

Current Status on ARECs

Korea Chemicals
Management Association



KCMA

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Korea Chemicals Management Association

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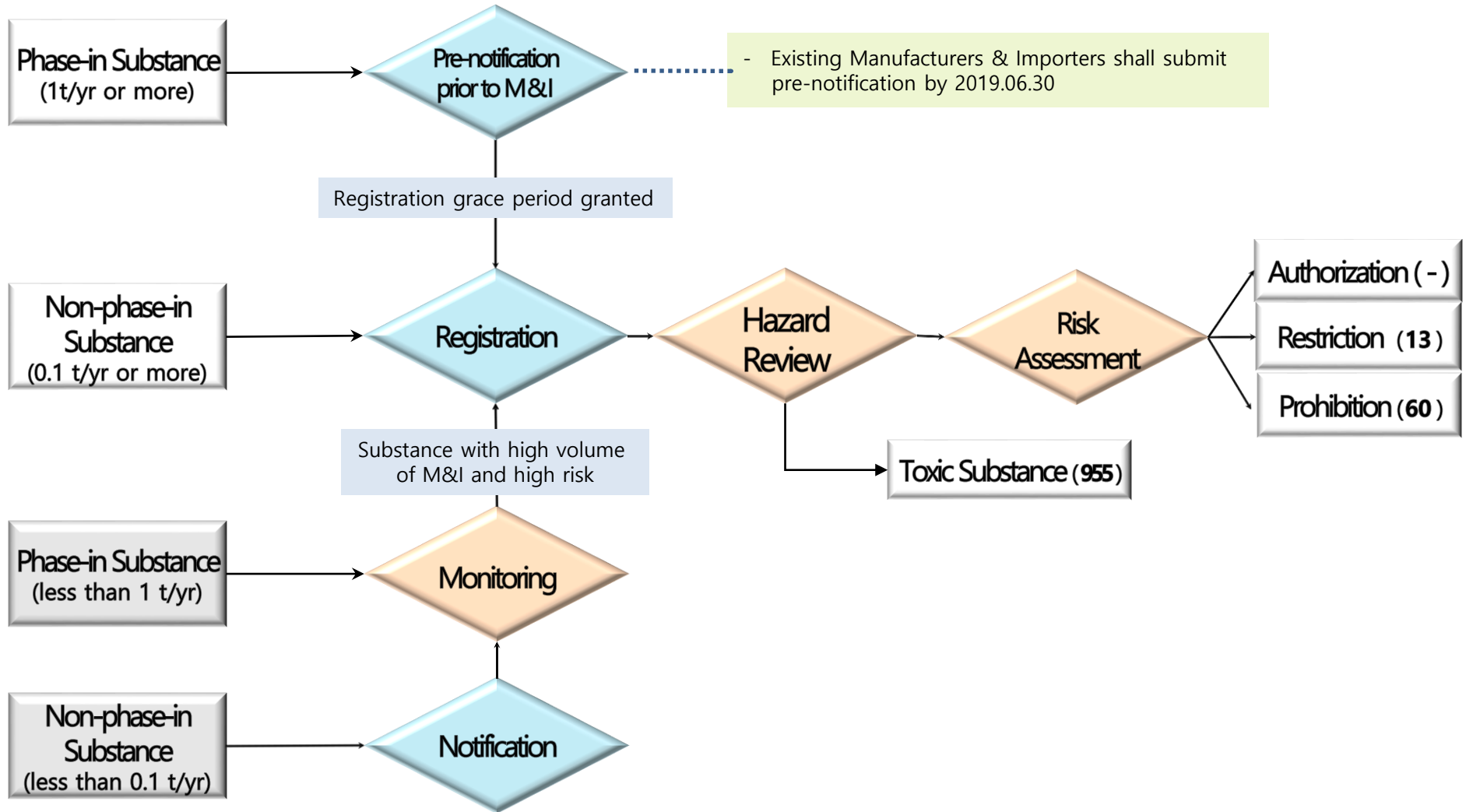
Chapter 01

Korea Chemicals Management Association

› Registration and Notification of Chemical Substance



Process of Evaluation



Pre-Notification

- Registration grace period is granted only 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

▶ Pre-notification Results

- A total of 16,743 substances
- Notification results according to tonnage band

Tonnage Band	Number of pre-notified substances
1,000 ton or more	1,906
100 ton or more ~ less than 1,000 ton	2,616
10 ton or more ~ less than 100 ton	5,492
1 ton or more ~ less than 10 ton	6,729

- Pre-notified CMR substances : 79 substances (Must be registered by 2021 regardless of tonnage band)

