

An industry perspective on the development of chemicals management frameworks across Latin America

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Main Chemical Regulatory Trends

- **1) Increased regulatory complexity across Latin America** -> New chemical regulations under development in several countries due to OECD requirements or driven by trade agreements.
- **2) Regulatory Cooperation not depending only on Trade Blocs** -> Collaboration through Technical Networks not depending only on political agreements (ex. Mercosur).
- **3) Faster regulatory information flow across regions in a connected society** -> Stronger influence from other regulations -> e.g. EU CSS; APEC Chemical Dialogue; Post-SAICM process.
- **4) Integrated regulatory demands across value chains** -> More informed consumers demanding safer and more sustainable products -> from Downstream to Upstream.
- **5) Higher environmental societal demands** -> Citizens demand more participation, more transparency and more protective regulations. E.g. PRTR, Climate Change, EPR and Plastics Regulations, Escazu Agreement

LARCF – Latin America Regulatory Cooperation Forum

LARCF -> A response from the industry to tackle those challenges!

A network of industry chemical associations aimed to promote dialogue and regulatory cooperation in Latin America (created in 2017).

- **Objectives:**

1. Improving cooperation among Latin America's industry associations, governments and the industrial sectors.
2. Providing capacity building for governments and industry.
3. Establishing a clear vision and roadmap for regulatory cooperation and implementation of chemical management systems.
4. Information sharing on national and international regulatory developments.

LARCF and Regulatory Cooperation

ICCA LARCF - Achievement in 2020:

- Creation of a Virtual Working Group on the Sound Management of Industrial Chemicals in Latin America (**VWG-SMC-LA**)
- **A two-way communication and participation mechanism between the governments and the private sector of Latin America as part of the actions to achieve the comprehensive management of industrial chemicals in the region.**

Participants:

- Chemical Industry Representatives and Government Officials.
- Observers from downstream users associations and UNEP.

LARCF and Regulatory Cooperation

Capacity Building Webinars:

2020:

- GHS – Challenges and opportunities in its implementation
- International Multilateral Environmental Agreements on Substances and the SAICM process post 2020

2021:

- Roadmap for the sound management of chemical for Latin America
- Risk based management schemes for industrial chemicals and chemical products in Latin America (Chile, Colombia, Costa Rica and Peru)



Some Challenges for the Industry

- **Higher Complexity to make business** -> Meet international chemical regulatory standards and compete with global players already used to more regulated markets.
- **Higher costs to ensure license to operate**->
 - > Potential fees for notification and registration
 - > Resources needed to perform tests or to obtain access to proprietary chemical data
 - > Resources for management of regulatory data and to ensure reliability of the supply chain information
 - > Potential Technical Barriers to Trade (e.g. licenses, administrative and legal costs such as consultants, translation of documents to local language, labeling and SDS authoring requirements etc.)
 - > Potential stricter EHS requirements for industrial operations
- **Impact on innovation** -> Potential restrictions on the use of substances and higher demand for innovative and greener solutions (e.g. safer and low carbon)

Some Challenges for the industry

- **Increased Advocacy Demands** -> More complex interactions with Governments, IGOs, NGOs and also with other stakeholders across the value chain
- **New legal aspects** -> Potential Confidentiality and Litigation issues
- **More requirements for IT systems** -> Integration of the business and regulatory data, IT data protection
- **Human Resources** -> New Profile for Regulatory and Product Stewardship professionals

Practical Issues for Industry in Latin America

1- Limited possibility to provide early comments on new regulations and late use of regulatory impact assessment tools

- > Lack of understanding how industry will be able to participate and early contribute in the process
- > Importance of participation of the industry in the regulatory impact assessment of new regulations
- > Participation of the industry on the development of second level regulations may be highly demanding

- OECD - Recommendation of the council on regulatory policy and governance (2012)



Practical Issues for Industry in Latin America

2- Access to Data for substance notification and registration

The burden to the industry will depend on complexity of the data requirements:

