



Premier Farnell



REACH Substances in Articles (Products)

Version 2 March 2009

Obligations within the supply chain

Web: www.global-legislation.com

Q&A: glegislation@premierfarnell.com

REACH Regulations

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Design with the best

Guide to compliance with the EU REACH Regulations

Introduction

REACH, Regulation (EC) 1907/2006, is the most significant piece of legislation to impact manufacturing in the last 25 years. It supersedes 40 existing legal measures as a harmonised system applying to all chemicals manufactured, used or present in products in the European Union (EU). 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 stands for Registration, Evaluation, Authorisation (and restriction) of Chemicals which describes its central process. **It has been assumed by some that because this regulation concerns "chemicals" it is of no relevance to the engineering and electrical products sector. This is definitely not the case.** All products are made of chemicals and REACH has both direct legal and indirect impacts on this sector.

Why should I be concerned about REACH?

REACH is complex; the regulations were adopted in December 2006 and came into force on 1st June 2007. The original 849 pages took 7 years to pass. It was subsequently reduced to 280 pages with official guidance running to many thousands more. Direct legal obligations arise for importers of substances into the EU, users and distributors of substances, and also manufacturers and importers of products - what REACH calls "articles".

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.

About this guide

This Farnell Guide looks to explain and distil the key requirements on producers or importers of "articles".

It is based on the European Chemical Agency (ECHA) official guidance and on the REACH regulation itself. There are also obligations on importers and manufacturers of substances, downstream users of substances and distributors but these are not dealt with here. For a comprehensive guide to REACH requirements focusing on the electrical and engineering products sector we recommend ERA's Guide to REACH compliance.

What is an article?

An article is the term used by REACH to define items whose form defines their function to a greater degree than their composition. To demonstrate this a straight forward example would be 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, solder, wire and paste, 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.

This distinction is important since the obligations on an importer/producer of substances differ and are much more extensive.

Obligations on manufacturers or importers of articles

REACH places obligations on legal entities which place articles on the EU market or manufacture them in the EU. Depending on the circumstances this could include:

- registering substances with the ECHA if they are intended to be released during normal or reasonably foreseeable conditions of use of an article,
- informing the recipient of the presence of a Substance of Very High Concern or SVHC (at >0.1%) in any article they receive, and how to use it safely if necessary,
- notifying the ECHA of the presence of a SVHC (>0.1% and >1 tonne per annum) in an article if exposure to this substance cannot be excluded during normal or reasonably foreseeable conditions of use or disposal,

Note that non-EU producers of articles may appoint "Only Representatives" in the EU to discharge their obligations. The circumstances under which each of these applies is explained below.

Obligation to register intentionally released substances

Registration of substances in articles is obligatory if all of the following criteria are met:

1. The substance is intended to be released from the article(s) during normal and reasonably foreseeable conditions of use
2. The total amount of the substance present in the articles with intended releases exceeds 1 tonne per annum (tpa) per producer or importer
3. The substance has not already been registered for that use.

Assuming all three of these criteria are met the article producer or importer has to register that substance. Those who have "pre-registered" will benefit from the much later deadlines for registration (the earliest of which is 30 November 2010).

The concept of intended release in criterion 1 requires some explanation. Where the release is the main function then it is probable that this would be seen as a substance in a container (and so registration obligations would apply as an importer/producer of substances). So in general this obligation would apply where the release is an intended function but not the main function of the article - the ECHA guidance gives an example of a scented eraser or a volatile corrosion inhibitor that is slowly released from packaging materials. Hence releases which do not form part of the intended function of the article - ageing, wear and tear, or accidents are not seen as intentional releases. The implication of this is that formation of dust on brake pads or bearings wear, loss of fluid from an electrolytic capacitor if it overheats or from a broken thermometer would not be seen as intended releases.

Obligation to provide information on the composition of articles

The central requirement of this obligation is to provide sufficient information to ensure safe use. Information must be provided where both the following criteria are met:

1. It is on the candidate list for authorisation (it is a Substance of Very High Concern)
2. The substance is present in the article at > 0.1% by weight of the article as produced in the EU or imported.

Note that there is no tonnage criterion nor are there exemptions due to exclusion of exposure or if the substance is already registered as this is a specific safety issue for the recipient - even if he/she is the only recipient.

Where provision of information is required, what the producer, importer or supplier of the article must do depends on the nature of the recipient of the article:

- Consumers: The article supplier must provide information on request necessary to ensure safe use within 45 days, free of charge.
- Any other recipient: The article supplier must provide automatically the name of the substance as a minimum plus any other information required to ensure **safe use**.

The kind of things that should be included in the Safe Use Data supplied with information around Substances of Very High Concern in articles is covered in ECHA guidance.

It differentiates between advice to consumers and professional users.

For example, consumers might be advised to keep a substance out of the reach of small children, avoid dermal exposure by not wearing certain clothing in direct contact with the skin, or avoid handling hazardous waste.

Professionals could be warned against dust inhalation from grinding (ensuring appropriate personal protection is used), and avoid leakage to the environment if using a product outdoors in the rain.

A typical safety checklist could be:

- Exposure controls / Personal protection
- Handling and storage
- Disposal consideration
- Fire fighting measures
- Transport information

Information could be included in safe use, or instructions for use data, and labels might be used in some cases.

This obligation applies as soon as a substance has been included on the candidate list for authorisation. This applies to any article supplied after that date. Hence the manufacturer of a product must ensure this information is passed down their distribution chain subsequent to and independent of product which has already been shipped.

