# Content and procedure of applications

Seminar on Applications for Authorisation

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# Outline

1. Is an application so complicated?
2. Content and format of an application
3. Application submission process
4. Initial processing timeline and pre-submission information session (PSIS)
5. Take home

# 1. Is an application so complicated?

- You know what you are talking about (*your* substance, *your* market, *your* business decision to apply or not)
- You know what you have to analyse and how to do it
- You need to document it clearly- according to a certain format - and convincingly to the Committees and the Commission
- Nothing really new, like other reports supporting a business decision (it is *not* a purely regulatory compliance issue)
- If everything is clear, it shouldn’t be complicated

# 2. Content and format of an application

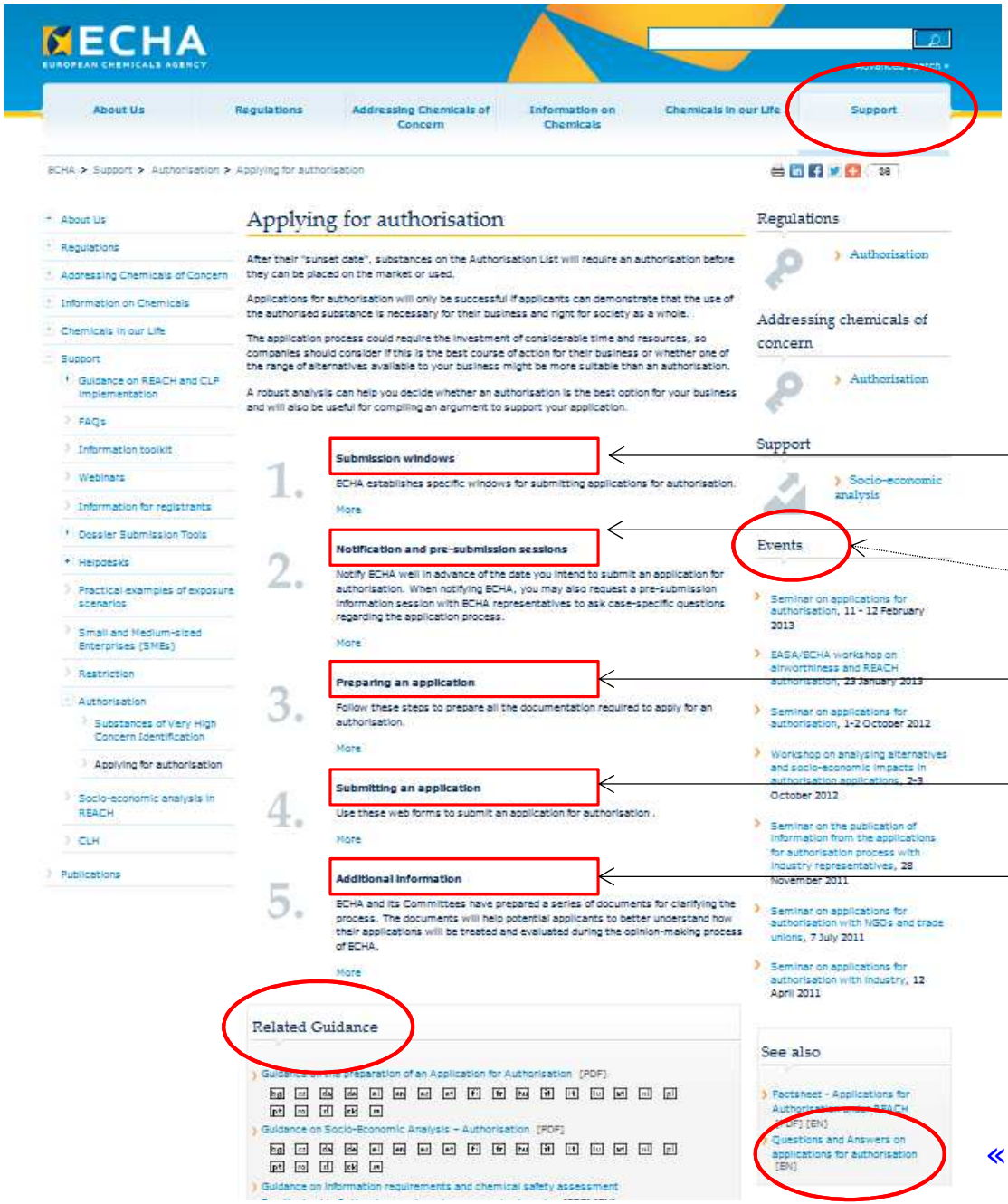
- Your main reference: the « ECHA AfA Support web pages »

http://echa.europa.eu/applying-for-authorisation

- Most comprehensive source of information

- Guidance documents, formats and templates, Q&As, Committees' documents; PPT presentations, videos *(to come)*, etc.

