Assessing the impact of the regulations on safe management of hazardous chemicals in China (Decree 591) on your business

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- Brief Introduction to Decree 591.
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## Chemical Management Policies in China

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<td>Order No. 7 - The Provisions on Environmental Administration of New Chemical Substances (15 Oct 2010)</td>
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<tr>
<td>Existing Chemicals Management - Import and Export of</td>
<td>Provisions on the First Import of Chemicals and the Import and Export of Toxic Chemicals (1994)</td>
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<td>Decree 591 – The Regulations on Safe Management of Hazardous Chemicals in China (1 Dec 2011) - Sub 1: Measures for The Administration of Registration of Hazardous Chemicals (1 Dec 2011); - Sub 2: Measures for The Administration of Operating Licenses for Hazardous Chemicals (1 Dec 2011);</td>
<td>Catalog of Hazardous Chemicals (to be updated and released soon);</td>
</tr>
<tr>
<td>Classification, Labelling and SDS</td>
<td>GB 20576 ~ GB 20602-2006; GB 13690-2009; GB 15258-2009; GB 190-2009; GB/T 16483 -2008;</td>
<td>China GHS, national standards</td>
</tr>
<tr>
<td>Occupational Exposure Limits &amp; Protection</td>
<td>Regulation on the Labor Protection in Workplaces Handling Toxic Materials</td>
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Decree 591 – Regulations on Safe Management of Hazardous Chemicals in China

- Replace decree 344, enter into force on 1 Dec 2011
Decree 591 – Regulations on Safe Management of Hazardous Chemicals in China

- Decree of State Council, Multi-ministries Involved;
- Main legislation regulating existing/hazardous chemicals;
- Implementing a license system;
- Requiring registration of hazardous chemicals;
- Requiring mandatory GHS classification and labeling for hazardous chemicals.
Mains Reasons for Revision

- Reform of governmental authorities
- Incomplete management system: users of hazardous chemicals are not regulated;
- Integration with other existing laws (Order No. 7, GHS);
- Keeping up to date with international trend (TSCA reporting, reporting under CSCL, CLP);
# A Break-down of Decree 591

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<th>Use</th>
<th>Operation</th>
<th>Transportation</th>
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<td>6</td>
<td>102</td>
</tr>
<tr>
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<td>6</td>
<td>20</td>
<td>8</td>
<td>12</td>
<td>8</td>
<td></td>
<td>16</td>
<td>4</td>
<td>74</td>
</tr>
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</table>
Supporting Measures and Laws for Decree 591

- **The Catalog of Hazardous Chemicals** (to be released in 2012);
- The Measures for the Administration of Production Licenses for Hazardous Chemicals;
- The Measures for the Administration of **Operating Licenses** for Hazardous Chemicals (2011);
- The Measures for the Administration of **Safe Use License** for Hazardous Chemicals (new in 2011);
- The Measures for the Administration of **Registration of Hazardous Chemicals** (revised in 2011) By State Administration of Work Safety (SAWS), China
- The Measures for the Administration of Standardization of Management of Hazardous Chemicals (released in 2011);
- The Measures for the Administration of Safety Clearance on Construction Projects for Hazardous Chemicals;
- The Measures for the Administration of Safety Supervision of Major Sources of Hazard;
- The Measures for the Administration of Safety Management of Transmission Pipeline for Hazardous Chemicals;
- The Measures for the Administration of Physical Hazard Identification and Classification for Hazardous Chemicals;
- The Measures for the **Registration of Environmental Administration of Hazardous Chemicals** for public consultations (issued by MEP);
The Scope of Decree 591 – Hazardous Chemicals

- **Hazardous chemicals** are defined as highly toxic chemicals and other chemicals which are toxic, corrosive, explosive, flammable and do harm to human body, facilities and environment.

