Chemical Business Association
100 YEARS 1923 - 2023

REACHLAW
COMPLIANCE. SUSTAINABILITY.

25 - 26.10.2023 | DAY 2

Chemical Regulations and Sustainability Symposium 2023

K-REACH: 2024 registration deadline

K-REACH:2024 registration deadline

Table of Content

Duration: 30 min

1. Overview
2. Scope & Requirements
3. Registration Process & 2024 Deadline
4. Cost & Penalties
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Overview

Law & Authorities

LAW

Toxic Chemicals Act
(enacted in 1992)

LIMITATIONS IN THIS ACT:
X Lack of chemical info.
X No system for transferring chemical info.
X Household chemicals in consumer product (e.g., humidifier disinfectant)

The Act on Registration, Evaluation, etc. of Chemicals (AREC'S) a.k.a K-REACH Act No. 18034

- Registration of chemical substance
- Hazard and Risk Assessment
- Authorization substance designation
- Supply chain management communication
- Management of high concerned product (consumer product)
- The use and amount reporting

Chemicals Control Act (CCA) Act No. 13035

- Chemical confirmation process
- Business permit for hazardous chemicals
- Survey on chemicals circulated in the market
- Safety management of hazardous chemicals
- Readiness & Response against chemical accidents

Source: NIER Sept 2023

Existing chemical substances (44510)

New substances

Hazardous Chemical substances (2200)

Subject to intensive control substances (830)

CMR substances (364)

Substances requiring preparation for accidents (99)

Enforced on Jan 1, 2015
Amended on Jan 1, 2019

AUTHORITIES

MOE: Ministry of Environment, Competent Authority

Supported by

NIER: The National Institute of Environmental Research

KECO: The Korea Environment Corporation

Local Environmental Office

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Overview

Role of Authorities & Industries

MOE: Ministry of Environment, Competent Authority

LOCAL ENVIRONMENTAL OFFICE

- Preliminary reporting and reporting confirmation of intensively controlled substances contained in products
- Appointment/dismissal confirmation

KOREA ENVIRONMENT CORPORATION (KECO)

- Confirm exemption from registration, etc.
- Confirmation of exemption from hazard review
- Pre-reporting of existing chemical substances
- Approval for use of test data
- Appointment/dismissal confirmation

Result notification ↑ Application ↓ Result notification ↑ Application ↓

INDUSTRY (MANUFACTURERS, IMPORTERS, APPOINTED PERSONS)

- Submission of reports for each task, such as reporting, registration, registration exemption, reporting of intensively controlled substances, etc.
- Application for approval to use test data

