



# Chemicals Regulation in Latin America: The Existing and Future Patchwork

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# Overview

- International Drivers
- Commonalities
- Types of Existing Laws
- Future Directions



# International Drivers



## TAKEAWAYS

- ✓ Assume adoption of major treaties – but with differences
- ✓ Awareness and dialogue about global chemicals issues

# International Commitments

		ARGENTINA	BRAZIL	CHILE	COLOMBIA	COSTA RICA	ECUADOR	MEXICO	PERU
<b>Basel Convention</b>	Hazardous Wastes	X	X	X	X	X	X	X	X
<b>Climate Change Convention &amp; Paris Agreement</b>	GHGs	X	X	X		X	X	X	X
<b>Stockholm Convention</b>	Persistent Organic Pollutants (POPs)	X	X	X	X	X	X	X	X
<b>Rotterdam Convention</b>	Prior informed consent procedure hazardous chemicals and pesticides	X	X	X	X	X	X	X	X
<b>Minamata Convention</b>	Mercury	X	X			X	X	X	X
<b>Montreal Protocol</b>	Ozone depleting substances	X	X	X	X	X	X	X	X
<b>Chemical Weapons Convention</b>	Chemicals used to make chemical weapons	X	X	X	X	X	X	X	X
<b>Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances</b>	Narcotics and Precursor Chemicals	X	X	X	X	X	X	X	X
<b>GHS Adoption</b>	Classification and Labeling of Chemicals	X	X		X	X	X	X	
<b>OECD Members</b>	Organization for Economic Co-operation and Development			X	IN PROGRESS	IN PROGRESS		X	
<b>MERCOSUR Members (Also Paraguay, Uruguay, Venezuela (suspended))</b>	Southern Common Market: Customs union and trading bloc	X	X						
<b>Andean Community Members (Also Bolivia)</b>	Customs union and trading bloc				X		X		X

# Administrative Commonalities

## Agency Commonalities

- Chemicals regulated by several agencies
  - Primary Agencies: Health, Agriculture, Environment, Customs, Labor, Transportation, Security
  - Lack coordination/jurisdictional issues/overlap
  - Role for states/provinces in some jurisdictions
- Little opportunity for judicial review

## TAKEAWAYS

- ✓ Assume chemicals regulated by several government agencies
- ✓ Assume little meaningful opportunity for administrative appeals; need for know-how and know-who is key

# Administrative Complexities: Mexico

Lifecycle Phase	Substance						
	Fertilizers	Pesticides	Toxic Substances	Minerals and Hydrocarbons	Pharmaceuticals	Food Additives	Explosives
<b>Import and Export</b>	Semarnat, Sagarpa, Ssa, SE, SHCP	Sagarpa, Ssa, Semarnat SE,SHCP	Semarnat, Ssa, SE, SHCP	SE, SHCP, SENER	Ssa, SE SHCP	Ssa, SE SHCP	Sedena, SE, SHCP
<b>Registry</b>	Ssa	Ssa	Ssa	Secofi, ASEA	Ssa	Ssa	Ssa
<b>Process and Use</b>	Semarnat, Ssa, Sagarpa, STPS	Semarnat, Ssa, Sagarpa, STPS	Ssa, SCT STPS	SE, STPS, SENER	Ssa, STPS	Ssa, STPS	Sedena, STPS
<b>Storage</b>	Ssa, SCT STPS	Ssa, SCT, STPS	Ssa, SCT STPS	SE, SCT, STPS, CRE	Ssa, SCT STPS	Ssa, SCT STPS	Sedena, STPS
<b>Transport</b>	Ssa, SCT, STPS	Ssa, SCT, STPS	Ssa, SCT STPS	SE, SCT STPS, Secofi, CRE	SCT	SCT	Sedena, SCT, STPS
<b>Sale</b>	Sagarpa, SE, Ssa	Sagarpa, SE, Ssa	SE, Ssa	SE, CRE	SE	SE, Ssa	Sedena
<b>Occupational Health</b>	Ssa, STPS	Ssa, STPS	Ssa, STPS	Ssa, ASEA	Ssa, STPS	Ssa, STPS	Ssa, STPS

<b>Semarnat</b>	Secretary of Environment
<b>Ssa</b>	Secretary of Health
<b>Sagarpa</b>	Secretary of Agriculture
<b>SE</b>	Secretary of Economy
<b>SHCP</b>	Secretary of Finance and Public Credit
<b>SCT</b>	Transport Secretary
<b>Sedena</b>	Defense Secretary
<b>STPS</b>	Secretary of Labor
<b>Secofi</b>	Secretary of Commerce and Industrial Development
<b>SENER</b>	Secretary of Energy
<b>ASEA</b>	The National Agency for Industrial Safety and Environmental Protection in the Hydrocarbons Sector
<b>CRE</b>	Energy Regulatory Commission

Source: COFEPRIS

# Legal Commonalities

## Legal Commonalities

- Numerous laws and regulations
  - Determining applicability challenging
  - Variety of registrations/authorizations
  - Range of liability sources
- Inconsistent treatment of chemicals—highly regulated/not regulated
- Country-specific regimes (not always based on an international/US/EU law) or unique hybrids

## TAKEAWAYS

- ✓ Build in additional time for determining compliance
- ✓ Be prepared for unique regulations, even where there are governing international standards
- ✓ Just because a product is on the market does not mean it is fully compliant

