Chemical Regulatory Updates in Latin America

An Overview of Regional and National Developments

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Topics

- Regional Context
- Regional Initiatives
- Countries Development
  - GHS
  - National Chemical Regulations
- Regulatory Summary
- Take-Home Messages

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Regional Context

Until recently, Latin American countries looked abroad rather than their regional neighbors for chemical regulations.

Recent Regional Initiatives

UNEP Special Programme

Institutional strengthening for chemical clusters

1st Report

Priority Issues on Chemicals and Waste and Potential Priority Cooperation

Action Plan (2021-2024)

Regional cooperation for sound management of chemicals

LARCF

Roadmap for management of chemicals

2015 — **2016** — **2017** — **2018** — **2020** — **2021** — **2022**

Intergovernmental Network on Chemicals and Waste for Latin America and the Caribbean

Focused on capacity building

Action Plan (2019-2020)

Regional cooperation for sound management of chemicals

Mercosur Action Plan (2021-2024)

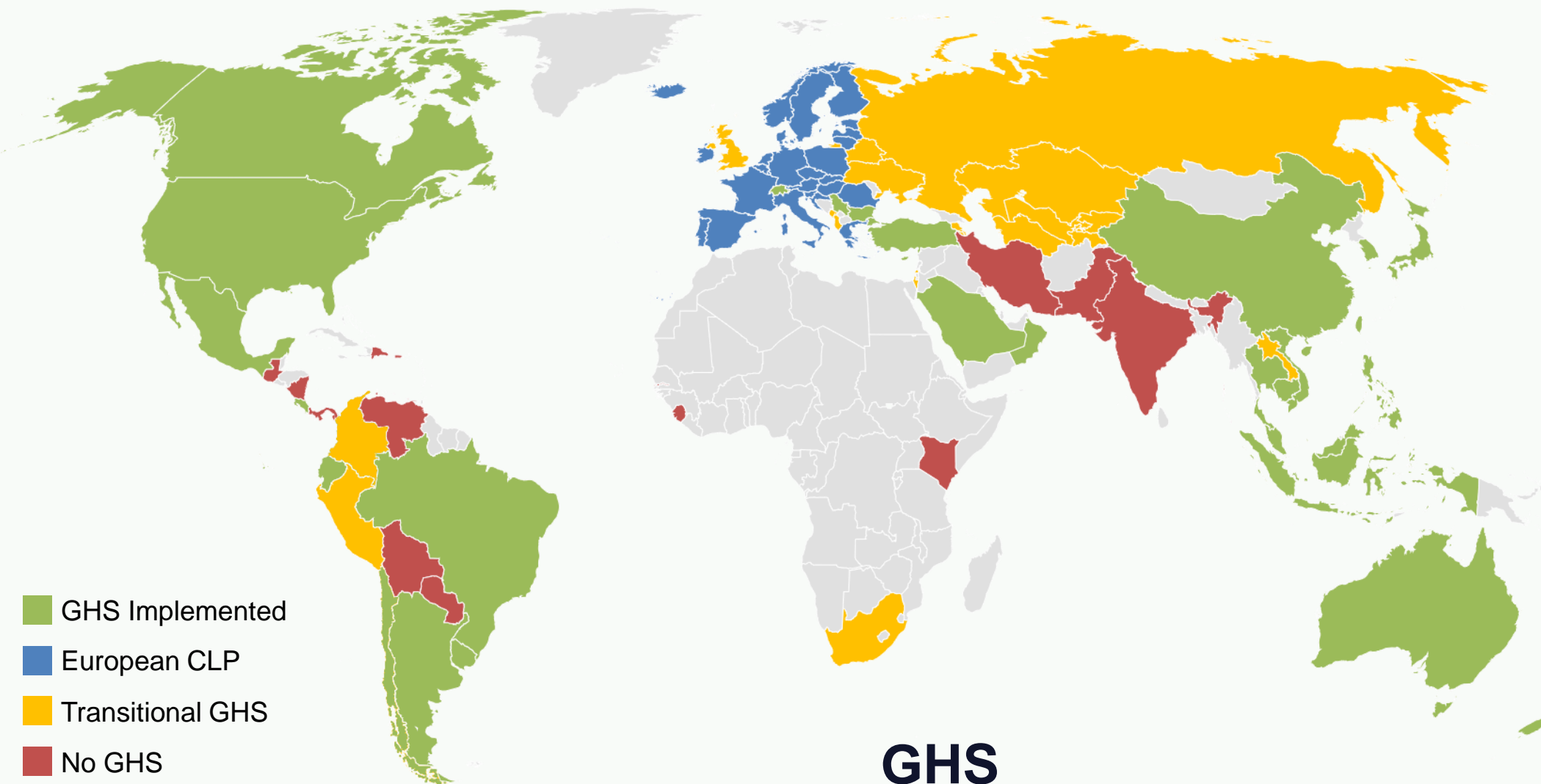Converge regulatory guidelines, including the GHS version adopted within the bloc

Events & Partnerships
- Risk approach on chemicals
- Virtual Annual Meeting

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Recent Regional Initiatives (1/2)

UNEP Special Programme

Institutional strengthening for chemical clusters

1st Report

Priority Issues on Chemicals and Waste, and Potential Priority Cooperation

2015　　2016　　2017　　2019

Intergovernmental Network on Chemicals and Waste for Latin America and the Caribbean

Focused on capacity building

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

Action Plan (2019-2020)

Regional cooperation for sound management of chemicals

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Recent Regional Initiatives (2/2)

Action Plan (2021-2024)

Regional cooperation for sound management of chemicals

LARCF

Roadmap for rational management of chemicals

2020

2021

2022

Mercosur Action Plan (2021-2024)

Converge regulatory guidelines, including the GHS version adopted within the bloc
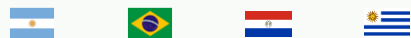
Events & Partnerships

- Risk approach on chemicals
- Virtual Annual Meeting

Countries Progression

Globally Harmonized System (GHS)

Worldwide Status

GHS Implemented
European CLP
Transitional GHS
No GHS

GHS

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Latin America GHS Status (1/5)

Mexico

Costa Rica

Colombia

Ecuador

Peru

Bolivia

Chile

Venezuela

Brazil

Paraguay

Uruguay

Argentina

Implemented

Transitional / Draft

Not foreseen

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Latin America GHS Status (2/5)

Mercosur

	Argentina	Brazil	Paraguay	Uruguay
GHS Version	5th version (2017)	4th version (2009)		4th version (2009)
Authority	Ministry of Labor	Ministry of Labor	Not implemented	Interministerial
Language	Spanish	Portuguese		Spanish
Regulation name	Resolution 801/2015 IRAM 41000	NR 26 ABNT 14725		Decree 307/2009 and 346/2011
Comments	-	Plans to update to GHS Rev. 7		-

Brazil

Paraguay

Uruguay

Argentina

Implemented

Transitional / Draft

Not foreseen

Mercosur is planning to harmonize regulations!

