

Process and support on applications for authorisations

Seminar on Applications for Authorisation

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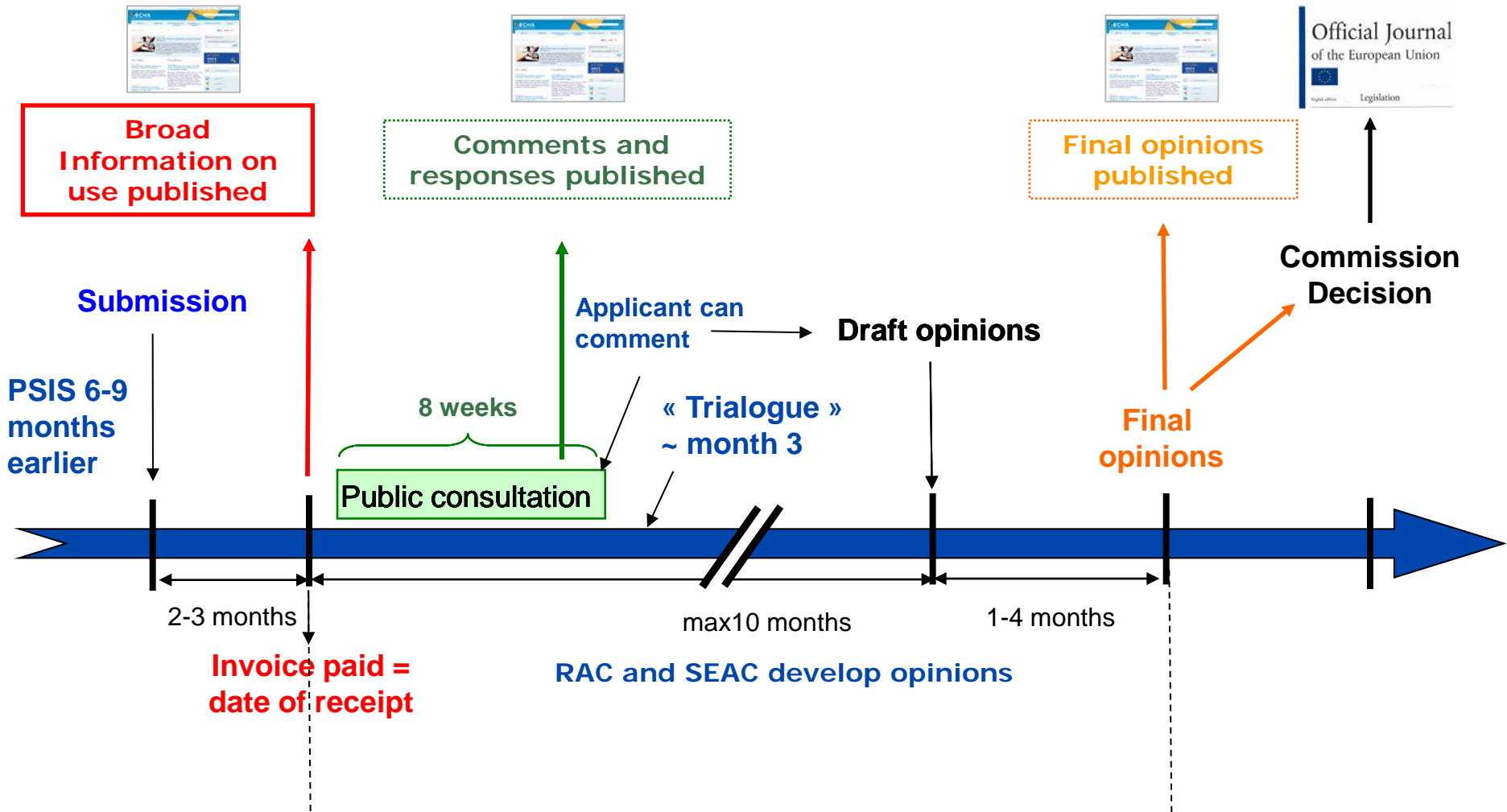
Outline

1. Timelines
2. Submission windows
3. Pre-submission information sessions (“PSIS”)
4. Where to find information and get additional support?

