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;

第 8 章

技术性贸易壁垒

第 8.1 条 定义

1. 本章中所使用术语的定义包含在《技术性贸易壁垒协定》附件 1 中，包括附件 1 的前言和解释性说明，在细节上作必要修改后纳入本章并应成为本章一部分。

2. 此外，就本章而言：

领事事务指一缔约方拟向另一缔约方领土出口的产品必须首先提交出口缔约方领土内的进口缔约方领事机构进行监管的要求，目的在于获得领事发票或领事签证，以开具合格评定文件；

销售许可指一缔约方为许可一产品在其领土内销售、分销或出售而对该产品予以批准或注册的一个或多个程序。该一个或多个程序在一缔约方国内法律或法规中可能有多种表述，包括产品“销售许可”、“许可”、“批准”、“注册”、“卫生许可”、“卫生注册”以及“卫生批准”。销售许可不包括通知程序；

互认协议指一具有约束力的政府间协议，用以承认对照一个或多个领域的适当技术法规或标准进行的合格评定结果，包括关于实施 APEC 1998 年 5 月 8 日的《电信设备合格评定互认安排》和 1999 年 7 月 7 日《电气及电子设备互认安排》所达成的政府间协议以及规定承认对照一个或多个领域的适当技术法规或标准进行的合格评定结果的其他协议；

互认安排指认可机构之间就承认认可制度的等效性(根据同行审查)，或合格评定机构之间就承认合格评定结果所达成的国际或区域安排(包括多边承认安排)；

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

上市后监督指一缔约方在一产品已投放其市场后所采取的使该缔约方能够监控或处理对该缔约方关于产品的国内要求遵守情况的程序；

《TBT 协定》指可能经修正的 WTO《技术性贸易壁垒协定》；以及

核实指为确认单个合格评定结果的真实性而采取行动，例如请求合格评定机构或认可、批准、许可或以其他方式承认合格评定机构的机构提供信息，但不包括要求一产品在进口缔约方领土内重复进行在出口缔约方或一第三方领土内已经进行的合格评定程序，除非在随机或非经常性基础上为监督目的而进行，或针对显示未遵守情况的信息进行。

第 8.2 条 目标

本章的目标旨在便利贸易，包括通过取消不必要的技术性贸易壁垒，增强透明度并促进更多的监管合作和良好规制实践。

第 8.3 条 范围

1. 本章适用于所有可能影响缔约方之间货物贸易的中央政府机构制定、采用和实施的所有技术法规、标准和合格评定程序(以及，如有明确规定，直属中央政府的地方政府机构的技术法规、标准和合格评定程序)，但第 4 款和第 5 款中所规定的除外。

2. 每一缔约方应在其职权范围内采取合理措施，鼓励其领土内负责制定、采用和实施技术法规、标准和合格评定程序的直属中央政府的地区或地方政府机构(视情况而定)遵守第 8.5 条(国际标准、指南和建议)、第 8.6 条(合格评定)、第 8.8 条(遵守技术法规和合格评定程序的期限)及本章每一附件。

3. 本章中所指的所有技术法规、标准和合格评定程序应解释为包括对其的任何修正和对这些技术法规、标准和合格评定程序

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.

的规则或产品范围的任何补充，但无实质意义的修正和补充除外。

4. 本章不得适用于一政府实体为其生产或消费要求所制定的技术规格。这些规格为第 15 章(政府采购)所涵盖。

5. 本章不得适用于卫生与植物卫生措施。这些措施为第 7 章(卫生与植物卫生措施)所涵盖。

6. 为进一步明确，本章中任何内容不得阻止一缔约方依照其在本协定、《TBT 协定》及任何其他相关国际协定项下的权利和义务采用或设立技术法规、标准或合格评定程序。

第 8.4 条 《TBT 协定》特定条款的纳入

1. 《TBT 协定》的下列条款在细节上作必要修改后纳入本协定，并成为本协定一部分：

(a) 第 2.1 条、第 2.2 条、第 2.4 条、第 2.5 条、第 2.9 条、第 2.10 条、第 2.11 条、第 2.12 条；

(b) 第 5.1 条、第 5.2 条、第 5.3 条、第 5.4 条、第 5.6 条、第 5.7 条、第 5.8 条、第 5.9 条；以及

(c) 附件 3 的 D 款、E 款和 F 款。

2. 对于仅指称违反根据第 1 款纳入的《TBT 协定》条款的争端，任何缔约方不得援用第 28 章(争端解决)下的争端解决。

第 8.5 条 国际标准、指南和建议

1. 缔约方认识到国际标准、指南和建议在支持更大程度的监管协调、良好规制实践和减少不必要的贸易壁垒方面的重要作用。

2. 在此方面，在《TBT 协定》第 2.4 条、第 5.4 条和附件 3 的基础上，为确定属《TBT 协定》第 2 条、第 5 条和附件 3 范围内的国际标准、指南或建议是否存在，每一缔约方应适用 WTO 技术性贸易壁垒委员会发布的、可能作出修订的《自 1995 年 1 月 1 日以来 WTO 技术性贸易壁垒委员会通过的决定和建议》(G/TBT/1/Rev.12)。

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:

3. 缔约方应，在可行且适当的情况下，相互合作，以保证有可能作为技术法规、合格评定程序基础的国际标准、指南和建议不会对国际贸易构成不必要的障碍。

第 8.6 条 合格评定

1. 在《TBT 协定》第 6.4 条基础上，每一缔约方给予位于另一缔约方领土内的合格评定机构的待遇不得低于其给予位于其自己领土或任何其他缔约方领土内的合格评定机构的待遇。为保证其给予此种待遇，每一缔约方应在认可、批准、许可或以其他方式承认位于另一缔约方领土内的合格评定机构的过程中适用其对在其自己领土内的合格评定机构所适用的相同或等效的程序、标准和其他条件。

2. 在《TBT 协定》第 6.4 条基础上，如一缔约方维持第 1 款中所列程序、标准或其他条件并要求检测结果、认证或检验作为一产品符合一标准或技术法规的明确保证，则该缔约方：

(a) 不得要求检测或认证该产品的合格评定机构或进行检验的合格评定机构位于自己领土内；

(b) 不得对位于其领土之外的合格评定机构强加要求，实际上会要求这些合格评定机构在该缔约方的领土内开设办公室；以及

(c) 应允许在其他缔约方领土内的合格评定机构向该缔约方提出申请，以确定这些机构符合该缔约方用以判断这些机构具备资质或以其他方式批准这些机构从事产品测试或认证或进行检验所要求的任何程序、标准和其他条件。

3. 第 1 款和第 2 款不得阻止一缔约方以符合其在《TBT 协定》项下义务的方式，仅在位于其自己领土内或另一缔约方领土内的特定政府机构内部开展针对一具体产品的合格评定程序。

4. 如一缔约方根据第 3 款开展合格评定，则在《TBT 协定》第 5.2 条和第 5.4 条关于信息要求的限制、合法商业利益的保护以及审议程序的充分性规定基础上，该缔约方应另一缔约方请求，应说明：

(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.[1] 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;

[1] The Committee shall be responsible for developing and maintaining a list of such arrangements.

