

A photograph of two workers wearing orange hard hats and high-visibility safety vests. They are looking down at a tablet computer held by the worker in the foreground. 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 on the Environmental Management of New Chemical Substance (MEP Order N°7), enacted by the Ministry of Environmental Protection (MEP) of China on October 15, 2010. On April 29, 2020, the Ministry of Ecology and Environment of the People's Republic of China published its Order N° 12 which will be implemented on January 1, 2021 and superseding the 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), apply for approval and can only proceed 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 are 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 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, 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 needed, also the Risk Assessment Report, including hazard assessment of the notified substance, exposure scenarios assessment and risk control measures, assessment results of environment and health risks and also the Socio-economic Benefit Analysis Report, if the substances are identified as highly hazardous new chemical substances, will be prepared.

If the testing is performed outside China, translation of summaries can be provided. Of course, also the notification dossier will be built, submitted and followed up with local authorities, as needed.

## 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 covering 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 No.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 plan, risk assessment preparation
- over the years a good connection was built with the reviewers of the SCC-MEE

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