# Toxic Release Inventories

## Toxic Release Inventories ("TRI")

- Mexico, Chile, Brazil
- Others reportedly underway
- Unique features

## TRI Data Can Be Indicator for:

- Regulations/policy focus
- Publicly available: NGO activity/citizens' suits

## TAKEAWAYS

- ✓ Some countries will have TRI and other reporting requirements
- ✓ Potential for expansion to include products that will become or emit wastes
- ✓ Area to watch for developments; precursor to chemicals inventories



# Chemical Inventories

## Typically no comprehensive inventory

- Mexico, Brazil, Colombia in process of developing
- Use of inventories likely to expand throughout region
- New/new-use chemicals largely unregulated

## Default chemicals import/export lists; GHS lists

- Lists still have ambiguity
- E.g., chemical + compounds, precursors, derivatives, mixtures
- Import authorization ++

## Not typically harmonized with any international standards

- REACH? TSCA?
- Harmonization and data acceptance will be key

## TAKEAWAYS

- ✓ No “inventories” like TSCA/REACH
- ✓ Use and scope of chemicals lists can be ambiguous
- ✓ Watch for developments

# Chemical and Sector Specific Regulations

Often underlying international driver

Easy to legislate (single focus)

Highly regulated substances and products

PBTs, pesticides, fertilizers, pharmaceuticals, cosmetics, food additives, batteries, electronics

## TAKEAWAYS

- ✓ Highly hazardous and PBT chemicals likely to be regulated
- ✓ Certain products likely to be regulated

# HazCom / GHS

## Existing HazCom & labeling laws

- Most based on old OSHA model adopted through technical standards
- Derived from labor law requirements, but can apply to manufacturers and importers

## Can raise import, marketability & compliance issues

- Spanish / Portuguese required
- In-country emergency phone number
- Country-specific nuances re formats, applicability, enforcement

## Regional shift to GHS

- Brazil & Uruguay, 2009
- Ecuador & Honduras, 2013
- Argentina & Mexico, 2015
- Costa Rica, 2017
- Colombia, proposed 2017
- Chile, in development



# GHS Hazard Classification

Most countries adopt all GHS hazard classes:  
physical, health, environmental

## Health hazard classification issues

- ◆ Mixture rule: constituent of >0.1% (or >1.0%) confers its hazard class on the mixture
- ◆ Substance classifications drawn from international sources: e.g., IARC
- ◆ May not adopt flexibility of UN Purple Book

## Scope variations

- ◆ Industrial chemicals
- ◆ Chemical products not marketed to individual consumers
- ◆ Chemical products used in a workplace
- ◆ All chemical products
- ◆ All products, ill-defined scope

## TAKEAWAYS

- ✓ Health hazard classification is uniquely problematic
- ✓ Beware the mixture rule
- ✓ Applicability of GHS is not harmonized

# GHS Hybrid Regulations



## Chile Hazardous Product Import Control (2016)

- Amended version of pesticide import control
- Covers substances & mixtures, including “finished products”
- Uses GHS health hazard classification
- Requires Health Ministry authorization to transport
- Applied by Customs at point of import



## Costa Rica Hazardous Chemical Product Labeling (2017)

- Amended version of pesticide labeling rule
- Covers all chemical products marketed to individual consumers
- Uses all GHS hazard classes
- Several country-specific label elements
- Requires registration as a hazardous chemical product

## TAKEAWAYS

- ✓ GHS is “going viral”
- ✓ So, is everything hazardous now?
- ✓ Agencies may not understand their own regulations

# Chemicals in Products

## Emerging priority

- Inspired by SAICM, EU directives
- Consumer safety regulations: e.g., children's products, paints, inks
- May implicate strong consumer protection statutes

## Regulation of chemicals over product life-cycle

- Product design ("DfE") "hazardous substance" restrictions
- Product testing & certification
- Product labeling (disclosure of "hazardous substances")
- Product end-of-life producer responsibility

## TAKEAWAYS

- ✓ Hazardous classification may be hazardous to your product
- ✓ Product safety: potential back-door to restrictions on "hazardous substances"

# Proposed Chemical Registries

## Brazil bill re: National Registry of Industrial Chemical Substances

- Drafted by agency-led, multi-stakeholder working group
- Would require registration of production & imports >1 ton/year
- Multi-agency committees would assess risks & impose risk management measures
- Public consultation in 2016; revision in progress



## Colombia draft decree re: Integral Management of Chemical Substances for Industrial Use

- Joint proposal of four ministries
- Would require registration of all substances for industrial use
- Would require company self-assessments & risk management plans
- Public consultation in 2017



## TAKEAWAYS

- ✓ Broad-based initiatives show momentum toward chemical registry laws
- ✓ Expect burdens of classification & assessment on industry

# Gap Analysis

Overreliance  
on GHS  
classification

Mix-&-match  
drafting

Assumption  
that “stricter is  
better”

High  
aspirations /  
low capacity

Closed  
rulemaking  
processes

Unclear scope  
definitions

Interagency  
jurisdiction  
issues

Enforcement  
via HTS codes

National pride →  
country-specific  
approaches

## TAKEAWAYS

- ✓ Hybridization of international standards with local law
- ✓ Stringency bias
- ✓ Implementation gaps leave “real” law unclear



# Looking Ahead

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Increasing focus on “hazardous substances”

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Seepage of GHS classification into other areas of law

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National chemical inventories & registries

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Regional spread of regulatory models

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Ongoing pursuit of “harmonization”

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SAICM 2020 inflection point

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Opportunities to shape emerging regimes – now is the time

## TAKEAWAYS

- ✓ Watch for the expansion of “hazardousness”
- ✓ Latin America – the next laboratory of chemical laws

# Thank you!



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