

A GUIDANCE NOTE FROM THE UK CHEMICALS STAKEHOLDER FORUM

What you need to know about REACH Authorisation

Version 2, November 2015

Introduction

REACH, which stands for Registration, Evaluation, Authorisation and Restriction of Chemicals, is a substantial piece of legislation controlling chemicals within the EU. It aims to improve the protection of human health and the environment from the risks of chemicals and stimulate innovation in the chemicals industry.

Authorisation is one of the REACH processes for managing the risks of certain hazardous substances, known as “Substances of Very High Concern” (SVHC), and promoting their replacement with safer alternatives. Substances that are subject to authorisation may not be used in the EU past their pre-determined “sunset” dates unless a company has been authorised to do so. This means use of the substance will only be permitted if there is adequate control or if there are clear benefits in continuing to use it.

This leaflet provides you with an introduction to REACH authorisation and what it might mean for your business. It also tells you where you can go to find out further information and get help. It has been prepared by the UK Chemicals Stakeholder Forum to help smaller companies in particular understand what the likely impacts of authorisation will be. The European Chemicals Agency (ECHA) is the body responsible for the administration of this legislation. You can find information on the REACH legal text, on-going consultations and current applications for authorisation [on its website](#).

Will authorisation affect my business?

REACH applies to chemical substances on their own, in mixtures and in articles (objects). As such, REACH has the potential to impact all UK business sectors. From chemical manufacturers, furniture makers and retailers to builders, food manufacturers and printers – all businesses use chemicals in their day-to-day operations.

Your business will be affected if you currently rely on a substance that is going to become subject to authorisation. The effect can be either direct, if you use the substance, or indirect if your business purchases products or materials which are made using that substance.

You will no longer be able to use the substance in the EU once its “sunset date” has passed, regardless of how important it is to your business, unless your specific use has been authorised. Conversely, there could be market opportunities for your business if it provides alternatives that could be used to replace substances that are being considered for authorisation.

That said, business should not unduly fear authorisation. Many businesses have chosen not to apply for authorisation, readily finding alternatives to the substance in question. Moreover, the application process for authorisation appears to be working and a number of successful applications have now been processed.

What are my options if a substance I use, directly or indirectly, will be subject to authorisation?

You have five key options:

- Replace the substance with a suitable alternative or adapt your process to avoid its use.
- Switch to products (articles) that avoid the use of the substance.
- Consider applying for authorisation.
- Ensure your use is covered by another authorisation.
- Cease use in the EU.

Where can I find out more about substitution?

Substitution is the replacement of a substance, process, product or service by another that maintains the same functionality. If a substance critical to your business is subject to authorisation then substitution may offer a solution. However, this needs to be done with care. The viability of substitutes needs to be assessed on health and environmental grounds as well as their technical performance and economic feasibility.

The UK Chemicals Stakeholder Forum has produced a useful introductory [guide to substitution](#) which describes the process and its potential pitfalls. Help and guidance is also available online and [Subsport](#) is a good starting point. This is a free information exchange on alternative substances and technologies, as well as providing tools and guidance for substance evaluation and substitution management.

In some cases, even though there may be substitution options available to you, you may still need to apply for authorisation to ensure there is adequate time to implement changes or to secure sufficient quantities of the alternative to meet your needs.

How can I obtain permission to continue to use a substance that will be subject to Authorisation?

Companies need to apply to the European Chemicals Agency (ECHA) for authorisation. Permission to continue to use a substance on the Authorisation List can be granted if the applicant demonstrates that:

- **The risks from the use of the substance are adequately controlled** (i.e. exposure does not exceed levels which may cause adverse effects to human health and the environment). This route only applies for substances for which a safe level (*“derived or predicted no effect level”*) can be determined; or
- **The risks to human health or the environment from the use of the substance are outweighed by the benefits to society** and there are no suitable alternative substances or technologies available. This route is for use for SVHCs for which a safe level (*“derived or predicted no effect level”*) cannot be determined **or** when adequate control cannot be demonstrated.

