

# A brief guide to REACH

what you need to know  
November 2008



# A BRIEF GUIDE TO REACH: WHAT YOU NEED TO KNOW

## REACH REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

(Corrected version published in the Official Journal of the EU, 29 May 2007)

### FOREWORD

REACH is recent, broad, complex EU chemicals legislation with relevance to a very large number of companies and other bodies in the UK. The implications of REACH for any particular substance and its manufacture and use, and the consequences for any organisation involved will vary from negligible to substantial. Proper appreciation of, and preparedness for such implications requires awareness and understanding of the legislation. UK government, through the UK REACH Competent Authority (CA) and other means, is putting considerable effort into raising awareness of REACH. However, help is needed from others and in this context the initiative shown by RSC and other bodies in producing guides such as this is very welcome.

I hope that this RSC guide will make a big contribution to promoting awareness and understanding of REACH among RSC members and other recipients. Please excuse one cautionary note - any brief guide to REACH must necessarily deal in approximations and generalisations. Two years of operation of the UK REACH CA Helpdesk has taught us that in dealing with an individual set of real-life (or hypothetical!) circumstances there is much scope for variability in their detailed features and regulatory consequences. Potentially crucial business issues are best resolved by a specific approach to a REACH enquiries point operated by the relevant industry or trade association, or the UK regulatory authority.

**Dr Steve Fairhurst**  
**Head of UK REACH Competent Authority**

We know from discussions with Royal Society of Chemistry members that many professional chemists are making the assumption that the REACH Regulation only applies to large chemical companies. They could not be more mistaken. The REACH Regulation is the most comprehensive piece of chemical regulation to appear anywhere in the world. Its 840 pages apply to virtually every use of every chemical, both naturally occurring and synthetic that is manufactured, imported or used within the 27 member states of the European Community. If you are a professional chemist you will almost certainly have new obligations as a result of the REACH Regulation. University lecturers, school teachers, chemists working in development, manufacturing, and formulation are all affected to different degrees. Similarly, everyone who uses chemicals in any manufacturing process gains new obligations. Since these are legal requirements, failure to comply could be a criminal offence. This short guide has been produced by the society to introduce professional chemists to their new obligations. It is not intended to be a comprehensive guide to REACH and it will not answer all your questions, however we hope it will provide you with sufficient information to alert you to your new responsibilities.

**Dr David Taylor**  
**Chair of RSC Environment, Health and Safety Committee, Policy Group**

### About the RSC

Since 1841, the RSC has been the leading society and professional body for chemical scientists and we are committed to ensuring that an enthusiastic, innovative and thriving scientific community is in place to face the future. The RSC has a global membership of over 44,000 and is actively involved in the spheres of education, qualifications and professional conduct. It runs conferences and meetings for chemical scientists, industrialists and policy makers at both national and local level. It is a major publisher of scientific books and journals, the majority of which are held in the RSC Library and Information Centre. In all its work, the RSC is objective and impartial, and is recognised throughout the world as an authoritative voice of the chemical sciences.

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## ACKNOWLEDGEMENTS

The information presented in this document has been drawn from the corrected version REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council (published in the Official Journal of the EU 29 May 2007 which can be found at: [eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2007:136:SOM:EN:HTML](http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2007:136:SOM:EN:HTML)) and guidance material produced by the UK REACH Competent Authority (<http://www.hse.gov.uk/reach/index.htm> which also operates the UK CA Helpdesk Tel: 0845 408 9575 - UKREACHCA@hse.gsi.gov.uk) the European Chemicals Agency ([echa.europa.eu/home\\_en.asp](http://echa.europa.eu/home_en.asp)) and the European Chemicals Bureau (<http://ecb.jrc.it/>) websites. **As the material on these sites is frequently updated we strongly recommend that readers seeking specific advice consult the above websites for the most up-to-date information and guidance.**

## WHAT IS REACH?

REACH is a new European Union Regulation concerning the Registration, Evaluation, Authorisation and restriction of Chemicals which came into force on 1 June 2007.

*A key element of the REACH Regulation is that it shifts the 'burden of proof' from the authorities to industry, which will now have to demonstrate that a chemical can be used safely for a specific use. Manufacturers, importers, and, for the first time, downstream users, will have to provide information to enable the end-user to manage the risk.*

REACH applies to substances manufactured or imported into the EU in quantities of 1 tonne per year or more. Generally, it applies to all individual chemical substances on their own, in preparations or in articles (if the substance is intended to be released during normal and reasonably foreseeable conditions of use from an article). A substance is defined under REACH as 'a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition'. An article is defined as an object which during production is given a specific shape, surface or design which determines its function to a greater degree than does its chemical composition. Although REACH includes a requirement for classification and labelling the criteria for determining the classification continue to be dealt with in Directives 67/548/EEC and 1999/45/EEC until the UN Globally Harmonised System is implemented in the European Union.

REACH replaces (wholly or in part) a number of European Directives and Regulations with a single system. Many of the obligations that applied to manufacturers, importers and downstream users, have been incorporated into REACH. This includes those parts of the Dangerous Substances Directive (67/548/EEC) concerning new substances, the Existing Substances Regulation (793/93), the Marketing and Use Directive (76/69/EEC) and parts of the Directive covering Dangerous Preparations (1999/45/EEC). It removes the distinction between 'new' and 'existing' chemicals listed in the 1981 European Inventory of Existing Commercial Chemical Substances<sup>1</sup>. The preparation of safety data sheets (SDS) for substances and preparations as set out in Directive 91/155/EEC will also be replaced by REACH (Article 31 and Annex II).

## AIMS OF REACH

REACH has several aims:

- To provide a high level of protection of human health and the environment from the use of chemicals
- To make manufacturers and importers who place chemicals on the market responsible for understanding and managing the risks associated with their use. (Placing on the market means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market)
- To allow the free movement of chemical substances within the EU market
- To enhance innovation in and the competitiveness of the EU chemicals industry

- To promote the use of alternative methods for the assessment of the hazardous properties of substances and read across of data

REACH requires all manufacturers and importers of substances to register them with the European Chemicals Agency (ECHA)<sup>2</sup>. **It will be illegal to manufacture or supply substances within the EU which have not been registered.** A registration package will be supported by a standard set of data on that substance<sup>3</sup>. The amount of data required is proportionate to the amount of substance manufactured or supplied<sup>4</sup>. A tool, called the Navigator, has been developed by the Commission services to help users identify their obligations under REACH. It can be found at [http://echa.europa.eu/reach\\_en.html](http://echa.europa.eu/reach_en.html) See also:

Annex VI: Information requirements referred to in Article 10

Annex VII: Standard information requirements for substances manufactured or imported in quantities of 1 tonne or more

Annex VIII: Criteria for substances registered in quantities between 1 and 10 tonnes

Annex VIII: Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more

Annex IX: Standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more

Annex X: Standard information requirements for substances manufactured or imported in quantities of 1,000 tonnes or more

Annex XI: General rules for adaptation of the standard testing regime set out in Annexes VII to X

## HOW REACH APPLIES TO YOU

If you are involved in the manufacture or use of chemicals in, or the import of chemicals into the EU then REACH applies to you. Almost every business in the UK will have responsibilities under REACH. REACH will impact most businesses in the UK in some way. It is important to understand what your role is.

### Manufacturers and Importers (Registrants)

A manufacturer is any natural or legal person established within the community who manufactures a substance (or extracts a substance in the natural state) within the Community. An importer is defined as any natural or legal person established within the Community who is responsible for the import (i.e. the physical introduction) into the EU customs territory.

Businesses that manufacture or import 1 tonne or more of any given substance from outside the EU each year are responsible for registering a dossier of information about that substance with the European Chemicals Agency. Manufacturers and importers of chemical substances are registrants. Some substances contained within articles may also need to be registered if these substances are intended to be released. Manufacturers and importers have to provide information on appropriate risk management measures for any particular use of the substance to Downstream Users.

