II. KEY GLOBAL CHEMICAL MANAGEMENT PREDICTIONS

C. ASIA

1. Chemical Substance Management in Asia
2018 saw the continued development primarily in China, S. Korea, Taiwan, and Vietnam of a wide range of chemical substance and product management statutes. 2019 is expected to bring changes to chemical control legislation in S. Korea, Taiwan, and Vietnam.

1.1 China

China is expected to continue its legislative changes and regulatory development as mandated in 2016 in its 13th Five Year Plan for Economic and Social Development. It is certain that more regulations and national/industrial standards will be released and more enforcement campaigns will be carried out in 2019. Enterprises should pay close attention to the upcoming regulations for their activities, such as substance notification and transport/storage of hazardous products, which may be affected.

Chinese government agencies went through major reorganization through mergers and setting up new offices in 2018. The Ministry of Environmental Protection (MEP) was rebranded and expanded to the Ministry of Ecology and Environment (MEE), while also assuming some responsibilities previously assigned to the National Development and Reform Commission (NDRC), Ministry of Water Resources, Ministry of Agriculture, and Ministry of Land and Resources. The Ministry of Agriculture was rebranded and expanded to the Ministry of Agriculture and Rural Affairs (MARA) to oversee agriculture, rural development, and land uses, including registration and supervision of pesticides, fertilizers, and veterinary medicine. The Ministry of Emergency Management (MEM) was established to be responsible for work safety issues and natural disasters, assuming the responsibilities of the State Administration of Work Safety (SAWS), including registration, licensing, and management of hazardous chemicals. The National Health and Family Planning Commission (NHFPC) and State Council Leading Office on Reform of the Medical and Health System were merged into the National Health Commission (NHC) to oversee healthcare, including registration and management of drinking water-related products, and food-related products such as food additives, and FCMs and articles. The China Food and Drug Administration (CFDA), the State Administration for Industry and Commerce (SAIC), and the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) were merged into the State Administration for Market Regulation (SAMR), a new competition law enforcement agency that takes over the anti-monopoly enforcement functions previously spread among the NDRC, Ministry of Commerce (MOFCOM), and SAIC. The SAMR is also responsible for food safety and the National Medical Products Administration (NMPA) under the SAMR is responsible for registration and supervision of medicines, medical devices, and cosmetics.

(a) Industrial Chemicals

The China State Council published on September 28, 2018, a Plan to Optimize Environmental Protection Regulations with an intention to improve environmental quality. The optimization plan includes repeal, consolidation, and optimization of current regulations, national/industrial standards, and normative documents regarding environmental protection to decrease inconsistencies and contradictions and ensure consistent alignment of local, provincial, and central legal stipulations. The regulations on chemicals will certainly continue evolving based upon the
commitment to a greener future that was laid out in the 13th Five Year Plan and the Belt and Road Ecological and Environmental Cooperation Plan in 2017.

The 13th Five Year Plan requires the MEE to develop strategies and regulatory measures for greener environment and protection of the ecosystem by 2020, which includes establishing a hazardous chemical database, capacity, and capability for hazard identification and risk assessment, management of hazardous chemicals and wastes, and improving control of toxic chemicals. Several new regulations have already been released or updated in 2018, including the List of Priority Control Chemicals (First Batch), the List of Toxic Chemicals Strictly Restricted (2018), and GB 36700.1-.8-2018 Guidance on Hazard Classification to the Aquatic Environment.

The implementation of the List of Priority Control Chemicals (First Batch) will gradually phase out products contained in the list. The first batch of priority chemicals contains 22 categories of chemicals that are mainly intrinsically hazardous and highly bioaccumulative, and have the potential to pose great risk to the environment and human health; many of these chemicals are also listed in Annex XIV of REACH. The list will be updated periodically, and the “Guideline for Screening Priority Chemicals” is expected to be released by 2020. It has been suggested that some of the priority chemicals may be incorporated into product-specific regulations in the future.