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

Required Information for registration dossier



	Data submitted	Registration requirement	Details
1	Information on Manufacturer/Importer	<input type="radio"/> Non-phase-in substance (0.1 t/yr or more for each company) <input type="radio"/> Phase-in substance (1 t/yr or more for each company)	<ul style="list-style-type: none"> Name, Location, Representative
2	Information on chemical substance		<ul style="list-style-type: none"> Identification of chemical (ex. Name, Molecular formula etc.)
3	Use of Chemical		<ul style="list-style-type: none"> Use classification, system confirmed use, uses not to be used
4	Classification and labeling of chemical		<ul style="list-style-type: none"> Global classification and labeling standards (e.g. GHS)
5	Physical and chemical properties		<ul style="list-style-type: none"> Differentiation by tonnage band (up to 47 items) Submission of abstract of test data (English and Korean)
6	Hazards		<ul style="list-style-type: none"> * submit full text if owned (can submit it in English or Korean)
7	Guidance on safe use		<ul style="list-style-type: none"> Personal protective equipment, first-aid measures, etc. in case of explosion, fire or leakage
8	Risks	<input type="radio"/> Substance(10 t/yr or more) <input type="radio"/> Substance that needs risk assessment as a result of hazard review	<ul style="list-style-type: none"> Exposure scenario describing handling, exposure controls, and management measures during the life-cycle of the chemical

Simplification of registration dossier for phase-in substance

▶ Data Requirement

- Substance classified as low hazard : Up to 33 test data (according to the tonnage band)
- Substance not classified and labeled : 15 test data, risk assessment can also be omitted

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

Hazard Classification and Labelling (example: acute toxicity)	Data Requirement	
	Before Revision	After Revision
High (Acute Toxicity classification 1~3) 	<ul style="list-style-type: none"> ○ Up to 47 test data - physicochemical 13 - human health 15 - environment 19 	Same as before
Low (Acute Toxicity classification 4) 		<ul style="list-style-type: none"> ○ Up to 33 test data (Physicochemical 13, human health 15, environment 5)
Not classified and labeled		<ul style="list-style-type: none"> ○ 15 test data

▶ Standards of confirming an entity subject of registration simplification

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

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)	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 1) Flash point 2) Explosive properties 3) Oxidizing properties 	<ol style="list-style-type: none"> 1) Viscosity 2) Dissociation constants in water 	-
Toxicological (15)	<ol style="list-style-type: none"> 1) Acute Toxicity: Oral (Acute Toxicity: Inhalation) 2) Bacterial Reverse Mutation Test 3) Skin irritation/corrosion 4) Skin sensitization 	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 1) Additional genotoxicity (Germ cell genotoxicity etc.) 	<ol style="list-style-type: none"> 1) 90d repeated dose toxicity 2) Teratogenicity 3) 2nd generation reproductive toxicity 4) Carcinogenicity
Eco-toxicological (19)	<ol style="list-style-type: none"> 1) Fish acute toxicity 2) Ready biodegradability 3) Daphnia Magna acute immobilization 	<ol style="list-style-type: none"> 1) Freshwater alga, growth inhibition 2) Hydrolysis as a function of pH 	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 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

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)	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 1) Flash point 2) Explosive properties 3) Oxidizing properties 	<ol style="list-style-type: none"> 1) Viscosity 2) Dissociation constants in water 	-
Toxicological (15)	<ol style="list-style-type: none"> 1) Acute Toxicity: Oral (Acute Toxicity: Inhalation) 2) Bacterial Reverse Mutation Test 3) Skin irritation/corrosion 4) Skin sensitization 	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 1) Additional genotoxicity (Germ cell genotoxicity etc.) 	<ol style="list-style-type: none"> 1) 90d repeated dose toxicity 2) Teratogenicity 3) 2nd generation reproductive toxicity 4) Carcinogenicity
Eco-toxicological (19)	<ol style="list-style-type: none"> 1) Fish acute toxicity 2) Ready biodegradability 3) Daphnia Magna acute immobilization 	<ol style="list-style-type: none"> 1) Freshwater alga, growth inhibition 2) Hydrolysis as a function of pH 	<ol style="list-style-type: none"> 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 	<ol style="list-style-type: none"> 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

