Current Status on AECs

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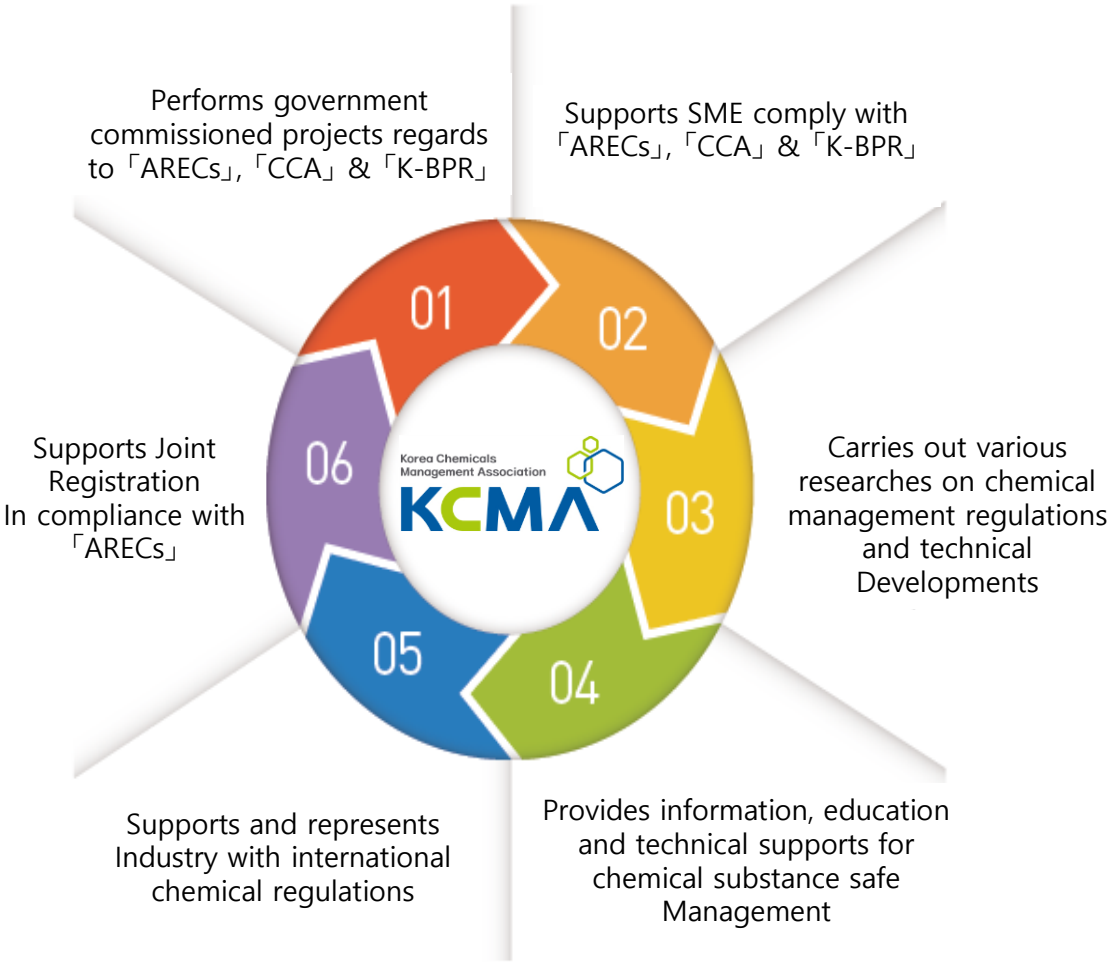
Korea Chemicals Management Association
KCMA

About KCMA

1. Established according to CCA Article 53 in 1991
2. Composed of over 1,200 member companies
3. 100 expert employees majored in chemistry, chemical engineering, environment engineering
4. Carry out six main projects covering twenty government commissioned projects



ARECs, CCA, K-BPR Related Organizations

MoE
(Ministry of Environment)

Establishment of chemicals substances regulation such as registration, evaluation and safe management

Regional Environmental Office

Report of manufacture and etc, product declaration, classification of hazardous chemical business and management

NIER
(National Institute of Environmental Research)

Chemical substances registration, evaluation, hazard evaluation and risk assessment