Manufacturers and Importers of substances in quantities of 1 tonne or more per year need to:

- Pre-register substances with the ECHA if they wish to secure the phase-in status (see page 11)
- In the case of non phase-in substances, send an inquiry to the Agency to find out whether the registration has already been submitted for the same substance

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<sup>1</sup>Article 1 Aim and Scope; Article 2 Application; Article 3 Definitions and Article 4 General Provision

<sup>2</sup>Article 6 General obligation to register substances on their own or in preparations; Article 7 Registration and notification of substances in articles; Article 8 Only representative of and non-community manufacturer

<sup>3</sup>Article 5 No data, no market; Article 10 Information required for general registration purposes; Article 11 Joint submission of data by multiple registrants

<sup>4</sup>Article 12 Information to be submitted depending on tonnage; Article 13 General requirements for generation of information on intrinsic properties of substances; Article 14 Chemical safety report and duty to apply and recommend risk reduction measures

- Collect and share existing information with other manufacturers/importers and propose to generate new, information on properties and use conditions of substances
- Prepare technical dossiers noting the special provisions that apply for isolated intermediates (substance manufactured for or used for chemical processing in order to be transformed into another substance)
- Prepare a Chemical Safety Assessment (CSA) and a Chemical Safety Report (CSR) including Exposure Scenarios (ES) and risk characterisation (for each chemical  $\geq 10$  tonnes per year per manufacturer/importer, which are dangerous or fulfil Persistent, Bioaccumulative and Toxic (PBT) or very Persistent, very Bioaccumulative (vPvB) criteria. The CSA should address all the identified uses of a substance on its own (including any major impurities and additives), in a preparation and in an article. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions. A CSR should be completed for all substances subject to registration in quantities of 10 tonnes or more per year per registrant
- Implement appropriate Risk Management Measures (RMMs) for manufacture and use
- Register substances, on their own or in preparations ( $\geq 1$  tonne/ per manufacturer/ importer)
- Keep information submitted in the registration up-to-date and submit updates to the Agency
- Classify and label substances and preparations that are placed on the market as well as notify/register classification of dangerous substances with the Agency for all substances placed on the market
- Prepare and supply Safety Data Sheets (SDS) for substances and preparations as required by Article 31 and Annex II to downstream users and distributors, recommending appropriate RMMs. Exposure Scenarios (ES) developed for substances 10 tonnes or more per year per manufacturer/importer in the CSA must be placed in an Annex to the SDS. In addition prepare and supply information on non-classified substances as required by **Article 32** to downstream users and distributors
- Conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work)
- Respond to any decision requiring further information as a result of the evaluation process
- Comply with any restrictions on manufacture, placing on the market and use of substances and preparations as set out in Annex XVII
- Apply for authorisation for use(s) of substances listed in Annex XIV

## Downstream Users

Businesses that use chemicals supplied by manufacturers or importers are considered to be downstream users. Downstream Users (DU) are any natural or legal persons established within the community, other than manufacturers or importers, who use a substance, either on its own or in a preparation, in the course of their industrial or professional activities. **This probably includes most businesses.** Downstream Users have a duty to use chemicals safely according to the risk management information provided by manufacturers and importers for each registered use of a chemical substance. Downstream Users have an obligation to inform manufacturers and importers how they use chemical substances so that they can develop appropriate risk management procedures. Downstream Users that don't want their suppliers to know about how they use the chemicals will need to provide information to the European Chemicals Agency on risk assessment and risk management measures for their uses i.e. they may have a duty to become registrants in such circumstances.

The duties of Downstream Users include:

- Checking that a substance they use is placed on the list of pre-registered substances published by the Agency. If not, and considered relevant, ask the Agency to add the substance to the list
- In the case of having relevant data, act as a data holder in a Substance Information Exchange Forum (SIEF). This is a

forum formed after the pre-registration phase, to share data on a given phase-in substance. Its principle aims are to facilitate data sharing for the purposes of registration and to agree on the classification and labelling of the substance

- Implementing RMMs as set out in SDS
- When receiving SDS with Exposure Scenarios annexed:
  1. If DU use is covered by the Exposure Scenario, implement Risk Management Measures as set out in ES annexes to Safety Data Sheets; or
  2. If DU use is not covered by the SDS annex, inform supplier of the use (i.e. make use known with the aim to make it an identified use) and await new SDS with updated ES(s) or conduct own chemical safety assessment and (if DU tonnage  $\geq$  1 tonne p.a.) notify the Agency
- Prepare and supply SDS(s) and recommend appropriate RMMs in them and annex ES(s) for further downstream use
- Prepare and supply information on non-classified substances as required by *Article 32* to other downstream users and distributors
- Pass on new information directly to their suppliers on the hazards of the substance and information that might call into question the RMM identified in the SDS for identified uses
- Conduct risk assessments and reduce risks for any chemical agent occurring at the workplace (Directive 98/24/EC on chemical agents at work)
- Respond to any decision requiring further information as a result of the evaluation of testing proposals in downstream user's reports
- Comply with any restrictions on manufacture, placing on the market and use of substances and preparations as set out in Annex XVII
- Use authorised substances as set out in the authorisation (this info should be found in the suppliers' SDS) or apply for authorisation for use(s) of substances listed in Annex XIV
- Notify the Agency about using an authorised substance

### Distributors and consumers

Note that distributors and consumers are not considered to be Downstream Users in terms of REACH. Distributors are defined as any natural or legal persons established within the community including retailers, who only store and place a substances on the market, on their own or in preparations for third parties. Note however that Businesses that sell chemicals (distributors) have specific duties to pass information down to their customers, and also to pass information back to their own suppliers when customers ask them to do so.

### Member States

Member State Competent Authorities must provide a National Helpdesk; enforce compliance with registration; evaluate selected priority substances and participate in the EU Committee process. Competent Authorities are established by the Member States to carry out the obligations arising from the REACH Regulation. Competent Authorities must provide advice to manufacturers, importers, downstream users and other interested parties on their respective responsibilities and obligations under REACH. Some of the other duties and responsibilities of Member States include evaluation of prioritised substances; identifying substances of very high concern for authorisation; suggesting restrictions and nominating candidates to membership of Agency committees on risk assessment and socio-economic analysis. In addition they appoint a member for the "member state committee" to resolve divergences of opinion on decisions following evaluation, consider proposals for harmonised classification and labelling, and identify substances for authorisation.

### European Chemicals Agency (ECHA)

The Agency in Helsinki was established for the day-to-day management of technical, scientific and administrative aspects of REACH and in some cases carrying out the technical, scientific and administrative aspects of the REACH Regulation and ensuring consistency at Community level in relation to these aspects. The Agency hosts the

Registration process; operates committee processes and operates the Restriction and Authorisation process. The Agency provides technical and scientific guidance and tools for the operation of REACH in particular to assist the development of chemical safety reports by industry and especially by Small and Medium Sized Enterprises (SMEs). In addition it receives and checks requests for research and development (PPORD) exemptions; Pre-registration and publishing a list of pre-registered substances on the Agency website. The Agency is also responsible for operating the rules on data-sharing for non-phase-in substances, Registration (including completeness checks); conducting dossier Evaluation of registrations including testing proposals and Authorisation and restrictions as well as dealing with complaints and appeals.

### **European Commission**

The Commission takes decisions on further information needs under the Evaluation process where there is no unanimous agreement by Member States; adds substances to the authorisation system; grants or rejects authorisations; takes decisions on restrictions and can take decisions on testing proposals if the Agency fails to make a decision.

### **Other stakeholders**

Trade or industry associations, NGOs, and the public can gain access to non-confidential information via the Agency website as well as request access to information. Stakeholders can submit scientifically valid, relevant information and studies addressed by the testing proposal published on the Agency website relating to Evaluation. They can also comment on substances which the Agency has proposed to be prioritised under authorisation and on uses which are to be exempted from the authorisation requirement and provide information on possible alternatives. Furthermore, Trade or industry associations, NGOs, and the public can comment on restriction proposals; contribute to socio-economic analysis for suggested restrictions; and comment on draft opinions from Agency's committee for risk assessment and committee for socio-economic analysis.

## **WHAT YOU CAN DO TO PREPARE FOR REACH**

Enterprises need to understand how REACH is going to impact on their supply chains before they can decide what actions to take. The first step should be to compile an inventory of every chemical substance (chemical elements and their compounds) that comes into, is part of, or goes out of the enterprise (feedstock, intermediates, products used or created). Enterprises should keep a record of each chemical substance and the tonnage used annually. If the enterprise produces or imports articles which contain substances intended to be released under normal or reasonably foreseeable conditions of use in quantities totaling over 1 tonne, then records need to be kept of these substances as well.