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

Test	1~10 ton/yr (A=15)	10~100 ton/yr (Includes A, B=37 → 15)	100~1,000 ton/yr (Includes B, , C=37 → 15)	1,000 ton or more (Includes C, , D=47 → 15)
Physico-chemical (13)	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 1) Flash point 2) Explosive properties 3) Oxidizing properties 	<ul style="list-style-type: none"> 1) Viscosity 2) Dissociation constants in water 	-
Toxicological (15)	<ul style="list-style-type: none"> 1) Acute Toxicity: Oral (Acute Toxicity: Inhalation) 2) Bacterial Reverse Mutation Test 3) Skin irritation/corrosion 4) Skin sensitization 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 1) Additional genotoxicity (Germ cell genotoxicity etc.) 	<ul style="list-style-type: none"> 1) 90d repeated dose toxicity 2) Teratogenicity 3) 2nd generation reproductive toxicity 4) Carcinogenicity
Eco-toxicological (19)	<ul style="list-style-type: none"> 1) Fish acute toxicity 2) Ready biodegradability 3) Daphnia Magna acute immobilization 	<ul style="list-style-type: none"> 1) Freshwater alga, growth inhibition 2) Hydrolysis as a function of pH 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> 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

- 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 requirement (Non-phase-in substance)

Test	0.1~1 ton/yr (9)	1 ton or more/yr (15 ~ 47)
Physicochemical properties properties	<ol style="list-style-type: none"> 1) State of the substance 2) Water solubility 3) Melting point 4) Boiling point 5) Vapor pressure 	<ul style="list-style-type: none"> - Data requirements are the same as those of those of phase-in substance - Simplified registration is not applicable for for non-phase in substance
Toxicological	<ol style="list-style-type: none"> 1) Acute Toxicity: Oral (Acute Toxicity: Inhalation) 2) Bacterial Reverse Mutation Test 	
Eco-toxicological	<ol style="list-style-type: none"> 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 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, polymeric compounds of low concern etc.

Chapter 02

Korea Chemicals Management Association

- › **Notification of Substance Subject to Intensive Control Contained in a Product**



Definition

“Substance subject to intensive control” is a substance that

- 1 Causes or is likely to cause cancer, mutation, reproductive disorders or disorders of the endocrine system in humans or animals
- 2 Is highly likely to accumulate in the bodies of humans, animals or plants and remains in the environment of an extended period of time
- 3 When exposed to humans, may cause damage to the internal organs such as lungs, liver, and kidneys
- 4 May pose a risk equivalent to or more serious than the substances above

672 designated substances

(MoE Notice 2018-233)[Annex 1–204 substances], [Annex 2–468 substances]

Notification of Substance Subject to Intensive Control Contained in a Product (ARECs article 32)

Notification

From July 1st of 2019, any person who produces or imports a product containing substances subject to intensive control and meets following criteria shall notify MoE prior to production and import of such product

