



Introduction to Revised K-REACH and Sub-ordinance

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Contents

- Overview of Korea chemical regulations
- Outline of K-REACH
- Revised K-REACH
- Strategy for industry compliance of K-REACH

Overview of Korea chemical regulations

Chemical Regulations in Korea

Object	Competent Ministry	Relevant Regulations
Industrial chemicals + Consumer chemical products	Ministry of Environment (MoE)	K-REACH, Chemical Control Act(CCA) + K-BPR
Industrial chemicals	Ministry of Employment & Labor (MoEL)	Industrial Safety and Health Law (ISHL)
Dangerous goods	National Emergency Management Agency (NEMA)	Dangerous Goods Management Act (DGMA)
Consumer goods	Ministry of Trade, Industry and Energy	Quality control and Safety management of industrial products act
Pesticide, Fertilizer, Feedstuff	Ministry of Food, Agriculture, Forestry & Fisheries	Pesticide Control Act, Fertilizer Control Act, Feed Act
Pharmaceutical, quasi-pharmaceutical, Drug, Cosmetics, Food and Food additives	Ministry of Health & Welfare	Pharmaceutical Affairs Act Act on the Control of Narcotics, etc. Cosmetics Act Food Sanitation Act
High pressured Gas Liquefied Petroleum Gas	Ministry of Trade, Industry and Energy	High pressured gas Safety Act

Overview of Korea chemical regulations

Chemophobia

- Biocides & hazardous chemicals in household chemical products



- Humidifier disinfectants

- PHMG (Polyhexamethylene guanidine)
- PGH (Oligo(2-)ethoxy ethoxyethyl guanidine chloride)
- PHMB (Polyhexamethylene biguanide)
- CMIT/MIT (Chloromethyl isothiazolinone/Methyl isothiazolinone)



- (Air) purifier filter

- OIT (octylisothiazolinone)



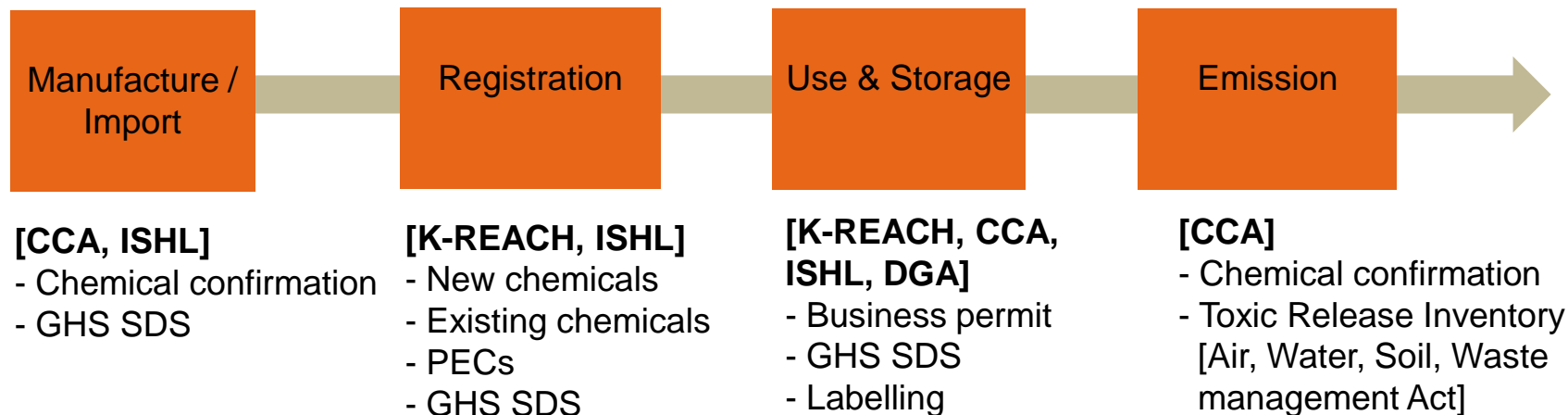
- Diaper or Sanitary pad

- DBP(Dibutyl phthalate)
- DEHP(Diethyl hexyl phthalate)

Overview of Korea chemical regulations

Life Cycle of Chemicals and Relevant Regulations

Industrial chemicals & Industrial chemical products



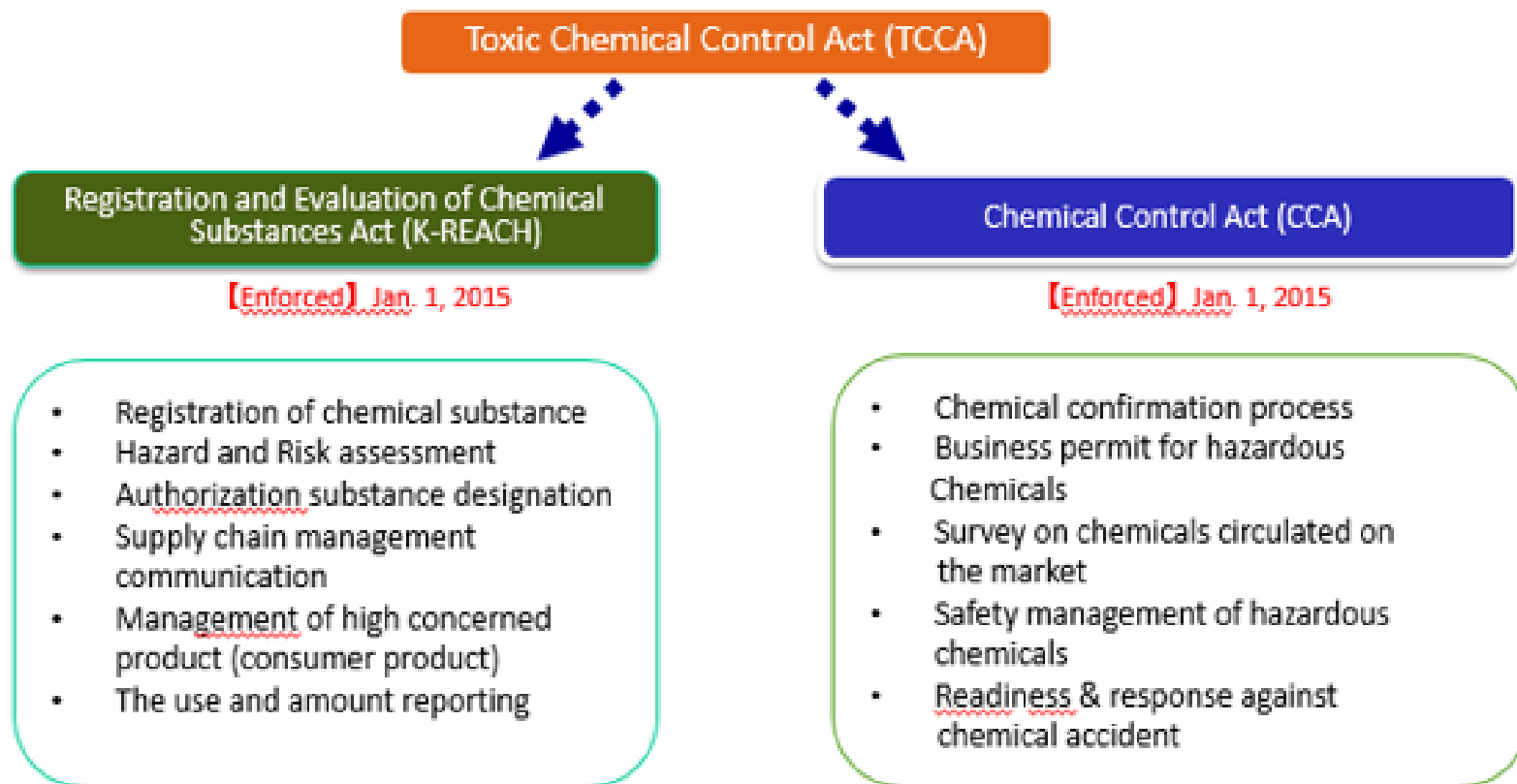
Consumer chemical products & biocidal products

