South Korea: Polymer Registration and Exemptions under TCCA and K-REACH Webinar

22 July 2014, 9:30am BST
Today’s webinar aims

• To outline the key registration and notification obligations for foreign manufacturers under K-REACH.

• To hear the options for the registration of polymers under the current TCCA and how this, and in particular exemptions, will be treated under K-REACH.
Jun Ho Lee, Senior Researcher, Risk Assessment Center, Korea Testing & Research Institute (KTR)

Young Gil Yang, Senior Researcher, Korea Testing and Research Institute (KTR)

Chair: Sarah Thompson, Hubs Editorial Content Manager, Chemical Watch.
v Please submit questions during the webinar using your chat box

v Any unanswered questions can be raised on our Forum following the webinar:  
http://forum.chemicalwatch.com/
K-REACH
Brief obligations for foreign manufacturers

Chemical Watch

2014. 7. 21.

Jun Ho Lee
Risk Assessment Center
Chemical and Environmental Division
KTR History

- **APR 01 ‘69** - Foundation of KTR
- **DEC 12 ‘02** - Established Incheon Laboratory
- **JUN 27 ‘12** - Registration as an Energystar EPA designated testing lab
- **MAR 10 ‘09** - Accredited by Det Norske Veritas
- **DEC 29 ‘09** - Accredited by American Bureau of Shipping
- **OCT 29 ‘09** - Accredited by Renault (French Republic)
- **OCT 13 ‘08** - Accredited by Chrysler Testing·Inspection·Failure factor analysis Institute
- **MAY 23 ‘08** - Established KTR Europe GmbH (Germany)
- **MAR 22 ‘07** - Established Ulsan laboratory
- **FEB 07 ‘07** - Established a branch in China
- **APR 17 ‘02** - Established Gimpo Laboratory
- **OCT 18 ‘11** - The nation’s first KOLAS registration of HEMP protection facilities assessment testing
- **JUL 08 ‘10** - New substances registration service at the European REACH (KTR Testing Results)
- **MAY 12 ‘10** - Established the Health Care Research Institute
- **JUN 25 ‘13** - Established the Materials and Parts Center in Busan
- **JUN 11 ‘13** - Registration as an Energystar EPA designated testing lab
- **OCT 29 ‘09** - Accredited by Det Norske Veritas
KTR Network

KTR is legally founded under the Framework Act on National Standards of Korea

Organization Structure
- Total 20 Offices
  (Headquarters, 7 Laboratories, 12 branches, 2 oversea branches)

Employees
- Total 850 employees

Gimpo Lab
Headquarters
Yongin Lab

Gimpo Lab
Incheon Lab
Ulsan Lab

Health Care Research Institute
Material & Components Laboratory

Germany Branch
China Branch

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Total 20 Offices
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Contents

1. Introduction
2. Annual Reporting
3. Registration
4. Notification
5. High Risk Concerned Products
6. Others
1 Introduction
Introduction - History

K-REACH Draft proposed by MoE

Compensated version of K-REACH passed
Sub-committee of Environment and Labor Committee (ELC)

Official Announcement of K-REACH

Enforcement of K-REACH

28th Sept 2012

4th April 2013

30th April 2013

18th Feb 2014

1st Jan 2015

24th April 2013

22nd May 2013

Final version with small updates passed the NA

Pre-announcement of K-REACH with Draft Presidential and Ministerial Decrees

Another K-REACH Draft proposed by NA Members
# Introduction - Comparisons

<table>
<thead>
<tr>
<th></th>
<th>Korea TCCA</th>
<th>EU K-REACH</th>
<th>EU REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject to Registration</td>
<td>New chemicals</td>
<td>Designated existing chemicals New Chemicals</td>
<td>Existing chemicals New Chemicals</td>
</tr>
<tr>
<td>Annual report of tonnages</td>
<td>X</td>
<td>O</td>
<td>X</td>
</tr>
<tr>
<td>Registrants</td>
<td>Manufacturer, Importer</td>
<td>Manufacturer, Importer, Representative</td>
<td>Manufacturer, Importer, Representative</td>
</tr>
<tr>
<td>Registration tonnage</td>
<td>0.1~1T, &gt;1T</td>
<td>&lt;1T, 1<del>10T, 10</del>100T, 100~1000T, &gt;1000T</td>
<td>1<del>10T, 10</del>100T, 100~1000T, &gt;1000T</td>
</tr>
<tr>
<td>Processing time</td>
<td>60 days</td>
<td>30 days</td>
<td>1~2 weeks</td>
</tr>
<tr>
<td>Evaluation</td>
<td>All dossiers</td>
<td>All dossiers</td>
<td>5% of all dossiers</td>
</tr>
<tr>
<td>Evaluation criteria</td>
<td>Hazards</td>
<td>Risks</td>
<td>Risks</td>
</tr>
<tr>
<td>Listing as existing</td>
<td>After 3 years</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Product</td>
<td>X</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>
# Obligations - Only Representative