Latin America GHS Status (3/5)

Andean Community

	Bolivia	Colombia	Ecuador	Peru
GHS Version		6th version (2018)	1st (2018)	
Authority		Interministerial	Ministry of Industry/INEN	
Language	Not implemented	Spanish	Spanish	Drafting the GHS adoption together with the National Chemical Regulation
Regulation name		Decree 1469/2018 (general) Resolution 773/2021 (Ministry of Labor)	INEN 78 (2013) & 2266 (2013)	

Colombia
Ecuador
Peru
Bolivia

- Implemented
- Transitional / Draft
- Not foreseen

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Latin America GHS Status (4/5)

Mexico 🇲🇽

Colombia

Peru

Chile

- 🟩 Implemented
- 🟨 Transitional / Draft
- 🟥 Not foreseen

Pacific Alliance

	Chile	Colombia	Mexico	Peru
GHS Version	7th version (2021)	6th version (2018)	5th version (2015)	
Authority	Ministry of Health	Interministerial	Ministry of Labor	
Language	Spanish	Spanish	Spanish	
Regulation name	Decree 57/2021	Decree 1469/2018 (general) Resolution 773/2021 (Ministry of Health)	NOM 018/2015	Drafting the GHS adoption together with the National Chemical Regulation
Comments	Mandatory from February 2022	-	-	

Latin America GHS Status (5/5)

Belize

Dominican Republic

Honduras

Nicaragua

Guatemala

El Salvador

Costa Rica

Panama

Implemented

Transitional / Draft

Not foreseen

Central American Integration System

Belize	Costa Rica	Dominican Republic	El Salvador
Guatemala	Honduras	Nicaragua	Panama

Costa Rica

GHS Version	6th version (2015)
Authority	Ministry of Health
Language	Spanish
Regulation name	RTCR 478/2015 (control) RTCR 481/2015 (labeling)

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GHS as a Gateway

GHS adoption

National Regulation

- Implemented
- Transitional / Draft
- Not foreseen
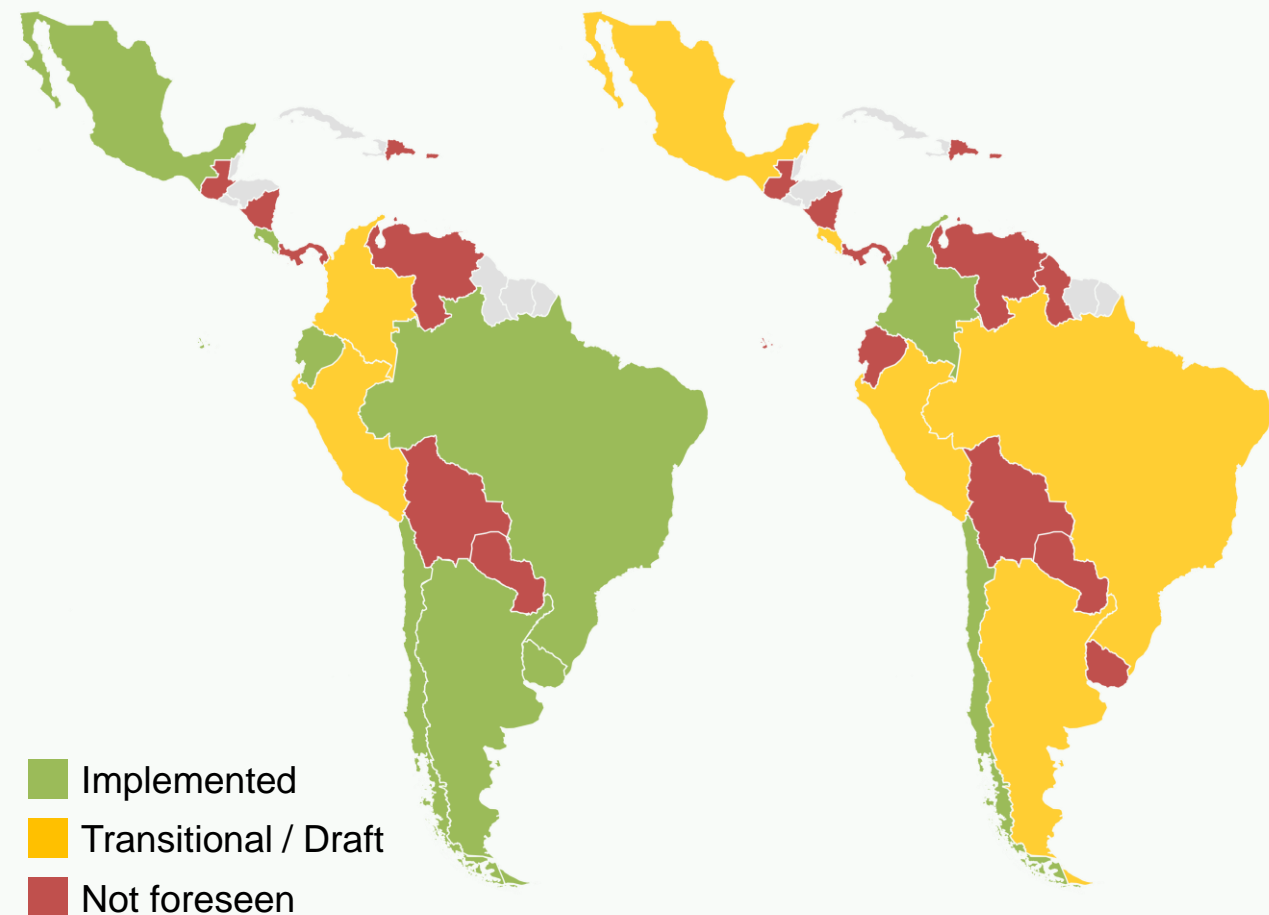
Country	GHS	National Regulation
Argentina	▲	▶
Bolivia	▼	▼
Brazil	▲	▶
Chile	▲	▲
Colombia	▶	▲
Costa Rica	▲	▼
Ecuador	▲	▼
Guatemala	▼	▼
Mexico	▲	▶
Paraguay	▼	▼
Peru	▶	▶
Uruguay	▲	▼
Venezuela	▼	▼

