

CHAPTER 5

TECHNICAL BARRIERS TO TRADE

ARTICLE 5.1

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 (hereinafter referred to as "TBT") and to enhance cooperation between the Parties in matters covered by this Chapter.

ARTICLE 5.2

Relation to the 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 are to be read, as appropriate, as references to the Interim Agreement on Trade between the European Union, of the one part, and the Common Market of the South, the Argentine Republic, the Federative Republic of Brazil, the Republic of Paraguay and the Oriental Republic of Uruguay, of the other part.
3. The term "Members" in the TBT Agreement means the Parties to this Agreement.

ARTICLE 5.3

Scope

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. This Chapter does not apply to:
 - (a) purchasing specifications prepared by governmental bodies for production or consumption requirements of governmental bodies; and
 - (b) sanitary and phytosanitary measures as defined in Annex A to the SPS Agreement.

ARTICLE 5.4

Definitions

For the purposes of this Chapter, the following definitions apply:

- (a) the definitions set out in Annex 1 to the TBT Agreement;
- (b) "supplier's declaration of conformity" means a 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;

- (c) "ISO" means the International Organization for Standardization;
- (d) "IEC" means the International Electrotechnical Commission;
- (e) "ITU" means the International Telecommunication Union;
- (f) "Codex Alimentarius" means the Codex Alimentarius Commission (hereinafter referred to as "Codex Alimentarius");
- (g) "ILAC" means the International Laboratory Accreditation Cooperation;
- (h) "IAF" means the International Accreditation Forum; and
- (i) "IECEE CB Scheme" means the Scheme of the IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components for Mutual Recognition of Test Certificates for Electrical Equipment.

ARTICLE 5.5

Joint cooperation on trade-facilitating initiatives

1. The Parties recognise the importance of intensifying their cooperation with a view to increasing mutual understanding of their respective systems and helping to eliminate or avoid the creation of TBT. 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 matters covered by this Chapter. Those proposals shall be transmitted to the TBT Chapter coordinator, nominated pursuant to Article 5.13, and may include:

- (a) information exchange on regulatory approaches and practices;
- (b) joint analysis of a sector or 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) the consideration of mutual or unilateral recognition of conformity assessment results.

3. Whenever one of the Parties proposes a specific trade-facilitating initiative, the other Party shall duly consider such proposal and reply within a reasonable period of time. If the other Party rejects the proposed initiative, it shall explain the reasons for its decision to the proposing Party.

4. The terms of the work envisaged in this Article shall be defined by, of the one hand, the European Union and, of the other hand, MERCOSUR or the Signatory MERCOSUR States engaged in each trade-facilitating activity, if needed, and may include establishing ad hoc working groups. In order to benefit from non-governmental perspectives on matters related to this Article, each Party may, as appropriate and in accordance with its rules and procedures, consult with stakeholders and other interested parties.

5. The Subcommittee on trade in goods, established pursuant to Article 22.3(4), shall discuss the results of the work carried out pursuant to this Article and may consider appropriate actions.
6. Nothing in this Article shall be construed as obliging 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.
7. If initiatives referred to in this Article are agreed and if that is necessary for their implementation, each Party shall facilitate the interaction of technical teams to demonstrate their conformity assessment schemes and systems in order to increase mutual understanding.
8. For the purposes of this Article, the European Union shall act through the European Commission.

ARTICLE 5.6

Technical regulations

1. Each Party shall 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.

2. In particular, the Parties shall:
- (a) use relevant international standards as a basis for their technical regulations, including any conformity assessment elements therein, except if such international standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued; if international standards are not 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 are considered inappropriate or ineffective for the fulfilment of the legitimate objective pursued;
 - (b) when reviewing their respective technical regulations, in addition to Article 2.3 of the TBT Agreement and without prejudice to Articles 2.4 and 12.4 of the TBT Agreement, increase the alignment of those regulations with relevant international standards; a Party shall consider among others any new development in the relevant international standards and whether the circumstances that have given rise to any divergence from any relevant international standards continue to exist;
 - (c) promote the development of regional technical regulations and encourage that these are adopted at national level and replace existing ones, in order to facilitate trade between the Parties;
 - (d) allow a reasonable interval between the publication of technical regulations and their entry into force for economic operators of the other Party to adapt¹;

¹ "Reasonable interval" shall be understood to mean normally a period of not less than 6 (six) months, except when this would be ineffective in fulfilling the legitimate objectives pursued.

