REACH: an opportunity for trade unions.Putting knowledge
to work in the workplace



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Preface

The REACH Regulation (Registration, Evaluation, Authorisation of CHemicals) came into force on 1 June 2007 throughout the European Union (EU). The new law has two main aims: to ensure a high level of protection for human health and the environment, including by improving knowledge and information about chemicals; and to enhance the competitiveness of the European chemical industry.

After close to a decade's rancorous debate, REACH replaced over 40 old laws with a single streamlined regulation. The core of this reform is that it shifts the burden of proof from the Member States onto industrial operators. REACH says that manufacturers and importers must evaluate the risks of using chemicals, and must supply users with adequate safety information.

The use of chemicals takes a heavy toll on European workers in all sectors - up to 30% of recognized occupational diseases and tens of thousands of preventable deaths each year are caused by exposure to hazardous substances. This causes wide social inequalities in health, and is why the European Trade Union Confederation (ETUC) and European Trade Union Institute (ETUI) have consistently pushed to get this reform onto the books and fully benefit the health and safety not just of workers but also consumers and the environment.

The text finally adopted at the end of 2006 is a balancing act between more ambitious proposals to protect human health and the environment and the chemical industry's determination, backed by many governments, to keep control over the decision of what to place on the market. It is too soon to tell what impact REACH will have. The reform will be phased in up to 2018. What real impact it will have cannot be said for certain from REACH's often unclear wording, but will be shaped by many factors that will determine how much worker and public oversight there is on what industry does.

Trade unions would be mistaken to ease up on their efforts in the belief that REACH implementation will now be plain sailing and that improvements in workplaces will follow as a matter of course. This is why the ETUC has fought for representation on the Management Board and all the scientific committees of the

European Chemicals Agency (ECHA), the body responsible for managing the Regulation and ensuring it is implemented consistently throughout the EU. At the sharp end — in workplaces — workers' reps will also have a key role in seeing that REACH delivers its potential benefits for occupational health and safety.

REACH will provide new knowledge about the hazards, exposures and risks of chemicals, but also encourage replacement of the most dangerous substances by safer alternatives. This new information should be used to best effect by firms to implement effective risk reduction measures so as to bring down the work-related disease and death tolls from exposure to hazardous chemicals.

This brochure has therefore been written for use by trade union reps in the countless workplaces across Europe where workers are exposed to chemicals. The first section explains the main points of the reform. The second tells you about your firm's obligations under REACH. The third details how REACH and specific EU worker protection laws link up and can act together, while the fourth and final section offers some practical ways of using REACH as a means for union action in workplaces.

— Laurent Vogel
Director, Health and Safety Department, European Trade Union Institute

Part 1 REACH: why was a Regulation needed?

Introduction

The chemical industry: a powerhouse of the economy...

The chemical industry is a key player in the world economy, making an undeniable contribution to Europe's economic prosperity through trade and jobs¹. It is the third largest manufacturing industry in the European Union of twenty-seven (EU-27). With 29,000 firms, mostly SMEs, it employs some 1.3 million people and provides millions of indirect jobs. Even excluding pharmaceuticals, its turnover was estimated at 537 billion euros in 2007, accounting for nearly 30% of world sales.

... that affects our daily lives and environment

Chemicals benefit our developed society in ways it could not do without. They are in almost every item or product used in daily life. Chemicals are part of our food, medicines, clothing, and so on.

But some of these chemicals can harm human health and the environment. They spread throughout our bodies from the products we use, eat or drink. Recent studies commissioned by NGOs have found chemicals present in breast milk, blood,

CEFIC, Fact and Figures, The European chemical industry in a worldwide perspective, www.cefic.org/ factsandfigures/

the umbilical cord, etc.² Chemicals also contaminate the environment, animals and the entire food chain.

A growing body of scientific research has pointed to a possible link between the rise in cancers, asthma, allergies, skin diseases, hormonal and reproductive tract disorders and contact with hazardous chemicals3.

Chemicals in our everyday lives

Toys: phthalates galore

Toys account for just a tiny share of the products that contain phthalates - additives used as plastic softeners, Shampoos, perfumes, deodorants and toothpastes conand as solvents in cosmetics. They are found in many tain stabilizers, preservatives, artificial musks, phthalates consumer products, from flooring to shoe soles, paints, inks, and so on. Some act as endocrine disruptors, meaning that they interfere with our hormone functions, causing fertility and reproductive problems. They can also trigger childhood asthma, leading the EU in 2005 to ban toys and childcare articles containing six phthalates that were toxic to reproduction from the European Textiles: organotin compounds (stannanes) market.

Computers: all manner of brominated flame retardants

development that can lead to permanent neurological masculinisation of female shellfish.

damage have been reported in rats subjected to chronic exposure (especially during pregnancy).

Cosmetics: musks and alkylphenols

and chemicals from the family of alkylphenols. Alkylphenols are used as emulsifiers, and as ingredients in industrial cleaning products, detergents, textile finishing, leather, etc. They are suspected of being endocrine disrupters that can affect the reproductive system.

Desk chairs, carpets, any fabric treated for fire-, stain- or mould-resistance all contain organotin compounds. They are used as stabilizers to mitigate the effects of light or heat, or as additives, fungicides or biocides in carpets, Like all electrical and electronic appliances, vehicles, paint, PVC products but also in food. They are part of lighting and wiring and even some treated textiles (car- a family of toxins known to affect the immune system. pets, sofas, etc.), computers contain brominated flame. They damage the enzyme system which regulates bioretardants (BFRs) to prevent outbreaks out and/or delay chemical reactions in our bodies, as well as development the spread of fire. BFRs are highly persistent in the envi- of the embryo and testes. Organotin compounds are ronment and the body. Their long-term toxicity is poorly used in paints for ship hulls, and are found in fish and researched, but signs of disrupted skeletal and brain seafood. They have even been held responsible for the

Workers are exposed, too

Hazardous substances are also found at many workplaces, both in and outside the chemical industry. Workers in different sectors like building, carmaking, textiles, farming, health care and research face daily exposure to chemicals⁴. In the most recent survey on working conditions in Europe⁵, over 20% of European workers reported breathing in fumes and vapour at work, and 15% reported handling hazardous substances for at least a quarter of their working time.

^{2.} See in particular: http://www.greenpeace.org, http://www.wwf.be, http://detox.panda.org

^{3.} On which, see the Paris Appeal: www.artac.info

^{4.} European Agency for Safety and Health at Work (EU-OSHA) (2003) Facts 33, http://osha.europa.eu/OSHA

Fourth European Working Conditions Survey (2005), http://www.eurofound.europa.eu/ewco/surveys/EWCS2005/ index.htm

About one in three of all occupational diseases recognised in Europe each year are due to exposure to hazardous chemicals⁶. Chemicals can cause different types of damage. Some can cause cancer, reproductive problems or birth defects. Yet others can cause brain disorders, impaired nervous systems, asthma and skin problems. The damage caused by hazardous substances can occur after a short exposure or by the build-up of these chemicals in the body. According to the European Agency for Safety and Health at Work, 74,000 deaths a year in the EU-27 are linked to exposure to hazardous substances at work⁷.

The old legislative framework was not working

Given how widespread chemicals are, staggeringly little is still known about them. There are up to 100,000 different recorded chemicals on the European market. To date, only 1% of all chemicals have actually been tested to assess their safety and the dangers they pose to the environment and human health, so the data on their health and environmental effects is patchy at best (see Table 1).

Table 1 Quality of health and environmental data for chemicals produced in quantities above 1000 tonnes/ producer/ year

Adequate data	14%
Partly adequate data	65%
No data	21%

Source: According to Hazardous chemicals can be substituted, The Ecological Council (2006), www.ecocouncil.dk

The EU has passed various laws since the 1960s to improve information about chemicals and restrict the use of those that present a risk to humans or the environment. This has produced a complicated, inefficient and unworkable system made up of 40-odd Directives and Regulations, which has allowed the chemical industry to continue putting chemicals on the market without providing information on their potential risks.

The Commission took a first step in 2001 by adopting the Chemicals White Paper⁸. This pulled together various proposals for framing an EU strategy for a future chemicals policy, and formed the basis for the Commission's proposed new policy on chemicals, put forward in October 2003. The draft policy sparked off an intense debate⁹ and it was not until three years later in December 2006 that a final version was adopted.

The unions at all times supported the REACH reform for better information and tighter controls on the use of chemicals, which they see as progress towards sustainable development¹⁰. It is a critical struggle for millions of European workers who are in daily contact with these chemicals in their workplace.

^{6.} Musu, T. (2006) *REACHing the workplace. How workers stand to benefit from the new European policy on chemical agents*, European Trade Union Technical Bureau, 2004 (see box p. 9), available at http://www.etui.org

Report - Expert forecast on emerging chemical risks related to occupational safety and health European Agency
for Safety and Health at Work, March 2009. Downloadable at http://osha.europa.eu/en/publications/reports/
TE3008390ENC_chemical_risks/view

^{8.} White Paper of the Commission of 27 February 2001 on the Strategy for a Future Chemicals Policy, COM (2001) 88 final. http://ec.europa.eu/environment/chemicals/background/white_paper.htm

^{9.} On which, see *The only planet guide to the secrets of Chemicals Policy in the EU, REACH: what happened and why?* (2004), http://www.wwf.be/detox/online_publications/theonlyplanetguide.pdf

 $[\]textbf{10.} \ \ \text{See the European Trade Union Confederation's website, http://www.etuc.org/r/830}$

What is REACH?

The new system adopted by the European Union is called REACH (which stands for Registration, Evaluation and Authorisation of CHemicals).

REACH is a Regulation (No. 1907/2006). This means it does not have to be re-enacted into national law like Directives do, but entered into force in all EU countries on 1 June 2007. Some adaptations will have to be made nationally, however, to implement the Regulation (like setting up help desks, etc.).