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Countries Progression

National Chemical Regulations

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Worldwide Status

Implemented
Transitional / Draft
Not foreseen
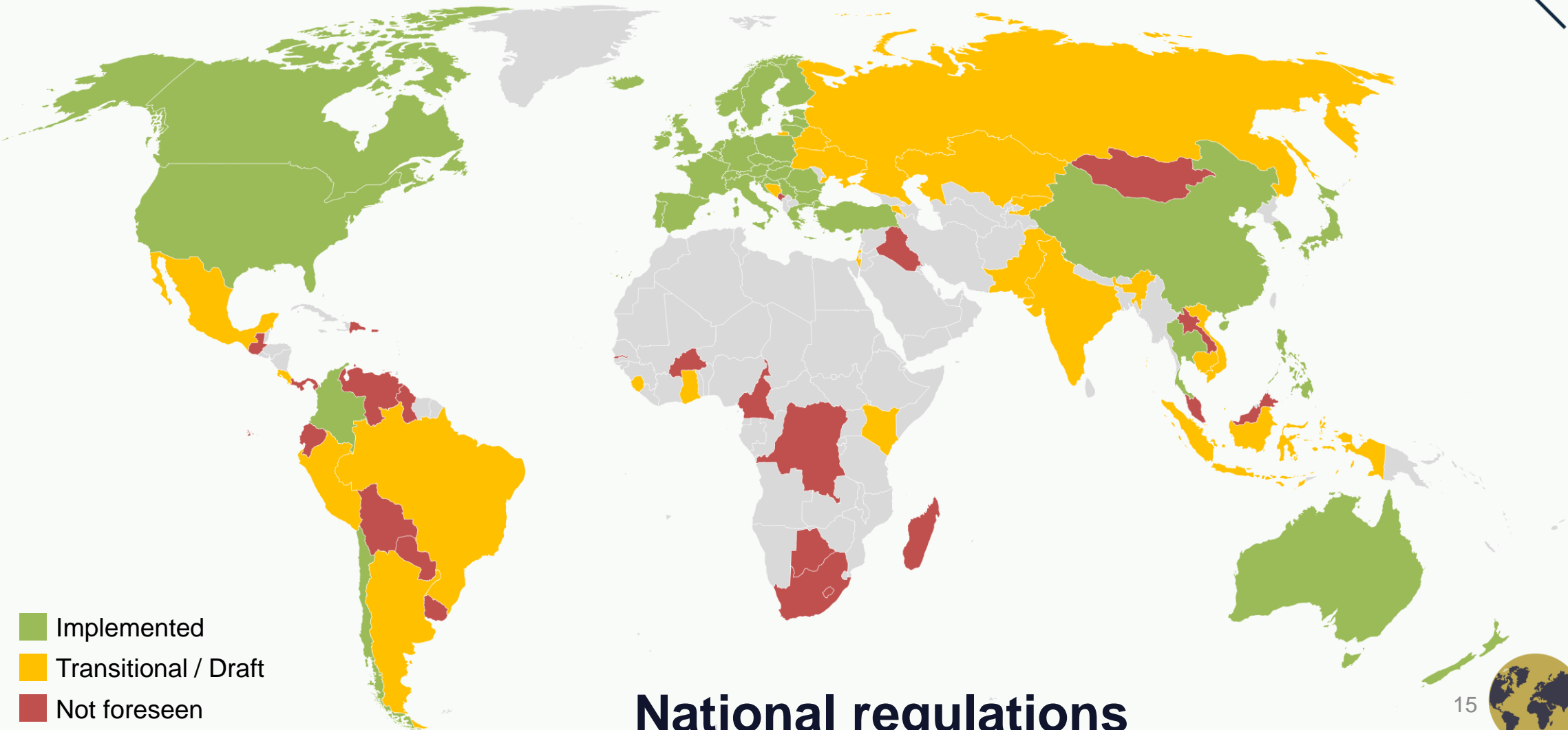
National regulations

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Latin America Regulation Status

Legend (map):
- 🟩 Implemented
- 🟨 Transitional / Draft
- 🟥 Not foreseen

Country	GHS	National Regulation	OECD Member
Argentina	▲	▶	▶ Prospective
Bolivia	▼	▼	▼ -
Brazil	▲	▶	▶ Key Partner; Prospective
Chile	▲	▲	▲ Since 2010
Colombia	▲	▲	▲ Since 2020
Costa Rica	▲	▼	▲ Since 2021
Ecuador	▲	▼	▼ -
Guatemala	▼	▼	▼ -
Mexico	▲	▶	▲ Since 1994
Paraguay	▼	▼	▼ -
Peru	▶	▶	▶ Prospective
Uruguay	▲	▼	▼ -
Venezuela	▼	▼	▼ -

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Chile

NCh 382

National Chemical Safety Policy Action Plan 2017–2022

Final Draft *Contraloría*

| 2003 | 2004 | 2016 | 2017 | 2018 | 2020 | 2021 |

NCh 2.190

Decree 43

Feb.

National Regulation

Public Comments

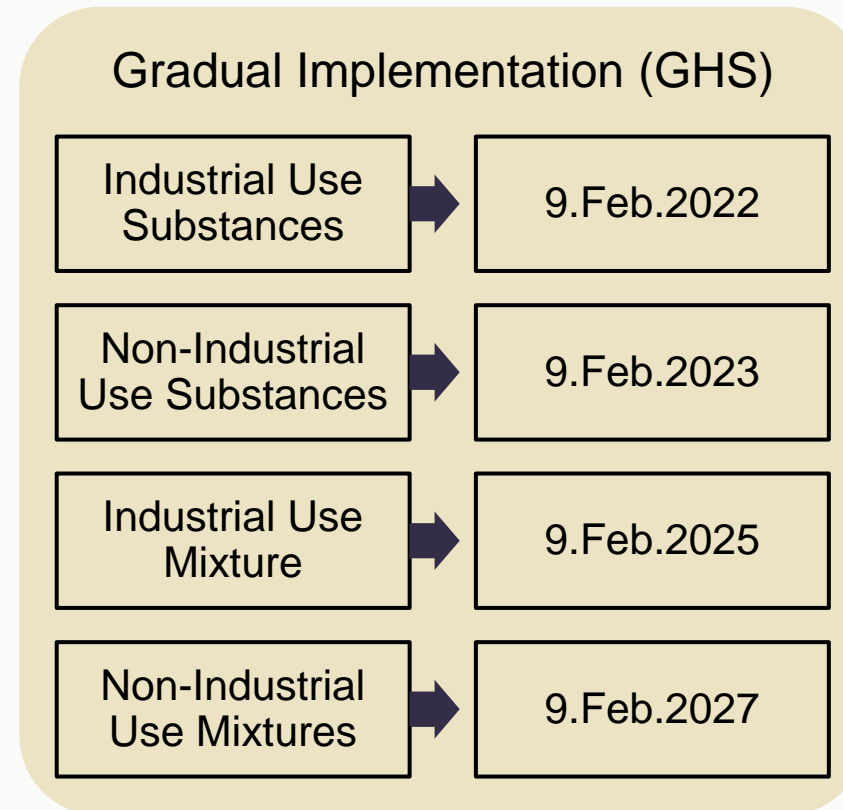Feb.
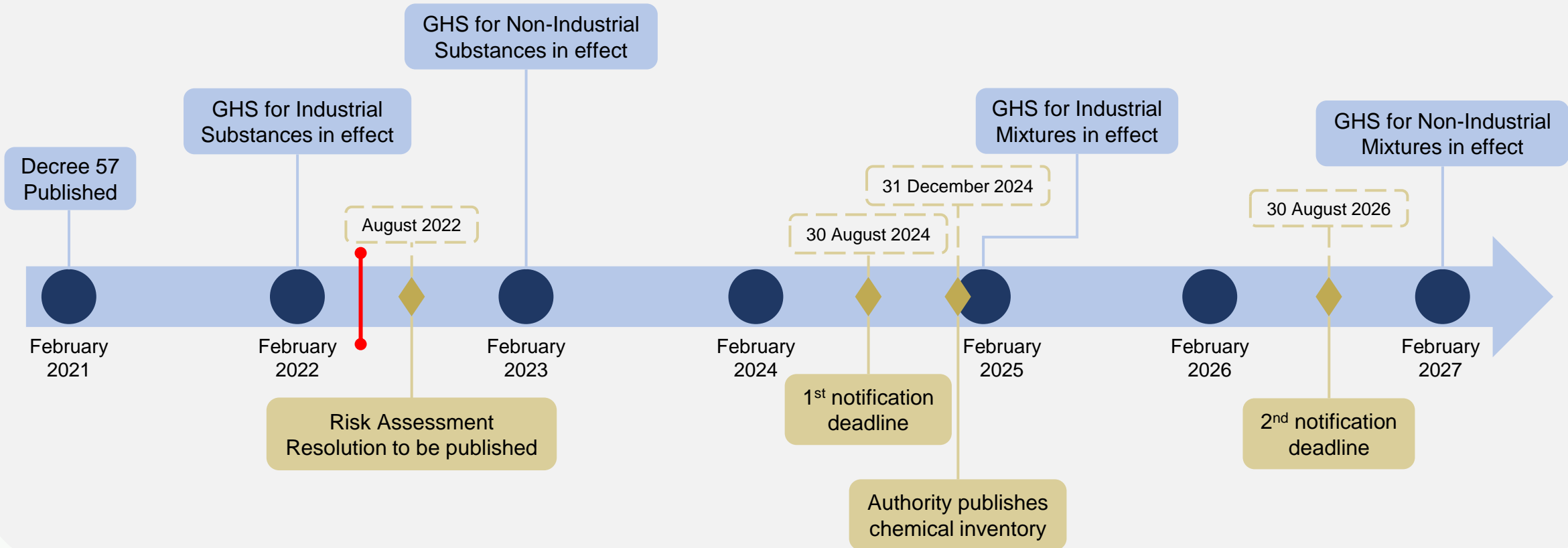
Decree 57