(a) 为何所要求的信息对评定合格和确定费用是必需的；

(b) 该缔约方如何保证所要求的信息机密性以保证保护合法商业利益的方式得到遵守；以及

(c) 对有关合格评定程序运用的投诉进行审议的程序和在一投诉属合理时采取纠正措施的程序。

5. 第 1 款和第 2 款(c)项不得阻止一缔约方使用互认协议认可、批准、许可或以其他方式承认位于其领土之外的合格评定机构。

6. 第 1 款、第 2 款和第 5 款中任何内容不阻止一缔约方核实由位于其领土之外的合格评定机构进行的合格评定程序的结果。

7. 在第 6 款基础上，为增强对各自领土内合格评定结果的持续可靠性的信心，一缔约方可就与位于其领土之外的合格评定机构有关的事项请求提供信息。

8. 在《TBT 协定》第 9.1 条基础上，一缔约方应考虑采取措施，接受由一属国际或区域互认安排签署方的认可机构授予的对该进口缔约方技术法规或标准认可的合格评定机构的评定结果。[1] 缔约方认识到这些安排可处理在批准合格评定机构时的关键考虑因素，包括技术能力、独立性和利益冲突的避免。

9. 在《TBT 协定》第 9.2 条基础上，任何缔约方不得由于一合格评定机构的认可机构属下列情况而拒绝接受该机构的合格评定结果，或采取具有直接或间接要求或鼓励另一缔约方或人拒绝接受该合格评定机构的合格评定结果效果的行动：

(a) 在拥有一个以上认可机构的一缔约方领土内运营；

(b) 属一非政府机构；

[1] 委员会应负责起草和保存此类安排的清单。

(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.

(c) 位于未设立承认认可机构程序的一缔约方领土内，但该认可机构获得国际认可，并符合第 8 款中的规定；

(d) 在该缔约方领土内未开设办公室；或

(e) 属营利性实体。

10. 第 9 款中任何内容不得禁止一缔约方以第 9 款中所列之外的理由拒绝接受一合格评定机构的合格评定结果，只要该缔约方可证明支持拒绝的理由，且此种拒绝与《TBT 协定》和本章不相抵触。

11. 一缔约方应最好通过电子方式公布其可用作确定合格评定机构是否有能力获得认可、批准、许可或其他承认的根据的程序、标准和其他条件，包括根据一互认协议给予的认可、批准、许可或其他承认。

12. 如一缔约方：

(a) 认可、批准、许可或以其他方式承认一在其领土内对一特定技术法规或标准的合格性进行评定的机构，而拒绝认可、批准、许可或以其他方式承认一在另一缔约方领土内对该技术法规或标准的合格性进行评定的机构；或

(b) 拒绝使用一互认安排，

则应另一缔约方请求，该缔约方应说明其决定的理由。

13. 如一缔约方不接受在另一缔约方领土内进行的一合格评定程序的结果，则应另一缔约方请求，该缔约方应说明其决定的理由。

14. 在《TBT 协定》第 6.3 条基础上，如一缔约方拒绝另一缔约方提出的为缔结一互认各自合格评定程序结果的协议而开展谈判的请求，则应该另一缔约方请求，该缔约方应说明其决定的理由。

15. 在《TBT 协定》第 5.2.5 条基础上，一缔约方征收的任何合格评定费用应以提供服务所需的近似成本为限。

16. No Party shall require consular transactions, including related fees and charges, in connection with conformity assessment.[2]

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[3] 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

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

[3] 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.

16. 任何缔约方不得要求关于合格评定的领事事务，包括相关规费和费用。[2]

第 8.7 条 透明度

1. 每一缔约方应允许其他缔约方的人，以不低于其给予本国人的条件，参与其中央政府机构[3]的技术法规、标准和合格评定程序的制定。

2. 鼓励每一缔约方考虑在技术法规、标准和合格评定程序的制定过程中提供额外透明度的方法，包括通过使用电子工具和公众宣传或磋商。

3. 如适当，每一缔约方应鼓励在其领土内的非政府机构遵守第 1 款和第 2 款中的义务。

4. 每一缔约方应公布中央政府机构关于新技术法规和合格评定程序的所有提案、关于修正现行技术法规和合格评定程序的所有提案，以及所有新技术法规和合格评定程序的最终文本和对现行技术法规和合格评定程序的最终修正文本。

5. 一缔约方可确定关于技术法规和合格评定程序提案的形式，可采用的形式包括：政策提案、讨论文件、拟议的技术法规和合格评定程序的摘要或拟议的技术法规和合格评定程序的草案文本。每一缔约方应保证其提案包含拟议技术法规和合格评定程序可能包含的内容足够详细，以充分告知利害关系人和其他缔约方其贸易利益是否可能受到影响及如何受到影响。

6. 每一缔约方应最好通过电子方式，在单一官方刊物或网站上公布《TBT 协定》或本章下要求一缔约方通知或公布的、可能对贸易产生重大影响的、中央政府机构关于新技术法规和合格评定程序的所有提案、关于修正现行技术法规和合格评定程序的所

[2] 为进一步明确，本款不得适用于在销售批准或重新批准进程中正在核实合格评定文件的一缔约方。

[3] 一缔约方通过例如向利害关系人提供就其拟议制定的措施提出评论的合理机会并在该措施制定过程中考虑这些评论，即符合这一义务。

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.[4]

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.

[4] 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.

有提案，以及所有新技术法规和合格评定程序的最终文本和对现行技术法规和合格评定程序的最终修正文本。[4]

7. 每一缔约方应采取其可获得的合理措施以保证直属中央政府的地区政府或地方政府(视情况而定)公布关于新技术法规和合格评定程序的所有提案、关于修正现行技术法规和合格评定程序的所有提案，以及所有新技术法规和合格评定程序的最终文本和对现行技术法规和合格评定程序的最终修正文本。

8. 每一缔约方应保证可通过官方网站或刊物获得直属中央政府的地区或地方政府的所有新技术法规和合格评定程序的最终文本和对现行技术法规和合格评定程序的最终修正文本，并在可行的限度内，关于新技术法规和合格评定程序的所有提案和关于修正现行技术法规和合格评定程序的所有提案，并最好整合到一单一网站。

9. 每一缔约方应将关于符合相关国际标准、指南或建议(如有)中的技术内容且可能对贸易产生重大影响的新技术法规和合格评定程序的提案按照根据《TBT 协定》第 2.9 条或第 5.6 条设立的程序作出通知。

10. 尽管有第 9 款的规定，但是如一缔约方出现或威胁出现安全、健康、环境保护或国家安全的紧急问题，则该缔约方可将符合相关国际标准、指南和建议(如有)技术内容的新技术法规和合格评定程序按照根据《TBT 协定》第 2.10 条或第 5.7 条设立的程序在法规或程序采用之时作出通知。

11. 每一缔约方应努力将直属中央政府的地区或地方政府(视情况而定)提出的关于符合相关国际标准、指南或建议(如有)中的技术内容且可能对贸易产生重大影响的新技术法规和合格评定程序的提案按照根据《TBT 协定》第 2.9 条或第 5.6 条设立的程序作出通知。

[4] 为进一步明确，一缔约方可通过保证本款中的拟议和最终措施在 WTO 官方网址公布或通过其他方法通过该网站提供而遵守这一义务。

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:

12. 为确定一拟议的技术法规或合格评定程序是否可能对贸易产生重大影响且是否应依照《TBT 协定》第 2.9 条、第 2.10 条、第 3.2 条、第 5.6 条、第 5.7 条或第 7.2 条或本章作出通知，一缔约方应考虑，除其他因素外，与之相关的可能经修订的《自 1995 年 1 月 1 日以来 WTO 技术性贸易壁垒委员会通过的决定和建议》(G/TBT/1/Rev.12)。

13. 依照《TBT 协定》第 2.9 条、第 3.2 条、第 5.6 条或第 7.2 条或本章发布通知和提交通知的一缔约方应：

(a) 在通知中包括对提案目标及其如何处理这些目标的说明；及

(b) 在通知 WTO 成员的同时，通过依照《TBT 协定》第 10 条设立的咨询点将通知和提案通过电子方式传送其他缔约方。

14. 每一缔约方应通常给予另一缔约方或另一缔约方的利害关系人自其根据第 13 款传送一提案之日起 60 天时间对该提案提出书面评论。一缔约方应考虑另一缔约方或另一缔约方的利害关系人关于延长评论期的任何合理请求。鼓励有能力的缔约方将时限延长至 60 天以上，例如 90 天。

15. 鼓励每一缔约方在评论期结束与采用通知的技术法规或合格评定程序之间提供充足时间供其考虑收到的评论并准备答复。

16. 每一缔约方应努力在一技术法规或合格评定程序的最终文本通过或公布之时对最终文本作出通知，作为对根据《TBT 协定》第 2.9 条、第 3.2 条、第 5.6 条或第 7.2 条或本章提交的拟议措施原通知的补遗。

17. 依照《TBT 协定》第 2.10 条或第 5.7 条或本章提交通知的一缔约方，应同时将该通知和技术法规或合格评定程序的文本通过第 13 款(b)项中所指的咨询点通过电子方式传送给其他缔约方。

18. 不迟于可能对贸易产生重大影响的一最终技术法规或合格评定程序公布之日，每一缔约方应最好通过电子方式：

(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;[5]

(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

[5] 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.

