

# Content of Applications for Authorisation

and

# Update on Restrictions

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*ECHA – Risk Management Implementation*

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# Presentation Scope

- Content of Authorisation Applications
    - Requirements
    - Main elements
    - Further information
  - Update on Restrictions
    - Restrictions currently in the process
    - Upcoming restriction dossiers
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# Content of Authorisation Applications

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# Content requirements

- To provide the needed information to decision-makers in order to be granted an authorisation to use or to place on the market for a use a substance listed on Annex XIV
    - Information needs
      - Opinion elements (Art. 64)
      - Decision criteria (Art. 60)
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# Authorisation Decision

- Risks are adequately controlled  $\Rightarrow$  CSR, (SP)

OR

- Socio-economic benefits outweigh risk  $\Rightarrow$  SEA, CSR

AND

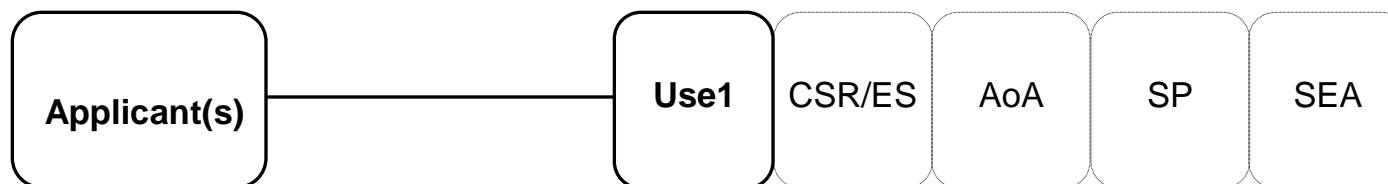
- No suitable alternative substances or technologies  $\Rightarrow$  AofA
  - In addition:
    - Conditions  $\Rightarrow$  CSR, AofA, SEA, SP
    - Monitoring arrangements  $\Rightarrow$  CSR
    - Review period  $\Rightarrow$  CSR, AofA, SEA, SP
-

# Application Content

- Main elements – Art. 62 of REACH
    - Basis for conformity check
      - Art. 64.2 – performed by RAC/SEAC
        - Substance identity
        - Applicants
        - Uses applied for
        - Chemical Safety Report
        - Analysis of Alternatives
        - Substitution Plan
      - Additional elements
        - Art. 62.5
          - Socio-Economic Analysis
          - Justification for not considering certain risks to HH & Env
    - Administrative elements
      - Application form (including Broad information on uses)
      - Concordance table
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# Uses Applied for

- Definition of uses for which authorisation is sought
  - Use descriptor system (IUCLID Sec.3.5), reference to ES
  - Detailed description of each use applied for (IUCLID Sec.3.10)
- Authorisation granted by use => Use-oriented dataset approach



- Consistent definition
    - Conformity check issue
  - Can be confidential
  - Scope – *How to develop the description on uses in the context of Authorisation*, ECHA 2011
-

# Broad information on uses

- Non-confidential equivalent to Uses applied for
- Published on ECHA's website for public consultation on alternatives (Art. 64.2)
- Collected information from 3<sup>rd</sup> parties is considered by RAC/SEAC in their opinion on the availability and suitability of alternatives
- Must be meaningful for public consultation purposes

⇒ Impact on assessment of AofA

⇒ Impact on number of requests for clarification from RAC/SEAC

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# Broad information on uses

- Applicant's proposal to be considered by ECHA
    - Discussed during pre-submission information sessions (optional)
    - Draft in application (web)form (optional)
      - Potential revisions by ECHA
      - Applicant given 1 opportunity to comment on the amended draft
      - Final decision by ECHA
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# Chemical Safety Report

- Purpose:
    - To assess the risks to human health and the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV
  
  - ⇒ Essential for concluding whether:
    - risks are adequately controlled in accordance with section 6.4 of Annex I
    - OR
    - minimisation of emissions and exposures as far as possible, and to show that the likelihood of adverse effects is reduced
  
  - ⇒ Impact on:
    - Conditions
    - Monitoring arrangements
    - Review period
-

# CSR for Authorisation

- **Mandatory assessment report – conformity check**
    - Reference to own report submitted for registration
      - Current CSR
      - Revised CSR:
        - To refine the ES
        - Applying only for some of the uses of the substance
    - New CSR or Permission to refer to a CSR of a previous applicant
  - **Link to Analysis of Alternatives**
    - “risks arising from the intrinsic properties specified in Annex XIV” vs. all risks
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# Analysis of Alternatives

