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Top International News in Chemical Policy and Regulation: March 2018: Americas and Asia

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ANDEAN COMMUNITY

Andean Community Notifies New Cosmetic Products

Regulation: The Andean Community, a customs union comprised of the South American countries of Bolivia, Colombia, Ecuador, and Peru, has notified the World Trade Organization (WTO) of its intent to promulgate a draft Technical Regulation that addresses the labeling of cosmetic products within Member States. The “*Proyecto de Reglamento Técnico Andino Sobre Etiquetado de Productos Cosméticos*” (Draft Andean Technical Regulation on the Labeling of Cosmetic Products; Draft Technical Regulation) addresses the following items or sections: Purpose, Scope, Definitions, Labeling Requirements, Conformity Assessment, Inspection and Monitoring, and Supplementary and Transitional Provisions, all with the stated aim of protecting human health and safety.

In concert with the statutory requirements of the Andean Community, member countries must, upon adoption at the Community level, implement the Draft Technical Regulation into their national laws. Colombia and Ecuador, via [COL/231](#) and [ECU/338](#), have already announced plans to do so. The final date for comments on the Draft Technical Regulation is **May 17, 2018**.

AUSTRALIA

NICNAS Begins Public Consultation On Draft General Rules, Categorization Guidelines, And Transitional

Rules: In 2015, the Australian government began a process to reform its National Industrial Chemicals Notification and Assessment Scheme (NICNAS). NICNAS regulates new and existing chemicals, including chemicals used in solvents, adhesives, plastics, paints, inks, fuels, cosmetics, and household cleaning. As reported previously, the aim of the reforms is to rebalance post- and pre-market requirements to reflect the risk of a new chemical, to streamline the current risk assessment process for new and existing chemicals, to better use international assessment materials, and to create a more appropriate compliance tool, among other things. In 2017, the Australian government submitted to Parliament a package of six bills that will establish a new national regulatory scheme for industrial chemicals. The [Industrial Chemicals Bill 2017](#) describes the Australian Industrial Chemicals Introduction Scheme (AICIS), a legislative framework for a reformed, risk-based regulatory scheme for Australia to continue to regulate the introduction of industrial chemicals. NICNAS has begun a [public consultation](#) on the following draft documents that, together with the Industrial Chemicals Bill 2017, will form the scheme for the introduction of industrial chemicals in Australia:

- [Industrial Chemicals \(General\) Rules 2018 \(General Rules\)](#): The General Rules contain details on how the



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introduction of industrial chemicals will be regulated under the new framework;

- [Industrial Chemicals Categorization Guidelines \(Categorization Guidelines\)](#): The Categorization Guidelines contain the technical details and requirements that industrial chemical importers and manufacturers will need to categorize their chemical introductions under the new scheme; and
- [Industrial Chemicals \(Consequential Amendments and Transitional Provisions\) Rules 2018 \(Transitional Rules\)](#): The Transitional Rules describe how processes under the previous laws will transition to the new scheme.

NICNAS states that consultation on the draft rules and guidelines will be of key interest to:

- Businesses that regularly introduce chemicals into Australia, including those in the cosmetic and personal care, and general industrial chemistry sectors;
- Downstream businesses that depend on the use or supply of industrial chemicals;
- Organizations providing consultancy and regulatory services on industrial chemical regulation;
- Individuals and organizations having a public policy interest in industrial chemical regulation; and
- Commonwealth, state, and territory risk managers.

NICNAS will run targeted briefings and information sessions with regulated entities, interested businesses, and other stakeholders during the public consultation period. The sessions will be sector-specific and cover issues or aspects of the Rules and Categorization Guidelines that are relevant to a particular sector. To participate, stakeholders should contact NICNAS. Comments are due **May 4, 2018**. The legislative package to establish the AICIS is expected to be debated in the Senate **later in 2018**. Because of the delay in passing the legislative package, Australia will postpone commencement of the new scheme to **July 1, 2019**. Until AICIS takes effect, NICNAS will remain in place.

BRAZIL

Ministry Of Environment Develops Electrical And Electronic Equipment Regulation: The Brazilian *Ministério do Meio Ambiente* (Ministry of Environment, MMA) has announced plans to develop a series of technical standards that would regulate hazardous substances used in electrical and electronic equipment. Similar in concept to the EU's Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS 2) ([Directive 2011/65/EU](#)), the proposed standards will place limits on the amount of a variety of heavy metals and other products used in products, including, but not limited to, washing machines, small appliances, computer equipment, toys, and medical devices. Specifically, the standards would restrict cadmium, mercury, hexavalent chromium, polybrominated biphenyls, diphenyl polybrominated ethers, and lead.

