Evaluation of Applications by Committees

Seminar on Applications for Authorisation
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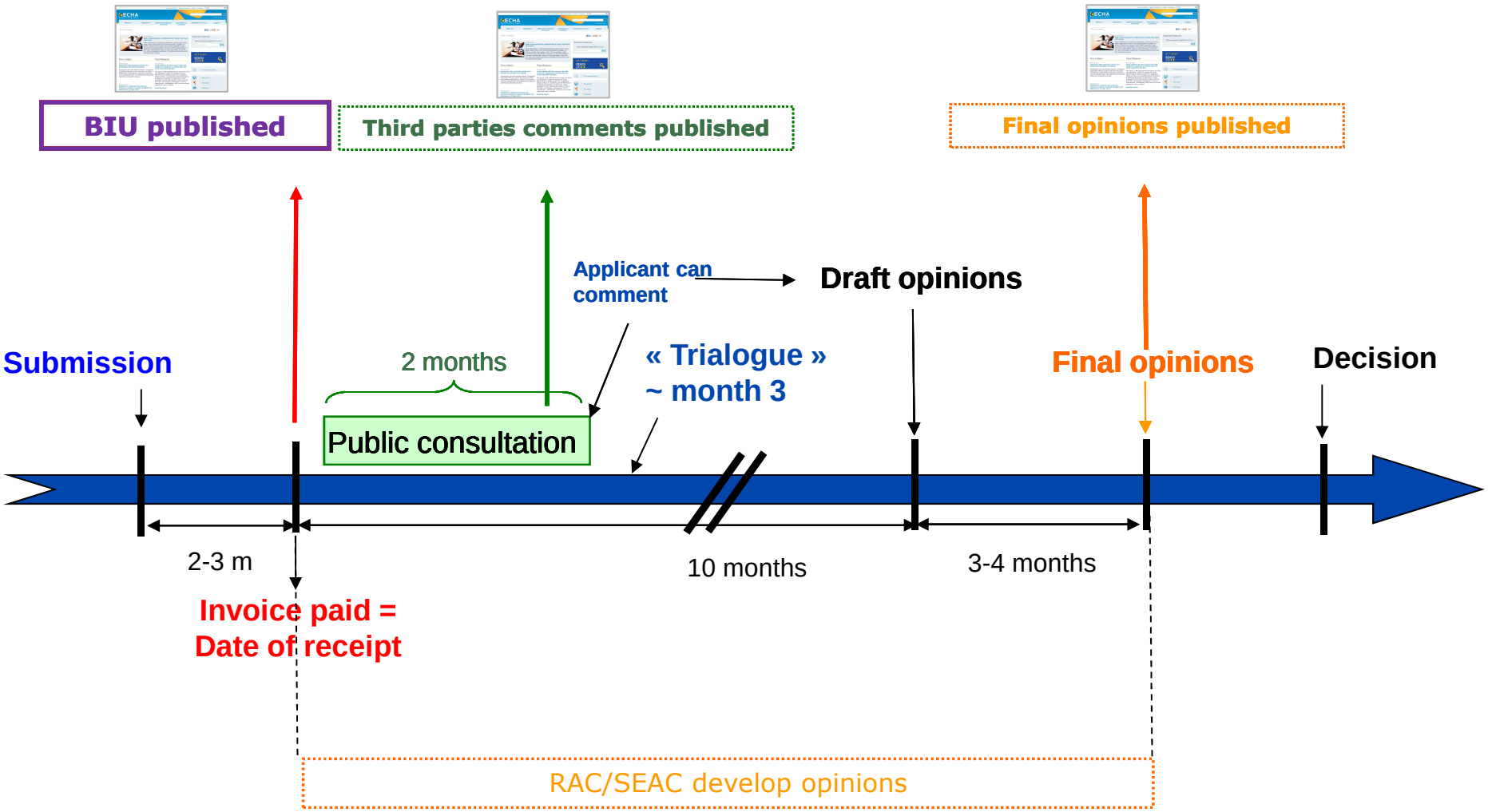
Outline

1. Opinion-making timeline
2. Roles of the Scientific Committees
3. Opinion-making process
4. Remaining risk
5. Evaluation of alternatives
6. Cooperation between SEAC and RAC
7. Conclusions

- Responses to questions

1. Opinion-making timeline



2.1 Committee for Socio-economic Analysis (SEAC)

Article 64(4) specifies that the draft opinions shall include the following elements:

- An assessment of the **socio-economic factors** and
- the **availability**, **suitability** and **technical feasibility** of **alternatives.**

