

## **CHAPTER**

### **TECHNICAL BARRIERS TO TRADE**

#### *Article 1*

##### **Objective**

The objective of this Chapter is to facilitate trade in goods between the Parties by identifying, preventing and eliminating unnecessary technical barriers to trade and to enhance cooperation between the Parties in matters covered by this Chapter.

#### *Article 2*

##### **Relationship with the WTO TBT Agreement**

1. The Parties reaffirm their rights and obligations under the TBT Agreement which is hereby incorporated into and made part of this Agreement.
2. References to “this Agreement” in the TBT Agreement, as incorporated into this Agreement, are to be read, as appropriate, as references to the Agreement between the European Union and its Member States and MERCOSUR.
3. The term “Members” in the TBT Agreement, as incorporated into this Agreement, shall mean the Parties to this Agreement.

#### *Article 3*

##### **Scope, coverage and definitions**

1. This Chapter applies to the preparation, adoption and application of standards, technical regulations and conformity assessment procedures that may affect trade in goods between the Parties.
2. For the purpose of this Chapter, the definitions of Annex I of the TBT Agreement shall apply.
3. Notwithstanding paragraph 1, this Chapter does not apply to:

- (i) purchasing specifications prepared by governmental bodies for production or consumption requirements of such bodies; or
- (ii) sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.

*Article 4*

**Joint cooperation on trade facilitating initiatives**

1. The Parties recognize the importance to intensify their cooperation with a view to increasing mutual understanding of their respective systems and to help eliminate or avoid the creation of technical barriers to trade. In this regard, the Parties shall work towards the identification, promotion, development, and implementation, as appropriate of trade facilitating initiatives, on a case-by-case basis.
2. A Party may propose to the other Party sector specific initiatives in areas covered by this Chapter. Those proposals shall be transmitted to the TBT Chapter Coordinator may include among others:
  - a) information exchanges on regulatory approaches and practices;
  - b) joint analysis of a sector or a group of products;
  - c) initiatives to further align technical regulations and conformity assessment procedures with relevant international standards;
  - d) the promotion of the use of accreditation to assess the competence of conformity assessment bodies; and
  - e) considering mutual or unilateral recognition of conformity assessment results.
3. Whenever one of the Parties suggests a specific trade facilitating initiative, the other Party shall duly consider the proposal and reply in a reasonable time. If the other Party rejects the suggested initiative, it shall explain the reasons for its decision to the other Party.
4. The terms of the work envisaged in this article will be defined by the engaged Parties, when needed. This may include establishing ad hoc working groups. In order to gain non-governmental perspectives on matters related to this article, each Party may consult, as appropriate, with stakeholders and interested parties in accordance with their domestic rules and procedures.
5. The results of the understandings reached under this Article shall be reported to the Chapter Coordinator. The Chapter Coordinator will transmit the recommendations to the Trade Committee of the Agreement for the appropriate measures.
6. Nothing in this Article shall be construed as to oblige a Party to:
  - a) deviate from domestic procedures for preparing and adopting regulatory measures,

- b) take actions that would undermine or impede the timely adoption of regulatory measures to achieve its public policy objectives, or
- c) adopt any particular regulatory outcome; fully respecting the Parties' right to regulate.

7. When agreed and necessary for the implementation of the initiatives under this Article, the Parties shall facilitate the access of technical teams to demonstrate their conformity assessment schemes and system in order to increase mutual understanding.

#### *Article 5*

#### **Technical regulations**

1. The Parties agree to make best use of good regulatory practices with regard to the preparation, adoption and application of technical regulations, as provided for in the TBT Agreement, including, for example, preference for performance-based technical regulations, use of impact assessments or stakeholder consultation. In particular, the Parties agree to:

