

REACH and Articles

If you are producing or importing articles then you may have responsibilities under REACH. This leaflet will help you understand the key issues you will need to consider.

This leaflet provides an overview of the key issues associated with articles under REACH; it is not intended to provide comprehensive guidance. The European Chemicals Agency (ECHA) has published comprehensive "*Guidance on the requirements for substances in articles*" and readers are advised to consult this if they require more detailed information (available on the ECHA website).

What is an article under REACH?

An article is defined in REACH as '*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*'.

In a general sense, an article can usually be considered to be a finished product. Some examples of articles are clear cut, for example a fork, telephone and a car (with telephones and cars being made from many smaller 'component articles'). However, sometimes it is not as easy to tell if something meets this definition. For example, a metal bar can be an article if it has already been produced with a certain shape or size so that it can be engineered into another object (which will itself be an article). However it will not be an article if it hasn't been produced in this way and is simply to be melted to make another metallic object. In this second use, the shape of the bar is not important, but the metal is.

It is the duty of the manufacturer/importer to decide if they are dealing with an article (where the shape, surface or design is most important) or a substance/mixture (where chemical composition is most important). The ECHA guidance cited above explains this further and gives examples of how to make this decision.

There are certain difficult cases, for example candles or bullion bars where good arguments can be made for considering the object as either an article or a mixture/substance. In all cases, it is important that the duty-holder considers their decision carefully and makes a judgement one way or the other. Industry associations can have an important role to play in ensuring the consistency of decisions made by different companies. It is recommended that the reasons for any decision should be documented for future reference; this would be useful should the decision be challenged at a future date.

Packaging of any description is usually considered as an article under REACH. If you receive goods to your premises from outside the EU or supply goods which are packaged, you need to consider the issues below for the packaging.

Note - you are **not** required to submit a registration to ECHA for an article, rather, it is the substance(s) in the article that may, in specific circumstances, be subject to (registration) requirements under REACH (see below).

When during a manufacturing process does a substance become an article?

Articles are usually manufactured from raw materials that are substances or mixtures. During the manufacturing process the substances/mixtures are used to give the object a shape, surface or design which determines its main function and at this point it becomes an article. Some materials, for example, plastics, metals or fabrics undergo several stages of processing before becoming the final object (e.g. a bottle, a knife or a shirt respectively). Objects made from aluminium illustrate the case for deciding when a material stops being a substance/mixture.

Bauxite, a mineral ore is extracted, refined and enters the REACH system as aluminium oxide (a substance). This oxide is chemically transformed into aluminium metal which may be supplied as ingots of metal or alloy (a mixture). The ingots don't have an end use function and are therefore not yet articles (the ingot shape is for convenient transport and handling). The main function of ingots is to be melted and further processed, which is also not an end use function. From the ingots, for example sheets could be formed. These sheets could be either directly used or further processed into another product. As the direct use is possible, e.g. for making a roof, the sheets have an end use function, which is determined by the shape of the sheet. Thus, the transition point to the article is the sheet.

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It is important, particularly when a company is importing, that they are clear what they are importing and in what form.

Does the article contain any “Substances of Very High Concern” (SVHC)?

SVHC are substances that have hazards with serious consequences, e.g. they cause cancer, or they have other harmful properties and/or remain in the environment for a long time with their amounts in animals gradually building up. A list of these substances, the so called ‘candidate list’ of SVHCs is available on the ECHA website. This list is updated on a regular basis (usually in June and December each year). These SVHC are candidates for a process under REACH called “authorisation” and also serves as the key list of all SVHC covered by REACH. The Candidate List should not be confused with the list of substances requiring authorisation. These substances are included in Annex XIV of the REACH Regulation (Annex XIV substances are drawn from the Candidate List). There are a number of duties you must comply with if your article contains an SVHC:

Communicating Information on substances in articles

Any supplier of an article containing a SVHC on the candidate list in a concentration above 0.1 % weight/weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article. This must include, as a minimum, the name of the SVHC. In this context a ‘recipient of an article’ is somebody who will use or handle it as part of their work. This does not include consumers. The same requirements also apply should a consumer request this information. Suppliers should provide the consumer with the information free of charge and within 45 days of receipt of the request. This duty applies as soon as a substance appears on the candidate list. Therefore, suppliers of articles are advised to identify if any of the SVHCs currently on the list are used in the manufacture of their articles so that they are in a position to provide the required information within the 45 day deadline. To do this you may need to contact your supplier. [UK REACH CA Information Leaflet Number 12 – Substances of Very High Concern](#) gives further details.