- Chemicals meeting GHS classification criteria shall be regarded as hazardous chemicals under Decree 591 (*CIRS’s interpretation*);

- **Out of Scope**
  - explosives for civil use;
  - fire cracker, fireworks;
  - radio-active substances;
  - dangerous chemical for national defense;
The Scope of Decree 591 – Catalog of Hazardous Chemicals

- **Hazardous chemicals** listed in the Catalog are subject to extra requirements (application for licenses, registration, etc);
- **Hazardous chemicals** not listed in the Catalog are subject to general requirements (GHS classification, labeling and SDS, etc);

Current Catalog of Hazardous Chemicals (2002)
http://www.chinasafety.gov.cn/whpcx.htm

- currently more than 3,700 chemicals;
- a new Catalog to be released in 2012.
## The Scope of Decree 591 – Catalog of Hazardous Chemicals – Sub-lists

<table>
<thead>
<tr>
<th>Sub-lists</th>
<th>Extra Requirements</th>
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<tbody>
<tr>
<td>List of Highly Toxic Chemicals</td>
<td>Purchase permit, record-keeping</td>
</tr>
<tr>
<td>List of Precursors for Explosives</td>
<td>Reporting, record-keeping</td>
</tr>
<tr>
<td>List of Hazardous Chemicals for Priority Management</td>
<td>Emergency response plan, safe use license, etc.</td>
</tr>
<tr>
<td>List of Priority Hazardous Chemicals for Environment Management</td>
<td>On-site inspection, environment risk assessment report</td>
</tr>
</tbody>
</table>
The Scope of Decree 591 - Activities

The following activities involving hazardous chemicals are regulated in China:

- Production and Storage
- Use
  - Use hazardous chemicals to manufacture products
- Operation
  - Import
  - Distribution
  - Warehouse
  - Sales
- Transportation
Provisions for Safe Production and Storage of Hazardous Chemicals (Article 11-27)

- **General Requirement for Production and Storage**
  - responsible person and qualified professionals;
  - regular inspection and maintenance to facilities;
  - safety evaluation report every three years;
  - recording substance flow for highly toxic chemicals and precursors for explosives;
  - suppliers of chemical packages or containers shall possess National Industrial Products Manufacture Certificate;

- **Extra Requirements for Producers**
  - Registration of hazardous chemicals;
  - Production license;
  - SDS and chemical labels according to national standards;
  - Application for National Industrial Products Manufacture Certificate if a chemical is within industrial products catalog;
  - Report environmental release information to MEP if a chemical is classified as priority hazardous substance for environmental management
Provisions for Safe Use of Hazardous Chemicals (Article 28-32, 16, 21, 22, 23, 27)

• **General Requirement**
  - responsible person and qualified professionals;
  - regular inspection and maintenance to facilities;
  - chemical management system to ensure safe use;
  - recording substance flow for highly toxic chemicals and precursors for explosives;
  - **safe use license** (*);
  - report environmental release information to MEP if a chemical is classified as priority hazardous substance for environmental management

• **Note(*)**
  - Not all users of hazardous chemicals need to apply;
  - Certain criteria must be met;
Provisions for Safe Operation of Hazardous Chemicals (Article 33-42)

Operation
- Import
- Distribution
- Warehouse
- Sales

• General Requirement
  - responsible person and qualified professionals;
  - application for purchase permit and recording substance flow for highly toxic chemicals and precursors for explosives;
  - Operating license (*);
  - cannot sell chemicals without right SDS and labels;
  - cannot buy hazardous chemicals from companies without proper licenses.

• Note(*)
  - Operating license from SAWS must be applied first before a business license is granted from Industrial and Commercial Bureau.
Provisions for Transportation of Hazardous Chemicals (Article 43-65)

- **General Requirement**
  - qualification tests required for operating employees;
  - road transport permit;
  - signal labeling;
  - extra requirement for transport of hazardous chemicals using inner waterways;
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Application of Licenses

Any legal entities producing/using/operating hazardous chemicals in China shall obtain a license from local authorities of work safety.

Safe Production License
Safe Use License(*)
Operating License(**)
Transportation Permit

Note: Companies based outside of China cannot apply for a license.
Note*: This is a new requirement under decree 591.
Note**: This has been revised under decree 591.
Safe Use License (Article 29)

The Measures for the Administration of Safe Use License for Hazardous Chemicals (2011) – License Required When

- **The industry sector** of a company is listed in the Catalog of Applicable Industry Sector for the Safe Use License of Hazardous Chemicals (for example, production of fertilizer); and

- **The used quantity** has reached the threshold volume (*current 62 chemicals*) ;

