K-REACH:
How to *reach* it?

Sookie Hong
3E Company
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Content: K-REACH

- Regulatory Landscape
- Requirements in Details
  - Exclusions/Exemptions
  - Report, Registration, and Notification
  - Data for hazard evaluation or risk assessment
  - K-REACH and GHS
- Draft Amendments
- Regulatory Timelines and Forecast
- Conclusion

Korea REACH

- "K-REACH" (Act on Registration and Evaluation of substances (aka "AREC") – Ministry of Environment (MoE))

K-REACH

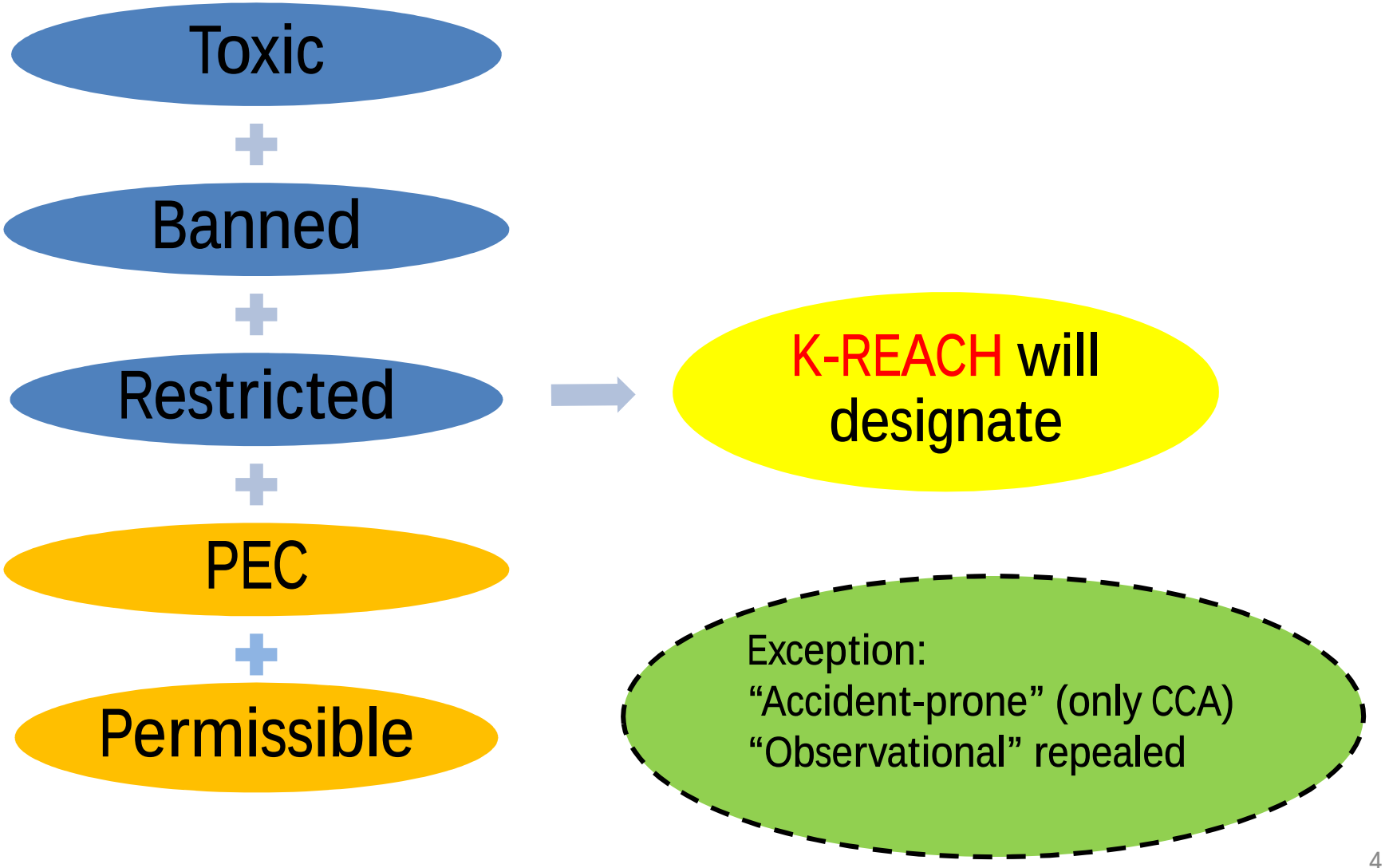
- Risk assessment/preventive control (pre-market)
- Designation of hazardous substances (toxic, banned, restricted)

