



Ministry of Environment



Korea Environment Institute



Act on Registration and Evaluation, etc. of Chemical Substances(ARECS) No. 40

**Korea Environmental Policy Bulletin
Vol. XIII Issue 2, 2015**

Table of Contents

I. Act on Registration and Evaluation, etc. of Chemical Substances (ARECS)	1
1. Background of ARECS Enactment	1
2. Process of ARECS Enactment	3
II. Overview of ARECS	5
1. Reporting and Registration of Chemicals	7
2. Hazard Review and Risk Assessment of Chemicals	9
3. Risk-Based Chemical Management	9
4. Communication of Chemical Information	10
5. Management of Products of Risk Concerns	11
III. Implementation Plan and Expected Benefits	15
1. Implementation Plan	15
1.1 Securing Safety Data on Chemicals	15
1.2 Management of Hazardous Substances in Household Chemical Products	17
1.3 Disclosure of Safety Data	18
1.4 Infrastructure Building	19
2. Expected Benefits	21
Reference	21

Summary

Korea has the fifth largest chemical industry in the world. The total volume of chemicals is increasing at a rate of 6.4% every year, and hazardous chemicals at a rate of 8.2% annually. Despite the rapid growth, the safety threats on humans or the environment posed by hazardous chemicals in the Korean market has not been fully and closely verified, and only some of the chemicals have been verified their hazards.

In addition, there was a growing awareness that we need to establish an advanced chemical management system taking into account the domestic situation and the international trend toward strengthened chemical management. Hence, the Act on Registration and Evaluation, etc. of Chemical Substances (hereinafter referred to as “ARECS”) has been enforced since January 1, 2015.

The main idea of ARECS is as follows: First, compile critical information for managing chemicals through a mandatory registration system for all non-phase in chemicals (the so-called new substances) and phase-in chemicals (the so-called existing substances) that are manufactured in or imported to Korea more than one ton per year. Then, conduct hazard and risk assessments based on the information in order to understand chemical substance’s accurate properties, hazards, and risks caused by exposure; Secondly, based on the results of the assessments, the government designates and manages hazardous chemical substances and 15 types of chemical products containing such hazardous chemicals with more expertise. In particular, to manage those products, the government designated products of risk concerns and came into effect labeling standards; Third, ARECS ensures to communicate safety data such as hazard data, restricted use and precaution within the supply chain, so that can be used for workplace safety and serve consumer’s right to know.

The first step for ARECS implement is to make more chemical substances go through hazard

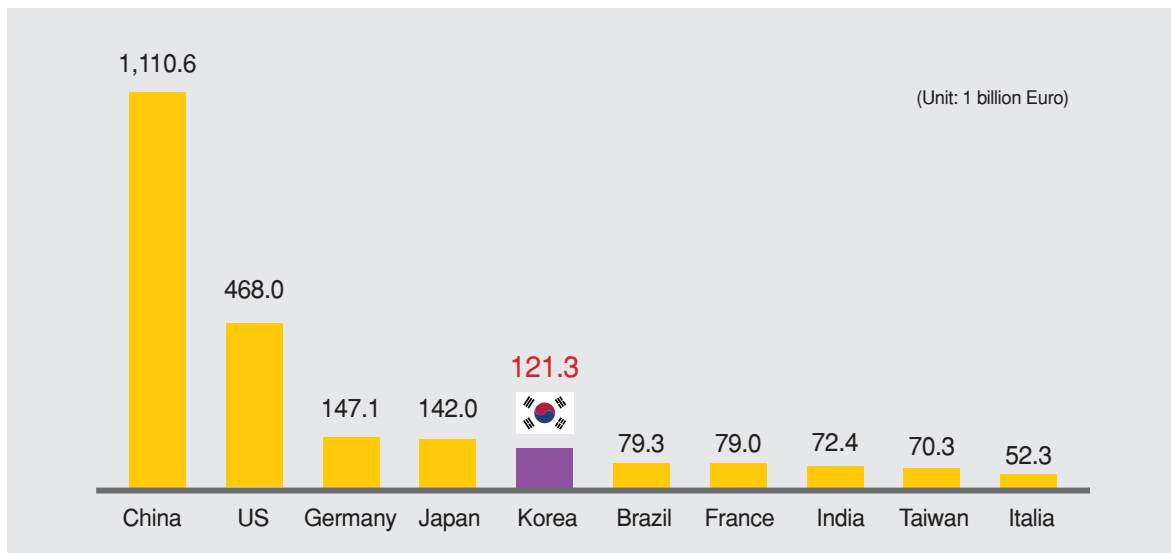
review. Only 5% of chemical substances in the Korean market went through hazard review so far, but the government aims to increase the rate to 50% by 2020. To do so, the government promotes the infrastructure for generating hazard test data, and develops technologies for hazard review and risk assessment. The second step is to extend the scope of chemical substances subject to authorization, restricted substances, prohibited substances and toxic substances, and designate and manage products of risk concerns. To meet this goal, ME will strengthen monitoring on priority chemicals, conduct preliminary risk assessment and perform product inspections. The third step is to build a data communication system within the supply chain, provide an integrated information service for the public, and adapt stakeholders' opinions to the policies. For the basic elements for ARECS implement, the government takes measures to build the infrastructure for hazard testing and the IT system for information sharing, develop training programs, and promote development of alternatives and alternative technologies for emission and risk reduction. While doing so, a variety of supporting programs for small and medium-sized enterprises (SMEs) are provided to help them build the capability to comply with the legal requirements under ARECS, such as compliance with mandatory registration and risk data.

With the introduction of ARECS, the information on chemical substances in the market is compiled, and the information makes it possible to take preventive measures for chemical management. Also, the development of environment-friendly and high value-added chemicals leads to the innovation of businesses. While the companies enhance their capacity for the compliance, their competitiveness in the international market would also be strengthened with more decent new jobs created. In the long-term, we expect that ARECS contributes to achieve sustainable growth based on green chemistry.

