Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Made Simple: Compliance of Chemical Substances, Mixtures or Articles under REACH

The European Regulation **(EC) No 1907/2006** is better known as "**REACH**" and applies to all chemical substances. **REACH** means the **Registration, Evaluation, Authorisation and Restriction of Chemicals** and is concerned with the risks posed by chemicals to ensure a high level of protection of human health and the environment, their safe use and alternative methods for assessing the hazards of substances. Therefore, REACH is likely to impact on companies of all sizes within the European Union ("EU"). Every manufacturer or importer of chemicals is responsible for the safety of the products that they place on the EU market, writes Dr Rosanna Cooper.

Does REACH Apply to your Company?

REACH applies to your organisation if you are a **manufacturer**, **importer** or **downstream user** of chemical substances as follows:

Manufacturer	**Does your company manufacture chemicals, either for your own use or to supply to other organisations within or outside of the EU/EEA? If yes, REACH will apply to your organisation.**
Importer	Does your company purchase any chemicals or articles containing chemicals from outside the EU/EEA such as: individual chemicals; mixtures for onwards sale; or finished products, like clothes, certain furniture or plastic goods? If so, REACH is likely to be applicable to your business.
Downstream users	Does your company handle any chemicals in your industrial or professional activity? If so, REACH is likely to be applicable to your business.

Direct Applicability

REACH directly applies in all Member States of the European Union ("EU") and the European Economic Area ("EEA"). It therefore applies in Iceland, Liechtenstein and Norway. REACH further applies to **chemical substances imported** into the EEA from non-EU countries such as Switzerland.

Companies established outside the EU

If your business is established **outside the EU**, you **do not have to comply with the obligations of REACH**, even if you export products into the EU. The responsibility for complying with REACH, such as pre-registration or registration lies with the **importers**

established in the EU, or with your representative as a non-EU manufacturer established in the EU.

Aim and Scope

REACH is applicable to the **manufacture**, **placing on the market** or **use of substances** and **mixtures** described in Article 3:

- **Substances** on their own;
- In **mixtures;**
- In **articles**; and
- The **placing on the market of mixtures**.

Subject to Articles 6, 7, 21 and 23, **substances on their own, in mixtures or in articles shall not be manufactured in the Community or placed on the market unless they have been registered**…

Manufacturers, **importers** and **downstream users** of **substances** and **mixtures** must ensure that they **manufacture**, **place on the market** or **use** such **substances** in a way that do not adversely affect human health or the environment.

Any **manufacturer**, **importer**, or where relevant **downstream user**, may, whilst retaining full responsibility for complying with its obligations under this Regulation, **appoint a third party representative for all proceedings** under Article 11, Article 19, Title III and Article 53 involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.

At a Glance

Some of the key definitions used in REACH and listed in Article 3, are below:

Article	means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition
Distributor	means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties
Downstream user	means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user
Importer	means any natural or legal person established within the Community who is responsible for import
Manufacturer	means any natural or legal person established within the Community who manufactures a substance within the Community
Manufacturing	means production or extraction of substances in the natural state

Mixture	means a mixture or solution composed of two or more substances
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
Producer of an article	means any natural or legal person who makes or assembles an article within the Community
Site	means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared
Substance	means 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
Supplier of an article	means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market
Supplier of a substance or a mixture	means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture
Use	means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation

Application of REACH

REACH applies to **substances** used in:

- Medicinal products for human or veterinary use;
- Food or feedingstuffs including use:
  - as a food additive in foodstuffs;
  - as a flavouring in foodstuffs;
  - as an additive in feedingstuffs;
  - in animal nutrition.

REACH does **NOT** apply to:

- Radioactive substances;
- Substances, on their own, in a mixture or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
- Non-isolated intermediates;
- The carriage of dangerous substances and dangerous substances in dangerous mixtures by rail, road, inland waterway, sea or air;
- Waste;
- Mixtures in the finished state, intended for the final user:
  - medicinal products for human or veterinary use;
  - cosmetic products;

- medical devices which are invasive or used in direct physical contact with the human body;
- food or feedingstuffs including use:
  - as a food additive in foodstuffs;
  - as a flavouring in foodstuffs;
  - as an additive in feedingstuffs;
  - in animal nutrition.