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Only Representative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge on chemical substances</td>
<td>• Knowledge on chemical substances</td>
</tr>
<tr>
<td></td>
<td>• More than 3 years of experience on chemical managements</td>
</tr>
<tr>
<td>What ORs can do</td>
<td>• Annual report (updates)</td>
</tr>
<tr>
<td></td>
<td>• Registration (updates, changes, exemptions)</td>
</tr>
<tr>
<td></td>
<td>• Enquiry for registration</td>
</tr>
<tr>
<td></td>
<td>• Notification</td>
</tr>
<tr>
<td></td>
<td>• Communication of information</td>
</tr>
<tr>
<td>Considerations</td>
<td>A legal entity to represent foreign companies for K-REACH</td>
</tr>
<tr>
<td></td>
<td>• Reliability and Sustainability are important</td>
</tr>
<tr>
<td></td>
<td>• Appoint of OR is to be notified to authorities</td>
</tr>
</tbody>
</table>
2 Annual Reporting
# Obligations – Annual Reporting

<table>
<thead>
<tr>
<th>Annual Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Which</strong></td>
</tr>
<tr>
<td>• New chemical substances</td>
</tr>
<tr>
<td>• Existing substances manufactured, imported or <strong>sold</strong> more than 1 ton per annum</td>
</tr>
<tr>
<td><strong>Who</strong></td>
</tr>
<tr>
<td>Manufacturer, Importer or Seller (OR for foreign companies)</td>
</tr>
<tr>
<td><strong>What</strong></td>
</tr>
<tr>
<td>• Reporter information (name, address, contact info)</td>
</tr>
<tr>
<td>• Substance information (name, CAS no)</td>
</tr>
<tr>
<td>• Tonnage</td>
</tr>
<tr>
<td>• Uses</td>
</tr>
<tr>
<td><strong>Seller</strong></td>
</tr>
<tr>
<td>Someone who sells chemical substances for industrial uses</td>
</tr>
<tr>
<td><strong>Tonnage</strong></td>
</tr>
<tr>
<td>Amount from 1st Jan till 31st Dec</td>
</tr>
<tr>
<td><strong>When</strong></td>
</tr>
<tr>
<td>By 30\textsuperscript{th} April next year</td>
</tr>
<tr>
<td><strong>Update</strong></td>
</tr>
<tr>
<td>• Change of reporter information (within 1 month)</td>
</tr>
<tr>
<td>• Change of uses (within 1 month from the date of acknowledgement of the change)</td>
</tr>
<tr>
<td><strong>First AR</strong></td>
</tr>
<tr>
<td>30\textsuperscript{th} April 2016 (Tonnage form 1\textsuperscript{st} Jan 2015 ~ 31\textsuperscript{st} Dec 2015)</td>
</tr>
</tbody>
</table>
**Exemptions**

- Chemical substances imported as incorporated in machines;
- Chemical substances imported along with machines or devices for commissioning test;
- Chemical substances in products in solid form, performing certain functions and does not release during normal condition of use;
- Other chemical substances as listed in the Presidential Decree that are manufactured or imported for uses in research, studies, etc.
  - Reagents
  - R&D
  - Non-isolated intermediates
## Obligations – Communication (Annual Report)