TCCA à CCA

- Hazardous substances management (licensing, inspection)
- Response to emergency/chemical accidents

  – New chemical notification under TCCA removed
  – Hazard testing under TCCA transferred to K-REACH

Chemical Lists Designated by K-REACH



K-REACH Legal Framework

- Act on Registration and Evaluation of substances ("AREC")
  - Presidential Decree stipulates:

    Grace period of existing chemical registration

    Exempted substances for R&D (i.e. reagents, non-isolated intermediate, low-risk polymer, etc.)

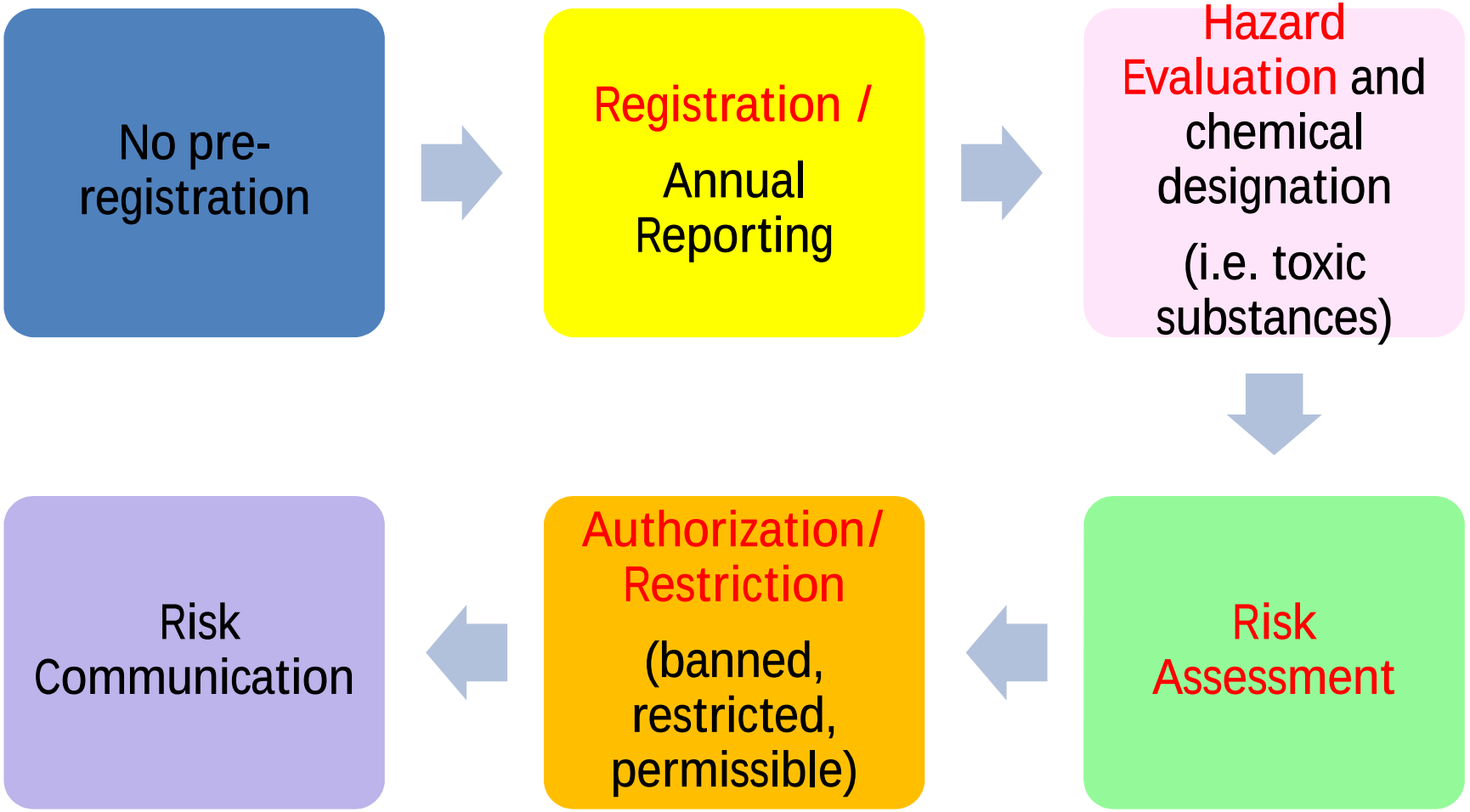
  - Ministerial Decree specifies:

    Required documents for registration exemption application, required test data, hazard assessment methods, content of risk communication, etc.