The List of Toxic Chemicals Strictly Restricted for Import and Export (2014), which contains 162 categories of chemicals, was replaced by the List of Toxic Chemicals Strictly Restricted (2018). The 2018 revision is mainly based on the Stockholm and Rotterdam Conventions and contains ten categories of toxic chemicals. The uses of these toxic chemicals are prohibited, except for some special permitted uses, due to their serious adverse effects to human health or the environment.

The national standards, GB 36700.1-.8-2018 Guidance on Hazard Classification to the Aquatic Environment, provide supplementary classification guidance on aquatic environmental hazards. GB 36700.1-.7-2018 is based on Annex 9 of Revision 4 of the UN GHS and will become effective on April 1, 2019; GB 36700.8-2018 relates to Annex 10 of UN GHS Revision 4 and became effective on January 1, 2019. The GB 36700.1-.8 plus already implemented GB 30000.28-2013 enable China to align fully with the UN GHS Revision 4 with respect to aquatic environmental hazard classification.

Strengthening the enforcement of regulations was one of the key governmental efforts for improvement of environmental quality in 2018. MEE has conducted several enforcement campaigns against water and air pollution in 2018, which have resulted in the shutdown of thousands of factories and global shortages of many raw material supplies, including some pesticides and preservatives such as benzisothiazolinone (BIT). (Reisch MS, Shortage of BIT, A Key Preservative, Looms. C&EN. Volume 96(36) (Sept. 10, 2018), available at https://cen.acs.org/business/consumer-products/Shortage-BIT-key-preservative-loats/96/i36.) The Jiangsu provincial government announced on September 4, 2018, the closing of 1,000 chemical factories over the next three years. A new chemicals inspection campaign was also initiated in Shanghai to enforce registration and annual reporting of new chemicals.
The Environmental Management of New Chemical Substances (MEP Order No. 7), that has been in force since 2010 and is a revision of the 2003 regulations of new chemical substances, is currently under revision. The revised draft version has been under internal review since fall 2017 and is expected to be released in the first half of 2019.

SAWS drafted a new law called the Law on the Safety of Hazardous Chemicals for internal review in 2017. It was expected that the law might replace the current State Council Decree 591 Regulations on Safe Management of Hazardous Chemicals, which provides a legal framework for hazardous chemicals, including general provision for production, uses, licensing, and registrations of hazardous chemicals, GHS promulgation, and transport of dangerous goods. SAWS was, however, dissolved and its responsibilities were assigned to the newly established MEM in the overhaul of the executive branch of the Chinese government in early 2018, which will likely delay the progress of the proposed Law on the Safety of Hazardous Chemicals.

The Rules on Restriction of the Use of Hazardous Substances in Electrical Appliances and Electronic Products (China RoHS2) became effective on July 1, 2016. Its implementation requires the Ministry of Industry and Information Technology (MIIT) to develop a standard achieving management catalogue and a list of its exemptions. The Standard Achieving Management Catalogue for the Restriction of the Use of Hazardous Substances in Electrical Appliances and Electronic Products (First Batch) and the Exemption List for the Restriction of the Use of Hazardous Substances of the Standard Achieving Management Catalogue have been released and will be implemented on March 12, 2019.

The Standard Achieving Management Catalogue (First Batch) includes refrigerators, air conditioners and filters, washing machines, electric water heaters, printers, copy machines, fax machines, television sets, monitors, personal computers, handsets for wireless communication, and telephones, totaling 12 types of products that must comply with the hazardous substance restriction limits, set out in national standard GB/T 26572-2011. The Exemption List contains details on 39 products or component parts that are exempt from the hazardous substance restrictions of China RoHS2, and their limits, if applicable; for example: mercury in certain lamps, lead in certain glass, alloys, or lamps, cadmium in certain electronic products, and hexavalent chromium as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators.

