*	*Upstream* (*farm-level*) *programmes such as:* *A. Training persons who apply pesticides* *B. Purchasing registered pesticides for growers* *C. Auditing growers' application of pesticides and records thereof* *D. Requiring periodic pesticide residue analysis*

	reports
***C** - raw mushrooms could contain heat-stable staphylococcal enterotoxin from improper grower handling*	*Upstream (farm-level) programmes such as:* *A. Training growers on handling of raw product* *B. Ensuring growers' use of proper, effective refrigeration equipment* *C. Ensuring prompt delivery of raw product after picking*

DATE:_____ APPROVED BY:_____

Module 8 - Establish critical limits for each critical control point - Task 8/Principle 3

Objective

To provide the trainees with the necessary knowledge and abilities to establish critical limits for the critical control points in the HACCP system

Suggested methods of instruction

- Lecture
- Exercises

Aids

- Overhead transparencies/slides
- Handout

Reference

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

Time frame

- One hour lecture
- One hour exercise
- One hour reports on exercise

Content

- Critical limits
- Operating limits
- Example, Form 10

Exercise

The instructor should have each "HACCP team" complete the "Critical limits" column on Form 10 and identify the critical control points in their selected operation. Each team will then present a report, using overhead transparencies, explaining the critical limits established for each CCP.

Learning outcome

The trainees should have the necessary knowledge and abilities to establish critical limits for each CCP.

CRITICAL LIMITS

At each critical control point (CCP)/critical limits are established and specified.

Critical limits are defined as criteria that separate acceptability from unacceptability. A critical limit represents the boundaries that are used to judge whether an operation is producing safe products. Critical limits may be set for factors such as temperature, time (minimum time exposure), physical product dimensions, water activity, moisture level, etc. These parameters, if maintained within boundaries, will confirm the safety of the product.

The critical limits should meet requirements of government regulations and/or company standards and/or be supported by other scientific data. In some cases, food control regulatory authorities provide information on which to establish the critical limits based on known food hazards and the results of risk analysis (e.g. the time/temperature requirements for thermal processes such as pasteurization, cooking, retorting; maximum number and size of physical contaminants, chemical residues).

It is essential that the person(s) responsible for establishing critical limits have a knowledge of the process and of the legal and commercial standards required for the product.

Sources of information on critical limits include:

- Scientific publications/research data
- Regulatory requirements and guidelines
- Experts (e.g. thermal process authorities, consultants, food scientists, microbiologists, equipment manufacturers, sanitarians, academics)
- Experimental studies (e.g. in-house experiments, contract laboratory studies)

If the information needed to establish critical limits is not available, a conservative value should be selected or regulatory limits used. Rationale and reference materials used should be recorded. The materials become part of the support documentation of the HACCP plan.

Once the critical limits are established, they are recorded on Form 10 together with the description of the process step, CCP number and hazard description.

Examples of critical limits are included in Table 1. Other examples include the following:

- An acidified beverage that requires a hot fill and hold as the thermal process may have acid addition as the CCP. If insufficient acid is added or if the temperature of the hot fill is insufficient, the product would be underprocessed with potential for the growth of pathogenic spore-forming bacteria. The critical limits in this case would apply to pH and fill temperature.
- Beef patties are cooked in a continuous oven. More than one critical limit is set to control the hazard of heat-resistant pathogen survival. The critical limits could be: minimum internal temperature of the patty; oven temperature; time in the oven determined by the belt speed in rpm; patty thickness. These examples illustrate that CCPs may be controlled by more than one critical limit.

OPERATING LIMITS

If monitoring shows a trend towards lack of control at a CCP, operators can take action to prevent loss of control of the CCP before the critical limit is exceeded. The point at which operators take such action is called the "operating limit". Operating limits should not be confused with critical limits. Often, the operating limits are more restrictive and are established at a level that would be reached before the critical limit is violated; i.e. they should prevent a deviation from critical limits.

Table 1 EXAMPLES OF CRITICAL LIMITS

Hazard	CCP	Critical limit
Bacterial pathogens (non-sporulating)	Pasteurization	72°C for at least 15 seconds

Metal fragments	Metal detector	Metal fragments larger than 0.5 mm
Bacterial pathogens	Drying oven	A_w<0.85 for controlling growth in dried food products
Excessive nitrite	Curing room/brining	Maximum 200 ppm sodium nitrite in finished product
Bacterial pathogens	Acidification step	Maximum pH of 4.6 to control *Clostridium botulinum* in acidified food
Food allergens	Labelling	Label that is legible and contains a listing of correct ingredients
Histamine	Receiving	Maximum of 25 ppm histamine levels in evaluation of tuna for histamine[a]

[a] Regulatory action level is 50 ppm, but histamine levels may increase during processing. Therefore industry may want to set lower histamine critical limits at receiving.

An operator may observe a trend towards loss of control, such as the failure of a cooker to maintain the desired temperature consistently. Observing a trend towards loss of control early and acting on it can save product rework or, worse yet, product destruction. When the critical limit is exceeded, corrective action is required (see Task 10/Principle 5). For this reason a processor may choose to operate a CCP at a limit more conservative than the critical limit. Such operating limits may be selected for various reasons:

- For quality reasons, e.g. higher cooking temperatures for flavour development or product texture

- To avoid exceeding a critical limit, e.g. using a cooking temperature higher than the critical limit as an alarm point, to warn the operator that the temperature is approaching the critical limit and needs adjusting

- To account for normal variability, e.g. setting a cooker with 2°C variability at least 2°C above the critical limit to avoid violating it

The process may need to be adjusted when the operating limit is exceeded. Such actions are called "process adjustments" (see Figure). A processor should use these adjustments to prevent loss of control and the need for product disposition. Table 2 shows examples of critical limits versus operating limits.

Critical and operating limits

Table 2 CRITICAL LIMITS VERSUS OPERATING LIMITS

Process	Critical limit	Operating limit
Acidification	pH 4.6	pH 4.3
Drying	0.84 A_w	0.80 A_w
Hot fill	80°C	85°C
Slicing	2 cm	2.5 cm

Example

FORM 10

HACCP PLAN

PRODUCT NAME(S): *Canned mushroom*

Process step	CCP No.	Hazard description	Critical limits	Monitoring procedures	Deviation procedures	HACCP records
9. Can inspecting/ depalletizing	***CCP 1B***	*Post-process contamination*	*Can manufacturer's specifications*			

		resulting from incorrect cans, damaged cans and serious defects	*No defects*			
	CCP 1P	*Harmful extraneous materials (HEM) ,e.g. wood, glass, metal fragments*	*No HEM*			
20. Weighing	***CCP 2B***	*Overfilling resulting in underprocessing*	*Maximum fill weight as specified in the scheduled process*			
22. Head spacing	***CCP 3B***	*Insufficient headspace resulting in excessive internal pressure and distorted seams*	*Minimum headspace as specified in the scheduled process*			
23. End feeding/ closing/inspecting	***CCP 4B***	*Post-process contamination resulting from damaged or defective ends or improper double seams*	*Can manufacturer's specifications No serious problems*			
25. Thermal processing	***CCP 5B***	*Inadequate heat treatment*	*Maximum time lapse between closing and retort up, minimum IT, minimum time and temperature for vent and cook as specified in the scheduled process Heat-sensitive indicator changes colour*			
26. Cooling	***CCP 6B***	*Post-process contamination of product from cooling water*	*Detectable residual chlorine levels to 2 ppm in the cooling water*			

DATE:_____ APPROVED BY:_____

Module 9 - Establish a monitoring system for each critical control point - Task 9/Principle 4

Objective

To provide the trainees with the necessary knowledge and abilities to establish a monitoring system for each critical control point in the HACCP plan

Suggested methods of instruction

- Lecture
- Exercise

Aids

- Overhead transparencies/slides
- Handout

Reference

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

Time frame

- 30 minutes lecture
- 30 minutes exercise
- 30 minutes reports on exercise

Content

- Monitoring
- Design of a monitoring system
- Example, Form 10

Exercise

The instructor should have each "HACCP team" complete the monitoring procedures column on Form 10 and identify the monitoring procedures for each CCP. Each team will then present a report, using overhead transparencies, explaining the monitoring procedures.

