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**CHAPTER 8**

**TECHNICAL BARRIERS TO TRADE**

**Article 8.1: Definitions**

1. For the purposes of this Chapter:

The definitions of the terms used in this Chapter contained in Annex 1 of the TBT *Agreement*, including the chapeau and explanatory notes of Annex 1, are incorporated into this Chapter and shall form part of this Chapter *mutatis mutandis*.

**consular transactions** means requirements that products of a Party intended for export to the territory of another Party must first be submitted to the supervision of the consul of the importing Party in the territory of the exporting Party for the purpose of obtaining consular invoices or consular visas for conformity assessment documentation;

**marketing authorisation** means the process or processes by which a Party approves or registers a product in order to authorize its marketing, distribution or sale in the Party's territory. The process or processes may be described in a Party's domestic law or regulations in various ways, including "marketing authorisation", "authorisation", "approval", "registration", "sanitary authorisation", "sanitary registration" and "sanitary approval" for a product. Marketing authorisation does not include notification procedures;

**mutual recognition agreement** means a binding government to government agreement for recognition of the results of conformity assessment conducted against the appropriate technical regulations or standards in one or more sectors, including government to government agreements to implement the *APEC Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment* and the *Electrical and Electronic Equipment Mutual Recognition Arrangement* and other agreements that may be entitled "mutual recognition arrangements" but nonetheless provide for the recognition of conformity assessment conducted against appropriate technical regulations or standards in one or more sectors;

**mutual recognition arrangement** means an international or regional arrangement (including a multilateral recognition arrangement) between accreditation bodies recognising the equivalence of accreditation systems (based on peer review) or between conformity assessment bodies recognising the results of conformity assessment;

**post-market surveillance** means procedures taken by a Party after a product has been placed on its market to enable the Party to monitor or address compliance with the Party's domestic requirements for products;

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

**verify** means action to confirm the veracity of individual conformity assessment results, such as requesting information from the conformity assessment body or the body that accredited, approved, licensed or otherwise recognised the conformity assessment body, but does not include requirements that subject a product to conformity assessment in the territory of the importing Party that duplicate the conformity assessment procedures already conducted with respect to the product in the territory of the exporting Party or a third party, except on a random or infrequent basis for the purpose of surveillance, or in response to information indicating non-compliance.

**Article 8.2: Objective**

The objective of this Chapter, including its Annexes, is to facilitate trade, including by eliminating unnecessary technical barriers to trade, enhancing transparency, and promoting greater regulatory cooperation and good regulatory practice.

**Article 8.3: Scope**

1. This Chapter applies to the preparation, adoption and application of all technical regulations, standards and conformity assessment procedures of central government bodies (and, where explicitly provided for technical regulations, standards and conformity assessment procedures of governments on the level directly below that of the central government) that may affect trade in goods between the Parties, except as provided in paragraphs 3 and 4.

*Ibis.* Each Party shall take such reasonable measures, within its authority, to encourage observance by local government bodies on the level directly below that of the central government within its territory which are responsible for the preparation, adoption and application of technical regulations, standards and conformity assessment procedures with Articles 8.5 (International Standards, Guides and Recommendations), 8.6 (Conformity Assessment Procedures), 8.7 (Compliance Period for Technical Regulations and Conformity Assessment Procedures), and each of the Annexes to this Chapter.

2. All references in this Chapter to technical regulations, standards and conformity assessment procedures shall be construed to include any amendments thereto and any addition to the rules or the product coverage thereof, except amendments and additions of an insignificant nature.

3. This Chapter does not apply to technical specifications prepared by governmental entities for production or consumption requirements of such entities but such specifications are covered by Chapter 15 (Government Procurement).

4. This Chapter does not apply to sanitary and phytosanitary measures but such measures are covered by Chapter 7 (Sanitary and Phytosanitary Measures).

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5. For greater certainty, nothing in this Chapter shall prevent a Party from adopting or maintaining technical regulations or standards, in accordance with its rights and obligations under this Agreement, the TBT Agreement and any other relevant international obligations.

**Article 8.4: Incorporation of Certain Provisions of the TBT Agreement**

1. The following provisions of the TBT Agreement are hereby incorporated into and made part of this Agreement, *mutatis mutandis*:

- (a) Articles 2.1, 2.2, 2.4, 2.5, 2.9, 2.10, 2.11, 2.12;
- (b) Articles 5.1, 5.2, 5.3, 5.4, 5.6, 5.7, 5.8, 5.9; and
- (c) Paragraphs D, E and F of Annex 3.

2. No Party shall have recourse to dispute settlement under Chapter 28 (Dispute Settlement) for a dispute that exclusively alleges violation of the provisions of the TBT Agreement incorporated into paragraph 1 of this Article.

**Article 8.5: International Standards, Guides and Recommendations**

1. The Parties acknowledge the important role that international standards, guides and recommendations can play in supporting greater regulatory alignment, good regulatory practice and reducing unnecessary barriers to trade.

2. In this respect, and further to Articles 2.4 and 5.4 and Annex 3 of the TBT Agreement, in determining whether an international standard, guide or recommendation within the meaning of Articles 2 and 5 and Annex 3 of the TBT Agreement exists, each Party shall apply the *Decision of the TBT Committee on Principles for the Development of International Standards, Guides and Recommendations With Relation to Articles 2, 5 and Annex 3 of the TBT Agreement (G/TBT/1/Rev.10)*, issued by the WTO Committee on Technical Barriers to Trade.

3. The Parties shall cooperate with each other, where feasible and appropriate, to ensure that international standards, guides and recommendations that are likely to become a basis for technical regulations and conformity assessment procedures do not create unnecessary obstacles to international trade.

**Article 8.6: Conformity Assessment**

1. Further to Article 6.4 of the TBT Agreement, each Party shall accord to conformity assessment bodies located in the territory of another Party treatment no less

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favourable than that it accords to conformity assessment bodies located in its own territory or in the territory of any other Party. In order to ensure that it accords such treatment, each Party shall apply to conformity assessment bodies located in the territory of another Party the same or equivalent procedures, criteria and other conditions that it may apply where it accredits, approves, licenses or otherwise recognises conformity assessment bodies in its own territory.

2. Paragraphs 1 and 4 shall not preclude a Party from undertaking solely within specified government bodies located in its own territory or in another Party's territory, conformity assessment in relation to specific products, subject to its obligations under the TBT Agreement.

3. Where a Party undertakes conformity assessment pursuant to paragraph 2, and further to Article 5.2 and Article 5.4 of the TBT Agreement concerning limitation on information requirements, the protection of legitimate commercial interests and the adequacy of review procedures, the Party shall, upon the request of another Party explain:

- (a) how the information required is necessary to assess conformity and determine fees;
- (b) how the Party ensures that the confidentiality of the information is respected in a manner that ensures legitimate commercial interests are protected; and
- (c) the procedure to review complaints concerning the operation of the conformity assessment procedure and to take corrective action when a complaint is justified.

4. Further to Article 6.4 of the TBT Agreement, where a Party maintains procedures, criteria and other conditions as set out in paragraph 1 and requires test results, certifications, and/or inspections as positive assurance that a product conforms to a standard or technical regulation, it:

- (a) shall not require the conformity assessment body testing or certifying the product, or the conformity assessment body conducting an inspection, to be located within its territory;
- (b) shall not impose requirements on conformity assessment bodies located outside its territory that would effectively require such conformity assessment bodies to operate an office in that Party's territory; and
- (c) shall permit conformity assessment bodies in other Parties' territories to apply to the Party for a determination that they comply with any procedures, criteria and other conditions the Party requires to deem them competent or otherwise approve them to test or certify the product or conduct an inspection.

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5. Paragraphs 1 and 4(c) shall not preclude a Party from using mutual recognition agreements to accredit, approve, license or otherwise recognise conformity assessment bodies located outside its territory, subject to its obligations under the TBT Agreement.

