Evaluation of applications by Committees

Seminar on Applications for Authorisation

28 April, 2014

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ECHAs Committees

Independent Scientific Committees, members nominated by MS but appointed by the Board of ECHA in their individual capacity as scientists

- Committee for Risk Assessment (RAC, 42 members):
  - 130 CLH, 9 Restriction, 1 Authorisation opinions
- Committee for Socio-economic Analysis (SEAC, 32 members)
  - 9 Restriction, I Authorisation

Preparatory activities

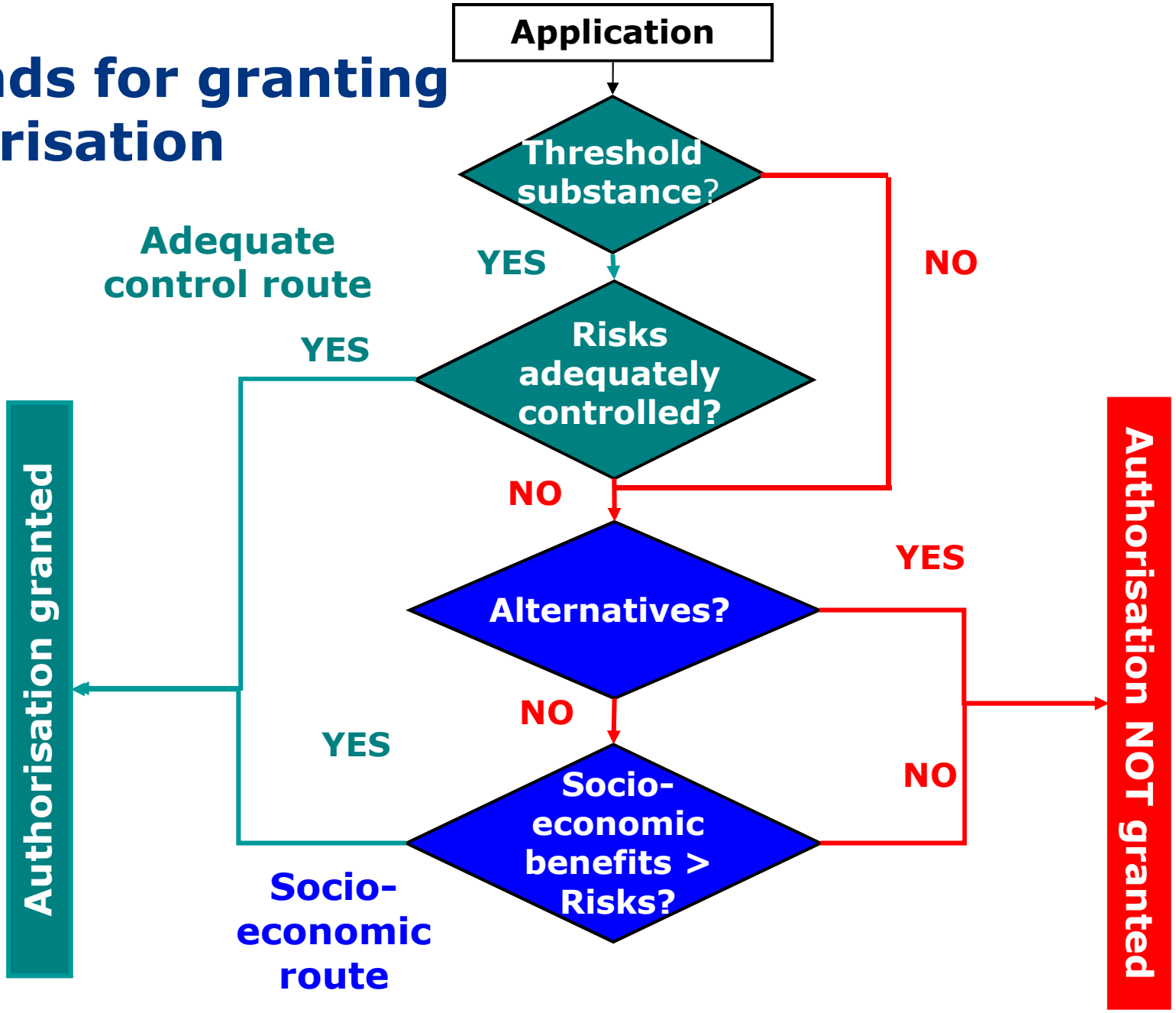
- RAC 20 / SEAC 14 (2012): ***Common approach*** of RAC and SEAC in opinion development on applications for authorisation - how RAC and SEAC evaluate applications

- RAC 21/ SEAC 15 (2012): Public information in the process – ***Broad Information on Uses*** (BIU)

- RAC 25 / SEAC 19 (2013): ***Length of the review period*** – case by case but Committee procedure provides a clear indication (short, 7 or 12 years).

