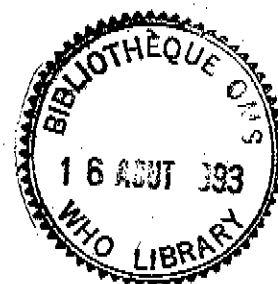

Training Considerations
for the Application of the
Hazard Analysis
Critical Control Point
System to Food
Processing
and Manufacturing



World Health Organization
Division of Food and Nutrition
Food Safety Unit
1993





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TRAINING CONSIDERATIONS FOR THE APPLICATION OF THE
HAZARD ANALYSIS CRITICAL CONTROL POINT SYSTEM
TO FOOD PROCESSING AND MANUFACTURING

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1. PREFACE

These considerations are intended for use in the development of training materials for the food processing and manufacturing industry and for government health and food authorities; they were developed during a consultation on Hazard Analysis Critical Control Point training convened by the World Health Organization (WHO) in Geneva, Switzerland, 17-19 March 1993. A list of participants is attached in Annex I. A report on this consultation is available as document WHO/FNU/FOS/93.2. These training considerations are consistent with the concepts outlined in the Codex document, "Guidelines for the application of the Hazard Analysis Critical Control Point (HACCP) system", adopted by the 20th Session of the Joint FAO/WHO Codex Alimentarius Commission hosted by WHO in Geneva from 28 June to 7 July 1993 (Annex II). As the Codex text was intended as a broad policy statement, these considerations have also drawn upon other national and international HACCP references and documents to provide more specific guidance in the training of HACCP applications to food processing and manufacturing. These considerations take into account current training approaches and experiences. A number of basic HACCP references (listed in Annex III) have assisted in the preparation of this document and acknowledgement is extended to those authors for their work in this field. Readers are directed to these references for more detailed information on the theory and application of HACCP.

WHO, in collaboration with the food industry, is developing model training materials based on these considerations. Persons interested in further information regarding these materials and in possible WHO cooperation for the introduction of the HACCP system into food processing and manufacturing as well as other stages of the food supply should contact the Chief, Food Safety Unit, Division of Food and Nutrition, World Health Organization, CH-1211 Geneva 27.

2. INTRODUCTION

The Hazard Analysis Critical Control Point (HACCP) system identifies specific hazards and measures for their prevention and control to ensure the safety of food. HACCP is a tool used to assess hazards, estimate risks and establish specific control measures that emphasize prevention and control rather than reliance on end-product testing and traditional inspection methods. The HACCP system is capable of accommodating change, such as advances in equipment design, improvements in processing procedures and technological developments related to the product. In addition to enhanced food safety, the benefits of applying HACCP include better use of resources and more timely response to production problems. The application of the HACCP system can also aid inspection by regulatory authorities by focusing on matters of high health risk and promote domestic and international trade by increasing confidence in food safety.

While HACCP can be applied throughout the food chain from the primary producer to final consumer, these training considerations are intended mainly for the food processing and manufacturing industry and for government authorities responsible for the safety of food produced by this sector. Seven principal activities are employed in the development of HACCP plans whose implementation can ensure the goal of safer food. These principal activities include hazard assessment, Critical Control Point (CCP) identification, and establishment of critical limits and procedures for monitoring, corrective action, verification and documentation. If a deviation from critical limits at a CCP occurs, it can be detected in a timely manner and appropriate steps taken to re-establish control before potentially hazardous products reach the consumer.

The successful application of HACCP is facilitated by a multidisciplinary approach and requires the full commitment and involvement of the management and workforce. Training and education in the application of the principal activities of HACCP are essential for the development and implementation of HACCP plans by industry and for verification inspection by regulatory authorities. HACCP can be compatible with quality management systems, such as the ISO 9000 series, but is intended to specifically address high risk operations that could result in injury or outbreaks of foodborne disease. Hence, HACCP is the system of choice for the management of food safety.

Many food manufacturers and processors have already applied the HACCP system to their operations. The level of safety assurance offered by the HACCP system is fast becoming the standard for the food industry in industrialized countries. Food safety authorities in the United States, Canada and the European Community (EC) promote the use of HACCP. HACCP is also being incorporated into the Codex Codes of Practice for a number of food commodities. Consequently, there is a growing need to promote appreciation for and understanding of HACCP by governments and the food industry, particularly in developing countries. Because different interpretations of the HACCP concept have caused some confusion, internationally agreed HACCP training materials are needed to provide a clear and consistent presentation of HACCP and to assure that food inspectors and food operators are trained to apply HACCP in a uniform manner.

3. TRAINING OBJECTIVE AND GOALS

These training considerations are intended as a general introduction to the HACCP concept and its full application. While the HACCP concept can be applied to all stages of the food supply, training in the application of the HACCP system to food processing and manufacturing offers an opportunity to gain experience in all principal activities of the system. In addition, as most countries have some food processing operations which would warrant the implementation of HACCP systems, it is also hoped that this training will have some practical applications in even the least developed countries.

3.1 Training objective

The training objective considered by this document is to develop a common understanding of the application of the principal activities of HACCP to food processing and manufacturing to ensure the production of safe food.

