Comprehensive Economic and Trade Agreement Regulatory Cooperation Forum

Work Plan

The Comprehensive Economic and Trade Agreement (CETA) Regulatory Cooperation Forum (RCF) Work Plan is a living document and will be updated on an ongoing basis as regulatory cooperation opportunities arise, and following each RCF meeting

Background

On September 21, 2017, the Canada-EU CETA entered into force provisionally. Chapter 21 lays out the framework for regulatory cooperation activities, including the establishment of the RCF. The chapter builds on and replaces an existing agreement between the EU and Canada on regulatory cooperation *('Framework on Regulatory Co-operation and Transparency between the Government of Canada and the European Commission, done at Brussels on 21 December 2004').*

The role of the RCF is to facilitate and promote regulatory cooperation between the Parties. RCF will perform the following functions:

- Provide a forum to discuss regulatory policy issues of mutual interest that the Parties have identified through, among others, consultations conducted in accordance with Article 21.8.
- Assist individual regulators to identify potential partners for cooperation activities and provide them with appropriate tools for that purpose, such as model confidentiality agreements.
- Review regulatory initiatives, whether in progress or anticipated, that a Party considers may provide potential for cooperation. The reviews, which will be carried out in consultation with regulatory departments and agencies, should support the implementation of this Chapter.
- Encourage the development of bilateral cooperation activities in accordance with Article 21.4 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.

RCF Structure

On the EU side the work is led jointly by DG GROW and DG TRADE and on the Canadian side jointly by the Treasury Board of Canada Secretariat and Global Affairs Canada.

EU Co-chairs:

- Eric Mamer (DG GROW, European Commission)
- Ignacio Garcia-Bercero (DG TRADE, European Commission)

Canadian Co-chairs:

- Jeannine Ritchot (Treasury Board of Canada Secretariat)
- Doug Forsyth (Global Affairs Canada)

RCF will:
- Report annually to the CETA Joint Committee on the implementation of CETA Chapter 21;
- Convene annually unless the parties decide otherwise;

- Provide an annual forum, unless the Parties decide otherwise, for regulators to engage in topic-specific discussions and update the RCF co-chairs on the status of their cooperation activities;
- Debrief stakeholders following the annual RCF meetings, providing opportunities for stakeholders who cannot be physically present to engage virtually;
- As required, provide ongoing support and guidance to facilitate regulator-to-regulator discussions on existing and potential regulatory cooperation issues; and
- Post online RCF agendas, work plans and reports.

Stakeholder Involvement

To inform their regulatory cooperation activities, including the exchanges of regulators at RCF meetings, both Parties have carried out consultations in line with the Article 21.8 of CETA, in order to collect views of European and Canadian stakeholders for potential topics where EU and Canadian regulators can meaningfully cooperate.

- In January 2018, the Commission published a call for proposals inviting civil society to come forward with suggestions for topics for regulatory cooperation with Canada. The Commission received 26 responses to this call which have been made public[1].
- From February to April 2018 Canada sought comments from stakeholders on potential areas for regulatory cooperation with the European Union, including aligning regulatory systems, streamlining duplicative procedures, or working collaboratively in areas that will be impacted by new or disruptive technologies. Canada received close to 40 responses and, with stakeholder permission, has committed to make them public.

Each Party may choose to conduct additional stakeholder consultations to inform their issues and sectors of interest under the RCF.

Work Plan Development

Informed by the input Canada and the Commission received through their consultations, the Parties have exchanged proposals that outline the issues, sectors and regulatory areas that are of interest to them. Through internal analysis and discussions with their respective regulators, as well as through dialogues with one another, the Parties are working to identify those issues that are of mutual interest. While these dialogues and exchanges continue, both Parties have agreed that work on the exchange of information on the safety of consumer products as defined in the Article 21.7 of CETA should start expeditiously

As the Parties reach agreement on areas that are of mutual interest, they will work with regulators to add these items to a table of cooperation areas (Annex A), which includes actions and timelines.

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[1] http://trade.ec.europa.eu/consultations/index.cfm?consul_id=248

Overview of CETA RCF Regulatory Cooperation Areas

Sector: Consumer product safety

Canadian Department: Health Canada

European Department: European Commission, Directorate-General for Justice and Consumers (DG JUST)

Regulatory Cooperation Statement: The safety of consumer products sold on their national markets is a major concern for regulators around the world. The increased globalization of markets and supply chains, the rise of online/cross-border shopping, and the increasing number of new products reaching markets have made physical borders non-existent. The same consumer products or types of products appear in similar markets, which means that authorities in the EU and in Canada often face similar product safety challenges. In this context, it is imperative that the Government of Canada and the European Union regulators cooperate to efficiently identify potential dangerous consumer products.