  - Guidance and Notices provides:

    Product notification, data and cost sharing, chemical "confirmation" requirement, classification/labeling, registration dossier, testing method, data protection, etc.

K-REACH Overview



K-REACH: Requirements (1)

Requirements	Act of K-REACH (May 22, 2013)
Reporting Requirement	(Art. 8) • Importers, Manufacturers, and Sellers (excluding users) • Quantity AND Use Report • All new substances and ≥ 1 ton/year for existing substances • Every year
Registration	(Art. 9 - 17) • Importers, Manufacturers • All new substances • ≥ 1 ton/year for designated existing substances • < 1 ton if considered hazardous to human health or environment
Risk Assessment	(Art. 24) • ≥ 100 ton/year initially • ≥ 10 ton/year after year 5 (i.e., 2020)

K-REACH: Requirements (2)

Requirements	Act of K-REACH (May 22, 2013)
Risk Communication (SDS, chemical properties, use, exposure scenario, and safe use guidelines, quantity of use/sale, etc.)	(Art. 29 - 30) • End user and seller **ó** manufacturer and importer (Optional for downstream user "upon request by manufacturer or importer" (Art .30))
Product Notification	(Art. 32 - 37) • Report of hazardous substances in products exceeding 1 ton/year • Product risk assessment/safety standard • Product sale ban/recall

K-REACH Key Points

- Effective from January 1, 2015
- Only Representatives ("OR" policy)
  - Foreign companies need to appoint a representative for reporting, registration, notification, etc.
  - Eligibility of representatives
    - § Korean citizenship holder

      Or

    - § A person or business entity who has an address in Korea

CBI under K-REACH

- Period of data protection: 15 years
- Not eligible for CBI:
  - Chemical common name, trade name, and product name
  - Chemical or product use
  - Safe use information of chemical or product (i.e. precautionary statements for handling, disposal, etc.)
  - Accident response
  - Physico-chemical properties
  - Hazards/Risk information

Out of Scope

- Radioactive substances
- *Pharmaceutical and quasi-pharmaceutical
- Narcotics
- *Cosmetics and related raw materials
- *Agricultural substances and their active ingredients
- Fertilizers
- Food and food additives
- Animal feeds
- Gun powder and military supplies
- Health supplements
- Medical devices

*: Precursors used to manufacture active ingredients are subject to K-REACH

Existing vs. New Chemical Substances

- “Existing” chemical substances
  - Chemical substances distributed for commercial purposes domestically before February 2, 1991 and announced by the MOE on December 23, 1996
  - Chemical substances for which the hazard evaluation has been completed under the Toxic substances Control Law after February 2, 1991 and was published by the MOE

à Basically it is listed in KECI (Korea Existing Chemical Inventory)

- “New” chemical substances
  - Not listed in KECI

Annual Reporting

- Subject: ALL new substances regardless of quantity and existing substances manufactured, imported, or sold ≥ 1 t/y
- Who? Manufacturer, importer, and seller
  - Seller who sells substances for industrial use
- What? Quantity and use
  - 55 Use categories designated by the MoE
- For 2015 reporting, deadline is by June 30, 2016

Exemptions of Reporting

a) Existing substances below 1 ton/yr (manufacture, import, sale)
b) Imported substances equipped in machinery
c) Imported substances contained in experimental machinery or equipment
d) Substances contained in finished article and not released during its use
e) PPORD
f) Reagents
g) Non-isolated intermediates

