

## CHAPTER 8

### TECHNICAL BARRIERS TO TRADE

#### Article 8.1: Definitions

1. 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*.

2. In addition, for the purposes of this Chapter:

**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 authorise its marketing, distribution or sale in the Party's territory. The process or processes may be described in a Party's laws 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* of May 8, 1998 and the *Electrical and Electronic Equipment Mutual Recognition Arrangement* of July 7, 1999 and other agreements that 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;

**TBT Agreement** means the *WTO Agreement on Technical Barriers to Trade*, as may be amended; and

**verify** means to take 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 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 shall apply to the preparation, adoption and application of all technical regulations, standards and conformity assessment procedures of central level of government bodies (and, where explicitly provided for, technical regulations, standards and conformity assessment procedures of government bodies at the level directly below that of the central level of government) that may affect trade in goods between the Parties, except as provided in paragraphs 4 and 5.

2. Each Party shall take reasonable measures that are within its authority to encourage observance by regional or local government bodies, as the case may be, on the level directly below that of the central level of government within its territory which are responsible for the preparation, adoption and application of technical regulations, standards and conformity assessment procedures, of Article 8.5 (International Standards, Guides and Recommendations), Article 8.6 (Conformity Assessment), Article 8.8 (Compliance Period for Technical Regulations and Conformity Assessment Procedures) and each of the Annexes to this Chapter.

3. All references in this Chapter to technical regulations, standards and conformity assessment procedures shall be construed to include any amendments

to them and any addition to the rules or the product coverage of those technical regulations, standards and procedures, except amendments and additions of an insignificant nature.

4. This Chapter shall not apply to technical specifications prepared by a governmental entity for its production or consumption requirements. These specifications are covered by Chapter 15 (Government Procurement).

5. This Chapter shall not apply to sanitary and phytosanitary measures. These are covered by Chapter 7 (Sanitary and Phytosanitary Measures).

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

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

1. The following provisions of the TBT Agreement are 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 a violation of the provisions of the TBT Agreement incorporated under paragraph 1.

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

1. The Parties recognise 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, to determine whether there is an international standard, guide or recommendation within the meaning of Articles 2 and 5 and Annex 3 of the TBT Agreement, each Party shall apply the *Decisions and Recommendations adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995 (G/TBT/1/Rev.12)*, as may be revised, issued by the WTO Committee on Technical Barriers to Trade.

3. The Parties shall cooperate with each other, when 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 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 the same or equivalent procedures, criteria and other conditions to accredit, approve, license or otherwise recognise conformity assessment bodies located in the territory of another Party that it may apply to conformity assessment bodies in its own territory.

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

- (a) shall not require the conformity assessment body that tests or certifies 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 those 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 to otherwise approve them to test or certify the product or conduct an inspection.

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

4. If a Party undertakes conformity assessment under paragraph 3, and further to Articles 5.2 and 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, on 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 required 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.

5. Paragraphs 1 and 2(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.

6. Nothing in paragraphs 1, 2 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 the Parties' respective territories, a Party 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 measures to approve conformity assessment bodies that have accreditation for the technical regulations or standards of the importing Party, by an accreditation body that is a signatory to an international or regional mutual recognition arrangement.<sup>1</sup> The Parties recognise that these 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 no Party shall refuse to accept conformity assessment results from a conformity assessment body or take actions that have the effect of, directly or indirectly, requiring or encouraging another Party or person to refuse to accept 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;

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

- (c) is domiciled in the territory of a Party that does not maintain a procedure for recognising accreditation bodies, provided that the accreditation body is recognised internationally, consistent with the provisions in paragraph 8;
- (d) does not operate an office in the Party's territory; or
- (e) is a for-profit entity.

10. Nothing in paragraph 9 prohibits a Party from refusing to accept conformity assessment results from a conformity assessment body on grounds other than those set out in paragraph 9 if that Party can substantiate those grounds for the refusal, and that refusal is 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 accreditation, approval, licensing or other recognition granted pursuant to a mutual recognition agreement.

