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Ad Hoc Group on Food Safety

OVERVIEW AND COMPENDIUM OF INTERNATIONAL ORGANISATIONS WITH FOOD SAFETY ACTIVITIES

This document was approved by the Ad Hoc Group on Food Safety at its 27-28 April meeting.

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FOREWORD

As part of the OECD response to the request of G8 Heads of State and Government "to undertake a study of the implications of biotechnology and other aspects of food safety", the OECD Council established the Ad Hoc Group on Food Safety. This Group, composed of senior officials and experts from capitals with food safety policy responsibilities, was asked to report on what is being done at the national and international level to address current and emerging food safety issues. Specifically, the Terms of Reference for the Ad Hoc Group were:

- To supervise the compilation of a compendium of current and planned international food safety systems and activities, as outlined in Annex 3 of *OECD Work on Biotechnology and Other Aspects of Food Safety* [C(99)148(REV4)];
- To undertake the compilation of a compendium of current and planned national food safety systems and activities, based on reports from Member countries in which reference may be made to precautionary approaches and principles;
- To provide a report to Council on the results of its work, including the compendia of international and national food safety systems and activities, the ongoing work across the Organisation and related work underway in capitals or otherwise available to members, as part of the response to the G8 request, in order to contribute to international and national efforts in the area of food safety.

Under the chairmanship of Dr. Ewald Wermuth, Special Advisor to The Netherlands Minister for Agriculture, Nature Management and Fisheries on Biotechnological and Safety Issues, the Ad Hoc Group on Food Safety prepared and approved the final report for transmission to the OECD Council. This report includes the following elements:

- Overview of Food Safety Systems and Activities: Executive Summary
  [SG/ADHOC/FS(2000)6/FINAL]
- Overview of National Food Safety Systems and Activities
  [SG/ADHOC/FS(2000)5/FINAL]
- Overview of International Organisations with Food Safety Activities
  (Part I of Overview and Compendium of International Organisations with Food Safety Activities)
  [SG/ADHOC/FS(2000)4/FINAL]
- Compendium of National Food Safety Systems and Activities
  [SG/ADHOC/FS(2000)5/ANN/FINAL]
- Compendium of International Organisations with Food Safety Activities
  (Part II of Overview and Compendium of International Organisations with Food Safety Activities)
  [SG/ADHOC/FS(2000)4/FINAL]

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I. OVERVIEW OF INTERNATIONAL ORGANISATIONS WITH FOOD SAFETY ACTIVITIES

A. Institutional Structure and Regulatory Framework

"International standards have an increasing influence on national food safety systems, but must be adopted by national governments to have force of regulation or legislation."

1. The Food and Agriculture Organisation (FAO), World Health Organisation (WHO) and the International Office of Epizootics (OIE) have complementary food safety mandates to protect the health of consumers, to prevent the spread of disease and to ensure that the procedures followed in the trade of food products are fair (see chart). The Codex Alimentarius Commission (Codex), which manages the joint FAO/WHO food standards programme, sets international standards for food. The OIE defines sanitary norms for international trade in animals and animal products. The World Trade Organisation (WTO), the Organisation for Economic Co-operation and Development (OECD) and the United Nations Environment Programme (UNEP), do not have food safety mandates *per se* but carry out related activities in the areas of economics, trade and environment. The WTO rules provide an effective framework for the application of food safety measures in international trade.

2. The FAO, WHO and OIE do not have compliance or enforcement responsibilities but provide standards, guidelines and recommendations. The modalities of establishing standards, guidelines and recommendations differ between organisations according to their particular mandate. Within the framework of Codex, the responsibility for risk assessment normally lies with joint FAO/WHO expert committees and consultations, while responsibility for risk management lies with the Commission and its subsidiary bodies. Apart from improving access to Codex standards and to the Codex decision-making process, the Codex system is not currently involved in risk communication although it is looking to increase this aspect of its work.

3. The food standards, guidelines and other recommendations of the Codex Alimentarius are based on the principle of sound scientific analysis and evidence with regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

4. For foods moving in international trade, Codex standards, guidelines and recommendations, OIE recommendations and standards developed by International Plant Protection Convention (IPPC) are recognised under the WTO's Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures. WTO Members are encouraged to base their SPS measures on international standards, guidelines and recommendations. Where such standards are not used, the measures must be based on a risk assessment. A WTO Member has the right to determine what level of sanitary protection it considers is appropriate within its territory, but the objective of minimising negative trade effects should be taken into consideration. Governments must avoid arbitrary or unjustifiable distinctions in the levels of risk they consider appropriate in different situations, if these differences result in discrimination or are a disguised restriction

of trade. Measures to achieve a members appropriate level of protection must be based on scientific principles and not maintained against available scientific evidence. The measures cannot be more trade restrictive than necessary to achieve the appropriate level of health protection, taking into account technical and economic feasibility. Article 5.7 of the SPS Agreement provides that WTO members may provisionally adopt a SPS measure on the basis of pertinent information, including that from Codex and other sources.

B. Activities Addressing Food Safety Issues

"Key issues under discussion are the role of science and the extent to which other factors are taken into account in establishing Codex standards."

5. **Developing International Food Safety Frameworks:** The principles of risk analysis are being integrated more fully into the work of Codex. The Codex Committee on General Principles is developing Working Principles for Risk Analysis. These will be included in the Codex Procedural Manual and are intended for application in the framework of Codex and to provide advice to governments where applicable. The FAO, WHO and OIE have expanded outreach programmes aimed at improving food safety systems in developing countries and facilitating greater developing country participation in the development and national acceptance of international standards, guidelines and recommendations.

6. **International Standards for the Products of Modern Biotechnology:** An *Ad Hoc* Intergovernmental Task Force has been established by the Codex Alimentarius Commission to develop standards, guidelines or recommendations for foods derived from biotechnology. The Codex Committee on Food Labelling is developing labelling provisions for foods derived from biotechnology. International agreement has not been reached as to specific provisions in either case. FAO and/or WHO have held a number of consultations and workshops related to the safety of foods derived from biotechnology and a further joint consultation that will support the work of the Codex Task Force is planned. The OECD has established a Task Force to promote international harmonisation in the safety assessment of products of modern biotechnology. To date, the safety of biotechnology has not been a major issue of discussion in WTO, with discussions primarily in the Technical Barriers to Trade (TBT) Committee on labelling requirements for genetically modified food products introduced by several WTO Members.

7. **Precautionary Approaches and Principles:** Precaution is widely recognised by international organisations with food safety responsibilities as an essential element of risk analysis. Working Principles for Risk Analysis are being developed by the Codex Committee on General Principles. Within the section on Risk Management, the draft Principles include provisions to allow risk managers to apply a precautionary approach/principle when the scientific evidence is insufficient and there is evidence to suggest that negative effects will occur but it is difficult to evaluate their nature and extent.

8. **Addressing Socio-Economic Concerns:** Concerns over biotechnology as well as concerns, in some countries, over food safety go beyond the matter of human health and safety; there are economic, social, environmental and ethical issues. Effects on food quality, availability and costs, animal welfare and biodiversity are some of the emerging issues. When elaborating standards, Codex has regard, where appropriate, to "other legitimate factors" relevant for the health protection of consumers and for the promotion of fair practices in food trade. As regards the general aspects of "other factors" in the decision process, the Codex Committee on General Principles has made some progress in developing a general orientation for Codex work in the framework of risk analysis, with the understanding that other Codex Committees responsible for risk analysis can provide specific clarification on the integration of such factors in their work. There is little economic analysis at the international level aimed at assessing the costs and benefits, both for consumers and for industry, associated with food safety risks and regulations, or of the trade impacts.

"Building consensus towards international standards, and a greater involvement of developing countries, are key goals."

9. **Communication and Consultation:** Meetings of the Codex Alimentarius Commission and its committees are open to member countries, Intergovernmental Organisations (IGOs) and Non-Governmental Organisations (NGOs). Codex member countries are encouraged to involve stakeholders in the formulation of national positions to be taken on Codex documents. Measures are in hand to further improve the transparency of the Codex process, as well as that of the FAO and WHO expert bodies responsible for risk assessment. Codex committees and other IGO's are examining how best to improve risk communication. Greater participation by consumer organisations in the work of Codex is being encouraged and measures to improve consensus building within the Codex system are under discussion.

10. **Foodborne Disease Surveillance:** WHO is considering the introduction of a global strategy for the surveillance of foodborne disease and the collection and exchange of data between countries and regions. OIE collects, processes and disseminates data on animal disease occurrences that could endanger animal or human health. These surveillance activities provide Member countries with the essential information needed to launch national disease control programmes.

11. **Capacity Building:** In many countries of the world, the increasing awareness of food safety issues, independent of issues related to biotechnology, has underlined the need for strengthening local technical and scientific capabilities, and for additional educational tools pertinent to each level of society. WHO, in collaboration with other international organisations, in particular, FAO and OIE, is helping developing countries to evaluate the consequences for health of, and establish priorities for strategies to deal with, foodborne disease. FAO, WHO and the WTO Secretariat are undertaking a considerable amount of capacity building work in developing countries, in their respective fields of competence. In developed countries, WHO, will promote the concept that strengthening local technical and scientific capability in the food safety area in developing countries can be mutually beneficial for developed countries. There are also technical assistance provisions in the SPS Agreement.

International Organisations with a Food Safety Mandate

Organisations	**WHO** UN Specialised Organisation Treaty, 1948 **World Health Organization** Geneva	**FAO** UN Specialised Organisation Treaty, 1945 **Food and Agriculture Organization** Rome	**OIE** Global organisation Treaty, 1924 **International Office for Epizootics** Paris
Member Countries	191	180 + EC	155
Mandate	Human Health Constitution Art 2(u) to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products	Improve nutrition and enhance production and distribution of food and agricultural products Promote international food trade through cooperating in the Establishment of international standards, guidelines and recommendations	Animal Health and zoonoses Establishes international standards in the area of animal health, provides guidance on the incidence and combat of animal diseases; including those that can be transmitted to humans through the food chain; and harmonizes regulations for trade in animals and animal products.
Food Safety Programme	**Joint FAO/WHO Food Standards Programme: Codex Alimentarius Commission** sets international standards and guidelines for food: • Food additives, agricultural and veterinary chemicals and contaminants, maximum permitted levels and MRL's. • Pesticide registration requirements: maximum residue levels, (MRL's). • Food safety risk assessment--Precaution in Food Safety • Harmonization of food safety & quality regulations • Food import/export inspection & certification:.equivalence; • Novel Foods/Foods from biotechnology; Animal Feed & Food Safety • General Principles of Food Hygiene: Hazard Analysis Critical Control Point, HACCP; Good Agricultural Practices; Good Manufacturing Practices • Food Allergies; • Food Labelling (Cited in the WTO SPS agreement) Food safety risk assessment through: JECFA (food additives, contaminants, veterinary drugs); JMPR (pesticide residues); *ad hoc* expert consultations (microbiological hazards, biotechnology, animal feed, etc.)		**International Animal Health Code Commission:** Minimum health guarantees required of trading partners **The Standards Commission:** Harmonizes diagnostic methods for animal diseases and the control of biological products used for disease control **The Fish Diseases Commission:** Collects information on aquatic diseases and their control. Developed an International Health Code for Aquatic Animals. (Cited in the WTO SPS Agreement)
Food Safety Activities	**Food Safety Program:** Exposure assessment to chemicals (GEMS); Safety assessment of food technologies; BSE; International health regulations. **Foodborne Disease:** Surveillance and management; Antimicrobial resistance monitoring; Food handling. **International Program on Chemical Safety:** Pesticides, toxic chemicals - classification and labelling; Food additives risk assessments; Lead for endocrine disruptors.	**FAO & WHO** **Technical Assistance and Capacity Building:** Support developing countries: Training on appropriate levels of protection, hygiene and development of equivalence. Assist in infrastructure building; legislation; develop food regulatory capacities, inspectional, scientific, enforcement; Train in safe food handling and Good Manufacturing Practices, food production procedures and Good Agricultural Practices. Develop risk analysis capabilities; Advise on a full range of food safety issues.	- BSE -Zoonoses, Brucellosis - Antibiotic Resistance and utilisation of veterinary medicines - Evaluation of control authorities
Websites	http://www.who.org	http://www.fao.org	http://www.oie.org

II. COMPENDIUM OF INTERNATIONAL ORGANISATIONS WITH FOOD SAFETY ACTIVITIES

A. Institutional Structure and Regulatory Framework

12. Because of the multi-disciplinary nature of food safety-related activities, several international organisations are engaged in activities dealing with this subject. The organisations with responsibility for food safety are the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) and the International Office of Epizootics (OIE). Food safety is addressed by other international organisations including the UN Environment Programme (UNEP) and the World Trade Organization (WTO) and the Organisation for Economic Co-operation and Development (OECD) although their mandates give priority to environmental or trade objectives. The WTO's SPS Agreement encourages Members to harmonise food safety measures and recognises Codex, OIE and IPPC as the appropriate international standard-setting organisations. Observers from international governmental organisations (IGOs) participate in meetings relating to food safety organised by other IGOs thus ensuring co-ordination between their programmes whilst recognising their different mandates.

