Content of Applications for Authorisation

Seminar on Applications for Authorisation

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Evgenia Stoyanova
Risk Management Implementation
ECHA

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

Application Content (1)

- 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
  - May also include – Art. 62.5
    - Socio-Economic Analysis
    - Justification for not considering certain risks to human health & the environment

Application Content (2)

- Substance & use information
- Applicant information
- Assessment reports:
  - Adequate control argumentation
    - Chemical Safety Report (CSR)
    - Analysis of Alternatives
    - Socio-Economic Analysis (SEA)
    - Substitution Plan (if suitable alternative)
  - Socio-economic argumentation
    - Chemical Safety Report (CSR)
    - Analysis of Alternatives
    - Socio-Economic Analysis (SEA)
- Administrative information

Substance Information

Purpose: to define the scope of the authorisation & to collect substance-specific data to enable independent assessment of the application

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
- Hazard endpoint information
  - Physical and chemical properties
  - Environmental fate and pathways
  - Ecotoxicological information
  - Toxicological information

- Instructions:
  - Data Submission Manual, Part 22 - How to Prepare and Submit an Application for Authorisation using IUCLID 5
  - How to present an argumentation for substance grouping – Practical guide 6: How to report read across and categories
- Format: IUCLID 5.4, sections 0.2, 1.1-1.4, 2 – 3.4, 3.6 – 3.8, 4 – 8, 11, 12

Applicant Information

Purpose:

to identify who is applying for authorisation

- Required information
  - Legal entity and billing information
  - Other relevant information

- Instructions:
  - Data Submission Manual
- Format:
  - REACH IT
  - IUCLID 5.4: Legal entity information (LEOX) upload in Section 1.1
  - Submission webforms

Uses Applied For

Purpose:

to define the scope of the requested authorisation

- Required information:
  - Use descriptor system
  - Detailed description of (each) use applied for
- NB: Uses applied for can be confidential
  - Different from the (brief wording for) Broad information on uses (to be published on ECHA's website to launch the public consultation on alternatives)
- Instructions:
  - Data Submission Manual
  - How to describe uses in the context of authorisation
  - Chapter R.12: Use descriptor system of the Guidance on information requirements & chemical safety assessment (CSA)
- Format: IUCLID 5.4, sections 3.5 & 3.10

Chemical Safety Report

- Mandatory assessment report
- Non-confidential Summary & ES to be published on ECHA's website as part of the Broad information on uses package for the public consultation on alternatives

Purpose:

1. 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

2.a) 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

2.b) 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 5.4
  - Applicant's own CSR for authorisation
  - Reference to CSR submitted by the same applicant for registration
  - Permission to refer to a CSR of a previous applicant

Analysis of Alternatives

- Mandatory assessment report
- Part of the Broad information on uses (BIU) package to be published on ECHA's website to launch public consultation on alternatives
- Confidential Annex (not to be published on ECHA's website)

Purpose:

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

- Instructions:
  - Guidance on the preparation of an application for authorisation, Chapter 3
- Template: http://www.echa.europa.eu/applying-for-authorisation/
- Attachment in Section 3.10 of IUCLID 5.4
  - Assessment report
  - Permission to refer to AofA of a previous applicant

Substitution Plan

- Mandatory assessment report, when the Analysis of Alternatives shows availability of suitable alternatives
- Non-confidential Summary to be published on ECHA's website as part of BIU package to launch public consultation on 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: http://www.echa.europa.eu/applying-for-authorisation/
- Attachment in Section 3.10 of IUCLID 5.4
  - Assessment report
  - Permission to refer to AofA of a previous applicant

Socio-Economic Analysis

- Essential for applications under the socio-economic route
  - 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) [Art. 60(4)]
- Non-confidential Summary to be published on ECHA's website as part of the BIU package to launch public consultation on alternatives

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: http://www.echa.europa.eu/applying-for-authorisation/
- Attachment in Section 3.10 of IUCLID 5.4
  - Assessment report
  - Permission to refer to SEA of a previous applicant

Justification for not considering certain risks to human health & the environment

- 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 from an installation for which a permit was granted in accordance with the IPPC Directive (IED)
  - discharges 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 5.4

