

# COMPREHENSIVE SUPPORT REACH REGISTRATION

## Regulatory Services

**Intertek Assuris supports its customers with the technical know-how needed to create robust dossiers and chemical safety reports, ensuring submission of quality registration dossiers by doing the right thing, the right way, the first time.**



### Background

European Union (EU) manufacturers and importers may have REACH registration obligations for substances manufactured or imported at one tonne per year and above.

If you have a registration obligation under REACH you must have submitted a registration, and have it approved before manufacturing or importing your substance at above 1 tonne per year.

A company is exposed to increased business risk by starting compliance efforts late, and the time required to complete a registration should not be underestimated.

Boost your stretched resources and/or avoid potentially costly errors through support from our experts with their deep knowledge of the REACH regulation.

Intertek has an enviable record of successful 2010, 2013 and 2018 registrations and can support you delivering comprehensive registration services for REACH in a timely and cost-effective manner throughout all stages from planning, through to testing and to completed registration.

### Your Advantages

- Management of registrations in the required timeframe for your business
- Efficient testing strategies developed, based on thorough data gap analysis
- Avoidance of poor compromises to meet compliance
- Time and cost-efficient support by experienced specialists
- Support beyond registration to manage updates, authority requests, etc.

### REACH Registration Technical Dossier Services

- REACH Technical Dossier data gap analysis:
  - Perform literature searches to locate available data on substances of interest
  - Evaluate existing study reports and rate according to Klimisch criteria
  - Analyse available data against the REACH requirements to identify key studies and any gaps
  - Confirm key studies and prepare robust study and endpoint summaries
  - Develop Derived-No-Effect-Levels (DNELs) and Predicted-No-Effect-Concentrations (PNECs)
  - Perform PBT and Chemical Safety Assessment

- Fill any gaps using scientific strategies that may include the use of:
  - REACH testing (substance identification, sameness testing, physicochemical property determination, toxicological, ecotoxicological, etc.)
  - Exposure Scenarios
  - Waiver arguments
  - (Q)SARs and extrapolation
  - Read-across data
- Creation of IUCLID 6 Dossier
- Preparing relevant Chemical Safety Reports (CSR) that cover client's use patterns
- Submission of completed REACH Registration Dossier to ECHA
- SIEF and Consortia Management when needed
- Review and revise classification and labelling (EU CLP / UN GHS) and prepare extended Safety Data Sheets
- Consulting support from Intertek REACH Specialists

## REACH Services

- Conduct an assessment of a company's current REACH status: review all substances and determine obligations under REACH, identify company obligations, gaps in information, provide a compliance strategy
- Act as an Only Representative for non-EU companies wishing to register their substances for their supply chain in the EU – includes annual reporting of volumes, provide analysis reports each year
- Provide reporting services for OR clients' Non-EU customers through OR Supply Chain services
- Provide reporting services for clients' supplier covered substances and collection/retention of Declaration of REACH Compliance (DRC)
- Provide annual reporting/analysis for Non-OR clients to monitor volumes for potential imminent registrations
- Provide assistance in building joint submission dossiers: communicate with SIEF, obtain LOA, act as a third party representative and develop substance identification and registration strategies
- Conduct analytical testing necessary to complete registration of substances

## REACH Testing Programs

Our extensive knowledge of global chemical regulations and considerable experience from successful registrations, allows us to develop tailored REACH testing programs designed to facilitate a successful registration.

This service includes substance identification and sameness testing and delivering highly relevant technical guidance to ease your registration process. With strengths in data assessment, we can identify any data gaps in the information to complete a dossier and develop efficient strategies to address such gaps whilst minimizing unnecessary testing costs. Services can be delivered to ISO 17025 or Good Laboratory Practice (GLP) standards as required.



## The Intertek Advantage

Intertek Assuris has extensive expertise and experience having worked with a variety of clients across multiple industries. Let our experienced professionals take care of your REACH obligations allowing your people to focus on core business needs. We can support your brand protection and market share through regulatory compliance. Client's benefiting from our services can enjoy lower costs through outsourcing and continuous, convenient and accessible support.

## About Intertek

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

**Total Quality. Assured.**

## FOR MORE INFORMATION



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