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**FOOD SAFETY AND  
GLOBALIZATION OF TRADE IN FOOD**

***A challenge to the public health sector***

*This document was prepared in collaboration with the World Trade Organization to assist government decision-makers in developing policies to improve national food safety programmes at the same time as complying with the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.*

FOOD SAFETY UNIT  
PROGRAMME OF FOOD SAFETY AND FOOD AID  
WORLD HEALTH ORGANIZATION

1997

## **1. Introduction: before 1994...**

Without doubt, the present-day international trade in food is playing an increasingly important role in the provision of safe and nutritious diets for the world's populations.

This international trade also has a two-fold benefit: it introduces a wider variety of foods into the diet by providing consumers with a bigger and better choice of products; and it provides food exporting countries with foreign exchange, which is indispensable for the economic development of many countries, and thus for an improvement in the standard of living for many peoples.

International trade in foods, however, can be impeded by tariff and non-tariff barriers at the national border. Some of them may be required to protect the health of consumers or to protect domestic economy, others are just detrimental to international trade. To address this concern, the Joint FAO/WHO Codex Alimentarius Commission (**Codex** in short) was established in 1962 to protect the health of the consumer and, at the same time, to ensure fair practices in food trade. Codex has been working since and has elaborated a number of food standards, guidelines and recommendations. However, while member governments of Codex have been asked to accept these standards, it has been left for governments to decide whether they should or should not implement them, and Codex texts have not been directly linked to an international trade scheme such as the General Agreement on Tariffs and Trade (GATT).

## **2. What has changed since 1995?**

The Uruguay Round of Multilateral Trade Negotiations was concluded in April 1994 by the signing of the Marrakesh Agreement and it gave birth to a number of multilateral trade agreements to which all Members of the World Trade Organization (WTO) - established in January 1995 - are committed.

One important outcome of the Uruguay Round was that countries agreed to reduce tariff barriers for many agricultural commodities so as to encourage free trade. As a result, non-tariff barriers became a real concern because they could undermine the promotion of international trade if put into practice in an arbitrary or discriminatory way.

To address some of these concerns, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (in short, the SPS Agreement) was drawn up to ensure that countries apply measures to protect human and animal health (sanitary measures) and plant health (phytosanitary measures) based on the assessment of risk, or in other words, based on science. The SPS Agreement incorporates, therefore, safety aspects of foods in trade.

It is important to mention another WTO agreement here, the Agreement on Technical Barriers to Trade (the TBT Agreement). This agreement, which had been in existence as a plurilateral agreement since the Tokyo Round, was revised and converted into a multilateral agreement through the Uruguay Round. It covers all technical requirements and standards (applied to all commodities), such as labelling, that are not covered by the SPS Agreement. Therefore, the SPS and TBT Agreements can be seen as complementing each other.

One of the main objectives of the SPS Agreement is to protect human and animal health, and the phytosanitary situation in all WTO Member countries. This is to be addressed through the establishment of a multilateral framework of rules and disciplines that will guide the development, adoption and enforcement of sanitary and phytosanitary measures and minimize their negative effects on trade. As a natural consequence, the SPS Agreement recognized the standards and related texts of the Codex Alimentarius Commission as international points of reference. Today the SPS Agreement is regarded as being a strong instrument which will further the goal of the Codex

Alimentarius Commission, that is, to harmonize food standards worldwide.

Likewise, international standards established by the International Office of Epizootics (OIE) and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention (IPPC) have been recognized in the SPS Agreement as providing references with regard to animal and plant life or health.

In order to comply with the provisions of the SPS Agreement, it may often be necessary to strengthen national food control systems. This may require both manpower and financial investment. To address these particular difficulties, which may be encountered by any developing country, the SPS Agreement also includes provisions for technical assistance to be provided by other countries, or through international organizations. The SPS Agreement thus provides an ideal opportunity for developing countries to build modern food control and safety schemes, or to upgrade existing ones.

Furthermore, to allow the least-developed countries sufficient time in which to meet the requirements of the SPS Agreement, the application of certain provisions can be delayed until January 2000 for these countries.<sup>1</sup> Also, countries can request specific, time-limited exceptions, in whole or in part, from obligations of this Agreement, taking into account their financial, trade and development needs.<sup>2</sup>

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<sup>1</sup> Article 14 of the SPS Agreement.

