

Introduction to Korean-REACH



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K-REACH Objectives



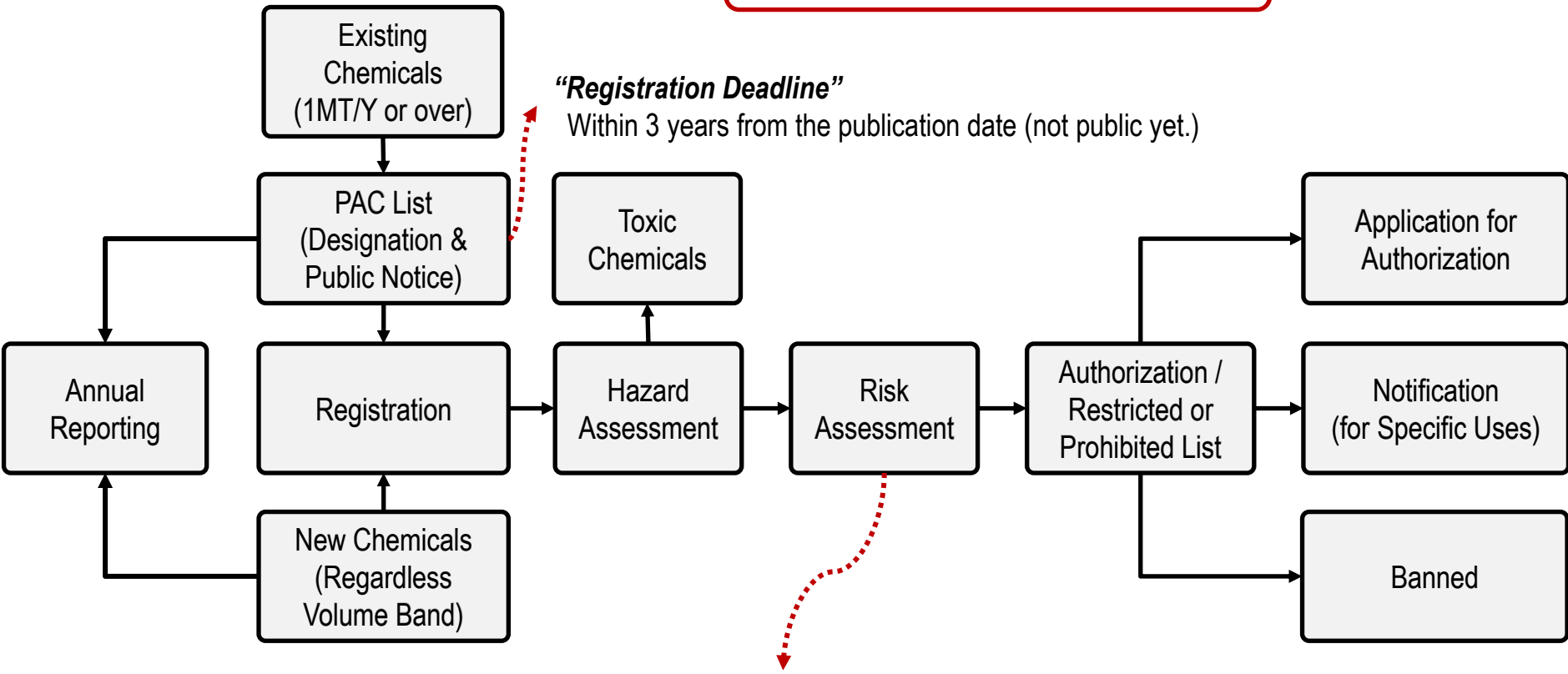
Chemicals in household products have remained a gray area of chemical management in Korea, because many of them are registered as existing chemicals and used without any type of chemical risk assessment. (Ref. Lee et al., Fatal Misuse of Humidifier Disinfectants in Korea: Importance of Screening Risk Assessment and Implications for Management of Chemicals in Consumer Products, 2012)



- ❖ Preliminary assessment of chemicals which may have potential risk to public health and environment, and obtain hazard and risk information prior to market distribution.
- ❖ Protection of public health and environment from chemical accidents and risks in unidentified chemical substances through 'No Data, No Market' principle
- ❖ Enhance national competitiveness through regulatory process that aims to use and develop environmental friendly alternatives

K-REACH Outline

PAC: Priority Assessment Chemical
corresponding to "Phase-in substance(s)
subject to registration"



"Registration Deadline"
Within 3 years from the publication date (not public yet.)

