Process and support on applications for authorisations

Seminar on Applications for Authorisation

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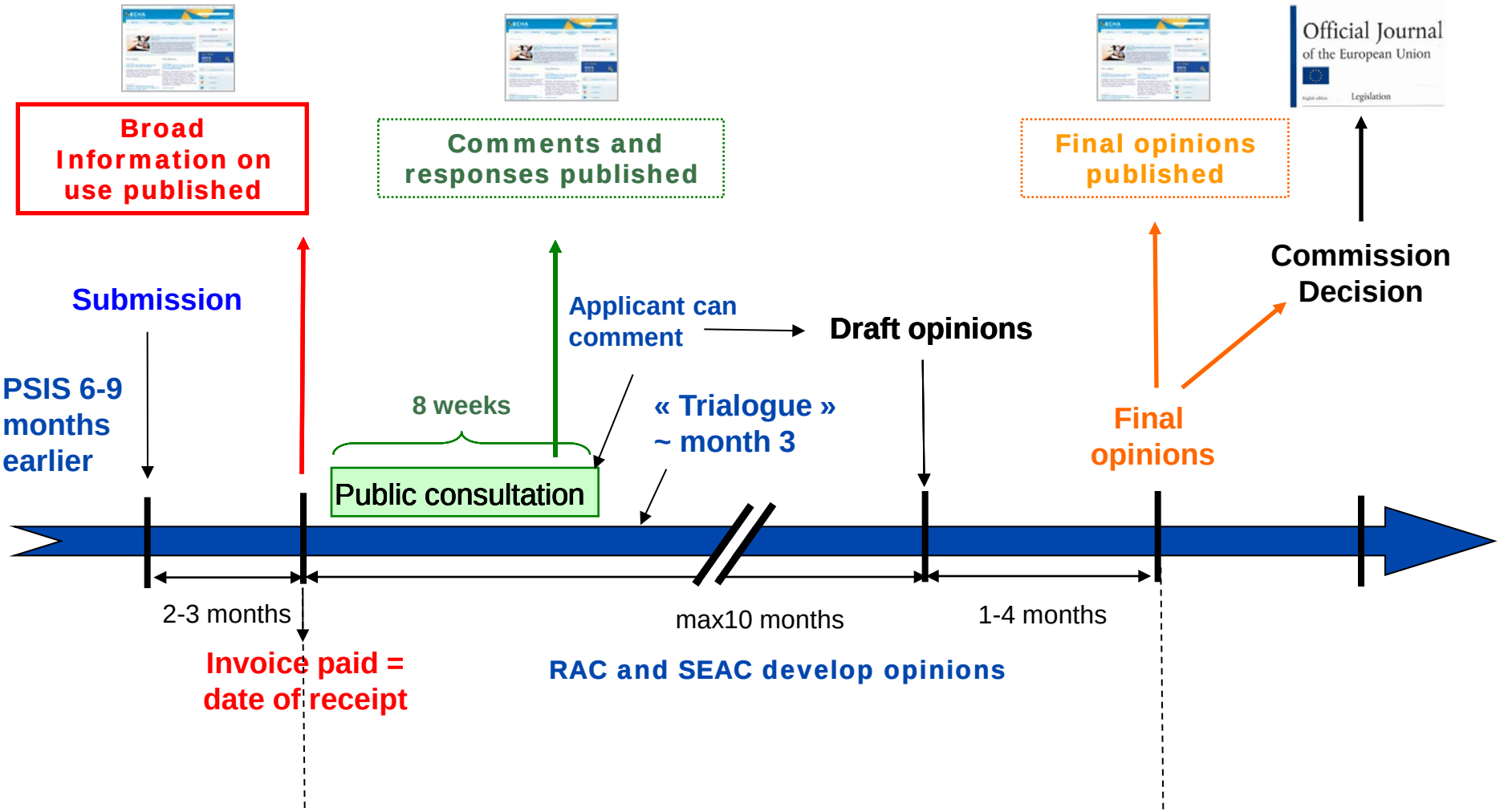
Outline