6. Nothing in paragraphs 1, 4 and 5 precludes a Party from verifying the results of conformity assessment procedures undertaken by conformity assessment bodies located outside its territory.

7. Further to paragraph 6, in order to enhance confidence in the continued reliability of conformity assessment results from each other's territories, the Parties may request information on matters pertaining to conformity assessment bodies located outside its territory.

8. Further to Article 9.1 of the TBT Agreement, a Party shall consider adopting provisions to approve conformity assessment bodies that hold accreditation for the technical regulations or standards of the importing Party with an accreditation body that is a signatory to an international or regional mutual recognition arrangement.<sup>1</sup> Parties recognise that such arrangements can address the key considerations in approving conformity assessment bodies, including technical competence, independence, and the avoidance of conflicts of interest.

9. Further to Article 9.2 of the TBT Agreement, a Party shall not refuse to accept, or take actions which have the effect of, directly or indirectly, requiring or encouraging the refusal of acceptance by other Parties or persons of conformity assessment results from a conformity assessment body because the accreditation body that accredited the conformity assessment body:

- (a) operates in the territory of a Party where there is more than one accreditation body;
- (b) is a non-governmental body;
- (c) is domiciled in the territory of a Party that does not maintain a procedure for recognising accreditation bodies<sup>2</sup>;
- (d) does not operate an office in the Party's territory; or
- (e) is a for-profit entity.

10. For greater clarity, nothing in paragraph 9 prohibits a Party from refusing to accept conformity assessment results from a conformity assessment body where it can

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<sup>1</sup> The Committee on Technical Barriers to Trade shall be responsible for developing and maintaining a list of such arrangements.

<sup>2</sup> Provided that the accreditation body is recognised internationally, consistent with the provisions in paragraph 8.

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substantiate such refusal, provided that such actions are not inconsistent with the *TBT Agreement* and this Chapter.

11. A Party shall publish, preferably by electronic means, any procedures, criteria and other conditions that it may use as the basis for determining whether conformity assessment bodies are competent to receive accreditation, approval, licensing, or other recognition including where such recognition is granted pursuant to mutual recognition agreements.

12. Where a Party accredits, approves, licenses or otherwise recognises bodies assessing conformity to a particular technical regulation or standard in its territory, and refuses to accredit, approve, license, or otherwise recognise a body assessing conformity with that technical regulation or standard in the territory of another Party, or declines to use a mutual recognition arrangement, it shall, on request of the other Party, explain the reasons for its refusal.

13. Where a Party does not accept the results of a conformity assessment procedure conducted in the territory of another Party, it shall, on the request of the other Party, explain the reasons for its decision.

14. Further to Article 6.3 of the TBT Agreement, where a Party declines a request of another Party to enter into negotiations for the conclusion of an agreement for mutual recognition of results of each other's conformity assessment procedures, it shall on the request of that other Party, explain the reasons for its decision.

15. Further to Article 5.2.5 of the TBT Agreement, any conformity assessment fees imposed by a Party shall be limited in amount to the approximate cost of services rendered.

16. No Party shall require consular transactions, including related fees and charges, in connection with conformity assessment<sup>3</sup>.

### **Article 8.7 Transparency**

1. Each Party shall allow persons of the other Parties to participate in the development of technical regulations, standards and conformity assessment procedures by its central government bodies.<sup>4</sup> Each Party shall allow persons of the other Parties to participate in the development of these measures on terms no less favourable than those it accords to its own persons.

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<sup>3</sup> For greater certainty, this paragraph shall not apply to a Party verifying conformity assessment documents during a marketing authorisation or reauthorisation process.

<sup>4</sup> A Party satisfies this obligation by, for example, providing interested persons a reasonable opportunity to provide comments on the measure it proposes to develop and taking those comments into account in the development of the measure.

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2. Each Party is encouraged to consider methods to provide additional transparency in the development of technical regulations, standards and conformity assessment procedures, including through the use of electronic tools and public outreach or consultations.

3. Where appropriate, each Party shall encourage non-governmental bodies in its territory to observe the requirements in paragraphs 1 and 2.

4. Each Party shall publish all proposals for new technical regulations and conformity assessment procedures and proposals for amendments to existing technical regulations and conformity assessment procedures, and all final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, of central government bodies.

*4bis.* For greater certainty, proposals for technical regulations and conformity assessment procedures may take the form, as determined by the Party, of, but are not limited to: policy proposals; discussion documents; summaries of proposed technical regulations and conformity assessment procedures; or the draft text of proposed technical regulations and conformity assessment procedures. Each Party shall ensure such proposals contain sufficient detail about the likely content of the proposed technical regulations and conformity assessment procedures so as to adequately inform interested persons and other Parties about whether and how their trade interests might be affected.

*4ter.* Each Party shall publish, preferably by electronic means, in a single official journal or website all proposals for new technical regulations and conformity assessment procedures and proposals for amendments to existing technical regulations and conformity assessment procedures, and all new final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, of central government bodies, that a Party is required to notify or publish under the TBT Agreement or this Chapter, and that may have a significant effect on trade.<sup>5</sup>

5. Each Party shall take such reasonable measures as may be available to it to ensure that all proposals for new technical regulations and conformity assessment procedures and proposals for amendments to existing technical regulations and conformity assessment procedures, and all final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, of local governments on the level directly below that of the central government are published.

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<sup>5</sup> For greater certainty, a Party may comply with this obligation by ensuring that all proposals for new technical regulations and conformity assessment procedures and proposals for amendments to existing technical regulations and conformity assessment procedures, and all new final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, that a Party is required to notify or publish under the TBT Agreement or this Chapter, and that may have a significant effect on trade, are published on, or otherwise accessible through, the WTO's official website.

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*5bis.* Each Party shall ensure that all final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, and to the extent practicable all proposals for new technical regulations and conformity assessment procedures and proposals for amendments to existing technical regulations and conformity assessment procedures, of local governments on the level directly below that of the central government are accessible through official websites or journals, preferably consolidated into a single website.

6. Each Party shall notify WTO Members according to the procedures established under Article 2.9 and Article 5.6 of the TBT Agreement, of proposals for new technical regulations and conformity assessment procedures that are in accordance with the technical content of relevant international standards, guides or recommendations, if any, and that may have a significant effect on trade.

*6bis.* Notwithstanding paragraph 6, where urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a Party, that Party may notify WTO Members of a new technical regulation or conformity assessment procedure that is in accordance with the technical content of relevant international standards, guides or recommendations, if any, upon the adoption of the regulation or procedure according to the procedures established under Article 2.10 or Article 5.7 of the TBT Agreement.

7. Each Party shall endeavour to notify WTO Members of proposals for new technical regulations and conformity assessment procedures that are in accordance with the technical content of relevant international standards, guides and recommendations, if any, and that may have a significant effect on trade, of its local governments on the level directly below that of the central government.

8. For the purposes of determining whether a proposed technical regulation or conformity assessment procedure may have a “significant effect on trade of other Members” and should be notified pursuant to Article 2.9, Article 2.10, Article 3.2, Article 5.6, Article 5.7 or Article 7.2 of the TBT Agreement or this Chapter, a Party shall consider, *inter alia*, the relevant *Decisions and Recommendations Adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995* (G/TBT/1/Rev. 10).

9. Any Party publishing a notice and filing a notification in accordance with Article 2.9, Article 3.2, Article 5.6 or Article 7.2 of the TBT Agreement or this Chapter shall:

- (a) include in the notification an explanation of the objectives of the proposal and how it would address those objectives; and
- (b) transmit the notification and the proposal electronically to the other Parties through their enquiry points established in accordance with Article 10 of the TBT Agreement, at the same time as it notifies WTO Members.



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10. Each Party shall normally allow 60 days after it transmits a proposal under paragraph 9 for another Party or an interested person of another Party to provide comments in writing on the proposal. A Party shall consider any reasonable request from another Party or an interested person of another Party for extending the comment period. A Party that is able to provide a time limit beyond 60 days, such as 90 days, is encouraged to do so.

