GPC
Global Product Compliance

ICC
Indian Chemical Council

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Global Chemical Regulatory Webinars (Certificate)

How to comply with K-REACH

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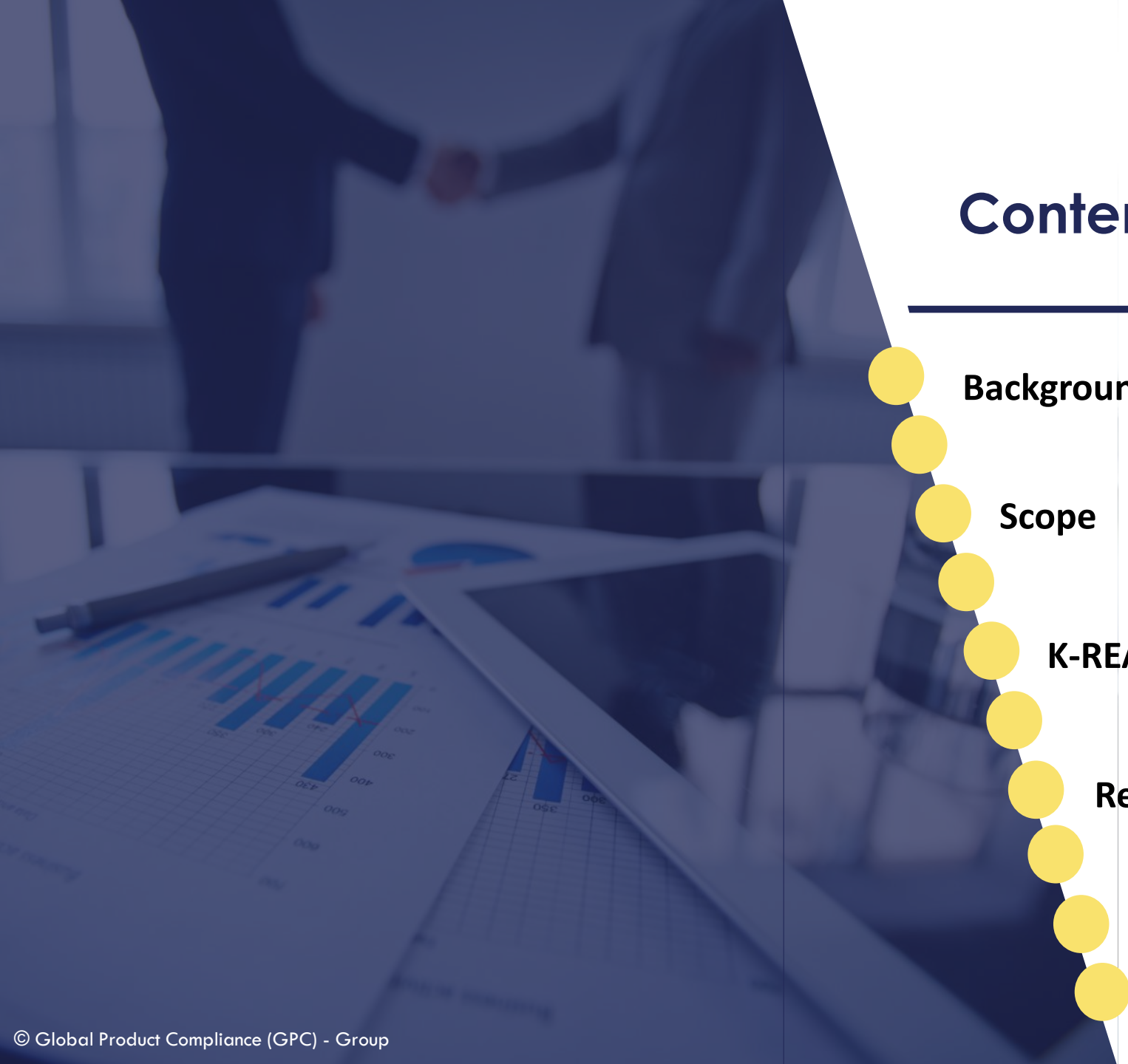
Europe | India | South Korea | Eurasia | Turkey | Taiwan | Australia | Ireland