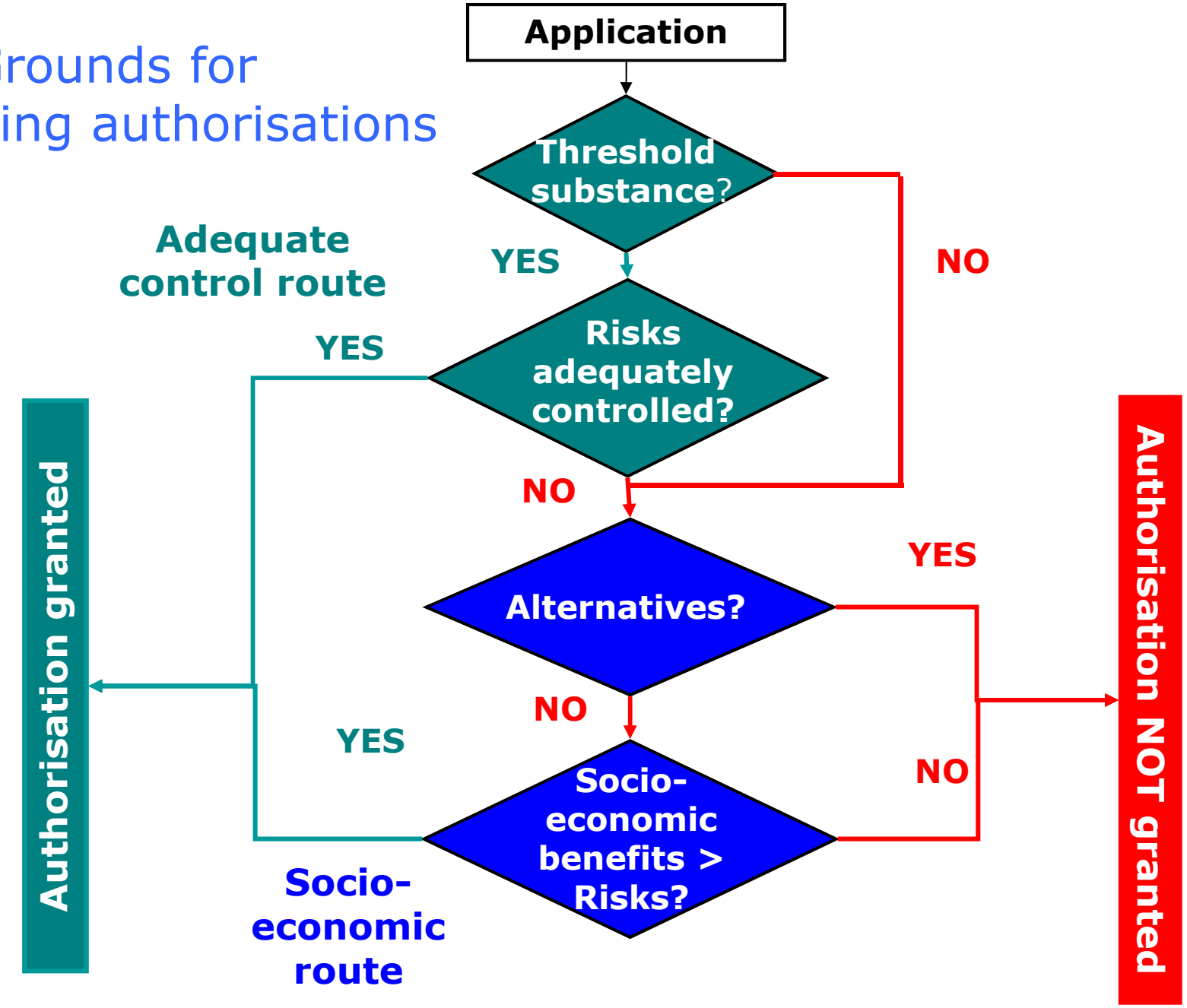
2.2 Committee for Risk Assessment (RAC)

Article 64(4) specifies that the draft opinions shall include the following elements:

An assessment of the

- **risk to human health** and/or the **environment** arising from the use(s) of the substance,
- including the **appropriateness** and **effectiveness** of the **risk management measures** and, if relevant,
- an assessment of the **risks** arising from possible **alternatives.**

3.1 Grounds for granting authorisations



3.2 SEAC's and RAC's evaluation of the applications

- Evaluate and validate information in applications:
  - Are methods appropriate and applied consistently?
  - Are conclusions logical?
  - Is evidence robust, is the scope correct?
  - Are all relevant issues included?
  - Are decisions not to include specific toxicological endpoints justified?
  - Are efforts in applicant's assessments proportionate given the importance of the application?
- Applicant's work is the basis for the evaluation
  - with information from public consultation

