

Perspectives and guidelines on food legislation, with a new model food law

Jessica Vapnek
Melvin Spreij

for the
Development Law Service
FAO Legal Office

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ABBREVIATIONS

AB	WTO Appellate Body
AoA	WTO Agreement on Agriculture
ADI	Acceptable Daily Intake
CAHFSA	Caribbean Agricultural Health and Food Safety Authority
CARICOM	Caribbean Community
CARIFORUM	Caribbean Forum of African, Caribbean and Pacific States
CBD	Convention on Biological Diversity
CCP	Codex Contact Point
CESCR	Committee on Economic, Social and Cultural Rights
Codex	Codex Alimentarius Commission
CPE	WHO Department of Communicable Diseases Control, Prevention and Eradication
DSB	WTO Dispute Settlement Body
DSU	WTO Dispute Settlement Understanding
DVS	Director of Veterinary Services
EC	European Communities
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FIVIMS	Food Insecurity and Vulnerability Mapping Systems
FOS	WHO Department of Food Safety, Zoonoses and Foodborne Diseases
GATT	General Agreement on Tariffs and Trade
GIEWS	Global Information and Early Warning System on Food and Agriculture
GM	Genetically Modified
GMO	Genetically Modified Organism
HACCP	Hazard Analysis and Critical Control Point
IAC	IFOAM Accreditation Criteria for Certification of Organic Production and Processing
IBS	IFOAM Basic Standards for Organic Production and Processing
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICPM	Interim Commission on Phytosanitary Measures

IFOAM	International Federation of Organic Agriculture Movements
IGWG	Intergovernmental Working Group on Implementation of the Right to Food
IICA	Inter-American Institute for Cooperation on Agriculture
INFOSAN	International Food Safety Authorities Network
INTERFAIS	WFP International Food Aid Information System
IOAS	International Organic Accreditation Service
IPFSAPH	International Portal on Food Safety, Animal and Plant Health
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMRA	Joint FAO/WHO Expert Committee on Microbiological Risk Assessment
JMPR	Joint FAO/WHO Meeting on Pesticides Residues
LDC	Least Developed Country
LIFDC	Low Income Food Deficit Country
MERCOSUR	<i>Mercado Común del Sur</i> (Southern Common Market)
MRL	Maximum Residue Limit
NAFTA	North American Free Trade Agreement
NFIDC	Net Food-Importing Developing Country
NGO	Nongovernmental Organization
OIE	<i>Office internationale des épizooties</i> (World Organisation for Animal Health)
PAHO	Pan-American Health Organization
PCBs	Polychlorinated Biphenyls
SADC	Southern African Development Community
SPFS	Special Programme for Food Security
SPS	Sanitary and Phytosanitary
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
SQAM	Standardization, Quality Assurance, Accreditation and Metrology
STDF	Standards and Trade Development Facility
TBT Agreement	WTO Agreement on Technical Barriers to Trade
TRIPs	WTO Agreement on Trade-Related Aspects of Intellectual Property
UN	United Nations
UNHCHR	United Nations High Commissioner for Human Rights
US	United States

USDA	United States Department of Agriculture
WFS	World Food Summit
WHO	World Health Organization
WTO	World Trade Organization

PREFACE

The increasing globalization of food trade and the harmonization of food standards and food safety measures have led to significant changes in the international and national regulatory frameworks for food. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) named the Codex Alimentarius as the source of international standards on food safety, which has had a profound impact on the status of Codex standards, guidelines and recommendations in international food trade, particularly among members of the WTO. In addition, there is an increasing recognition of the need to integrate and improve coordination of regulatory activities among national and international bodies to better protect human, animal and plant life and health, as well as the environment, without creating unnecessary barriers to trade. On the other hand, food policies are expanding to take account not only of food safety and food security but also nutrition and the human right to food.

Recent dramatic episodes of food-borne disease accidents and outbreaks have raised concerns about the effectiveness of current food control systems in protecting consumers and have sparked increased attention to the regulatory frameworks that govern food safety and food trade. Unease over microbiological and chemical contaminants of the food chain and the use of food additives, pesticides and veterinary drugs, as well as heightened consumer interest in diet-related health issues, have also raised the profile of food safety control systems. At the same time, population growth, urbanization and new technologies are influencing food production in unprecedented ways, thus requiring more vigilance by all those involved in the food chain – from primary producers to the consumer – to ensure food safety.

These developments have given rise to new legislative needs. National regulatory frameworks have to be adjusted to meet international and regional obligations, while the distribution of responsibilities for the food sector at national level requires rigorous review. Traditionally, inspection and monitoring activities have often been dispersed among ministries of health, veterinary services, agriculture and fisheries, with the concomitant administrative burdens and inefficient resource use. Acknowledging the need to update and modernize their food regulatory frameworks, many countries have been reviewing their food legislation and related enactments to identify gaps and overlaps in responsibilities in the food control system and to foster

collaboration among responsible ministries. There is a growing tendency to combat fragmentation and to improve the national legal and administrative framework by adopting a basic food law which establishes a primary authority to oversee the food system “from farm to fork”.

Dissatisfaction with the legislative framework for food control is often widespread at national level, but it is not always obvious what steps are required in order to comprehensively analyse the legislative scheme. This book aims to assist food control authorities in addressing this specific need. It builds on the recent publication by FAO and WHO entitled “Assuring Food Safety and Quality: Guidelines for Strengthening National Food Systems”, which provided comprehensive advice on the many considerations affecting the design of national food control systems. The present text draws on FAO’s experience in providing technical assistance to governments in developing new food laws and regulations, by setting out and examining the many elements of the national system which should be taken into account in a comprehensive review of national regulatory frameworks for food.

The book begins by examining the empirical and regulatory changes at the international and national levels which have driven alterations in attitudes toward food control, food safety and food trade. It then reviews the international context of food regulation, identifying and discussing the international organizations and international instruments that have an impact on food law. The book goes on to examine the broad range of topics that constitute a country’s national legal framework for food, advocating an inclusive approach in the assessment and revision of national legal frameworks for food. The goal is to present the range of subject matters that may touch on food, identifying the overlaps as well as the inter-relationships, with an eye toward drawing as many issues as possible into one framework food law.

The book next explores the principal expressions and trends in food policy which should be taken into consideration when developing a food law, and examines how they might be reflected in national legislation. Thereafter, the book considers the social, political, legal and economic backdrop which will inform the national lawmaking process. Taking into account the constellation of policies, institutions and resources existing at national level, governments can choose a legislative strategy that best meets their national needs. Toward that end, the text offers concrete recommendations for the preparation of a basic national food law, including three variants of a new

model food law. The book culminates in an overall review of the lessons learned as well as some cross-cutting themes.

In addition to the principal authors, Jessica Vapnek and Melvin Spreij, this publication has benefited from the research assistance of Lillian Pinzon, Ben Walsby and Erin Morrow and the earlier analytical work of Jonathan Lindsay and George Sarpong. Many others have reviewed and made comments on previous drafts, including in particular Alan Randell, as well as David Fraser, Leo Hagedoorn, Peter Lallas, Kerstin Mechlem, Kazuaki Miyagishima, Victor Mosoti, Margret Vidar and David Wilson. It is hoped that the resulting study will prove useful to governments and researchers alike.

Mohamed Ali Mekouar
Chief
Development Law Service
Legal Office

Ezzeddine Boutrif
Chief
Food Quality and Standards Service
Food and Nutrition Division

INTRODUCTION

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I. CONTEXT OF FOOD LAW

Over the last decade, there have been significant changes in the national and international regulatory frameworks governing food control, food safety and food trade. The adoption of the Codex Alimentarius as the source of international food standards by the World Trade Organization Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) in 1995 has been one of the most significant recent influences on food regulation worldwide, and can be seen as an acknowledgment of the increasing globalization of food production and food trade. Worldwide outbreaks of food-borne disease, with concomitant media attention and outspoken consumer concerns, have also triggered unprecedented interest in food control and food regulation and in the country-level infrastructures which govern food safety.

Equally, the last decade has seen heightened interest in the intersections between food safety and other areas of agriculture which have heretofore been treated separately, such as plant quarantine and animal quarantine. Often these topics are combined under the heading “biosecurity”, which is generally understood to mean protection from the environmental, economic and human health risks of potentially harmful plant and animal pests and diseases, alien invasive species and genetically modified organisms. In a number of countries, governments have vested food safety, animal quarantine and plant quarantine authority in a single executive agency which carries out inspections “from farm to fork” and aims to protect animal, plant and human life and health.

A variety of developments have driven these changes. The next sections explore some of the empirical and regulatory changes over the last decades which have influenced discussions and policy formulation regarding food control, food safety and food trade at international and national levels.

II. INTERNATIONAL LEVEL

2.1. Empirical

No description of the changing environment for food trade can ignore the increasing globalization of trade over the last decade or more. According to international trade statistics published by the World Trade Organization (WTO),

world food exports had reached a total value of US\$543 billion per year in 2003. This figure reflects an increase of US\$75 billion from 2002 and a further US\$31 billion from 2001. Moreover, this trend is set to continue, with the export of maize products from developed to developing countries, to take one example, predicted to rise from 30 million tonnes in 1995 to 68 million tonnes by 2025. International trade in food has grown enormously as countries rely on one another to secure an adequate and varied food supply through the import and export of food products. This has both raised the potential for countries to export products and increased the risks of the spread of food hazards through the ease of moving products from place to place. At the same time, the lowering of trade barriers has raised fears among developing countries that their exports will not be competitive on the market or that developed countries may “dump” unsatisfactory products in their markets because of the lack of enforceable controls.

In the coming years, countries will have improved access to export markets, but this will be accompanied by greater competition and the need to ensure confidence in the safety of the food supply. This latter can be achieved through the application of the “farm to fork” principle, according to which all links in the food chain should be checked to assure food safety and quality, and through the incorporation of a preventive approach to food safety. National, regional and international information-sharing can assist in combatting consumers’ fears, and research can improve the scientific understanding of food-related risks.

Privatization is another trend which has had an influence on global food trade. In Central and Eastern Europe and other countries in transition to market economies, privatization is obviously related to the dismantling of socialist governing structures. But it is not restricted to this context. Whether through domestically inspired reform, or under pressure from outside in the form of structural adjustment programmes and the like, countries around the world are facing the need to revise legal structures in a direction that disentangles government from the market and from the provision of services, that favours private investment and that improves the legal environment for private trade. In the food sector, this might be implemented at national level by, for example, turning over food inspection and food analysis responsibilities to a parastatal or independent agency, and harmonizing and streamlining regulatory and

bureaucratic requirements for the entry into the market as a food business or food trader.

In contrast to globalization, harmonization and other examples of convergence, one trend appears to celebrate the potential of divergence – namely, the growing emphasis on decentralization of government powers and responsibilities. Legal frameworks are being changed to reflect policies promoting local decisionmaking in a wide variety of fields. Decentralization is a strategy that is widely embraced in principle by governments and international agencies, and is one that finds expression in numerous legal instruments. One of the motivating factors may be the desire to manage more effectively than central governments have been able to do, alone. Another may be to reduce cumbersome bureaucracies that may leave gaps in coverage in certain sectors or certain regions, particularly in rural areas. For food control, a strategy to reorient legal texts and institutions toward these ends might involve assigning district and municipal authorities the mandate to inspect food businesses at local level.

2.2. Regulatory

Significant regulatory activity has taken place in the international arena with regard to food over the last several years. The Uruguay Round of Multilateral Trade Negotiations in 1994 led to the establishment of the WTO in January 1995. Agriculture was included in the trade talks in a significant way for the first time and it was agreed to reduce tariff barriers for many agricultural products in order to encourage free trade. Two agreements relevant to food, the SPS Agreement and the Agreement on Technical Barriers to Trade (TBT Agreement), were concluded within the framework of the WTO. These agreements set important parameters governing the adoption and implementation of food quality and food safety measures.

The TBT Agreement, which had been in existence as a voluntary agreement (the “Standards Code”) since the Tokyo Round (1973–1979), was converted into a binding multilateral agreement through the Uruguay Round. It covers all technical requirements and standards (applied to all commodities), such as labelling, that are not covered under the SPS Agreement.

The SPS Agreement was drawn up to ensure that countries apply measures to protect human and animal health (sanitary measures) and plant health (phytosanitary measures) based on an assessment of risk, or in other words, based on science. The aim is the establishment of a multilateral framework of guidelines and rules that will orient the development, adoption and enforcement of harmonized sanitary and phytosanitary measures and minimize their negative effects on trade. The use of international standards is intended to allow countries to prioritize the use of their often limited resources and to concentrate on risk analysis.

As noted, Codex Alimentarius is the main instrument for the harmonization of food standards, and constitutes a collection of internationally adopted food standards, codes of practice and maximum residue limits of pesticides and veterinary drugs in food. The objectives of Codex are to protect the health of consumers, to ensure fair practices in food trade and to promote the coordination of all food standards work undertaken by national governments. Under the SPS Agreement, Codex standards, guidelines and recommendations have been granted the status of a reference point for international harmonization. They also serve as the basic texts to guide the resolution of trade disputes. WTO members are called upon to base their national food safety measures on international standards, guidelines and other recommendations adopted by Codex where they exist, and so long as a country employs these standards, its measures are presumed to be consistent with the provisions of the SPS Agreement. (Countries may also apply stricter standards than the Codex standards, so long as those are based on science.) Thus, while Codex standards in and of themselves are not binding, they have become binding on WTO members through the SPS Agreement.

The growth in the number of countries joining the WTO and therefore bound by its agreements has created a flurry of interest in revising legislation to meet international obligations and to capture the principles of these agreements, such as harmonization, equivalence and non-discrimination. Similarly, countries eager to join regional groupings such as the European Union (EU) have been faced with the task of conforming their national laws on a wide range of subjects to EU requirements. The Caribbean Community (CARICOM) and the North American Free Trade Agreement (NAFTA), among others, have also influenced the legislation of their members, especially although not exclusively on trade

matters. Regional standard-setting organizations have been building on international models while tailoring standards and measures to regional interests. The creation of new regional economic groupings such as the African Union confirms the expectation that regional harmonization efforts will continue to grow.

III. NATIONAL DEVELOPMENTS

3.1. Empirical

At country level, expanding populations have continued to pose great challenges to world food systems. To feed growing numbers of people, agricultural yields and animal husbandry practices have had to improve; pre- and post-harvest losses have to be reduced; food processing and distribution systems are becoming more efficient; and new technologies and strategies are being adopted. Developing countries in particular have had to cope with poor post-harvest infrastructure, including the lack of safe water, electricity, storage facilities, roads and means of transport.

Not only is population expected to increase, but much of that increase will take place in urban areas. Virtually all the population growth expected from now to 2030 will be concentrated in urban areas, as the world's urban population rises from 2.9 billion in 2000 to 5 billion by 2030. Migration to urban areas and increasing urbanization create greater demand for food, and the higher population density increases the risk of health hazards.

In both urban and rural areas, much has changed in the way food is produced, prepared and sold, and this has raised the potential for new risks. For example, new technologies allow food products to travel farther and stay fresh longer, but paradoxically the growing volume of international trade in agricultural products has made the rapid transmission of food hazards more likely and rapid reaction more problematic. As food is produced, prepared and moved around the globe, it can be affected not only by microbes but also by chemicals and environmental contaminants. Misuse of pesticides during production and storage can lead to high levels of residues, and heavy metals and other contaminants can enter food through soil or water. Dioxins can enter the animal feed supply from feed additives, and animal feed affected with mycotoxins can contaminate milk and

meat. Antibiotic drug residues arising from improper animal feed or treatment may contribute to the growing antibiotic resistance of micro-organisms.

The use of genetically modified organisms (GMOs) in food production is another trend that has triggered interest and concern about food safety and food trade in recent years. Advances in biotechnology have permitted the artificial transfer of genetic material from one organism to another, including across species boundaries. This has the potential to broaden the range of alterations that can be made to food and to expand the spectrum of possible food sources, but it may also have the potential to harm human health, agriculture or the environment. Advances through genetic modification of food may be able to improve the world's food supply, reduce potential losses due to pests, diseases, transport and storage and provide health benefits through added vitamins or nutrients, although consumers are increasingly vocal in expressing concerns about potential unintended harmful effects of such food.

A new market for agricultural products has arisen to meet rising consumer demand for safe food products and foodstuffs. Organic agriculture aims to produce food while respecting ecosystems, preserving soil fertility and preventing pest problems. In addition to prohibiting the use of GMOs at all stages of food production, processing and handling, it tightly restricts the use of fertilizers and pesticides.

Media interest in genetically modified foods and in food-borne disease outbreaks has raised public awareness in many countries, and consumers are becoming more organized and more active. Improved access to scientific knowledge, including through the internet, has helped consumers to gain a better understanding of food safety issues. Consumers are insisting on better protection in the whole food supply chain, expecting that both domestic and imported foods will meet basic quality and safety standards and will conform to requirements relating to food hygiene, labelling, additives and residues. Citizens concerned about biological, chemical and environmental hazards, including the potential risks from GMOs, will likely continue to call for greater attention and resources to be allocated to food safety issues.

3.2. Regulatory

National legal frameworks governing food control and food safety vary widely in their complexity and their coverage. Some countries have no food legislation whatsoever, relying solely on international instruments such as Codex standards. Other countries may have comprehensive food legislation but it may be outdated, having been in place for decades. Still others may have religious codes operating in tandem with statutory rules, or may have written policies that are only partially reflected in enforceable and enacted legislation.

Typically the legal framework governing food in a particular country reflects a mix of political, societal, economic and scientific forces. Laws and regulations may not have been updated or may have constantly been amended, creating a maze of rules which regulators, industry and consumers find difficult to understand. Changes may have been influenced by the need to develop a regulatory framework for the domestic market or to promote exports. In such cases the legislative instruments may have addressed only specific products or specific food-related activities, and the whole system can therefore lack coherence and be quite complex. Although some sectoral regulation is inevitably necessary in any food control system, the overall goal is to address most food issues comprehensively in a basic food law, accompanied by implementing regulations and standards.

The difficulty in many countries is to identify the institution or institutions which will be charged with the authority to implement the basic food legislation once it has been amended or enacted. Historically, food control has been considered to be within the purview of the ministry responsible for health (as food safety implicates human health), although certain sectors, such as inspection of meat or other animal products, have traditionally been assigned to the veterinary services. The veterinary services unit is usually located within the ministry responsible for agriculture, whereas the responsibility for controlling the safety and quality of fish products may rest with a separate ministry responsible for fisheries. The sundry assignments of responsibility may or may not lead to conflicts, overlaps and gaps with the ministry responsible for health at country and local level.

Local authorities may have been given responsibility for the tourism sector, such as hotels and restaurants, whereas still other ministries or agencies may have

responsibility for inspection of street markets, street sellers, labelling and weights and measures. Businesses wishing to produce, store or sell food may have to apply for a licence from yet one more ministry, the ministry responsible for commerce or trade and industry. For purposes of inspection, locally produced food may come under one umbrella, whereas border controls of imported food may fall under another, such as the customs authority. Such potential problems may be magnified in countries with federal systems, as the structures and divisions among federal ministries may be mirrored in an equal number of competing or overlapping ministries at state level.

The above description should make it clear why many countries have turned to reviewing their food legislation in order to identify gaps and overlaps in responsibilities, and to assign ultimate authority for carrying out food control and food safety activities. While these goals are laudable, it is worth noting that not all problems are legal, nor may the solutions necessarily be found through legislative modifications or new enactments. What is often the most critical precursor step is to convene representatives of the many agencies and ministries involved in food control activities in the country and to foster collaboration, so that the areas of individual action and the areas needing cooperation can be systematically identified and assigned. Only with proper analysis and identification can appropriate legislative modifications be made to implement these changes.

IV. PURPOSE OF THE STUDY

It is against the backdrop of these national, regional and international trends that the FAO Legal Office has decided to commission the present study. Past publications have explored various topics under the broad category of food law, such as “An Outline of Food Law” (1975) and “Legislation Governing Food Control and Quality Certification” (1995), but much of this material has been overtaken by events. For example, the Model Food Law of 1976 (jointly prepared by FAO and the World Health Organization, WHO) is nearly 30 years old and can no longer meet the needs of countries wishing to assess and revise their food legislative frameworks, particularly in light of the WTO, the SPS Agreement and Codex standards, many of which have been developed within the last 25 years. New issues have arisen, past concerns have morphed into new themes and recent work by FAO and other intergovernmental and

nongovernmental actors should be embraced and incorporated into new recommendations for national governments.

This study attempts to fill that need. Chapter 2 explores the international context of food legislation and food regulation, identifying and discussing the international organizations having an impact on food law. These include the WTO, Codex, the *Office international des épizooties* (OIE) and regional groupings such as the EU, CARICOM, the Southern African Development Community (SADC) and others. Chapter 3 examines the kinds of topics relevant to food that are regulated at national level and that can be considered part of a country's national legal framework relevant to food. Some of this regulation will take place through specific sectoral laws, whereas other elements will be addressed as component parts of other laws. The subject matters range from provisions directly addressing food, such as legislation on street foods, on the manufacture and inspection of meat or fish products or on the control of food residues, to provisions not specifically addressing food but having an impact on it. This last category would include legislation addressing public health, water, land and the environment. Chapter 3 aims to assist policymakers in identifying the broad range of legislative instruments and legislative provisions that may have an impact on food and that should be taken into account in any comprehensive assessment of the existing national regulatory framework for food.

Chapter 4 turns to the policy environment in which food legal frameworks are updated. The chapter identifies and discusses major policy trends, some of which are not usually taken into account in the preparation of food legislation, and posits that certain prominent issues should be given higher priority. For example, food security, food aid and the right to food cannot be ignored in any discussion of forward-thinking legislative action with regard to food. Some food policies can be addressed in the kind of umbrella food law introduced in Chapter 5; others will require separate legislative action at national level.

Chapter 5 begins with a pragmatic analysis of the context for national lawmaking, identifying and analysing the factors that may affect the choices to be embraced or rejected in the revision or preparation of legislation. These include the kind of legislative system in the country at issue (common law vs. civil law; federal vs. non-federal); the constellation of existing legislation (what does it say; should it be changed or not; can it be changed or not); the existing institutions

and current government policies (e.g. decentralization; privatization; short- and long-term strategies); politics and the human element (powerful and not powerful ministries; turf battles; historical divisions of responsibilities); the level of development in the country; and the availability of various kinds of resources.

Chapter 5 next turns to the subject of comprehensive food laws, positing that although some sectoral regulation is inevitable (as outlined in Chapter 3), and although there will be some political, resource and other constraints, there is a place for drafting basic food legislation at national level. This chapter encapsulates recommendations based on the FAO Legal Office's lengthy experience in providing assistance to member countries in revising and updating their national legal frameworks for food, in collaboration with FAO's Food Quality and Standards Service. The chapter discusses the possibilities for, as well as the advantages and disadvantages of, centralizing most food control activities into one law, and then outlines suggested provisions to be included. Among other advantages, countries that revise their food laws at the beginning of the 21st century will be able to meet their international obligations (as outlined in Chapter 2) and to capture important food policies (as outlined in Chapter 4).

The last chapter, Chapter 6, concludes by reviewing the material explored in the study and drawing out some cross-cutting themes. In particular, while the earlier chapters consistently supported the centralization of food-related activities, this chapter goes further by proposing the consolidation of animal and plant health authorities with food safety as well. The intersection of food safety with animal health and plant protection, or biosecurity, is extremely topical at international and national levels, and its implications for food safety and food control regulation must be considered.

The Appendix contains three versions of a new model food law as alternatives to the FAO/WHO Model Food Law of 1976. The first version establishes a central food authority; the second captures a system in which existing ministries maintain control over food safety, although one takes a leading role; and the third encapsulates an integrated approach, with certain tasks assigned to a central authority and others retained by the line ministries.

This text aims to be a comprehensive study of the variegated field of food law, by describing existing legal and regulatory frameworks and identifying best

legislative practices. It should neatly complement the recent publication produced jointly by the Food and Nutrition Division of FAO and the Food Safety Department of WHO entitled “Assuring Food Safety and Quality: Guidelines for Strengthening National Food Systems”, which updates the technical recommendations for national governments in organizing their food control systems.

V. WHAT IS FOOD LAW?

Before turning to the international context of food law, and then to the existing and desirable elements of national food law frameworks, it is important to define “food law”. The term is generally used to apply to legislation which regulates the production, trade and handling of food. The narrow view would restrict this meaning to the regulation of food control, food safety and food trade at national level, and would focus on laws and regulations that refer to food in general or to specific kinds of food. Food safety laws, fish inspection laws, export rules for foods of animal origin – all these would fit within this category. On this understanding, international considerations are minimal, and are only taken into account in relation to imports and exports.

The broader view would look at the wide variety of fields that must actually be regulated in order to ensure the production, trade and handling of safe food, and would take all of these into account. In other words, everything having to do with food at national level, whether directly or indirectly, would come within the ambit of food law. This would accordingly require a definition of food law that takes cognizance of the many legislative provisions, wherever they may be found, which are relevant to ensuring safe food. Falling into this category would be specific food safety laws as well as consumer protection or fraud deterrence laws, laws on weights and measures, customs laws, import and export rules, meat inspection laws, fish products inspection rules, laws on pesticide and veterinary drug residues and laws controlling fertilizers and animal feeds, among many others.

This more comprehensive perspective would also acknowledge that one cannot examine legislation on the production, sale and handling of food in isolation. Thus, “food law” would include not only regulation of food control, food safety and food trade, but also food security as well as implementation of the right to

food. Moreover, this wider view would consider the intersection with other operational and legislative areas such as plant protection and animal health, on the understanding that they are inextricably linked with issues of food control, food safety and food trade.

The present study subscribes to the broader view, advocating an inclusive approach in the assessment and revision of national legal frameworks for food. This standpoint informs the authors' support for the centralization of food control activities at national level (and even for the establishment of independent central authorities that address all sanitary and phytosanitary measures at national level). At the same time, we acknowledge that certain subject matters more easily lend themselves to being addressed and regulated in food-specific legislation, whereas inevitably there are other areas better left to other government agencies or units outside the centralized structure and better left to sectoral regulation. Nonetheless, it is hoped that the comprehensive framework outlined here will prove useful to those carrying out an analysis at national level in order to identify the numerous component parts of a country's regulatory framework for food. Only through the identification and assessment of each and every activity, institution, policy and legislative provision related directly or indirectly to food at national level can governments identify strengths, weaknesses, overlaps and gaps. Thereafter, after taking into account the constellation of policies, institutions and resources operative and existing at national level, governments can choose a legislative strategy that best meets their present national needs and international obligations.

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I. INTRODUCTION

In many countries, local authorities are assigned responsibility for human health protection, on the assumption that they are best able to address local problems through locally tailored solutions. Indeed, the regulation of food control, food safety and food trade generally takes place at national and sub-national levels. Nonetheless, at the outset of the 21st century it is impossible to ignore the international context in which national regulation takes place, as international issues have grown in prominence and influence in recent years. This is both because of the extraordinary interdependence of nations in the trade arena, as well as the growing recognition on the part of national governments of the need or the obligation to base their own standards on those prepared under the auspices of international organizations. Efforts to find solutions to the questions of global food insecurity and to provide substance to concepts such as the right to adequate food have also bolstered interest in collaboration in the international arena.

A plethora of governmental, intergovernmental and nongovernmental organizations (NGOs) are active to varying degrees in the formulation of food standards and the search for solutions to global food problems. United Nations (UN) agencies, UN common system organizations, NGOs, advocacy groups and treaty bodies devote their resources and expertise to one or more of the issues exercising governments and industries with respect to food control, food safety and food trade. Accordingly, this chapter turns to the twin issues of international standard-setting and international guidance, examining some of the most influential international and regional organizations which either serve as the fora for governments and other parties to discuss and resolve food-related concerns or which produce and disseminate guidelines or other forms of advice.

II. WORLD TRADE ORGANIZATION

2.1. Background and structure

From 1948 to 1994, successive rounds of multilateral negotiation under the General Agreement on Tariffs and Trade (GATT) established the governing international rules for trade between states. Whereas the first negotiations focused on lowering tariffs on imported goods, later negotiations also covered non-tariff barriers. The latest and largest negotiation round was the Uruguay Round of Multilateral Trade Negotiations from 1986 to 1994, which led to the creation of the World Trade Organization (WTO) on

1 January 1995. The Uruguay Round included not only goods but also services and intellectual property, and for the first time brought agricultural products under the discipline of international trade rules.

The WTO, located in Geneva, Switzerland, was established as the international body to deal with rules of the multilateral trade system among states. Its objectives are to help trade flow as freely as possible, to further liberalize trade through negotiation and to set up an impartial means of settling disputes. Currently, the WTO membership includes 147 member states and one regional economic integration organization, while many other countries are negotiating membership. These latter, as well as a number of international organizations, have observer status at the WTO. Major decisions are made by the entire membership and are normally achieved through consensus: although a majority vote is possible, to date it has never been used.

The highest decisionmaking body is the Ministerial Conference, which meets at least once every two years. More routine work is supervised by the General Council, which consists of the special ambassadors or heads of delegations of countries having diplomatic missions in Geneva, and which meets several times per year. The General Council also meets as the Dispute Settlement Body to oversee procedures for settling disputes, and meets as the Trade Policy Review Body to analyse members' trade policies. Numerous other specialized councils, committees, working parties and negotiating groups deal with a wide range of issues and areas. The WTO Secretariat, headed by a Director General, provides administrative and technical support, carries out trade policy analyses, assists in the resolution of trade disputes and addresses accession negotiations for new members.

2.2. Functions

At the heart of the WTO are trade agreements, ministerial decisions and declarations that provide the legal ground rules for international commerce. All WTO members have signed and ratified the agreements in their parliaments or legislatures, and all are bound by the agreements' provisions and requirements. Foremost is the Marrakesh Agreement Establishing the World Trade Organization, which serves as an umbrella agreement, and annexed to it are various agreements on trade in goods and services, trade-related aspects of intellectual property rights, dispute settlement, trade policy reviews, some plurilateral agreements and a number of ministerial

declarations and decisions. Currently, there are about 60 such agreements, declarations and decisions in place.

For trade in goods, the GATT 1947 was updated and incorporated into the GATT 1994. It is the principal agreement governing trade in goods and contains a number of principles that form the foundation of the multilateral trading system, including “most-favoured nation treatment” – if you treat one country favourably, you have to do the same for all other WTO members – and “national treatment”, i.e. imported goods must be treated the same as locally produced goods. It also contains provisions on general exceptions for important policy areas, including protection of human, animal or plant life or health and the conservation of exhaustible natural resources.

Other agreements and decisions deal with specific issues, and several of these have important implications for the food sector. The Agreement on Agriculture (AoA) led to a considerable reduction in tariffs on agricultural imports and exports, in domestic support measures and in export subsidies, while non-tariff barriers such as permits and import quotas were eliminated or restricted. The Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) requires WTO members to provide minimum standards of intellectual property protection, including the protection of new plant varieties, through patent rights, a *sui generis* system or some combination thereof. Furthermore, TRIPs protects the names of particular food products associated with specific geographic places (geographical indications).

While formulating these agreements which are aimed at the liberalization of trade, participants in the Uruguay Round also recognized that their implementation could have negative effects on those countries that rely on food imports and aid. For this reason, the Decision on Measures Concerning the Possible Negative Effects of the Reform Programme on Least-Developed and Net Food-Importing Developing Countries was taken, which sought to establish a mechanism to safeguard such countries’ ability to import food during the period of reform. Among other things, the decision incorporates differential treatment in terms of export credit for net food-importing developing countries and financial assistance from the World Bank and the International Monetary Fund. But it is the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement) which have the most important consequences for national food legislation.

2.3. Implementation of the WTO agreements

2.3.1. SPS Agreement

The SPS Agreement sets out the rights and responsibilities of WTO members wishing to apply measures to protect human and animal life and health (sanitary measures) and plant life and health (phytosanitary measures). To minimize such measures' negative effects on trade, the SPS Agreement requires that they be applied only to the extent necessary and that they be based on an assessment of risk, taking into account scientific evidence, relevant processes and production methods, inspection, sampling and testing methods, specific diseases or pests, ecological and environmental conditions and, in the case of animal and plant life and health, relevant economic factors. Furthermore, national SPS measures must not be applied in a manner that constitutes arbitrary or unjustifiable discrimination or a disguised restriction on trade.

For food safety, the SPS Agreement encourages WTO members to base their national measures on the international standards, guidelines and recommendations adopted by the Codex Alimentarius Commission (Codex). For animal and plant life and health, measures are to be based on those standards adopted and recommended by the *Office internationale des épizooties* (OIE, the World Organization for Animal Health) and the International Plant Protection Convention (IPPC), respectively. Although the SPS Agreement acknowledges the limitations of means, it encourages the participation of member states, in particular developing countries, in these international organizations, so that they can contribute to the formulation of sanitary and phytosanitary measures and have sufficient information to make decisions regarding the approval of international standards.

The main implication of the SPS Agreement for national legal frameworks is that so long as a member state employs international standards in the formulation of its national measures, these are presumed to be consistent with the provisions of the agreement. However, member states are allowed to adopt measures that establish a higher level of protection than that provided by the relevant international standard if there is a scientific justification, based on risk assessment. Measures may not arbitrarily or unjustifiably discriminate between member states where identical or similar conditions prevail, and importing member states are obliged to accept the measures of other member states as equivalent if the exporting country

objectively demonstrates to the importing country that its measures achieve the importing country's appropriate level of protection. See Box 1.

The SPS Agreement also requires member states to establish national enquiry points, which offer advance notice of any new or changed measures, thus giving other member states an opportunity to comment on them. Finally, member states must take into account the special needs of developing countries, in particular the least developed countries, which are granted longer time frames for compliance with the agreement.

2.3.2. TBT Agreement

The TBT Agreement seeks to ensure that technical regulations and standards, including packaging, marking and labelling requirements as well as testing and certification procedures, do not create unnecessary obstacles to international trade. The TBT Agreement covers all technical standards not covered by the SPS Agreement, and applies to all food products, including agricultural products.

The TBT Agreement recognizes the right of WTO member states to adopt the measures they consider appropriate, although such measures should not be more trade-restrictive than necessary to fulfil legitimate objectives such as the prevention of deceptive practices or the protection of human health and safety, animal or plant life and health or the environment.¹ Measures to achieve these objectives can be justified based on scientific and technical information, related processing methods or the end use of products. Measures shall not create unnecessary obstacles to trade and discrimination among member states is prohibited.

Unlike the SPS Agreement, the TBT Agreement does not recommend the use of a specific international standard-setting body. In practice, if a member state observes the standards, guidelines and recommendations of Codex in developing its national food-related measures, these are presumed to comply with the TBT Agreement. To foster harmonization, the TBT Agreement encourages member states to use international standards where appropriate, but does not require states to change their levels of protection as a result.

¹ It is worth noting that unlike the SPS Agreement, the TBT Agreement incorporates the concept of "proportionality", i.e. member states must take account of the risks caused by non-fulfilment of a legitimate objective. It is unclear how this would be interpreted in the dispute settlement process.

Box 1 Scientific Justification for Sanitary Measures: The Beef Hormone Case

In 1989, the European Community (EC) banned the use of synthetic hormones and prohibited the importation of beef produced with them. Because the United States uses growth hormones in beef production, the ban essentially blocked United States beef exports to the EC (from 1992, to the European Union (EU)). The United States maintained that growth hormones were safe and therefore the ban was not scientifically justified. The EU argued that the impacts of the hormones on human health were unknown and stated that it had applied the precautionary principle, which essentially states that lack of full scientific certainty cannot justify inaction. With the entry into force of the SPS Agreement in 1995, Codex adopted standards accepting residue levels of synthetic hormones in meat. That same year the United States and then Canada launched formal WTO dispute settlement procedures (see section 2.4) against the EU with regard to the hormone ban.

A WTO panel held that the ban violated WTO obligations because it was not based on scientific evidence, risk assessment or international standards. In 1998, the Appellate Body (AB) modified the panel's findings, reiterating that national sanitary measures need not be based on international standards so long as they are scientifically justified. Although the AB declined to take a position on whether the precautionary principle was a general principle of international law, it noted that the principle finds reflection in certain provisions of the SPS Agreement. The AB agreed with the panel that the EU ban was not based on risk assessment and the EU was given 15 months to comply. When it did not, Canada and the United States imposed 100 percent tariffs on selected EU imports with a trade value equal to the lost beef exports.

Instead, the EU conducted a scientific re-evaluation of the risks to human health from hormone residues in beef treated with growth hormones. In September 2003, it adopted a new directive maintaining the permanent prohibition on one hormone and imposing a provisional ban on five others. In October 2003, it notified the WTO that it had implemented the WTO ruling of 1998 and that, as a consequence, the sanctions imposed by Canada and the United States were no longer justified. Those two countries disagreed and since then have refused to lift their sanctions. In November 2004, the EU launched formal WTO dispute settlement procedures against Canada and the United States regarding their continued imposition of sanctions.

The TBT Agreement does encourage standard equivalence between countries through the acceptance of standards of other countries in explicit bilateral agreements.

A Code of Good Practice for the Preparation, Adoption and Application of Standards by standardizing government bodies is included as an annex to the TBT Agreement. National enquiry points function as information collection points for manufacturers and exporters on the latest standards in their markets, and notify other member states of any draft measures. It is worth noting that, like the SPS Agreement, the TBT Agreement requires member states to take into account the special development, financial and trade needs of developing countries, with a view to ensuring that regulations, standards and procedures do not create unnecessary obstacles to exports from them.

2.3.3. Position of developing and least-developed countries

Both the SPS and TBT Agreements include special and differential treatment provisions to address the needs of developing and least developed countries, which make up about two-thirds of the WTO membership. Still, limited technical, human and financial resources continue to hamper many of these countries' ability to achieve their health and food safety objectives. While most countries have legislative and regulatory frameworks on sanitary and phytosanitary issues, many provisions are outdated and are not harmonized with the SPS and TBT Agreements or with standards set by the relevant international organizations. More importantly, many countries face very real constraints on their capacity to implement and enforce sanitary measures and technical regulations. Due to a lack of infrastructure (regulatory and standardizing bodies, accredited laboratories or other testing facilities to conduct risk analysis), many nations are unable to provide the necessary scientific and technical justification for the sanitary measures they apply to food imports.

To address these and other implementation problems, WTO member states have agreed to provide developing countries with technical assistance, either bilaterally or through the appropriate international organizations. Assistance can be provided, among other things, toward preparing sanitary measures and technical regulations, facilitating participation in the activities of international bodies and establishing proper infrastructure. Assistance may take the form of advice, credits, donations, grants, training and equipment.

2.4. Dispute settlement

WTO members failing to comply with international food standards or otherwise violating the SPS or the TBT Agreement can be challenged in several ways. First, whenever a draft measure is notified, member states may ask for justification. Second, the question of whether a member state is failing to apply an international food standard may be brought before the SPS Committee or the TBT Committee, which, respectively, manage those agreements. Third, countries can resort to dispute settlement as laid down in a separate WTO agreement entitled the Understanding on Rules and Procedures Governing the Settlement of Disputes (Dispute Settlement Understanding, or DSU). WTO members are obligated to follow the procedure contained in the DSU and to refrain from making determinations of violations or suspending trade concessions unilaterally.

The DSU sets out in considerable detail the rules and timetables to be followed in the resolution of disputes. Dispute settlement is the responsibility of the Dispute Settlement Body (DSB), which has the authority to establish “panels” of experts to consider a case and to issue a report and recommendations which the DSB may adopt or reject. A panel ruling is automatically adopted unless there is a consensus to reject it. A standing Appellate Body reviews decisions of the panels, and its determinations are forwarded to the Chair of the DSB who then places it on the DSB’s agenda for formal adoption. The DSB also monitors the implementation of rulings and takes action against member states that fail to comply. See Box 2 for an example of a dispute under the TBT Agreement.

The first stage of the procedure, which can last up to 60 days, begins with a request by the complaining country to the allegedly offending country to settle the dispute through consultations. If the dispute so warrants, third parties having an interest can join the consultations. If the consultations fail, the complaining country can request the establishment of a panel, which marks the beginning of the second stage (up to 45 days for the appointment of a panel, plus 6 months for the panel to conclude its report). Subsequently, the panel’s report is submitted to the DSB, which must either adopt or reject the report within 60 days.

Either country can appeal a panel’s ruling. Appeals generally do not last more than 90 days, and are limited to a challenge to the panel’s legal findings and conclusions. Upon finalization of the report by the Appellate Body, the

report must be adopted by the DSB within 30 days. Like panel rulings, appellate reports may only be rejected by consensus.

Box 2 Interpreting the TBT Agreement: The EU-Sardines Dispute

In 2001, Peru requested a consultation with the EU over concerns that an EU regulation prevented Peruvian export companies from using the trade description “sardines” for their products. Regulation (EEC) No. 2136/89 provided that only products prepared from a particular species of fish, *Sardina pilchardus*, could be marketed as “sardines” within EU boundaries. *Sardina pilchardus* is found mainly within European fishing areas, while another similar fish, *Sardinops sagax*, is found mainly in the Eastern Pacific and therefore along the Peruvian coastline. Peruvian exporters had been trading this product in the EU under the trade description “Peruvian sardines”. Using Regulation No. 2136/89 as a basis, the EU prohibited the application of this trade description to products containing *Sardinops sagax*.

Peru argued that the regulation was an unjustifiable barrier to trade and in breach of the TBT Agreement and the GATT. In support of these contentions, Peru quoted Codex Standard 94 which lists 21 species of fish which could be traded as sardines, among them *Sardinops sagax*.

As a part of the consultation process, the DSB established a panel, and Canada, Chile, Colombia, Ecuador, Venezuela and the United States reserved rights as third parties. After a sufficient period of consultation failed to produce a settlement, Peru requested the composition of a panel to decide the matter. The panel decided that the regulation was inconsistent with the TBT Agreement.

The EU appealed the decision, arguing among other things that the regulation was not a “technical regulation” and that Codex Standard 94 was not a “relevant international standard” under the TBT Agreement.

The DSB adopted the Appellate Body decision, confirming that Codex Standard 94 is a relevant international standard, that the EU had not used it as a basis for the regulation and that the EU had nullified and impaired the benefits of Peru under the TBT Agreement. The EU and Peru agreed on a reasonable amount of time for the EU to implement the decision, which it did by amending the regulation.

2.5. Current negotiations and initiatives

In 2001, WTO member states agreed to start a new round of trade negotiations on a wide range of subjects identified in the Doha Declaration. The Declaration provides the mandate for such future negotiations and was adopted at the Fourth Ministerial Conference of the WTO in Doha, Qatar, in November 2001. The Declaration explicitly recognizes the special needs of developing and least developed countries, which had raised a number of issues to be included in the negotiations. Among these were the difficulties developing countries face in implementing the present WTO agreements, as well as the subsidies, support and protection that developed countries provide to their agricultural sectors.

The Fifth Ministerial Conference of the WTO at Cancun, Mexico, in September 2003 was foreseen as a decisive halfway point in the new round of trade negotiations, where decisions should have been taken in key areas such as agriculture, services and non-agricultural market access. However, the conference failed due to profound divisions between developed and developing countries. The WTO General Council then adopted a framework agreement in July 2004 which sets the key parameters for further negotiations in five key areas – agriculture, industrial tariffs, trade facilitation, development issues and services – and identified the date and location of the next Ministerial Conference, namely, Hong Kong, China, in December 2005. Originally, the Doha Round of trade negotiations was scheduled to be completed on 1 January 2005, but it is currently envisaged that the negotiations will continue at least until 2006, or even 2007 when the Seventh Ministerial Conference of the WTO takes place.

Another initiative is the Standards and Trade Development Facility (STDF), which was jointly inaugurated at the Fourth Ministerial Conference by the heads of FAO, OIE, WTO, the World Bank and the World Health Organization (WHO), with the objective of enhancing the capacity of developing countries to participate in negotiations, to develop SPS standards and to implement those standards at national level. Several other international technical organizations with expertise in SPS issues have joined the initiative, including the IPPC and Codex. These last two arrangements are, as noted, identified in the SPS Agreement as the sources of international standards in the fields of plant protection and food safety, respectively. The OIE serves the same purpose with respect to international standards in animal health.

The STDF is both a coordinating and a financing mechanism, for the latter purpose providing funds for technical assistance projects in developing countries which will draw on the expertise of the participating international organizations. Some of the projects have focused, for instance, on strengthening the capacities of developing countries to participate in the development of food safety and plant and animal health measures, and by extension helping them to meet those standards. These efforts are aimed at helping developing countries reduce barriers to exports and improve the livelihoods of producers. In accordance with the themes agreed at Doha, enhancing the capacity of developing countries to strengthen their sanitary and phytosanitary measures is seen very much as a win-win solution: the hope is that the work of the STDF will help spur growth and therefore reduce poverty in developing countries while assuring safer imports for wealthier nations.

In pursuit of similar objectives, in 2003 FAO and WHO established a trust fund for the participation of developing countries in Codex meetings and seminars. The \$40 million fund is expected to run for 12 years and was established in response to concerns raised by developing countries that they had been unable to participate in the Codex process due to the costs involved. The twin objectives of the trust fund are to help increase the participation of the world's 120 least developed countries in the work of Codex and accordingly to improve food standards within these countries' national frameworks in accordance with Codex.

III. CODEX ALIMENTARIUS

3.1. Background and structure

During the early 20th century, many individual countries set about developing food laws and standards according to their own circumstances and needs. At the same time, rapid progress was being made in food science and technology, and more information about food and food-related matters was becoming available to the public. But whereas previously consumers' concerns had extended only as far as the "visibles" – weights and measures, size variations, misleading labelling and poor quality – concerns now included a fear of the "invisibles", i.e. health risks that could not be seen, smelled or tasted, such as micro-organisms, pesticide residues and environmental contaminants.

Heightened consumer interest in these issues as well as increased concern about the potential for food standards to be applied as trade barriers led to the establishment of the Codex Alimentarius Commission (Codex) by a resolution of the governing bodies of the UN Food and Agriculture Organization (FAO) in 1961 and the World Health Organization (WHO) in 1963. Its primary objectives are to protect consumer health and to ensure fair practices in food trade through the elaboration, harmonization and publication of food standards and other related texts. Codex is the only international organization that brings together scientists, technical experts, government regulators and international consumer and industry organizations to develop food standards.

Codex operates based on its Procedural Manual, which consists of the Codex Statutes and Rules of Procedure which together outline Codex's membership, the appointment and responsibilities of officers, the frequency and operation of Codex sessions, the voting procedures (including observer status) and the preparation of records, reports and budget allocations. The Codex Alimentarius Commission meets in principle every two years in plenary session, alternately at FAO headquarters in Rome and WHO headquarters in Geneva, although it may meet more frequently when the need arises. Membership is open to all members of FAO or WHO, and currently includes 171 countries and one regional economic integration organization.

