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CHAPTER [...] **TECHNICAL BARRIERS TO TRADE**

Article 1 **OBJECTIVES**

The objectives of this Chapter are to facilitate and increase trade in goods between the Parties by ensuring that technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to trade, by enhancing joint cooperation between the Parties, including on the implementation of the Agreement on Technical Barriers to Trade in Annex 1A to the WTO Agreement (hereinafter referred to as “TBT Agreement”), and by pursuing appropriate ways to reduce unnecessary negative effects on trade of measures within the scope of this Chapter.

Article 2 **Scope**

1. This Chapter shall apply to the preparation, adoption and application of technical regulations, standards and conformity assessment procedures of central government bodies as defined in the TBT Agreement, that may affect the trade in goods between the Parties.
2. Each Party shall take such reasonable measures as may be available to it to encourage the observance by local government bodies on the level directly below that of a central government within its territory which are responsible for the preparation, adoption and application of technical regulations and conformity assessment procedures of the provisions of Article 5 (Technical regulations), Article 6 (International Standards), Article 7 (Standards), Article 8 (Conformity Assessment Procedures), Article 9 (Transparency), Article 10 (Market Surveillance) and Article 11 (Marking and Labelling).
3. This Chapter shall not apply to:
 - (a) purchasing specifications prepared by governmental bodies for production or consumption requirements of such bodies; or
 - (b) sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures in Annex 1A to the WTO Agreement.

Article 3 **Reaffirmation and Incorporation of the TBT Agreement**

1. The Parties reaffirm their rights and obligations under the TBT Agreement and the following provisions of the TBT Agreement are incorporated into and made part of this Agreement, mutatis mutandis:

- (a) Article 2 (Preparation, Adoption and Application of Technical Regulations by Central Government Bodies);
- (b) Article 3 (Preparation, Adoption and Application of Technical Regulations by Local Government Bodies and Non-Governmental Bodies);
- (c) Article 4 (Preparation, Adoption and Application of Standards);
- (d) Article 5 (Procedures for Assessment of Conformity by Central Government Bodies);
- (e) Article 6 (Recognition of Conformity Assessment by Central Government Bodies);
- (f) Article 7 (Procedures for Assessment of Conformity by Local Government Bodies);
- (g) Article 8 (Procedures for Assessment of Conformity by Non-Governmental Bodies);
- (h) Article 9 (International and Regional Systems);
- (i) Annex 1 (Terms and their Definitions for the Purpose of this Agreement); and
- (j) Annex 3 (Code of Good Practice for the Preparation, Adoption and Application of Standards).

2. Where a dispute arises regarding a particular measure which a Party alleges exclusively in breach of the provisions referred to in paragraph 1 (a) to (j), it shall select, in derogation of paragraph 1 of Article 27 of Chapter XX (Dispute Settlement), the dispute settlement mechanism under the WTO Agreement.

Article 4 Definitions

For the purposes of this Chapter, the terms and definitions set out in Annex 1 of the TBT Agreement shall apply.

Article 5 Technical Regulations

1. The Parties recognise the importance of good regulatory practice with regard to the preparation, adoption and application of technical regulations, in particular the work carried out by the WTO TBT Committee on good regulatory practice. In this context, the Parties undertake to:

- (a) when developing a technical regulation:
 - (i) assess in accordance with their respective laws and regulations or administrative guidelines the available regulatory or non-regulatory alternatives to the proposed technical regulation that may fulfil the Party's legitimate objective, in order to ensure that the proposed technical regulation is

not more trade-restrictive than necessary to fulfil a legitimate objective, in accordance with Article 2.2 of the TBT Agreement.

Nothing in this provision shall affect the rights of each Party to prepare, adopt and apply measures without delay where urgent problems including safety, health, environmental protection or national security arise or threaten to arise.

- (ii) endeavour to systematically carry out impact assessments for technical regulations with significant effect on trade, including an assessment of their impact on trade;
 - (iii) wherever appropriate, specify technical regulations based on product performance requirements, rather than design or descriptive characteristics.
- (b) without prejudice to Article 2.3 of the TBT Agreement, review adopted technical regulations at appropriate intervals, preferably not exceeding five years, in particular with a view to increasing their convergence with relevant international standards. In undertaking this review, the Parties shall, *inter alia*, take into account any new development in the relevant international standards and whether the circumstances that have given rise to divergences from any relevant international standard continue to exist. The outcome of these reviews shall be communicated and explained to the other Party upon request.