<sup>2</sup> Article 10.

### 3. What are the benefits and challenges of the SPS Agreement?

#### *Rights and Obligations*

As with most agreements, the SPS Agreement provides both rights and obligations to contracting parties, i.e. WTO Members.

#### *Information Exchange*

Many trade problems can be prevented if trading partners share information with each other about sanitary measures before they are put into force. This can best be achieved when notifications are made before such measures are enacted by regulatory authorities and other countries are afforded an opportunity to comment. This is one of the most important concepts of the SPS Agreement, and it is called **transparency**.<sup>3</sup>

Notifications from countries about their proposed sanitary/phytosanitary measures are regularly made available to WTO Members, either by direct mailing or via Internet, and any WTO Member country can address enquiries to another Member country regarding its sanitary requirements, practices and agreements. To facilitate this, each WTO Member country establishes one **Enquiry Point** which is responsible for providing answers to all reasonable questions from interested Members, as well as relevant documentation. Also, all sanitary and phytosanitary regulations which have been adopted need to be published promptly to allow interested Members to become acquainted with them.

To implement the transparency provision, each country should establish well-organized procedures with regard to the setting of national regulations which allows other countries to comment on any proposed new

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<sup>3</sup> Article 7.

measure before it is finalized. In addition, coordination between competent governmental departments should be established in order to ensure the effective operation of Enquiry Points.

### ***International Harmonization***

No matter what side of the globe they live on, consumers should enjoy adequate protection against the risks of foodborne diseases. This can be achieved, without restricting international trade, if all countries **harmonize** their regulations by using international standards as a basis for their sanitary measures.

For food safety, the SPS Agreement recognizes, as the international reference, 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 practices.

Codex standards and related texts are deemed necessary to protect human health. **As long as a country employs these standards, its measures are presumed to be consistent with the provisions of the SPS Agreement.** Harmonization with Codex will eliminate the necessity of one country having to provide other countries with justifiable reasons as to why the measures they are applying are necessary in order to protect human health.

Many new ideas are being integrated into Codex texts. These include the recommendation to adopt a **risk-based** approach in achieving food safety objectives. One such approach is the Hazard Analysis and Critical Control Point (HACCP) system.<sup>4</sup> This risk-oriented approach, recommended by the Codex General Principles of Food Hygiene,

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<sup>4</sup> Codex Alimentarius, Supplement to Volume 1B General requirements (Food Hygiene), 1997.

allows the food industry and governments to target limited resources to the most critical steps of food production and distribution, rather than having to comply with a long list of product and procedure specifications as has been traditionally prescribed. The application of the HACCP principles, be it voluntary or mandatory, presupposes that the national food regulatory authority should also adapt itself to this approach, and this puts more emphasis on the authority's audit and training functions than on the physical inspection and laboratory analysis of consignments. Although this does not completely eliminate the necessity for inspection of the final product, the concept of **process control** needs to be stressed in any national food safety programme.

Another important trend in Codex is its **horizontal approach**. Codex is in the process of elaborating general standards covering food additives, contaminants and toxins to provide a wider basis for protecting consumers' health. Countries can better adapt themselves to this approach by implementing a **generic regulation** applicable to a wide range of products rather than maintaining an inventory of registered foods with specifications.

### ***Risk Assessment***

WTO Members retain the right to take sanitary measures necessary for the protection of human life or health. In so doing, countries can determine which is the appropriate level of sanitary protection, which may be higher than that achieved by adhering to stipulated international standards. The sanitary measures, however, must be based on **risk assessment**.<sup>5</sup> WTO Members have to ensure that these measures are non-discriminatory, not more trade-restrictive than necessary and are not maintained without sufficient **scientific evidence**.

As yet, international standards do not cover all aspects of food safety, and it may be

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<sup>5</sup> Article 5.

necessary for a country to introduce sanitary measures in those areas where international standards are non-existent. In such a case, efforts should be made to expedite the work of the Codex Alimentarius Commission to establish a new text covering the field in question. If a country has to employ a sanitary measure before an international standard is established, then it should apply risk assessment when determining the content of such measure.

