

PART THREE – TECHNICAL STANDARDS

CHAPTER 7: SANITARY AND PHYTOSANITARY MEASURES

Article 7-01

Definitions

For the purposes of this Chapter, the Parties shall use the definitions and terms established:

- (a) in the Agreement on the Application of Sanitary and Phytosanitary Measures of the WTO Agreement (Agreement on Sanitary and Phytosanitary Measures);
- (b) by the International Office of Epizootics (OIE);
- (c) in the International Convention on Phytosanitary Protection; and
- (d) by the Codex Alimentarius Commission.

Article 7-02

General Provisions

1. This Chapter applies to the principles, rules and procedures relating to the sanitary and phytosanitary measures which regulate or which may, directly or indirectly, affect trade in agricultural, fish and forest products between the Parties and other trade in plants and animals, their products and byproducts.
2. Through mutual cooperation, the Parties shall facilitate trade in agricultural, fish and forest products that present no sanitary or phytosanitary risks and undertake to prevent the introduction or spread of pests or diseases and to improve plant and animal health and food safety.
3. The competent authorities shall be the authorities with legal responsibility for enforcing compliance with the sanitary and phytosanitary requirements established in this Chapter.
4. The Parties revoke the document mentioned in Annex 7-02.

Article 7-03

Rights of the Parties

The Parties may:

- (a) adopt, maintain or apply any sanitary or phytosanitary measure in their territory only to the extent necessary to protect human, animal or plant life or health, in accordance with this Chapter;
- (b) apply their sanitary and phytosanitary measures only to the extent necessary to achieve an appropriate level of protection, taking into account technical and economic feasibility; and
- (c) verify that plants, animals and plant and animal products for export are subject to strict sanitary and phytosanitary monitoring, certifying compliance with the requirements of the importing Party.

Article 7-04

Obligations of the Parties

1. Sanitary and phytosanitary measures shall not constitute a disguised restriction on trade or create unnecessary obstacles to trade between the Parties.
2. Sanitary and phytosanitary measures shall be based on scientific principles, be maintained only where there are sufficient grounds and be based on an appropriate risk assessment.
3. Where identical or similar conditions exist, a sanitary or phytosanitary measure shall not discriminate arbitrarily or unjustifiably between its goods and similar goods of the other Party or between the goods of the other Party and similar goods of a non-Party.
4. The Parties shall provide the necessary facilities to verify control, inspection and approval procedures and sanitary and phytosanitary programmes.

Article 7-05

International Standards and Harmonization

1. Each Party shall use international standards, guidelines or recommendations as the basis for its sanitary and phytosanitary measures, in order to harmonize them or make them compatible with those of the other Party.
2. Notwithstanding paragraph 1, the Parties may adopt a sanitary or phytosanitary measure that offers a level of protection different from that which would be achieved by measures based on an international standard, guideline or recommendation, or which is higher, if there is scientific justification.

3. To achieve closer harmonization, the Parties shall follow the guidelines of the competent international organizations: the International Convention on Phytosanitary Protection for plant health; the OIE for animal health; and the standards of the Codex Alimentarius Commission with respect to food safety and tolerance limits.

4. The parties shall also take into consideration the standards and guidelines of other international organizations of which they are members.

5. The Parties shall establish sanitary and phytosanitary harmonization systems for sampling, diagnosis, inspection and certification of animals, plants, their products and byproducts and food safety.

Article 7-06

Equivalence

1. Without reducing the appropriate level of protection, the Parties shall accept to the fullest extent possible, their sanitary and phytosanitary measures as equivalent.

2. Each Party shall accept the sanitary and phytosanitary measures of the other Party as equivalent, even if they differ from its own, providing scientific information is furnished to demonstrate that they achieve the appropriate level of protection of the other Party.

3. To establish equivalencies between sanitary and phytosanitary measures, the Parties shall adopt reasonable procedures to facilitate access to their territory for the purposes of inspection, tests and other pertinent measures.

