

An Overview of K-REACH & Chemical Regulatory Updates

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Korea

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Agenda

01 Overview of K-REACH

02 Main Provisions of K-REACH

03 Korea Regulatory Updates

04 Wrap-up / Frequent Q&A

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01

Overview of K-REACH

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K-REACH << Overview

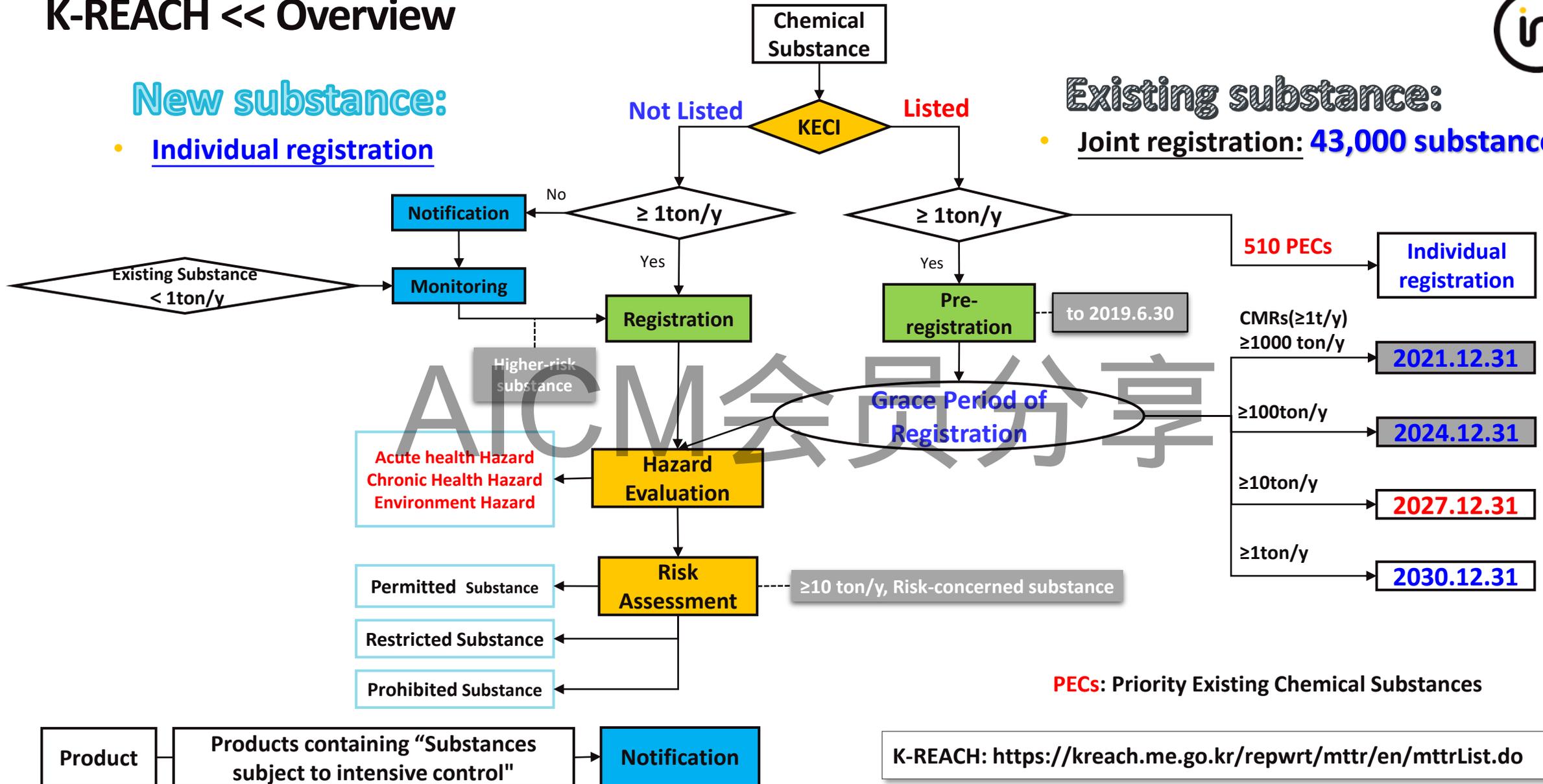


New substance:

- Individual registration

Existing substance:

- Joint registration: **43,000** substances



PECs: Priority Existing Chemical Substances

K-REACH: <https://kreach.me.go.kr/repwrt/mtr/en/mtrList.do>

02

Main Provisions of K-REACH

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Main Provisions under K-REACH



1. OR Appointment

- By overseas manufacture/production site

2. Pre-registration

- Existing substances ≥ 1 ton per year

3. Registration

- Joint Registration : Existing substances ≥ 1 ton/year
- Individual Registration : 510 PEC substances ≥ 1 ton/year

