European Commission
Enterprise and Industry Directorate-General

European Commission workshop on RIP 3 - Development of REACH Guidance for Industry

Brussels, 25 September 2006

Authorisation procedure: From identification of substances to decision making

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AUTHORISATION

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- Background
- Phases in authorisation procedure
  - How they work
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AIM of authorisation

Ensure the good functioning of the internal market while assuring that risks from substances of very high concern are properly controlled and that these substances are eventually substituted where economically and technically viable

Authorisation
- basics

- Substances included in Annex XIV are subject to authorisation
- Continued use of a substance included in Annex XIV to REACH requires that after the sunset date the use has been authorised
- Authorisations are granted for specific uses of a substance
- A downstream user may use a substance if an authorisation is granted to an actor up his supply chain for that use

Authorisation - basics

Exemptions

- **General exemptions**
  - **Art 2(5) (e.g., uses in food)**
  - **Art 2(8)(b) (uses as intermediates)**
  - **Art 55(3)-(6) (e.g., uses in biocides)**

- **Use specific exemption (included in Annex XIV)**
  - **Existing specific Community legislation already require proper control of risks related to uses or categories of uses**
  - **Whether product and process oriented research and development (PPORD) requires authorisation**

Overview of authorisation procedure (1)

- **Step 1**

  Inclusion of substances in the list of substances subject to authorisation (Annex XIV)