3.3 Interaction between the Applicant and SEAC and RAC

- Applicant can comment on information given in the Public Consultation
- A "trialogue" held between applicant and rapporteurs (and stakeholder observers and third parties, if required) – see:
  http://echa.europa.eu/documents/10162/13555/stakeholder_participation_in_afa_en.pdf
- SEAC may require additional information on alternatives
- If necessary, SEAC and RAC can request additional information from the applicant (on any issue)
- Applicant has the right to comment on draft opinion
- Structured contacts to ensure efficiency & consistency

4. RAC: Remaining risk

- Demonstration of adequate control only possible in case of threshold substance
- Remaining risk (as described by applicant) is the starting point for the health or environmental impact assessment. RAC to validate and assist SEAC in their evaluation of the impact
- RAC to evaluate/modify Operational conditions (OC) and risk management Measures (RMM) to control the remaining risk

5. RAC and SEAC: Evaluation of alternatives

- If risks are adequately controlled:
  - Risks of alternatives evaluated vs review period and conditions
  - RAC does not need to focus on these

- If non-threshold substance (i.e. risks are not adequately controlled)
  - SEAC needs to check if the alternatives are technically **AND** economically feasible
  - If so: RAC would need to focus on the risks of alternatives

  - **If alternatives are not technically or economically feasible**

✧***They are not suitable in any case***

★***It does not matter if they are less or more risky than the Annex XIV substance***

6.1 RAC and SEAC – Main areas of cooperation

- Evaluation of alternatives
- Evaluating health and environmental impacts

Cooperation also necessary to recommend:

- Review period as well as additional conditions and monitoring arrangements
  - Based on Analysis of Alternatives, Substitution Plan and SEA
  - Remaining risks may affect review period or additional conditions

6.2 RAC and SEAC: From risk to impact to socio-economic assessment

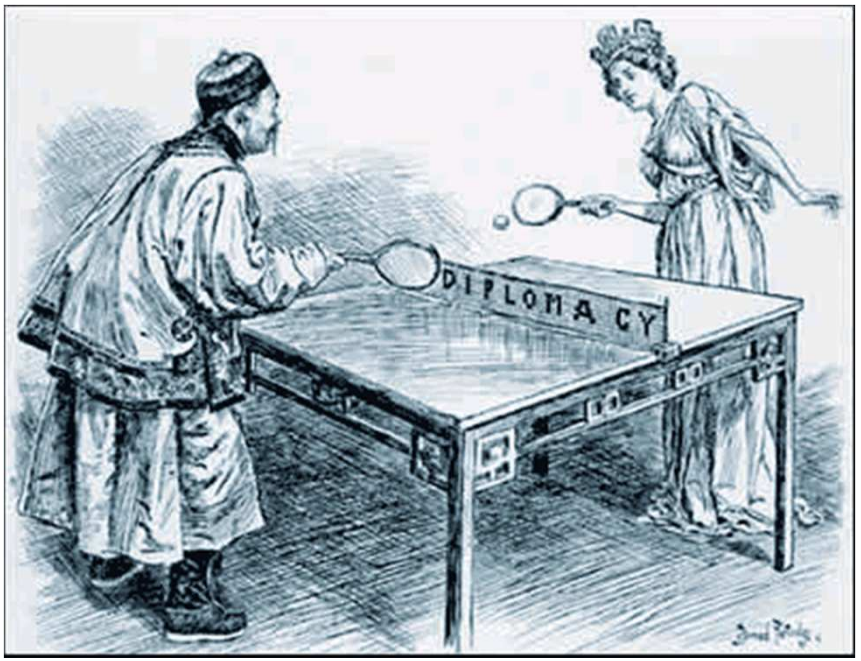
- Residual risk as a starting point: RAC to advise SEAC on the accuracy of the health or environmental impact assessment
  - Possible issues: Lack of data, inadequate models, uncertainties not described, assumptions not justified
- SEAC to evaluate 'benefits of authorisation' (i.e. "costs of not using the substance")
- Based on impacts and costs, SEAC forms its opinion – are applicant's conclusions valid?
  - Requires close cooperation between RAC and SEAC (in particular the Rapporteurs)

7. Conclusions

- Primary objective of RAC and SEAC:
  Consistent opinions of high scientific quality to support the desicion making of the European Commission

- Need a streamlined process (workload, deadlines, consistency)
- Cooperation between RAC-SEAC crucial -- remits are clear
- Committees evaluate and validate information provided by applicants and third parties

- Several opportunities for applicants to communicate with Committees – but



- Avoid ping-pong
- Very difficult to make applications 'complete' during opinion making!

Thank You!