13. This section provides a factual description of international organisations and their functions related to food safety. Part A identifies the main organisations with responsibilities for food safety, Part B identifies those organisations with environmental, economic or trade responsibilities and Part C outlines in more detail the various treaties, conventions and programmes relating to food safety, some of which are the responsibility of more than one organisation.

International Organisations with Responsibilities for Food Safety

Food and Agriculture Organisation of the United Nations (FAO)

14. The main objective of FAO is to ensure food for all by securing improvements in the efficiency of production and distribution of all food and agricultural products. Overall FAO policy is agreed by consensus by member Governments at the biennial FAO Conference. Many FAO food safety activities are carried out in the Economic and Social Department, Food and Nutrition Division although there are also many food safety-related activities integrated into programmes carried out by FAO's Agriculture and Fisheries Departments. Many of FAO's food safety activities are carried out in collaboration with other international organisations. The main food safety activities of FAO are: Codex Alimentarius (with WHO); the safety evaluation of food, agricultural and veterinary chemicals (with WHO); the International Code of Conduct on the Distribution and Use of Pesticides; and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. FAO has an extensive programme of education and training related to food safety, carried out mainly through its decentralised structure.

World Health Organisation (WHO)

15. The mission of WHO, which has 191 Member Countries, is to achieve the highest possible standard of health for all. The WHO Constitution states that one of the prime functions of the Organisation shall be "to develop, establish and promote international standards with respect to *food*, biological, pharmaceutical and similar products". In addition, WHO has broad mandates of relevance to food safety, including: acting as the directing and co-ordinating authority in international health work; promoting and

conducting research in the field of health; and assisting in developing an informed public opinion among all peoples on matters of health.

16. The Food Safety Programme is the focal point for food safety activities in WHO; other WHO programmes with food safety related activities include the Cluster on Communicable Diseases (CDS) and the Programmes on Chemical Safety (PCS), Nutrition (NUT), Water, Sanitation and Health (WSH), and International Health Regulations. Many of WHO's food safety activities are carried out in collaboration with other international organisations, including: International Programme on Chemical Safety (with FAO and ILO); Global Environment Monitoring System/Food Contamination Monitoring and Assessment Programme (with UNEP, FAO and the International Atomic Energy Agency (IAEA)); and the Codex Alimentarius (with FAO).

International Office of Epizootics (OIE)

17. The OIE was founded by treaty in 1924 to improve hygiene and public health by preventing the spread of diseases in animals and animal products in international trade. While this 155 member organisation is not in the UN system, OIE collaborates with WHO and FAO in global food safety activities. The OIE develops international standards, guidelines and recommendations relating to animal health and zoonosis. The OIE informs countries about the occurrence and control of animal diseases, co-ordinates global studies on the monitoring and control of diseases and harmonises import and export regulations concerning animal health.

18. The International Committee, OIE's highest body, meets annually. Resolutions adopted by the Committee are prepared with the assistance of three Commissions: Foot and Mouth Disease and Other Epizootics; Standards; and Fish Diseases. A fourth Commission on the International Animal Health Code is involved in the development of international recommendations for safeguarding trade in animals and animal products. In addition, four Working Groups contribute to dissemination of scientific and technical information amongst Member Countries: Biotechnology; Informatics and Epidemiology; Veterinary Medicinal Products; and Wildlife Diseases. Regional Representations help to co-ordinate national disease control programmes and International Reference Laboratories and Collaborating Centers provide technical support in monitoring and controlling animal diseases, mainly to developing countries. OIE has permanent working relations with over twenty other international organisation, including FAO, WTO and PAHO.

International Organisations with Trade or Environmental Responsibilities

UN Environment Programme (UNEP)

19. UNEP exists to provide leadership and encourage partnerships in caring for the environment. It coordinates with global international organisations with food safety mandates. Two UNEP activities are particularly relevant to food safety: the International Programme on Chemical Safety (IPCS) (with WHO) and the Global Environmental Monitoring System (GEMS). UNEP also provides the secretariat for the Convention on Biological Diversity (CBD), a multilateral environmental agreement.

20. The Protocol on Biosafety was agreed by Parties to the CBD in January 2000. The Protocol focuses on transboundary movement of any living modified organism (LMO) resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, other than those that are pharmaceuticals for human use that are addressed by other international agreements or organisations. In particular, the Protocol sets out procedures for advance informed agreement between importing and exporting countries for LMOs intended for deliberate release into the

environment. The Protocol sets out the minimum information that must be supplied by the exporting country prior to the intentional transboundary movement of LMOs. The information required includes a risk assessment report, however, the focus is environmental risks rather than risks to human health.

21. In relation to LMOs for direct use as food or feed, or for processing, when a Party to the Protocol makes a final decision regarding the domestic use, including placing on the market, of an LMO that may be subject to transboundary movement, the Party is required to inform other Parties of that decision. The information to be provided to other Parties would include the risk assessment report. The objective of the risk assessment is to identify and evaluate the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity taking also into account risks to human health. The Protocol contains provisions for using the precautionary approach in the decision-making process.

World Trade Organisation (WTO)

22. The WTO, was established in 1995 following completion of the Uruguay Round negotiations. It had a Membership of 136 countries and territories at the end of April 2000. Its essential functions include: administering and implementing multilateral trade agreements; providing a forum for multilateral trade negotiations; seeking to resolve trade disputes; contributing to transparency of national trade policies; co-operation with other international institutions involved in global economic policy-making. A unified dispute settlement system ensures enforcement of all WTO agreements. Whilst WTO does not have a mandate to develop food safety standards, it does place disciplines on the use of food safety measures to avoid their use as unjustified or disguised barriers to trade. Of the WTO agreements, most significant for food safety, is the Agreement on the Application of Sanitary and Phytosanitary Measures (The SPS Agreement). Article 3.4 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) states that "Members shall play a full part, within the limits of their resources, in the relevant international organisations, in particular the Codex Alimentarius Commission, the International Office of Epizootics and the international and regional organisations operating within the framework of the International Plant Protection Convention, to promote within these organisations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures." The WTO Agreement on Technical Barriers to Trade (the TBT Agreement) addresses food quality requirements and any issues related to food which may not be covered by the SPS Agreement.

Organisation for Economic Co-operation and Development (OECD)

23. OECD was established in 1961 to promote policies designed to contribute to the development of the world economy; sound economic expansion in member countries as well as non-member countries in the process of economic development and the expansion of world trade. OECD currently has 29 Member countries; it works through consensus.

24. The OECD has undertaken some analysis of the costs and benefits associated with food safety risks and regulations, or of the trade impacts (for example, regulatory reform of the agri-food sector, trade considerations of food safety and quality, commodity market analysis, etc.). These studies have found that, particularly where it relates to consumers and industry, it has been difficult to quantify the benefits, costs and other impacts.

25. With respect to biotechnology and other aspects of food safety, the role of the OECD is to assist governments improve the safety assessment process, enhance international harmonisation and mutual recognition, increase public confidence in the regulatory system, and improve interactions with non-government organisations through the establishment of discussion fora, etc. Agriculture, Environment and

Science Industry and Technology are the key directorates involved while Trade and Public Management also address related issues.

26. OECD's involvement in biotechnology dates back to 1982 and encompasses three principal domains: human health, agriculture and food and environmental applications. A key objective is to provide a balanced view of modern biotechnology in order to permit governments and society at large to make decisions concerning its development and use in the short and long-run. While the benefits from modern biotechnology can be immense, particularly in the area of health, it also brings with it a number of uncertainties that may be viewed differently among countries and stakeholders. Such differences can result in severe trade tensions and disputes, which can hamper further development and limit potential benefits of biotechnology. The OECD thus contributes to reducing trade tensions or disputes, by its objective analytical work, by its efforts at regulatory harmonisation and by providing for on-going discussions and consensus-building.

Treaties, Conventions and Programmes Relating to Food Safety

Codex Alimentarius Commission (CAC)

Institutional structure and regulatory framework

27. The CAC was established in 1961/62 by FAO and WHO to implement the Joint FAO/WHO Food Standard Programme, the purpose of which includes: protecting the health of the consumers and ensuring fair practices in the food trade; and promoting co-ordination of all food standards work undertaken by international governmental and non governmental organisations.

28. The CAC elaborates international standards, codes of practice, guidelines and related texts addressing the safety and quality of foods moving in the international food trade. To date, the CAC has developed about 240 standards covering processed, semi-processed or raw foods intended for sale to the consumer or for intermediate processing; over 40 hygienic and technological codes of practice; evaluated some 80 veterinary drugs and over 1200 food additives; set over 3250 maximum levels for pesticide residues; and specified 25 guidelines for contaminants. These recommendations, standards or guidelines are advisory, however, on matters related to food safety they are recognised as reference standards by the SPS Agreement.

29. The membership of the CAC is open to all member nations and associated members of FAO and WHO that are interested in international food standards. At present its membership stands at 165 countries. The CAC meets once every two years to adopt draft standards, codes of practice, guidelines and other texts proposed by its subsidiary bodies.

30. The CAC's subsidiary bodies are: the Executive Committee which meets annually to assist the CAC; 6 Regional Co-ordinating Committees; 8 General Subject Committees; 12 Commodity Committees; and 3 *ad hoc* Inter-governmental Task Forces. They have their own terms of reference specific to their work. Among these subsidiary bodies (a full list is given in Annex 1), there are eight whose main subjects are related to food safety, namely: the Codex Committees on Food Hygiene, Food Additives and Contaminants, Pesticide Residues, Residues of Veterinary Drugs in Foods, and Meat Hygiene (adjourned *sine die*) and Inter-governmental Task Forces on Foods Derived from Biotechnology, and Animal Feeding. In addition, general principles related to food safety, such as risk analysis working principles have been considered by the Codex Committee on General Principles. The food safety aspects of fish and fishery products are dealt with by the Codex Committee on Fish and Fishery Products; methods of analysis and sampling for ensuring the safety of food, excluding those for residues of pesticides and veterinary drugs,

are among the responsibilities of the Codex Committee on Methods of Analysis and Sampling; and the labelling of foods, including the provisions related to food safety is considered by the Codex Committee on Food Labelling.

31. These committees and task forces meet annually or biennially. There is a mechanism within the CAC to establish new subsidiary bodies to address new or emerging issues and abolish existing bodies when their tasks have been completed.

32. In the sessions of the CAC and its subsidiary bodies, international organisations granted "Observer" status can participate. They can comment on the subjects on the agendas and distribute memoranda at these sessions.

Operation

33. The operation of the CAC and its subsidiary bodies follows its Rules of Procedure contained in the *Codex Alimentarius Commission Procedural Manual*. Administrative support to the CAC is provided by the Codex Secretariat located in the premises of FAO. Its main task is the preparation and organisation of sessions of the CAC and its subsidiary bodies, in the case of the latter, in collaboration with their host country governments. In addition, it serves as a link to the Codex Contact Points of Member countries, disseminates information to Member countries and other interested parties and co-ordinates work with other international organisations.

How decisions are adopted

34. When a Codex Committee proposes to elaborate a new or revised standard, it should first consider the priorities established by the Commission in the Medium-Term Plan of Work and the Criteria for the Establishment of Work Priorities, such as consumer protection against health risk and fraudulent practices, and diversification of national legislation and resultant impediment of trade. This proposal shall be considered by the CAC or its Executive Committee for approval. New work may be initiated by the Commission or the Executive Committee. The elaboration of standards follows the Codex Elaboration Procedure stipulated in the Procedural Manual. There are two types of procedure: Uniform Normal Procedure and Uniform Accelerated Procedure (for further details see Annex 2).

35. All decisions at the Committee level are made through discussions by Member government delegations. In almost all cases, decisions are made by consensus. Only the Commission can adopt texts recommended by its subsidiary bodies as final texts. It makes every effort to reach agreement on the adoption or amendment of standards by consensus. Decisions to adopt or amend standards may be taken by voting only if such efforts to reach consensus have failed.

36. The CAC in 1995 adopted Four Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors Are Taken into Account. These statements are pertinent to the work on food safety and are attached (Annex 3).

37. All Codex final texts adopted by the CAC are compiled in the *Codex Alimentarius* and sent to Member governments for acceptance.

