

**GLOBAL ADMINISTRATIVE LAW RELATED PROVISIONS IN THE  
TRANS-PACIFIC PARTNERSHIP**

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*Explanatory Note: This descriptive document collates in full text those provisions in the Trans-Pacific Partnership Agreement (TPP) as initially concluded on 4 February 2016 which reflect aspects of global administrative law as developed in Benedict Kingsbury, Nico Krisch & Richard B. Stewart, *The Emergence of Global Administrative Law*, 68 *LAW & CONTEMP. PROB.* 15 (2005).*

*Some of these provisions were suspended in the renegotiation of the agreement without the United States as the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP), which entered into force on 30 December 2018. These are labeled accordingly. The document makes no claim to comprehensiveness or full accuracy and is mainly intended as an illustration of procedural requirements in trade and regulatory agreements and perhaps as a useful resource for other scholars.*

The suggested citation is Paul Mertenskötter, *Global Administrative Law Related Provisions in Trans-Pacific Partnership*, NYU IILJ MegaReg Project 2019 ([iilj.org/megareg/remote-control](http://iilj.org/megareg/remote-control)).

This document accompanies the theoretical account of treaty requirements for procedures as instruments of political control as developed in Paul Mertenskötter & Richard B. Stewart, *Remote Control: Treaty Requirements for Regulatory Procedures*, 104 *CORNELL L. REV.* 165-232 (2018).

**Contents**

<b>I.</b>	<b>Reforms to Domestic Rule-Making Procedures</b> .....	2
<b>II.</b>	<b>Reforms to Domestic Review of Rule-Making</b> .....	9
<b>III.</b>	<b>Technologies For Regulatory Governance</b> .....	11
<b>IV.</b>	<b>Institutions for Regulatory Coordination and Supervision of Regulation</b> .....	15
<b>V.</b>	<b>TPP’s Relation to Global Rule-Making</b> .....	23
<b>VI.</b>	<b>Labour</b> .....	24
<b>VII.</b>	<b>Environment</b> .....	28
<b>VIII.</b>	<b>Procedure for Pharmaceutical Patents</b> .....	32
<b>IX.</b>	<b>Fair and Equitable Treatment</b> .....	40
<b>X.</b>	<b>State to State Dispute Settlement</b> .....	42

## I. REFORMS TO DOMESTIC RULE-MAKING PROCEDURES

*The SPS Chapter has a detailed provision about transparency in SPS related rule-making procedures.*

### **Article 7.13: Transparency**

1. The Parties recognise the value of sharing information about their sanitary and phytosanitary measures on an ongoing basis, and of providing interested persons and other Parties with the opportunity to comment on their proposed sanitary and phytosanitary measures.
2. In implementing this Article, each Party shall take into account relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations.
3. A Party shall notify a proposed sanitary or phytosanitary measure that may have an effect on the trade of another Party, including any that conforms to international standards, guidelines or recommendations, by using the WTO SPS notification submission system as a means of notifying the other Parties.
4. Unless urgent problems of human, animal or plant life or health protection arise or threaten to arise, or the measure is of a trade-facilitating nature, a Party shall normally allow at least 60 days for interested persons and other Parties to provide written comments on the proposed measure after it makes the notification under paragraph 3. If feasible and appropriate, the Party should allow more than 60 days. The Party shall consider any reasonable request from an interested person or another Party to extend the comment period. On request of another Party, the Party shall respond to the written comments of the other Party in an appropriate manner.
5. The Party shall make available to the public, by electronic means in an official journal or on a website, the proposed sanitary or phytosanitary measure notified under paragraph 3, the legal basis for the measure, and the written comments or a summary of the written comments that the Party has received from the public on the measure.
6. If a Party proposes a sanitary or phytosanitary measure which does not conform to an international standard, guideline or recommendation, the Party shall provide to another Party, on request, and to the extent permitted by the confidentiality and privacy requirements of the Party's law, the relevant documentation that the Party considered in developing the proposed measure, including documented and objective scientific evidence that is rationally related to the measure, such as risk assessments, relevant studies and expert opinions.
7. A Party that proposes to adopt a sanitary or phytosanitary measure shall discuss with another Party, on request and if appropriate and feasible, any scientific or trade concerns that the other Party may raise regarding the proposed measure and the availability of alternative, less trade-restrictive approaches for achieving the objective of the measure.
8. Each Party shall publish, preferably by electronic means, notices of final sanitary or phytosanitary measures in an official journal or website.
9. Each Party shall notify the other Parties of final sanitary or phytosanitary measures through the WTO SPS notification submission system. Each Party shall ensure that the text or the notice of a final sanitary or phytosanitary measure specifies the date on which the measure takes effect and the legal basis for the measure. A Party shall also make available to another Party, on request, and to the extent permitted by the

confidentiality and privacy requirements of the Party's law, significant written comments and relevant documentation considered to support the measure that were received during the comment period.

10. If a final sanitary or phytosanitary measure is substantively altered from the proposed measure, a Party shall also include in the notice of the final sanitary or phytosanitary measure that it publishes, an explanation of:

(a) the objective and rationale of the measure and how the measure advances that objective and rationale; and

(b) any substantive revisions that it made to the proposed measure.

11. An exporting Party shall notify the importing Party through the contact points referred to in Article 7.6 (Competent Authorities and Contact Points) in a timely and appropriate manner:

(a) if it has knowledge of a significant sanitary or phytosanitary risk related to the export of a good from its territory;

(b) of urgent situations where a change in animal or plant health status in the territory of the exporting Party may affect current trade;

(c) of significant changes in the status of a regionalised pest or disease;

(d) of new scientific findings of importance which affect the regulatory response with respect to food safety, pests or diseases; and

(e) of significant changes in food safety, pest or disease management, control or eradication policies or practices that may affect current trade.

12. If feasible and appropriate, a Party should provide an interval of more than six months between the date it publishes a final sanitary or phytosanitary measure and the date on which the measure takes effect, unless the measure is intended to address an urgent problem of human, animal or plant life or health protection or the measure is of a trade-facilitating nature.

13. A Party shall provide to another Party, on request, all sanitary or phytosanitary measures related to the importation of a good into that Party's territory.

*In relation to conformity assessment, the TPP requires the Parties to publish the criteria and procedures to assess conformity assessment bodies and, if asked, to give reasons for its non-recognition of such conformity bodies.*

#### **Article 8.6 Conformity Assessment**

[...]

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.

*The TPP's TBT chapter includes an important transparency provision which requires Parties to allow "persons of the other Parties" to participate in domestic central government rule-making. These foreign persons are to be afforded national treatment in their participation rights.<sup>1</sup> From the perspective of third party interests, these provisions seem discriminatory, as only "persons of the other Parties" can rely on the TPP to have access to domestic rule-making procedures. As mentioned before, it will be interesting to see how broadly or narrowly defined a grouping the "persons of the other Parties" will be.*

#### **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 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 existing technical

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<sup>1</sup> TPP, Article 8.7.1

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.

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.

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

13. A Party that publishes a notice and that files a notification in accordance with Article 2.9, 3.2, 5.6 or 7.2 of the TBT Agreement or this Chapter shall:

(a) include in the notification an explanation of the objectives of the proposal and how it would address those objectives; and

(b) transmit the notification and the proposal electronically to the other Parties through their enquiry points established in accordance with Article 10 of the TBT Agreement, at the same time as it notifies WTO Members.

14. Each Party shall normally allow 60 days from the date it transmits a proposal under paragraph 13 for another Party or an interested person of another Party to provide comments in writing on the proposal. A Party shall consider any reasonable request from another Party or an interested person of another Party to extend the comment period. A Party that is able to extend a time limit beyond 60 days, for example 90 days, is encouraged to do so.

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

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

17. A Party that files a notification in accordance with Article 2.10 or 5.7 of the TBT Agreement and this Chapter shall, at the same time, transmit the notification and text of the technical regulation or conformity assessment procedure electronically to the other Parties through the enquiry points referred to in paragraph 13(b).

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

(a) make publicly available an explanation of the objectives and how the final technical regulation or conformity assessment procedure achieves them;

(b) provide as soon as possible, but no later than 60 days after receiving a request from another Party, a description of alternative approaches, if any, that the Party considered in developing the final technical regulation or conformity assessment procedure and the merits of the approach that the Party selected;

(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.

*The Intellectual Property Chapter also includes a short Transparency Provision*

#### **Article 18.9: Transparency**

1. Further to Article 26.2 (Publication) and Article 18.73.1 (Enforcement Practices with Respect to Intellectual Property Rights), each Party shall endeavour to make available on the Internet its laws, regulations, procedures and administrative rulings of general application concerning the protection and enforcement of intellectual property rights.

2. Each Party shall, subject to its law, endeavour to make available on the Internet information that it makes public concerning applications for trademarks, geographical indications, designs, patents and plant variety rights.

3. Each Party shall, subject to its law, make available on the Internet information that it makes public concerning registered or granted trademarks, geographical indications, designs, patents and plant variety rights, sufficient to enable the public to become acquainted with those registered or granted rights.

*The Transparency Chapter sets out general publication requirements for state actions.*

#### **Article 26.2: Publication**

1. Each Party shall ensure that its laws, regulations, procedures and administrative rulings of general application with respect to any matter covered by this Agreement are promptly published or otherwise made available in a manner that enables interested persons and Parties to become acquainted with them.

2. To the extent possible, each Party shall:

(a) publish in advance any measure referred to in paragraph 1 that it proposes to adopt; and

(b) provide interested persons and other Parties with a reasonable opportunity to comment on those proposed measures.