3.2 Training goals

The training goals considered include:

to promote a common approach for the identification of hazards, Critical Control Points and critical limits;

to agree on terminology and basic understanding of HACCP principal activities;

to share knowledge and practical experience in applying HACCP principal activities;

to promote understanding and awareness of food safety practices through education; and,

to impart the skills necessary to allow both the public and private sectors to use HACCP appropriately to promote food safety.

4. HACCP PRINCIPAL ACTIVITIES

The following seven principal activities form the essential basis for the application of the HACCP system. Because clear, concise definitions are essential for training purposes and are important for promoting communication and cooperation between government and industry, a glossary of HACCP terms for food processing and manufacturing is given in Annex IV.

- | | |
|------------------------|---|
| PRINCIPAL ACTIVITY 1 - | Conduct hazard analysis, identify hazards and specify control measures. |
| PRINCIPAL ACTIVITY 2 - | Identify Critical Control Points (CCPs). |
| PRINCIPAL ACTIVITY 3 - | Establish critical limits at each CCP. |
| PRINCIPAL ACTIVITY 4 - | Establish monitoring procedures. |
| PRINCIPAL ACTIVITY 5 - | Establish corrective action procedures. |
| PRINCIPAL ACTIVITY 6 - | Establish verification procedures. |
| PRINCIPAL ACTIVITY 7 - | Establish documentation procedures as appropriate. |

5. APPLICATION OF HACCP BY THE FOOD PROCESSING AND MANUFACTURING INDUSTRY

5.1 Introduction

The concept of HACCP can apply to the entire food chain where food is grown, harvested/slaughtered, processed/manufactured and prepared for final consumption through a variety of food industry sectors using different technologies. The HACCP concept can also be applied during the planning and development stage so that potential hazards can be "designed-out" of products and processes. While the application of HACCP principal activities to the various sectors requires some flexibility, HACCP has been successfully applied to specific situations, such as catering, but applications of HACCP to other segments of the food chain, particularly primary production, are not yet fully developed. The application of HACCP in this document is limited to food manufactured and processed by medium- to large-scale operations, but may also be applicable to smaller operations where safety of the food is of critical importance.

5.2 Benefits

There are numerous benefits that accrue to food industry with the application of HACCP systems as a management tool for food safety control. Some key benefits are as follows:

- o The HACCP approach is a systematic approach which can be applied to all aspects of food safety, including biological, chemical and physical hazards, at all stages of the food chain, including raw materials, growth, harvesting, purchase, production, distribution, and storage, to final product use.
- o HACCP systems provide scientifically sound bases for demonstrating that all reasonable precautions have been taken to prevent a hazard from reaching the consumer.

- o The HACCP approach shifts emphasis from statistically unreliable end-product testing which is often retrospective to a prevention-oriented approach for the production of safe food products.
- o Application of the HACCP concept is a cost-effective method of assuring food safety and preventing foodborne disease and injuries.
- o HACCP systems focus resources on those parts of the process critical for assuring safe products.
- o HACCP systems can reduce product losses due to spoilage.
- o HACCP systems encourage confidence in the safety of food products and thus promotes confidence in food trade and stability of food businesses.
- o HACCP systems can facilitate the design and construction of new food processing facilities and equipment by predicting potential hazards and suggesting control measures.

5.3 Application of HACCP principal activities

Before embarking on the development of a HACCP plan, it is essential to specify the scope of the HACCP application. This will include whether the plan is to consider one or more types of hazards, namely biological, chemical or physical. When developing a HACCP plan for the first time, consideration of only one type of hazard is often more practical; the choice is usually determined by the process and the product. The end-point of the plan also needs to be defined, i.e., does the plan finish when the food leaves the factory or should consideration be given to subsequent use and appropriate instruction.

In the application of the seven HACCP principal activities to the food processing and manufacturing sector, the following specific points should be kept in mind:

5.3.1 Assembly of team

The type of HACCP plan to be developed will influence the composition of the HACCP team. The team will need to include a range of expertise and have access to necessary information in order to confidently identify the hazards, Critical Control Points, and critical limits associated with the process and/or product under consideration. The team should include a designated chairperson and a rapporteur to record any decisions taken. The number of persons on the team will vary depending upon the foods and type of operation being considered, nature of anticipated hazards and sophistication of control measures desired. For smaller organizations, it may be appropriate for one person to fulfil more than one role provided that the team is capable of obtaining and using all relevant information for the prevention and control of hazards. Outside expert advice should be obtained from other sources as necessary.

5.3.2 Description of the product

A full description of the product under study, or intermediate product if only part of the process is being looked at, should be prepared. The product should be defined in terms of composition, structure, processing (e.g., has product been heated and to what extent), packaging system, storage and distribution conditions, required shelf-life, and instructions for use.

5.3.3 Identification of intended use

The intended use should be based on the expected uses of the product by the end-user or consumer. In certain cases, vulnerable groups of the population, e.g., infants and children, pregnant women, the health-impaired and the elderly, may have to be considered.

