

Electronic Component Stocking Distributor

Simple Guide to REACH Regulations

REACH came into effect on 1st June 2007. It is new EU-wide legislation on chemicals and their safe use. It deals with Registration, Evaluation, Authorisation and Restriction of Chemicals. A major part of REACH is the requirement for those who manufacturer in, or import into, the EU, over 1 tonne a year of 'Substances' are required to register with the European Chemicals Agency (ECHA). Generally, it applies to all individual chemical substances on their own, in preparations or in articles (if intended to be released during normal and reasonable foreseeable conditions of use from an article). If you do not register your substances, then the data will not be available and as a result you will no longer be able to manufacturer (in the EU) or import them into the EU, i.e., no data, no market.

What is the aim of REACH?

- ▶ To provide a high level of protection of human health and the environment from the use of chemicals.
- ▶ To make the people who place chemicals on the market (manufacturers and importers) responsible for understanding and managing the risks associated with their use.
- ▶ To allow the free movement of substances on the EU market.
- ▶ To enhance innovation in and the competitiveness of, the EU chemicals industry.
- ▶ To promote the use of alternative methods for the assessment of hazardous properties of substances.

Who does REACH apply to?

For many firms REACH registration will be the most costly and time-consuming part of compliance. Generally, anyone that makes or imports a chemical into the EU above one tonne per year will need to register it with the Agency (there are exemptions to REACH Registration). Registration involves producing a dossier of information in collaboration with other manufacturers or importers. The obligations for manufacturers and importers of a substance are essentially the same.

Your REACH role!

To establish what your role is under REACH, you should fall into one of the following 4 categories.

- ▶ **Manufacturer / Importer** – You manufacturer or directly import a substance, on its own or in a preparation, of > 1 tonne per year.
- ▶ **Producer / importer or supplier of articles** – you manufacturer / import articles or place them on the market.
- ▶ **Distributor (including retailers)** – you store and place on the market a substance, on its own or in a preparation.
- ▶ **Downstream user** – Everyone that uses a chemical, for example, to make a product, to clean a floor, to lubricate a machine, to print on their packaging, etc,... has to make sure that their use of a chemical is listed within the dossier.

Companies outside the EU can not register chemicals themselves but they can appoint an EU based agent, an “only representative”, on their behalf.

REACH Made Simple

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Hints, Tips and Actions

Components Contain Chemicals

It has been assumed by some that because this regulation concerns “chemicals” it is of no relevance to the engineering, electronics and electrical products sector. This is definitely not the case.

No Data – No Market

It is thought that it applies to around 30,000 chemicals currently in use. REACH shifts the onus from regulators to industry to show that the chemicals it uses are safe on the basis of “no data – no market”.

REACH Facts

REACH replaces 40 existing pieces of legislation, was originally 849 pages & took 7 years to pass!

Marketing Choice

Better position to manage the impact of REACH so as to maintain a globally competitive position

Only Representative

A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, or formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil as his only representative, the obligations of importers. Only Representatives are natural or legal persons:

- ▶ Established in the EU; and
- ▶ Having sufficient background in the practical handling of substances and the information related to them (for more information go to <http://echa.europa.eu>).

REACH Pre-Registration

As the 1st of December 2008 deadline for general pre-registration has already passed, the only pre-registration function now available is for late pre-registration. Anyone who manufactures or imports 1 tonne or more of any chemical substance per year, should pre-register

The 1st pre-registering stages were between 1st June 2008 - 30th November 2008. This is mainly for Manufacturers and importers of chemicals. There is a list of Substances of Very High Concern (SVHC) that REACH focuses on.

Which materials might be SVHCs?

The “Candidate List” of substances of very high concern for authorisation was published in October 2008. This list includes several that are used in or to make electrical equipment. The current list is as follows:

