# Evaluation of Applications for Authorisation by RAC and SEAC

**Seminar on applications for authorisation**
**18 – 19 April 2017**

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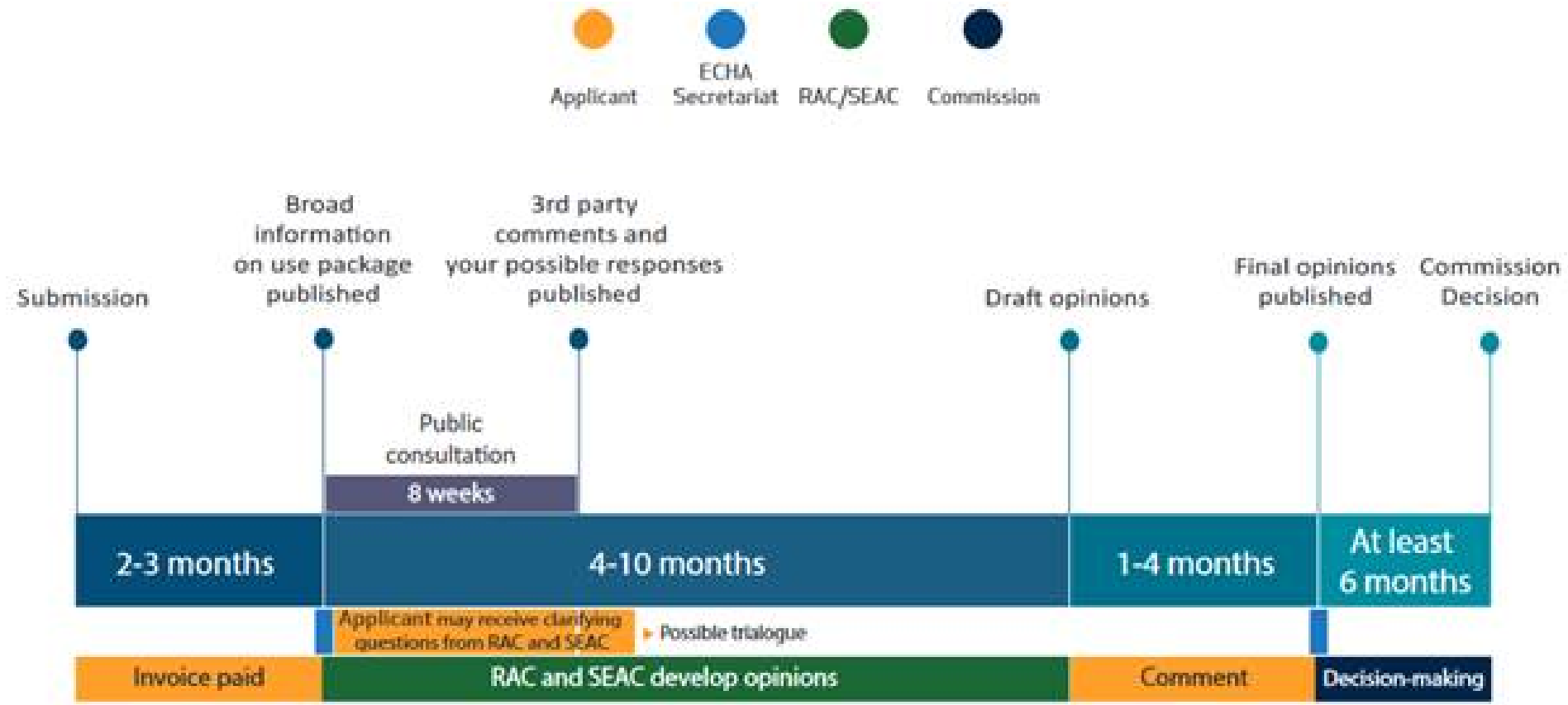
# Overview: opinion development



# Opportunities for the applicant to engage with ECHA and the Committees

- Pre-submission Information Session at ECHA
- Rapporteurs from both Committees ask for written clarifications of issues
  - 1-2 rounds of questions
- Trialogue meeting between applicant(s), rapporteurs and third parties to clarify details:
  - Can cover any aspect of an application
  - Information from the public consultation – especially with regard to alternatives
  - Not always needed

# Committee roles: RAC

**RAC evaluates AfAs the basis of:**

- Risks posed by the use (and the alternatives), including the hazard(s) and exposures
- Appropriateness and effectiveness of risk management measures (RMM) in place
- Adequate control or minimisation of risks (non-threshold)

**RAC may recommend:**

- Additional conditions and monitoring arrangements - linked to the uncertainties
  - Related to appropriateness of OCs and RMMs
  - Related to monitoring

**RAC communicates:** its concerns regarding the uncertainties and the control of risk to SEAC and the European Commission

