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APEC Chemical Dialogue: Risk Assessment Policy Tools

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April 2023

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1. Regulatory Cooperation Report

APEC Chemical Dialogue Regulatory Cooperation Report

Table of Contents

I. 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.

II. Regulatory Cooperation Case Studies

A. Bilateral Cooperation

1. 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 economies 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 economies, 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 economies, and the two economies 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.

2. U.S.-Canada Regulatory Cooperation Council (RCC)

Launched in 2011, the U.S. – Canada Regulatory Cooperation Council (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 economies. 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.

3. Latin American Bilateral Regulatory Cooperation

Argentina-Brazil **Memorandum of Understanding** 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 domestic 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.

B. Regional Cooperation

1. 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). 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.

2. ASEAN - Japan Chemical Safety Database

The ASEAN – Japan Chemical Safety Database 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 economies, including ASEAN economies and Japan.

Government authorities of each member provide the regulatory information and GHS classification results for the database. Sample Safety Data Sheets (SDSs) and Labelling are voluntarily provided through member economies. 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.

3. Pacific Alliance - Regulatory Cooperation Annexes

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 economies 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 economies 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.

4. 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.

5. ASEAN Regulatory Cooperation Project (ARCP)

The ASEAN Regulatory Cooperation Project (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 member 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, a member setting up its own 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

6. <u>Latin America Regulatory Cooperation Forum (LARCF)</u>

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 economies in Latin America. To date, the participants include nine chemical industry associations; two downstream user associations; thirty chemical industry participants; fifty professionals; and five economies (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 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.

C. Multilateral Cooperation

1. OECD Mutual Acceptance of Data

The OECD MAD system harmonises domestic 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 domestic GLP compliance monitoring programme and;
3. The domestic GLP compliance monitoring programme must have undergone a successful evaluation by the OECD.

If all three criteria are met, all OECD member economies, 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.

D. Global Cooperation

1. 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 economies, mostly lower and middle-income economies, 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 (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 economies 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 economies with lead paint laws have paint with low levels of lead. To help economies establish laws, the Alliance developed the Model Law and Guidance for Regulating Lead Paint (Model Law), 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 economies to establish laws for all types of paint as the most effective way to eliminate lead paint. Currently only 76 (less than 40%) economies have lead paint laws (see UNEP map), and not all of these regulate all types of paint. Nevertheless, momentum is growing as more and more economies 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.

2. Regulatory Cooperation Checklist

Regulatory Cooperation Checklist

Table of Contents

III. Introduction

The APEC Chemical Dialogue's work on regulatory cooperation aims to build capacity and technical skills among chemical sector regulatory officials in APEC economies and increase cooperation and regulatory alignment within the region. This work helps to reduce non-tariff barriers and make regulatory systems more efficient while maintaining high levels of protection for human health, safety, and the environment.

The APEC Chemical Dialogue Regulatory Cooperation Checklist seeks to supplement the APEC Chemical Dialogue Regulatory Cooperation Report[1], endorsed by the APEC Chemical Dialogue in 2020, by providing APEC economies and their regulators a step-by-step guide to implementing regulatory cooperation discussions. The following components for regulatory cooperation reflect a sub-set of best practices identified by other international organizations such as the OECD's International Regulatory Co-operation Toolkit[2]. The Checklist works within the framework already provided by the OECD International Regulatory Cooperation Toolkit, but provides a step-by-step, practical process to support an APEC economy that is interested in entering regulatory cooperation discussions with a partner economy.

Tackling complex, interconnected and rapidly changing trans-boundary policy challenges requires economies to work together. International regulatory cooperation (IRC) plays a strong role to "harness" and create common rules of globalization and mobilizes an extensive variety of stakeholder in the national and international rulemaking environment. This includes policy makers and regulators across policy areas on each economy, intergovernmental organizations, and international networks of regulators, among others. This document aims to support international regulatory cooperation through providing practical steps of engagement.

The regulatory cooperation components are sequenced in an order that aims to first establish, and then build, trust between chemical regulators in individual economies over time. Ultimately, regulator trust (trust with whom?) is the critical prerequisite to more robust and sustainable regulatory cooperation.

