Guidebook on
Registration Data Sharing and Cost Sharing under K-REACH

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비용분담에 관한 안내서

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Note: The Guidance was written in Korean. The English Tranlation is for reference only. In case of discrepancy the original version in Korean shall prevail.

Guidebook on Registration Data Sharing and Cost Sharing

February 2015

환경부

<Notes>

- This guidebook covers information on how to share data and share costs that should be considered by those who wish to manufacture and import chemicals subject to registration under The Act on Registration and Evaluation of Chemicals (“K-REACH”) when fulfilling duties.
- This guidebook has been prepared by collecting the opinions from experts and their relevant agencies through the pilot project (2014~2015) for preparation, production and submission of the joint submission data of the phase-in substances subject to registration as part of the pilot project (2012~2013) operated and promoted by the government in the process of enacting K-REACH.
- This guidebook has no legal and mandatory force, and is a technical reference on the general method of sharing data to apply for registration and cost sharing. The responsibility to consider individual particularity lies in the person who should perform such legal duties.
- This guidebook should be interpreted and applied in consideration of the items specified in K-REACH and its Enforcement Ordinance, Enforcement Rule, notification and established rules. In the event of any difference from the details of the relevant legislation and higher-level rules, they shall prevail.

Application of the Guidebook

The Act on Registration and Evaluation of Chemicals (initially published on May 22, 2013 as Act No. 11789) was enacted to protect the public's health and environment from the risks of unknown chemical substances. It gets out of the management system of assessing chemical hazards which is limited to the entities that manufacture & import non-phase-in substances (784 entities[1]) under the Toxic Chemicals Control Act (TCCA, Act No. 11998) and furthermore, introduces a new preventative management system for all chemical substances.

The Act on Registration and Evaluation of Chemicals (hereinafter referred to as the "Act") outlines a registration system that examines and evaluates the hazards and risks of both non-phase-in and phase-in substances, and is designed to report the hazardous chemical substances of products used by end consumers and mandate transmission of information on hazards during movement and sale or purchase of such chemical substances. It is expected that when the Act comes into effect on January 1, 2015, such chemical substances will be more safely used and handled at home and in the workplace. In addition, new industries are expected to grow, including the development of production and management technologies for hazard and risk information for safe management of chemicals at workplaces, as well as development of alternative technologies such as eco-friendly materials.

As the Act takes effect, the main obligations for chemical handlers to fulfill are chemical registration and product notification. A person who intends to manufacture or import non-phase-in substances or phase-in substances of more than 1 ton[2] per year shall apply for registration with the data necessary for registration prior to manufacture or import in accordance with Article 10 of the Act. A person who intends to manufacture or import a product containing hazardous chemical substances (**ChemLinked comment: the notification scope has been narrowed down from the "product containing hazardous chemical substances" to the "product containing priority management substances" according to the revised K-REACH, Law No.15512 of 20 March 2018, thus "product containing priority management substances" is used in this translation hereafter. For your reference: in total 672 substances were designated for priority management in Dec 2018, of which 204 substances have been effective from July 1, 2019 and the other 468 substances will be effective from July 1, 2021.*) shall notify before manufacture or import if content of a priority management substance exceeds 0.1 % w/w and the total amount of the priority chemical substances contained in the product exceeds 1 ton per year in accordance with Article 32. In the case of failure to comply with the relevant obligations, such as the above registration or notification, imprisonment of less than 5 years or fines of up to one hundred million KRW will be incurred in accordance with Article 50 of the Act. Therefore, those who manufactures or imports chemical substances shall not be negligent to perform their obligations of registration and product notification.

