

Brazil Proposes Sweeping Chemicals Legislation

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Brazil's Ministry of the Environment has proposed a bill that would establish an expansive chemical regulatory regime consisting of registration and reporting requirements, substance risk assessments, and risk management measures including potential restrictions on the production, import and use of substances.

On June 30, 2016, Brazil's Ministry of the Environment posted for public comment a [draft bill](#) to monitor, evaluate and control the use of industrial chemicals produced in or imported into Brazil. While the proposal remains several steps away from becoming law, its development marks the first time that a Latin American government has made a serious effort to develop comprehensive chemicals legislation. The fact that this bill was drafted by the administration of impeached President Dilma Rousseff and released under her rival, acting President Michel Temer, suggests that this is a widely supported initiative with momentum toward enactment, independent of any specific political party agenda.

The bill would establish the framework of a chemical regulatory regime with three major components:

- A registry of chemical production and imports,
- A risk assessment process, and
- A risk management program authorized to regulate chemicals and impose use restrictions.

The bill's initial impact would fall largely on the chemical industry, but as the regulatory program develops through the phases of risk assessment and risk management, it would potentially affect a wide range of products and industries. It may also spur other countries in Latin America, such as Mexico, to consider similar initiatives—chemical products are currently regulated in piecemeal fashion throughout the region.

The bill is the result of a two-year research and drafting effort conducted by a working group of the Ministry's National Chemical Safety Commission, which included representatives of several agencies and one each from the chemical industry and non-profit sector. The working group has reported that

it studied the chemical laws and regulatory programs of the U.S., Canada, EU, China, and other countries, and blended elements from several sources to create a unique piece of legislation, though its overall structure appears to be modeled on the U.S. Toxic Substances Control Act (TSCA). As an intentional hybrid of multiple approaches to chemical regulation, the bill is likely to raise issues of harmonization that may be best addressed in the initial comment period, which ends August 14, 2016.

General Scope and Exclusions

The bill would define a covered “industrial chemical substance” as: “a chemical element and its compounds, in a natural state or obtained through a manufacturing process, including any additive necessary to preserve its stability and any impurity that derives from the process used, but excluding any solvent that can be separated without affecting the substance’s stability or modifying its composition.” The terminology “element and its compounds” may lead to unintended ambiguity over the classification of substances under the bill—whether, for example, mercury and its compounds count as a single substance or several—although other parts of the bill suggest that each individual substance is likely to correspond to a particular Chemical Abstracts Service (CAS) number.

The proposed definition appears broad enough to encompass all substances derived for use in commerce, but the following categories would be excluded from regulation:

- Radioactive chemical substances;
- Chemical substances in development or intended exclusively for research;
- Non-isolated reaction intermediaries, impurities, contaminants, and substances produced through unintentional reactions;
- Ores and their concentrates, and other rocks and minerals, except those that are chemically modified or that are composed of or contain substances classified as hazardous according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) criteria;
- Metals and alloys in forms used for structural purposes;
- Active ingredients of pesticides; and
- Active ingredients of human and veterinary medicines.

Some of the proposed exclusions generally align with those provided under the laws of other jurisdictions, but with some potentially significant variations. For example, the bill’s exclusions for pesticides and medicines would be limited to active ingredients, whereas under TSCA the equivalent exclusions are based more broadly on the scope of the federal laws that regulate pesticides and medicines.

National Chemical Registry

The bill would create the National Registry of Industrial Chemical Substances to collect information about covered substances. Companies that produce or import any covered substance in a quantity of one ton or more annually would be obligated to submit information to the Registry, including the

substance's name and CAS number, the scale of annual production or import, the substance's uses, and any applicable GHS hazard classification. Lower threshold quantities may be established for particular substances based on their risks to the environment and human health.

The registration requirement would apply to substances produced or imported either in pure form or in intentional mixtures. The bill does not specify whether the chemical constituents of imported products that are mixtures, such as paints, inks and cleaning products, would count toward the quantities subject to registration. The bill includes other provisions that apply separately to both mixtures and "finished products," which suggests that finished products would not be regarded as mixtures and therefore not subject to registration, although the precise distinction between these categories is unclear.