Source: https://kreach.me.go.kr/

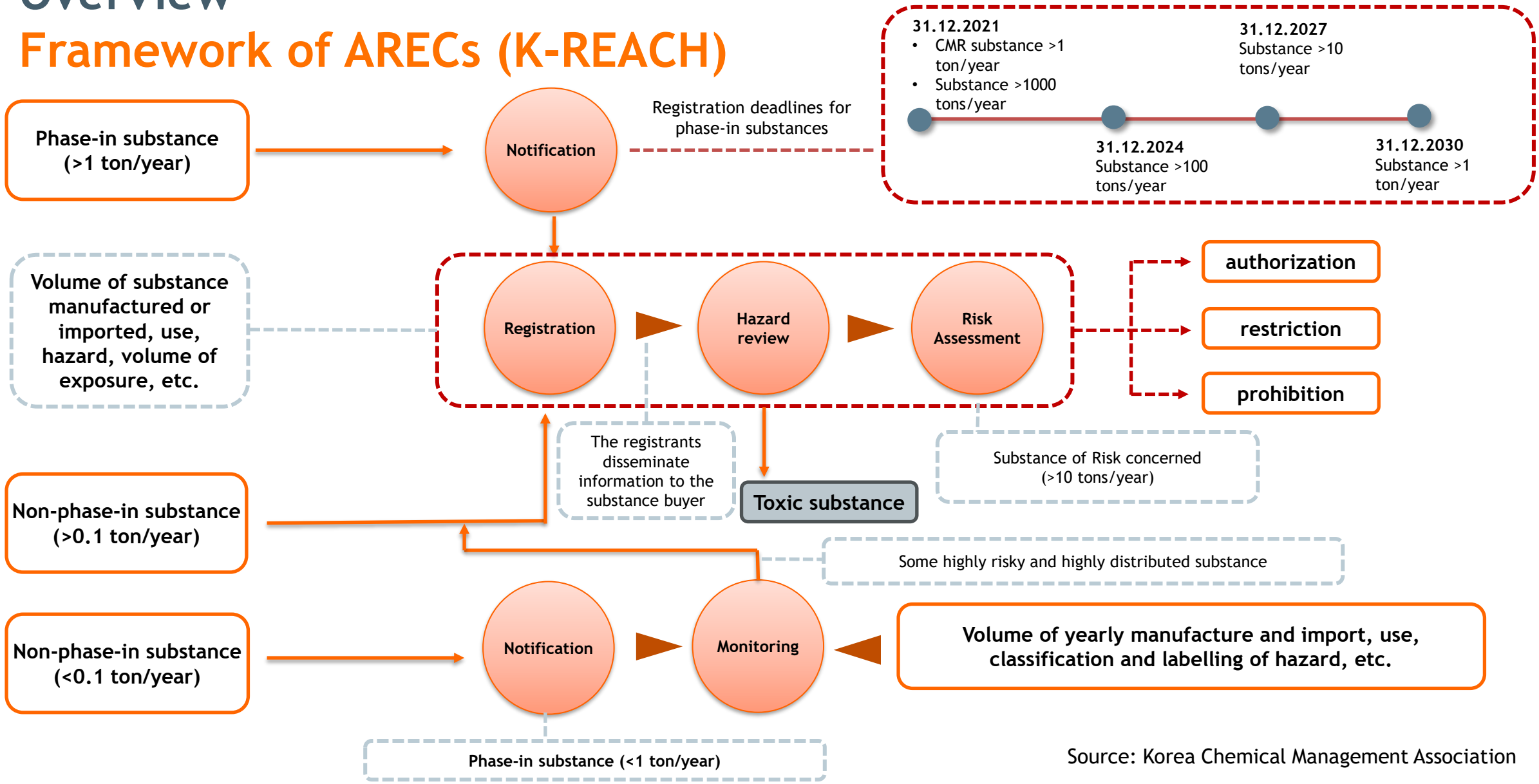
Result notification ↑ Application ↓

NATIONAL INSTITUTE OF ENVIRONMENTAL RESEARCH (NIER)

- **Report/registration of new chemical substances**
- **Registration of existing chemical substances**
- **Hazard screening**
- **Designated as toxic substance**
- **Risk assessment**
- **Appointment/dismissal confirmation**
- **Confirmation of report by person who has undergone hazard review**
- **Confirmation of registration inquiry**
- **Verification of consent to use vertebrate animal test data**
- **Confirm individual submission of registration application**

Overview

Framework of AECs (K-REACH)



Source: Korea Chemical Management Association

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Scope and Requirements

Scope of Application (Act article3)

This Act shall not apply to chemical substances falling under any of the following:

01 Radioactive substances and mixtures

02 Drugs of the Pharmaceutical Affairs Act and quasi-drugs

03 Narcotics

04 Cosmetic products & and raw materials used for cosmetics

05 Pesticides and active ingredients

06 Fertilizers

07 Explosives and Munitions

08 Food, Food additives & Feed

09 Hygiene products

10 Medical devices

11 Health functional foods

12 Biocidal substances and biocidal products

Scope and Requirements
Exemptions

Exemption from registration or notification
Self Declaration

①
1. Imported as imbedded into the machine
2. Imported together with machine or equipment used for test operation
3. Contained in a product that performs a certain function
4. very low risk declared and publicly announced by MoE
    1. Impurities, by-products ETC
    2. Substances existing in nature
    3. Amino acids and its salts

Exemption from registration or notification
Only after confirmation from Authority
within 30 days

②
1. wholly exported overseas
2. Imported to manufacturer another chemical to be wholly exported overseas
3. Used for scientific experiment, analysis or research such as reagents
4. chemical for research and development
5. Some polymer compounds
6. Surface treated substances
7. Non-isolated intermediate
8. Isolated intermediate

② Subject, period and documents of the confirmation of exemption from registration, etc.

