



Authorisation under REACH

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 - The Agency's work programme
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 - Inclusion of substances into Annex XIV
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 - Application
 - Granting
 - Review

1. Introduction

Objective of authorisation:

- ↪ Ensure the good functioning of the internal market
- ↪ Assure that risks arising from SVHCs are properly controlled
- ↪ Eventually substitute SVHCs where economically and technically viable

1. Introduction

Basics:

- ↪ Substances included in Annex XIV are subjected 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

1. Introduction

Before preparing an Annex XV dossier proposing identification of a substance as a SVHC:

Is authorisation the most appropriate instrument to control the risks to human health or the environment?

- Take into account the scope of and exemptions from authorisation
- Other instruments to be considered
 - Restriction under REACH, take into account
 - a streamlined procedure for restrictions of consumer uses of Cat 1 & 2 CMRs
 - no new restrictions related to SVHC properties after inclusion in Annex XIV
 - Other legislation

1. Introduction

Step 1: Inclusion of substances in the list of substances subject to authorisation (Annex XIV)

- Establishment of the candidate list
- The Agency's work programme
- Prioritisation of substances from the candidate list
- Inclusion of substances into Annex XIV

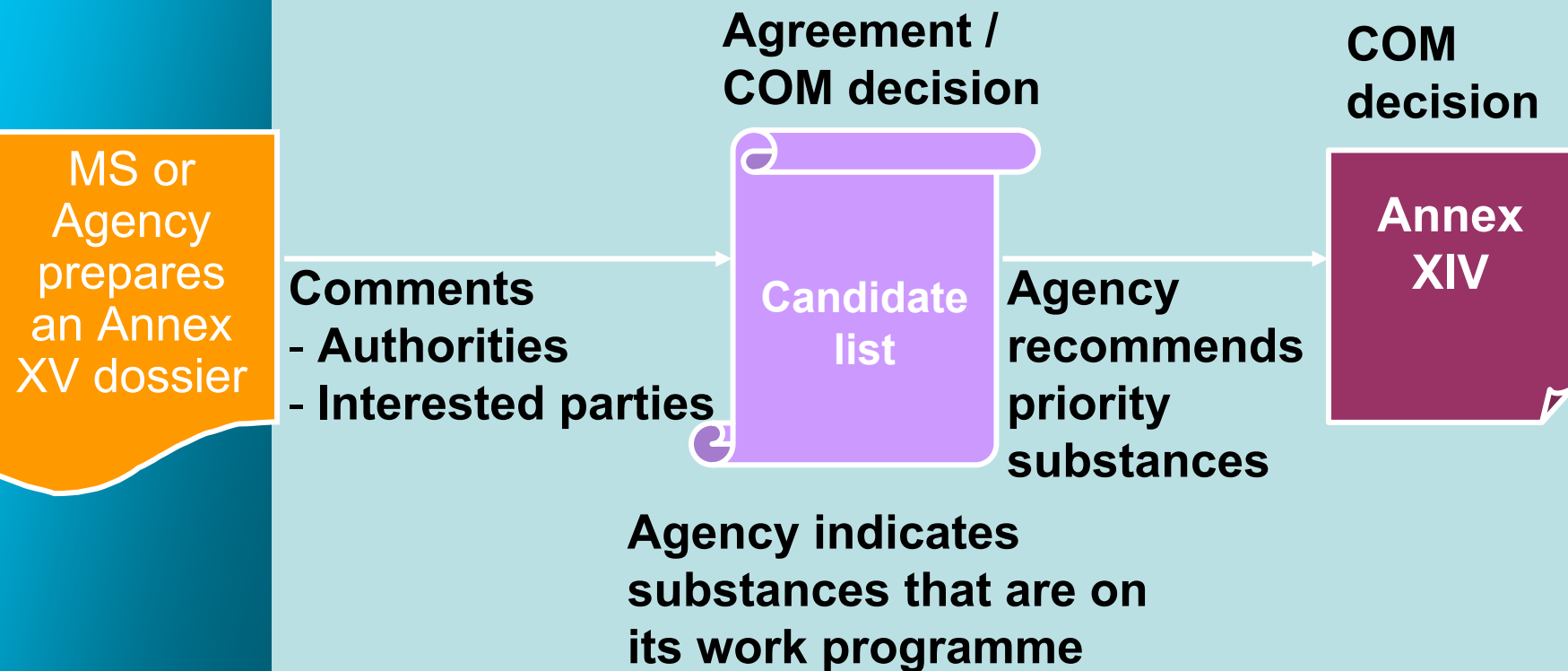
Step 2: Granting the authorisation

- Application for authorisation
- Granting the authorisation
- Reviewing the authorisation

