

CHAPTER 3

GOOD REGULATORY PRACTICES

Article 3.1: Definitions

For the purposes of this Chapter:

regulation means a measure of general application, with which compliance is mandatory, adopted, issued, or maintained by a regulatory authority of the territory represented by a Party except as set forth in Annex 3-A;

regulatory authority means a central level administrative authority or agency of the authorities of the territory represented by a Party that develops, proposes, or adopts a regulation, and does not include legislatures or courts; and

regulatory cooperation means an effort between the authorities of the territory represented by a Party and the authorities of the territory represented by the other Party to prevent, reduce, or eliminate unnecessary regulatory differences to facilitate international trade and investment and promote economic growth, while maintaining or enhancing standards of public health and safety and environmental protection.

Article 3.2: Subject Matter and General Provisions

1. The Parties, through their Designated Representatives, recognize that implementation of practices by all regulatory authorities to promote regulatory quality through greater transparency, objective analysis, accountability, and predictability can facilitate international trade and investment and promote economic growth, while contributing to the ability of the authorities of the territory represented by each Party to achieve their public policy objectives (including health, safety, labor, environmental, and sustainability goals) at the level they consider appropriate. The application of good regulatory practices can support greater regulatory compatibility between the regulatory authorities, which can reduce or eliminate, as appropriate, unnecessarily burdensome or duplicative regulatory requirements and encourage cooperation to address shared transboundary and global challenges.

2. The Parties, through their Designated Representatives, also recognize the importance of transparency in the regulatory development process and the need to engage persons that may have an interest, including small enterprises, workers' organizations, rural communities, and individuals that may be historically disadvantaged, vulnerable, or marginalized, such as women, minorities, and Indigenous peoples.

3. Accordingly, this Chapter sets out obligations and other provisions with respect to good

regulatory practices, including practices relating to the planning, design, issuance, implementation, and review of regulations.

4. For greater certainty, this Chapter does not prevent the Parties, either on their own or through their Designated Representatives, from:

- (a) pursuing public policy objectives (including health, safety, labor, environmental, and sustainability goals) at the level they consider to be appropriate;
- (b) determining the appropriate method of implementing their obligations in this Chapter within the framework of the legal system and institutions of the territories represented by the Parties; or
- (c) adopting good regulatory practices in addition to those that are set out in this Chapter.

Article 3.3: Central Regulatory Coordinating Bodies or Mechanisms

Recognizing that institutional arrangements are particular to the system of the authorities of the territory represented by a Party, the Parties, through their Designated Representatives, note the important role of central regulatory coordinating bodies and mechanisms in promoting good regulatory practices; performing key advisory, coordination, and review functions to improve the quality of regulations; and developing improvements to their regulatory systems. Each Party, through its Designated Representative, intends to establish or maintain central regulatory coordinating bodies or mechanisms within their mandates and consistent with the laws of the territory represented by the Party.

Article 3.4: Internal Consultation, Coordination, and Review

1. Each Party, through its Designated Representative, shall adopt or maintain processes or mechanisms to pursue, among others, the following objectives:

- (a) promoting adherence to good regulatory practices, including those set forth in this Chapter, by all regulatory authorities;
- (b) identifying and developing improvements to regulatory processes by all regulatory authorities;
- (c) identifying potential overlap or duplication between proposed and existing regulations and preventing the creation of inconsistent requirements by all regulatory authorities;

- (d) reviewing regulations early in the development process to take into account compliance with international trade and investment obligations, including, as appropriate, review of the use of relevant international standards, guides, and recommendations;
- (e) promoting consideration of regulatory impacts, including burdens on small enterprises, of information collection and implementation; and
- (f) encouraging regulatory approaches that promote job creation, innovation, and competition in the marketplace.

2. Each Party, through its Designated Representative, shall make publicly available online a description of the processes or mechanisms referred to in paragraph 1. Each Party, through its Designated Representative, shall strive to provide that information on a website described in Article 3.7 or through links from that website.