<table>
<thead>
<tr>
<th>Index</th>
<th>Name/Other Name</th>
<th>Minimum Quantity (t/y)</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>氯/Chlorine</td>
<td>180</td>
<td>7782-50-5</td>
</tr>
<tr>
<td>2</td>
<td>氨/Ammonium</td>
<td>360</td>
<td>7664-41-7</td>
</tr>
</tbody>
</table>
Operating License


- Scope: Catalogue of Hazardous Chemicals;
- Actives: Import, Distribution, Sales, Warehouse Operation, Other
- No longer differentiate type A and type B license;
- More documents are required: employment injury insurance, etc;
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Registration of Hazardous Chemicals in China(*)

Two Bodies

- National Registration Center for Chemicals (NRCC) of State Administration of Work Safety (SAWS) and;
- Local Environmental Protection Authorities (MEP).

*Only domestic companies can register.*

<table>
<thead>
<tr>
<th></th>
<th>2002</th>
<th>2011</th>
</tr>
</thead>
</table>
| Scope                | • Hazardous Chemicals  
• Highly Toxic Chemicals  
• Not clearly defined | • Catalog of Hazardous Chemicals  
• Hazardous Chemicals If Confirmed by Authorities |
| Registrant           | • Producer  
• Storage Companies | • Producer  
• Importer (New!) |
| 24h emerg. number    | • Not Specified | • Mandatory |
| Annual Report, GHS SDS/Label | • No | • Yes |
| Supervision          | • None | • Detailed procedure |
Registration of Hazardous Chemicals with NRCC (Article 67)

- Required Information
  - Legal entity information;
  - Classification and labeling (GHS);
  - Physico-chemical properties;
  - Main uses;
  - Hazard properties;
  - Safety requirement for storage, use and transport;
  - Emergency responses;

- Renewed every 3 years
- Report volume annually;
Registration of Hazardous Chemicals with NRCC (Article 67) - Concept

- Reporting under Japan CSCL;
- TSCA IUR Rules;
- C&L notification.
# Registration of Hazardous Chemicals with MEP (Article 6.4)

The Measures for the Registration of Environmental Administration of Hazardous Chemicals (Draft 2011, New!)

<table>
<thead>
<tr>
<th><strong>Scope</strong></th>
<th><strong>Registration with MEP</strong></th>
<th><strong>Registration with NRCC</strong></th>
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<tbody>
<tr>
<td></td>
<td>▪ Catalog of Hazardous Chemicals</td>
<td>▪ Catalog of Hazardous Chemicals</td>
</tr>
<tr>
<td></td>
<td>▪ Priority hazardous chemicals for environmental management (PHCs)</td>
<td>▪ Hazardous Chemicals If Confirmed by Authorities</td>
</tr>
<tr>
<td></td>
<td>▪ List of toxic chemicals severely restricted to be imported into or exported from China (LTCs)</td>
<td></td>
</tr>
<tr>
<td><strong>Registrant</strong></td>
<td>▪ Producer</td>
<td>▪ Producer</td>
</tr>
<tr>
<td></td>
<td>▪ Companies using hazardous chemicals to manufacture products</td>
<td>▪ Importer (New!)</td>
</tr>
<tr>
<td></td>
<td>▪ <strong>Importer/Exporter of LTCs</strong></td>
<td></td>
</tr>
</tbody>
</table>
Registration of Hazardous Chemicals with MEP (Article 6.4)

- General Information
  - Environment administration registration form including legal entity information, name, category, volume, uses, operational method, aquatic toxicity data and risk management measures;
  - Production/safe use/operating licenses and business license;
  - Environment emergency responses;

- Extra requirement for PHCs
  - Environmental risk assessment report;
  - On-site inspection;
  - Report release and migration information annually.
Registration of Hazardous Chemicals with MEP (Article 6.4) – List of PHCs

- not easily degradable, bio-accumulative, causing serious harm to human health and living beings after long-term exposure;
- extremely un-degradable and extremely bio-accumulative;
- causing acute toxicity or chronic toxicity to aquatic environment;
- causing serious hazards to human health or the environment;
- chemicals subject to any international environment conventions;
- chemicals liable to accidents and causing severe hazards to the ecological environment;
- other chemicals for which risks need to be reduced;
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Chapter 2, Article 15:
Producers of hazardous chemicals shall provide SDS and affix chemical safety labels on packages. The SDS and labels shall be prepared in accordance with national standards (in Chinese). – NEW!