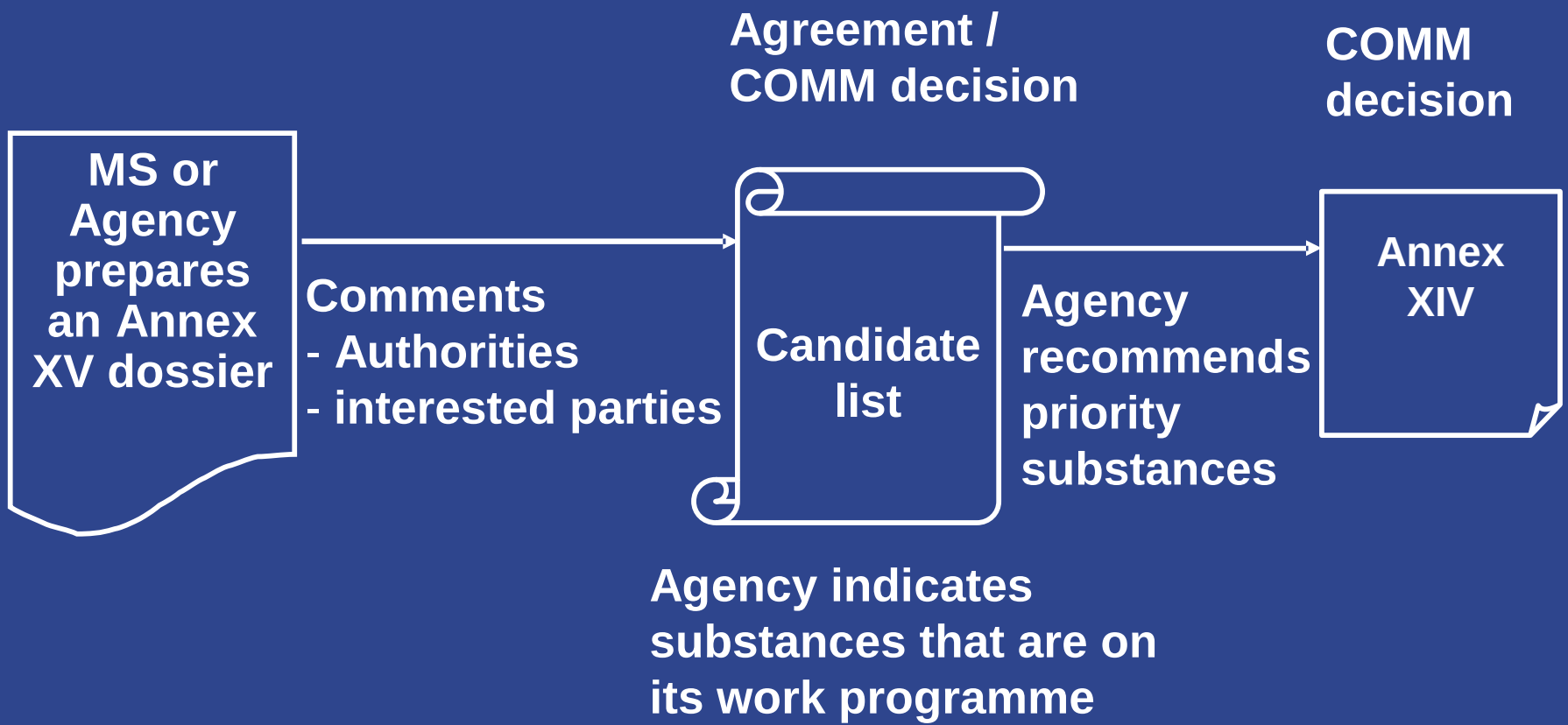
- **Step 2**

  Granting the authorisation

Overview of authorisation procedure (2)

Step 1 –

Inclusion of substances in the list of substances subject to authorisation (Annex XIV)



Authorisation procedure – (3)

Step 2-

Granting the authorisation

Phases of the authorisation procedure

- **Identification of substances for the candidate list (Art 58)**
- Prioritisation of substances
- Inclusion of substances on annex XIV
- Application for authorisation
- Granting of authorisation
- Review of authorisation

Substances of very high concern (SVHC)

Substances that may be included in Annex XIV

- **CMR substances (cat 1 and 2)**

  Carcinogenic, mutagenic and toxic for reproduction substances meeting the criteria for classification in category 1 and 2

- **PBT and vPvB substances**

  Persistent, bioaccumulative and toxic substances and very persistent and very bioaccumulative substances in accordance with criteria in Annex XIII

- **Substances of equivalent concern with scientific evidence of probable serious effects**

A proposal for the identification - Annex XV dossier

Who

- A Member State or the Agency on a request from the Commission prepares

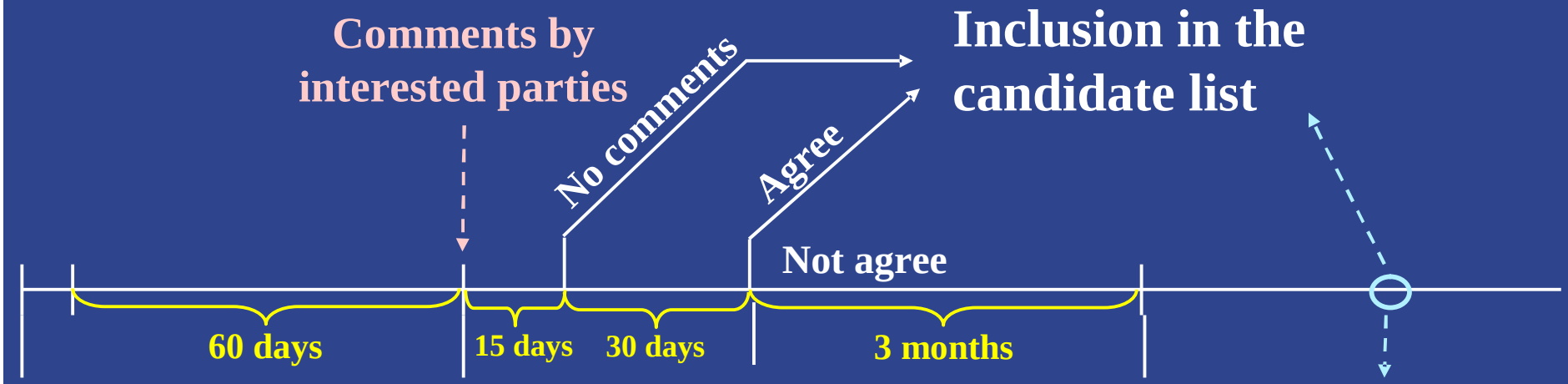
What

- Proposal, incl. identity of the substance
- Justification that the substance is a SVHC
- Information on exposures, alternative substances and risks

