FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses

World Health Organization

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ACRONYMS

BRC	British Retail Consortium
CCFH	Codex Committee on Food Hygiene
CCP	Critical Control Point
EFSIS	European Food Safety Inspection Service
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GDP	Gross Domestic Product
GHP	Good Hygienic Practice
GLP	Good Laboratory Practice
GMO	Genetically modified organism
GMP	Good Manufacturing Practice
GRAS	Generally Recognized As Safe
HACCP	Hazard Analysis Critical Control Point (System)
OAS	Organization of American States
OECD	Organisation for Economic Co-operation and Development
QA	Quality Assurance
SACNASP	South African Council for Natural Scientific Professions
SLDB	Small and/or Less-Developed Business
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
SQF	Safe Quality Food
SSOP	Sanitation Standard Operating Procedures
TBT Agreement	Agreement on the Technical Barriers to Trade
USDA	United States Department of Agriculture
WHO	World Health Organization
WTO	World Trade Organization

FOREWORD

The Hazard Analysis and Critical Control Point (HACCP) system was introduced approximately 20 years ago as a means to control food-related hazards. It has become increasingly important at national and international levels. It is widely recognized that good hygienic practices (GHPs) form the basis or an integral part of HACCP. Over the years, governments and food businesses have gained a wealth of experience in the application of GHP/HACCP and many lessons have been learned.

HACCP or HACCP-based systems (including good hygienic practices) are important for all food businesses along the food chain. However, in some countries HACCP has been most successfully introduced in large food businesses supplying export markets – perhaps because the adoption of HACCP systems is sometimes a basic requirement in major international food markets. Nevertheless, governments increasingly acknowledge that small and/or less developed businesses (SLDBs) provide an important source of food and contribute to the national economy, and the importance of consumer protection applies equally to all food businesses.

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) support the continual development of national policies to improve food safety and quality with the overall objective of protecting consumer's health and furthering economic development. This document provides guidance to governments and relevant stakeholders and proposes the development of national HACCP strategies to include the implementation of HACCP systems in SLDBs.

Worldwide, SLDBs present diverse and sometimes very complex challenges to ensuring food safety. Language, illiteracy and cultural differences may be more difficult to overcome in one country than in another. On the other hand, many challenges to small and medium-sized businesses are similar, irrespective of geographical location: lack of resources (time, labour and financial) and lack of technical expertise.

This document is designed to assist national food safety authorities in the development of a HACCP strategy for SLDBs within a national food safety policy. It is the product of collective national and international experience. Wherever possible, examples of national approaches are provided. While acknowledging the barriers facing SLDBs in their attempts to implement HACCP systems, approaches to addressing these barriers that have been tried and tested around the world are presented. The objective is to provide FAO/WHO member countries and relevant stakeholders with practical solutions for the implementation of HACCP in SLDBs.

1. INTRODUCTION

1.1 BACKGROUND

The principles of the Hazard Analysis and Critical Control Point (HACCP) system have been adopted by the Codex Alimentarius Commission and guidelines to its application are provided in an Annex to the General Principles of Food Hygiene (FAO and WHO, 2003). During consideration of the draft HACCP standard (Rev. 3) at the 22nd session of the Codex Alimentarius Commission (ALINORM 97/37, para. 34), some delegations expressed their concern that difficulties might be encountered in applying the HACCP system in small businesses and in developing countries. Subsequently, the matter of barriers to HACCP application in small and/or less developed businesses (SLDBs)[2] was extensively debated in the Codex Committee on Food Hygiene (CCFH) between 1997 and 2003 (CCFH, 1997-2001 and 2003). A joint Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) expert consultation in 1998 (WHO, 1998) and a WHO expert consultation in 1999 (WHO, 1999) both addressed aspects of this topic.

At the 35th Session of the Codex Committee on Food Hygiene in 2003, it was agreed that FAO and WHO would develop HACCP guidelines for SLDBs, highlighting potential obstacles and approaches to overcome them. This request from member countries arose during the deliberations over the revision of the Recommended International Code of Practice: General Principles of Food Hygiene, including the Annex on "HACCP and Guidelines for its Application" (FAO and WHO, 1993).

In 2004, FAO/WHO convened an electronic discussion group of experts with experience in this field to exchange views and share information. The inputs were considered by FAO and WHO in collaboration with Dr Wayne Anderson, Food Safety Authority of Ireland, who prepared the first draft of the guidelines on the request of both organizations.

The draft was discussed and developed further at an expert meeting convened by FAO and WHO in Rome from 13 to 15 December 2004; prior to finalization, it was subject to a peer review process.

These guidelines aim to fulfil the Codex request and to provide the member states of the CCFH with practical solutions for the implementation of the HACCP system in SLDBs.

1.2 FAO/WHO GUIDANCE DOCUMENT

1.2.1 Objectives

This document aims to assist in the development of national policy, strategies and action plans aimed at improving food safety and trade through the application of HACCP in SLDBs throughout the world. It identifies the barriers to the application of HACCP in SLDBs and

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[2] The term "SLDB" was adopted by CCFH in 1999. A full definition is given in Chapter 2 on p. 9.

provides solutions based on the experience of experts in their respective countries. In this regard, flexible approaches to the implementation of HACCP are described.

1.2.2 Scope

Approaches that could be adopted by national governments to improve food safety and trade by facilitating HACCP application in SLDBs are elaborated herein. The needs of larger, more technically advanced food businesses are not specifically considered, although this document could also be applied to them. The information provided is applicable to SLDBs engaged in food processing and preparation, distribution and storage, wholesale, retail and catering activities. Although not specifically aimed at primary food production (animal husbandry and on-farm activities), it could also be of assistance to governments applying HACCP-based systems at farm level.

Appropriate activities are presented for use by national governments in the development of national policy, strategy and action plans. The aim is not to directly provide solutions to SLDBs for implementing HACCP in their food businesses. However, adaptations of the Codex HACCP system used by national governments are presented briefly for further research by interested parties. It is stressed that the solutions provided need to be adopted and tailored, taking into account national circumstances: no single solution is the optimum choice in all situations.

1.2.3 Descriptive terms

For the purposes of this document, the following terms were agreed:

Good hygienic practices:	All practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.[3]
Codex HACCP system:	A system which identifies, evaluates and controls hazards which are significant for food safety, described in the Annex to the Codex General Principles of Food Hygiene (FAO and WHO, 2003).
HACCP-based system:	A system that is consistent with the seven principles of HACCP but does not conform to the layout or steps of the Guidelines for the Application of the Codex HACCP system.
Food Safety Management System:	A holistic system of controls that manage food safety in a food business. Includes GHPs, the HACCP system, management policies and traceability/recall systems.

1.2.4 Target audience

The guidance document is for use by governments developing national policy aimed at the application of HACCP in SLDBs, and by professionals advising on national policy development (e.g. government officials, food industry associations, consultants, auditors, trainers/education

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[3] The term "good hygienic practices" is based on the definition of food hygiene documented in the Codex General Principles of Food Hygiene (CAC/RCP 1 – 1969, Rev. 4 [2003]). For consistency, the term GHPs is used throughout the document, recognizing that in some countries other terms, such as "prerequisite programmes", "GMPs" (good manufacturing practices) or "SSOPs" (Sanitation Standard Operating Procedures) may be used.

specialists). However, it may also be of use to other groups of people, for example, food business managers and food enforcement officers.

1.2.5 Document overview

The underlying principles and the broad logic upon which the guidance has been developed are as follows:

- Together with GHP, HACCP is recognized as an appropriate and useful tool for enhancing the safety of food products and providing adequate food safety assurance.
- HACCP is for use by all food businesses; however, SLDBs experience a number of constraints which can make HACCP implementation difficult.
- There is a greater uptake of HACCP (and hence improved controls) in larger food businesses often involved in the export market.
- Food businesses play a vital role in adopting food safety management systems and are a key stakeholder in food safety policy development.
- In addition to the action taken by the food businesses themselves, governments are responsible for creating a scientific, technical and financial environment favourable to HACCP implementation, with specific consideration for SLDBs.
- Government interventions are best developed within the overall framework of a national HACCP strategy, implemented through a planned process. A comprehensive strategy covers all types of food business and pays specific attention to the needs of SLDBs.
- Involvement of relevant partners in the development of this strategy is essential.
- Government support through a HACCP strategy is especially important where SLDBs are concerned. Effective implementation of the strategy requires a number of support activities as well as the development of specific guidance for HACCP application.

On the basis of these concepts, the document is organized as follows:

- **Chapter 1** provides the historical background and a summary of the work of the Codex Alimentarius Commission on HACCP. It presents the scope and targeted audience and describes the roles of government and food businesses with respect to HACCP implementation, with GHPs as an integral component.

- **Chapter 2** comments on the specifics of the small business sector and the challenges faced in the application of HACCP. The text is based on the experiences of member countries as raised in the Codex Committee on Food Hygiene and includes challenges faced by SLDBs:
  - within the food business;
  - related to staff; and
  - resulting from an inadequate supporting environment.

- **Chapter 3** outlines the steps proposed for the development of a HACCP strategy within a national food safety policy. The criteria for measuring the success of the strategy are discussed.

- **Chapter 4** outlines a number of strategic activities to facilitate HACCP implementation in SLDBs, including overall support activities (e.g. financial, guidance materials, training, regulatory requirements) and the development of HACCP-based approaches.

- **Annex 1** gives examples of approaches taken in a number of countries to facilitate HACCP implementation, with particular consideration for SLDBs.
- **Annex 2** provides information on how the seven principles of HACCP can be implemented in a specific SLDB environment.

1.3 THE HACCP SYSTEM

1.3.1 The food safety burden

Data from WHO suggest that food-borne disease (together with water) is a significant contributor to mortality from diarrhoeal disease (2.1 million deaths in 2000). Each year, food-borne disease causes an estimated 76 million illnesses, 325 000 hospitalizations and 5 000 deaths in the United States of America, and 2 366 000 cases, 21 138 hospitalizations and 718 deaths in England and Wales (Adak *et al.*, 2005; Mead *et al.*, 1999). A recent OECD (Organisation for Economic Co-operation and Development) report assumed that the burden of food-borne disease is probably similar in most OECD countries. Many countries, including developing countries, lack strong surveillance and reporting systems and therefore statistical estimates are not available. Furthermore, food-borne disease often goes unreported, with the result that the economic and health impacts are greater than the figures suggest in many countries. Improvements in the protection of public health rely on improvements in the safety of food. In this regard, governments, the food industry and consumers have a shared responsibility to adopt the best practices for the control of food safety hazards.

1.3.2 Codex Guidelines on HACCP

The Codex HACCP system (FAO and WHO, 2003) has several features that characterize it. Seven basic HACCP principles are established and then elaborated into a logical sequence of 12 steps for implementation (Figure 1). Guidance in the form of a decision tree is provided for the identification of critical control points (CCPs), and an example of a HACCP worksheet demonstrates a possible layout for a documented plan. The HACCP system should not be implemented until a food business is operating in accordance with good hygienic practices (GHPs) and in compliance with appropriate food safety requirements. It should be noted, however, that the Codex HACCP system is the written product of experience gained in the application of HACCP systems in large and relatively technically sophisticated food businesses. Some governments implement the Codex system according to the 12 steps defined in the guidelines, while others develop or promote systems encompassing the seven principles, without following the 12-step process. Further flexibility is rare, given that the Codex HACCP system is the reference standard in international trade disputes.

FIGURE 1
Logical sequence for the application of HACCP
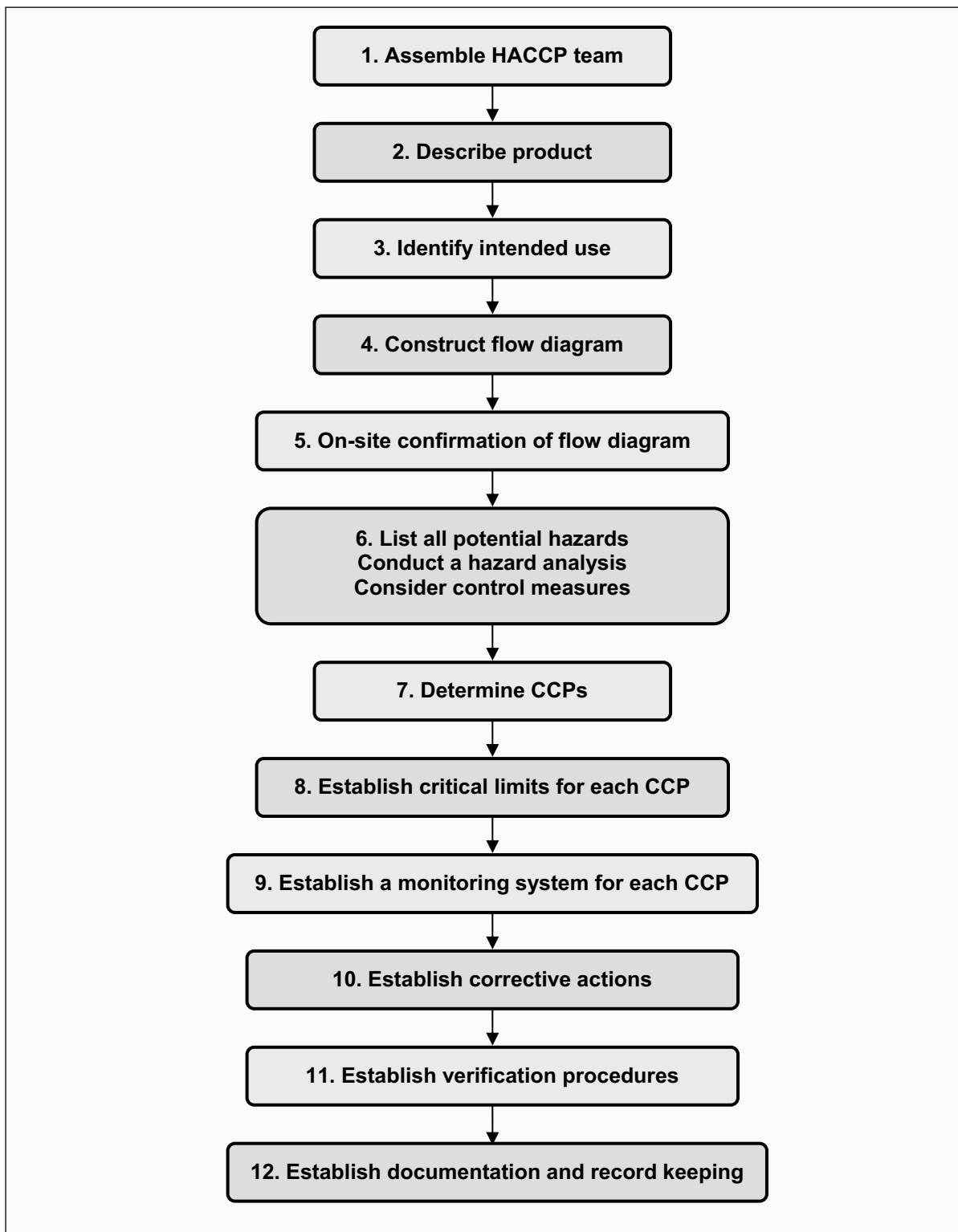
Source: FAO and WHO, 2003, p. 42.

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The most recent version (Rev. 4, 2003) of the Codex HACCP System and Guidelines for its Application includes amendments addressing issues relating specifically to SLDBs. Examples are:

- *Assemble HACCP team (Step 1)*
  - *Where such expertise is not available on site, expert advice should be obtained from other sources, such as, trade and industry associations, independent experts, regulatory authorities, HACCP literature and HACCP guidance.*

- *Describe product (Step 2)*
  - *Within businesses with multiple products, for example, catering operations, it may be effective to group products with similar characteristics or processing steps, for the purpose of development of the HACCP plan.*

- *Establish documentation and record keeping (Step 12)*
  - *Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilised as part of the documentation, provided that those materials reflect the specific food operations of the business.*
  - *A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.*

While these improvements provide added flexibility, it is unlikely that they are sufficient to enable SLDBs to implement HACCP; further supporting initiatives are required to address the obstacles faced by SLDBs.

This document emphasizes the use of the HACCP principles as a means to assure the safety of food; however, the concept can be applied to other aspects of food quality.

1.3.3 Role of government and potential benefits

The role of governments goes beyond adopting and monitoring compliance with national food legislation: they should actively promote food safety measures through the adoption of food safety management systems such as HACCP. The success with which food businesses establish and implement HACCP may be directly related to the supporting environment created by the government, including alliances with food businesses; this is particularly true in the case of SLDBs. SLDBs face very significant challenges when adopting HACCP, and active intervention by the government is required. In most countries, the SLDB sector accounts for a substantial part of the food industry, makes an important contribution to the national food supply and is an important source of employment contributing to the local economy. It is therefore important that a national policy is adopted to increase levels of food safety in this sector. At the same time, advocacy of the HACCP system provides mutual benefits to the government, including safer food and hence increased public health protection, which in turn may increase the confidence of both national consumers and tourists. This, combined with better opportunities to increase trade, results in economic growth and national development.

1.3.4 Role of food businesses and potential benefits

Food businesses bear the ultimate responsibility for assuring the quality and safety of the foods they produce. The food must reach the consumer in its intended state and there must be adequate consumer information concerning the intended use of the product. Food businesses are under growing pressure from governments and buyers to demonstrate that they implement effective systems to meet basic GHP and HACCP requirements for food safety. Initial responsibility for HACCP lies within the food industry, in particular with management:

- Food must be produced in a hygienic manner.
- The source of incoming raw materials must be considered.
- A risk-based approach – such as the HACCP system – must be implemented to achieve food safety.

Food businesses are also required to interact and comply with government requirements regarding food safety management systems, inspection and auditing. Food industry associations give food businesses a stronger voice in discussions with government and other interested parties, and help work towards improving the overall standard of a specific food sector. They can also raise awareness, promote technical transfer of information and increase provision of training.

It is recognized worldwide that the HACCP system:

- provides clear benefits to food businesses;
- enhances the safety of food; and
- reduces cases of food-borne disease.

Benefits resulting from the implementation of HACCP systems have been identified (CCFH, 1999; Taylor, 2001; Quintana and FAO, 2002) and some are described below:

- Staff and business owners gain confidence and are better equipped for informed discussion on food safety measures with food inspectors, third party auditors, consultants, trading partners, consumers and others.
- A HACCP system is essentially a management tool and its development requires an investment resulting in cost reductions to SLDBs in the medium and long term: more efficient use of staff, provision of adequate documentation and reduced waste.
- The increased level of process control can result in product consistency and improvements in traceability, with beneficial cost implications for SLDBs as access to some markets is increased and more customers are attracted.
- The development of a HACCP system can be a valuable team-building exercise for an SLDB; it can lead to improved education and awareness of staff working in SLDBs and staff members are empowered when their input is sought and valued; this in turn can have a positive effect on the development of the SLDB, as it demonstrates an ability to manage change.
- HACCP provides a basis for defence against litigation and can bring reduced insurance costs.

1.3.5 Exploring approaches for HACCP in SLDBs

Adoption of the Codex HACCP system has led to confusion among food safety practitioners and food businesses (already facing numerous constraints – see Chapter 2), with the result that

implementation has been partial or ineffective. Therefore, systems have been developed with a more flexible approach and are usually referred to as "HACCP-based systems" or "systems based on the principles of HACCP". They are faithful to the seven principles of HACCP, but do not require the business to follow the traditional 12-step approach as outlined in the Codex guidelines. Nevertheless, it is important that SLDBs have a good understanding of the controls they are putting in place as, ultimately, it is they who are responsible for food safety.