The inventory will serve to highlight substances of vital importance to an enterprise and how REACH could impact on their supply. This is also an opportunity to consider alternatives should supplies of some chemical substances become difficult to procure. Enterprises should address the following questions:

- What is each substance used for?
- What quantities of each substance are used annually?
- Are the all the uses of substances by an enterprise going to be supported by their registrants?
- Are there any chemicals that are currently used that may be 'substances of very high concern' and, if so, are there alternative substances or processes that could replace these?

## 1. Important Dates

REACH came into operation in the all EU Member States on **1 June 2007**.

In order to make the REACH process manageable for the large number of substances subject to registration, the Regulation distinguishes between 'phase-in' and 'non-phase-in', i.e. new, substances.

Phase-in substances are defined as:

- Listed in the European Inventory of Existing Chemical Substances (EINECS)
- Manufactured (but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this.) in the EU at least once after 31 May 1992 and before 1 June 2007.
- No-longer polymers (NLP's) i.e. substances that were on the EU market between 18 September 1981, when the new substance notification scheme began operating, and 31 October 1993 as then exempt polymers but that did not meet the 'polymer' definition that came into force on the later date. It was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this.

Manufacturers, importers or only representatives have to pre-register 'phase-in' substances with the ECHA during the period **1 June to 30 November 2008** in order to take advantage of the 'phase-in' periods under REACH. Failure to pre-register means the chemical cannot be manufactured or imported into the EU.

The submission deadlines for the review programme for 'phase-in' substances is based on the tonnage and whether substances are classified as carcinogenic, mutagenic or toxic for reproduction or very toxic to aquatic organisms and which may cause long term adverse effects in the aquatic environment (i.e. labelled with R50/53):

- |  |                    |
|--|--------------------|
| ● > 1 tonne p.a. (Category 1 or 2 CMRs under CHIP) | by 1 December 2010 |
| ● > 100 tonnes p.a. (R50/53)                       | by 1 December 2010 |
| ● > 1,000 tonnes p.a.                              | by 1 December 2010 |
| ● > 100 tonnes p.a.                                | by 1 June 2013     |
| ● > 1 tonne p.a.                                   | by 1 June 2018     |

New Substances which were notified under the EU new substance notification scheme are considered as having been registered, as are active substances regulated under the Plant Protection Products Directive and the Biocidal Products Directive. ECHA will allocate registration numbers by **30 November 2008**. When a previously-notified new substance reaches a tonnage trigger threshold, the registrant must update the registration dossier with the appropriate safety information.

New substances, i.e. those not listed on EINECS, could be notified under the old scheme until **31 May 2007**. The national Competent Authorities who accept notifications on behalf of the EU have two months to finish outstanding notification matters, before transferring responsibility to ECHA. A substance that is 'new' means that it is not on EINECS and has not been manufactured previously. These substances must be registered from the **1 June 2008**, they are not eligible for 'phase-in' and are called 'non phase-in' substances under REACH. Registration for existing substances (that have not been pre-registered) starts from **1 December 2008**.

As from **1 June 2008**, registration is needed before non-phase in substances can be manufactured or imported. There is a duty for the potential registrant to make an inquiry to ECHA to find out whether the substance has already been registered and hence if some or all of the necessary safety data exist. First recommendation of priority substances to be considered for authorisation published by ECHA on **1 June 2009**.

Enterprises need to build relationships with their suppliers and downstream users. They need to establish if suppliers will maintain the supply of substances important to their businesses and whether it is commercially viable for suppliers to do so. If enterprises do not want to share commercially sensitive information with registrants about their uses of chemicals they must compile risk assessments themselves and submit these directly to the European Chemicals Agency. In all cases enterprises need to determine their role in relation to each substance on the inventory - see 'How REACH applies to you'.

Under REACH, former notified 'new substances' are regarded as having been registered (Article 24). Some substances are specifically excluded from REACH, namely, radioactive substances; substances under customs supervision; the transport of substances; non-isolated intermediates; waste; and some naturally occurring low-hazard substances. There is also an exemption from the general obligation to register for product and process orientated research and development. (PPORD) (Article 9).

Some substances, covered by more specific legislation, have tailored provisions, including; human and veterinary medicines; food and foodstuff additives; and plant protection products and biocides<sup>5</sup>. Other substances have tailored provisions within the REACH legislation, provided they are used under specified conditions, namely; isolated intermediates and substances used for research and development<sup>6</sup>

## PRE-REGISTRATION

The first major new REACH activity for manufacturers/importers of substances is pre-registration<sup>7</sup>, in order for the company to take advantage of this activity the substance must be what is known as a 'phase-in' substance. This means that:

- The substance is listed on EINECS
- The substance was manufactured in the Community, or in countries acceding to the EU on the 1st January 1995 or on 1st May 2004, but not placed on the market by the manufacturer, at least once in the 15 years before entry into force of this Regulation, provided the manufacturer has documentary evidence of this. Basically, the substance was not placed on the market at all and was a site limited or export only chemical, however evidence of this must be provided.
- The substance was placed on the market in the Community, or in the countries acceding to the EU on 1st January 1995 or on May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8 (1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this (so called 'no longer polymer' substances).

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<sup>5</sup>Article 15 Substances in plant protection products and biocidal products; and Article 16 Duties of the Commission, the Agency and registrants of substances regarded as being registered

<sup>6</sup>Article 17 Registration of on-site isolated intermediates; Article 18 Registration of transported isolated intermediates and Article 19: Joint submission of isolated intermediates by multiple registrants

<sup>7</sup>Article 28 duty to pre-register for phase-in substances

## 2. PPORD Information Requirements

After 1 June 2008, substances manufactured in the community or imported for the purposes of product and process oriented research and development (PPORD) by a manufacturer/ importer/ producer of articles/ in cooperation with listed customers and in quantities which are limited for the above purpose are exempt from the general obligation to register for five years.

PPORD includes any scientific development of a product, or the further development of a substance on its own, in preparations or in articles, in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance.

The manufacturer can apply for the PPORD to be extended for another five years, if justified, or another ten years if a pharmaceutical. However, the manufacturer/ importer or producer of articles will have to supply the following information to ECHA in IUCLID 5 (see sections 1, 2, and 4 of Annex VI for details):

- Manufacturer/importer identity
- Substance identity
- Quantities involved (*overall manufactured quantities used for the production of an article that is subject to registration and/or imports in tonnes per registrant per year in the calendar year of the registration*)
- Classification and labelling (*Where information on classification and labelling is not available, reasons for such lack of information should be given*)
- List of customers involved in the research (*names and addresses*)

IUCLID5 (International Uniform Chemical information Database) is a tool that enables the preparation of registration and other REACH dossiers

If the above applies to any of the substances a company imports or manufactures then they can pre-register the substance from the 1 June 2008 to 30 November 2008 (inclusive). Pre-registration will mean informing the European Chemicals Agency (ECHA) using a publically available software system (IUCLID 5) of:

- The name of the substance as specified in section 2 of REACH Annex VI, this includes CAS, EINECS or other identification codes
- The name and address of the contact person or representative
- The envisaged deadline for the registration and the tonnage band, and
- Identifier information of any structurally similar chemical which one may wish to rely on to provide useful evidence on hazards as part of a registration package

The European Commission will make the pre-registration list public so that potential registrants can find each other. The potential registrants can then come together and form a 'Substance Information Exchange Forum' (SIEF) where they can negotiate sharing their available data and the costs of generating any new data.

Please note that although pre-registration is not a legal requirement of REACH, it is recommended that companies do pre-register in order to take advantage of the phased-in tonnage deadlines for registration and the SIEF arrangements.

**Substances that are not pre-registered may not be manufactured or imported into the community after the 1st of June 2008 unless they have been formally registered.**

It is estimated that around 30,000 substances will require registration. In order to cope with the large number of chemical substances, registration is to take place in three phases over 11 years.

### 3. Categories of Substance Exempt from Registration

- The specific substances listed in Annex IV of the Regulation
- Substances covered by Annex V:
  - Degradants from environmental factors
  - Chemical degradants from storage
  - Products from use
  - Products from reaction with additives
  - By-products
  - Hydrates, providing the anhydrous form is registered
  - Non-dangerous natural substances
  - Hydrogen, oxygen, nitrogen and the noble gases
  - Minerals, ores and ore concentrates, cement clinker, natural gas, liquid petroleum gas, natural gas condensate process gases, crude oil, coal and coke
- Monomers bound into polymers, but note that registration is required if the monomer is present at  $\geq 2\%$  (w/w) in the polymer and is at  $\geq 1$  tonne per annum
- Polymers
- Food and food ingredients
- Waste and certain recycled materials
- Substances needed in the interests of defence

See Annex IV Exemptions From The Obligation To Register In Accordance With Article 2(7)(A); Annex V Exemptions From The Obligation To Register In Accordance With Article 2(7)(B).