Learning outcome

The trainees should have the necessary knowledge and abilities to establish monitoring procedures for each CCP established.

MONITORING

The Codex *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* defines monitoring as "the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control".

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Therefore, it is important to specify fully how, when and by whom monitoring is to be performed.

The purposes of monitoring include the following:

- To measure the performance level of the system's operation at the CCP (trend analysis)

- To determine when the performance level of the system results in a loss of control at the CCP, e.g. when there is deviation from a critical limit (see Task 10)

- To establish records that reflect the performance level of the system's operation at the CCP to comply with the HACCP plan

Monitoring is the process that the producer relies upon to show that the HACCP plan is being followed. It provides the producer with accurate records enabling the producer to show that the conditions of production are in compliance with the HACCP plan.

Ideally, monitoring should provide information in time to allow any adjustments to the process, thus preventing loss of control of the process and critical limits being exceeded. In practice, operating limits (as discussed in Section 3, Module 8) are often used to provide a safety margin which allows extra time to adjust the process before the critical limit is exceeded.

There are many ways to monitor the critical limits of a CCP. Monitoring can be done on a continuous (100 percent) or batch basis. Where feasible, continuous monitoring is preferred, as it is more reliable. Continuous monitoring is designed to detect shifts around target levels, thus allowing correction of these shifts and preventing deviation beyond the critical limits. Where monitoring is not continuous, the amount and frequency of monitoring should be sufficient to provide an acceptable level of assurance that the CCP is under control. The higher the frequency of monitoring (i.e. the less time between each instance of monitoring), the less product will be affected when there is a loss of control at the CCP.

A further consideration when establishing a monitoring system is the time taken to achieve a result from the monitoring procedure. Most monitoring procedures will need to be rapid, as they relate to on-line processes which in general do not leave time for lengthy analytical testing. For this reason physical and chemical measurements or visual observations, which may be done rapidly, are often preferred to microbiological testing. Examples of some physical and chemical measurements taken to monitor critical limits are temperature, time, pH, moisture level and water activity (A). It is essential that all monitoring equipment be properly calibrated for accuracy.

Monitoring procedures performed during the operation should result in written documentation which will serve as an accurate record of the operating conditions. Monitoring records provide information on conditions during the operation and allow for action to be taken in the event of a loss of control or for a process adjustment to be made if there is a trend towards a loss of control.

Accurate monitoring procedures and associated records provide information to the operator and allow for decisions to be made on the acceptability of the lot at a particular stage in the process. To complete the monitoring process, data derived from monitoring should be reviewed and evaluated by a designated person or persons with knowledge and authority to carry out corrective actions when indicated (see Task 10).

The worst scenario is that in which monitoring procedures indicate that any one of the critical limits is exceeded, which indicates loss of control of a CCP. This lack of control is considered to be a deviation resulting in the production of a hazardous or unsafe product. The situation requires immediate identification and control of the affected product and corrective action.

Responsibility for monitoring should be clearly defined, and individuals must be adequately trained in the monitoring procedures for the CCP for which they are responsible. They must also fully understand the purpose and importance of monitoring. The individual should have ready access to the monitoring activity, must be unbiased in monitoring and must accurately report the monitoring activity.

DESIGN OF A MONITORING SYSTEM

The control measures discussed at Task 6 are intended to control a hazard or hazards at each CCP. The monitoring procedures will determine if the control measures are being implemented and ensure that critical limits are not exceeded. The monitoring specifications for each CCP should be written on Form 10 (see example). They should give information on:

- What will be monitored
- How critical limits and preventive measures will be monitored
- Frequency of monitoring
- Who will monitor

What will be monitored?

Monitoring may mean measuring a characteristic of the product or of the process to determine compliance with a critical limit. Examples include:

- Measurement of the time and temperature of a thermal process
- Measurement of cold-storage temperatures
- Measurement of pH
- Measurement of A_w

Monitoring may also mean observing whether a control measure at a CCP is being implemented. Examples include:

- Visual examination of sealed cans
- Verification of vendor's certificates of analysis

It is also important to remember at this stage that monitoring procedures may determine if operating limits are being adhered to rather then the critical limits, so that the operator has time to make any necessary process adjustment.

How will critical limits and preventive measures be monitored?

Deviation from a critical limit should be detected in as short a time as possible to allow corrective action to limit the amount of adversely affected product. To ensure accurate knowledge of conditions during the process, the monitoring procedures should provide rapid (real-time) results and should not involve lengthy analytical procedures. Microbiological testing is rarely effective for monitoring CCPs for this reason, and also because large sample-sizes would be needed to find microorganisms at levels that may cause illness. Instead, physical and chemical measurements (e.g. pH, A_w, time, temperature) are preferred, as they can be done rapidly and can often be related to the microbiological control of the process.

Effective monitoring depends upon the proper selection and calibration of the measuring equipment. The equipment used for monitoring CCPs will vary depending on the attribute being monitored. Examples of monitoring equipment include:

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

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

Operators should be trained in proper use of the monitoring equipment and should be provided with a clear description of how the monitoring should be carried out. The details should be relevant to the type of monitoring performed; for example, it would be important to specify that temperature measurements for a heating process should be made at the coldest point of the process, while temperature measurements for a cooling process should be made at the warmest part.

Monitoring frequency

Monitoring can be continuous or non-continuous. Where possible, continuous monitoring is preferred; it is possible for many types of physical or chemical methods. Examples of continuous monitoring include:

- Measuring the time and temperature of a pasteurization or retorting process
- Checking each package of frozen, mechanically chopped spinach with a metal detector
- Monitoring the container closures on glass jars by passing them under a dud detector

For continuous monitoring to be effective, it is necessary to review the monitoring results periodically and take action when appropriate. The length of time between checks is important as it is directly related to the amount of product involved when there is a deviation from a critical limit.

Where non-continuous monitoring is the chosen system, the frequency of monitoring should be determined from historical knowledge of the product and process. When problems are detected the frequency of monitoring may need to be increased until the cause of the problem is corrected. The following questions will help to determine the correct frequency:

- How much does the process normally vary?
- How close is the operating limit to the critical limit?
- How much product is the processor prepared to risk if there is deviation from the critical limit?