Article 7-07

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. The Parties shall ensure that their sanitary and phytosanitary measures are based on an adequate assessment, as appropriate to the circumstances, of the risks to human and animal life and health and to the preservation of plant health and shall prevent harmful effects of the inputs used in protection and production, taking into account the guidelines and risk assessment techniques established by the competent international organizations.

2. On assessment of risk and determination of the appropriate level of protection, the Parties shall take account of the existence of specific diseases or pests; recognition of pest- or disease-free areas and areas of low pest or disease prevalence, programmes for eradication or control, the structure and organization of sanitary and phytosanitary services, procedures for protection, surveillance, diagnoses and treatments to ensure the safety of the product.

3. In establishing their appropriate level of protection, the Parties shall take into account the objective of minimizing the negative effects on trade and, with the

purpose of achieving consistency in protection levels, shall avoid arbitrary or unjustifiable distinctions that could lead to discrimination or which constitute a disguised restriction on trade between the Parties.

4. Where a Party performs a risk assessment and concludes that the scientific information is insufficient, it may adopt a sanitary or phytosanitary measure on the basis of available information, including information from the competent international organizations as well as from sanitary or phytosanitary measures applied by the other Party. Once the necessary information becomes available, the Party shall conclude the assessment and, when warranted, shall proceed to modify the sanitary or phytosanitary measure.

Article 7-08

Recognition of Pest- or Disease-Free Areas and Areas of Low Pest or Disease Prevalence

1. The Parties shall recognize pest- or disease-free areas and areas of low pest or disease prevalence on the basis of geographic location, ecosystems, epidemiological surveillance and the effectiveness of sanitary or phytosanitary controls in such areas, among the main factors.

2. A Party that declares an area in its territory to be free from a given pest or disease shall demonstrate that condition objectively to the satisfaction of the other Party and give it assurances that the area shall be maintained as such, based on the protection measures adopted by the heads of the sanitary or phytosanitary services.

3. A Party interested in obtaining recognition of an area that is free from a given pest or disease shall make application to the other Party and provide it with the corresponding scientific and technical information.

4. The Party receiving the application for recognition shall decide on it within a period agreed upon in advance with the other Party and may conduct verifications with respect to inspections, tests and other procedures. In the event it refuses the application, it shall give the technical grounds for its decision in writing.

5. The Parties shall agree on specific requirements whose compliance shall permit a good produced in an area of low pest or disease prevalence to be imported, if the appropriate level of protection is provided.

Article 7-09

Control, Inspection and Approval Procedures

Pursuant to this Chapter, the Parties shall apply the provisions of Annex C of the Agreement on Sanitary and Phytosanitary Measures relating to control, inspection and approval procedures, including systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs.

Article 7-10

Transparency

Each Party, when proposing the adoption or modification of a sanitary or phytosanitary measure for general application on the central or federal level, shall notify through its competent authorities:

- (a) the adoption and modification of such measures and facilitate information on them, in accordance with Annex B of the Agreement on Sanitary and Phytosanitary Measures, and shall make the pertinent adaptations;
- (b) changes or modifications in sanitary or phytosanitary measures with a significant effect on trade between the Parties, no less than 60 days prior to the entry into force of the new provision, to permit the other Party to comment. In emergency situations the term shall be waived, in accordance with Annex B of the Agreement on Sanitary and Phytosanitary Measures;
- (c) changes in the field of animal health and the appearances of exotic diseases and diseases of List A of the OIE, within 24 hours after detection of the problem;
- (d) changes in the field of plant health, such as the appearance of quarantine pests or the spread of pests under official control, within 72 hours after verification; and
- (e) findings of epidemiological importance and significant changes in relation to diseases and pests not included in (b) or (c) that could affect trade between the Parties, within a maximum of 10 days.

Article 7-11

Committee on Sanitary and Phytosanitary Measures

1. The Parties establish a Committee on Sanitary and Phytosanitary Measures Committee comprised of representatives of each of them, with responsibilities for sanitary and phytosanitary matters. The Committee shall be established within 30 days after this Agreement comes into force.
2. The Committee shall coordinate and apply the provisions of this Chapter, oversee the fulfilment of its objectives, facilitate consultations or negotiations on specific sanitary and phytosanitary matters and issue the pertinent recommendations.

