GCCM
US & Canada regulatory updates

Alejandra Acosta

Content

- Chemicals regulation in the USA
- Chemicals regulation in Canada
- Canada/US-coop.

Chemicals regulation in the USA

US chemistry sector at a glance

Impact on U.S. Economy

The U.S. chemical industry is responsible for more than a quarter of the U.S. GDP, supports the production of almost all commercial and household goods, and is essential to economic growth.

The U.S. chemical industry is a **$768 billion** enterprise that supports more than **25%** of total U.S. GDP

96% of U.S. goods in 2016 were manufactured using Chemical Sector products

The U.S. chemical industry is one of the world's **largest chemical producers** → **15%** of the world's chemicals come from the U.S.

Generation of U.S. Employment

From research and development to manufacturing, the U.S. chemical industry employs nearly 800,000 people, while creating jobs in the many other industries it touches.

The U.S. Chemical Sector directly employs nearly **800,000 employees** → Every job created by the business of chemistry generates **6.8 jobs elsewhere** → **6 million** U.S. jobs created

Contribution to U.S. Exports

The business of chemistry is America's largest exporting sector, supplying an eighth of the world's chemical needs.

Total value of U.S. chemical exports per year **$174 billion**

Chemicals and related products make up **10 cents of every $1 of U.S. exports**

Chemicals are highly regulated within the US

Department of Homeland Security

Cybersecurity and Infrastructure Security Agency

Chemical Facility Anti-Terrorism Standards

3,355 facilities regulated (as of 2018)

Transportation Security Administration

Rail Transportation Security Final Rule

46 key urban areas covered by secure chain-of-custody inspections

U.S. Coast Guard

Maritime Transportation Security Act of 2002

3,200 facilities of all types covered (as of 2013)

Environmental Protection Agency

800,000 regulated facilities (as of 2018)

Department of Transportation

Pipeline and Hazardous Materials Safety Administration

13,829 shippers covered by the security plan and training requirements (as of 2017)

Department of Health and Human Services

Food and Drug Administration

$1 trillion worth of products regulated per year including drugs, cosmetics, and medical and consumer products

Department of Labor

Occupational Safety and Health Administration

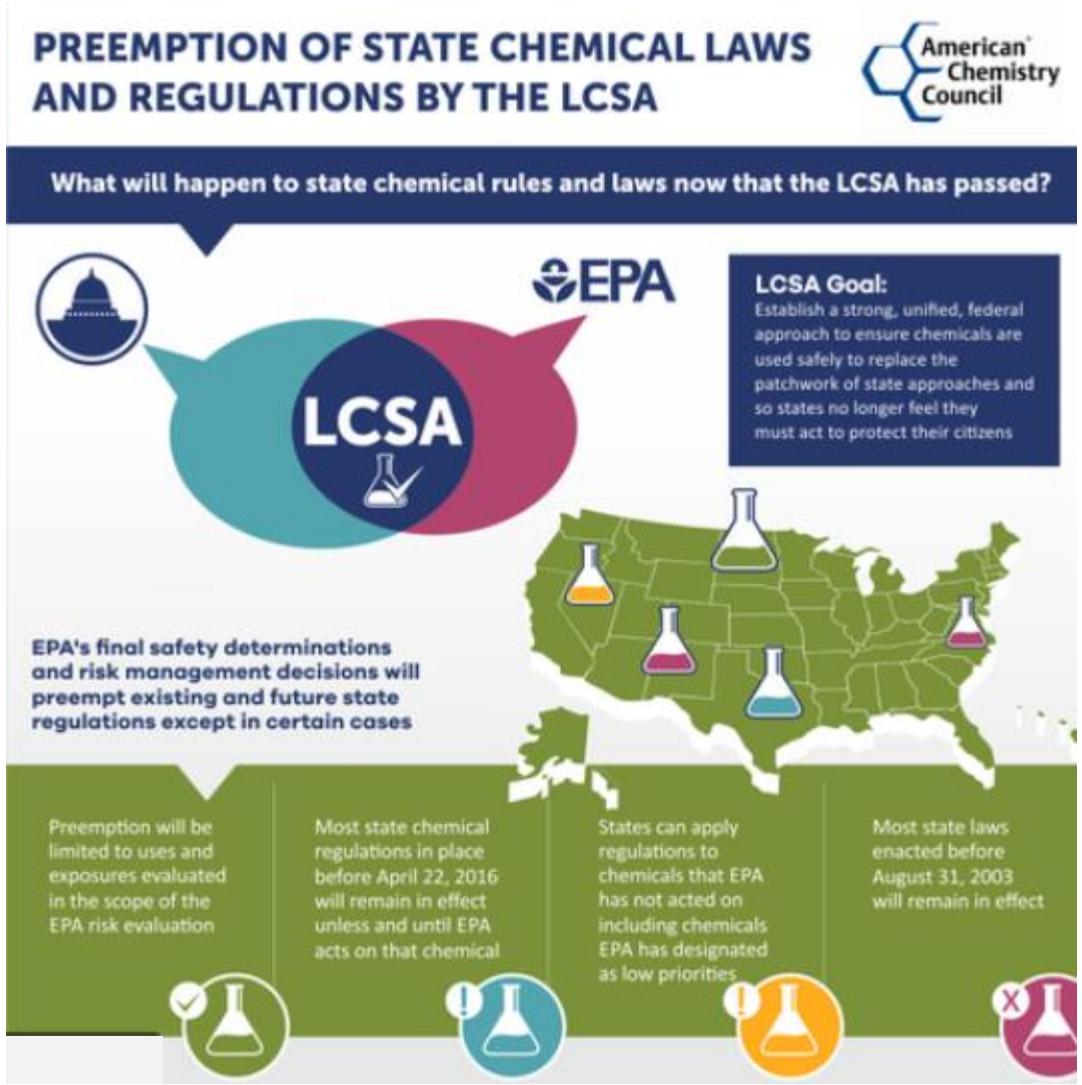
700 enforcement inspections of chemical manufacturing facilities in 2017

Department of Justice

Bureau of Alcohol, Tobacco, Firearms and Explosives

9,815 licensee/permittees are subject to security rules (as of 2017)

Federal vs state regulations



Toxic Substances Control Act

New Chemicals

Any chemical introduced or a significant new use of an existing chemical required notice and/or EPA review before commercialization. Generally viewed as effective.

Existing Chemicals

All chemicals in commerce when TSCA was enacted were “grandfathered” - no EPA review was required for the chemicals to remain in use. Became a greater source of debate.

TSCA Reform

June 22, 2016

President Obama Signs the Frank R. Lautenberg Chemical Safety for the 21st Century Act into law

Summary of Key Reforms

- A prioritization process
- Risk-based process
- Scientific Standard
- Cost-benefit in rule-making
- Expanded Authority
- CBI Protections
- Fees

Principle Provisions of TSCA

- **Section 4 -** testing of existing chemicals
- **Section 5 -** screening of new chemicals or new uses of existing chemicals
- **Section 6 -** risk management
- **Section 8 –** information collection and reporting

Other Provisions:
Section 7 – imminent hazard
Section 9 - relationship of TSCA to other federal laws
Section 11 – inspections
Section 12 - chemical export
Section 13 - chemical import
Section 14 – CBI
Sections 15, 16 and 17 - prohibited acts, penalties & EPA's enforcement powers.
Section 20 and 21 - citizen actions
Section 26 – use of categories versus specific substances

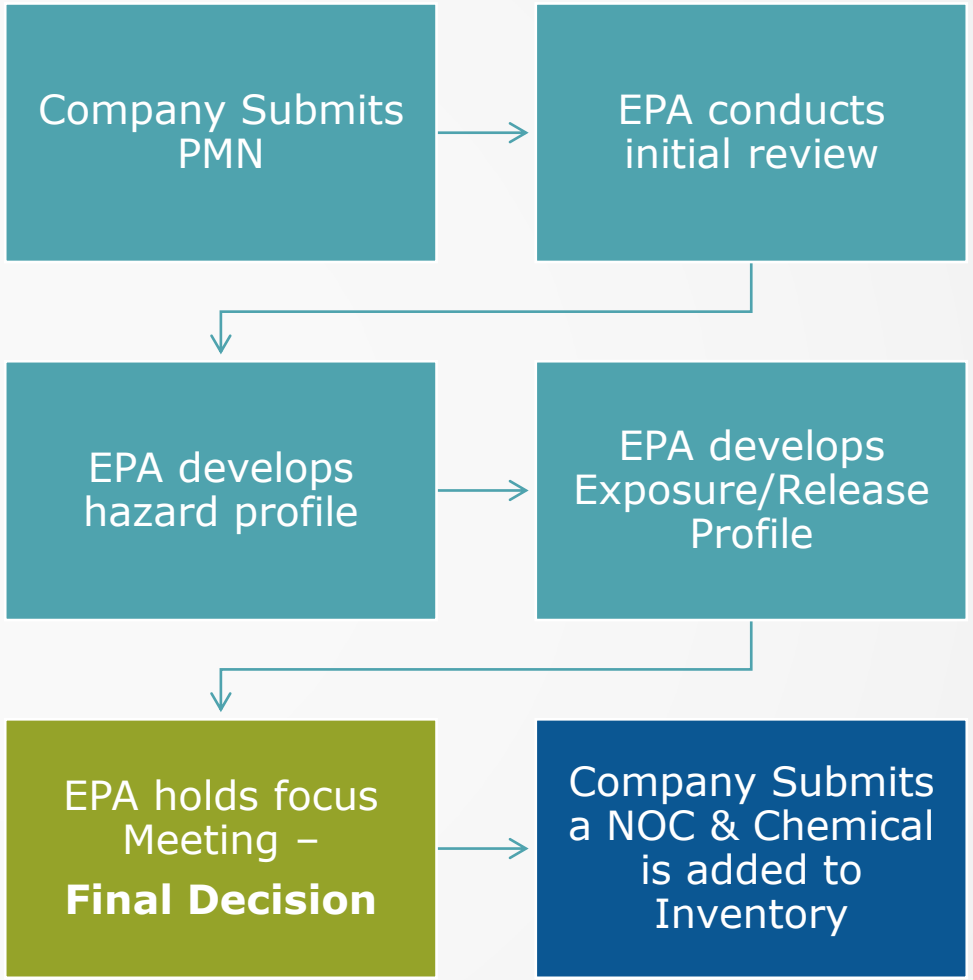
In the Beginning

Companies informed EPA which Chemicals were being produced at that time

That list of chemicals resulted in the initial TSCA inventory (1979)

Any chemical developed after 1979 has gone through New Chemical Review

New Chemical Review



TSCA Inventory

TSCA Inventory ≠ Chemicals in Commerce

The TSCA inventory is a comprehensive list of all chemicals ever allowed by EPA to be manufactured.

Chemical Data Reporting

CDR reporting happens every 4 years and is the best reflection of chemicals actually being used in commerce.

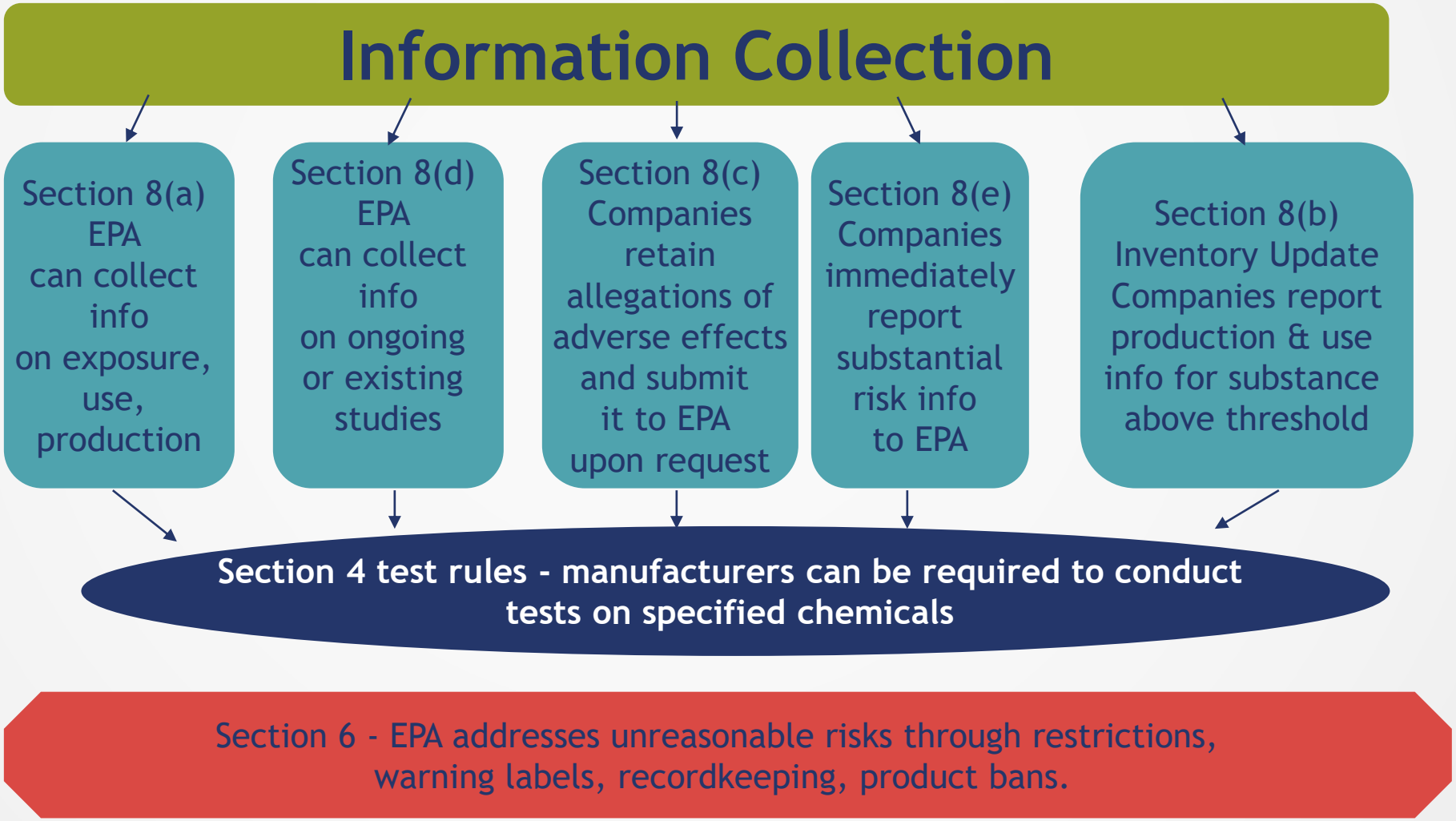
Under LSCA: Inventory Reset

Used to clarify which chemicals are in use today

Active Chemicals

Post reset, all chemicals considered “active” will undergo screening for prioritization & possible risk evaluation

Existing Chemicals



Prioritization

EPA conducts risk based screening of all active chemicals from the inventory to identify those in need of a full evaluation

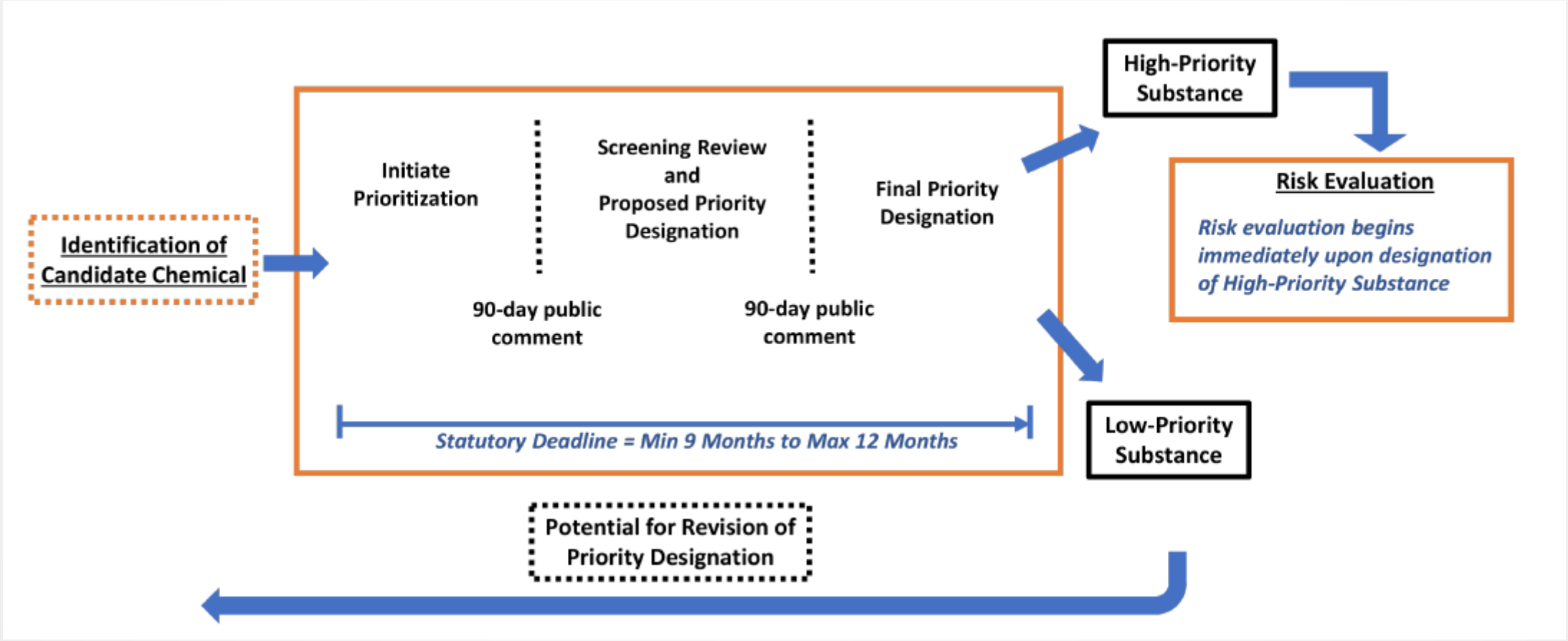
Low Priority Chemicals

- Remain in use without further action
- Can be reprioritized based on new information at any time

High Priority Chemicals

- Require a risk evaluation
- For each risk evaluation completed, EPA must designate a new high priority chemical