Who will monitor?

In developing the HACCP plan consideration should be given to assigning responsibility for monitoring. Individuals assigned to monitor CCPs may include:

- Line personnel
- Equipment operators
- Supervisors
- Maintenance personnel
- Quality assurance personnel

Once assigned, the individual responsible for monitoring a CCP must:

- Be adequately trained in the CCP monitoring techniques
- Fully understand the importance of CCP monitoring
- Have ready access (be close) to the monitoring activity
- Accurately report each monitoring activity
- Have the authority to take appropriate action as defined in the HACCP plan
- Immediately report critical limit deviation

It is important that the responsible individual report all unusual occurrences and deviations from critical limits immediately to make sure that process adjustments and corrective actions are made in a timely manner. This person should record and sign all monitoring results and occurrences associated with monitoring CCPs. Records and documents associated with monitoring CCPs should also be signed by one or more responsible reviewing officials of the company.

Example

FORM 10

HACCP PLAN

PRODUCT NAME(S): *Canned mushroom*

Process step	CCP No.	Hazard description	Critical limits	Monitoring procedures	Deviation procedures	HACCP records
9. Can inspecting/ depalletizing	***CCP 1B***	*Post-process contamination resulting from incorrect cans, damaged cans and serious defects*	*Can manufacturer's specifications No defects*	*Continuous visual monitoring by the depalletizer operator*		
	CCP 1P	*Harmful extraneous materials* (*HEM*) *,e.g. wood, glass, metal fragments*	*No HEM*	*Continuous visual monitoring by the depalletizer operator*		

20. Weighing	***CCP 2B***	*Overfilling resulting in underprocessing*	*Maximum fill weight as specified in the scheduled process*	*On-line check-weigher to eject over- and underfilled cans after filling*		
22. Head spacing	***CCP 3B***	*Insufficient headspace resulting in excessive internal pressure and distorted seams*	*Minimum headspace as specified in the scheduled process*	*Headspace check done after closing on consecutive samples, at least, one from each head, by seam mechanic at start-up and every hour*		
23. End feeding/ closing/inspecting	***CCP 4B***	*Post-process contamination resulting from damaged or defective ends or improper double seams*	*Can manufacturer's specifications No serious problems*	*Continuous visual monitoring of ends by closing machine operator*		
				Visual examination of sealed cans at start-up, after severe jam-ups and after adjustments as well as every half hour, and tern-down examination every 4 hours on consecutive samples, one from each head, by closing machine operator		
25. *Thermal processing*	***CCP 5B***	*Inadequate heat treatment*	*Maximum time lapse between closing and retort up, minimum IT, minimum time and temperature for vent and cook as specified in the scheduled process Heat-sensitive indicator changes colour*	*QC to check on time lapse between closing and retort up (at least once per period) Retort operator to check on IT, time and temperature for vent and cook and thermograph Busse unloader to check heat-sensitive indicator tape Busse unloader to segregate product if no*		

				indicator tape or no colour change of indicator tape		
26. Cooling	***CCP 6B***	*Post-process contamination of product from cooling water*	*Detectable residual chlorine levels to 2 ppm in the cooling water*	*Chlorine checks every hour at exit of cooling water*		

DATE:_____ APPROVED BY:_____

Module 10 - Establish corrective actions - Task 10/Principle 5

Objective

To provide the trainees with the necessary knowledge and abilities to establish effective procedures for corrective actions when there are deviations from critical limits at critical control points

Suggested methods of instruction

- Lecture
- Exercise

Aids

- Overhead transparencies/slides
- Handout

Reference

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

Time frame

- 45 minutes lecture
- 45 minutes exercise
- 45 minutes reports on exercise

Content

- Establishing corrective actions
- Deviation
- Corrective action procedures
- Deviation and corrective action records
- Deviation procedures
- Example, Form 10

Exercise

The instructor should have each "HACCP team" complete the deviation procedures column on Form 10 and identify the deviation procedures for the CCPs. The teams should also consider and describe generic deviation procedures that are applicable to all critical limit deviations. Each team will then present its report, using overhead transparencies, explaining the deviation procedures established for each CCP.

Learning outcome

The trainees should have the necessary knowledge and abilities to establish effective deviation and corrective action procedures to be followed in the event of deviations from critical limits at CCPs.

ESTABLISHING CORRECTIVE ACTIONS

The Codex *Hazard Analysis and Critical Control Point* (*HACCP*) *system and guidelines for its application* defines corrective action as "any action to be taken when the results of monitoring at the CCP indicate a loss of control".

Loss of control is considered as a deviation from a critical limit for a CCP. Deviation procedures are a predetermined and documented set of actions to be implemented when a deviation occurs. All deviations must be controlled by taking action(s) to control the non-compliant product and to correct the cause of non-compliance. Product control includes proper identification, control and disposition of the affected product. The control and disposition of the affected product and the corrective action(s) taken must be recorded and filed.

The diversity of possible deviations at each CCP means that more than one corrective action may be necessary at each CCP. When a deviation occurs, it will most likely be noticed during the routine monitoring of the CCP. Deviation and corrective action procedures are prescribed so that employees responsible for CCP monitoring understand and are able to perform the appropriate corrective action(s) in the event of a deviation.

Process adjustments should also be made when monitoring results indicate a trend towards loss of control at a CCP. Action should be taken to bring the process within the operating limits before a deviation occurs.

The deviation procedures at each CCP should be recorded on Form 10 (see example).

DEVIATION

The Codex guidelines for the application of the HACCP system define deviation as "failure to meet a critical limit". Procedures should be in place to identify, isolate and evaluate products when critical limits are exceeded. Inadequate deviation procedures could result in unsafe products and the eventual recurrence of the deviation.

The producer should control deviations as follows.

Identification of deviation

The producer should have a system in place to identify deviations when they occur.

Isolation of affected product

The producer should have effective procedures in place to isolate, mark clearly and control all product produced during the deviation period.

- All affected product, i.e. that processed since the last point at which the CCP was known to be under control, should be isolated.

- Isolated product should be clearly marked, e.g. with firmly attached tags, with information including: hold number, product, amount, date held, the reason for the hold, the name of the person holding the product.

- The producer should maintain control of the product from the hold date to the date of final disposition.

Evaluation of affected product

Product evaluation should be conducted by a qualified person. For example, thermal process deviations would be evaluated by a competent process authority or reference centre.

The evaluation of affected product should be adequate to detect potential hazards, i.e. it should be ensured that sampling is adequate to identify the extent of the problem, that the tests are appropriate, that the judgement is based on sound science and that the product is not released until the evaluation has determined that no potential hazard exists.

CORRECTIVE ACTION PROCEDURES

Since the main reason for implementing HACCP is to prevent problems from occurring, corrective action should be taken to prevent deviation at a CCP. Corrective action should be taken following any deviation to ensure the safety of the product and to prevent recurrence of the deviation.

Corrective action procedures are necessary to determine the cause of the problem, take action to prevent recurrence and follow up with monitoring and reassessment to ensure that the action taken is effective. If the corrective action does not address the root cause of the deviation, the deviation could recur.

Reassessment of the hazard analysis or modification of the HACCP plan may be necessary to eliminate further occurrence.

