K-REACH - Enhanced safety for all

Newsletter-4 | April 2021

Second segment

Main contents of the K-REACH Act

- The subject of hazard evaluation has been extended to existing as well as new chemicals (for manufacturers or importers of 1 ton or more).
- There is a transition from hazard-oriented management to "risk"-based management. Such a management considers toxicity as well as environmental exposure risks, thus providing the basis for setting safety standards and labeling standards for household chemical products.
- Registered substances are being reviewed and evaluated by the government and designated as toxic substances, which are subject to authorization with restrictions, as well as complete prohibition for import/manufacture and use.
- An information system has been established, which is in operation for the companies to comply with implement the K-REACH Act, with ease.
- The revised act, designates green chemical center/s to support small and medium enterprises.
- The K-REACH Act consists of a total of 8 chapters, 54 articles, and supplementary provisions, as shown in the table below.

Table 1) K-REACH System (Chapter 8, Article 54)

Chapter 1: General Provisions	Articles 1 to 7	• Purpose, definition, scope of application, responsibilities of state and business operators. • Establishment of basic plans for evaluation of chemical substances, etc.
Chapter 2: Registration of Chemical Substances	Articles 8 to 17, Article 17-2, Article 17-3	• Registration/report of chemical substances, exemption from registration, etc. / change registration/report, etc. • Materials and methods to be submitted when applying for registration of chemical substances, etc. • Joint use of existing registration application data, special cases for vertebrate animal test data, etc. • Imposition and collection of fines.

Chapter 3: Hazard Assessment and Risk Assessment of Chemical Substances	Articles 18-24	• Hazard screening and hazard evaluation, etc. • Designation of toxic substances and disclosure of results of hazard evaluation. • Designation and cancellation of designation of test institutes, etc. • Risk assessment.
Chapter 4: Designation and Change of Permitted Substances, etc.	Articles 25~28	• Designation and cancellation of permitted substances. • Designation and cancellation of restricted substances or prohibited substances.
Chapter 5: Provision of Information on Chemical Substances	Articles 29~31	• Provision of information on chemical substances, etc. • Provision of information of downstream users, etc.
Chapter 6: Management of Products Containing Chemical Substances	Articles 32-37	• Report of critical management substances contained in products. • Provision of information on chemical substances contained in products.
Chapter 7: Supplementary Provisions	Article 38~, Article 48-2	• Registration application by a person appointed by an overseas manufacturer or producer. • Establishment and operation of a chemical substance information processing system. • Designation, operation and cancellation of designation of the Green Chemical Center. • Report and inspection, record and preservation of documents, delegation and consignment of authority, etc.
Chapter 8: Penalty	Articles 49-54	• Penalties, punishment rules, fines.

In principle the process involves

Fig 1 graphically presents the **Chemical substance registration and evaluation management according to the K-REACH Act.**

