

What to do when a substance appears on the Authorisation List

Introduction

This short document explains briefly how Authorisation might affect you if you supply products containing substances that end up in Annex XIV to REACH and which actions you may need to take, depending on your role in the supply chain.

What Authorisation means

Authorisation is a process to identify Substances of Very High Concern and effectively ban them as chemicals from the EU / EEA market where their risks cannot otherwise be adequately controlled. It does not directly control the import or supply of articles (non-chemical components or finished goods) although such products are likely to be affected by the identification of a chemical as a Substance of Very High Concern in regards to Article 33 disclosure.

Each entry in Annex XIV of REACH includes both a “sunset date” and a “latest application date”. As a general rule, once a substance is included in the Authorisation List it cannot be used after the sunset date unless that use is exempted, or the company or someone above them in the supply chain has been granted an Authorisation for that use. However, if a company submitted an application before the latest application date, and it is still under consideration, they may continue to use the substance until a decision has been made.

Unlike registration, there is no tonnage threshold for a substance to be subject to Authorisation – use of the substance at any level must be authorised, unless an exemption applies.

What if you supply a product containing an Annex XIV substance?

If you have identified any of the substances listed in Annex XIV in the products (finished goods or chemicals) you supply you may well be under considerable pressure to substitute the SVHC with an alternative substance – perhaps publicly and from your supply chain as well as from your legal duties.

We are sure you’d like more information on how you may be affected if that substance is added to Annex XIV. What you must do depends on your role under REACH. The following page summarises the main obligations for manufacturers and importers, for Downstream Users, and for suppliers of articles.

Don’t forget that the Candidate List, the prioritised substances and Annex XIV will continue to be updated in the future, so keep an eye out for future proposals that may affect your products. Forewarning of potential changes will give your business more time to construct a management

strategy, be that to accept (and, if necessary, apply for Authorisation), substitute (for alternative substances or technologies) or withdraw (the product from supply).

If you are a substance manufacturer or importer:

As well as any registration obligations on you as manufacturers and importers, if your substance is included in the Authorisation List you must hold a valid Authorisation for your use(s) and those of the supply chain which you are supporting. After the sunset date you must not use or place on the market a substance for a use that is not authorised, unless exemptions apply or you are awaiting the outcome of an Authorisation application submitted prior to the latest application date.

If you are a Downstream User:

You may only use substances on the Authorisation List for uses that have been authorised (or are exempted). There are two options for you if you wish to use a substance subject to Authorisation:

- Obtain the substance from a Manufacturer, Importer or Downstream User holding a valid Authorisation for that use. In this case, you must inform ECHA that you are using an authorised substance, and must use the substance within the limits of the Authorisation; or
- Obtain your own Authorisation for that use.

If you are granted an Authorisation for a particular use, then we understand that it grants you permission to use the substance for that use, and to be supplied the substance for that use by your immediate supplier. However, as a Downstream User you cannot apply for Authorisation for uses up your own supply chain.

So, for example, if your supplier is a formulator (a DU) and they supply you with a mixture containing an Annex XIV substance, you cannot apply for Authorisation for the formulation of that mixture, only for your own uses. Our understanding is that your Authorisation would cover the supply of the mixture to you. However, in order to be allowed to formulate that mixture either the formulator would need his own Authorisation, or the Manufacturer/Importer of the Annex XIV substance would need to cover that use (formulation) in his own application for Authorisation.

If you are a Distributor:

As a Distributor you store and place on the market substances – alone or in mixtures – for third parties. Although the definition of “use” at Article 3(24) includes storage, you are not regarded as a Downstream User. Distributors are excluded from Article 56, and therefore you are not eligible to apply for Authorisation unless you are also a Manufacturer, Importer or Downstream User.

When applying for Authorisation, companies must analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution – tasks that are usually regarded as possible only by those who use the substance.

If you are a supplier of articles:

For articles produced in the EU / EEA, for example producing a plastic bottle from its constituent chemicals, any substance used that is subject to Authorisation must be covered by a valid Authorisation for that use.

Imported articles containing substances in Annex XIV do not need Authorisation: the Authorisation process does not cover import or use of articles containing substances on the Authorisation List.

However, if you supply those imported articles, communication (to customers, to consumers on request) and notification (to ECHA) obligations may apply to you, as triggered by the inclusion of the substance on the Candidate List. These communication and notification obligations apply when the substance is present above 0.1% w/w in the article.

Further details on the Candidate List obligations are available on the ECHA website, at <http://echa.europa.eu/web/guest/candidate-list-obligations>.

Need further help?

If you still feel unsure about how Authorisation may affect you, you can get advice by emailing our Helpdesk at enquiries@reachready.co.uk or calling +44 (0) 207 901 1444.

If your customers or suppliers need advice on Authorisation, get them to sign up to REACHReady's Gold service at <http://www.reachready.co.uk/> and let us help them!