- > Industry may rely to the use of public data and need to access to supplier information through long and often complex supply chains
- > Need to evaluate the quality of the available data (eg. OECD test data)
- > Need of collaboration between industry of different sectors and across the value chain to ensure the industry is following the best practices to avoid retesting and that they are paying a fair price to data

- **Example from the proposed ammendment to the Brazilian Chemical Bill (6120/2019):**

Art. 29. A fim de respeitar os direitos de propriedade de fabricantes e importadores que realizam estudos inéditos no Brasil para subsidiar a avaliação de risco de substâncias químicas ou para prestar informações relativas às novas substâncias químicas, estes deverão ter, por um período de cinco e dez anos, respectivamente, contados a partir da apresentação dos estudos, o direito de reclamar uma **compensação de outros fabricantes e importadores** que se beneficiem destes dados, por meio de carta de acesso.

§ 1º O período estabelecido no caput será cessado quando qualquer outro país tornar públicas as informações de avaliação de risco para condições similares de uso da mesma substância química no Brasil, estando garantido no mínimo um ano de proteção;

Givaudan

§ 2º Após o período de proteção, as autoridades competentes deverão **garantir o acesso do público às informações apresentadas** resguardadas as informações que se constituem como segredo de indústria ou comércio e sem prejuízo das demais normas de tutela à propriedade intelectual, ao meio ambiente, à saúde pública, ao consumidor e à defesa da concorrência.

§ 3º **É facultado o compartilhamento de dados** entre fabricantes e importadores, e a apresentação conjunta de estudos referentes às substâncias químicas em avaliação ou às novas substâncias químicas.

Practical Issues for Industry in Latin America

3- Notification of all substances to build national inventory

- > Notifiers may include low volume substances (below mandatory threshold) to ensure grandfathering all substances already existing in the market and avoid additional requirements for new substances
- > May require more intensive use of resources to manage the information of larger number of substances

- Example from Colombia Draft Chemical Regulation (version December 2020):

Artículo 5. Inventario nacional de sustancias químicas de uso industrial. El Inventario nacional de sustancias químicas de uso industrial es una base de datos de información sobre las sustancias químicas producidas o importadas en el territorio nacional, que permite asociar a cada sustancia, las cantidades fabricadas o importadas, los usos identificados y la peligrosidad.

Para tal fin, las personas naturales y jurídicas que durante el plazo a que hace referencia el párrafo 1 del presente artículo, importen o fabriquen **más de cien (100) kilogramos anuales de sustancias químicas de uso industria**, ya sean monoconstituyentes, multiconstituyentes y las incorporadas en las mezclas, deberán suministrar a través del aplicativo informático que para tal fin definan los Ministerios de Comercio, Industria y Turismo, Salud y Protección Social y Ambiente y Desarrollo Sostenible, la siguiente información:

Practical Issues for Industry in Latin America

4- Different Prioritization criteria for risk assessment

- > Different criteria and different lists of prioritized substances may impact and different timing in data requirements between countries in the region
- > Countries may collaborate and share a common list of prioritized substances for risk assessment - > This may make sense between neighboring countries in order to share resources (ex. Mercosur)
- > Countries may consider to use as a reference existing lists of prioritized substances from other jurisdictions

- Example from the Argentine Chemical Bill (4339-D-2019):

Artículo 17º: **Priorización de sustancias.** Para la priorización de sustancias, el CESQUI deberá contemplar, entre otros:

a. propiedades peligrosas: persistencia, bioacumulación, toxicidad, carcinogenicidad, mutagenicidad,

toxicidad para la reproducción;

b. exposición para humanos o ambiente: potencial nivel de exposición; cantidad de producción o importación, desvíos de utilización generalizados que resulten en perjuicios para la salud o el ambiente, poblaciones vulnerables expuestas;

c. que la sustancia se encuentre bajo algún acuerdo o convención internacional, de las cuales Argentina sea parte, o que esté incluida en alguna alerta internacional pertinente al campo de aplicación de la presente; y

d. que la sustancia no hubiera atravesado un proceso de evaluación de riesgo desarrollado por autoridades nacionales competentes.