Article 3.5: Information Quality

1. Each Party, through its Designated Representative, shall adopt or maintain publicly available guidance or mechanisms that encourage regulatory authorities, when developing a regulation, to:

- (a) seek the best, reasonably obtainable information, including scientific, technical, economic, or other information, relevant to the regulation they are developing;
- (b) rely on information that is appropriate for the context in which it is used; and
- (c) identify sources of information in a transparent manner, as well as any significant assumptions and limitations.

2. If a regulatory authority systematically collects information from members of the public, each Party, through its Designated Representative, shall provide that the regulatory authority should:

- (a) use sound statistical methodologies before drawing generalized conclusions concerning the impact of the regulation on the population affected by the regulation; and
- (b) avoid unnecessary duplication and otherwise minimize unnecessary burdens on those being surveyed.

Article 3.6: Early Planning

1. Each Party, through its Designated Representative, shall make publicly available online annually a list of regulations reasonably expected to be adopted, or proposed to be adopted, within the following 12 months. Each regulation identified in the list shall be accompanied by:
 - (a) a concise description of the planned regulation;
 - (b) a point of contact for a knowledgeable individual in the regulatory authority responsible for the regulation; and
 - (c) an indication, if known, of sectors to be affected and whether there is any expected significant effect on international trade or investment.
2. Entries in the list should include, to the extent available, time periods for subsequent actions, including time periods for those providing opportunities for public comment under Article 3.9.
3. Each Party, through its Designated Representative, shall strive to provide the information in paragraphs 1 and 2 on the website described in Article 3.7.3.

Article 3.7: Regulatory Transparency Tools

1. The Parties, through their Designated Representatives, recognize that using information technology can enhance processes for developing and implementing regulations, improve a regulatory authority's operational performance, provide greater access to information, and increase participation in the regulatory process. Accordingly, each Party, through its Designated Representative, shall use information technology tools that increase transparency and efficiency, where appropriate.
2. Each Party, through its Designated Representative, shall ensure that final regulations are published and maintained on a single, free, publicly available website. On the website, each Party, through its Designated Representative, shall endeavor to organize the regulations by regulatory authority or regulatory area to allow for ease of use, including searchability.
3. Each Party, through its Designated Representative, shall maintain a single, free, publicly available website that, to the extent practicable, contains all information required for publication pursuant to Article 3.9.
4. A Party, through its Designated Representative, may comply with paragraph 3 by making publicly available information on, and providing for the submission of comments through, more than one website, provided the information can be accessed, and submissions can be made, from

a single web portal that links to other websites.

5. Each Party, through its Designated Representative, shall allow for the acceptance of digital signatures and digital record submissions for regulatory approvals and compliance documentation, where appropriate.

Article 3.8: Use of Plain Language

Each Party, through its Designated Representative, should provide that proposed and final regulations are written using plain language to ensure that regulations are written in a clear, concise, and well-organized manner, recognizing that some regulations address technical issues and that relevant expertise may be required to understand or apply them.

Article 3.9: Transparent Development of Regulations

1. During the period described in paragraph 2, when a regulatory authority is developing a regulation, the Party, through its Designated Representative, shall, under normal circumstances,¹ publish:

- (a) the proposed text of the regulation along with its regulatory impact assessment, if any;
- (b) an explanation of the regulation, including its objectives, how the regulation achieves those objectives, the rationale for the material features of the regulation, and any major alternatives being considered;
- (c) an explanation of the data, other information, and analyses the regulatory authority relied upon to support the regulation; and
- (d) the name and contact information of an individual official from the regulatory authority with lead responsibility for developing the regulation who may be contacted concerning questions regarding the regulation.

