Applying for an Authorisation

Introduction

If a substance is listed in Annex XIV of REACH, you will not be able to place on the EU / EEA market or use that substance in the EU / EEA after the 'sunset date' without a valid authorisation. Once the decision has been made to apply for an authorisation, the process itself will be both time-consuming and resource intensive so it is important the project is properly planned. If others, within your supply chain or involved in other supply chains, are also intending to apply for an authorisation there may be elements of the application that can be created jointly. There are benefits and disadvantages associated with collaborating with fellow applicants; deciding when to work together and which aspects of the application to submit individually will be an important aspect of the application.

This document explores the different options available to you in applying for an authorisation, and the process involved in each.

Components of an application

As you'll see below, there are two different routes that can be taken in applying for an authorisation, the adequate control route and the socio-economic route. Whilst some components of an application are common to both, others will only be required for one of the two routes. This section looks at all the components that may be involved, and highlights which routes they are applicable to.

Chemical Safety Report

A Chemical Safety Report (CSR) is a document which assesses all the risks to both human health and the environment associated with the specific use or uses applied for in the authorisation. Many applicants will already have submitted a CSR when registering the substance, however for those that are: downstream users; did not need to register; or whose registration did not require it, a CSR will need to be completed. Those companies which did submit a CSR as part of their application may wish to update the CSR to make it more precise for the particular exposure scenario relating to the application, however if no changes are made, and authorisation is to be based on all intended uses in the CSR, it does not need to be re-submitted. Guidance on chemical safety reports, and the chemical safety assessments on which they are based, are available to gold subscribers in the registration section of the website.

A chemical safety report will need to be submitted regardless of which route to authorisation is chosen, however the objective of the report will differ in each case. Where the route followed is of "adequate control", the exposure scenarios must demonstrate that exposure will be controlled below the relevant derived no effect levels (DNELs). It may mean adjusting the risk management measures (RMMs) or operational conditions, and perhaps choosing to sacrifice from the authorisation application those uses which lead to high emissions. With the socio-economic route, adequate control is not possible to achieve, however it must be considered whether the chemical safety

assessment has minimised emissions and exposure as far as possible. If not, again the RMMs or operational conditions may need to be changed.

Analysis of Alternatives

An Analysis of Alternatives (AoA) must be included in all applications, and should be undertaken as part of the process of deciding whether an application should be made or not. The AoA should involve a robust, and impartial, assessment of the alternative substances and technologies available for each use of the substance for which authorisation is sought. 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. A template for the AoA is available from the ECHA website, although where multiple uses are being considered completing this template each time can be a burdensome process and you may be better served using its content as a checklist.

Substitution plan

If the AoA shows that suitable alternatives exist, then the application must include a substitution plan. The substitution plan sets out a commitment by the applicant to transfer to the alternative substance or technology stated, and provides a timetable for the transferral. The timetable should detail the proposed actions to be undertaken, with justifications as to why they are required and details as to who will perform them. Methods of monitoring the plan to ensure it is followed and key milestones are met should also be included. Remember, an authorisation has a time-limited review period and demonstrating that a substitution plan has been well-prepared and followed could ensure the authorisation is granted for the period required, or assist in the renewal of an approval.

R&D plan

Whilst research and development is not a mandatory part of an application for authorisation, previous efforts made should be considered in determining the suitability of alternatives. It is also advisable to document its consideration where no suitable alternatives have been identified; otherwise any authorisation which is granted is likely to have a very short review period. Documenting any planned future development will demonstrate a commitment to the replacement of the Annex XIV substance when this becomes a feasible option. If you are concerned about confidentiality of R&D activity, this, along with a number of other parts of the application, may be indicated as such.

Socio-economic analysis

Although socio-economic analysis (SEA) is only a requirement for an application in which adequate control cannot be demonstrated, it may be used to support an application by either route. It is also another one of the application documents which can be used to assess whether an application is likely to be successful prior to making the decision to apply.