5.3.4 Construction of flow diagram and facility layout

Prior to the hazard analysis, it is necessary to examine carefully the process/product under consideration and produce a flow diagram around which the HACCP plan can be based. The format of the flow diagram is a matter of choice; there are no rules for presentation, except that each step in the process (including process delays) should be outlined in sequence in the flow diagram from the selection of raw materials through to processing, distribution, and retail and customer handling. The flow diagram should be prepared with sufficient technical data for the study to proceed. A diagram of the layout of the facility indicating equipment placements and movements of products and personnel through the process should also be prepared.

Examples of the type of data needed include, but are not necessarily limited to: all raw materials/ingredients and packaging used (biological, chemical and physical data); sequence of all process steps (including raw material addition); time/temperature history of all raw materials, intermediates and final product, including potential for delay; flow conditions for liquids and solids; product recycle/rework loops; equipment design features (including presence of void spaces); efficacy of cleaning and disinfection procedures; environmental hygiene; personnel routes; routes of potential cross-contamination; high- and low-risk area segregation; personal hygiene practices; storage and distribution conditions; and consumer use instructions.

5.3.5 On-site confirmation of flow diagram and facility layout

The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation, and amend the flow diagram and facility layout where appropriate.

5.3.6 Listing of all hazards associated with each step and consideration of any control measures to eliminate or minimize hazards (Principal Activity 1)

The HACCP team should list all the biological, chemical and/or physical hazards that may be reasonably expected to occur at each step, including acquisition and storage of ingredients. A hazard is unacceptable contamination of a biological, chemical or physical nature, and/or survival or multiplication of microorganisms of concern for food safety, and/or unacceptable production or persistence in foods of toxins or other undesirable products of microbial metabolism. Biological hazards include pathogenic microbes (parasites, bacteria and viruses) and toxigenic plants and animals. Chemical hazards include, among others, pesticides, cleaning compounds, antibiotics, heavy metals, and additives such as sulfites. Physical hazards include objects - such as metal fragments, glass, and stones - that may cut the mouth, break teeth, cause choking, or perforate the alimentary tract. The team must then describe and consider what control measures, if any, exist which can be applied for each hazard.

Control measures are those actions and activities that can be used to eliminate hazards or reduce their impact or occurrence to acceptable levels. More than one measure may be required to control a specific hazard and more than one hazard may be controlled by a specified measure. No attempt is made at this step to establish CCPs.

5.3.7 Establishment of Critical Control Points (Principal Activity 2)

After hazards have been identified, a CCP decision tree may be used to determine whether a step is a CCP for the identified hazard. A model HACCP decision tree for establishing CCPs is given in Diagram 1 of Annex II, but training in its use may be required to assure its proper application. Applications of the model decision tree may differ slightly, depending on whether the operation is for production, slaughter, processing and manufacturing, storage, distribution or other sectors.

While the establishment of CCPs can be facilitated by the application of a decision tree, other methods have also been used to determine CCPs. However, the decision tree approach should be used in training and during the initial applications by inexperienced HACCP team members.

All hazards which may be reasonably expected to occur, or be introduced, at each step, should be considered. If a hazard has been identified for which no control measure exists, the product or process should be modified so that the hazard is eliminated or reduced to acceptable or minimal levels.

5.3.8 Establishment of critical limits for each CCP (Principal Activity 3)

Critical limits must be specified for each control measure at each CCP. In some cases, more than one critical limit will be specified at a particular CCP. Criteria often used include temperature, time, moisture level, pH, water activity, available chlorine, and sensory parameters such as visual appearance and texture. Critical limits may be derived from a variety of sources such as regulatory standards or guidelines, literature surveys, experimental studies and/or expert advice.

In some cases, processing variations may require the use of target levels to ensure that critical limits are met. Target levels are criteria which are more stringent than critical limits and which are used by a processor to reduce the risk of exceeding a critical limit. For example, a critical limit may require that a food be formulated to a final pH of 4.6 or less to prevent growth of certain pathogens. Due to variations that may occur during the preparation of the food, the processor might decide to establish a target level of pH 4.5 to reduce the risk that the critical limit (i.e., pH 4.6) is exceeded.

5.3.9 Establishment of a monitoring system for each CCP (Principal Activity 4)

Monitoring is the periodic measurement or observation at a CCP to determine whether a critical limit or target level has been met. The monitoring procedure must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time for corrective action to be taken to maintain control of the process before there is a need to reject the product. If monitoring is not continuous, then the frequency of monitoring must be sufficient to guarantee that the CCP is in control.

Monitoring procedures for CCPs should be carried out rapidly and, therefore, lengthy analytical testing will not be feasible in most cases. Physical and chemical measurements are preferred over the slower microbiological testing. Certain physical and chemical parameters can be used to indicate the microbiological control of the product.

Monitoring must be conducted by a designated person with knowledge and authority to carry out corrective actions when indicated.

5.3.10 Establishment of corrective actions (Principal Activity 5)

Corrective actions are those actions to be taken either when monitoring results show that a CCP has deviated from its specified critical limit or target level or, preferably, when monitoring results indicate a trend towards loss of control. In the latter case, actions may be taken to adjust the process and maintain control before the deviation leads to a loss of control and hence to a safety hazard. Disposition actions need to be taken with food that has been produced during the time period that the CCP was out of control. Both corrective actions and disposition actions should be documented in the HACCP record-keeping. Responsibility for documenting these actions must be clearly assigned.

