Legal Requirements of Korean Biocide Regulation (K-BPR) and Korean REACH (K-REACH)

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I. The Chemical Industry in Korea

Although the market is currently weakening somewhat, the South Korean chemical market has experienced strong growth in recent decades. The market volume in 2012 was approximately 125 billion euros, which catapulted South Korea to 6th place in the ranking of the leading chemical nations. In 2017, Korea accounted for 2.9% of world chemical sales.¹

According to *Statistics Korea*, there were² about 4,800 companies (with ten or more employees) in the chemical and pharmaceutical industries in South Korea in 2016. They employed a total of around 171,000 people and produced products worth US\$130 billion. Almost 90% of the companies are small to medium-sized enterprises (SMEs) with less than 50 employees. The Korean chemical industry is thus characterised by small and medium-sized enterprises with little experience in the field of safe chemical management. Since the July 2011 free trade agreement between South Korea and the EU many chemicals can now be traded duty-reduced or duty-free, which has boosted trade in chemical products.

The strong growth is mainly due to the progressive development of Korean competencies in new fields of technology, which often require the use of special high-tech materials. Consequently, Korea is not only a major producer but also has a high demand for chemical products, which is met by imports, mainly from Japan, China, the USA and Germany. In 2013, for example, Korea imported chemical products worth approximately US \$ 47 billion.³

II. The Tightening of Chemicals Legislation in Korea

Unfortunately, the growing chemicals market has also resulted in an increase in industrial accidents and occupational accidents involving chemicals, as well as increased exposure of consumers to chemicals. For this reason, Korean chemical legislation has been fundamentally revised in recent years and is now similar in many respects to the EU REACH Regula-

tion⁴ for industrial chemicals. Although the Korean chemicals legislation was already at a fairly high level, the policy responded with a further tightening of laws and regulations. On 30 April 2013, the Korean variant of REACH (ARECS or K-REACH)⁵ was adopted by the South Korean parliament. On 1 January 2015, K-REACH came into force and made new demands on the chemical industry, in particular on Korean manufacturers, importers and users. This also affects non-Korean companies exporting chemical products to Korea.

Unlike in the EU, however, in the first step not all existing substances above the 1 t/a threshold were registered, but only certain priority substances which were published in a so-called PEC list (Priority Evaluation Chemicals). The initial draft of the PEC list was published in October 2014 and contains 518 substances. As a rule, substances can be found here that either meet certain eco-toxicological criteria, are used in large volumes in Korea or are expected to be have a high exposure. The listed substances had to be registered within 3 years, until 30 June 2018.

In the second step, K-REACH was revised and instead of creating further PEC lists as planned, the regulations were further adapted to EU-REACH. All substances with volumes >1 t/a that are put on the market after the amendment have to be registered. Further details and above all the innovations are ex-

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- 1 VCI, 'Chemical Industry' (2018).
- 2 GTAI - German Trade Invest, 'Industry check - South Korea' (November 2018).
- 3 German-Korean IHK (AHK), 'KORUM, Chemical Industry' No 51 (June 2014).
- 4 Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- 5 Act No11789 of the Korean Ministry of Environment of the Council of 22 May 2013 concerning the Registration and Evaluation of Chemical Substances.

plained in Chapter III. The requirements of K-REACH in the version of 2015 as well as the experiences with the PEC registrations were described extensively by Drohmann⁶ and Seo.⁷

The *Safety Control Act of Household Chemical Products and Biocidal Products*⁸, also known as *Korean-BPR*, was enacted on 20 March 2018 and entered into force on 1 January 2019. This regulation is intended to close a gap and ensure safe handling of biocides and household chemicals. In November 2018, the South Korean Ministry of the Environment published corresponding implementing regulations and guidelines for biocides. The basic framework of the new law is based on the EU Biocide Ordinance (BPR)⁹, which serves as a 'guide' for implementation.

III. The K-REACH amendment

In December 2016, the Ministry of Environment (MoE)¹⁰ started the revision of K-REACH, the Korean Parliament passed the amended law on 8 March 2018 and it came into force on 1 January 2019. A major innovation is that there will be no further PEC lists of priority substances. All substances >1 t/a (unless they are excluded) are to be registered with transition periods comparable to EU REACH, depending on the volume band or classification as CMR substance. The main changes to the law are as follows:

- Annual quantity reports to MoE are not required.

- Substances >1 t/a that are not classified according to GHS have reduced data requirements at registration.
- Pre-registration for all existing substances >1t/a in the period 1 January - 30 June 2019.
- 31.12.2021 - Registration deadline for CMR substances (>1 t/a) and substances >1,000 t/a.
- 31.12.2024 - Registration period for substances >100 t/a.
- 31.12.2027 - Registration period for substances >10 t/a.
- 31.12.2030 - Registration period for substances >1 t/a.
- Publication of 3 substance lists - CMR substances, excluding substances and priority control substances.

