Overview of The Act on the Registration and Evaluation of Chemicals (K-REACH) and Korea GHS

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<td>Food additives</td>
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<td>Agricultural Chemicals</td>
<td>Ministry for Food, Agriculture, Forestry &amp; Fisheries</td>
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<td>Fertilizer</td>
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<td>Fertilizers Control Act</td>
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<td>High Pressure Gas</td>
<td>Ministry of Knowledge Economy</td>
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<td>Radioactive Substances</td>
<td>Ministry of Education science and technology</td>
<td>Atomic Energy Act</td>
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### Korea: Chemical Regulatory Framework

#### Toxic Chemicals Control Act (TCCA)

- K-REACH, 1 Jan 2015
  - Registration of chemical substances
  - Hazard and risk assessments
  - Listing as authorization substances
  - Sharing of info on chemical substances
  - Control of risk concerned products

- Chemical Control Act (CCA), 1 Jan 2015
  - Statistical survey of chemical substances
  - Safety control of hazardous substances
  - License related to toxic substances
  - Imposing chemical accident reporting obligations and establishing emergency response system.

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K-REACH: Timeline

Entry into Force

2013.4.30

Act Passed National Assembly

2015.1.1

Registration: new substances

Registration: designated existing substances (>=1t/y)

Grace period: max 8 years

2 yrs from listing

5 yrs from listing

8 yrs from listing
K-REACH: Break-down

8 Chapter, 54 Articles and an addendum

- General Rules (article 1 ~ 7) – Definition & scope etc
- Registration of chemical Substances (article 8 ~ 17)
- Hazardous Evaluation and Risk Assessment of chemical substances (article 18 ~ 24)
- Listing and changing authorization substances (article 25 ~ 28)
- Communication of chemical substance information (article 29 ~ 31)
- Management of Risk Concerned products (article 32~37)
- Supplementary Provisions (article 38 ~ 48)
- Penalties (article 49 ~ 54)
- Addendum (article 1 ~ 7)
K-REACH: Definition

1) Existing Substance
   - Chemical substances distributed for commercial uses in Korea prior to February 2, 1991 and published by MoE;
   - ~42,652 substances (up to Jan 2013).

2) New Substance
   - Other than above;
   - i.e., new substance notified between 2012-2014 but not published.
3) Hazardous Substance  Includes:

- **Toxic chemical substance**: published by MOE as hazardous;
- **Authorization substance**: published by MoE due to high risks, prior authorization required for use;
- **Restricted substance**: published by MoE, restricted for certain uses;
- **Prohibited substance**: published by MoE, banned for all uses;
- other substances with potential hazards or risks;

http://ncis.nier.go.kr/totinfo/TotInfoList.jsp?sub=02
4) Product

Means each of following that are likely to result in the exposure of chemicals to consumers as final consumer goods or parts thereof and accessories.

- Product consisting of a mixture.
- Product of which the chemicals are not released during the course of uses and perform a certain function in a particular solid form.

5) Risk-concerned products

Mean the ones published by MoE as they are concerned to pose risks to public health or environment:

- Consumer product (cleaner, detergent, adhesive, etc);
- Biocidal products (disinfectant, insect repellant, preservative, etc)
1) **K-REACH does not apply to:**

- Radioactive substances;
- Pharmaceutical products and quasi-drugs;
- Narcotics;
- Cosmetics and raw materials for cosmetics;
- Pesticides and active ingredients for pesticides;
- Fertilizers;
- Food, food additives, food device & food packaging;
- Feeds;
K-REACH: Overview

Existing substance ≥ 1t/y

Designated existing substance ≥ 1t/y

Toxic substance

Authorization substance

Restricted/prohibited substance

Annual Report

Registration

Hazard evaluation

Risk Assessment

New substance
1) **Notifier:**
Manufacturer/Importer/Only Representative;

2) **Target Substance**
   - New substance;
   - Existing substance $\geq 1$ t/y;

3) **Information To Be Reported**
   - Volume;
   - Use;
4) Reporting of Changes

When substance is used for other purposes;

5) Exemptions from Reporting

- Substance imported as an internal component of machinery.
- Substance imported with machinery/equipment for trial operation;
- Substance contained in a product in a solid form to perform a certain function without being released during normal use.
- Other substances manufactured/imported for investigation and research purposes, which are prescribed in the Presidential Decree.
K-REACH: Registration

1) Registrant:
   Manufacturer/Importer/Only Representative;

2) Target Substance
   - New substance irrespective of volume;
   - Designated existing substance $\geq 1\text{t/y}$;
   - $< 1\text{t/y}$ but causing serious damage to public health and environment
3) Exemptions from registration (does not require confirmation)

- Substance imported as an internal component of machinery;
- Substance imported with machinery or equipment for trial operation;
- Substance contained in a product in a solid form to perform a certain function with no intention of being released normal conditions of use.