### Communication of information within supply chain for annual report

<table>
<thead>
<tr>
<th>Information communication</th>
<th>Manufacturers or importers may request information required for annual report from downstream users</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer/Importer</strong></td>
<td><strong>Downstream User/Seller</strong></td>
</tr>
<tr>
<td>Name</td>
<td>Name</td>
</tr>
<tr>
<td>substance/product information</td>
<td>Substance/product information</td>
</tr>
<tr>
<td>tonnage (can be left out)</td>
<td>Use/sell tonnages</td>
</tr>
<tr>
<td>Possible/restricted uses</td>
<td>Specific use information</td>
</tr>
<tr>
<td>Guidance on safe use</td>
<td>Exposure information</td>
</tr>
<tr>
<td>Physico-chemical/hazards information</td>
<td>measures taken for safe use</td>
</tr>
<tr>
<td>Related regulations</td>
<td></td>
</tr>
</tbody>
</table>

**DU**

Manufacturer of importer needs to provide chemical substance properties, uses, tonnages safe use information and etc when downstream user requests such information.
3 Registration
### Obligations – Registration (General)

| Which | New chemical substances  
|       | Designated Existing substances manufactured or imported more than 1 ton per annum  
|       | (or <1 tpa when requested by Minister of Environment)  
|       | Substances will be designated every 3 years  
|       | 3 years of grace period from the date of official announcement |
| Who   | Manufacturer or Importer (OR for foreign companies) |
| What  | Registrant information (name, address, contact info)  
|       | Substance information (name, CAS no, concentration, molecular formula, impurities, etc)  
|       | Tonnage, Uses, C&L  
|       | Physico-Chemical Properties  
|       | Hazardous and Risk Information  
|       | Guidance on safe use  
|       | Other information requested by Ministerial Decree |
| Tonnage | Amount from 1st Jan till 31st Dec of the year of submission |
| Announcement | Substance name and cas no/KE no, Grace period  
|       | Required test data (for substances <1 tpa, requested by MoE) |
### Obligations - Registration (Simplified)

<table>
<thead>
<tr>
<th>Registration (Simplified)</th>
<th>Before 2020</th>
<th>After 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonnage</td>
<td>&lt; 1ton</td>
<td>&lt;100 Kg</td>
</tr>
<tr>
<td>Registration</td>
<td>Simplified</td>
<td>Simplified</td>
</tr>
<tr>
<td>Process time</td>
<td>3 days</td>
<td>3 days</td>
</tr>
<tr>
<td>Required data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Registrant information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Uses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Substance information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Exposure information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• No hazard data required</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Obligations - Registration (Polymers)

<table>
<thead>
<tr>
<th>Tonnage</th>
<th>Data for Polymer properties</th>
<th>Data Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 ~ 10</td>
<td>• Number-average molecular weight&lt;br&gt;• Monomer information&lt;br&gt;• Remaining monomers&lt;br&gt;• Content of oligomers with less than 1,000 Daltons&lt;br&gt;• Acid or base solution stability</td>
<td>• Physical state&lt;br&gt;• Water solubility&lt;br&gt;• Melting point&lt;br&gt;• Boiling point&lt;br&gt;• Vapor pressure</td>
</tr>
<tr>
<td>10 ~ 100</td>
<td></td>
<td>Above endpoints plus&lt;br&gt;• Acute toxicity oral (Inhalation)&lt;br&gt;• AMES,&lt;br&gt;• Short-term toxicity testing on fish&lt;br&gt;• Ready Biodegradation</td>
</tr>
<tr>
<td>100 ~ 1000</td>
<td></td>
<td>General Data Requirement for 1 ~ 10 tpa</td>
</tr>
<tr>
<td>1000~</td>
<td></td>
<td>General Data Requirement for 10 ~ 100 tpa</td>
</tr>
</tbody>
</table>
## Obligations – Registration (Intermediates)

<table>
<thead>
<tr>
<th>Registration (Intermediate)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Which</strong></td>
</tr>
<tr>
<td>• Substances produced during the production of another substance.</td>
</tr>
<tr>
<td>• All amount is used within the process to produce the other substance</td>
</tr>
<tr>
<td>• Do not include non-isolated intermediates</td>
</tr>
<tr>
<td><strong>What</strong></td>
</tr>
<tr>
<td>• Registrant information (name, address, contact info)</td>
</tr>
<tr>
<td>• Substance information (name, CAS no, concentration, molecular formula, impurities and etc)</td>
</tr>
<tr>
<td>• Uses</td>
</tr>
<tr>
<td>• C&amp;L</td>
</tr>
<tr>
<td>• Physico-Chemical Properties of General data requirement</td>
</tr>
<tr>
<td>• Hazardous and Risk Information (if available)</td>
</tr>
<tr>
<td>• Guidance on safe use (if available)</td>
</tr>
<tr>
<td>• Other information requested by Ministerial Decree (if available)</td>
</tr>
</tbody>
</table>
### Obligations – Registration (Biocides)

