Korea REACH – Know Your Legal Obligations
October 23, 2014

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Dr. Ok-Sun Jung is the President of the Seoul, South Korea-based consulting firm Safe Chemicals, Co. Ltd. Dr. Jung is a member of the stakeholder forum that advises the Ministry of Environment on the implementation of Korea REACH.
Preliminary Word

- This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual’s specific circumstances. The interpretation and application of the law to an individual’s specific circumstance depend on many factors. This presentation is not intended to provide legal advice.

- The information provided in this presentation is drawn entirely from public information. The views expressed in this presentation are the author’s alone and not those of the author’s clients.
Overview of Korea REACH

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The Problem

- Large numbers of chemicals grandfathered onto existing National chemical inventories
- Most have not been assessed by regulatory agencies
- Data are lacking for many of these non-assessed substances (but situation is improving because of EU REACH)
- How best to deal with the legacy of the past
The EU Approach under REACH

- No Data/No Market for all substances over 1 ton/year per legal entity (few exceptions)
- Priority based largely on tonnage
- Lock-step data requirements based on tonnage
- Industry performs assessment with checks by the Government
- Industry proposes and implements Risk Management Measures
- Separate track to phase-out/eliminate Substances of Very High Concern (SVHCs)
- Restrictions for highly dangerous substances
- High administrative burdens on industry, unnecessary testing costs, bureaucratic, creates economic dislocation.
The Korean Approach

- Shares many EU REACH elements but through the lens of the Toxic Chemicals Control Act (TCCA)
- Identification of Existing Chemicals in Commerce > 1 ton per annum
- Prioritization of Existing Chemicals based on Hazard and Tonnage
- Data Call-in for Priority Existing Chemicals
- Hazard and Risk Assessment by Authorities
- Risk Management
- Authorization for SVHCs
- Restrictions and Bans for high risk chemicals
- Separate provisions for biocides and consumer products
More Granular Details (Exclusion from Scope)

- Radioactive substances under the Nuclear Safety Act
- Pharmaceutical products and quasi under the Pharmaceutical Affairs Act
- Narcotics under the Narcotics Control Act
- **Cosmetics and ingredients under the Cosmetics Act**
- Pesticides and active ingredients under the Pesticides Control Act
- **Fertilizers under the Fertilizer Control Act**
- Food, food additives, devices and **container/packages under the Food Sanitation Act**
- Animal Feed under the Feeds Control Act
- **Gunpowder under the Firearms, Swords and Gunpowder Control Act**
- Military suppliers under the Military Supplies Control Act and the Defense Acquisition Program Act
- Health supplements under the Functional Health Foods Act
- Medical devices under the Medical Devices Act
More Granular Details (Annual reporting)

- Annual reporting by manufacturer and importer (or representative) of substance ID, tonnage and use by 30 April (may change to 30 June) of the following year. More limited reporting by distributors.
- Reporting obligation applies to new substances in any amount and existing substances produced or imported in annual quantities of one ton or more.
- The reporting data will be used, together with information on hazard and risk, to designate existing substances subject to registration.
- Exemptions from annual reporting include articles, R&D substances, non-isolated intermediates.
More Granular Details (Registration Existing Chemicals)

- List of designated existing substances subject to registration will be announced every three years. Three tiers are contemplated.
- Exemptions from registration include R&D chemicals/ low-risk polymers/ impurities/non-isolated intermediates/ Articles/ Export-only substances at 10 ton or less per year. Need to apply and receive confirmation of exempt status.
- Registrants will have 3 years to submit the registration dossier/Data depends on tonnage/Compliance check within 30 days/ Updates required if certain information changes.
- Lead Registrant/Joint Dossier/Opportunity to Opt-Out/ Mandatory sharing of animal data for fair and accurate compensation
- GLP data generally required but there may be some flexibility/Robust summaries/ Limited opportunity for adaptation of data requirements/Test plans for higher-tier data
- IT system not compatible with IUCLID
More Granular Details (Hazard and Risk Assessment)

- Hazard assessments of registered substances conducted by National Institute of Environmental Research (NIER), who may order a company to submit further data if they deem it necessary.
- Risk assessment data (CSR) is submitted according to manufacture/import tonnage and requirement is phased-in:
  - 2015: >100 ton/year
  - 2017: >70 ton/year
  - 2018: > 50 ton/year
  - 2019: > 20 ton/year
  - 2020: > 10 ton/year
- NIER performs risk assessment on substances >10 tons/yr or if hazard assessment indicates need at lower tonnage.
- Ministry of Environment (MoE) seems to have unbridled discretion to impose risk management measures.
Supply Chain Communications, etc

- Similar to REACH SDS requirements.
- Concerns about ability of downstream users to protect confidential uses.
- Public dissemination of registration information.
- Product notification: Manufacturer or importer of consumer products which contains hazardous substances must notify the regional authorities if total quantity of hazardous substances is present at 0.1% or more and exceeds 1 ton per year (by calendar year per substance.) Notification does not apply to articles with no release. Exemption from notification can be requested if no exposure or substance already registered for same use.
Positive Aspects of K-REACH

- Unlike EU REACH, registration of existing chemicals is limited to chemicals selected on the basis of hazard potential and tonnage.
- Some 2000 existing chemicals will be subject to registration under K-REACH in comparison to the some 30,000 substances that are expected to be registered in the EU by mid-2018.
- Initial draft list of some 500 existing substances subject to registration expected to issue in late 2014.
- Unlike EU REACH, registration of monomers in polymers is not required. Instead, existing polymers are potentially subject to registration based on hazard and low-risk polymers can qualify for an exemption upon application to the MoE.
- Under K-REACH all registration dossiers will undergo hazard assessment and may undergo risk assessment on the basis of the outcome of the hazard assessment or the registered volume. Under the EU system registration dossiers undergo a mechanical compliance check with some percentage of dossiers ultimately selected for evaluation.
Positive Aspects of K-REACH (2)

- K-REACH contains provisions for use of alternatives to animal testing including in-vitro data, QSAR and read-across, limited exposure-based waiving, and test plans for higher-tiered data.

- Unlike EU REACH there appears to be no explicit provision for use of weight of the evidence and many of the EU REACH derogations from testing are absent. However, per Article 18(6) and Appendix 4 of the draft Ministerial Decree, NIER is required to publish exemption criteria from testing.

- K-REACH provides an only representative mechanism to allow non-Korean manufactures to assist their South Korean customers by indirectly taking over the registration obligation. The only representative must submit his credentials to the MoE and be qualified to act.
Negative Aspects of K-REACH

- Difficult for non-Korean actors to engage in the process.
- Time allotted to register existing substances identified as being subject to registration is too compressed particularly for the first tranche.
- No explicit exemptions are provided for many of the categories of substances exempted under Annex V of EU REACH.
Negative Aspects of K-REACH (2)

- The IT portal that will be used for registration/notification purposes is not aligned with IUCLID.
- Concerns have been expressed about available protections for confidential business information.
- K-REACH lacks the opportunity for an administrative appeal of MoE decision-making as there is no counterpart to the ECHA Board of Appeals.
- Although a public consultation forum has been organized to work on implementation issues, its work is not widely publicized or widely accessible to non-Korean operators.
Thank you

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II. Annual Manufacture/Import Reporting

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( osjung@safechemicals.net )

Note
- PD: Presidential Decree (Enforcement Decree)
- MD: Presidential Decree (Enforcement Rule)
- Product under K-REACH:
  “Any object, or its part/or component as used by consumer finally
  (“Article” + Consumer products in liquid)
- NIER: National Institute of Environmental Research
- KCMA: Korea Chemicals Management Association
1. Overview of Annual Reporting [Act Art. 8]

