A guide to REACH obligations for electrical product manufacturers
Introduction

Many manufacturers are unfamiliar with the details of REACH which is the European Regulation governing chemical substances. This Regulation was introduced to ensure safe production, use and management of substances in Europe and covers the life cycle of substances including their use in ‘articles’.

REACH is based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected. An important objective of this Regulation is to encourage and in certain cases to ensure that substances of very high concern (SVHC) are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available.

In order to achieve its objectives, this Regulation lays down specific duties and obligations on manufacturers, importers and downstream users of substances on their own, in preparations and in articles.

In this document we provide an overview of the key aspects of the REACH Regulation and a glossary of useful terms and details of manufacturer’s obligations.

Glossary of Terms used in the context of REACH compliance

**Actors in the supply chain:** means all manufacturers and/or importers and/or downstream users in a supply chain

**Article:** means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

**Distributor:** means 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

**Downstream user:** means 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. A distributor or a consumer is not a downstream user.

**ECHA:** the European Chemicals Agency
**European Community (EC):** The European Community, consisting of the 27 EU Member States plus the EEA states (Iceland, Liechtenstein and Norway). These states are all under the REACH Regulation.

**CLP:** EC 1272/2008 on Classification, Labelling and Packaging of substances and mixtures. This incorporates into EU Community Law the internationally agreed classification, labelling and packaging criteria of the UN Global Harmonisation System (GHS).

**Importer:** means any natural or legal person established within the Community who is responsible for import;

Preparation: means a mixture or solution composed of two or more substances

Producer of an article: means any natural or legal person who makes or assembles an article within the Community

**REACH:** Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

**Recipient of an article:** means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers

**SDS:** Safety Data Sheet

**Substance:** means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

**Supplier of an article:** means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market

**SVHC:** Substance of Very High Concern

**Use:** means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;
Key steps to determining your REACH obligations

**Product definition:** Most products are composed of a mixture of articles and substances, with the packaging considered as a separate article under REACH. It is important to determine the REACH requirements for each part of a product. There are some products which are made up of components that are regulated under different pieces of EU Legislation resulting in them being completely or partially exempt from REACH.

**Position in the supply chain:** Downstream Users and Article Producers have different REACH obligations to substance Manufacturers or Importers. It is important to check the REACH compliance of suppliers as this determines how a company's role is defined under REACH. Substances are the raw materials used in the production of articles therefore they need to be registered in the supply chain for that use. Use information needs to be communicated up the supply chain to support companies doing substance registrations. Whilst many product manufacturers can rely on their suppliers of components and raw materials to take care of REACH compliance, very few realise that under REACH they are defined as suppliers of articles and this means that they have specific REACH obligations to the recipients of their articles.

**Substances of Very High Concern (SVHC):** Companies need to be aware of SVHC in their supply chain. SVHC on the Authorisation Annex have sunset dates, the date after which they cannot be manufactured, imported or used in Europe without Authorisation. If no authorisation is granted, and no safer substance is substituted for that use, this may result in raw materials and components being no longer available in Europe. If SVHC are present in an article at >0.1% (w/w) the article manufacturer/importer has obligations to the article recipients and consumers, and if >1T/y is manufactured/imported then the company has additional obligations to ECHA unless the SVHC has already been registered in the supply chain.

**Product definition: What constitutes an Article?**

The latest draft guidance on requirements for substances in Articles published in April 2011 helps companies understand how to define an Article under REACH. In article 3(3) of REACH an article is an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition. In this sense, the production step of an article can also be understood to include the assembly of the components, which can themselves be articles, of a complex article (e.g. a laptop).

A set of objects that are merely collected together to be supplied does not have a particular production step during which a specific shape, surface or design is given.
to the set or kit. This applies regardless of whether the objects are used separately (like the pans of a cookware set), used together (like in a portable power tool consisting of tool, battery and charger), or assembled into a single object (like a flat pack furniture). Therefore, a set of objects cannot be regarded as one article, but has to be regarded as many articles, substances and/or mixtures.