NICS
(National Institute of Chemical Safety)

Chemical accident prevention, countermeasures, handling facility safety management

KECO
(Korea Environment Corporation)

Hazardous chemical handling facility inspection and safety diagnosis

KEITI
(Korea Environmental Industry & Technology Institute)

Chemical product safety standard and labelling standard management and management of chemical products distribution

KCMA
(Korea Chemicals Management Association)

Verification statement, hazardous substances safety education, support to industry complying with regulation

CONTENTS

Korea Chemicals Management Association

Chapter 01

AREChs Introduction

Purpose and History

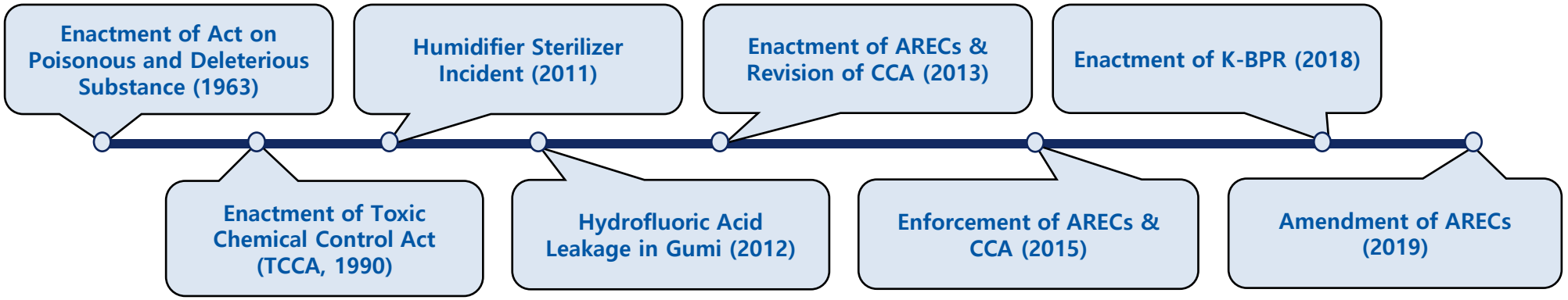
Purpose

Act on Registration, Evaluation, etc. of Chemicals (AERECs)

The purpose of this Act is to protect public health and the environment by providing for matters regarding

- Registration and notification of chemical substances
- Review and assessment of hazards and risks of chemical substances
- Designation of hazardous chemical substances

History



Chapters

Scope of Registration

Until Dec 31st, 2018

Phase-in Substance → ≥ 1ton/yr → **Designation of substances subject to registration** (Designate and notify every 3 years) → **Registration**

Non-Phase-in Substance (Regardless of Volume) → **Registration**

From Jan 1st, 2019

Phase-in Substance

- ≥ 1ton/yr (Registration) → **Subject to registration by 2030 according to substances' hazard data, and volume** → **Registration**
- < 1ton/yr → Designation of substances subject to registration? → Yes → Designation of substances subject to registration → **Registration**