12. If a Party:

- (a) accredits, approves, licenses or otherwise recognises a body assessing conformity with 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
- (b) declines to use a mutual recognition arrangement,

it shall, on request of the other Party, explain the reasons for its decision.

13. If 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, if a Party declines the request of another Party to enter into negotiations to conclude an agreement for mutual recognition of the results of each other's conformity assessment procedures, it shall, on 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 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>2</sup>

### **Article 8.7: Transparency**

1. Each Party shall allow persons of another Party to participate in the development of technical regulations, standards and conformity assessment procedures by its central government bodies<sup>3</sup> on terms no less favourable than those that it accords to its own persons.

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. If appropriate, each Party shall encourage non-governmental bodies in its territory to observe the obligations 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 new final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, of central government bodies.

5. A Party may determine the form of proposals for technical regulations and conformity assessment procedures, which may take the form of: 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 that its proposals contain sufficient detail about the likely content of the proposed technical regulations and conformity assessment procedures to adequately inform interested persons and other Parties about whether and how their trade interests might be affected.

6. 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

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<sup>2</sup> For greater certainty, this paragraph shall not apply to a Party verifying conformity assessment documents during a marketing authorisation or reauthorisation process.

<sup>3</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.

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>4</sup>

7. 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 new final technical regulations and conformity assessment procedures and final amendments to existing technical regulations and conformity assessment procedures, of regional or local governments, as the case may be, on the level directly below that of the central level of government, are published.

8. Each Party shall ensure that all new 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 regional or local governments on the level directly below that of the central level of government are accessible through official websites or journals, preferably consolidated into a single website.

9. Each Party shall notify 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, according to the procedures established under Article 2.9 or 5.6 of the TBT Agreement.

10. Notwithstanding paragraph 9, if urgent problems of safety, health, environmental protection or national security arise or threaten to arise for a Party, that Party may notify 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 that regulation or procedure, according to the procedures established under Article 2.10 or 5.7 of the TBT Agreement.

11. Each Party shall endeavour to notify proposals for new technical regulations and conformity assessment procedures of regional or local governments, as the case may be, on the level directly below that of the central level of government 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 according to the procedures established under Article 2.9 or 5.6 of the TBT Agreement.

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<sup>4</sup> For greater certainty, a Party may comply with this obligation by ensuring that the proposed and final measures in this paragraph are published on, or otherwise accessible through, the WTO's official website.



12. For the purposes of determining whether a proposed technical regulation or conformity assessment procedure may have a significant effect on trade and should be notified in accordance with Article 2.9, 2.10, 3.2, 5.6, 5.7 or 7.2 of the TBT Agreement or this Chapter, a Party shall consider, among other things, the relevant *Decisions and Recommendations Adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995* (G/TBT/1/Rev. 12), as may be revised.

13. A Party that publishes a notice and that files a notification in accordance with Article 2.9, 3.2, 5.6 or 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.

14. Each Party shall normally allow 60 days from the date it transmits a proposal under paragraph 13 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 to extend the comment period. A Party that is able to extend a time limit beyond 60 days, for example 90 days, is encouraged to do so.

15. 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.

16. Each Party shall endeavour to notify 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, 3.2, 5.6 or 7.2 of the TBT Agreement or this Chapter.

17. A Party that files a notification in accordance with Article 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 referred to in paragraph 13(b).

18. No later than the date of publication of a final technical regulation or conformity assessment procedure that may have a significant effect on trade, each Party shall, preferably electronically:

- (a) make publicly 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, if any, that the Party considered in developing the final technical regulation or conformity assessment procedure and the merits of the approach that the Party selected;<sup>5</sup>
- (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, that the Party made to the proposal for the technical regulation or conformity assessment procedure, including those made in response to comments.

19. Further to paragraph J of Annex 3 of the TBT Agreement, each Party shall ensure that its central government standardising 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 referred to in paragraph 6.

