2019 PRODUCT REGULATORY FORECAST

Authors:

Paula Diaz, *EHS Regulatory Consultant at Enhesa*
Michael Pantelides, *Head of Product Stewardship*
Elise Saade, *EHS Regulatory Consultant at Enhesa*
Gillian Wener, *EHS Regulatory Consultant at Enhesa*
Seong Won Hong, *EHS Regulatory Consultant at Enhesa*

with an introduction by:
Tjeerd Hendel-Blackford, *Head of Thought Leadership at Enhesa*

enhesa
Worldwide Compliance Intelligence

TABLE OF CONTENTS

enhesa
Worldwide Compliance Intelligence

2019 PRODUCT REGULATORY FORECAST

Introduction

Enhesa's team of EHS Regulatory Analysts are continually tracking new environmental, health and safety laws, proposals and policy developments that impact chemicals and electrical/electronic products in more than 285 jurisdictions around the world. Analysts write a report with a detailed business impact analysis for every development; each report is categorized according to our standardized topic headings and allows us to look at trends across the world.

In this paper, **we will provide you with key insights into the most exciting upcoming changes affecting products for 2019 and beyond**. We will cover five global regions and focus on the following topics:

· **RoHS and RoHS like Regulations**

· **Internet of Things**

· **Energy Efficiency**

· **Circular Economy**

· **Chemicals management**

Global Statistical Trends

Figure 1 shows the **increasing number of new regulatory and policy developments over the past four years,** during which the number of developments i**ncreased by 35 percent globally**.
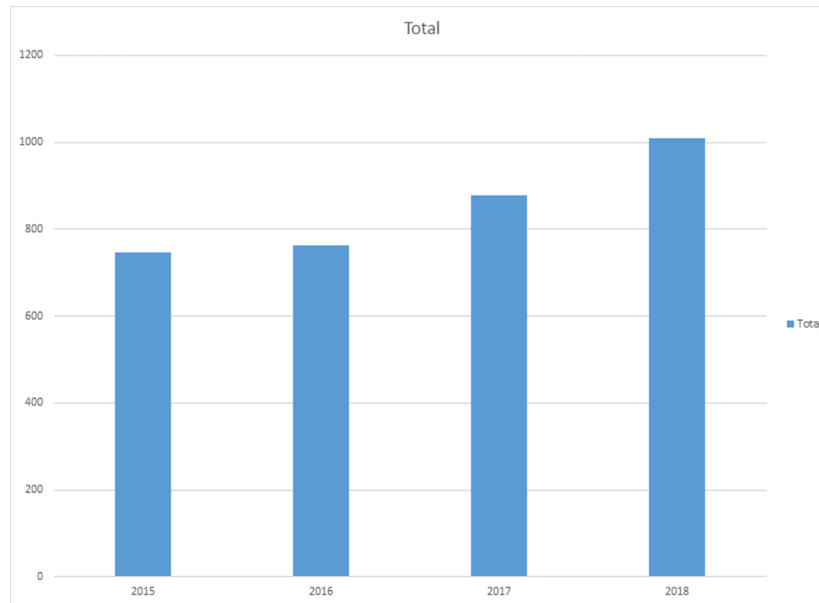

Figure 1

Figure 2 highlights the **top 20 countries in terms of reported new developments**. The **EU** comprises a large portion of the annual new developments; the top five countries make up nearly 50 percent of the reported issues. The most impressive increase in the number of reported issues took place in the **Asia Pacific region**.
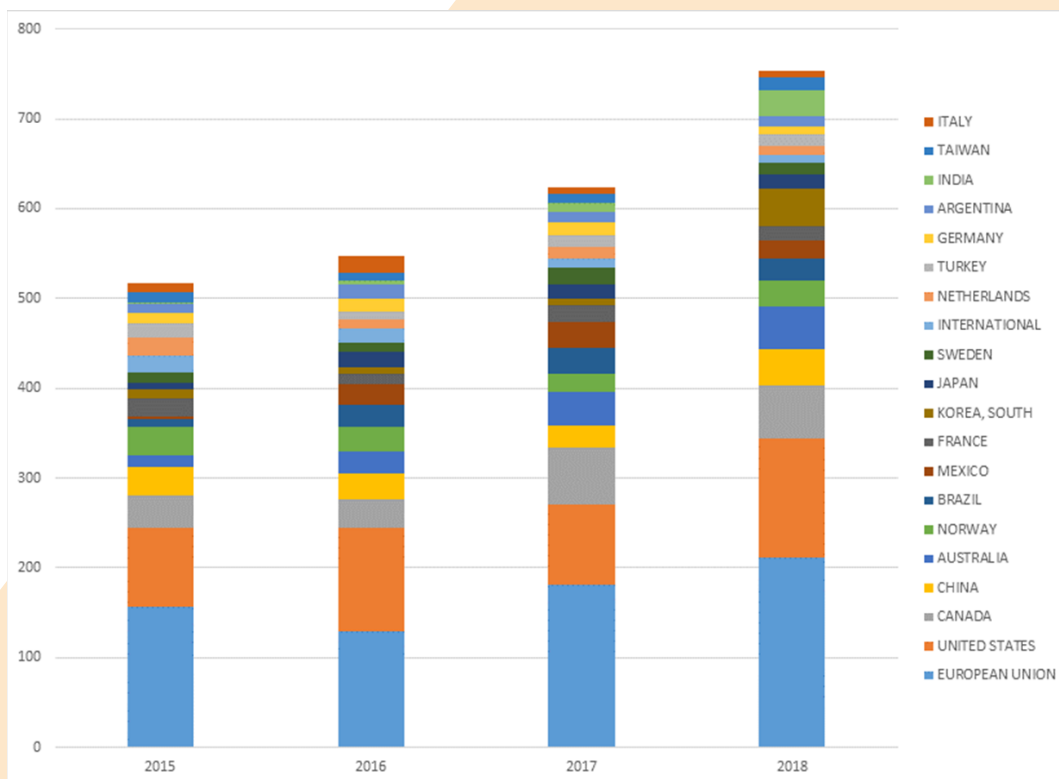