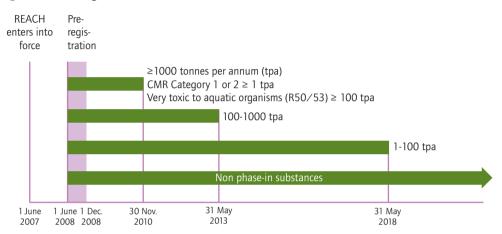


Figure 1 REACH registration timeline

There are three main elements to REACH:

- 1. **R for** *Registration*: all chemical substances manufactured or imported into the EU in quantities above one tonne/year (about 30,000 substances) have to be registered in a central database managed by the new European Chemicals Agency. Manufacturers and importers must supply data on individual substances (properties, uses and handling recommendations) to a preset timetable running up to 2018 (see Figure 1). The bigger the quantities produced, the more detailed the information has to be.
 - > For more details on the registration procedure: http://guidance.echa.europa.eu/registration_en.htm
- 2. E for Evaluation: two kinds of evaluation will be done: dossier evaluation by the Agency, and substance evaluation by Member States coordinated with the Agency. The former will be done to ensure that registration dossiers are in order (compliance check) and review producers' testing proposals. The latter will enable manufacturers to be asked for additional information or may result in further action (restriction or authorisation) under the REACH system in cases where there is a potential risk to health or the environment.
 - > For more details on the evaluation procedure: http://guidance.echa.europa.eu/evaluation_en.htm

- **3.** A for *Authorisation*: producers will have to get authorisation for each use to be made of the "substances of very high concern" included in Annex XIV of REACH. Substances that can be identified as being of very high concern are CMR (carcinogenic, mutagenic or reprotoxic i.e., toxic to reproduction), PBT (persistent, bioaccumulative and toxic), vPvB (very persistent and very bio-accumulative), and other substances causing serious and irreversible effects to humans and the environment. Authorisations are granted on a case by case basis and will be time-limited. REACH also provides for a system of restrictions by which to limit the manufacture, use or marketing of certain hazardous substances where the risks to human health or the environment are considered unacceptable.
 - > For more information on authorisation and restriction procedures: http://guidance.echa.europa.eu/authorisation_en.htm http://guidance.echa.europa.eu/restriction_en.htm

REACH also introduces a mechanism for exchanging information. The various actors in the supply chain are required to put out information on the substances they manufacture, distribute or use, both downstream (from supplier to customer) and upstream (from customer to supplier). This includes information on the properties of substances, the risks associated with their use and risk management measures.

> For more details on the information exchange procedures: http://guidance.echa.europa.eu/communication supply en.htm

There is also another European regulation closely related to REACH. This — the so-called CLP Regulation — sets new rules for the classification, labelling and packaging of chemical substances and mixtures in the European Union¹¹. It entered into force in January 2009, introducing into the EU new criteria for classification and labelling based on the United Nations' Globally Harmonised System (UN GHS). Under the new CLP rules, chemicals will have to be reclassified by 1 December 2010 (mixtures by 1 June 2015). The CLP Regulation also requires producers to send the European Chemicals Agency a notification of classification for all hazardous substances or mixtures placed on the market for inclusion in an inventory that will be made public.

> For more details on the CLP Regulation: http://www.echa.europa.eu/clp/clp_regulation_en.asp

What will REACH do?

It reverses the burden of proof

The big benefit of the REACH reform is that it shifts the burden of proof from the authorities to industry. Unlike the old system, it will no longer be down to the authorities to assess the risks of a substance before putting risk reduction measures in place. In future, producers will have to show through registration dossiers that the substances they produce in quantities above one tonne per year can be used safely. Registration dossiers for substances already on the market must be submitted to a timetable that runs up to June 2018, while the

^{11.} Regulation (EC) 1272/2008.

dossiers for those first marketed after June 2008 absolutely must be handed in before they are placed on the market.

This change will mean that data is produced more quickly. In the past, underresourcing of authorities, cumbersome procedures and a lack of toxicological data meant that evaluating a single substance could take up to five or six years.

Also, the risks of exposure will be somewhat clearer as downstream users of chemicals will have to indicate the purposes they are using them for.

A single procedure for the marketing of chemicals

REACH establishes a single, coherent system for marketing chemicals in Europe. It does away with the distinction between "existing" substances — already on the market in 1981 — and "new" substances — put on the market after 1981 — as well as the different marketing rules attached to them under the old legislation. REACH replaces the Regulation on the evaluation and control of the risks of existing substances (793/93) and the Directive on restrictions on the marketing and use of certain hazardous substances and preparations (76/769/EEC). The existing restrictions remain in force, however, and are included in an annex to REACH. The Dangerous Substances Directive (67/548/EEC), which set rules for the notification of new substances, and the Preparations Directive (1999/45/EC), have been amended to bring them into line with REACH.

The provisions on safety data sheets¹² (SDS) have been included in the REACH Regulation. They will be improved by additional information coming from the registration requirements, including the exposure scenarios that now have to be annexed to them.

Improved communication throughout the supply chain

In the past, information on chemicals provided in the supply chain was all one way — from manufacturers to downstream users through labels and safety data sheets. With REACH, users of a chemical will have to notify their supplier what they are using it for in order to get from him the information needed to use it safely. The supplier can then adapt that chemical's safety data sheet for all identified uses¹³. The supplier also has a duty to notify a customer if he advises against the intended use (for health or environmental protection reasons). The two-way exchange of information up and down the supply chain is an important change introduced by REACH that should significantly improve the management of chemical risks throughout the production chain.

Data will be more available and transparent

REACH will make data on chemicals a bit more transparent. All non-confidential information on registered substances will be available to the public free of charge on the European Chemicals Agency website. These data will be useful not only to the medical profession, researchers and occupational health professionals, but to all consumers and members of the public who want more information on the chemicals they are exposed to.

^{12.} Directive 91/155/EEC amended by Directive 93/112/EEC and Directive 2001/58/EC.

^{13.} This applies to chemicals imported or produced in quantities >10 tpa, for which a chemical safety report is required.

The European Chemicals Agency

REACH set up a new European agency — the European Chemicals Agency (ECHA), based in Helsinki, Finland. Its main job is to manage the technical, scientific and administrative aspects of the REACH Regulation's requirements for the registration, evaluation, authorisation and restriction of chemicals. It is also responsible for certain provisions of the CLP Regulation, including management of the classification and labelling inventory. After a year of preparation, ECHA started work on 1 June 2008, the date when REACH and the first obligations on firms came into force.

The European Chemicals Agency

The European Chemicals Agency is composed of:

- a Management Board, responsible for adopting the annual budget, work programme and annual report. The Board appoints the Executive Director;
- an Executive Director, the legal representative of the Agency, responsible for the day to day management and administration of the Agency, including responsibility over its finances. The Executive Director reports and is accountable to the Management Board;
- a **Secretariat** to support the three Committees and Forum and undertake work on the registration and evaluation processes, as well as the preparation of guidance, maintenance of databases and provision of information:
- a Member State Committee to resolve differences of opinion on draft decisions proposed by the Agency or It is worth noting that European workers have seats on Member States and make proposals for identification the Agency's Board and all its Committees. of substances of very high concern;
- on evaluations, on applications for authorisation, on etui.org/ > HesaMag

proposals for restrictions and on classification and labelling;

- a Committee for Socio-economic Analysis to prepare opinions on applications for authorisation, on proposals for restrictions and on questions relating to the socioeconomic impact of proposed legislative action;
 - a Forum on enforcement matters to coordinate a network of Member States' competent authorities responsible for enforcement;
- a Board of Appeal to decide on appeals against decisions taken by the Agency. Appeals are allowed only against decisions of the Agency taken on registration and evaluation of dossiers, exemptions from registration for substances used in research and development, and sharing of data between producers.

See: Musu, T. (2008) The European Chemicals Agency, keystone of - a **Risk Assessment Committee** to prepare opinions REACH, *HESA Newsletter*, No.34. Downloadable from http://hesa.

REACH – protecting workers' health and safety

Interaction with the worker protection laws

REACH sets the rules for using and marketing chemicals. But there is also an EU law intended to improve the safety and health of workers — Framework Directive 89/391/EEC. This provided the basis for two directives that deal specifically with chemical risks:

- the 1998 Directive on the protection of workers from the risks related to exposure to chemical agents at work (Chemical Agents Directive 98/24/EC);
- the 2004 Directive on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Carcinogens Directive 2004/37/EC).

REACH applies without prejudice to these two laws. This means that all the obligations laid down in these Directives that have been carried over into the national laws of each EU member state still apply. All businesses in the EU therefore have to meet the requirements set by REACH as well as those laid down in the worker protection laws.

This should create synergies, and REACH should help make these Directives work to better effect:

- by generating the information needed to better protect workers, especially by improving risk assessment and risk management;
- improving the transmission of data and communication throughout the production chain;
- through authorisation and restriction procedures, encouraging replacement of the most dangerous chemicals by safer alternatives.

Workplace union representatives have a key role to play here. Not only will they have to ensure that REACH is applied without prejudice to the national worker protection laws, but also see that where the two sets of laws can interact, they do so in practice (see Part 4.)

But still a lukewarm success in trade union eyes

The European Parliament and Council's negotiation and adoption of REACH prompted an unprecedented flurry of lobbying. Trade unions worked throughout to improve the provisions on health protection for workers, consumers and the environment. They consistently called for a mandatory substitution principle (to drive business innovation) and for the registration dossiers to supply sufficient data on substances to ensure effective risk management.

This, however, was to reckon without the chemical industry ... which brought its full weight to bear on the various stakeholders to cut back the scope of the law reform and water down the final text of the Regulation compared to what it initially set out to achieve.

Even so, REACH does make some real progress, like reversing the burden of proof, Chemical Safety Reports, introducing a real communication system between suppliers and users in the supply chain, and stricter rules for using and marketing the most hazardous substances.