1.3.6 Interdependency between HACCP systems and good hygienic practices

This document provides guidance on the application of HACCP in small businesses; nevertheless, a logical approach ensues and it goes without saying that a HACCP system is based upon and should take into account basic prerequisite programmes (i.e. GHPs). Prerequisite programmes outline the measures taken to ensure that premises, equipment, transport and employees do not contribute to or become food safety hazards. Without these basic principles (e.g. sanitation, pest control, personnel practices), a risk-based system such as HACCP will fail. The application of GHP and HACCP acknowledges two schools of thought:

- All the basic prerequisite programmes should be in place in a food business before preparing a HACCP plan.
- A risk-based approach to food safety management can be applied by strengthening the GHP programme, while completing the HACCP plan.

Which path to take (or whether to use a combination of both) is a matter of national policy with due regard to importing country requirements. The basic GHP programme is of prime importance for food safety, as stressed in the fourth revision of the Annex on HACCP (contained in the Codex General Principle of Food Hygiene – FAO and WHO, 2003):

Prerequisite programmes to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system.

While following these guidelines and considering the national policy options for the application of HACCP in the small business sector, it is necessary to take account of the existing food hygiene controls in the food business sector being targeted. What is the existing level of GHPs? Are they adequate? Where is strengthening required?

Government assessment through planned inspection and auditing programmes should review the application of good hygiene principles as well as other food safety management systems operated by the food business. Where GHPs are inadequate, the initial objective of HACCP in SLDBs should be basic hygiene improvement. Hazard analysis can help focus on priority areas where improved hygiene is necessary. A specific HACCP plan – i.e. with identification of CCPs and control charts – could be developed to increase confidence in the control of parameters critical for food safety.

2. THE SMALL BUSINESS SECTOR AND CHALLENGES FACED WORLDWIDE

The food industry in most countries is a major sector, sometimes accounting for the highest proportion of the gross domestic product (GDP). In 2002, India's food industry was valued at US$75 billion and accounted for 30 percent of the GDP (Anandavally and FAO, 2002). In many countries, the food industry comprises mainly small businesses which are responsible for a large share of the food consumed. In 2002, Thailand reported a total of 57 217 food factories: 1 percent (444 factories) were classed as large plants, 3 percent (1 763) medium and up to 96 percent (55 010) small (Keeratipibul, Tutanathorn and FAO, 2002). Small businesses also provide a large share of the total employment in the food sector and make a vital contribution to the economic well-being of the community at local level. United Kingdom statistics suggest that 99 percent of food businesses are small companies employing 50 percent of the total food industry's workforce and contributing 38 percent of its financial turnover (DTI, 1999). For other countries not specifically referenced here (including developing countries), the proportion of SLDBs is considered to be similar.

All national governments aim for indigenous small food businesses to thrive, but they must at the same time protect public health. To this end, it is important to develop a food safety policy and strategy for the implementation of HACCP in SLDBs. While not food exporters, SLDBs have a strong impact on local and regional economies and a potentially immense impact on the health of local consumers and therefore national public health.

In most countries, SLDBs are classified by size, using economic measures such as financial turnover and number of employees. In 2001, the concept of defining small businesses on the basis of their qualities was introduced (Taylor, 2001):

- They serve local customers.
- They have a limited share of the available market.
- They are owned by one person or by a small group of people.
- They are mostly owner-managed and independent of ownership by larger groups of companies.

It is thus easier to define the types of business that need help in implementing HACCP. However, a food business's level of development and expertise must also be considered: in its broadest sense, the term "SLDB" encompasses both small businesses and larger businesses lacking the ability to develop effective food safety management systems.

Therefore, for the purposes of this document, the term SLDB is taken as the definition adopted in the report of the WHO Consultation on "Strategies for Implementing HACCP in Small and/or Less Developed Business" in 1999 (WHO, 1999) and introduced to the CCFH in 1999 (CCFH, 1999):

> *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 to the number of staff or volume of production.

The strategies and approaches described in Chapter 4 are applicable to both small and less developed businesses. National circumstances dictate which approaches are the most appropriate for which type of business, and governments need to identify the obstacles that may face SLDBs when implementing HACCP. Not all barriers apply in all countries and their relative importance also differs. With a complete understanding of the barriers to HACCP implementation in SLDBs, national governments can develop better policies and select the most appropriate solutions (see Chapter 3). The barriers to HACCP implementation in SLDBs may initially seem daunting; governments need to understand them and should not be deterred from progressing towards solutions. There are clear benefits to the implementation of HACCP in SLDBs (see Chapter 1).

The obstacles to the application of HACCP in SLDBs were discussed in detail at the 35th session of the CCFH (CCFH, 2003) and are summarized below. Recent publications, including the FAO country case studies on HACCP application (Anandavally and FAO, 2002; Keeratipibul, Tutanathorn and FAO, 2002; Quintana and FAO, 2002; Gelli, 2002) and an FAO survey on the application of HACCP in SLDBs (Costarrica, 2004), have also shed light on additional HACCP barriers. Matters raised within the FAO/WHO electronic discussion group and during the expert meeting held in Rome, December 2004, provided additional information. All these findings are included in the summaries below.

2.1 CHALLENGES WITHIN THE FOOD BUSINESS

2.1.1 Infrastructure and facilities

For many SLDBs, HACCP means additional costs in upgrading facilities before the system is even applied. This can be an insurmountable barrier for some SLDBs unless support is provided by governments or trade associations. Furthermore, hygiene management can be hindered by the local infrastructure (inadequate power, water, sewage disposal and transport facilities) and SLDBs usually lack the resources to provide on-site solutions (e.g. sewage treatment). Again, governments have an undeniable role in resolving these difficulties.

2.1.2 Basic hygiene

Good hygienic practices tend to be lacking in SLDBs more than in other food businesses. It is common for SLDBs to face a variety of problems: inadequate location, layout or size of facility, non-cleanable structures, old non-cleanable equipment and poor staff training. Some countries face basic sanitation problems, such as easy access to potable water and safe disposal of waste; furthermore, it is often difficult for SLDBs to obtain raw materials from reliable and affordable sources. Prerequisite programmes therefore result ineffective, HACCP is difficult to implement, and there is little effect on hazard control. On the other hand, strict adherence to the dogma that HACCP cannot be implemented without full control over the prerequisites has also impeded the uptake of HACCP in SLDBs.

2.2 STAFF-RELATED CHALLENGES

2.2.1 Awareness and expertise

The owners and operators of SLDBs may be committed to ensuring food safety; however, because of their immersion in the day-to-day running of their businesses, they are often unaware of the importance of HACCP. On the other hand, they may know about HACCP, but lack the technical competence and business skills necessary to operate an effective prerequisite programme and set up a HACCP system as envisaged in the Codex Alimentarius guidance (FAO, 2003). Even with several years of government promotion of HACCP, a significant number of SLDBs remain ignorant of the concept (FSAI, 2001; Mortlock, Peters and Griffiths, 1999), and those businesses which have heard of HACCP are often "swamped" by technical jargon, which is in itself a barrier to clear communication and acceptance of the benefits of HACCP. Most people in SLDBs are not technically skilled enough to conduct a meaningful hazard analysis; since this is an early step in the implementation process, this barrier alone can stop the process in its tracks. It is therefore important that the materials produced focus on the needs and abilities of those to whom they are targeted and that they are presented in as user-friendly a way as possible.

2.2.2 Education and training

For successful HACCP implementation, the concept must be understood by food business owners and managers. Their understanding and commitment is crucial if staff are to effectively operate a food safety management system (of which HACCP is one aspect). Specific training courses did not used to exist and only recently has HACCP been integrated in university curricula; consequently, many business owners have not been exposed to HACCP at all or have received only cursory instruction. What is more, HACCP is still largely taught by theorists in the formal education system: the Codex HACCP system is often rigidly adhered to and practical implementation issues are not always covered.

While processes in different SLDBs are often quite alike, there can also be marked variation between seemingly similar businesses. Training must take account of this diversity and needs to move away from the "one size fits all" concept. Literacy levels are sometimes low; training must be tailored to account for this and may have to be more practical (i.e. use of demonstrations) than theoretical. Training locations should be suited to the needs of the trainees. The challenges may be further compounded where there is a high turnover of staff – a common situation in many SLDBs. In some countries, SLDBs are family-run enterprises passed down through generations and employing traditional methods of food production. Many workers and managers in such businesses may not be trained in even basic food hygiene; training may need to include all relevant hygiene aspects rather than simply targeting HACCP. In some countries, food hygiene training courses are provided separately; it may now be preferable to provide training courses which integrate basic hygiene and HACCP principles.

In short, new training approaches need to be developed to meet the specific needs of SLDBs. A key factor to be taken into consideration is the literacy level, as workers must be able to read and write in order to fill out simple records effectively.

2.2.3 Technical support

SLDBs often lack the technical expertise required to implement HACCP and may need external support. In particular, they need help to identify the hazards associated with their food processes; such help must be readily accessible (note that the sheer expense of expertise is a further obstacle) and easy to understand. SLDBs often lack the capacity to differentiate between good and bad experts. Although in some countries, expertise is available through consultants, there is no guarantee of the standard of advice. In such countries and in other countries where consultancy is rarely available, governments and industry/trade associations are responsible for providing adequate, accessible technical support for SLDBs.

2.2.4 Human resources

SLDBs normally have to maintain tight control over their costs. Consequently, labour rarely exceeds the level necessary for the day-to-day running of the business. This problem often prevents resource allocation for the implementation of HACCP systems and curtails the amount of training received by staff (other than on-the-job training). In some sectors there is a high rate of staff turnover, or staff tend to work on short temporary contracts; management is therefore reluctant to invest in training for HACCP. This is sometimes criticized as lack of commitment to HACCP; however, it may not be an attitude problem, rather the result of the fact that human resources in SLDBs are a scarce commodity. In reality, however, staff training can have long-term benefits, even with high staff turnover rates, as some staff will move to other businesses or sectors, and training can lead to increased awareness of food safety practices in the home.

2.2.5 Psychological factors

In order to successfully implement HACCP in SLDBs, behaviour change is required. Behaviour is deeply rooted in a person's psyche and it is sometimes essential to understand the psychological constraints on people in SLDBs faced with implementing HACCP. Gilling *et al.* (2001) used a medical model to examine this barrier to HACCP implementation in different-sized food businesses. Their findings suggest that more barriers to HACCP implementation were perceived by SLDBs than by larger businesses. Barriers envisaged by all companies, large and small, include:

- customer demands;
- time/cost pressures;
- lack of motivation; and
- the belief that HACCP would not necessarily make a difference in their own business.

Additional barriers in SLDBs are psychological constraints, including:

- lack of self-efficacy (the belief that a person has the capability to organize and execute a course of action);
- inertia (the inability to overcome the habit of a previous practice due to lack of desire to change); and
- agreement (cannot see how HACCP can deliver safer food on their premises).

Inertia and agreement are often deep rooted in the owner's belief that the SLDB is already producing safe food without a HACCP system. Such psychological constraints tend to be inadequately addressed and passed off as "lack of management commitment", a phrase often seen in HACCP literature.

2.3 CHALLENGES DUE TO INADEQUATE SUPPORTING ENVIRONMENT

2.3.1 Financial issues

Financial constraints are a practical barrier to implementing HACCP, felt by governments and industry alike, and can be particularly acute in SLDBs. As a result, the assistance provided by governments and trade associations is not adequate to affect change. Good hazard control can lead to savings for governments (e.g. lower public health costs and reduced workplace absenteeism); however, these are rarely appreciated or used to offset initial financial investment.

While the costs associated with HACCP can be daunting for SLDBs, they may also be perceived to be higher than they actually are (e.g. cost of external consultants). A real cost is staff time: the time necessary for training and subsequent implementation can hinder the day-to-day running of an SLDB. It is necessary to consider the potential long-term savings that a good HACCP system can accrue, not least the protection against harm to the consumer and against potential litigation that can follow food poisoning incidents. There is lack of evidence of the cost-benefit ratio of the HACCP system: the lack of data and studies relating to HACCP implementation and its impact on food safety means that the visible benefits of HACCP are not so evident.

2.3.2 Government infrastructure and commitment

National governments and their associated agencies and bodies must be committed to HACCP systems in SLDBs. External and internal commitment is important for the development and implementation of a successful HACCP initiative in SLDBs. An appropriate common policy for the application of GHP/HACCP in SLDBs is needed to achieve uniformity among trainers. Insufficient government commitment, inadequate professional knowledge of HACCP (including inadequately trained auditors), poor coordination within government structures and/or inconsistency in HACCP enforcement or application are not conducive to the creation of a food safety culture in which HACCP can thrive. In this respect, one of the most important tasks of governments is to make industry aware of the benefits of and the need for introducing HACCP to produce safe food. However, the sheer number of SLDBs poses a major challenge. Governments must train staff responsible for introducing HACCP in SLDBs. An important issue is the mindset and skills of inspectors which need to be adapted to ensure they can assess the effectiveness of HACCP systems in food businesses and rely less on traditional inspection methods.

2.3.3 Legal requirements

SLDBs can be persuaded to implement HACCP when it is a legal requirement and – importantly – properly enforced. The presence alone of a legal requirement is not sufficient to stir all SLDB owners into affirmative action, but it can be considered part of a framework to promote HACCP implementation. However, when drafting legal provisions with respect to HACCP, the nature of

the system should not be too rigidly described as it hampers flexibility and the ability of an SLDB to apply the system to their business. It should be noted that legal HACCP is not a necessity, rather a matter of national policy: it will work in some countries and cultures, but perhaps not at all in others. Any legal requirement should attempt to work in tandem with existing initiatives that may be taken by the food industry itself.

2.3.4 Business awareness and attitude of industry and trade associations

Market forces and export requirements have been central to the implementation of HACCP in many food businesses. The implementation of food safety management systems incorporating HACCP can be a prerequisite to market access. This is particularly evident if businesses are export oriented or if they supply into large retail multinational businesses. Many SLDBs, on the other hand, only supply the domestic market and there is no significant presence of large multinational retailers in some countries; as a result, SLDBs in catering and other sectors have been reluctant to implement HACCP – this is also the case for SLDBs supplying direct to consumers or local retailers and caterers. Trade associations have a role to play in promoting HACCP; however, in many countries they do not exist and, even when they are present, SLDBs are likely to be under-represented compared to larger food businesses.

2.3.5 Customer awareness

Many SLDBs are customer focused, whether they are conscious of this or not. Indeed, many SLDBs have direct contact with consumers in a way that larger businesses cannot achieve. Therefore, the consumer can be a very strong driver for change, but when customers (and consumers) do not perceive food safety as an issue of fundamental importance, it is unlikely that SLDBs will be driven to implement HACCP. In many countries – especially developing countries – consumer awareness (and the pressure that can be placed on food businesses) is in the early stages of development: it is the responsibility of government and international organizations to educate consumers in this regard. Where consumers are illiterate, the challenges are compounded: elementary education can supply healthcare knowledge which forms the basis of GHP/HACCP training. The mass media are in an excellent position to educate consumers and to promote the demand for safe food and appropriate control systems. However, it may also have a negative effect if not handled properly and if journalists are not appropriately informed.

Food safety should form an important part of business dealings throughout the food chain. Food (raw or intermediate) should be purchased from businesses implementing HACCP systems. Combined with greater consumer awareness, this should create demand and a strong driving force to undertake improvements in food safety. It is the government's responsibility to:

- consider the potential impact on the food supply chain (providing support where there is a demand for raw materials from businesses implementing HACCP);
- take account of the impact on price (i.e. increases); and
- intervene with regard to the subsequent availability of raw materials.

2.3.6 Communication

Poor communication between governments, industry and consumers can impede the introduction of HACCP. Communication strategies – covering the content of the communication as well as the channels for communication – need to be part of any HACCP policy or strategy. Often the only point of official contact with SLDBs is through official inspectors; if these people are not resourced, trained and allowed to provide advice as well as conduct official inspections, it can hamper a national strategy aimed at increasing HACCP implementation.

3. DEVELOPMENT OF A HACCP STRATEGY FOR SLDBS WITHIN A NATIONAL FOOD SAFETY POLICY

3.1 INTRODUCTION

Governments are responsible for public health and economic development; improvements in food safety – including the implementation of HACCP in food businesses – can have a positive effect in both areas. Agriculture and the agribusiness sector make an important contribution to the national economy in many countries. The specific nature of the sector varies from country to country in terms of food products, types of technology employed, size of businesses, access to domestic and export markets, and development of GHPs and HACCP programmes. A wide range of stakeholders are working towards the common goal of food quality and safety: government departments (health, agriculture, fisheries, education, development, trade and industry/enterprise), scientific institutes, food associations, trainers, consultants and auditors, in addition to external influences (buyers, accreditation organizations and standard-setting agencies).

National food safety policies serve to coordinate and maximize the efforts of all stakeholders working towards the common goal of food quality and safety. The overall goal of a food safety policy may be to safeguard the quality and safety of the total food supply, leading to:

- reduction in the incidence of food-borne disease;
- improvements in nutrition and quality of life; and
- enhanced food security through a vibrant food business sector.

Effective food safety policies set the strategic direction for food control activities and provide a framework for the implementation of specific strategies to achieve the overall goals. The status and delivery mechanisms for food safety policies vary from country to country, depending on stages of development, food safety problems and administrative arrangements. Figure 2 outlines the relationship between the national food safety policy, individual strategies and strategic activities to achieve the goals of the policy.

The application of GHP and HACCP programmes along the food chain is a priority for governments and food businesses, and HACCP systems cannot be successfully applied if GHPs are not in place (CCFH, 1997; CCFH, 1998; Anandavally and FAO, 2002; Keeratipibul, Tutanathorn and FAO, 2002; Quintana and FAO, 2002; Gelli and FAO, 2002; Costarrica, 2004). A national HACCP strategy should address the situation of all food businesses in a country, and where SLDBs account for a significant amount of the food produced and consumed, special emphasis should be given to understanding the specific needs of SLDBs and some elements of the national strategy should be tailored to these needs. Where there is no national government-led food safety policy, decisions tend to be taken by other stakeholders, such as the more organized elements of the food industry, market forces and organizations outside of the country. Initiatives by these stakeholder groups are important, especially when there is a lack of government support; however, they may result in fragmented or differing approaches, which in turn can be to the particular detriment of the development and sustainability of SLDBs, with resulting social impact.

FIGURE 2
Government policy and strategies
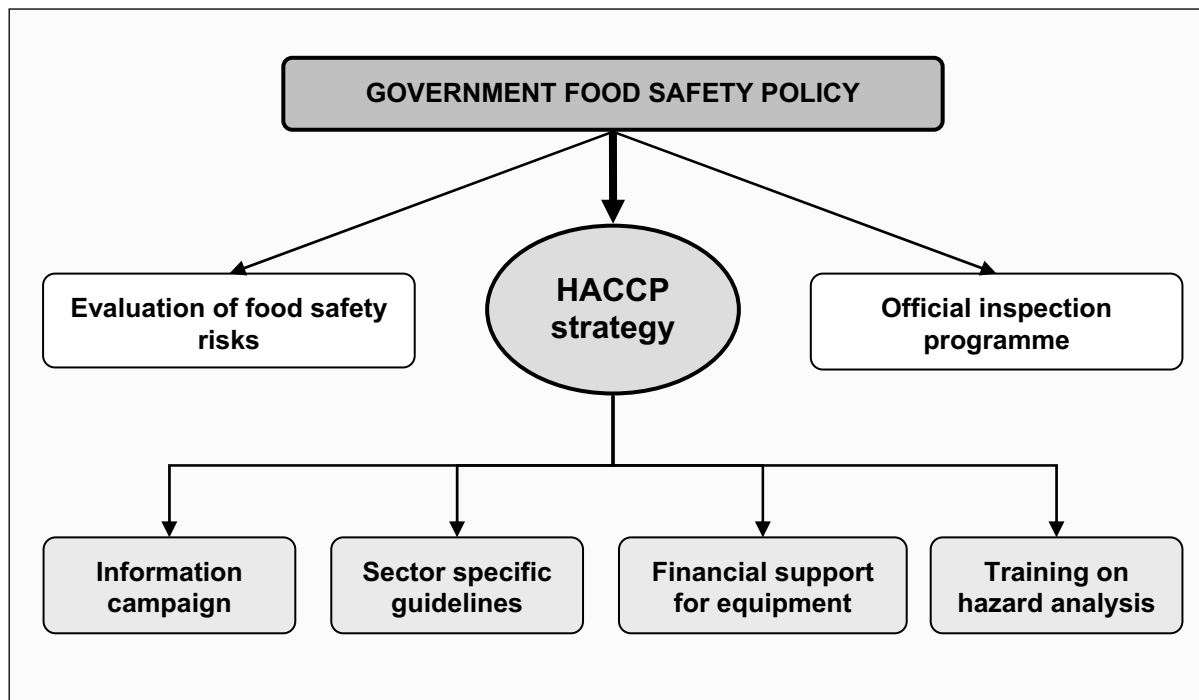
Given the barriers facing the implementation of HACCP in SLDBs (see Chapter 2), many activities are needed on many different fronts involving a range of stakeholders. To achieve the desired goals of the food safety policy, activities must be organized in the most efficient and effective manner. HACCP is based on a coherent interdepartmental and multidisciplinary approach and requires full stakeholder involvement.