3. To the extent possible, when introducing or changing the laws, regulations or procedures referred to in paragraph 1, each Party shall endeavour to provide a reasonable period between the date when those laws, regulations or procedures, proposed or final in accordance with its legal system, are made publicly available and the date when they enter into force.

4. With respect to a proposed regulation<sup>2</sup> of general application of a Party's central level of government respecting any matter covered by this Agreement that is likely to affect trade or investment between the Parties and that is published in accordance with paragraph 2(a), each Party shall:

(a) publish the proposed regulation in an official journal, or on an official website, preferably online and consolidated into a single portal;

(b) endeavour to publish the proposed regulation:

(i) no less than 60 days in advance of the date on which comments are due; or

(ii) within another period in advance of the date on which comments are due that provides sufficient time for an interested person to evaluate the proposed regulation, and formulate and submit comments;

(c) to the extent possible, include in the publication under subparagraph (a) an explanation of the purpose of, and rationale for, the proposed regulation; and

(d) consider comments received during the comment period, and is encouraged to explain any significant modifications made to the proposed regulation, preferably on an official website or in an online journal.

5. Each Party shall, with respect to a regulation of general application adopted by its central level of government respecting any matter covered by this Agreement that is published in accordance with paragraph 1:

(a) promptly publish the regulation on a single official website or in an official journal of national circulation; and

(b) if appropriate, include with the publication an explanation of the purpose of and rationale for the regulation.

## II. REFORMS TO DOMESTIC REVIEW OF RULE-MAKING

*The Transparency Chapter has a general provision about the ability to review and appeal administrative actions.*

### **Article 26.3: Administrative Proceedings**

With a view to administering in a consistent, impartial and reasonable manner all measures of general application with respect to any matter covered by this Agreement, each Party shall ensure in its administrative proceedings applying measures referred to in Article 26.2.1 (Publication) to a particular person, good or service of another Party in specific cases that:

- (a) whenever possible, a person of another Party that is directly affected by a proceeding is provided with reasonable notice, in accordance with domestic procedures, of when a proceeding is initiated, including a description of the nature of the proceeding, a statement of the legal authority under which the proceeding is initiated and a general description of any issue in question;
- (b) a person of another Party that is directly affected by a proceeding is afforded a reasonable opportunity to present facts and arguments in support of that person's position prior to any final administrative action, when time, the nature of the proceeding and the public interest permit; and
- (c) the procedures are in accordance with its law.

### **Article 26.4: Review and Appeal**

1. Each Party shall establish or maintain judicial, quasi-judicial or administrative tribunals or procedures for the purpose of the prompt review and, if warranted, correction of a final administrative action with respect to any matter covered by this Agreement. Those tribunals shall be impartial and independent of the office or authority entrusted with administrative enforcement and shall not have any substantial interest in the outcome of the matter.

2. Each Party shall ensure that, with respect to the tribunals or procedures referred to in paragraph 1, the parties to a proceeding are provided with the right to:

- (a) a reasonable opportunity to support or defend their respective positions; and
- (b) a decision based on the evidence and submissions of record or, where required by its law, the record compiled by the relevant authority.

3. Each Party shall ensure, subject to appeal or further review as provided for in its domestic law, that the decision referred to in paragraph 2(b) shall be implemented by, and shall govern the practice of, the office or authority with respect to the administrative action at issue.

In the TPP's SPS Chapter, Parties are required, except in emergencies, to notify any proposed SPS Measures and to allow interested persons and other Parties to "provide written comments on the proposed measure". The written comments or a summary thereof are to be published.<sup>2</sup> The regulating Party only has an obligation, if so asked, to respond a commenting Party, not interested persons more generally.<sup>3</sup> With respect to the equivalence of SPS measures, domestic regulators, upon request, need to provide reasons for their determination that another Party's SPS measures are not equivalent to its own. This is an

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<sup>2</sup> TPP, Article 7.13.5.

<sup>3</sup> TPP, Article 7.13.4.

example of the accountability mechanism being only open to state parties. The extent to which economic interests can lobby a Party to demand reasons will depend on the country-specific circumstances.

In relation to Government Procurement, the TPP Parties are required to establish or maintain an impartial administrative or judicial authority that is independent of the procuring entities and which can review complaints about the Party's compliance with its TPP-based procurement obligations.<sup>4</sup>

The Labour chapter includes similar provisions requiring the Parties to provide for judicial review and enforcement of the Parties' labor laws for persons with a "recognised interest" under its law. The category of "recognized interests" may circumscribe both the categories of parties that can sue, as well as the substantive provisions that can be invoked. For example, it will depend on the domestic law's attitude toward international law, whether the Labor Chapter's commitments create "recognized interests" for purposes of the domestic law.

The Environment Chapter includes provisions requiring Parties to allow "an interested person residing or established in its territory" to request the Party's competent authorities to investigate alleged violations of environmental law.<sup>5</sup> The Parties are to consider these requests in accordance with its law.<sup>6</sup> Additionally, the Parties are to ensure the availability of administrative or judicial review for the enforcement of its environmental laws. The proceedings are to be "fair, equitable, [and] transparent" and have to comply with due process of law.<sup>7</sup> The Chapter moreover established specific consultation procedures for possible transgressions of the environmental commitments of the TPP.<sup>8</sup>

With respect to intellectual property protections, the Parties similarly commit to give rights holders access to "civil judicial procedures" allowing for the enforcement of any rights covered by the IP chapter.<sup>9</sup> With respect to granting producers of generics and biosimilars access to a market based on previous information, the accountability mechanisms are particularly strong. The "patent holder" is entitled, as per the agreement, to a notice about the application prior to approval.<sup>10</sup> Moreover, the patent holder is entitled to a process which grants adequate time to pursue administrative or judicial proceedings, including obtaining preliminary injunctions, in relation to a possible patent infringement.<sup>11</sup> The agreement does not define the "patent holder" which leaves the question presumably one of national law. To the extent that third-party producers are patent-holders, they may also benefit from these provisions (e.g. European pharmaceutical companies).

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<sup>4</sup> TPP, Article 15.22.1.

<sup>5</sup> TPP, Article 20.7.2.

<sup>6</sup> *Ibid.*

<sup>7</sup> TPP, Article 20.7.3.

<sup>8</sup> *See*, TPP, Articles 20.19-23.

<sup>9</sup> TPP, Article 18.74.

<sup>10</sup> TPP, Article 18.51.1(a).

<sup>11</sup> TPP, Article 18.51.1(b)-(c).

### III. TECHNOLOGIES FOR REGULATORY GOVERNANCE

#### **Regulatory Impact Assessment**

*Regulatory Impact Assessment is featured in a long article on the “Implementation of Core Good Regulatory Practices”*

#### **Article 25.5: Implementation of Core Good Regulatory Practices**

1. To assist in designing a measure to best achieve the Party’s objective, each Party should generally encourage relevant regulatory agencies, consistent with its laws and regulations, to conduct regulatory impact assessments when developing proposed covered regulatory measures that exceed a threshold of economic impact, or other regulatory impact, where appropriate, as established by the Party. Regulatory impact assessments may encompass a range of procedures to determine possible impacts.
2. Recognising that differences in the Parties’ institutional, social, cultural, legal and developmental circumstances may result in specific regulatory approaches, regulatory impact assessments conducted by a Party should, among other things:
  - (a) assess the need for a regulatory proposal, including a description of the nature and significance of the problem;
  - (b) examine feasible alternatives, including, to the extent feasible and consistent with laws and regulations, their costs and benefits, such as risks involved as well as distributive impacts, recognising that some costs and benefits are difficult to quantify and monetise;
  - (c) explain the grounds for concluding that the selected alternative achieves the policy objectives in an efficient manner, including, if appropriate, reference to the costs and benefits and the potential for managing risks; and
  - (d) rely on the best reasonably obtainable existing information including relevant scientific, technical, economic or other information, within the boundaries of the authorities, mandates and resources of the particular regulatory agency.
3. When conducting regulatory impact assessments, a Party may take into consideration the potential impact of the proposed regulation on SMEs.
4. Each Party should ensure that new covered regulatory measures are plainly written and are clear, concise, well organised and easy to understand, recognising that some measures address technical issues and that relevant expertise may be needed to understand and apply them.
5. Subject to its laws and regulations, each Party should ensure that relevant regulatory agencies provide public access to information on new covered regulatory measures and, where practicable, make this information available online.
6. Each Party should review, at intervals it deems appropriate, its covered regulatory measures to determine whether specific regulatory measures it has implemented should be modified, streamlined, expanded or repealed so as to make the Party’s regulatory regime more effective in achieving the Party’s policy objectives.
7. Each Party should, in a manner it deems appropriate, and consistent with its laws and regulations, provide annual public notice of any covered regulatory measure that it reasonably expects its regulatory agencies to issue within the following 12-month period.

8. To the extent appropriate and consistent with its law, each Party should encourage its relevant regulatory agencies to consider regulatory measures in other Parties, as well as relevant developments in international, regional and other fora when planning covered regulatory measures.

#### **Article 25.9: Notification of Implementation**

1. For the purposes of transparency, and to serve as a basis for cooperation and capacity building activities under this Chapter, each Party shall submit a notification of implementation to the Committee through the contact points designated pursuant to Article 27.5 (Contact Points) within two years of the date of entry into force of this Agreement for that Party and at least once every four years thereafter.