The producer's corrective action programme should include the following:

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

DEVIATION AND CORRECTIVE ACTION RECORDS

Records should be available to demonstrate the control of products affected by the deviation and the corrective action taken. Adequate records permit verification that the producer has deviations under control and has taken effective corrective action.

The following information should be recorded in the deviation and corrective action records.

Deviation

- Product/code
- Date produced/held/released
- Reason for the hold
- Amount of product held
- Results of evaluation: amount analysed, analysis report, number and nature of defects
- Signature of personnel responsible for hold and evaluation
- Disposition of held product (if appropriate)
- Signed authorization for disposition

Corrective action

- Cause of deviation identified
- Corrective action taken to correct deficiency
- Follow-up/assessment of effectiveness of corrective action
- Date
- Signature of person responsible

DEVIATION PROCEDURES

The following are some examples of deviation procedures for different products.

Canned vegetables

The scheduled thermal process for canned vegetables is not met because of a loss in steam pressure during retorting. The operator notices the deviation before the end of the process time and refers to the written deviation procedure.

The deviation procedure states that the operator should add on a required additional processing time. Additional minutes are added on. This is only part of the corrective action. The deviation procedure also states that the action must be recorded and the affected lots held until a process authority has authorized and signed off for the release of the product.

After the process cycle is finished, the lot is tagged and is moved to the detention area. The corrective action taken has corrected the problem and has controlled the affected product.

During the next shift, the scheduled thermal process for a different batch of canned vegetables is not met because of another loss in steam pressure. The operator notices the deviation after the end of the process cycle and refers to the written deviation procedure.

The deviation procedure for canned vegetables states that the product is to be tagged and moved to the detention area. The deviation procedure also states that the action must be recorded and the affected lots held until a full evaluation is done by a process authority as to disposition of the product.

After the process cycle is finished, the lot is tagged and is moved to the detention area. The corrective action taken has corrected the problem and has controlled the affected product.

As there have been two deviations of a similar nature, it is important for the processor to examine the root cause of the deviation, i.e. to determine the reason for the loss in steam pressure and the actions that should be taken to prevent recurrence of the problem.

Milk

Antibiotics in incoming raw milk are detected by a rapid screening test. The detected level exceeds the established critical limit. The milk receiver refers to the deviation procedure.

The deviation procedure states that the milk is to remain in the truck and not be unloaded. The procedure also describes the follow-up action. The processor will follow up with the milk supplier involved.

All corrective actions are recorded.

Cooked sausages

Cooked sausages are sliced with equipment that has not been cleaned with the specified frequency. The supervisor notices that the slicer has excessive product buildup and believes that the sausages are being subjected to excessive bacterial contamination.

The deviation procedure states that the supervisor must hold all product produced since the last recorded clean-up. The product under hold is subjected to microbiological testing and is not released until the laboratory results are received. The deviation procedure also states that the employee responsible for equipment cleaning should be questioned as to the reason for the deviation from the specified procedure and be retrained as necessary.

Example

FORM 10

HACCP PLAN

PRODUCT NAME(S): *Canned mushroom*

Process step	CCP No.	Hazard description	Critical limits	Monitoring procedures	Deviation procedures	
9. Can inspecting/ depalletizing	***CCP 1B***	*Post-process contamination resulting from incorrect cans, damaged cans and serious defects*	*Can manufacturer's specifications No defects*	*Continuous visual monitoring by the depalletizer operator*	*Can depalletizer operator to remove any incorrect cans, cans with serious defects and damaged cans and to inform QC Operator to hold remainder of pallets and QC to investigate*	
	CCP 1P	*Harmful extraneous materials (HEM), e.g. wood, glass, metal fragments*	*No HEM*	*Continuous visual monitoring by the depalletizer operator*	*Can depalletizer operator to remove any cans with HEM and to inform QC Operator to hold remainder of pallet and QC to investigate*	

20. Weighing	***CCP 2B***	*Overfilling resulting in underprocessing*	*Maximum fill weight as specified in the scheduled process*	*On-line check-weigher to eject over- and underfilled cans after filling*	*Line operator to adjust weight of ejected can manually by adding or taking away mushrooms*	
22. Head spacing	***CCP3B***	*Insufficient headspace resulting in excessive internal pressure and distorted seams*	*Minimum headspace as specified in the scheduled process*	*Headspace check done after closing on consecutive samples, at least one from each head, by seam mechanic at start-up and every hour*	*Closing machine mechanic to adjust headspaces and to inform QC Operator to hold and QC to investigate all product run since last satisfactory results*	
23. End feeding/closing/inspecting	***CCP 4B***	*Post-process contamination resulting from damaged or defective ends or improper double seams*	*Can manufacturer's specifications No serious problems*	*Continuous visual monitoring of ends by closing machine operator*	*Closing machine operator to remove any damaged or defective ends and to inform. QC Operator to hold and QC to investigate ends and sealed cans if necessary*	
				Visual examination of sealed cans at start-up, after severe jam-ups and after adjustments as well as every half hour, and teardown examination every 4 hours on consecutive samples, one from each head, by closing machine operator	*Seamer mechanic to adjust closing machine and to inform QC Operator to hold. and QC to investigate all product run since last. satisfactory inspection*	
25. *Thermal processing*	***CCP 5B***	*Inadequate heat treatment*	*Maximum time lapse between closing and retort up, minimum IT, minimum time and temperature*	*QC to check on time lapse between closing and retort up* (*at least once per period*) *Retort operator to check*	*Retort operator to adjust time and temperature of cook as per authorized contingency*	

			for vent and cook as specified in the scheduled process Heat-sensitive indicator changes colour	*on IT, time and temperature for vent and cook and thermograph Busse unloader to check heat-sensitive indicator tape Busse unloader to segregate product if no indicator tape or no colour change of indicator tape*	*plan and to inform QC Operator to hold and QC to investigate all product suspected of deviation*	
26. Cooling	***CCP 6B***	*Post-process contamination of product from cooling water*	*Detectable residual chlorine levels to 2 ppm in the cooling water*	*Chlorine checks every hour at exit of cooling water*	*Retort operator to adjust chlorine and to inform QC Operator to hold and QC to investigate all product run since last satisfactory check*	

DATE:_____ APPROVED BY:_____

Module 11 - Establish verification procedures - Task 11/Principle 6

Objective

To provide the trainees with the necessary knowledge and abilities to establish procedures for verifying control at each of the CCPs and for validating the adequacy of the overall HACCP plan

Suggested methods of instruction

- Lecture
- Exercise

Aids

- Overhead transparencies/slides
- Handout

Reference

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

Time frame

- 45 minutes lecture
- 45 minutes exercise
- 45 minutes reports on exercise

Content

- Verification
- Description of verification activities
- Role of microbiological testing in HACCP verification
- Verification frequency
- Records of verification
- Regulatory verification

Exercise

The instructor should have each "HACCP team" complete the verification column on Form 10 and identify the verification procedures for each CCP. The teams should also identify procedures for validating the HACCP plan. Each team will then present a report, using overhead transparencies, explaining the verification procedures established for each CCP and for validation of the HACCP plan.

Learning outcome

The trainees should have the necessary knowledge and abilities to establish verification procedures for each CCP and for the HACCP plan.

