



**FOOD AND AGRICULTURE ORGANIZATION
OF THE UNITED NATIONS**



WORLD HEALTH ORGANIZATION

ASSURING FOOD SAFETY AND QUALITY:

GUIDELINES FOR STRENGTHENING NATIONAL FOOD CONTROL SYSTEMS

Joint FAO/WHO Publication

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1. PREAMBLE

Effective national food control systems are essential to protect the health and safety of domestic consumers. They are also critical in enabling countries to assure the safety and quality of their foods entering international trade and to ensure that imported foods conform to national requirements. The new global environment for food trade places considerable obligations on both importing and exporting countries to strengthen their food control systems and to implement and enforce risk-based food control strategies.

Consumers are taking unprecedented interest in the way food is produced, processed and marketed, and are increasingly calling for their Governments to accept greater responsibility for food safety and consumer protection.

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have a strong interest in promoting national food control systems that are based upon scientific principles and guidelines, and which address all sectors of the food chain. This is particularly important for developing countries as they seek to achieve improved food safety, quality and nutrition, but will require a high level of political and policy commitment.

In many countries, effective food control is undermined by the existence of fragmented legislation, multiple jurisdictions, and weaknesses in surveillance, monitoring and enforcement. These guidelines seek to provide advice to national authorities on strategies to strengthen food control systems to protect public health, prevent fraud and deception, avoid food adulteration and facilitate trade. They will enable authorities to choose the most suitable options for their food control systems in terms of legislation, infrastructure and enforcement mechanisms. The document delineates the overarching principles of food control systems, and provides examples of possible infrastructures and approaches for national systems.

The target users of these Guidelines are national authorities concerned with ensuring food safety and quality in the interests of public health and consumer protection. The Guidelines will also be of assistance to a range of other stakeholders including consumer groups, industry and trade organizations, farmer groups and any other groups or associations that influence national policy in this area.

2. INTRODUCTION

The publication ***Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems*** was prepared to enable national authorities, particularly in developing countries, to improve their food control systems.

These Guidelines replace the earlier FAO/WHO publication ***Guidelines for Developing an Effective National Food Control System*** (1976) - FAO Food Control Series No. 1; WHO Food Control No. 1. For over 25 years this publication has been the definitive reference for developing countries in planning, organizing, and implementing their national food control programmes. Much has changed in the intervening period. There have been advances in the control of foodborne hazards as well as improvements in food inspection and surveillance systems. Globalization of the food supply chain, the increasing importance of the Codex Alimentarius Commission, and the obligations emerging from the World Trade Organization (WTO) Agreements have resulted in unprecedented interest in the development of food standards and regulations, and the strengthening of food control infrastructure at the country level.

The challenges for food control authorities include:

- Increasing burden of foodborne illness and new and emerging foodborne hazards;
- Rapidly changing technologies in food production, processing and marketing;
- Developing science-based food control systems with a focus on consumer protection;
- International food trade and need for harmonization of food safety and quality standards;
- Changes in lifestyles, including rapid urbanization; and
- Growing consumer awareness of food safety and quality issues and increasing demand for better information.

Globally, the incidence of foodborne diseases is increasing and international food trade is disrupted by frequent disputes over food safety and quality requirements. Many food control systems need to be revised and strengthened if improvements are to be realized. It has never been more important for developing countries to implement and enforce a food control system based on the modern concept of risk assessment. These Guidelines provide important information on the principles and practices of food control and the trend away from a merely punitive to a preventive approach to food control.

Responsibility for food control in most countries is shared between different agencies or ministries. The roles and responsibilities of these agencies may be quite different and duplication of regulatory activity, fragmented surveillance and a lack of coordination are common. There may also be wide variations in expertise and resources between the different agencies, and the responsibility for protecting public health may conflict with obligations to facilitate trade or develop an industry or sector.

These Guidelines provide information for government agencies to assist in the development of national food control systems and to promote effective collaboration between all sectors involved in the management and control of food safety and quality. They highlight the importance of developing effective relationships and mutual support among government agencies and institutions involved in food control and other stakeholders, particularly the food industry and consumer groups.

3. IMPORTANT FOOD ISSUES

3.1 Food Safety, Quality and Consumer Protection

The terms food safety and food quality can sometimes be confusing. Food safety refers to all those hazards, whether chronic or acute, that may make food injurious to the health of the consumer. It is not negotiable. Quality includes all other attributes that influence a product's value to the consumer. This includes negative attributes such as spoilage, contamination with filth, discoloration, off-odours and positive attributes such as the origin, colour, flavour, texture and processing method of the food. This distinction between safety and quality has implications for public policy and influences the nature and content of the food control system most suited to meet predetermined national objectives.

Food control is defined as:

....a mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all foods during production, handling, storage, processing, and distribution are safe, wholesome and fit for human consumption; conform to safety and quality requirements; and are honestly and accurately labelled as prescribed by law.

The foremost responsibility of food control is to enforce the food law(s) protecting the consumer against unsafe, impure and fraudulently presented food by prohibiting the sale of food not of the nature, substance or quality demanded by the purchaser.

Confidence in the safety and integrity of the food supply is an important requirement for consumers. Foodborne disease outbreaks involving agents such as *Escherichia coli*, *Salmonella* and chemical contaminants highlight problems with food safety and increase public anxiety that modern farming systems, food processing and marketing do not provide adequate safeguards for public health. Factors which contribute to potential hazards in foods include improper agricultural practices; poor hygiene at all stages of the food chain; lack of preventive controls in food processing and preparation operations; misuse of chemicals; contaminated raw materials, ingredients and water; inadequate or improper storage, etc.

Specific concerns about food hazards have usually focused on:

- Microbiological hazards;
- Pesticide residues;
- Misuse of food additives;
- Chemical contaminants, including biological toxins; and
- Adulteration.

The list has been further extended to cover genetically modified organisms, allergens, veterinary drugs residues and growth promoting hormones used in the production of animal products. For more details see Annex 3.

Consumers expect protection from hazards occurring along the entire food chain, from primary producer through consumer (often described as the **farm-to-table** continuum). Protection will only occur if all sectors in the chain operate in an integrated way, and food control systems address all stages of this chain.

As no mandatory activity of this nature can achieve its objectives fully without the cooperation and active participation of all stakeholders e.g. farmers, industry, and consumers, the term **Food Control System** is used in these Guidelines to describe the integration of a mandatory regulatory approach with preventive and educational strategies that protect the whole food chain. Thus an ideal food control system should include effective enforcement of mandatory requirements, along with training and education, community outreach programmes and promotion

of voluntary compliance. The introduction of preventive approaches such as the Hazard Analysis Critical Control Point System (HACCP), have resulted in industry taking greater responsibility for and control of food safety risks. Such an integrated approach facilitates improved consumer protection, effectively stimulates agriculture and the food processing industry, and promotes domestic and international food trade.

3.2 Global Considerations

(a) International Trade

With an expanding world economy, liberalization of food trade, growing consumer demand, developments in food science and technology, and improvements in transport and communication, international trade in fresh and processed food will continue to increase.

Access of countries to food export markets will continue to depend on their capacity to meet the regulatory requirements of importing countries. Creating and sustaining demand for their food products in world markets relies on building the trust and confidence of importers and consumers in the integrity of their food systems. With agricultural production the focal point of the economies of most developing countries, such food protection measures are essential.

(b) Codex Alimentarius Commission

The Codex Alimentarius Commission (CAC) is an intergovernmental body that coordinates food standards at the international level. Its main objectives are to protect the health of consumers and ensure fair practices in food trade. The CAC has proved to be most successful in achieving international harmonization in food quality and safety requirements. It has formulated international standards for a wide range of food products and specific requirements covering pesticide residues, food additives, veterinary drug residues, hygiene, food contaminants, labelling etc. These Codex recommendations are used by governments to determine and refine policies and programmes under their national food control system. More recently, Codex has embarked on a series of activities based on risk assessment to address microbiological hazards in foods, an area previously unattended. Codex work has created worldwide awareness of food safety, quality and consumer protection issues, and has achieved international consensus on how to deal with them scientifically, through a risk-based approach. As a result, there has been a continuous appraisal of the principles of food safety and quality at the international level. There is increasing pressure for the adoption of these principles at the national level. See Annex 4 for further details.

(c) SPS and TBT Agreements

The conclusion of the Uruguay Round of Multilateral Trade Negotiations in Marrakech led to the establishment of the WTO on 1 January 1995, and to the coming into force of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT). Both these Agreements are relevant in understanding the requirements for food protection measures at the national level, and the rules under which food is traded internationally.

The SPS Agreement confirms the right of WTO member countries to apply measures to protect human, animal and plant life and health. The Agreement covers all relevant laws, decrees, regulations; testing, inspection, certification and approval procedures; and packaging and labelling requirements directly related to food safety. Member States are asked to apply only those measures for protection that are based on scientific principles, only to the extent necessary, and not in a manner which may constitute a disguised restriction on international trade. The Agreement encourages use of international standards, guidelines or recommendations where they exist, and identifies those from Codex (relating to food additives, veterinary drugs and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practices), to be consistent with provisions of SPS. Thus, the Codex standards serve as a benchmark for comparison of national sanitary and phytosanitary measures. While it is not compulsory for Member States to apply Codex Standards, it is in their best interests to harmonize their national food standards with those elaborated by Codex.

The TBT Agreement requires that technical regulations on traditional quality factors, fraudulent practices, packaging, labelling etc imposed by countries will not be more restrictive on imported products than they are on products produced domestically. It also encourages use of international standards. See Annex 5 for further details.

4. ELEMENTS OF A NATIONAL FOOD CONTROL SYSTEM

4.1 Objectives

The principal objectives of national food control systems are:

- Protecting public health by reducing the risk of foodborne illness;
- Protecting consumers from unsanitary, unwholesome, mislabelled or adulterated food; and
- Contributing to economic development by maintaining consumer confidence in the food system and providing a sound regulatory foundation for domestic and international trade in food.

4.2 Scope

Food control systems should cover all food produced, processed and marketed within the country, including imported food. Such systems should have a statutory basis and be mandatory in nature.

4.3 Building Blocks

While the components and priorities of a food control system will vary from country to country, most systems will typically comprise the following components.

(a) *Food Law and Regulations*

The development of relevant and enforceable food laws and regulations is an essential component of a modern food control system. Many countries have inadequate food legislation and this will impact on the effectiveness of all food control activities carried out in the country.

Food law has traditionally consisted of legal definitions of unsafe food, and the prescription of enforcement tools for removing unsafe food from commerce and punishing responsible parties after the fact. It has generally not provided food control agencies with a clear mandate and authority to *prevent* food safety problems. The result has been food safety programmes that are reactive and enforcement-oriented rather than preventive and holistic in their approach to reducing the risk of foodborne illness. To the extent possible, modern food laws not only contain the necessary legal powers and prescriptions to ensure food safety, but also allow the competent food authority or authorities to build preventive approaches into the system.

In addition to legislation, governments need updated food standards. In recent years, many highly prescriptive standards have been replaced by horizontal standards that address the broad issues involved in achieving food safety objectives. While horizontal standards are a viable approach to delivering food safety goals, they require a food chain that is highly controlled and supplied with good data on food safety risks and risk management strategies and as such may not be feasible for many developing countries. Similarly, many standards on food quality issues have been cancelled and replaced by labelling requirements.

In preparing food regulations and standards, countries should take full advantage of Codex standards and food safety lessons learned in other countries. Taking into account the experiences in other countries while tailoring the information, concepts and requirements to the national context is the only sure way to develop a modern regulatory framework that will both satisfy national needs and meet the demands of the SPS Agreement and trading partners.

Food legislation should include the following aspects:

- it must provide a high level of health protection;
- it should include clear definitions to increase consistency and legal security;

- it should be based on high quality, transparent, and independent scientific advice following risk assessment, risk management and risk communication;
- it should include provision for the use of precaution and the adoption of provisional measures where an unacceptable level of risk to health has been identified and where full risk assessment could not be performed;
- it should include provisions for the right of consumers to have access to accurate and sufficient information;
- it should provide for tracing of food products and for their recall in case of problems;
- it should include clear provisions indicating that primary responsibility for food safety and quality rests with producers and processors;
- it should include obligation to ensure that only safe and fairly presented food is placed on the market;
- it should also recognise the country's international obligations particularly in relation to trade; and
- it should ensure transparency in the development of food law and access to information.

Guidelines for the development of food laws are contained in Annex 6.

(b) Food Control Management

Effective food control systems require policy and operational coordination at the national level. While the detail of such functions will be determined by the national legislation, they would include the establishment of a leadership function and administrative structures with clearly defined accountability for issues such as: the development and implementation of an integrated national food control strategy; operation of a national food control programme; securing funds and allocating resources; setting standards and regulations; participation in international food control related activities; developing emergency response procedures; carrying out risk analysis; etc.

Core responsibilities include the establishment of regulatory measures, monitoring system performance, facilitating continuous improvement, and providing overall policy guidance.

(c) Inspection Services

The administration and implementation of food laws require a qualified, trained, efficient and honest food inspection service. The food inspector is the key functionary who has day-to-day contact with the food industry, trade and often the public. The reputation and integrity of the food control system depends, to a very large extent, on their integrity and skill. The responsibilities of the inspection services include:

- Inspecting premises and processes for compliance with hygienic and other requirements of standards and regulations;
- Evaluating HACCP plans and their implementation;
- Sampling food during harvest, processing, storage, transport, or sale to establish compliance, to contribute data for risk assessments and to identify offenders;
- Recognizing different forms of food decomposition by organoleptic assessment ; identifying food which is unfit for human consumption; or food which is otherwise deceptively sold to the consumer; and taking the necessary remedial action;
- Recognizing, collecting and transmitting evidence when breaches of law occur, and appearing in court to assist prosecution;
- Encouraging voluntary compliance in particular by means of quality assurance procedures;
- Carrying out inspection, sampling and certification of food for import/export inspection purposes when so required;

- In establishments working under safety assurance programmes such as HACCP, conduct risk based audits.

Proper training of food inspectors is a prerequisite for an efficient food control system. As current food systems are quite complex, the food inspector must be trained in food science and technology to understand the industrial processes, identify potential safety and quality problems, and have the skill and experience to inspect the premises, collect food samples and carry out an overall evaluation. The inspector must have a good understanding of the relevant food laws and regulations, their powers under those laws, and the obligations such laws impose on the food sector. They should also be conversant with procedures for collecting evidence, writing inspection reports, collecting samples and sending them to a laboratory for analysis. With gradual introduction of HACCP systems in the food industry, the inspector should be trained to handle HACCP audit responsibilities. Clearly, there is a continuing need for training and upgrading the skills of existing inspectional staff and having a policy for human resource development, especially the development of inspectional specialists in specific technical areas.

As human resources in some food control agencies in developing countries may be limited, environmental health inspectors are often also asked to work as food inspectors. This is not the ideal situation as they may lack the skills and knowledge to effectively evaluate and inspect food operations. If environmental health inspectors must be used, then they should be carefully supervised and provided with on-the-job training.

(d) *Laboratory Services: Food Monitoring and Epidemiological Data*

Laboratories are an essential component of a food control system. The establishment of laboratories requires considerable capital investment and they are expensive to maintain and operate. Therefore careful planning is necessary to achieve optimum results. The number and location of the laboratories should be determined in relation to the objectives of the system and the volume of work. If more than one laboratory is required, consideration should be given to apportioning the analytical work to achieve the most effective coverage of the food analyses to be performed and also to having a central reference laboratory equipped for sophisticated and reference analyses.

All food analysis laboratories may not be under the control of one agency or ministry, and a number could be under the jurisdiction of the states, provinces and local authorities. The Food Control Management should, however, lay down the norms for food control laboratories and monitor their performance.

The laboratories should have adequate facilities for physical, microbiological and chemical analyses. In addition to simple routine analysis, the laboratories can be equipped with more sophisticated instruments, apparatus and library facilities as required. It is not only the type of equipment that determines the accuracy and reliability of analytical results but also the qualification and skill of the analyst and the reliability of the method used. The analytical results of a food control laboratory are often used as evidence in a court of law to determine compliance with regulations or standards of the country. It is therefore necessary that utmost care be taken to ensure the efficient and effective performance of the laboratory. The introduction of analytical quality assurance programmes and accreditation of the laboratory by an appropriate accreditation agency within the country or from outside, enables the laboratory to improve its performance and to ensure reliability, accuracy and repeatability of its results. Prescription of official methods of sampling and analysis also support this effort.

An important element of a national food control system is its integration in a national food safety system so that links between food contamination and foodborne diseases can be established and analyzed. Access to reliable and current intelligence on the incidence of foodborne illness is critical. The laboratory facilities for this type of activity are generally situated outside the food control agencies. It is essential, however, that effective linkages are established between food control agencies and the public health system including epidemiologists and microbiologists. In this way information on foodborne diseases may be linked with food monitoring data, and lead to appropriate risk-based food control policies. This information

includes annual incidence trends, identification of susceptible population groups, identification of hazardous foods, identification and tracing of causes of foodborne diseases, and the development of early warning systems for outbreaks and food contamination.