***In order to benefit from these phased-in deadlines manufacturers or suppliers need to pre-register their substances from 1st June to 30th November 2008 (inclusive).***

Pre-registration allows companies to continue manufacturing and importing their phase-in substances for several years until the registration deadline is reached. The objective of pre-registration is to facilitate sharing of data between registrants, where possible, in order to reduce unnecessary testing, especially on vertebrate animals, and to decrease costs for the industry. A list of all pre-registered substances will be published on the website of the ECHA by 1 January 2009 (Article 20 Duties of the Agency). This list will facilitate the identification of potential registrants of the same substance for the purpose of data sharing.

For pre-registration, the potential registrant needs to submit to the Agency only basic information on the produced or imported substance<sup>8</sup>. Pre-registration is not a legal requirement of REACH but is strongly advised by the UK Competent Authority. If manufacturers or importers fail to pre-register a phase-in substance, they will need to register it immediately as a 'new' substance before continuing manufacturing or importing.

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<sup>8</sup>Article 21 Manufacturing and import of substances; Article 22 Further duties of registrants.

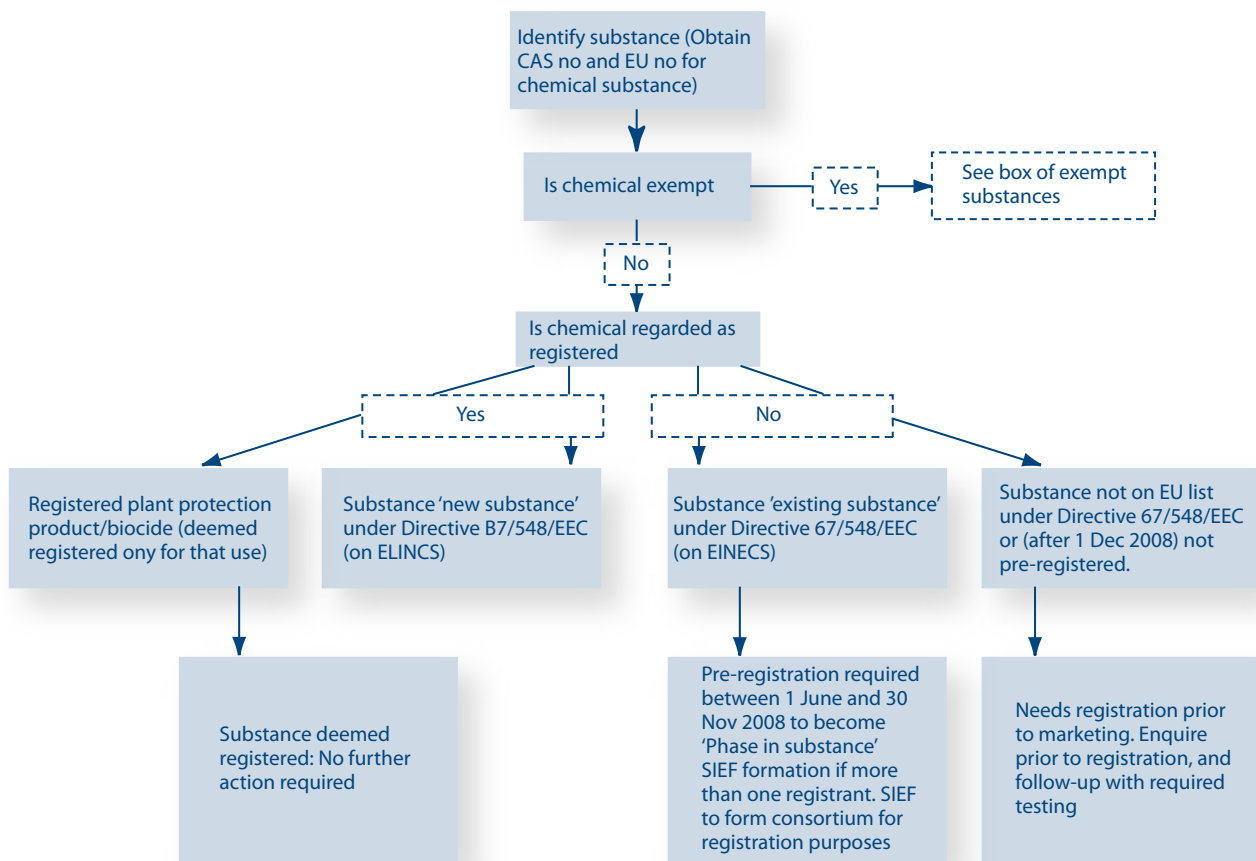


Figure 1. Requirement to Register

## INFORMATION IN THE SUPPLY CHAIN

The passage of information up and down the supply chain is a key feature of REACH<sup>9</sup>. Users should be able to understand what manufacturers and importers know about the dangers involved in using chemicals and how to control risks<sup>10</sup>. However, in order for suppliers to be able to assess these risks they need information from the users about how they are used. REACH provides a framework in which information can be passed both up and down supply chains.

### Communication down the supply chain (from suppliers to users)

REACH requires manufacturers and importers of a substance on its own or in a preparation to communicate how their substances or preparations can be used safely for humans and for the environment.

*The main instrument for this communication down the supply chain is the Safety Data Sheet (SDS)*<sup>11</sup>

The manufacturer, importer or downstream user is required to prepare the SDS according to a similar principle as he did before REACH came into force. The main difference is that when required, the SDS will also have an annex including exposure scenarios specifying the conditions under which the substance or preparation can be used safely, for uses that have been identified. The quality of the SDSs is expected to improve due to REACH as more information will be available as a result of the registration process.

*If an SDS is not required, the supplier still has to communicate key risk information about the substance, in particular stating if the substance is subject to authorisation or restriction, together with any other available and*

<sup>9</sup>Article 33 Duty to communicate information on substances in articles

<sup>10</sup>Article 35 Access to information for workers

<sup>11</sup>Article 31 Requirements for Safety Data Sheets

*relevant information to enable appropriate risk management.<sup>12</sup> Furthermore, suppliers of articles shall inform their customers about substances of very high concern contained in concentrations above 0.1%. Also consumers can request such information.*

Distributors are not considered as downstream users under REACH but should pass on information received from their suppliers to their customers to ensure they can use the substance or preparation safely.

### **Communication upstream (from users to suppliers)**

The manufacturers and importers often do not know what the substance is used for, and how it is used, and therefore need to collect such information from users in order to assess how risks can be adequately controlled for the different identified uses. The downstream users have, on the other hand, the detailed knowledge of their uses and also an interest in having these covered by the suppliers' exposure scenarios. This is needed so that DUs are able to continue the use and receive relevant information on how to control possible risks.

*Upstream communication by an actor in the supply chain is mandatory in a number of situations. This includes the communication of new information on the hazardous properties that become available as well as of information that may call into question the appropriateness of the risk management measures recommended by the supplier<sup>13</sup>.*

Downstream users have a right to make their use known to the supplier and in doing so have to provide sufficient information to prepare an exposure scenario<sup>14</sup>. This upstream communication will play an important role when a registrant will prepare a chemical safety report, including exposure scenarios if required, as a part of the registration dossier. Distributors have a general obligation to pass on information received to the next actor in the supply chain. See: Annex XII General Provisions For Downstream Users To Assess Substances And Prepare Chemical Safety Reports.

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<sup>12</sup>Article 32 Duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required

<sup>13</sup>Article 34 Duty to communicate information on substances and preparations up the supply chain

<sup>14</sup>Article 37 Downstream user CSAs and duty to apply and recommend risk reduction measures; Article 38 Obligation for downstream users to report information and Article 39 Application for downstream user obligations

## REGISTRATION

Registration is the process of collecting and collating specified sets of information on the properties of substances. How much information is needed depends on the tonnage and hazards associated with the substance that is to be registered. These requirements can be found within the REACH text. The information is then used to perform an assessment of the hazards and risks that a substance may pose and how these risks can be controlled. This information and the associated assessment are then submitted to the European Chemicals Agency (ECHA) in Helsinki.