Successful HACCP development and implementation are interconnected with other strategies:

- Improvement of official food control and inspection system (including inspector training).
- Improvement of official laboratories.
- Appropriate evaluation of food safety risks.
- Improvement of local infrastructure (water, roads, electricity supply).
- Higher quality construction of food premises and facilities.

Each strategy comprises a range of specific activities and the various strategies must be coherent in order for the HACCP strategy to be successful.

3.2 DEVELOPMENT OF STRATEGY FOR HACCP IMPLEMENTATION

The first step is to broadly list the desired objectives and outcomes in terms of food safety and/or economics and on the basis of the national food safety policy. The strategy should focus on the creation of an environment with a sound foundation of GHPs to facilitate HACCP implementation in SLDBs. In some countries it is possible to conceive a single all-encompassing strategy incorporating all HACCP activities in all SLDBs, irrespective of food sector. In other

countries it may be necessary to develop a series of strategies aimed at SLDBs in specific food sectors; the strategies need to be coordinated to ensure that they enact and reflect the national food safety policy.

In either case, the steps outlined in this chapter for the creation of effective strategies are applicable. Note that the term "strategy" used in the context of this document refers to a single national HACCP strategy comprising a series of coordinated strategic activities implemented through a planned process. Where GHPs are not already systematically applied, the first objective is basic hygiene improvement. The strategy should be based on sound and comprehensive information and concern itself with solutions and their likely impact. The sector of the food industry and size of business concerned should be specified. Only if a strategy is developed correctly, can its implementation through specific activities (see Chapter 4) culminate in the achievement of the desired policy outcomes.

Figure 3 presents the logical sequence of steps to be followed for the successful development of a HACCP strategy. It is not essential that governments follow the exact order; for example, it may be appropriate to assess the impact of the draft strategy before consulting with stakeholders.

3.2.1 Gather information

Information concerning HACCP implementation in SLDBs should be obtained from both external international sources and internal national sources.

- *External.* It is important to learn from the experiences of other countries: organizations such as FAO and WHO are very useful repositories of information relevant to national strategy, as are the Web sites of national governments or their agencies, in addition to the published literature (Mortlock, Peters and Griffiths, 1999; Panisello, Quantick and Knowles, 1999; CFIA, 2004). It is important for governments to be aware that influences vary between countries (e.g. food industry profile, economic performance, organizations and support structures, infrastructure); they may underlie the adoption of a particular strategy but may not necessarily be communicated openly – strategies adopted in one country may not be effective in another. Brief summaries of some national experiences are provided in Annex 1.

- *Internal.* To obtain information internally, initial consultation with the relevant stakeholders is vital; they often have information that is not publicly available and which places other information in the correct context. Surveys are a useful tool – for example, a structured questionnaire which should be statistically validated (FSAI, 2002; Quintana and FAO, 2002; Burt, 2001). Results must be interpreted carefully, as the information obtained from SLDB self-diagnosis may not be entirely compatible with similar information gained by a third party audit of a business's food safety management system. It is recommended that survey results are cross-checked with, for example, official inspection reports, trade body reports or other available surveys. The findings need to be broadly consistent and any anomalies should be investigated before developing a strategy on the basis of possible misinformation.

FIGURE 3
Logical sequence for development of strategy for HACCP implementation
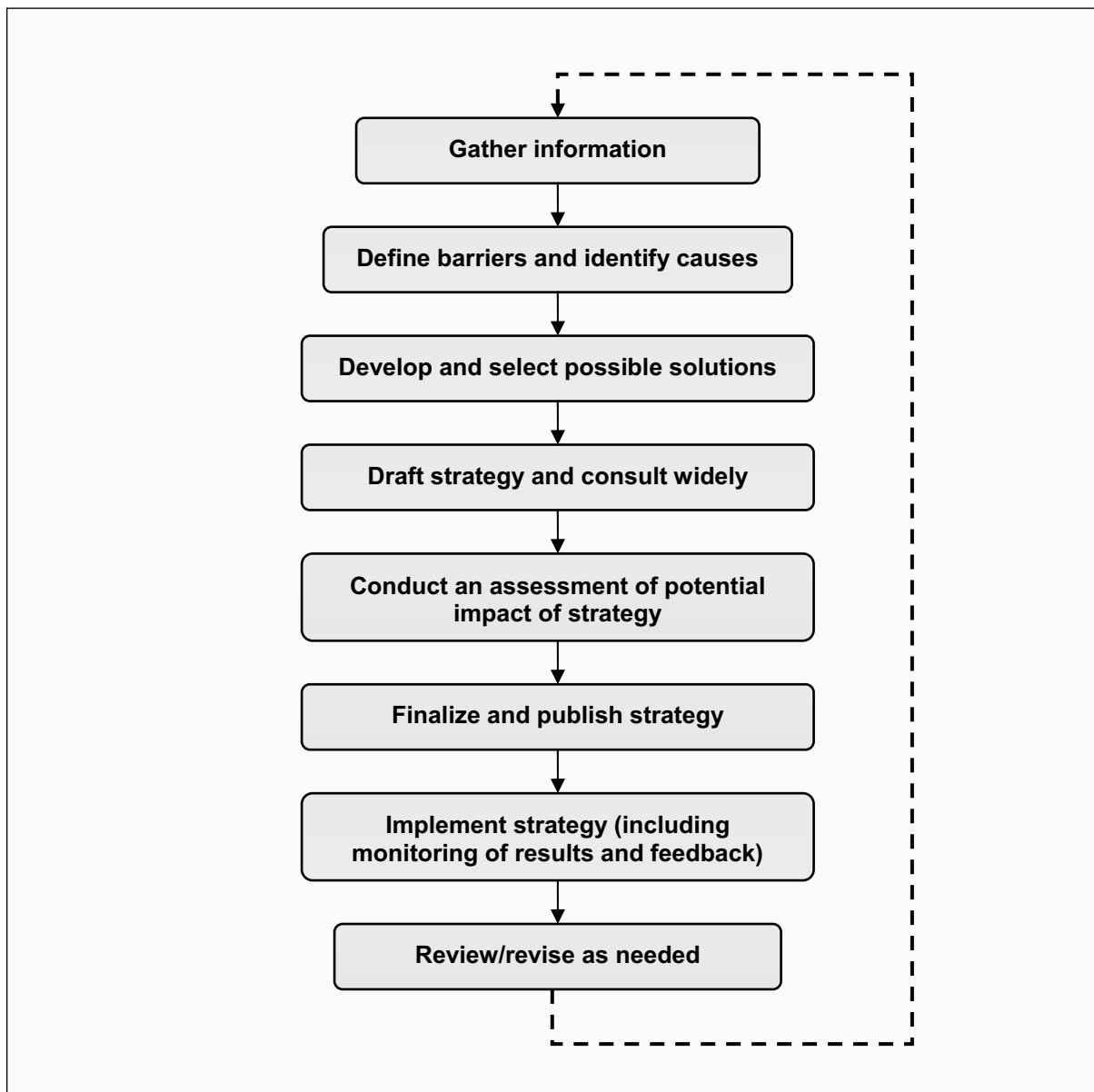
Examples of relevant national information are given below. They are not comprehensive: governments should develop a more exhaustive list relevant to their national circumstances.

- Food-borne illness
  - Underlying causes of sporadic food-borne illness and outbreaks

- Economic and structural profile of the food industry
  - Contribution to GDP
  - Food business size profile
  - Export versus import
  - Employment figures
  - Skills and education of staff at all levels

- – Level of quality assurance (QA) programmes, including basic hygiene programmes
- – Availability of skilled personnel

- Food safety support structures
  - – Government
  - – Industry
  - – Third party

- Internal pressures/strengths and challenges
  - – Legal requirements
  - – Political drivers
  - – Basic infrastructure
  - – Level of economic development
  - – Official food control structure, organization and resources
  - – Cultural considerations

- External pressures/opportunities and weaknesses
  - – Export requirements
  - – Legal requirements
  - – WTO rules

Much of this information is readily available to governments and gaps can be filled by commissioning studies. For example, full national diagnostic studies can be carried out in conjunction with FAO – the information gathered is incorporated in one document and used to support policy decisions (Anandavally and FAO, 2002; Keeratipibul, Tutanathorn and FAO, 2002; Quintana and FAO, 2002; Gelli, 2002; Costarrica, 2004).

3.2.2 Define barriers and identify causes

Once the information has been gathered, the barriers can be identified and defined. Barriers to HACCP tend to have public health and economic consequences. It is important for a national government to decide on the relative priorities of these two factors as they are inextricably linked (if the health risk in question is high, for example, it may be preferable to hinder industry – and therefore the economy – in order to protect the public).

An analysis of the information available can identify correlations between the barrier and the possible causes. However, it is important to distinguish between correlation and causality. For example, the number of outbreaks of food poisoning may be inversely correlated with the level of HACCP implementation, but this does not necessarily mean that food-borne disease outbreaks can be reduced only by the implementation of HACCP in SLDBs.

Identification of the cause of a barrier may require SLDBs to provide specific and detailed information. Hence, information gathering becomes an iterative process throughout a strategy's lifetime.

3.2.3 Develop and select possible solutions

A variety of approaches can be adopted to develop solutions to overcoming the identified barriers (Osborn, 1967). Techniques include:

- analysis of detailed surveys;
- provision of possible solutions by survey respondents themselves; and
- brainstorming.

It is recommended that governments generate solutions to their own problems taking into account local needs and challenges (see Chapter 4). In particular:

- Focus on national requirements: one country's needs do not always reflect another's (e.g. a voluntary approach may work for one government, while mandatory may be more appropriate for another).
- Identify the role of different government agencies and other main stakeholders in the implementation.
- Refer to information gathered at the start of the strategy development to ensure that solutions are practical.
- Incorporate into the strategy any identified incentives (e.g. a state-funding agency or schemes for promoting exports) already in place for the implementation of HACCP in SLDBs.

3.2.4 Draft strategy and consult widely

After drafting a strategy based on the definition of the problem and the best possible solutions, it is recommended to consult a wide range of stakeholders (consumers, food industry, government bodies, research or scientific organizations, and possibly organizations in other countries). The strategy should have a goal linked to the food safety policy and objectives linked to the achievement of that goal. In turn, specific activities can be defined under each objective to ensure the objective is met (Figure 2). The strategy is thus likely to be more creative, more effective and more widely adopted. Governments should take all possible steps to gain commitment for a HACCP strategy, and participation in strategy development can be a means of achieving this (FSAI, 2002; FSA, 2003; ASEZA, 2005; Gelli, 2002; Celaya, 2004). A strategy develops over time and therefore it is important that regular reviews, continuous evaluation and measures of progress are built into the framework; modifications can be made in the light of changing circumstances brought on by its implementation. However, it should not be forgotten that the strategy is linked to a national policy which should always be enacted.

The strategy must include a coordinated plan of action to enable the solutions to be implemented within a realistic time scale, taking into account the many barriers. The consultation phase should be designed to elucidate the issues surrounding the implementation of a strategy as well as to test the underlying thinking behind it.

The method of consultation varies widely from country to country. Countries may have a standard consultation process which is applied when new legislation or standards are being implemented, e.g. consultation in advance of new directives in the United Kingdom (FSA, 2004)

or consultative groups to assist in the development of new standards used by the Food Standards Australia New Zealand (FSANZ, 2004). Web-based consultation can be effective, but in some countries it may be necessary to physically engage the stakeholders either indirectly (via a consultation document) or directly (via focus meetings or stakeholder forums). A combination of Web-based comment and physical meetings often proves to be most desirable. The choice of consultation mechanism depends on the intended target audience.

The consultation process is essential for the strategy to have a good chance of success. It is a means of involving and gaining commitment from stakeholders; this in turn creates "ownership" of the strategy and eases its future implementation. Indeed, governments should be wary of consultation approaches which fail to engage with all stakeholders or that are not transparent; likewise, they should ensure that the information provided during consultation is acted upon. Otherwise the strategy is likely to be undermined and its implementation may prove difficult.

3.2.5 Conduct assessment of potential impact of strategy

The information gathered should also be used to conduct an assessment of the potential impact of implementation of the strategy, in particular to:

- anticipate the possible effects on each stakeholder group;
- examine issues relating to the economic resources; and
- envisage the potential social impact.

For example, a strategy that includes mandatory HACCP implementation may result in the closure of a significant number of SLDBs, unless sufficient support structures are put in place. Implementation costs may also be passed on to consumers via price increases, with negative repercussions for the market. By assessing the likely impact of a policy, it is possible to determine what actions may be necessary to limit the impact; in doing so, the seeds of a strategy are sown. Experience has shown that a certain level of impact is unavoidable and it is, therefore, important that governments anticipate and tolerate the ensuing economic and social outcomes of their actions.

3.2.6 Modify and publish strategy

On the basis of information gathered from the consultation phase and the impact assessment, it may be necessary to modify the strategy. The strategy should then be published in an appropriate form and communicated widely to all stakeholder groups. An active rather than a passive approach is recommended in this regard, because it is important that everyone affected by the strategy has access to it and is actively involved in its implementation.

3.2.7 Implement strategy

Once the strategy has been agreed upon and officially published, an action plan is required – for example, steering groups or a specific agency could be responsible for execution of the strategy. Irrespective of the implementation method chosen, national government should ensure that all stakeholders are involved to some extent, depending on national circumstances.

A government embarking on a HACCP implementation plan must provide sufficient financial and human resources to achieve its objectives. An under-resourced approach could be perceived by SLDBs as a lack of government commitment to the detriment of the strategy.

Matters requiring consideration include: the sequencing of activities within a HACCP strategy; whether the application of HACCP will be voluntary or mandatory; and the option of a stepwise approach. For example, in some countries a progressive GHP-to-HACCP approach or a voluntary-to-mandatory-HACCP approach have been used successfully to ensure implementation.

The timing of the implementation must be determined. For example, if the strategy includes mandatory implementation of HACCP for all food business types, the following are examples of implementation timing strategies:

- All food businesses to have HACCP implemented by a specified date. This approach is transparent and "fair" in the eyes of food businesses, but it is difficult for the regulator to resource as all food businesses require government-supplied resources at the same time.

- Time frames developed using a risk-based approach, i.e. high-risk businesses must meet HACCP requirements first. This ensures that resources are directed towards "problem" areas. However, there are potential disadvantages, including:
  - allocation of resources to determine the risk (using food-borne illness data and consumption data);
  - need to determine food categories; and
  - need for supplier specifications and resulting increased demand on resources (for example, if food services [e.g. caterers] are identified as high risk, they will have to agree specifications with their suppliers and take action to monitor compliance).

Training is an essential component of any government strategy. Steps should be taken to facilitate the availability and delivery of appropriate training to government officials, in particular, those responsible for assisting SLDBs to implement HACCP. These officials may need detailed training in HACCP and specific training in HACCP-based approaches (see Chapter 4). As traditional inspection methods are inappropriate for assessment of HACCP in food businesses, government officials may need to develop relevant auditing skills. Where consultants are used to assist SLDBs in implementing HACCP, they should also be given appropriate training.

3.2.8 Review and revise as needed

Those responsible for implementing the strategy should also be responsible for monitoring and reviewing its progress on a regular basis and carrying out necessary modifications. To ensure sustainable, long-term success, there should be periodic assessments (and hence public recognition of significant progress) during the implementation phase. This will reaffirm commitment to the strategy and the findings from periodic review can be used to improve and adjust the strategy as required.

3.3 CRITERIA FOR MEASURING SUCCESS OF STRATEGY

The impact of the activities and, ultimately, the delivery of the national strategy must be measured. By carrying out an appraisal during review, it is possible to modify the strategy as it progresses. If a HACCP strategy works, there should be an increase in the number of SLDBs implementing HACCP. On the other hand, there have been cases where HACCP has been introduced as a mandatory requirement, with the result that processing units are closed down or inadequate HACCP systems are implemented. Therefore, to measure the true impact of a strategy, indicators should be clearly defined to ensure that they are representative when gauging to what extent the overall objective of the strategy is being achieved. Measurements taken before, during and after can be used to analyse trends and demonstrate improvements, which in turn provide greater public health protection.

3.3.1 How to measure HACCP implementation

- Quantify the increase in the number of SLDBs using HACCP systems and the patterns associated with uptake (e.g. Is it sector specific? Are certain size businesses or businesses at a certain level of development omitted?).
- Distinguish the level of implementation of the system and any behavioural or attitude changes occurring as a result; determine what barriers remain or, indeed, whether new barriers have arisen.

It is important to examine the "before" and "after" scenarios and planning is essential: a "measurement" should be taken before the strategic activity is undertaken and then during and after its completion. Strategy development should include consideration of how to measure the HACCP implementation and selection of appropriate indicators. While not essential for all elements of the strategy, it is particularly important for financial support systems, training and any introduction of HACCP-based systems.

A professional auditor examines in detail both the extent of implementation and the quality of the HACCP system. A business can quite feasibly have a HACCP system in place but that same system may not actually be valid or offer the necessary level of food hazard control. Similarly, a well-designed HACCP system can be implemented badly. Professional auditors must determine the precise state of affairs by observing and questioning all staff in the SLDB as well as examining documentation and records. Professional auditors may be independent, qualified, third party experts or qualified government officials. In both cases, they should work to an agreed transparent protocol to increase the consistency of the exercise (FSAI, 2004). The level of detail achieved corresponds to the level of financial and human resources available – the extent of the exercise depends on national circumstances. To minimize costs, a statistical sample of SLDBs can be audited.

While it is difficult to directly assess changes in knowledge, attitude and behaviour in food safety, a number of psychological tools have been used successfully, for example:

- The narratology approach uses in-depth, non-directive interviews and subsequent detailed content analysis to assess the "psyche" of the interviewee. If undertaken before and after an

intervention, psychological change in knowledge, attitude and behaviour within the business can be determined.

- Design a risk management module linking the food business risk category and the grading score rates of the inspection report to decide the frequency and schedule of inspection (e.g. ASEZA, 2005). This system can provide a systematic science-based methodology to monitor food business compliance and enhanced performance. There must be an inspection scoring before the strategy is implemented against which you can compare at determined times after the strategy has been implemented.

