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Global Chemical Product Innovation & Developments: Australia, Canada, China, Israel, South Korea, UK

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ARGENTINA

ANMAT Issues Cosmetics Safety Guidance:

Argentina's *Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* (National Drug, Food and Medical Technology Administration; ANMAT) has notified the World Trade Organization (WTO) of its intent to publish the *Guía Referencial para la Evaluación de Seguridad de Productos Cosméticos, para la Higiene Personal y Perfumes* (Reference Guide to Safety Assessment for Cosmetic and Personal Hygiene Products and Perfumes; *Guía*). The *Guía* contains general guidance geared toward assisting cosmetics sector entities in choosing appropriate safety design mechanisms for cosmetic and personal hygiene products and perfumes. Among the informational items contained in the *Guía* are guidance pertaining to the choice of ingredients, appropriate label design(s), and promotion of safe conditions of use. Entry into force was expected on March 22, 2019.

AUSTRALIA

Australia's New Chemical Scheme Will Begin July 1, 2020; Early Regulatory Changes Now In Effect:

The Industrial Chemicals Act 2019, which was passed by Parliament in February 2019 and received Royal Assent in March 2019, creates the Australian Industrial Chemicals Introduction Scheme (AICIS), a new regulatory scheme for the importation and manufacture of industrial chemicals in Australia. As of **July 1, 2020**, AICIS will replace the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The ban on the use of new animal test data for ingredients solely used in cosmetics will also begin on **July 1, 2020**. The following early regulatory changes are now in effect under NICNAS:

- No more annual reporting for permit holders and self-assessed assessment certificate holders;
- Shorter timeframes for Approved Foreign Scheme assessments;

- Polymers of low concerns are exempt from notification;
- Expansion of the polymers of low concern criteria;
- Changes to the definition of a new synthetic polymer; and
- Safety data sheets (SDS) and labels are no longer required for cosmetics introduced at low volumes.

NICNAS is currently consulting on changes to the draft General Rules for the new scheme. The focus of the consultation is on amendments contained in the Industrial Chemicals Act 2019 that bring in new requirements for introducers. According to NICNAS, these requirements are that introducers will now need to make a one-off declaration for exempted introductions at the end of the registration year in which the introduction first occurs. In addition, during passage of the Act, the government agreed to explore how the General Rules could limit the use of new animal test data for introductions where the chemical has multiple end uses, including in cosmetics. Comments are due **May 17, 2019**.

BRAZIL

Brazilian Government Grants Approval To Highly Toxic Pesticides:

The *Ministro da Agricultura* (Ministry of Agriculture) has issued approval notices for 40 pesticide-containing products, including sulfoxaflor, a systemic insect neurotoxin that is believed to affect vulnerable bee populations. Notably, some of the pesticide active ingredients granted approval by the *Ministro* in recent months are either extremely or highly toxic, such as methomyl and imazethapyr. The *Coordenador Geral de Pesticidas* (General Coordinator of Pesticides) has published a list containing in excess of 130 registration applications for pesticides, all of which were submitted during the final quarter of 2018. Registration applications may take up to five years to evaluate completely.

Comment Period For Glyphosate Uses Opened By Authority:

Brazil's *Agência Nacional de Vigilância Sanitária* (Brazilian Health Regulatory Agency; ANVISA) has opened its Draft Resolution No 613 (February 28, 2019) for public comment. Resolution No. 613 would maintain approval of glyphosate, a potent herbicide, but with new restrictions on its use. The central focus of the recommendation appears to be protection of agricultural workers and those who live near the fields.

Among the proposed recommendations are:

- Banning oil/water emulsion formulations to reduce the possibility of inhalation or absorption exposure;
- Establishing a rotating work schedule with respect to application activities (mixture, supply and application) so that no worker works in all of the phases, thereby minimizing exposure;
- Increasing the Personal Protective Equipment (PPE) and keeping workers from re-entering treated areas;

- Adopting technology to reduce the dispersion;
- Establishing a safety zone of 10 meters at the application field when there are communities within 500 meters of the field;
- Establishing a definition and criteria for exposure and tolerance limits for field workers;
- Adjusting the tolerance limits for chronic exposure(s);
- Defining a limit for acute exposure;
- Banning the concentrated product for amateur gardeners; and
- Prohibiting polyoxyethylene tallow amine (POEA) in concentrations over 20% in formulated products based on glyphosate.