Members are represented by delegations led by senior officials appointed by their governments, and each member state has one vote. Countries which are not yet members may attend meetings of Codex and its subsidiary bodies as observers, and representatives of industry, consumer associations and international academic institutes granted observer status may also participate, although no observers may vote. According to the Rules of Procedure, decisions should be taken by a majority of the votes cast, although in practice most standards, guidelines and codes of practice are adopted by consensus.

An Executive Committee acts on behalf of the Codex Commission between its sessions, generally meeting once per year as well as once before each Commission session. It consists of the Chair of the Commission, three Vice-Chairs, Coordinators (if any) appointed by the Commission for certain regions or groups of countries plus seven further members, one each from the following areas: Africa; Asia; Europe; Near East; North America; South-West Pacific; and Latin America and the Caribbean. The Executive Committee may make proposals to the Commission regarding the general

orientation, strategic planning and work plan of the Commission, and may also assist in the management of the Commission's standards development programme. The Executive Committee may establish such sub-committees from among its members as it may deem necessary to enable it to exercise its functions as effectively as possible.

The Codex secretariat is based at FAO headquarters in Rome and is responsible for providing administrative support, organizing the sessions and coordinating the work of Codex's subsidiary bodies. Six Codex Coordinating Committees act in an advisory capacity, working toward making Codex responsive to regional interests and the concerns of developing countries.

3.2. Functions

3.2.1. Standard-setting

More than forty years after its creation, the Codex Alimentarius (Latin for "food code") has become the authoritative collection of internationally adopted food standards covering all the principal foods traded internationally, whether processed, semi-processed or raw. The Codex Alimentarius is also supplemented by the many maximum residue limits established for pesticides in foods and animal feeds, residue levels for veterinary drugs in foods of animal origin and acceptable levels of food additives and contaminants.

The preparation of draft food standards and related texts, whether they be intended for worldwide use, for a given region or for a select group of countries, takes place in Codex committees. Membership in these committees is open to all Codex member states, and international organizations may attend as observers committee sessions that are of interest to them. Generally, committees are financially maintained and hosted by member states. The two types of Codex committees are Commodity Committees and General Subject Committees.

Codex Commodity Committees are often referred to as vertical committees because they develop standards that apply to aspects of specific foods or classes of food. Such standards generally concern quality factors such as the composition or presentation of certain products. The Codex Commodity Committee subject matters range from fresh fruits and vegetables to processed meat and poultry products. Currently, eleven such committees are active or in recess. See Box 3. Some of these committees have completed

their work and have ceased operation for an unspecified period of time until there is the need to call them back into service, while still others have remained active for the purpose of reviewing standards in order to bring them in line with current practice.

In recent years, there has been a shift in focus away from quality concerns towards food safety and the protection of human health. Thus, within Codex attention has turned to “horizontal” subjects – food hygiene, labelling, additives and contaminants – which, unlike vertical standards, cut across different types and classes of foods. As a result, the General Subject Committees have grown in responsibility and prominence. These committees develop concepts and principles applicable to foods in general or applicable to specific foods or groups of foods, reviewing provisions in Codex commodity standards and developing recommendations pertaining to consumer health and safety. Currently, there are nine such committees, including the Committee on Food Additives and Contaminants, the Committee on Food Hygiene and the Committee on Food Labelling. See Box 3.

In addition to the established committees, from time to time Codex, following its Rules of Procedure, establishes *ad hoc* task forces to deal with specific new problems and issues. At present, one *ad hoc* task force is in the process of developing standards, guidelines and recommendations for foods derived from biotechnology. See Box 3. The *ad hoc* task forces function in the same manner as the Codex General Subject and Commodity Committees except that they are dissolved after the specified work is completed or when the time limit allocated for the work has expired.

General Subject Committees often rely on expert advice, consulting internationally recognized experts in special subject areas and seeking guidance from independent FAO/WHO expert committees not officially part of the Codex structure. One of these is the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which provides advice to two of the General Subject Committees, the Committee on Food Additives and Contaminants and the Committee on Residues of Veterinary Drugs in Foods. JECFA carries out toxicological evaluations of substances intended for use as food additives, establishes specifications for “food grade” chemicals used as additives, evaluates contaminants, naturally occurring toxicants and residues of veterinary drugs and develops principles for the safety assessment of chemicals in food. The Committee on Food Additives and Contaminants and the Committee on Residues of Veterinary Drugs in

Foods consider JECFA's recommendations in elaborating maximum or safe levels of the substances falling within their mandates. More recently, FAO and WHO convened the Joint Expert Meetings on Microbiological Risk Assessment (JEMRA). Though not a statutory body of FAO and WHO, JEMRA meets regularly to conduct risk assessments of micro-organisms in foods and provides advice to the Codex Committee on Food Hygiene.

Box 3 Codex Committees and Task Forces (and hosting country)

General Subject Committees

Committee on Food Additives and Contaminants (Netherlands)

Committee on Food Hygiene (United States)

Committee on Food Labelling (Canada)

Committee on General Principles (France)

Committee on Import/Export Inspection and Certification Systems (Australia)

Committee on Methods of Analysis and Sampling (Hungary)

Committee on Nutrition and Foods for Special Dietary Uses (Germany)

Committee on Pesticide Residues (Netherlands)

Committee on Residues of Veterinary Drugs in Food (United States)

Commodity Committees

Committee on Cereals, Pulses and Legumes (United States)

Committee on Cocoa Products and Chocolate (Switzerland)

Committee on Fats and Oils (United Kingdom)

Committee on Fish and Fishery Products (Norway)

Committee on Fresh Fruits and Vegetables (Mexico)

Committee on Meat and Hygiene (New Zealand)

Committee on Milk and Milk Products (New Zealand)

Committee on Natural Mineral Waters (Switzerland)

Committee on Processed Fruits and Vegetables (United States)

Committee on Sugars (United Kingdom)

Committee on Vegetable Proteins (Canada)

Ad Hoc Task Forces

Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology (Japan)

National inputs into the contents of the many Codex standards and guidelines are solicited and taken into account through the system of Codex Contact Points (CCPs), units responsible at national level not only for circulating information received from the Codex secretariat to national

stakeholders but also sending country comments back to the secretariat. Although the establishment of a CCP is a requirement imposed on all Codex member states, the effectiveness of CCPs varies greatly, as their operation depends on national policies and legislation as well as on government structures, practices and decisions on resource allocation. The main functions of CCPs, as outlined in the Codex Procedural Manual, are to ensure information exchange and effective coordination on Codex matters and other food-related issues at national level.

In addition to the CCP scheme, a number of countries have established a National Codex Committee to assist in the elaboration of Codex standards and other instruments. Such a committee can serve as a national forum in which representatives of food industries, consumers and the relevant government authorities discuss the implications of proposed standards and thus contribute to Codex deliberations. Many National Codex Committees are also charged with proposing draft standards, regulations and other instruments to update and improve the country's legislative framework for food.

3.2.2. Publications

In addition to its many food standards, the Codex Alimentarius contains advisory instruments such as guidelines, principles, recommendations and codes of practice, with the goal of improving compliance with Codex standards. The codes of hygienic practice provide guidance on the production of food that is safe and suitable for consumption, whereas the codes of technological practice aim to ensure that the processing, transport and storage of food are carried out such that consumers receive end products that are wholesome and of the requisite quality. Many of these Codex instruments have been revised and updated over the years. For example, the Recommended International Code of Practice on General Principles of Food Hygiene, which is one of the most widely used Codex texts applying to all foods, has been revised four times since its adoption. During its recent revisions, the concept of risk analysis and management tools such as the Hazard Analysis and Critical Control Point (HACCP) system were included to emphasize the food chain approach, from primary production through to final consumption, highlighting the key hygiene controls required at each stage.

New instruments have been prepared over the last decade as well. For example, Guidelines for the Production, Processing, Labelling and Marketing

of Organically Produced Foods (1999) were developed in light of the growing production of and international trade in organically produced food, with a view to facilitating trade and preventing misleading claims. There are also several noteworthy initiatives in the area of biosafety. For example, the *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology developed Principles of Risk Analysis of Foods Derived from Modern Biotechnology and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants and of Foods Produced using Recombinant-DNA Microorganisms, which were adopted as official Guidelines at the 26th Session of Codex in July 2003.

As of July 2005, Codex and its committees and task forces had established and published 202 commodity standards, 38 commodity-related guidelines and codes of practice, seven general standards and guidelines on food labeling, five general codes and guidelines on food hygiene, five guidelines on food safety risk assessment, 14 standards, codes and guidelines on contaminants in food and 22 standards, guidelines and other recommendations on sampling, analysis, inspection and certification procedures. In addition, Codex established and published 2579 maximum limits for pesticide residues (covering 213 pesticides), 7292 food additive provisions (covering 222 food additives) and 377 maximum limits for veterinary drugs (covering 44 veterinary drugs).

3.3. Adoption of Codex standards

The Codex Procedural Manual contains a detailed procedure for the discussion and adoption of food standards, which also applies to the adoption of codes of practice, guidelines and other advisory texts. In 2002, the parent organizations of Codex commissioned a joint evaluation of the Codex Alimentarius and other FAO and WHO food standards work with a view to making Codex more effective and responsive to emerging needs. Recommendations of the evaluation were presented to Codex, FAO and WHO in 2003. At the 27th and 28th Sessions of Codex in June/July 2004 and July 2005, respectively, the Commission adopted several amendments to sections of the Procedural Manual, including amendments to the procedures for the elaboration of codex standards and related texts.

To ensure a unified approach in the area of standards development, the Commission takes its decisions based on a strategic plan stating the broad priorities against which individual proposals for standards (and revision of standards) are evaluated. The plan covers a six-year period and is renewed

every two years. In addition, an ongoing critical review by the Executive Committee ensures that proposals for new work and draft standards submitted to the Commission for adoption continue to meet the strategic priorities of the Commission and can be developed within a reasonable period of time, taking into account the requirements and availability of scientific expert advice. The Executive Committee reviews the status of development of draft standards against the time frame agreed by the Commission and reports its findings to the Commission. It may propose an extension of the time frame or the cancellation of work, or it may propose that the work be undertaken by a committee other than the one to which it was originally entrusted, including through the establishment of a limited number of *ad hoc* subsidiary bodies, if appropriate.

Prior to approval, each proposal for new work or revision of a standard should be accompanied by a project document prepared by the committee or a member state. The project document should detail the purposes and the scope of the standard, its relevance and timeliness, the main aspects to be covered, its relevance to the Codex strategic objectives, the relation between the proposal and other existing Codex documents, the need for and availability of expert scientific advice, the need for technical input to the standard from external bodies and the proposed time-line for completion of the new work, which should not normally exceed five years.

The subsequent procedure for developing or revising a standard normally consists of eight steps, as follows: in Step 1, the Commission – or, subject to its approval, a subsidiary body – decides to elaborate a Codex standard, taking into account the critical review conducted by the Executive Committee, and decides which Codex committee should undertake the work. At Step 2, the Codex secretariat arranges for the preparation of a proposed draft standard. At Step 3, the proposed draft standard is sent to CCPs and interested international organizations for comments. At Step 4, the Codex secretariat, which has collected all the comments, sends them through the host government secretariat to the concerned Codex committee, which discusses proposed amendments and also decides whether to propose that the draft text advance to Step 5.

If so decided by the relevant committee, the proposed draft standard is submitted through the secretariat to the Executive Committee for critical review and to the Commission with a view to its adoption as a draft standard (Step 5). In taking any decision at this step, the Commission will give due consideration to the outcome of the critical review and to any comments that

may have been submitted by the member states regarding any potential economic implications of the proposed draft standard. At Step 6, the draft standard is again sent to the CCPs and interested international organizations for comments. At Step 7, comments and proposed amendments are considered at another session of the committee and, if so decided by the committee, the proposed draft standard is again submitted through the secretariat to the Executive Committee for critical review and to the Commission with a view to its final adoption as a Codex standard (although during the Codex session written proposals for further amendments are still considered) (Step 8).

The stepwise approach outlined above gives member states and observers two rounds of opportunities to express their views on the proposed texts (Steps 3/4 and 6/7). In addition, they can express their views when the draft standard is being considered for adoption at the Commission session (Steps 5 and 8). The Commission (or the approved subsidiary body) may also decide that the urgency of elaborating a Codex standard is such that an accelerated elaboration procedure, allowing for the omission of Steps 6 to 8, should be followed. While taking this decision, all appropriate matters shall be taken into consideration, including the likelihood of new scientific information becoming available in the immediate future. In practice, the accelerated procedure has been used mainly where consensus already exists – for instance, where there is a need to amend an existing text.

As noted above, national inputs into the development of Codex standards are collected through the Codex General Subject and Commodity Committees, as well as through the system of CCPs and National Codex Committees. Still, how countries choose to apply Codex standards and related texts at national level depends on the country's legal and administrative structure and its policy priorities. Ideally, there is parliamentary-level legislation in place that establishes institutions and creates enforcement powers, while more detailed provisions on procedures and on food standards are confined to subsidiary regulations. This ensures that changes may be more easily made, for instead of having to approach the legislature to amend the umbrella food law, the relevant minister or other executive authority may elaborate new regulations or amend existing ones to act upon new developments. For a more detailed discussion of national legislative options, see Chapter 5.

3.4. Impact of the WTO agreements

Over the first thirty years of Codex's existence, the acceptance of food standards was largely confined to developing countries. The common wisdom was that standards were being elaborated in order to assist developing countries by providing them with ready-made standards to adopt, which would help them gain access to the major markets of Europe and North America. Developed countries, however, were generally unwilling to adopt and implement Codex standards as that might mean having to modify their long-established food control systems.

This changed in 1995 with the establishment of the WTO and the coming into force of the SPS and TBT Agreements. As noted above, the SPS Agreement recognizes Codex as the source of international standards for food safety, although standards that result in a higher level of sanitary protection may be applied (if there is a scientific justification). The TBT Agreement also recognizes Codex standards, although indirectly, by referring to "international standards". Since all WTO members must comply with the SPS and TBT Agreements, the implementation of Codex standards in national legislation has become the appropriate measure of compliance for developed and developing countries alike.

The specific recognition of Codex standards, guidelines and recommendations within the SPS Agreement and the acknowledgement of Codex as an international standard-setting body *vis-à-vis* the TBT Agreement have significantly raised Codex's profile and expanded interest in its activities. This has pushed Codex to revise standards in several areas, and more importantly to consider in more detail the approach it uses to develop and adopt food standards. Because the SPS Agreement requires WTO member states to base their sanitary measures on scientific principles and on risk assessment techniques, Codex has taken steps to ensure that its standards, guidelines and other recommendations on food safety are based on sound scientific analysis, scientific evidence and risk assessment. This led to the adoption by the Commission in 2003 of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. At present, risk analysis guidance for governments is still under discussion in the Committee on General Principles.

IV. **OFFICE INTERNATIONALE DES ÉPIZOOTIES (WORLD ORGANISATION FOR ANIMAL HEALTH)**

4.1. **Background and structure**

The *Office internationale des épizooties* (OIE), or World Organisation for Animal Health, is an international organization created in 1924 and located in Paris, France. With 167 member states, its objectives are to guarantee the transparency of animal disease status in countries around the world and to collect, analyse and disseminate scientific veterinary information. OIE member countries, usually through their official veterinary services, commit to collecting information on animal diseases extant in their territories, which the OIE then analyses and distributes in order to facilitate prevention and control elsewhere. The OIE also provides expertise and technical support to member countries requesting assistance with animal disease control and eradication operations, including for diseases transmissible to humans (zoonoses). In addition, the OIE develops standards for international trade in animals and animal products with the intention of preventing the transmission of animal diseases.

The International Committee, which consists of one permanent technical delegate from each member country, is the highest decisionmaking body of the OIE and meets at least once per year. Each member has one vote, and various intergovernmental and international organizations have been granted observer status and may attend meetings. The OIE's daily operations are managed by the Central Bureau, headed by a Director General, which implements and coordinates the OIE's informational, technical cooperation and scientific activities.

Several commissions, elected by the International Committee, support the work of the OIE. An Administrative Commission meets twice a year, examining technical, administrative and budget matters and, in particular, the OIE programme of work. In addition, five Regional Commissions (Africa, Americas, Asia/Far East/Oceania, Europe and Middle East) promote and organize activities at regional level. Finally, Specialist Commissions, of which there are currently four, meet two or three times annually to study problems relating to epidemiology and the prevention and control of animal diseases, and to develop and revise OIE's international standards. The Specialist Commissions consist of members experienced in veterinary science and regulatory issues, elected by the International Committee and drawn from all regions. The Foot and Mouth Disease and Other Epizootics Commission

assists in identifying the most appropriate strategies and measures for disease prevention and control; the Standards Commission establishes standards for methods of diagnosing animal diseases and for testing biological products; and the Fish Diseases Commission compiles information on diseases of fish, crustaceans and mollusks and their methods of control. Finally, the International Animal Health Code Commission is responsible for updating the eponymous Code.

4.2. Functions

4.2.1. Standard-setting

Historically, the international standards for animal health developed and adopted under the auspices of the OIE were not mandatory for its member countries. The Codes and Diagnostic Manuals recommend rather than command, and the OIE does not have the remit or the administrative capacity to verify if member countries have implemented its recommendations. However, after the establishment of the WTO and the coming into force of the SPS Agreement, the OIE became the principal reference body for international standards concerning animal health, and accordingly standard-setting rose in importance as a primary task of the OIE alongside its traditional role of reporting disease information and disease control methods. Since all WTO members (i.e. most OIE member states) must comply with the SPS Agreement, the implementation of OIE standards in national legislation has become essential. Different standards may be applied only where the importing country demonstrates scientifically to the exporting country that national animal health conditions require standards over and above those established by the OIE.

The OIE's animal health standards are developed and revised by the OIE Specialist Commissions, assisted by working groups and with support from collaborating centres and reference laboratories. A new or revised standard may be requested by the International Committee, by a Regional Commission, by a member state or by an interested international organization such as FAO or WHO. Draft standards are first circulated to all member states for systematic review and comment, a process that is generally coordinated and communicated through national veterinary services. The Commission then revises the draft, taking into account comments received, and presents the amended draft to the International Committee for adoption. Thus OIE standards are the result of a consensus of experts from OIE member states.

4.2.2. Publications

The international standards prepared by the OIE are collected in the Terrestrial Animal Health Code and the Manual of Standards for Diagnostic Tests and Vaccines, and in their equivalent documents for aquatic animals, the International Aquatic Animal Health Code and the Diagnostic Manual for Aquatic Animal Diseases. The Terrestrial Animal Health Code contains standards, guidelines and recommendations for national sanitary measures aimed at preventing the introduction of animal diseases (both those harmful only to animals as well as those also harmful to humans) through the international trade in animals, animal genetic material and animal products. The Terrestrial Animal Health Code includes general provisions for animal health, recommendations applicable to specific diseases and model international veterinary certificates.

The Terrestrial Animal Health Code's general provisions contain, among other things, guidelines and principles for conducting transparent, objective and defensible risk analysis for international trade. Because of variations in animal health situations in different countries, the Code offers options to importing countries, all of which reflect the view that only by considering the animal health situation in the exporting country can the importing country precisely articulate the requirements which are to be met for imports.

The Manual of Standards for Diagnostic Tests and Vaccines has been prepared by the Standards Commission, and it complements the Terrestrial Animal Health Code's trade provisions. It describes internationally agreed laboratory methods for the diagnosis of OIE-listed diseases and other diseases important to international trade, as well as requirements for the production and control of biological products (mainly vaccines). The Manual aims to harmonize these essential elements of animal disease prevention, surveillance and control so as to facilitate health certification in connection with trade in animals and animal products.

A separate Aquatic Animal Health Code and a Diagnostic Manual for Aquatic Animal Health Diseases have been prepared by the Fish Diseases Commission in acknowledgement of the fact that the epidemiology of aquatic diseases and the methods of disease control differ from those of land animals. The Code gives detailed definitions of the minimum health guarantees required of trading partners in order to avoid the risk of spreading aquatic animal diseases, and includes sections on import risk analysis and import/export procedures. The Code also contains sections on

health control and hygiene, and includes model international health certificates for trade in live and dead aquatic animals.

4.3. The OIE and food safety

The OIE's publications reflect its traditional interest in the collection of information on animal diseases worldwide and on the prevention of animal disease transmission. An important development has been the growing recognition within OIE of the importance of the intersection between animal health and food safety. The OIE has begun to focus as well on the prevention of animal diseases from a food safety point of view, even where the diseases may not affect animals at all (but only humans). The OIE recently coined the term "animal production food safety" to reflect this new field, which captures the importance of reducing risks to human health through effective measures imposed even before the slaughter of animals and the primary processing of their products.

Accordingly, a permanent Working Group on Animal Production Food Safety has been established to coordinate the OIE's food safety activities. The Working Group met for the first time in November 2002 and since then met again in July 2003 and April 2004. Its mandate is to review and develop food safety standards and guidelines in this area, collaborating with other international organizations, to avoid contradictions, to address overlaps and gaps in the current constellation of standards and to ensure the optimal use of available expertise. To this end, the Working Group includes several experts from Codex and from Codex Committees and reflects a broad geographical base. It also intends to take into account the special needs of developing countries.

The Working Group has drawn up a detailed work programme for the development of standards on animal production food safety covering pre-slaughter and the time period before the first transformation of animal products, with a primary focus on food safety measures applicable at the farm level. The Working Group has identified as priorities the joint review of OIE and Codex standards to identify gaps and duplications, and the development of procedures for common and linked standards and for their mutual recognition. The group has started work on the chapters of the Terrestrial Animal Health Code that deal with tuberculosis and brucellosis in order to better address animal production food safety issues.

Among the short-term priorities of the Working Group are improvements in traceability, testing, inspection and certification. At its April 2004 meeting, the Working Group recommended that the OIE work with Codex and other relevant international organizations to review international standards to maximize harmonization. The Working Group also intends to improve the current level of OIE input into Codex texts and to develop a method for the most effective utilization of Codex expertise in the work of OIE *ad hoc* groups.

4.4. The OIE and animal welfare

Many countries have a history of animal welfare or animal protection law, some of it dating to the 1800s. The 20th century saw considerable expansion of legal protection for food animals with many countries creating provisions that require humane animal transportation and humane handling and killing of animals at slaughter plants. Beginning in the 1980s a number of countries, especially in Europe, created new laws requiring welfare standards for animals on farms. These often include minimum space requirements, bans on certain forms of confinement (cages for hens, individual stalls for pregnant sows), and restrictions on specific practices believed to cause pain. In some cases, these laws are expected to result in increased costs of production, and producers in the affected countries have expressed concern about having to compete against lower-priced imports from countries with less demanding animal welfare standards.

By the 1990s, there was significant debate about whether countries with high animal welfare standards could block imports from countries lacking equivalent standards. Various mechanisms, including the SPS Agreement and the GATT, were proposed as means whereby this could occur, but in each case there were significant counter-arguments.

The development and acceptance of internationally harmonized standards is an obvious way to avoid conflict among countries over the use of animal welfare standards as a barrier to trade. In 2002, recognizing the close link between animal welfare and animal health, the International Committee of the OIE voted to begin developing international animal welfare standards. The International Committee decided that the OIE would give priority to the welfare of animals used in agriculture and aquaculture, and that transportation, humane slaughter and killing for disease purposes would be addressed first, followed by housing and management. Other topics, such as research animals and wildlife, would be addressed as resources permitted.

Accordingly, a permanent Working Group on Animal Welfare was established and held its first meeting in October 2002 and subsequent meetings in February and December 2004. Its primary task is to provide a sound foundation from which to elaborate draft recommendations and standards for the identified priorities relating to animal welfare. Draft standards are currently under development and if they are adopted by the International Committee, the standards could play a role in international trade similar to that of other OIE standards.

V. INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

5.1. Background and structure

In 1946, 25 countries met to create an international organization to “facilitate the international coordination and unification of industrial standards”, which led to the establishment of the International Organization for Standardization (ISO). The ISO is a nongovernmental organization whose membership is currently made up of the national standards institutes of 150 countries, overseen by a central secretariat in Geneva. In some cases the member institutes are governmental while in others they are entirely private industry initiatives. Membership of the ISO works on the basis of one member per country, whichever national standards institute or similar organization is the most representative of standardization in the member state.

There are three levels of membership within the ISO. Full members, known as “member bodies”, each have one vote, whatever the size or strength of the economy of the country concerned. Member bodies can exercise full voting rights in any policy or technical committee of the ISO. In addition, ISO has two categories of membership for countries with fewer resources which therefore pay reduced membership fees. Although such members do not have a vote, they participate in order to remain up to date on standardization developments. The first category, “correspondent members”, are usually organizations in countries which do not yet have a fully developed national standards system. Such members do not take an active part in the technical work, but are entitled to be kept fully informed about the work of interest to them. The second category, “subscriber members”, are institutes from countries with very small economies that nevertheless wish to maintain contact with international standardization. Such members have full access to information about the international

standardization process, which assists them in learning about the standards that their products will need to meet on the export market.

All strategic decisions are referred to the ISO members, which meet in an annual General Assembly. The proposals are developed by the ISO Council, which is drawn from the membership and meets three times per year. Membership of the Council is rotated to ensure that it continues to be representative of the ISO membership as a whole. Operations of the ISO are managed by a permanent Secretary General who in turn reports to the President, who is elected for two years.

5.2 Functions

5.2.1. Standard-setting

The ISO will only begin development of a new standard when there is clearly a market requirement for it. An industry group or other interested party will communicate the perceived need for a new standard to the ISO via one of ISO's members, which then proposes the new work item to the ISO as a whole. If accepted, the proposal is then referred to the relevant technical committee (made up of experts from the relevant industry, business and technical sectors) which will apply its specialized expertise to the development of the standard. The work of the technical committees is guided by three general policy development committees which ensure that the broader interests of conformity assessment, consumer policy and developing country matters are considered alongside the specific technical aspects of standard development.

The technical committee meets to discuss and debate until it has reached a consensus draft, which is then submitted as a draft international standard to the entire ISO membership for comment and voting. This is a five-month vote, during which many members, in formulating their position on the draft standard, employ public review procedures at national level designed to make draft standards known and available to interested parties and the general public at country level and thereafter to take account of any feedback received. Those members which have chosen to be participating members of the technical committee are under an obligation to vote, while all other members are entitled to vote if they so wish. A draft standard is approved if two-thirds of the participating members of the committee vote in favour of the standard and not more than one quarter of all votes cast are negative. The text of the final draft international standard, with eventual

modifications, is then submitted again to the entire ISO membership, this time for a two-month vote. However, this vote can only constitute approval or rejection of the standard and may be omitted if the draft international standard received full approval during the first round and the modifications made were minimal. If the result is positive, a new international standard is created.

5.2.2. Publications

As the world's main formulator of technical standards for many industrial, technical and business sectors, the ISO since 1946 has published more than 13,700 international standards across a diverse range of sectors. Although ISO standards are voluntary, they may be adopted as part of a national regulatory framework or incorporated into national legislation. And in many sectors, "peer pressure" or the wish to gain access to import or export markets can make even voluntary standards into *de facto* mandatory ones. Similarly, large companies often make voluntary standards a mandatory requirement for small suppliers, heightening the importance of such standards.

Whereas the vast majority of ISO standards refer to specific products or services, ISO is also celebrated for its development of generic standards that can be applied to any organization, large or small, whatever its product or service. In particular, the ISO 9000 series has earned a global reputation as the basis for establishing quality management systems. Best known is the ISO 9001:2000 standard which specifies the requirements for a quality management system for any organization that needs to demonstrate its ability to consistently provide products that meet customer needs and applicable regulatory requirements. In addition, the ISO 14000 series, which is primarily concerned with environmental management, outlines what organizations should do to minimize harmful effects on the environment caused by their activities.

In September 2005, ISO published ISO 22000, *Food safety management systems – Requirements for any organization in the food chain*, which outlines the requirements for implementing food safety management systems in all types of organizations along the food chain, ranging from feed producers, primary producers, food manufacturers, transport and storage operators to retail and food service establishments – plus related organizations such as producers of equipment, packaging material, additives and ingredients. The new standard, which was developed by experts from the food industry along with

representatives of specialized international organizations and in cooperation with Codex, harmonizes relevant national and international food safety standards and incorporates HACCP principles (see Chapter 3, section 2.3.1). Another benefit of ISO 22000 is that it extends the approach of the ISO 9001:2000 quality management standard, which is widely implemented but does not itself specifically address food safety. Although ISO 22000 can be implemented on its own, it is designed to be fully compatible with ISO 9001:2000 and it allows for their joint or integrated implementation.

The publication of ISO 22000 is to be complemented by an ISO Technical Specification (ISO/TS 22004) giving guidance on the implementation of the standard, with particular emphasis on small and medium-sized enterprises. Another Technical Specification (ISO/TS 22003) will set out principles for the accreditation of ISO 22000 certification bodies and define the rules for auditing food safety management systems for conformity to the standard. Finally, ISO 22005, *Traceability in the feed and food chain - General principles and guidance for system design and development*, is to be circulated as a draft international standard.

VI. INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS

6.1. Background and structure

Organic agriculture is a method of production which avoids or strictly limits the use of GMOs as well as certain external agricultural inputs such as pesticides, veterinary drugs, additives and fertilizers. Worldwide, more than 26 million hectares of farmland are currently under organic management. The organic market, which was valued at US\$25 billion in 2003, is rapidly expanding and is far from the niche market it may once have been. Financial considerations currently limit consumer demand mainly to the industrialized world: organic products are generally priced higher than their conventional counterparts both to cover the higher cost of production and processing and to capture unseen savings linked to issues such as environmental protection, animal welfare and rural development. At present, North America, Japan and Western Europe provide the bulk of global revenues. Nevertheless, as more countries develop economically and as their populations become increasingly educated and more affluent, demand for organic products can be expected to rise.

The International Federation of Organic Agriculture Movements (IFOAM), established in 1972 and located in Bonn, Germany, is the international umbrella organization of organic agriculture organizations. Currently uniting more than 750 member organizations in 108 countries, its goal is the worldwide adoption of ecologically, socially and economically sound systems based on the principles of organic agriculture. Through international conferences, meetings and other fora, IFOAM facilitates an ongoing dialogue about the status and future of organic agriculture. IFOAM has developed and maintains the Organic Guarantee System, which unifies the organic world through a common system of standards, verification and market identity. IFOAM also implements specific projects that facilitate the adoption of organic agriculture, particularly in developing countries, and represents the organic agriculture movements at the United Nations and other intergovernmental agencies.

The IFOAM General Assembly, which is IFOAM's democratic decisionmaking forum, meets every three years in conjunction with the IFOAM Organic World Congress and elects the World Board. The World Board, based upon the recommendation of the IFOAM membership, appoints members to IFOAM's many official committees, working groups and temporary task forces, which address specific aspects of organic agriculture management. The Norms Management Committee, the Standards Committee and the Criteria Committee play an essential role in the development and continual improvement of the Organic Guarantee System. Other committees include the Development Forum, which works towards the development of organic agriculture in developing countries, the Programme Strategy Committee and the Government Relations Committee.

IFOAM has also established a number of groups to address the specific needs of various geographical areas. Four regional groups (Asia, the Mediterranean, the German-speaking countries and the European Union as a whole), plus two national groups (Japan and France), respond to and mould organic agriculture at the regional level. In addition, the IFOAM member organizations have established a number of sector-specific groups and initiatives including, *inter alia*, the Organic Retailers Association, the Aquaculture Group and the Farmers' Group.

6.2. Functions

6.2.1. Standard-setting

Organic standards have long been used to represent a consensus within the organic agriculture movement about what an “organic” claim on a product means, and to convey that information to consumers. Because organic foods cannot be distinguished from conventional foods at a glance, consumers depend entirely on third-party certification, i.e. the process according to which public or private certification bodies provide assurance that organic products have been produced and handled according to applicable standards. Organic certification was first instituted in the 1970s by the regional organic farming groups that first developed organic standards, and today certification is required by many countries for any kind of “organic” claim on a product label. Certification not only leads to consumer trust in the organic product system and the products, but also gives organic farming a distinct identity and makes market access easier.

The IFOAM Organic Guarantee System is designed to facilitate the development of quality organic standards and certification worldwide, and to provide an international guarantee of those standards and certification. The Organic Guarantee System enables organic certifiers to become “IFOAM Accredited”, based on their compliance with IFOAM norms, which consist of the *IFOAM Basic Standards for Organic Production and Processing* (IBS) and the *IFOAM Accreditation Criteria for Certification of Organic Production and Processing* (IAC). The IBS contain the principles, recommendations and required baseline standards that guide operators in producing their organic crops and maintaining organic integrity in the further handling and processing of organic commodities. The IAC derive from the ISO norms for the operation of certifying bodies, but also reflect the particular circumstances of organic production and processing. IFOAM has also developed policies for the use of the IFOAM Seal, which demonstrates compliance with IFOAM norms, and which assures wholesalers, retailers and consumers that a product and its producer are organically certified within the IFOAM Organic Guarantee System.

IFOAM accreditation is awarded to certification bodies that comply with the IFOAM accreditation criteria and that employ either the IBS or national or regional certification standards approved by IFOAM as being compliant with the IBS. Accreditation is carried out by the International Organic Accreditation Service (IOAS) under an agreement with IFOAM. Although

IOAS operates as an independent body, it is a key organ of the Organic Guarantee System, accepting and reviewing accreditation applications, conducting site evaluations and granting accreditation.

The IBS are subject to periodic revision by IFOAM's Standards Committee after approval of a revision plan by the World Board, although specific revisions or new areas of the IBS may also be initiated by IFOAM members. Draft revisions (normally two drafts) of the IBS are circulated to the membership and other key stakeholders for comments, which the Standards Committee takes into account in the preparation of the next draft. The final draft is circulated to the membership with a deadline for making motions. If motions are received, then "contact groups", comprised of the motion maker, the Standards Committee and the Norms Management Committee, are constituted with the aim of resolving the motion. If no resolution is achieved, the motion goes out to the membership for a vote. The final draft is amended accordingly and sent for another membership vote. The quorum for voting is 25% of the IFOAM membership and decisions are taken by simple majority. If the required number of votes are not cast, then the World Board makes the decision on the motions and/or on the revision draft.

Regular revisions of the IAC start after the Norms Management Committee approves a revision plan submitted by the Criteria Committee and informs the World Board accordingly. The draft revisions (normally two drafts) are circulated to IFOAM's membership and other key stakeholders for consideration and comment. The Criteria Committee reviews the comments on the draft and takes due consideration of the suggestions when preparing the next draft. The final draft is circulated to the IFOAM membership, the IOAS and IFOAM-accredited certification bodies with a deadline for making motions. Again, if motions are received, contact groups may be employed. The World Board makes the final decision on the revision based upon a recommendation of the Norms Management Committee.

6.2.2. Publications

As noted, the two pillars of the Organic Guarantee System are the IBS and the IAC, which together are called the IFOAM norms. The IBS are structured as "standards for standards". As published, they provide a framework for certification bodies and standard-setting organizations worldwide to develop their own more detailed certification standards which take into account specific local conditions. The IAC, on the other hand, establish requirements for the conduct of organic certification by

certification bodies. As noted, the IAC together with the IBS establish the requirements for certification bodies seeking IFOAM accreditation. However, the IFOAM norms also have an impact beyond the IFOAM Organic Guarantee System: they are generally respected as the international guidelines for the elaboration of national standards and inspection systems, and they are often used as a reference by standard-setters and legislators in national and international arenas.

In addition to the IFOAM norms, IFOAM publishes the periodical “Ecology and Farming” as well as a number of monographs and other texts. Their subject matters range from biodiversity to organic inspection to organic seed. Some are proceedings of global meetings while others represent the latest research on organic agriculture’s relationship to issues such as climate change, sustainable agriculture and food security.

VII. UNITED NATIONS SPECIALIZED AGENCIES

7.1. U.N. Food and Agriculture Organization

7.1.1. Technical departments²

In addition to its joint work with WHO in Codex, the Food and Agriculture Organization of the United Nations (FAO) addresses a variety of food-related activities through its technical departments. In this context, the most significant is the Economic and Social Department, which has, among others, a Food and Nutrition Division. Through publications, training courses and technical assistance projects, the Food Quality and Standards Service within that Division works with member countries on strengthening national food control programmes. The Service also offers advice on policy, institutions, regulations, Codex standards, training and capacity building with regard to laboratories, inspection procedures, good manufacturing practices, good hygiene practices, HACCP and numerous other food-related subjects, including the control of street foods.

The Economic and Social Department also hosts the secretariat of the Committee on World Food Security (which serves as the forum within the UN to review and monitor world food security policies), the secretariat of the Food Insecurity and Vulnerability Mapping Systems (FIVIMS – which

² By fall 2005, proposals were under consideration to restructure and rename several of FAO’s technical departments.

coordinates a network of national information systems that measure food insecurity and vulnerability), the Global Information and Early Warning System on Food and Agriculture (GIEWS – which acts as the source of updated information on food production and food security in all countries of the world) and the Intergovernmental Working Group on Implementation of the Right to Food (which works toward international consensus on the substance and modes of implementation of the right to adequate food, see Chapter 4). The Department also publishes the annual “State of Food and Agriculture”, which reports on current developments affecting world food and agriculture, and the “State of Food Insecurity in the World”, which provides the latest estimates of the number of chronically hungry people in the world.

FAO’s Technical Cooperation Department coordinates the Special Programme for Food Security (SPFS), which is an interdisciplinary scheme geared toward increasing food production, improving stability of supplies and generating rural employment in Low Income Food Deficit Countries (LIFDCs). The main goal of the SPFS, through technical assistance and policy development, is to increase the accessibility of food supplies and thus help LIFDCs to improve food security at both national and household levels. The underlying assumption is that in most such countries the means to increase food availability exist but the objectives are not realized because of a range of constraints. The SPFS works with governmental and nongovernmental partners to identify these constraints and to mitigate their effects. The SPFS grew out of the 1996 World Food Summit and the World Food Summit: *five years later*, where governments committed to reducing hunger and malnutrition and achieving sustainable food security worldwide (see Chapter 4).

7.1.2. Legal Office

The FAO Legal Office, which is part of the Office of the Director General, has among its mandates the provision of technical assistance to member countries toward the development, formulation and revision of legislative and regulatory frameworks for food. FAO’s view is that sound legal frameworks and well-designed laws are essential to achieving sustainable development in agriculture, as they help build strong foundations for good governance. They also enable meaningful participation by all types of stakeholders, from central governments to rural communities, and protect rights and define responsibilities. FAO considers the establishment of predictable, appropriate and fair rules as fundamental for the purpose of

encouraging investment, facilitating the operation of markets and setting norms for responsible behaviour.

With regard to food control, food safety and food trade, the Legal Office contributes in five main areas. First, the Office is involved in a number of international initiatives, including the formulation of legal instruments at the regional and international levels. The Code of Conduct for Responsible Fisheries, the International Plant Protection Convention and the International Treaty on Plant Genetic Resources for Food and Agriculture are some of the international instruments which have drawn on FAO's legal expertise. Second, the Legal Office provides legal advisory services to member countries under the auspices of technical assistance projects funded by FAO and other donors. Often working with the relevant technical units of FAO such as the Food and Nutrition Division, FAO lawyers and legal consultants help governments analyse and improve their food laws, and assist in the preparation of draft bills, regulations, standards, agreements and other legal texts in harmony with international requirements. The Office also advises on institutional structures and compliance with international legal instruments, such as the WTO SPS Agreement.

Third, the Legal Office, in collaboration with the Economic and Social Department, works toward the development of international guidelines for the realization of the right to food. As noted above, FAO serves as the secretariat for the Intergovernmental Working Group on Implementation of the Right to Food, and has also published a number of papers and articles in this area, including "The Right to Adequate Food in Emergencies", "The Legal Framework for Food Security", "The Right to Food in Theory and Practice", "What is the Right to Food?" and "Extracts from International and Regional Instruments and Declarations, and other Authoritative Texts Addressing the Right to Food". The Office's research and writing constitute its fourth main activity, with its lawyers and consultants writing on legal developments in the food safety area. Among these are "Legislation Governing Food Control and Quality Certification", "Legislation on Foods for Infants and Small Children", "International Food Standards and National Laws" and "An Outline of Food Law".

Finally, the Legal Office is involved in the collection and dissemination of legal information. Foremost among these initiatives is the comprehensive internet-based legislative database, FAOLEX, which contains treaties and national laws and regulations. Selected relevant legal texts on food and other

areas within FAO's mandate have been summarized and indexed in English, French or Spanish.

7.2. World Health Organization

The World Health Organization (WHO), the United Nations specialized agency responsible for health matters, was established in 1948 with the objective of assisting all peoples to attain the highest possible level of health. Health is defined in WHO's constitution as not merely the absence of disease or infirmity, but as a state of complete physical, mental and social well-being. WHO is governed by 192 member states through its World Health Assembly, which has as its main tasks the approval of WHO's programme and budget and the determination of major policy questions.

Food-borne diseases cause untold economic and social harm in developed and developing countries, with the poorest bearing the greatest burden. WHO's Department of Food Safety, Zoonoses and Foodborne Diseases (FOS) works to reduce the negative impacts of food-borne diseases, collaborating with other WHO departments (in particular the Communicable Diseases cluster), regional offices, WHO collaborating centres and other international and national agencies. For example, WHO works closely with FAO to address food safety issues along the entire food production chain.

WHO's work in the food safety area includes strengthening national food safety systems, promoting good manufacturing practices and educating retailers and consumers on food handling. WHO also promotes laboratory-based surveillance as well as the monitoring of pathogens in food. In cooperation with its member states, WHO is working toward the development of internationally agreed guidelines for in-country data collection. WHO is also compiling outbreak and surveillance databases, and is broadening its epidemic surveillance capacity to include food-borne disease outbreaks.

Increasingly, member states have urged WHO to be more proactive in communicating about food safety, and WHO has been asked to provide tools and support to member states to increase their capacity to respond to health emergencies. In this connection, WHO launched a new International Food Safety Authorities Network (INFOSAN), which also comprises a food safety emergency network (INFOSAN Emergency). FOS publishes the newsletter "Food Safety News", and has recently prepared a study on modern food biotechnology, human health and development.

WHO also works to limit the impact of zoonoses, which are communicable diseases transmitted from animals to humans, since a significant proportion of the new diseases that have affected humans over the past 10 years have been caused by pathogens originating from animals or products of animal origin. Many of these diseases have the potential to spread over long distances and to become global problems. WHO's veterinary public health goals include improving surveillance and containment of zoonoses, as well as the surveillance and containment of resistance to antimicrobial agents in animals. Veterinary public health activities are currently implemented by WHO through the Department of Communicable Diseases Control, Prevention and Eradication (CPE) in close collaboration with FOS. The veterinary public health programme in WHO is closely linked with various aspects of the work of FAO and the OIE, in relation to zoonoses, food safety and the public health aspects of trade in animals and animal products. In this area WHO has recently published a report of the WHO/FAO/OIE joint consultation on emerging zoonotic diseases, while the Pan-American Health Organization (PAHO) has published "Zoonoses and communicable diseases common to man and animals".

VIII. REGIONAL AND SUBREGIONAL BODIES

As the purpose of this chapter is to examine the international context in which national regulation on food takes place, the discussion to this point has identified and described the main international organizations having to do with food and has explained their relevance. But an assessment of the range of supra-national activities cannot look only to the global arena: equally important are regional organizations and groupings that work to establish regional standards and to provide guidance for national governments. For some subject matters, international organizations or arrangements explicitly rely on regional groupings to develop regional standards as well as to discuss international standards and to solicit inputs into their development. For other subject areas, regional arrangements operate more independently, although international standards may be developed with regional considerations in mind. Of course, under the SPS Agreement, these standards may depart (upward) from the international consensus only where clearly justified and based on science (risk assessment).

The relationship between a regional economic grouping and its relevant standard-setting organization varies. At one end of the spectrum may be an arrangement whereby the standards established by a regional body have direct legal effect within the region (such as in the Gulf Region under the

auspices of the Gulf Cooperation Council); elsewhere, standards may be established by a regional standard-setting body but not be binding on the country members of the regional economic grouping, although they may be persuasive (such as for certain instruments issued within the EU).

Equally, the attention accorded to trade and food safety issues differs among economic groupings. Some regional organizations, such as CARICOM, are focusing an increasing amount of attention on food safety issues; others may not have addressed food safety except under the aegis of Codex, if at all. The following subsections introduce only a sampling of regional organizations which have addressed food safety or food trade in recent years.

8.1. Caribbean

For the Caribbean, the Caribbean Community (CARICOM) and the Caribbean Forum of African, Caribbean and Pacific States (CARIFORUM) are the two most significant economic groupings. Their memberships are mainly overlapping, except that Montserrat is a member only of the former, whereas the Dominican Republic is a member only of the latter. CARICOM has among its objectives the promotion of economic integration among its member states, and the establishment of a single market and economy. Similarly, CARIFORUM works toward better coordination of EU support and improved regional integration and cooperation. A majority of the CARIFORUM members have signed the Cotonou Agreement, which is the main international aid and trade agreement between the African, Caribbean and Pacific states and the EU, and which came into force in March 2000.

At present, member states of the Caribbean, with the assistance of the Inter-American Institute for Cooperation on Agriculture (IICA), PAHO and the FAO Legal Office, are working toward the establishment of a centralized agency to cover food safety, animal health and plant health matters in the Caribbean region, the Caribbean Agricultural Health and Food Safety Authority (CAHFSA). Many governments in the region consider the creation of CAHFSA essential to enable them to participate in international discussions – including standard-setting – and to fulfil their obligations under the relevant international WTO agreements, activities which are currently limited by the lack of resources in individual countries.

Many of the national agencies are small, understaffed and underfunded and need assistance to develop their services to the appropriate level to permit compliance with international agreements and standards. Discussions are

currently under way to identify which spheres of activity might be assigned to the new CAHFSA and which would continue to be carried out at national level. Capacity-building will be necessary to strengthen the national agencies to carry out their activities and to implement standards at national level. The ultimate goal is for Caribbean countries to maintain and expand their export markets for agricultural products.

8.2. Southern African Development Community

The purpose of the Southern African Development Community (SADC), which was created by treaty in 1992 to replace the Southern African Development Coordinating Conference, is to promote regional cooperation, trade and economic development. One of its core mandates is food, agriculture and natural resources, and toward that end SADC works toward the development, promotion and harmonization of its member states' sanitary and phytosanitary policies. Those member states are Angola, Botswana, the Democratic Republic of the Congo, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe.

The cornerstone of SADC's subregional trade integration effort is the Trade Protocol, signed in August 1996. Discussions on sanitary and phytosanitary measures (SPS) and on the food safety regulations necessary to implement the Trade Protocol started several years later. In November 2000, the SADC Consultative Forum on SPS/Food Safety convened a workshop in Windhoek, Namibia, which acknowledged the pressing need to develop a harmonized SPS/Food Safety Annex to the Trade Protocol in order to facilitate trade in agricultural products within SADC. The Consultative Forum adopted a three-phase Plan of Action: first is an inventory of existing legislation (laws, regulations, practices, multi- and bilateral agreements); second is an assessment including recommendations for action to harmonize SPS measures among the SADC member states and for a draft SADC SPS/Food Safety Annex; and third is the actual negotiation and implementation of the annex.