- (Elements of) answers to many potential applicant's questions can be found there




« AfA support page »

**when to submit your application**

**inform and meet ECHA**

previous presentations

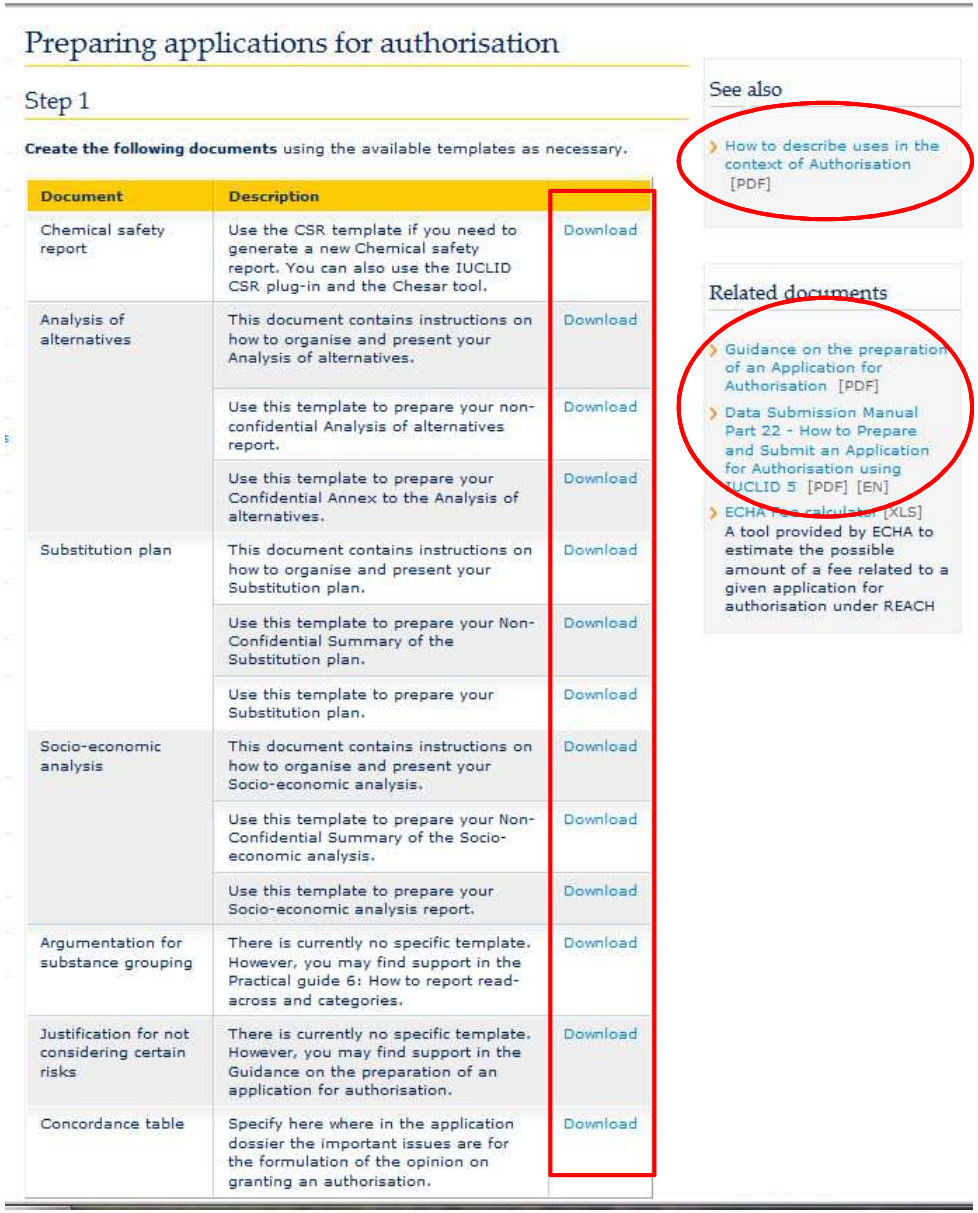
**templates and guidance**

**submission webforms**

**info on decision process, applicants' and stakeholders' participation, BIU etc.**

« AfA Q&As »