Former notified 'new substances' are deemed as already registered (Article 24). The phase-in substances (substances which have long been on the EU market – essentially 'existing substances') and the non-phase-in substances have different timelines for registration under REACH (Article 23 Specific provisions for phase-in substances Article 25 Objectives and general rules; Article 28 Duty to pre-register for phase-in substances).

***Substances which have not previously been placed on the EU market and phase-in substances which have not been pre-registered, must be registered before they can be manufactured, placed on the market or used (Article 26 Duty to inquire prior to registration; Article 27 Sharing existing data in the case of registered substances).***

For phase-in substances which are manufactured or imported in a quantity of 1 tonne or more per year and which have been pre-registered, the registration provisions will apply in a stepwise way to facilitate the transition to REACH.

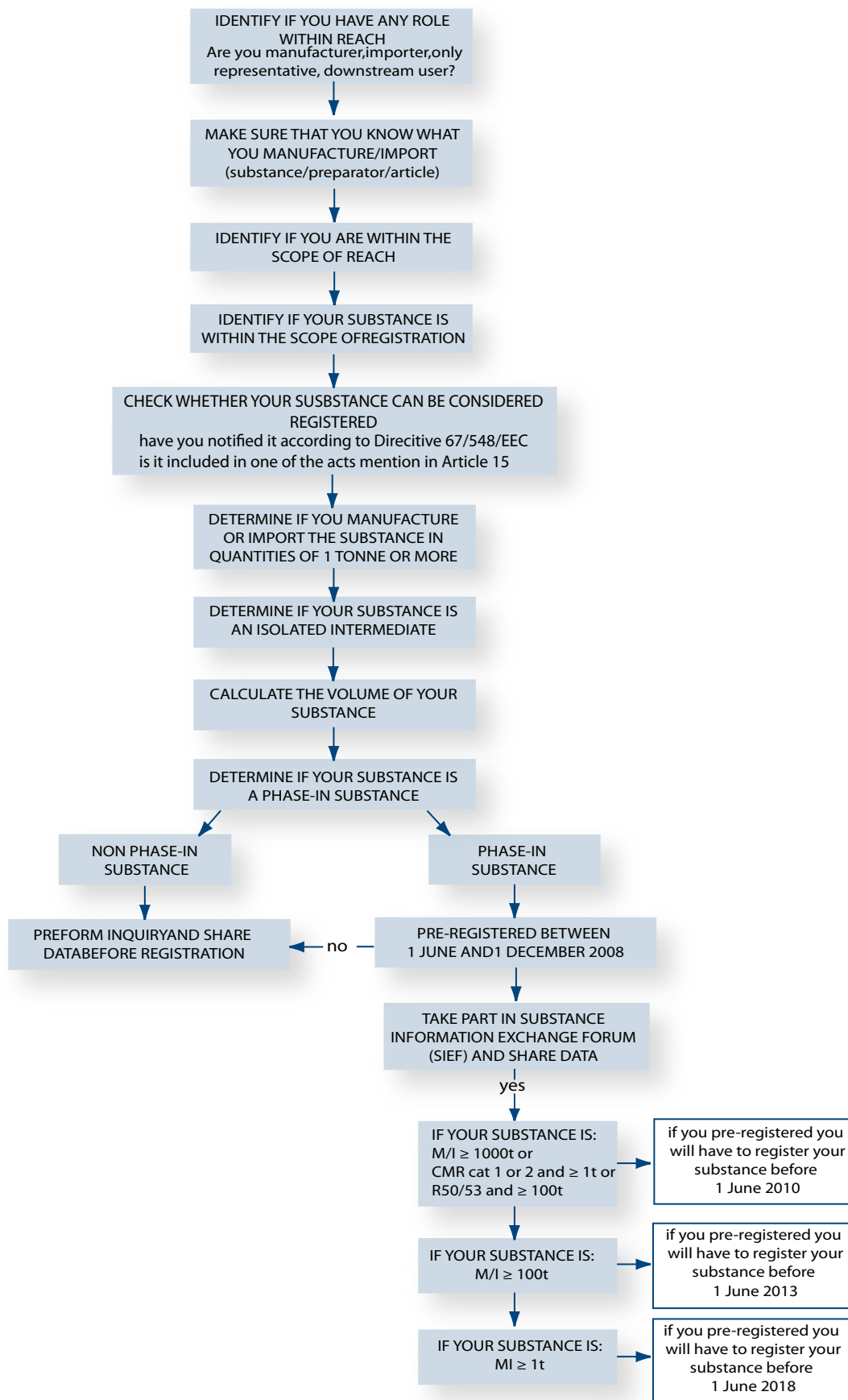
Substances manufactured or imported at or above 1000 tonnes/year as well as Carcinogenic Mutagenic or Reprotoxic substances category 1 and 2 (CMR cat 1 and 2) manufactured or imported at or above 1 tonne/year, or substances classified as dangerous for the aquatic environment with R50/53 and manufactured or imported at or above 100 tonnes/year will have to be registered before 1 December 2010, while substances manufactured or imported in lower volumes will have to be registered before 1 June 2013 (if 100 – 1000 tonnes/year) or 1 June 2018 (if 1 – 100 tonnes/year).

Similar obligations were in place before REACH for certain substances, e.g. substances notified under the former chemicals legislation for new substances. These substances are considered as already registered under REACH. However, such registrations will need to be updated as appropriate if new circumstances arise, e.g. if production or import is increased to a higher tonnage band or if new information becomes available.

***Failure to register means that the substance cannot be manufactured or imported.***

Manufacturers and importers of substances have a general obligation to collect and collate specified sets of information on the properties of those substances they manufacture or supply at or above 1 tonne per year, per company (legal entity). This information is used to perform an assessment of the hazards and risks that a substance may pose and how those risks can be controlled. To demonstrate that this has been done, manufacturers and importers need to submit: a **technical dossier**, for substances in quantities of 1 tonne or more per year, and, in addition, a **chemical safety report**, for substances in quantities of 10 tonnes or more per year to the European Chemicals Agency in Helsinki. Around 80% of all registered substances are likely to require no further action.

The technical dossier contains information on the properties and classification of a substance as well as on uses and guidance on safe use. The information required to determine the properties of the substances varies according to the tonnage in which the substance is manufactured or imported. The higher the tonnage the more information on the intrinsic properties of the chemical is required. The information requirements are set out in the Annexes VI to XI of the Regulation.



**Figure 2. The Registration Process**

(Source ECHA Guidance on Registration)

The chemical safety report documents the hazards and classification of a substance and the assessment as to whether the substance is Persistent (P), Bioaccumulative (B) and Toxic (T) or vPvB (very Persistent very Bioaccumulative). The chemical safety report also describes "exposure scenarios". See Annex I General Provisions For Assessing Substances And Preparing Chemical Safety Reports; Annex II Guide To The Compilation Of Safety Data Sheets; Annex XV Dossiers.

#### 4. Timings for Registration

- Former 'new substances' under Directive 67/548/EEC are deemed registered
- Register new substances at  $\geq 1$  tonne p.a. before manufacture or import
- Pre-registration of phase-in substances between 1 June 2008 and 1 December 2008
- Registration for phase-in substances:
  - Category 1 or 2 CMR's ( $> 1$  tonne p.a.) by 1 December 2010
  - $> 100$  tonnes p.a. (R50/53) by 1 December 2010
  - $> 1,000$  tonnes p.a. by 1 December 2010
  - $> 100$  tonnes p.a. by 1 June 2013
  - $> 1$  tonne p.a. by 1 June 2018
- Draft decisions for phase-in substances for further testing:
  - Category 1 or 2 CMR's ( $> 1$  tonne p.a.) by 1 December 2012
  - $> 100$  tonnes p.a. (R50/53). by 1 December 2012
  - $> 1,000$  tonnes p.a. by 1 December 2012
  - $> 100$  tonnes p.a. by 1 June 2016
  - $> 1$  tonne p.a. (if any) by 1 June 2022

The **Safety Data Sheet** (SDS) provides a mechanism for transmitting appropriate safety information on classified substances and preparations, including information from the relevant Chemical Safety Report down the supply chain to the immediate downstream users. The existing provisions of the safety data sheets directive (91/155/EEC) are carried over into the REACH legislation with additional requirements on the provision of SDS when substances (or preparation containing them) are PBT or vPvB. Where chemical safety assessments (CSAs) are performed according to registration requirements, relevant exposure scenarios shall be annexed to the SDS and passed up or down the supply chain accordingly. Any new information which comes to light on the hazardous properties of a substance, or information which may lead to alterations of risk management measures outlined in the Safety Data Sheet shall be passed up the supply chain.