Draft guidance for authorities on preparing proposals

- RIP 4.4 (finalised)

Inclusion in the candidate list



Agency and the Commission

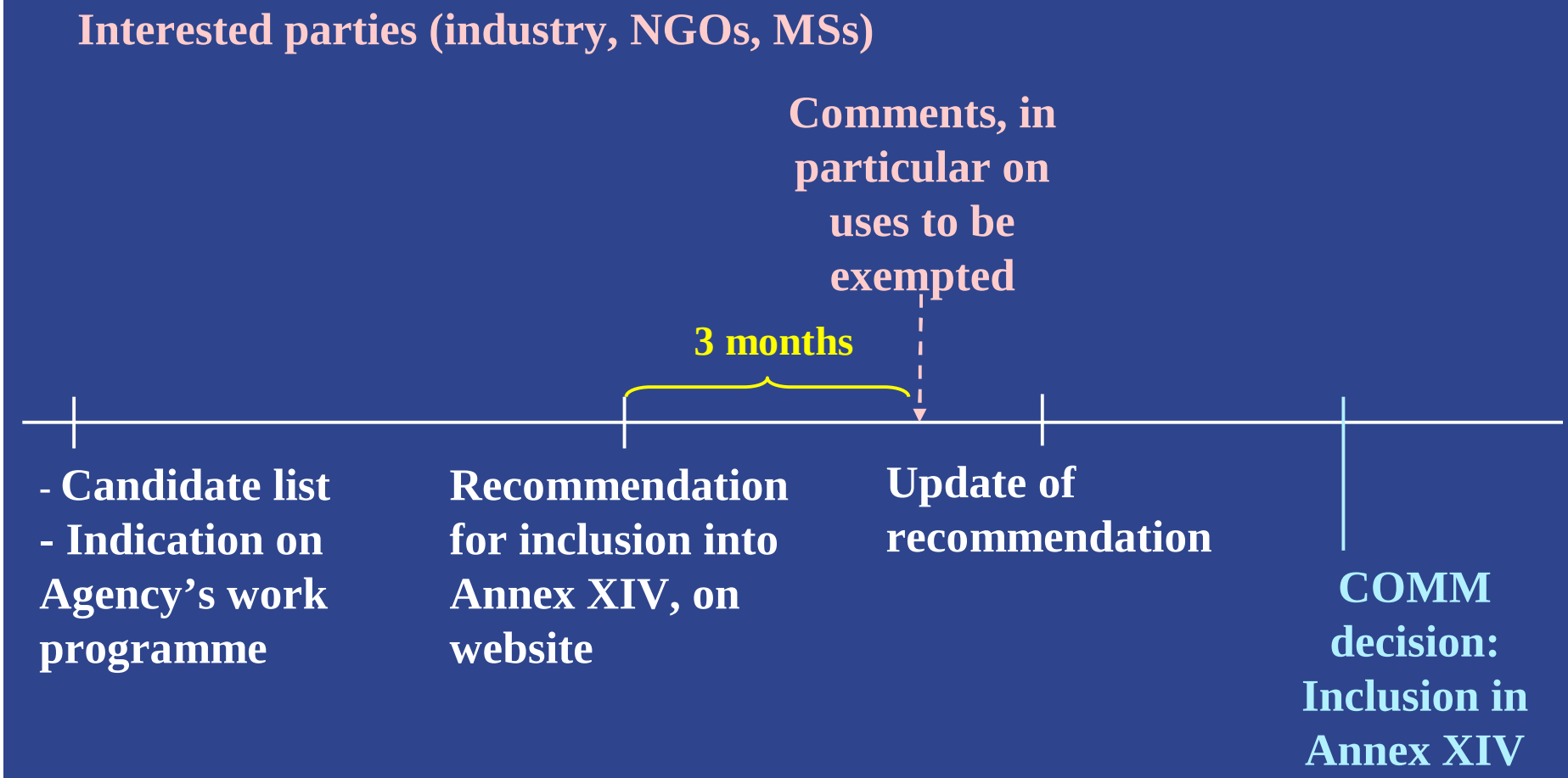
Phases of the authorisation procedure

- Identification of substances for the candidate list
- **Prioritisation of substances**
- **Inclusion of substances on annex XIV (Art 57)**
- Application for authorisation
- Granting of authorisation
- Review of authorisation

