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TOXIC SUBSTANCES

South Korea's Parliament recently approved legislation to establish a chemicals management system, K-REACH, similar to the European Union's REACH program. K-REACH contains reporting and notification rules that in some ways mirror EU REACH, but also contains important new requirements. This article examines the requirements of the legislation and how key aspects compare with the requirements of EU REACH, how these requirements will impact companies operating in and trading with Korea, and steps companies can take to ensure their compliance.

How Much of What You Know About EU REACH Will Help You Comply With K-REACH? What Else Do You Need to Know?

By Maureen F. Gorsen and Dong Oh (Phil) Hong

I. Introduction

Commencing on Jan. 1, 2015, chemical manufacturers, formulators, distributors, and users will be required to comply with K-REACH. South Korea's Act on Registration, Evaluation, Authorization, and Restriction of Chemical Substances (K-REACH), as the name implies, is based on the principles embodied in the European Union's REACH. Both EU REACH and K-REACH shift the burden onto manufacturers and importers of chemicals to supply data to the government to ensure that substances sold are safe for use. Similar to EU REACH, K-REACH's impact will extend to manufacturers of products as well as chemicals. Like EU REACH, K-REACH will have broad influence on the global supply chain for chemicals in products.

Maureen F. Gorsen, Esq. is a partner with Alston & Bird LLP practicing environmental law in Sacramento, Calif. Dong Oh (Phil) Hong is a partner at Yoon & Yang LLC in Seoul. The opinions in this article do not represent the views of Bloomberg BNA, which welcomes other points of view.

K-REACH has adopted the overall framework of EU REACH. However, while in the processes of registration, authorization request, substance restriction or prohibition, and requirements for information transfer of the two are almost the same, they also have their own characteristics and requirements. K-REACH contains reporting/notification requirements pertinent to products that contain chemicals identified as toxic substances and sets forth product safety review provisions, product safety labeling requirements, and sales bans and recall provisions, all of which are not in EU REACH.

Currently, the official text of K-REACH is available only in Korean. While South Korean manufacturers and importers can comply directly, foreign manufacturers and exporters may comply through appointment of a local South Korean representative who will perform all required tasks on behalf of the foreign manufacturer or

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exporter. Many implementing details are not specified in the law, but will be set forth in future presidential or ministerial decrees.

It will be important to pay close attention for the next year or so, since the Ministry of Environment (MoE) will be working hard on developing the implementing regulations and guidance. These implementing regulations will flesh out critical aspects of the legislation, such as the criteria for deciding which existing substances will be subject to registration and which will be exempted from registration; the treatment of polymers, surface-treated particles, and alloys; the specific data requirements associated with each tonnage band; the use of read-across and alternative testing strategies; the precise mechanism for data sharing and data compensation; the procedure for securing confidentiality of data; the format for sharing information down the supply chain; and many other details.

II. The Basics of K-REACH

A. Reporting

Similar to EU REACH, K-REACH applies to new chemicals and chemicals produced or imported in amounts above one metric ton per year. The first phase in K-REACH is reporting. Manufacturers, importers, and downstream users of more than one metric ton of chemicals per year are required to make annual reports about the use and amount to the MoE (Article 8).

Chemicals subject to the reporting requirement are listed in the National Chemicals Information System (http://ncis.nier.go.kr/main/Main.jsp). The list includes 37,021 existing chemicals, or chemical substances domestically distributed before Feb. 2, 1991. The list also includes 6,878 chemical substances reviewed for hazardous materials characteristics under the Korean Toxic Chemicals Control Act after Feb. 2, 1991. Based on the results of the first annual report and toxicity data, the competent authorities will select Chemicals Subject to Evaluation (CSE) from existing chemicals.

There are some exceptions to this reporting requirement, for instance, chemicals serving as essential and inseparable parts of imported machines, chemicals made for test run purposes and imported with machines or devices, chemical substances that are in a particular solidified form and included in products that perform a certain function in which the chemicals are not released in the course of their use, or chemical substances used for investigation or research purposes (Article 8). Other chemicals may be designated as exempt by presidential decree.