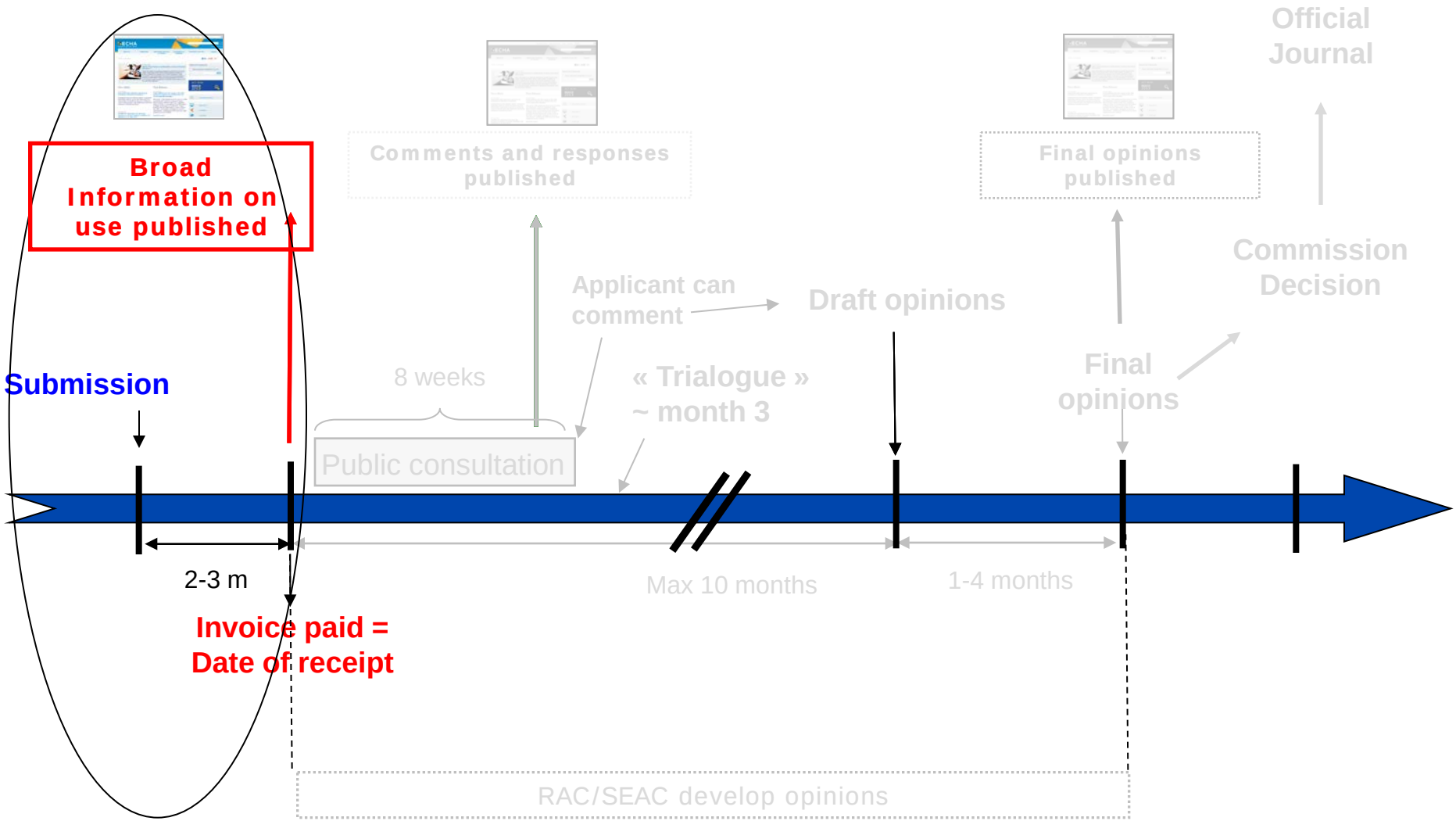
1. Timelines
2. Submission windows
3. Pre-submission information sessions (“PSIS”)
4. Where to find information and get additional support?