Remember articles are not just the physical products. Boxes, bags, packaging and instruction manuals are all considered separate articles. So a unit, its polystyrene packaging and its box are all considered articles in their own right.

**What are Substances of Very High Concern (SVHC) and what sort of products and components are they found in?**

According to REACH article 57, SVHC are substances classified as follows:

- Categories 1 and 2 for carcinogenicity, mutagenicity or toxicity for reproduction (CMR)
- Persistent, Bioaccumulative and Toxic (PBT)
- Very Persistent, very Bioaccumulative (vPvB)
- Substances for which there is scientific evidence for probable serious effects to human health or the environment, such as endocrine disruptors.

These types of substances have been identified by experts over decades of industrial and chemical experience as presenting risks to people and the environment.

In order to replace SVHC with less dangerous alternative substances, an authorisation process has been established. In the first step a Member State, or ECHA on request of the European Commission, can propose a substance to be identified as an SVHC. There is then a public consultation process after which if there is unanimous agreement it is added to the Candidate list. Currently, the Candidate list has 73 substances and this is expected to rise to 136 by the end of 2012. Ultimately, it should contain all substances meeting the classification criteria listed above. ECHA then prioritises which substances from the Candidate list are added to the Authorisation Annex XIV and given sunset dates. The current list of substances with sunset dates is provided below.

- 4,4’-Diaminodiphenylmethane (MDA) 21/08/2014
- 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) 21/08/2014
- Benzyl butyl phthalate (BBP) 21/02/2015
• Diisobutyl phthalate (DIBP) 21/02/2015
• Dibutyl phthalate (DBP)* 21/02/2015
• Bis(2-ethylhexyl) phthalate (DEHP)* 21/02/2015
• Lead sulfochromate yellow (C.I. Pigment Yellow 34) 21/05/2015
• Lead chromate 21/05/2015
• Diarsenic pentaoxide 21/05/2015
• Diarsenic trioxide 21/05/2015
• Lead chromate molybdate sulphate red (C.I. Pigment Red 104) 21/05/2015
• Tris(2-chloroethyl)phosphate (TCEP) 21/08/2015
• 2,4 – Dinitrotoluene (2,4-DNT) 21/08/2015
• Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane 21/08/2015

After the sunset date they cannot be manufactured, imported or used within Europe without Authorisation. The authorisation process includes providing scientific evidence that no safer viable alternative exists and a socioeconomic impact assessment showing that the removal of the substance has a greater detrimental impact than its hazardous properties. The last date to apply for authorisation is 18 months before the sunset date. *Only DBP and DEHP have uses, related to packaging of medicinal products, which are listed as exempt from authorisation.

ECHA published a document in March 2012 which provided information on the types of consumer articles known to contain SVHC according to information received from registration dossiers and SVHC notifications. One of the aims of this document was to highlight the variety of consumer goods that contain SVHC.

Many SVHC are used in plastics, pigments, lacquers, adhesives, flame retardants, corrosion inhibitors and high temperature insulation. The properties, published uses and article types that SVHC are known to be present in, provides evidence that they may be present in articles and article components used within electrical goods. Specific examples include:

• Phthalates such as DBP, DEHP and BBP are mainly used as plasticisers in polymers such as PVC. These have been notified as present in electronic
and plastic articles as well as machinery. They can be present in wire insulation on electrical articles and in packaging materials.

- HBCDD, with its flame retardant properties, can be found in the plastic housing of electrical/electronic articles.

- TCEP is used primarily as a plasticiser with flame-retarding properties for polyurethane, polyesters, polyvinyl chloride and other polymers. To date, it has been notified as present in coatings, but no specific consumer articles have been identified.

For the full range of articles containing SVHC please refer to the ECHA document (12 March 2012 Data on candidate list substances in articles). ECHA will update this document every 6 months.