3. The Committee's functions shall include:
 - (a) establishing adequate terms and conditions for the coordination and expeditious solution of matters submitted to it;
 - (b) immediately examining possible discrepancies that may arise in the application of this Chapter;
 - (c) promoting the facilities needed for the training and specialization of technical staff; and
 - (d) promoting cooperation and exchanges of technical staff, including cooperation in the development, application and observance of sanitary or phytosanitary measures.
4. The Committee shall establish the following sub-committees, inter alia: animal health, plant health, food safety, fisheries and agricultural chemicals. The members of the sub-committees shall be appointed by the competent authorities in their respective fields.
5. The sub-committees' functions shall include:
 - (a) preparing terms of reference for activities in their spheres of competence and reporting on their results to the Committee;
 - (b) establishing specific agreements on matters of interest involving greater technical and operational detail, for presentation to the Committee; and
 - (c) establishing mechanisms for expeditious exchanges of information in response to consultations by the Parties.
6. The Committee shall convene once a year, unless otherwise agreed, and shall report on the results of its work to the Commission. The sub-committees shall convene at least once a year, or as often as necessary, depending on the requirements of their programme of activities.

Article 7-12

Technical Consultations

1. Nothing in the Chapter shall prevent a Party from consulting the other Party when it has questions about the application or interpretation of its content.
2. Where one Party considers that a sanitary or phytosanitary measure of the other Party is interpreted or applied in a manner that is inconsistent with the provisions of this Chapter, it shall be required to demonstrate that inconsistency.
3. Where one Party requests consultations and notifies the Committee of its request, the Committee shall facilitate the consultations and may remit them to an

ad hoc working group or some other forum for advice or non-binding technical recommendations.

4. Where the Parties have held consultations under this Article without achieving satisfactory results, those consultations, if agreed by the Parties, shall constitute the consultations envisaged in Article 18-04 (Consultations).

Article 7-13

Relation to Other Chapters

The provision of Article XX(b) of the GATT 1994, included in Article 19-02(1) (General Exceptions), does not apply to any sanitary or phytosanitary measure.

CHAPTER 8 - STANDARDS-RELATED MEASURES

Article 8-01

Definitions

For the purposes of this Chapter:

approval procedure means any registration, notification or other mandatory administrative procedure for granting permission for a good or service to be produced, marketed or used for a stated purpose or under stated conditions;

assessment of risk means evaluation of the potential for adverse effects;

conformity assessment procedure means any procedure used, directly or indirectly, to determine that a technical regulation or standard is fulfilled, including sampling, testing, inspection, evaluation, verification, assurance of conformity, registration, accreditation and approval, separately or in different combinations;

international standard means a standards-related measure, or other guide or recommendation, adopted by an international standardizing body and made available to the public;

international standardizing body means a standardizing body whose membership is open to the relevant bodies of at least all the parties to the Agreement on Technical Barriers to Trade, including the International Organization for Standardization, the International Electrotechnical Commission, Codex Alimentarius Commission, the World Health Organization, the United Nations Food and Agriculture Organization, the International Telecommunication Union, or any other body that the Parties designate;

legitimate objective includes the guarantee for safety or protection of human, animal or plant life or health, the environment, or the prevention of practices which

may mislead or deceive consumers, including issues related to identifying goods or services, considering, among other things, where appropriate, fundamental climatic or other geographical factors, technological or infrastructural factors, or scientific justification;

make compatible means bring different standards-related measures of the same scope approved by different standardizing bodies to a level such that they are either identical, equivalent or have the effect of permitting goods or services to be used in place of one another or fulfil the same purpose;

services means any of the cross-border services sectors or subsectors set out in Annex 8-01;

standard means a document, approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for goods or related processes and production methods, or for services or related operating methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a good, process, or production or operating method;

standardizing body means a body having recognized activities in standardization;

standards-related measure means a standard, technical regulation or conformity assessment procedure;

TBT Agreement means the Agreement on Agreement on Technical Barriers to Trade, which forms part of the WTO Agreement; and

technical regulation means a document which lays down goods' characteristics or their related processes and production methods, or services' characteristics or their related operating methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a good, process, or production or operating method.

