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Summary

REACH is a highly complex regulatory requirement which requires technical expertise to navigate successfully. Charles River can advise and assist in many ways, including assessing data requirements, evaluating data and helping to prepare dossiers.

SAFETY ASSESSMENT

REACH Registration Support

Clients working in the pharmaceutical, biopharmaceutical, chemical, crop protection, food additive or animal health industry may need to consider compliance with (EC-1907/2006) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Charles River can advise and assist in many ways, including designing a registration strategy that suits the needs of their substance/portfolio.

REACH is one of the most complex chemical regulations in the world; compliance can be difficult to achieve. The key to success is collaboration among a multidisciplinary team of experts who understand what needs to be done. Clients who choose Charles River for a REACH solution benefit from our strong team of both regulatory specialists and scientists who are dedicated to the REACH-related fields of chemistry, ecotoxicology, environmental fate and toxicology.

Charles River can partner with clients across the whole process, from helping to assess data requirements and evaluating data to helping to prepare dossiers. For non-EU manufacturers, we can also perform the role of Only Representative. For importers or EU manufacturers, we can act as third-party representative.

Our Services Include:

- Project management
- Only representation for non-EU manufacturers
- Dossier compilation
- Substance Information Exchange Forum (SIEF) communication
- Substance identification process support
- Data gap analysis
- Support via quantitative structure-activity relationship (QSAR)
- Read-across and category-forming argumentation
- Study monitoring
- Classification and labelling proposal
- Human exposure and risk assessment
- Environmental exposure and risk assessment
- IUCLID6 technical dossier
- Discussions with ECHA when required
- Post-submission update of dossiers

EVERY STEP OF THE WAY

Successfully meeting REACH requirements starts with a plan. The Charles River 10-step approach will help ensure that the right steps are taken at the right time.

1. **Inventory:** This includes the identification of substances, tonnage information, use mapping and collection of in-house data.
2. **Late pre-registration/Inquiry:** This is the starting point of any registration.
3. **Refinement of inventory:** All SIEF data is gathered and a literature search conducted.
4. **Data evaluation:** This entails the preparation of robust study summaries, hazard assessments, classification and labelling PBT assessments.
5. **Determination of data gaps:** We perform a preliminary overview to identify data gaps in the dossier.
6. **Completion of data requirements:** Read-across and QSARs are used to fill in gaps when possible; if required, we can perform animal testing.
7. **Chemical safety assessment/report:** Classified substances at ≥ 10 t/y requiring labelling (e.g., toxic) need a complete chemical safety assessment including an exposure assessment, risk characterisation, determination of risk management measures and exposure scenario building, demonstrating safe use along the entire supply chain.
8. **Preparation of test proposals (>100 t/y):** Proposals and/or waivers are needed for substances exceeding 100 t/y that have data gaps.
9. **Dossier preparation, finalisation and submission:** All collected data is checked for completeness and quality and brought together in IUCLID to create the final dossier for submission.
10. **Safety data sheet:** We produce the (extended) safety data sheet for classified substances.

Think Strategically

The experts at Charles River have identified numerous ways to save time and money in achieving REACH compliance, and we are eager to share these strategies with clients:

- Properly grouping substances that can be tested together
- Formulating hypotheses to use data for read-across between similar substances
- Determining when Annex III can be used
- Directing counsel on exposure-based waiving and hazardous substance assessment
- Developing a testing strategy (or non-testing strategy for cosmetics) that accounts for registration needs in other parts of the world

The REACH 2018 deadline is fast approaching. Companies that have determined a particular substance is critical to their business should consider becoming the Lead Registrant for that substance.

In addition to assuring that business is not interrupted by missed deadlines, Lead Registrants are better able to control the process and guide the discussion. Being the lead does not mean doing all the work – each member of the SIEF is obligated to share existing studies, respond to requests for information and to compensate the Lead Registrant for all registration-related costs. Finally, Lead Registrants also retain ownership of studies, thus allowing the data to be used globally.

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