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

1. For the purposes of applying Articles 2.12 and 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 by the technical regulation or by the requirements concerning the conformity assessment procedure.

2. If 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. In addition to paragraphs 1 and 2, 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 period of time, under the

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<sup>5</sup> For greater certainty, no Party shall be required to provide a description of alternative approaches or significant revisions under subparagraph (b) or (d) prior to the date of publication of the final technical regulation or conformity assessment procedure.

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 specific 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 Articles 5, 6 and 9 of the TBT Agreement, the Parties acknowledge 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 its territory and another Party'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;
- (d) designate conformity assessment bodies or recognise another Party's designation of conformity assessment bodies;
- (e) unilaterally recognise the results of conformity assessment procedures performed in another Party's territory; and
- (f) accept a supplier's declaration of conformity.

2. The Parties recognise that a broad 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, among other things:
  - (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 of technical regulations of another Party as equivalent.

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 depends 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.

4. The Parties shall strengthen 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, on 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, on 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 are 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 receiving a request under this paragraph shall provide that information within a reasonable period of time, and if possible, by electronic means.
2. A Party may request technical discussions with another Party with the aim of resolving any matter that arises under this Chapter.
3. For greater certainty, with respect to technical regulations or conformity assessment procedures of regional or local governments, as the case may be, on the level directly below that of the central government that may have a significant effect on trade, a Party may request technical discussions with another Party regarding those matters.
4. The relevant Parties shall discuss the matter raised within 60 days of the date of the request. If a requesting Party considers that the matter is urgent, it may request that any discussions take place within a shorter time frame. The responding Party shall give positive consideration to that request.
5. 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.
6. Unless the Parties that participate in the technical discussions agree otherwise, 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 party.
7. Requests for information or technical discussions and communications shall be conveyed through the respective contact points designated pursuant to Article 27.5 (Contact Points).

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

1. The Parties hereby establish a Committee on Technical Barriers to Trade (Committee), composed of government representatives of each Party.
2. Through the Committee, the Parties shall strengthen their joint work in the fields of technical regulations, standards and conformity assessment procedures with a view to facilitating trade between the Parties.

3. The Committee's functions may include:
- (a) monitoring the implementation and operation of this Chapter, including any other commitments agreed under this Chapter, and identifying any potential amendments to or interpretations of those commitments pursuant to Chapter 27 (Administrative and Institutional Provisions);
  - (b) monitoring any technical discussions on matters that arise under this Chapter requested pursuant to paragraph 2 of Article 8.10 (Information Exchange and Technical Discussions);
  - (c) deciding on priority areas of mutual interest for future work under this Chapter and considering proposals for new sector-specific initiatives or other initiatives;
  - (d) encouraging cooperation between the Parties in matters that pertains to this Chapter, including the development, review or modification of technical regulations, standards and conformity assessment procedures;
  - (e) encouraging cooperation between non-governmental bodies in the Parties' territories, as well as cooperation between governmental and non-governmental bodies in the Parties' territories in matters that pertains to this Chapter;
  - (f) facilitating the identification of technical capacity needs;
  - (g) encouraging the exchange of information between the Parties and their relevant non-governmental bodies, if appropriate, to develop 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;
  - (h) encouraging, on request of a Party, the exchange of information between 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 Commission on the implementation and operation of this Chapter.
4. The Committee may establish working groups to carry out its functions.
  5. To determine what activities the Committee will undertake, the Committee 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.
  6. The Committee shall meet within one year of the date of entry into force of this Agreement and thereafter as decided by the Parties.

#### **Article 8.12: Contact Points**

1. Each Party shall designate and notify a contact point for matters arising under this Chapter, in accordance with Article 27.5 (Contact Points).
2. A Party shall promptly notify the other Parties of any change of its contact point or the details of the relevant officials.
3. The responsibilities of each contact point shall include:
  - (a) communicating with the other Parties' contact points, 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 territory on relevant matters pertaining to this Chapter;
  - (c) consulting and if appropriate, coordinating with interested persons in its territory on relevant matters pertaining to this Chapter; and
  - (d) carrying out any additional responsibilities specified by the Committee.