Applications for authorisation need to include:

- A **chemical safety report** covering the risks arising from the substance’s properties and demonstrating how those risks should be managed.
- An **analysis of alternatives** considering alternative substances, the technical and economic feasibility of using a different substance and any research and development activities you are doing to search for an alternative.
- A **substitution plan** outlining research, action and timeline required to switch to alternative substances and technologies if they exist but aren’t immediately available.
- A **socio-economic analysis**, if required or recommended. This should clearly demonstrate that the benefits to society of using the substance outweigh the costs to human health and the environment.

Whilst some information can be taken from generic sources, the application will need to provide a significant amount of data specific to your company. ECHA has systems in place to safeguard information that is commercially sensitive.

You will have one opportunity to discuss your draft application with ECHA ahead of submitting your application, in a Pre-Submission Information Session. Once submitted, applications are considered by two committees of independent scientific experts at ECHA, and subject to public consultation, before forming an opinion as to whether or not, in their view, the conditions for authorisation have

been fulfilled. These opinions are then considered by the European Commission which takes the final decision on granting authorisation.

Seeking authorisation can be time consuming and resource intensive. It is therefore important that you are proactive in managing the application and that the project is thoroughly planned. Before deciding to apply you must consider all the options available to you. It is essential for you to fully understand what the impact would be if you can no longer use the substance in the EU.

The European Commission is currently considering a number of options to simplify applications in a limited number of cases (substances used in spare parts and repairs and those used in low volumes).

How are substances added to the Authorisation List?

There are three key steps before a substance is subject to authorisation. The process is outlined in **Diagram 1** and explained below.