11. Each Party is encouraged to provide sufficient time between the end of the comment period and the adoption of the notified technical regulation or conformity assessment procedure for its consideration of, and preparation of responses to, the comments received.

12. Each Party shall endeavour to notify WTO Members of the final text of a technical regulation or conformity assessment procedure at the time the text is adopted or published, as an addendum to the original notification of the proposed measure filed under Article 2.9, Article 3.2, Article 5.6 or Article 7.2 of the TBT Agreement or this Chapter.

13. A Party filing a notification in accordance with Articles 2.10 or 5.7 of the *TBT Agreement* and this Chapter, shall at the same time transmit the notification and text of the technical regulation or conformity assessment procedure electronically to the other Parties through the enquiry points referenced in paragraph 9(b) above.

14. No later than the date of publication of a final technical regulation or conformity assessment procedures that may have a significant effect on trade each Party shall, preferably by electronic means:<sup>6</sup>

- (a) make publically available an explanation of the objectives and how the final technical regulation or conformity assessment procedure achieves them;
- (b) provide as soon as possible but no later than 60 days after receiving a request from another Party a description of alternative approaches that the Party considered in developing the final technical regulation or conformity assessment procedure, if any, and the merits of the approach that the Party selected;
- (c) make publicly available the Party's responses to significant or substantive issues presented in comments received on the proposal for the technical regulation or conformity assessment procedure; and
- (d) provide as soon as possible but no later than 60 days after receiving a request from another Party, a description of significant revisions, if any,

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<sup>6</sup> For greater certainty, no Party shall be required to provide a description of alternative approaches or significant revisions under subparagraphs (b) or (d) prior to the date of publication of the final technical regulation or conformity assessment procedure.

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that the Party made to the proposal for the technical regulation or conformity assessment procedure, including those made in response to comments.

15. Further to Annex 3(J) of the TBT Agreement, each Party shall ensure that the publication of its central government standardizing body's work programme containing the standards it is currently preparing and the standards it has adopted is available through the central government standardising body's website or the website referenced in paragraph 4*ter* of this Article.

**Article 8.8: Compliance Period for Technical Regulations and Conformity Assessment Procedures**

1. For the purposes of applying Article 2.12 and Article 5.9 of the TBT Agreement, the term "reasonable interval" means normally a period of not less than six months, except when this would be ineffective in fulfilling the legitimate objectives pursued.

2. When feasible and appropriate, each Party shall endeavour to provide an interval of more than six months between the publication of final technical regulations and conformity assessment procedures and their entry into force.

3. Further to paragraphs 1 and 2 and for greater clarity, in setting a "reasonable interval" for a specific technical regulation or conformity assessment procedure, each Party shall ensure that it provides suppliers with a reasonable amount of time under the circumstances, to be able to demonstrate the conformity of their goods with the relevant requirements of the technical regulation or standard by the date of entry into force of the technical regulation or conformity assessment procedure. In doing so, each Party shall endeavour to take into account the resources available to suppliers.

**Article 8.9: Cooperation and Trade Facilitation**

1. Further to Article 5, Article 6 and Article 9 of the TBT Agreement, the Parties recognise that a broad range of mechanisms exist to facilitate the acceptance of conformity assessment results. In this regard, a Party may:

- (a) implement mutual recognition of the results of conformity assessment procedures performed by bodies located in each other's territory with respect to specific technical regulations;
- (b) recognise existing regional and international mutual recognition arrangements between or among accreditation bodies or conformity assessment bodies;
- (c) use accreditation to qualify conformity assessment bodies, particularly international systems of accreditation;

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- (d) designate conformity assessment bodies or recognise the other Party's designation of conformity assessment bodies;
- (e) unilaterally recognise the results of conformity assessment procedures performed in the other Party's territory; and
- (f) accept a supplier's declaration of conformity.

2. The Parties recognise that a wide range of mechanisms exist to support greater regulatory alignment and to eliminate unnecessary technical barriers to trade in the region, including:

- (a) regulatory dialogue and cooperation to, *inter alia*:
  - (i) exchange information on regulatory approaches and practices;
  - (ii) promote the use of good regulatory practices to improve the efficiency and effectiveness of technical regulations, standards and conformity assessment procedures;
  - (iii) provide technical advice and assistance, on mutually agreed terms and conditions, to improve practices related to the development, implementation and review of technical regulations, standards, conformity assessment procedures and metrology; or
  - (iv) provide technical assistance and cooperation, on mutually agreed terms and conditions, to build capacity and support the implementation of this Chapter;
- (b) greater alignment of national standards with relevant international standards, except where inappropriate or ineffective;
- (c) facilitation of the greater use of relevant international standards, guides and recommendations as the basis for technical regulations and conformity assessment procedures; and
- (d) promotion of the acceptance as equivalent technical regulations of another Party.

3. With respect to the mechanisms listed in paragraphs 1 and 2, the Parties recognise that the choice of the appropriate mechanism in a given regulatory context will depend on a variety of factors, such as the product and sector involved, the volume and direction of trade, the relationship between Parties' respective regulators, the legitimate objectives pursued and the risks of non-fulfilment of those objectives.

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4. The Parties shall intensify their exchange and collaboration on mechanisms to facilitate the acceptance of conformity assessment results, to support greater regulatory alignment and to eliminate unnecessary technical barriers to trade in the region.

5. A Party shall, upon request of another Party, give due consideration to any sector specific proposal for cooperation under this Chapter.

6. Further to Article 2.7 of the TBT Agreement, a Party shall, upon the request of another Party, explain the reasons why it has not accepted a technical regulation of that Party as equivalent.

7. The Parties shall encourage cooperation between their respective organisations responsible for standardisation, conformity assessment, accreditation and metrology, whether they be public or private, with a view to addressing issues covered by this Chapter.

**Article 8.10: Information Exchange and Technical Discussions**

1. A Party may request another Party to provide information on any matter arising under this Chapter. A Party so requested shall provide such information within a reasonable period of time, and where possible, by electronic means.

2. A Party may request technical discussions with another Party with the aim of resolving any matter arising under this Chapter.

*2bis.* With respect to technical regulations or conformity assessment procedures of local governments 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 another Party regarding such matters.

3. The relevant Parties shall discuss the matter raised within 60 days of the request. If a requesting Party believes that the matter is urgent, it may request that any discussions take place within a shorter time frame. In such cases, the responding Party shall give positive consideration to such a request.

4. The Parties shall endeavour to resolve the matter as expeditiously as possible, recognising that the time required to resolve a matter will depend on a variety of factors, and that it may not be possible to resolve every matter through technical discussions.

5. Unless the Parties participating in the technical discussions otherwise agree, the discussions and any information exchanged in the course of the discussions, shall be confidential and without prejudice to the rights and obligations of the participating Parties under this Agreement, the WTO Agreement, or any other agreement to which both Parties are a party.

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6. Requests for information or technical discussions and communications shall be conveyed through the respective Chapter Coordinators.

**Article 8.11: Committee on Technical Barriers to Trade**

1. The Parties hereby establish the Committee on Technical Barriers to Trade (the Committee), which shall comprise representatives of each Party.

2. Through the Committee, the Parties shall intensify their joint work in the fields of technical regulations, conformity assessment procedures and standards with a view to facilitating trade between and among the Parties.

