Content and submission of applications

Seminar on Applications for Authorisation

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Outline

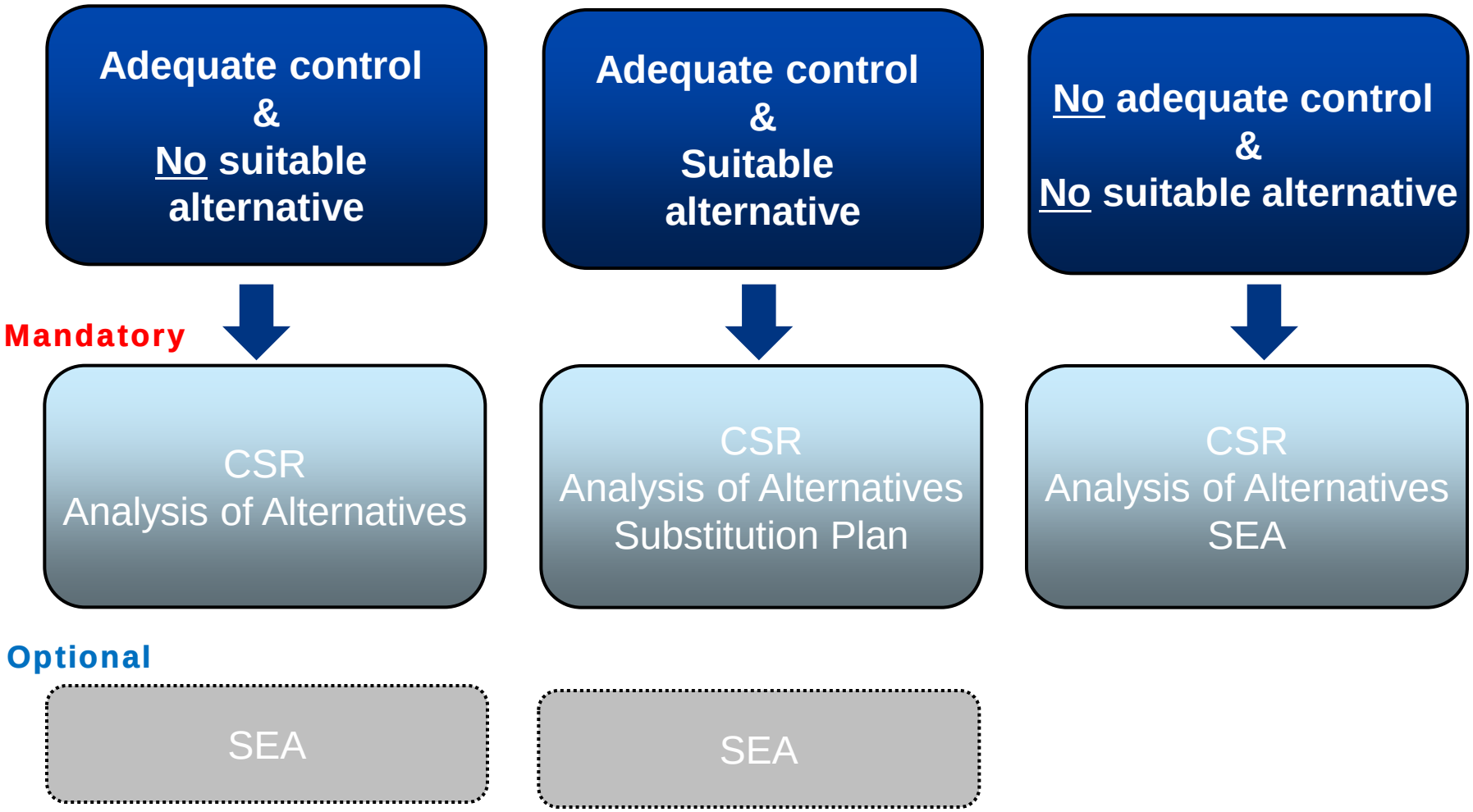
1. Content and format of an application
2. Application submission process
3. Take home

Content and format of an application

- 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
    - Applicant's details
    - Uses applied for
    - Chemical Safety Report (including the Exposure Scenarios)
    - Analysis of Alternatives
    - Substitution Plan (if suitable alternatives exist)
  - May also include – Art. 62.5
    - Socio-Economic Analysis
    - Justification for not considering certain risks to human health & the environment
- Additional information

Assessment Reports: possible packages



Substance information

Purpose: to define the scope of the authorisation & to collect data on the substance

Required Information

Sufficient information to enable identification of the substance:

- Annex XIV identifier ("entry number")
- Annex VI section 2 information (substance name, composition, etc.)

For multi-substance applications:

-Argumentation for substance grouping

Other substance/process information (optional)

Classification and labelling
Endpoint information
Environmental fate and pathways
(Eco)toxicological information
Forms in the supply chain
Estimated quantities
Technological process
Production sites
Exposure estimates
Etc.

Instructions:

- Data Submission Manual, Part 22 - How to Prepare and Submit an AfA – UPDATED April 2014
- Argumentation for substance grouping – Practical guide 6: How to report read across and categories

Format:

IUCLID 5: refer to the "REACH Application for authorisation" template

Argumentation for grouping to be attached to section Category or Section 13 in IUCLID

Applicant information

Purpose: to identify who is applying for authorisation

Required information

- Legal entity details and UUID
- Role in the supply chain
- Contact person details
- Billing information

Note

Applicant(s) information fields in IUCLID, REACH-IT and submission webforms: consistency required!