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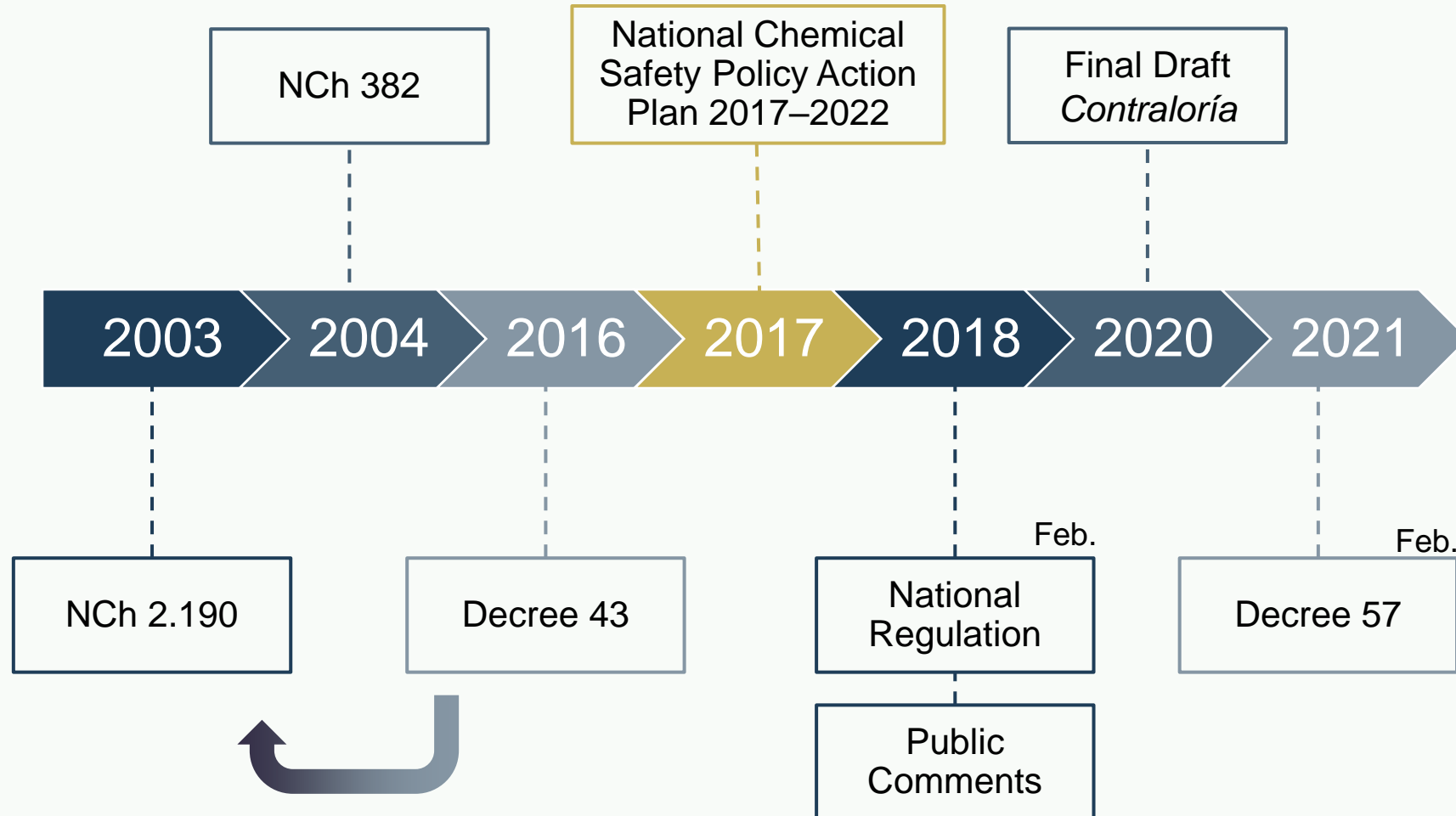
Chile

Decree 57: Regulation on the classification, labeling and notification of chemical substances and mixtures (2021)

- Authority: Ministry of Health

- National Chemical Regulation

- Make GHS mandatory (7th version)