- a) use relevant international standards as a basis for their technical regulations including any conformity assessment elements therein, except when such international standards would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued. Where international standards have not been used as a basis for a technical regulation, which may have a significant effect on trade, a Party shall, upon request of the other Party, explain the reasons why such standards have been judged inappropriate or ineffective for the aim pursued.
- b) when reviewing their technical regulations, in addition to the Article 2.3 and without prejudice to the Articles 2.4 and 12.4 of the TBT Agreement, to increase their alignment with relevant international standards. The Parties shall consider, inter alia, any new development in the relevant international standards and whether the circumstances that have given rise to any divergence from any relevant international standard continue to exist.
- c) promote the development of regional technical regulations and that these are adopted at national level and/or replace existing ones, in order to facilitate trade between the Parties; and
- d) allow a reasonable interval between the publication of technical regulations and their entry into force for economic operators of the other Party to adapt. The phrase "reasonable interval" shall be understood to mean normally a period of not less than 6 months, except when this would be ineffective in fulfilling the legitimate objectives pursued.
- e) to carry out the impact analysis of planned technical regulations in accordance with its respective rules and procedures.
- f) when preparing technical regulations, to take due account of the characteristics and special needs of micro, small and medium-sized enterprises.

*Article 6*

**Standards**

1. The Parties reaffirm their obligation under Article 4.1 of the TBT Agreement, particularly in respect to taking all reasonable measures to ensure that all standardizing bodies within their territories accept and comply with the Code of Good Practice for the Preparation and Adoption of Standards in Annex 3 to the TBT Agreement.
2. International standards developed by ISO, IEC, ITU, CODEX ALIMENTARIUS shall be considered to be the relevant international standards within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement.
3. A standard developed by other international organisations, could also be considered relevant international standard within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement, provided that
  - (a) it has been developed by a standardization body which seeks to establish consensus either:
    - i) among national delegations of the participating WTO Members representing all the national standards bodies in their territory that have adopted, or expect to adopt, standards for the subject matter to which the international standardization activity relates, or,
    - ii) among governmental bodies of participating WTO Members, and,
  - (b) it has been developed in accordance with the TBT Committee Decision on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5, and Annex 3 of the TBT Agreement.
4. With a view to harmonizing standards on as wide a basis as possible the Parties shall encourage, within the limits of their competence and resources, the standardizing bodies within their territories, as well as the regional standardizing bodies of which they or the standardizing bodies within their territories are Members, to:
  - a) to participate, within the limits of their resources, in the preparation of international standards by relevant international standardizing bodies;
  - b) cooperate with the relevant national and regional standardization bodies of the other Party in international standardization activities;
  - c) use relevant international standards as a basis for the standards they develop, except where such international standards would be ineffective or inappropriate, for instance because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems;
  - d) avoid duplication of, or overlap with the work of international standardizing bodies;

- e) promote the development of standards at regional level and the adoption of such standards by national standardizing bodies thereby replacing existing national standards;
- f) to review national and regional standards not based on relevant international standards at regular intervals, with a view to increasing their alignment with relevant international standards; and
- g) to foster bilateral cooperation with the standardization bodies of the other Party.

5. The Parties should exchange information on:

- a) their use of standards as a basis for, or in support of, technical regulations;
- b) cooperation agreements implemented by either Party on standardization, for example on standardization issues in free trade agreements with third parties, and
- c) each other's standardization processes, and the use of international, regional or sub-regional standards as a basis for their national standards.

#### *Article 7*

### **Conformity assessment procedures and accreditation**

1. The provisions set out in Article 5 (Technical Regulations) with respect to the preparation, adoption and application of technical regulations shall also apply to conformity assessment procedures.
2. If a Party requires conformity assessment as a positive assurance that a product conforms with a technical regulation, it shall:
  - a) select conformity-assessment procedures proportionate to the risks involved;
  - b) consider in the regulatory process the use of the supplier's declaration of conformity as assurance of conformity among other options for showing compliance with technical regulations; and
  - c) if requested, provide information to the other Party on the reasons for selecting a particular conformity assessment procedure for specific products.
3. If a Party requires third party conformity assessment as a positive assurance that a product conforms with a technical regulation, and it has not reserved this task to a governmental body as specified in paragraph 4, it shall:
  - a) preferentially use accreditation to qualify conformity assessment bodies;
  - b) make best use of international standards for accreditation and conformity assessment, as well as international agreements involving the Parties' accreditation bodies, for example,