Contents

Background

- K-REACH: The Act on Registration and Evaluation of Chemical Substances (ARECs)
- enforced on January 1st, 2015
- amendment being effective since October 14th, 2021
- to protect public health and the environment
  - the registration and reporting of chemical substances
  - the review and assessment of hazards and risks of chemical substances
  - the designation of hazardous chemical substances
  - producing and utilizing information on chemical substances

Scope

Existing substance

- Phase-in substance
- Chemical substances that were notified by the Minister of Environment
  - Distributed in Korean market before February 2nd, 1991
  - Had hazard reviews after Feb 2nd, 1991

PEC substance

- Priority Existing Chemicals
- 510 substances that are designated by the Minister of Environment due to its hazards

New substance

- Non-phase-in substance
- All chemical substances excluding phase-in substances

Scope: Exception

Radioactive materials	Nuclear Safety Act
Drugs and quasi-drugs	Pharmaceutical Affairs Act
Narcotics	Act on the Narcotics Control Act
Cosmetics and raw materials used for cosmetics	Cosmetic Act
Pesticides and active ingredients	Pesticide Control Act
Fertilizer	Fertilizer Control Act
Foods, food additives, apparatus, containers and packages	Food Sanitation Act
Feed	Control of Livestock and Fish Feed Act
Explosives	Act on Control of Guns, Swords, and Explosives
Munitions	-Act on the Management of Military Supplies -Defense Acquisition Program Act
Health functional foods	Health Functional Foods Act
Medical devices	Medical Devices Act
Hygiene products	Hygiene Products Control Act
Biocidal substances and biocidal products	Act on Safety Control of Consumer Chemical Products and Biocides

K-REACH obligations

WHO

- Chemical manufacturers and importers in South Korea
- Only Representative (OR) appointed by foreign manufacturers

WHAT

- Pre-registration
- Registration
- Report
- Exemption

WHEN

- Before manufacture or import to South Korea
- Before registration deadline

K-REACH obligations

Registration

- **PEC substances** over 1 ton per year
  - Grace period: June 30th, 2018
  - Before manufacture or import
- Over 100 KG of **new substances** per year
  - No grace period
  - Before manufacture or import
- Over 1 ton of **existing substances** per year
  - Grace period:

Over 1000ton	2021	
100-1000ton	2024	Pre-registration
10-100ton	2027	Pre-registration
1-10ton	2030	Pre-registration

Report

- Less than 100 KG of new substances per year
- New substances that obtained confirmation of exemption from hazard reviews according to “Hazardous Chemical Substance Control Act”
  - Polymers only composed of existing substances and notified by the Minister of Environment
- Product containing priority control substance

K-REACH obligations

No action required exemption

- A chemical substance contained in a machine imported
- A chemical substance imported along with a machine or device used for a test run
- A chemical substance contained in a product performing a certain function in a specific solid form, which does not leak in the process of using the product
- A chemical substance of very low risk designated and publicly notified by the Minister of Environment following deliberation by the Evaluation Committee