2. In its initial notification, each Party shall describe the steps that it has taken since the date of entry into force of this Agreement for that Party, and the steps that it plans to take to implement this Chapter, including those to:

(a) establish processes or mechanisms to facilitate effective interagency coordination and review of proposed covered regulatory measures in accordance with Article 25.4 (Coordination and Review Processes or Mechanisms);

(b) encourage relevant regulatory agencies to conduct regulatory impact assessments in accordance with Article 25.5.1 (Implementation of Core Good Regulatory Practices) and Article 25.5.2;

(c) ensure that covered regulatory measures are written and made available in accordance with Article 25.5.4 (Implementation of Core Good Regulatory Practices) and Article 25.5.5;

(d) review its covered regulatory measures in accordance with Article 25.5.6 (Implementation of Core Good Regulatory Practices); and

(e) provide information to the public in its annual notice of prospective covered regulatory measures in accordance with Article 25.5.7 (Implementation of Core Regulatory Practices).

3. In subsequent notifications, each Party shall describe the steps, including those set out in paragraph 2, that it has taken since the previous notification, and those that it plans to take to implement this Chapter, and to improve its adherence to it.

4. In its consideration of issues associated with the implementation and operation of this Chapter, the Committee may review notifications made by a Party pursuant to paragraph 1. During that review, Parties may ask questions or discuss specific aspects of that Party's notification. The Committee may use its review and discussion of a notification as a basis for identifying opportunities for assistance and cooperative activities to provide assistance in accordance with Article 25.7 (Cooperation).

#### **Equivalence Assessment**

*The chapter on Sanitary and Phytosanitary (SPS) measures includes more specific rules for regulatory decision-making, relating in particular to equivalence assessment and science and risk analysis.*

#### **Article 7.8: Equivalence**

1. The Parties acknowledge that recognition of the equivalence of sanitary and phytosanitary measures is an important means to facilitate trade. Further to Article 4 of the SPS Agreement, the Parties shall apply equivalence to a group of measures or on a systems-wide basis, to the extent feasible and appropriate. In determining the equivalence of a specific sanitary or phytosanitary measure, group of measures or on a systems-wide basis, each Party shall take into account the relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations.

2. On request of the exporting Party, the importing Party shall explain the objective and rationale of its sanitary or phytosanitary measure and clearly identify the risk the sanitary or phytosanitary measure is intended to address.
3. When an importing Party receives a request for an equivalence assessment and determines that the information provided by the exporting Party is sufficient, it shall initiate the equivalence assessment within a reasonable period of time.
4. When an importing Party commences an equivalence assessment, that Party shall promptly, on request of the exporting Party, explain its equivalence process and plan for making the equivalence determination and, if the determination results in recognition, for enabling trade.
5. In determining the equivalence of a sanitary or phytosanitary measure, an importing Party shall take into account available knowledge, information and relevant experience, as well as the regulatory competence of the exporting Party.
6. The importing Party shall recognise the equivalence of a sanitary or phytosanitary measure if the exporting Party objectively demonstrates to the importing Party that the exporting Party's measure:
  - (a) achieves the same level of protection as the importing Party's measure; or
  - (b) has the same effect in achieving the objective as the importing Party's measure.<sup>2</sup>
7. When an importing Party adopts a measure that recognises the equivalence of an exporting Party's specific sanitary or phytosanitary measure, group of measures or measures on a systems-wide basis, the importing Party shall communicate the measure it has adopted to the exporting Party in writing and implement the measure within a reasonable period of time.
8. The Parties involved in an equivalence determination that results in recognition are encouraged, if mutually agreed, to report the outcome to the Committee.
9. If an equivalence determination does not result in recognition by the importing Party, the importing Party shall provide the exporting Party with the rationale for its decision.

### **Risk Assessment**

*The SPS Chapter includes a provision about the Parties' obligations to conduct a risk assessment when taking sanitary or phytosanitary measures.*

#### **Article 7.9: Science and Risk Analysis**

1. The Parties recognise the importance of ensuring that their respective sanitary and phytosanitary measures are based on scientific principles.
2. Each Party shall ensure that its sanitary and phytosanitary measures either conform to the relevant international standards, guidelines or recommendations or, if its sanitary and phytosanitary measures do not conform to international standards, guidelines or recommendations, that they are based on documented and objective scientific evidence that is rationally related to the measures, while recognising the Parties' obligations regarding assessment of risk under Article 5 of the SPS Agreement.

3. Recognising the Parties' rights and obligations under the relevant provisions of the SPS Agreement, nothing in this Chapter shall be construed to prevent a Party from:

- (a) establishing the level of protection it determines to be appropriate;
- (b) establishing or maintaining an approval procedure that requires a risk analysis to be conducted before the Party grants a product access to its market; or
- (c) adopting or maintaining a sanitary or phytosanitary measure on a provisional basis.

4. Each Party shall:

- (a) ensure that its sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Parties where identical or similar conditions prevail, including between its own territory and that of other Parties; and
- (b) conduct its risk analysis in a manner that is documented and that provides interested persons and other Parties an opportunity to comment, in a manner to be determined by that Party.<sup>4</sup>

5. Each Party shall ensure that each risk assessment it conducts is appropriate to the circumstances of the risk at issue and takes into account reasonably available and relevant scientific data, including qualitative and quantitative information.

6. When conducting its risk analysis, each Party shall:

- (a) take into account relevant guidance of the WTO SPS Committee and international standards, guidelines and recommendations;
- (b) consider risk management options that are not more trade restrictive<sup>5</sup> than required, including the facilitation of trade by not taking any measure, to achieve the level of protection that the Party has determined to be appropriate; and
- (c) select a risk management option that is not more trade restrictive than required to achieve the sanitary or phytosanitary objective, taking into account technical and economic feasibility.

7. If an importing Party requires a risk analysis to evaluate a request from an exporting Party to authorise importation of a good of that exporting Party, the importing Party shall provide, on request of the exporting Party, an explanation of the information required for the risk assessment. On receipt of the required information from the exporting Party, the importing Party shall endeavour to facilitate the evaluation of the request for authorisation by scheduling work on this request in accordance with the procedures, policies, resources, and laws and regulations of the importing Party.

8. On request of the exporting Party, the importing Party shall inform the exporting Party of the progress of a specific risk analysis request, and of any delay that may occur during the process.

9. If the importing Party, as a result of a risk analysis, adopts a sanitary or phytosanitary measure that allows trade to commence or resume, the importing Party shall implement the measure within a reasonable period of time.

10. Without prejudice to Article 7.14 (Emergency Measures), no Party shall stop the importation of a good of another Party solely for the reason that the importing Party is undertaking a review of its sanitary or phytosanitary measure, if the importing Party permitted the importation of that good of the other Party when the review was initiated.

#### IV. INSTITUTIONS FOR REGULATORY COORDINATION AND SUPERVISION OF REGULATION

*For TPP, the central administering institution is the Trans-Pacific Partnership Commission (TPP Commission) composed of ministers or senior officials.*

##### **Article 27.1: Establishment of the Trans-Pacific Partnership Commission**

The Parties hereby establish a Trans-Pacific Partnership Commission (Commission), composed of government representatives of each Party at the level of Ministers or senior officials. Each Party shall be responsible for the composition of its delegation.

##### **Article 27.2: Functions of the Commission**

1. The Commission shall:

- (a) consider any matter relating to the implementation or operation of this Agreement;
- (b) review, within three years of the date of entry into force of this Agreement and at least every five years thereafter, the economic relationship and partnership among the Parties;
- (c) consider any proposal to amend or modify this Agreement;
- (d) supervise the work of all committees, working groups and any other subsidiary bodies established under this Agreement;
- (e) consider ways to further enhance trade and investment between the Parties;
- (f) establish the Rules of Procedure referred to in Article 28.13 (Rules of Procedure for Panels), and, where appropriate, amend those Rules;
- (g) review the roster of panel chairs established under Article 28.11 (Roster of Panel Chairs and Party Specific Lists) every three years and, when appropriate, constitute a new roster; and
- (h) determine whether this Agreement may enter into force for an original signatory notifying pursuant to Article 30.5.4 (Entry into Force).

2. The Commission may:

- (a) establish, refer matters to, or consider matters raised by, any *ad hoc* or standing committee, working group or any other subsidiary body;
- (b) merge or dissolve any committees, working groups or other subsidiary bodies established under this Agreement in order to improve the functioning of this Agreement;
- (c) consider and adopt, subject to completion of any necessary legal procedures by each Party, a modification to this Agreement of 1:
  - (i) the Schedules to Annex 2-D (Tariff Commitments), by accelerating tariff elimination;
  - (ii) the rules of origin established in Annex 3-D (Product-Specific Rules of Origin) and Annex 4 A (Textiles and Apparel Product-Specific Rules of Origin); or
  - (iii) the lists of entities, covered goods and services, and thresholds contained in each Party's Annex to Chapter 15 (Government Procurement);
- (d) develop arrangements for implementing this Agreement;

- (e) seek to resolve differences or disputes that may arise regarding the interpretation or application of this Agreement;
- (f) issue interpretations of the provisions of this Agreement;
- (g) seek the advice of non-governmental persons or groups on any matter falling within the Commission's functions; and
- (h) take any other action as the Parties may agree.

3. Pursuant to paragraph 1(b), the Commission shall review the operation of this Agreement with a view to updating and enhancing this Agreement, through negotiations, as appropriate, to ensure that the disciplines contained in this Agreement remain relevant to the trade and investment issues and challenges confronting the Parties.

