

Factsheet

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Applications for authorisation under REACH



Authorisation is one of the REACH processes for managing the risks of hazardous substances. It aims to ensure that risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives, without introducing unwanted disruptions to

the functioning of the internal market. Therefore, it is possible to apply for an authorisation for a substance included in the Authorisation List (i.e. Annex XIV of the REACH Regulation).

The Authorisation procedure is described in Title VII of the REACH Regulation (EC) No. 1907/2006.

THE AUTHORISATION PROCEDURE

The uses of substances on the Authorisation list on the EU market are suspended after the so-called sunset date which is set on a case-by-case basis for each substance. Unless an exception applies, these substances may only be placed on the market if an authorisation has been granted for a specific use.

The Commission decides on the granting or refusing of authorisations. For that, ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) provide the Commission with opinions on applications for authorisation.

The up-to-date Authorisation List is available on ECHA's website.

SUPPLY CHAIN CONSIDERATIONS

A manufacturer, an importer or a downstream user of a substance on the Authorisation List may prepare an application for authorisation for its own uses or for the uses for which they intend to place the substance on the EU market. A duly mandated only representative of a non-EU manufacturer can also submit an application.

The supply chain coverage of an authorisation is important to consider:

- **If a manufacturer or an importer applies:**

The authorisation can cover the manufacturer's or importer's downstream uses of the substance for its customers base ("top-down" coverage).

- **If a downstream user applies:**

The authorisation has a limited coverage. It covers the applicant itself, its customers (down the supply chain) and its immediate supplier (one level up in the supply chain) if this one is only placing the substance on the market (not using the substance itself). A downstream user cannot therefore cover actors up its supply chain other than the substance manufacturer or importer, this one being its immediate supplier.

THE IMPORTANCE OF DOWNSTREAM USERS AND SUPPLY CHAIN COMMUNICATION

Compared to manufacturers or importers, downstream users may have a greater interest in ensuring that an authorisation is granted if they depend on particular substances being available. This does not automatically mean that all downstream users should apply for an authorisation themselves. However, it does imply that manufacturers and downstream users of chemicals should set up supply chain communication from the outset to share information (including the chemical safety report) and discuss the most efficient form of cooperation. In the authorisation process, communication along the supply chain is a key function.

