REACH

REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS

charles river

Introduction to REACH

What is REACH?

The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a European chemical law that creates a single registration system for both new and existing chemicals. Implemented in June 2007, the REACH regulation (EC) No 1907/2006 charges the chemical industry with the responsibility of assessing the hazards and managing the risks posed by the substances they manufacture, import and use.

Why is it important?

REACH impacts a wide range of industries: (bio)pharmaceutical (e.g., intermediates), chemical, and crop protection (e.g., formulants). REACH requires comprehensive data on substances submitted for registration. Data will be included in a central disseminated database held by the European Chemicals Agency (ECHA). Failing to register substances can result in disruption or failure of business operations.

REACH deadlines

Under this law, substances manufactured or imported up to 100 tonnes/year that were submitted by the pre-registration deadline of December 2008 were allowed a 10-year grace period to achieve full registration. June 2018 is fast approaching; it is recommended that companies have data in place by the end of 2017 in order to leave time for risk assessment, chemical safety reporting and dossier filing.

What do we do?

The process for achieving full registration is complex and lengthy. With less than 2 years before the deadline, companies must act now. This guide provides comprehensive information to help you plan and implement a program to complete your registration submission accurately and on time.

Challenges

REACH laws affect all companies, whether they are just entering the European market or have been in business for 100 years. Pre-registered substances manufactured or imported in quantities as low as 1-100 tonnes per year must satisfy REACH requirements before June 2018.

REACH demands a new level of precision in the analysis and characterisation of the chemical composition of the substances. Often, companies lack the resources or expertise to produce and/or evaluate the required data.

Alternatives to animal-based safety assessment are encouraged, though the industry and its authorities often do not have the experience and/or capabilities to perform these relatively new tests.

Compliance is not simple, and companies are finding that out the hard way. The 2015 progress report from ECHA showed that compliance checks revealed only 18% of dossiers required no further action.

COMMON PITFALLS

- Incorrect or ambiguous substance identification
- Misuse/Incorrect use of read-across (using data from one or more similar substances to make judgments about the hazardous properties of a substance)
- Using QSARs without proper documentation and justification
- The Chemical Safety Report (CSR) contains the use description and exposure assessment which often do not reflect the actual use and conditions of uses, and the information on the personal protective equipment is incorrect or limited
- No assessment containing a demonstration of minimisation of emissions for recognised PBT/vPvB substances

Assess and understand

Companies must first assess and understand their business portfolio to determine which of the substances the company produces or imports are subject to REACH.

01

Inventory

An inventory includes the identification of substances, tonnage information, use mapping and collection of in-house data.

02

Pre-registration inquiry

The pre-registration or an inquiry is the starting point of any registration process.

Refine, evaluate and determine

03

Refinement of inventory

Inventory refinement involves collection of all Substance Information Exchange Forum (SIEF) data and conduct of a literature search.

04

Data evaluation

The data evaluation entails preparation of summaries, hazard assessments, and classification and labelling.

05

Determination of data gaps

Based on steps 2, 3 and 4, the data gaps are determined.

Complete, assess and propose

06

Completion of data requirements

Data requirements are completed by implementing read-across and quantitative structure-activity relationship (QSAR) evaluations when possible. When absolutely necessary, (animal) testing is performed.

07

Chemical safety assessment and report

Classified substances require labelling (e.g., toxic) and >10tpa need a complete cycle analysis, exposure assessment, risk characterisation, determination of risk measures and risk scenario building.

08

Test proposal

Testing proposals are needed for substances exceeding 100 tonnes/year that have data gaps.

Finalise and prepare

All REACH programs conclude with extensive documentation for registration.

09

Dossier preparation, finalisation and submission

All collected data is brought together in the International Uniform Chemical Information Database (IUCLID) system and the dossier created.