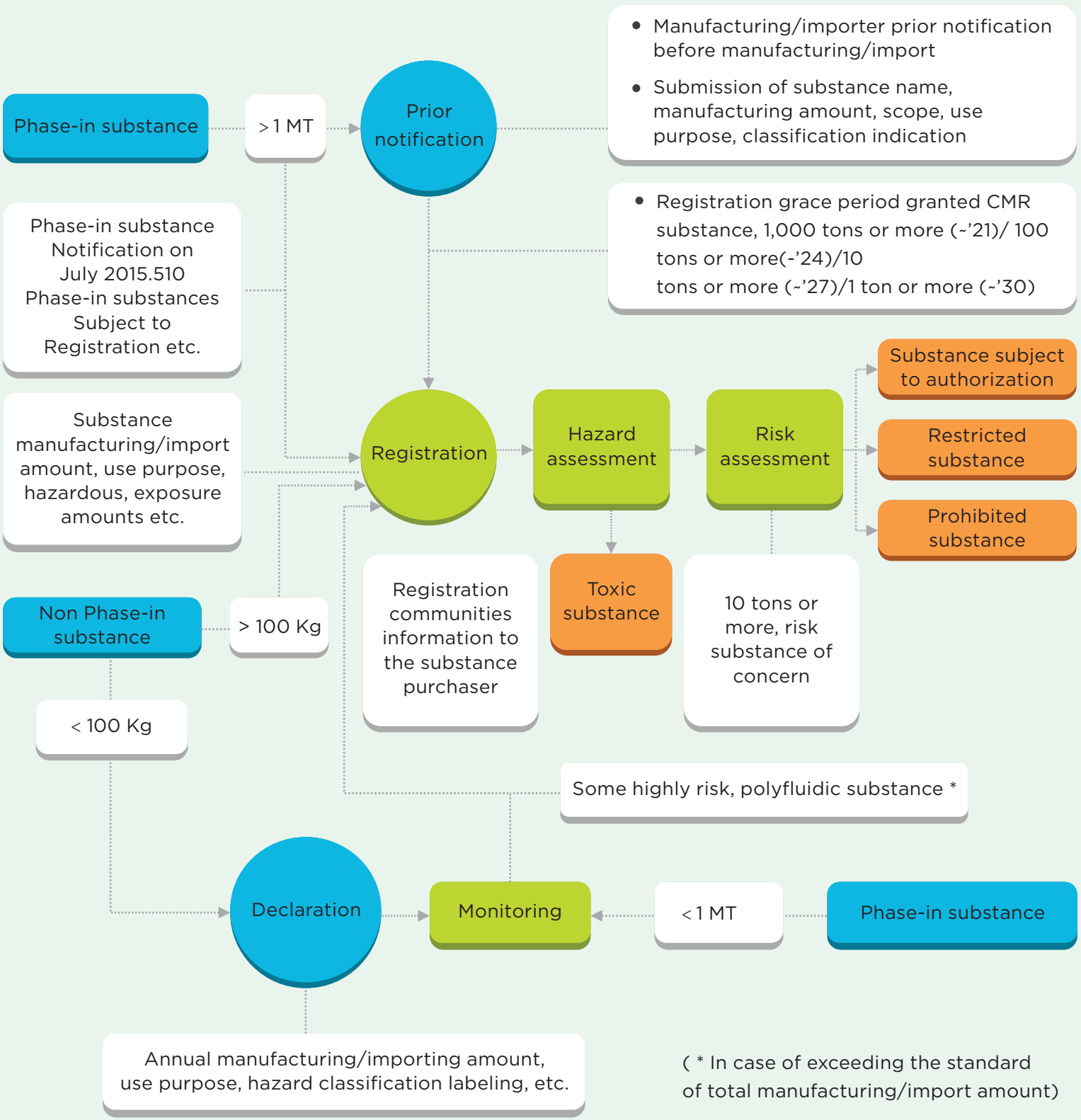

Figure 1) Chemical substance registration and evaluation procedure

The act provides a time-frame for compliance with K-REACH, as described in the Table 2, below.

Table 2) Registration grace period by weight range of manufacturing and importing

Weight range	Registration grace period
Substances of 1,000 tons or more per year and CMR* substances of 1 ton or more per year	December 31, 2021
In the range of 100 - 1,000 tons per year	December 31, 2024
10 - 100 tons per year range	December 31, 2027
1 - 10 tons per year range	December 31, 2030

CMR (Carcinogenic, Mutagenic or Toxic for Reproduction): A substance designated and notified by the Minister of Environment as a substance that causes or may cause cancer, mutation, or abnormal fertility.

References

1. Explanation of the Act on the Registration and evaluation, etc. of Chemical Substances, Ministry of Environment, 2019
2. What is the K-REACH Act? (Act on the Registration and evaluation, etc. of Chemical Substances)" Jong-ik Lee, Managing Director, Chemical Industry Division, Deloitte's Anjin Accounting Firm
3. ESG ISSUE REPORT, the K-REACH Act, From Crisis to Opportunity (Impacts for Investors by the Implementation of the K-REACH Act), 2013,4, SUSTINVEST, Donghyun Ko
4. 'Problems of the K-REACH Act and Solutions for Successful Settlement' by the Korea Economic Research Institute.
5. Saemi Shin, Sang-Hoon Byeon,* Jong-Ryeul Sohn, and **Kyong Whan Moon;** Int J Environ Res Public Health. 2019 Nov; 16(22): 4409 (doi: 10.3390/ijerph16224409).
6. http://chemical-net.env.go.jp/pdf/Korea_Lee_e.pdf
7. https://icca-chem.org/news/how-do-we-calculate-the-number-of-chemicals-in-use-around-the-globe/
8. You J., Chung Y.-J. Case Analysis of the Harmful Chemical Substances' Spill. Fire Sci. Eng. 2014;28:90–98. doi: 10.7731/KIFSE.2014.28.6.090.
9. A Study on the Characteristics of Hazardous Pollutant Emissions in Korea from 2007 to 2016
10. Ji Young Im, BoKyeong Kim, HyunJi Kim, MyeongJi Lee, DaYoung Jeon, JiSung Ryu, DaeSik Yun, YongChul Jang & ChungSoo Lee; International Journal of Environmental Research; volume 14, pages 335–346(2020)

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Acknowledgment:
Acknowledge the support of our director - Research and Innovation Dr. Abhay Deshpande.

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