- (e) carry out the impact analysis of planned technical regulations in accordance with their respective rules and procedures; and
- (f) when preparing technical regulations, take due account of the characteristics and special needs of micro, small and medium-sized enterprises.

ARTICLE 5.7

Standards

1. The Parties reaffirm their obligations under Article 4.1 of the TBT Agreement, particularly in respect of taking all reasonable measures to ensure that all standardising bodies within their territories accept and comply with the Code of Good Practice for the Preparation Adoption and Application of Standards in Annex 3 to the TBT Agreement.
2. International standards developed by ISO, IEC, ITU or the Codex Alimentarius shall be considered as the relevant international standards within the meaning of Articles 2 and 5 and Annex 3 to the TBT Agreement.

3. A standard developed by other international organisations may also be considered a relevant international standard within the meaning of Articles 2 and 5 and Annex 3 to the TBT Agreement, if:

- (a) it has been developed by a standardising body which seeks to establish consensus either:
 - (i) among national delegations of the participating WTO Members representing all the national standardising bodies in their territory that have adopted, or expect to adopt, standards for the subject matter to which the international standardisation activity relates; or
 - (ii) among governmental bodies of participating WTO Members; and
- (b) it has been developed in accordance with the WTO TBT Committee Decision on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2 and 5 and Annex 3 to the TBT Agreement.

4. With a view to harmonising standards on a basis as wide as possible each Party shall encourage, within the limits of its competence and resources, the standardising bodies within its territory, as well as the regional standardising bodies of which that Party or the standardising bodies within its territory are members, to:

- (a) participate, within the limits of their resources, in the preparation of international standards by relevant international standardising bodies;
- (b) cooperate with the relevant national and regional standardising bodies of the other Party in international standardisation 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 standardising bodies;
- (e) promote the development of standards at regional level and the adoption of such standards by national standardising bodies, thereby replacing existing national standards;
- (f) 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) foster bilateral cooperation with the standardising bodies of the other Party.

5. The Parties should exchange information through the TBT Chapter coordinators, nominated pursuant to Article 5.13, on:

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

ARTICLE 5.8

Conformity assessment procedures and accreditation

1. The provisions set out in Article 5.6 with respect to the preparation, adoption and application of technical regulations 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 ILAC and IAF;

- (c) consider to join or, as applicable, encourage its testing, inspection and certification bodies to join any functioning international agreements or arrangements for harmonisation or facilitation of acceptance of conformity assessment results;
 - (d) within its territory, promote competition between conformity assessment bodies designated by the authorities for a particular product or set of products with a view to enabling 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 judgment;
 - (f) ensure that there are no conflicts of interest between accreditation bodies and conformity assessment bodies, or between activities of market surveillance authorities and activities of conformity assessment bodies;
 - (g) allow, to the extent possible, conformity assessment bodies to use subcontractors to perform testing or inspections in relation to the conformity assessment, including subcontractors located in the territory of the other Party; and
 - (h) publish online 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 point (g) of paragraph 3 shall be construed as prohibiting a Party from requiring subcontractors to meet the 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.

5. 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 that Party. In such cases, that Party shall:

- (a) establish the conformity assessment fees in accordance with the approximate cost of the services rendered and, upon request of an applicant for conformity assessment, provide the different elements included in those fees; and
- (b) in principle, make the conformity assessment fees publicly available or, publicly available or, when such information is not publicly available, provide it upon request.

6. Notwithstanding paragraphs 3 to 5 of this Article, in the fields which are listed in Annex 5-A, in which the European Union accepts supplier's declaration of conformity as assurance that a product conforms to a technical regulation, and in which a Signatory MERCOSUR State requires mandatory third-party testing or certification for these fields, the Signatory MERCOSUR State shall, as an assurance that a product conforms with the requirements of a Signatory MERCOSUR State's technical regulations, accept certificates or, in cases where such acceptance is not provided for under its relevant laws and regulations, accept test reports issued by conformity assessment bodies that are located in the territory of the European Union and which have been accredited for the relevant scopes by an accreditation body member of the international arrangements for mutual recognition of the ILAC and the IAF; or accept certificates that have been issued under the IECEE CB Scheme. In order to accept such certificates or test reports, a Signatory MERCOSUR State 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 European Union and the conformity assessment body located in the territory of the Signatory MERCOSUR State.

