The authorisation application procedure

Seminar on applications for authorisation
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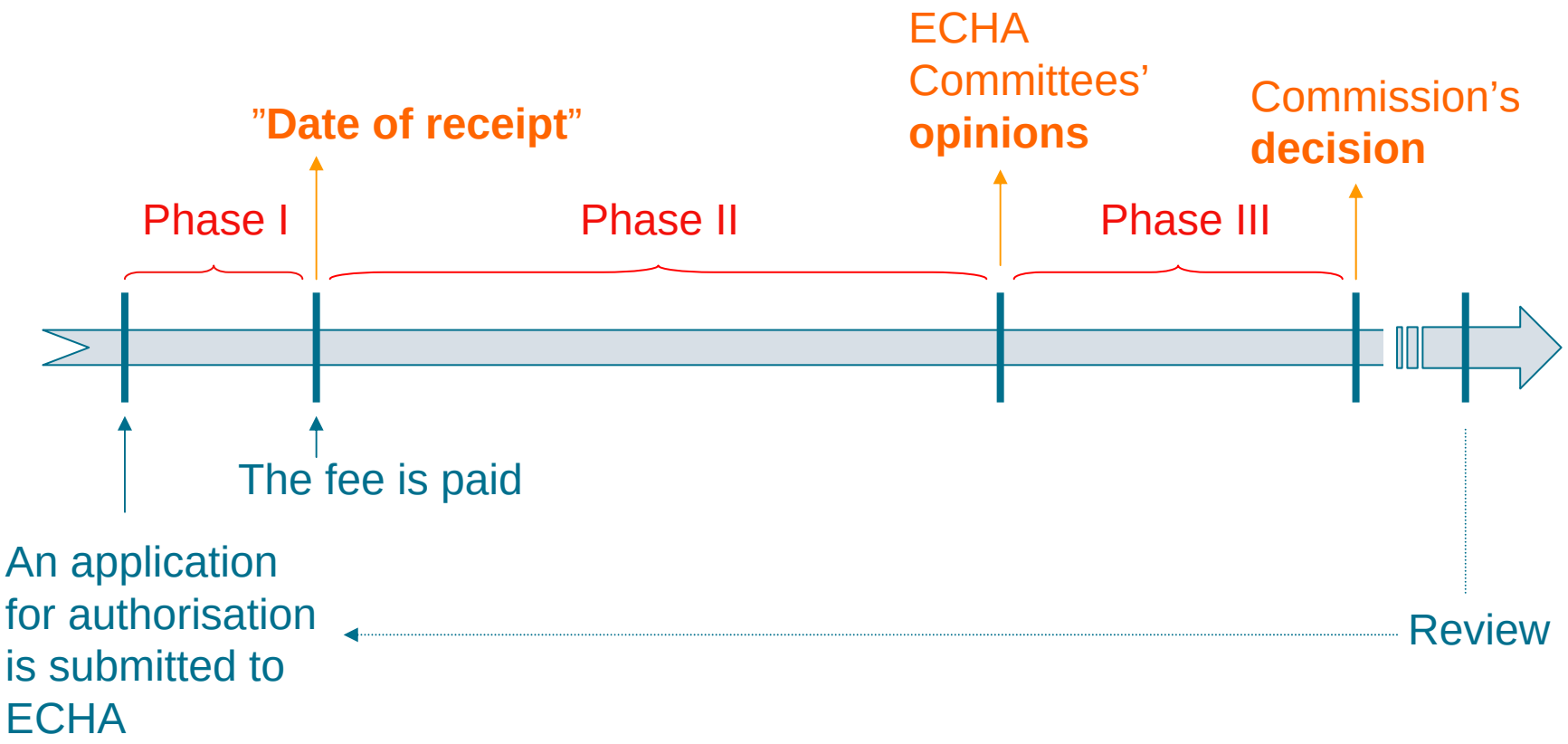
Objectives of this presentation