Practical Issues for Industry in Latin America

5- Concept of New Substance and Risk Assessment Requirements

The impact of the industry will depend on alternatives allowed by the regulations for new substances:

- > Simplified Notification requirements for existing substances in other existing international inventories
- > Possibility of joint presentation of Risk Assessments by registrants
- > Mutual Acceptance of Risk Assessments done in the same region
- > Depending on the regulations, a new substance may enter in the public inventory of existing substances immediately after first notification

- Example from Chile´s Regulation « Decree 57/2019 »

Artículo 295.- Una vez realizada la notificación, el Ministerio de Medio Ambiente dictará una Resolución con todas las sustancias notificadas, hasta el 31 de diciembre de ese mismo año.

Artículo 297.- Una vez efectuada la primera notificación, las sustancias nuevas deberán continuar con su proceso de notificación cada dos años, según lo establecido en el inciso primero del artículo 294.

Practical Issues for Industry in Latin America

6- Complex Requirements for Importers

- > Importers usually does not have the same level of technical knowledge about the substances as the manufacturers
- > Higher burden to manufacturers and importers to provide periodic reporting (annual/biannual) to the inventory
- > Need of higher technical capacity to continuously integrate new regulatory and scientific information for the classification of substances, especially for NCS/UVCB
- > Challenge to conciliate different GHS self-classifications from different suppliers of the same substance and to access data from the substance manufacturer which may be unknown especially in the case of the ingredients of imported mixtures in long and complex supply chains

- Example from Chile´s Regulation « Decree 57/2019 »

Artículo 14.- La Autoridad Sanitaria o Ambiental, podrá solicitar a los fabricantes o importadores los antecedentes utilizados para determinar la clasificación de los peligros de sustancias o mezclas, conforme al presente reglamento.

Artículo 15.- El fabricante o importador deberá estar en conocimiento de la nueva información científica o técnica que pueda afectar a la clasificación de las sustancias o mezclas, de manera que cuando la información esté disponible y se considere adecuada y fiable, de acuerdo a lo señalado en el artículo 7, deberá efectuar una nueva evaluación de conformidad con el presente reglamento.

Practical Issues for Industry in Latin America

7- Notification from Foreigner Manufacturers

- > Foreigner manufacturers may not be able to use Legal representatives in the country -> Higher burden to the industry due to the need of continuous interaction between foreigner suppliers and importers
- > This may require complex agreements between parties and common service providers to ensure confidential data is protected
- > Alternatively, governments may create systems to receive confidential data directly from foreigner manufacturers

- **Example from the proposed ammendment to the Brazilian Chemical Bill (6120/2019):**

Art. 8º Estão obrigados a prestar informações no Cadastro, nos termos do artigo 6º, os fabricantes de substâncias químicas em si e os importadores de substâncias químicas em si ou quando utilizadas como ingredientes de misturas.

Parágrafo único: O importador poderá dar acesso a campos específicos do Cadastro ao fabricante estrangeiro para que este preste as informações diretamente, conforme regulamento.

Practical Issues for Industry in Latin America

8- Different Criteria for acceptance of data

- > Use of alternative methods to animal testing such as Read Across and QSAR may not be harmonized,
- > Different Criteria to waive testing may be applied
- > Countries may not have a complete laboratory infrastructure to perform OECD tests and have a limited knowledge on the use of alternative methods to animal testing

- Example from the Peru´s Draft Chemical Regulation (August 2020):

Artículo 11.- De los datos usados en los mecanismos para la gestión de sustancias químicas

11.1 Los datos que se utilicen en la aplicación e implementación de los mecanismos para la gestión de sustancias químicas de la presente Ley, **deben provenir de fuentes de información confiables, de conformidad con los criterios establecidos en el Reglamento de la presente Ley.**

11.2 La persona que use información de terceros para la aplicación e implementación de los mecanismos para la gestión de sustancias químicas de la presente Ley, **debe demostrar su derecho a usarla** conforme se establezca en el Reglamento de la presente Ley.