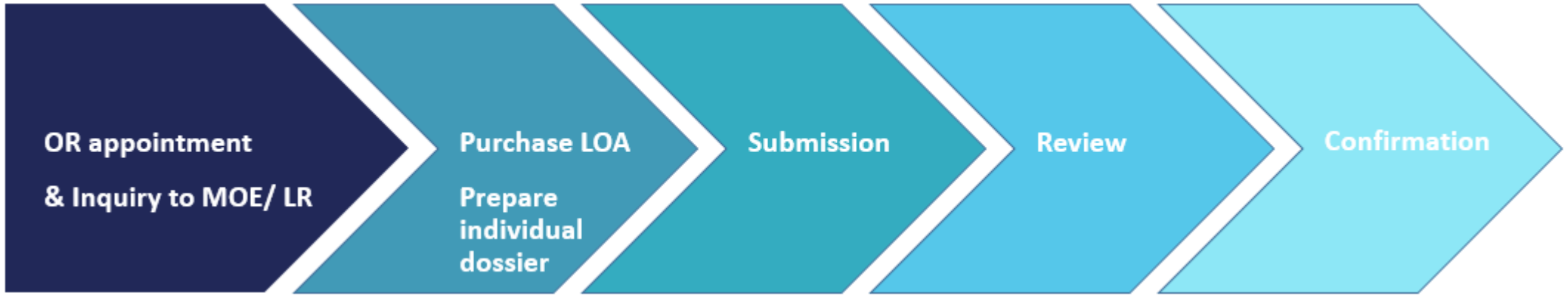
K-REACH obligations

Confirmation required exemption

- A chemical substance manufactured or imported to export the whole amount
- A chemical substance manufactured or imported for manufacturing other chemical substances to export the whole amount of such other chemical substances
- A chemical substance for scientific experiments, analysis or research, such as reagents
- A chemical substance for research and development purposes
- Polymers that meet some conditions
- A chemical substance formed by reacting functional groups on the surface of a substance subject to surface treatment with another substance
- A non-isolated intermediate
- An on-site isolated intermediate, the leakage or exposure of which is blocked by technical means

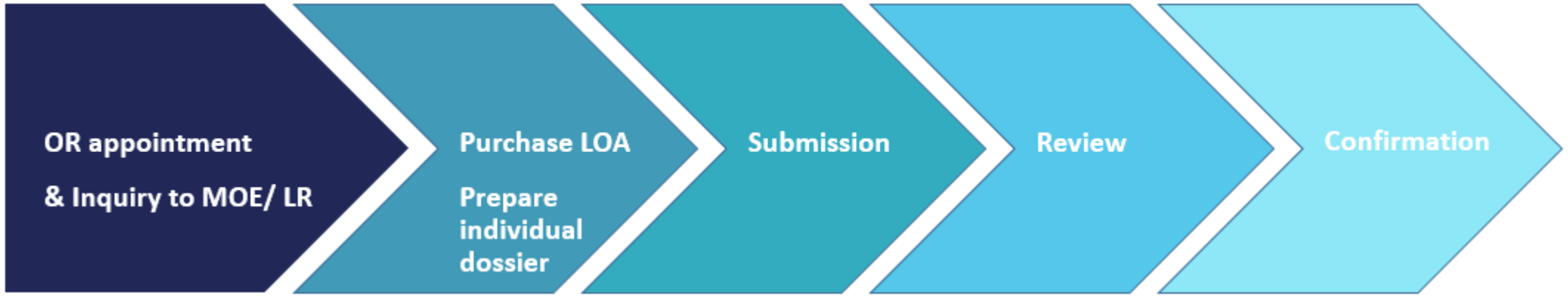
Registration: process

PEC & New substance

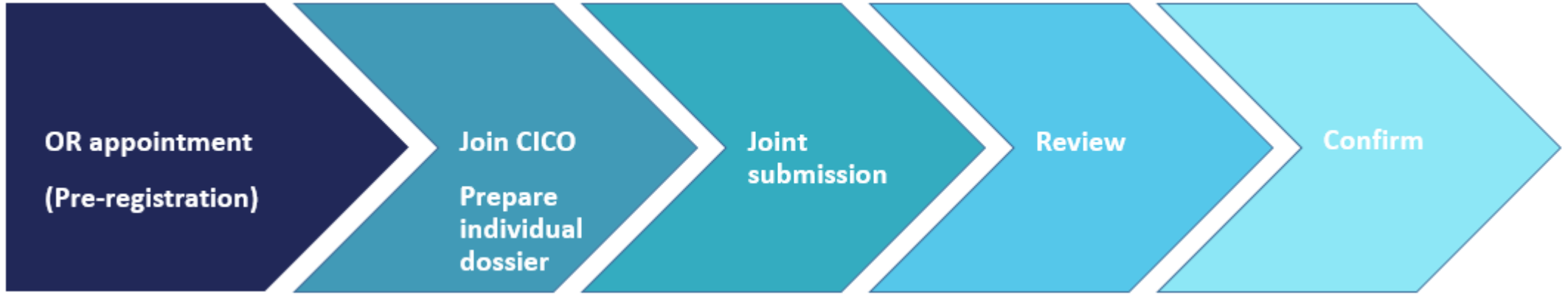


Registration: process

PEC & New substance



Existing substance



Registration: CICO

CICO

- CICO: Chemical Substance Information Communicative Organization
- Similar to EU REACH's SIEF
- For joint submission and sharing the cost

