

Strategies for Implementing HACCP in Small and/or Less Developed Businesses

Report of a WHO Consultation

**In collaboration with the
Ministry of Health, Welfare and Sports, The Netherlands**

The Hague, 16-19 June 1999



**Food Safety Programme
World Health Organization**

This document is available on the Internet at:
<http://www.who.int/fsf>

Copies may be requested from:
World Health Organization
Food Safety Programme
CH-1211 Geneva 27

E.mail: foodsafety@who.int
Fax: +41 22 791 48 07

© World Health Organization, 1999

This document is not a formal publication of the World Health Organization (WHO), and all rights are reserved by the Organization. The document may, however, be freely reviewed, abstracted, reproduced and translated, in part or in whole, but not for sale nor for use in conjunction with commercial purposes.

The views expressed in documents by named authors are solely the responsibility of those authors.

Contents

Abbreviations		
1.	Introduction	1
2.	Background	2
3.	Objectives	3
4.	Scope	3
5.	Strategies for implementing HACCP in Small and/or Less Developed Businesses (SLDBs)	4
5.1	Benefits of and Barriers to Implementing HACCP	5
5.2	Overcoming Barriers - Promoting and Implementing HACCP in SLDBs	6
5.3	Advice on Development of Sector-Specific Industry Guides	14
5.4	Guidelines for the Application of the HACCP System to SLDBs	19
6.	Conclusions and Recommendations	26
Annex 1	List of Participants	27
Annex 2	List of Background Papers	29
Annex 3	Glossary	31

Abbreviations

CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CCP	Critical Control Point
CM	Control Measures
FAO	Food and Agriculture Organization of the United Nations
GHP	Good Hygienic Practices
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Point
PRP	Prerequisite Programme (see also Glossary under “Prerequisites for HACCP”)
SLDB	Small and/or Less Developed Business
WHO	World Health Organization
WTO	World Trade Organization

1. Introduction

The World Health Organization (WHO), in collaboration with the Ministry of Health, Welfare and Sports, The Netherlands, convened a Consultation on the *Development of a Strategy for the Implementation of HACCP in Small and/or Less Developed Businesses*. The Consultation took place in The Hague, The Netherlands, 16-19 June 1999. The list of participants is presented in Annex 1.

The meeting was opened by Dr Henk Verburg, Chief Veterinary Public Health Officer, Inspectorate for Health Protection, The Netherlands. In addressing the Consultation, Dr Verburg explained that a major role of the Inspectorate in the Netherlands is to enhance safety of food produced and distributed by small businesses. Like in many parts of the world, small food businesses represent a large proportion of food enterprises and are responsible for a large share of food consumed by the population. Many of them still lack adequate food safety management programmes and do not meet the national or European Union requirements. Dr Verburg emphasized the significance of microbiological contamination of food and the need for improving the safety of food produced and prepared by small businesses for better consumer protection and expressed his support for the work that the Consultation was undertaking.

On behalf of the WHO, Dr Yasmine Motarjemi, WHO Food Safety Programme, welcomed the participants to the Consultation. She explained that one of the key roles of the WHO Food Safety Programme is to promote food safety and provide guidance on how to achieve this. For a number of years, WHO has promoted the application of the Hazard Analysis and Critical Control Point (HACCP) system in food enterprises. In a series of consultations and workshops, the Organization has enhanced the common understanding of the HACCP system by harmonizing the terminology and the approach for its application. WHO has also placed particular importance on the application of a HACCP approach to strengthening the training and education of food handlers in cottage industries, restaurants and street food vendors.^{1,2}

In a previous WHO consultation on the *Hazard Analysis Critical Control Point System: Concept and Application*, with the participation of the Food and Agriculture Organization of the United Nations (FAO), May 1995, it was recommended that once countries have decided to implement HACCP, they ought to develop strategies which reflect their perceived needs.³ The consultation also recommended that factors to be considered when determining priorities should include epidemiological information on foodborne diseases, high-risk foods or processes, and the economic importance of the sectors under consideration. In this regard, it is pertinent to recall that foodborne diseases, a major public health problem of the contemporary world, are estimated to annually affect up to 10% or more of the population in the industrialized countries. Although no estimation can be made for the developing countries, it is believed that the prevalence of foodborne diseases in these regions of the world is even greater. Worldwide, the incidence of diarrhoeal diseases alone has been estimated at 4000 million cases per year, which *per se* indicates a serious underlying food safety problem. Epidemiological investigations have also

¹ *Application of the Hazard Analysis Critical Control Point (HACCP) System for the Improvement of Food Safety: WHO Supported Case Studies on Food Prepared in Homes, at Street Vending Operations, and in Cottage Industries*. WHO document WHO/FNU/FOS 93.1. World Health Organization, Geneva, 1993.

² Bryan, F. *Hazard Analysis Critical Control Point Evaluations. A guide to identifying hazards and assessing risks associated with food preparation and storage*. World Health Organization, Geneva, 1992.

³ *Hazard Analysis Critical Control Point System: Concept and Application. Report of a WHO Consultation with the participation of FAO*. WHO document WHO/FNU/FOS/95.7. World Health Organization, Geneva, 1995.

indicated that a large proportion of foodborne diseases results from poor hygienic handling of food in small businesses, which may in itself be a reflection of poor management practices. Thus, the importance of this Consultation which aims to address the problems faced by small and/or less developed businesses (SLDBs) with regard to food safety and, in particular, implementation of HACCP.

Dr Motarjemi thanked all the participants and representatives of organizations present for having accepted the WHO invitation and expressed appreciation to those governments, institutes and organizations that have supported their participation. She thanked the Ministry of Health, Welfare and Sports of the Netherlands, in particular Dr Jaap Jansen, for hosting the meeting.

In closing, Dr Motarjemi stated that the outcome of the Consultation was an important first step in examining and addressing the problems of SLDBs. She hoped that the recommendations of the Consultation would be widely disseminated and seriously considered by the health and food control authorities in Member States. Any feedback on the practicability of the recommendations was welcome and would be taken into consideration when further developing the strategy.

The Consultation elected Mr John Barnes as Chairperson, Ms Zahara Merican as Vice-Chairperson, and Mr Jeffrey Brown as Rapporteur. The deliberations of the Consultation were based on a number of background papers (listed in *Annex 2*) and the work carried out by working groups led by Dr Jaap Jansen, Prof. Michiel van Schothorst, and Mr Richard Souness.

2. Background

Worldwide, it is recognized that the application of the HACCP system to food production and preparation has clear benefits and the potential of enhancing food safety and preventing many cases of foodborne diseases. These benefits have been outlined in Section 5.1 of this report as well as in other WHO documents.^{4,5} While the application of HACCP is making headway in large food industries, SLDBs have, for different reasons, experienced difficulties in implementing HACCP (see Section 5). However, the importance of enhancing food safety in SLDBs in strategies for preventing foodborne illnesses cannot be overemphasized.⁶

The problems of implementing HACCP in small industries and in developing countries have been the subject of extensive discussions at meetings of the Codex Committee on Food Hygiene (CCFH). It has been recognized that there is a need to develop a strategy for implementing the HACCP system or an equivalent risk-based system in industries where the food safety management system is not fully developed and resources are scarce. The Joint FAO/WHO Consultation on the *Role of Government Agencies in Assessing HACCP* (Geneva, 2-6 June 1998)⁷ also acknowledged the need to work on facilitating and evaluating the implementation of HACCP in small businesses. At the Thirtieth Session of the CCFH, a working group chaired by the

⁴ Bryan, F L. *Hazard Analysis Critical Control Point Evaluations. A guide to identifying hazards and assessing risks associated with food preparation and storage*. World Health Organization, Geneva, 1992.

