

Comments on K-REACH and Lessons from EU REACH

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As with many countries, Korea is pursuing a chemicals management approach that ensures substances being placed on its market are assessed for risk potential based on its use patterns while placing the burden of safe use on chemical businesses*.

Although K-REACH is largely modeled on the European Union's (EU) REACH, there are a few slight differences. One difference is that entities placing chemical substances on the market need to be prepared to pay additional fees to the governmental agencies that are involved in registration activities to gain a "self-funded/sufficient" presence. We often refer to this as "pay to play." Fees have not yet been discussed or presented in association with K-REACH.

Industry has begun to recognize the "pay to play" principles, where higher supplied volumes require greater data requirements, which in turn increase the cost of the registration and the fees associated with the registration. Per capita costs may be reduced for higher tonnages by creating Consortia or "Lead Groups" for specific substances, which share the costs of testing and dossier preparation among the larger and/or more active companies. Expenses can be recouped by selling the right to refer to data in the initial submission to other registrants in a "Letter of Access."

Letter of Access fees can also be anticipated for K-REACH as the need to share data is inherent in the regulation. The EU has set 12 years from the time of submission to the European Chemicals Agency as the time period in which compensation is to be paid to the data owner by other registrants to refer to those data. K-REACH establishes a 15-year period, similar to the U.S. compensation period under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The specific language contained in Letters of Access must be carefully constructed, limiting the use of data to particular jurisdictions and uses. The longevity of EU REACH-related dossier preparation in the IUCLID 5 system has been assured. Dossiers prepared for EU REACH can be updated and revised with minimal effort for application under K-REACH, another measure that will reduce the costs for global registration strategies.

Korean entities sharing data and expecting compensation for reliance on their data must plan to be active within the regulatory landscape for the duration of the regulation. Many of the Lead Registrants and Consortia created as a result of EU REACH did not anticipate the need to continue to remain active until the end of the EU's registration structure. Indeed, many Lead Registrants and larger companies active in the first round of EU REACH activities have already withdrawn from Substance Information Exchange Forums (SIEF) and consortia entities to avoid continued fees.

K-REACH has been debated for years and is not unexpected, although due to the complexities of the discussions, some

aspects of K-REACH may not be expected by some interested parties. K-REACH will likely include the registration of different substances from those registered in the EU as the South Korean market is key to the electronics industry, whereas the EU is primarily consumer led.

The global chemical regulatory landscape is ever-evolving. While K-REACH represents a significant change for chemical regulation in South Korea, the EU REACH regulatory program is familiar to many chemical manufacturers, formulators, distributors, and users globally. This familiarity, and the investment made by the global chemicals industry in EU REACH, will facilitate the implementation of K-REACH to the benefit of industry, the government, and other stakeholders.

*Chemical business means the entity that manufactures, imports, uses, or sells/supplies chemicals for commercial purposes.

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Bergeson & Campbell, P.C.'s consulting affiliate The Acta Group, with offices in Beijing China, Manchester England, and Washington D.C., provides comprehensive strategic support for global chemical registration, regulation, and sustained compliance. Since K-REACH's inception, Acta's scientists and business and regulatory specialists have actively assessed the legislation and its implications and can assist clients in complying with K-REACH today and preparing for future developments. Contact Leslie S. MacDougall at lmacdougall@actagroup.com or visit www.actagroup.com for more information.