5.3.11 Establishment of verification procedures (Principal Activity 6)

Procedures for verification must be established to ensure that the HACCP system is working correctly. Monitoring and auditing methods, procedures and tests, including random sampling and analysis, can be used for this purpose. The frequency of verification should be sufficient to provide assurance that the HACCP plan and its implementation will prevent food safety problems. Examples of verification activities include: review of the HACCP system and its records; procedures used to determine if CCPs are under control; review of corrective actions and product-disposition actions when critical limits are not met; and, validation of established critical limits.

5.3.12 Establishment of record-keeping and documentation (Principal Activity 7)

Adequate, accurate record-keeping and documentation are essential to the application of the HACCP system. Documentation of HACCP procedures at all steps should be included and assembled in a manual. Examples of records are: HACCP plan; CCP monitoring records; deviations file; corrective/disposition action file; modification file; verification data; and, review data as well as such information as the cleaning and disinfection file. In practice, establishing record-keeping and documentation is often dealt with by the HACCP team prior to or in conjunction with establishing verification procedures.

5.3.13 Implementation of the HACCP plan

Once the HACCP plan has been developed for the process, it has to be applied and implemented. The following points will need to be considered in order to facilitate this:

- a. allocation of responsibility for the management and supervision of the plan, monitoring of CCPs and record-keeping and documentation;
- b. development of simple, but clear, work instructions for the monitoring of CCPs;
- c. development of recording sheets and other documentation;
- d. training and education of staff based on the HACCP plan and on work instructions indicating what, how, when and who should do what; and,
- e. allocation of responsibility for decisions on corrective actions and disposition actions.

5.3.14 Review of the HACCP plan

In addition to the verification procedures outlined above, it is necessary to have a system in place that will automatically initiate a review of the HACCP plan prior to any changes which may affect the safety of the product, including the following: change in raw material or product formulation; change in processing system; change in factory layout or environment; modification to processing equipment; change in cleaning and disinfection programme; change in packaging, storage, or distribution system; change in staff and/or responsibilities; anticipated change in consumer use; and, receipt of information indicating a health risk associated with the product.

Data arising from HACCP reviews must be documented and form part of the HACCP record-keeping system. Any changes arising from a HACCP review must be fully incorporated into the HACCP plan. This is because these changes may mean that certain CCPs' control measures or specified critical limits or target levels may have to be changed and/or additional CCPs or control measures may have to be put in place. It is essential for a user to be sure that accurate up-to-date information is available from the records. Additionally, senior management will quite properly expect that resources used to establish HACCP are not wasted and that record-keeping and documentation reflect the actual operation of the process. A system of management for the maintenance of the HACCP record-keeping system is, therefore, required and its proper operation is essential.

6. APPLICATION OF HACCP BY GOVERNMENT HEALTH AND FOOD AUTHORITIES

6.1 Introduction

Implementation of the HACCP system by industry is recognized as the optimal management tool to assure food safety through cost-effective regulatory programmes. The application of the HACCP system by the various sectors of the food chain from primary production to the consumer, including processing, manufacturing, distribution, retailing and final preparation can contribute significantly to the safety of the food supply. However, it is essential that government authorities understand and appreciate the benefits of the HACCP concept and their role in the implementation of HACCP by industry.

6.2 Benefits

There are numerous benefits for government health and food authorities and for consumers with the implementation of the HACCP system as a regulatory tool for food safety control. Some key benefits are as follows:

- o HACCP is a systematic approach which can be applied to cover all aspects of food safety, including biological, chemical and physical hazards, at all stages of the food chain, including raw materials, growth, harvesting, purchase, production, distribution and storage, to final product use.
- o HACCP systems provide scientifically sound bases for demonstrating that all reasonable precautions have been taken to prevent a hazard from reaching the consumer.
- o HACCP systems focus on the prevention of food safety hazards instead of relying on traditional inspection practices to detect unsafe products before consumption.

- o HACCP implementation provides government inspection systems with the optimal and cost-effective food safety control tool devised to date.
- o The HACCP approach identifies all conceivable hazards that can be reasonably expected to occur.
- o The HACCP approach focuses inspection resources on the critical aspects of food production relating to food safety.
- o HACCP systems, as a preventive approach, can minimize public health risks associated with the consumption of food.
- o Application of HACCP promotes confidence in the safety of food products and thus promotes trade and stabilizes the food business.

6.3 Role of government authorities in HACCP

The basic role of government health and food authorities is to ensure the appropriate application of HACCP principal activities by the various food sectors and to facilitate HACCP implementation as deemed practical or necessary. Cooperation between the industry and government authorities is essential. Government authorities have a responsibility to provide leadership in food safety control by accepting and promoting the HACCP principal activities elaborated above for the food processing and manufacturing industry. In some cases, new regulations or legislative authority may be required to permit regulatory authorities to employ HACCP as an inspection tool. In other cases, HACCP may be encouraged by government for use as part of a voluntary programme by the food industry. The determination regarding mandatory or voluntary implementation and the need for regulatory/legislative authority will depend on the existing regulatory programmes and prevailing conditions at the national, state/provincial and local levels.