[1] https://www.apec.org/-/media/Files/Groups/CD/2020/Chemical-Dialogue-Regulatory-Cooperation-Report---clean.docx
[2] https://www.oecd.org/gov/regulatory-policy/irc-toolkit.htm

IV. Key Steps for Regulatory Cooperation

PREPARING

1. Who are you interested in cooperating with?

Identify which economy or economies you are interested in cooperating with.

- ☐ Identify metrics to evaluate possible partners, for example:
  - Bilateral trade and investment profile
  - Levels of intra-company trade in the chemical industry
  - Engagement in multilateral fora (WTO, OECD Chemicals Committee, or regional fora (APEC)
  - Regulatory status/maturity

- ☐ Identify motivators for engaging in regulatory cooperation, for example:
  - Achieving specific regulatory objectives
  - Aligning / harmonize regulations
  - Reducing trade and investment barriers
  - Improving the efficiency of one's own regulatory system
  - Achieving a mutual reduction in regulatory burden
  - Achieving mutual recognition on certification schemes
  - More efficient government expenditure of scarce resources
  - Easier acquisition of relevant information and data
  - Achieving a balance of economic priorities with public and workers' welfare
  - Responsiveness in providing technical assistance and support
  - Learning and sharing best regulatory practices
  - Accessing latest relevant scientific and economic studies supportive of regulation and/or regulatory impact assessment
  - Recognition or awards on the successful implementation of the objectives of the cooperation or activities/ programs/best practices which can be adopted by other economies.

PLANNING

2. What do you want to achieve by engaging in regulatory cooperation?

Determining the key objectives you want to achieve through regulatory cooperation is a critical step that can occur as you identify possible partners for regulatory cooperation or after you identify those partners. There are a number of approaches to determine those objectives. Those approaches can include the following action items:

- ☐ Describe existing regulatory approaches used by each partner, ideally in defined areas.

- ☐ Conduct an appraisal of you and your partner's organizational capacity to undertake cooperation. It may be that limited resources dictate the form of cooperation.

- ☐ Understand each partner's goals for cooperation. Possible questions include:
  - What is the issue area you want to focus on?
  - What are your targets/goals for the issue area?

- What is the current state-of-play for the issue area?
- What is the ideal outcome for achieving the targets/goals?
- What are the gaps/challenges between the current state-of-play and the ideal outcome? How was it overcome? Lessons learned?
- What are the policies of each partner that needs to be aligned?
- Are the goals implementable within an agreed time frame?

☐ Conduct a public consultation:
- Are there key objectives early on in the regulatory cooperation process to identify and consult the stakeholders most likely to be impacted by cooperation?
- Is there a mechanism to ensure that all comments on a regulatory cooperation proposal are adequately addressed before it is finalized?

What are the emerging issues that may affect current agreements / activities or state of the cooperation?

☐ Conduct surveys and gather position papers from regulators and regulated communities.

☐ Undertake information exchange, technical cooperation and assistance (e.g. mentoring, best regulatory practices, case studies, etc)

☐ Undertake impact analysis of proposed regulatory cooperation.

☐ Develop indicators to measure performance and effectiveness of the potential regulatory cooperation process

- Use indicators to review what has been accomplished through previous internal and bilateral processes

☐ Develop mitigating / adaptive measures on an international level, on global issues like pandemic.

3. How do you plan to achieve your objectives?

☐ Establish a written strategy outline and/or plan for engagement. This can help identify potential alignments and misalignments with your potential partner. Elements of a written strategy include:

- Establishing a coordination mechanism in government on regulatory cooperation activities and practices to build consensus and common language.[3]
- Raising awareness on regulatory cooperation – inform and seek public comment from a broader audience (stakeholders, regional platforms such as APEC) on what you are trying to accomplish.
- Establishing linkages to Multilateral Environmental Agreements, SAICM and other related chemical and wastes global initiatives.

☐ Develop a process for stakeholder consultation on regulatory cooperation proposals (including notice and comment). Public consultation is one of the key regulatory tools

[3] OECD International Regulatory Cooperation Policy Brief, 2018. http://www.oecd.org/gov/regulatory-policy/international-regulatory-cooperation-policy-brief-2018.pdf

employed to improve transparency, efficiency and effectiveness of regulation[4]. This can include:

- Receiving industry and civil society input on potential regulatory cooperation provisions.