Prioiritisation of substances to Annex XIV

- **Priority is given to substances on the candidate list with**
  - **PBT or vPvB properties**
  - **wide dispersive use; or**
  - **high volumes**
- **Timetable**
  - **the first recommendation by the Agency at the latest 2 years after entry into force,**
  - **further recommendations at least every second year**
- **Guidance**
  - **Priority setting methods are developed in RIP 4.3/4.5**
  - **Guidance for authorities on inclusion of the substances in Annex XIV in RIP4.3**
  - **Available in spring 2007**

Inclusion of substances in Annex XIV



Entries in Annex XIV

- The identity of the substance
- Identified property: Why in the Annex (PBT, vPvB, C cat 1…)
- Sunset date(s)
- Application date(s) – at least 18 months before the sunset date
- Review periods for certain uses, if appropriate
- Uses or categories of uses exempted
  - Community legislation already ensures proper control of risks
  - May contain conditions

Phases of the authorisation procedure

- Identification of substances for the candidate list
- Prioritisation of substances
- Inclusion of substances on annex XIV
- **Application for authorisation (Art 61)**
- Granting of authorisation
- Review of authorisation

Autorisation application

Who

- manufacturer(s), importer(s) and/or downstream user(s)

For what

- Several substances
- Several uses
- Applicant’s own uses, his downstream actors’ uses

When and where

- Needs to be submitted to the Agency by the application date defined in Annex XIV

Authorisation application - content (1)

- An authorisation application has to specify the applicant(s) and the substance(s) and use(s) applied for, and include
  - A Chemical Safety Report covering the risks arising from the intrinsic properties specified in Annex XIV
  - An analysis of alternatives considering
    - risks
    - technical and economical feasibility
    - NB alternatives may be alternative substances or technologies

Autorisation application - content (2)

- An authorisation application may include
  - A socio-economic analysis
  - A substitution plan
  - A justification for not considering risks covered by
    - IPPC permit
    - Prior regulation under Water Framework Directive (point sources)

Authorisation application - guidance

RIP 3.7

- Draft guidance for industry on developing an authorisation application
  - Start in autumn 2007
  - Finalisation in autumn 2007

RIP 3.2

- Methodology guidance to develop a CSR (also) for an authorisation application
  - Scoping study finalised in July 2005
  - Final draft TGD: Ongoing, finalisation in June 2007

RIP 3.9

- Methodology guidance to develop a SEA (also) for authorisation application
  - Scoping study finalised in May 2006
  - Final draft TGD: Start in autumn 2006, finalisation in autumn 2007

Phases of the authorisation procedure

- Identification of substances for the candidate list
- Prioritisation of substances
- Inclusion of substances on annex XIV
- Application for authorisation
- **Granting of authorisation (art 59)**
- Review of authorisation

Granting the authorisation

The Commission shall grant an authorisation if

- **Risks are adequately controlled**
- **N.B: not applicable for PBTs, vPvBs and non-threshold CMs**