- Manufacturers/importers >1ton/year
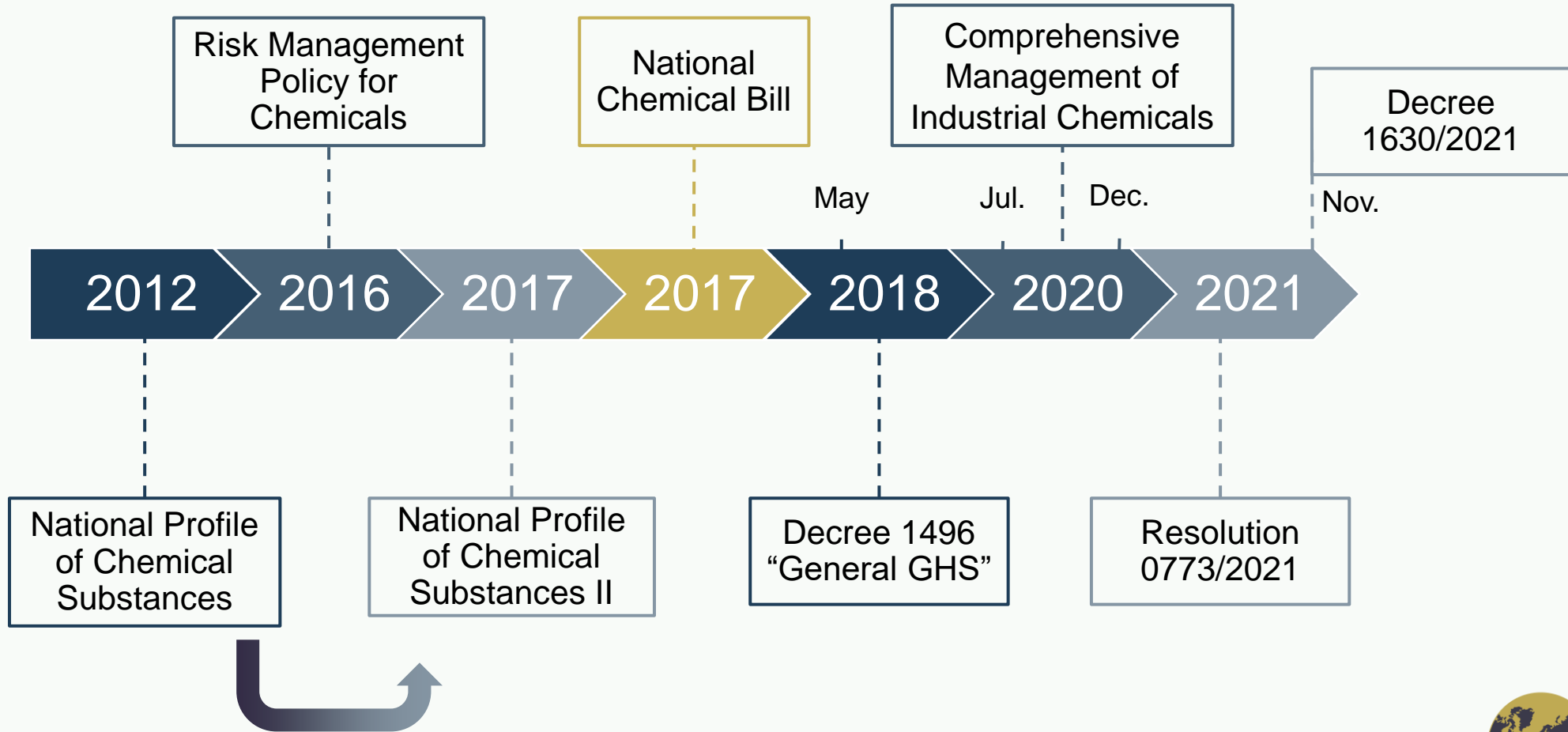
- Updates made every 2 years

Gradual Implementation (GHS)

Industrial Use Substances	9.Feb.2022
Non-Industrial Use Substances	9.Feb.2023
Industrial Use Mixture	9.Feb.2025
Non-Industrial Use Mixtures	9.Feb.2027

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Chile

GHS for Non-Industrial Substances in effect

GHS for Industrial Substances in effect

GHS for Industrial Mixtures in effect

GHS for Non-Industrial Mixtures in effect

Decree 57 Published

31 December 2024

30 August 2024

August 2022

30 August 2026

February 2021

February 2022

February 2023

February 2024

February 2025

February 2026

February 2027

Risk Assessment Resolution to be published

1st notification deadline

Authority publishes chemical inventory

2nd notification deadline

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Colombia

Resolution 0773/2021: GHS in the Labor Sector

- Authorities: Ministry of Labor
- Adopts GHS 6th version
- Follows European CLP

GHS Transitional periods

Substances	Mixtures
↓	↓
7.Apr.2023	7.Apr.2024
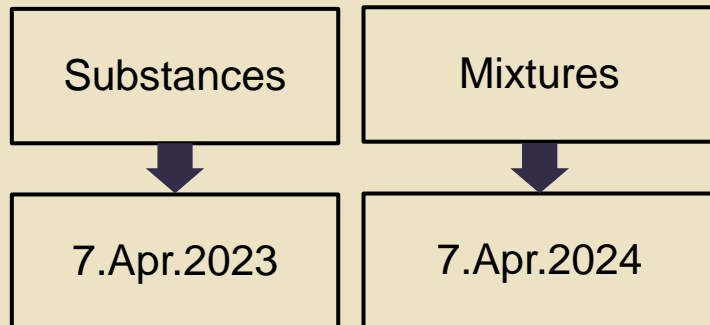
Decree 1630/2021: Chemical Regulatory Framework in Colombia

- Authorities: Cooperation between Ministries
  - (Commerce, Labor, Health, and Environment)
- New Managing Instruments
  - Chemical Inventory
  - Prioritization of Chemicals
  - Risk Evaluation & Risk Reduction
- New Monitoring Programs
  - Registry for Emission and Transfer of Contaminants (RETC)
  - Toxicological Management System (SGT)

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Colombia

+ 6 Months

The ministries cooperation will announce the:

- *Computer Software*
- *Guiding Manual*

+ 6 Months

After the initial notification period, new substances must be notified within a 6-month deadline

+ 3 Years

Manufacturers and importers will have a 3-year window to submit their 1st substance notification after the Computer Software release

Yearly Updates

Manufacturers and importers shall submit early updates into the Computer Software