#### **Article 8.13: Annexes**

1. The scope of the Annexes on Pharmaceuticals, Cosmetics, Medical Devices and Proprietary Formulas for Prepackaged Foods and Food Additives is set out in each respective Annex. The other Annexes to this Chapter have the same scope as that set out in Article 8.3 (Scope).

2. The rights and obligations set out in each Annex to this Chapter shall apply only with respect to the sector specified in that Annex, and shall not affect any Party's rights or obligations under any other Annex.

3. Unless the Parties agree otherwise, no later than five years after the date of entry into force of this Agreement and thereafter at least once every five years, the Committee shall:

- (a) review the implementation of the Annexes, with a view to strengthening or improving them and if appropriate, make recommendations to enhance alignment of the Parties' respective technical regulations, standards 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 those sectors.



## ANNEX 8-A

### WINE AND DISTILLED SPIRITS

1. This Annex shall apply 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 retail sale of wine or distilled spirits;

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

**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 is produced authorises under its laws and regulations.<sup>6</sup>

3. Each Party shall make information about its laws and regulations concerning wine and distilled spirits publicly available.

4. A Party may require a supplier to ensure that any statement required by that Party to be placed on a wine or distilled spirits label is:

- (a) clear, specific, truthful, accurate and not misleading to the consumer; and

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<sup>6</sup> For the United States, the alcohol content of wine must be not less than seven per cent and not more than 24 per cent.

- (b) legible to the consumer; and

that such labels be firmly affixed.

5. If a Party requires a supplier to indicate information on a distilled spirits label, the Party shall permit the supplier to indicate that information on a supplementary label that is 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 the information indicated on a supplementary label meet the requirements in paragraph 4.

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

7. Each Party shall permit suppliers to use the term "wine" as a product name. A Party may require a supplier to indicate additional information on a wine label concerning the type, category, class or classification of the wine.

8. With respect to wine labels, each Party shall permit the information set out in subparagraphs 10(a) through (d) to be presented in a single field of vision for a container of wine. If this information is presented in a single field of vision, then the Party's requirements with respect to placement of this information are satisfied. A Party shall accept any of the information that appears outside a single field of vision if that information satisfies that Party's laws, regulations and requirements.

9. Notwithstanding paragraph 8, 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 laws or regulations.

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

- (a) 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. A Party shall permit the supplier to affix the

supplementary label 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 on a supplementary label meet the requirements set out in paragraph 4.

11. For the purposes of paragraphs 4, 5 and 10, if 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 another label.

12. If 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 a supplier to place a lot identification code on a wine or distilled spirits container, if the code is clear, specific, truthful, accurate and not misleading, and shall permit the supplier to determine:

- (a) where to place the lot identification code on the container, provided that the code does not cover up essential information printed on the label; and
- (b) the specific font size, readable phrasing and formatting for the code provided that the lot identification code is legible by physical or electronic means.

14. A Party may impose penalties for the removal or deliberate defacement of any lot identification code provided by the supplier and placed on the container.

15. No Party shall require a supplier to indicate any of the following information on a wine or distilled spirits container, 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 a supplier to indicate a date of minimum durability or expiration on products<sup>7</sup> that could have a shorter date of minimum durability or expiration than would normally be expected by the consumer because of: their packaging or container, for example bag-in-box wines or individual serving size wines; or the addition of perishable ingredients.

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<sup>7</sup> For Peru, all distilled spirits with less than 10 % alc/vol must have a date of minimum durability.

16. 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.

17. No Party shall prevent imports of wine from other Parties solely on the basis that the wine label includes 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 or vintage character. This paragraph shall not apply to a Party that 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>8</sup>

18. 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 that oenological practice.

19. 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>9</sup>

20. 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.

