Applications for Authorisation: ECHA's supporting activities

CEFIC REACH Implementation Workshop XII

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Outline

- To prepare or not to prepare an application?
- Some highlights of the application process
- ECHA’s support activities
- Take home

To prepare or not to prepare an application

The key question to you

- What will be the impact on my business if the substance can no longer be used in the EU?

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Core business issue: commercial, technical, strategic, not just environmental or H&S compliance

- Analysing options and impacts tells you whether you need to apply for authorisation:

If you find that the costs of alternatives exceed the current risks

⇒ You have a case for authorisation

⇒ And you have done the analysis you need for your application

There is a world outside your business

- A substance might be critical to your business, but is it also critical for your suppliers, customers, competitors?
- You might not identify any viable alternatives, but third parties might (through public consultation)
- You might control risks to your environment and health, but the substance might also generate risks to your downstream users and customers

⇒ **You need to look wider than your immediate (commercial, technical, environmental) context**

But it might help your case as well (e.g. higher costs for downstream users)

Some highlights on the procedure

Overview of publication of information in the AfA process

BIU published

Third parties comments published

Final opinions published

Submission

2 months

Public consultation

Applicant can comment

Applicant's hearing (« trialogue »)

Draft opinions

Final opinions

Decision

PSIS

2-3 m

Invoice paid = Date of receipt

10 months

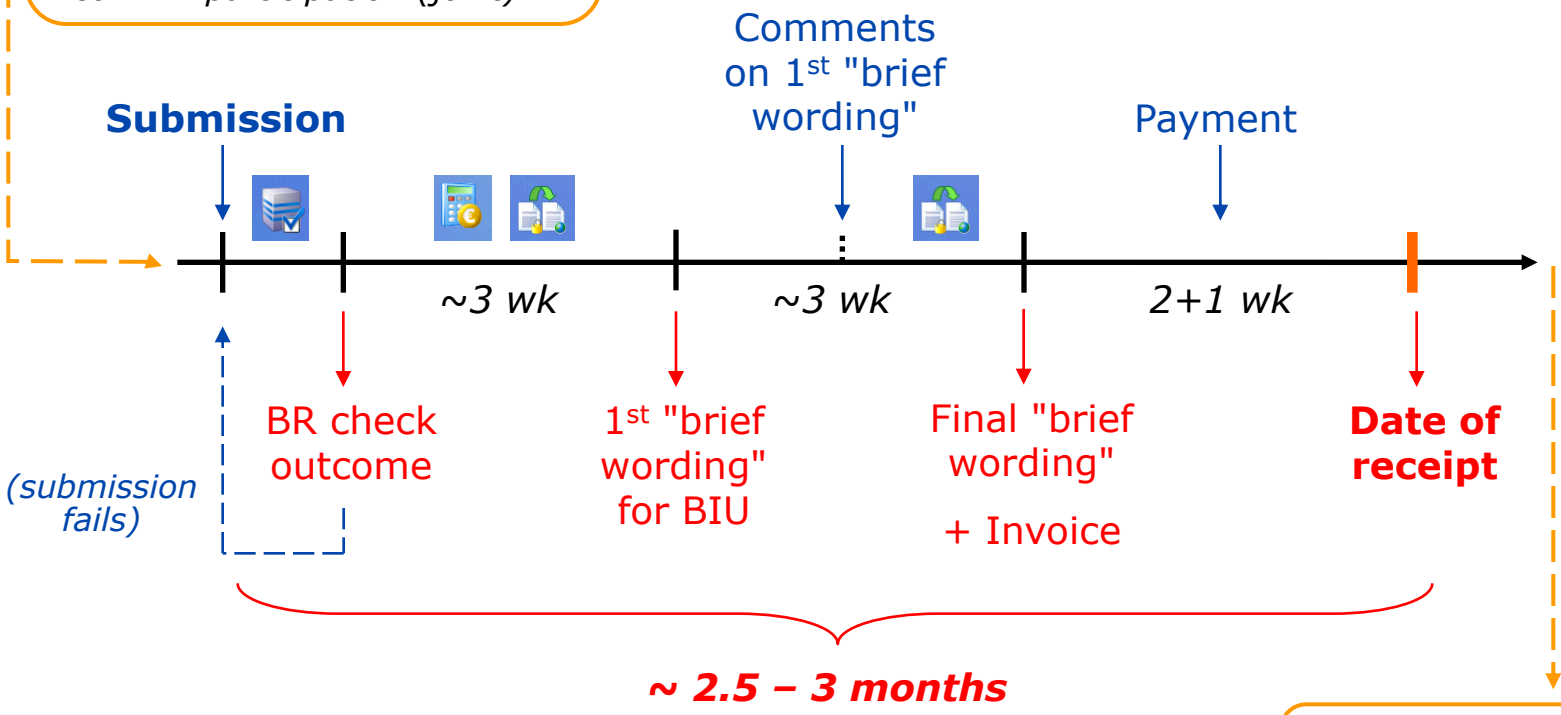
3-4 months

Pre-processing

RAC/SEAC develop opinions

Initial processing timeline

- *sign-up in REACH-IT*
- ***fill in substance dataset***
- *attach application form, export dossier*
- *confirm participation (joint)*

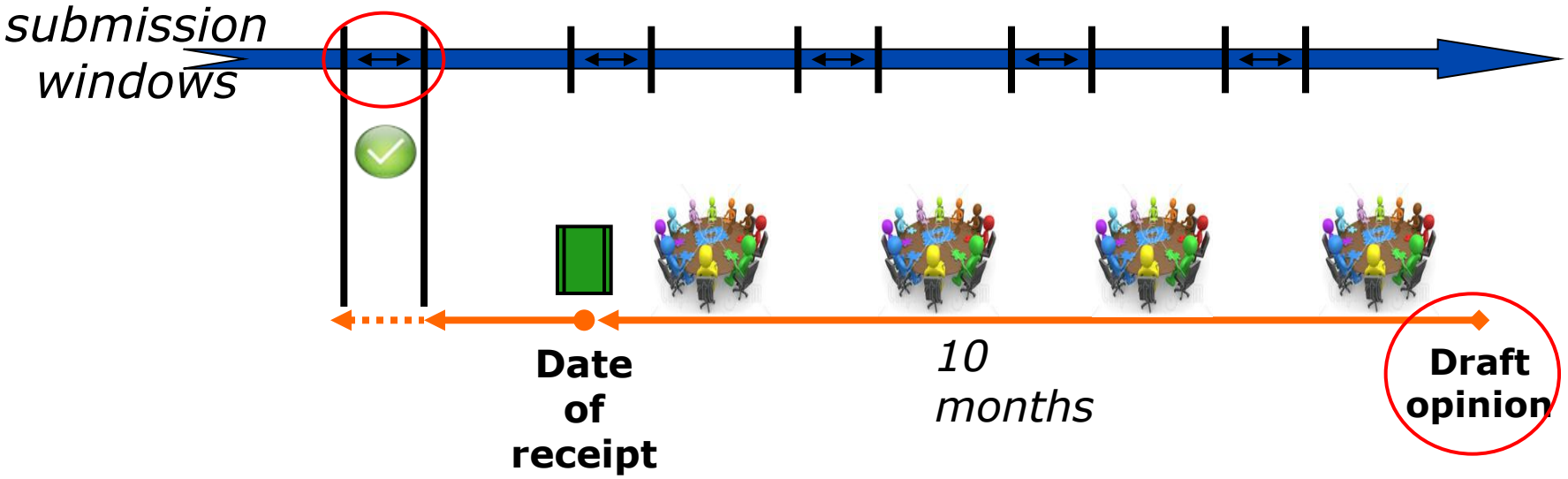


- ***Public consultation***
- ***Committees start work on conformity check and opinion***