- Mandatory assessment report – conformity check
- REACH objective:
  - Progressive replacement of SVHCs by suitable alternatives where these are economically and technically feasible

⇒ Conclusion on whether there are suitable and available alternatives

⇒ Impact on:

- Review period, conditions, and monitoring arrangements
-

# AofA for Authorisation

- Steps:
    - Identify possible alternatives (for each use applied for)
    - Identify relevant R&D that is appropriate for the analysis
    - Determine suitability and availability of alternatives:
      - Suitability:
        - Risks of alternatives
        - Technical feasibility for the applicant
        - Economic feasibility for the applicant
      - Availability
    - Determine actions and timescales that may be required to make possible alternatives suitable and available for the applicant
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# Substitution Plan

- Mandatory assessment report, when AofA shows availability of suitable alternatives – conformity check
- Purpose:
  - to present the applicant’s commitment to take the actions needed to substitute the Annex XIV substance with a suitable alternative within a specified timetable

⇒ Conclusion on the review period

⇒ For adequate control route (Art. 60.2)

(SEA route – benefits exceed risk and no suitable alternatives)

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# Socio-Economic Analysis

- Analysis of socio-economic impacts is practically a must for
  - Non-threshold CMRs as well as PBTs and vPvBs

⇒ Conclusion on whether the socio-economic benefits of continued use outweigh the risk to HH or ENV

- Also useful for threshold substances for which adequate control of risks cannot be demonstrated
  - applicant may decide to use both reasoning
    - e.g. if RAC considers that risks are not adequately controlled the applicant could have analysed that the benefits > risks
  - in support of review period argumentation

⇒ Impact on:

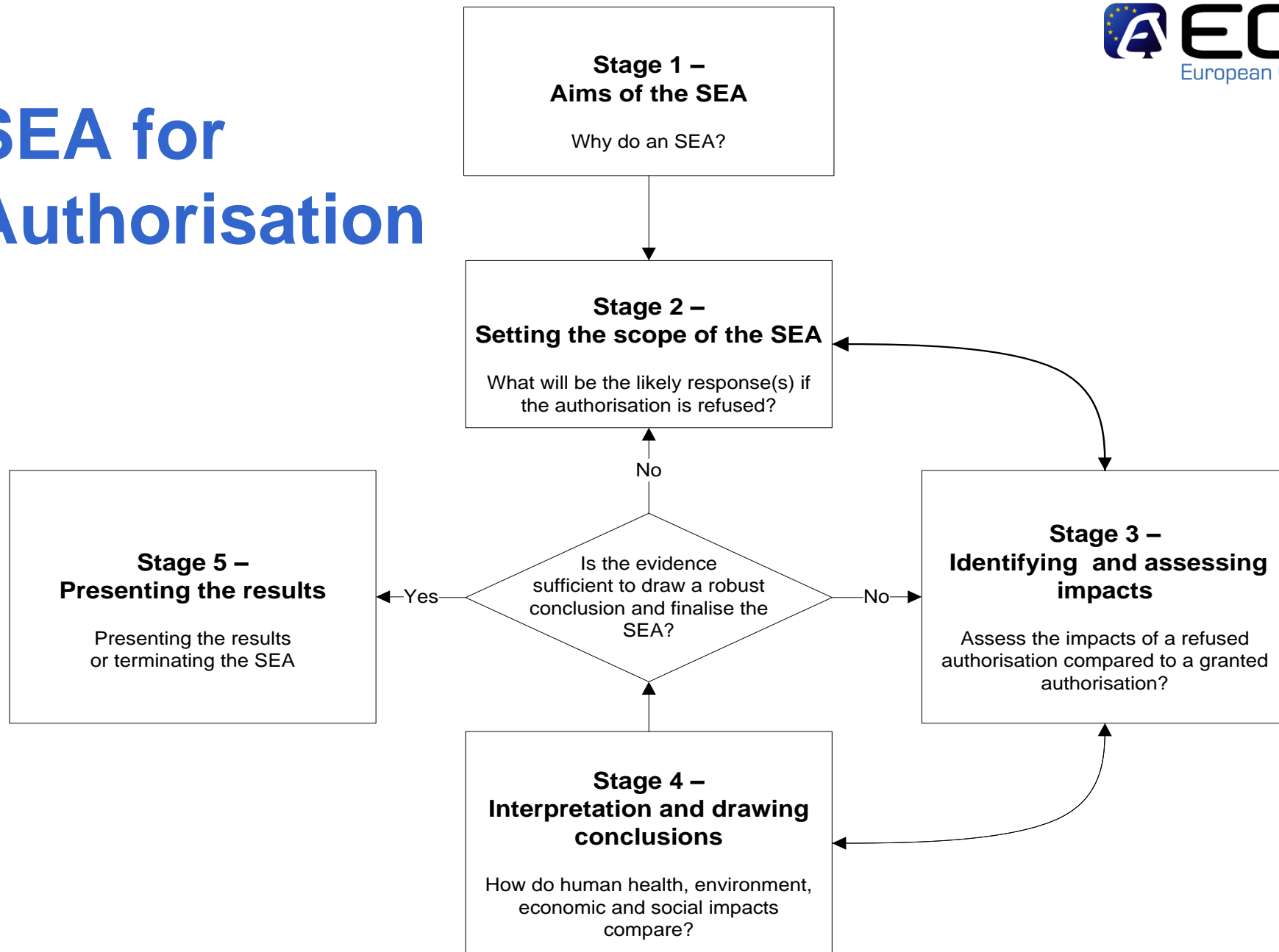
- review period, conditions, and monitoring arrangements
-