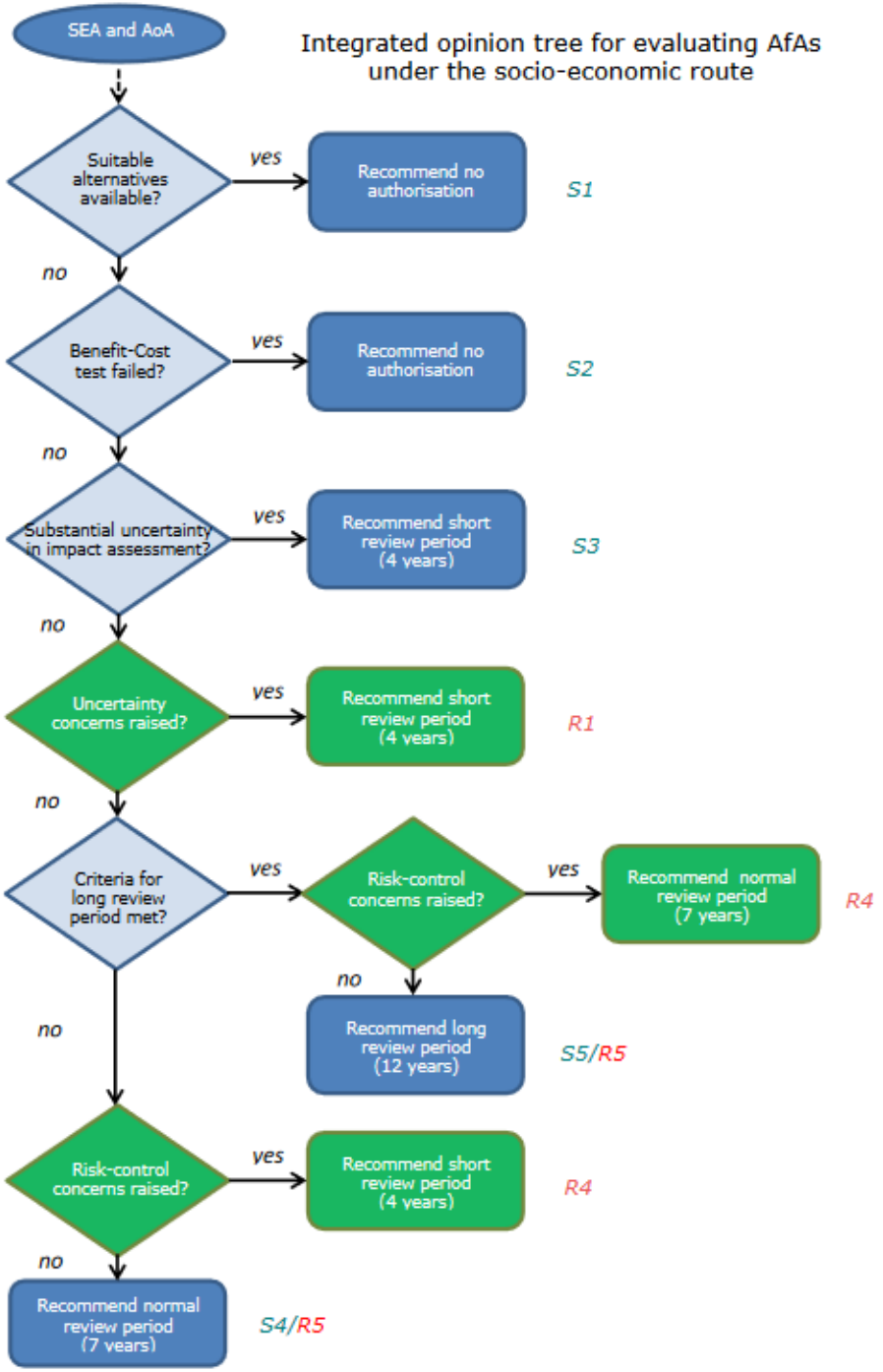
# Committee roles: SEAC

**SEAC evaluates AfAs on the basis of:**

- Whether the applicant's assessment of risks and benefits of continued use is plausible
- Technical and economic feasibility, and availability of alternatives
- Comments from the Public Consultation (main purpose is to gather information on alternatives)
- Evidence presented for justifying the length of the time-limited review period

- **SEAC may recommend additional conditions**
  - related to the progress of substitution

# Opinion tree for evaluating AfA's under SEA route:



# RAC perspective

# RAC evaluates: the process(es) and the respective RMMs

- Exposure through all relevant routes and to relevant populations and compartments, e.g. inhalation, dermal, workers, exposure to and via environment
- The frequency, duration and overall sequence of activities / tasks
- Potential for shift-long, combined, exposure
- Situations where the usual RMMs may not work (e.g. maintenance, cleaning, sampling…)

*Descriptions, diagrams, photographs & videos – helpful*

# RAC evaluates: Operating Conditions & Risk Management Measures - 1

## Minimisation of exposure is the aim!

## Engineering controls

- Use of closed (and automated) systems:
  - not always substantiated - based on monitoring results
  - do manual tasks with potential for exposure still occur ?
- General and Local Exhaust Ventilation (LEV):
  - e.g. location, effectiveness, maintenance, exhaust treatment
- Separation/containment:
  - is it sufficient or is additional ventilation needed (to prevent escape of the contaminant to other work areas or offices )

# RAC evaluates: Operating Conditions & Risk Management Measures - 2

- **Administrative and organisation controls**
  - Training, maintenance, supervision, access restriction, hygiene
  - Theory vs practice: individual work practices can significantly affect resulting exposure (~2 orders magnitude difference)
- **Use of Personal Protective Equipment (PPE)**
  - Justification for the selection of specific PPE – mask and filter type / glove type
  - Routine use vs last resort (hierarchy of control?)
  - Is there over-reliance on high-efficiency PPE equipment (is it feasible to work in for long stretches and is it effective?)
  - Is PPE properly maintained and replaced as necessary?