21. No Party shall 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,

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<sup>8</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, as amended. 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>9</sup> For Japan, this obligation is met through implementation of “the standard on labelling of domestic wine” by its domestic producers, dated 23 December 1986, as amended. For New Zealand, the obligation in this paragraph will become effective 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.

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

22. If a Party deems that certification of wine is necessary to protect human health or 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.

23. A Party shall normally permit a wine or distilled spirits supplier to submit any required certification, test result or sample only 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 Party's procedure to assess conformity with its technical regulation or standard, it shall not require a sample quantity larger than the minimum quantity 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 the Party has information that a particular product may be non-compliant.

24. Unless problems of human health or 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 the products are sold within a period of time after the date the technical regulation, standard or conformity assessment procedure enters into force, stipulated by the authority responsible for that technical regulation, standard or conformity assessment procedure.

25. Each Party shall endeavour to assess other Parties' laws, regulations and requirements in respect of oenological practices, with the aim of reaching agreements that provide for the Parties' acceptance of each other's mechanisms for regulating oenological practices, if appropriate.

## ANNEX 8-B

### INFORMATION AND COMMUNICATIONS TECHNOLOGY PRODUCTS

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

1. This section shall apply to information and communication technology (ICT) products that use cryptography.<sup>10</sup>
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 unauthorised use; and is limited to the transformation of information using one or more secret parameters, for example, 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 shall 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, for example, 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

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<sup>10</sup> For greater certainty, for the purposes of this section, a "product" is a good and does not include a financial instrument.

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.

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 of that Party, including those of central banks; or (b) measures taken by a Party pursuant to supervisory, investigatory or examination authority relating to financial institutions or markets.

5. For greater certainty, this Section shall not be construed to prevent a Party's law enforcement authorities from requiring service suppliers using encryption they control to provide, pursuant to that Party's legal procedures, unencrypted communications.

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

1. This section shall apply 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>11</sup>

4. The Parties recognise that a Party may require testing, for example, 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 shall prevent a Party from verifying a supplier's declaration of conformity.

6. Paragraph 3 shall not apply with respect to a product:

- (a) that a Party regulates as a medical device, 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 shall apply to telecommunications equipment.

2. The Parties are encouraged to implement the *APEC Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment* of May 8, 1998 (MRA-TEL) and the *APEC Mutual Recognition Arrangement for Equivalence of Technical Requirements* of October 31, 2010 (MRA-ETR) with respect to each other or other arrangements to facilitate trade in telecommunications equipment.

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<sup>11</sup> Nothing in this paragraph shall be construed to require Mexico to apply this paragraph in a manner inconsistent with its *Ley Federal Sobre Metrología y Normalización*.



## ANNEX 8-C

### PHARMACEUTICALS

1. This Annex shall apply to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation<sup>12</sup> and notification procedures of central government bodies that may affect trade in pharmaceutical products between the Parties. This Annex shall not apply to a technical specification prepared by a governmental entity for its production or consumption requirements or a sanitary or phytosanitary measure.
2. A Party's obligations under this Annex shall apply to any product that the Party defines as a pharmaceutical product pursuant to paragraph 3. For the purposes of this Annex, preparation of a technical regulation, standard, 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, the review of relevant scientific or technical information, and the consideration of the characteristics or design of alternative approaches.
3. Each Party shall define the scope of the products subject to its laws and regulations for pharmaceutical products in its territory and make that information publicly available.
4. Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 3, for the 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 a disease or condition in humans, or intended to affect the structure or any function of the body of a human.
5. Each Party shall identify the agency or agencies that are authorised to regulate pharmaceutical products in its territory and make that information publicly available.
6. If more than one agency is authorised to regulate pharmaceutical products within the territory of a Party, that Party shall examine whether there is overlap or duplication in the scope of those authorities and take reasonable measures to eliminate unnecessary duplication of any regulatory requirements resulting for pharmaceutical products.

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<sup>12</sup> The application of this Annex to marketing authorisations is without prejudice to whether a marketing authorisation meets the definition of a technical regulation, standard or conformity assessment procedure.