[Korea BPR]

- Approval of biocide active substance
- Approval of biocide product

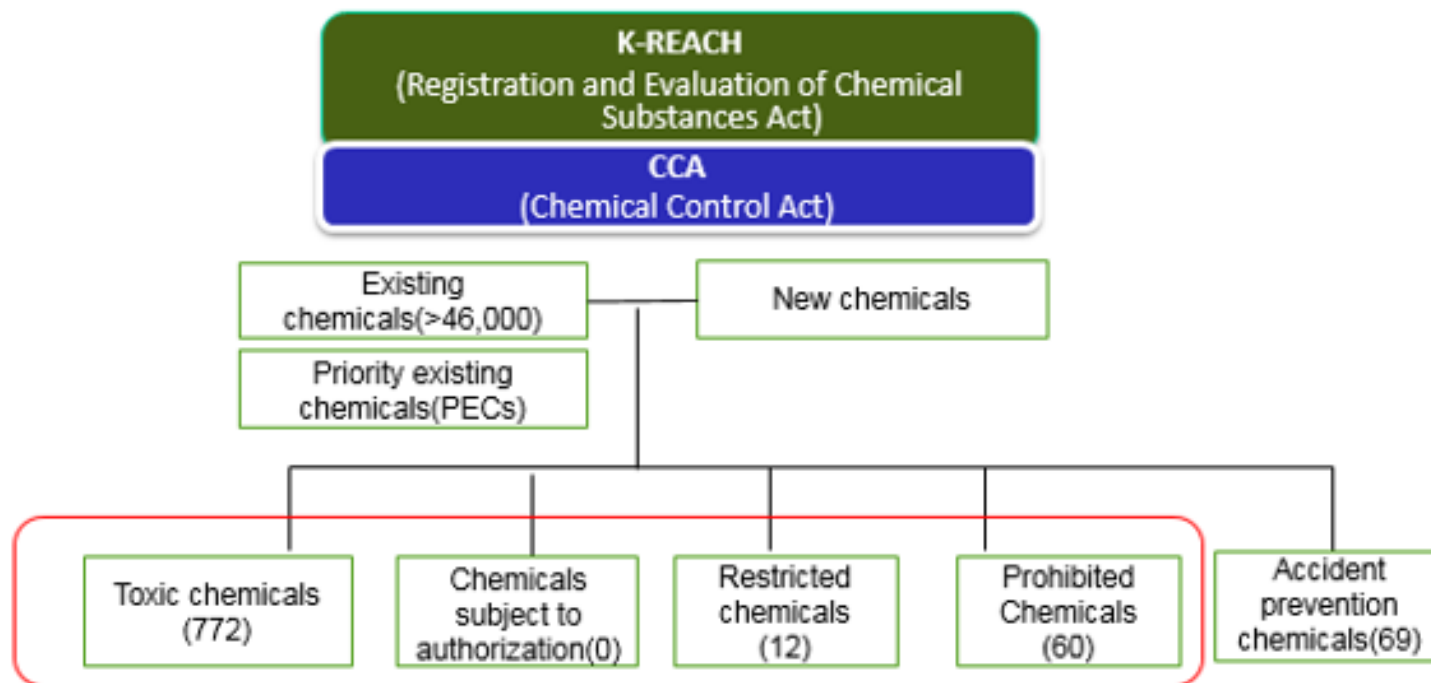
K-REACH: Korea REACH
CCA: Chemical Control Act
ISHL: Industrial Safety and Health Law
DGA: Dangerous Goods Act

Outline of Korea REACH



Previous Korea chemical regulation, TCCA, and new regulation K-REACH & CCA

Outline of Korea REACH



<http://ncis.nier.go.kr/ncis/Index>

<Chemical inventory in Korea>

Note : The numbers in bracket keep on increasing

Outline of Korea REACH

<http://ncis.nier.go.kr/en/main.do>

ncis National Chemicals
Information System

KOREAN

Chemical Search

CHEMICALS INFORMATION SYSTEM

Chemical Search

Popular Keywords 1310-73-2 | 황산 | 67-56-1 | 108-88-3 | 7732-18-5

Phase-in substances subject to registration

Toxic substances

Restricted substances

Prohibited substances

Substances requiring preparation for accidents

Search **[Korea chemical inventory]** with CAS no. or chemical name

Outline of Korea REACH

Example

Chemical Search

All

50-00-0

Search

Search Results 3

Search within results

Search



10 Items per Page

CAS No. ▾	Chemical Name ▾	NIER's No.						Percentage & Regulatory Information
		KE No. ▾	Phase-in substance subject to registration ▾	Toxic substance ▾	Restricted substance ▾	Prohibited substance ▾	Substance requiring preparation for accidents ▾	
68650-00-0	Fatty acids, tall oil polymers with pentaerythritol, phthalic anhydride and tung oil, oxidized	KE-16170						
50-00-0	Formalin [Other names : Formaldehyde:]	KE-17074	1	97-1-345	06-5-5		1	View info
13150-00-0	Sodium 2-[2-[2-(dodecyloxy)ethoxy]ethoxy]ethyl sulfate	KE-31442						