"Deadline for Submission of Risk Information based on Volume Band"



K-REACH Exemption

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

- **Radioactive substances** of the Atomic Energy Act;
- **Pharmaceuticals and non-pharmaceutical drugs** of the Pharmaceutical Affairs Act;
- **Narcotics** of the Act on the Control of Narcotics;
- **Cosmetics** and materials of the Cosmetics Act;
- **Ingredients and agrochemicals** of the Agrochemicals Control Act;
- **Fertilizers** of the Fertilizer Control Act;
- **Food, food additives, tools, containers and package** of the Food Sanitization Act;
- **Livestock feeds** of the Act on Control of Livestock and Fish Feeds;
- **Ammunitions** of the Act on the Control of Firearms, Swords, Explosives;
- **Military supplies** of the Act on the Management of Military Supplies and of the Defense Acquisition Program Act;
- **Health functional food** of the Health Functional Food Act;
- **Medical devices** of the Medical Device Act.

K-REACH Definition

- **Chemical substance(s)**
 - Any chemical element and/or compound, any substance obtained through artificial reactions thereto, and any substance obtained by chemical modification, extraction, or purification of a substance that exists in nature;
- **Preparation(s)**
 - Any substance or solution composed of two or more substances;
- **Phase-in substance(s)** means any of the following:
 - Chemical substances domestically distributed for commercial purposes prior to February 2, 1991 and publicly announced by the Minister of Environment after consultation with the Minister of Employment and Labor; or
 - Chemical substances examined with respect to hazards after February 2, 1991 pursuant to the former Toxic Chemicals Control Act and publicly announced by the Minister of Environment.
- **Non-phase-in substance(s)**
 - All chemical substances excluding phase-in substances;
- **Phase-in substance(s) subject to registration**
 - Phase-in substances deemed necessary to register for the purposes of the hazard examination or the risk evaluation and publicly announced by the Minister of Environment after deliberation of the Chemical Substance Evaluation Committee.

Phase-in = Existing
Non-phase in = New

K-REACH Definition Cont'd

- **"Product(s)"** means any of the following that are final consumer goods, or parts or accessories thereof, and are likely to expose consumers to chemical substances:
 - A product consisting of a preparation; and/or
 - A product functioning in a specific solid form and not releasing any chemical substance therein when used.
- **"Product(s) of concern over risks"** means any of the following chemical products that the Minister of Environment notifies, after consultation with the head of an appropriate central administrative agency, as likely to pose a risk to public health or the environment:
 - Products used by general consumers mainly as household items such as cleaners, air fresheners, adhesives, polishes, deodorizing agents, synthetic detergents, bleaching agents, and fabric softeners; or
 - Products used to kill or disturb/hinder the activity of harmful living things, except humans and animals, such as insect repellents, disinfectants, and preservatives.
- **"Downstream user(s)"**
 - A person who uses a chemical substance or preparation in the course of business activities (in the case of a corporation, it shall be limited to a legal entity that is established in Korea) with the exception of a person who manufactures, imports, or sells chemical substances or preparations, or consumers.

Polymer to be registered itself
rather than its monomer(s).