(a) 公开提供关于目标和最终技术法规或合格评定程序如何实现上述目标的说明；

(b) 尽快但不迟于收到另一缔约方请求后 60 天提供关于该缔约方在制定最终技术法规或合格评定程序过程中曾考虑的替代方法(如有)及该缔约方所选方法的优点的说明；[5]

(c) 公开提供该缔约方对所收到的关于技术法规或合格评定程序提案的评论意见中重要或实质问题的答复；以及

(d) 尽快但不迟于收到另一缔约方请求后 60 天内提供关于该缔约方对技术法规或合格评定程序的提案所作重要修改(如有)的说明，包括针对评论意见所作的重要修改。

19. 在《TBT 协定》附件 3 的 J 款基础上，每一缔约方应保证其中央政府标准化机构的工作计划，包含其目前正在制定的标准和已经采用的标准可通过中央政府标准化机构的网站或第 6 款中所指的网站获得。

第 8.8 条 遵守技术法规和合格评定程序的期限

1. 就实施《TBT 协定》第 2.12 条和第 5.9 条而言，“合理时间间隔”通常指一段不少于 6 个月的期限，除非这一时限无法实现技术法规或有关合格评定程序的要求所追求的合法目标。

2. 如可行且适当，每一缔约方应努力在最终技术法规和合格评定程序的公布和生效之间提供 6 个月以上的时间间隔。

3. 除第 1 款和第 2 款外，在为一具体技术法规或合格评定程序设置“合理时间间隔”时，每一缔约方应保证对供应商提供的合理期限，在这种情况下，能使其在具体技术法规或合格评定程序

[5] 为进一步明确，不得要求任何缔约方在最终技术法规或合格评定程序公布之日前提供(b)项或(d)项下替代方法或重大修改的说明。

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;

生效日之前证明其货物符合技术法规或标准的相关要求。在这样做时，每一缔约方应努力考虑供应商可获得的资源。

第 8.9 条 合作和贸易便利化

1. 在《TBT 协定》第 5 条、第 6 条和第 9 条基础上，缔约方认识到存在一系列广泛的机制可便利合格评定结果的接受。在此方面，一缔约方可：

(a) 对于具体技术法规，实施对位于自己领土内和另一缔约方领土内的机构进行的合格评定程序的结果的相互承认；

(b) 承认认可机构或合格评定机构之间的现行区域和国际互认安排；

(c) 使用认可程序，特别是国际认可制度，授予合格评定机构资质；

(d) 指定合格评定机构或承认另一缔约方指定的合格评定机构；

(e) 单方面承认在另一缔约方领土内进行的合格评定程序的结果；以及

(f) 接受供应商符合性声明。

2. 缔约方认识到存在一系列广泛机制可支持更大程度的监管协调并消除本区域内不必要的技术性贸易壁垒，包括：

(a) 监管对话和合作，特别是：

(i) 就监管方法和实践交流信息；

(ii) 促进良好规则实践的使用以提高技术法规、标准和合格评定程序的效率和有效性；

(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.

(iii) 根据双方同意的条款和条件，提供技术建议和援助，以改进与技术法规、标准、合格评定程序和计量的制定、实施和审议相关的做法；或

(iv) 根据双方同意的条款和条件，提供技术援助和合作，以进行能力建设并支持本章的实施；

(b) 国家标准与相关国际标准更大程度的协调，但不适合或无效的情况除外；

(c) 促进更多使用相关国际标准、指南和建议作为技术法规和合格评定程序的根据；以及

(d) 促进作为等效技术法规接受另一缔约方的技术法规。

3. 对于第 1 款和第 2 款中所列机制，缔约方认识到在指定的监管背景下对适当机制的选择取决于多种因素，例如所涉产品和部门、贸易量和流向、缔约方各自监管者之间的关系、追求的合法目标和这些目标无法实现的风险。

4. 缔约方应加强关于机制的交流和合作以便利合格评定结果的接受、支持更大程度的监管协调以及取消本区域内不必要的技术性贸易壁垒。

5. 应另一缔约方请求，一缔约方应适当考虑本章下的任何特定部门合作提案。

6. 在《TBT 协定》第 2.7 条基础上，应另一缔约方请求，一缔约方应说明其未作为等效技术法规而接受该另一缔约方的技术法规的理由。

7. 缔约方应鼓励其各自负责标准化、合格评定、认可和计量的机构之间开展合作，无论此类机构属公共还是私有，以期处理本章所涵盖的事项。

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.

第 8.10 条 信息交流和技术讨论

1. 一缔约方可请求另一缔约方提供关于本章项下产生的任何事项的信息。收到请求的一缔约方应在一合理期限内提供该信息，且如可能，通过电子方式提供。

2. 一缔约方可请求与另一缔约方进行技术讨论，以期解决本章项下产生的任何事项。

3. 为进一步明确，对于直属中央政府的地区或地方政府(视情况而定)的可能对贸易产生重大影响的技术法规或合格评定程序，一缔约方可请求与另一缔约方就这些事项进行技术讨论。

4. 相关缔约方应在提出请求之日后 60 天内讨论所提事项。如提出请求的缔约方认为该事项紧急，则可请求在更短的时限内进行任何讨论。作出回应的缔约方应对此种请求给予积极考虑。

5. 缔约方应努力尽快解决该事项，同时认识到解决问题所需时间将取决于多种因素，且可能无法通过技术讨论解决每一事项。

6. 除非参加技术讨论的缔约方另有议定，否则讨论及讨论过程中交流的任何信息应保密且不得损害参加讨论的缔约方在本协定、《WTO 协定》或双方均为参加方的其他协定项下的权利和义务。

7. 信息请求或技术讨论及交流请求应通过根据第 27.5 条(联络点)指定的各自联络点进行传递。

第 8.11 条 技术性贸易壁垒委员会

1. 缔约方特此设立技术性贸易壁垒委员会(委员会)，由每一缔约方的政府代表组成。

2. 通过该委员会，缔约方应加强在技术法规、标准和合格评定程序领域的联合工作，以期便利缔约方之间的贸易。

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

3. 该委员会的职能可包括：

(a) 监督本章的实施和运用，包括根据本章议定的任何其他承诺，并确定根据第 27 章(管理和机构条款)对这些承诺的任何可能修正或解释；

(b) 监督根据第 8.10.2 条(信息交流和技术讨论)提出的对本章下产生的事项所进行的任何技术讨论；

(c) 决定本章下未来工作中具有共同利益的优先领域，并考虑关于特定部门新倡议或其他倡议的提案；

(d) 鼓励缔约方之间就与本章有关的事项开展合作，包括技术法规、标准和合格评定程序的制定、审议或修改；

(e) 鼓励在缔约方领土内的非政府机构之间以及缔约方领土内的政府机构与非政府机构之间就与本章有关的事项开展合作；

(f) 便利技术能力需求的确定；

(g) 鼓励缔约方与其相关非政府机构之间交流信息，如适当，就在制定标准、指南、建议、政策或与本章相关的其他程序的非政府、区域、诸边和多边机构或系统中正在讨论的事项制定共同方法；

(h) 应一缔约方请求，鼓励缔约方之间就非缔约方的特定技术法规、标准和合格评定程序以及系统性问题交流信息，以期形成共同方法；

(i) 采取缔约方认为将协助其实施本章和《TBT 协定》的任何其他步骤；

(j) 根据《TBT 协定》项下的任何进展情况审议本章，并根据这些发展情况制定对本章进行修正的建议；以及

(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).