(e) *Information, Education, Communication and Training*

An increasingly important role for food control systems is the delivery of information, education and advice to stakeholders across the farm-to-table continuum. These activities include the provision of balanced factual information to consumers; the provision of information packages and educational programmes for key officials and workers in the food industry; development of train-the-trainer programmes; and provision of reference literature to extension workers in the agriculture and health sectors.

Food control agencies should address the specific training needs of their food inspectors and laboratory analysts as a high priority. These activities provide an important means of building food control expertise and skills in all interested parties, and thereby serve an essential preventive function.

5. STRENGTHENING NATIONAL FOOD CONTROL SYSTEMS

5.1 Principles of Food Control: Issues for Consideration

When seeking to establish, update, strengthen or otherwise revise food control systems, national authorities must take into consideration a number of principles and values that underpin food control activities, including the following:

- Maximizing risk reduction by applying the principle of prevention as fully as possible throughout the food chain;
- Addressing the farm-to-table continuum;
- Establishing emergency procedures for dealing with particular hazards (e.g. recall of products);
- Developing science-based food control strategies;
- Establishing priorities based on risk analysis and efficacy in risk management;
- Establishing holistic, integrated initiatives which target risks and impact on economic well-being; and
- Recognizing that food control is a widely shared responsibility that requires positive interaction between all stakeholders.

Certain key principles and related issues are discussed below.

(a) *Integrated farm-to-table concept*

The objective of reduced risk can be achieved most effectively by the principle of prevention throughout the production, processing and marketing chain. To achieve maximum consumer protection it is essential that safety and quality be built into food products from production through to consumption. This calls for a comprehensive and integrated **farm-to-table** approach in which the producer, processor, transporter, vendor, and consumer all play a vital role in ensuring food safety and quality.

It is impossible to provide adequate protection to the consumer by merely sampling and analysing the final product. The introduction of preventive measures at all stages of the food production and distribution chain, rather than only inspection and rejection at the final stage, makes better economic sense, because unsuitable products can be identified earlier along the chain. The more economic and effective strategy is to entrust food producers and operators with primary responsibility for food safety and quality. Government regulators are then responsible for auditing performance of the food system through monitoring and surveillance activities and for enforcing legal and regulatory requirements.

Food hazards and quality loss may occur at a variety of points in the food chain, and it is difficult and expensive to test for their presence. A well structured, preventive approach that controls processes is the preferred method for improving food safety and quality. Many but not all potential food hazards can be controlled along the food chain through the application of good practices *i.e.* good agricultural practices (GAP), good manufacturing practices (GMP), and good hygienic practices (GHP).

An important preventative approach that may be applied at all stages in the production, processing and handling of food products involves the Hazard Analysis Critical Control Point system (HACCP). The principles of HACCP have been formalised by the Codex Committee on Food Hygiene¹, and provide a systematic structure to the identification and control of foodborne hazards. Governments should recognize the application of a HACCP approach by the food industry as a fundamental tool for improving the safety of food.

¹ Codex Alimentarius (1997). Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application. Annex to CAC/RCP 1-1969, Rev. 3 (1997)

(b) Risk Analysis

The Codex Alimentarius Commission defines risk analysis as a process composed of three components:

- **Risk assessment** - a scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterization.
- **Risk management** - the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed selecting appropriate prevention and control options.
- **Risk communication** - the interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk analysis is well established for chemical hazards, and FAO and WHO are now extending the experience and expertise developed from risk analysis of chemical hazards to that of microbiological hazards.

Risk analysis must be the foundation on which food control policy and consumer protection measures are based. While not all countries may have sufficient scientific resources, capabilities, or data to carry out risk assessments, it may not even be necessary in all cases to generate local data for this purpose. Instead countries should make full use of the international data and expertise as well as data from other countries that are consistent with internationally accepted approaches. Risk assessments carried out at the international level by JECFA, JMPR (See Annex 7), and other expert bodies are particularly useful. Developing countries should take a pragmatic approach and develop a cadre of scientists to interpret such data and assessments, and to use this information for the development of national food control programmes.

Codex standards take into account risk assessments carried out at the international level and are accepted as scientifically valid under the SPS Agreement. Hence their adoption and implementation within national food control systems is encouraged.

Risk management should take into account the economic consequences and feasibility of risk management options, and recognize the need for flexibility consistent with consumer protection requirements.

(c) Transparency

A food control system must be developed and implemented in a transparent manner. The confidence of consumers in the safety and quality of the food supply depends on their perception of the integrity and effectiveness of food control operations and activities. Accordingly, it is important that all decision-making processes are transparent, allow all stakeholders in the food chain to make effective contributions, and explain the basis for all decisions. This will encourage cooperation from all concerned parties and improve the efficiency and rate of compliance.

Food control authorities should also examine the manner in which they communicate food safety information to the public. This may take the form of scientific opinion on food safety matters, overviews of inspection activity, and findings on foods implicated in foodborne illnesses, food poisoning episodes, or gross adulteration. All this could be considered as a part of risk communication to enable consumers to better understand the risks and their responsibilities for minimizing the impact of foodborne hazards.

(d) Regulatory Impact Assessment

When planning and implementing food control measures, consideration must be given to the costs of compliance (resources, personnel, and financial implications) to the food industry, as

these costs are ultimately passed onto consumers. The important questions are: Do the benefits of regulation justify the costs? What is the most efficient management option? Export inspection systems designed to assure the safety and quality of exported foods, will protect international markets, generate business and secure returns. Animal and plant health measures improve agricultural productivity. In contrast, food safety is an essential public health goal and may impose costs on producers, yet investments in food safety may not be immediately rewarded in the market place.

Regulatory impact assessments (RIA) are of increasing importance in determining priorities and assist food control agencies in adjusting or revising their strategies to achieve the most beneficial effect. They are, however, difficult to carry out. Two approaches have been suggested for determining cost/benefit of regulatory measures in food safety:

- Theoretical models can be developed to estimate *willingness to pay* (WTP) for reduced risk of morbidity and mortality; and
- *Cost of illness* (COI) covering lifetime medical costs and lost productivity.

Both approaches require considerable data for interpretation. COI estimates are perhaps easier for policy makers to understand and have been widely used to justify measures for food control, even though they do not measure the full value of risk reduction. Not surprisingly, it is easier to perform a RIA for an export inspection intervention, than for regulatory policy which achieves a public health outcome.

5.2 Developing a National Food Control Strategy

The attainment of food control system objectives requires knowledge of the current situation and the development of a national food control strategy. Programmes to achieve these objectives tend to be country specific. Like socioeconomic considerations, they are also influenced by current or emerging food safety and quality issues. Such programmes also need to consider international perceptions of food risks, international standards, and any international commitments in the food protection area. Therefore, when establishing a food control system it is necessary to systematically examine all factors that may impinge upon the objectives and performance of the system, and develop a national strategy.

(a) Collection of Information

This is achieved through the collection and collation of relevant data in the form of a Country Profile (See Annex 8). This data underpins strategy development, with stakeholders reaching consensus on objectives, priorities, policies, roles of different ministries/agencies, industry responsibilities, and timeframe for implementation. In particular, major problems associated with the control and prevention of foodborne diseases are identified so that effective strategies for the resolution of these problems can be implemented.

The profile should permit a review of health and socioeconomic issues impacting on foodborne hazards, consumers concerns, and the growth of industry and trade, as well as identification of the functions of all sectors which are directly and indirectly involved in ensuring food safety and quality and consumer protection. The collection of epidemiological data on foodborne illness is an indispensable component of a country profile and should be done whenever possible.

(b) Development of Strategy

The preparation of a national food control strategy enables the country to develop an integrated, coherent, effective and dynamic food control system, and to determine priorities which ensure consumer protection and promote the country's economic development. Such a strategy should provide better coherence in situations where there are several food control agencies involved with no existing national policy or overall coordinating mechanism. In such cases, it prevents confusion, duplication of effort, inefficiencies in performance, and wastage of resources.

Devising strategies for food control with clearly defined objectives is not simple, and the identification of priorities for public investment in food control can be a challenging task. The strategy should be based on multi-sectoral inputs and focus on the need for food security, and consumer protection from unsafe adulterated or misbranded food. At the same time it should take into consideration the economic interests of the country in regard to export/import trade, the development of the food industry, and the interests of farmers and food producers. Strategies should use a risk based approach to determine priorities for action. Areas for voluntary compliance and mandatory action should be clearly identified, and timeframes determined. The need for human resource development and strengthening of infrastructure such as laboratories should be also considered.

Certain types of food control interventions require large fixed capital investments in equipment and human resources. While it is easier to justify these costs for larger enterprises, imposing such costs on smaller firms who may coexist with larger enterprises may not be appropriate. Therefore the gradual phasing in of such interventions is desirable. For example, countries may allow small enterprises longer periods of time to introduce HACCP.

The strategy will be influenced by the country's stage of development, the size of its economy, and the level of sophistication of its food industry. The final strategy should include:

- A national strategy for food control with defined objectives, a plan of action for its implementation, and milestones;
- Development of appropriate food legislation, or revision of the existing legislation to achieve the objectives defined by the national strategy;
- Development or revision of food regulations, standards and codes of practice as well as harmonizing these with international requirements;
- A programme for strengthening food surveillance and control systems;
- Promotion of systems for improving food safety and quality along the food chain *i.e.* introduction of HACCP-based food control programmes;
- Development and organization of training programmes for food handlers and processors, food inspectors, and analysts;
- Enhanced inputs into research, foodborne disease surveillance, and data collection, as well as creating increased scientific capacity within the system; and
- Promotion of consumer education and other community outreach initiatives.

5.3 Strengthening Organizational Structures for National Food Control Systems

Given the wide scope of food control systems, there are at least three types of organizational arrangements that may be appropriate at the national level. These are:

- A system based on multiple agencies responsible for food control - Multiple Agency System;
- A system based on a single, unified agency for food control - Single Agency System;
- A system based on a national integrated approach - Integrated System.

(a) Multiple Agency System

While food safety is the foremost objective, food control systems also have an important economic objective of creating and maintaining sustainable food production and processing systems. In this context, food control systems play a significant role in the following:

- Ensuring fair practices in trade;
- Developing the food sector on a professional and scientific basis;
- Preventing avoidable losses and conserving natural resources; and
- Promoting the country's export trade.

The systems that deal specifically with these objectives can be sectoral *i.e.* based upon the need for development of the particular sector such as fisheries, meat and meat products, fruit and vegetables, milk and milk products. These systems can be mandatory or voluntary, and put into effect either through a general food law or a sectoral regulation. Examples include:

- An export inspection law that identifies foods to be covered for mandatory export inspection prior to export; or offers facilities for voluntary inspection and certification for exporters.
- Specific commodity inspection regulations, such as for fish and fish products, meat and meat products, or fruit and vegetable products which are implemented by different agencies or ministries given this mandate under relevant law(s).
- Regulated systems for grading and marking of fresh agricultural produce which go directly for sale to the consumer or as raw material for industry. They are mostly confined to quality characteristics so that the producer gets a fair return for his produce and the buyer is not cheated.

Where sectoral initiatives have resulted in the establishment of separate food control activities, the outcome has been the creation of multiple agencies with responsibilities for food control. Typically, under such arrangements the food control responsibilities are shared between Government Ministries such as Health, Agriculture, Commerce, Environment, Trade and Industry, and Tourism, and the roles and responsibilities of each of these agencies are specified but quite different. This sometimes leads to problems such as duplication of regulatory activity, increased bureaucracy, fragmentation, and a lack of coordination between the different bodies involved in food policy, monitoring, and control of food safety. For example, the regulation and surveillance of meat and meat products may be separate from food control undertaken by a Ministry of Health. Meat inspection is often done by Ministry of Agriculture or primary industry personnel who undertake all veterinary activities, and the data generated may not be linked to public health and food safety monitoring programmes.

Food control systems may also be fragmented between national, state and local bodies, and the thoroughness of implementation depends upon the capacity and the efficiency of the agency responsible at each level. Thus consumers may not receive the same level of protection throughout the country and it may become difficult to properly evaluate the effectiveness of interventions by national, state or local authorities.

While multiple food control agencies may be the norm, they suffer from serious drawbacks including:

- Lack of overall coordination at national level;
- Frequent confusion over jurisdiction and resultant inefficiencies in performance;
- Differences in levels of expertise and resources and hence uneven implementation;
- Conflict between public health objectives and the facilitation of trade and industry development;
- Limited capacity for appropriate scientific inputs in decision-making processes;
- Lack of coherence leading to over-regulation or time gaps in adequate regulatory activity; and
- Reductions in the confidence of domestic consumers and foreign buyers in the credibility of the system.

During the preparation of a national food control strategy, it is important to consider the type and size of the organization(s) that are necessary to implement the strategy. It is often not possible to have a single unified structure or an integrated food control system, due to various historical and political reasons. In such cases, it is necessary for the national food control strategy to clearly identify the role of each agency to avoid duplication of effort and to bring about a measure of coherence among them. It should also identify areas or segments of the food chain which require special attention and need additional resources for strengthening.

(b) Single Agency System

The consolidation of all responsibility for protecting public health and food safety into a single food control agency with clearly defined terms of reference has considerable merit. It acknowledges the high priority that Government places in food safety initiatives and a commitment to reducing the risk of foodborne disease. The benefits that result from a single agency approach to food control include:

- Uniform application of protection measures;
- Ability to act quickly to protect consumers;
- Improved cost efficiency and more effective use of resources and expertise;
- Harmonization of food standards;
- Capacity to quickly respond to emerging challenges and the demands of the domestic and international marketplace; and
- The provision of more streamlined and efficient services, benefiting industry and promoting trade.

While a national strategy helps to influence both the legislation and the organizational structure for enforcement, it is not possible to recommend a single organizational structure that will universally meet the requirements and resources of every country's socioeconomic and political environment. The decision has to be country specific and all stakeholders should have the opportunity to provide inputs into the development process. Unfortunately, there are often few opportunities for countries to build a new food control system based on a single agency.

(c) Integrated System

Integrated food control systems warrant consideration where there is desire and determination to achieve effective collaboration and coordination between agencies across the farm-to-table continuum. Typically, the organization of an integrated food control system would have several levels of operation:

- Level 1: Formulation of policy, risk assessment and management, and development of standards and regulations.
- Level 2: Coordination of food control activity, monitoring, and auditing.
- Level 3: Inspection, and enforcement.
- Level 4: Education and training.

In reviewing and revising their food control systems, governments may wish to consider a model which calls for the establishment of an autonomous national food agency which is responsible for activities at Levels 1 and 2, with existing multi-sectoral agencies retaining responsibility for Level 3 and 4 activities. The advantages of such a system include:

- Provides coherence in the national food control system;
- Politically more acceptable as it does not disturb the day to day inspection and enforcement role of other agencies;
- Promotes uniform application of control measures across the whole food chain throughout the country;
- Separates risk assessment and risk management functions, resulting in objective consumer protection measures with resultant confidence among domestic consumers and credibility with foreign buyers;
- Better equipped to deal with international dimensions of food control such as participation in work of Codex, follow-up on SPS/TBT Agreements, etc;
- Encourages transparency in decision-making processes, and accountability in implementation; and

- Is more cost-effective in the long term.

Responding to these benefits, several countries have established or are in the process of creating such a policy making and coordinating mechanism at the national level. Case studies demonstrating national food control systems in selected countries are presented in Annex 9.

By placing management of the food supply chain under a competent, autonomous agency, it is possible to fundamentally change the way food control is managed. The role of such an agency is to establish national food control goals, and put into effect the strategic and operational activities necessary to achieve those goals. Other functions of such a body at the national level may include:

- Revising and updating the national food control strategy as needed;
- Advising relevant ministerial officials on policy matters, including determination of priorities and use of resources;
- Drafting regulations, standards and codes of practice and promoting their implementation;
- Coordinating the activity of the various inspection agencies, and monitoring performance;
- Developing consumer education and community outreach initiatives and promoting their implementation;
- Supporting research and development; and
- Establishing quality assurance schemes for industry and supporting their implementation.

An integrated National Food Control Agency should address the entire food chain from farm-to-table, and should have the mandate to move resources to high priority areas and to address important sources of risk. The establishment of such an agency should not involve day-to-day food inspection responsibilities. These should continue to lie with existing agencies at national, state/provincial, and local levels. The agency should also consider the role of private analytical, inspection, and certification services particularly for export trade.

See Annex 10 for further details on selected organizational components of a National Food Control Agency.

See Annex 11 for details on possible activities to be undertaken during the establishment and initial operation of a National Food Control Agency.

5.4 Funding National Food Control Systems

The funds and resources required for reorganizing and strengthening food control systems would normally be made available from the national government. In countries where food control responsibilities are spread across many government agencies it may be necessary to negotiate a revised funding structure and establish transition arrangements to ensure continuity of funds and resources. For this to occur, it is essential there is full commitment by the government for establishing appropriate structures and developing policies to deliver the optimum level of consumer protection.