- Develop written implementation plans that could include benchmarks for advancing and achieving regulatory cooperation goals. Such benchmarks can address:
  - Sharing information and data on specific regulatory issues, including gaps and challenges
  - Eliminating requirements that are not supported by appropriate; compliance/enforcement actions;
  - Avoiding regulations that are: burdensome, costly, impractical, more resource intensive than required;
  - Ensuring regulatory cooperation/action is based on relevant and objective scientific and/or technological information and processes;
  - Personal exchange to provide hands-on insights into how the prospective partners actually work in practice. This can provide a benchmark on the practical compatibility of each other's systems;
  - Developing reporting mechanisms among partners; and/or
  - If there are similarities in regulation, sharing of results of regulatory impact analysis

COOPERATING

4. How do you communicate with your regulatory cooperation partners?

- Participate in an informal dialogue to provide an exchange of information. Exchanges of information can help identify ways to eliminate unnecessary or duplicative data generation and create efficiencies for both governments and industry. This can be in the form of:

  - Annual plenary and informal meetings, so regulators from different economies mutually benefit from having a better understanding of each other's regulatory systems, including laws and regulations concerning chemicals management and of the classification of chemicals based on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

  - Joint seminars for local industries especially MSMEs trade association etc. from each region to prevent non-necessary technical trade barriers and better regulatory understanding/compliance.

  - Engaging in established regulatory cooperation schemes as an observer (e.g., in the OECD MAD scheme) in order to better understand how such schemes operate and to determine if entering into a formal engagement is appropriate.

  - Develop reporting mechanisms among partners (reporting template can be developed).

- Undertake stakeholder consultations on the proposed agenda for cooperation. This may include:

[4] 2016 Final Report on Good Regulatory Practice in APEC Economies

- Communicating to stakeholders that the activity will address particular issues (e.g., through industry roundtables, webinars, or notice and comment); and

- Fostering stakeholder participation to ensure that a common understanding of the technical and scientific information exists.

5. How do you develop a formal agenda with potential partners?

If you and your partner (or partners) choose to move forward after an informal dialogue and transparent consultation process, you can:

- ☐ Identify and establish a negotiating team from relevant government agencies/offices.

- ☐ Draft a written agenda based on priorities discussed during the informal dialogue and consultation process.

6. How do you memorialize regulatory cooperation?

Recognition and incorporation of international standards can support regulatory cooperation by allowing alignment of technical specifications for a sector of choice – like chemicals.[5] To memorialize regulatory cooperation, economies can:

- ☐ Develop a Memorandum of Understanding (MOU) on regulatory cooperation. An MOU expresses an alignment of commitments between parties, indicating an intended common line of action. Through the elimination of unnecessary regulatory differences, MOUs can promote economic growth, innovation, competitiveness, and job creation. *[ex. U.S.-Canada Regulatory Cooperation Council (RCC) MOU[6]; Argentina-Brazil Memorandum of Understanding on Regulatory Cooperation for the Sound Management of Chemical Substances and Chemical Products[7]]*

- ☐ Develop mechanisms to ensure their compliance with the multilateral environmental agreements to which they are a party, and other initiatives in which they participate, including strategies for GHS implementation.

- ☐ Include regulatory cooperation provisions in bilateral/multilateral trade and/or science agreements. *[ex. Sectoral Annex 12.A of the U.S.-Mexico-Canada Agreement[8]]*

- ☐ Publish the results of regulatory cooperation in official journals of their respective government.

- ☐ Review and monitor progress of cooperation

[5] As defined by the OECD.
[6] https://www.whitehouse.gov/wp-content/uploads/2018/06/US-CanadaMOU.pdf
[7] https://www.argentina.gob.ar/noticias/bergman-y-su-par-de-brasil-firmaron-un-convenio-por-la-gestion-de-sustancias-y-productos
[8] https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/12_Sectoral_Annexes.pdf

OPERATIONALIZING

7. How do you promote capacity building [within and across economies]?

Trainings, workshops, etc. can help stakeholders, including regulators, manage the unique challenges associated with sound chemicals management and examine sustainable solutions. For example, economies can:

- ☐ Develop trainings and/or workshops to:
  - Promote awareness of and knowledge about chemical hazards;
  - Manage risks associated with manufacture and use of chemicals;
  - Create risk assessment, regulatory impact training;
  - Develop the necessary national infrastructure and capacities for regulatory and voluntary approaches to chemical management[9];
  - Develop guidance documents on GHS implementation alignment;
  - Establish websites where information (video materials, announcements, new policies, events, etc.) can be quickly shared among partners and/or other stakeholders; and/or
  - Develop instructional or presentation materials that can be publicly shared for easy reference anytime when they are needed.