Outline of Korea REACH

ALL

General Information

Classification and Labelling

General Information

Structural Formula



• [CAS No] 50-00-0

• [Molecular Formula] CH₂O

• [Phase-in substances] KE-17074

• [Molecular Weight] 30,03

• [RTECS No] LP8925000

• [UN No] 1198,2209

• [EC No] 200-001-8

• [HS No]

• [IACS No]

Content

Chemical Information	NIER's No	Content(%)	Prohibited information Limited information
Phase-in substance	KE-17074		
Toxic substance	97-1-345	Formalin or mixture containing 1% and above.	
Restricted substance	06-5-5	Formaldehyde or mixture containing 1% and above.	Manufacture, import, sales, store-transport, and use of Wood veneers for furniture, fabrics, ? baby products for age under 3, wallpaper adhesives, and leather softeners are prohibited.
Substance requiring preparation for accidents	1	Formalin or mixture containing 1% and above.	
OECD HPV Chemical	V		
Phase-in substance subject to registration	1		

Outline of Korea REACH

ALL

General Information

Classification and Labelling

Classification and Labelling

Signal words : **Danger**



[GHS02]



[GHS04]



[GHS05]



[GHS06]



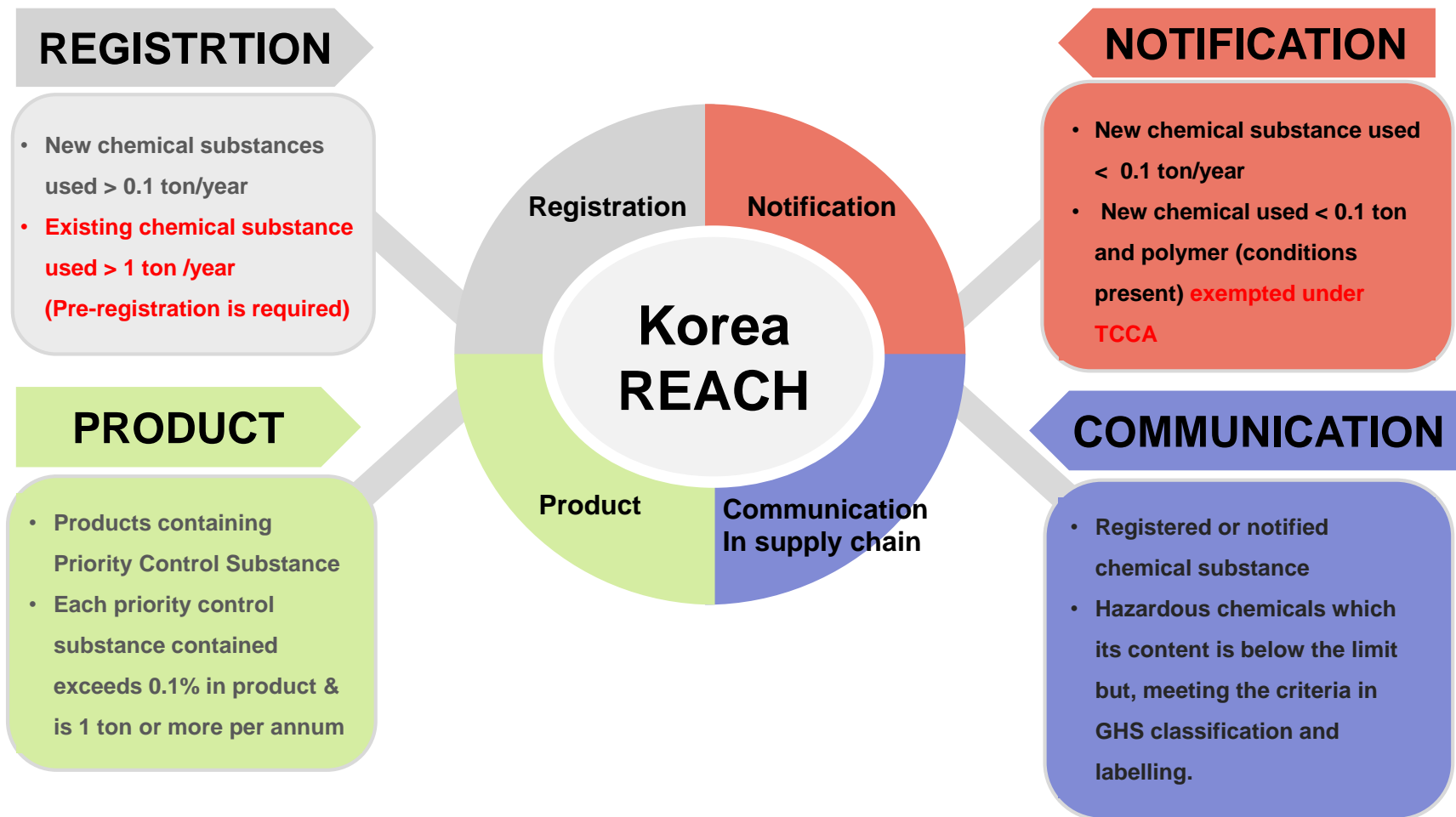
[GHS08]

M Value : -
UN No : **1198 , 2209**

[Print Label](#)

Hazard Classification		Hazard entered	
Flammable gases	1	H220	Extremely flammable gas.
Gases under pressure	2	H280	Contains gas under pressure: may explode if heated.
Acute Oral Toxicity	3	H301	Toxic if swallowed.
Acute dermal toxicity	3	H311	Toxic in contact with skin.
Acute Inhalation Toxicity	2	H330	Fatal if inhaled.
Skin corrosion/irritation	1	H314	Causes severe skin burns and eye damage.
Skin sensitization	1	H317	May cause an allergic skin reaction.
Carcinogenicity	1	H350	May cause cancer.