2. When a Party considers that its technical regulation and a technical regulation of the other Party that have the same objectives and product scope are equivalent, the Party may request in writing, with the detailed reasons, that the other Party recognises them as equivalent. The other Party shall give positive consideration to accepting these technical regulations as equivalent, even if they differ, provided that it is satisfied that the technical regulation of the requesting Party adequately fulfils the objectives of its own technical regulation. Where a Party does not accept a technical regulation of the other Party as equivalent to its own, it shall, upon request of the other Party, explain its decision.

3. At the request of a Party that has an interest in developing a technical regulation similar to a technical regulation of the other Party, such other Party shall provide, to the extent practicable, relevant information, including studies or documents, except for confidential information, on which it has relied in its development.

4. Each Party shall uniformly and consistently apply requirements related to the placing on the market of products which are established through technical regulations for its whole territory. If a Party has substantiated reasons that

- (1) any of these requirements are not applied uniformly and consistently, and
- (2) this situation leads to significant impact on bilateral trade,

this Party may notify, in writing, the substantiated reasons to the other Party with a view to clarifying, and if appropriate, addressing the issue in a timely manner by the Contact Points or other appropriate bodies established under this Agreement.

Article 6

International Standards

1. For the purpose of applying this Chapter and the TBT Agreement, standards issued by international organizations such as the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC), the International Telecommunication Union (ITU), the *Codex Alimentarius* Commission, the International Civil Aviation Organisation (ICAO), the World Forum for Harmonisation of Vehicle Regulations (WP.29) within the framework of the United Nations Economic Commission for Europe (UNECE), the United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UN/SCEGHS), and International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) shall be considered as relevant international standards within the meaning of Article 2, Article 5 and Annex 3 of the TBT Agreement, provided that in their development the principles and procedures set out in the Decision of the WTO Committee on Technical Barriers to Trade on Principles for the Development of International Standards, Guides and Recommendations With Relation to Article 2, Article 5 and Annex 3 of the Agreement (G/TBT/9, 13 November 2000, Annex 4) have been followed, except when such standards or relevant parts of them would be ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.

2. With a view to harmonizing standards on as wide a basis as possible, the Parties shall encourage national or regional standardizing bodies within their Area:

- (a) to play a full part, within the limits of their resources, in the preparation by relevant international standardizing bodies of international standards;
- (b) to 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;
- (c) to avoid duplication of, or overlap with, the work of international standardizing bodies;
- (d) to review their standards not based on relevant international standards at appropriate intervals, preferably not exceeding five years, with a view to increasing their convergence with relevant international standards.

3. When developing technical regulations or conformity assessment procedures,

- (i) each Party shall use relevant international standards, guides or recommendations, or the relevant parts of them, to the extent provided in paragraph 4 of Article 2 and paragraph 4 of Article 5 of the TBT Agreement, as a basis for its technical regulations and conformity assessment procedures and avoid deviations from, or additional requirements as compared to the relevant international standards, except when the Party developing the technical regulation or conformity assessment procedure can demonstrate, based on relevant information, including available scientific or technical evidence, that such international standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, as

referred to in paragraph 2 of Article 2 and paragraph 4 of Article 5 of the TBT Agreement;

- (ii) where a Party does not use such international standards, guides or recommendations, or the relevant parts of them, referred to in paragraph 1, as a basis for its technical regulations or conformity assessment procedures, it shall, upon request of the other Party explain the reasons why such international standards have been deemed inappropriate or ineffective for the fulfilment of the legitimate objectives pursued, as referred to in paragraph 2 of Article 2 and paragraph 4 of Article 5 of the TBT Agreement, and provide the relevant information, including available scientific or technical evidence on which this assessment is based, and identify the parts of the respective technical regulation or conformity assessment procedure which substantially deviate from the relevant international standards, guides or recommendations.

4. Each Party shall encourage its national or regional standardizing bodies within their territories to cooperate with the relevant standardising bodies of the other Party in international standardising activities. Such cooperation may take place in international standardising bodies of which both Parties or standardising bodies of both Parties are members.

Such bilateral cooperation could be aimed, *inter alia*, at promoting the development of international standards; facilitating the development of common standards in areas of shared interest where there are no international standards, in particular as regards new products or technologies; further enhancing the exchange of information between the Parties' standardising bodies.