Article 8-02

General Provision

Apart from the provisions of the TBT Agreement, the Parties shall apply the provisions of this Chapter.

Article 8-03

Scope and Coverage

1. This Chapter applies to the standards-related measures of the Parties and measures that may, directly or indirectly, affect trade in goods or services between them.

2. This Chapter does not apply to sanitary and phytosanitary measures, which are covered by Chapter 7 (Sanitary and Phytosanitary Measures).

Article 8-04

Basic Rights and Obligations

1. Each Party may, in pursuing its legitimate objectives, establish the levels of protection that it considers appropriate and may develop, adopt, apply or maintain any standards-related measure to ensure fulfilment of its legitimate objectives, and measures for the application of and compliance with standards-related measures, including approval procedures.

2. Each Party shall comply with this Chapter and adopt measures to ensure compliance and, within its ability, measures to that end with respect to non-governmental standardization organizations that are duly accredited in its territory.

3. With respect to standards and technical regulations, each Party shall accord the goods and service providers of the other Party national treatment and treatment no less favourable than that it accords to similar goods and service providers of a non-Party country.

4. No Party may prepare, adopt, maintain or apply any standards-related measure with a view to or with the effect of creating an unnecessary obstacle to trade between the Parties. To that end, standards-related measures shall not restrict trade more than is necessary to fulfil a legitimate objective, taking into account the risks that not fulfilling it would create. An unnecessary obstacle to trade shall not be deemed to be created where:

(a) the demonstrable purpose of the measure is to achieve a legitimate objective;

(b) it conforms to an international standard; and

(c) the measure does not operate to exclude goods of the other Party that meet that legitimate objective.

5. Each Party shall use existing international standards or standards whose adoption is imminent as the basis for its own standards-related measures, unless such standards are not an effective or appropriate means of fulfilling its legitimate objectives.

Article 8-05

Compatibility

1. Recognizing the central role of standards-related measures in achieving legitimate objectives, the Parties shall, in accordance with this Chapter and the TBT

Agreement, work jointly to enhance the level of safety and of protection of human, animal and plant life and health, the environment and consumers.

2. Without reducing the level of safety or of protection of human, animal or plant life or health, the environment or consumers, without prejudice to the rights of either Party under this Chapter, and taking into account international standardization activities, the Parties shall, to the greatest extent practicable, make compatible their respective standards-related measures.

3. A Party shall, on request of the other Party, seek as far as practicable through appropriate measures, to promote the compatibility of a specific standard that is maintained in its territory with the standards maintained in the territory of the other Party.

4. On the express and written request of a Party, setting forth its reasons, the other Party shall give favourable consideration to the possibility of accepting technical regulations of that Party as equivalents, even if they differ from its own, provided that, in cooperation with that Party, it is convinced that the regulations comply with the legitimate objectives of its own regulations.

5. On the request of a Party, the other Party shall inform it in writing of its reasons for not accepting a technical regulation as equivalent.

Article 8-06

Assessment of Risk

1. A Party may, in pursuing its legitimate objectives, conduct an assessment of risk. In conducting an assessment, a Party may take into account, among other factors relating to a good or service:

- (a) assessments of risks performed by international standardization organizations;
- (b) available scientific evidence or technical information;
- (c) intended end use;
- (d) processes or production methods provided they influence the nature of the end good or service;
- (e) operating, inspection, sampling or testing processes or methods; or
- (f) environmental conditions.

