

Chemicals: Are you ready for REACH?



Do you:

1. **Manufacture, import, sell, or use** chemicals?
2. **Manufacture, import, sell, or use** products which are intended to release chemicals?

... then you may be affected by the European Union (EU) Regulation on the **Registration, Evaluation, Authorisation and restriction of CHemicals (REACH)**.

The REACH Regulation is hailed as the most significant piece of European legislation to affect the chemicals industry in recent time. The main text comprises some 849 pages. Serious responsibilities fall upon all those in the chemical "supply chain".

Application

All individual chemical **substances¹** manufactured or imported into the EU in quantities of 1 tonne per year or more on their own, in preparations, or in articles (i.e. 'products' - if the substance is intended to be released during normal and reasonably foreseeable conditions of use, for example, ink released from print cartridges) will be caught.

Responsibility

This lies with the "natural or legal persons" that manufacture, import, place on the market or use these substances. The most onerous requirements are placed on the importers and manufacturers who will need to register substances and provide detailed dossiers of information to the European Chemicals Agency, including safety data sheets. Down stream users will need to ensure their uses are covered by the supplier's risk assessments and that the information is passed up the supply chain.

Issues to be wary of

- **Who has responsibility?** – It may not be clear, for example where operational sites are shared by different companies or where substances are imported from outside the EU.
- **Can continuity of supply be assured?** – Some companies may decide to stop producing certain chemicals because of compliance costs. Also, a failure to register substances will require them to be taken off the market.
- **Substances of very high concern (SVHC)?** – (Eg, carcinogenic, mutagenic or toxic to reproduction) are intended to be phased out and replaced by e of safer alternatives and will require separate authorisation for ongoing use. At the time of writing, the European Chemicals Agency is consulting on a list of candidates for classification as SVHC, which is to close on 14 August 2008.
- **What about preparations?** – Mixtures of substances (eg, paint) are not required to be registered but may contain registered substances, information about which needs to be communicated down the supply chain.
- **Non EU Company importing chemicals into the EU?** – You may need to consider setting up an EU-based company, although it is possible to appoint an Only Representative (OR) to represent your interests.
- **Exemptions?** – There are several categories of exemption, for example, wastes (although note materials recovered from waste will be caught) and substances under customs supervision, as well as natural substances (eg, minerals, ores, cement clinker, and certain fuels), unless chemically modified and substances regulated by other legislation.
- **SMES?** – Reduced fees apply and additional guidance and assistance is available.

- **Commercially Confidential Information** – It may be possible to opt out of joint registration requirements where users wish to keep information confidential.

Key dates

Pre-registration 1 June 2008 to 30 November 2008 – chemicals already known in the EU (so-called 'phase-in' substances) may be pre-registered within this period. Pre-registration will, in most cases, allow a delay in the requirements for full registration and is relatively simple. Other key stages are as follows:

Table 1.1	Action
30 November 2008	Pre-registration for 'phase-in' substances ends
1 December 2008	Registration for existing substances (that have not been pre-registered) starts
1 January 2009	List of pre-registered substances published and 'Substance Information Exchange Forums' (SIEFs) formed
PHASE 1 1 December 2010	The following pre-registered 'phase-in' substances should have been registered when supplied at: <ul style="list-style-type: none">■ ≥ 1.000 tonnes per annum (tpa) or;■ ≥ 100 tpa and classified under the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP) as very toxic to aquatic organisms or;■ ≥ 1 tpa and classified under CHIP as Cat 1 or 2 carcinogens, mutagens or reproductive toxicants
PHASE 2 1 June 2013	Deadline for registration of substances supplied at ≥ 100 tpa
PHASE 3 1 June 2018	Deadline for registration of substances supplied at ≥ 1 tpa

Cost

Pre-registration will be free. Full registration is, however, subject to fees based on tonnage use. For example, standard fees for the main registration requirements are currently as follows:

Table 1.2	(EUR)	
	Individual Submission	Joint Submission
Fee for substances in the range of 1 to 10 tonnes	1,600	1,200
Fee for substances in the range 10 to 100 tonnes	4,300	3,225
Fee for substances in the range 100 to 1,000 tonnes	11,500	8,625
Fee for substances above 1,000 tonne	31,000	23,250

Costs associated with the assessment of chemicals and preparation of dossiers will vary, but could be significant.

1 "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."