**Applicants' questions**



## Preparing applications for authorisation

### Step 1

**Create the following documents** using the available templates as necessary.

| Document | Description | |
|---|---|---|
| Chemical safety report | Use the CSR template if you need to generate a new Chemical safety report. You can also use the IUCLID CSR plug-in and the Chesar tool. | Download |
| Analysis of alternatives | This document contains instructions on how to organise and present your Analysis of alternatives. | Download |
| | Use this template to prepare your non-confidential Analysis of alternatives report. | Download |
| | Use this template to prepare your Confidential Annex to the Analysis of alternatives. | Download |
| Substitution plan | This document contains instructions on how to organise and present your Substitution plan. | Download |
| | Use this template to prepare your Non-Confidential Summary of the Substitution plan. | Download |
| | Use this template to prepare your Substitution plan. | Download |
| Socio-economic analysis | This document contains instructions on how to organise and present your Socio-economic analysis. | Download |
| | Use this template to prepare your Non-Confidential Summary of the Socio-economic analysis. | Download |
| | Use this template to prepare your Socio-economic analysis report. | Download |
| Argumentation for substance grouping | There is currently no specific template. However, you may find support in the Practical guide 6: How to report read-across and categories. | Download |
| Justification for not considering certain risks | There is currently no specific template. However, you may find support in the Guidance on the preparation of an application for authorisation. | Download |
| Concordance table | Specify here where in the application dossier the important issues are for the formulation of the opinion on granting an authorisation. | Download |

See also

- How to describe uses in the context of Authorisation [PDF]

Related documents

- Guidance on the preparation of an Application for Authorisation [PDF]
- Data Submission Manual Part 22 - How to Prepare and Submit an Application for Authorisation using IUCLID 5 [PDF] [EN]
- ECHA Fee calculator [XLS]
  A tool provided by ECHA to estimate the possible amount of a fee related to a given application for authorisation under REACH

« Preparing applications for autorisation » section contains:

**Available formats and guidance on:**

- **CSR**
- **AoA**
- **Substitution Plan**
- **SEA**
- **Substance grouping**
- **Justification for not considering certain risks**
- **Concordance table**

## Additional information

ECHA and its Committees have prepared a series of documents for clarifying the process. The documents will help potential applicants to better understand how their applications will be treated and evaluated during the authorisation opinion-making process of ECHA.

| Document | Description | |
|---|---|---|
| Participation of applicants, third parties and stakeholder observers in the application for authorisation process | This note defines ECHA's approach to the participation of applicants, third parties and stakeholder observers in the application for authorisation process | Download |
| How RAC and SEAC intend to evaluate the applications | Outline of the key principles in the development of RAC and SEAC opinions is provided. It focuses on issues where a common approach is needed in both RAC and SEAC. | Download |
| Reporting format for the RAC and SEAC opinions | Format used by ECHA's Committees to write their opinions is provided. | Download |
| Public sections of RAC and SEAC opinions | Parts of RAC and SEAC opinions which will be made publicly available are indicated. | Download |
| Publication of information on applications during the opinion-making process | A description of information from applications for authorisations that will be made publicly available is outlined. | Download |
| Working procedure for RAC and SEAC for developing opinions | Describes the main roles and tasks of the (co-)rapporteurs, the members of RAC and SEAC, and the ECHA secretariat as well as the timelines related to the opinion-making process. | Download RAC SEAC |
| Working procedure for RAC and SEAC on conformity check | Describes the main roles and tasks of the (co-)rapporteurs, the members of RAC and SEAC, and the ECHA secretariat as well as the timelines related to the conformity check of the applications. | Download RAC SEAC |

« Additional information » section currently contains documents related to:

- **Participation of applicants, stakeholders and third parties**
- **Evaluation of the applications by the Committees**
- **Information made public (BIU, opinions)**
- **Committees working procedures and formats**