<table>
<thead>
<tr>
<th>Item</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Substance subject to Reporting</td>
<td></td>
</tr>
</tbody>
</table>
- New Chemical Substance: All (No Volume Limit)  
- Existing Chemical Substance: ≥ 1 ton/y  
- **Impurities and By-products: Not Required** |
| Responsible body |  
- Manufacturer/Importer/Seller  
- Only Representative (OR) assigned by foreign manufacturer/formulator [Act. 38.1(1)]  
- In case of Toll Manufacturing [MD Art. 6.3]  
  - Consignor may report submitting below information:  
    - ⇒ Information on Consignee, documents evidencing consignment (e.g. Contract)  
  ※ Definition of Seller (MD Art. 6.5)  
    - Any person selling chemical substances to industrial users to use raw materials at business site, excluding seller who sell directly to the final consumers of the product.  
    - ⇒ Reporting Requirement is placed on chemicals for industrial use. |
| Period for Reporting (MD Art. 6.1) | By June 30 of the Following Year  
( Reporting for 2015: by June 30, 2016) |
| Submission | To Local Environmental Office (River Env. Office / Regional Env. Office) |
### 1. Overview of Annual Reporting [Act Art. 8] - Cont’d

<table>
<thead>
<tr>
<th>Item</th>
<th>Contents</th>
</tr>
</thead>
</table>
| Manufacturer/Importer/Seller/OR | - Information on manufacturer/importer/seller/OR (if OR is assigned) (Company name, Address, Contact information, etc.)  
- Chemical Identity (Chemical name, Identification No., etc.)  
- Volume  
- Use (PD Annex 1) |
| Seller | - Information on seller (Company name, address, contact information, etc.)  
**Note**  
If information on product name, customer, identified components and use is submitted, **following information may be omitted.**  
- Chemical Identity (Chemical Name, Identification No., etc.)  
- Volume  
- Use (PD Annex 1) |

MOE obtains this information from manufacturer/importer/OR.
### Chemical substance subject to Exemption from Reporting (Act Art. 8.2; PD Art. 7)

- Chemical substances imported as contained in machinery
- Chemical substances imported together with the relevant machinery or equipment for its test run
- Chemical substances contained in “Product” in solid state with specific shape for certain function as not released during its use
- Chemical substances for scientific experiments, analysis, or research such as reagent
- Chemical substances for R&D which fall within any of the followings:
  a. For development of chemical substances or products
  b. For improvement or development of process
  c. For test of application field of chemical substances
  d. For pilot production of chemical substance or pilot production of products or commodities
- Non-isolated intermediate

### Reporting of Changed matters (PD Art. 8; MD Art. 7)

Submission of Report of Changes (MD Form No. 1) to Local Environment Office:

- Changes in company name, address, contact information, etc.: Within 1 month from the date when change occurs
- Change in Use Category: Within 1 month from the date of recognizing such change
### Reporting Form [MD Form No. 1]

**OR is the reporter if appointed.**

**Per each chemical substance**

**Use Category**

**All relevant importers to be listed.**

If OR is the reporter, total annual volume can be listed.
2. Use Category [PD Annex 1]

<table>
<thead>
<tr>
<th>Use Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Absorbers and Adsorbents</td>
<td>Substances which absorb or absorb gases or liquids</td>
</tr>
<tr>
<td>2. Adhesive, binding agents</td>
<td>Substances which force two surfaces to be adhesive</td>
</tr>
<tr>
<td>3. Aerosol Propellants</td>
<td>Substances which force to spurt the contents from the packages by spraying the gases as condensed or liquidated gases</td>
</tr>
<tr>
<td>4. Anti-condensation agents</td>
<td>Substance which prevents from condensation on the surface in the air</td>
</tr>
<tr>
<td>5. Anti-freezing agents</td>
<td>Substance which prevents from freezing</td>
</tr>
<tr>
<td>6. Anti-set-off and anti-adhesive agents</td>
<td>Substance which prevents from being adhered</td>
</tr>
<tr>
<td>7. Anti-static agents</td>
<td>Substance which prevent from occurrence of static electricity or degrade</td>
</tr>
<tr>
<td>8. Bleaching agents</td>
<td>Substance used for bleaching or whitening</td>
</tr>
<tr>
<td>9. Cleaning/washing agents and additives</td>
<td>Use to remove the pollutants and impurities of the surfaces. But industrial washing and cleaning agents falls within the criteria of “detergent, solvent and attenuant” of No 46</td>
</tr>
</tbody>
</table>

<Use Category>
### 3. Who must Report in case of Manufacture/Formulation in Korea

<table>
<thead>
<tr>
<th>Manufacturers of A, B, C</th>
<th>Formulator of A + B + C (Trade name X)</th>
<th>Seller of X</th>
<th>End user (Industry)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting Requirement:</td>
<td>Reporting Requirement:</td>
<td>Reporting Requirement:</td>
<td>Reporting Requirement:</td>
</tr>
<tr>
<td>• Manufacturer of A</td>
<td>• As Seller of X (Reporting by Trade name X)</td>
<td>• Seller of X (Reporting by Trade name X)</td>
<td>None</td>
</tr>
<tr>
<td>• Manufacturer of B</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Manufacturer of C</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. Who must Report in case of importation?

Note: If volume of Existing Chemical Substance K ≥ 1 ton/y

- **Reporting by Korean Importer**
  - [Local Environmental Office]
  - [Information Processing System]
  - Importer
  - B
  - C
  - D

- **Reporting by Only Representative(OR) appointed by Foreign Manufacturer/Formulator**
  - [Local Environmental Office]
  - [Information Processing System]
  - Only Representative
  - B
  - C
  - D
  - A
### Method for Volume Counting – Reporting per chemical substance

#### Trade name X

<table>
<thead>
<tr>
<th>Substance</th>
<th>Trade name X</th>
<th>Trade name Y</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Content</td>
<td>Importer I</td>
</tr>
<tr>
<td>Import amount of X or Y</td>
<td>10 ton</td>
<td>10 ton</td>
</tr>
<tr>
<td>Import Volume of Substance A</td>
<td>5%</td>
<td>0.5 ton</td>
</tr>
<tr>
<td>Import Volume of Substance B</td>
<td>10%</td>
<td>1 ton</td>
</tr>
</tbody>
</table>

- Substance to be reported by Importer I: Substance B(1.2 ton)
- Substance be reported by Importer II: Substance B(1.2 ton)
- Substances be reported by Importer III: Substance A(2.25 ton) & Substance B(4.5 ton)

If A and B are Existing Chemical Substances
Thank You for Your Attention!

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III. Registration of New Substances and New Polymers

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Note
• PD: Presidential Decree (Enforcement Decree)
• MD: Presidential Decree (Enforcement Rule)
• Product under K-REACH:
  “Any object, or its part/or component as used by consumer finally
  (“Article” + Consumer products in liquid)
• NIER: National Institute of Environmental Research
• KCMA: Korea Chemicals Management Association
1. Overview of New Chemical Registration

Definition of New Chemical Substance [Act Art. 2(4)]
Chemical Substances excluding Existing Chemical Substances
- Including Chemicals not published by Dec. 31, 2014 after completion of Hazard Review under TCCA

No Volume Limit for Registration [Act Art. 10.1]

Impurity and Byproduct ⇒ Registration is not required.
- No Content Limitation ⇒ May be prescribed in NIER’s Public Notice for Registration Process

Registrant [Act Art. 10.1]
- Manufacturer/Importer
- Only Representative (OR) assigned from foreign manufacturer/formulator [Act Art. 38.1(2)]
- In case of Toll Manufacturing [MD Art. 10.2]
  Consignor can be a registrant submitting the following information additionally:
  (1) Information on consignee (Company name, Address, Contact information, etc.)
  (2) Documents evidencing the consignment such as a copy of the consignment contract

Time of Registration: Prior to manufacture or import [Act Art. 10.1]

Calculation of Volume for Registration
- Predicted Volume from Jan. 1 to Dec. 31 in the year of registration

• Notifier can manufacture/import the notified substance without re-Registration under K-REACH.
• Notification is required by June 30, 2015’
• No Grace Period!
1. Overview of New Chemical Registration

<Frame of New Chemical Registration>

- **Visit NIER website** (http://ncis.nier.go.kr/ncis/Index)
- **Check whether substance is New Chemical**
  - Act Art. 2(3) Act Art. 2(4)
- **If Yes, Check whether Chemical is Exempt from Registration**
  - Act Art. 11 PD Art. 10
- **If Not Exempt, Check Data Requirement per Tonnage Band/Data Waiver**
  - MD Annex 4
- **If necessary, Submission of Inquiry for Data Sharing with Proceeding Registrant(s)**
  - Act Art. 16.2 MD Art. 28.1
- **Submission of Dossier (Registration)**
  - Act Art. 14 MD Art. 18
- **Completeness Check by NIER**
  - Act Art. 14 MD Art. 18
- **Receipt of Registration Certificate**
  - Act Art. 10.4 MD Art. 11

- **Manufacture/Import**
  - • < 1ton/y: 7 days
  - • ≥ 1ton/y: 30days

- **Change of Registration**
  - Act Art. 12
  - • Change in tonnage band
  - • Change in use, hazard/risk
1. Overview of New Chemical Registration

<Registration of New Chemical in Article>

Exempt from Registration

No

Released during use?

