REACH authorisation: A guide

Sam Wright and **Richard Elsmore** of **JSC International** overview the submission process for authorisation under REACH

Under the REACH Regulation, substances listed on the Authorisation List in Annex XIV require an authorisation dossier for a specific use to be submitted and evaluated by the European Chemicals Agency (ECHA) in order to permit continued use on the EU market. The process of dossier submission is complex, with specific information required in the registration dossier and a detailed evaluation and review process by several committees.

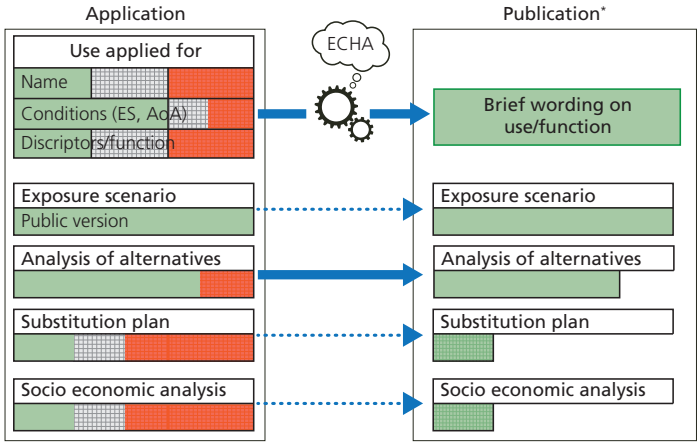
The aim of the authorisation process is to control and restrict the sale or use of Substances of Very High Concern (SVHCs). An SVHC is a substance that may have serious and often irreversible effects on human health and the environment.

Authorisation is a two-step process whereby a Member State or ECHA initially proposes that a SVHC be added to the Candidate List for authorisation. These substances can be tracked on the Registry of Intentions a public list of substances for which a SVHC, classification or restriction dossier is intended to be submitted.

In the second step, a substance may be included in the Authorisation List itself. Such substances cannot be placed on the market or used after the so-called 'sunset date' unless an authorisation has been granted for a specific use, or if the use has been exempted from authorisation. As soon as a substance is included in the Authorisation List, manufacturers, importers or downstream users (DUs) may apply for an authorisation.

The European Commission (EC) made a commitment in 2013 to include 'all relevant known' SVHCs in the Candidate List by 2020, which will increase the number of substances that can be added to the Authorisation List. ECHA regularly assesses the Candidate List substances to determine which ones should be included in the Authorisation List as a priority.

Prioritisation is mainly based on information on the uses and volumes of the substances on the EU market that fall within the scope of the authorisation requirement. Before sending its recommendation to the EC, ECHA launches a public consultation which lasts for 90 days. As of May, 22 substances were on the Authorisation List, while a further 151 were on the Candidate List.



Source: ECHA

Figure 1 - Publicly available information

Applications for authorisation are on the rise. Eight were submitted in 2013 and, as of May, ECHA had received a further five. The substances for which authorisation applications had been received are: bis(2-ethylhexyl) phthalate (DEHP); dibutyl phthalate (DBP); lead sulfochromate yellow (CI Pigment Yellow 34); lead chromate molybdate sulphate red (CI Pigment Red 104); diarsenic trioxide; and, hexabromocyclododecane, in 13 applications.

So far, two substances are moving towards the end of the authorisation process. ECHA's scientific committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) have adopted opinions on an application for authorisation for the use of DBP and an application for the use of DEHP. The EC will make the final decision based on ECHA's opinions. Current progress and statistics are presented on the ECHA webpage (http://echa.europa.eu/ addressing-chemicals-of-concern/authorisation/applications-for-authorisation/received-applications).

Applying for authorisation

Manufacturers, importers or DUs can apply for an authorisation for the placing on the market or the use of a substance on the Authorisation List. Certain uses of substances on the list are exempt from the authorisation process, including in scientific R&D (Article 56(3)), cosmetics (human health (Article 56 (5a)) and substances in mixtures at <0.1% (Article 56 (6a)), among others.