through the mechanisms of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF);

c) consider to join or, as applicable, encourage their testing, inspection and certification bodies to join any functioning international agreements or arrangements for harmonization and/or facilitation of acceptance of conformity assessment results;

d) promote that, within the territory of each of the Parties, conformity assessment bodies designated by the authorities for a particular product or set of products may compete to enable economic operators to choose amongst them;

e) ensure that conformity assessment bodies are independent of manufacturers, importers and distributors in the sense that they carry out their activities with objectivity and independence of judgement;

f) ensure that there are no conflicts of interest between accreditation bodies and conformity assessment bodies as well as between activities of market surveillance authorities and activities of conformity assessment bodies;

g) allow to the extent possible that conformity assessment bodies use subcontractors to perform testing or inspections in relation to the conformity assessment, including subcontractors located in the territory of the other Party. Nothing in this subparagraph shall be construed to prohibit a Party from requiring subcontractors to meet the same requirements that the conformity assessment body to which it is contracted would be required to meet in order to perform the contracted tests or inspection itself; and

h) publish in a website a list of the bodies that it has designated to perform such conformity assessment and relevant information on the scope of each such body's designation.

4. Nothing in this Article shall preclude a Party from requesting that conformity assessment in relation to specific products is performed by specified government authorities of the Party. In such cases, the Party shall:

a) establish the conformity assessment fees in accordance with the approximate cost of the services rendered and upon the request of an applicant for conformity assessment, provide the different elements included in them; and

b) in principle make the conformity assessment fees publicly available. When not publicly available, these fees shall be provided upon request.

5. Notwithstanding the provisions of paragraphs 2-4, in the fields listed in Annex 1, where EU accepts Supplier's Declaration of Conformity, i.e. first-party attestation issued by the manufacturer on his sole responsibility based on the results of an appropriate type of conformity assessment activity and excluding mandatory third party assessment, as assurance that a product conforms to a technical regulation and where a Mercosur Party requires mandatory third party testing or certification for these fields, the Mercosur Party shall, as an assurance that a product conforms with

the requirements of a Mercosur Party's technical regulations, accept certificates, or in cases it is not possible under its relevant laws and regulations, test reports issued by conformity assessment bodies that are located in the territory of the EU and which have been accredited for the relevant scopes by an accreditation body member of the international arrangements for mutual recognition of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) or, certificates that have been issued under the IECEE CB Scheme. A Mercosur Party may require in its relevant laws and regulations that bilateral arrangements, including memoranda of understanding exist between the conformity assessment body located in the territory of the EU and the conformity assessment body located in the territory of the Mercosur Party in order to accept such certificates or test reports.

6. When supplier's declaration of conformity, as defined in paragraph (5), is considered a valid conformity assessment procedure in the European Union, test report issued by conformity assessment bodies that are located in the territory of the MERCOSUR Party, is accepted as a valid document in the process of demonstrating that a product conforms with the requirements of EU Party's technical regulations. The manufacturer shall remain responsible in all cases for the conformity of the product.

7. Paragraph 5 also applies where a Mercosur Party introduces new mandatory third party testing or certification requirements for the fields specified in Annex 1, in accordance with paragraph 9. Where EU Party introduces mandatory third party testing or certification requirements for the fields specified in Annex 1, in accordance with paragraph 9, the Parties shall discuss if any steps need to be taken to ensure reciprocity as regards the acceptance of tests reports or certificates issued by conformity assessment bodies that are located in the territory of the MERCOSUR party.

8. At the request of either Party, the Joint Committee may review, based on the agreed recommendation of the Chapter Coordinators, the list of fields in Annex 1.

