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White Paper

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Registration, Evaluation, Authorisation and Restriction of Chemicals  
(REACH) Regulations

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Complimentary Advice for Clients

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## Executive Summary

The purpose of this document is to raise awareness of, and help you identify your obligations under, the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **CH**emicals regulation (REACH), which came into force in the UK on the 1<sup>st</sup> June 2007. We have studied the regulations in great depth and it is clear that action is required, to a greater or lesser extent, by all companies.

REACH aims to ensure that the risks posed by the use of chemicals are assessed, documented, minimised and communicated and that unsafe substances are replaced with safe substances. It places the responsibility for assessing chemicals with manufacturers and importers, under the aegis of the newly created European Chemicals Agency, and tasks users with ensuring that they inform upstream suppliers about the uses of chemicals and pass relevant information downstream to other users.

Since the regulation requires “use” to be registered, downstream users need to inform suppliers of their substance use and ask for pre-registration details, Safety Data Sheets (SDS) and other information by the end of 2008. Ultimately, if a use has not been registered for a chemical, then it will be against the law to use the chemical in that way.

There are several important features to note:

1. REACH applies to ALL chemicals, not only those used in industrial processes, but also those used on a day-to-day basis, for example furniture, cleaning products, paints, clothing etc;
2. REACH applies to all businesses within the supply chain. The criteria determining the level of compliance required are often complex;
3. One organisation can have several different roles, and therefore different obligations, under REACH. The terms used in REACH to describe a role may be quite differently interpreted elsewhere. A description of the REACH definitions is provided in the [Glossary](#);
4. REACH only applies to the chemicals ([substances](#)) within products ([preparations](#) or [articles](#)) not to the products themselves;
5. A pre-registration “window” will open on the 1<sup>st</sup> June 2008. This offers a free and simple way of continuing production and use of certain “phase-in” substances and extends registration deadlines for those substances to 2010-2018. The window closes on 30<sup>th</sup> November 2008 after which a full registration must take place;
6. Substances, and uses, not complying with REACH will not be able to be traded or used.

If you are not already actively dealing with REACH we urge all our clients to take the following steps as soon as possible:

1. Identify any chemical (substance) that is present in any product which you use within the business;
2. Decide what kind of user ([Actor](#)) of chemicals you are, remember that you could be a distributor of one chemical and a downstream user of another;
3. Review the status of any chemicals you make, import, use or place on the market;
4. Identify your obligations with respect to those chemicals;
5. Create full upstream and downstream communications channels.

To help with Steps 1 and 2, please work through the short questionnaire on the following page.

If you suspect you have an obligation and would like some further assistance to identify and respond to your obligation(s), please contact Hazel Lobo on 01491 682850 or by email to [hlobo@jwilliamsassociates.co.uk](mailto:hlobo@jwilliamsassociates.co.uk).

## Questionnaire

It is important to note that you may have more than one role under the regulations and should therefore assess ALL [substances](#) individually.

Select the correct response and then go to the appropriate next question (Questions 1, 3, 5 & 6 apply to all). For an explanation of any of the terms used, click on the word.

**Question 1.** Do you manufacture [substances](#) on their own, in [preparations](#) or in [articles](#) in the EU?

**YES** - go to question 2.

**NO** - You have no obligation as a manufacturer. Go to question 3.

**Question 2.** Are you manufacturing more than 1 tonne of any substance per year?

**YES** - you should read [Obligations – note 1](#). Then continue at question 3.

**NO** - You have no obligation as a manufacturer. Go to question 3.

**Question 3.** Do you import [substances](#) on their own, in [preparations](#) or in [articles](#) from outside the EU?

**YES** - go to question 4.

**NO** - You have no obligation as an importer. Go to question 5.

**Question 4.** Are you importing more than 1 tonne of any substance per year?

**YES** - you should read [Obligations – note 2](#). Then continue at question 5.

**NO** - You have no obligation as a manufacturer. Go to question 5.

**Question 5.** Are you a retailer or distributor of substances on their own, in preparations or in articles?

**YES** - You should read [Obligations - note 3](#). Then continue at question 6.

**No** - go to question 6.

**Question 6.** Do you use any substances on their own, in preparations or in articles in the course of your industrial or professional activities?