(k) 向自贸协定委员会报告本章的实施和运用情况。

4. 委员会可设立工作组以履行其职能。

5. 在确定委员会将采取开展的活动时，委员会应考虑在其他场合正在开展的工作，以期保证委员会所开展的活动不会对该工作造成不必要的重复。

6. 委员会应在本协定生效之日起 1 年内及此后按缔约方所决定的日期召开会议。

第 8.12 条 联络点

1. 依照第 27.5 条(联络点)，每一缔约方对于本章下产生的事项应指定并通知一联络点。

2. 一缔约方应将其联络点的任何变化或相关官员的具体信息迅速通知其他缔约方。

3. 每一联络点的职责应包括：

(a) 与其他缔约方的联络点进行沟通，包括便利讨论、请求及就本章下产生的事项及时交流信息；

(b) 与其领土内的相关政府机构，包括监管机构，就与本章有关的相关事项进行沟通并协调其参与；

(c) 与其领土内的利害关系人就与本章有关的相关事项进行磋商，如适当，与之进行协调；以及

(d) 承担委员会规定的任何额外职责。

第 8.13 条 附件

1. 关于药品、化妆品、医疗设备和预包装食品和食品添加剂专有配方的附件的范围列在每一附件中。本章其他附件与第 8.3 条(范围)中所列范围相同。

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.

2. 本章每一附件中所列权利和义务仅适用于附件中规定的部门，且不得影响任何缔约方在任何其他附件下的权利或义务。

3. 除非缔约方另有议定，否则不迟于本协定生效之日后 5 年及此后至少每 5 年一次，委员会应：

(a) 审议附件的实施情况，以期增强或改进附件，且如适当，提出建议以加强缔约方在附件所涵盖部门中中各自技术法规、标准和合格评定程序的协调；及

(b) 考虑制定关于其他部门的附件是否可促进本章或本协定目标的实现并决定是否向自贸协定委员会建议缔约方启动谈判以达成涵盖这些部门的附件。

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.[6]

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

[6] For the United States, the alcohol content of wine must be not less than seven per cent and not more than 24 per cent.

附件 8-A
葡萄酒和蒸馏酒

1. 本附件应适用于葡萄酒和蒸馏酒。

2. 就本附件而言：

容器指用于零售葡萄酒或蒸馏酒的任何瓶、桶、木桶或其他封闭置物容器，不考虑其尺寸或制作材质；

蒸馏酒指可饮用的酒精蒸馏液，包括白酒、威士忌、朗姆酒、白兰地、杜松子酒、龙舌兰酒、麦斯卡尔酒及这些酒类所有供消费用的稀释物或混合物；

标签指在葡萄酒或蒸馏酒主容器上书写、印刷、模印、标记、凸印、压印或牢固粘贴在主容器上的任何品牌、标识、图画或其他描述性材料；

酿酒方法指酿酒原料、工序、处理和工艺，但不包括用于最终销售的加贴标签、装瓶或包装；

单一视野指无需转动容器即可看到的一主容器表面的任何部分，但其底部和盖除外；

供应商指生产商、进口商、出口商、装瓶商或批发商；以及

葡萄酒指依照经葡萄酒酿造国国内法律法规许可的酿酒方法，通过专门由新鲜葡萄、葡萄汁或源于新鲜葡萄的产品经完全或部分酒精发酵酿造的饮品。[6]

3. 每一缔约方应使其有关葡萄酒和蒸馏酒的国内法律法规的信息可公开获得。

4. 一缔约方可要求一供应商保证该缔约方所要求置于葡萄酒或蒸馏酒标签上的声明内容为：

(a) 清晰、具体、真实、准确且不会误导消费者；及

[6] 对于美国，葡萄酒酒精含量不得小于 7%、大于 24%、

(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

(b) 可为消费者所易读；及

且此类标签须牢固粘贴。

5. 如一缔约方要求供应商在蒸馏酒标签上标示信息，则该缔约方应允许供应商在蒸馏酒容器粘贴的副标签上标示该信息。每一缔约方应允许供应商在进口之后、但在该产品在该缔约方领土内许诺销售之前，在进口蒸馏酒容器上粘贴副标签，并可要求供应商在海关放行之前粘贴副标签。为进一步明确，一缔约方可要求副标签上标示的信息符合第 4 款中的要求。

6. 每一缔约方应允许在葡萄酒或蒸馏酒标签上标示的按体积计的酒精成分以酒精量(alc/vol)表示，例如 12% alc/vol 或 alc12%vol，并以至多保留一位小数的百分比标识，例如 12.1%。

7. 每一缔约方应允许供应商使用“葡萄酒”一词作为产品名称。每一缔约方可要求供应商在葡萄酒标签上标示关于葡萄酒类型、类别、等级或分类等额外信息。

8. 对于葡萄酒标签，每一缔约方应允许第 10 款(a)项至(d)项中所列信息出现在葡萄酒容器的单一视野中。如这一信息出现在单一视野中，则该缔约方关于放置这一信息的要求即达到。每一缔约方应接受出现在单一视野外的符合该缔约方法律、法规和要求的任何此种信息。

9. 尽管有第 8 款，但是对于少部分不常用的容器尺寸，一缔约方可要求净含量显示在主要显示版面上，如该缔约方的法律或法规特别要求。

10. 如一缔约方要求葡萄酒标签标示除下列之外的其他信息：

(a) 产品名称；

(b) 原产地；

(c) 净含量；或

(d) 酒精含量，

则其应允许供应商在葡萄酒容器上粘帖的副标签上标示此类信息。每一缔约方应允许供应商在进口之后、但在产品在该缔约方

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[7] 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.

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

领土内许诺销售之前，在进口葡萄酒容器上粘帖副标签，并可要求供应商在海关放行之前粘帖副标签。为进一步明确，一缔约方可要求副标签上的信息符合第 4 款中所列要求。

11. 就第 4 款、第 5 款和第 10 款而言，如进口葡萄酒或蒸馏酒容器有一个以上标签，则缔约方可要求每一标签均可见且不会混淆其他标签上的强制信息。

12. 如一缔约方有一种以上官方语文，则该缔约方可要求葡萄酒或蒸馏酒标签上的信息使用每一种官方语文以同等显著程度显示。

13. 每一缔约方应允许供应商在葡萄酒或蒸馏酒容器上放置批次识别编码，条件是编码清晰、具体、真实、准确且不引起误解，并应允许供应商确定：

(a) 在容器上何处放置批次识别编码，只要编码不覆盖标签所印基本信息；及

(b) 具体字体大小、可读短句和编码格式，只要批次识别编码可通过物理或电子方式辨识。

14. 一缔约方可对去除或故意损毁供应商提供并放置于容器上的批次识别编码的行为予以处罚。

15. 任何缔约方不得要求供应商在葡萄酒或蒸馏酒的容器、标签或包装上标示下列任何信息：

(a) 生产或制造日期；

(b) 有效日期；

(c) 保质期；或

(d) 最迟销售日期，

但是对于由于包装或容器或易腐成分的添加而使产品的保质期或有效日期比消费者所通常预期的更短，例如盒装葡萄酒或单次分量葡萄酒，一缔约方可要求供应商在产品[7]上标示保质期或有效日期。

[7] 对于秘鲁，小于 10 % alc/vol 的所有蒸馏酒必须标示保质期。

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.[8]

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.[9]

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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[8] 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*.

