

# Content and Structure of Authorisation Applications

*Seminar on applications for authorisation  
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# Presentation Scope

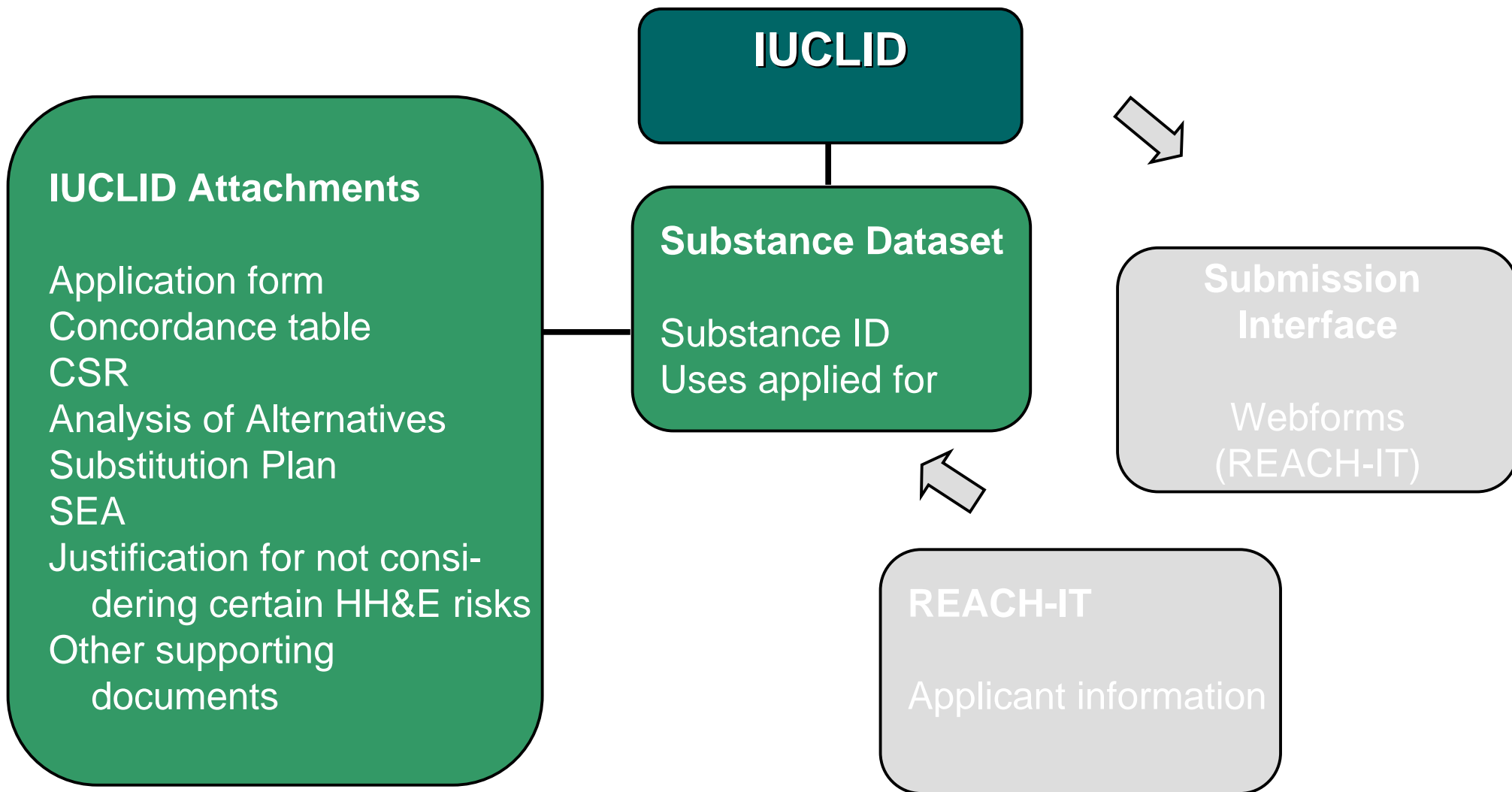
- A brief overview of the content and structure of authorisation applications
  - How to organise and present your analysis in the application for authorisation
  - What is important for opinion-making
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# Purpose

- 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
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- Main elements – Art. 62 of REACH
    - Basis for conformity check
      - Determines whether the application contains all requirements listed in Article 62 for each use applied for in order to enable the processing of the application by the Committees
        - Substance identity
        - Applicants
        - Uses applied for
        - Chemical Safety Report
        - Analysis of Alternatives
        - Substitution Plan
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# Application Structure



# Application Form & Concordance Table

Applicants to summarise essential information to facilitate the processing of the application by ECHA and the Committees

- Application Form:
  - Mapping of Substance(s), Applicant(s), Use(s) applied for
  - Broad information on uses
    - Applicant's proposal for the public consultation on alternatives to be considered by the Agency
- Concordance table
  - To show where in the application the applicant discusses critical issues relevant for opinion making

Templates:

- Submission webforms – ECHA website
- Concordance table template – ECHA website

**Attachments to IUCLID**

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## Substance ID

- Sufficient information to enable identification of the substance:
  - Annex XIV identifier
  - Annex VI, section 2
- Substance grouping (for multi-substance applications)
  - Argumentation for substance grouping

## Other Substance information

- Classification and labelling
- Endpoints information
  - Physical and chemical properties
  - Environmental fate and pathways
  - Ecotoxicological information
  - Toxicological information