2. Where a Party establishes a level of protection that it considers appropriate to achieve its legitimate objectives and conducts an assessment of risk, it should avoid arbitrary or unjustifiable distinctions between similar goods or services in the level of protection it considers appropriate, where the distinctions:

- (a) result in arbitrary or unjustifiable discrimination against goods or service providers of the other Party;
- (b) constitute a disguised restriction on trade between the Parties; or
- (c) discriminate between similar goods or services for the same use under the same conditions that pose the same level of risk and provide similar benefits.

3. Where a Party conducting an assessment of risk determines that available scientific evidence or other information is insufficient to complete the assessment, it may adopt a provisional technical regulation on the basis of available relevant information and in accordance with the TBT Agreement. The Party shall, within a reasonable period after information sufficient to complete the assessment of risk is presented to it, complete its assessment, review and, where appropriate, revise the provisional technical regulation in the light of that assessment.

4. A Party shall provide the other Party upon request with documentation on its risk-assessment processes and the factors it takes into account in conducting the assessment and in establishing the level of protection it considers appropriate in accordance with Article 8-04.

Article 8-07

Conformity Assessment Procedures

1. Conformity assessment procedures shall be prepared, adopted and applied so as to grant access for goods and services originating in the territory of the other Party under conditions no less favourable than those accorded to suppliers of like good or service of the Party or of a non-Party in a comparable situation.

2. With respect to its conformity assessment procedures, each Party shall ensure that:

- (a) procedures are initiated and completed as expeditiously as possible, in non-discriminatory order;
- (b) the normal processing period for each such procedure is published or the anticipated processing period is communicated to the applicant upon request;
- (c) when receiving an application, the competent body or authority 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 assessment 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 conformity assessment if the applicant

so requests; and that, upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

- (d) information requirements are limited to what is necessary to assess conformity and determine fees;
- (e) the confidentiality of information about a good or service originating in the territory of the other Party arising from or supplied in connection with such conformity assessment procedures is respected in the same way as for a domestic good or service and in such a manner that legitimate commercial interests are protected;
- (f) any fees imposed for assessing the conformity of a good or service originating in the territory of the other Party are equitable in relation to any fees chargeable for assessing the conformity of like goods or services of national origin, taking into account communication, transportation and other costs arising from differences between the location of facilities of the applicant and the conformity assessment body;
- (g) the siting of facilities used in conformity assessment procedures and the selection of samples are not such as to cause unnecessary inconvenience to applicants or their agents;
- (h) whenever specifications of a good or service are changed subsequent to the determination of its conformity to the applicable technical regulations or standards, the conformity assessment procedure for the modified good or service is limited to what is necessary to determine whether adequate confidence exists that the good or service still meets the technical regulations or standards concerned; and
- (i) a procedure exists to review complaints concerning the operation of a conformity assessment procedure and to take corrective action when a complaint is justified.

3. To facilitate trade, a Party shall give sympathetic consideration to a request by the other Party to negotiate agreements for the mutual recognition of the results of their respective conformity assessment procedures.

4. Each Party shall, as far as practicable, accept the results of conformity assessment procedures in the other Party, provided they offer satisfactory guarantees, equivalent to those provided by the procedures carried out by the accepting Party in its territory or which are carried out in its territory and whose results it accepts, that the pertinent good or service conforms to the applicable technical regulation or standard adopted or maintained in the territory of that Party.

5. Before accepting the results of a conformity assessment procedure, as provided in paragraph 4, and with the aim of enhancing the sustained reliability of the results of the conformity assessment of each Party, the Parties may consult on

aspects such as the technical capacity of conformity assessment bodies, including verified conformity with relevant international standards through methods such as accreditation.

6. Recognizing that this should be to the mutual advantage of the Parties, each Party shall accredit, approve or otherwise recognize the conformity assessment bodies in the territory of the other Party under conditions no less favourable than it accords to such bodies in its territory.

Article 8-08

Approval Procedures

Each Party shall apply the pertinent provisions of Article 8-07(2) to its approval procedures, with the appropriate modifications.

Article 8-09

Notification, Publication and Transparency

1. A Party proposing to adopt or modify a technical regulation or a conformity assessment procedure applied to a technical regulation, except where the urgent circumstances established in Articles 2.10 and 5.7 of the TBT Agreement exist, shall publish a notice and notify the other Party in writing of the proposed measure at least 60 days prior to the adoption or modification of the measure, other than a law, as to enable interested persons to become acquainted with it.