K-REACH Definition

- The definition of (general) polymer under Korean REACH is equal to OECD's one that allows the 2% rule.
- For registration of polymer to have the K-REACH compliance, polymer characteristics data as well as toxicity data are required as follows:

Tonnage	TCCA (Before 2015)	Korean REACH (as of 2015)
1 – 10 tpa		Polymer characteristic properties <ul style="list-style-type: none"> – Physical state – Water solubility – Mp, Bp, Vapour Pressure
10 – 100 tpa	Polymer characteristic properties such as: <ul style="list-style-type: none"> • Monomer's chemical name, • CAS No and Composition; • Molecular Weight and its distribution test data; • wt% of unreacted material; • wt% of Mw less than 1000; • Stability test in acidic/ alkaline solution 	<ul style="list-style-type: none"> – Dataset for 1 – 10 tpa plus – Acute oral toxicity (inhalation) – AMES test – Short-term toxicity test on fish – Ready Biodegradation
100 – 1000 tpa		Data requirements for 1 – 10 ton of non-polymer registration (Next slide)
+ 1000 tpa	<p style="text-align: center;">Commonly requirely regardless its tonnage band</p>	Data requirements for 10 – 100 ton of non-polymer registration (Next slide)

Test Category (Physic./ Tox./ Ecotox.)

Higher Cost and Time spent in K-REACH compared to TCCA

Test Requirement	Korean REACH					TCCA		
	0.1 – 1	1 – 10	10 – 100	1000	+ 1000	Simple	< 1	> 1
▶ Physical State	X	X	X	X	X			
▶ Melting Point	X	X	X	X	X	X	X	X
▶ Boiling Point	X	X	X	X	X	X	X	X
▶ Vapor Pressure	X	X	X	X	X	X	X	X
▶ Water Solubility	X	X	X	X	X	X	X	X
▶ Partition coefficient n-octanol/water		X	X	X	X	X	X	X
▶ Relative Density		X	X	X	X	X	X	X
▶ Granulometry		X	X	X	X			
▶ Flammability			X	X	X			
▶ Explosive properties			X	X	X			
▶ Oxidising properties			X	X	X			
▶ Viscosity				X	X			
▶ Dissociation constant				X	X			
▶ Acute toxicity	X	X	X	X	X	X	X	X
▶ Irritation	X	X	X	X	X			X
▶ Sensitization		X	X	X	X			X
▶ Mutagenicity	X	X	X	X	X	X	X	X
▶ Repeat dose toxicity			X	X	X			
▶ Carcinogenicity					X			
▶ Reproductive toxicity			X	X	X			
▶ Aquatic acute toxicity	X	X	X	X	X			X
▶ Effects on terrestrial organisms				X	X			
▶ STP Microbial Toxicity				X	X			
▶ Toxicity using spiked sediment					X			
▶ Degradation			X	X	X		X	X
▶ Bio-accumulative				X	X			
▶ Adsorption/ Desorption					X			

Exemption from Registration

- Low Volume Exemption (LVE) less than 1 ton per year for existing substance
- Imported chemical equipped in machinery
 - Imported chemicals with machinery or equipment for R&D purposes
 - The substance contains in finished article (product) but does not released during its uses
- Manufactured or imported only for export up to 10 ton per year
- Chemical reagent for R&D purposes

TCCA

- ▶ Non-ionic polymers with $M_w > 10000$
- ▶ Polymers with $M_w > 1000$ contain any monomer neither new or toxic chemical.

K-REACH

- ▶ Polymers with $M_w > 1000$ and Content of oligomer with $M_w < 500$ is less than 2 wt%
- ▶ Polymers with $1000 < M_w < 10000$ and Content of oligomer with $M_w < 500$ is less than 10 wt% and Content of oligomer with $M_w < 1000$ is less than 25 wt%

Except for:

- ▶ Cationic polymer (excluding cationic polymer, that is neither water soluble nor dispersible in water, is only used in solid phase.)
- ▶ Polymer with $M_w < 10000$ contains hazardous chemical, epoxy compound, aziridine compound or new chemical as monomer with more than 2 wt%.

Application for exemption to KCMA is required.

K-REACH Registration

- K-REACH is valid only for Korean manufacturers and importers.
 - An Only Representative can be appointed by a non-Korean manufacturer to manage and cover imports.
 - Downstream users shall provide him/her with information on the substance being used and/or sold such as its use, exposure, quantity used and/or sold, and instructions for safe use thereof.
 - If the total quantity of a hazardous chemical substance contained in a product exceeds one ton a year, the person who produces or imports such product shall declare to the Korean Ministry of Environment about the name, content, hazard information, and use of the hazardous chemical substance contained in the product prior to production or import.
 - Polymers itself need to be registered under K-REACH.
- From the aspects in time and cost, **we advise companies producing a new chemical substance conduct notification under TCCA (Toxic Chemical Control Act) before enforcement of Korean REACH.**
- The data/information for registration application that were registered more than 15 years ago may be utilized without the consent of the owner.