The following points still stand in need of future improvement, however:

- registration is required only for quantities of 1 tonne/year upwards about 1/3 of the 100,000 chemicals listed on the European market. At this volume level, REACH is worse than the legislation introduced in 1981 for "new" chemicals, which set the notification threshold at 10 kg/year;
- the information supplied by manufacturers in their registration dossiers is not properly quality-controlled;
- Chemical Safety Reports are required for substances produced in quantities above 10 tonnes/year (only about 1/3 of the substances subject to registration);
- the toxicological and ecotoxicological data required for the registration of substances produced in quantities between 1 and 10 tpa are not enough to really improve their classification and labelling;
- some carcinogens and mutagens can still be used even if there are safer alternatives. This
 is contrary to the EU worker protection laws (see Part 3);
- chemicals at the nanometre scale (nanomaterials) are not sufficiently covered by the REACH registration rules.



Does it apply to my firm?

REACH applies not only to the chemical manufacturing industry, but to all industries that use chemicals, like the textile, construction, woodworking, concrete, cement, glassmaking, brickmaking, paint, clothing, paper, electronics, carmaking and other industries. But it also applies to service industry workers, some of whom routinely use chemicals, like hospital and industrial cleaning workers.

The products that come under REACH are substances (white spirit, acetone, etc.) preparations (paints, glues, etc.), but also substances contained in preparations (solvent in paint or glue) and articles (flame retardants in office chairs, phthalates in toys, etc.).

So it is highly likely that REACH does apply to your firm.

The actors in REACH

The role of firms under REACH depends on the activity they carry out with a chemical. REACH distinguishes the following actors in the production chain:

- manufacturers of substances: means any natural or legal person established in the EU who manufactures a substance in one or more Member States. Manufacturing means production or extraction of substances in their natural state;
- importers of substances means any natural or legal person established within the Community who is responsible for the import of a substances. "Importing" means physical introduction into the customs territory of the European Union;
- producers of articles: means any natural or legal person established within

the EU who makes or assembles an article in one or more Member States. An "article" under REACH means any object that has been given a specific shape, surface or design so that it can be used for a specific purpose (e.g. manufactured goods such as cars, clothes and computer chips);

- **importers of articles**: means any natural or legal person established within the Community who is responsible for the import of an article;
- downstream users: means any industrial user of chemicals, whether formulators of preparations (e.g., paint producers) or users of chemicals such as oils or lubricants in other industrial processes or producers of manufactured articles (e.g., electronic components);
- distributor: means any natural or legal person established in the EU, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.

Companies that deal with chemicals may have more than one role under REACH, even for the same substance (see box).

In some circumstances, companies can also appoint representatives under REACH to carry out certain obligations, like third party representatives or only representatives 14.

Example of a titanium dioxide supply chain

Titanium dioxide (TiO₃), also known as titanium white, are downstream users for REACH. is a white pigment widely used as a bleaching agent and opacifier in products like paint, plastic, paper, ink, food time. For example, Company D, which formulates paint and toothpaste. It is also found in cosmetics and skin care products as well as in almost all sunscreens, where it upstream in the supply chain (see the example with helps protect the skin against ultraviolet rays. In 2006, it the TiO₂ supplied by B) and an importer for another was classified as possibly carcinogenic to humans (Group substance which it incorporates into its formulation if 2B) by the International Agency for Research on Cancer it sources that chemical from outside the EU, such as (IARC)*.

Company A which imports titanium dioxide (TiO₂) into the EU is an importer. Company B which produces tances that he markets if they are directly imported into TiO₂ in one EU country is a manufacturer. In our example, TiO₃ is sold to Company C, which uses it to make tinting pastes. Company D manufactures paint using C's paste. Both companies are downstream users. So too are company E, which manufactures window-frames and paints them with D's paint, and F, the professional painter who downstream user of the same substance if he buys ceruses that paint, because they use the substance as part tain quantities of the substance (in this case, TiO₂) which of their industrial or professional activities.

Note that a downstream user is not necessarily at the end of the supply chain. In our example, company E which a distributor but a downstream user. uses the paint is a downstream user along with companies C and D which are upstream in the production chain.

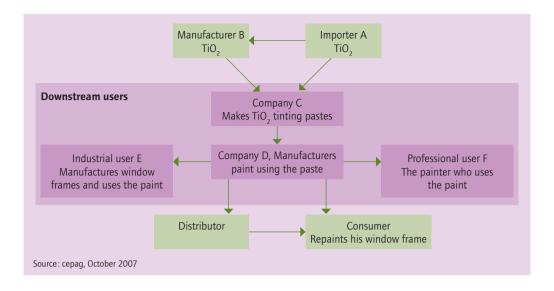
The distributor is the company that buys paint from D, stores it and places it on the market. Neither the distributor nor the consumer who repaints his window-frame

But a company can fulfil different roles at the same can be a downstream user for a substance purchased another pigment purchased in the United States.

A distributor can also be an importer for some substhe EU. In many cases, a manufacturer will also be a downstream user for the substances he purchases (e.g., company B, which produces TiO₂ is a downstream user for the reagent needed to manufacture it, for cleaning products, etc.). He may even be a manufacturer and he manufactures in Company A to build up stocks.

Under REACH, a firm that packages products is not

* See http://monographs.iarc.fr/ENG/Meetings/ 93-titaniumdioxide.pdf



What each actor has to do under REACH

The Regulation makes different requirements according to the role that your firm plays in the supply chain. The main obligations that each actor may have under the REACH rules are described below.

If your firm is a manufacturer/importer of substances, it must:

- 1. Register each substance with the European Chemicals Agency if it is manufactured or imported by it in quantities of 1 tonne or more per year. Any substance that is not registered cannot be manufactured or imported into the EU;
- 2. Notify the European Chemicals Agency before 3 January 2011 of the classification and labelling of all substances to be registered or classified as hazardous and placed on the EU market regardless of their production volumes;
- 3. Communicate down the supply chain on safety data sheets the information needed for the safe use of substances produced in quantities of 10 tonnes or more per year;
- 4. Request and obtain authorisation for the use and placing on the market of substances listed in Annex XIV of REACH the list of substances subject to authorisation;
- 5. Comply with the restrictions on use or placing on the market of substances included on the list of restrictions (Annex XVII of REACH).

If your firm is a producer/importer of articles, it must:

- 1. Register each substance with the European Chemicals Agency if it is present in articles in quantities above one tonne per year and if it is to be released under normal or reasonably foreseeable conditions of use (e.g., printer cartridges);
- 2. Notify the Agency of the presence of more than 0.1% (weight/weight) in an article of a substance of very high concern included in the list of candidate substances for authorisation. This requirement applies if the substance is present in articles in quantities above one tonne per year and if a human or environmental exposure cannot be excluded;

3. Communicate to industrial and professional users sufficient information for the safe use of articles that contain more than 0.1% (weight/weight) of a substance of very high concern included in the list of candidate substances for authorisation. This information must also be given to consumers at their request.

If your firm is a downstream user of chemicals, it does not have to register them but:

- It must check that its use of a substance is included among the "identified uses" in the 1. safety data sheet. If it is, it must take the risk management measures that have been attached to the safety data sheet for that use.
 - If it is not, the company has two options:
 - it can communicate a description of its use to the supplier in order to make it an identified use and enable him to add the appropriate risk management measures to the safety data sheet; or
 - if it wants to keep the use confidential, it must prepare its own Chemical Safety Report, implement the associated risk management measures and communicate them if need be to the next actor in the supply chain. It must also notify certain information to the Agency.
- It must obtain authorisation for a personal use of the substances of very high concern 2. listed in Annex XIV of REACH. For the use of such substances to be authorised, they must be obtained from a company that has received authorisation for that use and used in accordance with the conditions laid down in that authorisation.
- It must comply with the restrictions on use or placing on the market of substances 3. listed in Annex XVII of REACH — the list of restrictions.

If your firm is a distributor of chemicals, it must:

- Communicate the safety data to the supply chain via safety data sheets: 1.
- Comply with the restrictions on use or placing on the market of substances listed in 2. Annex XVII of REACH — the list of restrictions.

It is also worth noting that any of the above actors who place hazardous substances and/ or mixtures on the market also have classification and labelling obligations under the CLP Regulation.

A Navigator to find your way around REACH

The European Chemicals Agency (ECHA) has developed as dangerous?, etc. an interactive Navigator to help manufacturers, importers, downstream users, distributors of chemicals and im- question to help the Navigator user reply. A new Navigaporters of articles to find out what obligations they have tor session has to be run separately for each substance, under REACH and the CLP Regulation.

As REACH is based on substances, the Navigator provides a list of obligations for a specific substance. To access the Navigator http://guidance.echa.europa.eu/ The list of obligations is based on the answers the user navigator_en.htm

gives to a series of questions: e.g., is the substance manufactured or imported? In what tonnage? Is it classified

Additional explanations are provided for each as answers can differ from one substance to another.

What REACH means for your firm

Economic implications

Many firms, particularly small and medium-sized ones (SMEs), are still unaware of their obligations under REACH. If your firm fails to comply with these obligations, it could be acting unlawfully and run into legal and financial problems. In order to carry on manufacturing, importing or using substances, your firm will have to register them and may need to apply for authorisation from the European Chemicals Agency. If it does not, they will have to be withdrawn from the market, and that could seriously affect its business or industrial activities. Some manufacturing processes might have to be stopped or changed at short notice, supplies of some articles could be interrupted, etc.

If REACH does apply to your firm, it needs to start getting itself ready to comply with the Regulation's requirements now. Doing that will entail a fair amount of extra work and cost, especially for preparing registration dossiers, paying registration fees, getting any authorisation needed, or fulfilling the information obligations in the supply chain.

The idea is also that REACH will enhance the medium and long-term competitiveness of the European chemical industry. By encouraging firms to market chemicals that are less dangerous to human health and the environment, this legislative reform should drive innovation by European businesses, and enable them to get a competitive edge over companies elsewhere in the world.