3. The Committee's functions may include:

- (a) monitoring the implementation and operation of this Chapter, including its Annexes and any other commitments agreed under this Chapter, and identifying any potential amendments to or interpretations of such commitments pursuant to the Chapter 27 (Administrative and Institutional Provisions);
- (b) monitoring any technical discussions on matters arising under the Chapter requested pursuant to paragraphs 2 or *2bis* of Article 8.10 (Information Exchange and Technical Discussions);
- (c) agreeing to priority areas of mutual interest for future work under this Chapter and considering proposals for new sector specific or other initiatives;
- (d) encouraging cooperation between and among the Parties in matters pertaining to this Chapter, including the development, review, or modification of technical regulations, standards and conformity assessment procedures;
- (e) encouraging cooperation between and among non-governmental bodies in the Parties' territories, as well as cooperation between governmental and non-governmental bodies in the Parties' territories in matters pertaining to this Chapter;
- (f) facilitating the identification of technical capacity needs;
- (g) encouraging the exchange of information between and among Parties and their relevant non-governmental bodies, where appropriate, on the development of common approaches regarding matters under discussion in non-governmental, regional, plurilateral and multilateral bodies or systems that develop standards, guides, recommendations, policies or other procedures relevant to this Chapter;

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- (h) at a Party's request, encouraging the exchange of information among the Parties regarding specific technical regulations, standards and conformity assessment procedures of non-Parties as well as systemic issues, with a view to fostering a common approach;
  - (i) taking any other steps the Parties consider will assist them in implementing this Chapter and the TBT Agreement;
  - (j) reviewing this Chapter in light of any developments under the TBT Agreement, and developing recommendations for amendments to this Chapter in light of those developments; and
  - (k) reporting to the TPP Commission on the implementation and operation of this Chapter.
4. The Committee may establish working groups to carry out these functions.
5. Each Party shall designate a Chapter Coordinator, and shall provide the other Parties with the name of its designated Chapter Coordinator, the contact details of the relevant officials in that organisation, including telephone, fax, email and other relevant details.
6. A Party shall notify the other Parties promptly of any change of its Chapter Coordinator or any amendments to the details of the relevant officials.
7. The responsibilities of each Chapter Coordinator shall include:
- (a) communicating with the other Parties' Chapter Coordinators, including facilitating discussions, requests and the timely exchange of information on matters arising under this Chapter;
  - (b) communicating with and coordinating the involvement of relevant government agencies, including regulatory authorities, in its territories on relevant matters pertaining to this Chapter;
  - (c) consulting and, where appropriate, coordinating with interested persons in its territory on relevant matters pertaining to this Chapter; and
  - (d) additional responsibilities as the Committee may specify.
8. The Committee shall meet within one year of the date of entry into force of this Agreement and thereafter as agreed by the Parties. The Committee shall carry out its work through communication means agreed by the Parties, which may include e-mail, teleconference, video-conference, meetings at the margins of other regional or international fora, or other means.

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9. Decisions of the Committee shall be taken by consensus.
  
10. In determining what activities the Committee shall undertake, the Parties shall consider work that is being undertaken in other fora, with a view to ensuring that any activities undertaken by the Committee do not unnecessarily duplicate that work.

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**Article 8.12: Annexes**

1. Except for the Annexes on Proprietary Formulas for Prepackaged Foods and Food Additives, Cosmetics Products, Medical Devices and Pharmaceutical Products, where scope is defined in each respective Annex, the Annexes shall have the same scope as set out in Article 8.2: Scope as germane to the product specified within each relevant Annex.
2. The rights and obligations set out in each Annex to this chapter apply only to the sector specified in the applicable Annex, and shall not affect any Party's rights and obligations under any other Annex.
3. Unless the Parties otherwise agree, no later than five years after the date of entry into force of this Agreement, and thereafter at least once every five years, unless the Parties otherwise agree, the Committee shall:
  - (a) review implementation of the Annexes, with a view to strengthen or improve them and, where appropriate, make recommendations to enhance alignment of the Parties' respective standards, technical regulations and conformity assessment procedures in the sectors covered by the Annexes; and
  - (b) consider whether the development of annexes concerning other sectors would further the objectives of this Chapter or the Agreement and decide whether to recommend to the Commission that the Parties initiate negotiations to conclude annexes covering such sectors.



## **ANNEX 8-A: WINE AND DISTILLED SPIRITS**

### *Scope*

1. This Annex applies to wine and distilled spirits.
2. For the purposes of this Annex:

**container** means any bottle, barrel, cask, or other closed receptacle, irrespective of size or of the material from which it is made, used for the sale of wine or distilled spirits at retail;

**distilled spirits** means a potable alcoholic distillate, including spirits of wine, whiskey, rum, brandy, gin, tequila, mezcal and all dilutions or mixtures thereof for consumption;

**label** means any brand, mark, pictorial or other descriptive matter that is written, printed, stencilled, marked, embossed or impressed on, or firmly affixed to the primary container of wine or distilled spirits;

**oenological practices** means winemaking materials, processes, treatments, and techniques, but does not include labelling, bottling, or packaging for final sale;

**single field of vision** means any part of the surface of a primary container, excluding its base and cap, that can be seen without having to turn the container;

**supplier** means a producer, importer, exporter, bottler or wholesaler;

**wine** means a beverage that is produced by the complete or partial alcoholic fermentation exclusively of fresh grapes, grape must, or products derived from fresh grapes in accordance with oenological practices that the country in which the wine was produced authorises under its domestic laws and regulations.<sup>7</sup>

3. Each Party shall make information about its domestic laws and regulations concerning wine and distilled spirits publicly available.
4. A Party may require that suppliers ensure that any statements that the Party requires to be placed on wine and distilled spirits labels are:
  - (a) clear, specific, truthful, accurate, and not misleading to the consumer; and
  - (b) legible to the consumer; and that such labels be firmly affixed.

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<sup>7</sup> For the United States, wine means a beverage that is produced by the complete or partial alcoholic fermentation exclusively of fresh grapes, grape must, or products derived from fresh grapes in accordance with oenological practices that the country in which the wine was produced authorises under its domestic laws and regulations, and that contains an alcohol content of not less than 7 percent and not more than 24 percent.

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5. For greater certainty, with respect to paragraphs 4, 6 and 11, where there is more than one label on a container of imported wine or distilled spirits, a Party may require that each label be visible and not obscure mandatory information on the other label.

6. Where a Party requires a supplier to indicate information on a distilled spirits label, the Party shall permit the supplier to indicate such information on a supplementary label affixed to the distilled spirits container. Each Party shall permit a supplier to affix the supplementary label on the container of the imported distilled spirits after importation but prior to offering the product for sale in the Party's territory, and may require that the supplier affix the supplementary label prior to release from customs. For greater certainty, a Party may require that information indicated on a supplementary label be clear, specific, truthful, accurate, legible, not misleading to the consumer, and firmly affixed to the container, as provided in paragraph 4.

7. Each Party shall permit the alcoholic content by volume to be indicated on a wine or distilled spirits label to be expressed by alc/vol (e.g., 12% alc/vol or alc12% vol), and to be indicated in percentage terms to a maximum of one decimal point (e.g., 12%, 12.0%, 12.1%, 12.2%).

8. Each Party shall permit suppliers to use the term "wine" as a product name. Each Party may require suppliers to indicate further information on wine labels concerning the type, category, class, or classification of the wine.

9. With respect to wine labels, each Party shall permit the information set out in subparagraphs 11 (a) to (d) below to be presented in a single field of vision for containers of wine. If these items are presented in a single field of vision, then the Party's requirements with respect to placement of these four items shall have been met. Each Party shall accept any of these items that appear outside a single field of vision provided its laws, regulations and requirements have been satisfied.

10. Notwithstanding paragraph 9, a Party may require net contents to be displayed on the principal display panel for a subset of less commonly used container sizes if specifically required by that Party's domestic laws or regulation.

11. If a Party requires a wine label to indicate information other than:

- (a) the product name;
- (b) country of origin;
- (c) net contents; or
- (d) alcohol content,

it shall permit the supplier to indicate the information on a supplementary label affixed to the wine container. Each Party shall permit the supplier to affix the supplementary label

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on the container of the imported wine after importation but prior to offering the product for sale in the Party's territory, and may require that the supplier affix the supplementary label prior to release from customs. For greater certainty, a Party may require that information indicated on a supplementary label be clear, specific, truthful, accurate, legible, not misleading to the consumer, and firmly affixed to the container, as provided in paragraph 4.

12. Where a Party has more than one official language, it may require that information on a wine or distilled spirits label appear in equal prominence in each official language.