⁵ *HACCP: Introducing the Hazard Analysis and Critical Control Point System*. WHO document WHO/FSF/FOS/97.2. World Health Organization, Geneva, 1997.

⁶ *Foodborne disease: a focus on health education*. World Health Organization, Geneva (in press).

⁷ *Guidance on Regulatory Assessment of HACCP. Report of a Joint FAO/WHO Consultation on the Role of Government Agencies in Assessing HACCP*. WHO document WHO/FSF/FOS/98.5, pp 25-28. World Health Organization, Geneva, 1998.

Netherlands was requested to review the problems of this sector and develop specific recommendations on this issue. A meeting was held in The Hague, in April 1998, in which delegates from 12 countries from different parts of the world, representatives of the Codex Secretariat, WHO and the International Commission on Microbiological Specifications for Foods participated. The meeting discussed the problems of developing countries and small food industries and identified a number of barriers to the implementation of the HACCP system that warrant reflection and recommendations for ways to overcome them.⁸

It was recognized that, regardless of the stage of development of a country, small businesses usually have greater difficulties in implementing HACCP and that the Codex *Hazard Analysis and Critical control Point System and Guidelines for its Application*⁹ is developed from the perspective of large food industries and not well-adapted to small businesses. It was concluded that governments and professional trade bodies have a clear role to play in facilitating the implementation of HACCP in small businesses and other food businesses with less developed food safety management systems (referred to as less developed businesses), and that there is a need to develop specific guidelines for them.

The outcome of the meeting was presented at the Thirty-first Session of the CCFH (Orlando, 26-30 October 1998) and led to an extensive discussion on the subject. Delegates from many countries and representatives of FAO and WHO recognized the importance of the subject and supported further work in this field, in particular the development of guidelines for the application of HACCP in SLDBs.

3. Objectives

The objectives of the Consultation were to:

- Review the difficulties experienced when applying the HACCP system in SLDBs.
- Consider the initiatives and approaches taken by different governments or sectors in assisting SLDBs in implementing HACCP.
- Define the role of governments and professional trade bodies in assisting SLDBs in implementing HACCP.
- Develop a strategy for implementing HACCP in SLDBs, considering different practical options.

4. Scope

For the purpose of this report, the term “small and/or less developed businesses” (SLDBs) shall mean businesses that because of their size, lack of technical expertise, economic resources, or the nature of their work, encounter difficulties in implementing HACCP in their food business. The term “less developed business” refers to the status of the food safety management system and not

⁸ Discussion paper on HACCP in small and less developed businesses (CX/FH 98/12), prepared by the Netherlands and presented at the Codex Committee on Food Hygiene, Orlando, Florida, 26-30 October 1998.

⁹ *Hazard Analysis and Critical Control Point System and Guidelines for its Application*. In “Food Hygiene Basic Texts”. Secretariat of the Joint FAO/WHO Food Standards Programme, FAO, Rome, 1997.

to the number of staff or volume of production. The Consultation addressed the implementation of HACCP in SLDBs in both developing and industrialized countries.

As an initial step in the development of a strategy for the implementation of HACCP in SLDBs, the Consultation reviewed the benefits and barriers to the implementation of HACCP in SLDBs. Emphasis was placed on the identification and examination of potential barriers, and developing guidance on ways to overcome these.

5. Strategies for implementing HACCP in Small and/or Less Developed Businesses (SLDBs)

Certain external conditions (e.g. regulations, market forces, expectations for due diligence, or promotion by public health and food control authorities) are increasing the pressure on the SLDBs to apply HACCP. SLDBs have in the past been discouraged from utilizing HACCP because of the guidance provided, which proved to be too complex for them. However, the seven principles of HACCP can be applied to all businesses processing or preparing food, irrespective of size or nature of their work, provided that food business operators have been adequately trained and have access to necessary equipment, practical support materials and information.

Where they are not able to develop and implement all the elements of the HACCP system by themselves, they will need external support. However, if SLDBs are to successfully implement HACCP, they will need to have management commitment to the process and be able to perform, at least, activities relating to the process description, monitoring, corrective actions and record keeping. Even when an SLDB does not have the ability to perform, on its own, all the essential elements of HACCP, a responsible and adequate food safety management system should still be the goal of the business.

An important consideration in implementing HACCP in SLDBs is the recognition that there exists a critical interdependency between HACCP and prerequisite programmes (PRP).¹⁰ Prior to implementing HACCP, businesses must be engaged in good hygienic practices (GHP). By first implementing GHP, the difficulties associated with implementing HACCP are minimized and businesses are encouraged to follow a graduated or stepwise approach to HACCP implementation¹¹.

There is a need for governments to encourage regulators, industry, educational institutes and, where appropriate, independent experts to accept their role in assisting SLDBs in applying HACCP. It is the key role of all stakeholders, including governments, industry, consumers and the media, to overcome barriers to implement HACCP. It is important for these stakeholders to consult and work together to determine priorities and time-scales for implementing HACCP. Initiatives to implement HACCP in SLDBs may be local, regional, national or international. Initiatives may also be general or focus on sectors (i.e. street vendors, food manufacturers, and food service).

In order to help facilitate strategies for the implementation of HACCP in SLDBs, the Consultation specifically considered three issues:

¹⁰ Prerequisite programmes refer to all practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety, as described in the Codex Alimentarius Commission's General Principles of Food Hygiene and other Codes of Practice.

¹¹ Motarjemi, Y and Käferstein, F. *Food Safety, Hazard Analysis and Critical Control Point and the Increase in Foodborne Diseases: A Paradox?* Food Control, 1999, 10:325-333.

- Analysing the benefits and barriers to the implementation of the HACCP system in SLDBs and recommending approaches to overcome these barriers;
- Providing advice for development of sector-specific industry guides; and
- Developing specific guidelines for the application of HACCP in SLDBs.

5.1 Benefits of and Barriers to Implementing HACCP

5.1.1 Benefits

There are clear benefits of implementing HACCP for all sectors: government, food industry and consumers alike. The following benefits should encourage businesses and governments to implement HACCP:

- Benefits to consumers
 - Reduced risk of foodborne disease;
 - Increased awareness of basic hygiene;
 - Increased confidence in the food supply; and
 - Improved quality of life (health and socio-economic).
- Benefits to industry
 - Increased consumer and/or government confidence;
 - Reduced legal and insurance costs;
 - Increased market access;
 - Reduction in production costs (reduced recall \ wastage of food);
 - Improved product consistency;
 - Improved staff-management commitment to food safety; and
 - Decreased business risk.
- Benefits to governments
 - Improved public health;
 - More efficient and targeted food control;
 - Reduced public health costs;
 - Trade facilitation; and
 - Increased confidence of the community in the food supply

5.1.2 Barriers

A number of barriers impede the implementation of HACCP in SLDBs. Potential barriers to the implementation of HACCP need to be identified and examined as an initial step in the development of any HACCP implementation strategy.

These barriers vary from country to country or from sector to sector. Some may be due to internal factors in individual businesses, e.g. the level of knowledge or resources available to a business. Others may be due to external factors, such as the availability of government or industry support.

The barriers may include:

- Lack of government commitment;
- Lack of customer and business demand;
- Absence of legal requirements;
- Financial constraints;
- Human resource constraints;
- Lack of expertise and/or technical support;
- Inadequate infrastructure and facilities; and
- Inadequate communications.

5.2 Overcoming Barriers - Promoting and Implementing HACCP in Small and/or Less Developed Businesses

The following issues may need to be considered in any strategy to promote HACCP implementation in SLDBs.

5.2.1 Government Commitment

Government¹² commitment is probably the single most important factor in the development and implementation of a successful HACCP initiative. In this respect, one of the most important tasks of governments is to raise the awareness of industry to the benefits of and the need for introducing HACCP to produce safe food.