# SEA for Authorisation

- Analysis of negative and positive impacts of:
    - “Applied for use” scenario: applicant/its DUs can continue using the substance for specific uses
  - vs.
  - “Non use” scenarios: authorisation is refused: substance cannot be used
  - Impacts considered:
    - human health, environmental, economic
    - social, wider economic, distributional
  - Benefits of authorisation:
    - reduced costs to the applicant, other actors in the supply chain (incl. consumers) and society as whole
  - Costs of authorisation:
    - negative human health or environmental impacts
  - Perspective – society as a whole
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# SEA for Authorisation



# Possible application packages

**Adequate control  
&  
No suitable  
alternative**

**Adequate control  
&  
Suitable  
alternative**

**Socio-ec benefits  
> risks  
(No adequate control &  
No suitable alternative)**

Threshold substances

Threshold substances

Threshold &  
Non-threshold substances

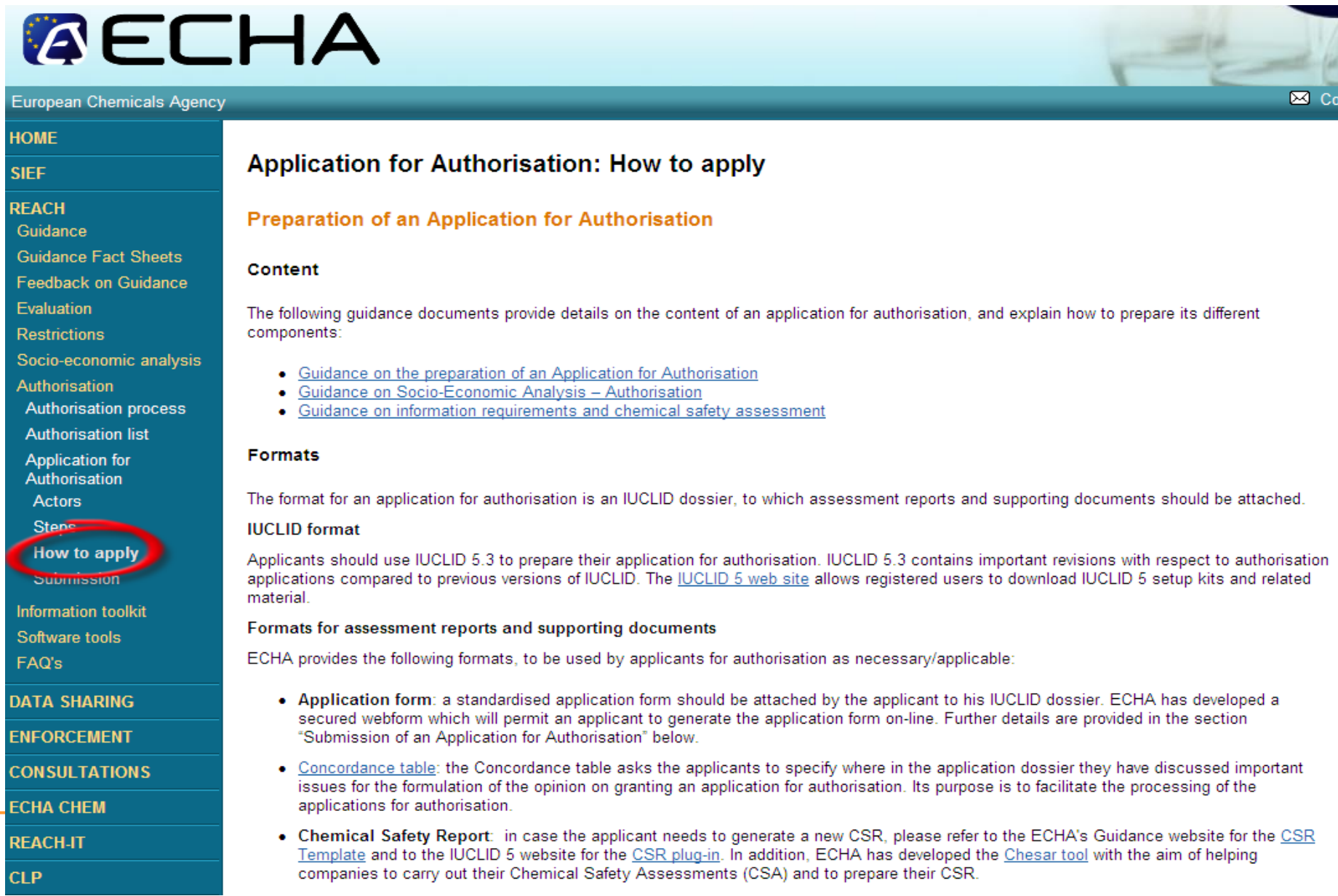
CSR  
Analysis of Alternatives  
SEA  
Substance & Applicant info