As to TBT, SADC member states have undertaken the Standardization, Quality Assurance, Accreditation and Metrology (SQAM) initiative, whose objective is to progressively eliminate any technical barriers to trade among member states and between SADC and other regional and international trading blocs. The SQAM initiative fosters harmonization among its

members on issues of standardization, accreditation, certification, conformity assessment, testing, inspection and metrology.

SADC has also established a Food Security Programme, which comprises a number of national and regional projects designed to enhance food security in the region. The programme encourages member states to implement measures in the medium and long term to increase agricultural productivity and food production, and to promote trade in agricultural commodities.

Finally, a continuing matter of debate among the SADC member states is concern over the presence of GMOs in food aid, and thus SADC has established a technical forum to provide guidance on GMO issues. SADC has since drafted and adopted common guidelines on the handling of GMOs and the products resulting from biotechnology. The guidelines, which cover policy and regulations on genetically modified crops and food, as well as capacity building, public awareness and food aid, state that the SADC Region should develop common policy and regulatory systems based either on the Cartagena Protocol on Biosafety or on the African Model Law on Biosafety.

With regard to the handling of food aid, SADC members have agreed to try to source food aid from within the region. SADC also supports the following principles: there should be a harmonized management and information system to facilitate transboundary movement; donors providing food aid should comply with Article 8 of the Cartagena Protocol requiring prior written notification; all grain or other plant material containing GMOs should be sterilized or milled before distribution; and food aid in transit should be clearly identified and labelled. Members without an existing regulatory framework for biotechnology should not import genetically modified food aid until such guidelines are in place and toward that end should develop national biotechnology policies and strategies, increase efforts to establish national biosafety regulatory systems and sign and ratify the Cartagena Protocol.

8.3. *Mercado Común del Sur (MERCOSUR)*

In 1991, Argentina, Brazil, Paraguay and Uruguay signed the Treaty of Asunción, in which they agreed to establish the Southern Common Market (*Mercado Común del Sur*, or MERCOSUR). This integration process led to the establishment of a customs union in 1995 and subsequently a transition phase with a view to constituting the common market, which will last until 2006. The member states established an institutional framework, which, in

contrast to other regional groupings such as the EU, rejects any notion of supra-nationality. However, in 1998, a common mechanism for political consultations – the so-called “Political MERCOSUR” – was formalized, in which member countries participate as full members.

In the area of food, MERCOSUR has developed a number of harmonizing technical regulations over the years, including compositional requirements for certain foodstuffs, rules on food additives, food labelling, packaging and weights and measures. These regulations, however, are not directly applicable but must be implemented through national legislation in each member state.

8.4. European Union

The European Union (EU) was established in 1992 by means of the Treaty of Maastricht. Current member states are Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Germany, Hungary, Finland, France, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Malta, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden and the United Kingdom. Furthermore, in April 2005 Bulgaria and Romania signed accession treaties with the EU paving the way to join the organization on 1 January 2007. Additionally, the EU recently agreed to open accession negotiations with two other countries, Croatia and Turkey.

The EU is built upon “three pillars”: (1) the European Communities (EC), which have been deepened by economic and monetary union; (2) common foreign and security policy; and (3) justice and home affairs. Under the first pillar, the Community institutions may, in their respective areas of responsibility, draw up legislation which applies directly in the EU member states. At the heart of the EC is the single market with its four basic freedoms (free movement of goods, free movement of workers, freedom to provide services and free movement of capital and payments) and its rules on competition. Under the second and third pillars, however, no powers have been transferred from the EU member states to the Community institutions and the activities and tasks of the latter are therefore limited to encouraging and supporting collaboration.

Since the early days of European integration, food law has formed part of the body of legislation within the framework of the EC. Most food law is in the form of regulations and directives. Whereas regulations are directly applicable in all member states, directives allow member states the choice of forms and methods to implement them in their national law – although after

an initial period, directives also acquire full legal force and effect. The implementation of the legislation is strengthened by the existence of the European Court of Justice, which interprets states' choices in implementing the directives and in so doing creates a corpus of judicially created law in the EU. The Health and Consumer Protection Directorate General has the task of keeping EU food legislation up to date.

Historically, European food law was developed on an *ad hoc* basis and was mainly directed at the need to create an internal market. In 1997, the European Commission – the executive body of the EU – launched a discussion document (“Green Paper”) with the aim of initiating a public debate on the further development of European food law. In 2000, the Green Paper was followed by a White Paper on Food Safety, which outlined a comprehensive range of actions needed to modernize existing EU food legislation, to make it more coherent, understandable and flexible, to promote better enforcement of legislation and to provide greater transparency *vis-à-vis* consumers.

The White Paper led to the adoption of a new basic framework for European food legislation, the General Food Law (Regulation (EC) No. 178/2002), which lays down the general principles and requirements of EU food law and sets out procedures relating to food safety. The regulation applies to all stages of the production, processing and distribution of food and feed, embodying a number of definitions and principles such as the application of risk analysis, transparency, traceability and precaution. An important attribute of the regulation is that it assigns to farmers, food operators and feed manufacturers the primary responsibility for food safety. The regulation also establishes the European Food Safety Authority, which provides independent scientific advice and support while establishing close links with and cooperating with relevant bodies in EU member states. It assesses risks through scientific advice and provides information to the general public about food risks.

Issuance of the White Paper also resulted in a number of European Commission proposals – some of which are still in the legislative process – intended to cover the whole spectrum of food-related issues including animal feed, animal health and welfare, contaminants and residues, food hygiene and food labelling. For example, the Commission is currently in the process of revising food hygiene rules, putting forward proposals for new regulations that will merge, harmonize and simplify the detailed and complex hygiene requirements currently contained in Council Directive 93/43/EEC and a

number of related directives. The Commission is also tightening and streamlining the rules on novel foods, i.e. foods and food ingredients that have not yet been used for human consumption, in particular those containing or derived from GMOs.

In April 2004, the EU adopted key legislation, Regulation (EC) No. 882/2004, on official controls performed to ensure compliance with feed and food law, animal health and animal welfare rules. The regulation reorganizes official controls on food and feed so as to integrate controls at all stages of production and in all sectors, using the “farm to fork” approach, and describes in more detail how the basic principles of food law are to be interpreted and implemented. The regulation seeks to establish a common regime for control of food and feed imports, based on risk assessment.

Among other things, the regulation provides for a harmonized EU-wide approach to the design and development of national food and feed control systems; a common approach to imports of food and feed from third countries; audits on members states’ national food control systems in order to assess their effectiveness; audits to verify compliance or equivalence of third country control systems and legislation with EU requirements; and support to developing countries. Under the present control system for food and feed in the EU, the Food and Veterinary Office carries out inspections in member states and third countries to ensure implementation and enforcement by the competent national authorities. This control system is expected to apply until the regulation with its new institutional framework enters into force in January 2006, at which time the directives on food and feed that are currently in effect will be repealed and replaced by the provisions of the new regulation.

Once Regulation No. 882/2004 comes into force, all member states will be expected to perform official controls to ensure that they are maintaining standards at every stage of the production process. The regulation requires that member states designate competent authorities which will perform the controls, and which themselves will be audited to ensure effectiveness and impartiality. Control systems will be supplemented by contingency plans which member states must establish to deal with potential emergencies where food or feed is found to pose a serious threat to humans or animals. Each member state must designate a liaison body to coordinate, transmit or receive requests for assistance. Finally, the regulation provides for enforcement measures at EU level as well as at national level, to address

problems of non-compliance with feed and food law, including animal health and welfare rules.

IX. CONCLUSION

At first glance, national and local legal instruments, such as regulations on the sale of street food, do not immediately bring to mind international issues or concerns. But as the preceding discussion has revealed, national regulation on food safety and trade takes place against a backdrop of negotiation, rulemaking and standard-setting in the international arena. Influential international and regional organizations bring together national governments, experts and observers in devising standards and guidelines combining national experiences and international expertise – standards which can then be used in fashioning national laws and regulations. The process is dynamic, ideally with information about practical and local concerns flowing from countries to the global or regional fora, where new scientific information may be available, and then back again to national decisionmakers. Not least among the advantages of such a process is that it fosters the sharing of experience at supra-national level. Regulatory problems can be shared among countries with similar circumstances, and so international and regional solutions devised.

Nonetheless, laws, regulations and standards developed at international level cannot be “imported”, as their effectiveness depends on their suitability in specific national contexts. Each country requires policies and legislation tailored to its needs, based on an in-depth analysis of the circumstances in the country, including its existing legislative and regulatory framework for food, policy objectives, institutional capacities and social, ecological, political and economic conditions. These many factors are examined and discussed in Chapter 5. At national level, widespread consultation among governmental and nongovernmental institutions, central and local authorities, community groups and private sector actors will inform the drafting of a sound and workable nationally tailored regulatory framework based on international norms.

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NATIONAL REGULATORY FRAMEWORKS FOR FOOD

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I. INTRODUCTION

As outlined in Chapter 1, this study defines “food law” to include all legislation that has an impact, directly or indirectly, on food, and accordingly its scope is very wide. This chapter describes and outlines the universe of subject matters that can be considered to be related to food, although of course not all of these will be universally addressed nor will they always be essential at national level. As noted in the previous chapter, each country has its own international obligations, policies, legislative traditions, institutional structures and budgetary and resource constraints, leading it to pick and choose in determining its national legislative strategies for the regulation of food. These choices will be addressed more completely in Chapter 5, which examines the myriad factors that determine a country’s legislative priorities and how it will go about addressing these.

Because of the vast number of topics that can be included under the heading of “food law” and considered to form part of a country’s regulatory framework for food, the authors have made conceptual divisions and distinctions. The discussion proceeds along a spectrum from areas of regulation most directly relevant to food to areas not specifically addressing but nonetheless affecting food. Some of the reasons that a particular topic falls into one category rather than another may be arguable, but we hope that the conceptual framework presented here will prove useful.

The chapter first explores areas of regulation specifically addressing food, including legislation on particular kinds of food such as foods of animal origin, novel foods, “functional” foods, street foods and “organic” foods. Also falling into this category is legislation regulating harmful substances in food and feed including food additives, residues of pesticides and veterinary drugs and contaminants. Next the chapter examines rules on how food is prepared, treated and sold, including legislation on food hygiene, food irradiation and food labelling. Finally, the chapter discusses legal provisions that are not directly targeted at food but that nonetheless affect the food sector, such as consumer protection, public health, water, land and environment.

II. AREAS OF REGULATION SPECIFICALLY ADDRESSING FOOD

2.1. Legislating on particular kinds of food

2.1.1. Foods of animal origin

Foods of animal origin, such as meat, poultry, fish, milk and eggs, form an important part of the nutritional needs of the world's population. These foods contain animal protein, which can be broken down into amino acids and which are essential for growth and development, for tissue maintenance and repair and for healing and recovery from disease. As opposed to plant protein, which does not always provide all essential amino acids in a given food (but rather must be complemented through combination with another), animal protein contains all those essential acids required by the human body. Additionally, foods of animal origin are important sources of vitamins and minerals such as iron, copper and calcium. Foods of animal origin thus have a high nutritional value and although they are not essential for a healthy diet, they can make it easier to maintain one.

Over the last several decades, the worldwide demand for meat, poultry, milk and eggs has rapidly increased, in particular in developing countries, and this trend – often called the “livestock revolution” – is expected to continue. Meat consumption in developing countries has risen from only 10 kg per person per year in 1964-1966 to 26 kg per person per year in 1997-1999, and is projected to rise still further to 37 kg per person by 2030. The consumption of milk and dairy products in developing countries has also seen rapid growth from 28 kg per person per year in 1964-66 to 45 kg per person now, and may rise to 66 kg by 2030. Income and population growth, urbanization, changes in lifestyle and food preferences, increasing international food trade and advances in technology have all contributed to these changes in diet.

At the same time, more than one billion people rely on fish products as an important source of animal protein, in particular in coastal areas. Although since the late 1980s world population growth has occasionally outpaced the growth of total fish supply, consumption is expected to rise again, in particular through aquaculture, which is currently one of the fastest-growing food production systems in the world. Taking into account solely income growth and dietary changes, the average intake of fish products could reach 22.5 kg per person per year by 2030, although a more likely range for

demand is between 19 and 20 kg per person per year, since the supply of fish products will be limited by environmental factors.

The control and inspection of foods of animal origin demand special attention and may not be as straightforward as for other kinds of food, in part because animals and fish can suffer from a variety of diseases, only some of which can be transmitted to humans. As a general matter, inspections of foods of animal origin serve a two-fold purpose, i.e. the determination of whether animals are suffering from diseases which they can transmit to one another (thereby raising animal health concerns) or from diseases which they can transmit to humans (thereby raising public health concerns). As to the latter, certain kinds of microbes and other harmful organisms which occur only in foods of animal origin can be extremely lethal. Tuberculosis, salmonella, trichinosis, bovine spongiform encephalopathy and shellfish poisoning are only some of the harms that can arise from inadequate controls on foods of animal origin.

Inspection activities have to cover the entire sequence from farm to fork in order to ensure that nowhere in the food chain is there a risk to human health. Proper control begins with an inspection of how the animals or fish are being raised, fed, farmed and treated, which implies coordination with farmers and with veterinary and fisheries staff. Next, the methods by which the animals are slaughtered must be assessed and inspected, to ensure not only that the animals are treated humanely, but also that the processes do not cause environmental damage or raise human health risks. Here again, inspections are serving manifold purposes. Where there is an intervening treatment carried out on the final products (such as pasteurization or heat application) to ensure their harmlessness to humans, such treatment should also be properly verified. And finally, controls must be exercised on how food products of animal origin are transported and stored.

Throughout the inspection chain, owners and operators bear the responsibility for identifying those points at which there is the greatest risk of contamination, and for imposing a system of science-based controls to mitigate those risks. This process is known as the Hazard Analysis and Critical Control Point (HACCP) system, which will be discussed further in section 2.3.1. HACCP principles and procedures are routinely included in legislation on the control of foods of animal origin.

In many countries the regulation and control of foods of animal origin is administratively and legislatively separate from the regulation of other kinds

of foods and food products. One argument for this is that the control of these products is best exercised by the ministries and staff with specific expertise in these sectors. Thus, although in many countries the overall responsibility for food control and food safety may lie with the ministry responsible for health, the control of the trade, manufacture, storage and inspection of meat products may be delegated to the national veterinary services, whose duties and powers are regulated in veterinary legislation such as animal health or meat inspection laws. Similarly, the control of the trade, manufacture, storage and inspection of fish and aquaculture products may be assigned to the ministry responsible for fisheries and the national fish inspection services, whose duties and powers are regulated in fisheries legislation.

There are persuasive reasons and powerful support for the position that foods of animal origin should be regulated by the ministries and personnel with background and training in these matters. The World Organisation for Animal Health (OIE), in fact, supports the assignment of enforcement authority for meat inspection to veterinary services departments. This recommendation likely derives from the fact that only veterinarians are capable of identifying particular diseases in animals, and therefore they should oversee the operation of slaughterhouses. The suggestion could be made, however, that since this recommendation emanates from the foremost organization of veterinarians worldwide, it is worth examining the opposing view.

One argument against the OIE position is that it ignores the numerous advantages to be gained from regulating all foods under one umbrella. These advantages will be explored more fully in Chapter 5, but in short, centralizing food activities facilitates information collection on disease outbreaks, optimizes accessibility of laboratory and other resources to carry out inspection and control, enhances the central authority's ability to rapidly assign resources in case of a disease outbreak and allows for the trouble-free transfer of information across disciplines, thus improving the training of inspectors and increasing their effectiveness.

Often, the suggestion that all foods, even meat and fish products, should be regulated by a central food authority is understood to mean that non-veterinarians will be inspecting slaughterhouses and certifying the safety of foods of animal origin. But this collapses two separate issues: the argument for a central food authority does not mean that non-specialized inspectors will be inspecting products of animal origin; it simply means that all

inspectors – even those specialized in the inspection of foods of animal origin – will report to and operate under the auspices of the central authority. While it is true that in many countries the ministry responsible for food safety (often the ministry responsible for health) has historically operated with limited resources, and therefore veterinarians have been loath to operate under its aegis and have sought independence in their control activities, the actual resource limitations must be separated from the ideal ones. In other words, if an efficient and effective central food authority can be set up, then there are no strong reasons why veterinarians and fisheries experts – despite their special training – should not operate under the umbrella of that authority.

2.1.2. Other specific kinds of foods

In many countries, other specific kinds of foods are subject to special regulatory attention as well. This includes food products intended or designed to satisfy the nutritional requirements of specific population groups, such as infants, the elderly, pregnant women, dieters, diabetics and sportsmen/sportswomen. Occasionally, some countries have also passed special legislation to require iodine supplementation in certain foodstuffs, as iodine deficiencies can affect the thyroid hormones that regulate many bodily functions. Iodine supplementation may be important for individuals who do not eat meat, seafood or other animal products, or who have a greater requirement for iodine (such as pregnant or breastfeeding women).

New or novel food products are appearing at an increasing rate because of rapid developments in food technology, biotechnology and molecular biology. In many countries the quick succession of new products, stimulated by both increasing opportunities and changing consumer demands, has led to the enactment of specific legislation. Over the years, various definitions have been given for novel foods but none of these has gained general acceptance. The Canadian Food and Drug Regulations, for instance, define novel foods as genetically modified foods, products that have never been used as a food or foods that result from a process that has not been previously used for food. The EU Novel Foods Regulation defines novel foods as food or food ingredients which do not have a significant history of consumption within the EU before May 1997 (Regulation (EC) No. 258/97), although the EU also separately regulates the authorization, labelling and traceability of foods and food ingredients that consist of, contain or are derived from GMOs (Regulations (EC) No. 1829/2003 and (EC) No. 1830/2003).

“Functional foods”, which are another category of food products attracting increasing legislative attention, consist of foods that are modified, developed or treated to improve their traditional nutritional characteristics and have a positive effect on the body beyond their traditional value. Examples of actions that may lead to the creation of functional foods are elimination of constituents with a negative contribution to nutritional value; addition of positive components; replacement of negative components; and balancing the product’s nutrient composition. Functional foods should not be confused with novel foods, however. Although functional foods may be novel, this novelty is not a strict necessity. Novel foods lose their novel character with time (for example kiwi fruit that reached Western markets many years ago), whereas functional foods maintain their functionality. Novel foods must be subject to a safety evaluation, whereas for functional foods it is also their efficacy that counts.

For these, as for all of the preceding kinds of food mentioned, neither the specific properties of such foods, nor the type of inspection called for nor the expertise required of food inspectors justifies their separate regulation. Dietetic, infant, genetically modified and functional foods alike must be safe for human consumption, i.e. they must not harm human health, contain improper additives and residues or quantities thereof and they must be packaged, labelled and sold properly.

While it is true that infants, the elderly, people with particular illnesses such as diabetes or those with severe food allergies are more sensitive to certain kinds of food, once the government has evaluated the risks scientifically and elaborated applicable standards, the application and enforcement of those standards should properly address consumer concerns. There is nothing peculiar about these foods that justifies parliamentary-level legislation: the same skills are required of all food inspectors, and the same procedures have to be followed for inspecting containers and labelling, for taking, sealing and transmitting samples and for acting on violations of the legislative provisions. On the contrary, in an area so clearly affected by science and scientific advancement, the drive to enact special parliamentary-level legislation is probably not wise. Regulations, which can more easily be changed, would be the more appropriate home for legislation covering such foods.

Just as with foods of animal origin, there may be historical reasons why some of the above kinds of food have been addressed separately and not within a general food law, but equally those reasons may not necessarily stand up to

sustained scrutiny. In many cases, countries may have enacted specific legislation, for example on infant foods, on breastfeeding or on iodine supplements, solely because of pressure from particular donors. Such pressure is not necessarily negative, since such specific laws may at one time have served a useful purpose. For example, in the absence of any food regulation at all, governments could take comfort in the fact that at least some limited areas were being addressed. Moreover, even in jurisdictions with existing food legislation, in many cases the legislative and institutional frameworks were patchy and riddled with overlaps and gaps, and thus specific legislation at least assigned clear-cut responsibilities in certain limited areas.

To satisfy the concerns of government officials who may have been implementing these special laws on infant foods, iodine fortification and the like, or who may be responding to increasing consumer or political pressure to address specific kinds of foods such as genetically modified foods, a new umbrella food law could include specific provisions or chapter headings addressing the control of such foods. While in a purely legal sense such special treatment may not be necessary (since a general provision stating that *all* food must be safe for human consumption and must meet quality, hygiene and labelling rules would cover all food including foods for special purposes and genetically modified foods¹), it may be wise as a policy matter in some countries to include such a special breakdown in the umbrella food law. Legislation often serves a public education function, and consumers reading a food law which includes in its chapter headings “infant foods”, “dietetic foods”, “genetically modified foods” and the like, will be sensitized to the fact that such foods are subject to particular government attention and may call for especial vigilance. Alternatively, specific categories of food could be addressed in subsidiary regulations rather than in special chapters of the food law. As noted, scientific advancements and evolving viewpoints may mean that the requirements for the regulation of such foods are likely to

¹ It is worth stressing here that the discussion turns only on genetic modification as it relates to food for human consumption. Governments may have a variety of other concerns about GMOs, for example regarding seed quality, plant protection and the environment, and may seek to enact special legislation with those objectives in mind. This may occur even where existing plant protection and environmental legislation can already be interpreted to cover GMOs, since just as in the food context, there are often strong consumer and political pressures to take specific regulatory action on GMOs. Some commentators argue that strict regulation may indeed protect human health and the environment but may discourage investment and research into potentially useful applications of GMOs.

change more often and sooner than for other foods, and thus, relegating to implementing regulations all details regarding the inspection and labelling of such foods as well as the applicable quality standards means that amendments can more easily be made.

2.1.3. Street foods

Greater numbers of people are eating food outside the home due to working families, long distances between work and home and escalating time pressures. In most cities around the world, in particular in developing countries experiencing rapid population growth and urbanization, street foods fill an important gap. FAO defines street foods as ready-to-eat foods and beverages prepared and sold by vendors and hawkers especially in streets and other similar public places. This definition encompasses a wide variety of foods, drinks, ingredients and methods of retail and processing. The kinds of foods available in a particular area will depend on local eating habits and the socioeconomic environment.

The street food sector is large, informal and complex, providing a means of livelihood and a readily accessible and affordable source of food for millions of people. Food safety, however, is a major concern, as street foods are often sold and prepared under unhygienic conditions, with limited availability of safe water, sanitary services, refrigeration and facilities for garbage disposal. There is also limited control exercised on the ingredients of such foods. For all these reasons, street foods have a greater potential for causing serious food poisoning outbreaks through microbiological contamination, improper use of food additives and the presence of residues and environmental contaminants.

Because of the high risks involved, over the last 10 years FAO has worked with a number of countries in various parts of the world in the evaluation of the quality, safety and economics of street foods and in devising recommendations for their control. In 1995, FAO held a Technical Meeting on Street Foods in Calcutta, in order to review the progress made in improving street food quality and safety at global level, to analyse different experiences and lessons learned and to provide the international community with an updated set of recommendations and guidelines to stimulate improvement. As a result of this Technical Meeting, a “Guideline Action Plan on Street Foods” was developed which includes essential elements and identifies strategies for action for the improvement of the street food sector. See Box 1.

The Food Quality and Standards Service of FAO has a comprehensive programme to assist national and municipal authorities in ensuring the quality and safety of street foods. In addition, the Codex Regional Committees have elaborated codes of hygienic practices for the preparation and sale of street foods as well as for the design of control measures for street-vended foods. Regional codes have been completed for Latin America and the Caribbean and Africa, while a code of practice for the Near East is in draft form.

The issuance of operating licences for street food sellers is the primary means of street food control. The licence is generally granted only after a thorough inspection and may include restrictions on the types of food to be prepared, the sites where they may be sold and the required means of storage and sale. In principle, this should lead to street sellers being situated in the safest locations and selling safer food, either because they are restricted to selling only the kinds of foods that are less likely to cause harm or because they are required to follow certain procedures in storing, serving and selling the food. Inspectors are routinely authorized to take in fees, which, in principle, are cycled back into the system, allowing for more effective control. Moreover, since the system licenses some sellers and not others, consumers learn which street sellers can be presumed to be selling safe food. In such a system, it is an offence to sell food without a licence or in an area not approved by authorities. Licences may also be suspended or revoked where sellers fail to follow applicable rules, such as hygiene rules imposed in connection with the grant of the licence.

Whether because street foods are a relatively new phenomenon or because they were not considered as a category of food raising special concerns until comparatively recently, many existing national food laws do not address the issue, nor can their general provisions be interpreted so as to apply to street foods. In many cases, governments have now enacted separate legislation on street foods, mainly at the local level. The development and application of municipal by-laws and decrees has the advantage that local solutions can be devised for local problems, since local authorities are most familiar with their regulatory needs. On the other hand, incorporating the regulation of street foods into the umbrella national food law would permit consistency and uniformity in the control of all types of food prepared and sold in the country, including street foods.

As discussed in the preceding sections, there are generally few justifications for separately regulating specific kinds of food, and this would apply equally

to street foods. While there may be a need to include provisions in the food law establishing the licensing scheme described above, this would not otherwise justify specific legislation on street foods, since the hygiene and other concerns are the same as for other kinds of food. The details of the licensing and inspection system for street foods can be elaborated as subsidiary regulations or municipal by-laws. In any case, at whichever level regulation and control do take place, they should be complemented by training of food vendors and inspectors and educating consumers.

Box 1 Guideline Action Plan on Street Foods

The purpose of the Guideline Action Plan on Street Foods, developed in connection with FAO's Technical Meeting on Street Foods held in Calcutta in 1995, is to determine certain strategies for ensuring street food safety which could be applied in different parts of the world. The plan first calls for recognition that the informal street sector has a legitimate place in a city and that the city's infrastructure and facilities should be managed and developed so that street foods and the orderly life of the city can coexist and even support one another. The plan recognizes that this would generally entail permitting the operation of a street food industry while controlling the conditions under which it functions.

The second step in the plan requires that street vendors be issued with licences to operate, which may specify the food, location and time frame for their operations. The plan suggests that it may be wise to develop categories of street foods based on a health risk assessment, and to designate some as "high risk foods" and others as "lower risk foods". The plan also calls for good coordination between public health authorities, police and local administrations, and encourages the establishment of street vendor associations in order to ensure proper representation and fairness.

The plan next stresses the importance of a review of existing legislation related to food, the preparation of codes of practice for street foods and proper training of food inspectors. Finally, the plan calls for a strong educational and training component, provision of basic facilities such as space, water, electricity, lavatories and garbage disposal services and the involvement of appropriate technical institutions to enable further scientific and technical inputs appropriate to the needs of both vendors and consumers. States are invited to implement the plan on a trial basis in selected cities, states or regions before implementing it nationally.

2.1.4. “Organic” foods

As outlined in Chapter 2, the production of organic food is rapidly expanding across the globe. The growth in organic production has been accompanied by a proliferation of legislation, at least in developed countries, to protect organic producers from unfair competition and consumers from deception and fraud (i.e. the misrepresentation of agricultural produce as organic when it is not). In addition, the desire to gain access to major export markets has proven to be a stimulating factor for the adoption of new legislative frameworks for organic production in a number of developing countries. For instance, plant and animal products imported into the European Union may only be labelled “organic” if they conform to Regulations (EC) 2092/91 (on plant products) and (EC) 1804/99 (on products from organically managed livestock).

“Organic” legislation generally lays down minimum rules governing the production, processing and import of organic products, including certification and inspection procedures, labelling and marketing. The IFOAM norms are widely known and employed in developing these rules. Some countries have enacted parliamentary-level legislation on organic production, establishing and regulating the operation of certification bodies and elaborating lists of permitted and prohibited inputs. These last are generally found in subsidiary instruments, as they may need to be frequently updated. Other jurisdictions have relied on a few basic provisions in general food legislation, providing that all food labelled as organic must meet the production and processing requirements set out in implementing regulations. Either strategy will generally be sufficient to establish and enforce an organic agriculture scheme.

Specific requirements may provide that the name of the certification body be stated on the label, as well as the type of organic standards that have been followed throughout the production and processing of the food. Specific provisions may also regulate the use of specifically developed logos for organic products. Because consumer confidence in the integrity of “organic” claims is essential if organic foods are to be sold at a premium, the legislation should include strict enforcement provisions. Where a basic food law does not impose high enough penalties for fraud or mislabelling, it may need to be amended and strengthened.

In addition to their particular production and labelling standards, organic foods must meet the same quality and safety standards applied to

conventional foods: the “organic” label does not exempt producers and processors from complying with general regulatory requirements such as food hygiene or labelling rules. If national regulations require the establishment of food safety programmes based on the HACCP system (see section 2.3.1), then such programmes should be established in the organic sector as well. Certification bodies must assure that *all* relevant processes and rules are adhered to in the production of organic foods.

2.2. Regulating harmful substances in food and feed

Throughout the food chain, a number of substances may be added to or may unintentionally affect or become a part of food, which may cause risks to human health. Some substances are harmful *per se*, whereas others are harmful only above certain limits or in combination with other substances. The levels of these substances in food are controlled through prohibitions on the use of particular substances and through the establishment and monitoring of maximum safe levels and maximum residue limits (MRLs). The main principle is that every addition – direct or indirect – requires an authorization from a competent authority based on an evaluation of the potential risks to human health.

As noted in Chapter 2, in elaborating maximum safe levels and MRLs for substances falling within their mandates, both the Codex Committee on Food Additives and Contaminants and the Codex Committee on Residues of Veterinary Drugs in Foods consider the recommendations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). JECFA carries out toxicological evaluations of substances intended for use as food additives, establishes specifications for “food grade” chemicals used as additives, develops principles for the safety assessment of chemicals in food and evaluates contaminants, naturally occurring toxicants and residues of veterinary drugs. Similarly, the Codex Committee on Pesticide Residues considers the recommendations of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), which carries out toxicological evaluations and proposes MRLs for pesticides in food.

Because the terrain is constantly shifting due to incremental scientific advancements, the rules on harmful substances in food are almost always incorporated into a country’s subsidiary regulations rather than in parliamentary-level legislation. Where it is the line minister or the head of the central food authority who is accorded the power to elaborate and issue updated values for particular substances, the necessary changes to the

applicable regulations and standards are easier to make. Thus, the main legislation simply needs to contain a provision stating that the minister or head has the power to establish and enforce safe levels of particular substances in food, including the power to ban those deemed not safe in even minimal quantities. The next sections address in further detail the various kinds of substances that can be found in food and that can raise human health risks.

2.2.1. Food additives

Food additives are chemicals which are intentionally added to food during its preparation or storage to fulfil a specific technological function. They can either be derivatives of natural products or synthetically produced. Colouring agents are one type of additive which are routinely added to items such as margarines, soft drinks and confectionery products. Similarly, flavour enhancers such as hydrolysed vegetable protein are often found in desserts, salad mixes, ice creams and barbeque sauces. Emulsifiers, for example lecithin and mono- or diglycerides, are used to enable particles of one substance within a product to disperse into a second substance within the same product, and are found in, among other things, chocolates, dessert mixes and breads. Similarly, stabilizers, including gelatine and pectin, aid in the creation of a smooth texture and are typically used in the preparation of cream cheeses, baked products and sauces. Another category of food additives is artificial sweeteners, which may be used in a wide range of food items including soft drinks, confectionery products and dairy products, in place of sugar.

Regulations on food additives, which usually appear as subsidiary instruments under the main food legislation, should list the minimum requirements for their composition and quality (“food grade specifications”), the additives which may be used (to the exclusion of others), the foods in which they may be used and the maximum levels, if any. Most food additives may only be used in limited quantities in certain food products. If no quantitative limits are foreseen for the use of a food additive, then the additive should be used according to good manufacturing practice, i.e. only as much as necessary to achieve the desired technological effect.

Food additives may only be authorized if they present no risk to human health and should therefore be subject to a strict scientific safety evaluation before their approval for use. This is particularly necessary since food additives are consumed in relatively large concentrations in comparison to

concentrations of pesticide or veterinary drug residues. Assessments must be based on all toxicological data and other relevant available information in order to determine the Acceptable Daily Intake (ADI). The ADI must provide a large safety margin and is the amount of each food additive that can be consumed daily over a lifetime without any adverse effect on human health.

2.2.2. Pesticide residues

Pesticides are routinely applied in modern farming during the manufacture, storage, transport, distribution or processing of agricultural products in order to repel or destroy pests and to prevent and mitigate crop losses. Seeds are often treated with fungicides before planting, while farmers use insecticides, bactericides and herbicides to protect growing crops against, *inter alia*, insects, microbiological agents and weeds. Pesticides are also applied to protect foods during transportation and storage and for better control of insects and rodents in food establishments.

Some pesticides may be used without great hazard to health, as they quickly disappear or break down into harmless substances. Others, however, persist and may leave unsafe residues in foods. Still other pesticides can be so poisonous that strict controls are needed at every stage of the food production process. In addition, if pesticides are improperly stored or disposed of, they may contaminate soil, rivers, lakes and ground water, with potentially harmful effects on crops or on water for drinking or irrigation. Exposure to some pesticides at levels above those normally found in foods may lead to adverse health effects and cause birth defects, nerve damage or cancer.

Whereas the registration, use and control of pesticides is normally regulated in separate legislation, such as laws on chemicals or pesticides (see section 3.1.1), the regulation of pesticide residues in food is usually addressed under general food legislation. This includes the setting and monitoring of MRLs for pesticides, i.e. the maximum concentrations of pesticide residues (expressed as mg/kg) legally permitted in foods. These MRLs do not represent maximum toxicological limits but instead are based on good agricultural practice, meaning they represent the maximum safe level that one would expect if the pesticide is used according to the rules and restrictions of its authorization. Nonetheless, when MRLs are set, care should be taken to ensure that the maximum levels do not give rise to toxicological concerns.

MRLs should be below the level that causes any detectable toxic effect on consumers as expressed by the ADI.

2.2.3. Veterinary drug residues

Veterinary drugs are chemicals administered to animals to prevent and treat diseases, to provide humane means of restraint and pain relief and to improve production. Among the several hundred veterinary drugs in use are antibiotics (which kill or inhibit micro-organisms), beta-adrenoreceptor blockers (which prevent sudden death due to stress during transport), anti-helminthics (which eliminate parasitic worms) and tranquilizers. By eating foods of animal origin, humans are liable to consume whatever veterinary drugs the animal has been exposed to. If found at certain levels in those foods, some veterinary drug residues may have an adverse impact on human health.

Antibiotics raise some of the most serious risks, as their consumption may lead to antibiotic resistance in humans, thereby compromising the efficacy of antibiotics in treating infections. The use of particular antibiotics in animals increases the potential for resistant bacteria to develop in the animal products, which in turn could make humans consuming those products less responsive to future treatment with that antibiotic. Hormones are another substance of concern. As a general rule, hormone use on animals (mainly cattle, pigs and poultry) is confined to intensive-management farming, where oestrogen-like hormones are used to grow the animal more quickly and economically and to control oestrus. While it has been argued that some hormones are carcinogenic or can lead to the early onset of puberty in humans, advocates maintain that, when used according to good veterinary practice, they present no risk to the public. See Chapter 2, Box 1.

While the registration and control of veterinary drugs is usually regulated in specifically targeted legislation (see section 3.1.2), the level of risk associated with exposure to residues of veterinary drugs in food is generally regulated under general food legislation. Again, this includes the setting and monitoring of MRLs for veterinary drugs, i.e. maximum concentrations of residues (expressed as mg/kg) resulting from the use of a veterinary drug legally permitted or recognized as acceptable in food. In addition, withdrawal periods are often defined during which foods derived from animals that have been treated with particular drugs cannot be consumed. Tranquilizers used immediately before slaughter, for instance, would not be dissipated or

removed through the normal metabolic process and thus require the establishment of an appropriate withdrawal period.

Just as with MRLs for pesticides, MRLs for veterinary drugs do not represent maximum toxicological limits but are rather based on good practices in the use of veterinary drugs. Nevertheless, care should be taken that the MRL is kept below the level that causes any detectable toxic effect on humans as expressed by the ADI, i.e. the estimated amount of a veterinary drug that can be ingested daily over a lifetime without appreciable health risk.

2.2.4. Contaminants

Contaminants are manufactured or naturally occurring chemicals which are not intentionally added to food but may enter food during its production, preparation or storage or through environmental contamination. Mycotoxins, for instance, are produced by different genera of fungi and may, under the right conditions of temperature and humidity, grow on agricultural products such as grains, cereals, edible nuts and dried fruits. If ingested in low doses over long periods of time, aflatoxins, the most toxic of these substances, can cause liver cancer.

Polychlorinated biphenyls (PCBs), dioxins and heavy metals, such as mercury, lead or cadmium, are some of the chemicals that can enter food through contaminated soil or water. Taken up by fish and small organisms in water and by animals that feed on them, these chemicals accumulate in fish and may reach levels that are many thousands of times higher than in water. Depending on the amounts, animals that have eaten food containing such chemicals over a period of time may suffer from anaemia, acne-like skin conditions, stomach and thyroid problems and in extreme circumstances, liver damage and death.

From a human health perspective, some health services have concluded that PCBs are particularly nefarious chemicals which are probably carcinogenic to humans. Studies have shown that pregnant women who were exposed to relatively high levels of PCBs in the workplace or ate large amounts of fish contaminated with PCBs had babies that weighed slightly less than babies of women who did not have such exposure, and the infants also showed abnormal responses. Other studies suggest that the immune system in children born to and nursed by mothers exposed to increased levels of PCBs is also affected.

Unlike food additives, pesticides and veterinary drugs, environmental contaminants cannot easily be made to disappear from the food supply by regulatory action. Although regulations may provide for limits that are set at scientifically determined maximum safe or “tolerable” levels, these levels are not always sufficient to protect the entire population. It is for this reason that additional advice is often provided to certain population groups, for instance to pregnant women, so that they avoid eating large predatory fish.

Finally, it is worth noting that contaminants include not only environmental contaminants but also substances that enter the food chain due to carelessness in food processing. Such contaminants are not usually regulated individually as their presence under any circumstance usually denotes a failure to comply with basic processing requirements and good practices. Legislation on how food is prepared and treated will be further discussed in section 2.3 below.

2.2.5. Residues in animal feed

As indicated in section 2.1.1, proper control on foods of animal origin should cover the entire sequence from farm to fork, including an inspection of how the animals are being farmed, fed and raised. Contamination of animal feed – intentionally or unintentionally – can take place at any stage of the production process up to the point of feeding and may lead to the presence of harmful substances in foods of animal origin. For example, environmental contaminants (such as dioxins, PCBs and heavy metals) may appear in animal feed where plant materials used for feed have been grown in areas with high levels of contamination.

Although the frequency of human health problems caused by contaminated animal feed is relatively low in comparison with hazards arising further along the food chain, there have been notable exceptions. These include the presence of infectious agents such as salmonellae in animal feed which caused widespread illness and more recently, the appearance of variant Creutzfeldt-Jakob Disease (“mad cow” disease), which scientists strongly believe is caused by ruminant animal proteins in animal feed.

In light of this, many countries establish and monitor MRLs not only for pesticides and contaminants in food but also for pesticides and contaminants in animal feed, in particular where the animals or their products are likely to be consumed by humans. Although the rules may occasionally be found in specifically targeted legislation addressing the production, use and control of

animal feed (see section 3.1.3), more frequently they are elaborated and adopted under general food legislation.

2.3. Establishing how food is prepared, treated and sold

2.3.1. Food hygiene

Food hygiene legislation generally sets out the basic principles and rules to be followed by owners and operators of food establishments during the preparation, processing, manufacturing, handling, packaging, transportation, storage and distribution of food in order to ensure a safe, sound and wholesome product fit for human consumption. The principles and rules are usually elaborated in general food hygiene regulations under a country's basic food law, although product-specific regulations may apply to certain food establishments, for example establishments that handle foods of animal origin such as slaughterhouses and fish markets.

Traditionally, producers and regulators have depended on spot checks of manufacturing conditions and random sampling of final products to ensure safe food. This approach, however, tends to be reactive rather than preventive, and is thus less efficient and cost-effective. Due to growing public concern over the safety of food, there has been a trend toward the adoption of a more preventive approach to the control of food products throughout the entire food chain (“from farm to fork”). Modern food hygiene legislation thus requires producers not only to make sure that the food is prepared, treated and sold in a hygienic way but also to identify food safety hazards and ensure that safety controls are implemented, maintained and reviewed.

The most common system used by food establishments to ensure that hazards are identified and controls are in place is the Hazard Analysis and Critical Control Point (HACCP) system. HACCP imposes responsibility on the owner or person in charge of the production, processing or handling of food products to set up control systems and to take appropriate precautions to prevent contamination at certain “critical control points” in the food production chain. See Box 2. This usually requires the owner to carry out inspection and sampling on raw materials and on cleaning and disinfection methods. Owners must also keep written records and inform relevant authorities when a serious public health risk is found.

Box 2 The Seven Principles of HACCP

The HACCP system is considered to consist of seven principles, whose implementation must be underpinned by sound scientific knowledge.

(1) *Analysing hazards.* The first goal is to identify potential hazards associated with a food as well as the measures needed to control those hazards. A hazard can be biological, chemical or physical.

(2) *Identifying critical control points.* The next step is to identify the critical control points in a food's production, i.e. the points at which each potential hazard can be controlled or eliminated.

(3) *Establishing preventive measures with critical limits for each control point.* The next task is to determine the precise measures necessary to eliminate the problem, such as cooking a food at a certain minimum temperature and time.

(4) *Establishing procedures to monitor the critical control points.* The fourth step requires setting up procedures for monitoring the critical control point, for example by identifying the person who will supervise the preventive action and outlining what that supervision should consist of.

(5) *Establishing corrective actions to be taken when monitoring shows that a critical limit has not been met.* The next goal is to set out the remedial measures that must be taken if the critical limit for a particular food is not met. This could include procedures for disposing of food which does not meet requirements.

(6) *Establishing procedures to verify that the system is working properly.* This task is related to step (4), and consists of establishing procedures to monitor the monitoring systems. For example, the system could require period inspection of testing machines to ensure that they are providing accurate measurements.

(7) *Establishing effective recordkeeping to document the HACCP system.* The final step requires recordkeeping of hazards, their control methods, the monitoring systems in place and the corrective actions taken.

HACCP is widely implemented in most developed countries, and in many developing countries as well. Because HACCP has been adopted by Codex as the international standard for food safety, implementation of the HACCP system is understood to reduce barriers to international trade. Many developed countries – the United States and the countries of the EU first and foremost – have made implementation of the HACCP system a specific legal requirement for certain imported food products (mainly meat and fish), which has spurred developing countries to implement strict HACCP rules in their own legislation. However, implementation is often limited to establishments that produce, process and handle food products for export rather than for the local market. This is because implementation of HACCP can be expensive, and countries tend to focus on those areas representing

the highest earnings potential. With expertise and human resources often lacking, limited resources are usually allocated to areas with the highest perceived value.

New challenges to the food supply are prompting some governments to consider adopting HACCP more widely. The appearance of a number of new food pathogens, as well as heightened public health concern about the human health effects of chemical contamination, drive this trend. Other important factors are the expansion in the size of the food industry, the diversity of products manufactured and imported and the processes used, all of which call for more systematic control. By focusing on prevention, HACCP can allow governments to more efficiently and effectively allocate limited resources in overseeing the food safety system. As HACCP places responsibility for ensuring food safety on the food manufacturer or distributor, inspectors are free to focus more on auditing and monitoring activities. Moreover, recordkeeping requirements allow investigators to assess overall compliance rather than compliance on the particular day that an inspection is carried out.

In addition to HACCP requirements, food hygiene regulations typically deal with the physical plant of food establishments, providing that it must be kept clean and maintained in good condition so as to permit proper cleaning and disinfection. Drainage facilities must be adequate and designed and constructed so as to avoid the risk of contamination of food products. Other requirements deal with the availability of adequate ventilation, lighting, sanitary and hand-washing facilities as well as a sufficient supply of potable water. Provision must also be made for the removal and storage of food waste and other refuse. In addition, food hygiene regulations generally contain requirements on personal hygiene, for instance that personnel in food establishments must maintain a high degree of personal cleanliness and wear suitable clothing. No person known or suspected to be a carrier of a disease which can be transmitted through food should be allowed to work in any food handling area if there is a possibility of contaminating the food.

Food hygiene regulations also encompass the safety of food contact materials, which means those materials and articles intended to come into contact with food, such as cork, glass, metal, paper, plastic, rubber, textiles, wax or wood. Food contact materials consist not only of food packaging materials but also cookware, cutlery, dishes, containers and food processing machinery and equipment. The term is also understood to cover all materials and articles which are in contact with water intended for human

consumption, such as water tanks, but does not include fixed public or private water supply systems. As a general rule, food contact materials should be safe and should not transfer their constituents into food in quantities that endanger public health, nor should they adversely affect the nature or quality of the food.

2.3.2. Food irradiation

Food irradiation consists of the physical treatment of packaged or bulk food products with carefully controlled amounts of ionizing radiation for a specific time in order to destroy or neutralize organisms that cause spoilage and decomposition, to control sprouting, ripening and insect damage or to eliminate pathogens that cause food-borne illness. In many cases irradiation can be an effective alternative to the use of pesticides. A number of countries have approved food irradiation but its use is still not widespread, mainly due to a lack of public acceptance and because irradiation facilities are expensive to build. Each year a few hundred thousand tonnes of food products and ingredients are irradiated worldwide, although this is only a small fraction of the total volume of processed food.

Despite much scientific evidence that irradiation causes no harmful chemical changes and only minimal nutritional changes to food, there is widespread consumer concern about the safety and wholesomeness of irradiated food, in particular regarding any potential long-term effects. And indeed there are perceptible effects on certain foods, depending on the type of food, the irradiation source and the total absorbed dose. For example, irradiation is known to cause undesirable flavour changes in dairy products and tissue softening in some fruits, such as peaches and nectarines. Many countries therefore consider specific applications of food irradiation on a case-by-case basis, either accepting whole classes of irradiated foods or limiting acceptance to just a few food items.

Legislation on food irradiation can take many forms. In some countries, laws on nuclear energy and radiation have been promulgated to govern the operations of industrial irradiators which process non-food products such as medical supplies, and such laws can also be applied to food irradiation facilities. In other countries, specific regulations on food irradiation have been adopted, most often under the country's basic food law. Such regulations generally establish a competent authority responsible for approving (classes of or individual) irradiated foods, issuing licences to food irradiation facilities and providing advice on food irradiation in general.

Usually, the legislation establishes the modalities and conditions under which food may be irradiated, such as the packaging materials, monitoring, qualifications of personnel, emergency procedures, transport and handling, while the labelling of irradiated foods so as to distinguish them from non-irradiated foods may be addressed in specific labelling regulations.