1. Introduction

Step 1 –

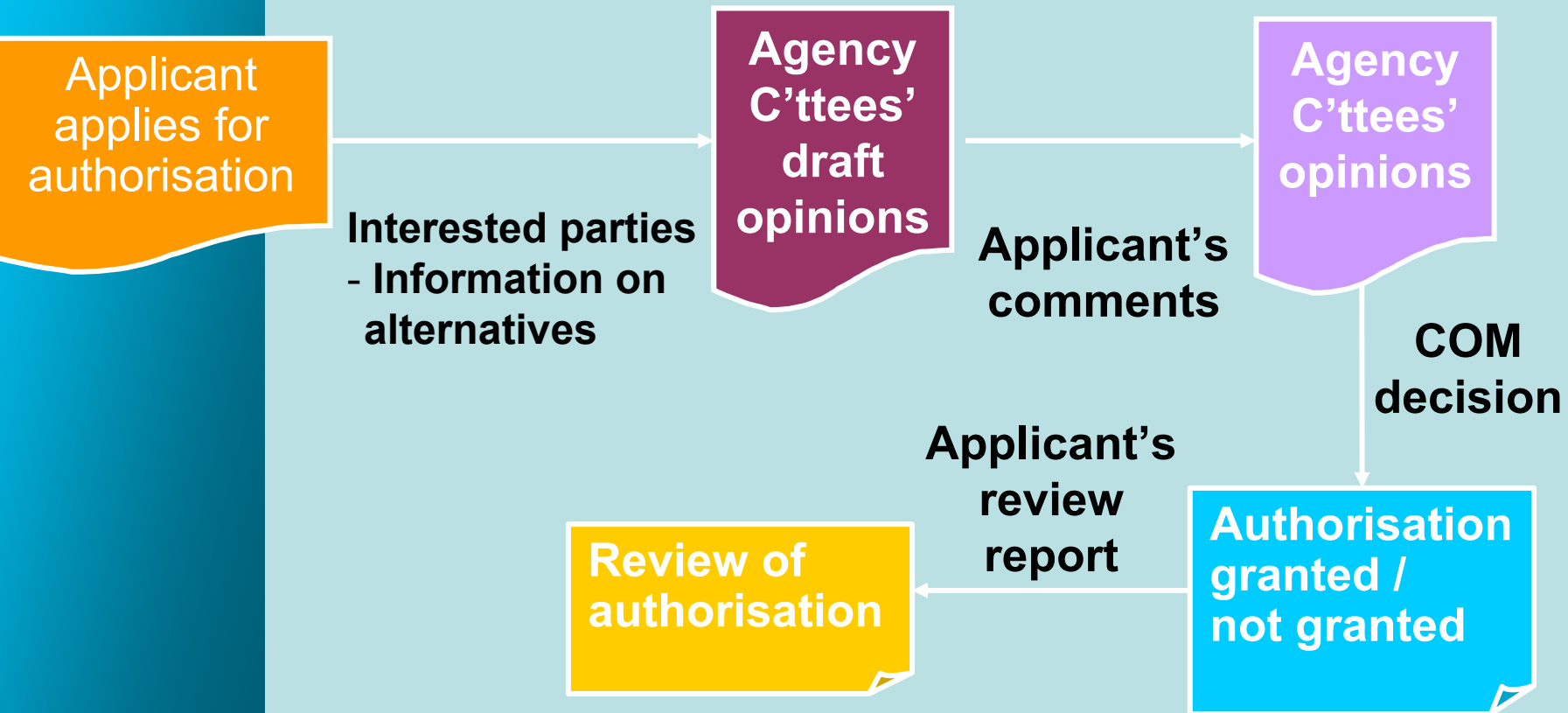
Inclusion of substances into the list of substances subject to authorisation (Annex XIV)



