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CHAPTER 28

GOOD REGULATORY PRACTICES

Article 28.1: Definitions

For the purposes of this Chapter:

regulation means a measure of general application adopted, issued, or maintained by a regulatory authority with which compliance is mandatory, except as set forth in Annex 28-A;

regulatory authority means an administrative authority or agency at the Party's central level of government that develops, proposes or adopts a regulation, and does not include legislatures or courts; and

regulatory cooperation means an effort between Parties to prevent, reduce, or eliminate unnecessary regulatory differences between jurisdictions to facilitate trade and promote economic growth, while maintaining or enhancing standards of public health and safety and environmental protection.

Article 28.2: Subject Matter and General Provisions

1. The Parties recognize that implementation of government-wide practices to promote regulatory quality through greater transparency, objective analysis, accountability, and predictability can facilitate international trade, investment, and economic growth, while contributing to each Party's ability to achieve its public policy objectives (including health, safety, and environmental goals) at the level of protection it considers appropriate. The application of good regulatory practices can support the development of compatible regulatory approaches among the Parties, and reduce or eliminate unnecessarily burdensome, duplicative, or divergent regulatory requirements. Good regulatory practices are also fundamental to effective regulatory cooperation.

2. Accordingly, this Chapter sets forth specific obligations with respect to good regulatory practices, including practices relating to the planning, design, issuance, implementation, and review of the Parties' respective regulations.

3. Nothing in this Chapter prevents a Party from:

- (a) pursuing its public policy objectives (including health, safety, and environmental goals) at the level it considers to be appropriate;
- (b) determining the appropriate method of implementing its obligations in this Chapter within the framework of its own legal system and institutions; or

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- (c) adopting good regulatory practices that supplement those that are set out in this Chapter.

Article 28.3: Central Regulatory Coordinating Body

Recognizing that institutional arrangements are particular to each system of governance, the Parties note the important role of their respective central regulatory coordinating bodies in promoting good regulatory practices among their regulatory authorities; performing key advisory, coordination and review functions to improve the quality of regulations; and developing improvements to their regulatory system. The Parties intend to maintain their respective central regulatory coordinating bodies, within their respective mandates and consistent with their law.

Article 28.4: Internal Consultation, Coordination, and Review

1. The Parties recognize that internal processes or mechanisms providing for consultation, coordination, and review among domestic authorities in the development of regulations can increase regulatory compatibility among the Parties and facilitate trade. Accordingly, each Party shall adopt or maintain those processes or mechanisms to pursue, among others, the following objectives:

- (a) promoting government-wide adherence to good regulatory practices, including those set forth in this Chapter;
- (b) identifying and developing improvements to government-wide regulatory processes;
- (c) identifying potential overlap and duplication between proposed and existing regulations, and preventing the creation of inconsistent requirements across authorities;
- (d) supporting compliance with international trade and investment obligations, including, as appropriate, the consideration of international standards, guides, and recommendations;
- (e) promoting consideration of regulatory impacts, including burdens on small enterprises¹ of information collection and implementation and
- (f) encouraging regulatory approaches that avoid unnecessary restrictions on competition in the marketplace.

2. Each Party shall make publicly available a description of the processes or mechanisms referred to in paragraph 1.

¹ For greater certainty and for purposes of this Chapter, for Mexico “small enterprises” also include medium enterprises.

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Article 28.5: Information Quality

1. Each Party recognizes the need for regulations to be based upon information that is reliable and of high quality. To that end, each Party should adopt or maintain publicly available guidance or mechanisms that encourage its 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 it is 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 through identical questions in a survey for use in developing a regulation, each Party shall provide that the authority should:

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

Article 28.6: Early Planning

Each Party shall publish annually a list of regulations that it reasonably expects within the following 12 months to adopt or propose to adopt. Each regulation identified in the list should be accompanied by:

- (a) a concise description of the planned regulation;
- (b) a point of contact for a knowledgeable person 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.

Entries in the list should also include, to the extent available, time tables for subsequent actions, including those providing opportunities for public comment under Article 28.9.

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Article 28.7: Dedicated Website

1. Each Party shall maintain a single, freely accessible internet website that, to the extent practicable, contains all information that it is required to publish pursuant to Article 28.9.
2. A Party may comply with paragraph 1 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.

Article 28.8: Use of Plain Language

Each Party should provide that proposed and final regulations are written using plain language to ensure that those regulations are clear, concise, and easy for the public to understand, recognizing that some regulations address technical issues and that relevant expertise may be required to understand and apply them.