For substances manufactured or imported in quantities starting at 10 tonnes, the chemical safety report(CSR) documents the hazards and classification of the substance and the assessment as to whether the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB). If the substance is classified as dangerous or is PBT or vPvB, then an exposure assessment and risk characterisation shall be performed to demonstrate that the risks are adequately controlled. This exposure assessment is done using **exposure scenarios** for each use of the substance.

## 5. Only Representatives

**Non-Community manufacturers** exporting chemical substances into the EU can appoint an EU-based representative called an Only Representative (OR). The only representative takes over all obligations of the importer under REACH (Article 8). The Only representative duties include:

- Pre-register with the European Chemicals Agency (ECHA)
- Register with the ECHA, on behalf of the non-EU manufacture
- Co-ordinate the sharing of test data with the Substance Information Exchange Forum (SIEF)
- Co-operate in commissioning new studies with other SIEF members
- Work within the SIEF normally to produce a joint registration dossier for submission to the ECHA
- Work within the SIEF to determine the classification and labelling of the substance
- Negotiate, within the SIEF, for further studies (normally only for substances at > 100 tonnes per annum)
- Prepare a Chemical Safety Report (CSR), which is needed for most substances at > 10 tonnes per annum. A CSR includes a Risk Assessment covering all the uses by the importers and their downstream users. Hence the OR has the obligation to facilitate and participate in communication in the supply chain
- Prepare an EU format Safety Data Sheet (SDS), which is needed for 'dangerous' substances and those that are PBT or vPvB. The SDS includes an annex of the summary of the CSR (if available) for downstream users
- Update the SDS & CSR as new information on uses or hazardous properties becomes available and inform the importers and downstream users
- Supply registration information to importers and downstream users even if the substance is not 'dangerous' and does not have a SDS or CSR
- Collect information from the non-EU manufacturer, importers and downstream users on new uses & hazardous properties
- Update the registration dossier with such new information and inform the ECHA
- Keep information on file for 10 years for submission on request
- Keep up to date information on all EU importers within the supply chain and the imported quantities for each of these customers
- Inform the importers of their status as an OR
- Have a sufficient background in practical handling of substances and information on them

Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. They must include the appropriate risk management measures and operational conditions that, when properly implemented, ensure that the risks from substances are adequately controlled. They should cover all the manufacturers' or importers' own uses and uses made known to the manufacturer or importer by their downstream users.

## 6. Annex VI Information Needed for Registration

- Technical dossier (in a specified electronic format):
  - Technical data on the registrant, identification of the substance, manufacture and use and guidance on safe use
  - Robust summaries of safety data
  - Proposed classification and labelling
  - Statement whether animal testing was conducted
  - Proposal for any further testing
- Chemical Safety Report, for substances at > 10 tonne per annum. This is a risk assessment including PBT and vPvB assessment

The registration dossier has to be submitted electronically, to the ECHA, and Registrants must pay a fee for submitting a dossier. Registrants must update their registration as appropriate, e.g. if the production or import increases to a higher tonnage band or on the basis of new information that requires modification to the dossier.

## 7. Alternative Registration Safety Data

- Annexes VII to X give standard data requirements (in column 1) and rules for omitting tests or additional studies (in column 2)
- Annex XI covers adapting the standard data requirements:
  - existing non-standard and/or non-GLP data
  - historical human data
  - weight of evidence
  - SAR
  - grouping and “read across”
  - suitable in vitro tests, but confirmation of negative results may be needed from non-validated in vitro methods
  - data waivers, i.e. a study is technically impossible
  - substance-tailored exposure driven testing

In cases where a substance is manufactured or imported by more than one company, they are encouraged to jointly register (submit information) on the hazardous properties of the substance and its classification. The companies must work together to get an agreement on information sharing through a Substance Information Exchange Forum (SIEF), but the details of how this information is shared is the responsibility of the parties involved<sup>15</sup>. If registrants agree they can also submit a joint chemical safety report. Under this approach business specific (e.g. company name) and business sensitive (e.g. how it is used) information is submitted separately by each company. Companies who submit joint registrations via a SIEF benefit from a reduced registration fee.

The Agency (ECHA) is responsible for managing all registration dossiers. The Agency will perform a simple electronic completeness check at the dossier submission stage. A positive completeness check does not imply any form of approval of the registration dossier or use of the substance from the Agency. The quality of the information submitted may be checked afterwards in the evaluation process.

<sup>15</sup>Article 29 Substance Information Exchange Fora; Article 30 Sharing of data involving tests

## EVALUATION

Evaluation is triggered by the volume of the substance imported or manufactured or where there are justified reasons to suspect that a substance poses a risk to human health or the environment. The ECHA and the Member States Competent Authorities (Health and Safety Executive in the UK) will carry out different types of evaluations to determine the need for further information on the registered substance. There are three types of evaluation, covering three different objectives:

**Dossier Compliance check:** The European Chemicals Agency may select any registration dossier to check whether the appropriate information is available and has been adequately reported<sup>16</sup>. The registrant may be asked to submit further information if necessary<sup>17</sup>. This is a check of the quality of the information submitted by industry. It will be undertaken by the ECHA in Helsinki and will be on a sample (at least 5%) of dossiers submitted at each tonnage level.

**Dossier Testing Proposal Evaluation:** For substances registered at the highest tonnage levels ( $\geq 100$  tonnes/annum) a proposal is made by the registrant detailing those animal tests they consider are required from the list of standard tests. The ECHA will evaluate these testing proposals to prevent unnecessary animal testing<sup>18</sup>. For chemicals manufactured or imported in a quantity of 100 tonnes or more, no testing shall be conducted for the information specified in Annexes IX and X of the REACH Regulation. Instead, a testing proposal must be submitted in the registration dossier. The Agency will then evaluate whether the testing proposal is adequate before such a test is performed. The objective of this procedure is to prevent unnecessary animal testing, i.e. the repetition of existing tests, and poor quality tests.

**Substance evaluation:** When the Agency or a Member State Competent Authority has an indication that a substance may pose a risk to human health or the environment, the Agency will include that substance on a list for "substance evaluation"<sup>19</sup>. For each substance on this list, one Member State will evaluate in more detail whether further information is needed and in that case the registrant(s) will be requested to provide such information<sup>20</sup>.

A key regulatory outcome of evaluation could be the imposition of restrictions on the manufacture, supply or use of a substance<sup>21</sup>. Substance evaluation may also lead to a substance being added to the priority list for Authorisation or a proposal to change the classification and labelling.

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<sup>16</sup>Article 41 Compliance check for registrations

<sup>17</sup>Article 42 Check of information submitted and follow-up dossier evaluation; Article 43 Procedure and time periods for examination of testing proposals.

<sup>18</sup>Article 40 Examination of testing proposals

<sup>19</sup>Article 44 Criteria for substance evaluation

<sup>20</sup>Article 45 Competent Authority; Article 46 Requests for further information and check of information submitted; Article 47 Coherence with other activities; Article 48 Follow up to substance evaluation and Article 49 Further information on on-site isolated intermediates