[9] 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.

16. 任何缔约方不得要求供应商在葡萄酒或蒸馏酒容器、标签或包装上放置商标或商品名的译文。

17. 任何缔约方不得仅根据葡萄酒标签包括描述葡萄酒或与葡萄酒酿造相关的下列描述词或形容词而阻止源自其他缔约方的葡萄酒进口：酒庄(chateau)、经典的(classic)、葡萄园(clos)、柔滑的(cream)、有酒渣的(crusted/crusting)、精美的(fine)、迟装型年份酒(late bottled vintage)、高贵的(noble)、珍藏(reserve)、宝石红(ruby)、特藏(special reserve)、索莱拉(solera)、级别较高的(superior)、酒泥陈酿(sur lie)、陈年黄色波特酒(tawny)、年份(vintage)或年份特征(vintage character)。本款不得适用于在 2003 年 2 月前与另一个或一组国家订立协议要求在其领土内销售的葡萄酒标签上限制使用此类术语的缔约方。[8]

18. 任何缔约方不得要求供应商在葡萄酒的标签或容器上披露酿酒方法，除非为满足与该酿酒方法有关的人类健康或安全的合法目标。

19. 每一缔约方应允许葡萄酒标为 Icewine, ice wine, ice-wine(冰酒)或这些术语的类似变形，仅当该葡萄酒专门使用在葡萄藤上自然冻结的葡萄酿造。[9]

20. 每一缔约方应努力使其对任何具体类型、类别、等级或分类的蒸馏酒的质量和特性要求仅根据用于生产该特定类型、类别、等级或分类的蒸馏酒的最低乙醇含量、原材料、添加成分以及生产程序。

21. 任何缔约方不得要求进口葡萄酒或蒸馏酒经葡萄酒或蒸馏酒在其领土内生产的缔约方的一官方认证机构或经该葡萄酒或蒸馏酒在其领土内生产的缔约方所承认的一认证机构就下列事项进行认证：

(a) 葡萄酒的年份、品种和区域主张；或

(b) 蒸馏酒的原材料和生产工序，

[8] 本款中任何内容不得解释为要求加拿大以不符合其在经修正的《欧盟-加拿大葡萄酒协定》附件 5 之 A 条(3)项下义务的方式适用本款。本款中任何内容不得解释为要求马来西亚以不符合根据马来西亚《1983 年食品法》制定的《1985 年食品法规》法规 18(1A)的方式适用本款。

[9] 对于日本，这一义务通过国内生产商实施订于 1986 年 12 月 23 日并经修正的“本国葡萄酒标签标准”得以满足。以于新西兰，本款中的义务将在本协定对新西兰生效之日后 3 年生效。一旦生效，新西兰应通过保证自新西兰出口的葡萄酒标为 icewine, ice wine, ice-wine(冰酒)或这些术语的类似变形以实施该义务，仅当此种葡萄酒专门使用在葡萄藤上自然冻结的葡萄酿造。

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.

但是如葡萄酒或蒸馏酒在其领土内生产的缔约方要求此种认证，则该缔约方可要求葡萄酒或蒸馏酒就(a)项或(b)项进行认证；如该缔约方对葡萄酒的年份、品种或区域主张有合理合法关注，则可要求葡萄酒就(a)项进行认证；如认证是核实关于酒龄、原产地或特性标准等所必需的，则可要求蒸馏酒就(b)项进行认证。

22. 如一缔约方认为葡萄酒认证是为保护人类健康或安全或为实现其他合法目标所必需的，则该缔约方应考虑《食品法典委员会关于设计、生产、发行及使用通用官方认证的指导方针》(CAC/GL 38-2001)，特别是使用经不时修正的关于官方证书和官方承认证书的官方证书通用示范。

23. 一缔约方通常应允许葡萄酒或蒸馏酒供应商仅随一特定品牌、生产商和批次的首批装运货物提交任何要求的认证、测试结果或样品。如一缔约方要求供应商提交产品样本用于该缔约方评定与其技术法规或标准的合格性的程序，则其要求的样品数量不得大于完成相关合格评定程序所必需的最低数量。本规定中任何内容不阻止一缔约方对测试或认证结果进行核实，例如在一缔约方获悉一特定产品可能不合格的情况下。

24. 除非一缔约方发生或威胁发生健康或安全问题，否则一缔约方通常不得对在一技术法规、标准或合格评定程序生效之日前已投放该缔约方领土内市场的葡萄酒或蒸馏酒适用任何最终技术法规、标准或合格评定程序，条件是该产品在由负责该技术法规、标准或合格评定程序的主管机关规定的在该技术法规、标准或合格评定程序生效之日后的一期限内销售。

25. 如适当，每一缔约方应努力评估其他缔约方关于酿酒方法的法律、法规和要求，以期达成规定缔约方相互接受各自的酿酒方法监管机制的协议。

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.[10]

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

[10] For greater certainty, for the purposes of this section, a "product" is a good and does not include a financial instrument.

附件 8-B
信息和通信技术产品

A 节：使用密码术的信息和通信技术(ICT)产品

1. 本节应适用于使用密码术的信息和通信技术(ICT)产品。[10]

2. 就本节而言：

密码术指对数据进行变换的原理、手段或方法，目的在于掩藏其信息内容，防止其在不被识别的情况下被篡改或防止在未经授权的情况下被使用；且限于使用一个或多个秘密参数(例如加密变量)或相关密钥管理进行的信息转换；

加密术指将数据(明文)转换为一种此后不使用密码算法重新转换(密文)即无法易于理解的形式；

密码算法或**密码**指一种将密钥与明文混合生成密文的数学过程或公式；以及

密钥指与一密码算法一同使用的一参数，密码算法确定其运行方式，知悉密钥的实体可复制或逆转其运行，而不知悉密钥的实体则不能。

3. 对于使用密码术并设计用于商业应用的一产品，任何缔约方不得强制实施或设立一技术法规或合格评定程序，作为制造、出售、分销、进口或使用该产品的条件而要求该产品的制造商或供应商：

(a) 向该缔约方或缔约方领土内的人转让或使其可获取属制造商或供应商专有的且与该产品中的密码术相关的特定技术、生产工序或其他信息，例如一专用

[10] 为进一步明确，就本节而言，一“产品”为一货物，不包括金融工具。

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

密钥或其他秘密参数、算法说明或其他设计细节；

(b) 与其领土内的人合伙；或

(c) 使用或集成一特定密码算法或密码，

但该产品是由或为该缔约方的政府制造、出售、分销、进口或使用的情况除外。

4. 第 3 款不得适用于：(a)一缔约方采用或维持的与接入由该缔约方政府所有或控制的网络相关的要求，包括中央银行的要求；或(b)一缔约方根据与金融机构或市场有关的监督、调查或检查权力所采取的措施。

5. 为进一步明确，本节不得解释为阻止一缔约方的执法机关要求服务提供者使用由其控制的加密术，根据该缔约方的法律程序提供未加密的通信。

B 节：信息技术设备(ITE)产品的电磁兼容性

1. 本节应适用于信息技术设备(ITE)产品的电磁兼容性。

2. 就本节而言：

ITE 产品指主要功能为通过除无线电发射或接收之外的手段对数据或电信信息进行录入、存储、显示、检索、传送、处理、转换或控制(或以上各项的组合)的任何装置或系统或其组件，为进一步明确，主要功能为无线电发射或接收的作为任何产品或其组件除外；

电磁兼容性指一设备或系统在其电磁环境中可靠运行并不对其环境中的任何其他设备或系统产生无法忍受的电磁干扰的能力；以及

供应商符合性声明指供应商关于一产品根据对合格评定程序结果的评估而符合一特定标准或技术法规的证明。

3. 如一缔约方要求对一 ITE 产品符合一关于电磁兼容性的标

supplier's declaration of conformity.[11]

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.