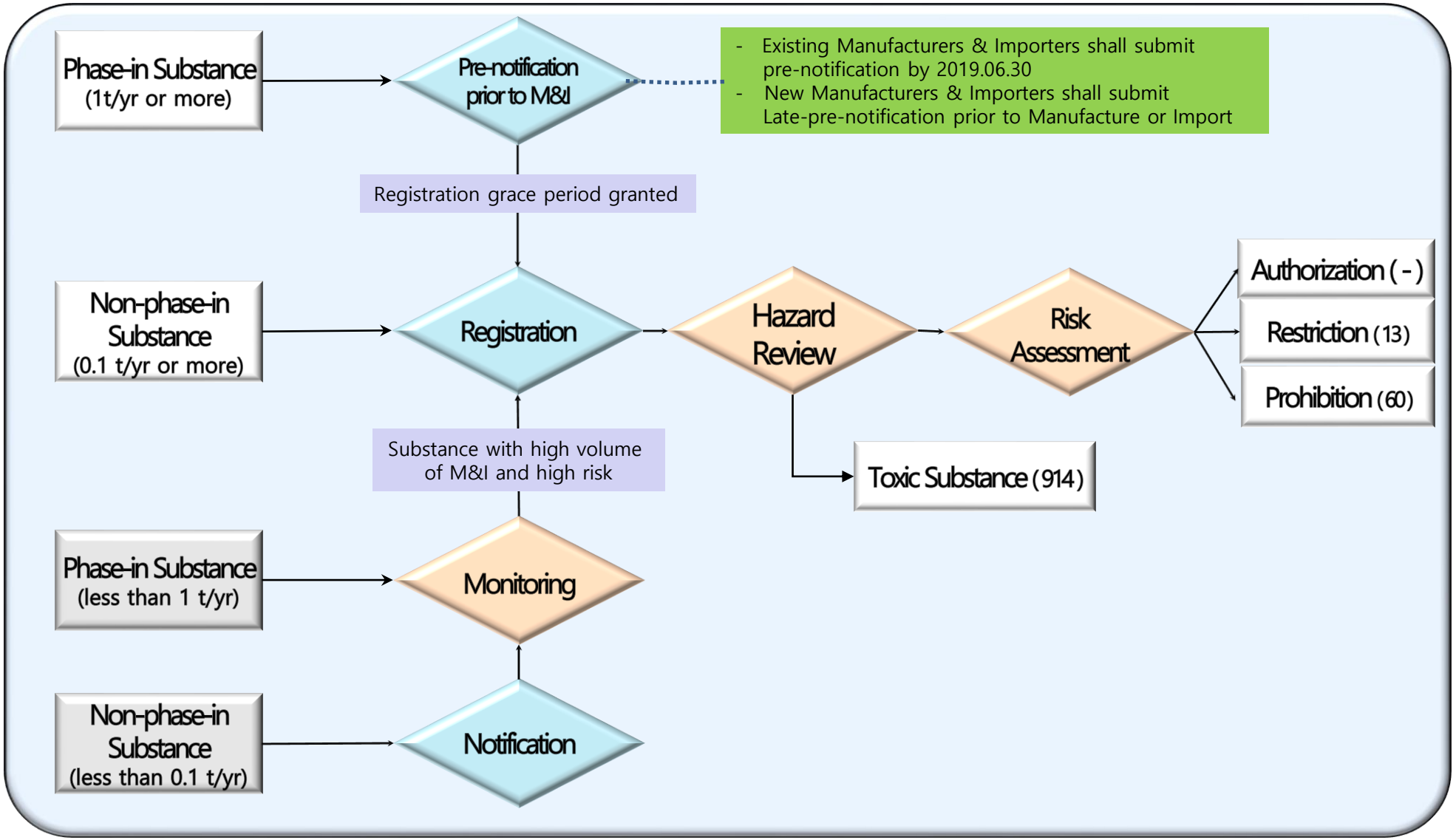
Non-Phase-in Substance

- < 0.1ton/yr → **Subject to Notification of Hazard, and Classification & Labeling** → **Hazardous & Exceed National Limit of Total Annual Volume**
  - **· Phase-in : 10 ton**
  - **· Non-phase-in : 1 ton**
  - No → Data generation by government / Monitoring
- ≥ 0.1ton/yr (Registration) → **Registration**

Registration: Companies generate and submit hazard data by themselves

○ Phase-in Substance (Total 44,478 kinds, May 2019)
- Annex 1 (Distributed chemical substances before Feb 1991) : 37,091 kinds
- Annex 2 (Hazard review thereof have been conducted after Feb 1991) : 7,387 kinds

Process of Evaluation



Chapter 02

Main Points of ARECs amendment

Registration of Phase-in Substance

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Registration

○ Any person who manufactures or imports 1 ton or more of phase-in substance per year

○ Until 2030, registration grace period differs according to substances' hazard and M•I volume

Registration grace period

'21.12.31

- 1 t/yr or more of CMR Substance per year (364 kinds),
- 1,000 t/yr or more of phase-in substance per year

'24.12.31

- 100 t/yr or more of phase-in substance per year

'27.12.31

- 10 t/yr or more of phase-in substance per year

'30.12.31

- 1 t/yr or more of phase-in substance per year

➢ (Joint Registration) Any person who intends to register shall individually apply for registration, but the data for registration shall be submitted jointly by forming a consortium

Pre-Notification

○ Registration grace period is only granted when the substance is pre-notified prior to manufacture · import