1. Introduction

Step 2-

Granting the authorisation



2. Substances subject to authorisation

- 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

3. Exemptions

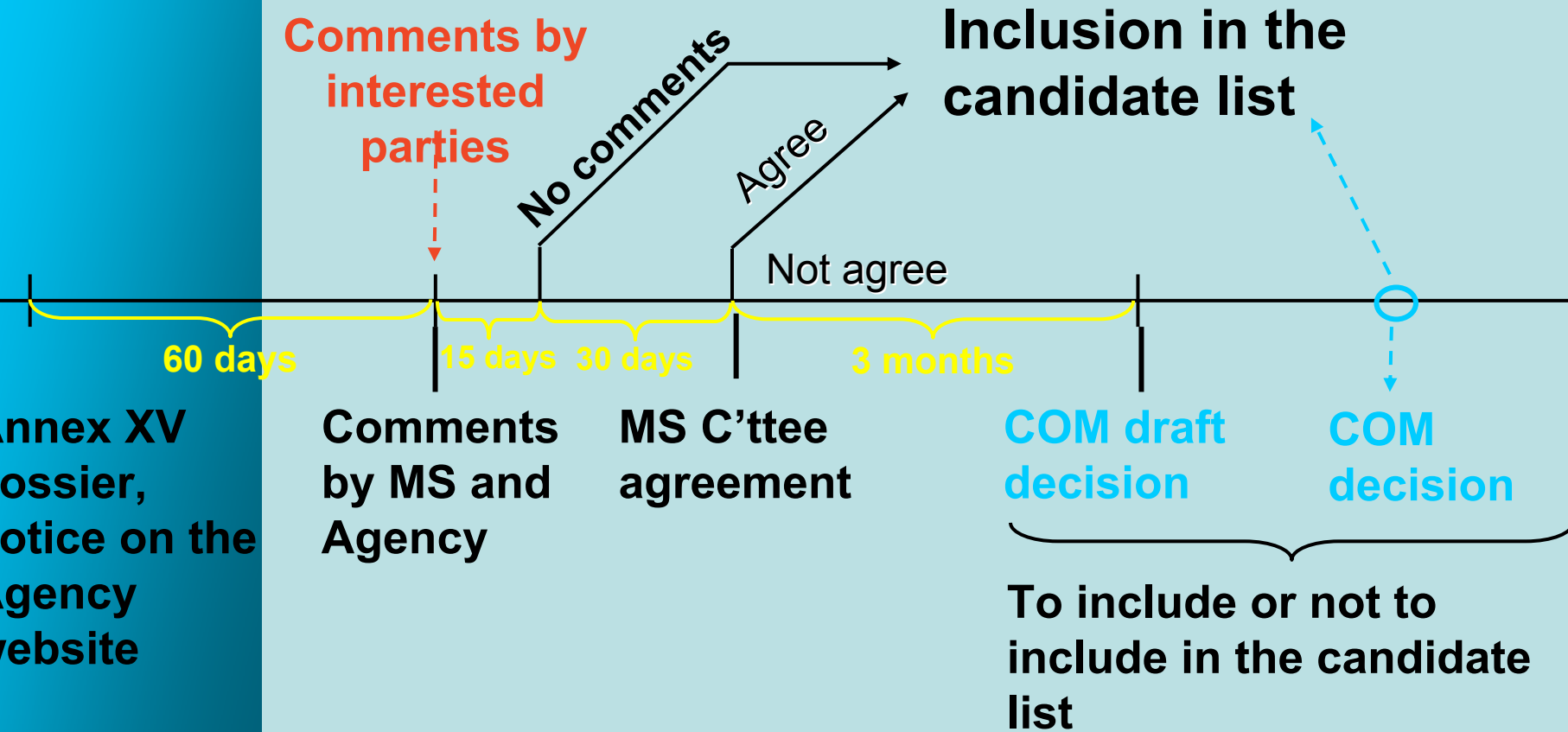
❖ General exemptions

- Art 2(5) (e.g. uses in food)
- Art 2(8)(b) (uses as intermediates)
- Art 56(1)-(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 PPORD requires authorisation