I . Act on Registration and Evaluation, etc. of Chemical Substances(ARECS)

1. Background of ARECS Enactment

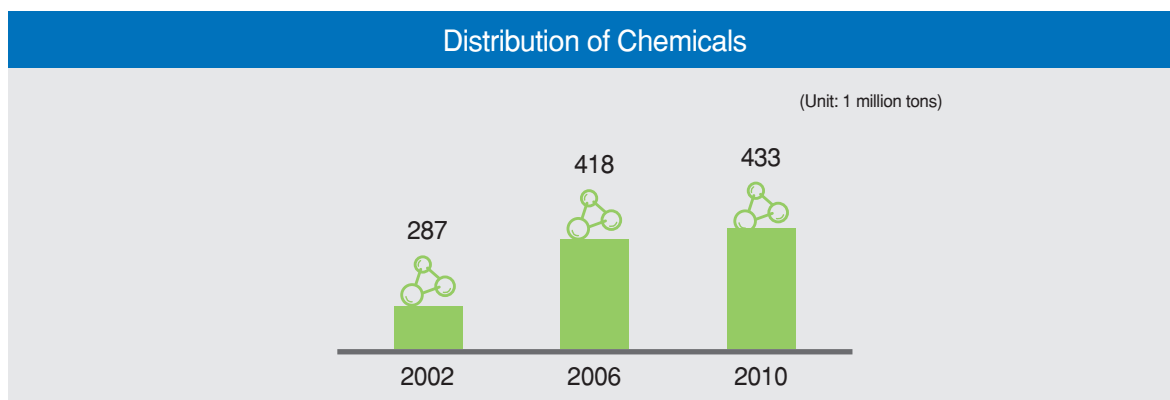
Today, there are 105 million chemical substances in the global market, with only 340,000 of them being regulated.¹ The chemical industry of Korea has grown to the world's 5th largest, owing to the petrochemical industry (based on sales in 2014).



Source: CEFIC(2016); Ministry of Environment (2015a)

<Figure 1> Korean Chemical Industry's Volume compared to Other Countries

¹ The website of the American Chemical Society (Ministry of Environment, 2015e, Requote)



Source: Ministry of Environment (2015a)

<Figure 2> Chemicals Distributed in the Korean Market

There are around 45,000 chemical substances in the Korean market and 400 new chemicals brought into the market every year. The chemical market in Korea is growing at an annual average of approximately 6.4%, while hazard data of only 5% of substances in the market are known. Despite the fact that chemicals are used in virtually every corner of our daily lives, ranging from household detergents to automobiles and electronics, their safety has been partially verified.

Since the previous Toxic Chemicals Control Act (TCCA) enforced in February 1991, the TCCA had been the basis of safety evaluation and management of chemical substances until 2014, including hazardous substances. Based on the legislation, companies produced the information on new chemicals² and applied for hazard review performed by the government. Meanwhile, some chemical substances were under the control of other laws: For example, the Occupational Safety and Health Act by the Ministry of Employment and Labor, the Safety Control of Dangerous Substances Act by the Ministry of Public Safety and Security, the Pharmaceutical Affairs Act by the Ministry of Health and Welfare(MoHW), the Pesticide Control Act by the Ministry of Agriculture, Food and Rural Affairs, and the Quality Control and Safety Management of Industrial Products Act by the Ministry of Trade, Industry and Energy(MoTIE).

However, public demand for sound chemical management grew stronger than ever before after the humidifier disinfectant incident in April 2011. Chemicals such as PHMG³ and PGH⁴ were

² Phase-in chemicals: Chemicals introduced in the Korean market until February 2, 1991, including the chemicals announced by the Minister of Environment after discussing with the Minister of Employment and Labor, and chemicals which went through hazard review after February 2, 1991 in accordance with the previous TCCA and were announced by the Minister of Environment. All chemicals that are not phase-in chemicals are considered as non-phase-in chemicals

³ Polyhexamethyleneguanidine Phosphate

⁴ Poly(2-(2-ethoxy)ethoxyethyl guanidium hydrochloride)

used in humidifier disinfectant without verified safety data, resulting in lung damages of many people. To prevent recurrence of such chemical accidents, the government needs to have hazard and risk data, information about uses of chemical substances before they are placed on the market. However, the TCCA had several limitations like the followings: First, a review system under the TCCA was focused only on hazard. Therefore, there was no sufficient consideration on exposure levels and risks. Safety verification was not fully conducted for each different use of chemical substances, even though the risk of chemical substance on humans and the environment is varied according to its use and use condition; Secondly, the TCCA attempted to have hazard data mainly on non-phase-in chemicals while the businesses were exempted from the responsibility to generate safety data on existing chemicals, which account for the majority of chemicals in the Korean market. Even though the TCCA targeted that chemical substances are handled and used in a way that minimizes exposure to chemical substances, the law remained wrongful awareness that chemical substances can be used with no restriction if it is not a toxic substance, and allowed poor responsibility of the polluter industry.

In the meantime, the European Union introduced its Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) in June 2007 with an objective to prevent and reduce risks on health and the environment posed by expanding use of chemicals. Japan also announced a revised version of the law on reporting and evaluation of chemicals in April 2010. China introduced its new chemical management program. The global chemical regulations has a tendency to adopt the principle of 'No Data, No Market', leading to more stringent chemical regulations. An advanced chemical management system in Korea was needed than ever before, considering the limitations of Korean chemical management system and the global trend.

2. Process of ARECS Enactment

The Ministry of Environment (ME) started to prepare a draft version of the Act on Registration and Evaluation, etc. of Chemical Substances (ARECS) since late 2010. The draft version was made based on experiences and lessons learned when addressing the EU REACH (December 2010), and was reviewed by the industries to listen their voices before the draft version was submitted to the National Assembly of Korea (September 23, 2012). After the review and evaluation by the National Assembly, ARECS was officially enacted and promulgated (May 22, 2013). In this process, a joint meeting between ME and MoTIE was held on March 19, 2012, where deciding to run a joint-ministerial pilot program from May 2012 to February 2013. These efforts aimed at reducing burdens of the industry while staying on the objectives of ARECS.

After the enactment of ARECS, a consultative group consisting of representatives of the industries and civic groups was formed at the initial stage of designing subordinate laws. A total of 29 meetings were held between August 2013 and December 2014. In addition, meetings with economic organizations were also held to hear their opinions. By doing so, the drafts of subordinate laws were designed in cooperation with stakeholders for better enforcement and acceptability.