China is gradually phasing out ozone-depleting substances (ODS). The uses of hydrochlorofluorocarbons (HCFC) will also be phased out as were uses of chlorofluorocarbons (CFC), halons, carbon tetrachloride, methyl chloroform, and methyl bromide. MEE announced that the uses of dichlorofluoroethane (HCFC-141b) as a foaming agent for the production of refrigerators, freezers, refrigerated containers, and electric water heaters will be banned as of January 1, 2019.

New legislation addressing soil contamination, the Soil Pollution Prevention and Control Law, became effective on January 1, 2019, and sets out general principles for soil pollution prevention, risk management and control, pollution liability, public participation, supervision, and enforcement. The law introduces a series of soil pollution prevention and control management systems, including a soil environment database and information sharing platform, a management system for cropland,
controls for pesticides and fertilizers, an inventory of construction land subject to risk control and remediation, and a directory of entities subject to key supervision for soil contamination.

(b) Agricultural Chemicals

China revised its pesticide regulations in 2017, which significantly changed the pesticide registration requirements and process in China. The revisions significantly impact foreign/multinational entities. Two requirements in particular are noteworthy: the requirement that chemistry and toxicology tests completed in countries without a MAD agreement with China must be repeated in China, and that foreign entities cannot directly distribute or sell pesticides in China, but must distribute or sell pesticides through either their own distribution entity in China or engage pesticide distribution agents in China.

Chinese MARA will gradually phase out highly toxic pesticides and complete the first 15-year registration review and reevaluation cycle by 2022. There are 40 banned and 32 restricted pesticides in China currently; four additional pesticides will be banned, including the production and use of sulfluramid on March 25, 2019, the marketing and use of phorate, aldicarb, and acesulfame on October 1, 2020, and of their production on October 1, 2023. Five of the restricted pesticides will have additional restrictions, including prohibition of agricultural use of bromomethane and endosulfan starting on January 1, 2019, and March 26, 2019, respectively, and banned uses of acephate, carbosulfan, and dimethoate on vegetables, fruits, tea leaves, fungus, and Chinese medicine herbs starting on August 1, 2019. It is expected that methylisophosphorus, phosphine, omethoate, and aluminum phosphide will be phased out by 2020 and carbofuran, methomyl, and chloropicrin will be phased out by 2022. The initial ten pesticides for the first 15-year registration review and reevaluation cycle are glyphosate, carbendazim, triazophos, atrazine, imidacloprid, alachlor, butachlor, dimethacarb, metolcarb, and quintozene.


(c) Food Contact Regulations

The Chinese regulatory system for FCMs and articles is comprised of a series of national food safety standards (NFSS) for FCMs, including GB 4806.1-2016 on general requirements, GB 9685-2016 on the use of 1,294 approved additives for FCMs, GB 5009.156-2016 general principles of pre-treatment methods for migration test, GB 31604.1-2015 general principles of migration tests, GB 31603-2015 general hygienic practice for FCM production, material standards, and test guidelines for individual substances under the Food Safety Law. GB/T 14251-2017 General Technical Standard for Metal Container of Canned Food became effective on October
China’s NHC announced on May 9, 2018, that the draft NFSS on Food-contact Starch-based Plastic Materials and Articles and the draft NFSS on Food-contact Composite Materials and Articles were available for public comment. The draft standards define the FCMs and impose manufacturing and migration testing requirements. The China National Center for Food Safety Risk Assessment (CFSA) is drafting several new FCM NFSSs, including standards for adhesives and printing ink, and migration tests for several substances, which are expected to be released in 2019. Several existing FCM standards are also under revision, including GB 31604.1-2015, GB 4806.6-2016 on plastic resins, GB 4806.7-2016 on plastic materials and articles, GB 4806.8-2016 on paper and cardboard, GB 4806.9-2016 on metal and alloy, GB 4806.10-2016 on paints and coatings, GB 4806.11-2016 on rubbers, and GB 31604.7-2016 on decolonization test.