<table>
<thead>
<tr>
<th>Tonnage</th>
<th>General data requirements</th>
<th>Data Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1 ~ 1 (from 2020)</td>
<td></td>
<td>General Data Requirement for 1 ~ 10 tpa (15 endpoints)</td>
</tr>
<tr>
<td>1 ~ 10</td>
<td>Data regarding active ingredients</td>
<td>General Data Requirement for 10 ~ 100 tpa (26 endpoints)</td>
</tr>
<tr>
<td>10 ~ 100</td>
<td></td>
<td>General Data Requirement for 100 ~ 1000 tpa (37 endpoints)</td>
</tr>
<tr>
<td>100~</td>
<td></td>
<td>General Data Requirement for 1000 ~ tpa (47 endpoints)</td>
</tr>
</tbody>
</table>
| No confirmation required | Chemical substances imported as incorporated in machines;  
| | Chemical substances imported along with machines or devices for commissioning test  
| | Chemical substances in products in solid form, performing certain functions and does not release during normal condition of use |
| Confirmation Required | Manufactured or imported less than 10 ton per annum AND all of the manufactured or imported chemical substances are exported  
| | Reagents for scientific study, analysis or research  
| | R&D purpose of  
| | Development of chemicals or products  
| | Improvement or development of process  
| | Testing application scope of chemicals  
| | Pilot production  
| | Polymer with Low Concerns (temp name)  
<p>| | Surface treated substance where treating and treated are both not subject to registration |</p>
<table>
<thead>
<tr>
<th>Obligations – Registration (Uses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 吸水/吸著剤 (Absorbents and Adsorbents)</td>
</tr>
<tr>
<td>2. 適著剤 (Adhesive, binding agents)</td>
</tr>
<tr>
<td>3. 噴射薬剤 (Aerosol Propellants)</td>
</tr>
<tr>
<td>4. 水温保持剤 (Anti-condensation agents)</td>
</tr>
<tr>
<td>5. 防冷剤 (Anti-freezing agents)</td>
</tr>
<tr>
<td>6. 適着防止剤 (Anti-set-off and anti-adhesive agents)</td>
</tr>
<tr>
<td>7. 静電防止剤 (Anti-static agents)</td>
</tr>
<tr>
<td>8. 脱色剤 (Bleaching agents)</td>
</tr>
<tr>
<td>9. 清洗剤, 세척剤 (Cleaning/washing agents and additives)</td>
</tr>
<tr>
<td>10. 彩色剤 (Colouring agents)</td>
</tr>
<tr>
<td>11. 部分剤 (Complexing agents)</td>
</tr>
<tr>
<td>12. 電導剤 (Conductive agents)</td>
</tr>
<tr>
<td>13. 部分防止剤 (Corrosion inhibitors)</td>
</tr>
<tr>
<td>14. 除菌剤 (Cosmetics)</td>
</tr>
<tr>
<td>15. 分散剤 (Dustbinding agents)</td>
</tr>
<tr>
<td>16. 前期金刑を含む金属表面加工剤 (Metal surface treatment products, including electroplating products)</td>
</tr>
<tr>
<td>17. 炎薬, 炎爆剤 (Explosive)</td>
</tr>
<tr>
<td>Obligations</td>
</tr>
<tr>
<td>-------------</td>
</tr>
<tr>
<td>35. 향료 (Odour agents)</td>
</tr>
<tr>
<td>36. 산화제 (Oxidising agents)</td>
</tr>
<tr>
<td>37. pH 조절제 (pH-regulating agents)</td>
</tr>
<tr>
<td>38. 농약 (Pesticides)</td>
</tr>
<tr>
<td>39. 의약품/의약품중간체 (Pharmaceuticals)</td>
</tr>
<tr>
<td>40. 사진현상재료 등 광화학물 (Photochemicals)</td>
</tr>
<tr>
<td>41. 촉매등 공정조절제 (Process regulators)</td>
</tr>
<tr>
<td>42. 환원제 (Reducing agents)</td>
</tr>
<tr>
<td>43. 복사용 물질 (Reprographic agents)</td>
</tr>
<tr>
<td>44. 반도체 (Semiconductors)</td>
</tr>
<tr>
<td>45. 연화제/경화제 (Softner/hardner)</td>
</tr>
<tr>
<td>46. 탈지제, 용매 및 희석제 (Cleaning agent, solvent, thinner)</td>
</tr>
<tr>
<td>47. 안정제 (Stabilisisers)</td>
</tr>
<tr>
<td>48. 계면활성제/표면활성제 (Surface-active agents)</td>
</tr>
<tr>
<td>49. 가죽처리 약품 (Leather tanning, finishing, impregnation and care products)</td>
</tr>
<tr>
<td>50. 점도조정제 (Viscosity adjusters)</td>
</tr>
</tbody>
</table>
4 Notification
# Obligations – Notification

