The Korean REACH

Humidifier Sterilizer Incidents in Korea (2006 ~ 2011)

Polyhexamethylene guanidine phosphate (n/x=1~2)
(PHMG phosphate)
CAS RN 89697-78-9

- 1994, 1st Humidifier Sterilizer introduced to market
- 2006 ~ 2010, Numerable damaged lung cases reported, but cause not identified
- Apr 2011, Epidemiological Investigation initiated
- Aug 2011, Investigation concluded: humidifier sterilizer responsible
- Sep 2011, Animal test initiated
- Nov 2011, Relevant products driven out of market
- Apr 2014, Study of 361 cases completed: 75 deaths, 93 damages
- Apr 2015, Study of addition 169 cases: 17 deaths, 32 damages
- Total of 217 victims (92 deaths, and 125 damages)
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Korean Act on Registration and Evaluation of Chemicals

- Apr 2011: Humidifier Sterilizer Incident
- Sep 2012: Chemical Accident in Gumi
- May 2013: Enactment of K-REACH
- Dec 2014: Enforcement Ordinance & Decree
- Jan 2015: Enforcement of K-REACH

* 12 Implementing guidelines finalized (Dec 2014)

Major Arguments during Legislation

<table>
<thead>
<tr>
<th>Arguments</th>
<th>Settled</th>
</tr>
</thead>
<tbody>
<tr>
<td>① Registration exemption for R&amp;D</td>
<td>Exempted same as at present, but w/ additional safety devices (submission of management plan, etc.)</td>
</tr>
<tr>
<td>② Registration of non-phase-in substance in small amount</td>
<td>Even small amount of substance should be registered, &amp; Simplified materials for submission &amp; Shortened registration period</td>
</tr>
</tbody>
</table>
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- Lack of chemical info.
- No system for transferring chemical info.
- Household chemicals in consumer product (e.g. humidifier disinfectant)

Toxic Chemicals Act
(Enacted in 1992)

Chemicals Control Act
Registration & Evaluation of Chemical Substances

Promulgation of K-REACH enactment on May 22, 2013

Promulgation of revised CCA on Jun. 4, 2013

Enforced on Jan. 1, 2015

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Chapters

✓ Chapter 1 : General provision (Article 1 ~ 7)
✓ Chapter 2 : Registration of Chemicals (Article 8 ~ 17)
✓ Chapter 3 : Hazard evaluation & Risk assessment (Article 18 ~ 24)
✓ Chapter 4 : Designation of authorization chemicals and etc. (Article 25~28)
✓ Chapter 5 : Communication on chemicals information (Article 29 ~ 31)
✓ Chapter 6 : Management of risk concerned product (Article 32 ~ 37)
✓ Chapter 7 : Supplementary provisions (Article 38 ~ 48)
✓ Chapter 8 : Penalties (Article 49 ~ 54)
✓ Addendum (Article 1 ~ Article 7)
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Exempted from the Act:

- Radioactive substances
- Medicinal products and quasi-drugs
- Narcotics
- Cosmetics
- Agrochemicals and active ingredient
- Fertilizer
- Food and food additives, packaging
- Feed
- Explosives such as gunpowder
- Military supplies
- Health functional food
- Medical appliance
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Definitions (1)

Phase-in Chemicals
- Chemicals domestically distributed for commercial purpose prior to February 2, 1991 and publicly announced as such by the MoE (37,021 substances)
- Chemical substances that has undergone the Hazard examination process after February 2, 1991 under TCCA and publicly announced as such by the MoE (6,163 substances)
- Most of the chemical substances that has undergone the Hazard examination process between Jan 1, 2012 and Dec 31, 2014, but not yet announced as such by MoE (1,277 substances) → to be confirmed and announced after consultation with the companies

Non-phase-in Chemicals
- All chemical substances excluding phase-in chemicals

Phase-in Chemicals subject to Registration
- Chemicals designated out of phase-in chemicals based on exposure potential such as circulation volume, hazards of chemicals, etc., published by MoE
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Definitions (2)

Hazard
- properties of chemical substances, including toxicity, which are detrimental to human health or the environment
  → (1) Hazard Examination: initiated by the registration of companies
    (2) Hazard Evaluation: initiated by the government (without the registration)

Risk
- degree of damage to human health or the environment when exposed to hazardous chemical substances
  → Risk Assessment: If production/import volume $\geq 100$ton/year (to be strengthened as 10ton/year by 2020)

or needed by the result of the hazard examination/evaluation
Definitions (3)