At the same time the Party, through its Designated Representative, publishes the information listed

¹ For the purposes of paragraphs 1, 4, and 5, “normal circumstances” do not include, for example, situations in which: publication in accordance with those paragraphs would render the regulation ineffective in addressing the particular harm to the public interest that the regulation aims to address; if the authorities of the territory represented by the Party consider that urgent problems (for example, of safety, health, or environmental protection) arise or threaten to arise for the territory represented by the Party; or if the authorities of the territory represented by the Party consider that the regulation has no substantive impact upon members of the public, including persons of the territory represented by the other Party.

in subparagraphs (a) through (d), the Party, through its Designated Representative, shall also make publicly available data, other information, and scientific and technical analyses the regulatory authority relied upon in support of the regulation, including any risk assessment.

2. Each Party, through its Designated Representative, shall publish the items required to be published under paragraph 1 before the regulatory authority finalizes its work on a regulation² and at a time that will enable the regulatory authority to take into account the comments received and, as appropriate, make revisions to the text of the regulation published under paragraph 1(a).

3. After the items identified in paragraph 1 have been published, the Party, through its Designated Representative, shall ensure that any interested person, regardless of domicile, has an opportunity, on terms no less favorable than those afforded to a person of the territory represented by the Party, to submit written comments on the items identified in paragraph 1 for consideration by the relevant regulatory authority. Each Party, through its Designated Representative, shall allow interested persons to submit any comments or other input electronically and may also allow written submissions by mail to a published address or through another technology.

4. If a Party, through its Designated Representative, expects a proposed regulation to have a significant impact on international trade or investment, the Party, through its Designated Representative, should normally provide a time period to submit written comments or other input on the items published in accordance with paragraph 1 that is:

- (a) not less than 60 days from the date the items identified in paragraph 1 are published;
or
- (b) a longer time period, as appropriate due to the nature and complexity of the regulation, in order to provide interested persons adequate opportunity to understand how the regulation may affect their interests and to develop informed responses.

5. With respect to proposed regulations not covered by paragraph 4, each Party, through its Designated Representative, shall endeavor, under normal circumstances, to provide a time period to submit written comments or other input on the information published in accordance with paragraph 1 that is not less than four weeks from the date the items identified in paragraph 1 are published.

6. Each Party, through its Designated Representative, shall consider reasonable requests to extend the comment period under paragraph 4 or 5 to submit written comments or other input on a proposed regulation.

² For TECRO, a regulatory authority “finalizes its work” on a regulation when a regulation is promulgated by the regulatory authority. For AIT, a regulatory authority “finalizes its work” on a regulation when a final rule is signed and published in the *Federal Register*.

7. Each Party, through its Designated Representative, shall, without undue delay, make publicly available online any written comments received respecting proposed regulations, except to the extent necessary to protect confidential information or withhold personal identifying information or inappropriate content. If it is impracticable to make publicly available online all the comments on the website provided for in Article 3.7.3, the Party, through its Designated Representative, shall endeavor to make those comments publicly available on the website of the relevant regulatory authority. Each Party, through its Designated Representative, shall also normally make publicly available online a list, docket, or other form of compilation, identifying persons, according to their self-identification, that have submitted public comments.

8. Before a regulatory authority finalizes its work on a regulation, each Party, through its Designated Representative, shall evaluate any relevant information provided in written comments received during the comment period.

9. When a regulatory authority finalizes its work on a regulation, the Party, through its Designated Representative, shall, without undue delay, make publicly available online the text of the regulation, any final regulatory impact assessment, and other items as set out in Article 3.12.

10. Each Party, through its Designated Representative, shall strive to publish items identified in this Article that are generated by the regulatory authorities in a format that can be read and digitally processed through word searches and data mining by a computer or other technology.

Article 3.10: Expert Advisory Groups and Bodies

1. The Parties, through their Designated Representatives, recognize that regulatory authorities may seek expert advice and recommendations with respect to the preparation or implementation of regulations from groups or bodies that include persons who are not representatives of the Parties or of the authorities of the territories represented by the Parties. The Parties, through their Designated Representatives, also recognize that obtaining that advice and those recommendations should be a complement to, rather than a substitute for, the procedures for seeking public comment pursuant to Article 3.9.3.