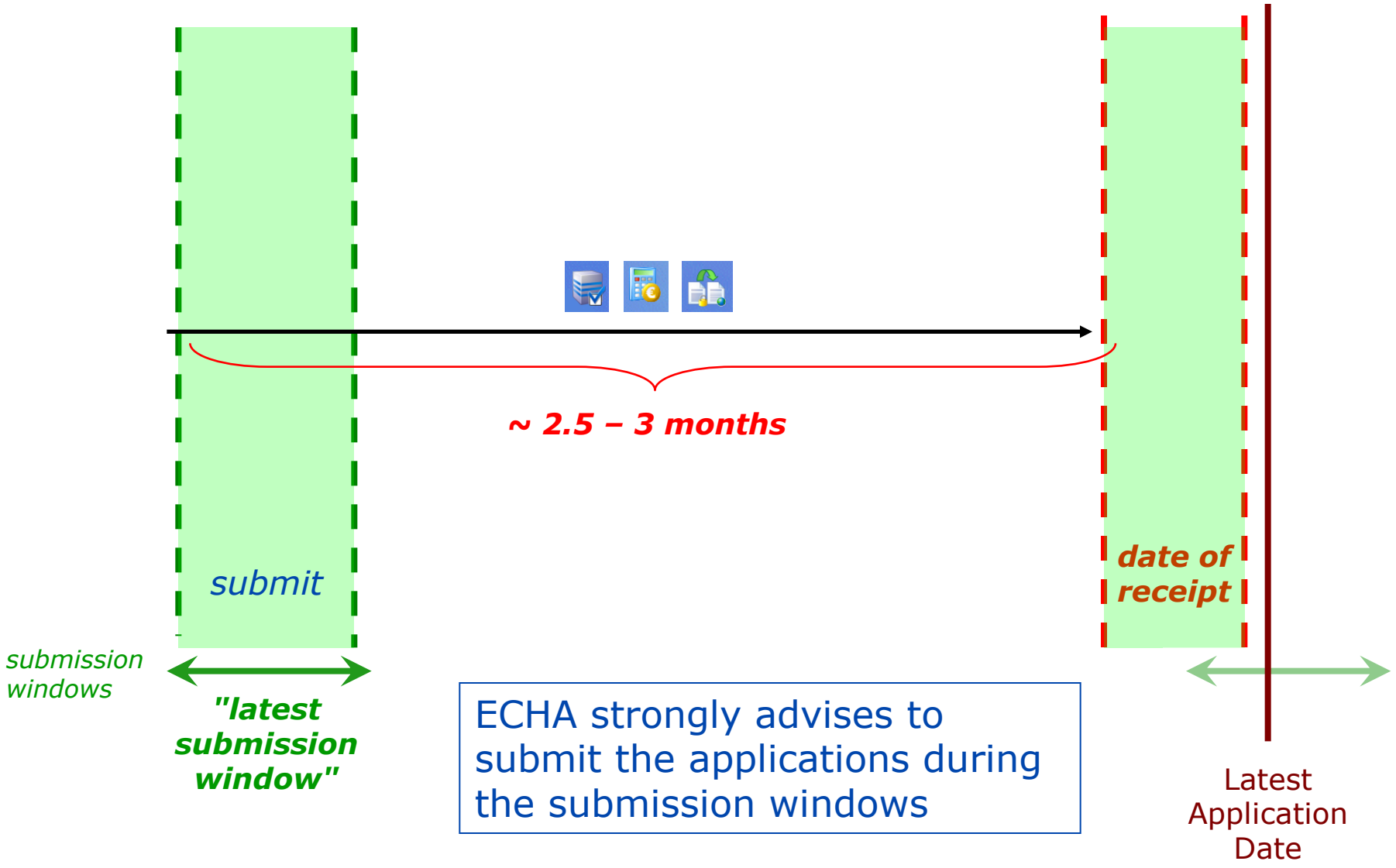
Submission windows

Applications preferably submitted to ECHA at specific periods (announced on ECHA web pages; every 3 months)

synchronisation with scheduled Committees meetings, for effective preparation of opinions



"Latest submission window"



ECHA strongly advises to submit the applications during the submission windows

Differences in applying before or after the Latest Application Date (LAD)

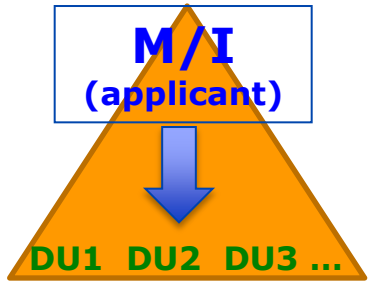
Q: Can I apply after the Latest Application Date (LAD)?