Certain substances are **exempted** under REACH:

- Substances included in Annex IV, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;
- Substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;
- Substances on their own or in mixtures, registered in accordance with Title II, exported from the Community by an actor in the supply chain and re-imported into the Community by the same or another actor in the same supply chain who shows that:
- Where the substance being re-imported is the same as the exported substance;
- Substances, on their own, in mixtures or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:
  - the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and
  - the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.
- On-site isolated intermediates and transported isolated intermediates.

Requirement for Registration of Substances

There is a general obligation under **REACH to register substances on their own or in mixtures with** the European Chemicals Agency ("ECHA"), unless it is stated otherwise in the regulation. From 31 May 2013, all substances manufactured or imported above **100 tonnes per year have to be registered**.

…Any manufacturer or importer of a substance, either on its own or in one or more mixtures, in quantities of **one tonne or more per year** shall submit a **registration** to the Agency.

The amount of data that has to be supplied is proportionate to the amount of substance supplied. There is a requirement on companies to demonstrate to ECHA how substances can be safely used. Users have to be informed of all risk management measures. Authorities such as the Health and Safety Executive ("HSE") in the UK can restrict the use of such substances if the risks cannot be managed. If the data for substances are not registered with ECHA, the substances cannot be placed on the market for sale in the EU.

Registration

The pre-registration under **REACH** allows manufacturers and importers to take advantage of the **phased-in deadlines** for **full registration**. This depends on the properties of the **substances** and their production volume. The late pre-registration period for companies

manufacturing or importing substances to be registered by **31 May** 2018 will close on **31 May 2017**.

Any importers that have not pre-registered their substances can pre-register late under the transitional provisions. For any volumes imported into the EU at an annual volume of one tonne or more per importer, the registration will be due by **1 June 2018**.

Any importer that is importing a mixture of an annual volume of one tonne or more into the EU must register all substances contained in that mixture.

If a substance is contained in several mixtures it is required to be registered only once.

Under Article 10, general Information must be submitted for achieving registration. Some of the information required is listed below:

- A **technical dossier** including:
  - The **identity of the manufacturer(s) or importer(s)**;
  - The **identity of the substance**;
  - Information on **the manufacture and use(s) of the substance**;
  - The **classification and labelling of the substance**;
  - Guidance on **safe use of the substance**;
  - All **physicochemical, toxicological and ecotoxicological** information that is relevant and available to the registrant, for example:
    - certain **non-phase-in** and **phase-in substances** meeting specific criteria; and
    - information on **physicochemical properties** of **phase-in substances** manufactured or imported in prescribed quantities.

- A **chemical safety report**.

A chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.

The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a mixture or in an article or a group of substances.

A chemical safety assessment does not have to be performed for a substance which is present in a mixture if the concentration is below a certain amount.

Joint Registration

REACH makes allowances for **joint submission** of data by multiple registrants.

The companies supply confidential information separately. They work jointly to agree on the information they would share via a **Substance Information Exchange Forum** ("SIEF").

Fees

There is a **fee** payable to **register a substance** depending on whether your company is classed as micro, small or medium-sized enterprise.

Small and Medium-sized Enterprises can benefit from reduced fees under the REACH, CLP and Biocidal Products Regulations. The reductions depend on the company size as defined by the Commission Recommendation 2003/361/EC and can be up to 95% from the standard fee for a REACH registration.

Registration and Notification of Substances in Articles

Any producer or importer of articles must submit a registration to ECHA for any substance contained in those articles, if both the following conditions are met:

- The substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
- The substance is intended to be released under normal or reasonably foreseeable conditions of use.

Any producer or importer of articles must notify ECHA, if both the following conditions are met:

- The substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
- The substance is present in those articles above a concentration of 0.1 % weight by weight (w/w).

Some of the information to be **notified** includes the following:

- The **identity and contact details** of the producer or importer;
- The **identity of the substance**(s);
- The **classification of the substance**(s);
- A **brief description of the use**(s) of the substance(s) in the article and of the uses of the article(s);
- The tonnage range of the substance(s), such as 1 to 10 tonnes, 10 to 100 tonnes and so on.

Appointment of Representative if Manufacturing outside the EEA

In accordance with Article 7, the **manufacturer** (by a natural or legal person established outside the EU), of a **substance on its own**, in **mixtures** or **in articles**, **formulates a mixture** or **produces an article that is imported into the EU** may by mutual agreement **appoint a representative** established in the EU to **fulfil its obligations to importers**.