Article 28.9: Transparent Development of Regulations

1. During the period described in paragraph 2, when a regulatory authority is developing a regulation, the Party shall, under normal circumstances,² publish:
 - (a) the text of that 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 what data, other information, and analyses it relied upon to support the regulation; and
 - (d) the name and contact information of an individual official who may be contacted to address questions regarding the regulation.

At the same time, the Party shall also make publicly available data, other information, and scientific and technical analyses it relied upon in support of the regulation, including any risk assessment.

² For paragraphs 1 and 4, “normal circumstances” do not include, for example, situations where publication in accordance with those paragraphs would render the regulation ineffective in addressing the particular harm to the public interest which the regulation aims to address; where urgent problems (e.g., of safety, health, or environmental protection) arise or threaten to arise for a Party; or where the regulation has no substantive impact upon members of the public, including persons of another Party.

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2. With respect to the items required to be published under paragraph 1, each Party shall publish them before the regulatory authority finalizes its work on the regulation³ 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. The Parties are encouraged to publish government-generated items identified in this Article in a format that can be read and digitally processed through word searches and data mining by a computer or other technology.

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

4. If a Party expects a draft regulation to have a significant impact on trade, the Party should normally provide a time period to submit written comments and other input on the items published in accordance with paragraph 1 that is:

- (a) not less than 60 calendar days from the date the items identified in paragraph 1 are published; or
- (b) a longer time period as is 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 informative responses.

With respect to other draft regulations, a Party shall endeavor, under normal circumstances, to provide a time period to submit written comments and 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.

5. With respect to regulations referred to in paragraph 4, each Party shall consider reasonable requests to extend the comment period.

6. Each Party shall endeavor to promptly make publicly available any written comments it receives, except to the extent necessary to protect confidential information or withhold personal identifying information or inappropriate content. If it is impracticable to post all such comments on the website provided for in Article 28.7 the regulatory authority of a Party shall endeavor to make those comments available via its own website.

7. Before finalizing its work on a regulation, a regulatory authority of a Party shall evaluate any information provided in written comments received during the comment period.

³ For Canada a regulatory authority “finalizes its work” on a regulation when a final regulation is published in Canada Gazette, Part II. For Mexico a regulatory authority “finalizes its work” on a regulation when the final Act of General Application is issued and published in the Official Gazette. For the United States, a regulatory authority “finalizes its work” on a regulation when a final rule is signed and published in the Federal Register.

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8. When a regulatory authority of a Party finalizes its work on a regulation, the Party shall promptly publish the text of the regulation, any final impact assessment, and other items as set out in Article 28.12.

Article 28.10: Expert Advisory Groups

1. The Parties recognize that their respective regulatory authorities may seek expert advice and recommendations with respect to the preparation or implementation of regulations from groups or bodies that include non-governmental persons. The Parties further recognize that obtaining such advice and recommendations should be a complement to, rather than a substitute for, the procedures seeking public comment pursuant to Article 28.9.4.

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

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

This Article does not apply to a group or body that is established to enhance intergovernmental coordination, or to provide advice related to international affairs, including national security.⁴

3. Each Party shall encourage its regulatory authorities to ensure that the membership of any expert group or body 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 such groups or bodies can provide an important additional perspective or expertise affecting government operations, each Party shall encourage its regulatory authorities to provide public notice of:

- (a) the name of any expert group or body it creates or uses, 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; and
- (d) a summary of the outcome of these meetings.

⁴ For greater clarity, this Article does not apply to Mexico's National Standardization Advisory Committees (Comité Consultivo Nacional de Normalización), established under article 62 of the Federal Law on Metrology and Standardization.

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Each Party shall endeavor, as appropriate, to make publicly available any supporting documentation, and recognizes the importance of providing a means for interested persons to provide inputs to the expert groups.

Article 28.11: Regulatory Impact Assessment

1. The Parties recognize that regulatory impact assessment is a tool to assist regulatory authorities in assessing the need for and potential impacts of regulations they are preparing. Each Party should encourage the use of regulatory impact assessments in appropriate circumstances when developing proposed regulations that have anticipated costs or impacts exceeding certain thresholds established by the Party.

2. Each Party shall maintain procedures that promote the consideration of the following when conducting a regulatory impact assessment:

- (a) the need for a proposed regulation, including a description of the nature and significance of the problem it is intended to address;
- (b) feasible and appropriate regulatory and non-regulatory alternatives that would address the need identified in subparagraph (a), including the alternative of not regulating;
- (c) benefits and costs of the selected and other feasible alternatives, including the relevant impacts (such as economic, social, 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 and monetize; and
- (d) the grounds for concluding that the selected alternative is preferable.