Government awareness and commitment can be influenced by:

- Epidemiological data on foodborne diseases and food contamination;
- Consumer awareness and concerns;
- The need for food safety and HACCP for export of foods to other countries; and
- Advocacy by international organizations, e.g. Codex Alimentarius Commission, WHO, FAO and the World Trade Organization (WTO).

To promote HACCP and secure the commitment of enterprises, governments may need to draw the attention of food enterprises to the:

- Benefits achieved in rationalization of food safety management;
- Risks inherent in certain foodstuffs or production processes;
- Costs, including compensation costs resulting from production failure; and
- Value of HACCP in safeguarding the enterprise's image from any associated outbreaks and/or product recalls.

¹² All government agencies, including health, agriculture, trade, tourism, industry, planning, etc.

5.2.2 Customer and Business Demand

Food safety should form an important part of business-to-business dealings throughout the food chain. As such, businesses should ensure that they purchase food from appropriate suppliers, transporters and retailers who, in turn, implement food safety management systems. This should, in conjunction with better-informed consumers, create a demand for improvements in food safety.

Industry and trade associations have a particularly important role to play in promoting HACCP in SLDBs and in supporting them in the implementation of the HACCP system. If associations are not in existence, then consideration should be given to their establishment.

The role of such associations may include:

- Assistance in the production of industry guides (see Section 5.3);
- Communication of information pertinent to implementation of HACCP;
- Collection of data on products, hazards and risks;
- Development of product specifications;
- Information on generic HACCP plans;
- Training, material, advice and central expertise;
- Negotiating cost-effective services and support for SLDBs (e.g. bulk purchase or reduced prices for trade members); and
- Working with and representing the sector in the mass media and governments.

Consumer demand can be an important driving force for encouraging businesses to implement the HACCP system. Government and international organizations have an important role in educating consumers in this regard. The mass media can exert a powerful influence in educating consumers, promoting the demand for safe food and appropriate control systems. However, it may also have a negative effect, if not handled and informed appropriately.

5.2.3 Legal Requirements

In many cases, the move to introducing HACCP systems may be led by industry. The stimulus may come from within a company itself where, for enhancing food safety and/or quality or for market reasons, a decision has been made to adopt HACCP. Food industries experienced in food safety management systems are more likely to appreciate the need to move to HACCP. Generally they recognize the importance of HACCP in allowing them to gain access to domestic and foreign markets, to protect the company's reputation and to satisfy the customer's demand.

For SLDBs it is more probable that active government intervention will be required to promote and facilitate this change. To this end, when appropriate, governments may need to consider the necessity of mandatory measures^{13, 14}. Whether HACCP is implemented under voluntary or mandatory schemes, governments could:

- Prioritize the industry sectors for which implementation of HACCP is more important;

¹³ HACCP: *Introducing the Hazard Analysis and Critical Control Point System*. WHO document WHO/FSF/FOS/97.2. World Health Organization, Geneva, 1997.

¹⁴ Motarjemi, Y and Käferstein, F. *Food Safety, Hazard Analysis and Critical Control Point and the Increase in Foodborne Diseases: A paradox?* Food Control, 1999, 10:325-333.

- Consider establishing HACCP implementation committees or fora in collaboration with all interested parties (including consumers, industry representative, trade associations, etc.);
- Organize media campaigns;
- Develop guidance materials and generic models;
- Train regulatory authorities in HACCP;
- Ensure, via regulatory authorities, and other bodies that GHP is being practised;
- Fund initiatives to accelerate the implementation of HACCP in high-risk sectors;
- Develop schemes that recognize HACCP systems; and
- When necessary, review food laws to shift from end-point testing to a safety management system approach.

5.2.4 Cost Considerations

Economic constraints can be a practical barrier to implementing HACCP for both governments and industry. These constraints could mean that the provision of assistance by government or industry/trade associations or the capacity of the business itself to implement HACCP is considerably reduced. However, in considering the costs of implementing HACCP systems, it is important to take into account the long-term savings that could accrue to government (in particular public health) and industry budget. These savings could include:

- Reduced public health costs due to reduced foodborne disease;
- Reduced litigation due to reduced food safety failures;
- Reduced spoilage due to improved handling, storage, and processing of food; and
- Reduced labour disputes due to improved management / staff commitment.

To alleviate economic constraints, it is important to ensure efficient use of available financial resources. This may be achieved, for example, by:

- Developing sector-specific guides and generic plans covering components of HACCP implementation common to all businesses in a sector; and
- Bulk purchasing of equipment or services by an industry/trade association or government to support HACCP implementation, thereby minimizing the cost of implementation by individual businesses.

Economic constraints can also be mitigated by spreading the costs over a longer period of time, thereby reducing the annual cost of implementation. Approaches to spreading the costs can include:

- Phasing implementation over time so that government and business deal with manageable incremental steps, for example first introduce GHP and then gradually implement the HACCP system based on prioritizing risks to public health;
- Focusing implementation on a sector-by-sector basis.

5.2.5 Human Resource Constraints

Human resources are valuable assets in any business. However, frequently, outbreaks of foodborne illnesses can be traced back to human failure and weaknesses in the management system. Many barriers encountered in implementing HACCP are also related to human resources.

One of the major human resource barriers is the lack of management commitment and understanding of HACCP. In this respect there is often a need to change attitude and organizational culture towards new management approaches. A low perception of risks can also be a fundamental problem encountered when implementing HACCP. Furthermore, lack of time coupled with rapid turnover of staff as well as lack of expertise and training of personnel may prove to be additional barriers. The paucity of expertise is perpetuated by the absence of food safety in the curricula of professional schools.

The following should therefore be considered as part of any HACCP initiative:

- Food safety is a management function where GHP and HACCP are central to the running of a successful and morally responsible business.
- Awareness programmes identifying the economics and social benefits of implementing HACCP are essential for regulatory officials, managers of SLDBs and food handlers.
- During the early stages of the HACCP plan development, businesses need to commit additional staff time and resources, when necessary.
- Where the introduction of HACCP involves behavioural or organizational changes, the new food safety roles and responsibilities need to be explicitly identified and handled sensitively.
- Government or trade associations should help with the development and formulation of registers of HACCP qualified advisers or experts.

Adequate training is important for overcoming barriers related to human resources. For guidance on training and model curricula, reference is made to the WHO document entitled *Training Aspects of the Hazard Analysis Critical Control Point System*^{15,16,17} as well as to some other manuals produced by FAO and WHO. The following considerations in relation to training of staff of SLDBs need to be stressed:

- Training programmes should include both employees within SLDBs and enforcement officials.
- Training should lead to behavioural changes and not just focus on acquisition of knowledge. Thus, training should aim at enhancing competency and involve assessment thereof.

¹⁵ *Training Aspects of the Hazard Analysis Critical Control Point System (HACCP). Report of a WHO Workshop on Training in HACCP.* WHO document WHO/FNU/FOS/96.3. World Health Organization, Geneva, 1996.

¹⁶ *HACCP: Principles and Practice. A WHO/ICD Manual.* WHO document WHO/SDE/PHE/FOS/99.3. World Health Organization, Geneva, 1999.

¹⁷ *Food Quality and Safety Systems. A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point System.* Food and Agriculture Organization of the United Nations, Rome, 1998.

- Training guidelines need to be adapted to the local requirements taking into account cultural and linguistic differences.
- Training should be tailored to the needs of the SLDBs, and is best carried out on-site or should be based on specific work-related examples.
- Flexible delivery of training should be considered, including distance learning, on-the-job training, and recognition of prior experience.
- Training should be communicated/delivered at a level and in a manner appropriate to the target audience.
- Training material should conform with the recommendations of national standards, Codex requirements and, where appropriate, involve external certification of courses and/or teaching material.
- Completion of successful HACCP training should be associated with an appropriate motivational or reward framework; this may need to be linked to longer-term employment or promotional benefits or other staff retention strategies.
- Management must be seen to value training and owner/managers themselves should therefore be trained and supply all the facilities needed to fulfil training requirements.
- Training should not be considered a one-off event. It needs updating and, if possible, maintenance of training logs.
- HACCP training should promote understanding, be interactive and build on existing food hygiene training or equivalent experience.

