**APEC Chemical Dialogue:**

**Regulatory Cooperation Report**

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# **Introduction**

The chemical industry drives global economic growth and serves as a critical component of more than 85% of manufacturing supply chains, underpinning millions of direct and indirect jobs around the Asia-Pacific region. However, barriers to trade in chemicals increase costs and reduce employment. It is therefore critical that governments and industry cooperate with one another on trade and regulatory policy issues.

The Asia-Pacific Economic Cooperation (APEC) Chemical Dialogue serves as a forum for government officials and industry representatives to find solutions to challenges facing the chemical industry and users of chemicals in the Asia-Pacific region. It reflects APEC member economies' recognition of the importance of engaging with the private sector and building public-private sector dialogue and cooperation for mutual benefit. The APEC Chemical Dialogue's (CD) Regulators Forum seeks to address two fundamental challenges that can hinder the chemical industry's contributions to APEC's broader economic growth and integration, namely the need to: (1) build capacity and technical prowess among chemical sector regulatory officials in APEC economies; and (2) increase regulatory cooperation and alignment within the region

The Regulatory Cooperation Report aims to identify, share, and capture best practices and actionable approaches for APEC chemical regulators seeking to engage in regulatory cooperation with trade partners. The Report provides a range of regulatory cooperation mechanisms available in the chemical sector through case studies from current bilateral cooperation, regional cooperation, and global cooperation. The information included in this report was voluntarily submitted by CD members and represents a non-exhaustive list of regulatory cooperation activities in the region.

# **Regulatory Cooperation Case Studies**

## **Bilateral Cooperation**

### **Australia-Canada Regulatory Cooperation**

In 2007, Australia recognised the Canadian Environmental Protection Act’s new substances regulations as an ‘Approved Foreign Scheme’ under the Industrial Chemicals (Notification and Assessment) Act 1989. Under this arrangement, Australia’s previous National Industrial Chemicals Notification and Assessment Scheme (NICNAS) adopted the Canadian hazard assessment and conducted its own exposure and risk assessment. Australian industry benefited from reduced fees for notifications submitted to NICNAS under the Approved Foreign Scheme provisions, and assessment outcomes between the two countries were more likely to be aligned. The benefits to the Australian and Canadian regulators included reduced duplication of risk assessment effort, capacity building through the sharing of methodologies and approaches (facilitating potential harmonisation), and a trusted source of peer review feedback.

This cooperative arrangement was created on the foundation of similar governmental systems in the two countries, as well as similar, science-based and risk-based chemical assessment systems. As a result, a formal cooperative arrangement for new chemical hazard assessments has been in place since 2002. A number of confidence building projects were undertaken prior to Australia recognising Canada’s new chemicals assessment scheme, such as a comparison of the hazard assessment outcomes of previously assessed chemicals in both countries, and the two countries also exchanged staff to facilitate mutual understanding and cooperation.

In 2008 NICNAS introduced similar arrangements with the US EPA. In 2019, the concept was expanded to encompass risk assessments from prescribed authorities in Canada, the US and the European Union under the “international assessment pathway” of the new Australian Industrial Chemicals Introduction Scheme (AICIS) that replaced the NICNAS in July 2020.

**Best Practices (examples):**

* Sharing (or swapping) staff so each economy could gain a better understanding for each other’s regulatory systems
* Examining and identifying regulatory similarities to help build legislative mechanisms to support science-based chemical regulation
* Utilising relevant international standards (trusted international risk assessments) by NICNAS and AICIS, which help to reduce the impact of chemical regulation on international trade flows.

### **U.S.-Canada Regulatory Cooperation Council (RCC)**

Launched in 2011, the [U.S. – Canada Regulatory Cooperation Council](https://legacy.trade.gov/rcc/) (RCC) brings together regulatory officials, industry, and other stakeholder members of the public from the U.S. and Canada to promote economic growth, innovation, competitiveness, and job creation through the elimination of unnecessary regulatory differences between the two countries. RCC's leadership in both economies is located in central parts of the government. For the United States, RCC leadership is in the Office of Management and Budget. For Canada, RCC leadership is in the Treasury Board Secretariat.