## Notification of products containing hazardous chemical substances

| Notification | When consumer products contain hazardous chemical substances more than 0.1% by weight  
|             | AND manufactured or imported over 1tpa |
| Product     | means an item or its component or part used by an end user with a possibility to cause consumers to be exposed to a chemical substance, including  
|             | An item of preparation  
|             | An item in which the chemical substance contained in it performs a certain function in the form of a solid without leaking during use |
| Information required for Notification | Notificant information (Name, address, contacts, etc)  
|                                       | Product Information (Name, contents, instruction manual, etc)  
|                                       | Containing Hazardous Chemical substance information (name, %)  
|                                       | Available classification and hazards information of HCS  
|                                       | Function of HCS within the product  
|                                       | Use of the product |
### Obligations – Communication (Notified Product)

**Communication of information within supply chain for Notified products**

<table>
<thead>
<tr>
<th>Information communication</th>
<th>Suppliers of notified products containing hazardous chemical substances are required to provide related information to downstream users and consumers</th>
</tr>
</thead>
</table>
| Information               | • Product name  
                          | • Containing hazardous chemical substance name and content %  
                          | • Possible/restricted uses  
                          | • Instruction manual and use conditions  
                          | • Exposure measures and safe handling information |
5 High Risk Concerned Products
<table>
<thead>
<tr>
<th>High Risk Concerned Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safety and labelling criteria</strong></td>
</tr>
</tbody>
</table>
| **High Risk Concerned Product** | High risk concerned products: means a chemical product listed by the Minister of Environment after consultation with the head of the relevant central authority as one deemed to have potential risk to human health or the environment, including, but not limited to:  
  - A product used by consumers on their daily lives such as detergent, air freshener, adhesive, polisher, deodorant, bleach or fabric softener.  
  - A product used to kill, interrupt or immobilize harmful organisms except for human beings and animals such as insect repellent, sanitizer or preservative. |
| **Products** |  
  - Products not satisfying safety and labelling criteria can not be sold  
  - Substances in high risk concerned products with no safety and labelling criteria can be requested for registration |
6 Others
Substances subject to Registration
• Draft list is to be expected by October, 2014

Announcement of Presidential and Ministerial Decrees
• Final version is expected by September, 2014

Enforcement of K-REACH
• 1st January, 2015

K-REACH IT Platform
• To be prepared and opened before the enforcement date
• Similar to EU REACH-IT system
THANK YOU

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Polymer Registration

2014. 7. 22

Younggil YANG
Risk assessment center
Korea Testing and Research Institute(KTR)
1. TCCA

2. K-REACH
1. TCCA
Current Registration Requirement

Meet the polymer definition?
- Yes
  - Meet the exemption criteria?
    - Yes
      - Registration exemption application (KCMA)
    - No
      - Polymer registration (NIER)
- No
  - Standard registration (NIER)

Physico-chemical property
Toxicity & Eco-toxicity (Max. 11 endpoints)

Or

Physico-chemical property
Toxicity & Eco-toxicity (2 endpoints)

GPC(Mn, Content of Mn<1,000), Acid/Alkali stability
Polymers that meet the criteria below can be exempt from new chemical notification under current Toxic Chemical Control Act(TCCA).

