The Latest Developments of Chemical Legislation in China

Enabling Chemical Compliance for A Safer World

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- New Chemical Substance Management
- Existing Chemicals Management in China
- GHS Implementation: Current Status and Challenges
- Practical Advice for Chemical Companies Doing Businesses with/in China
# Chemical Management Policies in China

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<th>Regulations</th>
<th>Key Words</th>
</tr>
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<tr>
<td>New Chemicals Management</td>
<td>Order No. 7 - The Provisions on Environmental Administration of New Chemical Substances (15 Oct 2010)</td>
<td>IECSC, China REACH</td>
</tr>
<tr>
<td>Existing Chemicals Management - Import and Export of Toxic Chemicals</td>
<td>Provisions on the First Import of Chemicals and the Import and Export of Toxic Chemicals (1994)</td>
<td>List of toxic chemicals severely restricted to be imported into or exported from China</td>
</tr>
<tr>
<td>Existing Chemicals Management - Hazardous Chemicals</td>
<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 (to be revised soon); - Sub 2: Measures for The Administration of Operating Licenses for Hazardous Chemicals (in consultation);</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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Provisions on Environmental Administration of New Chemical Substances (2010)

New chemicals not listed on IECSC shall be notified to the Chemical Registration Center (CRC) of MEP irrespective of volume;

IECSC Online Search

http://www.crc-mep.org.cn/ieescweb/IECSC.aspx?La=1

3,166 substances marked as confidential, further inquiry to CRC required
## Exemptions

| Chemicals subject to other laws | Pesticides, cosmetics, pharmaceuticals, food and feed additives, etc. *(Intermediates or raw materials are not exempt)*. |
| Substances existing in nature | Natural polymers, etc; *(Natural substances extracted or processed by chemical methods can not be exempted)*. |
| Products of non commercial purpose or unintentionally produced | Impurities: single impurity less than 10% and total content of impurities shall not exceed 20%; Waste and by-products. |
| Special categories | Glass, cement, alloys, non-isolated intermediate substances and articles, etc. |
Notification Body

- Domestic manufacturer/importer;
- Foreign manufacturer/exporter: two options

Ask importer to notify;  
Appoint qualified Chinese agent;
Types of Notification

- Scientific Research Record
- Simplified Notification Under Basic Conditions
- Simplified Notification Under Specific Conditions
- Typical Notification
Scientific Research Record

- For R & D substances less than 0.1t/y; or
- For the purpose of introducing sample to China for test.

- No test data is required;
- Only takes 5~10 working days;
- Results published by MEP regularly.
Simplified Notification under Basic Conditions

- For new chemical substances less than 1t/y;
- 1-3 eco-toxicological tests must be carried out in China;
- Takes 4-6 months.

<table>
<thead>
<tr>
<th>No.</th>
<th>Test Name</th>
<th>Test Scheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ready biodegradability</td>
<td>The test must be conducted at first.</td>
</tr>
<tr>
<td>2</td>
<td>Acute toxicity study with Brachydanio rerio</td>
<td>The test must be conducted if the substance is not ready biodegradable.</td>
</tr>
<tr>
<td>3</td>
<td>Earthworm, acute toxicity test</td>
<td>The test must be conducted if the LC50 of fish cannot be obtained when the solubility of the substances in water is less than 100mg/L and the substance is not shown to be toxic to aquatic life at its saturated concentration.</td>
</tr>
</tbody>
</table>
Simplified Notification under Specific Conditions

- For export only with volume under 1t/y;
- For scientific research with volume between 0.1-1t/y;
- For product and technological research with tonnage less than 10 ton per year (up to 2 years);
- For polymers with all monomers already listed in IECSC (if the polymer itself is not listed) or polymers containing less than 2% new chemicals weight by weight; and low concern polymers;

- No test data is required;
- Takes 2-3 months.
## Typical Notification

- Four levels (1-10, 10-100, 100-1000, 1000+);
- The higher the tonnage band, more data required;