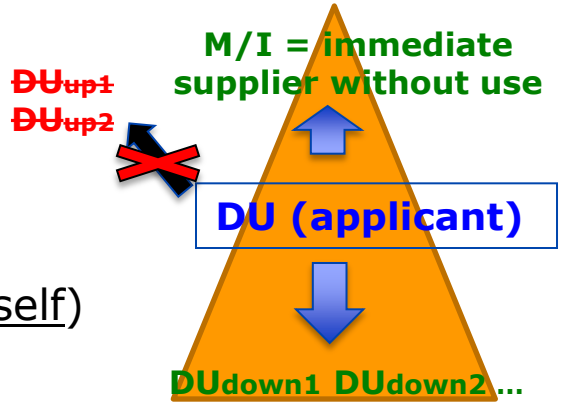
A: Yes, but after the Sunset Date, you will have to stop using/placing the substance on the market until you benefit from an authorisation granted by the Commission

➔ When applying before the LAD, the "transitional arrangements" apply, i.e. the substance can be used/placed on the market after the Sunset Date if no decision has been taken yet by the Commission.

Supply chain covered by the authorisation

- An applicant can be:
  - a manufacturer or importer
    - ➔ the authorisation covers the manufacturer's DUs
      "top-down" coverage
  - a downstream user
    - ➔ the authorisation covers:
    - the applicant itself;
    - its clients **down** the supply chain;
    - its immediate supplier if this one is only placing the substance on the market (no use itself)
  - an only representative,
  - any combination of these.





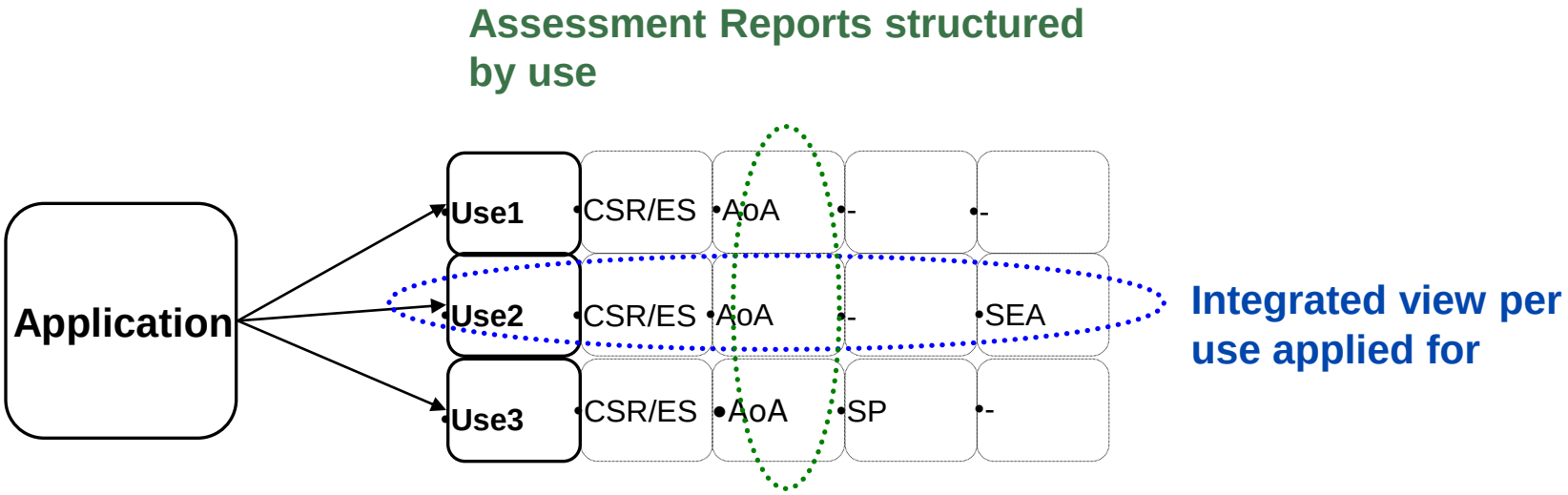
In some cases, DUs will be the main actors in AfA. Make sure all your supply chain is aware of its implication in the process.