Yes

Existing Chemical?

Yes

Go to Registration/Exemption Process for Existing Chemicals

No

Check Annual Volume

Registration Process per Tonnage band

Change of Registration

• Change in tonnage band
• Change in use, hazard/risk

Any “Product” in solid state with specific shape for certain function

EU REACH: Intentionally Released
1. Overview of New Chemical Registration

< Check Whether New Chemical Substance in question is Exempt From Registration Requirement >

1. Is New Chemical Excluded from Scope of Act?

2. Exempt from Definition of Chemical Substance?
   - Chemical Substance means Any element, compound, substance obtained by any artificial chemical reaction to element(s) or compound(s), or any substance chemically modified, extracted or purified from substances in nature. [Same as TCCA]

3. Exempt from Registration Requirement? [Act Art. 11; PD Art. 10]
1. Overview of New Chemical Registration

<Exclusion of Scope of Act>

Act Art. 3
• Radioactive Substances (Act Art. 3(1))
• Pharmaceuticals/quasi-pharmaceutical products (Act Art. 3(2))
• Narcotics (Act Art. 3(3))
• Cosmetics/raw materials for Cosmetics (Act Art. 3(4))
• Agricultural chemical products/active substances (Act Art. 3(5))
• Fertilizers (Act Art. 3(6))
• Food, food additives, equipment, food container, and package (Act Art. 3(7))
• Animal feeds (Act Art. 3(8))
• Explosives under “Act for Control of Gun, Sword, and Explosives, etc.” (Act Art. 3(9))
• Military Supplies excluding routine items of Art. 3 of “Military Supplies Control Act” (Act Art. 3(10))
• Health functional food (Act Art. 3(11))
• Medical device (Act Art. 3(12))

Precursors of active substances for Agricultural chemicals or Pharmaceuticals are subject to K-REACH.

If applied in multi-uses, it must comply with all relevant Acts!!

Please Check!
1. Overview of New Chemical Registration

Documents for Registration

[Application form]
- Low Volume Registration: MD Form No. 3
- Typical Registration: MD Form No. 2

- Information on Registrant (Company name, address and representative)
- Chemical Identity
- Use [PD Annex 1]
- Classification/Label
- Physico-chemical properties of the chemical substance;
- Hazard
- Risk (Limited to chemical substance ≥ 10 ton/y) including exposure scenario in which handling method, exposure control and risk management measure are described
- Information for safe use (including information on personal preventative equipment, emergency measure against explosion, fire, leak, etc.); and
- Other information specified in MD

Timeline for Submission of CSR

- ≥ 100 ton/y: From Jan. 1, 2015
- ≥ 70ton/y: From Jan. 1, 2017
- ≥ 50ton/y: From Jan. 1, 2018
- ≥ 20ton/y: From Jan. 1, 2019
- ≥ 10ton/y: From Jan. 1, 2020

"Chemical Safety Report" in EU REACH
### 2. Exemption from Registration [Act Art. 11; PD Art. 10]

#### Chemical Substances Exempt from Registration

<table>
<thead>
<tr>
<th>Item</th>
<th>Contents</th>
</tr>
</thead>
</table>
| Exemption Process Is not Required [Act Art. 11.1] [Act Art. 8.2(1-3)] | - Any chemical substance imported as contained in machinery  
- Any chemical substance imported together with the relevant machinery or equipment for its test run  
- Any chemical substance contained in “Product” in solid state with specific shape for certain function as not released during its use ⇒ Related to “Article” |
| Exemption Application Process with KCMA [PD Art. 10] [Application time] | - Any chemical substance for scientific experiments, analysis or research such as reagents, etc. [Every Year]  
- Any chemical substance for R&D: [Per R&D Project]  
  a. For development of chemical substances or products.  
  b. For improvement or development of process  
  c. For testing of applicable field in use  
  d. For pilot manufacturing of chemical substance or pilot production of products or commodities  
- Any chemical substance ≤ 10 ton/y for Export Only [Every Year] | Manufacturer/importer/OR can apply R&D Exemption for Customers.
## Chemical Substances Exempt from Registration – Cont’d

<table>
<thead>
<tr>
<th>Item</th>
<th>Contents</th>
</tr>
</thead>
</table>
| **Exemption Application Process with KCMA** [PD Art. 10] | **Low Concerned Polymer** [At the first manufacture/importation]  
  a. Mn $\geq$ 10,000  
  Mw 1,000: < 5%; and Mw 500: < 2%  
  b. Mn $\geq$ 1,000 ~ < 10,000  
  Mw 1,000: < 25%; Mw 500: < 10% |
| ※ Following polymers are not exempt [PD Art. 10.2]  
  1. Cationic polymers (however, excluding cases used only in its solid state, as polymers not dissolved or dispersed in water.)  
  2. Polymers Mn < 10,000, which contain new chemical substances or as monomers/reactants exceeding 2 wt%. |
| | **Any chemically surface treated chemical substances in which both “Basic Substance and Surface Treated Substance are Existing Chemicals.”** [At the first manufacture/importation] |

Means polymers such as ion exchange resin
### 3. Low Volume Registration

**Note:** If accumulated amount of manufacture/import is > 1 ton, additional data for Hazard Review may be required.

<table>
<thead>
<tr>
<th>Item</th>
<th>Contents</th>
</tr>
</thead>
</table>
  - From Jan 1, 2020: New Chemical Substance < 100 Kg/y |
| Application form [MD Form No. 3] | “Application form for Registration of New Chemical Substance in Low Volume” |
| Required Information |  - By Dec. 31, 2019: New Chemical Substance < 1 ton/y  
  - Trade name, address and representative of manufacturer or importer  
  - Chemical Identification(chemical name, molecular formula, structure, etc.)  
  - Use information  
  - Exposure Information [See MD Form No. 3]  
  - From Jan 1, 2020: Following test data are required if ≥100 kg/y - < 1 ton/y [MD Annex 4(5)]  
  - Physico-chemical properties: Appearance/physical state, water solubility, melting/freezing point, boiling point, vapour pressure  
  - Acute oral toxicity  
    (Acute inhalation toxicity in case the main route is inhalation)  
  - Ames  
  - Acute toxicity to fish  
  - Biodegradation (Ready) |
Application form of Low Volume Registration

3 days. 7 days if more detailed review is necessary

Exposure Information

<table>
<thead>
<tr>
<th>Use Category</th>
<th>Industrial/Professional Use</th>
<th>Consumer Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detailed description of use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use</td>
<td>Use in closed system</td>
<td>Use resulting in inclusion into or onto matrix</td>
</tr>
<tr>
<td>Use</td>
<td>Non-dispersive use</td>
<td>Dispersive use</td>
</tr>
<tr>
<td>Use</td>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure information</th>
<th>Consumer Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure route</td>
<td>Water</td>
</tr>
<tr>
<td>Exposure pattern</td>
<td>Accidental/Non-Frequent</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Life Cycle Data</th>
<th>Physical-Chemical Properties</th>
<th>Health Hazards</th>
<th>Environmental Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount of manufacture or import</td>
<td>Estimated annual manufacture and use</td>
<td>Average volume of manufacture and use per day</td>
<td></td>
</tr>
<tr>
<td>and use days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount of manufacture or import and use days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated annual manufacture and use days</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. Protection of Information [Act Art. 45]

- **Period for Protection of Confidential Information [PD Art. 32]**
  Max. 15 Years (5 years at Registration + 2 times Renewal)

- **Not Protected Information [Act Art. 45; PD Art. 33]**
  - Common name, Trade Name or Product name
  - Use of chemical substance or product
  - Safe use of chemical substance such as handling precautions, disposal methods, etc.
  - Safe use of product
  - Information on countermeasures against accidents
  - Physico-chemical properties
  - Summarized Hazard information
  - Summarized Risk information
  - Other information that MOE recognizes the necessity of disclose and publishes in order to protect human health and environment
5. Registration or Notification of Changes [Act Art. 12]

**Registration of Changes**
- Change in tonnage band
- Changes in use, hazard or risk

**Notification of Changes**
- Changes in Company Name, Address or the representative of Registrant
6. Data Sharing [Act Art. 16]

Before Tests, Please check below point!