VERIFICATION

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

Careful preparation of the HACCP plan with clear definition of all the necessary items does not guarantee the plan's effectiveness. Verification procedures are necessary to assess the effectiveness of the plan and to confirm that the HACCP system adheres to the plan. Verification allows the producer to challenge the control measures and to ensure that there, is sufficient control for all possibilities; for example, verification may ensure that adequate contingency procedure plans are in place when critical limits are exceeded at a CCP.

Verification should be undertaken by an appropriately qualified individual or individuals who are capable of detecting deficiencies in the plan or its implementation. Verification should be undertaken at the completion of the HACCP study; whenever there is a change in product, ingredients, process, etc.; when a deviation occurs; in the event of newly identified hazards; and at regular predetermined intervals.

Routine monitoring activities for critical limits should not be confused with verification methods, procedures or activities.

DESCRIPTION OF VERIFICATION ACTIVITIES

Each HACCP plan should include verification procedures for individual CCPs and for the overall plan. HACCP plans are expected to evolve and to improve with experience and new information. Periodic verification helps improve the plan by exposing and strengthening weaknesses in the system and eliminating unnecessary or ineffective control measures. Verification activities include:

- HACCP plan validation
- HACCP system audits
- Equipment calibration
- Targeted sample collection and testing

HACCP plan validation

Validation is the act of assessing whether the HACCP plan for the particular product and process adequately identifies and controls all significant food safety hazards or reduces them to an acceptable level. HACCP plan validation should include:

- Review of the hazard analysis

- CCP determination

- Justification for critical limits, based for example on current good science and regulatory requirements

- Determination of whether monitoring activities, corrective actions, record keeping procedures and verification activities are appropriate and adequate

Validation involves ensuring that the HACCP plan is based on current good science and current information and is appropriate for the actual product and process. A scientific and technical review is performed to ensure that there is a sound scientific and technical basis for decisions regarding which hazards are being controlled, which hazards are not being controlled and how identified hazards are being controlled. This review could incorporate the use of new scientific information and data gathered for the purpose of the verification. The process of validating an existing HACCP plan should also include:

- Review of HACCP audit reports
- Review of changes to the HACCP plan and the reasons for those changes
- Review of past validation reports
- Review of deviation reports
- Assessment of corrective action effectiveness
- Review of information on consumer complaints
- Review of linkages between the HACCP plan and GMP programmes

HACCP plan validation is an ongoing, periodic procedure. Validations may be scheduled at a pre-set frequency. However, other factors may trigger a review of the plan to determine if changes are necessary. These factors could include changes to the raw materials, product or process; adverse audit findings; recurring deviations; new scientific information about potential hazards or control measures; and consumer complaints and/or product rejections by customers.

HACCP system audits

As part of verification, audits are performed to compare the actual practices and procedures of the HACCP system with those written in the HACCP plan.

Audits are systematic and independent examinations involving on-site observations, interviews and review of records to determine whether the procedures and activities stated in the HACCP plan are implemented in the HACCP system. These examinations are usually performed by one or more independent persons who are not involved in implementation of the HACCP system. Audits may be performed for individual CCPs and/or for the overall plan.

On-site observation may include, for example, visual inspection to ensure that:

- The product description and flow chart are accurate
- Monitoring required by the HACCP plan at the CCPs is performed
- Processes are operating within established critical limits
- Records are filled out accurately and at the time observations are made

Records to be reviewed during auditing of the HACCP plan include, for example, those demonstrating that:

- Monitoring activities have been performed at the locations specified in the HACCP plan

- Monitoring activities have been performed at the frequencies specified in the HACCP plan

- Affected product has been controlled and corrective actions have been taken whenever monitoring has indicated the occurrence of a deviation from critical limits

- Equipment has been calibrated at the frequencies specified in the HACCP plan Audits should occur frequently enough to ensure that the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and product.

Calibration

Calibration involves checking instruments or equipment against a standard to ensure accuracy. Calibration should be documented and the records should be available for review during verification.

Calibration of appropriate equipment and instruments used in the development and, implementation of the HACCP plan should be carried out, during monitoring and/or verification,

- At a frequency sufficient to assure continuous accuracy

- According to procedures established in the HACCP plan (which can be based on instrument or equipment manufacturer specifications)

- By checking accuracy against a recognized standard

- Under conditions similar or identical to those under which the instrument or equipment will be used

Calibration of CCP monitoring equipment is important; if the equipment is out of calibration, then monitoring results will not be accurate and may be completely unreliable. When the equipment monitoring a CCP is out of calibration, the CCP is considered to have been out of control since the last documented calibration.

Targeted sample collection and testing

Verification may also include targeted sampling and testing and other periodic activities. Targeted sampling and testing involves taking product samples periodically and testing them to ensure that critical limits are appropriate for product safety.

Targeted sampling may be carried out to check vendor compliance when receipt of material is a CCP and purchase specifications are relied on as critical limits. For example, in the case of cooked shrimp, the processor may purchase shrimp under a supplier's guarantee for sulphite levels less than 100 ppm. A sample may be collected for laboratory analysis on a quarterly basis to ensure that sulphite levels are compliant with the supplier's guarantee.

When critical limits are set for equipment operation, product samples may be taken to ensure that the equipment settings are appropriate to provide product safety.

When sampling and testing is used as a verification tool, the usefulness of the test often depends on how the material is sampled. The risk and level of confidence needed will determine the sample size and the method of sample collection.

ROLE OF MICROBIOLOGICAL TESTING IN HACCP VERIFICATION

Sampling and microbiological testing are usually not adequate by themselves to ensure food safety. Microbiological testing is seldom effective for monitoring CCPs and cannot be used as a means of process control because of the lengthiness of analytical procedures and the inability to provide results in real time. In addition, detection of pathogenic microorganisms can be difficult if contamination of the product at the CCP is at a low level or is unevenly distributed in the food sample, necessitating large and numerous samples.

Microbiological testing does have a role in HACCP verification, however: when critical limits are established for the elimination of pathogens or their reduction to an acceptable level, microbiological testing can be used to verify the HACCP plan's effectiveness and to ensure that the identified microbiological limits have not been exceeded. In this instance, the length of time involved in the analytical procedures does not create operational difficulties.

VERIFICATION FREQUENCY

Verification activities should be performed according to a pre-established schedule described in the HACCP plan or whenever there are indications that the food safety status may have changed. These indications may include:

- On-line observations that CCPs may not be operating within critical limits
- Record reviews indicating inconsistent monitoring
- Record reviews indicating that CCPs are repetitively operated outside critical limits
- Consumer complaints or product rejections by customers
- New scientific data

Verification procedures should be scheduled at a frequency that ensures that the HACCP plan is being followed continuously and that measurements remain accurate within established limits. Thus, the length of time between scheduled verification activities should match the level of confidence in the continuous and accurate performance of the HACCP plan.

The frequency of verification activities may change over time. A history of verification activities indicating that the process is consistently in control may support safe reduction of the frequency of verification activities.

RECORDS OF VERIFICATION

Verification activities should be documented in the HACCP plan. Records should be made of the results of all verification activities. Records of verification should include methods, date, individuals and/or organizations responsible, results or findings and action(s) taken.

