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Guide to REACH Regulations

Version 9 April 2010

Use with our REACH Substances in Articles Guide

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Guide to compliance with the EU REACH Regulations

The EU REACH regulations (EC 1907/2006) were adopted in December 2006, and came into force on 1st June 2007. It's 849 pages took 7 years to approve. REACH is a regulation which many companies in the European Union (EU) 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 understood. REACH addresses 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 briefly 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 the most frequently used 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 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 **Chemicals**.

Q2: Who is affected by REACH?

A: REACH is a regulation that affects 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 (prior to 1 December 2008).

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 have pre-registered chemicals before 1 December 2008. If they failed to do this, they will not be permitted to manufacture or import these chemicals until they have been registered which could take many months. Pre-registration was free whereas registration can be complex and fees are charged. The only exception where late pre-registration is possible is for substances manufactured or imported after 1st December 2008 in quantities of > 1 tonne p.a. for the first time. For example, if a manufacturer imported only 500 kg in 2008, there were no registration requirements for this substance. However, if they intend to import 2 tonnes in 2009, they should use the late pre-registration procedure to allow them to import the substance until it is registered. Late pre-registration is permitted until the registration deadlines specified by REACH (see the Registration section page 5).



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 are classified as “Substances of Very High Concern” (SVHCs). These 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 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 registered (see comments in Q3).
- If you import articles (see Q2) into the EU that contain 1 tonne or more p.a. of a substance that is intentionally released (see Q9), this will need to be 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 from 2011.
- 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.
- If you supply articles containing a SVHC included in the "Candidate List" (see Q8) 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 and disposal. This information must be provided to business customers as soon as a substance that is included in the "Candidate List" of SVHCs is identified at >0.1% by weight of the supplied item (and within 45 days to consumers on request). Remember this obligation applies to any items including free samples, spare parts, accessories and packaging. **This is a legal obligation.** However, registration information and compliance certificates are not obligatory.
- 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.
- If you receive an exposure scenario for a substance or preparation from a supplier, you will have 12 months to comply with the conditions specified. Exposure scenarios describe the way that substances and preparations may be used safely and alternatives will not be permitted after the 12-month grace period. If the exposure scenario does not cover your process, then you should contact your supplier to determine if it is equivalent. Otherwise changes to processes may be needed.

Q8: Which materials might be SVHCs?

A: One of the ECHA's jobs is to determine which substances are SVHCs and publish a "Candidate List" of substances. The first two batches of SVHCs have been published (30 in total) and, at the time of writing, 8 more are under consultation. The current list is as follows:

Substance	CAS No.	Uses by electronics industry
Anthracene	120-12-7	Unlikely
4,4'-Diaminodiphenylmethane (or methylene dianiline)	101-77-9	Ingredient in some adhesives
Dibutyl phthalate (DBP)	84-74-2	Plasticiser in flexible PVC and other plastics. Also used in inks, lacquers and adhesives
Cobalt dichloride	7646-79-9	Colour indicator in silica gel sachets
Diarsenic pentaoxide	1303-28-2	Chemical intermediate, not used by electronics industry
Diarsenic trioxide	1327-53-3	Chemical intermediate, not used by electronics industry
Sodium dichromate, dihydrate	7789-12-0	Used to make passivation coatings and for hard chrome plating
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	Fragrance
Bis (2-ethyl(hexyl)phthalate) (DEHP)	117-81-7	Plasticiser in flexible PVC and other plastics. Also used in inks, lacquers and adhesives. May also be used in electrolytic capacitors
Hexabromocyclododecane (HBCDD)	25637-99-4	Flame retardant for polystyrene
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	Uncommon flame retardant and plasticiser for paints, rubbers, adhesives and plastics
Bis(tributyltin)oxide (TBTO)	56-35-9	Biocide, may be present in polyurethane foam
Lead hydrogen arsenate	7784-40-9	Unlikely - used as a pesticide
Benzyl butyl phthalate (BBP)	85-68-7	Plasticiser in flexible PVC and other plastics. Also used in inks, lacquers and adhesives
Triethyl arsenate	15606-95-8	Unlikely - used as a pesticide
Anthracene oil	90640-80-5	None known