Figure 2

Figure 3 shows the **10 most popular product regulation topics covered over the past four years**. It is interesting to note the chemicals-focused developments (e.g. use and marketing restrictions, classification and labeling and chemical restrictions) feature most prominently.
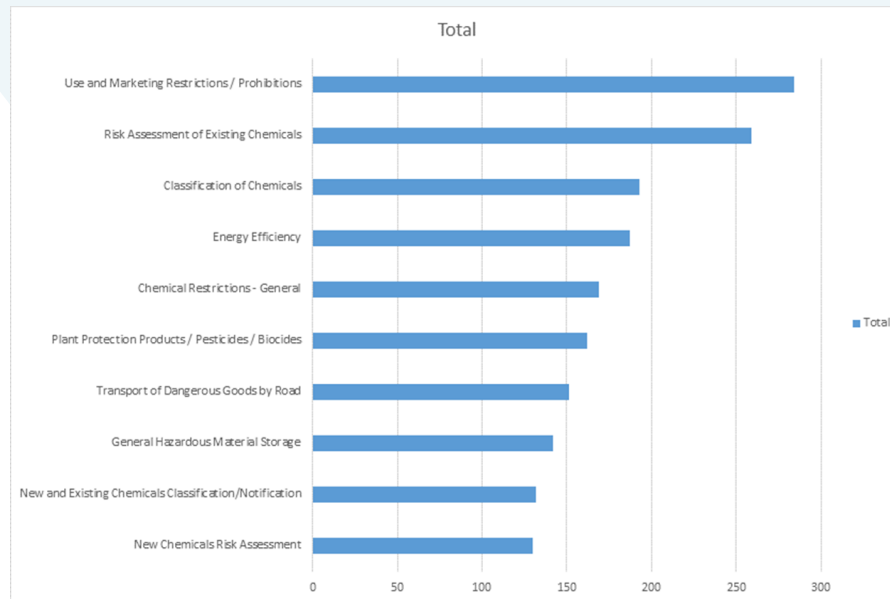

Figure 3

RoHS-Like Legislation
Europe

The use of certain hazardous substances in electrical and electronic products (EEE) is restricted under the "Restriction on Hazardous Substances" (RoHS) Directives.

Directives are not immediately applicable or enforceable by law in all EU countries, meaning that it is up to the individual Member States to decide how to implement goals set by the EU through its Directive. This is the case with the RoHS Directives.

 "RoHS 2" is currently the applicable Directive it replaced the first EU RoHS directive (RoHS 1) and entered into force on July 21, 2011. Like RoHS 1, RoHS 2 restricts the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers in EEE. Nevertheless, many differences exist between RoHS 1 and RoHS 2. For example, RoHS 2 is an "Open Scope" Directive. It applies to all EEE products that are "dependent on electric current or electromagnetic fields for at least one intended function." In RoHS 2, the EEE definition is broadened to include products which use electricity for any intended function. The previous definition was quite broad because it only included products that were dependent on electricity for their primary function. This new scope enters into force on July 22, 2019.

RoHS-Like Legislation: Europe

This means that all equipment that does not belong to the current product categories but has at least one electrical function (no matter how small) will be considered EEE and will have applicable RoHS 2 requirements. Many toys with secondary electronic functions and all equipment that is dependent on electric currents or electromagnetic fields are now considered EEE.

We are also expecting some changes to the list of restricted substances. For example, the methodology for identifying and assessing substances for possible restrictions is expected to be updated. In addition, several exemption requests will also be assessed.

New restrictions are in the pipeline. **Sweden** is pushing for the restriction of Medium-chained chlorinated paraffins (MCCPs) before the RoHS review in Spring 2019.[1] As of January 2019, the proposal is with the European Commission for next steps.

The RoHS 2 Review in Spring 2019 will assess the performance of the RoHS 2 Directive since its entry into force in 2011 and review 7 substances.

Another important development will be the entry into force of the Phthalates (DEHP, DBP, BBP, DIBP) restriction for all EEE on July 22, 2019 (and on July 21, 2021 for medical devices and monitoring and control instruments). While this development is known as RoHS 3, it is directly related to a Directive that amended RoHS 2. Even if the restrictions come into force, we will still be operating under the RoHS 2 regime.