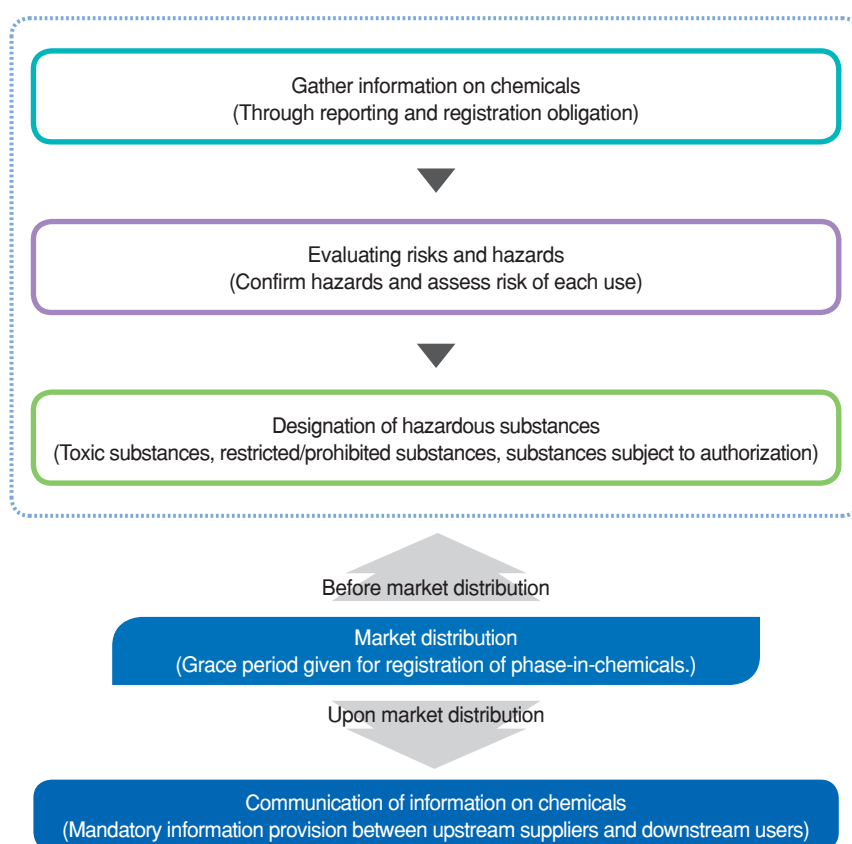
Source: Ministry of Environment (2015a)

<Figure 3> Enactment Process for ARECS

The process to enact subordinate laws began in January 2014. The draft laws were discussed by the related ministries (January 23 – February 6, 2014), and then a preliminary announcement of enactment was made (February 18 – April 21, 2014). Then, the Enforcement Decree (December 9, 2014) and Enforcement Rules (December 24, 2014) were promulgated after reviews by the Regulation Reform Committee (June 5 – 13 and July 25, 2014) and the Ministry of Government Legislation (July - December 2014). Finally, ARECS took effect on January 1, 2015.

II . Overview of ARECS

The main idea of ARECS is to gather necessary information for sound chemical management (mandatory registration of chemicals), fully understand properties of the chemicals (hazard and risk assessments), ensure safe management of hazardous substances (designation of hazardous substances), precisely manage products containing hazardous substances (designation of products of risk concerns, and development of safety labelling standards), and make the information on hazardous substances available publically.



Source: Ministry of Environment (2015a)

<Figure 4> Key Elements of ARECS

There were several remarkable changes after the ARECS took effect: First, chemicals subject to registration were expanded from non-phase-in substances (300 substances per year) to phase-in substances (510 substances for the Phase 1), and gather their information for hazard review and risk assessment; Secondly, hazard review focused only on acute toxicity assessment expands its scope to chronic health impact (from 10 categories to 34 categories of environmental health hazards). Furthermore, risk assessment and management are performed based on each different uses of

chemical substances; Third, the obligation to communicate chemical information was imposed stakeholders in the supply chain so that the information is communicated between upstream parties (transferer) and downstream parties (transferee). A transferer of a substance should provide information on risks, hazards, registered and restricted use, and safety data to transferee(s). In the meantime, a transferee should provide use information and exposure data of chemicals that are necessary for fulfilling registration obligation under ARECS.

ARECS focuses on preventive measures of chemical management in order to ensure safety of all chemicals before they are released into the market. Those who intend to import or manufacture a substance is required to register hazard and risk data of the substance prior to placing it on the market, so that the businesses hold responsibility to prove safety of chemical substance. When a substance is found to have higher risk as a result of risk assessment, the substance is to be designated as hazardous chemical substance. If its use is inevitable, preventive measures must be taken for blocking any risks when it is distributed in the market. In case where such chemicals are not managed with proper preventive measures, they are to be banned from the market.

Act		Before ARECS	ARECS
		TCCA	ARECS
Information Gathering	System	Registration	Reporting and Registration
	Targets	Non-phase-in chemicals	Non-phase-in chemicals Phase-in chemicals
	Contents	Hazards	Use, handled volume, hazards, risks
Evaluation	Targets	Non-phase-in chemicals	Non-phase-in chemicals Phase-in chemicals
	Subjects	Hazards	Hazards, risks
Communication	Targets	N/A	Communicating information between the supplier and the user
	Contents	N/A	Information on risks, hazards, applications, and safe use information

Source: Ministry of Environment (2015a)

<Figure 5> Major Changes after ARECS Enforcement

1. Reporting and Registration of Chemicals

Companies have obligations of “reporting” to submit information on manufacture, import and sale of chemicals, and “registration” to submit information on chemicals such as use, properties, hazards and risks. In particular, the core element of ARECS is the registration obligation. The registration obligation allows the national authorities to know detailed safety data of chemical substances prior to their distribution in the market. Under the registration system, manufacturers and importers should prepare and submit chemical information before placing it on the market, to the national authorities. Under the previous TCCA, only non-phase-in chemicals exceeding 0.1 ton per year went through a hazard review, and there were no control on phase-in chemicals. However, ARECS expands the scope of chemicals subject to registration and chemicals subject to hazard review to phase-in substances and all non-phase-in substances.

The reporting obligation is newly adopted under ARECS. It requires all manufacturers, importers and sellers of non-phase-in substances or phase-in substances (1 ton or more) to submit data every year including chemical name, quantity handled and use of a substance they handle. With this reporting obligation, volumes and uses of chemical substances in the market could be identified. This data is used as a critical resource to designate phase-in substances subject to registration.