3.3.2 Indicators of successful HACCP implementation

Indicators help governments decide whether HACCP is being successfully implemented in an SLDB or a sector; it is then possible to decide whether targets have been achieved and to determine the strategy's success. The relevant indicators depend on national circumstances and the strategic approach adopted. Research in this area is still in its infancy but some indicators have been determined and are given below as guidance:

- History or track record of the SLDB:
  - number of compliance violations;
  - findings of enforcement officers; and
  - number of associated food safety incidents.

- Number of consumer complaints (either by business or by sector).
- Change in number of reported food-borne illnesses associated with a business or sector.
- Number of certified businesses in a sector.
- Number of product recalls in a business or sector.
- Number of rejections or detentions in importing countries.
- Number of new SLDBs recorded as having adopted HACCP.
- Results of inspection missions by foreign competent authorities (where relevant).

While not strictly quantitative indicators, positive and negative trends can be monitored by reviewing the following:

- Assessment of on-site documentation and records (appropriateness, accuracy and validity).
- Comparison study of business achievements (based on risk management profile, scored inspection report and grading scale).

In the Netherlands, the enforcement officer uses a checklist based on one or more HACCP topics during every inspection. The results (i.e. whether compliant or not) are entered into a laptop computer and analysed. This gives an idea of the sector's compliance with HACCP-related items and provides input for further action (e.g. future priorities, communication with the sector association, provision of additional information to the sector). The selection of indicators based on enforcement officers' records can vary over time due to experience gained during the process.

4. STRATEGIC ACTIVITIES TO FACILITATE HACCP IMPLEMENTATION IN SLDBS

This chapter provides examples of the types of activity that may be considered as part of the strategy. Enacted individually, the activities are unlikely to resolve difficulties for SLDBs – hence the need for a complete and coherent strategic approach. While it is important to assess the existing level of application of good hygienic practices (see Chapter 1), it should be noted that application of a risk-based system such as HACCP does not replace or negate the need for a strong GHP programme. Indeed, both GHP and HACCP may be interdependently strengthened for a comprehensive approach to producing food safely. In many countries, SLDBs require effective support to strengthen the application of GHPs and the HACCP system.

National approaches, where some or all of the following strategic activities have been undertaken, are summarized in Annex 1. Annex 2 outlines the application of specific activities for each of the seven principles of HACCP in SLDBs.

Two distinct and equally valid groupings of strategic activities are outlined in this chapter:

- Section 4.1 describes activities that are vital to support HACCP implementation in SLDBs.
- Section 4.2 describes HACCP-based approaches successfully developed and implemented by various national governments and other concerned parties.

No single activity should be used in isolation, nor is it necessary to include all examples of the strategic activities described for a successful HACCP strategy.

If a national government has developed its strategy in a similar way to that outlined in the previous chapter, there should be sufficient information available to enable selection of the best strategic activities. Section 4.1 presents some of the most effective features of the various activities, their respective advantages (and disadvantages, where appropriate) and some of the challenges that may arise. Examples of effective strategic activities are also provided.

4.1 SUPPORT ACTIVITIES

4.1.1 Provision of financial support

A government embarking on a HACCP implementation strategy must provide financial and human resources to achieve its goals. However, these resources are often directed towards the development of materials for SLDBs or official control activities, rather than being directly accessible in the form of support and assistance.

It should also be recognized that the financial costs associated with HACCP represent a significant barrier for SLDBs, and access to the materials and training required for HACCP implementation may require the provision of financial support. Funds can be made available in different ways:

- In some countries, grant aid may be available through established trade associations.
- An innovative voluntary initiative was implemented by the Government of Hungary to attract funding from the public sector and industry in order to enable food businesses to obtain up to 50 percent of costs for the development of HACCP plans. This government-managed scheme also facilitated training within food businesses (Sebok, 2002).
- In many countries, the government has provided financial support for improving good hygienic practices and HACCP development, for example in Thailand (Keeratipibul, Tutanathorn and FAO, 2002), Brazil (Gelli and FAO, 2002) and Chile (Quintana and FAO, 2002). The emphasis in these cases was on GHPs, as the governments' view was that without proper GHP, SLDBs were not able to implement HACCP.[4]
- In Canada, the HACCP adaptation programme provided financial support for the agri-food sector (Agriculture and Agri-Food Canada, 2005).
- In Colombia, the Research Center for Economy and International Competitiveness, Universidad Javeriana, runs a programme supporting GMP (good manufacturing practice) implementation in SLDBs with national funds for SLDB development.[5]

When financial support is provided to SLDBs to facilitate HACCP implementation (through, for example, HACCP plan development or training), policy-makers should make available appropriate support facilities. This requires coordination and cooperation between the different bodies involved to ensure delivery of the support. The procedures for accessing financial support must be simple, in order to facilitate uptake by SLDBs; there should be appropriate control measures in place to ensure that the support provided is used effectively.

Financial support	
Some features	*Advantages*
Funds targeted for HACCP development in SLDBs Funds targeted for development of sector-specific HACCP-based hygiene codes Improved equipment and facilities Administration by single agency via local support structure Simple mechanism to obtain funds Support mechanism to raise awareness of financial support Monitoring system to evaluate success	Facilitates HACCP implementation as part of a holistic approach Provides opportunity for improved equipment and facilities Raises level of training and technical ability Demonstrates government commitment to SLDBs Minimizes potential social and economic impact of mandatory HACCP approach Creates awareness about HACCP within food industry sector and about key factors to be controlled (e.g. time-temperature)
Examples	*Potential challenges*
Targeted funds for general hygiene and HACCP training Grants linked to purchase of government-approved training courses and HACCP systems or other certified/recognized programmes Financial loans available with favourable low-rate or long-term payback provisions for SLDBs Access to equipment calibration services at reduced rates or grants to purchase equipment Provision of basic equipment (e.g. thermometers)	Not available in countries with limited budgets Not effective in isolation of other support activities May need support from government-approved HACCP programmes and training Can prove expensive for governments Limited in time and requires suitable spending evaluation structures

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[4] Further examples of strengthening good hygienic practices as the progressive means to implementing HACCP at a later stage are documented in Celaya (2004) and Costarrica (2004).

[5] www.puj.edu.co/centro/cieci/index.html

4.1.2 Provision of guidance and explanatory information

Most government HACCP strategies are characterized by the provision of guidance and information in the form of manuals, short booklets, leaflets, videos etc. Such guidance is valuable for raising awareness of HACCP in SLDBs, providing clear advice and clarifying the HACCP concept, but the practical content tends to be limited and so it is not sufficient alone to increase HACCP implementation in SLDBs.

Numerous short documents or leaflets have been developed to introduce the concept of HACCP and the advantages that the system offers for SLDBs (see Annex 1). Guidance booklets explain the terminology surrounding HACCP and food safety in an attempt to address the technical barriers described in Chapter 2. Specific guidance has also been developed by governments for particular types of SLDB. Guidance documents tend to advise and point the SLDB in the right direction rather than giving practical help. They provide information and enhance capacity among food businesses, but also increase consumer awareness of the importance of food safety and good hygienic practices, which can result in pressure being exerted on food businesses to improve overall levels of food safety.

Guidance and explanatory information	
Some features	*Advantages*
Short and specific Promotional and instructive Suitable for training in specific sectors A "gateway" to further information and advice Written in plain, simple language Available in appropriate languages Usefully illustrated Containing good practical examples of use to SLDBs Relatively inexpensive (or free) to print and distribute Including advice on the approaches to HACCP implementation, particularly hazard identification, identification of CCPs and validation/verification of HACCP systems Relevant to problems faced by a specific sector	Can communicate simple messages well Likely to be read if written and published correctly Offers first introduction to the subject and available services Provides continuing support as new people enter a food business Functions as reference material Can engage SLDBs initially Enhances awareness and commitment of SLDBs Can signal support for SLDBs
Examples	*Potential challenges*
Manuals "How To" guides Technical references Hazard guides Promotional documents Videos	Initial engagement must be followed up by other means, because SLDBs may need more detailed help to implement HACCP SLDBs often need support with further lines of advice and communication Nuances or complexity are not communicated Certain level of literacy in recipient is assumed

Examples of publications are given below:

- In Chile, the Agriculture and Livestock Service, Department of Agriculture, developed several guidance documents on GMP, HACCP, traceability and other food safety subjects (SAG, 2006).

- In Argentina, the Phytosanitary and Food Safety Agency, Department of Agriculture, developed several guidance documents for evaluation of HACCP in the meat and poultry sector and criteria for evaluating HACCP auditors (SENASA, 2001).
- In Peru, the Peruvian Asparagus and Other Vegetables Institute[6] and the Peruvian Export Promotion Agency[7] developed a model and a technical standard for the safe production of asparagus that was successfully implemented throughout the country (the third asparagus producer worldwide) (PROMPEX and IPEH, 2004).

4.1.3 Provision of HACCP training

Training is essential for the implementation of a sustainable HACCP system and no government strategy should neglect this element. The provision of short formal and informal training for SLDB staff is examined herein. SLDBs have specific training challenges due to their size and financial constraints (see Chapter 2), and it is important to identify the respective needs of all food business operators. It is the responsibility of governments to facilitate the availability and delivery of appropriate training to the SLDB sector.

Initiatives vary depending on the education structure in a country. For example:

- Some governments have sponsored and organized formal training courses provided by selected commercial entities or other institutions – e.g. Thailand (Keeratipibul, Tutanathorn and FAO, 2002), Brazil (Gelli and FAO, 2002) and Chile (Quintana and FAO, 2002).
- In Costa Rica, the Center for Food Technology Research and Transfer runs a training and assistance GMP/HACCP programme covering several countries in Central America; since 1990, it has had support from the Seafood HACCP Alliance (United States of America), the Natural Resources Institute (United Kingdom) and the Multinational Project for Quality Management and Productivity of SLDB (Organization of American States [OAS]).[8]
- Countries without the resources to formally establish and sponsor training can set standards for courses developed by third parties (e.g. trade organizations) or develop documents with an approved syllabus for HACCP training courses. The documents can be used by SLDBs to determine whether the training they are investing in is of the correct standard. Such documents have been developed and used in Ireland.
- In New Zealand, the regulator has worked alongside training organizations to develop unit standards for HACCP (including on-site assessments of food businesses to determine the food handler's competency).
- In Canada, the Canadian Food Inspection Agency has a partnership with a national training organization to develop training material for the seafood processing sector. The National Seafood Sector Council has developed and facilitated delivery of training across Canada in HACCP, personal hygiene, sanitation etc. (NSSC, 1996-2006).

A further initiative involves sponsoring experts to go into SLDBs and provide in-house advice and training specific to the business (Gelli, 2002; Costarrica, 2004) – it is resource intensive, but extremely effective. Whatever approach to training is adopted, it must take into account the level

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[6] www.ipeh.org/index.asp
[7] www.prompex.gob.pe
[8] http://www.cita.ucr.ac.cr

of literacy and numeracy within the SLDB and it must be aware of any time and financial limitations. Where food workers have a knowledge of basic hygiene principles (e.g. through elementary schooling), it is possible to optimize the resources invested in HACCP training.

HACCP training	
Some features	*Advantages*
Short and specific for food business Facilitates flow of information and skills development Covers prerequisite programmes as well as HACCP Does not take staff away from SLDBs for long periods Practical sector-oriented rather than theoretical Element of follow-up in business itself: • practical help in implementing newly learned information • checks that learning outcomes have been realized • mechanism to verify that training outcomes are consistent with the national approach, such as a government standard or an approved syllabus Cost accessible Widely available Includes "train the trainers" component Developed in consultation with SLDBs Accessible when needed	Facilitates implementation of HACCP Aligned with enforcement standards where HACCP is mandatory, but flexible enough to facilitate HACCP application in SLDBs Can be tailored towards SLDB needs and processes Demonstrates government support for SLDBs
Examples	*Potential challenges*
On-site training and internal training Self-learning including distance learning Provision of case studies and materials Established syllabus course with uniform content	Can be resource-intensive in SLDBs (costs include time and human resources) Requires support structures and follow-up

4.1.4 Voluntary schemes

HACCP or HACCP-based systems may be implemented through voluntary programmes. In some cases, implementation can be in stages: starting with voluntary HACCP and progressing to mandatory HACCP. Voluntary and mandatory schemes can also be implemented in parallel, depending on various factors, including the food business sector and the importing country requirements (Costarrica, 2004).

Regardless of whether HACCP is mandatory or voluntary, SLDBs require guidance and resources to assist them in applying a successful HACCP system. Examples of voluntary schemes are given below:

• In Malaysia, HACCP implementation by food companies is voluntary (Merican, 2000).
• The Thai Department of Fisheries has used voluntary HACCP programmes to enhance food safety practices, standards and the process for approval of fishery products for export (Suwanrangsi and Keerativiriyaporn, 2004).
• SafeFood Production NSW in Australia has introduced a voluntary HACCP-based food safety plan for the goat milk industry (SafeFood Production New South Wales, 2003.).

Voluntary schemes
Some features
May precede mandatory schemes or complement them in certain sectors Do not require transition phase for implementation Require government information campaign to publicize programme and benefits Open to application from all types of food business May include an award/mark for businesses demonstrating compliance May have greater application in the domestic markets where importing country requirements do not need to be considered May be developed by government or food industry associations Need to emphasize the benefits of HACCP to small businesses

Advantages	*Disadvantages*
Businesses can develop and implement the system at their own rate Free choice to implement the system, therefore business should have desire to succeed Clear management commitment Less pressure on government as businesses gradually adopt the scheme, and hence stagger the rate at which they require assessment of their conformity May relieve the burden on inspection rates, with those premises following the voluntary scheme being inspected less frequently May reduce burden on laboratory analysis of end-products	High-risk premises may not apply for voluntary approach; may therefore operate without best practices Food businesses may improve food safety management systems at varying rate May not contribute to higher levels of national food safety where take-up by businesses is low Food inspection services may interpret the requirements differently, leading to non-uniform application Less influence by government agency and so difficult to measure impact throughout food businesses

4.1.5 Mandatory provisions and enforcement

Promoting HACCP as a legal requirement can facilitate its implementation in SLDBs – but only if the required support is provided. The majority of SLDBs want to comply with the law but may not be able to do so for a wide variety of reasons. Governments should therefore consider implementing a voluntary HACCP scheme prior to the introduction of mandatory HACCP. Mandatory HACCP should only be used as part of an overall strategy that includes advice, training and means of support outlined in this chapter, including the application of GHPs. Risk to consumers should be taken into consideration and those food sectors that are a significant source of food-borne illness should be targeted.

Enforcement officers and inspectors are often the only available technically qualified personnel with whom SLDBs have regular contact. While their primary task is to ensure compliance with legal requirements, they also have an important advisory role. For this reason, enforcement officers should not be directly involved in developing the HACCP system for SLDBs; on the contrary, they may guide an SLDB towards compliance by providing sources of advice and training. If enforcement officers do provide advice on HACCP plan development or implementation, it should be made clear how this may affect their enforcement role. One guiding principle may be that any advice given by enforcement officers is given in the context of meeting the requirements. In some countries, separate roles are formulated: officers responsible for enforcement, and officers with advisory or educational roles.

SLDBs should be encouraged and given sufficient time to comply with mandatory HACCP. The enforcement policy of a country is a matter for national governments and depends on social and economic issues. There is evidence that HACCP implementation is enhanced if legal action is used appropriately and reserved for those businesses which consistently demonstrate unwillingness to comply.

The introduction in stages of mandatory provisions can be effective. For example, when implementing HACCP in a specific sector, voluntary compliance could be permitted for a certain period (with the option of offering incentives) before making the provisions mandatory. The sector is thus in a position to identify the hazards of concern and develop appropriate systems for control in reasonable time. In some countries, HACCP has been mandatory for export food plants and gradually introduced to the domestic sectors. Appropriate communication should be made of any such measures.

Mandatory provisions	
Some features	
Implemented after GHP programmes are in place Introduced as part of holistic legal framework Gradual implementation of mandatory requirements Flexible drafting of legal requirements focusing on principles of HACCP rather than on the process of implementing it Implemented with associated enforcement policy Stepwise approach towards enforcement Wide communication of legal requirements and enforcement policy Consistent enforcement in line with enforcement policy Preceded by provisional voluntary scheme and suitable training where appropriate Availability of "tools" (codes, templates etc.) to aid implementation developed in consultation with members of the relevant food sector	
Advantages	*Disadvantages*
Demonstrate national intent for HACCP implementation Allow for legal protection of public health Act as additional lever for HACCP implementation Increase credibility among importing countries With appropriate support and enforcement, can reduce time for HACCP implementation Reduce requirement for businesses to assess hazards associated with incoming goods, where goods are sourced from a business operating according to HACCP principles	Will not work without associated support structure for SLDBs Could result in unacceptable social and economic impact Can stifle innovative HACCP implementation if legal requirement drafted too rigidly Misuse of resources where prerequisite programmes still lacking

4.1.6 HACCP certification

Certification is a procedure by which a third party gives written assurance that a product or a process is in conformity with the corresponding standard. The certificate is a convincing demonstration to the buyer that the supplier complies with certain standards.

Certification systems for compliance with an agreed HACCP standard are implemented in many countries as part of voluntary or mandatory programmes. They can be linked to international

schemes, such as British Retail Consortium (BRC) or Safe Quality Food Standard. In many countries, the retail sector is increasingly directly involved; it has developed its own standards outlining the requirements and conditions which must be met by suppliers.

HACCP certification	
Some features	
Requires sound standard to assess compliance Includes assessment of GHPs as well as HACCP Needs trained and qualified third party auditors Requires promotion among food businesses to ensure uptake Should not be too costly or cumbersome a process Established by government or private groups Can be within a voluntary or mandatory programme	
Advantages	*Disadvantages*
Can raise levels of food safety Can facilitate trade and assessment of quality programmes between different stages in the food chain Can reduce pressure on national food control system Can facilitate national and international trade Independent assessment of food business	May provide false sense of security if not properly implemented May not have adequate emphasis on food safety requirements Additional costs to food businesses may exclude SLDBs Too many certification schemes may confuse food businesses May over-emphasize attaining a certificate without focusing on potential food hazards Requires third party auditors

4.1.7 Provision of technical expertise by consultants and other advisors

SLDBs are limited by the technical capacity at their disposal; consequently, they often require external technical help from government, trade associations, education institutions or commercial advisors. The growth of HACCP is mirrored by the growth in available advice. However, not all advice is appropriate or applicable and the quality of professional advice can vary considerably among consultants. Consultants may have the required HACCP knowledge, but they may make its implementation very complicated for SLDBs; in other cases, consultants may lack practical knowledge in a specific field.

Ideally, a government ensures that the provision of advice is regulated. In reality, governments rarely have the resources to do this. However, governments can seek to ensure that approved sources of advice are available and accessible; to this end, various measures can be taken:

- Many governments link up with education institutes to deliver training and consultancy or they support trade association initiatives; however, given the sheer number of SLDBs, it is difficult to meet the demand for advice.
- Guidelines help SLDBs select consultants; but this does not give a 100 percent success rate (e.g. Ireland).
- Some countries have systems of consultant registration and certification – useful for maintaining the quality of advice. In New Zealand, for example, consultants are assessed against a unit standard, and they can be recognized as being competent in that area.

- Written advice can be provided to food businesses to assist them in selecting an appropriate food consultant.
- A system of registration for consultants is in place in South Africa, where natural scientists (including HACCP trainers) register with the South African Council for Natural and Scientific Professions (SACNASP). This organization has been recently mandated through a parliamentary act to take legal action and prosecute those members who do not act professionally according to the Code of Conduct of SACNASP (SACNASP, 2003). The Web site includes a copy of the act, as well as the application process, registration criteria, application forms and application fees.
- Groups of SLDBs can be created to access a single source of advice, share experiences and to some extent learn from each other; this can also lead to reduced costs for SLDBs in securing advice.

