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TRANS-PACIFIC PARTNERSHIP (TPP)  
REGULATORY COHERENCE

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Declassify on: Four years from entry into force  
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REGULATORY COHERENCE

ARTICLE X.1: GENERAL PROVISIONS

1. Regulatory coherence includes: [TPP countries should discuss further the appropriate scope for a definition of regulatory coherence]
2. The parties affirm the importance of:
  - a. sustaining the benefits of the Agreement through provisions on regulatory coherence, particularly in terms of facilitating increased trade in goods and services and increased investment among the Parties;
  - b. each Party's sovereign right to identify its regulatory priorities and establish and implement regulatory measures to address these priorities, at the levels that a Party considers appropriate;<sup>1</sup>
  - c. the role that regulation plays in achieving public policy objectives, such as protecting the environment, worker rights, and public and worker health and safety;
  - d. a wide range of stakeholder input in the development and implementation of regulatory measures; and
  - e. regional regulatory cooperation

taking into account the Parties' international obligations.

ARTICLE X.2: ESTABLISHMENT OF CENTRAL COORDINATION AND REVIEW PROCESSES OR MECHANISMS, INCLUDING NATIONAL COORDINATING BODIES

1. The Parties recognize that regulatory coherence can be facilitated through domestic mechanisms that increase inter-ministerial consultation and coordination associated with processes for developing regulatory measures of general application. The Parties further recognize that engagement among Parties on regulatory matters can be enhanced through ensuring that information on regulatory measures is centrally collected and widely disseminated. Accordingly, each Party shall endeavor to ensure that it has a process or mechanism to facilitate central coordination and review of certain new regulatory measures ("covered regulatory measures") at the central level of government, and should consider establishing and maintaining a national coordinating body for this purpose. Each Party should determine the scope of covered regulatory measures on the basis of criteria made available to the

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<sup>1</sup> ...: This text may need to be reconsidered in light of whether text in the Preamble of the Agreement or in other chapters provides additional guidance on a Party's right to regulate in pursuit of legitimate objectives.

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public, whether through law, regulation or other measures. Recognizing that each Party may determine the appropriate scope of covered regulatory measures, it should ensure that coverage is significant and not arbitrarily limited in order to avoid application of this Chapter.

2. The Parties recognize that, while the design, scope of authority, and institutional location of national coordinating bodies or other appropriate processes or mechanisms will vary depending on their respective national circumstances (including differences in levels of development and political and institutional structures), the body, process or mechanism referred to in Article X.2.1 should generally have certain overarching characteristics to enable maximum effectiveness in promoting regulatory coherence as follows:

- a. Publicly-available legal or administrative documents that specify institutional elements, and that grant sufficient resources and stature to be credible within the government and with external stakeholders;
- b. the authority to review covered regulatory measures to determine the extent to which the development of such measures adheres to good regulatory practices, which may include but are not limited to those set out in Article X.3 [below], and make recommendations based on that review;
- c. an important role in advancing the transparency disciplines set out in Chapter X of this Agreement;
- d. the ability to strengthen coordination and consultation among ministries within the government so as to minimize overlap and duplication, prevent the creation of inconsistent requirements across ministries, and ensure development of coherent regulatory approaches by, inter alia, allowing all ministries with an interest in a particular covered regulatory measure to participate in its development;
- e. the ability to make recommendations for systemic regulatory reform for consideration by decision-makers; and
- f. a periodic public report on its activities, including with respect to specific regulatory measures reviewed, any proposals for systemic regulatory reform, and an update on its own institutional development.

3. Through its national coordinating body, process or mechanism, each Party should seek to maintain channels of communication with: (i) any regulatory authority at the Party's central level of government for which the body does not exercise review responsibility with respect to the development of its regulatory measures; and (ii) relevant subcentral governmental bodies within the Party's territory, as feasible and appropriate.

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ARTICLE X.3: IMPLEMENTATION OF CORE GOOD REGULATORY PRACTICES

1. Through its national coordinating body, process or mechanism, each Party, in carrying out responsibilities for reviewing covered regulatory measures, should generally encourage relevant regulatory authorities, consistent with domestic law, to conduct regulatory impact assessments (RIAs) when developing covered regulatory measures that exceed a threshold of economic impact established by a Party, to assist in designing a measure to best achieve the Party's objective.

a. An RIA should identify, among other things:

- (1) the problem and the policy objective that the regulatory authority intends to address, including an assessment of the significance of the problem and a description of the need for regulatory action;
- (2) potentially effective and reasonably feasible alternatives to achieve the policy objective; and
- (3) where appropriate, the grounds for concluding that the selected alternative achieves the policy objectives in a way that maximizes net benefits, including qualitative benefits, while also considering distributional impact.<sup>2</sup>

b. An RIA should include the following elements:

- (1) a consideration of whether, for all aspects of the planned regulatory measure, there is a need to regulate to achieve the policy objective or whether an objective can be met by non-regulatory and/or voluntary means, consistent with domestic law;
- (2) an assessment, to the extent feasible and consistent with domestic law, of the costs and benefits of each available alternative, including not to regulate, recognizing that some costs and benefits are difficult to quantify and monetize;
- (3) an explanation why the alternative selected is superior to the other available alternatives identified, including, if appropriate, through reference to the relative size of net benefits of the available alternatives; and
- (4) decisions based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities, mandates, and resources of the particular regulatory authority.

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<sup>2</sup> "Net benefits" refer to the differences between a planned regulatory action's anticipated benefits and costs.