CSR  
Analysis of Alternatives  
Substitution Plan  
SEA  
Substance & Applicant info

CSR  
Analysis of Alternatives  
SEA  
Substance & Applicant info

# Resources: ECHA website

[http://echa.europa.eu/reach/authorisation\\_under\\_reach/authorisation\\_application/authorisation\\_how\\_en.asp](http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_how_en.asp)



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 like Guidance, Fact Sheets, etc.), Authorisation (with sub-items like process, list, application, etc.), Information toolkit, Software tools, and FAQ's. The 'How to apply' link under the 'Steps' sub-item is circled in red. The main content area is titled 'Application for Authorisation: How to apply' and contains sections for 'Preparation of an Application for Authorisation', 'Content', 'Formats', and 'IUCLID format'. The 'Content' section lists three guidance documents. The 'Formats' section describes the IUCLID dossier format. The 'IUCLID format' section explains the use of IUCLID 5.3. The 'Formats for assessment reports and supporting documents' section lists three types of forms: Application form, Concordance table, and Chemical Safety Report.

## Application for Authorisation: How to apply

### 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.

# Applications for Authorisation

- Pre-notify
    - [echa\\_application\\_for\\_authorisation@echa.europa.eu](mailto:echa_application_for_authorisation@echa.europa.eu)
  - Pre-submission information sessions with applicants
    - 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
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# Key messages

- Begin your analysis early
- Consult available resources
  - guidance documents, manuals, website material, pre-submission information sessions



# Update on Restrictions

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# Restrictions under consideration

- Dimethylfumarate in articles:
    - SEAC final opinion on adopted in June
  - Lead in jewellery:
    - SEAC final opinion in September 2011
  - 5 phenylmercury substances and mercury in measuring devices
    - RAC final opinion adopted/agreed in June 2011
    - SEAC draft opinion
      - Adopted/agreed in June 2011
      - Public consultation until Aug 16, 2011
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# Upcoming restriction dossiers

- 4 Phthalates
    - DEHP – Bis(2-ethylhexyl) phthalate
    - BBP – Benzyl butyl phthalate
    - DBP – Dibutyl phthalate
    - DIBP – Diisobutyl phthalate
      - To be resubmitted by Denmark in summer/autumn 2011
      - Combined effects of the 4 classified phthalates to human health (REP 1B) and emissions to indoor environment and direct exposure from certain articles
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# Further information

- Restrictions under consideration
    - [http://echa.europa.eu/reach/restriction/restrictions\\_under\\_consideration\\_en.asp](http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp)
  - Registry of Intentions
    - [http://echa.europa.eu/chem\\_data/reg\\_intentions\\_en.asp](http://echa.europa.eu/chem_data/reg_intentions_en.asp)
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**Thank You**

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