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Regional and Bilateral Initiatives

Government of Canada - European Commission



Framework on Regulatory Co-operation and Transparency

A. GENERAL

I. Introduction

The Government of Canada and the European Commission (Commission)

Seeking to address new challenges and opportunities by enhancing regulatory co-operation, and to work towards preventing and eliminating unnecessary barriers to trade and investment while ensuring better quality and effective regulations to achieve public policy objectives,

Committed to ensuring high levels of protection via regulation for their essential public interests including human, animal, plant life or health, and the environment,

Confirming that this Framework, as a non-legally binding document, cannot affect commitments under bilateral, regional and multilateral environment, health, safety or other international agreements to which either the Government of Canada and/or the European Communities may be a party,

Recognizing that regulation impacts society, and that a strong regulatory environment is one that balances social, environmental and economic interests, and increases public confidence and trust in government institutions, regulators and their decision-making practices,

Recognizing also that increased regulatory dialogue between the Commission and the Government of Canada has the potential to enhance the bilateral relationship and that the Commission and the Government of Canada share many of the same broad objectives and values when developing sound policies and regulations to protect the public and the environment,

Recognizing further that it is desirable that this dialogue take place within a Framework, while at the same time noting that the voluntary Framework should not be considered legally binding for either the Government of Canada, the European Commission, or the European Communities,

Noting that this Framework provides a useful instrument to exchange views on various regulatory activities including those which may subsequently be subject to discussion in the relevant agreements under the World Trade Organization, and that this Framework is without prejudice to the rights and obligations derived from those agreements,

Taking into account the shared commitment to regulatory reform as reflected in the EU "Better Regulation Package" and the Government of Canada's "Smart Regulation" initiative,

Noting the potential for further co-operation in trilateral, multilateral and regional fora on issues of mutual concern and interest to regulators and policy makers in the areas of standardization and regulation,

Desiring to build on the long and fruitful co-operation between the European Union and Canada since the 1976 Framework Agreement for Commercial and Economic Co-operation, the 1996 Joint Action Plan and the 1998 EU-Canada Trade Initiative, as well as the various bilateral sectoral agreements,

Desiring to implement the Joint Statement of the EU-Canada Summit of December 2002, where leaders recognised that "regulatory co-operation is considered a priority by our respective business communities" and having "agreed to intensify our regulatory dialogue"

Seeking to implement the *Joint Action Plan for Regulatory Co-operation and Dialogue* adopted at the EU-Canada Summit in May 2003, where four broad "ways and means" were identified, notably,

- i. a senior level **regulatory policy seminar** on the respective internal regulatory approaches and procedures which was held in June 2003 with the objective of achieving a common understanding on the potential for EU-Canada regulatory co-operation;
- ii. a review of **existing areas of bilateral co-operation** between regulators in specific sectors to assess the need and appropriate means for improved co-operation;
- iii. a review of **stakeholders' concerns and market access barriers**,
- iv. the development of a **Framework for Regulatory Co-operation**,

Noting the leaders' commitment at the EU-Canada summit of March 2004 to negotiate a new Trade and Investment Enhancement Agreement (TIEA) between Canada and the European Communities and its Member States to further stimulate our bilateral economic relationship, and their agreement to make regulatory co-operation a key element of the future agreement,

have established this Framework to enhance regulatory co-operation, and to

work towards preventing and eliminating unnecessary barriers to trade and investment while ensuring effective regulations to achieve public policy objectives.

II. Objectives

1. The objectives of this Framework include:

- i. To offer high level political support to the process of co-operation between policy makers, technical experts and regulators of the Government of Canada and the Commission;
- ii. To support existing, and encourage new, co-operation between regulators by providing ideas for how such co-operation could take place;

2. The objectives of regulatory co-operation include

A. Regulatory Governance

to achieve a better understanding of each side's regulatory systems and obtain from each other the benefit of expertise and perspective for enhancing the efficacy of regulations, identifying alternative instruments, recognizing the associated impacts of regulations, and to deepen our understanding of the manner in which regulations are implemented and compliance is achieved.

