

# COMPREHENSIVE SUPPORT REACH REGISTRATION

## Regulatory Services

**Intertek Health Environmental & Regulatory Services (HERS) 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