# RAC evaluates: Exposure assessment

- Exposure measurements (preferred)
  - Contextual information: LOD/LOQ, number of samples, duration of sampling, task performed during sampling, static or personal, uncertainty (mean vs 90$^{th}$ percentile)
- Exposure modelling – on its own or with monitoring
  - Input parameters indicated?
  - Is there an overreliance on Tier I (screening) models?
- Biomonitoring data (useful where an appropriate method is available)

# DNELs / Dose-response relationships

- RAC will continue to derive DNELs/dose-response relationships for Annex XIV substances
  - Exception: endocrine disrupting substances
- ECHA aims to publish them at least 12 months before the latest application date
- Coal Tar Pitch and Anthracene Oil
  - Dose-response relationship for carcinogenicity to be published by the end of 2017

# Endocrine disrupting substances

- It is unlikely that RAC will establish in advance:
  - if a threshold exists or not
  - what dose-response relationship should apply in an evaluation

- It is up to the applicant to consider:
  - If a threshold exists - **see COM(2016)814, p.5**
  - If a dose-response relationship can be derived

- In any case RAC will assess to what extent the RMMs and OCs have minimised the risk

# SEAC perspective

# What SEAC looks at: Analysis of Alternatives

- Identification of alternative substances and technologies
  - How is the short-list of alternatives derived?
  - Could the function of Annex XIV substance be replaced?
  - Why can some ”sub-uses” be substituted while others cannot?
- Assessment of alternatives
  - Are time and resources to transition to an alternative sufficiently well justified?
  - Are commercially available alternatives included in the analysis?
- Is the AoA used as basis for defining the non-use scenario in the SEA?

# What SEAC looks at: Non-use scenario

- Is the non-use scenario credible?
  - "Shut-down" or "complete relocation" should be analytically supportable
  - Is there a discussion of the applicant's options – what would be the impacts of changing to an alternative?
- Is the focus on net costs?
  - If an operation is closed down, are the savings included, too
  - An alternative could be more expensive but result in some gains (e.g. quality of the end product or reduced energy consumption)
  - Do not double counting of costs along the supply chain
- Is unemployment properly addressed?
  - The freed up labour cost can be spent on other economic activities.
  - Unemployed in non-use scenario is not permanent (empirics: about 2 years)
- Loss of revenue or profits?
  - Loss of revenue exaggerates socio-economic impact
  - Change in profits is more appropriate

# What SEAC looks at: Socio-economic impacts

- Are the impacts analysed also from society's point of view?
  - The use of a substance might be critical to one company, but its suppliers, customers or competitors might easily do without it
  - Lost revenue of someone in the supply chain may be compensated by increased revenue of those supplying or using the alternatives
- Are assumptions and uncertainties recognised?
  - Uncertainty does not in itself invalidate the conclusions but they need to be described and, where possible, minimised
  - An uncertainty analysis tests whether different assumptions or estimates could affect the conclusions and, if so, how significant this effect may be.
- Is the review period well justified?
  - SEAC looks at every application with the "review process" firmly in mind
  - Linked to availability of alternatives and timeline for substitution
  - Recommend a short review period where there are significant uncertainties in CSR, AoA or SEA

# What SEAC looks at: health impacts

- Non-threshold substances with dose-response relationship:
  - Carcinogens: value of statistical life (VSL), value of statistical cancer case (VSCC)
  - Other health impacts as relevant, see SEAC's reference WTP catalogue
- Threshold substances: break-even analysis if risk not adequately controlled
  - Logic: how many cases would need to be observed AND the benefits would still outweigh the risks?
- PBTs/vPvBs: cost-effectiveness of emission abatement
  - Similar approach for endocrine disrupters?

# How RAC & SEAC conclude on a case?

# How the committees derive review periods

- RAC assesses the risks and the uncertainties in the CSR. To a large extent, RAC's message to SEAC is based on the uncertainties
- SEAC accounts for the uncertainties highlighted by RAC and those from the SEA and AoA in their opinion, mainly in the recommendation on the length of the review period.
- The **normal** review period is **7 years**
- Large uncertainties in the AfA generally lead RAC and SEAC to recommend strict conditions and/or short(er) review period (see also opinion tree). Too large uncertainties are likely to undermine the granting of the authorisation.
- Less uncertainty combined with a clear motivation can lead to a long review period
- See SEAC review period paper

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