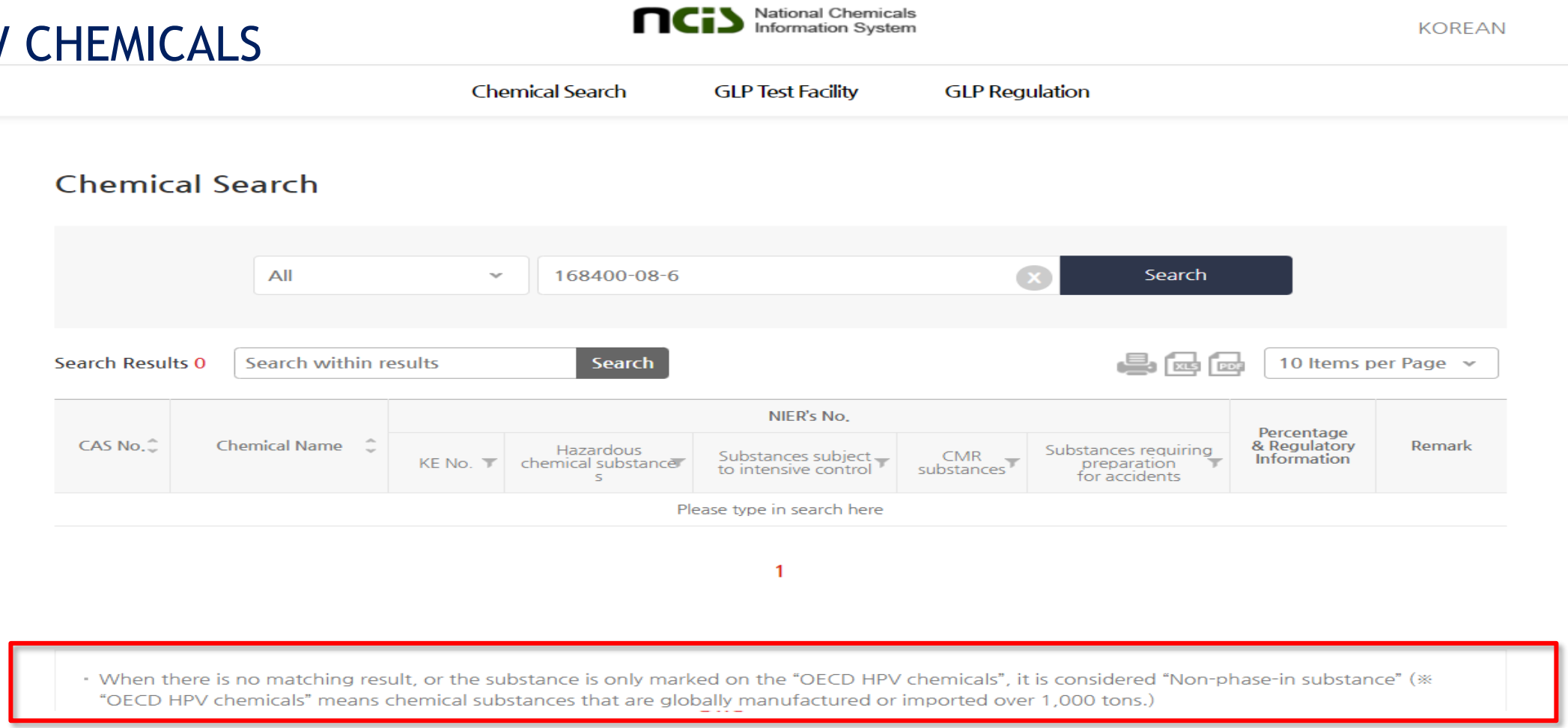
Information Required to submit
- Name, CAS No., and estimated volume of manufacture or import

Subject	Period	Documents to be Submitted
1. A chemical manufactured or imported to be wholly exported overseas	Annual unit	Exporting country and export volume
2. A chemical manufactured or imported in order to manufacture another chemical to be wholly exported overseas		
3. A chemical for scientific experiment, analysis or research such as reagents	first time	Specific uses, duration of testing, analysis, research, photos or brochures of chemicals or products, etc.
4. A chemical for research and development - development, etc. of a chemical substance and product	R&D planning unit	Duration of R&D, research institute, safety management plan (submit the current status of safety managers, follow-up measures, and results of post-processing more than 0.1 ton), etc.
5. Some polymer compounds	first time	Name of the monomers, CAS No. and content ratio (%), test data for number average molecular weight and molecular weight distributions
6. A substance which surface has been treated - Both the target and surface treated materials of surface treatment under any of the following subparagraphs: ①For registered chemicals ②When notified as non-phase-in substances less than 0.1 ton ③For chemicals not subject to registration ④In case of pre-registered phase-in substances within the registration grace period	first time	Registration on surface treated subject and surface treatment substance (registration number or receipt), phase-in substance notification(notification form), non-phase-in substance notification (notification number or receipt) or documents process diagrams, reaction structure formula and surface treatment rates that prove that they are not eligible for registration
7. Non-isolated intermediate	first time	Process diagram, etc.
8. Isolated intermediate whose outflow or leakage is blocked by technical means	first time	Process diagram, methods of blocking outflow and leakage, etc.