How information is obtained

38. For the elaboration of Codex Standards, the usual way to obtain information is to request it from Member countries and international observer organisations by Codex circular letters. Information may also be obtained through working papers, including discussion papers prepared by Member countries on a voluntary basis.

39. In the case of the elaboration of maximum residue limits for pesticides and veterinary drugs, the CAC uses as a basis the recommendations of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in food and the Environment and of the WHO Core Assessment Group (so called Joint FAO/WHO Meeting on Pesticide Residues; JMPR) and Joint FAO/WHO Expert Committee on Food Additives (JECFA), respectively. These two bodies are scientific advisory bodies independent and separate from the CAC. The JECFA also provides the specifications of food additives.

40. In certain specific cases, expert consultations are held by FAO, WHO or jointly by these two organisations or with other organisations to address these specific problems and provide scientific advice to the CAC and Member countries.

Role of stakeholders and private industry; How Scientists are recruited; How the expertise is used

41. The CAC is an inter-governmental body, Member governments and recognised international observer organisations participate in the sessions of the Commission and its subsidiary bodies. The delegate designated by a national government speaks on behalf of that government and not for him/herself. Member governments are responsible for selecting members of their delegations from government, academia, industry and consumer groups according to their expertise in relation to the items of the agenda. The Commission has encouraged the involvement of consumers in standard-setting activities at the Codex and national levels.

42. There are a number of industry group organisations as well as consumer organisations that participate actively as international non-governmental organisations (INGOs) in discussions at Codex sessions. The number of these organisations has increased sharply in recent years.

Co-operation and co-ordination activities across IGOs

43. FAO and WHO collaborate with the CAC, for example through: holding expert consultations; providing scientific information to Codex; or holding seminars and workshops related to Codex work. The CAC is an observer organisation at the WTO's SPS Committee. WTO's representatives participate in the sessions of the Commission and some Codex Committees as do representatives of other international organisations with food safety activities.

How three areas of risk analysis are covered

44. Risk analysis was first discussed officially by the CAC in 1993. Since that time, risk analysis has been one of most important items on its agenda. With the aid of expert consultations, the CAC has adopted definitions of risk analysis terms related to food safety, statements of principles relating to the role of food safety risk assessment, an action plan for Codex-wide development and application of risk analysis principles and guidelines, and a number of recommendations to Codex itself, member governments and FAO and WHO concerning risk communication.

45. The Codex Committee on General Principles is elaborating risk analysis working principles to provide guidance to the relevant Committees and those Codex Committees dealing with food safety have been considering the integration of risk analysis in their work on a regular basis. A diagram showing the linkages among those involved in the risk analysis process in the Codex system is given in Annex 4.

a) Risk assessment

46. For Codex purposes, risk assessment is defined as "a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization."

47. The Codex system receives advice on the risk assessment of chemicals in food (i.e.: additives, including those produced by biotechnology; chemical contaminants; pesticide residues; and veterinary drug residues) from two independent scientific committees: JECFA and JMPR, appointed by FAO and WHO. However, although the expert committees are responsible for the risk assessment process, risk assessment policies are the responsibility of the CAC on the advice of its appropriate committees, including those on: Food Additives and Contaminants; Residues of Veterinary Drugs in Food; and Pesticide Residues.

48. Risk assessments of biological agents (bacteria; viruses; helminths, etc.) in food have hitherto been studied on a case by case basis by the Codex Committee on Food Hygiene with advice from other bodies outside the Codex system, e.g., the International Commission on Microbiological Specifications for Food (ICMSF) and *ad hoc* expert consultations organised by FAO and/or WHO. Given the magnitude of health and trade problems caused by foodborne biological hazards, an expert advisory body in Microbiological risk assessment, comparable to JECFA and JMPR, is being established by FAO and WHO to provide regular advice on such hazards.

49. Since 1990, the WHO and FAO have held several major expert consultations on biotechnology. In 1999, Codex set up an Ad Hoc Task Force on Biotechnology. Although there is not, at present, a standing expert committee for biotechnology along the lines of JMPR and JECFA discussions are underway between WHO and FAO to set up a roster of food safety experts that would include experts on biotechnology, to facilitate setting up expert committees and consultations in this and other food safety fields. A Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology will take place 29 May-2 June 2000. There is currently within the Codex system, no specific provision for the risk assessment of novel foods (including those derived by biotechnology) although the 1991 FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade recommended that the terms of reference of JECFA should be reviewed to encompass foods produced by biotechnology.

50. Risk assessments in relation to nutrition are within the remit of the Codex Committee on Nutrition and Foods for Special Dietary Uses.

b) Risk management

51. For Codex purposes, risk management is defined as "the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options".

52. Within the Codex system, risk management is usually the responsibility of the Codex committees under the overall guidance of the CAC. Codex principles of risk management are guided by CAC Statements of Principles Concerning the Role of Science in the Codex Decision-making Process and the

Extent to Which Other Factors are Taken Into Account. The CAC Statements (Annex 3) require that standards, guidelines and other recommendations of Codex shall be based on the principle of sound scientific advice and evidence, and where appropriate, Codex will have regard to other legitimate factors relevant to health protection of consumers and for the promotion of fair practices in food trade. To date, "other legitimate factors", have not been defined in the risk management context.

c) Risk Communication

53. Risk communication has been defined by Codex as "the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions".

54. Risk communication is promoted by the Codex system as an important component of risk analysis. The Codex General Principles of Food Hygiene also specifically make mention of the need for consumer education. However, apart from improving access to Codex standards through the internet and other media, the Codex system *per se* is not currently involved in risk communication; relevant Codex Committees have yet to discuss the recommendations of the CAC adopted at its 23rd Session (Annex 5).

Other FAO/WHO Joint Activities

Joint Expert Committee on Food Additives (JECFA)

55. JECFA is an independent expert committee that provides a scientific input into the Codex decision making process in relation to additives, chemical contaminants and veterinary drug residues. In particular, JECFA carries out toxicological evaluations to establish an Acceptable Daily Intake (ADI) for a food additive, Provisional Tolerable Weekly Intake (PTWI) or Provisional Maximum Tolerable Daily Intake (PMTDI) for chemical contaminants, and an ADI and Maximum Residue Level (MRL) for veterinary drugs.

56. In selecting members for a JECFA meeting, FAO and WHO follow a systematic process. The selection of members is made only after a careful consideration of their scientific credentials, with emphasis being placed upon individual expertise. A balance of scientific expertise, academic and government disciplines and geographic representation is considered essential. The Directors-General formally notify Member governments when their citizens are selected as members to serve on expert panels. Members attend in the capacity of individual experts, not as representatives of any body, organisation or government institution. To ensure the independence of their experts, FAO and WHO meet the costs of attendance of all their invited experts; however, FAO and WHO do not pay honoraria. A roster of experts has been put in place in WHO.

57. In considering individuals as members of JECFA, several sources may be used by FAO and WHO for developing a list of suitable candidates. Common sources include: knowledge of individuals with the necessary scientific expertise and reviews of unsolicited personnel histories; recommendations from member governments and relevant national and international organisations; identification of individuals that are invited to plan, participate or chair programs at national or international meetings related to the subject area; and reviews of scientific publications. Selection of members is made with careful consideration to scientific expertise and will include all scientific disciplines deemed necessary to address relevant scientific issues on the agenda, including toxicology, pathology, oncology, pharmaceutical science, chemistry or biochemistry.

58. JECFA meetings are devoted exclusively either to the evaluation of food additives and contaminants or to veterinary drug residues in foods. They are convened at the discretion of the Directors-General of FAO and WHO in response to a request of the Codex Committees on Residues of Veterinary Drugs in Food or Food Additives and Contaminants, as appropriate. Member Countries of FAO and WHO may also request JECFA advice on substances under its competence. Data for review are submitted by the industry (manufacturers, distributors or users of a substance), governments, and other interested parties or taken from the open scientific literature.

59. A report summarising the conclusions of each meeting is published in the WHO Technical Report Series. These reports reflect the unanimous agreement of Committee members. In the very rare event where unanimous agreement is not achieved, a minority report may be included. The summary report conveys the transparency of the JECFA deliberations and is commonly used by Codex member states in their decisions regarding the advancement of recommended MRLs. For this reason, the JECFA summary report clearly and accurately reflects the decision-making process of the Committee. It is prepared in a transparent, objective manner and capable of withstanding peer review by all interested parties.

60. Toxicological monographs summarising the safety data and providing full references to the literature on the food additives, contaminants, and veterinary drugs reviewed by the Committee are published in the WHO Food Additive Series (FAS). Monographs on the specifications for the identity and purity of food additives and residues, summarising the data used for recommending MRLs for veterinary drugs, are published in the FAO Food and Nutrition Paper (FNP) series. The compendium on Food Additives Specifications is published as part of FNP 52. The compendium of monographs pertaining to the assessment of veterinary drugs is part of FNP 41.

61. Throughout its existence, JECFA has developed and established principles for the safety assessment of chemicals in food. To improve the consistency and quality of its decision-making process, the International Programme on Chemical Safety (IPCS) sponsored the publication of Environmental Health Criteria No.70 that consolidates and updates the principles for the safety assessment of food additives and contaminants in food.

Joint Meetings on Pesticide Residues (JMPR)

62. JMPR is an independent scientific committee consisting of the FAO Panel of Experts on Pesticide Residues in Food and in the Environment and the WHO Core Assessment Group. JMPR carries out toxicological evaluations of pesticide residues resulting in an estimate of the Acceptable Daily Intake (ADI). JMPR also recommends Maximum Residue Limits (MRLs) for individual pesticides on specific commodities. The results of these evaluations, which are published in the FAO Plant Production and Protection Paper Series, are used by the Codex Committee on Pesticide Residues (CCPR) and other Codex committees in taking risk management decisions. The reports and residue monographs of JMPR are published by FAO, while the toxicological monographs are published by WHO.

63. The procedures for the appointment of members of JMPR and the working practices of JMPR are essentially the same as those for JECFA.

Ad hoc Expert Consultations, etc

64. *Ad hoc* Expert Consultations, meetings and study groups are held jointly by FAO and WHO (and other organisations) to respond to specific requests from member countries or the CAC on various aspects

of food quality and safety. In recent years such *ad hoc* Expert Consultations, etc. have been organised on a wide range of food safety issues such as:

- The Application of Risk Analysis to Food Standards, Geneva, 1995
- Risk Management and Food Safety, Rome, 1997
- Food Consumption and Exposure Assessment of Chemicals, Geneva 1997
- The Application of Risk Communication to Food Standards and Safety Measures, Rome, 1998
- The International Conference on Mycotoxins, Tunisia, 1999 (with UNEP)
- Biotechnology and Food Safety, Geneva, 1990 and Rome, 1996

65. The process for identifying and selecting experts for these consultations is similar to that applied for JECFA and JMPR experts. Reports are published either by FAO or by WHO depending on the subject.

Microbiological safety

66. FAO and WHO have taken steps towards the development of an international strategy and supporting mechanisms for risk assessment of microbiological hazards in food. Currently, this strategy includes: implementation of a series of expert consultations; organisation of technical meetings contributing to the integration of risk assessments of microbiological hazards at international level; and creation of a database.

67. The Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods in 1999 recognised that the "Principles and Guidelines for the conduct of microbiological risk assessment" adopted by the 23rd session of the CAC provides a basic framework for microbiological risk assessment at the international level. It recommended that a vehicle (meetings of experts) for the provision of expert advice on microbiological food safety risk assessment be established by FAO and WHO to provide advice in response to specific requests from FAO, WHO and the CAC.

International Consultative Group on Food irradiation (ICGFI)

68. ICGFI was established in 1984 through a declaration drafted by representatives of the Member States of FAO, the International Atomic Energy Agency (IAEA) and WHO. Its mandate was initially for five years although this was subsequently extended until the present. Activities of ICGFI dealing directly with food safety include:

- Task Force on the Use of Irradiation to Ensure Hygienic Quality of Food (1986)
- Microbiological Criteria of Food to be Processed Including Irradiation (1989)
- Consultation on Wholesomeness of Food Irradiated with Doses Above 10 kGy (1994)
- Joint FAO/IAEA/WHO Study Group on High-Dose Irradiation: Wholesomeness of Food Irradiated with Doses above 10 kGy (1997)

69. In addition, ICGFI has published reports in the field of food safety that include:

- Enhancing Food Safety through Irradiation (1999)
- Safety of Poultry Meat: from Farm to Table (1999)

Other WHO Activities

International Programme on Chemical Safety (IPCS)

70. IPCS is a joint programme of WHO, UNEP and the International Labour Organisation (ILO). The main roles of IPCS are to establish the scientific basis for the safe use of chemicals and to strengthen national capabilities and capacities for chemical safety. The areas of activity include evaluation of chemical risks to human health and the environment, methodologies for evaluation of hazards and risks, prevention and management of toxic exposures and chemical emergencies and chemical risk communication. IPCS projects include: harmonisation of approaches to the assessment of risks from exposure to chemicals; and leadership and advice to projects to establish the state of the science of endocrine disruptors, a project with OECD to harmonise generic and technical terms used in chemical hazard/risk assessment. The FAO/WHO Joint Expert Committee on Food Additives (JECFA) and the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) are within the IPCS and provide expert advice to the Codex system. Members of IPCS expert committees are selected from lists of suitable candidates nominated by governments and non-governmental organisations.

Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food)

71. Established in 1976, GEMS/Food is implemented by WHO in collaboration with national and international Bodies (including FAO, IAEA and UNEP) interested in human exposure to chemicals through food. The main objective of GEMS/Food is to compile data on food contamination and human exposure from different countries for global synthesis, evaluation and presentation. Data is collected through WHO Collaborating Centres and other institutions in nearly 70 countries. GEMS/Food-generated exposure data supports the risk management activities of bodies such as the Codex Committee on Food Additives and Contaminants (CCFAC) and the Codex Committee on Pesticide Residues (CCPR) as well as national governments.

WHO Surveillance Programme on Foodborne Diseases

72. The aim of WHO's surveillance programme on foodborne diseases is to strengthen and co-ordinate global efforts on the surveillance of foodborne diseases and outbreak response including the surveillance and containment of antimicrobial resistant foodborne bacteria. The main elements of the programme are:

- Development of Guidelines for Strengthening of Integrated National Foodborne Disease Surveillance Systems with a focus on national activities with the view towards facilitating regional surveillance

- Development and extension of WHO Recommended Surveillance Standards to Foodborne Diseases

- Strengthening national capacities and infrastructure for laboratory based surveillance of priority foodborne diseases

- Strengthening national capacities to detect, monitor and respond to the emergence of antimicrobial resistant foodborne pathogens

- Development and co-ordination of global networks of foodborne disease surveillance laboratories and

- Strengthening of WHO's Epidemic Surveillance capacities to include foodborne disease and outbreaks of regional and global scope.

Other FAO Activities

International Plant Protection Convention (IPPC)

73. The IPPC is a treaty established in 1952 and administered by FAO through the IPPC Secretariat located in the Division for Production and Protection of Vegetable Products. The purpose of IPPC 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. It requires member countries to put in place appropriate checks and certification and disinfection procedures and to make information available. The Convention deals with the protection of plant life and has no direct relevance to food safety.

74. FAO's pesticide management activities aim to manage the multifaceted risks associated with the use of pesticides. The IPPC Secretariat works on the same programme of crop protection and pesticide management and is located in the same Division of FAO as the JMPR Secretariat. It is responsible for: reinforcing international co-operation with respect to the Convention; developing international standards for phytosanitary measures; centralising and disseminating information on plant parasites that could be present in imports; and providing technical assistance to developing countries.

75. The IPPC is recognised by the SPS Agreement as the appropriate standard setting organisation for plant health. Although the Convention is legally binding, standards developed and adopted by the IPPC are not. However, deviations must be based on scientific principles and evidence. Emergency or provisional measures may be taken by member countries to protect plant health but these must be reviewed for scientific justification.

Code of Conduct for Responsible Fisheries (CCRF)

76. Adopted in 1995 by the FAO Conference, the CCRF provides a framework for the sustainable use and conservation of aquatic biodiversity. The Code requires that States should adopt appropriate measures to ensure the right of consumers to safe, wholesome and unadulterated fish and fishery products and establish and maintain effective national safety and quality assurance systems to protect consumer health and prevent commercial fraud. States should also set minimum standards for safety and quality assurance and make sure that these standards are effectively applied throughout the industry. They should promote the implementation of quality standards agreed within the context of the FAO/WHO Codex Alimentarius Commission and other relevant organisations or arrangements. States should co-operate to achieve harmonisation, or mutual recognition, or both, of national sanitary measures and certification programmes as appropriate and explore possibilities for the establishment of mutually recognised control and certification agencies.

77. The Fisheries Department of FAO undertakes a large number of technical project activities to meet these goals.

FAO/IAEA Training and Reference Centre for Food and Pesticide Control (TRC)

78. FAO and IAEA established the TRC in 1998 as part of the programme of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture. The main objective of the TRC is to assist national food control laboratories in Member States of FAO and IAEA to strengthen their analytical capabilities for food safety and quality, especially with regard to food contaminants, through training, quality assurance services and technology transfer. TRC's activities include research, training, proficiency tests, validating analytical methods related to microbiological, mycotoxin, pesticide and veterinary drug residues, toxic metal and radionucleotide contamination of food.

OIE Food Safety Activities

79. In relation to food safety, OIE's activities are complementary to those of the Codex Alimentarius on diseases, such as brucellosis, tuberculosis and bovine spongiform encephalopathy, which are or might be transmitted to human beings through the food chain; and consideration of residues in food arising from the administration of biological agents such as vaccines (including recombinant vaccines) or due to emerging bacteria resistant to antimicrobials. OIE recommendations have a status under the SPS Agreement similar to that of Codex standards. OIE publishes the *International Animal Health Code* that defines animal health standards for international trade in animals and animal products. The OIE also publishes a *Manual of Standard Methods for Diagnostic Tests and Vaccines* to be applied in international trade.

80. A priority function of OIE is to inform Governmental veterinary services of the occurrence and course of epizootics that could endanger animal or human health. An early warning system has been established through which Member countries are alerted to the outbreak of any disease that might have serious repercussions on public health or the economy of animal production. This warning mechanism is supplemented by information received from Member countries and distributed regularly.

81. By collecting, processing and disseminating data on the world animal health situation, the OIE provides Member countries with the essential information needed to launch national control programmes and to formulate animal health regulations for international trade.

WTO Activities Relevant to Food Safety

Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

82. The SPS Agreement creates legally binding obligations for WTO Member governments to ensure, *inter alia*, that any food safety measures they impose which affect international trade are scientifically justified and based on a risk assessment. The Agreement defines risk assessment as: "The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

83. The Agreement also identifies some of the factors that should be considered in the assessment of risk. No specific risk assessment techniques are imposed, although WTO Members are to take into account the techniques developed by Codex, OIE and IPPC. The SPS Agreement requires that governments provide information and documentation regarding their risk assessment procedures, including the factors taken into consideration, upon request by interested trading partners.

84. The SPS Agreement encourages WTO Members to harmonise their SPS measures on the basis of international standards, guidelines and recommendations developed by international organisations. Members may adopt SPS measures to achieve higher levels of protection than that provided by the international standards if they have a scientific justification. For food safety, the SPS Agreement identifies the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice. For animal health and zoonoses, the SPS Agreement references the guidelines developed by the International Office of Epizootics. For plant health, the international standards developed under the auspices of the International Plant Protection Convention are referenced. For matters not covered by the above organisations, the SPS Committee may identify appropriate standards promulgated by other relevant international organisations open for membership to all Members. If a WTO Member does not base its measure on a relevant international standard, it must ensure that its requirements have a scientific justification or are based on a risk assessment.

85. Although the term "risk management" does not appear in the SPS Agreement, the focus of the agreement is on the measures taken by WTO Member governments to address sanitary and phytosanitary risks which may have an effect on international trade, rather than on the risks *per se*. A WTO Member has the right to determine what level of sanitary protection it considers is appropriate within its territory, but the objective of minimising negative trade effects should be taken into consideration. Governments must avoid arbitrary or unjustifiable distinctions in the levels of risk they consider acceptable in different situations, if these differences result in discrimination or are a disguised restriction of trade. In addition to the requirements that measures be based on scientific principles and not maintained against available scientific evidence, the measures cannot be more trade restrictive than necessary to achieve the desired level of health protection, taking into account technical and economic feasibility. Article 5.7 of the SPS Agreement, provides that WTO members may provisionally adopt, a sanitary or phytosanitary measure on the basis of pertinent information, including that from Codex and other sources. The WTO member adopting a provisional measure in these circumstances must seek to obtain the additional information necessary for a more objective risk assessment, and review its provisional measure within a "reasonable" period of time.

86. The SPS Agreement indicates that WTO Members should facilitate the provision of technical assistance to developing countries, either bilaterally or through the appropriate international bodies. Furthermore, when a country changes its food safety requirements, it should consider providing technical assistance if needed to allow developing country exporters to adjust to the new requirements. Developed countries should also, to the extent health protection allows, phase in new food safety requirements on products of export interest to developing countries. The obligations of the SPS Agreement were not fully applicable to developing countries until 1997, and to the least developed countries until 2000. There is provision for a developing country to seek an exception from the obligations of the agreement taking into account its financial, trade and development needs.

87. WTO Members are required to publish their food safety regulations. Furthermore, they must give advance notice of any new or modified requirements which are not based on the international standards and which may affect trade, and solicit comments on these from interested trading partners. In urgent situations, advance notification is not required, but the measures taken must be immediately notified and comments considered. The notifications are submitted to the WTO Secretariat, which promptly

circulates them to all Members and makes them publicly available. Since 1995, close to 2,000 notifications have been submitted on sanitary and phytosanitary measures. Each WTO Member is also required to establish a national enquiry point to respond to all reasonable requests for information and documentation regarding its food safety measures.

88. The SPS Committee oversees the implementation of the SPS Agreement and provides a forum for consideration of any food safety matter of concern to a WTO Member; it normally meets three times per year. Decisions in the SPS Committee are taken on the basis of consensus. All 136 WTO Members are automatically members of the SPS Committee, and any government with observer status to the WTO (including the 30 or so countries currently negotiating their accession to the WTO) enjoys observer status in the SPS Committee. Non-governmental entities cannot attend meetings of the SPS Committee, however a number of international or regional intergovernmental organisations do have observer status, including the CAC, FAO, WHO, OIE, IPPC and, on an *ad hoc* basis, the OECD.

89. The work of the SPS Committee focuses on any particular concern raised by a WTO Member, and the Committee has thus considered, *inter alia*, BSE-related trade restrictions, measures taken in response to the Belgian dioxin contamination, the EC's modification of maximum allowable levels of aflatoxins in various foods, Australia's regulations concerning benzoic acid in sauces and the EC's restrictions on fish from certain cholera-affected African countries. The Committee also routinely monitors the use of international standards by WTO Members, implementation concerns of developing countries, and technical assistance needs and programs. The Committee recently undertook a review of the implementation of the SPS Agreement, and held a special meeting to discuss the implementation of the notification and information provisions.

90. In the context of implementation of the SPS Agreement, the WTO closely co-operates with the three international standard-setting organisations mentioned above, and in particular with the Codex regarding food safety. This co-operation involves not only active participation in the work of some Codex Committees, but also joint national or regional technical assistance activities related to the implementation of the SPS Agreement. Furthermore, the SPS Committee developed a procedure to monitor the use of international standards, guidelines and recommendations which may have a major trade impact. Where problems with significant trade impact are identified, related to the use, non-use or absence of international standards, the SPS Committee may request the Codex, OIE or IPPC to examine the matter.

91. The WTO also has a close collaboration with other international organisations, including the WHO. The revision of the WHO's International Health Regulations is being considered by the SPS Committee, in order to avoid potential overlap or conflict. The WTO has also participated in joint technical assistance activities with WHO.

92. The WTO also contains provisions for the settlement of trade disputes, including disputes regarding food safety measures. Upon request from a WTO Member government, a panel of three individuals may be established to examine whether a particular measure violates obligations under any WTO agreement, including the SPS Agreement. The SPS Agreement provides for the dispute settlement panel to seek the advice of scientific or technical experts. The international organisations identified above may be asked to identify experts for consideration by the panel, in consultation with the parties to the dispute. Experts from the international organisations may also be invited to advise the panel. (A Codex expert provided information to the panel in the complaint regarding the European Union's ban on imports of meat from cattle treated with growth-promoting hormones.) Once selected, the experts may be asked to provide both written and oral replies to questions from the panel on technical and scientific aspects of the dispute. The written replies to the questions and a transcript of the meeting with the scientific experts are annexed to the panel's report.

93. The WTO dispute settlement procedure provides the possibility of a government to appeal the decision of a panel. In such cases, three of the WTO's standing Appellate Body judges will examine the legal decisions of the panel, and may sustain, elaborate on, or overturn these. The report of the panel, as modified by the Appellate Body, is submitted for approval by all WTO Members sitting as the Dispute Settlement Body. Approval is essentially automatic, unless there is a consensus not to approve. The panel and Appellate Body reports are publicly available documents.