[11] 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*.

准或技术法规作出积极保证，则应接受供应商符合性声明。[11]

4. 缔约方认识到一缔约方可要求进行测试以支持一供应商符合性声明，例如通过一经认可的独立实验室，要求对该供应商符合性声明进行注册，或要求提交支持该供应商符合性声明的必要证据。

5. 第 3 款中任何内容不得阻止一缔约方核实一供应商符合性声明。

6. 第 3 款不得适用于下列一产品：

(a) 一缔约方作为医疗设备、医疗设备系统或医疗设备组件或医疗设备系统的组件进行监管的产品；或

(b) 该缔约方证明存在该产品将对安全或无线电发射或接收装置或系统造成有害电磁干扰的高风险。

C 节：电信设备的区域合作活动

1. 本节应适用于电信设备。

2. 鼓励缔约方互相适用订于 1998 年 5 月 8 日 APEC《电信设备合格评定互认安排》(MRA-TEL)和订于 2010 年 10 月 31 日 APEC《技术要求等效性互认安排》(MRA-ETR)或其他安排以便利电信设备贸易。

[11] 本款中任何内容不得解释为要求墨西哥以不符合其《联邦计量和标准化法》的方式适用本款。

ANNEX 8-C

PHARMACEUTICALS

1. This Annex shall apply to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation[12] 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.

[12] 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.

附件 8-C
药品

1. 本附件应适用于中央政府机构对可能影响缔约方之间药品贸易的技术法规、标准、合格评定程序、销售许可[12]和通知程序的制定、采用和实施。本附件不得适用于一政府实体为其生产或消费要求所制定的技术规格或卫生或植物卫生措施。

2. 一缔约方在本附件下的义务应适用于该缔约方根据第 3 款定义为药品的任何产品。就本附件而言，一技术法规、标准、合格评定程序或销售许可的制定酌情包括对所涉风险的评估、采取措施处理这些风险的需要、对相关科学或技术信息的审议以及对替代方法的特性或设计的考虑。

3. 每一缔约方应规定其领土内需遵守其药品法律法规的产品范围并使这一信息可公开获得。

4. 认识到每一缔约方均需根据第 3 款规定的本附件涵盖的产品范围，就本附件而言，药品可包括人用药品或生物制剂，专门用于人类疾病或状况的诊断、治愈、缓解、治疗或预防或专门用于影响人类身体的结构或任何功能。

5. 每一缔约方应确定在其领土内授权监管药品的一个或多个机构，并使这一信息可公开获得。

6. 如一缔约方领土内一个以上机构授权监管药品，则该缔约方应检查这些机构的范围是否存在重叠或重复并采取合理措施消除对药品由此产生的任何不必要和重复的监管要求。

[12] 本附件对销售许可的适用不影响销售许可是否符合一技术法规、标准或合格评定程序的定义。

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

7. 缔约方应酌情通过相关国际倡议寻求合作，例如旨在实现协调的倡议，以及支持此类国际倡议的区域倡议，以提高各自药品法规和监管活动的协调。

8. 在制定或实施药品销售许可的法规时，每一缔约方应考虑通过国际合作努力制定的相关科学或技术指导文件。鼓励每一缔约方考虑与国际努力相协调的在区域范围内制定的科学或技术指导文件。

9. 对于药品制定、采用或实施不属技术法规或合格评定程序定义范围的一销售许可或通知程序或要素，每一缔约方应遵守《TBT 协定》第 2.1 条和第 5.1.1 条中所列义务。

10. 每一缔约方认识到申请人应负责向一缔约方提供充分信息供该缔约方对药品作出监管决定。

11. 每一缔约方应根据下列内容作出其关于是否对一特定药品授予销售许可的决定：

(a) 安全和疗效信息，包括，如适当，临床前和临床数据；

(b) 产品制造质量的信息；

(c) 与产品安全、疗效和使用相关的标签信息；以及

(d) 其他可能直接影响产品使用者健康或安全的事项。

为此目的，任何缔约方不得要求将有关产品的销售数据或相关财务数据作为此种决定的一部分。此外，每一缔约方应努力不要求提供价格数据作为此种决定的一部分。

12. 每一缔约方应以及时、合理、客观、透明和公正的方式管理对药品设立的任何销售许可程序，并确定和管理任何利益冲突以减轻任何连带风险。

(a) 每一缔约方应在一合理期限内向请求获得一药品销售许可的申请人提供其所作决定。缔约方认识到作

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.[13, 14]

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

[13] 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.

[14] 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.

出销售许可决定所需的合理期限可能受到一产品新颖性或可能产生的监管影响等因素的影响。

(b) 如一缔约方确定在其管辖范围内审核的一药品销售许可申请存在的缺陷已导致或将导致作出不予许可的决定，则该缔约方应告知请求获得销售许可的申请人并提供申请存在缺陷的理由。

(c) 如一缔约方对一药品要求销售许可，则该缔约方应保证任何销售许可决定可接受应销售许可申请人请求而援引的申诉或复议程序。为进一步明确，该缔约方可设立一申诉或复议程序，既可以是负责作出销售许可决定的监管机构的内部程序，例如争议解决或复议程序，或该监管机构外部的程序。

(d) 如一缔约方要求对以往已自该缔约方获得销售许可的药品进行定期重新许可，则该缔约方应在就定期重新许可作出决定前，允许该药品按照以往销售许可的条件继续保留在其市场上，除非该缔约方确定存在一重大健康或安全关注。[13,14]

13. 在制定药品监管要求时，一缔约方应考虑其可获得的资源和技术能力从而将可能造成下列影响的实施要求减至最低程度：

(a) 抑制保证药品安全、疗效或制造质量的程序的有效性；或

[13] 为进一步明确，缔约方认识到未及时提交的、包含不充分信息的、或在其他方面不符合一缔约方要求的重新许可申请对于重新许可决定而言属存在缺陷。

[14] 越南可通过如下方式遵守其在本款下的义务：即允许重新许可申请在销售许可失效前的 12 个月期限内提交，或销售许可失效日期前的一期限内提交，该期限应比《越南卫生部关于药品注册通知》中所规定的期限或随后的相关文件中该部对以往注册药品的重新许可或重新注册申请所给予的期限(以较长者为准)长 6 个月。

(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.[15]

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.

[15] For Viet Nam, this obligation shall not apply until January 1, 2019.

(b) 导致显著拖延关于在其市场销售的药品的销售许可。

14. 任何缔约方不得将一药品获得制造国中一监管机构的销售许可作为该产品获得该缔约方销售许可的条件。

15. 为进一步明确，一缔约方可接受另一监管机构先前颁发的销售许可作为一产品可能符合其要求的证据。如存在监管资源限制，一缔约方可要求将获得经由该缔约方确定并公布的多个参照国中一国的销售许可作为该产品获得该缔约方销售许可的条件。

16. 对于药品销售许可申请，每一缔约方应审核由请求获得销售许可的申请人以符合可能经修正的关于人用药品注册技术要求的国际协调会议《通用技术文件(CTD)》中原则的格式提交的安全、疗效和制造质量信息，同时认识到 CTD 不一定处理涉及与一缔约方关于批准一特定产品销售许可的决定相关的所有方面。[15]

17. 缔约方应寻求改进在药品检验方面的合作，且为此目的，对于在另一缔约方领土内的药品检验，每一缔约方应：

(a) 在开展一检验前通知其他缔约方，除非有合理理由相信这样做会损害检验的有效性；

(b) 如可行，允许另一缔约方主管机关的代表观察该检验；以及

(c) 在检验之后尽快将其结果通知该另一缔约方，如该结果将公开发布，则在不迟于发布前的一合理时间作出通知。如检验缔约方认为这些结果属机密性质而不应披露，则不要求该缔约方向该另一缔约方通知其结果。

18. 缔约方应寻求适用通过关于药品检验的国际共同努力所制定的相关科学指导文件。

[15] 对于越南，这一义务在 2019 年 1 月 1 月前不得适用。

ANNEX 8-D

COSMETICS

1. This Annex shall apply to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation[16] 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

[16] 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.