Verification procedures for the overall HACCP plan should be documented in a file for the HACCP plan.

REGULATORY VERIFICATION

Verification should be a routine part of regularly scheduled government inspections. The reasons for regulatory verification activities include, among others: government obligation in consumer protection, support to the food industry (particularly medium- and small-scale food industry) and assistance to industry in trade opportunities where certification is required.

The inspector should document the existence and implementation of the HACCP plan. Regulatory verification should also involve review and/or audit of the adherence of the processor's HACCP system to its HACCP plan. In particular, the inspector should focus on the following:

- Review of the hazard analysis
- Review of the CCP determination
- Verification that the critical limits are based on good science and meet regulatory requirements
- Review of the deviation and corrective action procedures
- Review of the verification procedures
- Review of records to verify that the HACCP plan is being followed effectively at all times
- Verification of the accuracy of CCP monitoring equipment

Regulatory verification can also be used to challenge the HACCP plan in the event of outbreaks of illness or consumer complaints. Verification in such situations would include review of the company consumer complaint file. New technological information or an industry request for consultation may also result in verification actions by regulatory agencies.

Compliance actions should be taken when regulatory verifications indicate deficiencies in the HACCP plan or implemented HACCP system that could result in health hazards in the food products.

Module 12 - Establish documentation and record keeping - Task 12/Principle 7

Objective

To provide the trainees with the necessary knowledge and abilities to establish appropriate documentation of the HACCP plan and records of the HACCP system

Suggested methods of instruction

- Lecture
- Exercise

Aids

- Overhead transparencies/slides
- Handout

Reference

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

Time frame

- 45 minutes lecture
- 45 minutes exercise
- 45 minutes reports on exercise

Content

- Documentation and record keeping
- Support documents
- Records generated by the HACCP system
- Documentation of methods and procedures used
- Records of employee training programmes
- Example, Form 10

Exercise

The instructor should have each "HACCP team" establish the documentation required for the HACCP plan, complete the HACCP record column on Form 10 and identify the specific records that should be kept for each CCP in the HACCP system. Each team will then present a report, using overhead transparencies, showing the documentation of the HACCP plan and the HACCP records established for each CCP in the HACCP system.

Learning outcome

The trainees should demonstrate the necessary knowledge and abilities to establish documentation of the HACCP plan and records of the HACCP system.

DOCUMENTATION AND RECORD KEEPING

Records are essential for reviewing the adequacy of the HACCP plan and the adherence of the HACCP system to the HACCP plan.

A record shows the process history, the monitoring, the deviations and the corrective actions (including disposition of product) that occurred at the identified CCP. It may be in any form, e.g. processing chart, written record, computerized record. The importance of records to the HACCP system cannot be overemphasized. It is imperative that the producer maintain complete, current, properly filed and accurate records.

Four types of records should be kept as part of the HACCP programme:

- Support documentation for developing the HACCP plan
- Records generated by the HACCP system
- Documentation of methods and procedures used
- Records of employee training programmes

SUPPORT DOCUMENTS

The HACCP plan support documents include information and support data used to establish the HACCP plan such as the hazard analysis and records documenting the scientific basis for establishing the CCPs and critical limits. Examples include:

- Data used to establish the control measures to prevent microbiological growth
- Data used to establish the shelf-life of the product (if age of the product can affect safety)
- Data used to establish the adequacy of critical limits in ensuring the safety of the product

The HACCP plan support documents should also include a list of the HACCP team members and their responsibilities, as well as all the forms produced during the preparation of the HACCP plan, showing:

- Product description and intended use
- Flow diagram
- Hazard analysis
- Identification of CCPs
- Identification of the critical limits for each CCP, including data from experimental studies or information collected to support the critical limits
- Documented deviation and corrective action plans
- Planned verification activities and procedures
- Identification of the preventive measures for each hazard

Support documents may also include correspondence with consultants, as well as documents detailing how the HACCP plan was developed.

RECORDS GENERATED BY THE HACCP SYSTEM

HACCP system records are kept to demonstrate adherence of the HACCP system with the HACCP plan. These records are used to demonstrate control at CCPs in the food process. By tracking records generated by the HACCP system, an operator or manager can become aware that a process is approaching its critical limit. Review of records can be instrumental in identifying trends and in making operational adjustments. Timely corrective action can be taken if a critical limit is violated.

The required HACCP records to be kept at each CCP should be written on Form 10 (see example). Failure to document the control of a CCP would be a critical departure from the HACCP plan.

The records generated by the HACCP system include all activities and documentation required by the plan, as follows.

Monitoring records for all CCPs

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

- Form title

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

Deviation and corrective action records

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

Verification/validation records

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

DOCUMENTATION OF METHODS AND PROCEDURES USED

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

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

RECORDS OF EMPLOYEE TRAINING PROGRAMMES

Records should be kept of all employee training. This is of particular importance for employees involved in monitoring critical limits for CCPs and those involved with deviation review, corrective actions and verification. These employees must be trained to understand fully the appropriate procedures/methods and actions to be taken regarding control of CCPs.

Example

FORM 10

HACCP PLAN

PRODUCT NAME(S): *Canned mushroom*

Process step	CCP No.	Hazard description	Critical limits	Monitoring procedures	Deviation procedures	rec
9. *Can inspecting/ depalletizing*	***CCP 1B***	*Post-process contamination resulting from incorrect cans, damaged cans and serious defects*	*Can manufacturer's specifications No defects*	*Continuous visual monitoring by the depalletizer operator*	*Can depalletizer operator to remove any incorrect cans, cans with serious defects and damaged cans and to inform QC Operator to hold remainder of pallets and QC to investigate*	*contai report Low v detect report*
	CCP 1P	*Harmful extraneous materials* (*HEM*), *e.g. wood, glass, metal fragments*	*No HEM*	*Continuous visual monitoring by the depalletizer operator*	*Can depalletizer operator to remove any cans with HEM and to inform QC Operator to hold remainder of pallet and QC to investigate*	*contai report*
20. Weighing	***CCP 2B***	*Overfilling resulting in underprocessing*	*Maximum fill weight as specified in the scheduled process*	*On-line check-weigher to eject over- and underfilled cans after filling*	*Line operator to adjust weight of ejected can manually by adding or taking away mushrooms*	*contro Daily g report*
22. Head spacing	***CCP 3B***	*Insufficient headspace resulting in excessive internal pressure and distorted seams*	*Minimum headspace as specified in the scheduled process*	*Headspace check done after closing on consecutive samples, at least one from each head, by seam mechanic at start-up and every hour*	*Closing machine mechanic to adjust headspaces and to inform QC Operator to hold and QC to investigate all product run since last satisfactory results*	*seam inspec report Daily g report*
23. End feeding/closing/inspecting	***CCP 4B***	*Post-process contamination resulting from*	*Can manufacturer's specifications No serious*	*Continuous visual monitoring of ends by closing machine*	*Closing machine operator to remove any*	*seame report Doubl*