Comments will be accepted until **June 6, 2019**.

CANADA

Canada Promulgates Environmental Emergency Regulations:

On March 6, 2019, Canada published a Canada Gazette notice promulgating the Environmental Emergency Regulations, 2019, which are intended to reduce the frequency and severity of accidental releases of hazardous substances into the environment. The Regulations require that any person who owns or has the charge, management, or control of a regulated substance at or above certain quantities notify Environment and Climate Change Canada. For higher-risk facilities, an environmental emergency plan must also be prepared, brought into effect, and exercised. Schedule 1 of the final regulations includes 249 substances that pose an acute hazard to the environment or to human health should an accidental release occur. The Regulations will come into force on **August 24, 2019**.

Canada Publishes Information Received In Response To 2017 Inventory Update (Chemicals And Polymers):

In April 2019, Canada published a summary of the results of its 2017 Inventory Update (chemicals and polymers). The Inventory Update surveyed substances on the Domestic Substances List (DSL), the Non-DSL, and the Revised In Commerce List. It considered substances identified by emerging science and domestic and international regulatory programs, as well as changes in Canadian commerce. According to Canada, the files provide an overview of the information gathered, including: type of submission; reported substances; substances that are manufactured or imported; industrial sectors involved; substance functions and commercial uses reported; and intended use (in commercial activity, in consumer activity, and by children). Canada states that it will use the information to update the commercial status of these substances, to inform priority setting, and to support risk assessment and risk management activities.

CHINA

China Seeks Suggested Amendments To Guidance On Catalog Of Hazardous

Chemicals:

The National Registration Center for Chemicals (NRCC) issued a notice on March 18, 2019, requesting comment on how to amend the Guidance for the Implementation of the Catalog of Hazardous Chemicals. In general, the almost 3,000 substances listed in the Catalog of Hazardous Chemicals are subject to Decree 591 and its subordinate regulations addressing their safe management throughout the supply chain. Listed substances need a license to be produced, used, or imported. The public comment period provides stakeholders an opportunity to comment on the classifications provided or request clarification on how to classify a chemical product. Comments are due **April 30, 2019**.

ISRAEL

Competent Authority Issues Revised Mandatory Standard Relating To Drain Cleaners:

The Ministry of Industry, Trade and Labor (MOITAL) has revised Mandatory Standard SI 2250 Part 1, which addresses the safety, packaging and marketing requirements for domestic use drain cleaners. SI 2250 revises Israeli Mandatory Standard SI 2250 Part 1 from January 2008.
The **2019** Standard adds a reference to Mandatory Standard SI 2301 Part 1 as part of the normative references in paragraph two, it removes paragraph four, which had previously dealt with the information required for marketing such substances, and removes Annex A. The new Standard will have a phase-in period of three years for the date of its passage into national law. During that three-year period, either the 2008 or **2019** Standard may be followed.

ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)

OECD Will Hold Webinar On AOP Framework:

OECD will hold a webinar on the adverse outcome pathway (AOP) framework on **April 30, 2019**. OECD describes the AOP framework as a collaborative tool that applies an innovative approach for collecting mechanistic knowledge from various sources that can eventually support chemical safety assessment. The webinar will address the following questions:

- What is the AOP framework and why should you care?
- Why are we developing AOPs?
- Why collaborations are encouraged and why should scientific societies be brought in?
- What are the opportunities for collaboration in AOP development?
- How can your scientific achievements contribute to the overall knowledge?

Questions may be submitted in advance to ehs.contact@oecd.org by **April 26, 2019**. OECD states that submitting them in advance will help it determine the focus topics. Speakers will include:

- Nathalie Delrue (OECD Secreteriat): OECD AOP Program;

- Kate Willett (Humane Society International): An introduction to the AOP framework;
- Jason O'Brien (Environment Canada): AOP collaborative development; and
- Dan Villenueve (U.S. Environmental Protection Agency (EPA)): Examples of AOP application in chemical risk assessment.

