

Chemical Regulatory Updates in Latin America

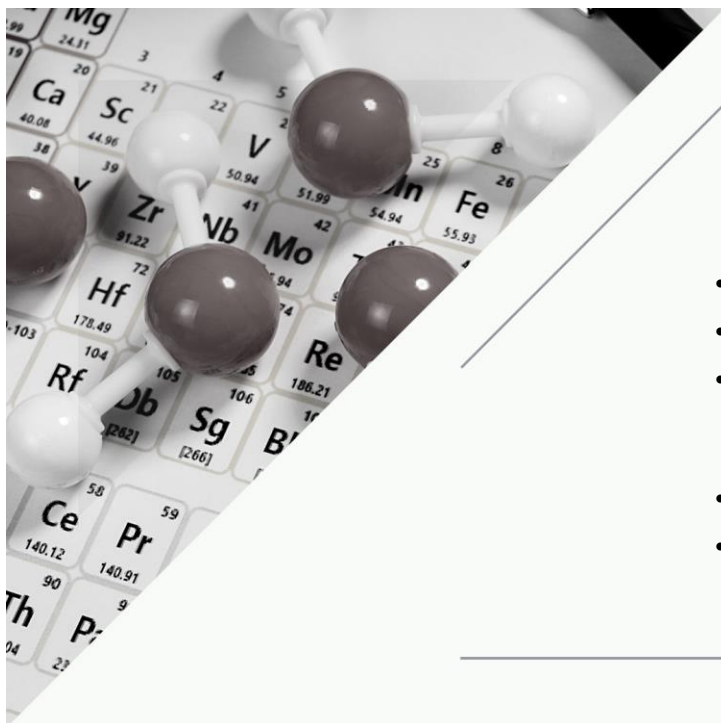
An Overview of Regional and National Developments



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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



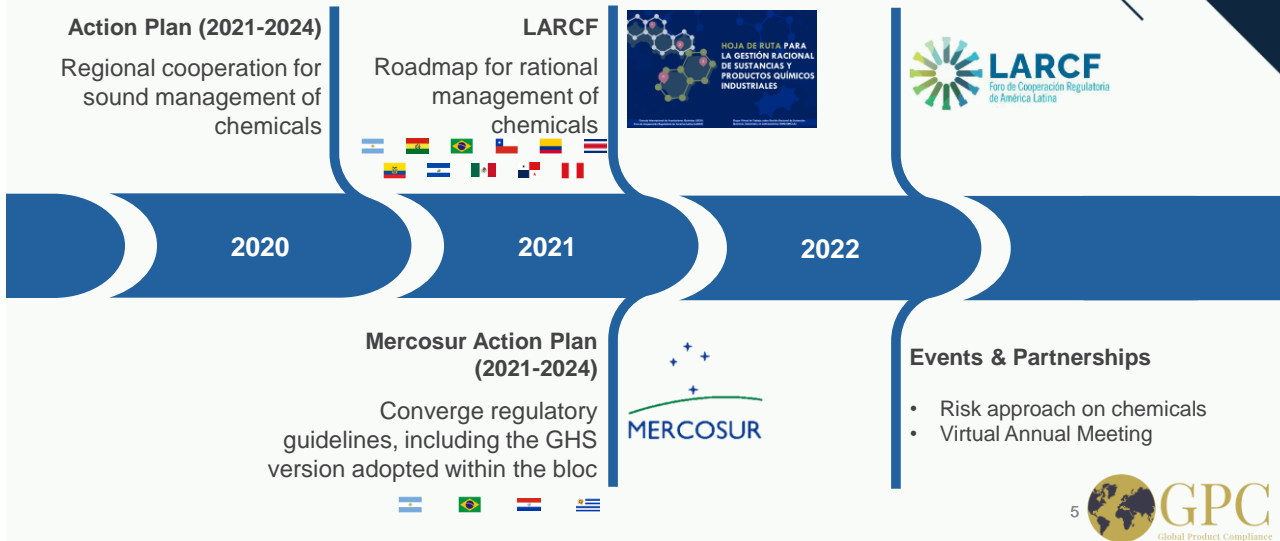
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Recent Regional Initiatives (1/2)



