

REACH - Authorisation

This leaflet provides a brief introduction to the REACH Authorisation provisions.

What is Authorisation?

Authorisation is one of the REACH processes for managing the risks of hazardous substances. Substances that are subject to authorisation may not be used in the EU, unless a company (and their registered users) have been authorised to do so. This will mean that eventually these substances are phased out of all non-essential uses.

The substances that qualify for consideration for authorisation are known as 'Substances of Very High Concern' (SVHC). More information on SVHCs is given in [UK REACH Competent Authority Leaflet Number 12 - Substances of Very High Concern](#).

Substances to which authorisation will apply are listed in Annex XIV of REACH. For each substance included on Annex XIV, a deadline will be set after which use of that substance in the EU must stop (known as the 'sunset date'), unless Authorised. Some substances may be accompanied by a list of specific-uses that do not require authorisation.

Once the sunset date has passed for an Annex XIV substance, only uses which have been specifically 'authorised' (or which do not require authorisation) will be allowed.

How are substances added to the Authorisation list (Annex XIV)?

Before a substance can be included on Annex XIV it must be identified as an SVHC and placed on the [Candidate List](#). Member States or the European Commission can prepare a dossier to identify a substance as a SVHC. These dossiers are subject to a formal procedure for addition to the Candidate List which includes public consultation. Periodically, ECHA will look at the substances on the Candidate List and will identify and recommend priority substances to add to Annex XIV. The European Commission, in collaboration with Member States and the European Parliament, will then decide which of these recommendations to take forward for addition to Annex XIV.

A number of other lists have been created – for instance by industry groups or Non-Government Organisations. These other lists have no legal status under REACH, and should not be confused with the official Candidate List or Annex XIV.

Who will be affected?

Businesses may be affected in a number of ways when a substance is placed on Annex XIV.

Those businesses who use a substance (or a mixture containing a substance) that is listed on Annex XIV will no longer be allowed to use it after the sunset date unless they are covered by an authorisation (or the uses are exempt from authorisation). This could lead to changes in the way you handle the substance in a different way.

Some businesses may choose to discontinue manufacture and/or use rather than apply for authorisation and those that do apply may have their applications rejected. This could mean that a substance or preparation you use is no longer available.

Even if you do not use a substance listed on Annex XIV you may still be affected if the substance is used further up your supply chain. Goods used by your business may be manufactured using a substance on Annex XIV. If authorisation is not granted for that use, you may no longer be able to obtain these goods. If an authorisation is granted, then the cost of the goods could increase.

Identification as an SVHC and inclusion on the Candidate List also leads to other duties. These are explained more fully in [UK REACH Competent Authority Leaflet Number 12 – SVHC](#) and [UK REACH Competent Authority Leaflet Number 9 - Articles](#)

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How are authorisations granted?

Where authorisation is required for a given use, companies will need to apply to ECHA for that authorisation and pay a (non-refundable) fee. Applications may be made by manufacturers, importers or downstream users and may be made by one or several applicants. Applications may cover one substance or a group of substances (where all the substances in the group share certain similar properties) and may be for one or several uses. Joint applications and applications covering more than one substance will cost less overall than making separate applications.

There are two routes to getting an authorisation:

- The adequate control route - the application needs to demonstrate that the risks to human health or the environment from the use of the substance is adequately controlled. This route only applies for SVHCs for which an effect threshold can be determined;
- The socio-economic route - this route is for use when adequate control cannot be demonstrated or for SVHCs for which an effect threshold cannot be determined. This includes substances classified as category 1 and 2 carcinogens and mutagens and those meeting the criteria for persistent, bioaccumulative and toxic and very persistent and very bioaccumulative

For more details on this see http://echa.europa.eu/chem_data/authorisation_process_en.asp

Companies can apply for authorisations for their own uses of substances and also for downstream uses in their supply chain. Where a downstream user has been granted an authorisation, it will also allow supply of that substance by their immediate upstream supplier to that downstream user for the Authorised use.

The application will need to specify the use(s) for which authorisation is sought, including any relevant use of the substance in mixtures and/or incorporation into articles. It will also need to include a 'Chemical Safety Report' (CSR) covering the risks related to the properties that led to identification as an SVHC (unless already submitted as part of a registration by the applicant). Compiling a Chemical Safety Report is a significant task.

In all cases, the applicant for the authorisation must provide an assessment of alternatives and should include a substitution plan if the conclusion is that there is a feasible alternative. For the socio-economic route the application must also include a socio-economic analysis to show that the risk to human health or the environment is outweighed by the socio-economic benefits as well showing that there are no suitable alternatives.

Decisions on whether or not to grant authorisations will be taken by the European Commission. They will take into account the advice of ECHA's advisory committees and any information received from third parties about alternative substances or technologies. The decision must be agreed by Member States.

The holders of an authorisation and downstream users that supply mixtures containing the substance must include the authorisation number on their product labels. Downstream users that are relying on an authorisation granted to an actor further up their supply chain must ensure that they use the substance within the conditions of the authorisation. They must also notify ECHA that they are using the substance within 3 months of first receiving it.

Authorisations will not be granted for uses that are prohibited by a REACH 'restriction'.