B. Good regulatory practice to create better regulations

to advance bilateral co-operation between regulators and policy makers in order to promote transparency and predictability in the development and establishment of regulations, improve the planning and development of regulatory proposals, avoid unnecessary regulatory differences, and minimize administrative costs.

C. Facilitate trade and investment

to facilitate bilateral trade and investment by building on existing co-operative arrangements, reducing unnecessary differences in regulation, and identifying new appropriate modalities for co-operation in specific sectors.

D. Promote competitiveness and enhance the climate for innovation

to contribute to the improvement of competitiveness and efficiency of industry by reducing duplicative regulatory requirements and pursuing compatible regulatory initiatives where possible while ensuring a high level of protection to citizens and the environment.

3. Activities within the Framework will:

- a. Contribute to achieving high levels of safety for the protection of human, animal or plant life or health, the environment, consumers;

- b. Be fully consistent with any applicable domestic and international legal requirements, including rules and policies on transparency of government activities to the public at large, and preserve the integrity of the domestic regulation development process;
- c. Encourage, as appropriate, co-operation on a bilateral, trilateral, plurilateral or multilateral basis, which includes taking into account work carried out in multilateral and international institutions such as the Organization for Economic Co-operation and Development (OECD), the United Nations (UN), or other relevant international bodies involved in regulatory activities and;
- d. Not duplicate or overlap with any existing formal or informal arrangements for regulatory co-operation, unless so mutually agreed to by regulators.

III. Field of Application

4. This document represents the Framework under which regulators of the Government of Canada and the services of the Commission are encouraged to co-operate on a voluntary basis as broadly as possible. "Regulators" refers to officials – in regulatory departments in Canada and the services of the Commission - having policy competence for specific sectoral issues in each jurisdiction.
5. The Framework concerns regulatory activities during the planning and development of regulations for such measures that are covered by the WTO Agreement on Technical Barriers to Trade and the Agreement on the Application of Sanitary and Phytosanitary Measures where the Government of Canada and the Commission have jurisdiction, including the development of regulations for submission as legislative proposals.
6. The Framework concerns any regulations, and amendments to existing regulations, which regulators of either side believe may have significant effects on bilateral trade and investment, and/or where regulators on both sides agree that co-operation would be of mutual benefit, and that have been identified under the procedure in section V.

B. Operational

IV. Elements of Regulatory Co-Operation

The Government of Canada and the Commission seek to fulfil the objectives set out in section II by encouraging bilateral regulatory co-operation in the following areas:

A. Regulatory Governance

7. With a view to achieving a better understanding of good regulatory governance and working toward promoting best practices in the development of regulatory proposals, regulators and policy makers should engage in ongoing bilateral discussions, including in the area of regulatory reform (such as Better Regulation and Smart Regulation) and their effects on the Canada-EU relationship; identify lessons learned; explore, where appropriate, alternative approaches

to regulation; and exchange experiences with regulatory tools and instruments, including regulatory impact assessments and compliance strategies.

B. Good regulatory practice to create better regulations

Consultation and Exchange of Information

8. Regulators are encouraged to consult with their counterparts on a bilateral, trilateral, plurilateral or multilateral basis, as appropriate, and exchange information during the regulation development process. Such consultation and exchange may occur throughout the development process, beginning as early as possible in that process.
9. Regulators may share non-public information to the extent that such information may be shared with foreign governments in accordance with their applicable rules. A Model Confidentiality Arrangement is attached (Annex I [html](#) [pdf](#)).

Selection of Regulatory Approaches

10. Regulators are encouraged to exchange information with counterparts about contemplated approaches to regulatory requirements and choice of regulatory instrument, at the earliest stage possible, in order to:
 - a. Better understand the rationale behind regulatory choices and examine the possibilities for greater convergence on how to state the objectives of regulations and to define the scope of regulations. The interface between regulations, voluntary standards and conformity assessment should also be addressed in this context;
 - b. Compare methods and assumptions used in analyzing regulatory proposals, including, where appropriate, analysis of technical and/or economic practicability, and benefits in relation to the objective pursued, of any major alternative regulatory requirements and approaches considered. Such information exchange should 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;
 - c. Examine opportunities to minimize unnecessary divergences in regulations through means such as achieving harmonized, equivalent or compatible solutions or to consider the use of mutual recognition, as appropriate, in specific cases.