- To give an overview of the different phases of the procedure, from the submission of an application dossier to ECHA until the Commission's final decision

- To introduce some particular aspects of the procedure, to be further detailed later in the day

The authorisation applications procedure
The different phases



Phase I - Initial checks & related preparatory activities
Purpose (1/2)

- To make sure that an application dossier is processable by ECHA, i.e. that:

CHECKS

  - it does not contain any viruses,
  - it is in the right format,
  - it contains the minimal administrative and technical information for ECHA to be able to handle and store it (i.e. the « type of submission » is correct, minimal substance identifiers, information on the applicant is there, etc.)

!*Note: these "initial checks" are different from "Conformity Check" to be performed by ECHA Committees (Phase II)*

Phase I - Initial checks & related preparatory activities
Purpose (2/2)

- To determine and invoice the fee

- To develop the wording for the public consultation on ”*broad information on uses*” applied for (alternatives)

Phase I - Initial checks & related preparatory activities Outcome

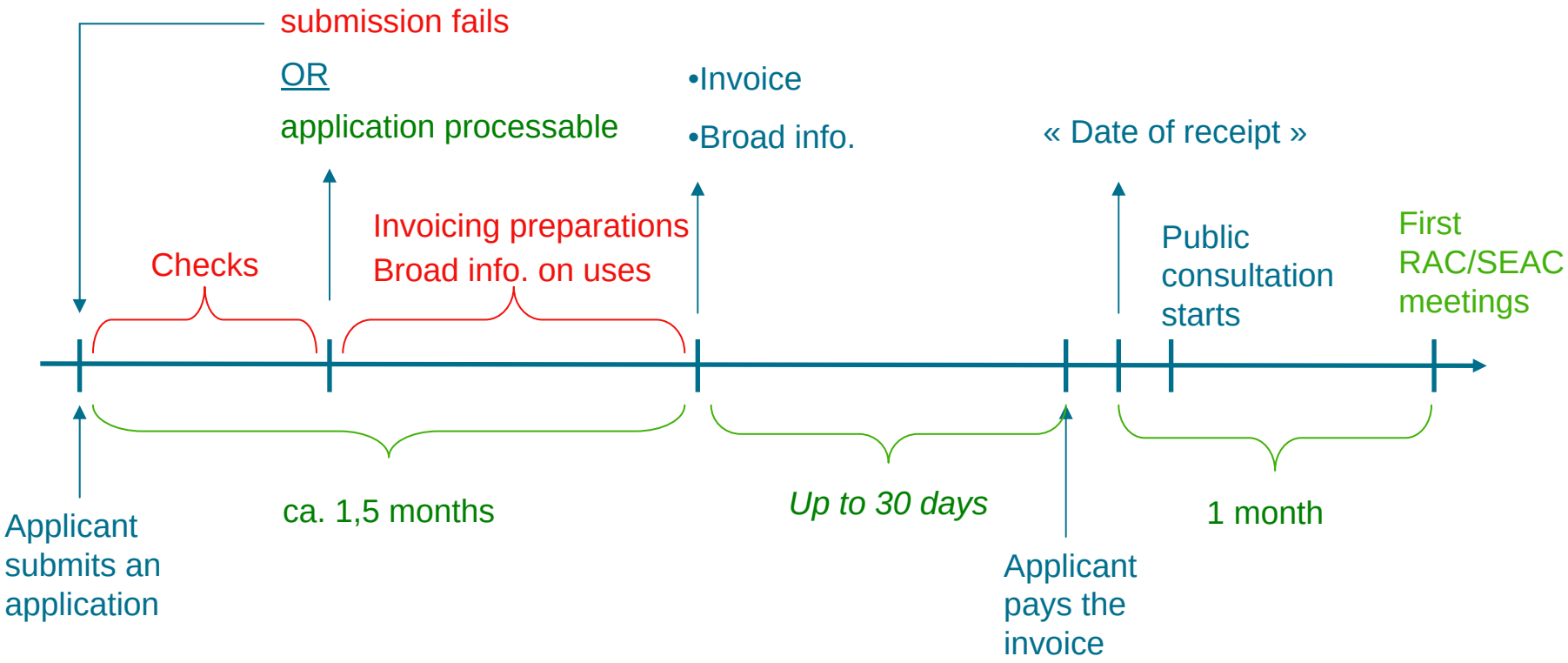
- Initial checks:
  - the submission can either pass, or fail;
  - if the submission fails:
    - the application has to be re-submitted;
    - a **report** is provided with the reason(s) for failure.
- Broad description of uses: ECHA will determine, on the basis of a proposal by the applicant (voluntary basis), the **wording** to be published for consultation purposes
- Invoicing:
  - an **invoice** is sent to the applicant, to be paid within 30 days
  - once the invoice is paid, ECHA will aknowledge the ”***date of receipt***”, which is the starting point for the next phase