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	

"Uses applied for"

ECHA recommends to structure the assessments reports by use

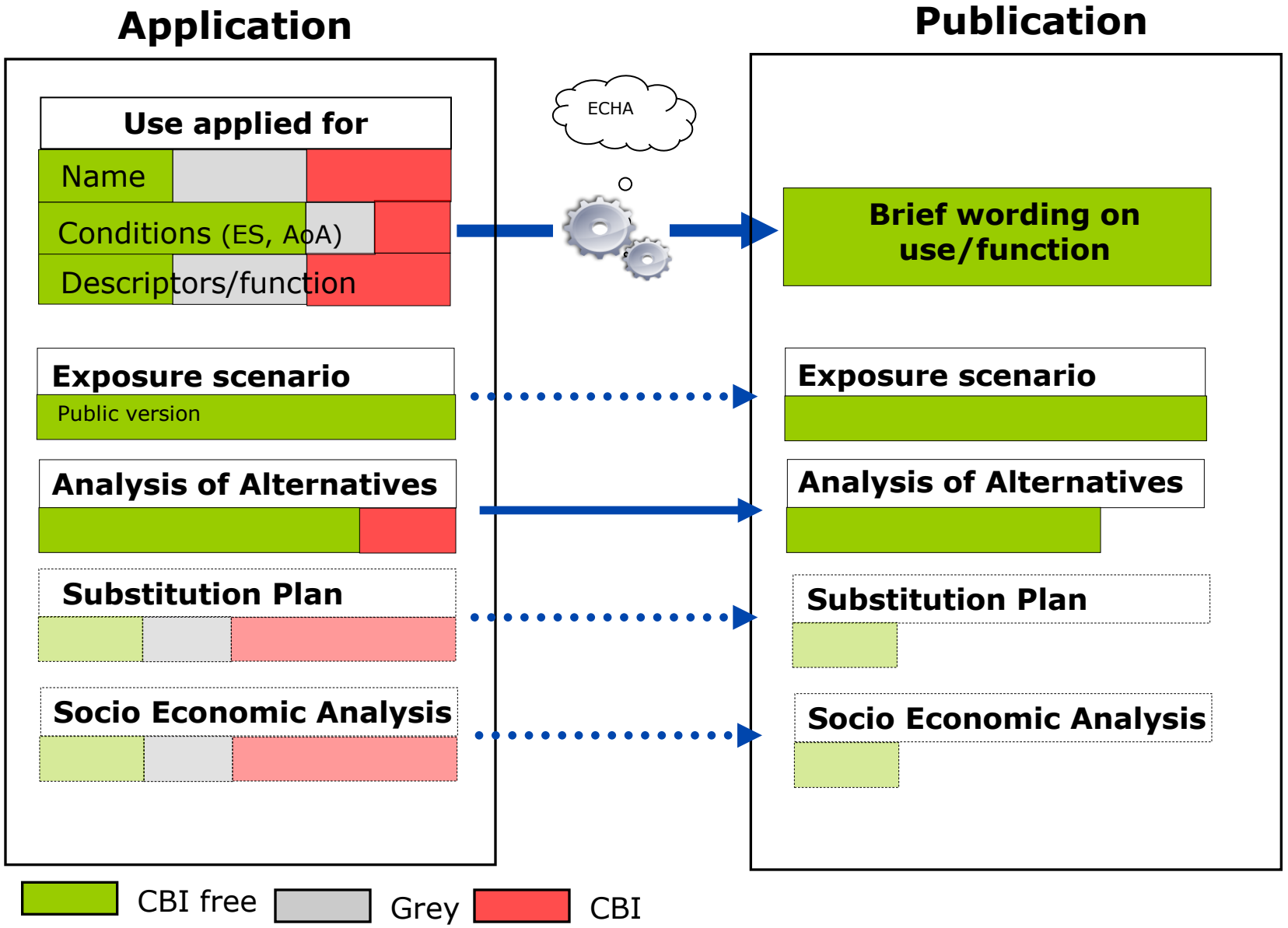


BIU / Public consultation

ECHA intends to publish…

- Name of the applicant
- "Brief wording" of the Broad Information on Use including
  - Name of the use
  - Conditions of use (exposure, functional requirements)
  - List of use descriptors (codes, function)
- Public version of the Exposure Scenario
- Public version of the Analysis of Alternatives
- Public version of the Substitution Plan
- Public version of the Socio-economic Analysis

Public consultation on alternatives – information made publicly available



ECHA’s support activities

ECHA guidance documents

- Guidance Documents and user manuals (content / procedure):
  - Guidance on the preparation of an Application for Authorisation
  - Guidance on Socio-Economic Analysis – Authorisation
  - "How to develop the description of uses in the context of Authorisation" document
  - Data Submission Manual Part 22 - How to Prepare and Submit an Application for Authorisation using IUCLID 5
- Templates for:
  - CSR
  - Analysis of Alternatives (updated Oct 2012)
  - Substitution Plan (updated Oct 2012)
  - Socio-economic analysis (updated Oct 2012)

ECHA support pages on the web

- Are the main ECHA info source to prepare an AfA
  http://echa.europa.eu/web/guest/applying-for-authorisation

  - « Additional information » section

    currently contains information on:

    - evaluation process by RAC and SEAC
    - information which are made publicly available
    - other documents on important AfA topics will be uploaded when available

  - « Questions & Answers » and « FAQs » sections

    Additional Q&As addressing most frequent questions are developped. Check regularly!