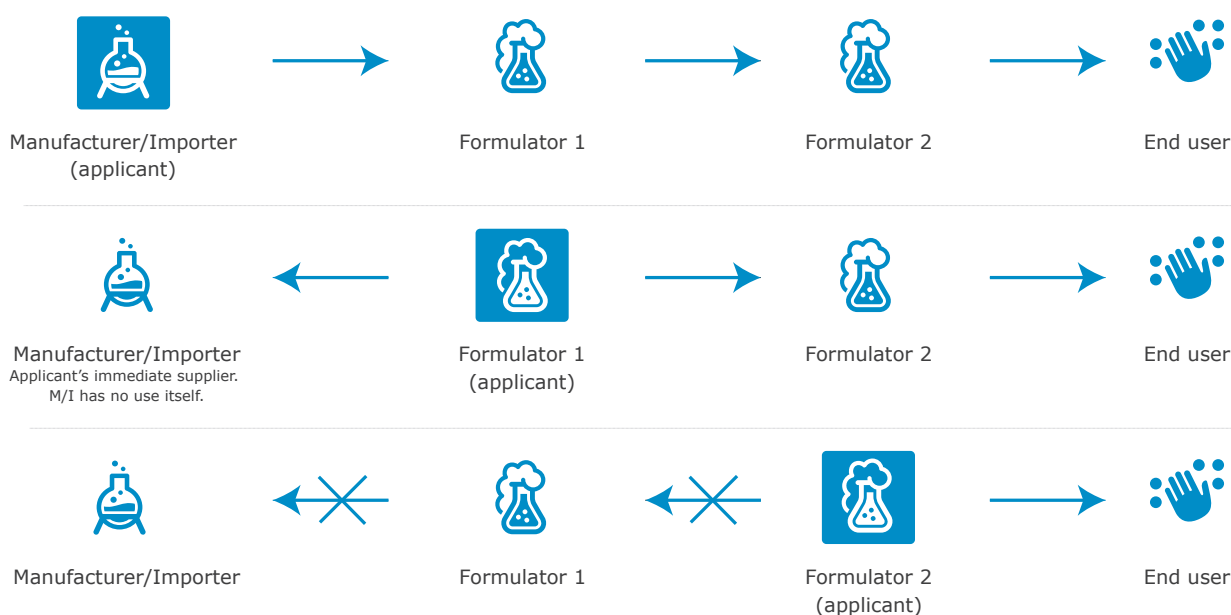


Figure 1. Authorisation: supply chain coverage. The arrows indicate authorisation coverage

HOW IS AN AUTHORISATION GRANTED OR REFUSED?

The criteria for granting an authorisation are defined in Art. 60 of REACH:

- Under the “adequate control route” (Art. 60(2)) an application shall be granted if the risk to human health and the environment from the use of the substance arising from the intrinsic properties specified in the Authorisation List is adequately controlled.
- Under the “socio-economic route” (Art. 60(4)), an authorisation may be granted if it is shown that (i) the socio-economic benefits outweigh the risk to human health and the environment from the use of the substance and (ii) there is no suitable alternative substances or technologies.

The factors to be taken into account for assessing the availability of suitable alternatives are described in Art. 60(5) and in the Guidance on Applications for Authorisation.

The Committees prepare their draft opinions for the application for authorisation within 10 months of receipt of the application. The opinions are based on the application, as well as any information received during the public consultation on possible alternatives run by ECHA, and any further information on alternatives that the applicant or interested parties have provided, based on request from the Committee for Socio-Economic Analysis. Applicants can comment on the draft opinions before they are adopted by the Committees.

Within three months of receipt of the Committees' opinions, the Commission prepares a draft decision as to whether or not the authorisation should be granted. Subsequently, the Commission adopts the decision granting or refusing the authorisation.

PREPARING APPLICATIONS FOR AUTHORISATION

ECHA's guidance and manuals illustrate how to apply for an application for authorisation and explain how to prepare the different parts of an application:

- Guidance on the preparation of an Application for Authorisation
- Guidance on Socio-Economic Analysis: Authorisation
- Guidance on information requirements and chemical safety assessment
- How to describe uses in the context of Authorisation

To prepare an application for authorisation in IUCLID:

- Data submission manual – part 22: How to prepare and submit an application for authorisation using IUCLID

Format and templates

The format for an application for authorisation is a IUCLID dossier, to which assessment reports and supporting documents need to be attached. These are summarised below. All the formats and detailed instructions are available on ECHA's website.

ECHA provides templates to be used by applicants for authorisation as necessary and applicable:

- **Chemical safety report:** documenting the chemical safety assessment of the substance and demonstrating the adequate control or minimisation of the risk arising from the use of the substance applied for.
- **Analysis of alternatives:** showing whether there are any suitable alternative substance(s) or technology(ies) to the substance(s) for the uses applied for.
- **Socio-economic analysis:** gathering socio-economic arguments in support of the application for each use of the substance applied for.
- **Concordance table:** specifying where in the application is discussed important issues for the formulation of the opinion on granting the authorisation.

For threshold substances where adequate control is demonstrated and where suitable alternative(s) is(are) available to the user:

- **Substitution plan:** showing the applicant's commitment to take the actions needed to substitute the substance with suitable alternative substance(s) or technology(ies) for the use(s) applied for within a specified timetable.

Notification of intent and pre-submission information session

ECHA invites the potential applicants to notify well in advance their intention to submit an application. ECHA also gives the opportunity to future applicants to ask for a pre-submission information session with ECHA staff members to ask case-specific questions regarding the regulatory and procedural aspects of the application for authorisation process.

Pre-submission information sessions should be held the latest about six months before the submission of the application for authorisation.