The representative must also comply with all other **obligations of importers under REACH**. The representative must:

- Have **sufficient background** in the **practical handling of substances** and the information related to them;
- Keep available and **up-to-date information on quantities imported** and customers sold to;
- Keep information on the **supply of the latest update of the safety data sheet** referred to in Article 31.

Once a representative is appointed, there is an obligation on the **non-EU manufacturer** to inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as **downstream users** for the purposes of **REACH**.

Exemption for Research and Development

Certain provisions do not apply to substances manufactured or imported in the EU for research and development.

Articles 5, 6, 7, 17, 18 and 21 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.

The exemptions mainly relate to substances in plant protection and biocidal products:

Plant Protection Products	An active substance manufactured or imported for use in plant protection products which fulfils the conditions specified in Article 15(1) of REACH is deemed registered for the purposes of REACH as the substance would have undergone a rigorous assessment under the legislation governing plant protection products. The active substances of co-formulations manufactured or imported for use in plant protection products fall under Article 15(1) of REACH and are deemed registered for the purposes of REACH. The active ingredients must be listed in Annex I of 91/414/EEC (Plant Protection Products Directive), or in one of the other specific pieces of legislation relating to plant protection products. If not, they will be treated as other substances under REACH and for any amounts of one tonne or more per year manufactured or imported (on their own, in mixtures, or in articles), they must be registered.
Biocides	An active substance that is manufactured or imported for use in biocidal products only and fulfils the conditions in Article 15(2) of REACH is deemed registered under REACH as the substances would have undergone a rigorous assessment under the Biocidal Product Regulation. The active substances of co-formulations manufactured or imported for use in **biocidal products** fall under REACH, unless they are exempted under Annex IV or V. Otherwise, a manufacturer or importer of such substances on their own, in mixtures or in articles in amounts of one tonne or more per year must register them.
For both Biocidal and Plant Protection Products	Any active substance which can be used in biocidal and/or plant protection products and for other purposes is regulated by REACH and must be registered, if used in the amounts of one tonne or more per year.
Waste	Importing or processing waste does not fall under REACH. The recovery process of waste as a substance, mixture or article falls within the REACH, subject to certain exemptions.

CLP Regulation

The manufacturer and importer must ensure that the products are **classified, labelled and packaged** in accordance with the European Regulation (EC) No 1272/2008 on **classification, labelling and packaging of substances and mixtures** ("CLP").

Updating Registration

Under Article 22, a registrant is responsible for keeping the information pertaining to the company's registration update, including any:

- Change in the status, such as being a manufacturer, an importer or a producer of articles, or in the identity, such as his name or address;
- Change in the composition of the substance;
- Changes in the annual or total quantities manufactured or imported or in the quantities of substances present in articles produced or imported if these result in a change of tonnage band, including cessation of manufacture or import;
- New identified uses for which the substance is manufactured or imported;
- New knowledge of the risks of the substance to human health and/or the environment;
- Change in the classification and labelling of the substance;

ECHA communicates the information to the HSE in the UK.

Other Key Provisions

- Parties can share existing data in the case of registered substances.
- There is an obligation to keep information:
  - Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or mixture. That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to any competent authority of the Member State in which he is established or to the Agency, without prejudice to Titles II and VI.
  - In the event of a registrant, downstream user or distributor ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the registrant, downstream user or distributor's undertaking or assuming responsibility for the placing on the market of the substance or mixture concerned shall be bound by the obligation in paragraph 1 in place of the registrant, downstream user or distributor.

Safety Data Sheet

- There is a requirement for **safety data sheets**.

1. The supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex II:

(a) where a substance meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008 or a mixture meets the criteria for classification as dangerous in accordance with Directive 1999/45/EC; or

(b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or

(c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b).

6. The safety data sheet shall be dated and shall contain the following headings:

1. identification of the substance/ mixture and of the company/undertaking;
2. hazards identification;
3. composition/information on ingredients;
4. first-aid measures;
5. fire-fighting measures;
6. accidental release measures;
7. handling and storage;
8. exposure controls/personal protection;
9. physical and chemical properties;
10. stability and reactivity;
11. toxicological information;
12. ecological information;
13. disposal considerations;
14. transport information;
15. regulatory information;
16. other information.

The safety data sheet must be provided free of charge on paper or electronically no later than the date on which the substance or mixture is first supplied.

9. Suppliers shall update the safety data sheet without delay on the following occasions:

(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;

(b) once an authorisation has been granted or refused;

(c) once a restriction has been imposed.

