



Where to get further information

*Seminar on applications for authorisation
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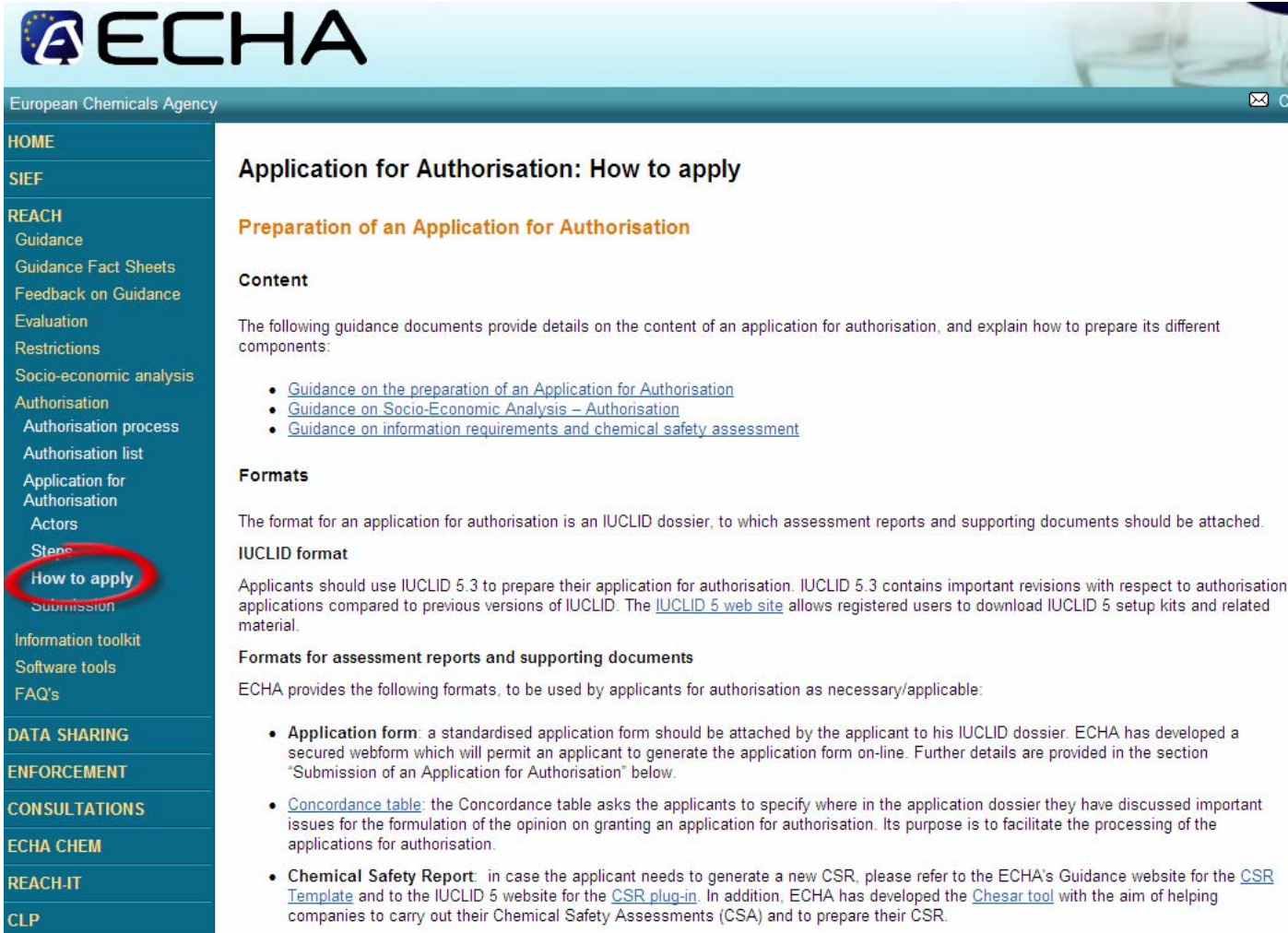