13. Each Party shall permit suppliers to place lot identification codes on wine and distilled spirits containers, provided that they are clear, specific, truthful, accurate and not misleading. Each Party may impose penalties for the removal or deliberate defacement of any lot identification code provided by the supplier and placed on the container. In doing so, each Party shall permit suppliers to determine:

- (a) where to place the lot identification codes on the containers, provided that such codes do not cover up other essential information printed on the label; and
- (b) the specific font size, readable phrasing, and formatting for the codes provided that lot identification codes are legible by either physical or electronic means.

14. No Party shall require a supplier to indicate any of the following information on wine or distilled spirits containers, labels or packaging:

- (a) date of production or manufacture;
- (b) date of expiration;
- (c) date of minimum durability; or
- (d) sell by date,

except that a Party may require suppliers to indicate a date of minimum durability or date of expiration on products<sup>8</sup> that on account of their packaging or container (such as bag-in-box wines or individual serving size wines), or the addition of perishable ingredients, could have a shorter date of minimum durability than would normally be expected by the consumer.

15. No Party shall require a supplier to place a translation of a trademark or trade name on a wine or distilled spirits container, label or packaging.

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<sup>8</sup> For Peru, all distilled spirits with less than 10% alc/vol must have a date of minimum durability.

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16. Each Party shall not prevent imports of wine from other Parties solely on the basis that the wine labels include the following descriptors or adjectives describing the wine or relating to wine-making: chateau, classic, clos, cream, crusted/crusting, fine, late bottled vintage, noble, reserve, ruby, special reserve, solera, superior, sur lie, tawny, vintage, and vintage character.<sup>9 10 11</sup>

17. No Party shall require a supplier to disclose an oenological practice on a wine label or container except to meet a legitimate human health or safety objective with respect to the relevant oenological practice.

18. Each Party shall permit wine to be labelled as Icewine, ice wine, ice-wine, or a similar variation of those terms, only if the wine is made exclusively from grapes naturally frozen on the vine.<sup>12, 13</sup>

19. Each Party shall endeavour to base its quality and identity requirements for any specific type, category, class, or classification of distilled spirits solely on minimum ethyl alcohol content and the raw materials, added ingredients, and production procedures used to produce that specific type, category, class or classification of distilled spirits.

20. A Party shall not require imported wine or distilled spirits to be certified by an official certification body of the Party in whose territory the wine or distilled spirits were produced or by a certification body recognised by the Party in whose territory the wine or distilled spirits were produced regarding:

- (a) vintage, varietal, and regional claims for wine; or
- (b) raw materials and production processes for distilled spirits,

except that the Party may require that wine or distilled spirits be certified regarding (a) or (b) if the Party in whose territory the wine or distilled spirits were produced requires such certification, that wine be certified regarding (a) if the Party has a reasonable and

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<sup>9</sup> This paragraph shall not apply to a Party if the Party has entered into an agreement with another country or group of countries no later than February 2003 that requires the Party to restrict the use of such terms on labels of wine sold in its territory.

<sup>10</sup> Nothing in this paragraph shall be construed to require Canada to apply this paragraph in a manner inconsistent with its obligations under Article A(3) of Annex V of the *EU-Canada Wine Agreement*.

<sup>11</sup> Nothing in this paragraph shall be construed to require Malaysia to apply this paragraph in a manner inconsistent with its Regulation 18(1A) of the *Food Regulations 1985* under the *Food Act 1983*.

<sup>12</sup> For Japan, this obligation will be met through implementation of “the standard on labelling of domestic wine” by its domestic producers, dated 23 December 1986, and any amendments thereto.

<sup>13</sup> The obligation in this paragraph will become effective for New Zealand three years after the date on which this Agreement enters into force for New Zealand. Once effective, New Zealand shall implement the obligation by ensuring that wine exported from New Zealand is labelled as icewine, ice wine, ice-wine, or a similar variation of these terms, only if such wine is made exclusively from grapes naturally frozen on the vine.

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legitimate concern about a vintage, varietal, or regional claim for wine, and that distilled spirits be certified regarding (b) if certification is necessary to verify claims such as age, origin or standards of identity.

21. Where certification of wine is deemed necessary by a Party to protect human health and safety or to achieve other legitimate objectives, that Party shall consider the *Codex Alimentarius Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CAC/GL 38-2001), in particular the use of the generic model official certificate, as amended from time-to-time, concerning official and officially recognised certificates.

22. A Party shall normally permit a wine or distilled spirits supplier to submit any required certification, test result or sample solely with the initial shipment of a particular brand, producer and lot. If a Party requires a supplier to submit a sample of the product for the purpose of the Party's procedure to assess conformity to its technical regulation or standard, it shall not require a sample quantity larger than is strictly necessary to complete the relevant conformity assessment procedure. Nothing in this provision precludes a Party from undertaking verification of test results or certification, for example, where a Party has information that a particular product may be non-compliant.

23. Except where problems of health and safety arise or threaten to arise for a Party, a Party shall not normally apply any final technical regulation, standard or conformity assessment procedure to wine or distilled spirits that have been placed on the market in the Party's territory before the date on which the technical regulation, standard or conformity assessment procedure enters into force, provided that said products are sold within a period that has been stipulated by the relevant authority, after the technical regulation, standard or conformity assessment procedure enters into force.

24. Each Party shall endeavour to assess other Parties' laws, regulations and requirements in respect of oenological practices, with the aim of reaching agreements providing for the mutual acceptance by the Parties of each other's respective mechanisms for regulating oenological practices, where appropriate.

## **ANNEX 8-B: INFORMATION AND COMMUNICATIONS TECHNOLOGY PRODUCTS**

### **Section A: Information and Communication Technology (ICT) Products that Use Cryptography**

1. This section applies to information and communication technology (ICT) products that use cryptography. For greater certainty, for purposes of this section, a “product” is a good and does not include financial instruments.

2. For the purposes of this section:

**cryptography** means the principles, means or methods for the transformation of data in order to hide its information content, prevent its undetected modification or prevent its unauthorized use; and is limited to the transformation of information using one or more secret parameters (e.g., crypto variables) or associated key management;

**encryption** means the conversion of data (plaintext) into a form that cannot be easily understood without subsequent re-conversion (ciphertext) through the use of a cryptographic algorithm;

**cryptographic algorithm** or **cipher** means a mathematical procedure or formula for combining a key with plaintext to create a ciphertext; and

**key** means a parameter used in conjunction with a cryptographic algorithm that determines its operation in such a way that an entity with knowledge of the key can reproduce or reverse the operation, while an entity without knowledge of the key cannot.

3. With respect to a product that uses cryptography and is designed for commercial applications, no Party may impose or maintain a technical regulation or conformity assessment procedure that requires a manufacturer or supplier of the product, as a condition of the manufacture, sale, distribution, import or use of the product, to:

- (a) transfer or provide access to a particular technology, production process, or other information (such as a private key or other secret parameter, algorithm specification or other design detail), that is proprietary to the manufacturer or supplier and relates to the cryptography in the product, to the Party or a person in the Party’s territory;
- (b) partner with a person in its territory; or
- (c) use or integrate a particular cryptographic algorithm or cipher,

other than where the manufacture, sale, distribution, import or use of the product is by or for the government of the Party.

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4. Paragraph 3 shall not apply to: (a) requirements that a Party adopts or maintains relating to access to networks that are owned or controlled by the government, including those of central banks; or (b) measures taken pursuant to supervisory, investigatory or examination authority relating to financial institutions or markets. For greater certainty, nothing in this Section shall be construed to prevent law enforcement authorities from requiring service suppliers using encryption they control from providing, pursuant to legal procedures, unencrypted communications.