94. To date, five SPS disputes have been examined by panels and the Appellate Body. Separate United States and Canadian complaints against the European Union's ban on imports of meat treated with growth-promoting hormones are the only cases involving food safety concerns. Separate Canadian and U.S. complaints against Australian restrictions on imports of salmon addressed animal health protection, whereas a United States complaint against Japan involved protection of plants from insect damage. The WTO dispute settlement panels have examined and judged both the risk assessments undertaken by governments and their risk management decisions, in the light of the obligations of the SPS Agreement.

The Agreement on Technical Barriers to Trade (TBT Agreement)

95. The TBT Agreement also creates legally binding obligations on WTO Members. It applies to any food safety regulation which may fall outside the scope of the SPS Agreement, as well as to other food quality requirements such as nutritional standards, composition, grading, packaging and labelling. Most GMO labelling requirements, for example, have been discussed in the context of the TBT Agreement and the "consumer's right to know", rather than in the context of food safety concerns under the SPS Agreement. The TBT Agreement also encourages WTO Members to base their standards or technical regulations on internationally-developed standards, but does not explicitly identify the relevant standard-setting bodies. Furthermore, a government may choose not to base national requirements on an international standard if it considers this inappropriate to achieve its particular objectives. These objectives may include the prevention of deceptive practices, protection of human, animal or plant health or safety (if not covered by the SPS Agreement) or of the environment. The TBT Agreement requires notifications similar to those for sanitary or phytosanitary measures, and further requires notification of bilateral technical agreements and compliance by national standard-setting bodies with a Code of Good Practice for the Preparation, Adoption and Application of Standards.

OECD Food Safety Activities

Task Force for the Safety of Novel Foods and Feeds

96. The Task Force for the Safety of Novel Foods and Feeds is comprised of individuals from those ministries or agencies, which have responsibility for the safety assessment of products of modern biotechnology (including genetically modified foods). The work of the Task Force builds on the long experience in food safety-related activities at OECD. By the end of 1990, work had been established to develop principles for the safety assessment of products of modern biotechnology. The main achievement of this work was development of the concept of *substantial equivalence.*

97. The safety assessment of defined differences and non-substantially equivalent products was discussed at an OECD Workshop at Oxford (OECD, 1996). The group took the first steps in identifying strategies that can be used to establish the safety of food produced by biotechnology when there is no acceptable counterpart for comparison and therefore the concept of substantial equivalence cannot be applied. By 1997, several member countries had gained experience in the safety assessment of foods derived through modern biotechnology. Various reviews concluded that the determination of the concept

provides equal or increased assurance of the safety of foods derived from genetically modified plants as compared with foods derived through conventional methods (OECD, 1998).

Working Group for the Harmonisation of Regulatory Oversight in Biotechnology

98. The Working Group for the Harmonisation of Regulatory Oversight in Biotechnology is comprised of experts from those ministries or agencies, which have responsibility for the environmental safety assessment of products of modern biotechnology (including genetically modified varieties). Initially, much of the effort was concentrated on the environmental and agricultural implications of field trials of genetically modified crops. This was followed by a consideration of the scale-up, and commercialisation, of crop plants. In 1995, arrangements for environmental biosafety, food safety as well as varietal registration and seed certification were reviewed.

99. Since that time, the Working Group has focused on promoting harmonisation through the development of consensus documents. The goal is to identify common elements in the safety assessment of a new variety developed through modern biotechnology, in order to encourage information sharing and prevent duplication of effort among countries. The common elements fall into two general categories: the biology of the host species or crop; and the gene product.

OECD Working Group on Pesticides: work on Maximum Residue Limits (MRLs)

100. The OECD Working Group on Pesticides is striving to improve the scientific basis for the establishment of pesticide Maximum Residue Levels (MRLs). MRLs are established to allow the free trade of food commodities, to minimise the exposure of consumers to residues and to promote Good Agricultural Practice. MRLs can be set nationally, but international MRLs are recommended by Codex. Codex MRLs, according to the SPS Agreement are taken to be the international reference and can therefore be used as the presumptive levels in the event of a trade dispute. However, since the data requirements underpinning the establishment of MRLs are not harmonised on a global basis, some countries have problems in accepting Codex MRLs, which in turn can cause trade disruptions. In an effort to improve this situation, a joint EU/OECD workshop was held in York, UK in September 1999 to develop recommendations for minimum data requirements for establishing MRLs. The results of the workshop will be published and used as guidance by OECD Member countries. The workshop's recommendations have been forwarded to the Chair of the Codex Committee on Pesticide Residues for discussion at the May Codex meeting and they will also be brought to the attention of the JMPR when it meets in September 2000.

101. In addition to work on data requirements, a joint OECD/FAO project to develop a global zoning system for residue field trials was agreed by the Working Group on Pesticides in February 2000. This project involves mapping the world into geographic zones within which pesticide residue behaviour would be expected to be comparable. Such a system has a number of benefits including: 1) improving confidence in the supporting data used to set MRLs and thus enhancing food safety assurances based on these data; 2) facilitating international trade by supporting the establishment of import tolerances based on data developed anywhere within the same zone; and 3) increasing the opportunity to establish MRLs for minor crops by accepting data from the same zone that has been produced in a different part of the world.

OECD Schemes for the Varietal Certification of Seeds Moving in International Trade

102. The OECD Seed Schemes were developed primarily to facilitate international trade in seed, by harmonising varietal certification procedures and identification labels. The Schemes are implemented by a

total of forty-eight Member and non-member countries across all continents. Their essential purpose is to harmonise the assessment and certification of identity and purity of cultivated crop plant varieties - including genetically modified ones.

103. National and international regulation of products of modern biotechnology, in particular the segmentation of some markets into GMO and non-GMO products, will have a direct impact on international seed trade. In August 1999, the International Seed Federation (FIS) proposed an initiative to examine the feasibility of establishing a system approach, based on the existing OECD seed certification schemes, for measuring and certifying the transgenic purity of seed in response to market demanded or publicly required thresholds. This approach could include a defined methodology for product identification and traceability, as well as harmonized protocols for operation and monitoring, based on shared and accessible technologies. The initiative reflects the seed industry's resolve to find science-based solutions supported by formal management system controls for responding to public and regulatory concerns.

104. Given the essential role played by the OECD Seed Schemes in the international seed trade, FIS considered that the discussions should take place in that forum, all the more so that the International Seed Testing Association, the Association of Official Seed Certification Agencies (AOSCA) and the Association of Official Seed Analysts (AOSA) are also involved in the discussion of the OECD Seed Schemes.

B. Activities Addressing Food Safety Issues

105. This section focuses on current and emerging issues that are being addressed or considered within the food safety and other activities of intergovernmental organisations and identifies new areas of development. The medium-term plan 1998-2002 of the CAC, agreed at its meeting in June-July 1999 is attached (Annex 6) and provides further details of planned Codex activities. Also attached (Annex 7) are recommendations agreed by the WHO Executive Board in January 2000 that, if agreed at the World Health Assembly later in 2000, will provide the future framework for WHO’s food safety activities.

Developing International Food Safety Frameworks

106. The work of Codex has a dual function: protecting the health of consumers and promoting fair practices in food trade. However, recognition of Codex standards in the SPS Agreement as the basis for the international harmonisation of food safety measures has greatly increased interest in, and focus on, the work of Codex. In anticipation of this increased importance within the WTO framework, in 1991, Codex shifted the main orientation of its work away from vertical commodity committees toward horizontal committees addressing food safety issues and is developing principles for risk analysis to be applied within the Codex system.

107. The Conference on International Food Trade beyond 2000 recommended that “WHO should consider updating and harmonising, between JECFA and JMPR, the common principles of the toxicological evaluation of food chemicals (e.g. natural constituents, additives, contaminants, residues of pesticides and residues of veterinary drugs) and publish this information in a consolidated document”. The Conference also recommended that “approaches used for the calculation of dietary intakes of residues by JECFA and JMPR be harmonised” and that “FAO should provide advice to member governments on guidelines for dietary intake studies”.

108. For the microbiological risk assessment of food in international trade, FAO and WHO will establish a new *ad hoc* expert advisory body, as requested by the CAC. The conclusions of this body will support the work of the Codex Committee on Food Hygiene (CCFH) and other Codex committees. In addition, FAO and WHO will be holding a number of meetings and consultations related to microbiological risk assessment and hazard characterisation and developing databases and mechanisms for information exchange.

109. An *ad hoc* Intergovernmental Task Force on Animal Feeding was established by the CAC and will meet for the first time in June 2000. The Task Force is charged with developing guidelines or standards, as appropriate, on Good Animal Feeding practices with the aim of ensuring the safety and quality of foods of animal origin. The Task Force is required to produce a preliminary report to the CAC in 2001 and a final report in 2003.

International Standards for the Products of Modern Biotechnology

110. An *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology has been established by the CAC. The objectives of the Task Force are to develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair trade practices. A preliminary report to the CAC is due in 2001 with a final report due in 2003. At its first meeting, the Task Force agreed to proceed with the elaboration of a set of broad general principles for risk analysis of foods derived from biotechnology and specific guidance on the risk assessment of foods derived from biotechnology. The Task Force agreed to give preference to guidance that was applicable to all foods derived from biotechnology. It also agreed that consideration should be given to the development of guidelines for transparency in decision-making and the participation of all stake-holders in the decision-making process, and that careful attention should be given to the development of adequate and appropriate definitions drawing on other agreed texts.

111. The Codex Committee on Food Labelling is developing recommendations for the labelling of foods obtained through biotechnology through an amendment to the general standard for the labelling of prepackaged foods. Section 2 (Definition of Terms) and Section 5 (Additional Mandatory Requirements) are due to be discussed at Step 3 of the Codex procedure (Annex 2) in May 2000.

112. In collaboration with international partners, FAO and WHO will provide the scientific basis for decisions regarding human health and nutrition aspects of foods produced by biotechnology. Other considerations relevant to the assessment of this new technology will be explored in collaboration with other agencies. FAO and WHO will be holding a joint expert consultation on the safety and nutritional evaluation of foods derived from biotechnology in May/June 2000. Amongst the topics to be addressed will be five scientific questions raised by the Codex *ad hoc* Intergovernmental Task Force

113. The safety of biotechnology has not been a major issue of discussion in WTO to date, although countries have been notifying biotechnology related measures under both the SPS and TBT Agreements. To date, discussions have occurred primarily in the TBT Committee, with respect to labelling requirements on genetically modified food products introduced by several WTO Members. The TBT Agreement permits governments to impose labelling requirements necessary to fulfil legitimate objectives, although Members disagree on whether providing information on the method of production to consumers is a legitimate objective. The discussion of biotechnology in the SPS Committee has been limited to an informal information session with the secretariat of the Convention on Biological Diversity with respect to the status of the negotiations of the Biosafety Protocol.

114. The OECD continues to do major work on some aspects of biotechnology, research and development and research policies, scientific and technological infrastructure of biotechnology, intellectual property rights and biotechnology statistics. The OECD Task Force for the Safety on Novel Foods and Feeds is focusing on further efforts to promote international harmonisation in the area of the safety assessment of products of modern biotechnology. The main product of work currently, is the development of consensus documents, which, on a crop-by-crop basis, summarise information, which is used in the determination of substantial equivalence. The OECD Working Group for the Harmonisation of Regulatory Oversight in Biotechnology is currently considering how to make the next steps towards harmonisation. It is expected to initiate work to identify more clearly the differences between Member countries in their regulatory decision making.

Precautionary Approaches and Principles

115. Whilst precaution has been and remains an essential element of the Codex decision-making process, the application of precautionary approaches and principles has yet to be defined in a structured manner. In its general recommendations, the FAO Conference on International Food Trade Beyond 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition, *inter alia*, "called upon all parties to recognise that precaution has been and should remain an essential element of risk analysis in the formulation of national and international standards, and agreed that the Codex Alimentarius Commission was the most appropriate forum to discuss this issue". In addition, the Conference concluded that the Codex Committee on General Principles was the most appropriate forum to discuss the relevance of, and clarify terms such as, the "precautionary principle" and "precautionary approach" as they might apply to food safety and to work on these issues as appropriate. Working Principles for Risk Analysis are being developed by the Codex Committee on General Principles. Within the section on Risk Management, the draft Principles include provisions to allow risk managers to apply a precautionary approach when the scientific evidence is insufficient and there is evidence to suggest that negative effects will occur but it is difficult to evaluate their nature and extent.