If an application for authorisation is made at least 18 months before the sunset date, then, unless already rejected, the applicant can continue using the substance after the sunset date has passed, until a decision on the application is taken. Each Annex XIV entry will specify this application date. Applications can continue to be made after application date, but uses must stop after the sunset date and until authorisation is granted.

Each authorisation will be reviewed after a specified time (which will vary in each case) and may be amended or withdrawn as a result of the review. Holders of an authorisation will have to submit a review report at least 18 months before the review is carried out for use to continue. The Commission can also decide to review an authorisation at any time if circumstances change.

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Exemptions from Authorisation

Some uses of substances are automatically exempt from the requirements of authorisation. This is mostly because they are controlled under other more appropriate laws.

Articles 2 and 56 exempt the following uses:

- Use in medicinal products for human or veterinary use;
- Use as a food additive or flavouring in foodstuffs;
- Use in animal nutrition or as an additive in feeding stuffs;
- Use as an 'on-site isolated intermediate' or a 'transported isolated intermediate';
- Use for scientific research and development;
- Use in plant protection products within the scope of 91/414/EEC;
- Use in biocidal products within the scope of 98/8/EC;
- Use as motor fuels covered by Directive 98/70/EC;
- Use as fuels in closed systems, or use as fuel in mobile or fixed combustion plants of mineral oil products;
- Use of a substance, when present in a mixture (preparation):
 - below 0.1 % weight/weight for a substance which is on Annex XIV due to 'environmental' or 'equivalent concern' properties;
 - below the lowest of the concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to Regulation (EC) No 1272/2008 which result in the classification, for a substance which is on Annex XIV due to properties not mentioned above is present

Note that REACH defines the terms 'on-site isolated intermediate', 'transported isolated intermediate' and scientific research and development in Article 3.

For substances that are on Annex XIV only because of hazards to human health, or because they are identified as 'equivalent concern' the following uses do not need to be considered for authorisation:

- Use in cosmetic products within the scope of 76/768/EEC;
- Use in food contact materials within the scope of Regulation (EC) 1935/2004.

Use in these product areas is already controlled under separate legislation.

What should you do now?

Chemical manufacturers, importers & downstream users

Currently Annex XIV does not contain any substances, but to help you prepare there are several places where you can get information on the substances that could be subject to authorisation:

- [Annex XIV recommendations](#) (substances on the Candidate list that have been recommended for Annex XIV)
- The [Candidate List](#) (substances that are identified as SVHC and may be added to Annex XIV)
- The [SVHC Consultation list](#) (substances actively being considered for addition to the Candidate List)
- The [Registry of Intentions](#) (substances where there is an intention to add it to the Candidate list)

The UK Competent Authority [e-bulletin](#) provides updates on substances that have passed the Registry of Intentions step.

If you supply or use a substance that is likely to appear on Annex XIV and the purpose for which it is being used is not covered by the exemptions outlined above, you should consider whether the substance can be substituted or a less-hazardous, alternative substance. Once added to Annex XIV, you could plan to phase-out your use of the substance by the sunset date.

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If a suitable alternative is not available, then you should consider whether to apply for authorisation to cover uses in your supply chain. ECHA will publish detailed guidance on the application process.

Downstream users

Downstream users should contact their suppliers to find out if the supplier intends to apply for an authorisation and whether they can benefit from this. There may be ways in which a user can help to prepare such an application. The type of information that your suppliers will need includes:

- detailed information on the technical functions that you need from the substance (not just broad use categories);
- information on whether your customers require you to use that substance in your process and the reasons why;
- the identity of possible alternative substances that you could use in your process and any technical or economic barriers to substitution. This could include information on the technical performance of your product and the effect of substitution on your production costs and the costs of your products to your customers;
- information on possible alternative processes that could be used and any technical or economic barriers that you would face if you changed your process.

This list is not exhaustive.

You may need to gather information from your customers about the consequences to them if you make a substitution,

If your current suppliers do not intend to apply for authorisation, then one approach is to find an alternative supplier who will be able to include you in their authorisation. Alternatively, you could apply for an authorisation yourself and that would allow someone to supply to you.

Articles manufactures and users

The makers of some types of article may be indirectly affected by addition of a substance to Annex XIV. The articles most likely to be affected are complex articles that are assembled from many smaller articles; for example, cars, electronics, furniture, etc. If a substance on Annex XIV is used in the production of components/parts that you use, then the availability, price and technical characteristics of these may change significantly in the long run. You should identify materials and products that are critical for the running of your business and contact suppliers of these goods to find out if there will be any changes as a result of the inclusion of substances on Annex XIV, to help you plan accordingly. The supporting document that accompanies each entry on the [Candidate List](#) includes information about known uses of the substances and should help you to target which suppliers to contact.

All

Anybody who will be affected by authorisation should consider approaching trade associations or other sources of business support that might be well-placed to offer advice for a specific business type or industry sector.

Further information

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

Email: UKREACHCA@hse.gsi.gov.uk

Website: www.hse.gov.uk/reach

Detailed guidance on the various processes relating to authorisation and information on how to take part in public consultation exercises is available on the European Chemicals Agency's website at: http://echa.europa.eu/chem_data/authorisation_process_en.asp

