The “A” of REACH

An introduction to Authorisation

Authorisation is a process in REACH to identify and manage substances of very high concern (SVHCs) by promoting their substitution with less hazardous alternatives. The SVHCs which are subject to Authorisation are listed in Annex XIV to REACH, commonly known as the Authorisation List. Each entry in Annex XIV includes both a “sunset date” and a “latest application date”. As a general rule, where a substance is included in the Authorisation List it cannot be supplied for use or used after the sunset date unless that use is exempted or an authorisation has been granted.

Who can apply?

Manufacturers, importers and downstream users are entitled to apply for authorisation. In addition, duly mandated Only Representatives of non-EU manufacturers can apply (ECHA Q&A [568]). Distributors (defined in REACH as *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 mixture, for third parties*) cannot apply for authorisation.

If a downstream user is granted authorisation for his use(s), that DU can be supplied by its immediate supplier. However, distributors are transparent in the supply chain if they do not use the substance themselves. Therefore, an authorisation granted to a DU covers the manufacturer or importer and any distributors in between, provided that none of those upstream actors are using the substance.

Latest application date

The term “latest application date” in Annex XIV is actually something of a misnomer. A manufacturer, importer, Only Representative or downstream user may still apply for authorisation after that date; however, if they did so and their application is still pending when the sunset date arrives the use and supply must cease while waiting for the outcome of the application. If, instead, they applied by the latest application date then the use could continue after the sunset date while the application was pending.

The approach

For threshold-effect substances, the applicant needs to demonstrate that there is “adequate control” in the use applied for, i.e. that the exposure is below the relevant DNEL (for human health effects) and PNEC (for environmental effects). Where it is not possible to achieve adequate control, or where the SVHC is a non-threshold substance, the application must instead show that there are no suitable alternatives and that the socio-economic benefits of the use outweigh the risks.

How much will it cost?

The base fee to apply for authorisation is 53,300 EUR, payable to the European Chemicals Agency, ECHA. For additional substances, uses and applicants, top-up fees apply. SMEs can benefit from reduced fees; the reduction depends on the size of the company as defined by the Commission Recommendation 2003/361/EC.

In addition to the ECHA fees are the costs associated with preparing the application, for example for expert services in preparing an Analysis of Alternatives, a Socio-Economic Analysis and a Chemical Safety Assessment.

Further information

If you are interested in finding out more about how Authorisation works in practice, why not come along to our next Introduction to Authorisation workshop. This intensive and interactive day is aimed at anyone in the chemical manufacturing, importing and chemical-using sectors involved with Annex XIV substances. The day will also be of interest to anyone who has identified that their supply chain uses a Candidate List substance that may be added to Annex XIV and needs to consider the consequent business continuity issues.

Our Gold subscribers can access our more detailed guidance on the Authorisation process, applying for Authorisation and socio-economic analysis on the password-protected section of the REACHReady website. If you aren’t a Gold subscriber yet, sign up today (currently £400 + VAT per subscriber).