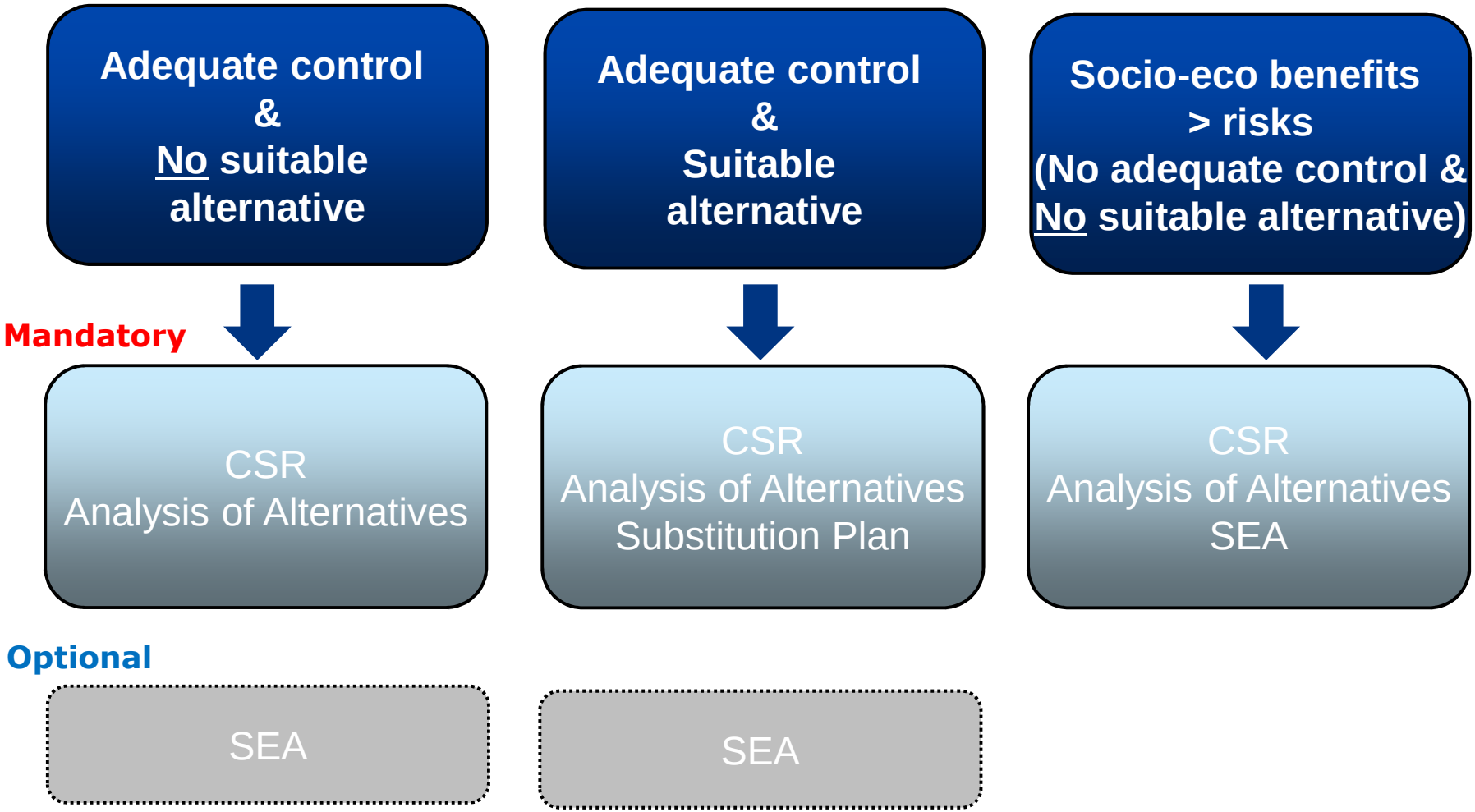
**These are important documents and more will come – please read and check regularly!**

# Application content

- 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

## Substance ID

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 suply chain
Estimated quantities
Technological process
Production sites
Exposure estimates
Etc.

Instructions:

- Data Submission Manual, Part 22 - How to Prepare and Submit an AfA using IUCLID 5
- Argumentation for substance grouping – Practical guide 6: How to report read across and categories

Format:

IUCLID 5.4: refer to the "REACH Application for authorisation" template

# 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: exact consistency required!

Instructions:
Data Submission Manual, Part 22
Format:
- REACH-IT account
- IUCLID 5.4: Legal entity information (LEOX) upload in Section 1.1
- Submission webforms (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 types of use descriptions:

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

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 5.4 sections 3.5 & 3.10; submission webforms

# 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
- Public version of the Exposure Scenarios to be published on ECHA's website (as part of the BIU package for the public consultation on alternatives)

Note

The CSR can be:

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

- Consistency between ES names and numbers in IUCLID section 3.7.1 and the CSR!