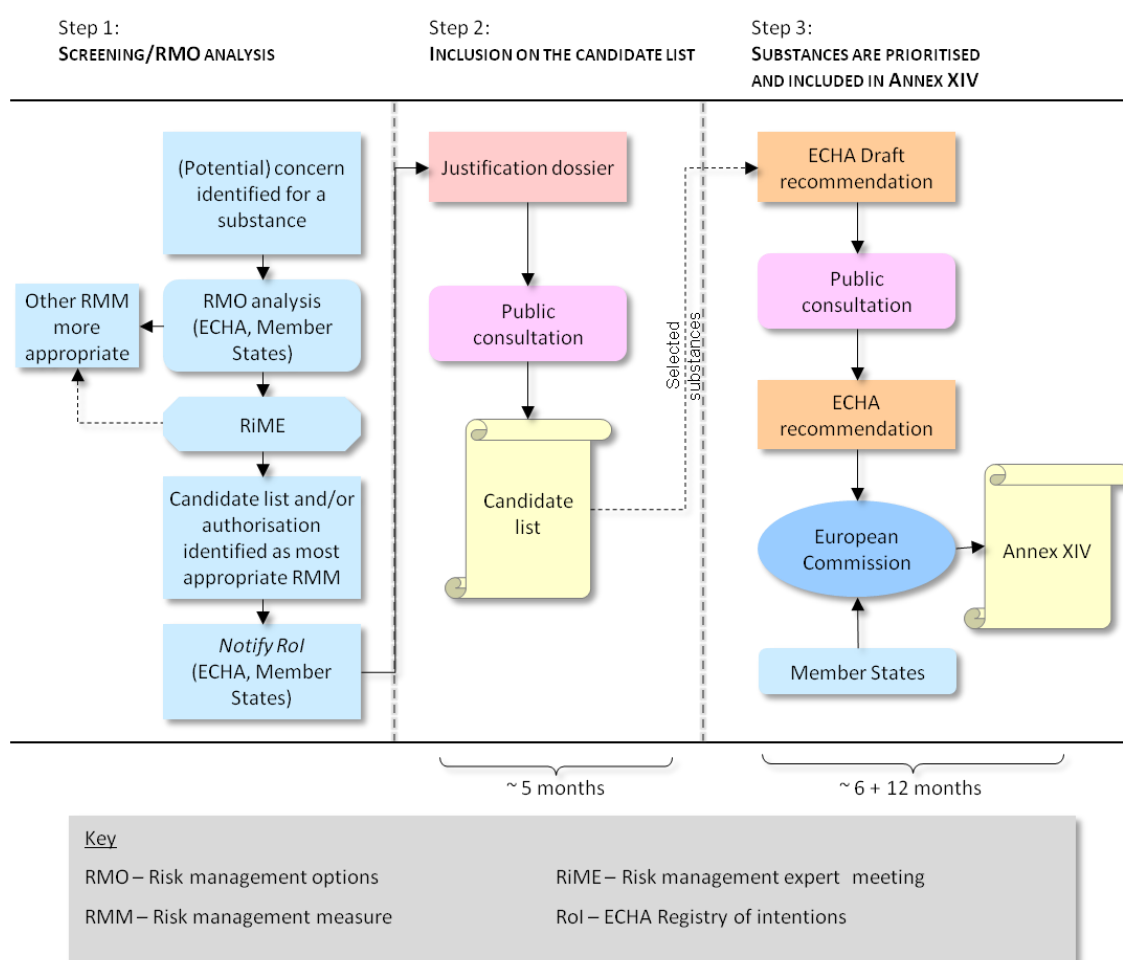


Diagram 1: How substances are chosen for authorisation

- *Identifying the most appropriate risk management measure (Step1)*

Through screening activities, authorities identify potential substances of concern that might require further action. ECHA or a Member State carries out a risk management options (RMO) analysis to decide whether measures are needed and, if so, what the most appropriate action would be. Substances being examined are listed in the Public Authority Coordination Tool, on ECHA’s website.

If it is agreed that Authorisation is the most appropriate route, it is notified in ECHA's registry of intentions (RoI). This gives advance warning of ECHA's or Member States' intentions.

- *Inclusion of SVHCs on the candidate list (Step 2)*

Once on the RoI, the Member State or ECHA prepares a justification dossier (also known as an 'Annex XV dossier') to set out why the substance can be defined as an SVHC and should be included on the Candidate list for authorisation. The dossier is subject to a public consultation, during which interested parties can submit relevant information.

- *Prioritisation and inclusion in the authorisation list (Step 3)*

Periodically, ECHA is required to recommend to the Commission which substances from the Candidate List should be prioritised for authorisation, based on the substance's properties, uses and volumes. ECHA's draft recommendation is subject to a public consultation. The Commission, in collaboration with Member States, finally decides whether the proposed substances should be included in the Authorisation List (REACH Annex XIV).

It is important to note that while not all substances on the Candidate List will be recommended for authorisation, substances are being prioritised for authorisation every year and once that occurs the inclusion in the Authorisation List is a relatively quick process.

What are the key dates to consider in the authorisation process?

The Authorisation List outlines the date by which the use of the substance must stop ("the sunset date") without authorisation, and any exemptions. Sunset dates are typically (but not always) set three years after the substance has been added to Annex XIV.

If you cannot substitute the substance and are considering continuing to use it, an application for authorisation must be submitted. The Authorisation List includes the "latest application date", which is set at least 18 months before the sunset date. Companies meeting this deadline can continue to use the substance after the sunset date until their authorisation application has been fully processed.

How can I keep track of which substances are being targeted?

It is important to monitor developments in order to plan for, and manage, potential changes. You should monitor the [Public Authority Coordination Tool](#), the [Registry of Intentions](#), the [Candidate List](#) and the [Authorisation List](#). These are regularly updated. The Candidate List is usually updated twice a year and public consultations occur in March-April and September-October ahead of the update. Details of substances that are being prioritised for inclusion on Annex XIV can be found on the [ECHA website](#). Consultations on new proposals typically run in the autumn each year.

You can also sign up for [ECHA news alerts](#) or the [HSE eBulletin](#). Organisations such [EEF](#) and [REACHReady](#) also provide free alerts. These services will notify you when substances are identified as SVHCs, subject to consultation and prioritised for inclusion in, or added to, Annex XIV.

Are there any exemptions to authorisation?