  - Presentations from:

    - AfA seminars
    - Workshop on Analysis of Alternatives and Socio-economic analysis

ECHA seminars, workshops and PSIS

- Additional seminars on AfA

  11-12 February 2013 (register from 10 Dec till 11 Jan)

  17 June 2013 (tbc)

- **PSIS**: When advanced with your AfA preparation: notify ECHA and request a « *pre-submission information session* (PSIS)» (6-7 months before submitting the application), if needed, to clarify questions you may have on procedural aspects

- Ask ECHA for technical advice (eg. through Helpdesk), make suggestions, too.

ECHA presentations, webinars and other targeted support planned for 2013

- ECHA/EASA Workshop on 23 January 2013 (targeted to aviation industry sector)
- Video on how to submit the AfA dossier in practice (REACH-IT, IUCLID, webforms): Jan-Feb 2013

  Feedback welcome. Might be turned into a webinar later
- Webinars? Suggestions for topics are welcome
- Others to come…

Other sources of information

- Your national REACH Helpdesk
- Your industry sector association
- Events organised by third parties

Take home messages

Take home

- You should apply if the use of the substance clearly adds value and the remaining risks are small
- First question: not *how* you apply for authorisation, but *what will happen to my business if the Annex XIV substance can no longer be used in the EU?*
- Authorisation concerns your 'core business': Own it! Do not leave it to your environment department or consultants
- Think outside your business to find the right scope for your assessment
- A strong case for authorisation probably means an easier application; the more marginal the case becomes, the more resources, time, analysis, etc. the application will need
- Start to prepare early enough
- Check ECHA's website regularly (AfA support section)
- Involve your supply chain (up and down), communication is crucial and be aware that Dowstream users will play a key role.

Thank You!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Information on Chemicals
Chemicals in our Life
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Information on Chemicals
Chemicals in our Life
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Information toolkit
Webinars
Information for registrants
Dossier Submission Tools
Helpdesks
Practical examples of exposure scenarios
Small and Medium-sized Enterprises (SMEs)
Restriction
Authorisation
Substances of Very High Concern Identification
Applying for authorisation
Socio-economic analysis in REACH
CLH
Publications
Applying for authorisation
After their "sunset date", substances on the Authorisation List will require an authorisation before they can be placed on the market or used.
Applications for authorisation will only be successful if applicants can demonstrate that the use of the authorised substance is necessary for their business and right for society as a whole.
The application process could require the investment of considerable time and resources, so companies should consider if this is the best course of action for their business or whether one of the range of alternatives available to your business might be more suitable than an authorisation.
A robust analysis can help you decide whether an authorisation is the best option for your business and will also be useful for compiling an argument to support your application.
1.
Submission windows
ECHA establishes specific windows for submitting applications for authorisation.
More
2.
Notification and pre-submission sessions
Notify ECHA well in advance of the date you intend to submit an application for authorisation. When notifying ECHA, you may also request a pre-submission information session with ECHA representatives to ask case-specific questions regarding the application process.
More
3.
Preparing an application
Follow these steps to prepare all the documentation required to apply for an authorisation.
More
4.
Submitting an application
Use these web forms to submit an application for authorisation .
More
5.
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 opinion-making process of ECHA.
Regulations
Authorisation
Addressing chemicals of concern
Authorisation
Support
Socio-economic analysis
Events
Seminar on applications for authorisation, 1-2 October 2012
Workshop on analysing alternatives and socio-economic impacts in authorisation applications, 2-3 October 2012
Seminar on the publication of information from the applications for authorisation process with industry representatives, 28 November 2011
Seminar on applications for authorisation with NGOs and trade unions, 7 July 2011
Seminar on applications for authorisation with industry, 12 April 2011
See also

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