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 5.4

# 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

Required information

- AoA is a mandatory assessment report
- Public version to be published on ECHA's website (as part of the BIU package for the public consultation on alternatives)
- Confidential Annex

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 5.4

# 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
- Confidential part
- Non-confidential summary to be published on ECHA's website (as part of the BIU package for the public consultation on alternatives)

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 5.4

# 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)]
- Confidential part
- Non-confidential summary to be published on ECHA's website (as part of the BIU package for the public consultation on alternatives)

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 5.4

# 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 5.4

# Additional information

Purpose:

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

Required information

- Application form (generated by the Submission webforms):
  - Mapping of the -*Substance(s)/Applicant(s)/Use(s) applied for*- combinations
  - "Brief wording" (to be part of the BIU package): Applicant's proposal for the public consultation on alternatives to be considered by ECHA
- Public version of the Exposure Scenarios (to be attached to section 13 of IUCLID)
- 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:

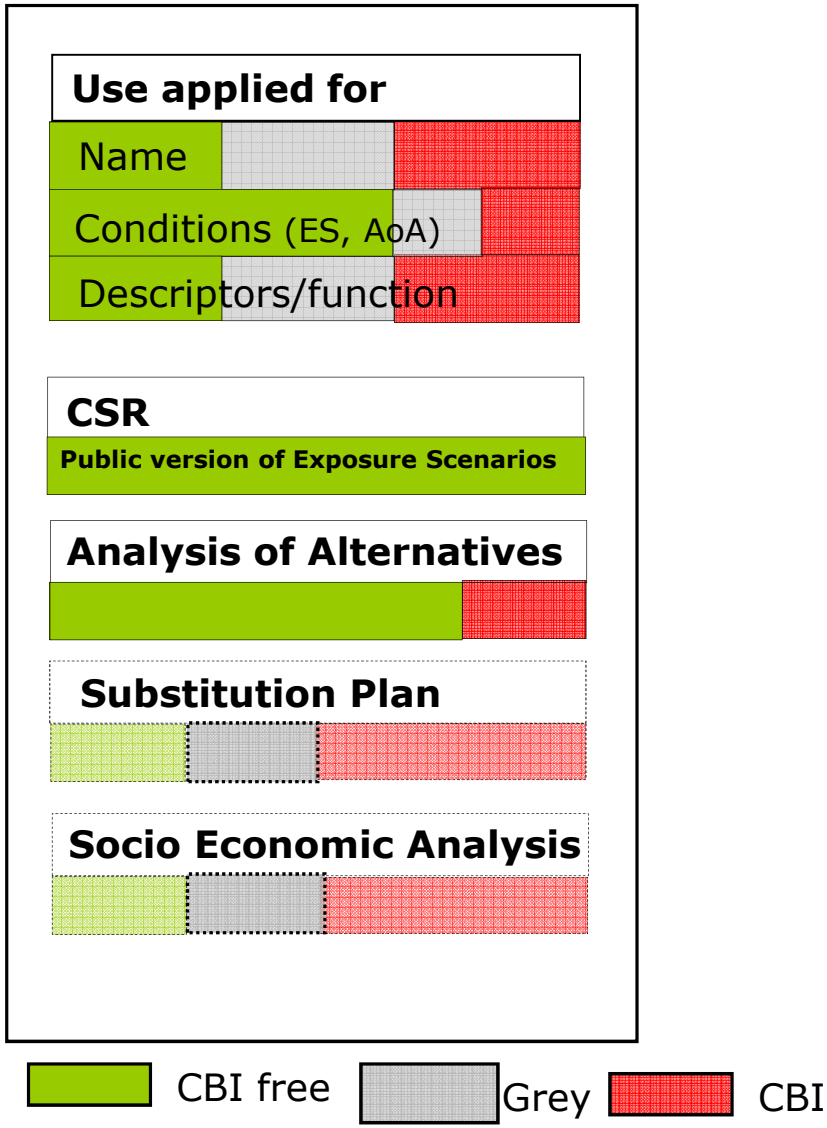
- Data Submission Manual, Part 22

Format:

- AfA support web pages:
  - "Submitting applications for authorisation" : Submission webforms
  - "Preparing an application" : Concordance table template
- Attachments to Section 13 of IUCLID 5.4