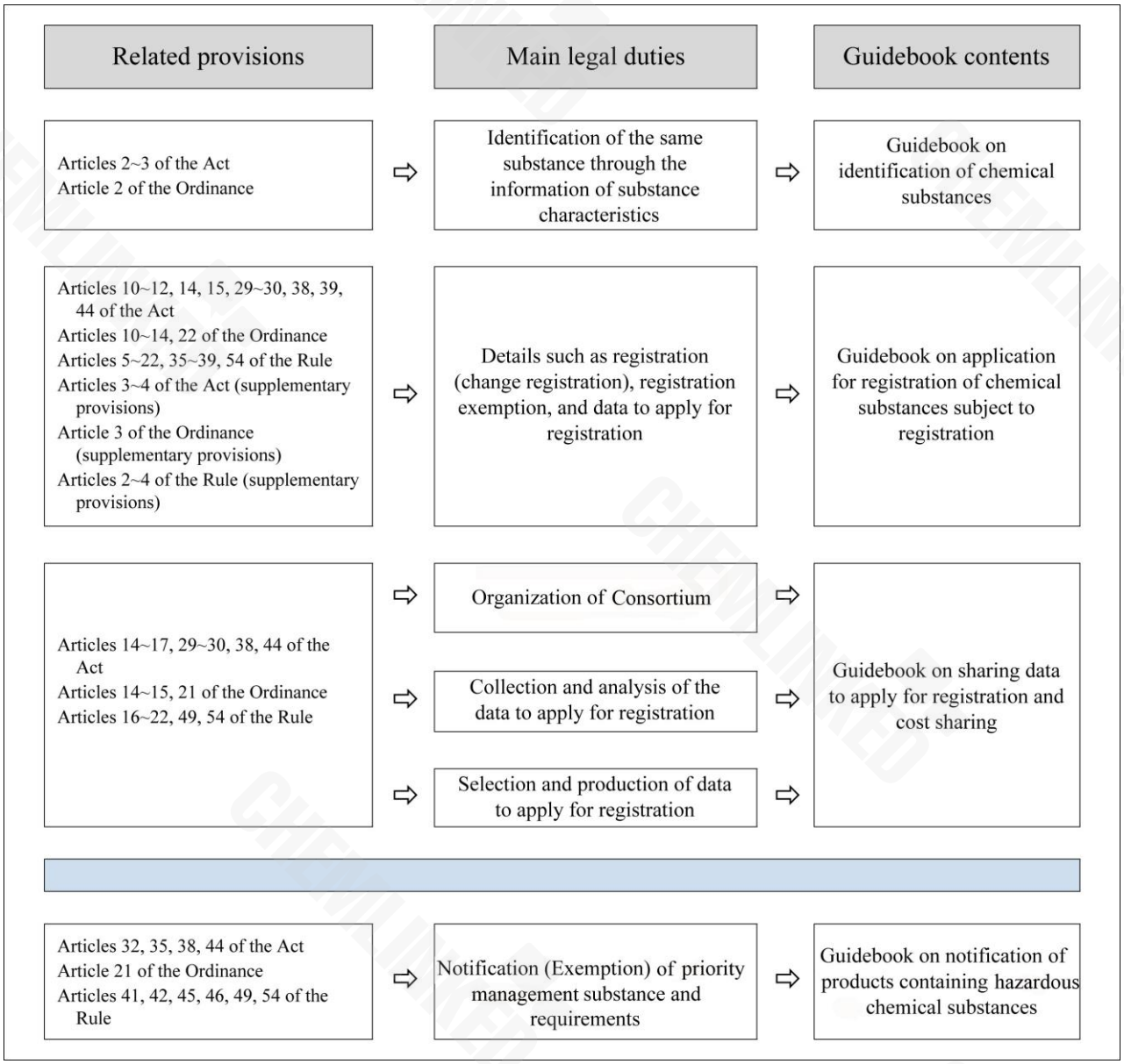
To supplement the Act, Enforcement Ordinance, and Enforcement Rule in managing the system, and to make it easier for the parties directly involved in implementing the Act to understand and refer to the relevant process, the Ministry of Environment has prepared four guidebooks for "identification of chemical substances", "registration data sharing and cost sharing", "application for registration of chemical substances subject to registration" and "notification of products containing hazardous chemical substances". This guidebook includes the series of procedures from

[1] Number of entities tested for hazards as of 1991.

