THE IMPACT, IMPORTANCE, AND INTERSECTION of K-REACH and K-OSHA: What You Need to Know

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South Korea has been utilizing two powerful tools, the Korean Act on the Registration and Evaluation of Chemicals (K-REACH) and the Occupational Safety and Health Act (K-OSHA) to actively regulate chemicals to protect public health and the environment. There are important dates looming in 2024 and 2025 for both K-REACH and K-OSHA.

For K-REACH, registration is due by 31 December 2024 for existing substances of 100 t/y or more. The expected implementation of registration for new chemical substances of 1 t/y or more is January 2025. For K-OSHA, material safety data sheet (MSDS) submission for existing chemical product manufacture or import between 1 ton and 10 ton is required by 16 January 2025.

Sometimes harmonious, sometimes not when it comes to chemical regulations and compliance, these two wide-reaching Acts have had and will continue to have a major impact on any company manufacturing or importing chemicals into Korea.

The main difference between K-REACH and K-OSHA is their areas of focus: While K-REACH focuses on the registration and evaluation of chemical substances, K-OSHA focuses on the registration of safety data sheets (SDS) and the safe use of chemicals in the workplace. Companies must understand the requirements and comply with both regulations prior to the manufacture or import of chemical substances and products to ensure they successfully navigate doing business in the Korean market.

EXPERT ANALYSIS

Editor's Note: 3E is expanding news coverage to provide customers with insights into topics that enable a safer, more sustainable world by protecting people, safeguarding products, and helping businesses grow. Expert Analysis articles, produced by 3E subject matter experts, researchers, and consultants as well as external thought leaders, examine the regulations, trends, and forces impacting the use, manufacture, transport, and export/import of chemicals.

K-REACH Regulatory Overview

Having adopted the legislative structure of the European Union's REACH Regulation, Korea's Ministry of Environment (MoE) implemented the *Korean Act on the Registration and Evaluation of Chemicals* (K-REACH) in 2015, with the aim of protecting public health and the environment from risks caused by chemical substances. The four main components of K-REACH are:

- Registration/Notification of Chemical Substances
- Priority Control Substance Notification in Chemical Products
- Hazard Evaluation and Risk Assessment of Chemical Substances
- Sharing Information of Chemical Substances

Registration and Notification of Chemical Substances

Under K-REACH, existing chemical substances manufactured or imported into Korea in quantities of at least 1 ton or more per year between 2016 and 2018 were eligible for pre-registration. The pre-registration period ended on 30 June 2019. As of 1 July 2019, companies that failed to complete pre-registration are prohibited from manufacturing, importing, or exporting non-registered substances in quantities of 1 ton or more per year, unless they now undertake the K-REACH registration process. This process must be completed prior to manufacturing or importation. The registration requirements are based on the tonnage imported or manufactured per year. K-REACH registration is required for the following substances and amounts:

- New substances manufactured or imported in quantities of 0.1 ton or more per year. (Starting from 1 January 2025, the quantities are expected to be 1 ton or more per year.)
  - If lower than 0.1 ton per year, a notification is required.
- Existing substances manufactured or imported in quantities greater than 1 ton per year.

Priority Control Substance Notification in Chemical Products

In accordance with Article 32 of K-REACH, companies that manufacture or import any product containing priority control substances (PCS) must notify the MoE before manufacturing or importation occurs, if the product meets both of the following requirements:

- Percent of a single priority control substance exceeds 0.1% w/w per product, and
- The gross weight of the priority control substances contained in total products manufactured or imported is 1 ton or more per year.

A company that manufactures or imports products containing priority control substances is required to submit a product declaration (Form 28 “제품에 함유된 중점관리물질 신고서” in K-REACH Enforcement Rule) – along with instructions on use and a photo of the product – starting on the day after which the total amount of each PCS contained in the product manufactured or imported by that company exceeds 1 ton per year.

Hazard Evaluation and Risk Assessment of Chemical Substances

The registered chemical substances must undergo hazard evaluation conducted by the MoE (to be exact, the National Institute of Environment Research, NIER, a quasi-governmental agency under the MoE). Following a hazard evaluation, the NIER makes information pursuant to these toxic substances – including chemical names and hazard properties – published via ministerial notices.[1]

Depending on the results of the hazard evaluation, the MoE also conducts a risk assessment of the substances that may be subject to authorization, restriction, or prohibition requirements, based on the following criteria:

- If the annual quantities of the substances are manufactured or imported in quantities of 10 tons or more.
- If hazard evaluation indicates that further risk assessment is necessary.

