



European
Commission

COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT (CETA)

1ST MEETING OF THE CETA REGULATORY COOPERATION FORUM

DECEMBER 14, 2018 (BRUSSELS AND BY VIDEOCONFERENCE)

REPORT

1. Discussion between Regulatory Cooperation Forum Co-Chairs on organisational issues and follow-up.

The Co-Chairs of the Regulatory Cooperation Forum (RCF) welcomed the work carried out to set up the first RCF meeting, highlighting the consultation with stakeholders to identify topics for discussion.

The proposed RCF work plan was adopted. It identifies five fields of cooperation between the EU and Canada (discussed below). Co-chairs agreed to ask the EU and Canada leads for each item in the work plan to populate the table in the work plan annex in early 2019. Both sides welcomed the useful and important nature of the topics and confirmed the Co-Chairs' willingness to considering additional topics in the future, including suggestions from stakeholders. The Co-chairs proposed to review the list of work plan items annually.

In order to respond to the great level of public interest shown for the RCF, promote transparency, and facilitate consultations with stakeholders, the Co-chairs agreed to publish the RCF work plan online. Co-chairs agreed to provide public updates on each of the work plan items in summer 2019. As well, the Co-chairs committed to developing an 'infographic' or general list of questions and answers for stakeholders to illustrate the link between RCF and other CETA committees.

Finally, it was confirmed that the Rules of Procedure adopted at the Joint Committee Meeting of September 26, 2018 would also be applicable mutatis mutandis to the RCF.

2. Discussion with Regulators on the topics proposed for the work plan:

The RCF, established under article 21.6 of CETA, builds on the existing regulatory cooperation agreement between the EU and Canada signed in 2004. To prepare for this first meeting, both the EU and Canada held stakeholder consultations to identify issues, priorities, and sectors that the RCF could consider for its first work plan. The topics proposed for the work plan were drawn from the consultations and based on feedback from EU and Canadian regulators, and then agreed to by EU and Canadian Co-chairs. The EU and Canada also took into account the readiness of the topics proposed for regulatory cooperation and whether or not the topics were already part of other CETA committees or existing bilateral or international dialogues. Regulators from both sides provided an update on the feedback received during the consultations, how the initiatives were identified for cooperation, bilateral discussions to date, and next steps.

The first four topics will be developed over the coming year. The last topic has already seen the conclusion of an administrative arrangement for the exchange of information on dangerous non-food consumer products between the European Commission's Directorate-General for Justice and Consumers (DG JUST) and Health Canada on 13 November 2018, during International Product Safety Week.

a. Cybersecurity and the Internet of Things

The deployment of connected devices (Internet of Things) in the marketplace is a growing area of economic activity fuelling broad innovation as well as risk. Proactive collaboration between the 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. Dialogue under the RCF would assist in having a better understanding of Canadian and EU participation in these initiatives, as well as where Canada and the EU stand with respect to how consumer IoT devices are currently being regulated and addressed in the marketplace, including in specific sectors.

On this basis, both sides agreed that a more thorough analysis could be conducted with respect to identifying the impact of possible differences in regulation, certification, or labelling approaches. Respective teams on both sides will engage in this regard in the next months.

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 RCF. Canada and the EU share an interest in collaborating on 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. This will allow the parties to exchange information regarding practical implementation results that may inform respective transportation protocols and facility design/ purchase.

Both sides agreed to engage on this specific aspect of animal welfare in the coming year.

c. “Cosmetics-like” Drug 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 products 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 existing EU-Canada MRA agreements and therefore cannot benefit from them. Confirmatory re-testing requirements for “cosmetic-like” low risk products can be duplicative and result in additional cost and delay in market access.