Revised K-REACH – Overview



REGISTRATION

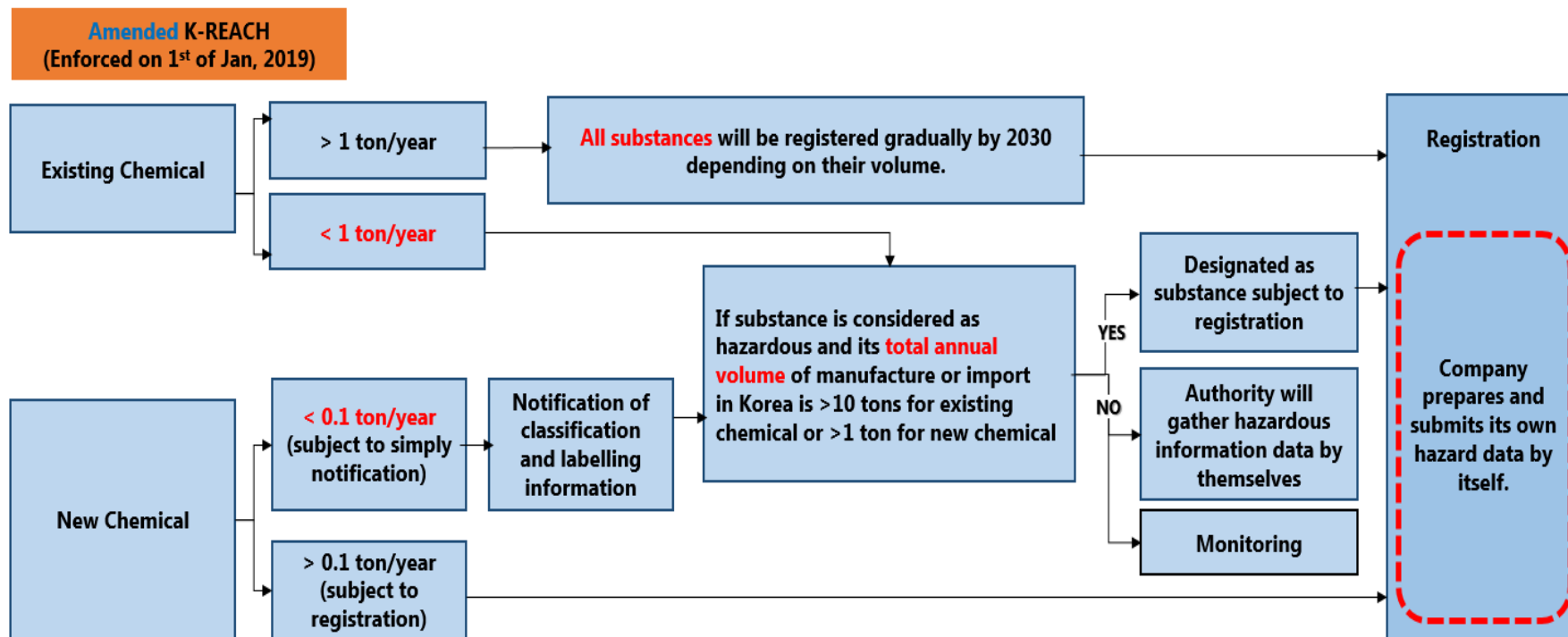
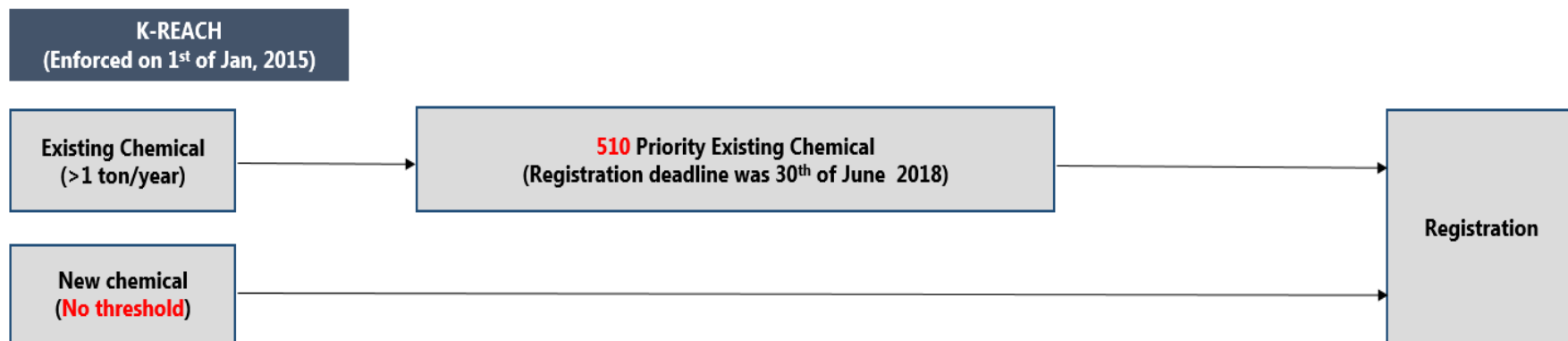
Revised K-REACH : Registration

K-REACH vs. EU-REACH

	Korea REACH (revised version)	EU REACH
Pre-registration	○ (Tonnage band, C&L and use) → Can update	○ (Tonnage band) → One time
Registration	New chemicals >100kg/year → Notification for <100kg/year of new chemicals	New & existing chemicals > 1 ton/year
	All existing chemical >1 ton/year	
Polymer	Not exempt from registration → Polymer registration	Exempt from registration, but its monomer needs to be registered
Data requirements	Higher volume, more data 0.1-1 (only for new chemical from 2020), 1-10, 10-100, 100-1000, and >1,000 ton CSR required for ≥ 10 ton/year → Simplified data allowed according to GHS classification of existing chemical	Higher volume, more data 1-10, 10-100, 100-1000, and >1,000 ton CSR required for ≥ 10 ton/year
Joint submission	○ (Mandatory)	○(Mandatory)
Only Representative	○*	○

* OR : A native person having Korean citizenship or a business unit having an address in Korea

Revised K-REACH : Registration



Joint registration : 510 PEC

Current status of joint registration OF 510 PEC

- As of 31st Dec 2018, among the announced 510 PEC chemicals; **367** chemical consortiums were formed, **343** chemical dossiers were submitted and registration results of 342 chemicals were given.
- Statistical survey has revealed that actual manufacture or import 1 ton or more was carried out by 367 chemical consortiums.