1. Do you want Data Sharing with Preceding Registrant?

2. How can you share Data with Preceding Registrant(s)?
   - You may submit “Inquiry” to NIER [MD Art. 28]
   - NIER will reply the below information to submitter:
     - Preceding Registrants
     - Submitted data
     - Previous submitters of inquiries
   
   - Sharing by compensation to Data Owner
   - Anyone can use Data submitted before 15 years or longer (Without Compensation)

3. What Data can be shared? [MD Art. 27]
   - Physico-chemical properties
   - Hazard Data
6. Data Sharing – Cont’d

<Special Treatment of Vertebrate Animal Test Data [Act Art. 17]>

Sharing of Vertebrate Animal Test Data [Art. 17(1) and 2]
- Shared for registration with data owner’s grant
- Anyone can use the submitted data longer than 15 years ago without data owner’s grant
- If Data Owner of existing Vertebrate Animal Test Data refuses its sharing, Registrant may not submit that data.

For this process,
⇒ Submit “Application for Confirmation on Refusal of Sharing on Vertebrate Animal Test Data [MD Form No. 14] to KCMA
⇒ MOE may requires submission of relevant data within the period specified in MD if necessary for Hazard Review.

Reasons for Refusal of Sharing on Vertebrate Animal Test Data [Act Art. 17.3; PD Art. 14]
- May not be refused except the case of improper compensation to Data Owner.
### 7. Data Requirement [MD Annex 4]

#### Physico-Chemical Properties

<table>
<thead>
<tr>
<th>Test Item</th>
<th>TCCA</th>
<th>K-REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 1t</td>
<td>≥ 1t</td>
</tr>
<tr>
<td>Appearance/Physical state</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Melting/Freezing Point</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Density</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Vapour Pressure</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>n-Octanol/Water Partition Coefficient (Pow)**</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Granulometry</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Dissociation Constant</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Flammability</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Explosive Properties</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

**Note. TP: Test plan may be submitted**

****: GLP test data are required.
## 7. Data Requirement [MD Annex 4] – Cont’d

### Hazard on Human Health

<table>
<thead>
<tr>
<th>Test Item</th>
<th>TCCA</th>
<th>0.1-1t (From Jan 1, 2020)</th>
<th>1-10t</th>
<th>10-100t</th>
<th>100-1000t</th>
<th>&gt;1000t</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Acute dermal toxicity or Acute inhalation toxicity (based on exposure route)</td>
<td></td>
<td></td>
<td>✓ (TP)</td>
<td>✓ (TP)</td>
<td>✓ (TP)</td>
<td></td>
</tr>
<tr>
<td>Skin irritation/corrosion</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Eye irritation/corrosion</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Sensitization</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>AMES test</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>In vitro Chromosome aberration</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>In vivo Genotoxicity</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Additional in vivo Genotoxicity (Germ Cell Mutagenicity)</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Subacute repeated dose toxicity (28 days)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Subchronic repeated dose toxicity (90 days)</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Reproductive screening toxicity</td>
<td></td>
<td></td>
<td>✓ (TP)</td>
<td>✓ (TP)</td>
<td>✓ (TP)</td>
<td></td>
</tr>
<tr>
<td>Reproductive toxicity (Two Generation)</td>
<td></td>
<td></td>
<td>✓ (TP)</td>
<td>✓ (TP)</td>
<td>✓ (TP)</td>
<td></td>
</tr>
<tr>
<td>Fetal Development toxicity</td>
<td></td>
<td></td>
<td>✓ (TP)</td>
<td>✓ (TP)</td>
<td>✓ (TP)</td>
<td></td>
</tr>
</tbody>
</table>

For all tests, GLP test data are required.
If result of Ames test is positive, in vitro chromosomal aberration test and in vivo mutation test are required.

<table>
<thead>
<tr>
<th>Test Item</th>
<th>TCCA</th>
<th>K-REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 1t</td>
<td>≥ 1t</td>
</tr>
<tr>
<td>Acute toxicity to fish</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Acute toxicity to Daphnia</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Growth inhibition on aquatic plants</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Fish chronic toxicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daphnia chronic toxicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Terrestrial plant acute toxicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short-term toxicity to terrestrial invertebrates (Earth worm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Terrestrial plant chronic toxicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term toxicity to terrestrial invertebrates (Earth worm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activated sludge respiration inhibition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benthic organism(Chronic) toxicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biodegradation (Ready)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Biodegradation (Inherent)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For all tests, GLP test data are required.
### 7. Data Requirement [MD Annex 4] – Cont’d

<table>
<thead>
<tr>
<th>Test Item</th>
<th>TCCA</th>
<th>K-REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 1t</td>
<td>≥ 1t</td>
</tr>
<tr>
<td>Hydrolysis in accordance with pH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identification of degraded products</td>
<td></td>
<td>✓ (TP)</td>
</tr>
<tr>
<td>Further information on Environment fate and behavior</td>
<td></td>
<td>✓ (TP)</td>
</tr>
<tr>
<td>Bioaccumulation**</td>
<td></td>
<td>✓ (TP)</td>
</tr>
<tr>
<td>Adsorption/desorption</td>
<td></td>
<td>✓ (TP)</td>
</tr>
<tr>
<td>Additional adsorption/desorption information</td>
<td></td>
<td>✓ (TP)</td>
</tr>
</tbody>
</table>

**: GLP test data are required.

Not clear legally whether literature data can be acceptable!
8. Data Waiver [PD Art. 12]

Please consider all points before tests!

- (1) Low Volume Registration
  - By Dec. 31, 2019: < 1 ton/y
  - From Jan. 1, 2020: < 100 kg/y

- (2) Isolated intermediate

- (3) (Q)SARs

- (4) In-vitro test

- (5) Read across

- (6) Technically impossible

- (7) Test by other reliable test method
  - Certain data are not required.
  - Data waiver or submission of alternative test data for certain data are accepted.