**What are my obligations?**

When producing an article the main REACH obligations relate to knowing which SVHC, if any, are present in the final article and how much is present. Once a substance is added to the Candidate list, it is regarded as an SVHC and the following obligations apply:

- Any producer or importer of articles shall notify ECHA if there is an SVHC present in an article at >0.1% (w/w) and the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year. The deadline for notification is 6 months from the inclusion of the substance on the Candidate list. If the substance is already registered for that use in the supply chain, or the article producer can exclude human exposure under normal conditions of use, no notification is required.

- If >0.1% (w/w) of an SVHC is present in an article the article recipient must automatically be provided with information on safe use. If the article recipient is a consumer, upon request the information on safe use must be provided within 45 days. The minimum information is the substance identity.

As substances are the raw materials used in the production of articles they need to be registered in the supply chain for that use. Often the article producer relies on their supplier to register the substances so that they are regarded as Downstream Users under REACH. Downstream users have the following obligations:

- The downstream user can make his use known to his supplier so that it will be registered as an identified use in the substance registration dossier. This information must be provided at least 12 months in advance of the registration deadline.
• If new hazard information becomes available, or any information that calls into question the appropriateness of the risk management measures sent from the supplier, this must be communicated up the supply chain.

• If a downstream user discovers that their supplier will not register then they can change to a supplier with a registration or perform a late pre-registration. Late pre-registrations must be completed more than 12 months before the relevant registration deadline.

The REACH registration requirements are for companies located within the EU. There is provision for manufacturers located outside EU to obtain substance registrations through employing a company within EU, an Only Representative, to take legal responsibility for the registration on their behalf. This removes the registration obligation from the EU importer and means that the non-EU manufacturer can sell into Europe through any EU importer rather than only to those EU importers who have registered.

**Compliance tips for articles**

• Document your procedure for determining whether your products are articles, substances, mixtures or a combination of articles and substances.

• Assess the level of REACH awareness and compliance of your suppliers as this will influence your responsibilities under REACH.

• Create specifications for the materials you source and communicate pass/fail criteria to your suppliers

• Be practical about SVHC screening and testing.

• Be aware of updates to the Candidate list and the Authorisation Annex.

• Be prepared to respond to requests from consumers about the presence of SVHC in your articles.

**How do I know what SVHC my Articles contain? Do I have to get a lab to test each product for each substance?**

If you are sourcing the components of the articles you produce from European suppliers, they should provide you as the article recipient with information about any SVHC present and information on safe use which you can then pass on to your customers. If you are importing the components from non-European suppliers they may or may not provide you with information. In this case it is important to have a strategy to ensure that you know if any SVHC are present in your articles.
and at what concentration, as well as determining information on safe use for your article recipients and consumers.

Testing your entire product range for every SVHC is one option open to you if you have the time and money to do so but it’s unlikely that all or even several of the SVHC will appear in one article, so this wouldn’t be cost effective. A combined approach using information from suppliers with a risk assessment based on the latest information about articles known to contain SVHC and screening analysis of representative samples should identify the articles most likely to contain SVHC. For example, if you use flame retardants, adhesives, sealants or even a certain type of pigment to colour your casings, based on the current candidate list substances, these are going to be obvious areas of risk that you yourself as a non-chemist can highlight to your partner laboratory as potential areas of concern. It could be that none of the SVHCs are present in the materials or components you have used, but your partner chemists will know to check these as areas of risk. After their basic assessment, if one or more SVHC are present, then more detailed analysis, testing or screening can be done.