ECHA's website

- The updated "*Application for Authorisation*" section contains:
 - the Authorisation List,
 - the overview of procedure and actors,
 - « *How to apply* » section with:
 - Links to guidance documents and Data Submission Manual
 - Templates for assessment reports and other attachments
 - Access to submission webforms
 - Further information: Q&As (fees), Fee Calculator
- It will be regularly updated in order to be the reference for applicants



New web pages on ECHA website



The screenshot shows the ECHA website interface. The top navigation bar includes the ECHA logo and the text 'European Chemicals Agency'. A left-hand menu lists various categories: HOME, SIEF, REACH (with sub-items: Guidance, Guidance Fact Sheets, Feedback on Guidance, Evaluation, Restrictions, Socio-economic analysis, Authorisation, Authorisation process, Authorisation list, Application for Authorisation, Actors, Steps, **How to apply**, Submission), Information toolkit, Software tools, and FAQ's. Below this are sections for DATA SHARING, ENFORCEMENT, CONSULTATIONS, ECHA CHEM, REACH-IT, and CLP. The main content area is titled 'Application for Authorisation: How to apply' and contains the following sections:

- Preparation of an Application for Authorisation**
- Content**

The following guidance documents provide details on the content of an application for authorisation, and explain how to prepare its different components:

 - [Guidance on the preparation of an Application for Authorisation](#)
 - [Guidance on Socio-Economic Analysis – Authorisation](#)
 - [Guidance on information requirements and chemical safety assessment](#)
- Formats**

The format for an application for authorisation is an IUCLID dossier, to which assessment reports and supporting documents should be attached.

IUCLID format

Applicants should use IUCLID 5.3 to prepare their application for authorisation. IUCLID 5.3 contains important revisions with respect to authorisation applications compared to previous versions of IUCLID. The [IUCLID 5 web site](#) allows registered users to download IUCLID 5 setup kits and related material.

Formats for assessment reports and supporting documents

ECHA provides the following formats, to be used by applicants for authorisation as necessary/applicable:

 - Application form:** a standardised application form should be attached by the applicant to his IUCLID dossier. ECHA has developed a secured webform which will permit an applicant to generate the application form on-line. Further details are provided in the section "Submission of an Application for Authorisation" below.
 - Concordance table:** the Concordance table asks the applicants to specify where in the application dossier they have discussed important issues for the formulation of the opinion on granting an application for authorisation. Its purpose is to facilitate the processing of the applications for authorisation.
 - Chemical Safety Report:** in case the applicant needs to generate a new CSR, please refer to the ECHA's Guidance website for the [CSR Template](#) and to the IUCLID 5 website for the [CSR plug-in](#). In addition, ECHA has developed the [Chesar tool](#) with the aim of helping companies to carry out their Chemical Safety Assessments (CSA) and to prepare their CSR.

For those who will apply

- ECHA intends to organise "pre-submission activities", to which future applicants can adhere on a voluntary basis.
- It would consist in:
 - a notification system: notifying well in advance to ECHA the intention to submit an application for authorisation will help the Agency in planning its resources; a notification is not binding and will not be communicated by ECHA to any other parties
 - a pre-submission discussion (*see next slide*)

Pre-submission discussion

- It is an opportunity for applicants to:
 - ask for clarifications on how to prepare and submit an application
 - give their preliminary views on a possible "*broad description of uses*" applied for
- It is not:
 - advice provided by ECHA to applicants to improve the content of the application, and in particular the assessments and the conclusions drawn by the applicant

Further communication actions

- After this seminar, ECHA is willing to develop other actions to:
 - raise the awareness and improve the understanding of the authorisation application requirement and procedure
 - provide the different actors to be involved in this procedure with all the necessary information and tools to be able to best contribute
- ECHA has already planned:
 - a presentation at the next Stakeholders' Day
 - an article in ECHA's next Newsletter
 - participation in external conferences on authorisation
- Any other ideas for specific seminars, webinars, publications,... are welcome

Conclusions

- ECHA website channels all the necessary information for potential applicants; it will be regularly updated
- Based on feedback, questions and suggestions received, ECHA will develop further (communication) actions