2.3.3. Food labelling

The main function of food labelling is to provide information about the nature and characteristics of food products in order to give consumers the opportunity to make a more informed choice. Food labelling should not mislead the consumer as to the product's characteristics or effects nor should it attribute to a product properties for the prevention, treatment or cure of a human illness. Food labelling regulations normally require that all labels indicate the name of the food, the ingredients, the weight or volume, nutrition information, the name and address of the manufacturer, the country of origin, instructions for use and storage and the expiry date. Moreover, these particulars must be indicated in a language easily understood by the consumer. Additionally, labels used for foods of animal origin, in particular meat products, are often required to show a traceability number in order to trace back the meat to the animal on the farm and indicate where the animal was born, raised and slaughtered. In the event of any problem detected during the time the animal was on the farm or the meat was being prepared for sale, the traceability number allows the authorities to trace the meat and withdraw it from the market.

Although food labelling requirements are most often stipulated in subsidiary regulations under a country's basic food law, specific labelling rules may occasionally appear in other types of legislation, for instance on consumer protection. In some countries separate legislation may govern the use of weights, volumes, measures and numbers. Such legislation might require that all goods sold by weight, volume, measure or number have a statement as to their quantity on the label, and might prescribe how this statement should appear on the label or packaging.

Geographical indications, i.e. marks applied to products that have a specific geographical origin and possess qualities or a reputation that are due to that place of origin, may also appear on the label or packaging. Most commonly, geographical indications consist of the name of the place of origin of the product. Agricultural products in particular may have qualities that are claimed to derive from their place of production and which are influenced by

specific local factors, such as climate and soil. Geographical indications may be used for a wide variety of agricultural products, such as, for instance, “Tuscany” for olive oil produced in this specific area of Italy, and “Roquefort” for cheese produced near the village of Roquefort in France. Geographical indications may also include agricultural products that originate in a larger geographical area, such as “Basmati rice” from India or “Darjeeling tea” from India or Sri Lanka. See Box 3.

Box 3 Geographical indications

Countries differ considerably in the way they handle geographical indications. Such indications may be protected under trademark laws, consumer protection laws, unfair competition laws or a combination of these. Some countries have adopted specific laws for the protection of geographical indications, applying internationally accepted rules such as those reflected in the Paris Convention for the Protection of Industrial Property (1883), the Lisbon Agreement for the Protection of Appellations of Origin and Their International Registration (1958) or more recently, the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), which has recognized the geographical indication as an intellectual property right. TRIPs requires its member countries to protect geographical indications if their use is likely to mislead the public as to the true place of origin of the product.

Because food labelling legislation may have been developed before there was widespread interest in geographical indications, and in light of the fact that the intellectual property issues may call for stricter government attention, most governments will choose to address geographical indications in separate legislation, even where most of the country’s food labelling provisions are addressed in subsidiary instruments under the food law.

III. AREAS OF REGULATION NOT SPECIFICALLY ADDRESSING BUT STILL AFFECTING FOOD

The chapter thus far has focused on those subject matters and legal instruments that can be considered as specifically addressing food, including legislation on particular kinds of food, on controlling harmful substances in food or on how food is to be prepared, treated and sold. But because the authors believe that the term “food law” refers also to legal provisions that are not directly targeted at food but that nonetheless affect the food sector, the main subject matters within this next category are explored below.

Not all subject areas that affect the food sector are outlined here, as they would be too numerous and the line had to be drawn somewhere, but the selection included should give a useful overview of those other types of legislation that the authors believe are relevant to food. When reviewing national legislative frameworks for food, at least the framework for the following subject areas should be taken into account, and in particular gaps, overlaps and inconsistencies should be identified. As stated throughout this text, it is advisable to combine as many legal provisions relating to food into one basic law, whose contents and form will be introduced in Chapter 5 and in the Appendix.

3.1. Registration schemes

Section 2.2 examined the kinds of substances that can intentionally or unintentionally become a part of food and thus call for regulation and control. Lists of prohibited substances, MRLs, permitted maximum levels of contaminants and withdrawal periods are employed to enable regulators to control these potentially harmful substances in food and feed. As indicated, the rules are almost always incorporated into a country's subsidiary regulations rather than in the basic food law.

But just as safe food cannot be assured only by inspecting the final product – but rather, safe processes must be implemented throughout the entire production chain – the safe use of chemicals, pesticides, veterinary drugs and animal feed can only be guaranteed through the implementation of a sequence of controls starting from their manufacture (or importation) and running through to their storage, labelling, sale, use, application and disposal. Whereas one of the purposes of such controls is the prevention of the numerous human health effects that can be caused by the ingestion of unsafe residues, they also serve a number of objectives above and beyond the protection of human health, including the prevention of harm to the environment, the maintenance of biodiversity and the protection of animal health, among others.

Countries may choose to regulate chemicals, pesticides, veterinary drugs and animal feed in a number of ways, and there is no particular strategy to be preferred above all others. Nonetheless, some broad trends in national legislative frameworks can be observed. Whereas some jurisdictions have enacted umbrella legislation on chemicals or hazardous substances, the more common approach is to formulate separate pieces of control legislation to facilitate the allocation and use of targeted expertise and resources. Thus,

rather than creating one authority to control the registration of all kinds of chemicals including pesticides and veterinary drugs, separate bodies and registration schemes have been set up through sectoral legislation. Each of these is now explored in turn.

3.1.1. Chemicals and pesticides

Legislative provisions governing chemicals and pesticides may be found in environmental legislation, for instance in legislation on hazardous waste or in legislation addressing specific sectors such as agriculture or transport. On the other hand, there may be specific chemicals or pesticides legislation, which prohibits or restricts the manufacture, import, use, possession, distribution or sale of such substances, requiring them to be registered under the law. A central cross-sectoral body – either a unit within the relevant ministry or an agency, board or commission – evaluates the scientific evidence relating to particular substances, and may either establish a list of prohibited substances (permitting all others) or a list of permitted substances (banning all others). In either case, the legislation may also require that certain conditions be met in relation to permitted substances, in order to address health and environmental concerns that arise during their production, use, trade or disposal (life cycle).

The regulatory body established in the legislation is generally authorized to collect, interpret and disseminate information, which allows it to identify and assess unacceptable risks to human or animal health or the environment and to communicate those risks to the public. It should also have the responsibility for evaluating applications for registrations, issuing licences and advising the minister or other relevant authorities on all issues relating to chemicals or pesticides. While its membership should be broad-based in order to draw upon all available expertise in the country and enable all affected actors to provide useful inputs, care should be taken to avoid conflicts of interest, for example by not permitting manufacturers and importers to sit on any regulatory body which will determine which substances will be registered within the country.

The legislation generally contains provisions on use, for example, requiring employers whose employees work with chemicals or pesticides to follow safety procedures and to provide appropriate training and equipment. The law should also regulate how chemicals and pesticides are stored, advertised, labelled, packaged, repackaged and disposed of. For example, the legislation may establish particular requirements for pesticide containers used for

storage, transport, sale or disposal, or may more generally prohibit the disposal of chemicals and pesticides in a manner that harms human health or the environment. Other provisions or laws may address issues relating to public health (e.g. worker safety), the right of communities to know of the presence or release of toxic substances and environmental contamination (air, soil, water, effects on wildlife) arising during production and other stages of the life cycle of the products.

For enforcement purposes, the legislation usually provides for specially appointed inspectors with the power to inspect establishments where certain activities in relation to chemicals or pesticides are taking place, and to search premises, aircrafts, vessels or vehicles if violations are suspected. Inspectors may also have the power to seize chemicals, pesticides, documents or other materials. Compliance is generally ensured through record-keeping responsibilities imposed on persons or entities importing, exporting, manufacturing, storing, distributing, selling and using specified substances, and inspection of these records helps the regulatory body track the movement of harmful chemical substances and pesticides throughout their life cycle.

3.1.2. Veterinary drugs

The main goal of regulating the supply of veterinary drugs is to guarantee their quality, safety and efficacy at the time of their administration to the animal. Matters usually covered by veterinary drugs legislation are the control of the introduction of drugs into the country (by manufacture or by importation), their circulation in the country and their supply to the end user. The legislation also identifies who is authorized to prescribe veterinary drugs, and prescribes rules for storage, labelling, record-keeping and inspection. It can also detail who may prepare veterinary drugs, using what techniques and under what conditions. Withdrawal periods before slaughter and permissible MRLs for meat and milk may also be established, although, as noted before, such rules are more likely to be found in regulations issued under a country's food law rather than in its veterinary legislation.

Veterinary drugs laws generally set up a central body to register and advise on all veterinary medicines in use in the country. National practice varies between countries wishing to administer veterinary medicines and human medicines under the same aegis and countries establishing a separate body for the control of veterinary drugs. The principal arguments in favour of the former are that a unified body can more easily share resources and

information; that with two bodies there is the risk of overlapping bureaucratic regimes with concomitant transaction costs passed on to consumers; that with two systems there is the possibility of abuse – with applicants seeking registration under the less demanding scheme; and finally, that there is significant overlap in the safety and other concerns applicable to human and animal drugs and so they should be regulated together.

By contrast, advocates of a separate system for the control of veterinary drugs argue that where human and animal drugs are regulated together, the latter will always receive less attention. They also point to the many special characteristics of veterinary drugs which argue for their separate regulation: first, their use raises human health risks, as discussed in section 2.2.3; second, some drugs are only used on animals, some are used only on humans, but even where they are used on both, the priorities may nonetheless be different; third, drugs are prescribed differently for different animal species, whereas all humans – except with rare exceptions – are treated alike for prescription purposes; fourth, administration of veterinary drugs to animals must be carefully monitored to check for resistance to particular formulations; and last, veterinary drugs are often administered by livestock owners, heightening the importance of instructions, labelling and extension services.

In the end, the decision on whether to regulate human and animal drugs with one regulatory body or two will depend on local traditions and priorities. A system with two registration schemes can be successful so long as there is close collaboration and sharing of information between the two bodies. Even where there is only one regulatory body, proper control can still be exercised if there is a separate specialist board making decisions on the registration of veterinary drugs. In any event, as discussed above (in relation to chemicals and pesticides) the membership of any regulatory body for veterinary drugs should not include stakeholders who will be directly affected by the body's decisions.

3.1.3. Animal feed

Animal feed legislation regulates the manufacture, importation, registration, sale, advertising and use of animal feed and the raw materials employed in its manufacture. Typically, a central body created in the legislation has responsibility for the evaluation and registration of animal feed in the country as well as the provision of advice to the minister or other relevant authorities on all issues relating to animal feed. This would include, for

example, determining which animal feed and raw materials are permitted or prohibited, or which special conditions may be attached to their manufacture, importation and use.

The regulatory body may also give advice on the use of feed additives, i.e. products used in animal nutrition to improve animal health or to enhance the quality of food of animal origin, although many such additives, such as growth promoters and antibiotics, may be covered by legislation on veterinary drugs. Again, the regulated should not be the regulators, serving on any regulatory body set up for animal feeds.

Since the production of animal feed is generally considered to form an integral part of the food chain, the legislation should require processors and handlers to implement quality assurance systems such as HACCP (see section 2.3.1) and to maintain adequate documentation to demonstrate compliance. Since contamination can take place at any stage of the production process, good manufacturing practices should be observed during the preparation and handling of animal feed. This means, for instance, that producers should obtain safe ingredients and follow proper preservation techniques. They must maintain facilities, equipment and means of transportation in a sanitary condition, and could consider using heat treatments or irradiation to control infectious agents.

The inspection of establishments where animal feed or raw materials are imported, manufactured, sold or used is mainly intended to assess the manufacturing process and implementation of the quality assurance system which is in place. As will be discussed further in Chapter 5 in relation to inspection of food, the trend in legislation on food and feed is away from an enforcement approach (with inspectors catching and punishing violators) and toward a collaborative approach (with inspectors educating businesses on how to implement and audit their own controls).

3.2. Consumer protection

Consumer protection is an umbrella term which encompasses all actions and activities aimed at safeguarding consumers' rights and interests. The crux of legal protection in this subject area is that consumers should have the right not to be harmed by unsafe and hazardous goods and services, to be informed about issues such as quality, quantity and price and to seek redress against fraud and other unfair trade practices. Some countries have one major consumer protection law which provides the basic principles of

consumer protection in the country and coordinates all other consumer protection laws and regulations; others have a limited consumer protection law covering only certain products and activities. Still others have enacted specific consumer protection legislation on issues such as product safety, labelling, advertising, standards, unfair terms in consumer contracts, doorstep and distance selling and consumer credit.

The difficulty arises where the provisions of a consumer protection law (which is likely to be enforced by the ministry responsible for commerce or trade) apply to food, while the more traditional food legislation which is enforced by the ministry responsible for agriculture or health covers the same issues. This can lead to a system of redundant enforcement and overlapping mandates for inspections, which can be burdensome for food businesses. One solution is for the consumer protection law to be amended so that it covers all products except for food. Another option is for the unit charged with enforcing the consumer protection law to focus only on specific areas with regard to food, such as advertising, labelling and weights and measures, while the ministry responsible for health or agriculture, or the national food authority as the case may be, focuses on all other aspects of food control, food safety and food trade.

3.3. Standards and certification

Another area of regulation which can apply to food is legislation on standards and certification. In many countries, a parliamentary-level law will set up a system for the establishment of standards for products and services in order to raise the levels of design, performance, safety, quality and reliability and to enhance overall consumer confidence. The standards will be developed either by the public authorities, by a parastatal agency or by a private independent standards organization, and are usually voluntary, i.e. adopted and applied by members of a producers' association or similar. However, some standards, applicable to certain products or services, may be made mandatory through their adoption as regulations (which is quite often the case for food standards), or they may become *de facto* mandatory by their ubiquity among trading partners.

In general the standards developed take the form of recommendations, guidelines or procedural steps, adherence to which is intended to ensure a basic level of quality or safety. The credibility of standards depends on the means by which they are adopted. For example, if a rigorous research and development or probationary procedure is adopted and implemented by the

foremost experts in the field, representing all necessary areas of expertise (including academics, practitioners, the private sector and consumers), the standards are generally considered more reliable. This would apply to standards set by the International Organization for Standardization (ISO) or the Codex Alimentarius Commission, as discussed in Chapter 2.

Standards can apply to quality (e.g. appearance, cleanliness, taste); safety (e.g. pesticide or hormone residues, microbial presence); authenticity (e.g. guarantee of geographical origin or use of a traditional process); and the propriety of the production process (e.g. with respect to worker health and safety or to environmental contamination). Typical kinds of food standards include those on food labelling, food additives, contaminants, methods of analysis and sampling, food hygiene, food import and export inspection systems and residues of veterinary drugs or pesticides. Where standards have been made legally binding through legislation, enforcement takes place through inspections or reporting requirements. Where standards are voluntary, producers and manufacturers will generally choose to adhere to such standards in order to ensure consumer confidence, to differentiate their products from competitors and to provide a minimum level of quality to discriminating consumers. Some companies will require all suppliers to follow particular standards, making them mandatory in all essential respects.

A related area is certification, which is the process used to guarantee that products and services meet the requirements of the established standards. This procedure was described in Chapter 2 in relation to organic food. Certification is usually carried out by private certification bodies, although in some countries certification is carried out by a governmental or quasi-governmental body. Just as with standards, certification can be voluntary or mandatory, or may be one or the other depending on the products or services involved. Certification relies on inspections to assess conformity with standards, whereby a stamp, certificate or label is affixed indicating that the product or service has been certified according to the applicable regulatory scheme and conforms to applicable standards. As was recommended for consumer protection laws, one way to avoid overlapping enforcement activities is to make the standards and certification legislation apply to all products except food. Otherwise the standards or certification body may be inspecting food products to ensure that they meet standards while at the same time several other agencies are inspecting the same businesses and products under other legislation.

In deciding whether the standards organization or the food authority should assume responsibility for the development and enforcement of food standards, the argument can be made that a single agency cannot have sufficient expertise to regulate cement, textiles, electronic goods and food, and that food is a product which calls for a uniform approach because of the serious human health implications of unsafe food. This would argue for the allocation of the most relevant expertise and resources to the control and regulation of food, and therefore the development and promulgation of food standards would be carried out under the general food legislation.

In many countries the National Codex Committee, which is housed either within the lead ministry for food control or within the national food authority, is the body with primary responsibility for establishing technical committees to prepare food standards. These committees are usually populated with experts from the relevant government agencies as well as from academia and consumer associations. By contrast, in countries where the standards authority retains the responsibility for developing and enforcing food standards, there should at a minimum be close coordination with and perhaps even direct reporting to the central food authority.

3.4. Public health

In many countries food safety may have been pulled under the umbrella of human health, with the legislative mandate and framework presented in one major piece of public health legislation, such as a public health law or a health protection law. Generally, this type of legislation has a broad scope and encompasses a wide variety of health-related issues, only one of which is food safety.

On the one hand, public health legislation is a natural home for food safety, in that food-borne diseases kill millions of people every year and are a serious threat to public health in both developed and developing countries. Apart from direct health consequences, food-borne diseases also impose a substantial strain on health care systems. On the other hand, there is the very real risk that overstretched ministries of health with limited inspection and laboratory facilities will not be able to effectively implement the myriad activities typically assigned to public health authorities, including the control of diseases, tobacco, alcohol, drug abuse, pharmaceuticals, medical devices, poisons, hazardous substances, radiation protection, health care, health professions, recreation and accident prevention – as well as food safety. More importantly, even where food safety control is carried out by the

ministry of health implementing public health legislation and inspecting food production and handling facilities, there is generally a glaring failure to exercise any control over primary production. As discussed in Chapter 1, proper food control requires a “farm to fork” approach, which cannot be achieved through public health legislation alone.

In the revision of national legislative frameworks for food, the framework for public health should be taken into account, and in particular the legislative review should identify gaps, overlaps and inconsistencies. For example, an existing public health law may establish a national health authority with certain tasks in the area of food control, and may empower health inspectors to inspect food premises and to confiscate and destroy food products. If this is the case, policymakers will have to decide whether the national health authority should continue to fulfil these tasks or whether they should be transferred to another ministry or to an independent central food authority established under new legislation.

3.5. Water

Water is essential during all stages of the food chain, although different stages of food production call for different water quality and quantity requirements. For primary food production, agriculture is by far the largest consumer of fresh water and requires one thousand times more than we use to drink and one hundred times more than we use to meet basic personal needs. Food production not only depends on water resources, but can also have serious negative effects upon them and on the environment. For example, improper use of pesticides and fertilizers or poor management of animal manure can contribute to serious pollution of ground and surface waters. If such water is then used for irrigation, livestock watering or other activities, serious harm to human (and animal) health may occur.

Most countries have basic water legislation in place, which generally encompasses a comprehensive water resources law and a set of implementing regulations. The law governs the functioning of the water sector and establishes the legal framework for national water resources management. It contains basic principles and rules concerning rights and access to water, and addresses preservation of water resources as well as water allocation among various users, such as agriculture, industry and municipalities.

In addition, the law may address the control of water pollution and, as fresh water becomes increasingly scarce, the treatment and use of waste water. In the past two decades there has been a notable increase in the use of waste water for crop irrigation – especially in arid and seasonally arid areas of both industrialized and developing countries – as well as for aquaculture. If not managed and controlled properly, waste water can raise significant risks for human health. Detailed provisions on water pollution and waste water are typically found in legislation separate from water resources legislation, although environmental and other sectoral legislation, for example on aquaculture, may deal with pollution issues as well.

Generally, water resources legislation does not address drinking water issues, which, instead, are often housed under public health legislation. Typical drinking water provisions include service regulations, drinking water quality standards, testing procedures, regulations for the development and protection of drinking water sources as well as proper supervision, inspection, maintenance and operation of water supply systems. Drinking water is of particular relevance further along the food chain where it is used for food processing and in the home. Water is used as an ingredient during food preparation, for washing food and for cleaning and disinfecting work tools and equipment. Water used in food processing establishments should thus meet drinking water standards, although in some cases there may be other special requirements for water quality.

In many food laws, the definition of food is so wide-ranging as to encompass any substance that is intended for human consumption, including drinking water. In countries where appropriate drinking water legislation is lacking, one important step (among others) may be to bring drinking water within the ambit of national food legislation. In that case, it may be up to the ministry or central food authority to help develop and enforce drinking water standards. On the other hand, where countries have sufficient expertise and resources in the relevant ministries, it may be opportune to exclude drinking water issues from the scope of the food law and regulate it separately. Whatever approach is taken, it is important to avoid gaps and overlaps resulting in multiple standards and inspection procedures.

One important provision that often exists in drinking water legislation holds the supplier of drinking water responsible for its quality up to a defined point in the distribution system, and not for any deterioration of the water quality as a result of poor plumbing or unsatisfactory storage tanks. Thus, food legislation should take over from where the drinking water legislation leaves

off and stipulate that food businesses must have an adequate water supply, sufficient for the intended uses and of potable quality, and that plumbing and storage tanks in food businesses should be of adequate size and design and installed and maintained so as to carry sufficient quantities of water to all areas where water is required. Of course, the need for clean drinking water is a large and multi-faceted problem with enormous consequences for human health and the preceding suggestions are framed within the context of broader efforts with regard to issues such as sewage, runoff and the like.

To supplement water in piped distribution systems, many consumers buy bottled drinking water for reasons of taste, convenience, fashion, emergencies, safety or potential health benefits. Natural mineral waters in particular have a long tradition of use and are often regulated as foods rather than drinking water. Food legislation should distinguish bottled drinking water from piped drinking water, as bottled water has its own standards, for example concerning its composition, bottling, storage and the materials used for its containers.

3.6. Land and environment

Land, like water, is a key resource in food production and requires legal and institutional arrangements on rights and access as a prerequisite to agricultural development and food security. Land tenure refers to a set of well-defined rights that a person or organization holds in land, and it implies the presence of an administrative system of land registration. If tenure is secure, the holder can reasonably expect to use the land to its best advantage in accordance with the right, to reap a timely and fair return and to enforce the right against non-holders. Access to and secure rights over land increase productivity, as appropriate tenure may encourage the holder to make longer-term investments in good and sustainable agriculture practices. For example, land tenure is critical to the adoption of organic agriculture, which, as discussed in Chapter 2, is becoming increasingly important in a number of countries. It is highly unlikely that tenant farmers will invest the necessary labour and weather the difficult conversion period without some guarantee of access to the land in later years, when the benefits of organic production are likely to emerge.

In addition to land tenure, land or environmental legislation often contains provisions on land use. For example, the law may provide for the development of land use plans, in which land is allocated among competing users including agriculture, industry, housing and the environment. Basic

land legislation may also address pollution matters and limit the use of fertilizers and pesticides or industrial activities that pollute the soil with toxic heavy metals. Although the protection of human health is generally not the lawmaker's primary concern, any provision that helps to prevent the land from being polluted ultimately affects the production of safe food crops and the health of grazing animals used for food production. It should be borne in mind, however, that pollution matters are also frequently addressed in general environmental legislation or other legislation dealing with the protection of specific natural resources, such as water or forests.

A notable trend in some countries is the development of specific legislation focusing on the protection and management of soil. Soil degradation, which is the process that lowers the current or potential capability of the soil to be productive, currently affects one third of the world's soils used for agriculture. Factors responsible for this deterioration include deforestation, over-exploitation of vegetation, over-grazing and soil pollution. Excessive use of fertilizers and pesticides also limits the ability of soil organisms to process wastes, which in turn makes the soil less productive, unproductive or, in the worst case, poisonous. Irrigation of the soil in dry areas with poor drainage can also make the soil too salty for growing crops. Again, although soil legislation is generally directed at the goal of increasing food production and improving food security, provisions on soil pollution ultimately contribute to improving food safety as well.

3.7. Licensing

Licensing legislation, which is generally implemented by ministries responsible for trade, industry or commerce, governs the issuance, suspension, amendment and cancellation of licences of various sorts, some of which may be relevant to food control, food safety and food trade. For example, the issuing ministry may have a system in place to award licences to individuals and companies intending to import, export, transport or produce food. Generally, an applicant will submit information on the company, the site to be used and the goods to be dealt with, and thereafter the issuing authority will examine the documentation and most likely perform a site inspection. Although in evaluating an application for such a licence from a food-related business the authority is likely to focus mainly on commercial concerns (is the applicant properly qualified, is the activity desirable, are the facilities appropriate?), there is a nexus with food safety: the determination of whether the facilities are adequate includes an examination of whether the

sanitary facilities are sufficient to guarantee that no risk to human health is caused.

A more direct link to food safety arises in connection with licences issued to establishments where food is served. As with street foods, discussed in section 2.1.3, a licence may be granted after a thorough inspection and may include restrictions on the kinds of food, the locations where they may be sold and other requirements for storage and sale. A similar although in many jurisdictions more formal system applies with regard to licences to run a restaurant or otherwise sell food to the public. Like licences issued to food producers, importers, exporters and transporters, licences for restaurant operation are often granted by the ministry responsible for industry, or at times the ministry responsible for health. In some countries, this authority is devolved to the municipal authorities while in others, the ministry responsible for tourism may play a role. The licensing legislation generally provides that after periodic (and often unannounced) inspections, licences may be suspended or revoked where merchants fail to follow the applicable rules or standards, for example hygiene rules.

In principle, there is no great harm in maintaining a system where licensing legislation allocates responsibility to a ministry other than the main ministry or authority responsible for enforcing food safety legislation. As noted, there are commercial concerns inherent in the issuance of licences for the operation of businesses, and there may be significant tourism implications for hotels, restaurants and the like. The key is to establish and maintain vigorous cooperation between the issuing authority and the main food authority. There must be a smoothly functioning system which grants a licence only where it is certain that the applicable requirements (including human health requirements) have been met, and which rapidly suspends or revokes a licence where such requirements are violated. Too often the decisionmaking process which evaluates applications is far removed from the inspection process, with potentially harmful results.

IV. CONCLUSION

In addition to the areas of law explored in this chapter, there are many others which could be considered to have an impact on food control, food safety and food trade. Seed legislation, for instance, is mainly concerned with seed quality and seed health, but in some circumstances seeds intended for seed production may instead be used for food or feed, in which case human health will need to be protected. Similarly, plant protection legislation,

although its primary objective is to protect plant resources by preventing the introduction or spread of pests, may raise human health concerns where an infested shipment of fruits or vegetables affects the safety or wholesomeness of commodities intended for human consumption. Legislation on the establishment and maintenance of slaughterhouses, or on the rearing and care of food-producing animals, may have, in addition to its animal welfare objectives, clear implications for human health.

Other laws and regulations that may have an impact, however tangential, on food include labour, credit, finance, investment, trade, tourism, taxation and transport laws. Labour laws, for instance, may contain provisions that could influence the transfer of government officials between various arms of the government or to autonomous food authorities. Credit and finance legislation may dictate the rules for the acquisition and implementation of expensive quality assurance systems, such as HACCP. Investment laws may stipulate which entities may participate in certain activities regarding food, for example by prohibiting or permitting private actors to carry out certain activities, such as standard-setting or certification, or by generally prohibiting or promoting private investment.

The existence of civil, criminal and administrative codes may be relevant as well. Whereas in some countries the powers that food inspectors may exercise and the sanctions that may be imposed are likely to be regulated in the food law itself, in other countries the investigative powers and penalties are often generally – and sometimes exclusively – regulated in criminal codes. Many countries also have administrative codes which set out the general legal framework for the application of administrative powers and the imposition of administrative penalties.

Although there may be an intersection with food control, food safety and food trade in all of the legislation mentioned in this chapter, it is not in every case that provisions in these laws or regulations will have to be repealed or moved to the main food law in order to avoid inconsistencies, overlaps and gaps. It should be sufficient in the assessment of the national framework simply to be aware of the universe of subject matters that may touch on food, trying to draw as many together as possible into one legal framework, while keeping in mind other relevant considerations, such as those that will be explored in Chapter 5. For example, there may be historic reasons why a particular ministry has always issued licences for food businesses and may continue to do so; there may also be significant resources attached to a

particular ministry, agency or unit which for various reasons cannot be shifted elsewhere.

The overarching goals are cooperation and the exchange of information made possible by the existence of a central food authority or other coordinating mechanism, which ensures that individual agencies, ministries and units are not operating in isolation but instead are made aware of the activities of their neighbours and how all of these activities affect one another in relation to food. Even better is actual coordination among all of the affected ministries, agencies and units, which can again be assured through national mechanisms such as the establishment of a national food authority, a food board or a National Codex Committee. These and other options for national regulation will be discussed in Chapter 5.

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I. INTRODUCTION

Chapter 2 explored the international context in which national regulation of food takes place, while Chapter 3 examined the many topics that are addressed through national legislation and that can be considered part of a country's regulatory framework for food. This includes laws and regulations addressing, *inter alia*, particular kinds of food (e.g. street foods, foods of animal origin), provisions on the control of additives, residues and contaminants in food as well as rules on how food is produced, treated and sold. The wider framework also includes legislation that may not specifically address food but has important implications for the regulation of its safety, quality and trade, such as legislation on water, the environment, land use, standards and weights and measures.

Before turning in Chapter 5 to the empirical circumstances which underpin the development of legislation at national level and the contents of a basic food law, this chapter analyses the policy environment in which food legislation is created. The chapter first introduces the concept of food policy and discusses the process by which it is formulated, refined and implemented at national level. It next describes some of the changes in national food systems and in the global environment for food trade that have triggered some shifts in the orientation of national food policies.

The chapter goes on to explore some of the principal expressions of food policy, including food security, the right to food, food aid and nutrition – issues that are on many countries' popular agendas but are not always taken into account during the process of developing and updating national food legislation. Just as in most fields of endeavour, experts in many fields relating to food, whether food control, food safety, food security or food trade tend to focus their efforts within their own areas, without much cross-fertilization. In some circumstances, there may be groups working on closely related topics, even within the same ministry, that do not communicate with one another or share knowledge and information. An important purpose of this chapter is to explore the areas of commonality where they have already been identified, to propose other points of intersection and to suggest subject matters and topics as to which integration is both desirable and feasible.

In addition to discussing how these several policies are usually implemented at national level, this chapter also suggests possible ways in which some of these might be taken into account and implemented in a basic food law of the type discussed in Chapter 5. The authors recognize, however, that some subject areas may have a more attenuated relationship with food safety and basic food legislation and accordingly policies touching on these issues should be implemented through separate legislation or through other policy tools.

II. FOOD POLICY

2.1. Formulation

Before enacting or revising legislation in a particular subject area, governments should first develop the policies which will be captured in the legislation and which will guide the law's implementation. Although it is not unknown for a legislative review process to begin before definite policy goals have been agreed, ideally the policies will either have been developed beforehand or, at a minimum, will be fully aired, discussed and refined over the course of the legislative review. In fact, in some cases it will only be in the course of analysing and discussing concrete draft legislative proposals that outstanding policy questions can be clearly identified and resolved.

The procedures for the formulation of policies at national level will vary depending on the prevailing political and institutional structures, but the elements to be considered are mainly the same. Governments must first take into account international interests and commitments, and then, national objectives such as the need to promote the development of one region or sector or the desire to satisfy certain basic needs. In this regard, policies directly bearing on food as well as those more tangentially related must be taken into account. Venues such as the FAO/WHO Forums for Food Safety Regulators allow for open discussion of food policy issues and the interplay between international consensus and national needs.

In many cases, policymakers will have to choose between conflicting policy goals. A desire to protect health may conflict with the desire to facilitate trade or to develop an industry or sector; the goal of expanding export markets may conflict with the desire to conserve water or to reduce pesticide use; and the

objective of moving surplus commodities into food distribution programmes may conflict with nutritional standards and needs. A rational food policy should consider all of these interests and, where there are conflicts, determine preferences. Economic considerations, including cost benefit analyses and resource constraints, will come into play, informing the choices to be made from among alternatives.

Throughout the policy formulation process it is advisable for technical experts and economists to provide advice to the political actors with whom the ultimate policy decisions rest. It is equally desirable (and obligatory, in the case of the right to food) to allow the various stakeholder and interest groups, whether geographical or sectoral, to have the opportunity to express their views and to participate in the policy formulation process. Ideally, the outcome is a deliberate statement which defines the issues and sets the directions for the future, stating clearly what the strategy or policy is and what it intends to accomplish.

Although adopted by governments, policies can originate elsewhere. For example, consumer and public pressure can dictate the policy direction of pending legislation on some food-related issues, such as genetically modified food or the production of organic food. Special lobby groups or action groups may advocate stronger governmental regulation and labelling, or may otherwise attempt to influence government decisionmakers. In some contexts, food policy may actually be created by corporations as well as by government. As noted earlier, in some areas, corporations have created standards and imposed them on producers as a precondition for purchase. Among other things, such standards may relate to how animals are raised, how crops are planted or how fish are culled from the sea. Because of the large purchasing power of such companies, the standards which they create and which embody their own policy preferences have a level of influence which may well equal or exceed that of government.

Donors may also drive the policymaking process, by tying the award of financing to the adoption of specific policies or even to the enactment of legislation on particular issues. As discussed in Chapter 3, donor priorities, however well-intentioned, rarely lead to comprehensive legislative strategies, but instead often result in piecemeal or *ad hoc* solutions to certain narrow issues, leaving others untouched. Worse, in some cases donors may press for wide-ranging or dramatic

change for which the groundwork has not been established at national level, with the expected unspectacular results.

As will be discussed further in Chapter 5, every country has its own policy priorities and political realities. The manifest differences in history, outlook, culture, resources and legal systems argue strongly for developing a food policy for a particular country in light of its particular circumstances, rather than relying on some sort of “model” which would not reflect the realities at hand. Once the overall nationally tailored policy is developed, policymakers should then develop a coherent set of detailed strategies and programmes to achieve the goals that the policy expresses. Each of these strategies may require a different mode or tool for its implementation.

2.2. Implementation

After the development of food policy comes implementation, which can be effected with an array of policy tools. Although these are often considered in isolation, they are generally inter-related, and policy implementation is most effective when a range of tools are deployed. The principal interventions and tools for the implementation of policy include legal instruments (including international agreements and national legislation); economic measures; guidelines and other nonbinding instruments; and awareness raising and public participation.

International agreements are formal, written instruments which encapsulate two or more countries’ policy compromises, and which are almost always vetted and approved by a majority in the implicated national legislatures before being signed. In the food area, as was discussed in Chapter 2, the Codex Alimentarius Commission is the foremost venue for the discussion of countries’ food policy concerns and objectives, and Codex standards generally reflect the consensus of its member countries. Food policy may also be captured in agreements between two or more countries seeking to foster trade in food products or intending to establish a bilateral or regional food agency.

At national level, food policy can be embodied in a country’s constitution, which might, for example, state that all citizens have the right to adequate food. This right is discussed more fully in Part IV of this chapter. More frequently, food

policy goals will be set out in the preamble or in the “Objectives and Scope” section of a basic food law, as will be discussed in Chapter 5. The law might state that it is intended to foster trade, to protect consumers or to improve human nutrition, for example. Other elements of a national food policy might not be articulated outright in the law but could instead be discerned from the law’s design, such as whether it follows the “command and control” model (seeking to regulate behaviour by establishing norms of conduct, monitoring compliance and imposing penalties for breach) and even the level of penalties which different activities attract. This latter reveals how the society evaluates, approves or disapproves of certain activities and to what degree.

In addition to legislation, a range of economic instruments, such as subsidies, taxes or charges, can be used to implement food policy goals. Supportive and penalizing measures can be used to encourage or discourage certain activities, such as the cultivation of certain crops, the use of pesticides or the export of particular products. Supportive measures can take the form of direct subsidies or tax reductions; penalties might involve charges for carrying out certain activities that the government seeks to discourage. Generally, such economic incentives and disincentives will be contained in legislation, although they may also appear in nonbinding agreements or codes of practice.

Among the nonbinding tools for policy implementation are guidelines and recommendations, which are developed by governments and experts in international fora, by governments at national level or by industry groups, and which outline means of complying with desired policies. Nonbinding agreements such as industry codes are similar to guidelines and recommendations, save that they may be more formal. Although not binding, codes have a high compliance rate, especially where industry members are involved in their formulation. Such involvement is desirable since industry members know their capacities, and furthermore, once they have signed on to a code there is “peer pressure” by other members to adhere to it. And whereas there might be reluctance to follow codes developed only by third parties such as consumer and advocacy groups, such concerns are assuaged where the codes have been developed after wide consultation with industry as well as other affected groups.

In the food area, codes on good agricultural practices, good manufacturing practices and good hygiene practices, as well as codes of ethics, have been

developed and agreed at international level, and there is burgeoning interest in their implementation. These kinds of codes can be exceedingly important implementation tools where the policy goal is the provision of safe food. To be effective (since adherence is voluntary), such nonbinding instruments should be developed in consultation with those that will be affected by them, and should also be clearly explained and justified.

Awareness raising and public participation constitute another kind of tool which can assist in the implementation of food policy. Professional groups as well as the general public can benefit from activities designed to promote awareness and increase knowledge of food control and food safety issues in the country. For the former group, conferences, workshops and publications are useful avenues to explore; for the latter, the media, fact sheets, posters, videos, rural radio and educational programmes in school can enhance awareness of food safety and consumer issues among the public. In both cases, the wider the reach, the more likely it is that such programmes will be able to assist in the effective implementation of national food policy.

2.3. Forward trends

Traditionally, national food policies, particularly in developing countries, have been targeted at food security, including issues such as hunger and malnutrition, food subsidies, food aid and the sufficiency of food supplies during emergencies. Although these concerns remain valid, especially in the poorest countries, there have been a number of empirical and policy shifts, some of which were explored in Chapter 1, and which have caused related shifts in the focus of food policy at national level.

Foremost among these is the change in the character of national food systems, where urbanization, technical advancements and industrialization are transforming the way food is produced, marketed and consumed. Increasingly, food is produced by large commercial growers or farmers and travels in long and sophisticated supply chains, and in the end is marketed by large food businesses to an increasing number of urban consumers. Unfortunately, while food can travel farther and faster, so can food-borne diseases.

In order to adapt to the changing nature of food systems, there has been a policy shift toward a food chain approach, i.e. the need to exercise control at all stages from production to consumption (from “farm to fork”). This can be achieved through an inspection system that relies on the application of preventive measures at all stages in the production, processing, handling, storage and distribution of food products rather than on the control of end products.

As described in Chapter 3, the increasing prevalence of the Hazard Analysis and Critical Control Point (HACCP) system demonstrates that food control has primarily become the responsibility of the food industry, which is called upon to guarantee the safety of the products it places on the market. Thus, government inspectors – in addition to seeking out and punishing violations – are also charged with educating owners of food businesses on proper procedures and assisting them in setting up their own methods of control (auto-controls). Although the end product must still meet the regulatory standards and the food inspector may of course collect samples for analysis, the main government task increasingly shifts to prevention, through monitoring and auditing the controls implemented by the operators themselves.

In other areas there have been equally important changes. In the health arena, concerns about malnutrition are now counterbalanced by interest in obesity and chronic diet-related diseases. Equally, in many countries there is increasing dissatisfaction with the traditional view of food security as only assuring an adequate supply of safe food to communities faced with food emergencies. The more comprehensive view posits that food security is not solely an emergency issue, and that governments should also take account of food security at the household level and should seek to assure that the food supplied is nutritious.

Finally, in recent years those advocating a rights-based approach to development have argued that food security can only be guaranteed through the recognition and implementation of the right to adequate food as a human right. The following sections will examine these and other areas which prompt governments to craft comprehensive food policies, and will assess how these can or should be taken into account in the development of national food laws.

III. FOOD SECURITY

3.1. Background

As stated above, one classical goal of food policy has been to achieve food security, which means ensuring food availability and combatting hunger. Although it is estimated that there is enough food produced in the world to satisfy the needs of all, many people still lack economic and physical access to it. Despite all efforts, the latest estimates, based on data from the years 1998-2000, put the number of undernourished people at 840 million, of whom 800 million live in developing countries. That figure represents a decrease of barely 2.5 million per year over the eight years since 1990-1992, the period used as the starting point for the drive launched at the World Food Summit (WFS) in 1996 to halve the numbers of the world's hungry by 2015. At its current pace, the WFS goal will be reached more than one hundred years late, closer to 2150 than 2015.

The importance of food security is revealed by how frequently it appears in international instruments, including those not relating only to food. For example, the WTO Agreement on Agriculture states that members should have regard to non-trade concerns including food security, and the Food Aid Convention sets forth as one of its objectives to contribute to world food security. The World Declaration on Nutrition and the Plan of Action on Nutrition, adopted at the 1992 International Conference on Nutrition, explicitly recognize the role of agriculture with regard to food security and nutrition.

The WFS was convened to raise awareness of issues surrounding world hunger and to garner high-level political support for making concrete progress in achieving food security. The WFS adopted two documents: the Rome Declaration on World Food Security (Rome Declaration) and the WFS Plan of Action. The Rome Declaration reaffirmed "the right of everyone to have access to safe and nutritious food, consistent with the right to adequate food and the fundamental right to be free from hunger". Under the WFS Plan of Action, food security exists when "all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life".

The WFS Plan of Action is composed of commitments which provide further detail to the Rome Declaration's policy statements. These commitments are intended to highlight diverse paths to a common objective – food security and a significant decrease in chronic hunger – at the individual, household, national, regional and global levels. According to the WFS Plan of Action, food security involves four conditions: 1) availability; 2) stability of supply; 3) access; and 4) utilization, which includes quality and safety of food as well as clean water, sanitation and the physical requirements for utilization. Fundamentally, food security can be viewed as an outcome or a goal toward which national governments strive through a variety of means.

3.2. Implementation at national level

National governments have a number of strategies available to improve food security, which vary depending on country circumstances. The general recommendations of the WFS Plan of Action are an essential resource for national policymakers in developing food policies at national level. Other strategies include developing national food security programmes and action plans, including institutional arrangements, and establishing inter-ministerial coordination mechanisms. Many of the countries which participated in the WFS have introduced institutional measures supporting the WFS Plan of Action – such as national food security commissions – to provide policy guidance and sectoral coordination and to ensure local government and farmer participation.

Whereas in the past national governments mainly focused on strengthening national food reserves and emergency systems to implement food security, more recently governments have begun to focus on increasing production, productivity and the year-round stability of food supplies. Approaches to implementing a food security policy might therefore include the reform of commercial and marketing structures, the amelioration of transport facilities and the review of national trade and pricing policies. Governments should also attend to enhancing agricultural production by increasing efficiency of water and land use, improving infrastructure and allotting resources to promising areas of research and innovation directed at improving the production, delivery and safety of food.

In the trade area, lowering barriers to trade can improve developing countries' ability to export food regionally and internationally, thus improving food security. Conversely, subsidized imports from developed countries may lead to cheaper food being available, which may benefit the urban poor but undermine farmers' market access.

Few countries implement food security policies through targeted legislation, although there are exceptions. In 2001, Niger established a National Food Security Commission responsible for coordinating and harmonizing national food security programmes and for following up implementation of the WFS commitments. Burkina Faso and Peru, as well, adopted legislation in 2002 implementing national food security strategies, and Ecuador, South Africa and Uganda are considering similar legislation. Tanzania (1991) and Zambia (1995) are among countries which have enacted legislation on strategic food reserves. In the main, however, food security policies are implemented through other tools, including government spending on social programmes (including food safety nets, school feeding schemes, health services and infrastructure support for small farmers) as well as policy reform in relevant areas such as land ownership, microfinance and trade.

The linkage between food security policy and the kinds of basic national legal frameworks explored in this study – those that focus on food control and food safety – is not necessarily obvious. But as explored above, where a state adopts a policy of food security, it undertakes to ensure not only that there is an adequate, stable and accessible food supply, but also that the food provided is nutritionally adequate and safe. Thus national legal frameworks directed at providing safe food form part of the overall effort to achieve food security. Moreover, national regulatory frameworks for food which create stable and efficient production and distribution systems help implement the goals of food security by ensuring accessibility. Although specific provisions referring to food security in the basic food law may not be necessary, lawmakers should certainly take into account the elements of food security policy and its overall goals when developing national legal frameworks for food.

IV. THE RIGHT TO ADEQUATE FOOD

4.1. Background

Whereas food security can be considered an objective or an endpoint, and governments can choose whether and how to achieve it, the right to adequate food triggers binding obligations on the part of states. In 1948, the Universal Declaration of Human Rights proclaimed that “[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food”. The right to food was further codified in 1966 in Article 11 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), an international treaty which entered into force in 1976 and is legally binding upon the 150 states which have ratified it. See Box 1.

Article 11 makes a distinction between the right to adequate food and the fundamental right to be free from hunger. The latter means that the state has an obligation to ensure, at a minimum, that people do not starve, and a state could satisfy this right by the adoption of policies to provide a minimum daily nutritional intake. The right to adequate food, however, includes an “adequacy” standard, the same standard which forms part of food security as discussed above, and which goes beyond the right to be free from hunger. The right to adequate food requires that the process by which people enjoy access to food must itself be consistent with other human rights and must not entail the sacrifice of one human right for another.

Although the right to food is sometimes understood to be solely a means of achieving food security, the relationship is more complex. In particular, because human rights law imposes significant obligations on states, in some situations food security might be satisfied while the right to food is not. If food supplies are provided in a discriminatory manner, a food security perspective might determine that recipients have sufficient supplies of safe and nutritious food, while the right to food would nonetheless be violated. Thus, as one commentator stated, “[w]hile people living off garbage dumps in slums can be

food secure ... their right to food is still not fulfilled, as picking rubbish is incompatible with their human dignity”.¹

The most extensive legal effort to clarify the content of the right to adequate food is in General Comment 12 to Article 11,² which was adopted in 1999 by the Committee on Economic, Social and Cultural Rights (CESCR), the supervisory mechanism of the ICESCR. It states: “The right to adequate food is realized when every man, woman and child, alone or in community with others, has physical and economic access at all times to adequate food or means for its procurement”. The General Comment goes on to clarify the adequacy standard, stating that the right to adequate food implies “the availability of food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances, and acceptable within a given culture” as well as “the accessibility of such food in ways that are sustainable and that do not interfere with the enjoyment of other human rights”.

According to General Comment 12, the principal obligation of states is to take steps to progressively achieve the full realization of the right to adequate food, individually and with international assistance and cooperation, to the maximum of their available resources. The right to adequate food imposes three types of obligations on states that are parties to the ICESCR: to respect, to protect and to fulfil the right. The obligation to respect requires states not to take any measures preventing access to adequate food. (Thus while states do not have a duty to distribute food to all their citizens, they may not interfere with individuals’ own efforts to provide for themselves.) The obligation to protect requires states to actively take measures to ensure that third parties do not deprive individuals of their access to adequate food, while the obligation to fulfil comprises two elements: to facilitate and to provide. The obligation to facilitate means that states should adopt measures intended to strengthen people’s access to and utilization of resources as well as the means to ensure their livelihood. The

¹ Mechlem at 644.