4. Exemption Confirmation from Registration

- Polymer Low Concern

5. Information Provision

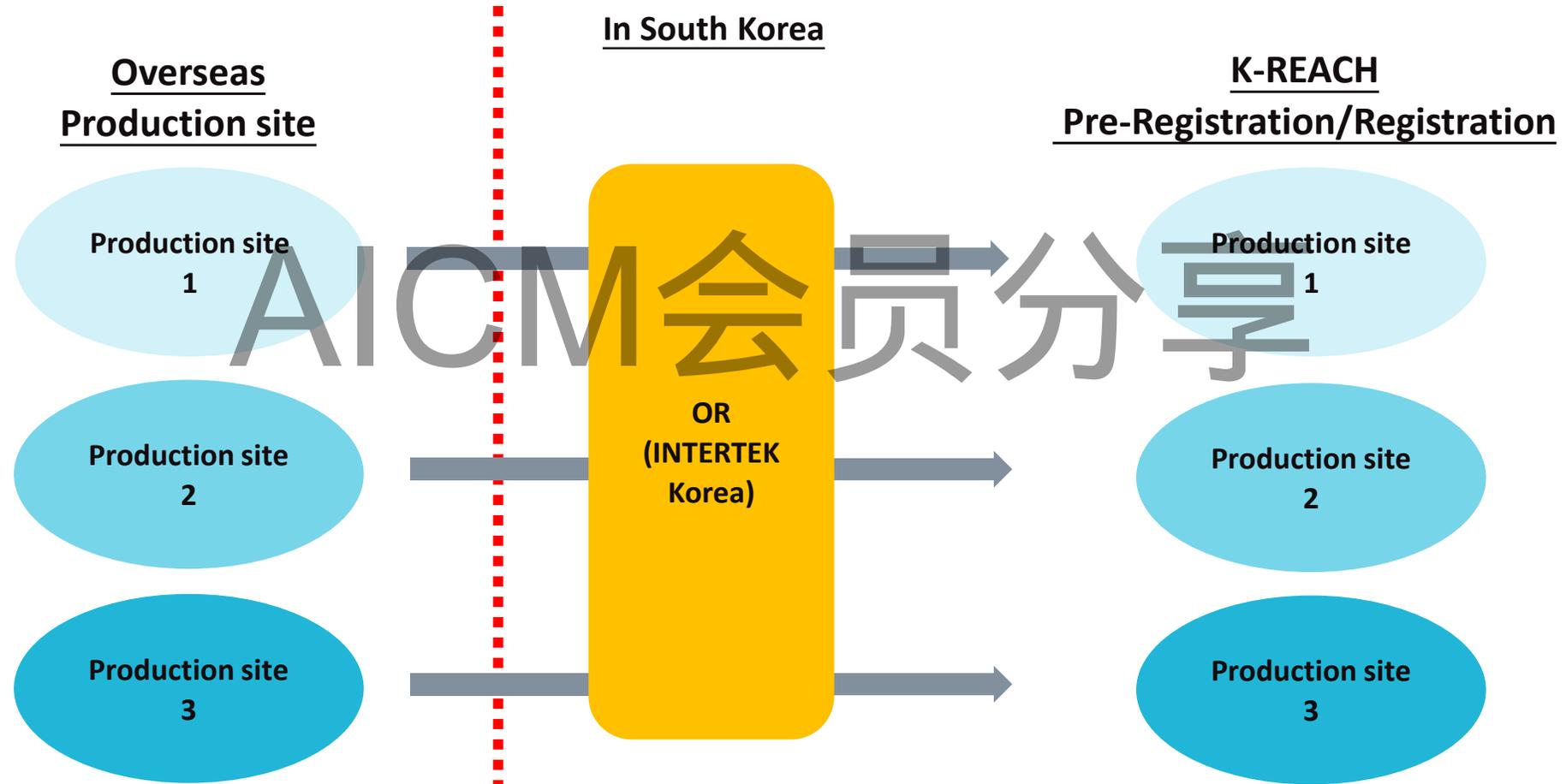
- After completing Pre-registration, Notification, Registration, PLC Exemption

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K-REACH OR Appointment

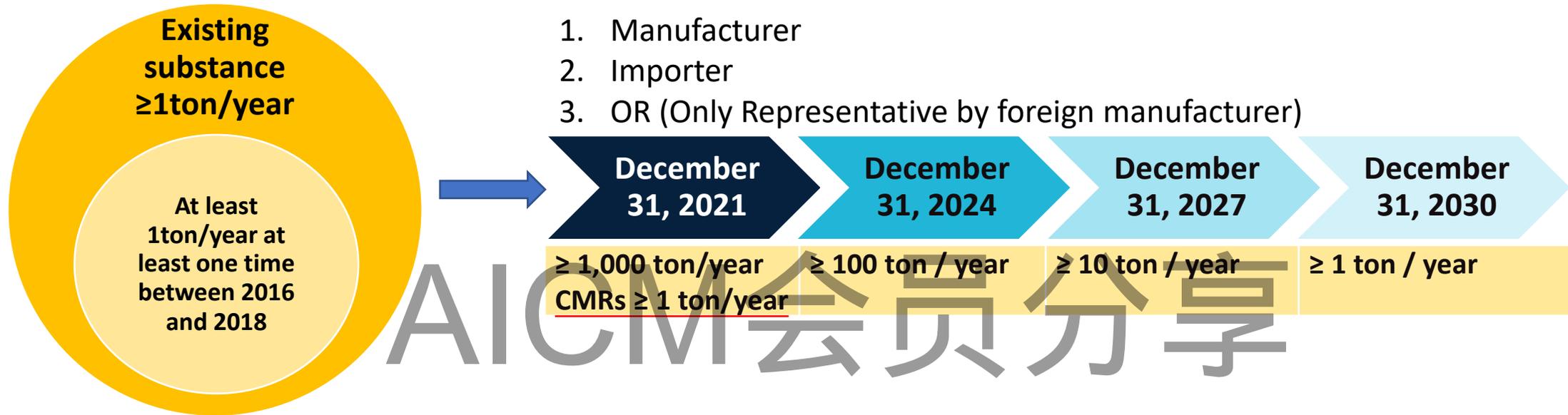
Overseas manufacturer must appoint OR by **each production site** of chemical substance