10

Creation of safety data sheet

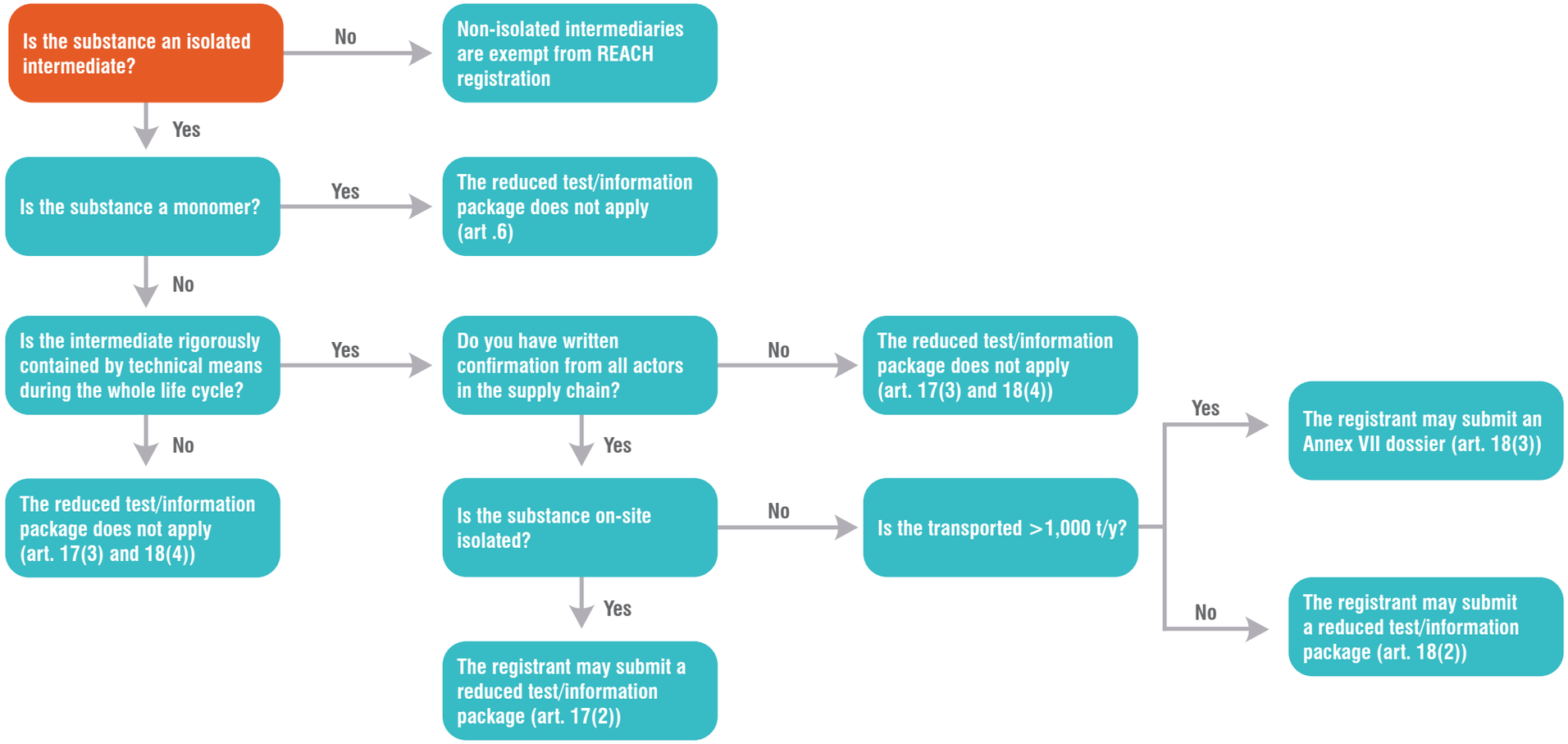
An additional ‘extended’ safety data sheet is required for classified substances.

Set priorities

- Confirm true substance identity and ensure your substance is pre-registered.
- Start with substances that are already defined/confirmed to register.
- Discuss your total portfolio for 2018 internally and, when required, with a consultant to look at grouping/read-across opportunities.
- Discuss the area of use of the data that needs to be generated (e.g., non-REACH, GLP/non-GLP, OECD/OPPTS, etc.).
- If working with a CRO, contact the chosen organisation for planning, study combinations, schedule reservation, and testing, at least on the longer running tests.

