

codex alimentarius commission

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DISCUSSION PAPER ON THE IMPLEMENTATION HACCP IN SMALL AND/OR LESS DEVELOPED BUSINESSES

(Prepared by the Netherlands)

BACKGROUND INFORMATION

At its 31st session the Codex Committee on Food Hygiene considered a document, CX/FH 98/12 “Discussion paper on HACCP in small and less developed businesses”, prepared by the Netherlands. This document had been developed following a meeting of the drafting group in April 1998.

It was agreed that the reference to developing countries in an earlier version of the document was not adequate, since difficulties in the application of HACCP existed both in developing and developed countries. The term “small and less developed businesses” was used to indicate that not only small business, but that also some larger but less developed industries encounter difficulties in properly applying the HACCP system. Therefore the meeting noted that in the application of the seven principles of HACCP some flexibility is needed, but that the principles themselves should be retained.

The committee also discussed whether or not the scope should cover both export industry and production for the domestic market. Several delegations supported the opinion that there should be no distinction on the basis of the destination of the product (export or domestic market) as the essential objective was to ensure consumer protection. In this sense, the concept of equivalence should be taken into account, as currently under discussion in the CCFICS. Countries that require application of the HACCP system for imported food should apply similar requirements to their local food production.

It was also pointed out that exchange of information between governments on the implementation of HACCP programmes and training would be useful to official authorities, as they would benefit from the experience of other countries in this relatively new discipline.

The representative of WHO supported work on HACCP in small and less developed businesses and offered its collaboration in the further development of the document. The importance of the document was stressed in order to address food safety problems associated with small businesses, as they are the source of a significant proportion of food borne diseases. The representative recommended that the outcome of the work on this question could be in the form of guidance to governments in the implementation of HACCP in small businesses.

The Committee agreed that the Netherlands should redraft the Discussion Paper.

1. WHO CONSULTATION ON STRATEGIES FOR IMPLEMENTING HACCP IN SMALL AND/OR LESS DEVELOPED BUSINESS

From 16 to 19 June 1999 the World Health Organization organized, in collaboration with the Netherlands Ministry of Health, Welfare and Sports, a *Consultation on Strategies for Implementing HACCP in Small and/or Less Developed Businesses*¹.

This Codex Discussion Paper is primarily based on the outcomes of the plenary discussion during the 31st session the Codex Committee on Food Hygiene. Additional to those, main subjects of the WHO Consultation mentioned above, are highlighted also in this discussion paper. Thus the report of the WHO consultation is an important source of information on the subject in this Revised Version of this Codex Discussion Paper.

In order to avoid unnecessary repetition and to maintain readability, some details from the report are not repeated here, but referenced only.

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.²

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 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 the WHO Consultation which aimed to address the problems faced by small and/or less developed businesses (SLDBs) with regard to food safety and, in particular, implementation of HACCP.

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 the present WHO Consultation report as well as in other WHO documents.^{3,4} 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 of the WHO consultation report). However, the importance of enhancing food safety in SLDBs in strategies for preventing foodborne illnesses cannot be overemphasized.⁵

The problems of implementing HACCP in small industries and in developing countries have been the subject of extensive discussions at previous 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

¹ WHO/SDE/PHE/FOS/99.7 "Strategies for Implementing HACCP in Small and/or Less Developed Businesses", report of a WHO Consultation.

² *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.

³ 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.

⁴ *HACCP: Introducing the Hazard Analysis and Critical Control Point System.* WHO document WHO/FSF/FOS/97.2. World Health Organization, Geneva, 1997.

⁵ *Foodborne disease: a focus on health education.* World Health Organization, Geneva (in press).

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)⁶ also acknowledged the need to work on facilitating and evaluating the implementation of HACCP in small businesses.

The drafting meeting in The Hague, in April 1998, 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.⁷ 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*⁸ 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 objectives of the WHO *Consultation on Strategies for Implementing HACCP in Small and/or Less Developed Businesses* 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.

For the purpose of the WHO report, the term “small and/or less developed businesses” (SLDBs) meant 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 to the number of staff or volume of production. The Consultation addressed the implementation of HACCP in SLDBs in both developing and industrialized countries.

⁶ *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.

⁷ 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.

⁸ *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.

2. STRATEGIES FOR IMPLEMENTING HACCP IN SMALL AND/OR LESS DEVELOPED BUSINESSES

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).⁹ 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 implementation¹⁰.

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).

2.1. Benefits of and Barriers to Implementing HACCP

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.

The benefits to consumers are: 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).