Risk assessment techniques used by international organizations have been published and are made widely available for reference. These techniques include methodologies in toxicological evaluation, exposure assessment and other related methods used by expert bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meetings on Pesticide Residues (JMPR). Sound knowledge of the functioning of these risk assessment bodies not only assists countries in better understanding the scientific background of international standards which are based on evaluations made by these bodies, but is useful in building national risk assessment procedures modelled on that used by the international bodies.<sup>6</sup>

When conducting risk assessment at the national level, it is desirable that authorities have available epidemiological data on the incidence of foodborne diseases in their country and information about the level of exposure of the country's population, particularly vulnerable groups, to foodborne hazards. Countries are encouraged to participate in the **Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food)** coordinated by WHO so as to either establish or improve their capacity to conduct monitoring of pesticide and contaminant intakes. At the international level, the monitoring data obtained from countries will provide important indicators in

establishing international standards for certain chemicals in foods. WHO also maintains a database on the incidence of foodborne diseases of microbial origin.

Another important element in the SPS Agreement is the concept of a **disease-free area**.<sup>7</sup> Recognizing the sanitary and phytosanitary characteristics of the geographical area from which the product originates and those of the area where the product is being received will help remove unnecessary measures and economize valuable resources. This consideration constitutes an integral part of the risk assessment exercise.

### *Equivalence*

In applying a particular sanitary measure, it is important to recognize what level of health protection will actually be achieved through its implementation. Where more than one measure is equally effective in achieving a given appropriate level of health protection, WTO Members are committed to accepting the sanitary measures used by other Members as being **equivalent measures**, even if they are different from their own requirements. The exporting country needs, of course, to demonstrate that its measures will achieve the appropriate level of sanitary protection laid down by the importing country.<sup>8</sup>

To reinforce the recognition of equivalency in the area of food in trade, it is useful to adhere to the Codex Principles for Food Import/Export Inspection and Certification and the Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems.<sup>9</sup>

It is however to be noted that while recognising equivalence, the SPS Agreement requires WTO Members to ensure that the

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<sup>6</sup> Article 5:1.

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<sup>7</sup> Article 6.

<sup>8</sup> Article 4:1.

<sup>9</sup> Codex Alimentarius Volume 1A.

sanitary or phytosanitary measures they establish or maintain are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.<sup>10</sup>

#### 4. What else can be done?

As the food safety provisions in Codex standards, guidelines and recommendations are recognized as international references to be used for harmonizing national regulations, it is of paramount importance that the health sector of each country fully participates in and contributes to the work of the **Codex Alimentarius Commission**. Otherwise there is a risk that the Codex Alimentarius Commission could adopt standards, guidelines or recommendations which might not be fully adequate from a health protection point of view.

To coordinate work of different ministries/departments responsible for food control, countries are encouraged to establish a **national Codex Committee**, with the participation of all government and other key players, which would serve as a focal point for information exchange and the development of a national Codex policy. In addition to sending delegations to Codex meetings, countries can provide written comments in reply to Codex Circular Letters, which is a cost-effective means of participating in the work of Codex.

In order to overcome the delay in mailing Codex documents, an increasing number of Codex working papers are available on **Internet** for easy access by government agencies and other interested parties. If representation by the health sector in Codex meetings is not possible, diplomatic representatives stationed in those countries where Codex meetings are held could be mobilized so that their country's positions are

better reflected in the deliberations and decisions of Codex.

Another important forum in which the health sector should take full part is the WTO Committee on Sanitary and Phytosanitary Measures (**SPS Committee**) which holds sessions in Geneva. The SPS Committee carries out the functions necessary to implement the provisions of the SPS Agreement. It provides a regular forum for consultations between countries, and questions can be asked of Member delegations regarding the specific notifications which they have made.

WTO Members, especially those who encounter difficulty in meeting the requirements of the SPS Agreement, are encouraged to request **technical assistance** from other Members during the sessions of the SPS Committee, or at any other time. Technical advice, credits, donations and grants, including training opportunities, can be provided to Members in need, either bilaterally or through international organizations.<sup>11</sup> Representatives of relevant international organizations are often present as observers at meetings of the SPS Committee, and requests for technical information can also be discussed with them directly.