1. K-REACH Pre-Registration

: To be granted the registration grace period



- **Late pre-registration** is available at this moment
- Submit basic information (e.g. substance name, manufacturing/importing volume, substance nature(polymer), classification/labelling, use category & detailed use, consumer use, **Importers list** in case of OR)
- **BUT**, already manufacturing or importing the relevant substance(a person who has been manufacturing or importing at least one ton per year of the relevant substance at least one time since 2016)
→ Late pre-registration is not available



3. K-REACH Registration

: Joint Registration (Existing Substances)

CICO(Chemical substance Information Communicative Organization, Korean SIEF)

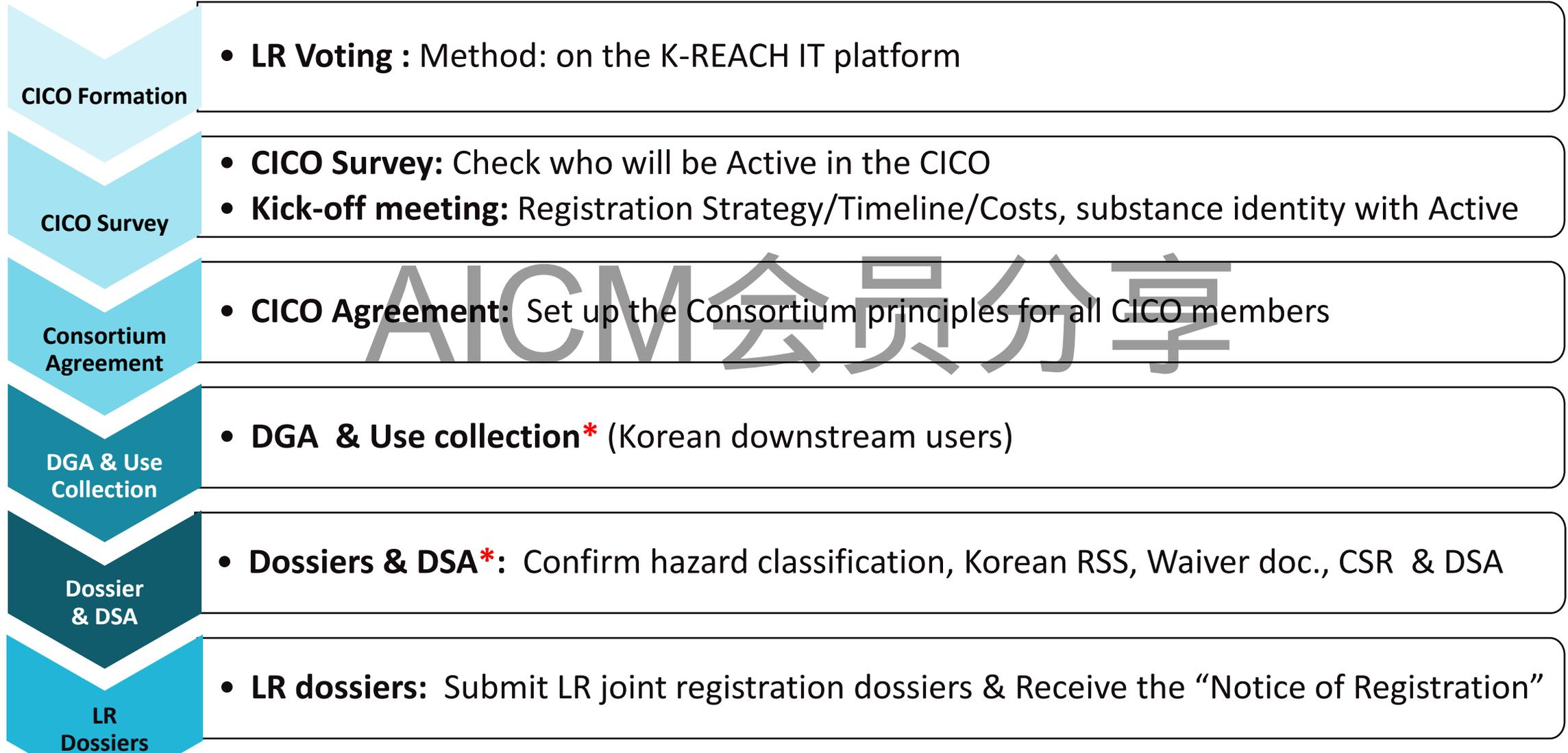
An organization formed by joining K-REACH online joint registration system with respect to the same existing chemical substance(s) among those who have completed pre-registration.