1. Timelines

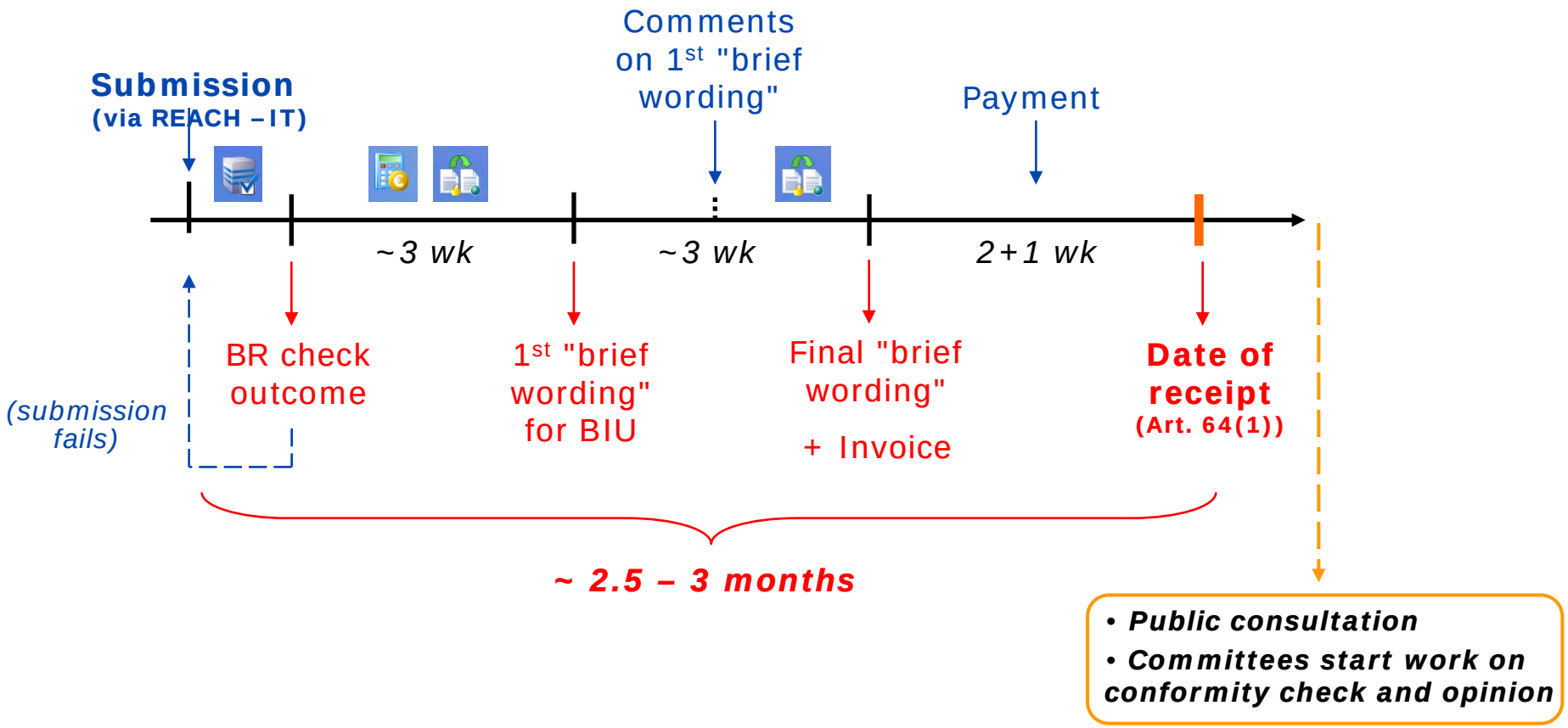
Timeline: the main steps



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:

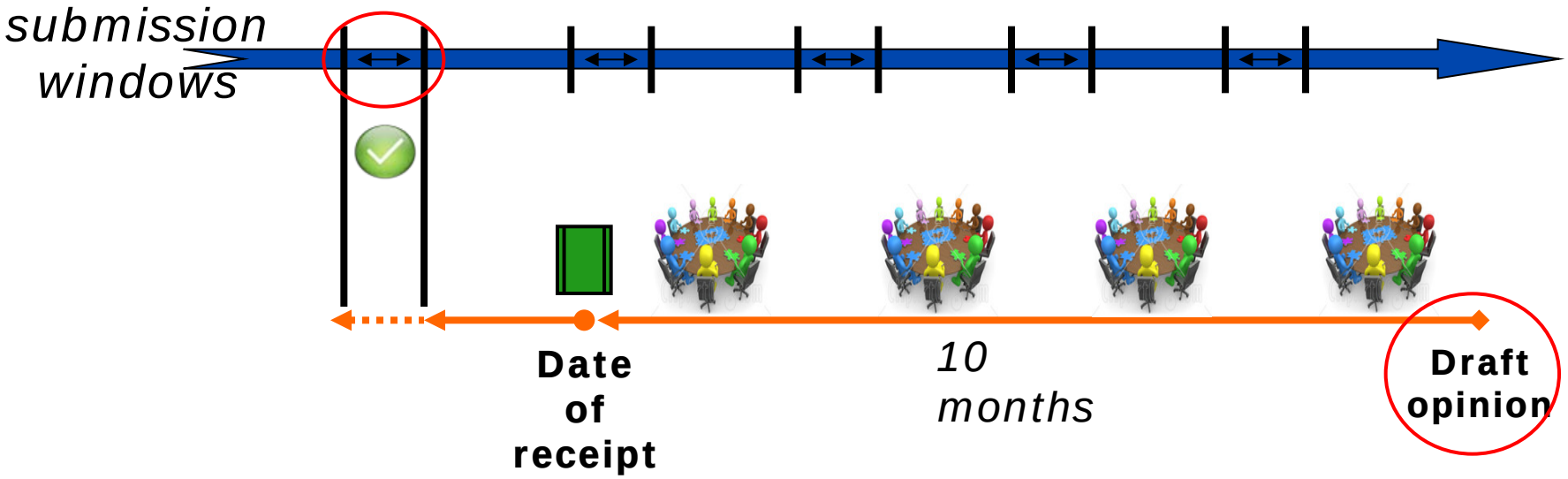
the opinion making process starts once ECHA has received the application fee (i.e. ~2.5 – 3 months after the application has been submitted)