- Company name, and contact information
- Substance name
- Annual volume of manufacture · import
- Classification and labeling of substance
- Use of substance

Registration of Phase-in Substance

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Required Information for registration dossier

	Data submitted	Registration requirement	Details
1	Information on Manufacturer/Importer	○ Non-phase-in substance (0.1 t/yr or more for each company) ○ Phase-in substance (1 t/yr or more for each company)	· Name, Location, Representative
2	Information on chemical substance		· Identification of chemical (ex. Name, Molecular formula etc.)
3	Use of Chemical		· Use classification, system confirmed use, uses not to be used
4	Classification and labeling of chemical		· Global classification and labeling standards (e.g. GHS)
5	Physical and chemical properties		· Differentiation by tonnage band (up to 47 items) · Submission of abstract of test data (English and Korean) * submit full text if owned (can submit it in English or Korean)
6	Hazards		
7	Guidance on safe use		· Personal protective equipment, first-aid measures, etc. in case of explosion, fire or leakage
8	Risks	○ Substance(10 t/yr or more) ○ Substance that needs risk assessment as a result of hazard review	· Exposure scenario describing handling, exposure controls, and management measures during the life-cycle of the chemical

Registration of Phase-in Substance

Simplification of registration dossier for phase-in substance

Data to be submitted with registration dossier

- **Substance classified as low hazard : submit up to 33 test data according to the tonnage band**
- **Substance not classified or labeled : submit 15 test data, risk assessment can be excluded**

※ Excluding a person who intends to manufacture or import substance for consumer uses

Hazard Classification and Labelling example (acute toxicity)	Test data to be submitted with registration dossier	
	Before Revision	After Revision
High (Acute Toxicity classification 1~3) 	o **Up to 47 test data** - physicochemical 13 - human health 15 - environment 19	**Same as before**
Low (Acute Toxicity classification 4) 		o **Up to 33** (Physicochemical 13, human health 15, environment 5)
Not classified or labeled		o **15 in total**

Standard for confirming registration data simplification

- **Classification and labelling information for pre-notification or notification of change**
- **Test data**

Registration of Phase-in Substance

Simplification of test data according to the hazard classification

Classification (Appendix 7 of the Rules)		Registration by tonnage range as before	Simplification target	
Hazard Labeling		**Symbol (A)**	**Exclamation mark (B)**	**No labelling (C)**
Data to be submitted		If any of the following hazard are classified -**Submit up to 47 data**	If there are no labeling of any hazards in (A) and any of the hazards are classified as below - **Submit up to 33 data**	**If there are no hazard classifications of (A) and (B)** - **Submit only 15 data**
1	Acute toxicity	1, 2, 3	4	-
2	Skin Corrosion/Irritation	Corrosion 1	Irritation 2	-
3	Serious eye damage/ eye irritation	1	2	-
4	Respiratory or skin sensitizer	Respiratory 1	Skin 1	-
5	Germ cell mutagenicity	1, 2	-	-
6	Carcinogenicity	1, 2	-	-
7	Reproductive toxicity	1, 2	Additional Classification (No Symbol)	-
8	STOT-SE	1, 2	3	-
9	STOT-RE	1, 2	-	-
10	Aspiration Hazard	1, 2	-	-
A-1	Acute aquatic toxicity	1	-	-
A-2	Chronic aquatic toxicity	1, 2	-	3, 4
B	Hazardous to Ozone Layer	-	1	-

Registration of Phase-in Substance

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Physicochemical properties and toxicological test data (High hazards)

