

Assessment Collaboration Framework between the United States Environmental Protection Agency, Environment and Climate Change Canada, and Health Canada

Introduction and Background

Vision/Purpose: Enhance alignment and collaboration on chemical risk assessment activities.

Canada and United States Regulatory Cooperation Council

In 2011, the Governments of the United States (U.S.) and Canada launched the Canada-United States Regulatory Cooperation Council (RCC) to facilitate closer cooperation between Canada and the U.S. on the development of more effective approaches to regulation that strengthen the economy, enhance competitiveness, and provide greater protection to public safety and welfare. In 2017, the Governments committed to continue their dialogue on regulatory issues and pursue shared regulatory outcomes that reduce trade impediments, reduce costs, increase economic efficiency, and streamline regulations without compromising health, safety, and environmental standards.

The RCC's *Joint Forward Plan*¹ sets out commitments for Canadian and U.S. regulatory departments and agencies to establish Regulatory Partnership Statements (RPS). Under the RCC Chemicals Management Work Plan, the United States Environmental Protection Agency (U.S. EPA) and Environment and Climate Change Canada (ECCC) have established a RPS² that outlines how regulatory cooperation on chemicals management will occur going forward under the RCC. While the U.S. EPA and ECCC are formally identified as lead authorities responsible for this RPS, Health Canada (HC) is an equal partner in this regulatory partnership.

Regulatory Partnership Statement

The Regulatory Partnership Statement between U.S. EPA and ECCC can be summarized as follows:

The U.S. EPA and ECCC are committed to continue working together to deliver benefits for the public, industry and regulators while maintaining public protection, health, safety, security and the environment.

The RPS outlines a consistent and predictable mechanism for engaging with stakeholders bi-nationally, with an aim to facilitate opportunities and reduce barriers to alignment, including minimizing the duplication of efforts on common risk assessments, scientific tools and models.

ECCC, in partnership with HC, and the U.S. EPA will advance aspects of cooperation on chemicals regulation, with a focus on chemical risk assessment. The work will center on areas that will support chemical risk assessment including, but not limited to, information gathering and sharing, technical work-sharing and scientific collaboration.

¹ Canada – United States Regulatory Cooperation Council Joint Forward Plan. Available from: <https://www.canada.ca/en/treasury-board-secretariat/corporate/transparency/acts-regulations/canada-us-regulatory-cooperation-council/joint-forward-plan-august-2014.html>

² Canada – United States Regulatory Cooperation Council (RCC). Regulatory Partnership Statement between the United States Environmental Protection Agency and Environment and Climate Change Canada. Available from : <https://www.canada.ca/en/environment-climate-change/corporate/international-affairs/partnerships-countries-regions/north-america/canada-united-states-environmental-regulatory-partnership.html> or <http://trade.gov/rcc/>.

Based on priorities identified by lead authorities, work plans will be a product of mutual agreement between the regulatory partners, and will focus on tangible benefits for regulators and stakeholders. Work plans will be informed by programmatic priorities and stakeholder input.

In order to further operationalize the implementation of the RPS for chemical risk assessment activities, an Assessment Collaboration Framework, referred to hereinafter as the "Framework", was developed by the U.S. EPA, ECCC and HC, in consultation with stakeholders from both countries.

Assessment Collaboration Framework

The U.S. EPA, ECCC and HC are committed to continue working together on chemical risk assessment. More specifically, the partners involved in regulatory cooperation are: the Risk Assessment Division of the Office of Pollution Prevention and Toxics of the U.S. EPA, the Science and Risk Assessment Directorate (SRAD) in the Science and Technology Branch of ECCC and the Safe Environments Directorate (SED) in the Healthy Environments and Consumer Safety Branch of HC.

The U.S. EPA, ECCC and HC have common policy objectives under the *Toxic Substances Control Act*, as amended by the *Frank R. Lautenberg Chemical Safety for the 21st Century Act* (TSCA, 2016) and the *Canadian Environmental Protection Act, 1999* (CEPA, 1999), respectively, to reduce risks posed by chemicals to human health and the environment. The organizations share similar principles with respect to the assessment of chemicals, including (but not limited to):

- Protection of the environment and human health;
- Risk-based approaches;
- Scientific integrity;
- Cooperation in support of efficient and robust decision-making (e.g., fit-for-purpose);
- Transparency, engagement and continued communication with stakeholders, including the public; and,
- Commitment to process (e.g., ongoing identification of priorities, continuous improvement/modernization, accountability, reporting, performance measurement, continuing collaboration).

