

A photograph of two men wearing orange hard hats and high-visibility yellow safety vests. They are looking down at a tablet computer held by the man on the right. The background is a blurred industrial or construction site.

New Chemical Substance Notification in China

In Europe there is EU REACH; in China there is China REACH. For companies importing chemicals from China to Europe compliance with both legislations is of utmost importance.

In China, chemical substances are regulated by the Measures for the Environmental Management and Registration of New Chemical Substances (MEE Order N° 12), enacted by the Ministry of Ecology and Environment. This order was implemented on January 1, 2021 and replaced previously existing legislation (MEP Order N° 7).

This chemical regulation applies to activities regarding research, manufacture, import, processing and use of new chemicals and as a result, **companies who plan to manufacture or import chemicals** not listed in the Inventory of Existing Chemical Substance in China (IECSC) must submit notification dossiers of the chemicals to the Solid Waste and Chemicals Management Center of MEE (SCC-MEE) and apply for approval. They can only proceed with manufacture or import after receiving the notification certificate.

In essence EU REACH and China REACH aim for the same objectives: ensure a high level of protection of human health and the environment, standardise the management of new chemical substances, scientifically assess and control the health and environmental risks of new chemical substances. They both put the burden on the industry to generate the data, they both have a tiered approach with increasing number of test data to be generated for higher volume chemicals, they both have provisions to stimulate competitiveness and innovation.

Does this make the two regulations the same?
Which substances need to be registered? What about exemptions? Data requirements? Make use of existing data? Uses of the chemicals? Timelines for registration and approval? What about substances in articles?
And polymers? Post-notification obligations?
Notification cost? Individual versus joint submissions?
And what about existing chemicals?

EU REACH and China REACH have so many things in common but are even more different in so many details.

For companies that buy and import chemicals from China, it is important to understand how China REACH may affect their business and how non-compliance with the local regulations may disrupt their supply chain.

How to start your journey?

Understand which substances or products your company is importing from China, or which substances or products your Chinese supplier or partner is manufacturing in China, and assess these products with regards to China REACH.

Arcadis has a team of experts in place in Europe, US, and China that can support you to assess whether the chemicals you import from China into EU or US are compliant with the local regulations and identify mutual compliance requirements with actors up and down the supply chain under the Chinese “Measures for Environmental Management and Registration of New Chemical Substances”. Based on the classification, the manufactured or imported volumes and the existing supply chain, a set of regulatory obligations will be identified and compliance strategies will be developed, including timelines and resource estimates.

What if China REACH notification obligations are identified?

What is the impact on your operation and what will your company need to do to ensure compliance in the supply chain to minimise chances on interruptions. What are your options and what will it cost?

In case chemicals are identified that trigger China REACH notification obligations for you or your supplier in China, our team will check the IECSC (public and confidential part) and work with you to develop a strategy and build the notification dossier(s) as required. This will include the data gap analysis and developing the strategy for the necessary substance ID, physico-chemical, environmental fate, toxicological and ecotoxicological testing in an international accredited or Chinese certified laboratory as required by the regulation. Our in-house experts will also organise, coordinate, monitor and follow up on the studies and tests at these testing facilities. If the testing is performed outside China, translation of summaries can be provided.

The notification dossier will be built, submitted and followed up with local authorities, as needed. If required, the Risk Assessment Report (including environmental and human health hazard, exposure and risk assessment results as well as risk control measures) and the Socio-economic Benefit Analysis Report (required for highly hazardous new substances) will be prepared as well and added to the notification dossier.

About Arcadis

Arcadis is the leading global Design & Consultancy firm for natural and built assets. Applying our deep market sector insights and collective design, consultancy, engineering, project and management services we work in partnership with our clients to deliver exceptional and sustainable outcomes throughout the lifecycle of their natural and built assets. We are 36,000 people, active in over 70 countries that generate €4 billion in revenues. We support UN-Habitat with knowledge and expertise to improve the quality of life in rapidly growing cities around the world.

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Our Experience

• EU REACH team

- 10+ years of experience with EU REACH
- supporting and working with consortia, multinationals but also SME's on compliance with EU REACH
- developing and implementing compliance strategies
- developing endpoint coverage strategies and testing
- hazard and risk assessments
- dossier building for REACH registration
- preparing Risk Management Option Analysis (RMOA's), analysis of alternatives, socio-economic analysis and apply for REACH Authorisation

• China REACH team

- 10+ years of experience in chemical registrations in China
- successfully registered 500+ simplified and regular substances under MEP Order N° 7
- supporting local Chinese companies but also multinationals with Headquarters in Europe or US
- proven practical experience with substance analysis, data gap analysis, substance information query and QSAR prediction, developing testing strategies, risk assessment preparation
- over the years a good connection was built with the reviewers of the SCC-MEE

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