



Premier Farnell

**Step-by-Step Guide
to the
REACH
Regulations**

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REACH Regulations

A Premier Farnell Company



Farnell

Guide to compliance with the EU REACH Regulations

The EU REACH regulations were adopted in December 2006, and came into force on 1st June 2007. REACH is a regulation which many companies in the European Union (EU) will have to comply with. There is no Member State legislation required to implement REACH, except to define enforcement and penalties. REACH was introduced because many thousands of chemicals are used in the EU, some in very large quantities, but the risks to human health and to the environment from many of these are not widely known. REACH intends to address this by making manufacturers and importers of chemicals responsible for producing data to define the hazards and risks from around 30,000 substances that are manufactured or imported in quantities of 1 tonne or more per year in the EU. This document explains the REACH regulations and gives guidance on how manufacturers and importers need to comply.

Background:

- The number of incidents of allergies, asthma, certain types of cancer, and re-productive disorders are on the increase in Europe and chemicals are considered as one possible cause
- If REACH succeeds in reducing chemical-related diseases by only 10%, the health benefits are estimated at €50 billion over 30 years
- 100,106 chemicals were reported to be on the market in 1981, the only time that chemicals have been listed in the EU
- The chemicals sector is the third largest manufacturing industry in the EU, encompassing 31,000 companies and 1.9 million people
- Internationally, the EU is the leading chemicals producing area, its €580 billion representing 33% of global sales
- For 99% of chemicals (by volume), information on properties, uses and risks is sketchy. There is no data for about 21% of them, and another 65% come with insufficient data. Only 3% have been fully tested
- The costs of registration, including the necessary testing, are estimated at €2.3 billion over the 11 years that it will take to register all the substances covered by REACH. The total costs, including those to downstream users, are estimated at €2.8 billion to €5.2 billion, depending on the extent to which registration costs will increase prices of chemicals and the costs of substituting chemicals that will be withdrawn
- REACH replaces 40 existing pieces of legislation

Data Source: European Commission



Q1: What does REACH stand for?

A: Registration – the necessity to submit a (technical) dossier on the properties of a substance. Q3 explains who will need to register. Evaluation – of the dossier by the authorities.

Authorisation and restriction – on the use of a substance or preparation of **CH**emicals.

Q2: Who is affected by REACH?

A: REACH is far-reaching legislation that will affect manufacturers and importers of **substances** (chemicals) **preparations** (mixtures or solutions of substances), as well as distributors of chemicals and manufacturers and importers of **articles**.

An article is the term used by REACH to define items whose form defines their function to a greater degree than their composition. An easy example is a polystyrene cup. Although it is pure polystyrene, its form (a cup shape) means that it is an article not a substance. Common industry examples are packaging, electronic components, wire, PCBs and finished equipment. By contrast, solders, alloys, paints and adhesives are examples of preparations or mixtures of substances.

There will be cases where it is not clear whether an item is an article (i.e. the substance is an integral part) or a substance in a container. The ECHA guidance provides detailed criteria by which to judge such cases. Printer cartridges and liquid filled thermometers are classic borderline cases. The former is seen as containing a substance (ink or toner) in a container, the latter is seen as an article containing a substance (the temperature indicating liquid) as an integral part.

Summary, REACH affects:

- **Manufacturer / Importer** – you manufacture or import a substance on its own or in a preparation of 1 tonne or more per year
- **Producer / Importer or supplier of articles** – you produce or import articles
- **Distributor (including retailers)** – you store and place on the market a substance, on its own or in a preparation
- **Downstream User** – you use a substance, either on its own or in a preparation, in the course of industrial or professional activities (for example: formulation, dilution, repackaging, spraying, painting).

Q3: Who is responsible for registration of chemicals?

A: All manufacturers and importers of substances, preparations and substances in articles that are “intentionally released” during use. There is a lower weight limit of 1 tonne per manufacturer / importer per year for registration to apply.

There is a requirement for manufacturers and importers of substances to register them with the European Chemicals Agency, ECHA, based in Finland. (<http://echa.europa.eu>). In order for a substance to be registered, the registrant will need to submit data that is specified by the REACH regulations. It is not possible to register a substance without the required data and unregistered chemicals cannot be manufactured or supplied within the EU beyond certain specified dates unless they have been pre-registered.

Every manufacturer and importer of a chemical (>1 tonne per year) has to register. For example, if there are three manufacturers of one chemical in the EU and each produces more than the 1 tonne limit then all three will have to register it. They can collaborate and share test results to minimise costs. Each of these registrants will also need to state how the chemicals are used based on information supplied by their customers (downstream users, see Q7).

