

Brazil Moves Closer to National Chemical Inventory

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On October 15, 2015, the Brazilian Ministry of Environment (*Ministério do Meio Ambiente*, or MME) announced plans to develop a national chemical Inventory (Inventory), with initial legislation expected by December 31, 2015. Due to a sometimes contentious debate between industry and the MME (Authority), the Inventory process had been considerably delayed. In a Brazilian chemical industry forum on June 23, 2016, it was announced that significant progress has been made toward implementing legislation by year's end.

Background

There are no specific laws on chemical control regulations. There are, however, specific laws that apply to pesticides, sanitizing products, explosives, and their raw materials, chemicals used in the workplace, and chemicals used for illicit drugs. Several departments and agencies act in a complementary manner, but there is conflict and overlapping roles.

Historically, this authority has been fragmented, primarily residing among three Ministries:

- The National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, or ANVISA) is similar to the U.S. Food and Drug Administration (FDA). Administratively, it is linked to the Ministry of Health. ANVISA primarily has jurisdiction over consumer goods and sanitizing products (cleaning products, pest and disease control products for home use, disinfectants, and related products).
- The Ministry of Agriculture and Supply (*Ministério da Agricultura, Pecuária e Abastecimento*, or MAPA) primarily regulates manufacturers, formulators, distributors, and importers of fertilizers, agricultural commodities, agriculture-related products, and veterinary products.
- The MME primarily holds sway over manufacturers, formulators, distributors, and importers of chemicals not used in agribusiness.

Presently, the key law that has regulated chemicals, to varying degrees, is Federal Decree 2657/98 (Decree). The Decree defines the terms "chemicals" and "hazardous chemicals," and sets forth (limited) requirements.

Recent Developments

In December 2015, a representative of the Brazilian Chemical Industry Association (Associação Brasileira da Indústria Química, or ABIQUIM) commented publicly that the plan was to use the Canadian Domestic Substances List (DSL) as a model for the new regulation, but stated specifically that it would not involve simply incorporating the current DSL into national law in Brazil. The intent, however, was to mirror certain key concepts, such as a notification scheme, a positive list, and a regulatory review process.

Earlier this year, legislation stalled as negotiations between industry and the Authority grew argumentative during the collaborative process. A key point of contention was that the National Chemicals Safety Commission (*Comitê Nacional Sobre Segurança Química*, or CONASQ) wanted the Brazilian chemical industry to provide data on known substances to the Authority so that risk and management measures could be implemented. ABIQUIM and other companies challenged this request, as they believed it would place domestic manufacturers at a competitive disadvantage compared to manufacturers outside the country that did not need to provide this information.

This aspect, coupled with the legislative turmoil in the country, appeared to delay indefinitely any legislation this year. It was announced on June 23, 2016, however, that the bill, the Industrial Chemicals Regulation (*Regulação de Substâncias Químicas Industriais*, or *Regulação*) has been fast-tracked toward eventual approval. Of key note is that "active agents" for use in medicines and plaguicides (pesticides) will be removed from inclusion on the proposed chemical inventory. This is, of course, similar to how the Toxic Substances Control Act (TSCA) excluded substances regulated under other statutes. The *Regulação* is expected to be published in the Brazilian Official Gazette, the *Diário Oficial*, shortly, with a notice and comment period of approximately 30 days. At the conclusion of that period, the Authority will respond to all comments raised, and then the *Regulação* will proceed to the Congress for a vote.

Discussion

While the draft legislation has yet to be released generally, the initial framework of the regulation appears to be intact (e.g., similar to the DSL in concept), although key items, such as the notification process and exemptions, among other aspects, remain to be shared. Companies seeking to enter the Brazilian chemical market, or those already present that are looking to expand their offerings, should keep a careful eye on the legislation, as it appears poised to move quickly after considerable delay.

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