附件 8-D
化妆品

1. 本附件应适用于中央政府机构对可能影响缔约方之间化妆品贸易的技术法规、标准、合格评定程序、销售许可[16]和通知程序的制定、采用和实施。本附件不得适用于一政府实体为其生产或消费要求所制定的技术规格或卫生或植物卫生措施。

2. 一缔约方在本附件下的义务应适用于该缔约方根据第 3 款定义为化妆品的任何产品。就本附件而言，一项技术法规、标准、合格评定程序或销售许可的制定酌情包括对所涉风险的评估、采取措施处理这些风险的需要、对相关科学或技术信息的审议以及对替代方法的特征或设计的考虑。

3. 每一缔约方应规定其领土内需遵守其化妆品法律法规的产品范围并使这一信息可公开获得。

4. 认识到每一缔约方均需根据第 3 款规定本附件涵盖的产品范围，就本附件而言，化妆品可包括专门以涂抹、泼洒、滴洒、喷洒或以其他方式施用于包括唇齿在内的人体表面以达到清洁、美容、保养、提高吸引力或改变外观目的的产品。

5. 每一缔约方应确定在其领土内授权监管化妆品的一个或多个机构，并使这一信息可公开获得。

6. 如一缔约方领土内一个以上机构授权监管化妆品，则该缔约方应检查这些机构的范围是否存在重叠或重复并采取合理措施消除对化妆品由此产生的任何不必要和重复的监管要求。

7. 缔约方应酌情通过相关国际倡议寻求合作，例如旨在实现

[16] 本附件对销售许可的适用不影响销售许可是否符合一技术法规、标准或合格评定程序的定义。

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.

协调的倡议，以及支持此类国际倡议的区域倡议，以提高各自化妆品法规和监管活动的协调。

8. 在制定或实施化妆品法规时，每一缔约方应考虑通过国际合作努力制定的相关科学或技术指导文件。鼓励每一缔约方酌情考虑与国际努力相协调的在区域范围内制定的科学或技术指导文件。

9. 对于对化妆品制定、采用或实施的、但不属技术法规或合格评定程序定义范围内一销售许可或通知程序或要素，每一缔约方应遵守《TBT 协定》第 2.1 条和第 5.1.1 条中所列义务。

10. 每一缔约方应保证对化妆品的监管采取基于风险的方式。

11. 在将基于风险的方式应用到化妆品监管时，每一缔约方应考虑到化妆品一般预期对人类健康或安全造成的潜在风险低于医疗设备或药品。

12. 任何缔约方不得对仅颜色深浅或香味差异存在不同的化妆品实施单独的销售许可程序或子程序，除非一缔约方确定存在一重大健康或安全关注。

13. 每一缔约方应以及时、合理、客观、透明和公正的方式管理对化妆品设立的任何销售许可程序，并确定和管理任何利益冲突以减轻任何连带风险。

(a) 如一缔约方对一化妆品要求销售许可，则该缔约方应在一合理期限内向申请人提供其所作决定。

(b) 如一缔约方对一化妆品要求销售许可并确定在其管辖范围内审核的一化妆品销售许可申请存在的缺陷已导致或将导致作出不予许可的决定，则该缔约方应告知销售许可的申请人并提供申请存在缺陷的理由。

(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.[17]

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.

[17] 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.

(c) 如一缔约方对一化妆品要求销售许可，则该缔约方应保证任何销售许可决定可接受应销售许可申请人请求而援引申诉或复议程序。为进一步明确，该缔约方可设立一申诉或复议程序，既可以是负责作出销售许可决定的监管机构的内部程序，例如争议解决或复议程序，或该监管机构外部的程序。

(d) 如一缔约方已对其领土内一化妆品授予销售许可，则该缔约方不得对该产品适用定期重新评估程序作为保留其销售许可的条件。

14. 如一缔约方对一化妆品设立销售许可程序，则该缔约方应考虑用其他机制取代这一程序，例如自愿或强制通知和上市后监督。

15. 在制定化妆品监管要求时，一缔约方应考虑其可获得的资源和技术能力从而将可能造成下列影响的实施要求减至最低程度：

(a) 抑制保证化妆品安全或制造质量的程序的有效性；或

(b) 导致显著拖延关于在其市场销售的化妆品的销售许可。

16. 缔约方不得要求提交销售信息作为产品获得销售许可的条件，包括关于价格或成本的信息。

17. 一缔约方不得要求一化妆品以标签标明销售许可或通知号码。[17]

18. 任何缔约方不得将一化妆品获得制造国中一监管机构的销售许可作为该产品自该缔约方获得销售许可的条件。为进一步明确，本条不禁止一缔约方接受另一监管机构先前颁发的销售许可作为该产品可能符合其要求的证据。

[17] 本款不适用智利和秘鲁。在本协定生效之日起不超过 5 年的期限内，智利和秘鲁应以符合各自在本章和《TBT 协定》项下义务的方式，审议各自的标签要求以审查是否能够实施其他监管机制。应另一缔约方请求，智利和秘鲁应分别向委员会报告各自的审议情况。

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.

19. 任何缔约方不得要求化妆品附自由销售证明作为在该缔约方领土内销售、分销或出售的条件。

20. 如一缔约方要求化妆品制造商或供应商在产品标签上标示信息，则该缔约方应允许制造商或供应商在进口之后、但在该产品在该缔约方领土内许诺销售或供应之前，依照该缔约方国内要求，通过在产品上重新粘帖标签或使用副标签的方式标示所要求的信息。

21. 任何缔约方不得要求为确定化妆品的安全性而进行动物测试，除非不可获得评估安全性的有效替代方法。然而，一缔约方可在确定化妆品安全性时考虑动物测试的结果。

22. 如一缔约方制定或采用化妆品良好生产规范指南，则应使用化妆品的相关国际标准或其相关部分作为其指南的根据，除非这些国际标准或其相关部分对实现所追求的合法目标无效或不适当。

23. 在遵守其国内法律法规的前提下，每一缔约方应努力分享自化妆品上市后监督过程中得到的信息。

24. 每一缔约方应努力分享其自身或其相关机构关于化妆品成分的调查结果。

25. 每一缔约方应努力避免对仅颜色深浅或香味差异存在不同的化妆品进行重新测试或重新评估，除非为人类健康或安全目的而进行。

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[18] 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.

[18] 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.