GB 2763 NFSS -- Maximum Residue Limits (MRL) of Pesticides in Food has been updated every two years since 2012. The latest version (GB 2763-2016) was implemented on June 18, 2017. The NHC published GB 2763.1-2018 NFSS -- MRLs of 43 Pesticides in Food on June 21, 2018, with the implementation date of December 21, 2018. Draft MRLs for 105 pesticides were notified to the WTO on Technical Barriers to Trade on February 19, 2018, with no implementation date provided. China’s MARA also released for public comment in 2018 several NFSSs on MRLs; these limits will be integrated into the next revision of GB 2763 and are expected to be implemented in 2019.

1.2 New Zealand

The New Zealand Environmental Protection Authority (New Zealand EPA) announced in October 2018 that it would be “ramping up” its chemical reassessments program and taking action on a priority chemicals list to ensure that risks to people and the environment continue to be managed effectively. When New Zealand EPA approves a chemical for use in New Zealand, the approval does not expire and can be amended or revoked only through formal action. New Zealand EPA states that it has already established the grounds for reassessment and completed a call for information for the herbicide paraquat. On October 29, 2018, New Zealand EPA announced that it is investigating products containing synthetic pyrethroids as part of the reassessments program. The call for information on such products will close February 1, 2019.

A sub-group of the Hazardous Substances and New Organisms (HSNO) Decision-Making Committee will consider further grounds for other chemicals on the priority list “in the near future.” If the sub-group decides that grounds exist to reassess a chemical, and an application is made for the reassessment to progress, then New Zealand EPA will consider issues such as manufacture and import volumes; use and application information; environmental exposure mitigation measures; scientific and technical information; cultural impacts; and the existence of alternatives. The sub-group will make a decision about the reassessment, and could make no change to the existing approval; increase or change the controls, or rules, around the chemical’s use, or revoke the existing approval and ban its use.

1.3 South Korea
2019 is expected to be a busy time in S. Korea resulting from substantial revisions of the chemical control legislation in the country that imposes new requirements on stakeholders. The amended Act on the Registration and Evaluation of Chemicals (K-REACH) is expected to come into force on January 1, 2019. After the implementation date, any person who intends to manufacture or import a new substance, or an existing chemical substance in quantities of one metric ton or greater per year must register under K-REACH. New substances must be registered before manufacture or importation. To ease the registration process, all new chemical substances manufactured or imported in quantities less than 100 kilograms per year will require only a notification, which includes administrative information but not a hazard evaluation of the substance.

All existing chemical substances manufactured or imported at greater than or equal to one metric ton per year shall be registered within given grace periods. There are different deadlines for each tonnage tier. The first deadline of **December 31, 2021**, is for existing chemical substances greater than or equal to 1,000 metric tons per year and for existing chemical substances at greater than or equal to one metric ton per year that are CMR. The next deadline, **December 31, 2024**, is for existing chemical substances within the 100-1,000 metric tons per year band. By **December 31, 2030**, existing substances from 1-100 metric tons per year shall be completed.

Before registration, existing substances must be notified to the Ministry of Environment (MoE) in advance to benefit from the grace periods. The pre-notification period will start on January 1, 2019, and end on **June 30, 2019**. This pre-notification will require the company’s information, substance name, volume, classification, and end uses. During this time of pre-notification, one can manufacture or import the pre-notified substances without full registrations. A S. Korean-based OR shall be appointed for foreign manufacturers who import chemical substances that require pre-notification or registration.