#### 5. And more questions?

*Question 1: Do developing countries benefit from the SPS Agreement?*

*Answer:* Yes. Adherence to the Agreement provides an opportunity to upgrade a national food safety programme, with assistance provided by international or bilateral cooperation organizations or agencies. It will result in better protection of the health of consumers domestically, and in improved confidence with regard to exported products on world markets. Moreover, if exporting developing countries base their sanitary and

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<sup>10</sup> Article 5:6.

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<sup>11</sup> Article 9.

phytosanitary measures on international standards, they will be less exposed to arbitrary restrictions from importing countries.

**Question 2: What is the difference between SPS and TBT?**

*Answer:* As far as foods are concerned, the SPS Agreement covers those aspects related to health, i.e., food additives, residues of veterinary drugs and pesticides, codes and guidelines of hygienic practice, etc. Other aspects such as labelling are covered by the TBT Agreement. The figure on page 7 shows an example.

**Question 3: How can one obtain a Code x text?**

*Answer:* All Codex Member countries have a national Codex Contact Point. It serves as a documentation centre for Codex standards, guidelines and recommendations, as well as for all Codex working papers. Also, a CD-ROM containing all final Codex texts in three languages (English, French and Spanish) is available from the Codex Secretariat.

**Question 4: What is Risk Assessment as it relates to food safety?**

*Answer:* Risk Assessment is defined in the **SPS Agreement** 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”. As it relates to food safety, the **Codex** interim definition for Risk Assessment is “a scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterization.”

**Question 5: Does each WTO member always have to tackle risk assessment in order to fulfil the obligations of the SPS Agreement?**

*Answer:* No. As long as countries base their food regulations and import requirements on Codex standards, guidelines and recommendations, they are fulfilling their obligations in regard to the SPS Agreement. However, when setting regulations in areas where no international standards exist, when applying more stringent requirements to imported products than to domestic products, or when applying import requirements which are stricter than Codex standards, guidelines and recommendations, countries ought to ensure that those measures are based on risk assessment.

**Figure: Fruit Juice**

( Figure is not available on this electronic file.)



## 6. Suggested reading

Frank L. Bryan: *Hazard Analysis Critical Control Point Evaluations* WHO, 1992 (ISBN 92-4-154433-3)

FAO/WHO. *Codex Alimentarius Commission. Procedural Manual: Tenth Edition* Issued by the Secretariat of the Joint FAO/WHO Food Standards Programme, FAO, Rome, 1997 (ISBN 92-5-104014-1)

UNEP/FAO/WHO. *The Contamination of Food (GEMS/Food)* UNEP, Nairobi, Kenya, 1992

WHO. *Evaluation of Programmes to Ensure Food Safety* 1989 (ISBN 92-4-154247-0)

WHO. *Guidelines for Predicting Dietary Intake of Pesticide Residues (revised)* (GEMS/Food in cooperation with the Codex Committee on Pesticide Residues), WHO/FSF/FOS/97.7, 1997

WHO. *Guidelines for Strengthening a National Food Safety Programme*, WHO/FNU/FOS/96.2, 1996

WHO. *HACCP - Introducing the Hazard Analysis and Critical Control Point System* WHO/FSF/FOS/97.2, 1997

WHO. *Working together for safe food - GEMS/Food* WHO/FSF/FOS/97.9, 1997

WTO. *The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* GATT, 1994 (ISBN 92-870-1121-4)

## ANNEX 1

**WTO AGREEMENT ON THE APPLICATION OF  
SANITARY AND PHYTOSANITARY MEASURES**

*Members,*

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

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

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

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

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

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

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

*Desiring* therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b)<sup>1</sup>;

*Hereby agree* as follows:

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<sup>1</sup> In this Agreement, reference to Article XX(b) includes also the chapeau of that Article

### **Article 1 - General Provisions**

1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.
3. The annexes are an integral part of this Agreement.
4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

### **Article 2 - Basic Rights and Obligations**

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

### **Article 3 - Harmonization**

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.
2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.
3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be

appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5<sup>2</sup>. Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement.

4. Members shall play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within these organizations the development and periodic review of standards, guidelines and recommendations with respect to all aspects of sanitary and phytosanitary measures.