United Kingdom progress

The UK Government launched a public consultation on draft enforcement regulations on 2 June 2008, which builds upon existing regulatory regimes. UK enforcement provisions must be in place by 1 December 2008. Current proposals are that the Health and Safety Executive will be responsible for taking enforcement action for non-compliance in respect of registration and the supply chain, but it will be the Environment Agency who will enforce environmental breaches of the regime at installations subject to environmental controls (e.g. facilities operating under an environmental permit). Punishment for breaches of REACH (e.g. non-registration, obstructing enforcing authorities, providing false statements and failing to provide information) will depend on the offence, however, there are potentially severe consequences. The maximum sentence is an unlimited fine and/or two years' imprisonment. It is anticipated that new regulations will be laid before Parliament by November 2008 following closure of the consultation on 25 August 2008.

Actions

Audit

- Prepare a list of all the chemicals, and their constituent parts and quantities, that come into, are a part of, or go out of your business.
- Identify any which may be of very high concern.
- Identify who supplies them.

Assess

- Which chemicals are the most important to the business and where priorities lie.
- What role your company plays in relation to each substance – Manufacturer? Importer? Downstream user?
- Whether exemptions apply.
- Where multiple entities are involved, who actually manufactures or imports.
- Whether information about the substance is commercially confidential and would therefore warrant seeking separate registration
- Whether your company is as an SME.

Act

- Pre-register where possible.
- Contact your suppliers and customers to discuss their intentions and programmes for complying with REACH.
- Start financial budgeting for compliance and allocate human resources.
- Prepare contingencies for chemicals where supply issues may arise.

WARNING

Any applicable substances that have not been pre-registered by 31 November 2008 must be taken off the market until a full registration has been carried out. Trading and use of non-registered chemicals will be a criminal offence.

REGISTRATION REQUIREMENTS HAVE COMMENCED, SO YOU NEED TO ACT NOW.

Berlin
Ebertstraße 15
10117 Berlin
Tel +49 (0)30 88 56 36 0
Fax +49 (0)30 88 56 36 100

Brussels
Trône House
4 Rue du Trône
B-1000 Brussels
Tel +32 (0)2 289 6060
Fax +32 (0)2 289 6070

Cambridge
24 Hills Road
Cambridge CB2 1JW
Tel +44 (0)1223 446400
Fax +44 (0)1223 446401

Dubai
P.O. Box 33675
28th Floor Al Moosa Tower II
Sheikh Zayed Road
Dubai, United Arab Emirates
Tel +971 (0)4 332 3324
Fax +971 (0)4 332 3325

Düsseldorf
Königsallee 92a
D-40212 Düsseldorf
Tel +49 (0)211 83 87 0
Fax +49 (0)211 83 87 100

Frankfurt a. M.
Senckenberganlage 20-22
D-60325 Frankfurt a. M.
Tel +49 (0)69 971 30 0
Fax +49 (0)69 971 30 100

Hamburg
Hanseatic Trade Center
Am Sandtorkai 41
20457 Hamburg
Tel +49 (40) 3 68 03-0
Fax +49 (40) 3 68 03-280

London
Carmelite
50 Victoria Embankment
Blackfriars
London, EC4Y 0DX
Tel +44 (0)20 7300 7000
Fax +44 (0)20 7300 7100

Munich
Isartorplatz 8
D-80331 Munich
Tel +49 (0)89 2 10 38 0
Fax +49 (0)89 2 10 38 300

Paris
42 avenue Montaigne
75008 Paris
Tel +33 (0)1 72 74 03 33
Fax +33 (0)1 72 74 03 34

Representative offices:
Alicante
Paseo Explanada de España No. 1,
4-Izda E-03002 Alicante, Spain
Tel +34 (0)96 51 42 805
Fax +34 (0)96 52 00 248

Shanghai
15th Floor United Plaza
Unit 1509
No. 1468 Nanjing West Road
200040 Shanghai, China
Tel +86 (21)6247 7247
Fax +86 (21)6247 7248

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For further information, please contact

Brian Greenwood
Partner and Head of Group
DDI +44 (0)20 7300 4724
E-mail b.greenwood@taylorwessing.com

Luke Hinchey
Associate
DDI +44 (0)20 7300 4649
E-mail l.hinchey@taylorwessing.com

Sherryl L'oken
Professional Research Lawyer
DDI +44 (0)20 7300 4958
E-mail s.loken@taylorwessing.com



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