K-REACH Registration

Registration – Information to be submitted

- Name, location, and representative of a person who intends to manufacture or import the chemical substance;
- Identification information of the chemical substance such as name, molecular formula, structure, etc.;
- Use;
- Classification and labeling;
- Physical and/or chemical properties;
- Information on the hazards;
- **Information on risks of the chemical substance** including the method of handling throughout the life cycle and the exposure scenario describing the method of control and management of exposure. (This shall apply only to the case where the intended manufacturing and/or import quantity of the chemical substance is more than 10 tons per year.);
- Information pertaining to the guidance on safe use (e.g. protective equipment, emergency measures for explosion, fire, or leak); and
- Other information determined by the Ordinance of the Ministry of Environment.

K-REACH Registration

Deadlines of Risk Assessment Report

- MoE shall evaluate the risk of any chemical substance falling under any of the following subparagraphs, among the chemical substances registered based on the result of the hazard examination thereof, and notify the registrant of the result of such risk evaluation:
 - Chemical substances of which manufacturing and/or import quantity is more than 10 tons per year; or
 - Chemical substances deemed necessary to make risk evaluation based on the result of hazard examination.
- If necessary for the risk evaluation, the MoE may order a registrant to submit information required for the risk evaluation.
- The deadlines of submitting risk assessment report depend on annual tonnage.

Tonnage	Enforced date
More than 100 tons a year	1st Jan 2015
70 – 100 ton per year	1st Jan 2017
50 – 70 ton per year	1st Jan 2018
20 – 50 ton per year	1st Jan 2019
10 – 20 ton per year	1st Jan 2020

Example

12 MT/A of Existing Chemical Substance on the 1st PAC List

I Registration

A substance on the 1st PAC list should be registered within 3 years from the date of publication of the list by NIER/ MoE. Required information is as follows:

- Registrant (Should be located in Korea)
- Chemical Substance Identification
- Uses
- C&L
- Physchem. Properties (Max. 12 tests studies required.)
- Hazard information (Max. 34)
- Guidance on Safe Use
- Other information specified in Ministerial Decree

II Risk Assess.

Submission for a substance over 10MT/A is due by 2020.

III Annual Report.

A company should annually report production/import volume and use information in a standard format to KCMA/ NIER/ MoE

The first annual report will be required in 2016 (April)
for the business in 2015 as the enforcement year of K-REACH.

K-REACH Registration

Registration - Joint Submission

- Similar to EU REACH, Korea REACH also requires joint submission:
- Hazard data will be submitted by a lead registrant on behalf of other registrants and joint registrants will submit their own dossier individually;
- Any person who intends to submit a registration later may use registration data submitted by another applicant after obtaining the owner's permission;
- Any person who intends to submit a registration may inquire the MoE about previous registration data of the same chemical substance;
- Individual submission(or opt out) is possible when:
 - Exposure of CBI causes commercial damage;
 - Joint submission costs more than individual submission;
 - Other cases are listed in Presidential Decree;
- However, a “Confirmation of Individual Submission” from the Ministry of Environment (MoE) is required for individual submission.

K-REACH Registration

Registration - Fee

- A person who intends to conduct any of the following activities shall pay fees prescribed by the Ordinance of the Ministry of Environment:
 - Registration of chemical substances;
 - Confirmation of registration exemption for chemical substances;
 - Registration of changes in chemical substances;
 - Approval for use of the findings of hazard evaluation;
 - Declaration of products containing hazardous chemical substances; and/or
 - Confirmation of declaration exemption for products containing hazardous chemical substances.
- Exact amount is not available yet, but amount will vary by volume band, company size and submission channels (joint/ individual) etc..