 In addition to the RoHS revisions, the European Commission is investing in a better system to identify substances of concern; this will reduce the presence of chemical substances in commercialized products and improve their traceability. This will be achieved through a new database on the presence of substances included in the Candidate List of substances of very high concern (SVHCs) in articles; an Enhanced Interface between chemical, product and waste legislation and a harmonized interpretation and implementation of end-of-waste rules.

With regards to the new database, the **EU** wants to improve access to information for companies on the composition of the discarded goods they handle by the time the goods become waste. This will have significant implications for companies producing, importing or selling EEE; companies will have to notify ECHA about the presence of SVHCs in their articles. As metal lead (Pb) is now included on the Candidate List, nearly all EEE products will need to be registered in the database.

 As for the Enhanced Interface between chemical, product and waste legislation, the European Commission wants to ensure the uptake, when possible, of secondary raw materials by promoting non-toxic material cycles.

Finally, concerning the Harmonized interpretation and implementation of end-of-waste rules, the European Commission wants to further facilitate the use of recovered material within the EU.

[1] MCCPs are typically used in EEE as a flame retardant and plasticizer in certain plastic materials such as plastic polyvinyl chloride (PVC) used in cable sheathing and are considered to be very dangerous to the health.

Middle East

Several Arab States are expected to adopt RoHS-like legislation following a proposed technical regulation that was notified to the World Trade Organization (WTO) last year**. Bahrain, Kuwait, Qatar, Saudi Arabia, Oman, Yemen** and the **United Arab Emirates (UAE)** proposed a Technical Regulation (TR) to restrict the use of certain hazardous substances in EEE.

In terms of the restricted substances the TR would cover, the list as it stands resembles that of RoHS. In fact, Annex 2 of the technical regulation specifies the maximum permissible concentration (in weight) of substances in homogeneous materials that would be allowed in EEE. For example, a 0.1 percent limit would apply to :

- Lead
- Mercury
- Hexavalent chromium
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ethers (PBDE; Bis(2-ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

A 0.01 percent limit would apply to Cadmium. Restrictions to phthalates would apply to various equipment with specified phase-in dates.

Member states will have to enact national legislation for the adoption of the provisions of the TR. The first country to do so was the **UAE,** which enacted its own RoHS-like regulation (Decision No. 10 of 2017). The Decision entered into force on April 28, 2017 and adopted similar annexes and the same concentrations limits as the TR. We are still expecting specified penalties for violations and mandatory **UAE** standards for the implementation of the Decision.

Latin America

The restriction of hazardous chemicals in electronic equipment is a topic of current interest in Latin America. For example, **Brazilian** authorities are preparing a proposal Decree based on the RoHS 2 Directive. The work group for the proposal's preparation is composed of members of the government, industry and civil society representatives. They held their last meeting on December 6, 2018, where the final text of the proposal was approved.

During their previous meetings, the work group was considering subjecting vehicles to the proposal. However, the final draft did not include any reference to vehicles. The proposal must go through the whole legislative procedure in order to be approved. It is unknown if recent change of government in **Brazi**l will impact the development of this proposal. Companies are advised to keep an eye on the implications of the new government for the chemicals agenda.

Mexico has expressed interest in the elaboration of a proposal based on RoHS 2 and has asked **Brazil** for collaboration. Due to the change of the government in Mexico, it is unlikely that this collaboration will happen soon—chemical management is not on the environmental agenda of the new government.

Asia Pacific

Implementation of RoHS-like legislation will continue to be a major development in many Asian jurisdictions. Countries including **China, South Korea** and **Taiwan** are continuing to implement RoHS-like legislations—or introduce more stringent RoHS and WEEE requirements.

In **China**, beginning March 12, 2019, 12 types of electronic products—such as refrigerators, air conditioners, washing machines and tablets—will be included in the scope of products subject to RoHS-like legislation. The legislation will be titled Management Measures on the Restriction of the Use of Hazardous Substances in Electronic and Electrical Equipment (aka China RoHS 2). Manufacturers and importers of those products will be subject to restrictions on the use of hazardous substances, import/export and labeling requirements. In particular, some examples of restrictions on the use of hazardous substances include limitations on the inclusion of lead to 0.1 percent in mass, inclusion of mercury to 0.1 percent in mass and inclusion of cadmium to 0.01 percent in mass.

A proposal was introduced on October 5, 2018 in **South Korea** to make existing RoHS and WEEE requirements more stringent. If the proposal is adopted, manufacturers and importers of electronic products—such as dehumidifiers, toasters, electric water heaters, hair dryers, scanners and navigation devices—would have to comply with restrictions on hazardous substances for the first time. The scope of restrictions on hazardous substances would be expanded to include substances such as DEHP, BBP, DBP and DIBP. The proposed expansion of restricted hazardous substances mirrors previous changes made by the European Restriction of Hazardous Substances Directive.

In **Taiwan**, implementation of RoHS-like legislation has been an ongoing process since 2016 and will continue into 2019. Since January 1, 2019, products such as charger of electric bicycles or power supplier for cigar lighters in cars are subject to RoHS requirements for the first time.