[2] However, in case of the substance designated & notified by Minister of Environment, it shall amount to less than 1 ton.

identification of substances that forms the basis of legal compliance process to registration, and notification of products containing priority management substances.

The legal process and obligations covered by each guidebook can be illustrated as follows.



First of all, the guidebook on “identification of chemical substances” covers general methods of confirming the information of chemical substances and other identification methods according to types of substances, e.g. a single substance or a polymer compound, so that the chemical substance handled by a business entity can be identified whether it is subject to legal obligations.

The guidebook on “registration data sharing and cost sharing” focuses on how to organize and operate a consortium, how to collect and analyze the joint submission data, the process of choosing the individual submissions and how to share costs fairly and transparently so that the business entity who should register the same phase-in substances may refer to them in case of generating and sharing the joint submission data required by law and sharing the cost. However, the principle of data sharing prescribed by law, in particular, Article 17 Special Case on Vertebrate Animal Test Data of the Act applies even in the case of registering non-phase-in substances, and therefore may be used by all the business entities that are obligated to register.

The guidebook on "application for registration of chemical substances subject to registration" has been prepared according to Article 10 of the Act and is intended to be used in the process of fulfilling the registration obligation by anyone who intends to manufacture and import more than 1 ton per year of the phase-in substances and all the non-phase-in substances. Its main contents include the scope of business entities that should fulfill the registration obligations and substances subject to registration, the substances applicable for confirmation of exemption from registration and the method of confirming registration exemption, the required documents and procedures for registration application, follow-up management after registration application, change of registration and notification, etc.

Finally, the guidebook on the "notification of products containing hazardous chemical substances" focuses on the subject of notification, confirmation of the subject exempt from notification, and its content and methods.

The main contents of each guidebook are summarized as follows.

Category		Main content
Substance identification	Identification of chemical substances	■ General method of identifying chemical substances ■ Method of identifying substances by type (single component, polymer etc.) ■ Method of identifying the same substance
Substance registration	Sharing the data to apply for registration and cost sharing	■ Organization and operation of consortium ■ Method of collecting, analyzing and submitting the joint submission data (including individual submissions) ■ Method of fair cost sharing
	Application for registration of chemical substances subject to registration	■ Confirmation of substances subject to registration, registration period, registration procedure, method of preparing registration documents ■ Confirmation of substances subject to registration exemption, method of preparing registration exemption documents ■ Ex post facto management after applying for registration, change of registration, etc.
Product notification	Notification of products containing priority management substances	■ Confirmation of notification exemption and notification of products containing priority management substances ■ How to prepare the documents for notification exemption and notification of products containing priority management substances

Though these four guidebooks are prepared based on industry opinions and consultation with experts and the relevant governmental authorities and have no direct legal and mandatory force, we recommend that parties concerned to use them as essential references in complying with the Act.

Table of contents

List of tables

List of figures

Definition of key terms (Article 2 of the Act)