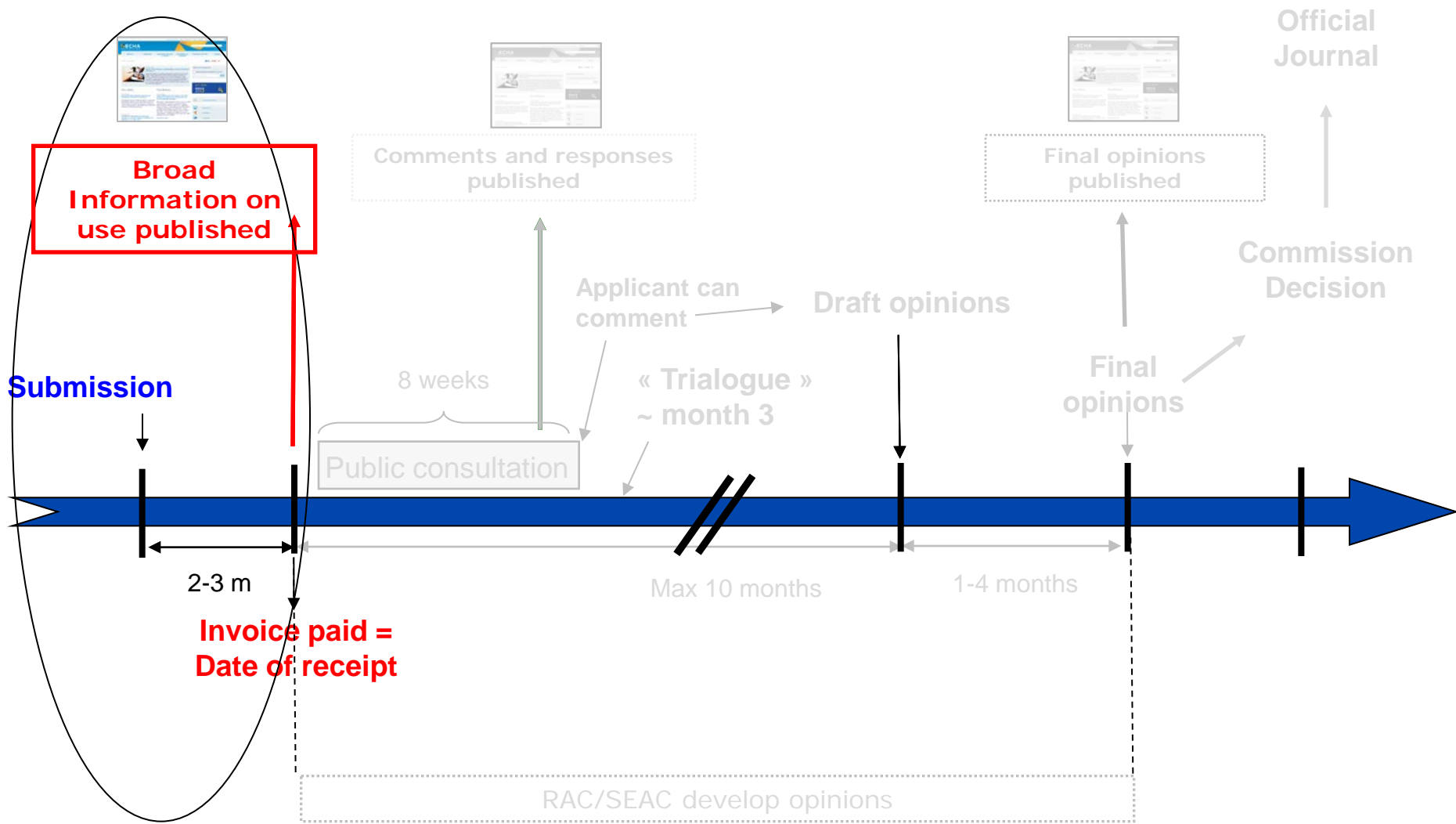
1. Timelines



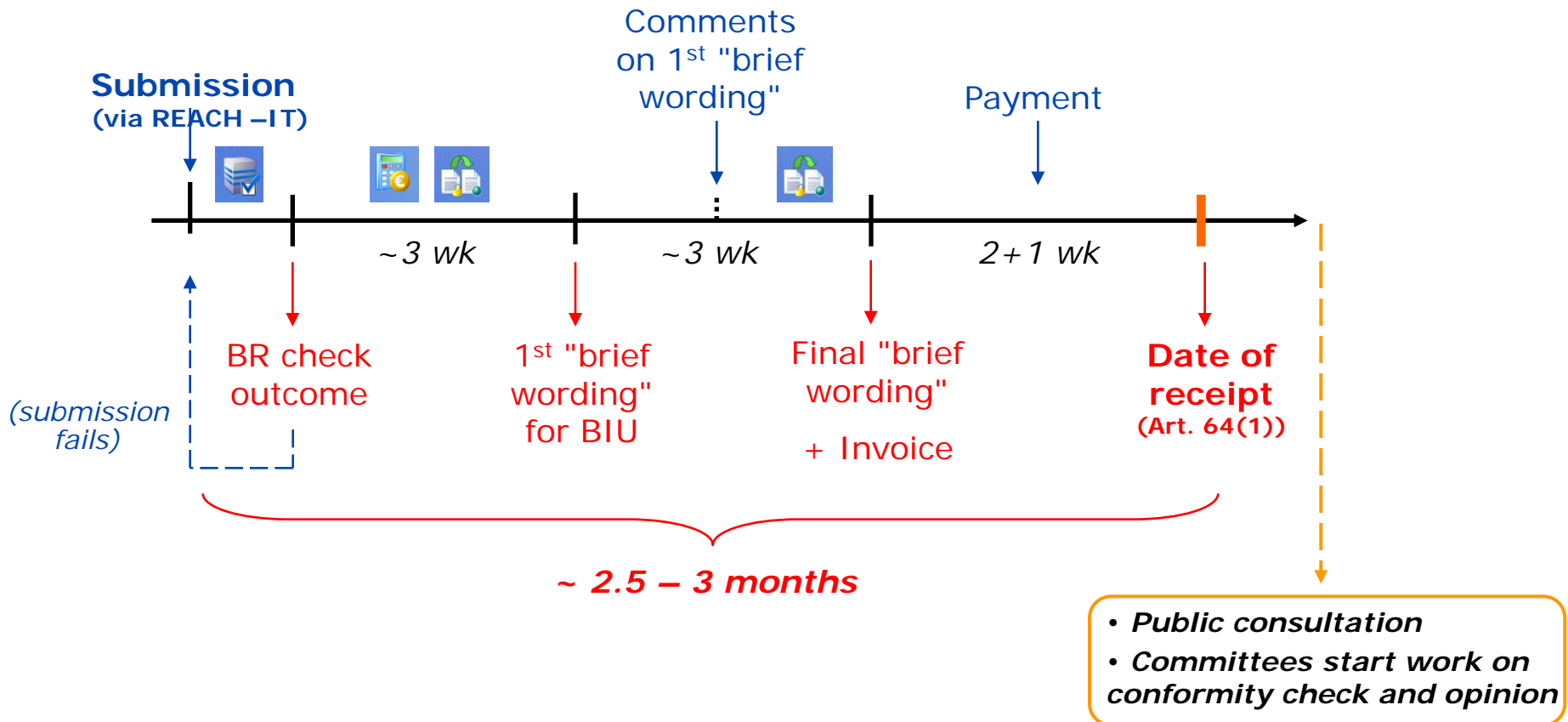
Timeline: the main steps




Initial processing



Initial processing timeline



Clarification on « date of receipt » (1/2)

- April 2013: COM's clarification on date of receipt:
 - If the application is submitted before the 'latest application date', the applicant can continue to use the substance after the 'sunset date', while waiting for the Commission decision (transitional arrangements set in Art 58(1)(c)(ii))
 -  If Business Rules checks do not pass and you re-submit *after* the LAD, you will not benefit anymore from the transitional arrangements!
 - See Q&A 571 and 572 for more details
- ➔ ECHA recommends that you submit your application during the previous submission window (~3 months earlier than the LAD), or alternatively at the very beginning of the latest submission window.