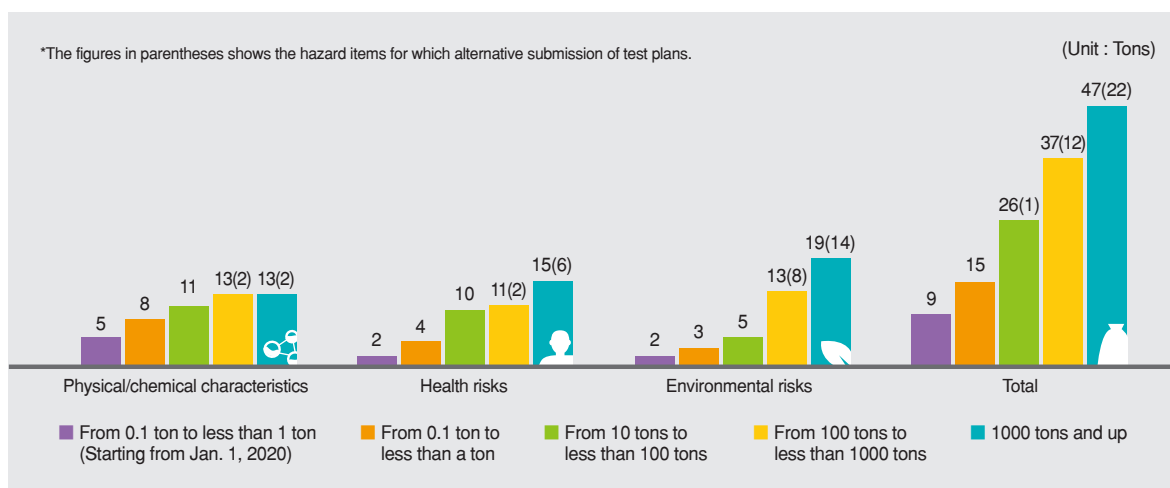
The registration process under ARECS was rearranged, similar to those under EU REACH, by means of separating registration process from review process. In this system, registration completion notice is issued within 30 days from the date when an application is accepted (3 to 7 days for a new chemical substance in small volume). This is a significant reduction of time compared to 60 days under the previous TCCA. In addition, test data requirements about chemical properties and hazards in registration dossier are differentiated according to tonnage bands of manufactured or imported volume. Also, companies are required to prepare and submit data necessary for hazard assessment, exposure assessment and safety identification in order. In the case where hazards could be identified based only on scientific evidences, relevant test data are exempted from submission. In some cases, test data may be replaced by a test plan with the cooperation of testing agencies.

	Data for Registration Application	Registration Criteria	Remark
1	Manufacturer/Importer-related Data		Name, address and representative
2	Material Data	• Non-phase-in substance	Name and identifiable data such as the molecular formula or structural formula
3	Usage		Usage category, confirmed usage and disallowed usage
4	Classification/Label	• Phase-in substance subject to registration (1 ton or more annually)	International category/label standard (GHS)
5	Physical/Chemical Properties		Differentiation (up to 46) according to the tonnage
6	Hazards		Whole test document or test summary to be submitted
7	Safety Use Guideline		Protective gear, follow-up to explosion, fire or leakage, etc.
8	Risks	• 100 tons or more annually (to be further regulated by phase)	The followings are carried out in order: 1) Hazard examination; 2) Exposure assessment (exposure scenario/exposure forecast); 3) Safety confirmation.
9	Exposure Data or Expected Amount		

*Test data on physical/chemical properties and hazards to human health or the environment (differentiated according to tonnage)

Source: Ministry of Environment (2015f)

<Table 1> Information Required for Registration under ARECS



Source: Ministry of Environment (2015a)

<Figure 6> Hazards Data Requirement for Each Tonnage

2. Hazard Review and Risk Assessment for Chemicals

In case of chemicals subject to registration, the government uses hazard data gathered from the registration system for reviewing the hazards to health and the environment. During its hazard review, the government reviews whether hazard level of certain substance meets the standard for toxic substance designation or not. Also, it decides which classification and labeling standards are applied, by considering hazard levels such as physical danger, hazard on human health and the environment, etc.

Furthermore, the government enhanced a hazard assessment system for chemicals that are not subject to registration. This is to perform hazard assessments on hazardous substances proactively and prevent any blind spots in chemical management. That is to say, the government collects hazard data and conducts hazard assessments for chemical substances listed in international conventions, substances imported or manufactured 10 tons or less for export only, substances of which hazards were identified by alternative test data, substances used to develop test methods, substances of risk concerns, substances manufactured by small and medium-sized enterprises (SMEs) or nanomaterials, even though they are not subject to registration.

The government uses risk data submitted by enterprises and directly collected by the government all together for risk assessments of chemical substances. Potential dangers are identified based on hazard data (hazard identification), and the correlation between substance dose and toxic response is identified using animal tests (dose-response assessment). Then, the use of chemical substance is identified, and exposure level is determined based on exposure scenarios* of each use (exposure assessment). Finally, the potential risk is identified (determination of risk level).

*Exposure Scenario: this is the data that describes how to manufacture and use a chemical substance in its life cycle, how to control its exposure to humans and the environment, and how to encourage downstream users to control exposure, etc. This scenario is the basic data for exposure estimation.

If once-registered use of a substance is changed or a new use is confirmed, registrants have to update their registration before using the substance for the changed or new use.

3. Risk-Based Chemical Management

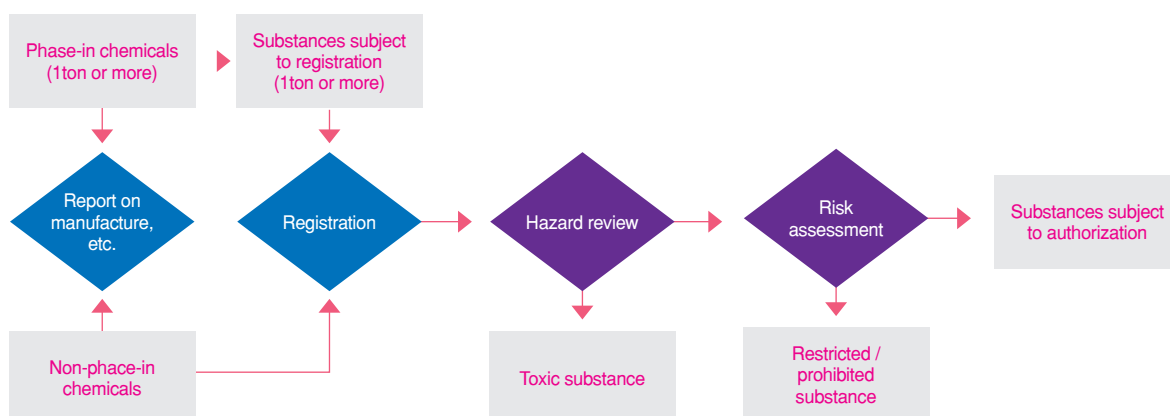
The government performs hazard review based on hazard data submitted by registrants. If the hazard review results indicate that a substance is hazardous, the substance is designated as toxic substance for safe management. There are regulatory requirements for handling toxic substances, such as business permission, handling standards and off-site consequence analysis in accordance with the Chemicals Control Act (CCA).

Of chemical substances placed on the market, substances of risk concerns and highly-toxic substances are designated as substance subject to authorization for special management. Highly-toxic substance means the substances with carcinogenic, mutagenic or reprotoxic

properties (CMRs), endocrine disrupting properties, persistence, etc. Before designating certain chemical substance as substance subject to authorization, risk assessment should be conducted to closely investigate effects on health or the environment. Further more, the national authorities evaluate the socio-economical costs resulting from the designation.

Once a substance is designated as substance subject to authorization, any person who intends to manufacture, import or use the substance should obtain an authorization from the national authorities for each intended use of the substance. Without the authorization, any use of such chemicals is restricted. Designation as substance subject to authorization allows the government to control chemicals of risk concerns and highly-toxic substances, and also encourages development of alternatives.

