A GUIDANCE NOTE FROM THE UK CHEMICALS STAKEHOLDER FORUM

What you need to know about REACH Authorisation

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.

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 some form of chemicals in their day-to-day operations.

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 unless a company has been authorised to do so. This will mean that such substances are eventually phased out of all non-essential uses.

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 where to 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.

Will Authorisation affect my business?

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 that use the substance.

If your specific use has not been authorised, you will no longer be able to use the substance in the EU regardless of how important it is to your business. 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.

What are my options if a substance I use is 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

Up for Authorisation: Chromium trioxide, also known as chromic acid, is classified as carcinogenic and mutagenic. It is used for metal finishing because of its excellent anti-corrosion properties and as such is widely used by a range of sectors for functional chrome plating or for decorative use. In many cases, while it is used in the plating process it isn't present in the end product. Only Authorised uses will be allowed from 21 September 2017. In some cases it is possible to use less hazardous forms of chromium to achieve the same result.

with care. The viability of substitutes needs to be assessed on health and environmental grounds as well as their technical performance.

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 tools and guidance for substance evaluation and substitution management.

How can I obtain permission to continue to use the substance?
Companies need to apply to the European Chemicals Agency's (ECHA). Permission to continue to use a substance subject to Authorisation 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;
- **The risks to human health or the environment from the use of the substance are outweighed by socioeconomic benefits** 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.

The application will need to include:

- A **chemical safety report** covering the risks arising from the substances properties and demonstrating adequate control of the risk, if this isn't already available.
- 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 actions and timelines required to switch to alternative substances and technologies if they exist but aren't immediately available.
- The application may also include a **socio-economic analysis,** if required.

Applications are initially assessed by the ECHA's technical committees and the analysis of alternatives is open to public scrutiny. The European Commission has the final decision on whether to grant Authorisation or not. Seeking Authorisation can be time consuming and resource intensive. It is therefore important that you are proactive in managing Authorisation and that the project is thoroughly planned. Before deciding to apply you must therefore 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.

How are substances identified for Authorisation?
There are three key steps to consider before a substance is subject to Authorisation. The process is outlined in **Diagram 1** and explained below.

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

Through screening activities, authorities identify potential substances of concern that might require further action. When there is sufficient understanding of the properties of the substance, ECHA or the responsible Member State then carry out a risk management options (RMO) analysis to decide whether measures are needed and, if so, what the most appropriate regulatory route would be. The proposed approach is reviewed by a group of Risk Management Experts (RiME). If it is agreed that Authorisation is the most appropriate route, it is then notified to ECHA's registry of intentions (RoI). The RoI gives advance warning of ECHA's or Member States' intentions to take action.

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

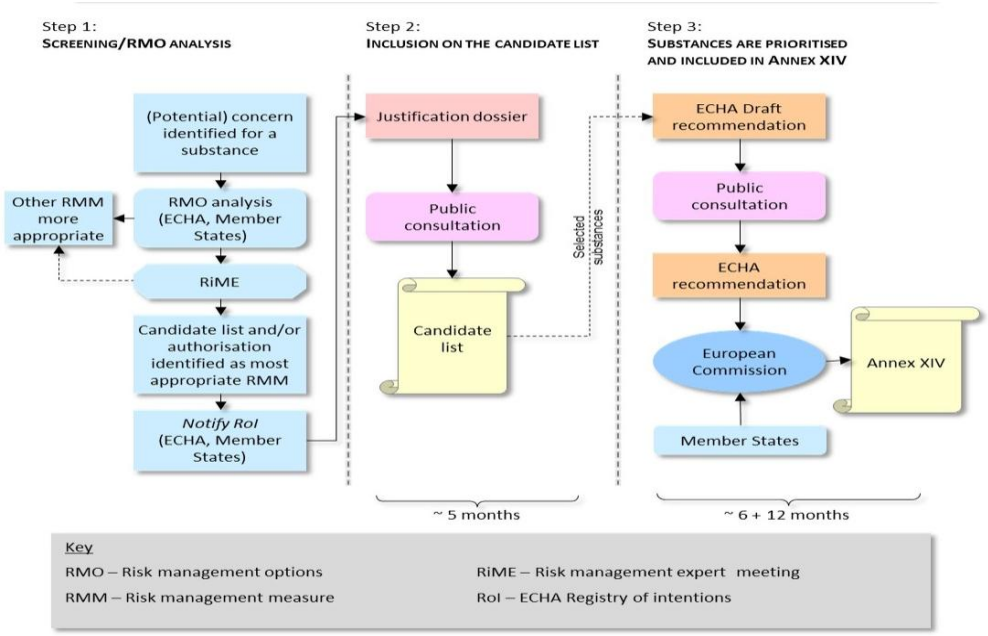
Once on the RoI, the responsible Member State or ECHA then prepares a justification dossier (also known as an 'Annex XV dossier') to formally set out why the substance can be defined as SVHC and should be included on the candidate list for Authorisation. The dossier is subject to a public consultation, during which interested parties can submit relevant information. If comments are received during public consultation, unanimous agreement by ECHA's Member State Committee (MSC) is needed before the substance's inclusion in the candidate list.

