Guidance on deciding whether to apply for authorisation

Introduction

Seeking authorisation will be a time-consuming and expensive process, and there are no guarantees that an application will be successful. In each case a fee, as set out in Regulation (EC) No 340/2008 and subsequent amendments, must be paid to ECHA for each authorisation application; the standard fee for authorisation is in excess of €54,000 (there are reductions for SMEs, but top-up fees apply for additional uses, substances and applicants). With this in mind, as an applicant you want to be fairly confident of success before an authorisation is sought. This short document is aimed at helping those manufacturing, importing, supplying or using substances listed in Annex XIV to REACH to decide whether undertaking an application for authorisation is the best course of action.

Routes to authorisation

An application for Authorisation for specific uses of a substance included in Annex XIV takes one of two approaches: the 'socio-economic route' or the 'adequate control route'.

1. Adequate control route

This approach is relevant for Annex XIV substances: that are CMRs or substances of an equivalent level of concern; for which a threshold can be established (DNEL or PNEC); and for which the implemented risk management measures can be shown to control below these levels. Adequate control should be demonstrated through a chemical safety report.

Where adequate control has been demonstrated, this does not mean that the overall intention of the authorisation process can be ignored. Attempts to substitute Annex XIV substances for less hazardous alternatives must still be made and, alongside the chemical safety report, an analysis of alternatives (AoA) must be conducted. If the AoA shows that there are suitable alternatives available, then the applicant must prepare and submit a substitution plan which details how and in what timetable the applicant will conduct the transferral to the substitute. If no suitable alternatives exist then an R&D plan needs to be submitted in its stead.

2. Socio-economic route

This route is used for Annex XIV substances which cannot be adequately controlled. That is: substances described above but where it is not possible to reduce exposure below threshold levels; non-threshold CMRs and substances of equivalent concern; and PBT and vPvB substances. An authorisation can be granted if there are no suitable alternatives to the Annex XIV substance and the socio-economic benefits of use of the Annex XIV substance included in the application outweigh the risks to the environment and human health (see further information here).

As demonstrated by the above, there are a number of aspects to an application whichever route is taken, but two of these should be integral to the decision making process as well. An application is only going to be granted if the use of the substance clearly adds value in the European Union and the risks related to its use are low, therefore undertaking an analysis of alternatives and a socioeconomic analysis will allow you to decide whether an application is likely to be successful. If these two undertakings demonstrate that there are lower hazard alternatives available, or that the risks outweigh the benefits then the cost of an application has been saved. If they do not then you have a case for authorisation, and you will have already prepared a large part of the material required to make an application.

Analysis of Alternatives

The AoA should involve a robust, and impartial, assessment of the alternative substances and techniques available for each use of the substance which has been applied for. For each alternative the feasibility of its introduction, both technical and economic, should be assessed with consideration also made as to what reduction in risk to the environment and human health there will be. Where potentially suitable alternatives are identified, it should be considered how quickly it would be possible to introduce them. If the technology or economics would not allow the introduction of an alternative substance or technique before the sunset date listed for the Annex XIV substance, then an application for authorisation may still be necessary. The application will need to include a suitable substitution plan, and if approved, the length of the authorisation will reflect the timetables given.

If no viable alternative options are established, the application must include a research and development plan. This being the case, an AoA should not only look at existing alternatives but also the potential for future alternatives through an assessment of research being undertaken. Again evidence of this kind could influence the review period of an authorisation granted. Evidence of previously undertaken R&D can also be used to identify why an identified alternative will not be feasible.

Once again it should be highlighted that the analysis of alternatives should be a robust and impartial exercise. If this is not the case then it could lead to an expensive decision to apply for authorisation being made, when it is unlikely to be successful. Remember also that once an application has been made, public consultation may identify other alternatives that may be suitable substitutes so the analysis should be thorough and consult a number of sources in attempting to identify all available alternatives.

Socio-economic analysis

Although socio-economic analysis (SEA) is only a requirement for an application in which no suitable alternatives have been found and adequate control cannot be demonstrated, it forms a useful part of the decision-making process and can support an application by either route.

The purpose of the SEA is to analyse all relevant impacts of granting or refusing an application, therefore it must begin by defining both the use applied for and the ‘non-use’ situation. The SEA should then establish: the commercial impact; the impact on consumers; the social implications; the availability/feasibility of alternatives; the benefits for human health and the environment; and the wider implications of both scenarios. Wherever possible this should be quantified.

If the SEA clearly demonstrates that the benefits outweigh the risk then you will be left in a position where you can be confident in applying for authorisation and, provided it is conducted in a balanced and objective manner, the risk assessment committee and socio-economic analysis committee within ECHA should draw the same conclusions.

Need further help?

If you do not have the expertise to undertake the processes described above within your company, email our Helpdesk at enquiries@reachready.co.uk or call +44 (0) 207 901 1444 and ask about our Matchmaker service. This will allow us to put you in touch with REACHReady Approved Service Providers who have experience in managing the Authorisation process.

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!