4. In conducting a review pursuant to paragraph 3, the Commission shall take into account:

- (a) the work of all committees, working groups and any other subsidiary bodies established under this Agreement;
- (b) relevant developments in international fora; and
- (c) as appropriate, input from non-governmental persons or groups of the Parties.

### **Article 27.3: Decision-Making**

1. The Commission and all subsidiary bodies established under this Agreement shall take all decisions by consensus, except as otherwise provided in this Agreement, or as otherwise decided by the Parties.<sup>2</sup> Except as otherwise provided in this Agreement, the Commission or any subsidiary body shall be deemed to have taken a decision by consensus if no Party present at any meeting when a decision is taken objects to the proposed decision.

2. For the purposes of Article 27.2.2(f) (Functions of the Commission), a decision of the Commission shall be taken by agreement of all Parties. A decision shall be deemed to be reached if a Party which does not indicate agreement when the Commission considers the issue does not object in writing to the interpretation considered by the Commission within five days of that consideration.

### **Article 27.4: Rules of Procedure of the Commission**

1. The Commission shall meet within one year of the date of entry into force of this Agreement and thereafter as the Parties may decide, including as necessary to fulfil its functions under Article 27.2 (Functions of the Commission). Meetings of the Commission shall be chaired successively by each Party.

2. The Party chairing a session of the Commission shall provide any necessary administrative support for such session, and shall notify the other Parties of any decision of the Commission.

3. Except as otherwise provided in this Agreement, the Commission and any subsidiary body established under this Agreement shall carry out its work through whatever means are appropriate, which may include electronic mail or videoconferencing.

4. The Commission and any subsidiary body established under this Agreement may establish rules of procedures for the conduct of its work.

*The TBT Chapter requires Parties to provide information to other Parties about regulatory measures covered by the TBT chapter if asked to do so.*

**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.

[...]

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.

*For the SPS chapter, the TPP establishes the Committee on Sanitary and Phytosanitary Measures (CSPS).<sup>12</sup>*

**Article 7.5: Committee on Sanitary and Phytosanitary Measures**

1. For the purposes of the effective implementation and operation of this Chapter, the Parties hereby establish a Committee on Sanitary and Phytosanitary Measures (Committee), composed of government representatives of each Party responsible for sanitary and phytosanitary matters.

2. The objectives of the Committee are to:

(a) enhance each Party's implementation of this Chapter;

(b) consider sanitary and phytosanitary matters of mutual interest; and

(c) enhance communication and cooperation on sanitary and phytosanitary matters.

3. The Committee:

(a) shall provide a forum to improve the Parties' understanding of sanitary and phytosanitary issues that relate to the implementation of the SPS Agreement and this Chapter;

(b) shall provide a forum to enhance mutual understanding of each Party's sanitary and phytosanitary measures and the regulatory processes that relate to those measures;

(c) shall exchange information on the implementation of this Chapter;

(d) shall determine the appropriate means, which may include *ad hoc* working groups, to undertake specific tasks related to the functions of the Committee;

(e) may identify and develop technical assistance and cooperation projects between the Parties on sanitary and phytosanitary measures;

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<sup>12</sup> TPP, Article 8.11.1.

(f) may serve as a forum for a Party to share information on a sanitary or phytosanitary issue that has arisen between it and another Party or Parties, provided that the Parties between which the issue has arisen have first attempted to address the issue through discussions between themselves; and

(g) may consult on matters and positions for the meetings of the Committee on Sanitary and Phytosanitary Measures established under Article 12 of the SPS Agreement (WTO SPS Committee), and meetings held under the auspices of the Codex Alimentarius Commission, the World Organisation for Animal Health and the International Plant Protection Convention.

4. The Committee shall establish its terms of reference at its first meeting and may revise those terms as needed.

5. The Committee shall meet within one year of the date of entry into force of this Agreement and once a year thereafter unless Parties agree otherwise.

*The SPS chapter establishes a mechanism for Cooperative Technical Consultations (CTCs) between one or more requesting Parties and the responding Party to discuss SPS matters that may dampen trade.<sup>13</sup> These consultations are to include the relevant trade and regulatory agencies and are to be confidential, unless otherwise specified.<sup>14</sup> To the extent that rule-making initiatives, and first substantive determinations, are made in the CTCs, third parties may find it difficult to have their interests considered.*

#### **Article 7.17: Cooperative Technical Consultations**

1. If a Party has concerns regarding any matter arising under this Chapter with another Party, it shall endeavour to resolve the matter by using the administrative procedures that the other Party's competent authority has available. If the relevant Parties have bilateral or other mechanisms available to address the matter, the Party raising the matter shall endeavour to resolve the matter through those mechanisms, if it considers that it is appropriate to do so. A Party may have recourse to the Cooperative Technical Consultations (CTC) set out in paragraph 2 at any time it considers that the continued use of the administrative procedures or bilateral or other mechanisms would not resolve the matter.

2. One or more Parties (requesting Party) may initiate CTC with another Party (responding Party) to discuss any matter arising under this Chapter that the requesting Party considers may adversely affect its trade by delivering a request to the primary representative of the responding Party. The request shall be in writing and identify the reason for the request, including a description of the requesting Party's concerns about the matter, and set out the provisions of this Chapter that relate to the matter.

3. Unless the requesting Party and the responding Party (the consulting Parties) agree otherwise, the responding Party shall acknowledge the request in writing within seven days of the date of its receipt.

4. Unless the consulting Parties agree otherwise, the consulting Parties shall meet within 30 days of the responding Party's acknowledgement of the request to discuss the matter identified in the request, with the aim of resolving the matter within 180 days of the request if possible. The meeting shall be in person or by electronic means.

5. The consulting Parties shall ensure the appropriate involvement of relevant trade and regulatory agencies in meetings held pursuant to this Article.

<sup>13</sup> TPP, Article 7.17.1-4.

<sup>14</sup> TPP, Article 7.17.5&6.

6. All communications between the consulting Parties in the course of CTC, as well as all documents generated for CTC, shall be kept confidential unless the consulting Parties agree otherwise and without prejudice to the rights and obligations of any Party under this Agreement, the WTO Agreement or any other international agreement to which it is a party.

7. The requesting Party may cease CTC proceedings under this Article and have recourse to dispute settlement under Chapter 28 (Dispute Settlement) if:

(a) the meeting referred to in paragraph 4 does not take place within 37 days of the date of the request, or such other timeframe as the consulting Parties may agree under paragraphs 3 and 4; or 7-16

(b) the meeting referred to in paragraph 4 has been held.

8. No Party shall have recourse to dispute settlement under Chapter 28 (Dispute Settlement) for a matter arising under this Chapter without first seeking to resolve the matter through CTC in accordance with this Article.

*For the TBT chapter, the TPP establishes the Committee on Technical Barriers to Trade (CTBT).<sup>15</sup>*

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

1. The Parties hereby establish a Committee on Technical Barriers to Trade (Committee), composed of government representatives of each Party.

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

3. The Committee's functions may include:

(a) monitoring the implementation and operation of this Chapter, including any other commitments agreed under this Chapter, and identifying any potential amendments to or interpretations of those commitments pursuant to Chapter 27 (Administrative and Institutional Provisions);

(b) monitoring any technical discussions on matters that arise under this Chapter requested pursuant to paragraph 2 of Article 8.10 (Information Exchange and Technical Discussions);

(c) deciding on priority areas of mutual interest for future work under this Chapter and considering proposals for new sector-specific initiatives or other initiatives;

(d) encouraging cooperation between the Parties in matters that pertains to this Chapter, including the development, review or modification of technical regulations, standards and conformity assessment procedures;

(e) encouraging cooperation between non-governmental bodies in the Parties' territories, as well as cooperation between governmental and non-governmental bodies in the Parties' territories in matters that pertains to this Chapter;

(f) facilitating the identification of technical capacity needs;

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<sup>15</sup> TPP, Article 8.11.1.

- (g) encouraging the exchange of information between the Parties and their relevant non-governmental bodies, if appropriate, to develop common approaches regarding matters under discussion in non-governmental, regional, plurilateral and multilateral bodies or systems that develop standards, guides, recommendations, policies or other procedures relevant to this Chapter;
  - (h) encouraging, on request of a Party, the exchange of information between the Parties regarding specific technical regulations, standards and conformity assessment procedures of non-Parties as well as systemic issues, with a view to fostering a common approach;
  - (i) taking any other steps the Parties consider will assist them in implementing this Chapter and the TBT Agreement;
  - (j) reviewing this Chapter in light of any developments under the TBT Agreement, and developing recommendations for amendments to this Chapter in light of those developments; and
  - (k) reporting to the Commission on the implementation and operation of this Chapter.
4. The Committee may establish working groups to carry out its functions.
  5. To determine what activities the Committee will undertake, the Committee shall consider work that is being undertaken in other fora, with a view to ensuring that any activities undertaken by the Committee do not unnecessarily duplicate that work.
  6. The Committee shall meet within one year of the date of entry into force of this Agreement and thereafter as decided by the Parties.

*The TPP also requires each party to designate a “Contact Point” for matters arising under the TBT Chapter:*

**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.

*The Committee on Regulatory Coherence (CRC)<sup>16</sup> is to coordinate the implementation of the Regulatory Coherence chapter and to identify future priorities. Crucially from the perspective of third parties, “the*

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<sup>16</sup> TPP, Article 25.6.1.