Test	1~10 ton/yr (A=15)	10~100 ton/yr (Includes A, B=26)	100~1,000 ton/yr (Includes B, C=37)	1,000 ton or more (Includes C, D=47)
Physico-chemical (13)	1)State of the substance 2)Water solubility 3)Melting point 4)Boiling point 5)Vapor pressure 6)Octanol/water partition coefficient 7)Density 8)Granulometry	1)Flash point 2)Explosive properties 3)Oxidizing properties	1)Viscosity 2)Dissociation constants in water	-
Toxico-logical (15)	1) Acute Toxicity: Oral (Acute Toxicity: Inhalation) 2)Bacterial Reverse Mutation Test 3)Skin irritation/corrosion 4)Skin sensitization	1) Acute Toxicity: Dermal (Acute Toxicity: Inhalation) 2)Eye irritation/corrosion 3)Chromosomal Aberration 4)Genotoxicity 5)28d repeated dose toxicity 6)Reproductive/developmental toxicity screening	1)Additional genotoxicity (Germ cell genotoxicity etc.)	1) 90d repeated dose toxicity 2) Teratogenicity 3) 2nd generation reproductive toxicity 4) Carcinogenicity
Eco-toxico-logical (19)	1) Fish acute toxicity 2) Ready biodegradability 3) Daphnia Magna acute immobilization	1)Freshwater alga, growth inhibition 2)Hydrolysis as a function of pH	1)Inherent Biodegradability 2)Identification of degradation products 3)Fish, chronic toxicity 4)Daphnia Magna chronic toxicity 5)Terrestrial invertebrates acute toxicity 7)Respiration Inhibition Activated sludge 8)Absorption/desorption	1)Environmental fate and behavior studies 2)Terrestrial plants chronic toxicity 3)Terrestrial invertebrates chronic toxicity 4)Further studies on absorption/desorption 5) Sediment organisms chronic toxicity 6) Bioaccumulation

Registration of Phase-in Substance

Physicochemical properties and toxicological test data (Low hazards)

Test	1~10 ton/yr (A=15)	10~100 ton/yr (Includes A, B=26)	100~1,000 ton/yr (Includes B, C=~~37~~→29)	1,000 ton or more (Includes C, D=~~47~~→33)
Physico-chemical (13)	1)State of the substance 2)Water solubility 3)Melting point 4)Boiling point 5)Vapor pressure 6)Octanol/water partition coefficient 7)Density 8)Granulometry	1)Flash point 2)Explosive properties 3)Oxidizing properties	1)Viscosity 2)Dissociation constants in water	-
Toxico-logical (15)	1) Acute Toxicity: Oral (Acute Toxicity: Inhalation) 2)Bacterial Reverse Mutation Test 3)Skin irritation/corrosion 4)Skin sensitization	1) Acute Toxicity: Dermal (Acute Toxicity: Inhalation) 2)Eye irritation/corrosion 3)Chromosomal Aberration 4)Genotoxicity 5)28d repeated dose toxicity 6)Reproductive/developmental toxicity screening	1)Additional genotoxicity (Germ cell genotoxicity etc.)	1) 90d repeated dose toxicity 2) Teratogenicity 3) 2nd generation reproductive toxicity 4) Carcinogenicity
Eco-toxico-logical (19)	1) Fish acute toxicity 2) Ready biodegradability 3) Daphnia Magna acute immobilization	1)Freshwater alga, growth inhibition 2)Hydrolysis as a function of pH	1)Inherent Biodegradability 2)Identification of degradation products 3)Fish, chronic toxicity 4)Daphnia Magna chronic toxicity 5)Terrestrial invertebrates acute toxicity 7)Respiration Inhibition Activated sludge 8)Absorption/desorption	1)Environmental fate and behavior studies 2)Terrestrial plants chronic toxicity 3)Terrestrial invertebrates chronic toxicity 4)Further studies on absorption/desorption 5) Sediment organisms chronic toxicity 6) Bioaccumulation

Registration of Phase-in Substance

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Physicochemical properties and toxicological test data (Not classified or labeled)

Test	1~10 ton/yr (A=15)	10~100 ton/yr (Includes A, B=~~26~~→15)	100~1,000 ton/yr (Includes B, C=~~37~~→15)	1,000 ton or more (Includes C, D=~~47~~→15)
Physico-chemical (13)	1)State of the substance 2)Water solubility 3)Melting point 4)Boiling point 5)Vapor pressure 6)Octanol/water partition coefficient 7)Density 8)Granulometry	1)Flash point 2)Explosive properties 3)Oxidizing properties	1)Viscosity 2)Dissociation constants in water	-
Toxico-logical (15)	1) Acute Toxicity: Oral (Acute Toxicity: Inhalation) 2)Bacterial Reverse Mutation Test 3)Skin irritation/corrosion 4)Skin sensitization	1) Acute Toxicity: Dermal (Acute Toxicity: Inhalation) 2)Eye irritation/corrosion 3)Chromosomal Aberration 4)Genotoxicity 5)28d repeated dose toxicity 6)Reproductive/developmental toxicity screening	1)Additional genotoxicity (Germ cell genotoxicity etc.)	1) 90d repeated dose toxicity 2) Teratogenicity 3) 2nd generation reproductive toxicity 4) Carcinogenicity
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Registration or Notification of Non-phase-in Substance