Annual Reporting

- (Article 8) A company manufacturing, importing or selling new chemical and existing chemical substances (exceeding 1 ton per year) shall report its amount and use etc. to the MoE by **every end of April** as follows:

	K-REACH	Japanese CSCL
Applicant	<ul style="list-style-type: none"> – Manufacturer; – Importer (Only Representative) or; – Seller 	<ul style="list-style-type: none"> – Manufacturer; – Importer
Cut-off (Annual Volume)	<ul style="list-style-type: none"> – Existing chemical > 1 ton per year – All new chemical substance (no cut-off) 	1 ton per year
Cut-off (Composition)	No cut-off	<ul style="list-style-type: none"> – 10% for general chemical – No cut-off for priority chemical
Use category	65 Categories	50 Category and 280 Sub-category
Reporting contents	<ul style="list-style-type: none"> – Applicant information – Chemical information – Amounts produced, imported or sold – Use category of the chemical – Specific use 	<ul style="list-style-type: none"> – Applicant information – Chemical information – Amounts produced, imported and shipped – Use category of the chemical – Specific use
Exemption from annual reporting	<ul style="list-style-type: none"> – R&D chemicals – Imported chemicals equipped in machinery – Imported chemicals with machinery or equipment for its trial operation – Substances contained in a finished article, but not released during its use – Non-isolated intermediate 	<ul style="list-style-type: none"> – R&D chemicals – Imported chemicals equipped in machinery – Imported chemicals with machinery or equipment for its trial operation – Substances contained in a finished article, but not released during its use – Non-isolated intermediate

K-REACH Evaluation

Evaluation

- The MoE shall evaluate the hazards of a chemical substance deemed necessary to carry out hazard evaluation, including chemical substances that Korea is required to evaluate among the chemical substances of which hazards are to be evaluated by an international agency:
 - A person who intends to use the outcome of hazard evaluation for the registration of chemical substances or application for hazard examination subject to foreign country's laws (e.g. EU REACH CSR) shall obtain the approval of the Minister of Environment therefor.
 - Matters necessary for approval of the use of results of hazard evaluation shall be prescribed by the Ordinance of the Ministry of Environment.
- Based on the result of hazard assessment and risk assessment, substances may be put into the following categories after evaluation:
 - Toxic substance
 - Authorization substance
 - Restricted substance
 - Prohibition substance

K-REACH Evaluation

Evaluation – Substance Categories

- **Toxic substance**
 - Hazardous chemical substances as determined and publicly announced by the Minister of Environment in accordance with the standards
- **Authorization substance**
 - Any chemical substance deemed to pose a risk that the Minister of Environment publicly announces after consultation with the head of an appropriate central administrative agency and deliberation of the Chemical Substance Evaluation Committee in order to have such substance manufactured, imported, or used with the authorization of the Minister of Environment;
- **Restricted substance**
 - Any chemical substance deemed to pose a high risk that the Minister of Environment publicly announces after consultation with the head of an appropriate central administrative agency and deliberation of the Chemical Substance Evaluation Committee in order to prevent such substance from being manufactured, imported, sold, stored/preserved, transported, or used for such purpose;
- **Prohibition substance**
 - Any chemical substance deemed to pose a high risk that the Minister of Environment publicly announces after consultation with the head of an appropriate central administrative agency and deliberation of the Chemical Substance Evaluation Committee in order to prohibit such substance from being manufactured, imported, sold, stored/preserved, transported, or used for any purpose.