The RCC helps to coordinate various inputs from regulatory departments and agencies, maintains detailed work plans, and ensures everything is publicly available. For coordination purposes, the economies have ongoing, informal conference calls between regulators, including from the U.S. Environmental Protection Agency, the U.S. Department of Labor, Health Canada, and Environment and Climate Change Canada.

***Best Practices:***

* Under the auspices of the Regulatory Partnership Statement published in 2015 that encouraged ongoing collaboration on chemicals and engagement of stakeholders, U.S. EPA partnered with Environment and Climate Change Canada and Health Canada to implement the RCC Chemicals Management Work Plan between 2015 and 2018.
* Throughout the implementation of the work plan, stakeholders made significant contributions by participating in technical working groups and roundtables and submitting valuable comments which informed and shaped the projects.

### **Latin American Bilateral Regulatory Cooperation**

Argentina-Brazil [**Memorandum of Understanding**](https://www.argentina.gob.ar/noticias/bergman-y-su-par-de-brasil-firmaron-un-convenio-por-la-gestion-de-sustancias-y-productos) on Regulatory Cooperation for the Sound Management of Chemical Substances and Chemical Products was signed in October 2018 for a period of 5 years. Argentina and Brazil agreement intend to achieve synergies towards the sound management of chemicals through Regulatory convergence and to foster trade facilitation in Mercosur.

***Best Practices:***

This MOU included the next areas of cooperation:

* Draft of public policies and regulations;
* Development of mechanisms to ensure the compliance to the multilateral environmental agreements;
* Systems of transboundary control of chemical substances;
* Mutual recognition of data existent in the national inventory of substances;
* Mutual recognition of risk assessments of prioritized substances;
* Strategies for Globally Harmonized System of Classification and Labelling of Chemicals (GHS) implementation;
* Activities of monitoring and pollution control for implementing PRTR;
* Analysis of Persistent Organic Pollutants (POP) and chemical substances in general, as well as process for gathering and analyzing toxicological information;
* Enforcement and inspection regimes;
* Programs to prevent chemical accidents;
* Strategies for communication and awareness;
* Processes for stakeholder consultation and its linkage to decision making;
* Platforms of information; and
* Criteria and procedures for the assessment of public policies.

## **Regional Cooperation**

### **United States-Mexico-Canada Agreement: Provisions on regulatory cooperation for chemical substances**

The United States-Mexico-Canada Agreement (USMCA, but also known as CUSMA in Canada and T-MEC in Mexico) entered into force on July 1, 2020. This agreement contains a number of industry-specific provisions in the Sectoral Annexes Chapter (See [Chapter 12](https://protect-us.mimecast.com/s/y2-ZCXDk2rcnnmk2c6S7hl?domain=urldefense.proofpoint.com)). The first annex concerns “Chemical Substances.” The provisions are divided into four sections: 1. Definitions; 2) Scope; 3) Competent Authorities; 4) Enhancing Regulatory Compatibility; and 5) Data and Information Exchange. They outline specific areas of cooperation (e.g., GHS alignment, data sharing, protection of confidential business information, development of chemical inventories, risk assessment, and scientific criteria) where regulators could create efficiency gains in their regulatory work and avoid duplication of effort and resources. They also obligate the parties to the agreement to “share any available data or assessments on particular chemical substances” and “adopt or maintain procedures to prevent the disclosure of confidential information that appears in the data or assessments.” Above all, these provisions preserve the rights of the governments to regulate to protect human health and safety and the environment.

***Best Practices:***

The USMCA Sectoral Annex for Chemical Substances will reduce red tape for trade in chemicals and generate efficiencies for regulators by:

* Making efforts to align risk assessment methodologies and risk management measures for chemical substances;
* Minimizing unnecessary economic barriers or impediments to technological innovation; and
* Where appropriate, using a risk-based approach to the assessment of chemicals.

### **ASEAN - Japan Chemical Safety Database**

[The ASEAN – Japan Chemical Safety Database](https://www.ajcsd.org/chrip_search/html/AjcsdTop.html) is a free database that includes chemical regulatory information, Globally Harmonized System of Classification and Labelling of Chemicals (or GHS) classification results, and risk and hazard information, among other issues. The purpose of the Database is to enhance transparency and to reduce compliance risk on chemical safety among the participant countries, including ASEAN countries and Japan.