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Registration

○ **Any person who manufacture • import 0.1 ton or more of non-phase-in substance per year**

Registration prior to M/I

Physicochemical properties and toxicological test data required for registration (Non-phase-in substance)

Test	0.1~1 ton/yr (9)	Over 1 ton/yr (15 ~ 47)
Physicochemical properties	1) State of the substance 2) Water solubility 3) Melting point 4) Boiling point 5) Vapor pressure	- Data requirements are the same as those of phase-in substance - Simplified registration is not applicable for non-phase in substance
Toxicological	1) Acute Toxicity: Oral (Acute Toxicity: Inhalation) 2) Bacterial Reverse Mutation Test	
Eco-toxicological	1) Fish acute toxicity 2) Ready biodegradability	

Notification

○ **Any person who manufacture • import less than 0.1 ton of non-phase-in substance per year**

*** Annual M/I volume, classification and labelling, uses (including Data protection request, Verification of exemption on hazard review and etc. if applicable)**

Notification prior to M/I

Exemption from Registration · Notification

Exemption from registration or notification without additional procedure

1. A chemical substance imported as a substance embedded into a machine
2. A chemical substance imported along with a machine or device used for a test run
3. A chemical substance that is contained in a product that fulfills a certain function in a solid state with specific shape without discharging any chemical substance in its use
4. A chemical substance with very low risk designated and publicly notified by Ministry of Environment (MoE Notification – Annex 1, 2)

* Impurities, by-products, substances existing in nature as themselves, amino acids and its salts, charcoal, activated carbon (only applies to water treatment agents) and etc.

Exempted by confirmation of exemption from registration or notification

1. A chemical substance manufactured or imported to export the whole amount thereof
2. A chemical substance for scientific experiment, analysis or research, such as reagents
3. Non-isolated intermediates, and isolated intermediates whose outflow or leakage is blocked by technical means
4. A chemical substance which surface has been treated, some polymeric compounds and etc.

Hazard Review of Chemical Substance

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Scope

MoE(NIER) conducts hazard review of all of registered chemical substances and informs registrant of the results thereof

- Non-phase-in Substance : Within 6 month of decision notice of registration(registration of change)
- Phase-in Substance : Within 1 year of decision notice of registration(registration of change)

Data Requirement

Physicochemical properties and hazard data

- Where necessary for hazard review, MoE may order a registrant to submit data necessary for hazard review

Evaluation Decision

1. Appropriateness and trustworthiness of data submitted with registration dossier
2. Appropriateness and trustworthiness of data additionally submitted
3. Whether a substance is to be designated as a toxic chemicals (Currently 914 chemicals are designated)
4. Classification and labelling (physical, health, and environmental hazard)

Risk Assessment of Chemical Substance

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Scope

MoE(NIER) conducts a risk assessment on any of the following chemical substances based on the results of hazard review and informs a registrant of the results thereof

- A chemical substance that are manufactured or imported at least ten tons per year
- A chemical substance that risk assessment is deemed necessary based on the results of hazard review thereof

Data Requirement

Human health & environmental hazard, PBT assessment, exposure assessment, and safety verification data

- Where necessary for risk assessment, MoE may order a registrant to submit data necessary for risk assessment

Evaluation Decision

1. Appropriateness and trustworthiness of submitted data
2. Restriction (prohibit M/I for specific uses, currently 13 chemicals are designated)
3. Prohibition (prohibit M/I for all uses, currently 60 chemicals are designated)
4. Authorization (Substance subject to authorization prior to M/I, no substance is designated yet)

Notification of Substance Subject to Intensive Control Contained in Product

Any person who produces or imports any product containing substances subject to intensive control shall notify name, content, hazard data and etc. of substance to the MoE prior to production and import of such product