<table>
<thead>
<tr>
<th>Notification Level</th>
<th>Level I</th>
<th>Level II</th>
<th>Level III</th>
<th>Level IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonnage level (ton/a)</td>
<td>( \geq 1 \text{ t/a}, &lt; 10 \text{ t/a} )</td>
<td>( \geq 10 \text{ t/a}, &lt; 100 \text{ t/a} )</td>
<td>( \geq 100 \text{ t/a}, &lt; 1,000 \text{ t/a} )</td>
<td>( \geq 1,000 \text{ t/a} )</td>
</tr>
<tr>
<td>Minimum Data endpoint required</td>
<td>Qualitative &amp; Quantitative</td>
<td>2~3</td>
<td>2~3</td>
<td>2~3</td>
</tr>
<tr>
<td></td>
<td>Physico-chemical</td>
<td>9 (solid) 12 (liquid)</td>
<td>9 (solid) 12 (liquid)</td>
<td>9 (solid) 12 (liquid)</td>
</tr>
<tr>
<td></td>
<td>Toxicity</td>
<td>9</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Eco-toxicity</td>
<td>7</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Estimated testing Period (months)</td>
<td>4 to 6</td>
<td>6 to 8</td>
<td>10 to 15</td>
<td>&gt;15</td>
</tr>
</tbody>
</table>

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![CRS Logo](logo.png)
Typical Notification

- Required Notification Materials

- Typical notification form
- Risk assessment report
- Testing report
- Other related documents
- GHS Classification
- Chinese SDS
- Laboratory certificate
## New Substance Management: China vs US

<table>
<thead>
<tr>
<th></th>
<th>US TSCA</th>
<th>China REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td>R &amp; D Exemption</td>
<td>No approval is required</td>
<td>Scientific research record(&lt;0.1t/y) or simplified notification.</td>
</tr>
<tr>
<td>Test Marketing Exemption</td>
<td>Application for test market exemption</td>
<td>Simplified notification is required. Up to 10t/y and 2 years.</td>
</tr>
<tr>
<td>Low Volume Exemption</td>
<td>Submission of standard PMN form and prior approval is required.</td>
<td>Does not exist. Full data set for typical notification (1-10t/y) is required.</td>
</tr>
<tr>
<td>Low Release / Low Exposure</td>
<td>Prior approval is required</td>
<td>Equivalent exemption does not exist.</td>
</tr>
<tr>
<td>New Polymer</td>
<td>No approval is required if polymer meets certain conditions.</td>
<td>Simplified notification or typical notification with reduced data requirement.</td>
</tr>
<tr>
<td>General new chemical substances.</td>
<td>Physio-chemical/toxicological/eco- toxicological data is not mandatory</td>
<td>Minimum data requirement must be met.</td>
</tr>
</tbody>
</table>
## Post-notification Obligations

<table>
<thead>
<tr>
<th>Type</th>
<th>Category</th>
<th>Management Type</th>
<th>Obligations of certificate holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typical notification</td>
<td>General new substances</td>
<td>Basic management (6 requirements)</td>
<td>1. Communicate SDSs; 2. Implement risk management measures; 3. Submit first-activity report; 4. Keep documents on file for over 10 years; 5. Do not sell chemicals to downstream users who are not capable of implementing risk management measures; 6. Submit updates if a new hazard arises;</td>
</tr>
<tr>
<td></td>
<td>Hazardous new substances</td>
<td>General management (8 requirements)</td>
<td>7. Submit annual report (for previous year); 8. Comply with &quot;&lt;&lt;The Measures for The Administration of Registration of Hazardous Chemicals&gt;&gt;&quot;;</td>
</tr>
<tr>
<td></td>
<td>High environmental concern</td>
<td>Key management (11 requirements)</td>
<td>9. Submit report on disposal information; 10. Submit substance circulation info; 11. Submit annual plan (for next year);</td>
</tr>
<tr>
<td>Simplified notification</td>
<td></td>
<td>Annual management (2 requirements)</td>
<td>1. Submit annual plan (for next year); 2. Keep documents on file for over 10 years;</td>
</tr>
<tr>
<td>Scientific research record</td>
<td></td>
<td>Specified management (2 requirements)</td>
<td>1. Shall be used in special facilities and under the direction of professional personnel; 2. Can only be used for R&amp;D;</td>
</tr>
</tbody>
</table>
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Existing Chemicals Management

- Toxic chemicals restricted to be imported/exported
- Hazardous chemicals

- Other existing chemicals are less regulated or subject to other laws.
Provisions on the First Import of Chemicals and the Import and Export of Toxic Chemicals (issued in 1994);

- Foreign exporters shall apply for a registration certificate with CRC of MEP with its partner and pay $10,000 if exporting toxic chemicals;
- Domestic importers or exporters shall apply for import or export clearance notification to customs;