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Recent Regional Initiatives (2/2)



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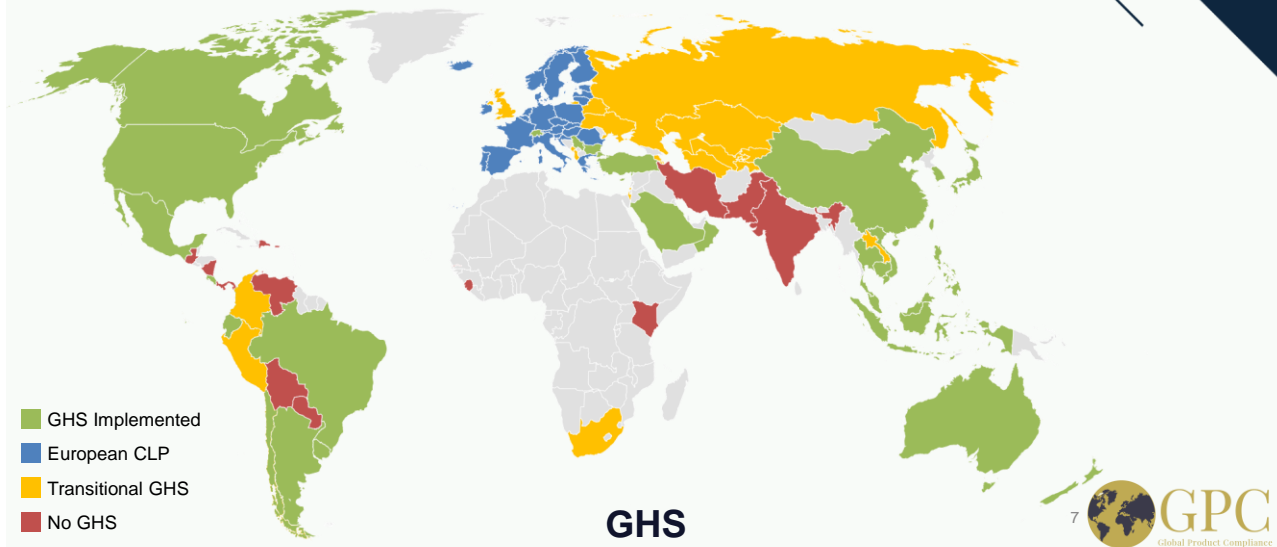
Countries Progression

Globally Harmonized System (GHS)



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Worldwide Status



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Latin America GHS Status (1/5)



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Latin America GHS Status (2/5)



Mercosur

	Argentina	Brazil	Paraguay	Uruguay
GHS Version	5 th version (2017)	4 th version (2009)	Not implemented	4 th version (2009)
Authority	Ministry of Labor	Ministry of Labor		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		-

Mercosur is planning to harmonize regulations!



Latin America GHS Status (3/5)



Andean Community

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



Latin America GHS Status (4/5)



Pacific Alliance

	Chile	Colombia	Mexico	Peru
GHS Version	7 th version (2021)	6 th version (2018)	5 th version (2015)	Drafting the GHS adoption together with the National Chemical Regulation
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	
Comments	Mandatory from February 2022	-	-	



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Latin America GHS Status (5/5)



Central American Integration System

Belize	Costa Rica	Dominican Republic	El Salvador
Guatemala	Honduras	Nicaragua	Panama