CHEMICAL PRIORITIZATION PROCESS

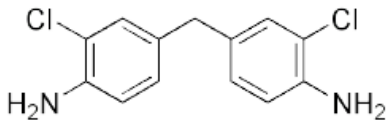


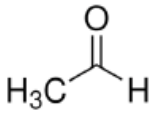
CHEMICAL PRIORITIZATION 2023-2024

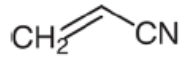
Chemical Name	Existing Assessments	CDR	TRI	HAP	MCL	Hazardous Substance	Hazardous Waste	Carcinogen	Persistent and Bioaccumulative	Environmental Hazard Data	Environmental Exposure Data
4,4'-Methylene bis(2-chloroaniline)	PPRTV	✓	✓	✓				✓	✓		✓
Acetaldehyde	IRIS	✓	✓	✓		✓	✓	✓		✓	✓
Acrylonitrile	IRIS, ATSDR	✓	✓	✓		✓	✓	✓		✓	✓
Benzenamine	IRIS, PPRTV	✓	✓	✓		✓	✓	✓		✓	✓
Vinyl chloride	IRIS, ATSDR	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

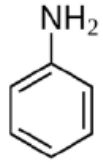
Potential Uses

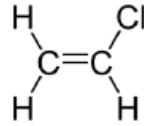
- **4,4'-Methylene bis(2-chloroaniline):** CASRN 101-14-4
  - Manufacturing and processing of chemicals (e.g., rubber, plastics, resins)
- **Acetaldehyde:** CASRN 75-07-0
  - Manufacturing and processing of chemicals (e.g., adhesives, petrochemicals)
  - Intermediates for products (e.g., packaging and construction materials)
- **Acrylonitrile:** CASRN 107-13-1
  - Manufacturing and processing of chemicals (e.g., plastics, paint, petrochemicals)
- **Benzenamine:** CASRN 62-53-3
  - Manufacturing and processing of chemicals (e.g., dyes, pigments, plastics, petrochemicals)
- **Vinyl Chloride:** CASRN 75-01-4
  - Manufacturing and processing of chemicals (e.g., plastics)











Risk Evaluation

High Priority chemicals will undergo a full evaluation of hazards, uses, exposure, to determine risk

EPA will determine if a chemical meets LCSA's safety standard, meaning it does not pose an unreasonable risk

Risk Evaluations must:

- Be Peer Reviewed
- Consider groups like pregnant women, children, the elderly & workers
- Be based solely on health & environmental considerations
- Employ clear scientific standards for scientific quality & reliability & the most relevant studies to ensure the most credible studies carry the most weight

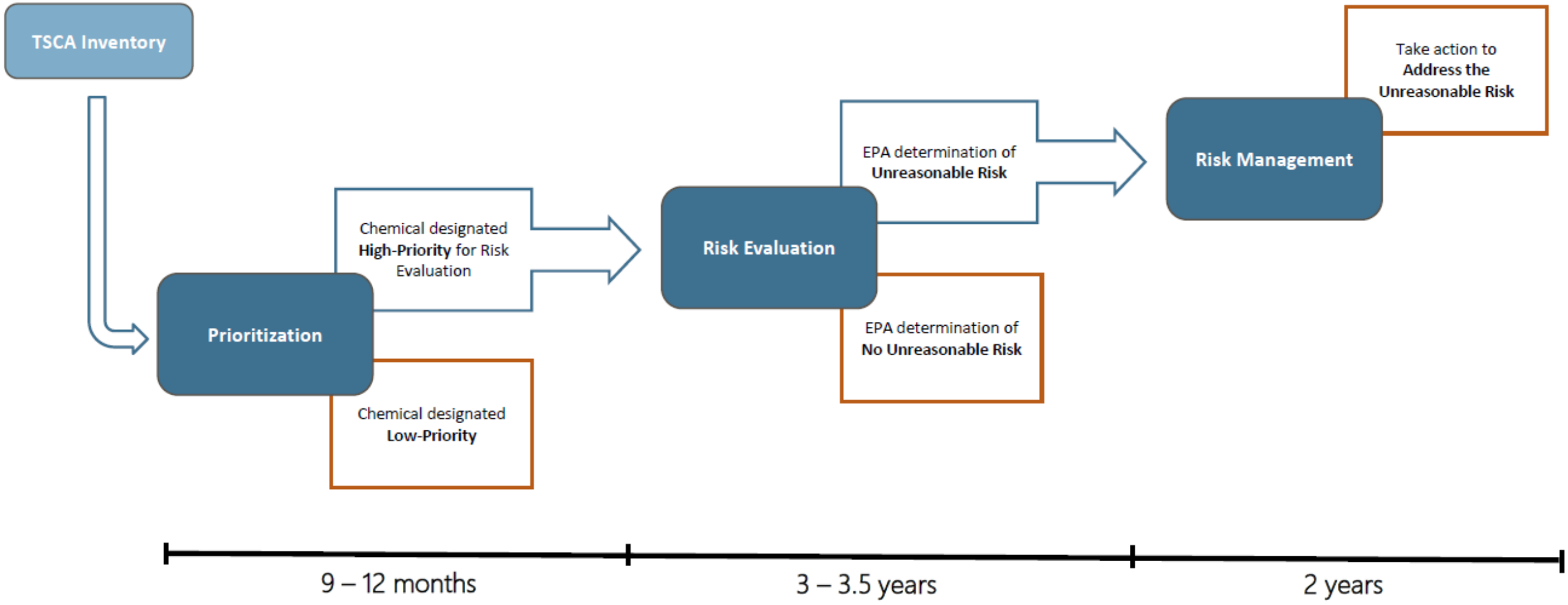
Chemicals that meet the safety standard are cleared for use

Chemicals that DO NOT meet the safety standard require risk management

Risk Management

- Chemicals that **do not** meet TSCA's safety standard are subject to risk management
- Risk management must also include a cost/benefit analysis and the feasibility of alternatives
- EPA Options include:
  - Labeling requirements
  - Handling instructions
  - Training/Licensing/Certification
  - Use restrictions
  - Phase Outs
  - Bans

EVALUATING RISKS OF EXISTING CHEMICALS



Benefits to an Risk-Based Approach to Chemicals Management

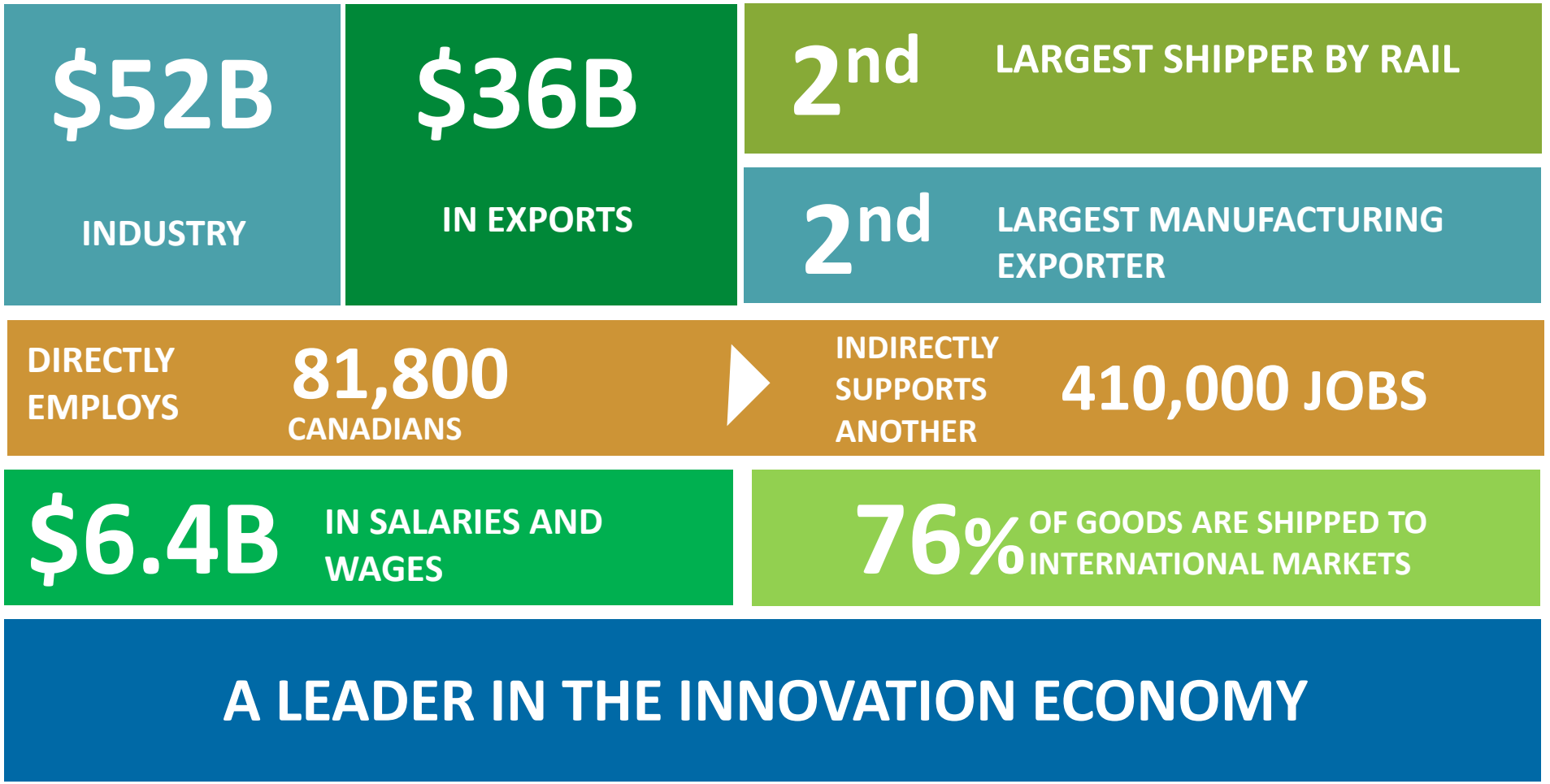
- More efficient use of resources as focus is on doing work where it is needed
- Focus on available information helps speed decisions; enhanced techniques to avoid duplicative testing
- Fosters increased public confidence as government is conducting assessments based on industry information
- Trade-distorting non-tariff barriers avoided
- Enhanced opportunities for bilateral and multilateral cooperation

Questions?

Chemicals regulation in Canada

Canada's Chemistry Sector at a Glance

95% of manufacturing products come from the plastics and chemistry sector



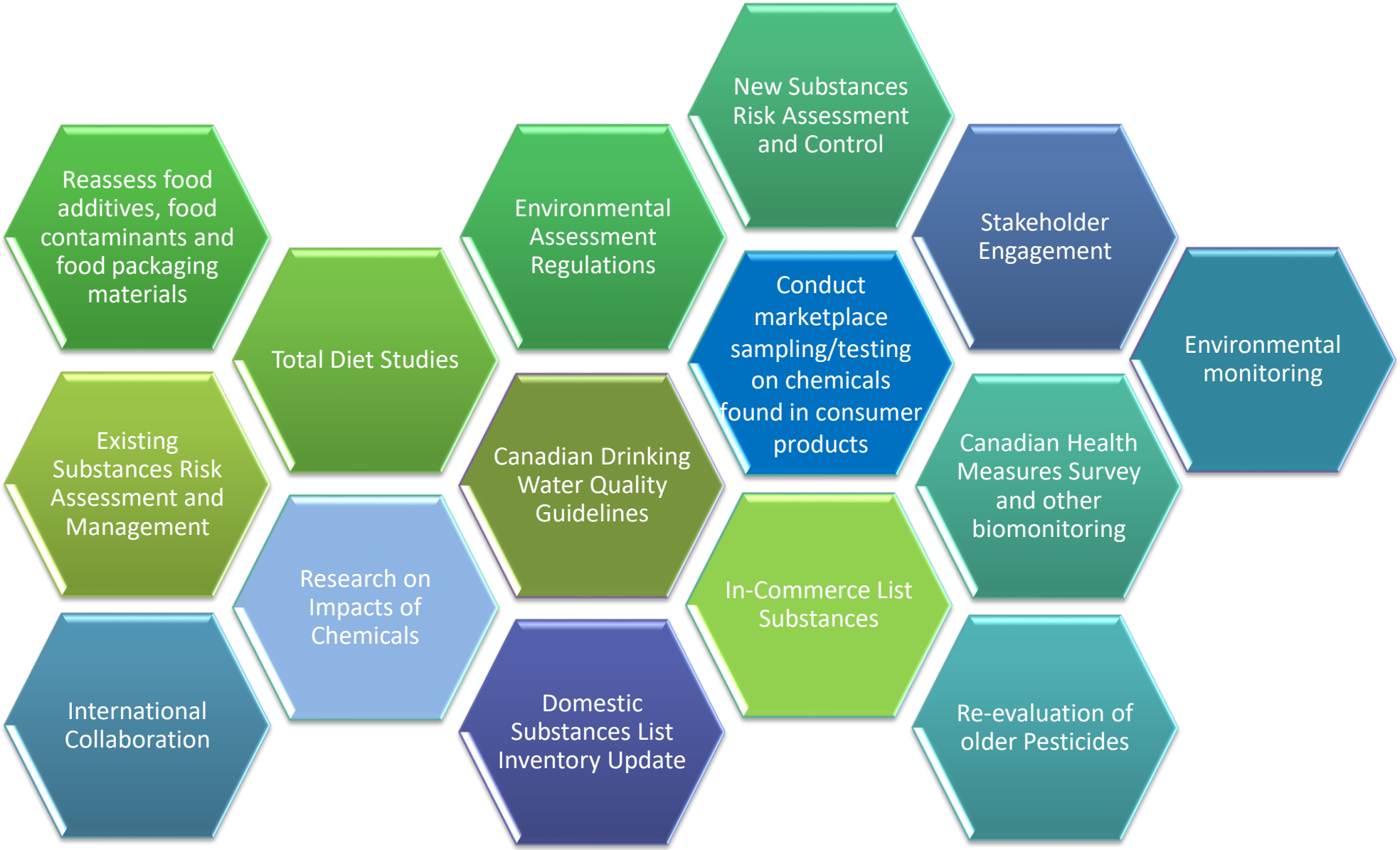
Chemicals management plan

Canada’s approach to chemicals management is a world leader and has served as the model for many other chemicals’ management regimes around the world.

The risk-based approach is fundamental to the Canadian Environmental Protection Act (CEPA 1999) and the Chemicals Management Plan, jointly administered by Environment and Climate Change Canada and Health Canada.

Industry works with the government and non-government organisations to ensure CEPA 1999 continues to be trusted by Canadians.

CEPA


New Substances Risk Assessment and Control
Reassess food additives, food contaminants and food packaging materials
Environmental Assessment Regulations
Stakeholder Engagement
Total Diet Studies
Conduct marketplace sampling/testing on chemicals found in consumer products
Environmental monitoring
Existing Substances Risk Assessment and Management
Canadian Drinking Water Quality Guidelines
Canadian Health Measures Survey and other biomonitoring
Research on Impacts of Chemicals
In-Commerce List Substances
International Collaboration
Domestic Substances List Inventory Update
Re-evaluation of older Pesticides

Other programs that address chemical substances

In addition to CEPA 1999, there are many other federal programs and agencies involved in addressing chemical substances, including:

Consumer product safety

Drugs and health products

Food and nutrition

Pesticides and pest management

Workplace Hazardous Products

CEPA

Legislation

- Canadian Environmental Protection Act 1999

CEPA

Legislation

- Canadian Environmental Protection Act 1999

Categorization

- Domestic Substances list – 23,000 (1999-2006)

CEPA

Legislation

- Canadian Environmental Protection Act 1999

Categorization

- Domestic Substances list – 23,000 (1999-2006)

Priority Substances

- 4000 priority substances (2000-2005)

CEPA

Legislation

- Canadian Environmental Protection Act 1999

Categorization

- Domestic Substances list – 23,000 (1999-2006)

Priority Substances

- 4000 priority substances (2000-2005)

CMP1

- 200 Substances considered potentially harmful
- Significant New Activity requirements
- Rapid Screening of lower risk substances