Substance	CAS No.	Uses by electronics industry
Anthracene oil, anthracene paste, distn. lights	91995-17-4	None known
Anthracene oil, anthracene paste, anthracene fraction	91995-15-2	None known
Anthracene oil, anthracene low	90640-82-7	None known
Anthracene oil, anthracene paste	90640-81-6	None known
Coal tar pitch, high temperature	65996-93-2	None known
Acrylamide	79-06-1	None, used to make polyamide polymers and other substances
Aluminosilicate, refractory ceramic fibres		Thermal insulation, e.g. furnace insulation, heaters, car parts (catalytic converters, metal reinforcement, heat shields, brake pads) and in the aerospace industry (heat shields)
Zirconium aluminosilicate refractory ceramic fibres		Thermal insulation, e.g. furnace insulation, heaters, automotive parts (catalytic converters, metal reinforcement, heat shields, brake pads), aerospace parts (heat shields)
2,4-dinitrotoluene	121-14-2	Mainly as a chemical intermediate. Very rarely used as a plasticiser
Di-isobutyl phthalate	84-69-5	Plasticiser in PVC, rubbers, lacquers, adhesives, potting and sealants. Common replacement for DBP (which is already classified as a SVHC)
Lead chromate	7758-97-6	Yellow pigment used in inks (e.g. for labels), paints and in plastics
Lead chromate molybdate sulphate red (C I Pigment Red 104)	12656-85-8	Red pigment used in inks, paints and plastics
Lead sulfochromate yellow (C I Pigment Yellow 34)	1344-37-2	Flame retardant used mainly in rigid and flexible polyurethane. Also used in polyisocyanurate foam, unsaturated polyester resins, PVC, adhesives, elastomers, cellulose acetate, nitrocellulose and epoxy resins
Tris (2-chloroethyl) phosphate	115-96-8	Flame retardant used mainly in rigid and flexible polyurethane. Also used in polyisocyanurate foam, unsaturated polyester resins, PVC, adhesives, elastomers, cellulose acetate, nitrocellulose and epoxy resins



Suppliers should now be informing their customers if any of these substances are present in any item at >0.1%. The ECHA will propose more SVHCs in the future and are likely to include a variety of materials that are present in electrical equipment such as lead, cadmium, 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. It is recommended that users check manufacturer's safety data sheets (MSDS) as these will list all dangerous ingredients (including their hazards) that are present in substances and preparations, but suppliers do not need to provide MSDS for articles. All category 1 or 2 carcinogens, mutagens or reproductive toxins, will eventually be listed as SVHCs as well as certain other types of hazardous substance specified in Article 57 of the REACH regulations. Manufacturers are obligated to make the latest version of the MSDS available to downstream users as well as providing Safe Use data where an SVHC is present in an article.

The ECHA has approved 7 substances for "authorisation of use." These will be added to Annex XIV. Substances in Annex XIV cannot be used after specified (sunset) dates unless they have been authorised. Authorisation will be given only for specific uses and will be time limited, and costly.

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

A: ECHA has published guidance and some examples to 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 (known under REACH as an "Only Representative"). 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 fell into scope should have been pre-registered by now unless under 1 tonne is produced or imported annually. Registration must follow a specific timetable. Any substances 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 also 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.

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 should have pre-registered the chemicals before the 1st December 2008 and will 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 (sunset) 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? They may 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?

4 Ask your supplier to provide information on any SVHCs that are present in any items, substances or preparations that they supply. Safe use data is required where an SVHC is present in an article.

Be prepared to answer many questions from your customers who will want information on SVHCs present in your products.

Registration

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) should have been pre-registered before the 1st December 2008. Pre-registration allows their use until they are registered. Substances that were not pre-registered cannot be produced, imported or used (>1 tonne per year per legal entity) until they are registered. Deadlines have been imposed for registration that ensure that those with the highest volumes and the most hazardous substances are considered first. This ensures that chemicals will be reviewed as part of a staggered assessment and registration programme. The registration deadlines are:

- More than 1000 tonnes per year, >1 tonne of CMRs and > 100 tonnes of substances classified as R50/53 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

CMR = Carcinogen, Mutagen, Reproductive toxin

R50/53 = Substances that are toxic to the aquatic environment and may cause long-term adverse effects.

Marketing and Use Directive

From June 2009 the Marketing and Use Directive (76/769/EEC) became Annex XVII of the REACH Regulations.

The legislation, with its numerous amendments, imposes restrictions on hazardous substances.

Some are already banned in the EU, such as asbestos and polychlorinated biphenyls and, as a result, they cannot be sold or used. Others are restricted from use other than in certain applications. There are restrictions on certain materials that are used in toys and others, such as textiles that come into contact with the skin. Nickel cannot be used where significant skin contact occurs in applications such as jewellery and watch cases for example.

Once sitting in REACH annex XVII then several substances could become prime SVHC candidates, for example benzene, arsenic compounds, mercury, cadmium etc.

Legal Obligations

There many myths around what information is legally obligated.

Name of any SVHC present in an article	<input checked="" type="checkbox"/>
Safe Use data to accompany the above	<input checked="" type="checkbox"/>
MSDS should be automatically supplied at time of order	<input checked="" type="checkbox"/>
MSDS should be automatically supplied retrospectively when updated	<input checked="" type="checkbox"/>
Pre-registration / registration information	<input type="checkbox"/>
Certificates of compliance	<input type="checkbox"/>

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.