Clarification on « date of receipt » (2/2)

- “Date of receipt” in the meaning of Art. 64(1) is not affected:

the opinion making process starts once ECHA has received the application fee (i.e. ~2.5 – 3 months after the application has been submitted)

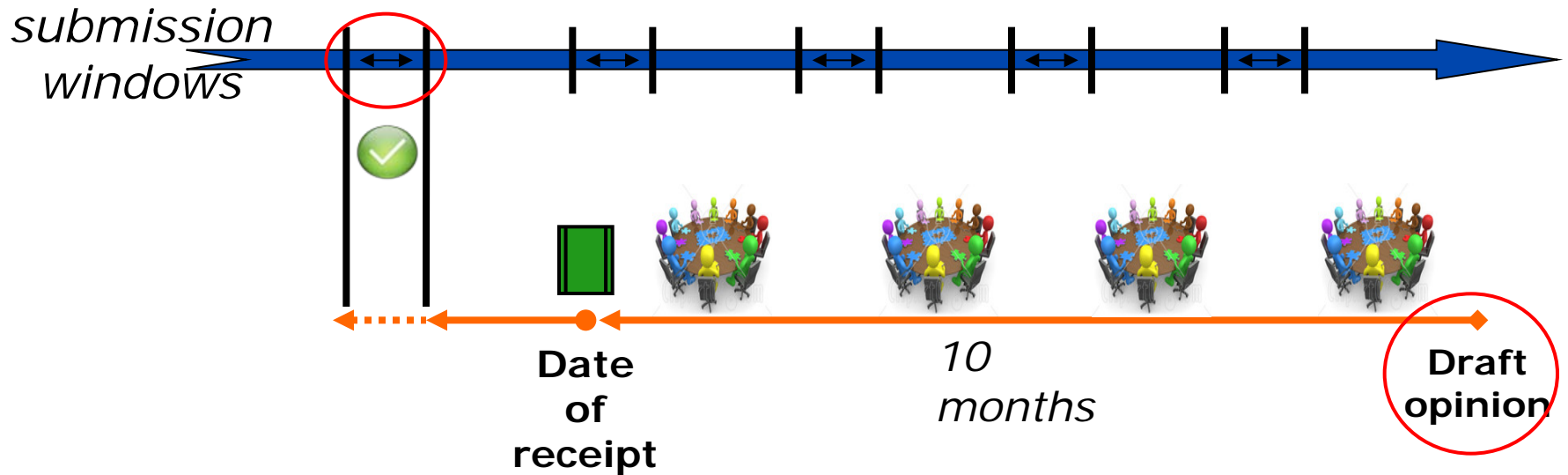
2. Submission windows



Submission windows (1/3)

Specific periods for submission of Applications to ECHA
(announced on ECHA web pages; every 3 months)

synchronisation with scheduled Committees meetings, for effective preparation of opinions



Submission windows (2/3)

- Most of the latest application dates are falling in a submission window but not all (e.g. Trichloroethylene)
- You can benefit from the transitional arrangements of Art. 58(1)(c)(ii) of REACH, if you submit your applications to ECHA during any of the submission windows before the latest submission window corresponding to the substance.
- You do not need to wait the latest submission window
- As explained above (to benefit from the transitional arrangements) ECHA advises to submit before the latest submission window

Submission windows (3/3)

DEHP:

- LAD: 21/08/2013
- Latest Submission Window: 7-21/08/2013

TCE:

- LAD: **21/10/2014**
- Latest Submission Window: **7-21/08/2014**


| Submission window - (corresponding latest application date) | Substances |
|---|---|
| 2013 | |
| 20 May – 3 June | Submission window available for all substances |
| 7 – 21 August (21 August 2013) | Submission window available for all substances and latest submission window for: <ul style="list-style-type: none"> - DEHP (EC 204-211-0) - BBP (EC 201-622-7) - DBP (EC 201-557-4) - DIBP (EC 201-553-2) |
| 7 – 21 November (21 November 2013) | Submission window available for all substances and latest submission window for: <ul style="list-style-type: none"> - Diarsenic trioxide (EC 215-481-4) - Diarsenic pentaoxide (EC 215-116-9) - Lead chromate (231-846-0) - Lead sulfochromate yellow (C.I. pigment yellow 34) (EC 215-693-7) - Lead chromate molybdate sulphate red (C.I. pigment red 104) (EC 235-759-9) |
| 2014 | |
| 7 – 21 February (21 February 2014) | Submission window available for all substances and latest submission window for: <ul style="list-style-type: none"> - HBCDD (EC 221-695-9 and 247-148-4) - TCEP (EC 204-118-5) - 2,4-Dinitrotoluene (EC 204-450-0) |
| 7 – 21 May | |
| 7 – 21 August (21 October 2014) | Submission window available for all substances and latest submission window for: <ul style="list-style-type: none"> - Trichloroethylene (EC 201-167-4) |
| 7 – 21 November | Submission window available for all substances |

3. Pre-submission information sessions (“PSIS”)



Notification and pre-submission information session (« PSIS ») (1/2)

Objective:

- address case-specific questions on regulatory/procedural aspects
- clarify critical elements for the public consultation on alternatives and facilitate the development of the "broad information on use"
-  • NOT to provide consulting services or advice. The assessment of the application only starts 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/applying-for-authorisation/notification-and-pre-submission-information-sessions>

Notification and pre-submission information session (« PSIS ») (2/2)

Mutual learning process!

PSIS considered very useful by the (potential) applicants:

- Helped to clear some misunderstandings
- Highlight and clarify important aspects

Very useful for ECHA too:

- Better understanding of what is not clear or what worries potential applicants
- We know what is likely to come – better planning

4. Where to find information and get support?





ECHA support

- ECHA's website: main ECHA info source to prepare an AfA entrance gate to all material:
<http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/afa>
Q&As!
- Seminars & workshops
- Pre-submission information sessions ("PSIS")
- Helpdesk (primary contact point for questions)
- Make suggestions too! Send an email to:
[applications-authorisation \[at\] echa.europa.eu](mailto:applications-authorisation@echa.europa.eu)

Applications for Authorisation

REACH allows companies to apply for an authorisation to continue or start using and placing substances included in the Authorisation List (Annex XIV of REACH) on the market. You can find information on the process itself and support to prepare and submit your application through the links below.

Authorisation List



The list of substances subject to authorisation, latest application dates and sunset dates.

[More](#)

Submission windows



Time frames for submitting applications for authorisation.

[More](#)

Evaluating applications



How the opinion-making process works and committees' documents on how applications are treated and evaluated.

[More](#)

Applying for Authorisation



Guidance documents, templates, presentations, Q&A, fee calculator, how to submit.

[More](#)

Current consultations



Comment on the applications for authorisation by providing information on safer alternatives.

[More](#)

Past consultations and opinions



The page contains the applications, the comments received during the public consultations and the applicants' responses.

[More](#)

See also

- [Factsheet: Applications for Authorisation under REACH \[PDF\] \[EN\]](#)
- [Statistics on received applications](#)
- [Process and actors](#)

Related events

- [29-30 April 2014 ECHA workshop on sharing experience on applications for authorisation](#)
- [28-29 April 2014 ECHA seminar on Applications for Authorisation](#)
- [27-28 March 2014 ECHA Workshop on submitting applications for authorisation for chromates in an efficient way](#)
- [2 December 2013 Space Stakeholders' Day on REACH](#)
- [17 June 2013 ECHA information session on Critical Raw Materials and REACH](#)
- [17 June 2013 Seminar on Applications for Authorisation](#)
- [11 - 12 February 2013 Seminar on applications for authorisation](#)
- [23 January 2013 EASA/ECHA workshop on airworthiness and REACH authorisation](#)
- [Previous events](#)

when to submit your application

Guidance, templates, Q&As, PSIS requests, Instructions to submit

info on opinion process, applicants' and stakeholders' participation, BIU, reference DNELs/dose-response, etc.