**What happens if you find >0.1% SVHC in your final article?**

Check whether the SVHC is registered in your supply chain for use in the production of articles. If yes, then there is no requirement to notify ECHA as this will have been covered in the original registration. If the SVHC is not already registered for this use, and greater than one metric tonne per year is imported or used in the production of articles, then the identity of the substance along with its use and the use of the article must be notified to ECHA. According to the latest draft guidance on articles the requirement to notify is dependent on production or import and does not apply to SVHC in articles imported or produced before the SVHC they contain was added to the Candidate list. If they are continuing to import or produce, companies have six months from inclusion of a substance on the Candidate list to submit a notification to ECHA.

As Candidate list substances will ultimately be subject to Authorisation, you should find out if your suppliers intend to obtain an Authorisation for the relevant substances in your articles. If your supplier will obtain an authorisation then you are required to inform ECHA of your use of the substance to enable ECHA to accurately monitor and enforce authorisation. If they are not seeking authorisation, then you should seek alternative materials or components to replace the ones presenting risk.

The detection of greater than 0.1% of an SVHC in your article triggers the automatic requirement to provide information on safe use to your article recipients. These could be installers or system ‘pack’ compositors. In order to provide appropriate information on safe use, the downstream uses of the article as well as the potential routes of exposure must be known.
If an end user, consumer, requests this information it must be provided to them free of charge and within 45 days. This applies to substance in articles imported or produced before the SVHC they contain was added to the Candidate list as the requirement to provide information on safe use is linked to the supply of the article.

Importers, manufacturers and retailers are all considered ‘actors’ in the supply process, so all have an obligation to provide this information on to professional customers, or supply it to end users on request.

**Supply chain communication: chemical product labelling and Safety Data Sheets**

The REACH Regulation does not specify the method of supply chain communication for information on safe use of articles. It may be achieved via instructions for use and packaging, information on labels, link to a website or standard communication formats developed by industry sector associations. Whatever communication format is used it must make the information on safe use readily available to the recipient of the article or the consumer.

As “production of an article” is a recognised use for substances in the REACH regulation, substances in the supply chain should be registered for that use. Information of the substance hazard will be communicated using Safety Data Sheets (SDS) and product labelling and this should be available in the supply chain. As article producers based in Europe you will be part of the supply chain and in receipt of information in those formats. Therefore, you should be aware of current changes in product labelling and SDS formats.

Chemical product labelling is one form of communication to consumers and in Europe is regulated by EU Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP). This European Regulation is based on the Global Harmonisation System (GHS). It is a method of communicating risk through hazard pictograms, signal words, hazard and precautionary phrases.

Substances have to be labelled according to 1272/2008 since 1 December 2010. There is a transitional period where substances already in Europe that were packaged and labelled according to Directive 67/548/EC prior to 1 Dec 2010 can be placed on the market without being repackaged and labelled until December 2012. EC 1272/2008 will also apply to mixtures from 1 June 2015 with the same
additional 2 year transition period for mixtures already packaged and labelled in accordance with Directive 1999/45/EC. If you import chemical substances that are hazardous you have one month from import to notify the classification and labelling to ECHA in accordance with 1272/2008. A database of notified classifications is available on the ECHA webpage.

Safety Data Sheets are the main form of communication of chemical risk to customers who are not consumers. The format of SDS has been recently updated in Regulation 453/2010 to incorporate the changes arising from REACH and CLP. The 16 main sections of an SDS are as follows:

1. Identification of the substance/mixture and of the company/undertaking (this includes a section on recognised uses of the substance and uses advised against)

2. Hazards identification (this includes classification and label elements)

3. Composition/information on ingredients

4. First-aid measures

5. Fire-fighting measures

6. Accidental release measures

7. Handling and storage

8. Exposure controls/personal protection

9. Physical and chemical properties

10. Stability and reactivity

11. Toxicological information

12. Ecological information

13. Disposal considerations

14. Transport information

15. Regulatory information

16. Other information

Annex. Exposure Scenarios related to the uses described in section 1
For non-hazardous substances there is no requirement to produce exposure scenarios as there is no risk from the use of the substance. For very hazardous substances registered for a wide variety of uses, the exposure scenario annex can be hundreds of pages long. In some cases, when there are multiple uses of a substance in a single environment the risk management measures advised are for the use with the maximum exposure risk as it can be said that other uses with lesser exposure will also be adequately controlled by the advised risk management measures. Downstream users must implement risk management measures that apply to their use of the substance as described in the supplier’s SDS.