CICO member Status Options	Lead registrant	Lead the whole process of consortium operation as a consortium leader
	Active member	Participate in every consortium management process; Submit opinion and participate in prior cost sharing
	Passive member	Not participated in every consortium management process; Register with a share of finally determined cost; Need to purchase only Letter of Access(LOA)
Late registrant	Need to register substances after the registration grace period, before manufacture/importing; Register through purchasing Letter of Access(LOA) from the relevant consortium	



3. K-REACH Registration

: Joint Registration Brief Process (Existing Substances)





3. K-REACH Registration : **Joint Registration** Test Data Requirements

	1 ~ 10 ton (total 15)		10 ~ 100 ton (incl. 15, total 26)	100 ~ 1,000 ton (incl. 26, total 37)	Over 1,000 ton (incl. 37, total 47)
Physico-chemical properties (13)	1) Physical Status 2) Water solubility 3) Melting/Freezing point 4) Boiling point 5) Vapor pressure	6)* Octanol/water partition coefficient 7) Density 8) Granulometry (Particle size distribution)	9) Flash Point/Flammability 10) Explosive properties 11) Oxidizing properties	12) Viscosity 13) Dissociation constant	-
Hazards to human (15)	1)* Acute oral toxicity (Acute inhalation toxicity) 2)* In vitro Bacterial Reverse mutation (Ames) 3) Skin irritation/corrosion 4) Skin sensitization		5)* Acute dermal toxicity or Acute inhalation toxicity 6)* Eye irritation/corrosion 7)* In vitro Mammalian Chromosomal Aberration 8) In vivo Mammalian genotoxicity (Micronucleus) 9) Repeated-dose toxicity (28 days) 10) Screening for Reproductive & Development Toxicity	11)* Additional genotoxicity/mutation (germ cell genotoxicity/mutagenicity, etc.)	12)* Repeated-dose toxicity (90 days) 13)* Prenatal Developmental Toxicity Study 14)* Two-generation reproductive toxicity 15) Carcinogenicity
Hazards to environment (19)	1)* Acute Fish toxicity 2)* Ready biodegradability 3)* Acute toxicity to daphnia magna		4)* Growth inhibition of freshwater algae 5) Hydrolysis as a function of pH	6)* Inherent biodegradability (1), (2) 7) Identification of degradation product (1), (2) 8)* Fish chronic toxicity (1), (2) 9)* Chronic toxicity to Daphnia magna (1), (2) 10) *Acute toxicity to Terrestrial plant (1), (2) 11)* Acute toxicity to Terrestrial Invertebrate (1), (2) 12)* Activated Sludge Respiration Inhibition Test (1), (2) 13) Adsorption & desorption (1), (2)	14) Additional information on environmental fate & behavior (1), (2) 15)* Chronic toxicity to terrestrial plant (1), (2) 16)* Chronic toxicity to terrestrial invertebrates living (1), (2) 17) Additional information on adsorption & desorption (1), (2) 18)* Chronic toxicity to sediment organism (1), (2) 19)* Bioaccumulation (1), (2)

Remarks:

* Test data that must be submitted as a document recording the test results conducted by the GLP test institute

(1) Test data that can be omitted based on risk data and exposure information

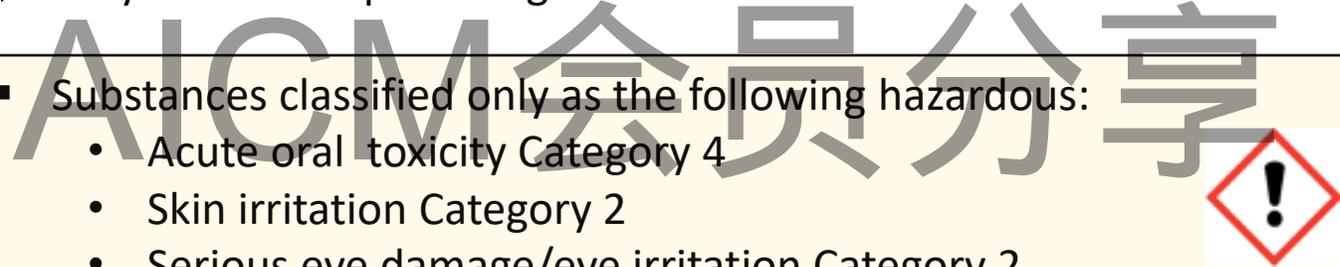
(2) Test data that can be submitted test proposal



3. K-REACH Registration

: Joint Registration Simplified Test Data Requirements (√ Not Applicable for Substances with Consumer Use)

Non-Classified	<ul style="list-style-type: none">▪ Existing substance, not classified as hazardous▪ Existing substance, Hazardous to the aquatic environment (Chronic) classified only as Category 3 / Category 4 <p>▶ Only 15 data required regardless of the amount manufactured or imported.</p>
Low-Classified	<ul style="list-style-type: none">▪ Substances classified only as the following hazardous:<ul style="list-style-type: none">• Acute oral toxicity Category 4• Skin irritation Category 2• Serious eye damage/eye irritation Category 2• Skin sensitization Category 1• Reproductive toxicity – Category other than 1 and 2• Specific target organ toxicity-Single exposure Category 3• Hazardous to the ozone layer Category 1 <p>▶ Environmental toxicity data is only 10~100 ton registered data Available to submit max. 33 data</p>