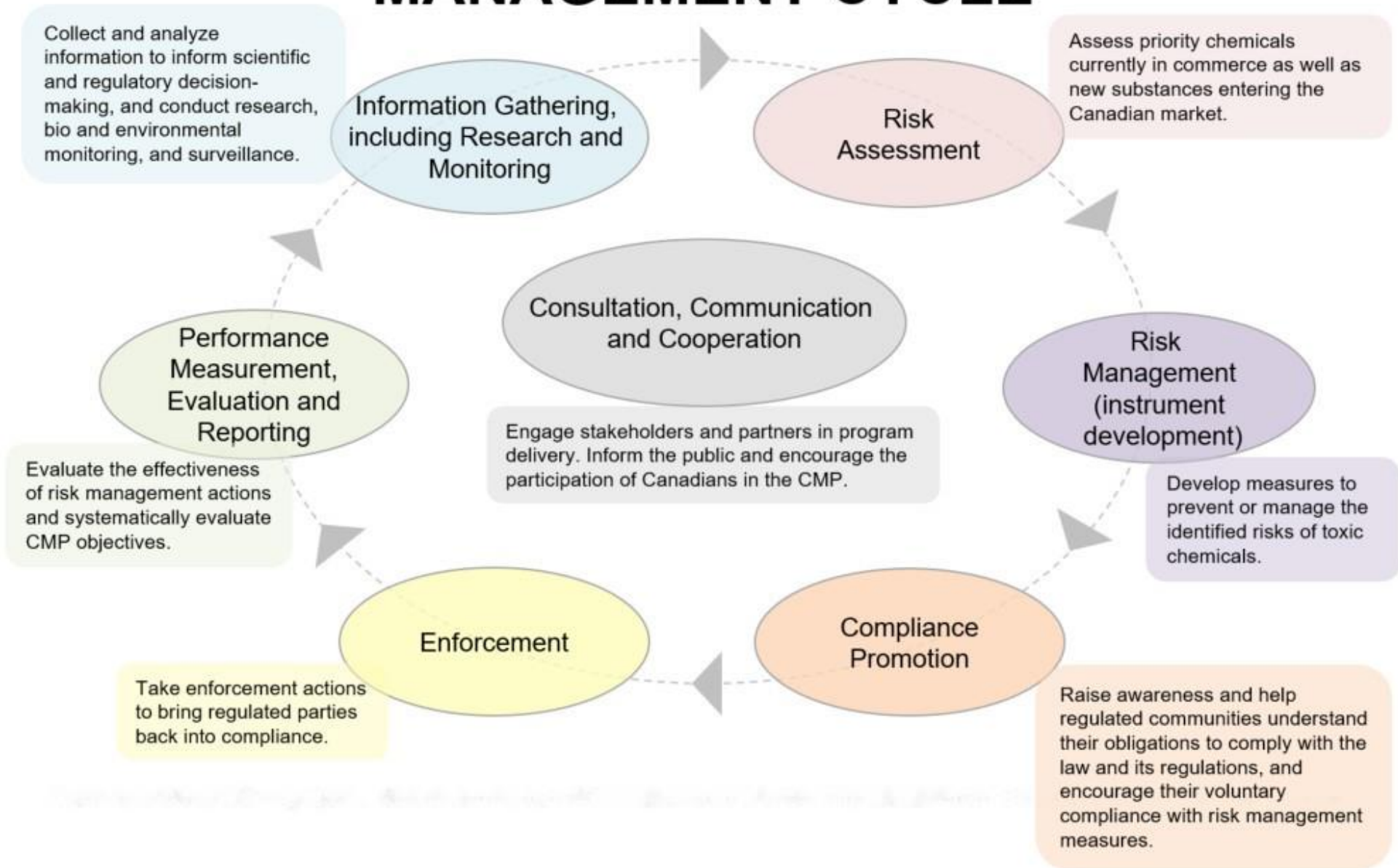
CMP2

- Groups of Substances

CMP3

- More complicated Assessments

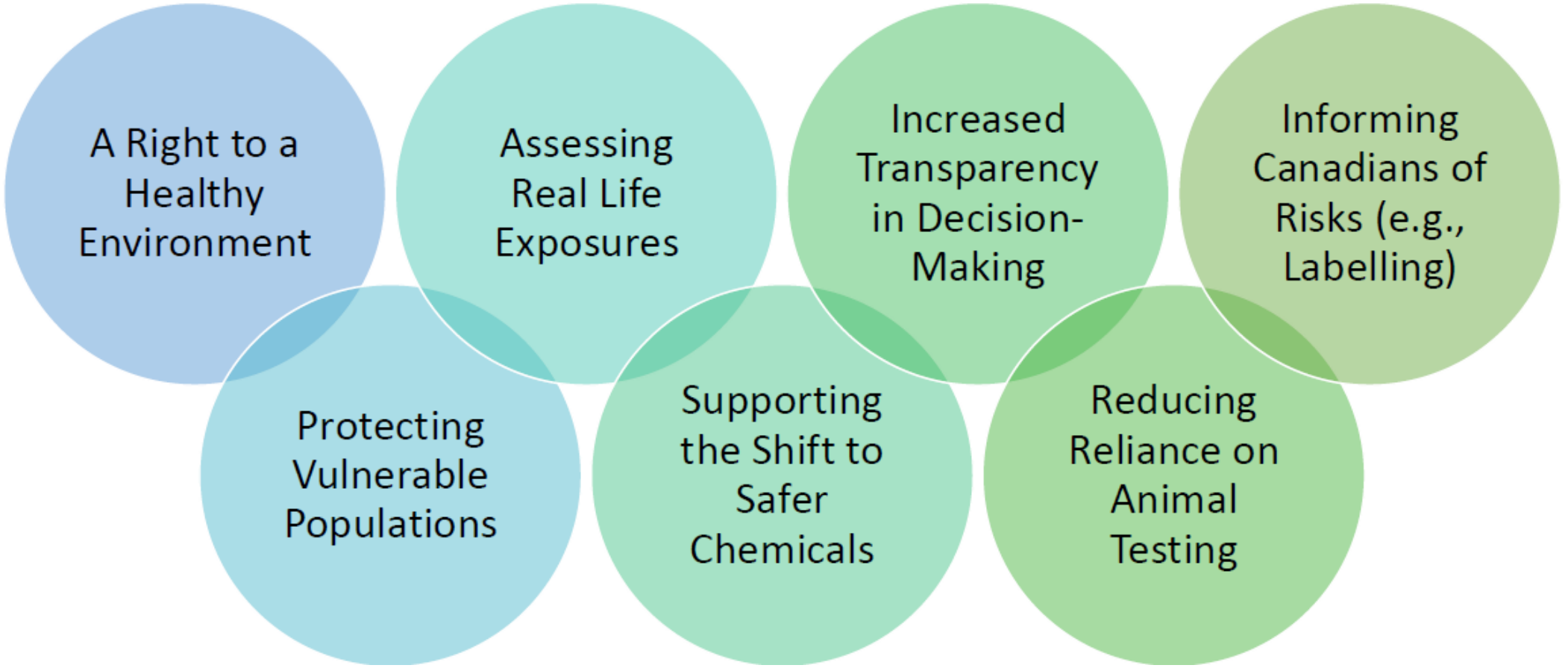
CANADA'S CHEMICALS MANAGEMENT CYCLE



Risk Management Potential

- Only if assessment concluded “CEPA toxic” – i.e., unacceptable risk to health or environment
- Actions required but regulations only where needed
  - “Best Placed Act” concept, so not necessarily CEPA regulations or measures
- Also used are other “non regulatory” measures:
    - Pollution Prevention Plans
    - Codes of Practice
    - Environmental Performance Agreements or MOUs (Memorandum of Understanding)
- Little risk management has been needed
    - + 500 risk management actions developed and implemented
    - Relatively few toxic findings; most required limited, reasonable measures
    - Highest number of “Toxics” identified in Challenge substances

Key themes in Bill S-5



International Engagement

- Chemicals management in Canada requires continued cooperation with international partners and organisations for:
  - Technical cooperation - emerging science, approaches, methodologies
  - To support and meet international commitments, Multilateral environmental agreements
  - Builds relationships with bilateral and regional partners and influences international agendas
- Current bilateral or multilateral works:
  - Bilateral Cooperation, RCC, ECHA-Canada MoU, China, Australia
  - Multilateral with OECD, SAICM, and with Environmental Agreements,
  - capacity building work

Questions?

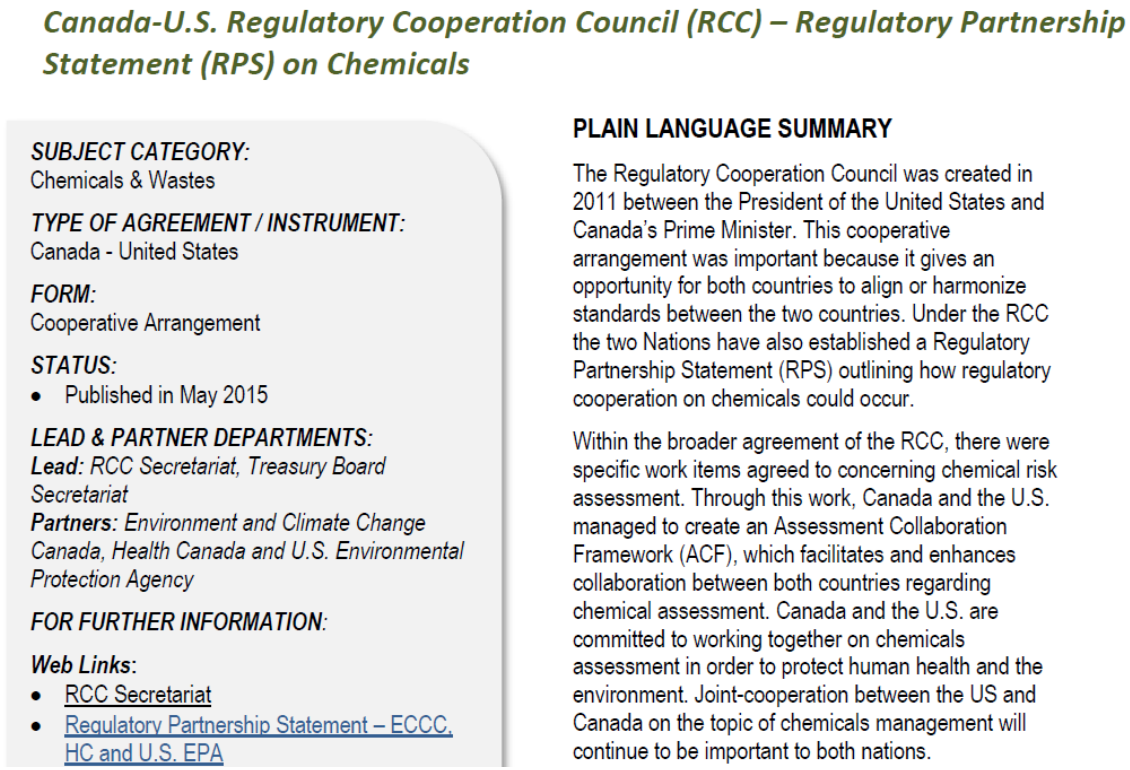
Canada/US-coop.

Canada-United States Regulatory Cooperation Council (RCC)

- Created in 2011
- 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.
- The RCC helps to coordinate various inputs from regulatory departments and agencies, maintains detailed work plans, and ensures everything is publicly available.

Canada-United States Regulatory Cooperation Council (RCC) Initiative on Chemicals Management

- Gives an opportunity to align or harmonize standards and reduce barriers to alignment between the two countries in their approaches to chemicals risk assessment, including minimizing the duplication of effort in the development of assessment and scientific techniques
- Regulatory Partnership Statement (RPS) outline how regulatory cooperation on chemicals could occur.
- Assessment Collaboration Framework (ACF), which facilitates and enhances collaboration between both countries regarding chemical assessment.



Canada-U.S. Regulatory Cooperation Council (RCC) – Regulatory Partnership Statement (RPS) on Chemicals

SUBJECT CATEGORY:
Chemicals & Wastes

TYPE OF AGREEMENT / INSTRUMENT:
Canada - United States

FORM:
Cooperative Arrangement

STATUS:
- Published in May 2015

LEAD & PARTNER DEPARTMENTS:
Lead: *RCC Secretariat, Treasury Board Secretariat*
Partners: *Environment and Climate Change Canada, Health Canada and U.S. Environmental Protection Agency*

FOR FURTHER INFORMATION:

Web Links:
- RCC Secretariat
- Regulatory Partnership Statement – ECCC, HC and U.S. EPA

PLAIN LANGUAGE SUMMARY

The Regulatory Cooperation Council was created in 2011 between the President of the United States and Canada's Prime Minister. This cooperative arrangement was important because it gives an opportunity for both countries to align or harmonize standards between the two countries. Under the RCC the two Nations have also established a Regulatory Partnership Statement (RPS) outlining how regulatory cooperation on chemicals could occur.

Within the broader agreement of the RCC, there were specific work items agreed to concerning chemical risk assessment. Through this work, Canada and the U.S. managed to create an Assessment Collaboration Framework (ACF), which facilitates and enhances collaboration between both countries regarding chemical assessment. Canada and the U.S. are committed to working together on chemicals assessment in order to protect human health and the environment. Joint-cooperation between the US and Canada on the topic of chemicals management will continue to be important to both nations.

Regulatory Partnership Statement (RPS)

- High-level governance between them and a commitment to work together moving forward; opportunities for stakeholders to provide input, inform strategies, identify priorities and discuss progress on initiatives; and a mechanism for annual reviews of work plans to consider adjustments and provide status updates on the progress
- Support chemical risk assessment including, but not limited to, areas such as:
  - information gathering;
  - information sharing;
  - technical work-sharing;
  - scientific collaboration;
  - international collaboration; and,
  - risk assessment methodology.
- Align these efforts with on-going work under the OECD and will leverage this forum to further dialogue with stakeholders
- Develop work plans

2019-2020 RCC Work Plan: Pesticides

Canadian Department: Health Canada, Pest Management Regulatory Agency

United States Department/Agency: Environmental Protection Agency, Office of Pesticides Program

Regulatory Cooperation Statement:

Health Canada's Pest Management Regulatory Agency (PMRA) and the United States (U.S.) Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) are working together to foster an atmosphere of ongoing cooperation, collaboration, and regular communication to better align regulatory approaches in the following areas:

A. Alignment of Pesticide Residue Chemistry
B. Joint Review (JR) Process Improvements (New Chemicals/Uses)
C. Pesticide Re-evaluation and Post-Market Joint Reviews
D. Pollinator Protection and Neonicotinoid Pesticides
E. Pest Control Emerging Technologies
F. New Approach Methodologies (NAMs)
G. Emerging Pesticide Issues

Work Plan:

Initiative	Desired outcome(s)	Activities	Reporting
Workstream A: **Alignment of Pesticide Residue Chemistry** [by harmonizing use of the Organization for Economic Cooperation and Development (OECD) Maximum Residue Limit (MRL) Calculator]	Further development of joint standardized requirements that assist in establishing and aligning maximum residue limits.	• A set of case studies will be documented by Canada and the U.S. to determine reasons for non-harmonized Crop Group MRLs within North America to eventually enable development of a standardized and consistent method for determining Crop Group MRLs.	

2019-2020 RCC Work Plan: Pesticides

Regulatory Partnership Statement (RPS)

Department/Agency	United States	Canada
	U.S Environmental Protection Agency	Health Canada, Environment and Climate Change Canada

Regulatory area to be addressed	**Chemicals Management**
	The United States Environmental Protection Agency (EPA), Health Canada (HC) and Environment and Climate Change Canada (EC) have common policy objectives under the Canadian Environmental Protection Act (CEPA) and Toxic Substances Control Act (TSCA) to reduce risks to human health and the environment posed by chemicals. Both Canada and the U.S. have in place programs to meet these objectives including aspects such as: information gathering, priority-setting, scientific research, risk assessment and risk management. Canada-U.S. collaboration in these areas will make work more effective and efficient for both governments, as they work towards joint program initiatives, and for stakeholders who will benefit from an aligned approach on chemicals management. The U.S. Environmental Protection Agency, Environment and Climate Change Canada and Health Canada published an RCC Chemicals Management Work Plan in May 2015 that focused on two areas: • Significant New Activity (SNAc) Provisions and Significant New Use Rules (SNURs) • Risk Assessment This 2016 RCC Chemicals Management Work Plan shares information on progress and results to date in these two work plan areas and provides timelines for remaining planned work and deliverables. Also identified in the 2016 RCC Chemicals Management Work Plan are several areas where Canadian and U.S. stakeholders have noted potential benefits of a future collaboration between these partners. Discussions to scope a future RCC Work Plan in one or more of these areas will be undertaken throughout 2016/17, with the intent to publish a new Chemicals Management Work Plan in June 2017. Web conferences will be offered in December 2016, June 2017 and December 2017 to provide updates on progress in implementation of the activities described in this Work Plan Update.

Chemicals Management

Department/Agency	United States	Canada
	Department of Labor – Occupational Safety & Health Administration (OSHA)	Health Canada – Workplace Hazardous Materials Bureau (WHMB)

Regulatory area to be addressed	**Globally Harmonized System for Classification and Labelling of Chemicals (Workplace Hazards)** Health Canada and the United States (U.S.) Department of Labor will continue to promote ongoing collaboration on implementing the Globally Harmonized System of Classification and Labelling (GHS) in their respective jurisdictions. The objective is to ensure that the requirements in Canada and the U.S. for hazard classification and communication can and will be met now and in the future, to the greatest extent possible, with one label and one safety data sheet that would be acceptable in both countries, without reducing the level of safety or protection to workers. This work is in line with the 2013 Memorandum of Understanding (MOU) between Health Canada and the U.S. Department of Labor.

Workplace Chemicals

United States-Mexico-Canada Agreement (USMCA): Provisions on regulatory cooperation for chemical substances

- Entered into force on July 1, 2020.
- 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.”

Questions?