9. Notwithstanding paragraph (5), either Party may introduce requirements for mandatory third party testing or certification for the fields specified in this Annex, for products falling within the scope of this Annex under the following conditions:

- a) the introduction of such requirements or procedures are justified under the legitimate objectives referred to Article 2.2 of the TBT Agreement;
- b) the reasons for the introduction of any such requirements or procedures are supported by substantiated technical or scientific information regarding the performance of the products in question;
- c) any such requirements or procedures are not more trade-restrictive than necessary to fulfil the Party's legitimate objective, taking account of the risks that non-fulfilment would create; and
- d) the Party could not have reasonably foreseen the need for introducing any such requirements or procedures at the time of entry into force of this Agreement.

10. The obligation of a Party under paragraph (5) is without prejudice to market surveillance competences, including carrying out additional testing on samples by the Party at the point of entry, on a non-discriminatory basis.

*Article 8*

**Transparency**

1. The Parties reaffirm their transparency obligations under the TBT Agreement with regard to the preparation, adoption and application of standards, technical regulations and conformity assessment procedures, and agree to:
  - a) take the other Party's views into account where a part of the process of developing a technical regulation is open to public consultation;
  - b) ensure, in accordance with its respective rules and procedures, when developing major technical regulations and conformity assessment procedures which may have a significant effect on trade that transparency procedures exist that allow persons of the Parties to provide input through a formal public consultation process, except where urgent problems of safety, health, environmental protection or national security arise or threaten to arise. Each Party shall allow persons of the other Party to participate to such consultation in terms no less favourable than those accorded to its own persons, and whenever possible make the results of that consultation process public;
  - c) allow in principle a period of at least 60 days for the other Party to provide written comments on the proposed technical regulations and conformity assessment procedures. Where urgent problems of safety, health, environmental protection or national security arise or threaten to arise, articles 2.10 and 5.7 of the TBT agreement apply. A Party shall consider a reasonable request to extend the comment period;
  - d) provide, in case the notified text is not in one of the official WTO languages, a clear and comprehensive description of the content of the measure in the WTO notification format;
  - e) if a Party receives written comments on its proposed technical regulation or conformity assessment procedure from the other Party:
    - i. if requested by the other Party, discuss the written comments, whenever possible with the participation of its competent regulatory authority and at a time when they can be taken into account;
    - ii. reply in writing to the comments whenever possible no later than the date of publication of the technical regulation or conformity assessment procedure;
  - f) provide, if requested by the other Party, information regarding the objectives of, legal basis and rationale for, a technical regulation or conformity assessment procedure that the Party has adopted or is proposing to adopt;
  - g) provide information on the adoption and the entry into force of the technical regulation or conformity assessment procedure and the adopted final text through an addendum to the original notification to the WTO;

- h) consider a reasonable request from the other Party, received prior to the end of the comment period following the transmission of a proposed technical regulation, to extend the period of time between the adoption of the technical regulation and its entry into force, except where the delay would be ineffective in fulfilling the legitimate objectives pursued;
- i) provide means for free access to the electronic version of the notified text with the notification; and
- j) if standards are made mandatory through incorporation or referencing in a draft technical regulation or conformity assessment procedure, the transparency obligations related to TBT notification set out in this Article and in Articles 2 or 5 of the TBT Agreement shall be fulfilled.

2. The Parties shall ensure that all technical regulations and mandatory conformity assessment procedures adopted and in force are publicly available on an official website free of charge. The Parties shall always provide unrestricted access to all information relevant to the achievement of conformity with a technical regulation. When standards provide presumption of conformity with technical regulations and these standards are not referred to in those technical regulations, Parties shall ensure access to the information on corresponding standards.

3. A Party shall, upon reasonable request of the other Party or its economic operators, provide information on technical regulations in force and, as appropriate and available, written guidance on compliance with the technical regulations, without undue delay.