Technical expertise provided by consultants and other advisors	
Some features	
Advice and training linked to national strategy Government organization/approval of education institutes and trade organizations Regulation of freelance consultants to ensure high quality of advice for: • registration • certification Clear communication with SLDBs to indicate where best advice is available Easily accessible to SLDBs	
Advantages	*Disadvantages*
Supports HACCP strategy Develops skills within SLDB Reduces government expenditure Provides on-site technical support critical to HACCP implementation in SLDBs	Can be resource intensive for governments to set up and regulate Difficult for government to properly manage such systems Can be a source of poor information Costs passed on to SLDBs

In addition to the activities described, there are other steps that governments may take in order to successfully implement their HACCP strategy:

- Conduct cost/benefit analysis to help SLDBs with financial planning.
- Develop effective communication systems between different government bodies and between government and SLDBs (directly or via organized groups) to ensure a consistent message and reduce the likelihood of misunderstandings.
- Facilitate transfer of expertise from more developed businesses to SLDBs: a large business can assist a small supplier in the development of its HACCP plan or it can provide technical support to similar SLDBs. Such arrangements are to the benefit of the larger partner in that the reputation of the food sector is better protected.
- Create small clusters of SLDBs to share available resources and pool experiences and technical understanding.
- Fund local resource centres where low-cost HACCP guidance/support/training can be made available.

- Consider how to maintain continued support to ensure that GHP and HACCP are understood and implemented correctly.
- Develop educational curricula on GHP/HACCP for schools and universities.
- Develop Internet- or CD ROM-based training courses to provide low-cost effective training programmes or guidelines on HACCP.

4.2 HACCP-BASED APPROACHES

The Codex general guidelines allow for a degree of flexibility in interpreting its methodology – provided they are underpinned by all seven HACCP principles. Alternative methods, often referred to as "HACCP-based approaches", may be the best way of facilitating HACCP implementation in SLDBs as they offer various means for achieving the same objective. Nevertheless, where HACCP-based plans are introduced, notification must be communicated to all national stakeholders to obtain consensus.

If a national government decides to develop HACCP-based approaches as part of its HACCP strategy, programmes should be tested on a small number of businesses prior to a full launch in all food businesses. A pilot programme should be carefully monitored and the outcomes used to fine-tune the approach.

There are pros and cons to HACCP-based approaches, but they are not all applicable to all forms of HACCP-based approaches.

HACCP-based approaches	
Advantages	*Disadvantages*
Improved food safety Integration within overall food safety management system Facilitate and speed up HACCP and prerequisite programme implementation Clear guidance for good practices related to hygiene and safety Good basis for training and education Encourage instructed, continuous and consistent application of HACCP in SLDBs Strengthen audit and enforcement measures Provide more prescriptive HACCP solutions favoured by SLDBs Easier to assemble and manage Do not require SLDB staff to have in-depth knowledge of HACCP and related technical expertise Provide useful holistic overview Record keeping at elementary level (documentation usually covered by guidance document itself: no extra work for SLDB)	International trade partners may require proof of equivalence to Codex HACCP system Unlikely to be implemented without adequate training Limited effectiveness in SLDBs with low literacy skills, unless very specific HACCP-based approaches are developed for this target group Resource-intensive during development, unless supported by extensive structure of trade associations or other industry groupings May not always be specific for SLDBs but targeted at all sizes of industry in a particular sector Need to be validated for effectiveness Lack of organization of SLDBs into trade groups may not favour use of these approaches Focus may be on the documented plan rather than its actual application in the business Difficult to anticipate all hazards introduced by subtle variations on seemingly standard processes Element of technical knowledge required to adapt them

Some of the HACCP-based approaches developed and implemented by national governments and other concerned parties are explained below.

4.2.1 Codes and standards documents

Codes and standards documents (e.g. codes of hygienic practice, agreed national standards) are voluntary or mandatory (depending on government policy), sector-specific, detailed sets of rules and practices aimed at providing information and facilitating HACCP implementation. Codes and standards documents vary in terms of the level of detail they provide on HACCP; they usually also cover the related elements (e.g. prerequisite programmes, recall procedures, traceability, management commitment) and may actually describe a full food safety management system. The final document may be government approved: SLDBs conforming to the code or standard are considered to comply with the law.

Hygiene codes work well in the Netherlands, for example: food businesses are compelled by law to be members of their respective trade association, which results in strong trade association coverage and support to the food sector (see Annex 1).

Some features of effective codes and standards documents:

- Cover the related elements (e.g. prerequisite programmes, recall procedures, traceability, management commitment) and provide a full food safety management system.
- Written and approved by governments in collaboration with SLDBs directly or through industry associations.
- Technical decisions carried out by qualified expert.
- Recognized by enforcement officers.
- Written in plain and simple language (HACCP jargon may be replaced with simple language – e.g. "hazards" is replaced with "things that can go wrong" and "things that may harm consumers").
- Flexible and "tailor-made" to cater for the needs of SLDBs.
- Sector-specific (e.g. bakery, slaughterhouse, street vendors).
- Identify classical CCPs, critical limits and corrective actions.
- Support simple forms of record keeping (e.g. temperature management, cleaning programmes, incoming raw materials).
- Accessible and well distributed.
- Supported with readily available advice.

4.2.2 Generic HACCP-based plans

Generic HACCP-based plans have been generated by governments and other stakeholders to help SLDBs implement HACCP. A pre-developed general HACCP plan needs to be further tailored and adapted by the individual food business; its basic format is as follows:

- A flow diagram describes the food process to which the generic plan is applicable.
- Hazard analysis is completed and the most common critical control points (CCPs) and their critical limits are identified.
- Corrective actions are detailed.
- Guidance on documentation is often given.

Well-known examples of this approach have been developed by the United States Department of Agriculture (USDA) covering meat and poultry establishments (e.g. USDA Generic Model for Poultry Slaughter, 1999).

Generic plans aim to help food operators think through the food safety problems that can occur and how they can be controlled; they enable food businesses to adapt to site-specific variations in process and product. The approach is best suited to businesses operating processes that are consistent within the sector, in particular linear processes (e.g. animal slaughter, meat cutting, fruit and vegetable washing and packing). They are less appropriate for complex multi-pathway processes (e.g. in the retail and catering sectors), where an alternative method is to assemble individual generic plans using a modular approach:

- Subprocess components are chosen from various generic plans (sometimes termed "pick and plug"), and are then assembled into a tailor-made HACCP plan.
- Hazards are identified and CCPs and critical limits set for each of the subprocesses.
- Food business selects subprocesses relevant to its own business.
- Can be used to generate numerous different HACCP plans for multiple processes.
- Level of interpretation and customization by the SLDB is required.

New Zealand has successfully used the modular approach (see Annex 1), as has Northern Ireland (FSANI, 2003). In addition, a generic HACCP-based plan for eggs is being promoted in New Zealand (NZFSA, 2004).

Generic HACCP-based plans vary in the amount of support they offer. Some plans identify the appropriate hazards, while others only suggest the possible hazards (requiring the SLDB to select the hazards applicable to their own processes). Some require the HACCP plan to be developed from the reference documents provided, while others generate the modular documents in such a way that they can actually become the documented HACCP plan (in this respect they often resemble a workbook).

In the latter case, the food business owner/manager works from the start to the end of the workbook completing the sections as directed taking into account the actual processes used in their own SLDB. The completed workbook becomes the plan. Most systems developed to date still require a moderate level of record keeping. However, recent developments have provided modular systems where the daily record-keeping requirement is minimal (FSANI, 2003).

Because these HACCP-based systems do not look like traditionally developed HACCP systems, it is essential that governments are involved in their development. This is particularly important where a strategy includes mandatory HACCP, because enforcement officers may not recognize the system as compliant. It is important that SLDBs and enforcement officers undergo similar training.

Some features of effective generic HACCP-based plans:

- Developed in collaboration with all stakeholders (government officials, SLDBs, trade associations, educators etc.).
- Specific to a sector where processes are similar.

- Provide a documented hazard analysis and associated references.
- Provide a standardized layout for the whole plan which includes CCPs, their critical limits and corrective actions.
- Explain briefly how the critical limits control the hazard(s).
- Provide examples of documentation and guidelines on its completion.
- Outline methods and frequencies of verification and validation.
- Clearly communicate the need for on-site adaptation.

4.2.3 Evolving HACCP-based methodologies

Evolving HACCP-based methodologies lie between traditional approaches (created by and wholly specific to a particular business) and completely generic approaches (involving the application of previously prepared plans and controls). The difficulties faced by SLDBs are discussed earlier in this document (see Chapter 2) and intermediate systems have been developed to address these problems. These systems may at first seem too far removed from Codex HACCP. However, if they are firmly based on the seven principles, they are likely to offer a way forward for those SLDBs which find traditional methods of HACCP too difficult, time-consuming or costly to implement. Evolving HACCP-based methodologies apply one or more of the following methods:

- Supplying businesses with information on risks and hazards pertinent to their particular type of food production in order to reduce the levels of scientific knowledge and judgement required by the business.
- Merging both the general (i.e. prerequisite) and specific (i.e. HACCP) hazards in a way that businesses can understand and therefore control.
- Grouping similar hazards and controls to facilitate the operation of HACCP by the business.
- Utilizing methods that reduce the quantity of record keeping (e.g. use of a "diary" or simplified records based on "management by exception").
- Refocusing enforcement and audit requirements onto the business's understanding and control of processes (this might be typified as "self-audit" monitoring).

An example of the use of one of these evolving methodologies is the "Safer Food Better Business" system developed by the United Kingdom Food Standards Agency (see Annex 1):

- Merges both the general (i.e. prerequisite) and specific (i.e. HACCP) hazards.
- Criticality is indicated by the level and frequency of monitoring required.
- Record keeping focuses on a diary signed on a daily basis by the person responsible for food safety.
- Record keeping is by exception, i.e. making a written record only when things go wrong and corrective actions are undertaken.
- Verification done routinely by self-audit, i.e. activity is undertaken by the manager responsible and intermittently by official enforcement officers.

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ANNEX 1

Overview of national approaches to facilitate
HACCP application in SLDBs[9]

The extent to which governments are involved in facilitating HACCP implementation is a matter of national policy. Many governments, faced with a low level of HACCP uptake in the food industry, make policy decisions to facilitate implementation. However, the approach taken depends on the objectives set by the national policy itself. Following an analysis of the existing levels of implementation, most countries examine the barriers facing the food industry and attempt to overcome them through the realization of specially developed initiatives. Some governments attempt to measure HACCP compliance at the start and end of initiatives to gauge the effect and assess value for money. The types of initiative depend on cultural, economic, organizational and geographical factors, which vary from country to country.

The case study summaries below are a useful reference. They give a good indication of the wide range of activities and different approaches adopted to support HACCP application in SLDBs. Food safety systems tend to be more advanced in food businesses involved in food export, while foods destined for domestic markets are generally produced under less controlled conditions.

Brazil

NATIONAL FACTORS SUPPORTING APPROACH

- Food control in Brazil is managed by several parties, principally the Ministry of Health, the Ministry of Agriculture, Livestock and Supply, and the Ministry of Industry, Development and Trade.
- The control system is evaluated and revised to reflect the evolution of the production process and economic and social development in Brazil. Initially an isolated system of regulations and actions, it has developed into a broader integrated system.
- The government has been seeking to improve efficiency, involving institutions with their own managerial resources and a degree of autonomy.
- In 1999, the National Health Surveillance Agency (ANVISA) was created to: protect and promote the population's health; ensure the safety of products and services; and encourage participation of the population when developing policies and programmes.
- Regulatory decisions are made on the basis of the three recognized ANVISA values: knowledge, transparency and accountability.
- ANVISA promotes training of its own labour force and of the staff of the National Health Surveillance System, which includes professionals from the states, municipalities and federal districts.
- Partnerships with education and research institutions are being established.

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[9] The authors of the case study summaries are listed on p. x.

BRIEF DESCRIPTION OF THE APPROACH AND OUTCOMES TO DATE

- Staff training is important for the implementation of the new food safety regulations:
  - The partnership with the University of Brasilia, by means of the post-graduate specialist course in health surveillance, led to the graduation of over 300 specialists.
  - The Pan-American Health Organization, through the Pan-American Institute for Food Protection and Zoonoses, organizes courses for technicians and auditors in HACCP and provides training for a further 1 254 health surveillance technicians at state and municipal level.
  - Through the partnership with the National Industrial Training Service, over 3 500 technicians from the food industry and food service enterprises have been trained in the implementation of HACCP methodology in their activities.

- The nationwide "Safe Foods Program" disseminates knowledge and provides guidance to small and medium-sized food enterprises concerning good manufacturing and handling practices, resulting in an increase in the supply of safe foods.
- The "Portal for Scientific Information on Health Surveillance" – established by ANVISA, in partnership with the Latin American and Caribbean Health Sciences Information Center – provides online access to the main international sources of health information, including bibliographical collections, catalogues of Web sites related to health surveillance and directories of regulatory and research institutions from several countries.
- Risk analysis procedures allow ANVISA, in health surveillance activities, to initiate a pioneering and innovative process of deregulation of registration for a significant number of food groups, assessed as being low risk for human consumption. Such action allows ANVISA to employ its resources more efficiently and effectively, concentrating its efforts on high-risk groups of food products.

LESSONS LEARNED AND THE FUTURE

- The focus on risk analysis allows ANVISA to update the existing regulatory framework, working in partnership with a significant number of education, scientific and technological research institutions, within the country and abroad.
- At present, ANVISA relies on a technical food committee (with representatives from seven universities), a technical-scientific commission on functional foods for evaluation of new foods and claims on labels (representatives from nine other universities) and technical groups with specialists in the areas of food additives, food packaging materials and food safety assessment (representatives from universities and research centres).
- Transparency in the regulation process is achieved through the participation of food producers, consumers and professional associations in the regulation-building process: open public consultation to gather input from interested parties.
- The decentralization of regulation and sanitary inspection activities in countries with large territories such as Brazil is an important issue. The Unified Health System brings together all health organizations, both public and private – although private organizations only participate in a supplementary manner. ANVISA is one of the organizations in this system. It operates in a decentralized manner, with responsibilities shared among the federal, state, district and municipal governments.

- It is increasingly important to understand the external environment through participation in international fora such as Codex Alimentarius, Mercosur (the free trade agreement between Argentina, Brazil, Paraguay and Uruguay), the SPS Agreement (Agreement on the Application of Sanitary and Phytosanitary Measures), the Biodiversity Convention (Cartagena Protocol) and other international agreements. By understanding the external environment, the food production sector and exporters can be increasingly involved in international food trade.

Cameroon

NATIONAL FACTORS SUPPORTING THE APPROACH

- Since 2000, a government structure has existed for the normalization and certification of food products.
- The Cameroon Ministry of Public Health has issued a guide on the handling of foods sold in public places.
- Since 1990, numerous consumer associations have existed.
- The industrial sector and the state collaborate to control the quality of locally produced foods as well as imported foods.
- Educational institutions train engineers and technicians specialized in food quality control.

BRIEF DESCRIPTION OF THE APPROACH AND OUTCOMES TO DATE

Different ministries have different roles (often assisted by consumer associations):

- The Ministry of Public Health must safeguard the health of consumers and is, therefore, responsible for food safety. Controls are carried out to ensure conformity to manufacturing norms, labelling regulations and nutrition composition requirements. Inspections target production units (breweries, salt factories, milk products companies, bakeries etc., focusing on the production environment), finished or imported food products, and the equipment and utensils used to handle foods.
- The Ministry of Agriculture is responsible for the registration of agricultural inputs (fertilizers, pesticides etc.) and carries out phytosanitary controls through decentralized services at provincial and divisional level.
- The Ministry of Trade and Industry is responsible for the elaboration of national norms.
- The Ministry of Fishery and Animal Husbandry registers veterinary products and carries out controls at abattoirs, ports and markets through decentralized services at provincial and divisional level.
- The Ministry of Water carries out controls mostly on mineral water.
- The Ministry of Higher Education is responsible for fundamental and applied research in food quality and for training of food quality engineers and technicians.

Controls and inspections reveal occurrences of the following:

- Use of pesticides and insecticides to preserve food.
- Poor hygienic conditions in restaurants and where food is sold in public places.
- Poor cold-chain facilities resulting in meat and fish becoming spoiled.

- Absence of adherence to labelling requirements.
- Lack of awareness of food norms among manufacturers and food importers.
- Presence of expired food products on the market.

Major difficulties include the following:

- Absence of facilities and infrastructure, and shortage of qualified staff.
- Lack of knowledge of elaborated and international norms for controls among most interested partners, importers, local producers etc.
- Absence of coordinated action in the food sector.

LESSONS LEARNED AND THE FUTURE

It is difficult to coordinate the operations of the numerous ministries involved: as a result, HACCP application is not very rigorous in Cameroon. It is therefore imperative to identify all institutions directly and indirectly involved, define their responsibilities and establish a framework of coordination and partnership. In the long term, a food safety agency should be created.

Canada

NATIONAL FACTORS SUPPORTING APPROACH

- There is no national policy for HACCP implementation. Three levels of government (federal, provincial and municipal) are responsible for food safety and each authority has adopted differing strategies to address food safety challenges.
- The Canadian Food Inspection Agency (CFIA) is responsible for all federal inspection activities related to food safety, including foods which are imported into Canada or which are destined for export out of Canada or between provinces.
- The CFIA has two strategies for HACCP implementation for federally registered food processing establishments:
  - Quality Management Program (QMP) for the fish processing sector – mandatory since 1992 and implemented in approximately 1 000 establishments.
  - Food Safety Enhancement Program (FSEP) for the agrifood sector (meat, processed fruit and vegetables, egg, dairy, honey and maple syrup) – currently a voluntary programme, but legislation amendments will be passed in the near future to make it mandatory for the meat processing sector.

- The CFIA is also working with industry on an on-farm food safety programme, to implement food safety systems based on HACCP at farm level.

BRIEF DESCRIPTION OF THE APPROACH AND OUTCOMES TO DATE

The CFIA was formed in 1997, amalgamating the food safety responsibilities of three different federal departments and bringing together separate food safety strategies for the different food sectors. These strategies (QMP and FSEP) have continued to evolve to address the specific

challenges of the different sectors. However experiences are shared between the two programmes to facilitate harmonization and improvement.

The fish-processing sector in Canada is large and diverse and heavily reliant on international markets. Over 80 percent of Canadian fish products are exported to some 125 different countries each year with a value in 2003 of Can$4.7 billion. As HACCP is a requirement for imports to most of these markets, its effective implementation is essential for maintaining this important industry. The Canadian Government worked closely with industry, associations and institutions to ensure that the necessary tools and guidance are available to facilitate the design and implementation of individual processor QMP plans. In consideration of the technical and resource challenges facing industry, it was necessary to design a programme which is flexible but which at the same time adequately addresses all food safety concerns.

FSEP recognizes and audits HACCP systems (prerequisite programmes and HACCP plans) in federally registered establishments within the commodities of meat and poultry, processed products, dairy, shell eggs, processed eggs, honey, maple and hatcheries. The CFIA adopts a voluntary approach in all of the aforementioned commodities, with the exception of meat and poultry, where HACCP is expected to become mandatory. The agency will investigate the potential for the remaining commodities with regard to mandatory requirements, taking into account the industry readiness and international requirements.

