REGULATORY COOPERATION

Article X.1: Scope

This Chapter applies to the development, review and methodological aspects of regulatory measures of the Parties' regulatory authorities that are covered by,*inter alia*, the *TBT Agreement,* the *SPS Agreement*, the *GATT 1994,* the *GATS*, and Chapters X (TBT); X (SPS); [X (CBTS)]; X (Environment); X (SD); X (Labour); [and, X ~~(~~ (Investment, **Sections 1, 2, 3, 4 and 5**)] of this Agreement.

The Parties agree to return to the list of Chapters in brackets, as necessary, in consultation with other Leads upon the completion of other Chapters. As regards Investment, it is proposed to reflect the rules-based Investmentprovisions in Article X.1. With respect to CBTS, the EU requests a final discussion upon completion of the CBTS and Financial Services Chapter(s) in view of ensuring that this reference does not extend to financial services.

Article X.2: Principles

1. The Parties affirm their rights and obligations relating to regulatory measuresunder the *TBT Agreement*, *SPS Agreement,GATT 1994* and *GATS*.

2. The Parties commit themselves to ensuring high levels of protection for human, animal and plant life or health, and the environment in accordance with the *TBTAgreement*, *SPS Agreement*, *GATT 1994* and *GATS*.

3. The Parties recognise the value of regulatory cooperation with their relevant trading partnersboth bilaterally and multilaterally. The Parties will, whenever practicable and mutually beneficial, approach regulatory cooperation in a way that is open to participation by other international trading partners.

4. Without limiting the ability of each Party to carry out its regulatory, legislative and policy activities, the Parties commit themselves to further developing their regulatory cooperation in light of their mutual interest in order to: (a) prevent and eliminate unnecessary barriers to trade and investment; (b) enhance the climate for competitiveness and innovation, including through pursuing regulatory compatibility, recognition of equivalence, and convergence; and (c) promote transparent, efficient and effective regulatory processes that better support public policy objectives and fulfil the mandates of regulatory bodies, including through the promotion of information exchange and enhanced use of best practices.

5. The provisions of this Chapter replace the Government of Canada – European Commission Framework on Regulatory Cooperation and Transparency and shall governthe activities previously undertaken in the context of that Framework.

6. The Parties may undertake regulatory cooperation activities, on a voluntary basis. For greater certainty,neither Party is obliged to enter into particular regulatory cooperation activities, and either Party may refuse to cooperate or may withdraw from cooperation.However, if a Party refuses to initiate regulatory cooperation or withdraws from such cooperation, it should be prepared to explain the reasons for its decision to the other Party.

Article X.3 Objectives of Regulatory Cooperation

The objectives of regulatory co-operation include:

(a) Contributing to the protection of human life, health or safety, animal or plant life or health and the environment by:

(i) leveraging international resources in areas such as research, pre-market reviews and risk analysis to address important regulatory issues of local, national and international concern; and

(ii) contributing to the base of information used by regulatory departments for identifying, assessing and managing risks.

(b) Building trust, deepening mutual understanding of regulatory governance and obtaining from each other the benefit of expertise and perspective to:

(i) improve the planning and development of regulatory proposals;

(ii) promote transparency and predictability in the development and establishment of regulations;

(iii) enhance the efficacy of regulations;

(iv) identify alternative instruments;

(v) recognize the associated impacts of regulations;

(vi) avoid unnecessary regulatory differences; and

(vii) improve regulatory implementation and compliance.

(c) Facilitating bilateral trade and investment by:

(i) building on previously existing co-operative arrangements;

(ii) reducing unnecessary differences in regulation; and
(iii) identifying new ways of working for co-operation in specific sectors.

(d) Contributing to the improvement of competitiveness and efficiency of industry by:
(i) minimizing administrative costs wherever possible;

(ii) reducing duplicative regulatory requirements and consequential compliance costs wherever possible; and

(iii) pursuing compatible regulatory approaches including, if possible and appropriate, through:

a). the application of regulatory approaches which are technology-neutral, and
b). the recognition of equivalence or the promotion of convergence.

Article X.4 Regulatory Cooperation Activities

The Parties endeavour to fulfill the objectives set out in Article X.3 by undertaking regulatory co-operation activities. These activities may include:

1. Engaging in ongoing bilateral discussions on regulatory governance, including to:

(a) discuss regulatory reform and its effects on the Canada-EU relationship;

(b) identify lessons learned;

(c) explore, if appropriate, alternative approaches to regulation; and

(d) exchange experiences with regulatory tools and instruments, including regulatory impact assessments, risk assessment and compliance and enforcement strategies.