- (8) Not exposed
  - MD Annex 8(3)
8. Data Waiver [PD Art. 12] – Cont’d

[PD Art. 12]
Certain Study Data may not be submitted for following substances:

1. Chemical substances in volume specified in PD Annex 2;
   (By Dec. 31, 2019 < 1ton/y; From Jan. 1, 2020 < 100kg/y);
2. Isolated intermediates Not exempt;
3. Chemical substances < 10ton/y for which hazard to human health/environment may be
   judged through result obtained from (Q)SAR program recognized internationally;
4. Chemical substances for which hazard to human health/environment may be judged through
   result obtained from in vitro test method recognized and verified internationally;
5. Chemical substances for which hazard to human health/environment may be judged through
   result obtained from chemical substances having similar structure;
6. Chemical substances for which tests are impossible technically;
7. Chemical substance for which hazard to human/environment may be judged through study
   result obtained by other test method equal to or greater than internationally recognized test
   method; OR
8. Chemical substances expected not to be exposed to humans/environment based on the
   Documents for Application of Registration. ⇒ See the next page
### MD Annex 8(3)

Following studies may not be submitted based on exposure scenario and exposure information:

<table>
<thead>
<tr>
<th>Physico-Chemical Properties</th>
<th>Health Hazards</th>
<th>Environmental Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Viscosity</td>
<td>1) Additional Genotoxicity</td>
<td>1) Fish chronic toxicity</td>
</tr>
<tr>
<td>2) Dissociation constant</td>
<td>2) Short-term repeated dose toxicity(28days)</td>
<td>2) Daphnia chronic toxicity</td>
</tr>
<tr>
<td></td>
<td>3) Sub-chronic repeated dose toxicity (90days)</td>
<td>3) Short-term toxicity to plants</td>
</tr>
<tr>
<td></td>
<td>4) Reproductive/Developmental toxicity(Screening)</td>
<td>4) Short-term toxicity to invertebrates(Earth Worm)</td>
</tr>
<tr>
<td></td>
<td>5) Reproductive toxicity (Pre-natal development)</td>
<td>5) Terrestrial Plant chronic toxicity</td>
</tr>
<tr>
<td></td>
<td>6) 2 Generation Reproduction</td>
<td>6) Earthworm chronic toxicity</td>
</tr>
<tr>
<td></td>
<td>7) Carcinogenicity</td>
<td>7) Activated sludge respiration inhibition</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8) Benthic organism(Chronic) toxicity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>9) Biodegradation(Inherent)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10) Identification of degradation products</td>
</tr>
<tr>
<td></td>
<td></td>
<td>11) Environmental fate and behavior</td>
</tr>
<tr>
<td></td>
<td></td>
<td>12) Bioaccumulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13) Adsorption/desorption (Screening)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14) Further information on adsorption/desorption</td>
</tr>
</tbody>
</table>
9. Test Plan

Submission of Test Plan [Act Art. 14.3, MD Art. 21.1]
- Certain information on physico-chemical properties and hazard may be replaced by Test Plan.

Contents of Test Plan [MD Art. 21.2]
- Test name
- Name of organization scheduled to conduct test as designated by MOE
  * Act Art. 14.2 ⇒ Domestic Test organization as designated by MOE
  + OECD GLP Test organization
- Reason why described test organization cannot conduct the relevant test
- Detailed test method
- Detailed test schedule
- Predicted date for submission of test data
10. Acceptance of Test Data

**Accepted Test Data**
- Test data conducted in testing organization located in Korea as designated by MOE [Act Art. 22; PD Art. 17]
- Test data conducted in foreign testing organization in compliance with OECD GLP [Act Art. 14.2(2); MD Art. 20]

**Evidencing document:**
* GLP Certificate issued by any OECD member country; or
* GLP statement to mention that the test result complies with OECD GLP

**Type of Test Data**
- Full text of test data or
- Robust Summary (including Purpose of test, Test method, Summary of test result)

*Note: MIER may require full text of test data in case of submission of Robust Summary if needed for Hazard Review of substance [MD Art. 34.1(7)]
11. Change in Scope of Exemption for Polymers

**OECD Polymer Definition**

**Scope of Exemption under TCCA**
- Nonionic polymers with the number-average molecular weight $\geq 10,000$
- Polymers with the number-average molecular weight $\geq 1000$, in which the monomers do not fall within the criteria of New Chemical Substance or Hazardous Chemical Substance (excluding inorganic compounds)
- Polymers composed of monomers excluding monomers $\leq 2$ wt%, which do not fall within the criteria of New Chemical Substance
- Block Polymers in which all blocks are not New Chemical Substance
- Graft Polymers in which parts of stem and branch are not New Chemical Substance

**Scope of Exemption for Polymers under K-REACH**
- Polymers $M_n \geq 10,000$
  - $M_w < 1,000$: $< 5\%$
  - $M_w < 500$: $< 2\%$
- Polymers $M_n \geq 1,000 \sim < 10,000$
  - $M_w < 1,000$: $< 25\%$
  - $M_w < 500$: $< 10\%$

**Not Exempt**

Note: Following polymers are not exempt from Registration. (PD Art. 10.2)
1. Cationic polymers (however, excluding cases used only in its solid state, as polymers not dissolved or dispersed in water.)
2. In Polymers $M_n < 10,000$, if any of followings are used exceeding 2wt% as monomers/reactants:
   - New chemical substance or
   - Chemical substances designated by MOE
12. Data Requirement for Polymers [MD Annex 4(6)]

- **Basic Physico-chemical Properties**
  - Appearance/physical state
  - Water solubility
  - Melting point/freezing point
  - Boiling point
  - Vapour pressure

- **Polymer Characteristics**
  - Number average molecular weight and molecular weight distribution
  - Monomer composition information (monomer name and content(%))
  - Content of residual monomers (%)
  - Content of MW 1,000 or less(%)
  - Stability in acidic and alkaline condition

- **Basic Physico-chemical Properties +**
  - n-Octanol/Water partition coefficient
  - Density
  - Granulometry

- **Polymer Characteristics**
  - Acute oral toxicity
  - Ames
  - Skin irritation/Skin corrosion
  - Skin sensitization

- **Basic Physico-chemical Properties +**
  - Acute toxicity to fish
  - Daphnia acute toxicity
  - Biodegradation (Ready)

- **Polymer Characteristics**
  - Acute dermal/or acute inhalation toxicity
  - Ames
  - In vitro Chromosome aberration
  - In vivo Genotoxicity
  - Sub acute repeated dose toxicity (28days)
  - Reproductive toxicity(Screening)
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
  - Biodegradation (Ready)
  - Growth inhibition on aquatic plants
  - Hydrolysis in accordance with pH

- **Basic Physico-chemical Properties +**
  - Acute oral toxicity
  - Ames
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
  - Biodegradation (Ready)

- **Polymer Characteristics**
  - Acute oral toxicity
  - Ames
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
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  - Acute dermal/or acute inhalation toxicity
  - Ames
  - In vitro Chromosome aberration
  - In vivo Genotoxicity
  - Sub acute repeated dose toxicity (28days)
  - Reproductive toxicity(Screening)
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
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  - Hydrolysis in accordance with pH

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  - Daphnia acute toxicity
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  - Acute dermal/or acute inhalation toxicity
  - Ames
  - In vitro Chromosome aberration
  - In vivo Genotoxicity
  - Sub acute repeated dose toxicity (28days)
  - Reproductive toxicity(Screening)
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
  - Biodegradation (Ready)
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  - Hydrolysis in accordance with pH

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  - Acute oral toxicity
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  - Daphnia acute toxicity
  - Biodegradation (Ready)

- **Basic Physico-chemical Properties +**
  - Acute dermal/or acute inhalation toxicity
  - Ames
  - In vitro Chromosome aberration
  - In vivo Genotoxicity
  - Sub acute repeated dose toxicity (28days)
  - Reproductive toxicity(Screening)
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
  - Biodegradation (Ready)
  - Growth inhibition on aquatic plants
  - Hydrolysis in accordance with pH

- **Polymer Characteristics**
  - Acute oral toxicity
  - Ames
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
  - Biodegradation (Ready)

- **Basic Physico-chemical Properties +**
  - Acute dermal/or acute inhalation toxicity
  - Ames
  - In vitro Chromosome aberration
  - In vivo Genotoxicity
  - Sub acute repeated dose toxicity (28days)
  - Reproductive toxicity(Screening)
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
  - Biodegradation (Ready)
  - Growth inhibition on aquatic plants
  - Hydrolysis in accordance with pH

- **Polymer Characteristics**
  - Acute oral toxicity
  - Ames
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
  - Biodegradation (Ready)

- **Basic Physico-chemical Properties +**
  - Acute dermal/or acute inhalation toxicity
  - Ames
  - In vitro Chromosome aberration
  - In vivo Genotoxicity
  - Sub acute repeated dose toxicity (28days)
  - Reproductive toxicity(Screening)
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
  - Biodegradation (Ready)
  - Growth inhibition on aquatic plants
  - Hydrolysis in accordance with pH