Additional Exemptions from Reporting

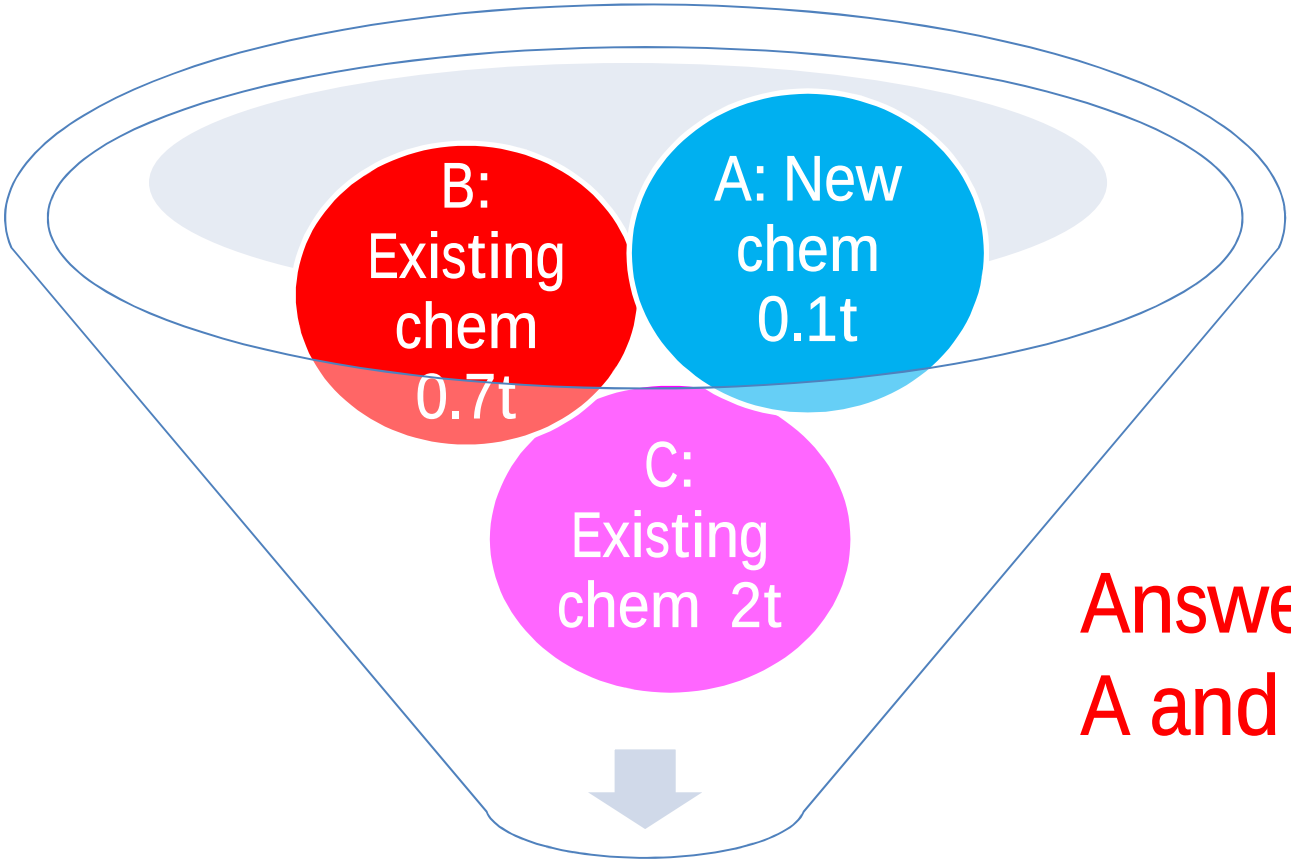
[별표1]

위해성이 매우 낮다는 충분한 정보가 알려져 있는 기존화학물질(제2조제1호 관련)

연번	KE번호	CAS번호	화학물질명
1		50-70-4	D-글루코오스(D-glucitol C6H14O6)
2		50-81-7	아스코르브산(Ascorbic acid C6H8O6)
3		50-99-7	포도당(Glucose C6H12O6)
4		57-48-7	과당(Fructose C6H12O6)
5		56-87-1	L-리신(L-lysine C6H14N2O2)
6		57-50-1	순수 자당(Sucrose, pure C12H22O11)
7		58-95-7	α-토코페릴 아세테이트(α-tocopheryl acetate C31H52O3)
8		59-23-4	갈락토오스(Galactose C6H12O6)
9		59-51-8	DL-메티오닌(DL-methionine C5H11NO2S)
10		63-42-3	유당(Lactose C12H22O11)
11		69-65-8	D-만나당(D-mannitol C6H14O6)
12		87-79-6	L-소르보스(L-sorbose C6H12O6)
13		123-94-4	순수 글리세롤 스테아레이트(Glycerol stearate, pure C21H42O4)
14		124-38-9	이산화탄소(Carbon dioxide CO2)

K-REACH Quiz

- Mixture scenario



Answer:
A and C

Which one(s) are subject to annual reporting?