Instructions: Authorisation data submission manual

IUCLID: Sections 0.2, 1.1-1.4, 2 – 3.4, 3.6 – 3.8, 4 – 8, 11, 12

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# Applicant Information

- Legal entity and billing information
- Other relevant information

Application form

IUCLID: Sections 1.5, 1.7-1.9, and legal entity information (LEOX) upload

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# Uses Applied for

- Use description:
  - Use descriptor system
  - Detailed description of (each) use applied for

## Instructions:

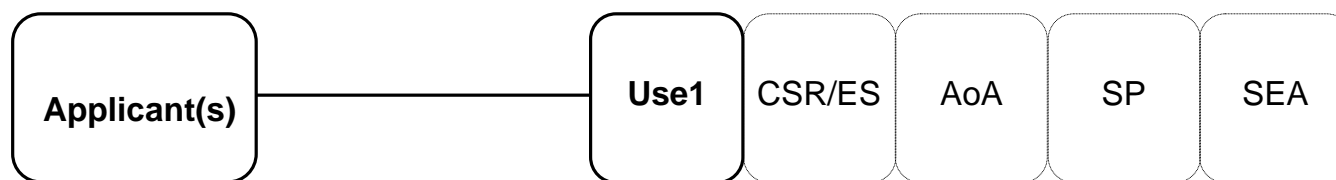
- Authorisation data submission manual
- Chapter R.12: *Use descriptor system of Guidance on information requirements and CSA*

**IUCLID Sections 3.5 and 3.10**

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# Assessment reports

- Chemical Safety Report
- Analysis of Alternatives
- Substitution Plan
- Socio-Economic Analysis
- Justification for not considering certain risks to HH & ENV
- Approach: Use-oriented dataset



- Attachments to IUCLID
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# Chemical Safety Report

- Mandatory assessment 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
    - to demonstrate that for the use(s) of the substance(s) concerned, the risks are adequately controlled in accordance with section 6.4 of Annex I
- OR
- to demonstrate minimisation of emissions and exposures as far as possible, and to show that the likelihood of adverse effects is reduced

## Instructions:

- Guidance on information requirements and chemical safety assessment
- Template: Part F – Guidance on information requirements and CSA

## Attachment to Section 13 of IUCLID

- Reference to CSR submitted for registration
  - Assessment report
  - Permission to refer to a CSR of a previous applicant
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# Analysis of Alternatives

- Mandatory assessment report
- Purpose:
  - to determine the availability of suitable alternative substances or techniques based on an assessment of:
    - risks from alternatives,
    - technical feasibility of substitution, and
    - economic feasibility of substitution.

## Instructions:

- Guidance on the preparation of an application for authorisation, Chapter 3
- Template: ECHA website

## Attachment in Section 3.10 of IUCLID

- Assessment report
  - Permission to refer to AofA of a previous applicant
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# Substitution Plan

- Mandatory assessment report, when the Analysis of Alternatives shows availability of suitable alternatives
- Purpose:
  - to present the applicant's commitment to take the actions needed to substitute the Annex XIV substance with a suitable alternative substance or technology within a specified timetable

## Instructions:

- Guidance on the preparation of an application for authorisation, Chapter 4
- Template: ECHA website

## Attachment in Section 3.10 of IUCLID

- Assessment report
  - Permission to refer to SP of a previous applicant
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# Socio-Economic Analysis

- Essential for applications under the socio-economic route
  - Art. 60(4):
    - to demonstrate that the socio-economic benefits of continued use outweigh the risk to human health or the environment from the use of the substance(s)
- Purpose:
  - to describe and analyse all relevant impacts of granting vs. refusing an authorisation
  - to provide additional socio-economic information to be used in setting the conditions for authorisation or defining the review period

## Instructions:

- Guidance on SEA – Authorisation process
- Template: ECHA website

## Attachment in Section 3.10 of IUCLID

- Assessment report
  - Permission to refer to SEA of a previous applicant
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# Justification for not considering certain risks to HH & Env

- Optional
- Purpose:
  - to justify why the committees should not consider in the processing of the application the risks to human health or the environment arising from:
    - emissions of an Annex XIV substance from an installation for which a permit was granted in accordance with the IPPC Directive
    - discharges of an Annex XIV substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)g of the Water Framework Directive (Directive 2000/60/EC) and legislation adopted under Article 16 of that Directive. (Art. 62(5b))

## Instructions:

- Guidance on the preparation of an application for authorisation

**Attachment in Section 3.10 of IUCLID**

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# Other documentation

- Other information that the applicant deemed relevant

Attachments to Section 13 of IUCLID

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# Assessment reports – possible packages

**Adequate control  
&  
No suitable  
alternative**

**Adequate control  
&  
Suitable  
alternative**

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

CSR  
Analysis of Alternatives

CSR  
Analysis of Alternatives  
Substitution Plan

CSR  
Analysis of Alternatives  
SEA

SEA

SEA

# Key messages

- Begin your analysis early
  - Consult available resources
    - guidance documents, manuals, website material, pre-sub discussions
  - Use the report templates to minimise follow up questions from the Committees
    - Organise by use
  - Be detailed
    - Lack of information may mean:
      - Non-conformity
      - Requests from Committees with short answer periods
    - Incomplete analysis may mean shorter review periods
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**Thank You**

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