The deadline for registration would be three years after the date when the Registry is established. After the deadline, the production and import of covered substances would be conditioned on prior registration. (Presumably, this condition would apply only to annual quantities at or above the registration threshold, although the bill does not specify this.) Unlike TSCA and some other chemical laws, the bill would not establish a notification requirement for new substances, instead relying on threshold quantities for inclusion in the Registry.

Companies would be required to update information previously submitted to the Registry in case of any change in a registered substance's uses, scale of annual production or import, or GHS hazard classification. In many cases, this could amount to an annual reporting requirement, as the quantities of a given substance that a company produces or imports from year to year, as well as end-uses, are likely to vary depending on commercial opportunities.

Failure to register, submission of false, misleading or incomplete information, and failure to update existing submissions to the Registry would be violations potentially subject to a range of penalties, including fines, confiscation of products, and suspension or cessation of activities.

The bill would not directly provide for the protection of confidential business information. However, it includes an assurance that personal, industrial and commercial information submitted to the Registry would be subject to the protections of secrecy and confidentiality provided by other laws.

Risk Assessments

An interagency Technical Committee on the Evaluation of Industrial Chemical Substances would be formed to select substances from the Registry and evaluate their environmental and health risks. The Technical Committee would be directed to select substances based on the following factors:

- Persistence, bioaccumulation or toxicity to the environment;
- Carcinogenicity, mutagenicity or toxicity to reproduction;
- Characteristics of endocrine disruptors, based on scientific evidence;
- Relevant potential for human and environmental exposure;
- Appearance in alerts, international agreements or conventions to which Brazil is a signatory; and

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- Scientific evidence of serious effects on health or the environment not listed above, but of equivalent concern.

Apart from listing the selection factors, the bill does not explain how candidate substances would be prioritized for risk assessments. The bill also lacks details on the assessment process, and provides no standard of safety or risk to guide the Technical Committee's determinations and recommendations for further regulatory action.

Registered producers and importers of a substance under assessment would be required to submit information, studies, and safety data sheets to support the risk assessment. The submission of false, misleading or incomplete studies would be a violation potentially subject to the aforementioned penalties.

Risk Management Measures

Based on the results of a risk assessment for a given substance, an interagency panel called the Industrial Chemical Substances Deliberative Committee would be authorized to impose risk management measures. The bill lists several types of measures that could be imposed individually or in combination:

- Voluntary agreement between government and industry;
- Lower threshold quantity for required submissions of information to the Registry;
- Bans on the production, import, export, sale and use of the substance;
- Restrictions on the production, import, export, sale and use of the substance;
- Limits on the concentration of the substance in intentional mixtures or finished products; and
- Requirement of prior authorization for production or import.

Producers and importers of substances subject to risk management measures would be required to submit additional information to the Registry periodically. In addition to the producers and importers of a managed substance, compliance with risk management measures would also be mandatory for manufacturers and importers of finished products that use or contain a managed substance.

As with the risk assessment process, the bill does not provide either procedural or substantive guidelines for the Deliberative Committee's risk management decisions. Whereas the types of measures authorized—including bans and other restrictions—appear significant enough to merit a formal rule-making process with public participation, the bill merely requires the Deliberative Committee to consult the federal agencies that oversee industrial sectors that could be impacted before it issues a risk management decision.

Path Forward

The Ministry has created an online form (<http://hotsite.mma.gov.br/consultasubstanciasquimicas/formulario/>) as the sole method for

submitting comments on the bill. The comment period ends at 11:00 p.m. (Brasilia time) on August 14, 2016.

Following its review of comments, the Ministry intends to send a revised version of the bill to the Congress. There is no clear indication yet of how the bill is likely to fare in the legislative process, but the circumstances of its publication appear to indicate some breadth of support. The bill has survived a transition of power from one party to another, with an accompanying change in Ministry leadership, and has progressed despite the political crisis that has paralyzed many other Brazilian initiatives in recent months.

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