7. The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonisation, as well as regional initiatives that support those international initiatives, as appropriate, to improve the alignment of their respective regulations and regulatory activities for pharmaceutical products.

8. When developing or implementing regulations for marketing authorisation of pharmaceutical products, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.

9. Each Party shall observe the obligations set out in Articles 2.1 and 5.1.1 of the TBT Agreement with respect to a marketing authorisation, notification procedure or elements of either that the Party prepares, adopts or applies for pharmaceutical products and that do not fall within the definition of a technical regulation or conformity assessment procedure.

10. Each Party recognises that the applicant is responsible for providing sufficient information to a Party for it to make a regulatory determination on a pharmaceutical product.

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

- (a) information, including, if appropriate, pre-clinical and clinical data, on safety and efficacy;
- (b) information on the manufacturing quality of the product;
- (c) labelling information related to the 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 data or related financial data concerning the marketing of the product as part of the determination. Further, each Party shall endeavour to not require pricing data as part of the determination.

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

- (a) Each Party shall provide an applicant that requests marketing authorisation for a pharmaceutical product with its determination

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 regulatory implications that may arise.

- (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 decision not to authorise its marketing, that Party shall inform the applicant that requests marketing authorisation and provide reasons why the application is deficient.
- (c) If a Party requires a marketing authorisation for a pharmaceutical product, the Party shall ensure that any marketing authorisation determination is subject to an appeal or review process that may be invoked at the request of the applicant. 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) If a Party requires periodic re-authorisation for a pharmaceutical product that has previously received marketing authorisation from the Party, the Party shall allow the pharmaceutical product to remain on its market under the conditions of the previous marketing authorisation pending a decision on the periodic reauthorisation, unless the Party identifies a significant health or safety concern.<sup>13, 14</sup>

13. When developing regulatory requirements for pharmaceutical products, a Party shall consider its available resources and technical capacity in order to minimise the implementation of requirements that could:

- (a) inhibit the effectiveness of procedures for ensuring the safety, efficacy or manufacturing quality of pharmaceutical products; or

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<sup>13</sup> For greater certainty, the Parties recognise that an application for reauthorisation that is not filed in a timely manner; that contains insufficient information; or that is otherwise inconsistent with a Party's requirements, is deficient for the purposes of the reauthorisation decision.

<sup>14</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 re-authorisation or re-registration application for a previously registered pharmaceutical products, whichever is longer.

- (b) lead to substantial delays in marketing authorisation regarding pharmaceutical products for sale on that Party's market.

14. No Party shall require that a pharmaceutical product receive marketing authorisation from a regulatory authority in the country of manufacture as a condition for the product to receive marketing authorisation from that Party.

15. For greater certainty, a Party may accept a prior marketing authorisation that is issued by another regulatory authority as evidence that a product may meet its own requirements. If there are regulatory resource limitations, a Party may require a marketing authorisation from one of a number of reference countries to be established and made public by that Party as a condition for the product's marketing authorisation from that Party.

16. For a marketing authorisation application for a pharmaceutical product, each Party shall review the safety, efficacy and manufacturing quality information submitted by the applicant requesting 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), as may be amended, recognising that the CTD may not address all aspects relevant to a Party's determination to approve marketing authorisation for a particular product.<sup>15</sup>

17. The Parties shall seek to improve their collaboration on pharmaceutical inspection, and to this end, each Party shall, with respect to the inspection of a pharmaceutical product within the territory of another Party:

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

18. The Parties shall seek to apply relevant scientific guidance documents that are developed through international collaborative efforts with respect to inspection of pharmaceuticals.

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<sup>15</sup> For Viet Nam, this obligation shall not apply until January 1, 2019.

## ANNEX 8-D

### COSMETICS

1. This Annex shall apply to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation<sup>16</sup> and notification procedures of central government bodies that may affect trade in cosmetic products between the Parties. This Annex shall not apply to a technical specification prepared by a governmental entity for its production or consumption requirements or a sanitary or phytosanitary measure.