7. If supplier's declarations of conformity are considered a valid conformity assessment procedure in the European Union, test reports issued by conformity assessment bodies that are located in the territory of the Signatory MERCOSUR State, shall be accepted as a valid document in the process of demonstrating that a product conforms with the European Union's technical regulation requirements. The manufacturer shall remain responsible in all cases for the conformity of the product.
8. Paragraph 6 also applies where a Signatory MERCOSUR State introduces new mandatory third-party testing or certification requirements for the fields specified in Annex 5-A, in accordance with paragraph 10 of this Article. If the European Union introduces mandatory third-party testing or certification requirements for the fields specified in Annex 5-A, in accordance with paragraph 10 of this Article, the Parties shall discuss in the Subcommittee on trade in goods, referred to in Article 5.14, whether 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 Signatory MERCOSUR State.
9. The Trade Council may adopt a decision to amend Section A of Annex 5-A.
10. Notwithstanding paragraph 6 of this Article, either Party may introduce requirements for mandatory third-party testing or certification for the fields specified in Annex 5-A, for products falling within the scope of that Annex under the following conditions:
- (a) the introduction of such requirements or procedures are justified under the legitimate objectives referred to in 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 date of entry into force of this Agreement.

11. Paragraph 6 is without prejudice to the exercise, on a non-discriminatory basis, of market surveillance competences by the authorities of a Party, including additional testing on samples at the point of entry.

ARTICLE 5.9

Transparency

1. With regard to the preparation, adoption and application of standards, technical regulations and conformity assessment procedures, each Party shall:
 - (a) take the other Party's views into account if the process of developing a technical regulation is open to public consultation, wholly or partially;
 - (b) when developing major technical regulations and conformity assessment procedures which may have a significant effect on trade ensure in accordance with its respective laws and regulations that transparency procedures are in place that allow persons of the Parties to provide input through a formal public consultation process, except when urgent problems of safety, health, environmental protection or national security arise or threaten to arise;

- (c) allow persons of the other Party to participate in the consultation process referred to in point (b) on terms no less favourable than those accorded to its own persons and, whenever possible, make the results of that consultation process public;
- (d) allow, in principle, a period of at least 60 (sixty) days for the other Party to provide written comments on the proposed technical regulations and conformity assessment procedures, and consider a reasonable request to extend the comment period;
- (e) provide, in cases where 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;
- (f) if it receives written comments on its proposed technical regulation or conformity assessment procedure from the other Party:
 - (i) discuss, upon request by the other Party, the written comments, whenever possible with the participation of its competent regulatory authority and at a time when they can be taken into account; and
 - (ii) reply in writing to the comments, whenever possible no later than the date of publication of the technical regulation or conformity assessment procedure;
- (g) 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;
- (h) 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;

- (i) consider a reasonable request from the other Party, received prior to the end of the comment time period following the transmission of a proposed technical regulation, to extend the time period between the adoption of the technical regulation and its entry into force, except when the delay would be ineffective in fulfilling the legitimate objectives pursued; and
 - (j) provide free of charge access to the electronic version of the notified text with the notification.
2. For the purposes of point (d) of paragraph 1, 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 shall apply.
3. 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 Article 2 or 5 of the TBT Agreement shall be fulfilled.
4. Each Party 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. Each Party shall always provide unrestricted access to all information relevant to the achievement of conformity with a technical regulation. If standards provide a presumption of conformity with technical regulations and these standards are not referred to in those technical regulations, each Party shall ensure access to the information on corresponding standards.
5. Each Party shall, upon a 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 5.10

Marking and labelling

1. The Parties' technical regulations including or dealing exclusively with mandatory marking or labelling shall observe the principles of Article 2 of the TBT Agreement.
2. In particular, if a Party requires mandatory marking or labelling of products:
 - (a) it 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) and if a Party requires any prior approval, registration or certification of the labels or 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) and if a Party requires the use of a unique identification number, the Party shall issue such number to the economic operators of the other Party without undue delay and on a non-discriminatory basis;
 - (d) and provided that it is not misleading, contradictory or confusing in relation to the importing Party'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 Party of the products; and

- (ii) nomenclatures, pictograms, symbols or graphics adopted in international standards;
 - (e) it shall accept, whenever possible, 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) if 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, it shall 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. 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 5.5.