As the result of risk assessment, a substance having higher risk level in a certain use is designated as restricted substance, and the use of the substance is prohibited. There are 12 restricted substances designated so far. If the result of risk assessment shows that the risk is high in all uses, the substance is to be designated as a prohibited substance. Manufacture, import or use of such substance is strictly prohibited unless the substance is used for scientific research and analysis. As of now, there are 60 prohibited substances under ARECS.



Source: Ministry of Environment (2015d)

<Figure 7> Key Processes for Reporting, Registration, Evaluation and Assessment under ARECS

4. Communication of Chemical Information

If a person supplies a registered substance or a mixture containing the registered substance to a downstream user, the supplier should provide the information on risks, hazards, permissible use, prohibited use, and safe handling requirements to the downstream user. When the information is changed while distributing the substance, such change should be provided

to downstream users within one month. Also, manufacturer or importer of non-registered substance or mixture containing such substance must provide the information regarding safe use of the substance, upon request by a downstream user or seller.

When a manufacturer or importer requests information on chemical substance, user or seller of the substance and mixtures should provide the information, including the amount used or sold, use description, exposure data, etc. Based on the information received, the manufacturer or importer should fulfill reporting and registration obligations. This is an essential step to bring the supply chain into risk assessment on each use of chemical substance. Vice versa, a manufacturer or importer should provide the information on properties, uses, manufacturing or importing quantity and precautions for safety use, to a downstream user or seller of such substance or mixture, upon their request.

5. Management of Products of Risk Concerns

After the humidifier disinfectant incident, more sophisticated and comprehensive management is required for household chemical products. Based on such understanding, the responsibility of managing such products has been transferred from the MoTIE to ME since 2015. ARECS is focused on preventive measures confirming product safety before placing on the market. Consequently, manufacturers and importers are required to declare it to the national authorities when the product contains more than 0.1% by weight of hazardous substance, which exceeds 1 ton a year.

As of now, 15 types of products of risk concerns are under the control of the government. Of those, eight types were once controlled by MoTIE and seven types were added recently. They consist of five product groups: detergents; coating/adhesive agents; fragrance; dyeing materials; and biocides. Products other than the five groups are managed under the Cosmetics Act (Ministry of Food and Drug Safety, MFDS), the Quality Control and Safety Management of Industrial Products Act (MoTIE) and the Pharmaceutical Affairs Act (MFDS).

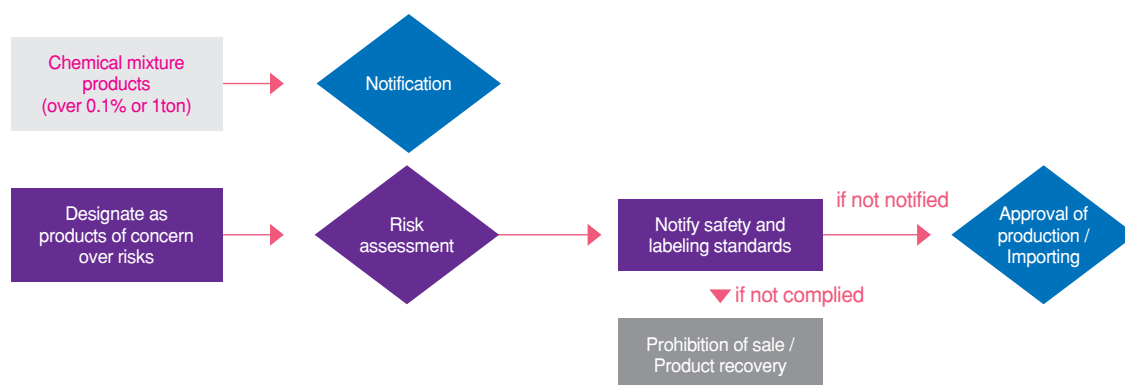
Product Groups	Product Types	Applications
Detergent	Cleaner Sticker Remover Detergent for Automobiles (Spray type)	<ul style="list-style-type: none"> - For kitchen (oven, hood for kitchen range, etc.) - For bathroom (toilet, etc.) - For removing mold - For pipe - For furniture and shoes - For washing machine - For humidifier and air conditioner - For glass - For removing sticker and adhesive, etc.
	Synthetic detergent	<ul style="list-style-type: none"> - For general textile - For home dry cleaning, etc.
	Bleaching Agent	<ul style="list-style-type: none"> - For general textile - For removing stain, etc.
	Fabric Softener	<ul style="list-style-type: none"> - For general textile, etc.
	Coating Agent	<ul style="list-style-type: none"> - For polishing automobile
Coating / Adhesive Materials	Water Repellent for Waterproof Agent for Automobile (spraying type) Anti-Skid Agent for Automobile (spray-type)	<ul style="list-style-type: none"> - For water repellent or waterproof agent for automobile - For anti-skid for automobile - For polishing building, furniture, etc.
	Corrosion Inhibitor	<ul style="list-style-type: none"> - For anti-corrosive lubrication - For anti-corrosion of automobile
	Anti-fogging Agent	<ul style="list-style-type: none"> - For glass, mirror, etc. - For lens - For automobile, etc.
	Adhesive	<ul style="list-style-type: none"> - For general usage - For instant glue - For wig - For fake eyelashes - For artificial nails
	Air freshener	<ul style="list-style-type: none"> - For indoor air - For automobile interior, etc.
Fragrance Materials	Deodorizing Agent (microbial deodorant) Deodorizing Agent for Automobile (spray type)	<ul style="list-style-type: none"> - For indoor air - For clothes, textile and shoes - For automobile interior, etc.
	Tattoo Ink	<ul style="list-style-type: none"> - For permanent tattoos on body and lips - For semi-permanent make-up tattoos
Dye / Dyeing Materials	Bleaching/ Dyeing Agent Paints for Automobile(spray-type)	<ul style="list-style-type: none"> - For dyeing clothes - For painting automobile - For bleaching clothes, etc.
	Disinfectant	<ul style="list-style-type: none"> - For kitchen - For bathroom - For sewer - For pipe - For air conditioner and humidifier - For automobile interior
Materials to kill organisms (Biocides)	Insect Repellent	<ul style="list-style-type: none"> - For clothes - For bathroom and food (to eradicate rice weevil, etc.)
	Preservative	<ul style="list-style-type: none"> - For woods

Source: Ministry of Environment (2015e)

<Table 2> Products of Risk Concerns under ARECS

For managing products of risk concerns, the government conducts risk assessment to set the standards for health hazards. Result from the assessment is used to make safety and labelling standards, aiming at restricting use and dose of substance in products. For example, the national authorities banned to use PHMG, causing the humidifier disinfectant incident, for fragrance (spraying type). Formaldehyde in detergents is limited to 5mg/kg.