*Committee shall establish appropriate mechanisms to provide continuing opportunities for interested persons of the Parties to provide input on matters relevant to enhancing regulatory coherence.”<sup>17</sup> It will have to be determined, whether the “interested persons of the Parties” will cover resident aliens, subsidiary-corporations or international-NGOs that could themselves represent a wider set of interests.*

#### **Article 25.6: Committee on Regulatory Coherence**

1. The Parties hereby establish a Committee on Regulatory Coherence (Committee), composed of government representatives of the Parties.
2. The Committee shall consider issues associated with the implementation and operation of this Chapter. The Committee shall also consider identifying future priorities, including potential sectoral initiatives and cooperative activities, involving issues covered by this Chapter and issues related to regulatory coherence covered by other Chapters of this Agreement.
3. In identifying future priorities, the Committee shall take into account the activities of other committees, working groups and any other subsidiary body established under this Agreement and shall coordinate with them in order to avoid duplication of activities.
4. The Committee shall ensure that its work on regulatory cooperation offers value in addition to initiatives underway in other relevant fora and avoids undermining or duplicating such efforts.
5. Each Party shall designate and notify a contact point to provide information, on request by another Party, regarding the implementation of this Chapter in accordance with Article 27.5 (Contact Points).
6. The Committee shall meet within one year of the date of entry into force of this Agreement, and thereafter as necessary.
7. At least once every five years after the date of entry into force of this Agreement, the Committee shall consider developments in the area of good regulatory practices and in best practices in maintaining processes or mechanisms referred to in Article 25.4.1 (Coordination and Review Processes or Mechanisms), as well as the Parties’ experiences in implementing this Chapter with a view towards considering whether to make recommendations to the Commission for improving the provisions of this Chapter so as to further enhance the benefits of this Agreement.

#### **Article 25.7: Cooperation**

1. The Parties shall cooperate in order to facilitate the implementation of this Chapter and to maximise the benefits arising from it. Cooperation activities shall take into consideration each Party’s needs, and may include:
  - (a) information exchanges, dialogues or meetings with other Parties;
  - (b) information exchanges, dialogues or meetings with interested persons, including with SMEs, of other Parties;
  - (c) training programmes, seminars and other relevant assistance;
  - (d) strengthening cooperation and other relevant activities between regulatory agencies; and
  - (e) other activities that Parties may agree.
2. The Parties further recognise that cooperation between Parties on regulatory matters can be enhanced through, among other things, ensuring that each Party’s regulatory measures are centrally available.

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<sup>17</sup> TPP, Article 25.8.

**Article 25.8: Engagement with Interested Persons**

The Committee shall establish appropriate mechanisms to provide continuing opportunities for interested persons of the Parties to provide input on matters relevant to enhancing regulatory coherence.

## V. TPP'S RELATION TO GLOBAL RULE-MAKING

*The TBT includes provisions making explicit reference to other global rule-making venues and how TPP Parties should both utilize the standards set at these forums to the extent feasible and cooperate to influence the setting of standards in these forums.*

### **Article 8.5.3 International Standards, Guides and Recommendations**

1. The Parties recognise the important role that international standards, guides and recommendations can play in supporting greater regulatory alignment, good regulatory practice and reducing unnecessary barriers to trade.
2. In this respect, and further to Articles 2.4 and 5.4 and Annex 3 of the TBT Agreement, to determine whether there is an international standard, guide or recommendation within the meaning of Articles 2 and 5 and Annex 3 of the TBT Agreement, each Party shall apply the *Decisions and Recommendations adopted by the WTO Committee on Technical Barriers to Trade Since 1 January 1995 (G/TBT/1/Rev.12)*, as may be revised, issued by the WTO Committee on Technical Barriers to Trade.
3. The Parties shall cooperate with each other, when feasible and appropriate, to ensure that international standards, guides and recommendations that are likely to become a basis for technical regulations and conformity assessment procedures do not create unnecessary obstacles to international trade.

TPP calls on the Parties, to the extent appropriate, to “consider regulatory measures in other Parties, as well as relevant developments in international, regional and other fora when planning covered regulatory measures.”<sup>18</sup>

The TPP's SPS Committee has the mandate to “consult on matters and positions” for the WTO's SPS Committee, the Codex Alimentarius Commission, the World Organisation for Animal Health and the International Plant Protection Convention.<sup>19</sup> This intra-agreement cooperation may be to leverage the Parties' combined regulatory influence to shape the rules of the global economy generally. This cooperation of agreement members in global rule-making may be significant for third parties.

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<sup>18</sup> TPP, Article 25.5.8.

<sup>19</sup> TPP, Article 7.5.3(g).

## VI. LABOUR

### **Article 19.5: Enforcement of Labour Laws**

1. No Party shall fail to effectively enforce its labour laws through a sustained or recurring course of action or inaction in a manner affecting trade or investment between the Parties after the date of entry into force of this Agreement.
2. If a Party fails to comply with an obligation under this Chapter, a decision made by that Party on the provision of enforcement resources shall not excuse that failure. Each Party retains the right to exercise reasonable enforcement discretion and to make bona fide decisions with regard to the allocation of enforcement resources between labour enforcement activities among the fundamental labour rights and acceptable conditions of work enumerated in Article 19.3.1 (Labour Rights) and Article 19.3.2, provided that the exercise of that discretion, and those decisions, are not inconsistent with its obligations under this Chapter.
3. Nothing in this Chapter shall be construed to empower a Party's authorities to undertake labour law enforcement activities in the territory of another Party.

### **Article 19.8: Public Awareness and Procedural Guarantees**

1. Each Party shall promote public awareness of its labour laws, including by ensuring that information related to its labour laws and enforcement and compliance procedures is publicly available.
2. Each Party shall ensure that persons with a recognised interest under its law in a particular matter have appropriate access to impartial and independent tribunals for the enforcement of the Party's labour laws. These tribunals may include administrative tribunals, quasi-judicial tribunals, judicial tribunals or labour tribunals, as provided for in each Party's law.
3. Each Party shall ensure that proceedings before these tribunals for the enforcement of its labour laws: are fair, equitable and transparent; comply with due process of law; and do not entail unreasonable fees or time limits or unwarranted delays. Any hearings in these proceedings shall be open to the public, except when the administration of justice otherwise requires, and in accordance with its applicable laws.
4. Each Party shall ensure that:
  - (a) the parties to these proceedings are entitled to support or defend their respective positions, including by presenting information or evidence; and
  - (b) final decisions on the merits of the case:
    - (i) are based on information or evidence in respect of which the parties were offered the opportunity to be heard;
    - (ii) state the reasons on which they are based; and
    - (iii) are available in writing without undue delay to the parties to the proceedings and, consistent with its law, to the public.
5. Each Party shall provide that parties to these proceedings have the right to seek review or appeal, as appropriate under its law.

6. Each Party shall ensure that the parties to these proceedings have access to remedies under its law for the effective enforcement of their rights under the Party's labour laws and that these remedies are executed in a timely manner.

7. Each Party shall provide procedures to effectively enforce the final decisions of its tribunals in these proceedings.

8. For greater certainty, and without prejudice to whether a tribunal's decision is inconsistent with a Party's obligations under this Chapter, nothing in this Chapter shall be construed to require a tribunal of a Party to reopen a decision that it has made in a particular matter.

#### **Article 19.9: Public Submissions**

1. Each Party, through its contact point designated under Article 19.13 (Contact Points), shall provide for the receipt and consideration of written submissions from persons of a Party on matters related to this Chapter in accordance with its domestic procedures. Each Party shall make readily accessible and publicly available its procedures, including timelines, for the receipt and consideration of written submissions.

2. A Party may provide in its procedures that, to be eligible for consideration, a submission should, at a minimum:

(a) raise an issue directly relevant to this Chapter;

(b) clearly identify the person or organisation making the submission; and

(c) explain, to the degree possible, how and to what extent the issue raised affects trade or investment between the Parties.

3. Each Party shall:

(a) consider matters raised by the submission and provide a timely response to the submitter, including in writing as appropriate; and

(b) make the submission and the results of its consideration available to the other Parties and the public, as appropriate, in a timely manner.

4. A Party may request from the person or organisation that made the submission additional information that is necessary to consider the substance of the submission.

*In addition to the establishment of a Labour Council and Labour Contact Points, the TPP sets up mechanisms for public engagement and Party to Party labour consultations.*

#### **Article 19.14: Public Engagement**

1. In conducting its activities, including meetings, the Council shall provide a means for receiving and considering the views of interested persons on matters related to this Chapter.

2. Each Party shall establish or maintain, and consult, a national labour consultative or advisory body or similar mechanism, for members of its public, including representatives of its labour and business organisations, to provide views on matters regarding this Chapter.