LESSONS LEARNED AND THE FUTURE

The design and implementation of QMP and FSEP is a learning experience. The most significant lessons learned to date are as follows:

- Take a stepwise approach to industry implementation. Do not expect industry to be able to implement everything right away, but work towards continuous improvement and focus on what has been accomplished and not on what the processor has left to do.
- Listen and communicate. When a processor has a problem with certain requirements, it is not because he does not want to produce a safe product, it is because he may not understand the requirement or its importance. Be willing to listen, have the requirements clearly laid out and communicate them.
- Be flexible. Allow the processors to develop a HACCP system to fit their operation; this will increase ownership and lead to more effective implementation and continuous improvement.
- Provide tools to assist the processor in understanding the requirements, for example, guides and Web sites.
- Avoid generic plans. Generic plans lead to a forced fit. In QMP, example plans based on industry input were provided and used for illustrative purposes only.
- Apply a clear enforcement process for those who fail to comply with a regulatory programme. It is important to be neither too strict nor too soft on enforcement – commitment will be lower if processors do not think they will be assessed and programme effectiveness will suffer as a consequence.

To date, most of the effort has been directed at HACCP design implementation. For the future, it is important to be able to measure the performance of the food safety strategies. Indicators must be identified to demonstrate that food safety is actually being achieved. This process will

produce data and information on the effectiveness of both the individual processor's controls and the programme design and maintenance.

India

NATIONAL FACTORS SUPPORTING APPROACH

- Legislation exists to specifically address exports; in some areas (seafood, dairy, poultry, eggs, honey), GHP and HACCP implementation is mandatory.
- A single body organizes the official export certification process.
- HACCP for exports is already implemented in around 450 units.
- There is a large pool of official auditors.

BRIEF DESCRIPTION OF THE APPROACHES AND OUTCOMES TO DATE

A number of organizations have a role in the regulatory policies for food safety. The Ministry of Health and Family Welfare is responsible for food safety at domestic level, including food imports. While HACCP implementation is not currently mandatory in the domestic sector, there is a well-defined export control system.

The Export (Quality Control and Inspection) Act 1963 empowers central government to: notify commodities for pre-shipment inspection and certification; specify minimum standards (generally recognizing international, importing countries' standards and contractual specifications); and prescribe the system of export inspection and certification (consignment-wise or a systems approach). The system of export control is operated by the Export Inspection Council of India (EIC – India's official export certification body) through its regional organizations, export inspection agencies (with head offices in Chennai, Delhi, Kochi, Kolkata and Mumbai and 41 sub-offices including laboratories around the country).

Over the years, under the provision of the act, nearly 1 000 commodities have been notified by the government for pre-shipment inspection and certification prior to export. Sectors covered include chemicals, pesticides, rubber products, engineering products, food and agricultural produce, textiles and footwear. Food is one of the major areas and includes Basmati rice, black pepper, marine products, fruit and vegetable products, egg products and dairy produce. Inspection and certification of all notified commodities were initially compulsory, but in the early 1990s (as part of economic reforms), export certification procedures were simplified allowing various categories of exporters to be exempt from compulsory pre-shipment inspection and certification by EIC. However, with the establishment of the WTO, quality issues gained significance, as did the role of standards and legislation, especially in relation to food safety. Marine products, egg products, dairy produce, poultry products, meat and meat products, and honey are subject to compulsory export certification by EIC. Certification is not compulsory for other food products (although many of them are notified under the act) and in many cases (e.g. when an importing country demands certification), EIC certifies the products on a voluntary basis.

In most of the above products, Food Safety Management Systems based Certification is implemented, based on Codex HACCP/GMP/GHP. The certification system involves approval of the units (based on an assessment against the requirements prescribed in the respective notifications), followed by periodic surveillance by EIC with a three-tier approach:

- Periodic monitoring: check records; process controls including sanitation and hygiene; take samples of raw material, water, ice, swabs, processed/finished products etc. for independent testing for various parameters.
- Supervisory visits by senior level officials: ensure compliance by units and monitoring officers.
- Corporate audits by head office: check compliance and effectiveness of the system; build accountability of the regional offices.

The above approach, in which HACCP is a part of the system, is being implemented in more than 450 export-based food-processing units in the areas of fish and fishery products, dairy products, poultry products, meat and meat products, and egg products.

In addition to EIC, export promotion bodies are important for assisting processing units to implement HACCP. Such promotional bodies are active in various sectors (e.g. marine, spices, agricultural and tea). They develop guidelines and modules for specific sectors and organize projects for groups of industries to assist in HACCP implementation and similar activities. For example, the Agricultural Processed Food Products Development Authority oversaw a mango pulp processing project: the project lasted about 2 years and assistance was provided to around 24 export units to implement HACCP.

LESSONS LEARNED AND THE FUTURE

To date, the emphasis has been on HACCP in export-oriented units, but the focus is now shifting to domestic industries. Efforts are being made to introduce GAP (good agricultural practices) at the primary production levels with the involvement of promotional bodies as well as the Ministry of Agriculture and Ministry of Health and Family Welfare. Some of the initiatives taken are described below:

- A HACCP accreditation programme is being established by the National Accreditation Body in India, the Quality Council of India.
- HACCP implementation in the country is being further intensified through a World-Bank-assisted capacity-building project implemented with the collaboration of the Ministry of Health and Family Welfare.
- Sectors identified in the first phase include: dairy, meat and poultry, fruits and vegetables, bakery and hospitality. The aim is to prepare training manuals and initiate training in HACCP. The second phase covers seafood, infant food, sweets and confectionery, ice cream and frozen confectionery, and institutional catering.
- Training manuals were prepared for the first phase. Training in HACCP, GMP and GLP (good laboratory practices) for industry is conducted in association with trade associations, including the Confederation of Indian Food, Trade and Industry, Federation of Indian Chamber of Commerce and Industry, hotel and restaurant associations, National Dairy Development Board and Confederation of Indian Industry.

- HACCP-based training modules for certain sectors (e.g. dairy, meat and poultry, fruits and vegetables, bakery and hospitality) have already been developed, while others are under development.
- A HACCP stand-alone certification scheme is being developed by EIC, based on Codex HACCP; it will specifically address the export-oriented units to meet the Codex requirements and those of importing countries.

Ireland

NATIONAL FACTORS SUPPORTING APPROACH

- There is a national policy for consumer protection and HACCP compliance.
- National legislation requires HACCP in food businesses for 4 years prior to any initiative.
- A single body organizes the official inspection process.
- The official inspectorate is well trained, motivated and resourced.
- There are motivated trade associations.
- Ample third party expertise is available for the food industry.

BRIEF DESCRIPTION OF THE APPROACH AND OUTCOMES TO DATE

The Irish Government set up an independent government agency, the Food Safety Authority of Ireland (FSAI), to oversee national food safety in 1999. One of the FSAI's policies was to improve the compliance of the food industry to European Community legislation requiring food businesses to have a food safety management system based on HACCP principles.

A telephone survey of food businesses was conducted in 2000 to determine the level of compliance with established European legislation and to identify barriers to successful HACCP implementation.[10] This was followed by a workshop involving official inspectors and the food industry. At the workshop, a national HACCP strategy was developed with input from all stakeholders. The strategy was defined in detail by a national HACCP steering group consisting of representatives of the FSAI and ten health boards responsible for inspecting 40 000 of the 43 000 food businesses in Ireland.[11] Most of these businesses are in the retail and food service sectors and are SLDBs. At the same time, an industry forum was created with representatives from the food service sector. A forum consisting of retailers already existed.

The strategy was executed in steps focusing all resources on one target group at a time. Target groups were selected based on the risk posed to consumer health and on the resources available to help that group. HACCP information was developed for each group selected, using input from the official inspectors and industry fora.[12] Each target group began with inspection and assessment by the official inspectors so as to create a baseline.[13] This was followed by provision

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[10] www.fsai.ie/industry/haccp/survey_HACCP_july2001.pdf

[11] www.fsai.ie/industry/haccp/industry_haccp_strategy.asp

[12] www.fsai.ie/publications/haccp/HACCP_CATERING.pdf
   www.fsai.ie/publications/haccp/WHAT_IS_HACCP.pdf
   www.fsai.ie/publications/haccp/HACCP_TERMINOLOGY.pdf
   www.fsai.ie/publications/haccp/HACCP_EXTERNAL_CONSULTANT.pdf

[13] http://www.fsai.ie/publications/haccp/HACCP_EXTERNAL_CONSULTANT.pdf

of advice from inspectors, distribution of relevant materials and awareness campaigns by both the FSAI and trade associations. In each case, a deadline was set for completion of the target group.

A guidance note for HACCP inspectors was developed to provide advice on enforcement measures to be taken.[14] Upon completion of the process in a target group, full inspections are carried out to determine improvement. Official action is encouraged for those SLDBs who have shown no sign of commencing HACCP implementation.

The first target group – hotels – was completed in June 2004 and good progress has been made. However, a small but significant group of hotels have not started to develop HACCP plans; they will be the target of potential enforcement actions.

LESSONS LEARNED AND THE FUTURE

Although it is still early to determine the full effects of the Irish approach, it appears to be working based on the measures of HACCP implementation in target groups before and after application of the strategy. However, it is resource intensive for the official inspectors and progress can only be made in one target group at a time. The strategy represents an approach based on affirmative action by official inspectors backed by national support from the government and trade associations. It leaves food businesses to develop their own systems providing only guidance rather than generic HACCP systems. It is recognized that in the near future, in order to tackle certain types of SLDB, a simplified HACCP-based approach may be necessary and resources will have to be allocated for this purpose.

Japan

NATIONAL FACTORS SUPPORTING APPROACH

- HACCP is not required by national food safety laws and regulations.
- A voluntary HACCP and GHP approval system was introduced under the Food Sanitation Law in 1995, applicable to milk and milk products, meat products, surimi-based products, low acid canned food, and soft drink establishments. In spite of this, a huge outbreak associated with a milk-based drink manufactured in a HACCP-approved establishment occurred in 2000. Both government and industry still face major challenges to enhance the importance of food safety among food safety managers in food manufacturing plants.
- In 1998, the HACCP Support Law came into force: food industries interested in introducing HACCP and a quality assurance control system based on the HACCP principles were offered low interest rate loans and tax reductions in order to update facilities and equipment. Under this law, industry organizations for each commodity develop standards and request approval from both the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Health, Labour and Welfare (MHLW). Once the standards are approved, businesses belonging to the organization and needing low interest rate loans to update facilities (e.g. separating dirty and clean zones) and equipment (e.g. automatic temperature monitoring equipment) can apply for approval of a HACCP-based plan by the industry organization to access the loan and authorize the benefits of the reduced tax rate.

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[14] www.fsai.ie

- The food sanitation inspectors of the national and district governments take a 3-day training course and perform separate roles:
  - National: review of HACCP and GHP documents and on-site verification for approval by the MHLW.
  - District: routine establishment inspections.

- Seventeen district governments and large cities began a voluntary-based HACCP approval system for certain food businesses, e.g.:
  - Tokyo Metropolitan Government (system more GHP based).
  - Hyogo District Government (HACCP and GHP-based systems for meat processing, poultry slaughtering and processing, seafood processing, large-scale catering and lunch box preparation establishments).
  - Wakayama, Tottori and Aichi districts (systems for large-scale catering, lunch box preparation, hotel and inn restaurants, confectionery manufacturing, ready-to-eat meals).
  In addition, other districts began promoting HACCP in small and medium-sized food establishments.

- With financial support from the MAFF, the Japan Food Hygiene Association (an industry organization for promoting food safety among its members) has conducted HACCP training courses for food industries.

BRIEF DESCRIPTION OF THE APPROACH AND OUTCOMES TO DATE

Following the *Escherichia coli* O157:H7 outbreak in Sakai in 1996, the need to introduce and implement the HACCP system in food businesses was recognized by both industry and government. Since the introduction of a voluntary-based HACCP approval system under the Food Sanitation Law, approval has been given by the MHLW to:

- 158 milk processing establishments;
- 179 milk product manufacturing establishments;
- 82 meat product manufacturing establishments;
- 24 surimi-based product manufacturing establishments;
- 36 low acid canned food manufacturing establishments; and
- 87 soft drink manufacturing establishments.

Under the HACCP Support Law, 20 industry organizations for different commodities (e.g. frozen food, ready-to-eat food, lunch box, confectionery and bakery) apply MHLW/MAFF-approved standards. Moreover, 205 establishments have developed HACCP plans, obtained approval from the industry organization, and received low interest rate loans from a MAFF-related financial organization. In addition, food industry organizations have developed guidance on HACCP, GHP and SSOP (Sanitation Standard Operating Procedures).

More than 200 food establishments have been approved by district government under the HACCP approval system.

From April 2003 to March 2005, 4 166 people took the 1-day basic HACCP training courses, 580 people took 4-day advanced HACCP training courses, and 36 people took trainer courses conducted by the Japan Food Hygiene Association.

LESSONS LEARNED AND THE FUTURE

- Strong commitment from top level management is needed to introduce HACCP in both large businesses and SLDBs.
- Continuous and appropriate implementation of a HACCP plan is as critical as development of the plan.
- Development of a precise flow diagram, in particular identification of where and how raw or intermediate materials are re-used, is very important to assess the probability of contamination.
- Provision of appropriate training for all employees involved in HACCP implementation, making them understand the role and responsibility of each employee under the HACCP plan, is a key factor for success.

Mexico

NATIONAL FACTORS SUPPORTING APPROACH

- National policy for protection against health risks is based on risk analysis.
- Two main organizations are in charge of food safety with complementary functions:
  - the Health Department (the competent authority for food safety); and
  - the Agriculture Department (the competent authority for animal and plant health).

- A stepwise approach is adopted from voluntary to mandatory: first GHP, then GMP and SSOP, followed by voluntary HACCP.
- National regulations exist requiring mandatory GHP (since 1996), and there are mandatory documentation requirements for the whole food industry (since 2000).

BRIEF DESCRIPTION OF THE APPROACH AND OUTCOMES TO DATE

Mexico has a population of over 100 million. There are 1.8 million food premises – food industry establishments, food wholesalers and retailers, food services (fixed and street vendors) – of which 61 percent are one-person food premises and only 1.3 percent are facilities with more than 51 employees. Food industry employees on average receive a formal education of 7 to 8 years, i.e. the vast majority have received only elementary education.

The Federal Commission for the Protection against Health Risk (COFEPRIS) was formed in 2002 by integrating all federal departments with regulatory responsibilities in the Department of Health, i.e. those responsible for food and consumer products, drugs and medical devices, environmental health, health services, organ transplants and blood transfusions, and labour health. Risk analysis principles are applied for public health protection and a specific division has been developed for risk assessment. Risk management actions include regulation, inspection and

compliance, as well as non-regulatory measures, such as education, training and self-inspection agreements with the food industry.

The National Service of Agri-Food Health, Safety and Quality (SENASICA) depends on the Secretariat of Agriculture, Animal and Fisheries. It was formed in 2001 to amalgamate the federal departments of animal and plant health. SENASICA has a regulatory role to support food safety as an important factor for the expansion of national and foreign markets for meat, poultry, honey and fruit.

COFEPRIS and SENASICA coordinate all activities from farm to table with the involvement of federal government departments (e.g. Economy and Environment), but further efforts are required to develop a seamless food control system. SENASICA promotes GAP and GMP in the production of fruits and produce by distributing guidelines and providing financial support for food safety programmes implemented by private companies.

The national food safety policy has been applied consistently since 1992. However, HACCP is mandatory only when demanded by export markets (GHP/HACCP are certified upon request of the competent authority of the importing country). The Secretariat of Health is concentrating on meeting mandatory GHP and documentation requirements in food industry and trade.

Until 1996, GHP was voluntary. Subsequently, it became mandatory for the food industry through regulations developed through broad consultation with all stakeholders. HACCP is only mandatory for the seafood industry (since 1997). In 1996, GMP regulations for several food industries were developed. Between 1992 and 2002, more than 500 000 GHP guidelines and generic HACCP guidelines for different industry and food service sectors were developed and distributed. In 2000, mandatory documentation of cleaning, sanitation and pest programmes came into effect, reinforcing the prerequisites for HACCP implementation.

A training programme for food inspectors and industry was launched in collaboration with the National Autonomous University of Mexico, covering GHP, HACCP and HACCP auditing; more than 400 people have been trained in the last 13 years. A training programme for food inspectors began in 1996; by 2005 more than 2 000 officials had been trained in various subjects.

In 1993, a strategy of focusing on specific food industry groups was introduced. Target groups were selected on the basis of a risk approach and resources were invested to improve food safety. The approach was resource intensive, but while there were major improvements in salt iodization and fluoridation, pasteurized milk, purified water and seafood, only minor food safety improvements were seen in other food groups comprising larger numbers of SLDBs, such as fresh cheese, public markets and restaurants.

The Mexican Official Standards of GHP for the food industry and food service sector have been in effect for over 8 years and are due for review. COFEPRIS intends to include HACCP on a voluntary basis, as a first step towards implementing HACCP in high-risk sectors (if all stakeholders are in agreement).

LESSONS LEARNED AND THE FUTURE

- GHP, GMP and HACCP implementation are part of a continuous learning process.
- Mandatory GHP and SSOP for all food businesses has laid the foundations for implementation of HACCP on a voluntary basis, leading in turn to mandatory HACCP in selected high-risk industries once the system is mature and resources are available.
- COFEPRIS is working towards third party GHP/HACCP auditing as a tool to support voluntary implementation of food safety programmes for interested industries, including the food service sector.
- To improve the efficiency and effectiveness of food safety measures, it is important to raise awareness through elementary education.

The Netherlands

NATIONAL FACTORS SUPPORTING APPROACH

The Netherlands has a population of 16 million. A total of 130 000 companies are active in the production or distribution of food. Of these, 3 500 are considered larger industrial businesses; the remainder are medium-sized and small businesses, and generally lack knowledge of and experience in HACCP. Most of these businesses are not able to develop and implement a food safety system by themselves.

In accordance with the EU directive 43/93, the basic obligations for food safety became law in 1996. While some companies immediately saw the advantages of food safety provisions, it was clear that without due pressure from the government and consumer associations, implementation would not succeed.

Historically, the Netherlands has a wide range of branch associations. Associations and boards have legal status and fulfil a very important role between the government and food businesses. Every food company in a specific branch is obliged by law to become a member of the relative association. In return, companies are represented and supported by the branch association in different ways. There is open communication between associations and government through discussion groups, where all associations, consumer organizations and the Food and Consumer Product Safety Authority (VWA) are represented and can discuss the introduction of legislation concerning food.

BRIEF DESCRIPTION OF APPROACH AND OUTCOMES TO DATE

Hygiene guides:

- Branch associations representing certain food sectors have developed branch-specific hygiene guides concerning food safety based on HACCP. The guides:
  - provide assurance that food prepared in the sector is safe;
  - provide basic prerequisite hygiene advice and instructions related to food safety; and
  - use terminology that is understandable, taking into account the level of education and cultural background of the users of the document.

- The Minister of Public Health and consumer organizations received this initiative with enthusiasm.
- Guides are discussed in the aforementioned discussion groups. Following discussion and agreement with the VWA, the hygiene guide receives approval from the Minister of Public Health for a period of 4 years, after which, the hygiene guide needs to be re-evaluated.
- Between 1997 and 1999, more than 25 hygiene guides received approval.
- The legal articles are formulated so that the food business owner may choose how to implement food safety measures and controls – developing and implementing a personalized food safety system or implementing an approved HACCP-based hygiene guide. Food businesses not operating according to a food safety system or hygiene guide are considered to be committing a legal offence.
- In 2001, the first hygiene guides were evaluated. Microbiological verification criteria were introduced and it became possible to verify different stages in the process by analysing in-process samples against different microbiological criteria. Currently, there are ten hygiene guides containing microbiological verification criteria suitable for SLDBs.