#### *Article 9*

### **Marking and labelling**

- 1. The Parties affirm that their technical regulations including or dealing exclusively with mandatory marking or labelling will observe the principles of Article 2 of the TBT Agreement.
- 2. In particular, the Parties agree that where a Party requires mandatory marking or labelling of products:
  - a) the Party shall only require information which is relevant for consumers or users of the product or authorities to indicate the product's conformity with the mandatory technical requirements;
  - b) Where a Party requires any prior approval, registration or certification of the labels of markings of the products, as a precondition for placing on the market products that otherwise comply with its mandatory technical requirements, it shall ensure that the requests submitted by the economic operators of the other Party are decided without undue delay and on a non-discriminatory basis;
  - c) where a Party requires the use of a unique identification, the Party shall issue such number to the economic operators of the other Party without undue delay and on a non-discriminatory basis;

d) provided it is not misleading, contradictory or confusing in relation to the importing country's regulatory requirements and the legitimate objectives under the TBT Agreement are not compromised thereby, the Party shall permit:

i) information in other languages in addition to the language required in the importing country of the goods;

ii) nomenclatures, pictograms, symbols or graphics adopted in international standards.

e) the Party, whenever possible, shall accept that supplementary labelling, and corrections to labelling take place in customs warehouses or other designated areas at the point of import as an alternative to labelling in the country of origin;

f) the Party shall, in cases where it considers that the protection of public health and the environment, the protection against deceptive practices and any other legitimate objectives under the TBT Agreement are not compromised thereby, endeavour to accept non-permanent or detachable labels, rather than labels physically attached to the product, or inclusion of relevant information in the accompanying documentation.

3. This article Paragraph (2) shall not apply to marking or labelling of medicinal products.

4. If a Party considers that marking or labelling requirements for a product or a sector in the other Party could be improved, it may propose a trade facilitating initiative to address its concerns in conformity with Article 4 of this Chapter.

## *Article 10*

### **Cooperation and technical assistance**

1. To contribute to fulfilling the objectives of this Chapter, the Parties agree to, inter alia:

a) Promote cooperation and joint activities and projects between their respective organizations, public and/or private, national and/or regional, in the fields of technical regulations, standardization, conformity assessment, metrology and accreditation;

b) Promote good regulatory practices through the exchange of information, experiences and best practices about, inter alia, regulatory impact assessment, regulatory stock management and risk assessment and public consultation;

c) Exchange views on market surveillance;

d) Strengthen the technical and institutional capacity of the national regulatory, metrology, standardization, conformity assessment and accreditation bodies, supporting the

development of their technical infrastructure, including labs and testing equipment, and sustaining the continuous training of human resources;

- e) Promote, facilitate and, whenever possible, coordinate their participation in international organizations and other fora related to technical regulations, conformity assessment, standards, accreditation and metrology;
  - f) Support technical assistance activities by national, regional and international organizations in the areas of technical regulations, standardization, conformity assessment, metrology and accreditation;
  - g) endeavor to share available scientific evidences and technical information among regulatory authorities of the Parties, to the extent necessary to cooperate or pursue technical discussions under this Chapter, with the exception of confidential or other sensitive information.
2. A Party shall give appropriate consideration to proposals of the other Party for cooperation under this Chapter.

### *Article 11*

#### **Technical discussions**

1. Each Party may request to discuss any concern that arises under this Chapter; including any draft or proposed technical regulation or conformity assessment procedure of the other Party that the Party considers might significantly adversely affect trade between the Parties. A Party shall deliver its request to the Chapter Coordinator of the other Party designated pursuant to Article 13 and it shall identify:
- a) the issue;
  - b) the provisions of this Chapter to which the concerns relate; and
  - c) the reasons for the request, including a description of the requesting Party's concerns.
2. Any information or explanation provided at the request of a Party in accordance with this Article shall be provided within 60 days, which may be extended with prior justification by the reporting Party. When an issue has been previously addressed between the Parties in any fora, a Party may request directly a discussion, in person or via video or teleconference, within 60 days of the date of the request. In such cases the responding Party shall make every effort to be available for such discussion. In case the Parties have not had a discussion under this Article in the previous 12-months period, the request may not be refused by the other Party. If the requesting Party believes that the matter is urgent, it may request that any meeting take place within a shorter time frame. In such cases, the responding Party shall give positive consideration to such a request. The Parties shall make every attempt to arrive at a mutually satisfactory resolution of the matter.