Yes. Some uses of substances are automatically exempt from the requirements of authorisation. This means that they can still be used in certain circumstances even if they have been included on the Authorisation list. This is mostly because risks posed by the substance are already controlled through other existing European legislation. The exemptions are detailed in Article 2 and Article 56 of REACH and include, for example, substances used in medicinal or veterinary products, substances used in food and feed stuffs and on-site isolated and transport isolated intermediates. Check before starting any work and always seek clarification from your competent authority (the HSE in the UK).

Is it possible to challenge proposals for substances to be subject to authorisation?

There are a number of opportunities for interested parties to input into the authorisation process, and this can affect whether or not a substance ends up on Annex XIV.

It is important that you monitor consultations and input when you can. The most effective way is to submit comments via industry sector groups and trade associations. Information on uses of the substance (including information on the tonnages used per use, exposures or releases resulting from these uses, the complexity of the supply chain, views on transitional arrangements, proposals for exemptions, etc.) is particularly welcomed.

It may also be prudent to engage with Member States or ECHA when they are preparing a dossier identifying a substance as a SVHC. This could prevent the substance being listed on the candidate list, for example if it can be demonstrated that there are other more effective ways to manage the risks posed by the substance (e.g. restriction) than authorisation.

Does authorisation apply to research and development activities?

Maybe. If you use a substance for scientific research and development, then this is exempt. Scientific research and development is defined as any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume of less than 1 tonne per year. This would include using a substance for monitoring or control purposes.

There is also discretion to exempt, on a case-by-case basis, the use of a substance for product or process orientated research and development (PPORD). If you want to use a substance subject to authorisation for PPORD you will need to check Annex XIV to see whether an exemption is in place.

Does authorisation apply to imported goods?

Yes and no. Authorisation only applies to chemical substances. An importer cannot import a substance on Annex XIV (on its own or in a mixture) after the sunset date unless an authorisation has been granted which allows them to do so. However, authorisation applies only to the use of the substance in the manufacture of an article, not to the presence of the substance in the article itself. Therefore, articles containing a substance on Annex XIV can be imported into the EU without the need for an authorisation. However, in order to produce the article within the EU using a substance on Annex XIV, an authorisation would be required. Both EU producers and importers of articles have an obligation under certain conditions to notify ECHA about the presence of “candidate list substances” in the articles. More information on the notification of substances in articles can be found on the [ECHA website](#).

It is also important to note that a substance within an article could be proposed for a ‘restriction’ if it is deemed to present risks to human health and/or the environment which are not being sufficiently controlled. Substances which are subject to a restriction are listed in Annex XVII of REACH. If a restriction is introduced for a substance, its presence in an article (either produced in the EU or imported from outside the EU) could be limited or prohibited altogether.

Who can apply for authorisation?

European chemical manufacturers, chemical importers, Only Representatives of non-European chemical manufacturers, formulators and companies using chemicals downstream (and any combination of these) can apply for an authorisation. Companies that use chemicals have a fundamental role as applications are required for the “use” of the substance. These “downstream users” have two options if they wish to use a substance subject to authorisation:

- Obtain the substance from a manufacturer, importer or another downstream user that holds a valid authorisation for that particular use.
- Directly apply for authorisation for their use.

A chemical manufacturer or importer may submit an application to cover all users down the supply chain. Under these circumstances, downstream users must notify ECHA if they are using a substance for which an authorisation has been granted for their use. If an authorisation is granted directly to a downstream user, it only allows for the substance to be “placed on the market” for that use by its **immediate** supplier (one level up that supply chain).

Early communication in the supply chain is therefore crucial. Chemical manufacturers and downstream users should share information and discuss the most efficient way to cooperate. The dominant company in the supply chain may have an interest in coordinating action.

How long do authorisations last?

Authorisations do not last forever. When an authorisation is granted, a ‘time-limited review period’ is set. The duration of the review period is assigned on a case-by-case basis, taking into account information in the application. The likely (default) review periods are 4, 7 or 12 years. Towards the end of the review period, if the company wants to continue using the substance, it must submit an updated application for authorisation, which will be assessed as before.