Article 7 Standards

1. The Parties reconfirm their obligations under Article 4.1 of the TBT Agreement to ensure that national or regional 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. The Parties recall that, pursuant to the definition of a standard in Annex 1 of the TBT Agreement, compliance with standards is not mandatory. Where a standard is required to comply with, through incorporating or referencing it, in a technical regulation or conformity assessment procedure, the Party in question shall comply with the transparency obligations set out in Article 2.9 or 5.6 of the TBT Agreement, and in Article 9 of this Chapter in developing the draft technical regulation or conformity assessment procedure.

3. Each Party shall encourage, subject to its laws and regulations, its national or regional standardizing bodies to ensure adequate participation of interested persons¹ within the Area of that Party in the standard development process and to allow persons of the other Party to participate in consultation procedures, which are available to the general public, on terms no less favourable than those accorded to its own persons.

¹ (legal scrubbing) "interested persons" as defined in Transparency Chapter.

4. The Parties undertake to exchange information on:

- (a) their use of standards in support of demonstrating or facilitating compliance with technical regulations;
- (b) their standard-setting processes, in particular the manner and extent to which international or regional standards are used as a basis for their regional or national standards; and
- (c) co-operation agreements or arrangements on standardization with third parties or international organizations.

Article 8 **Conformity Assessment Procedures**

1. The provisions set out in paragraphs 1(a)(i) and 1(a)(ii) and 1(b) of the Article (Technical Regulation) with respect to the preparation, adoption and application of technical regulations shall also apply, *mutatis mutandis*, to conformity assessment procedures.

2. Further to paragraph 1.2 of Article 5 of the TBT Agreement, each Party shall ensure that conformity assessment procedures are not more strict or are not applied more strictly than is necessary to give the importing Party adequate confidence that products conform with the applicable technical regulations or standards, and take into account the risks associated with products, including the risks non-conformity would create.

3. The Parties recognise that a broad range of mechanisms exist to facilitate the acceptance of the results of conformity assessment procedures. Such mechanisms may include:

(a) mutual recognition agreements for the results of conformity assessment procedures with respect to specific technical regulations conducted by bodies located in the other Party;

(b) co-operative and voluntary arrangements between conformity assessment bodies located in the Parties;

(c) plurilateral and multilateral recognition agreements or arrangements to which the Parties are participants;

(d) use of accreditation to qualify conformity assessment bodies;

(e) government designation of conformity assessment bodies, including bodies located in the other Party;

(f) recognition by a Party of results of conformity assessment procedures conducted in the other Party; and

(g) manufacture's or supplier's declaration of conformity.

4. The Parties shall exchange information on the range of such mechanisms. A Party shall, upon request of the other Party, provide information:

- (a) on these and similar mechanisms with a view to facilitating the acceptance of conformity assessment results;
- (b) on factors, including assessment and management of risk, considered when selecting appropriate conformity assessment procedures for specific products;
- (c) on accreditation policy including on international standards for accreditation, and international agreements and arrangements in the field of accreditation, including those of the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF) to the extent possible and used by a Party in a specific area.

5. Having regard to those mechanisms, each Party shall:

- (a) use whenever possible in accordance with its laws and regulations a supplier's declaration of conformity as assurance of conformity with applicable technical regulations;
- (b) use accreditation with authority derived from government or performed by government, as appropriate as a means to demonstrate the technical competence to qualify conformity assessment bodies;
- (c) when accreditation is established by law as a necessary separate step to qualify conformity assessment bodies, ensure the independence of accreditation activities from conformity assessment activities, and the absence of conflicts of interest between accreditation bodies and the conformity assessment bodies they accredit. The Parties may comply with this obligation by means of separation of conformity assessment bodies from accreditation bodies.

This subparagraph shall not apply to the conformity assessment activities performed by a Party itself when a Party retains the final decision making authority on the conformity of a product;

- (d) consider joining, or, as applicable, not prohibit testing, inspection and certification bodies from joining, international agreements or arrangements for the facilitation of acceptance of conformity assessment results;
- (e) not prohibit economic operators from choosing among conformity assessment bodies, insofar as two or more conformity assessment bodies are authorised by a Party to carry out conformity assessment procedures required for placing a product on the market.

6. The Parties shall cooperate in the field of mutual recognition in accordance with the Agreement on Mutual Recognition between Japan and the European Community, signed at Brussels on 4 April 2001. The Parties may also decide to extend its coverage with respect to product scopes, applicable regulatory requirements and recognized conformity assessment bodies in accordance with its relevant provisions.