< Current status of joint registration under process >

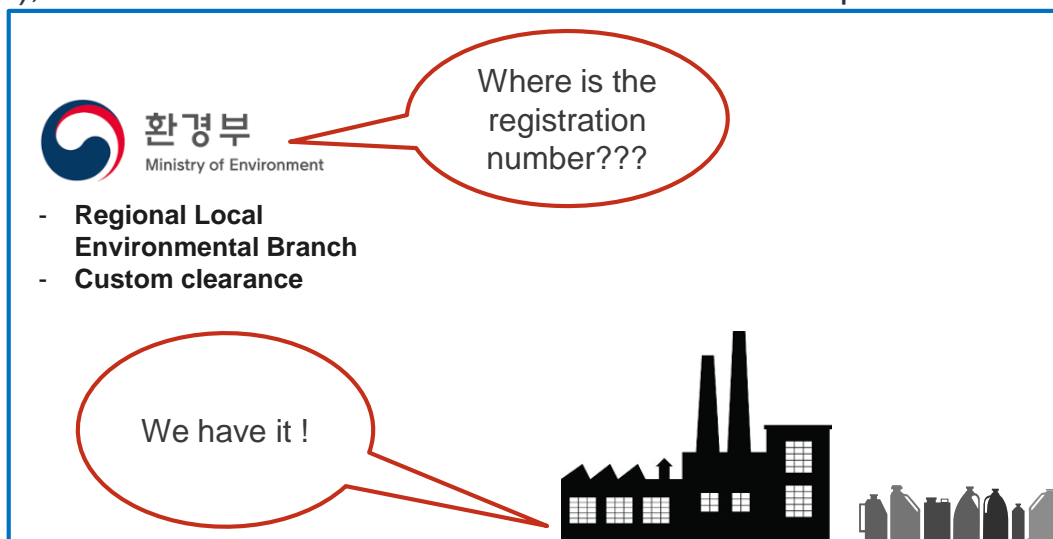
Chemicals			Business		
Total number	Registration completed	Under review	Total number	Registration completed	Under review
343	342	1	3,286	3,251	35

- **With termination of grace period**, registration is required prior to manufacture or import for anyone who intends to manufacture or import 1 ton or more of PEC substances per annum.
- If breached, **penalty up to 10million or 5 years of imprisonment per violation AND 5% of sales are unavoidable.**

Joint registration : 510 PEC

Current status of joint registration after termination of grace period

- As of 31st Dec 2018, registration number is required at the custom clearance when importing
- Continuous registration occurred by a passive member
- Continuous change in registration occurred – addition of new use and change in tonnage
- Increased demand for information communication within supply chain
- In 2018, the NIER (National Institute of Environmental Research) assessed risks for Phenol (one of the PEC substances)
- From this year (2019), the NIER's risk assessment will continue and expand.



Joint registration : Pre-registration of existing chemical >1 ton

- **Deadline : June 30th 2019**

- **No pre-registration, no grace period of registration given!!**

1. Enter K-REACH portal (<https://kreachportal.me.go.kr>)
: Login with business e-certificate

2. Pre-registration (change in) of existing chemicals
1) Submission : Single pre-reg. submission / Change in pre-reg.
2) Multiple submissions : If numerous substances are handled, download an excel sheet to fill in the information for submission

The screenshot displays the K-REACH portal interface. At the top, a navigation bar includes links for '사전신고' (Pre-registration), '등록' (Registration), '등록연계' (Registration continuation), '보고' (Reporting), '신고' (Reporting), '선임/책임신청' (Appointment/Responsibility application), '유해성심사' (Hazard assessment), and 'My page'. The user is logged in as 'chemtopia님' with a profile picture and a '트렌' (Trend) indicator.

Below the navigation bar, a red box highlights the '사전신고' link. Another red box highlights the '기존화학물질 사전(변경)신고' (Existing chemical substance pre-registration (change) report) link.

The main content area is titled '사전신고' (Pre-registration). It contains a search bar and a list of pre-registration records. The search bar includes fields for '등록일자' (Registration date) with a date range from 2018-01-14 to 2019-01-14, '신고구분' (Report type) set to '전체' (All), and '상태' (Status) set to '전체' (All). There are also input fields for '화학물질명' (Chemical name), 'KNo', 'CASNo', '상호명' (Trade name), '사업자번호' (Business registration number), '성명(대표자)' (Name (Representative)), '연락처' (Contact), and '접수번호' (Receipt number). A '검색' (Search) button is located to the right of the search fields.

Below the search bar, there is a table of pre-registration records. The table has columns for '구분' (Category), '접수일자' (Receipt date), '접수번호' (Receipt number), '화학물질명' (Chemical name), 'KNo', 'CASNo', '선임' (Appointment), '상태' (Status), and '완료일자' (Completion date). The table is currently empty.

At the bottom of the page, there is a sidebar with a list of links: '화학물질 정보처리시스템' (Chemical substance information processing system), '공동등록 협의제가입' (Joint registration agreement), '업무절차안내' (Business procedure guide), '일반등록' (General registration), '소량등록' (Small quantity registration), '변경등록' (Change registration), '등록연계' (Registration continuation), '선임/책임' (Appointment/Responsibility), and '유해성심사' (Hazard assessment).

A red box highlights the '입찰작성' (Bid writing) button in the bottom right corner of the main content area.

Joint registration : Pre-registration

Application form

Applicant (Included a representative appointed by Article 38)	Company Name	Business Registration No.			
	Name (Representative)	Contact Information of person in charge (E-mail:)			
	Company Address	(Tel:) (Fax:)			
Contents of Notification	Chemical Substance(s) Name (Generic Name)				
	KECL No. (CAS No)				
	Molecular · Structural Formula(s)				
	①Range and form of expected annual manufacture (import) volume	<input type="checkbox"/> over 1t below 10t <input type="checkbox"/> over 10t below 100t <input type="checkbox"/> over 100t below 1000t <input type="checkbox"/> over 1000t <input type="checkbox"/> polymer <input type="checkbox"/> transported isolated intermediate <input type="checkbox"/> on-site isolated intermediate			
	②Classification ·Labelling	Classification			
		Labelling			
Use(s)	③Use Classification				
	④Explanation of detailed use	<input type="checkbox"/> Industrial/ Professional Use () <input type="checkbox"/> Consumer Use ()			
Contents of Change in Notification	Before Change		After Change		
Importer (if reporter is appointed by Article 38)	⑤Company Name	⑥Business Registration No.	⑦ Representative	⑧Name and contact of the person in charge	⑨Importing Country

- Substance information
- Volume & type of substance
- C&L information
- Use information*
- Change in notification
- Importer information

Joint registration : Pre-registration

Change in notification

Within 1 month from the date when change occurs, if :

- Notified range of annual manufacture or import quantity has changed
- Contact number, address or company name of the applicant has changed
- (If you are an OR), there is a change in list of substance importers
- (If you are a consignor of chemical notified), there is a change in list of manufacturer of chemicals consigned

Within 1 month from the date when change was known, if :

- Labelling and classification of chemical substance has changed.
- (New consumer use identified) Purpose of use under 55 use classification has changed.