Note that electrical equipment manufacturers sometimes import unusual chemicals (special paints, adhesives, etc.) from outside of the EU for their production processes

Chemical manufacturers and importers should pre-register chemicals before the end of November 2008. If they fail to do this, they will not be able to manufacture or import these chemicals until they have been registered. Pre-registration is free and straightforward whereas registration can be complex and fees are charged.

Q4: Are all chemicals treated in the same way?

A: No, the data required for registration depends on the quantity produced or imported, with more technical data required for 1000 tonnes per year than is required for only 1 tonne per year. The deadlines for registration of the largest quantities, and those of highest concern, are much earlier than for smaller quantities.

The most hazardous chemicals are considered differently and will be classified as “Substances of Very High Concern” (SVHCs). These will include those that are toxic, carcinogenic, mutagenic, reproductive toxins and harmful to the environment. These may need to be “authorised” before they can be used and authorisation will not be given if there are safer alternatives or if the substance cannot be safely controlled.



Q5: Are metals included by REACH?

A: Yes, metals are chemicals or preparations. Pure metals such as copper are a single substance whereas alloys are mixtures of materials. Brass for example is a mixture of copper and zinc.

Q6: Are plastics included by REACH?

A: No, polymers are excluded from REACH but any residual monomer and any additives contained within them may need to be registered

Polymer – a polymer is the main constituent of a plastic and consists of many molecules of much simpler chemicals called monomers that are chemically bonded together

Monomer – Monomers are the building blocks of polymers. Single monomer molecules are joined to other monomer molecules to build much larger structures that are called polymers. One polymer molecule may contain 100's or 1000's of monomer units.

Q7: What does REACH mean to users of chemicals and preparations?

A: REACH affects downstream users in a variety of ways. These include:

- **Withdrawal of materials from the market** – this will occur and the EC estimate that 2% of chemicals will be withdrawn. This will happen where the cost of producing the data for registration is higher than expected future profits, but could also occur if a material contains a substance that is an SVHC. The authorisation process is expensive and quite onerous and some suppliers may decide to withdraw products instead. Also, the ECHA may not allow a chemical that poses an unacceptable risk or if they believe that safer alternatives exist.
- **If you import 1 tonne or more per annum (p.a.) of a chemical or 1 tonne or more of a chemical in a preparation from outside the EU, then this will need to be pre-registered and registered.**
- **If you import articles into (see Q2) the EU that contain 1 tonne or more p.a. of a substance that is intentionally released (see Q9), this will need to be pre-registered and registered.**
- **If you import articles that contain a SVHC (> 1 tonne of the substance p.a.) at a concentration of >0.1% by weight, you will need to notify the ECHA**
- **If you import a chemical or preparation to use as a process material (e.g. a special paint or adhesive) and this contains a chemical that is classified as a SVHC, then you may need to apply for authorisation for its use.**

There is no lower weight limit for this requirement and so will be necessary even if only small amounts are used.

- If you supply articles containing a SVHC you will be obliged to provide your customers with at least the name of the substance and also any necessary instructions for its safe use. The latter is likely to include recycling of the product at end-of-life. This information must be provided to business customers as soon as the ECHA confirms a substance is an SVHC. Suppliers will therefore need to know in advance if their products contain substances that are likely to be classified as SVHCs.
- Chemicals are registered for specific uses (these are used to prepare exposure scenarios – see Q11) and you should ensure that you inform the registrant how you use materials, especially if this is unusual. If the registrant does not include your use you will have 12 months to either change the production process or you may be able to use the chemical if you submit your own chemical safety report to the ECHA.

Q8: Which materials might contain SVHCs?

A: One of the ECHA's jobs is to determine SVHCs and publish a list of substances that will require authorisation by June 2009. A list of confirmed SVHCs was published in October 2008. This list includes several that are used in electrical equipment and more substances will be considered every six months. SVHCs that are proposed in the future are likely to include a variety of materials that are present in electrical equipment such as lead (used in solders, some glasses, various electronic components, etc.), cadmium (plating, pigments, switch contacts, etc.), hexavalent chromium (passivation coatings), beryllium and arsenic. They are also likely to include many fairly common chemicals that are widely used in materials such as polyurethane paints and resins, various types of adhesives, sealants, plating chemicals and solvent cleaners. Metals may also contain SVHCs if they contain lead, arsenic or cadmium. It is recommended that users check manufacturer's safety data sheets (MSDS) as these will list all dangerous ingredients and document their hazards. If any are category 1 or 2 carcinogens, mutagens or reproductive toxins, then these are likely to be SVHCs. Manufacturers are obligated to make the latest version of the MSDS available to downstream users.

Q9: What is the definition of a "released" chemical?