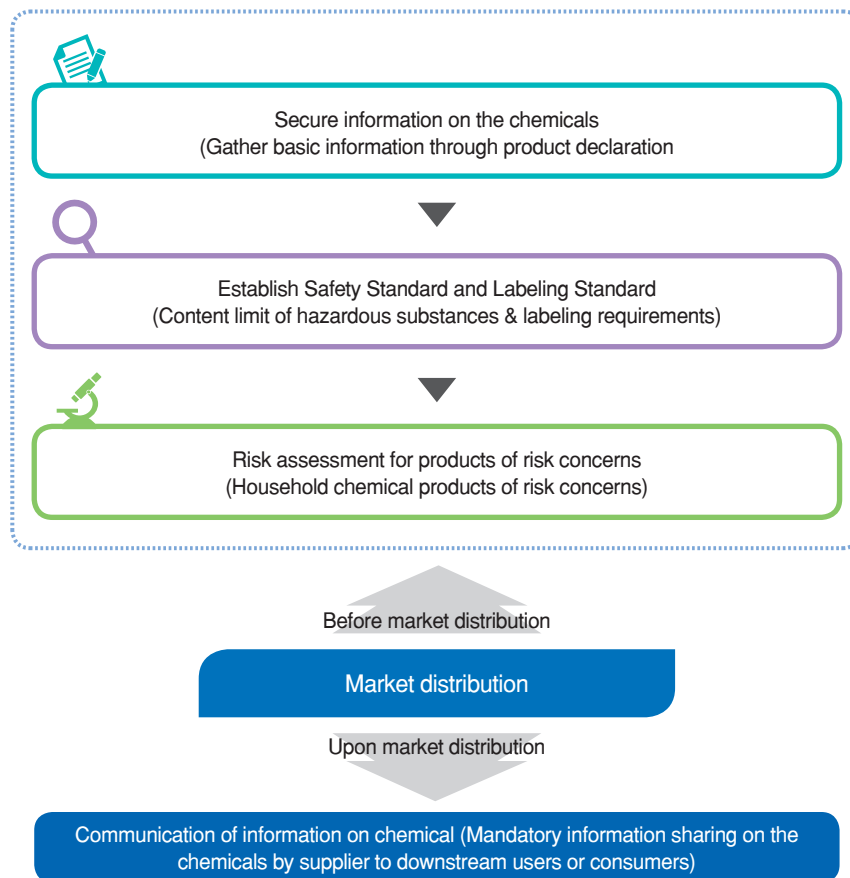
In addition, the government is implementing the labeling standard for products of risk concerns with a view to inform consumers of hazards of the products. The standard includes the product's name, ingredients, function, form, permissible dose and user precautions.



Source: Ministry of Environment (2015d)

<Figure 8> Key Processes Related to Household Chemical Products under ARECS

Supplier of a product that contains a hazardous substance (such as toxic substance, substance subject to authorization, restricted substance or prohibited substance) should provide a downstream user with the following information: name of product; name and weight ratio of hazardous substance in product; allowable uses and prohibited uses of product; user instructions; use condition; and precautions. Also, if a consumer requests, the information should be provided within 45 days from the date of request, free of charge.



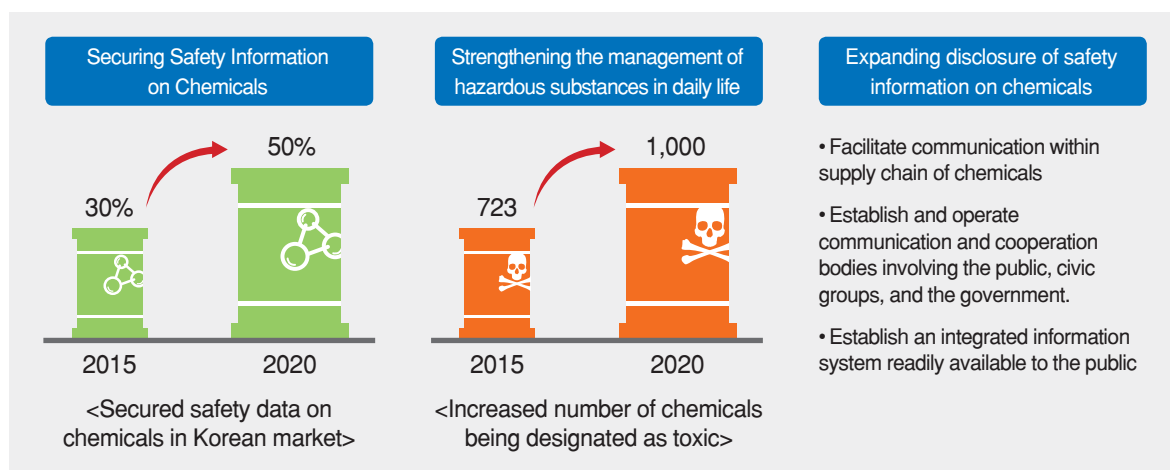
Source: Ministry of Environment (2015a)

<Figure 9> Key System for Managing Household Chemical Products under ARECS

Ⅲ . Implementation Plan and Expected Benefits

1. Implementation Plan

ARECS allows the authorities to have safety data on chemicals, strengthen management of hazardous chemicals in our daily life. In addition, the scope of safety data disclosure is widened under ARECS.



Source: Ministry of Environment (2015a)

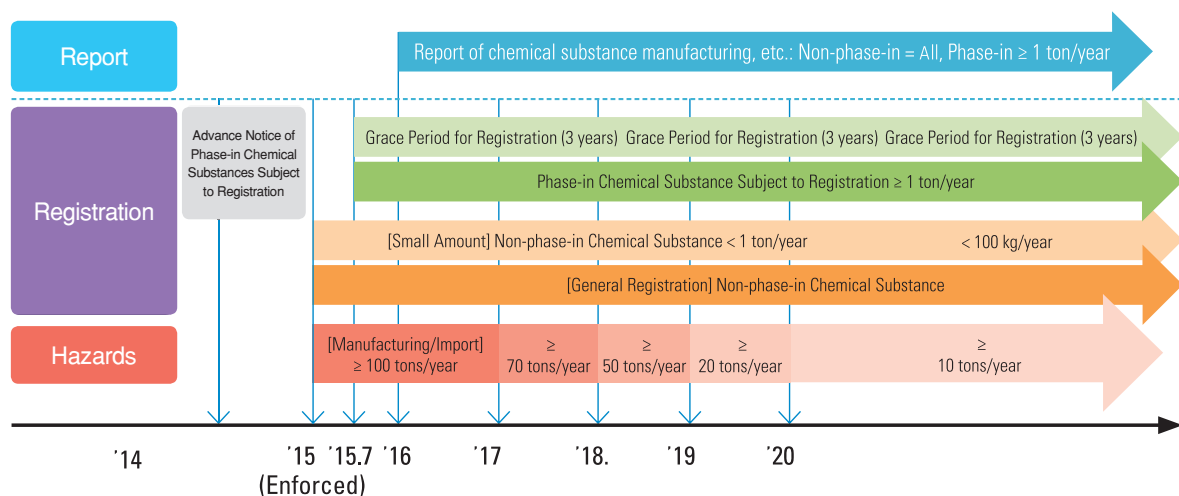
<Figure 10> Enhancement of ARECS Implementation