2. A Party's obligations under this Annex shall apply to any product that the Party defines as a cosmetic product pursuant to paragraph 3. For the purposes of this Annex, preparation of a technical regulation, standard, 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, the review of relevant scientific or technical information, and the consideration of the characteristics or design of alternative approaches.

3. Each Party shall define the scope of the products subject to its laws and regulations for cosmetic products in its territory and make that information publicly available.

4. Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 3, for the purposes of this Annex, a cosmetic product may include a product that is intended to be rubbed, poured, sprinkled, sprayed on or otherwise applied to the human body including the mucous membrane of the oral cavity and teeth, to cleanse, beautify, protect, promote attractiveness or alter the appearance.

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

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

7. The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonisation, as well as regional initiatives

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<sup>16</sup> The application of this Annex to marketing authorisations is without prejudice to whether a marketing authorisation meets the definition of a technical regulation, standard or conformity assessment procedure.

that support of those international initiatives, as appropriate, to improve the alignment of their respective regulations and regulatory activities for cosmetic products.

8. When developing or implementing regulations for cosmetic products, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.

9. Each Party shall observe the obligations set out in Articles 2.1 and 5.1.1 of the TBT Agreement with respect to a marketing authorisation, notification procedure or elements of either that the Party prepares, adopts or applies for cosmetic products and that do not fall within the definition of a technical regulation or conformity assessment procedure.

10. Each Party shall ensure that it applies a risk-based approach to the regulation of cosmetic products.

11. In applying a risk-based approach in regulating cosmetic products, each Party shall 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.

12. 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, unless a Party identifies a significant human health or safety concern.

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

- (a) If a Party requires marketing authorisation for a cosmetic product, that Party shall provide an applicant with its determination 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 decision not to authorise its marketing, that Party shall inform the applicant that requests marketing authorisation and provide reasons why the application is deficient.

- (c) If a Party requires a marketing authorisation for a cosmetic product, the Party shall ensure that any marketing authorisation determination is subject to an appeal or review process that may be invoked at the request of the applicant. 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) If 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.

14. If a Party maintains a marketing authorisation process for cosmetic products, that Party shall consider replacing this process with other mechanisms such as voluntary or mandatory notification and post-market surveillance.

15. When developing regulatory requirements for cosmetic products, a Party shall consider its available resources and technical capacity in order to minimise the implementation of requirements that could:

- (a) inhibit the effectiveness of procedures 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 that Party's market.

16. 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.

17. No Party shall require a cosmetic product to be labelled with a marketing authorisation or notification number.<sup>17</sup>

18. No Party shall require that a cosmetic product receive marketing authorisation from a regulatory authority in 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.

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<sup>17</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.

19. 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.

20. If 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 relabelling the product or by using 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.

21. No Party shall require that a cosmetic product be tested on animals to determine the safety of that cosmetic product, unless there is no validated alternative method available to assess safety. A Party may, however, consider the results of animal testing to determine the safety of a cosmetic product.

22. If 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 unless those international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued.

23. Each Party shall endeavour to share, subject to its laws and regulations, information from post-market surveillance of cosmetic products.

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

25. Each Party shall endeavour to avoid re-testing or re-evaluating cosmetic products that differ only with respect to shade extensions or fragrance variants, unless conducted for human health or safety purposes.