**List of Toxic Chemicals Severely Restricted to Be Imported into or Exported from China**

*(total 156 substances, updated in 2011, full list available from CIRS website)*

<table>
<thead>
<tr>
<th>Serial No</th>
<th>Chemical Name</th>
<th>CAS No</th>
<th>Customs Goods ID</th>
<th>Serial No</th>
<th>Chemical Name</th>
<th>CAS No</th>
<th>Customs Goods ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mercury sulfide</td>
<td>1344-48-5</td>
<td>2617901000</td>
<td>81</td>
<td>ZINC ARSENIDE</td>
<td>12044-55-2</td>
<td>2853009022</td>
</tr>
<tr>
<td>2</td>
<td>Arsenic</td>
<td>7440-38-2</td>
<td>280480000000</td>
<td>82</td>
<td>gallium arsenide</td>
<td>1303-00-0</td>
<td>2853009022</td>
</tr>
<tr>
<td>3</td>
<td>Mercury</td>
<td>7439-97-6</td>
<td>280540000000</td>
<td>83</td>
<td>Dichloromethane</td>
<td>75-09-2</td>
<td>2903120001</td>
</tr>
<tr>
<td>4</td>
<td>arsenic acid</td>
<td>7778-39-4</td>
<td>2811199020</td>
<td>84</td>
<td>Dichloromethane</td>
<td>75-09-2</td>
<td>2903120090</td>
</tr>
<tr>
<td>5</td>
<td>meta-arsenic acid</td>
<td>10102-53-1</td>
<td>2811199020</td>
<td>85</td>
<td>Chloroform</td>
<td>67-66-3</td>
<td>2903130000</td>
</tr>
<tr>
<td>6</td>
<td>pyroarsenic acid</td>
<td>13453-15-1</td>
<td>2811199020</td>
<td>86</td>
<td>1,2-dichloroethane</td>
<td>107-06-2</td>
<td>2903150000</td>
</tr>
</tbody>
</table>
Regulations on Safe Management of Hazardous Chemicals in China (2011)

- 《危险化学品安全管理条例》or Decree 591;
- Issued on 2 March 2011 and will come into force on 1 Dec 2011;
- Main legislation regulating existing chemicals;
- Requiring mandatory GHS classification and labeling for hazardous chemicals.
Regulations on Safe Management of Hazardous Chemicals in China (2011)

- Definitions of Hazardous Chemicals
- The Scope of the Regulation
- Main Obligations
- Operating License
- Registration of Hazardous Chemicals
- Labeling and SDSs for Hazardous Chemicals
Definitions of 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.

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 soon.
The Scope of the Regulation

The following activities involving hazardous chemicals are regulated in China:

- Production and Storage
- Use
- Sales and Marketing
- Transportation
## Main Obligations

<table>
<thead>
<tr>
<th>For companies in China</th>
<th>For foreign companies</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Production permit for producers;</td>
<td>• Labeling and SDS compliant with Chinese GHS national standards.</td>
</tr>
<tr>
<td>• Transport permit for transporter;</td>
<td></td>
</tr>
<tr>
<td>• Operating license for other actives;</td>
<td></td>
</tr>
<tr>
<td>• Registration of hazardous chemicals;</td>
<td></td>
</tr>
<tr>
<td>• Labeling and SDS</td>
<td></td>
</tr>
<tr>
<td>• Safety management system;</td>
<td></td>
</tr>
<tr>
<td>• Qualified professional;</td>
<td></td>
</tr>
<tr>
<td>• Other requirements.</td>
<td></td>
</tr>
</tbody>
</table>
Operating License

- Any legal entities operating and marketing hazardous chemicals in China shall obtain operating license from the State Administration of Work Safety (SAWS).