- Polymers with Mn no less than 1,000, of which monomers do not fall into new chemical or toxic substance (excluding inorganic compounds);
- Polymers which are composed of monomers, excluding monomer less than 2 weight %, not falling into new chemical substance;
- Block polymers of which no block falls into new chemical substance;
- Graft polymers of which both stem and branches do not fall into new chemical substance;
- Non-ionic polymers having Mn larger than 10,000;
Current Registration Requirement

1. Meet the polymer definition?
   - Yes
     - Standard registration
   - No
     - Mn ≥ 1,000?
       - Yes
         - Monomer is neither new or toxic chemical?
           - Yes
             - Registration exemption application
           - No
             - Mn ≥ 10,000?
               - Yes
                 - Registration exemption application
               - No
                 - Non-ionic?
                   - Yes
                     - Registration exemption application
                   - No
                     - Polymer registration

2. No
   - Mn ≥ 1,000?
     - Yes
       - Monomer is neither new or toxic chemical?
         - Yes
           - Registration exemption application
         - No
           - Mn ≥ 10,000?
             - Yes
               - Registration exemption application
             - No
               - Non-ionic?
                 - Yes
                   - Registration exemption application
                 - No
                   - Polymer registration
Current Registration Requirement

Full notification

Low volume notification

Polymer notification

Simplified notification

- Full notification
- Low volume notification
- Polymer notification
- Simplified notification

Main uses and physico-chemical properties such as melting point, boiling point, vapor pressure, solubility, n-octanol/water partition coefficient, etc.

Data on main discharge route to the environment and expected discharge quantity.

- Acute oral toxicity test
- AMES
- Chromosomal Aberration
- Biodegradability test
- Acute fish toxicity
- Acute Daphnia magna toxicity
- Acute algae toxicity
- Skin irritation test
- Eye irritation test
- Skin sensitization test

- Acute oral toxicity test
- AMES
- Chromosomal Aberration
- Biodegradability test
- Number-average molecular weight (Mn) and its distribution
- Data on monomer and residual monomer content
- Acid/alkali stability
- Content of Mn<1,000

- Acute oral toxicity test
- AMES

- Acute oral toxicity test
- AMES

- Acute oral toxicity test
- AMES

- Acute fish toxicity

* Depending on the results of Ames test and Chromosomal Aberration, micronucleous test may be required.
2. K- REACH
Definition of Polymer

“Polymer” means a chemical compound which is composed of more than one monomer repeating in series, and has its own peculiar molecular distribution depending on the repeated monomer inside the molecule. In the polymer compound, at least 3 monomer units form a covalent bond with a minimum of 1 monomer unit or with other reactants, and the content of the resulting molecules should be more than 50%. The weight percentage of the molecules having the same molecular weight should not exceed 50%.

If a polymer, excluding the monomer contained in less than 2 weight %, falls into the existing chemical pursuant to Article 2(3), the polymer shall be considered as an existing chemical. (2% Rule)
Registration Requirement

Exemption criteria is changed

Meet the polymer definition?

Yes → Yes

Registration exemption application (KCMA)

No → No

Polymer registration (NIER)

Meet the exemption criteria?

Yes

Standard registration (NIER)

No
Chemicals requiring confirmation of registration exemption

- A chemical substance manufactured or imported in not greater than 10 tons per year for the purpose of exporting the whole quantity
- The chemical reagent in the case that a chemical reagent is manufactured/imported in annual basis for scientific experiment, analysis or research purposes
- The chemical manufactured/imported once for R&D purpose falls under any of following cases:
  - In case of development of a chemical or a product/good;
  - In case of renovation/development of a process;
  - In case of testing of new application of a chemical; or
  - In case of trial manufacturing of a chemical or trial production of a product/good.
- The polymer of low concern is manufactured/ imported for the first time
- The chemical substance in the case that a chemically surface-treated chemical substance, for which base substance for surface treatment and substance to treat the surface of base substance are not new chemicals or existing chemicals subject to registration, is manufactured/imported for the first time
Conditions for exemption from examination of toxicity (TCCA)

- Polymers with Mn less than 1,000, which do not fall into new chemical or toxic substance (excluding inorganic compounds)
- Polymers which are composed of monomers, excluding monomer less than 2 weight %, not falling into new chemical substance
- Block polymers of which no block falls into new chemical substance
- Graft polymers of which both stem and branches do not fall into new chemical substance
- Non-ionic polymer compounds having Mn no less than 10,000
Polymer of Low Concern

- Polymers with a number-average molecular weight (NAVG MW) must be greater than or equal to 10,000 daltons and these polymers must have oligomer content less than 2 percent by weight below 500 daltons and less than 5 percent by weight below 1,000 daltons.