2. For the purposes of this Article, an **expert group or body** means a group or body:

- (a) established by the central level authorities of the territory represented by the Party;
- (b) the membership of which includes persons who are not employees or contractors of a Party or of the authorities of the territory represented by the Party; and
- (c) the function of which includes providing advice or recommendations, including of a scientific or technical nature, to a regulatory authority with respect to the preparation or implementation of regulations.

This Article does not apply to a group or body that is established to enhance coordination between the authorities of the territory represented by a Party or to provide advice related to international affairs or the essential security interests of the authorities of the territory represented by the Party.

3. Each Party, through its Designated Representative, shall ensure that the membership of any expert group or body established by the regulatory authorities includes a range and diversity of views and interests, as appropriate to the particular context.

4. Recognizing the importance of keeping the public informed with respect to the purpose, membership, and activities of expert groups and bodies, and that those expert groups or bodies can provide an important additional perspective or expertise on matters affecting the operations of the authorities of the territory represented by a Party, each Party, through its Designated Representative, shall encourage the regulatory authorities to provide public notice of:

- (a) the name of any expert group or body they create or use, and the names of the members of the group or body and their affiliations;
- (b) the mandate and functions of the expert group or body;
- (c) information about upcoming meetings of an expert group or body;
- (d) a summary of the outcome of any meeting of an expert group or body; and
- (e) a summary of the final outcome on any substantive matter considered by an expert group or body.

5. Each Party, through its Designated Representative, shall make publicly available, preferably on the relevant regulatory authority's website, any final documents made available to or prepared for or by the expert group or body, except to the extent necessary to protect confidential information or withhold personal identifying information.

6. Each Party, through its Designated Representative, should provide a means for interested persons to provide input to expert groups or bodies, including by allowing interested persons to:

- (a) attend or appear before meetings of an expert group or body; or
- (b) submit written comments to an expert group or body.

Article 3.11: Regulatory Analysis

1. The Parties, through their Designated Representatives, recognize that a regulatory authority may analyze a proposed regulation to anticipate and evaluate its likely consequences.

2. Each Party, through its Designated Representative, shall consider procedures that encourage a regulatory authority to examine the following when developing regulations that have anticipated costs or impacts exceeding certain levels established by each Party, through its Designated Representative:

- (a) the need for a proposed regulation, including a description of the nature and significance of the problem the regulation is intended to address;
- (b) feasible and appropriate regulatory and non-regulatory alternatives that would address the need identified in subparagraph (a), including alternatives to direct regulation;
- (c) anticipated impacts of the selected and other feasible alternatives (such as economic costs and benefits, social, equity, environmental, public health, and safety effects), as well as risks and distributional effects over time, recognizing that some costs and benefits are difficult to quantify or monetize due to inadequate information. The analysis of these impacts by the regulatory authority may vary according to the complexity of the issue as well as the available data and information; and
- (d) the grounds for concluding that the selected alternative is preferable.

3. Each Party, through its Designated Representative, should consider whether a proposed regulation may have significant adverse economic effects on a substantial number of small enterprises. If so, the Party, through its Designated Representative, should consider potential steps to minimize those adverse economic impacts, while allowing fulfillment of the objectives.

Article 3.12: Final Publication

When a regulatory authority finalizes its work on a regulation, the Party, through its Designated Representative, shall, without undue delay, publish in the text of the regulation, in the final regulatory impact assessment, or in another document:

- (a) the date by which compliance is required;
- (b) an explanation of how the regulation achieves the stated objectives, the rationale for the material features of the regulation (to the extent different than the explanation provided for in Article 3.9), and the nature of and reasons for any significant revisions made since making the regulation available for public comment;
- (c) the regulatory authority's views on any substantive issues raised in timely submitted comments;

- (d) major alternatives, if any, that the regulatory authority considered in developing the regulation and reasons supporting the alternative that it selected;
- (e) the relationship between the regulation and the key evidence, data, and other information the regulatory authority considered in finalizing its work on the regulation;
- (f) any forms or documents required to comply with the regulation and indication of their expected availability, which should be, to the extent possible, made publicly available online; and
- (g) a point of contact for a knowledgeable individual in the regulatory authority responsible for implementing the regulation who may be contacted concerning questions regarding the regulation.