5.2.6 Technical Support

SLDBs often lack the technical expertise required to implement HACCP alone and may therefore need external support. The capacity of governments and industry/trade associations to provide adequate technical support is a critical factor in the successful implementation of HACCP by SLDBs.

The type of technical support that could be offered by governments or industry/trade associations may include:

- Providing relevant, technical training with consideration given to the level of education, culture and language of the SLDB managers and staff;
- Facilitating the availability of appropriate, current, scientific support;
- Facilitating access to low cost analytical services;
- Providing accessible, sector-specific generic guidance to businesses, such as industry guides, templates¹⁸, and generic HACCP plans; and
- Establishing and maintaining foodborne disease surveillance programmes and facilitating access to collected epidemiological data.

¹⁸ A document providing general advice on the development of a Guide, which may include advice on content, structure, issues to be covered and the development process.

5.2.7 Infrastructure and Facilities

Implementation of HACCP may require improvements in the infrastructure and facilities, both within the community and the business itself. In this regard both governments and businesses have certain responsibilities:

- a) Governments have a role and, in some instances, even an obligation to ensure that the appropriate infrastructure (electricity, roads, safe water supply, sewage facilities) is in place and that environmental pollution is minimized.
- b) Businesses should ensure that:
 - Premises, work surfaces and equipment are designed, constructed and maintained appropriately to facilitate cleaning and to minimize any possibility of cross-contamination;
 - Appropriate facilities to encourage personal hygiene are available to staff;
 - Adequate, calibrated monitoring equipment is available and used correctly; and
 - In addition to visual assessment, where possible, rapid tests are used to provide real time results.

5.2.8 Communications

Inadequate communications between the government and businesses and between businesses can impede the introduction of HACCP. Communication strategies need to be part of any HACCP initiative.

Communication strategies should include:

- Information on the need for change and the benefits of HACCP¹⁹.
- Encouraging production of guides for industry containing exemplary materials detailing the application of HACCP to various sectors of industry (see Section 5.3).
- Providing additional and specific guidance for SLDBs (see Section 5.4).
- Education of consumers regarding the importance of food safety for health through various channels, including the introduction of food hygiene teaching in schools. Trade associations and consumer groups could also sponsor such measures through providing financial and/or teaching resources.

To ensure a common understanding, it is important to use a consistent and accurate terminology, such as that contained in Codex documents. The use of appropriate and effective channels for communication is equally important for effective communication. These may for example include:

- Industry/trade associations
- Trade press and exhibitions
- Enforcement authorities
- Mass media
- Production of leaflets, posters, videos, and other aids

¹⁹ HACCP: *Introducing the Hazard Analysis and Critical Control Point System*. WHO document WHO/FSF/FOS/97.2. World Health Organization, Geneva, 1997.

- Developing registers or lists of businesses, colleges, universities and educational bodies
- Websites.

5.2.9 Evaluation

From the outset, each initiative should be carefully planned and the costs estimated. However, to increase the likelihood of success, prior to implementation, evaluation should be carried out with regard to industry's perception of barriers, attitudes towards HACCP, preferred sources of information and methods for optimum communication. Evaluation should include qualitative and quantitative data.

After implementation, the HACCP initiative should be evaluated to assess cost-effectiveness, compliance with legislation (if appropriate), adherence to schedule and how improvements could be made.

Evidence of the success of HACCP implementation is also important for raising the awareness of food businesses of the benefits of HACCP. The impact of HACCP initiatives on the enhancement of food safety can be measured directly (e.g. through data collected from programmes for surveillance of foodborne diseases or monitoring contamination of food) or indirectly (e.g. through data collected in industries on the results of auditing or inspection of design and implementation of HACCP and PRPs) (see Figure 1).

5.2.10 Time scale

The time scale will form the framework for evaluation, which may for maximum benefit, involve market research prior to implementation. The precise nature of the time scale will depend on the individual country's or industry's priorities and may be set year by year, or as short, medium and long term.

	What is Evaluated?	Methods used
<p>Producer</p> <p>↓</p> <p>HACCP Plans and PRPs</p> <p>↓</p> <p>Surfaces Equipment Plant</p> <p>↓</p> <p>Food produced</p> <p>↓</p> <p>Health of the Nation</p>	<p>Knowledge Attitudes Behaviour Ownership Training</p> <p>of operatives and managers</p> <p>Quality of plans</p> <p>Design and implementation</p> <p>Design/ Construction/Cleanliness</p> <p>Cleaning programmes</p> <p>Microbiological & chemical quality</p> <p>Foodborne illness trends and risks</p>	<p>Questionnaires, Attitude, Scales, Audit, Observation</p> <p>Audit, Inspection</p> <p>ATP bioluminescence, Microbiological testing, Audit / observation</p> <p>Microbiological and chemical testing, APC, Indicator organisms, Presence of pathogens or chemical contaminants</p> <p>Epidemiological surveillance</p>

Figure 1. Direct and indirect ways to evaluate the likely food safety success of HACCP

5.3 Advice on Development of Sector-Specific Industry Guides

5.3.1 Introduction

Many countries have developed sector-specific industry guides to aid the implementation of HACCP. These guides prove to be a particularly useful source of guidance for SLDBs and play an important role in improving food safety and helping businesses to implement HACCP. In many countries, they have been developed in a coordinated way involving all stakeholders, such as business operators, trade associations, regulatory agencies and consumer groups in which case they represent a common understanding between all parties on the application of legislation and practical HACCP controls.

5.3.2 Current Status of Guides

In some countries, such as the member states of the European Union, legal requirements for HACCP or HACCP-based food safety management control systems are already in place. Sector-specific guides to GHP and HACCP have been developed, which may be used voluntarily by food industries to comply with the provisions of the legislation. The Codex *Recommended International Code of Practice on General Principles of Food Hygiene* and the Codex text on the *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application* have also facilitated the preparation of these guides, which are now widely used in many countries, e.g. Brazil, Canada, Colombia, France, Germany, Ireland, Italy, Mexico The Netherlands, Spain, the UK and USA.

Guides have been developed for a considerable range of business types within the wholesale, processing and retail sectors (e.g. catering, butchers and bakery trades, markets and fairs). It should also be stressed that the use of a guide represents only one means of achieving compliance with legal requirements.

Depending on their scope, target sector, local legal requirements, and other local conditions, the guides vary in content. They may address GHP, the application of the principles of HACCP, food microbiology, or staff training. Some are illustrated with flow diagrams, generic HACCP plans and checklists. Some contain advice on additional measures on the basis of good practices which go beyond statutory requirements.

5.3.3 Benefits

Guides can be useful both for an individual business and for the business sector. They provide practical assistance to food industry sectors in order that they may better comply with legal requirements on food safety, including HACCP requirements where such exist. Trade associations also use guides to improve the standard of food safety and to promote increased public confidence in products produced. Guides may also form the basis for a common understanding between specific food sectors and the regulatory authorities with regard to the application of legislation and practical application of HACCP. They will also assist in overcoming some of the barriers identified earlier and can help the communication process between all stakeholders. To industry sectors, guides provide harmonized criteria for food safety and, in effect, an agreed sector norm on necessary good hygienic practices. In some cases, guides are used as a basis for training programmes.

