Revised new chemical substance notification - China REACH

Topics covered:
New mandatory notifier under China REACH;
New notification types under China REACH;
New scope under China REACH;
New notification area under China REACH;
New dossier requirement under China REACH;
New substance classification under China REACH;
New obligation for certificate holders under China REACH

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Ireland
Singleton House, Laurence Street
Drogheda, Co. Louth, Ireland
Tel: +353 41 9806 916 | Fax: +353 41 9806 999
Email: info@cirs.ie

China
Floor 11 Building A, Westlake Plaza
391 Wen'er Road, Hangzhou City
Zhejiang Province, P. R. China
Tel: +86-5718720 6555 | Fax: +86-5718720 6533
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<tr>
<th>Items</th>
<th>Current version</th>
<th>Revised version</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 Mandatory notifier</strong></td>
<td>Domestic manufacturer</td>
<td>The notifier should be the legal entity in China</td>
</tr>
<tr>
<td></td>
<td>Domestic importer</td>
<td></td>
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<tr>
<td></td>
<td>Foreign trader</td>
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</tbody>
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**Notes:** If your company wishes to export new chemicals into China, you are not permitted to register by yourself. However, you can: 1) Ask your subsidiary in China to register the substance; 2) Ask your client (mainly the importers in China) to register the substance 3) Rely on a local Chinese agents to register the substance. If you choose the first option, you should make sure that the personnel in the Chinese subsidiary are knowledgeable enough to carry out the registration, if not, it will be time and cost consuming. If you choose option two, you may lose your initiative in the trading relationship with your Chinese client. Thus, choosing an agent with specialist expertise for carrying out this kind of registration may be the best option.

| 2 Notification types         | Typical notification                                 | Typical notification; Simplified notification;     |
|                             | Notification exemption                                | Scientific Research Record                         |

**Note:** New chemical substances to be manufactured or imported at or above the annual volume of 1 ton are subject to typical notification.

The simplified notification pertains to new chemical substances manufactured or imported at annual quantities of less than one tonne per year. The 'China REACH' regulation also combines four simplified categories, which includes:

- Use as an intermediate and for export only: New chemical substances to be produced or imported into China solely for use as an intermediate or solely for export (if the volume produced or exported is less than one tonne per year).
- Scientific research: New chemical substances to be produced or imported for the purpose of scientific research with an annual quantity greater than 0.1 tonne but less than one tonne;
- Technological R&D: New chemical substances to be produced or imported for the purpose of technological research and development with an annual quantity of less than 10 tonnes;
- Polymer: New chemical substances that form less than 2 percent of a polymer and polymers of low concern.

Scientific research record is required when the new chemical substance used for scientific research has an annual quantity lower than 0.1 or if the sample is to be tested in laboratories in China.

<table>
<thead>
<tr>
<th>3 Notification scope</th>
<th>New chemical substance; Preparation that contains new chemical substance;</th>
<th>New chemical substance; Preparation that contains new chemical substance; Manufacured articles “designed to intentionally released” new chemical substance</th>
</tr>
</thead>
</table>

**Notes:** It may extend new chemical substance registration requirements to a broad range of manufactured items.
### 4 Notification area

- The activities of exporting or manufacturing new chemical substance into or within the territory of China
- The activities of introducing new chemical substance from boded areas and processing/manufacturing zones into the territory of China

**Notes:** The obligations imposed under the Regulation extends to new chemical substances being managed in bonded areas and exported to processing/manufacturing zones. Thus, new chemical substances being manufactured in or imported into these areas will be subject to registration.

### 5 Dossier requirement

- Typical notification form which shall contain the detailed information of substance's physicochemical, toxicological and ecotoxicological properties, emergency and pollution prevention measure, waste disposal methods etc;
- Testing report for the individual testing endpoints;
- The certificate document of the testing agents;

**Notes:** It has introduced Chinese MSDS’s, recommended classification and labeling and chemical risk assessment reports as mandatory parts of the notification dossier for the purpose of better evaluation of the new chemical substance.

### 6 Substance classification

- No specific category for new chemical substances

**Notes:** First, substances will be classified as either general chemical substances or hazardous (harmful) substances. Hazardous substances that are classified for persistence, bio-accumulative or as a hazard to ecological or human physical health will then be separately classified as hazardous substances of priority for environmental management. It has imposed different management obligations for the certificate holder in line with the different classifications of the new chemical substances.
| 7 Obligation for the certificate holder | Submission of substance flow sheet; Updating the notification dossier with the alternative tonnage band | Updating the notification dossier with the alternative of tonnage band; Updating the notification dossier with the alternative end use (for hazardous substances of high environmental management priority) The certificate holder shall communicate the necessary information regarding the new chemical substance along the supply chain; The certificate holder shall adopt appropriate risk control measures during the manufacturing of new chemical substance; The certificate holder shall submit the substance report sheet for the first activity; The certificate holder for the “simplified notification” shall submit the report of the new chemical substance’s activities in the previous year; The certificate holder of a new chemical substance of high environmental management priority shall submit a substance flow sheet within 30 days of delivering the substance to other users. The certificate holder of hazardous new chemical substances shall submit the annual planning for manufacturing and exporting of the new chemical substance. |

**Notes:** It will impose more obligations for the certificate holder under this regulation.