The benefits to industry are: 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.

⁹ 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.

¹⁰ 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.

As benefits to governments can be mentioned: 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.

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.

2.2. 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.

2.2.1. Government Commitment

Government¹¹ 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 should be stressed. 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, should be indicated.

2.2.2. 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.

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.

¹¹ All government agencies, including health, agriculture, trade, tourism, industry, planning, etc.

2.2.3. Role of Industry and Trade Associations

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, communication of information pertinent to implementation of HACCP and collection of data on products, hazards and risks.

Other subjects for industry support could be the development of product specifications, providing information on generic HACCP plans, and help with training, material, advice and central expertise. Further to that: 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.

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.

2.2.4. Legal Requirements

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^{12, 13}. Whether HACCP is implemented under voluntary or mandatory schemes, governments could prioritize the industry sectors for which implementation of HACCP is more important, consider establishing HACCP implementation committees or fora in collaboration with all interested parties (including consumers, industry representative, trade associations, etc.) and organize media campaigns.

Governments should develop guidance materials and generic models and train regulatory authorities in HACCP.

Authorities having jurisdiction could ensure, via regulatory authorities, and other bodies that GHP is being practised and develop schemes that recognize HACCP systems, and when necessary, review food laws to shift from end-point testing to a safety management system approach.

Initiatives could be funded to accelerate the implementation of HACCP in high-risk sectors.

2.2.5. 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.

¹² HACCP: *Introducing the Hazard Analysis and Critical Control Point System*. WHO document WHO/FSF/FOS/97.2. World Health Organization, Geneva, 1997.

¹³ 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.

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. Also the purchase of equipment or services in bulk by an industry/trade association or government could 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.

2.2.6 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.

2.2.7 Training

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*^{14,15,16} as well as to some other manuals produced by FAO and WHO.

HACCP training should promote understanding, be interactive and build on existing food hygiene training or equivalent experience.

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 and training

¹⁴ *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.

¹⁵ *HACCP: Principles and Practice. A WHO/ICD Manual.* WHO document WHO/SDE/PHE/FOS/99.3. World Health Organization, Geneva, 1999.

¹⁶ *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.

should lead to behavioural changes and not just focus on acquisition of knowledge. Thus, training should aim at enhancing competency and involve assessment thereof.

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.

Training guidelines need to be adapted to the local requirements taking into account cultural and linguistic differences.

Flexible delivery of training should be considered, including distance learning, on-the-job training, and recognition of prior experience and should be communicated/delivered at a level and in a manner appropriate to the target audience.

Training material should conform to 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.

2.2.8 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. The availability of appropriate, current, scientific support should be facilitated and also access to low cost analytical services.

Providing accessible, sector-specific generic guidance to businesses, such as industry guides, templates¹⁷, and generic HACCP plans are critical success factors.

Establishing and maintaining foodborne disease surveillance programmes and facilitating accesses to collected epidemiological data are important for underpinning sector-specific hazard analysis.

2.2.9 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.

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.

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 should be available to encourage personal hygiene of staff.

Adequate, calibrated monitoring equipment must be available and used correctly; and in addition to visual assessment, where possible, rapid tests must be used to provide real time results.

¹⁷ 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.

2.2.10 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. These strategies should include:

- Information on the need for change and the benefits of HACCP¹⁸.
- Encouraging production of guides for industry containing exemplary materials detailing the application of HACCP to various sectors of industry.
- Providing additional and specific guidance for SLDBs.
- 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 and even mass media. Other options for proper communication include the production of leaflets, posters, videos, and other aids, developing registers or lists of businesses, colleges, universities and educational bodies and implementation of relevant Internet websites.

2.2.11 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).

Indirect assessment of success could be based on data collected in industries on the results of auditing or inspection of design and implementation of HACCP.

The time scale will form the framework for evaluations, 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.

¹⁸ HACCP: *Introducing the Hazard Analysis and Critical Control Point System*. WHO document WHO/FSF/FOS/97.2. World Health Organization, Geneva, 1997.

3. ADVICE ON DEVELOPMENT OF SECTOR-SPECIFIC INDUSTRY GUIDES

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.

3.3.1 *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.

3.3.2 *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. Guides can 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.

3.3.3 *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.