If your firm is a downstream user of chemicals, it is also important for it to identify as soon as possible those substances of very high concern on its purchase list that are sourced from suppliers who might eventually drop out of the market as a result of REACH's authorisation and restriction procedures. Replacing them as soon as possible by safer alternatives could be a profitable strategy for your firm. Taking REACH into account in your firm is therefore a matter of economic life or death.

Health and safety at work implications

But REACH also has implications for worker protection, because the new rules have increased producers' liability. They now have to show that the chemicals they are placing on the market can be used safely. By making available and spreading around new knowledge about the dangers, exposures and risks of chemicals, REACH will enable improved measures to be taken for reducing the hazards of work. As mentioned above, REACH should also encourage firms to replace extremely dangerous substances by safer alternatives or processes. This should help bring down the still inordinately high levels of occupational diseases due to the use of chemicals in Europe. A study commissioned by the European Trade Union Confederation from the University of Sheffield has shown that REACH could spare the EU 90,000 cases of occupational diseases related to the use of dangerous substances each year¹⁵. This would translate into total average savings of 3.5 billion euros over ten years for the EU. These savings will benefit social security systems through reduced costs, workers through an improved quality of life, and employers across all sectors through avoidance of sickness absence-related lost productivity.

REACH to deliver 3.5 billion euros savings over 10 years, ETUC press release, 20 October 2005, http://www.etuc. org/a/1654

The benefits that REACH can deliver for workers' health will also depend on what synergies can be established between REACH and the existing worker protection laws in Europe. Below, we look in detail at the linkages between these two types of law.

Part 3 REACH and the EU worker protection laws

Two sets of laws that work together

As well as the REACH Regulation, which lays down the rules for placing on the market and using chemicals in the EU, there are also other EU laws that protect workers, especially those exposed to chemicals. The basic law is the 1989 Framework Directive on improving the safety and health of workers at work (89/391/EEC). Nearly two dozen individual directives have been adopted under it, covering a range of risk factors and different categories of workers¹⁶. Two of these individual directives concern exposure to chemicals — the Directive on the protection of workers from the risks related to exposure to chemical agents at work (Chemical Agents Directive 98/24/EC), and the Directive on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Carcinogens Directive 2004/37/EC).

The Chemical Agents Directive

The Directive on the protection of workers from the risks related to exposure to chemical agents at work (98/24/EC) was adopted on 7 April 1998. Better known as the Chemical Agents Directive, it covers all chemical substances and preparations produced or used at the workplace regardless of the quantities they are used in or their classification.

^{16.} On which, see Lone Jacobson, Viktor Kempa, Laurent Vogel (2006) Finding your way in the European union health and safety policy. A trade union guide, ETUI.

Under this, employers must:

- 1. Determine whether any hazardous chemical agents¹⁷ are present at the workplace;
- 2. If so, assess the risks arising from them;
- 3. If there are risks, take measures to prevent and reduce those risks. These measures are in order of priority:
 - replace the hazardous chemical agent by a chemical agent or process that is not hazardous or is less hazardous;
 - avoid or minimise the release of the hazardous chemical agent;
 - apply collective protection measures at the source of the risk (e.g.: ventilation);
 - apply individual protection measures (e.g. masks, gloves, glasses, etc.).
- 4. Provide surveillance of their workers' health;
- 5. Comply with existing occupational exposure limit values (OELV);
- 6. Evaluate the effectiveness of risk reduction measures implemented and update them on a regular basis.

On top of these, employers also have obligations to inform and train their workers.

The production, manufacture or use at work of some chemicals can be banned if they pose risks to workers' health. This has already been done in respect of four chemicals listed in Annex III of the Directive.

One important thing to note is that the EU worker protection laws do not apply to domestic workers or self-employed workers.

> The national laws implementing the Chemical Agents Directive in each EU Member State can be found at: http://eur-lex.europa.eu > Simple search > CELEX number 71998L0024

The Carcinogens and Mutagens Directive

The Directive on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (2004/37/EC) is the codified version of Directive 90/394/EC (known as the Carcinogens Directive), which it repealed along with all its subsequent amendments. It lays down an order of priority for employers' obligations to reduce and replace Category 1 or 2 carcinogens or mutagens as well as obligations to inform and train workers.

The first of these measures is the obligation to replace the carcinogen or mutagen by a substance which is not dangerous or is less dangerous. It must be replaced if it is technically possible to do so, irrespective of the cost. If replacement is technically impossible, the employer must ensure that the carcinogen or mutagen is manufactured or used in a closed system. If it is not possible for him to do this, he must ensure that the exposure of workers is reduced to as low a level as possible.

The Directive also provides for binding occupational exposure limit values (OELVs) to be established where possible. To date, limit values have been set under the Directive for only three substances — benzene, vinyl chloride monomer and hardwood dust¹⁸.

Revision of this Directive is under way but falling behind — the European Commission has been working on it since 2004. Under procedures, the social partners (European

^{17.} The definition of hazardous chemical agent is not limited to dangerous substances or preparations according to the criteria of Classification, Labelling and Packaging Regulation (EC) 1272/2008, but also includes fumes generated by processes or substances that become dangerous because of how they are used.

^{18.} A binding OELV was also established for asbestos under Directive 83/477/EEC.

employers and unions) have been consulted twice about possible changes and an impact assessment study is under way to assess the health, socio-economic and environmental aspects of the possible amendments. These include revised OELVs for the three existing substances, a new system to derive OELVs for new substances based on objective risk criteria, and extending the scope of the Directive to substances that are toxic to reproduction (reprotoxins). The Commission's draft revised Directive should be available in autumn 2010¹⁹.

> The national laws implementing Directive 2004/37/EC in each EU Member State can be found at: http://eur-lex.europa.eu > Simple search > CELEX number 72004L0037

Comparison of REACH and the worker protection laws

Regulation and Directive – different legal bases

Like all EU Directives, the Chemical Agents Directive and the Carcinogens Directive have been implemented by Member States by carrying over the obligations laid down by them into their national laws. REACH, on the other hand, is a Regulation, so its provisions — translated verbatim into all 23 official languages of the EU — are directly applicable in all Member States.

This is because the legal basis of REACH is Articles 94 and 95 of the EU Treaty, which provides for national laws to be fully harmonised, so that in theory Member States cannot impose further limitations at national level. By contrast, the legal basis of the worker protection laws is Article 137 of the Treaty, which aims only to harmonise Member States' laws at a minimum level, allowing states to impose higher standards than the EU rules. This means that Chemical Agents Directive and Carcinogens Directive requirements may vary from one country to another within the EU.

Applies along with other laws

REACH applies "without prejudice" to the worker protection laws (Article 2.4 of REACH). This means that REACH will affect neither the Chemical Agents Directive nor the Carcinogens Directive, and businesses will have to fulfil not just the REACH requirements but also those that have been carried over into each country's national law from the EU worker protection directives.

Applies to different areas

REACH applies to all chemicals produced in the European Union but also to substances produced elsewhere in the world that are exported to member countries of the EU, whereas the EU's the worker protection laws obviously do not apply outside the EU.

^{19.} See the "Chemicals" main topic on the site http://www.etui.org/

Scope

The Chemical Agents Directive applies to all chemicals and the Carcinogens Directive to all substances classified as carcinogenic or mutagenic (categories 1 and 2), regardless of the quantities used at the workplace. REACH, however, lays down requirements for registration and chemical safety assessment that depend on the quantity produced (see Table 2). It is important to note, however, that there is no exemption based on production volumes for the authorisation and restriction requirements of REACH. Similarly, the requirement to supply a safety data sheet for a substance classified as dangerous and the requirements to classify and label substances apply regardless of the quantities produced.

Table 2 Scope of legislation based on volumes

Legislation Depends on volume		Special Condition
REACH Regulation		
Registration	yes	All substances ≥1 t/year
Chemical safety assessment	yes	All substances ≥ 10 t/year
Authorisation	No	All substances of very high concern
Restriction	No	All substances for which risks are unacceptable
Safety data sheet	No	All hazardous substances and preparations containing dangerous substances
CLP (Classification, Labelling No and Packaging) Regulation		All hazardous substances or preparations put on the market
Chemical Agents Directive No		All substances present at the workplace
Carcinogens Directive	No	All carcinogens and mutagens (category 1 and 2) present at the workplace

A common focus: risk assessment.

The Chemical Agents and Carcinogens Directives place the responsibility for protecting workers' health and safety on employers. They have to identify, assess and control the risks of chemicals. Control is done first by eliminating the risks, or if this is not possible, minimising them. The cornerstone of this procedure is the risk assessment done by employers based on information provided on labels and in safety data sheets to identify and take risk management measures that are appropriate for the use of substances at the workplace. This is a written document, and workers and their representatives must also be consulted on what goes into it.

With REACH, manufacturers and importers of chemicals must assess the risks they pose not only to workers but also to consumers and the environment, and must give downstream users (often employers) indications on how to reduce those risks. REACH makes industrial operators who place substances on the market (manufacturers and importers being the start of the chain) responsible for obtaining and transmitting information on substances.

Even though REACH makes industrial operators responsible for developing risk management measures and annexing them to safety data sheets, this does not take away from employers' obligations under the Chemical Agents and Carcinogens Directives. Employers still have to assess the risks and decide how to control them at their own workplace. The additional information generated by REACH and transmitted throughout the supply chain should help employers improve their risk assessment under the worker protection directives.

The combined effects of REACH and the worker protection laws

There should not be any conflict between REACH and the worker protection laws (WPLs): the requirements of each piece of legislation strengthen and supplement those of the others. The Table 3 shows how these laws work together to form a comprehensive system for controlling risks related to exposure to chemicals in the workplace.