3. Each Party should consider whether a proposed regulation may have significant adverse economic effects on a substantial number of small enterprises. If so, the Party should consider potential steps to minimize such adverse economic impact, while continuing to allow the Party to fulfill its objectives.

Article 28.12: Final Publication

1. When a regulatory authority of a Party finalizes its work on a regulation, the Party shall promptly publish, in a final regulatory impact assessment or other document:

- (a) the date by which compliance is required;
- (b) an explanation of how the regulation achieves the Party's objectives, the rationale for the essential features of the regulation (to the extent different than the explanation provided in Article 28.9), and the nature of and reasons for any

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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; and
 - (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.
2. Each Party shall ensure that all regulations in effect are online and publicly available.

Article 28.13: Retrospective Review

1. Each Party shall adopt or maintain procedures or mechanisms to conduct retrospective reviews of its regulations in order to determine whether modification or repeal is appropriate. Retrospective reviews may be initiated, for example, pursuant to a Party's law, on a regulatory authority's own initiative, or in response to a suggestion submitted pursuant to Article 28.14.

2. When conducting retrospective reviews, each Party should consider, as appropriate:
- (a) the effectiveness of the regulation in meeting its initial stated objectives, such as the actual social or economic impacts;
 - (b) any circumstances that have changed since the development of the regulation, including availability of new information;
 - (c) new opportunities to eliminate unnecessary regulatory burdens;
 - (d) ways to address unnecessary regulatory differences that may adversely affect trade among the Parties, including through the activities listed in Article 28.17.3; and
 - (e) any relevant views expressed by members of the public.
3. Each Party shall include among the procedures or mechanisms adopted pursuant to paragraph 1 provisions addressing impacts on small enterprises.
4. Each Party is encouraged to publish, to the extent available, any official plans and results of retrospective reviews.

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Article 28.14: Suggestions for Improvement

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

Article 28.15: Information About Regulatory Processes

1. Each Party shall publish online a description of the processes and mechanisms employed by its 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 shall also publish online:

- (a) a description of the functions and organization of each of its regulatory authorities, 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 of its regulatory authorities;
- (c) the legal authority for regulatory authorities' verification, inspection, and compliance activities;
- (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 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 Party's law to import, export, sell, market, or use a good.

Article 28.16: Annual Report

Each Party shall prepare and make publicly available, on an annual basis, a report setting forth:

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- (a) to the extent feasible, an estimate regarding the annual costs and benefits of economically significant regulations, as established by the Party, issued in that period by its regulatory authorities, on an aggregate or individual basis; and
- (b) any changes, or any proposals to make changes, to its regulatory system.

Article 28.17: Encouragement of Regulatory Compatibility and Cooperation

1. The Parties recognize the important contribution of dialogues between their respective regulatory authorities in promoting regulatory compatibility and regulatory cooperation where appropriate, and in order to facilitate trade and investment and to achieve regulatory objectives. Accordingly, each Party should encourage its regulatory authorities to engage in mutually beneficial regulatory cooperation activities with relevant counterparts of one or more of the other Parties in appropriate circumstances to achieve these objectives.

2. The Parties recognize the valuable work of cooperation fora, and intend to continue to work together to further regulatory compatibility on a mutually beneficial basis in such fora or under this Agreement. The Parties also 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 should encourage input from members of the public to identify promising avenues for cooperation activities.

3. The Parties recognize that a broad range of mechanisms including those set forth in the WTO Agreement, exists to help minimize unnecessary regulatory differences and facilitate trade or investment, while contributing to each Party's ability to meet its public policy objectives. These activities may include, as appropriate to the particular circumstances:

- (a) early stage formal or informal exchange of technical or scientific information or data, including coordinating research agendas, to reduce duplicative research;
- (b) exploring possible common approaches to the evaluation and mitigation of risks or hazards, including those potentially posed by the use of emerging technologies;
- (c) wherever appropriate, regulating by specifying performance requirements rather than design characteristics, to promote innovation and facilitate trade;
- (d) seeking to collaborate in relevant international fora;
- (e) exchanging information, such as of technical or practical nature, on regulations that each Party is developing to maximize the opportunity for common approaches;
- (f) co-funding of research in support of regulations and implementation tools of joint interest;

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- (g) facilitating the greater use of relevant international standards, guides, and recommendations as the basis for regulations, testing, and approval procedures;
- (h) when developing or implementing regulations, considering relevant scientific or technical guidance documents developed through international collaborative initiatives;
- (i) considering common approaches to the display of product or consumer information;
- (j) considering the development of compatible platforms or formats for industry submission of product information for regulatory review;
- (k) coordinating in the implementation of regulations and sharing compliance information, including, as appropriate by entering into confidentiality agreements; and
- (l) periodically exchanging information, as appropriate, concerning any planned or ongoing post-implementation review or evaluation of regulations in effect affecting trade or investment.