3. K-REACH Registration



: Joint Registration Simplified Test Data Requirements

	1 ~ 10 ton (total 15)	10 ~ 100 ton (incl. 15, total 26)	100 ~ 1,000 ton (incl. 26, total 29)	Over 1,000 ton (incl. 29, total 33)
Physico-chemical properties (13)	1) Physical Status 2) Water solubility 3) Melting/Freezing point 4) Boiling point 5) Vapor pressure	6) *Octanol/water partition coefficient 7) Density 8) Granulometry (Particle size distribution)	9) Flash Point/Flammability 10) Explosive properties 11) Oxidizing properties	12) Viscosity 13) Dissociation constant
Hazards to human (15)	1) *Acute oral toxicity (Acute inhalation toxicity) 2) *In vitro Bacterial Reverse mutation (Ames) 3) Skin irritation/corrosion 4) Skin sensitization	5) *Acute dermal toxicity or Acute inhalation toxicity 6) *Eye irritation/corrosion 7) *In vitro Mammalian Chromosomal Aberration 8) In vivo Mammalian genotoxicity (Micronucleus) 9) Repeated-dose toxicity (28 days) 10) Screening for Reproductive & Development Toxicity	11) *Additional genotoxicity/mutation (germ cell genotoxicity/mutagenicity, etc.)	12) *Repeated-dose toxicity (90 days) 13) *Prenatal Developmental Toxicity Study 14) *Two-generation reproductive toxicity 15) Carcinogenicity
Hazards to environment (19)	1) *Acute Fish toxicity 2) *Ready biodegradability 3) *Acute toxicity to daphnia magna	4) *Growth inhibition of freshwater algae 5) Hydrolysis as a function of pH		

**Non-classified as hazardous :
Only 15 data**

**Low hazard classification :
Max. 33 data**



3. K-REACH Registration

: Joint Registration HOW MUCH IT COST € ₩ \$

Consortium Management Cost

Equally sharing the cost

- Consortium management service
- Technical service(DGA, Korean RSS etc.)

CSR preparation Cost

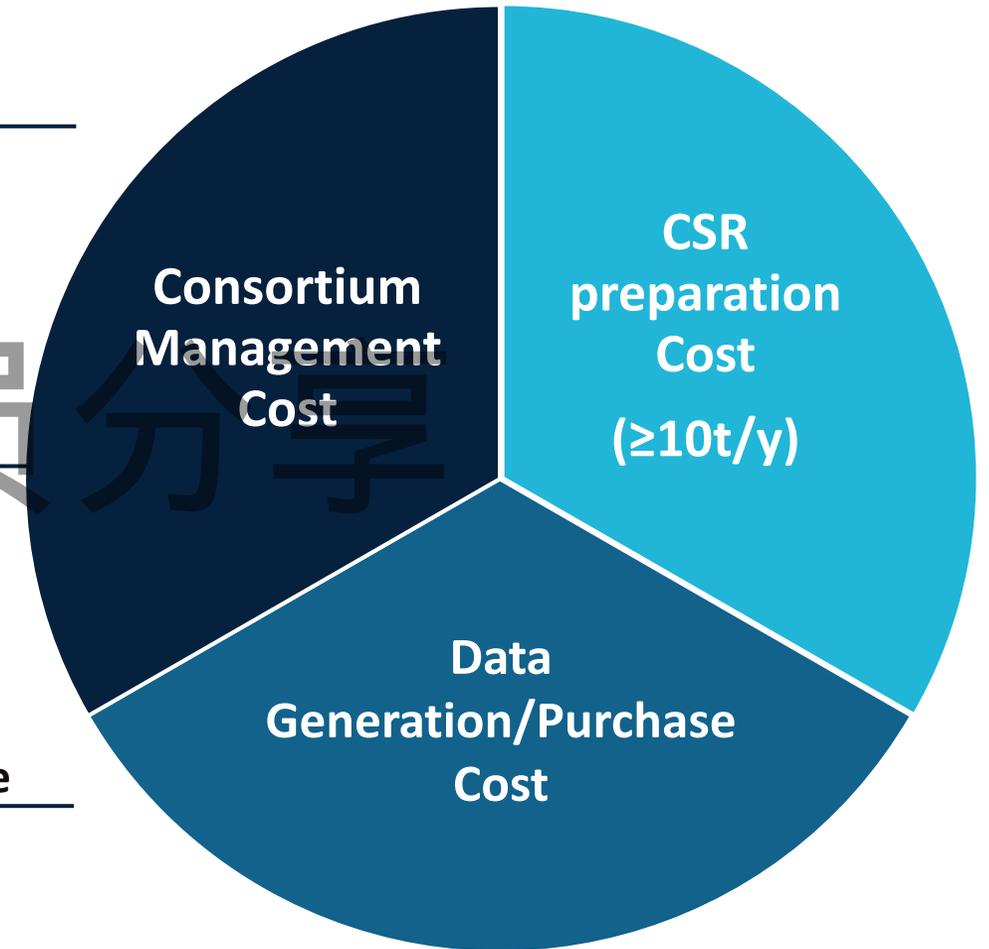
Individual/joint submission

- $\geq 10\text{t/y}$ registration
- Additional cost may incur by the number of use/Exposure scenario