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

#### ***Article 4 - Equivalence***

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

2. Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.

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

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members

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<sup>2</sup> For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

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shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility<sup>3</sup>.

7. In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

8. When a Member has reason to believe that a specific sanitary or phytosanitary measure introduced or maintained by another Member is constraining, or has the potential to constrain, its exports and the measure is not based on the relevant international standards, guidelines or recommendations, or such standards, guidelines or recommendations do not exist, an explanation of the reasons for such sanitary or phytosanitary measure may be requested and shall be provided by the Member maintaining the measure.

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

1. Members shall ensure that their sanitary or phytosanitary measures are adapted to the sanitary or phytosanitary characteristics of the area - whether all of a country, part of a country, or all or parts of several countries - from which the product originated and to which the product is destined. In assessing the sanitary or phytosanitary characteristics of a region, Members shall take into account,

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<sup>3</sup> For purposes of paragraph 6 of Article 5, a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade.

inter alia, the level of prevalence of specific diseases or pests, the existence of eradication or control programmes, and appropriate criteria or guidelines which may be developed by the relevant international organizations.

2. Members shall, in particular, recognize the concepts of pest- or disease-free areas and areas of low pest or disease prevalence. Determination of such areas shall be based on factors such as geography, ecosystems, epidemiological surveillance, and the effectiveness of sanitary or phytosanitary controls.

3. Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively. For this purpose, reasonable access shall be given, upon request, to the importing Member for inspection, testing and other relevant procedures.

#### ***Article 7 - Transparency***

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

#### ***Article 8 - Control, Inspection and Approval Procedures***

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

#### ***Article 9 - Technical Assistance***

1. Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, inter alia, in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment to allow such countries to adjust to, and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

2. Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

#### ***Article 10 - Special and Differential Treatment***

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members.

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2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports.

3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs.

4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations.

#### ***Article 11 - Consultations and Dispute Settlement***

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement, except as otherwise specifically provided herein.

2. In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

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

#### ***Article 12 - Administration***

1. A Committee on Sanitary and Phytosanitary Measures is hereby established to provide a regular forum for consultations. It shall carry out the functions necessary to implement the provisions of this Agreement and the furtherance of its objectives, in particular with respect to harmonization. The Committee shall reach its decisions by consensus.

2. The Committee shall encourage and facilitate ad hoc consultations or negotiations among Members on specific sanitary or phytosanitary issues. The Committee shall encourage the use of international standards, guidelines or recommendations by all Members and, in this regard, shall sponsor technical consultation and study with the objective of increasing coordination and integration between international and national systems and approaches for approving the use of food additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.

3. The Committee shall maintain close contact with the relevant international organizations in the field of sanitary and phytosanitary protection, especially with the Codex Alimentarius Commission, the International Office of Epizootics, and the Secretariat of the International Plant Protection Convention, with the objective of securing the best available scientific and technical advice for the administration of this Agreement and in order to ensure that unnecessary duplication of effort is avoided.

4. The Committee shall develop a procedure to monitor the process of international harmonization and the use of international standards, guidelines or recommendations. For this purpose, the Committee should, in conjunction with the relevant international organizations, establish a list of international standards, guidelines or recommendations relating to sanitary or phytosanitary measures which the Committee determines to have a major trade impact. The list should include an indication by Members of those international standards, guidelines or recommendations which they apply as conditions for import or on the basis of which imported products conforming to these standards can enjoy access to their markets. For those cases in which a Member does not apply an international standard, guideline or recommendation as a condition for import, the Member should provide an indication of the reason therefore, and, in particular, whether it considers that the standard is not stringent enough to provide the appropriate level of sanitary or phytosanitary protection. If a Member revises its position, following its indication of the use of a standard, guideline or recommendation as a condition for import, it should provide an explanation for its change and so inform the Secretariat as well as the relevant international organizations, unless such notification and explanation is given according to the procedures of Annex B.

5. In order to avoid unnecessary duplication, the Committee may decide, as appropriate, to use the information generated by the procedures, particularly for notification, which are in operation in the relevant international organizations.

