

Evaluation of Applications by Committees

Seminar on Applications for Authorisation
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Outline

1. Roles of the Scientific Committees
 2. Opinion-making process
 3. Which endpoints to consider
 4. Remaining risk
 5. Evaluation of alternatives
 6. Cooperation between SEAC and RAC
 7. Conclusions
- Responses to questions

1.1 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**.



1.2 Committee for Risk Assessment (RAC)

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

An assessment of the

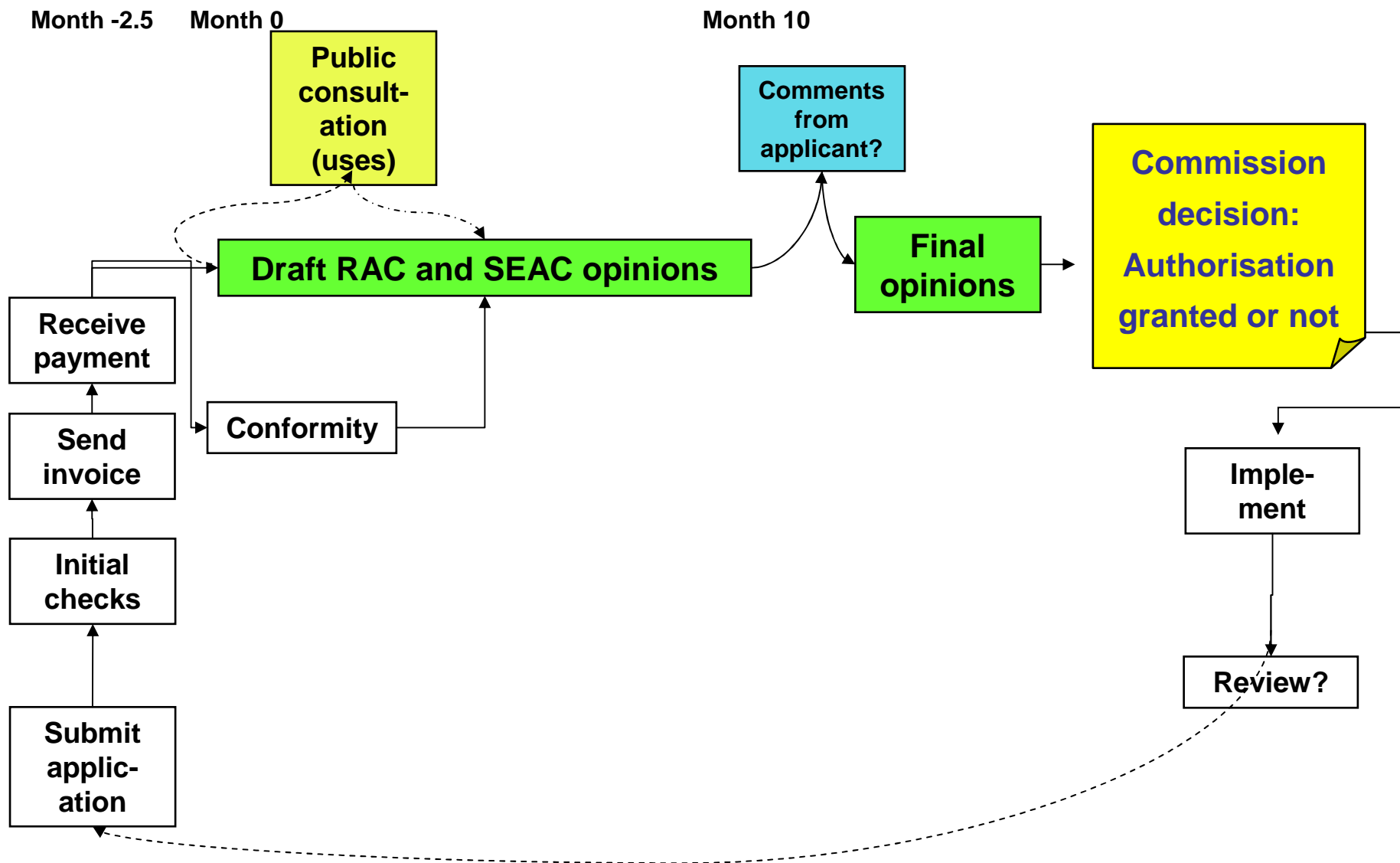
- **risk to human health** and/or the **environment** arising from the use(s) of the substance,
- including the **appropriateness** and **effectiveness** of the **risk management measures** and, if relevant,
- an assessment of the **risks** arising from possible **alternatives**.