- RAC 24 - ongoing: ***Reference DNELs*** for phthalates (DEHP, DBP, BBP) and dose-response relationships for hexavalent chromium, inorganic arsenic compounds and trichloroethylene published.

Grounds for granting authorisation



What do RAC and SEAC do with Applications for Authorisation?

RAC and SEAC decide on conformity

RAC recommends:

- on adequate control for threshold substances
- on whether the risks have been minimised for non-threshold substances

RAC advises SEAC:

- on any reason for shortening the review period from the standard, e.g. due to remaining risk concerns
- on additional conditions such as monitoring requirements

What do RAC and SEAC do with Applications for Authorisation?

SEAC evaluates:

- whether the use of the substance can continue after the sunset date as described by the applicant
- what would happen to the applicant and their DU's in socio-economic terms should the authorisation not be granted
- the technical and economic feasibility of the alternatives and their availibility
- the length of the review period

What do RAC and SEAC do with Applications for Authorisation?

The Committees provide a recommendation on:

- Granting or not granting the authorisation
- Should additional conditions and monitoring arrangements be applied?
- How long should the review period be?

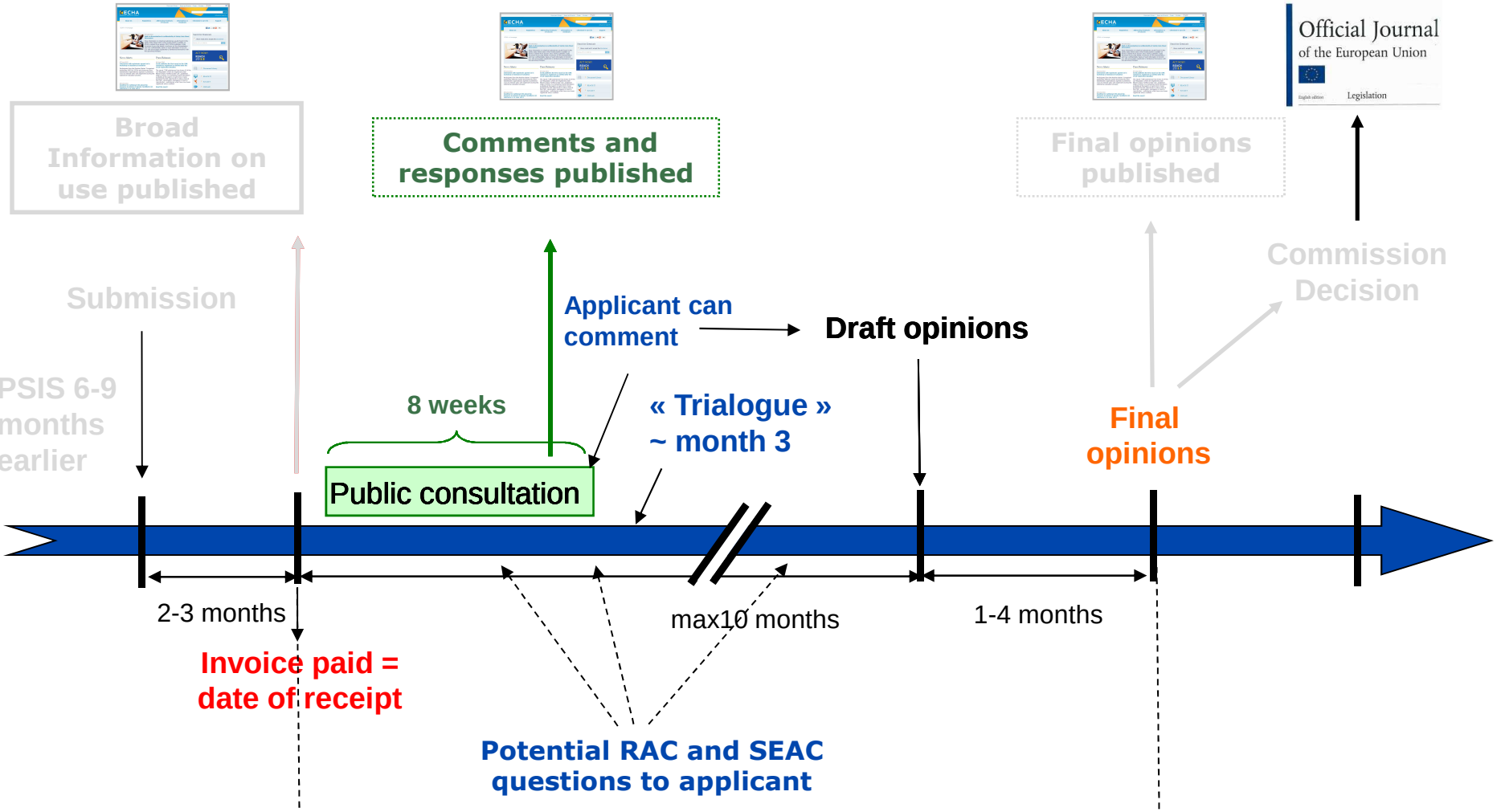
RAC and SEAC: From risk to impact to socio-economic assessment