6. The Committee may, on the basis of an initiative from one of the Members, through appropriate channels invite the relevant international organizations or their subsidiary bodies to examine specific matters with respect to a particular standard, guideline or recommendation, including the basis of explanations for non-use given according to paragraph 4.

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

#### ***Article 13 - Implementation***

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

#### ***Article 14 - Final Provisions***

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

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Agreement with respect to their existing sanitary or phytosanitary measures affecting importation or imported products, where such application is prevented by a lack of technical expertise, technical infrastructure or resources.

## ANNEX A

### DEFINITIONS<sup>4</sup>

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

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

2. *Harmonization* - The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.
3. *International standards, guidelines and recommendations*
  - (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
  - (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;

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<sup>4</sup> For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

- (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
- (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

4. *Risk assessment* - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

5. *Appropriate level of sanitary or phytosanitary protection* - The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

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

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

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

## **ANNEX B**

### **TRANSPARENCY OF SANITARY AND PHYTOSANITARY REGULATIONS**

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*Publication of regulations*

1. Members shall ensure that all sanitary and phytosanitary regulations<sup>5</sup> which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them.
2. Except in urgent circumstances, Members shall allow a reasonable interval between the publication of a sanitary or phytosanitary regulation and its entry into force in order to allow time for producers in exporting Members, and particularly in developing country Members, to adapt their products and methods of production to the requirements of the importing Member.

*Enquiry points*

3. Each Member shall ensure that one enquiry point exists which is responsible for the provision of answers to all reasonable questions from interested Members as well as for the provision of relevant documents regarding:
  - (a) any sanitary or phytosanitary regulations adopted or proposed within its territory;
  - (b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures, which are operated within its territory;
  - (c) risk assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;
  - (d) the membership and participation of the Member, or of relevant bodies within its territory, in international and regional sanitary and phytosanitary organizations and systems, as well as in bilateral and multilateral agreements and arrangements within the scope of this Agreement, and the texts of such agreements and arrangements.
4. Members shall ensure that where copies of documents are requested by interested Members, they are supplied at the same price (if any), apart from the cost of delivery, as to the nationals<sup>6</sup> of the Member concerned.

*Notification procedures*

5. Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:
  - (a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;

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<sup>5</sup> Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

<sup>6</sup> When "nationals" are referred to in this Agreement, the term shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

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

*General reservations*

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

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## ANNEX C

### CONTROL, INSPECTION AND APPROVAL PROCEDURES<sup>7</sup>

1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:

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

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<sup>7</sup> Control, inspection and approval procedures include, inter alia, procedures for sampling, testing and certification.

to what is necessary to determine whether adequate confidence exists that the product still meets the regulations concerned; and

- (i) a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified. Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs which prohibits or restricts access to its domestic markets for products based on the absence of an approval, the importing Member shall consider the use of a relevant international standard as the basis for access until a final determination is made.

2. Where a sanitary or phytosanitary measure specifies control at the level of production, the Member in whose territory the production takes place shall provide the necessary assistance to facilitate such control and the work of the controlling authorities.

3. Nothing in this Agreement shall prevent Members from carrying out reasonable inspection within their own territories.

**ANNEX 2**

**TRENDS IN PARTICIPATION  
IN CODEX ALIMENTARIUS COMMISSION SESSIONS**

( Figures are not available on this electronic file.)

*For further information, please contact:*

**World Health Organization (WHO)**

Programme of Food Safety and Food Aid  
World Health Organization  
1211 Geneva 27, Switzerland

Web-site: <http://www.who.ch/fsf/>  
E-mail: [foodsafety@who.ch](mailto:foodsafety@who.ch)  
Facsimile: +41.22.791.0746 or 4807

**Joint FAO/WHO Codex Secretariat**

Joint FAO/WHO Food Standards Programme  
Food and Agriculture Organization  
Via delle Terme di Caracalla  
00100 Rome, Italy

Web-site: <http://www.fao.org/WAICENT/faoinfo/economic/esn/codex/codex.htm>  
E-mail: [codex@fao.org](mailto:codex@fao.org)  
Facsimile: +39.6.570.54593

**World Trade Organization (WTO)**

Agriculture and Commodities Division  
World Trade Organization  
1211 Geneva 21, Switzerland

Web-site: <http://www.wto.org/wto/goods/sps.htm>  
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