Internet of Things (IoT)

Europe

In **Europe**, the last two years witnessed an exponential rise in policy actions to accelerate IOT take-up and unleash its potential. For example, the launch of the Alliance for Internet of Things Innovation[2] helped establish a competitive European IoT market and create new business models. Actions were also completed by policy documents such as the Digital Single Market Strategy[3] and "Advancing the Internet of Things in Europe,"[4] a staff working document. The documents included several elements to accelerate further developments on IoT and establish a thriving IOT single market.

However, technological developments don't come without challenges. For this reason, the **EU** proposed several legal solutions concerning liability issues in IoT environments and the free flow of data across national borders in its European data economy"[5] initiative last January. Because liability is important for enhancing legal certainty around the IoT products and services, the **EU** decided to work on adapting the two EU directives that are directly related to product liability.

Last April, the **EU** published a staff working document on liability for emerging digital technologies.[6] It concluded that the Product Liability Directive is an adequate tool; however, the **EU** found that new and more relevant definitions were needed. Many changes are expected, including defining what defective product is and the burden of proof, to the limitation period and cases of the exclusion of liability.

In mid-2019, we are expecting the Commission to issue guidance on the Product Liability Directive and a report on the broader implications for (potential gaps in and orientations for) the liability and safety frameworks for artificial intelligence, the Internet of Things and robotics.

United States

With recent well-publicized incidents regarding the use of hacked internet connected devices to shut down websites, the **United States** is making moves towards regulation of the IoT.

The Federal Trade Commission has issued guidance on device safety and there are a number of related statutes proposed in the U.S. Congress. Most notably, a statute has been adopted in **California** (SB 327) under which, beginning January 1, 2020, manufacturers of any "connected device" will need to equip the device with "reasonable" security features.

2] https://ec.europa.eu/digital-single-market/en/alliance-internet-things-innovation-aioti

[3] https://ec.europa.eu/commission/priorities/digital-single-market/

[4] https://ec.europa.eu/digital-single-market/en/news/staff-working-document-advancing-internet-things-europe

[5] https://ec.europa.eu/digital-single-market/en/policies/building-european-data-economy

[6] https://ec.europa.eu/digital-single-market/en/news/european-commission-staff-working-document-liability-emerging-digital-technologies

In 2015, the **U.S.** Federal trade commission (FTC) issued recommendations for companies developing IoT devices, including the need to build security into devices at the outset, rather than as an afterthought in the design process. For example, providing a patch or alteration after a product is in the hands of consumers may be impossible. Companies should consider measures to keep unauthorized users from accessing consumers' devices, data or personal information stored on a network. The FTC also advocated for strong law enforcement to incentivize the proper safety practices.

There are several pending bills on this topic in Congress:

First, The Cyber Shield Act of 2017 (S. 2020, 115 Cong. (2017)) proposes a voluntary program where manufacturers of IoT devices adhere to certain IoT security protocols; in return, manufacturers are given government certification that their devices are secure, most likely a sticker affixed to the device.

The Cybersecurity Improvement Act of 2017 (S.1691, 115 Cong. (2017)), would require a vendor of IoT devices meet certain criteria before a U.S. government agency can purchase the device. Federal procurement is a large market and rules often proceed those rolled out nationwide. The proposed legislation would require that IoT devices are patchable, do not contain known vulnerabilities, rely on standard protocols and do not contain hard-coded passwords. Industry can develop third-party device certification standards that provide equivalent, or more rigorous, device security requirements. We expect more activity in this area in the future.

Energy Efficiency

Americas

Although not yet adopted by the governments of Canada, Mexico and the United States, the United States-Mexico-Canada Agreement (USMCA) foreshadows greater collaboration on issues of chemical regulation and the efficiency of electronics. Under the USMCA, each country must designate a competent authority to establish and enforce energy performance standards and related test procedures; the three states will endeavor to harmonize requirements.

Asia

Improvement of energy efficiency is a common goal for many Asian jurisdictions. Notably, many jurisdictions are increasing the scope of electronic products that must have an energy efficiency label. This will increase consumers' awareness of energy efficiency of various electronic products and will motivate manufacturers and importers to improve their products' energy efficiency. Some jurisdictions have made improving the required energy efficiency standards of various electronic products a key focus.

On October 1, 2018, **Singapore** added products such as air conditioners, lamps and televisions to the list of products that must be registered with the National Environment Agency (NEA) and require energy efficiency labels. In addition, manufacturers and importers of regulated motors must register their products with NEA and attach appropriate energy efficiency.

In **Hong Kong**, since June 1, 2018, manufacturers or importers of electronic products such as televisions, storage type electric water heaters and washing machines must comply with the energy efficiency labeling requirements. As part of the required process, manufacturers or importers of those products must submit their products to accredited testing labs for energy efficiency testing and then affix labels that reflect the results of such testing.

In **New Zealand**, a joint proposal with **Australia** was recently issued on June 13, 2018 to include LED lamps in the scope of products subject to energy efficiency requirements. If this proposal is adopted, it would go into effect sometime in 2020. The proposed minimum energy performance standard (MEPS) would be in line with the revised EU minimum standards set to go into force in September 2020.