Use category (55 Category)

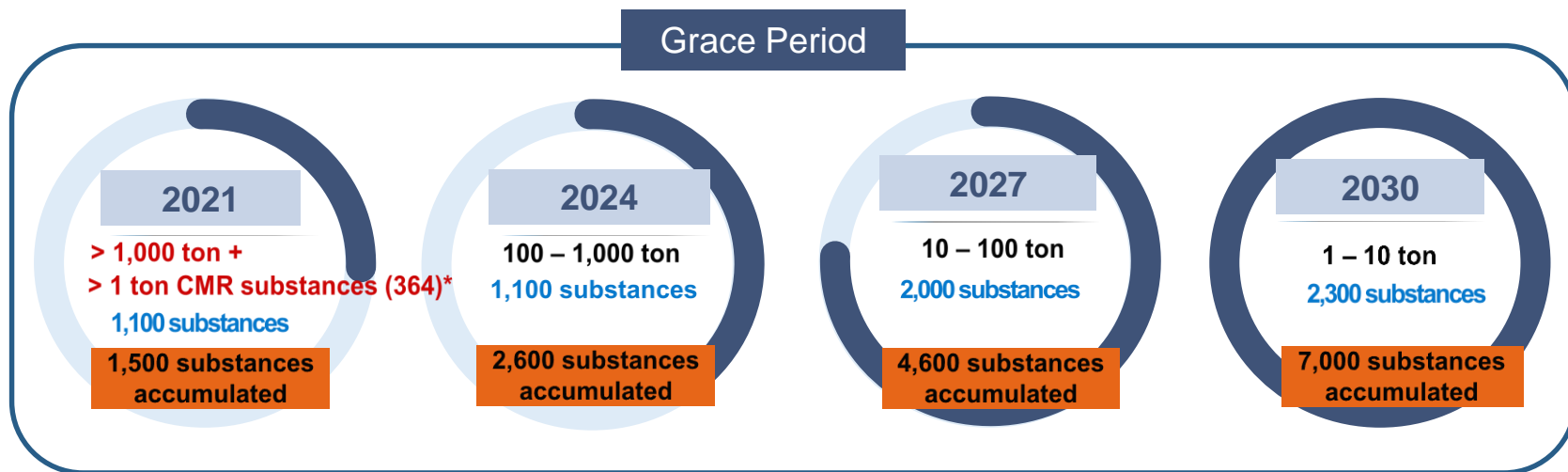
1. Absorbents and Adsorbents	20. Fillers	39. pH-regulating agents
2. Adhesive, binding agents	21. Fixing agents	40. Pesticides
3. Aerosol Propellants	22. Flame retardants and fire preventing agents	41. Pharmaceuticals/its intermediate
4. Anti-condensation agents	23. Flotation agents	42. Photochemicals

Joint registration : Registration period

Registration

To anyone who manufacture or import 1 ton or more of existing chemicals per annum, grace period will be granted in phase according to its hazard, manufacture or import quantity

Grace Period



31 December 2021
(Law)

31 December 2024
(Law)

31 December 2027
(Presidential decree)

31 December 2030
(Presidential decree)

Note* : The list of CMR (364 substances) has been released by the MoE.

K-REACH Data requirement

K-REACH toxicological data requirements

Volume Band	0.1-1 MT (From 2020)	1-10 MT	10-100 MT	100-1,000 MT	≥1,000 MT
Category (No. of data)	S (9)	A (15)	B (26, including A)	C (37, including B)	D (47, including C)
Physio-Chemical Properties	1. Physical status 2. Water solubility 3. Melting/ freezing point 4. Boiling point 5. Vapour pressure	1. Physical status 2. Water solubility 3. Melting/ freezing point 4. Boiling point 5. Vapour pressure 6. Octanol/water coefficient (GLP) 7. Relative density 8. Granulometry (particle size distribution)	1. Flammability 2. Explosive property 3. Oxidizing property	1. Viscosity 2. Dissociation constant	
Human Health Toxicity Test	1. Acute oral toxicity (If exposure route is inhalation, then inhalation toxicity is required) 2. Ames test	1. Acute oral toxicity (If exposure route is inhalation, then inhalation toxicity is required) 2. Ames test 3. Skin corrosion/ irritation 4. Skin sensitization	1. Acute dermal toxicity or acute inhalation toxicity 2. Eye irritation / corrosion 3. In vitro mammalian chromosomal aberration test 4. In vitro mammalian gene mutation test (micronucleous test) 5. Repeated dose toxicity (28d) 6. Screening for reproductive/ developmental toxicity	1. Additional mutation test (Germ cell mutagenicity, etc.)	1. Repeated dose toxicity (90d) 2. Parental developmental toxicity study 3. Two generation reproductive toxicity 4. Carcinogenicity study

K-REACH Data requirement

Volume Band	0.1-1 MT (From 2020)	1-10 MT	10-100 MT	100-1,000 MT	≥1,000 MT
Category (No. of data)		A (15)	B (26, including A)	C (37, including B)	D (47, including C)
Environmental Toxicity Test (GLP)	1. Acute fish toxicity 2. Ready biodegradability	1. Acute fish toxicity 2. Ready biodegradability 3. Acute daphnia toxicity	1. Acute algae toxicity 2. Hydrolysis as a function of pH	1. Inherent biodegradability 2. Identification of degradation products 3. Chronic daphnia toxicity 4. Chronic fish toxicity 5. Short-term toxicity to plants 6. Short-term toxicity to invertebrates (earthworm) 7. Activated sludge respiration inhibition test 8. Adsorption/ desorption screening test	1. Fate and behaviour in the environment 2. Long-term toxicity testing on plants 3. Long-term toxicity testing on invertebrates (earthworm) 4. Additional adsorption/ desorption screening 5. Long-term toxicity to sediment organisms 6. Bio-concentration

K-REACH Data requirement

Simplified data submission on registration of existing chemical

Hazard (Classification and Labeling)	Data to submit for registration	
	Previous K-REACH	Amended K-REACH
High (i.e. Acute Toxicity Classification 1-3)	47 dossiers at most (Physiochemical 13, Human health 15, and Environment 19)	47 dossiers at most (Physiochemical 13, Human health 15, Environment 19)
Low (i.e. Acute Toxicity Classification 4)		33 dossiers at most (Physiochemical 13, Human health 15, Environment 5)
Not Classified or Labeled (-)		15 dossiers at most (Physiochemical 8, Human health 4, Environment 3)

- Simplified dossier with less toxicological data submission for existing chemical can be possible for the following cases according to Article 5, Paragraph 2, sub-paragraph 1 of the K-REACH :
 - When a substance's hazard is not classified: only 15 toxicological data, which are equivalent to 1-10 MT registration data requirement, are required to submit and risk assessment report is omitted to submit.
 - When a substance's hazard is classified as low: only 33 toxicological data are required to submit.
- Classification and labeling information needs to be submitted when the pre-registration of existing chemical is done.