Scope and Requirements

How to check your chemical obligations at NIER

NEW CHEMICALS



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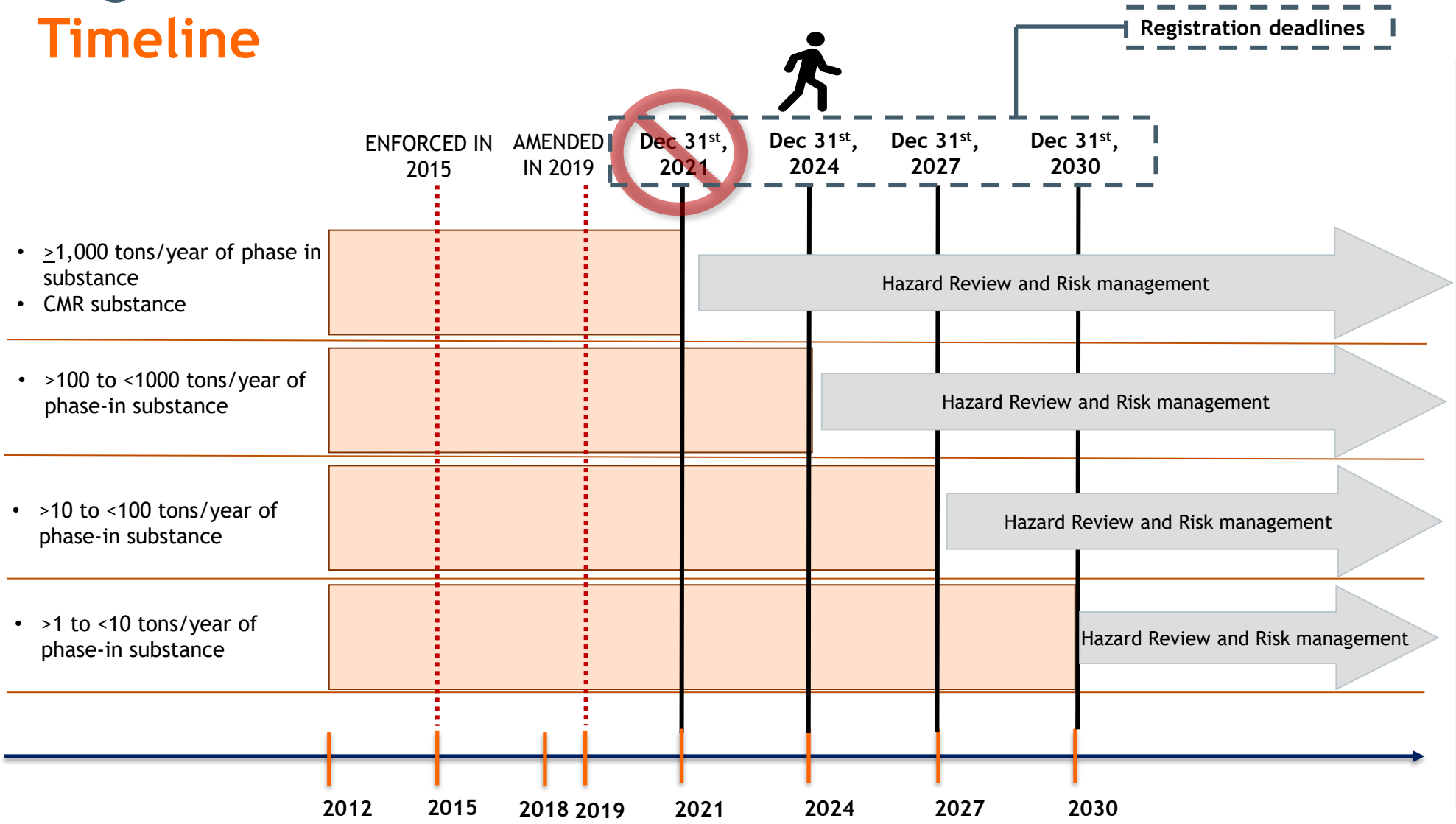
Registration Process & 2024 Deadline

Timeline



Existing: Registration deadline has been passed for >1000tpa, any substance subject to registration will first have to be registered before being placed on the Korea market.

This registration process is initiated with an Inquiry

New Substances registration:

All new substances

@ ≥ 100 kg

@ < 100 kg simply notification is enough

Registration Process & 2024 Deadline

(1) Only Representative (OR) Appointment

Step I

Appoint OR

1. **Receive OR-related documents from overseas manufacturers/ producers**
 - Information on chemicals
 - Copy of OR appointment contract