Article 9 Transparency

1. When developing a technical regulation or conformity assessment procedure which may have a significant effect on trade, the Parties agree:

- (a) to carry out consultation procedures, subject to their laws and regulations, which are available to the general public and make the results of such consultations and any existing impact assessments publicly available;
- (b) to allow persons of the other Party to participate in such consultation procedures which are available to the general public on terms no less favourable than those accorded to its own persons.
- (c) to take the other Party's views into account when carrying out such consultation procedures which are available to the general public, and upon request provide written responses in a timely manner to the comments made by the other Party ;
- (d) further to Article 5(a)(ii), to make publicly available the results of the impact assessment, if carried out, including of the impact on trade, on a proposed technical regulation or conformity assessment procedure;
- (e) to endeavour to provide, upon request, a summary of the impact assessment referred to in subparagraph (d) in English.

2. The Parties agree when making notifications in accordance with Article 2.9.2 or 5.6.2 of the TBT Agreement, to:

- (a) allow in principle at least 60 days following the notification for the other Party to provide comments in writing to the proposal, except where urgent problems of safety, health, environmental protection or national security arise or threaten to arise; where practicable, to give appropriate consideration to reasonable requests for extending the comment period;
- (b) provide the electronic version of the full notified text together with the notification;
- (c) provide, in case the notified text is not in one of the official WTO languages, a detailed and comprehensive description of the content of the measure in the notification format, as well as, if already available, a translation of the notified text in one of the official WTO languages;
- (d) reply in writing to written comments received from the other Party on the proposal, no later than the date of publication of the final technical regulation or conformity assessment procedure;

- (e) provide information on the adopted final text through an addendum to the original notification;
 - (f) 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.
 - (g) ensure that the WTO TBT Enquiry Point provides information and answers in one of the official WTO languages to reasonable enquiries from the other Party or from interested parties of the other Party on adopted technical regulations and conformity assessment procedures.
3. Each Party shall, on request of the other Party, provide information regarding the objectives of, and rationale for, a technical regulation or conformity assessment procedure that the Party has adopted or is proposing to adopt.
4. Each Party shall ensure that all adopted technical regulations and conformity assessment procedures are publicly and freely available on official websites and, if already available, in English.

ARTICLE 10 MARKET SURVEILLANCE

1. For the purpose of this Article, “market surveillance” is a public authority function separate from and carried out after conformity assessment and means activities conducted and measures taken by public authorities on the basis of procedures of a Party to enable the Party to monitor or address compliance of products with the Party’s requirements as set out in the relevant legislation.

2. The Parties undertake, *inter alia*, to:

- a) exchange information on market surveillance and enforcement activities (for instance, on the authorities responsible for market surveillance and enforcement, or on measures taken against dangerous products);
- b) ensure the independence of market surveillance functions from conformity assessment functions with a view to avoiding conflicts of interest. This shall not apply to authorisation functions by a Party itself relating to final decisions on the conformity of a product. The Parties may comply with this obligation by means of separation of market surveillance authorities from conformity assessment bodies.
- c) ensure that there are no conflicts of interest between market surveillance authorities and the persons concerned, including the manufacturer, the importer and the distributor, subject to control or supervision.

ARTICLE 11
MARKING AND LABELLING

1. The Parties note that a technical regulation may include or deal exclusively with marking or labelling requirements. Accordingly, if a Party develops marking or labelling requirements as a technical regulation, the Party shall ensure that such requirements are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade and are not more trade restrictive than necessary to fulfil legitimate objectives as referred to in paragraph 2 of Article 2 of the TBT Agreement.

2. In particular, the Parties agree that, where a Party requires marking or labelling of products as a technical regulation:

- (a) Information required for such marking or labelling of products shall be limited to what is relevant for persons concerned, including consumers, users of the product or authorities, to indicate the product's compliance with regulatory requirements;
- (b) unless necessary to fulfil a legitimate objective, the Parties shall not require any prior approval, registration or certification of the labels or markings of products as a precondition for placing on its market products that otherwise comply with its mandatory technical requirements;
- (c) where a Party requires the use of a unique identification number for marking or labelling, the Party shall issue such number to the persons concerned, including the manufacturer, the importer and the distributor without undue delay and on a non-discriminatory basis;
- (d) provided it is not misleading, contradictory or confusing or legitimate objectives are not compromised thereby, in relation to the information required in the country of destination of the goods, the Party shall permit the following:
 - i. information in other languages in addition to the language required in the country of destination of the goods;
 - ii. international nomenclatures, pictograms, symbols or graphics;
 - iii. additional information to that required in the country of destination of the goods;
- (e) the Party shall accept that labelling and corrections to labelling take place in customs warehouses at the point of import as an alternative to labelling in the exporting Party unless such labelling is required to be carried out by approved persons for reasons of public health or safety.
- (f) the Party shall, in cases where it considers that legitimate objectives under the TBT Agreement are not compromised thereby, endeavour to accept non-permanent or detachable labels, or marking or labelling in the accompanying documentation rather than physically attached to the product.

