

Reports

Brazilian Chemical Industry Outlook and Current Chemical Regulatory Scenario

Nicia Mourão and Jaime Sales*

I. Introduction

Brazil is ranked the 8th country in the world in terms of production of chemicals, however it has not yet developed a comprehensive regulation for the safe handling of industrial chemicals. Several attempts were made in the past, but until now, none of them have resulted in an effective implementation of specific legislation on the topic.

A long and detailed work was carried out between 2014 and 2018, by the National Commission on Chemical Safety (Comitê Nacional Sobre Segurança Química CONASQ), led by the Ministry of Environment (*Ministério do Meio Ambiente* - MMA) that is now extinct. This effort of dialogue and agreement among all stakeholders related to the management of chemicals in the country, culminated in a proposal for a draft bill in 2018. Unfortunately, until today this draft bill was not forwarded by the MMA for consideration of the Congress. In parallel, an individual proposal by one Congressman, aware of the importance of the chemical safety issue, was presented to the Congress at the end of 2019, but this is still waiting the appointment of a rapporteur.

Other attempts, including integration with other South American countries, are underway. These are mainly based on initiatives coordinated by companies and some chemical industry associations in the region, with the objective to achieve a broader alignment and harmonization of regional regulations on chemicals management.

Taking into consideration the large scale of chemicals production in Brazil compared to other countries, and the lack of an overarching regulation for the management of industrial chemicals, it appears that there is an urgent need for the adoption of a such a piece of legislation in the country.

II. Overview of Key Factors About Brazil and its Chemical Industry Market

Brazil is the 5th largest country in the world in terms of both area and population, and is the 8th largest economy in Purchasing Power Parity (PPP). It is also the largest and most populated country in South America. It is home to 212 million people, slightly more than all the other South American countries put together (210 million). It covers 14% of the world's freshwater resources and owns the most competitive renewable feedstock in the world (sugar cane, cellulose, oil seeds, palm trees). It is also worth mentioning that Brazil has a growing domestic market and a high potential for sustainable growth, due to its large population and its constantly growing middle class.

It is well known that Brazil has been emerging from a corruption crisis, which has caused a deep recession that started in 2016. A slow recovery was underway, and the economy was estimated to expand by approximately 2.2% in 2020.¹ Unfortunately, all predictions and plans are no longer valid because of the recent pandemic caused by COVID-19.

Despite all this, the Brazilian Chemical Industry is still maintaining a good position in the international markets.

In figures, the Brazilian chemical industry has more than 4000 chemical companies, including large, medium and small sizes enterprises, distributed across almost all Brazilian States. It accounts for

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* Nicia Mourão, Managing Partner, Mourão Henrique Consultores Associados LTDA, Brazil. For correspondence <nicia@mourao-henrique.com>. Jaime Sales, Managing Director, Regulatory Advisors Chemservice Iberia S.L., Castellón, Spain. For correspondence <j.sales@chemservice-group.com>.

1 Trade Economics, 'Brazil GDP Growth Rate 1996-2020' <<https://tradingeconomics.com/brazil/gdp-growth>> accessed 1 June 2020.

US\$ 128 billion in net sales of which industrial chemicals, accounted for 51% (US\$ 65.2 billion) of the total. It represents 12% of the Brazilian industrial GDP. Despite its size, the chemical trade in Brazil has shown a sequence of successive and increasing deficits in the foreign trade balance, due to the economic and political crisis that Brazil is experiencing today.

This increase in imports and the availability of a high quality and competitive renewable raw material sector would indicate that there are great opportunities for local production and expansion of the chemicals value chain, mainly based on renewable feedstock.

According to a study sponsored by the Brazilian Development Bank² in 2012, cosmetics and personal care, agrochemicals, food additives for animals and chemicals for oil exploration and production, are among the segments that could successfully compete in the global market. The study concludes that investment opportunities in the production of chemicals in Brazil using alternative technologies from renewable sources (notably biomass) could positively impact the Brazilian trade balance.

Raising competitiveness is a crucial challenge for the country in order to achieve higher growth in the medium-term.

III. Collaboration Between South American Countries on Chemicals

Among the twelve countries of South America, four stand out in terms of chemicals production - Brazil, Argentina, Chile and Colombia. All of them have a significant production of chemicals and are on their way to implementing chemical control legislations. These four countries together represent more than 80% of the Growth Domestic Product (GDP) in South America. Brazil is the largest country with a gross GDP of over \$ 3 billion and has 48% of the region's GDP and 49% of the region's population.