Phase I - Initial checks & related preparatory activities Actors involved

- ECHA Secretariat:
  - performs the checks,
  - determines the fee and sends the invoice,
  - develops the wording for broad description of uses applied for.

- The applicant:
  - pays the invoice,
  - event. comments on the wording for broad description of uses as developed by ECHA Secretariat.

Phase I - Initial checks & related preparatory activities Timeline

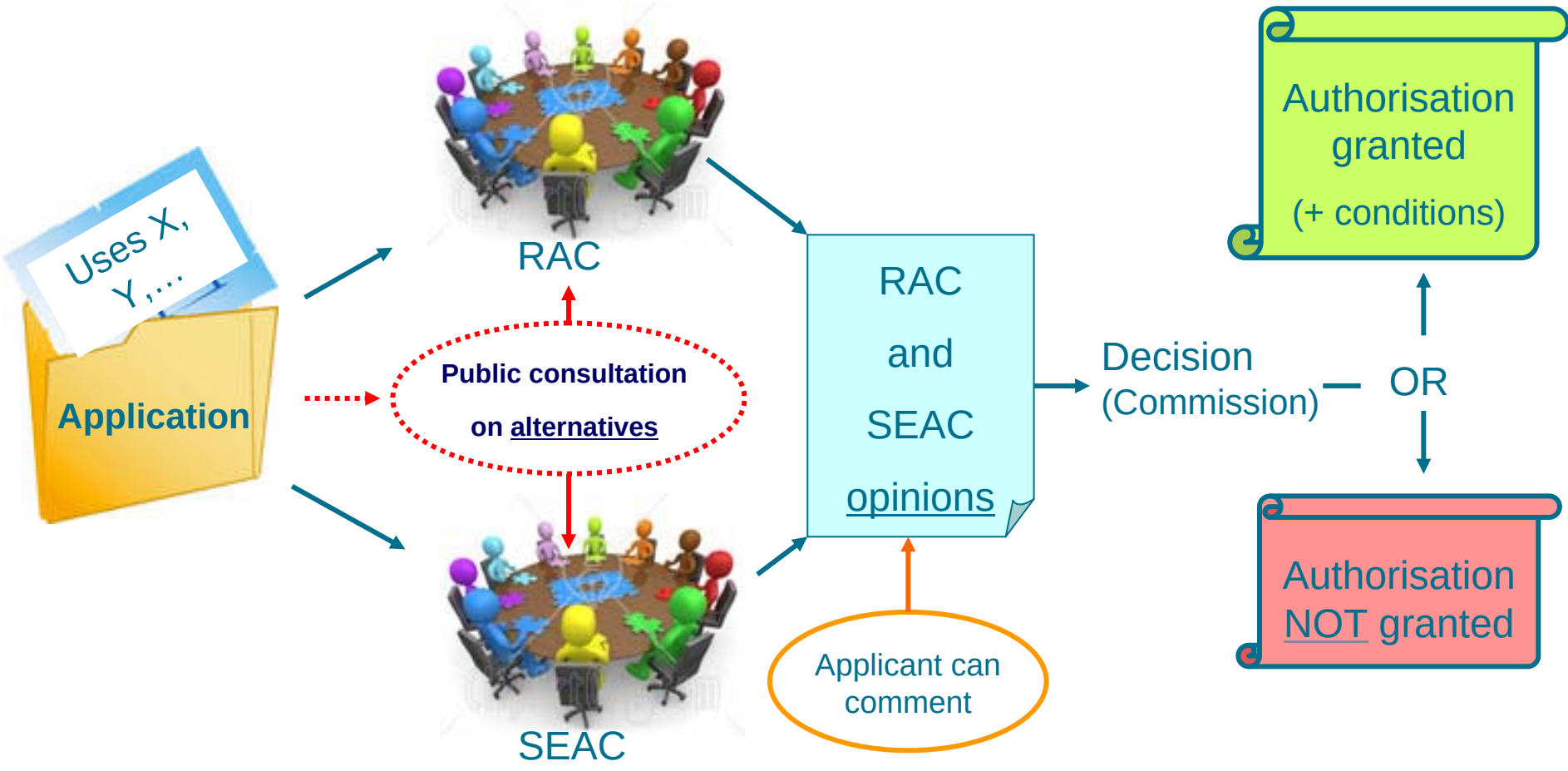


Phase II - The opinion-making
Purpose

- To deliver opinions which will support the Commission in its decision

- For that, ECHA's Committees will:
  - check the conformity of the application with the requirements of Art. 62 for the content of an application ("*Conformity Check*"),
  - give their opinion on the decision criteria (adequate control of risks, availability of alternatives, socio-economic benefits),
  - poss. suggest additional conditions, incl. monitoring arrangements, for the authorisation,
  - suggest a duration for the review period.

Phase II - The opinion-making Overview



Phase II - The opinion-making

Activities and actors involved (1/2)

- ECHA Committees (RAC and SEAC):
  - check the conformity, and poss. request additional information
  - assess the (content of the) application, and poss. request clarifications
  - assess the information on alternatives from the public consultation and poss. request/require further information on alternatives from third parties/the applicant
  - develop and adopt their opinions

- ECHA Secretariat:
  - provides RAC and SEAC with secretarial support
  - runs the public consultation on broad information on uses

Phase II - The opinion-making

Activities and actors involved (2/2)

- The applicant:
  - when requested, provides RAC and SEAC with additional information