- **Polymer Characteristics**
  - Acute oral toxicity
  - Ames
  - Skin irritation/Skin corrosion
  - Skin sensitization
  - Acute toxicity to fish
  - Daphnia acute toxicity
  - Biodegradation (Ready)
## 13. Competent Authority for Submission of Documents for Registration

<table>
<thead>
<tr>
<th>Legal Procedure</th>
<th>Authority</th>
<th>Period</th>
<th>Issued Certificate</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Registration of Chemical Substances</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documents for Registration of “New Chemical Substances”</td>
<td>NIER</td>
<td>( \leq 30 \text{days} )</td>
<td>Notice of Registration of Chemical Substance</td>
<td>▪ New Chemical Substances ( \geq 1 \text{ton/y} )</td>
</tr>
<tr>
<td></td>
<td></td>
<td>( \leq 3 \text{days} ) ( \leq 7 \text{days} )</td>
<td>Notice of Registration of Chemical Substance</td>
<td>▪ New Chemical Substances &lt; 1ton/y by Dec. 31, 2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>▪ New Chemical Substances &lt; 100 kg/y from Jan. 1, 2020</td>
</tr>
<tr>
<td>Registration for Change in Registration</td>
<td>NIER</td>
<td>( \leq 30 \text{days} )</td>
<td>Notice of Registration for Change in Registration of Chemical Substance</td>
<td>▪ Change in annual volume: Within 1 month from the date of change occurred</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>▪ Change in use: Within 1 month from the date of recognizing the change</td>
</tr>
<tr>
<td></td>
<td></td>
<td>( \leq 3 \text{days} ) ( &lt; 7 \text{days} )</td>
<td></td>
<td>▪ Change in risk &amp; hazard: Within 6 months from the date of recognizing the change</td>
</tr>
<tr>
<td>Notification for Change in Registration</td>
<td>NIER</td>
<td>( \leq 3 \text{days} )</td>
<td>Notice of Notification for Change in Registration of Chemical Substance</td>
<td>▪ New Chemical Substances &lt; 1ton/y</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>▪ In case where Company name, Address of registrant or Representative are changed: Submitted within 1 month from the date when change occurred</td>
</tr>
</tbody>
</table>
### 13. Competent Authority for Submission of Documents for Registration - Cont’d

<table>
<thead>
<tr>
<th>Legal Procedure</th>
<th>Authority</th>
<th>Period</th>
<th>Issued Certificate</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration of Chemical Substances (Cont’d)</td>
<td>Application for Confirmation on Exemption from Registration</td>
<td>KCMA</td>
<td>General: ≤ 3days; Extended: ≤ 10days</td>
<td>Result Notice on Application for Confirmation on Exemption from Registration of Chemical Substance</td>
</tr>
<tr>
<td>Notification of chemical substances already registered under TCCA</td>
<td>New Chemical Substances: By June 30, 2015 “Existing Chemical Substances Subject to Registration”: Within 6 months from the date of publication</td>
<td>NIER</td>
<td>General: ≤ 30days after the Expiry date; Extended:</td>
<td>Notice on the Notification by the Person who has received the Result of Hazard Review</td>
</tr>
</tbody>
</table>

* If additional review is necessary

- Chemical substances not published after the completion of Hazard Review under TCCA (means that Chemical substances which Hazard Review has been completed during Jan 1, 2012 to Dec. 31, 2014)
Thank You for Your Attention!

Safe Chemicals Co., Ltd.
(www.safechemicals.net)
Registration of Existing Substances

Oct. 23, 2014
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Washington, DC ● Brussels ● San Francisco ● Shanghai
MAIN MESSAGE

- If You are Familiar with REACH Registration, then Registration of Existing Substances under K-REACH Holds Few Surprises.
- There are Differences in the Process
- And the Korean Authorities are Much More Involved than the EU Authorities
Designation of Existing Chemical Substance Subject to Registration

- The lists of existing chemicals subject to registration will be published every 3 years and the substances are to be registered within 3 years from the date of publication.
- 1st draft list of priority existing chemicals is expected to contain approx. 500 substances and to be published sometime in 4Q 2014 after the Decrees are finalized.
- Draft list will be published but not clear whether Industry will be provided an effective opportunity to comment on the list of substances.
## Criteria for Selection

<table>
<thead>
<tr>
<th>Priority</th>
<th>Hazard</th>
<th>Exposure</th>
<th>Number of substances</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Priority 1</strong></td>
<td>CMR or PBT</td>
<td>20-20,000 ton</td>
<td>372</td>
</tr>
<tr>
<td></td>
<td>HPV</td>
<td>≥ 20,000 ton</td>
<td></td>
</tr>
<tr>
<td><strong>Priority 2</strong></td>
<td>CMR or PBT</td>
<td>1-20 ton</td>
<td>791</td>
</tr>
<tr>
<td></td>
<td>H410(R50/53) or Toxic chemical</td>
<td>10-20,000 ton</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HPV</td>
<td>1,000-20,000 ton</td>
<td></td>
</tr>
<tr>
<td><strong>Priority 3</strong></td>
<td>H410(R50/53) or Toxic chemical</td>
<td>1-10 ton</td>
<td>923</td>
</tr>
<tr>
<td></td>
<td>HPV</td>
<td>100-1,000 ton</td>
<td></td>
</tr>
</tbody>
</table>
Registration Process

- Registration dossier essentially the same as an EU REACH dossier.
- Robust summaries
- IT system not compatible with IUCLID
- Application in Korean language
- Registration number issued within 30 days of submission of completed dossier.
  (similar to EU REACH compliance check)
Exemptions from Testing

- Exemption from Standard Tests is Possible in the case of:
  - QSAR can be used for the registration of chemicals at < 10 ton/year
  - In-vitro test methods can be used to satisfy certain endpoints
  - Read-across to data on structurally similar substances
  - Testing not technically feasible
  - No exposure
Updating the Registration

- Very similar to Article 22 of EU REACH
- Changes in manufacturing/import volume (1 month to update)
- Changes in use information (1 month to update)
- Changes in physico-chem properties, hazard & risk information: Within 6 months from the date new info is known
- In case of changes in name/address/company representative of registrant, within one month from the data of occurrence.
Test Plans

- Similar to REACH but no public consultation to identify potential data holders
- Test plan requires the following information:
  - Identification of data requirement
  - Test lab that will conduct the test
  - Details of test methods
  - Details of test schedule
  - Estimated submission date
- NIER will review the test plan and notify the applicant of the acceptance or modification of the plan.
- The applicant will need to submit the data within the specified submission date, and if the test data are not submitted within the due date, the substance is deemed not to be registered.
- In cases where the data cannot be submitted within the due date due to the reason of force majeure of the test lab, NIER may extend the due date.
Joint Submission

- Similar to Article 11 of REACH
- Data which must be submitted jointly (unless opt-out accepted) are:
  - Physico-chemical property data
  - Hazard information
  - Test plan
- If all registrants agree, following data may also be jointly submitted:
  - Risk information (CSR)
  - Guidance for safe use
- Manufacturers/importers of the joint submission need to appoint a lead registrant. If they fail to appoint a lead registrant, a company who manufactures/imports the largest amount of the existing chemical per year at the time of registration is designated as the lead registrant.
- Where the registrants do not agree on cost sharing basis, the costs are divided based on the numbers of registrants and manufacturing/import volume.
Opt-out from Joint Submission

- Different Classification and Labeling
- Where data owner does not provide details of the cost to allow a fair and accurate basis for cost sharing
- Registrant must receive approval to opt-out
Joint Submission (2)

- No Substance Information Forum (SIEF)
- How will Potential Registrants identify each other?
- What form will the collaboration take?
- How will Competition law considerations come into play?
- How will non-Korean data holders interface?
Other Registration Details

- Inquiry by Potential New Registrants -- Similar to Article 26 of REACH
- LOA to data needs to be submitted with the Registration papers
- If owner of Vertebrate animal data refuses to share, Registrant can apply for permission not to submit.
Hazard Assessment

