

## CHAPTER 9: MEASURES ON STANDARDS, METROLOGY, AND AUTHORIZATION PROCEDURES

### Article 9.01 Definitions

1. For purposes of this Chapter, the following terms shall be understood as:

**administrative refusal:** action taken in the exercise of its authorities by a public body of the importing Party to prevent the entry in its territory of a consignment that does not comply with its technical regulations, conformity assessment procedures or metrological requirements;

**assessment of risk:** evaluation of potential adverse effects on legitimate objectives that could impede trade;

**authorization procedure:** any mandatory administrative procedure for granting registration, license or any other approval for a good to be produced, marketed or used for a stated purpose or under stated conditions;

**comparable situation:** situation that offers the same level of safety or protection for reaching a legitimate objective;

**conformity assessment procedure:** 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 as well as their combinations;

**international standard:** a standard, guide or recommendation, adopted by an international standardizing body and made available to the public;

**international standardizing or metrological body:** a standardizing or metrological body whose membership is open to at least all the Members of the WTO, including the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the Codex Alimentarius Commission (CAC), the International Organization of Legal Metrology (OIML), the International Commission on Radiation Units and Measurements, Inc. (ICRU), or any other body that the Parties designate;

**legitimate objectives:** national security requirements, prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or the environment;

**make compatible:** to 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 to be used in place of one another or for fulfilling the same purpose;

**standard:** 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, with which compliance is not mandatory. It

may also include, or deal exclusively with, terminology, symbols, packaging, marking or labeling requirements as they apply to a good, process or production method;

**standardization measures:** the rules, technical regulations, requirements of metrology or procedures for conformity assessment;

**TBT Agreement:** the WTO Agreement on Technical Barriers to Trade; and

**technical regulation:** document which lays down characteristics of goods or their related processes and production 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 method.

2. Except as defined in paragraph 1, the Parties shall use the terms of the current ISO/IEC Guide 2: 1996 "Standardization and Related Activities-General Vocabulary".

### **Article 9.02 General Provisions**

1. In addition to the provisions of the WTO Agreement, the Parties shall apply the provisions of this Chapter.

2. The Parties shall use the relevant dispute settlement provisions of the WTO Agreement, instead of Chapter 15 (Dispute Settlement) of this Agreement for any formal disputes, related to their rights and obligations under the TBT Agreement.

### **Article 9.03 Scope of Application**

1. This Chapter shall apply to the measures adopted by the Parties on standards, authorization procedures, and metrology, as well as on related measures that may directly or indirectly affect the trade in goods between the Parties.

2. This Chapter shall not apply to sanitary and phytosanitary measures.

### **Article 9.04 Basic Rights and Obligations**

#### *Right to Adopt Standardization Measures*

1. Each Party may develop, adopt, apply, and maintain:

(a) measures on standards, authorization procedures, and metrology, according to the provisions of this Chapter; and

(b) technical regulations and conformity assessment procedures that allow the Party to reach its legitimate objectives.

### *Unnecessary Barriers*

2. No Party shall develop, adopt, maintain or apply measures on standards, authorization procedures or metrology that have the purpose or effect of creating unnecessary trade barriers to the other Party.

### *Non-Discriminatory Treatment*

3. Each Party shall, in relation to measures on standardization, authorization procedures, and metrology, accord to the goods of the other Party national treatment and treatment no less favorable than that it accords to like goods of any other country.

### *Use of International Standards*

4. In the development or implementation of its measures on standardization, authorization procedures or metrology, each Party shall use international standards where they exist or their completion is imminent, or use the relevant parts of them, except where such international standards would not be an effective or appropriate means for fulfilling the legitimate objectives because of fundamental climatic, geographical, technological or infrastructural factors, or scientifically verified reasons.

## **Article 9.05 Assessment of Risk**

1. In pursuing its legitimate objectives, each Party conducting risk assessments shall take into account:

- (a) risk assessments carried out by international standardizing or metrological bodies;
- (b) available scientific evidence or technical information;
- (c) related processing technology; or
- (d) intended end uses of goods.

2. Where a Party establishes a level of protection that it considers appropriate and conducts an assessment of risk, it shall avoid arbitrary or unjustifiable distinctions between similar goods in the level of protection it considers appropriate, where the distinctions:

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

3. A Party shall provide to the other Party, upon request, relevant documentation on its risk assessment processes and on the factors taken into account when conducting the assessment and definition of protection levels, according to Article 9.04.

#### **Article 9.06 Compatibility and Equivalence**

1. Without prejudice to the rights conferred by this Chapter and taking into account the international activities on standards and metrology, the Parties shall, to the greatest extent, make compatible their respective standards and metrology measures, without reducing the level of safety or protection to human, animal or plant life or health, the environment and consumers.

2. A Party shall accept as equivalent to its own any technical regulations of the other Party, when in cooperation with the other Party, the importing Party determines that the technical regulations of the exporting Party adequately fulfill the legitimate objectives of the importing Party.