  - event. comments on the draft opinions

- Interested third parties:
  - provide information on possible alternatives during the public consultation on broad information on uses
  - when requested, provide RAC and SEAC with additional information on alternatives

Phase II - The opinion-making Timeline

- ECHA Committees have **10 months** to draft their opinions, from the ”*date of receipt*”

+

- the applicant has **2 months** to comment

+

- then, depending on whether or not the applicant comments on the draft opinions, ECHA Committees have up to **2 months** to adopt their final opinions

Phase III – The decision-making

- The Commission takes the final decision (comitology)
- The Commission has 3 months to draft its decision after receiving ECHA's Committees opinions; then, no specific deadlines required for the adoption

After the Commission decision is made:

- Non-confidential versions (”*summaries*”) of the decisions will be published in the Official Journal of the European Union, as well as on ECHA’s website; full decisions will be sent to the applicant

- Granted authorisations will be subject to review (as set in decisions + can be reviewed at any moment if conditions have changed)

- Downstream users who are not the authorisation holder will have to notify ECHA of their use (system still to be developed)

Conclusions

- It is a complex procedure, with many steps and strict timelines:
  - it is important that all parties involved – and in particular applicants – understand it
  - to make it work, there is a need to optimize the process at each step
- Once the clock of the Committees has started, RAC and SEAC have only 10 months to make their views and draft their opinions
- Commission needs to have a good basis for its decision-making process
- Overall, the quality and completeness of the application is the key