The new, dated version of the information, identified as 'Revision: (date)', shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture **within** the preceding 12 months. Any updates following registration shall include the registration number.

10. From 1 December 2010 until **1 June 2015**, the safety data sheets for substances shall contain the classification according to both Directive 67/548/EEC and Regulation (EC) No 1272/2008.

10. Where mixtures are classified in accordance with Regulation (EC) No 1272/2008 during the period from its entry into force until **1 June 2015**, that classification may be added in the safety data sheet, together with the classification in accordance with Directive 1999/45/EC. However, until **1 June 2015**, where substances or mixtures are both classified and labelled in accordance with Regulation (EC) No 1272/2008 that classification shall be provided in the safety data sheet, together with the classification in accordance with Directives 67/548/EEC and 1999/45/EC respectively, for the substance, the mixture and its constituents.

Downstream users

In accordance with Article 37, a downstream user or distributor may provide information to assist in the preparation of a registration.

Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a mixture with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.
Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.

For registered substances, the manufacturer, importer or downstream user must comply with the obligations laid down in Article 14 either before the next supply of the substance on its own or in a mixture to the downstream user making the request, provided that the request was made at least one month before the supply, or within one month after the request, whichever is the later.

A downstream user is required to prepare a chemical safety report in certain circumstances.

Evaluation

All dossiers submitted in support of registrations will be subject to an evaluation in accordance with REACH.

ECHA may examine any registration in order to verify any of the following:

- That the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;
- That the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;
- That any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;
- That any explanation(s) submitted in accordance with Article 11(3) or Article 19(2) have an objective basis.
- Once the dossier evaluation is completed, the Agency shall notify the Commission and the competent authorities of the Member States of the information obtained and any conclusions made. The competent authorities shall use the information obtained from this evaluation for the purposes of Article 45(5), Article 59(3) and Article 69(4). The Agency shall use the information obtained from this evaluation for the purposes of Article 44.

ECHA publishes a report on the progress on applications on its website.

Authorisation requirement

There is a list of substances subject to authorisation in Annex XIV.

…all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

1. A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:
   (a) the use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or
   (b) the use(s) of that substance on its own or in a mixture or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2); or
   (c) the date referred to in Article 58(1)(c)(i) has not been reached; or
   (d) the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; or
   (e) in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.
2. A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.
3. Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex XIV shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted.

Once an authorisation is granted, it is subject to review at any time and has to be kept updated.

Applications for authorisations

An application for an **authorisation** must be made to ECHA in accordance with the requisite procedures. Applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance. Applications may be made by one or several persons.

Applications may be made for one or several substances that meet the definition of a group of substances in Section 1.5 of Annex XI, and for one or several uses. Applications may be made for the applicant's own use(s) and/or for uses for which he intends to place the substance on the market.

An application for authorisation must include the following information:

- the identity of the substance(s), as referred to in Section 2 of Annex VI;
- the name and contact details of the person or persons making the application;
- a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in mixtures and/or the incorporation of the substance in articles, where this is relevant;
- unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;

- an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant;
- where the analysis referred to in point (e) shows that suitable alternatives are available, taking into account the elements in Article 60(5), a substitution plan including a timetable for proposed actions by the applicant.

Conclusion

The provisions of REACH are very involved and manufacturers, importers and distributors of chemicals must take heed and ensure compliance to avoid penalties.

The author is Dr Rosanna Cooper of RT Coopers Solicitors. She is an expert in regulatory law, in particular, REACH and chemicals regulation. Dr Cooper is a chartered chemist and a fellow of the Royal Society of Chemistry. She may be contacted on +44 (0) 207 488 9947 or by email: enquiries@rtcooperssolicitors.com. For more information on the services provided by RT Coopers on regulatory law and product regulation visit http://www.rtcoopers.com/practice_chemicals.php, http://www.rtcoopers.com/practice_biocides.php and http://www.rtcoopers.com/practice_regulatory.php.

Tags

Consumer Products, Product Regulation, Consumer Law, REACH, Chemical Regulation, Regulatory Law, Chemical REACH Lawyers, Regulation of Chemicals and Chemical Ingredients, Chemicals, Pesticides, Product Regulation, Regulatory Solicitors, EU Regulatory Law, REACH Lawyers, Product Regulations, Chemical Manufacturer, Chemical Use, Chemicals, Regulatory Lawyer, Chemical Regulation Law, Regulated Industries REACH, REACH and Chemical Regulations Legal Advice