Thanks for your attention

Alejandra Acosta

GCCM
LATAM regulatory updates

Alejandra Acosta

Content

- Brief intro to the LAC region and chemical regulations
- Examples of regulatory schemes for chemicals throughout South/Latin America
  - GHS in the workplace and consumer products
  - Inventories and Risk Management
  - Main communalities and differences
  - Cooperation platforms
- Political developments and foresight for the American continents
- Green Chemistry Policy in N- & S-American countries

Brief intro to the LAC chemical industry

Chemicals in LATAM

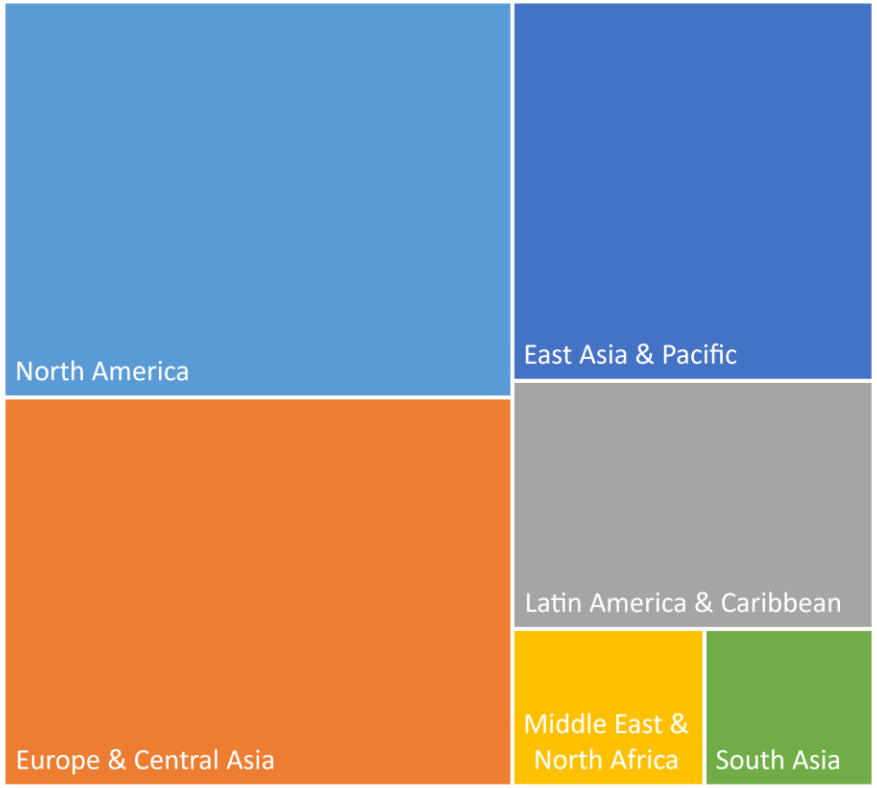
Country	Chemical Industry participation in GDP (BUS$)- 2021	GDP per capita (PPP) (USD/inhabitants)	GDP Growth
Argentina	50.7*	22,117	4 %
Brazil	47.7	14,739	0.8 %
Chile	12.7 **	24,433	1.5%
Colombia	N/A	15,610	5.8 %
Peru	N/A	12,878	3 %
Mexico	26.4	20,867	2 %

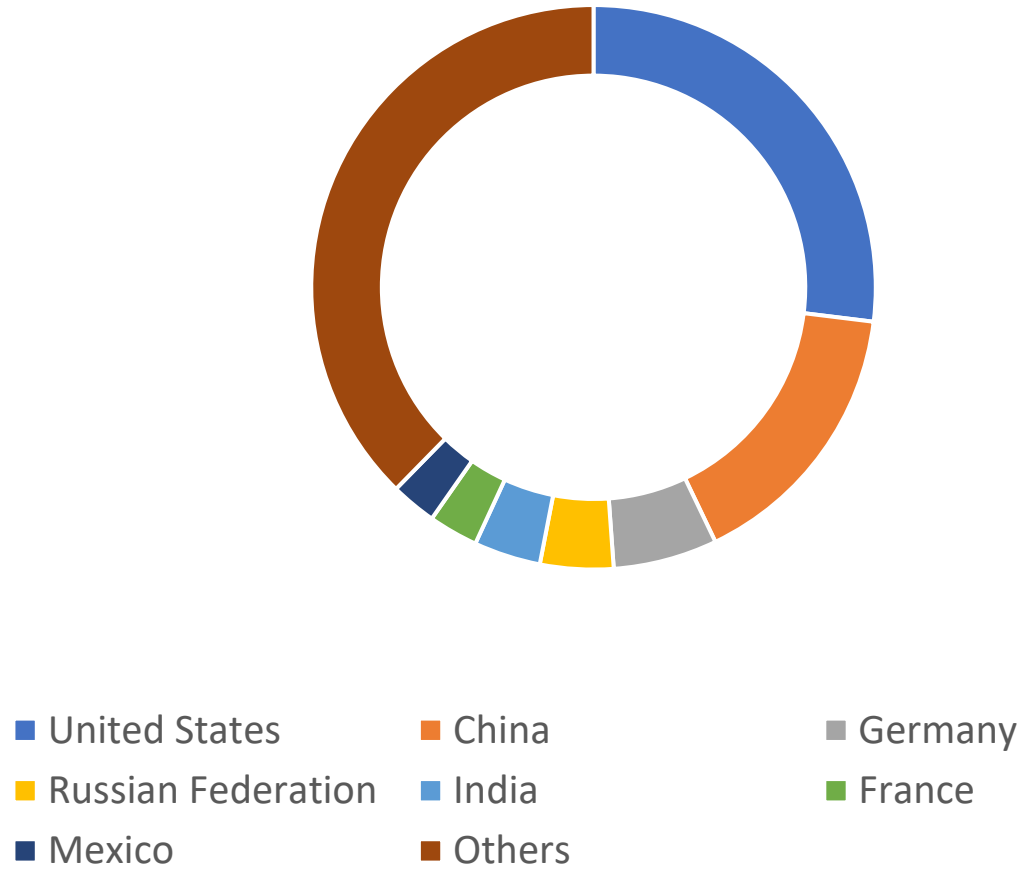
Source: APLA GBR Reports 2022

* Based on the extrapolation of OECD Argentina Survey 2019 data

** ASIQUIM

Chemicals imports in LATAM





Latin America & Caribbean 2021 Chemical Imports Region and Country Share, World Integrated Trade Solution, World Bank. Link.

Chemicals in LAC

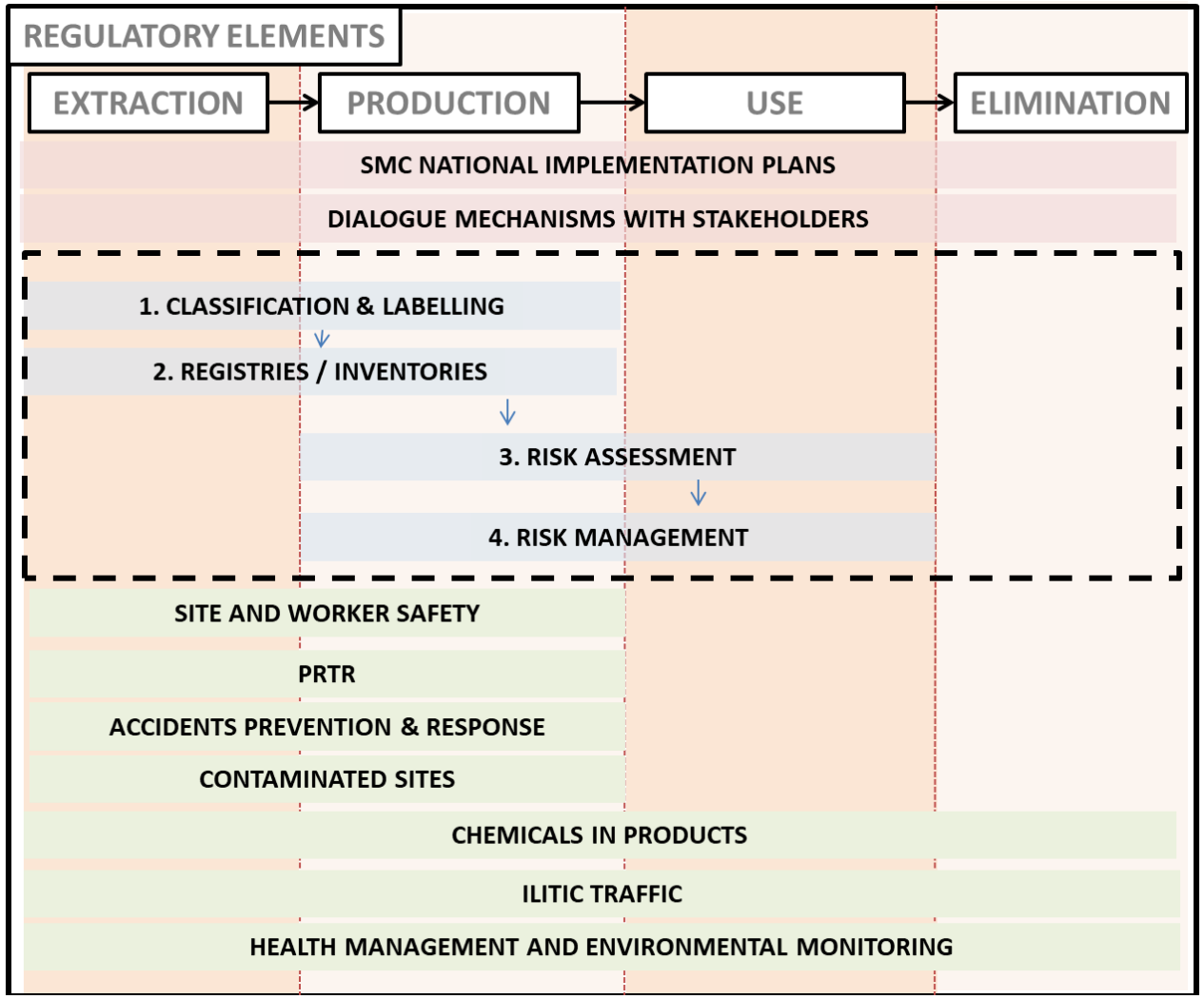
World reserves in LAC

61% of lithium
39% of copper
32% of silver and nickel
31% of fresh water
22% of iron
20% of oil
20% of forests
12% of arable land

8% of world gross domestic product

Examples of regulatory schemes for chemicals throughout South/Latin America

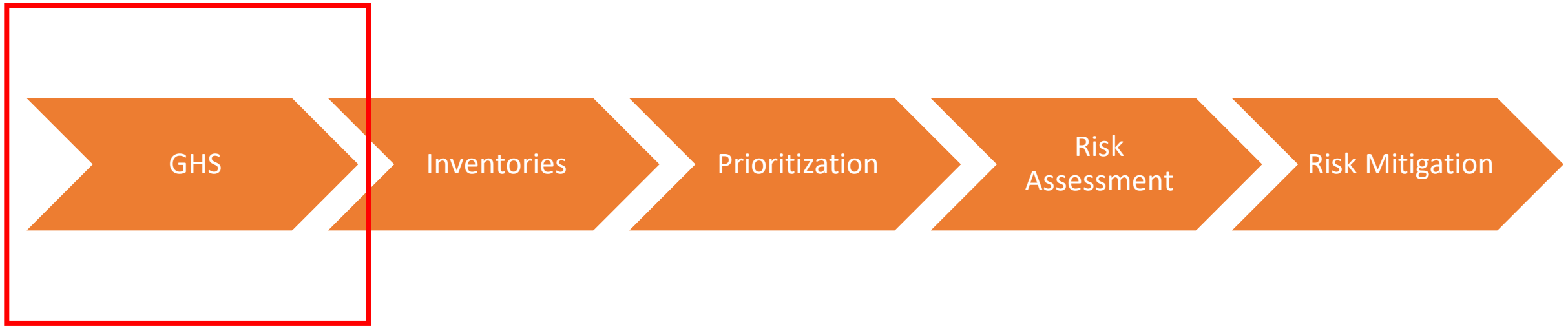
Building blocks of chemical regulations



Source: Roadmap for the SMC, VWG-SMC-LA, LARCF

Scope of today's presentation
Industrial Chemicals

Scope of today's presentation
Industrial Chemicals



GHS in the workplace and consumer products

Global Harmonized System (GHS)

9

Countries that have made progress in the implementation of the GHS for workplace or consumer products

- Very few countries have fully implemented the system and others are at a legal drafting stage.
- The general trend in LAC is to implement GHS in the industrial sector (“workplace”, “professional use”).
- Some countries have adopted or are in the process of adopting the GHS for agrochemicals.
- Most have regulations for the transport sector based on the United Nations Recommendations on the Transport of Dangerous Goods.
- Fewer countries require GHS labeling on consumer products.

GHS for workplace in the region

7	Brazil (starting July 2025), Chile (also consumer goods), Uruguay
6	Colombia, Peru (TBD)
5	Argentina, Mexico
1	Ecuador (Storage and handling of dangerous goods)
	In Transition / Implementation

Global Harmonized System (GHS)

Country	Regulatory Reference	Date of publication	Scope (workplace, consumer products, others)	Edtion	Are all GHS building blocks adopted?	Observations related to date of entry into force and transitional periods if any
Argentina	Resolution SRT 801/15	2015	Workplace (industrial sector)	5	Yes	Executive office is currently working in a new draft bill that includes GHS implementation (except pharma, food additives, and cosmetics).
Brazil	Ordinance No.26 (on hazard communication) of the Ministry of Labour implemented the GHS in the workplace. Technical provisions for the implementation of the GHS are given in the standards developed by the Brazil Association of Technical Standards (ABNT). First version of standard: ABNT NBR 14725	2009	Workplace (industrial sector)	4	No	Standard 14725 adopted to bring it into line with the 7th revised edition of the GHS as from July 2025
Chile	DS 57/2019	2021	In force for workplace and consumer.	7	No	Includes official classification list based in CLP (EU). Deadlines: •Industrial substances: 2022 •Industrial substances in mixtures: 2025 •Non-industrial substances: 2023 •Substances in non-industrial mixtures: 2027 Mandatory classification specific substances: based on CLP Annex VI. • Deviation possible: subject to authorization. • Additional/more severe hazard classes: not subject to authorization
Colombia	Decree 1496:2018 Adopts GHS for: workplace, pesticides, transport, consumer products. Res 773:2021 implements GHS in workplace	2018	Workplace: 6th edition. Full implementation begins 2023	6	Yes	The Resolution 773:2021 allows for a transitional period of 2 years for substances and 3 years for mixtures

Global Harmonized System (GHS)

Country	Regulatory Reference	Date of publication	Scope (workplace, consumer products, others)	Edtion	Are all GHS building blocks adopted?	Observations related to date of entry into force and transitional periods if any
Costa Rica	Decree No. 40.457-S and its Technical Regulation RTCR 481: 2015 Decree No.40457-S , and Technical Regulation RTCR 481: 2015	2017	Industrial chemicals (workplace and some consumer products) Agrochemicals	6	Yes	Technical regulation RTCR 478:2015 entered into force on 2 May 2018 Registration of hazardous products is required
Ecuador	Resolution No. 13 067 adopted the technical regulation IRTE INEN 078	2018	Storage and handling of dangerous goods	1	Yes	The technical regulation was amended in 2014 to postpone the entry into force of the standard until 1 February 2018, and is in force since then.
Mexico	Official Mexican Standard NOM-018-STPS-2015	2015	Workplace	5	No	Became mandatory on 8 October 2018.
Peru	Decree 1570/23	2023	Industrial chemicals	TBD	TBD	**Classifications, SDS and Labels are to be approved by health and environmental authorities.** Further details are to be defined through secondary regulation.
Uruguay	Decree 307/009 and its amendment by Decree 346/011	2011	Workplace	Most recent (automatic updates)	Yes	

Global Harmonized System (GHS)

Opportunities	
Using a higher level of legislation to implement GHS would provide a greater support for its implementation: - responsibilities could be assigned to different authorities - all types of hazards could be included (physical, health and environmental) - GHS in could be implemented in different sectors simultaneously, promoting coherence among them.	For economies that do not have sufficient resources to carry out proper market enforcement and that most of the chemicals used are imported, it would be interesting to evaluate if setting the necessary mechanisms to carry out border control by customs would mean an economy of scale and a way to achieve better implementation rates
Adopting GHS within a trade bloc	Inclusion of GHS related requirements in the chemicals registration systems that are being set up in the region, and use software for checking GHS compliance upon chemical registration
Including GHS provisions within free trade agreements	Market pressures, being part of a multinational corporation, corporate social responsibility, or adherence to global initiatives for environmental protection and/or chemical safety often cause companies to voluntarily implement GHS.
Countries that find difficulties in approving a mandatory instrument coud evaluate starting with voluntary technical standards or other types of instruments that permit the GHS implementation in a multi-sectorial and coordinated manner.	Concentrate the few enforcement resources of countries in the downstream sectors, aimign trigger a chain effect, where companies would encourage their suppliers -intermediates in the supply chain- to comply with GHS, and they would do the same, until reaching the upstream.
Consider a phased implementation, giving the private sector the necessary time to adapt procedures and gather information, and allowing authorities to gain experience and make any necessary adaptations along the way	Inclusion of GHS in standards such as ISO
Include a transition period where products can be classified or labelled under the GHS or under the old system giving the private sector time to adapt procedures and gather information, and also to run out of stock of materials already packed	Implementing GHS using QR codes
Design, maintain and make available a continuous training and support system	Establishment of multi-stakeholder arrangements for consultation during design and implementation phases
Engage with the following actors as they are key for providing GHS trainings and support to companies: unions, industrial chambers, work risk insurers, and consulting companies	Assess the commonalities and differences with the main trading partners in terms of adoption of GHS in the early stages, when designing the legislation.
Facilitate access to information on chemicals, preferably in local language. The development of practical tools to access chemicals data at the global or regional level, such as databases with information on harmonized classifications for labels and SDS, would be very beneficial for companies.	Consult main trading partners and the WTO before passing a legislation, to ensure it does not create unnecessary obstacles to trade
Once the regulatory framework on GHS is adopted, develop technical guides for its implementation, particularly SMEs	Include provisions allowing imported chemicals classified and labelled in accordance with more recent revised editions of the GHS
Use of specific software to classify and prepare the SDS	Engage with the following organizations and foras to promote GHS and its effective implementation: WTO, Basel, Rotterdam and Stockholm conventions and SAICM, OECD, ILO, Regional and bilateral free trade agreements, Trade standards and certification schemes, and the Intergovernmental network on chemicals and waste for Latin America and the Caribbean.

