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Requirements for South Korean Manufacturers and Importers of Chemicals Continue to Change

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The latest revisions to the *Act on Registration, Evaluation, etc. of Chemicals* [Act No. 15844, October 16, 2018] in South Korea (K-REACH) entered into force on January 1, 2019. Its first significant compliance deadline required manufacturers and importers to pre-register existing substances by June 30, 2019. The industry is now shifting its focus to registration requirements that provide the following phase-in timelines.

- Substances imported or manufactured > 1,000 tons/year and carcinogens, mutagens, and reproductive toxins (CMR) > one ton/year must be registered by **December 31, 2021**;
- Substances imported or manufactured December 31, 2024.
- Substances imported or manufactured December 31, 2027.
- Substances imported or manufactured December 31, 2030.

Article 11 of the Act provides exemptions from registration for substances contained in imported machinery, substances imported with machinery or devices for use in a test run, and substances in a specific solid form contained in a product and not released during use. Other exemptions include substances considered to present low risk as designated by the Minister of Environment and substances manufactured or imported for export only.

South Korea's *Enforcement Decree of the Chemical Substance Registration and Evaluation Act,* revised on December 24, 2018, provides additional details for determining eligibility for exemption from registration and includes specific criteria for polymers and other substances of low concern. Entities manufacturing or importing these substances must submit notifications and obtain confirmation of exemption from registration from the Minister of Environment to be exempt.

With a remarkably short notice and comment period, South Korea is moving swiftly to make changes to its chemical registration requirements yet again. The latest proposal is to temporarily relax some data requirements for registrations of new and research and development (R&D) substances through the end of **2021**.

Formation of Substance Information Exchange Forums (SIEF) and voting for lead registrants has begun and is moving forward at a brisk pace, catching many businesses that pre-registered substances off guard and forcing them to act quickly to ensure that interests in South Korea for relevant registrations are addressed.

Implementing the regulation that was proposed in April, following revisions to South Korea's Occupational Safety and Health Act (OSHA) issued in final on January 15, 2019, includes making significant changes to Material Safety Data Sheet (MSDS) requirements. Proposed changes include the following.

- Manufacturers and importers must submit MSDSs to the South Korea Ministry of Employment and Labor (MoEL).
- Names and amounts of chemicals in mixtures not classified under the Globally Harmonized System (GHS) criteria must be submitted separately.
- Reviews are required for components withheld from disclosure as trade secrets on the MSDS, and if approved, must be renewed every five years thereafter.
- Foreign manufacturers can use an Only Representative (OR) to submit the data on behalf of Korean importers.

These changes are to enter into force **January 16, 2021**. The implementing regulation is expected to be issued in final in early **2020**.

South Korea’s Ministry of Environment (MoE) published rules in September regarding data requirements for biocidal substance and product approvals under the Consumer Chemical Products and Biocides Safety Act (K-BPR). Information requirements include:

- Applicant and manufacturer details;
- Names of substances, molecular formulas, and chemical compositions;
- Product types for use of substances;
- Purity levels of substances; and
- Characteristics of, and impurities contained in, substances.

Entities must also provide information on exposure, uses, categories of users (*e.g.*, children), and main routes of exposure. Test data for human health and environmental impacts are also required. Some exemptions for submission of hazard information are available if exposure levels are low or testing is technically impossible.

K-BPR also requires the following information for products:

- Details regarding substances in the product, including their regulatory status;

- Handling precautions;
- Methods of disposal;
- Details of the manufacturing process; and
- Labeling information.

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