Table 3 The combined effects of REACH and the WPLs

	REACH	WPLs	Combined effects
Scope	REACH applies to most substances, mixtures and some articles that are manufactured or imported, placed on the market or used in the EU. Specific obligations are laid down for each actor in the supply chain. They depend on the dangers of the substance and the risks to workers, consumers and the environment, but also the quantities manufactured or imported. REACH requires that: — all substances manufactured or imported from 1 tonne/year upwards must be registered unless they are specifically exempted; — all registrations from 10 tonnes/year upwards must be accompanied by a Chemical Safety Report giving a detailed assessment of the risks associated with each specific use of the substance; — the use of "substances of very high concern" listed in Annex XIV of the Regulation must be specifically authorised; — restrictions may be imposed on any substance that poses unacceptable risks, including those that do not require to be registered; — for all hazardous substances or mixtures containing hazardous substances, all risk management measures identified in the Chemical Safety Report must be included in the safety data sheet supplied to all downstream users.	The Chemical Agents Directive applies to all chemicals manufactured or used at the workplace. Measures must be taken to control the risks of all hazardous substances and all non-hazardous substances that become hazardous because of the way they are used in workplaces, including substances derived from a process, like wood dust or welding fumes. The Carcinogens Directive applies to all carcinogens and mutagens (category 1 and 2) present at the workplace. It requires employers to replace them with safer alternatives or to take measures to control the risks.	Two complementary sets of laws which together cover all chemicals and share the aim of protecting workers.

Risk assessment	REACH makes manufacturers and importers responsible for ensuring that the safety data sheets describe the risk management measures needed to enable the substances they place on the market to be used safely. In some cases, downstream users have to fulfil manufacturers' and importers' responsibilities for compiling the information required by REACH.	The worker protection laws require employers to assess the risks to the health and safety of employees exposed to hazardous substances or non-hazardous substances that become hazardous. In some cases, employers also have to arrange appropriate health surveillance for their employees.	Each actor in the chemical manufacture, import, supply or use chain has responsibilities under REACH and under the worker protection laws. The risk reduction measures established by REACH will help employers to do the risk assessment required by the worker protection laws.
Reference values for exposure	REACH requires registrants of certain substances to define the exposure threshold below which the risks to human health are considered to be controlled (derived no-effect levels, DNELs). DNELs are used to establish the risk management measures that must be notified to downstream users. The DNELs are defined for each route of exposure (inhalation, dermal, oral) and each population (workers, consumers).	In the WPLs, the European Commission proposes indicative occupational exposure limit values (OELVs) for certain substances which member states must take into account when setting their own national OELVs for these substances. OELVs apply to workers exposed by inhalation. OELVs that are binding for all EU countries have also been set for some substances. As well as the OELVs set at EU level, most national laws also have OELVs for many other substances. They are binding on employers in most European countries.	DNELs and indicative OELVs are all based on health. DNELs are defined by registrants, indicative OELVs by a European Scientific Committee (SCOEL). Employers have to observe the DNELs established by registrants, but also existing national OELVs. If both a DNEL and an OELV that is binding at national level exist for the same substance, the employer must observe the lower value.
Risk control measures	REACH requires downstream users to comply with the risk management measures established by registrants. Authorisation and restriction procedures will reduce the number of extremely hazardous substances on the market.	The WPLs require employers to take measures to reduce identified risks. The Carcinogens Directive obliges employers to use safer alternatives if available.	The risks that workers are exposed to will be much better controlled. Many more hazardous substances will be taken off the market, which will encourage the development of safer alternatives.
Information and training	REACH will fill gaps in what we know of the hazards and risks of very many chemicals. This information, including risk management measures, must be supplied to employers. This will give them more information on the substances they use.	The WPLs require employers to provide workers with the information and training they need for the safe use of chemicals used at workplaces.	Together REACH and the WPLs will ensure that employers and workers will be better informed about the substances they use.

Source: adapted from *REACH and Chemical Agents Directive in the workplace - Guidance for employers on controlling risks from chemicals*, drawn up by the Luxembourg Advisory Committee's working group on chemicals (see www.etui.org)

How does the employer have to assess the risks?

Although they have to fulfil requirements under both REACH and the worker protection laws, this does not mean that employers incur a "double duty" — they will only have to do things once when doing their risk assessment. Below is a step-by-step guide to the chemical risk assessment as employers ought to be doing it under the European worker protection laws, also taking into account their obligations under REACH.

- 1. Identify the presence of substances at the workplace that are hazardous to workers or the environment.
- 2. Study the risk management measures proposed under REACH in the safety data sheet and the exposure scenarios associated with each hazardous substance used at the workplace.
- 3. Assess whether the use of the hazardous substance can be eliminated or replaced by a less hazardous substance or process. The employer should already have done this assessment under the Chemical Agents Directive (Articles 5.2 and 6), but REACH should give him more and more reliable information.
- 4. If exposure to hazardous substances cannot be avoided, continue to follow the Chemical Agents Directive requirements. In particular, the employer must:
 - Assess the risks to workers' health and safety taking into account: the hazardous properties of the substance (e.g., toxic, irritant, explosive, etc.); information collected from the supplier the safety data sheet for example; the level, type and duration of exposure, the quantity of the substance used, the conditions and constraints in which the substance is used; any national occupational exposure limit values (OELVs); and, where available, the conclusions to be drawn from any medical surveillance already carried out.
 - Continue to follow the requirements of the Chemical Agents Directive, which sets the following order of priority for prevention and control measures: (1) avoid or minimise the release of the hazardous substance (control of emissions at source); (2) apply collective protection measures at the source of the risk (good ventilation, appropriate organisational measures); (3) where exposure cannot be prevented by other means, apply individual protection measures.
- 5. If the use of the hazardous substance is not covered by an exposure scenario in the safety data sheet, inform the supplier (manufacturer, importer or distributor) of the proposed use of the substance to make it into an "identified use" and send him the information needed to help him prepare an exposure scenario as required by REACH.
- 6. Compare the risk control measures taken for the hazardous substance used at the workplace under the Chemical Agents Directive with the risk reduction measures arising out of REACH that are annexed to the safety data sheet.
 - An extended safety data sheet may contain new information on the substance and require the chemical risks to be re-assessed in line with the Chemical Agents Directive requirements. The employer must be able to show that the risk assessment is adequate, i.e., that all appropriate measures have been identified and applied to control the risks adequately based on the information provided by the supplier or derived from any other relevant source. Further assessment of exposures by sampling ambient air might be needed, for example.
 - If the employer can show that the measures to control the risks taken by him under the Chemical Agents Directive are sufficient to ensure that the exposure of workers does not exceed the derived no-effect levels (DNELs) recommended by the supplier

- in the safety data sheet, he need not apply any other control measures recommended by the supplier.
- If the employer considers that the risk reduction measures (or some of them) proposed in the safety data sheet are not appropriate, he must notify his supplier, who will then have to pass the information on through the supply chain right up to the registrant or the person who drew up the measures under REACH. The registrant can then check his risk assessment and adapt it to the information received if need be or confirm that the risk reduction measures initially proposed should remain in force.
- If the employer cannot show that the risk control measures he has put in place under the Chemical Agents Directive are adequate, he must adapt them to reflect the new information provided by REACH.
- Check that the final control measures put in place meet the requirements of the 7. worker protection laws, including the rules on substitution and the order of priority of risk reduction measures. The use of personal protective equipment must be confined to cases where the risks cannot be controlled by other means.
- If employers follow all the above steps, they should in most cases be in order with all 8. their obligations under REACH and under the EU worker protection laws. However, they may have additional obligations in certain particular circumstances.

Things to remember

REACH should deliver better protection of workers' ous chemicals off the market

Although REACH is a new regulation that intro- REACH.

duces a new way of thinking, the obligations of the EU worker protection laws continue to apply as before.

REACH does not give employers a "double duty". health and safety by increasing the information pro- Where employers already meet the requirements of the vided, establishing new channels of communication be- worker protection laws, in most cases they will only have tween employers and suppliers, and taking many hazard- to check their risk management and adapt it if need be to take account of the new information provided by

Employers' specific obligations

Compiling a Chemical Safety Report

If the use made of a substance by the employer (or downstream user) is not covered by an exposure scenario in the safety data sheet, he will have to draw up a Chemical Safety Report. This can occur in the following cases:

- Where the employer has provided his supplier with the information required to make it an "identified use" (see point 5 above) and the supplier has advised against that use for reasons related to protection of health or the environment;
- Where the employer does not inform his supplier of a specific use which is not covered by the conditions described in the safety data sheet exposure scenario (e.g., because it is confidential, or he has simply forgotten to inform the supplier).

As well as having an obligation to draw up the Chemical Safety Report himself, the employer also has to provide certain information to ECHA before beginning or continuing that specific use. This information includes the identity of the employer, the identity of the substance and its REACH registration number, the identity of the supplier and a general description of the use. These particulars do not have to be notified to ECHA if the substance is used in quantities below 1 tonne per year for this particular use.

Using substances that are of very high concern or subject to restrictions

REACH subjects substances of very high concern to authorisation. These substances include the carcinogens and mutagens that are listed in Annex XIV of REACH.

In most cases, authorisation to use a substance of very high concern should already have been obtained by an upstream actor in the supply chain (the manufacturer or importer, for example). In this case, the employer (or any downstream user) does not need to get a separate authorisation provided his use of the substance complies with the authorisation conditions described in the safety data sheet and if he has notified ECHA of his intention to use the substance within three months after the first delivery by the supplier.

An employer who wishes to use a substance listed in Annex XIV of REACH for a use that it is not authorised for must get an authorisation from ECHA before using it.

ECHA will keep a register of downstream users who are using the substances listed in Annex XIV of REACH. This information will be made available to Member States.

If a substance of very high concern has been refused authorisation for a specific use, an employer may not reapply for an authorisation for the same use. He must discontinue that use.

If a safer alternative is available, the Carcinogens and Mutagens Directive says the employer must use it instead. So the employer has an obligation to check whether a safer alternative is available for the intended use, even if the specific use has been authorised by REACH.

If substitution is not possible, REACH and the Carcinogens Directive require employers to reduce the exposure to substances listed in Annex XIV of REACH to as low a level as is technically possible.