The participating organizations recognize that this Framework focuses on areas of technical collaboration on science and regulatory issues and practices related to chemical assessments. Issues pertaining to policy development in this area are generally considered beyond the scope of the Framework. However, work under this Framework may identify or inform policy issues.

Goals

The overall goal of the Framework is to facilitate and enhance collaboration between the three governmental organizations for the risk-based assessment of chemicals within their respective legislative and regulatory context. Stakeholder engagement and broad communication to the public are additional goals of the Framework. The Framework will enable enhanced alignment on risk assessment of chemicals, including identification of risk assessment priorities, information gathering and sharing, risk assessment methodologies, work sharing and joint assessments.

The goals will be achieved through the implementation of a Rolling Work Plan (see Appendix 1). Rolling Work Plan elements will be reflected in the annual operational plans of each government.

Means of collaboration and engagement

Collaboration among the three governmental organizations, as well as stakeholder engagement and communication with the public, are core to the Framework.

1. Collaboration

General avenues to collaborate on science and practices, including joint reviews, among the three governmental organizations may include staff interchanges, bilateral collaboration in multilateral fora (i.e., face to face meetings, conference calls), use of existing mechanisms of communication, new avenues of communication (e.g., Ad hoc or Specialized Groups) and a shared portal for information exchange. The three governmental organizations will develop and implement the Framework and identify priority work areas within the Rolling Work Plan.

2. Stakeholder Engagement

Stakeholder engagement in the Framework is key to the process and outcomes and shall happen via face-to-face meetings, webinars, conference calls, and use of existing and new mechanisms of communication (i.e., Ad Hoc Groups and other Specialized Groups or Committees).

- Stakeholder Advisory Group – multistakeholder group which provides input to initiatives in the Rolling Work Plan, as appropriate; is a resource for identification of participants in Ad Hoc or Specialized Groups, as needed. The group will be engaged in updates to the rolling work plan.
- Ad-Hoc or Specialized Group – government representatives from U.S. and Canada will co-chair Ad-Hoc or Specialized Groups comprised of governmental officials and stakeholders with expertise in particular technical areas.

3. Public Outreach

The Rolling Work Plan will be published and available to the public. Existing mechanisms within the government agencies will be used to ensure the public is aware of activities being undertaken as part of the Assessment Collaboration Framework.

Information sharing

The Framework is intended to establish appropriate avenues for the exchange of information among the three government organizations, between the government organizations and stakeholders to the extent possible while protecting confidential business information (CBI). The governmental organizations understand that in their respective countries, national legislation provides protection of CBI submitted by industry. Stakeholders will have a role in facilitating the sharing of information to help advance the Framework. Points of contacts (see Rolling Work Plan in Appendix 1) will be established for the three government organizations for the efficient exchange and discussion of information established in the Rolling Work Plan. Existing mechanisms (i.e., Stakeholder Advisory Group) as well as new avenues (e.g., Specialized Groups or Committees) will be used for communication.

Other / duration and modification / administration

This Framework will remain valid for an indeterminate period unless the participating organizations decide otherwise in writing. The framework is intended to be flexible to accommodate changes to the Rolling Work Plan (see Appendix 1) as it goes through periodic updates. This Framework will be reviewed on a regular basis to ensure its relevancy and that its goals are being met.

This Framework is established within the parameters of the organizations' respective mandates and Acts, and is not intended to be legally binding.

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Date: 27 July 2018

Jeffery Morris, Director General, OPPT, U.S. Environmental Protection Agency



Date: 28-06-2018

Jacqueline Gonçalves, Director General, SRAD, Environment and Climate Change Canada



Date: 03-07-2018

David Morin, Director General, SED, Health Canada

Appendix 1

2018 Rolling Work Plan

for the Assessment Collaboration Framework between the U.S. EPA, and
ECCC and HC

The Rolling Work Plan forms an integral part of the Framework, but can be amended separately by mutual written consent and shall be updated annually.

Milestones for the short and medium terms will be established along with a number of agreed upon "Regulatory Areas of Focus", and respective "Planned Initiatives" and/or "Priority Work Areas".

Additional elements of the Rolling Work Plan may include: peer reviews, work sharing, staff exchange, webinars, and/or sharing educational materials.

Performance will be measured by regular communication and collaboration between participating organizations including adherence to commitments as specified in the Rolling Work Plan.