For individual businesses, one major advantage of the guides is that they provide a single agreed source of guidance. Furthermore, if a guide contains advice on the application of HACCP in SLDBs, it can improve the operators' knowledge and understanding of the risks associated with their products, provide them with practical advice on how to control those risks and thereby enhance the safety of the foods produced and promote a consistent approach to the implementation of HACCP. The guide will also help minimize the burden of instituting a HACCP system and the advice is made available at a relatively low cost.

It should, however, be stressed that a guide cannot be a substitute for an operator's individual responsibility for his business. Operators still need to analyse their own operation for potential food safety problems and ensure that the necessary controls are in place. A potential difficulty with a guide is that, in an attempt to make it as comprehensive and authoritative as possible, it may grow to such a size that its use becomes less attractive.

5.3.4 Essential Considerations when Developing a Guide

- All stakeholders should be involved in the development process.
- Guides should be practical and user-friendly for the intended audience.
- They should address compliance with local food safety requirements
- Even when not written specifically for small businesses, they should take into consideration the practical concerns of SLDBs within the sector with regard to HACCP application.
- Local and cultural customs and practices should be taken into account.
- Guides should be reviewed periodically or whenever a new significant hazard emerges, or legislation is changed.

5.3.5 Contents of a Guide

If a guide is to be successful, it must meet the needs of its users. While the emphasis in this report is on the application of HACCP, it should be stressed that prerequisite programmes should also be in place. Nevertheless, for practical reasons, there may be additional benefits in incorporating basic hygiene advice in the guides. Guides should also clearly distinguish between measures that are necessary to ensure basic hygiene and those that form part of the HACCP programme.

The following is a suggested list of contents:

- Scope and field of application
- Objective
- Glossary of terms
- General Principles of Food Hygiene and their practical application to the sector concerned. Advice in this section can be based on the Codex *Code of General Principles of Food Hygiene*. Issues to be covered in this section include:
 - Design and facilities
 - Control of operation
 - Maintenance and sanitation
 - Personal hygiene
 - Transportation

- Model programmes or standard operational procedures, including issues such as pest control and cleaning/sanitation
- Examples of documents and records can be useful, such as:
 - Monitoring records
 - Medical questionnaires
- Training

Information regarding training should be relevant and tailored to the needs of the sector concerned. Consideration should be given to the appropriate level and type of training, including training in GHP, HACCP and the use of the guide itself. Guides could also include suggestions for training syllabi. The training needs of the sector can also be considered during the development of the guide. It may also be useful to include information on the training available, particularly where national training standards or accredited courses are available.
- HACCP

The guide should include practical advice on HACCP. This can include information on the concept of HACCP and, more importantly, how the principles of HACCP can be applied practically in SLDBs within the sector concerned.

With regard to HACCP, the guide should contain advice on:

 - The likely food safety hazards in businesses
 - How these relate to operational steps
 - Appropriate control measures
 - Critical control points
 - Critical limits
 - Monitoring procedures
 - Corrective actions
 - Verification procedures

For the SLDBs, it is important that the guidance on verification is kept as practical as possible. To this end, checklists to aid the verification may also be included in the guides.²⁰

Some countries have systems that allow persons other than the business operators, such as enforcement officials, clients or professional trade organisations, to be part of the verification process.

 - Validation

The expertise for validation is unlikely to exist within an SLDB. Therefore, externally validated data may be needed. This may include, for example, legal requirements, national standards or international standards, such as those recommended by the Codex Alimentarius Commission, or standards recommended by trade associations or bodies, which will ensure the effectiveness of the process.

²⁰ *Guidance on Regulatory Assessment of HACCP. Report of a Joint FAO/WHO Consultation on the role of Government Agencies in Assessing HACCP.* WHO document WHO/FSF/FOS/98.5, pp 25-28. World Health Organization, Geneva, 1998.

- Documentation and records

The question of documentation for small businesses has often been a vexed one. Guides should identify those documents and records that need to be kept to provide confidence that the controls are in place and being maintained. Record keeping can be simple and should be designed to meet the needs of individual businesses. Such documents and records can include:

- Temperature records
- Cleaning records
- Staff absenteeism
- Check lists
- Staff training records

Advice on the retention time of documents and records should also be included.

5.3.6 Generic HACCP Plans

For SLDBs, a generic HACCP plan may form a useful starting point. Generic plans are examples of HACCP plans developed for a food commodity or process that may be used as guidance for business operators producing such commodities or using such processes. Generic plans are not appropriate for use until customized for a specific food or food process.

5.3.7 Terminology

Care should be taken with the terminology used. Scientific language or jargon may be poorly understood by users of the guide and may only serve to obscure the meaning.

5.3.8 Managing the Development Process

Care should be taken to ensure that a mechanism or procedure is in place to ensure that all stakeholders are involved in the production of the guides. The earlier and closer the involvement of all interested parties, the greater the chances of success. Inputs from state and local regulators, industry and consumers should be sought. This may be achieved through:

- A working group to draft the guide;
- A consultation process; and
- Seminars and/or public hearings.

Consideration should be given to the piloting of a draft to test its applicability and usefulness to the targeted business sector.

Ideally industry sectors should lead the development and elaboration of guides. However, Governments should recognize that they may need to facilitate the development process, especially where industry representation is weak or absent. To help achieve the above objectives, a template detailing advice on the compilation of such guides could be drawn up centrally by the government. Such a system exists in some countries (e.g. France and the UK) where the templates have included advice on:

- Drafting process

- Consultation
- Structure
- Layout
- Advice on contents
- Responsibility

Some countries have chosen to use national standardization bodies to develop guides. This is in recognition of their expertise and experience in developing guidance and their ability to achieve consensus. Guidance documents published as national standards may also be used as the basis of certification programmes.

5.3.9 Official Approval and Evaluation

It may be useful for governments to put in place a mechanism to officially approve guides. Such a function could be performed by a government department or through a state or other agency approved for the purpose. This will allow businesses and enforcement agencies to use a guide, confident that it is not in conflict with the food safety legislation. Official approval in advance of final publication of a guide is preferable.

To determine the effectiveness of a guide, after a reasonable period, an evaluation of the guide should be carried out, preferably by the same experts who developed the guide. For clarity, every guide should contain a reference to its date of issue and any current or previous guidance that it replaces.

5.3.10 Making Use of the Guides

SLDBs, in particular benefit from being able to use a single agreed source of guidance. Therefore, having made the effort to produce the guide, it is equally important to ensure that the potential users are aware of its availability. In parallel with the development phase, arrangements for the marketing of the guide should be considered. The same parties, who contributed to the elaboration of the guide, can help in this process. Potential users, channels and methods of distribution should be identified. If not distributed free of charge, it is important that the price of a guide does not become a barrier to its purchase and use.

Access to and use of guides can be enhanced by:

- Distribution through trade associations and regulatory agencies;
- Advertising and organizing information seminars;
- Providing training based on the guide; and
- Government support in promoting the guides.

5.4 Guidelines for the Application of the HACCP System to Small and/or Less Developed Businesses²¹

5.4.1 Introduction

The following guidelines are proposed to provide advice on the application of the HACCP principles in Small and/or less Developed Businesses (SLDBs)²², as defined by the Codex Alimentarius Commission in the *Recommended International Code of Practice - General Principles of Food Hygiene*.²³ In developing these guidelines, it is recognized that the seven principles of HACCP can be applied with flexibility in SLDBs, given that adequate support and relevant prerequisites are in place. Consideration should also be given to the level of resources available to, and the constraints faced by, SLDBs throughout the food chain.

5.4.2 Prerequisite Programmes (PRP)

In order to successfully implement HACCP, food businesses should, as part of prerequisite programmes (PRPs), already be operating according to the *Codex General Principles of Food Hygiene*, the applicable Codex Recommended Codes of Practice, and according to the food safety legislation. In situations where it would be difficult to establish a critical limit, but where control is nevertheless important (e.g. personnel hygiene), the relevant control measure should be addressed within the PRPs.