Source: Obstacles and opportunities of GHS implementation in the LAC region and its links to trade, UNITAR, 2022

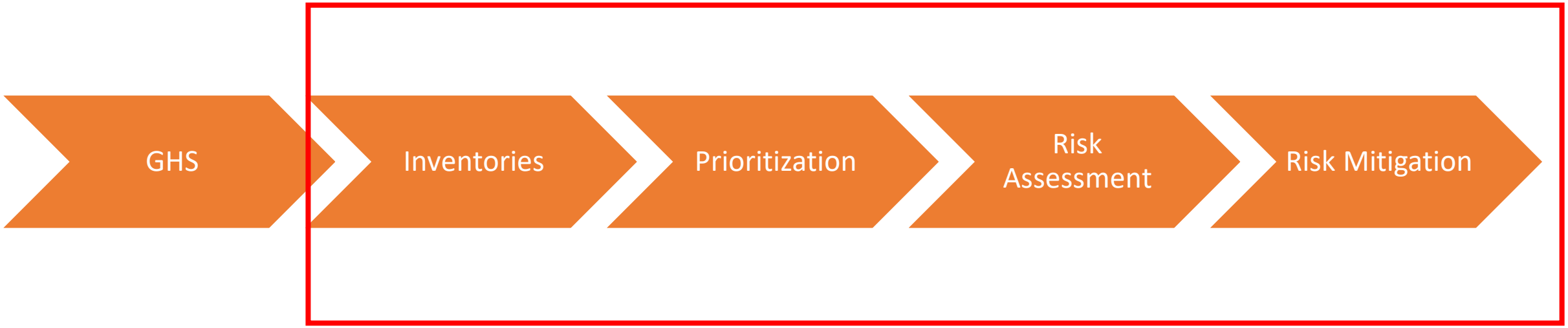
Global Harmonized System (GHS)

Barriers	
Technical knowledge and resources gap is found in SMEs compared to large companies	lack of enforcement agents and capacities
Low supply capacity of national chemical laboratories in the development of tests that are required for the characterization of chemical substances at the toxicological and eco-toxicological level	Lack of stricter controls in the countries derives in that the common approach used by companies is that the classification and labelling are carried out by translating labels and SDS of the country of origin that can -or cannot- match the requirements in the country of destination
Lack of technical, financial and qualified personnel resources to address and implement the requirements established by the GHS act as an obstacle to export chemicals, particularly for SMEs	When requirements differ between countries, a lack of harmonization in terms of classifications and SDS should be expected. Given that it is not often to do the necessary adaptations according to de destination countries requirements, obstacles to trade can occur, inadequate treatment could be given at the national level or in local jurisdictions due to its legal status, and confusion among workers at facilities or emergency services and consumers can be expected due to the non-harmonized information for the same chemical

Source: Obstacles and opportunities of GHS implementation in the LAC region and its links to trade, UNITAR, 2022

Inventories and Risk Management

Scope of today's presentation
Industrial Chemicals

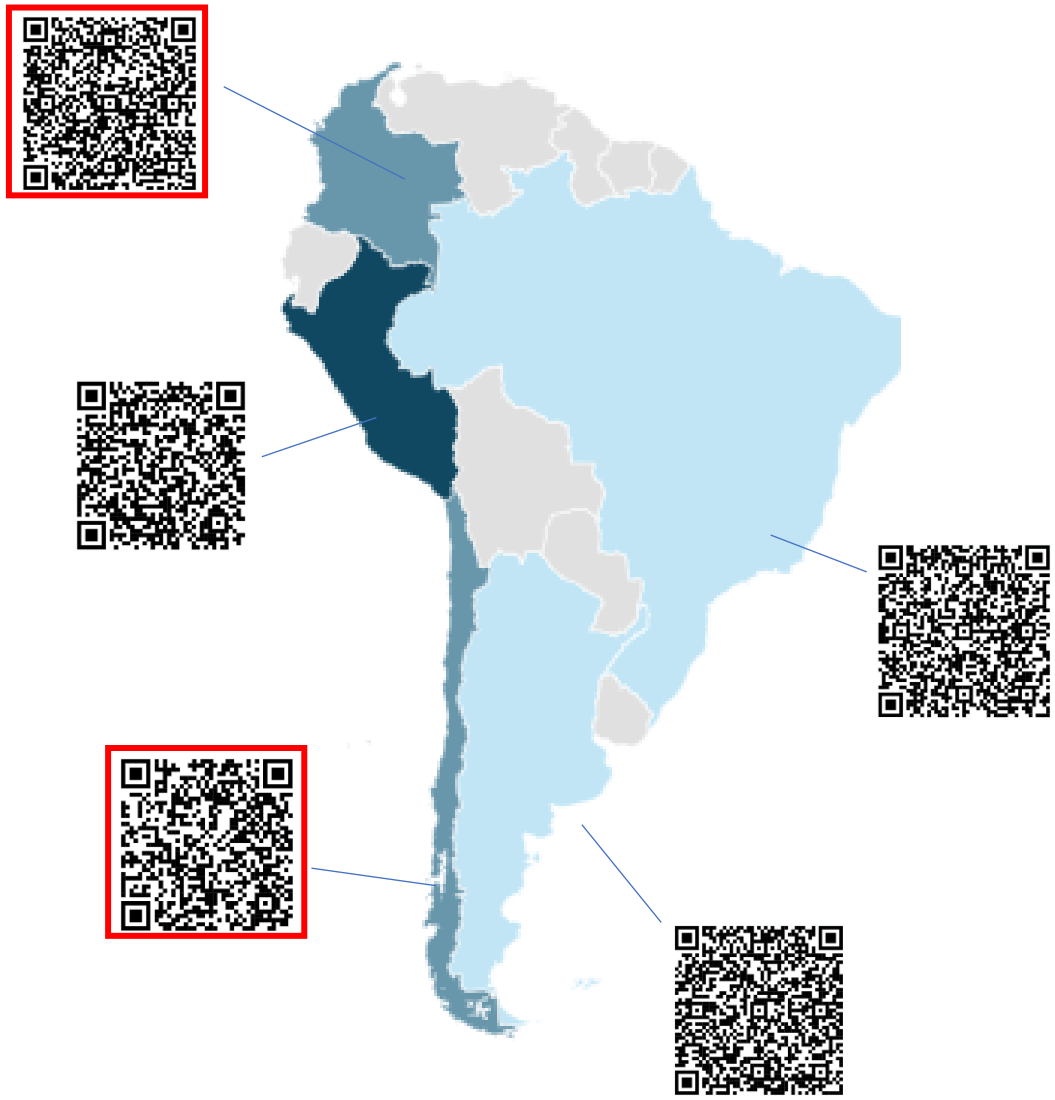


Inventories and Risk Management Legislation for Industrial Chemicals

5 **Countries that have made progress in the implementation of Chemical Inventories and Risk management legislation for industrial chemicals**

- In general, lack of specific regulations for industrial chemicals in the region
- 3 countries have legislation in force: Chile, Colombia, and Peru
- 2 have laws pending before Congress: Argentina and Brazil
- No countries have fully implemented the system
- Implementation is mostly driven by the motivation to join the OECD

Industrial Chemicals Registries



Peru: Decree approved, pending secondary regulation

Chile, Colombia: Implementation in process

Argentina, Brazil: Draft Legislations

In Transition / Implementation

Main communalities and differences

Scope

Hazardous substances + substances in mixtures

Hazardous substances + Mixtures + substances in imported mixtures (TBD)

Substances + hazardous substances present in mixtures above GHS classification threshold.

Substances + substances in mixtures

Substances + hazardous substances in mixtures

High level of heterogeneity in the region

Information requested

Enough to support prioritization

- Producer / Importer
- Identity of the substance
- Quantity Imported or Produced
- Hazards
- Recommended Uses

Information requested

	Chile	Colombia	Peru
Main regulation	• ID producer/importer • ID legal representative • For manufacturers, address of the premises • ID chemical, including CAS, IUPAC. • Annual quantity in ranges • GHS hazard classification. • Identified uses • SDS	• ID producer/importer • ID chemical, including CAS • Annual quantity • GHS hazard classification. • Identified uses	• ID producer/importer • ID chemical, including CAS, IUPAC. • recommended uses; • quantity • SDS content • risk assessment if applicable
Instructive	• RUT • Country of manufacture • If manufactured in Chile: Resolution approving the manufacture • Physical Condition • Bioaccumulation: octanol/water partition coefficient, Unit, Method, Bioconcentration factor, FBC, Method. • Persistence: Medium, Method, Degradation Half-Life • Uses of the substance (industrial, professional or home), Supplemental of sector of use, Product category • Quantities per use	• Indicate if its present in a mixture • Indicate if inorganic • Indicate if Hydrate • molecular weight • molecular formula • Main use • Particular use • CIIU and CPC	
Other	• Bi-annual updates	• Annual updates • Bulk notification allowed	

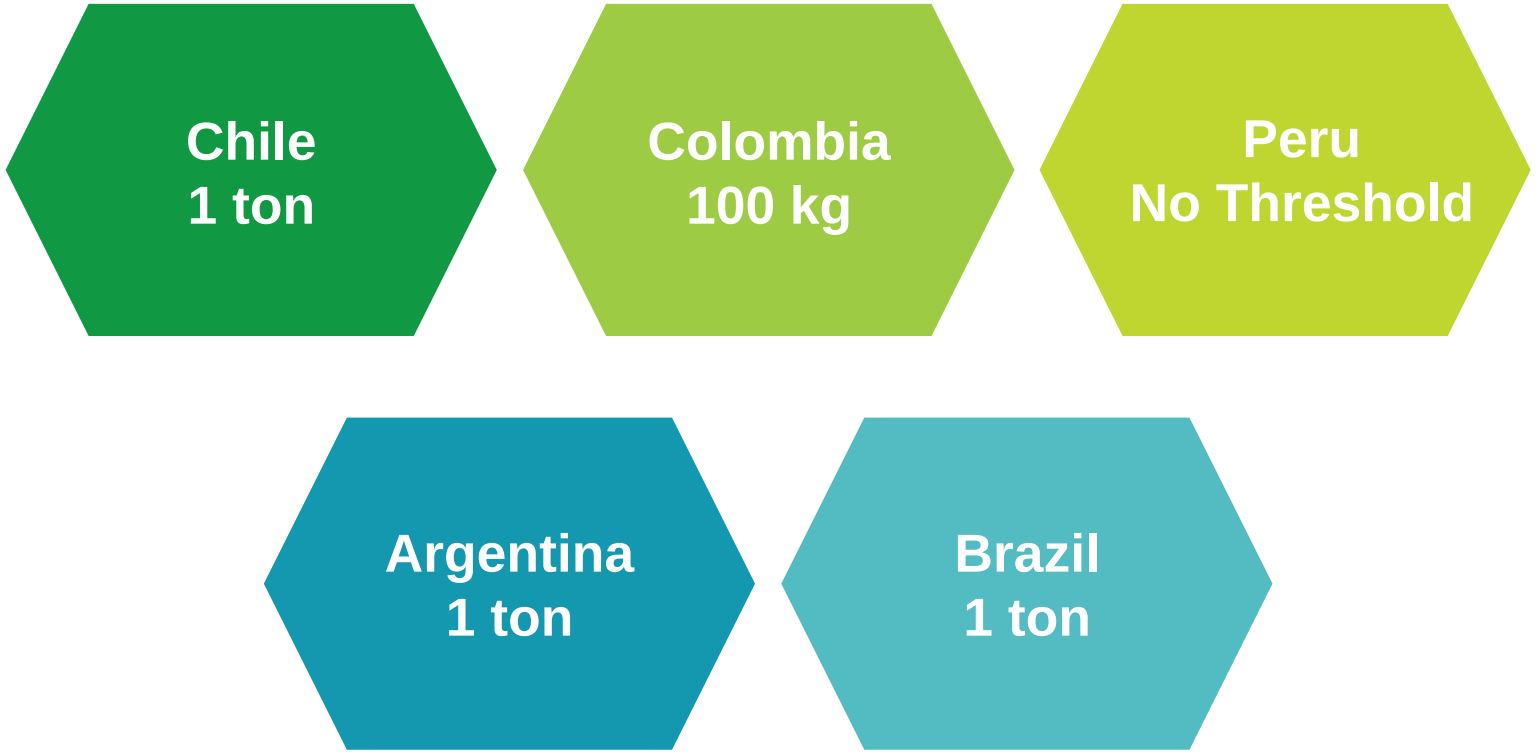
Exclusions

Chemicals	Colombia	Chile	Peru
Agrochemicals	X	X	X
Animal food and food additives	X	X	X
Articles	X	X	X
By-products that have not been imported or marketed as such	X		
Chemical weapons/Substances used in the interest of defense	X		
Chemicals used for tobacco and derivates			
Cosmetics	X	X	
Health products (includes cosmetic products, household hygiene products and personal hygiene products) authorized and recognized with Mandatory Health Notification (NSO)			X
Explosives	X		
Fertilizers	X		
Food and food additives	X	X	X
Gases			
Household and professional pesticides	X		
Hydrates of a substance or hydrated ions	X		
Impuruties	X		X
Diagnostic reagents	X		
Livestock input	X		
Medical Devices		X	X

Chemicals	Colombia	Chile	Peru
Minerals of natural origin		X	
Narcotic and psychotropic substances	X		
Non-commercial samples	X		X
Non-isolated intermediates	X	X	X
Personal hygiene products			
Pesticide residues in food		X	
Pharmaceuticals	X	X	X
Polymers	X		
Radioactive substances	X	X	X
Substances in development or solely for research		X	X
Substances in temporary storage under customs supervision	X	X	X
Substances of natural origin without chemical processing	X		X
Substances resulting from a chemical reaction that occurs incidentally	X		X
Substances with a specific regulation	X		
UVCB	X		
Veterinary use	X		X
Water treatment products		X	
Waste	X		
Hazardous Waste		X	

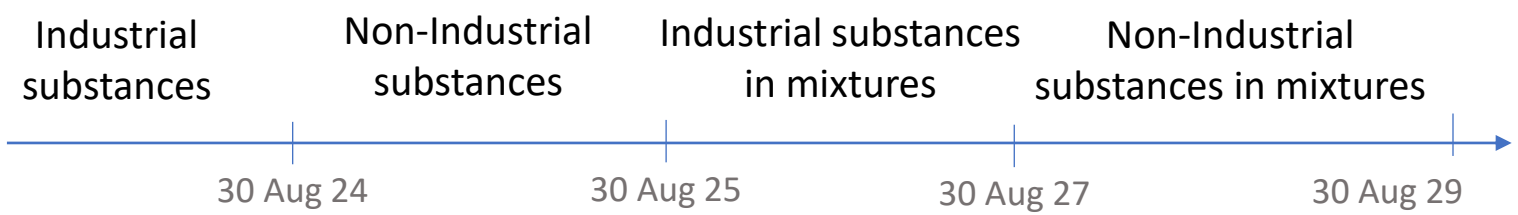
Thresholds

CUT-OFF THRESHOLD FOR NOTIFICATION
- Capture all substances present in the territory
- Give a reference of the magnitude



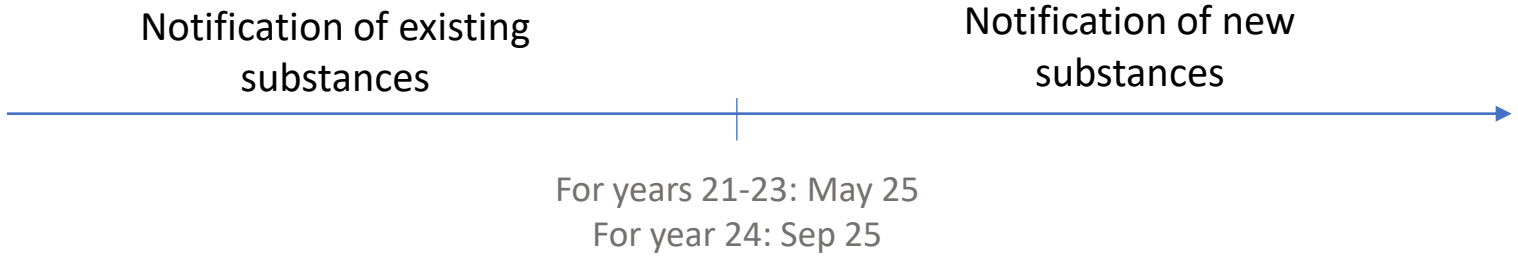
Timeline for notifications

Chile



Beyond deadlines: new substances need to be notified before commerce + provide more info

Colombia



Beyond deadlines: new substances need to be notified within 6 months

Peru

One year for the secondary regulation – Delay is expected

Argentina

Brazil

Confidentiality

Confidential information

- *Detailed Usage Information.*
- *Exact quantities of manufacture or import.*
- *Complete toxicological / ecotoxicological study reports.*
- *Composition of chemical products*

Confidential information under specific conditions

- *Name and/or unique chemical identifier (e.g., CAS number, CAS name, chemical name)*
- *Name of the notifier.*

Examples of Non-Confidential OECD 0205

- *Trade names or commonly used names;*
- *General usage data;*
- *Handling Precautions*
- *Recommended methods for waste disposal and management;*
- *Safety measures in the event of an accident;*
- *Physical and chemical data, with the exception of data revealing the identity of chemicals. If the physical and chemical data make it possible to deduce from them the identity of the chemical substance, only ranges of values can be given;*
- *Summaries of health, safety and environmental data, including accurate figures and interpretations.*

Confidential information

Chile	Colombia	Peru
The Decree refers to **National Law on Access to Public information.** In the case of a request for sensible information, for example, that could affect commercial or economic interests, the State Administration agency will notify the affected individuals so they can oppose the disclosure, providing a written explanation for their objection. If a valid opposition is raised in a timely manner, the agency cannot release the requested information unless overturned by the established Council following due process.	The Decree refers to **National Law on Access to Public information**. The Instructive links to the OECD related instruments. **Users can determine the fields that will be confidential** and add the respective support as described in Law 1712 of 2014, as well as in Andean Decision 486 of 2000. This support will be issued by the natural or legal person specifying the confidential nature of information such as commercial matters, patent rights, business secrets, etc.	Exceptionally and with due justification, and in order to protect the commercial, industrial and/or technological secret, the manufacturer or importer of chemical substances may request MINAM, for a maximum period of five (5) years or as long as said secret, **the IUPAC nomenclature and CAS registration number of the chemical substance** are considered confidential information. The request is made in accordance with the provisions of the Regulations of this Legislative Decree.

Foreign representative

- Colombia: The exclusive representative from abroad is the actor **appointed by an INSQUI user** and who **resides outside the national territory** whose function is to **report the confidential information** associated with the SQUIs that are imported into the country.

- Brazil: natural or legal person **established in the country**, with financial, administrative and technical capacity, who, in common **agreement with the foreign manufacturer** of chemical substances or mixtures, acts as its exclusive representative and **assumes the responsibilities and obligations imposed to the importer** in this Law.