Step II

Submit OR application

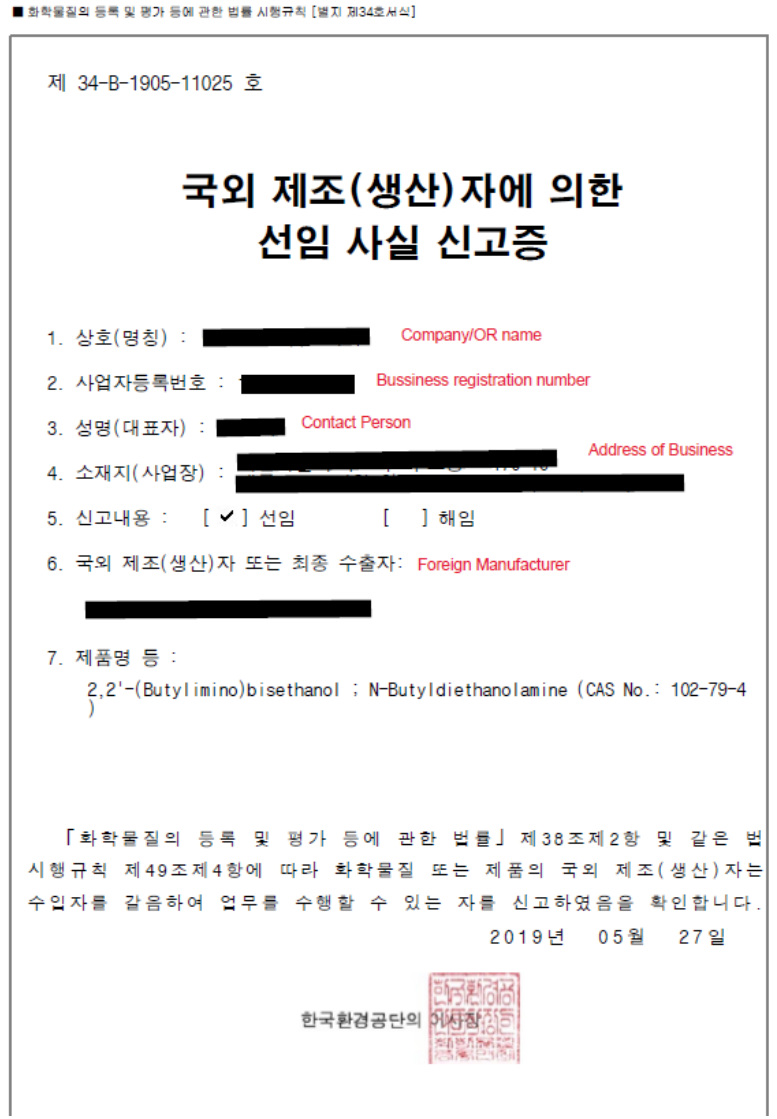
2. **Log-in to the IT system**
 - Chemical Information Process System
3. **Prepare and submit the application** # Required
 #Document proving that OR is a citizen of Republic of Korea or a person domiciled in the Republic of Korea
 #Document proving the appointment such as a copy of OR appointment

Step III

Review & Inform Result (KECO)

4. **Submission (Reject) → Review → OR Appointment concluded**
5. **Inform OR when concluded** (Receipt of OR certificate)

Timeline: 2-3 weeks



■ 화학물질의 등록 및 평가 등에 관한 법률 시행규칙 [별지 제34호서식]

제 34-B-1905-11025 호

국외 제조(생산)자에 의한 선임 사실 신고증

1. 상호(명칭) : [redacted] Company/OR name
2. 사업자등록번호 : [redacted] Bussiness registration number
3. 성명(대표자) : [redacted] Contact Person
4. 소재지(사업장) : [redacted] Address of Business
5. 신고내용 : [✔] 선임 [ ] 해임
6. 국외 제조(생산)자 또는 최종 수출자: Foreign Manufacturer
   [redacted]
7. 제품명 등 :
   2,2'-(Butylimino)bisethanol ; N-Butyldiethanolamine (CAS No.: 102-79-4)

「화학물질의 등록 및 평가 등에 관한 법률」 제38조제2항 및 같은 법 시행규칙 제49조제4항에 따라 화학물질 또는 제품의 국외 제조(생산)자는 수입자를 갈음하여 업무를 수행할 수 있는 자를 신고하였음을 확인합니다.

2019년 05월 27일

한국환경공단의 이사장

OR Appointment Declaration

REACH LAW

Registration Process & 2024 Deadline

(1) OR can perform multiple acts for overseas manufacturers

① Chemical registration, pre-notification and report of change
② Applications for confirmation of exemption and change from registration
③ Registration of changes or reporting of changes
④ Report of intensive control substances contained in products
⑤ Individual submission of data for application for registration of existing chemicals
⑥ Provision of information on registered substance
⑦ Confirmation of whether the owner of vertebrate test data has consented to use the vertebrate test data
⑧ Provision of information dissemination
⑨ Provision of information dissemination on substances contained in products
⑩ Application for data protection request (CBI)

Registration Process & 2024 Deadline

Co-Registration-Joint Registration

2- 3 weeks

2- 3 months

Ongoing

OR Appointment

1

See Slide 14

Pre-Notification *(Late Pre-Registration)*

2

See Figure 2
Include Importer details once OR is appointment and cover his uses

Data Sharing (CICO)

3

- *Most time Consuming work*
- *Start as early as possible to identify Lead Registrant & Cost Sharing Principles*
- *Agree on Dossier Content*

Co-registration

4

See Slide 19

Information Exchange with DU

5

- **Form 27 (Exchange)** *within 1 month from request*
- **Form 26 with MSDS** *submit to DU and keep record for enforcement*

