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:

- Outi Slotboom (DG GROW, European Commission)
- Rupert Schlegelmilch (DG TRADE, European Commission)

Canadian co-chairs:

- [redacted] (Treasury Board of Canada Secretariat)
- [redacted] (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.

- Stakeholder submissions to the Commission have been made public on the Commission's website.
- Stakeholder submission to Canada have been published on the Canada.ca website.

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.

Annex A

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 and take appropriate action on potentially dangerous consumer products.

Initiative: Regular exchange of information between the EU RAPEX alert system and Canada's RADAR consumer product incident reporting system (CETA Article 21.7(4)-(6)); ad hoc information exchange and cooperation on other aspects of non-food product safety (CETA Article 21.7(3)).

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 potentially dangerous products in each jurisdiction
    - Better capacity for coordination of communication, market surveillance and enforcement activities in both jurisdictions
    - Improved collaboration between regulators of both jurisdictions

Activities	Timelines	Status	Comments
CETA Article 21.7(4)-(6)			
Regular exchange of information between EU Safety Gate/RAPEX and Canada's RADAR systems	2022	Ongoing	Regular exchange of information continues as per the administrative agreement between DG JUST and Health Canada. The EU recently revamped the Safety Gate International-Canada module to present data in a more user-friendly format. The EU delivered training to Canadian users on the Safety Gate/RAPEX data. Canada will be delivering an

Activities	Timelines	Status	Comments
			information session for EU users on the RADAR data and operation process.
CETA Article 21.7(3)			
Coordinated market surveillance activity	2022	Ongoing	Following the first successful coordinated market surveillance project on heavy metals in children's jewelry in 2021, participants exchanged their experiences in online market surveillance with a view to identifying best practices and new ways of tackling common challenges. This is especially important given the rapid acceleration of e-commerce, a result of the COVID-19 pandemic and the resulting product safety challenges. Participants continue discussions on possible alignment for further cooperation.
Coordinated awareness-raising campaign	July 2021, March 2022, August/Sept 2022	Completed (planning future outreach)	Participants have collaborated on joint communication initiatives, including the following: children's water safety (summer 2021), Safe Sleep Week (March 2022), and online shopping by youth (summer 2022). Participants will continue their collaboration on outreach in 2023.
Bilateral tele-conferences	2022	Ongoing	Regular meetings at the technical level continue to allow participants to identify possible areas of cooperation to improve the safety of consumer products in the markets within their respective jurisdictions.

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, which necessarily entails long distance transport of animals for multiple purposes, but which poses unique challenges. Animal welfare in general remains an issue of ongoing public concern. Canada looks forward to all opportunities to understand how other jurisdictions are handling these issues and to share our learnings.

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 animal welfare issues (e.g. long distance transport, slaughter and farming).

Desired outcome:

- Information sharing on Canada's and the EU's agenda on animal welfare (e.g. actions on animal welfare under the Farm to Fork Strategy)
- Information and experience sharing regarding long-distance transport of animals (e.g. rules & protocols for feed/water/rest stops, experience with carriers for various species, and resulting animal welfare outcomes)
- 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 animal welfare outcomes in relation to slaughter

Activities	Timelines	Status	Comments
Video-conference - Continued technical information exchange between Canada and the EU	November 24, 2021	Completed	The discussion focused on the following: Recent animal welfare events and activities from both sides Information from Canada on challenges related to recent flooding Information from EC about key animal welfare activities Canada position on the Inception impact assessment of the EU animal welfare acquis Protection of animals during transport with a focus on sea transport Animal welfare labelling
Video-conference - Continued technical information exchange between Canada and the EU	July 7, 2022	Completed	Successful meeting, including exchange of information on the following subjects: Adverse impacts on animal welfare (e.g. extreme weather, diseases, market interruptions, other crises with impact on animals) Welfare of horses used for meat production in Canada (i.e. transport and slaughter)

Activities	Timelines	Status	Comments
			Update on progress to revise the EU animal welfare acquis Plans for cages from both sides Potential trade implications related to animal welfare initiatives
Video-conference - Continued technical information exchange between Canada and the EU	November 23, 2022	Completed	Successful meeting, including exchange of information on the following subjects: Update on progress to revise the EU animal welfare acquis EU 'Fitness Check' initiative Protection of animals during transport Welfare of horses used for meat production in Canada (i.e. transport and slaughter) Livestock Transport Training & Certification program Shortage of veterinarians and farm workers – challenges for welfare Animal Health Canada, NFACC & Codes of Practice
Bilateral tele-conferences	Biannually	Ongoing	Continued technical information exchange between Canada and the EU.