5.4.3 Management Commitment

Management commitment is essential for implementing and maintaining an effective HACCP system. Management commitment should be communicated to all personnel. It should be clear from the beginning who is responsible for the development of the HACCP plan, and in some medium-size industries a HACCP coordinator could be nominated.

Management commitment should extend to the provision of appropriate training for managers themselves and staff in basic food hygiene and HACCP to a level commensurate with their responsibilities, as well as validation of the elements of the HACCP plan to ensure that the plan is effective when implemented.

²¹ These guidelines may be useful when developing sector specific guidance as well as for helping individual businesses in the application of the HACCP system.

²² The term *small and/or less developed businesses* refers to businesses that either because of their size, lack of technical and/or economic resources, or the nature of their work, could encounter difficulty in implementing HACCP in their food business. The term *less developed business* refers to the status of the food safety management system (i.e. business with less developed systems for managing food safety) and not to the number of staff or volume of production.

²³ CAC. *Recommended International Code of Practice – General Principles of Food Hygiene*. CAC/RCP 1-1969, Rev.3. In “Food Hygiene Basic Texts”. Secretariat of the Joint FAO/WHO Food Standards Programme, FAO, Rome, 1997.

5.4.4 Preliminary Procedures

5.4.4.1 Team Approach to HACCP in SLDBs²⁴

The traditional approach to HACCP advocates a team approach utilizing both in-house and external expertise to design the HACCP plan. In SLDBs, the full range of expertise may not be available in-house and business managers may need to seek appropriate external support such as:

- HACCP literature
- Approved guidance documents
- Regulatory authorities
- Academia, and other independent experts
- Industry associations.

A team-based approach does not necessarily imply a diversity of expertise or a range of people who often have to be employed at a considerable cost. It may be sufficient that a well-trained individual in possession of a relevant and approved guide is able to implement HACCP in-house.

5.4.4.2 Describe the processes and products to be covered²⁵

In applying HACCP, the scope of the HACCP plan has to be clearly defined. In SLDBs, this could mean some or all of the following:

- Specific individual products;
- Groups of products with similar characteristics (e.g. presenting similar risks); and
- Processing steps that are used for a number of similar products.

It may be appropriate to focus on products individually and identify relevant food safety information such as composition, physical/chemical structure, treatment, preservatives, etc., on a product-by-product basis. However, in multi-product small businesses, such as catering operations, it may be simpler to focus on products with similar characteristics. Products should be correctly and clearly categorized.

The *intended use* of the product, such as the probable handling by the end-user or the consumer, should also be considered. In specific cases, vulnerable groups may have to be considered.

If a business is using a *guide*, it is important that it is specific to the foods and/or processes under consideration.

²⁴ This relates to the *task 1* of the Codex text on *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*.

²⁵ This relates to the *tasks 2 and 3* of the Codex text on *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*.

5.4.4.3 Describe and confirm processes²⁶

In order to apply HACCP to an SLDB, the processing steps should be described. Ideally, this may be done through a flow diagram, which could be done for each product. However, where a wide range of products are produced by a business (e.g. in many retail / catering businesses) such a procedure may not be practical. In such circumstances, the diagram may instead describe the processing of products grouped according to risk categories and to which similar processes will be applied. Another approach to describing the processing operations may be achieved without specific attention to product types. In this case, the diagram may focus on operational procedures such as the receipt of materials, handling, storage, preparation, thermal processing and serving of food, providing that the risk profile of the different products are similar, e.g. a variety of hot soups utilizing different ingredients and where the risk profiles are similar.

Whatever form the diagrams take, their benefits for SLDBs should be recognized. They enable owners or managers and even food handlers to better understand the flow of materials through their business. They provide a foundation for the systematic approach inherent to the application of HACCP, covering food and operations from receipt to delivery to the customer. They permit easier identification of routes of contamination and methods of control of critical control points (CCPs). They may also be useful in the verification of the system.

In addition to flow diagrams, a schematic plan of the establishment could also help highlight potential areas of cross-contamination. The accuracy of the flow diagram should be confirmed by the SLDB operator against the actual physical layout of the establishment and, if necessary, corrected.

5.4.5 Application of the HACCP Principles

5.4.5.1 Principle 1: Conduct a Hazard Analysis

Following an initial review of prevailing foodborne disease problems in the region, the hazards recognized as significant and likely to occur at any step of the process should be identified. These may be of a microbiological nature (e.g. pathogenic organisms), a chemical nature (e.g. pesticide residues), and/or a physical nature (e.g. pieces of glass).

In conducting the hazard analysis, the SLDB could consult or make use of any sector-specific database or guide that contains information on hazards relevant to the process/product or make use of external expertise. However, the SLDB should take appropriate steps to ensure that any additional hazards are considered and evaluated, including any hazard that could be introduced by raw materials.

Points that should be considered while performing a hazard analysis include:

- The likely occurrence of hazards and the 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;
- Quality of raw materials
- Conditions leading to the above; and

²⁶ This relates to the *tasks 4 and 5* of the Codex text on *Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*.

- Identification of control measures.

5.4.5.2 Principle 2: Determine the Critical Control Points (CCPs)

Determination of Critical Control Points (CCPs) must follow a logical consideration of all steps where hazards can be controlled. When determining whether a step or process is a CCP, the SLDB must consider whether control can be applied at that step or process and if a loss of control at that point will result in a potential hazard in the finished product.

There may be more than one CCP at which control can be 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^{27, 28}. However, training may be needed to use it successfully. It should be used for guidance when determining CCPs. A decision tree may not be applicable to all situations, but its use may facilitate transparency and verification.

5.4.5.3 Principle 3: Establish Critical Limits

Critical limits must be specified for each critical control point for safety. The critical limits of each CCP must be realistic, yet sufficient to provide the necessary food safety assurances.

Measurable and observable criteria used to set critical limits may include measurements of temperature, time, pH, and level of available chlorine. However, measurements of many of these criteria may be beyond the means of most SLDBs because of either lack of knowledge, lack of access to support services or simply because of the capital cost of certain measurements.

SLDBs should be encouraged to make the best use of the temperature and time criteria that are more relevant to their everyday experience and practices. While sensory evaluation is not the best tool to assess critical limits, this could be used in support of the other measurements listed.

Industry guides can be instrumental in identifying the most appropriate criteria for the critical limits as well as setting the limits themselves. Caution should be taken, however, to ensure that these generic limits fully apply to the specific operation or product under consideration.

5.4.5.4 Principle 4: Establish a system to monitor control of the CCP

Monitoring is essential in making sure that critical steps are under control. It will identify where a loss of control has occurred or if there is a trend towards a loss of control. It will also identify the required corrective actions to the process to restore or maintain control. The monitoring procedures must be able to detect loss of control at the CCP. The frequency of monitoring must be sufficient to guarantee that no unsafe product reaches the consumer. Results from monitoring must be recorded and evaluated by a person trained to carry out corrective actions.

While the SLDB may have to resort to outside expertise in performing the first three principles, monitoring remains the responsibility of the individual establishment.

In establishing the monitoring procedure, the following questions need to be addressed:

²⁷ HACCP: *Introducing the Hazard Analysis and Critical Control Point System*. WHO document WHO/FSF/FOS/97.2. World Health Organization, Geneva, 1997.

²⁸ CAC. *Hazard Analysis and Critical Control Point System and Guidelines for its Application*. In "Food Hygiene Basic Texts". Secretariat of the Joint FAO/WHO Food Standards Programme, FAO, Rome, 1997.

- Which parameters are measured and what are the critical limits?
- How is it monitored?
- When and how often will the CCP be monitored?
- Who will be responsible for monitoring?
- Is the monitoring procedure practical and reliable?