Can I trust the materials my suppliers provide me with?

When working with high quality and trusted suppliers, the materials you receive should be accurate and comprehensive, as they too are under scrutiny from European Chemicals Agency and the UK competent authority as part of their enforcement programme. If you have concerns about the validity and accuracy of the material you receive from them, ask your REACH compliance partner laboratory to conduct a Supplier Assessment of your behalf.

As the first substance registration deadline included SVHC classified as carcinogenic, mutagenic and toxic for reproduction, there is a lot of information on these SVHC available in the technical dossiers published on the ECHA webpage. This can be used to evaluate the information on safe use of an SVHC received from suppliers.

What enforcement activities are happening for REACH?

Authorities are:

- Checking that registrations have been completed
- Checking that Safety Data Sheets are up-to-date and compliant
- Checking that CLP requirements have been met especially as substances must be classified, packaged and labelled according to CLP at import.
- Testing products themselves

Whilst enforcement penalties vary considerably between Member States, administrative or criminal penalties or a combination of both can be applied - including name-and-shame public displays, fines of up to 1m euro, injunctions/market withdrawals, closure of establishments, confiscation and destruction of articles or even prison sentences.
Summary notes

- Electrical products are subject to REACH regulations.
- It’s not just the products themselves that are subject to the legislation. The box, bag, packaging and instruction manual are all subject to it too.
- The presence of Substances of Very High Concern (SVHC) needs to be considered through assessment of material from your supply chain, and with a chemical specialist.
- If a SVHC is found in one of your articles in 0.1% by weight, then you need to a) Provide information to your customers on safe use and b) make safe use information available to your consumers within 45 days when they request it.
- Additionally, if the substance is present in articles in quantities totalling over 1 tonne per producer or importer per year, then you need to a) notify the European Chemicals Agency and b) communicate information on safe use so that it is readily available for the article recipient or consumer.

How Intertek can help

**REACH Management solutions** - Intertek provide REACH management solutions specifically tailored to your business needs and requested degree of support. Solutions include product definition and risk analysis of complete product ranges, supply chain communication and information database management, SVHC testing schedules, ECHA substance registrations and SVHC notifications, CLP notifications and training courses on REACH and CLP compliance.

**SVHC Screening** - Intertek’s SVHC screening service is a risk based approach designed to identify the presence of any Candidate listed SVHC substance. Qualitative screens are carried out on homogenized materials to detect or eliminate the presence of SVHCs.

If high levels of these substances are detected further analytical testing is required. The SVHC screening solution provides a cost-effective alternative to testing that demonstrates product compliance with the SVHC disclosure requirements.

**SVHC Testing** - Intertek will perform comprehensive testing services for REACH Substances of Very High concern (SVHC) over 0.1% w/w. Intertek’s global laboratories use modern analytical, quantification, and de-formulation techniques on soluble and insoluble materials to create a comprehensive fingerprint of each product for use in the SVHC declaration provided to the Client for each product tested.
Supplier Assessment - Intertek offers REACH ‘Supplier Audit & Assessment’ Solutions that can help you to determine the data integrity of the materials you receive from them for extra peace of mind.

- Determine REACH-readiness of supplier
- Evaluate supplier’s methods of information collection and data storage
- Score suppliers for performance against a quantitative set of criteria

With a proven track record of REACH project management, outsourcing, and registration in the EU, we can provide a range of services from general regulatory support to complete project management of your company’s REACH programme.

For more information on specific testing and certification information, please contact Intertek at 1-800-WORLDLAB, email icenter@intertek.com, or visit our website at www.intertek.com.