Government authorities of each member country provide the regulatory information and GHS classification results for the database. Sample Safety Data Sheets (SDSs) and Labelling are voluntarily provided through member countries. The database is managed by the National Institute of Technology and Evaluation (NITE) in Japan.

"Top page" and "Search (multilingual)" are available in 9 languages including ASEAN local languages (Burmese, English, Indonesian, Japanese, Khmer, Lao, Malay, Standard Thai, Vietnamese). The substance list, hazard information of each substance and legal and regulatory information of each economy are available in English.

**Best Practices:**

* Sharing information of laws and regulations concerning chemicals management and of the classification of chemicals based on GHS in each economy so each economy could gain a better understanding for each other’s regulatory systems and classification of chemicals.
* Recognize and converge the classification of chemicals in each economy.

### **Pacific Alliance - Regulatory Cooperation Annexes**

The [Pacific Alliance](https://alianzapacifico.net/en/what-is-the-pacific-alliance/) is a regional cooperation between Chile, Colombia, Mexico and Peru that was established in April 2011. The objective of the Alliance is to build a deep integration between member countries to drive further growth, development, and competitiveness to overcome socioeconomic inequality and promote the social inclusion of its inhabitants.

The Pacific Alliance Regulatory Cooperation Working Group and its Sub-Group on Technical Barriers to Trade are responsible for ensuring that standards, technical regulations, and conformity assessment procedures do not become unnecessary obstacles to trade. To date, the Pacific Alliance has completed negotiations on five sectoral annexes: cosmetics, medical devices, food supplements, pharmaceutical products and organic products. The Alliance is currently negotiating an annex on household cleaning products, and in the last Presidential Declaration by the Pacific Alliance, signed on 6 July 2019 in Lima, Peru, an agreement was reached to consider initiating negotiations on a new sector on regulatory cooperation.

In August 18, 2020, the Subgroup on Technical Barriers to Trade met in order to advance negotiations of the Annex for household cleaning products, taking into consideration the last letter sent by the industry dated August 4, 2020, reaching an agreement regarding pictograms labeling.

The NSO Code or Sanitary Registration Number, is the only pending issue in the annex, the position of Chile, Colombia and Mexico is to support the industry proposal: "In those countries that currently require NSO code or sanitary registration number, within a period of 3 years from the entry into force of this annex, requirement will be eliminated". The group is awaiting Peru´s position in the above matter to conclude the negotiation.

***Best Practices:***

* Reduce trade transaction costs for household cleaning products.
* Facilitate commercial operations of their products among members.
* Facilitate potential harmonization of technical requirements.
* Eliminate requirements that do not comply with the appropriate compliance/enforcement actions.

### **Chinese Taipei Institutional Cooperation with Japan and Korea**

Aimed at enhancing regional cooperation and contribution to risk-based safe chemicals management systems, the National Institute of Technology and Evaluation (NITE) of Japan, Safety and Health Technology Center (SAHTECH) of Chinese Taipei, and Korea Chemical Management Association (KCMA) of Korea signed Memorandum of Understanding (MoU), respectively, during 2015-2017. Under the MoUs, this cooperation focuses on the chemical policy system of the three regions, as well as important issues related to chemical management, such as source management, chemical products management, risk management and communication, alternative testing methods, and common practice challenges etc. In practice, several bilateral meetings (Japan-Chinese Taipei, Japan-Korea, Chinese Taipei-Korea) have been held annually to share the updated regulatory progress and the best practices of implementation since 2015.

***Best Practices:***

* Through the cooperation and annual bilateral meetings, each institution can mutually benefit from having a better understanding of each other’s regulatory system. Information and best practice experiences exchanged in the events are further shared with local stakeholders and industries, respectively.
* Setting benchmarks for regulatory implementation best practices, and therefore further affecting the establishment or amendment of the regulatory system in each region.
* Mutual seminars are held for local industries from each region to prevent non-necessary technical trade barriers and better regulatory understanding/compliance.
* Exchange newsletters and regulatory updates for redistribution to local industries.