Joint submission	Individual submission
• Classification and labelling • Physical and chemical properties • Hazards of the chemical substance • (Testing plan)	• Risk assessment • Guidance on safe use

Different roles in CICO

LR (Lead registrant)	• Voted by other CICO members • (Designate the CICO manager) • Decision making • Pre-investment for data preparation when the cost is not fixed • Profits from selling LOA to passive members
Active member	• Decision making • Pre-investment for data preparation when the cost is not fixed • Profits from selling LOA to passive members
Passive member	• Purchase LOA • No pre-investment • The price is fixed • Additional cost

Registration: application data

●: Required, ○: According to the applicable condition, △: If owned

Details	Chemical substance	Isolated intermediate	Polymer
Company name, address, representative name	●	●	●
Information on chemical substance; substance name, formula, structure	●	●	●
Use classification of the chemical substance	●	●	●
Classification and labelling of the chemical substance	●	●	●
Physical and chemical properties of the chemical substance	●	●	●
Hazard information of the chemical substance	●	◐	○
Risk information of the chemical substance; including exposure scenario (if 10+ tpa)	○	△	○
Guidance on safe use	●	△	●

◐: In case of transport isolated intermediate

Registration: required data

Volume	1-10 tpa	10-100 tpa	100-1000 tpa	Over 1000 tpa
Category/no of data	**A (15)**	**B (26, including A)**	**C (37, including B)**	**D (47, including C)**
Phys-chem properties	• Physical status • Water solubility • Melting/freezing point • Boiling point • Vapour pressure • Octanol/water coefficient • Density • Granulometry (particle size distribution)	• Flammability • Explosive property • Oxidising property	• Viscosity • Dissociation constant	
Human toxicity	• Acute oral toxicity • Ames test • Skin corrosion/irritation • Skin sensitisation	• Acute dermal toxicity/acute inhalation toxicity • Eye irritation/corrosion • In vitro mammalian gene mutation test (micronucleus test) • In vivo Mammalian genotoxicity • Repeated does 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
Environmental toxicity	• Acute fish toxicity • Ready biodegradability • Acute daphnia toxicity	• Acute algae toxicity • Hydrolysis as a function of pH	• Inherent biodegradability • Identification of degradation products • Chronic daphnia toxicity • Chronic fish toxicity • Short-term toxicity to plants • Short-term toxicity to invertebrates (earthworm) • Activated sludge respiration inhibition test • Adsorption/desorption screening test	• Additional information regarding fate and behavior 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 • Bio-concentration

* Some data can be exempted depending on hazard information

Registration

Reporting of change

- Trade name, name, location of registrant
- Representative of registrant
- Importers (if registered by an OR)

➢ Report in 1 month

Registration of change

- Increased tonnage band (in 1 month)
- Usage (in 1 month)
- Hazard and risk information (in 6 month)
  - Changes in hazard information that might occur changes in classification and labelling
  - Changes in risk information that might affect human health or environment

Summary

WHO

- Chemical manufacturers and importers in South Korea
- Only Representative appointed by foreign manufacturers

Existing substance

- Registration
- Over 1 ton

Over 1000ton	2021
100-1000ton	2024
10-100ton	2027
1-10ton	2030

PEC substance

- Registration
- Over 1 ton
- Before manufacture or import

New substance

- Registration
- Over 100 KG
- Before manufacture or import

- No action required exemption
- Confirmation required exemption
- Check application data requirements based on substances - data exemption

Thank You!

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