# Comprehensive Economic and Trade Agreement Regulatory Cooperation Forum Work Plan

**30 October 2020**

*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:

- Kamil Kiljanski (DG GROW, European Commission)
- Rupert Schlegelmilch (DG TRADE, European Commission)

Canadian Co-chairs:

- James van Raalte (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 published them 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.

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

**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 RAPEX and Canada's RADAR systems | Q1-Q4 2020, Q1-Q4 2021 | Ongoing | Regular exchange of information is up and running, as per the administrative agreement between DG JUST and Health Canada |
| **CETA Article 21.7(3)** | | | |
| Coordinated market surveillance activity | Q1-Q4 2020, Q1-Q2 2021 | Ongoing | Participants agreed on the modalities of a coordinated market surveillance activity on heavy metals in children's jewellery sold online. On the EU side, testing has started in August 2020. Sampling and testing is planned in Canada for Q4 2020 – Q1 2021. |
| Coordinated awareness-raising campaign | Q4 2020, Q2 2021 | In planning | Following a coordinated awareness-raising campaign on the risk of button batteries for children in November 2019, the Participants are discussing possible further communication campaigns for winter 2020 and summer 2021. |

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| Bilateral teleconferences | Q1-Q4 2020, Q1-Q4 2021 | Ongoing | Participants are holding regular teleconferences at working level to discuss consumer product safety issues (including emerging issues such as covid19-related products) and to identify possible areas of cooperation to improve the safety of consumer products in the markets within their respective jurisdictions. |

**Sector: "**Cosmetic-Like" Drug Products

**Canadian Department:** Health Canada
**European Department:** European Commission, Directorate-General Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)

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

**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.

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

| Activities | Timelines | Status | Comments |
|---|---|---|---|
| Exemption from re-testing/quarantine of EU sunscreen products | Completed | Closed as of July 1, 2020 | Given success, pilot project has been implemented through regulation. |
| Exemption from re-testing/quarantine of EU low risk cosmetic-like products, i.e. toothpastes and antidandruff shampoos | Targeting FY 2020 - 2021 | - With the coming into force of the regulatory amendments under the Canada-United States-Mexico Agreement, requirements for re-testing and quarantine of imported low-risk cosmetic-like products (including Anti-dandruff shampoos) from certain recognized countries and regions (including MRA partners[2]) has been removed.<br><br>- Exploring future exemption from re-testing/quarantine for other lower-risk products including toothpastes. | Health Canada is exploring expanding the list of products through a consultation with external stakeholders. |

[2] From the EU, Bulgaria, Cyprus and Luxembourg are excluded as they have not yet been assessed by Health Canada and will be added to the list once the evaluation has been completed.

**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.

| Activities | Timelines | Status | Comments |
|---|---|---|---|
| Activity 1 – Identification of possible differences between GMP inspections conducted outside of the territories of the Parties | Completed | A document identifying the differences between inspections conducted within the national territory and in third countries shows that the differences are similar for both parties. This document was tabled at the Joint Sectoral Group on Pharmaceuticals (JSG) of 21/11/2019, and following internal consultation by both parties, was considered finalised. | Once recognised, article 5(2) should then be applicable to third party inspections with respect to medicinal products or drugs of the operational scope of the Annex 1 of the CETA Protocol on GMPs for Pharmaceuticals. |
| Activity 2 – Decision process | Goal for completion postponed to Q4/2020 due to pandemic | The document developed under Activity 1 will go through internal approvals of the respective Parties before final decision on the implementation. Decision to be taken by written exchange and | For medicinal products, or drugs covered by the operational scope of the Annex 1 of the CETA Protocol on Pharmaceuticals, the conclusion of the |