4. Procedure authorisation-step1

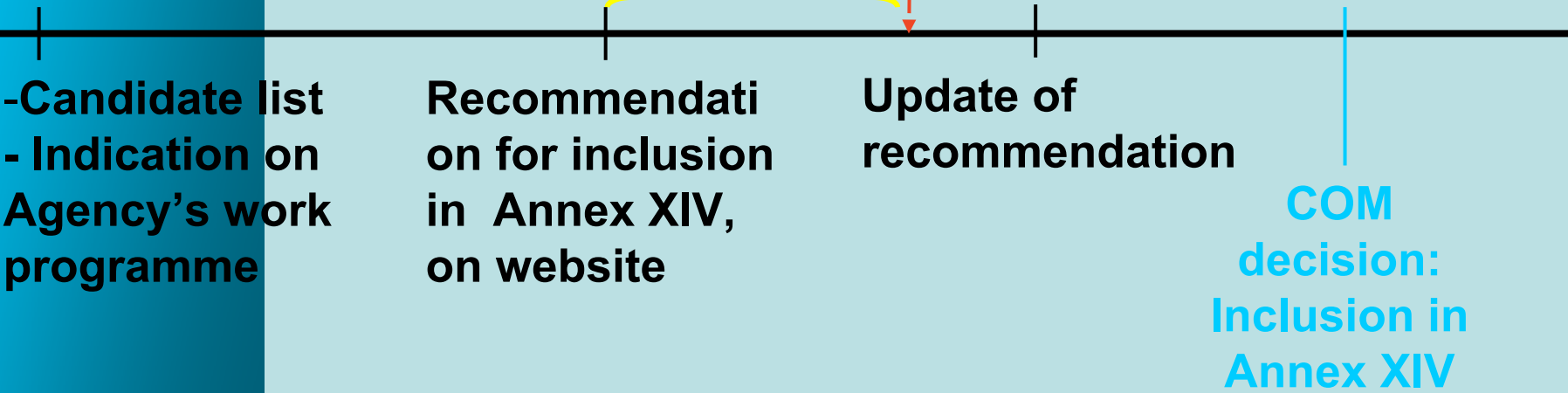


4. Procedure authorisation-step1

Interested parties (industry, NGOs, MSs)

Comments, in particular on uses to be exempted

3 months



Agency and the Commission

4. Procedure authorisation–step 1

- ❖ Establishment of the candidate list (Art. 59)
- ❖ The Agency's work programme
- ❖ Prioritisation of substances
- ❖ Inclusion of substances into Annex XIV

Establishment of the candidate list

A proposal for the identification in the Annex XV dossier:

WHO?

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

WHAT?

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

HOW?

- Guidance for authorities on preparing proposals for Annex XV SVHCs has been developed

4. Procedure authorisation-step1

- ❖ Establishment of the candidate list
(Art. 59)
- ❖ The Agency's work programme
- ❖ Prioritisation of substances
- ❖ Inclusion of substances in Annex XIV

The Agency's work programme

- ❖ The Agency's work programme will contain the substances from the candidate list on which the Agency intends to work with a view to decide whether they should be recommended as priority substances.
- ❖ The candidate list will be a 'living' document updated annually.
- ❖ The work to be carried out by the Agency might include different tasks

4. Procedure authorisation-step1

- ❖ Establishment of the candidate list (Art. 59)
- ❖ The Agency's work programme
- ❖ **Prioritisation of substances**
- ❖ Inclusion of substances in Annex XIV

Prioritisation of substances

- ❖ Priority is given to substances on the candidate list with
 - PBT or vPvB properties
 - wide dispersive use; or
 - high volumes

- ❖ Timetable
 - Debated in the MS C'ttee
 - the first recommendation at the latest 2 years after entry into force: 1 June 2009
 - further recommendations at least every second year

4. Procedure authorisation-step 1

- ❖ Establishment of the candidate list (Art. 59)
- ❖ The Agency's work programme
- ❖ Prioritisation of substances
- ❖ Inclusion of substances in Annex XIV