- ☐ Identify pool of subject matter experts (SME) in each participating economy that can assist in the capacity building activities.

8. What types of activities can you pursue to operationalize your cooperation strategy?

If both parties have a good understanding for how common issues are addressed in different jurisdictions and confidence in their respective internal procedures, they can identify additional efficiencies and reduce mutual regulatory burdens. Activities could include:

- ☐ Identifying regulatory similarities or alignments between economies. This can help:
  - Build regulatory mechanisms to support science-based chemical regulation;
  - Align risk assessment methodologies and risk management measures for chemical substances;
  - Recognize and converge the classification of chemicals in each economy;
  - Facilitate potential alignment of technical requirements;
  - Provide access to existing databases;
  - Prioritize a risk-based approach when an economy is revising or improving their chemicals management system, and/or
  - Develop monitoring and reporting activities of the economies.

- ☐ Facilitating inclusive stakeholder consultation (including foreign), to gather information about the operationalizing of regulatory cooperation and ensure that findings are fed into regulatory processes and further exchanges between partners.[10]

[9] As referenced by ICCA.
[10] OECD International Regulatory Cooperation Policy Brief, 2018. http://www.oecd.org/gov/regulatory-policy/international-regulatory-cooperation-policy-brief-2018.pdf

EVALUATION

9. How can you evaluate whether the cooperation process was successful?

Creating an evaluation process can help economies improve future cooperation, and to understand if previous cooperation efforts were successful. This process can include the following action items:

- Develop indicators to measure performance and effectiveness of the regulatory cooperation process (resource - OECD Measuring Regulatory Performance).
- Use indicators to review what has been accomplished through internal and bilateral processes.
- Analyze results to identify lessons learned, areas for improvement, and best practices moving forward through an established periodic evaluation process.
- Review the regulatory cooperation and its results through internal and bilateral processes – identify lessons learned, areas for improvement, and best practices moving forward.
- Undertake stakeholder consultations on the completed cooperation to facilitate feedback. This may include:
    - Notice and comment;
    - Stakeholder roundtables;
    - One-on-one meetings;and
    - Surveys on the progress/status of the implementation of the cooperation

V. Resources

APEC Resources

- Final Report on Good Regulatory Practice in APEC Economies
- Best Practice Principles Checklist for Chemicals Regulation
- APEC Chemical Dialogue Regulatory Cooperation Report
- APEC-OECD Cooperation on Regulatory Reform
- APEC-OECD Integrated Checklist on Regulatory Reform

OECD Resources

- The International Regulatory Co-operation Toolkit - OECD
- Regulatory impact analysis - OECD
- Recommendations and Guidelines on Regulatory Policy - OECD
- Indicators of Regulatory Policy and Governance - OECD
- Best Practices / Guidelines - OECD

World Bank

- World Bank Group Environmental, Health, and Safety Guidelines

3. Methods, Tools and Approaches for Risk Assessment

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 can increase costs and reduce employment. Barriers can include lack of capacity and inefficiencies in risk assessment procedures which can drive up costs, delay introduction of innovative products, and impair health and environmental protection. As chemicals are found in more than 85% of manufacturing supply chains, the social, health, environmental, and economic cost of delay is felt economy-wide.

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.

This document provides a compendium of guidance documents and tools that help economies and stakeholders to develop risk assessments. The resources focus on approaches that assist in conducting a basic level risk evaluation.

This compendium serves as an additional resource for APEC economies to take action and achieve high standards of protection for human health and safety and the environment, foster greater innovation, and prevent barriers to trade. Additional Chemical Dialogue resources include the APEC Chemical Dialogue Regulatory Cooperation Report (2020) and the APEC Best Practice in Chemical Regulation Checklist (2016).

