

Readers' guide for preparing an application for authorisation

The purpose of the readers' guide

The purpose of this readers' guide is to give potential applicants, and their consultants, an overview of the existing documents that should be read before preparing and submitting an application for authorisation, including information on how applications are assessed by the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC).

A lot of material is available, including two guidance documents, over 10 documents on how applications are evaluated by our scientific committees and over 70 questions and answers on specific topics. These are spread out across several different web pages.

This readers' guide is intended to be adapted in the future based on readers' needs. If you think that any useful information or documents have been omitted, or if you have any questions or suggestions for improvement, please let us know by emailing us at: application-authorisation@echa.europa.eu

1. OVERVIEW

For a quick overview of the application process, visit our [support page on how to apply for authorisation](#).

The guidance on the [preparation of an application for authorisation](#) gives an overview of the authorisation process and describes the main elements of an application for authorisation.

2. DEVELOPING THE ASSESSMENT REPORTS

An authorisation is always use-specific and a key step in the preparation of the application is therefore the description of the use(s) applied for. The guidance on [how to develop the description of uses](#) provides further information on this process.

2.1 Chemical safety report

The chemical safety report covers the risks to human health and/or the environment from the use of the substance arising from its intrinsic properties specified in Annex XIV. The guidance on information requirements and chemical safety assessment provides generic guidance on how to [prepare a chemical safety report](#). For some applicants, the guidance on [occupational exposure estimation](#) and on [preparing a downstream](#)

[user chemical safety report](#) may also be relevant.

If the applicant uses the [reference derived no-effect levels \(DNEL\) and dose-response relationships](#) published by RAC, it does not need to provide the hazard data necessary to derive DNELs or dose-response relationships.

2.2 Analysis of alternatives and socio-economic analysis

In the analysis of alternatives, the applicant analyses the technical feasibility, economic feasibility, availability and risk reduction potential of alternative substances or technologies. Section 3 of the guidance on the [preparation of an application for authorisation](#) gives further technical information on this. SEAC's note on how it assesses [economic feasibility](#) in applications for authorisation is also relevant.

The socio-economic analysis describes what would happen if the applicant was not able to continue using the substance, and what costs and benefits this would create for society. The guidance on the [preparation of a socio-economic analysis](#) provides more information on this. In order to estimate the human health benefits, applicants can also use the findings of an ECHA study published in 2015 on [willingness-to-pay to avoid certain health impacts](#).

The impact of substances identified as persistent, bioaccumulative and toxic (PBT) or very persistent very bioaccumulative (vPvB) are usually not possible to monetise. Applicants applying for these substances should read SEAC's note on the [evaluation of applications for PBT and vPvB substances](#).

We have selected [examples of socio-economic analyses and analyses of alternatives](#) from received applications that could be read by future applicants. These examples are illustrative in terms of the clarity of reporting, the coverage of the key issues as well as the extent to which the analyses are evidence-based and referenced.

3. EVALUATION OF APPLICATIONS

Information about how applications are assessed by RAC and SEAC can be found in the note on the [common approach of RAC and SEAC in opinion development on applications for authorisation](#), the [working procedure for RAC and SEAC for developing opinions on applications for authorisation](#) and the note on the [opinions of RAC and SEAC on applications for authorisation](#).

The note on [publication of information on applications during the opinion-making process](#) outlines what information will be made publicly available, while the note on [participation of applicants, third parties and stakeholder observers in the application for authorisation process](#) describes the roles of the various actors in the opinion-making process.

For information about RAC's and SEAC's experience so far we recommend reading [previous opinions](#), as well as the presentations made by RAC's Chairman and SEAC's Chairman at the [Conference on Lessons Learnt on Applications for Authorisation](#) held in February 2015 and the [Workshop on Streamlining Applications for Authorisation](#) of November 2015.

All authorisation decisions have a time-limited review period. A note published by RAC and SEAC further explains how the [length of the proposed review period](#) is determined.

4. QUESTIONS AND ANSWERS AND FREQUENTLY ASKED QUESTIONS

We have developed an extensive series of [questions and answers](#) to frequently asked questions on applications for authorisation.

5. PRESENTATIONS IN SEMINARS, WORKSHOPS

Presentations given in [events related to applications for authorisation](#) are accessible from our website.