- The substance content of each individual product exceeds 0.1% w/w

AND

- The total quantity of each substance in whole products exceeds 1t/yr

▶ Substance subject to intensive control

(672 substances designated, 204 effective from Jul 2019, 468 effective from Jul 2021)

1. A substance that causes or is likely to cause cancer, mutation, reproductive disorders or endocrine system disorders of humans or animals
2. A substance that is highly likely to accumulate in body of human, animal or plant and remains in the environment for an extended period of time
3. A substance that may cause damage to the internal organs such as lungs, liver, and kidneys when there is repetitive or long exposure

Information Provision of Chemical Substance

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▶ Information provision within the supply chain

1. Downstream users shall provide necessary information on uses, exposure and volume for manufacturers or importers to carry out the registration or notification

2. Any transferor of chemical substances shall provide information on registered or notified substance to the transferee (including hazardous chemical substances that are not registered during the grace period)

▶ Protection of CBI (Confidential Business information) - Effective from Jan 1st, 2020

Currently, the information of chemical may be kept confidential to transferee, unless it is hazardous chemical substance.

1. Chemical substance not classified as health and environmental hazard may be kept confidential to transferee

2. Chemical substance classified as health and environmental hazard may be kept confidential if the confidentiality request is accepted by the Minster of Environment

3. Hazardous chemical substance and CMR substance that are contained the amount of content standard or more which are classified to have physical risk, health hazard or environmental hazard shall be transferred with information provision

Disclosure of Chemical Information

▶ Information disclosure to public

The Ministry of environment discloses chemical information on the website publicly to let people easily identify and utilize the information on hazard and risk of chemical

- Classification and labeling of chemical substance
- List of toxic substances, substance subject to authorization, restriction and prohibition
- Physicochemical properties, hazards, risks, and etc.

Appointed OR by overseas Manufacturer and producer

▶ Overseas Manufacturers and Producers for ARECs compliance

Overseas manufacturers and producers can appoint an OR who satisfy the requirement under ministerial decree to implement the tasks below

1. Registration, notification of phase-in & non-phase-in substance, and report on change
2. Application for exemption on registration
3. Registration and notification on change
4. Individual submission of registration dossier
5. Inquiry of registration status of a substance
6. Confirmation of permission on using vertebrate animal test data
7. Information provision
8. Notification of substance subject to intensive control
9. Request and cancellation on protection of confidentiality

Penalty and Administrative Fines

A manufacturer or importer who commits a violation below can be fined for the amount of 5% or less than sales

- **Any manufacturer or importer who falsely registered or failed to register a chemical substance**
- **Any manufacturer or importer who falsely registered or failed to register such change of a chemical substance**

▶ Calculation of penalty

Penalty = Period of violation X Daily fine

- **Period of violation : Period of time from initial M·I of a substance to detection of violation**
- **Daily fine amount : Annual sales of a violator X (1/360) X 5%**
- **Annual sales : Average sales of three previous years of a violation**

* Penalty can vary depending on the period, number of occurrences and etc. of violation

Penalty Provision

▶ Imprisonment for not more than 5 years or a fine of not exceeding a hundred million won

Any person who

- manufactures or imports a non-phase-in substance or phase-in substance without registration or after false registration
- manufactures or imports a non-phase-in substance without notification or after making a false notification
- fails to register a change in a chemical substance or falsely registers such change
- produces or imports a product containing a substance subject to intensive control without notifying the substance subject to intensive control contained in the product or after falsely notifying such substance

▶ Imprisonment for not more than 3 years or a fine of not exceeding fifty million won

Any person who

- manufactures or imports a non-phase-in substance or phase-in substance without obtaining confirmation of exemption from registration, etc. or after obtaining false confirmation of exemption from registration
- fails to submit data or submits false data, in violation of an order to submit data

▶ Imprisonment for not more than 1 years or a fine of not exceeding thirty million won

- Any person who fails to provide information on a chemical substance or provides false information

Resources (ARECs and Chemical Information)

Korea Chemicals Management Association KCMA

▶ Act on Registration, Evaluation and etc. of Chemicals (English version)

- https://tinyurl.com/ARECs2019

▶ Korean Chemical Inventory, NCIS (National Chemicals Information System)

- http://ncis.nier.go.kr/en/main.do

▶ Guidance of ARECs (English)