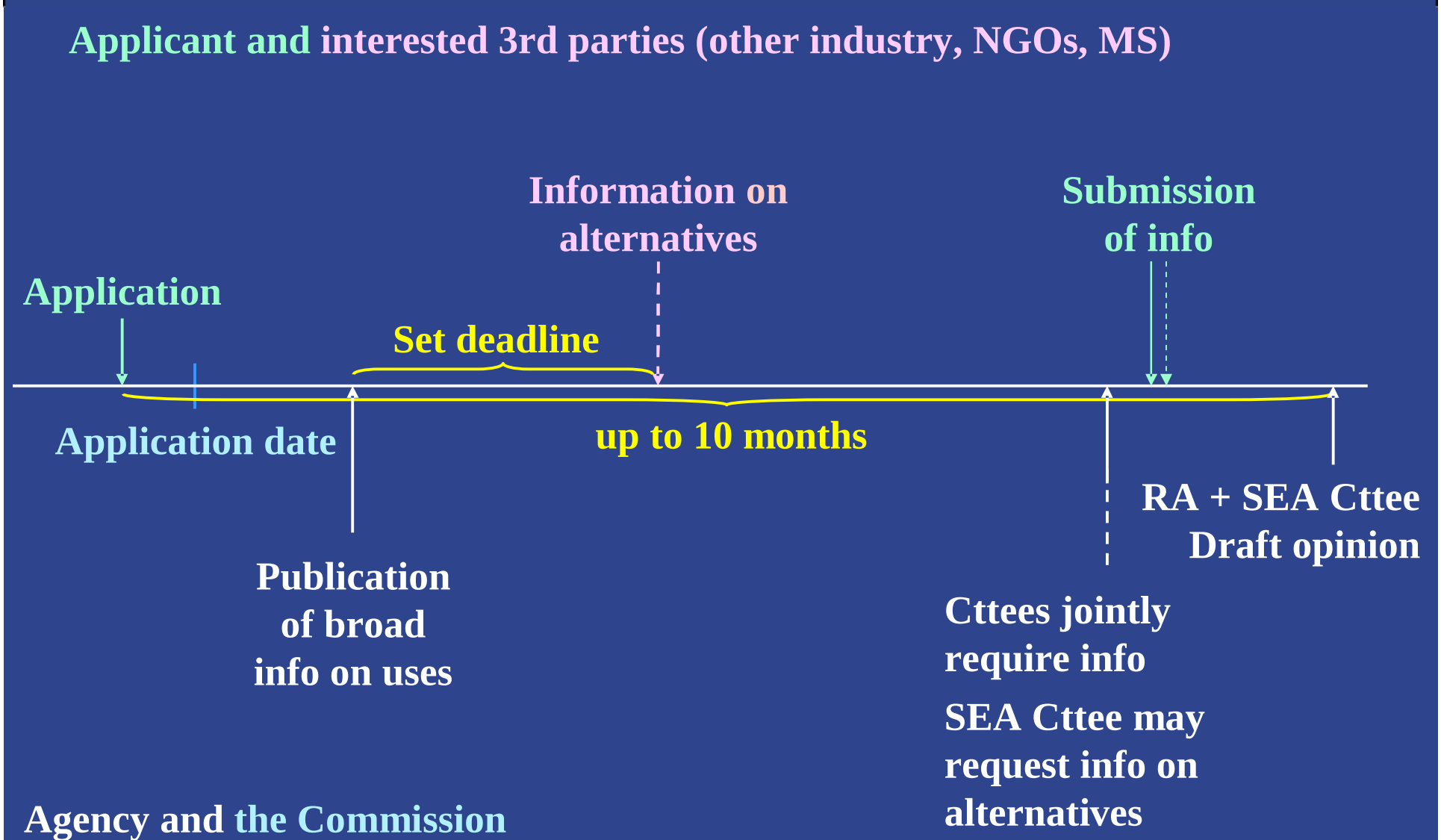
The Commission may grant an authorisation if

- **Socio-economic benefits outweigh the risks**
- **There are no technically and economically viable alternatives**