Prioritization and Risk Assessment Guidelines

- Colombia
  - Decree: 2021
  - IT instructive: May 2022
  - Chemical Substance Prioritization Instrument Regulation: May 2025 (estimated)

- Chile
  - D.S. 57 of 2019 – Published in 2021
  - “The Ministry of Health, within a period of 18 months from the publication of this regulation”
  - Public WTO Consultation with the criteria: January 2024

- Peru
  - 1 year after the entry into force of the Executive Decree establish the guidelines for the preparation of risk assessments and prioritization

Prioritization Criteria under analysis

Chile	Colombia	Peru
• Health hazards (except acute toxicity, corrosivity, eye injury, and aspiration hazard) • Hazards to the environment. • Annual import or manufacturing volume of the substance/whether pure or contained substance in a mixture • Sector of use of the substance, as such or in mixtures (Industrial, Home Professional) • Environment and Health authorities may consider additional criteria. Among the additional factors, the persistence and bioaccumulation of the substances, endocrine disrupting capacity, will be considered.	• Environmental Hazards (Acute and Chronic Aquatic Toxicity) Health Hazards (CMR, Systemic Toxicity, Acute Toxicity, Other Health Hazards) • Quantity (in ranges) • Uses (primary and secondary, industry sectors and products, additional information)	• Hazard classification. • Probability and degree of exposure according to the type of recommended use. • Relationship with international conventions. • Relationship with national and international regulations. • Quantities imported and manufactured annually. • Persistence, bioaccumulation, acute toxicity and STOT

RMS-IC
Chile

Prioritization and risk assessment procedure

- Clarification of CBI data
- Foreign representative figure
- Iterations in the prioritization process
- Clear process on the selection of substances of interest
- Includes aspects like persistency, bioaccumulation or endocrine disruptiveness – not included in the decree
- Producers or importers are responsible for developing risk assessments > responsible for presenting
- Obligation for importers and producers not included in the Inventory beyond de prioritization deadline
- Clarity on non-compliance
- Non-recommended uses to be evaluated if included in RA by Producers or importers
- Public consultation on list of substances of interest and risk mitigation measures

WORLD TRADE ORGANIZATION

G/TBT/N/CHL/671

5 January 2024

(24-0105) Page: 1/2

Committee on Technical Barriers to Trade Original: Spanish

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1. Notifying Member: CHILE

If applicable, name of local government involved (Articles 3.2 and 7.2):

2. Agency responsible:

Ministerio de Salud (Ministry of Health)

Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:

Subsecretaría de Relaciones Económicas Internacionales, SUBREI - *Ministerio de Relaciones Exteriores* (Under-Secretariat for International Economic Relations, Ministry of Foreign Affairs)

3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6 other:

Products covered (HS or CC

Access consultation here

Responsibility for Risk Assessments

Chile	Colombia	Peru
• Industry prepares risk assessment (18 months – Draft) • Companies may jointly carry out the risk assessment of a certain substance, which may include supplier companies without representation in Chile. • Review by the Environmental Authority, with the participation of the Ministry of Health or whoever the Environmental Authority entrusts this task • The authority must rule on the conformity of the risk assessment within a period of 2 years, which will be suspended if the evaluator requires complementary and/or additional background information. The statement must include the risk management measures that must be implemented for the different uses. (Draft) • Importers and manufacturers must communicate to users the risk management measures accepted for the identified uses, by including them in the SDS and/or label. • The deadline for the delivery of this information will be up to 6 months, and may be extendable (Draft)	• Industry prepares the risk assessment • Industry must develop and implement a risk reduction and management program for the environment and health, which contains the knowledge and management of the risk associated with the identified use of the substance. • Joint submission is allowed	• Industry prepares risk assessment • Approval by the Ministry of Health (75 days) with the favorable opinion of the Environmental Authority (30 days)

Chile – Basic information required

Minimum content: Problem formulation, Hazard identification, Hazard description, Exposure assessment, Risk characterization

Technical guides
Human health: Technical guidelines and criteria, such as the WHO ER toolkit, also methodologies developed in the US, Canada and Europe, which may provide more specific approaches or tools.
Environment: OECD technical guidelines and criteria: Toolkit for environmental risk assessment or any other recognized in this field.

Studies or tests: Internationally validated and carried out by laboratories accredited through OECD GLP or ISO 17025 Standard. Peer-reviewed publications or scientific literature.

Local conditions - exposure: identified uses in the country, existing exposure scenarios, operational conditions, risk management measures applied

- Carried out and supervised by professionals who have training and experience and are clearly identified

Some concerns raised for Risk Assessment

Who presents the RA, industry that imported/produced the chemical in the past based on registries or companies willing to do so in the future?

Joint submissions are compulsory?

Who is responsible for the non-recommended uses?

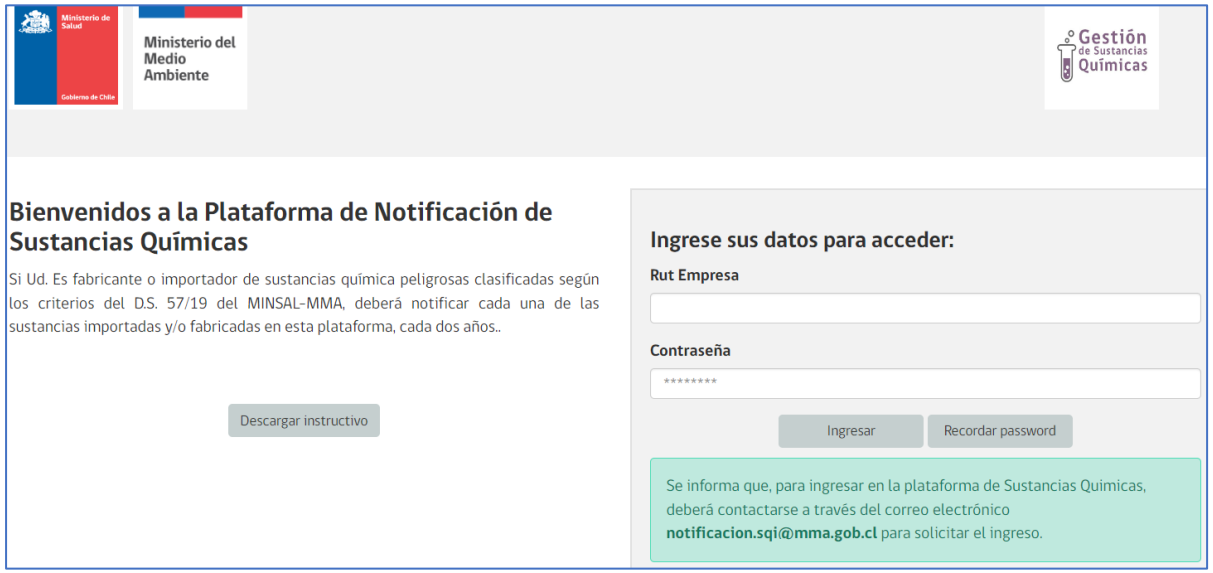
Other relevant aspects

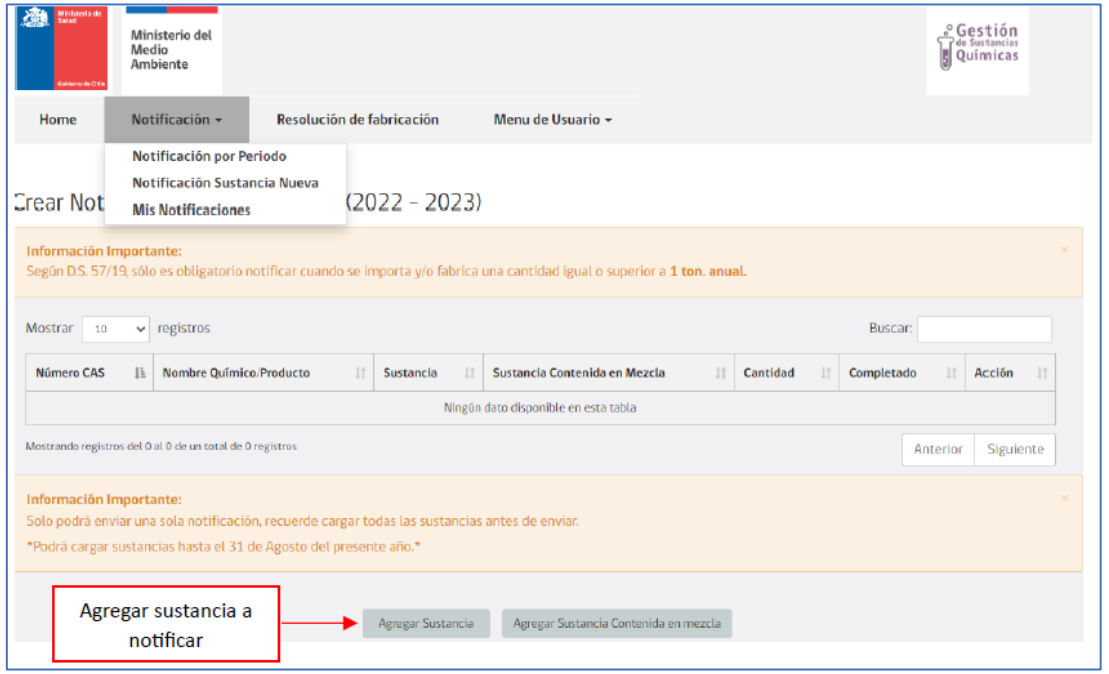
Designated Authorities	Inter-Ministerial Committees
Fees	Non-compliance and sanctions
Industry Involvement	Data sharing

Argentina Senasa Resolution 694/2024

Relevant documents to support implementation

Chile



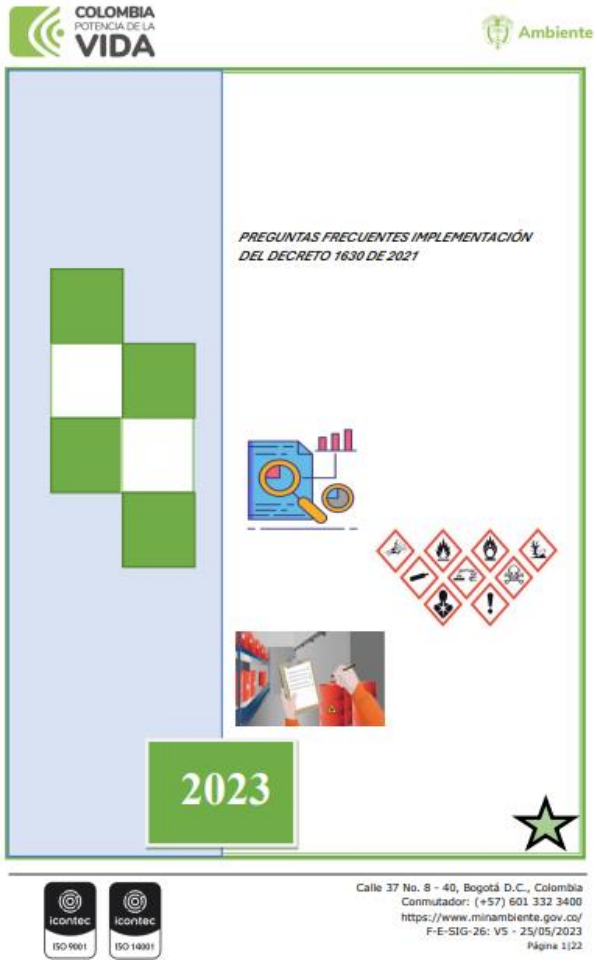


Access Instructive here

Relevant documents to support implementation

Colombia

Access INSTRUCTIONS FOR COMPLETION OF THE COMPUTER APPLICATION FOR THE NATIONAL INVENTORY OF CHEMICALS FOR INDUSTRIAL USE here



Access Q&A here

Challenges and Opportunities

Need of technical expertise and resources	Participate and contribute at an earlier stage of regulatory developments
Impact on trade and innovation	Regulatory cooperation mechanisms
Lack of mechanisms for generating and sharing information	Take the leadership and drive the chemical & waste policy agenda

Questions?

Cooperation platforms

Intergovernmental network on chemicals and waste for Latin America and the Caribbean

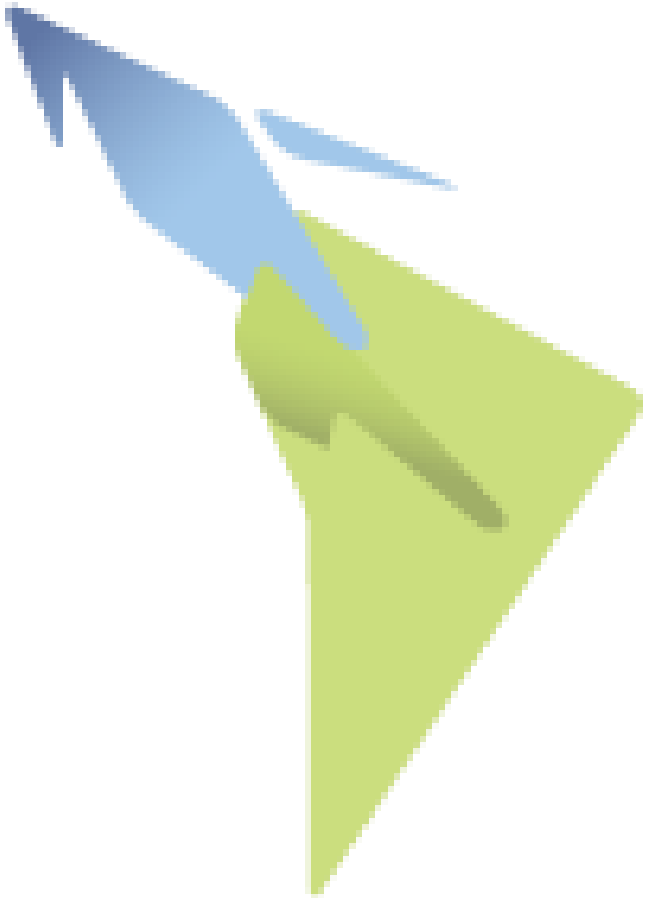
Established by the **XX Meeting of the Forum of Ministers of the Environment** (Cartagena, 2016)

Objective: regional cooperation and exchange of experiences

Members: 29 national focal points and 11 non-governmental actors.

Steering Committee for the period 2021-2022: Peru (Chair), Argentina (Vice-Chair), Ecuador, Guyana, Honduras, Panama, Trinidad and Tobago and Uruguay

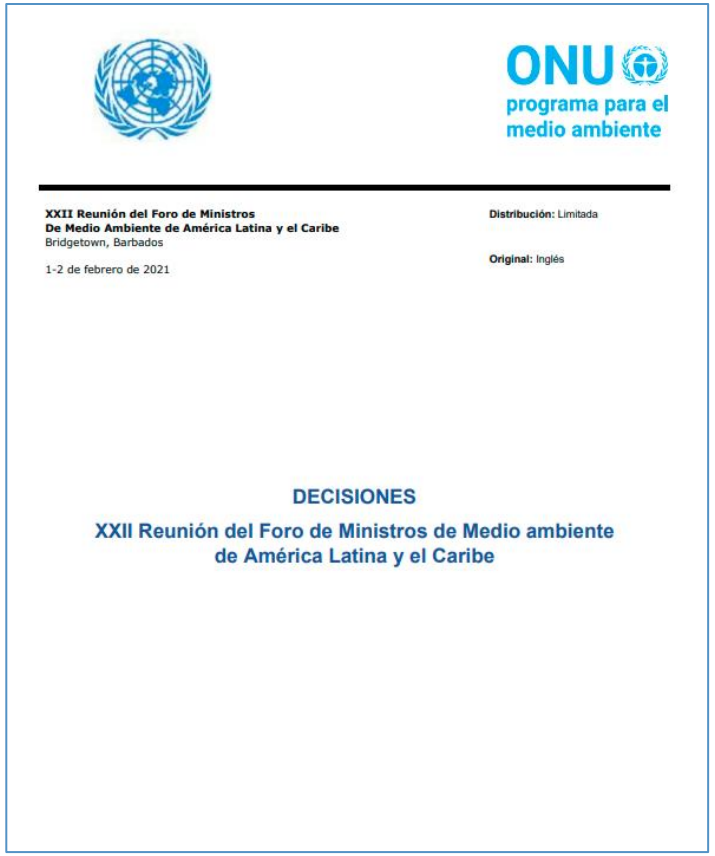
Secretariat: Office for Latin America and the Caribbean of the UN Environment Program.



Intergovernmental network on chemicals and waste for Latin America and the Caribbean

XXII Forum of Ministers of the Environment of Latin America and the Caribbean

February 1-2, 2021



ONU programa para el medio ambiente

XXII Reunión del Foro de Ministros
De Medio Ambiente de América Latina y el Caribe
Bridgetown, Barbados

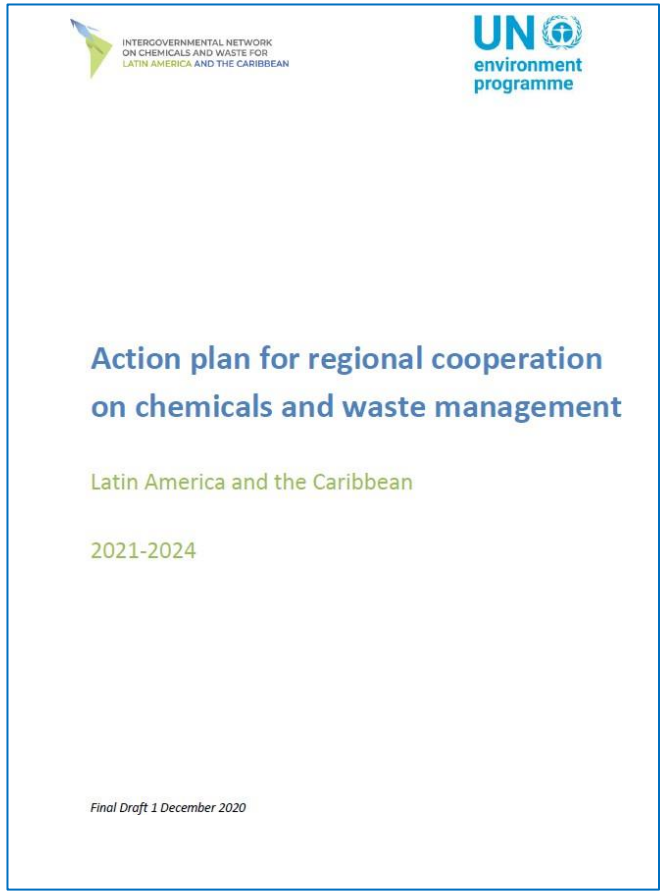
1-2 de febrero de 2021

Distribución: Limitada

Original: Inglés

DECISIONES

XXII Reunión del Foro de Ministros de Medio ambiente de América Latina y el Caribe



INTERGOVERNMENTAL NETWORK ON CHEMICALS AND WASTE FOR LATIN AMERICA AND THE CARIBBEAN

UN environment programme

Action plan for regional cooperation on chemicals and waste management

Latin America and the Caribbean

2021-2024

Final Draft 1 December 2020

Intergovernmental network on chemicals and waste for Latin America and the Caribbean