Intermediates
- Chemical substances that are produced in the process of making some other chemical substances and entirely consumed within that process.
  → (1) **Non-isolated Intermediates**: Not intentionally removed or isolated from the production facility
    ⬤ exempted from registration
  (2) **Isolated Intermediates**: Other than isolated intermediates
    ⬤ exempted from registration if leak or exposure is technically blocked

Polymers
- Molecules characterized by the sequence of one or more types of monomer units
  → Polymers of low risk concern are exempted from registration
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Overview of Registration Process

- **Reporting**
  - Phase-in Chemicals (≥ 1 ton/year)
    - Designation as phase-in chemicals subject to Registration
  - Non-phase-in Chemicals (all)
- **Registration**
  - Designation as Toxic Chemicals
  - Hazard Examination
  - Risk Assessment
  - If ≥ 100 ton/year or depending on hazard examination results
- **Designation as**
  - Authorization Chemicals
  - Restricted/Prohibited Chemicals
  - Considering international treaty

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Reporting (Article 8)

- Purpose:
  - Basic data for selecting substance subject to registration
  - Grasp those responsible for joint registration for same substance
  - Understanding the status of registration compliance
  - Confirming any change after registration

- What to Report: Non-phase-in substance & at least 1 ton per year of Phase-in substance

- How to report: Manufacture, import and sale from Jan 1 to Dec 31, by Jun 30 every year

- Who Reports?
  Those who manufacture, import and sell chemical substances
  (VS. Registration is for those who manufacture and import chemical substance)

  => Only those selling chemical substance to person who uses it as raw material in workplace
  (except those selling a product to person who consumes it in workplace & person who
  sells a product directly to consumer)

Exempted from reporting

1. Chemicals in imported machineries
2. Chemicals in imported machinery devices for test-run
3. Chemicals contained in solid form product that is not released during use
4. Manufactured/imported substances for the purpose of research and studies
5. Others chemicals listed in Presidential Decree etc.
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Registration (Article 10)

- **Purpose**: To get the health and safety information of chemicals
- **What to Report**: “ALL” non-phase-in substance & at least 1 ton per year of phase-in substance subject to registration
- **Who reports HOW?**: Prior to manufacture or import.

- **Separation of registration and examination procedures** (same as EU)
  - Registration: procedure for checking whether all dossiers are rightly prepared
  - Examination: procedure for reviewing contents of all dossiers

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**Toxic Chemicals Control Act**

- Application
- Examination
- Manufacture & Import

**K-REACH**

- Application
- Registration
- Manufacture & Import
- Examination

**Examination Period**: 60 days

**Examination Period**: down to 30 days

For small amount: to 3~7 days
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Phase-in Substances subject to Registration (Article 9)

- Designated every 3 years: Consider amount of use & data on hazards and risks
- 3 years of grace period
- Prior notice and public comments

1\textsuperscript{st} (2015) 2\textsuperscript{nd}(2018) 3\textsuperscript{rd} (2021)

Grace Period for 1\textsuperscript{st} Grace Period for 2\textsuperscript{nd} Grace period for 3\textsuperscript{rd}

※ Prior notice of 1\textsuperscript{st} list given in Dec 2014, and scheduled to be finalized in June 2015
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## Registration Dossier (Article 10 & 14)

<table>
<thead>
<tr>
<th></th>
<th>Info. For Regis.</th>
<th>Standard for Regis.</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Identity of Manufacturer/Importer</td>
<td></td>
<td>- Name, location, representative</td>
</tr>
<tr>
<td>2</td>
<td>Identity of Substance</td>
<td></td>
<td>- name, identity data (e.g. molecular formula, structural formula)</td>
</tr>
<tr>
<td>3</td>
<td>Use</td>
<td>○ Non-phase-in substance</td>
<td>- classification system of uses, confirmed use, impermissible use</td>
</tr>
<tr>
<td>4</td>
<td>Classification &amp; Labeling</td>
<td>○ Phase-in substance subject to registration (more than 1 ton per year)</td>
<td>- items of global classification and labeling standard (i.e. GHS)</td>
</tr>
<tr>
<td>5</td>
<td>Physicochemical Properties</td>
<td></td>
<td>- differentiated according to tonnage (maximum 46)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- submitted as full test data or summery</td>
</tr>
<tr>
<td>6</td>
<td>Hazards</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Guidance on Safe Use</td>
<td></td>
<td>- PPE, responses when explosion, fire or release is occurred, etc.</td>
</tr>
<tr>
<td>8</td>
<td>Hazards</td>
<td>○ More than 100 tons per year (getting stricter)</td>
<td>1) hazard evaluation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2) exposure evaluation (exposure scenario / exposure forecast)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3) prepared in priority of safety confirmation</td>
</tr>
<tr>
<td>9</td>
<td>Exposure info., Estimated quantities</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>