Initiative: Exchange of information between the EU RAPEX alert system and RADAR, Canada's consumer product incident reporting system

Desired Outcome: Canadian and European regulators have timely and detailed consumer product safety information coming from each other, allowing for better informed decisions to fulfill their mandate of improving the health and safety of their citizens in relation to consumer products:

- Easier access to important information related to recalled products in each jurisdiction
- Better capacity for coordination of recall and/or surveillance activities in both jurisdictions
- Improved collaboration between regulators of both jurisdictions

Project Timeline

Activities	Timelines	Status	Comments
Technical exchange of information between EU RAPEX and Canada's RADAR systems	Q1, Q2, Q3, Q4	Ongoing	Following a testing phase, the exchange of information started on June 5, 2019.
Possible coordinated market surveillance activity	Q3, Q4	In planning	Participants exploring the possibility of implementing coordinated joint market surveillance activities.
Possible joint awareness-raising campaign	Q4	In planning	Participants exploring the possibility of organising a joint awareness-raising campaign addressed at consumers.
Bilateral meetings	Q1, Q2, Q3, Q4	Ongoing	Following the signing of the administrative arrangement, both Participants have decided to hold

		4	regular monthly meetings at working level to discuss consumer product safety issues and identify possible areas of cooperation to improve the safety of consumer products in the markets within their respective jurisdictions. Since January 2019, three meetings have taken place.

Sector: "Cosmetic-Like" Drug Products

Canadian Department: Health Canada

European Department: European Commission, Directorate-General Health and Food Safety (DG SANTE)

Regulatory Cooperation Statement: Canada is seeking to increase regulatory harmonization with the EU regarding specific "cosmetic-like" products.

Initiative: Eliminate Canada's quarantine and confirmatory re-testing requirements for low-risk "cosmetic-like" drug products imported from the E.U.

Desired Outcome:

- Eliminating Canada's quarantine and confirmatory re-testing for certain types of low-risk drug "cosmetic-like" products from the EU to reduce unnecessary regulatory differences and burden to industry.
- Modernize Canada's regulatory framework for self-care products (including cosmetics, natural health products and non-prescription drugs) by tailoring the level of oversight to their level of risk and allow for continued innovation in the field of health products, while reducing any unnecessary burden and duplicative red tape.
- Health Canada is considering an expansion of the Pilot to include additional types of low-risk "cosmetic-like" OTC products fabricated in compliant EU facilities.

Project Timeline

Activities	Timelines	Status	Comments
Exemption from re-testing/quarantine of EU sunscreen products	Q4 2019	Came into effect 14-02-2019	No set expiry date. The intent is for this to remain in force until such time as regulatory amendments are made.
Possible exemption from re-testing/quarantine of EU low risk cosmetic-like products, i.e. toothpastes and antidandruff shampoos	Targeting FY2019/20	Possible exemption from re-testing/quarantine of EU toothpastes and antidandruff shampoos	Health Canada is contemplating a number of regulatory amendments which could lead to these exemptions. Timelines to be determined by timing of regulatory amendments, which are separate from the Sunscreen pilot expansion.

Sector: Pharmaceutical Inspections

Canadian Department: Health Canada

European Department: European Commission, Directorate-General Health and Food Safety (DG SANTE)

Regulatory Cooperation Statement: In October 2016, Canada and the EU signed the Comprehensive Economic and Trade Agreement (CETA) Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical product. In addition to allowing continued mutual recognition each other's certificates of GMP compliance, the Protocol article 5(2) indicates that Canada and the EU may accept certificates of GMP compliance issued by an equivalent regulatory authority of the other Party with respect to a manufacturing facility outside the territory of the Parties.

These certificates are currently exchanged on a voluntary basis by Canadian and European Regulatory Authorities in situations deemed appropriate by the Parties.

There is an opportunity to officially recognize pharmaceutical inspections conducted in third countries and implement the exchange of certificates in order to further enhance cooperation and regulatory alignment between the EU and Canada.

Initiative: Expanding the existing approach of recognizing inspection results from the respective Parties to include inspections that are conducted in countries outside of the respective Parties' jurisdictions (i.e. extra-jurisdictional inspections)

Desired Outcome: Mutual recognition of inspection results would lead to more efficient and effective regulatory oversight and benefits trade between Canada and the EU without diminishing the high standards of safety and quality that exist in both jurisdictions. It would also reduce regulatory burden on industry and lead to better regulatory alignment among international regulatory partners.