Notifying ECHA of SVHCs in articles

If you produce or import an article you may be required to ‘notify’ ECHA if the article contains an SVHC on the candidate list if both the following conditions are met:

- (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year; **and**
- (b) the substance is present in those articles above a concentration of 0.1 % w/w.

When substances are included on the candidate list, then a notification will be required no later than 6 months after the date the substance is put on the list.

If you import several articles containing the same SVHC within them you need to consider the %w/w of the substance in each article and the total tonnage. For each article that contains the substance at 0.1% (w/w) or more, then the tonnage of the substance must be summed to identify any potential notification duty.

The requirement to notify does **not** apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use, including disposal (this is unlikely to be straightforward). In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

Notification is also **not** required if the substance has already been registered for that use. This registration can be made by anyone and does not need to be from within the same supply chain. It will be important to check the situation with suppliers and or trade associations before going ahead and producing a notification.

How to calculate the 0.1 % weight/weight concentration

Following the judgement of the European Court of Justice of 10 September 2015 (Case C-106/14), the concentration limit (0.1 % w/w) should be calculated for each article present in complex products (i.e., products composed of/assembled from several articles) as long as these articles keep a special shape, surface or design or as long as they do not become waste. The full implications of this judgement are still being worked out and in 2016 ECHA will revise their guidance to account for the ruling.

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The judgement can be viewed at: <http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-106/14>.

Does the article intentionally release a substance during use?

There are very few examples of intended release of a substance from an article. One might be the release of fragrance from a scented bin liner or eraser. Many objects that at first sight might be considered as articles as a whole are better described as a mixture within a container; examples are a pen, a toner cartridge or an aerosol. With all of these items the substances/mixtures within the container (the ink, toner or air freshener respectively) are the most important part of the function of the object and the container (pen body, cartridge or can) is a means of controlling release of the contents. The majority of articles that release substances fall into this latter category and in such cases the substances would need to be considered for registration. Note the containers (e.g. pen barrel, cartridge or can) are articles in their own right and so all the other provisions relating to articles still apply to these components.

ECHA guidance document highlights a number of criteria that should be applied to an object to identify whether it is an article with intentional release or a substance or mixture in a container. Generally, if the release of substances or mixtures from an object is the main function of the object, then the object is regarded a substance/mixture in a special container or on a special carrier material and **not** an article with an intended release of substances, as per the examples above. Therefore, the intended release of substances from an article normally applies to a secondary function or a specific added quality of the article.

The regulation is clear that it is only substances that are **intentionally** released from articles (under normal or reasonably foreseeable conditions of use) that should be considered for registration.

The guidance states that release is not considered to be intended if:

- it occurs during removal of 'impurities' from a semi-finished or finished article during its production process (before marketing as a finished article).
- it occurs during use or maintenance of the article and is meant to improve the product quality in a wide sense or the safety as a side effect but the released substances do not contribute to the function of the article.
- it is an unavoidable side-effect of the functioning of the article – i.e. without the release, the article would not work but release is not intended *per se* (e.g. wearing down of a car tyre or brake pad)
- the substance is formed during chemical reactions of any kind which occur when using the article
- it is incidental, for example could be forced by improper use or in an accident.

If you produce or import an article that does intentionally release a substance and the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year, then you will be required to submit a registration to ECHA for the substance contained in those articles. However, if the substance has already been registered for that use then a registration would not be required. The registration for your use can be made by anyone and does not need to be from within the same supply chain.

Further information

For advice on the application of REACH obligations, you can contact the UK REACH Competent Authority's national helpdesk:

Email: UKREACHCA@hse.gov.uk

Website: www.hse.gov.uk/reach