Regulators from both sides will further explore the possibility for Canadian importers of EU sunscreen products to be exempt from quarantine and re-testing, which is not required by the EU for such products manufactured in Canada and imported into the EU. The EU welcomes an exemption on sunscreen products as well as future expansion of the scope to include antidandruff shampoos and toothpastes which are also regulated as cosmetic products in the EU but may be regulated as drug products or natural health products in Canada.

d. Pharmaceutical Inspections

Canada and the EU ratified in 1998 a MRA that includes recognition of pharmaceutical Good Manufacturing Practices (GMP) compliance inspections conducted in their own respective territories. Under the MRA, the Annex on GMP Compliance Certification covering human and veterinary medicinal products has been operational since February

2003. The MRA has been incorporated into CETA under the Protocol on the mutual recognition of the compliance and enforcement programme regarding good manufacturing practices for pharmaceutical products. In addition to allowing continued mutual recognition of each other's GMP inspections conducted on sites located in their own respective territories, 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. Regulators from both sides discussed the potential for an eventual alignment of EU and Health Canada practices and the processes related to the mutual recognition of GMP inspections conducted in third countries.

It was agreed to continue these discussions over the next year.

- 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 respective domestic markets is a major priority for EU and Canadian regulators. 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. The same consumer products or types of products appear in similar markets, including the EU and Canada. This means that authorities in the EU and 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, during 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 officials signed an administrative arrangement to exchange non-personal information on dangerous non-food consumer products. This arrangement was endorsed by the CETA Committee on Trade in Goods on 29 November 2018. 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 welcomed the agreed administrative arrangement and took stock of the context, scope, and type of information that will be

exchanged under the administrative arrangement. Furthermore, it was agreed that it would be relevant for the RCF to receive a report of the implementation of the administrative arrangement at the next meeting.

3. Other Business – no other points discussed

4. Regulatory Cooperation Forum Debrief to Stakeholders and exchange of views

Following the discussion with regulators, RCF Co-chairs and regulators from the EU and Canada debriefed civil society stakeholders about the Forum's activities. Audiences from multiple physical locations participated in this exchange: stakeholders participating in person in Brussels, in Ottawa via video conference, and from desks and conference rooms via web streaming (where questions were raised via e-mail). Several stakeholders in Brussels and Ottawa commented on the initiative of the EU and Canada to strengthen regulatory cooperation and stressed in particular the importance of the work initiated on the exchange of information on dangerous non-food products, animal welfare, and cybersecurity.

Many questions were raised, including about topics not currently included in the RCF work plan e.g., cheese quotas, data protection, and others. Stakeholders also suggested including other issues for subsequent work plans, such as services, agricultural products, and standards in the automobile sector.

The Co-chairs expressed openness to receiving suggestions from stakeholders for new topics, if there is a common interest. They also reinforced that topics which fall under the scope of discussions or are already being discussed in other committees established under CETA will be avoided. Finally, they noted that the RCF was likely to focus on voluntary regulatory cooperation on new and emerging issues for which regulators in both Parties see an interest initiating an exchange of views and developing converging regulatory approaches. In this light, Co-chairs encouraged stakeholders to consider these points when making recommendations going forward.

Stakeholders welcomed the increased efforts of transparency and asked these to be continued. The Co-chairs confirmed that a report detailing the outcomes of the meeting, along with the RCF work plan, and additional information on the work plan items will be made public early in the new year.

5. Wrap-up and next steps

The next RCF meeting will take place in approximately one year (fall 2019) in Canada. Both sides will take stock of the progress made on the work plan items midway through 2019. In the meantime, suggestions of additional topics for future cooperation are welcome and regulators are encouraged to work together to achieve positive outcomes on the identified five work plan items.

Participants:

1. *Regulatory Cooperation Forum*

- *Co-Chairs*
 - *Director, Directorate A, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, European Commission*
 - *Director, Directorate E, Directorate-General for Trade, European Commission*
 - *Executive Director, Regulatory Policy and Cooperation Directorate, 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, Global Affairs Canada, and the Mission of Canada to the EU*
- *Officials from the European Commission's Directorate-General for Trade*
- *Regulators and officials from the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, 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 and officials from Health Canada, Agriculture and Agri-Food Canada, and Innovation, Science and Economic Development Canada*
- *Registered stakeholders attending the Stakeholders Debrief session (in person, via videoconference, or via web streaming) – List of registered participants attached as annex*