**Section B: Electromagnetic Compatibility of Information Technology Equipment (ITE) Products**

1. This section applies to the electromagnetic compatibility of information technology equipment (ITE) products.

2. For the purposes of this section:

**ITE product** means any device or system or component thereof that has a primary function of entry, storage, display, retrieval, transmission, processing, switching, or control (or combinations thereof) of data or telecommunication messages by means other than radio transmission or reception and, for greater certainty, excludes any product or component thereof that has a primary function of radio transmission or reception;

**electromagnetic compatibility** means the ability of an equipment or system to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances with respect to any other device or system in that environment; and

**supplier's declaration of conformity** means an attestation by a supplier that a product meets a specified standard or technical regulation based on an evaluation of the results of conformity assessment procedures.

3. If a Party requires positive assurance that an ITE product meets a standard or technical regulation for electromagnetic compatibility, it shall accept a supplier's declaration of conformity.<sup>14</sup>

4. The Parties recognise that a Party may require testing (e.g. by an independent accredited laboratory) in support of a supplier's declaration of conformity, registration of the supplier's declaration of conformity, or submission of evidence necessary to support the supplier's declaration of conformity.

5. Nothing in paragraph 3 prevents a Party from verifying a supplier's declaration of conformity.

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<sup>14</sup> Nothing in this paragraph shall be construed to require Mexico to apply this paragraph in a manner inconsistent with its Ley Federal Sobre Metrologia y Normalizacion.

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6. Paragraph 3 shall not apply with respect to any product:
  - (a) that a Party regulates as a medical device, or a medical device system, or a component of a medical device or medical device system; or
  - (b) for which the Party demonstrates that there is a high risk that the product will cause harmful electromagnetic interference with a safety or radio transmission or reception device or system.

**Section C: Regional Cooperation Activities on Telecommunications Equipment**

1. This section applies to telecommunications equipment.
2. The Parties are encouraged to implement the APEC Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment (MRA-TEL) and the APEC Mutual Recognition Arrangement for Equivalence of Technical Requirements (MRA-ETR) with respect to each other or other arrangements to facilitate trade in telecommunications equipment.



## **ANNEX 8-C: PHARMACEUTICALS**

1. This Annex applies to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation and notification procedures<sup>15</sup> of central government bodies, other than technical specifications prepared by governmental entities for production or consumption requirements of such entities and sanitary or phytosanitary measures, that may affect trade in pharmaceutical products between the Parties. A Party's obligations under this Annex apply to any product that the Party defines as a pharmaceutical product pursuant to paragraph 2. For the purpose of this Annex, preparation of a standard, technical regulation, conformity assessment procedure or marketing authorisation includes, as appropriate, the evaluation of the risks involved, the need to adopt a measure to address those risks, review of relevant scientific or technical information, and consideration of the characteristics or design of possible alternative approaches.

1 *bis*. Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 2, for purposes of this Annex, a pharmaceutical product may include a human drug or biologic that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or condition in humans or intended to affect the structure or any function of the body of a human.

2. Each Party shall define the scope of the products subject to its statutes and regulations for pharmaceutical products in its territory and make such information publicly available. Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 2, for purposes of this Annex, a pharmaceutical product may include a human drug or biologic that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or condition in humans or intended to affect the structure or any function of the body of a human.

3. Each Party shall identify the agency or agencies that are authorised to regulate pharmaceutical products in its territory and make such information publicly available.

4. Where more than one agency is authorised to regulate pharmaceutical products within the territory of a Party, the Party shall examine whether there is overlap or duplication in scope of those authorities and take reasonable measures to eliminate unnecessary duplication of any regulatory requirements resulting for pharmaceutical products.

5. The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonization, as well as regional initiatives in support of such

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<sup>15</sup> The application of this Annex to marketing authorisations is without prejudice to whether a marketing authorisation meets the definition of a standard, technical regulation or conformity assessment procedure.

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international initiatives, as appropriate, to improve the alignment of their respective pharmaceutical products regulations and regulatory activities.

6. Each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts with respect to pharmaceutical products when developing or implementing regulations for marketing authorisations of pharmaceutical products. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with such efforts, as appropriate.

*6bis.* Each Party shall observe the obligations in Articles 2.1 and 5.1.1 of the TBT Agreement with respect to any marketing authorisation or notification procedure or element thereof that it prepares, adopts or applies for pharmaceutical products that do not fall within the definition of a technical regulation or conformity assessment procedure.

7. Each Party recognises that the responsibility of providing sufficient information on which a Party makes regulatory determinations on a pharmaceutical product rests with the applicant.

*7bis.* Each Party shall make its determination on whether to grant marketing authorisation for a specific pharmaceutical product on the basis of:

- (a) information, including, where appropriate, pre-clinical and clinical data, on safety and efficacy;
- (b) information on manufacturing quality of the product;
- (c) labelling information related to safety, efficacy and use of the product; and
- (d) other matters that may directly affect the health or safety of the user of the product.

To this end, no Party shall require sale or related financial data concerning the marketing of the product as part of such a determination. Further, each Party shall endeavour not to require pricing data as part of the determination.

8. Each Party shall administer any marketing authorisation process it maintains for pharmaceutical products in a timely, reasonable, objective, transparent, and impartial manner, and identify and manage any conflicts of interest so as to mitigate any associated risks.

- (a) Each Party shall provide an applicant seeking marketing authorisation for a pharmaceutical product with its determination regarding marketing authorisation within a reasonable period of time. The Parties recognise that the reasonable period of time required to make a marketing authorisation determination may be affected by factors such as the novelty of a product or legitimate regulatory implications that may arise.

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- (b) If a Party determines that a marketing authorisation application for a pharmaceutical product under review in its jurisdiction has deficiencies that have led or will lead to a non-authorisation decision, that Party shall inform the applicant seeking marketing authorisation and provide reasons why the application is deficient.
- (c) If a Party requires marketing authorisation for a pharmaceutical product, the Party shall ensure that any marketing authorisation determinations are subject to an appeal or review process that may be invoked at the request of the applicant seeking market authorisation. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body.
- (d) Where a Party requires periodic reauthorisation for a pharmaceutical product that has previously received marketing authorisation by the Party, the Party shall allow the pharmaceutical product to remain on its market under the conditions of the previous marketing authorisation pending its decision on the periodic reauthorisation, except where a Party identifies a significant health or safety concern.<sup>16</sup>

For greater certainty, the Parties recognise that an application for reauthorisation that is not timely filed, that contains insufficient information, or that is otherwise inconsistent with a Party's requirements is deficient for purposes of the reauthorisation decision

9. When developing regulatory requirements for pharmaceutical products, each Party shall consider its available resources and technical capacity so as to minimise the implementation of requirements that could:

- (a) inhibit the effectiveness of the procedure for ensuring the safety, efficacy or manufacturing quality of pharmaceutical products; or
- (b) lead to substantial delays in marketing authorisation regarding pharmaceutical products for sale on its market.

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<sup>16</sup> Viet Nam may comply with its obligations under this paragraph by allowing for applications for reauthorisation to be filed within the 12 month period, prior to the expiry date of the marketing authorisation, or within a period prior to the expiry date of the marketing authorisation that is six months longer than the period provided for in Viet Nam's Ministry of Health Circular on Registration of Drugs, or subsequent relevant instrument, for the Ministry to grant a reauthorisation or re-registration application for a previously registered pharmaceutical product, whichever is longer.

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10. No Party shall require that a pharmaceutical product receive marketing authorisation from the country of manufacture as a condition for the product receiving marketing authorisation from the Party.<sup>17</sup>

11. With respect to applications for marketing authorisation for pharmaceutical products, each Party shall accept for review safety, efficacy, and manufacturing quality information submitted by a person seeking marketing authorisation in a format that is consistent with the principles found in the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* Common Technical Document (CTD), including any amendments thereto, recognising that the CTD does not necessarily address all aspects relevant to a Party's determination to approve marketing authorisation for a particular product.<sup>18</sup>

12. The Parties shall seek to improve their collaboration on pharmaceutical inspection, and to that end each Party shall, with respect to the inspection of pharmaceuticals products within the territory of another Party:

- (a) notify that Party prior to conducting an inspection, unless there are reasonable grounds to believe that doing so could prejudice the effectiveness of the inspection;
- (b) where practicable, permit representatives of that Party's competent authority to observe such inspection; and
- (c) notify that Party of its findings as soon as possible following an inspection and, if the findings will be publicly released, no later than a reasonable time before any such release. However, the inspecting Party is not required to notify its findings if it considers that its findings are confidential and should not be disclosed.