6

Priority themes

33

Actions

526,200 $

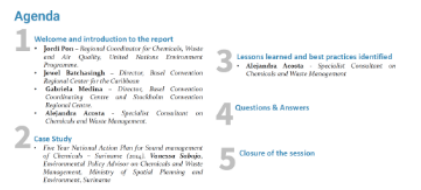
Budget

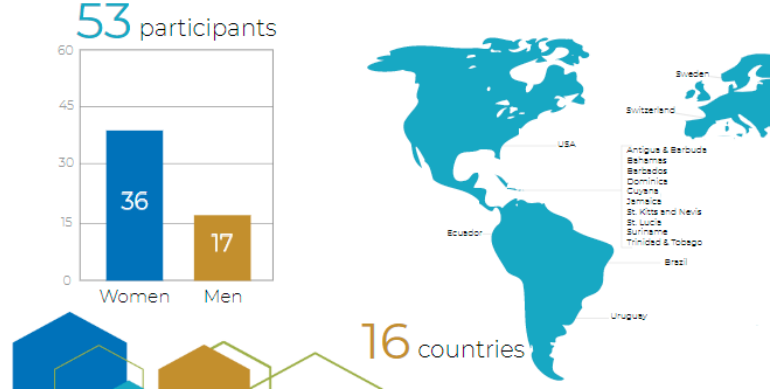
Estimated to be movilized

- Governance and coordination mechanisms
- Knowledge, information and monitoring
- SAICM priority themes
- Basel, Roterdam y Stockholm Conventions
- Mercury
- Waste management

Intergovernmental network on chemicals and waste for Latin America and the Caribbean

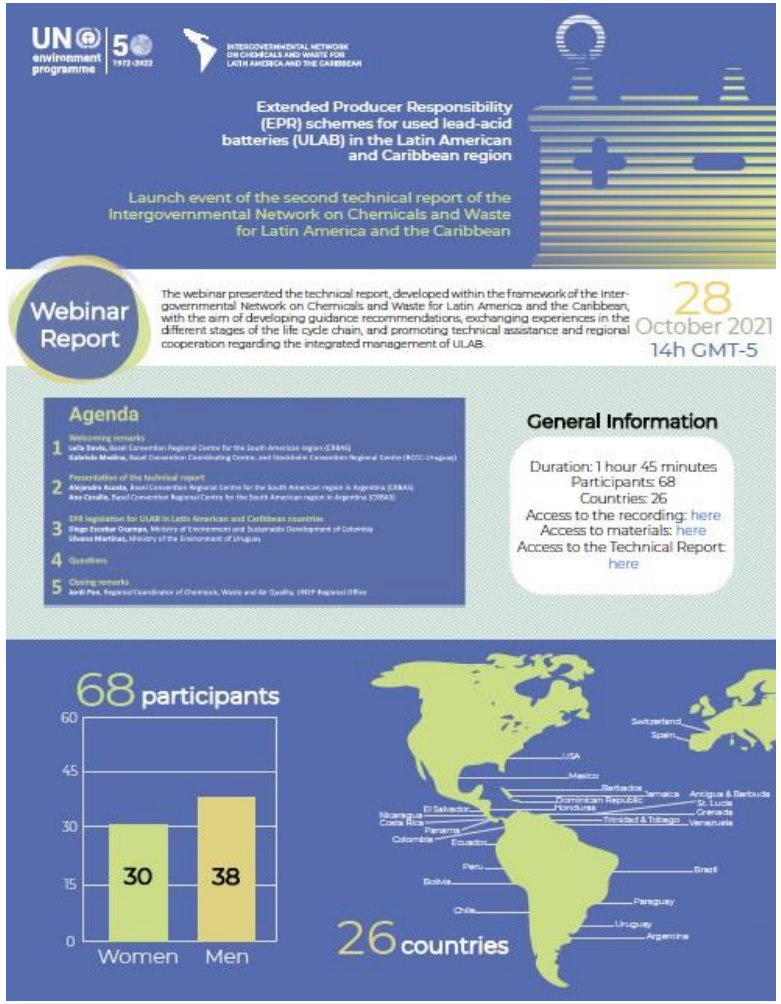
Report on legal and institutional frameworks for the integrated management of chemicals in Latin America and the Caribbean





Intergovernmental network on chemicals and waste for Latin America and the Caribbean

Extended Producer Responsibility (EPR) for Used Lead Acid Battery schemes in Latin America and the Caribbean



Intergovernmental network on chemicals and waste for Latin America and the Caribbean

Improving communication on the sound management of chemicals

Intergovernmental network on chemicals and waste for Latin America and the Caribbean

Latin American Regulatory Cooperation Forum

LARCF
Latin American Regulatory Cooperation Forum

ICCA

Promote regulatory cooperation in Latin America in the safe management of chemicals with the purpose of strengthening interaction between the public and private sectors, exchanging resources efficiently and enabling scenarios of transparency and trust in regulatory decision-making that have an impact on the region's chemical industry

Activities

VWG-SMC-LA

1. **Roadmap for Sound Management of SyPQ**
   Sep 2020 – Apr 2021
   Download here

2. **Inventories**
   Abr 2021 – Mar 2022
   Descargar here

3. **Prioritization**
   Apr 2022 – Nov 2022
   Downloadhere

4. **Risk Assessment**
   2023
   Download here

Risk Mitigation
IN DEVELOPMENT

Activities

Newsletters

- Bi-monthly publication of the LARCF including:
  - Emerging Regulations
  - Events
  - Regional information
  - Partnership Information

Subscribe here

Activities

Technical Webinars

- 4 webinars planned in 2024
- 4 webinars were held in 2023
- Average attendance: 200
- Simultaneous interpreting
- Related to SQI Inventory and Risk Management Regulations

1. **Elements of toxicology and ecotoxicology -** March 28 - 470 attendees.
2. **Functionalities of the module of the foreign representativeof Colombia** - June 21 - 70 attendees.
3. **Notification of Chemicals in Chile** - June 28 - 150 attendees.
4. **Data and Information Requirements and Management: Challenges and Solutions for Chemical Regulatory Compliance** - August 31 - 150 attendees.

Activities

Regulations Repository

- In development
- Repository of GHS Regulations and Inventories in the countries of the LARCF Associations

					GHS			
Country	Type GHS - IC (Industrial	Regulatory Reference	Link	Date of publication	Scope (workplace, consumer products, others)	Edition in force	Are all GHS building blocks adopted?	Others
Argentina	GHS	Resolution SRT 801/15 SUPERINTENDENCIA DE RIESGOS DEL TRABAJO	https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-801-2015-245850	2015	Workplace (industrial sector)	5	Yes	
		Resolución 3359 / 2015 SUPERINTENDENCIA DE RIESGOS DEL TRABAJO	https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-3359-2015-252805					
		Resolución 155 / 2016 SUPERINTENDENCIA DE RIESGOS DEL TRABAJO	https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-155-2016-260950					
		Disposición Conjunta 3 / 2017 GERENCIA DE PREVENCION SUPERINTENDENCIA DE RIESGOS DEL TRABAJO	https://www.argentina.gob.ar/normativa/nacional/disposici%C3%B3n-3-2017-275671					
		Disposición Conjunta 6 / 2017 GERENCIA TECNICA SUPERINTENDENCIA DE RIESGOS DEL TRABAJO	https://www.argentina.gob.ar/normativa/nacional/disposici%C3%B3n-3-2017-275671					
Brazil	GHS	Ordinance No.26 (on hazard communication) of the Ministry of Labour implemented the GHS in the workplace. Technical provisions for the implementation of the GHS are given in the standards developed by the Brazil Association of Technical Standards (ABNT). First version of standard: ABNT NBR 14725	https://www.gov.br/trabalho-e-previdencia/pt-br/acesso-a-informacao/participacao-social/conselhos-e-orgaos-colegiados/ctpp/normas-regulamentadora/normas-regulamentadoras-vigentes/norma-regulamentadora-no-26-nr-26	2009	Workplace (industrial sector)	4	No	Updated: - ABNT NRB 14725-1:2009 Terminology (correct - ABNT NRB 14725-2:2019, Amend.1 (2019) Hazard Class - ABNT NRB 14725-3:2017 Labelling - ABNT NRB 14725-4:2014 Safety Data Sheet o Standard 14725 is currently being revised to bring it into line with the 7
Chile	GHS	Decree 57/2019	https://www.bcn.cl/leychile/navegar?idNorma=1155752	2021	In force for workplace and consumer.	7	No	Includes official classification list based in CLI Deadlines for classification and labelling •Industrial substances: 2022 •Industrial substances in mixtures: 2025 •Non-industrial substances: 2023 •Substances in non-industrial mixtures: 20
								Decree 1496 of 2018: This decree establishes the mandatory adoption of the GHS for substa

Activities

5th Latin American Regulatory Cooperation Meeting on Chemicals

- It will be held in November in São Paulo, Brazil
- Representatives of the Government and Private Sector of the region, as well as international experts
- 2 days of immersion in regulatory advances in the region and training on emerging issues

Contact LARCF if you would like to receive the invitation

Other examples of Good Regulatory Practices in Latin America

Chile

- Intergovernmental Forum on Chemical Safety - 1994
- National Chemical Safety Policy - 1999-2007 (Last Update - 2017-2022)
- National Committee for the Coordination GHS implementation in Chile – 2012

Brazil

- ABNT - CB-10 – SESAMA – Committee for the study of Environment, Health and Safety related to chemical products – Civil Society technical group that coordinated the GHS Implementation in Brazil – Established in 1999
- CONASQ – National Committee on Chemical Safety **-** Multi-stakeholder forum composed of 22 institutions coordinated by the Ministry of Environment such as other ministries of state, regulatory agencies (IBAMA and ANVISA), research institutes and academia, private sector (chemical industry and downstream users) and NGOs – Existed between 2000-2019.
- CONASQ´s 5 years work resulted in a Draft bill on National Chemicals Management Policy in 2018

Other examples of Good Regulatory Practices in Latin America

Costa Rica

- National Chemical Safety Policy - Executive Decree No. 40148/2017 – First Country in Latin America to establish a National Registry of Substances -2018

Colombia

- National policy for the management of the risks associated with the use of chemical substances – CONPES 3868/2016

Argentina

- Interministerial Table of Substances and Chemical products - Decree 504/2019 - Draft bill on National Chemicals Management Policy - 2019

Mexico

- National Advisory Committee for the Sound Management of Chemical Substances, Organic Persistent Compounds and Hazardous Waste subject to international environmental agreements – Coordinated by SEMARNAT- 2011
- Draft – National Policy for the Sound Management of Chemicals – Coordinated by General Health Council (CSG) - 2019

Questions?

Break

Political developments and foresight for the American continent

Challenges and Opportunities for American countries

Challenges for governments

- Conflicting Agendas – Increase political relevance of the chemical policy agenda, including their implementation as part of their governmental strategic plans
- Changes in governments, public agenda and priorities
- Lack of a regional institutional strength to coordinate regulatory initiatives
- Scarce resources for implementation of chemical regulatory schemes
- Weakened Economies – More vulnerability – Increasing Social inequality

Opportunities for governments

- Development of cost-effective and science-based chemical schemes & regulations, compatible with main partner countries
- Have a clear delineation of responsibilities and effective and transparent accountability mechanisms
- Learning from best practices on existing chemical regulations worldwide -> eg. Impact assessments, and Science and Evidence based decisions
- Regulation should be the minimum necessary to achieve the objectives
- Use of globally existing chemical data ->need to create local exposure models
- Regulatory Cooperation – Enhance Intra and Inter Regional Initiatives
- Sharing resources -> Use existing collaboration platforms -> strengthen collaboration with Private sector, Academia, IGOs and NGOs
- Minimize the impact on competitiveness, avoid restrictions on international trade flows

Challenges and Opportunities for American countries

Challenges for Industry

- Meet international Chemical Policy standards
- Costs related to licenses to operate
- Investments needed to perform tests
- Need of developing technical expertise
- Build laboratory infrastructure
- Impact on innovation
- Technical barriers to trade
- Stricter EHS requirements for industrial operations

SMEs challenges:

- Low awareness about the environmental impact
- Difficulties in access to financing and investment
- Uncertainty associated with the costs, execution times and long-term results of the new processes related to the mitigation of environmental impact
- Need to properly train staff
- Limited access to information, knowledge and technology
- Low capacity to respond to stricter regulation
- Barriers to participate in green goods markets and global value chains: high demand for financial resources

Opportunities for Industry

- SDGs + MEAs + OECD + Trade Agreements + Chemical Policy Trends + New Normal - > Require More Resilient Businesses
- Increase chemical industry resilience to attract investment and to better compete in a challenging trade environment in Latin America
- Invest in collaborative innovation to create more sustainable solutions
- Promote integration of agendas – Chemicals management and Sustainability
- Take the leadership and drive the chemical & waste policy agenda
- Participate and contribute at an earlier stage of regulatory developments
- Build dialogue and trust between public and private stakeholders (industry associations, upstream-downstream sectors, NGOs and IGOs) using existent forums (eg. BIAC at OECD, Trade Agreement committees)
- Increase efforts in science and regional initiatives in risk based assessments for providing evidence for policy makers on regulatory decisions
- Take advantage of the biodiversity and renewable resources in the region

OECD – impacts on regulations

American countries in the OECD:

- USA - Member since May 1961
- Canada - - Member since May 1961
- Mexico - Member since May 1994
- Chile – Member since May 2010 (accepted 6 years after application)
- Colombia – Member since May 2020 (accepted 7 years after application)
- Costa Rica – in May 2020 Accession was approved (ongoing national process)
- Argentina, Brazil and Peru –OECD opened accession discussions
- Roadmap for the OECD accession: Brazil and Peru (June, 2022).

OECD Membership - Potential Benefits:

- Attract more foreign direct investments and reduce the cost of international financing
- Enhance governance efficiency, transparency and accountability
- Foster a more stable and predictable regulatory framework despite administration changes
- Allow opportunity to exchange experiences and gaining support for policy evaluations and reforms that promote trade and investment
- Allow the country to participate and influence in global development agendas
- Generate reputational effects which will increase confidence in business and from consumers

OECD – impacts on regulations

Examples of 6 OECD council acts (from a total of 22 acts) related to chemicals that are covered by existing draft regulations in Latin America:

Data and Information:
Decision on the Minimum Pre-marketing set of Data in the Assessment of Chemicals [C(82)196/Final]
Recommendation on the OECD List of Non-Confidential Data on Chemicals [C(83)98/Final]
Recommendation on the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96/Final]
Chemical Assessment:
Recommendation on Guidelines in Respect of Procedures and Requirements for Anticipating the Effects of Chemicals on Man and the Environment [C(77)97/Final]
Decision-Recommendation on the Systematic Investigation of Existing Chemicals [C(87)90/Final]
Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Chemicals - [C(2018)51]

- **Chile** - Examples of the Accession Agreement – Established deadlines for implementation of legal instruments related to Chemicals – Timeframe deadline: 2013

Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163]
Decision-Recommendation of the Council on the Systematic Investigation of Existing Chemicals [C(87)90]
Decision of the Council concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals [C(82)196]
Recommendation of the Council establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97]
Recommendation of the Council on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215]

Timeframe: Chile accepts the instruments listed above with a timeframe for implementation until the end of 2013.

North America

- Biodiversity loss, primarily driven by pressures from land use change, habitat fragmentation, and persistent impacts of invasive species, agriculture, and resource extraction (UNEP, 2016).
- Freshwater and marine ecosystems, highly diverse in North America, are at high risk, with threats from climate change, land-use change, chemical pollution, and resource harvesting (UNEP, 2023).
- Another priority issue is climate change. North America is responsible for a large share of the global greenhouse gas emission, with transportation a main contributor. (UNEP, 2019).
- Though the United States Clean Air Act had significant impact on improving air quality in the region, issues remain. While airborne particulate matter concentrations have significantly decreased in the region, ground-level ozone pollution remains a particular concern (UNEP, 2019).

- Sustainable chemistry is still not a national priority. Similarly, it is not a priority for investors.
- Much of the federal government's focus on and resources for addressing chemicals to date has gone toward studying, regulating, or avoiding problem chemicals, such as PFAS or bisphenol A, rather than identifying innovative solutions in the first place.
- Meanwhile, investors are beginning to see the risks inherent in investing in chemicals or chemical products of concern.
- Advocacy pressure, including new scorecards and metrics to evaluate firms' chemical footprints, is leading major retailers including Amazon and Walmart to publish new chemicals policies.
- Numerous states have enacted transparency requirements or restrictions on chemicals.

USA

- In the coming decade, three high-priority environmental issues—climate change, the plastics crisis, and environmental justice—are likely to further accelerate interest in sustainable chemistry research and commercialization.
- Although federal coordination will be needed to develop the national “blueprint” for sustainable chemistry, ensuring the right structure with adequate resources and leverage to drive research, innovation, and commercialization is also critical.
- Despite passage of the Sustainable Chemistry Research and Development Act, sustainable chemistry is still not a national priority at the level of, say, climate action. Similarly, it is not a priority for investors.
- Meanwhile, investors are beginning to see the risks inherent in investing in chemicals or chemical products of concern.
- Advocacy pressure, including new scorecards and metrics to evaluate firms’ chemical footprints, is leading major retailers including Amazon and Walmart to publish new chemicals policies.
- Numerous states have enacted transparency requirements or restrictions on chemicals.
- High possibility of Donald Trump winning a second presidency

Political developments in LAC Countries

In recent decades, most countries in Latin America and the Caribbean have approved environmental legislation and have created environmental institutions at ministerial level.

While progress has been made, environment ministries remain weak both politically and from a budgetary perspective

There is a widespread perception that these ministries must solve environmental problems on their own while the rest of the state apparatus is limited to maintaining its usual routine.

Enforcement of environmental regulations is relatively weak. the authorities do not always have the necessary financial and technical resources to implement them effectively.