2. Where a standardizing body of one Party proposes to adopt or modify a standard or conformity assessment procedure applied to a standard, that Party shall publish a notice and notify the other Party in writing of the proposed measure at an early appropriate stage, to enable interested persons to become acquainted with it.

3. The Parties shall make notifications under paragraphs 1 and 2 in accordance with the formats established in the TBT Agreement or such formats as are agreed to by the Parties.

4. Each Party shall notify the other annually of its standardization plans and programmes.

5. Each Party shall keep a list of its standardization measures which, upon request, shall be made available to the other Party, and shall ensure that where copies of documents are requested by the other Party or by interested persons of that Party, they are supplied at the same price, apart from the actual cost of delivery, as the price for domestic purchase.

6. Where a Party allows non-governmental persons in its territory to be present during the process of development of standards-related measures, it shall also allow non-governmental persons from the territory of the other Party to be present. The non-governmental persons of the territory of the other Party shall be permitted to

express opinions and make comments on the standardization measure being developed.

7. For the purposes of this Article, the authorities named in Annex 8-09 shall be responsible for making the notifications.

Article 8-10

Limitations on the Provision of Information

Nothing in this Chapter shall be construed to require a Party to furnish any information the disclosure of which would impede law enforcement or otherwise be contrary to the public interest.

Article 8-11

Committee on Standards-Related Measures

1. The Parties hereby establish a Committee on Standards-Related Measures, comprising representatives of each Party, in accordance with Annex 8-11.

2. The Committee's functions shall include:

(a) monitoring the implementation, compliance and administration of this Chapter;

(b) considering particular matters on standardization-related measures and measurement systems of the other Party or measures related thereto, when a Party has questions regarding the interpretation or application of this Chapter, in order to provide technical advice or non-binding recommendations;

(c) facilitating the process by which the Parties make compatible their standards-related measures and measurement systems;

(d) providing a forum for the Parties to consult on issues relating to standards-related measures and measurement systems;

(e) promoting technical cooperation between the Parties;

(f) helping to develop and strengthen the standardization, technical regulation, conformity assessment and measurement systems of the Parties;

(g) reporting annually to the Commission on the application of this Chapter;

(h) facilitating the negotiation of agreements on mutual recognition;

- (i) on the request of a Party, evaluating and recommending to the Commission for approval, the inclusion of specific services sectors or subsectors in Annex 8-01, such inclusion to be made through a decision of the Commission; and
 - (j) establishing relevant sub-committees and determining the scope of their activities and mandate.
- 3. The Committee shall meet at least once a year, unless the Parties otherwise agree.
- 4. The Parties establish a Telecommunications Standards Sub-Committee comprised of representatives of each Party. The Sub-Committee's functions shall be to:
 - (a) develop a work programme, within twelve months of the date of entry into force of this Agreement, including a timetable, for making compatible to the greatest extent possible, the standards-related measures of the Parties for authorized equipment as defined in Chapter 12 (Telecommunications);
 - (b) address other matters respecting the standardization of telecommunications equipment or services and such other matters as it considers appropriate; and
 - (c) take into account relevant work carried out by the Parties in other fora, and that of non-governmental standardizing bodies.

Article 8-12

Technical Cooperation

- 1. A Party shall, on the request of the other Party:
 - (a) provide to that Party information and technical assistance on mutually agreed terms and conditions to enhance that Party's standards-related measures, and related activities, processes and systems; and
 - (b) provide to that Party information on its technical cooperation programmes regarding standards-related measures relating to specific areas of interest.
- 2. Each Party shall encourage standardizing bodies in its territory to cooperate with the standardizing bodies in the territory of the other Party, such as through membership in international standardizing bodies.
- 3. To the extent practicable, each Party shall inform the other Party of the international agreements, conventions or programmes it has entered into on standardization measures.