### **ASEAN Regulatory Cooperation Project (ARCP)**

[The ASEAN Regulatory Cooperation Project](https://scic.sg/asean/) (ARCP) aims to encourage regulatory cooperation and convergence by addressing non-tariff barriers due to divergence of chemical management regulations. The ARCP initiative is aligned to the directive of the ASEAN Economic Community (AEC), which promotes the use of good regulatory practices to help establish regulatory environments that encourage free and open trade and investment while protecting human health, safety, environment and security. The ARCP is led by the American Chemistry Council (ACC), CEFIC, Japan Chemical Industry Association (JCIA), and Singapore Chemical Industry Council (SCIC) in joint-efforts to advance chemical regulatory cooperation in the ASEAN region.

***Best Practices:***

* Regulators should avoid regulations that are: burdensome, costly, impractical, more resource intensive then required
* A prioritized risk-based approach should be used when a country is revising or improving their chemicals management system
* Elements of a Risk-Based System include:
  + Identification of chemicals in commerce based on existing and available data; screening assessment and prioritization of all chemicals in commerce;
  + A full range of risk management actions, ranging from labeling to bans and phase outs;
  + Public Transparency & Stakeholder Consultation; and
  + Protection of Confidential Business Information.
* **Capacity and capability building to support the implementation of sound chemicals management systems:**
  + Development of ASEAN Guidance Documents on GHS implementation alignment and development of a Chemical Inventory for ASEAN Member States’ (AMS) reference.
  + Risk Assessment training.
  + Training on use of ASEAN prioritization tools in priority setting for risk assessment of chemicals.
  + Provision of introductory knowledge to human health and eco-toxicology.
* **Establishment of an effective AMS network for regular exchanges of regulatory developments and exchange of information and experience in chemicals management system implementation by ASEAN Member States:**
  + Regular workshops to provide the platform for sharing including:
    - Case study sharing on challenges on GHS and Chemical Inventory implementation experiences with reference to the ASEAN Guidance Documents developed, (for example: sharing of issues among AMS (related to non-technical barriers to trade) in their process of Chemical Inventory and GHS implementation due to the adaptation of different building blocks / cut-off limit and different GHS versions, country setting up own country specific SDS format and GHS labelling requirement including small volume limit and labelling cut-off, labelling size etc, as well as case study of GHS implementation approaches in other regions beyond AMS).
    - Good practices sharing among AMS on their promotional tools, compliance tools, capacity and capability building programmes including the different level and type of GHS training courses conducted, the effectiveness of its outreach and knowledge building towards driving the successful implementation of GHS. Provided interactive gallery walk and story board exhibition booths regarding GHS Implementation. Good practices sharing also among AMS towards driving the successful implementation of Chemical Inventory.
  + Development of reference working document on comparison of GHS implementation among AMS in overall landscape, classification, and labelling as key sources of information aimed at seeking alignment

### **Latin America Regulatory Cooperation Forum (LARCF)**

LARCF promotes information sharing and technical discussions on chemical and waste regulatory developments in Latin America and supports the organization of Regulatory Cooperation events. The overarching goal of the LARCF is to drive the implementation and establishment of consistent, effective and science-based chemical systems in countries in Latin America.To date, the participants include nine chemical industry associations; two downstream user associations; thirty chemical industry participants; fifty professionals; and five countries (Argentina, Brasil, Chile, Colombia, and Mexico). The LARCF has four objectives:

1. Improve regulatory cooperation between LATAM chemical industry associations and increase engagement in projects in coordination with ICCA guidance and principles.
2. Leverage communication and information sharing on regulatory developments within regional industry networks and promote capacity building initiatives for governments and industry national associations in Latin America related to key topics such as SAICM and OECD requirements.
3. Establish an industry vision and roadmap for regulatory cooperation in order to support the implementation of chemical management systems by governments in Latin America.
4. Support the Latin America Chemical Industry National Associations on alignment of positions on key international regulatory issues, such as the Sound Management of Chemicals, through a trust building dialogue with government and international bodies.