Registration (1)

- All new substances regardless quantity and "designated existing substances" 1 ton or more per year
- Who? Manufacturer, Importer
- Registration for new substances must be done prior to manufacture or import **à** no grace period
- Process time:

  - 3-7 days for substances < 1 t/y
  - 30 days for substances ≥ 1 t/y

Registration (2)

- "Designated existing substances subject to registration" (aka "PEC" (Priority Evaluation Chemicals)) will be issued by MoE every 3 years based on the criteria of total quantity in commerce and hazard/risk concerns. Grace period for registration: 3 years from announcement

  à First batch PEC with 510 substances published (July 1, 2015)

순번	화학물질 명칭*	고유번호 (CAS No.)	등록 유예기간
1	Formaldehyde ; Formalin	50-00-0	고시일로부터 3년
2	Benzo[def]chrysene ; Benzo[a]pyrene	50-32-8	고시일로부터 3년
3	Ethyl carbamate	51-79-6	고시일로부터 3년

Registration (3)

- What to submit:
  - Information of importer, manufacturer, or representative
  - Chemical identity/information (name, CAS, molecular formula, structure, impurities/by-products, estimated quantities of import or manufacture)
  - Intended use
  - Classification and labeling **à** GHS
  - Physio-chemical properties
  - Hazard information
  - Risk information including exposure scenario (only imported or manufactured 10 tons or more per year)
  - Guidance of safe use
  - Others… (CBI application, etc.)

Exemptions of Registration

a) Imported substances equipped in machinery
b) Imported substances contained in experimental machinery or equipment
c) Substances contained in finished article and not released during its use
d) *Substances manufacture domestically or imported ≤ 10 ton/yr to export for military purpose
e) *Reagents for R&D
f) Surface treated substances
g) Non-isolated intermediates
h) PLC (cationic polymers are subject to registration)

*"Confirmation of Registration Exemption" must be submitted every year. (*for now*)

Existing substances will not be selected as PEC

- Impurities and by-products
- Minerals, ores, ore concentrates, cement clinker, crude oil, coal
- Natural gas, liquefied petroleum gas, natural gas condensate
- Vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oil, animal waxes
- Fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts
- Glycerol
- Process gases and components thereof
- Coke, magnesium oxides
- Glass, ceramic frits
- Compost and biogas
- Hydrogen and oxygen

Types of Registration

Standard	Low volume (before 2020)	Low volume (after 2020)
• All new and designated substances ≥ 1 t/y; high risk concerned < 1 t/y • Hazard data, physico-chemical, etc.	• New < 1 t/y • No hazard data submission (but exposure information for use is required)	• New < 100 kg/y • No hazard data submission (but exposure information for use is required)

Data Submission (1)

- Mandatory Joint-submission for PEC

  The justifiable reasons for individual submission:

  - Compromised trade secret that may cause damage to business
  - If joint submission is more costly than individual submission
  - Classification and labeling from same testing category are different among registrants

à "Confirmation of Individual Submission" from the KCMA required

- Sharing vertebrate animal test data for new substances

  A person must obtain the prior approval from the owner of the data that had been submitted for registration (Act Art. 16 - 17)

  Exception: no consent is needed if the data which 15 years have passed since its use for registration

à If refused by the owner, the data submission can be waived with a "Confirmation" from KCMA

- Industry can check with the NIER if existing data available

Data Submission (2)

- Test proposal showing test information and schedules may be accepted in lieu of testing data of physico-chemical, toxicity, and eco-toxicity (like EU REACH) **à** Only if testing data proven as unavailable.
- MoE only accepts data generated from locally certified labs (GLP) or internationally qualified labs (OECD) (except physico-chemical data)
- Some data submission during registration maybe waived
  - QSAR for substances imported or manufactured below 10 ton per year
  - Isolated intermediates
  - New substances with low volume (1 t until 1/1/2020)

Hazard Review/Risk Assessment

- NIER will conduct hazard review on registered substances:
  - new substances within 6 months
  - PEC within 1 year

à Designate and publish toxic chemical substances

- Additional data for risk assessment are required for registration; gradual reduction of quantity :

  ≥ 100 ton/yr by Jan. 1, 2015;
  ≥ 70 ton/yr by Jan. 1, 2017;
  ≥ 50 ton/yr by Jan. 1, 2018;
  ≥ 20 ton/yr by Jan. 1, 2019;
  ≥ 10 ton/yr by Jan. 1, 2020

à Start counting the date of registration certificate received, NOT the date of registration submission.