SOUTH KOREA

Reminder On The Upcoming June 30, 2019, Registration Deadline For Existing Chemical Substances In South Korea:

The South Korea amendment to the Act on Registration and Evaluation, etc of Chemical Substances (K-REACH) came into effect on January 1, 2019. All existing chemical substances (*i.e.,* substances that are listed on the existing chemical inventory in South Korea) manufactured in or imported to South Korea at greater than or equal to one ton per year are now subject to registration.

Existing chemical substances must be pre-registered by the fast-approaching deadline of **June 30, 2019**. Pre-registered substances benefit from registration grace periods that allow existing chemical substances to be imported without full registrations.

Substance Type	**Registration Deadline**
>1000 t/y existing substances >1 t/y CMR substances	**December 31, 2021**
100-1000 t/y existing substances	**December 31, 2024**
10-100 t/y existing substances	**December 31, 2027**
1-10 t/y existing substances	**December 31, 2030**

More information, including who needs to pre-register, how to determine the status of a chemical substance, what happens if pre-registration is not complete by the **June 30, 2019**, deadline, and the information needed to pre-register, is available in Acta'sApril 16, 2019, memorandum, "Reminder on the Upcoming June 30, 2019, Registration Deadline for Existing Chemical Substances in South Korea."

TAIWAN

Taiwan EPA Amends Regulation Of New And Existing Chemical Substances Registration:

On March 11, 2019, the Taiwan Environmental Protection Administration (Taiwan EPA) promulgated the amended Regulations of New and Existing Chemical Substances Registration. On April 18, 2019, Taiwan notified WTO that the regulations were promulgated on March 11, 2019, and came into effect on the same day. The WTO notification includes an English translation of the amended Regulations. For an existing chemical substance first manufactured or imported in an annual volume of 100 kilograms or more, a registrant shall, within six months from the date of

occurrence of the fact, apply for the phase 1 registration and submit certain chemical information. No existing chemical substance may be manufactured or imported unless the registration approval is obtained within the specified time period. Appendix 6 of the English translation includes the designated list of 106 existing chemical substances subject to standard registration, the quantity thresholds, and the deadlines to complete the standard registration of the 106 chemical substances:

1. For a phase 1 registration number first obtained before **December 31, 2019**, the registrant shall:

    1. Complete the standard registration before **December 31, 2022**, for substances tonnages at tonnages of one ton or more but less than 100 tons, based on the registered annual manufactured or imported volume at the time of obtaining the phase 1 registration number; or

    2. Complete the standard registration before **December 31, 2021**, for substances at tonnages of 100 tons or more, based on the registered annual manufactured or imported volume at the time of obtaining the phase 1 registration number.

2. For a phase 1 registration number first obtained after **January 1, 2020**, the registrant shall, counting from January 1 of the following year upon obtaining the number:

    1. Complete the standard registration within three years, for substances at tonnages of one ton or more but less than 100 tons, based on the registered annual manufactured or imported volume at the time of obtaining the phase 1 registration number; or

    2. Complete the standard registration within two years, for substances at tonnages of 100 tons or more, based on the registered annual manufactured or imported volume at the time of obtaining the phase 1 registration number.

3. For an existing chemical substance at annual tonnages of less than one ton when first obtaining the phase 1 registration number, the registrant shall:

    1. Complete the standard registration before **December 31, 2022**, for the substance's actual manufactured or imported annual volume reaches one ton or more before **December 31, 2019**; or

    2. Complete the standard registration within three years, counting from January 1 of the following year, for the substance's actual manufactured or imported annual volume reaches 1 ton or more after **January 1, 2020**.