NOTIFICATION

K-REACH notification

Low volume notification of new chemicals

Chemical registration → Notification	
New chemical notification required	1. New chemical <100kg 2. LVE(<100kg) and LCP * under TCCA (within 2yrs)
When	Before manufacture/import
How to submit	Chemical Information Processing System (IT)
Relevant Authority	National Institute of Environmental Research (NIER) (7~14days)
Required information	-Company Name -Chemical Name -Classification -Use Info -Hazard information if owned (Notification of change required if classification, use info within 1 month when found)

Note* : Not all LCP under TCCA, but LCP met some condition designated by the MoE.

K-REACH notification

Designation of Chemical Registration Required for Low Volume Chemicals

Type	Registration Required Amount	Total National Amount
New chemical	< 0.1 ton / year	> 0.1 ton / year (<u>Individual company's volume < 0.1t/yr</u>)
Existing chemical	< 1 ton / year	< 1 ton / year (<u>Individual company's volume < 1t/yr</u>)



The Evaluation Committee review hazard and risk of chemical



The MOE can potentially designate a list of substances required to register

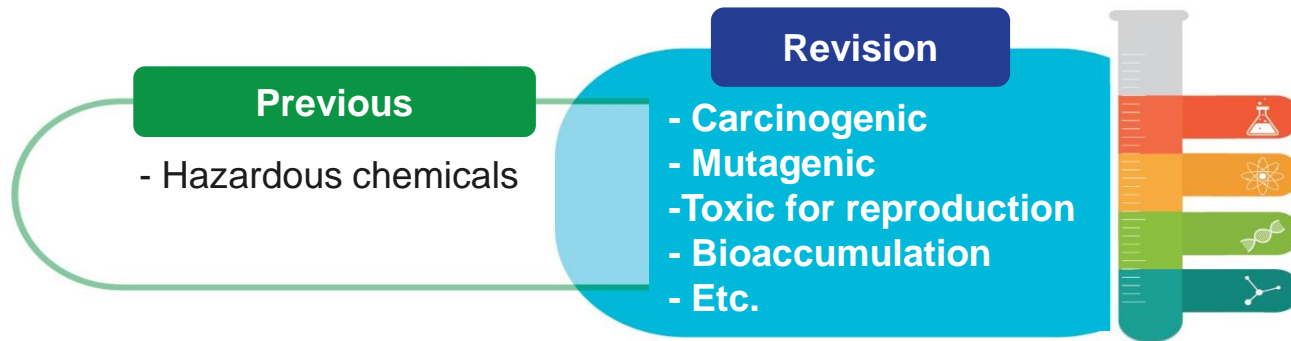
PRODUCT

K-REACH product

Product Notification of Priority Control Substances (PCS)

- Current product notification is required for consumer product containing hazardous chemical substances which are classified by Korean authority.
- This makes loop hole for other high-risk concerned substances such as CMR substances

- **Designation of Priority Control Substances**
- **Consumer products** containing PCS are required for product notification



Hazardous chemical defined under K-REACH

- (1) Toxic chemical
- (2) Authorized chemical
- (3) Restricted chemical
- (4) Prohibited chemical
- (5) Others

PCS designated by below criteria

- (1) CMR(Carcinogenic/Mutagenic/Reproductive toxicity)
- (2) EDCs(Endocrine-Disrupting Chemicals)
- (3) PBT(Persistent, Bioaccumulative and Toxic substances)
- (4) STOT(Specific Target Organ Toxicity)
- (5) EU SVHC(Substances of very high concern)

K-REACH product

Product Notification of Priority Control Substances (PCS)

Appendix 1 - List of Priority Control Substance (PCS) (204)

(Effective from July 1st, 2019)

: The MoE's Notice No. 2018-233

No	Chemical name	CAS No.	Reference
1	Formaldehyde	50-00-0	CMR
2	Benzo[def]chrysene	50-32-8	CMR, PBT
3	Mechlorethamine	51-75-2	CMR
4	Urethane	51-79-6	CMR

Appendix 2 - List of Priority Control Substances (PCS) (468)

(Effective from July 1st, 2021)

: The MoE's Notice No. 2018-233

No	Chemical name	CAS No.	Reference
1	4,5,6,7,7-Pentamethyloctan-3-ol	52-24-4	CMR
2	dibenz[a,h]anthracene	53-70-3	CMR
3	N-Nitrosodiethylamine	55-18-5	CMR

K-REACH product

Product Notification of Priority Control Substances (PCS)

- A company manufacturing or importing a product containing a PCS shall notify

1) Name, content and hazard information of PCS contained in the product

2) Exposure information and use of the PCS contained in the product

- Before manufacturing/importing, if both of the following conditions are met:

1) The content of each PCS per product > 0.1% of its total weight

2) The total amount of PCS contained in the whole product > 1 ton/year

→ 204 types of the PCS will be enforced on July 1st, 2019

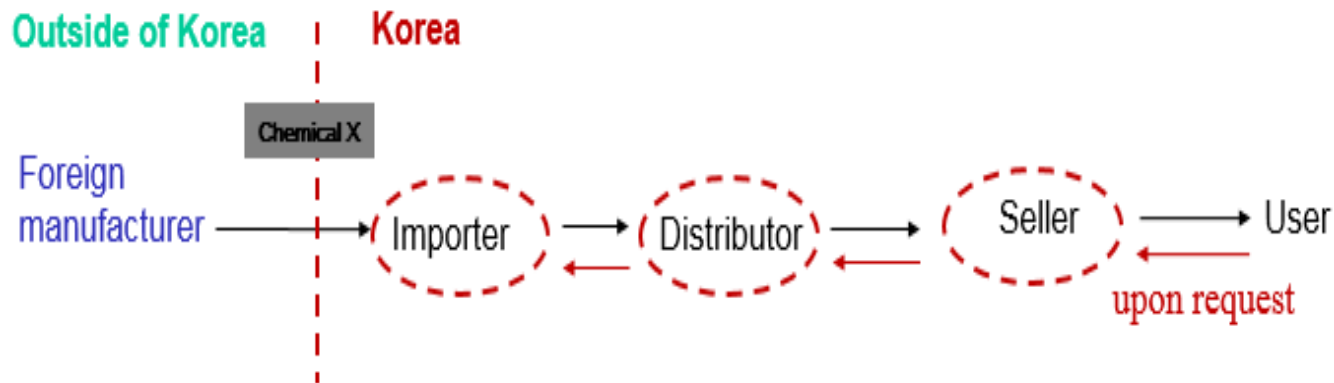
→ 468 types of the PCS will be enforced on July 1st, 2021



