

**SELECTED WORLD HEALTH ORGANIZATION ACTIVITIES  
RELEVANT TO THE IMPLEMENTATION OF THE WTO AGREEMENT  
ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES**

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**I. INTRODUCTION**

1. Food, one of the essential requisites for human life, may pose a risk to health, if its nutritional value and safety are not adequate for consumer protection. Therefore, governments, and in particular, the health sector, carry a prime responsibility to minimise this risk. In line with the efforts undertaken by national governments, WHO, since its establishment, has been given a mandate to “develop, establish and promote international standards with respect to food...”<sup>1</sup> Ensuring that foods produced and processed for exportation comply with food safety standards and codes of hygienic practice constitutes one of the necessary conditions for the protection of the health of consumers and for the facilitation of international trade.

2. Under the Joint FAO/WHO Food Standards Programme, WHO has been one of the parent Organizations of the Codex Alimentarius Commission (CAC) since its establishment in 1962. As the international agency dealing with health, WHO bears main responsibility for health and safety aspects of Codex standards, guidelines and recommendations so that they appropriately protect the health of consumers. The CAC has established more than 200 food commodity standards and more than forty hygienic and technological practice codes, and set more than 3200 maximum residue limits for pesticides.

3. Over the years, WHO, in conjunction with FAO (and IAEA), has also been convened a series of meetings of three scientific advisory bodies on food additives, on pesticide residues and on food irradiation, known as the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food (JECFI), respectively. More sporadically, scientific advisory bodies were also convened to address biological aspects of food safety as well as other issues. Although these bodies are not part of the CAC, they have continuously provided scientific advice for the consideration by the Codex Committee on Food Additives and Contaminants (CCFAC), the Codex Committee on Pesticide Residues (CCPR), the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) and other Codex Committees, thus providing the CAC with the scientific basis of its decision-making.

4. The need for food standards that serve as international benchmarks has become even more apparent in the process of the Uruguay Round of Multilateral Trade Negotiations. The Round was concluded in Marrakesh in April 1994 by signing of the Final Act comprising a number of Multilateral

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<sup>1</sup> Constitution of the World Health Organization, Article 2(u), 1946

Agreements on Trade in Goods. Among them is the Agreement on the Application of Sanitary and Phytosanitary Measures, in view of which the Director-General of WHO issued a Circular Letter to the Ministers of Health of Member States that year calling for increased participation of the national health sectors in the work of the CAC concerning food safety and the strengthening of national food control systems<sup>2</sup>. The Agreement, guaranteeing WTO Members the right to set their own level of sanitary and phytosanitary protection and to apply necessary measures, requires that these measures be based on scientific principles and on international standards, guidelines and recommendations, where they exist. In relation to food safety, the Agreement specifically refers to the standards and other texts established by the CAC.

5. Since July 1995, WHO, in addition to its representation on the Secretariat of the CAC, has been given the status of observer in the WTO Committee on Sanitary and Phytosanitary Measures and intends to strengthen collaboration in the area of food safety with WTO and national governments which are expected to comply with the SPS Agreement.

## II. INTERNATIONAL NORM SETTING REGARDING ACCEPTABLE RISK IN FOOD

6. Regulatory control of chemicals in food, including food additives, contaminants and residues of pesticides and veterinary drugs, should constitute one of the essential components of food control systems of any country. However, not all countries in the world have the capacities or resources to carry out the task of toxicologically evaluating those chemicals. JECFA and JMPR serve to fill this gap and to promote international harmonization of assessment methods. To ensure scientific impartiality, the members of JECFA or JMPR are recognised scientists who serve in their individual capacity as experts and not as representatives of their governments or employers.