B. Registration

Similar to EU REACH, K-REACH requires registration of chemicals and submission of comprehensive data sets to the MoE. Manufacturers and importers of any new chemical or designated existing chemicals in quantities of one ton or more per year must submit registrations or receive an exemption from registration (Articles 10-13). It is not currently known which existing chemicals will be subject to the registration requirement. It is expected that these will be designated and publicly announced by a ministerial decree, based on volumes present in Korea and hazards and risks posed (Article 9). As of June 24, the MoE had stated an intention to select only 2,000 chemicals from this list for registration.

As part of registration, data and documents regarding physical and chemical properties and toxicity, including all results of tests conducted by approved testing laboratories must be submitted (Article 14). Approved Korean testing laboratories will be designated by ministerial decree, and, with respect to foreign testing laboratories, only those confirmed to comply with the Organization for Economic Cooperation and Development's Good Laboratory Practice (GLP) are eligible. The data requirements include an analysis of exposure risks through the life cycle of the chemical, a review of all handling and management methods, and exposure control. K-REACH allows for joint or common use of data sets, and requires data sharing to limit the need for vertebrate animal test data (Articles 16, 17). The details of data sharing are expected to be determined by ministerial decree. But it looks promising that there will not be a need for duplication of data supplied for EU REACH.

For smaller manufacturers and importers, there is a grace period based on annual tonnage. The first registration period commences Jan. 1, 2015, for the manufacture or import of substances in annual volumes of between 100 and 1,000 tons. For the 70 to 100 ton band, registration submission is required by Jan. 1, 2017. For the 50 to 70 ton band, the submission date is Jan. 1, 2019. For substances in the 10 to 50 ton band, submission starts Jan. 1, 2020.

C. Evaluation

The MoE will evaluate registered chemicals that are manufactured or imported in volumes of more than 10 tons per year and designated as a toxic substance (Article 20). However, a grace period is expected, which will be notified by an executive order (Article 25, Paragraph 1). For annual amounts of more than 100 tons, assessment starts Jan. 1, 2015; for annual amounts of more than 70 tons, assessment starts Jan. 1, 2017; for annual amounts of more than 50 tons, assessment starts Jan. 1, 2019; and for annual amounts of more than 10 tons, assessment starts Jan. 1, 2020. Hazardous chemical substances subject to evaluation, approved laboratories, and the test procedures will be notified by a presidential decree.

The MoE will examine all registered chemicals for their toxicity and hazardous properties. Based on the results of the examination, the MoE will designate toxic chemicals (Articles 18 and 20). The ministerial decree will further determine specifics regarding the examination, such as data submission orders.

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D. Authorization

After the risk evaluation, the MoE will designate a list of chemicals that will require ministry authorization prior to manufacture, use, or import in Korea (Article 25). The chemicals that are likely to be placed on the authorization list are those that exhibit one of the following characteristics:

1. Cause cancer, mutations, impairment of reproductive ability, endocrine disruption to humans, or raise concerns about such effects;

2. Accumulate in humans, animals, or plants in high concentrations and persist in the environment for a long period; or

3. Pose risks greater or equal to those set forth under number 1 or number 2 above.

The last category is unclear, but the first two are similar to the criteria for chemicals included in the EU REACH authorization list. Under EU REACH, a chemical on the authorization list cannot be produced or used in the European Union after a set ''sunset date'' unless an authorization has been granted for a specific use. The Korean MoE will similarly issue a ministerial decree that will grant grace periods.

It is not clear what standards the MoE will use to grant authorization. In the European Union, authorization is given only if the benefits of continued use of the substance outweigh the risks or if the potential risks are considered to be limited or ''adequately controlled.'' The responsibility for seeking authorization lies solely with the producer or importer of a substance. The time period for an authorization review is on a case-by-case basis.

Authorization is a time-consuming and costly process, since it includes a comprehensive investigation and requires thorough documentation of the chemical's hazards and risks to health and the environment. In addition, there are no guarantees that an authorization will be awarded, even after a company has invested huge amounts of resources and time to defend its use. Competitors and other third parties will be able to challenge any attempt to get a permit by presenting a solution that involves less-dangerous substances. The European Union is required by EU REACH to consider available information about alternatives when making judgments about granting authorization.