COMMUNICATION

K-REACH communication

Communication in supply chain



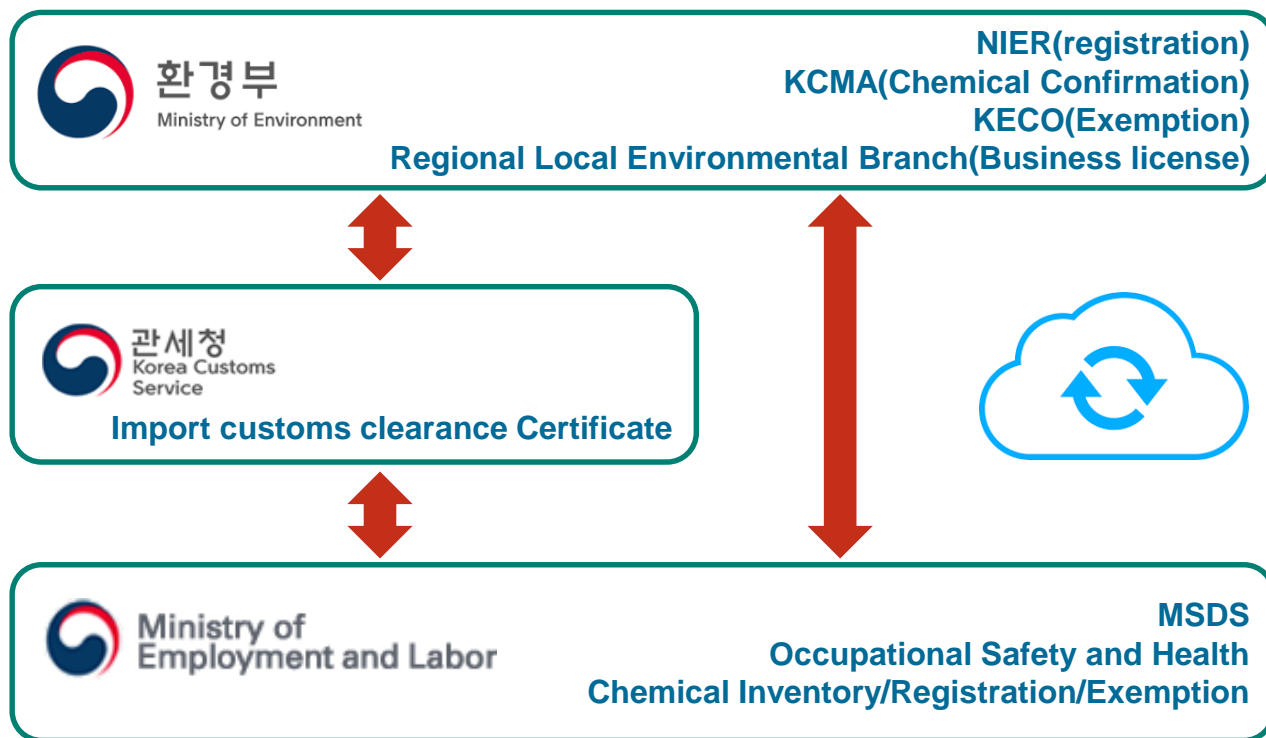
Delivering and sharing of information within supply chain

- ① Anyone who yields chemical substances to the recipients, must pass on information (chemical name, hazard, etc.) used for registration or (pre)notification.
- ② Downstream users must provide information, such as use purpose, exposure, use and sales quantity of chemical substances, in order for the manufacturer or importer to register or to apply for changes in registration.

PENALTY

Penalty

Government Inspection – Potential future plan



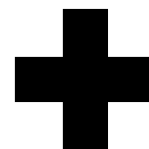
Penalty

Increased penalty

Fine for non-compliance



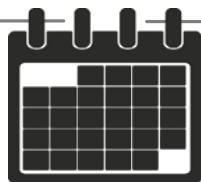
Up to 5% of Sales



Up to USD 100k or
3yrs imprisonment



Significance



Length/Times



Earned Profit



Ability to pay

Strategy for industry compliance

Strategy for industry compliance of K-REACH

1. To help companies comply with K-REACH, it is recommend to be proactive.

Because of the need to pre-notify substances by 30 June or risk a ban, they are encouraged to **establish an internal inventory of chemical substances, to avoid any substance being omitted.**

2. The deadline for pre-notification of existing chemicals exceeding 1ton/year under K-REACH is 30 June 2019. Affected companies should therefore **prepare this well in advance.**

3. For chemical > 1,000 tons/year and CMR substances, the registration deadline is 2021.

Be active and move forward!! And, determine your membership strategically in consortium.

4. There are uncertainties in registration such as taking a long time for purchasing existing data, therefore, companies have to put forth their endeavor to **complete their joint registrations sooner.**

5. Besides, **export's scientific judgement and its ground** are very important when Read-across and (Q)SAR data are submitted, and eventually it will make registrants save **a big registration cost** and will protect animal well-fare by waiving data.

Strategy for industry compliance of K-REACH

6. Therefore, help of experienced specialist in this field is indispensable.

7. Although polymers are subject to registration, a considerable number will not need to be due to the 'low concern polymer exemption'(LCP). It is therefore recommended that industry prepares relevant data to meet the LCP conditions for this.

THANK YOU

Chemtopia provides

- ✓ Only representative
- ✓ Reporting service
- ✓ Registration dossier preparation
- ✓ Consortium management
- ✓ Risk assessment
- ✓ GLP test arrangement
- ✓ Web based K-REACH supporting system
- ✓ Web based GHS creator
- ✓ (Q)SAR



Any questions or concerns, please contact
@ Email: chemtopia@chemtopia.net
Tel: +82-2-826-9100