Annex XVII of REACH lists the substances, preparations and articles whose marketing and/or use are restricted. All actors in the supply chain, including all employers, must comply with these restrictions.



REACH is an opportunity to get better management of chemical risks at workplaces and better protection for workers' health and safety and the environment. The combined effects of REACH and the worker protection laws should be to make chemical hazards better controlled and ultimately bring down the number of occupational diseases and deaths related to using hazardous substances.

Workers and their workplace reps can play a key role in making the most of what REACH can do and ensuring that chemical risks are better controlled. Practical things that can be done in any workplace where chemicals are used are described below.

Inventory of substances

To find out which substances might come under REACH, companies will need to make an inventory of all the chemicals they manufacture, import and/or use. REACH does not give them an express duty to make such an inventory, but there is no way of not doing it if they are to comply with their obligations under the Regulation.

This inventory should contain the following information for each substance:

- The identification data: trade name of the substance, identification numbers (CAS, EC, ELINCS/EINECS, etc.), IUPAC name, chemical formula.
- $\boldsymbol{-}$ The quantities manufactured, imported or used annually.
- The intended uses.

REACH applies to substances as such or contained in preparations or articles. In the latter case, in what concentration is the substance present in the preparation or article? If it is a polymer, from which monomer is it made?

- The role played by the company in relation to the substance: manufacturer, importer, downstream user or distributor?
- The hazards: how should the substance be classified according to the labelling or safety data sheet?

Action by union reps

The inventory of chemicals handled in the company, their uses and the quantities used are an invaluable source of basic information for preventing chemical risks. Most national laws require the inventory to be made available to workers or union reps. If your firm does not have an inventory, ask for it to be compiled for all substances (hazardous and non-hazardous). The REACH regulation is a good additional argument for getting your employer to supply an inventory of chemicals.

Labelling

The label is the first place to look for information on a chemical substance or preparation. In the EU, all substances or preparations placed on the market must carry a label that complies with the Classification, Labelling and Packaging Regulation (Regulation (EC) No. 1271/2008) which came into effect on 20 January 2009.

If the substance or preparation is classified as hazardous, the supplier must ensure that the label is Regulation-compliant and contains all the necessary information, including:

- the product identifiers (chemical name or trade name);
- the supplier's identity (name, full address and telephone number of the manufacturer, importer or distributor);
- the hazard pictograms (there are nine possible ones which will eventually replace the old black symbols on an orange background);
- the hazard statements (equivalent to the R phrases in the existing legislation);
- precautionary statements (equivalent to the S phrases in the existing legislation);
- additional information (equivalent to the additional risk phrases in the existing system).

The hazard classification of the chemical substance/preparation is the responsibility of the manufacturer, importer or downstream user ("self-classification") unless the substance has a classification harmonised at Community level. If it does, the supplier has to apply it. The classification of approximately 8,000 hazardous substances has been harmonised at EU level. The list of these substances is included in Annex VI of the CLP Regulation.

REACH's requirements to register substances produced in quantities above one tonne per year will improve information on the toxicological and ecotoxicological properties of around 30,000 chemicals. This should have an effect on how they are classified and gradually reduce the number of hazardous substances that are marketed without being properly labelled.

REACH and the CLP Regulation also require manufacturers and importers who place a hazardous substance on the market — irrespective of its production volume — to notify its classification and labelling to ECHA (unless that information has already been supplied in a registration dossier). ECHA will include this information in a classification and labelling inventory which will be regularly updated and made publicly available on its website.

This inventory will contain basic information on tens of thousands of chemical substances and preparations, including the list of 8,000 hazardous substances that have a harmonised classification. It will identify disagreements over classification and labelling of the same substance on the market by different suppliers and will help Member States (or manufacturers themselves) in calling for a harmonised classification. Where a substance has been classified in some but not all hazard classes or categories, the inventory will also give clues as to the reasons for the missing classification, including whether the data are available or not. This is particularly important in knowing whether the substance is not classified because testing was not done, or because the tests indicated no hazards.

Action by union reps

- Make sure that workers in your firm can access the labels of all substances and preparations used. They contain
 essential information on their dangers and safety precautions.
- Make sure that workers in your firm understand what the labels say. If they don't, insist that your employer
 provides training, reminding him that he has an obligation to do so under the worker protection laws.
- If your firm puts hazardous substances or preparations on the market, remind your employer that he has obligations under the CLP Regulation (classification and labelling) and REACH (notifications to ECHA).
- Check the classification and labelling inventory on the ECHA website to find additional information on the substances and preparations you use. Where the classification that you have for a product differs from that shown in the inventory, insist that your firm updates the labelling.
- If you find from the inventory that a hazardous substance used by your firm is not classified as carcinogenic, mutagenic or toxic to reproduction (category 1 or 2) because the information is missing (tests not performed), insist that it be eliminated or replaced by a non-hazardous substance. If your employer cannot replace it, insist on risk reduction measures equivalent to those used for CMR (category 1 or 2), like working in a closed system.

Safety data sheets

The person (manufacturer, importer or distributor) responsible for placing a hazardous substance or preparation on the market must provide a safety data sheet (SDS) to every customer who is a professional user. This was already an obligation under previous EU law, and has been included in the REACH regulation with some additional requirements aimed at improving the quality of information provided in the SDS.

SDS have a standardised layout comprising 16 headings (see Table 4) and must be provided free of charge in printed or computerised form in the official language of the Member State in which the hazardous substance or preparation is placed on the market. They are the main means of providing professional users with all the information needed to protect the environment and health and safety at work.

The main improvement that REACH has made to the SDS is for substances for which a Chemical Safety Report (CSR) is required in the registration dossier (substances produced in quantities equal to or greater than 10 tonnes/year) and which are classified as hazardous or evaluated as PBT or vPvB (Persistent Bioaccumulative and Toxic / very Persistent very Bioaccumulative).

In such cases, the SDS must contain an Annex detailing the exposure scenarios for each identified use of the substance. An exposure scenario is a series of data describing the conditions under which the risks associated with an identified use of the substance can be controlled throughout its life cycle. It contains the operational conditions (duration and

frequency of use, quantity used, temperature, etc.) and the risk management measures (ventilation, type of gloves, wastewater disposal, etc.). A specimen exposure scenario that complies with the REACH requirements is contained in the Annex (see p. 40). New SDS including exposure scenarios will gradually replace the data sheets currently found in workplaces.

Table 4 Main changes made by REACH to safety data sheets

SDS headings	Changes made by REACH
1. Identification of the substance/preparation and of	Indication of the registration number assigned to the
the company/undertaking	substance by ECHA
2. Hazard identification	Clear distinction between hazardous and non-hazardous preparations. The substance's classification must be consistent with that provided to ECHA for the classification and labelling inventory
3. Composition/information on ingredients	Headings 2 and 3 of the old SDS have been swapped around
4. First aid	
5. Fire-fighting measures	
6. Accidental release measures	
7. Handling and storage	
8. Exposure controls/personal protection	OELVs plus mention of any DNELs and PNECs (see glossary)
9. Physical and chemical properties	
10. Stability and reactivity	
11. Toxicological information	Summary of information from the registration dossier for the substance
12. Ecological information	Indication of the results of the PBT assessment
13. Disposal considerations	
14. Transport information	
15. Regulatory information	Mention of the existence of a Chemical Safety Report and any authorisations or restrictions associated with the substance
16. Other information	Mention of any uses of the substance advised against
Annex (when a CSR is required in the registration dossier)	Exposure scenarios detailing the operational conditions and risk management measures

Action by union reps

- See that workers in your firm can access all the SDS for the substances and preparations used.
- If any SDS are missing, ask the suppliers for them. If an SDS dates from before REACH came into force (June 2007), ask the suppliers for the updated version that complies with the Regulation.
- Make sure that workers understand and use what the SDS says. If they don't, insist that your employer provides training, reminding him that he has an obligation to do so under the worker protection laws.
- Make sure that the risk assessment done by your employer complies with that described above.
- If a REACH registration number is shown on the SDS (line 1) you will find useful additional information on the substance on the ECHA website*.
- If the SDS includes exposure scenarios, check whether the use of the substance or preparation in your firm is actually covered by one of these scenarios.
- If your use is covered, insist that the supplier's recommended risk management measures are properly put in
 place in your firm. If you don't think these measures are appropriate for your use, tell your employer so that he
 can ask the supplier for an adapted safety data sheet.
- If the use of the substance or preparation in your firm is not covered by an exposure scenario, remind your employer that he:
 - can notify the supplier (to make it an identified use and enable him to adapt his SDS); or
 - must himself draw up a Chemical Safety Report and provide certain information to ECHA before continuing with this specific use (see above).
- If SDS Heading 8 (Exposure Control/Personal Protection) contains both a nationally-set occupational exposure limit value (OELV) and a supplier's recommended derived no-effect level (DNEL) for the same duration and route of exposure, insist that your employer puts in place the protective measures needed to ensure that workers are not exposed to anything higher than the lower of the two values.
- *http://apps.echa.europa.eu/registered/registered-sub.aspx

Elimination and replacement

REACH means that industrial operators have to obtain authorisation to use and market substances of very high concern included in the candidate list for authorisation (shortened to just "candidate list")²⁰ and then transferred to Annex XIV of the Regulation (the list of substances actually subject to authorisation). This lengthy, costly and uncertain procedure — authorisation may not be granted — was designed to encourage industrial operators to eliminate the most hazardous substances on the market or to replace them with safer alternatives. REACH also includes a system for banning the manufacture, marketing or use of certain hazardous substances (see Annex XVII of the Regulation, also called the list of restrictions).

Also, the specific the EU worker protection laws put elimination and replacement first in the order of priority of control measures to protect workers against the risks related to the use of chemicals. The Carcinogens Directive (2004/37/EC) says that carcinogens and mutagens actually have to be replaced if it is technically possible to do so, no matter the cost. The Community provisions on eliminating and replacing hazardous substances at the workplace have been implemented into the national laws of all EU countries.