Inclusion in Annex XIV

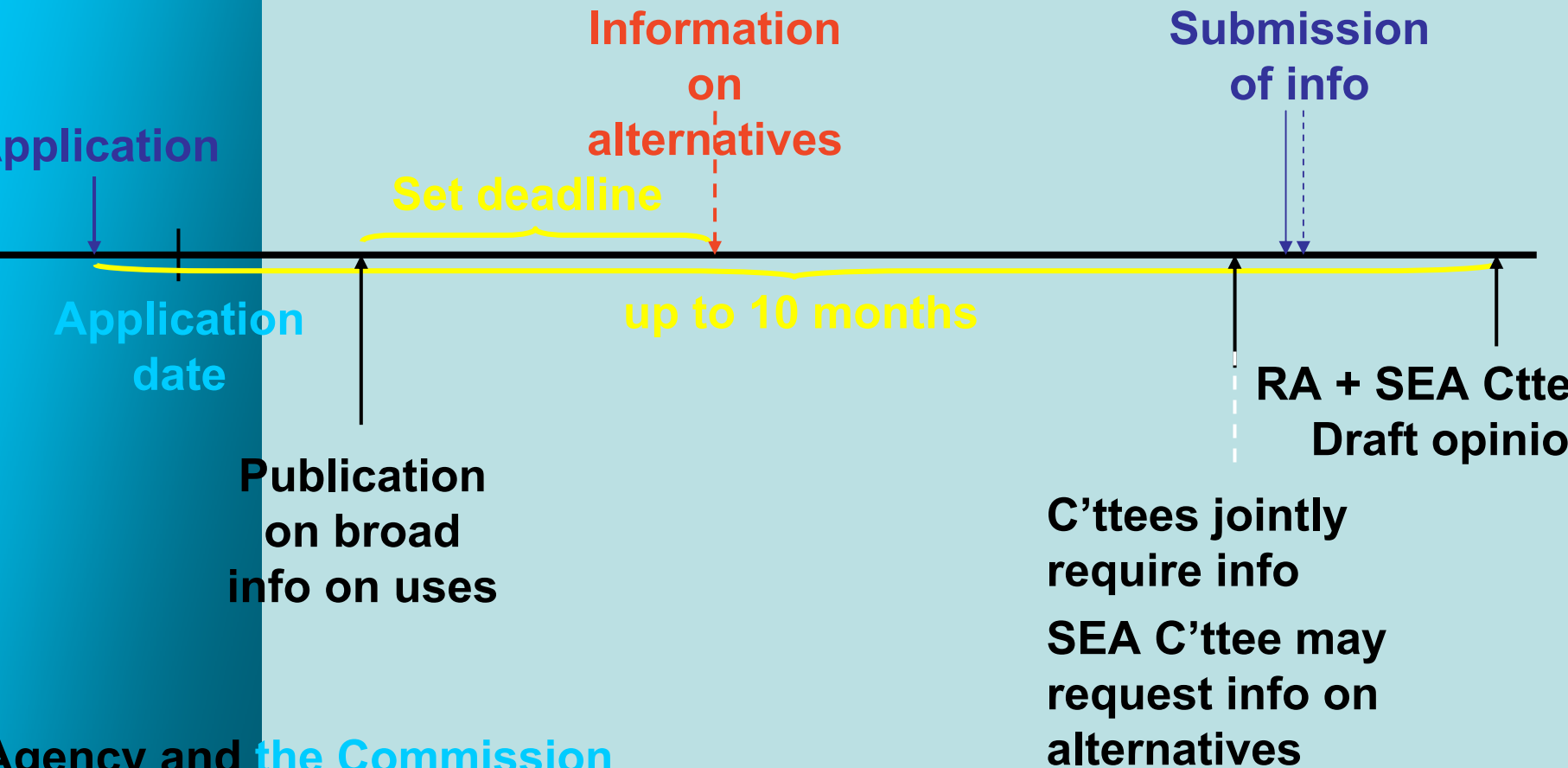
- The Agency has to consider whether to propose to exempt uses or categories of uses when making a proposal for inclusion of substances in Annex XIV
 - Condition: The existing specific Community legislation already imposes minimum requirements properly controlling the risks
- The Agency has to take into account when finalising its proposal
 - The comments by interested parties, in particular on uses which should be exempt
 - The opinion of the MS C'ttee
- The COM takes the decision
 - Annex XIV will specify any uses or categories of uses exempted
 - Exemptions may be subject to conditions

Inclusion in Annex XIV- Entries

- The identity of the substance
- 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