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:* - 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:* - 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:* - 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:* - 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 plannification

4. Where to find information and get support?

ECHA support

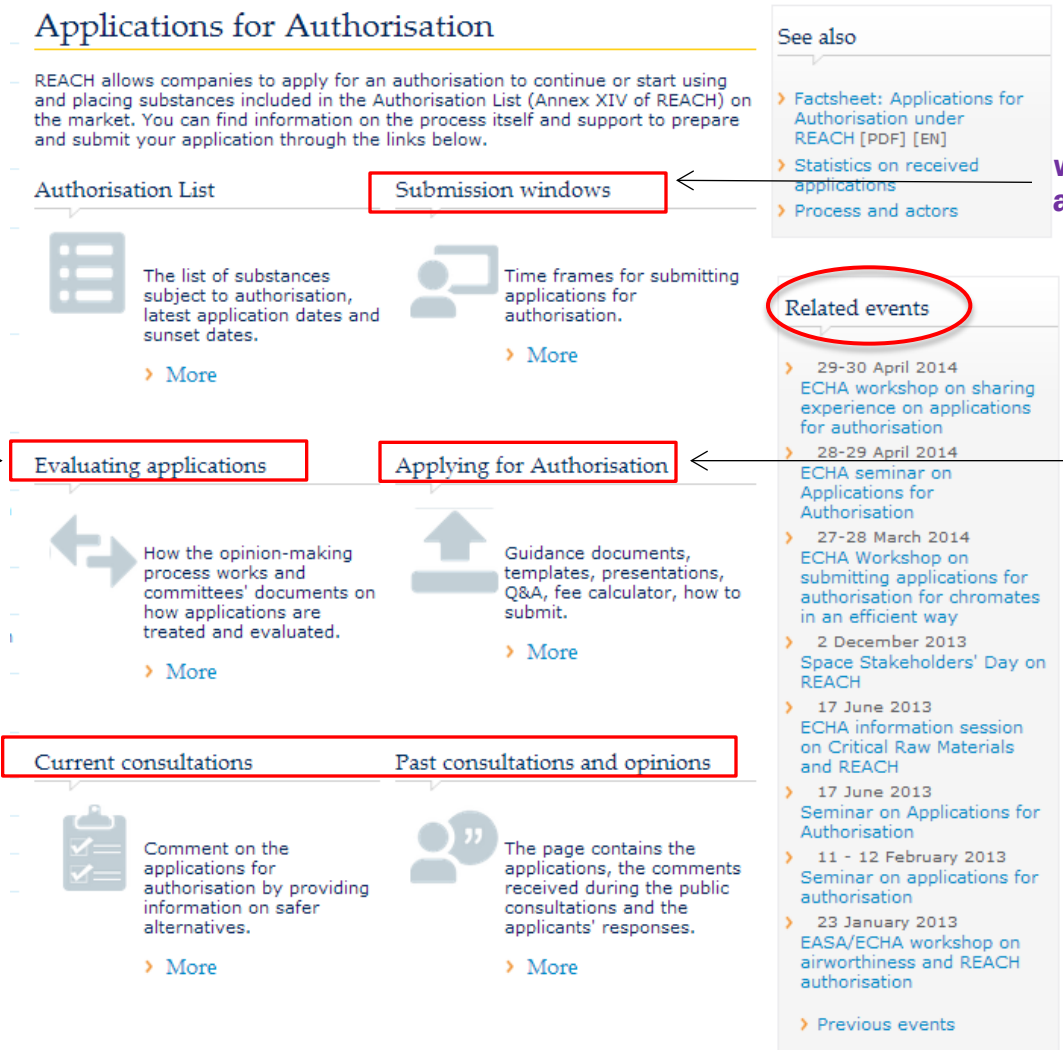
- ECHA's website: main ECHA info source to prepare an AfA
  entrance gate to all material:

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

ECHA's website: AfA landing page



when to submit your application

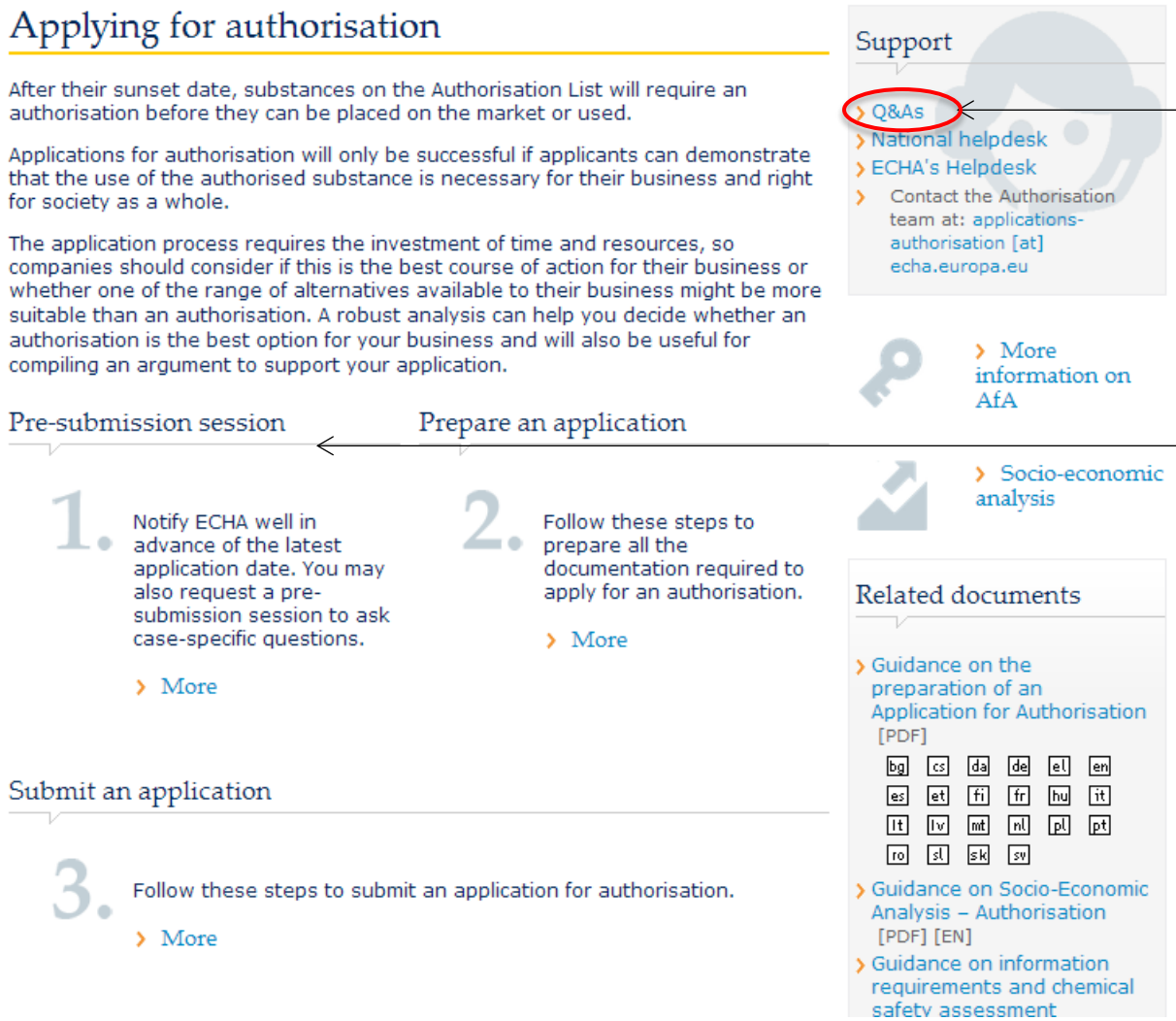
info on opinion process, applicants' and stakeholders' participation, BIU, reference DNELs / dose-response, etc.