A: ECHA has recently published guidance and some examples will illustrate this:

- Scent that is slowly released from soap or any other material is an intentional release from an article
- Solvent in an aerosol can is not a released chemical but is a preparation (the solvent) within an article (the can)
- Ink in an inkjet printer cartridge is intentionally released and the authorities have decided that this is a preparation (the ink) in an article (the cartridge)
- The liquid (alcohol or mercury) in a glass thermometer may be released if the thermometer is broken accidentally. This is not however an intended release and so registration of the liquid (>1 tonne p.a.) will not be required.



Q10: How are equipment manufacturers located outside the EU affected?

A: Manufacturers based outside the EU are not affected directly. They cannot register chemicals or obtain authorisation. If they want to do this they will have to appoint an EU agent (called an "Only Representative" by REACH). Also, there are no obligations relating to substances within products unless they are SVHCs in which case they will need to pass this information to EU importers. However, there are possible indirect implications. EU importers of their products will ask for information about the chemicals within products. Even if non-EU manufacturers' products are not sold in the EU, they could be affected by the withdrawal of materials from the market. This is likely to occur as the EU is a large market and producers may stop selling their products around the world if they are forced to withdraw from Europe. Further implications may be new legal restrictions imposed outside the EU. It is possible that other countries and States in the USA and Canada could impose new restrictions on chemicals as REACH produces more comprehensive test data on them.

Q11: How does REACH work?

A: Substances that fall into scope will need to be registered according to a specific timetable. Any not registered become illegal to supply or import into the EU except for the few that are outside the scope of the regulation.

Substances to be registered with the ECHA under REACH require a technical dossier for quantities of 1 tonne per year or more and a chemical safety report (CSR) for quantities of 10 tonnes per year or more.

REACH defines what is required in the technical dossier and will contain, for example, information on the properties, uses, the classification of a substance (e.g. toxic, etc.), specified test data and guidance on safe use.

The CSR documents the hazards and classifications of a substance and if it is found to meet the specified criteria (i.e. it is hazardous), then the registrant will need to provide an exposure scenario and carry out a risk assessment.

The exposure scenario is a description of how the chemical should be used safely and downstream users are obliged to use chemicals in the ways that these define. Any other uses would be assumed to be unsafe and will not be permitted.

Q12: What should I do now?

A: As all commercial users of chemicals will be affected by REACH, it is recommended that a strategy is defined and followed. This should start now!

Most manufacturers use chemicals and preparations. Manufacturers should audit their own business and production processes to answer the following questions:

- 1 Do you manufacture or import any substances from outside the EU in quantities of 1 tonne or more per year?
- 2 Do you import articles from outside the EU that contain 1 tonne or more of an intentionally released substance?

If you answered yes to either of these questions then you will need to pre-register the chemicals between 1st June and 1st December 2008 and register according to the REACH timetable (see registration). ECHA recommends that downstream users of chemicals should provide details of how they use chemicals to their suppliers in order to ensure that these are included in Exposure Scenarios.

Some more questions:

- 3 Do any of your products contain SVHCs? If the answer is yes, you will need to provide information to your customers.
- 4 Do any of the chemicals, preparations or materials you use contain a substance likely to be classified as a SVHC? If the answer is yes, then there is a risk that this may be withdrawn from the market without warning. It is best to avoid the use of materials containing SVHCs in new products unless there is no alternative.
- 5 SVHCs may not be used in the EU to make products, even in small quantities, after dates that will be specified by ECHA unless they have been authorised. Users as well as manufacturers and importers can request authorisation but should seek professional advice first.

The next step is to contact your materials suppliers to ask them the following questions:

- 1 Can your suppliers confirm that REACH will not affect the supply of materials that you currently use? It is likely that they will not be able to confirm this but your question will encourage them to find out what plans their suppliers have and warn you of withdrawals as soon as possible.
- 2 Do your suppliers require information on how you use their products? If you use chemicals in an unusual way, you should provide details. Remember that if your use is not included in the exposure scenario that is written by the registrant, you cannot continue to use it in this way unless you submit your own chemical safety report to the ECHA or change your production process.



- 3 Have they provided an up-to-date copy of the MSDS data sheet and do they have processes to automatically update you if the content changes?

Be prepared to answer questions from your customers who may want information on your plans or about chemicals present in your products.

Pre-Registration and registration:

Since 1/6/08 pre-registration of substances that are manufactured or imported in quantities of 1 tonne or more per year, and already on the market in the EU (so called "phase in" substances) has been possible for a limited period of just 6 months. This ensures that the chemical will be considered as part of a staggered assessment and registration programme starting with the highest volume and most hazardous substances:

- More than 1000 tonnes per year must be registered by 30/11/10
- 100 to 1000 tonnes must be registered by 31/5/13
- 1 to 100 tonnes must be registered by 31/5/18

Please note:

The information contained in this guide is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavour to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation.