Risk Assessment 101

General Methods- Human Health Risk Assessment

EU Practical Guides for REACH, CLP, and BPR. This website provides links to practical information to help fulfill reach requirements.

Malaysia Manual on Simple Risk Assessment and Control for Chemicals (SiRAC) 2019. This manual was developed to provide guidance to carry out an assessment of risk to health due to exposure to chemicals hazardous to health using the Simple Risk Assessment and Control for Chemicals (SiRAC) method to ensure compliance with Malaysia's Occupational Safety and Health Act.

U.S. EPA Conducting a Human Health Risk Assessment. This website provides details on the basic considerations of a risk assessment, starting with planning and scoping through risk characterization.

U.S. EPA A Framework For Assessing Health Risk of Environmental Exposures To Children. This framework serves as a resource on children's health risk assessment and lays out a process to evaluate risks based on lifestage specific considerations.

OECD Manual for the Assessment of Chemicals. This manual provides guidance on data gathering, evaluating quality of data, guidance for grouping substances, use of structure activity relationships, hazard assessment, and exposure assessment

WHO Human Health Risk Assessment Toolkit: Chemical Hazards. This toolkit aims to provide users with guidance to identify, acquire, and use the information needed to assess chemical hazards,

exposures, and the corresponding health risks in their given risk assessment contexts at local and national levels.

ICCA Global Product Strategy: ICCA Guidance on Chemical Risk Assessment. This document was produced for developing regions and small and medium-sized companies to help them perform risk assessment under GPS.

General Methods- Environmental Risk Assessment

Australia (NEPC) (2009): Environmental Risk Assessment Guidance Manual for Industrial Chemicals: The Guidance Manual provides an overview of: the steps taken to carry out an environmental risk assessment on industrial chemicals, including lifecycle considerations; what data are needed and how they are used; nationally adopted criteria, such as Persistence/Bioaccumulation/Toxicity (PBT); how international considerations are taken into account; and how risk assessors come to their recommendations about environmental risk management actions.

OECD Environmental Risk Assessment Toolkit. This website provides practical tools on environmental risk assessment, with links to relevant OECD products that can be used in each step of the workflow. [note links to the OECD tools from the page do not work]
U.S. EPA Ecological Risk Assessment. This website provides details on the basic considerations of an ecological risk assessment, starting with planning and scoping through risk characterization.

Problem Formulation

RISK21 Risk Assessment Formulation Tool (RAFT). This tool was developed to help streamline the problem formulation step in the by providing a fill-in-the-blanks template for a diagrammatic conceptual model and guidance in choosing its contents.

U.S. EPA. Framework for Human Health Risk Assessment to Inform Decision Making. EPA/100/R-14/001, Apr 2014. This document presents issues to consider, provides suggested questions to ask during risk assessment planning and execution, and identifies some useful practices. The intended audience for this document includes those who assess risk, those who use the information within and outside EPA (e.g., risk managers) and those interested in the process by which EPA conducts risk assessments.

Hazard Assessment

Australia Working out your Hazards Using Read-Across Information. This guide describes the read-across method and how you can determine if read-across is suitable to help describe your chemicals hazard.

Canada Approaches for addressing data needs in risk assessment. In the absence of experimental data, this website and fact sheet provides information on how to use predictive tools to assess hazard.

OECD Hazard Assessment. This website provides information to inform hazard assessment including links to IATA examples, OECD harmonized templates, the QSAR toolbox, and OECD testing series.

Exposure Assessment

OECD Exposure Assessment. This website provides links to Emission Scenario Documents, screening tools for multimedia chemical fate models, and other tools for exposure assessment.

U.S. EPA Expobox Exposure Assessment Tools by Tiers and Types. This Website provides links to tools and guidance documents to conduct screening level and refined risk evaluations

U.S. EPA. Guidelines on Human Exposure Assessment. This guidance presents the policies and practices at EPA for conducting exposure assessment.

U.S. EPA Exposure Factors Handbook. This handbook is intended for use by exposure and risk assessors both within and outside the U.S. EPA as a reference tool and primary source of exposure factor information.

Risk Characterization

U.S. EPA Risk Characterization Handbook. This Handbook provides a single, centralized body of risk characterization implementation guidance for risk assessors and risk managers to help make the risk characterization process transparent and the risk characterization products clear, consistent and reasonable (TCCR).