



European
Commission

COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT (CETA)

1ST MEETING OF THE CETA REGULATORY COOPERATION FORUM

DECEMBER 14, 2018 (BRUSSELS AND BY VIDEOCONFERENCE)

PROPOSED AGENDA

1. Discussion between Regulatory Cooperation Forum Co-Chairs on organisational issues and follow-up.
2. Discussion with Regulators on the following topics proposed for the work plan:
 - a. Cybersecurity and the Internet of Things

The deployment of connected devices (Internet of Things) in the market place is a growing area of economic activity fuelling broad innovation as well as risk. Proactive collaboration between private sector, government and civil society efforts is underway through other fora, to foster adoption and mitigate the risks created by the increased diversity and volume of connected devices. Dialogues under the RCF would assist in having a better understanding of Canadian and EU participation in these initiatives, as well as where each country stands with respect to how consumer IoT devices are currently being regulated and addressed in the market place including in specific sectors. On this basis, a more thorough analysis could be conducted with respect to the impacts of differences in regulation, certification or labelling approaches.

b. Animal Welfare – transportation of animals

Technical cooperation on animal welfare was included within the scope of the EU-Canada Veterinary Agreement through an exchange of letters between the parties in 2004. Under CETA, animal welfare has been included in the scope of the Regulatory Cooperation Forum. Canada and the EU share an interest in outcomes-based results for animal welfare. The EU and Canada have identified the topic of long distance transport of animals as a first topic for engagement within the context of the Forum, to be developed in the coming year. This will allow the parties to exchange information regarding practical implementation results that may inform respective transportation protocols and facility design/ purchase.

c. Cosmetics-like Products

There are different requirements related to confirmatory and identification testing of imported drugs, depending on where the product is manufactured and whether the country and product are covered by Mutual Recognition Agreements (MRAs). Some “cosmetic-like” products regulated as drugs in Canada are classified as cosmetics in the EU and are not subject to the same regulatory requirements and oversight as drugs. Many of these “cosmetics-like products” are not included in the EU-Canada MRA agreements and therefore cannot benefit from it. The need for confirmatory re-testing requirements for “cosmetic-like” low risk products could be duplicative and result in additional cost and delay in market access and the first RCF will explore the possibility of addressing this issue.

d. Pharmaceutical Inspections

Canada and the EU ratified a Mutual Recognition Agreement (MRA) that includes recognition of pharmaceutical inspections in 1998. Under the MRA, an Annex on Good Manufacturing Practices (GMP) Compliance Certification covering human and veterinary medicinal products has been operational since February 2003. CETA includes a Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical product, replacing the 1998 MRA Treaty. In addition to allowing continued mutual recognition of each other’s certificates of GMP compliance, the Protocol’s 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. The first RCF meeting discussion will explore the potential for an eventual

alignment of EU and Health Canada practices and the processes related to inspections conducted in third countries.

- e. Exchange of information between the EU RAPEX alert system and RADAR, Canada's consumer product incident reporting system

The safety of consumer products sold on our national markets is a major priority for regulators around the world. The increased globalisation 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; and the same consumer products or types of products appear in similar markets, such as the EU and Canada. This means that authorities in the EU and in Canada often face similar product safety challenges. In this context, it is important that regulators coordinate their efforts internationally to efficiently identify potential dangerous consumer products. On 13 November 2018, at the occasion of the International Product Safety Week, the European Commission's Directorate General for Justice and Consumers (DG JUST) and the Department of Health of Canada (Health Canada) signed an administrative arrangement for exchange of information on dangerous non-food consumer products. The objective of the administrative arrangement is to better protect consumers from products which pose a risk to their health and safety, as the exchange of information on dangerous products found on either side of the Atlantic will enable regulators to better target respective enforcement activities and to be alerted to new and emerging risks. The RCF will be an occasion to take stock of the state of play and explain the context, scope and type of information that will be exchanged under the administrative arrangement.

- 3. Other Business
- 4. Regulatory Cooperation Forum Debrief to Stakeholders and exchange of views
- 5. Wrap-up and next steps

Participants:

- *Regulatory Cooperation Forum Co-Chairs*
 - o *Director, Directorate A, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, European Commission*
 - o *Director, Directorate E, Directorate-General for Trade, the European Commission*

- *Executive Director, Regulatory Cooperation, Regulatory Affairs Sector, Treasury Board of Canada Secretariat*
- *Director General, Trade Agreements and Negotiations, Market Access, Global Affairs Canada*
- *Officials from the Treasury Board of Canada Secretariat and Global Affairs Canada*
- *Officials from the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, the European Commission's Directorate-General for Trade, the European Commission's Directorate-General for Health and Food Safety, the European Commission's Directorate-General for Communications Networks, Content and Technology (CNECT), the European Commission's Directorate-General for Justice and Consumers.*
- *Regulators representing each topic (in person or via videoconference)*
- *Registered stakeholders will attend the Stakeholders Debrief session*