While the production of safe food products is and remains the primary responsibility of industry, government health and food authorities have responsibilities both as enforcers and as facilitators. The extent to which government authorities serve in each capacity depends on laws, policies and other factors. As enforcers, regulatory authorities assess the appropriate implementation of HACCP plans and confirm that they are properly designed and effectively implemented. For the effective implementation of HACCP systems, rigid interpretation, application, and enforcement of HACCP principal activities and procedures should be avoided. The specific food safety hazards represented by a food product, preparation procedures, and scope and style of operation will dictate the rigor of the HACCP application and the degree of record-keeping, documentation and confirmation activities relating to enforcement. Regulatory authorities must be aware of these characteristics when designing confirmation procedures for a given operation. The function of an inspector in the HACCP system is to confirm that the HACCP plan has been properly designed and implemented, and is operating effectively. The inspection procedures used in a facility employing a HACCP system will be substantially different than traditional inspection practices. Regulatory authorities inspecting a HACCP system must be trained in HACCP applications and must learn to focus on the conceptual features of the HACCP system rather than on the physical features emphasized by the traditional approach.

As facilitators, government authorities can advise and assist the industry in developing HACCP plans and in implementing appropriate food safety controls. For example, government authorities may develop or facilitate the writing of model HACCP plans for various food products or operations. They may also provide HACCP training for the industry and collaborate in the development of individual HACCP systems. This

role may be particularly important in instances where a government regulation requires implementation of HACCP systems for food safety control. However, it is important to recognize that at no time can the industry transfer legal responsibility for food safety and liability to the government under a HACCP plan. The government can provide helpful information to the food industry for the development of HACCP plans by conveying the results of epidemiological investigations and public-health surveillance programmes. These data can help in identifying hazards, assessing risks and establishing CCPs in order to improve HACCP plans.

6.4 Application of HACCP principal activities

While a comprehensive role for government authorities in the development and implementation of HACCP systems is described here, the actual involvement of government health and food authorities will depend on national procedures as dictated by law or practice. Consequently, the term "confirmation" as used in this section should be understood to refer to a range of possible activities from active involvement on the HACCP team to auditing of the HACCP plan and its implementation during inspections.

Confirmation inspections may occur in a manner and frequency deemed necessary and appropriate by health and food authorities based on the significance of the potential food safety hazards represented by a given food product, process or operation.

6.4.1 Assembly of HACCP team

Confirmation should be obtained that the appropriate technical information required to establish an effective HACCP system was accessible and was employed in the development of the HACCP plan. Government authorities, acting in the role of facilitators, may provide guidance for the HACCP team.

6.4.2 Description of the product

Confirmation should be obtained that the product's composition is accurately and comprehensively described in order to support the development of an effective HACCP system. Regulatory authorities should not have unlimited access to proprietary information. However, all components and characteristics of the product which could represent food safety hazards should be accessible.

6.4.3 Identification of intended use

Confirmation should be obtained that the product has been accurately and adequately described regarding its intended use and target population, if any.

6.4.4 Construction of product flow diagram and facility layout

Confirmation should be obtained that the product flow diagram is accurate and identifies all significant operational steps and procedures and that the layout identifying equipment and the factory or production area is adequate for designing appropriate HACCP plans for food safety control.

6.4.5 On-site verification of product flow diagram and facility layout

Confirmation should be obtained that the flow diagram and facility layout have been verified.

6.4.6 Listing of all hazards associated with each step and consider any control measures to address identified hazards (Principal Activity 1)

Confirmation should be obtained that all hazards which may be reasonably expected to occur have been considered. Ensure that the HACCP team has access to information regarding emerging hazards and new risks known by regulatory authorities, e.g., recently-recognized pathogens, foodborne-disease outbreaks and hazard occurrences.

6.4.7 Identification of Critical Control Points (Principal Activity 2)

Confirmation should be obtained that CCPs have been appropriately identified to control food safety. Confirmation should include assurance that all potential hazards and their likelihood of occurrence have been addressed. Government health and food authorities have a duty to promptly share new information and experiences on food safety with industry to ensure that CCPs are determined correctly and that appropriate modifications can be made to HACCP plans. Regulatory authorities have the right to challenge the industry to justify its assessment of CCPs.

6.4.8 Establishment of critical limits for each CCP (Principal Activity 3)

Confirm that critical limits have been established and are effective for all CCPs identified. Critical limits may exist in regulation. If there is a demonstrated need for critical limits in regulation to ensure food safety and they do not already exist, then appropriate regulations should be developed which incorporate them. Any establishment of microbiological critical limits should be based on "The General Principles for the Establishment and Application of Microbiological Criteria for Foods" as described in the Codex Procedural Manual.

6.4.9 Establishment of a monitoring system for each CCP (Principal Activity 4)

Confirm that the industry has established points and procedures for monitoring at each CCP. Ensure that the results of monitoring are incorporated in subsequent operations including corrective actions, if necessary. Government authorities may provide guidance for effective monitoring activities.