Securing sufficient resources may be a problem, as the trend towards reduced public sector spending is influencing governments to review their priorities and funding arrangements. Cost recovery is practised in many countries. It is important that this is managed carefully as any costs passed directly onto the food industry will ultimately be passed onto consumers as an indirect tax on food. This falls disproportionately on the poorer sectors of society. Cost recovery options include fees for licensing, inspection activity, and food analysis. In some countries the trend towards smaller governments has resulted in the contracting of food control services from the private sector. This involves private providers contracted to undertake specific food control activities such as food inspection and surveillance.

6. SPECIFIC ISSUES OF DEVELOPING COUNTRIES

6.1 Food Systems

Food production, processing, and marketing systems are complex. In many developing countries they are also highly fragmented and dependent upon a large number of small producers. While this may have socioeconomic benefits, as large quantities of food pass through a multitude of food handlers and middlemen, the risk of exposing food to unhygienic environments, contamination and adulteration increases. Problems occur as a result of poor post-harvest handling, processing and storage of food and also due to inadequate facilities and infrastructure such as the absence or shortage of safe water supply, electricity, storage facilities including cold stores, and transport facilities and networks, etc. Furthermore, a majority of food producers and handlers lack appropriate knowledge and expertise in the application of modern agricultural practices, food hygiene, and good food handling practices.

This does not mean that all food from such sources is unsafe. Many traditional food production and handling practices have in-built food safety margins based on years of experience. Problems arise because of the inability to cope with the introduction of emerging intensive agricultural practices, increasing urbanization, stress on natural resources, and new food safety risks.

6.2 Food Processing Industry

The food processing industry in developing countries ranges from sophisticated state-of-the-art facilities to small artisanal operations producing traditional foods for the local community. The size of these processing units is quite variable – from a few large plants to a majority of small and cottage scale units with very limited resources for effective technological inputs. At the least developed end of this continuum, these premises are ill equipped to deal with the maintenance of food safety and quality in a scientific and sustained manner. Governments often support these small units as they provide employment and generate income for their operators. The challenge for developing countries is to provide incentives for the effective expansion of these small units so they may absorb better technology.

Food processors in developing countries also face problems with the reliability and timely delivery of raw material, as well as variations in overall quality. Smallholders usually produce raw materials, and a lack of infrastructure in the producing areas results in variability in the quality of these materials. This calls for greater vigilance by the food processing units and for food control activity to be implemented at all stages along the food supply chain.

6.3 Street Foods

Studies in developing countries have shown that up to 20-25% of household food expenditure is incurred outside the home, and some segments of the population depend entirely on street foods. This has been one of the consequences of rapid urbanization, with millions of people having no access to a kitchen or other cooking facilities. There are millions of single workers without families and a large floating population who move in and out of the city for work, and these people largely depend upon street foods for their daily sustenance.

In many developing countries, street food vendors are an important component of the food supply chain. Being reasonably priced and conveniently available, street food satisfies a vital need of the urban population. These ready-to-eat foods and beverages are prepared and/or sold by vendors or hawkers mainly in streets or other convenient public places such as around places of work, schools, hospitals, railway stations, and bus terminals.

Food safety is a major concern with street foods. These foods are generally prepared and sold under unhygienic conditions, with limited access to safe water, sanitary services, or garbage disposal facilities. Hence street foods pose a high risk of food poisoning due to microbial contamination, as well as improper use of food additives, adulteration and environmental contamination.

6.4 Food Control Infrastructure and Resources

Food control infrastructure in many developing countries tends to be inadequate, due to limited resources and often poor management. Food control laboratories are frequently poorly equipped and lack suitably trained analytical staff. This is accentuated where multiple agencies are involved in food control. A lack of overall strategic direction means that limited resources are not properly utilized. Food control systems may also suffer from poorly or inadequately developed compliance policies.

Modern food control systems call for science-based and transparent decision-making processes, and require access to qualified and trained personnel in disciplines such as food science and technology, chemistry, biochemistry, microbiology, veterinary science, medicine, epidemiology, agricultural sciences, quality assurance, auditing and food law. Food control authorities need to better appreciate the role of science in the risk-based approach, and to take advantage of scientific resources in the international community.

6.5 Technical Assistance: Role of International Agencies

The need for technical assistance in strengthening food control systems in developing countries is well recognized. FAO and WHO are the two main specialized agencies of the United Nations involved in food quality and safety technical cooperation programmes with developing countries.

FAO assistance in food control and food standards is a major activity and is delivered at global, regional, and country levels. Published manuals of food quality control cover a range of different aspects of food control systems and are used internationally. Meetings, seminars and workshops are conducted in all regions of Africa, Asia and the Pacific, Latin America and the Caribbean, Eastern Europe, the Near East and North Africa. Technical assistance is provided in many areas such as the following:

- Establishing or strengthening national food control systems and infrastructure;
- Assistance in preparation of food law and regulations;
- Workshops on developing national strategies for food control;
- Assistance in establishing or improving food analysis capabilities;
- Assessing the implications of SPS and TBT Agreements (see Annex 5);
- Providing training in food inspection, analysis and food handling;
- Providing training of trainers in HACCP;
- Providing training in management of food control systems; and
- Assistance in strengthening National Codex Committees (see Annex 4).

WHO has in recent years substantially increased the priority of its food safety activities at international and regional level. The Organization also provides technical assistance at international, regional, and country levels. Under its decentralized structure, WHO is divided into six regions, with Regional Offices responsible for providing assistance to Member States in developing and strengthening their National Food Safety Programmes. Regional Offices currently undertake a range of capacity building initiatives designed to safeguard consumer health. The nature and extent of these activities is influenced by available resources, but includes the following.

- Developing regional and national food safety policy and strategies;
- Preparation of food legislation, food regulations and standards, and codes of hygienic practice;
- Implementation of food inspection programmes;
- Promoting methods and technologies designed to prevent foodborne diseases, including the application of the HACCP system;

- Developing or enhancing food analysis capability;
- Development and delivery of hygiene training and education programmes;
- Establishing healthy markets and enhancing the safety of street food; and
- Promoting the establishment of foodborne disease surveillance activity.

Both the SPS Agreement (Article 9) and TBT Agreement (Article 11) specifically refer to the need to provide technical assistance to developing countries. Such assistance may be in areas of processing technologies, research and infrastructure, establishment of national regulatory bodies, etc. In particular, developed countries which import food from developing nations are required, upon request, to provide technical assistance to the developing exporting countries to enable these countries to meet their SPS or TBT obligations in international food trade. Details of the SPS and TBT Agreements are contained in Annex 5. This new opportunity to access technical assistance under the WTO Agreements has not yet been fully utilized by developing countries.

Technical assistance in the food control area may also be obtained through the World Bank, other development banks, and from bilateral donor agencies. Access to such funds is dependent upon the priority that developing countries attach to strengthening their food control systems as reflected in their national development plans.

ANNEX 1. Glossary

Audit	A systematic examination to determine whether what is actually happening complies with documented procedures.
Codex Alimentarius Commission	The Codex Alimentarius Commission is a subsidiary body of the Food and Agriculture Organization of the United Nations and the World Health Organization. The Commission is entrusted with the elaboration of international standards of food to protect the health of consumers and to ensure fair practices in the food trade.
Codex Committees	These subsidiary bodies of the Codex Alimentarius Commission include nine general subject committees, fifteen specific commodity committees, six regional coordinating committees and time-limited ad-hoc Intergovernmental Task Forces on specific subjects.
Critical Control Point	A step at which control is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
Equivalence	The process of recognition that enables the sanitary and phytosanitary measures employed in one country to be deemed equivalent to those of a second country, trading in the same product, although different control measures are being practised.
Farm-to-Table	Includes all steps involved in the production, storage, handling, distribution and preparation of a food product.
Food Contaminant	Any biological or chemical agent, foreign matter, or other substance not intentionally added to food which may compromise food safety or suitability.
Food Control	A mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all foods during production, handling, storage, processing and distribution are safe, wholesome and fit for human consumption; conform to quality and safety requirements; and are honestly and accurately labelled as prescribed by law.
Food Hygiene	All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.
Food Inspection	The examination, by an agency empowered to perform regulatory and/or enforcement functions, of food products or systems for the control of raw materials, processing, and distribution. This includes in-process and finished product testing to verify that they conform to regulatory requirements.

Food Surveillance	The continuous monitoring of the food supply to ensure consumers are not exposed to components in foods, such as chemical contaminants or biological hazards, which pose a risk to health.
Good Agricultural Practices (GAP)	Practices of primary food producers (such as farmers and fishermen) that are necessary to produce safe and wholesome agricultural food products conforming to food laws and regulations.
Good Manufacturing Practices (GMP)	Conformance with codes of practice, industry standards, regulations and laws concerning production, processing, handling, labelling and sale of foods decreed by industry, local, state, national and international bodies with the intention of protecting the public from illness, product adulteration and fraud.
GMO	Genetically modified organism.
HACCP Plan	A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.
HACCP System	The hazard analysis critical control point system (HACCP) is a scientific and systematic way of enhancing the safety of foods from primary production to final consumption through the identification and evaluation of specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing.
Hazard	A biological, chemical or physical agent in, or condition of, food with the potential to cause harm.
Hazard Analysis	The process of collecting and interpreting information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.
JECFA	Joint FAO/WHO Expert Committee on Food Additives.
JMPR	Joint FAO/WHO Meeting on Pesticide Residues.
Monitoring	In a HACCP plan, the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control.
RIA	Regulatory impact assessment.
Risk Analysis	A process consisting of three components: risk assessment, risk management and risk communication.
Risk Assessment	A scientifically based process consisting of the following steps: hazard identification, hazard characterization, exposure assessment, and risk characterization.

Risk Characterization	The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.
Risk Communication	The interactive exchange of information and opinions concerning risks among risk assessors, risk managers, consumers and other interested parties.
Risk Management	The process of weighing policy alternatives in the light of results of risk assessment, and, if required, selecting and implementing appropriate control options, including regulatory measures.
SPS	Sanitary and Phytosanitary Agreement of the World Trade Organization (WTO).
TBT	Technical Barriers to Trade Agreement of the World Trade Organization (WTO).
Verification	In HACCP, the use of methods, procedures, or tests in addition to those used in monitoring to determine compliance with the HACCP plan, and/or whether the HACCP plan needs modification in order to enhance food safety.
WTO	The World Trade Organization (WTO) is the international organization that establishes the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments. The goal is to help producers of goods and services, exporters, and importers conduct their business.

ANNEX 2. Addresses and Key Contacts

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO)

Food Quality and Standards Service
Food and Nutrition Division
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00100 Rome
Italy
Web Site: <http://www.fao.org>

WORLD HEALTH ORGANIZATION (WHO)

Food Safety Department
Cluster on Sustainable Development and Healthy Environments (FOS/SDE)
World Health Organization
20 Avenue Appia
1211 Geneva 27
Switzerland
Web Site: <http://www.who.int/fsf/>

JOINT FAO/WHO CODEX SECRETARIAT

Secretariat of the Joint FAO/WHO Food Standards Programme
Food and Nutrition Division
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00100 Rome
Italy
Web Site: <http://www.codexalimentarius.net/>

WORLD TRADE ORGANIZATION (WTO)

World Trade Organization
Rue de Lausanne 154
CH-1211 Geneva 21
Switzerland
Web Site: <http://www.wto.org>

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
Australia
Web Site: <http://www.foodstandards.gov.au>
or
PO Box 10559
The Terrace, Wellington
6036
New Zealand

U.S. DEPARTMENT OF AGRICULTURE (USDA)

U.S. Department of Agriculture
Room 4861 South Building
1400 Interdependence Avenue, SW
Washington, DC 20250
USA
Web Site: <http://www.fsis.usda.gov>

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

U. S. Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001
USA
Web Site: <http://www.fda.gov>
<http://www.cfsan.fda.gov/list.html> FDA Center for Food Safety and Applied Nutrition

FOOD SAFETY AUTHORITY OF IRELAND (FSAI)

Food Safety Authority of Ireland
Abbey Court, Lower Abbey Street
Dublin 1
Ireland
Web Site: <http://www.fsai.ie>

CANADIAN FOOD INSPECTION AGENCY (CFIA)

Canadian Food Inspection Agency
9 Camelot Drive
Nepean
Ontario K1A 0Y9
Canada
Web Site: <http://www.inspection.gc.ca/>

EUROPEAN COMMISSION (EC)

European Commission
B-1049 Brussels
Belgium
Web Site: http://europa.eu.int/pol/food/index_en.htm

European Food Safety Authority (EFSA)

Web Site : <http://www.efsa.eu.int/>

ANNEX 3. Considerations of Food Safety and Consumer Protection

Food safety is an essential public health issue for all countries. Foodborne diseases due to microbial pathogens, biotoxins, and chemical contaminants in food represent serious threats to the health of thousands of millions of people. Serious outbreaks of foodborne disease have been documented on every continent in the past decades, illustrating both the public health and social significance of these diseases. Consumers everywhere view foodborne disease outbreaks with ever-increasing concern. Outbreaks are likely, however, to be only the most visible aspect of a much broader, more persistent problem. Foodborne diseases not only significantly affect people's health and well-being, but they also have economic consequences for individuals, families, communities, businesses and countries. These diseases impose a substantial burden on health-care systems and markedly reduce economic productivity. Poor people tend to live from day to day, and loss of income due to foodborne illness perpetuates the cycle of poverty.

The integration and consolidation of food industries and the globalization of the food trade are changing the patterns of food production and distribution. Food and feed are distributed over far greater distances than before, creating the conditions necessary for widespread outbreaks of foodborne illness. In a recent crisis, more than 1500 farms in Europe received dioxin-contaminated feed from a single source over a two-week period. Food produced from animals given this contaminated fodder found its way onto every continent within weeks. The international spread of meat and bonemeal prepared from cattle affected by bovine spongiform encephalitis (BSE) needs no further description. The full economic consequences of such incidents and the anxiety raised among consumers are still being assessed.

Other factors account for the emergence of food safety as a public health issue. Increasing urbanization leads to greater requirements for transport, storage and preparation of food. In developing countries, food is often prepared by street vendors. In developed countries, up to 50% of the food budget may be spent on food prepared outside the home. All these changes lead to situations in which a single source of contamination can have widespread, even global consequences.

The globalization of the food trade offers many benefits to consumers, as it results in a wider variety of high-quality foods that are accessible, affordable and safe, meeting consumer demand. The global food trade provides opportunities for food-exporting countries to earn foreign exchange, which is indispensable for the economic development of many countries. However, these changes also present new challenges to safe food production and distribution and have been shown to have widespread repercussions on health.

Food safety programmes are increasingly focusing on a farm-to-table approach as an effective means of reducing foodborne hazards. This holistic approach to the control of food-related risks involves consideration of every step in the chain, from raw material to food consumption. Hazards can enter the food chain on the farm and can continue to be introduced or exacerbated at any point in the chain.

Although significant progress has been made in many countries in making food safer, thousands of millions of people become ill each year from eating contaminated food. The emergence of increased antimicrobial resistance in bacteria causing disease is aggravating this picture. The public is increasingly aware of the risks posed by pathogenic microorganisms and chemical substances in the food supply. The introduction of new technologies, including genetic engineering and irradiation, in this climate of concern about food safety is posing a special challenge. Some new technologies will increase agricultural production and make food safer, but their usefulness and safety must be demonstrated if they are to be accepted by consumers.

Furthermore, the evaluation must be participatory, transparent and conducted using internationally agreed methods.

Until recently, most systems for regulating food safety were based on legal definitions of unsafe food, enforcement programmes for the removal of unsafe food from the market and sanctions for the responsible parties after the fact. These traditional systems cannot respond to existing and emerging challenges to food safety because they do not provide or stimulate a *preventive* approach. During the past decade, there was a transition to risk analysis based on better scientific knowledge of foodborne illness and its causes. This provides a preventive basis for regulatory measures for food safety at both national and international levels. The risk-based approach must be backed by information on the most appropriate and effective means to control foodborne hazards.

Microbiological Hazards

The dangers of foodborne pathogenic microorganisms have been known for decades. The risk of milk-borne transmission of tuberculosis and salmonellosis was recognized early in the twentieth century, and control by pasteurization was an early intervention. Similarly, problems with botulism were managed by controlling the application of heat to low acid foods in hermetically sealed containers. Despite remarkable advances in food science and technology, foodborne illness is a rising cause of morbidity in all countries and the list of potential foodborne microbial pathogens keeps increasing. Furthermore, foodborne illness is a major cause of preventable death and economic burden in most countries. Unfortunately, most countries have limited data on foodborne disease and its impact on public health.

It is only recently that the burden of food contamination and foodborne disease have been systematically assessed and quantified. Studies on foodborne disease outbreaks in the USA, Australia, Germany, and India have confirmed the enormity of the problem with millions being affected or dying from foodborne diseases. The data indicates that up to 30% of the population in industrialized countries may be affected by foodborne illness each year. The global incidence of foodborne disease is difficult to estimate, but in 1998 it was estimated that 2.2 million people, including 1.8 million children, died from diarrhoeal diseases.