3. The importing Party shall provide to the exporting Party, on request, its reasons in writing for not treating a technical regulation as equivalent under paragraph 2.

#### **Article 9.07 Conformity Assessment**

1. Each Party shall develop, adopt, and apply conformity assessment procedures to accord access to like goods from the territory of the other Party under conditions no less favorable than those accorded to its like goods or to those of any other country, in a comparable situation.

2. With regard to its conformity assessment procedures, each Party shall:

- (a) initiate and complete these procedures as expeditiously as possible and on a non-discriminatory basis;
- (b) publish the procedure and the normal period of each procedure or, upon request, to convey this information to the applicant;
- (c) have the competent body or authority review without delay upon receipt of an application if the documentation is complete and communicate to the applicant as soon as possible and with accuracy and thoroughness the findings of the assessment, so that the applicant may take corrective measures as needed and even when the application shows deficiencies, proceed with the conformity assessment as far as possible if requested by the applicant and, upon request, inform the applicant of the stage of the procedure and explain any possible delay;
- (d) request only the information necessary to assess the conformity and calculate the fees;

- (e) respect the confidentiality of the information about a good of the other Party obtained by such procedures or provided in connection with them, in the same manner as in the case of goods from the Party, so as to protect the legitimate trade interests;
- (f) make equitable the fees imposed for assessing the conformity of a good of the other Party, compared with the fees that would be collected for assessing the conformity of a like good of this Party, taking into account communication, transportation, and other costs due to differences in location of the applicant's premises and of the conformity assessment body;
- (g) ensure that the location of premises used in conformity assessment procedures and sampling procedures do not cause unnecessary inconvenience to applicants or their agents;
- (h) if the specifications of a good are modified after the determination of its conformity with technical regulations or applicable standards, limit the conformity assessment procedure for the modified good to the extent necessary to determine with due assurance that the good shall continue to conform to the technical regulations or applicable standards; and
- (i) establish a procedure for reviewing the claims related to the application of a conformity assessment procedure and adopt corrective measures if the claim is justified.

3. With the aim of advancing the facilitation of trade, a Party shall consider favorable a request from the other Party to initiate negotiations designed to conclude agreements for the mutual recognition of the results of their respective conformity assessment procedures.

4. To the extent practicable, each Party shall accept the results of conformity assessment procedures carried out in the territory of the other Party, provided that those procedures offer enough confidence, equivalent to the confidence of its own procedures and that the good meets the technical regulations or applicable standards adopted or maintained in the territory of this Party.

5. Before accepting the results of a conformity assessment procedure under paragraph 4 and with the aim of strengthening the sustained reliability of the results of conformity assessment of each Party, the Parties may consult about matters such as the technical capacity of conformity assessment bodies, including the verified compliance with relevant international standards through means such as accreditation.

6. Each Party, recognizing that the outcome shall be to the mutual advantage of both Parties, shall accredit, approve or recognize conformity assessment bodies in the territory of the other Party, in conditions no less favorable than those accorded to conformity assessment bodies in its territory.

7. The Parties may use the capacity and technical infrastructure of the accredited bodies established in the territory of the Parties in the conformity assessment procedures.

#### **Article 9.08 Authorization Procedures**

1. Each Party shall develop, adopt and apply authorization procedures to accord access to like goods from the territory of the other Party under conditions no less favorable than that accorded to its goods or to the goods of any other country, in a comparable situation.

2. In relation to its authorization procedures, each Party shall:

- (a) initiate and complete these procedures as expeditiously as possible and in a non-discriminatory manner;
- (b) publish the procedure and the normal period of each procedure or upon request to convey this information to the applicant;
- (c) have the competent authority review without delay upon receipt of an application if the documentation is complete and communicate to the applicant as soon as possible and with accuracy and thoroughness the results of the authorization, so that the applicant may take corrective measures as needed, and even when the application shows deficiencies, proceed with the authorization procedure as far as possible if requested by the applicant and, upon request, inform the applicant of the stage of the procedure and explain any possible delay;
- (d) request only the information necessary to authorize and calculate the fees;
- (e) respect the confidentiality of the information about a good of the other Party obtained by such procedures or provided in connection with them, in the same manner as in the case of goods from the Party, in order to protect the legitimate trade interests;
- (f) make equitable the fees imposed for authorization procedure with respect to a good of the other Party, compared with the fees that would be collected for an authorization procedure of a like good of this Party, taking into account communication, transportation, and other costs due to differences in location of the applicant's premises and of the authorizing body; and
- (g) establish a procedure for reviewing the claims related to the application of an authorization procedure and adopt corrective measures if the claim is justified.

#### **Article 9.09 Metrology**

Each Party shall ensure, to the extent practicable, the documented traceability of its standards and the calibration of its measuring instruments, according to the recommendations of the Bureau International des Poids et Mesures

(BIPM) and the International Organization of Legal Metrology (OIML), and comply with the requirements set out in this Chapter.