² General Comments are not legally binding *per se*, but are widely viewed as authoritative. In this context, the mandate of the Committee on Economic, Social and Cultural Rights implies the power to provide such authoritative interpretations, which states implicitly endorse by referring to them in national reports.

obligation to provide means that whenever individuals or groups are unable, for reasons beyond their control, to enjoy the right to adequate food by the means at their disposal, states have the obligation to fulfil that right directly by providing adequate food, especially to those who for reasons of age, disability, unemployment or other disadvantages cannot fend for themselves. This obligation also encompasses persons who are victims of natural or other disasters. The right to adequate food can be fulfilled by individuals' own efforts or their efforts in community with others, and must be enjoyed by all without any adverse distinction based on race, religion, sex, language, political opinion or other status.

Box 1 Article 11 - International Covenant on Economic, Social and Cultural Rights (ICESCR)

1. The States Parties to the present Covenant recognize the right of everyone to an adequate standard of living for himself and his family, including adequate food, clothing and housing, and to the continuous improvement of living conditions. The States Parties will take appropriate steps to ensure the realization of this right, recognizing to this effect the essential importance of international co-operation based on free consent.
2. The States Parties to the present Covenant, recognizing the fundamental right of everyone to be free from hunger, shall take, individually and through international co-operation, the measures, including specific programmes, which are needed:
 - (a) To improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge, by disseminating knowledge of the principles of nutrition and by developing or reforming agrarian systems in such a way as to achieve the most efficient development and utilization of natural resources;
 - (b) Taking into account the problems of both food-importing and food-exporting countries, to ensure an equitable distribution of world food supplies in relation to need.

The WFS Plan of Action recommended defining the content of the right to adequate food more clearly and identifying ways to implement it, nominating the UN High Commissioner for Human Rights (UNHCHR) to take the lead in this work. To date, the UNHCHR has convened three expert consultations, the first on the content of the right to food, the second on the role of international organizations and the third on implementation at national level. In addition, a Special Rapporteur on the Right to Food was appointed by the UN High Commission on Human Rights to report to the Commission and the UN General Assembly on ways to implement the right to adequate food and on violations of the right.

4.2. Implementation at national level

Although the right to adequate food is recognized at the international level, its effective enjoyment depends on implementation by national governments. State parties to the ICESCR are required to adopt, *inter alia*, the legislative measures necessary to realize the right to adequate food. While recognizing that the most appropriate ways and means of implementing the right will vary significantly from one state to another, the CESCR, which monitors compliance with the ICESCR, has stated that governments should adopt a national strategy to ensure food and nutrition security for all, based on human rights principles.

In 2002, Heads of State and Government attending the World Food Summit: *five years later* invited the FAO Council to establish an Intergovernmental Working Group “to elaborate, with the participation of stakeholders ... a set of voluntary guidelines to support member states’ efforts to achieve the progressive realization of the right to adequate food in the context of national food security” (IGWG). The guidelines are meant to be a practical tool illustrating how to implement the right to food and outlining a rights-based approach to achieving food security. The IGWG completed its task in September 2004, and in November 2004, the Voluntary Guidelines were adopted by the FAO Council. In response to many calls for implementation of the Voluntary Guidelines, FAO is currently developing a programme on mainstreaming the right to food throughout its field of activities and is supporting countries in implementing the Voluntary Guidelines at national level.

Box 2 The People's Union for Civil Liberties v. Government of India, et al.

India's Constitution does not expressly recognize the fundamental right to food. However, cases brought before the Supreme Court of India alleging violations of this right have been premised on the much broader "right to life and liberty" found in Article 21 of the Constitution.

In May 2001, the People's Union for Civil Liberties filed a landmark public interest petition. The case revealed that over 50 million tonnes of food grains were lying idle on the premises of the Food Corporation of India despite widespread hunger in the country. Initially, the case was brought against the Union of India, the Food Corporation and six state governments. Subsequently, the list of respondents was extended to include all states and Union territories. The petition focused on the general need to uphold the "right to food", alleging that the state was negligent in providing food security. The petition also alleged that the government's relief works were inadequate.

The Supreme Court found as fact that surplus food stocks were available and, at the same time, that deaths from starvation were occurring in a number of locations. The court then formally recognized the right to food and issued an interim order directing the states to implement eight centrally sponsored food security schemes, as well as to take other measures to improve the situation.

The case is still ongoing, but the court has issued a number of other interim orders which have, among other things, directed the state governments to cook midday meals for all children in government and government-assisted schools, to complete the identification of the beneficiaries of certain welfare programmes, to improve the implementation of food schemes and employment programmes and to appoint commissioners to monitor progress in executing the court's rulings.

The recognition of the right to food can be distinguished from a food security goal in that the former is a human right, and thus an inherent and inalienable right of every individual without any discrimination based on race, sex, religion, language or other such factors. As mentioned above, all human rights are inter-related and mutually reinforcing. The UN, in its efforts to mainstream human

rights in its work, is developing frameworks for a rights-based approach to development, which applies also to food security. The main principles of such an approach are deemed to include participation, accountability, non-discrimination, empowerment and the rule of law. This implies that food security programmes and policies must focus on the most disadvantaged and must be formulated with their participation, and government actors must be held accountable for the delivery of services and their other statutory roles. The poor and hungry must be empowered to exert and claim their right to food; fundamentally, the food security policy and food law must be consistent with human rights.

A useful first step in a strategy to implement the right to food is a careful review and assessment of all relevant existing policies, legislation and institutions. The purpose of such a review is to determine how effectively the state is already implementing obligations to respect, protect and fulfil the right to food, not only in the substantive areas of food production, processing, distribution, marketing and consumption, but also in the underlying infrastructure. States will also need to review their policies with regard to agriculture, nutrition, social development, environment and trade in order to define a coherent policy framework that is conducive to the elimination of hunger and the realization of the right to food at national level. Based on the findings of such a review, states will then be able to identify the specific areas in which corrective legislative action is needed and to adopt an agenda for change.

An important step towards the recognition of the right to adequate food at national level can be the incorporation of the right in the constitution or bill of rights. Several countries already have provisions on the right to food in their national constitutions,² while others have constitutional provisions in place that recognize the right to food as part of the right to an adequate standard of living or related rights such as rights of the child, the right to health or the right to social security or to a minimum wage.

² Countries with constitutional provisions making direct mention of the right to food (applicable to the whole population) include Bangladesh, Ecuador, Ethiopia, Guatemala, Guyana, Haiti, Islamic Republic of Iran, Democratic People's Republic of Korea, Malawi, Moldova, Namibia, Nicaragua, Nigeria, Pakistan, Panama, South Africa, Sri Lanka, Uganda and Ukraine.

Human rights law calls for the establishment of a system to provide a remedy when a right is violated, which is a requirement recognized under customary international law. General Comment 12 recommends that “any person or group who is a victim of a violation of the right to adequate food should have access to effective judicial or other appropriate remedies at both national and international levels”. Where the right to food is constitutionally recognized or incorporated directly into national legislation, courts are more likely to be able to adjudicate violations of the right to food, as in the example presented in Box 2.

Implementing the obligation to facilitate the right to adequate food requires states to create and maintain an “enabling environment” within which people are able to meet their food needs. This might require the adoption of measures aimed at improving access to and utilization of resources, perhaps through legislation in the areas of trade, distribution, transport, pricing policies and land and water use. Finally, the obligation to provide may be met at national level by the provision of certain social services or emergency aid programmes. Meeting the obligations of the right to food may therefore overlap with the obligations of a food aid policy, discussed in the next Part.

A basic food law can serve as an important tool for the realization of the right to adequate food by providing a legislative foundation for the provision of safe food. More specifically, a state’s obligation to protect can be met through the establishment of a comprehensive food control system and regulatory framework which ensures food safety from farm to fork. The obligation to protect also requires regulating the conduct of non-state actors, and by implication the establishment of a regulatory framework for the protection of food safety, nutrition and the environment. States should empower inspectors to assess how effectively food businesses are implementing safety controls and should establish trace-back systems and quality assurance schemes. The law should also incorporate measures to protect consumers from misrepresentation and fraud in the packaging, labelling, advertising and sale of food, thus privileging the freedom of information. And finally, where legislation requires the state to participate in regional and international efforts to develop science-based standards, this means that states will elaborate and adopt the most up-to-date and effective food safety measures.

Where the human right to food is a high priority for government, the food law could include a framework for the progressive realization of the right to food, for example by assigning institutional responsibility for elaborating and adopting policies to redress the weaknesses in the existing situation. The law could also contain some provisions on the type of entitlements it provides, for example that there must be emergency reserves to distribute in case of crop failure, that targeted assistance must not discriminate on the basis of sex, language, religion or race, that expecting and lactating mothers are entitled to special protection, that children are entitled to certain vitamin supplements in case of need and that school children from poor families are entitled to free school meals.

Countries may also consider including the realization of the right to adequate food as one of the goals of the food law as stated in the preamble. As will be discussed in Chapter 5, although the preamble has no real legal effect, it outlines why the law is enacted and what purposes it is intended to serve. Adverting to the right to adequate food would anchor the basic food legislation within the overall framework of international and national efforts to assure that consumers have access to adequate and safe food.

V. FOOD AID

5.1. Background

What constitutes “food aid” is a matter of considerable controversy. Some authors define it as “the international sourcing of concessional resources in the form of or for the provision of food”,³ while others include national domestically funded distribution of food in the definition.⁴ FAO maintains a register of transactions that would be considered to be food aid, of which there are currently 22. Of these, all involve international sourcing or financing of food aid.

Another contentious element in the definition is whether food aid should be an outright free gift, in other words, whether food aid can involve commercial or

³ Barrett & Maxwell at 1.

⁴ von Braun at 2.

non-commercial transactions. In *EC-Wheat flour*, a 1981 dispute under the General Agreement on Tariffs and Trade (GATT) between the European Community (EC) and the United States of America, the two parties took differing approaches to what constitutes food aid. The EC argued that food aid constituted only transactions involving outright gifts, while according to the United States, food aid was broader and included sales on concessional terms. The panel decision recognized the challenge of distinguishing between commercial and non-commercial food aid transactions but did not go on to make a determination. The issue is even more complicated now, with the difficulty in differentiating between normal food aid transactions and subsidized exports.

Whichever way one looks at it, food aid can increase the overall availability of food and improve the access of vulnerable individuals to food. It is therefore an important tool in the realization of the right to adequate food and food security. However, food aid may undermine local production, distort markets and prices, change dietary habits and create individual and national dependence on food aid. FAO, the WTO and the International Grains Council have taken steps to ensure that food aid does not distort markets and displace commercial food trade. Within FAO, for instance, the Consultative Subcommittee on Surplus Disposal (CSSD), a subcommittee of the Committee on Commodity Problems, was established in 1954 with the mandate of “monitoring international shipments of surplus agricultural commodities used as food aid in order to minimize the harmful impact of these shipments on commercial trade and agricultural production”. The CSSD has developed a set of rules and procedures to assist food aid donor countries to identify and keep account of the food aid transactions they are involved in.

Food aid is usually given when a crisis resulting from a natural disaster or civil unrest deprives part or all of the population of the food necessary for survival. The main international organization that channels food aid is the World Food Programme (WFP), see Box 3. However, food aid can also be channelled without the intervention of international organizations like WFP, either bilaterally from government to government, or through nongovernmental organizations (NGOs). Often, multilateral agencies like WFP and bilateral government donors may use NGOs for field distribution.

Box 3 World Food Programme

The World Food Programme (WFP), which was established in 1965 by parallel resolutions of FAO and the United Nations General Assembly “for as long as multilateral food aid is found feasible and desirable”, is the food aid arm of the UN. Its mandate focuses on delivering food aid in emergency situations and eradicating hunger and poverty. WFP uses food aid to support economic and social development and promote world food security in accordance with the recommendations of the UN and FAO. In 2004, WFP, operating in 80 countries, distributed food to 113 million of the poorest people in the world. WFP food aid operations usually represent an average of 35-40 percent of the global food aid in a given year.

WFP, which has its headquarters in Rome, is governed by an Executive Board consisting of 36 member states. The Executive Director, appointed jointly by the UN Secretary General and the Director General of FAO for a fixed five-year term, sits at the head of the Secretariat of WFP. The General Regulations, which came into force on 1 January 2004, provide the legal framework within which WFP operates. To finance its humanitarian and development projects WFP relies entirely on voluntary contributions: donations consist of cash, food (such as flour, beans, oil, salt and sugar) or the basic items necessary to grow, store and cook food (such as agricultural tools, warehouses and kitchen utensils). Since WFP has no independent source of funds, all donations must be accompanied by the cash needed to move, manage and monitor WFP food aid.

Donor and recipient countries should take into account a number of international instruments in order to maximize the positive, life-saving and development impacts of food aid and minimize the negative effects. The main international instrument of this nature is the Food Aid Convention. The convention was first negotiated during the Kennedy Round of GATT negotiations and adopted in 1967 as part of the International Grains Agreement. It has been revised based on negotiations from time to time; the application of the most recent version has been extended until 30 June 2007. The convention is specifically devoted to food aid, and its objectives are “to contribute to world food security and to improve the ability of the international community to respond to emergency food situations and other food needs of developing and

low-income countries”. Toward this end, the convention provides a framework for the supply of food aid, establishing quantitative commitments for certain developed countries and elaborating principles for the delivery of aid. Article IX also provides that member countries have the option of making their food aid contribution in the cash equivalent of their minimum commitment levels. The WTO Agreement on Agriculture (AoA) captures the same spirit in stating that “aid shall be provided to the extent possible in fully grant form or on terms no less concessional than those provided for in ... the Food Aid Convention” (Article 10.4(c)). Not all food aid falls within the convention, however: only the food, mostly grain, that is pledged by specific donors is included.

General Comment 12 on the right to adequate food notes that states have an obligation to provide food to individuals who are unable to provide food for themselves for reasons beyond their control. Although states are obliged to find immediate solutions (mainly by constituting national food security stocks), addressing the right to adequate food in emergencies should not be seen solely in terms of the distribution of emergency food aid. Long-term solutions should also be sought in order to ensure food security and the sustained availability of the food supply. The Food Aid Convention specifically draws attention to the need to take account of the longer-term rehabilitation needs of the recipient countries.

Although food aid is generally not considered a means to a sustainable food supply, it may be the only source of food available in emergency situations and is thus an acceptable, albeit temporary, measure. In certain emergency situations, the needs of those affected may exceed the capacity or, in some cases, the will of the state to respond. In those cases, the obligation to provide food entails a duty to seek international support and to accept assistance from other sources to ensure the availability and accessibility of the necessary food. According to General Comment 12, “a State claiming that it is unable to carry out its obligation for reasons beyond its control ... has the burden of proving that ... it has unsuccessfully sought to obtain international support to ensure the availability and accessibility of the necessary food”.

The AoA approaches food aid from a different perspective, stating that countries cannot directly or indirectly tie food aid to commercial exports of agricultural products, in other words, that food aid may not become a disguised means of

subsidizing agricultural exports. The AoA therefore contains criteria to distinguish food aid from agricultural export subsidies. Annex 2 of the AoA identifies domestic food aid as a permissible “green box” subsidy,⁵ which is seen as not having an adverse effect on trade or production. Likewise, in the WTO Decision on Measures Concerning the Possible Negative Effects of the Reform Programme on Least-Developed and Net Food-Importing Developing Countries, member countries agreed to establish appropriate mechanisms to ensure that implementation of the results of the Uruguay Round on trade in agriculture does not adversely affect the availability of food aid to meet the needs of developing countries, especially those that are least developed and net food-importing.

In the 2001 Doha Ministerial Conference, WTO members committed themselves to review food aid contributions with a view to better identifying and meeting food aid needs of least developed countries (LDCs) and net food-importing developing countries (NFIDCs). It was agreed that WTO members that are food aid donors will ensure that their levels of food aid are maintained during periods in which the prices of basic foodstuffs in the world market are on the increase, and also that food aid to LDCs and NFIDCs is given fully in grant form.

In the on-going Doha Round of trade negotiations, negotiations on food aid fall within the wider negotiations on export competition. The reason for including food aid within these negotiations was that donor countries, especially the United States, give surplus production, mostly of grain, as food aid. (Since 1970, the United States has contributed an average of six million tonnes of food aid annually, and has been the source of 50-60 percent of the total grain food aid.) Hence, food aid discussions are held alongside those on export subsidies, export credits and state-trading enterprises. The objectives of the negotiations on export competition are both to get the EU to eliminate its extensive export subsidies program and the United States to remove the subsidies component of its export

⁵ To qualify as a green box subsidy, a measure must have no effect on trade or production, or at most a minimal effect. It must also conform to a number of other criteria set out in the AoA. Provided these general and specific criteria are satisfied, there are no limits to the value of subsidies each member can provide under the green box.

credit schemes. Regarding food aid, the objective is to agree on how to regulate the provision of food aid “which is not in conformity with operationally effective disciplines”. In addition, the negotiations address the role of international organizations in the distribution of food aid and the related humanitarian and developmental issues.

5.2. Implementation at national level

5.2.1. Donor countries

At national level, food aid policy is generally adopted by developed countries which undertake to provide food aid to countries in need. Donor countries may state which form of food aid they will provide, and also determine whether food aid is to be given to governments, NGOs, international organizations or some combination of these.

Donor countries may develop legislation or strategy documents stating the objectives of the food aid policy, which can be short-term (provision of food in emergency situations) or long-term (provision of food aid for development purposes). The legislation or policy instruments might also dictate the various forms in which food aid can be supplied: grants of food or of cash; sales of food for the non-transferable and non-convertible currency of the recipient country; and sales of food on concessional credit. Donor country legislation might also set up the mechanism by which funding is obtained. A good example of such legislation is the United States Agricultural Trade Development Act of 1954, known as Public Law 480 (or “Food for Peace”), which authorizes surplus grain to be given away as food aid to countries facing starvation. Such food aid can also be given in exchange for foreign currency, which is later given back to the countries as economic development assistance.

In the EU, Council Regulation (EC) No. 1292/96 lays out the EU’s food aid policy and food aid management strategy and sets down guidelines on special operations in support of food security. In addition to this regulation, there are also a number of Commission regulations on the issue, including Commission Regulation (EC) No. 2298/2001, which establishes detailed rules for the export of products supplied as food aid and Commission Regulation (EC) No. 2519/97,

which lays down general rules for the mobilization of products to be supplied under Regulation No. 1292/96 as Community food aid.

Where a donor country is a party to the Food Aid Convention, mechanisms to ensure that the government meets the quantitative commitments contained in that convention are required. For example, the legislation might set up the structure whereby donors either purchase food for aid or provide surpluses from their own harvests. A donor country might also wish to adopt measures to ensure that the food aid it supplies can be provided without causing trade-distorting effects or creating dependencies in the recipient country. This may include following the delivery principles and guidelines set forth in the Food Aid Convention. Concern for the effect of food aid on local production and markets in the recipient countries may manifest itself in the establishment of certain rules regarding food aid, such as providing for locally purchased food aid as opposed to direct transfers from farmers and suppliers in the donor country.

According to the Food Aid Convention, food aid should meet international quality standards, be consistent with the dietary habits and nutritional needs of recipients and be suitable for human consumption. The convention states that “members shall pay particular attention to meeting the particular nutritional needs of ... children”. Therefore, as part of the implementation of their food aid policies, donor states may seek to establish guidelines on the nutritional content of the food provided as food aid.

5.2.2. Recipient countries

To be effective, food aid policy should be integrated into the national food policies, plans and programmes of developing countries. Recipient states may, for example, adopt a policy stating that they will not hinder access to humanitarian assistance (which includes food and food-related aid) or hinder the passage of humanitarian consignments such as food aid. Either of these will assist the state in satisfying its obligation to protect the right to food. A state might also satisfy its obligation to facilitate the right to food by putting into place a proper food aid distribution network to facilitate the transit of humanitarian consignments. For example, Indonesia had banned rice imports in order to protect local farmers, but recently decided to make an exception for humanitarian agencies and humanitarian aid. Other countries have made explicit

the goal of reducing dependence on food aid as part of their national food security policies.

Box 4 Genetically Modified Food Aid

In 2002, a number of developing countries, including many Southern African countries, expressed concern about genetically modified (GM) crops supplied as food aid by multilateral agencies. Their concerns regarded both food safety (the suitability of GM food products for human consumption) as well as the environment (the potential effects on local biodiversity from the unintended dissemination of such products). Other countries expressed fears that the introduction of GM food would negatively affect their trade with markets such as the European Union, which has prohibited some GM foods while requiring others to be specially labelled.

Reacting to the concerns in Southern Africa, FAO, WHO and WFP issued a joint statement in August 2002 stating that “the consumption of foods containing genetically modified organisms (GMOs) now being provided as food aid in Southern Africa is not likely to present human health risks. Therefore, these foods may be eaten”. In response, some countries decided to accept GM corn as food aid but only after it had been milled, thus preventing any recipients from planting the corn.

International law does not currently address GMOs in food aid, although the issue is under discussion within Codex. It is therefore up to the government of the receiving state to determine whether to accept food aid that includes GMOs.

An interesting question, to which there is not yet any clear answer, is whether a country that refuses GM food aid, in the absence of a clear scientific justification, thereby denies its population access to food and violates the right to food. On the other hand, could a country which accepts such food aid in the face of scientific uncertainty as to its safety be considered as violating the right to “adequate” food?

Through legislation or other policy tools, recipient countries may decide to state not only whether or not or which form of food aid they will accept, but also the quantity or quality which is acceptable. For example, states may want to make

sure that the food provided is culturally acceptable. They might also regulate whether food aid meets certain standards of safety, for example that food has been properly processed, or that there are no alien species which may contaminate domestic species. For instance, the African Model Law on Biosafety specifically includes food aid under its definition of “deliberate release”, “release” and “placing on the market”. This means that any food aid which contains alien species is identified and subjected to regulation under the Model Law. Recipient states may also dictate the permitted uses of food aid, for example by prohibiting its planting in order to prevent the “pollution” of local varieties. Recipient countries might therefore maintain a list of approved food aid commodities or of the appropriate uses of food aid. There have been instances where states have rejected food aid where it did not meet their national requirements. See Box 4.

In order to effectively implement the goals of a food aid policy, the recipient country may need to create an agency or organization or to assign responsibility to an existing agency or department which will manage the receipt and distribution of food aid. The mandate of any such agency or department will be to maximize the effectiveness, timeliness, sourcing and targeting of food aid. It should also assess the success of the country’s food aid programmes.

5.2.3. Implications for basic food law

Whether in emergency situations or as a matter of course, states should ensure that food is safe. General Comment 12 states that “[p]roducts included in international food trade or aid programmes must be safe and culturally acceptable to the recipient population”. The Code of Ethics for International Trade in Food (Code of Ethics), adopted by Codex, also recognizes the applicability of general principles of food safety in food aid transactions. As stated above, a recipient state may set forth certain standards of safety which the food aid should meet, and this will be covered in the basic framework for food. For example, the food law will state that all food for consumption, which includes food provided as food aid, must be safe.

The Code of Ethics acknowledges that there may be special circumstances under which it is neither possible nor desirable to apply certain of its provisions, such as in emergency situations. In order to take account of these special

circumstances, countries may find it useful to include a general provision in their basic food law that authorizes the minister or head of the food authority to exempt food aid from certain requirements under the law. For example, the recipient country might decide that imported products provided as food aid do not require import permits or the payment of import fees. In order to facilitate the receipt of food aid, the minister could also decide in specific circumstances that certain food quality standards will not apply to food aid products. On the other hand, all provisions having to do with food aid could be included in a separate legal or policy document, leaving the basic food law to cover all other kinds of food. Because food aid necessarily comes into play in unexpected situations, this may be the better strategy.

VI. NUTRITION

6.1. Background

There are two main types of chronic nutritional problems that are found at the ends of the spectrum of malnutrition: those arising from an insufficient intake of good quality and safe food and those stemming from an excessive or unbalanced intake of food or certain types of food. The former has been the main concern of governments seeking to alleviate hunger and to provide adequate food to their populations, while the latter is only now calling for increased attention. In addressing malnutrition, governments have had to re-examine policies relating to production, trade, pricing and marketing of food and agricultural commodities, all of which have an impact on the ability of populations, especially at-risk populations, to access nutrient-rich food.

Urbanization, economic development and market expansion are having a significant impact on the health and nutritional status of populations as food and food products are increasingly produced and traded in a market that has expanded from an essentially local base to an increasingly global one. As standards of living have improved, so food availability has expanded and become more diversified. Changes in the world food economy are reflected in shifting dietary patterns with negative consequences particularly in developed countries and countries in transition. Traditional plant-based diets (fruits and vegetables) are being replaced by energy-dense diets high in fat, particularly saturated fat (often of animal origin), and high in refined carbohydrates such as sugars. These

patterns are combined with a decline in energy expenditure that is associated with a sedentary lifestyle: decreased physical activity due to motorized transport, labour-saving devices in the home, the phasing out of physically demanding manual tasks in the workplace and leisure time that is largely devoted to sedentary pastimes. Because of these changes in dietary and lifestyle patterns, chronic diet-related diseases – including obesity, diabetes, cardiovascular disease, hypertension, stroke, osteoporosis and some types of cancer – are causing more and more disability and premature death, placing burdens on already overtaxed national health budgets. By 2020 diet-related chronic diseases are projected to account for almost three-quarters of all deaths worldwide.

Obesity in particular is raising concern both in industrialized societies and in low-income countries. Whereas in 1995 there were an estimated 200 million obese adults worldwide, by 2000 this number had risen to over 300 million. Once considered mostly a problem in the United States, obesity is now becoming prevalent throughout Asia, Europe, Latin America and parts of Africa. In some countries, the levels of obesity have doubled or tripled over the past decade. Although almost all countries are experiencing an obesity epidemic, there is great variation between and within countries. In low-income countries, obesity is more common in middle-aged population groups, people of higher socioeconomic status and those living in urban communities. In more affluent countries, obesity is not only common in the middle-aged, but is becoming increasingly prevalent among younger adults and children. Furthermore, it tends to be associated with lower socioeconomic status, and the urban-rural differences are diminished or even reversed.

The risks of cardiovascular disease, hypertension and diabetes have been rising along with increasing weight. In developing countries, it is estimated that over 115 million people suffer from obesity-related problems. Diabetes, in particular, is on the rise. It was recently estimated that the number of people in the developing world with diabetes will increase from 84 million in 1995 to 228 million in 2025.

In order to develop a global strategy to combat the growing burden of chronic diseases, WHO and FAO launched an independent expert report on Diet, Nutrition and the Prevention of Chronic Diseases in 2002. The expert report contains the best currently available scientific evidence on the relationship of

diet, nutrition and physical activity to chronic diseases, and concludes that a diet low in saturated fats, sugars and salt and high in vegetables and fruits, together with regular physical activity, will have a major impact on combatting the high toll of death and disease. In May 2004, WHO introduced a Global Strategy on Diet, Physical Activity and Health, which was developed in order to provide to member states and other interested stakeholders a range of recommendations and policy options to reach the goal of improving public health through healthy eating and physical activity. FAO and WHO have stressed that solutions to the global surge in chronic diseases will require stronger linkages between those involved in health and agriculture, at global, regional and national levels.

6.2. Implementation at national level

As outlined in Parts III and IV of this chapter, the provision of safe and nutritious food is now recognized not only as a human need but also as a basic right. To satisfy the right to adequate food and to fulfil the adequacy element of food security, states must incorporate nutritional considerations into development activities, correcting negative aspects of existing food patterns and guiding dietary change where necessary. It is not a matter only of improving production and consumption of food, but of providing all consumers with products that meet their expected level of nutrition.

According to the Plan of Action on Nutrition from the 1992 International Conference on Nutrition, “improved nutrition requires the coordinated efforts of relevant government ministries, agencies and offices with mandates for agriculture, fisheries, and livestock, food, health, water and public works, supplies, planning, finance, industry, education, information, social welfare and trade”. Implementation of improved nutrition goals also requires the cooperation of universities and research institutions, food producers, processors and marketers, the health care community, educators, the media and NGOs involved in all of these sectors.

Although some aspects of nutrition policy may be implemented through legislation at national level (as will be discussed below), the other tools explored in section 2.2 are also likely to come into play. In order to achieve nutritional objectives, governments should carry out a review of existing domestic policies by product sector, in order to identify, on the one hand, any subsidies or trading

arrangements which are privileging undesirable foods, and on the other, supply constraints or import barriers which are negatively affecting desirable foods. At the same time, governments can consider putting into place economic or regulatory tools to encourage farmers to shift resources from the production of less to more desirable products and to assist producers in modifying their production methods, for example for purposes of raising leaner meat animals.

In addition, the Plan of Action on Nutrition calls on states to develop appropriate community-based nutrition education programmes in conjunction with appropriate communication strategies, and to give high priority to ensuring that these programmes reach target groups. Governments should therefore ensure that nutrition education and training programmes are implemented in communities and schools, providing information on proper food preparation and nutritional values.

Legislation will be useful for the implementation of nutrition policy in three main areas. First, and most generally, a state may wish to include a provision in its basic food law stating that all food produced and sold in the country must not only be safe, but also nutritious. Specific standards of nutrition would most likely be set forth in the implementing regulations. The second area is advertising and marketing: some states have enacted strict rules prohibiting and penalizing the marketing of unhealthy foods, particularly those high in saturated fat, salt and free sugars, to children.

The most significant nutrition-related subject that will be addressed in legislation is labelling. Both the WHO Global Strategy of 2004 and the WHO/FAO expert report discussed in section 6.1 acknowledge the role of consumer information and labelling in helping consumers make healthy and informed dietary choices. Nutrition labelling has been shown to encourage more healthful diets among people who read labels, and most countries already have legislation requiring some form of nutrition labelling. In many jurisdictions, the food legislation will set out basic rules for the minimum information required on food labels (including the language they must be in), while in other countries nutrition labelling is voluntary unless a nutrition or health claim is made or unless the foods are intended for special dietary uses. Subsidiary regulations may also mandate different label formats.

The regulation of nutrition and health claims on food labels and in advertising varies widely among countries and regions. Different definitions exist, some of which are equivalent, some not. In some cases “health claim” is used to refer to what is termed “nutrition claim” in other jurisdictions. Nevertheless, nutrition claims can generally be understood as statements or suggestions that a food has particular nutritional properties including, but not limited to, the energy value, the protein, fat and carbohydrate content and the vitamin and mineral content. There are two generally accepted forms of nutrition claim: the first is a nutrient content claim describing the presence or absence of a nutrient level (“low in fat”), while the second is a nutrient comparative claim describing nutrient content relative to another version of the product or another product (“reduced fat” or “lower in fat than”).

For health claims, a wide range of definitions exist, but generally they can be understood as statements or suggestions that a relationship exists between a food or a constituent of that food and health. Such claims have proved controversial, as regulators must balance the potential to attain public health objectives through certain foods with the fact that health claims can deceive or mislead consumers if not based on scientific data clearly showing the link between a nutrient or a food substance with health. There is widespread consensus that “medical claims”, i.e. claims that nutrients, foods or their constituents can play a role in preventing, treating or curing diseases, should be prohibited. In fact, medical claims are explicitly prohibited by the Codex General Guidelines on Claims and are also prohibited by legislation in many countries. Nevertheless, countries still vary widely over permitting references to disease or disease reduction on food labels and in advertising.

At the international level, nutrition labelling and nutrition and health claims have been addressed by Codex, whose Committee on Food Labelling develops guidelines for member states. Codex has developed three standards and guidelines relevant to nutrition labelling: the General Standard for the Labelling of Prepackaged Foods sets down the underlying principle that labelling should not be false, deceptive or misleading; the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Use recommends that any food intended for a special dietary use display a nutrition label; and the Guidelines on Nutrition Labelling recommend that nutrition labelling be voluntary unless a nutrition claim is made. Codex guidelines on health claims,

which remain in draft, state that health claims should only be permitted if they are consistent with national health policy, supported by scientific evidence, do not imply disease prevention, do not encourage bad dietary practice and are made in the context of the total diet. These Codex documents should inform the development of national labelling rules.

VII. CONCLUSION

This chapter started by analysing the policy environment in which food legislation is created, as food policy is the foundation on which national regulatory frameworks for food are based. Before choosing and establishing a certain type of food system, governments must first decide upon the overall objectives that such a system is intended to serve. Is the goal the provision of safe food? Ensuring food security? Implementing the right to food? Liberalizing markets in agricultural products, or promoting nutrition and a healthy diet? Or some combination of these? In some cases, governments may be faced with conflicting policy goals, requiring careful weighing and evaluation.

In order to implement food policies on the subjects discussed in this chapter, governments have at their disposal a wide variety of tools, of which legislation is only one. For instance, to improve food security, governments may need to look at the entire policy and regulatory framework underpinning food production, commodity prices and trade, as many elements of that framework affect access to food. To implement the right to food, governments may have to revise their overall perspective on hunger, putting individuals at the centre of development, with inalienable and enforceable rights.

It should be clear from the above that basic food legislation alone cannot address and resolve all of the concerns explored in this chapter. Nonetheless, it serves a critical role, since the unifying theme of all of the policy areas explored in this chapter is the primacy of safe food. Food security, the right to food, food aid, nutrition and healthy diet policies all require that the food provided be first and foremost safe for consumption. The Rome Declaration on World Food Security reaffirmed “the right of everyone to have access to safe and nutritious food, consistent with the right to adequate food and the fundamental right to be free from hunger”. The definition of the right to food in General Comment 12

suggests that “adequate” implies not only the provision of food of sufficient quantity but also of sufficient quality, i.e. food that is safe.

Another cross-cutting issue among the topics explored in this chapter is the importance of access. Ensuring or improving the ability of people to have access to safe food underlies food security, the right to food, food aid and proper nutrition and diet. Equally important is that the accessed food be nutritious, meaning that it has to provide the expected nutritional value. The main policies explored in this chapter are compromised where food is produced in such a way that nutritional components are negatively affected, where food is adulterated or misleadingly labelled or where it is improperly processed, stored or handled.

Although government units and experts concerned with food safety may consider that theirs is a scientific and technical area with little connection to issues such as food security or the right to food, all are committed to the provision of adequate and safe food. A basic food law can thus be considered an integral part of a national strategy to achieve many of the food policies explored here. Having examined the policy environment in which food legislation is created, the next chapter turns to the other contextual elements which will have a bearing on the development of basic food laws at national level.

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MAKING NATIONAL LAWS

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I. ASSESSING THE BACKDROP

After exploring the international backdrop against which national regulation on food takes place (Chapter 2), this text examined the range of topics that can be considered part of a country's national legal framework for food (Chapter 3) as well as the ways in which food policies can or should be incorporated into that framework (Chapter 4). This chapter now turns to the process of making a national food law. Relevant and enforceable food laws and regulations are essential to the development of a modern food control system: if a country has inadequate food legislation, it cannot carry out food control activities effectively, which can negatively affect human health and trade.

Part I of this chapter begins with a discussion of the general context for national lawmaking, identifying and analysing the factors that may affect the choices to be made in the revision or preparation of legislation. Each country has its own history, politics, traditions, international obligations, legislation, institutions and resources, all of which will affect its priorities and strategies for the regulation of food. Any new legislation must be developed with these factors in view, in order to ensure that the law is closely tailored to national circumstances. Among these national circumstances are factors affecting implementation of the legislation, which is the subject of Part II. Part III then turns to basic food laws, what they consist of and how they should be designed, while Part IV examines model laws. Although there are limitations to the use of model food laws, they can assist in certain contexts, when applied judiciously and if tailored to national needs. The chapter introduces three versions of a New Model Food Law. One incorporates the creation of a central national food authority, one relies on existing multiple agencies and one integrates both approaches, assigning certain functions to a central food authority while preserving the authority of existing ministries and agencies as to certain activities and responsibilities. To dispel any concerns for the fate of the 1976 FAO/WHO Model Food Law, the chapter concludes with an analysis of the weaknesses of that law.

1.1. Legislative system

The type of legislation that will be developed in a particular country depends in the first instance on the national legal system, i.e. the system in place for interpreting and enforcing the law. Does the country have a civil law, common law or Islamic law system, or some combination of these? The most common legal system in the world is the civil law system, which has its

roots in Roman law and which is based on written legal codes. It applies in continental Europe, in countries that were former colonies of continental powers and in other countries that have later adopted Western legal systems (e.g. Japan). The main alternative to the civil law system is the common law system, which is based on precedents created by judicial decisions over time. The common law system developed among Anglo-Saxon peoples, and applies in the United Kingdom (except Scotland), the United States (except Louisiana), Australia, Canada (except Quebec), New Zealand and generally every other country that has been colonized at one time or another by Britain. Some countries might be viewed more accurately as applying elements of both these major systems of law. For example, the United States has common law traditions through the use of court precedent in the formation of law, but is also becoming highly “codified” through legislation in some areas, such as federal environmental law. Another influential legal system is Islamic law (*Sharia*), which is derived from the Koran and can be found in the Middle East and in some African countries.

Regardless of the formal legal system, the role of law in society varies enormously from country to country. In some countries, legislation seems generally effective, while in others it appears to have little impact. In many cases this reflects the overall perception of laws and government authority within the culture, although it may also demonstrate distrust arising from rampant corruption or frustration with arduous bureaucratic procedures. It may also arise from confusion about applicable laws.

In many countries statutory law exists side by side with customary law, the latter consisting of the written and unwritten rules which have developed from the customs and traditions of communities. Established patterns of behaviour acquire the force of customary law when they become the undisputed rule by which certain rights or obligations are regulated between members of a community. In some countries, the status of customary law in relation to national statutory law is ambiguous; in others, the custom is codified and explicitly recognized by national legislation, or it gives legal recognition to the decisions of traditional authorities. For example, Samoa’s Village Fono Act of 1990 assigns to the village traditional councils (fonos) the power to make rules for the maintenance of hygiene in the village and to punish any violations (article 5). A number of other countries explicitly recognize customary law in relation to the abstraction of water for domestic purposes, i.e. for drinking, for hygiene and for watering livestock.

1.2. Existing legislation

Before developing new legislation, it is essential to identify and analyse the existing constellation of legal provisions covering the subject area. This helps determine the range of reforms that will be necessary, while outlining the parameters within which any new regulation will take place. As to food, in some cases there may be no basic food law, in which case entirely new legislation must be drafted. In other cases, there may be an existing legal framework for food but it may be outdated or insufficient, or rife with overlaps and gaps, and thus call out for a complete overhaul. In still other cases, only minor changes may be necessary, for example to add a few specific obligations or to enhance coordination. Carrying out an initial analysis of the existing framework serves yet one more purpose: if it leads to the determination that the current legislation is good enough, time may be better spent on other matters such as improving implementation and enforcement of existing laws.

An analysis of the existing framework should begin with the constitution, if any, as it serves as the supreme law of the land and defines how the legislative, executive and judicial functions and responsibilities are assigned within the country. It may allocate some powers to the national authorities (or federal authorities, in a federal system), some to the state or provincial governments and some to the local or municipal authorities. In a few cases, the constitution may contain an explicit reference to food, such as the constitutional right to food (see Chapter 4, footnote 2). The constitution may also indicate which subject matters are to be regulated at which level of government, which will affect both how new legislation is developed and how it will be enforced. If, for example, the constitution states that all matters relating to public health are to be regulated at local level, then it may simply not be possible to draft a national food law providing for centralized enforcement.

Equally, if the constitution establishes a hierarchy between international obligations and national legal provisions, then this will be an important consideration. As discussed in Chapter 2, the national legislative framework consists not only of the laws, regulations and other instruments issued at national level, but also the international agreements and organizations to which the country may be a party. A country which has signed any international agreements or joined any international organizations relevant to food may have international obligations which should be reflected in its national food law.

After a review of the constitution and the international backdrop, the analysis should turn to the country's legislation specifically covering food. As noted in Chapter 3, the national legal framework for food cannot be understood without reference to the numerous pieces of legislation that address food control, food safety and food trade in all of its various forms. This includes legislation addressing particular kinds of food or regulating harmful substances in food, as well as all legislation not specifically addressing food but having an impact on it. Most important, however, will be the country's umbrella food law, if it has one. Part III of this chapter should prove useful in a determination of the strengths and weaknesses of such a law, and should offer useful guidance where one is being developed.

It should be borne in mind that the relevant instruments will consist not only of national-level legislation but will also include subsidiary legislation, such as ministerial regulations, as well as laws enacted by lower-level governments. Depending on the context, court decisions may come into play, as well as customary law and practice, if any. In some instances, a particular activity that is anticipated in the new food law may be directly prohibited by an existing law. If, for instance, the legislation intends for food agencies and institutions to charge fees for their services and keep those fees (so as to strengthen their inspection apparatus or to build their own laboratories, for example), problems will arise if existing legislation requires that all fees for services go the central government, which then allocates funds for food-related regulation as it does for other matters. As another example, the desire to out-source inspection or food analysis activities to the private sector – an observable trend in many countries – may conflict with an existing law that prohibits the delegation of public powers except to government officials.

The last area for examination is legislation and rules which may have unintended effects on the regulation of food. Some regulatory obstacles and constraints may be indirect but may nonetheless affect food-related activities by increasing costs, often through bureaucratic rules and procedures. There are examples in virtually every legal system of procedural hurdles that make legislation extremely difficult to use or apply, while the policy reasons for creating those hurdles in the first place may be long-forgotten. In food law, this can be illustrated by the numerous licensing requirements established by different laws which an applicant must satisfy before operating a food business, ranging from a general permit to establish a business to a specific licence for the production, trade, import or export of certain food or for the sale of food in a particular form or location. Different laws may also authorize the inspection of the same food products and businesses,

sometimes several times over. In addition to food or public health laws, some countries have special laws to promote tourism and have established separate tourism authorities that are responsible for the issuance of licences to hotels and restaurants and the inspection of such locales, resulting in a burdensome inspection regime which can add significantly to the cost of doing business. The analysis of the existing framework will identify such inconsistencies and overlaps, so that they can be resolved, insofar as possible, in the revision or creation of an efficient basic framework for food.

1.3. Institutions and resources

The institutional framework will also have significant implications for the review process. One common problem is the failure to identify which ministry, agency or organization has the ultimate power to make certain decisions on food policy and food control, to inspect food products or businesses and to set and enforce food standards. Alternatively, there may be contradictory provisions within the applicable legislation that appear to give the same or overlapping powers to different entities.

Import and export inspection systems, for instance, are often located within the ministry responsible for commerce or trade, while the import and export of food products may fall within the ambit of the basic food law enforced by the ministry responsible for health or agriculture. Similarly, the consumer protection law, which is likely to be enforced by the ministry responsible for trade, may apply to the labelling and advertising of food, while the basic food law does the same. Other topics which are relevant to food safety, such as application and use of pesticides, might be allocated to the ministry in charge of the environment or agriculture.

Meat inspection and fish inspection are other common areas of overlap, with separate pieces of legislation allocating enforcement powers to the veterinary or fisheries department as well as to customs officials, and often to the ministry responsible for health. Other potential flashpoints are the control of food businesses in cities, which may find themselves subject to inspection by the central ministry responsible for health as well as the municipal authorities. Grocery stores and markets may be subject to inspection by the food authority, the municipal authorities, the consumer department and the standards bureau, with some inspections focusing on weights and measures, others on containers and labels and others on the ingredients of the products on offer. These are only a few examples of the circumstances that often raise

frustration levels high enough (on the part of inspectors as well as the public) to spur interest in reforming the food control system.

These kinds of overlapping responsibilities are among the most prevalent and the most harmful weaknesses of food control systems around the world. Affected systems are bedeviled by duplication of resources (e.g. where one food business is inspected by two or three different agencies) and burdensome bureaucracies (e.g. where a potential food producer must apply to two or three agencies for a licence or permit). Confusion over roles and functions can also arise from the failure to properly allocate powers among different levels of government in a decentralized system, or from the assignment of powers to different sub-agencies that do not function well together and that seek to preserve their proper spheres of influence.

Apart from duplication of regulatory activity and “turf-defending” behaviour among government units, another deleterious result of conflicting assignments of responsibility is that key implementing agencies may find that their authority to undertake certain actions is open to legal challenge. To avoid this, it is crucial that boundaries be clearly identified and that mandates, powers and responsibilities be delineated as specifically as possible. This can be accomplished through clear assignments of authority in the primary food legislation bolstered where necessary by carefully drafted memoranda of understanding which are agreed between and among the various ministries or agencies involved in food control.

The question of which ministry or agency should take the lead in the enforcement of food legislation cannot be answered in the abstract but must be resolved by reference to the circumstances at play in a particular country. In many countries, the ministry responsible for health is traditionally identified as the primary authority for food safety issues, while in others it is the ministry responsible for agriculture. Still other systems allocate control of the production process to the ministry responsible for agriculture and the control of food products later in the food chain to the ministry responsible for health, while the establishment of food standards and the control of labelling and weights and measures are allocated to the ministry responsible for commerce or trade.

The amount and kind of resources which each ministry or unit possesses will influence the decision regarding which should take the lead in enforcement, although the resource situation should not be considered immutable. The fact that one ministry has in the past had a more fruitful relationship with

donors and so boasts a state-of-the-art laboratory does not necessarily mean that it also has the human resources to carry out inspections or even to use the laboratory equipment properly. It is necessary to make a very fair and real assessment of the kinds of resources – physical, financial, laboratory, human – available within each entity before making a determination as to the suitability of assigning inspection or laboratory responsibilities to it.

Although the choice of ministry to take the lead in food control and food safety depends on the particular circumstances in each country, and as a practical matter is always influenced by local politics, there are some persuasive reasons for increasing involvement by the ministry responsible for agriculture. Foremost among these, as mentioned before, is the trend toward addressing food safety issues along the entire food production chain from farm to fork. Many hazards enter the food chain during the production process, which should be controlled through the application of good agricultural practices, good manufacturing practices and good hygiene practices. Generally, the ministry responsible for agriculture has the necessary skills and knowledge to build the required safety and quality into the food product right from its primary production. And because agricultural exports are often a critical part of many countries' (especially developing countries) foreign exchange earnings, there are strong justifications for the agricultural sector making significant investments to ensure that food products meet established standards. Involvement of the ministry responsible for agriculture is also a better way to secure farmers' capital investments, in that preventive measures are applied and unsafe products can be removed earlier along the food chain.

The ministry responsible for health, by contrast, may not be the ideal candidate for the primary leadership role in the food control system. This is because in addition to its food safety remit, the ministry is generally responsible for a large variety of other health-related issues, including health care, pharmaceuticals, tobacco control, recreation and disease. The participation of the ministry responsible for health is important nonetheless, in setting up food safety standards and measures to protect consumer health, including in the event of a food-borne disease outbreak or emergency situations involving food contamination. This ministry must also be involved in the establishment of national food safety policy (see chapter 4) and, in particular, in setting the “appropriate level of protection” which guides the establishment of food safety standards.

In most countries, inspection and laboratory facilities within the ministry responsible for health are often shared and overstretched, and resources are limited. Moreover, as a practical matter, unless there is a major food-borne disease outbreak or other food-related crisis, in many countries food safety will never have the prominence or priority within the ministry as do other issues such as AIDS or accessibility of medical care. For these and other reasons, strong arguments can be made that the primary responsibility for food control and food safety should lie with the ministry responsible for agriculture.