November 30, 2021

Decree 1630 published
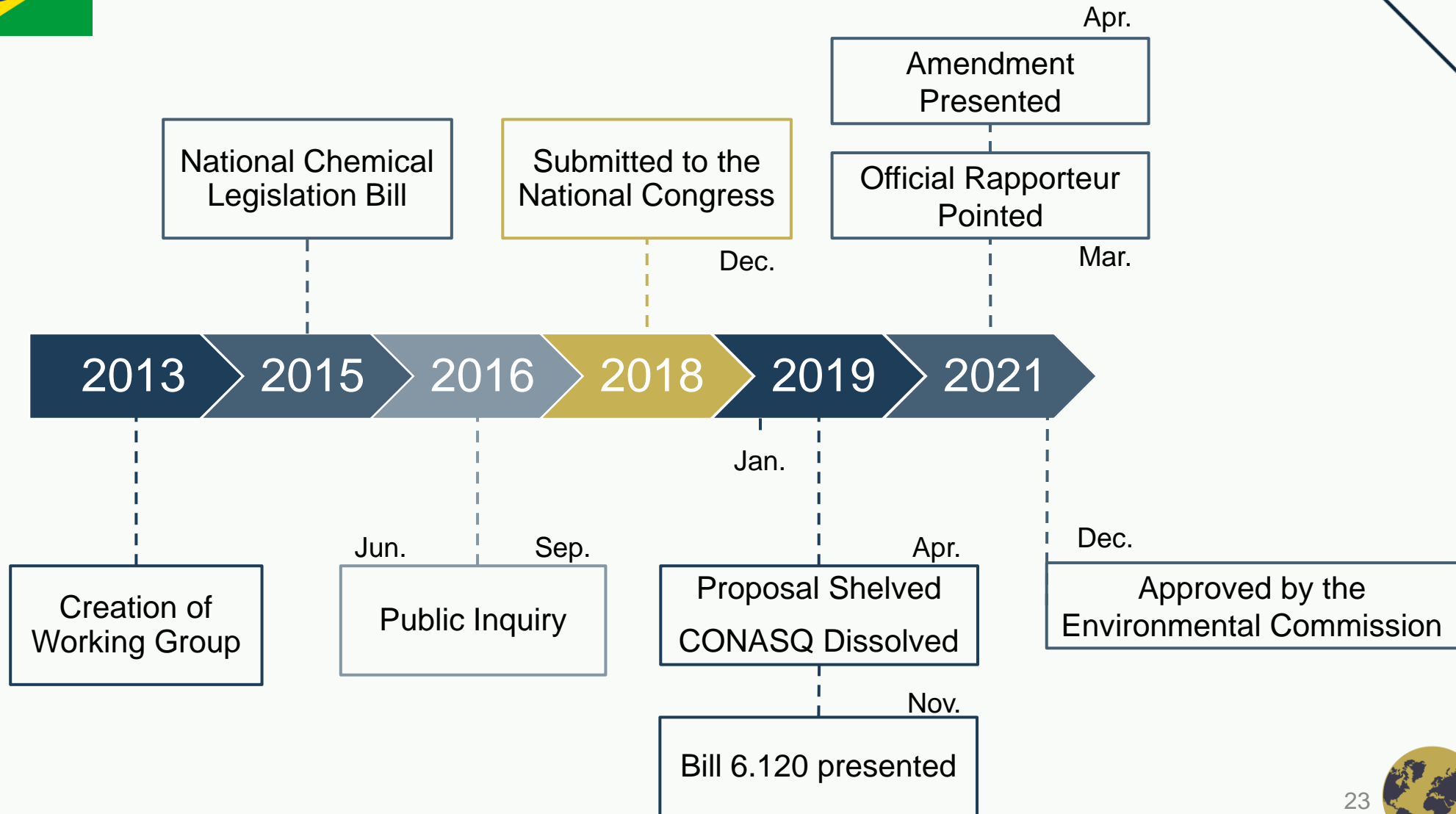
November 2021 • May 30, 2022 // May 30, 2025 • November 30, 2025 • May 30, 2026
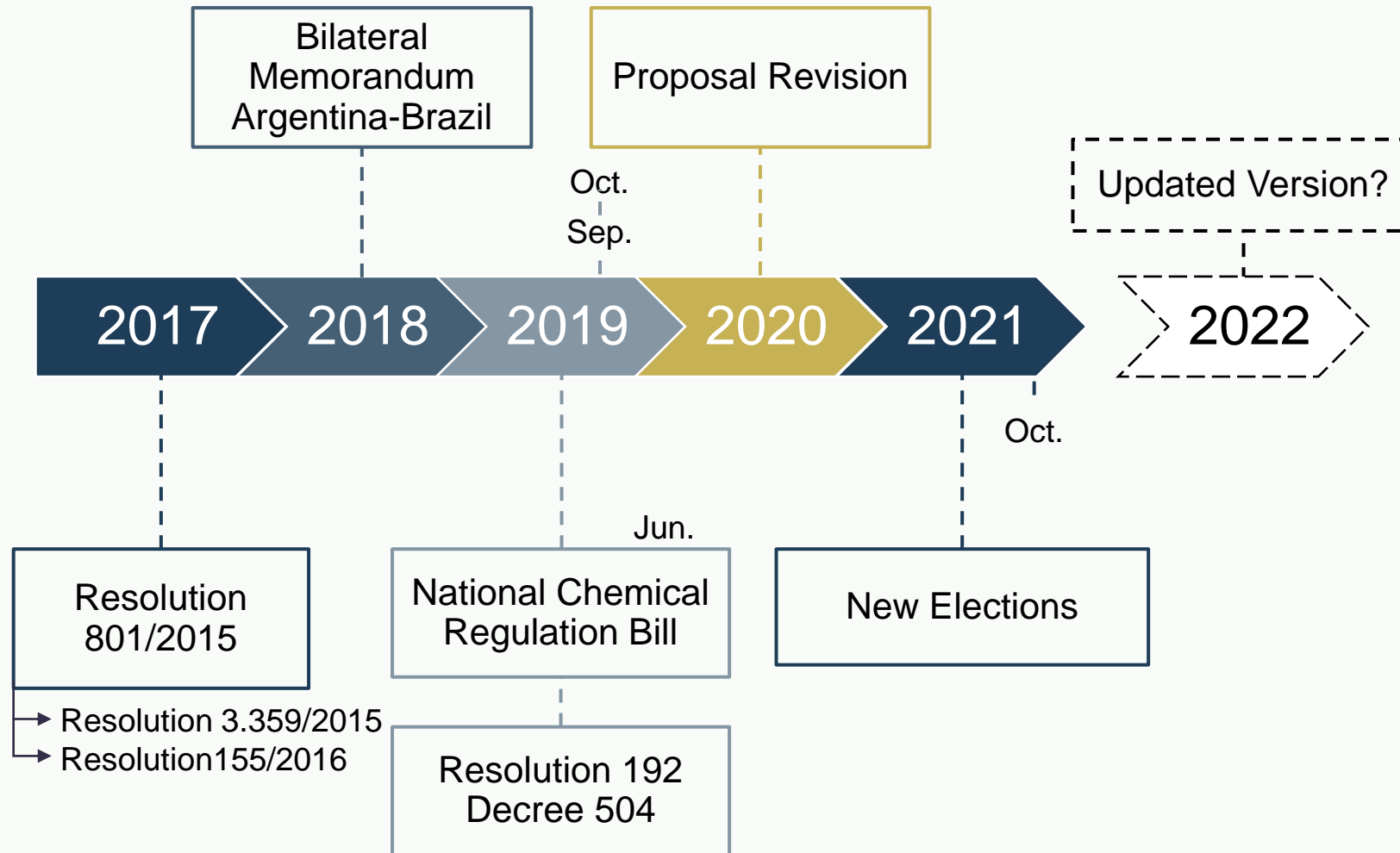
Transitional Period

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Brazil

2013 — Creation of Working Group

2015 — National Chemical Legislation Bill

2016 — Public Inquiry (Jun. — Sep.)