Substance Name	Reason for Proposing	Cas Number	EC Number	Uses By Electronics Industry
Anthracene	PBT	120-12-7	204-371-1	Unlikely, it's used in production of the red dye alizarin, wood preservatives, insecticides and coating materials.
4,4'-Diaminodiphenylmethane (MDA)	CMR	101-77-9	202-974-4	Ingredient in some adhesives and resins.
Dibutyl phthalate (DBP)	CMR	84-74-2	201-557-4	Plasticiser in flexible PVC & other plastics. It is also used in inks, lacquers and adhesives.
Cyclododecane	PBT	294-62-2	206-33-9	Unlikely, it is used as a temporary binder, intermediate for speciality chemicals, non-reactive sublimable adhesive.
Cobalt dichloride	CMR	7646-79-9	231-589-4	Used to help detect moisture e.g. drying agents such as silica gel.
Diarsenic pentaoxide	CMR	1303-28-2	215-116-9	Chemical intermediate, not used by electronics industry.
Diarsenic trioxide	CMR	1327-53-5	215-481-4	Chemical intermediate, not used by electronics industry.
Sodium dichromate	CMR	7789-12-0		Used to make passivation coatings & for hard chrome plating.
Musk xylene	VpVB	81-15-2	201-329-4	Artificial Fragrance used in household products, cosmetics & fragrances.
Bis (2-ethylhexyl)phthalate) DEHP	CMR	117-81-7	204-211-0	Used as a plasticizer in manufacturing PVC. Also used as hydrolic fluid, dielectric fluid in capacitors & solvent in lightsticks.
Hexabromocyclododecane (HBCDD)	PBT	25637-99-4	247-148-4	Flame retardant in polystyrene & thermal insulation in building industry.
Alkanes, (Short Chain Chlorinated Paraffins (SCCP's)	PBT	85535-84-8	287-247-5	Uncommon flame retardant & plasticiser for paints, rubbers, adhesives and plastics.
Bis(tributyltin)oxide (TBTO)	PBT	56-35-9	200-268-0	Biocide may be present in polyurethane foam & is used as a wood preservative.
Lead hydrogen arsenate	CMR	7784-40-9	232-064-2	Unlikely, used as a pesticide.
Triethyl arsenate	CMR	15606-95-8	427-700-2	Unlikely, used as a pesticide.
Benzyl butyl phthalate (BBP)	CMR	85-68-7	201-622-7	Plasticiser in flexible PVC & other plastics. It is also used in inks, lacquers and adhesives.

PBT = Persistent, Bio-accumulative, and Toxic

CMR = Chemicals classified as Carcinogenic, Mutagenic or toxic to Reproduction

vUVB = very Persistent, very Bio-accumulative (Definition in accordance with Directive 67/548/EEC)

REACH - 11 Year Programme

Everyone that manufactures a product within the EU is likely to be affected to some degree; if you make or import a chemical substance, REACH is likely to be one of the biggest programmes of work your company will have to undertake over the next 11 years.

Industry Cost of €6 billion

REACH comes at a considerable cost, the most accepted overall price tag is €6 billion but REACHReady think this is an underestimate! REACH is seen as industry's responsibility and industry, therefore, has to foot the bill.

Accelerating Component Obsolescence

REACH will accelerate the obsolescence of components and materials and increase the level of information required on the composition of products beyond the mere 6 substances (plus potentially 4 new ones) covered by the RoHS Directive. Industry needs to be aware of the implications of REACH.

Understanding REACH

Understanding the REACH Regulations could save you money on costly redesigns due to restricted substances such as lead.

Chemicals not covered by REACH

Polymers are excluded from REACH but any residual monomer and any additives contained within them may need to be registered.

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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.

What if you forgot to pre-register?

If the company is new to the market, it will still be able to take advantage of the phase-in registration deadlines, provided there is more than a year until the relevant deadline (see time line).

If your company misses pre-registration for a substance you will not be able to benefit from these transitional periods. In this case you will have to submit a registration dossier for that substance before you can continue manufacturing or importing 1 tonne or more per year after 1 December 2008.

This may imply that you have to discontinue manufacturing or importing of the substance until you have received a registration number from ECHA.

To receive a registration number you have to:

- ▶ File an inquiry to ECHA to determine whether a registration or an inquiry was previously submitted for the same substance;
- ▶ Obtain and assess relevant physico-chemical, health and environmental data and use information in order to compile your registration dossier;
- ▶ Submit the dossier and pay the related fee to ECHA.

Is it possible to pre-register after 1st December 2008?

If you are manufacturing or importing phase-in substances in quantities of 1 tonne or more for the first time, after 1 December 2008 you can still benefit from the extended registration deadlines if you pre-register:

- ▶ At the latest six months after manufacturing or importing exceeds the one-tonne threshold; and
- ▶ At least twelve months before the relevant deadline for registration.

Manufacture or import for the first time, refers to the first time after the entry into force of REACH (1 June 2007).

Total Exemptions

Substances that fall into any of the categories below are totally exempted from the requirement of REACH:

- ▶ Radioactive substances within the scope of Council Directive 96/29/Euratom;
- ▶ Substances, on their own, in a preparation or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
- ▶ Non-isolated intermediates;
- ▶ The carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air;
- ▶ Waste as defined in Directive 2006/12/EC.

European Union Member States can also create specific exemptions in the interest of defence. In the UK the Ministry of Defence (MoD) will be responsible for issuing these exemptions. They should be contacted directly for advice on using this exemption.

Saving Europe €54 billion

The European Commission also calculates that REACH would save Europe 54bn euros (£336bn) over 30 years because fewer people would fall ill as a result of exposure to chemicals.

Restrictions To Your Business

The EU have in place a restrictions procedure, which enables the EU to regulate throughout the European Community the following: conditions for manufacture, placing on the market or use of certain dangerous substances, or the prohibition of any of these activities.

What is Restricted?

Any substance on its own, in a preparation or in an article may be subject to EC-wide restrictions if it is demonstrated that risks are not adequately controlled.

Level of Authorisation

When substances of very high concern are used and placed on the market, authorisation is required.