As touched upon above, agriculture and health are not the only ministries which share responsibilities for food control and food safety. Many others may be involved as well, including commerce, environment, fisheries, interior (i.e. municipal authorities), tourism and trade. The mandates, powers and responsibilities of each of these are generally quite different, as are their levels of expertise and resources. Inspection and control may be exercised effectively in the urban centres but sporadically in the regions, and some sectors of the food chain may be intensely scrutinized because of the multiplicity of inspectors while others may receive little or no regulatory attention.

To avoid the problem of choosing from among the many ministries with legitimate roles and interests in the food control system and having to iron out the conflicts among them, a number of countries have opted to restructure their institutional framework entirely so as to establish an autonomous national food authority with responsibility for coordinating and overseeing all food control activities in the country. This institutional set-up is discussed further in section 3.1.2.1. However, since the choice of how to allocate food control authority may be affected by existing government policies, the next step is to review those policies and their relevance to food law.

1.4. Policies and priorities

In every country, a variety of policies, strategies and priorities of national, regional or international provenance affect the development of the legal framework relevant to food control, food safety and food trade. As discussed in Chapter 4, there are a variety of food-related issues, including food security, food aid, the human right to food and nutrition, which should also be taken into account in the development of national food legislation. Another important policy with implications for food regulation is the overall

agricultural policy; others include environment, public health, industry, land use and development. Good governance policies, such as access to information, participation in decisionmaking, transparency and accountability will also affect the legislative design and influence the way a particular government interacts with civil society on matters related to food law. In some situations governments are obligated to incorporate certain policies in their national legislation, while in others they may simply choose to do so.

As an example, many countries have embraced the decentralization of government responsibilities and the devolution of powers to provincial or lower levels of government. The purpose is to ensure public participation in decisionmaking and to promote more effective management of resources, since local authorities are generally more familiar with their regulatory needs and staffing and other resource constraints. In practice, the existence of a decentralization policy or decentralization law might mean that in any new legislative framework for food, local authorities might be given the power to regulate on certain defined issues, to carry out some inspections and to issue licences to street food vendors or other food businesses, while the central authority might retain only a broad policymaking role. The decentralization policy might also mean that in new legislation, the regulating power remains with the central administration while enforcement of the food legislation is entrusted to local authorities.

Privatization is another strategy which many countries are implementing through legislation on various subjects, particularly in countries in transition to market economies where socialist governing structures are being dismantled. Elsewhere, due to limited public resources, many countries are increasingly faced with the need to revise their legal structures in a direction that is more favourable to private investment and the disentanglement of government from the market and from the provision of services. With regard to food, these policies underpin the trend toward allocating limited public resources and expertise to monitoring and auditing while the industry itself guarantees the safety of the products it places on the market. Some governments may also choose to out-source their inspection and laboratory activities to contracted private parties.

Other policy influences on national food legislation include globalization and regionalization. The desire to join regional organizations, such as the European Union, MERCOSUR or CARICOM, will spur countries to update and conform their food legislation to those organizations' requirements. There may also be an overall policy on the integration and participation of

the country in the global economy and in international organizations, which would affect the design of the national food law. In a country with the stated goal of collaborating with international organizations in general or of joining the WTO in particular, for example, the National Codex Committee would likely figure prominently. Finally, where a country has a strong interest in biosecurity, this will be of significance in how the food law is developed. This important policy approach will be discussed in Chapter 6.

II. CONSIDERING IMPLEMENTATION

A thorough analysis of the legal framework consists not only of an assessment of the legal system and a review of relevant policies, legislation and institutions. It is also important to assess the actual effect that relevant laws and regulations have on the ground, examining how they are applied in practice and the ways in which they influence the behaviour of individuals and institutions. Often, there are gaps between the objectives and policy goals of a law and what is actually achieved once it is enacted. Many ambitious laws, internally coherent and technically well-drafted, may fall short of their intended purposes or have quite unintended secondary effects for a number of reasons, explored below. This kind of analysis is important because if the reasons the current legislation is not satisfactory are not changed, then new legislation is unlikely to work any better.

2.1. Acknowledging politics and the human element

The effectiveness of any new law may be undercut by the failure of officials or institutions to devote sufficient resources or energy to its implementation. In many cases this is due to a simple lack of resources or capacity, especially in many developing countries. In other circumstances, the passage of a new law may have been a way to demonstrate political commitment to reforms about which the government is actually ambivalent. Implementation may in some instances be compromised by corruption, a problem which governments may be unable or unwilling to combat with the necessary vigour. There may also be opposition among government units and staff to new institutional set-ups, such as national food authorities, as this would often result in a transfer of government officials from related ministries. Resistance is often inspired by fear that terms and conditions of employment will change or cease, for instance due to a transfer from the public sector to authorities nested in the private sector. Particularly in those ministries which have been in place for some time, the resistance to change can be great.

The absence of necessary political will to ensure effective implementation may also be related to the manner in which the new law has been formulated and adopted. For instance, one ministry with a particularly powerful minister may successfully push for the enactment of a new food law without garnering the support of the other ministry or ministries whose duties and responsibilities will be altered by the new food law, or which may be called upon to help in its implementation.

Where this is the case, necessary collaboration may fall victim to institutional jealousies, turf-defending behaviour and passive resistance of government institutions and officials who feel their interests were not taken into account in the enactment of the new legislation. As will be discussed below, government officials should be considered a stakeholder group whose interests must be considered during the process of elaboration of the legal framework for food. Widespread participation as part of a policy of good governance is vital to the process of legal change.

2.2. Taking implementation into account in the legislative design

In some cases, legislation may prove difficult to implement because of a simple lack of resources or because of the failure to anticipate the pragmatic details of putting the law into effect, such as modes of enforcement and costs of implementation. There are many examples of well-drafted laws that have been enacted without sufficient prior attention to the level of development of a country and its existing resources and which, as a result, prove difficult to implement.

For example, in many countries the resolution of legal disputes is the responsibility of a court system that is overburdened and underfinanced, while alternatives to the traditional court system may be few or nonexistent. As a result, even good laws may not be properly enforced for lack of judicial mechanisms. One viable enforcement alternative that the law can offer is the use of administrative remedies, i.e. sanctions imposed by an administrative agency or an independent institution, such as a food authority, for violations. Such sanctions might include a simple warning, suspension or revocation of specific licences (such as a licence to operate a food business) or a monetary penalty. There may be improved efficiency where the law delegates these kinds of enforcement powers to a food agency or food authority, since the

standard of proof is generally much lower than the criminal standard¹ and cases can be resolved without burdensome or lengthy criminal court procedures.

As another example, a food law may create various food boards, commissions and procedures in an attempt to coordinate and structure food control activities in the country, but these may require financial or human resources that the government does not have. The law should reflect reasonable expectations about the government's ability to monitor the food production and distribution process, taking into account the fact that inspection services are often understaffed and lacking in basic infrastructure, such as buildings, equipment and vehicles. In addition, where laboratories do exist, they may not have the appropriate means to perform necessary analyses of pesticide residues, hormones, mycotoxins, chemical contaminants or other specific substances.

One strategy for addressing the problem of limited resources is to incorporate into the legislation a cost recovery scheme according to which the food authority may charge and retain fees for inspections carried out under the law. Many variations are possible here, such as fees charged for each inspection, for each laboratory analysis or only where the producer or importer requests an inspection outside of normal business hours. Food businesses might also be required to pay a monthly or an annual inspection fee. As discussed in section 1.2, incorporation of a cost recovery scheme may or may not be legally possible, as some countries require all government-acquired fees to be consigned to the consolidated fund administered by the ministry responsible for finance, which then allocates the funds through the normal budgetary process.

Another solution to scarce resources is to pool them across sectors. Where each ministry or unit has a few scattered laboratories with minimal facilities, the advantages of collaboration and cooperation are obvious. In many cases, inspection activities can be integrated, and in some circumstances equipment and human resources may also be shared. Section 3.1.2.1 discusses in more

¹ Whereas in criminal court proceedings (in common law jurisdictions) the guilt of the accused must usually be established "beyond a reasonable doubt", in administrative proceedings the standard of proof is usually the "preponderance of the evidence" or the "balance of probabilities" – in other words, more likely than not. By contrast, in civil law jurisdictions the main difference may be the burden of proof or the hierarchy of the means of proof.

depth the arguments for centralizing food control activities, while Chapter 6 examines biosecurity and the trend toward combining not only food safety but also animal and plant health under the auspices of one agency or body.

2.3. Collecting stakeholder inputs

It is a widely accepted axiom among the cadre of experts who work closely with governments in developing legislation that both the quality of a law and its successful implementation depend in large part on the effective engagement of civil society in its preparation. In the food area, stakeholders include governmental and nongovernmental actors, central and local authorities, producers, consumers, scientific and academic interests, the tourism industry and many private sector organizations. Some stakeholders may be organized into lobby groups or pressure groups, such as consumer protection organizations, producers' associations or labour unions, or they may participate as individuals in the consultation process which should accompany the development of the law. In some instances, when the law is finally enacted, such stakeholders may have a formal role in the institutional structures established (e.g. they may be included among the members of the country's food board or council). Stakeholders may also contribute where there is a period of public comment required under the law before any new regulations can be adopted.

The obligation to consult with stakeholders in the process of legislative drafting goes beyond simply holding a few seminars or workshops at the end of the process. It requires a true commitment to listening to and understanding the needs, objectives, insights and capacities of the intended users of the food law and others potentially affected by it, throughout the entire review, analysis and drafting process. This is time-consuming work that ideally should entail patient consultations in the field with people directly affected, not simply in a distant capital city. Consultations should start early, not only when a first draft has already been completed.

Broad participation not only improves the quality of the law, but it is also a significant factor in improving implementation. By helping create a consensus in favour of the law, it thereby improves compliance and fosters a sense of "ownership". Where the law reflects the perceptions and views of all stakeholders, this may inspire organized support of the law and active pressure for its enforcement, as opposed to indifference or passive resistance, which can impede implementation as effectively as active opposition does. At the very least, public participation publicizes the

legislation to society at large, among those directly affected by it as well as those more tangentially involved.

Government officials should be considered another important stakeholder group in the legislative formulation process, as they will have equally important concerns where new food legislation is being developed. As noted above, staff of units who feel that their responsibilities under the new system have been dramatically altered without their consent may find ways to resist or undercut implementation of the law. In addition, lack of regulators' involvement in the process means ignorance of the contents and procedures of the new law, which can lead to improper enforcement. This can be avoided not only by holding national consultations throughout the entire legislative preparation process, but also by publicizing the new legislation once enacted and educating officials and the public about its contents. Food inspectors, for instance, should be properly trained in enforcing the law and especially its accompanying regulations, as many of these are highly detailed and technical. The absence of widespread understanding and support on the part of those doing the regulating can seriously undermine implementation just as it can with respect to those against whom the legislation will be enforced.

2.4. Assessing the feasibility of change

After identification and analysis of the universe of relevant legislation, and an assessment of the existing constraints in the legal, institutional and policy environments, the next step is to assess the feasibility of correcting the shortcomings identified or at least mitigating their impact. If the problems have arisen in practice, how can the defects in implementation be cured? If instead it is the legal framework which needs modification, what technical and political steps are required, and what obstacles stand in the way? Can the changes be accomplished through the issuance of regulations or administrative rules by the line ministry in charge? Often, this is the easiest and quickest solution. Will they require the co-operation of another ministry, an agreement between two ministers or the attention of Parliament or Cabinet? This may take considerably longer and may entail greater political uncertainties.

It is important to have a realistic understanding of how open to change the decisionmakers are in a particular setting. In some contexts it may be possible to propose, draft and adopt needed legal reforms; in other countries and other circumstances the legislation must stay in place and reformers must work within the regulatory parameters, however imperfect they are. In either case, it is

essential to have a complete understanding of the legislative framework in all of its complexity so that appropriate strategies can be developed with that framework in mind.

An important related question is how high a priority to assign to any potential change. It is often possible to achieve promising results in a less than ideal environment. This calls for a realistic approach to the development of new legislation and new institutional structures. Laws that require sudden changes in deeply ingrained behaviour, significant new resources or dramatic upheavals in institutional set-ups without the prefatory groundwork, may prove difficult to implement. On the other hand, although it is often tempting to find temporary or stop-gap solutions to existing legislative and institutional flaws, it is important to keep the longer view in mind. Special care must be taken to ensure that the eagerness of governments and other actors to find a solution does not result in legislation being rushed through, which may undercut its effectiveness in both the short and long terms. Thus the question is not “what is the perfect solution?”, but rather, “what is the most economical and simplest strategy that meets the country’s minimum policy needs, while taking into account the real circumstances at play?”

Therefore the sequence to be followed by countries wishing to update their legal frameworks for food is first to analyse the existing legislation, next to define the universe of food-related activities being carried out in the country, next to identify the implicated institutions and personnel, then to dispassionately assess the real and potential resources and the capabilities of those actors, next to conceptualize the ideal deployment of resources in light of the government’s goals and priorities and then finally to temper that ideal conception based on the empirical circumstances and limitations identified. Once this analysis is completed, governments can begin the process of deciding what institutions, coordination mechanisms, policies, powers, offences and philosophical approaches to food control to include in their basic food law.

III. DEVELOPING A NATIONAL FOOD LAW

National regulatory frameworks governing the food sector vary widely in their sophistication and scope. Some countries have no specific food legislation but instead employ general public health or consumer protection legislation; others may directly apply international instruments, such as Codex Alimentarius standards, guidelines and codes of conduct. Still others may have a variety of

laws and regulations that were enacted to address specific food issues, or to assign food-related responsibilities to particular ministries or government units, creating a maze of conflicting or overlapping rules. Legislation may have been in place for decades and may not reflect modern concepts, principles or definitions, or may have been amended or added to in some parts and not others, creating inconsistencies. In such circumstances an update of the national legal framework for food is highly desirable.

As discussed in Chapter 1, food law should be understood to comprise the many subject matters that need to be regulated in order to guarantee the safe production, trade and handling of food. Chapter 3 outlined those many subject areas, which range from laws on harmful residues to laws only tangentially related to food. The breadth of topics makes clear that a government's or a ministry's desire to "enact a basic food law" or to sweep aside the many contradictions, overlaps and gaps in an existing system through the enactment of comprehensive legislation may not be easy to satisfy. Nonetheless, after careful study, governments can achieve the goal of combining as many food-related activities as possible into one legal and institutional framework. While there will inevitably be some subject matters best addressed by institutions and personnel that are specially qualified, and there may be historical or scientific reasons why some domains are stubbornly resistant to change, policymakers should be able to identify those activities that can be combined into one administration and under the aegis of basic legislation for the food control system. This chapter focuses on the process of developing such legislation.

3.1. Elements of basic food laws

Although the order of the provisions and substance of a basic food law will vary depending on the legislative practice in the country as well as the many factors discussed in Parts I and II of this chapter, such a law will generally contain provisions falling into the following categories: (i) introductory provisions, including the objectives, scope and definitions; (ii) enabling and administrative provisions defining the structures that will operate under the law and assigning their powers and responsibilities; (iii) specific provisions applicable to food and to its manufacture, import, export and sale; (iv) offences and penalties for infringement; and (v) miscellaneous provisions, including identification of existing legislation that the new law repeals or amends as well as establishment of the power to make regulations. Each of these is now examined in turn.

3.1.1. Introductory provisions

Important provisions in the food law will describe what the law covers and state its objectives. These provisions may have no real legal effect, but instead operate as a kind of policy statement explaining why the law was enacted and what purpose it is intended to serve. For example, the preamble or one of the early provisions may state that the object of the law is to “regulate the manufacture, sale, import and export of food” or “to protect human health”. Other common objectives are “to promote trade”, “to improve nutrition” and “to protect consumers”. As noted in Chapter 4, some countries may wish to state explicitly that the law is designed to promote food security or to implement the right to adequate food.

After stating the objectives or purposes, the law may then proceed to outline its scope, i.e. what activities and subject matters it covers. For instance, the law may include a broad statement that it applies to the production of food from harvest and slaughter up through eventual marketing and sale. Alternatively, the law may be limited in scope to certain steps along the chain, or it may exclude certain activities which are definitively covered by other legislation.

Next, the food law will have to include a list of definitions of the main terms employed. In drafting the definitions, internationally agreed sources such as Codex should be used, along with other national legislation on related subjects, if any. The list of definitions in the food law is not a glossary of food control terms in general, but rather explicates only those terms that appear in the law. At base, the definitions section serves as a reference point for terminology about which doubts may arise in the enforcement of the law. For example, if the definition of “owner” in the law is vague or restricted and does not cover importers, exporters, agents and the like, then someone charged with importing unsafe food may be able to avoid prosecution under the law by arguing that he or she was not the “owner” of the food. On the other hand, some definitions may be unnecessary if a country has an Interpretation Act which serves to define some terms uniformly for purposes of interpreting all of the country’s legislation.

The definition of “food” obviously has a special role in delimiting the application of the law. “Food” can refer to foodstuffs specifically, can refer to anything that humans can ingest, can include or exclude water and can specifically exclude drugs, tobacco and chewing gum. The decision on how to define food in the law will depend on which institutions are responsible for enforcing the law and what their expertise is. Although there is no strict rule, it

is generally advisable to exclude tobacco, cosmetics and drugs, since their control may call for expertise not readily available in the ministry or agency which is likely to be charged with enforcing the food law. If possible, the definition of food should employ Codex terminology.

The definition of “food business” will also be an important one, enabling the enforcing authority to exercise control over all places where food is manufactured, packed, prepared, served and sold. Policymakers must decide whether the law is meant to cover all such sites, including those not normally considered commercial undertakings, such as work canteens, schools and hospitals. Similar expansive meanings should also be accorded the definition of “sell”, to ensure that it covers offering, advertising, storing, displaying, delivering and the like, whether for money or for exchange. Once again the purpose of broadening the definition is to avoid any loopholes in enforcement, where a potential violator could argue that he or she was not dealing in food for a profit and therefore not “selling” the food and accordingly should not be prosecuted.

3.1.2. Enabling and administrative provisions

An essential task of the food law will be to define the powers that will be exercised under it and to identify the public authorities in whom those powers are vested. As a general rule, provisions in this category will address: (1) the body or bodies responsible for administering the food control system; (2) the establishment and functioning of the advisory food board or food council, if any; (3) the inspection corps and the powers and responsibilities of food inspectors; and (4) the laboratory scheme.

3.1.2.1. *Food authority*

In assigning responsibility for carrying out food control in the country, the food law may maintain a system in which multiple agencies are responsible for different aspects of food control, while at the same time charging one ministry with taking the lead role in coordinating food control activities in the country and for enforcing the food law.² Such a system is captured in Version 2 of the New Model Food Law presented in the Appendix. Alternatively, it may be decided to create a new central authority, governmental or quasi-governmental,

² As discussed in section 1.3, there are strong arguments to be made for assigning this responsibility to the ministry responsible for agriculture rather than the ministry responsible for health, although this will be a policy decision of the government.

which will coordinate and implement all activities in the food control system. Canada, Ireland and Belize have chosen this route, according to which all the various components of the system, i.e. coordination, policy development, inspections, laboratories and administrative procedures, operate under the aegis of this one organization. This is the “single agency approach” presented in Version 1 of the New Model Food Law in the Appendix. (All three versions of the New Model Food Law are discussed at greater length in section 4.2 below.)

An intermediate solution – between multiple ministries and a single executive authority – is to maintain the allocation of responsibilities for discrete areas of food control to several ministries and agencies while simultaneously creating a supra-ministerial authority to oversee and coordinate the operations of the whole system. Thus the ministry responsible for agriculture might control areas of primary production, while the ministry responsible for health inspects all locales where food is prepared and served, the customs department controls the borders and the municipal authorities inspect grocery stores and markets – all under the umbrella of a coordinating authority which also has responsibility for formulating food policy. This is a desirable option where, for reasons outlined earlier, it is not feasible or desirable to sweep aside ministries, agencies or other governmental units that have responsibility for certain areas of food control and to establish in their stead a single executive authority. Because it integrates inspection by the line ministries with the creation of an overall coordination mechanism, this can be called the “integrated approach”, captured in Version 3 of the New Model Food Law in the Appendix. It is often a more politically palatable option where the single agency approach is considered too dramatic a change.

The three systems offer distinct advantages and disadvantages. A self-contained structure – the single agency or the integrated approach – is more likely to avoid problems of conflicts, overlaps and duplication of activities (and in fact the very existence of gaps, inconsistencies and controversies in the existing regime of food safety may be one impetus for the creation of a new central authority underpinned by legislation). On the other hand, the transfer of human and physical resources from existing ministries and agencies to a newly created organization has its attendant financial costs and disruption of control during the early stages of its operation. By contrast, relying on the multiple agency approach is less expensive and causes minimal disruption but its success depends first on the clear definition of each entity’s sphere of influence, and second on the good will of the various entities engaged in food control. Where the delineation of responsibilities under the

food law (and via agreements between entities) is insufficiently specific, or where there is no desire on the part of the entities involved in food control to collaborate and to streamline operations, such a system is unlikely to succeed.

3.1.2.2. Food board

Whatever the overall enforcement authority decided upon, it is highly advisable for the basic food law to establish a food board or food council to assist the minister or the head of the food authority in the law's enforcement. Such a board should include representatives of all the ministries and agencies involved in food control activities in the country, including agriculture, health, customs, municipal authorities, standards, trade and industry. If the board is to have a regulatory role (for example, issuing licences to food businesses and making decisions on suspending or revoking them), then it should not have representatives of the private sector, as this would raise potential conflicts of interest, where the regulated are acting as the regulators. On the other hand, where the board is purely advisory, it is desirable to include not only consumer representatives but also representatives of producers, importers and exporters. Some boards include a legal expert to assist in preparing regulations, and others a representative of an institute of higher education or a research institute in the country.

As noted, the mandate of the board may be purely advisory or it may include some executive authority. The provisions in the law will make the board's role clear. For example, a provision might state that the mandate of the board is to "advise the minister on the manufacture, import, export, labelling, transport, handling and sale of food" or to "assist the minister in the enforcement of the law". In addition to the tasks already mentioned, other possible functions of the board may be that it proposes and assists in preparing new regulations under the food law, resolves appeals by citizens objecting to official actions taken under the food law, provides advice in emergency situations, develops national food policy and carries out public information activities to sensitize the population on food safety issues. Where there is a central food authority, the board acts as one of the principal organs of the authority, with concomitant regulatory and oversight roles.

In some countries, the food board or food council serves as the National Codex Committee, in which case it sets government position on various issues discussed at the Codex Alimentarius Commission and its subsidiary bodies and

coordinates government inputs into the development of international Codex standards³ (see Chapter 2).

3.1.2.3. Inspection and analysis

Another important administrative structure that should be created and defined in the food law is an inspection service, with a corps of inspectors responsible for enforcing the law. Traditionally, food legislation encapsulated an enforcement approach to inspections, with inspectors charged with seeking out violators, documenting evidence and initiating the processes leading to punishment under the law. In recent years, there has been a significant shift in approach to inspections, with inspectors exercising a more educational and collaborative role, functioning more like extension agents training those who run food businesses in the requirements of the law and their obligations under it. Rather than carrying out inspections for the purpose of discerning violations of the food law, inspectors exercise more of an auditing function, observing the results of the food businesses' own control and monitoring processes⁴ (see section 2.3 of Chapter 4).

The membership of the inspection corps will depend on the institutional structure set up in the law as well as the logistical needs of the ministry or agency at the head of that institutional structure. If only one ministry is responsible for enforcing the law, then the inspectors are most likely to be employees of that ministry. Similarly, if it is a central food authority that enforces the law, then the inspectors are likely to be staff working under its auspices. In some jurisdictions where there is a hybrid system (see Version 2 or Version 3 of the New Model Food Law in the Appendix) or where there are staff shortages, the law may refer to the power of the minister (or head of the food authority) to appoint “or designate” inspectors under the law: this enables the responsible authority to use not only its own employees but also employees of other ministries and agencies in the enforcement of the law. For example, even where the ministry responsible for health is the ministry assigned overall

³ In other countries the National Codex Committee may be a separate entity or may be a subsidiary committee of the food board. Whatever the set-up, participation in Codex activities is both advisable and beneficial – and if the country has joined or is considering joining the WTO, arguably essential.

⁴ Because laws are about rules, and because they do contain lists of offences and penalties, they will always read as if they reflect a purely enforcement approach, but this may not necessarily be the case. To discern the approach and philosophy of the food authority, it will be necessary to consult policy documents and to observe the training, outlook and comportment of food inspectors.

enforcement authority under the law, it may wish to rely on customs officers at border points if there are not sufficient ministry of health employees to serve at those remote locations. Under such circumstances, a customs officer is “designated” an inspector for purposes of enforcing the food law.

In addition to outlining the powers to be exercised, the law must also establish guidelines for the exercise of those powers, and identify any limitations on them. Thus the law will define the scope of the powers accorded to inspectors under the law and how they should go about exercising them (although in some legislative systems these will be listed in separate criminal procedure rules or general administrative legislation). Normally inspectors are given the power to stop and search persons and vehicles, with or without a warrant, where they suspect that the law is being violated. They may also enter premises where food is being manufactured, treated, graded, packed, marked, labelled, stored, sold, handled or served, although in most countries there is an exception for a dwelling place, where special permission must be sought. Inspectors may ask for information or documentation from the person in charge of a food business, and may weigh, count, measure, mark, seal or open any samples of food. In collecting information they may take samples or photographs, read any values recorded by measuring instruments installed at the food business or take their own measurements.

Inspectors also have stronger enforcement powers where they discover a problem at the food business: they may issue an improvement notice ordering a food business to make certain improvements within a specified time, and in the meantime they may seize food, destroy it if it poses a hazard to human health or shut down all or part of the food business. They may also have the power – on a temporary or permanent basis – to issue and withdraw licences to operate a food business. With regard to foods of animal origin, inspectors often have specific powers to deal with particular situations such as the power to prohibit or restrict imports and exports and the movement of animals and animal products within the country. Inspectors should also have the power to slaughter or to order the destruction of infected or dead animals and of animals belonging to surrounding farms.

The food law should also outline some additional responsibilities and rights of inspectors and of citizens affected by the exercise of inspection powers. For instance, the law should oblige owners, managers and employees of the inspected premises to cooperate with inspectors. Equally, however, where resistance is expected or where assistance is otherwise required, the law will generally provide that inspectors may call upon the forces of public order,

local administrations and customs authorities in the exercise of their powers. This may be for routine matters like entering a food business, or it may be for purposes of implementing extraordinary measures such as quarantine, slaughter, road blocks and the like. Finally, the law ought to bind the inspectors to confidentiality, so that they will not reveal any information gained during inspections about the operation of food businesses.

In addition to the inspection corps, the law should establish a system for identifying and certifying official laboratories and analysts that will carry out the required analysis of samples taken under the law. Usually the minister or the head of the food authority is accorded the power in the law to identify and select the official laboratories; the law ought to allow broad leeway in that selection, because in many countries there is an increasing need and desire to rely on private laboratories for some or all of these functions.

Subsidiary legislation under the food law will usually indicate whether fees are to be charged for inspections and laboratory analyses. In most cases there is a basic fee to be charged for each inspection or analysis, although in other jurisdictions fees are charged only where the inspection or analysis takes place outside of normal business hours. In some other jurisdictions fees are assessed on an annual basis, which reinforces the impression that the food businesses are paying for a continuous service which underpins their own efforts at monitoring and control.

3.1.3. Specific provisions on food

One of the main purposes of basic food laws is to outline a variety of requirements applicable to food. Accordingly, the main law creates the power to regulate specific aspects of food, for instance by broadly stating that the minister or the head of the food authority has the power to develop rules for specific food-related issues such as hygiene, packaging, transport, labelling, advertising, additives, adulteration and contamination. The food law will generally contain substantive provisions in these areas, stating for example that that exported food is subject to inspection, that food manufacturers must establish trace-back procedures, that food businesses must follow and enforce established hygiene rules, that food business operators must keep detailed records and that labels must conform to particular models. Some food laws include the requirement that all food sold in the country be accompanied by a warranty, which will describe the nature

and quality of the food.⁵ Some laws will have specific provisions for street food, while others will address this through generally applicable hygiene rules. Although the basic outlines for these and other topics are established in the main law, most of the details will be contained in subsidiary regulations. This division is discussed further in section 3.2 below.

The food law is likely to contain rules applicable to imported and exported food. Generally, there will be a requirement that importers or exporters apply for the relevant permits from the appropriate authority, and there may be other documentary requirements, some of which derive from other legislation. For example, in most jurisdictions plant products must be accompanied by a phytosanitary certificate issued by the exporting country's national plant protection organization.

Imported consignments are usually subject to an inspection either at the port of entry or at the final destination (if the container has been sealed and marked upon entry). Similarly, export consignments are generally subject to inspection at the exit point, although where the authority has built up relationships with particular exporters, inspections may also be carried out at the place of business where the food products are packed.

In inspecting imported and exported food, inspectors may take samples (in accordance with detailed rules for taking, sealing and marking set out in regulations) and may detain the food until the analysis has been completed; inspectors may order that food be reconditioned or relabelled if it meets only some of the requirements; and as a last resort, an inspector may destroy food where it is found dangerous for human health and reconditioning or relabelling would not resolve the problem.

Some jurisdictions include provisions in the food law addressing certain kinds of food, such as baby foods, novel foods, functional foods or genetically modified foods. As discussed in Chapter 3, the justification for such special treatment in food legislation is in most cases lacking, as just as for other kinds of food, these special kinds of food must be safe for human consumption. Nonetheless, where there is significant public pressure, the government may need to demonstrate that it has taken action on issues of consumer concern, and accordingly the food law could be designed with specific chapter headings or specific sections addressing such foods. Again,

⁵ The New Model Food Law does not include warranties, as in many jurisdictions the concept will be covered through contract law.

the basic law will contain only the skeleton, while the flesh is in the regulations.⁶

3.1.4. Offences and penalties

Once the food law has created the powers to be exercised under it and the public authorities in whom those powers are to be vested, and once it has established the parameters within which those authorities operate, it will have to delegate to those public authorities the power to punish. Offences must be defined, along with the penalties that may be imposed and finally the procedures applicable once an offence has been committed. Deciding what activities are to be considered offences under the law is a policy decision to be made in the formulation of the law. Even where the inspectorate operates under a collaborative approach, there will always be a need to define some offences under the law (and to set the accompanying penalties), since some food businesses will fail to implement control schemes, to audit them properly or otherwise to observe the law. (See section 3.1.2.3 and footnote 4.)

Some of the common offences contained in food laws include using a prohibited process in manufacturing food; storing or selling food under unsanitary conditions; selling adulterated or contaminated food or food that does not meet established standards; operating a food business without a proper licence; failing to establish or maintain a trace-back system; importing or exporting food without the proper documentation; publishing a false or misleading advertisement about any food; failing to ensure that all employees of a food business follow proper handling procedures; obstructing or hindering an inspector in the performance of his or her official functions; giving false information to an inspector; pretending to be an inspector; tampering with any samples taken under the law; and many others.

Offences under the food law can also be committed by inspectors, although many food laws neglect to include these. Some of the violations inspectors can commit are seizing food for any reason other than that it is likely to cause harm to human health or does not meet quality standards (this is to prevent

⁶ This division is particularly important to observe with regard to these sometimes controversial subject matters, as their requirements may be even more likely to change and evolve in the light of advancing scientific knowledge and developing viewpoints. Ensuring that the details for packaging, labelling and advertising of such foods are contained in subsidiary regulations means that necessary changes can more easily be made.

corruption); failing to disclose a financial interest in a food business; and disclosing to any other person any information acquired in the exercise of official functions under the law.

Having defined the offences, the law must then outline the applicable penalties. Once again it will be a policy choice how to punish violations of the law, although the legal and judicial system will also dictate the kinds of penalties that specific violations attract. Although some countries rely solely on a criminal enforcement system, others complement this system by establishing administrative penalties for certain violations of the food law.

In both common law and civil law systems, administrative sanctions generally share two principal characteristics. First, the power to impose them is vested in an administrative agency, not a judicial body. In the food area, this would mean that part of the executive branch of government or an independent food authority would have the power to punish certain kinds of violations. Second, administrative penalties are imposed outside the judicial process, i.e. without the intervention of any court. As a consequence, the regulator is not required to prove a matter to the criminal standard (see footnote 1) and is not constrained by criminal court procedures. Administrative penalties thus constitute a viable alternative enforcement mechanism which can be more cost-effective, timely and practical than criminal penalties.

Penalties, whether administrative or criminal, may take different forms. They include daily fines if a food business does not meet the terms of an improvement notice issued by an inspector; suspension or revocation of a licence to manufacture, import or export food; imprisonment; and the forfeiture of foods and other items used in the commission of an offence. Some laws incorporate enhanced fines for persistent offenders. To guarantee citizens' rights, deprivation of liberty (imposition of a term of imprisonment) is excluded from the scope of administrative sanctions and can only be imposed by a criminal court.

The law should next set out the procedures applicable once an offence has been committed. The main purpose of procedural rules in legislation of all kinds, including food legislation, is to guarantee constitutional rights or other basic legal rights. Procedures regarding notice, the right to a hearing and the right to appeal a negative decision are designed to protect an individual's rights, particularly the right to due process and to a proper defence. Thus in most food laws, once a violation has been committed, notice is served upon the

offender to inform him or her of the facts, the date and nature of the offence and the assessed sanction. Notice is served prior to the imposition of a penalty so as to afford the accused a reasonable opportunity to object, either in writing or in person. In addition, an offender is granted the right to appeal a decision of the executive authority to a higher authority or to civil or administrative courts, within a specified period.

Finally, it is important to ensure that the level of the penalties is high enough to be a deterrent while at the same time low enough not to be disproportionate to the offence committed. One way to ensure that punishments are appropriate for minor infractions such as those committed by street sellers (e.g. selling without a licence, selling in an unapproved location or violating hygiene rules) is to incorporate into the law a system of fixed penalties or “spot fines”, which can be imposed immediately by inspectors according to the established procedures. Such fines are similar to parking tickets in many jurisdictions, where a summons immediately issued must be returned with the accompanying fine, or the offender can choose to appear to contest the charge.

In many countries the prescribed fines and penalties contained in food laws are low or otherwise not deterrent enough, in part because of the devaluation of the country’s currency over time. Because the listed penalties are embodied in the parent enactment, their enhancement would entail an amendment to the law, and so the penalties remain at the same level for years or decades while their deterrent value declines. One solution to this persistent problem is to enact a separate law which includes a multiplier, i.e. which states that all penalties listed in the food law are hereby multiplied by 100, 500 or 1000, as the case may be. Another strategy is to avoid listing specific penalties in the law but instead to list a range, and to accord to the court the power to select the appropriate penalty within the listed range. So long as the upper level is sufficiently high, such a strategy can avoid the effects of inflation for a number of years, although it may still only be effective for a limited time.

One innovative solution is to tie the penalties to a neutral economic parameter, for instance the monthly salary of a civil servant of a particular grade. Thus a minor offence might be defined as one quarter the monthly salary of a civil servant from a medium management level, while a serious offence might attract a penalty equivalent to 10 times that same monthly salary. The advantage of this method is that it does not name particular amounts, and thus the penalties can be expected to rise over time – although

this assumes that the government eventually raises its civil servants' salaries. In some countries this may not necessarily be a valid assumption, but this system may still be an improvement over listing a fixed amount in a law which may take years to be enacted – during which time the currency may already have devalued and will likely continue to decline.

To assist with enforcement, some countries use tools other than criminal and civil penalties. (See section 2.2. of Chapter 4.) For example, economic instruments such as market mechanisms and pricing can be used instead of penalties to foster compliance. Although these may rely on legislation for institutional support and monitoring, they primarily influence behaviour through financial incentives and disincentives (taxes and subsidies). For example, tax abatements can be used to encourage responsible behaviour and fees can be used to punish the opposite.

3.1.5. Miscellaneous provisions

Food laws routinely contain provisions covering other outstanding issues that do not fit into any of the categories already addressed. For example, miscellaneous provisions may address liability issues, stating that inspectors or officials are not liable for anything done in good faith in the performance of their functions under the law. Other provisions may specify the liability of corporate officers in the case of a corporation committing an offence under the law.

The food law may also specify legal presumptions applicable to the enforcement of the law, although this will depend on the legislative practice in the country, since in some countries presumptions will be contained in a civil procedure or criminal procedure law applicable to all proceedings and all legislation. Typical presumptions include the presumption that a certificate of analysis purporting to be signed by the director or head of an official laboratory shall be accepted as *prima facie* evidence of the facts contained in it; the presumption that a package which bears the name and address of a manufacturer was manufactured by that person; the presumption that anything normally sold for human consumption is being sold for human consumption; and the presumption that all substances in a container or consignment from which a sample was taken are the same as the sample that was actually taken.

Because any new law will make significant changes to the food control system, there may be some existing laws, regulations or operating instructions that will

have to be changed or repealed. In such cases the food law will have to list which provisions in other laws must be repealed or amended to reflect the changes. This is an important provision, since, as discussed in Chapter 3, there are often provisions on food scattered throughout the legislative framework that will be affected by the new law. If earlier laws are being replaced, then the new law may state that they are repealed in their entirety, or it may list specific provisions that have been repealed. The law may also include some transitional provisions which maintain existing laws or regulations in force until a specific time or until a specified action takes place. The discussion in Chapter 3 should provide a useful list in the examination of current provisions that may need to be repealed or amended upon the enactment of a new basic food law.

Toward the end of the food law, there usually appears a provision listing the many subject matters that the minister (or other person in whom the authority has been vested, such as the head of the central food authority) may address through regulations in order to carry out the purposes of the law. The list of regulations may be extremely detailed or it may simply give broad outlines of the kinds of topics that may be addressed. In either case, the power to make regulations is rarely limited, since the law usually contains a general statement that the relevant authority may “make all regulations deemed necessary to achieve the purposes of the law”. Depending on the subject matter, the responsible authority can be assisted in the preparation of regulations and other subsidiary instruments, whether by the food board, the National Codex Committee, technical committees or the various units involved in food control.

Some of the kinds of subject matters that normally appear in such food regulations were discussed in Part II of Chapter 3, as well as in section 3.1.3 above. These include rules on food hygiene, food irradiation and food labelling. Other issues which are likely to appear in subsidiary instruments include provisions on the organization and functioning of the food board established in the main law; detailed procedures for the issuance and repeal of licences to operate food businesses, including the criteria to be used by the licensing agency in the licensing decisions; and how inspectors should go about their work inspecting consignments of food and taking samples. Regulations may also define the qualifications of inspectors and analysts operating under the food law, as well as training requirements for food handlers. The dividing line between what should be contained in the basic law and what should be included in regulations and other subsidiary instruments under the law is addressed in the next section.

3.2. Subsidiary instruments

Although the form of the legal framework for food in a particular country will depend on a number of factors – including the legal system, the legislative tradition and the other influences already discussed – one widespread drafting convention is that most parliamentary-level legislation, including legislation on food, is generally kept as basic as possible, with the details and specific requirements confined to the subsidiary instruments, including regulations, rules, schedules and forms.

Relegating the details to the implementing instruments (regulations and the like) serves two purposes. First, it facilitates passage of the principal legislation, because the more general the law, the less likely it is to be objectionable to other ministries and government authorities. Second, keeping the legislation basic ensures that any needed amendments based on scientific advancements or changing political circumstances can more quickly and easily be made. That is, instead of having to approach the legislature to amend the food law, the relevant executive authority (usually the minister responsible for agriculture or health, although in some countries it may be the head of the central food authority – and sometimes the Prime Minister) has the power to issue and amend subsidiary instruments and thus to act upon new developments.

Subsidiary instruments under principal legislation appear in several forms, and the terminology varies depending on the jurisdiction. Most generally, the categories include regulations (sometimes called rules), schedules and forms. Regulations or rules are usually written in the same format as parliamentary-level acts, that is, their provisions read like substantive articles or sections of laws. By contrast, schedules are usually more in the form of lists. For example, a food law may have attached to it a schedule containing lists of inspection fees, lists of banned additives and lists of the kinds of information that should be contained on food labels. Forms, like schedules, do not usually resemble parliamentary-level laws or regulations; instead they contain, as the name suggests, the models of forms for applications, certificates, receipts and other documents which are required under the food law.

The dividing line between what is to be included in the parliamentary-level legislation and what should be in the subsidiary instruments again depends on the legislative and other traditions in the country, but some general observations can be made. First, as already noted, any elements that are likely to change should not be included in the main law. This would include

provisions based on the state of scientific or technological knowledge, as well as any provisions that depend on a particular set of empirical circumstances. For example, it would not be advisable for the main legislation, in establishing the membership of an advisory board, to include too detailed a list of members (especially if the list has been developed with particular people in mind), since with time, those self-same people may move to different jobs within the same institutions or to different positions altogether. The problem is that if the legislation identifies the membership too closely, future ministers would nonetheless be bound by those provisions. Similarly, the specific minister, ministry, department or division will not generally be named in the main legislation, as portfolios may change, i.e. the Minister of Agriculture and Fisheries may become the Minister of Agriculture and Cooperatives from one year to the next, which risks making at least one provision of the legislation obsolete. Thus generally the legislation would refer to the “minister responsible for agriculture” or the “minister responsible for health”.

It goes without saying that subsidiary instruments should not conflict with the main act. Terms defined in the main act should not have divergent definitions in the regulations, and procedures set out in the principal legislation should be used as the skeleton on which to build more comprehensive procedures in the subsidiary instruments. Equally, every effort should be made to ensure that the food rules or regulations create a comprehensive whole in their own right. Thus at some future date if the main act is repealed, the system established in the subsidiary instruments could remain. If the system is well designed, then the repealing act could provide – as is often the case – that all subsidiary regulations issued under the repealed act remain valid as if made under the new act, unless and until they are specifically repealed.

Another important principle is that the subsidiary instruments should serve the purposes and objects of the main act and not create powers in themselves. Because regulations and other similar instruments are interpreted by reference to the main legislation, they may be subject to challenge if they do anything more than amplify powers and duties established in the main act. Thus, the grant of any official powers must take place in the main legislation. Inspectors could not, for example, be given in regulations the power to stop and search vehicles, since an aggrieved citizen could thereafter challenge those regulations (and the government action taken under them) as *ultra vires* because not underpinned by the main statute. However, this caveat should be tempered by the recognition that once the broad outlines of

particular powers have been established in the main act, the details can be left to the subsidiary instruments which will implement the act. It is common in many countries, for example, for a food act to be paired with a linked set of food regulations, with the latter fleshing out the roles and responsibilities of the institutions and persons created or designated in the main act.

A discussion of the subsidiary instruments to food laws is not complete without a mention of food standards. As discussed in Chapter 2, the identification of the Codex Alimentarius Commission as the source of international standards on food, under the umbrella of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), has increased the prominence of its standards and has triggered interest among many countries in adopting such standards at national level. Similarly, many veterinary standards elaborated by the OIE (World Organization for Animal Health), which was also identified by the SPS Agreement as a source of standards, are directly relevant to food matters.

Standards can be horizontal or vertical, mandatory or optional. Horizontal standards refer to standards applicable across a wide range of foods (for example, standards on packaging or labelling), whereas vertical standards refer to standards applicable to one particular food product. As noted earlier, Codex and OIE standards, although they are not binding in themselves, have become binding on WTO members through the SPS Agreement. Member countries may depart from the international standards only where they can justify such departure based on science and based on risk analysis. Whether standards are implemented through provisions in the main act, through regulations, through schedules and forms or through some other means will depend on government preferences, but as noted above, it is most advisable to leave details to lower-level enactments which the Council of Ministers, a specific minister or the head of the central food authority can issue, amend or repeal with greater ease.

IV. MODEL LAWS

4.1. Generally

Countries seeking to update their national legal frameworks in certain subject areas often examine the laws of neighbouring countries to learn about different ways to approach the issues and to implement selected policies. They may also seek guidance from international sources which contain “best practices” or recommendations for legislative and regulatory change. And, at

times, they will seek “model laws” on the subject from the self-same international sources, such as FAO and WHO. In most cases, model laws do not exist, and this is usually a good thing. The FAO Legal Office is not alone in discouraging the use of such laws, in the firm belief that laws cannot be developed at a remove from national conditions; rather, they must be tailored to national circumstances, including the national food policy, and developed – in consultation with national officials and stakeholders – with those circumstances firmly in view. This was stated most clearly in a recent publication of FAO’s Food and Nutrition Division:

Unfortunately [the 1976 FAO/WHO Model Food Law] 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. (FAO Food and Nutrition Paper No. 76, Annex 6)

On the other hand, where there is broad international consensus on the contents of legislation on a particular subject, there can be advantages to the preparation and circulation of guidelines for the development of legislation on that subject and, in some cases, even a model law. Where there is a strong regional identity and a strong desire to enact harmonized legislation, for example, there will be benefits to circulating a model law which has been agreed upon in a regional forum but which is still understood by individual countries to require significant work at national level to tailor the model to national circumstances.

Some topics lend themselves better to this process: in the plant protection field, for example, FAO has prepared drafting instructions or model phytosanitary legislation for the Gulf Region, for the Caribbean and for Central America. One reason the use of model legislation has been fruitful in the phytosanitary arena is that there are few significant policy issues which have to be resolved in national legislation – unlike in the food control and food safety area. For example, although countries may have to decide whether there is a need in their national plant protection law to have a Plant Protection Board to advise the minister responsible for agriculture on phytosanitary issues, this is not a decision of the same magnitude as the decision whether to create a central food authority or the decision to move

enforcement of food legislation from the ministry responsible for health to the ministry responsible for agriculture or vice versa. Because, as we have seen, the food control area is rife with overlaps and gaps among enforcing authorities, it does not lend itself easily to “model” or formulaic solutions.

Nonetheless, as should be clear from the discussion in Part III of this chapter, there are a number of elements of basic food laws which do not vary dramatically from country to country, and these could be captured in a model food law. And in the present environment of shrinking resources, not all countries have access to the international and individualized advice and consultation that might be required in order to independently update their national legal frameworks for food. Moreover, the desirability of “harmonization” has been increasingly recognized in international fora. For example, the SPS Agreement specifically encourages countries to harmonize food safety standards, while the WTO Agreement on Technical Barriers to Trade (TBT Agreement) seeks to foster harmonization with regard to technical regulations, such as packaging and labelling. For all of these reasons, there is some value to the dissemination of a model food law.

4.2. New Model Food Law

With the context outlined in Parts I and II of this chapter as backdrop, and using the broad outlines of the substance of a basic food law as introduced in Part III, the authors have developed a New Model Food Law drawing on FAO’s experience in providing legislative advice to member countries around the world. The new model has been informed by consultations with experts throughout FAO’s technical departments, in particular the Food and Nutrition Division, which has worked closely with the FAO Legal Office in advising member countries on institutional, legislative and regulatory issues relating to food.