2. Consulting with each other as appropriate and exchanging information during the regulatory development process. This consultation and exchange may occur throughout the regulatory development process, and should begin as early as possible in that process.

3. Sharing non-public information to the extent that such information may be made available to foreign governments in accordance with the applicable rules of the Party.

4. Sharing proposed technical or sanitary and phytosanitary regulations that may have an impact on trade with the other Party at as early a stage as possible so that comments and proposals for amendments may be taken into account,

5. Providing, upon request by the other Party, copies of the proposed regulation, subject to applicable privacy laws, and allowing sufficient time for interested parties to provide comments in writing.

6.Exchanging information about contemplated regulatory actions, measures or amendments under consideration, at the earliest stage possible, in order to:

(a) better understand the rationale behind regulatory choices, including instrument choice, and examine the possibilities for greater convergence on how to state the objectives of regulations and how to define their scope. The interface between regulations, standards and conformity assessment should also be addressed in this context;

(b) compare methods and assumptions used in analyzing regulatory proposals, including, when appropriate, analysis of technical or economic practicability and benefits in relation to the objective pursued of any major alternative regulatory requirements and approaches considered. This information exchange may also include compliance strategies and impact assessments, including a comparison of the potential cost-effectiveness of the regulatory proposal to that of major alternative regulatory requirements and approaches considered;

7. Examining opportunities to minimize unnecessary divergences in regulations through means such as:

(a) Conducting concurrent or joint risk assessments and regulatory impact assessments if practicable and mutually beneficial,

(b) achieving harmonized, equivalent or compatible solutions, or

(c) considering the use of mutual recognition in specific cases.

8.Cooperating on issues regarding the development, adoption, implementation and maintenance of international standards, guides and recommendations.

9.Examining the appropriateness and possibility of collecting the same or similar data about the nature, extent and frequency of problems potentially warranting regulatory action when it would expedite making statistically significant judgments about those problems.

10. Periodically conducting comparisons of data collection practices.

11. Examining the appropriateness and the possibility of using the same or similar assumptions and methodologies as those used by the other Party when analyzing data and assessing underlying issues to be addressed through regulation in order to:

(a) reduce differences in identifying issues; and

(b) promote similarity of results.

12. Periodically comparing analytical assumptions and methodologies.

13. Exchanging information on the administration, implementation and enforcement of regulations, as well as on the means to obtain and measure compliance.

14. Conducting co-operative research agendas in order to:

(a) reduce duplicative research;

(b) generate more information at less cost;

(c) gather the best data;

(d) establish, when appropriate, a common scientific basis;

(e) address the most pressing regulatory problems in a more consistent and performance-oriented manner; and

(f) minimize unnecessary differences in new regulatory proposals while more effectively improving health, safety and environmental protection.

15. Conducting post-implementation reviews of regulations or policies.

16. Comparing methods and assumptions used in those post-implementation reviews.

17. When applicable, making summaries of the results of those post-implementation reviews available to each other.

18.Identifying the appropriate approaches to reducing any adverse effects of existing regulatory differences on bilateral trade and investment in sectors identified by a Party, including, when appropriate, through greater convergence, mutual recognition, minimising the use of trade distorting regulatory instruments, and use of international standards including standards and guides for conformity assessment.

[19. Exchanging information, expertise and experiences in the field of animal welfare in order to promote collaboration on animal welfare between the Parties.]

Placement of this text in the Regulatory Cooperation Chapter to be finalized at Chiefs' level.

Article X.5: Compatibility of Regulations

With a view to enhancing convergence and compatibility between regulatory measures of the Parties, each Party shall, when appropriate, consider the regulatory measures or initiatives of the other Party on the same or related topics. Thisconsideration does not prevent either Party from adopting differing measures or pursuing differing approaches for reasons including different institutional and legislative approaches, or circumstances, values or priorities particular to that Party.

Article X.6: Role and Composition of the Regulatory Cooperation Forum

1. A Regulatory Cooperation Forum ("the RCF") shall be established to facilitate and promote regulatory cooperation between the Parties in accordance with the provisions of this Chapter.