ARTICLE 5.11

Cooperation and technical assistance

1. To contribute to the fulfilment of the objectives of this Chapter, each Party shall, inter alia:
- (a) promote cooperation and joint activities and projects between their respective organisations, public or private, national or regional, in the fields of technical regulations, standardisation, 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, standardisation, conformity assessment and accreditation bodies, supporting the development of their technical infrastructure, including laboratories and testing equipment, and sustaining the continuous training of human resources;
 - (e) promote, facilitate and, whenever possible, coordinate their participation in international organisations and other fora related to technical regulations, conformity assessment, standards, accreditation and metrology;
 - (f) support technical assistance activities by national, regional and international organisations in the areas of technical regulations, standardisation, conformity assessment, metrology and accreditation; and
 - (g) endeavour to share available scientific evidence 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 5.12

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. The requesting Party shall deliver its request to the TBT Chapter coordinator of the other Party nominated pursuant to Article 5.13 and 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 requested in accordance with paragraph 1 shall be provided no later than 60 (sixty) days after the date of the request of a Party in accordance with paragraph 1. The deadline may be extended with prior justification by the requested Party.

3. If an issue has been previously addressed between the Parties in any forum, a Party may request directly a discussion, in person or via video or teleconference, no later than 60 (sixty) days after the date of such request. In such cases, the requested Party shall make every effort to be available for such discussion.

4. If the Parties have not had a discussion under this Article in the previous 12-month 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 a meeting take place within a shorter timeframe. 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.
5. For greater certainty, a Party may request technical discussions with the other Party pursuant to paragraph 2 also 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.
6. Following the technical discussion, the Parties may conclude that the issue could be better addressed through a trade-facilitating initiative, in accordance with Article 5.5.
7. This Article is without prejudice to a Party's rights and obligations under Chapter 21.

ARTICLE 5.13

TBT Chapter coordinator

1. Each Party shall nominate a TBT Chapter coordinator and notify the other Party in the event of any 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 TBT Chapter coordinators include:
 - (a) supporting the Subcommittee on trade in goods, referred to in Article 5.14, in the exercise of the functions;
 - (b) supporting trade-facilitating initiatives and technical discussions, as appropriate, in accordance with Articles 5.5 and 5.12 respectively;
 - (c) exchanging information on work undertaken in non-governmental, regional and multilateral fora related to standards, technical regulations and conformity assessment procedures; and
 - (d) reporting any relevant development related to the implementation of this Chapter to the Subcommittee on trade in goods, referred to in Article 5.14, whenever appropriate.
3. The TBT Chapter coordinators shall communicate with one another by any agreed method that is appropriate to carry out their functions, which may include email, teleconferences, video conferences and meetings.

ARTICLE 5.14

Subcommittee on trade in goods

The Subcommittee on trade in goods, established pursuant to Article 22.3(4), shall have the following functions, in addition to those listed in Article 22.3, and Article 2.14:

- (a) discuss the results of the work carried out pursuant to Article 5.5 and consider appropriate actions;

- (b) provide a forum for the Parties to discuss the need to take steps to ensure reciprocity in accordance with Article 5.8(8);
- (c) foster cooperation in accordance with Article 5.11 and support technical discussions, as appropriate, in accordance with Article 5.12;
- (d) endeavour to discuss at least annually the issues covered under paragraph 2 of Section C of Annex 5-B; and
- (e) provide a forum for the Parties to cooperate and exchange information on any issues relevant for the implementation of Annex 5-B.

CHAPTER 6

SANITARY AND PHYTOSANITARY MEASURES

ARTICLE 6.1

Objectives

The objectives of this Chapter are to:

- (a) protect human, animal or plant life or health in the territory of the Parties while facilitating trade between the Parties in so far as sanitary and phytosanitary (hereinafter referred to as "SPS") measures are concerned;