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

ECHA is required to periodically make a recommendation to the Commission on which substances from the candidate list should be prioritised for Authorisation. The prioritisation is based on the available information on the substance's properties, uses and volumes. The draft ECHA recommendation is subject to a public consultation and then followed by a MSC's opinion. The Commission in collaboration with Member States finally decides whether the proposed prioritised substances should be included in the Authorisation list (REACH Annex XIV). Substances listed in Annex XIV are subject to Authorisation.

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.

Diagram 1: How substances are chosen for Authorisation



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") unless authorised and any exemptions, if any. Sunset dates are typically (but not always) set three years after the substance has been published in Annex XIV.

If you cannot substitute the substance and are considering continuing to use the substance, 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 Registry of Intentions, the Candidate List and the Authorisation List. Both 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 from June to September 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. It includes, 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 (i.e. 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 does not apply to substances which are an integral part of an imported article. 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.

It is important to note that a substance within an article could become subject to a 'Restriction' at any time. 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 prohibited.

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 them) 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 that use.

A chemical manufacturer or importer's Authorisation may cover all users down the supply chain. However, a downstream user **cannot** apply for Authorisation for uses up its own supply chain. If a downstream user is granted Authorisation it only allows for the substance to be "placed on the market" for that use by its **immediate** supplier (one level up his 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 applying and/or 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 review periods are 4, 7 or 12 years.

Is the Authorisation process different for SMEs?
No, REACH provisions apply to duty holders irrespectively of the company size.

Up for Authorisation:
Trichloroethylene is an industrial solvent commonly used as a degreaser of metal parts. It is sold under a variety of trade names but may also be referred to as TCE, Trike, Tricky or Tri. Whilst highly effective, it is classified as a carcinogen and groundwater contamination by the substance has become an important environmental concern for human exposure. Due to concerns about its carcinogenicity, it should only be used in industrial application in a fully closed system, supported by employee monitoring and recycling. Only Authorised uses will be allowed from 21 April 2016.

How much does it 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 €39,975 for a medium-sized business to €5,330 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 only represent 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. This can be significant. 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?
It is possible to cooperate with other applicants during the preparation of some, or all, of the elements involved in the application. Cooperation with other companies might help to reduce costs.

There are benefits and disadvantages associated with collaborating with other applicants. Deciding when to work together and which aspects of the application to submit individually will be an important decision. When it comes to the analysis of alternatives or the socio-economic analysis for instance, or if you are describing processes that demonstrate adequate control, there are some parts which may need to be completed individually to maintain confidentiality of business information. 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 are a downstream user, 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 application 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 (Chemical Industries Association), Joanne Lyall (formally Society of Chemical Industry), David Santillo (Greenpeace), Silvia Segna (Chemical Industries Association), David Taylor (Royal Society of Chemistry). Non-Forum members - Keith Bailey (Defra - REACH Team Leader), Patrice Mongelard (Defra - UKCSF Secretary) and Lindsay Peppin (HSE - UK REACH Competent Authority) also contributed to this work.