South Korea has also been making it a key focus to increase energy efficiency by increasing the scope of products that are subject to MEPS and energy efficiency labeling requirements. If the proposal issued on July 9, 2018 is adopted, manufacturers or importers of three products—industrial freezers, industrial air compressors or digital signs—would have to comply with MEPS and energy efficiency labeling requirements for the first time beginning in 2019. Further, if the proposal is adopted, manufacturers or importers of vacuum cleaners would have to comply with more stringent MEPS.

In **China**, a mandatory system known as green product certification is likely to be launched in the future. Under this system, manufacturers or importers of applicable products must affix a green product labeling showing the energy efficiency and certifying that those products meet the required MEPS and other requirements. As proposed, products such as solar power water heating systems would be subject to these requirements.

Latin America

We identified several initiatives aimed at protecting the environment through the regulation of energy efficiency and labeling. For example, as of April 1, 2019 in **Colombia**, energy labeling and conformity assessments will be mandatory for air conditioning equipment, Multi-Split motors and single-phase and three-phase submersible motors used exclusively for pumping systems.

Stricter energy efficiency indexes for air conditioners, refrigerators, freezers and insulating liquid distribution transformers will apply as of 2019 in **Brazil**. Furthermore, new testing procedures have been established to ensure compliance with energy efficiency labels in **Uruguay**. The **Dominican Republic** is discussing labeling requirements to provide users with information on energy efficiency and energy consumption.

As of July 1, 2019, manufacturers of certain household electric lamps must ensure they comply with a maximum level of specific energy consumption or minimum level of energy efficiency corresponding to class in **Argentina**.

Circular Economy

Europe

In 2018, the **EU** saw a major development with the introduction of proposed ban or restrictions on single-use plastics. The proposed bans concern the prohibition on the placing of the most harmful single-use plastics which can be affordably replaced on the market—for example, plastic cotton buds and balloon sticks.

As for the proposed restrictions, these would aim to reduce the consumption of single-use plastics for which an alternative is not yet available through:

- Design and labeling obligations
- National reduction in consumption
- Waste management
- Producer's clean-up obligations

On a broader level, it is worth noting that a public consultation on the EU Product Policy Framework recently ended on January 24, 2019. The (pending) results of this could have implications on EU policy measures.

Latin America

The concept of circular economy is not completely new in Latin America. During recent years, we have reported on several developments intended to make companies placing products on the market responsible for those products (and their packaging) once they become waste.

For example, companies placing lubricant oils on the market in the Amazonian region in **Brazil** will be required to collect empty lubricant oil packaging and ensure its sound disposal.

Circular Economy: Latin America

Similar requirements have been proposed in **Colombia**. Companies placing prepackaged goods on the Colombian market must develop and implement an environmental waste management plan for packaging. Companies will have to comply with annual recovery goals, report on the amount and types of packaging placed on the market, create awareness campaigns and coordinate the take back and recovery of the packaging.

Companies placing products contained in steel packaging on the market, such as those used for food, paints, cosmetics and aerosols, are advised to closely follow the development of a public consultation started in January 2018 to establish take-back requirements for this type of packaging.

In line with this, take-back and reporting requirements will apply to companies placing packaging or packaged products on the market in the **State of Rio de Janeiro** as of May 2019.

For the first time, a proposal has been made in **Argentina** to regulate the planned obsolescence of electrical and electronic equipment (EEE). This will seek to:

- Avoid EEEE lifespans being viewed as limited to a certain number of uses
- Prevent situations where a product is impossible to repair because of lack of adequate spare parts or because repair is impossible
- Prevent the scenario where a computer program stops working after the operating system is updated
- Prevent the proliferation of marketing campaigns by companies aimed at making consumers perceive existing products as obsolete

 If companies place EEE products on the market, there labels will have to contain information regarding:

- Maximum useful life of the product [according to the certification and standardization methods that will be adopted by the authority]
- Availability of pieces of the product
- Usage meter of the life of the product indicating, for instance, the amount of impressions, number of washes or amount of shots
- Maintenance, repair and use

Parts essential to the operation of EEE products will have to be provided upon consumer request—at a reasonable price and waiting period. It will be prohibited to seal essential pieces of EEE to prevent the user from replacing or repairing parts. The Argentinian government hopes that these measures will help consumers to make more environmentally friendly choices.

Asia

Circular economy is another goal for many Asian jurisdictions heading into 2019. Countries like **South Korea, Thailand**, and **India** have made it a key point to better implement aspects of circular economy by introducing more stringent recycling requirements on manufacturers or importers of certain products.

In **South Korea**, manufacturers or importers must comply with target recycling rates set by the Ministry of Environment for their products. Recently in October 2018, two proposals were issued by the Ministry of Environment to make the recycling rate more stringent for products such as composite material and film sheet type packaging, fluorescent light bulbs, refrigerators, water coolers, personal computers and televisions. For example, the target recycling rate for refrigerators would be increased from 70 to 80 percent and from 65 to 80 percent for personal computers.

In **Thailand**, a proposal was issued on March 29, 2017 (which is still in an ongoing legislative process) that would introduce a holistic regulatory framework to better manage waste. The proposed regulatory framework would control the volume of waste generated and promote more reuse and recycling. Namely, producers would have to comply with an overarching system that includes requirements at the product design stage, waste disposal, reuse or recycle all geared to minimizing waste management.