E. Restricted and Prohibited Chemicals

In addition to the authorization list, the MoE will publish a list of restricted or prohibited chemicals (Article 27). Chemicals on this list will be either restricted from being manufactured, imported, sold, stored, saved, or transported for certain purposes, or prohibited from being manufactured, imported, sold, stored, saved, or transported for all purposes. The authority here again is quite broad and the Korean MoE will consult with internal administrative agencies and an evaluation committee prior to selecting the chemicals and publishing them by presidential decree. The list will be based on findings by the MoE that a chemical:

- poses risks based on a hazard and risk assessment;
- is recognized as having risks by an international organization;
- is prohibited or restricted by international treaty or convention; or
- has a better substitute, either an alternative substance or a new technology, and has been lifted from the authorization list.

Hence, THE K-REACH restriction list has the potential to be broader than the EU REACH restriction list and broader than its Substances of Very High Concern (SVHCs), listed in the REACH Annex XIV, which must have at least one of the following characteristics:

- carcinogenic, mutagenic, or toxic for reproduction (CMRs) category 1 and 2;
- persistent, bioaccumulative, and toxic (PBTs);
- very persistent and very bioaccumulative (vPvBs); or
- give rise to an ''equivalent level of concern.''

Chemicals in the final category do not necessarily fall into any of the other categories, but have nonetheless proven to cause a similar level of harm to human health or the environment. Examples include hormone-disrupting chemicals, the so-called endocrine disruptors.

F. Supply Chain Management

K-REACH contains obligations to provide information on chemicals along the supply chain, both upstream and downstream (Articles 29 and 30). Information must include the chemical registration number, name, information on hazards and risks, and information on safe use. Where a Material Safety Data Sheet (MSDS) is required under the Occupational Safety and Health Act (OSHA), the information is to be provided on the MSDS. Additional requirements and special template forms are expected to be established by ministerial decree.

G. Product or Article Manufacturers

Manufacturers and importers of products or articles have an obligation to report under K-REACH, similar to chemical manufacturers and importers. However, the thresholds are different. The duty to notify is triggered only when the content of the chemical in products exceeds one ton per year or the concentration exceeds 0.1 percent (Article 32).

Products that contain chemicals listed by the ministerial decree will have labeling, supply chain, and/or consumer information mandates. In those cases, the product manufacturer must provide the name of the chemical contained in its products, its use, conditions, and other information along the supply chain, and/or provide information on the safe use of the product to the consumers where the ministerial decree determines there is demand from the consumers (Article 35).

K-REACH grants broad powers to the MoE. It allows the MoE to conduct risk assessments on products (Article 33); to establish safety standards and labeling standards (Article 34); to prohibit the sale and import of products that fail the safety standards or the labeling standards (Article 36); and to recall or dispose of them (Article 37). It appears that while EU REACH shifts risk assessment to industry, K-REACH is reserving the authority for the state to conduct them in addition to requiring industry to do them. It is anticipated that among the products likely to receive MoE attention are cleaning agents, air fresheners, adhesives, polishes, deodorants, detergent, bleach, and fabric softener that regular

consumers use, or products such as insecticides, disinfectants, and preservatives that kill, interfere with, or undermine harmful organisms.

III. Conclusion

In sum, K-REACH adds new reporting, registration, analysis, and supply chain information requirements that in some parts mirror EU REACH, but in some parts are original. Even where the chemical data and information are the same, K-REACH will require additional paperwork to meet the particulars of the anticipated slew of ministerial decrees and the hiring of an authorized Korean representative to prepare and submit all materials in Korean.

The substantive result may be different under K-REACH, as Korean authorities will conduct their own risk assessments of products containing listed chemicals. Further, K-REACH may set unique safety and labeling standards for products and chemicals. The Korean MoE may also establish strict orders such as recalls, a ban on sales, disposal requirements, and criminal penalties for violations of any such order.

Frequently Asked Questions on K-REACH

How much of what has already been prepared for EU REACH can be utilized for K-REACH? What new original content will K-REACH require?

To the extent that EU REACH data submitted was prepared by labs following the Organization for Economic Cooperation and Development's Principles of Good Laboratory Practice, they will be accepted by K-REACH at the time of application for registration (Article 14). Because the MoE has not yet announced specifics regarding submission documents, we still do not know what additional data will be needed for K-REACH.

How do non-Korean speakers comply? Will the government provide an English translation of the law or allow for compliance in languages other than Korean?

Non-Korean manufacturers and suppliers may use an authorized Korean representative (Article 38). While an electronic submission system is anticipated, documents submitted to the government are generally in Korean. The Korean government is expected to announce an official English K-REACH ordinance soon.