### JECFA

7. JECFA was first convened by FAO and WHO in 1956, in order to elaborate specifications for the identity and purity of individual food additives that have been toxicologically tested and are in commerce and to evaluate the toxicological data on these food additives and estimate acceptable human intakes. The scope of the evaluations were later extended to also cover contaminants and residues of veterinary drugs in food. During each meeting, the JECFA members invited by WHO are primarily responsible for reviewing the toxicological and related data and for establishing, where possible, acceptable daily intakes (ADIs) or other endpoints of assessment and for establishing principles for toxicological evaluation and testing. On the other hand, the members invited by FAO are primarily responsible for preparing and reviewing the specifications for identity and purity of food additives and for estimating maximum residues limits (MRLs) in foods of veterinary drugs when they are used in accordance with good practice in the use of veterinary drugs.

8. JECFA has so far established ADIs and other endpoints for over 700 additives, contaminants and veterinary drug residues in food. The reports of meetings have been published in the WHO Technical Report Series (TRS). The safety data and literature references on the chemicals reviewed by JECFA are published as toxicological monographs in the WHO Food Additive Series (FAS).

### JMPR

9. JMPR was convened for the first time in 1963, in order to evaluate the toxicological and other pertinent data on those pesticides known to leave residues in food. It comprises two separate groups of scientists, i.e. the WHO Expert Group on Pesticide Residues (WHO Expert Group) and the FAO

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<sup>2</sup> C.L.8.1994, WHO

Panel of Experts on Pesticide Residues in Food and the Environment (FAO Panel of Experts). The WHO Expert Group has responsibility for reviewing toxicological and related data and for establishing, where possible, an ADI for humans, while the FAO Panel of Experts has responsibility for reviewing pesticide use patterns, data on the chemistry and composition of pesticides, and methods of analysis of pesticide residues, and for recommending MRLs that might occur in food commodities following the use of pesticides according to Good Agricultural Practices.

10. The primary endpoints of assessment of JMPR are ADIs and MRLs. JMPR has evaluated more than 200 compounds, most of which have been visited several times as such or in terms of specific pesticide/food combinations. Detailed evaluations of the toxicological and other safety data are available as monographs published by WHO.

#### IPCS

11. Since 1980, the WHO activities concerned with the safety assessment of food chemicals has been incorporated into the International Programme on Chemical Safety (IPCS). IPCS is a collaborative activity of the International Labour Organisation (ILO), United Nations Environment Programme (UNEP), and the World Health Organization (WHO). A network of 76 Participating Institutions, which play a role in relation to specific tasks within IPCS, is operational in 32 countries. The activity of IPCS includes administering the WHO Expert Group on Pesticide Residues and the WHO part of JECFA.

12. IPCS provides comprehensive risk assessment of chemicals, including industrial chemicals, pesticides and natural toxins, the result of which has been published as Environmental Health Criteria series. More practical information is provided in the Health and Safety Guides and the International Chemical Safety Cards.

13. IPCS is actively involved with developing methodology for risk assessment. Current activities include the preparation of monographs on principles for assessing health risks from exposure to chemicals, principles for evaluating health risks to human reproduction associated with exposure to chemicals, and principles for evaluating chemical effects on the aging process. Collaborative studies are in progress on application of short-term tests for genotoxicity, carcinogenicity, neurotoxicity, and immunotoxicity.

14. A project has also been initiated on the harmonization of approaches to the assessment of risk from exposure to chemicals. The objective of this project is to harmonise approaches to risk assessment through global understanding of how countries view specific issues and to strive for agreement on basic principles. The project will consider effects of concern, critical effects used in setting limits, dose-response relationships, test methods, data interpretation, extrapolation, models and uncertainty factors.

#### IARC

15. The International Agency for Research on Cancer (IARC) was established by WHO in 1965 in order to meet the need for an internationally coordinated attack on cancer. IARC has been conducting both epidemiological and laboratory research designed to identify the causes of cancer, including chemicals, toxins and metals in food. Both biological and epidemiological data relevant to carcinogenic agents are reviewed by a working group of experts and published in IARC Monographs on the Evaluation of Carcinogenic Risks to Humans.