- Residual risk as a starting point: RAC advises SEAC on the accuracy of the health or environmental impact assessment
  - Possible issues: lack of data, incorrect risk calculation, uncertainties not described, assumptions not justified
- SEAC to evaluate 'benefits of authorisation' (including "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)

Interaction between the Applicant and SEAC and RAC

- Applicant can comment on information given in the Public Consultation
  - Comments and responses posted on ECHA's website
- 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
- "Trialogue" held with rapporteurs
  - Applicants do not participate in the plenary meetings

Timeline: applicants' input during the opinion-making



Trialogue between the Applicant and the Rapporteurs

- Opportunity to discuss technical/scientific issues
- Input: application, information submitted through public consultation and questions from rapporteurs
- Stakeholder observers :
  - are invited to the Trialogue for transparency and information
  - excluded if confidential business information is discussed
  - can ask questions during a Q&A session
- Held about 4 weeks after close of public consultation
- Further info:

http://echa.europa.eu/documents/10162/13555/stakeholder_participation_in_afa_en.pdf

Experience with trialogues

- Useful opportunity to explain the case and discuss key aspects with the Rapporteurs preparing the opinion for RAC and SEAC
- Preceded by a set of questions from the Rapporteurs which provide the main points for discussion
- Open questions should be resolved at the trialogue – the dossier will go to Committee shortly afterwards
- It is not an opportunity for improving the dossier, this should already be of a high standard and ready for evaluation

Accredited stakeholders may (or may not) observe the deliberations of RAC and SEAC

- ECHA's Confidentiality Advisor advises the Chairmen as to whether cases, should be 'observed' or 'non-observed' by stakeholders
  - Based on information presented in a) the application, b) the public consultation and c) discussed during the Trialogue
- If discussions of CBI are likely to be 'unavoidable', that part of the case may be handled as 'non-observed'
  - A non-confidential briefing given
- Appropriate balance between transparency and confidentiality

Confidentiality issues

- Committee meetings are not public – members and stakeholders have all signed confidentiality agreements
- Meetings are held by default in 'observed' sessions, i.e. with stakeholders present, to ensure transparency. For SEAC, the need for 'non-observed' sessions may be more frequent
- Only if there is a need to discuss CBI will the sessions be switched briefly to 'non-observed'
- Balance is needed in confidentiality claims - large sections marked 'confidential' slow down the process severely
- Be careful what you agree to in letters of access to CSR's!

Efficiency in processing AfA will be key

- Many more applications to follow
- Tight deadlines mean that effective decision-making is essential
- Committees will focus on key elements, no time to unravel poorly prepared submissions or interpret unclear statements
- Cases should therefore be clearly and concisely presented

Some important tips to applicants

- Be clear in your descriptions of industrial processes
  - Committee members, evaluating the applications, need to be able to visualise and understand your industrial processes
  - Explain how you do things in your workplace in a way which is understandable to outsiders
  - Include pictures, diagrams, etc.; avoid jargon and abbreviations
- Exposure scenarios: describe for each the conditions of use, the assumptions underlying the calculations and the RMMs in place
- If using models, try and corroborate with biomonitoring and/or air monitoring and visa versa
  - surrogate data on related chemicals measured in the same workplace could be useful

Some important tips to applicants (contd.)

- Some applications are prepared jointly but if submitted separately…….

  ➔ Indicate clearly which information is common and which sections are applicant-specific

- Do not repeat yourself several times in the same document or among the various documents

  Do not dilute a strong message in a long, wordy or repetitive way

- Think twice when claiming information "confidential" – see next slide…….

Conclusions

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

- Committees evaluate and validate information provided by applicants and third parties

- Need a streamlined process (workload, deadlines, consistency)

- Cooperation between RAC-SEAC crucial - remits are clear

- Several opportunities for applicants to communicate with Committees (in particular the Trialogue)

Describe the workplace exposures and the existing RMMs accurately

Where possible, corroborate the risk assessment (modelled and measured)!

Applications should be complete and of a high standard; they will be evaluated as we find them

Thank You!

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More information:
http://echa.europa.eu/web/applying-for-authorisation