à Designate and publish banned, restricted, and permissible chemical substances

Authorization/Restriction

- Authorization - Designation of “Permissible” substances
  - Results of hazard evaluation and risk assessment that demonstrate high risk
  - Substances with high risk of CMR, endocrine disruptors
  - PBT, vPvB
  - Other substances with similar high risks
  - Must have a permit to manufacture, import, or use

- Restriction - Designation of “Restricted / Banned”
  - Results of hazard evaluation and risk assessment that demonstrate high risk
  - Designated by international institutes as high risk
  - Substances that have been removed from Permissible list
  - Banned (all usage) or restricted (partial usage) from manufacture, import, sell/store, transport, or use

Product Control (1)

- Safety management for “Risk concerned products”

1) Household products – cleansers, adhesives, deodorizers, air fresheners, bleaching agents, detergents, fabric softener, etc.
2) Biocide products – preservatives, disinfectants, insecticides, etc.

- Product Notification prior to manufacture or import: exceeding 1 ton/yr per “hazardous substance” containing 0.1 % in product
  - Substance name, concentration, use in product, hazard properties
  - Exceptions: chemical substances not released from product during its use, substances in finished articles, etc.

Product Control (2)

- Hazardous Substances here means:
  - K-REACH designated ones: Toxic, permissible, restricted, or banned substances
- "Exemption from Notification" can be granted to:
  - Release of hazardous substance in product is controlled
  - Hazardous substance in the product already registered for the respective use
- Risk assessment requirement per product category
- MoE will publish safety standard, labeling, packaging, and safety information for consumers
- Safety, labeling criteria will include hazardous substances that are not allowed in risk-concerned product, concentration limit, migration, evaporation, etc.
- For product that fails to meet safety standard, MoE can ban or recall

Post-Registration (1)

All records below must be kept for 5 years

- Chemical information
- Annual Report (including exemption application)
  - Registrants' information change **à** within 1 month
  - Change in Use **à** within 1 month
- Chemical registration (including exemption application)
  - Change in annual volume **à** within 1 month
  - Change in risk/hazard info **à** within 6 months

Post-Registration (2)

- Notification of risk-concerned product that contains hazardous substances (including exemption application)
- Risk communication
- CBI information

What to submit where?

Importer,
Manufacturer,
(Seller),
OR

Registration,
Existing testing data
inquiry

National Institute of Environmental Research

Annual reporting,
Product notification

Local MoE

Chemical identification,
Exemption application,
Applying for individual
registration for PEC, etc.

KCMA
KOREA CHEMICALS MANAGEMENT ASSOCIATION

EU vs. K-REACH

	EU REACH	K-REACH
Pre-registration	Yes	No
Annual reporting	No	Yes
Existing chemical registration	All existing substances 1 ton or more	Only PEC 1 ton or more
Joint registration	Mandatory	Mandatory (for PEC)
Registration types	Standard; Intermediate Use only; PPORD	Standard; Low volume
Hazard evaluation /risk assessment	Industry	Government (MoE)

K-REACH facts that may interest you... (1)

- Nano materials are subject to hazard evaluation under K-REACH
- Testing data that was used for registration with ECHA is acceptable for K-REACH registration (but QSAR or Read-across from EU REACH may not be acceptable)
- Non-GLP testing data for physio-chemical properties other than Pow are acceptable
- New substances approved of LVE (100 kg) under TCCA are considered as exempted for K-REACH registration
- K-REACH does not grant “expedited” registration process for new substances even if they have been used by OECD member countries

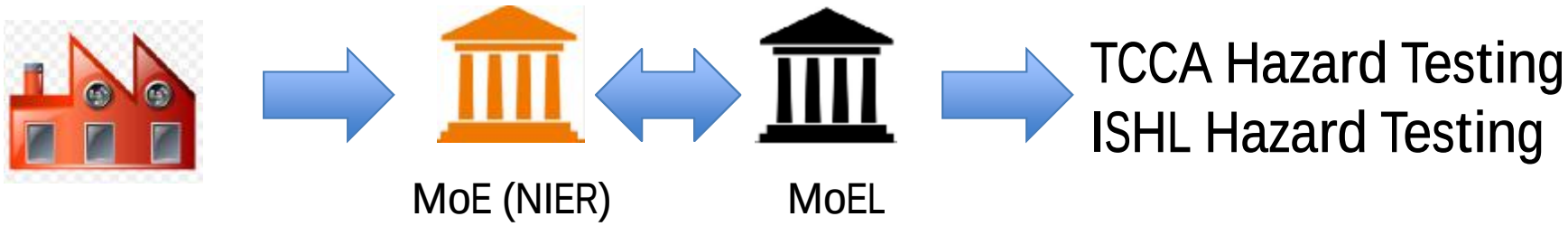
K-REACH facts that may interest you... (2)