### 1.4 Taiwan

In Taiwan, the full legislature passed on December 21, 2018, a bill amending the Toxic Chemical Substance Control Act (TCSCA). As reported in our 2018 Forecast, in 2017, the Taiwan Environmental Protection Administration (Taiwan EPA) proposed and approved revisions to the TCSCA. The changes were sent to the national legislature for review in 2017 and expected to be adopted in 2018, but instead were forwarded to the Social Welfare, Health, and Environmental Protection Affairs Committee (Committee) for review. In 2018, during the Committee’s review, the Committee revised the bill to include the creation of a National Chemical Substances Control Board. Under the legislation, the Board will be tasked with policy related to chemical substances; decision-making; and cross-ministerial policy coordination. The Committee also revised the legislation to strengthen the toxic chemical disaster response and reporting systems and improve the insurance and liability provisions. Under the bill, the TCSCA will be renamed the Toxic and Chemical Substances of Concern Control Act. A rider to the legislation calls for Taiwan EPA to draft a bill within one year to regulate the existing chemicals manufactured, imported, and used in Taiwan. Once the legislation is signed into law, Taiwan EPA is expected to review over 30 subordinate laws and proposed updates as necessary.
As reported in Acta’s May 11, 2018, Global Regulatory Update, Taiwan EPA notified the WTO of proposed amendments to the regulations regarding the registration of new and existing chemical substances on March 31, 2018. The major amendments include designating the first 106 priority existing chemicals (PEC) that will be subject to the registration of existing chemical substances. The proposed amendments were expected to be promulgated by the end of 2018. Taiwan EPA planned to adopt the amendments almost a year earlier, with registration for the PECs beginning January 1, 2019, and annual reports on the volumes of PECs sold due in 2019. The delay means that registration will begin July 1, 2019, and the annual reports will be due in 2020 instead of 2019. The list of PECs is available in the English translation submitted to WTO.

1.5 Vietnam

Vietnam has spent several years developing a National Chemicals Inventory that will list existing chemicals in commerce in Vietnam. The first draft Inventory, released by the Ministry of Industry and Trade (MOIT) in 2016, contained approximately 3,000 chemical substances, while the most recent draft National Chemical Inventory, released in September 2018, contains over 31,000 chemical substances. Once MOIT issues a final National Chemicals Inventory, chemicals not included on the list will be considered new, and companies will be required to conduct an assessment and register the new chemical before import or manufacture.

In 2017, Vietnam replaced a number of regulations under the Law on Chemicals with Decree No. 113/2017/ND-CP specifying and providing guidelines for implementation of certain articles of the Law on Chemicals and Circular No. 32/2017/TT-BCT clarifying the Law on Chemicals and Decree No. 113/2017/ND-CP. Decree No. 113/2017/ND-CP, which took effect November 25, 2017, lists chemicals that are:

- Subject to conditional production or import (Appendix I);
- Restricted from production or trade (Appendix II);
- Prohibited (Appendix III);
- Required to have incident prevention and response plans (Appendix IV); and
- Subject to mandatory declaration (Appendix V).

Circular No. 32/2017/TT-BCT, which took effect December 28, 2017, includes information on the classification and labeling of chemicals and guidance on compiling SDSs, as well as declaring imported chemicals. In 2019, Vietnam intends to continue with administrative reforms and improve the permit system for chemicals. Vietnam will also review the implementation status of the Law on Chemicals since its adoption in 2007.

2. GHS Initiatives

2019 is not expected to bring significant changes to GHS within the region. Summaries of some specific changes to GHS in the region are provided below.

2.1 Japan

In Japan, the government launched the GHS Inter-ministerial Committee. This committee began to exchange information to establish GHS-related domestic laws,
promote the classification of substances in Japan, and implement the GHS classification of substances requiring a SDS under the Pollutant Release and Transfer Register (PRTR) Law, the Industrial Safety and Health Law (ISHL), and the Poisonous and Deleterious Substances Control Law (PDSCL). The National Institute of Technology and Evaluation (NITE) also provides GHS classifications performed by relevant Japanese Ministries in accordance with GHS Classification Guidance for the Japanese Government. The NITE list was last updated in May of 2018. 2019 is not expected to bring any significant changes to Japan’s approach to GHS.