The monitoring system will be effective only if the owner of the establishment, the manager and employees are given the knowledge, skills, and the responsibility for preparing safe food. The SLDB should train the employees to carefully follow the procedures, monitor CCPs, and take corrective action if critical limits are not met.

5.4.5.5 Principle 5: Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control

Specific corrective actions must be developed for each CCP. Corrective actions must specify what needs to be done to bring the CCP under control and ensure that potentially unsafe products are not marketed.

Corrective actions include:

- Steps to correct the problem;
- Steps to deal with the affected product.

Any corrective measure undertaken with regard to a specific step should be easily implemented and understood by the employee performing the activities. Any corrective action taken should be documented and communicated to management in order that the system can be modified, if necessary, and reoccurrence of the problem prevented.

Whenever a critical limit is not met, a corrective action should be carried out immediately. Training of all staff is therefore essential to prevent delays. Corrective actions may be simple, such as continuing to heat food to the required temperature or reconditioning of the food. Sometimes it may be necessary to take more severe steps, such as rejection of a load of incoming ingredients. External support may be necessary to make such a judgement.

5.4.5.6 Principle 6: Establish Verification Procedures

Verification is carried out to determine if the HACCP system is working correctly and eventually to highlight deficiencies that need to be rectified. Verification may also be initiated for other reasons, e.g. changes in the processes with potential safety consequences.

Verification is usually performed by someone other than the person who is responsible for performing the activities specified in the plan, e.g. monitoring. Verification may, for instance, be carried out by the manager of the establishment, supervisor of the person responsible for a specific monitoring activity, the regulatory authority, or other agencies.

In order to have workable verification procedures for an SLDB, the methodologies must be simple to perform and easy to record.

Verification should occur at a frequency that can ensure that the HACCP plan is being followed in order to:

- Minimize adulterated/unsafe product from reaching the consumer
- Minimize the number of affected products requiring a corrective action.

Verification activities should:

- Ensure that prescribed practices are consistently followed;
- Ensure that the personnel have the tools and facilities for proper personal hygiene and sanitary practices (e.g. hand-washing facilities, sanitizing equipment, cleaning supplies, temperature measuring devices, and sufficient gloves);
- Ensure that calibrations have been conducted as needed and according to the requirements of the equipment;
- Ensure that control procedures are being followed;

5.4.5.7 Principle 7: Establish documentation concerning all procedures and records relevant to the HACCP principles and their application.

HACCP procedures should be documented. Accurate documentation and record keeping is essential to the application of a HACCP system. Documentation and record keeping should be appropriate to the nature and size of the operation. Documentation and records should be sufficient to enable the business to be confident that controls are in place and being maintained.

Records document that the critical limits at each CCP were met or that appropriate corrective actions were taken when the limits were not met. Records should also show that the actions performed were verified. The simplest record-keeping system that lends itself to integration into existing operations is always best. A simple yet effective system is easier to use and to be communicated to employees. The record-keeping system can use existing paperwork, such as delivery invoices and simple checklists for documenting product temperatures.

Simple logs for recording are perhaps the most common records currently maintained. All practices and actions of the HACCP system should be documented to aid the SLDB, or its designated external auditors, in their verification activities.

Examples of documentation:

- Hazard analysis;
- CCP determination; and
- Critical limit determination.

Where the SLDB has used guides and other relevant material as the basis for their HACCP system, copies of these materials should be kept.

Examples of records:

- Monitoring activities, e.g. recorded temperature;
- Corrective actions taken; and
- Verification procedures performed.

5.4.6 Validation of the HACCP system

Throughout the application of the HACCP system various confirmation activities are required to validate that the elements of the HACCP plan are effective. These activities need to take place at all stages of the HACCP system, for example, confirmation that critical limits are appropriate and that identified hazards are reduced to acceptable levels or eliminated. The responsibility for validation will vary depending on the nature and size of the business and the availability of resources.

The expertise for validation may not exist within an SLDB. Therefore, SLDBs may need to use external validated data. These may be found in legal requirements, national standards, Codex Alimentarius Standards, or standards recommended by trade associations or bodies.

6. Conclusions and Recommendations

1. Given the barriers to the implementation of HACCP by SLDBs, governments and industry/trade associations should develop strategies to facilitate its implementation.
2. When implementing HACCP in SLDBs, attention should be paid to the strategies identified and guidelines developed by this Consultation.
3. Recognizing the important role that sector-specific guides play in implementing HACCP in SLDBs, every effort should be made to prepare and disseminate such documents.
4. It is recommended that international organizations, such as FAO and WHO, set up a central database of existing guides including information on their scope, language and intended use and make it accessible through a website.
5. In order to assist developing countries, international organizations, such as FAO and WHO, should explore ways and means to provide support to governments and industries on an on-going basis.
6. Where HACCP systems have been developed and/or approved at national level, their acceptance across national borders needs to be examined and facilitated by establishing a formal scheme of international recognition with the involvement of international organizations and bodies.
7. The Consultation recalled the recommendations of a previous FAO/WHO Consultation on the *Role of Government Agencies in Assessing HACCP* and stressed the need to develop a glossary of essential terms in the area of HACCP and food safety and their equivalence in other languages.
8. The Consultation recommended that the report of the meeting should be brought to the attention of the Codex Committee on Food Hygiene. The report should be taken into consideration in the development of a Codex discussion paper, which is being prepared for the 32nd Session of the Codex Committee on Food Hygiene on the same subject.

Annex 1

List of Participants

1. Ms Luisa Aguilar Zambalamberri, Ministerio de Sanidad y Consumo, Paseo del Prado 18-20, E-28014 Madrid, Spain
2. Mr John Barnes (*Chairman*), Principal, Joint Food Safety and Standards Group, Department of Health, Room 503A, Skipton House, 80 London Road, London SE1 6LH, United Kingdom
3. Mr Hans Beelen, Region South, Inspectorate for Health Protection, Commodities and Veterinary Public Health, Ministry of Health, Welfare, and Sport, P.O. Box 2280, 5202 CG Den Bosch, The Netherlands
4. Ms Shelley Bray, Acting Director Inspection Strategies Division, Canadian Food Inspection Agency, Room 228 East, 59 Camelot Drive, Nepean, Ontario K1A0Y9, Canada
5. Mr Jeffrey M. Brown (*Rapporteur*), Division of HACCP Programs, U.S. Food and Drug Administration (FDA), 200 C Street SW, Washington D.C. 20204, USA
6. Dr Esteban Delgado, Group Technical Director, Cristal International Ltd., C/ Foners, 1, 1º B., 07006 Palma de Mallorca, Spain
7. Dr John Ezenwa Ehiri, School of Health Technology, P.M.B. 7016, Aba Abia State, Nigeria
8. Dr. vet. Alberto Ferrazzi, Servizio Veterinario, Azienda Provinciale Servizi Sanitari, Piazza Leani 11/A, 38068 Rovereto, Italy
9. Dr Christopher Griffith, Head of Food Safety Research and Consultancy, University of Wales, Institute Cardiff, Colchester Avenue, Cardiff CF34 9XR, United Kingdom
10. Dr Hector J. Lazaneo, Director, Meat Safety Division, Ministry of Livestock, Agriculture and Fisheries, Montevideo 11200, Uruguay
11. Mr Martin Liefhebber, Nederlands Bakkerij Centrum (Netherlands Bakery Centre), P.O. Box 360, 6700 AJ Wageningen, The Netherlands
12. Ms Zahara Merican (*Vice-chairperson*), Principal Research Officer, Technical Services Centre, Malaysian Agriculture Research and Development Institute (MARDI), P.O. Box 12301 G.P.O., 50774 Kuala Lumpur, Malaysia
13. Drs Rahardjo, Head of Sub-Directorate of Food Control, Directorate General of Food & Drug Control, Ministry of Health, Jl. Percetakan Negara no.23, Jakarta 10560, Indonesia
14. Mr Jairo Romero, Director, HACCP Committee, Asociacion Colombiana de Ciencia y Tecnologia de Alimentos, Calle 21 No. 3-52, P. O. Box 4371, Santa Fe de Bogotá, Columbia
15. Ms Shashi Sareen, APEDA, Ministry of Commerce, 3rd floor, Ansal Chambers No.II, 6 Bhikaji Cama Place, New Delhi 110066, India
16. Dr Rudolf Schmitt, Ecole d'Ingénieur du Valais (EIV), Route du Rawyl 47, CH-1950 Sion, Switzerland
17. Mr Richard Souness, Program Manager, Food Safety, Australia New Zealand Food Authority, P.O. Box 7186, Canberra MC ACT 2610, Australia