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| | | endorsed during next JSG in 2020. | equivalence assessment of differences and similarities in the conduct of third party inspections (Activity 1) should take into account the recognition of the outcome of inspections in third countries by both Parties. |
| Activity 3 - Exchange of GMP information on inspections conducted outside of the territories of the Parties | Goal for completion postponed to Q2/2021 due to pandemic | Further discussion will be conducted with HC, European National Competent Authorities (EUNCAs) and EMA on the content of the GMP certificate to be exchanged for inspections of sites located in third countries. In addition, affected regulatory procedures will need to be amended. | The implementation date of the project, which is currently targeted for April 2021, will be proposed to the relevant CETA decision committee. It will be supported by a communication to stakeholders, with an evaluation at the subsequent JSG meeting. |

| **Sector:** Cybersecurity |
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| **Canadian Department:** Innovation, Science, and Economic Development Canada<br>**European Department:** European Commission, Directorate-General for Communications Networks, Content, and Technology (DG CONNECT) |
| In view of changes in policy priorities, EU and Canadian regulators have decided to discontinue working on cybersecurity in the framework of CETA's Regulatory Cooperation Forum, whilst keeping dialogue open on this issue. Both sides also recognize the usefulness of a dialogue on privacy and data protection and are in contact to determine the appropriate channel for that. |

**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 |
|---|---|---|---|
| Teleconference - Technical information exchange between EU and Canada. | November 2019 | Completed – February 2020 | Identified a need for further information exchange. |
| Video-conference - Technical information exchange between EU and Canada. | 17 February 2020 | Completed | Topics discussed included long distance animal transport, mobile slaughterhouses, and latest developments on animal welfare in both Canada and EU, possible future topics (e.g. labelling). |
| Information and document sharing | February – November 2020 | Ongoing | COVID delays moved meeting plans to the fall |
| Teleconference – Continued technical information exchange between Canada and the EU | October – November 2020 | In planning | Information sharing on Canada's and the EU agenda on animal welfare; long distance animal transport and protection at slaughter (e.g. maximum shackling times and electrical parameters for waterbath stunning of poultry) |

**Sector:** Pediatric Medicines

**Canadian Department:** Health Canada
**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:**
Health Canada (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 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 worksharing, which HC has been developing over the past few years, such as:

- **ACSS Consortium**: In partnership with Australia, Switzerland and Singapore, 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.

Partnership between HC and the European Medicines Agency (EMA) in pediatrics would support international alignment in regulatory review and, potentially, aligned review processes, thus reducing burden on industry to meet unique requirements in both jurisdictions and potentially eliminating multiple requests for information from both regulators. This would be an attractive pathway for industry looking to follow efficient review processes, and would 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 | September - October 2020 | Not yet started | |
| EMA to share internal standard operating procedures (SOPs) and | September – October 2020 | Not yet started | |

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| processes related to the review of PIPs (from pre-submission meetings to market authorization) | | | |
| EMA to share finalised PIP reviews (for pharmaceuticals and biologics) | Concept to be discussed further in 2nd half of 2021 | Not yet started | Dependent on need to redact personal data in documents (clarification ongoing). Business continuity due to COVID-19 and related capacity constraints to be considered. |
| HC to attend EMA's Paediatric Committee (PDCO) meetings (as an observer, without being involved in the review process) | October 2020 - May 2021 | Not yet started | Participation at PDCO plenaries taking place virtually due to COVID-19 situation. |
| HC to participate in parallel reviews / shadow the EMA in the review of PIPs from submission to approval, including participating in / observing the PDCO meeting(s) | Concept to be discussed further in 2nd half of 2021 | Not yet started | Dependent on need for PIP redactions (above). Business continuity due to COVID-19 and related capacity constraints to be considered. |
| Health Canada to share relevant analyses of international pediatric drug approvals/activities developed as part of its ongoing paediatric policy development process | Ongoing | Ongoing | Specific analyses will be listed here as they are conducted and/or when they are shared with the EMA. |
| HC and EMA to explore further collaboration options | To be considered of initial discussion in late 2021 / early 2022 | Not yet started | Experiences from above actions to be assessed. Business continuity due to COVID-19 and related capacity constraints to be considered. |