1.3 Different opinions?

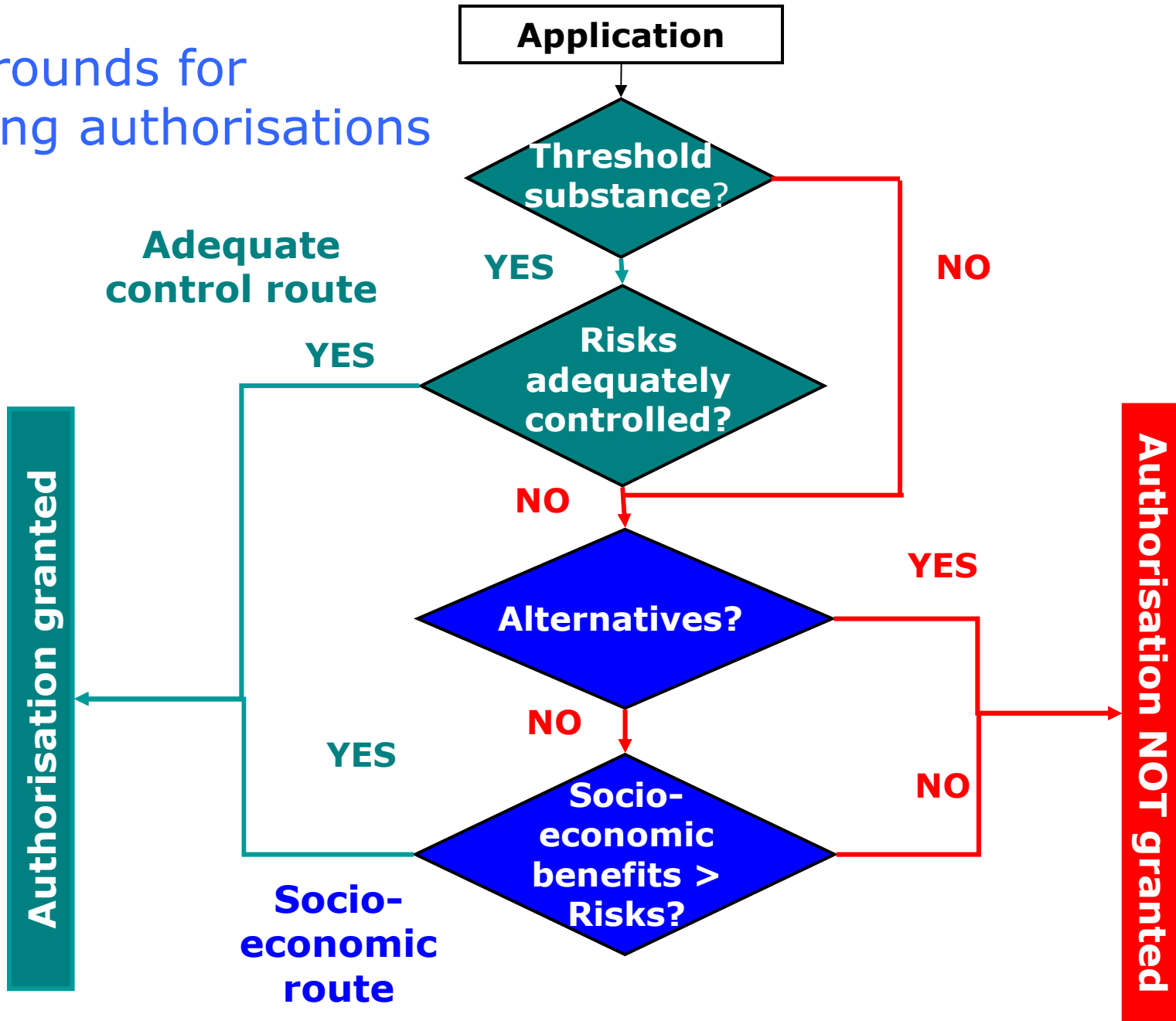
- Question: Is it possible for RAC and SEAC to have different/contradicting opinions?

No. The Committees remits are well defined (but cooperation is essential).

2.1 Opinion making process



2.2 Grounds for granting authorisations



2.3 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

2.4 Interaction between the Applicant and SEAC and RAC

- Applicant can comment on information given in the Public Consultation
- A “dialogue/hearing” held between applicant and rapporteurs (and third parties, if required)
- 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

3. RAC: Which endpoints to consider

- Questions: Which endpoints should be addressed?
Criteria for threshold substance?
- Decision criteria to grant authorisation:
 - Threshold (DNEL/PNEC) => Adequate control
 - Annex XIV properties only
 - Article 60(2)
 - No adequate control => Benefits outweigh risks
 - Focus on Annex XIV properties
 - Art 62(4)(d): CSR covers risks from Annex XIV properties
 - Suitable alternatives: all risks/endpoints

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

5.1 RAC and SEAC: Evaluation of alternatives

- If risks are adequately controlled:
 - Risks of alternatives evaluated in 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***

5.2 RAC and SEAC: Evaluation of alternatives – information from third party

- Question: How is information from third parties evaluated?
- Evaluated in similar fashion as the information from the applicant
 - If SEAC considers that the alternatives are technically **AND** economically feasible
 - Important for RAC to consider the risks

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 decision 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!