Even though these are legal obligations, the unfortunate fact is that replacement is not yet being done in all cases. Very many businesses are still using extremely hazardous substances, at best under confinement or with emission control, sometimes with personal protective equipment, and at worst with no protection whatever.

REACH offers a great opportunity to remind employers of their legal obligations to protect workers' health, and to encourage them to eliminate or replace the most hazardous substances by safer alternatives.

In March 2009, the European Trade Union Confederation (ETUC) has put together a list of chemicals that unions want prioritised for authorisation under REACH²¹. The list contains 306 substances of very high concern, including 191 that are known to cause recognised work-related diseases. A year on, 24 chemicals on the ETUC list featured among the 30 officially-listed candidate substances.

As well as identifying substances that are apt to be candidate-listed in future, the union list goes further in ranking chemicals by reference to their intrinsic toxicological properties, and identifying those that cause recognised occupational diseases at EU level.

Action by union reps

- Make a list of the substances of very high concern used in your firm (CMRs, PBTs, endocrine disruptors, etc.) to help get them eliminated or replaced by less hazardous alternatives.
- If the substance is a category 1 or 2 carcinogen or mutagen, make sure your employer complies with the order
 of priority of obligations in the Carcinogens and Mutagens Directive (2004/37/EC), including replacing them
 by a safer alternative if it is technically possible, whatever the cost.
- If the substance is toxic to reproduction, persuade your employer to also replace it by a safer alternative if there is one available.
- If the substance is included on the list of candidate substances for authorisation under REACH (the candidate list), remind your employer that he has information obligations towards his customers and ECHA. These obligations also apply to preparations and articles that contain this substance. Advise him to eliminate or replace that substance as soon as possible.
- If the substance is included on the list of substances subject to authorisation under REACH (Annex XIV), remind your employer that he has to apply to ECHA for authorisation before starting (continuing) to use it*.
 Advise him to eliminate or replace that substance as soon as possible.
- If the specific use of a category 1 or 2 carcinogen or mutagen is covered by an authorisation under REACH
 and if there is a technically possible safer alternative, remind your employer that he is obliged to use the
 alternative.
- If the substance is included on the union list of priority substances for authorisation under REACH or the register of intentions on the ECHA website**, remind your employer that it is highly likely to feature in future on the Annex XIV candidate list (authorisations) or Annex XVII (restrictions) of REACH. Advise him to eliminate or replace that substance as soon as possible.
- * For more on these obligations, http://echa.europa.eu/doc/candidate_list/candidate_list_obligations.pdf
- **http://echa.europa.eu/chem_data/reg_intentions_en.asp

^{21.} The union list is available on-line at http://www.etuc.org/a/6023

Elimination and replacement: how it's done

Three steps for replacing one substance by another:

- 1. Identify alternatives: look for alternative processes that do away with the need to use a chemical, or replacement substances if elimination is impossible. There may be many readily-available alternatives, for example, where the substance to be replaced is used in a common process like spray painting or degreasing;
- 2. Compare the alternatives: assess the risks of all these solutions, as well as the substance and the process used, and compare the results. Check national safety and health at work, environmental protec- The plus-points of replacement tion and product safety rules to ensure that all solutions are legal and compatible. Set the minimum Eliminating the use of hazardous substances or replacing standards to be achieved:
- 3. Take the decision: decide on the basis of the re- The benefits of elimination or replacement include: gulatory requirements (including REACH), technical 1. feasibility, potential impacts on product quality, costs, especially the investment and training re- 2. quired to use the new product. Remember that for 3. trade unions, reducing the impact on health and the environment must come first.

Where can you find information on alternatives?

Replacement remains an under-used risk reduction strategy. But there is a wide range of information available, especially on the Internet, where examples of successful replacement by companies, governments and private organisations can be found.

- The "Good Practice" page on the European Agency for Safety and Health at Work's website is a good starting point: http://osha.europa.eu/good_practice/risks/ dangerous_substances/
- The Danish Ecological Council's "Hazardous substances can be substituted" report contains many examples of successful replacement: http://www.ecocouncil.dk/ english/
- The French Agency for Environmental and Occupational Health and Safety (AFSSET) also has a first-rate site on replacement of CMRs (also in English and Spanish): http://www.replacement-cmr.fr/

them by less harmful products pays dividends all round.

- Immediate and long-term improvements in the health of workers exposed to hazardous substances;
- A reduction in environmental pollution;
- Cutting business costs through:
 - a reduction in sick leave;
 - lower spending on control measures;
 - reduced insurance costs;
 - savings on protective equipment;
 - reduced consumption of the chemical;
 - use of cheaper materials;
 - more efficient manufacturing processes.

Source: Elimination and replacement of hazardous substances at the workplace (2003) European Agency for Safety and Health at Work, Facts No. 33

Glossary

Α

Article

An object composed of one or more substances or one or more preparations, which during production is given a specific shape, surface or design which determines its final use more than does its chemical composition. Examples: computer, book, toy, car.

В

Bioaccumulative (substance)

Bioaccumulative substances tend to concentrate in the tissues of living organisms and to biomagnify – i.e., pass up the food chain. Example: dioxins.

Biocide

Refers to a wide range of chemical product types that include pesticides and antibiotics for medical, veterinary, household and industrial use, non agri-food disinfectants, etc. The Biocidal Products Directive (98/8/EC) defines biocides as: "Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means." The Directive contains a comprehensive list of 23 product types .

(Bio)persistence

Refers to the time for which a substance (particle, fibre, etc.) remains or is retained in body tissues or organs.

С

Carcinogen, carcinogenic

Something that can cause cancer.

CAS

The CAS number or CAS registry number of a substance is its unique index number in the database

of the Chemical Abstracts Service (CAS), a division of the American Chemical Society (ACS). The CAS assigns these identifiers to every chemical that has been described in the literature. The CAS also maintains and markets a database of these chemicals known as the CAS Registry. Approximately 30 million compounds have been assigned a CAS number to date. About 4,000 new numbers are added every day. The intention is to make database searches more convenient, as chemicals often have many names. Almost all molecule databases today allow searching by CAS number.

CMR substances

Substances that are carcinogenic, mutagenic or toxic to reproduction under the Directive on the classification, labelling and packaging of hazardous substances (67/548/EEC).

CSR: Chemical Safety Report

The chemical safety report documents the chemical safety assessment for a substance on its own, in a preparation or in an article or a group of substances. In other words, the Chemical Safety Report (CSR) is a document, which details the process and the results of a Chemical Safety Assessment (CSA). Annex I of the REACH Regulation contains general provisions for performing CSAs and preparing CSRs.

D

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.

DNEL (level)

Derived No-Effect Level: the level of exposure to the substance below which no adverse effects on human health are expected to occur.

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.

Ε

EINECS number

The EINECS number is used to identify a chemical substance listed in the European Inventory of Existing Commercial Chemical Substances. The list is closed and contains 100 204 substances put on the EU market between 1 January 1971 and 18 September 1981 (see http://ecb.jrc.it/esis/).

ELINCS number

The ELINCS number is used to identify chemicals listed in the European LIst of Notified Chemical Substances. These are substances that became commercially available after 18 September 1981.

Exposure Scenario

Describes how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control exposure of humans and the environment, including operational conditions and risk management measures. These exposure scenarios can also cover one specific process or use or several processes or uses as appropriate.

1

Identified use

A use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user.

Importer

Any natural or legal person established within the Community who is responsible for importing chemicals.

IUPAC

The International Union of Pure and Applied Chemistry (IUPAC) is a nongovernmental organisation concerned with advancing the chemical sciences. Its members are national chemistry societies. It is the recognised authority for developing rules to be adopted for the nomenclature, symbols and terminology of chemical elements and their derivatives through its Interdivisional Committee on Nomenclature and Symbols which sets the IUPAC nomenclature. See http://www.iupac.org/

M

Manufacturer

Any natural or legal person established within the Community who manufactures a substance within the Community.

Monomer

A substance which is capable of forming covalent bonds with other like or unlike molecules in a polymer-forming reaction. Glucose is the monomer of starch

Mutagen

Something that creates mutations.

0

Occupational exposure limit value (OELV)

Some jobs expose workers to concentrations of substances in workplace air (gases, vapours, aerosols, etc.) that can be harmful to their health. Zero exposure to a pollutant is all-but impossible to achieve without banning all use of the polluting product. Preventing the occurrence of occupational diseases due to exposure to such pollutants means minimising and setting limits on exposure to it. This is done by defining airborne concentrations that must not be exceeded. These are the occupational exposure limit values (OELVs). For more details, http://osha.europa.eu/good_practice/risks/ds/oel/

P

PBT substances

Persistent, bioaccumulative and toxic within the meaning of Annex XIII of REACH.

Pesticides

Chemicals used to destroy harmful plants and

organisms (pests). They include fungicides, herbicides and insecticides.

PNEC (concentration)

The Predicted No-Effect Concentration is estimated from laboratory tests. It represents a concentration below which the substance is not expected to have any harmful effects on the environment.

Polymer

A substance consisting of molecules characterised by the sequence of one or more types of monomer units. The molecules are distributed over a range of molecular weights. Differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer can be natural or obtained by chemical modification of a natural polymer, or fully synthesised by chemical or enzymatic polymerisation. Examples: Cellulose, starch and proteins are natural polymers. Polyvinyl chloride (PVC), polyethylene (PE), polypropylene (PP) are industrial polymers.

Preparation

A mixture or solution composed of two or more substances. Example: paint.

S

Safety Data Sheet (SDS)

The safety data sheet is the main tool used in industry for communicating information on the hazards of hazardous substances and preparations through the supply chain. Annex II of REACH explains what information should be included under each of the 16 safety data sheet headings.