The MoE encourages joint submission of evaluation and risk assessment data through a designated representative. However, a registrant may request permission from the MoE to individually submit data if the disclosure of trade secrets of the enterprise is expected to cause considerable commercial loss or if joint submission is likely to be more expensive than individual submission.

As a final stage of the K-REACH scheme, Authorization, the MoE is developing a list of "chemicals that are subject to authorization." In October (legal notice) and November (actual list of substances) 2022, 11 substances were proposed (see the below table).

As for the latest update, among proposed 11 substances in 2022, the MoE Public Notice No. 2023-254 on 22 September 2023 nominated three priority substances: Dibutyl phthalate; DBP (CAS RN 84-74-2), Benzyl butyl phthalate; and BBP (CAS RN 85-68-7) and Di-(2 ethylhexyl)phthalate; DEHP (CAS RN 117-81-7). The public comment period ended on 25 October 2023.

Until the MoE publishes subordinate provisions and guidance for the industry, it is still too early to understand the detailed requirements for these chemicals.

Sharing Information/Communication with Downstream Users and Consumers

According to Article 29 of K-REACH, any company that manufactures or imports registered chemical substances – or mixtures containing such substances – must provide certain information to downstream users including:

- Name, location, and phone number of the chemical substance safety information provider.
- Name of the product as well as the name (or generic name) of the chemical substance(s) in the product.
- Registration number(s), notification numbers, or other unique identifiers[2] of the chemical substance(s).
- Classification and labeling of the chemical substance(s).
- Recognized uses or restricted uses of the chemical substance(s).

연번	물질명	CAS번호
1	Benzene	71-43-2
2	Bisphenol A; 4,4'-isopropylidenediphenol	80-05-7
3	Dibutyl phthalate; DBP	84-74-2
4	Benzyl butyl phthalate; BBP	85-68-7
5	4,4'-methylenebis[2-chloroaniline]	101-14-4
6	Di-(2-ethylhexyl)phthalate; DEHP	117-81-7
7	Orange lead	1314-41-6
8	Lead monoxide	1317-36-8
9	Chromium trioxide	1333-82-0
10	Lead sulfochromate yellow	1344-37-2
11	Strontium chromate	7789-06-2

- Physical and chemical properties of the chemical substance(s).
- Information pertinent to the hazard posed by the chemical substance(s) to human health and the environment.
- Summarized information on the exposure scenario and risk information (such as measures to mitigate risks).
- Information on composition of chemical substance(s) classified as hazardous.
- Information concerning the safe use of the chemical substance(s) (such as operational methods, measures to take in an emergency, responses in case of leaking, recommended protective equipment, and proper method of disposal).
- Regulatory information pursuant to the chemical substance(s).

In addition, companies that transfer a product containing priority control substances (PCS) must also submit information to downstream users prior to or upon transfer of the product to the assignee.[3] The information submitted should include:

- Product name
- Content
- Hazard
- Exposure scenarios
- Use and classification of the PCS contained in the product.

The information submitted should not include any information considered to be confidential business information (CBI). However, information associated with the consumer chemical product subject to safety confirmation should be included in this submission.[4]

K-OSHA Regulatory Overview

In the wake of increasing chemical accidents over the years, the Ministry of Employment and Labor (MoEL) amended and implemented the *Occupational Safety and Health Act* (K-OSHA) with significant changes in January 2021.

One of the most prominent changes includes the Material Safety Data Sheet (MSDS[5]) registration requirement, which is unprecedented. Previously, the MSDS was communicated between upstream manufacturers and downstream users without the authority's involvement. Additionally, in MSDS Section 3, the claim of confidential business information (CBI) is no longer allowed. Companies that wish to conceal their business' confidential chemicals must apply for CBI and obtain the MoEL's approval.

The key requirements under the amended K-OSHA are:

- MSDS registration (submission)
  - MSDS Registration Number displayed on the first page of MSDS.
  - CBI application for the authority's approval.
  - Industry to provide "substitute" name (e.g., generic name).
  - Section 3 on MSDS – CBI approval number, approved substitute name, CBI validity/expiration date to be displayed.
- Non-hazardous chemical verification.

1) MSDS Registration Requirement

Pursuant to Article 110 and 111 of K-OSHA, a business owner is obliged to provide an MSDS if they intend to manufacture, import, use, transport, or store chemical substances (or mixtures containing substances) subject to the provisions outlined in Article 104 of K-OSHA.[6] Critically, all MSDS must be submitted to the MoEL.[7] When submitting the MSDS, the MSDS preparer must select at least one of the 48 use categories outlined in Appendix 5 of the standard (MoEL Notice 2020-130) and indicate said use category on the MSDS. The preparer must also indicate more than one use category on the MSDS for chemical substances and mixtures that have been classified as hazardous to health in the workplace.[8]

Once the MSDS is reviewed, the MoEL will assign an MSDS registration number to that MSDS and this number must subsequently appear at the top of the MSDS.[9] In addition, if the company that has prepared the MSDS has submitted alternative names or generic names to the MoEL (in lieu of actual chemical names) in support of a CBI claim, that information must be included. If CBI is approved or partially approved, the approval number and expiration date also must be displayed in Section 3 of the MSDS. It is noteworthy that the CBI approval number is given per **product**, not per substance.