Sharing Information on Regulatory Proposals

11. Regulators should endeavour to
 - a. share proposed technical or sanitary and phytosanitary regulations, where such measures may have an impact on trade, with their counterparts at as early a stage as possible so that comments and proposals for amendments may be taken into account,

- b. provide, upon request by their counterparts, copies of the proposed regulation and allow sufficient time for interested parties to provide comments in writing

Monitoring of Forthcoming Regulatory Proposals

12. Regulators are encouraged to periodically exchange information of ongoing or planned regulatory proposals. Such information could include annual work programs listing the new regulations, and the amendments to existing regulations, that are likely to be proposed or adopted in the next year.
13. When annual work programs are exchanged and upon request by their counterparts, regulators are encouraged to supplement the annual work programs, to the extent possible, with information regarding regulatory approaches under consideration, including potential benefits, costs and other impacts for all parties, domestic and non-domestic, where assessed and available.

Identification and Selection of Issues to be Addressed through Regulation

14. Regulators are encouraged to:
 - a. **Data collection.** Examine the appropriateness and possibility of collecting the same or similar data about the nature, extent and frequency of problems potentially warranting regulatory action where it would expedite making statistically significant judgments about those problems. Periodically conduct comparisons of data collection practices.
 - b. **Data collection methodologies.** Examine the possibility and appropriateness of using the same or similar assumptions and methodology as those used by their counterparts for analyzing the data and determining the magnitude and causes of specific problems and, on this basis, to consider possibilities to bring them closer. Periodically compare analytical assumptions and methodologies.
 - c. **Compliance Strategies.** Exchange information on the administration and implementation of regulations, as well as on the means to obtain and measure compliance.

Research

15. Technical experts and regulators are encouraged to conduct co-operative research agendas in order to reduce duplicative research; generate more information at less cost; gather the best data; establish where appropriate a common scientific basis; address the most pressing regulatory problems in a more consistent and performance-oriented manner; with the intention to minimize unnecessary differences in new regulatory proposals, while more effectively improving health, safety and environmental protection.

Post-implementation review of regulations

16. Technical experts and regulators are encouraged to conduct post

implementation reviews of regulations or policies and to:

- a. Compare methods and assumptions used in such reviews.
- b. Where applicable, make summaries of the results of post-implementation reviews available to regulators of the other side.

C. Facilitating Trade and Investment

17. Regulators are encouraged to co-operate wherever possible during the regulation making stage, including by utilising any of the provisions described in section IV, with the aim of reducing unnecessary regulatory differences and minimising instances of duplicate regulatory requirements that adversely impact trade between our two regions while ensuring a high level of protection and working towards effective regulations for the sake of public interests.
18. Regulators are also encouraged to co-operate in the identification of the appropriate approaches to reducing any adverse effects of existing regulatory differences on bilateral trade and investment in identified sectors, including where appropriate, through greater convergence, mutual recognition, minimising the use of trade distorting regulatory instruments, and use of international standards including such standards and guides for conformity assessment,

D. To boost competitiveness and enhance the climate for innovation

19. The dialogue on good governance could include issues such as how to create a proper balance between diverging objectives of regulatory policies, including how to take into account the competitiveness and efficiency of industry while ensuring a high level of protection for citizens and the environment.

V. Procedural Aspects of the Framework

20. The Government of Canada and the Commission should engage in ongoing dialogue to meet the objectives of the Framework. Such an exchange may take place between regulators through websites (for example by creating “networks”), via teleconferences, joint seminars or workshops, and specific meetings including in the margins of the Trade and Investment Sub Committee (“TISC”) or any other committee established to this effect, including those established under the proposed EU-Canada Trade and Investment Enhancement Agreement.
21. Regulators in the Commission and in the Government of Canada may agree between themselves on the ways and means by which they wish to co-operate in their area of competence.
22. Both sides, represented by the regulators concerned, should work jointly to identify specific sectors or proposals for regulatory co-operation set out in section IV, and areas in which regulatory co-operation could be further expanded or established ex novo.
23. The functioning of this Framework, and progress on identified regulatory projects, should be followed-up on an ongoing basis at least annually by the Canada-EC Regulatory Co-operation