K-REACH Communication

Supply Chain Communication

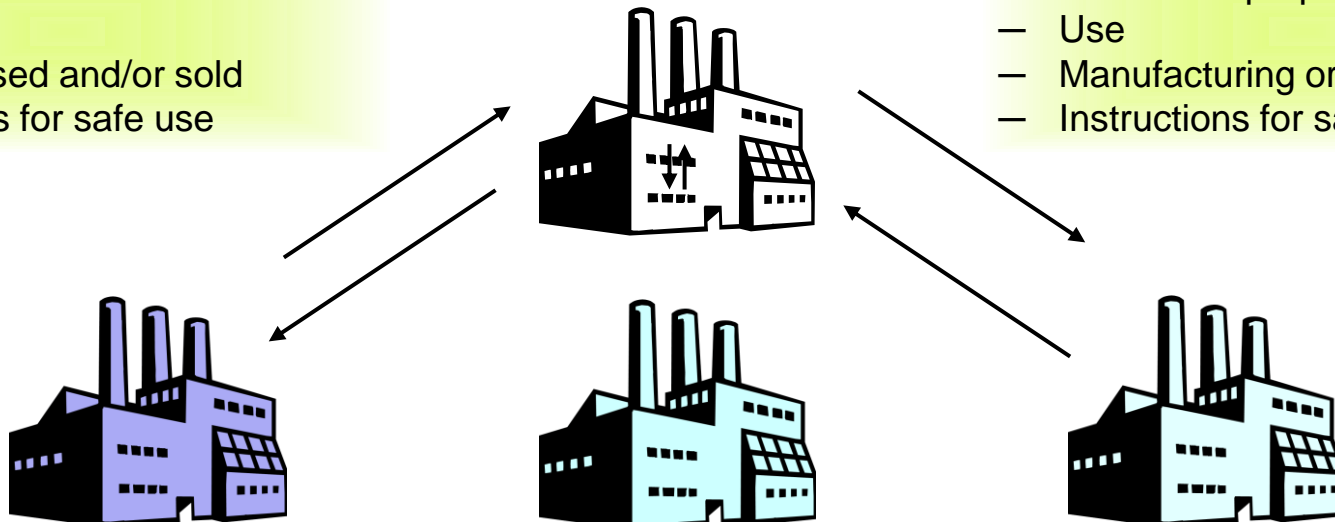
- Upon request of a manufacturer or importer of a chemical substance or preparation for the purpose of reporting on manufacturing, etc. and registration, a downstream user and a seller of such chemical substance or preparation shall provide him/her with information on the substance being used and/or sold such as its use, exposure, quantity used and/or sold, and instructions for safe use thereof.
- Upon request of a downstream user and a seller of a chemical substance or preparation, a manufacturer or importer of such chemical substance or preparation shall provide him/her with information on the substance such as its properties, use, manufacturing or import quantity, and instructions for safe use thereof.

Down to Up:

- Use
- Exposure
- Quantity used and/or sold
- Instructions for safe use

Up to Down:

- Substance properties
- Use
- Manufacturing or import quantity
- Instructions for safe use



Only Representative

(Article 38) A company manufacturing chemicals outside Korea shall appoint Only Representative (OR) as their importer to fulfill the legal obligations under K-REACH as follows:

- Annual Reporting and its update
- Registration Application
- Inquiry of registration status
- Confirmation of individual submission
- Supply Chain Communication

Supplier
(Only Representative)

Registration Information
in MSDS



Use, exposure, amount,
safe use info. etc.

Downstream User/ Distributor
(Only Representative)

- Product notification
- Exemption Application
- Hazardous communication
- CBI application
- Consortia Representation

- OR shall be notified to Korean MoE with specific documentation that approves OR's qualification and business experience at least 3 years in handling chemical information.

K-REACH Challenge

Uncertainties

- Availability of existing data (e.g. from EU-REACH)
- When 1st PAC (Priority Assessment Chemical Substances) list becomes public?
- New IT Tool applied to K-REACH rather than using IUCLID 5
- Some core elements of EU-REACH not present (e.g., SIEF, Consortia)
- No guidance documents available yet
- No data sharing rules available
- No details on annual reporting (volume tracking) available
- Indirect imports into Korea?

K-REACH Services of Chemservice

- Monitoring of K-REACH Legislation
- Acting as Only Representative for non-Korean Manufacturers
- Consortia Building & Representation
- Exemption Verification (e.g. for Polymers with KCMA)
- Communication with Value Chain and Regulators
- Use Clarification and Assignment (65 Categories)
- Annual Reporting
- Data Gap Analysis
- Robust Study Summaries (in Korean)
- Dossier Preparation
- Korean SDS & Label creation

➤ **Your existing established EU contacts will be your interface for K-REACH implementation !**