4) Confirmation of exemption required

- M/I<=10t/y in/into Korea and to be exported in its entirety
5) **Documents Required:**

- Legal entity information & substance identity;
- Use information;
- Classification and Labeling of chemical substance
- Physico-chemical properties of chemical substance
- Hazard information of chemical substance
- Risk information including exposure scenario (For >=10t/y substance, different deadlines apply).
- Guidance on safe uses
- Other data prescribed by the Ministerial Decree
6) **Reduced Requirements**  
   - Available for some substances (<1t/y new substance, PLC, R&D substance etc.) listed in the Presidential Decree;

7) **Joint submission:**  
   - Mandatory;

8) **Opt-out;**  
   - Allowed (approval from MOE required;)

9) **Testing proposal;**  
   - Accepted.
10) Submission of Data for Risk Assessment

<table>
<thead>
<tr>
<th>Tonnage</th>
<th>Deadline of Submission</th>
</tr>
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<tbody>
<tr>
<td>≥100 ton per year</td>
<td>1st Jan 2015</td>
</tr>
<tr>
<td>70 ~100 ton per year</td>
<td>1st Jan 2017</td>
</tr>
<tr>
<td>50 ~70 ton per year</td>
<td>1st Jan 2018</td>
</tr>
<tr>
<td>20 ~50 ton per year</td>
<td>1st Jan 2019</td>
</tr>
<tr>
<td>10 ~20 ton per year</td>
<td>1st Jan 2020</td>
</tr>
</tbody>
</table>
1) **Period**: Between now and 1 Jan 2015;

2) **Transitional Measures**:

   - Any person who had received an exemption confirmation of hazard examination pursuant to current TCCA shall be deemed to have received an exemption confirmation of registration under K-REACH.
     - Applicable to: small volume(<100kg/y, R&D substance, new polymer of low concern, 2% polymer rule, surface treatment substance).

   - Any person who made new substance notification pursuant to current TCCA shall be deemed to have completed registration of substance under K-REACH.
1) Notifier:
M/I of **products** containing **hazardous substance** \( \geq 1 \text{t/y} \);

2) Information to be notified
- name of chemical substance, content
- information on its hazards and use

3) Exemptions from notification (does not require confirmation)
- A product in which the substance is contained in **solid** form to perform a certain function and **is not released** under normal use;

4) Confirmation of notification exemption required
- Exposure to human/environment can be excluded
- **Chemical substances already registered for that use**
K-REACH: Risk Assessment of Risk-concerned Product

Risk-concerned Product (A or B) → Safety · Labeling Standard

- Non-compliant → Prohibition from Sales
- Order of Withdrawal
- Unpublished → Require Approval

A. Household consumer product
- Cleaner
- Perfumery
- Adhesives
- Polish
- Fabric softener
- ...

B. Biocidal product
- Insect repellents
- Disinfectants
- Preservatives
- ....
K-REACH: Only Representative

1) **Appointed by:** a foreign manufacturer;

2) **Qualification of OR:** to be specified by MoE;

3) **Responsibilities of the representative**
   - annual reporting under Article 8;
   - registration under paragraph 3 of Article 10;
   - product notification under Article 32;
   - other activities as specified in the Presidential Decree
## Comparison between EU, Korea and China

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<tr>
<th>Items</th>
<th>Korea REACH</th>
<th>EU REACH</th>
<th>China REACH</th>
</tr>
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<tbody>
<tr>
<td>Registration Object</td>
<td>New substance; Designated existing substance&gt;=1t/y;</td>
<td>New substance&gt;=1t/y; Existing substance&gt;=1t/y;</td>
<td>New substance</td>
</tr>
<tr>
<td>Who can register</td>
<td>M/I/OR</td>
<td>M/I/OR</td>
<td>M/I/OR</td>
</tr>
<tr>
<td>Type of Registration</td>
<td>Wait for guidance (full/reduced)</td>
<td>PPORD, intermediate, full</td>
<td>R&amp;D; simplified; full</td>
</tr>
<tr>
<td>Tonnage Level</td>
<td>1-10, 10-100, 100-1000, 1000+(expected)</td>
<td>1-10, 10-100, 100-1000, 1000+</td>
<td>1-10, 10-100, 100-1000, 1000+</td>
</tr>
<tr>
<td>Polymer</td>
<td>Registration of polymer itself</td>
<td>Registration of monomer &amp; reactant(&gt;=2%)</td>
<td>Registration of polymer itself</td>
</tr>
<tr>
<td>Risk Assessment</td>
<td>&gt;=10t/y</td>
<td>&gt;=10t/y</td>
<td>1-10t: qualitative; &gt;=10t: quantitative</td>
</tr>
<tr>
<td>Submission of Risk Info</td>
<td>Can be separated from dossier</td>
<td>In dossier</td>
<td>In dossier</td>
</tr>
</tbody>
</table>
## Comparison between EU, Korea and China