In **India**, electronic waste rules were amended on March 22, 2018 to introduce more stringent e-waste collection requirements for producers of applicable electronic products. Companies that manufacture electronic products such as printers and fluorescent lamps must comply with more stringent waste collection rates going forward. In particular, manufacturers are required to collect 20 percent of e-waste generated for the financial year of 2018 to 2019. For the financial year of 2019 to 2020, they will be required to collect 30 percent of e-waste generated.

Chemicals

Asia

There are two key issues that will impact environmental requirements for manufacturers or importers of products going forward in the Asia Pacific region.

First of those issues is the implementation of updated GHS regulations. GHS regulations refer to Globally Harmonized System of Classification and Labeling of Chemicals and requires manufacturers or importers of certain chemicals to identify and communicate the health and safety information of their products by affixing appropriate labels and filling out safety data sheets (SDS).

Chemicals: Asia

In **Taiwan**, under the recently amended Regulation of Labeling and Hazard Communication of Hazardous Chemicals, manufacturers or importers of certain hazardous substances must comply with more stringent classification and labeling requirements—particularly to protect workers who deal with such chemicals onsite. Beginning January 1, 2020, companies manufacturing, importing, supplying or providing certain hazardous chemicals to their workers must include the CAS registry number of such chemicals in SDS.

In the **Philippines,** implementation of the 4th edition of GHS has been an ongoing process since 2016 and will continue well into 2019. Since 2016, different types of chemicals have been part of a staggered implementation process. In 2019, a broad spectrum of chemicals defined as "mixtures or mix of two or more chemicals that do not cause a chemical reaction" will be added to the scope of GHS. Therefore, in 2019, manufacturers or importers of mixtures will have to comply with provisions of the 4th edition of GHS.

The final common issue and goal of many Asian jurisdiction lies in the ratification and implementation of a treaty known as the Minamata Convention on Mercury. The Minamata Convention is designed to protect human health and the environment from emissions and releases of mercury and mercury compounds by controlling and limiting the use of mercury in end products, various processes as well as industries. The Minamata Convention also addresses issues such as export/import; safe storage and waste disposal of mercury and certain products containing mercury.

In **China**, the Minamata Convention was ratified by the National People's Congress in 2016 and an implementing regulation was passed in to law on August 16, 2017. The implementation process through the regulation will take effect at various points starting from 2019 until 2026 and will effect products that facilities may manufacture or import, as well as how facilities may carry out certain processes. For example, beginning January 1, 2019, companies must not use mercury or mercury compounds to produce acetaldehyde. Beginning January 1, 2021, companies must not import or export any switches or relays that contain mercury with certain exceptions. Then, beginning January 1, 2026, companies must not manufacture mercury thermometers. Finally beginning on August 16, 2027, companies must not use mercury or mercury compounds to produce sodium methoxide, potassium methoxide, sodium ethoxide or potassium ethoxide.

In **Japan**, the implementation of the Convention started in 2018 and will continue into 2020. As of January 1, 2018, companies are banned from manufacturing batteries containing mercury except for certain button zinc air batteries.Companies are banned from manufacturing certain types of fluorescent lamps such as compact, linear and cold cathode types. Thereafter, beginning December 31, 2020, companies will be banned from manufacturing alkaline manganese batteries, switches, high pressure mercury vapor lamps, merbromin, barometers and thermometers.

Finally, in **India**, the Minamata Convention was approved for ratification by the Union Cabinet on February 7, 2018. The implementation process is likely to begin sometime in 2019 and will continue well into 2025 giving companies plenty of transition time to adjust with the changes to their manufacturing processes.

United States, Federal

In order to look forward at developments in chemicals regulation in the **United States**, we have to briefly look backwards. An important development in **U.S.** chemicals legislation deals with the Toxic Substances Control Act (TSCA) of 1976. In 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, or "New TSCA," greatly expanded the authority and reach of the U.S. Environmental Protection Agency (EPA). TSCA regulates the introduction of new chemicals and already existing chemicals, including establishing a national chemical inventory. Manufacturers, importers and processors of chemical substances must submit certain notifications, implement specific safety precautions and provide safety information to EPA.

EPA's expanded authority under New TSCA gives us a map for coming changes. First, the law establishes a framework for clearing up the patchwork of state chemical regulations. Currently, those state regimes are complex and, sometimes, contradictory.

New TSCA also establishes new safety standards for substances that have gone unregulated for decades and creates new risk-based safety standards to include special consideration for pregnant women, children and other groups.

In the two years since New TSCA passed, EPA has been steadily promulgating regulations to comply with the deadlines set by Congress. With the rollout, significant progress has been made in several areas; one example being the establishment of user fees for different submissions that a manufacturer, importer or processor of a chemical is required to make under the TSCA program. Fees have long been required for premanufacture notifications and significant new use notifications. *The revised rule* introduces new fees for companies required to submit information by test rule, test order or enforceable consent agreement made with EPA. Additionally, companies that manufacture or process a chemical substance that is subject to a risk evaluation, including one conducted at the manufacturer's request, are subject to these new fees.