Post registration maintenance

6

- *Dossier maintenance for Changes*
- *Track regulatory updates*

Form 26

1. Chemical safety information provider's name or company name, location and phone number
2. Product name and the name or generic name of chemical
3. Registration number or notification number and Cas No. of chemical
4. Classification and labeling
5. Allowable or restricted use of chemical
6. Physical and chemical properties and the information relating to human health and environmental hazards
7. Summary exposure scenario and the risk information such as risk reduction measures
8. Volume of hazard chemical content if hazard chemical is contained
9. Information concerning safe use of the relevant chemicals, how to deal with an emergency such as fire, how to prevent leakage, and how to dispose the chemical protective equipment, etc.
10. Regulatory information

Form 27

1. Name or company name of the manufacturer or importer
2. Name or generic name and product name
3. The volume of chemicals
4. Available or limited use of chemical
5. Information concerning safe use of the relevant chemical such as how to handle the chemicals, how to deal with an emergency such as fire, how to prevent leakage, and how to dispose the personal protective equipment, etc.
6. Information on the physical and chemical properties and hazard
7. Regulatory information for the relevant chemical

Figure 2 Pre-notification

- Name of chemicals
- Annual volume of manufactured or imported chemical
- Classification and labeling of chemicals
- Use of chemical substances
- Company name, location and contact information of a person who intend to register
- Company name, location and contact information of person who wants to import chemicals (when a person appointed by the overseas manufacturer or producer pre-notifies)
- Company name, location, and contact information of chemical contractors (when consignee pre-notifies)

REACH LAW

Late pre-registration is still possible under certain conditions

Registration Process & 2024 Deadline

Tips to comply with 31.12.2024 Deadline

Appoint OR, Notification & Registration Status

- Appoint your OR
- Notification with Importer details
- Check if lead registrant (LR) is appointed & if correct tonnage is registered by him (>= your exports to Korea)

Joint Registration as Co-Registrant

- Check your substance is same as LR using Substance Identification Test
- Check C&L is same as registered substance
- Obtain use information from importer and confirm
- Check if LoA purchase includes CSR for your uses
- Agree on Letter of Access Fee (LoA) & Execute Data Sharing Agreement covering how future cost or refund is calculated

Post Registration

- Inform your importers of Registration Certificate
- Update your MSDS
- Submit Form No. 27 (eSDS) within one month from the date requested by the Korean importer

Stay upto date with the regulation

- Keep your dossier upto date for changes
- Follow https://kreach.me.go.kr/

Registration Process & 2024 Deadline

Requirements

Requirement	Existing Chemicals (Phase in substances) >1 ton/year	New chemicals (non-Phase in substances) >0.1 ton/year	New chemicals (non-Phase in substances) <0.1 ton/year	Polymer	Intermediates	PEC Substance
Notification	Yes	NA	NA	Yes	Yes	NA
Inquiry	NA	Yes	Yes	NA	NA	NA
Registration	Yes	Yes	Yes	Yes	Yes	Yes
Exemption or Notification without addition procedures	NA	Yes	Yes	Low concern polymer	Non-isolated Intermediates	NA
Form 26 & MSDS (KOSHA)	Yes	Yes	Yes	Yes	Yes	Yes
Record keeping	Yes	Yes	Yes	Yes	Yes	Yes
Mandatory Substance Identification and Quantification Testing	Yes	Yes	Yes	Yes/ Polymer testing	Yes	Yes
Data requirements: See Appendices	Yes	Yes	Yes	Yes	Yes	Yes

Registration Process & 2024 Deadline

(3) Registration Dossier Content

The name, location, and representative person who intends to manufacture or import the chemical

1. Information on manufacturer or importer

2. Information on chemical substance

Information on the identification of the chemical, such as the name, molecular formula, and structural formula of the chemical

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)

- Differentiation by tonnage band & hazard (15 to 47 test items)
(1) High (acute toxicity classification 1~3): 47: *(physicochemical 13, human health 15, environment 19)*
(2) Low (acute toxicity classification 4: upto 33 *(physicochemical 13, human health 15, environment 5)*
(3) Not classified and labeled: 15 in total
- Submission of abstract of test data (English and Korean)*submit full text if owned
See Appendices

5. Physical and chemical properties

6. Hazards

7. Guidance on safe use

8. Risks

- Information under 1 to 7
  - Non-phase-in substance (more than 0.1 ton per year
  - Phase-in substance (> 1 ton per year)
- Information under 8
  - Substances > 10tpa
  - Substance that needs risk assessment as a result of hazard review

Personal protective equipment, first-aid measures, etc. in case of explosion, fire or leakage

Create dossier and submission to Authority

Exposure scenario describing handling, exposure controls, and management measures during the life-cycle of the chemical