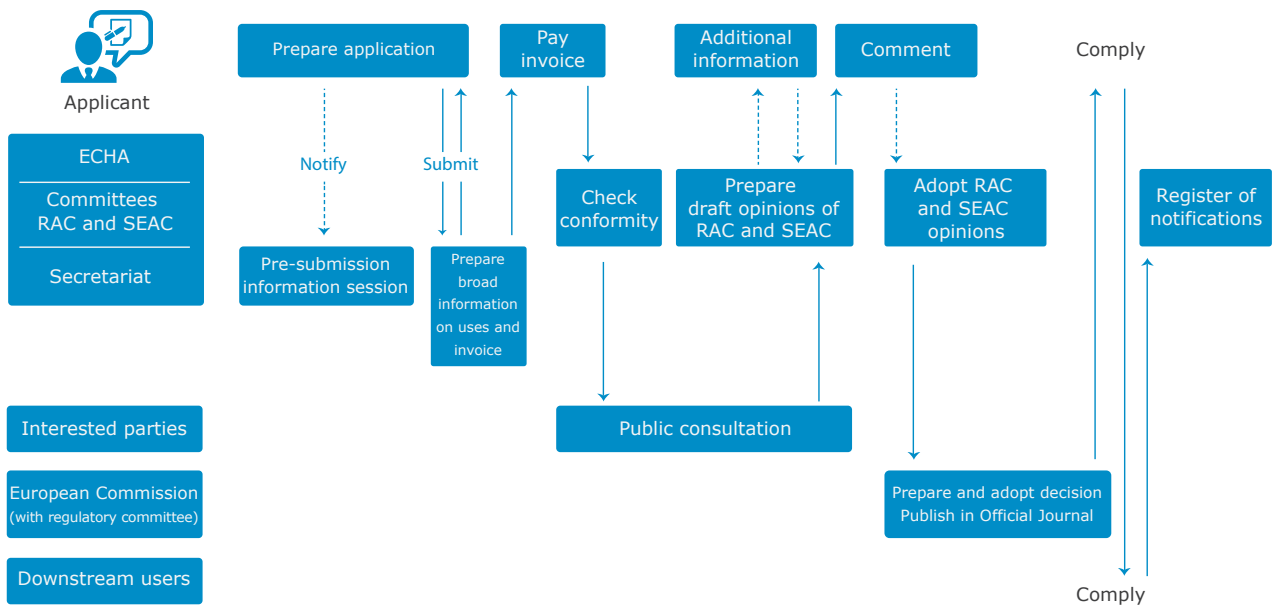


Figure 2. The application for authorisation process: actors and steps

Submission windows

ECHA establishes specific windows for submitting applications for authorisation (see ECHA website). Submitting the applications within these windows ensures the minimum processing time for the applications by ECHA and its Committees.

Fees and reductions for small and medium-sized enterprises

A fee has to be paid to ECHA for the development of the opinion by ECHA's Committees. The level of the fee depends on the number of uses and exposure scenarios, substances and applicants covered by the application. However, small and medium-sized enterprises (SMEs) can get up to 90% reduction on the application fee provided that they qualify for this.

ECHA will verify the SME status of all applicants. If it concludes that the size of a company is larger than claimed when applying for authorisation, the applicant needs to pay the difference in authorisation fee as well as an administrative charge.

ECHA has made available a Fee Calculator on its website. This is a very useful tool to estimate the fee before submission.

PUBLIC CONSULTATION ON ALTERNATIVES

The purpose of public consultation is to gather additional, relevant and meaningful information on possible alternatives for the uses applied for. It offers the opportunity for public engagement in the

regulatory process. ECHA's scientific committees take into account the information submitted by interested third parties in the development of their opinions.

For each combination of applicant/substance/use applied for, a public consultation on alternatives will be launched. The consultation lasts eight weeks, starting from the publication on ECHA's website of the "broad information on uses" package which consists of:

- The name of the applicant
- "Brief wording":
 - Name of the use
 - Conditions of use (exposure, functional requirements)
 - List of use descriptors (codes, function)
- Public version of the Exposure Scenario
- Public version of the Analysis of Alternatives
- Public summary of the Socio-economic Analysis
- Public summary of the Substitution Plan

FURTHER INFORMATION

More information is available in the ECHA website at:

<http://echa.europa.eu/addressing-chemicals-of-concern>
<http://echa.europa.eu/applying-for-authorisation>