Article 3.13: Review of Regulations Currently in Effect

1. The Parties, through their Designated Representatives, recognize that adopting or maintaining procedures or mechanisms to carry out review of regulations can ensure that a regulation remains relevant and meets its intended policy objective.

2. If a regulation currently in effect is reviewed, the Party, through its Designated Representative, should consider, as appropriate:

- (a) the effectiveness of the regulation in meeting its initial stated objectives;
- (b) any circumstances that have changed since the development of the regulation, including availability of new information;
- (c) impacts on small enterprises;
- (d) ways to address regulatory differences between the authorities of the territories represented by the Parties with a view to avoiding unnecessary disruptions to international trade and investment; and
- (e) relevant suggestions from any interested persons submitted pursuant to Article 3.14.

3. Each Party, through its Designated Representative, should make publicly available online, to the extent available and appropriate, any official plans or results of a review.

4. Each Party, through its Designated Representative, should consider how to make regulatory review procedures and mechanisms more agile, especially when facing shared transboundary and

global challenges.

Article 3.14: Suggestions for Improvement

Each Party, through its Designated Representative, shall provide the opportunity for any interested person to submit for consideration to a regulatory authority written suggestions for the issuance, modification, or repeal of a regulation. The basis for those suggestions may include, for example, that in the view of the interested person, the regulation has become ineffective at protecting health, safety, welfare, or the environment, has become more burdensome than necessary to achieve its objective (for example, with respect to its impact on international trade and investment), fails to take into account changed circumstances (such as fundamental changes in technology, or relevant scientific and technical developments, or relevant international standards), or relies on incorrect or outdated information.

Article 3.15: Information About Regulatory Processes and Authorities

1. Each Party, through its Designated Representative, shall publish online a description of the processes and mechanisms employed by the regulatory authorities to prepare, evaluate, or review regulations. The description shall identify the applicable guidelines, rules, or procedures, including those regarding opportunities for the public to provide input.
2. Each Party, through its Designated Representative, shall also make publicly available online:
 - (a) a description of the functions and organization of each regulatory authority, including the appropriate offices through which persons can obtain information, make submissions or requests, or obtain decisions;
 - (b) any procedural requirements or forms promulgated or utilized by any regulatory authority;
 - (c) the legal authority for verification, inspection, and compliance activities by the regulatory authorities;
 - (d) information concerning the judicial or administrative procedures available to challenge regulations; and
 - (e) any fees charged by a regulatory authority to a person of the territory represented by a Party for services rendered in connection with the implementation of a regulation, including for licensing, inspections, audits, and other administrative actions required under the law of the territory represented by the Party, to import, export, sell, buy, market, or use, as appropriate, either a good or a service.

Each Party, through its Designated Representative, shall, without undue delay, publish online any material changes to this information as well as any changes, or any proposals to make changes, to the regulatory system of the authorities of the territory it represents.

Article 3.16: Encouragement of Regulatory Compatibility and Cooperation

1. The Parties, through their Designated Representatives, recognize that regulatory compatibility and cooperation can contribute to achieving shared regulatory objectives and assisting the authorities of the territories represented by the Parties in meeting shared transboundary and global challenges. Accordingly, where appropriate, each Party, through its Designated Representative, should encourage the regulatory authorities to engage in mutually beneficial regulatory cooperation activities with the relevant counterparts of the authorities of the territory represented by the other Party in appropriate circumstances to achieve these objectives.

2. The Parties, through their Designated Representatives, recognize that effective regulatory cooperation requires the participation of regulatory authorities that possess the authority and technical expertise to develop, adopt, and implement regulations. Each Party, through its Designated Representative, should encourage input from members of the public to identify promising avenues for cooperation activities.