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<thead>
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<th>EU REACH</th>
<th>China REACH</th>
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<tr>
<td>Joint submission</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Not Mandatory</td>
</tr>
<tr>
<td>Inquiry Process</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Testing Proposal</td>
<td>Accepted</td>
<td>Accepted</td>
<td>No</td>
</tr>
<tr>
<td>Administrative fee to authority</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Restriction /Authorization</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Annual Report</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Cosmetic ingredients</td>
<td>Exempt from registration</td>
<td>Not exempt</td>
<td>Not exempt</td>
</tr>
<tr>
<td>Other Issues</td>
<td>Product notification Risk Assessment of risk-concerned products</td>
<td>SVHC notification</td>
<td>Some eco-toxicology tests must be done in China</td>
</tr>
</tbody>
</table>
## How to Comply with Korea REACH & GHS (1/2)

<table>
<thead>
<tr>
<th>Item</th>
<th>What to do</th>
</tr>
</thead>
</table>
| **Annual reporting**      | - Draw up a list of substances exported to Korea & volume;  
- Decide who will do annual reporting: Korean importer or OR;  
- OR can keep your confidential business information. |
| **Registration**          | - Track the list of designated existing substances sub. to registration  
- Track the guidance on registration;  
- Application of exemption confirmation under TCCA or submit new substance notification under TCCA. |
| **Toxic, authorization, restricted, prohibited substances** | - Obtain relevant lists from [http://ncis.nier.go.kr](http://ncis.nier.go.kr) and check it against your products;  
- Keep track of designation of authorization substances. |
<table>
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<tr>
<th>Item</th>
<th>What to do</th>
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<tbody>
<tr>
<td><strong>Sharing of information on chemical substances</strong></td>
<td>- Update your SDSs after registration;</td>
</tr>
<tr>
<td></td>
<td>- Check the format to be given by authorities.</td>
</tr>
<tr>
<td><strong>Products containing hazardous chemical substances</strong></td>
<td>- Identify if your products contain hazardous substances (&gt;=1t/y);</td>
</tr>
<tr>
<td></td>
<td>- Choose between Korean importer or OR;</td>
</tr>
<tr>
<td></td>
<td>- Keep track of the notification requirements to be issued</td>
</tr>
<tr>
<td><strong>Risk concerned products</strong></td>
<td>- Identify if any of your products is a risk concerned product;</td>
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<td>- Make sure that your products comply with the relevant safety and labeling standards.</td>
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**Summary**  
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1) Main Standard:
Standards on classification and labelling of chemical substances and the Material Safety Data Sheet (MoEL Notice No. 2012-14)

2) Implementation Period
β Substance: 1 July 2010; Mixture: 1 July 2013;

3) Building Blocks vs UN GHS Rev 4
β CHEMICALLY UNSTABLE GAS Category A/B
β AEROSOLS Cate. 3
β FLAMMABLE LIQUIDS Cate. 4
β SKIN CORROSION / IRRITATION Cate. 3
β ACUTE TOXICITY Cate. 5
β AQUATIC TOXICITY (ACUTE) Cate. 2 & 3
4) Compulsory Classification List

- Mandatory to follow C&L conducted by NIER for toxic chemicals (>620);
- http://ncis.nier.go.kr/ghs/board/list_1_view.jsp?board_id=00202&seq=6

For amended list of GHS classification and labelling list of Toxic Chemicals, please click here.

Label system, please click here.
5) SDS

β Section 3: ± 5%; if the contents are less than 5%, the lower limit shall be indicated as “≥ 1% (0.1% for carcinogens and germ cell mutagens, 0.2% for respiratory sensitizers, and 0.3% for reproductive toxicants);

β Section 3: substance name, CAS or content may not be shown in case of confidential data.

http://www.kosha.or.kr/msds/msdsMain.do?menuId=69
6) Labelling

β Standard GHS labelling elements;
β Supplier info must be a supplier based in Korea;
β 4 pictograms & 6 p-statements limits: Not compulsory;
β Container<=100ml: h&p statements can be omitted;

<table>
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<tr>
<th>Capacity</th>
<th>Size of label</th>
<th>Size of pictogram</th>
</tr>
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<tbody>
<tr>
<td>500 L ≤ Capa.</td>
<td>450 cm²</td>
<td>1/40 of surface area; Min. 0.5 cm²</td>
</tr>
<tr>
<td>200 L ≤ Capa. ≤ 500L</td>
<td>300 cm²</td>
<td></td>
</tr>
<tr>
<td>50 L ≤ Capa. ≤ 200L</td>
<td>180 cm²</td>
<td></td>
</tr>
<tr>
<td>5 L ≤ Capa. ≤ 50L</td>
<td>90 cm²</td>
<td></td>
</tr>
<tr>
<td>Capa. ≤ 5L</td>
<td>&gt;5% of area</td>
<td></td>
</tr>
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</table>
7) **Languages**

- Korean (not required for an imported chemical reagent for lab use & research purpose);
- English accepted for chemical name & foreign company name;

8) **Impact of K-REACH on Korea GHS**

- More harmonized classifications (for tox. chemicals) published;
- When transferring registered substance, companies will need to provide the following information in SDSs:
  - registration number;
  - name;
  - information on its hazards and risks;
  - information on safety control and others;
Summary

- Korean Chemical Regulatory Framework;
- Korea REACH Introduced & Advice Given;
- Korea GHS Summarized.
Thank You!

谢谢！