# Application content : summary

## Application

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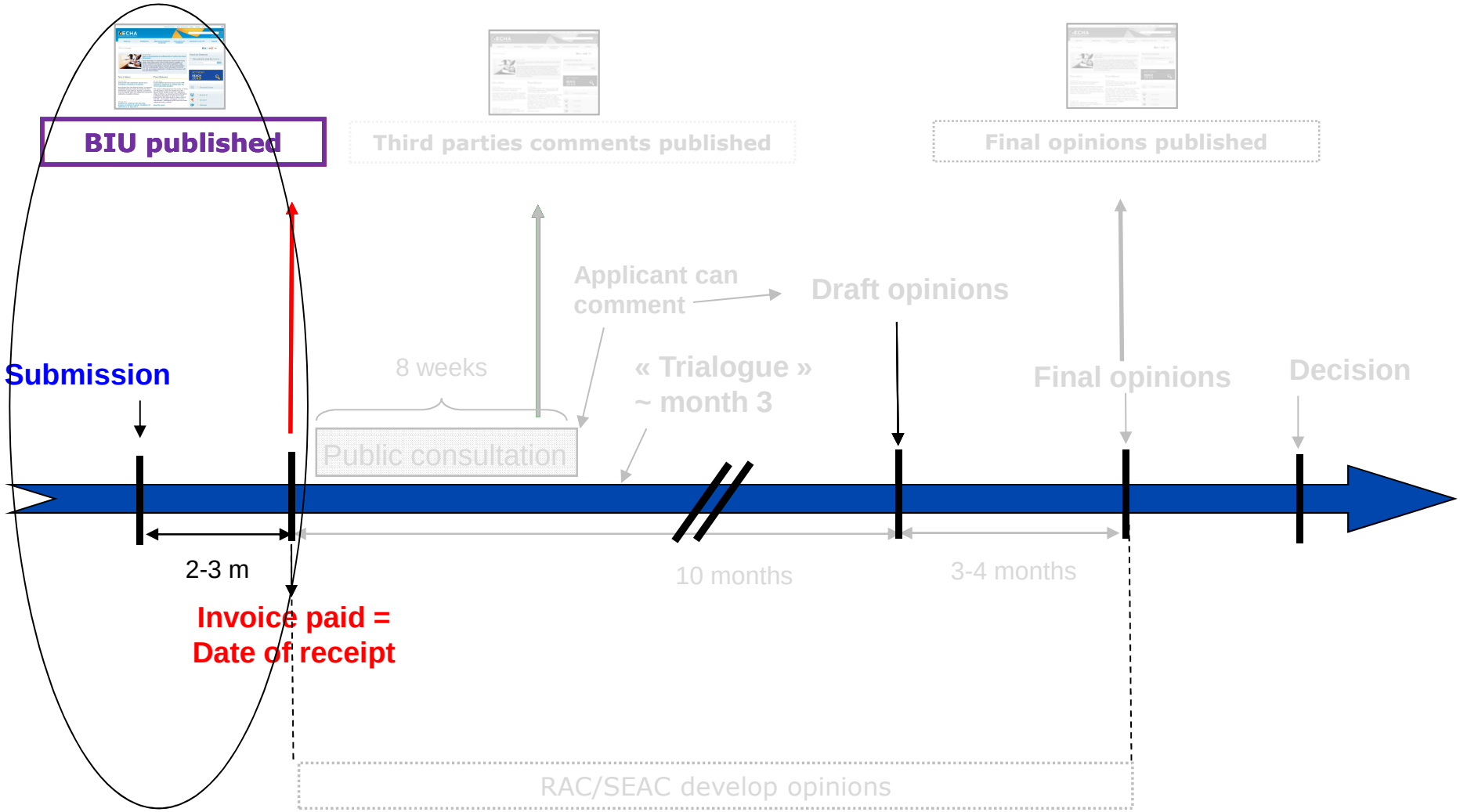
# 3. Application submission process

1. • Sign-up in REACH-IT
2. • Create your IUCLID substance dataset (including all the assessment reports)
3. • Generate the application form (webform 1)
4. • Generate the IUCLID dossier (including the application form)
5. • Submit your application (webform 3)