- NIER will perform a hazard assessment of the data in the dossier within 1 year of submission for existing chemicals
- May ask for additional information
- Priority given to substances assessed by International organizations, subject to UN Conventions, high tonnage chemicals and very hazardous chemicals
- Hazard assessment report shared with Registrants and will be made public and may be used for foreign registrations if permission is granted to do so.
Risk Assessment

- Based on results of Hazard assessment and for all substances >10 tons/ year.
- NIER performs the risk assessment and may ask for more information.
- MoE has expansive authority to impose risk management measures
Public Dissemination of Registration Data

- Similar to REACH
- No CBI protection for:
  - Trade names
  - Use information
  - Information on safe use
  - Physico-chemical information
  - Hazard data summaries
Thank you

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V. The Korean REACH Stakeholder Forum

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(osjung@safechemicals.net)
Cooperation with Industries

- Stakeholders Forum was established on Aug. of 2013 by 30 parties.
  - Ministry of Environment (MOE) and Ministry of Trade, Commerce and Industry
  - Industries sectors (Industries Association, Industries, Korean Chamber of Commerce, KCMA, etc.)
  - NGOs (Environment Protection, Consumer Products, Labor – related organization)
  - Experts (Consulting companies and Professors)

- Stakeholders Forum
  - 10 times Stakeholders Forum
  - 2 times Small Group Meetings
  - 11th Meeting will be held Oct. 24, 2014.

- Preparation of Drafts based on results from discussion in Stakeholders Forum
- Publication of Drafts on Feb. 18, 2014
- Drafts have been changed.
## 2. Members of Stakeholders Form

<table>
<thead>
<tr>
<th>Item</th>
<th>Contents</th>
</tr>
</thead>
</table>
| Industries (12)      | ▪ 4 Large Companies  
                        ▪ 2 Small and Medium Companies and 2 Industries Associations covering Small and Medium Companies  
                        ▪ 2 Korean Branch Offices of Foreign Companies (US and EU based companies)  
                        ▪ 2 Public Organizations to cover industries (Korean Chemicals Management Association, Korean Chamber of Commerce and Industry) |
| NGOs/ experts (12)   | ▪ 5 NGOs  
                        ▪ 7 Consulting companies, Professors                                                                                                                                               |
3. Main Changes of MOE Drafts in Stakeholders Form

**Reporting**
- Reduced Information Requirement for Sellers
- In case of toll manufacturing, either of requesting company or manufacturing companies may report

**Designation of “Existing Chemical Substance Subject to Registration”**
- Pre-Notice will be published before the official publication of final version

**Interim Measures for Chemical Substances under TCCA**
- Chemical substances notified under TCCA should be considered as “New Chemical Substances” under K-REACH before those are published on the official gazette with below exception:
  - Notifier, who receives “Notice on Review Result” from NIER under TCCA before the enforcement date of K-REACH, does not have the legal obligation for Re-Registration of the relevant chemical substance under K-REACH (Addendum Article 3 of Act)

**Data Requirement**
- QSAR/Read across approach can be acceptable in certain cases (≤ 10 ton/y)
- Robust Summary can be submitted on behalf of full text of test reports
- Condition for data waiver will be specified.
Designation of Hazardous Substances

- Criteria for designation of “Substance Subject to Permission” will be clearly defined with detailed description.
- Also, it will be more clear by designating and proposing “inventories of chemical substance subject to permission” after interagency discussion with other Ministries and review by Assessment Committee.
- Before the designation of any hazardous chemical substance, hazard, existence of alternative substance(s), availability of technology and economic condition of industries will be considered.

Information Providing Requirement

- Information on component and content is excluded from scope of required information.
- Information on volume of manufacture/import/sale may be provided as total volume per company.
- In case that any chemical name is confidential, generic name can be provided.
- Method for information transfer will be standardized in certain format for maximization of utilization and reduction of cost burden etc.

Registration fee

It will be different according to the size of business.
4. Main Changes of MOE Drafts in Stakeholders Form - Cont’d

**Information Providing Requirement on Raw Materials**
- Information on component and content is excluded from scope of required information.
- Information on volume of manufacture/import/sale may be provided as total volume per company.
- In case that any chemical name is confidential, generic name can be provided.
- Method for Information transfer will be standardized in certain format for maximization of utilization and reduction of cost burden etc.

**Products Containing Hazardous Chemical Substance**
- Impurities, Intermediates, and Byproducts will be excluded from Notification Requirement like cases in Registration, but the information on Impurities, Intermediates, and Byproducts contained in “Substances subject to Notification” should be submitted.

**Provision of Information on Components in Products (Article 35)**
- Information on “Hazardous Substances” and their content, and Safe Handling Method will be required for information transfer, but as for other substances than “Hazardous Substances”, information transfer would not be required.
- Information on confidential will be excluded for this requirement except for “Hazardous Substances.”
Thank You for Your Attention!

Safe Chemicals Co., Ltd.
( www.safechemicals.net )
VI. Regulation of Biocides and Consumer Product under K-REACH

Ok-Sun Jung Ph.D.
( osjung@safechemicals.net )

Note
- PD: Presidential Decree (Enforcement Decree)
- MD: Presidential Decree (Enforcement Rule)
- Product under K-REACH:
  “Any object, or its part/or component as used by consumer finally (“Article” + Consumer products in liquid)
- NIER: National Institute of Environmental Research
- KCMA: Korea Chemicals Management Association
1. Definition of Product [Act Art.2]

Any object, or its part/or component as used by consumer finally, with any possibility of exposure of chemical substance to consumer as listed below:

a. Any “Product” in mixture [e.g. cleaning agents, deodorant, ink or toner for printer, watercolor for students, etc.]

b. Any “Product” in solid state with specific shape for certain function from which any chemical substance is not released during its use [“Article” in EU REACH]
2. Basic Frame of Products Management under K-REACH

<Products (Articles & Mixtures for Consumer Use)>

Product means “Any object, or its part/or component as used by consumer finally”

- **Requirement**:
  - Registration of Released Chemical
  - Notification of Products Containing Hazardous Chemical Substances
- **Obligatory Provision of Information** (Before or At the Time of Transfer)
  - Request (Obligation to provide Information within 45 days from the date of request)
- **Designation of Risk Concerned Products, etc.**

- **When any product containing Registered Substance or Hazardous Chemical Substance is transferred to the Transferee**

- **On Request (Voluntarily)**

- **[Manufacturer]**
- **[Importer]**
- **[Government Office]**
- **[Transferee of Product]** (Wholesaler)
- **[Retailer]**
- **[Final Consumer]**
3. Exemption from Notification [Act Art. 32]

**Exempt products**
- Any chemical substance not intended to be released to human or the environment under normal foreseeable condition of use [Act Art. 32.2(1); MD Art. 52.2]
  - The case where the exposure may be blocked means the case where the Hazardous Chemical Substance in Product is not in direct contact with human body and leakage to the environment is prevented.
- Any chemical substance registered already for the use of relevant product [Act. 32.2(2)]

**Documents for submission [MD Art. 52]**
- MD Form No. 30
- Information of Composition
- Documents evidencing the exemption from notification

**Information for submission [MD Form No. 30]**
- Information on the notifier (Company, address, contact info., etc.)
- Information on the product (Product name, use, etc.)
- Chemical name, contents (%), use (function) of Hazardous Chemical Substances
- Estimated annual manufacture/import volume
- Reasons for exemption from notification
4. Notification of Products containing Hazardous Chemical Substance
[Act Art. 32]

<table>
<thead>
<tr>
<th>Item</th>
<th>Required Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notifier</td>
<td>Manufacturer/Importer</td>
</tr>
</tbody>
</table>
| Chemical substance subject to Notification | ▪ Content of Hazardous Chemical Substances > 0.1 wt% within a Product and ▪ Annual volume of each Hazardous Chemical Substance: > 1 ton/y in Products