*12bis:* The Parties shall seek to apply relevant scientific guidance documents developed through international collaborative efforts with respect to inspection of pharmaceuticals.

## **ANNEX 8-D: COSMETICS**

1. This Annex applies to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation and

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<sup>17</sup> For greater certainty, a Party may accept a prior marketing authorisation issued by another regulatory authority as evidence that a product may meet its own requirements, or, as a result of regulatory resource limitations, require marketing authorisation from one of a number of reference countries established and made public by that Party as a condition for the product receiving marketing authorisation from the Party.

<sup>18</sup> For Viet Nam, this obligation shall not apply until January 1<sup>st</sup>, 2019.

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notification procedures<sup>19</sup> of central government bodies, other than technical specifications prepared by governmental entities for production or consumption requirements of such entities and sanitary or phytosanitary measures, that may affect trade in cosmetic products between the Parties. A Party's obligations under this Annex apply to any product that the Party defines as a cosmetic product pursuant to paragraph 2. For the purpose of this Annex, preparation of a standard, technical regulation, conformity assessment procedure or marketing authorisation includes, as appropriate, the evaluation of the risks involved, the need to adopt a measure to address those risks, review of relevant scientific or technical information, and consideration of the characteristics or design of possible alternative approaches.

*1bis.* Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 2, for purposes of this Annex, a cosmetic product may include a product intended to be rubbed, poured, sprinkled, or sprayed on, or otherwise applied to the human body including the mucus membrane of the oral cavity and teeth for cleansing, beautifying, protecting, promoting attractiveness, or altering the appearance.

2. Each Party shall define the scope of the products subject to its statutes and regulations for cosmetic products in its territory and make such information publicly available.

3. Each Party shall identify the agency or agencies that are authorised to regulate cosmetic products in its territory and make such information publicly available.

4. Where more than one agency is authorised to regulate cosmetic products within the territory of a Party, the Party shall examine whether there is overlap or duplication in scope of those authorities and eliminate unnecessary duplication of any regulatory requirements resulting for cosmetic products.

5. The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonization, as well as regional initiatives in support of such international initiatives, as appropriate, to improve the alignment of their respective cosmetic products regulations and regulatory activities.

6. Each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts with respect to cosmetic products when developing or implementing regulations for cosmetic products. Each Party is encouraged to consider regionally- developed scientific or technical guidance documents that are aligned with such efforts, as appropriate.

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<sup>19</sup> The application of this Annex to marketing authorisations is without prejudice to whether a marketing authorisation meets the definition of a standard, technical regulation or conformity assessment procedure.

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*6bis.* Each Party shall observe the obligations in Article 2.1 and Article 5.1.1 of the TBT Agreement with respect to any marketing authorisation or notification procedure or element thereof that it prepares, adopts or applies for cosmetic products that do not fall within the definition of a technical regulation or conformity assessment procedure.

7. Each Party shall ensure that when regulating cosmetic products it applies a risk-based approach.

*7bis.* Further to paragraph 7, each Party shall, when regulating cosmetic products, take into account that cosmetic products are generally expected to pose less potential risk to human health or safety than medical devices or pharmaceutical products.

*7ter.* No Party shall conduct separate marketing authorisation processes or sub-processes for cosmetic products that differ only with respect to shade extensions or fragrance variants, except where a Party identifies a significant health or safety concern.

8. Each Party shall administer any marketing authorisation process it maintains for cosmetics products in a timely, reasonable, objective, transparent, and impartial manner, and identify and manage any conflicts of interest so as to mitigate any associated risks.

- (a) If a Party requires marketing authorisation for a cosmetic product, that Party shall provide the cosmetic product marketing authorisation applicant with its determination regarding marketing authorisation within a reasonable period of time.
- (b) If a Party requires marketing authorisation for a cosmetic product and it determines that a marketing authorisation application for a cosmetic product under review in its jurisdiction has deficiencies that have led or will lead to a non-authorisation decision, that Party shall inform the applicant seeking marketing authorisation and provide reasons why the application is deficient.
- (c) If a Party requires marketing authorisation for a cosmetic product, the Party shall ensure that any marketing authorisation determinations are subject to an appeal or review process that may be invoked at the request of the applicant seeking market authorisation. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body.

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- (d) When a Party has granted marketing authorisation for a cosmetic product in its territory, the Party shall not subject the product to periodic re-assessment procedures as a condition of retaining its marketing authorisation.

*8bis.* Where a Party maintains a marketing authorisation process for cosmetic products, that Party shall consider to replace this process with other mechanisms such as voluntary or mandatory notification and post-market surveillance.

9. When developing regulatory requirements for cosmetic products, each Party shall consider its available resources and technical capacity so as to minimise the implementation of requirements that could:

- (a) inhibit the effectiveness of the procedure for ensuring the safety or manufacturing quality of cosmetic products; or
- (b) lead to substantial delays in marketing authorisation regarding cosmetic products for sale on its market.

*9bis.* No Party shall require the submission of marketing information, including with respect to prices or cost, as a condition for the product receiving marketing authorisation.

*9ter.* A Party shall not require a cosmetic product to be labelled with a marketing authorisation or notification number.<sup>20</sup>

10. No Party shall require that a cosmetic product receive marketing authorisation from the country of manufacture, as a condition for the product receiving marketing authorisation from the Party. For greater certainty, this provision does not prohibit a Party from accepting a prior marketing authorisation issued by another regulatory authority as evidence that a product may meet its own requirements.

*10bis.* No Party shall require that a cosmetic product be accompanied by a certificate of free sale as a condition of marketing, distribution or sale in the Party's territory.

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<sup>20</sup> This paragraph does not apply to Chile and Peru. Within a period of no more than five years from the date of the entry into force of this Agreement, Chile and Peru shall each review their respective labelling requirements in order to examine whether other regulatory mechanisms can be implemented, in a manner consistent with their obligations under this Chapter and the TBT Agreement. Chile and Peru shall separately report to the Committee about their review upon request of another Party.

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11. Where a Party requires a manufacturer or supplier of a cosmetic product to indicate information on the product's label, the Party shall permit the manufacturer or supplier to indicate the required information by relabeling the product or supplementary labelling of the product in accordance with the Party's domestic requirements after importation but prior to offering the product for sale or supply in the Party's territory.

12. No Party shall require animal testing for determining the safety of cosmetic products, unless there is no validated alternative method available to otherwise assess safety. A Party may, however, consider the results of animal testing in determining the safety of a cosmetic product.

13. Where a Party prepares or adopts good manufacturing practice guidelines for cosmetic products, it shall use relevant international standards for cosmetic products, or the relevant parts of them, as a basis for its guidelines except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.

14. The Parties shall endeavour to share, subject to domestic laws and regulations, information resulting from post-market surveillance of cosmetic products.

15. Each Party shall endeavour to share information on its findings or the findings of its relevant institutions regarding cosmetics ingredients.

*15bis.* Each Party shall endeavour to avoid re-testing or re-evaluating cosmetic products that differ only with respect to shade extensions or fragrance variants, except when conducted for health or safety purposes.



### **ANNEX 8-E: MEDICAL DEVICES**

1. This Annex applies to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation and notification procedures<sup>21</sup> of central government bodies, other than technical specifications prepared by governmental entities for production or consumption requirements of such entities and sanitary or phytosanitary measures, that may affect trade in medical devices products between the Parties. A Party's obligations under this Annex apply to any product that the Party defines as a medical device pursuant to paragraph 2. For the purpose of this Annex, preparation of a standard, technical regulation, conformity assessment procedure or marketing authorisation includes, as appropriate, the evaluation of the risks involved, the need to adopt a measure to address those risks, review of relevant scientific or technical information, and consideration of the characteristics or design of possible alternative approaches.