REACH considers substances to be of very high concern if they are:

- carcinogenic, mutagenic or toxic for reproduction (CMR), categories 1 and 2 according to Directive 67/548/EEC or
- persistent, liable to bioaccumulate and toxic (PBT), or very persistent and very liable to bioaccumulate (vPvB) according to Annex XIII or
- others such as endocrine disruptors, PBTs and vPvBs not meeting Annex XIII criteria for which there is scientific evidence of probable serious effects to human health or the environment.

The definition of the percentage limit for SVHCs in articles and for provision of information to customers has proved contentious. The guidance states that the 0.1% concentration applies to the total article and not individual components or material that make up the end product. Several member states lobbied for the tighter restrictions around individual articles.

Note that the RoHS definition "by weight in a homogeneous material" does NOT apply under REACH.

Obligation to notify the use of an SVHC

The obligation to notify the authorities of a use of substance in an article applies where the following criteria are all met:

1. It is on the "Candidate List" (it is a Substance of Very High Concern)
2. The substance is present in the article at > 0.1% by weight of the total article as produced in the EU or imported
3. The substance is present in the articles produced or placed on the EU market in quantities > 1 tpa per producer/importer
4. Exposure to humans or the environment cannot be excluded during normal or reasonably foreseeable conditions of use, including disposal

The first Candidate List of 15 confirmed SVHCs was published in October 2008. This includes several that are used in or to make electrical equipment. 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	7546-79-9	Colour indicator in silica gel sachets and moisture indicator cards
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
Triethyl arsenate	15606-95-8	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



Regarding exposure to humans or the environment. Normal conditions of use means “the conditions associated with the intended function of an article”. Normal conditions would generally be explained in the manual or instructions for use. Reasonably foreseeable uses means conditions of use that are not as originally intended by the producer “but which can be anticipated as likely to occur because the form, shape or function of that article”.

Examples of reasonably foreseeable conditions of use include:

- “high likelihood” accidents (e.g. breakage of fragile containers where the substance is an integral part of the article - such as a liquid filled thermometer - releasing the substance)
- uses not in accordance with the function of the article “but which can be anticipated because function and appearance of the article also suggests other uses than the intended ones”
- “extremely intensive uses (e.g. a consumer working with a tool 12 hours a day for three months when building his own house)”
- recycling processes.

Such uses would not include professional or industrial uses which are “clearly and noticeably excluded” (i.e. it is being used in a way which is not intended), where the use is specifically advised against - say by a label, or by clear misuse.

The guidance considers the concepts of release and how to address this in great detail. It states that “exposure to humans or the environment can be excluded in the following situations”:

- there is no release of the substance of concern during normal and reasonably foreseeable conditions of use(s) or disposal
- there is a release but the article is embedded during use(s) and the substance will not escape to the environment or come into contact with humans during use or disposal. This could be the case e.g. for electronic parts inside of machinery.”

Ways of showing that no exposure occurs include arguments based on

- “knowledge of the article and its service life, e.g. the SVHC is fully contained in the article, and the article is collected and disposed of in a manner that prevents any release to the environment and exposure to humans under normal and reasonably foreseeable conditions” (if not released during the recycling processes which are applied)
- “knowledge of the substances properties, e.g. the substance is fully immobile in the article due to the way it is included and because of its inherent physicochemical properties”
- “quantification based on exposure models, demonstrating no exposures during service life and disposal”
- “measurements proving that no emissions from the article take place including during its disposal.”

These arguments are of crucial importance if for example you are a manufacturer/importer of beryllium oxide heat sinks or electrolytic capacitors.

Starting from the 1 June 2011, the obligation to notify will apply six months after the substance has been placed on the candidate list. Notification is not required for a substance in articles which has been produced or imported before the substance has been included on the candidate list for authorisation.

Notification requires providing your contact details, the registration number of the substance if available, the identity, and classification of the substance, a brief description of the use(s) of the substance and of the articles in which it is present, and the tonnage band of the substance. Hence, it is not an onerous obligation.

What documentation is required?

Documentation is of key importance in fulfilling ones obligations under REACH. This will record the process and criteria used, the judgements made and the basis for these (references, supporting evidence etc.). This is important even if you have no obligations in your view in case this is challenged by competent bodies (enforcement authorities), customers or auditors. REACH requires such information to be kept for at least 10 years. Ways of achieving REACH compliance include incorporating these requirements in your company's management systems, carrying out assessment in conformance with the work flows provided in the REACH guidance, or following other good practice (e.g. common approaches developed by industry).

Notification and information

Knowledge of the presence of SVHCs in your articles is critical for notification and provision of information purposes. Requesting this information from suppliers is difficult even though EU based suppliers are obligated to provide it. Priority should be given to educating those involved in production,



design and procurement within your organisation and also your supply chain about the requirements of REACH and what is needed of them to ensure compliance. Consider also how you will interact with your supply chain (e.g. what questionnaire should you use) and what data infrastructure you might need (e.g. can you build on what you are already doing for RoHS compliance?).

Possible SVHCs can be determined through their properties - examining Material Safety Data Sheets (MSDS) you receive will reveal this for substances you use. You should also consult the list of proposed candidates discussed earlier. For articles you will need to ask your suppliers. Estimating the quantities of SVHCs present in your articles will then determine your obligations.

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.

For more information:

- Farnell dedicated website www.global-legislation.com
- Your questions to: glegislation@premierfarnell.com
- ERA Technology: info@era.co.uk
www.era.co.uk/rfa
- European Chemicals Agency (ECHA)
www.echa.europa.eu/home_en.asp