Special provisions have been established for chemicals that are solely used in research and development (R&D). Chemicals or products for scientific experiments, analysis, or research – or chemicals such as reagents that are used to develop chemicals or products, improve and develop the production process, test the application of chemicals in the workplace, and for pilot production of chemicals or products – are exempted from some MSDS requirements.[10]

2) Non-Hazardous Notification Requirement

The revised K-OSHA does not require non-hazardous chemicals to be listed in the MSDS. ("Non-hazardous chemicals" are those not classified in the GHS standard.) However, according to K-OSHA Article 110(2) and K-OSHA Rule Article 162, companies are mandated to report non-hazardous chemical names and concentrations via an online system. For imported products, importers submit the Chemical Verification Form (shown in the K-OSHA Enforcement Rule Form 62, 화학물질 확인서류) as well as the Letter of Confirmation (LoC) provided by a foreign manufacturer to the KOSHA (agency) prior to manufacture or import to justify non-hazardous chemicals present in the product.

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K-REACH and K-OSHA: Comparative Analysis

To fully comply with two major regulations with requirements that are heavily imposed on the pre-stage of manufacture or import, it is necessary to identify differences and similarities between them and unique requirements for the industry to bear in mind. Here are the main areas to compare:

Definitions

- Hazardous Chemicals
  - **K-REACH** – According to K-REACH Act Art. 2(10), "hazardous chemicals" are defined by the MoE's designated lists:
    - Toxic chemicals
    - Banned chemicals
    - Restricted chemicals
    - Chemicals subject to authorization (upcoming)
  - **K-OSHA** – According to K-OSHA Act 104, hazardous chemicals/factors are defined as chemical or physical factors that cause an adverse effect on workers' health. The hazards criteria are based on K-OSHA Enforcement Rule Annex 18, which is a GHS classification. In other words, K-OSHA's "hazardous chemicals" are ones that fall into the GHS classification criteria. Additionally, they are subject to MSDS requirements. Thus, they can be called "MSDS-subjected chemicals."

Exclusions and Exemptions

Certain exclusions, such as pharmaceuticals, narcotics/psychotropics, food and food additives, cosmetics, and medical devices, overlap between K-REACH and K-OSHA. The mentioned items are controlled by other ministries, and therefore, they are out of scope of K-REACH and K-OSHA. However, the raw materials for cosmetics still require MSDS registration under K-OSHA, whereas they are excluded from K-REACH registration. Additionally, wastes are excluded only from K-OSHA, and K-BPR biocides and hygiene products under Hygiene Control Act are excluded only from K-REACH.

As for exemptions, both K-REACH and K-OSHA grant exemptions for chemicals used for R&D purposes and finished articles with certain conditions. K-REACH registration is exempted for chemicals with very low risk that the MoE published (MoE Notice No. 2018-234, Appendices 1 and 2).

Use Categories

When registering a chemical substance under K-REACH and MSDS submission under K-OSHA, companies must identify their chemicals' use purposes by selecting the use categories defined by the authorities. It is important that the industry choose the proper use category table that is unique per jurisdiction.

For K-REACH registration, companies must use chemical use categories defined in Appendix 2 in the K-REACH Enforcement Order, totaling 55 categories.

In contrast, for MSDS submission under K-OSHA, companies are required to choose among 48 use categories listed in Appendix 5 of the MSDS Standard (MoEL 2020-130) and display it in Section 1 of their MSDS.

“Certain exclusions, such as pharmaceuticals, narcotics/psychotropics, food and food additives, cosmetics, and medical devices, overlap between K-REACH and K-OSHA.

Applying for Confidential Business Information

When considering applying for K-REACH Confidential Business Information (CBI), companies need to start with the Chemical Control Act (CCA) CBI, which is a prerequisite.

Under the provisions of the CCA, **all** chemical substances must be evaluated and notified before being manufactured in and/or imported into Korea. According to Article 9 of the CCA, anyone who intends to manufacture or import a chemical substance or chemical product must provide the Korea Chemical Management Association (KCMA) a *Chemical Identification Detail Form* (화학물질확인 명세서) prior to manufacturing or importing any chemical products into Korea **for the first time**.