4. Authorisation Procedure-step2

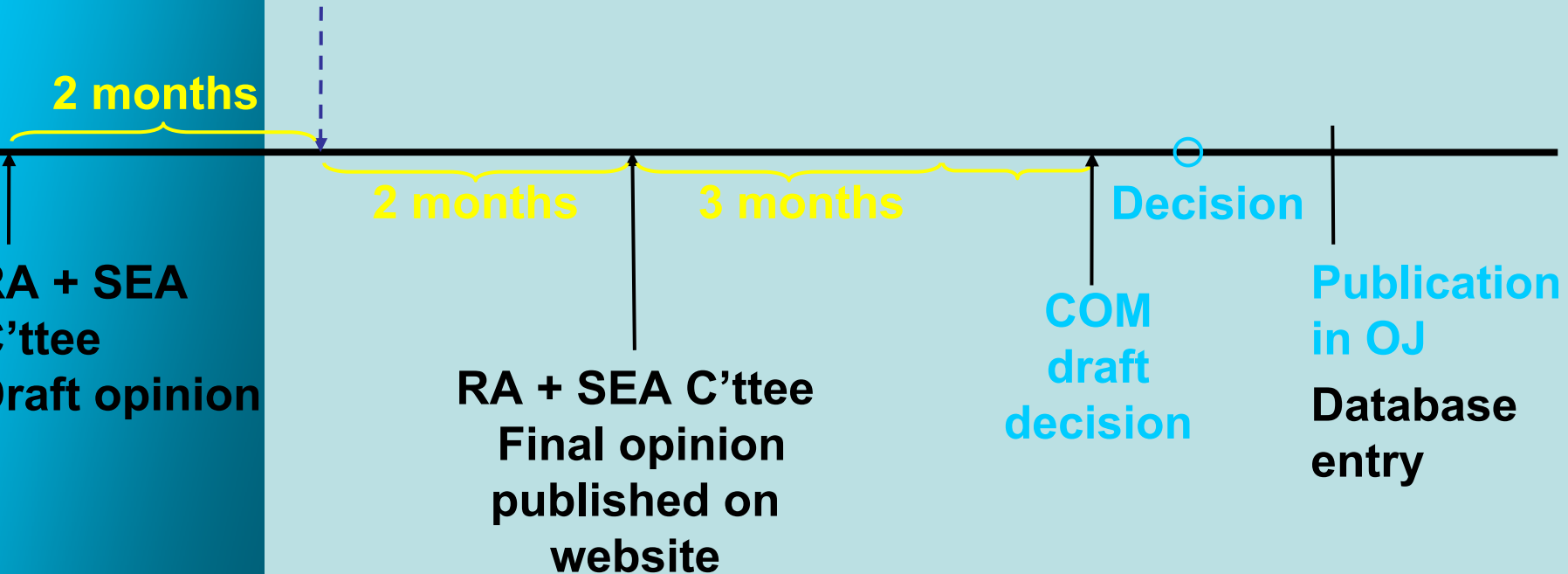
Applicant and interested 3rd parties (other industry, NGOs, MS)



4. Authorisation Procedure- step 2

Applicant

Comments



Authorisation application

An application for authorisation

- May be prepared by manufacturer(s), importer(s) and/or downstream user(s)
- May cover
 - Several substances
 - Several uses
 - Applicant's own uses, his downstream actors' uses
- Needs to be submitted to the Agency by the application date defined in Annex XIV

Authorisation application

- An authorisation application has to specify the applicant and the substance and uses covered, and include
 - A CSR 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

Authorisation application

- An authorisation application **may include**
 - A socio-economic analysis
 - A substitution plan
 - A justification for not considering risks covered by
 - An IPPC permit
 - Prior regulation under Water Framework Directive (point sources)
- The application **shall not include** the risks to human health from the use of a substance in a medical device (regulated by Dir 90/385/EEC, 93/42/EEC or 98/79/EC)

Granting the authorisation

- The Commission shall grant an authorisation if
 - Risk are adequately controlled
 - NB not applicable for PBTs, vPvBs and non-threshold CMRs
- The Commission may grant an autorisation if
 - Socio-economic benefits outweigh the risks
 - There are no technically and economically viable alternatives

Granting the authorisation

- **Authorisation decision:**
 - Person(s) to whom the authorisation is granted
 - Identity of substance(s)
 - The use(s) for which granted
 - Any conditions
 - The time-limited review period
 - Any monitoring arrangements

Review of an authorisation

- The authorisation decisions **will include** a time-limited review period
- Holder of the authorisation to submit a review report at the latest 18 months before the expiry of the review period
- In addition, an authorisation **may be reviewed** e.g.
 - Environmental quality standards are not met
 - An EQS referred to in the IPPC directive is not met
 - If the environmental objectives set in accordance with the WFD (Art 4(1)) are not met
 - Circumstances of the original authorisation have changed
 - changes that affect the risk or the socio-economic impact
 - New information on substitutes
- The COM **shall withdraw** the authorisation
 - use(s) subsequently prohibited or restricted by POP Regulation (850/2004/EC)

Questions