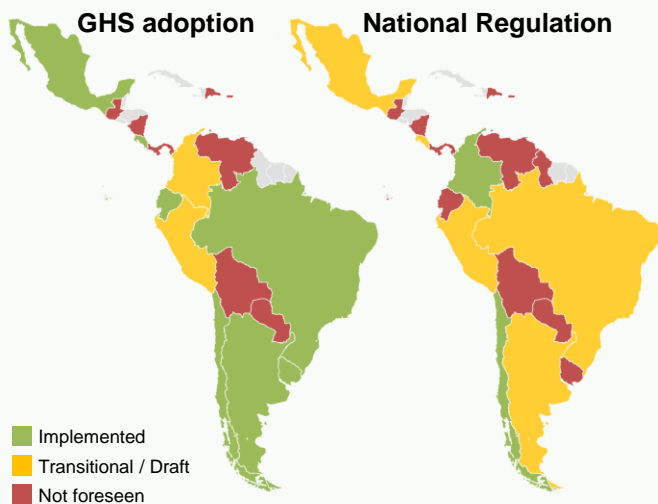
Costa Rica

GHS Version	6 th 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



Country	GHS	National Regulation
Argentina	▲	▶
Bolivia	▼	▼
Brazil	▲	▶
Chile	▲	▲
Colombia	▶	▲
Costa Rica	▲	▼
Ecuador	▲	▼
Guatemala	▼	▼
Mexico	▲	▶
Paraguay	▼	▼
Peru	▶	▶
Uruguay	▲	▼
Venezuela	▼	▼

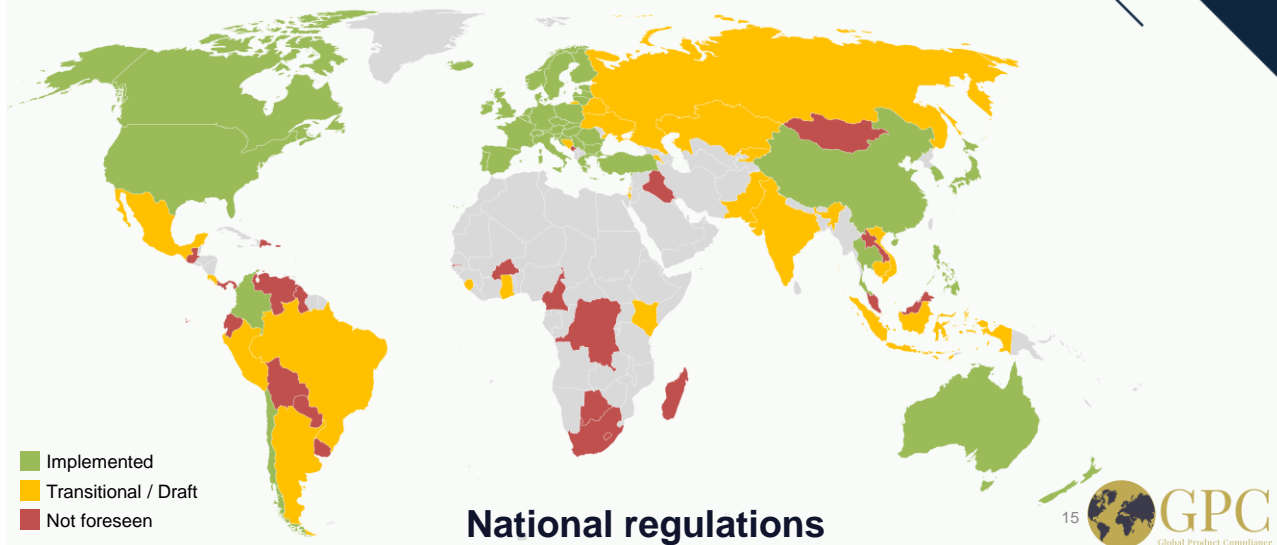


Countries Progression

National Chemical Regulations



Worldwide Status



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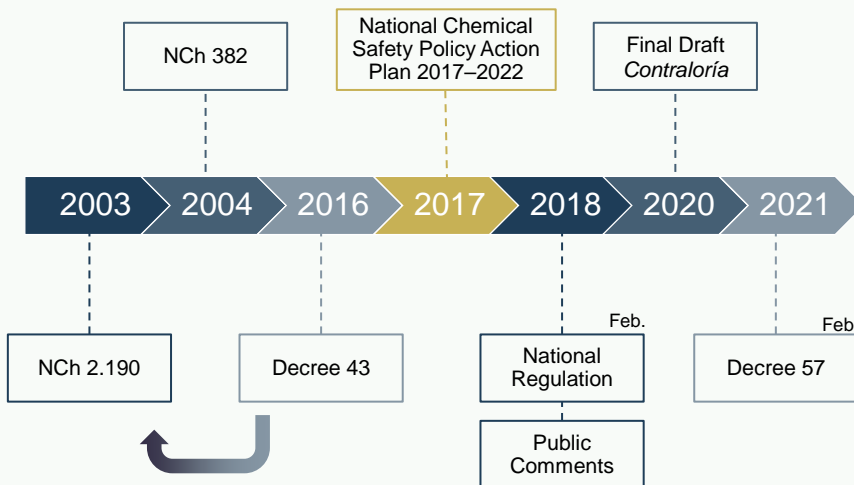
Latin America Regulation Status