#### **Article 19.15: Labour Consultations**

1. The Parties shall make every effort through cooperation and consultation based on the principle of mutual respect to resolve any matter arising under this Chapter.
2. A Party (requesting Party) may, at any time, request labour consultations with another Party (responding Party) regarding any matter arising under this Chapter by delivering a written request to the responding Party's contact point. The requesting Party shall include information that is specific and sufficient to enable the responding Party to respond, including identification of the matter at issue and an indication of the legal basis of the request under this Chapter. The requesting Party shall circulate the request to the other Parties through their respective contact points.
3. The responding Party shall, unless agreed otherwise with the requesting Party, reply to the request in writing no later than seven days after the date of its receipt. The responding Party shall circulate the reply to the other Parties and enter into labour consultations in good faith.
4. A Party other than the requesting Party or the responding Party (the consulting Parties) that considers that it has a substantial interest in the matter may participate in the labour consultations by delivering a written notice to the other Parties within seven days of the date of circulation by the requesting Party of the request for labour consultations. The Party shall include in its notice an explanation of its substantial interest in the matter.
5. The Parties shall begin labour consultations no later than 30 days after the date of receipt by the responding Party of the request.
6. In the labour consultations:
  - (a) each consulting Party shall provide sufficient information to enable a full examination of the matter; and
  - (b) any Party participating in the consultations shall treat any confidential information exchanged in the course of the consultations on the same basis as the Party providing the information.
7. Labour consultations may be held in person or by any technological means available to the consulting Parties. If labour consultations are held in person, they shall be held in the capital of the responding Party, unless the consulting Parties agree otherwise.
8. The consulting Parties shall make every attempt to arrive at a mutually satisfactory resolution of the matter through labour consultations under this Article, taking into account opportunities for cooperation related to the matter. The consulting Parties may request advice from an independent expert or experts chosen by the consulting Parties to assist them. The consulting Parties may have recourse to such procedures as good offices, conciliation or mediation.
9. In labour consultations under this Article, a consulting Party may request another consulting Party to make available personnel of its government agencies or other regulatory bodies with expertise in the matter that is the subject of the labour consultations.
10. If the consulting Parties are unable to resolve the matter, any consulting Party may request that the Council representatives of the consulting Parties convene to consider the matter by delivering a written request to the other consulting Party through its contact point. The Party making that request shall inform the other Parties through their contact points. The Council representatives of the consulting Parties shall convene no later than 30 days after the date of receipt of the request, unless the consulting Parties agree otherwise, and shall seek to resolve the matter, including, if appropriate, by consulting independent experts and having recourse to such procedures as good offices, conciliation or mediation.

11. If the consulting Parties are able to resolve the matter, they shall document any outcome including, if appropriate, specific steps and timelines agreed upon. The consulting Parties shall make the outcome available to the other Parties and to the public, unless they agree otherwise.
12. If the consulting Parties have failed to resolve the matter no later than 60 days after the date of receipt of a request under paragraph 2, the requesting Party may request the establishment of a panel under Article 28.7 (Establishment of a Panel) and, as provided in Chapter 28 (Dispute Settlement), thereafter have recourse to the other provisions of that Chapter.
13. No Party shall have recourse to dispute settlement under Chapter 28 (Dispute Settlement) for a matter arising under this Chapter without first seeking to resolve the matter in accordance with this Article.
14. A Party may have recourse to labour consultations under this Article without prejudice to the commencement or continuation of cooperative labour dialogue under Article 19.11 (Cooperative Labour Dialogue).
15. Labour consultations shall be confidential and without prejudice to the rights of any Party in any other proceedings.

## **VII. ENVIRONMENT**

*The Environment chapter features relatively detailed provisions about domestic regulations and administrative proceedings in relation to its environmental laws.*

### **Article 20.7: Procedural Matters**

1. Each Party shall promote public awareness of its environmental laws and policies, including enforcement and compliance procedures, by ensuring that relevant information is available to the public.
2. Each Party shall ensure that an interested person residing or established in its territory may request that the Party's competent authorities investigate alleged violations of its environmental laws, and that the competent authorities give those requests due consideration, in accordance with the Party's law.
3. Each Party shall ensure that judicial, quasi-judicial or administrative proceedings for the enforcement of its environmental laws are available under its law and that those proceedings are fair, equitable, transparent and comply with due process of law. Any hearings in these proceedings shall be open to the public, except when the administration of justice otherwise requires, and in accordance with its applicable laws.
4. Each Party shall ensure that persons with a recognised interest under its law in a particular matter have appropriate access to proceedings referred to in paragraph 3.
5. Each Party shall provide appropriate sanctions or remedies for violations of its environmental laws for the effective enforcement of those laws. Those sanctions or remedies may include a right to bring an action directly against the violator to seek damages or injunctive relief, or a right to seek governmental action.
6. Each Party shall ensure that it takes appropriate account of relevant factors in the establishment of the sanctions or remedies referred to in paragraph 5. Those factors may include the nature and gravity of the violation, damage to the environment and any economic benefit the violator derived from the violation.

### **Article 20.8: Opportunities for Public Participation**

1. Each Party shall seek to accommodate requests for information regarding the Party's implementation of this Chapter.
2. Each Party shall make use of existing, or establish new, consultative mechanisms, for example national advisory committees, to seek views on matters related to the implementation of this Chapter. These mechanisms may include persons with relevant experience, as appropriate, including experience in business, natural resource conservation and management, or other environmental matters.

### **Article 20.9: Public Submissions**

1. Each Party shall provide for the receipt and consideration of written submissions from persons of that Party regarding its implementation of this Chapter. Each Party shall respond in a timely manner to such submissions in writing and in accordance with domestic procedures, and make the submissions and its responses available to the public, for example by posting on an appropriate public website.
2. Each Party shall make its procedures for the receipt and consideration of written submissions readily accessible and publicly available, for example by posting on an appropriate public website. These procedures may provide that to be eligible for consideration the submission should:
  - (a) be in writing in one of the official languages of the Party receiving the submission;

- (b) clearly identify the person making the submission;
  - (c) provide sufficient information to allow for the review of the submission including any documentary evidence on which the submission may be based;
  - (d) explain how, and to what extent, the issue raised affects trade or investment between the Parties;
  - (e) not raise issues that are the subject of ongoing judicial or administrative proceedings; and
  - (f) indicate whether the matter has been communicated in writing to the relevant authorities of the Party and the Party's response, if any.
3. Each Party shall notify the other Parties of the entity or entities responsible for receiving and responding to any written submissions referred to in paragraph 1 within 180 days of the date of entry into force of this Agreement for that Party.
4. If a submission asserts that a Party is failing to effectively enforce its environmental laws and following the written response to the submission by that Party, any other Party may request that the Committee on Environment (Committee) discuss that submission and written response with a view to further understanding the matter raised in the submission and, as appropriate, to consider whether the matter could benefit from cooperative activities.
5. At its first meeting, the Committee shall establish procedures for discussing submissions and responses that are referred to it by a Party. These procedures may provide for the use of experts or existing institutional bodies to develop a report for the Committee comprised of information based on facts relevant to the matter.
6. No later than three years after the date of entry into force of this Agreement, and thereafter as decided by the Parties, the Committee shall prepare a written report for the Commission on the implementation of this Article. For the purposes of preparing this report, each Party shall provide a written summary regarding its implementation activities under this Article.

*The TPP sets up a relatively complicated and specifically sequenced dispute-settlement structure for disagreements about the Environment Chapter.*

#### **Article 20.20: Environment Consultations**

1. The Parties shall at all times endeavour to agree on the interpretation and application of this Chapter, and shall make every effort through dialogue, consultation, exchange of information and, if appropriate, cooperation to address any matter that might affect the operation of this Chapter.
2. A Party (the requesting Party) may request consultations with any other Party (the responding Party) regarding any matter arising under this Chapter by delivering a written request to the responding Party's contact point. The requesting Party shall include information that is specific and sufficient to enable the responding Party to respond, including identification of the matter at issue and an indication of the legal basis for the request. The requesting Party shall circulate its request for consultations to the other Parties through their respective contact points.
3. A Party other than the requesting or the responding Party that considers it has a substantial interest in the matter (a participating Party) may participate in the consultations by delivering a written notice to the contact point of the requesting and responding Parties no later than seven days after the date of circulation

of the request for consultations. The participating Party shall include in its notice an explanation of its substantial interest in the matter.

4. Unless the requesting and the responding Parties (the consulting Parties) agree otherwise, the consulting Parties shall enter into consultations promptly, and no later than 30 days after the date of receipt by the responding Party of the request. 5. The consulting Parties shall make every effort to arrive at a mutually satisfactory resolution to the matter, which may include appropriate cooperative activities. The consulting Parties may seek advice or assistance from any person or body they deem appropriate in order to examine the matter.

#### **Article 20.21: Senior Representative Consultations**

1. If the consulting Parties have failed to resolve the matter under Article 20.20 (Environment Consultations), a consulting Party may request that the Committee representatives from the consulting Parties convene to consider the matter by delivering a written request to the contact point of the other consulting Party or Parties. At the same time, the consulting Party making the request shall circulate the request to the contact points of other Parties.

2. The Committee representatives from the consulting Parties shall promptly convene following the delivery of the request, and shall seek to resolve the matter including, if appropriate, by gathering relevant scientific and technical information from governmental or non-governmental experts. Committee representatives from any other Party that considers it has a substantial interest in the matter may participate in the consultations.

#### **Article 20.22: Ministerial Consultations**

1. If the consulting Parties have failed to resolve the matter under Article 20.21 (Senior Representative Consultations), a consulting Party may refer the matter to the relevant Ministers of the consulting Parties who shall seek to resolve the matter.

2. Consultations pursuant to Article 20.20 (Environment Consultations), Article 20.21 (Senior Representative Consultations) and this Article may be held in person or by any technological means available as agreed by the consulting Parties. If in person, consultations shall be held in the capital of the responding Party, unless the consulting Parties agree otherwise.

3. Consultations shall be confidential and without prejudice to the rights of any Party in any future proceedings.

#### **Article 20.23: Dispute Resolution**

1. If the consulting Parties have failed to resolve the matter under Article 20.20 (Environment Consultations), Article 20.21 (Senior Representative Consultations) and Article 20.22 (Ministerial Consultations) within 60 days after the date of receipt of a request under Article 20.20, or any other period as the consulting Parties may agree, the requesting Party may request consultations under Article 28.5 (Consultations) or request the establishment of a panel under Article 28.7 (Establishment of a Panel).