Consultations and opinions

“Applying for AfA” page

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 requires the investment of 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 their 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.

Pre-submission session

1. Notify ECHA well in advance of the latest application date. You may also request a pre-submission session to ask case-specific questions.

> [More](#)

Submit an application

3. Follow these steps to submit an application for authorisation.

> [More](#)

Prepare an application

2. Follow these steps to prepare all the documentation required to apply for an authorisation.

> [More](#)

Support

- > **Q&As**
- > National helpdesk
- > ECHA's Helpdesk
- > Contact the Authorisation team at: [applications-authorisation \[at\] echa.europa.eu](mailto:applications-authorisation@echa.europa.eu)



> [More information on AfA](#)



> [Socio-economic analysis](#)

Related documents

- > [Guidance on the preparation of an Application for Authorisation \[PDF\]](#)

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| bg | cs | da | de | el | en |
| es | et | fi | fr | hu | it |
| lt | lv | mt | nl | pl | pt |
| ro | sl | sk | sv | | |

- > [Guidance on Socio-Economic Analysis – Authorisation \[PDF\] \[EN\]](#)
- > [Guidance on information requirements and chemical safety assessment](#)

Q&As: several issues addressed, updated regularly.
Stay up to date!

Ask for a PSIS

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

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

Formats, guidance and tools:

- CSR
- AoA
- Substitution Plan
- SEA
- Substance grouping
- Justification for not considering certain risks
- Concordance table
- How to describe the uses
- Data submission manual
- ECHA application fee calculator

<http://echa.europa.eu/applying-for-authorisation/preparing-applications-for-authorisation>

Evaluating applications

How the opinion-making process works and committees' documents on how applications are treated and evaluated.

| 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 |
| Submission of information on alternatives | Instructions of how interested third parties can submit information for the public consultation on alternatives for applications for authorisation. | Download |
| | Non-confidential template | Download |
| | Confidential template | 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 | A description of information from applications for authorisations that | Download |

contains information on:

- **Participation of applicants, stakeholders and third parties**
- **Evaluation of the applications by the Committees**
- **Information made public (BIU, opinions)**
- **Committees working procedures and formats**
- **Length of review period**
- **Reference DNELs/dose-response relationships**
- **etc**

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

<http://echa.europa.eu/applying-for-authorisation/evaluating-applications>

Partners' service for applicants (upcoming...)

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

Partners' service for applicants

Companies, consortia, industry associations and consulting companies are welcome to use partners' service for applicants to find a suitable partner for their authorisation applications. Also companies who have possible substitutes could use this service.

You can use the service in two ways:

1. you can **find potential applicants' identity and contact details**, information on the substances, uses, role in the supply chain and type of collaboration looked for;
2. you can **add your information so that others can contact you**. All information provided in this form will be made public.

The use of this service is limited to the substances on the Authorisation List (Annex XIV of REACH) and the substances which are recommended for inclusion in the Authorisation List.

Looking for partners to prepare for an application for authorisation?

Wish to learn from your suppliers or your clients?

Lack specific skills or knowledge to prepare an application?

Download the contact list

I have taken note of the [Legal notice](#).

Contact list [XLS]

Express your interest

› [Fill in the webform](#)

Partners' service for applicants (upcoming...)

Downloadable Excel sheet with the following information:

- Substance
- Number of uses + use names
- Company name, country
- Contact person, E-mail
- (website)
- Type of organisation (company/consortium/industry association/consultant/other)
- Role in the supply chain (M/I/DU/OR/other)
- Collaboration type
 - Company looking for other companies or consortia for collaboration
 - Consortium proposing collaboration
 - Industry association proposing collaboration
 - Consultant proposing services
 - Other
- Any further information (free text field)

Take home

- Check ECHA's website regularly (especially the Q&As)
- Request PSIS
- Use the partners' service for applicants
- Submit during the submission windows
- Make suggestions too!

Thank You!