3. The Parties, through their Designated Representatives, recognize that a broad range of mechanisms, including those set forth in the WTO Agreement, exists to help minimize unnecessary regulatory differences and to avoid unnecessary disruptions to international trade and investment, while contributing to meeting the public policy objectives of the authorities of the territories represented by the Parties.

Article 3.17: Committee on Good Regulatory Practices

1. The Parties, through their Designated Representatives as appropriate, hereby establish a Committee on Good Regulatory Practices (the GRP Committee) composed of representatives of the Parties and relevant representatives of the authorities of the territories represented by the Parties, including relevant regulatory authorities and any coordinating bodies.

2. Through the GRP Committee, the Parties, through their Designated Representatives, shall enhance their communication and collaboration in matters relating to this Chapter.

3. The GRP Committee's functions include:

- (a) monitoring the implementation and operation of this Chapter, including through updates on regulatory practices and processes of the authorities of the territories represented by the Parties;

- (b) exchanging information on effective methods for implementing this Chapter, including with respect to relevant work in international forums;
- (c) consulting on matters and positions in advance of meetings in international forums that are related to the work of this Chapter, including opportunities for workshops, seminars, and other relevant activities to support strengthening of good regulatory practices;
- (d) considering suggestions from a diverse array of stakeholders regarding opportunities to strengthen the application of good regulatory practices;
- (e) considering developments in good regulatory practices with a view to identifying future work for the GRP Committee and improving the operation and implementation of this Chapter;
- (f) exploring opportunities to cooperate to advance the application of good regulatory practices; and
- (g) taking any other steps that the Parties, through their Designated Representatives, consider will assist them in implementing this Chapter.

4. Each Party, through its Designated Representative, shall provide opportunities for persons of the territory represented by the Party to provide views on the implementation of this Chapter.

5. In carrying out its work, the GRP Committee shall take into account the activities of other committees, working groups, and other subsidiary bodies established under this Agreement in order to avoid duplication of activities.

6. Unless the Parties, in consultation with their Designated Representatives, decide otherwise, the GRP Committee shall meet at least once a year. The Parties, in consultation with their Designated Representatives, shall endeavor to schedule meetings to permit participation of representatives engaged in the work of other relevant chapters in this Agreement. The GRP Committee may also invite persons that may have an interest to contribute to its work.

Article 3.18: Contact Points

Each Party, in consultation with its Designated Representative, shall designate and notify a contact point for matters arising under this Chapter, in accordance with Article 7.7 (Contact Points), and without undue delay notify the other Party of any material changes to its contact point.

ANNEX 3-A

ADDITIONAL PROVISIONS CONCERNING THE SCOPE OF “REGULATIONS” AND “REGULATORY AUTHORITIES”

1. The following measures are not regulations for the purposes of this Chapter:
 - (a) general statements of policy or guidance that do not prescribe legally enforceable requirements;
 - (b) for **TECRO**: a measure concerning:
 - (i) a military or foreign affairs function of the authorities of the territory represented by TECRO;
 - (ii) the management, personnel, public property, loans, grants, benefits, or contracts of an agency of the authorities of the territory represented by TECRO;
 - (iii) the organization, procedure, or practice of an agency of the authorities of the territory represented by TECRO; or
 - (iv) financial services or anti-money laundering measures.
 - (c) for **AIT**: a measure concerning:
 - (i) a military or foreign affairs function of the authorities of the territory represented by AIT;
 - (ii) the management, personnel, public property, loans, grants, benefits, or contracts of an agency of the authorities of the territory represented by AIT;
 - (iii) the organization, procedure, or practice of an agency of the authorities of the territory represented by AIT; or
 - (iv) financial services or anti-money laundering measures.
2. The following entities are not regulatory authorities for the purposes of this Chapter:
 - (a) for **TECRO**: the President of the territory represented by TECRO; and
 - (b) for **AIT**: the President of the territory represented by AIT.