Committee established for this purpose. In particular, this committee should follow the overall progress of the Framework, discuss horizontal issues, plan seminars focused on regulatory issues, identify areas for improvement, disseminate best practices, and facilitate implementation of the framework in areas of mutual concern. This does not prejudice the role of the TISC or any other committee established under the TIEA.

24. Regulators may establish working groups – if they so desire- in their area of competence voluntarily agreed to with their counterparts in Canada and the European Communities to address issues of common concern.
25. Projects undertaken under the Framework will be listed in an implementation plan to facilitate follow-up. It is understood that the plan will evolve as required and agreed to by both sides to allow for the continuous identification of opportunities to achieve the objectives established under the Framework.

ANNEX I

ARRANGEMENT

BETWEEN THE

**DIRECTORATE GENERAL OF..... OF THE EUROPEAN
COMMISSION**

AND

THE DEPARTMENT OF.....OF CANADA

ON THE SHARING OF NON -PUBLIC INFORMATION

The Directorate General of of the European Commission and the Department ofof Canada ("the Parties") have recognized a need to further strengthen their relationship as encouraged by the voluntary Framework for Regulatory Cooperation between the Government of Canada and the Commission ("the Framework").

The Parties consider that one of the aims of the Framework includes exchanging between each other the benefit of information, expertise, research and ideas for alternative approaches to regulation, which may make it desirable to facilitate the sharing of non-public information in the interest of better regulatory cooperation. Non-public information" is understood to consist of any information not in the public domain.

In order to permit such an exchange of information, the Parties have recorded in this Arrangement the protection they will provide, consistent with applicable legislation or regulations, to non-public information, which they may exchange between each other in respect of regulatory activities covered by the Framework.

This Arrangement does not contain legal obligations for the Parties. In particular, it does not require them to exchange any information and they may limit the scope of the information exchanged under this Arrangement as appropriate.

The exchange of information under this Arrangement may be subject to prior authorization from persons or organizations that originally provided the information to either Party and that may become the subject of an exchange under this Arrangement.

The Parties undertake to use any information which has been exchanged under this Arrangement, and is not otherwise in the public domain, only for the purposes of the Framework and not for any other purpose.

Either Party will take due account of any suggestion made by the other Party with regard to the functioning of the exchange of information envisaged in this Arrangement.

The Parties will inform each other in due time of any changes in the applicable legislation or regulations which may affect the exchange of information envisaged in this Arrangement.

When a request is received by either Party for disclosure to third parties of non-public information exchanged under this Arrangement, the Party receiving the request will consult with the other Party before disclosing the information concerned. Each Party will take into account, to the extent possible, the views provided by the other Party in arriving at a decision whether to disclose the non-public information concerned.

The Directorate General ofof the European Commission will not disclose to third parties non-public information, including confidential commercial information, that was provided to its officials or representatives by the Department ofof Canada, subject to Regulation (EC) No 1049/2001 or any other applicable domestic law of the European Communities. In case the Directorate General ofof the European Commission is under a legal obligation to disclose certain non-public information that was obtained from the Department of of Canada, it will immediately inform the Department.

The Department ofof Canada will not disclose to third parties non-public information, including confidential commercial information, that was provided to its officials or representatives by the Directorate General of..... of the European Commission, subject to the Access to Information Act, the Privacy Act or any other applicable domestic law of Canada. In case the Department ofof Canada is under a legal obligation to disclose certain non-public information that was obtained from the Directorate General ofof the European Commission it will immediately inform the Directorate General.


The foregoing represents the understanding reached between the Parties, not binding in international law, on the matters referred to in this Arrangement.

Signed at _____ on this ____ day of _____, 200X, in the English and French languages, each version being equally valid.

For the Directorate General
of.....of the European
Commission

For the Department ofof
Canada

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