2. The RCF shall perform the following functions:

   (a) Provide a setting for discussion of regulatory policy issues of mutual interest identified by the Parties through, *inter alia*, any consultations conducted in accordance with Article X.8;

   (b) Assist individual regulators in identifying potential partners for cooperation activities and provide appropriate tools, such as model confidentiality agreements;

   (c) Review regulatory initiatives, whether in progress or anticipated, that either Party considers provide potential for cooperation;these reviews, which will be carried out in consultation with regulatory departments and agencies, should support the implementation of this Chapter;

   (d) Encourage the development of bilateral cooperation activities in accordance with Article X.4 and, on the basis of information obtained from regulatory departments and agencies, review the progress, achievements and best practices of regulatory cooperation initiatives in specific sectors.

3. The RCF shall be co-chaired by a senior representative of the Government of Canada at the level of a Deputy Minister, equivalent or designate and a senior representative of the European Commission at the level of a Director General, equivalent or designate and shall comprise relevant officials of each Party. The Parties may together invite other interested parties to participate in the meetings of the RCF.

4. The RCF shall:

   (a) adopt its own terms of reference, procedures and work-plan at its first meeting after the entry into force of this Agreement;

   (b) meet within one year from the date of entry into force of this Agreement and at least annually thereafter, unless the Parties decide otherwise;

   (c) report to the [CETA's Trade Council] on the implementation of this Chapter as appropriate.

Article X.7: Further Cooperation of the Parties

1. Pursuant to Article X.6.2(c) and to enable monitoring of forthcoming regulatory projects and to identify opportunities for regulatory cooperation, the Parties shall periodically exchange information of ongoing or planned regulatory projects in their areas of responsibility. This information should include, where appropriate, new technical regulations, and the amendments to existing technical regulations that are likely to be proposed or adopted.

2. The Parties may facilitate regulatory cooperation through the exchange of officials pursuant to a specified arrangement.

3. The Parties endeavourto cooperate and share information on a voluntary basis in the area of non-foodproduct safety. Such cooperation or exchange of information may in particular relate to:

   - scientific, technical, and regulatory matters, to help improve non-food product safety;
   - emerging issues of significant health and safetyrelevance falling within the scope of their respective authority;
   - standardisation related activities;
   - market surveillance and enforcement activities;
   - risk assessment methods and product testing;
   - coordinated product recalls or other similar actions.

4. The Parties may establish reciprocal information exchange on the safety of consumer products and on preventive, restrictive and corrective measures taken in this regard. In particular, Canada may receive access to selected information from the EU RAPEX alert system, or, if applicable, its successor, with respect to consumer products as referred to in Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety; the EU may receive early warning information on restrictive measures and product recalls from Canada's consumer product incident reporting system, known as RADAR, or, if applicable, its successor, with respect to consumer products as defined in the *Canada Consumer Product Safety Act* and cosmetics as defined in the *Food and Drugs Act*. This reciprocal exchange of information shall be possible on the basis of a separate arrangement laying down the details referred to under paragraph 6.

5. Before the first information exchange provided for under paragraph 5, the Parties shall ensure that the detailed measures to implement such exchanges are endorsed by *<a CETA Committee to be determined>*.These detailed measures shall include specification on the type of information to be exchanged, the modalities for the exchange, the application of confidentiality rules and rules on personal data protection.

6. The <*CETA committee to be determined*> shall endorse the detailed measures under paragraph 6 within 1 year from the date of entry into force of the Agreement unless extended by the Parties.

7. The Parties may make modifications or corrections to the detailed measures referred to in paragraph 6. Any modification or correction to the detailed measures shall be endorsed by the <*relevant CETA Committee*>.

8. References in this Article to specific laws, regulations or other legal instruments of a Party include, if applicable, any subsequent amendments or successors to them.

Article X.8: Consultations with Private Entities

In order to gain non-governmental perspectives, the Parties may jointly or separately consult, as appropriate, with stakeholders and interested parties, including representatives from academia,think-tanks, non-governmental organizations, business, consumer and other organizations by any means they deem appropriate on matters relating to the implementation of this Chapter.

Article X.9: Contact Points

1. The Contact Points responsible for communications related to mattersarising under this Chapter are:

    a. in the case of Canada: the Technical Barriers and Regulations Division of the Department of Foreign Affairs, Trade and Development or its successor;

    b. in the case of the European Union: the International Affairs Unit of the Directorate-General for Enterprise and Industry, European Commission, or its successor.

2. Each Contact Point is responsible for consulting and coordinating with its respective regulatory departments and agencies, as appropriate, in matters arising under this Chapter.