1.1 Safety Data of Chemicals

Only 5% of chemicals on the market were identified their hazards, which was limited to acute toxicity in most cases. Under ARECS, the government designated 510 phase-in chemicals subject to registration in July 2015, for its Phase 1 designation. This registration obligation requires the businesses to submit physicochemical properties, hazard and risk data on health and environment by 2018.

Furthermore, the government has a plan to designate more phase-in substances subject to registration, based on the information that the businesses submit to fulfill their reporting obligation. By doing so, the government targets to have safety data on more than half of the chemicals on the market by 2020, based on its quantity distributed.

III. Implementation Plan and Expected Benefits



<Figure 11> ARECS Reporting/Registration Roadmap

For approximately 500 types of chemical substances that were listed for priority management, the government has a plan to establish and operate domestic and global monitoring systems, and compile hazard and risk data owned by assessment institutes. ARECS requests maximum 34 items for hazard test, but only 17 out of 34 test items can be produced in Korea. For the other 17 tests, the national authorities will develop necessary infrastructure by 2016 and transfer relevant techniques to private testing institutes in order to build their capability.

In consideration of the global trend led by developed countries such as the US and EU that reduces animal tests and uses more alternative testing methods, the government plans to develop detailed guideline for using alternative testing methods in the industries, and encourage the private sector to use alternative test data through a dedicated organization that will be established.

In order to ensure independent and reliable hazard review guidelines for the entire test items (up to 47 items) are needed. However, such guidelines are available only for seven test items. For independent hazard review on the substances subject to registration, the hazard review guidelines for 47 items will be prepared by 2020. Also, hazard review technologies that are up to the global standards will be developed. In addition, the government plans to develop assessment methods for companies so that they can check risks of their products by themselves before placing on the market. Also, the exposure coefficients and product exposure assessment models will be developed given the situations in Korea, with a view to lay a foundation for risk

assessment that is suitable to Korea.

Under the previous laws and regulations, the sound management of high risk chemicals has not been fully implemented. For example, a substance designated as carcinogenic substance by the International Agency for Research on Cancer (IARC) was not on the list of toxic chemicals, which clearly show the need to improve relevant existing systems. To deal with this issue under ARECS, the national authorities decided to carry out hazard reviews on registered substances and designate more toxic substances, if appropriate. The government plans to have assessment data about around 2,000 new substances of less than 1 ton a year that are registered without hazard data, by means of referring to those of EU REACH and others. If necessary, the national authorities may request additional data to companies for reviewing the hazards of substances. In case where a substance already completed a hazard review under the previous TCCA, re-review may be performed in consideration of structural similarity and specific functional groups.

As of now, there are 40 types of Class 1 carcinogenic chemical substances in the Korean market. Of those, only 22 types are designated as hazardous substances. Against this backdrop, the government will ensure that high-risk chemicals go through risk assessment, socio-economic analysis and are reviewed by the evaluation committee. Then, they may be designated as substance subject to authorization, restricted or prohibited substance, if appropriate.

In order for comprehensive and systematic designation and management of hazardous substances, a national roadmap for managing hazardous substances will be developed. Under the roadmap, the government will compare and analyze the substances regulated globally and domestically, establish a list of candidate substances, set a priority in consideration of hazard and distributed quantity of such substances, and prepare a management plan.

1.2 Management of Hazardous Substances in Household Chemical Products

Household chemical products vary significantly depending on their producers or uses even though they belong to the same product group. Therefore, it is essential to upgrade relevant safety and labeling requirements continuously after examining whether a product contains any substance subject to authorization, restricted substance, prohibited substance or highly toxic substance like CMR substances (carcinogenic, mutagenic, or reprotoxic substance). In addition, the government plans to list major ingredients in such products, mainly focusing on air freshener and odor eliminator that can pose higher risk through inhalation exposure. Also, it will perform risk assessment on those higher-risk products, and adapt the assessment results to the safety and labeling standards.

ARECS does not prescribe details of procedures, methods and criteria for designating products of risk concerns. For this reason, designation and management on such products are

not fully implemented. The national authorities need to survey the current status of household chemical products in the market, decide candidate products, build risk assessment and safety standards, hear voices of stakeholders, and establish a dedicated system for designating products of risk concerns.

By 2020, the national authorities will designate more than 25 products of risk concerns gradually by means of investigating which products have risk concerns and what hazardous substances are contained in product not controlled by the national management system, and their potential exposure.

Once a product is designated as product of risk concerns, its safety standard and labeling standard are determined based on risk assessment. For the current 15 types of products of risk concern, the national authorities will conduct reassessment on their risks to enhance their safety standard. It will also provide guidelines for their quality management. In addition, pre-market risk assessment will be introduced in order to strengthen the businesses' responsibility to verify product safety.

Safety of such products in the market will be examined annually by the government. Then, when a product fails to meet the safety standard, the product will be recalled, banned from the market, destroyed or get a correction order. Also, with the cooperation of consumer groups or other related organizations, efforts will be made to conduct continuous monitoring on the compliance with labeling requirements, distribution of illegal products, and safety verification about new products.

To prevent any incident caused by household chemical products, more experts will be hired for investigation about household chemical products. Overseas and domestic cases will be compiled and analyzed to deal with these kinds of harm caused by chemicals.

1.3 Disclosure of Safety Data

The supply chain of chemicals is highly complicated involving a number of different stakeholders, such as manufacturer, importer, downstream user who uses the chemical as raw material or parts, seller and end-user. Since data sharing might be hindered due to trade secrets, guidelines for effective communication within the supply chain will be introduced, and a case book about trade secret protection will be published by the national authorities. Also, the "Chemical Information Communication Program" will be developed to transfer registered and assessed information directly to a data disclosure system, and such program will be distributed for the industry. In addition, the national authorities are now making an approach for integrating similar systems of other ministries.