The economic cost associated with foodborne diseases caused by microorganisms has only recently been estimated. In the US, the costs of human illness due to seven specific pathogens have been estimated to range between US \$6.5 billion to \$34.9 billion². The medical costs and value of lives lost from five foodborne infections in England and Wales were estimated at UK £300-700 million annually in 1996³. The cost of an estimated 11,500 cases of food poisoning per day in Australia was calculated at AUD \$2.6 billion annually⁴. Yet on the basis of per capita income, the economic burden on people in India affected by an outbreak of *Staphylococcus aureus* food poisoning was found to be higher than in case of a similar outbreak in the US⁵.

Major outbreaks involving *E.coli* and *Salmonella* have highlighted problems with food safety and increased public anxiety that modern farming systems, food processing and marketing may not provide adequate safeguards for public health. While our understanding of the ecology of food poisoning organisms and the environment in which they may grow and survive has increased, our ability to control some of these organisms has declined. This may be due in part to modified production practices, lack of control of hazards at the farm level, industry difficulties in controlling hazards during production, growing demand for fresh foods, the trend towards minimal processing of foodstuffs and longer shelf-life for many foodstuffs. For example, *Salmonella* persists as a major cause of food poisoning and its incidence is on the rise. *Salmonella Typhimurium* DT 104 is

² Buzby, J.C. and Roberts, T. (1997). Economic costs and trade implications of microbial foodborne illness. World Health Statistics Quarterly, 50, (1/2), 57-66

³ Robert, J.A. (1996). Economic evaluation of Surveillance. London, Dept of Public Health and Policy.

⁴ Australia New Zealand Food Authority (1999). Food Safety Standards – Costs and Benefits. (ANZFA).

⁵ Sudhakar, P.; Nageswara Rao, R.; Bhat, R. and Gupta, C.P. (1988) The economic impact of foodborne disease outbreak due to *Staphylococcus aureus*. Journal of Food Protection, 51, (11)

widely distributed in cattle herds and is resistant to several antibiotics. The incidence of this organism is on the increase, as is the number of antibiotic resistant isolates. More than one third of people infected by this organism require hospitalization with approximately three percent of cases being fatal.

Enterohaemorrhagic *Escherichia coli* O157:H7 has emerged as a significant foodborne pathogen, and has been highly publicised through major outbreaks of disease. *E.coli* O157:H7 was first recognized as a pathogen in 1982, but progress to identify reservoirs and sources of the organism was initially hampered by a lack of sufficiently sensitive detection methods. Other strains of enterohaemorrhagic *E.coli* (EHECs) pose a particular problem in that they are impossible to differentiate culturally from other flora in the gut. Identification requires advanced techniques.

E.coli O157:H7 serves as an example of the limitation of the present knowledge and understanding of many pathogens and how they contaminate food. In the past few decades a range of microorganisms have emerged as potential causes of foodborne disease. Several relatively unknown bacteria have been identified as major causes of foodborne illness e.g. *Campylobacter jejuni*, *Vibrio parahaemolyticus*, and *Yersinia enterocolitica* may cause foodborne illness. As microorganisms have the ability to adapt, modified modes of food production, preservation and packaging have resulted in altered food safety hazards. For example, organisms such as *Listeria monocytogenes*, and to a lesser extent *Clostridium botulinum*, have emerged and re-emerged because of changes in the way high-risk foods are packaged and processed.

A range of protozoa and viruses may also infect food e.g. *Cryptosporidium parvum*, *Toxoplasma gondii*, *Clonorchis sinensis*, Norwalk virus, and hepatitis A. The effective prevention and control of these organisms requires widespread education and possibly new initiatives such as HACCP being introduced at primary production level.

Chemical Hazards

Chemical hazards are also a significant source of foodborne illness, although the effect is often difficult to link to a particular food and may occur long after consumption. In particular, there have been long-standing concerns about the chemical safety of food due to misuse of pesticides during food production and storage, resulting in the occurrence of undesirable residues. Similarly, heavy metal contaminants can enter food through soil or water or food contact material, as can other environmental contaminants such as PCBs. All can lead to acute or chronic illness.

More recently, contamination from dioxins entering the animal feed supply has highlighted both the importance of controlling the whole food chain and the international concerns about food safety systems. Misuse and illegal use of food additives create their own food safety problems. Phthalates in infant formulae, substances in food with oestrogenic activity, and veterinary drug residues, etc have also heightened public concern.

These problems are not confined to food produced on land. They also include algal toxins in fish and the widespread use of chemicals in fish farming. Mycotoxins are another group of highly toxic or carcinogenic chemical contaminants of biological origin produced by certain species of fungi. Five important mycotoxins are aflatoxins, ochratoxins, fumonisins, zearalenone, and trichothecenes. Crops such as peanuts, corn, pistachio, walnuts, copra are susceptible to mycotoxin contamination. Aflatoxins are among the most studied mycotoxins, and the relationship between aflatoxin ingestion and primary liver cancer is well established. Almost all plant products can serve as substrates for fungal growth, and subsequently mycotoxin contamination of human food and animal feed. Animal feed contaminated with mycotoxins can result in the carry-over of toxins through milk and meat to consumers.

While the importance of chemicals hazards is well recognized, our understanding of the effect of chemicals in food intolerances and allergies, endocrine system disruption, immunotoxicity, and certain forms of cancer are incomplete. Further research is necessary to determine the role of

chemicals in foods in the etiology of these diseases. In developing countries, little reliable information is available on the exposure of the population to chemicals in food.

Food Adulteration

Consumers, particularly in developing countries, are often exposed to wilful adulteration of their food supply. This can lead to health hazards and to financial losses for the consumer. Adulteration of milk and milk products, honey, spices, edible oils, and the use of colours to mask product quality to cheat the consumer are quite common. Although risks associated with adulteration are usually low, such episodes invoke public outrage and anger as it violates public trust in the integrity of the food supply. With 60-70% of the income of middle class families in developing countries being spent on food, food adulteration can impact heavily on both the family budget and the health status of the family members.

Genetically Modified Organisms (GMO) and Novel Foods

Modern biotechnology, also referred to as *genetic engineering* or *genetic manipulation*, involves transfer of hereditary material (DNA, RNA) from one organism to another in a way that cannot be achieved naturally *i.e.* through mating or cross breeding. Genetic engineering can now transfer the hereditary material across species boundaries. This can broaden the range of genetic changes that can be made to food and can expand the spectrum of possible food sources.

The accelerating pace of developments in modern biotechnology has opened a new era in food production and this may have a tremendous impact on world food supply systems. However, there are considerable differences of opinion among scientists about the safety, nutritional value and environmental effects of such foods.

Overall, it is argued that the consequences of some gene transfer methods are less predictable when compared to those of traditional plant breeding methods and considerable scientific evidence will be needed to clear these foods from points of view of nutrition, food safety and impact on the environment. The revolutionary nature of modern biotechnology and its likely impact on world food resources has created worldwide interest and debate among scientists, consumers and industry as well as among policy makers at national and international levels.

Urbanization, Nutrition and Food Security

In 2020, the world population is projected to reach 7.6 billion, an increase of 31% over the mid-1996 population of 5.8 billion. Approximately 98% of the population growth occurring during this period will take place in developing countries. While urbanization is a global phenomenon, it has been estimated that between the years 1995 and 2020 the developing world's urban population will double, reaching 3.4 billion. Such population growth poses great challenges to world food security and food systems. Further extension of improved agriculture and animal husbandry practices; use of measures to prevent and control pre- and post-harvest losses; more efficient food processing and distribution systems; introduction of new technologies including the application of biotechnology, and others will have to be exploited to increase food availability to meet the needs of growing populations.

Growing urbanization and associated changes in the way food is produced and marketed have led to a lengthening of the food chain and potential for introducing or exacerbating foodborne hazards.

ANNEX 4. Understanding the Joint FAO/WHO Codex Alimentarius Commission

THE COMMISSION

The Eleventh Session of the Conference of FAO in 1961 and the Sixteenth World Health Assembly in 1963 both passed resolutions to establish the Codex Alimentarius Commission. The two bodies also adopted the Statutes and Rules of Procedure for the Commission.

The Statutes provide the legal basis for the Commission's work and formally reflect the concepts behind and reasons for its establishment. Article 1 of the Statutes provides the Commission with its purposes, terms of reference and objectives:

ARTICLE 1

The Codex Alimentarius Commission shall ... be responsible for making proposals to, and shall be consulted by, the Directors-General of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is:

- (a) Protecting the health of consumers and ensuring fair practices in the food trade;
- (b) Promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations;
- (c) Determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;
- (d) Finalizing standards elaborated under (c) above and, after acceptance by governments, publishing them in a Codex Alimentarius either as regional or world wide standards, together with international standards already finalized by other bodies under (b) above, wherever this is practicable;
- (e) Amending published standards, after appropriate survey in the light of developments.

Article 2 defines eligibility for membership of the Commission which is open to all Member Nations and Associate Members of FAO and WHO. In 2002, membership comprised 167 countries, representing 97 percent of the world's population.

The Rules of Procedure of the Codex Alimentarius Commission describe and formalize working procedures appropriate to an intergovernmental body. They provide for:

- Conditions of membership of the Commission;
- The appointment of Commission officers, including the chairperson, three vice-chairpersons, regional coordinators and a secretary, and prescribe their responsibilities;
- The establishment of an executive committee to meet between Commission sessions, to act on behalf of the Commission as its executive organ;
- The frequency and operation of Commission sessions;
- The nature of agendas for Commission sessions;
- Voting procedures;
- Observers;
- Preparation of Commission records and reports;
- Establishment of subsidiary bodies;
- Procedures to be adopted in the elaboration of standards;

- Allocation of a budget and estimates of expenditure; and
- Languages to be used by the Commission.

Currently, the Commission meets every two years, alternately at FAO headquarters in Rome and at WHO headquarters in Geneva. Between sessions of the Commission, the Executive Committee acts on behalf of the Commission. Plenary sessions of the Commission are attended by as many as 500 people. Representation at sessions is on a country basis. National delegations are led by senior officials appointed by their governments. Delegations may, and often do, include representatives of industry, consumers' organizations and academic institutes. Countries that are not yet members of the Commission sometimes attend in an observer capacity.

A number of international governmental organizations and international NGOs also attend in an observer capacity. Although they are "observers", the tradition of the Codex Alimentarius Commission allows such organizations to put forward their points of view at every stage except in the final decision, which is the exclusive prerogative of Member Governments.

To facilitate continuous contact with member countries, the Commission, in collaboration with national governments, has established country **Codex Contact Points** and many member countries have **National Codex Committees** to coordinate activities nationally.

Interest in Codex Alimentarius activities has been growing steadily since the Commission began, and the increasing involvement of developing countries in its work has been a highlight of the progress made as well as a vindication of the foresight shown by the founders of the Commission.

The SPS and TBT agreements of the WTO have accorded additional status to the work of Codex. Codex standards are explicitly recognized as reference in international trade disputes.

THE COMMISSION'S OPERATIONS

Compiling the Codex Alimentarius

One of the principal purposes of the Commission is the preparation of food standards and their publication in the Codex Alimentarius.

The legal base for the Commission's operations and the procedures it is required to follow are published in the **Codex Alimentarius - Procedural Manual**, currently in its twelfth edition. Like all other aspects of the Commission's work, the procedures for preparing standards are well defined, open and transparent. In essence they involve:

- The *submission of a proposal* for a standard to be developed by a national government or a subsidiary committee of the Commission;
- *A decision by the Commission or the Executive Committee that a standard be developed as proposed.* "Formal Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies" assist the Commission or Executive Committee in their decision-making and in selecting or creating the subsidiary body responsible for steering standards through development;
- The preparation of a *proposed draft standard* is arranged by the Commission Secretariat and *circulated to Member Governments* for comment;
- Comments are considered by the subsidiary body that has been allocated responsibility for the development of the proposed draft standard, and this subsidiary body may present the text to the Commission as a *draft standard*;
- If the Commission adopts the draft standard, it is sent to governments a number of times in a step procedure which, if completed satisfactorily, results in the draft becoming a *Codex standard*. In an accelerated procedure, the number of steps required for the development of a standard varies from a maximum of eight to a minimum of five. In some circumstances, steps may be repeated. Most standards take a number of years to develop;

- Once adopted by the Commission, a *Codex standard* is added to the Codex Alimentarius.

A "Format for Codex Commodity Standards and their Content" is provided in the Procedural Manual of the Codex Alimentarius. It includes the following categories of information:

- *Scope* - including the name of the standard;
- *Description, essential composition and quality factors* - defining the minimum standard for the food;
- *Food additives* - only those cleared by FAO and WHO may be used;
- *Contaminants*;
- *Hygiene and weights and measures*;
- *Labelling* - in accordance with Codex General Standard for the Labelling of Pre-packaged Foods; and
- *Methods of analysis and sampling*.

In addition to commodity standards, the Codex Alimentarius includes *general standards*, which have across-the-board application to all foods and are not product-specific. There are general standards or recommendations for:

- Food labelling;
- Food additives;
- Contaminants;
- Methods of analysis and sampling;
- Food hygiene;
- Nutrition and foods for special dietary uses;
- Food import and export inspection and certification systems;
- Residues of veterinary drugs in foods; and
- Pesticide residues in foods.

The Commission and its subsidiary bodies are committed to revision of Codex standards and related texts as necessary to ensure they are consistent with and reflect current scientific knowledge. Each member of the Commission is responsible for identifying and presenting to the appropriate committee any new scientific and other relevant information that may warrant revision of existing Codex standards or related texts. The procedure for revision follows that used for the initial preparation of standards.

Structure of the Codex Alimentarius

- Volume 1A - General requirements;
- Volume 1B - General requirements (food hygiene);
- Volume 2A - Pesticide residues in foods (general texts);
- Volume 2B - Pesticide residues in foods (maximum residue limits);
- Volume 3 - Residues of veterinary drugs in foods;
- Volume 4 - Foods for special dietary uses (including foods for infants and children);
- Volume 5A - Processed and quick-frozen fruits and vegetables;
- Volume 5B - Fresh fruits and vegetables;
- Volume 6 - Fruit juices;
- Volume 7 - Cereals, pulses (legumes) and derived products and vegetable proteins;
- Volume 8 - Fats and oils and related products;
- Volume 9 - Fish and fishery products;

- Volume 10 - Meat and meat products; soups and broths;
- Volume 11 - Sugars, cocoa products and chocolate and miscellaneous products;
- Volume 12 - Milk and milk products;
- Volume 13 - Methods of analysis and sampling.

The volumes contain general principles, general standards, definitions, codes, commodity standards, methods and recommendations. The contents list is well organized for ease of reference, for example:

Volume 1A - General Requirements

1. General Principles of the Codex Alimentarius;
2. Definitions for the Purpose of Codex Alimentarius;
3. Code of Ethics for International Trade in Foods;
4. Food Labelling;
5. Food Additives - including the General Standard for Food Additives;
6. Contaminants in Food - including the General Standard for Contaminants and Toxins in Foods;
7. Irradiated Foods;
8. Food Import and Export Food Inspection and Certification Systems.

Published volumes of the Codex Alimentarius are available in English, French and Spanish, and individual standards are available on the World Wide Web and CD-ROM.

SUBSIDIARY BODIES

Under its Rules of Procedure, the Commission is empowered to establish two kinds of subsidiary body:

- *Codex Committees*, which prepare draft standards for submission to the Commission.
- *Coordinating Committees*, through which regions or groups of countries coordinate food standards activities in the region, including the development of regional standards.

A feature of the committee system is that, with few exceptions, each committee is hosted by a member country, which is chiefly responsible for the cost of the committee's maintenance and administration and for providing its chairperson.

General Subject Committees are so called because their work has relevance for a wide range of foodstuffs. General Subject Committees are sometimes referred to as "horizontal committees".

- *Committee on General Principles*, hosted by France;
- *Committee on Food Labelling*, hosted by Canada;
- *Committee on Methods of Analysis and Sampling*, hosted by Hungary;
- *Committee on Food Hygiene*, hosted by the United States;
- *Committee on Pesticide Residues*, hosted by the Netherlands;
- *Committee on Food Additives and Contaminants*, hosted by the Netherlands;
- *Committee on Import/Export Inspection and Certification Systems*, hosted by Australia;
- *Committee on Nutrition and Foods for Special Dietary Uses*, hosted by Germany (a General Committee for the purpose of Nutrition);
- *Committee on Residues of Veterinary Drugs in Food*, hosted by the United States;
- *Committee on Meat and Poultry Hygiene*, hosted by New Zealand.

Among other things, these Committees develop all-embracing concepts and principles applying to foods in general, specific foods or groups of foods; endorse or review relevant provisions in Codex commodity standards and, based on the advice of expert scientific bodies, develop major recommendations pertaining to consumers' health and safety.

Commodity Committees have responsibility for developing standards for specific foods or classes of food. In order to distinguish them from the "horizontal committees" and recognize their exclusive responsibilities, they are often referred to as "vertical" committees.

