

COMPLIANCE SERVICES FOR MEASURES FOR ENVIRONMENTAL MANAGEMENT OF NEW CHEMICAL SUBSTANCES (CHINA REACH)

The legislation «**Measures for Environmental Management of New Chemical Substances**» was revised and adopted at the 3rd executive meeting of the Ministry of Environmental Protection of the People's Republic of China, on 30 December 2009.

The revised version entered into force on **15 October 2010**, repealing the «Measures» promulgated by the former State Environmental Protection Administration on 12 September 2003.

Companies placing new chemical substances on the Chinese market must submit new chemical registrations to the Chemical Registration Centre (CRC) of the Ministry of Environmental Protection Agency (MEP) of China. They are required to apply and be granted a registration certificate from CRC prior placing those substances on the market.

Registration is compulsory for substances on their own, as constituents of mixtures, or contained in articles from which they are intentionally released under normal conditions of use.



CHINA REACH REGISTRATION SERVICES:

- **Legal Representation in China: Non-Chinese companies cannot submit new chemicals applications directly and must proceed via a registered regulatory representative (proxy) established in China.**
- **Preliminary substance evaluation, including :**
 - Checking of the Inventory of Existing Chemical Substances in China (IECSC)
 - Extended checking of the IECSC for substances registered with “confidential protection” tag
 - Data gaps assessment, qualifying documents for translation in Chinese language
- **Initial assessment**
 - Information and data collection
 - Data analysis and evaluation
 - Data gaps assessment, qualifying documents for translation in Chinese language
- **Preparation of testing report and relevant materials**
- **Testing for missing data**
 - Cost effectiveness strategy, and testing planning
 - Testing for physicochemical, toxicological and eco-toxicological properties
- **Generation of risk assessment Report**
 - Exposure assessment
 - Conclusion of the assessment of environmental and health risk
 - Risk control and management measures, etc.
- **Generation of the recommended classification and labelling**
- **Translations and notarisations**
- **Registration dossier generation, submission & follow up**
 - Standard registration : New chemical substances ≥ 1 T/y
 - Simplified registration : New chemical substances ≤ 1 T/y
 - Research and development registration, where applicable
- **Post registration mandatory activity reports**
 - For simplified registration
 - For new chemical substances of high environmental management priority
 - For hazardous new chemical substances
- **Chemical safety data sheet generation & updating**

ADDITIONAL SERVICES RELATED TO CHINA REACH COMPLIANCE:

- Assisting clients in readying for onsite inspections carried by enforcement authorities
- Regulatory and technical assistance
- Regulation monitoring and alerts for changes in legislation

Notes:

The obligation to register also applies to new substances placed on the Chinese market irrespectively of the volumes, that is, below the 1T/y threshold.

The principal categories of obligations are:

- Registration of substances on their own, in preparations or intended to be released from articles
- Implementation of safety measures and communication to users and processors
 - Documentation on risk management measures
 - Chemical safety instructions for processors and users
 - Monitoring hazardous emissions of substances considered of environmental concerns
- Production of annual manufacturing and impact reports

**EU REACH COMPLIANCE SERVICES (for the EU Market)**

We also provide registration services and regulatory assistance with respect to Regulation (EC) **No 1907/2006** of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (**EU REACH**), as well as CLP notifications, and labelling services in compliance with Regulation (EC) **No 1272/2008** on classification, labelling and packaging of substances and mixtures (**EU CLP**).

Please contact our consultants, chemists or regulatory experts, if your seek assistance.

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