2018 — Submitted to the National Congress (Dec.)

2019 — Proposal Shelved / CONASQ Dissolved (Jan. — Apr.); Bill 6.120 presented (Nov.)

2021 — Amendment Presented (Apr.); Official Rapporteur Pointed (Mar.); Approved by the Environmental Commission (Dec.)

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Brazil

Bill 6.120/2019: Provides for the inventory, evaluation and control of chemical substances

- Amendment captures important elements (e.g., Register of Substances)

- Scope Manufacturers and Importers >1ton/year

- Has to be approved by 4 commissions in the Deputies' Chamber

    - Approved by the Environmental Commission on December 17, 2021

    - Now, the regulation is under the <u>Social Security and Family</u> Commission's analysis

Argentina

Bilateral Memorandum Argentina-Brazil

Proposal Revision

Updated Version?

Oct.

Sep.

| 2017 | 2018 | 2019 | 2020 | 2021 | 2022 |

Oct.

Jun.

Resolution 801/2015

National Chemical Regulation Bill

New Elections

→ Resolution 3.359/2015
→ Resolution155/2016

Resolution 192 Decree 504

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Argentina

Chemical Regulation (last draft, 2019)

- Authority: Ministry of Labor

- Special Committee for Chemical Evaluation

- Priority List for Chemical Management

- Annual Update from Manufacturers and Importers

- 3 years transitional time

What is expected?

- Argentina is held elections in October 2021
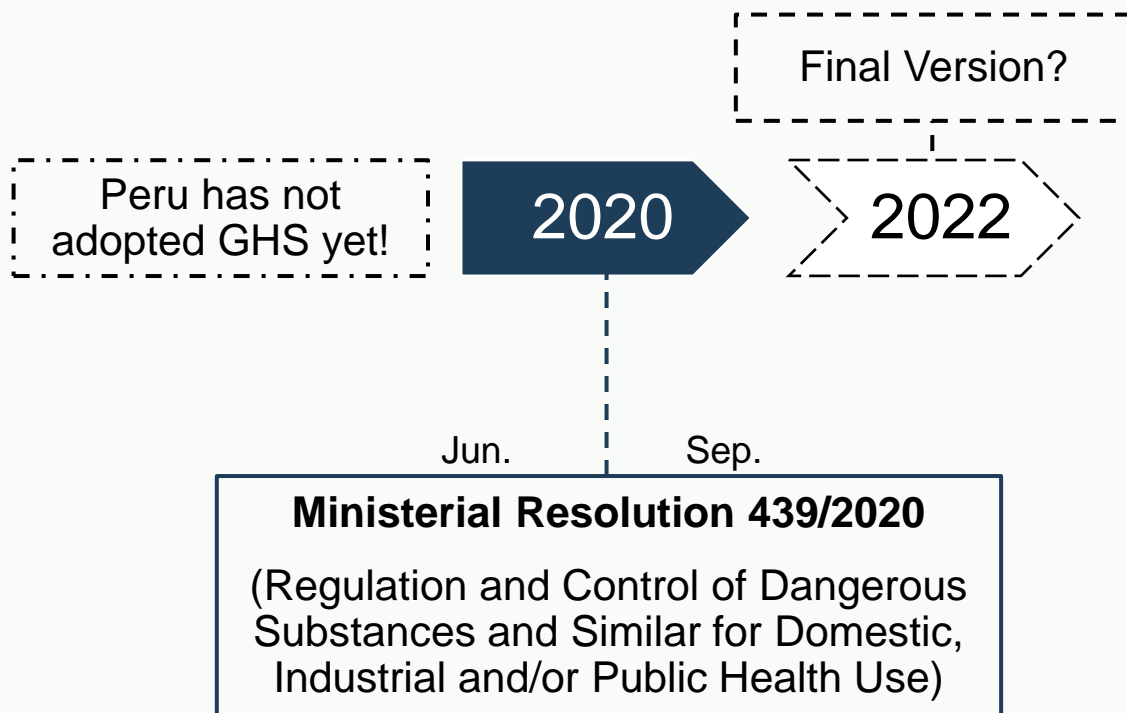
- Updated version may be published soon

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Mexico

Comprehensive National Policy for the Management of Chemical Substances

National Inventory of Chemicals Update

Updated Version?

| 2009 | 2014 | 2015 | 2019 | 2020 | 2022 |

GHS 5th revison
NOM-018-STPS-2015

Initial Chemical Inventory

Dec.

Changes to the Proposal (ANIQ)
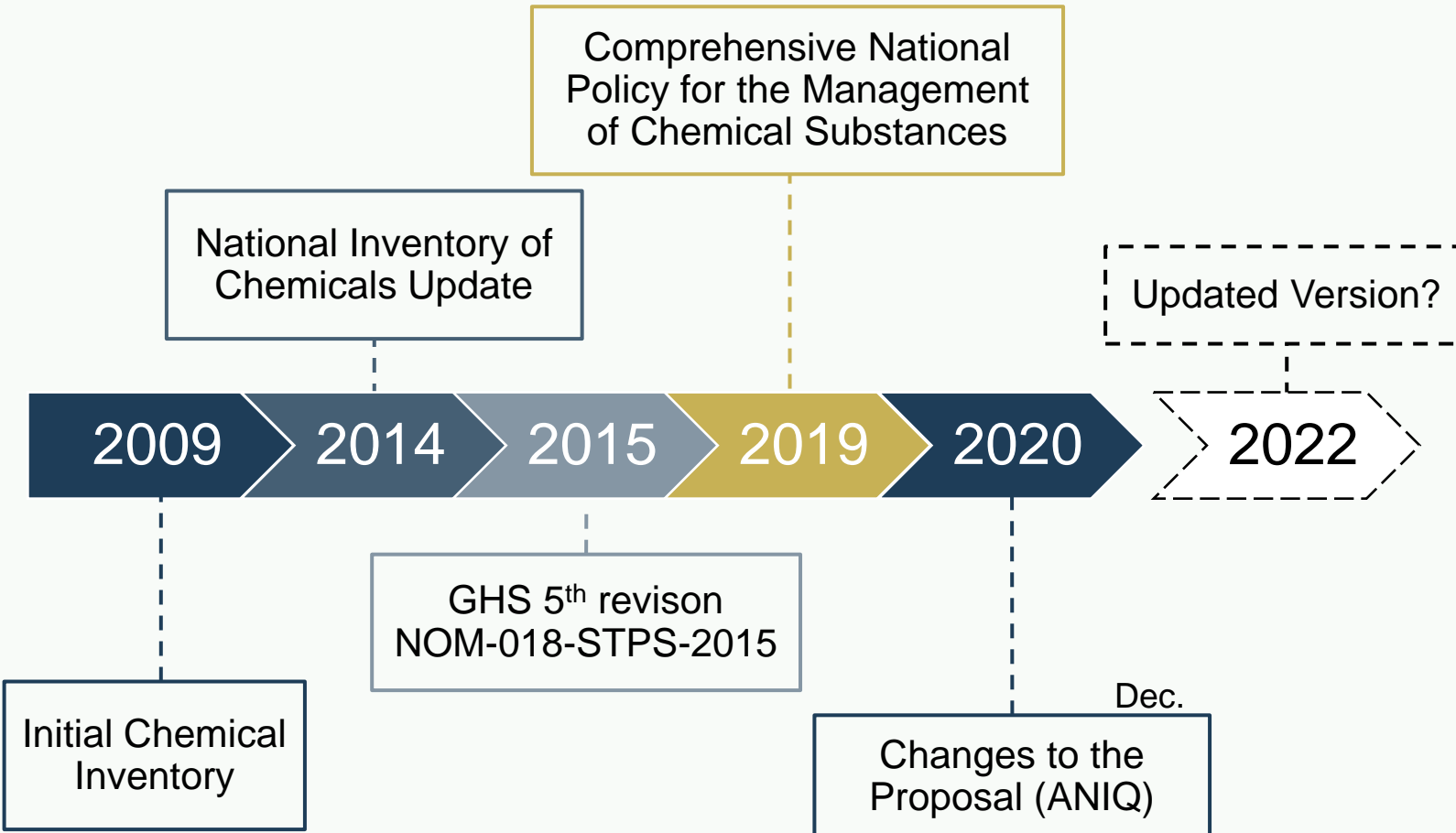
Main Differences between Proposals:

- The initial proposal is formulated by General Health Council (CSG)

- ANIQ is the Chemical Industry Association

Inventory *vs.* Registry

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Peru

Peru has not adopted GHS yet!

2020 → 2022

Final Version?

Jun.   Sep.

Ministerial Resolution 439/2020

(Regulation and Control of Dangerous Substances and Similar for Domestic, Industrial and/or Public Health Use)

Regulation and Control of Dangerous Substances and Similar for Domestic, Industrial and/or Public Health Use (Ministerial Resolution 439/2020):

- Authority: Ministry of Health

- Creates a National Register of Chemicals

- Address the Classification and Labeling

- Substances under a Risk Assessment

- Substances of VHC under Risk Management

- Proposes an Authorization Renewal every 3 years

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Summing Up

Country	Argentina*	Brazil*	Chile	Costa Rica
Observation	Prospective OECD member	OECD key partner (requested to join in 2017)	OECD member (2010)	OECD member (2021)
National Legislation	Regulatory framework for chemical substances risk management (Bill 4.339/2019)	Implements the inventory, risk assessment and control of chemical substances (Draft, 2018; Bill 6.120/2019)	Regulations for the classification, labeling and notification of hazardous chemicals and mixtures (Decree 57)	Draft starting
Risk consideration under	Government	Government	Industry	Industry (expected)
Amount threshold	≥ 1 ton/year	≥ 1 ton/year	≥ 1 ton/year	not decided
Status	Delivered to Congress in September 2019	Draft (2018) shelved; Bill 6.120/2019 under revision in Deputy Chamber	At official gazette on February 2021	In early developing stage

*In January, OECD opened an accession discussion for candidate countries: Argentina, Brazil, and Peru.

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Summing Up

Country	Colombia	Mexico	Peru*
Observation	OECD member (2020)	OECD member (1994)	Prospective OECD member
Legislation Name	Comprehensive Management of Industrial Chemical Substances, including risk management	Comprehensive National Policy for Management of Chemical Substances (2019)	Regulation and control of dangerous substances and similar for domestic, industrial and / or public health use (MINSA 439/2020)
Risk consideration under	Industry	Industry (expected)	Industry (expected)
Amount threshold	≥ 100 Kg /year	-	No threshold
Status	At official Gazette on November 30, 2021	The Industry association proposed changes to the current draft (Dec. 2020)	Joint GHS and chemical regulation to be close implemented. Public consultation ended on September 24, 2020

*In January, OECD opened an accession discussion for candidate countries: Argentina, Brazil, and Peru.

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Take-home Messages

Latin America is considered an Hotspot

- At least 6 countries are working on Chemical Regulations

Chemical industry associations have great impact on the proposals

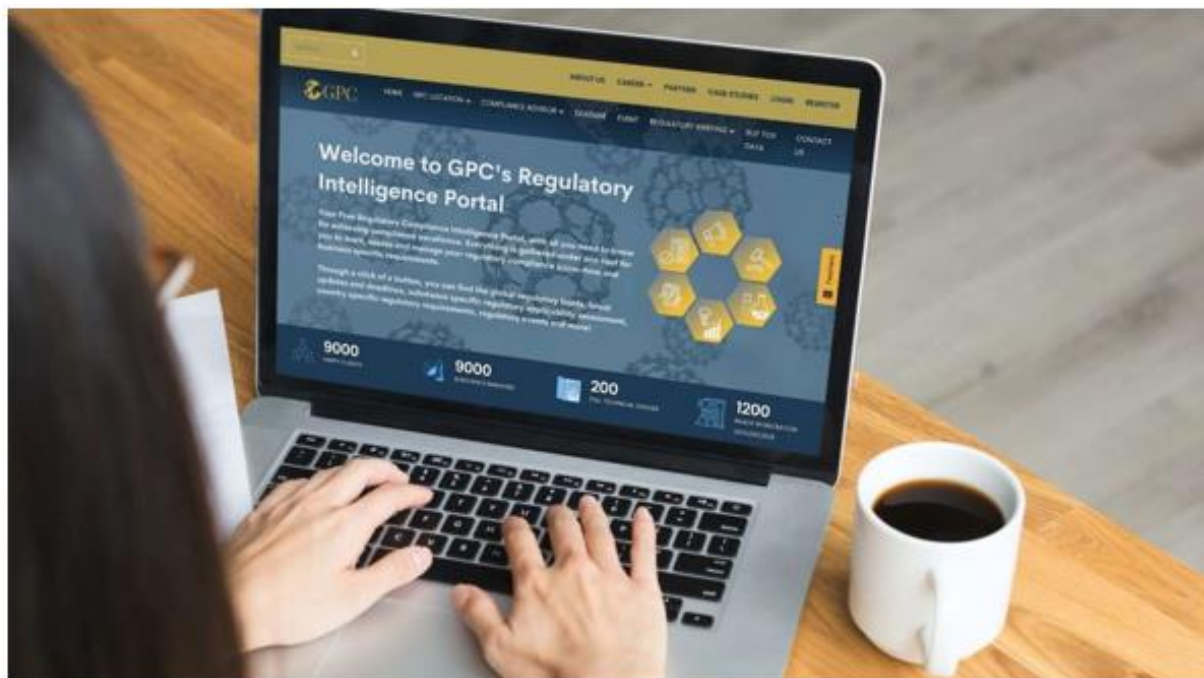General elections can considerably influence the legislative proposal fate

Regional Drivers:

- Willingness to join OECD

- Existing regulation: EU REACH, UK REACH, US TSCA …

The sure thing is that chemical regulations will take place sooner or later

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- 60+ regulatory summaries

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