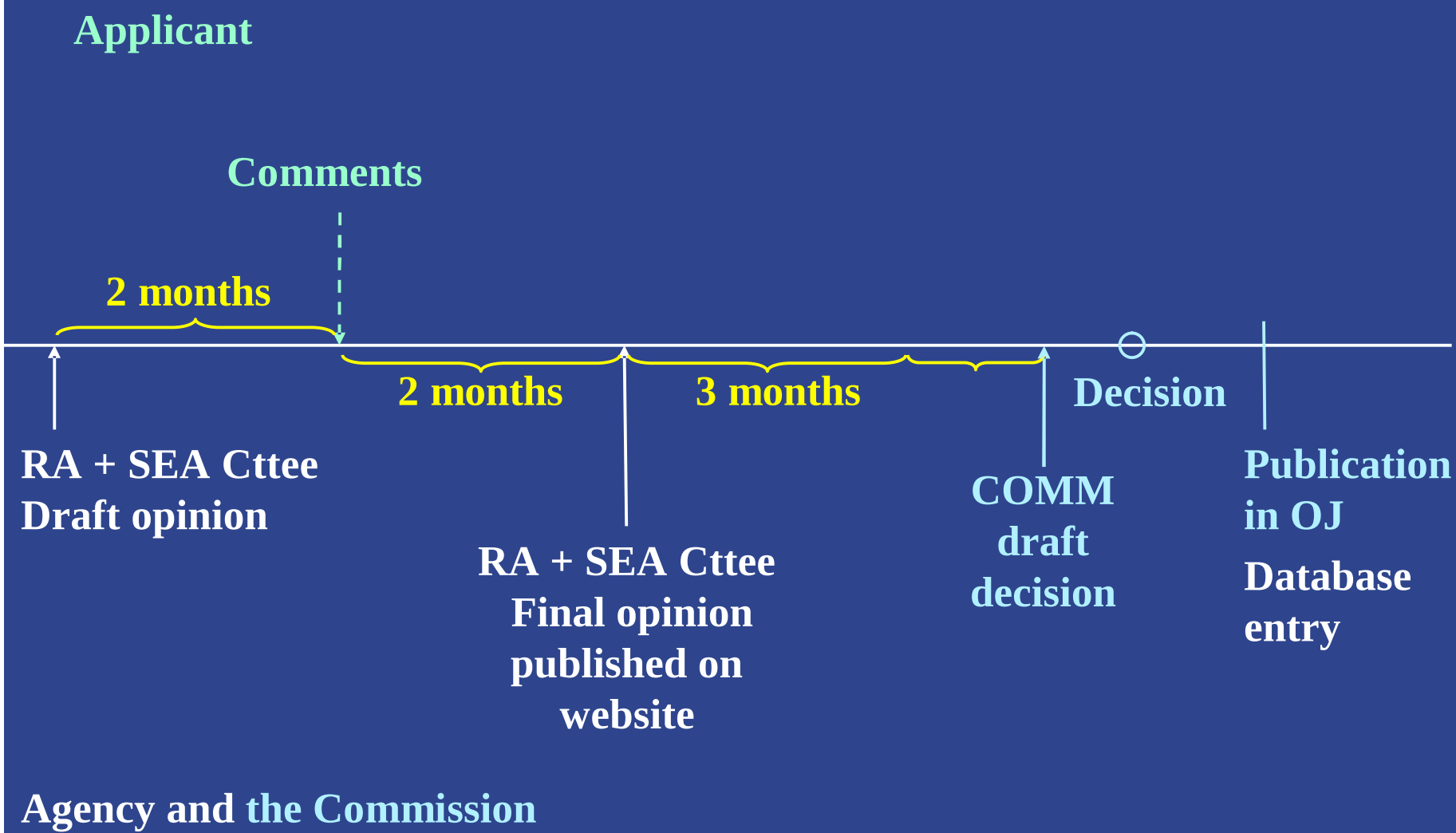
Authorisation decision

- Person(s) to whom granted
- Identity of substance(s)
- The use(s) for which granted
- Any conditions
- The time-limited review period
- Any monitoring arrangements

Authorisation Procedure



Authorisation Procedure (cont.)



Phases of the authorisation procedure

- Identification of substances for the candidate list
- Prioritisation of substances
- Inclusion of substances on annex XIV
- Application for authorisation
- Granting of authorisation
- **Review of authorisation (Art 60)**

Review of authorisation

- Holder of the authorisation to submit a review report at the latest 18 months before the expiry of the review period set in the authorisation decision

May be reviewed at any time if

- Changes that affect the risk or the socio-economic impact
- New information on alternatives
- Environmental quality standards are not met

Conclusions

- Apply to identified and prioritised substances of very high concern
- Time to prepare: Knowledge on substances that may be subject to authorisation available well in advance
- Several phases where industry may provide comments
- Possibilities to prepare one application for several uses, several substances or a combination of those
- Guidance will be available