6.4.10 Establishment of corrective actions (Principal Activity 5)

Confirm that the industry has identified effective corrective action procedures for deviations from the HACCP plan when they occur. Review and determine the adequacy of corrective actions taken when a deviation occurs by (a) recommending or requiring that a certain action be taken or (b) working with the industry to develop appropriate corrective actions to ensure food safety. Corrective actions should be based on an analysis of the root causes of HACCP system failures and changes should be made to prevent the recurrence of food safety hazards.

6.4.11 Establishment of verification procedures (Principal Activity 6)

Confirm that procedures exist to assess the effectiveness of the HACCP system. Verification procedures conducted by the industry should result in the collection and use of information to improve the effectiveness of the HACCP system. At a minimum, regulatory authorities should be made aware of the results of the industry's verification process. Depending on the degree of regulatory involvement and available resources, it may also be appropriate for government authorities to assume a more active role in verifying that HACCP systems are working as they are intended by:

- a. requiring access to records for CCPs related to deviations, corrective actions, product disposition and other pertinent information required for verification of food safety control;
- b. requiring access to HACCP plans restricted to food safety control;
- c. establishing verification inspection schedules at CCPs based on the degree of risk represented;
- d. direct observation of the HACCP system operation;
- e. collection and analysis of samples from CCPs or other appropriate points;
- f. review of critical limits to assess their effectiveness;
- g. review of industry records of verification procedures at CCPs which certify compliance with the HACCP plans or deviations from the plan and corrective actions taken;
- h. revalidation of existing HACCP plans, including on-site review and verification of flow diagrams and CCPs; and,
- i. review of modifications to the HACCP plan.

Confirmation inspections by government authorities may be indicated when:

- a. changes have been made in the HACCP plan;
- b. requested on a consultative basis;
- c. evidence indicates critical limits may be exceeded;
- d. new information indicates the potential for food safety hazards to occur in a given food product; and,
- e. foods produced have been implicated in a case or outbreak of foodborne disease.

6.4.12 Establishment of record-keeping and documentation (Principal Activity 7)

Confirm that appropriate records are kept and sufficient documentation exists on CCPs. The degree and type of records and documentation required will depend on the significance of the food safety hazards represented by the food product, manner of preparation, and type of operation involved. The records and documents that must be made available to regulatory authorities upon request should not include proprietary information unless that information is critically related to a food safety hazard.

Records and documentation required for confirmation inspections by regulatory authorities must be maintained and filed in such a manner that they may be readily retrieved and presented upon request.

7. FURTHER CONCLUSIONS AND RECOMMENDATIONS

In addition to the above discussion concerning the respective roles of industry and government in the application of HACCP to food processing and manufacturing, the following conclusions and recommendations are offered to provide additional guidance in the development and implementation of HACCP training courses:

- (1) Successful training in HACCP requires experience in the practical application of HACCP principal activities. It cannot be readily achieved by simply reading textbooks or similar materials. A useful structure for a training course is to have an introductory session followed by working groups which are assigned to study practical or case-study examples. The presentation and review of the working groups' conclusions are not only instructive to participants, but may also be used, along with some form of course assessment, by trainers to evaluate and improve the course. Where experienced personnel are available within a country, the course can further be improved by using the language and practical examples relevant to the country in which the course is being taught.
- (2) These training considerations should be used to develop training courses and materials for both trainers and those to be trained. While the considerations in this document relate to the food processing and manufacturing industry, an effort should be made to promote HACCP applications for other parts of the food chain such as primary production, harvest, catering and small food businesses with the aim of developing appropriate training materials for these sectors.
- (3) At least initially, joint HACCP training courses attended by both government and industry personnel can serve to promote a common understanding of HACCP and, in particular, its practical application in food operations.
- (4) Successful promotion of HACCP can be facilitated by first educating decision- and policy-makers in government and industry in the principal activities and benefits of HACCP.
- (5) Academia should be encouraged to include HACCP in their education curricula for professionals in food science and technology and related health and food fields.

ANNEX I

**LIST OF PARTICIPANTS OF THE WHO CONSULTATION ON
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ANNEX II

**CODEX GUIDELINES FOR THE APPLICATION OF THE HAZARD ANALYSIS
CRITICAL CONTROL POINT (HACCP) SYSTEM**

(Adopted by the 20th Session of the
Joint FAO/WHO Codex Alimentarius Commission, 1993)

PREAMBLE

The Hazard Analysis Critical Control Point (HACCP) system identifies specific hazards and preventative measures for their control to ensure the safety of food.* HACCP is a tool to assess hazards and establish control systems that focus on preventative measures rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from the primary producer to final consumer. As well as enhanced food safety, benefits include better use of resources and more timely response to problems. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the workforce. It also requires a team approach; this team should include appropriate experts. Examples might be agronomists, veterinarians, production personnel, microbiologists, medical experts, public health specialists, food technologists, chemists and engineers according to the particular study. The application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems.

DEFINITIONS

HACCP: A system which identifies specific hazard(s) and preventative measures (PMs) for their control.

Hazard: The potential to cause harm. Hazards can be biological, chemical or physical.

Critical Limit: A value which separates acceptability from unacceptability.

Critical Control Point (CCP): A point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels.

Corrective Action: The actions to be taken when the results of monitoring the CCP indicate a loss of control.