*1bis.* Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 2, each Party should define the scope of products subject to its statutes and regulations for medical devices in a manner that is consistent with the meaning assigned to the term "medical device" in the Global Harmonization Task Force Final Document entitled "Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'".

2. Each Party shall define the scope of the products subject to its statutes and regulations for medical devices in its territory and make such information publicly available.

3. Each Party shall identify the agency or agencies that are authorized to regulate medical devices in its territory and make such information publicly available.

4. Where more than one agency is authorised to regulate cosmetic products within the territory of a Party, the Party shall examine whether there is overlap or duplication in scope of those authorities and eliminate unnecessary duplication of any regulatory requirements resulting for cosmetic products.

5. The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonization, as well as regional initiatives in support of such international initiatives, as appropriate, to improve the alignment of their respective cosmetic products regulations and regulatory activities.

6. Each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts with respect to medical devices when developing or implementing regulations for marketing authorisations of medical

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<sup>21</sup> The application of this Annex to marketing authorisations is without prejudice to whether a marketing authorisation meets the definition of a standard, technical regulation or conformity assessment procedure.

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devices. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with such efforts, as appropriate.

*6bis.* Each Party shall observe the obligations in Article 2.1 and Article 5.1.1 of the TBT Agreement with respect to any marketing authorisation or notification procedure or element thereof that it prepares, adopts or applies for medical devices that do not fall within the definition of a technical regulation or conformity assessment procedure.

7. Recognising that different medical devices pose different levels of risk, each Party shall classify medical devices based on risk, taking into account scientifically relevant factors. Each Party shall ensure that, when it regulates a medical device, it regulates the device consistent with the classification the Party has assigned it.

*7bis.* Each Party recognises that the responsibility of providing sufficient information on which a Party makes regulatory determinations on a medical device rests with the applicant.

8. Each Party shall make its determination on whether to grant marketing authorisation for a specific medical device on the basis of:

- (a) information, including, where appropriate, clinical data, on safety and efficacy;
- (b) information on performance, design and manufacturing quality of the product;
- (c) labelling information related to safety, efficacy, and use of the product; and
- (d) other matters that may directly affect the health or safety of the user of the product.

To this end, no Party shall require sale, pricing, or related financial data concerning the marketing of the product as part of such a determination.

9. Each Party shall administer any marketing authorisation process it maintains for medical devices in a timely, reasonable, objective, transparent, and impartial manner, and identify and manage any conflicts of interest so as to mitigate any associated risks.

- (a) Each Party shall provide an applicant seeking marketing authorisation for a medical device with its determination regarding marketing authorisation within a reasonable period of time. The Parties recognise that the reasonable period of time required to make a marketing authorisation determination may be affected by factors such as the novelty of a product or legitimate regulatory implications that may arise.

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- (b) If a Party determines that a marketing authorisation application for a medical device under review in its jurisdiction has deficiencies that have led or will lead to a non-authorisation decision, that Party shall inform the applicant seeking marketing authorisation and provide reasons why the application is deficient.
- (c) If a Party requires marketing authorisation for a medical device, the Party shall ensure that any marketing authorisation determinations are subject to an appeal or review process that may be invoked at the request of the applicant seeking market authorisation. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body.
- (d) Where a Party requires periodic re-authorisation for a medical device that has previously received marketing authorisation by the Party, the Party shall allow the medical device to remain on its market under the conditions of the previous marketing authorisation pending its decision on the periodic re-authorisation, except where a Party identifies a significant health or safety concern.

10. When developing regulatory requirements for medical devices, each Party shall consider its available resources and technical capacity so as to minimise the implementation of requirements that could:

- (a) inhibit the effectiveness of the procedure for ensuring the safety, efficacy or manufacturing quality of medical devices; or
- (b) lead to substantial delays in marketing authorisation regarding medical devices for sale on its market.

11. No Party shall require that a medical device receive marketing authorisation from country of manufacture as a condition for the medical device receiving marketing authorisation from the Party.<sup>22</sup>

12. Where a Party requires a manufacturer or supplier of a medical device to indicate information on the product's label, the Party shall permit the manufacturer or supplier to indicate the required information by relabeling the product or supplementary labelling of

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<sup>22</sup> For greater certainty, a Party may accept a prior marketing authorisation issued by another regulatory authority as evidence that a medical device may meet its own requirements, or, as a result of regulatory resource limitations, require marketing authorisation from one of a number of reference countries established and made public by that Party as a condition for the medical device receiving marketing authorisation from the Party.

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the product in accordance with the Party's domestic requirements after importation but prior to offering the product for sale or supply in the Party's territory.

**ANNEX 8-F: PROPRIETARY FORMULAS FOR PREPACKAGED FOODS AND  
FOOD ADDITIVES**

1. This Annex applies to the preparation, adoption and application of technical regulations and standards of central government bodies that are related to prepackaged foods and food additives when sold as such, except that it does not apply to technical specifications prepared by governmental entities for production or consumption requirements of such entities or sanitary or phytosanitary measures.

2. The terms “food,” “food additive,” and “prepackaged” have the same meanings as set forth in the Codex General Standard for the Labelling of Pre-Packaged Food (CODEX STAN 1-1985) and the Codex General Standard for the Labelling of Food Additives When Sold as Such (CODEX STAN 107-1981), as amended from time-to-time.

3. Further to the TBT Agreement regarding the preparation, adoption and application of technical regulations and standards, when gathering information relating to proprietary formulas, each Party shall:

- (a) ensure that its information requirements are limited to what is necessary to achieve its legitimate objective; and
- (b) ensure that the confidentiality of information about products originating in the territory of another Party arising from or supplied in connection with the preparation, adoption, and application of technical regulations and standards is respected in the same way as for domestic products and in such manner that legitimate commercial interests are protected.

If a Party gathers confidential information relating to proprietary formulas, it may use such information in the course of administrative and judicial proceedings in accordance with its law, provided that the Party has procedures to maintain the confidentiality of the information in the course of such proceedings.

4. For greater certainty, nothing in paragraph 3 shall prevent a Party from requiring ingredients to be listed on labels consistent with CODEX STAN 1-1985 and CODEX STAN 107-1981, as amended from time-to-time, except when those standards would be an ineffective or inappropriate means for the fulfilment of a legitimate objective.

### **ANNEX8-G: ORGANIC PRODUCTS**

1. This Annex applies to a Party if that Party is developing or maintains standards, technical regulations, or conformity assessment procedures relating to the production, processing, or labeling of products as organic for sale or distribution within its territory.
  
2. Parties are encouraged to take steps to:
  - (a) exchange information on matters relating to organic production, certification of organic products, and related control systems, as appropriate; and
  - (b) cooperate with each other to develop, improve, and strengthen international guidelines, standards, and recommendations related to trade in organic products.
  
3. Where a Party maintains requirements relating to the production, processing, or labeling of products as organic, it shall enforce such requirements.
  
4. Each Party is encouraged to consider, as expeditiously as possible, a request for recognition or equivalence of the standards, technical regulations, or conformity assessment procedures relating to the production, processing, or labeling of products as organic of another Party. Each Party is encouraged to accept as equivalent or recognise the standards, technical regulations, or conformity assessment procedures relating to the production, processing, or labeling of products as organic of that other Party, provided the Party is satisfied that the standards, technical regulations, or conformity assessment procedures of the other Party adequately fulfill the objectives of the Party's standards, technical regulations, or conformity assessment procedures. Where a Party does not accept as equivalent or recognise the standards, technical regulations, or conformity assessment procedures relating to the production, processing, or labeling of products as organic of another Party, it shall, on the request of that other Party, explain its reasons.
  
5. Parties are encouraged to participate in technical exchanges to support improvement and greater alignment of standards, technical regulations, or conformity assessment procedures relating to the production, processing, or labeling of products as organic.