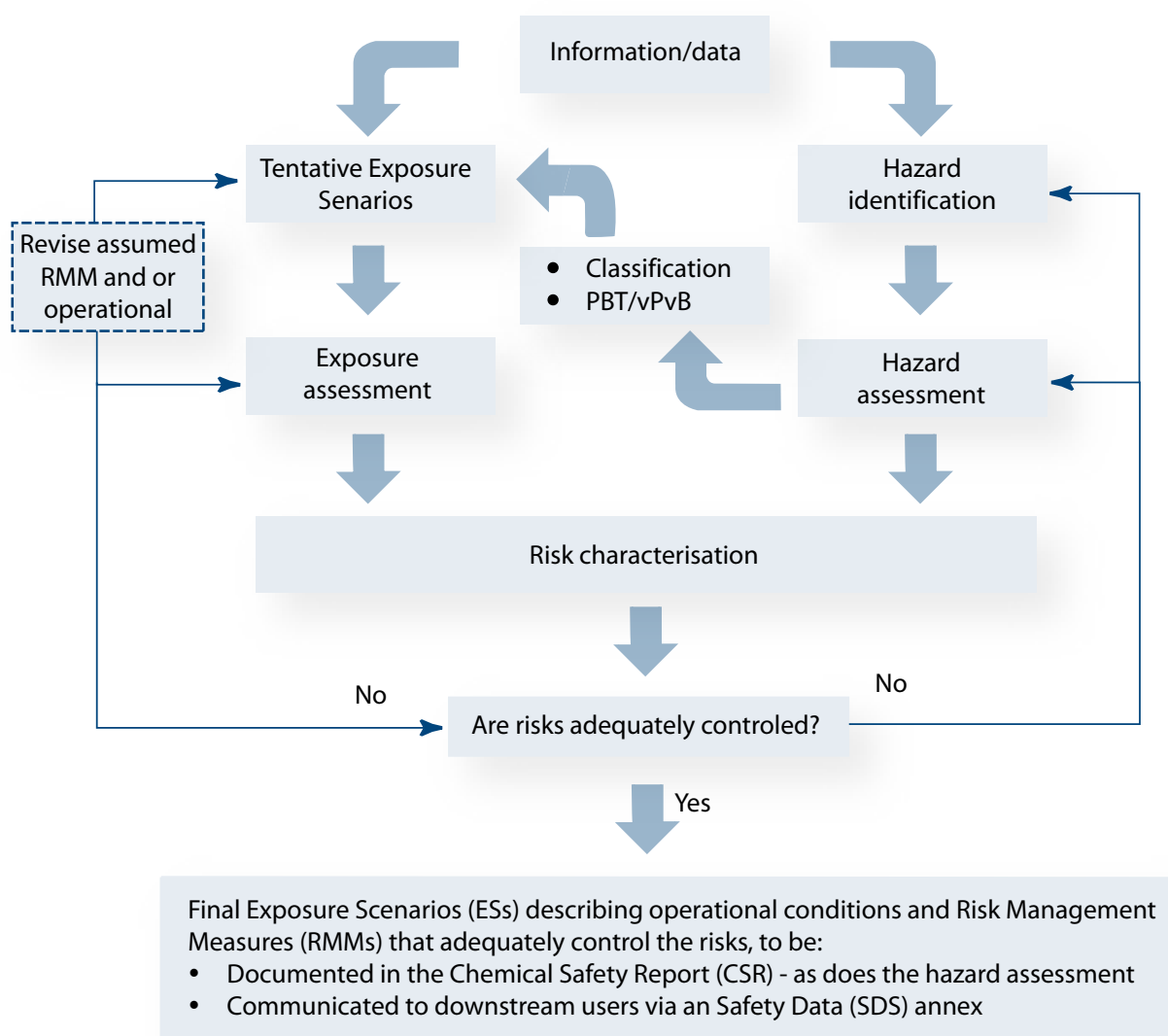
<sup>21</sup>Article 50 Registrants and downstream users' rights; Article 51 Adoption of decisions under dossier evaluation; Article 52 Adoption of decisions under substance evaluation; Article 53 Cost sharing without an agreement between registrants and/or downstream users and Article 54 Publication of information on evaluation

<sup>22</sup>Article 55 Aim of authorisation and consideration for substitution; Article 56 General provisions

## AUTHORISATION

In order to place on the market or use substances with properties that are deemed to be of “very high concern” industry must, if the regulator so requests by entry onto Annex XIV, apply for an authorisation<sup>22</sup>. There will be time limits for submission of data to support the request for Authorisation. The ECHA has to make recommendations as to what substances should be included in Annex XIV by 1 June 2009, however substances are unlikely to appear in Annex XIV before 30 November 2010.

*There is no tonnage threshold for a substance to be subject to authorisation.*



PBT – Persistent, Bioaccumulative, Toxic substances; vPvB – very Persistent and very Bioaccumulative substances  
(Source ECHA Guidance on Registration)

### Figure 3. Principles of the Chemical Safety Assessment

Authorisation, for specific uses, will be required for about 1,500 substances of very high concern. The European Commission is responsible for authorisation. The European Chemicals Agency (ECHA) in Helsinki will publish a list containing substances to be considered for the authorisation process by 1 June 2009. Substances of very high concern will be gradually included in Annex XIV of the REACH Regulation<sup>23</sup>. Once included in that Annex, they

<sup>22</sup>Article 55 Aim of authorisation and consideration for substitution; Article 56 General provisions

<sup>23</sup>Article 57 Substances to be included in Annex XIV; Article 58 Inclusion of substances in Annex XIV and Article 59 Identification of substances referred to in Annex XIV

cannot be placed on the market or used after a date to be set (the so-called sunset date) unless the company is granted an authorisation. A company wishing to market or use such a substance must submit an application to the ECHA for an authorisation. See ANNEX XIV List of Substances Subject to Authorisation.

## 8. Confidentiality Provisions

The registrant cannot claim confidentiality for:

- trade name and chemical name
- physico-chemical properties and the result of toxicology and ecotoxicology studies (and the determined Derived No-Effect Level (DNEL) or Predicted No-Effect Concentration (PNEC))
- purity and impurity (if relevant to classification)
- guidance on safe use
- non-confidential SDS information
- analytical methods for detection in humans or the environment
- the fact that animal testing was conducted

The authorisation process consists of four steps. Industry has obligations in the third step. However, all interested parties have the opportunity to provide input in steps 1 and 2.

### Step 1: Identification of substances of very high concern (by authorities)

Some substances have hazardous properties of very high concern because the effects they can have on humans and the environment are very serious and often irreversible. These include substances which are: Carcinogenic, Mutagenic or toxic to Reproduction (CMR) (category 1 or 2); Persistent, Bioaccumulative and Toxic (PBT); very Persistent and very Bioaccumulative (vPvB) according to the criteria in Annex XIII of the REACH Regulation, and/or identified, on a case-by-case basis, from scientific evidence as causing probable serious effects to humans or the environment of an equivalent level of concern as those above e.g. endocrine disruptors. See Annex XIII Criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances.

Substances of very high concern will be proposed by Member State Competent Authorities or the Agency (on behalf of the European Commission) by preparing a dossier in accordance with Annex XV. Interested parties can comment on substances for which a dossier has been prepared. The outcome of this process is a list of identified substances, which are candidates for prioritisation (the candidate list).

### Step 2: Prioritisation process (by authorities)

The substances on the candidate list are then prioritised to determine which ones should be subject to authorisation. Interested parties are invited to submit comments during this process. At the end of the prioritization process, the following decisions are taken: whether or not the substance will be subject to authorisation; which uses of the included substances will not need authorisation (e.g. because sufficient controls established by other legislation are already in place); and the “sunset date” by when a substance can no more be used without authorisation.

### Step 3: Applications for authorisation (by industry)

Applications for authorisation need to be made within the set deadlines for each use that is not exempted from the authorisation requirement. They must include among others: a Chemical Safety Report covering risks related to those properties that caused the substance to be included in authorisation system (unless already submitted as part of the registration) and an analysis of possible alternative substances or technologies including, where appropriate, information on research and development foreseen or already in progress to develop such alternatives.

Chemical substitution is one of many options in the process of reducing risk. Substitution is not a simple process

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<sup>24</sup> Article 62 Applications for authorisations; Article 63 Subsequent applications for authorisations

since it is necessary to ensure that the overall risk is reduced and that a decrease in one risk is not overshadowed by the increase in another. Effective substitution of a 'problem' chemical by an alternative requires an 'adequate' set of comparative data for the alternative. Another difficulty will be agreeing the purpose of substitution i.e. for 'safety' or for 'sustainability'. 'Authorisation' provides a sensible mechanism to exert control on 'hazardous substances' and 'substitution' is a desirable endpoint. But decisions on substitution need to be taken in a holistic manner.

If the analysis of alternatives reveals that there is a suitable alternative, the applicant must submit a substitution plan, explaining how he intends to replace the substance by the alternative. The suitability of available alternatives is assessed by taking into account all relevant aspects, including whether the alternative results in reduction of overall risks and is technically and economically feasible. An applicant can include a socio-economic analysis in his application, but in cases where one is not able to demonstrate adequate control of risks and where no suitable alternative exists, he must include one in his application.

A fee has to be paid for each application. For all applications, the Agency will provide expert opinions. The applicant can comment on these opinions.

#### **Step 4: Granting of authorisations (by the European Commission)**

Decisions on authorisation are made by the European Commission<sup>25</sup>. Applicants will have to demonstrate that risks associated with uses of these substances can be adequately controlled or that the socio-economic benefits of their use outweigh the risks. Applicants must also analyze whether there are safer suitable alternatives or technologies. If there are, then they must prepare substitution plans and if not, then they should provide information on research and development activities if appropriate.

Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. The "adequate control route" does not apply for substances for which it is not possible to determine thresholds and substances with PBT or vPvB properties. If the risk is not adequately controlled, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substances or technologies<sup>26</sup>. See Annex XVI Socio-Economic Analysis.

#### **9. Cost of Registration Safety Data**

Typical approximate costs for substances with no surrogate data or data waivers:

- Annex VII (if reduced data applies) at > 1 tonne p.a. but < 10 tonnes p.a. £20,000
- Annex VII (if full data applies) at > 1 tonne p.a. but < 10 tonnes p.a. £40,000 to £50,000
- Annex VII plus VIII at > 1 tonne p.a. but < 100 tonnes p.a. £140,000 to £190,000
- Annex IX at > 100 tonnes p.a. but < 1,000 tonnes p.a. £500,000 to £1,000,000 (highly variable)
- Annex X at > 1,000 tonnes p.a. £1,000,000 to £3,000,000 (extremely variable)

Note – Annex IX and Annex X - testing proposals only are required at registration, these requirements have to be agreed with ECHA before the testing is undertaken.

- Average cost for phase-in substances taking into account available studies, surrogate data and data waivers, adapted from a 2005 KPMG study: Annex VII (if reduced data applies) at > 1 tonne p.a. but < 10 tonnes p.a. ca. £8000
- Annex VII (if full data applies) at > 1 tonne p.a. but < 10 tonnes p.a. £16,000\*
- Annex VII plus VIII at > 1 tonne p.a. but < 100 tonnes p.a. £80,000\*
- Annex VII to IX at > 1 tonne p.a. but < 1,000 tonnes p.a. £225,000\*
- Annex VII to X at > 1 tonne p.a. and up to > 1,000 tonnes p.a. £260,000\*

\*Approximate costs calculated at April 2008

<sup>25</sup>Article 60 Granting of authorisations

<sup>26</sup>Article 64 Procedure for authorisation decisions

Downstream users may only use such substances for uses which have been authorised or apply themselves for authorisations for their own uses<sup>27</sup>. Where they obtain the substance from a company that was granted an authorisation for that use, they must stay within the conditions of that authorisation. Such downstream users must also notify the Agency that they are using an authorised substance<sup>28</sup>. All authorisations will be subject to review after a certain time-limit which will be set on a case-by-case basis<sup>29</sup>.

## RESTRICTIONS

Under REACH, some substances of very high concern may be subject to restriction<sup>30</sup>. The decisions regarding these would be made by the European Chemical Agency.

***Any substance that poses a particular threat can be restricted. There is no tonnage threshold for a substance to be subject to restriction.***

Restrictions take many forms, for example, from a total ban to not being allowed to supply it to the general public. Restrictions can be applied to any substance, including those that do not require registration. Restrictions of a substance can apply to all uses or to specific uses. Any substance on its own, in a preparation or in an article may be subject to restrictions if it is demonstrated that risks need to be addressed on a Community-wide basis. See Annex XVII Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Preparations and Articles.

This part of REACH takes over the provisions of the Marketing and Use Directive. REACH foresees a restriction process to regulate the manufacture, placing on the market or use of certain substances within the EU territory if they pose an unacceptable risk to health or the environment. Such activities may be limited or even banned, if necessary. The restriction is designed as a "safety net" to manage risks that are not addressed by the other REACH processes. All uses of a restricted substance which are not specifically restricted are allowed under REACH unless they are subject to authorisation, or other Community or national legislation regulating their use.

Interested parties will have an opportunity to comment and the Agency will provide opinions on any proposed restriction<sup>31</sup>. Deadlines for the decision-making process have been included in REACH in order to speed up the restriction procedure<sup>32</sup>.

Proposals for restrictions will be prepared by Member States or by the Agency on request of the Commission in the form of an Annex XV dossier<sup>33</sup>. The Annex XV dossier should demonstrate that there is a risk to human health or the environment that needs to be addressed at Community level and should identify the most appropriate set of risk reduction measures.

Annex XVII of the REACH Regulation contains the list of all restricted substances, specifying which uses are restricted. The existing restrictions set out in the Marketing and Use Directive (76/769/EEC), e.g. the ban on asbestos and restrictions on the uses of certain azo-dyes, were carried over to REACH.

## CLASSIFICATION AND LABELLING

An important part of chemical safety is the provision of clear information about any hazardous properties of a substance. Pre-existing EU chemicals legislation already requires industry to classify and label dangerous substances and preparations according to standard criteria. The classification of different chemicals according to their characteristics (for example, those that are corrosive, or toxic to fish, etc.) currently follows an established system, which is reflected in REACH.

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<sup>27</sup>Article 65 Obligation of holders of authorisations

<sup>28</sup>Article 66 Downstream users

<sup>29</sup>Article 61 Review of authorisations

<sup>30</sup>Article 67 General provisions

<sup>31</sup>Article 70 Agency Opinion: Committee for Risk Assessment; Article 71 Agency Opinion: Committee for Socio-economic Analysis; Article 72 Submission of an Opinion to the Commission; Article 73 Commission decision

<sup>32</sup>Article 68 Introducing new and amending current restrictions

<sup>33</sup>Article 69 Preparation of a proposal

*REACH builds on this existing legislation but does not contain the criteria nor the obligations relating to classification and labelling. These are currently laid down in the classification and labelling section of Directive 67/548/EEC and the Dangerous Preparations Directive 1999/45/EC.*

REACH will refer to this classification and labelling system, until it is replaced by a new Regulation on Classification, Labelling and Packaging of substances and mixtures. REACH also specifies the obligations for substances and preparation classified as dangerous, such as making a Safety Data Sheet available or conducting an exposure and risk assessment during the course of a chemical safety assessment.

To ensure that hazard classifications (and consequent labelling) of all substances manufactured in or imported into the EU are transparent, industry will be required to submit a notification of the hazard classification to the Agency at the latest by 1 December 2010 unless already submitted as part of a registration<sup>34</sup>. The Agency will then include this information in a **classification and labelling inventory** in the form of a database accessible via internet<sup>35</sup>.

This transparency will highlight divergences between classifications of the same substance and thereby create pressure to remove them over time through co-operation between notifiers and registrants or by an EU harmonised classification<sup>36</sup>. The harmonisation of EU classifications will especially be conducted for substances that are carcinogenic, mutagenic, or toxic to the reproduction or respiratory sensitisers. It is nevertheless also possible to harmonise the classification and labelling of other substances if justified at EU level. Member States can make such proposals to harmonise the classification of a substance by submitting an Annex XV dossier.

In view of the extensive global trade in chemicals and the aim to ensure safe use, transport and disposal, an internationally harmonised approach to classification and labelling has been developed by the United Nations (Globally Harmonised System for classification and labelling of chemicals, GHS). The new Regulation on Classification, Labelling and Packaging will introduce the criteria of the GHS in the EU legislation. In order to facilitate its implementation, the timing of the obligations will as far as possible be aligned with the relevant deadlines in the REACH Regulation<sup>37</sup>.

## TECHNICAL GUIDANCE DOCUMENTS

A list of guidance documents which are available, or will be available, can be found on the European Chemicals Agency (ECHA) website: [http://reach.jrc.it/guidance\\_en.htm#GD\\_PROCC#GD\\_PROCC](http://reach.jrc.it/guidance_en.htm#GD_PROCC#GD_PROCC)

These documents have been developed with the participation of many stakeholders (Industry, Member States and NGOs) within projects managed by the Commission. The objective of these documents is to facilitate the implementation of REACH by describing good practice on how to fulfil the obligations.

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<sup>34</sup>Article 113 Obligation to notify the Agency

<sup>35</sup>Article 112 Scope; Article 114 Classification and labelling inventory

<sup>36</sup>Article 115 Harmonisation of classification and labelling

<sup>37</sup>Article 116 Transitional arrangements

## GLOSSARY OF TERMS

CSA	Chemical Safety Assessments
CSR	Chemical Safety Report
DU	Downstream User
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Chemical Substances
ES	Exposure Scenario
PBT	Persistent, Bioaccumulative and Toxic
PPORD	Product and Process Orientated Research and Development
RMM	Risk Management Measures
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
vPvB	very Persistent very Bioaccumulative

This guide was prepared by the Environment, Health and Safety Committee of the Royal Society of Chemistry.

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