Until the middle of the last decade, South American chemical regulations were focused on specific

end products or sectors such as cosmetics, pharmaceuticals, household cleaning, benzene, asbestos and lead in paints. Different countries in the region have signed multilateral environment agreements such as Chemical Weapons, Illicit Drugs, Montreal, Basel, Stockholm and Minamata Conventions, among others.

By 2014, Brazil was already working on the development of its chemical control legislation, but there was still no significant interaction between the governments of the different countries in the region on this matter. Moreover, there was no forum for discussion between industry associations and chemical companies. Having such a forum for the interchange of ideas on regulations on the sound management of chemicals would encourage common foreign trade between the relevant countries, as well as the development of minimally coordinated policies for the control of chemical substances.

The main gaps delaying regulatory developments in the region involve the lack of a comprehensive legislation on industrial chemicals to use as a starting point, an absence of national inventories of chemicals in the markets and limited risk assessment studies related to human health and the environment regarding the chemicals placed on the South American market.

Besides that, the countries have focused their efforts on other International commitments such as:

- SAICM 2020 goals,
- OECD membership and obligations,
- The need to comply with the UN Sustainable Development Goals, and
- The negotiation of the Trade Agreement with the European Union.

All of these efforts have contributed to a new approach. Indeed, there were regional cooperation actions, especially in trade blocks like Mercosur and the Andean Community. However, as was historically the case, those trade negotiations have not covered issues related to the regulation of chemicals from a global perspective. Therefore, the status of the chemical regulatory developments continued to be quite different from country to country. The regulations were not harmonized and there were no truly regional initiatives to coordinate it. Although these countries have a diverse regulatory scenario, for the past few years they have been converging on some chemical control regulations principles.

² Bain & Company, 'Estudo do Potencial de Diversificação da Indústria Química Brasileira: Relatório Final' <<http://docplayer.com.br/259505-Bain-company-gas-energy-estudo-do-potencial-de-diversificacao-da-industria-quimica-brasileira-relatorio-final-1a-edicao.html>> accessed 1 June 2020.

New trends and initiatives in the region led to a change in positioning and a search for adaptation to the new international standards, resulting in a simultaneous development of comprehensive regulations on the management of chemicals in Brazil, Argentina, Colombia and Chile, and a search for regulatory cooperation initiatives between governments. The creation of the Intergovernmental Network of Chemicals and Waste for Latin America and the Caribbean in March 2016, which aimed to contribute to the implementation of the 2030 Agenda for Sustainable Development, has to some extent unified initiatives in those countries.

Other examples of international regulatory cooperation were the active regional participation on international chemical agreements. Representatives from countries in the region have been Co-Chairing SAICM Open-Ended Working Group (occupied by Brazil between 2017 and 2019, and currently by Uruguay), and the creation of the Chemical Industry Latin American Regulatory Cooperation Forum – an industry network initiative aiming at promoting dialogue and international regulatory cooperation between industry and governments in the region.

IV. Brazilian Structure for Chemical Safety Management

The Chemical Safety unit of the MMA is responsible for taking steps toward the sound management of chemical substances in the country, and the obligations arising from the international chemical conventions: Basel, Stockholm, Rotterdam and Minamata, of which Brazil is a signatory. The MMA is the technical focal point for all of these conventions, and it is responsible for coordinating the national implementation of these treaties, as well as of the Strategic Approach to the International Chemicals Management – SAICM Action Plan and Emerging Policy Issues program.

Brazil currently has many regulations to control chemicals, which are focused on specific end-uses or type of substances. The following table highlights the most important regulations dealing with chemicals that are currently in use in Brazil.

Moreover, the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* – ANVISA³), related to the Ministry of Health (*Ministério da Saúde* – MdS), is one of the main agencies

in terms of management of chemicals, and it operates in Brazil in parallel with the MMA. Created in 1999, ANVISA is an autarchy under a special regime and is present throughout the national territory through the coordination of ports, airports, borders, and customs. Its institutional purpose is to promote the protection of the human health, by means of sanitary control of the production and consumption of products and services subject to health surveillance, including the environments, processes, materials and technologies related to them.

The main products that fall under responsibility of ANVISA are:

- Pesticides
- Cosmetics
- Sanitizing products
- Drugs
- Pharmaceutical ingredients
- Smoking products
- Food
- Medical devices

It is to be noted that foreign companies cannot make administrative arrangements for issuing of pre-market approvals directly with ANVISA. Those companies will require partner companies legally constituted in Brazil that will be legally responsible for the products imported to and distributed in the Brazilian market.