2.2 The Philippines

2019 will see the completion of GHS implementation in the Philippines. Philippines Joint Administrative Order No. 1 of 2009 (JAO) established the coordinated effort to implement GHS. Eight governmental agencies that are part of the JAO are required to implement GHS. The Department of Environment and Natural Resources (DENR) issued a draft order in 2009 with expected transitions in various stages for industrial chemicals. The DENR Administrative Order No. 2015-09 was issued in May of 2015. Implementation is phased, with mixtures to be completed by 2019. The implementation is criteria-based according to Revision 3 of the UN model. No hazard classes or categories appear to have been excluded.

2.3 Vietnam

Vietnam’s Law on Chemical (Law 06/2007HQH12) was implemented in 2007. Subsequent Decrees and Circulars have been issued in support of the GHS framework. In late December of 2017, Decree 113/2017/TT-BCT, Decree 34/2017/ND-CP, and Circular 32/2017/ND-CP were issued by MOIT. The Decrees and Circular allow the use of classification in accordance with any version of the UN model from Revision 2 to current. Vietnam is allowing companies tremendous flexibility. Appendix 7 of Circular 32/2017/ND-CP includes exact guidance for those that do not wish to choose which revision of GHS to follow and appears to be in alignment with Revision 6 of the UN model. On July 31, 2018, the Vietnam National Chemical Database (CDAI) became available. The implementation of this database provides non-mandatory classifications mostly based on compiled lists from Japan, the United States, Europe, and other foreign companies operating in Vietnam. It also provides support and administrative procedures for the management of chemicals, sharing information between various departments in the chemical field, evaluating statistical data on chemical assessment, and providing information in response to chemical incidents.

D. AUSTRALIA

1. Timing of Australia’s New Regulatory Scheme for Introducing Industrial Chemicals Is Uncertain

As of this writing, the Australian Industrial Chemicals Introduction Scheme (AICIS) is still scheduled to begin July 1, 2019. The Australian government began work in 2015 to reform the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). As reported in our November 9, 2015, memorandum, “Australia Implementing Reforms to the National Industrial Chemicals Notification and
Assessment Scheme (NICNAS)," 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 use better international assessment materials, and to create a more appropriate compliance tool. In 2017, the Australian government submitted to Parliament a package of six bills that will establish the new regulatory scheme. The Industrial Chemicals Bill 2017 describes the legislative framework for AICIS, a reformed, risk-based regulatory scheme for Australia to continue to regulate the introduction of industrial chemicals. In 2018, NICNAS held public consultations 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**: The General Rules contain details on how the introduction of industrial chemicals will be regulated under the new framework;
- **Industrial Chemicals 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**: The Transitional Rules describe how processes under the previous laws will transition to the new scheme.

The House of Representatives passed the legislation without amendment on October 17, 2017, and the legislation is awaiting debate in the Senate in 2019. As a result, the bills may not be accepted until mid-2019. The General Rules, Categorization Guidelines, and Transitional Rules have not been issued in final.

In 2019, Safe Work Australia (SWA) will continue its review of workplace exposure standards (WES). According to SWA, the review will result in recommendations for WES values, notations, and the list of chemicals. After reviewing comments received in 2018 on the consultation regulation impact statement for the WES framework, SWA plans to release the decision regulation impact statement in early 2019. SWA began its evaluations of individual chemicals in 2018 and intends to complete its evaluations, as well as an independent peer review process, in May 2019. By the end of 2019, SWA intends to have completed its review and issue final, revised WES for airborne contaminants.

The Department of Agriculture and Water Resources began a public consultation in December 2018 on proposed changes to regulations for agricultural and veterinary chemicals regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The proposed amendments are intended to balance better regulatory effort with risk, improve the flexibility and responsiveness of the regulatory framework, and remove unnecessary restrictions. Draft measures include extending the range of applications that can be assessed as timeshift applications and broadening the range of application types that allow an active constituent to be approved with a product registration. The proposed changes would amend the Agricultural and Veterinary Chemicals (Administration) Regulations 1995, Agricultural and Veterinary Chemicals Code Regulations 1995, and Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995. The Department anticipates that
further regulatory amendments, including those related to other measures in the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (such as extending data protection as an incentive to register priority uses), will follow.

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