※ Hazardous Chemical Substance: Toxic chemical substance, chemical substance subject to Authorization, Restricted Chemical Substance, Prohibited Chemical Substance, any chemical substance with hazard or risk or with such concerns (Approx. 1,500 substances) |

| Document to be submitted [MD Art. 51, MD Form No. 28] | ▪ Information on notifier (Company, address, contact information, etc.) ▪ Information on OR appointed by Foreign Manufacturer pursuant to Act Art. 38 (Company name, address, contact information, etc.) ▪ Chemical name and contents of Hazardous Chemical Substance contained (Note: information on identified impurities and by-products are included, but submission of such information is not mandatory) ▪ Classification/Hazard information known on Hazardous Chemical Substance ▪ Use (function) of Hazardous Chemical Substance within Product ▪ Use of Product |
## 5. Competent Authority for Notification of Products

<table>
<thead>
<tr>
<th>Legal Procedure</th>
<th>Authority</th>
<th>Period</th>
<th>Issued Certificates</th>
<th>Remark</th>
</tr>
</thead>
</table>
| Notification of Products containing Hazardous Chemical Substances | Notification [MD Form 28]          |        | Certificate of Notification on Product containing Hazardous Chemical Substance       | Content in a product > 0.1wt% and annual volume of Hazardous Chemical Substances > 1 ton/y  
Time for notification: Between the day that it is confirmed that annual accumulated volume exceeds 1 ton and the day before the next manufacture/import  
However, if it is difficult to identify annual accumulated volume, may be notified April 30 of the next year with the reason of delay |
| Confirmation on “Exemption from Notification” [MD Form 30] | KCMA                               |        | Certificate for Confirmation on Exemption from Notification of Product containing Hazardous Chemical Substance |

* If additional review is necessary
6. Transfer of Information on Chemical Substance Contained in Product [Act Art. 35]

- **Transfer of information on chemical substance contained within product [Act Art. 35]**
  - Responsible body: Any person transferring product containing notified chemical substance
  - Required Information [MD Art. 55]
    - Trade name
    - Chemical name and contents of Hazardous Chemical Substance contained
      (Other Component Information is not transferred)
    - Available or restricted use
    - Method or condition for proper use
    - Handling precautions on emergency response action in case of exposure
  - Upon request from any consumer, shall provide the above information within 45 days [MD Art. 55]

- **Information on composition or content**
  - In case of trade secrets pursuant to Prevention of Unfair Competition Act and Trade Secret Protection Act, the information will not be provided.
  - In case Safety/Labeling Standards per product are published, entire information will be provided.

- **Time for transfer of information**
  At the time of transferring, or prior to the transfer of Notified Product
7. What is Risk Concerned Product?

- Any Product published as having concern of the risk to public health/environment by MOE among chemical products
  a. Daily supplies for living: Any Product used mainly by general consumers such as cleaning agents, air fragrance, adhesive, polish, deodorant, synthetic detergent, bleaching agent and fabric softeners, etc.
  b. Biocides: Any Product used for killing all hazardous organisms excluding human and animals for restricting or inhibiting activity of such organism, such as insecticide, disinfectant, preservative, etc.

⇒ All chemical products listed above are called consumer product.

- Currently daily supplies for living such as cleaning agents, air fragrance, adhesive, polish, deodorant, synthetic detergent, bleaching agent and fabric softeners are controlled under the KC certification system of the Quality Management and Industrial Product Safety Management Act of Minister of Trade, Industry and Energy

⇒ Under K-REACH, cleaning agents, air fragrance, adhesive, polish, deodorant, synthetic detergent, bleaching agent and fabric softeners will be controlled under K-REACH.
8. Management of Risk Concerned Product

- **Risk Assessment per Product Group of Risk Concerned Product [Act Art. 33. 1]**
  - Responsible body: MOE
  - MOE may require industries necessary information for Risk Assessment.
  - Establishment of Risk Assessment Plan every 2 years

- **Establishment of Safety and Labeling Standard per Product Group [Act Art. 34. 1]**
  - Safety Standard includes the information on restricted substance and content in use, migration level, or emission level of hazardous chemical substance in Product [Act Art. 34. 2]
  - In certain cases, Safety standard may include the standard for container or package of Product. [Act Art. 34.3]

- **Withdrawal, Prohibition of sale, Disposal, etc. of Risk Concerned Product [Act Art. 37]**
  Necessary actions such as withdrawal, prohibition of sale, disposal, etc. of the relevant product in case of damage to human health/environment as caused by selling or giving any product not in compliance.

- **Advance grant is necessary before the manufacture or import of any Risk Concerned Product for which Safety and Labeling Standard has not been published. [MD Art. 57]**

  **Documents to submit: Identical to the documents of application for registration [refer to Act Art.14. 1]**
  ⇒ Submission to NIER [MD Art. 57.2]
9. Management under the Quality Management and Industrial Product Safety Management Act

<Product subject to KC Certification System – Prior approval system before placed at Market

Products subject to Self-Confirmation of Safety
Manufacturer or importer shall notify to the safety certification authority by self confirming compliance of Safety Standard and attach KC mark on products or packages.
⇒ There are Safety standard for Hazardous Chemical Substance per product item. (Refer to the table below)

Subject to Safety and Quality Labeling

<Safety standard of Hazardous Chemical Substance per product under KC system>
e.g) cleaning agents, air fragrance, polish

<table>
<thead>
<tr>
<th>Cleaning agents</th>
<th>Hydrochloric acid, Sulfuric acid</th>
<th>≤ 10% (as HCl)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sodium hydroxide, Potassium hydroxide</td>
<td>≤ 5% (as NaOH)</td>
</tr>
<tr>
<td></td>
<td>Tetrachloroethylene</td>
<td>≤ 0.1%</td>
</tr>
<tr>
<td></td>
<td>Trichloroethylene</td>
<td>≤ 0.1%</td>
</tr>
<tr>
<td>Air fragrances</td>
<td>Methyl alcohol</td>
<td>≤ 0.2%</td>
</tr>
<tr>
<td></td>
<td>Formaldehyde</td>
<td>25mg/L</td>
</tr>
<tr>
<td>Polishes</td>
<td>Triphenyl tin compounds</td>
<td>Must not be detected</td>
</tr>
<tr>
<td></td>
<td>Tributyl tin compounds</td>
<td>Must not be detected</td>
</tr>
<tr>
<td></td>
<td>Organomercury compounds</td>
<td>Must not be detected</td>
</tr>
</tbody>
</table>

Home supplies containing chemical substances [Self-confirmation of safety by Annex 7]
10. Test Data Requirement in Biocides Products (MD Annex 4(7))

**Biocide Products**

Product such as insecticides, antiseptics, preservatives, etc. which are used in order to kill or disrupt or hinder the activities of hazardous organism excluding human and animals

**Date Requirement for active substances in biocides products**

10 times more strict requirement is applied compared to general industrial chemical substance

<table>
<thead>
<tr>
<th>Volume of Active substance in Biocide Products</th>
<th>Required Test Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\geq 1\text{ ton/y} \sim &lt; 10\text{ ton/y}$</td>
<td>Required data for $\geq 10\text{ ton/y} \sim &lt; 100\text{ ton/y}$ of chemical substances in other industrial uses</td>
</tr>
<tr>
<td>$\geq 10\text{ ton/y} \sim &lt; 100\text{ ton/y}$</td>
<td>Required data for $\geq 100\text{ ton/y} \sim &lt; 1,000\text{ ton/y}$ of chemical substances in other industrial uses</td>
</tr>
<tr>
<td>$\geq 100\text{ ton/y} \sim &lt; 1,000\text{ ton/y}$</td>
<td>Required data for $\geq 1,000\text{ ton/y}$ of chemical substances in other industrial uses</td>
</tr>
<tr>
<td>$\geq 0.1\text{ ton/y} \sim &lt; 1\text{ ton/y}$</td>
<td>Required data for $\geq 1\text{ ton/y} \sim &lt; 10\text{ ton/y}$ of chemical substances in other industrial uses (Enforcement date: Jan. 1, 2020)</td>
</tr>
</tbody>
</table>

Note: Data requirement for Biocides in industrial use is same with other cases in industrial use chemicals
Thank You for Your Attention!

Safe Chemicals Co., Ltd.
( www.safechemicals.net )
Thank You
Korea REACH – Know Your Legal Obligations
October 23, 2014

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