Monitor: To conduct a planned sequence of observations or measurements to assess whether a CCP is under control.

PRINCIPLES

HACCP is a system which identifies specific hazard(s) and preventative measures for their control. The system consists of the following seven principles:

PRINCIPLE 1

Identify the potential hazard(s) associated with food production at all stages, from growth, processing, manufacture and distribution, until the point of consumption. Assess the likelihood of occurrence of the hazard(s) and identify the preventative measures for their control.

* While the application of HACCP to food safety was considered here, the system can equally be applied to other aspects of food quality.

PRINCIPLE 2

Determine the points/procedures/operational steps that can be controlled to eliminate the hazard(s) or minimize its likelihood of occurrence - (Critical Control Point (CCP)). A "step" means any stage in food production and/or manufacture including raw materials, their receipt and/or production, harvesting, transport, formulation, processing, storage, etc.

PRINCIPLE 3

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 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 which include supplementary tests and procedures 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.

APPLICATION OF THE PRINCIPLES OF HACCP

During the hazard analysis 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, consumer populations at risk 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 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 given the context of the application.

Application

The application of HACCP principles requires the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

1. Assemble HACCP team

Assemble a multidisciplinary team that has specific knowledge and expertise appropriate to the product. Where such expertise is not available on site, expert advice should be obtained from other sources.

2. Describe product

A full description of the product should be drawn up, including information on composition 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. Each step within the specified area of operation should be analyzed for the particular part of the operation under consideration to produce the flow diagram. 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 hazards associated with each step and consider any preventative measures to control hazards (Principle 1)

The HACCP team should list all the biological, chemical or physical hazards that may be reasonably expected to occur at each step and describe the preventative measures that can be used to control these hazards.

The HACCP team next analyzes each hazard.

For inclusion in the list, hazards must be of a nature such that their elimination or reduction to acceptable levels is essential to the production of a safe food.

The team must then consider what preventative measures, if any, exist which can be applied for each hazard.

Preventative measures are those actions and activities that are required to eliminate hazards or reduce their impact or occurrence to acceptable levels. More than one preventative measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified preventative measure.

7. Apply HACCP Decision Tree to Each Step (Principle 2)

The identification of a CCP in the HACCP system is facilitated by the application of a decision tree (Diagram 1). All hazards that may be reasonably expected to occur, or be introduced at each step, should be considered. Training in the application of the decision tree may be required.

If a hazard has been identified at a step where control is necessary for safety, and no preventative 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 preventative measure.

Application of the decision tree determines whether the step is a CCP for the identified hazard. Application of the decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other.

8. Establish critical limits for each CCP (Principle 3)

Critical limits must be specified for each preventative measure. 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, Aw, and available chlorine, and sensory parameters such as visual appearance and texture.

9. Establish a Monitoring System for Each CCP (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 loss of control at the CCP. Further, monitoring should ideally provide this information in time for corrective action to be taken to regain control of the process before there is a need to reject the product. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is 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 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 (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.

Corrective action should also occur when monitoring results indicate a trend towards loss of control at a CCP. Action should be taken to bring the process back into control before the deviation leads to a safety hazard.

11. Establish Verification Procedures (Principle 6)

Establish procedures for verification that the HACCP system is working correctly. Monitoring 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 validate the HACCP system. Examples of verification activities include:

- Review of the HACCP system and its records.
- Review of deviations and product dispositions.
- Operations to determine if CCPs are under control.
- Validation of established critical limits.

12. Establish Record Keeping and Documentation (Principle 7)

Efficient and accurate record keeping is essential to the application of a HACCP system. Documentation of HACCP procedures at all steps should be included and assembled in a manual.

Examples are records associated with:

- Ingredients
- Product safety
- Processing
- Packaging
- Storage and distribution
- Deviation file
- Modifications to the HACCP system

An example of a HACCP worksheet is attached as Figure 2.