Data Generation/Purchase Cost

Cost sharing by the registered tonnage

- Purchasing the data(LOA) , such as EU consortium data
- Testing fee in case of non-conformance with existing data





3. K-REACH Registration

: Individual Registration (Existing substances)

According to Article 15 (Method for Submitting Data When Applying for Registration of Phase-In Substance),

- Registrants shall jointly submit data by designating a representative(LR):
- In any of the following cases, the registrant may individually submit data after obtaining “confirmation of individual submission” from the MOE:
 1. Where the disclosure of trade secrets of the enterprise is expected to cause considerable commercial loss;
 2. Where more expenses are incurred for joint submission than individual submission;
 3. Where any ground prescribed by Presidential Decree exists.
 1. Different hazard classification & labelling
 2. Different opinion with the LR regarding the selection of tests data for the same test item.
 3. Where a person has all data that he or she shall submit to apply for registration and has consented the use of such data for applying for registration free of charge by another manufacturer or importer who intends to register the same phase-in substance.

3. K-REACH Registration



: PEC Registration

CAS No. ⚡	Chemical Name ⚡	KE No. ⚡	Acutely/Chronically/Environment ⚡	Substances requiring preparation for accidents ⚡	Restricted/Prohibited/Permitted substances ⚡	Substances subject to intensive control ⚡	Persistent pollutants ⚡	Remark	Percentage & Regulatory Information
50-00-0	Formalin [Other names : Formaldehyde;]	KE-17074	Acutely · Chronically 97-1-345	1	06-5-5	별표-1		No grace period for registration	View info

- There is **no grace period for registration** when manufacture or import PECs over 1 ton/yr
→ Should be registered before manufacturing or importing
- MoE released the PEC list in 2015, which included **510 existing chemical substances**
- **PEC** registration has been completed by June 30, 2018, so late pre-registration is not available

PECs (Priority Existing Chemicals)



4. PLC Exemption of Confirmation from Registration

Confirm the existing polymer which has done pre-registration whether to meet below PLC criteria under K-REACH:

Scenario 1

- Number average molecular weight (Mn) >**1000 Da**~<**10000 Da** and
- Oligomers with molecular weight less than 1,000 Da <25% and
- Oligomers with molecular weight less than 500 Da <10% and
- **Non cationic polymer** (excluding high molecular compounds which are used only in solid state, and not soluble or dissolved in water) and
- Content of residual monomers (hazardous substances, priority control substance, new substances) in polymer less than 0.1%

Scenario 2

- Number average molecular weight (Mn) >**10000 Da** and
- Oligomers with molecular weight less than 1,000 Da <5% and
- Oligomers with molecular weight less than 500 Da <2% and
- **Non cationic polymer** (excluding high molecular compounds which are used only in solid state, and not soluble or dissolved in water)

Data Requirements:

1. monomers data, 2. GPC data, 3. Residual monomers data (if there is hazardous chemicals in monomers), 4. Uses and brief detailed use by Korean downstream users, 5. Korean importers list, 6. Annual tonnage, 7. Import product names

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5. K-REACH Information Provision Within Supply Chain

Downstream User -> Manufacturer/Importer

1. Information that manufacturer/importer needs to register substance or update already-registered information (e.g. **use, used quantity**)

Chemical Transferor -> Transferee

2. Information on registered or notified substance (e.g. use, hazard data), including unregistered hazardous substances during grace period

CBI Protection for Chemical Safety Information

1. May not provide CBI (components, concentration , etc.) if concerned substance is **not classified** as health/environmental hazard (**Excl. substances with unconfirmed hazards**).
2. May provide as CBI once after obtaining an approval from the MOE, if concerned substances is classified as health/environmental hazard
3. However, the information should be provided if a substance is hazardous substance or CMRs, classified as physical danger or health/environmental hazard, and contained more than concentration limit

03

Korea Regulatory
Updates

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1. K-REACH New Chemical Notification

1. New chemical Notification under K-REACH : < 0.1 ton/year → < 1 ton/year (from 1st Jan. 2025)

- The notification threshold for new chemicals has been adjusted to < 1 ton/year from < 0.1 ton/year.
 - Required to submit additional “**Data Source of Classification and Labelling**”
- New chemicals that were previously registered in the 0.1 - 1 ton/year before 1st Jan. 2025 are considered as already notified as < 1 ton/year.