The Appendix, which follows Chapter 6, contains the text of a New Model Food Law. As already introduced in section 3.1.2.1, the New Model Food Law is presented in three versions, reflecting the three main types of food control systems. Version 1, the “Single Agency System”, establishes a central food authority with a clearly defined mandate and functions. The benefits of such a system are many, including the ability to set and to implement a national food policy and to enforce food measures uniformly across sectors and across levels of government. Such a centralized system may also allow for a more efficient use of resources, and may offer an advantage in the case of a national food disease outbreak. A central food authority may also be

better placed to take account of a country's national and international obligations, and to participate effectively in the development of regional and international standards.

Version 2, the "Multiple Agency System", encapsulates a system in which there are multiple agencies responsible for food control in the country. As discussed earlier in this chapter, such a set-up may be a historical accident or may reflect a conscious choice to allocate responsibility, staff and resources to specific sectors. The weaknesses of such a system have already been explored: lack of coordination; overlaps or gaps in coverage; varying levels of implementation in the regions and the municipalities; and a resulting lack of confidence on the part of producers, importers, exporters and consumers. However, because food control systems do more than foster food safety (they also ensure fair trade practices and promote export trade), in some situations there can be strong reasons for developing or maintaining a system in which there is strong sectoral control. There may also be a desire to assign responsibility to local authorities who usually have a better sense of the local food trade and who may be able to respond more rapidly to food emergencies in their areas. In other cases the choice of the Multiple Agency System may simply be due to resistance to the establishment of any other kind. Although in this system there will be a variety of laws and regulations governing specific sectors, Version 2 of the New Model Food Law assumes that one ministry has primary responsibility for its implementation.

Version 3, the "Integrated System", treads the middle ground between these two approaches. It incorporates the view that the functions of a food control system can be divided into four levels or categories, and that the first two of these should be assigned to a central agency while the other two should remain under the responsibility of the multiple agencies which have been carrying out food control activities in the country. The categories are: (1) risk assessment and management, the formulation of policy and the development of laws, regulations and standards; (2) coordination of food control, monitoring and auditing; (3) inspection and enforcement; (4) education and training. Under this third version of the New Model Food Law, a central food authority is established but it does not have the kind of sweeping powers allocated to the single agency established in Version 1. Instead, the authority here is established for the limited but essential purposes set out in (1) and (2) above. That is, it will establish policy and coordinate the national food control system in its many aspects. The sectoral ministries and agencies will continue to exercise their inspection and enforcement functions, as well as their educational mandate, but under the overall oversight of the central

authority. In this situation, memoranda of agreement can help clearly define the respective mandates of these other entities.

The three versions of the New Model Food Law presented in the Appendix should not be viewed as immutable, but as exemplars reflecting the three main types of food control systems, one establishing a central food authority, one relying on multiple agencies and one retaining the existing multiple agencies for some purposes while establishing a limited central food authority for others. While the advantages of the first and third approaches are many, the diversity of variables explored in this chapter should make clear why, for many reasons, countries may select the second approach. In any case, the authors hope that countries will find it useful to start with the appropriate version of the New Model Food Law contained in the Appendix and then carefully and deliberately tailor it according to national needs.

4.3. The 1976 FAO/WHO Model Food Law

As noted earlier, there exists a 1976 Model Food Law developed by the FAO/WHO Food Standards Programme which has been circulating and which has influenced the development of a number of countries' food legislation. Countries continue to request copies of the 1976 Model Food Law, and its existence is well known. Thus, even if one wished to abandon altogether the use of model legislation in the food area, this would not be practical. Moreover, as noted above, there can be some advantages to the preparation and dissemination of a model law. Accordingly, this text provides one, in the hope that it will prove useful to those countries that continue to have a need or desire to consult model food legislation. Before abandoning the 1976 Model Food Law, however, it is important to understand its weaknesses – weaknesses which have led more and more legal practitioners to discourage its use, and which argue for its updating.

The introduction to the 1976 FAO/WHO Model Food Law states that it has been developed “in a general way so that it can be adapted to local conditions”, but the drafting fits neither a typical common law format nor a civil law format, but perhaps falls somewhere in between. For example, the order of items is not wholly coherent: offences appear in the second part (called “General Provisions”), whereas in a civil law jurisdiction they might not appear at all (they might appear in a criminal code), and in a common law jurisdiction they would appear almost at the end of the law, before “Miscellaneous Provisions”. A similar logic is absent from Part III of the

1976 Model Food Law, which addresses importation, warranties and defences, none of which have a great deal to do with one another.

In the vast majority of laws, the power of the minister or other relevant authority to make regulations will be one of the last provisions in the law, but Part IV (which is in the middle of the law) is the one referring to implementing regulations. The 1976 Model Food Law also has a number of typographical errors which detract from its effectiveness as a model, and there are two Article 7's, two Article 11(ii)(a)'s and two Article 19(a)'s.

In addition to these overall problems, there are specific problems within each Part, which will now be explored in turn. In Part I, there are a number of definitions and concepts missing, such as improvement notices and appeals against seizures and destruction of food under the law. Naturally, given the age of the 1976 Model Food Law, some of the definitions are not up to date nor are they in harmony with Codex. Some of the definitions are vague or problematic: "unsanitary conditions" is defined using the terms "dirt or filth" but neither "dirt" nor "filth" is defined; and while "ship" is further defined to include "any boat or craft", the more important term "vehicle", which appears in Article 11 of the law, is not defined. In the definition of "official laboratory", the law states that this means a laboratory operated by authorized officers (inspectors). This would prevent a government from using a private laboratory, which, in the current resource-scarce environment, many jurisdictions are interested in doing.

Article 4 states that any person who labels, packages, prepares, sells or advertises any food "in contravention of any regulations made under this act", commits an offence. As drafted, what this means is that although carrying out these activities in contravention of the *regulations* is a violation, committing them in violation of the *law* itself would not be. Article 6 is also vague, referring to the sale of food "to the prejudice of the purchaser", a concept which is not defined.

Article 7, which addresses offences, does not include all activities that ought to be penalized. While selling, preparing, packaging and storing food for sale under unsanitary conditions is made an offence, there is no reference to transporting or handling. Nor does Part II define any offences that can be committed in connection with import or export, or offences that can be committed by an inspector or authorized officer. As noted earlier, these would include taking samples for any purpose other than discerning if the

food law is being violated, taking a bribe or revealing proprietary information about a food business acquired during the exercise of official duties.

The first article of Part III refers to “satisfactorily relabeling or reconditioning”, but the law contains no criteria for what is “satisfactory” nor how that determination will be made. Next, the article states that goods must be relabelled or reconditioned within three months, and also that the exporter has a further one month to export the goods if such relabelling or reconditioning does not take place. It is not advisable to list specific time periods in a basic law; that is the kind of detail that belongs in an implementing regulation.

Article 9 is too broad, reading as if all grocers and food sellers must give a written warranty for every item sold. More importantly, the article states that the sale of any “article” must be accompanied by a warranty. However, “article” was defined in the definitions not only to apply to food, but also to labelling and advertising materials, and also to “anything used for the preparation, preservation, packing or storing of any food”. What this means is that under the 1976 Model Food Law, Article 9 requires that even someone selling a carton or a container or a pamphlet about food must provide a written warranty.

As mentioned earlier, Article 11 refers to the power to make regulations, which would normally appear toward the end of the law. Upon reading the list of regulations it is clear that the list is indeed out of place in Part IV, since it refers to the operations of a board which has not yet been introduced, and also to the taking of samples when the activities of authorized officers have not yet been discussed. More serious is the fact that Article 11(b)(xi) refers to regulations on the issuance of licences to premises where foods are prepared as well as the persons preparing such foods, and yet the issue of licensing is not mentioned anywhere in the 1976 Model Food Law. Section 3.2 of this chapter discussed a fundamental rule of legislative drafting, i.e. that all powers must be created in the main law while the implementing details are to be contained in the regulations. It is not sufficient for the 1976 Model Food Law to state that the minister can make regulations on licensing: the basic outlines of the licensing scheme must be described in the main law in order for it to be legally valid. Otherwise a food business which is affected by the exercise of official powers regarding a food licence could challenge that official activity as *ultra vires*, or outside the scope of legal authority.

Part V of the 1976 Model Food Law addresses Administration and Enforcement, but Article 12(a) is too broad and too vague, stating that the minister shall constitute a board to carry out the functions assigned to it, but failing to describe those functions or to indicate whether there are any limitations on which powers the minister may delegate to it. In most jurisdictions it would be improper for the minister to delegate his or her power to delegate or power to make regulations to the board, for instance, but Article 12(a) as drafted would permit this. Other essential parameters for the operation of the board should be defined in the law, while the subsidiary regulations would address more detailed matters such as the procedures to be followed at meetings and the board's reporting requirements.

Article 13 outlines the powers of authorized officers, which includes the power to stop and search and to enter premises where officers believe violations are occurring. However, the article does not state whether an officer needs a warrant. Nor does it indicate whether there is an exception for a dwelling place, which, in most jurisdictions, there would normally be. The article also states that officers may carry out such inspections during "reasonable" hours without defining these.

Article 13 does not outline the procedures applicable when an authorized officer seizes or detains any documentation, food or other articles. Moreover, although paragraph (f) states that the authorized officer should release the article when he is "satisfied" that all the provisions have been complied with, the absence of any procedures or any criteria for this determination raises the spectre of abuse. Where the authority is given the power to destroy articles that do not meet the requirements of the law, it is essential to indicate who is responsible for the associated costs.

The intention of Article 15 is to permit public officers to provide assistance where an authorized officer is not available, but it reads as if a public officer can seize food from anywhere at any time. The only criterion stated is that the minister has made a determination that the matter appears to "affect the general interests of the consumer". But as elsewhere in the 1976 Model Food Law, there are no criteria listed for that determination, and it is thus not difficult to imagine problems arising where someone affected by the exercise of this power challenges it in court.

Part VI deals with legal proceedings under the law. Article 17(a) broadly permits a court to cancel any licence issued under "any written law", which reads as if a food business owner could have any other kind of licence

cancelled where he or she violated the food law, which cannot be the case. Article 17 is intended to apply to licences to operate a food business, in which case the provisions should include the possibility that a court suspend a licence, that it impose conditions on the grant of the licence, that it cancel a licence to operate a specific food business and that it be able to prohibit a licence holder from applying for a further licence for a specific time.

Several other difficulties affect the provisions in this Part. Article 18(b) refers to the presumption that a manufactured good contains what is stated on the label, but does not mention imported or exported goods. Articles 18(a) and 19(a), by contrast, are too detailed for a parliamentary-level law, with the former specifying the kind of court with jurisdiction (“Subordinate Court”) and the latter stating that a summons is returnable in 14 days. These kinds of details will vary so dramatically from country to country that they should not be included in the main law. And finally, Article 21 is unsatisfactory as a repeal and savings provision: instead of stating that previous legislation is repealed, that conflicting provisions are preempted by this new legislation or that the earlier legislation (and subsidiary legislation issued under it) continues in force until specifically repealed, it states that the provisions of the food law are “in addition to and not in derogation of” the provisions of any other written law, which is not clear.

For all of these reasons, it should be clear that the 1976 FAO/WHO Model Food Law has reached the end of its useful life and needs to be replaced by modern food legislation. The last quarter-century has seen dramatic developments in the food safety arena, which the three versions of the New Model Food Law presented in the Appendix seek to reflect. Each country will know, based on the many factors explored in Chapter 5, which is the best model to take as a starting point from which to begin crafting a basic food law tailored to its national circumstances.

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I. LEGISLATING ON FOOD

An effective modern food control and food safety system requires a comprehensive and coherent national legal framework. This study has advocated the creation of a basic food law encompassing as many food-related activities as possible but tailored to fit each country's legislative background and unique identity. Fashioning this law calls for a multi-stage process, first identifying all food-related activities taking place within the country, then analysing existing legislative provisions and institutional set-ups and then, finally, taking into consideration the national political backdrop, available resources and policy priorities. Only then should the process of drafting comprehensive food legislation tailored to each country's particular circumstances begin.

Many areas of law have an impact on food control, food safety and food trade. Not only does this include legislation specifically addressing food (such as laws on certain kinds of food, on harmful residues in food or on how food is prepared, treated and sold), but there is also an array of laws and legislative provisions more tangentially related to food which nonetheless have an impact on it. One purpose of this study has been to broaden the conceptual envelope and embrace a wider range of laws and regulations than might normally be considered part of a country's regulatory framework for food. The authors believe that all of the subject areas introduced here – and there may be others as well – should be taken into account in the review and revision of a country's legal framework for food in order to ensure a truly comprehensive legislative solution.

National policymaking and lawmaking on food take place in the shadow of international negotiation and standard-setting carried out under the auspices of a variety of agreements and organizations. Governments as well as experts and observers bring their national experience to the international arena where a give-and-take informs the development of international standards which are then modified for implementation at national level. No national food law can be developed in isolation from the international context – neither from the constellation of international organizations and instruments which affect food nor from the empirical changes which those organizations reflect.

Food laws also capture and reflect policy trends, ranging from agricultural policies to decentralization policies to policies specific to food. Although a country's food security policy or food aid policy may not always have an

obvious link to the kind of basic food law introduced in this study, food laws should be developed only with a clear understanding of the most significant expressions of food policy at international and national level. A review of these policies reveals areas of commonality and fundamental concepts which should inform the development of even the most basic food law.

Countries seeking to update their food legislation often consult neighbouring countries' laws, international sources and model laws. While the first two of these are uncontroversial, the last can be problematic for reasons already explored: laws need to fit each country's institutional, legal, economic and political landscape, which formulaic solutions fail to consider. But it is also true that certain elements of food legislation are consistent from country to country, and these can be effectively captured in a model law. Countries basing their laws on model legislation can also reap the benefits of harmonization, which are not inconsiderable in a global market.

After a government has made its investigations and crystallized its ideal goals for the updated legal framework – the orientation of the law, the institutions it will establish and the policies it should reflect – the next step is to assess the feasibility of implementation. It is important to ask what technical and political steps will be required and what obstacles stand in the way. In some contexts it may be possible to adopt the needed legal reforms; in other countries and other circumstances it may be necessary to work within the existing regulatory parameters. In either case, no legislative proposal should be prepared and introduced without a hard look at the likelihood of its being adopted and the problems that may accompany its implementation.

To recapitulate, the food law itself should be kept as basic as possible, with details confined to subsidiary instruments – such as regulations, rules and schedules. This approach both facilitates the passage of principal legislation and simplifies amendment procedures. Although subsidiary instruments need to remain consistent with the purposes of the main act, they should contain the elements of the legislative scheme that are most likely to be subject to change. Together, the parent and subsidiary instruments should form an integrated and comprehensive whole.

II. CENTRALIZING AUTHORITY

Experience with the 1976 FAO/WHO Model Food Law has revealed a number of weaknesses which call for its updating. Some of the problems identified in Chapter 5 have led to the conclusion that this model has come

to the end of its useful life. In its place, this study proposes three variants of a New Model Food Law, encapsulating the three main approaches to designing national food control systems: the single agency approach (with one executive authority to oversee and carry out all food control activities in the country); the multiple agency approach (with existing ministries and agencies carrying out their sectoral activities but with a supra-ministerial advisory board to assist with coordination); and the integrated approach (with a central authority established to carry out policymaking and coordination while the line ministries continue with inspection and enforcement).

This study has refrained from being too free with advice, in the belief that every country will have its own goals and needs and no one blueprint can cover all situations. Nonetheless, readers will likely have discerned an inclination toward a centralizing approach, which, in our view, best serves the goals of integration and will best achieve a food chain approach to food safety while eliminating inconsistencies, overlaps and gaps.

Of the three systems introduced in the Appendix, the single agency system is most likely to avoid problems of conflicts and duplication of activities. On the other hand, the creation of such a centralized system may weigh heavily on governments which will face significant disruption in food control activities, at least at first. By contrast, adoption of a multiple agency system or integrated system is less expensive and will cause less disruption but its success will depend on the clear definition of each entity's sphere of influence and will also rely on cooperation. Where the delineation of responsibilities in the food law and in accompanying memoranda of understanding between affected ministries is insufficiently specific, or where there is no desire on the part of the agencies and ministries involved in food control to collaborate and to eliminate overlaps and gaps, such a system is unlikely to succeed.

Countries with significant food exports may favour a centralized system, as it offers uniformity of control measures across the food chain throughout the country. Other advantages include its ability to act quickly in the face of food-borne disease outbreaks or other food emergencies, a more efficient use of resources and improved cost-effectiveness. A centralized system may also be better equipped to deal with the international dimensions of food control and may boast greater transparency in decisionmaking and accountability in implementation.

Whatever the overall enforcement authority decided upon, the central food authority should be independent of any sectoral interest and of the food industry and should rigorously apply scientific methods in its assessment of risk. Its principal role is to serve as a coordinating mechanism for food control activities in the country, taking a strategic view across the whole food chain. It should foster public involvement in the policymaking process by consulting widely with all sectors and interest groups, and should communicate information to enable consumers to make informed choices.

Although many governments may come to accept the desirability of integrating food control activities, lingering doubt may remain in certain jurisdictions with strong decentralization policies. How can a government square a centralization policy for food with a system which is engaged in devolving authority and responsibility to regional or other sub-national organs in other spheres? The answer is that even in the most decentralized system there will always be certain activities and responsibilities which remain under central oversight, and food safety ought to be one of those. Policymaking – which is one of the principal responsibilities of a central food authority – is generally an activity that will remain at central level even in the most decentralized system. But more importantly, human health is too important to leave to the vicissitudes of regional or local variations in control.

III. INCORPORATING A BIOSECURITY APPROACH

An overarching theme of this study has been the need to take into account and to integrate the many activities and sectors that can be considered part of a country's regulatory system for food. Too often, experts in animal health are housed in one ministry or department, experts in agricultural production in another and experts in fisheries products in yet another (to mention only a few), making communication and coordination difficult and rare. This study has discussed some of the benefits of cross-sectoral coordination, including the ability to conserve and efficiently target resources and to exchange essential information.

The trend toward integration can also be observed in the burgeoning interest in biosecurity. Biosecurity involves the management of biological risks in a comprehensive manner not only to achieve food safety, but also to protect animal and plant life and health and to preserve the environment while contributing to its sustainable use. The assumption is that all of these sectors

are inextricably linked, and that the similarities in their regulatory frameworks argue for a unified and coordinated approach.

Box 1 International Plant Protection Convention

The International Plant Protection Convention (IPPC) is a multilateral treaty whose main purpose is to secure “common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control”. The IPPC was adopted in 1951, came into force in 1952 and has been revised twice, in 1979 and recently in 1997. The latest revision (which came into force on 2 October 2005) reflects the role of the IPPC under the WTO SPS Agreement, where it is identified as the organization responsible for phytosanitary standard-setting and the harmonization of phytosanitary measures affecting trade.

International standards and guidelines of the IPPC address topics such as export certification and pest risk analysis, i.e. the process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it. Standards cover conveyances, containers, storage places, soil and other objects or material capable of harbouring plant pests. Standards usually have their origin in national or regional initiatives, or are drafted by expert groups organized by the IPPC secretariat, housed at FAO.

The IPPC applies to the protection of both cultivated and natural flora and includes seeds and germplasm. It extends to the potential impacts of plant pests on the environment and includes genetically modified organisms (GMOs) that may directly or indirectly damage plants. In 1999, the Interim Commission for Phytosanitary Measures (ICPM), which is presently overseeing implementation of the IPPC, established a working group to study the phytosanitary aspects of GMOs, biosafety and invasive species. The ICPM is working with the Convention on Biological Diversity (CBD) and the Intergovernmental Committee for the Cartagena Protocol to explore ways to ensure that the risks of the movement of living modified organisms and alien invasive species are minimized through the development of common methodologies for risk analysis.

In the international arena, the instrument most relevant to biosecurity is the SPS Agreement, under which international standards for food safety, animal and plant life and health are provided by the Codex Alimentarius

Commission, the World Organization for Animal Health (OIE) and the International Plant Protection Convention (IPPC), respectively. The first two of these were discussed in Chapter 2; for an introduction to the IPPC, see Box 1. These three international standard-setting organizations are frequently referred to as “the three sisters” because of their close relationship under the SPS Agreement. Another relevant instrument is the Convention on Biological Diversity, which contains guidelines for the management of invasive alien species, as well as its supplementary agreement, the Cartagena Protocol, which addresses biosafety, i.e. protecting the environment and human health from the effects of modern biotechnology.

There are many other treaties or international instruments which deal with aspects of biosecurity from perspectives other than human health: the Ramsar Convention on Wetlands (1971) provides the framework for the conservation of wetlands and their resources; the International Treaty on Plant Genetic Resources for Food and Agriculture, which came into force in 2004, seeks to ensure the conservation and sustainable management of plant genetic resources; and the FAO Code of Conduct for Responsible Fisheries (1995) sets out principles and standards for the effective conservation, management and development of living aquatic resources. These agreements, organizations and programmes, among others, form part of the international framework for biosecurity.

Many forces drive the heightened interest in biosecurity, including the increasing and globalized trade in food and agricultural products, expanding populations, advances in communications and technology, changing consumer patterns, rising popular awareness of sanitary and phytosanitary issues and greater attention to biodiversity and the environment and the impact of agriculture on these. At the same time, governments must implement the biosecurity obligations they have assumed under international agreements.

Biosecurity recognizes common features among the relevant sectors, particularly in approaches to risk assessment and risk management, notification procedures, information exchange and international cooperation. Thus the main goal of a biosecurity approach is to reduce burdens and make efficient use of limited resources by harmonizing the regulatory frameworks of the implicated sectors. One attempt to address the goal of coordinated information exchange is the International Portal on Food Safety, Animal and Plant Health (IPFSAPH), which was created by FAO in collaboration with

many of the international standard-setting organizations introduced in Chapter 2. See Box 2.

Box 2 International Portal on Food Safety, Animal and Plant Health

The increasing demand for global sanitary and phytosanitary information comes from a variety of stakeholders such as national organizations dealing with trade, agriculture, food safety, environment and consumer protection, as well as international agencies and private actors. Obtaining accurate and current information, however, is a challenge. It may not be easy to locate current data and it may not always be clear which source represents the official position on a given subject. Furthermore, not only does internet access remain problematic in some countries, but information may not yet have been transferred to electronic media. In some cases, exporters must go through the lengthy and expensive process of contacting each trading partner directly to obtain standards and import information.

In view of these considerations, FAO, in association with the organizations responsible for international standard-setting in sanitary and phytosanitary matters (including Codex, WHO, OIE, WTO, the CBD and the IPPC) developed an internet-based portal – the International Portal on Food Safety, Animal and Plant Health (IPFSAPH) – which permits an authoritative search for standards, regulations and other relevant official international and national materials across the sectors of food safety, animal health and plant health. IPFSAPH was formally launched in May 2004.

Coordination of risk analysis and risk management is the most important unifying concept across each of the relevant biosecurity sectors. Risk analysis consists of the identification and assessment of risks, the management of these risks by means of laws, regulations and other measures and the communication of the risks to producers, traders, industry and consumers. Biosecurity recognizes that although risk analysis procedures may differ depending on the hazards addressed, the general principles for risk analysis in food and agriculture are the same.

The goal of biosecurity is to manage the risks associated with the introduction of plant pests, animal pests and diseases, zoonoses; the introduction and release of GMOs and their products; and the introduction and management of invasive alien species and genotypes, by utilizing a “whole cycle” approach which recognizes the sequential stages of hazard

identification and risk analysis. An important goal of biosecurity is to ensure the implementation of effective risk analysis procedures without creating unnecessary barriers to trade.

Cross-sectoral coordination in the areas of risk analysis and information exchange is particularly useful since a breakdown in security at one point in the food chain has consequences for other links in the chain. Developing countries, countries with economies in transition and small island states, some of which have vulnerable ecosystems, will benefit from a biosecurity approach, as they may not otherwise be able to afford the investments in infrastructure and human resources needed to effectively cover all areas in all of these sectors. Capacity building is therefore essential to establish and sustain national biosecurity systems, enabling countries to meet international biosecurity standards and to take advantage of trade opportunities.

Biosecurity is the logical next step after implementation of the kind of basic food law introduced in the Appendix, in particular the variant establishing a single agency which develops policy and carries out inspections “from farm to fork”. In the same way that regulating all foods under one umbrella is desirable for purposes of information collection and transfer and the ease of assigning resources, so the integration of food safety, animal and plant health and environmental concerns can improve cost efficiency, foster information exchange and reduce risks across disciplines. Increasingly, the traditional focus on regulating food and agriculture sectors individually is shifting to one of ensuring confidence in the overall regulatory framework for biosecurity. Thus a country’s adoption of a basic framework law for food control, food safety and food trade can be viewed as only the first step toward the full integration of the national regulatory framework for food safety and animal and plant life and health.

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APPENDIX
NEW MODEL FOOD LAW

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I. VERSION 1 (SINGLE AGENCY SYSTEM)

THE FOOD ACT OF 20__

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THE FOOD ACT OF 20__

AN ACT to control the manufacture, sale, import and export of food, to guarantee safe and adequate food and to provide for related matters.

PART I – PRELIMINARY

1. This Act may be cited as the Food Act.
2. In this Act, unless the context otherwise requires:

additive means any substance not normally consumed as food by itself and not normally used as a typical ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the production, manufacture, preparation, treatment, packing, packaging, transport or storage of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such food, but does not include contaminants or substances added to food for the purpose of maintaining or improving nutritional qualities;

adulterate means to make impure in order to give a false impression or value or to hide defects, by the addition of a foreign, inferior or inert substance to food, or by the exclusion or removal of a valuable or necessary ingredient of food;

advertisement includes any representation – written, pictorial, visual or otherwise – made for the purpose of promoting directly or indirectly the sale or disposal of any food or any substance represented as food;

appliance means the whole or any part of any implement, machine, instrument, apparatus or other object used or capable of being used in or in connection with the production, manufacture, treatment, packing, packaging, labelling, transport, handling, serving or storage of any food;

authorized officer means a person authorized and qualified to act as such under Article 13(1)(b) of this Act;

Authority means the Food Control Authority established in Article 3 of this Act;

Board means the Board of the Authority, established in Article 6 of this Act;

Committee means the Scientific Committee established in Article 12 of this Act;

contaminant means any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination, but does not include insect fragments, rodent hairs or other extraneous matter;

contamination means the introduction or occurrence of a contaminant in food;

Executive Director means the Executive Director of the Authority;
export means to export from [insert country name] by any means, and **exportation** has a corresponding meaning;

exporter includes any person who, whether as owner, consignor, consignee, agent or broker, is in possession of or in any way entitled to the custody or control of any food exported from [insert country name];

food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the production, manufacture, preparation or treatment of food, but does not include cosmetics or tobacco or substances used only as drugs;

food business means any business, however small, where production, manufacture, preparation, treatment, packing, packaging, transport, handling, serving, storage or sale in relation to food is carried out, whether for profit or not;

food production chain means all stages of production from primary production of food to food handling and food sale;

food safety means the assurance that food will not cause harm to the consumer when it is prepared or eaten according to its intended use;

import means to import into [insert country name] by any means, and **importation** has a corresponding meaning;

importer includes any person who, whether as owner, consignor, consignee, agent or broker is in possession of or in any way entitled to the custody or control of any food imported into [insert country name];

improvement notice means a notice served under Article 24 of this Act;

ingredient means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form;

label means any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food or its package;

manufacture includes processing and preservation and other related activities;

Minister means the Minister responsible for the administration, implementation and enforcement of this Act;

official analyst means a person authorized and qualified to act as such under Article 13(1)(c) of this Act;

official laboratory means a laboratory designated or approved as such under Article 13(2) of this Act;

OIE means the World Organisation for Animal Health;

owner or person in charge, in relation to any thing, includes any person having for the time being the possession, custody or control thereof;

package includes anything in which food is wholly or partially placed or wrapped and includes any basket, container, pail, tray or receptacle of any kind whether open or closed;

person includes a natural person or a body corporate;

premises includes any building, tent or other structure, permanent or otherwise, together with the land on which the same is situated and any adjoining land employed in connection therewith, used for the production, manufacture, packing, packaging, transport, handling, serving, storage or sale of any food;

prescribed means prescribed by this Act or by any regulations made hereunder;

production means the cultivation, rearing or growing of food including harvesting, milking and farmed animal production prior to slaughter;

sell includes to offer, advertise, keep, store, display, transmit, consign, convey or deliver for sale, or to exchange or to dispose of to any person in any manner whether for a consideration or otherwise, and **sold**, **selling** and **sale** shall have corresponding meanings;

stages of production includes import, storage, transport and sale;

street food means ready-to-eat food prepared or sold in streets and other public places;

substance includes any solid, liquid or gaseous materials;

this Act means this Act and any regulations, orders or notices made under it;

traceability means the ability to discern and identify, through all stages of production, manufacture and distribution, the origin and the final destination of a food-producing animal, food or substance intended to be or expected to be incorporated into a food;

treated means coloured, stained, powdered, polished, coated, stained, mixed, preserved, flavoured, diluted or thickened with any substance, and **treat** and **treatment** shall have corresponding meanings;

unsanitary conditions means such conditions or circumstances as might cause contamination of food or render the same injurious or dangerous to health;

vehicle means any vessel, aircraft, train, conveyance, cart, container, animal or other thing that can transport food from one place to another;

wholesome, in relation to food, means to be natural, clean, safe and not adulterated.

PART II – ADMINISTRATION

3.
 - (1) There is hereby established the Food Control Authority of [insert country name].
 - (2) The Authority shall be a body corporate with perpetual succession and an official seal capable of suing and being sued in its corporate name and shall have power to acquire, hold and dispose of land or any other property.
 - (3) The Authority shall, subject to this Act and subject to the overall authority of the Minister, be independent in the exercise of its functions and shall have all such powers as are necessary for the performance of its functions under this Act.

4. The principal functions of the Authority shall be to:
 - (a) employ risk management with the goal of ensuring that all:
 - (i) food produced in [insert country name], whether for domestic consumption or export; and

- (ii) food distributed or marketed in [insert country name], whatever its origin; meets the highest standards of food safety.
 - (b) take the lead in coordinating and harmonizing food control activities in [insert country name] at all stages of production, manufacture and distribution;
 - (c) prevent and protect against fraud in connection with the sale of food;
 - (d) formulate strategies and policies on food, nutrition and food security, including procedures for emergency response, and monitor their implementation;
 - (e) encourage and promote research on food matters within [insert country name];
 - (f) prepare and amend regulations, orders, standards, codes of practice and notices under this Act;
 - (g) consult widely with all sectors of the food chain in carrying out its activities under paragraphs (a)-(f) of this Article;
 - (h) provide advice, information or assistance to any public authority in relation to food control, food safety and food trade;
 - (i) obtain, compile and keep under review information concerning food control, food safety, food trade and nutrition in [insert country name];
 - (j) promote consumer education regarding food safety and nutrition;
 - (k) carry out any other matters in connection with or reasonably incidental to the foregoing.
5. In addition to an annual budgetary allocation of Parliament, funds of the Authority shall include:
- (a) such fees as may be charged by the Authority for services rendered by it;
 - (b) such moneys or other assets as may accrue to or vest in the Authority by way of grants, subsidies, donations or gifts.
6. (1) There shall be a Board of the Authority to be known as the Food Control Board.
- (2) Without prejudice to sub-Article (1), the Board shall:
- (a) advise the Minister on food control and food safety matters, including the production, manufacture, import, export, labelling and sale of food, on

- consumer protection and on emerging food control issues including street food;
- (b) exercise oversight responsibility for the performance of the functions of the Authority;
 - (c) provide assistance and advice on the formulation, review and implementation of food policy, including procedures for emergency response;
 - (d) propose and assist in the preparation and amendment of regulations, orders, standards, codes of practice and notices under this Act, consulting with the Scientific Committee on any matter related to that Committee's mandate;
 - (e) examine complaints and objections lodged in respect of decisions made or official actions taken under this Act;
 - (f) distribute information received from the Codex Alimentarius Commission, the OIE or other international or regional standard-setting bodies and coordinate the circulation of draft standards within [insert country name] and the collection of comments thereon from interested governmental and nongovernmental actors;
 - (g) advise on [insert country name]'s participation in the work of the Codex Alimentarius Commission and the OIE and their subsidiary bodies, including representation at meetings;
 - (h) promote consumer education regarding food safety and nutrition;
 - (i) on its own initiative, discuss any matter connected with food in [insert country name], and report to the Minister on its discussions;
 - (j) perform all other functions assigned to it by this Act or by the Minister.
7. (1) The Minister, on the advice of the Board, shall appoint an Executive Director to function as chief executive officer of the Authority, responsible for ensuring that the activities of the Authority are carried out efficiently and effectively.
- (2) The terms and conditions of the employment of the Executive Director shall be determined by the Board with the approval of the Minister.

- (3) The Executive Director shall carry on, manage and generally control the administration and business of the Authority and perform such other functions as may be assigned by this Act or by the Board.
 - (4) The Executive Director shall not hold any other office or position of profit or carry on any other business without the consent of the Board.
8.
 - (1) There is hereby established a secretariat responsible for supporting and facilitating the day-to-day activities of the Board, including meetings and correspondence, headed by a Secretary appointed by the Minister on the advice of the Board.
 - (2) The terms and conditions of the employment of the Secretary and such staff of the secretariat as the Minister may appoint shall be determined by the Board with the approval of the Minister.
9.
 - (1) The Board shall consist of the following members, selected according to their qualifications and appointed by the Minister:
 - (a) the Executive Director;
 - (b) one representative of each of the following:
 - (i) ministry responsible for agriculture;
 - (ii) ministry responsible for environment;
 - (iii) ministry responsible for fisheries;
 - (iv) ministry responsible for health;
 - (v) ministry responsible for local government;
 - (vi) ministry responsible for tourism;
 - (vii) ministry responsible for trade;
 - (viii) customs department;
 - (ix) national standards organization;
 - (x) a consumer association.
 - (2) Where the qualifications of the appointed members do not reflect all of the following fields:
 - (a) public health and epidemiology;
 - (b) food science and technology;
 - (c) food production;
 - (d) agricultural science and animal health;
 - (e) food marketing and trade;
 - (f) human nutrition;

- (g) legal or administrative affairs;
the Minister may appoint up to three additional members to ensure that the Board reflects the maximum of such expertise.
 - (3) Before appointing any person to be a member of the Board, the Minister shall consider whether he or she has any financial or other interest which in the Minister's opinion is likely to prejudice the exercise of that member's duties.
 - (4) The Chair and members of the Board shall hold office for three years and shall be subject to re-appointment for one additional three-year term. After a break of at least three years, they are then eligible for further reappointment in accordance with this Article.
 - (5) Members of the Board shall be paid a sitting allowance in consonance with the rates approved for public officers.
 - (6) The Minister may remove a member for misconduct, for infirmity of body or mind or for having been convicted of a crime.
- 10.
- (1) Members of the Board shall elect a Chair from among their membership at the first meeting of each year.
 - (2) At least one half the Board members present at any particular meeting shall constitute a quorum for purposes of transacting business.
 - (3) The Board may make provision for the conduct of its meetings and the procedures to be followed at such meetings but shall meet at least four times per year.
 - (4) The Board shall submit an annual report outlining its activities to Parliament and shall provide a copy of such report on request of any member of the public.
 - (5) Members of the public may attend all meetings of the Board although they may only participate where so authorized by the Chair, and in no case may they vote.
 - (6) The Board may appoint such subcommittees as it deems necessary, consisting of members, nonmembers or both, to assist it in the performance of its functions, although members of such subcommittees shall have no voting or remuneration rights arising from their participation.
- 11.
- (1) If it appears to the Minister that there has been a serious failure by the Authority or the Board to exercise its

- functions, he or she may give the Authority or the Board, as the case may be, such directions as he or she considers appropriate.
- (2) If the Authority or the Board fails to comply with such directions, the Minister may:
- (a) give effect to them (and for that purpose may exercise any power of the Authority or the Board); or
 - (b) remove all the members of the Board from office and, until new appointments are made, carry out the Authority's functions him- or herself or appoint any other person or persons to do so.
12. (1) The Minister shall, on the advice of the Board, appoint an independent Scientific Committee to carry out food safety risk assessments.
- (2) The Committee shall be responsible for:
- (a) evaluating, in response to official requests or on its own initiative, physical, chemical or biological risks to human health arising throughout the food production chain;
 - (b) advising the Minister or the Authority on the appropriate measures to be taken to protect consumer health;
 - (c) providing inputs into or developing proposed regulations or rules on subject matters within its mandate.
- (3) In carrying out its functions, the Committee shall take into account:
- (a) the latest scientific research;
 - (b) information regarding procedures, methods and means of production;
 - (c) the results of sampling and analysis;
 - (d) any other relevant data.
- (4) The Committee shall cooperate fully with the Authority, exchanging advice and information regarding risks, risk factors and risk perception, and in particular shall explain its risk assessments and the basis of its decisions.
- (5) The terms of office and the conditions of service of Committee members shall be determined by the Minister on the advice of the Board.

13. (1) The Minister may from time to time appoint or designate any person with the prescribed qualifications as:
 - (a) a member of the Scientific Committee;
 - (b) an authorized officer to carry out the functions assigned to such officers under this Act;
 - (c) an official analyst for purposes of enforcement of this Act.
- (2) The Minister on the advice of the Board may from time to time designate any laboratory as an official laboratory for purposes of enforcement of this Act.

PART III – GENERAL PROVISIONS

14. The Authority may ban or set limits on the presence of additives, contaminants and residues in food or animal feed.
15. Where the Authority determines that food of any specified class or description if imported or cultivated, taken or harvested from a specific area of [insert country name] may be dangerous or injurious to persons consuming that food, it may by order prohibit the importation, cultivation, taking, harvesting or obtaining of that food.
16. In the case of emergency or sudden necessity, the Authority may by order:
 - (a) totally prohibit the production, manufacture, preparation or sale of any food of the class specified by the Authority;
 - (b) impose conditions on the production, manufacture, preparation or sale of any food of that class;
 - (c) cause any food to be tested or examined as prescribed;
 - (d) cause any food to be held or isolated in any place and prohibit the removal of food from that place for such time as the Authority may prescribe;
 - (e) cause any food to be destroyed or otherwise disposed of as the Authority sees fit.
17. (1) All premises including warehouses used for the preparation, sale, exposure or storage of food shall be constructed as prescribed.
- (2) All food businesses shall apply for a licence in accordance with the prescribed procedures.

18. (1) Food businesses shall establish and implement a system enabling them to identify any person:
 - (a) who supplied; or
 - (b) to whom they supplied;a food-producing animal, food or substance intended to be or expected to be incorporated into a food.
- (2) Upon request of the Authority, food businesses shall make available all information collected under the system established under sub-Article (1).
19. Food businesses and their personnel shall follow all applicable hygiene rules established under this Act.
20. (1) Every package of food intended for sale in [insert country name] shall bear a label which:
 - (a) permits its traceability;
 - (b) sets out such particulars as may be prescribed.
- (2) Where food other than packaged food is displayed for sale, it shall be labelled as prescribed.

PART IV – INSPECTIONS

21. Inspections carried out under this Act may have as their object:
 - (a) food businesses and their surroundings and installations, as well as means of transportation, equipment and materials;
 - (b) food ingredients, additives, disinfectants and any substances or processes used in the production, manufacturing or handling of food;
 - (c) personnel employed at the food business;
 - (d) packaging material;
 - (e) cleaning, disinfecting and maintenance at the food business;
 - (f) labelling.
22. (1) Except for a dwelling place, an authorized officer may, without a warrant:
 - (a) enter any food business or other premises in which any food is being, or is suspected of being, produced, manufactured, treated, graded, packed, packaged, labelled, stored, handled, prepared, served or sold, or in which any other operation or activity in connection with food is being, or

suspected of being, carried out, and may, for the purpose of determining whether this Act is being violated:

- (i) inspect or search such premises, and examine any food, appliance, product, material, object or substance which is being, or is suspected of being, used or destined for use in connection with the production, manufacture, treatment, grading, packing, packaging, labelling, storage, handling, preparing, serving or sale of any food;
- (ii) demand any information regarding any such food, appliance, product, material, object or substance from the owner or person in charge of such premises;
- (iii) weigh, count, measure, mark, open and take samples in the prescribed manner of any food, product, material, object or substance or its package or container, or lock, secure, seal or close any door giving access to it;
- (iv) examine, make copies of or take extracts from any book, statement or other document found at such premises which refers to or is suspected of referring to such food, and demand from the owner or any person in charge of the premises an explanation of any entry in it;
- (v) inspect any operation or process carried out on such premises, and demand any information regarding such operation or process from the owner or person in charge of such premises or from any person carrying out such operation or process;
- (vi) read any values recorded by measuring instruments installed on the premises or by instruments in the possession of the authorized officer;
- (vii) take any photographs;

- (viii) seize any food, appliance, product, material, object, substance, book, statement or document which appears to provide proof of a contravention of any provision of this Act, providing a signed receipt in the prescribed form which shall be countersigned immediately by the owner or other person in charge of such premises or object.
 - (b) stop and search any vehicle in which food is being or is suspected of being transported, produced, manufactured, treated, graded, packed, packaged, stored, handled, prepared, served or sold or in which any other operation or activity in connection with food is being or is suspected of being carried out;
 - (c) stop, search and detain any person who is suspected of committing an offence under this Act.
 - (2) An authorized officer exercising his or her authority under this Article may request the presence and assistance of such law enforcement personnel as he or she considers necessary.
 - (3) An authorized officer shall exhibit his or her official identification card on demand by any person affected by the exercise or performance of any power, duty or function of such authorized officer under this Act.
23. During an inspection carried out under Article 22, the owner or other person in charge of the food business or any other person present at the food business:
- (a) may accompany the authorized officer;
 - (b) shall supply any information or documents requested by the authorized officer relating to installations, appliances, materials, procedures or other matters relevant to any inspection;
 - (c) shall permit the taking of samples and the gathering of evidence including photographs.
24. If an authorized officer has reasonable grounds for believing that an owner or person in charge of a food business is failing to comply

with this Act, he or she may serve an improvement notice on that owner or person in charge:

- (a) stating the authorized officer's grounds for believing that the Act is not being complied with;
- (b) specifying the measures which the authorized officer deems that the owner or person in charge must take in order to remedy the failures referred to in paragraph (a);
- (c) requiring the owner or person in charge to implement those measures, or measures which are at least equivalent to them, within the time period specified in the notice.

25. (1) Where it appears that any food at a food business is unfit for human consumption or is likely to cause harm or danger to human health, an authorized officer shall:
 - (a) seize and seal such food, and issue a notice to the owner or the person in charge of the food business that the food or any specified portion of it is temporarily not to be sold, removed, manipulated, tampered with or otherwise altered without the authorization of the authorized officer; or
 - (b) issue a written notice temporarily ordering the food removed to a specified place; or
 - (c) issue a written notice ordering the immediate destruction of the food.
- (2) Where any action is taken under sub-Article (1) because of a threat to human health, the authorized officer shall immediately notify the Authority which shall take action to notify other relevant governmental and nongovernmental actors so that all measures necessary to ensure public safety and the protection of consumers, including public warnings, recall orders, marketing restrictions, marketing bans or other appropriate measures, may be adopted.
- (3) As soon as practicable, and in any event within 14 days, an authorized officer acting under sub-Article (1)(a) or (b) shall review the situation at the affected food business to determine whether the circumstances that caused the notice no longer exist, and if the authorized officer:
 - (a) is so satisfied, he or she shall withdraw the notice, and where appropriate, allow the release of any food from the place where it is stored;

- (b) is not so satisfied, he or she may order that any such food be destroyed or disposed of so as to prevent its being used for human consumption, and shall supervise the destruction of such food.

PART V – IMPORT AND EXPORT

- 26. (1) No article of food shall be imported or otherwise brought into [insert country name] unless it is accompanied by the prescribed documents and unless it is offered up for inspection by the Authority at the port of entry.
- (2) The Minister on the advice of the Board may by regulation provide that certain articles of food shall not be imported into [insert country name] unless they have been produced or manufactured in accordance with any prescribed standards.

- 27. (1) An authorized officer may inspect any food imported into [insert country name] and, for the purposes of analysis or inspection thereof, take samples of any such food.
- (2) Where samples are taken under sub-Article (1), the authorized officer shall, in the presence of the owner or importer or any person in apparent control of the food, seal and mark them as prescribed.
- (3) Where a sample is taken pursuant to sub-Article (1), the consignment from which it was taken shall not be released by an authorized officer except upon production of an official analyst’s certificate to the effect that the food complies with the requirements of this Act.
- (4) The costs of any inspection, analysis and storage while analysis is being performed shall be borne by the importer.

- 28. (1) Subject to the provisions of sub-Article (2), the importation of any food which does not comply with the provisions of this Act is prohibited.
- (2) Where any article of food sought to be imported into [insert country name] would, if sold in [insert country name] constitute a contravention of this Act, the Authority may nonetheless permit its importation solely for the purpose of relabelling or reconditioning as prescribed.

- (3) In the event that any relabelling or reconditioning authorized under sub-Article (2) is not carried out within the prescribed time period, the importer shall export or destroy such food at his or her expense.
- (4) Where an importer fails to export or destroy imported food as required under sub-Article (3), the Authority may order the destruction of or destroy the imported food.
- (5) The Authority's decision to order the destruction of or to destroy food under sub-Article (4) shall not prevent the Government of [insert country name] from later recovering the costs of such destruction as a debt.

PART VI – OFFENCES AND PENALTIES

29.
 - (1) Any person who sells any food that:
 - (a) has in or upon it any poisonous or harmful substance;
 - (b) is not wholesome or is otherwise unfit for human consumption;
 - (c) is adulterated; or
 - (d) is injurious to human health;shall be guilty of an offence.
 - (2) In determining whether an article of food is injurious to human health, due regard shall be given not only to the probable effect of such food on the health of a person consuming it, but also to the probable cumulative effect of articles of substantially similar composition on the health of a person consuming such articles in ordinary quantities.
30.
 - (1) Any person who prepares or sells any food for which there is a standard prescribed shall be guilty of an offence unless the food complies with that standard.
 - (2) Any person who sells any food which bears or has attached to it, or is contained a package which bears or has attached to it, a name for a food for which there is a standard prescribed, shall be guilty of an offence unless the food complies with the standard prescribed for that food.
31.
 - (1) Any person who packs or labels any food in a manner which is false or misleading shall be guilty of an offence.