K-REACH pre-notification started on 1 January 2019 and ends on 30 June 2019. It is required for all substances produced or imported into Korea above a tonnage of 1 t/a. Only the pre-registered or pre-registered existing substances can benefit from the registration deadlines. The data requirements for notification are more comprehensive compared to REACH:

- Substance identity, CAS-No, etc.
- Estimated quantity of substance to be imported or manufactured
- GHS Classification and Labelling
- Usage information via descriptor system
- company information
- Proof of appointment is required for sole representatives

On the basis of a pre-announcement, appropriate transitional or registration periods will be granted. CMR substances >1t/a must already be registered by the first deadline of 31 December 2021. The MoE has compiled a list of 364 substances¹¹ classified as CMR. The list of exempted substances¹² contains 44 substances and is comparable to EU REACH Annex IV. Substances on the list 'Substances of Priority Control' must be notified to the MoE prior to manufacture or import. The 672 substances contained in the list are partially identical to the EU REACH SVHC¹³ list. The 'Priority Control' list distinguishes substances that are on the Korean market (204 substances) and must be notified from 1 July 2019. In addition, there are 468 substances for which it is unclear whether they are manufactured in Korea or im-

6 Dieter Drohmann, 'REACH in South Korea (K-REACH) - Consequence of Global Change in Chemicals Management' (2015) StoffR 4.

7 Ah - Reum Seo, 'Lessons learnt from Joint Registration Practice of PEC substances and outlook to K-REACH registration requirements' (2018) ICRL 2, 2018.

8 Korean Law No 15511 <https://images.chemycal.com/Media/Files/KOR798_KO_1_1.pdf> accessed 20 March 2019.

9 Biocidal Products Regulation (Regulation (EU) No 528/2012).

10 MoE, Ministry of Environment <<http://eng.me.go.kr/eng/web/index.do?menuId=6>> accessed 20 March 2019.

11 The list is available at <<http://files.chemicalwatch.com/2018-232%20CMR%20list.%20announcement.PDF>> accessed 20 March 2019.

12 The list is available <<http://files.chemicalwatch.com/2018-234%20exempted%20substances.%20announcement.PDF>> accessed 20 March 2019.

13 The list of Substances of Very High Concern (SVHC) is available at <<https://echa.europa.eu/de/candidate-list-table>> accessed 20 March 2019.

Table 1: Transition Periods According to CPD for Biocidal Products.

category	Biocidal product type	Grace period (years)
steriliser	1. disinfectant	3
	2. algicides	3
extirpator	3. rodenticides	3
	4. other vertebrate extirpator	5
	5. insecticide	3
	6. other invertebrate extirpator	5
	7. repellent	3
preservative	8. for product preservation	8
	9. For product surface treatment	8
	10. for textiles/leather	8
	11. For timber	5
	12. for building material	10
	13. for [raw] material/equipment	10
	14. for corpses/taxidermy	10
Others	15. antifoulant	10

ported. Notifications for these substances shall be made from 1 July 2021. Reports must also be made for products which contain 'Substances of Priority Control' from a concentration of >0.1%.

IV. The Korean Biocide Regulation (K-BPR)

According to the EU BPR, the law requires that the marketing of all biocidal products requires MoE ap-

proval before they can be placed on the Korean market. In addition, the active substances contained in the biocidal products must first be approved by the MoE. Active substances and biocidal products shall be authorised on the basis of their safety and efficacy.

For biocidal products already placed on the Korean market before the entry into force of the law, the distributors must notify the relevant information to the authority. The MoE then sets different transition periods for the notified 'waste biocidal products'. Anyone who manufactures or imports a biocidal active substance contained in a biocidal product placed on the Korean market before 31 December 2018 may notify the MoE of his company data, the name of the active substance, the type and composition of the biocidal product and the manufacturing or import volume. Based on the message, corresponding transition periods apply depending on the corresponding product type. A distinction is made between 15 biocidal product types in four categories. The transition periods are between three and ten years, with shorter periods for widely used products. Manufacturers and importers of biocidal existing substances must notify the substances to the MoE between 1 January and 30 June 2019 in accordance with certain requirements in order to benefit from the transitional periods. The transitional periods set out in Table 1 shall apply.

The MoE will communicate the transition periods for each active substance by the 31 December 2019. Depending on the use, hazard, risk or quantity, the deadlines can be adjusted accordingly by the MoE. Biocidal products containing active substances with transitional periods may be placed on the market until the transitional period. Biocidal products containing active substances without transition periods will be withdrawn from the market from 1 January 2021.

Distributors of active substances and biocidal products must notify the active substance and BP information by 30 June 2019 and thus apply for the transitional periods. In addition, appropriate active substance and product dossiers must be submitted within the transitional periods. For the active substance dossiers, the substance data must be created within this time or, if necessary, access rights must be secured via a 'Letter of Access'. The approval procedure shall be 18 months for active substances and 1 year for biocidal products after receipt of the complete notification dossier by the Authority. It should

be noted that for "treated articles" corresponding requirements apply, as under the EU BPR.

V. Conclusion

In K-REACH and K-BPR, the global trend towards stricter chemicals regulation continues. On the positive side, many requirements from EU REACH and EU BPR have been largely adopted, which will simplify implementation on the basis of experience in Europe.

Data sharing will become crucial for both K-REACH and K-BPR. This is another reason why global data sharing is becoming more and more necessary, makes sense and is becoming more and more urgent. Data sharing cannot only reduce the costs of studies but also reduce the amount of animal testing and helps in avoiding conflicting data.

It is therefore necessary to define and implement the conditions for global data sharing in the relevant consortium agreements. The experience of the last twelve years of consortium management has shown that data sharing among EU-REACH already brings with it challenges and global data sharing increases the demand for efficiency, coordination and expertise.¹⁴

¹⁴ Peters and Rectanus, 'Global Data Sharing - Requirement from REACH - Korean-REACH et al' (2017) StoffR 6.