

Lesson : Introduction to Food Rules, and Regulations

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.

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.

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.

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 internationale 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.

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.

CODEX ALIMENTARIUS

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.

Functions

3.1.1. 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.

3.1.2. 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).

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 timeline 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.

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.

UNITED NATIONS SPECIALIZED AGENCIES

U.N. Food and Agriculture Organization

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

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).

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.

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”.