Substances of Very High Concern (SVHC)

Around 1,500 substances fall into the SVHC. They are chemicals that: cause cancer, are toxic, take a long time to break down, serious/irreversible effect on humans & environment.

What is a substance?

A substance is a chemical element or compound.

What are your REACH obligations?

For article suppliers, communicating with their suppliers is the most important and efficient way to gather information on substances contained in their articles. Communication along the supply chain is one of the core instruments to ensure controlled use of substances. Article suppliers (producers/importers/distributors) normally have no legal obligation to communicate information on substances contained in their articles. Some information needed to comply can be derived from a material/manufacture's safety data sheet information of substances or preparations which have been used to manufacture an article. This information is either required to be provided, e.g. if an article producer uses the substance or preparation in his production, or should be requested, within 45 days, from the actors up the supply chain.

The article supplier **MIGHT** disclose the information; if and when the particular substance is included on the REACH Candidate List of Substances of Very High Concern for authorisation the supplier **MUST**, usually, disclose information on that substance present in the finished goods they sell to their customers.

SIEF Participation

After pre-registration under the REACH legislation, the next step is to form and participate in a SIEF, a critical role in the REACH process. The purpose of a Substance Information Exchange Forum (SIEF) is to help registrants of the same substance share information about the substance, which will also help avoid duplication of testing. You are obliged to be part of the SEIF for your substance and this process should not cost anything to join. This in turn places data sharing obligations upon you. Specifically; SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies and arrange for them to be carried out. It is important to record what you have done and why for every stage of the process, in the event of any challenge later. Each SIEF shall be operational until 1st June 2018 (the last registration deadline in REACH).

SIEF Process

As SIEF has no legal form, participants are free to organise themselves as suitable to meet their needs. Every SIEF formed will be different: some will have only a few members; some will have hundreds or even thousands. To some degree this will define how a SIEF will operate, most will go through the following process:

1. Pre – SIEF Discussion about the sameness of the substance.
2. Agreement on the same substance.
3. SIEF Formation
4. Data Sharing
5. Joint Submission

SIEF Benefits

By joining a SIEF you will benefit from the following:

- ▶ Reduce administration costs to help your business combat the REACH legislation.
- ▶ Encouraging data sharing.
- ▶ Reduces animal testing.
- ▶ Increases knowledge of new information/studies and testing proposals.
- ▶ Help classify the substance in accordance with EU criteria.
- ▶ Help identify any data gaps.
- ▶ Help increase knowledge of REACH for employees.

ECHA Recommended Substances

The ECHA will prepare recommended substances for inclusion, and interested parties will have an opportunity to comment on such recommendations.

EU Chemical Sourcing

Even if you source your chemicals from within the EU, the chances are you could still be affected.

Preparing for REACH

1. Set up admin/product management systems.
2. Develop portfolio's of substances affected by REACH.
3. Review & improve systems regularly.
4. Communicate potential business impact of REACH.

What do electronic distributors/ buyers need to do?

The supplier **MUST**, usually, disclose information on any substances listed on the list of substances of very high concern (SVHC) present in the finished goods they sell to their customers.

Benefits of REACH

Appropriate communication & active supply chain collaboration can make a more effective process and more profit. REACH can also improve customer satisfaction & service.

REACH

Registration, Evaluation, Authorisation, & Restriction of Chemicals.

The REACH timeline:

Date	Action
1 st June 2007	REACH came into force.
1 st June 2008	Pre-registration for existing ('phase-in') substances starts Registration for new ('non-phase-in') substances.
30 th November 2008	Pre-registration for 'phase-in' substances ends.
1 st December 2008	Registration for existing substances (that have not been pre-registered) starts
1 st January 2009	List of pre-registered substances published and SIEF's are formed (substance information exchange forum)
1 st June 2009	First recommendation of priority substances to be considered for authorisation published by ECHA.
1 st December 2010 PHASE 1	By this date the following pre-registered 'phase-in' substances should have been registered when supplied at: = 1000 tonnes per annum (tpa) or; =100 tpa and classified under CHIP as very toxic to aquatic organisms or; = 1 tpa and classified under CHIP as Cat 1 or 2 carcinogens, mutagens or reproductive toxicants.
1 st June 2013 PHASE 2	Deadline for registration of substances supplied at = 100 tpa.
June 2018 PHASE 3	Deadline for registration of substances supplied at = 1tpa

For more information on REACH and the Cyclops services:

Cyclops Electronics Ltd - www.cycelect.com

Questions to reach@cyclops-electronics.com

ERA Technology: www.era.co.uk/rfa

European Chemicals Agency - ECHA: www.echa.europa.eu/home_en.asp

The Reach Reassurance Service: www.reachready.co.uk

Please refer to the Regulations themselves for a full statement of the legal requirements. Although we endeavour to provide accurate information, there can be no guarantee that such information is accurate at the time of date received.

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Comprehensive Guide

For a comprehensive guide to REACH requirements focusing on the electrical and engineering products sector we recommend ERA's Guide to REACH compliance.



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