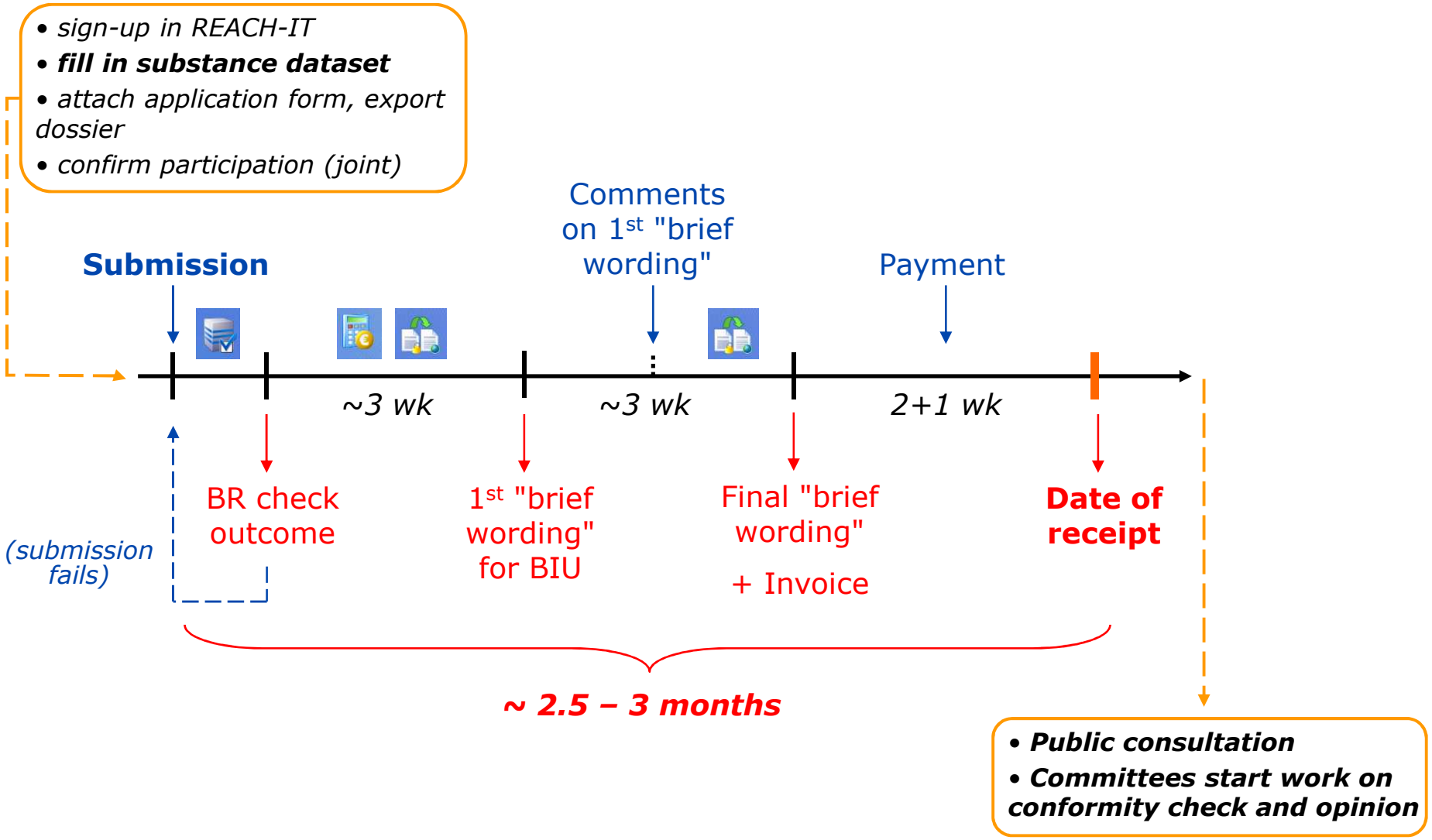
Instructions:

- Data Submission Manual, Part 22
- AfA support web page: Seminar on applications for authorisation, 1-2 October 2012 – "How to submit an application and initial checks by ECHA"
- From March 2013: demo videos on website