SIEF

Substance Information Exchange Forum. A SIEF is a forum to help registrants wanting to register the same substance. It facilitates data sharing between companies and avoids duplication of studies (testing not needed), and agrees on the classification and labelling of substances. SIEFs are run by industry, not by the European Chemicals Agency.

Substance

A chemical element and its compounds (natural or manufactured) including any additive and/or impurity but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. Example: Carbon is a substance because it is a chemical element. Calcium carbonate is a substance because it is a single compound.

Substances of Very High Concern

REACH classes substances as "of very high concern" (SVHC) if they are identified as: category 1 or 2 carcinogens, mutagens or reprotoxins (CMRs) under Directive 67/548/EEC; persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), according to Annex XIII of the Regulation; other substances which do not meet the above criteria but may disrupt the endocrine system or have PBT or vPvB properties.



vPvB substances

Very persistent and very bioaccumulative within the meaning of Annex XIII of REACH.

Annexes

Sample exposure scenario for a preparation for use in a professional cleaning product

1	Short Title of ES	Public Domain (SU22) Washing and cleaning products (PC35) Spraying outside industrial-professional settings and/or applications (PROC11)
2	Processes and activities covered in the ES	 The product is supplied as a concentrated solution to be diluted with water by the user The diluted product is sprayed onto surfaces to be cleaned. An appropriate trigger sprayer is used The product is then removed from the surface by wiping When the cloth is wet, it is rinsed out in water and thoroughly wrung The rinse water is changed at least every hour The equipment is cleaned
Ope	rational conditions of u	se
3	Duration and frequency of use	Workers (professionals): 8 hours/day, 5 worked days/week Consumers: The product is not intended for consumer use Environment: Up to 365 days per year
4.1	Physical form of the substance or mixture; ratio surface area/amount of articles	The product is a liquid. Aerosols may be formed during application
4.2	Concentration of substance in the mixture or article	The concentrations of the classified substance in the concentrate supplied are: A (surfactant): 6% B (solvent): 2% C (perfume): 0.3%
4.3	Amount used per time or per activity	Workers (professionals): 2 kg/d Consumers: The product is not intended for consumer use Environment: -
5	Other relevant operational conditions of use	Workers (professionals): Product concentration in the cleaning solution: 1% (relevant for inhalation and skin exposure) Temperature: room temperature, i.e., 20°C (relevant for inhalation). May vary between 15 and 30°C Repeated brief contact with the skin 12 times an hour for 30 seconds a time (relevant for skin exposure), making a total contact time of 0.8 h/day Environment: It is assumed that the entire product will be disposed of in wastewater. If the wastewater is not discharged through the sewage system, the capacity of receiving waters should be at least 1 000 m³/d

Risk Management Measures (RMM)				
Human health related RMM (workers and consumers)	Inhalation exposure: No action required Skin exposure: Gloves - e.g., latex gloves or similar material – to be worn when diluting the product Oral exposure: No oral exposure is expected The product is not intended for consumer use			
Environment related RMM	Preferably dispose of the cleaning water down the drain. Do not dispose of the cleaning water into small watercourses or water bodies			
Waste management related measures	No action required			
rmation on predicted ex	posures and guidance for downstream users			
Prediction of exposure and reference to sources used	Exposure of workers Inhalation: Inhalation exposure predicted by ECETOC TRA Risk-relevant compounds: A + C: A: 75 mg/m³; C: 2 mg/m³. ECETOC results adjusted for the actual concentration in the cleaning solution Skin exposure: Systemic skin exposure predicted by the HERA approach Risk-relevant compounds: A + C: A: 15.2 mg/kg bw/day, C: 1.8 mg/kg bw/day Local skin exposure: During dilution, the concentration of A (6%) is higher than the DNEL (1%) for local effects Environmental exposure: Not applicable			
Guidance to downstream user to evaluate whether he is working within the boundaries set by the ES	Norker Inhalation: Safety of use relative to inhalation is achieved irrespective of dilution of the product. Skin exposure: See that the product is diluted in a ratio of at least 1 to 10 before using it to clean. Use a bucket of water with a minimum capacity of 10 litres to clean the cloth frequently. Change the water in the bucket at least every hour. Do not use more than 2 kg of product a day. Use a trigger sprayer to apply the product Environment Preferably dispose of the cleaning water down the main. Do not dispose of the cleaning water into small watercourses or water bodies			
	Human health related RMM (workers and consumers) Environment related RMM Waste management related measures rmation on predicted ex Prediction of exposure and reference to sources used Guidance to downstream user to evaluate whether he is working within the boundaries set by			

Source:BERPC

Checklist on your firm's chemicals policy and what REACH will add

Things to ask your employer or yourself about your firm's chemicals policy	What REACH will add
Has the employer made an inventory of substances and preparations (hazardous or not) used at the workplace?	
Are they correctly labelled?	REACH will gradually help achieve uniformity in labelling. Consult the ECHA database (from mid-2011).
Have the workers been given information and/ or training on the use of hazardous substances and preparations?	REACH will ultimately improve knowledge about chemicals and the management of risks associated with their uses.
Does the firm have a safety data sheet for each hazardous substance and preparation? Have updates been received?	REACH will supplement and improve the SDS with additional data.
Is the firm applying the risk management measures annexed to the SDS?	REACH requires risk management measures to achieve adequate control to be annexed to the SDS.
Are the risk management measures proposed in the SDS appropriate to the firm?	REACH requires information to be supplied downstream and upstream in the supply chain.
Is the firm going to compile its own Chemical Safety Report (CSR)?	REACH enables downstream users to compile their own CSR in some cases.
Are the exposure limit values being observed in the workplace? Are there any substances for which derived no-effect levels (DNELs) have been established?	REACH will lead industry to develop DNELs for a large number of chemicals.
Are hazardous products being replaced by less hazardous ones? Are less hazardous alternatives being looked for?	REACH requires hazardous substances to be replaced in certain conditions.
Is the firm using substances that will be subject to authorisation?	REACH establishes an authorisation system. On 30 March 2010, ECHA published on its website an updated list of candidate substances for authorisation (the "candidate list"). The list contained 30 candidate substances. Other chemicals will be regularly added to. The list is available on http://echa.europa.eu/chem_data/candidate_list_en.asp
Can the substance subject to authorisation be replaced?	Look for alternatives. Point out the inconsistency between REACH and the worker protection laws.
Has ECHA made an authorisation dossier publicly available for any substance(s) used by the firm?	Consult and comment on the authorisation dossier if you can (possible alternatives).
Is the firm complying with the conditions of authorisation?	If there are no alternatives, consult the conditions of authorisation in the ECHA database.

The structure of the REACH Regulation

The REACH regulation, which has 849 pages in the version published in the *Official Journal*, is divided into 15 titles.

You can download the full text of the Regulation at http://eur-lex.europa.eu > Simple search > Official Journal > 2006/12/30 - L/396

Title I	Aim and scope of the Regulation. Contains all the definitions used in it.
Tiles II to V	Obligations to register substances (Title II), procedures for data sharing to avoid unnecessary animal testing (Title III), information obligations within the supply chain (Title IV), chemical safety assessments by downstream users (Title V).
Title VI	Evaluation. Three types of evaluation are defined: dossier evaluation, substance evaluation and evaluation of intermediate.
Title VII	Authorisation system and procedures for including substances on the list of substances subject to authorisation (Annex XIV).
Title VIII	Restrictions on the marketing and use of certain hazardous substances and preparations.
Title IX	Details the fees and charges and their allocation between the Agency and the competent authorities. See also Regulation (EC) No. 340/2008.
Title X	All about the European Chemicals Agency: composition, tasks, Management Board, Executive Director, committees, forum, Board of Appeal, budget, etc.
Title XI	Production of a classifications and labelling inventory by ECHA. See also CLP regulation (EC) No. 1272/2008.
Title XII	Requires the Commission to report and establishes the right of access to information held by the Agency.
Title XIII	Competent authorities.
Title XIV & XV	Enforcement and transitional and final provisions.

There are 17 annexes to the Regulation:

Annex I	General provisions for assessing substances and preparing Chemical Safety Reports. It defines the format for the Chemical Safety Report.
Annex II	Guide to the compilation of safety data sheets. Annex II has been recently revised (see http://register.consilium.europa.eu).
Annex III	List of criteria for determining the substances registered in quantities between 1 and 10 tonnes for which a complete dossier is required (in accordance with Annex VII).
Annex IV	List of substances exempted from registration because there is enough information available about them to consider them as causing minimal risk. Annex IV has been recently revised, see Regulation (EC) No. 987/2008.
Annex V	List of substances for which registration is not considered as appropriate or necessary. Annex V has been recently revised, see Regulation (EC) No. 987/2008.

Annex VI to XI	Details of the information to be submitted for registration and evaluation. The standard requirements for quantities at the lowest level are listed in Annex VII, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. The recently-revised Annex XI (see Regulation (EC) No. 134/2009) contains the general rules for adapting the standard testing regime set out in the previous Annexes. The precise information requirements differ for each registration according to tonnage, use and exposure. The Annexes therefore have to be considered as a whole and in conjunction with the overall requirements of registration, evaluation and the duty of care.
Annex XII	General provisions for downstream users to assess substances and prepare chemical safety reports for uses not covered by the Safety Data Sheet provided to them.
Annex XIII	Definition of criteria for identifying persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances. Annex XIII is currently under revision.
Annex XIV	List of substances subject to authorisation (as yet empty).
Annex XV	Sets out general principles for preparing dossiers to propose and justify (1) harmonised classification and labelling of CMRs, respiratory sensitizers and other effects on a case by case basis (2) identification of PBTs or vPvBs, or a substance of equivalent concern, (3) restrictions on the manufacture, placing on the market or use of a substance within the Community.
Annex XVI	Guidance for the preparation of socio-economic studies in support of an application for authorisation.
Annex XVII	List of restrictions on the manufacture, placing on the market and use of certain hazardous substances, preparations and articles. See also regulation (EC) No. 552/2009.