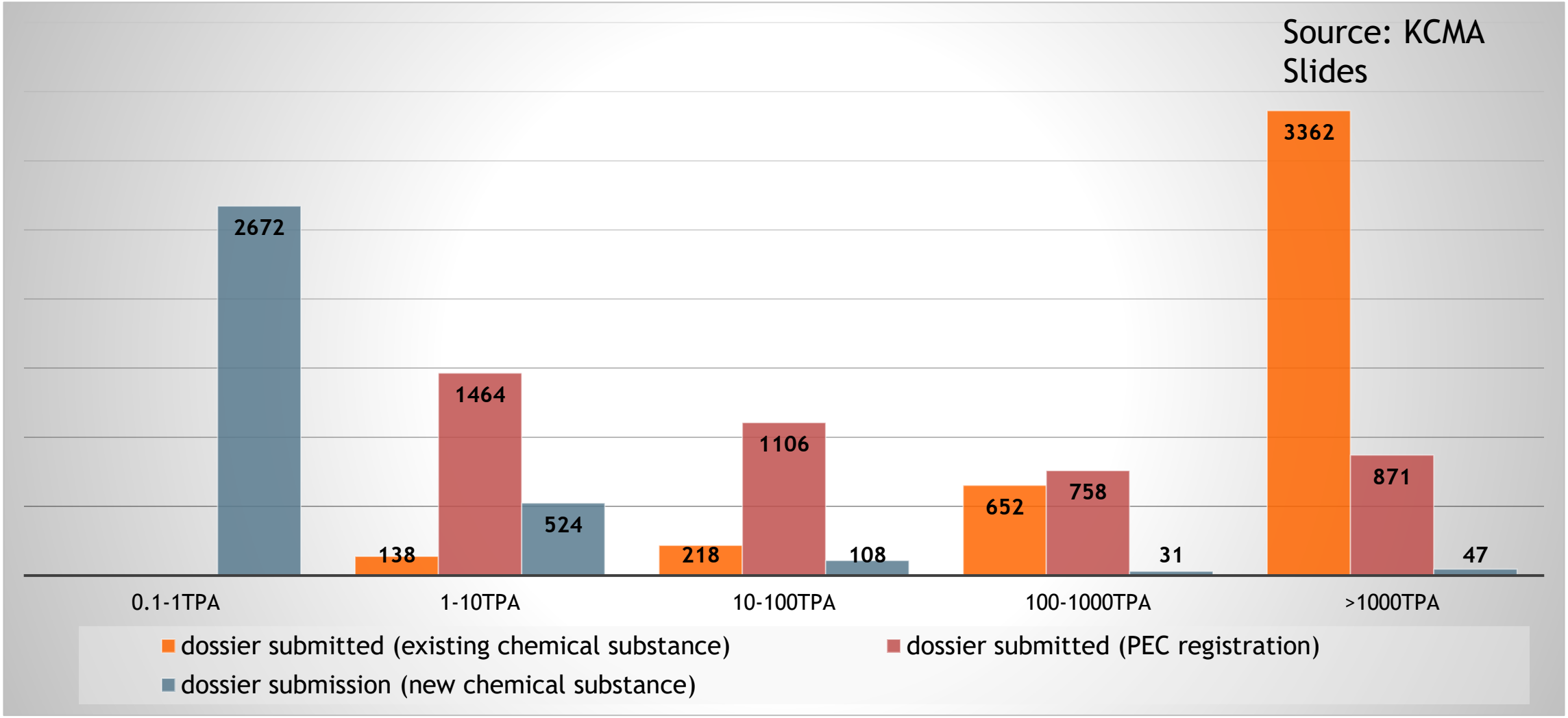
Authority Approval

Covered in Lead dossier

Co-registrant dossier content

Registration Process & 2024 Deadline

Registration Statistics



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Cost & Penalties
Authority Fees

Items	Amount in Korean won	Amount in EUR
Registration and reporting of chemical substances pursuant to Article 10 of the Act 1) Registration of chemical substances 2) Reporting of new chemical substances	 200,000 won 100,000 won	 140 EUR 70 EUR
Confirmation of exemption from registration, etc. of chemical substances in accordance with Article 11 (2) of the Act 1) Confirmation of exemption from registration 2) Confirmation of exemption from reporting	 50,000 won 30,000 won	 35 EUR 22 EUR
Change registration or change report of chemical substances pursuant to Article 12 of the Act 1) Change registration of chemical substances 2) Change report of chemical substances	 50,000 won 30,000 won	 35 EUR 22 EUR

Cost & Penalties

Cost of Registration

Fixed fee per substance

(22 – 140 EUR)

(1) Authority Fees

One-time fee

1. Data Cost
    1. No. of companies registering
    2. Type of submission (registration or exemption)
    3. Tonnage band
    4. Test Data & Chemical Safety Assessment/Report (for uses) to be generated or available
    5. Evaluation
2. Administrative Cost (Finance, Legal, Technical, Project Management, Administration)

(2) LoA/ Data Fees

Subject to the above parameters

One-time fee but of a Dynamic nature

1. Notification service
2. Type of work
    1. Co-Registration
    2. Lead Registration
    3. Exemptions
    4. CBI
    5. CSR/SDS
    6. Dossier updates
3. Annual Maintenance Service
    1. OR Obligations
    2. Communications
    3. Registration