Need to Apply

Road transport permit, No operating license

More info can be found in the Measures for The Administration of Operating Licenses for Hazardous Chemicals, which is in public consultations.
Registration of Hazardous Chemicals

Domestic manufacturers and importers of hazardous chemicals in China shall register hazardous chemicals with National Registration Center for Chemicals (NRCC) of SAWS- Chapter 6, Article 67

http://en.nrcc.com.cn

Note*: Foreign companies do not need to register.
Registration of Hazardous Chemicals (Online)

- Legal entity information;
- Classification and labeling;
- Phyiso-chemical properties;
- Main uses;
- Hazard properties;
- Safety requirement for storage, use and transport;
- Emergency responses;

More info can be found in the Measures for The Administration of Registration of Hazardous Chemicals, which is to be revised soon.
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 SDS and chemical safety label;
## Labeling and SDS for Hazardous Chemicals

<table>
<thead>
<tr>
<th>Offences</th>
<th>Penalties</th>
</tr>
</thead>
<tbody>
<tr>
<td>No proper operating 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>

### Our Interpretation

*China GHS applies to all chemicals. However, only failure to classify and label hazardous chemicals in accordance with China GHS will incur penalties.*
Labeling and SDS for Hazardous Chemicals

- **New Catalog of Hazardous Chemicals**
  - To be released before the beginning of 2012;
  - Might double in capacity (~7000 chemicals);
  - Might 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.
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### GHS Implementation: Current Status

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
</table>
| **2006** | Publication of 26 compulsory national standards (prefixed with "GB")  
- GB 20576 ~ GB 20602-2006 “Safety rules for classification, precautionary labeling and precautionary statements of chemicals;” |
| **2008** | Publication of two recommended standards (prefixed with "GB/T")  
- GB/T 16483-2008 (SDS);  
- GB/T 22234-2008 (Labeling of chemicals according to the GHS); |
| **2009** | Publication of three compulsory standards  
- GB 190-2009 (packaging): implements the 15th revised edition of the UN recommendations on the Transport of Dangerous Goods  
- GB 13690-2009 (classification and hazard communication) – implements GHS  
- GB 15258-2009 (precautionary labeling) - implements GHS |
| **2010** | The three compulsory standards published in 2009 entered into force on 1 May 2010. 1 year transitional period started from 1 May 2010 and will end on **1 May 2011**. |
| **2011** | Publication of revised Regulations on Safe Management of Hazardous Chemicals in China in March(expected enter into force on **1 Dec 2011**); |
GHS Implementation: Deadline

1 May 2011 - Official Deadline

All chemical substances must be classified and labeled in accordance with those standards.

1 Dec 2011

Failure to prepare SDSs and labels for hazardous chemicals according to those national standards after this date will incur penalties.
GB 20576 ~ GB 20602-2006 – 26 Classification Standards

- Based on the 1st edition of UN GHS(2003), 8 yrs behind;
- The following building blocks from the 4th revised edition of UN GHS(2011) are not adopted in China

- Chemically unstable gases category A and B;
- Non-flammable aerosols category 3;
- Respiratory sensitization subcategory 1A & 1B (China does have category 1);
- Skin sensitization subcategory 1A & 1B (China does have category 1);
- STOT- single exposure category 3;
- Aspiration category 1 and 2;
- Hazardous to the ozone layer category 1.
Consistent with UN GHS Rev 2;
Referring to 26 classification standards;
Example of a chemical label (refer to GB 15258-2009);
Example of SDS (refer to GB/T 16483-2008);

One example label from GB 13690-2009;
GB/T 16483-2008 – Content, Order and Sections of SDS

- Recommended standard, not mandatory;
- 16 headings, order and content the same as UN GHS;
- 24h emergency number must be a domestic number.
GHS Implementation: Challenges

- New Catalog of Hazardous Chemicals not available;
- Lack of data or expertise;
- No differentiation between substances and mixtures;
- Too many government bodies involved;
- Enforcement is weak.
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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;
  - Yes: Remind your Chinese supplier to apply for export clearance notification

- Is your chemical listed in the list of toxic chemicals severely restricted to be imported/exported from China?
  - Yes: Remind your supplier to apply for operating license, register hazardous chemicals, and prepare SDS & label, etc.
  - 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
  - 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
    - No
      - No
        - Appoint a local agent to submit new chemical notification; or ask your partner in China to notify.
  - No
    - 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
        - China GHS still needs to be followed even though there might be no penalties;
Resources

- IECSC(2010)
  http://www.crc-mep.org.cn/iecscweb/IECSC.aspx?La=1
- Catalog of Hazardous Chemicals(2002)
  http://www.chinasafety.gov.cn/whpcx.htm
- List of Toxic Chemicals Severely Restricted to Be Imported into or Exported from China
  http://www.cirs-reach.com/toxic_chemicals_list
- English version of the Provisions on the Environmental Administration of New Chemical Substances in China (2010)
  http://www.cirs-reach.com/China_REACH_Englis_Translation
- 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！