Company size determination

Instructions:

Data Submission Manual, Part 22

Step-by-step instructions for company size determination

Format:

- REACH-IT
- IUCLID 5: Legal entity information (LEOX) upload in Section 1.1
- Submission webforms for joint applications (ECHA website – AfA Support pages)

Uses Applied For

Purpose: to define the scope (in terms of uses) of the requested authorisation

Required information

- Use name and number
- Use descriptor system (PROC, ERC, PC, SU)
- Detailed description of each use applied for (conditions of uses, function, etc.)

Note

Two use descriptions:

- « Uses applied for »
- « Broad information on uses » (BIU)

Consistency of PROCs (in IUCLID, CSR – WCS, summary tables, etc.)

Instructions:

- Data Submission Manual, Part 22
- How to describe uses in the context of authorisation
- Guidance on information requirements & chemical safety assessment - Chapter R.12: Use descriptor system

Format:

- IUCLID 5 sections 3.5 & 3.10 and submission webforms (joint applications)

Chemical Safety Report

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

Required information

- CSR is a mandatory assessment report
NEW: Hazard data not needed if you use the RAC Reference DNEL/dose-response relationship (see Q&A 916)
- NEW: 9 (Exposure Scenarios) and 10 (Risk Characterisation) will be published on ECHA's website (BIU). Redacting of confidential info possible

Note

The CSR can be:

- the applicant's own CSR for authorisation,
- a reference to CSR submitted by the same applicant for registration, or
- a reference to CSR of a previous applicant

- Consistency of ES names and numbers throughout the application (IUCLID, CSR, AofA, SEA, SP, etc.)

Instructions:

- Guidance on information requirements and chemical safety assessment
- Chemical Safety Report – An illustrative example

Format:

- Guidance on info. requirements and chemical safety assessment – Part F: Exposure Scenario format
- AfA support web page: "Preparing an application" - templates
- CSR to be attached to Section 13 of IUCLID 5

Analysis of Alternatives ("AoA")

Purpose:

to determine the availability of suitable alternative substances or techniques based on an assessment of:

- technical feasibility of substitution,
- economic feasibility of substitution, and
- risks of the alternatives – net reduction in risk

Required information

- AoA is a mandatory assessment report
- NEW: Published on ECHA's website (as part of the BIU) with tonnage (band) per use. Redacting of confidential info possible

Note

- Applicant's own AoA, or
- Permission to refer to a AoA of a previous applicant

Instructions:

- Guidance on the preparation of an application for authorisation, Chapter 3

Format:

- AfA support web page: "Preparing an application"- templates
- Attachment to Section 3.10 of IUCLID 5

Substitution Plan

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 (if available) within a specified timetable

Required information

- Substitution Plan is a mandatory assessment report when the AoA shows availability of suitable alternatives
- Published on ECHA's website (as part of the BIU). Redacting of confidential info possible

Note

- Applicant's own Substitution Plan, or
- Permission to refer to a Subsitution Plan of a previous applicant

Instructions:

- Guidance on the preparation of an application for authorisation, Chapter 4

Format:

- AfA support web page: "Preparing an application"- templates
- Attachment to Section 3.10 of IUCLID 5

Socio-Economic Analysis ("SEA")

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

Required information

- 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)]

- NEW: Published on ECHA's website (as part of the BIU) with applicant's recommendation on length of review period. Redacting of confidential info possible

Note

- Applicant's own SEA, or

- Permission to refer to a SEA of a previous applicant

Instructions:

- Guidance on the preparation of socio-economic analysis as part of an application for authorisation

Format:

- AfA support web page: "Preparing an application"- templates
- Attachment to Section 3.10 of IUCLID 5

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

Format:

- No specific template
- Attachment to Section 3.10 of IUCLID 5

Additional information

Purpose:

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

Required information

- "Brief wording" (to be part of the BIU):
  Applicant's proposal for the brief wording that will be used for the public consultation on alternatives to be considered by ECHA (in IUCLID section 3.5)

- Application form (joint applications):
  Mapping of the -*Substance(s)/Applicant(s)/Use(s) applied for*- combinations

- Concordance table (to be attached to section 13 of IUCLID)
  To show where in the application the applicant discusses critical issues relevant for opinion making

Instructions:

- Data Submission Manual, Part 22

Format:

- Brief wording: IUCLID, Section 3.5
- Application form: AfA support web pages/Submitting applications for authorisation (Attachment to Section 13 of IUCLID 5)
- Concordance table: AfA support web pages/Preparing an application/Concordance table template (Attachment to Section 13 of IUCLID 5)

Application submission process

1. • Create/update your account in REACH-IT
2. • Joint applications only: webforms to generate the application form and for co-applicants to confirm their participation
3. • Create your IUCLID dossier
4. • Submit your application via REACH-IT
5. • Pay the invoice

Instructions:

- Data Submission Manual, Part 22
- AfA support web pages – “Submitting applications for authorisation ”

Take home

When preparing your application:

- Read the ECHA Guidance on AfA, SEA and « How to describe uses in the context of authorisation »
- Read the AfA Q&As (updated regularly)
- Use ECHA's templates
- CSR: Hazard data not needed if you use the RAC Reference DNEL/dose-response relationship (see Q&A 916)
- Be as transparent as possible
  - Claim 'confidential information' as little as possible
  - Follow instructions on what information can be considered confidential and how to claim information confidential
- Be clear and consistent throughout the application

Thank you!