- "Unknown" chemical substances are not allowed – must obtain information from suppliers
- For registration, use category per chemical substance must be specified – must obtain information from suppliers
- Registration Fee
  - Discounted fee for SME (up to 80%)
  - 100,000 KRW for new substances
  - 200,000 KRW for PEC
  - Other fees: exemption application (50,000 KRW); product notification (50,000 KRW)

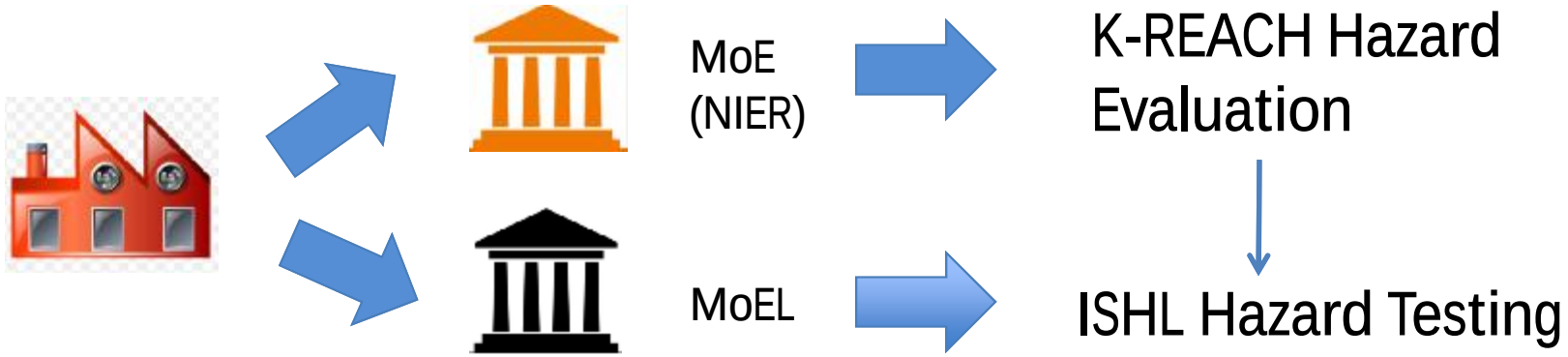
MoE vs. MoEL: data submission

Before K-REACH: one-time submission

TCCA (MoE) – ISHL (MoEL) Hazard Testing



After K-REACH: separate submission



K-REACH and GHS

1) During registration, GHS hazard classification and labeling (pictograms, H and P codes) information are required
2) Risk communication – SDS may be utilized

Classification/Labeling

- MoE adopted UN 3rd Rev. by including hazard class "Hazardous to Ozone Layer" (NIER No. 2014-45)

Safety Data Sheet (SDS)

- MoEL is a ruling authority on the format
- Updated SDS standard including K-REACH information (e.g. Sec 15) is pending

Draft amendments/latest notice

1) Draft - Ministerial Decree amendment proposal (MoE No. 2015-540)

- Simplifying documentation for R&D application
- Reagents for R&D application
- Selecting a lead registrant for joint registration
- Simplifying a representative change

2) Final - Exemptions from “Chemical Identification” requirement (MoE 2015-162)

- Published on September 1, 2015
- Exempted existing substances from annual reporting also exempted from chemical identification obligation

What Is Coming Up

- 510 PEC substances must be notified ("Chemical identification") to KCMA by January 2016 (within 6 months since published date)
- Annual report for 2015 due by June 30, 2016
- 510 PEC substances to be jointly registered by June 2018 (3 years since the published date)
- Risk assessment data ≥ 100 ton/yr until Dec. 2016; ≥ 70 from Jan. to Dec. 2017; ≥ 50 from Jan. to Dec. 2018…

Thank you for your attention!

경청해주셔서 감사합니다!