## ANNEX 8-E

### MEDICAL DEVICES

1. This Annex shall apply to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation<sup>18</sup> and notification procedures of central government bodies that may affect trade in medical devices between the Parties. This Annex shall not apply to a technical specification prepared by a governmental entity for its production or consumption requirements or a sanitary or phytosanitary measure.
2. A Party's obligations under this Annex shall apply to any product that the Party defines as a medical device pursuant to paragraph 3. For the purposes of this Annex, preparation of a technical regulation, standard, 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, the review of relevant scientific or technical information, and the consideration of the characteristics or design of alternative approaches.
3. Each Party shall define the scope of the products subject to its laws and regulations for medical devices in its territory and make that information publicly available.
4. Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 3, each Party should define the scope of products subject to its laws and regulations for medical devices in a manner that is consistent with the meaning assigned to the term "medical device" in the *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'* endorsed by the Global Harmonization Task Force on May 16, 2012, as may be amended.
5. Each Party shall identify the agency or agencies that are authorised to regulate medical devices in its territory and make that information publicly available.
6. If more than one agency is authorised to regulate medical devices within the territory of a Party, that Party shall examine whether there is overlap or duplication in the scope of those authorities and to take reasonable measures to eliminate unnecessary duplication of any regulatory requirements resulting for medical devices.

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<sup>18</sup> The application of this Annex to marketing authorisations is without prejudice to whether a marketing authorisation meets the definition of a technical regulation, standard, or conformity assessment procedure.

7. The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonisation, as well as regional initiatives that support of those international initiatives, as appropriate, to improve the alignment of their respective regulations and regulatory activities for medical devices.

8. When developing or implementing regulations for marketing authorisation of medical devices, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.

9. Each Party shall observe the obligations set out in Articles 2.1 and 5.1.1 of the TBT Agreement with respect to a marketing authorisation, notification procedure or elements of either that the Party prepares, adopts or applies for medical devices and that do not fall within the definition of a technical regulation or conformity assessment procedure.

10. 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 to that device.

11. Each Party recognises that the applicant is responsible for providing sufficient information to a Party for it to make a regulatory determination on a medical device.

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

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

To this end, no Party shall require sale data, pricing or related financial data concerning the marketing of the medical device.

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

- (a) Each Party shall provide an applicant that requests marketing authorisation for a medical device with its determination 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 device or regulatory implications that may arise.
- (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 decision not to authorise its marketing, that Party shall inform the applicant that requests 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 determination is subject to an appeal or review process that may be invoked at the request of the applicant. 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) If a Party requires periodic re-authorisation for a medical device that has previously received marketing authorisation from the Party, the Party shall allow the medical device to remain on its market under the conditions of the previous marketing authorisation pending a decision on the periodic re-authorisation, unless a Party identifies a significant health or safety concern.

14. When developing regulatory requirements for medical devices, a Party shall consider its available resources and technical capacity in order to minimise the implementation of requirements that could:

- (a) inhibit the effectiveness of procedures 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 that Party's market.

15. No Party shall require that a medical device receive a marketing authorisation from a regulatory authority in the country of manufacture as a

condition for the medical device to receive marketing authorisation from that Party.

16. For greater certainty, a Party may accept a prior marketing authorisation that is issued by another regulatory authority as evidence that a medical device may meet its own requirements. If there are regulatory resource limitations, a Party may require a marketing authorisation from one of a number of reference countries established and made public by that Party as a condition for the medical device's marketing authorisation from that Party.

17. If 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 relabelling the product or by using supplementary labelling of the device in accordance with the Party's domestic requirements after importation but prior to offering the device for sale or supply in the Party's territory.

## ANNEX 8-F

### PROPRIETARY FORMULAS FOR PREPACKAGED FOODS AND FOOD ADDITIVES

1. This Annex shall apply to the preparation, adoption and application of technical regulations and standards of central government bodies that are related to prepackaged foods and food additives. This Annex shall not apply to technical specifications prepared by a governmental entity for its production or consumption requirements or sanitary and phytosanitary measures.
2. For the purposes of this Annex, the terms “food,” “food additive” and “prepackaged” have the same meanings as set out 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 may be amended.
3. When gathering information relating to proprietary formulas in the preparation, adoption and application of technical regulations and standards, 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 a manner that protects legitimate commercial interests.

If a Party gathers confidential information relating to proprietary formulas, it may use that 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 those proceedings.

4. 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 may be amended, except when those standards would be an ineffective or inappropriate means for the fulfilment of a legitimate objective.

## ANNEX 8-G

### ORGANIC PRODUCTS

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