TURKEY

Turkey Secures EU Funds To Support KKDIK Implementation:

Turkey has obtained new funds from the EU to support implementation of KKDIK (Registration (Kayd?), Evaluation (De?erlendirilmesi), Authorization (?zni) and Restriction (K?s?tlanmas?) of Chemicals (Kimyasallar?n)) (Turkey REACH). Turkey has secured € 1.6 million as part of the Instrument for Pre-accession Assistance (IPA) program, "the means by which the EU supports reforms in the 'enlargement countries' with financial and technical help." The funds obtained will be

utilized by Turkey's Ministry of Environment and Urbanization (MoEU) to upgrade the KKDIK-related IT platform in alignment with the EU system. This is an important measure for industry as we approach the KKDIK pre-registration and registration deadlines because there have been efficiency- and compatibility-related concerns regarding IT systems used under KKDIK. Turkey used an initial budget of € 2.5 million in developing KKDIK, and the recent EU funds obtained by Turkey are expected to assist MoEU in building capabilities for KKDIK activities. In addition to the IT upgrade, MoEU is expected to utilize the EU funds to provide KKDIK-related training programs for industry and its staff, and adapt into Turkish quantitative structure-activity relationship (QSAR) models.

The KKDIK capacity building and support activities will be performed as part of a two-year project, expected to start in **2019**.

UNITED KINGDOM (UK)

DEFRA Issues Practical Guidance On UK REACH:

On March 25, 2019, the Department for Environment, Food, and Rural Affairs (DEFRA) issued a guidance document entitled "'Comply with UK REACH': what you need to know about the IT system for UK REACH." DEFRA's guidance document provides that, in the event that the UK leaves the EU without a deal, the online service "Comply with UK REACH" will replace ECHA's REACH-IT platform for UK REACH. The guidance document indicates that "[from] the day the UK leaves the EU," entities will be able to use the online platform to:

- Validate existing UK-held EU registrations (*i.e.*, grandfathering);
- Submit Downstream User Import Notifications (DUIN);
- Submit new substance registrations; and
- Submit new product- and process-orientated research and development (PPORD) notifications.

DEFRA provides further that communication will be required with the Health and Safety Executive (HSE), via e-mail, to ensure the following obligations are fulfilled:

- Validation of existing UK-held PPORDs (*i.e.*, grandfathering); and
- Provision of information on "any [authorization] matter (including new [authorization] application, grandfathering of existing [authorizations], and downstream user notifications of [authorized] uses)."

DEFRA indicates that "[t]o be ready for using UK REACH, it's a good idea to access your ECHA REACH-IT account and download all the information you hold there ... There is no guarantee that UK users will be able to retain access to ECHA REACH-IT once the UK leaves the EU and you will need your registration confirmation documents and ECHA decisions to comply with UK REACH."

In a section of the guidance entitled "Your UK REACH account," DEFRA indicates that "[o]nce the system is live, you will be able to sign in with a Government Gateway account if you already have

one … If you don't have one, you will be asked to create one." The guidance document provides that each legal entity may only have one UK REACH account. DEFRA's guidance indicates that Only Representatives (OR) will be able to create separate organization accounts to represent different clients. These accounts will be connected to ORs' main legal entity accounts for UK REACH, and "[compartmentalized] to protect [ORs'] clients' confidentiality."

DEFRA's guidance states "[?i]f you are an existing EU REACH registration holder you will need to validate your EU REACH registration(s) within 120 days after exit, for them to continue to be legally [recognized] in the UK." The guidance provides that, to validate EU REACH registrations under UK REACH, entities will "need to upload an IUCLID v.6 dossier on the UK REACH service." The guidance document indicates further that "business rules checks are not required for initial information dossiers submitted when grandfathering within 120 days of exit." DEFRA states "[y]ou will be issued with a UK REACH registration number … This number will be different from your EU REACH registration number." DEFRA indicates that the grandfathering process will take approximately five minutes per substance, and will have to be repeated for each substance.

DEFRA indicates that the process for new substance registrations under UK REACH will resemble the equivalent process under EU REACH. In conclusion to the guidance document, DEFRA provides an e-mail address for submission of questions and indicates that a dedicated helpline telephone number will be established to address queries "[f]rom exit day" onwards.