Additionally, EPA is moving forward on prioritizing chemicals for review. As these roll out, notice will be published in the federal register.

It is also worth highlighting the significant changes affecting the confidentiality of information submitted to EPA under TSCA. Recently, EPA has been working to provide additional clarity to manufacturers, importers and processors regarding the protection of confidential business information (CBI). EPA has developed guidance for companies regarding the provision of information to emergency responders and medical personnel. Companies should be aware of the expanded access to their CBI under TSCA as they consider their activities in the **U.S.**

Lastly with regard to the rollout under the new TSCA, the **U.S.** is required to phase out the use of animal testing for evaluating chemical safety —and regulations are coming down the pipeline.

The U.S. may see an increase of litigation to achieve bans or limitations on chemicals where the EPA fails to act as required by law. TSCA protects the right of individuals to sue in order to enforce the Act. Companies may see lawsuits for failure to comply with requirements, and EPA's actions might be challenged as well.

United States, States

As the **United States** goes its own way in many things, TSCA exists in the same universe as several individual US-state regimes also imposing requirements on chemical manufacturers, importers and processors.

Most notable, and impactful to companies, is **California**'s Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986. California is very often allowed to make its own, more stringent environmental requirements due to its size, large population and unique environmental challenges. When TSCA was amended in 2016, it established a carve out designed both to protect and limit Prop 65. Proposition 65 was inhibited from establishing requirements for the same chemicals for which EPA has begun an evaluation or already established requirements. This change still leaves a lot of room for independent action on the part of **California**; at the same time TSCA was amended in 2016, Proposition 65 and its implementing regulations were also amended.

California repealed and replaced its prior requirements relating to clear and reasonable warning regarding the safety of chemical substances. The new regulations, which became effective in 2018 made the following changes:

- **California** now requires warnings that are more visible, informative and specific to identified chemical exposures to be given to users.
- The state now provides more specific guidance to businesses on the required content for warnings for a wider variety of exposure situations and corresponding methods for providing those warnings.
- Most importantly, the state places the burden of responsibility to provide warnings on the manufacturer, producer, packager, importer, supplier or distributor of a product rather than on the retail seller in most situations.

With these new requirements, industry is gearing up to see a significant increase in litigation, as Proposition 65 allows for citizen enforcement. Companies should not only emphasize compliance with the revised Proposition 65, but also track new developments arising from litigation that might influence requirements applicable to labels or responsibilities under the law.

New York is another state with special chemicals regulation—notably, in the last year, manufacturers of household cleaning products must disclose their chemical ingredients and other information on their websites related to specific chemicals of concern. It stands to reason that this program may expand to other types of consumer chemicals or articles containing chemicals.

Latin America

The implementation of the United Nation's (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS) is one of the main trends for chemical management in **Latin America**.

As of today, in Latin America, only **Ecuador** and **Colombia** have fully implemented[7] the GHS while **Mexico, Brazil, Argentina** and **Uruguay** have only partially implemented GHS[8]. This means that GHS labeling requirements only apply to consumer products in Ecuador and Colombia.

Chile has also submitted draft regulations to fully implement GHS. They will clearly call for the labeling standards to apply to consumer products. In **Bolivia,** a proposal to partially implement GHS is being prepared.

Since 2014, the voluntary Standard that regulates the order and content of SDSs in **Venezuela** has been based on GHS.

Latin America's emerging chemical regulations can easily become barriers to access for chemical manufacturers that have focused only on the application of labeling requirements for large industrial chemicals. If a company is planning to import chemicals intended to be used by consumers, it must make sure that those chemicals are appropriately labeled in **Ecuador** and must keep track of the changes that will be introduced by Chilean proposal.

Another issue in **Latin Americ**a concerns establishing chemical inventories and comprehensive regulations around chemicals management.

For example, **Brazil** is discussing a REACH-like proposal. If approved, the draft law on the registration, evaluation and control of chemicals would require companies placing industrial chemicals in an amount equal to or greater than one ton per year to provide some information to the National Register of Chemicals such as:

- The identification of the producer or importer
- The CAS number of each chemical
- The quantity that is produced or imported per year
- The recommended uses of the chemicals
- The GHS hazard classification

[7] Full implementation of the GHS means that a country has implemented the GHS for all kind of products, including consumer and agriculture products. This is the rule in the European Union and Asia.

[8] Partial implementation of the GHS means that the implementation is limited to the industrial workplace excluding the agriculture and consumer sectors.

Chemicals: Latin America

The collected information will be used to create a National Inventory of chemicals. The significance of this is that chemical substances not listed in the inventory will be regarded as new chemical substances. Manufacturers and importers of new substances will need to register them and prepare a risk assessment. As an exception, some existing chemical substances, this is chemicals included on the inventory, will also be selected for evaluation. A list of substances subject to this extra requirement will be published.

In **Mexico**, one of the commitments derived from the UN Sustainable Development Goals and the Strategic Approach to International Chemicals Management (SAICM) is the publication of chemical inventories in order to promote chemical safety around the world. In addition to that, a new trade agreement between **U.S., Canada** and **Mexico** will likely enter into force in 2020. This new trade agreement could require **Mexico** to develop a risk based methodology for the evaluation of chemicals, as is the case today in **U.S.** and **Canada**. The National Catalog is the first step towards this final goal.