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	

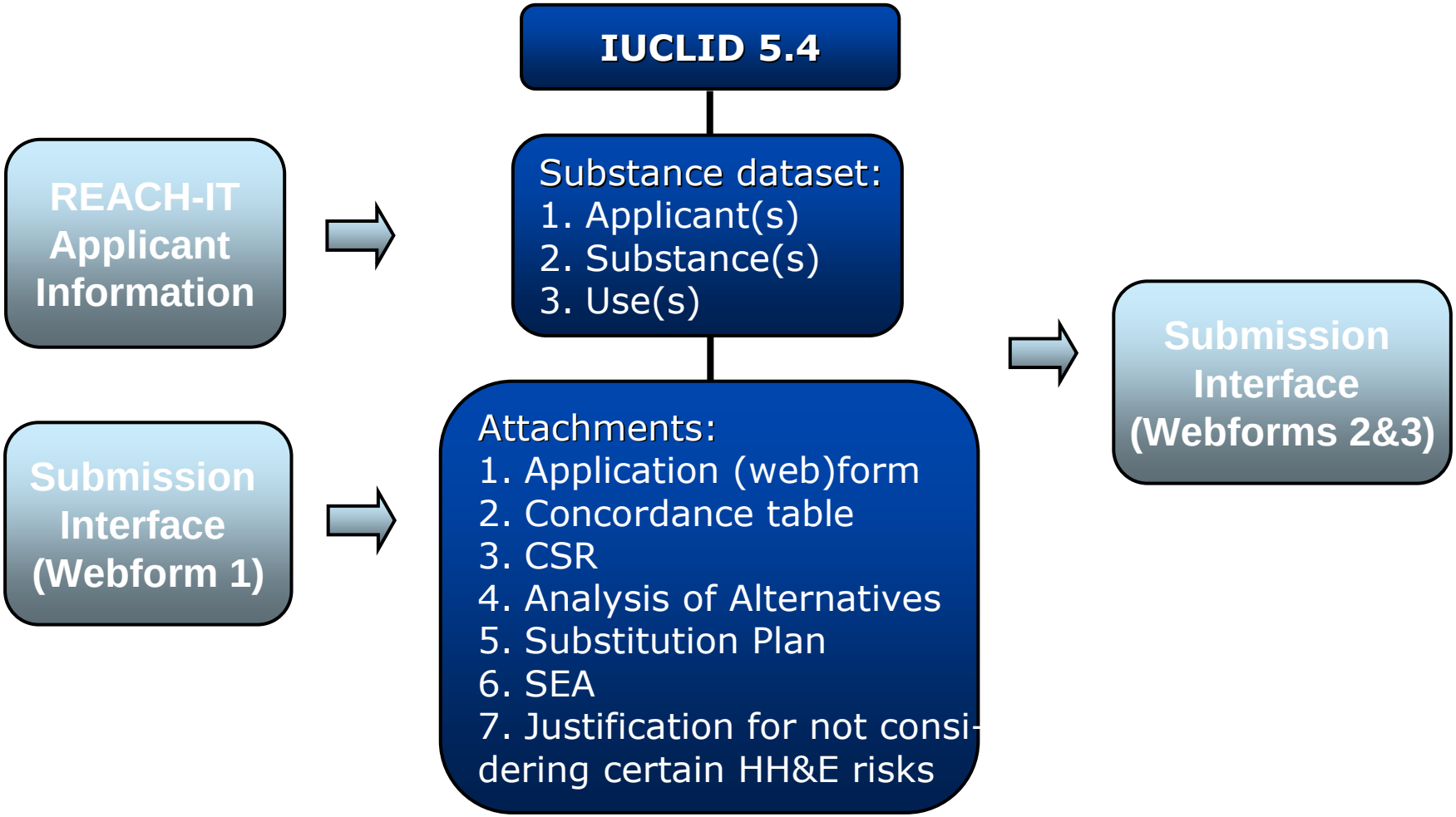
Administrative Information

Purpose:

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

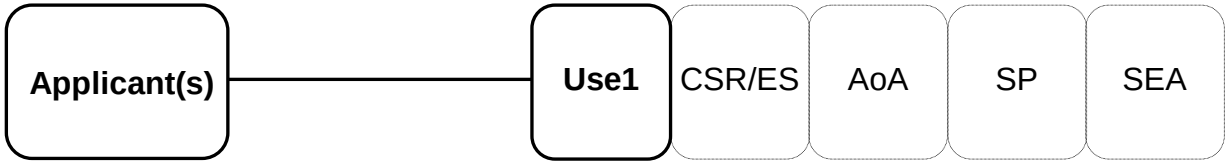
- Application form (Submission webforms):
  - Mapping of Substance(s), Applicant(s), Use(s) applied for
  - Broad information on uses – brief wording
    - Applicant's proposal for the public consultation on alternatives to be considered by ECHA
- Concordance table
  - To show where in the application the applicant discusses critical issues relevant for opinion making
- Instructions:
  - Data Submission Manual
- Templates:
  - Submission webforms: http://www.echa.europa.eu/applying-for-authorisation/
  - Concordance table template: http://www.echa.europa.eu/applying-for-authorisation/
- Attachments to IUCLID 5.4, Section 13

Application Structure



Overarching Principles

- Use-oriented dataset



- Open and transparent discourse
  - Confidential information – properly presented with a justification for confidentiality
- Use of templates (guidance docs and manuals)
  - Be detailed to minimise follow up questions from the Committees
    - Lack of information may mean:
      - Non-conformity
      - Committees requests for additional info with short answer periods
    - Incomplete analysis may mean shorter review periods
  - Consult available resources
    - Website material: http://www.echa.europa.eu/applying-for-authorisation/
    - National Help Desks and ECHA Help Desk
    - Pre-sub information sessions
- One official EU language

Thank You!