2. Notwithstanding Article 28.15 (Role of Experts), in a dispute arising under Article 20.17.2 (Conservation and Trade) a panel convened under Chapter 28 (Dispute Settlement) shall:

(a) seek technical advice or assistance, if appropriate, from an entity authorised under CITES to address the particular matter, and provide the consulting Parties with an opportunity to comment on any such technical advice or assistance received; and

(b) provide due consideration to any interpretive guidance received pursuant to subparagraph (a) on the matter to the extent appropriate in light of its nature and status in making its findings and determinations under Article 28.17.4 (Initial Report).

3. Before a Party initiates dispute settlement under this Agreement for a matter arising under Article 20.3.4 (General Commitments) or Article 20.3.6, that Party shall consider whether it maintains environmental laws that are substantially equivalent in scope to the environmental laws that would be the subject of the dispute.

4. If a Party requests consultations with another Party under Article 20.20 (Environment Consultations) for a matter arising under Article 20.3.4 (General Commitments) or Article 20.3.6, and the responding Party considers that the requesting Party does not maintain environmental laws that are substantially equivalent in scope to the environmental laws that would be the subject of the dispute, the Parties shall discuss the issue during the consultations.

## VIII. PROCEDURE FOR PHARMACEUTICAL PATENTS

*The TBT Chapter has a specific Annex about pharmaceuticals:*

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

1. This Annex shall apply to the preparation, adoption and application of technical regulations, standards, conformity assessment procedures, marketing authorisation<sup>12</sup> and notification procedures of central government bodies that may affect trade in pharmaceutical products between the Parties. This Annex shall not apply to a technical specification prepared by a governmental entity for its production or consumption requirements or a sanitary or phytosanitary measure.
2. A Party's obligations under this Annex shall apply to any product that the Party defines as a pharmaceutical product pursuant to paragraph 3. For the purposes of this Annex, preparation of a technical regulation, standard, conformity assessment procedure or marketing authorisation includes, as appropriate, the evaluation of the risks involved, the need to adopt a measure to address those risks, the review of relevant scientific or technical information, and the consideration of the characteristics or design of alternative approaches.
3. Each Party shall define the scope of the products subject to its laws and regulations for pharmaceutical products in its territory and make that information publicly available.
4. Recognising that each Party is required to define the scope of products covered by this Annex pursuant to paragraph 3, for the purposes of this Annex, a pharmaceutical product may include a human drug or biologic that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or condition in humans, or intended to affect the structure or any function of the body of a human.
5. Each Party shall identify the agency or agencies that are authorised to regulate pharmaceutical products in its territory and make that information publicly available.
6. If more than one agency is authorised to regulate pharmaceutical products within the territory of a Party, that Party shall examine whether there is overlap or duplication in the scope of those authorities and take reasonable measures to eliminate unnecessary duplication of any regulatory requirements resulting for pharmaceutical products.
7. The Parties shall seek to collaborate through relevant international initiatives, such as those aimed at harmonisation, as well as regional initiatives that support those international initiatives, as appropriate, to improve the alignment of their respective regulations and regulatory activities for pharmaceutical products.
8. When developing or implementing regulations for marketing authorisation of pharmaceutical products, each Party shall consider relevant scientific or technical guidance documents developed through international collaborative efforts. Each Party is encouraged to consider regionally-developed scientific or technical guidance documents that are aligned with international efforts.
9. Each Party shall observe the obligations set out in Articles 2.1 and 5.1.1 of the TBT Agreement with respect to a marketing authorisation, notification procedure or elements of either that the Party prepares, adopts or applies for pharmaceutical products and that do not fall within the definition of a technical regulation or conformity assessment procedure.

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

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

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

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

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

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

(b) If a Party determines that a marketing authorisation application for a pharmaceutical product under review in its jurisdiction has deficiencies that have led or will lead to a decision not to authorise its marketing, that Party shall inform the applicant that requests marketing authorisation and provide reasons why the application is deficient.

(c) If a Party requires a marketing authorisation for a pharmaceutical product, the Party shall ensure that any marketing authorisation determination is subject to an appeal or review process that may be invoked at the request of the applicant. For greater certainty, the Party may maintain an appeal or review process that is either internal to the regulatory body responsible for the marketing authorisation determination, such as a dispute resolution or review process, or external to the regulatory body.

(d) If a Party requires periodic re-authorisation for a pharmaceutical product that has previously received marketing authorisation from the Party, the Party shall allow the pharmaceutical product to remain on its market under the conditions of the previous marketing authorisation pending a decision on the periodic reauthorisation, unless the Party identifies a significant health or safety concern.

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

(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.

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.

*The Intellectual Property Chapter includes the two highly contested provisions about data-exclusivity for pharmaceuticals and biologics.*

**Article 18.50: Protection of Undisclosed Test or Other Data (suspended in CPTPP)**

1. (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product,<sup>51</sup> that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar<sup>52</sup> product on the basis of:

(i) that information; or

(ii) the marketing approval granted to the person that submitted such information, for at least five years<sup>53</sup> from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

(b) If a Party permits, as a condition of granting marketing approval for a new pharmaceutical product, the submission of evidence of prior marketing approval of the product in another territory, that Party shall not permit third persons, without the consent of a person that previously submitted such information concerning the safety and efficacy of the product, to market a same or a similar product based on

evidence relating to prior marketing approval in the other territory for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of that Party.

2. Each Party shall:

(a) apply paragraph 1, *mutatis mutandis*, for a period of at least three years with respect to new clinical information submitted as required in support of a marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration; or, alternatively,

(b) apply paragraph 1, *mutatis mutandis*, for a period of at least five years to new pharmaceutical products that contain<sup>56</sup> a chemical entity that has not been previously approved in that Party.

3. Notwithstanding paragraphs 1 and 2 and Article 18.51 (Biologics), a Party may take measures to protect public health in accordance with: (a) the Declaration on TRIPS and Public Health; (b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration on TRIPS and Public Health and that is in force between the Parties; or (c) any amendment of the TRIPS Agreement to implement the Declaration on TRIPS and Public Health that enters into force with respect to the Parties.

#### **Article 18.51: Biologics (*suspended in CPTPP*)**

1. With regard to protecting new biologics, a Party shall either:

(a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,

(b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection:

(i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least five years from the date of first marketing approval of that product in that Party,

(ii) through other measures, and

(iii) recognising that market circumstances also contribute to effective market protection to deliver a comparable outcome in the market.

2. For the purposes of this Section, each Party shall apply this Article to, at a minimum, a product that is, or, alternatively, contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment, or cure of a disease or condition.

3. Recognising that international and domestic regulation of new pharmaceutical products that are or contain a biologic is in a formative stage and that market circumstances may evolve over time, the Parties shall consult after 10 years from the date of entry into force of this Agreement, or as otherwise decided by the Commission, to review the period of exclusivity provided in paragraph 1 and the scope of application provided in paragraph 2, with a view to providing effective incentives for the development of new pharmaceutical products that are or contain a biologic, as well as with a view to facilitating the timely

availability of follow-on biosimilars, and to ensuring that the scope of application remains consistent with international developments regarding approval of additional categories of new pharmaceutical products that are or contain a biologic.

*The TPP features very specific and quite strong requirements for Parties' administrative procedures relating to the enforcement and administration of intellectual property rights.*

#### **Article 18.73: Enforcement Practices with Respect to Intellectual Property Rights**

1. Each Party shall provide that final judicial decisions and administrative rulings of general application pertaining to the enforcement of intellectual property rights:

(a) preferably are in writing and state any relevant findings of fact and the reasoning or the legal basis on which the decisions and rulings are based; and

(b) are published or, if publication is not practicable, otherwise made available to the public in a national language in such a manner as to enable interested persons and Parties to become acquainted with them.

2. Each Party recognises the importance of collecting and analysing statistical data and other relevant information concerning infringements of intellectual property rights as well as collecting information on best practices to prevent and combat infringements.

3. Each Party shall publish or otherwise make available to the public information on its efforts to provide effective enforcement of intellectual property rights in its civil, administrative and criminal systems, such as statistical information that the Party may collect for such purposes.

#### **Article 18.74: Civil and Administrative Procedures and Remedies**

1. Each Party shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered in this Chapter.

2. Each Party shall provide that its judicial authorities have the authority to order injunctive relief that conforms to Article 44 of the TRIPS Agreement, including to prevent goods that involve the infringement of an intellectual property right under the law of the Party providing that relief from entering into the channels of commerce.

3. Each Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority at least to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

4. In determining the amount of damages under paragraph 3, each Party's judicial authorities shall have the authority to consider, among other things, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.

5. At least in cases of copyright or related rights infringement and trademark counterfeiting, each Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority to order the infringer, at least in cases described in paragraph 3, to pay the right holder the infringer's profits that are attributable to the infringement.

6. In civil judicial proceedings with respect to the infringement of copyright or related rights protecting works, phonograms or performances, each Party shall establish or maintain a system that provides for one or more of the following:

- (a) pre-established damages, which shall be available on the election of the right holder; or
- (b) additional damages.

7. In civil judicial proceedings with respect to trademark counterfeiting, each Party shall also establish or maintain a system that provides for one or more of the following:

- (a) pre-established damages, which shall be available on the election of the right holder; or
- (b) additional damages.