Observers

18. Mr Matthew Mortlock, MscEcon (Research Assistant), School of Food and Consumer Science, University of Wales Institute, Cardiff (UWIC), Colchester Avenue, Cardiff, CF34 9XR, United Kingdom
19. Prof. Dr. D.A.A. Mossel, Eijkman Foundation for Medical Microbiological Education and Research, University of Utrecht, P.O. Box 6024, 3503 PA Utrecht, The Netherlands

International Organizations

20. *European Commission*: Ms Christine Majewski, Principal Administrator, DG III: Industry - Foodstuffs, legal, scientific and technical aspects, AN88, 4/36 European Commission, Rue de la Loi 200, B-1049 Belgium
21. *Food and Agricultural Organization of the United Nations (FAO)*: Ms Maria de Lourdes Costarrica, Senior Officer, Food Quality Liaison Group, Food Quality and Standards Service, Food and Nutrition Division, Via delle Terme di Caracalla, I-00100 Rome, Italy
22. *International Commission on Microbiological Specifications for Foods (ICMSF)*: Prof. M. van Schothorst, Secretary, International Commission on Microbiological Specifications for Foods (ICMSF), c/o Nestec Ltd., Avenue Nestlé 55, CH-1800 Vevey, Switzerland
23. *International Union of Food Science and Technology (IUFoST)*: Prof. M. van Schothorst, c/o Nestec Ltd., Avenue Nestlé 55, CH-1800 Vevey, Switzerland
24. *Industry Council for Development (ICD)*: Mr David Crean, Master Foods C.V., P. O. Box 1002, 3260 AA Oud – Beijerland, The Netherlands (*unable to attend*)

Secretariat

25. Dr Claudio R. Almeida, Regional Adviser on Food Safety, Pan American Health Organization, World Health Organization, 525 23rd Street NW, Washington DC 20037-2895, USA
26. Mr Raymond Ellard (*Temporary Adviser*), Food Safety Authority of Ireland, Abbey Court, Lower Abbey Street, Dublin 1, Ireland
27. Mr Anthony Hazzard, Short-term Professional, Food Safety Programme, World Health Organization, Avenue Appia 20, CH-1211 Geneva 27, Switzerland
28. Dr Jaap T. Jansen (*Temporary Adviser*), Inspectorate for Health Protection, Commodities and Veterinary Public Health, Ministry of Health, Welfare and Sport, P.O. Box 16108, 2500 BC's-Gravenhage, The Netherlands
29. Dr Marco F.G. Jermini, Food Safety Regional Adviser, WHO Regional Office for Europe, European Centre for Environment and Health (ECEH), Rome Division, Via Francesco Crispi 10, I-00187 Rome, Italy
30. Dr Yasmine Motarjemi (*Secretary*), Food Safety Programme, World Health Organization, Avenue Appia 20, CH-1211 Geneva 27, Switzerland

The contribution of Ms Nienke Blok, Ms Annette Enevoldsen, Ms Françoise Fontannaz, Ms Petra Hakkenbrak and Ms Wendy Kleinjan in the organization of the Consultation and in the finalization of the report is gratefully acknowledged.

Annex 2

List of Background Papers

1. *Problems associated with the implementation of HACCP in small or less developed businesses.* Previous discussions in Codex. Mr Jaap Jansen, Inspectorate for Health Protection, Commodities and Veterinary Public Health, Ministry of Health, Welfare and Sport, The Netherlands.
2. *Problems experienced in India in the application of HACCP and other systems needed to enhance food safety.* Ms Shashi Sareen, APEDA, Ministry of Commerce, India.
3. *United States Food and Drug Administration Perspective - HACCP at the Retail Level.* Mr Jeffrey M. Brown, Division of HACCP Programs, U.S. Food and Drug Administration (FDA), USA.
4. *Canada's experience with HACCP and small businesses.* Mr Vance McEachern, Canadian Food Inspection Agency, Canada.
5. *Industry Guides: A UK Perspective.* Mr John Barnes, Joint Food Safety and Standards Group, Department of Health, United Kingdom.
6. *An Introduction to the System in Spain.* Ms Luisa Aguilar Zambalamberri, Ministerio de Sanidad y Consumo, Spain.
7. *To comply with the Council Directive 93/43/EEC: A challenge for the companies, but also for the health service. The experience of the district of Trento – Italy.* Dr.vet. Alberto Ferrazzi, Servizio Veterinario, Azienda Provinciale Servizi Sanitari, Italy.
8. *Evaluating the success of HACCP in enhancing food safety in small businesses.* Drs C.J. Griffith, M.P. Mortlock and A.C. Peters, University of Wales, Institute Cardiff, United Kingdom.
9. *A survey of HACCP implementation in Glasgow.* Drs John E. Ehiri, George P. Morris and James McEwen, Liverpool School of Tropical Medicine, United Kingdom.
10. *The Cristal Programme: The application of HACCP in the tourist industry.* Drs E. Delgado and R.Y. Cartwright, Cristal International Ltd., Spain.
11. *Application of HACCP in small businesses.* Mr Jairo Romero, Columbia.
12. *The introduction of HACCP in craft bakeries.* Mr Martin Liefhebber, Nederlands Bakkerij Centrum (Netherlands Bakery Centre), The Netherlands.

13. *A model based on the experience of the Netherlands.* Mr Hans Beelen, Region South, Inspectorate for Health Protection, Commodities and Veterinary Public Health, Ministry of Health, Welfare, and Sport, The Netherlands.
14. *Quality assurance systems in small or less developed food industries.* Ms Maria de Lourdes Costarrica, Senior Officer, Food Quality Liaison Group, Food Quality and Standards Service, Food and Nutrition Division, FAO, Italy.
15. *HACCP for small businesses – Ireland.* Mr Raymond Ellard, Food Safety Authority of Ireland, Ireland
16. *A New Millennium Strategy for Ensuring the Microbiological safety of Foods and Catered Meals, Vended by Small or Less Developed Enterprises through Implementation of a HACCP Equivalent Hazard Control System.*
Prof. Dr. D.A.A. Mossel and Dr Corry B. Struijk, Eijkman Foundation for Medical Microbiological Education and Research, The Netherlands

Annex 3

Glossary

This glossary provides a list of definitions of terms used in the report. The glossary should not be used in lieu of the official definitions of the Codex Alimentarius Commission.

Checklist

A list that contains points/elements that may be considered during assessment. It is used as an aide-memoire to promote uniformity in assessment.

Control (noun)

The state wherein correct procedures are being followed and criteria are being met.

Control (verb)

To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control measure

An 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 be taken when the results of monitoring 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 value which separates acceptability from unacceptability.

Flow diagram

A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

Generic HACCP plans

These are examples of HACCP plans developed for a food commodity or process that may be used as guidance for business operators producing such commodities or using such processes. Generic plans are not appropriate for use until customized for a specific food and food process.

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 adverse health effect.

Hazard Analysis

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

Implementation of the HACCP plan

The ongoing execution and maintenance of 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.

Prerequisites for HACCP

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

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.