At present, the series of standards exist only as a recommendation within an official document from the *Ministério do Planejamento, Orçamento e Gestão* (Ministry of Planning, Budget and Management, MPOG). The document itself is not available, although a press release from the MMA may be viewed [here](#). The standards are a cooperative effort among multiple Ministries: the *Departamento de Qualidade Ambiental e Gestão de Resíduos* (Department of Environmental Quality and Waste Management, DQAR), the *Secretaria de Recursos Hídricos e Qualidade Ambiental* (Secretariat of Water Resources and Environmental Quality, SRHQ), the *Ministério do Meio Ambiente*, and the *Ministro da Justiça* (Ministry of Justice).

COSTA RICA

Draft Hazardous Waste Management Regulation Proposed: The Costa Rican *Ministerio de Salud* (Ministry of Health) and the *Ministerio de Medio Ambiente y Energía* (Ministry of Environment and Energy) have issued a draft Technical Regulation that would govern the classification and management of hazardous waste within the country. Specifically, the Technical Regulation would apply to the generation, transport, accumulation, treatment, "manipulation," "recovery," or disposal of hazardous waste. If passed, it would repeal the law currently in force with respect to hazardous waste management, Decree 37788-S-MINAE/2013.

PERU

Peru Issues New Solid Waste Management Law: The Peruvian *Ministerio de Medio Ambiente* (Ministry of Environment, MINAM) has promulgated Supreme Decree No. 014-2017-MINAM, also known as the "*Reglamento a la Ley de Gestión Integrada de Residuos Sólidos*" (Regulation to the Law for Integrated Management of Solid Wastes). Those familiar with Peruvian environmental regulation will recognize that the country previously had

another solid waste management regulation in force, Supreme Decree No. 057-2004-MINAM. The 2017 Decree incorporates a December 2016 update to the overarching “*Ley de Gestión Integral de Residuos Sólidos*” (Law for Integrated Management of Solid Wastes). Supreme Decree No. 014-2017-MINAM lays out additional requirements for a variety of parties. Such requirements include new obligations for generators of a variety of waste types, producer “take back” requirements for wastes generated from certain Prioritized Goods, and, perhaps most notably, an obligation for generators of used containers of hazardous substances or products containers to recover such.

SOUTH KOREA

K-REACH Amendments Expected To Be Promulgated Shortly And Be Enforced January 2019: The Ministry of Environment (MOE) [announced](#) on March 14, 2018, that amendments to the Act for the Registration and Evaluation of Chemicals (K-REACH) will be promulgated on **March 20, 2018**, and be enforced beginning **January 1, 2019**. As reported in our January 4, 2018, “[Predictions and Outlook for U.S. Federal and International Chemical Regulatory Policy 2018](#),” MOE proposed changes at the end of 2016 that would drastically alter the current legislation and require all substances imported over one ton per year to pre-register and eventually register substances regardless of inventory status.

As initially enacted, K-REACH would have designated priority existing chemicals (PEC) in three batches for registration. MOE announced the [first batch of PECs](#) on July 1, 2015, and PECs imported above one ton per year must be registered by **June 30, 2018**. This registration deadline is unchanged by the amendments. The amendments will apply a phase-in registration mechanism for the remaining existing chemical substances manufactured or imported in volumes greater than or equal to one ton per year, however. The amendments include the following registration deadlines, based on hazard and tonnage band:

- **2018:** 510 PECs;
- **2021:** Registration deadline for all substances used in volumes of over 1,000 tons per year and substances that are carcinogenic, mutagenic, or toxic to reproduction (CMR) used in volumes of one ton or more per year;
- **2024:** Registration deadline for substances used in volumes of 100 to 1,000 tons per year;
- **2027:** Registration deadline for substances used in volumes of ten to 100 tons per year; and
- **2030:** Registration deadline for substances used in volumes of one to ten tons per year.

To help MOE identify and manage potential registrants, and improve joint registration, companies will be required to report information such as the name of the company and the estimated volume of manufacture or import before beginning manufacture or import. Under the amendments, the registration periods based on volume will apply only to companies that pre-register.

MOE will strictly manage substances and products that contact substances that are designated “critically controlled substances.” Critically controlled substances can include the following categories: CMR substances; highly toxic substances; products that contain high amounts of residual substances (*i.e.*, > 0.1 percent and imported above one ton); and substances that cause harm to specific organs such as the lungs and liver.

The amendments will also implement a fine system intended to recover illegal economic benefits obtained by manufacturing or importing chemical substances without registering them. MOE states that it plans to implement the changes by communicating with stakeholders such as industry and non-governmental organizations.

THAILAND

Thailand Delays Implementation Of Existing Chemicals Inventory: The Thai Department of Industrial Works (DIW), which is the competent authority tasked with managing the Existing Chemicals Inventory (ECI), recently announced that the ECI is not expected to be promulgated before **2020**. The initial expectation was to have the ECI in force by the close of 2017. According to DIW, part of the delay may be attributed to DIW’s ongoing work toward developing the Hazardous Substance Single Submission System (HSSS) tool, expected to be available in **2019**.

Beginning in 2018, all documents may be submitted online, but a physical copy of the granted license must be obtained from DIW. Previously, this license had been available in electronic format. Once DIW implements a completely electronic system, the license will once again be available electronically.

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