		damaged or defective ends or improper double seams	*problems*	*operator*	*damaged or defective ends and to inform QC Operator to hold and QC to investigate ends and sealed cans if necessary*	*inspec report Low va detect report Conta integri inspec report*
				Visual examination of sealed cans at start-up, after severe jam-ups and after adjustments as well as every half hour, and teardown examination every 4 hours on consecutive samples, one from each head, by closing machine operator	*Seamer mechanic to adjust closing machine and to inform QC Operator to hold and QC to investigate all product run since last satisfactory inspection*	
25. *Thermal processing*	***CCP 5B***	*Inadequate heat treatment*	*Maximum time lapse between closing and retort up, minimum IT, minimum time and temperature for vent and cook as specified in the scheduled process Heat-sensitive indicator changes colour*	*QC to check on time lapse between closing and retort up* (*at least once per period*) *Retort operator to check on IT, time and temperature for vent and cook and thermograph Busse unloader to check heat-sensitive indicator tape Busse unloader to segregate product if no indicator tape or no colour change of indicator tape*	*Retort operator to adjust time and temperature of cook as per authorized contingency plan and to inform QC Operator to hold and QC to investigate all product suspected of deviation*	*operat Therm charts Low va detect report Heat-sensiti indica*
26. Cooling	***CCP 6B***	*Post-process contamination of product from cooling water*	*Detectable residual chlorine levels to 2 ppm in the cooling water*	*Chlorine checks every hour at exit of cooling water*	*Retort operator to adjust chlorine and to inform QC Operator to hold and QC to investigate all product run since last satisfactory*	*operat Low va detect report*

					check	

DATE:_____ APPROVED BY:_____

Annex 1 - Blank HACCP forms

FORM 1

PRODUCT DESCRIPTION

1. Product name(s)	
2. Important product characteristics of end product (e.g. A_w, pH, etc.)	
3. How the product is to be used	
4. Packaging	
5. Shelf-life	
6. Where the product will be sold	
7. Labelling instructions	
8. Special distribution control	

DATE: _____ APPROVED BY: _____

FORM 2

PRODUCT INGREDIENTS AND INCOMING MATERIAL

PRODUCT NAME(S):

DATE:_____ APPROVED BY:_____

FORM 3

FLOW DIAGRAM

PRODUCT NAME(S):

DATE: _____ APPROVED BY: _____

FORM 4

PLANT SCHEMATIC/FLOOR PLAN

PRODUCT NAME(S):

DATE:_____ APPROVED BY:_____

FORM 5

HAZARD IDENTIFICATION: BIOLOGICAL HAZARDS

PRODUCT NAME(S):

List all biological hazards related to ingredients, incoming material, processing, product flow, etc.

Identified biological hazards	Controlled at

DATE: _____ APPROVED BY: _____

FORM 6

HAZARD IDENTIFICATION: CHEMICAL HAZARDS

PRODUCT NAME(S):

List all chemical hazards related to ingredients, incoming material, processing, product flow, etc.

Identified chemical hazards	Controlled at

DATE:_____ APPROVED BY:_____

FORM 7

HAZARD IDENTIFICATION: PHYSICAL HAZARDS

PRODUCT NAME(S):

List all physical hazards related to ingredients, incoming material, processing, product flow, etc.

Identified physical hazards	Controlled at

DATE:_____ APPROVED BY:_____

FORM 8

CCP DETERMINATION

Process step/ incoming material	Category and identified hazard	Question 1	Question 2	Question 3	Question 4	CCP number

Instructions:

• **Category and identified hazard:** Determine if hazard is fully controlled by adherence to Codex General Principles of Food Hygiene. If **Yes**, indicate "GMPs", describe and proceed to next identified hazard. If **No**, proceed to Question 1.

• **Question 1: Do control preventive measure(s) exist?** If **No**, this is not a CCP. Identify how the hazard can be controlled before or after the process and proceed to the next identified hazard. If **Yes**, describe and proceed to the next question.

• **Question 2: Is the operation specifically designed to eliminate or reduce the likely occurrence of a hazard to an acceptable level?** If **No**, proceed to Question 3. If **Yes,** this is a CCP; identify it as such in the last column.

• **Question 3: Could contamination with identified hazard(s) occur in excess of acceptable level(s) or could these increase to unacceptable levels?** If **No,** this is not a CCP; proceed to the next identified hazard. If **Yes,** proceed to Question 4.

• **Question 4: Will a subsequent operation eliminate identified hazard(s) or reduce likely occurrence to an acceptable level?** If **No,** this is a CCP; identify it as such in the last column. If **Yes,** this is not a CCP; identify the subsequent step and proceed to the next identified hazard.

FORM 9

UNADDRESSED HAZARDS

PRODUCT NAME(S):

List any biological, chemical and/or physical hazards that are not controlled at the establishment.

Unaddressed hazard from previous list	Identified methods of addressing the hazard (e.g. cooking instructions, public education, use by date, etc.)

DATE:_____ APPROVED BY:_____

FORM 10

HACCP PLAN

PRODUCT NAME(S):

Process step	CCP No.	Hazard description	Critical limits	Monitoring procedures	Deviation procedures	HACCP records

DATE:_____ APPROVED BY:_____

Annex 2 - The application of risk analysis to food safety control programmes

RISK ANALYSIS

There are many hazards associated with food that can and do result in injury and harm to human health. Millions of people worldwide suffer from some sort of "food poisoning" each year. Uncontrolled application of agricultural chemicals, environmental contamination, use of unauthorized additives, microbiological hazards and other abuses of food along the food chain can all contribute to the potential of introducing or failing to reduce hazards related to food. With increased awareness of the effects of food hazards on human health, the increasing importance and rapid growth of world food trade and the demand by consumers for a safe food supply, analysis of the risks associated with food has become more important than ever before.

Consumers have expressed concern about the safety of food additives, agricultural and veterinary chemical residues, biological, chemical and physical contaminants, radionuclide contamination and uncontrolled and unacceptable food handling practices and processing which can result in the introduction of hazards to food at all stages along the food chain, from primary production to the consumer. These concerns have been voiced most often by consumers in the developed world; however, continuous improvements in global communication have heightened the interest of consumers throughout the world on these matters.

FOOD HAZARDS

The Codex Alimentarius Commission defines a hazard as a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. Therefore food hazards can be classified into three categories: physical, chemical or biological. Physical hazards (e.g. stones in rice or beans; bone pieces in meat) are the most easily understood; the impact of chemical and biological hazards on human health is far more difficult to understand because of the complexities of interactions between hazards and human biochemistry and the absence of scientific data to confirm the theories. Human responses to disease or to agents that cause adverse reactions are dependent on a number of variables, many of which are interlinked. In addition, health effects may be severe in one person, mild in another and completely absent in others.

PROCESS OF RISK ANALYSIS

The risk to the world's population from hazards in and on food depends largely on the degree of control exercised by producers, processors and official food control authorities to prevent or minimize the risks to acceptable safe levels. Food safety risk analysis is an emerging discipline, and the methods used for assessing and managing risks associated with food hazards are still being developed.

It is important to recognize the difference between "hazard" and "risk". As stated above, a hazard is a biological, chemical or physical agent in, or condition of, food with the potential to cause harm. In contrast, risk is the estimated probability and severity of adverse health effects in exposed populations consequential to hazards in food. Understanding the association between a reduction in hazards that may be associated with a food and the reduction in the risk of adverse health effects to consumers is of particular importance in development of appropriate food safety controls. Unfortunately, there is no such thing as "zero risk" for food (or for anything else).