- *Committee on Fats and Oils*, hosted by the United Kingdom;
- *Committee on Fish and Fishery Products*, hosted by Norway;
- *Committee on Milk and Milk Products* (formerly the FAO/WHO Committee of Government Experts on the Code of Principles for Milk and Milk Products), hosted by New Zealand;
- *Committee on Fresh Fruits and Vegetables*, hosted by Mexico;
- *Committee on Cocoa Products and Chocolate*, hosted by Switzerland;
- *Committee on Sugars*, hosted by the United Kingdom;
- *Committee on Processed Fruits and Vegetables*, hosted by the United States;
- *Committee on Vegetable Proteins*, hosted by Canada;
- *Committee on Cereals, Pulses and Legumes*, hosted by the United States;
- *Committee on Natural Mineral Waters*, hosted by Switzerland.

Commodity Committees convene as necessary and go into recess or are abolished when the Commission decides their work has been completed. New committees may be established on an ad hoc basis to cover specific needs for the development of new standards.

Host countries call meetings of Codex subsidiary bodies at intervals of between one and two years, according to need. Attendance at some Codex committees is almost as large as that drawn by a plenary session of the Commission.

Coordinating Committees have no standing host countries. Meetings are hosted by countries of a region on an ad hoc basis and in agreement with the Commission. There are six Coordinating Committees, i.e. one each for the following regions:

- Africa;
- Asia;
- Europe;
- Latin America and the Caribbean;
- Near East;
- North America and Southwest Pacific.

Coordinating Committees play an invaluable role in ensuring that the work of the Commission is responsive to regional interests and to the concerns of developing countries. They meet at one- to two-year intervals, with a good representation from the countries of their respective regions. Meeting reports are submitted to and discussed by the Commission.

Task Forces (ad hoc Intergovernmental Task Forces)

In order to expedite work on specific subjects, the Commission also establishes time-limited ad hoc intergovernmental task forces whose mandate normally does not exceed five years. The first three task forces were established in 1999 and dealt with:

- Foods derived from biotechnology (hosted by Japan);
- Animal feeding (hosted by Denmark);
- Fruit and vegetable juices (hosted by Brazil).

MEMBER COUNTRIES' ACCEPTANCE OF CODEX STANDARDS

The harmonization of food standards is generally viewed as a prerequisite to the protection of consumer health as well as allowing the fullest possible facilitation of international trade. For that reason, the Uruguay Round Agreements on the Application of Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) both encourage the international harmonization of food standards.

Harmonization can only be achieved when all countries adopt the same standards. The General Principles of the Codex Alimentarius specify the ways in which member countries may "accept" Codex standards. Forms of acceptance vary somewhat depending on whether the standard is a commodity standard, a general standard, or concerns levels for pesticide or veterinary drug residues or food additives. Generally, however, the proposed forms of acceptance are *full acceptance*, *acceptance with minor deviations* and *free distribution*. The ways of acceptance are clearly defined in the General Principles, and their suitability in the light of experience is subject to review by the Codex Committee on General Principles.

General principles, guidelines and recommended codes of practice

Instruments such as principles and codes have been developed for the express purpose of protecting the health of consumers against food-borne hazards. For example, *general principles* have been developed for the use of food additives, food import and export inspection and certification and the addition of essential nutrients to foods.

The Codex Alimentarius contains wide-ranging *guidelines* for the protection of consumers, including such diverse subjects as the Establishment and Application of Microbiological Criteria for Foods and Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade.

It also contains *codes of practice*, most of which are codes of hygienic practice providing guidance on the production of food that is safe and suitable for consumption - in other words, their purpose is to protect the health of consumers. The *Recommended International Code of Practice - General Principles of Food Hygiene* applies to all foods. It is particularly important in protecting consumers because it lays a firm foundation for food safety and follows the food chain from primary production through to final consumption, highlighting the key hygiene controls required at each stage.

The General Principles of Food Hygiene are supported by detailed *codes of hygienic practice* that have specific application to:

- Low-acid and acidified low-acid canned foods;
- Aseptically processed and packaged low-acid foods;
- Precooked and cooked foods in mass catering;
- The preparation and sale of street-vended foods (regional standard - Latin America and the Caribbean);
- Spices and dried plants;
- Canned fruit and vegetable products;
- Dried fruits;
- Desiccated coconut;
- Dehydrated fruits and vegetables including edible fungi;
- Tree nuts;
- Groundnuts (peanuts);
- Processed meat and poultry products;
- Poultry processing;
- Egg products;

- The processing of frog legs;
- Fresh meat;
- The production, storage and composition of mechanically separated meat and poultry meat Intended for further processing;
- The collection, processing and marketing of natural mineral waters.

The Codex Alimentarius also contains the *Recommended International Code of Practice for Control of the Use of Veterinary Drugs*, which has the express aim of preventing the use of drugs that create a hazard to human health.

There are also a number of so-called *codes of technological practice*, which are intended to ensure that the processing, transport and storage of foods produced to Codex standards are such that consumers receive end products that are wholesome and of the expected quality. Codes of technological practice exist for:

- Foods for infants and children;
- The packaging and transport of fresh fruit and vegetables;
- Storage and transport of edible oils and fats in bulk;
- Processing and handling of quick frozen foods

Further details of the Codex Alimentarius Commission, its work, and its publications may be found on the website: <http://www.codexalimentarius.net/>

ANNEX 5. Introducing the WTO SPS and TBT Agreements

5.1 AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

Members,

Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

Desiring to improve the human health, animal health and phytosanitary situation in all Members;

Noting that sanitary and phytosanitary measures are often applied on the basis of bilateral agreements or protocols;

Desiring the establishment of a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade;

Recognizing the important contribution that international standards, guidelines and recommendations can make in this regard;

Desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health;

Recognizing that developing country Members may encounter special difficulties in complying with the sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary or phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard;

Desiring therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)⁶;

Hereby agree as follows:

Article 1 General Provisions

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.
3. The annexes are an integral part of this Agreement.

⁶ In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.

4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

Article 2
Basic Rights and Obligations

1. Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.
2. Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.
3. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.
4. Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

Article 3
Harmonization

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.
2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.
3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.⁷ Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.
4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and

⁷ For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.

5. The Committee on Sanitary and Phytosanitary Measures provided for in paragraphs 1 and 4 of Article 12 (referred to in this Agreement as the "Committee") shall develop a procedure to monitor the process of international harmonization and coordinate efforts in this regard with the relevant international organizations.

Article 4 **Equivalence**

1. Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.
2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

Article 5 **Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection**

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.
4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.
5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.⁸
7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.
8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

Article 6
Adaptation to Regional Conditions, Including Pest- or Disease-Free Areas
and Areas of Low Pest or Disease Prevalence

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account, *inter alia*, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.
2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.
3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

Article 7
Transparency

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

⁸ For the purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

Article 8
Control, Inspection and Approval Procedures

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

Article 9
Technical Assistance

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, *inter alia*, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.
2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

Article 10
Special and Differential Treatment

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.
2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.
3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.
4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

Article 11
Consultations and Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.
2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

3. Nothing in this Agreement shall impair the rights of Members under other international agreements, including the right to resort to the good offices or dispute settlement mechanisms of other international organizations or established under any international agreement.

Article 12
Administration

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.
2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.
3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.
4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefor, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.
5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.
6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.

7. The Committee shall review the operation and implementation of this Agreement three years after the date of entry into force of the WTO Agreement, and thereafter as the need arises. Where appropriate, the Committee may submit to the Council for Trade in Goods proposals to amend the text of this Agreement having regard, *inter alia*, to the experience gained in its implementation.

Article 13 **Implementation**

Members are fully responsible under this Agreement for the observance of all obligations set forth herein. Members shall formulate and implement positive measures and mechanisms in support of the observance of the provisions of this Agreement by other than central government bodies. Members shall take such reasonable measures as may be available to them to ensure that non-governmental entities within their territories, as well as regional bodies in which relevant entities within their territories are members, comply with the relevant provisions of this Agreement. In addition, Members shall not take measures which have the effect of, directly or indirectly, requiring or encouraging such regional or non-governmental entities, or local governmental bodies, to act in a manner inconsistent with the provisions of this Agreement. Members shall ensure that they rely on the services of non-governmental entities for implementing sanitary or phytosanitary measures only if these entities comply with the provisions of this Agreement.

Article 14 **Final Provisions**

The least-developed country Members may delay application of the provisions of this Agreement for a period of five years following the date of entry into force of the WTO Agreement with respect to their sanitary or phytosanitary measures affecting importation or imported products. Other developing country Members may delay application of the provisions of this Agreement, other than paragraph 8 of Article 5 and Article 7, for two years following the date of entry into force of the WTO Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

ANNEX A
DEFINITIONS⁹

1. *Sanitary or phytosanitary measure* - Any measure applied:
 - (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
 - (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
 - (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
 - (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.
2. *Harmonization* - The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.
3. *International standards, guidelines and recommendations*
 - (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
 - (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
 - (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
 - (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.
4. *Risk assessment* - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.
5. *Appropriate level of sanitary or phytosanitary protection* - The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect

⁹ For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

human, animal or plant life or health within its territory. NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

6. *Pest- or disease-free area* - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease does not occur.

NOTE: A pest- or disease-free area may surround, be surrounded by, or be adjacent to an area - whether within part of a country or in a geographic region which includes parts of or all of several countries -in which a specific pest or disease is known to occur but is subject to regional control measures such as the establishment of protection, surveillance and buffer zones which will confine or eradicate the pest or disease in question.

7. *Area of low pest or disease prevalence* - An area, whether all of a country, part of a country, or all or parts of several countries, as identified by the competent authorities, in which a specific pest or disease occurs at low levels and which is subject to effective surveillance, control or eradication measures.

ANNEX B

TRANSPARENCY OF SANITARY AND PHYTOSANITARY REGULATIONS

Publication of regulations

1. Members shall ensure that all sanitary and phytosanitary regulations¹⁰ which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.
2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

Enquiry points

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:
 - (a) any sanitary or phytosanitary regulations adopted or proposed within its territory;
 - (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
 - (c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;
 - (d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.
4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals¹¹ of the Member concerned.

Notification procedures

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:
 - (a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;
 - (b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

¹⁰ Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

¹¹ When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

- (c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;
 - (d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.
6. However, where urgent problems of health protection arise or threaten to arise for a Member, that Member may omit such of the steps enumerated in paragraph 5 of this Annex as it finds necessary, provided that the Member:
- (a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);
 - (b) provides, upon request, copies of the regulation to other Members;
 - (c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.
7. Notifications to the Secretariat shall be in English, French or Spanish.
8. Developed country Members shall, if requested by other Members, provide copies of the documents or, in case of voluminous documents, summaries of the documents covered by a specific notification in English, French or Spanish.
9. The Secretariat shall promptly circulate copies of the notification to all Members and interested international organizations and draw the attention of developing country Members to any notifications relating to products of particular interest to them.
10. Members shall designate a single central government authority as responsible for the implementation, on the national level, of the provisions concerning notification procedures according to paragraphs 5, 6, 7 and 8 of this Annex.

General reservations

11. Nothing in this Agreement shall be construed as requiring:
- (a) the provision of particulars or copies of drafts or the publication of texts other than in the language of the Member except as stated in paragraph 8 of this Annex; or
 - (b) Members to disclose confidential information which would impede enforcement of sanitary or phytosanitary legislation or which would prejudice the legitimate commercial interests of particular enterprises.

ANNEX C

CONTROL, INSPECTION AND APPROVAL PROCEDURES¹²

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
 - (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;
 - (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;
 - (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;
 - (d) the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected in a way no less favourable than for domestic products and in such a manner that legitimate commercial interests are protected;
 - (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary;
 - (f) any fees imposed for the procedures on imported products are equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service;
 - (g) the same criteria should be used in the siting of facilities used in the procedures and the selection of samples of imported products as for domestic products so as to minimize the inconvenience to applicants, importers, exporters or their agents;
 - (h) whenever specifications of a product are changed subsequent to its control and inspection in light of the applicable regulations, the procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and
 - (i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified.

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

¹² Control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.
3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

5.2 EXTRACTS FROM THE AGREEMENT ON TECHNICAL BARRIERS TO TRADE

NOTE: The material below has been taken from the full text of the **AGREEMENT ON TECHNICAL BARRIERS TO TRADE**. Editorial symbols ¶¶¶¶ indicate where text has been deleted. Readers are strongly advised to read the original document to fully understand the implications of the TBT Agreement.

Members,

Having regard to the Uruguay Round of Multilateral Trade Negotiations;

Desiring to further the objectives of GATT 1994;

Recognizing the important contribution that international standards and conformity assessment systems can make in this regard by improving efficiency of production and facilitating the conduct of international trade;

Desiring therefore to encourage the development of such international standards and conformity assessment systems;

Desiring however to ensure that technical regulations and standards, including packaging, marking and labelling requirements, and procedures for assessment of conformity with technical regulations and standards do not create unnecessary obstacles to international trade;

Recognizing that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement;

Recognizing that no country should be prevented from taking measures necessary for the protection of its essential security interest;

Recognizing the contribution which international standardization can make to the transfer of technology from developed to developing countries;

Recognizing that developing countries may encounter special difficulties in the formulation and application of technical regulations and standards and procedures for assessment of conformity with technical regulations and standards, and desiring to assist them in their endeavours in this regard;

Hereby agree as follows:

Article 1 General Provisions

- 1.1 General terms for standardization and procedures for assessment of conformity shall normally have the meaning given to them by definitions adopted within the United Nations system and by international standardizing bodies taking into account their context and in the light of the object and purpose of this Agreement.

- 1.2 However, for the purposes of this Agreement the meaning of the terms given in Annex 1 applies.
- 1.3 All products, including industrial and agricultural products, shall be subject to the provisions of this Agreement.

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TECHNICAL REGULATIONS AND STANDARDS

Article 2

Preparation, Adoption and Application of Technical Regulations by Central Government Bodies

With respect to their central government bodies:

- 2.1 Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.
- 2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information related to processing technology or intended end-uses of products.
- 2.3 Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.
- 2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.
- 2.5 A Member preparing, adopting or applying a technical regulation which may have a significant effect on trade of other Members shall, upon the request of another Member, explain the justification for that technical regulation in terms of the provisions of paragraphs 2 to 4. Whenever a technical regulation is prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in paragraph 2, and is in accordance with relevant international standards, it shall be rebuttably presumed not to create an unnecessary obstacle to international trade.
- 2.6 With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.
- 2.7 Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided

¹³ ΨΨΨΨ - symbols indicate deletion of non essential text from the SPS Agreement

they are satisfied that these regulations adequately fulfil the objectives of their own regulations.

- 2.8 Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.

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Article 4
Preparation, Adoption and Application of Standards

- 4.1 Members shall ensure that their central government standardizing bodies accept and comply with the Code of Good Practice for the Preparation, Adoption and Application of Standards in Annex 3 to this Agreement (referred to in this Agreement as the "Code of Good Practice").

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- 4.2 Standardizing bodies that have accepted and are complying with the Code of Good Practice shall be acknowledged by the Members as complying with the principles of this Agreement.

CONFORMITY WITH TECHNICAL REGULATIONS AND STANDARDS

Article 5

Procedures for Assessment of Conformity by Central Government Bodies

- 5.1 Members shall ensure that, in cases where a positive assurance of conformity with technical regulations or standards is required, their central government bodies apply the following provisions to products originating in the territories of other Members:

5.1.1 conformity assessment procedures are prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions no less favourable than those accorded to suppliers of like products of national origin or originating in any other country, in a comparable situation;

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5.1.2 conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

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- 5.2 When implementing the provisions of paragraph 1, Members shall ensure that:

5.2.1 conformity assessment procedures are undertaken and completed as expeditiously as possible and in a no less favourable order for products originating in the territories of other Members than for like domestic products;

5.2.2 the standard processing period of each conformity assessment procedure is published or that the anticipated processing period is communicated to the applicant upon request;

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5.2.3 information requirements are limited to what is necessary to assess conformity and determine fees;

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5.2.5 any fees imposed for assessing the conformity of products originating in the territories of other Members are equitable in relation to any fees chargeable for

assessing the conformity of like products of national origin or originating in any other country,

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5.3 Nothing in paragraphs 1 and 2 shall prevent Members from carrying out reasonable spot checks within their territories.

5.4 In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant guides or recommendations issued by international standardizing bodies exist or their completion is imminent, Members shall ensure that central government bodies use them,

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Article 6
Recognition of Conformity Assessment by Central Government Bodies

With respect to their central government bodies:

6.1 Without prejudice to the provisions of paragraphs 3 and 4, Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.

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6.3 Members are encouraged, at the request of other Members, to be willing to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment procedures. Members may require that such agreements fulfill the criteria of paragraph 1 and give mutual satisfaction regarding their potential for facilitating trade in the products concerned.

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Article 9
International and Regional Systems

9.1 Where a positive assurance of conformity with a technical regulation or standard is required, Members shall, wherever practicable, formulate and adopt international systems for conformity assessment and become members thereof or participate therein.