ARTICLE 12
JOINT CO-OPERATION

1. The Parties shall strengthen their co-operation in the field of standards, technical regulations and conformity assessment procedures with a view to increasing the mutual understanding of their respective systems and facilitating access to their respective markets. The Parties recognise that existing regulatory co-operation dialogues are important means to strengthen such co-operation.
2. The Parties shall seek to identify, develop and promote trade facilitating initiatives of mutual interest.
3. Such initiatives may include:
 - (a) improving the quality and effectiveness of their standards, technical regulations and conformity assessment procedures, and promoting good regulatory practices through regulatory cooperation, including the exchange of information, experiences and data;
 - (b) where appropriate, simplifying their technical regulations, standards and conformity assessment procedures;
 - (c) increasing the convergence of their standards, technical regulations and conformity assessment procedures with relevant international standards, guides or recommendations;
 - (d) ensuring efficient interaction and cooperation of regulatory authorities at national, regional or international level;
 - (e) promoting or enhancing cooperation between organizations in the Parties in charge of standardisation, accreditation, and conformity assessment;
 - (f) exchanging information, insofar as possible, about TBT-related agreements and arrangements subscribed to at international level.

Article 13

CONTACT POINTS AND SPECIALISED-COMMITTEE ON TECHNICAL BARRIERS TO TRADE

1. The Parties shall designate a Contact point in the Government of Japan and in the European Commission. The Parties shall provide each other with the name and the contact details of relevant officials in that organization, including information on telephone, facsimile, e-mail and other relevant detail.
2. The Parties shall notify each other promptly of any change of its Contact point and of the information of the relevant officials.
3. The Contact point's functions shall include:

- (a) exchanging information on technical regulations, standards and conformity assessment procedures of both Parties or any other matters pursuant to this Chapter;
- (b) providing any information or explanation requested by a Party pursuant to this Chapter, in print or electronically, within a reasonable period of time agreed between the Parties and, if possible, within 60 days;
- (c) promptly clarifying and addressing, where possible, any issue that a Party raises related to the development, adoption or application of technical regulations, standards and conformity assessment procedures under this Chapter and the TBT Agreement.

4. The Parties hereby establish a Specialised-Committee on Technical Barriers to Trade (hereinafter referred to in this Article as “the Specialised-Committee”).

5. The functions of the Specialised-Committee shall be to:

- (a) review the implementation and operation of this Chapter;
- (b) review the joint cooperation in the development and improvement of technical regulations, standards and conformity assessment procedures as laid out in Article 10 of this Chapter;
- (c) review this Chapter in light of any developments under the WTO Committee on Technical Barriers to Trade established under Article 13 of the TBT Agreement, and if necessary, developing recommendations for amendments to this Chapter;
- (d) take any steps the Parties may consider that will assist them in implementing this Chapter and the TBT Agreement and in facilitating trade between the Parties;
- (e) discuss any matter arising under this Chapter, upon a Party’s request;
- (f) promptly address any issue that a Party raises related to the development, adoption or application of technical regulations, standards and conformity assessment procedures of the other Party under this Chapter and the TBT Agreement;
- (g) establish, if necessary to achieve the objectives of this Chapter, *ad hoc* technical working groups to deal with specific issues or sectors with a view to identifying a solution;
- (h) exchange information on the work in regional and multilateral fora engaged in activities related to technical regulations, standards and conformity assessment procedures;
- (i) report to the Joint Committee, as it considers appropriate, on the implementation and operation of this Chapter;
- (j) carry out other functions as may be delegated by the Joint Committee.

6. The Specialised-Committee and any *ad hoc* technical working group established shall be coordinated by:

- (a) in the case of Japan, the Ministry of Foreign Affairs,

(b) in the case of the EU, the European Commission.

Each authority referred to above will be responsible for coordinating with the relevant institutions and persons in their respective territories/Areas as well as ensuring that such institutions and persons are convened as necessary.

7. The Specialised-Committee shall be composed of representatives of the Parties.

8. Upon request of a Party, the Specialised-Committee shall meet at such times and venues or by means to be agreed.