Enforcement:

- Despite references to HACCP-based food safety systems in legislation and the availability of hygiene guides, compliance with the regulations is still not assured. In 1998, the government inspectorate began to enforce compliance with the procedures and working instructions related to the food safety systems.
- A phased approach of enforcement was chosen and the associations were consulted to identify the priorities. This working method has several advantages:
  - Branch associations can communicate priorities to all members, who then start working according to the hygiene guide.
  - Companies can implement food safety in stages and gradually become accustomed to securing food safety in a systematic way.
  - Instructions for the inspector are limited to agreed and established priorities.
  - Registration of the inspection results gives an overview of the level of observance of the procedures and working instructions.

Results:

- Food safety has been controlled as described above for 7 or 8 years and most companies are familiar with a hygiene guide.
- Several priorities (targets related to CCPs) have been identified and are checked during every inspection:
  - Receiving and storage of raw materials/goods
  - Temperature (storage/preparation)
  - Cleaning and disinfecting
  - Cross-contamination

- Steps have been taken to define CCPs:
  - Instructions and procedures related to the priorities in the hygiene guide

- Conformance procedures by the owner and personnel, implementing the right control measures and sufficient corrective action if necessary
- Recording of all measurements available concerning the CCP

LESSONS LEARNED AND THE FUTURE

After over 7 years working on the system of hygiene guides for SLDBs, it is possible to draw the following conclusions:

- Food business inspections have changed from full-scope inspections to target-related inspections on critical points. Inspectors require specific training.
- The inspection method is standardized: it is easier to monitor the national level of food safety in the different branches and it is possible to prioritize.
- A suitable hygiene guide exists for every type of SLDB. Nevertheless, some items require attention in the near future.
- The motivation of the owners and staff of SLDBs to act according to the hygiene guide can be improved in some situations, for example, through simplification of the hygiene guide.
- There is scope for improvement of the education of SLDB staff in relation to the hygiene guide.

New Zealand

NATIONAL FACTORS SUPPORTING APPROACH

- Single integrated agency with responsibility for all food-related legislation.
- Mandatory requirement for the application of GHP and HACCP in some sectors, particularly for exports (e.g. animal products, seafood and dairy).
- Intent to mandate HACCP-based programmes throughout the food industry.

BRIEF DESCRIPTION OF THE APPROACH AND OUTCOMES TO DATE

The New Zealand Food Safety Authority (NZFSA) was established on 1 July 2002. The Authority takes a new approach to food safety by bringing together the food safety functions of the Ministry of Agriculture and Forestry and the Ministry of Health. One objective of the NZFSA is to develop a seamless food regulatory regime across the entire food chain. Before addressing current initiatives, there follows a brief description of HACCP policy prior to the establishment of the NZFSA.

Meat, dairy and other food types used to be regulated differently, mainly in isolation from one another, and different approaches towards HACCP implementation had been developed. At the time of the establishment of the NZFSA, the meat and dairy sectors were heading towards full mandatory HACCP for business within specified time frames; the domestic sector had the option of voluntarily implementing HACCP-based programmes.

There were differences in the implementation of GHP and its association with HACCP:

- The Ministry of Agriculture and Forestry (responsible for the meat and dairy sectors) had separated GHP and HACCP requirements.
- The Ministry of Health had integrated GHP and HACCP, requiring that hazards for prerequisite programmes were identified for the following reasons:
  - Prerequisite programmes used in the domestic sector were out of date and prescribed.
  - The hazards controlled by the prerequisite programmes needed to be reconsidered to determine if they were adequate and appropriate for the process.
  - Experience indicated that these programmes became secondary to the HACCP component and were often forgotten.

LESSONS LEARNED AND THE FUTURE

The Animal Products group within the NZFSA reports success with the use of generic HACCP guides, plans and templates. The success has been aided by good working relationships with food sector associations, some of which include SLDBs. This means that the group can provide input for HACCP-based approaches and guidance materials/templates. A good example of an outcome of this collaborative approach is the "Risk Management Programme Template for Eggs".[15]

Another successful initiative from the Animal Products group is an active programme of revising generic HACCP work to reflect current HACCP thinking and of improving guidance and template material based on food business and external verifier feedback.

The Domestic and Imported Foods group within the NZFSA has continued with the voluntary implementation of HACCP-based programmes. The team has noted four particular areas of success:

- A resource folder including HACCP guidance, frequently asked questions and legislative requirements has been very well utilized by food businesses.[16]
- Template-based solutions seem to be readily implemented by all types of food business; the NZFSA template on staff sickness is an example of this.[17]
- Establishing processes for open dialogue between the NZFSA, local regulators, external verifiers and food businesses has been essential to ensure improvements in the HACCP-based programme approval process (including ongoing verification and on-site programme review).
- The voluntary shift towards HACCP-based programmes has worked particularly well for "chain type" food businesses. This is where the head office of a food business chain (e.g. fast food, service station or supermarket) develops one HACCP-based programme for all sites. The programme includes training on how to implement (including site-specific hazard identification) and comply with the programme on an ongoing basis, as well as extensive food safety training for each food handler. The level of success is greater when the head office is particularly active in following up with outlets after their external audits.

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[15] http://www.nzfsa.govt.nz/animalproducts/subject/eggs/index.htm
[16] http://www.nzfsa.govt.nz/processed-food-retail-sale/fsp/index.htm
[17] http://www.nzfsa.govt.nz/processed-food-retail-sale/templates/index.htm

The success of these "general agreements" or generic templates for "like" businesses has led to the view that successful implementation of HACCP-based programmes for SLDBs is dependent on the development of such tools.

The voluntary status of HACCP implementation within the domestic sector and harmonization of HACCP requirements between the food sectors is being developed under the New Zealand Food Safety Authorities Domestic Food Review.[18]

New Zealand proposes that risk-based management plans, known as "food control plans", will include "good operating practices" and HACCP. Good operating practices are intended to encompass relevant food safety and suitability sections of good agricultural, good manufacturing or good hygienic practices. Good operating practices should have the following characteristics:

- Able to control or assist in controlling a food safety hazard or food suitability issue, covering matters such as training.
- Science-based where possible.
- Relevant to the food type and food process.
- Documented under the following headings:
  - Purpose
  - Scope
  - Authorities and responsibilities
  - Materials and equipment
  - Actual procedure (including monitoring, corrective action and internal verification)
  - Recording and reporting

- Developed and documented prior to applying the HACCP principles.
- Reviewed in conjunction with applying HACCP principles.

Food control plans are intended to cover the following components to the level appropriate for the business:

- Responsibilities and authorities (administrative details such as name and address)
- Scope (product and process description)
- Relevant regulatory requirements
- Good operating practices (see above)
- Documentation and record keeping
- Application of HACCP principles (including hazard identification and analysis, critical control points and critical limit determination, critical control point monitoring and corrective actions when needed, and internal verification)
- Training
- External verification and verifier competencies and rights

The key to the successful application of food control plans is the simplicity of the plans and the role of the regulator.

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[18] http://www.nzfsa.govt.nz/policy-law/projects/domestic-food-review/index.htm

For successful implementation of the food control plans, the NZFSA, as the regulator in this area, is expecting to provide templates and other guidelines for food control plans to cover the needs of some 30 000 to 40 000 businesses. The balance (of food businesses) either already has plans in place or, because of size or the use of proprietary processes for example, develops individual plans covering their specific businesses.

Food control plan templates are generally presented as part of, or supported by, codes of practice for particular food sectors, with GHP and HACCP elements and any regulatory requirements clearly identified. Food control plan templates might already be available within a food sector or may well exist in a complementary form in another country (which might be adapted for New Zealand businesses).

The type of tool produced varies depending on the level of understanding of a particular food sector. HACCP principles are applied in developing the template, and small to medium-sized business operators do not need to repeat this step.

New Zealand has not commenced broad application of the above approach. Discussion papers proposing that food control plans be the tool of choice for food safety management in the future were released publicly. Depending on submissions, developments are expected to continue.

South Africa

NATIONAL FACTORS SUPPORTING APPROACH

- National legislation creating an enabling framework to make HACCP mandatory in different sectors of the food industry.
- An FAO TCP Project conducted to determine, amongst others, the applicability of HACCP principles in street-food vending (a type of SLDB).
- Hygiene regulations applicable in all sectors of the food industry developed as a means of harmonizing national hygiene standards.
- Strong collaboration between all food control authorities, the industry and the academic sector, through various working groups and committees.

BRIEF DESCRIPTION OF THE APPROACH AND OUTCOMES TO DATE

In South Africa, food control is mainly the responsibility of the agricultural and health sectors and of the South African Bureau of Standards (SABS).

The agriculture sector is responsible for:

- ensuring good agricultural practices;
- the control of abattoirs;
- development and enforcement of food quality standards;
- certain labelling standards;
- certain imports and exports;
- registration of genetically modified organisms (GMOs);
- registration of agricultural remedies; and
- the national SPS enquiry point.

In addition, the Department of Agriculture authorized the Perishable Products Export Control Board to conduct physical inspections of perishable products (e.g. fresh fruits and vegetables) for export from South Africa.

The health sector is responsible for:

- development of food safety and nutrition standards;
- food hygiene issues (excluding abattoirs);
- certain aspects of food labelling;
- the quality of certain products; and
- certain import activities.

The health sector operates on three levels – national, provincial and local:

- National Department of Health, through the Directorate: Food Control, is responsible for:
  - coordinating food control activities within the country;
  - developing policy and legislation;
  - supporting provinces and local authorities; and
  - the National Codex Contact Point.

- Provincial Departments of Health (of which there are nine), through the Environmental Health service, are responsible for:
  - coordinating, amongst others, food control activities within the province;
  - developing provincial norms and standards;
  - supporting and monitoring local authorities; and
  - rendering specialist services such as port health services on behalf of the national department.

- Local authorities, through the Environmental Health service, are responsible for:
  - enforcing legislation;
  - health promotion activities;
  - investigating complaints;
  - identifying and controlling health hazards; and
  - compliance monitoring and intersectoral collaboration.

The regulatory division of the SABS administers compulsory specifications (technical regulations) on behalf of the Minister of Trade and Industry for:

- canned and frozen fishery products; and
- canned meat products.

The minimum requirements of these specifications are based on GMP and GHP and also contain minimum consumer safety, compositional, quality and labelling requirements. The SABS inspection system is based on the surveillance and conformity assessment of factories, fishing vessels, processes and products. These specifications are also applicable to imported products. The SABS is also the competent authority for the certification of fish and fishery products for export.

Following several assessments of the South African food control system, it was found that the system was inefficient due to the fact that:

- there was no single or coordinated voice or body regarding food control issues;
- multiple jurisdictions, overlapping and outdated legislation were hampering effective regulation of food in South Africa;
- there was uncoordinated enforcement of the legislation;
- there was no national monitoring programme and no national database; and
- all these issues resulted in an ineffective and inefficient utilization of human and other resources.

Several models have been proposed for the new food control system, for example:

- *Multi-agency system*
  Food control responsibilities are shared between the departments of Health, Agriculture, and Trade and Industry. This system is very similar to the current system of food control in South Africa. It has the disadvantage of creating a fragmented system lacking coordination between the different agencies in food policy, monitoring and food control. There is also fragmentation between national, provincial and local authorities, which results in consumers not receiving the same level of protection throughout South Africa.

- *Single agency system*
  There is consolidation of responsibility for food control in a single agency with very clear terms of reference. This system allows for a rapid response to food safety problems and for more effective use of resources, including the harmonization of food standards and uniform application of norms and standards. This option is said to have many advantages, but unfortunately does not fall in line with current South African Constitutional arrangements, where some aspects of food control are a provincial competency.

- *Integrated system*
  Allows for the separation of policy from operational activities, thus separating risk assessment from risk management functions as it demarcates the role of the authority from that of the inspection agency. Such a system has the advantage of addressing the entire food chain.

Before any model can be considered, numerous factors require consideration:

- National constitutional requirements, taking account of national, provincial and local authority structures.
- Current strategic plans of national government departments.
- Food control activities located in other agencies.
- South Africa's obligations to WTO SPS/TBT (technical barriers to trade) agreements and other international trade agreements.
- Public health protection for all South Africans.

In addition, the scope of the food control system must be closely related to the cultural, economic and political conditions of South Africa, covering all agricultural food produced, processed and sold, as well as imported food.

The Department of Agriculture has undergone restructuring with the creation of the South African Agricultural Food and Quarantine Inspection Services and of several new Directorates:

- Animal Health
- Plant Health
- Food Safety and Quality Assurance

These changes are the first step towards the establishment of a single integrated food control system in order to address the problems of fragmentation, lack of coordination and duplication of efforts. The subsequent steps are as follows:

- Obtain approval of the system at top level.
- Appoint a taskforce to examine the different options and choose the most effective model for the South African situation.
- Develop/approve a policy framework.
- Develop/approve a comprehensive policy regarding structure, personnel, resources etc.
- Publish a relevant bill and promulgate the relevant act.
- Draw up and implement the new regulations.

The creation of a new food control system, even when deemed necessary and urgent, is clearly not a simple operation. Indeed, the need for a new food control system in South Africa was identified 10 years ago and, although officials at all levels of national and provincial food control agencies, industry representatives, accredited inspection bodies and private inspection groups all agree that the creation of a National Food Control Authority is necessary, the stakeholders are still a long way from a decision regarding which food control system model to follow and how to implement it.

Thailand

NATIONAL FACTORS SUPPORTING APPROACH

- National policy for consumer protection and HACCP compliance.
- National survey on the readiness for HACCP implementation in food businesses before setting the time frame requiring HACCP in national legislation.
- Single body organizing the official inspection process.
- Well-trained and highly motivated human resources (consultants, official inspectors and third party auditors).
- Coordination among the academic sector, industry and trade associations (food safety courses, research, training).

BRIEF DESCRIPTION OF THE APPROACH AND OUTCOMES TO DATE

Thailand has a large number of food factories and a food export policy, resulting in an overwhelming workload for the Thai Food and Drug Administration (Thai FDA, Ministry of Public Health) – the principal regulatory organization responsible for the nation's food safety system. Consequently, in October 2002, the Thai Government set up the National Bureau of Agricultural Commodity and Food Standards (ACFS) under the Ministry of Agriculture and Cooperatives to develop standards and oversee the food safety of agricultural commodities and food products for export. ACFS also acts as a national accreditation body (only for food and agricultural products) and accredits the inspection system of the Departments of Fisheries, Agriculture and Livestock Development (under the Ministry of Agriculture and Cooperatives) which control food and agricultural products produced for export.

Through ACFS, the Ministry of Agriculture and Cooperatives aims to harmonize the certification/inspection system and gain international recognition. ACFS works to improve the

compliance of food export establishments with importing countries' legislation, which requires a food safety management system based on the HACCP principles. A farm-to-table approach was introduced recently, with the implementation of good agricultural practices (GAP) at farm level and GMP and HACCP for food establishments.

The Department of Health (under the Ministry of Public Health) is responsible for food safety in the food service sector (restaurants, hotels, canteens, supermarkets, fresh markets, food shops and street vending). Thailand has a huge number of food businesses in this sector, most of which are SLDBs.

To summarize, the main responsibilities are as follows:

- ACFS oversees the safety of food products for export.
- Thai FDA is in charge of safety of food products for domestic consumption.
- Department of Health is in charge of the food service sector.

Initiatives to support HACCP implementation in Thailand have been ongoing for some time. For example, the National Food Institute (NFI) was established under the Ministry of Industry in 1996 to facilitate HACCP implementation. More recently, NFI has become a certifying representative for the Campden and Chorleywood Food Research Association (United Kingdom) and the European Food Safety Inspection Service (EFSIS) and, as a result, is no longer a neutral organization for HACCP development in Thailand. Therefore, a national centre for food safety information and HACCP implementation (including HACCP harmonization) is still needed to effectively implement HACCP in all food sectors.

Pressure from importing countries is the major factor currently dictating HACCP implementation. Thai consumers must therefore be educated so that pressure is applied to implement HACCP domestically. On 24 July 2001, Thai FDA issued GMP regulations (basic hygiene regulations that need to be implemented prior to a HACCP system); they present numerous obstacles for small food businesses however. Despite assistance from the government (e.g. loans with low interest rate and free consultations), GMP implementation is still not fully implemented across the country. While Thai FDA is attempting to overcome the obstacles and fully implement GMP regulation for all food sectors, HACCP remains voluntary and lacks a targeted time frame for implementation.

For effective HACCP implementation, a sufficient number of qualified consultants, auditors and inspectors require training. Moreover, training of personnel in the food businesses to create food safety awareness is also necessary and time-consuming. HACCP training courses are organized by NFI, universities and food associations. These courses focus on the HACCP documentation system; there are very few courses that focus on food hazard analysis. For Thailand – as well as the other developing countries – more systematic training methods need to be considered.

For the food service sector (under the control of the Department of Health), there is no clear direction for HACCP implementation, since application of Codex HACCP to this sector seems very difficult. Since 2002, the Department of Health has encouraged food businesses to join the "Clean Food Good Taste" project. Food businesses which respect the basic GHP will receive the

"Clean Food Good Taste" mark. A number of food businesses, including fresh markets, have joined this voluntary project. The HACCP-based system needs to be developed for this sector.

LESSONS LEARNED AND THE FUTURE

Implementation of GMP or GHP prior to HACCP implementation is proving effective, given that GMP/GHP is the foundation for HACCP implementation and does not require much knowledge of food hazard analysis – a concept which is difficult to understand for SLDBs.

Development of a HACCP system is resource intensive and requires harmonization. The appropriate HACCP-based system must be developed for the food business sector. It is not easy to estimate the time required to implement HACCP and a national survey is necessary. The lessons learned during HACCP implementation in the food export sectors and the future are summarized as follows:

Lessons learned	The future
Pressure to encourage HACCP implementation is necessary.	• National legislation for HACCP implementation should be clearly stated in advance. • Policy-makers are needed to target HACCP implementation through a risk-based prioritization approach. • Consumer education is necessary to apply pressure for HACCP implementation in food businesses producing for domestic consumption.
Development of HACCP system is varied, depending on third party auditors/inspectors.	• Central organization is needed for harmonization of the HACCP system. • Single body is needed to organize the official inspection process and control/accredit both government and private third party auditors, in order to reduce confusion among food businesses during the development of the HACCP system.
Training/education, experience and information on food safety (e.g. food hazards and their control) are not sufficient to effectively implement the HACCP system.	• Systematic training for all stakeholders is needed (how to create food safety awareness; hazard analysis for specific food sectors; integration of risk analysis into HACCP system). • Central organization is required for the development of HACCP system.

United Kingdom

NATIONAL FACTORS SUPPORTING APPROACH

- Large number of food premises (>540 000) of which over 60 percent are caterers.
- Catering premises are diverse with high turnover of staff and businesses and low level of literacy.
- National legislation for licensing of butcher's shops has required them to have a HACCP system since 2000.

- National legislation since 2002 requires meat plant operators to introduce hygiene procedures based on HACCP principles.
- A food safety initiative with specialist cheese-makers was launched in January 2002 to promote protocols based on HACCP.
- EU regulation requiring the first five principles of HACCP has been part of United Kingdom legislation since 1995.
- A food hygiene campaign launched in 2002 has targeted food businesses with the aim of reducing food poisoning.
- Enforcement and education take place primarily at local authority level.
- Many businesses in the manufacturing sector already operate HACCP-based food safety procedures due to customer requirements.

BRIEF DESCRIPTION OF THE APPROACH AND OUTCOMES TO DATE

The United Kingdom Food Standards Agency (FSA) was established in 2000 with the aim of protecting consumers and improving food standards. Progress with the implementation of food safety management procedures in food businesses based on HACCP principles is seen as a key factor in working towards the FSA's target of reducing food-borne disease. The FSA recognizes that, in order to achieve the public health objectives in forthcoming European Community legislation, many businesses will require further guidance to explain how they might comply with the new legislation by having in place a food safety management system based on the principles of HACCP.