- http://www.kcma.or.kr/eng/sub3/3_2.asp

Thank you

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Korea Chemicals Management Association
한국화학물질관리협회

[Attached Table] Substances Exempted from Registration or Notification

Korea Chemicals Management Association KCMA

[Annex 1] Substances existing in nature as themselves and etc. (8 Categories)

1. Impurities (substances that are created or present in other chemicals by chance or unintentionally, and are not imported or placed on the market by themselves)
2. By-products (substances that are unintentionally co-produced in manufacturing process of intended chemical substances, and are not imported or placed on the market by themselves)
3. If the chemical structure of natural substance is not altered
   A. Minerals, Ores, Ore concentrates, Natural-gas, Crude Oil, Coal
   B. Glass, Ceramic frits
   C. Liquefied Petroleum Gas, Natural-gas condensate
   D. Process Gas and their constituents
   E. Cork, Cement clinker, Magnesium Oxide
   F. Natural substances obtained by using man power/machine/gravity, by dissolving in water, by floatation, or by getting rid of moisture with heat other than the substances from 3-I to 3-V
4. If the chemical structure of natural resources is not altered
   A. Vegetable fat, Vegetable oil, Vegetable Wax
   B. Animal fat, Animal oil, Animal Wax
   C. Fatty acids from C6 to C24 and its salts of potassium, sodium, calcium and magnesium
   D. Glycerol
5. Amino acids and their salts, Sugars
6. Nucleobases that constitute DNA or RNA, Nucleosides that is from bases and sugar Necleotides that is from bases, sugar, and phosphate bonds
7. Compost and biofuels (bioethanol, biodiesel, biogas, etc.)
8. Hydrogen and oxygen

* Note: The hydrate form of chemical substances listed in Annex I is also included in the substance exempted from registration/notification

[Attached Table] Substances Exempted from Registration or Notification

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[Annex 2] Glucose • starch and etc. (44)

No	CAS No	Substance Name
1	50-70-4	D-glucitol
2	50-81-7	Ascorbic acid
3	50-99-7	Glucose
4	57-48-7	Fructose
5	56-87-1	L-lysine
6	57-50-1	Sucrose
7	58-95-7	α-tocopheryl acetate
8	59-23-4	Galactose
9	59-51-8	DL-methionine
10	63-42-3	Lactose
11	69-65-8	D-mannitol
12	87-79-6	L-sorbose
13	123-94-4	Glycerol stearate, pure
14	124-38-9	Carbon dioxide
15	137-08-6	Calcium pantothenate, D-form
16	150-30-1	DL-phenylalanine
17	527-07-1	Sodium gluconate
18	1338-43-8	Sorbitan oleate
19	7439-90-9	Krypton
20	7440-01-9	Neon
21	7440-37-1	Argon
22	7440-59-7	Helium
23	7440-63-3	Xenon
24	7727-37-9	Nitrogen
25	7732-18-5	Water

No	CAS No	Substance Name	
26	8002-43-5	Lecithins	
27	8029-43-4	Syrups, hydrolyzed starch	
28	8030-12-4	Tallow, hydrogenated	
29	9004-53-9	Dextrin	
30	9005-25-8	Starch	
31	9050-36-6	Maltodextrin	
32	14906-97-9	Sodium D-gluconate	
33	26836-47-5	D-glucitol monostearate	
34	61788-59-8	Fatty acids, coco, Me esters	
35	65996-61-4	Cellulose pulp	
36	67701-30-8	Glycerides, C16-18 and C18-unsaturated	
37	68131-37-3	Syrups, corn, dehydrated	
38	68308-54-3	Glycerides, tallow mono-, di- and tri-, hydrogenated	
39	68424-61-3	Glycerides, C16-18 and C18 -unsaturated, mono- and di-	
40	85665-33-4	Glycerides, C10-18	Note 1: The hydrate form of chemical substances listed in Annex II is also included in the substance exempted from registration/notification Note 2 : (#43, #44) Limiting to water treatment reagent according to 「Management of Drinking Water Act」article 3 clause 5)
41	16291-96-6	Charcoal	
42	68647-86-9	Charcoal, coconut shell	
43	64365-11-3	Activated charcoal	
44	7440-44-0	Carbon; Activated carbon	