Term	Definition
Phase-in substance	“Phase-in substance” means any of the following chemical substances: (a) Chemical substances publicly notified by the Minister of Environment in consultation with the Minister of Employment and Labor, which were domestically distributed for commercial purposes before February 2, 1991 (b) Chemical substances publicly notified by the Minister of Environment and where the hazard reviews thereof have been conducted pursuant to the former Toxic Chemicals Control Act after February 2, 1991
Priority existing chemical substances subject to registartion (PECs)	“Priority existing chemical substances subject to registartion” refer to the ones announced by the Minister of Environment after deliberation by the Chemicals Evaluation Committee pursuant to Article 7, recognized as necessary to register, and shall conduct hazard review pursuant to Article 18 or risk assessment pursuant to Article 24 of K-REACH.
Non-phase-in substance	“Non-phase-in substance” means all chemical substances excluding phase-in substances.
Business entity	“A business entity” means a person that manufactures, imports, uses or sells chemical substances for business purposes.
Generic name	“Generic name” means a name given in place of an actual chemical substance name to protect confidential data.
Downstream user	“A downstream user” means a person who uses chemical substances or mixtures in business activities (in the case of a corporation, limited to where it is incorporated in the Republic of Korea): Provided, That manufacturers, importers, sellers, or consumers of chemical substances or mixtures shall be excluded herefrom.
Sale	“Sale” means placing chemical substances, mixtures, or products on the market.
Registration grace period ※	A person who intends to manufacture or import non-phase-in substances or phase-in substances of more than 1 ton per year according to Article 10(1) of the Act, shall register before manufacture or import. However, a person who intends to manufacture or import phase-in substances according to Article 10(2) of the Act, may manufacture or import without registration during the given period as prescribed by the Presidential Decree, which is called “registration grace period”.
Consortium ※	A person, who intends to apply for registration of phase-in substances within the registration grace period according to Article 15(1) of the Act, shall respectively apply for registration according to Article 10(3) of the Act. The registration application data prescribed by the Ordinance of the Ministry of Environment shall be submitted jointly by

	designating a representative. “Consortium” means a voluntary organization formed by the registration applicants for the purpose of jointly submitting the data to apply for registration of phase-in substances.

※ Definitions inferred according to the relevant articles of the Act.

Chapter 1 Introduction

1. Meaning and purpose

"Toxic Chemicals Control Act (Act No. 11998)" aims to prevent hazards to human health and environment caused by chemicals and to properly control such toxic chemicals so that all citizens live in a healthy and pleasant environment. On the other hand, The Act on Registration and Evaluation of Chemicals (initially published on May 22, 2013 as Act No. 11789), as stated in Article 1, its main purpose is to protect public health and the environment by safely managing hazardous chemical substances and producing /utilizing information on chemical substances through registration of chemical substances, evaluation/assessment of hazards and risks of products containing hazardous chemical substances. Compared with the former Toxic Chemicals Control Act, the most prominent difference of the Act on Registration and Evaluation of Chemicals is the specific means for substances management. The Act on Registration and Evaluation of Chemicals (hereinafter referred to as the Act) specifies the concrete means for registration of chemical substances, evaluation/assessment of hazards and risks, and production and utilization of information on chemical substances.

Given this difference from the Toxic Chemicals Control Act, the importance of "registration of chemical substances" in the new legal system cannot be overemphasized. The information collected and produced by a person who intends to manufacture/import chemical substances while registering them shall be the basis for the safe use of chemical substances in the country and be passed on to the downstream users in the supply chain, and in some cases, to consumers. As oxygen flows through blood vessels and sustains human life, the information on use, hazards and risks of chemical substances is distributed in the supply chain and plays a role in preventing unexpected accidents in the workplaces of manufacturers, importers and downstream users who use chemical substances as raw materials, and ultimately protecting human health and the environment.

Among those who want to manufacture or import chemical substances, the most important factor that the person who intends to "register the chemical substances" under Article 10 of the Act shall consider is "data sharing". Articles 15 to 17 of the Act are related to this. Article 15 of the Act stipulates how to jointly submit the data by those who intend to apply for registration of the phase-in substances within the registration grace period. Article 16 of the Act stipulates how to jointly use the existing data to apply for registration by those who intend to newly apply for registration, and Article 17 stipulates how to use the existing test data performed by using vertebrate animals.

There are several reasons why the Act requires those who intend to fulfill the registration obligation to share the existing vertebrate animal test data, the data to apply for registration and the data held by those who intend to manufacture or import the same substance. First, the reason is that it is more cost-effective for a person who intends to manufacture or import a substance subject to registration to jointly collect and produce the data to be utilized than to individually submit the data by testing for each item. Second, from the standpoint of the reviewing authority (National Institute of Environmental Research) of the registration application data, it will be faster and more efficient to check the data jointly submitted by obligators rather than reviewing the completeness and validity of the data submitted by each obligator one by one. Third, as specified in Article 17 of the Act, the

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