Trade agreements

EU- Mercosur Trade Agreement - Chapter on Trade and Sustainable Development

- Article 2, (3) “A Party should **not weaken the levels of protection** afforded in domestic environmental or labour law with the intention of encouraging trade or investment”
- Article 10, (2) “In cases when scientific evidence or information is insufficient or inconclusive and there is a risk of serious environmental degradation or to occupational health and safety in its territory, a Party may adopt **measures based on the precautionary principle**”
- Article 13, (k) “**Sound Management of Chemicals and Waste**”

USMCA Free Trade Agreement – Sectoral Annexes – Chemical Substances

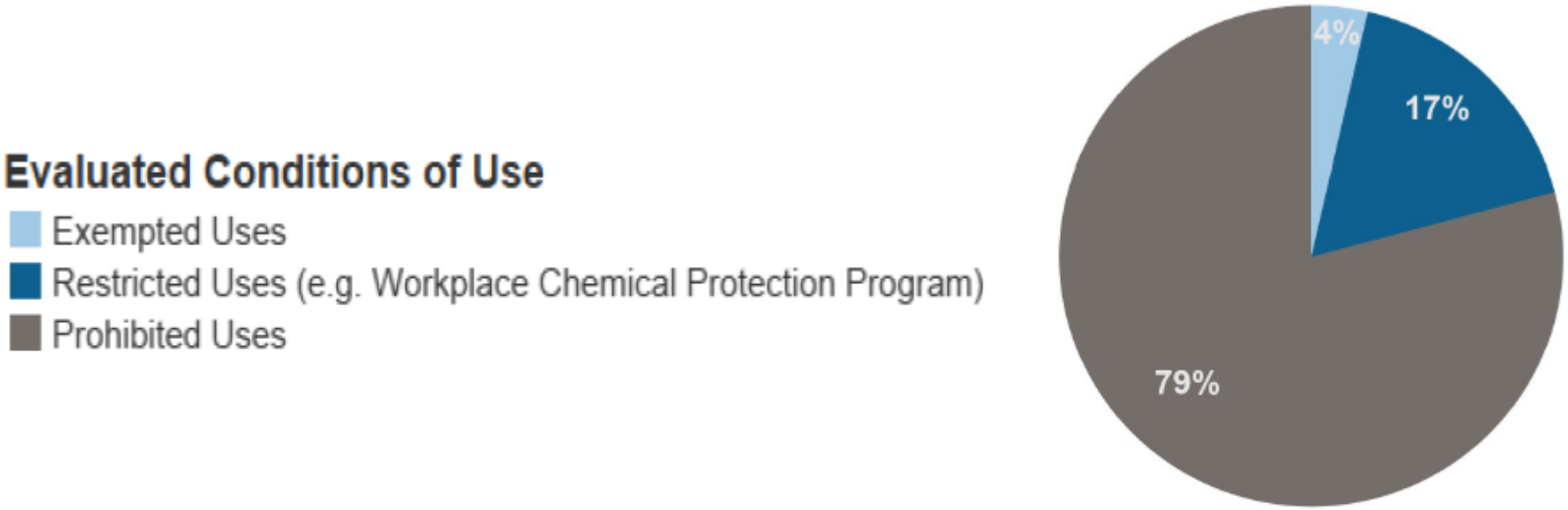
- **Article 12.A.4: Enhancing Regulatory Compatibility** “2. The Parties also recognize the importance of developing and implementing measures in a manner that achieves their respective level of protection without creating unnecessary economic barriers or impediments to technological innovation.”

- **Article 12.A.5: Data and Information Exchange** “2. Upon request of another Party, a Party shall share any available data or assessments on particular chemical substances, such as full data studies or robust data summaries.”

Questions?

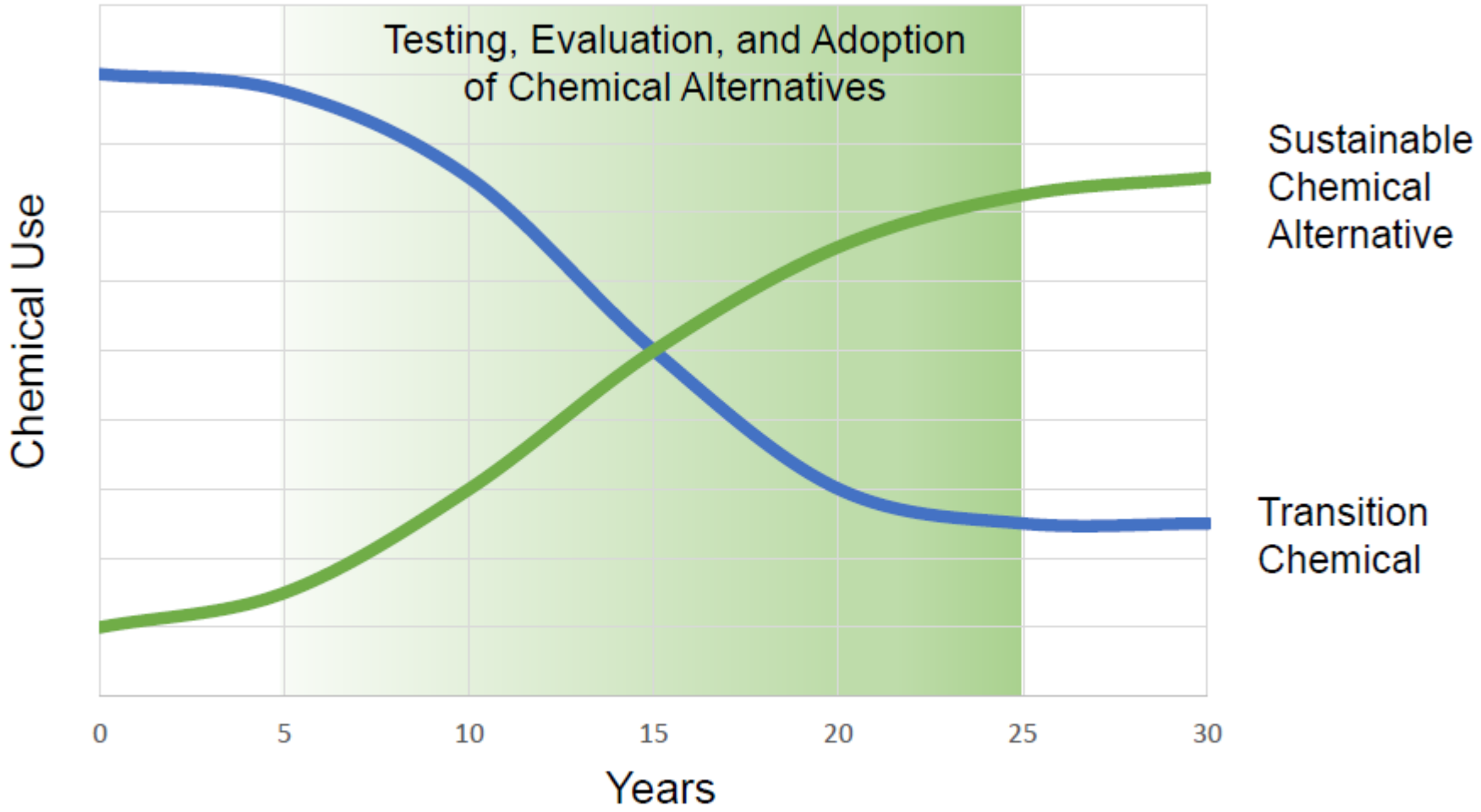
Green Chemistry Policy in N- & S-American countries

Future Regulatory Requirements Drive the Need to Rapidly Develop, Deploy and Adopt Alternatives



Landscape of Risk Management Under First 5 Public Draft EPA TSCA Rulemakings for High Priority Chemicals

The Ability to Plan for Regulation is Important Considering the Time Needed for Innovation and Adoption



Top Sectors to Prioritize Resilient Chemicals for Economic, Environmental, and Global Security

USA

Sustainable Chemistry Research and Development Act

- Legislation enacted Jan. 1, 2021
- Sustainable chemistry—an alternative term for green chemistry that federal legislators use—“can improve the efficiency with which natural resources are used to meet human needs for chemical products while avoiding environmental harm, reduce or eliminate the emissions of and exposures to hazardous substances, minimize the use of resources, and benefit the economy, people, and the environment”
- Encourages federal agencies to incorporate green chemistry requirements into grants they offer to academic researchers
- Directs to convene a multiagency task force that will, for the first time, coordinate federal funding and promotion of sustainable chemistry research.
- Formation of an interagency committee to determine the baseline status of sustainable chemistry activities across the federal government and the US economy. This baseline will be used to measure the progress and effectiveness of activities envisioned under the act
- Coordinated support for federal efforts in sustainable chemistry, including research and development, technology transfer, commercialization, and education and training
- Barriers to green and sustainable chemistry innovation and commercialization include:
  - lack of policy incentives and coordinated government leadership and investment,
  - limited funding for targeted research,
  - few incentives for educators to teach green chemistry
  - Existing chemicals and processes are cheap, utilize capitalized technologies, and are tightly integrated into existing global supply chains, where cost and performance drive decisions.

USA

EPA - Green Chemistry Challenge Awards.

- The Green Chemistry Challenge Awards promote the environmental and economic benefits of developing and using novel green chemistry.
- Throughout the 25 years of the awards program, EPA has presented awards to 128 winners. Since its inception, in 1996, EPA has received over 1,800 nominations.
- Through 2021, 133 winning technologies have made billions of pounds of progress, including:
    - 830 million pounds of hazardous chemicals and solvents eliminated each year—enough to fill almost 3,800 railroad tank cars1 or a train nearly 47 miles long.2
    - 21 billion gallons of water saved each year—the amount used by 980,000 people annually.3
    - 7.8 billion pounds of carbon dioxide equivalents released to air eliminated each year—equal to taking 770,000 automobiles off the road.4

Award	Company/ Academic Name	Summary	Technology	Industry
Academic	Professor Richard Laine (University of Michigan)	Upcycling/Valorizing a Plentiful Agricultural Waste (read more)	Renewable Resources, technologies that use a renewable resource in place of a petroleum-based or depleting resource	Specialty Chemicals
Design of Greener Chemicals	The Clorox Company	Clorox EcoClean™ Disinfecting Cleaner (read more)	Safer Chemical Products	Formulated Products
Greener Reaction Conditions	Captis Aire LLC	Chemical Adsorption Innovation Reduces Emissions (CAIRE™) Technology (read more)	Renewable Resources, technologies that use a renewable resource in place of a petroleum-based or depleting resource	Bulk and Commodity Chemicals; Specialty Chemicals
Greener Synthetic Pathways	Solugen	Decarbonizing the Physical World (read more)	Renewable Resources, technologies that use a renewable resource in place of a petroleum-based or depleting resource; Biotechnology > Use of Isolated Enzymes	Bulk and Commodity Chemicals; Specialty Chemicals
Small Business	Modern Meadow	Modern Meadow Bio-FREED™ Powered by Bio-Alloy™ (read more)	Biotechnology, including use of biological processes or microorganisms	Pigments, Dyes, and Colorants
Specific Environmental Benefit—Climate Change	Air Company	AIRMADE™ Carbon Technology: Photosynthesis-inspired Conversion of CO2 to Sustainable Aviation Fuels and Alcohols (read more)	Renewable Resources, technologies that use a renewable resource in place of a petroleum-based or depleting resource; Chemical Catalysts; Energy Technologies	Fuels, including biofuels

Canada

GreenCentre Canada

- Mission: to accelerate promising chemistry solutions that advance both the economy and the environment in unison
- Provide research and development services to different customer segments including: small companies, entrepreneurs, academic start-ups, and large and medium-sized corporations.
- Operates in two state-of-the-art facilities in Ontario for the development of chemical technologies—on both small and larger scales.
- Continued funding from the Ontario government enabled GCC to operate its IHC4 program which provided support to Ontario-based small- and medium-sized enterprises and entrepreneurs by developing, de-risking and scaling up their innovations.

Results

- Forward Water Technologies: simultaneously reduced the volume of dissolved salts in challenging wastewater while returning fresh water for re-use or surface release.

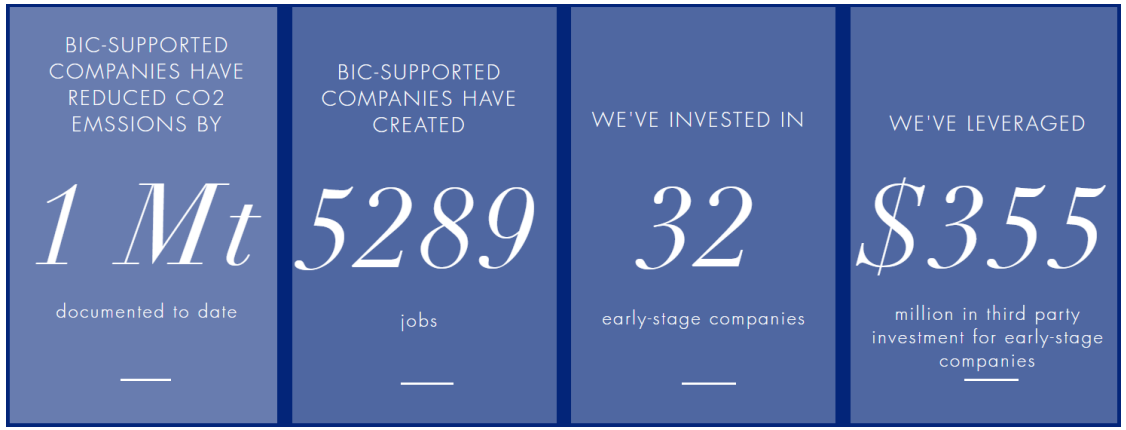
- The Lorama Group: an innovative outdoor paint/coating technology that is more environmentally friendly than existing products.

- Veolia Water Technologies: a novel water purification technology, it measures the polymer flocculent concentration in wastewater streams in real time.

Canada

Bioindustrial Innovation Canada

- Founded in 2008, provides critical strategic investment, advice and services to business developers of clean, green and sustainable technologies.
- Focused in these three areas
  - the industrial bioeconomy, which converts renewable resources, such as agricultural and forestry by-products and residues, into value-added bioenergy, biofuel, biochemical and biomaterials
  - sustainable processes, which efficiently use the world's limited resources (eg. water, energy) through innovative technologies
  - the circular economy, which recovers and reuses the world's limited resources
- In 2020, BIC received $15M contribution from FedDev Ontario



LAC countries

On the environmental side

- often irrational and unsustainable use of natural resources,
- advance of large-scale deforestation,
- excessive levels of air and water pollution,
- irreversible alteration of certain ecosystems
- lack of adequate treatment of solid waste and residual water
- lack of measures to control the environmental impact of production activities
- Latin America is a mega biodiverse region
- high potential for biomass production
- availability of large quantities of waste biomass

On the economic side

- economy and regional trade are in a recessive phase, and with a forecast reserved for the coming years
- fall in investment
- persistence of inequality and poverty
- lack of adequate regulatory frameworks or contradictory regulatory frameworks,
- insufficient coordination of existing technical and technological capabilities,
- market entry restrictions
- lack of funds to enhance the creation of innovative business enterprises

LAC countries

The great challenge for the countries of the region is to design and implement policies that address not only environmental challenges but also promote a transition towards a productive structure that improves productivity and the quality of employment

This proposal requires the complementarity between investments and strategies that focus on developing new technological and innovation capacities (in processes and products) that reduce the deterioration of the environment and promote a new form of commercial insertion.

***Inclusive* Green Chemistry**

LAC countries

Strategies and plans related to green production
Nova Industria Brasil – 2024 - 2033

Decree

Promote "the transition from the linear production model to a circular economy, in order to encourage the efficient use of natural resources and sustainable practices throughout the production chain."

The implementing decree calls for the following guidelines for the new Strategy:

- eliminating pollution and reducing the generation of waste and residues;
- maintaining the value of materials;
- regenerating the environment;
- reducing dependence on natural resources;
- sustainable production and consumption;
- extending the life cycle of each and every material; and
- ensuring a just, inclusive and equitable transition that addresses gender, racial, ethnic and socio-economic disparities.
- creating a regulatory and institutional environment favorable to the circular economy

Special lines of credit, non-refundable resources, patent regulations, a public works and procurement program

LAC countries

Strategies and plans related to green production

Country	Plans / Programmes	Objectives
Brazil	National Plan of Action for Sustainable Production and Consumption	Promote initiatives that generate real changes in the current production and consumption system, with a view to sustainability.
Chile	National Program for Sustainable Consumption and Production	Decouple the growth and development of the country from the degradation of the environment
Colombia	Green Growth Strategy	Guide the change in the production and consumption patterns of society towards environmental sustainability
	National Strategy for Sustainable Production and Consumption	
Guatemala	Cleaner Production National Policy	Contribute to social welfare, economic growth, increased competitiveness, improvement of the quality of the environment and the rational use of natural goods and services, through the application of Cleaner Production, as a tool for socio-environmental management.
Mexico	National Strategy for Sustainable Production and Consumption, since November 2012	Transversal economic, regulatory and educational measures, as well as communication and dissemination measures to promote the adoption of sustainable practices in production processes and consumption. Generation of intersectoral voluntary agreements that allow this transition to be accelerated.
	National Strategy for the Promotion of Cleaner and More Efficient Production	Achieve better levels of quality of life for the population and the protection of human health; and the promotion of productive efficiency, competitiveness and socio-environmental responsibility of companies
Dominican Republic	National Policy for Sustainable Production and Consumption	Promote changes in consumption and production patterns to minimize the environmental damage and risks generated by society, and at the same time guarantee human well-being and business competitiveness in the present and future.
Uruguay	National Action Plan on Sustainable Production and Consumption	Identify, coordinate, integrate and strengthen a set of actions, programs and projects aimed at preventing and minimizing the impacts on the environment derived from production and consumption

LAC countries

RECP Net

The Network for Resource Efficient and Cleaner Production (RECP*net*) brings together over 70 providers of RECP services on a global level, in order to catalyze the effective and widespread application of RECP in developing and transition countries. It does so by providing specialized, quality-assured, technical and advisory services and by facilitating and synergizing its members' capacities

UNIDO

UNEP

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Economic Affairs SECO

LAC countries

Green chemistry training needs

- Awareness throughout the chain of what the principles of Green Chemistry consist of. basic training courses in Green Chemistry.
- Advisers, consultants, technical personnel with experience, who provide support in green chemistry for the industry and in the development and implementation of other sustainable initiatives.
- More initiatives and research groups that support the development of green chemistry and the efficient use of energy in the national chemical industry.
- Courses/guides for the disposal and use of waste (chemical substances and containers that contain them).
- Training courses in circular economy with scope to the chemical sector.
- Awareness campaigns on environmental and sustainability issues for the chemical sector and consumers.
- Experts in process safety and environmental management

Regulations

Quality Standards

Identification of key sectors

Source: Global Quality and Standards Program (GQSP) Colombia

UNIDO argues that developing countries with emerging infrastructures and expanding industries have a particularly exciting opportunity to improve their competitiveness by applying the best practice of "doing more with less" to their new industrial facilities from the outset, rather than take the slower route, of first investing in traditional infrastructure and greening it later.

Questions?

Thanks for your attention

Alejandra Acosta