Example: Isolated intermediates

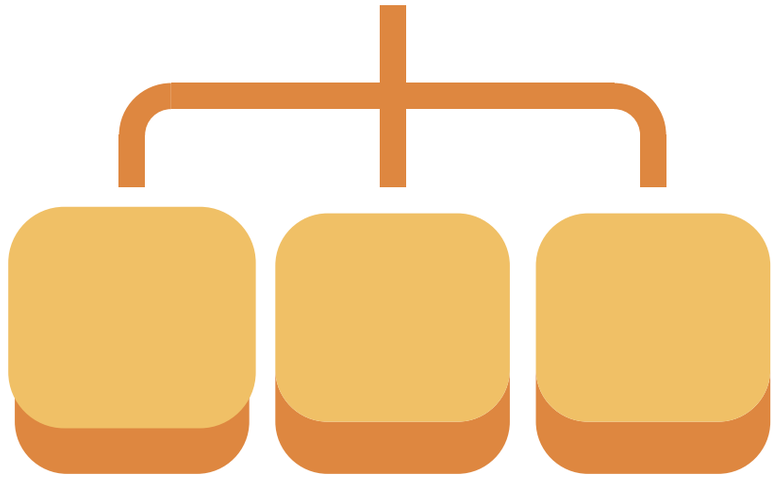
An intermediate is a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. These have to be registered unless they are non-isolated, (i.e., during synthesis they are not intentionally removed from the equipment in which the synthesis takes place). The amount of required safety data for these substances depends on the conditions of its manufacture and use.



Becoming a Lead Registrant

If, during your portfolio evaluation, you identify a substance that is especially important to your business, it is worth considering becoming the Lead Registrant.

Being the Lead Registrant for a chemical substance



- Assures your business is not interrupted by missed deadlines
- Helps you control the process and guide the discussion
- Does not entail that you do all the work
- Carries the added benefit of SIEF compensation for registration-related costs
- When testing is required, you own the study and can use it without additional costs in other global regions

Satisfying REACH requirements

All REACH programs conclude with extensive documentation for registration.

- Analytics and substance identification
- Physicochemical testing
- Environmental fate
- Ecotoxicology
- *In vitro* studies
- Comprehensive toxicology
- Regulatory knowledge

Internal vs. Outsourced Work

Before or during this process, it is important for companies to determine whether to complete the registration work in-house or outsource the work to a CRO. Most often, companies lack the resources or knowledge to satisfy all REACH requirements on their own. Global REACH expertise and program support is limited, but not impossible to find.

Whether you choose to manage the process in-house or hire a third party expert to guide you through preparing your dossier, you will want to examine your registration plan closely to identify areas of efficiency.

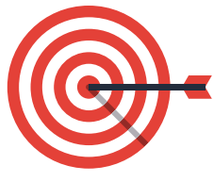
How to prepare

Build a team

Include project managers, regulatory advisors, scientists and analysts from REACH-related disciplines. It is important to remember the scope of REACH requirements. Your team might require specialty toxicologists (sensitisation, reproductive, ecotoxicology, etc.), chemists aware of requirements for substance identification and who are capable of performing a wide range of tests, environmental scientists (environmental fate) and others.

Develop a strategy

Create a timeline and milestones that will guide your program, incorporating all necessary testing to satisfy requirements in an efficient, cost-effective manner. Companies should seek to reduce the amount of testing required – by using Annex III, grouping, switching suppliers, or even phasing out use of certain substances. Advise your management: ‘No data, no market.’ Budget accordingly.