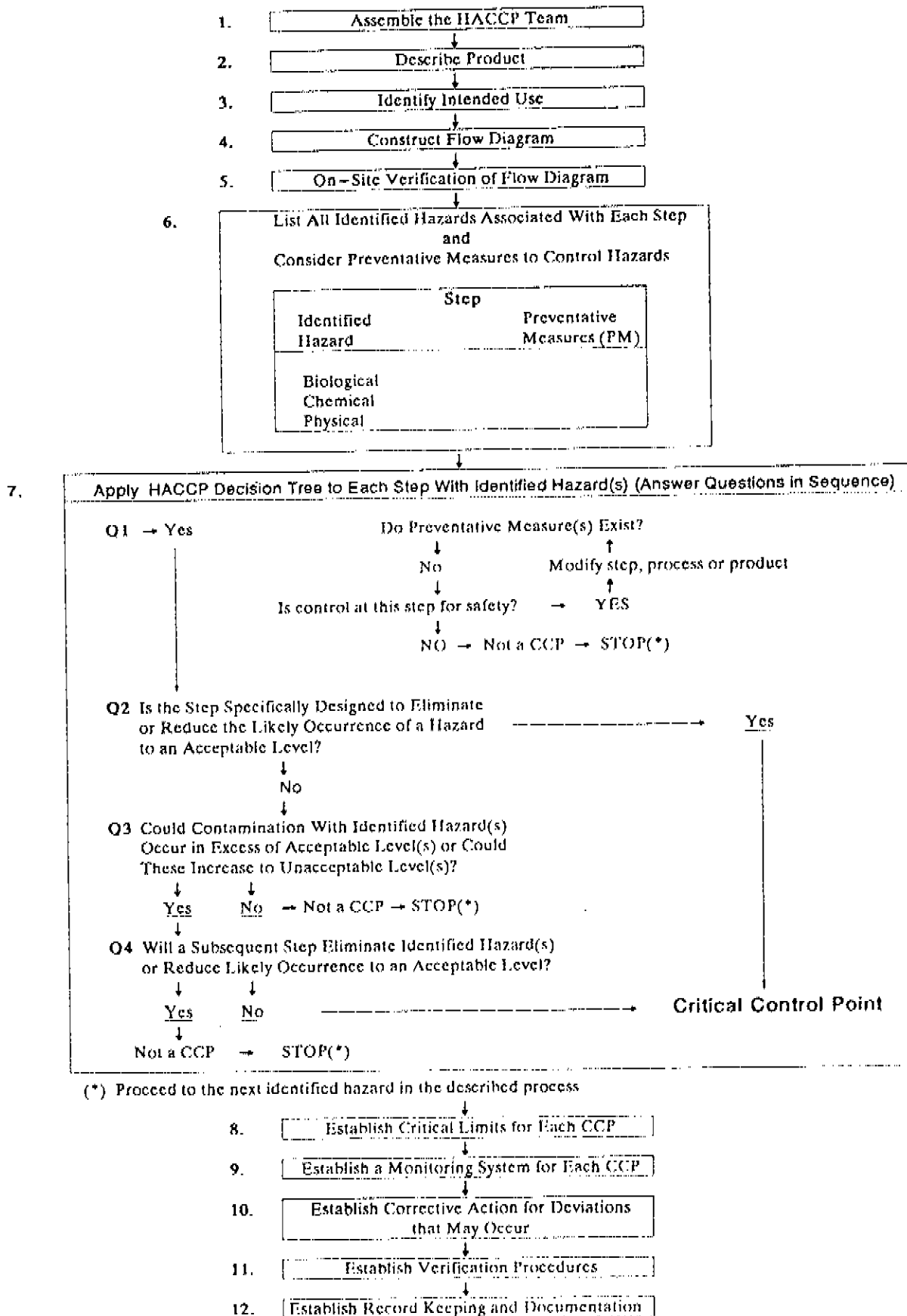
TRAINING

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. 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 (Blackwell Scientific Publications, Oxford Mead, UK, 1988, reprinted 1989). The section on training (Chapter 8) in the above monograph is equally applicable as an approach to training in respect to hazards other than those of a microbiological nature.

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.

DIAGRAM 1

Logic Sequence for Application of HACCP



(*) Proceed to the next identified hazard in the described process

Figure 2

HACCP WORKSHEET

1. Describe Product

2. Diagram process flow

3. List:

Step	Hazard(s)	Preventative Measure(s)	COP(S)	Critical Limit(s)	Monitoring Procedure(s)	Corrective Action(s)	Record(s)

4. Verification

ANNEX III

LIST OF BASIC HACCP REFERENCES

International Life Sciences Institute - Europe. "HACCP - A simple guide to understanding and applying the hazard analysis critical control point concept". Brussels (draft January 1993).

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"The role of food safety in health and development". Technical Report Series No. 705, WHO Geneva (1984).

"Report of the WHO/ICMSF meeting on Hazard Analysis Critical Control Point system in food hygiene. Geneva, 9-10 June 1980" VPH/82.37, WHO Geneva (1982).

ANNEX IV

GLOSSARY OF HACCP TERMS

Control:

To manage the conditions of an operation to establish the state wherein correct procedures are being followed and critical limits or target levels are being met.

Control Measure:

Those actions and activities that can be used to eliminate hazards or reduce their impact or occurrence to acceptable levels.

Corrective Action:

The action taken when monitoring at a CCP indicates a potential loss of control or when a critical limit is not met.

Critical Control Point (CCP):

A point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical Limit:

A value which separates acceptability from unacceptability.

HACCP Plan:

The written document which is based upon the principal activities of HACCP and which delineates the procedures to be followed to assure the control of a specific process or procedure.

Hazard:

A biological, chemical or physical agent or condition with the potential to cause harm.

Hazard Analysis:

The process of collecting and interpreting information to assess the risk and severity of potential hazards.

Monitor:

To conduct a planned sequence of observations or measurements of a control parameter to assess whether a CCP is under control.

Risk:

An estimate of the likely occurrence of a hazard.

Severity:

The seriousness of a hazard.

Step:

Any location or stage in food production and/or manufacture (including raw materials), their receipt and/or production, harvesting, transport, formulation, processing/manufacturing, storage, etc. as identified in the flow diagram.

Target Levels:

Values which are used to assure that critical limits are met.

Verification:

The use of methods, procedures, or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan, and/or whether the HACCP plan needs modification and revalidation.

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