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2. The Parties recognize that these and other Good Regulatory Practice concepts that may be relevant to an RIA analysis are reflected in the APEC-OECD Integrated Checklist on Regulatory Reform and the APEC Information Notes on Good Practices for Technical Regulation.
3. Each Party should ensure that covered regulatory measures are plainly written clear, concise, well organized and easy to understand, recognizing that some measures address technical issues and that relevant expertise may be needed to understand and apply them.
4. Each Party should ensure that relevant regulatory authorities provide appropriate public access to covered regulatory measures and their supporting documentation, regulatory analyses, data, and, where practicable, make this information available online for viewing and reproducibility, in accordance with the transparency disciplines set out in Chapter X of this Agreement.
5. Each Party should establish or maintain procedures for it to review, at intervals it deems appropriate, some or all of its existing stock of significant regulatory measures to determine whether specific regulatory measures should be modified, streamlined, expanded, or repealed so as to make the Party's regulatory program more effective in achieving the policy objective(s) pursued. For a Party reviewing its regulatory measures, relevant elements of consideration include whether such measures have become unnecessary or outdated by reason of changed circumstances, such as fundamental changes in technology, or their effectiveness could be enhanced through expansion or through regulatory cooperation activities.
6. Each Party should publish, on an annual basis, a regulatory agenda which includes any covered regulatory measure that it reasonably expects its regulatory authorities to issue within no less than the following twelve-month period.
7. Each Party should consider a variety of methods that can contribute to successful collaboration among Parties and their respective stakeholders with respect to covered regulatory measures, such as:
  - a. information exchanges, dialogues or meetings with other Parties;
  - b. information exchanges, dialogues, or meetings with interested stakeholders, including small- and medium-sized enterprises, of other Parties;
  - c. coordination of regulatory activities with other Parties;
  - d. participation in efforts to share best practices and harmonize relevant regulatory approaches, standards and related procedures, as well as consideration of such efforts in the development of regulatory measures; and

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- e. consideration of regulatory schedules that allow for sufficient time to consider regulatory approaches in other Parties, as well as relevant developments in international, regional and other fora to the extent appropriate and consistent with domestic law.

**ARTICLE X.4: SECTORAL APPROACHES**

The Parties recognize the value of developing specific approaches, where appropriate, aimed at enhancing regulatory coherence with respect to certain goods and services sectors to the extent they are subject to obligations under other chapters of this Agreement. Accordingly, and without prejudice to responsibilities prescribed for committees and other bodies established under other chapters of this Agreement, the Parties shall consult regularly on the implementation and operation of sectoral regulatory coherence provisions in other chapters of this Agreement and assess the relevance of any experience regarding these provisions in considering the potential for future sectoral approaches pursuant to Article X.X below.

**ARTICLE X.5: INSTITUTIONAL FRAMEWORK**

1. The Parties hereby establish a Committee on Regulatory Coherence. The Committee, which will make decisions based on consensus, shall convene within one year after the Agreement enters into force of the Agreement and at least once every [two] year[s] thereafter to consider issues associated with implementation and operation of this Chapter and to identify future priorities, including potential sectoral initiatives, for cooperative activities related to regulatory coherence among the Parties with respect to obligations under other chapters of this Agreement.
2. In identifying future priorities, the Committee shall take into account the activities of other bodies established under other chapters of this Agreement and shall ensure that there is no duplication of activities.
3. The Committee shall develop and maintain a work plan in order to ensure that its work on regulatory cooperation offers incremental value added and avoids undermining or duplicating initiatives underway in other relevant fora. Accordingly, the Committee should regularly take stock of cooperative activities in which Parties participate in other for a.
4. A Party shall promptly notify the Committee with relevant information regarding the process or mechanism established pursuant to Article X.2.1, including the responsibilities and activities of any body that may be established, as well as the scope of covered regulatory measures. Additionally, each Party shall identify, within one year after the Agreement enters into force, a point of contact to provide information, upon request by another Party, regarding implementation of Articles X.2 and X.3.

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5. At least once every [five] year[s] after the Agreement enters into force, the Committee shall consider developments in the areas of good regulatory practices and best practices in maintaining national coordinating bodies, processes or mechanisms, as well as the Parties' experiences in implementing Articles X.2 and X.3, with a view towards improving and strengthening disciplines in those areas.

**ARTICLE X.6: ENGAGEMENT WITH INTERESTED PERSONS**

At its first meeting, to ensure participation from a broad-based cross-section of interest in all Parties, the Committee on Regulatory Coherence shall establish mechanisms to ensure meaningful opportunities for interested persons to provide views on approaches to enhance regulatory coherence through the Agreement.

**ARTICLE X.7: DEFINITIONS**

"Regulatory measures" are measures of general application in proposed or final form adopted by regulatory bodies of the central level of government with which compliance is mandatory.

**ARTICLE X.8: DISPUTE SETTLEMENT**

Application of Chapter X [Dispute Settlement] to this Chapter is limited to the obligation to have "processes or mechanisms to facilitate central coordination and review of certain new regulatory measures." To establish an actionable breach of this obligation by another Party for purposes of Chapter X, a Party must demonstrate that the other Party (1) violated the obligation and (2) that such violation adversely affected trade and investment between those Parties.

**ARTICLE X.9: CONFIDENTIALITY**

Nothing in this Chapter would require a Party to make available information that is confidential, including information that disclosure of which could prejudice the competitive position of the person providing the information, or is otherwise exempted or prohibited from disclosure pursuant to the Party's domestic law.