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Chile



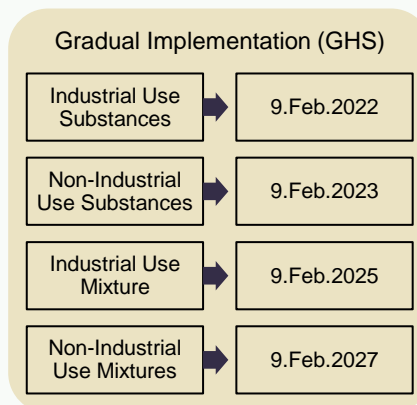
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Chile

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

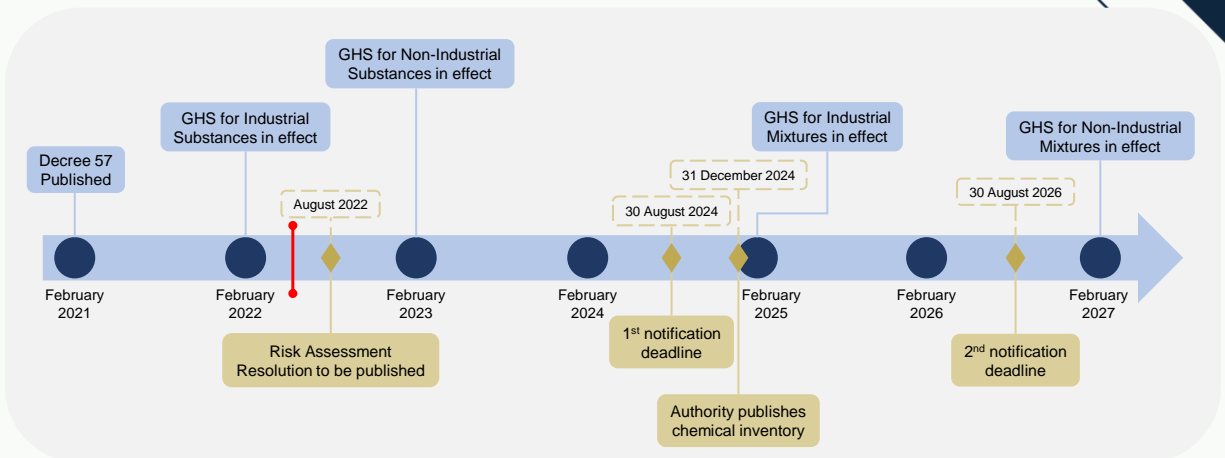
- Authority: Ministry of Health
- National Chemical Regulation
- Make GHS mandatory (7th version)
- Manufacturers/importers >1ton/year
- Updates made every 2 years



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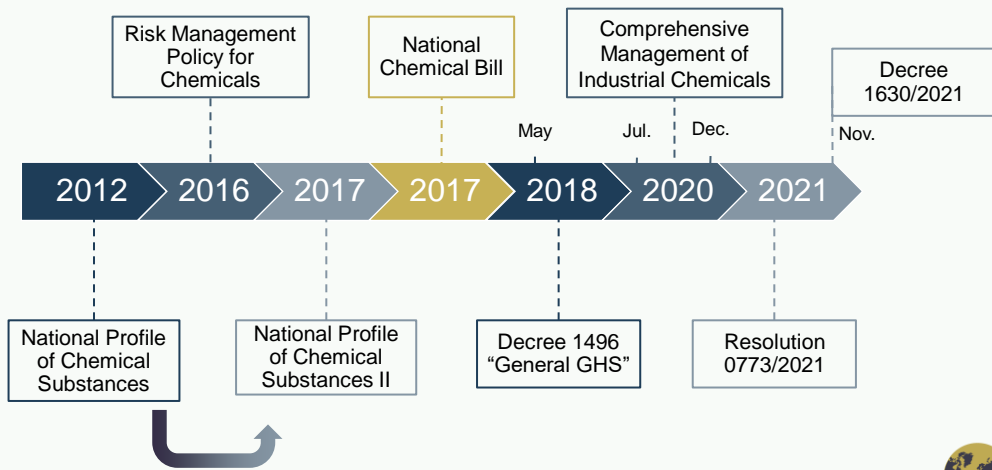
Chile