116. The WTO SPS Agreement embodies a precautionary approach. The agreement requires that WTO members' food safety measures be based on international standards or on risk assessments. In situations where the scientific evidence is insufficient, Article 5.7 of the SPS Agreement, provides that WTO members may provisionally adopt, a sanitary or phytosanitary measure on the basis of pertinent information, including that from Codex and other sources. The WTO member adopting a provisional measure in these circumstances must seek to obtain the additional information necessary for a more objective risk assessment, and review its provisional measure within a "reasonable" period of time. In the case of EC MEASURES CONCERNING MEAT AND MEAT PRODUCTS (HORMONES), the Appellate Body noted some aspects of the relationship of the precautionary principle to the SPS agreement:

> *"First, the principle has not been written into the SPS Agreement as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement. Secondly, the precautionary principle indeed finds reflection in Article 5.7 of the SPS Agreement. We agree, at the same time, with the European Communities, that there is no need to assume that Articles 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3 These explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which level may be higher (i.e., more cautious) than that implied in existing international standards, guidelines and recommendations. Thirdly, a panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to*

human health are concerned. Lastly, however, the precautionary principle does not, by itself and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement".

117. Japan invoked Article 5.7 in defence of its plant protection requirements. In that case, the Appellate Body noted that a provisional measure could not be justified unless the Member which adopted the measure actively sought to obtain the additional information necessary for a more objective assessment of risk, and subsequently reviewed its measure within a reasonable period of time.

118. The Protocol on Biosafety also incorporates a precautionary approach. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the potential adverse effects of a LMO on the conservation and sustainable use of biological diversity, taking also into account risks to human health, shall not prevent an importing Party from taking a decision in order to avoid or minimise such potential adverse effects. In implementing such action, parties are referred specifically to the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, as stated in the Preamble to, and Article 1 of, the Protocol. The Protocol requires that the Conference of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making.

Regulatory Enforcement and Compliance

119. In general, the intergovernmental organisations discussed in this report are not responsible for regulatory enforcement or compliance with respect to food safety these being matters for action by countries.

120. An important element of the work of the SPS Committee is to consider any concerns which may be raised with regard to compliance by governments with the obligations of the SPS Agreement. The discussion by the SPS Committee of specific trade concerns and difficulties of implementation have helped ensure enforcement of WTO Members' legal obligations. The WTO's dispute resolution provisions function as an effective enforcement mechanism when other avenues for seeking compliance have failed.

121. The Protocol on Biosafety requires that the Conference of the Parties shall, at its first meeting, consider and approve co-operative procedures and institutional mechanisms to promote compliance with the provisions of the Protocol and to address cases of non-compliance.

Addressing Socio-economic Concerns

122. Under step 3 of the procedures for the elaboration of Codex Standards and Related Texts (Annex 2), all proposed drafts are sent to Members of the CAC and international organisations for comment on all aspects including possible implications for their economic interests. A further opportunity exists at step 6 of the procedure for Members of the CAC to draw attention to any matter concerning the possible implications of a draft standard for its economic interest, including such matters that have not, in the Member's opinion, been satisfactorily resolved at an earlier step. Governments also have an opportunity at step 1 to comment on whether a standard should be developed and again at step 8 before a standard is adopted. In considering statements considering economic implications, the CAC should have due regard to the purposes of the Codex Alimentarius concerning protection of the health of consumers and ensuring fair trade practices as well as the economic interests of the Member concerned. When elaborating standards, Codex has regard, where appropriate, to "other legitimate factors" relevant for the health protection of consumers and for the promotion of fair practices in food trade. As regards the general

aspects of "other factors" in the decision process, the Codex Committee on General Principles is developing a general orientation for Codex work in the framework of risk analysis, with the understanding that other Codex Committees responsible for risk analysis can provide specific clarification on the integration of such factors in their work.

123. The SPS Agreement permits governments to determine the level of food safety protection they consider appropriate for their country. However, governments must avoid arbitrary or unjustifiable distinctions in health protection levels which result in discrimination, must be transparent with respect to the factors they have considered and the decisions they have taken, and must meet all of the requirements of the SPS Agreement with respect to the sanitary measures they impose.

124. Under the Protocol on Biosafety, Parties may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity. Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of LMOs.

Communication and Consultation

125. The basis for communication and consultation with stakeholders is the participation of international non-governmental organisations representing a full spectrum of interests in the work of the CAC, both by direct participation and the ability to provide written comments and proposals on draft Codex texts as they are being elaborated. Transparent principles for admitting NGOs as observers and the relationships between NGOs and the CAC were adopted by the CAC in 1999.

126. Since its 20th Session (1993) the CAC has taken steps to provide for greater participation by consumer groups in its work. The Codex Committee on General Principles is developing guidance on measurable objectives to assess consumer participation in Codex and has identified a number of measures to facilitate consensus in Codex discussions.

127. The increased awareness of food safety issues calls for scrutiny of the science base for making food safety decisions at both national and international levels. Chemical risk assessments, which have been carried out by JECFA and JMPR, are extremely valuable for Member States. This work will be strengthened and the results of these bodies' meetings will be made more readily and freely available to Member States. The procedures for the identification and selection of experts in these bodies is being reviewed. Criteria for selection will soon be published, including the conditions applying to "conflicts of interest" that have now been in place for some time.

128. FAO and WHO acknowledge the importance of open and understandable risk communication between all parties affected by foodborne risk, and will take the lead in global as well as regional communication. Apart from permitting useful dialogue between the stakeholders in the risk analysis process, such communication will strengthen information sharing and consumer education and build reliability into the process, which in turn will lead to improved food safety practices in domestic settings.

129. The SPS Agreement requires governments to publish their food safety regulations. In addition, WTO Members must notify trading partners of any proposed new or modified regulations, and solicit and consider comments on these. These notifications are publicly available documents. Governments must also provide, upon request, copies of their sanitary measures, bilateral or plurilateral agreements, risk assessments and any other relevant documentation.

130. The OECD Working Group for the Harmonisation of Regulatory Oversight of Biotechnology is also focusing on outreach activities. Of particular importance in this respect is the web site, BioTrack

Online. This comprises information on regulatory developments in OECD Member countries, including details of laws, regulations and the contact points of the responsible ministries and agencies. It also includes a database of field trials in OECD Member countries, as well as a database of those products, which have been commercialised.

Foodborne Disease Surveillance

131. WHO believes that a better evaluation of the burden of foodborne disease is needed to set priorities for future activities and that, where appropriate, Member States should set up systems for laboratory-based surveillance of foodborne disease, covering both outbreaks and sporadic cases, and for monitoring contamination of food. At the request of Member States, WHO will support capacity-building for data collection and surveillance systems. WHO will also initiate work to define a common format for harmonised data collection procedures and to determine the minimal data requirements needed from region to region. Recognising that the disease outcome is a real measure of the effectiveness of food safety interventions, WHO will consider developing regional and/or national targets for reduction of the incidence of disease, duly taking into account any international implications this would have.

132. OIE will continue to collect process and disseminate data on the world animal health situation to provide Member countries with the essential information needed to launch national control programmes and to formulate animal health regulations for international trade.

Capacity Building

133. In many countries of the world, greater concern with food safety has underlined the need for strengthening local technical and scientific capabilities, and for additional educational tools pertinent to each level of society. In developed countries, WHO will promote the concept that strengthening local technical and scientific capability in the food safety area in developing countries can be mutually beneficial. In strengthening food safety activities, WHO through its six Regional Offices will seek to respond to the differing food production conditions in different countries as well as the variation in societal and cultural settings and traditional foods. Likewise, WHO will substantially increase its technical co-operation activities with developing countries in order to protect the health of consumers through the production of safe food for both local consumption and export.

134. FAO, through its field and technical co-operation programme has provided direct capacity building in food quality and safety to the majority of its member countries. This includes programmes related to the safe use of agricultural chemicals, integrated pest management for the reduced use of pesticides, good hygienic practices in agriculture, animal production, fisheries and food processing based on the HACCP approach, and measures to reduce the development of mycotoxin contamination in specific foods. FAO has also provided direct technical assistance through field projects and other Member activities to Member countries to develop or strengthen national food control programmes. FAO's "Umbrella Programme" for support to Member countries in the application of the WTO Agreements affecting agriculture includes programmes enhancing the effectiveness of participation in the work of the CAC. In addition, FAO and WHO are presently developing a manual on risk analysis in order to facilitate the application of international principles and recommendation on this field. The manual includes information on risk assessment, risk management and risk communication, as well as outlining the importance of risk analysis as a tool in relation to SPS and also to Codex.

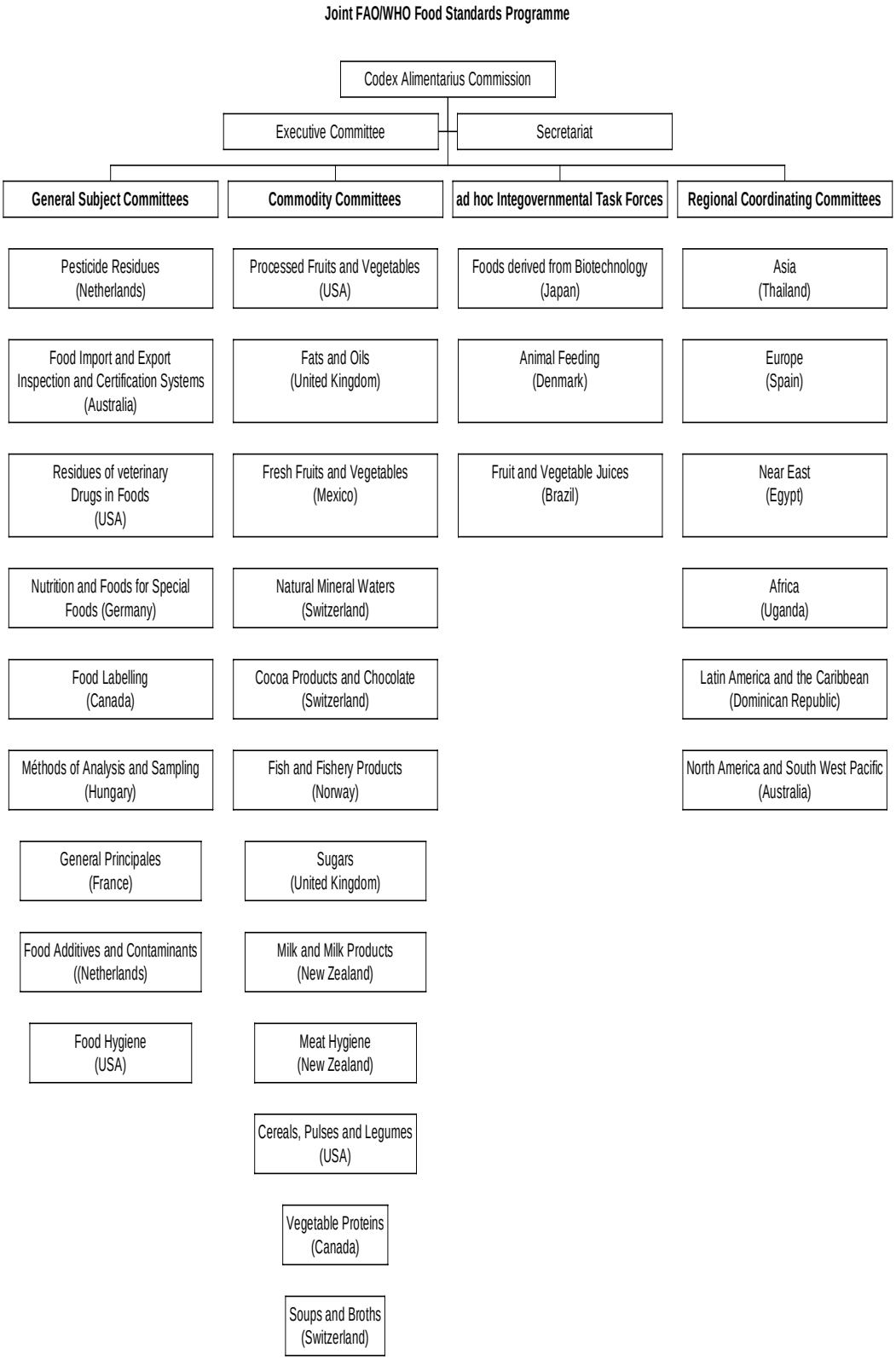
135. The SPS Agreement encourages governments to facilitate technical assistance to developing country Members, either bilaterally or through the appropriate international organisations. The SPS Committee has solicited information from governments on their technical assistance programs and needs

through a questionnaire. The WTO Secretariat also organises technical assistance activities in the food safety, animal and plant health protection areas. This assistance frequently takes the form of national or regional seminars organised in response to developing countries' needs, often with the participation of Codex representatives. The training sessions provide information on the functioning and responsibilities of each of the international organisations represented, and may include special workshops on risk assessment, equivalence, transparency, or other specific implementation concerns. To a limited extent, the WTO financially assists the participation of developing country officials in these and other more technical training programs. The WTO secretariat also assists developing country Members in dispute resolution.