#### GEMS/Food

16. Food may become contaminated by environmental pollutants and other harmful substances which cannot be detected by consumers. Consequently, all governments should establish effective health-oriented population-based monitoring programmes. To assist Member States in this effort, WHO

has provided technical advice, training and other support services to a growing network of GEMS/Food participating institutions which are located in over sixty countries worldwide. The Global Environmental Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food), which has been implemented by WHO since 1976, collects data on food contamination and periodically prepares documents on risk characterisation and other assessments of human exposure.

17. The contaminants chosen for monitoring include industrial pollutants, such as toxic metals, pesticides and naturally occurring toxicants. GEMS/Food has informed governments, the CAC and other relevant institutions as well as the public on levels and trends of contaminants in food, their contribution to the total human exposure and significance with regard to public health and trade. GEMS/Food also performs the calculations of the Theoretical Maximum Daily Intake (TMDI) and other pesticide exposure estimates for the use by CCPR. As part of its exposure assessment work, GEMS/Food maintains a database of food consumption based on a “global” diet and five “cultural” diets.

### JECFI

18. WHO has also been concerned about the safety of irradiated foods. The technology can, if properly used, be an effective tool to fight against foodborne diseases and food losses. To this end, JECFI was convened for the first time in 1964 to consider the technical basis for legislation on irradiated food. JECFI has subsequently reviewed a number of toxicological and other studies and concluded that the irradiation of foods up to an overall dose of 10 kGy is safe and introduces no special nutritional or microbiological problems. These results led to the adoption in 1983 by the CAC of the Codex General Standard for Irradiated Foods.

19. In 1984, the Joint FAO/IAEA/WHO International Consultative Group on Food Irradiation (ICGFI) was established to evaluate global developments in the field of food irradiation and to provide information, as required, to JECFI and the CAC. The activity of ICGFI, a group of government-designated experts, is supported by the Organizations and 44 Member Countries.

### Biological Hazards

20. In addition to chemical hazards, biological hazards have a potential to pose major health risks when ingesting foods. The inclusion of microbiological criteria in Codex standards has generally been guided by the Principles for the Establishment and Application of Microbiological Criteria for Foods, which is currently under review for updating.

21. More specifically, cholera, a notifiable disease under the International Health Regulations (IHR) of WHO, is known as one of the infectious diseases whose outbreaks often results in a dramatic fall in the country's food export. In 1992, upon the issue of the WHO guidance on Formulation of National Policy on the Control of Cholera, the Director-General of WHO drew attention of Member States to the fact that the risk of transmission of cholera from infected countries through the export of food commodities produced under Good Manufacturing Practice is minimal, and that consequently the placing of embargoes on the importation of such food is not an appropriate course of action to prevent the international spread of the disease<sup>3</sup>.

22. Guidelines for Cholera Control, also prepared by WHO, provide information on how to control and prevent its spread. It stresses the importance of food safety, safe water supply and personal hygiene for the prevention of cholera. The guidelines are intended primarily for use by managers of national programmes for cholera control, from the local to the international level.

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<sup>3</sup> C.L.17.1992, WHO

23. With regard to the theoretical risk of transmission of bovine spongiform encephalopathy (BSE) to humans, WHO initiated a consultation process and issued recommendations to protect public health.

#### Radioactive Hazards

24. Following the Chernobyl accident in 1986, WHO initiated an international consultation process, at the end of which the derived intervention levels for radionuclides in food were developed. These intervention levels formed the basis for the decision of the CAC to adopt, in 1989, the Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade<sup>4</sup>.

#### Safety Assessment of Biotechnology

25. WHO has been concerned with the health aspect of new technologies introduced in food production and food processing. The Workshop on Health Aspects of Marker Genes in Genetically Modified Plants (Copenhagen, September 1993) and the Workshop on the Application of the Principles of Substantial Equivalence to the Safety Evaluation of Foods or Food Components from Plants Derived by Modern Biotechnology (Copenhagen, November 1994) were held as continuation of the work on assessing the safety of foods produced by biotechnology which was started in 1990, jointly with FAO. The outcome of the above-mentioned consultation and workshops will constitute a basis for the planned development of Codex Guidelines for the Evaluation of Foods Produced by Biotechnology.