3. For greater certainty, with regard to technical regulations or conformity assessment procedures of national, regional or local governments, as the case may be, on the level directly below that of the central government that may have a significant effect on trade, a Party may request technical discussions with the other Party regarding those concerns in accordance with paragraph (2).
4. Following the technical discussion, the Parties may conclude that the issue could be better addressed through a Trade facilitating initiative, in accordance with article 4.
5. For greater certainty, this Article is without prejudice to a Party's rights and obligations under Chapter {XX (Dispute Settlement)}.

## Article 12

### **TBT Chapter coordinator**

1. Each Party shall nominate a TBT Chapter coordinator and inform the other Party if it changes. The TBT Chapter coordinators shall work jointly to facilitate the implementation of this Chapter and cooperation between the Parties in all TBT matters.
2. The functions of the Chapter Coordinators shall include:
  - a) monitoring the implementation and administration of this Chapter, addressing any issue that either Party raises related to any provision of this Chapter in a timely manner;
  - b) fostering cooperation in accordance with Article 10;
  - c) supporting trade facilitating initiatives and technical discussions as appropriate in accordance with Articles 4 and 12;
  - d) exchanging information on work undertaken in non-governmental, regional and multilateral fora related to standards, technical regulations and conformity assessment procedures;
  - e) reporting any relevant development related to the implementation of this Chapter to the {Sub-Committee on Trade in Goods} whenever appropriate.
3. The Chapter Coordinators shall communicate with one another by any agreed method that is appropriate to carry out their functions, which may include *inter alia*, email, teleconferences, video conferences and meetings.

## **ANNEX 1**

1. The Parties agreed the following fields:

- a) safety aspects of electrical and electronic equipment defined in paragraph (2)
- b) electromagnetic compatibility of equipment defined in paragraph (3)
- c) energy efficiency for EU products<sup>1</sup> covered by this Annex
- d) restriction of the use of certain hazardous substances in electrical and electronic equipment

### **Definitions**

2. For the purpose of this Annex 'safety aspects of electrical and electronic equipment' means the safety aspects of equipment which is dependent on electric currents in order to work properly and equipment for the generation, transfer and measurement of such currents and which is designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current, as well as equipment which intentionally emits or receives electromagnetic waves of frequencies lower than 3000 GHz with the purpose of radio communication or radiodetermination, with the exception of:

- a) equipment for use in an explosive atmosphere;
- b) equipment for use for radiology or medical purposes;
- c) electrical parts for goods and passenger lifts;
- d) radio equipment used by radio amateurs;
- e) electricity meters;
- f) plugs and socket outlets for domestic use;
- g) electric fence controllers;
- h) toys;
- i) specialised maritime, railway, aviation as well vehicle equipment;
- j) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes;
- k) construction products for permanent incorporation in buildings or civil engineering works and the performance of which has an effect on the performance of the building or civil engineering works, such as cables, fire alarms, electric doors; and

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<sup>1</sup> EU products means products imported from the EU into the territory of a Mercosur Party, excluding trans-shipments.

l) machinery (i.e. an assembly consisting of at least one moving part, powered by a drive system using one or more sources of energy such as thermal, electric, pneumatic, hydraulic or mechanical energy, arranged and controlled so that they function as an integral whole) other than ordinary office equipment, audio and video equipment, household appliances, information technology equipment, electric motors, as well as low-voltage switchgear and control gear.

3. For the purpose of this Annex 'electromagnetic compatibility of equipment' means the electromagnetic compatibility (disturbance and immunity) of equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents, with the exception of:

- a) equipment for use in an explosive atmosphere;
- b) equipment for use for radiology or medical purposes;
- c) electrical parts for goods and passenger lifts;
- d) radio equipment used by radio amateurs;
- e) specialised maritime, railway, aviation as well vehicle equipment
- f) measuring instruments;
- g) non-automatic weighing instruments;
- h) inherently benign equipment;
- i) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

4. For the purpose of this Annex “energy efficiency” means the ratio of output of performance, service, goods or energy to input of energy of a product with an impact on energy consumption during use.

5. For the sake of clarity, this Annex shall not cover whole aircrafts, vessels, railways, motor vehicles and their specialized equipment or parts thereof.