Even though a variety of chemical information is provided to the public, such information is dispersed in many different websites. Also, the results of hazard reviews and risk assessments are not linked to distribution information of products, which hamper the public access to

necessary information. To address this issue, the scattered systems will be integrated into one system by 2020 so that all information on chemicals can be available in one place. The integrated system will make it possible to manage all information of chemical substances by linking the results of hazard reviews and risk assessments with distribution information of the products.

In order to enhance accessibility to chemical information and convenience of the public, a smart-phone application will be also developed by 2017. With this, it would be easier to check hazardous substances and obtain relevant information for safe handling. Hazardous substances or products containing such chemicals can be used in a safer manner on the Korean market.

In addition, for more effective communication among the government, companies and public, a communication group will be established, consisting of representatives from civic groups, industries, media, experts and related agencies, under the Chemical Evaluation Committee prescribed in ARECS.

1.4 Infrastructure Building

ME has been building the infrastructure for enhancing hazard testing capacity and developing training programs, and developed the IT System on chemical risk and hazard data. From 2011 to 2014, ME had made an investment of approximately 22.8 billion KRW on basic research projects for the infrastructure of sound chemical management.⁵

ME plans functional advancement of the current chemical substance information processing system continuously, and will implement IT-based chemical management for lifecycle by means of linking with the waste system (the so-called Allbaro). To meet the growing demands on professionals for sound chemical management, ME has a plan to introduce a national licensing system and cultivate green chemical experts, so as to have more professionals who would enhance chemical safety and advance hazard review and risk assessment technologies in Korea.⁶

ME plans to support the development of feasible alternative technologies, for substituting hazardous chemical substances. This support will be made based on estimated demands on alternatives in the industries. For alternative technologies, ME will promote a project for integrating and linking all R&D projects run by each different ministries. The project includes the whole process of alternative application, from development of alternatives, three-year development of core technologies to two-year applicability test. Meanwhile, ME has been running other programs for development of chemical processing and emission reduction technologies.⁷

The government considered that the competency of SMEs would be the decisive factor for the successful settlement of ARECS. With this in consideration, the government plans to engage in

⁵ Ministry of Environment(2015b)

⁶ Ministry of Environment(2015b)

⁷ Ministry of Environment(2015b)

III. Implementation Plan and Expected Benefits

various supporting programs from 2015 to 2017: for example, a program for SMEs' compliance with registration system and preparation of risk-related information. Please see the below table for more information.

Item	Description
Test Data	<ul style="list-style-type: none"> - Focused on the chemicals manufactured by SMEs - Production and collection of hazard data for chemicals
Registration and Management	<ul style="list-style-type: none"> - Supports identification of chemical name and gathering of hazard information to facilitate registration - 1:1 expert consulting etc.
Risk Assessment	<ul style="list-style-type: none"> - Supports preparation of risk assessment reports and consulting - Enhancement of capability in preparing the reports
Joint Registration	<ul style="list-style-type: none"> - Support joint registration of phase-in chemicals subject to registration - Support formation of a Chemical substances Information Communicative Organization (CICO) and sharing of costs
Others	<ul style="list-style-type: none"> - On/Offline help center operation, etc.

Source: Ministry of Environment (2014)

<Table 3> SME Support Programs for ARECS (2015-2017)

ME provides one-to-one support for SMEs having less than 50 employees and the industries where SMEs account for the majority. This support aims to assist SMEs having difficulties in preparing the compliance with ARECS due to lack of information and experiences. By sending professional consultants to SMEs, the types, volumes and properties of chemical substances they use are identified. Then, the consultants check all legal requirements such as registration, reporting, authorization. Such efforts are intended to build capacity of SMEs so as to adapt to the new laws and regulations by themselves in the end. ME will keep supporting SMEs by embracing more industries and businesses into this supporting program. Under ARECS, a joint submission is applied to manufacturers or importers of the same existing substance subject to registration when they submit test data including physicochemical properties and hazards. However, many of the manufacturers and importers are SMEs having no experience of the registration obligation. It is foreseen that there must be difficulties in the process of joint submission by the businesses. For this reason, ME supports SMEs to complete their joint submission by means of helping establish a group for joint submission, appoint a lead registrant and prepare registration dossier, etc.⁸ Also, the national authorities published four guide books (Guidance for Identification of Chemicals, Guidance on Data Sharing and Costs Allocation, Guidance on Registration Application and Guidance on Reporting of Products Containing Hazardous Chemicals) that the industry could refer to.⁹

⁸ Ministry of Environment(2015c)

⁹ Ministry of Environment(2015c)

2. Expected Benefits

With the introduction of ARECS, preventive and preemptive management of chemicals based on scientific evidences can be realized by compiling safety data on chemical substances placed on the market. Companies submit and register hazard and risk data on substances they manufacture or import, and the government uses the submitted data for its risk assessment. The companies can use such data in manufacturing and using chemical substances in a safer manner, and the government enables to upgrade its chemical management policies based on the data.¹⁰

In addition, we expect that AREC accelerates the capacity-building for development of new chemicals that are mainly dependent on import, leading to the development of higher value-added and high functioning chemical substances. The authorization and restriction systems for each use of highly hazardous substances will trigger technical innovation of the industries and enhance the competitiveness of the Korean chemical industry in the global market. The mandatory submission requirement for chemical data will boost the demand on tests conducted by domestic GLP agencies, and create more new decent jobs with new industries such as chemical information management. Also, it is expected that ARECS will strengthen the competence of companies that export chemicals in responding to chemical regulations. In the long term, the sound chemical management based on safety data under ARECS will contribute to the sustainable growth with green chemistry.¹¹

Reference

Cefic Chemdata International. 2016. The European Chemical Industry Facts and Figures.

Korea Environment Institute. 2011. "A Review on the Draft Proposal for the Act on the Registration and Evaluation, etc. of Chemical Substances."

Ministry of Environment. 2014. Press Release (December 24, 2014) "Introduction of Advanced Chemicals Management System."

Ministry of Environment. 2015a. "Preventive Management of Chemicals for Safety – Checking Safety Information of Chemicals before Market Distribution."

Ministry of Environment. 2015b. "The First Basic Plan for Evaluation, etc. of Chemicals ('16~'20)."

Ministry of Environment. 2015c. "Chemical Management System."

Ministry of Environment. 2015d. "ECOREA 2015."

Ministry of Environment. 2015e. "Safety Management System for Household Chemical Product."

Ministry of Environment. 2015f. "Report and Registration of Chemical Substances."

¹⁰ Korea Environment Institute(2014)

¹¹ Korea Environment Institute(2014)



Ministry of Environment

Government Complex Sejong, 11, Doum6-Ro, Sejong-City,
30103, Republic of Korea
Tel. +82-44-201-6568



Korea Environment Institute

8F~11F, Bldg B, 370 Sicheong-daero, Sejong, 30147, Republic of Korea
Tel. +82-44-415-7777