The dossier submitted to the KMCA should include not only the *Chemical Identification Detail Form* but also any relevant documents, including the Letter of Confirmation (LoC, 확인관련서류 in Korean). The LoC (which is required by CCA) must list **all** components of the chemical substance or product to be manufactured or imported (except those eligible for CBI claims). Foreign manufacturers should provide a LoC or utilize their Korean representative(s) (aka “OR” for Only Representative) for this submission if they wish to protect CBI by not sharing such information with Korean importers.

As a next step of CBI claims for K-REACH registration, companies must use Form 37 “Application for Data Protection Request,” which can be found in the K-REACH Enforcement Rule.

The K-OSHA CBI process is very different from the one for the CCA/K-REACH. In order to apply for CBI, companies must use Form 63 *Application for Non-Disclosure*, in which all ingredients must be disclosed. For imported products, Korean importers must submit Form 62 *Chemical Verification Form* (화학물질확인서류) in the K-OSHA Rule along with the LoC provided by foreign manufacturers. Unlike the CCA/K-REACH LoC, which requires companies to identify if their product contains certain chemicals (e.g., toxic, restricted, banned, etc.), the K-OSHA LoC is a simple form for foreign manufacturers to certify that no hazardous chemicals are hidden from MSDS unless they are CBI-approved.

Conclusions

It is extremely important for companies to know that both K-REACH and K-OSHA require full compliance prior to manufacture and import. The requirements are highly complex and unique, requiring stakeholders to pay close attention in assessing their time and cost to achieve successful compliance. For foreign manufacturers, the best practice is to appoint a reliable Korean OR to protect their confidential information while successfully bringing their chemical products into the Korean market.

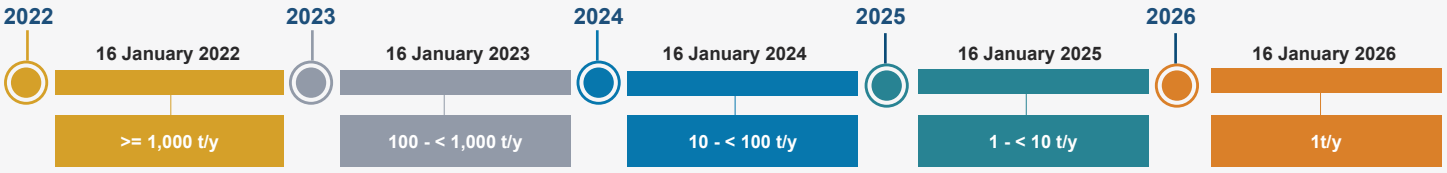
As for upcoming developments, the K-REACH authorization stage has been taking shape, led by the MoE. The industry will closely monitor the final version of the first batch of chemicals subject to authorization. However, detailed compliance procedures must be provided by the authority.

Another development to pay attention to is the effort of the two ministries, the MoE and the MoEL, to harmonize and simplify the CBI processes. There have been several notices in which the two authorities cross-reference CBI-related dossiers to reduce the industry's administrative burden.

Important Dates K-REACH and K-OSHA

K-REACH — For K-REACH, upon pre-registration in 2019, companies were granted a transitional period. The transitional periods were established to facilitate the registration of existing substances manufactured or imported in quantities of 1 ton or greater per year:

K-OSHA — K-OSHA granted grace periods for MSDS submission for existing MSDS, based on annual manufacture or import tonnage:



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[1] Designation of Toxic Chemical Substances (NIER notice) 유독물질의 지정, 국립환경과학원 고시.

[2] CBI concern may occur.

[3] Article 35 of K-REACH.

[4] The Consumer Chemical Product Subject to Safety Confirmation (안전확인대상 생활화학제품) is designated under the Act on Safety Management of Consumer Chemical Products and Biocides of Korea (K-BPR).

[5] While “SDS” is a common term globally, Korea continues using “MSDS”; thus, the author also uses the term “MSDS” in this paper.

[6] The business owner is not obliged to prepare the MSDS if they aremable to obtain a compliant MSDS from the manufacturer, supplier, or importer.

[7] With very few exceptions – for example, for R&D.

[8] MoEL Notice 2020-130, 12 November 2020.

[9] These requirements were instituted through MoEL Notice 2020-130,12 November 2020.

[10] MoEL Notice 2020-130, 12 November 2020. Companies are not required to submit MSDSs for R&D substances to the MoEL; however, an MSDS for these substances must be kept in the workplace or laboratory where they are used. In such cases, an English language MSDS is acceptable (i.e., a Korean translation is not required).

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