▷ Content of each individual product exceeds 0.1%



Notification prior to P·I

▷ Total quantity of each substance in whole products exceeds 1t/yr

Enforcement

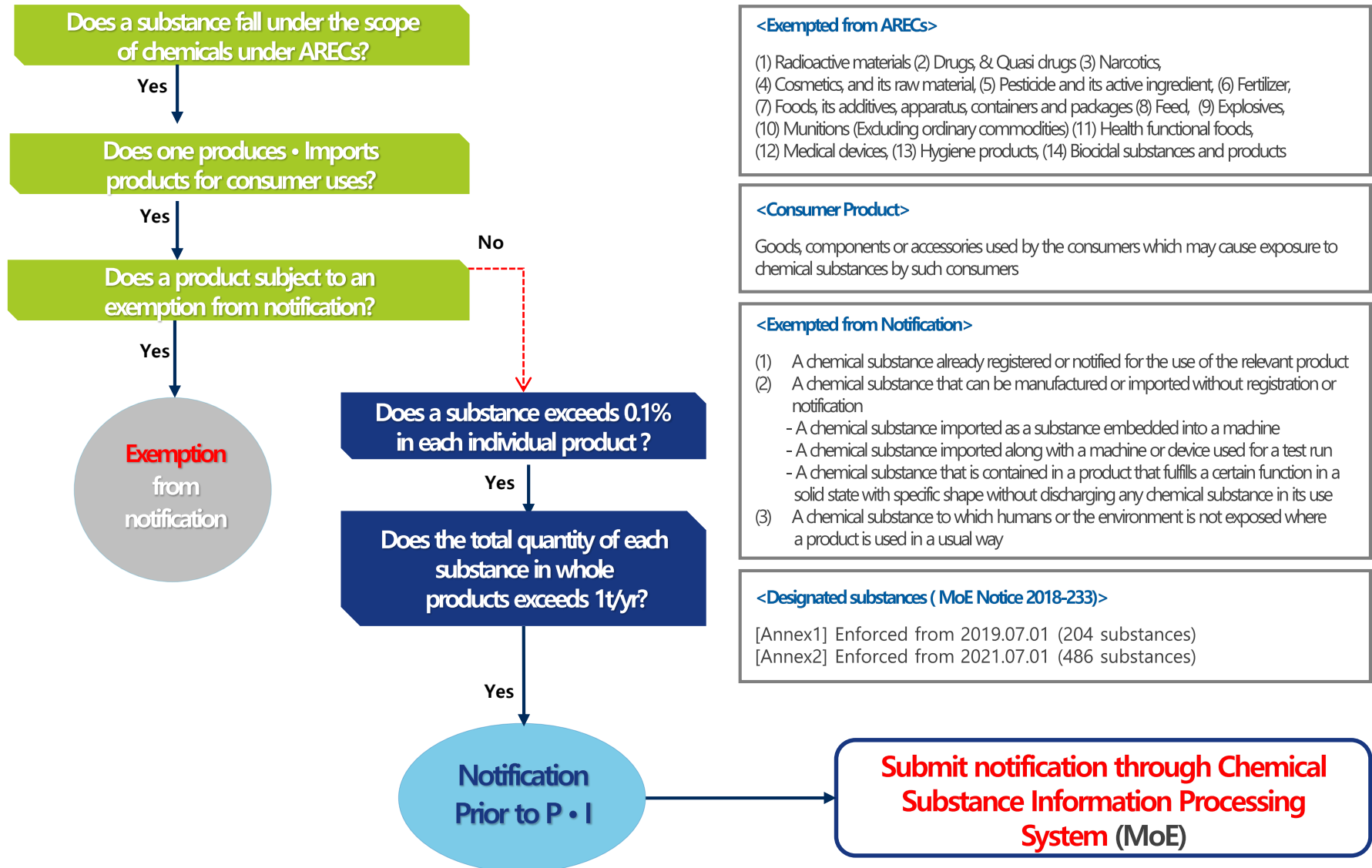
Enforced from '19.07.01

204 substances

Enforced from '21.07.01

468 substances

Notification process of substance subject to intensive control



Chapter 03

Korea Chemicals Management Association

➤ Information Provision and CBI of Chemical Substances



► Information provision within the supply chain

- 1 Any person who transfer 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)
- 2 Downstream users shall provide necessary information on uses, exposure and volume to manufacturers or importers, if the manufacturers or importers requested such information to carry out the registration or notification

► Protection of CBI (Confidential Business information) – Coming into effect on 2021 (expected)

Current act : Information of chemical may be kept confidential, except 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 Minister 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

Provision of Information on Substance Subject to Intensive Control Contained in Product (ARECs article 35)

- ▶ Any person who transfers a product containing a notified substance subject to intensive control shall prepare information and provide it to a person who acquires the product

▷ To a person who acquires the product within the supply chain

※ Such as painting or wallpaper business (professional use)



Provision before or on the transfer

▷ Wholesale-retail business and Consumer



Provision within 45 days after the request

Information contents (ARECs rule article 45)

- Name of product
- Name and content of substance subject to intensive control
- Notified uses and its restriction
- Instruction and conditions of uses
- Cautions such as storage, disposal method, and response strategy when exposed

- ▶ Protection of CBI (Confidential Business information) – Coming into effect on 2021 (expected)
Current act : Information of chemical may be kept confidential, except for 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 Minister of Environment ◀ Information provision of substance subject to intensive control contained in a product
- 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

▶ Data protection request (ARECs Rule, attached form 37)

- 1 If the data is CBI under article 2, sub-paragraph 2 of 「Unfair Competition Prevention and Trade Secret Protection Act」, one can request MoE for data protection of the identification and content information of chemical.
- 2 If the data is not applicable to 「Unfair Competition Prevention and Trade Secret Protection Act」 or already public, the data can be announced publicly despite the data protection request.

▶ Data that can be publicly announced despite the request

	Contents
Public Data	Substance/product identification that is already public on foreign website (Chemical Name, CAS No., Molecular formula, structural formula etc.)
Data not applicable to CBI	<ol style="list-style-type: none"> 1. Generic Name/ Product Name 2. Uses of substance/product 3. Information on safe use of substance/product (e.g. cautions, storage, disposal) 4. Response strategy in the case of chemical accident 5. Physicochemical property data 6. Hazard summary of chemical substance 7. Risk Summary of chemical substance 8. Information that minister of environment notify other than item 1-7 for the protection of humans health and the environment



* Maximum period of protection is 5 year, and it can be extended twice. (Maximum total : 15 years)

Thank you

Korea Chemicals
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