Sector: Pediatric Medicines

Canadian Department: Health Canada (HC)

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

Regulatory Cooperation Statement: Canada is seeking to learn from and increase regulatory harmonization with EMA's pediatric regulations (EC No 1901/2006 and EC No 1902/2006).

Initiative: Increase regulatory alignment with EMA's pediatric regulations and processes to improve access to pediatric medicines and to reduce burden on industry.

Desired Outcome:

HC is developing regulatory and policy initiatives to better support access to medicines for children. Drugs with pediatric indications or formulations that are available in Europe are not always submitted to Canada, possibly due to Canada's small market size. In addition, while the EU has regulatory authorities that require the submission of a Paediatric Investigation Plan (PIP) for a drug to be authorized, Canada does not currently have the same requirements. Work to address this second gap is in development.

Further collaboration with the EU on pediatric medicines may be beneficial, based on existing models of international collaboration and work-sharing, which HC has been developing over the past few years, such as:

- **Access Consortium**: In partnership with Australia, Switzerland and Singapore, and, most recently, the United Kingdom, HC has shared review work in order to create efficiencies, and to result in simultaneous drug approvals across multiple jurisdictions, while still taking independent regulatory decisions according to each country's own legal frameworks
- **Project Orbis**: HC has participated in parallel reviews with the US Food and Drug Administration (FDA), which have allowed for the sharing of information and expertise and aligned approval times

Increased collaboration between HC and the EMA in pediatrics would support international regulatory alignment, thus reducing burden on industry to meet unique requirements in both jurisdictions, which could ultimately result in greater access to medicines for more children worldwide.

Activities	Timelines	Status	Comments
General collaboration through EMA-FDA-HC-TGA (Therapeutic Goods Administration, Australia)-PMDA (Pharmaceutical and Medical Devices Agency, Japan) Paediatric Cluster discussions	Ongoing	Ongoing	No set expiry date
EMA to share review templates / internal documentation related to the review of Paediatric Investigation Plans (PIPs) with HC	June 2021 - June 2022	Ongoing	EMA shared a first batch of information in January 2021. HC has highlighted additional requests for information, and HC and EMA will continue to determine areas of specific interest as needed.
EMA to share internal standard operating procedures (SOPs) and processes related to the review of PIPs (from pre-submission meetings to market authorization)	June 2021 - June 2022	Ongoing	EMA shared a first batch of information in January 2021. HC has highlighted additional requests for information, and HC

			and EMA will continue to determine areas of specific interest as needed.
HC to attend EMA's Paediatric Committee (PDCO) meetings (as an observer, without being involved in the review process)	October 2020 and ongoing (ad hoc)	Ongoing	HC participated in the October 2020 PDCO meeting (virtually) and found it to be a very valuable experience. Ongoing attendance will continue on an ad hoc basis.
HC and EMA to share relevant activities developed as part of its ongoing paediatric policy and regulatory development process	Ongoing	Ongoing	HC shared its Pediatric Drug Action Plan and a draft version of a proposed pediatric regulation for comment in early 2021. HC and EMA have set-up quarterly check-ins to share updates and discuss this workplan.
Quarterly meetings between HC and EMA to engage in discussions on topics of interest.	Jan 2022 – Ongoing	Ongoing	HC shared information regarding risk-based approaches to classifying drugs. The EMA shared additional information regarding the process of PIP review and provided updates on the Evolutionary PIP.
EMA to share finalised PIP reviews (for pharmaceuticals and biologics)	TBD	Ongoing	Dependent on need to redact personal data in documents (clarification ongoing).
HC to observe the EMA in the review of PIPs from submission to approval, including observing the PDCO meeting(s)	TBD	Pending	Dependent on need for PIP redactions (above). Logistic discussions are planned to commence in the first half of 2023.
HC and EMA to explore further collaboration options	Ongoing	Ongoing	Experiences from above actions to be assessed on an ongoing basis.