8. Pre-established damages under paragraphs 6 and 7 shall be set out in an amount that would be sufficient to compensate the right holder for the harm caused by the infringement, and with a view to deterring future infringements.

9. In awarding additional damages under paragraphs 6 and 7, judicial authorities shall have the authority to award such additional damages as they consider appropriate, having regard to all relevant matters, including the nature of the infringing conduct and the need to deter similar infringements in the future.

10. Each Party shall provide that its judicial authorities, if appropriate, have the authority to order, at the conclusion of civil judicial proceedings concerning infringement of at least copyright or related rights, patents and trademarks, that the prevailing party be awarded payment by the losing party of court costs or fees and appropriate attorney's fees, or any other expenses as provided for under the Party's law.

11. If a Party's judicial or other authorities appoint a technical or other expert in a civil proceeding concerning the enforcement of an intellectual property right and require that the parties to the proceeding pay the costs of that expert, that Party should seek to ensure that those costs are reasonable and related appropriately, among other things, to the quantity and nature of work to be performed and do not unreasonably deter recourse to such proceedings.

12. Each Party shall provide that in civil judicial proceedings:

(a) at least with respect to pirated copyright goods and counterfeit trademark goods, its judicial authorities have the authority, at the right holder's request, to order that the infringing goods be destroyed, except in exceptional circumstances, without compensation of any sort;

(b) its judicial authorities have the authority to order that materials and implements that have been used in the manufacture or creation of the infringing goods be, without undue delay and without compensation of any sort, destroyed or disposed of outside the channels of commerce in such a manner as to minimise the risk of further infringement; and

(c) in regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed is not sufficient, other than in exceptional circumstances, to permit the release of goods into the channels of commerce.

13. Without prejudice to its law governing privilege, the protection of confidentiality of information sources or the processing of personal data, each Party shall provide that, in civil judicial proceedings concerning the enforcement of an intellectual property right, its judicial authorities have the authority, on a justified request of the right holder, to order the infringer or, in the alternative, the alleged infringer to provide to the right holder or to the judicial authorities, at least for the purpose of collecting evidence,

relevant information as provided for in its applicable laws and regulations that the infringer or alleged infringer possesses or controls. The information may include information regarding any person involved in any aspect of the infringement or alleged infringement and the means of production or the channels of distribution of the infringing or allegedly infringing goods or services, including the identification of third persons alleged to be involved in the production and distribution of the goods or services and of their channels of distribution.

14. Each Party shall provide that in relation to a civil judicial proceeding concerning the enforcement of an intellectual property right, its judicial or other authorities have the authority to impose sanctions on a party, counsel, experts or other persons subject to the court's jurisdiction for violation of judicial orders concerning the protection of confidential information produced or exchanged in that proceeding.

15. Each Party shall ensure that its judicial authorities have the authority to order a party at whose request measures were taken and that has abused enforcement procedures with regard to intellectual property rights, including trademarks, geographical indications, patents, copyright and related rights and industrial designs, to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of that abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.

16. To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, each Party shall provide that those procedures conform to principles equivalent in substance to those set out in this Article.

17. In civil judicial proceedings concerning the acts described in Article 18.68 (TPMs) and Article 18.69 (RMI):

(a) each Party shall provide that its judicial authorities have the authority at least to: (i) impose provisional measures, including seizure or other taking into custody of devices and products suspected of being involved in the prohibited activity; (ii) order the type of damages available for copyright infringement, as provided under its law in accordance with this Article; (iii) order court costs, fees or expenses as provided for under paragraph 10; and (iv) order the destruction of devices and products found to be involved in the prohibited activity; and

(b) a Party may provide that damages shall not be available against a non-profit library, archive, educational institution, museum or public non-commercial broadcasting entity, if it sustains the burden of proving that it was not aware or had no reason to believe that its acts constituted a prohibited activity.

#### **Article 18.75: Provisional Measures**

1. Each Party's authorities shall act on a request for relief in respect of an intellectual property right *inaudita altera parte* expeditiously in accordance with that Party's judicial rules.

2. Each Party shall provide that its judicial authorities have the authority to require the applicant for a provisional measure in respect of an intellectual property right to provide any reasonably available evidence in order to satisfy the judicial authority, with a sufficient degree of certainty, that the applicant's right is being infringed or that the infringement is imminent, and to order the applicant to provide security or equivalent assurance set at a level sufficient to protect the defendant and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to those procedures.

3. In civil judicial proceedings concerning copyright or related rights infringement and trademark counterfeiting, each Party shall provide that its judicial authorities have the authority to order the seizure or other taking into custody of suspected infringing goods, materials and implements relevant to the

infringement, and, at least for trademark counterfeiting, documentary evidence relevant to the infringement.

## **IX. FAIR AND EQUITABLE TREATMENT**

*As do almost all modern investment protection chapters in BITs and FTAs, TPP includes a provision about the minimum standard of treatment. The most important aspect of this standard is commonly regarded to be that of “fair and equitable treatment”. The TPP’s version of this standard is as follows:*

### **Article 9.6: Minimum Standard of Treatment**

1. Each Party shall accord to covered investments treatment in accordance with applicable customary international law principles, including fair and equitable treatment and full protection and security.
2. For greater certainty, paragraph 1 prescribes the customary international law minimum standard of treatment of aliens as the standard of treatment to be afforded to covered investments. The concepts of “fair and equitable treatment” and “full protection and security” do not require treatment in addition to or beyond that which is required by that standard, and do not create additional substantive rights. The obligations in paragraph 1 to provide:
  - (a) “fair and equitable treatment” includes the obligation not to deny justice in criminal, civil or administrative adjudicatory proceedings in accordance with the principle of due process embodied in the principal legal systems of the world; and
  - (b) “full protection and security” requires each Party to provide the level of police protection required under customary international law.
3. A determination that there has been a breach of another provision of this Agreement, or of a separate international agreement, does not establish that there has been a breach of this Article.
4. For greater certainty, the mere fact that a Party takes or fails to take an action that may be inconsistent with an investor’s expectations does not constitute a breach of this Article, even if there is loss or damage to the covered investment as a result.
5. For greater certainty, the mere fact that a subsidy or grant has not been issued, renewed or maintained, or has been modified or reduced, by a Party, does not constitute a breach of this Article, even if there is loss or damage to the covered investment as a result.

### **ANNEX 9-A CUSTOMARY INTERNATIONAL LAW**

The Parties confirm their shared understanding that “customary international law” generally and as specifically referenced in Article 9.6 (Minimum Standard of Treatment) results from a general and consistent practice of States that they follow from a sense of legal obligation. The customary international law minimum standard of treatment of aliens refers to all customary international law principles that protect the investments of aliens.

*The TPP’s Investment Chapter also includes provisions requiring the publicity of investor-state arbitral proceedings.*

### **Article 9.24: Transparency of Arbitral Proceedings**

1. Subject to paragraphs 2 and 4, the respondent shall, after receiving the following documents, promptly transmit them to the non-disputing Parties and make them available to the public:
  - (a) the notice of intent;

(b) the notice of arbitration;

(c) pleadings, memorials and briefs submitted to the tribunal by a disputing party and any written submissions submitted pursuant to Article 9.23.2 (Conduct of the Arbitration) and Article 9.23.3 and Article 9.28 (Consolidation);

(d) minutes or transcripts of hearings of the tribunal, if available; and

(e) orders, awards and decisions of the tribunal.

2. The tribunal shall conduct hearings open to the public and shall determine, in consultation with the disputing parties, the appropriate logistical arrangements. If a disputing party intends to use information in a hearing that is designated as protected information or otherwise subject to paragraph it shall so advise the tribunal. The tribunal shall make appropriate arrangements to protect such information from disclosure which may include closing the hearing for the duration of the discussion of that information.

3. Nothing in this Section, including paragraph 4(d), requires a respondent to make available to the public or otherwise disclose during or after the arbitral proceedings, including the hearing, protected information, or to furnish or allow access to information that it may withhold in accordance with Article 29.2 (Security Exceptions) or Article 29.7 (Disclosure of Information).

4. Any protected information that is submitted to the tribunal shall be protected from disclosure in accordance with the following procedures:

(a) subject to subparagraph (d), neither the disputing parties nor the tribunal shall disclose to any non-disputing Party or to the public any protected information if the disputing party that provided the information clearly designates it in accordance with subparagraph (b);

(b) any disputing party claiming that certain information constitutes protected information shall clearly designate the information according to any schedule set by the tribunal;

(c) a disputing party shall, according to any schedule set by the tribunal, submit a redacted version of the document that does not contain the protected information. Only the redacted version shall be disclosed in accordance with paragraph 1; and

(d) the tribunal, subject to paragraph 3, shall decide any objection regarding the designation of information claimed to be protected information. If the tribunal determines that the information was not properly designated, the disputing party that submitted the information may:

(i) withdraw all or part of its submission containing that information; or

(ii) agree to resubmit complete and redacted documents with corrected designations in accordance with the tribunal's determination and subparagraph (c). In either case, the other disputing party shall, whenever necessary, resubmit complete and redacted documents which either remove the information withdrawn under subparagraph (d)(i) by the disputing party that first submitted the information or redesignate the information consistent with the designation under subparagraph (d)(ii) of the disputing party that first submitted the information.

5. Nothing in this Section requires a respondent to withhold from the public information required to be disclosed by its laws. The respondent should endeavour to apply those laws in a manner sensitive to protecting from disclosure information that has been designated as protected information.

**X. STATE TO STATE DISPUTE SETTLEMENT**

[to be included]