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Article 11
Technical Assistance to Other Members

11.1 Members shall, if requested, advise other Members, especially the developing country Members, on the preparation of technical regulations.

11.2 Members shall, if requested, advise other Members, especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions regarding the establishment of national standardizing bodies, and participation in the international standardizing bodies, and shall encourage their national standardizing bodies to do likewise.

11.3 Members shall, if requested, take such reasonable measures as may be available to them to arrange for the regulatory bodies within their territories to advise other Members, especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions regarding:

- 11.3.1 the establishment of regulatory bodies, or bodies for the assessment of conformity with technical regulations; and
- 11.3.2 the methods by which their technical regulations can best be met.
- 11.4 Members shall, if requested, take such reasonable measures as may be available to them to arrange for advice to be given to other Members, especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions regarding the establishment of bodies for the assessment of conformity with standards adopted within the territory of the requesting Member.
- 11.5 Members shall, if requested, advise other Members, especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions regarding the steps that should be taken by their producers if they wish to have access to systems for conformity assessment operated by governmental or non-governmental bodies within the territory of the Member receiving the request.
- 11.6 Members which are members or participants of international or regional systems for conformity assessment shall, if requested, advise other Members, especially the developing country Members, and shall grant them technical assistance on mutually agreed terms and conditions regarding the establishment of the institutions and legal framework which would enable them to fulfil the obligations of membership or participation in such systems.
- 11.7 Members shall, if so requested, encourage bodies within their territories which are members or participants of international or regional systems for conformity assessment to advise other Members, especially the developing country Members, and should consider requests for technical assistance from them regarding the establishment of the institutions which would enable the relevant bodies within their territories to fulfil the obligations of membership or participation.
- 11.8 In providing advice and technical assistance to other Members in terms of paragraphs 1 to 7, Members shall give priority to the needs of the least-developed country Members.

Article 12
Special and Differential Treatment of Developing Country Members

- 12.1 Members shall provide differential and more favourable treatment to developing country Members to this Agreement, through the following provisions as well as through the relevant provisions of other Articles of this Agreement.
- 12.2 Members shall give particular attention to the provisions of this Agreement concerning developing country Members' rights and obligations and shall take into account the special development, financial and trade needs of developing country Members in the implementation of this Agreement, both nationally and in the operation of this Agreement's institutional arrangements.
- 12.3 Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members.
- 12.4 Members recognize that, although international standards, guides or recommendations may exist, in their particular technological and socioeconomic conditions, developing country Members adopt certain technical regulations, standards or conformity assessment procedures aimed at preserving indigenous technology and production methods and processes compatible with their development needs. Members therefore recognize that developing country Members should not be expected to use international standards as a

basis for their technical regulations or standards, including test methods, which are not appropriate to their development, financial and trade needs.

- 12.5 Members shall take such reasonable measures as may be available to them to ensure that international standardizing bodies and international systems for conformity assessment are organized and operated in a way which facilitates active and representative participation of relevant bodies in all Members, taking into account the special problems of developing country Members.

ANNEX 1

TERMS AND THEIR DEFINITIONS FOR THE PURPOSE OF THIS AGREEMENT

The terms presented in the sixth edition of the ISO/IEC Guide 2: 1991, General Terms and Their Definitions Concerning Standardization and Related Activities, shall, when used in this Agreement, have the same meaning as given in the definitions in the said Guide taking into account that services are excluded from the coverage of this Agreement.

For the purpose of this Agreement, however, the following definitions shall apply:

1. *Technical regulation*

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

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2. *Standard*

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

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3. *Conformity assessment procedures*

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

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4. *International body or system*

Body or system whose membership is open to the relevant bodies of at least all Members

5. *Regional body or system*

Body or system whose membership is open to the relevant bodies of only some of the Members

6. *Central government body*

Central government, its ministries and departments or any body subject to the control of the central government in respect of the activity in question

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ANNEX 6. Guidelines for Developing a National Food Law

The original 1976 FAO/WHO *Guidelines for Developing an Effective National Food Control System* contained a Model Food Law that has been used in many developing countries. Unfortunately this model has not always been appropriate because its precepts are not consistent with all legal systems. Many concepts and issues in food law have evolved over time and these were not reflected in the Model Food Law. In addition, strict adherence to the terms of the Model Food Law meant that many countries left out provisions, concepts and standards that their individual circumstances, administrative structures and legal frameworks required.

In this document, a set of guiding principles have been prepared. These principles describe a general approach to the drafting of food legislation, and as such they should be applicable to different legal systems. There is no substitute, however, for an in-depth analysis of the legal framework and the institutional set-up that directly or indirectly govern food production, import, export, distribution, handling and sale in a particular country. Only in that way can the particular and unique national needs be met.

In addition to legislation, governments need updated and internationally accepted food standards. In recent years, many highly prescriptive standards have been replaced by horizontal standards that address the broad issues involved in achieving food safety and quality objectives. While horizontal standards are a viable approach to delivering food safety goals, they require a food chain that is highly controlled and supplied with good data on food safety risks and risk management strategies and as such may not be feasible for many developing countries.

In preparing food regulations and standards, countries should take full advantage of Codex standards and food safety and quality lessons learned in other countries. Taking into account the experiences in other countries while tailoring the information, concepts and requirements to the national context is the only sure way to develop a modern regulatory framework that will satisfy both national needs and meet the demands of the SPS Agreement, TBT Agreement and trading partners.

Form and Content of Food Law

Legal provisions relating to food regulate specific activities, namely the production, processing and sale of food. Such provisions are designed with specific purposes, such as health protection and/or the promotion of fair trade in food commodities. Most commonly, they are contained in a general law covering all food products. The law addresses specific aspects of food safety, food adulteration, food quality and food control, such as inspection, the use of additives, prevention of food contamination, food labelling and import controls.

Most modern food legislation consists of a basic law upon which all other regulatory instruments are based. However, a number of countries have enacted, side by side with this basic law concerning food products in general, other laws governing either a distinct sector of food law, certain types of food processing or specific legal aspects of the production of or trade in foodstuffs.

The general form of the basic law depends on the legislative traditions of the particular country. One established practice in highly industrialized common law countries is to enact comprehensive and detailed texts which bring together practically all general provisions which may concern food. In such cases there is little left for the administrative authorities to do beyond prescribing the technical procedures for enforcement and detailed provisions in respect of particular foods.

An alternative approach is to limit the contents of the basic law to the enabling provisions (*i.e.* those that set up the administrative structures to enforce the law), together with a few very general principles. This approach is to be found in less developed countries, as well as in many countries where Roman, German or Scandinavian law prevails. This system has an inherent flexibility in that, within the general framework laid down by the law, the necessary powers are delegated to the appropriate authority to make rules governing the administration of the law, and to prescribe technical regulations and standards for specific foods.

Another advantage of this second approach, in all legal systems, is that because the law is basic and all details are confined to the regulations and standards, changes can be made more easily and quickly. For example, regulations and standards may need to be changed in response to scientific advancements, and rather than approaching Parliament to amend the law, the relevant Minister or Ministers usually have the power to issue any appropriate regulations or schedules and can therefore act to take account of the new developments.

In principle, there are eight categories of provisions to be found in a basic food law:

(a) Scope and Definitions

The first category describes the ambit of the law and provides the tools for its interpretation. A provision in the food law stating its purpose, objectives and/or scope must clearly precede all others. This provision may have no real legal effect, but instead operates as a kind of policy statement explaining why the law was enacted and what purpose it is intended to serve. It also can state the areas covered by the law.

Countries often include a list of definitions of the main terms employed. In drafting the definitions, internationally agreed sources should be consulted, along with other national legislation on related issues. It must be emphasized that the list of definitions is not a glossary of food control terms in general. Those definitions that are included must be only those that appear in the body of the law. The definitions should not be overly detailed but should be designed solely for the purpose of application and interpretation of the law in question. In particular, the definitions should be drafted with consideration to who might challenge the law at some future date. For example, if the law contains a definition of **to sell** that provides that **to sell means to exchange for money**, and if the law prohibits selling adulterated food, then someone charged with violating the law might hide proof of sale and attempt to argue that since he or she gave away the food for free (and not for money) the law was not violated.

(b) General Principles

In some legal systems, the basic food law contains a group of provisions articulating general principles that will govern the food control system. For example, the law may provide that all food in circulation in the country must be safe for human consumption, or the law may prohibit the adulteration of food. Other provisions may set out the basic rules to be observed by all persons engaged in the production, processing or sale of food. It should be borne in mind, however, that there exist many differences between countries. Some countries have a detailed statement of principles in the basic law, whilst others leave these principles to be laid down in general enforcement regulations, and still others include only a statement of objectives and purposes (as outlined above) and do not elaborate principles at all.

(c) Enabling Provisions

Every law must define the nature and the limits of the powers to be exercised under it and should designate the public authorities in whom those powers are to be vested. There are two categories of powers, namely formulation and control, which are usually not delegated to the same authority and which are not necessarily exercised at the same level of authority. Naturally, the law must also establish guidelines for and limitations on the exercise of these powers. Such enabling provisions establish the legality of the enforcement rules made by the executive authority and also protect private persons against that authority's arbitrary or excessive use of its powers.

The powers vested in the government or executive authority under these enabling provisions relate to the formulation of rules for the implementation of the law and for the intervention of the authority in order to ensure that the laws and its accompanying regulations are being observed.

(d) Administrative Provisions

Most food laws contain a category of provisions that set up particular administrative structures to carry out the activities necessary to enforce the law. For example, the law may establish a Food Control Agency, which brings together the many official actors from various ministries who are implicated in food control in the country. The food law does not usually delve into great detail on the functioning of the Food Control Agency, but instead describes its mandate, defines its membership, outlines some basic rules regarding the appointment and resignation of members and the establishment of technical committees, and provides for a Secretariat, if any. The law may provide that all other details that will govern the actions of the Food Control Agency will be established by regulation or by by-laws elaborated by the Agency itself. Other administrative structures that may or may not be created or defined in the food law are an inspection service and a licensing authority (for example to grant licenses to food manufacturers or importers). The law may also empower the Agency to delegate or license certain types of enforcement activities to different government agencies.

(e) Enforcement Provisions

Because no penalty may be imposed except by virtue of legal authority, food laws contain provisions delegating to an executive authority the power to sanction as well as to take preventive measures in the public interest. It goes without saying that the limits of such powers and the conditions governing their exercise must be laid down with precision in the basic law. Offences must be defined, along with the nature and limits of the penalties that may be imposed, together with the procedures for such imposition once the commission of an offence has been duly established. The law may also outline other necessary measures for the protection of the public, such as the seizure and confiscation of suspect food or the recall of products. It should be noted, however, that in some countries, specific offences and penalties are not elaborated, but instead the food law simply refers to the general provisions of the Criminal Code and the Code of Criminal Procedure.

With the trend away from an enforcement-oriented approach in food control, some countries have incorporated concepts from food control, such as HACCP, into their food laws. In general this may be achieved through the subsidiary regulations more than through the law, as the regulations may consist of elements such as guidelines for the inspection service. Under a purely enforcement-oriented approach, improper activities (packaging, transportation, etc.) would be described in the law, and any violation would be perceived and acted upon by an inspector so charged by the law. With a more collaborative and preventive approach, the inspectors might instead be charged with simply controlling the fact that a food enterprise is exercising its own controls on its production systems.

(f) Substantive Provisions

The food law will contain many substantive provisions relating to food control, production, import, export, transport, distribution and sale. These provisions may be very basic (“all food in the country must be safe for human consumption”), or may be more detailed, in which case the details are more likely to be found in the subsidiary legislation. For example, the regulations issued under the food law may outline all the precise information that must be contained on food labels (weight, name of manufacturer, sell-by date, etc.) and may even contain model labels in a specific format that must be followed throughout the country.

(g) Regulations

In most legal systems, the food law contains a provision or provisions listing the many subject matters that the Minister may address through regulations in order to carry out the purposes of the law. The main advantage of the regulations is that they can be easily changed. The list of regulations may be extremely detailed or it may simply give broad outlines to the kinds of topics

that the Minister may address. In either case, the Minister's powers are rarely limited, as in almost all cases the food law will contain a general statement that the Minister may "make all regulations he or she deems necessary to achieve the purposes of this law."

(h) *Repeal and Savings*

Where a new food law makes significant changes to the food control system, existing laws or regulations may have to be amended or repealed. In such cases the food law will have to list which provisions in which other laws are to be repealed or altered. However, in order not to dismantle the food control system entirely, many laws contain a provision stating that any regulations made under any provision repealed under the new law remain effective, just as if they had been issued under the new food law itself.

Form and Content of Food Regulations

As noted, the topics that may be addressed by regulations made by the executive authority under the basic law may be very broad. Generally, they fall into four categories:

(a) *Regulations Affecting Food Products in Genera*

Usually the purpose of this category of regulations is to establish general rules regulating the contents, handling, packaging and labelling of food products. These kinds of regulations are of particular importance in countries which do not include in the basic law rules governing the manufacture, processing and sale of food but leave it to the Minister to introduce detailed regulations. But whether or not general principles are laid down in the basic law, in one way or another a government authority must be entrusted with their implementation at the technical level.

(b) *Regulations Affecting Specific Food Products*

In many countries the provisions peculiar to each food may constitute specific and distinct regulations (for example novel foods, baby foods, special dietetic foods). The practice has developed in some other countries, however, of grouping such provisions, under different headings, into a comprehensive set of regulations governing food. Here, the legislative traditions may vary appreciably from one country to another.

(c) *Regulations for Organizational or Coordinating Purposes*

Although the main body of regulations putting into effect the food law will fall into the above two categories, there are a great number of internal regulations or 'house' rules that are of no direct concern to the public but which are required for the efficient operation of the administrative units created or empowered under the law. For example, regulations may address the functioning of the Food Control Agency, if any; the issuance, suspension and revocation of licenses of various kinds; the conduct of the inspection and analysis services; and so forth.

(d) *Schedules*

Many countries include detailed schedules among the subsidiary legislation to the basic food law. These will contain, for example, lists of inspection and sampling/analysis fees; models for application forms or certificates used under the law; and other detailed matters.

ANNEX 7. Introducing JECFA, JMPR, JEMRA and GM Food Risk Assessment

Food Safety Risk Assessment - International Scientific Panels

Risk assessment: scientific basis of food safety measures

FAO and WHO promote the application of risk assessment in all matters involving food safety. This must be based on sound scientific advice and evidence provided by panels of competent and independent experts. Risk assessment is one of the components of risk analysis – the other two being risk management and risk communication.

The Codex Alimentarius Commission (CAC) defines risk assessment as a scientifically based process consisting of the following four steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization. The risk assessment process is a means of providing an estimate of the probability and severity of illness attributable to a particular pathogen-commodity combination. The four-step process enables this to be carried out in a systematic manner, but the extent to which the steps are carried out will be dependent on the scope of the risk assessment. This can be defined clearly by the risk manager through ongoing dialogue with the risk assessor.

Risk assessments provide information for identifying and characterizing food hazards. Risk assessment information is useful in determining which hazards are of such a nature that their prevention, elimination or reduction to acceptable levels is necessary. The information is also useful in determining the most effective intervention strategies.

At present, there are two long-standing panels that provide advice to Codex, governments and industry. They are the Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). In addition, FAO and WHO convene ad hoc expert consultations whenever needed to address specific issues not covered by the permanent panels. In recent years, several expert consultations have been held on microbiological hazards in food, the risk assessment of foods derived from biotechnology and on animal feeding and food safety. FAO and WHO are currently studying the possibility of establishing an overall expert body on food safety risk assessment that would oversee the entire work in this field and ensure the necessary link, synergy and harmony between the specific expert panels and consultations.

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international expert scientific committee that is administered jointly by FAO and WHO. It has been meeting since 1956, initially to evaluate the safety of food additives. Its work now includes the evaluation of contaminants, naturally occurring toxicants and residues of veterinary drugs in food. To date, JECFA has evaluated more than 1300 food additives, approximately 25 contaminants and naturally occurring toxicants, and residues of approximately 80 veterinary drugs. The Committee has also developed principles for the safety assessment of chemicals in food that are consistent with current thinking on risk assessment and take account of recent developments in toxicology and other relevant sciences. As of June 2001 the Committee had met a total of 57 times.

JECFA serves as a scientific advisory body to FAO, WHO, and their member governments, and to the Codex Alimentarius Commission (CAC). Advice to the CAC on food additives, contaminants and naturally occurring toxicants is normally provided via the Codex Committee on Food Additives and Contaminants (CCFAC) and advice on residues of veterinary drugs via the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

All countries need to have access to reliable risk assessments of chemicals in food, but relatively few have the expertise and funds available to carry out separate risk assessments on large numbers of chemicals. JECFA performs a vital function in providing a reliable source of expert advice, and some countries use information from JECFA in formulating their own regulatory programmes. In the same way, CCFAC and CCRVDF develop standards for chemicals in food based on JECFA evaluations.