- Polymers with a number-average molecular weight (NAVG MW) in a range that is greater than or equal to 1,000 daltons and less than 10,000 daltons and these polymer must have oligomer content less than 10 percent by weight below 500 daltons and less than 25% by weight below 1,000 daltons.

Exceptions

- Cationic polymer compounds (excluding polymer compounds only used in solid form and does not dissolved or dispersed in water.)

- Polymer compounds with Mn under 10,000, which contains toxic chemical, epoxy compound, aziridine compound, or new chemical monomer exceeding 2 weight %.
Polymer of Low Concern

Meet definition of polymer?
- Yes: Proceed to next step
- No: Apply for chemical registration

Mn ≥ 10,000?
- Yes: Proceed to next step
- No: Apply for polymer registration

Mn ≥ 1,000?
- Yes: Proceed to next step
- No: Apply for polymer registration

Mn < 500: less than 2% & Mn < 1000: less than 5%?
- Yes: Proceed to next step
- No: Apply for polymer registration

Cationic?
- Yes: Apply for confirmation of registration exemption
- No: Proceed to next step

Only used in solid form and insoluble or not dispersed in water?
- Yes: Apply for polymer registration
- No: Proceed to next step

Hazardous chemicals, epoxy compounds, aziridine compound or new chemical monomer exceeding 2%?
- Yes: Apply for polymer registration
- No: Proceed to next step
Data Requirement

Polymer of low concern

- Name of the chemical, identification code, quantity to be manufactured/imported
- Chemical name of monomer, identification code, content (%) (excluding monomer less than 2%)
- Test data showing Mn and molecular weight distribution
- Test data on content (%) of molecular weight under 1,000 and under 500
- Data demonstrating that it does not fall into any of polymer compounds listed below:
  - Cationic polymer compounds (excluding polymer compounds only used in solid form and does not dissolved or dispersed in water.)
  - polymer compounds with Mn under 10,000, which contains toxic chemical, epoxy compound, aziridine compound, or new chemical monomer exceeding 2 weight %.

Details of data shall be publically announced by the Head of NIER
Registration

Required data for registration

① Name of manufacturer/importer, location, and representative
② Chemical name, molecular formula/structural formula, identification code, trade name, purity, names & content of confirmed impurities/by-products
③ Use of chemical
④ Classification and label of chemical
⑤ Chemical's physico-chemical properties
⑥ Hazards of chemical
⑦ Risks including an exposure scenario which describes handling methods and exposure control/control methods for the chemical’s whole life-cycle. (applies only when the volume to be manufactured/imported is 10 tons or more per year.)
⑧ Guidance data for safe use (protective gear, emergency response procedures for explosion, fire or leak)
⑨ Other data prescribed by the Environment Ministerial Decree.
### Required data for polymer registration

<table>
<thead>
<tr>
<th>Chemical Tonnage (T)</th>
<th>Polymer Property Test Data</th>
<th>Test Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10T</td>
<td>Number-average molecular weight and molecular weight distribution, Monomer name, identification code and content, Residual monomer content, Content of Mn not greater than 1,000, Stability in acidic/alkaline solution</td>
<td>physical state, water solubility, melting point, boiling point, vapor pressure (total 5 items)</td>
</tr>
<tr>
<td>10-100T</td>
<td>Same as the data for chemical 1-10T (total 15 items)</td>
<td></td>
</tr>
<tr>
<td>&gt;1000T</td>
<td>Same as the data for chemical 10-100T (total 26 items)</td>
<td></td>
</tr>
</tbody>
</table>
THANK YOU

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Tel: +82-31-999-3062, Email: ygyang@ktr.or.kr
Thank you for attending

What did you think about the webinar? Please take part in our email survey (in your inbox soon)

A downloadable recording of this presentation (with slides) will be available shortly.

If you have any questions, please contact Lorna (lorna@chemicalwatch.com)

NEXT

China Disinfectant Regulatory Reform, 31 July, 3:00pm BST
http://chemicalwatch.com/asiahub/china-disinfectant-webinar