The risk analysis process comprises three separate elements: risk assessment, risk management and risk communication. It is widely recognized as the fundamental methodology underlying the

development of food safety standards. Decisions are needed to determine what the hazards are and to identify their immediate, interim and long-term effects on human health (risk assessment); to establish the appropriate measures of control to prevent, reduce or minimize these risks (risk management); and to determine the best way to communicate this information to the affected population (risk communication).

Risk assessment

Risk assessment is a quantitative evaluation of information on potential health hazards from exposure to various agents. It involves four interrelated steps:

- Identification of the hazard and comprehension of the danger it represents, the impact in terms of human health and the circumstances under which the danger is present (hazard identification)

- Qualitative and/or quantitative evaluation of the adverse effects of the hazard on human health (hazard characterization)

- Qualitative and/or quantitative evaluation of the likely degree of consumption or intake of the hazardous agent (exposure assessment)

- Integration of the first three steps into an estimate of the likely adverse effect in the target population (risk characterization)

The entire risk assessment process requires the use of sound and scientifically derived information and the application of established scientific procedures carried out in a transparent manner. Unfortunately, sound scientific data are not always available for the qualitative and quantitative evaluations necessary for an absolutely sure final decision; consequently a degree of uncertainty must be factored into the decision.

The importance of risk assessment lies not only in its capacity for estimating human risk, but also in its function as a framework for organizing data as well as for allocating responsibility for analysis. The risk assessment process can include a variety of models for reaching conclusions; for example, the concept of acceptable daily intake (ADI) may be considered a component of risk assessment.

Biological hazards of concern to public health include pathogenic strains of bacteria, viruses, helminths, protozoa, algae and certain toxic products they may produce. Of these hazards, pathogenic bacteria in foods currently present the most significant problems internationally. Assessment of the risks associated with bacterial pathogens presents unique complications. Any method for assessing the risk of hazards from foodborne bacteria will be complicated by factors related to methods used to grow, process and store food for consumption. These factors can vary greatly depending on cultural and geographical differences. Such factors characterize the scenario for a given food and are an essential element for a risk assessment for bacterial hazards.

In many cases sufficient data will not be available to support a quantitative assessment of risks associated with bacterial pathogens. For a number of reasons, including the many uncertainties associated with how and when an organism may express its pathogenic potential, it has not yet been determined whether a quantitative risk assessment approach is possible and appropriate for characterization of risk associated with foodborne bacterial pathogens. Thus, by default, a qualitative approach to characterizing risk may be the only current alternative. To bring about regulatory changes the scientific community must advance beyond qualitative microbial risk assessment and generate the data needed to make quantitative assessments. FAO/WHO consultations had difficulty with quantitative microbiological risk assessment, and one recommendation is to establish an FAO/WHO Expert Committee on Microbiological Risk Assessment.

Chemical risk assessment is a fairly well established process and in general permits the assessment of risks from long-term chronic exposure to a chemical. It includes the assessment of food additives, residues of pesticides and other agricultural chemicals, residues from veterinary drugs, chemical contaminants from any source and natural toxins such as mycotoxins and ciguatoxin.

Risk assessment requires evaluation of relevant information and selection of the models to be used in drawing inferences from that information. Further, it requires recognition of uncertainties and,

when appropriate, acknowledgement that alternative interpretations of the available data may be scientifically plausible. Data uncertainties arise both from limitations on the amount of data available and from evaluation and interpretation of actual data obtained from epidemiological and toxicological studies. Model uncertainties arise whenever attempts are made to use data concerning phenomena that are likely to occur under other sets of conditions for which data are not available.

Risk management

Risk management is defined within the Codex Alimentarius as the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options including regulatory measures. The goal of the risk management process is to establish the significance of the estimated risk, to compare the costs of reducing this risk to the benefits gained, to compare the estimated risks to the societal benefits derived from incurring the risk and to carry out the political and institutional process of reducing the risk.

The outcome of the risk management process, as undertaken by committees within the Codex Alimentarius system, is the development of standards, guidelines and other recommendations for food safety. In the national situation it is likely that different risk management decisions could be made according to different criteria and different ranges of risk management options. Risk managers, in developing approaches to managing risk, use the risk characterization that results from the risk assessment process. Risk management decisions can be based on establishing safe handling procedures and practices, food processing quality and safety assurance controls and food quality and safety standards to control hazards in food. These standards must take into consideration the proper use of food additives which have been determined to be safe and their permitted levels and scientifically determined acceptable safe limits for contaminants and agricultural chemical residues in food, using the risk assessment process.

The outcome of the risk assessment process should be combined with the evaluation of available risk management options in order that a decision on management of the risk can be reached. Implementation of the management decision should be followed by monitoring of both the effectiveness of the control measure and its impact on the risk to the exposed consumer population, to ensure that the food safety objective is being met.

While research and scientific studies continue to provide the answers needed for making informed decisions in risk analysis related to hazards in food, the uncertainty and unresolved questions continue to cause concern to decision-makers. Only continued research and scientific study can provide the necessary answers. Until these answers are available, much of what is known about hazards and assessing and controlling risks is based on only partial information, with uncertainties factored into the analysis.

Risk communication

Risk communication is the third and final element of the risk analysis process. The Codex Alimentarius definition of risk communication is narrow: "an interactive process of exchange of information and opinion on risk among risk assessors, risk managers and other interested parties". A definition with broader scope is that of the United States National Academy of Sciences: "an interactive process of exchange of information and opinion among individuals, groups and institutions... [which] involves multiple messages about the nature of risk and other messages, not strictly about risk, that express concerns, opinions or reactions to risk messages or to legal and institutional arrangements for risk management".

Communicating the results of risk assessment and risk management serves many purposes. The quality and safety of food depends on responsible action by all involved at all stages in the food chain, including consumers. Consumers require access to adequate information about potential hazards and appropriate precautions to be taken in the final preparation and serving of food. In addition, consumers need to be aware of and to understand food safety control measures implemented by their government in the interest of consumers' health.

Communication provides the public with the results of expert scientific review of food hazard identification and assessment of the risks to the general population or to specific target groups such as infants or the elderly. Certain people, such as those who are immunodeficient, allergic or nutritionally deficient, require particular information. Communication provides the private and public sectors with the information necessary for preventing, reducing or minimizing food risks to acceptably safe levels through systems of food quality and safety management by either mandatory or voluntary means. It

also provides sufficient information to permit the populations with the greatest level of risk from any particular hazard to exercise their own options for achieving even greater levels of protection.

This training manual on food quality and safety systems is intended for trainers in food quality and safety assurance at the government and industry levels. It focusses on food hygiene practices and the Hazard Analysis and Critical Control point (HACCP) system. The manual consists of three sections: Principles and methods of training; Recommended International Code of Practice - General Principles of Food Hygiene; and The Hazard Analysis and Critical Control Point (HACCP) system. The last two sections were designed to reflect the recommendations and guidelines of the Codex Alimentarius Commission on food hygiene and HACCP worldwide. Each section is divided into specific training modules. This format allows the instructor to select sections and modules according to the levels of knowledge, experience and specific responsibilities of the students.