136. The Protocol on Biosafety places an obligation on Parties to cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety for the effective implementation of the Protocol including through existing national and international organisations and, as appropriate, through facilitating private sector involvement. The needs of the least developed and small island developing States and Parties with economies in transition are highlighted.

137. The International Reference Laboratories and Collaborating Centres of OIE provide technical support to developing countries in monitoring and controlling animal diseases. OECD, UNIDO and ICGEB have programmes to help capacity building for biosafety evaluation in developing countries, including workshops for future regulators.

Annex 1: Organisation Chart of the Codex System



Annex 2:
Procedures for the Elaboration of Codex Standards and Related Texts

Codex Alimentarius: Procedural Manual – 11th Edition
(A) Uniform Procedure for The Elaboration Of Codex Standards And Related Texts

STEPS 1, 2 AND 3

(1) The Commission decides, taking into account the "Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies", to elaborate a World-wide Codex Standard and also decides which subsidiary body or other body should undertake the work. A decision to elaborate a World-wide Codex Standard may also be taken by subsidiary bodies of the Commission in accordance with the above-mentioned criteria, subject to subsequent approval by the Commission or its Executive Committee at the earliest possible opportunity. In the case of Codex Regional Standards, the Commission shall base its decision on the proposal of the majority of Members belonging to a given region or group of countries submitted at a session of the Codex Alimentarius Commission.

(2) The Secretariat arranges for the preparation of a proposed draft standard. In the case of Maximum Limits for Residues of Pesticides or Veterinary Drugs, the Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Panel of Experts on Pesticide Residues (JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).

(3) The proposed draft standard is sent to Members of the Commission and interested international organisations for comment on all aspects including possible implications of the proposed draft standard for their economic interests.

STEP 4

The comments received are sent by the Secretariat to the subsidiary body or other body concerned which has the power to consider such comments and to amend the proposed draft standard.

STEP 5

The proposed draft standard is submitted through the Secretariat to Commission or to the Executive Committee with a view to its adoption a draft standard[1]. In taking any decision at this step, the Commission or the Executive Committee will give due consideration to any comments that may be submitted by any of its Members regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests. In the case of Regional Standards, all Members of the Commission may present their comments, take part in the debate and propose amendments, but only the majority of the Members of the region or group of countries concerned attending the session can decide to amend or adopt the draft. In taking any decisions at this step, the Members of the region or group of

[1] Without prejudice to any decision that may be taken by the Commission at Step 5, the proposed draft standard may be sent by the Secretariat for government comment prior to its consideration at Step 5, when, in the opinion of the subsidiary body or other body concerned, the time between the relevant session of the Commission and the subsequent session of the subsidiary or other body concerned requires such action in order to advance the work.

countries concerned will give due consideration to any comments that may be submitted by any of the Members of the Commission regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests.

STEP 6

The draft standard is sent by the Secretariat to all Members and interested international organisations for comment on all aspects, including possible implications of the draft standard for their economic interests.

STEP 7

The comments received are sent by the Secretariat to the subsidiary body or other body concerned, which has the power to consider such comments and amend the draft standard.

STEP 8

The draft standard is submitted through the Secretariat to the Commission together with any written proposals received from Members and interested international organisations for amendments at Step 8 with a view to its adoption as a **Codex standard.** In the case of Regional standards, all Members and interested international organisations may present their comments, take part in the debate and propose amendments but only the majority of Members of the region or group of countries concerned attending the session can decide to amend and adopt the draft.

(B) Uniform Accelerated Procedure For The Elaboration Of Codex Standards And Related Texts

STEPS 1, 2 AND 3

(1) The Commission or the Executive Committee between Commission sessions, on the basis of a two-thirds majority of votes cast, taking into account the "Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies", shall identify those standards which shall be the subject of an accelerated elaboration process[2]. The identification of such standards may also be made by subsidiary bodies of the Commission, on the basis of a two-thirds majority of votes cast, subject to confirmation at the earliest opportunity by the Commission or its Executive Committee by a two-thirds majority of votes cast.

(2) The Secretariat arranges for the preparation of a proposed draft standard. In the case of Maximum Limits for Residues of Pesticides or Veterinary Drugs, the Secretariat distributes the recommendations for maximum limits, when available from the Joint Meetings of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Panel of Experts on Pesticide Residues JMPR), or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). In the cases of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).

[2] Relevant considerations could include, but need not be limited to matters concerning new scientific information; new technology(ies); problems related to trade or public health; or the revision or updating of existing standards.

(3) The proposed draft standard is sent to Members of the Commission and interested international organisations for comment on all aspects including possible implications of the proposed draft standard for their economic interests. When standards are subject to an accelerated procedure, this fact shall be notified to the Members of the Commission and the interested international organisations.

STEP 4

The comments received are sent by the Secretariat to the subsidiary body or other body concerned which has the power to consider such comments and to amend the proposed draft standard.

STEP 5

In the case of standards identified as being subject to an accelerated elaboration procedure, the draft standard is submitted through the Secretariat to the Commission together with any written proposals received from Members and interested international organisations for amendments with a view to its adoption as a Codex standard. In taking any decision at this step, the Commission will give due consideration to any comments that may be submitted by any of its Members regarding the implications which the proposed draft standard or any provisions thereof may have for their economic interests.

Annex 3:
Joint FAO/WHO Food Standards Programme: Statements of Principles

(Extract from the Codex Procedural Manual: 11th Edition :)

A. Statements of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account

1. The food standards, guidelines and other recommendations of the Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.

4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

B. Statements Of Principle Relating To The Role Of Food Safety Risk Assessment

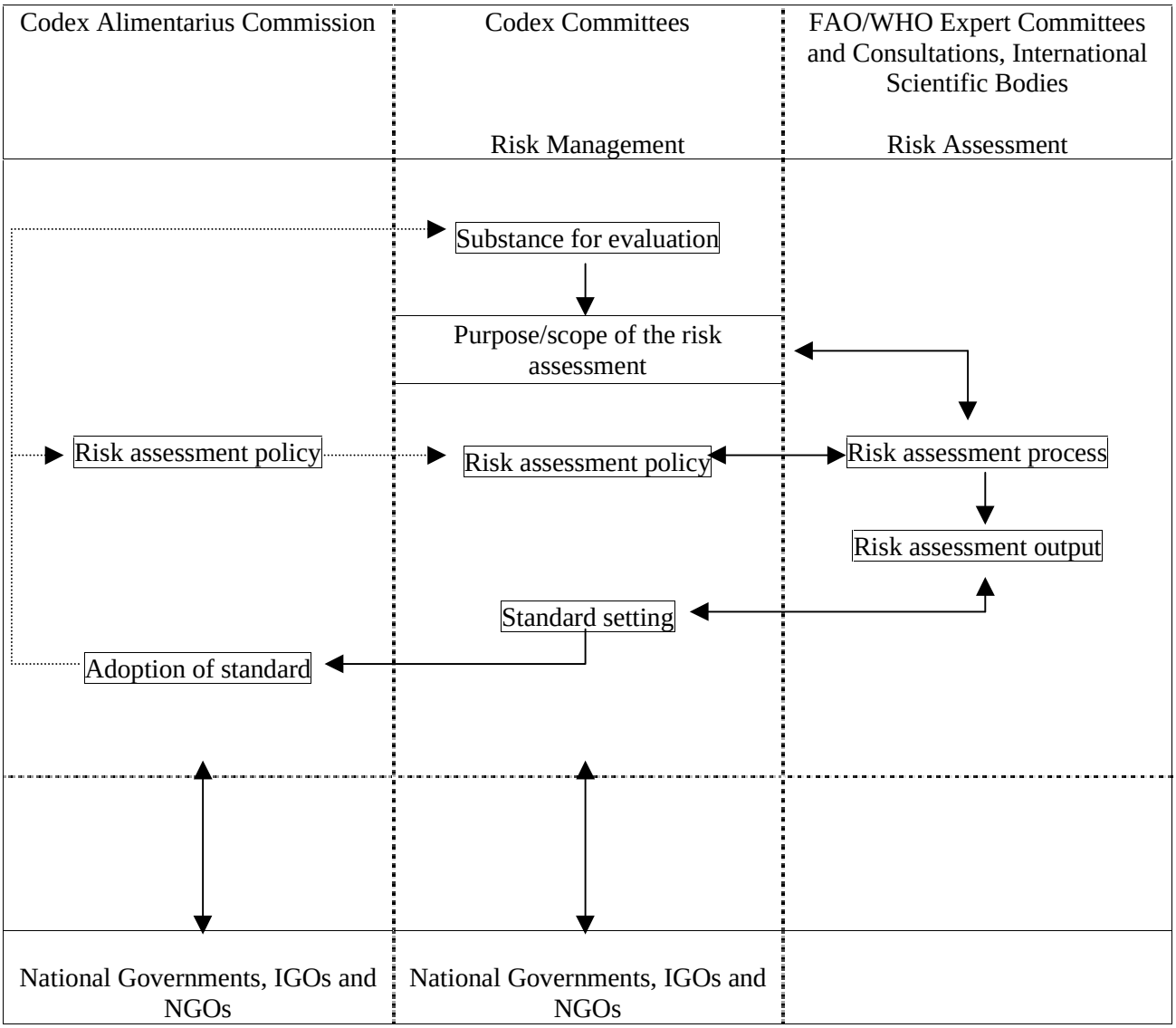
1. Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.

2. Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, and should be documented in a transparent manner.

3. There should be a functional separation of risk assessment and risk management, while recognising that some interactions are essential for a pragmatic approach.

4. Risk assessments should use available quantitative information to the greatest extent possible and risk characterisations should be presented in a readily understandable and useful form.

Annex 4:
Risk Assessment and Risk Analysis in the Codex System[3]



Interaction between the CAC, Codex Committees, FAO/WHO Expert Committees, National Governments, IGOs and NGOs in the risk analysis process (dotted arrows represent the iterative exchange of information)

[3] Adapted from *Towards Internationally Acceptable Standards for Food Additives and Contaminants Based on the Use of Risk Analysis*, Environmental Toxicology and Pharmacology, 5 (1998) 227-236

Annex 5:
Codex Alimentarius: Recommendations Relating to Risk Analysis

(Extract from ALINORM 99/37, Paragraphs 56-58)

Principles of Risk Analysis

56. The Commission then adopted the following recommendations to be applied in the framework of Codex:

a) Programmes that contribute to risk analysis should have high priority;

b) Relevant Codex Committees should continue to develop and to apply risk analysis principles and methodologies appropriate to their specific mandates within the framework of the Action Plan and report their progress to the Commission on a regular basis;

c) Proposals for new or amended definitions for use within the framework of risk analysis, as appropriate, should be considered by the Codex Committee on General Principles;

d) To overcome confusion about the usage of the terms "risk analysis" and "hazard analysis", the Commission should reiterate its definitions for these concepts and explain how they apply in practice;

e) The Commission should continue and expand its efforts to increase the participation of those national governments and NGOs that are members or observers but that are not presently active participants in Codex matters;

f) Relevant Codex committees should appoint a co-author from a developing country for position papers, where the main author(s) is from a developed country;

g) Relevant Codex committees should consider developing quality criteria for data used for risk assessment. To the extent possible such criteria should be consistent with one another, taking into account the technical differences in the disciplines covered;

h) Relevant Codex committees should consider the acute aspects of dietary exposure to chemicals in food;

i) Recognising that primary production in developing countries is largely through small and medium enterprises, risk assessment should be based on global data, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies;

j) Risk management should take into account the economic consequences and the feasibility of risk management options in developing countries. Risk Management should also recognise the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health.