The FSA carried out a survey of local authorities in 2001. The results of this survey indicated that the adoption of food safety management procedures based on HACCP principles was highest in food manufacturing premises and lowest in catering premises. An estimate of the prevalence of documented hazard analysis in retail and catering premises was made as part of surveillance studies carried out by the Local Authority Co-ordinating Office on Regulatory Services and the Health Protection Agency. The six studies carried out since 2001 in over 9 000 establishments in England and Wales reveal a wide variation in uptake of documented hazard analysis, from 8 percent (take-aways) to 70 percent (retail premises). The average figure over all establishments was 55 percent. In addition, recent surveys in Scotland and Northern Ireland indicated that the corresponding figure for catering premises only in these countries is about 35 percent. The FSA's strategy looks towards eventual full compliance with the requirements for food safety management based on HACCP principles in the forthcoming legislation.

The FSA's strategy is to produce a "tool kit" of guidance materials and supporting materials on different approaches to HACCP, recognizing the diversity of the industry and that there can be no "one size fits all" solution.

The FSA has decided to address the need for guidance materials in the catering sector first, given the high proportion of catering premises (about 60 percent), and because it is in this sector that most progress needs to be made. It is also a particularly difficult sector for which to produce guidance, since it cannot be treated as a manufacturing, production line operation. The nature and size of catering businesses is so diverse that it is highly improbable that any single approach will satisfy the requirements of the whole catering sector.

The FSA's "tool kit" of approaches provides businesses with the option to choose a route to compliance that best meets their business needs and preferred management style. Businesses are also free to use other models that facilitate compliance.

The FSA is developing a food safety management tool, "Safer Food, Better Business" (SFBB), based on its Food Hygiene Campaign, in conjunction with enforcers, caterers, HACCP experts and food scientists and trade associations. SFBB is aimed at small and medium-sized catering businesses (<10 employees), which account for almost 90 percent of all catering businesses in the United Kingdom, and targets the owner or manager of the business. FSA Scotland and Northern Ireland also have each produced guidance material.

Guidance materials are being developed in partnership with all relevant stakeholders. These include local authorities, industry representatives, trade associations and businesses. The FSA has recognized the need to build from the current level of knowledge in the business, particularly at the micro-business level, in achieving the implementation of a food safety management system. The FSA has also recognized the diversity found within the catering sector and has undertaken a number of projects to ensure that guidance materials are fully relevant to these sectors. A number of projects to test the feasibility of guidance and methods of delivery are currently underway. The results of this work will be used for the further development of guidance materials, the constituent parts of the agency's "tool kit" and the FSA strategy on implementation from 2005.

LESSONS LEARNED AND THE FUTURE

The United Kingdom approach – using the flexibility of the Codex General Principles of Food Hygiene to control a food operation and in accordance with the EU Regulations to provide small catering businesses with a "tool kit" of routes to compliance – is supported by a graduated and educative approach to enforcement. The success of the approach will be determined by trial results, which will be reflected in future guidance and business support. It is clear that the business sector (in this case, caterers) needs to be fully involved in the production of guidance materials and that materials must be thoroughly tested before wide-scale use. It is recognized that much of the further development of HACCP guidance is likely to be industry-led, and that full compliance may take several years. Consistent support at national and regional level will be provided through local authorities and trade associations, as well as by government.

The seven principles of the HACCP System and specific strategic activities in SLDBs

Annex 1 outlines various activities which may be implemented singly or in a combined way as part of the national policy for the application of HACCP in SLDBs. To reinforce where specific tools may be and have been used, information is presented below outlining methods to support SLDBs in complying with specific HACCP principles.

METHODS ASSOCIATED WITH ACHIEVING THE SEVEN PRINCIPLES OF HACCP

PRINCIPLE 1 – CONDUCT A HAZARD ANALYSIS

- Merging both the general (i.e. prerequisites) and specific (i.e. HACCP) hazards in a way that businesses can understand and consequently control.
- Grouping similar hazards and controls to facilitate the operation of HACCP by the business. Examples include the completion of maintenance requirements during cleaning and using the scope statement (which outlines the different processes undertaken by a food business) as the basis of a training requirements list.
- Identifying the hazard at a sufficient level of detail to allow the analysis to lead to identification of relevant and appropriate control measures[19]. Agents may be identified at various levels of detail:

Detail	e.g. Biological hazards
Broad category	Biological agents
	Bacteria, fungi, viruses, parasites
	Pathogens
	Pathogens (able to colonize the human gut)
	Salmonella
Very specific details	*Salmonella* Typhimurium *phage* type 104
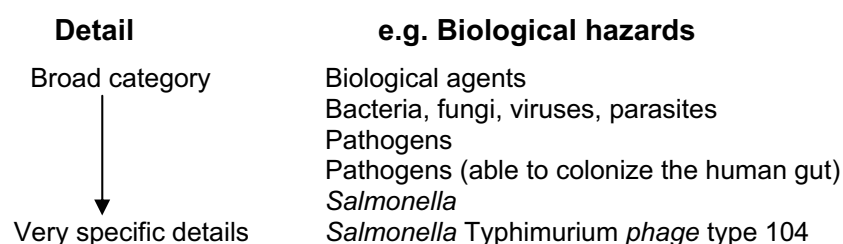
For example, in the preparation of meat pies which are consumed hot immediately after cooking, it is sufficient to identify pathogens as a likely hazard in raw meat ingredients. One could identify specific pathogens, such as *Salmonella, Campylobacter, Clostridium* and *Yersinia*, and parasites, such as *Toxoplasmosis Gondii*, but this would not change the control outcome. All vegetative pathogens and parasites are effectively destroyed by the heat treatment regimes during cooking; any spore formers (e.g. clostridia species), do not have time to regenerate. However, in the preparation of meat pies which are subject to storage and distribution, more detailed analysis is required. *Clostridia perfringens* and *Bacillus cereus* should

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[19] *Source:* New Zealand Ministry of Health, 2002. Guidance about the design, implementation and operation of Food Safety Programmes and the content of Codes of Practice, not published.

be identified, as these spore formers may flourish if the cooling rate and product storage temperature are not controlled. In the preparation of cooked rice, a more detailed approach is required. *Bacillus cereus* should be identified as a likely hazard in the ingredient rice and, because it is a spore former, it can survive the cooking process. Control needs to be applied to the cooling of the cooked rice and holding until final food preparation. The hazard needs to be identified at this more detailed level and the spore forming nature highlighted.

- Rewording hazards as "problems" and controls as "steps to manage the problems" (or similar expressions) can reduce confusion for a food business.

PRINCIPLE 2 – DETERMINE THE CRITICAL CONTROL POINTS (CCPS):

- Developing general guidance material to be used in association with the decision tree is helpful. The information needs to outline how to deal with prerequisite controls, hurdle technology and define acceptable and unacceptable limits. An example of such guidance material may be found on the New Zealand Food Safety Authority Web site: http://www.nzfsa.govt.nz/processed-food-retail-sale/fsp/faq/index.htm#P35_1457.
- Defining recommended critical control points is a possible approach for simpler food processors, for example in the food service industry. Care needs to be taken with this approach to ensure that the critical control points do not become prescribed. Food businesses should always have the option of using an alternative control system that has been assessed for equivalence.

PRINCIPLE 3 – ESTABLISH CRITICAL LIMIT(S):

- Validation is usually completed by scientific trials or reference to scientific literature. This is often seen as difficult for SLDBs, who do not have easy access to such information or the ability to understand it. It is common for validation to be completed by reference to dated and prescriptive legislation. The regulator's role is to collate commonly used critical limits and validate them through scientific literature. Limits "generally regarded as safe" (sometimes known as "GRAS") and including those associated with good hygienic practices, should also be included in this resource. By making these collations available to businesses, identification of adequate critical limits is aided.

PRINCIPLE 4 – ESTABLISH A SYSTEM TO MONITOR CONTROL OF THE CCP:

- Utilizing methods that reduce the quantity of record keeping (this may be in the form of a "diary" or simplified records based on "management by exception").
- The process of taking temperature measurements has been identified as a barrier to the implementation of HACCP. Visual monitoring to determine when the critical limit has been achieved is possible in two cases:
  - Where there is a large buffer between the critical limit and final temperature reached through the traditional method of cooking (e.g. frying of bacon to make crispy bacon rashers).

–   The correlation between the visual colour and texture change in the food and the critical limits achieved at this point is validated. Some validation work on this area has been completed and more continues. Unless there is validation to show the correlation in a food type, use of visual checks to determine when critical limits are achieved is not recommended.

*   Simple instructions on how to lessen the burden of monitoring should also be made available. This information should include the fact that where historical records covering the monitoring are available and consistency is observed, the amount of monitoring may be reduced.

PRINCIPLE 5 – ESTABLISH THE CORRECTIVE ACTION TO BE TAKEN WHEN MONITORING INDICATES THAT A PARTICULAR CCP IS NOT UNDER CONTROL:

No alternative strategies have been identified.

PRINCIPLE 6 – ESTABLISH PROCEDURES FOR VERIFICATION TO CONFIRM THAT THE HACCP SYSTEM IS WORKING EFFECTIVELY:

Internal verification solutions for businesses with a small number of staff include the following:

*   The food business's external verifier (auditor) checks records of CCP monitoring fortnightly (i.e. fax through records to the verifier). There is a potential cost issue associated with this option. A possible method to prevent this cost is to use people wanting to become auditors to verify this information. This would provide good training for these potential auditors and an internal verification within the food business.
*   The food business may approach a family member or associate to undertake the internal audit function. Food safety training for this person is essential to ensure a useful verification.
*   Initiating a "swap" programme between similar businesses: owners from similar businesses undertake the internal audit function of another business – and vice versa.
*   Allowing the food business to undertake its own internal verification and request that the external verifier (auditor) reviews the effectiveness of the internal verification system. If found inappropriate, the business would have to revert to another option outlined above.
*   Refocusing enforcement and audit requirements onto businesses' understanding and control of processes (this might be typified as "self-audit" monitoring).
*   The potential cost of external verification is another clear barrier to HACCP implementation. Other than the regulator funding or completing this task, options to resolve this issue are limited. In the United Kingdom's "Safer Food Better Business" system, the verification of the system is done routinely by self-audit – i.e. activity is undertaken by the manger responsible and intermittently by official enforcement officers.

PRINCIPLE 7 – ESTABLISH DOCUMENTATION CONCERNING ALL PROCEDURES AND RECORDS APPROPRIATE TO THESE PRINCIPLES AND THEIR APPLICATION:

- The diary option is one way of helping to ensure that records are kept with minimal effort. This system provides a place for all records taken for each working day.
- Checklists and pens positioned close to the area where monitoring is being undertaken can act as both a time saver and a reminder to the food worker.

An example of a system using the various methods outlined above is the "Safer Food Better Business" system developed by the UK Food Standards Agency (see Annex 1). The system merges both the general (i.e. prerequisites) and specific (i.e. HACCP) hazards, but their criticality is indicated by the level and frequency of monitoring required. The record-keeping element of the system is focused on a diary that is signed on a daily basis by the person responsible for food safety. Focus is on record keeping by exception, i.e. making a written record only when things go wrong and corrective action is undertaken. The verification of the system is done routinely by self-audit, i.e. activity is undertaken by the manager responsible and intermittently by official enforcement officers.

1/1	Review of food consumption surveys 1977 – Vol. 1. Europe, North America, Oceania, 1977 (E)
1/2	Review of food consumption surveys 1977 – Vol. 2. Africa, Latin America, Near East, Far East, 1979 (E)
2	Report of the joint FAO/WHO/UNEP conference on mycotoxins, 1977 (E F S)
3	Report of a joint FAO/WHO expert consultation on dietary fats and oils in human nutrition, 1977 (E F S)
4	JECFA specifications for identity and purity of thickening agents, anticaking agents, antimicrobials, antioxidants and emulsifiers, 1978 (E)
5	JECFA – guide to specifications, 1978 (E F)
5 Rev. 1	JECFA – guide to specifications, 1983 (E F)
5 Rev. 2	JECFA – guide to specifications, 1991 (E)
6	The feeding of workers in developing countries, 1976 (E S)
7	JECFA specifications for identity and purity of food colours, enzyme preparations and other food additives, 1978 (E F)
8	Women in food production, food handling and nutrition, 1979 (E F S)
9	Arsenic and tin in foods: reviews of commonly used methods of analysis, 1979 (E)
10	Prevention of mycotoxins, 1979 (E F S)
11	The economic value of breast-feeding, 1979 (E F)
12	JECFA specifications for identity and purity of food colours, flavouring agents and other food additives, 1979 (E F)
13	Perspective on mycotoxins, 1979 (E F S)
14	*Manuals of food quality control:*
14/1	Food control laboratory, 1979 (Ar E)
14/1 Rev.1	The food control laboratory, 1986 (E)
14/2	Additives, contaminants, techniques, 1980 (E)
14/3	Commodities, 1979 (E)
14/4	Microbiological analysis, 1979 (E F S)
14/5	Food inspection, 1981 (Ar E) (Rev. 1984, E S)
14/6	Food for export, 1979 (E S)
14/6 Rev.1	Food for export, 1990 (E S)
14/7	Food analysis: general techniques, additives, contaminants and composition, 1986 (C E)
14/8	Food analysis: quality, adulteration and tests of identity, 1986 (E)
14/9	Introduction to food sampling, 1988 (Ar C E F S)
14/10	Training in mycotoxins analysis, 1990 (E S)
14/11	Management of food control programmes, 1991 (E)
14/12	Quality assurance in the food control microbiological laboratory, 1992 (E F S)
14/13	Pesticide residue analysis in the food control laboratory, 1993 (E F)
14/14	Quality assurance in the food control chemical laboratory, 1993 (E)
14/15	Imported food inspection, 1993 (E F)
14/16	Radionuclides in food, 1994 (E)
14/17	Unacceptable visible can defects – a pictorial manual, 1998 (E F S)
15	Carbohydrates in human nutrition, 1980 (E F S)
16	Analysis of food consumption survey data for developing countries, 1980 (E F S)
17	JECFA specifications for identity and purity of sweetening agents, emulsifying agents, flavouring agents and other food additives, 1980 (E F)
18	Bibliography of food consumption surveys, 1981 (E)
18 Rev. 1	Bibliography of food consumption surveys, 1984 (E)
18 Rev. 2	Bibliography of food consumption surveys, 1987 (E)
18 Rev. 3	Bibliography of food consumption surveys, 1990 (E)
19	JECFA specifications for identity and purity of carrier solvents, emulsifiers and stabilizers, enzyme preparations, flavouring agents, food colours, sweetening agents and other food additives, 1981 (E F)
20	Legumes in human nutrition, 1982 (E F S)
21	Mycotoxin surveillance – a guideline, 1982 (E)
22	Guidelines for agricultural training curricula in Africa, 1982 (E F)
23	Management of group feeding programmes, 1982 (E F P S)
23 Rev. 1	Food and nutrition in the management of group feeding programmes, 1993 (E F S)
24	Evaluation of nutrition interventions, 1982 (E)
25	JECFA specifications for identity and purity of buffering agents, salts; emulsifiers, thickening agents, stabilizers; flavouring agents, food colours, sweetening agents and miscellaneous food additives, 1982 (E F)
26	Food composition tables for the Near East, 1983 (E)
27	Review of food consumption surveys 1981, 1983 (E)
28	JECFA specifications for identity and purity of buffering agents, salts, emulsifiers, stabilizers, thickening agents, extraction solvents, flavouring agents, sweetening agents and miscellaneous food additives, 1983 (E F)
29	Post-harvest losses in quality of food grains, 1983 (E F)
30	FAO/WHO food additives data system, 1984 (E)
30 Rev. 1	FAO/WHO food additives data system, 1985 (E)
31/1	JECFA specifications for identity and purity of food colours, 1984 (E F)
31/2	JECFA specifications for identity and purity of food additives, 1984 (E F)
32	Residues of veterinary drugs in foods, 1985 (E/F/S)
33	Nutritional implications of food aid: an annotated bibliography, 1985 (E)
34	JECFA specifications for identity and purity of certain food additives, 1986 (E F)
35	Review of food consumption surveys 1985, 1986 (E)
36	Guidelines for can manufacturers and food canners, 1986 (E)
37	JECFA specifications for identity and purity of certain food additives, 1986 (E F)

59   Nutrition education for the public, 1995 (E F S)
60   Food fortification: technology and quality control, 1996 (E)
61   Biotechnology and food safety, 1996 (E)
62   Nutrition education for the public – Discussion papers of the FAO Expert Consultation, 1996 (E)
63   Street foods, 1997 (E/F/S)
64   Worldwide regulations for mycotoxins 1995 – A compendium, 1997 (E)
65   Risk management and food safety, 1997 (E)
66   Carbohydrates in human nutrition, 1998 (E S)
67   Les activités nutritionnelles au niveau communautaire – Expériences dans les pays du Sahel, 1998 (F)
68   Validation of analytical methods for food control, 1998 (E)
69   Animal feeding and food safety, 1998 (E)
70   The application of risk communication to food standards and safety matters, 1999 (Ar C E F S)
71   Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, 2004 (E F S)
72   Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods – Risk characterization of *Salmonella* spp. in eggs and broiler chickens and *Listeria monocytogenes* in ready-to-eat foods, 2001 (E F S)
73   Manual on the application of the HACCP system in mycotoxin prevention and control, 2001 (E F S)
74   Safety evaluation of certain mycotoxins in food, 2001 (E)
75   Risk assessment of *Campylobacter* spp. in broiler chickens and *Vibrio* spp. in seafood, 2003 (E)
76   Assuring food safety and quality – Guidelines for strengthening national food control systems, 2003 (E F S)
77   Food energy – Methods of analysis and conversion factors, 2003 (E)
78   Energy in human nutrition. Report of a Joint FAO/WHO/UNU Expert Consultation, 2003 (E). Issued as No. 1 in the FAO Food and Nutrition Technical Report Series entitled Human energy requirements, Report of a Joint FAO/WHO/UNU Expert Consultation, 2004 (E)
79   Safety assessment of foods derived from genetically modified animals, including fish, 2004 (E)
80   Marine biotoxins, 2004 (E)
81   Worldwide regulations for mycotoxins in food and feed in 2003, 2004 (C E F S)
82   Safety evaluation of certain contaminants in food, 2005 (E)
83   Globalization of food systems in developing countries: impact on food security and nutrition, 2004 (E)
84   The double burden of malnutrition – Case studies from six developing countries, 2006 (E)
85   Probiotics in food – Health and nutritional properties and guidelines for evaluation, 2006 (E S)

86   FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses, 2006 (E)

Availability: November 2006

Ar – Arabic   Multil – Multilingual
C – Chinese   *   Out of print
E – English   **   In preparation
F – French
P – Portuguese
S – Spanish

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FAO and WHO support the continual development of national policies to improve food safety and quality with the overall objective of protecting consumers' health and furthering economic development. This document has been developed by FAO and WHO following a request from the Thirty-fifth Session of the Codex Committee on Food Hygiene (CCFH) for guidance on HACCP in small and/or less-developed businesses (SLDBs), to address obstacles, identified by member countries, facing the small food business sector. This document will assist national authorities in the development of national policy, strategies and action plans aimed at improving food safety and trade through the application of HACCP in SLDBs. It provides a historical background and a summary of the work of the Codex Alimentarius Commission on HACCP. It identifies the challenges facing small food businesses in the application of HACCP, outlines the steps for the development of a HACCP strategy and describes a number of strategic activities based on the collective experience of experts. Wherever possible, examples of national approaches are provided. The guidance document is for use by governments in developing national policy aimed at the application of HACCP in SLDBs, and by professionals advising on national policy development (e.g. government officials, food industry associations, consultants, auditors, trainers/education specialists). It promotes full interaction between governments and the small business sector.