Article 28.18: Committee on Good Regulatory Practices

1. The Parties hereby establish a Committee on Good Regulatory Practices (the Committee) composed of government representatives from each Party, including representatives from their central regulatory coordinating bodies as well as from relevant regulatory agencies.

2. Through the Committee, the Parties shall enhance their communication and collaboration in matters relating to this Chapter, including encouragement of regulatory compatibility and regulatory cooperation, with a view to facilitating trade between the Parties. The Committee's functions include:

- (a) monitoring the implementation and operation of this Chapter, including through updates on each Party's regulatory practices and processes;
- (b) exchanging information on effective methods for implementing this Chapter, including with respect to approaches to regulatory cooperation, and relevant work in international fora;
- (c) consulting on matters and positions for upcoming meetings in international fora 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 and to support improvements in approaches to regulatory cooperation.

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- (d) considering suggestions from stakeholders regarding opportunities to strengthen the application of good regulatory practices;
- (e) considering developments in good regulatory practices and approaches to regulatory cooperation with a view to identifying future work for the Committee or making recommendations as appropriate to the Commission for improving the operation and implementation of this Chapter; and
- (f) taking any other steps that the Parties consider will assist them in implementing this Chapter.

Each Party shall provide opportunities for persons of that Party to provide views on the implementation of this Chapter.

3. In carrying out its work, the 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.

4. Unless the Parties decide otherwise, the Committee shall meet at least once a year. The Parties shall endeavor to schedule Committee meetings to permit participation of government representatives engaged in the work of other relevant chapters in this Agreement. The Committee may also invite interested persons to contribute to its work.

5. The Committee shall provide an annual report on its activities.

Article 28.19: Contact Points

Each Party shall designate and notify a contact point for matters arising under this Chapter, in accordance with Article 30.5 (Agreement Coordinator and Contact Points). A Party shall promptly notify the other Parties of any material changes to its contact point.

Article 28.20: Application of Dispute Settlement

1. Recognizing that a mutually acceptable solution can often be found outside recourse to dispute settlement, a Party shall exercise its judgement as to whether recourse to dispute settlement under Chapter 31 (Dispute Settlement) would be fruitful.

2. Chapter 31 (Dispute Settlement) shall apply with respect to a responding Party as of one year after the date of entry into force of this Agreement for that Party.

3. No Party shall have recourse for dispute settlement under Chapter 31 (Dispute Settlement) for a matter arising under this Chapter except to address a sustained and recurring course of action or inaction that is inconsistent with a provision of this Chapter.

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ANNEX 28-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) **for all Parties:** General statements of policy or guidance that do not prescribe legally enforceable requirements;
 - (b) **for Canada:** a measure concerning (i) a military, foreign affairs, or national security function of the Government of Canada, (ii) public sector management, personnel, pensions, public property, loans, grants, benefits, or contracts, (iii) departmental organization, procedure, or practice, (iv) taxation, financial services or anti-money laundering measures, or (v) federal/provincial/territorial relations and agreements and relations with Aboriginal Peoples, (vi) a measure that does not constitute a regulation under the *Statutory Instruments Act*;
 - (c) **for Mexico:** a measure concerning (i) taxation, specifically those related with contributions and their accessories, (ii) public servants responsibilities, (iii) agrarian and labor justice, (iv) financial services or anti-money laundering measures, (v) public prosecutor’s office executing its constitutional functions, and (vi) navy and defense; and
 - (d) **for the United States:** a measure concerning (i) a military or foreign affairs function of the United States, (ii) agency management, personnel, public property, loans, grants, benefits, or contracts, (iii) agency organization, procedure, or practice, or (iv) financial services or anti-money laundering measures.

2. The following entities are not a regulatory authorities for the purposes of this Chapter:
 - (a) **for Canada:** the Governor in Council; and
 - (b) **for the United States:** the President.