- (2) Any person who sells any food with a false or misleading label shall be guilty of an offence.
32. Any person who:
- (a) prepares, stores, handles or sells food under unsanitary conditions;
 - (b) imports, exports, produces, manufactures, prepares, stores or sells food which otherwise violates any provision of this Act;
 - (c) operates a food business without any licence required by this Act or by any other legislation in force in [insert country name];
 - (d) fails to comply with an order issued under Article 15 or 16;
 - (e) fails to establish and implement a traceability system in accordance with Article 18(1);
 - (f) fails to follow the applicable hygiene rules established under this Act;
 - (g) fails to ensure that all personnel of a food business follow prescribed procedures;
 - (h) fails to label food as prescribed under Article 20;
 - (i) fails to comply with an improvement notice issued under Article 24;
 - (j) tampers with any food samples taken under this Act;
 - (k) breaks any seal or alters any markings made by an authorized officer without permission;
 - (l) fails to provide access, samples or information to an authorized officer upon request;
 - (m) gives false information to an authorized officer;
 - (n) attempts to improperly influence an authorized officer in the exercise of his or her official functions under this Act;
 - (o) poses as an authorized officer;
- shall be guilty of an offence.
33. An authorized officer who:
- (a) seizes food for any reason other than those prescribed in this Act;
 - (b) discloses any information acquired in the course of exercising his or her official functions under this Act except where required to do so by his or her supervisor or by any court;

- (c) accepts any monetary or other benefit from a person affected by the exercise of official powers under this Act; shall be guilty of an offence.
34. Any person who, for the purpose of effecting or promoting the sale of any food, publishes or causes to be published an advertisement which is false or misleading, shall be guilty of an offence.
35. Where an offence under this Act which has been committed by a body corporate is proven to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of:
- (a) any director, manager or other similar officer of the body corporate; or
 - (b) any person who was purporting to act in the capacity of a director, manager or similar officer;
- that person as well as the body corporate shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.
36. (1) Any person who commits an offence under this Act shall be liable to summary prosecution, and upon conviction:
- (a) in the case of a first offence, to a fine not less than ___ or to imprisonment for a term not exceeding ___ or to both;
 - (b) in the case of a subsequent offence, to a fine not less than ___ or to imprisonment for a term not exceeding ___ or to both;
 - (c) where the offence is a continuing offence, to an additional fine of not less than ___ or imprisonment for ___ days for each day on which the offence continues.
- (2) Upon the conviction of any person for any offence under this Act, the court may, in addition to any other sentence imposed:
- (a) suspend or cancel any licence to operate a food business issued to the convicted person;
 - (b) declare any food, appliance, product, material, substance or other object in respect of which the offence has been committed or which was used in connection with the commission of the offence

forfeited to the state and disposed of as the court may direct.

37. (1) If the owner of a food business is convicted of an offence under this Act, the court before which he or she is convicted may by order impose a temporary or permanent prohibition:
- (a) on the use of a particular process or particular equipment at the food business; or
 - (b) on the use of the premises for the purposes of running a food business; or
 - (c) on the participation by the owner in the management of the food business with respect to which the offence was committed, or with respect to any food business in [insert country name].
- (2) A court shall cancel a temporary order issued under sub-Article (1) where an authorized officer certifies that the conditions which led to the issuance of the order are no longer in effect.

PART VII – MISCELLANEOUS

38. (1) Any person aggrieved by an action or decision of an authorized officer or an official analyst under this Act may appeal to the Board within the prescribed time period.
- (2) If the aggrieved person is not satisfied with the decision of the Board, he or she may, in accordance with the prescribed procedures, appeal to the Minister, whose decision shall be final.
39. No member of the Board, authorized officer, official analyst or other representative of the Authority shall be liable to suit or to prosecution in respect of anything done in good faith in the performance of his or her functions under this Act.
40. (1) In any proceedings under this Act, a certificate of analysis purporting to be signed by the director or head of an official laboratory or by an official analyst shall be accepted as prima facie evidence of the facts stated therein, provided that:

- (a) the party against whom it is produced may require the attendance of the official analyst who performed the analysis, for purpose of cross-examination;
 - (b) no such certificate shall be admissible in evidence unless the party intending to produce it has, before the trial, given the party against whom it is intended to be produced reasonable notice of such intention together with a copy of the certificate.
 - (2) Evidence that a package containing any food to which this Act applies bore a name, address or registered trademark of the food business or person by whom it was produced, manufactured or packed, shall be prima facie evidence that such food was produced, manufactured or packed, as the case may be, by that food business or person.
 - (3) Any substance commonly used for human consumption, if sold or offered, exposed or kept for sale, shall be presumed, until the contrary is proved, to have been sold or, as the case may be, to have been or to be intended for sale for human consumption.
 - (4) Any substance commonly used for human consumption which is found on premises used for the preparation, storage or sale of that substance, and any substance commonly used in the production or manufacture of articles for human consumption which is found on premises used for the preparation, storage or sale of those articles, shall be presumed, until the contrary is proved, to be intended for human consumption.
 - (5) Any substance capable of being used in the composition or preparation of any article commonly used for human consumption which is found on premises in which that substance is prepared shall, until the contrary is proved, be presumed to be intended for such use.
 - (6) Where any person demands any food by a name prescribed for a food for which there is a standard prescribed, he or she shall be deemed to have demanded food which complies with that standard.
41. (1) In any proceedings for an offence under this Act it shall be a defence for the accused to establish that he or she could

- not with reasonable diligence have ascertained that the sale of the food would contravene this Act.
- (2) It shall be a defence under Article 31 to prove that someone could not reasonably have ascertained that the packaging or labelling was false or misleading.
42. In any proceedings under Article 34:
- (a) it shall be up to the defendant to prove that he or she did not publish the advertisement or did not cause it to be published;
- (b) it shall be a defence for the defendant to prove either:
- (i) that he or she did not know or could not with reasonable diligence have ascertained that the advertisement was false or misleading; or
- (ii) that, being a person whose business it is to publish or arrange for the publication of advertisements, he or she received it in the ordinary course of business and did not make any material alterations to it.
43. (1) The Minister may, on the advice of the Board, make regulations for the purpose of carrying out the provisions of this Act.
- (2) Without prejudice to the generality of sub-Article (1), the Minister may by order make regulations providing for any of the following:
- (a) the control of the cultivation, production, manufacture, storage, transport, packing, packaging, labelling and sale of all types of food, including food that is organically produced, genetically modified, dietetic or intended for infants or other population groups;
- (b) the preparing, handling and serving of food;
- (c) the construction, inspection and maintenance of food businesses, including hotels, boarding houses, markets, grocery stores and businesses selling street food;
- (d) the places at which, and the conditions under which, animals are slaughtered for human consumption;
- (e) the places at which, and the conditions under which, poultry, fish products, dairy products and

- other foods of animal origin are produced, processed or packaged for sale;
- (f) the places at which, and the conditions under which, crops are produced for food;
 - (g) the importation and exportation of foods, including any documentation and inspections required;
 - (h) the procedures applicable for the issuance, suspension and cancellation of licences to operate a food business;
 - (i) the acceptable levels of food additives, environmental contaminants, veterinary drugs, pesticides and other residues or other chemical and microbiological contaminants in foods;
 - (j) the procedures to be followed by authorized officers, official analysts and official laboratories in the exercise of their functions under this Act;
 - (k) the disposal or destruction of unsafe food;
 - (l) the fees payable in respect of the inspection and analysis of food;
 - (m) the forms to be used for the purposes of this Act, including applications, licences, permits, improvement notices and receipts for articles seized;
 - (n) offences and penalties;
 - (o) any other matters deemed necessary to achieve the purposes of this Act.
44. (1) The following enactments are hereby repealed:
- (a) ...
 - (b) ...
- (2) Without prejudice to sub-Article (1), in the event of any conflict or inconsistency between the provisions of this Act and any other enactment in force in [insert country name], the provisions of this Act shall prevail.

II. VERSION 2 (MULTIPLE AGENCY SYSTEM)

THE FOOD ACT OF 20__

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THE FOOD ACT OF 20_

AN ACT to control the manufacture, sale, import and export of food, to guarantee safe and adequate food and to provide for related matters.

PART I – PRELIMINARY

1. This Act may be cited as the Food Act.
2. In this Act, unless the context otherwise requires:

additive means any substance not normally consumed as food by itself and not normally used as a typical ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the production, manufacture, preparation, treatment, packing, packaging, transport or storage of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such food, but does not include contaminants or substances added to food for the purpose of maintaining or improving nutritional qualities;

adulterate means to make impure in order to give a false impression or value or to hide defects, by the addition of a foreign, inferior or inert substance to food, or by the exclusion or removal of a valuable or necessary ingredient of food;

advertisement includes any representation – written, pictorial, visual or otherwise – made for the purpose of promoting directly or indirectly the sale or disposal of any food or any substance represented as food;

appliance means the whole or any part of any implement, machine, instrument, apparatus or other object used or capable of being used in or in connection with the production, manufacture, treatment, packing, packaging, labelling, transport, handling, serving or storage of any food;

authorized officer means a person authorized and qualified to act as such under Article 8(1)(a) of this Act;

Board means the National Food Board established in Article 9 of this Act;

Committee means the Scientific Committee established in Article 13 of this Act;

contaminant means any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination, but does not include insect fragments, rodent hairs or other extraneous matter;

contamination means the introduction or occurrence of a contaminant in food;

export means to export from [insert country name] by any means, and **exportation** has a corresponding meaning;

exporter includes any person who, whether as owner, consignor, consignee, agent or broker, is in possession of or in any way entitled to the custody or control of any food exported from [insert country name];

food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the production, manufacture, preparation or treatment of food, but does not include cosmetics or tobacco or substances used only as drugs;

food business means any business, however small, where production, manufacture, preparation, treatment, packing, packaging, transport, handling, serving, storage or sale in relation to food is carried out, whether for profit or not;

food production chain means all stages of production from primary production of food to food handling and food sale;

food safety means the assurance that food will not cause harm to the consumer when it is prepared or eaten according to its intended use;

import means to import into [insert country name] by any means, and **importation** has a corresponding meaning;

importer includes any person who, whether as owner, consignor, consignee, agent or broker, is in possession of or in any way entitled to the custody or control of any food imported into [insert country name];

improvement notice means a notice served under Article 24 of this Act;

ingredient means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product although possibly in a modified form;

label means any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food or its package;

manufacture includes processing and preservation and other related activities;

Minister means the Minister responsible for the administration, implementation and enforcement of this Act;

official analyst means a person authorized and qualified to act as such under Article 8(1)(b) of this Act;

official laboratory means a laboratory designated or approved as such under Article 8(2) of this Act;

OIE means the World Organisation for Animal Health;

owner or person in charge, in relation to any thing, includes any person having for the time being the possession, custody or control thereof;

package includes anything in which food is wholly or partially placed or wrapped and includes any basket, container, pail, tray or receptacle of any kind whether open or closed;

person includes a natural person or a body corporate;

premises includes any building, tent or other structure, permanent or otherwise, together with the land on which the same is situated and any adjoining land employed in connection therewith, used for the production, manufacture, packing, packaging, transport, handling, serving, storage or sale of any food;

prescribed means prescribed by this Act or by any regulations made hereunder;

production means the cultivation, rearing or growing of food including harvesting, milking and farmed animal production prior to slaughter;

sell includes to offer, advertise, keep, store, display, transmit, consign, convey or deliver for sale, or to exchange or to dispose of to any person in any manner whether for a consideration or otherwise, and **sold**, **selling** and **sale** shall have corresponding meanings;

stages of production includes import, storage, transport and sale;

street food means ready-to-eat food prepared or sold in streets and other public places;

substance includes any solid, liquid or gaseous materials;

this Act means this Act and any regulations, orders or notices made under it;

traceability means the ability to discern and identify, through all stages of production, manufacture and distribution, the origin and the final destination of a food-producing animal, food or substance intended to be or expected to be incorporated into a food;

treated means coloured, stained, powdered, polished, coated, stained, mixed, preserved, flavoured, diluted or thickened with any substance, and **treat** and **treatment** shall have corresponding meanings;

unsanitary conditions means such conditions or circumstances as might cause contamination of food or render the same injurious or dangerous to health;

vehicle means any vessel, aircraft, train, conveyance, cart, container, animal or other thing that can transport food from one place to another;

wholesome, in relation to food, means to be natural, clean, safe and not adulterated.

PART II – ADMINISTRATION

3. The Ministry shall be responsible for the implementation and enforcement of this Act, and shall have all powers necessary for the performance of its functions under this Act.
4. The principal functions of the Ministry in relation to the implementation and enforcement of this Act shall be to:
 - (a) take the lead in coordinating and harmonizing food control activities in [insert country name] at all stages of production, manufacture and distribution;
 - (b) prepare and amend regulations, orders, standards, codes of practice and notices under this Act;
 - (c) consult widely with all sectors of the food chain in carrying out its activities under paragraphs (a) and (b) of this Article;
 - (d) promote consumer education regarding food safety;
 - (e) carry out any other matters in connection with or reasonably incidental to the foregoing.
5. The Minister may ban or set limits on the presence of additives, contaminants and residues in food or animal feed.

6. Where the Minister determines that food of any specified class or description if imported or cultivated, taken or harvested from a specific area of [insert country name] may be dangerous or injurious to persons consuming that food, he or she may by order prohibit the importation, cultivation, taking, harvesting or obtaining of that food.
7. In the case of emergency or sudden necessity, the Minister may by order:
 - (a) totally prohibit the production, manufacture, preparation or sale of any food of the class specified by the Minister;
 - (b) impose conditions on the production, manufacture, preparation or sale of any food of that class;
 - (c) cause any food to be tested or examined as prescribed;
 - (d) cause any food to be held or isolated in any place and prohibit the removal of food from that place for such time as the Minister may prescribe;
 - (e) cause any food to be destroyed or otherwise disposed of as the Minister sees fit.
8.
 - (1) The Minister may from time to time appoint or designate any person with the prescribed qualifications as:
 - (a) an authorized officer to carry out the functions assigned to such officers under this Act;
 - (b) an official analyst for purposes of enforcement of this Act;
 - (c) a member of the Scientific Committee established in Article 13.
 - (2) The Minister may from time to time designate any laboratory as an official laboratory for purposes of enforcement of this Act.
9.
 - (1) There is hereby established a National Food Board which shall be responsible for advising the Minister on all matters relating to food in [insert country name].
 - (2) Without prejudice to sub-Article (1), the Board shall:
 - (a) take all reasonable steps to ensure that all:
 - (i) food produced in [insert country name], whether for domestic consumption or export; and

- (ii) food distributed or marketed in [insert country name], whatever its origin; meets the highest standards of food safety.
- (b) advise the Minister on food control and food safety matters, including the production, manufacture, import, export, labelling and sale of food, on consumer protection and on emerging food control issues including street food;
- (c) prevent and protect against fraud in connection with the sale of food;
- (d) formulate strategies and policies on food, nutrition and food security, including procedures for emergency response, and monitor their implementation;
- (e) propose and assist in the preparation and amendment of regulations, orders, standards, codes of practice and notices under this Act;
- (f) encourage and promote research on food matters within [insert country name];
- (g) provide advice, information or assistance to any public authority in relation to food control, food safety and consumer protection;
- (h) obtain, compile and keep under review information concerning food control, food safety, food trade and nutrition in [insert country name];
- (i) examine complaints and objections lodged in respect of decisions made or official actions taken under this Act;
- (j) distribute information received from the Codex Alimentarius Commission, the OIE or other international or regional standard-setting bodies and coordinate the circulation of draft standards within [insert country name] and the collection of comments thereon from interested governmental and nongovernmental actors;
- (k) advise on [insert country name]'s participation in the work of the Codex Alimentarius Commission and the OIE and their subsidiary bodies, including representation at meetings;
- (l) promote consumer education regarding food safety and nutrition;

- (m) on its own initiative, discuss any matter connected with food in [insert country name], and report to the Minister on its discussions;
 - (n) perform all other functions assigned to it by the Minister.

- 10.
 - (1) There is hereby established a secretariat responsible for supporting and facilitating the day-to-day activities of the Board, including meetings and correspondence, headed by a Secretary appointed by the Minister on the advice of the Board.
 - (2) The terms and conditions of the employment of the Secretary and such staff as the Minister may appoint shall be determined by the Board with the approval of the Minister.

- 11.
 - (1) The Board shall consist of one representative of each of the following, selected according to their qualifications and appointed by the Minister:
 - (a) ministry responsible for agriculture;
 - (b) ministry responsible for environment;
 - (c) ministry responsible for fisheries;
 - (d) ministry responsible for health;
 - (e) ministry responsible for local government;
 - (f) ministry responsible for tourism;
 - (g) ministry responsible for trade;
 - (h) customs department;
 - (i) national standards organization;
 - (j) a consumer association.
 - (2) Where the qualifications of the appointed members do not reflect all of the following fields:
 - (a) public health and epidemiology;
 - (b) food science and technology;
 - (c) food production;
 - (d) agricultural science and animal health;
 - (e) food marketing and trade;
 - (f) human nutrition;
 - (g) legal or administrative affairs;the Minister may appoint up to three additional members to ensure that the Board reflects the maximum of such expertise.

- (3) Before appointing any person to be a member of the Board, the Minister shall consider whether he or she has any financial or other interest which in the Minister's opinion is likely to prejudice the exercise of that member's duties.
 - (4) Members shall hold office for three years and shall be subject to re-appointment for one additional three-year term. After a break of at least three years, they are then eligible for further reappointment in accordance with this Article.
 - (5) Members of the Board shall be paid a sitting allowance in consonance with the rates approved for public officers.
 - (6) The Minister may remove a member for misconduct, for infirmity of body or mind or for having been convicted of a crime.
12.
 - (1) Members of the Board shall elect a Chair from among their membership at the first meeting of each year.
 - (2) At least one half the Board members present at any particular meeting shall constitute a quorum for purposes of transacting business.
 - (3) The Board may make provision for the conduct of its meetings and the procedures to be followed at such meetings but shall meet at least four times per year.
 - (4) The Board shall submit an annual report outlining its activities to Parliament and shall provide a copy of such report on request of any member of the public.
 - (5) The Board may appoint such subcommittees as it deems necessary, consisting of members, nonmembers or both, to assist it in the performance of its functions, although members of such subcommittees shall have no voting or remuneration rights arising from their participation.
 - (6) Members of the public may attend all meetings of the Board although they may only participate where so authorized by the Chair, and in no case may they vote.
13.
 - (1) The Minister shall, on the advice of the Board, appoint an independent Scientific Committee to carry out food safety risk assessments.
 - (2) The Committee shall be responsible for:
 - (a) evaluating, in response to official requests or on its own initiative, physical, chemical or biological risks

- to human health arising throughout the food production chain;
 - (b) advising the Minister or the Authority on the appropriate measures to be taken to protect consumer health;
 - (c) providing inputs into or developing proposed regulations or rules on subject matters within its mandate.
- (3) In carrying out its functions, the Committee shall take into account:
- (a) the latest scientific research;
 - (b) information regarding procedures, methods and means of production;
 - (c) the results of sampling and analysis;
 - (d) any other relevant data.
- (4) The Committee shall cooperate fully with the Authority, exchanging advice and information regarding risks, risk factors and risk perception, and in particular shall explain its risk assessments and the basis of its decisions.
- (5) The appointment, terms of office and conditions of service of Committee members shall be determined by the Minister on the advice of the Board.

PART III – GENERAL PROVISIONS

14. (1) All premises including warehouses used for the preparation, sale, exposure or storage of food shall be constructed as prescribed.
- (2) All food businesses shall apply for a licence in accordance with the prescribed procedures.
15. (1) Food businesses shall establish and implement a system enabling them to identify any person:
- (a) who supplied; or
 - (b) to whom they supplied;
- a food-producing animal, food or substance intended to be or expected to be incorporated into a food.
- (2) Upon request of the Authority, food businesses shall make available all information collected under the system established under sub-Article (1).

16. Food businesses and their personnel shall follow all applicable hygiene rules established under this Act.
17. (1) Every package of food intended for sale in [insert country name] shall bear a label which:
- (a) permits its traceability;
 - (b) sets out such particulars as may be prescribed.
- (2) Where food other than packaged food is displayed for sale, it shall be labelled as prescribed.

PART IV – INSPECTIONS

18. Inspections carried out under this Act may have as their object:
- (a) food businesses and their surroundings and installations, as well as means of transportation, equipment and materials;
 - (b) food ingredients, additives, disinfectants and any substances or processes used in the production, manufacturing or handling of food;
 - (c) personnel employed at the food business;
 - (d) packaging material;
 - (e) cleaning, disinfecting and maintenance at the food business;
 - (f) labelling.
19. (1) Except for a dwelling place, an authorized officer may, without a warrant:
- (a) enter any food business or other premises in which any food is being, or is suspected of being, produced, manufactured, treated, graded, packed, packaged, labelled, stored, handled, prepared, served or sold, or in which any other operation or activity in connection with food is being, or suspected of being, carried out, and may, for the purpose of determining whether this Act is being violated:
 - (i) inspect or search such premises, and examine any food, appliance, product, material, object or substance which is being, or is suspected of being, used or destined for use in connection with the production, manufacture, treatment, grading, packing, packaging, labelling,

- storage, handling, preparing, serving or sale of any food;
- (ii) demand any information regarding any such food, appliance, product, material, object or substance from the owner or person in charge of such premises;
 - (iii) weigh, count, measure, mark, open and take samples in the prescribed manner of any food, product, material, object or substance or its package or container, or lock, secure, seal or close any door giving access to it;
 - (iv) examine, make copies of or take extracts from any book, statement or other document found at such premises which refers to or is suspected of referring to such food, and demand from the owner or any person in charge of the premises an explanation of any entry in it;
 - (v) inspect any operation or process carried out on such premises, and demand any information regarding such operation or process from the owner or person in charge of such premises or from any person carrying out such operation or process;
 - (vi) read any values recorded by measuring instruments installed on the premises or by instruments in the possession of the authorized officer;
 - (vii) take any photographs;
 - (viii) seize any food, appliance, product, material, object, substance, book, statement or document which appears to provide proof of a contravention of any provision of this Act, providing a signed receipt in the prescribed form which shall be countersigned immediately by the owner or other person in charge of such premises or object.

- (b) stop and search any vehicle in which food is being or is suspected of being transported, produced, manufactured, treated, graded, packed, packaged, stored, handled, prepared, served or sold or in which any other operation or activity in connection with food is being or is suspected of being carried out;
 - (c) stop, search and detain any person who is suspected of committing an offence under this Act.
 - (2) An authorized officer exercising his or her authority under this Article may request the presence and assistance of such law enforcement personnel as he or she considers necessary.
 - (3) An authorized officer shall exhibit his or her official identification card on demand by any person affected by the exercise or performance of any power, duty or function of such authorized officer under this Act.
- 20. During an inspection carried out under Article 19, the owner or other person in charge of the food business or any other person present at the food business:
 - (a) may accompany the authorized officer;
 - (b) shall supply any information or documents requested by the authorized officer relating to installations, appliances, materials, procedures or other matters relevant to any inspection;
 - (c) shall permit the taking of samples and the gathering of evidence including photographs.
- 21. If an authorized officer has reasonable grounds for believing that an owner or person in charge of a food business is failing to comply with this Act, he or she may serve an improvement notice on that owner or person in charge:
 - (a) stating the authorized officer's grounds for believing that the Act is not being complied with;
 - (b) specifying the measures which the authorized officer deems that the owner or person in charge must take in order to remedy the failures referred to in paragraph (a);
 - (c) requiring the owner or person in charge to implement those measures, or measures which are at least equivalent to them, within the time period specified in the notice.

22. (1) Where it appears that any food at a food business is unfit for human consumption or is likely to cause harm or danger to human health, an authorized officer shall:
- (a) seize and seal such food, and issue a notice to the owner or the person in charge of the food business that the food or any specified portion of it is temporarily not to be sold, removed, manipulated, tampered with or otherwise altered without the authorization of the authorized officer; or
 - (b) issue a written notice temporarily ordering the food removed to a specified place; or
 - (c) issue a written notice ordering the immediate destruction of the food.
- (2) Where any action is taken under sub-Article (1) because of a threat to human health, the authorized officer shall immediately notify the Ministry which shall take action to notify other relevant governmental and nongovernmental actors so that all measures necessary to ensure public safety and the protection of consumers, including public warnings, recall orders, marketing restrictions, marketing bans or other appropriate measures, may be adopted.
- (3) As soon as practicable, and in any event within 14 days, an authorized officer acting under sub-Article (1)(a) or (b) shall review the situation at the affected food business to determine whether the circumstances that caused the notice no longer exist, and if the authorized officer:
- (a) is so satisfied, he or she shall withdraw the notice, and where appropriate, allow the release of any food from the place where it is stored;
 - (b) is not so satisfied, he or she may order that any such food be destroyed or disposed of so as to prevent its being used for human consumption, and shall supervise the destruction of such food.

PART V – IMPORT AND EXPORT

23. (1) No article of food shall be imported or otherwise brought into [insert country name] unless it is accompanied by the prescribed documents and unless it is offered up for inspection by the Ministry at the port of entry.

- (2) The Minister on the advice of the Board may by regulation provide that certain articles of food shall not be imported into [insert country name] unless they have been produced or manufactured in accordance with any prescribed standards.
24.
 - (1) An authorized officer may inspect any food imported into [insert country name] and, for the purposes of analysis or inspection thereof, take samples of any such food.
 - (2) Where samples are taken under sub-Article (1), the authorized officer shall, in the presence of the owner or importer or any person in apparent control of the food, seal and mark them as prescribed.
 - (3) Where a sample is taken pursuant to sub-Article (1), the consignment from which it was taken shall not be released by an authorized officer except upon production of an official analyst's certificate to the effect that the food complies with the requirements of this Act.
 - (4) The costs of any inspection, analysis and storage while analysis is being performed shall be borne by the importer.
25.
 - (1) Subject to the provisions of sub-Article (2), the importation of any food which does not comply with the provisions of this Act is prohibited.
 - (2) Where any article of food sought to be imported into [insert country name] would, if sold in [insert country name] constitute a contravention of this Act, the Ministry may nonetheless permit its importation solely for the purpose of relabelling or reconditioning as prescribed.
 - (3) In the event that any relabelling or reconditioning authorized under sub-Article (2) is not carried out within the prescribed time period, the importer shall export or destroy such food at his or her expense.
 - (4) Where an importer fails to export or destroy imported food as required under sub-Article (3), the Minister may order the destruction of or destroy the imported food.
 - (5) The Minister's decision to order the destruction of or to destroy food under sub-Article (4) shall not prevent the Government of [insert country name] from later recovering the costs of such destruction as a debt.

PART VI – OFFENCES AND PENALTIES

26. (1) Any person who sells any food that:
- (a) has in or upon it any poisonous or harmful substance;
 - (b) is not wholesome or is otherwise unfit for human consumption;
 - (c) is adulterated; or
 - (d) is injurious to human health;
- shall be guilty of an offence.
- (2) In determining whether an article of food is injurious to human health, due regard shall be given not only to the probable effect of such food on the health of a person consuming it, but also to the probable cumulative effect of articles of substantially similar composition on the health of a person consuming such articles in ordinary quantities.
27. (1) Any person who prepares or sells any food for which there is a standard prescribed shall be guilty of an offence unless the food complies with that standard.
- (2) Any person who sells any food which bears or has attached to it, or is contained a package which bears or has attached to it, a name for a food for which there is a standard prescribed, shall be guilty of an offence unless the food complies with the standard prescribed for that food.
28. (1) Any person who packs or labels any food in a manner which is false or misleading shall be guilty of an offence.
- (2) Any person who sells any food with a false or misleading label shall be guilty of an offence.
29. Any person who:
- (a) prepares, stores, handles or sells food under unsanitary conditions;
 - (b) imports, exports, produces, manufactures, prepares, stores or sells food which otherwise violates any provision of this Act;
 - (c) fails to comply with an order issued under Article 6 or 7;
 - (d) operates a food business without any licence required by this Act or by any other legislation in force in [insert country name];

- (e) fails to establish and implement a traceability system in accordance with Article 15(1);
 - (f) fails to follow the applicable hygiene rules established under this Act;
 - (g) fails to ensure that all personnel of a food business follow prescribed procedures;
 - (h) fails to label food as prescribed under Article 17;
 - (i) fails to comply with an improvement notice issued under Article 21;
 - (j) tampers with any food samples taken under this Act;
 - (k) breaks any seal or alters any markings made by an authorized officer without permission;
 - (l) fails to provide access, samples or information to an authorized officer upon request;
 - (m) gives false or misleading information to an authorized officer;
 - (n) attempts to improperly influence an authorized officer in the exercise of his or her official functions under this Act;
 - (o) poses as an authorized officer;
- shall be guilty of an offence.
30. Any authorized officer who:
- (a) seizes food for any reason other than those prescribed in this Act;
 - (b) discloses any information acquired in the course of exercising his or her official functions under this Act except where required to do so by his or her supervisor or by any court;
 - (c) accepts any monetary or other benefit from a person affected by the exercise of official powers under this Act;
- shall be guilty of an offence.
31. Any person who, for the purpose of effecting or promoting the sale of any food, publishes or causes to be published an advertisement which is false or misleading, shall be guilty of an offence.
32. Where an offence under this Act which has been committed by a body corporate is proven to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of:
- (a) any director, manager or other similar officer of the body corporate; or

- (b) any person who was purporting to act in the capacity of a director, manager or similar officer;
that person as well as the body corporate shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly.
- 33.
- (1) Any person who commits an offence under this Act shall be liable to summary prosecution, and upon conviction:
 - (a) in the case of a first offence, to a fine not less than ___ or to imprisonment for a term not exceeding ___ or to both;
 - (b) in the case of a subsequent offence, to a fine not less than ___ or to imprisonment for a term not exceeding ___ or to both;
 - (c) where the offence is a continuing offence, to an additional fine of not less than ___ or imprisonment for ___ days for each day on which the offence continues.
 - (2) Upon the conviction of any person for any offence under this Act, the court may, in addition to any other sentence imposed:
 - (a) suspend or cancel any licence to operate a food business issued to the convicted person;
 - (b) declare any food, appliance, product, material, substance or other object in respect of which the offence has been committed or which was used in connection with the commission of the offence forfeited to the state and disposed of as the court may direct.
- 34.
- (1) If the owner of a food business is convicted of an offence under this Act, the court before which he or she is convicted may by order impose a temporary or permanent prohibition:
 - (a) on the use of a particular process or particular equipment at the food business; or
 - (b) on the use of the premises for the purposes of running a food business; or
 - (c) on the participation by the owner in the management of the food business with respect to

- which the offence was committed, or with respect to any food business in [insert country name].
- (2) A court shall cancel a temporary order issued under sub-Article (1) where an authorized officer certifies that the conditions which led to the issuance of the order are no longer in effect.

PART VII – MISCELLANEOUS

35. (1) Any person aggrieved by an action or decision of an authorized officer or an official analyst under this Act may appeal to the Board within the prescribed time period.
- (2) If the aggrieved person is not satisfied with the decision of the Board, he or she may, in accordance with the prescribed procedures, appeal to the Minister, whose decision shall be final.
36. No member of the Board, authorized officer or official analyst shall be liable to suit or to prosecution in respect of anything done in good faith in the performance of his or her functions under this Act.
37. (1) In any proceedings under this Act, a certificate of analysis purporting to be signed by the director or head of an official laboratory or by an official analyst shall be accepted as prima facie evidence of the facts stated therein, provided that:
- (a) the party against whom it is produced may require the attendance of the official analyst who performed the analysis, for purpose of cross-examination;
- (b) no such certificate shall be admissible in evidence unless the party intending to produce it has, before the trial, given the party against whom it is intended to be produced reasonable notice of such intention together with a copy of the certificate.
- (2) Evidence that a package containing any food to which this Act applies bore a name, address or registered trademark of the food business or person by whom it was produced, manufactured or packed, shall be prima facie evidence that such food was produced, manufactured or packed, as the case may be, by that food business or person.

- (3) Any substance commonly used for human consumption, if sold or offered, exposed or kept for sale, shall be presumed, until the contrary is proved, to have been sold or as the case may be, to have been or to be intended for sale for human consumption.
 - (4) Any substance commonly used for human consumption which is found on premises used for the preparation, storage or sale of that substance, and any substance commonly used in the production or manufacture of articles for human consumption which is found on premises used for the preparation, storage or sale of those articles, shall be presumed, until the contrary is proved, to be intended for human consumption.
 - (5) Any substance capable of being used in the composition or preparation of any article commonly used for human consumption which is found on premises in which that substance is prepared shall, until the contrary is proved, be presumed to be intended for such use.
 - (6) Where any person demands any food by a name prescribed for a food for which there is a standard prescribed, he or she shall be deemed to have demanded food which complies with that standard.
- 38.
- (1) In any proceedings for an offence under this Act it shall be a defence for the accused to establish that he or she could not with reasonable diligence have ascertained that the sale of the food would contravene this Act.
 - (2) It shall be a defence under Article 28 to prove that someone could not reasonably have ascertained that the packaging or labelling was false or misleading.
39. In any proceedings under Article 31:
- (a) it shall be up to the defendant to prove that he or she did not publish the advertisement or did not cause it to be published;
 - (b) it shall be a defence for the defendant to prove either:
 - (i) that he or she did not know or could not with reasonable diligence have ascertained that the advertisement was false or misleading; or
 - (ii) that, being a person whose business it is to publish or arrange for the publication of advertisements, he

or she received it in the ordinary course of business and did not make any material alterations to it.

40. (1) The Minister may, on the advice of the Board, make regulations for the purpose of carrying out the provisions of this Act.
- (2) Without prejudice to the generality of sub-Article (1), the Minister may by order make regulations providing for any of the following:
- (a) the control of the cultivation, production, manufacture, storage, transport, packing, packaging, labelling and sale of all types of food, including food that is organically produced, genetically modified, dietetic or intended for infants or other population groups;
 - (b) the preparing, handling and serving of food;
 - (c) the construction, inspection and maintenance of food businesses, including hotels, boarding houses, markets, grocery stores and businesses selling street food;
 - (d) the places at which, and the conditions under which, animals are slaughtered for human consumption;
 - (e) the places at which, and the conditions under which, poultry, fish products, dairy products and other foods of animal origin are produced, processed or packaged for sale;
 - (f) the places at which, and the conditions under which, crops are produced for food;
 - (g) the importation and exportation of foods, including any documentation and inspections required;
 - (h) the procedures applicable for the issuance, suspension and cancellation of licences to operate a food business;
 - (i) the acceptable levels of food additives, environmental contaminants, veterinary drugs, pesticides and other residues or other chemical and microbiological contaminants in foods;
 - (j) the procedures to be followed by authorized officers, official analysts and official laboratories in the exercise of their functions under this Act;

- (k) the disposal or destruction of unsafe food;
 - (l) the fees payable in respect of the inspection and analysis of food;
 - (m) the forms to be used for the purposes of this Act, including applications, licences, permits, improvement notices and receipts for articles seized;
 - (n) offences and penalties;
 - (o) any other matters deemed necessary to achieve the purposes of this Act.
41. (1) The following enactments are hereby repealed:
- (a) ...
 - (b) ...
- (2) Without prejudice to sub-Article (1), in the event of any conflict or inconsistency between the provisions of this Act and any other enactment in force in [insert country name], the provisions of this Act shall prevail.

III. VERSION 3 (INTEGRATED SYSTEM)

THE FOOD ACT OF 20__

ARRANGEMENT OF SECTIONS

PART I – PRELIMINARY

Section

1. Title
2. Interpretation

PART II – ADMINISTRATION

3. Establishment of Food Control Authority
4. Functions of Authority
5. Powers of Authority related to coordination
6. Powers of Authority related to information collection
7. Budget and funds of Authority
8. Establishment of Food Control Board
9. Executive Director
10. Secretariat
11. Membership of the Board
12. Functioning of the Board
13. Minister's reserve powers
14. Scientific Committee

PART III – OFFENCES AND PENALTIES

15. General offences
16. Offences by representatives of the Authority
17. Penalties

PART IV – MISCELLANEOUS

18. Good faith defence
19. Regulations
20. Savings and repeal

THE FOOD ACT OF 20__

AN ACT to coordinate food safety activities, to guarantee safe and adequate food and to provide for related matters.

PART I – PRELIMINARY

1. This Act may be cited as the Food Act.
2. In this Act, unless the context otherwise requires:

Authority means the Food Control Authority established in Article 3 of this Act;

Board means the Board of the Authority established in Article 8 of this Act;

Committee means the Scientific Committee established in Article 14 of this Act;

enforcement authority means a Ministry, Department, agency or other organism responsible for enforcing legislation relevant to food control, food safety and food trade in [insert country name];

Executive Director means the Executive Director of the Authority;

food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the production, manufacture, preparation or treatment of food, but does not include cosmetics or tobacco or substances used only as drugs;

food business means any business, however small, where production, manufacture, preparation, treatment, packing, packaging, transport, handling, serving, storage or sale in relation to food is carried out, whether for profit or not;

food production chain means all stages of production from primary production of food to food handling and food sale;

food safety means the assurance that food will not cause harm to the consumer when it is prepared or eaten according to its intended use;

manufacture includes processing and preservation and other related activities;

Minister means the Minister responsible for the administration, implementation and enforcement of this Act;

OIE means the World Organisation for Animal Health;

person includes a natural person or a body corporate;

premises includes any building, tent or other structure, permanent or otherwise, together with the land on which the same is situated and any adjoining land employed in connection therewith, used for the production, manufacture, packing, packaging, transport, handling, serving, storage or sale of any food;

prescribed means prescribed by this Act or by any regulations made hereunder;

production means the cultivation, rearing or growing of food including harvesting, milking and farmed animal production prior to slaughter;

street food means ready-to-eat food prepared or sold in streets and other public places;

this Act means this Act and any regulations, orders or notices made under it.

PART II – ADMINISTRATION

3. (1) There is hereby established the Food Control Authority of [insert country name].
(2) The Authority shall, subject to this Act and subject to the overall authority of the Minister, be independent in the exercise of its functions and shall have all such powers as are necessary for the performance of its functions under this Act.

4. The principal functions of the Authority shall be to:
 - (a) take the lead in coordinating and harmonizing food control activities in [insert country name] at all stages of production, manufacture and distribution;
 - (b) monitoring the performance of enforcement authorities in enforcing the legislation for which they are responsible;
 - (c) formulate strategies and policies on food, nutrition and food security, including procedures for emergency response, and monitor their implementation;
 - (d) encourage and promote research on food matters within [insert country name];
 - (e) prepare and amend regulations, orders, standards, codes of practice and notices under this Act;
 - (f) consult widely with all sectors of the food chain in carrying out its activities under paragraphs (a)-(e) of this Article;

- (g) provide advice, information or assistance to any public authority in relation to food control, food safety and food trade;
 - (h) obtain, compile and keep under review information concerning food control, food safety, food trade and nutrition in [insert country name];
 - (i) promote consumer education regarding food safety and nutrition;
 - (j) carry out any other matters in connection with or reasonably incidental to the foregoing.
5. For the purpose of performing its functions under paragraphs (a) and (b) of Article 4, the Authority may carry out any or all of the following activities:
- (a) setting standards of performance whether for enforcement authorities generally or for particular authorities in relation to the enforcement of any relevant legislation;
 - (b) seeking and collecting information from any member, officer or employee of the relevant enforcement authority;
 - (c) reporting to any enforcement authority on its performance in the enforcement of legislation for which it is responsible;
 - (d) providing guidance to any enforcement authority as to actions which the Authority considers would improve its performance regard to the enforcement referred to in paragraph (c).
6. For the purpose of performing its function under paragraph (g) of Article 4, the Authority may carry out any or all of the following activities:
- (a) monitor developments in science, technology and other relevant fields of knowledge including nutrition, disease and the environment;
 - (b) perform observations or arrange with other persons for observations to be performed with a view to obtaining information about any aspect of the production or supply of food, including information about:
 - (i) food premises, food businesses or commercial operations being carried out with respect to food, food sources or packaging;
 - (ii) agricultural premises, agricultural businesses or agricultural activities.

7. In addition to an annual budgetary allocation of Parliament, funds of the Authority shall include such moneys or other assets as may accrue to or vest in the Authority by way of grants, subsidies, donations or gifts.
8.
 - (1) There shall be a Board of the Authority to be known as the Food Control Board.
 - (2) Without prejudice to sub-Article (1), the Board shall:
 - (a) advise the Minister on food control and food safety matters, including the production, manufacture, import, export, labelling and sale of food, on consumer protection and on emerging food control issues including street food;
 - (b) exercise oversight responsibility for the performance of the functions of the Authority;
 - (c) provide assistance and advice on the formulation, review and implementation of food policy, including procedures for emergency response;
 - (d) propose and assist in the preparation and amendment of regulations, orders, standards, codes of practice and notices under this Act;
 - (e) distribute information received from the Codex Alimentarius Commission, the OIE or other international or regional standard-setting bodies and coordinate the circulation of draft standards within [insert country name] and the collection of comments thereon from interested governmental and nongovernmental actors;
 - (f) advise on [insert country name]'s participation in the work of the Codex Alimentarius Commission and the OIE and their subsidiary bodies, including representation at meetings;
 - (g) promote consumer education regarding food safety and nutrition;
 - (h) on its own initiative, discuss any matter connected with food in [insert country name], and report to the Minister on its discussions;
 - (i) perform all other functions assigned to it by this Act or by the Minister.

9.
 - (1) The Minister, on the advice of the Board, shall appoint an Executive Director to function as chief executive officer of the Authority, responsible for ensuring that the activities of the Authority are carried out efficiently and effectively.
 - (2) The terms and conditions of the employment of the Executive Director shall be determined by the Board on the approval of the Minister.
 - (3) The Executive Director shall carry on, manage and generally control the administration and business of the Authority and perform such other functions as may be assigned by this Act or by the Board.
 - (4) The Executive Director shall not hold any other office or position of profit or carry on any other business without the consent of the Board.

10.
 - (1) There is hereby established a secretariat responsible for supporting and facilitating the day-to-day activities of the Board, including meetings and correspondence, headed by a Secretary appointed by the Minister on the advice of the Board.
 - (2) The terms and conditions of the employment of the Secretary and such staff of the secretariat as the Minister may appoint shall be determined by the Board with the approval of the Minister.

11.
 - (1) The Board shall consist of the following members, selected according to their qualifications and appointed by the Minister:
 - (a) the Executive Director;
 - (b) one representative of each of the following:
 - (i) ministry responsible for agriculture;
 - (ii) ministry responsible for environment;
 - (iii) ministry responsible for fisheries;
 - (iv) ministry responsible for health;
 - (v) ministry responsible for local government;
 - (vi) ministry responsible for tourism;
 - (vii) ministry responsible for trade;
 - (viii) customs department;
 - (ix) national standards organization;
 - (x) a consumer association.

- (2) Where the qualifications of the appointed members do not reflect all of the following fields:
 - (a) public health and epidemiology;
 - (b) food science and technology;
 - (c) food production;
 - (d) agricultural science and animal health;
 - (e) food marketing and trade;
 - (f) human nutrition;
 - (g) legal or administrative affairs;the Minister may appoint up to three additional members to ensure that the Board reflects the maximum of such expertise.
 - (3) Before appointing any person to be a member of the Board, the Minister shall consider whether he or she has any financial or other interest which in the Minister's opinion is likely to prejudice the exercise of that member's duties.
 - (4) The Chair and members of the Board shall hold office for three years and shall be subject to re-appointment for one additional three-year term. After a break of at least three years, they are then eligible for further reappointment in accordance with this Article.
 - (5) Members of the Board shall be paid a sitting allowance in consonance with the rates approved for public officers.
 - (6) The Minister may remove a member for misconduct, for infirmity of body or mind or for having been convicted of a crime.
- 12.
- (1) Members of the Board shall elect a Chair from among their membership at the first meeting of each year.
 - (2) At least one half the Board members present at any particular meeting shall constitute a quorum for purposes of transacting business.
 - (3) The Board may make provision for the conduct of its meetings and the procedures to be followed at such meetings but shall meet at least four times per year.
 - (4) The Board shall submit an annual report outlining its activities to Parliament and shall provide a copy of such report on request of any member of the public.
 - (5) The Board may appoint such subcommittees as it deems necessary, consisting of members, nonmembers or both, to assist it in the performance of its functions, although

- members of such subcommittees shall have no voting or remuneration rights arising from their participation.
- (6) Members of the public may attend all meetings of the Board although they may only participate where so authorized by the Chair, and in no case may they vote.
13. (1) If it appears to the Minister that there has been a serious failure by the Authority or the Board to exercise its functions, he or she may give the Authority or the Board, as the case may be, such directions as he or she considers appropriate.
- (2) If the Authority or the Board fails to comply with such directions, the Minister may:
- (a) give effect to them (and for that purpose may exercise any power of the Authority or the Board); or
 - (b) remove all the members of the Board from office and, until new appointments are made, carry out the Authority's functions him- or herself or appoint any other person or persons to do so.
14. (1) The Minister shall, on the advice of the Board, appoint an independent Scientific Committee to carry out food safety risk assessments.
- (2) The Committee shall be responsible for:
- (a) evaluating, in response to official requests or on its own initiative, physical, chemical or biological risks to human health arising throughout the food production chain;
 - (b) advising the Minister or the Authority on the appropriate measures to be taken to protect consumer health;
 - (c) providing inputs into or developing proposed regulations or rules on subject matters within its mandate.
- (3) In carrying out its functions, the Committee shall take into account:
- (a) the latest scientific research;
 - (b) information regarding procedures, methods and means of production;
 - (c) the results of sampling and analysis;

- (d) any other relevant data.
- (4) The Committee shall cooperate fully with the Authority, exchanging advice and information regarding risks, risk factors and risk perception, and in particular shall explain its risk assessments and the basis of its decisions.
- (5) The appointment, terms of office and conditions of service of Committee members shall be determined by the Minister on the advice of the Board.

PART III – OFFENCES AND PENALTIES

- 15. Any person who:
 - (a) fails to provide information requested and sought by the Authority in the exercise of its functions under this Act;
 - (b) gives false or misleading information to a representative of the Authority;
 - (c) attempts to improperly influence a representative of the Authority in the exercise of his or her official functions under this Act;
 - (d) poses as a representative of the Authority;
shall be guilty of an offence.

- 16. Any representative of the Authority who:
 - (a) discloses any information acquired in the course of exercising his or her official functions under this Act except where required to do so by his or her supervisor or by any court;
 - (b) accepts any monetary or other benefit from a person affected by the exercise of official powers under this Act;
shall be guilty of an offence.

- 17. (1) Any person who commits an offence under this Act shall be liable to summary prosecution, and upon conviction:
 - (a) in the case of a first offence, to a fine not less than ___ or to imprisonment for a term not exceeding ___ or to both;
 - (b) in the case of a subsequent offence, to a fine not less than ___ or to imprisonment for a term not exceeding ___ or to both; and
 - (c) where the offence is a continuing offence, to an additional fine of not less than ___ or imprisonment

for ___ months for each day on which the offence continues.

PART V – MISCELLANEOUS

18. No member of the Board or representative of the Authority shall be liable to suit or to prosecution in respect of anything done in good faith in the performance of his or her functions under this Act.
19. The Minister may, on the advice of the Board, make regulations for the purpose of carrying out the provisions of this Act.
20. (1) The following enactments are hereby repealed:
 - (a) ...
 - (b) ...
- (2) Without prejudice to sub-Article (1), in the event of any conflict or inconsistency between the provisions of this Act and any other enactment in force in [insert country name], the provisions of this Act shall prevail.

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