V. Classification, Labelling and Safety Data Sheet Information

Regulatory Norms (*Normas Regulamentadoras* - NRs), also known as workplace safety norms, were created by the Ministry of Labor (*Ministério do Trabalho* – MdT) with the aim of providing a safe work environment. The NR-26, currently in force, determines that chemical products must be classified, preventively labelled, and have their hazardous properties specified in a safety data sheet. It was first published in 1978, and its last update was done in 2015. Products registered as sanitizing products by ANVISA are exempt from the obligations described in NR 26.

3 Agência Nacional de Vigilância Sanitária, 'Regulation of products' <<http://portal.anvisa.gov.br/regulation>> accessed 1 June 2020.

Sector of use	Relevant Brazilian Legislation
Chemical Weapons	Lei 9112/1995 – Exportação de Bens Sensíveis
	Decreto 1861/1996 – Exportação de Bens Sensíveis
	Decreto 2074/1996 – Cria a Comissão do CPAQ
	Decreto 2977/1999 – Promulgação da Convenção de Armas Químicas
	Decreto 4214/2002 – Controle de Exportação de Bens Sensíveis
	Portaria MCTI 437/2012 – Lista de Bens Sensíveis
Persistent Organic Pollutants(POPS)	Decreto 5472/2005 – Convenção de Estocolmo
Prior Informed Consent - Rotterdam Convention	Decreto 5360/2005 – Convenção de Roterdã
Minamata Convention	Decreto 9470/2018 – Convenção de Minamata
Precursors and Illicit Drugs	Decreto 154/1991 – Convenção de Drogas Ilícitas
	Lei 10357/2001 – Controle e Fiscalização de Produtos Químicos
	Decreto 4262/2002 – Controle de Produtos Químicos
	Portaria MJSP 240/2019 – Controle e Fiscalização de Produtos Químicos
Products Controlled by the Army	Lei 10834/2003 –Taxa de Fiscalização dos Produtos Controlados
	Decreto 10030/2019 – Aprova o Regulamento de Produtos Controlados
	Portaria MEX 118/2019 – Relação de Produtos Controlados pelo Exército
Industrial Property	Lei 9279/1996 – Propriedade Industrial
	Decreto 2553/1998 – Propriedade Industrial
Solid Waste	Lei 12305/2010 – Política Nacional de Resíduos Sólidos
	Decreto 7404/2010 – Regulamenta a Política Nacional de Resíduos Sólidos
Environmental Damage Prevention	Lei 9.605/1998 - Lei de Crimes Ambientais
	Resoluções CONAMA
	Resoluções Secretarias Estaduais de Meio Ambiente
Consumer Protection	Lei 8078/1990 – Código de Defesa do Consumidor
Transport of Hazardous Goods	Terrestre: Decreto 96044/1988
	Resolução ANTT 5232/2016
	Resolução ANTT 5848/2019
	Marítimo: Portaria 3/2013 SEC-IMO/IMDG Code
	Aéreo: ICAO/IATA Code + normas ANAC
Classification and Labelling	Lei 5452/1943 – Consolidação das Leis do Trabalho
	LEI 13467/2017 – Altera a Consolidação das Leis do Trabalho
	NR 26 e Portaria 229/2011
	ABNT NBR 14725 – Parte 2 (classificação GHS)
	ABNT NBR 14725 – Parte 3 (rotulagem GHS)
	ABNT NBR 14725 – Parte 4 (Fichas de Dados de Segurança GHS)
Protection of Workers Health	ABNT NBR 16725 – FDSR (Fichas de Dados de Segurança de Resíduos Químicos)
	Portaria 3214/1978
	NR 7 – PCMSO – Programa de Controle Médico de Saúde Ocupacional
	NR9 – PPRA – Programa de Prevenção de Riscos Ambientais
	NR 15 – Atividades e Operações Insalubres (inclui limites de exposição ocupacional)

Figure 1: Relevant Brazilian Legislation

The latest update of NR 26 determines that the information must follow the criteria established by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and that the aspects related to the classification must comply with the provisions of the official technical standard in force. This is implemented via technical standards developed by

the Brazilian Association of Technical Rules (Associação Brasileira de Normas Técnicas – ABNT). Those rules are known as Brazilian Norms (*Normas Brasileiras* – NBR). The standard in force related to GHS implementation is ABNT NBR 14725. This is divided into 4 parts, as follows:

- ABNT NBR 14725-1: 2009 – scope & terminology

- ABNT NBR 14725-2: 2009 – classification – 1st edition
- ABNT NBR 14725-3: 2012 – labelling – 4th edition
- ABNT NBR 14725-4: 2014 – safety data sheets – 4th edition

Originally, this Norm adopted all building blocks according to the UN GHS, including mixture classification cut-offs, but the 2019 amendment aligned the cut-offs of the classification of mixtures according to the European CLP. In terms of classification, the ABNT NBR 14725 is in the process of being updated to the UN Purple Book 7th edition. On January 1st, 2019, the MdT was officially extinguished, and its functions became part of the Special Secretariat for Social Security and Labor of the Ministry of Economy. (*Secretaria Especial de Previdência e Trabalho do Ministério da Economia*).

VI. Brazil Chemical Legislation

Although Brazil already has a significant amount of regulations⁴, as previously stated there is a lack of a comprehensive legislation on all chemical substances placed on the Brazilian market and the absence of an inventory of these substances. Moreover, there is no study concerning the analysis and characterization of the risk of the substances of high concern and no definition of risk management measures to prevent their potential adverse effects. In parallel, the need to comply with the provisions of SAICM of ensuring that 'by the year 2020, chemicals will be produced and used in ways that minimize significant adverse impacts on human health and the environment' have to be taken into consideration.

A Brazilian National Commission on Chemical Safety, (*Comitê Nacional Sobre Segurança Química – CONASQ*), was established in 2000, sponsored by the Ministry of Environment. It was a multi-stakeholder forum with 22 governmental institutions related to chemical management in the country and with representation of the industry, workers, NGO's and Academia.

CONASQ was in charge of discussing policies related to all chemical safety issues, related to: industrial chemicals, pesticides, mercury, lead in paints, chemicals in products and many others. As a result, in 2014, CONASQ launched the Technical Working Group (TWG) for Regulation of Chemical Substances", that

had the objective of discussing and proposing the strategies, institutional arrangements and a draft legislation to establish the control of public enforcement over the universe of chemical substances that are currently placed in the national market.

The goal of the draft law was 'to minimize the adverse impacts on health and the environment resulting from production, import and the use of hazardous chemicals'. The guiding principles of the proposal were:

- To build a notification system for the inventory for all substances,
- To use the GHS as the classification system for all sectors,
- To select and prioritise chemicals for risk assessment,
- To propose risk management measures for the prioritised chemicals,
- To establish sanctions and penalties for non-compliance, and
- To create a cost recovery system that would not result in an unnecessary burden on the business.

The TWG had 16 meetings during almost two years. The debate took into consideration chemical schemes from other countries and regions (mainly the European Union and Canada) that were used as benchmark, not as a model as such, but mainly as a reference. In April 2016, the TWG finalized its work and sent its proposal to CONASQ, who approved it, and submitted it to a public consultation from June to September 2016. The public consultation came up with more than 800 suggestions.

From January 2017 until November 2018, CONASQ analysed the contributions, reorganized the entire text and finalized the draft law. Then, in December 2018, MMA sent the draft Law to the Executive Office of the President for approval and referral to Congress. However, on January 1st, 2019, a new government assumed the Brazilian presidency. Later that year, in April, the new MMA released its priority agenda for the year and chemical safety was not included in it. Subsequently, CONASQ was eliminated by a Presidential Decree and the draft law remained unpublished.

4 ChemSafeTypro, 'Latest Updates of Chemical Regulations in Brazil' <https://www.chemsafetypro.com/Topics/Brazil/chemical_regulations_in_Brazil_and_developments.html> accessed 1 June 2020.

The English version of the draft bill can be accessed at the web of MMA⁵.

In November 2019, congressman Flavio Nogueira surprisingly presented in Congress a Bill on Inventory of Chemical Substances that was assigned with number 6120/2019. It was an independent initiative of this legislator that until then had no record of initiatives related to the chemical safety topics. His proposal took into account some points of the draft bill from CONASQ, and also from the Bill that was presented in the Argentinian Congress in 2019.

The Bill sets provisions for the creation of the National Inventory of Chemical Substances in order to consolidate an information base on the chemical substances produced or imported into the Brazilian territory. Currently, the Bill is awaiting the appointment of a rapporteur to continue its way in order to become a law.

