



# **ECHA's Committees' Readiness**

*Seminar on applications for authorisation  
12 April 2011*

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# Outline

1. Role of ECHA's scientific Committees
2. The opinion and the opinion-making process
3. Preparations in place

# Roles of RAC and SEAC in the authorisation process

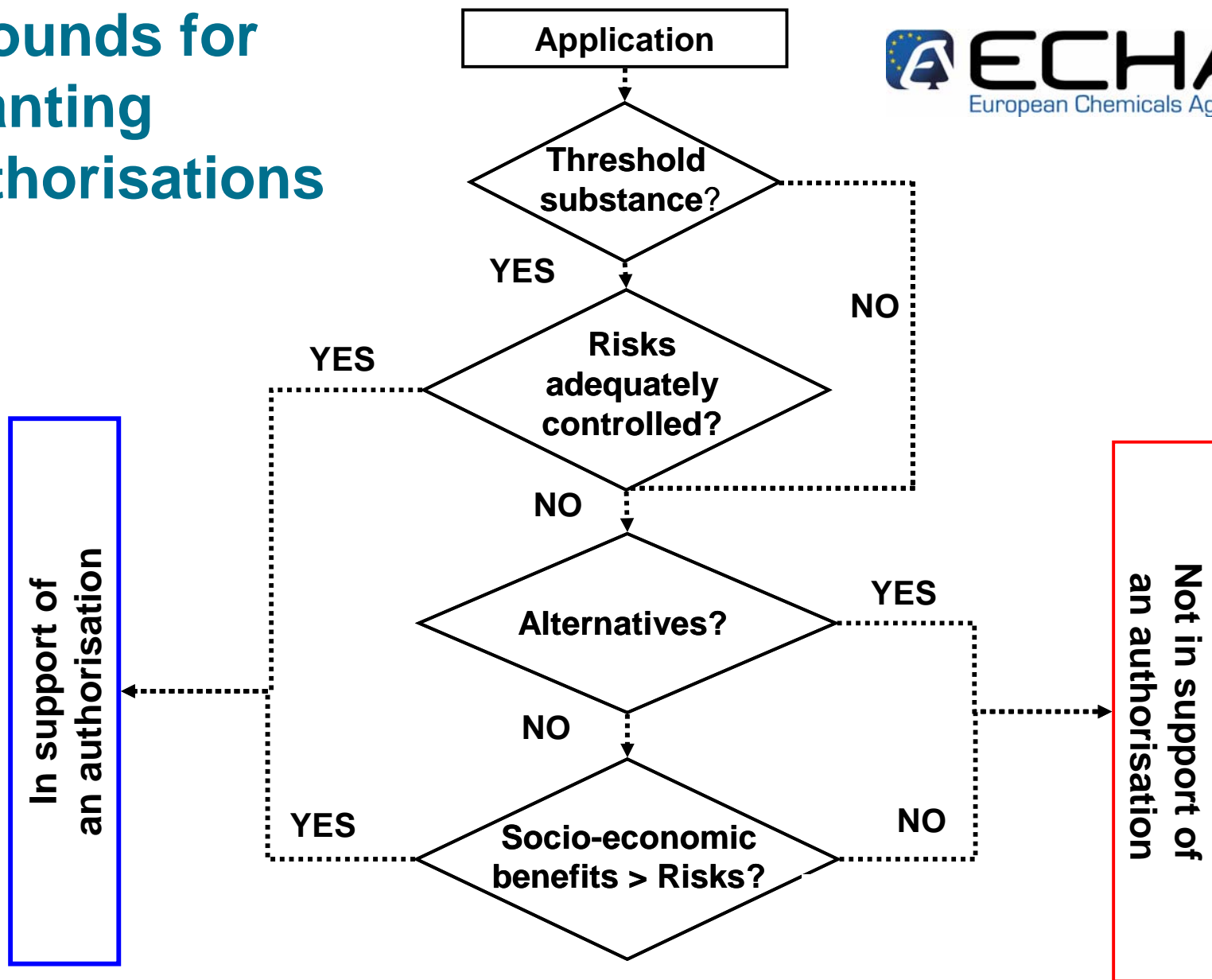
Article 64(4) specifies that the draft opinions shall include the following elements:

- Committee for Risk Assessment (RAC):
  - 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**;
- Committee for Socio-economic Analysis (SEAC):
  - An assessment of the **socio-economic factors** and the **availability, suitability** and **technical feasibility** of **alternatives**