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.

Socio-economic analysis is covered in more detail in further guidance available to gold subscribers.

Justification for not considering certain risks

The REACH regulation gives two situations in which justification for not considering risks to human health and the environment may be given. These situations are where: emissions of a substance from an installation are under a permit granted in accordance with Directive 96/61/EC dealing with integrated pollution prevention and control; or where discharges of a substance are governed by prior regulation under Article 11(3)(g) of Directive 2000/60/EC (the Water Framework Directive).

Routes to authorisation

As the above section highlighted, there are two different routes to authorisation available, each applicable to Annex XIV substances which share certain characteristics. The criteria through which a substance will qualify for each route is given below:

Adequate control route

This approach is applicable to substances listed on Annex XIV due to either being a carcinogen, mutagen or reprotoxin (CMR) or having equivalent level of concern; and for which a threshold can be established. The threshold will be in the form of derived no effect levels (DNEL) and predicted no effect concentrations (PNECs). The chemical safety report (CSR) should indicate that adequate control to below these thresholds has been achieved through the risk management measures in place.

In addition to the CSR, an application through this route must include an AoA and, dependent on the outcome, either a substitution plan or R&D plan. Although not strictly required, a SEA would also support the application.

Socio economic route

In this case, the authorisation is granted if the socio-economic benefits of using the substance outweigh the risks and that there are no suitable alternative substances or technologies for the applicant. This route is used for Annex XIV substances which cannot be adequately controlled. That is: substances described above where it is not possible to reduce exposure below threshold levels; non-threshold CMRs and substances of equivalent concern; and PBT and vPvB substances. If suitable alternatives are available in general but are not feasible for the applicant, an authorisation may be granted if a credible substitution plan is submitted (further information here). Authorisation cannot be granted via the socio economic route if the alternatives are feasible for the applicant.

Although it is not possible to achieve adequate control where no threshold exists a chemical safety report, demonstrating exposure has been sufficiently reduced, should still be included. The most important aspect of an application by this route however, is going to be the socio-economic analysis itself and our further guidance on socio-economic analysis will provide you with a useful starting point.

Joint vs. Individual Applications

In applying for an authorisation, it is possible to collaborate with other applicants on some, or all, of the elements involved in the application. What it is feasible to generate jointly will be determined by the individual circumstances of an application, however it is easy to see how agreement on the measures that constitute adequate control and the suitability of alternatives, could benefit an application. On the other hand, the substitution or R&D plan could be very different for two organisations, and indeed one company may not want to reveal all the details of their intentions to another. When it comes to the socio economic analysis, there are some parts which may need to be completed individually to maintain confidentiality of business information, however again it may benefit the application to have conducted analysis based on the wider impact of a products use jointly.

Where SIEFs had been formed for registration, these can be a good starting point for discussions about applications for authorisation. Remember however that authorisation is not tonnage dependent in the same way as registration so there will be other companies with an interest in Annex XIV substances, most notably those within your supply chain.

When to apply

Every entry in Annex XIV is given a sunset date and a latest application date. The sunset date is the date after which the substance cannot continue to be used unless an authorisation has been granted; or a decision is pending on an application made prior to the last application date. The key therefore is to ensure the application is submitted before the last application date, however in addition to this applications should be made during certain submission windows, of which there are four per year. The submission windows can be found on the ECHA website and are based around the dates when the risk assessment committee and socio-economic committee meet.

How to apply

Prior to application for an authorisation ECHA should be notified of the intention to apply, and the uses which will be applied for. This notification can be made through the ECHA website and should be done well in advance of the date on which you intend to supply. At this time, you may also request a pre-submission information session with ECHA to ask any questions you may have surrounding the application. This should be held at least six months prior to submitting the application.

Once the application has been prepared in the form of an IUCLID substance dataset, an application form (also available from the ECHA website) should be completed and attached to the dataset. Once created, the IUCLID dossier is then submitted through the ECHA website.

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. We can 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!