57. The Commission also endorsed the following recommendations addressed to governments:

a) Member governments should participate actively in Codex work. Governments should also consider, to the extent possible, the views of all interested parties when formulating the national position on a Codex matter. Further, governments are encouraged to communicate and explain the basis of the decisions of Codex to those same interested parties and to the public at large;

b) Governments should adopt organisational structures and procedures that assure transparency and that allow National Codex Committees to consider consumer and private sector opinions. Co-operation should be developed with the consumer and private sectors in risk communication -especially in developing simple messages concerning food quality and safety;

c) Governments are encouraged to incorporate principles of risk analysis when establishing or updating national legislation on food safety matters;

58. The Commission endorsed the following recommendations addressed to FAO and WHO:

a) FAO and WHO should develop harmonised training or other programmes designed to increase the understanding of the risk analysis process and the role of risk communication, both for member countries and for international organisations active in Codex work;

b) FAO and WHO should continue to assist, on a priority basis, developing countries by providing training at regional, sub-regional or national levels in introducing and applying different aspects of risk analysis, HACCP and good manufacturing, agricultural and hygienic practices and development of ways to apply risk-based good practices in small businesses;

c) FAO and WHO should take greater steps to strengthen their work in assisting developing countries to undertake dietary/nutrition studies, monitoring programmes and intake/exposure assessment;

d) FAO and WHO should strengthen transparency in scientific risk assessment. This includes transparency in the choice of experts and the advice being given including how uncertainties are addressed;

e) FAO and WHO, as parent organisations, should emphasize the need for increased interaction and communication between expert bodies, such as JECFA and JMPR, and the Codex Committees, such as CCFAC, CCRVDF and CCPR, and should request the expert advisory bodies and the subsidiary committees to cooperate along the principles of risk analysis;

f) The Commission reiterated its request to FAO and WHO to convene an international expert advisory body similar to JECFA and JMPR on the microbiological aspects of food safety to address particularly microbiological risk assessment.

Annex 6:
Codex Alimentarius: Medium-Term Plan for 1998 to 2002

(Extract from ALINORM 99/37, Appendix II)

GENERAL APPROACHES AND ISSUES

1. The general approach taken in the preparation of the Medium-Term Plan for the period realistically takes into account the financial situations facing the parent organisations and the UN system-wide desire for simplification and streamlining of existing structures. The emphasis on horizontal issues laid down by the Commission in recent years provides a satisfactory basis for this streamlining. Overall improvements in the procedures for decision-making and the acceptance of standards and related texts will be developed.

2. The world's food security needs stretching into the mid-21st Century were the focus of the World Food Summit, Rome, November 1996. The International Conference on Nutrition, 1992, stressed the importance of improved food quality and safety as a means of improving nutrition. The efficient use of sustainable agricultural resources and improvements in agricultural production efficiencies and food processing and marketing practices by all available safe technologies must be assured. In the Medium-Tern, therefore, high priority should be given to science-based standards, guidelines and other recommendations aimed at enhancing protection of consumers' health and removing unjustified impediments to trade in food produced and marketed by such means. Nevertheless, buyers who wish to have access to foods produced or processed by alternative methods should have adequate information and assurances that such alternative conditions have indeed been applied. Labelling and certification procedures for such alternative products may need to be considered in parallel with the development of guidelines for new production and processing technologies for mainstream food products, where these are deemed necessary.

3. Among other general issues which are included, the integration of risk analysis principles into the Codex decision-making process should be completed in the period by introducing necessary changes to the Procedures for the Elaboration of Codex Standards and Related Texts, the General Principles of the Codex Alimentarius, and the Criteria for the Establishment of Work Priorities. Specific guidance on the application of risk analysis principles should be provided to Codex Committees on one hand and to Member Governments on the other: the former guidance to be included in the Procedural Manual, the latter in the Codex Alimentarius itself. The challenges facing developing countries in applying risk analysis principles will need to be taken into consideration. Guidance will be developed for the identification, management, application and interpretation of legitimate factors other than science relevant to the health protection of consumers and for the promotion of fair practices in the food trade. Risk communication principles will be incorporated into the risk analysis framework and probably in food labelling requirements.

4. Continued priority should be given to the Commission's horizontal science-based work in the areas of food additives, contaminants, pesticide and veterinary drug residues, food hygiene, food labelling and nutrition. Consideration should be given to the development of standards in these areas for foods derived from biotechnology or traits introduced into foods by biotechnology, where this is scientifically Justified. Trade-related issues between governments of food inspection and certification and determination of equivalence and appropriate methods of analysis and sampling will also remain priority areas.

5. In the period 1998 to 2002 it will be proposed that the Commission will continue to reduce its work on commodity- specific standards in favour of horizontal or general standards. The modernisation of existing commodity standards, begun in 1993, and the transfer of material from commodity standards to applicable general standards should be completed in this period. The medium-term period should also see clarification of the relationship between the Commission and the World Trade Organisation's Committees on Sanitary and Phytosanitary Measures (SPS Committee) and on Technical Barriers to Trade (TBT Committee) especially insofar as notification of the use of standards or acceptance of standards is concerned.

6. The period should also see a significant increase in the use of electronic transmission of documents and storage of archival material. Co-operation with private-sector institutions and associations which is now an integral part of UN system-wide programming can also provide the Codex Alimentarius Commission with ways to facilitate the dissemination of Codex information and support the costs of archiving existing documentation.

7. Improvements in assuring transparency, the need to improved participation of non-governmental organisations as observers in the Codex decision-making process, and the need to take the views of these organisations into account when defining areas of work have been included in the Medium-Term Plan.

MEDIUM-TERM PLAN 1998 – 2002

Programme area	Medium-Term Objectives
General principles and rules of procedure	Integration of risk analysis principles into Codex procedures. Improved guidelines for participation of international non-government organisations. Improved procedures for decision making and consideration of acceptance of standards. Consideration of special or more flexible conditions which may apply to developing countries in the acceptance and application of standards.
Application of policy principles for risk management	Guidelines on the application and interpretation in risk management of legitimate factors other than science relevant to the health protection of consumers and for the promotion of fair practices in the food trade. Completion of the General Standard for the Use of Food Additives; General Standard for Contaminants in Foods. Maintenance of up-dated MRLs for Pesticides and Veterinary Drugs Residues and extension to coverage of products of particular interest to developing countries. Application of risk analysis principles for control of specific microbiological food borne hazards.
Food production and processing systems	Establishment of principles for the use of safe technologies in food production, processing and handling including those for specific food sectors. Consideration of standards, guidelines or other recommendations as appropriate for foods derived from biotechnology or traits introduced into foods by biotechnology on the basis of scientific evidence and risk analysis and having regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and the promotion of fair practices in food trade. Continued development of guidelines for food quality and safety management systems. Consideration of application of standards and related texts by small and medium scale enterprises, especially in developing countries.

Programme area	Medium-Term Objectives
Equivalence, mutual recognition and quality assurance of food control systems	Guidelines on equivalence and mutual recognition of testing procedures, inspection and certification systems. Recommendations on optimising control systems by official and voluntary quality assurance schemes.
Nutrition and consumer information	Review of the basis for nutrition requirements and relevant food information labelling requirements in light of scientific evidence, risk analysis and legitimate factors other than science relevant to the health protection of consumers and for the promotion of fair practices in the food trade and consumer information. Guidelines on claims and certification procedures for alternative production processes. Integration of food labelling and nutrition requirements.
Commodity standards	Finalisation of revision/simplification of Codex Commodity Standards. Elaboration of specific Commodity Standards where justified.
Strengthening transparency	Establish general recommendations to improve the transparency of Codex decision-making. Develop guidelines on the procedures for granting observer status to international non-governmental organisations in Codex Alimentarius. Procedures for the full availability to be made of results of Codex decisions to interested parties. Continuing effort to take into account the views of international non-governmental organisations while defining areas of work.
Publication	Transfer the contents of the Codex Alimentarius to the World Wide Web.
Administration	Transfer of Codex archives to electronic form (external funding).

Annex 7:
World Health Organisation Recommendations on Food Safety

(Executive Board Recommendation - January 2000)

The Executive Board,

Noting the report by the Director-General on the role of WHO in food safety,[4]

RECOMMENDS to the Fifty-third World Health Assembly the adoption of the following resolution:

The Fifty-third World Health Assembly,

Deeply concerned that foodborne illnesses associated with microbial pathogens, biotoxins and chemical contaminants in food represent a serious threat to the health of millions of people in the developing and developed world;

Recognising that foodborne diseases result in significant health and economic consequences for individuals, families, communities, businesses, and countries;

Acknowledging the importance of all services - including public health services -responsible for food safety, in ensuring the safety of food and in harmonising the efforts of all stakeholders throughout the food chain;

Aware of the increased concern of consumers about the safety of food, particularly after recent foodborne-disease outbreaks of international and global scope and the emergence of new food products derived from biotechnology;

Recognising the importance of the standards, guidelines and other recommendations of the Codex Alimentarius Commission for protecting the health of consumers and assuring fair trading practices;

Noting the need for surveillance systems for assessment of the burden of foodborne disease and the development of evidence-based national and international control strategies;

Mindful that food safety systems must take account of the trend towards integration of agriculture and the food industry and of ensuing changes in farming, production, and marketing practices and consumer habits in both developed and developing countries;

Mindful of the growing importance of microbiological agents in foodborne-disease outbreaks at international level and of the increasing resistance of some foodborne bacteria to common therapies, particularly because of the widespread use of anti-microbials in agriculture and in clinical practice;

Aware of the improvements in public health protection and in the development of sustainable food and agricultural sectors that could result from the enhancement of WHO's food safety activities;

[4] Document EB105/10.

Recognising that developing countries rely for their food supply primarily on traditional agriculture and small- and medium-sized food industry, and that in most developing countries, the food safety systems remain weak,

1. URGES Member States:

(1) to integrate food safety as one of their essential public health functions and to provide adequate resources to establish and strengthen their food safety programmes;

(2) to develop and implement systematic and sustainable preventive measures aimed at reducing significantly the occurrence of foodborne illnesses;

(3) to develop and maintain national, and where appropriate, regional means for surveillance of foodborne diseases and for monitoring and controlling relevant micro-organisms and chemicals in food; to reinforce the principal responsibility of producers, manufacturers, and traders for food safety; and to increase the capacity of laboratories, especially in developing countries;

(4) to integrate measures in their food safety policies aimed at preventing the development of microbial agents that are resistant to antibiotics;

(5) to support the development of science in the assessment of risks related to food, including the analysis of risk factors relevant to foodborne disease;

(6) to integrate food safety matters into health and nutrition education and information programmes for consumers, particularly within primary and secondary school curricula, and to initiate culture-specific health and nutrition education programmes for food handlers, consumers, farmers, producers and agro-food industry personnel;

(7) to develop outreach programmes for the private sector that can improve food safety at the consumer level, especially in urban food markets, and to explore opportunities for co-operation with the food industry to raise awareness regarding the use of good farming, hygienic and manufacturing practices;

(8) to co-ordinate the food safety activities of all relevant national sectors concerned with food safety matters, particularly those related to the risk assessment of foodborne hazards;

(9) to participate actively in the work of the Codex Alimentarius Commission and its committees, including activities in the emerging area of food-safety risk analysis;

2. REQUESTS the Director-General:

(1) to give, in view of WHO's global leadership in public health, and in collaboration and co-ordination with other international organisations, notably the Food and Agriculture Organisation of the United Nations (FAO), and within the Codex Alimentarius Commission, greater emphasis to food safety, and to work towards integrating food safety as one of WHO's essential public health functions, with the goal of developing sustainable, integrated food safety systems for the reduction of health risk along the entire food chain, from the primary producer to the consumer;

(2) to support Member States in the identification of food-related diseases and the assessment of foodborne hazards;

(3) to focus on emerging problems related to the development of antimicrobial-resistant micro-organisms stemming from the use of antimicrobials in food production and clinical practice;

(4) to put in place a global strategy for the surveillance of foodborne diseases and for the efficient gathering and exchange of information in and between countries and regions, taking into account the current revision of the International Health Regulations;

(5) to convene, as soon as practicable, an initial strategic planning meeting of food safety experts from Member States, international organisations, and nongovernmental organisations with an interest in food safety issues;

(6) to provide, in close collaboration with other international organisations active in this area, particularly FAO and the International Office of Epizootics (OIE), technical support to developing countries in assessing the burden on health and prioritising disease control strategies through the development of laboratory-based surveillance systems for major foodborne pathogens, including antimicrobial-resistant bacteria, and in monitoring contaminants in food;

(7) in collaboration with FAO and other bodies as appropriate, to strengthen the application of science in the assessment of acute and long-term health risks related to food, and specifically to support the establishment of an expert advisory body on microbiological risk assessment and to strengthen the expert advisory bodies that provide scientific guidance on food safety issues related to chemicals;

(8) to ensure that the procedures for designating experts and preparing scientific opinions are such as to guarantee the transparency, excellence and independence of the opinions delivered;

(9) to encourage research to support evidence-based strategies for the control of foodborne diseases, particularly research on risk factors related to emergence and increase of foodborne diseases;

(10) to examine the current working relationship between WHO and FAO, with a view to increasing the involvement and support of WHO in the work of the Codex Alimentarius Commission and its committees;

(11) to support Member States in providing the scientific basis for health-related decisions regarding genetically modified foods;

(12) to support the inclusion of health considerations in international trade in food;

(13) to make the largest possible use of information from developing countries in risk assessment for international standard-setting, and to strengthen technical training in developing countries.