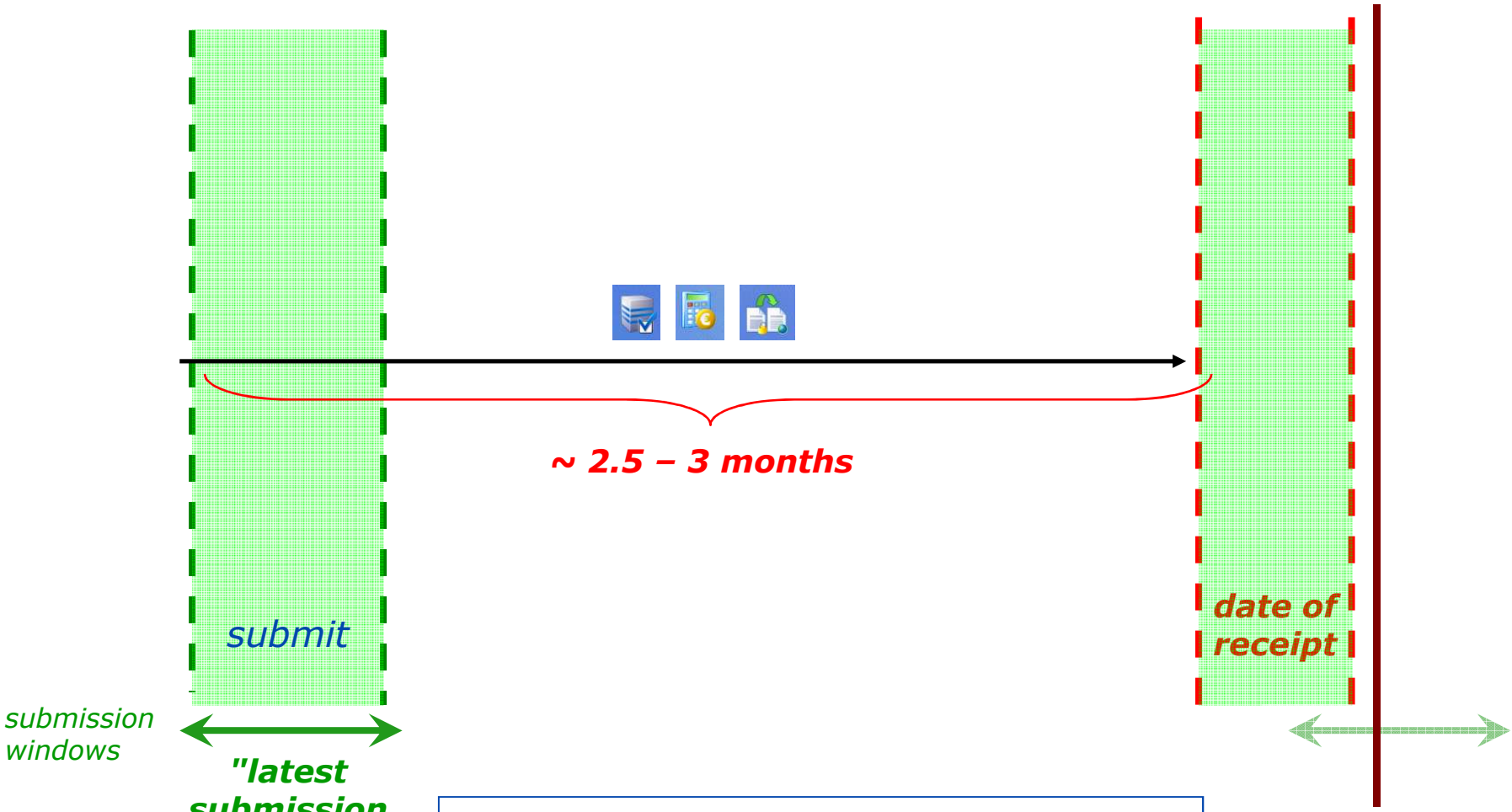
# 4. Initial processing timeline and PSIS



# Initial processing timeline



# "Latest submission window"




**ECHA strongly advises to submit the applications during the submission windows**

# Notification and pre-submission information session (« PSIS »)

Objective:

- to give future applicants for authorisation the opportunity to ask case-specific questions regarding the regulatory and procedural aspects of the authorisation application process
- clarify critical elements for the public consultation on alternatives and facilitate the development of the "broad information on uses" package

NOT to provide consulting services or advice. The assessment of the application only commence once ECHA is in receipt of the application for authorisation (fee received)

Logistics:

- Notify ECHA and request a PSIS minimum 8 months before the planned submission of the application
- Documents to send to ECHA and further details on:

http://echa.europa.eu/web/guest/applying-for-authorisation/notification-and-pre-submission-information-sessions

# 5. Take home

- Consult available resources
  - Website material: http://www.echa.europa.eu/applying-for-authorisation, including the **Q&As** and the "Additional information" table containing explanatory documents
  - National Help Desks and ECHA Help Desk
  - PSIS: to be requested 8 months before the submission of the application
- Be detailed and complete to minimise follow up questions from the Committees but do not make it complicated (the case should be clear)
- Be open and transparent
  - Confidential information – clearly identified with a solid justification for confidentiality
- Submit during the submission windows

Thank you!