Volume Change

Before

Notification: < 0.1 Ton
Registration: ≥ 0.1 Ton

After

Notification: < 1 Ton
Registration: ≥ 1 Ton

Effective date: Jan. 1, 2025

Data Requirements Change

Before

No data
required for
classification

After (**Confirm hazard classification**)

Data Source

1. Experiment/existing data
2. Confirm the availability of globally publicized assessment data
3. QSAR and other alternative methods

No data available for classification

From August 7, 2025

Substances with Unconfirmed Hazards



1. K-REACH New Chemical Notification

2. Amendments on Enforcement Rule of K-REACH (from 7th Aug. 2025)

1. Newly established criteria of “Substances with Unconfirmed Hazards”:

- Identify lacking essential hazard data

Criteria	Exclusion
<p>If no toxicity data source from any of the tests listed below are submitted, the new substance is classified as a “Substance with unconfirmed hazards.”</p> <ol style="list-style-type: none">1) Acute oral toxicity (or acute inhalation toxicity, if relevant)2) AMES and chromosomal aberration3) Acute Aquatic toxicity (fish and daphnia and algae)4) Biodegradability	<ol style="list-style-type: none">A. PolymersB. Existing chemicals that have not been registered within the grace periodC. Water solubility: less than 1 mg/L [exclusion of 3) & 4)]D. Used solely as intermediates or process regulators [exclusion of 3) & 4)]

2. Enhanced Disclosure of Chemical Information

- Korean authority will disclose information on **notified new chemicals** on official platforms in public.
 - Chemical name & CAS No., Use classification,
 - Classification & Labeling
- “Substances with unconfirmed hazards”: must disclose chemical info. to Korean downstream users²¹



2. Revised MSDS Format:

Amendments on **MSDS** Standards under **K-OSHA** (from 7th Aug. 2025)

- **Revised MSDS format:**
- **Section 15** for products containing “**substances with unconfirmed hazards**” shall state below contents:
 - Chemical name or “**generic name**” of “**substance with unconfirmed hazards**”
 - **Unconfirmed hazards endpoints** (e.g. acute oral, AMES....)
 - **Precautions for handling**
- **Existing MSDS in the old format** can be used **until June 30, 2026**, with information in Section 15.5.
- **Transitional Deadline of Updated Information Provision:** by **1st July, 2026**
- **Revision of Section 15 alone does not require the mandatory re-submission of the MSDS.**

Previous MSDS format (available until June 30, 2026)	Revised MSDS format (available from August 7, 2025)
<p>15. Regulatory Information</p> <p>15.1 Occupational Safety and Health Act (K-OSHA)</p> <p>15.2 Chemicals Control Act (K-CCA)</p> <p>15.3 Safety Control of Dangerous Substances Act</p> <p>15.4 Wastes Control Act</p> <p>15.5 Other Domestic and International Regulatory Information</p> <ul style="list-style-type: none"> • Act on Registration, Evaluation, etc. of Chemicals (K-REACH): <ul style="list-style-type: none"> Substances with Unconfirmed Hazards: <i>Substance A</i> <ul style="list-style-type: none"> - Unconfirmed hazards*: <i>Acute Oral Toxicity</i> - Handling precaution: <i>Refer to the Safe Use Guidelines for Substances with Unconfirmed Hazards provided by the National Institute of Chemical Safety and ensure safe handling in accordance with Article 5 of the Act.</i> 	<p>15. Regulatory Information</p> <p>15.1 Occupational Safety and Health Act (K-OSHA)</p> <p>15.2 Chemicals Control Act (K-CCA)</p> <p>15.3 Act on Registration, Evaluation, etc. of Chemicals (K-REACH):</p> <ul style="list-style-type: none"> • Substances with Unconfirmed Hazards: <i>Substance A</i> <ul style="list-style-type: none"> - Unconfirmed hazards*: <i>Acute Oral Toxicity</i> - Handling precaution: <i>Refer to the Safe Use Guidelines for Substances with Unconfirmed Hazards provided by the National Institute of Chemical Safety and ensure safe handling in accordance with Article 5 of the Act.</i> <p>15.4 Safety Control of Dangerous Substances Act</p> <p>15.5 Wastes Control Act</p> <p>15.6 Other Domestic and International Regulatory Information</p>



3 New Safety Management System

New Safety Management System under K-REACH & K-CCA (from 7th Aug. 2025)

- Previous Toxic substances are classified into “three Hazardous substances” under K-REACH & K-CCA as below:
 - Substances Acutely Hazardous to Human Health
 - Substances Chronically Hazardous to Human Health
 - Substances Hazardous to the Environment
- **Grace period of Changed LoC template under K-CCA (Aug.7 2025): until Dec. 31, 2025.**
- Updated list of 1,376 substances (CAS No., concentration limits):
 - Each hazardous substance has its own threshold limits, and a substance can fall into **multiple hazardous substances** with different threshold limit as below:

[Annex I] Product and substances information (Example)

Confidential business information can be marked with 'CBI'. But it is mandatory to disclose all information regarding the substance listed below

- Substances Acutely Hazardous to Human Health,
- Substances Chronically Hazardous to Human Health,
- Substances Hazardous to the Environment,
- Substances subject to authorization,
- Restricted substances,
- Prohibited substances,
- Substances requiring preparation for accidents as regulated under the Chemical Substance Control Act

