

[REACH Policy Reform – Questions and Answers](#)

Introduction

REACH, the new European reform for regulating chemical safety, will affect most businesses in Europe in one way or another, even those who would not normally consider themselves involved in chemical regulation.

Q1: What does REACH stand for?

A: REACH Policy Reform is a European Union regulation relating to the Registration, Evaluation, Authorisation and restriction of Chemicals.

Q2: How many chemicals does REACH cover?

A: Around 30,000 currently in use in volumes of 1 tonne or more per year, per legal entity. It also includes new chemicals.

Q3: What is affected by REACH?

A: “Substances” (chemicals), “preparations” (mixtures or solutions of substances) and “articles” (equipment, products, sub assemblies, components, parts – items which have a “special shape, surface or design which dictates its function to a greater degree than does its chemical composition” – for example clay is a preparation, but a pottery mug is an article).

Q4: What is the aim of REACH?

A: REACH will help protect human health and the environment. The number of allergies, asthma, certain types of cancer and reproductive disorders are on the increase throughout Europe. Chemicals may well be one of the causes. REACH also aims to enhance the competitiveness of the EU chemicals industry by encouraging innovation and seeking improved safety standards for its products.

Q5: Does REACH replace any existing legislation?

A: REACH has replaced 40 existing pieces of legislation.

Q6: What does REACH mean?

A: Registration - the necessity to submit a (technical) dossier on the properties of a substance or preparation under certain conditions

Evaluation - of the dossier by the authorities

Authorisation and restriction – on the use of a substance or preparation
Of Chemicals

Q7: What does REACH mean for your company?

A: You are affected if you:

- Manufacture or import chemical substances or mixtures of chemical substances (preparations such as paint, adhesives etc)
- Produce or import articles such as electronic components, sub-assemblies, toys etc, which contain substances to be included in a list of “substances of very high concern” (notification required if >0.1% by

weight and >1 tonne per annum) or which are intentionally released or release is reasonably foreseeable (eg ink or perfume) during their use, or during recycling (registration required if >1 tonne per annum).

- Process chemicals or you formulate preparations for end use (for example cleaning products, paints or motor oils) or you use these formulated products professionally. In this case you are a “downstream user”

Q8: How will you be affected?

A: If you are a:

- Manufacturer / Importer – you manufacture or import a substance on its own or in a preparation of more than 1 tonne per year
- Producer / Importer or Supplier of articles – you manufacture / import articles or place them on the market
- Distributor (including retailers) – you store and place on the market a substance, on its own or in a preparation
- Downstream User – you use a substance, either on its own or in a preparation, in the course of industrial or professional activities, (for example: formulation, dilution, repackaging, spraying, painting)
- Note: companies outside the EU cannot register chemicals themselves but can appoint an EU based “only representative” to act on their behalf

Q9: Who co-ordinates all of this?

A: The European Chemicals Agency (ECHA) based in Finland provides central guidance, hosts the registration process, operates committee processes as well as the authorisation process

Q10: How does REACH actually work?

A: Substances that fall into scope will need to be registered according to a specific timetable. Any not registered become illegal to supply or import into the EU unless they are outside the scope of REACH

Substances to be registered under REACH require a technical dossier for quantities of 1 tonne per year or more and a chemical safety report (CSR) for quantities of 10 tonnes per year or more.

REACH defines what is required in the technical dossier and will contain, for example, information on the properties, uses, the classification of a substance (toxic etc), specified test data as well as guidance on safe use.

The CSR documents the hazards and classifications of a substance and if it is found to meet the specified criteria (ie it is hazardous), then the registrant will need to provide an exposure scenario and carry out a risk assessment.

Q11: What are “exposure scenarios”?

A: A set of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends to control, exposure to humans and the environment. They must also include the appropriate risk management measures and operational conditions that, when implemented correctly, ensure that the risk from the substances are adequately controlled. They should cover the entire

manufacturers' or importers' own uses made known to the manufacturer or importer by their downstream users.

Q12: What if there is no data?

A: There is a requirement for manufacturers or importers of substances to register them with the European Chemicals Agency, ECHA. In order for a substance to be registered, the registrant will need to submit data that is specified by the REACH regulations. It is not possible to register a substance without the required data and unregistered chemicals cannot be used. This will not only affect chemical manufacturers and users but also downstream users.

Q13: What does "evaluation" mean?

A: Registration packages (dossiers) submitted under REACH can be evaluated for:

- Compliance Check – automated check to ensure that all of the information has been submitted by industry
- Dossier Evaluation – to check the quality of the data and a check that a suitable testing plan has been proposed for substances registered at the higher tonnage levels (over 100 tonnes per annum) where the data is not yet available and this is permitted by REACH
- Substance Evaluation – An evaluation of all the available data on a substance, from all registration dossiers. This is done by national Competent Authorities (see Q14) on substances that have been prioritised for potential regulatory action because of concerns about their properties or uses

Q14: What is a Competent Authority?

A: The authorities established by Member States to carry out the obligations arising from the REACH regulation, for example, the Health and Safety Executive in the UK.

Q15: Where can I find details of the European Chemicals Agency - ECHA?

A: Web address is <http://echa.europa.eu>