# The opinions of RAC and SEAC

- The opinions are focussed on giving advice on
  - whether the argumentation is robust
  - whether, after an assessment of all information, the applicant's application for authorisation seems justifiable
  - possible conditions and monitoring arrangements as well as the duration of the review period.
- Use one format for opinions and their grounds
- The grounds will contain detailed justification/reason
  - for the opinions of both RAC and SEAC.
- Opinions to be prepared in close cooperation between RAC and SEAC (coordinated through rapporteurs' dialogues)

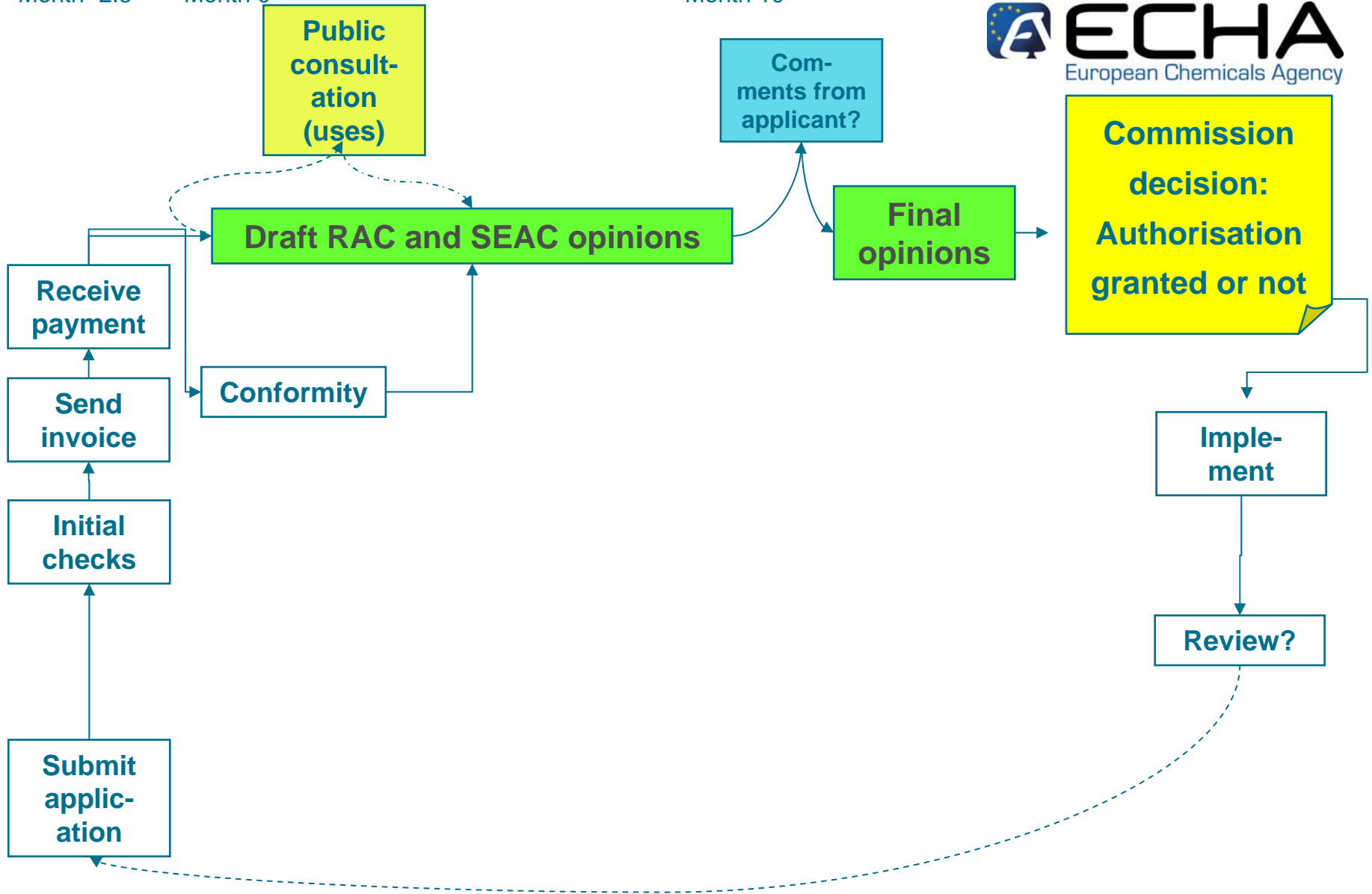
# Grounds for granting authorisations



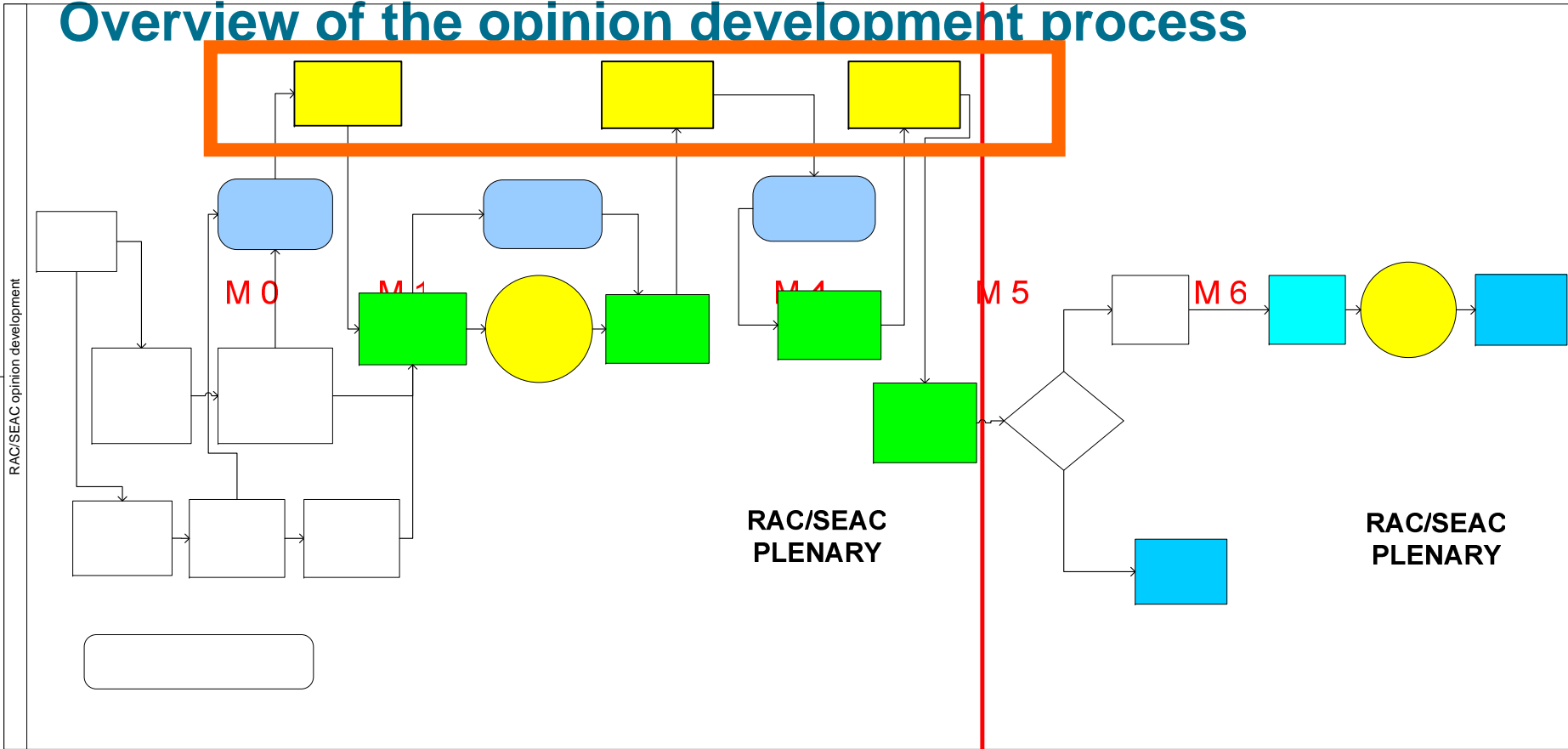
Month -2.5

Month 0

Month 10



# Overview of the opinion development process



Application received

1st Rapps dialogue

2nd Rapps dialogue

# Preparations

- In-depth discussions on the principles for the Committees' work with applications for authorisations
- Working procedures and templates
  - Conformity check working procedure & template to document outcome (agreed)
  - Working procedure for opinion-making (agreed) & format of the opinion (almost finalised)
  - Working procedure for appointment of rapporteurs (agreed)



# Main challenges

- Very tight timelines for the Committees' opinion-making
- Information has to be available early in the process
- Committees' workload will be closely monitored - working methods modified as needed

Thank you!