With the aim of updating and aligning the names and CAS numbers of chemicals in **Mexico**, a new project called "Guidelines of the National Catalog of Chemical Substances" updated the information from the National Inventory of Chemical Substances of 2009 and introduced the National Catalog of Chemical Substances. The Catalog is an informative list that does not impose any requirements on operators.

A proposal for the integral management of chemical substances is being discussed in **Argentina**. The proposal will follow the example of **Canada**, whereby the country will adopt a risk-based methodology for risk assessments. The proposal will approach the following topics:

- Chemical inventory
- Classification of chemicals
- Risk assessment
- Risk management measures

According to our contacts in the Argentinian authorities, the Law will likely be approved during 2020.

In **Chile**, provisions for the integral management of industrial chemicals are also in the pipeline. The proposal for the Classification, Labeling and Notification of Chemical Substances and Mixtures would implement the 6th edition of GHS in **Chile** and would impose notification requirements for companies placing on the market hazardous substances in volumes equal or greater than 1 tonne per year or substances which are carcinogenic, mutagenic or toxic for reproduction (CMR), irrespectively of the volume.

The approval of this proposal will start a process of update of existing chemical legislation and preparation of additional regulations to establish risk Assessment procedures and methodologies and compile a harmonized list for the classification of chemicals. This process will take several years.

 In line with the other **Latin American** countries, the integral management of industrial chemicals is also being discussed in *Colombia*. As a result, operators in **Colombia** should be aware that they may be required to:

- Register the industrial chemicals they place on the market
- Perform self-risk assessments
- Establish risk management programs

In **Costa Rica**, the Decree that implemented GHS also aimed to address the management of industrial chemicals. According to it, all non-hazardous chemicals that were previously exempt to any reporting requirement must now be notified to the Ministry of Health. Furthermore, all previously registered hazardous chemicals will be required to re-register. The renewal will be done in steps depending on the date of registration or notification.

Lastly, **Ecuador** received the support of the UN for its National Program for the correct management of chemicals during their life cycle. The Program aims to protect human health and the environment by improving the sound life-cycle management (LCM) of chemicals of concern, with a particular focus on Persistent Organic Pollutants (POPs) and mercury (Hg). This is the biggest project addressed to chemicals management in the LATAM region.

Conclusion

Product regulations continue to spread geographically. Typically, one country or region will take the lead on a specific subject and then other countries will follow. RoHS and REACH-like laws are good examples of this. Previously, new regulatory initiatives often originated in specific countries like the **Nordic** countries. However, w**e now increasingly see that such new initiatives can appear in many different countries and regions.** Examples of this include when the **U.S**. took the lead on the conflict minerals issue (and which was followed by the EU). or when **Saudi Arabia** introduced requirements on oxo-biodegradability of packaging which is now being discussed in other countries.

Another problem for companies is that when these new initiatives go global, each country carries it out their own way. This means that c**ompanies not only have to track down where something has been adopted, but also identify AND understand those small differences.** One small difference can be a huge deal, so companies end up managing and tracking many different versions of the same type of legislation.

Conclusion

To counter this, **we see continued attempts to harmonize rules at international level.** The globally harmonized system of classification and labellng of chemicals is for example constantly being updated. This works in theory, but countries are not implementing these rules uniformly; companies need to identify the specific version used by each country.

We also see a counter trend, where there is an effort to deregulate. The most obvious example would be the current **United States** administration, which has made it clear that under his term there would be less environmental regulation. We see the seed for a similar trend in **Mexico** and **Brazi**l. Concerns have also been raised that negotiations of trade agreements like The Transatlantic Trade and Investment Partnership (TTIP) between the **U.S**. and **EU** could mean deregulation in practice.

We can also see how technical innovation remains a driver for new regulation. At the moment, industry is still one step ahead of regulation.

In this paper, we have provided a relatively detailed overview of what you can expect in the upcoming years. But what can we expect in the long term? Climate Change is not something that will likely be solved in the next couple of years. We believe that **Climate Change is likely to lead to more stringent and new ways of regulating the product sector.** What we see in terms of energy and water efficiency requirements today is only a beginning. We are likely to see restrictions and incentives to encourage certain types of energy uses, such as renewable energy.

Circular Economy is a closely related concept where we can expect increased pressure to reuse packaging materials, alternatively making them biodegradable; we will also see increased pressure on the use of plastics. **Asia, Europe** and **Latin American** countries are all sending clear signals that these are priority areas.

We are likely to see more requirements on the use phase of consumer products as well, with an obligation to make products last longer and be easier to maintain and repair with obligations to supply spare parts for a certain amount of time and manuals, etc.

Another issue that will be increasingly regulated and that is part of the Circular Economy, is product Waste. Extended Producer responsibility will likely cover many more products in 10 years from now. Waste streams in **Asia** and **Africa** are likely to go through significant changes and reuse and recycling will be popular topics ahead.

We can expect more laws worldwide that will cover the new technologies. Internet of Things, the use of nanotechnology, 3D printing etc. will give rise to enhanced product safety regulation, data protection rules, notification and registration obligations for nanoforms of substances.