(3) Consultant Fees

Subject to above parameters

Both one-time & Annual

Cost & Penalties
Penalties

Action for non-compliance on registration, etc.(Article 13 of the Act)

- No one shall manufacture, import, use or sell chemicals that have not been registered or notified or have not been classified as a confirmation of exemption from registration, etc.
- MoE can order the manufacturer and importer of the substance to take measures such as suspension of manufacturing, import, use or sales, recovery, and disposal

Penalty and administrative fines (Article 50 -54 of the Act)

- Imprisonment not more than 5 years or Fines not exceeding 100 million won (~70k EUR)
- Imprisonment not more than 3 years or Fines not exceeding 50 million won (~35k EUR)
- Imprisonment not more than 1 years or Fines not exceeding 30 million won (~21k EUR)
- Fines not exceeding 10 million won (~7000 EUR)

Penalty Surcharges (Article 17(2) of the Act)

- Penalty surcharges of less than 2.5 to 5% of the sales may be imposed
- (Calculation method) the amount of penalty surcharges per day × the period for which a person commits an offence

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K-REACH & EU REACH Comparison

Description	K-REACH	EU REACH
OR appointment	Required approval from the authority	No approval from the authority
Pre-registration/Notification	Yes	Yes, but obsolete now
Registration	New chemicals simplified registration required for >=100kg/year new substances. All existing chemical >1 ton/year	New & existing chemicals > 1 ton/year
Registration of Polymers	Not exempted for registration	No, Registration of monomers instead of polymer *(REACH revision seek registration of certain type of polymers)*
Exemptions	Applicant must obtain exemption from authority prior to manufacturing or import	Authority do not invite exemption application – self declaration
Data Requirements	Higher volume, more data requirement Reduced data requirement (classification based)	Higher volume, more data requirement
SDS (Safety data sheet)	Submission to the authority	No submission required

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Conclusions

- Check if your substance is existing chemical and eligible for grace period
- Identify of LR is elected and registration is complete for 2024 deadline substance.
- Decide soon to register as Co-registrant or lead registrant as per your export business.
- Revision of Registration & notification (draft)
  - new chemical substance registration standard
    - (Before) manufacturer-import more than 100kg in a year
    - (After) manufacturer-import more than 1 ton in a year
  - Improve effectiveness of new chemical substances notification
    - Information requirement – source of data
    - Disclosure of data..
- Upcoming plans
  - Proceed with K-REACH rectification: supplementation & revisions
  - Discuss ARECs supplementary decree revision
  - Prepare practical guidance for implementation of the improved regulation

Thank You for Your Attention!

Contact Details

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Appendices

Data requirements : Physio chemical properties

Physio Chemical Properties	<1 t/a	1-10t/a	10-100t/a	100-1000t/a	1000& Above t/a
Physical status					
Water solubility					
Melting/ freezing point					
Boiling point					
Vapour pressure					
Octanol/water coefficient (GLP)					
Relative density					
Granulometry (particle size distribution)					
Flammability					
Explosive property					
Oxidising property					
Viscosity					
Dissociation constant					

Data requirements: Toxicity Test

Toxicity test (GLP)	<1 t/a	1-10t/a	10-100t/a	100-1000t/a	1000& Above t/a
Acute oral toxicity (If exposure route is inhalation then, inhalation toxicity)					
Ames test					
Skin corrosion/ irritation					
Skin sensitisation					
Acute dermal toxicity or acute inhalation toxicity					
Eye irritation/ corrosion					
In vivo mammalian chromosomal aberration test					
In vivo mammalian gene mutation test (micronucleous test)					
Repeated dose toxicity (28d)					
Screening for reproductive/ developmental toxicity					
Additional mutation test (Germ cell mutagenicity etc)					
Repeated dose toxicity (90d)					
Parental developmental toxicity study					
Two generation reproductive toxicity					
carcinogenicity study					

Data requirements : Environmental Toxicity Test

Environmental toxicity test (GLP)	<1 t/a	1-10t/a	10-100t/a	100-1000t/a	1000& Above t/a
Acute fish toxicity					
Ready biodegradability					
Acute daphnid toxicity					
Acute algae toxicity					
Hydrolysis as a function of pH					
inherent biodegradability					
Identification of degradation products					
chronic daphnid toxicity					
chronic fish toxicity					
short-term toxicity to plants					
short-term toxicity to invertebrates (earthworm)					
activated sludge respiration inhibition test					
adsorption/ desorption screening test					
fate and behaviour in the environment					
long-term toxicity testing on plants					
long-term toxicity testing on invertebrates (earthworm)					
additional adsorption/ desorption screening					
Long-term toxicity to sediment organisms					
bioconcentration					