In practice, you are more likely to have a short review period if there are uncertainties in your application. Clearly outline in your application what review period you are seeking and why.

Is the Authorisation process different for SMEs?

No, REACH provisions apply to all EU companies, and importers, irrespective of company size.

How much does an application cost?

A fee must be paid to ECHA for each authorisation application. The level of the fee depends on the number of uses, substances and applicants covered by the application. There are reduced fees for companies qualifying as medium, small and micro-enterprises as per the [EU SME definition](#). The reduced base fee covering one applicant, one substance and one use ranges from €40,575 for a medium-sized business to €5,410 for a micro-sized business. Please note that ECHA verifies the SME status of all applicants and administrative charges apply in case of incorrect claims. ECHA have a [“Fee Calculator Tool”](#) available to estimate the fee for authorisation applications.

However, note that the application fee is likely to represent only a small fraction of your costs. You will incur additional costs if consultancy support is needed, if you need to access technical information or if the preparation work is carried out with others or if legal disputes arise between parties. These costs can be significant. Experience from applications so far suggest an average total cost of €230,000. You should be confident of success before deciding whether applying for authorisation is the best course of action.

What steps can I take to reduce authorisation application costs?

You should first familiarise yourself with the process to understand what you can do in-house and what needs to be done externally. When using consultants it is strongly advised that you shop around for best value, possibly allocating different parts of the application to different consultants, as experience dictates.

It is possible to cooperate with other applicants during the preparation of some, or all, of the application. There are benefits and disadvantages in doing so. In some cases, it might help to reduce costs, though in others the added complexity of ensuring that confidential information remains confidential may add layers of management that increase costs.

Deciding when to work together and which aspects of the application to submit individually will be an important decision. Parts may need to be completed individually to maintain business confidentiality, for example the analysis of alternatives or the socio-economic analysis, or if you are describing processes that demonstrate controlled use of the chemical. However it may benefit the application to conduct a joint analysis of the wider impact of a product's use. If you do decide to work with other applicants, be mindful of competition law.

What should I be asking my supplier?

If you use a substance subject to authorisation, you may want to ask your suppliers what their intentions are. For example, whether they are considering substitutions or whether they intend to apply for authorisation. In the latter case, you should ensure they receive information to cover your use and those of your customers. If the authorisation is granted, your supplier will provide you with an authorisation number on the product's label and safety data sheet. If you decide to obtain an authorisation for your own use, you should ensure that your supplier intends to continue to supply the substance in the long term.

Once an authorisation has been granted, do other provisions of REACH still apply?

Yes. Other provisions of REACH continue to apply to the substance, as may be relevant.

How can I find out more?

You may be able to find out more about authorisation and whether it will affect your business from your supplier or others within your supply chain. You should also contact sector organisations, which may be coordinating or signposting relevant activity or may have developed guidance specifically for your area of business. The UK Competent Authority provides a REACH helpdesk. The helpdesk service is free and confidential and can be contacted at UKREACHCA@hse.gsi.gov.uk.

There are also a number of guidance materials available that you may find helpful:

- *Industry guidance: REACH authorisation [guidance for downstream users](#):*
- *HSE bite-size [information leaflets](#)
[ECHA website](#) and [ECHA Factsheet on applications for authorisation](#)*
- *ECHA's Guidance on the [preparation of an application for authorisation](#) and [Guidance on Socio-Economic Analysis – Authorisation](#)*

This guidance was drafted by a sub-Group of the UK Chemicals Stakeholder Forum comprising: Susanne Baker (EEF, the Manufacturers' Organisation) (Chair), Jo Lloyd (formerly Chemical Industries Association), David Santillo (Greenpeace), Silvia Segna (Chemical Industries Association) and David Taylor (Royal Society of Chemistry). Non-Forum members - Keith Bailey (Defra), Patrice Mongelard (Defra), Lindsay Peppin (HSE), Stavros Georgiou (HSE), Mike Holland (EMRC) and Richard Dubourg (The Economics Interface Limited) - also contributed to this work.

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