#### **Article 9.10 Notification**

1. In cases where there is no relevant international standard, or the technical content of a proposed technical regulation or of a conformity assessment procedure does not conform with the technical content of the relevant international standards, and if these technical regulations may have a significant impact on trade between the Parties, each Party shall notify, in writing, the other Party of the proposed measure, at least sixty (60) days before its adoption, allowing the interested parties to make comments, discuss these comments upon request, and take these comments and the results of these discussion into account.

2. If a Party faces serious problems or the threat of serious problems related to safety, health, environment protection, and national security, this Party may not present the communication prior to the project, but once adopted shall notify the other Party.

3. The notifications under paragraphs 1 and 2 shall be done following the models established in the TBT Agreement.

4. Within thirty (30) days of entry into force of this Agreement, each Party shall notify the other Party of the institution designated to carry out the notifications under this Article.

5. Each Party shall notify in writing the other Party of its standardization plans and programs.

6. When a Party rejects a shipment by an administrative decision, the Party shall notify the person in charge of the shipment of the technical reasons for the rejection, without delay and in writing via fax, courier, e-mail or other media.

7. Once the information required under paragraph 5 is completed, the Party shall immediately transmit it to the Information Center of the other Party.

#### **Article 9.11 Information Centers**

1. Each Party shall ensure the existence of an information center in its territory that may answer all reasonable questions and requests from the other Party and from interested persons and supply the relevant updated documentation relating to any measure on standards, metrology, conformity assessment procedures or authorization procedures adopted or proposed in its territory by governmental or non-governmental bodies.

2. Each Party designates the center set out in Annex 9.11(2) as Information Center.

3. If an information center requests copies of the documents referred to in paragraph 1 they shall be delivered without cost. The interested persons from the other Party shall receive copies of the documents at the same price as the nationals from this Party, plus the actual cost of shipment.

#### **Article 9.12 Technical Consultations**

1. When a Party considers that a measure on standards, technical regulations, metrology or authorization procedures of the other Party is interpreted or applied in an inconsistent way with the provisions of this Chapter, the Party will have the obligation to prove the inconsistency.

2. When a Party requests consultations and notifies the Committee specified in Article 9.13, the Committee shall facilitate the consultations and send them to an ad-hoc working group or to another forum for consultations.

#### **Article 9.13 Committee on Standards, Metrology, and Authorization Procedures**

1. The Parties hereby establish the Committee on Standards, Metrology, and Authorization Procedures, as set out in Annex 9.13.

2. The Committee will hear matters relating to this Chapter, without prejudice to the provisions of Article 14.05 (Committees), and shall have the following functions:

- (a) analyzing and proposing ways to resolve measures on standards, authorization procedures, and metrology that a Party considers a technical barrier to trade;
- (b) promptly addressing any issue that a party raises related to the development, adoption, application, or enforcement of standards, technical regulations, metrology requirements or conformity assessment procedures;
- (c) facilitating the process by which the Parties shall make compatible their measures on standards and metrology, giving priority, *inter alia*, to labelling and packaging;
- (d) promoting technical cooperation activities between the Parties;
- (e) providing assistance to the risk assessment activities carried out by the Parties;
- (f) working together to develop and strengthen the standards and metrology measures of the Parties; and
- (g) facilitating the process by which the Parties shall establish mutual recognition agreements.

3. The Committee shall meet if necessary as requested by the Parties.



4. All decisions of the Committee shall be taken by consensus unless, the Committee otherwise decides.

**ANNEX 9.11(2)**  
**Information Centers**

The Information Center referred to in Article 9.11(2) shall be composed of:

- (a) in the case of the Republic of China (Taiwan), the Ministry of Economic Affairs, through the Bureau of Standards, Metrology and Inspection, or its successor;
- (b) in the case of El Salvador, the Ministerio de Economía through the Dirección de Administración de Tratados Comerciales; or its sucesor; and
- (c) in the case of Honduras, la Secretaría de Estado en los Despachos de Industria y Comercio, through the Dirección de Producción y Consumo, Departamento de Normalización y Metrología, or its successor.

**ANNEX 9.13**  
**Committee on Standards, Metrology, and Authorization**  
**Procedures**

The Committee on Standards, Metrology, and Authorization Procedures established in Article 9.13 shall be composed of:

- (a) in the case of the Republic of China (Taiwan), the Ministry of Economic Affairs, through the Bureau of Standards, Metrology, and Inspection, or its successor;
- (b) in the case of the Republic of El Salvador, the Ministerio de Economía through the Dirección de Administración de Tratados Comerciales; or its successor; and
- (c) in the case of the Republic of Honduras, la Secretaría de Estado en los Despachos de Industria y Comercio, through the Dirección de Producción y Consumo, Departamento de Normalización y Metrología, or its successor.