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Colombia



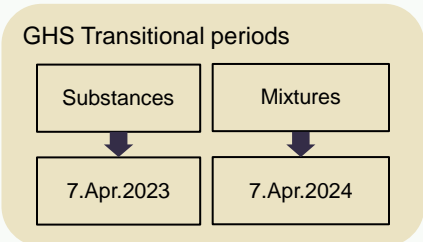
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Colombia

Resolution 0773/2021: GHS in the Labor Sector

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

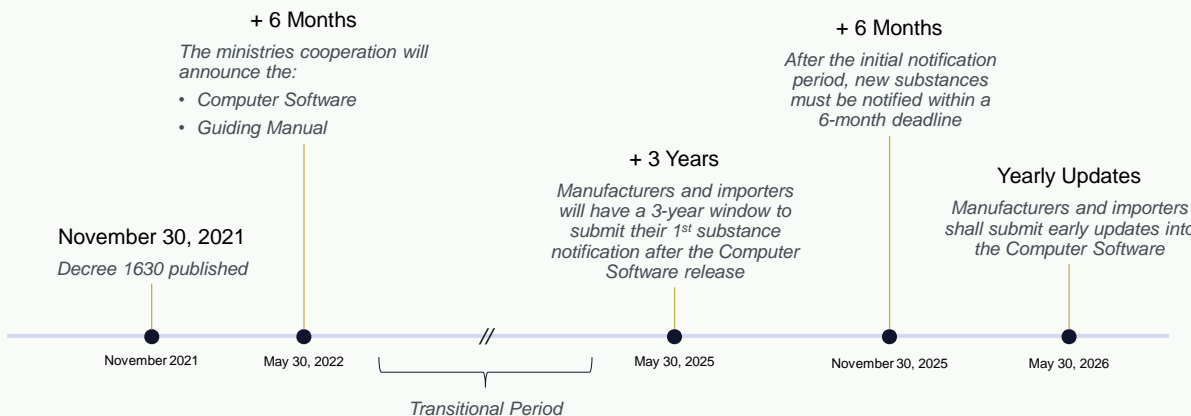


Decree 1630/2021: Chemical Regulatory Framework in Colombia

- 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)