Toxic substance

Chemical name	CAS No.	Content (%)	Chemical Division (P/N)	Substances Acutely Hazardous to Human Health ¹⁾	Substances Chronically Hazardous to Human Health ²⁾	Substances Hazardous to the environment ³⁾	Substances subject to authorization ⁴⁾	Restricted substances ⁵⁾	Prohibited substances ⁶⁾	Substances requiring preparation for accidents ⁷⁾
Sodium hydroxide	1310-73-2	25	P	V						
Hydrogen chloride	7647-82-0	25	P		V					V
CBI	CBI	P								
CBI	-13	N								
Impurity	1									
Total Content										100%

> K-CCA: Changed LoC template >

NICS's number	Chemical name	CAS No.	old threshold limit(%)	Amended threshold limit(%)		
				Substances Acutely Hazardous to Human Health	Substances Chronically Hazardous to Human Health	Substances Hazardous to the Environment
97-1-12	Nitrobenzene	98-95-3	0.3	25	0.3	
2023-1-1134	Dimethylamine	124-40-3	25	10		
2023-1-1139	Cobalt	7440-48-4	1	1	0.1	2.5



3 New Safety Management System

New Safety Management System under K-CCA (from 7th Aug. 2025)

- **Transitional Deadline under K-CCA:**
 - Verification of chemical, hazard labeling and import notification: 1 July 2026
 - Handling standards: 1 Jan 2027
 - Business permits / Accident prevention plan: 1 Jan 2028
 - Facility installation/management standards: 1 Jan 2030

General case : Deadline	Containing Benzene 0.1-1.0% case : Deadline
1) Before Jan 1, 2026 (Already in Use in Korea) :Transitional deadlines as above.	1) Before Jan 1, 2028 (Already in Use in Korea) :Transitional deadlines shifted by 2 years from above.
1) After Jan 1, 2026 (First Use in Korea) :No transitional deadline – comply from Jan 1, 2026	2) After Jan 1, 2028 (First Use in Korea) :No transitional deadline – comply from Jan 1, 2028



4. OR under K-CCA

OR system was adopted **under K-CCA** (from **7th Aug. 2025**)

Business Scope by OR	<ul style="list-style-type: none">• Submission of Verification of Chemicals (submit “LOC” under K-CCA)• Application of Permission for the Permitted chemicals (until now, no permitted chemicals)• Change of the Permission for the Permitted chemicals
Responsibility by OR	<ul style="list-style-type: none">• Declaration of OR Appointment or Dismissal to MoE• Provision of OR appointment and Affairs entrusted and results OR performed the affairs to importers• Provision of Information on Permitted Chemicals to Korean Importers (e.g., permission number, use, import period)

K-CCA (Korea Chemical Control Act)



5. Special MOE Public Notice: K-REACH Voluntary Surrender

Voluntary surrender for registration, change of registration and pre-registration under K-REACH

Publication date	On February 28, 2025
Concerned Authority	Ministry of Environment, Ministry of Justice
Voluntary Surrender Period	February 28 ~ October 27, 2025 (8 months)
Purpose	1) to provide an opportunity for manufacturers or importers without fulfilling their obligations for registration, change of registration, and pre-registration, 2) to report without facing legal disadvantages.
Reporting method	K-REACH IT System
Benefits for voluntary surrenders	Voluntary surrendering will result in exemption from penalties (up to 5 years imprisonment, fines up to 100 million KRW, or administrative fines up to 5% of sales revenue) and administrative sanctions.

- After the voluntary surrendering period ends, **intensive enforcement through guidance and inspections will be conducted to address violations of the K-REACH.**

04

Wrap Up/ Frequently Asked Questions

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Frequent Q&A



In case of the notified new substance before 2025, can the notifier only import below 100 kg?

- **No.** Even those who previously notified can still manufacture/import below 1 ton/year under the current law.

Are the new substances registered before 2025 in 0.1~1 ton/year considered to have been notified after the K-REACH amendments?

- **No.** They are considered registered regardless of K-REACH amendments, and any changes require “Change of Registration” or “Change of Reporting” accordingly.

Does the Korea authority(KECO) determine if a notified substance is a substance with unconfirmed hazards?

- **No.** Determining whether a new substance to be a substance with unconfirmed hazards is a voluntary report based on the notifier's judgment. The authority only reviews whether the submitted data matches the criteria for substance with unconfirmed hazards or not.

Can the notified new substances before August 7, 2025 also be considered as “substance with unconfirmed hazards”?

- **No.** The criteria for substances with unconfirmed hazards apply to substances notified **after August 7, 2025.**



Preparation for Late Pre-Registration and Passive Registration of Existing Substances

- If the chemical substances are exporting to South Korea for the first time, you should complete the late pre-registration for a grace period. If you intend to manufacture or import >1000 or 100-100, 10-100 tons/year, make your move immediately with Intertek.

Preparation for Tier 3 Registration ($10 \leq \text{ton} < 100$)

- K-REACH registration is a long-term project. The earlier you prepare, the more successful registration you can accomplish and the better position you can place yourself in the industry.

Confirmation of PLC Exemption

- Confirm in advance if any exemption can be applied to the existing polymer, thereby saving time and cost. Contact us, discuss with us, find the best way with us.

Voluntary Surrender (2025.02.28 ~ 2025.10.27)

- In case of not fulfilled the obligations under K-REACH regulation (pre-registration, registration, and change registration) before Feb. 27, 2025, report without legal disadvantage.

Thank you!



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