附件 8-E
医疗设备

1. 本附件应适用于中央政府机构对可能影响缔约方之间医疗设备贸易的技术法规、标准、合格评定程序、销售许可[18]和通知程序的制定、采用和实施。本附件不得适用于一政府实体为其生产或消费要求所制定的技术规格或卫生或植物卫生措施。

2. 一缔约方在本附件下的义务应适用于该缔约方根据第 3 款定义为医疗设备的任何产品。就本附件而言，一技术法规、标准、合格评定程序或销售许可的制定酌情包括对涉及风险的评估、采取措施处理这些风险的需要、对相关科学或技术信息的审查以及对替代方法的特征或设计的考虑。

3. 每一缔约方应规定其领土内需遵守其医疗设备法律法规的产品范围并使这一类信息可公开获得。

4. 认识到每一缔约方均需根据第 3 款规定的本附件涵盖的产品范围，每一缔约方应以符合 2012 年 5 月 16 日全球协调工作组核准的可能经修正的《“医疗设备”和“体外诊断(IVD)医疗设备”术语的定义》中对“医疗设备”一词所赋予意义的方式，规定需遵守其医疗设备法律法规的产品范围。

5. 每一缔约方应确定在其领土内授权监管医疗设备的一个或多个机构，并使这一信息可公开获得。

6. 如一缔约方领土内一个以上机构授权监管医疗设备的，则该缔约方应检查此类机构的范围是否存在重叠或重复并采取合理措施消除对医疗设备由此产生的任何不必要和重复的监管要求。

[18] 本附件对销售许可的适用不影响销售许可是否符合一技术法规、标准或合格评定程序的定义。

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.

7. 缔约方应酌情通过相关国际倡议寻求合作，例如旨在实现协调的倡议，以及支持此类国际倡议的区域倡议，以增强各自医疗设备法规和监管活动的协调。

8. 在制定或实施医疗设备销售许可的法规时，每一缔约方应考虑通过国际合作努力制定的相关科学或技术指导文件。鼓励每一缔约方酌情考虑与国际努力相协调的在区域范围内制定的科学或技术指导文件。

9. 对于对医疗设备制定、采用和实施的、但不属技术法规或合格评定程序定义范围的一销售许可或通知程序或要素，每一缔约方应遵守《TBT 协定》第 2.1 条和第 5.1.1 条中所列义务。

10. 认识到不同医疗设备产生不同程度的风险，每一缔约方应根据风险对医疗设备进行分类，同时考虑相关科学因素。每一缔约方应保证，在其监管一医疗设备时，其对设备的监管符合该缔约方对该设备指定的分类。

11. 每一缔约方认识到申请人应负责向一缔约方提供充分信息供该缔约方对医疗设备作出监管决定。

12. 每一缔约方应根据下列内容作出其关于是否对一特定医疗设备授予销售许可的决定：

(a) 安全和疗效的信息，包括，如适当，临床数据；

(b) 产品功效、设计和制造质量的信息；

(c) 与产品安全、疗效和设备使用相关的标签信息；以及

(d) 其他可能直接影响设备使用者健康或安全的事项。

为此目的，任何缔约方不得要求提供有关医疗设备销售的销售、定价或相关财务数据。

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

13. 每一缔约方应以及时、合理、客观、透明和公正的方式管理对医疗设备设立的销售许可程序，并确定和管理任何利益冲突以减轻任何连带风险。

(a) 每一缔约方应在一合理期限内向请求获得一医疗设备销售许可的申请人提供其所作决定。缔约方认识到作出销售许可决定所需的合理时间可能受到一设备新颖性或可能产生的监管影响等因素的影响。

(b) 如一缔约方确定在其管辖范围内审核的一医疗设备销售许可申请存在的缺陷已导致或将导致作出不予许可的决定，则该缔约方应告知销售许可的申请人并提供申请存在缺陷的理由。

(c) 如一缔约方对一医疗设备要求销售许可，则该缔约方应保证任何销售许可决定接受应销售许可申请人请求而援引的申诉或复议程序。为进一步明确，该缔约方可设立一申诉或复议程序，既可以是负责作出销售许可决定的监管机构的内部程序，例如争议解决或复议程序，或监管机构外部的程序。

(d) 如一缔约方要求对以往已自该缔约方获得销售许可的医疗设备进行定期重新许可，则该缔约方应在就定期重新许可作出决定前，允许该医疗设备按照以往销售许可的条件继续保留在其市场上，除非该缔约方确定存在一重大健康或安全关注。

14. 在制定医疗设备监管要求时，每一缔约方应考虑其可获得的资源和技术能力从而将可能造成下列影响的实施要求减至最低程度：

(a) 抑制保证医疗设备安全、疗效或制造质量的程序的有效性；或

(b) 导致显著拖延关于在其市场销售的医疗设备的销售许可。

15. 任何缔约方不得将一医疗设备获得制造国中一监管机构的

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.

销售许可作为该医疗设备获得该缔约方销售许可的条件。

16. 为进一步明确，一缔约方可接受另一监管主管机构先前颁发的销售许可作为一医疗设备可能符合其要求的证据。如存在监管资源限制，一缔约方可要求将获得经由该缔约方确定并公布的多个参照国中一国的销售许可作为该产品获得该缔约方销售许可的条件。

17. 如一缔约方要求医疗设备的制造商或供应商在产品标签上标示信息，则该缔约方应允许制造商或供应商在进口之后、但在该设备在该缔约方领土许诺销售或供应之前，依照该缔约方国内要求，通过在设备上重新粘帖标签或使用副标签的方式标示所要求的信息。

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.

附件 8-F
预包装食品和食品添加剂的专有配方

1. 本附件应适用于中央政府机构对与预包装食品和食品添加剂相关的技术法规和标准的制定、采用和实施。本附件不得适用于一政府实体为其生产或消费要求所制定的技术规格或卫生与植物卫生措施。

2. 就本附件而言，“食品”、“食品添加剂”和“预包装”等术语与可能经修正的《国际食品法典委员会预包装食品标签通用标准》(CODEX STAN 1-1985)和《国际食品法典委员会作为食品添加剂销售的食品添加剂标签通用标准》(CODEX STAN 107-1981)中所列含义相同。

3. 在技术法规和标准的制定、采用和实施过程中收集与专有配方相关的信息时，每一缔约方应：

(a) 保证其信息要求限于实现其合法目标所必需的程度；及

(b) 保证在技术法规和标准的制定、采用和实施中产生的或与之相关而提供的、关于源自另一缔约方领土的产品信息的机密性应以与国内产品相同的方式和保护合法商业利益的方式得到遵守。

如一缔约方收集与专有配方相关的机密信息，则可依照其法律在行政和司法程序中使用这一信息，只要该缔约方在这些程序的过程中保持信息的机密性。

4. 第 3 款中任何内容不得阻止一缔约方依照可能经修正的 CODEX STAN 1-1985 和 CODEX STAN 107-1981，要求在标签上列出成分，除非这些标准对实现一合法目标无效或不适当。

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.

附件 8-G
有机产品

1. 如一缔约方正在制定或设立与供在其领土内销售或分销的有机产品的生产、加工或标签相关的技术法规、标准或合格评定程序，则本附件应适用该缔约方。

2. 鼓励每一缔约方采取步骤以：

(a) 就关于与有机生产、有机产品认证及相关控制体系相关的事项交流信息；及

(b) 与其他缔约方合作以制定、改进和加强与有机产品贸易相关的国际指南、标准和建议。

3. 如一缔约方维持与有机产品的生产、加工或标签相关的要求，则该缔约方应执行此类要求。

4. 鼓励每一缔约方尽快考虑另一缔约方提出的关于承认另一缔约方的有机产品的生产、加工或标签相关的技术法规、标准或合格评定程序或承认其等效性的请求。鼓励每一缔约方等效接受或承认与该另一缔约方的有机产品的生产、加工或标签相关的技术法规、标准或合格评定程序，条件是该缔约方确信该另一缔约方的技术法规、标准或合格评定程序可满足该缔约方技术法规、标准或合格评定程序的目标。如一缔约方不能等效接受或不承认与该另一缔约方的有机产品的生产、加工或标签相关的技术法规、标准或合格评定程序，则应该另一缔约方请求，该缔约方应说明理由。

5. 鼓励每一缔约方参与技术交流以支持与有机产品的生产、加工或标签相关的技术法规、标准或合格评定程序的改进及更大程度的协调。