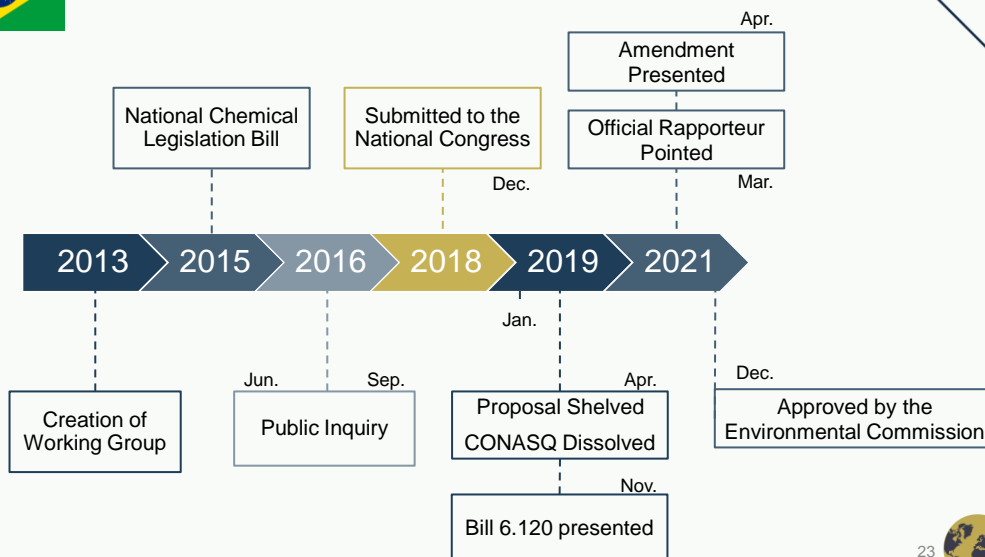


Colombia





Brazil



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Brazil

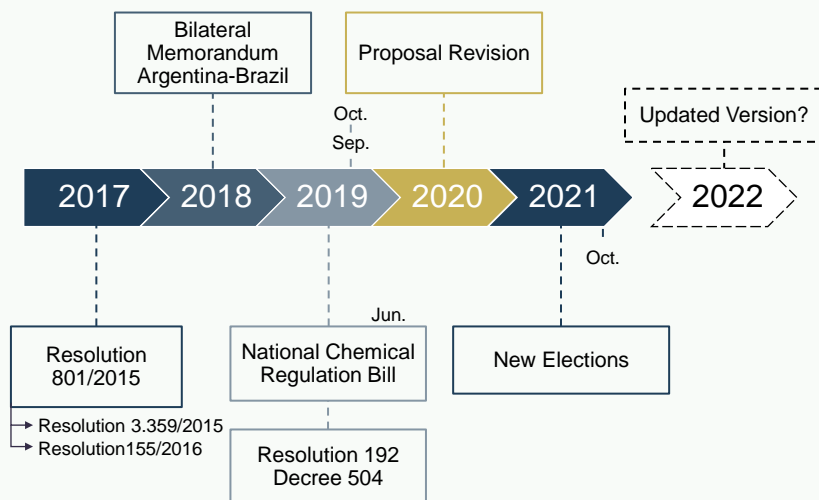
Bill 6.120/2019: Provides for the inventory, evaluation and control of chemical substances

- 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 Social Security and Family Commission's analysis

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Argentina



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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

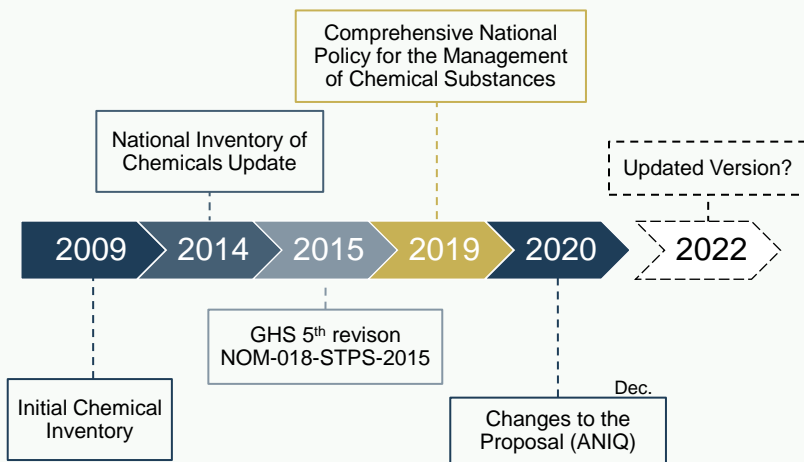
What is expected?

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

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Mexico



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



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 (MINSAs 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 ...

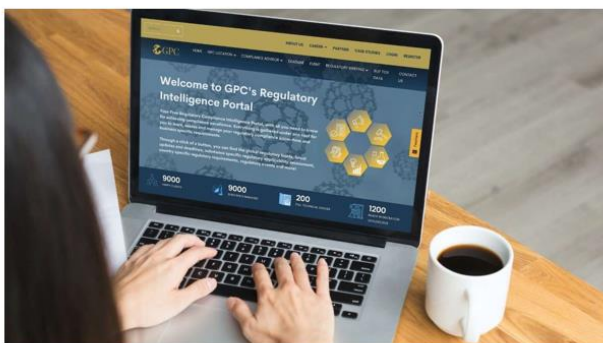


The sure thing is that chemical regulations will take place sooner or later



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