Applications will only be successful if applicants can demonstrate that the risk from use of the substance is adequately controlled (the 'adequate control route'). If not, an authorisation may still be granted if it can be proven that the socio-economic benefits of using the substance outweigh the risks and there are no suitable alternative substances or technologies (the 'socio-economic route').

The application process requires the investment of time and resources, so companies should consider if this is the best course of action for their business or whether switching to an alternative substance, if available, may represent a better option than authorisation. A robust analysis can help determine whether an authorisation is the best option and will also be useful for compiling an argument to support the application.

If the authorisation route is chosen, applicants must notify ECHA well in advance (i.e. eight months) of the intended date of submission of an application for authorisation, so that ECHA can ensure a proper resource planning and a smooth processing of all incoming applications. The notification will need to indicate the substance and provide a general description of the uses for which authorisation is being sought.

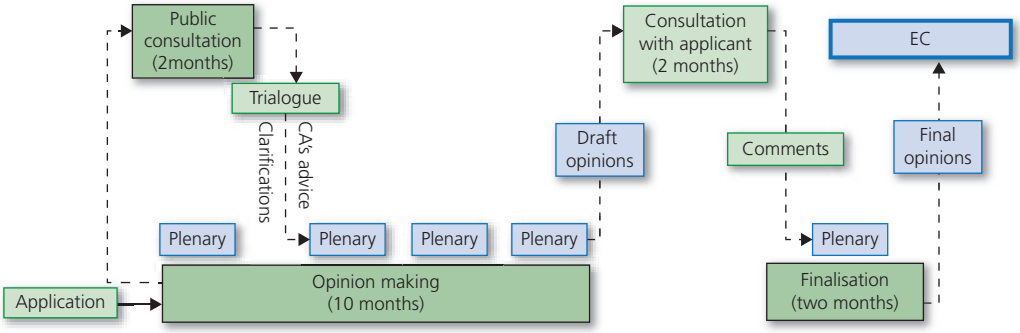
When notifying ECHA, a pre-submission information session (PSIS) with ECHA representatives can be requested to ask case-specific questions regarding the regulatory and procedural aspects related to the application. If the request is accepted, applicants will be asked to provide background information before the session. PSISs should be held, at the latest, six months before the submission of the application for authorisation.

The application for authorisation should include the identity, the use for which authorisation is sought, a chemical safety report (CSR), an analysis of the possible alternatives and, where alternatives are available, a plan to substitute the substance, including a timetable for proposed actions. A socio-economic analysis (SEA) is required where the applicant cannot show adequate control of risks. However, it is suggested that a SEA should be provided as supporting evidence to demonstrate the impact of the availability of the substance.

Submission windows

To aid ECHA with work planning, specific windows for submitting applications have been established for uploading the application submission. The aim is to ensure the minimum processing time for the application by both ECHA and its committees by synchronising the submission windows, which are announced on ECHA web pages every three months, with scheduled meetings.

Each substance on the Authorisation List is automatically assigned the latest application date by ECHA but not all fall within a submission window (e.g. for trichloroethylene, the latest application date is 21 October 2014 but its latest submission window is 7-21 August 2014). To ensure that the application is processed smoothly, ECHA recommends that you submit the application in one of the windows before the latest submission window.



Source: ECHA

Figure 2 - Timing of application case 'trialogue' in opinion-making procedure

If the dossier is submitted in any of the submission windows, applicants can benefit from Article 58(1)(c)(ii) of REACH on transitional arrangements allowing the continued use after the sunset date until the EC takes a decision on the application for authorisation. The EC has clarified this wording to confirm that the transitional arrangements only apply if the application is submitted before or at the latest application date.

If the dossier does not pass the Business Rules checks and re-submission is required, applicants will not benefit from the transitional arrangements. Therefore ECHA recommends that you submit your application either during the penultimate submission window or at the very beginning of the latest one. The opinion-making process starts once ECHA has received the application fee (i.e. about 2.5 to three months after the application has been submitted).

Public consultation

The authorisation process encompasses a public consultation on potential alternative substances. This starts just after the application has been received and lasts for eight weeks, allowing the public to review the application and add further information to make sure that all relevant information on alternatives are available to ECHA. Even though authorisation is an EU process, people from all over the world can comment.