For food additives, contaminants and naturally occurring toxicants, the Committee:

- elaborates principles for evaluating their safety;
- conducts toxicological evaluations and establishes acceptable daily intakes (ADIs) or tolerable intakes;
- prepares specifications of purity for food additives; and
- assesses intake.

For residues of veterinary drugs in food, the Committee:

- elaborates principles for evaluating their safety;
- establishes ADIs and recommends maximum residue limits (MRLs);
- determines criteria for the appropriate methods of analysis for detecting and/or quantifying residues in food.

For food additives, JECFA normally establishes ADIs on the basis of available toxicological and other relevant information. Specifications of the identity and purity are also developed for food additives, which help to ensure that the product in commerce is of appropriate quality, can be manufactured consistently, and is equivalent to the material that was subjected to toxicological testing.

For contaminants and naturally occurring toxicants, levels corresponding to 'tolerable' intakes such as the provisional maximum tolerable daily intake (PMTDI) or provisional tolerable weekly intake (PTWI) are normally established when there is an identifiable no-observed-effect level. When a no-observed-effect level cannot be identified the Committee may provide other advice depending on the circumstances.

In the case of veterinary drugs, data on good practice are evaluated and corresponding MRLs in animal tissues, milk or eggs are recommended. Such MRLs are intended to provide assurance that when the drug has been used properly, the intake of residues of the drug present in food is unlikely to exceed the ADI.

For more information, please see relevant FAO and WHO Websites:

<http://www.fao.org/es/esn/jecfa/jecfa.htm>

<http://www.who.int/pcs/jecfa/jecfa.htm>

FAO/WHO Joint Meeting on Pesticide Residues (JMPR)

The JMPR is comprised of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and in the Environment and the WHO Core Assessment Group. JMPR carries out toxicological evaluation of pesticide residues, normally resulting in an estimate of the ADI. In addition, JMPR proposes maximum residues limits (MRLs) for individual pesticides in or on specific commodities. These MRLs are primarily based on the residue levels estimated in supervised field trials when the pesticide is used according to Good Agricultural Practices (GAP). In cases where initial estimates indicate that the ADI may be exceeded, more refined intake calculations are performed using national food consumption data and information from pesticide residues monitoring programmes.

These Expert Committees establish chemical safety standards based on a review of toxicological studies in the more sensitive test animal species. They factor in an adequate level of safety, use risk assessment procedures, consider use and consumption patterns and define the specifications of the identity and purity of food grade chemicals to be used.

For more information, please visit the relevant FAO and WHO Websites:

http://www.fao.org/ag/agp/agpp/pesticid/jmpr/pm_jmpr.htm

<http://www.who.int/pcs/jmpr/jmpr.htm>

Microbiological risk assessment

Since 1999, and at the request of the CAC, FAO and WHO have initiated a series of joint expert consultations to assess risk associated with microbiological contamination of foods (JEMRA). This followed the adoption by the CAC of the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (MRA).

The aim of these joint expert consultations is to provide a transparent review of scientific data on the state of the art of MRA, and to develop the means of achieving sound quantitative risk assessments of specific pathogen-commodity combinations. The work includes an evaluation of existing risk assessments; a review of the available data and current risk assessment methodologies, highlighting their strengths and weaknesses and how they may be applied; provision of examples; and identification of data and information needs/gaps. A further aim of these consultations is the development of guidelines relating to the different steps of risk assessment, such as hazard characterization and exposure assessment. The purpose of such guidelines is to help the risk assessor, the risk manager and other interested parties to understand the principles and science behind the risk assessment steps.

A series of such consultations have already been organized. They have dealt with the risk assessment of *Salmonella* spp in broilers, *Salmonella Enteritidis* in eggs, *Listeria monocytogenes* in ready-to-eat foods, *Campylobacter* in broiler chickens, and *Vibrio* spp. in seafood. The work plan and priorities for MRA are established in close collaboration with the Codex Committee on Food Hygiene.

For more information, please visit the FAO and WHO relevant Websites:

http://www.fao.org/es/esn/food/risk_mra_jemra_en.stm

<http://www.who.int/fsf/micro/index.htm>

GM Food Risk Assessment

The use of modern biotechnology for the genetic modification of plants, microorganisms and animals for the production and processing of foods poses additional concerns to certain consumer groups. WHO and FAO recognize that modern biotechnologies have potential to raise agricultural productivity, reduce dependence on harmful chemicals and increase the nutritional value of foods. However, they also acknowledge that there are possible risks to human and animal health and to the environment, which require a case-by-case assessment.

FAO and WHO jointly organized a series of expert consultations to consider general safety and nutritional aspects of foods derived from modern biotechnology. The consultations addressed 'Strategies for Assessing the Safety of Foods Produced by Biotechnology' in 1990, 'Biotechnology and food safety' in 1996, and 'Safety aspects of genetically modified foods of plant origin' in 2000 and 2001. The latter consultations addressed specifically questions on safety that were raised by Codex Intergovernmental ad-hoc Task Force on Foods derived from Biotechnology. The 2000 Consultation reframed the concept of substantial equivalence and identified a set of priority issues that are to be addressed in future FAO and WHO consultations. The 2001 Consultation revised

the international guidelines on the assessment of potential allergenicity of novel recombinant proteins to address broader concerns or critics of the previous approach. A second consultation in 2001 was convened to consider the criteria essential for the risk assessment of food and food ingredients produced with the aid of or containing viable or non-viable genetically modified micro-organisms.

For more information, please visit the FAO and WHO relevant Websites:

http://www.fao.org/es/ESN/food/risk_biotech_en.stm

<http://www.who.int/fsf/GMfood/index.htm>

Selection of experts

For JECFA

FAO and WHO have complementary functions in selecting members for JECFA. FAO is responsible for selecting members to deal with the development of specifications for the identity and purity of food additives and the assessment of residue levels of veterinary drugs in food. WHO is responsible for selecting members to deal with the toxicological evaluations of the substances under consideration. Both FAO and WHO invite members who are responsible for assessing intake. The selection of members is made only after a careful consideration of the scientific credentials of the various candidates, and a balance of scientific expertise and other experience is considered essential. FAO and WHO have established rosters of experts from which individuals would be selected to serve at expert consultations. In order to establish rosters, FAO and WHO issue calls for applications, which describe the essential qualifications of the applicants, selection procedures for the roster and other relevant information. The rosters are posted on the respective WHO and FAO websites. FAO and WHO meet the costs of experts' attendance at JECFA meetings.

For JMPR

FAO, and WHO, have initiated a new approach for the identification, selection and nomination of its JMPR Panel Members. A roster call for submission of applications has been issued and given wide distribution.

This call describes the objective and criteria for Panel Membership. The review process of the applications received will be carried out in cooperation between FAO and WHO and with respected, well-known independent experts.

FAO/WHO New Procedure

A new procedure for the identification and selection of experts serving in joint FAO/WHO expert panels and consultations has been adopted in 2000 and has been applied since then. This new procedure enhances the principles of transparency, equal opportunity, excellence and independence, and seeks to harmonize the working procedures between different expert bodies and between FAO and WHO. This new procedure involves the following steps:

1. A call for experts is made in advance of each expert meeting. The call provides the background, objective and technical agenda of the expert meeting/consultation and indication of the profile required for the experts to be considered. It also includes clear indication of criteria to be used for selection, including expertise and workload involved. This call is disseminated widely, *i.e.* through Internet, communications to Member States, Codex Contact Points, and other relevant mailing lists.

2. A five-member selection panel composed of:

- One representative of FAO (from the technical unit concerned);
- One representative of WHO (from the technical unit concerned);
- Three experts designated by FAO and WHO.

The panel reviews the applications and identifies those experts who fulfil all conditions stipulated in the call.

3. The retained applicants are requested to sign a standard "Declaration of Interest" and indicate institutional affiliation before their names are included in the roster. The roster is maintained by the Secretariat and is publicly available on Internet.

4. The Secretariat selects individuals from the roster to serve on a given expert meeting taking into account pre-established criteria, including the agenda of the meeting, the geographical representation, and the representation of different schools of thought, etc.

5. The Secretariat invites the experts and reminds them of the fact that they serve in their personal capacity and not as representatives of their respective governments or institutions. It also stresses the issue of confidentiality of the documentation, deliberations and conclusion until the report is issued.

ANNEX 8. A Country Profile – Collection of Information

The development of a national food control strategy calls for the collection, collation and evaluation of the following type of information:

Status of food and agriculture sector

- Data and information on: primary food and agriculture production; food processing industry (*i.e.* types and number of establishments, processing capacity, value of production etc); food distribution and marketing.
- Information on formal (organized) and informal (cottage or household units, street-foods) industry.
- Potential for industry development.
- Food chain, and identification of key intermediaries who may influence quality and safety of foods.
- Market infrastructure including assets and deficiencies.
- Safety and Quality management programmes including level of HACCP implementation in the industry.
- Food consumption data. Information on consumers will include data on energy/protein intake, percentage of the population dependent upon subsistence economy, per capita income, etc.
- Cultural, anthropological, and sociological data is also important, including information on food habits and food preferences.

Food security, food imports and nutritional objectives

- Food demand for nutritional requirements; post-harvest food losses; type and quantities of food imports.

Consumer concerns or demand

- Consumer demand on safety, quality and information (labelling) issues.

Food exports

- Quantity and value of food exports and potential for growth in export trade.
- Data on detentions or rejections of food exported.
- Information on number and types of complaints from buyers and remedial action.
- Identification of foods with potential for export and target countries for export.

Epidemiological information

- Information on prevalence and incidence of foodborne disease; procedures used for investigating and notifying foodborne diseases; information on food incriminated; suitability of collected data for risk assessment purpose.

Food contaminant s data

- Information on prevalence and level of contamination of food; monitoring programmes for biological and chemical contamination of food; suitability of collected data for risk assessment purpose.

Human resources and training requirements

- Information on the number and qualification of personnel involved in food control *i.e.* staff engaged in inspection, analysis and epidemiological services; information regarding on-going training, and educational activities; projections on future staffing and training needs.

Extension and advisory services

- Information on the existing extension and advisory services for the food sector as provided by the government, industry, trade associations, non-governmental organizations, and educational institutions; train-the-trainer type of activities; training needs analysis.

Public education and participation

- Consumer education initiatives in food hygiene; potential for increased involvement and interaction between government, consumer associations, non-governmental organizations, and educational institutions in risk communication activities; risk communication to prevent foodborne diseases and possible improvements.

Government organization of food control systems

- Listing of government departments and authorities concerned with food safety and food control activities.
- Description of the food control system and an overview of the resources, responsibilities, functions, and coordination between the entities; methods of determining priorities for action; options for raising resources.

Food Legislation

- Current food legislative arrangements, including regulations, standards, and codes of practice.
- Information on authorities empowered to prepare regulations and standards, and how they coordinate their activities and consult with industry and consumer organizations.
- Capacity to carry out risk assessment.

Food control infrastructure and resources

- Organization of inspection, surveillance, and enforcement activities (national, provincial, and local levels).
- Number and qualifications of inspection personnel.
- Resources within inspection agency, and assessment of strengths and weaknesses. Analytical support facilities (number of laboratories, facilities and equipment, monitoring programmes, etc).
- Codes of hygienic practice.
- Licensing arrangements for food premises.

ANNEX 9. Case Studies – National Food Control Systems

An improved understanding of the risk based approach and growing awareness about the impact of food safety on public health and national economies, has led many countries, to make significant changes to their food control systems, in recent years. This response to the need for consumer protection against newly identified food hazards, coupled with the need for efficient use of public resources have practically forced national authorities in many industrialized countries to give priority to this task.

The current food scenario, particularly the work of the Codex Alimentarius Commission and the comparatively recent WTO Agreements on SPS and TBT, have reinforced the need for appropriate scientific inputs in food control decision-making processes and accelerated the review and reorganization of systems in many countries. While this is an on-going exercise and several changes are still in the offing in many countries, it is useful to study a few newer models or approaches that are emerging in the important area of strengthening food control infrastructure.

All countries that have revised or updated their food control systems expect benefits in terms of increased efficiency, greater ability to provide farm-to-table oversight of food safety, and enhanced international market access. Apart from enhanced objectivity in protection measures and consolidation of their activities, there is a move by governments to shift the responsibility for ensuring food safety to the food industry, with governments assuming an audit or oversight role.

Case study - Canada

Background

Food safety in Canada is a shared responsibility between the Federal Government (Health Canada and the Canadian Food Inspection Agency (CFIA)), provincial/territorial governments, the food industry and consumers.

The Canadian food safety system has been developed in a way that enables it to keep abreast of rapid changes in the nature of food, increased globalization of the food trade, and changing public expectations of food safety. Three fundamental principles underpin the food safety system:

- (a) the health of the population must remain paramount;
- (b) policy decisions must be grounded on scientific evidence; and
- (c) all sectors and jurisdictions must collaborate to protect consumers.

Regulatory framework

The *Food and Drugs Act* is the principal federal legislation covering food safety, and it prohibits the manufacture or sale of all dangerous or adulterated food products anywhere in Canada. The Act derives its authority from criminal law, and is supplemented by regulations designed to ensure food safety and nutritional quality.

Other federal trade and commerce legislation references the *Food and Drugs Act* and imposes additional requirements e.g. *Canada Agricultural Products Act*, *Meat Inspection Act*, *Fish Inspection Act*, *Feeds Act* and *Pest Control Products Act*, etc.

At the local level, provinces and territories are responsible for public health, including food surveillance, investigations and compliance. Therefore, provinces and territories also enact legislation to control foods produced and sold within their own jurisdictions. These laws are complementary to federal statutes. As legislative power cannot be delegated from one level of government to another, governments collaborate in areas of shared jurisdiction, such as food inspection, and establish partnerships to ensure effective and efficient program delivery.

Provinces and territories legislation also authorize municipalities to enact by-laws on food inspection.

Health Canada

Development of standards and policies

Health Canada sets standards and policies governing the safety and nutritional quality of all food sold in Canada. Government has the primary responsibility for identifying health risks associated with the food supply, assessing the severity and probability of harm or damage, and developing national strategies to manage the risks. Canada has adopted a risk analysis process that provides a common, consistent, comprehensive and scientifically sound mechanism to identify, assess and manage potential risks to public health. Accordingly, all food-policy decisions are made in a transparent and rational manner.

Health Canada also carries out foodborne disease surveillance activities providing a system for early detection and a basis for evaluating control strategies.

To ensure the federal system is one with checks and balances, the Minister of Health has responsibility for assessing the effectiveness of the Agency's activities related to food safety.

Canadian Food Inspection Agency - enforcement and compliance

The Canadian Food Inspection Agency (CFIA) is responsible for enforcing federal food safety policies and standards.

Mission and Objectives

In order to fulfil its mission of *Safe Food, Market Access and Consumer Protection*, the CFIA has adopted the following objectives:

- (a) to contribute to a safe food supply and accurate product information;
- (b) to contribute to the continuing health of animals and plants for protection of the resource base; and
- (c) to facilitate trade in food, animals, plants and their products.

Activities

The CFIA was created in 1997 and delivers federal inspection services to food safety as well as plant protection and animal health. The agency operates under the authority of 13 federal acts and 34 sets of regulations, and meets its responsibilities through 14 distinct programs.

CFIA is responsible for all federally mandated food inspection, compliance and quarantine services. Prior to 1997 these activities were undertaken by Agriculture and Agri-Food Canada, Health Canada, Industry Canada and Fisheries and Oceans Canada. CFIA develops and manages inspection, enforcement, compliance and control programs and sets service standards. It also negotiates partnerships with other levels of government and non-government organizations (NGOs), as well as industry and trading partners, with respect to inspection and compliance programs; and supplies laboratory support for inspection, compliance and quarantine activities. CFIA also issues emergency food recalls, and conducts inspections, monitoring and compliance activities along the food continuum. The Agency is supported by a national network of service laboratories.

The CFIA is responsible for the administration and enforcement of the following acts: Agriculture and Agri-Food Administrative Monetary Penalties Act, Canada Agricultural Products Act, Canadian Food Inspection Agency Act, Feeds Act, Fertilizers Act, Fish Inspection Act, Health of Animals Act, Meat Inspection Act, Plant Breeders' Rights Act, Plant Protection Act, and Seeds Act. The Agency is also responsible for enforcement of the Consumer Packaging and Labelling Act and the Food and Drugs Act as they relate to food, and the administration of the provisions of the Food and Drugs Act as they relate to food, except those provisions that relate to public health, safety or nutrition which remain under the responsibility of the Minister of Health.

Food safety partnerships

Coordination of the activities in Canada's food control system is exercised through a number of committees and established Memoranda of Understanding. For example, both Health Canada and the CFIA are involved in international activities related to food safety. Coordination of these activities is achieved through a Health Canada/CFIA Committee on International Food Safety. The Canadian Food Inspection System (CFIS) is a federal-provincial-territorial initiative to facilitate national harmonization, streamline the inspection process, and reduce regulatory pressures on industry. This initiative is managed by the Canadian Food Inspection System Implementation Group (CFSIG) which has membership representing the federal government (Health Canada and CFIA) as well as the governments of the provinces and territories."