Practical Issues for Industry in Latin America

9- CBI requirements

- > Most of the proposed regulations only define what is not confidential
- > Lack of definition on which chemical data could be considered confidential, if it is justified

- Example from of the Colombia Draft Chemical Regulation (December 2020):

Artículo 26. **De la información no confidencial.** No tendrá carácter confidencial, entre otra, la siguiente información sobre sustancias químicas de uso industrial:

- a) La denominación de las sustancias químicas.
- b) Los datos generales sobre los usos de las sustancias químicas.
- c) Los datos físicos y químicos relativos a la sustancia química, con excepción de los datos que revelen la identidad de la sustancia, en cuyo caso únicamente deberán proporcionarse rangos de valores. Estos rangos deben guardar proporción con la composición real de la sustancia.
- d) Los efectos en la salud, ambiente y seguridad, incluyendo cifras e interpretaciones de los mismos.
- e) Los métodos y medidas recomendadas para reducir los riesgos de manipulación, almacenamiento, transporte y uso.
- f) Los métodos de tratamiento, aprovechamiento o eliminación previstos para la sustancia química usada y de sus envases.
- g) Las medidas de seguridad y manejo en caso de accidente.
- h) Los primeros auxilios y el tratamiento médico que deben dispensarse en caso de que se produzcan daños corporales.

Practical Issues for Industry in Latin America

10- Capacity building

- > Ensure that training is broadly available for industry professionals and government officials to allow use of best regulatory practices and that informed decisions are taken by regulators
- > Scientific advisory committees may play an important role in risk management decisions

- **Example from the proposed ammendment to the Brazilian Chemical Bill (6120/2019):**

Art. 16. O Comitê Técnico poderá constituir **grupo consultivo** ou convidar especialistas e pesquisadores da academia, indústria e sociedade civil para subsidiar a avaliação de risco das substâncias químicas.

Parágrafo único: O grupo consultivo terá mandato temporário a ser definido pelo Comitê Técnico e a participação de seus membros será considerada prestação de relevante serviço público, sem incidência de remuneração.

Practical Issues for Industry in Latin America

11- Cost Recovery

- > Models for financing the chemical management systems may vary between countries
- > Countries may require registration fees, specific taxes on producers and importers etc.
- > Despite the industry contribution, a significant investment of public resources, which are usually scarce, will be needed to implement chemical regulations.

- Example from the Argentine Chemical Bill (4339-D-2019):

Artículo 23º: **Recuperación de costos.** A fin de asegurar la recuperación de costos de la implementación de la presente, se deberá asignar partida presupuestaria acorde. Asimismo, la autoridad de aplicación podrá establecer un régimen de contribuciones, aranceles u otros mecanismos, evitando que exista duplicación con los registros ya existentes.

Take Away Messages

- **The development of Chemical Regulations is moving ahead in Latin America -> OECD Requirements + Trade Agreements + Regulatory Trends + Societal Demands.**
- **Industry early participation in the policy making process is fundamental to achieve regulatory models that are suitable to those medium income economies and that at the same time can ensure adequate level of protection to human health and the environment.**
- **Even higher investments in regulatory compliance management and sustainable chemistry will be needed for the LA industry to better compete in a much more regulated environment.**
- **There are already several initiatives available for the private and public sectors for sharing best practices and allow regulatory convergence for the sound management of chemicals.**
- **Regulatory Cooperation is a must to effectively tackle those challenges.**

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Thank you!
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Contact:

Daniel Rios

Product Stewardship Manager – Americas

daniel.rios@givaudan.com