Will consortia be permitted to prepare joint submissions of registration dossiers and will the role of the lead registrant work in the same way as under EU REACH?

Yes, K-REACH also prescribes that registration dossiers may be submitted jointly by the appointed representative (Article 15), and where there is existing vertebrate animal test data, the registrant must use such data with the consent of the data holder, with limited exceptions (Article 17.

Can companies provide the exposure scenario information they collected for EU REACH in K-REACH?

Additional requirements on reporting of exposure scenarios, test plans, etc., are expected to be determined by the ministerial decree (Article 14). But a grace period for submission of exposure scenarios will be determined in accordance with the tonnage bands.

How is K-REACH treatment of polymers different from EU REACH?

Whereas EU REACH applies to monomers, K-REACH applies to polymers.

Are substances used only for research and development exempt from registration, notification, or reporting?

With respect to manufacturing and importing chemical substances for the purpose of investigation and research, the exemption applies only to the reporting and notification obligation (Article 8), not to the registration obligation (Article 11). However, it is possible that the ministerial decree will further exempt such substances from the registration requirement as well.

What ''safe use information'' must substance manufacturers or importers provide to downstream users/sellers, and in what form must this information be provided? Will it be the same as an extended safety data sheet (eSDS)?

Registration number and name of chemical substances, information about hazard and risk, information about safe use, other information prescribed by the ministerial decree, and information under Article 41 of OSHA (such as name, component and content, safety and health-related handling issues, and effects on the body and environment of chemical substances) are to be provided (Article 29). Additional information and forms are to be determined later. Therefore, it cannot be compared directly to eSDS of EU-REACH.

If a substance is classified as nonhazardous, does this mean it is exempt from registration, notification, or reporting?

If a substance is classified as nonhazardous, it is highly possible it will be removed from the list of existing chemical substances subject to registration , which will be designated by the ministerial decree (Article 9), though no law has been established yet.

Will test data from testing facilities outside Korea be acceptable in registration dossiers, or must all tests for registration be conducted by Korean facilities?

Test data about chemical and physical properties and hazards from test facilities approved by the MoE as complying with OECD GLP will be acceptable (Article 14).

What is the definition of a phase-in substance?

A phase-in substance is (1) a chemical substance that was commercially distributed to the domestic market before Feb. 2, 1991, and that is publicly notified by the minister of environment after consultation with the minister of employment and labor, or (2) a chemical substance that underwent hazard tests according to the Toxic Chemicals Control Act (TCCA) after Feb. 2, 1991, and that is publicly notified by the minister of environ-

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ment (Article 2). These substances will be found on the National Chemicals Information System (http://ncis.nier.go.kr/main/Main.jsp). It is anticipated that there will be approximately 2,000 chemicals on this list. The K-REACH registration requirement applies to all non-phase-in chemicals (new chemicals) regardless of tonnage.

Are nanomaterials subject to their own reporting and registration requirements?

No additional regulations exist regarding nanomaterials.

Are there fees for annual reporting or notification, as well as registration?

Fees for registration and reporting will be established by the MOE (Article 46). At this time, it is anticipated that there will be fees for registration, but not for reporting. There may also be fees established to notify , amend, or seek confirmation of exemption or use.

What kinds of data will the MoE use to conduct hazard assessment? Will it include in vivo test methods as well as in vitro? Will it include QSARs (quantitative structure activity relationships) or read-across (a method for filling data gaps)?

Nothing is specified yet. It is expected to be determined by the ministerial decree (Article 19).

When is the list of priority substances, i.e. substances that must be registered, expected to be published by the MoE? Will that be the only list, or does the MoE want all hazardous substances to be registered eventually?

The MoE has not announced when the lists will be published. However, it is anticipated that the lists and other decrees will begin to be announced and published in early 2014.

What are the main obligations that companies will continue to have under the Toxic Chemicals Control Act?

In large part, K-REACH replaces TCCA. The chemicals listed pursuant to TCCA will be transferred to K-REACH. If an evaluation has been performed on a chemical under TCCA, it will be considered registered for K-REACH. Similarly, chemicals that received an exemption under TCCA will have an exemption under K-REACH. TCCA will continue, however, to be the law governing safety, prevention, and emergency response for chemical accidents at manufacturing facilities in Korea.