Not all information on your application is provided to the public as ECHA only publishes information on the applicant and the substance as well as the 'Broad Information on Uses', which includes information about the use applied for, the use descriptors and function and the conditions of use. To have a transparent and meaningful consultation, the public versions of the analysis of alternatives, substitution plan, SEA and Exposure Scenarios are also made available (Figure 1).[1]

Public consultations are launched in batches four times per year, in February, May, August and November. They are advertised on the ECHA website (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation).

Interaction for the applicant

Applicants have the opportunity to comment on information given in the public consultation, as all comments and responses are posted on ECHA's website. The applicant has the ability to provide counter-arguments to public comments within two weeks of the end of the consultation. These counter-argument comments are also published.

Applicants may also need to provide any additional information to either the SEAC or the RAC as requested. To address the need for additional discussion, an application 'trialogue' between the applicant and the RAC and SEAC rapporteurs will be established in the opinion-making procedure. This is usually held four weeks after the end of the public consultation (Figure 2).

The trialogue allows rapporteurs to discuss with applicants any information on alternatives generated through public consultation or any other technical or scientific issues with the application. It is held after the public consultation so that rapporteurs can explore the significance of any relevant information received with applicants and third parties.

Rapporteurs will also be able to invite those third parties who submitted information to the public consultation which is of particular interest and relevance to the application. Stakeholder observers from RAC and SEAC will be invited to attend the trialogue to provide scrutiny and transparency, although applicants and third parties will have the opportunity to argue that certain information to be discussed is confidential and that observers should be excluded from any relevant parts of the meeting.

ECHA's confidentiality advisor directs RAC and SEAC chairs whether cases should be 'observed' or 'non-observed' by stakeholders. The decision is based on information presented in the application, public consultation and discussed during the trialogue. If discussions of confidential business information are likely to be 'unavoidable', the case will be classed as 'non-observed'

Finally the applicant has the right to comment on the draft opinion of the authorisation application. Adopted opinions for previous consultations can be found on a specific ECHA webpage (http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations).

Supply chain considerations

Manufacturers, importers and DUs can apply for and hold authorisations for their own uses or for uses down their supply chains. Therefore a DU can use a substance without applying or holding an authorisation provided that ECHA is notified (Article 66) and the substance is used in accordance with the conditions of an authorisation granted to an actor further up the chain (Article 56(2)).

A company may also supply the substance to his immediate DU for a use, provided that this DU holds an authorisation for that use (Article 56(1)(e)). In other words, a DU holding an authorisation can cover the placing on the market for his use(s) only one level up his supply chain but not any further up it. The rules regarding who can be the authorisation holder may have the potential to cause supply disruptions if there are missing links in the supply chain.

Following approval

Once the authorisation number has been published in the Official Journal, the holder of the authorisation is required to include, without delay, the authorisation number on the label before placing the substance, or a mixture, on the market. The same applies to DUs using an authorisation granted to an actor up his supply chain for that use.

The Safety Data Sheet (SDS) also requires updating without delay. If a SDS is not required, the DUs and/or distributors shall be informed of the details of either authorisation approval or refusal. In cases where a DU uses the substance on the basis of the authorisation granted to the supplier, the DU is required to notify ECHA within three months of the first supply of the substance.[3]

There are a number of guidance documents, user manuals and templates available on the ECHA website to help registrants with the Authorisation process:

- Guidance on the Preparation of an Application for Authorisation
- Guidance on Socio-Economic Analysis
- How to Develop the Description of Uses in the Context of Authorisation
- Data Submission Manual Part 22: How to Prepare & Submit an Application for Authorisation using IUCLID 5

Templates are available for CSR, analysis of alternatives, substitution plans and SEA.

References

1. M. Mottet, Applications for Authorisation: Status & ECHA's Supporting Activities, CEFIC REACH Information & Experience Exchange Forum, June **2013**
2. ECHA, Participation of Applicants, Third Parties & Stakeholder Observers in the Application for Authorisation Process: RAC/23/2012/06 (Rev. 1), SEAC/17/2012/06 (Rev. 1), Helsinki, 14 December **2012**
3. ECHA, Guidance on the Preparation of an Application for Authorisation, Version 1, January **2011**

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