3.3.4 *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:

1. Scope and field of application
2. Objective
3. Glossary of terms
4. 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 and transportation.
5. Model programmes or standard operational procedures, including issues such as pest control and cleaning/sanitation.
6. Examples of documents and records can be useful, such as monitoring records and medical questionnaires.
7. Training information that 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.
8. HACCP:
 - The guide should include practical advice on HACCP. This could be 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 and how these relate to operational steps. Appropriate

control measures should be included, in relation to critical control points with attached critical limits, monitoring procedures and 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.¹⁹ 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.
- **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 and staff training records. Advice on the retention time of documents and records should also be included.
- **Validation:** expertise on 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.

3.3.5 *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.

3.3.6 *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.

3.3.7 *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.

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.

3.3.8 *Use of a template*

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

¹⁹ *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.

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 the drafting process and set up of a consultation. Additional to that, in such a template advice can be provided on the structure, layout, and contents of a guide and about responsibilities involved.

3.3.9 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.

3.3.10 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.

4. GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM TO SMALL AND/OR LESS DEVELOPED BUSINESSES²⁰

4.1 Introduction

The available Guidelines for the Application of the HACCP System, which are part of the present Codex HACCP system, as defined by the Codex Alimentarius Commissions (Annex to CAC/RCP 1-1969, Rev. 3 (1997)), are not fully satisfactory for application in SLDBs. For that reason, the WHO Consultation on Strategies for Implementing HACCP in Small and/or Less Developed Businesses (June 1999) proposed an alternative set of guidelines, intended to provide specific advice on the application of the HACCP principles in Small and/or less Developed Businesses (SLDBs)²¹. 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.

The following text is an abbreviated “overview” version of the Guidelines for the Application of HACCP to SLDBs, as presented in the report of the WHO Consultation indicated above. For all details, read the WHO report²².

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.

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, in some medium-size industries a HACCP coordinator could be nominated.

²⁰ These guidelines may be useful when developing sector specific guidance as well as for helping individual businesses in the application of the HACCP system.

²¹ 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.

²² WHO/SDE/PHE/FOS/99.7 “Strategies for Implementing HACCP in Small and/or Less Developed Businesses”, report of a WHO Consultation.

4.4 Preliminary Procedures

4.4.1 Team Approach to HACCP in SLDBs

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.

4.4.2 Describe the processes and products to be covered

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.

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

4.4.3 Describe and confirm processes

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.

4.5 Application of the HACCP Principles

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.

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.

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. 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.

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 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.

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 and steps to deal with the affected product.

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.

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.

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.

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.

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.

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.

5. APPROACHES AND FORMATS OF GUIDANCE FOR CONSIDERATION

Practical experience during the last years has shown that three different practical situations can be observed relating to needed guidance with a view to optimise food safety:

1. Large industries, with good management in place and expertise in food hygiene and food safety are able to develop and maintain their own specific HACCP system, based on Hazard Analysis, good manufacturing practices and “prerequisite” basic hygiene. The present Codex General Principles and its HACCP annex with Guidelines for the Application of the HACCP, best serve this type of businesses.
2. Medium size industries, or less developed industries with limited skills and expertise in the area of food safety and its management, are probably better off with a template or a generic HACCP system approach, specifically intended for their industry sector. This template or generic system should preferably be drafted by representatives of their sector, supported by commercial consultants and/or government experts. Education in this area should include some understanding of specific hazards and their control. Otherwise this type of approach will not be effective.
3. Small businesses or industries of the SLDB category, lacking almost completely specific food hygiene expertise, will have considerable difficulties to properly apply a specific template or generic sector specific HACCP system as indicated under point 2. They cannot fill in the specifics, as needed, and thus are in a different position. The best approach in this area seems to be the use of a ready made, sector specific Code of Hygienic Practice, preferably drafted by representatives of the sector, with assistance from consultants and/or government. Training programmes should be primarily targeted at basic food hygiene and implementation of the Code of Practice specific to their sector, and should ideally also include some understanding of the most important hazards in their businesses.

Implementation strategies for HACCP in SLDBs should carefully consider the barriers connected to the above mentioned situations and develop in that context short term and long term strategies with realistic targets.

6. CONCLUSIONS AND RECOMMENDATIONS

1. The Codex Committee on Food Hygiene should consider the development and adoption of separate Guidelines for Application of HACCP in SLDBs as part of the General Principles document.
2. Given the barriers to the implementation of HACCP by SLDBs, governments and industry/trade associations should develop strategies to facilitate its implementation.
3. Special attention is needed regarding implementation strategies for SLDBs with very limited means and expertise in the area of food hygiene.
4. When implementing HACCP in SLDBs, attention should be paid to the strategies identified and guidelines developed by the WHO¹ Consultation.
5. 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.
6. 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.
7. 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.