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

Consultations and opinions

http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/afa

“Applying for AfA” page



Q&As: several issues addressed, updated regularly.

Stay up to date!

Ask for a PSIS

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

“Preparing an application” page

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" page

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:

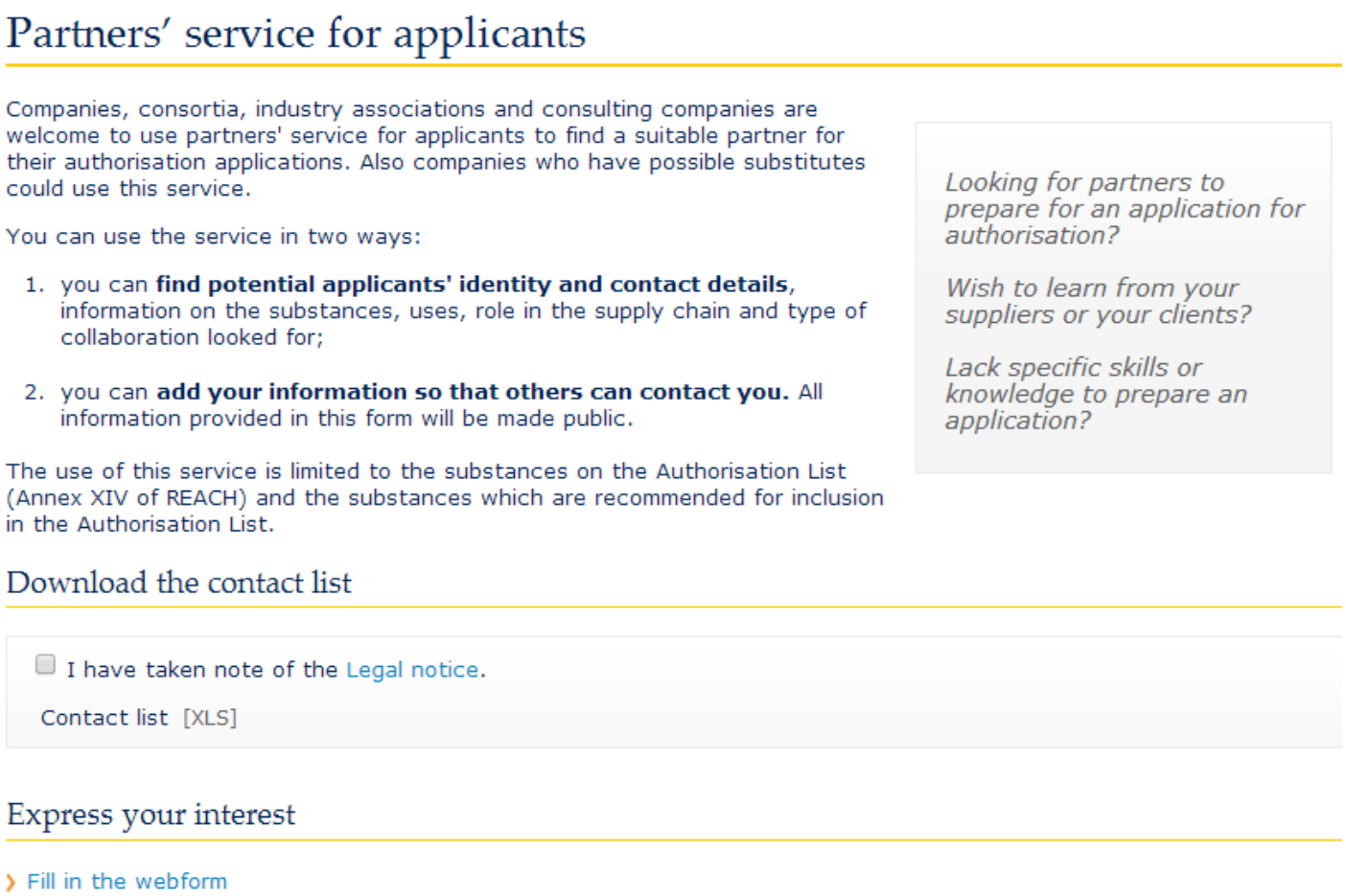
- **Participation of applicants, stakeholders and third parties**
- **Evaluation of the applications by the Committees**
- **Information made public (BIU, opinions)**
- **Committees working procedures and formats**
- **Length of review period**
- **Reference DNELs/dose-response relationships**
- **etc**

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!

ECHA
EUROPEAN CHEMICALS AGENCY

Thank You!