Implement the plan

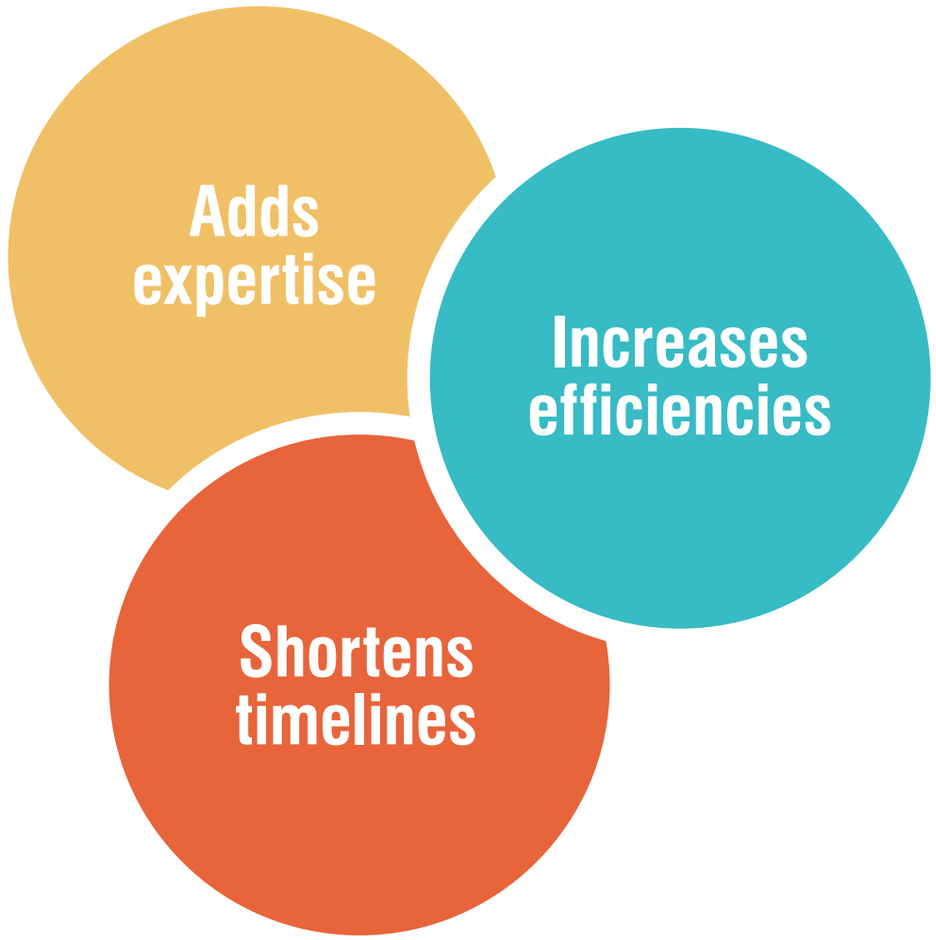
Conduct data evaluation and testing in-house or through a third party to stay on track with timelines. When a sufficient work force isn’t available in-house, the complete package or parts of the work can be outsourced. An experienced partner can increase your efficiency by helping you to develop and implement your plan.

Monitor ongoing requirements

The legal responsibilities of REACH don’t end when your dossier is submitted. Companies must monitor regulatory data requirements and updates to ECHA guidance documents to ensure their continued compliance. In addition, changes in use(s), increase in tonnage band and/or availability of new information, may require updates of your registration. Updates to IUCLID and REACH-IT can also impact your registrations.

Partnering with a contract research organisation

Not every company has the resources to handle REACH in-house, particularly with the sheer volume of registrations that they may need to manage.



Choosing the right CRO

Companies that have experience in handling REACH registrations succesfully can support specific activities or provide complete outsourced services. Few organisations, however, offer true multidisciplinary expertise to partner through strategy, planning and implementation of your program to follow the most efficient path to registration.

Your CRO partner should have

- Proven success in achieving complete registrations
- Knowledge and experience in dealing with European authorities
- Ability to handle the entire registration process on your behalf, if that's what you need
- An understanding of what is required for your substance identity
- Chemical safety assessment capabilities, exposure and risk refinement strategy
- The knowhow and ability to reduce the amount of required testing
- Global reach to meet the pan-European requirements of imported substances
- Ability to devise a testing strategy that anticipates and thus limits testing when required for other global regions

Charles River and REACH

Description	Number of Projects (2007-2015)
Lead dossier (incl. non-phase-in dossiers)	>220
Intermediates (incl. reviewing SCC)	>25
Member dossiers	>250
Full CSA/CSR	>110
ELINCS tonnage updates	>36
CLP notifications	>220
eSDS preparation	>47

Summary

REACH may be complicated, but its goals are noble. The regulation seeks to improve the protection of human health and the environment by identifying the intrinsic properties of chemical substances earlier and more efficiently. It also aims to enhance innovation in and the competitiveness of the EU chemicals industry.

Do not let the 2018 deadline sneak up on you. Create a plan that will give you peace of mind that your substances will be registered accurately and efficiently.

CONTACT INFORMATION

Europe: +44 (0) 1875 614545

North America: 1.877.274.8371

Email: askcharlesriver@crl.com

Web: www.criver.com

Resources

Click on the links below for additional information.

- Charles River REACH program management and services
- IUCLID software plays a central role in the IT environments of all organisations that manage scientific data on chemicals in a regulatory context. It is specifically used for REACH and biocides in the EU.
- The European Chemicals Agency (ECHA) website
- ECHA Guide: Alternatives to Animal Testing
- ECHA Lead Registrant Webinar Series

charles river

www.criver.com