Chapter 4, Article 37:
Companies cannot sell hazardous chemicals that do not have proper SDS and chemical safety label;
## Labeling and SDS for Hazardous Chemicals

<table>
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<tr>
<th>Offences</th>
<th>Penalties</th>
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<tbody>
<tr>
<td>No proper license</td>
<td>RMB 100,000 to 200,000</td>
</tr>
<tr>
<td>No SDS or label; SDS and labels do not comply with national standards</td>
<td>RMB up to 50,000; Repeated infringement up to RMB 100,000</td>
</tr>
<tr>
<td>Manufacturers and importers fail to register hazardous chemicals</td>
<td>RMB up to 50,000; Repeated infringement up to RMB 100,000</td>
</tr>
</tbody>
</table>
Labeling and SDS for Hazardous Chemicals

- New Catalog of Hazardous Chemicals
  - To be released at the beginning of 2012;
  - Two-step approach (~5000 chemicals for 1st step);
  - Contain harmonized classification similar to annex VI of CLP;
  - Classification based on CLP and Japan’s official classification;
  - Use of harmonized classification might be mandatory.
## New Catalog of Hazardous Chemicals

<table>
<thead>
<tr>
<th>序号</th>
<th>品名</th>
<th>别名</th>
<th>英文名</th>
<th>英文别名</th>
<th>CAS号</th>
<th>UN号</th>
<th>危险性类别</th>
<th>标志</th>
<th>警示词</th>
<th>危险性说明</th>
<th>备注</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>苯</td>
<td>Benzene</td>
<td>71-43-2</td>
<td>1114</td>
<td>易燃液体（类别2）</td>
<td>高度易燃液体和蒸气：吸入有害；引起皮肤刺激；引起严重眼睛刺激；可能致癌性：可致癌；对水生生物有害并且有长期持续影响。</td>
<td></td>
<td></td>
<td></td>
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Practical Advice – Buying Chemicals from China

Is your chemical listed in IECSC?
- Yes
- No
  - Ask and assist your Chinese supplier to notify the new chemical substance;

Is your chemical listed in the list of toxic chemicals severely restricted to be imported/exported from China?
- Yes
  - Remind your Chinese supplier to apply for export clearance notification
- No
  - Remind your suppliers to observe other laws, for example, occupational exposure limit, REACH, etc.

Is your chemical listed in the Catalog of Hazardous Chemicals?
- Yes
  - Remind your supplier to apply for licenses, register hazardous chemicals, and prepare SDS & label, etc.
- No
  - Remind your suppliers to observe other laws, for example, occupational exposure limit, REACH, etc.
Practical Advice – Exporting Chemicals to China

Is your chemical listed in IECSC?

Yes

Is your chemical listed in the list of toxic chemicals severely restricted to be imported/exported from China?

Yes

Registration of toxic chemicals with MEP; ask your partner in China to apply for import clearance notification

Yes

Is your chemical listed in the Catalog of Hazardous Chemicals?

Yes

Prepare SDS and label in accordance with China GHS; Ask your customer to comply with other requirements;

No

Prepare compliant SDS and labels

No

Appoint a local agent to submit new chemical notification; or ask your partner in China to notify.
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Summary – New Challenges

- Double registration with NRCC and MEP;
- Enlarged catalog;
- Importers need to register hazardous chemicals with NRCC from 1 Dec 2011;
- New requirements for users of hazardous chemicals in China: safe use license;
- SDS and labels must be China GHS compliant;
Resources

- IECSC(2010)
  http://www.crc-mep.org.cn/iecsweb/IECSC.aspx?La=1
- Catalog of Hazardous Chemicals(2002)
  http://www.chinasafety.gov.cn/whpdx.htm
- List of Toxic Chemicals Severely Restricted to Be Imported into or Exported from China
  http://www.cirs-reach.com/toxic_chemicals_list
- Overview of Chemical Management Polices in China
- Download English version of Chinese SDS and labeling standards.
  http://www.cirs-reach.com/China_GHS_Implementation
Thank you for your time!
谢谢您的时间！
시간 내주셔서 감사합니다！
お時間をいただき！
Happy Holidays