#### HACCP

26. WHO has been promoting the integration of Hazard Analysis Critical Control Point (HACCP) System in food control systems. In March 1993, WHO convened a consultation on HACCP training to develop a consensus approach in the application of HACCP to food processing and manufacturing. Another WHO consultation on HACCP was convened with the participation of FAO in May 1995 to review the concept and application of HACCP and propose improvements to the Codex Guidelines, which had been adopted by CAC in 1993. The recommendations of the Consultation, including a proposal for the revision of the Codex Guidelines for the Application of HACCP, are expected to be discussed in the forthcoming session of the Codex Committee on Food Hygiene. In response to the recommendations, WHO also plans to develop guidelines for the auditing of HACCP-driven industries.

#### Risk Analysis

27. At the request of the Codex Executive Committee, WHO organised, in collaboration with FAO, a consultation on the application of risk analysis to food standards issues, in March 1995. The Consultation was a significant event in the international application of risk assessment, particularly in the context of the CAC and trade implications of the SPS Agreement. It came up with a number of recommendations for the CAC, scientific advisory bodies, and to the national governments. Based on the outcome of the consultation, further FAO/WHO consultations on risk management and risk communication are expected to be convened in due course.

28. In an effort to improve the scientific basis of CAC decision-making, a joint FAO/WHO Consultation was held in May 1995 to make recommendations for the revision of guidelines used for predicting dietary intake of pesticide residues. The Consultation identified several opportunities for improving international exposure assessments and provided guidance to Member States in conducting national exposure estimates.

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<sup>4</sup> CAC/GL5-1989

### III. TECHNICAL COOPERATION

29. The compliance with the SPS Agreement presupposes the country's capability to appropriately conduct risk analysis<sup>5</sup> in food safety. Namely, Articles 2, 3 and 4 of the Agreement require WTO Members to:

- (i) apply sanitary and phytosanitary measures based on scientific principles;
- (ii) scientifically justify sanitary and phytosanitary measures which result in higher levels of sanitary and phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines and recommendations (e.g. Codex);
- (iii) demonstrate, as an exporting country, the equivalence of its sanitary and phytosanitary measures to those of importing countries in achieving the importing country's appropriate level of sanitary and phytosanitary protection.

30. Furthermore, Article 5 of the Agreement explicitly requires WTO Members to conduct scientific and consistent risk assessment<sup>6</sup>. As food consumption patterns may vary from one country to another, or, even within a country, it is essential for each Member State to be able to perform necessary chemical and biological analysis of food samples and to calculate the dietary exposure level of their population to foodborne hazards.

31. The application of HACCP system in almost every stage of the food chain would be one effective way for governments to meet the SPS agreement. HACCP has been recognised as the preferred risk assessment and risk management tool by an increasing number of countries as well as by the CAC. This demands extensive training of both food inspectors and food producers as well as the transformation of the national food control regulation from a prescriptive one to a HACCP-based one.

32. These requirements cannot be met unless the Member introduces an up-to-date food legislation and control system. Difficult as it might be for a developing country, adjustment to the SPS Agreement not only ensures access to foreign markets, but also leads to better health protection for its people. The improved food safety technologies and infrastructure, including the establishment of national regulatory bodies and laboratories, encourage the development of value-added industries and promotes the competitive quality of its food products. In this effort, WHO can provide policy guidance, information, technical advice and training opportunities on all matters related to health and safety requirements.

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<sup>5</sup> Risk analysis is a process consisting of three components: risk assessment, risk management and risk communication.

<sup>6</sup> Risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to food borne hazards. The process of risk assessment consists of (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment and (iv) risk characterisation.

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