There are several mechanisms for facilitating cooperation among governments, industry, academia, consumers and NGOs in Canada. Through an Integrated Inspection Systems approach, the CFIA works with food manufacturers and importers to develop and maintain a Hazard Analysis Critical Control Point (HACCP) system. The goal of the CFIA's compliance and enforcement activities is to move away from dependence on government inspections to increased use of government audits of industry activities. The audits are based on risk, supported by strong compliance and enforcement tools. The degree of ongoing government oversight and intervention depends on each company's history of compliance and the risk associated with its product.

The CFIA also facilitates the development of safety programs along the entire food continuum through programs such as the Canadian On-Farm Food Safety Program.

The Federal Provincial Territorial Committee on Food Safety Policy, under the leadership of Health Canada, develops, co-ordinates and provides leadership on food safety policies and standards, educational programs and the exchange of food safety information on issues of regional, national and international importance.

The Canadian Food Inspection System (CFI) is a federal-provincial-territorial initiative to facilitate national harmonization, streamline the inspection process, and reduce regulatory pressures on industry. Harmonization with international standards is an objective of all CFIS initiatives.

The Food-borne Illness Outbreak Response Protocol is a partnership among provincial and territorial governments, Health Canada, and CFIA that describes an integrated response to national and regional foodborne disease outbreaks, causing high levels of severe morbidity or mortality. The Protocol ensures that all responsible agencies are notified promptly and work collaboratively to mitigate and contain risks.

Risk-based approach

Health Canada has adopted a decision-making framework that provides a consistent, and comprehensive means of identifying, assessing, and managing risk. Similarly, CFIA has also adopted a risk-based approach to enforcement, compliance, and control processes. The concept of precaution is an intrinsic part of Health Canada and CFIA's risk analysis process. Uncertainties in scientific data are carefully considered in assessing the level of risk to which the public may be exposed and in the selection of an appropriate risk management strategy.

Risk management is accomplished through the establishment and enforcement of legislative and regulatory requirements, as well as the application of non-regulatory options such as guidelines, advice and education, and promotion of voluntary compliance by industry.

A number of factors are considered when selecting an appropriate risk management response, including legislative authority, international trade obligations, national policies, and feasibility, as well as socio-economic factors such as culture, consumer concerns and demographics.

Further developing the food safety framework

The Government of Canada is reviewing how to optimize operational efficiency and ensure stakeholder participation in food safety.

The factors that prompted Canada to review and restructure its food inspection system are not unique to Canada. The need to make more efficient use of limited public resources while ensuring the consumer is adequately protected are challenges faced by both developed and developing countries.

Case study - Ireland

Background

Aside from public health considerations, the importance of food production to the Irish economy necessitates independent and verifiable assurances as to the quality and purity of its food products. As a result, the Irish Government initiated a review of their food safety systems in 1996.

The outcome of the review was a recommendation to establish the Food Safety Authority of Ireland (FSAI) as a statutory, independent and science-based body, overseeing all functions relating to the food safety regulation of the food industry. On 1 January 1999, the Food Safety Authority of Ireland was formally established under the *Food Safety Authority of Ireland Act, 1998*. The Act:

- (a) established the Authority as an independent body accountable to the Minister for Health and Children;
- (b) transferred all responsibility for ensuring compliance with food safety legislation to the FSAI;
- (c) conferred powers on the Authority (which included those powers available under existing food safety legislation, as well as additional new enforcement powers);
- (d) provided that the existing food control enforcement arrangements at local and national level would remain in place, but would be carried out under 'contract' to the FSAI by various public bodies involved in food safety services delivery; and
- (e) provided mechanisms for the FSAI to keep food safety service delivery under review and to report to the Minister for Health and Children in relation to such matters, in particular on the scope for better co-ordination and delivery of the food inspection services.

Mission

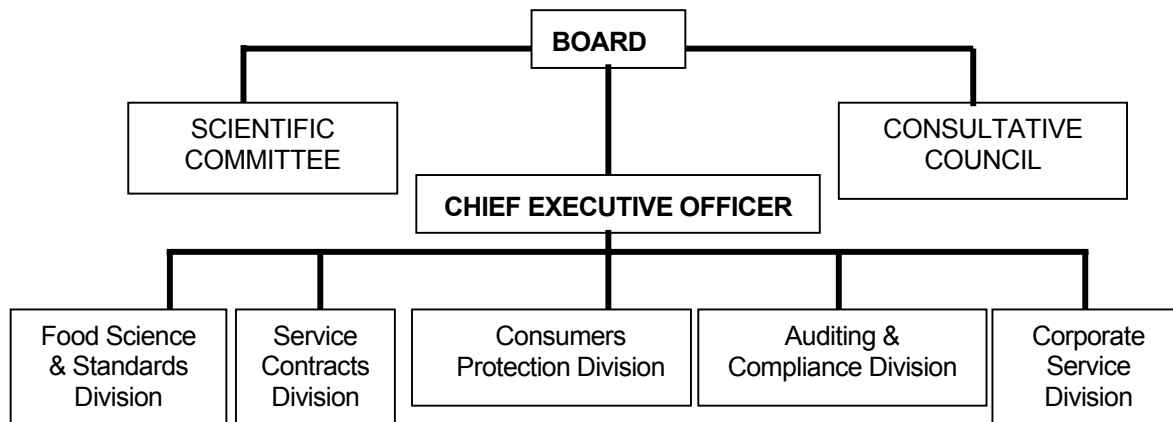
The Food Safety Authority of Ireland's mission is to protect consumers' health by ensuring that food consumed, distributed, marketed or produced in Ireland meets the highest standards of food safety and hygiene.

Structure

The Authority is a statutory, independent and science-based body, governed by a Board of ten members appointed by the Minister for Health and Children. A Consultative Council gathers the views of stakeholders involved in the production and consumption of safe food. A Scientific Committee prepares scientific advice on food safety issues. Decisions on food safety and hygiene take account of the latest and best scientific advice and information available from independent experts.

The FSAI is led by a Chief Executive who supervises a multidisciplinary team including many specialists e.g. public health practitioners, veterinarians, food scientists, environmental health specialists, microbiologists, public relations personnel, etc.

Food Safety Authority of Ireland Organizational Chart



Operations

The principal function of FSAI is to take all reasonable steps to ensure food produced, distributed or marketed in Ireland meets the highest standards of food safety and hygiene reasonably available and to ensure that food complies with legal requirements, or where appropriate with recognized codes of good practice.

The FSAI operates the national food safety compliance programme by means of service contracts with agencies currently involved in the enforcement of food legislation. This includes the Department of Agriculture, Food and Rural Development, the Department of the Marine and Natural Resources, Department of Environment and Local Government, as well as regionally based Health Boards and Local Authorities.

FSAI is also responsible for promoting communication, education and information on food safety matters (risk communication). This includes establishing and managing public relations and promotional activity, and developing and implementing policy on communication, education, and information for consumers, industry, and enforcement officers.

Food safety environment

Responsibility for creating food safety policy (risk management) lies with a number of Ministers of the Government, with the Minister for Health and Children having the coordinating role. Scientific advice upon which policy decisions are taken (risk assessment) is obtained from the Scientific Committee of the Food Safety Authority of Ireland. Food safety services (risk management) are delivered through a number of different Government Departments and agencies at national, regional and local level. The Food Safety Authority is responsible for ensuring the coordinated, effective, and seamless delivery of food safety services by those agencies.

The enforcement of food safety legislation relating to on farm activities is not within the scope of the FSAI. The Department of Agriculture, Food and Rural Development and Department of the Marine and Natural Resources enforce such legislation.

ANNEX 10. Selected Organizational Components of a National Food Control Agency

The National Food Control Agency must be perceived as a separate and distinct unit with clearly articulated goals and objectives, operating at the interface between Government and the various stakeholders in the food chain. It must be resourced with well-trained staff managing the key food control programs, and provide a transparent means of **controlling food across the whole food chain** i.e. consumer protection, promotion of food trade and industry by ensuring the safety and quality of food, and preventing fraudulent practices

While the actual structure of a National Food Control Agency will vary from country to country, the following notes describe the role, components, and activities of a typical agency:

- Independent of any specific sectoral interest/Ministry and of the food industry;
- Governed by a Management Board with a Chairperson and Directors;
- Management Board has wide ranging powers, including the formulation of food control policy and the provision of advice to Government;
- Provides a coordinating mechanism for uniform implementation of food control activities;
- Adopts a strategic view across the whole food chain and consults widely with all sectors of the food chain and all interest groups to ensure public involvement in the policy making process;
- Utilizes an open and transparent decision-making process, and able to make public its views on issues related to food safety, public health, and food control;
- Operates under the principle of protecting the health status of the consuming public, and providing information and advice that enables consumers to make informed choices;
- Responsibilities include the identification of legislative needs; monitoring the efficiency and effectiveness of law enforcement and food surveillance activities; commissioning research; etc;
- Statutory powers to coordinate, monitor and audit local agency and provincial food control activities, including food analysis, inspection, enforcement, and education;
- Possesses reserve powers that can be brought into effect in the event that enforcement bodies default or are negligent in their duties.

Management Board

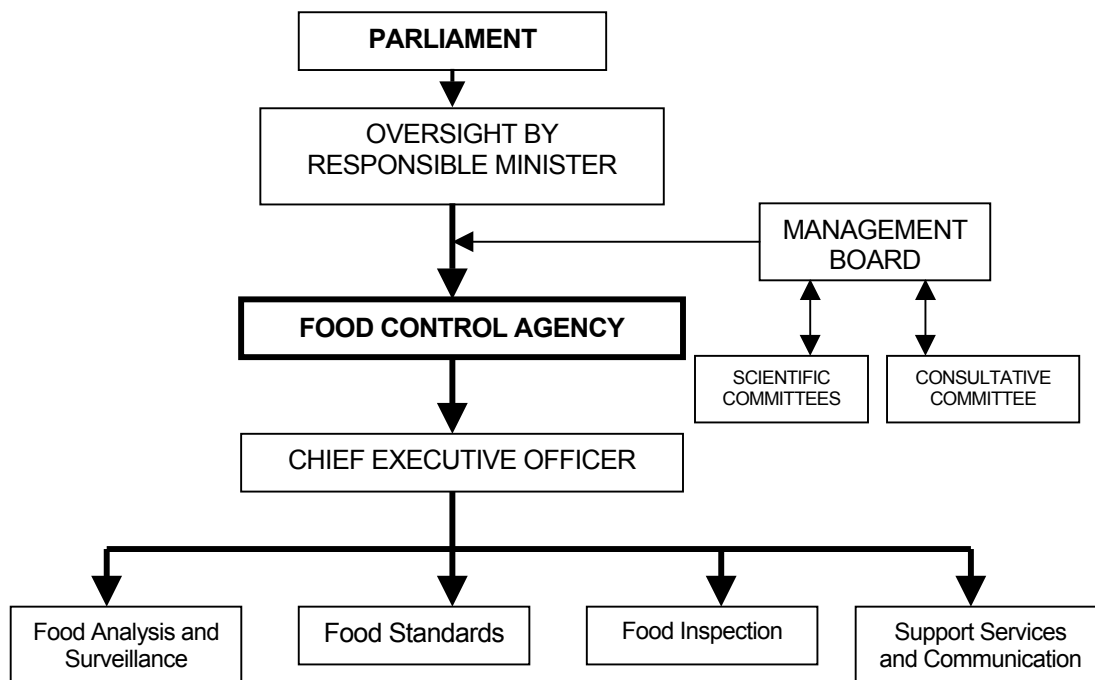
The Management Board should provide corporate governance of the Agency. The Board should satisfy itself as to the adequacy of the systems in place at different levels, take follow-up action as necessary, and give advice to the concerned Minister/s on any matter related to the Agency's mandate. The Management Board should preferably be accountable to the Parliament, or another legislative body of the country, through the concerned Minister, for all the Agency's activities and performance.

The number, conditions of engagement, and tenure of appointment of Board members will be determined by the legislation. In addition to representatives from various Ministries, other members of the Management Board will have experience or expertise in one or more of the following fields:

- Public health and epidemiology;
- Food science and technology;
- Food production;
- Agricultural science and animal health;

- Food marketing and trade;
- Human nutrition;
- Food law;
- Public administration;
- Consumer rights and affairs.

Figure 2: Possible Organizational Structure of a Food Control Agency



Board members should be responsible for taking expert advice and consulting widely to ensure that their decisions are based on the best scientific and technical advice available. As such they will be involved in a strategic role, setting the broad policy and resource framework for the activities of the Agency.

The main responsibility of the Board will be to advise on matters arising out of the administration of the food control system. It will determine matters of policy to the extent provided for within the law and provide overall coordination. It should have the authority to set up sub-committees or sub-groups to deal with specific issues of concern and have the option to co-opt experts for this purpose.

The powers of the Food Control Agency will be vested in the Management Board, and it will decide the extent to which it delegates responsibility for operational activities to the Chief Executive Officer and Agency staff. Ultimately, the Management Board should be accountable for the operations and actions of the Agency.

Chief Executive Officer

The Board, or the Minister on the recommendation of the Board, should appoint the Chief Executive Officer (CEO) of the Agency whose terms and conditions are determined by the Board. The CEO sits as a Member on the Board.

The CEO is responsible for the day-to-day operation of the Agency and the supervision of Agency staff, and directly accountable to the Chairperson of the Management Board. The CEO's

responsibilities include the provision of advice to the Board, the drafting of legislation, and representation in international negotiations on food standards.

The Scientific Committee

It may also be necessary to have a separate Scientific Committee to assist and advise the Board in matters of scientific nature. The need for appropriate scientific inputs in food control decision-making processes has increased considerably as a result of the SPS Agreement and the norms set by the Codex Alimentarius Commission. Therefore, the need for such a Committee at a national level has increased significantly. The Committee should be consulted on matters such as:

- Scientific and technical questions relating to food safety and hygiene, including risk assessment;
- Food standards and codes of practice;
- Research;
- Nutritional value and content of food and labelling;
- Implementation and administration of food inspection services; and
- Monitoring and evaluation including regulatory impact assessment.

The Consultative Committee

Broad consultation with industry and trade groups and other concerned stakeholders should be facilitated through the establishment of a "Consultative Committee". This Committee would meet as required to provide views and advice to the Management Board on pertinent issues related to food safety and its regulation throughout the food chain.

Programme Structure

The internal structure of the Agency will reflect the principal functions underpinning the management of the food control system. Key areas of responsibility may be defined as programmes, with managers who report to the CEO. Programme areas may typically include the following:

- (a) Food Analysis and Surveillance/Food Research;
- (b) Food Standards;
- (c) Food Inspection;
- (d) Support Services/Communication.

ANNEX 11. Possible Activities to be Undertaken during the Establishment of a National Food Control Agency

ACTIVITY	OUTCOME
Review national food control needs and means	<ul style="list-style-type: none"> • Develop a National Food Control Strategy with a blueprint describing national food control goals and an outline the programme • Identify resource needs of the programme
Draft legislation to establish a National Food Control Agency	<ul style="list-style-type: none"> • Establishment of an autonomous National Food Control Agency • Secure financial resources to operate the Agency
Create Agency, Board, and Committees and recruit staff	<ul style="list-style-type: none"> • Formation of Management Board • Selection of Chairman and Members • Formation of Scientific and Coordinating Committees • Draft five-year plan and submit to Minister • Establish relationship with other enforcement agencies • Organize staff appointments and determine conditions of appointment
Establish the National Food Control Agency	<ul style="list-style-type: none"> • Appointment of Agency staff • Development of Agency programmes • Preparation of operational procedures for Agency activities
Develop food laws, food regulations, and food standards	<ul style="list-style-type: none"> • Review food legislation and draft a new food law where necessary • Identify the need for food regulations and standards and their harmonization with Codex • Integrate the HACCP-approach into food regulations
Review food analysis infrastructure, resources, and capability	<ul style="list-style-type: none"> • Establish key regional reference laboratories • Identify capital and recurrent needs of the network of regional analytical laboratories • Train laboratory staff • Prepare operational procedures and develop standard methods of food analysis • Develop inter-laboratory quality assurance programmes and prescribe criteria for utilizing laboratories outside the Government system
Review food inspection activities and human resource requirements	<ul style="list-style-type: none"> • Develop a coordinated national programme of food inspection, including raw materials and agricultural produce • Prepare inspection procedures and reporting arrangements for food inspectors • Review the training needs of food inspectors • Develop an ongoing programme of human resource development for inspection and enforcement personnel
Review other resource needs and infrastructure requirements	<ul style="list-style-type: none"> • Availability of food hygiene training material • National reporting of data on food quality and foodborne disease, food trade detentions, etc • Development of national food recall procedures • Preparation of communication strategies for food safety information to consumers and industry
Review food research commitments and needs	<ul style="list-style-type: none"> • Identify priority areas for research on the basis of epidemiological and food surveillance data • Research resource needs identified • Initiate effective research programmes • Collect and evaluate scientific information on food hazards, risk assessment, and risk management