## **Multilateral Cooperation**

### **OECD Mutual Acceptance of Data**

The OECD MAD system harmonises national approaches to the creation of chemical hazard test study data that underpins chemical risk assessment, so that industry is not faced with a plethora of conflicting or duplicative requirements, governments are provided with a common basis for working with each other, and non-tariff barriers to trade are reduced. The principal tools for harmonisation are a set of OECD Council Decisions which make up the OECD Mutual Acceptance of Data (MAD) system, including its OECD Guidelines for the Testing of Chemicals and OECD Principles of Good Laboratory Practice (GLP).

The MAD criteria for non-clinical health and safety test studies are:

1. The study must have been conducted according to OECD Test Guidelines and OECD Principles of GLP;
2. The study must have been conducted in a test facility which has been inspected by a national GLP compliance monitoring programme and;
3. The national GLP compliance monitoring programme must have undergone a successful evaluation by the OECD.

If all three criteria are met, all OECD member countries, as well as adherents to MAD, must accept the study data.

***Best Practices:***

* Utilising relevant international standards wherever possible to create data from hazard assessment studies, based on mutually agreed test study guidelines.
* Reducing the impact of chemical regulation on international trade flows by ensuring regulators assess chemicals using the same, science-based hazard-based study data.
* Chemical regulations should have a clear delineation of regulatory responsibilities and effective and transparent accountability mechanisms – this is achieved by separating the creation of study data from the subsequent chemical assessment process, and requiring test facilities to adhere to GLP requirements and be independently audited.

## **Global Cooperation**

### **Strategic Approach to International Chemicals Management (SAICM)**

SAICM is a multi-stakeholder, multi-sector forum to achieve the sound management of chemicals and waste by 2020. One of SAICM’s primary objectives is the development and enforcement of chemical management systems around the globe. Through information sharing, exchange of best practices, capacity building, and other activities, SAICM provides a forum for greater regulatory cooperation. Additionally, through the Emerging Policy Issue (EPI), SAICM provides an opportunity for governments and stakeholders to work together closely on policy options to address issues of concern, such as lead in paint.

***Best Practices:***

Lead is a human health hazard, and lead paint is a significant source of exposure, in particular for children and workers. More than 60% of countries, mostly lower and middle-income countries, still allow lead paint, and paint with extremely high levels is found wherever testing is conducted there. To address this global issue, the International Conference on Chemicals Management (ICCM) at its second session in 2009, identified lead paint as an emerging policy issue under the Strategic Approach to International Chemicals Management (SAICM) framework. The ICCM, at its third to fourth sessions, continued to affirm the goal of eliminating lead paint and in 2011 mandated the creation of the [Global Alliance to Eliminate Lead Paint](https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/global-alliance-eliminate-lead-paint) (Lead Paint Alliance).

The Lead Paint Alliance, a joint initiative led by the United Nations Environment Programme (UNEP) and the World Health Organization (WHO), established a global Advisory Council chaired by the U.S. Environment Protection Agency (USEPA). The work of the Alliance aims to support the introduction of laws on phasing out the manufacture, import and sale of paints containing lead and eventually to eliminate the risks from such paint. The Alliance has also demonstrated that there are technically feasible alternatives to lead paint available in developing countries at costs comparable to paint with lead and that the production of paint without added lead is possible.

The only way to effectively eliminate lead paint is to enact lead paint laws. The Alliance has found that countries with lead paint laws have paint with low levels of lead. To help countries establish laws, the Alliance developed the [Model Law and Guidance for Regulating Lead Paint (Model Law)](https://www.unenvironment.org/resources/publication/model-law-and-guidance-regulating-lead-paint), which provides a template for lead paint laws that can be customized to address country-specific legal frameworks. The Model Law promotes eliminating lead from all paints and establishing a lead concentration limit of 90 ppm. It is supported by a broad coalition of governments, industry, and environmental groups.

The Lead Paint Alliance is working with countries to establish laws for all types of paint as the most effective way to eliminate lead paint. Currently only 76 (less than 40%) countries have lead paint laws (see [UNEP map](https://chemicalswithoutconcern.org/content/lead-paint-law-map)), and not all of these regulate all types of paint. Nevertheless, momentum is growing as more and more countries work toward establishing laws. In Asia, China recently lowered existing lead limits for some paints, and Vietnam, Cambodia and Laos are developing lead paint laws.