The most important aspects of the Bill are highlighted below:

- Government is responsible for the management of the Inventory.
- It applies to substances on their own, in mixtures or in articles and in volume higher than the threshold of 1 tonne per year of production or import, considering the average of the last 3 years.
- Notification data requirements include substance identity, CAS number, recommended uses, safety data sheet, classification information, and risk assessment analysis for all substances in the inventory.
- It adopts GHS as the mandatory classification system.
- Data related to hazard and risk are not confidential but substance identity can be confidential in special circumstances.
- Chemicals of unknown or variable composition-UVCB must be registered as a single chemical.
- Properties candidates for prioritization include Carcinogenic, Mutagenic and Reprotoxic (CMR), Persistent, Bioaccumulative and Toxic (PBT), Endocrine Disruptors (ED); furthermore, exposure levels, quantities produced or imported or potential misuse can also be taken into account. In ad-

dition, substances that are covered by an international agreement or convention can also be prioritized.

- Manufacturers, exporters and importers of chemical substances are obliged to provide information to the National Inventory of Chemical Substances.
- Animal testing should be the last resort to determine the hazard of a chemical.
- Infringements of the law are subjected to administrative sanctions.
- The Government is responsible for setting up an Assessment Committee to assess the risks of the substances and recommend risk management measures.

A wide range of sectors and substances already regulated by other Brazilian regulations are exempt from notification. These exemptions are as follows:

- I. Radioactive substances
- II. Chemical substances under development or intended exclusively for research
- III. Non-isolated reaction intermediates
- IV. Chemicals, mixtures, articles subject to customs control
- V. Narcotic, psychotropic, immunosuppressive substances
- VI. Substances used exclusively as ingredients of tobacco
- VII. Metallic alloys
- VIII. Explosives and their accessories
- IX. Residues
- X. Products subject to specific regulations
 - a) Agrochemicals, pre-mixtures for agrochemicals and technical products
 - b) Medicines, medical gases
 - c) Cosmetics, toiletries, perfumes
 - d) Sanitizers
 - e) Veterinary products
 - f) Foods, food additives and manufacturing technology co-formulants
 - g) Products intended for animal feed
 - h) Fertilizers, inoculants, soil correctives
 - i) Wooden preservatives
 - j) Environmental remediation products
- XI. The following substances, as long as they are not chemically modified, or that are constituted by:
 - a) Minerals
 - b) Coal, coke, crude oil, natural gas, LPG
 - c) Natural gas, gases
 - d) Natural substances

⁵ Ministério do Meio Ambiente, 'Draft Brazil Chemical Control bill' <https://www.mma.gov.br/seguranca_quimica/substancias_quimicas/Draft-Brazil-Chemical-Control-bill_English-Revised_Version-CONASQ-meeting-September_-2018_MMA.pdf> accessed 1 June 2020.

- e) Fats, essential oils
- f) Glass, frits, and ceramics

VII. Conclusion

The foundation is already in place for society to build a better and safer environment. Chemical awareness and safety are obligations and aspirations that we all share - the government, the industry, the employees, and the citizens. It is expected that the governments have the wisdom and leadership for establishing sound safety standards and regulations that keep us and the environment safe and healthy.

As we have seen in this article, the Brazilian market is attractive for investments in local production. Chemical industry sectors using alternative technologies from renewable sources have potential markets that are relevant in a global context. Opportunities that can attract national and foreign investors were identified in areas of growing international demand that can lead to a successful and competitive production of consumer products.

There is an increasing demand globally for governments to prioritise the means to manage chemicals responsibly in their economic and social priorities. Good chemicals management for the protection

of human health and the environment and for fostering the circular economy are becoming a key part of the business strategy of the chemical companies. It is also an important driver of consumer preferences in developed and emerging markets, opening new prospects for sales and profits. For all these reasons, governments that establish good chemical regulatory frameworks are setting the base for sustainable development worldwide.

In this context, Brazil as the leading country in South America in terms of population, economic relevance and chemicals production should not fall behind in the development of an overarching policy on sound management of industrial chemicals, while clarifying the hierarchy of the regulatory landscape and involved agencies in terms of adequate controls of chemicals and their uses. Significant efforts have been done in the past by the government and industry, and useful proposals have been put forward. In spite of the political uncertainty that Brazil has faced over the past five years, this progress should not be wasted and the country should continue to strive on the objecting of implementing a global regulation on the management of chemicals, thus not falling behind from similar initiatives in the South American region. This will strengthen the Brazilian industry and keep the country on the chemical world map.