Project Timeline

Activities	Timelines	Status	Comments
Activity 1 – Reliance on GMP inspections conducted outside of the territories of the Parties	Goal for completion Q2/2020	Two discussions took place where both Parties are working on identifying the scope and developing an action plan	
Activity 2 - Exchange of GMP information on inspections conducted outside of the territories of the Parties	Goal for completion Q1/2020	Both Parties to establish a process and agree on the type of information to be exchanged by Q3 2019	

Sector: Cybersecurity
Canadian Department: Innovation, Science, and Economic Development Canada
European Department: European Commission, Directorate-General for Communications Networks, Content, and Technology (DG CONNECT)
Regulatory Cooperation Statement: The deployment of connected devices, or "internet of things" (IoT) devices, in the marketplace is a growing area of economic activity, with a potential for risk. The growth of IOT devices and their ability to generate data is fuelling innovation in the development of algorithms supporting Artificial Intelligence (AI).

The increased connectivity of devices combined with the volume of connected devices available raises the risk of cybersecurity threats that can lead to real life safety issues for citizens related to areas such as health, transportation, and critical infrastructure.

To realize the benefits of the digital and connected economy, there needs to be an environment of trust and accountability regarding the safety and security of these devices. Citizens and businesses must trust the technology they interact with, have a predictable environment, and rely on the safeguards protecting them in the marketplace. Mechanisms, such as labelling, can provide consumers with the necessary safety and security information of IOT devices. A multi-jurisdictional approach could strengthen the benefit of IOT product labelling.

There is a need for greater cooperation between Canada and EU to identify, categorize, and address risks to connected devices, including addressing increased standardization, transparency, and design regulation when designing, developing and deploying these products. We must also consider challenges and risks regarding liability, supply chain security, criminal use, privacy, and cyber security. Maintaining a balance between regulation and innovation is important.

Initiative: Align Canadian and EU IOT regulations and standards, as necessary.
Desired Outcome:
- Through ongoing cooperation seek to prevent the development of regulatory barriers to IOT devices as they ready to enter the Canadian and EU marketplaces
- Exchange information regarding safety issues pertaining to IOT devices in areas such as health, transportation, or critical infrastructure
- Developing a common considerations and objectives for future regulatory and/or labelling approaches

Project Timeline

Activities	Timelines	Status	Comments
High-level update call to discuss development on addressing IoT security issues in each jurisdiction.	June 2019	Shared links to recent government announcements related to Canada's Digital Charter	-Canada presents Year-one report of Canadian Multistakeholder Process on IoT Security after released for public comment. -Launch of Canada's Digital Charter and marketplace reform proposals

			EU presents progress/result of EU Cybersecurity Act
Drafting of a short fiche on framework policies in respective jurisdictions to be considered for possible future regulatory cooperation on IoT security issues.	November – December 2019: Canada will complete an initial draft and then will go through iterative process with EU counterparts		
Exchange of views on cybersecurity conformity assessment and labelling.	At least two calls between June-October 2019		Subjects: - baseline requirements for Consumer IoT; - approaches to conformity assessment and labelling
Stakeholder engagement to brief respective communities on the progress of this discussion and the short fiche on framework policies	December 2019		Explore the role of marketplace framework laws in support of IoT standards and approaches including labelling

Sector: Animal Welfare

Canadian Department: Agriculture and Agri-Food Canada

European Department: European Commission, Directorate-General Health and Food Safety (DG SANTE) and Directorate-General Trade (DG TRADE)

Regulatory Cooperation Statement: Canada has a very large geographical territory. Long distance transport of animals is essential for several reasons. For example, large breeding operations that raise stock for domestic and international trade often situate their facilities in remote areas for biosafety purposes and to minimize disease risk, which necessitates longer transport to markets; facilitating the ongoing exchange of breeding stock across Canada is critical to maintaining the genetic well-being of animal populations, especially as global biodiversity continues to decline; specialization and consolidation of breeding functions for some species, specifically poultry and swine, is beneficial to gain economies of scale and to focus investments on genetic improvement, but necessitates long distance transport to markets.

The European Union is also interested in Canadian experience on this topic and information sharing between Canada and the EU will facilitate a better understanding of the benefits and challenges of both systems.

Initiative: information sharing regarding various aspects of long distance animal transportation

Desired Outcome:
- information sharing regarding regulations and standards for long-distance transport of animals, specifically across member states
- improved appreciation of the respective approaches to animal welfare of Canada and the EU, and applicability to long distance transport of animals
- information sharing regarding rules & protocols for feed/water/rest stops
- information sharing regarding transportation carriers used for swine, cattle and sheep
- information sharing regarding the variety, practical utility, cost and measurable animal welfare outcomes of the various types of transport by species

Project Timeline

Activities	Timelines	Status	Comments
Teleconference - Technical information exchange between EU and Canada.	June 2019	Completed – fully met	Identified a need for further information exchange.
Information and document sharing	June – Nov. 2019	Ongoing	As identified in June meeting
Teleconference – Continued technical information exchange between Canada and the EU	November 2019	In planning	