**YES** - You should read [Obligations - note 4](#).

**No** - please consider carefully ALL products/materials you use. Printer Inks, for example, contain substances in preparations and are used by many downstream users.

## Obligations

1. If you manufacture more than 1 tonne of a substance per year, you may have obligations as a manufacturer. You should take immediate action to identify which substances you need to register and what steps you need to take.
2. If you import more than 1 tonne of a substance per year, from outside the EU, you may have obligations as an importer. You should take immediate action to identify the steps you need to take.
3. As a distributor or retailer, your only obligation is to forward information, upstream and downstream, in the supply chain. However, you must ensure that you have all necessary information and must keep a database of information on each substance/preparation for at least 10 years after the last supply - REACH Article 36
4. As a downstream user, you have obligations set out in Articles 37-39 of REACH. In summary, these include the need to:
  - a. check that your use of a substance, preparation or article is registered;
  - b. ensure that if an SDS supplied to you has one or more exposure scenarios attached, you comply with the conditions described;
  - c. determine whether or not you also have obligations as a formulator or a refiller. If so, take steps to identify any additional obligations you incur;
  - d. pro-actively alert suppliers of your uses and determine whether or not those uses will be (pre-)registered;
  - e. if you sell on, determine your clients' usage and pass this information upstream to your suppliers;
  - f. ensure that you are aware of any authorisation requirements for substance use and that authorisation is approved. If your use is not authorised by an upstream member of your supply chain, you will have to apply for authorisation for your own use and, if relevant, for your clients' use;
  - g. check the registration status of substances in any articles that you produce or import;
  - h. be particularly aware of any substances, preparations or articles you use that contain more than 0.1% (w/w) of certain substance of high concern (SHC) or substances of very high concern (SVHC) as determined in Article 57 of REACH. Use of these substances, preparations or articles may require you to notify the Chemicals Agency and your clients under Articles 7 and 33(1) of REACH.

Further information on obligations is available from The ECHA website at <http://reach.jrc.it/> You will also find an IT tool – Navigator – to help identify the status of substances.

## Glossary

**Article:** Any object whose specific shape, surface or design determines its function to a greater extent than its chemical composition does. Examples include furniture, books, toys, kitchen appliances, textiles, electronic chips etc. It is important to note that, under the REACH regulations, only the substances should be registered, the article should not. The legislation applies individually to any substance within the scope of the regulations. For further guidance on identifying articles, visit [http://reach.jrc.it/guidance\\_en.htm](http://reach.jrc.it/guidance_en.htm)

**Preparations:** Mixtures or solutions of two or more *substances*. Preparations typically include paints, varnishes and inks. The key differentiator between a preparation and a multi-constituent substance is that preparations are created by blending two or more substances without a chemical reaction taking place. It is important to note that, under the REACH regulations, only the substances should be registered, the preparation should not. The legislation applies individually to any substance within the scope of the regulations.

### REACH roles (Actors):

**Article Producer:** *End user* who incorporates substances or preparations into articles. Article producers have special obligations under REACH;

**Distributor:** 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 preparation, for third parties.” REACH Article 3 (14). Distributors are not considered *downstream users*, but have obligations under REACH;

**Downstream User:** 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 preparation, 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.” REACH Article 3 (13);

**End User:** Anyone using substances or preparations in the course of business or professional activities who does not supply further downstream;

**Formulator:** Any downstream user who mixes substances and/or preparations to make other preparations to place on the market. Provided not chemical reaction takes place, there is no manufacture obligation;

**Importer:** Any “natural or legal person established within the Community who is responsible for import;

**Manufacturer:** Any “natural or legal person established within the Community who manufactures a substance within the Community”. REACH Article 3 (9);

**Refiller:** Anyone who transfers substances or preparations from one container to another. Considered a downstream user, even if they do not use or apply the substances or preparations in any other activity. Refillers have additional obligations under REACH;

**Retailer:** Anyone who sells substances and/or preparations to private consumers and/or professional users in a retail store. Retailers are a subgroup of Distributors - see [Distributor](#);

**Substance:** A chemical element and/or its components. Includes both manufactured substances (like methanol or formaldehyde) and substances that are naturally occurring. For full guidance on identifying substances, visit [http://reach.jrc.it/guidance\\_en.htm](http://reach.jrc.it/guidance_en.htm).