Amendment To UK REACH And Explanatory Memorandum Published:

The UK has made available an Amendment to the Draft UK REACH Statutory Instrument and an Explanatory Memorandum. The Explanatory Memorandum provides that, "[a]fter the [Draft UK REACH Statutory Instrument] was laid," industry expressed concerns regarding the transitional import provision. Industry was concerned that, as drafted, the provision would lead to disruption in the supply chain for substances imported from outside the EEA. Industry was also concerned that the provision did not allow an OR to send "the required notification to the UK Agency."

The Explanatory Memorandum states "[t]his instrument adds to the transitional import provision … The revised version will also apply to imports to the UK from outside of the EEA where an EEA-based [OR] had registered the substance under the EU REACH Regulation prior to exit ... It also inserts a new provision that allows UK-based [ORs] to provide the notification to the UK Agency." The Explanatory Memorandum indicates, in the "Policy Background" section, that under the UK REACH transitional import notification system entities importing "[chemicals] will need to submit basic data on the company, substances and information on safe use within 180 days ... The interim notification will need to be replaced with a full registration after two years."

The Explanatory Memorandum indicates that the transitional import provision in the UK REACH Statutory Instrument covers imports from "manufacturers or other producers in the EEA," and also "covers the situation where a chemical is imported into the EEA under a registration held by an EEA-based [OR] and then sold on into the UK." The Explanatory Memorandum states that the UK REACH Statutory Instrument "does not include the situation where a chemical was registered by an EEA-based [OR] but is imported directly into the UK from outside the EEA." The Explanatory Memorandum provides that the revised text in the Amendment to the UK REACH Statutory Instrument "brings these importers within the scope of the transitional import provision." The Explanatory Memorandum indicates that this "fulfils the intention that all chemicals registered under EU REACH should be able to access the UK market after exit through the transitional provisions."

The Explanatory Memorandum provides that UK importers are “exempt from the duty to register that would otherwise lie with them” when covered by an OR’s registration for a substance, but the UK REACH Statutory Instrument “does not allow for a UK-based [OR] to carry out the transitional notification for the same chemical.” The Amendment to the UK REACH Statutory Instrument “reverses this so a UK-based [OR] can complete the notification, in which case the importer will be exempt from this duty.” The Explanatory Memorandum states this will reduce burdens on importers and “avoid unnecessary duplication” by importers and ORs. The Explanatory Memorandum states ORs will “also have easier access to better information about the chemicals, especially in the case of chemical mixtures or chemicals in articles ... This means that the regulator will receive better information, which will contribute to the intention of increasing the effective management of chemicals in the UK.”

The Amendment to the Draft UK REACH Statutory Instrument elaborates modifications to the UK’s draft post-Brexit REACH framework, including revisions to Article 127E and addition of Article 127EA, addressed above.

UNITED NATIONS (UN)

UNEP Releases Global Chemicals Outlook II:

On March 12, 2019, the UN Environment Program (UNEP) announced the release of the Global Chemicals Outlook II: From Legacies to Innovative Solutions -- Implementing the 2030 Agenda for Sustainable Development. According to the report, countries will not meet the internationally agreed goal to minimize the adverse impacts of chemicals and waste by **2020**, “meaning that urgent action is required to reduce further damage to human health and economies.” The report finds:

- The size of the global chemical industry exceeded U.S.$5 trillion in 2017 and is projected to double by **2030**;
- The benefits of action to minimize the adverse impacts of chemicals have been estimated in the high tens of billions of U.S. dollars annually; and
- International treaties and voluntary instruments have reduced the risks of some chemicals and wastes, but progress has been uneven and implementation gaps remain.

The report states that solutions exist, however:

- Frontrunner companies -- from chemical producers to retailers -- are introducing sustainable supply chain management, full material disclosure, risk reduction beyond compliance, and human rights-based policies;
- Consumer demand, as well as green and sustainable chemistry education and innovation (e.g., though start-ups), are among the important drivers of change. They can be scaled up through enabling policies, reaping the potential benefits of chemistry innovations for sustainable development; and
- Global knowledge gaps can be filled. This can be achieved, for example, by taking steps to harmonize research protocols, considering health or environmental impact information and harm caused to set priorities, and strengthening the science-policy interface through

enhanced collaboration of scientists and decision-makers.

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