

# “Consultations in the framework of the authorisation procedure ”

**ECHA’s Second Stakeholders Day**

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- 1. The authorisation procedure**
- 2. When and how are stakeholders involved**
- 3. Experiences; what went well, what went wrong**
- 4. Conclusions**

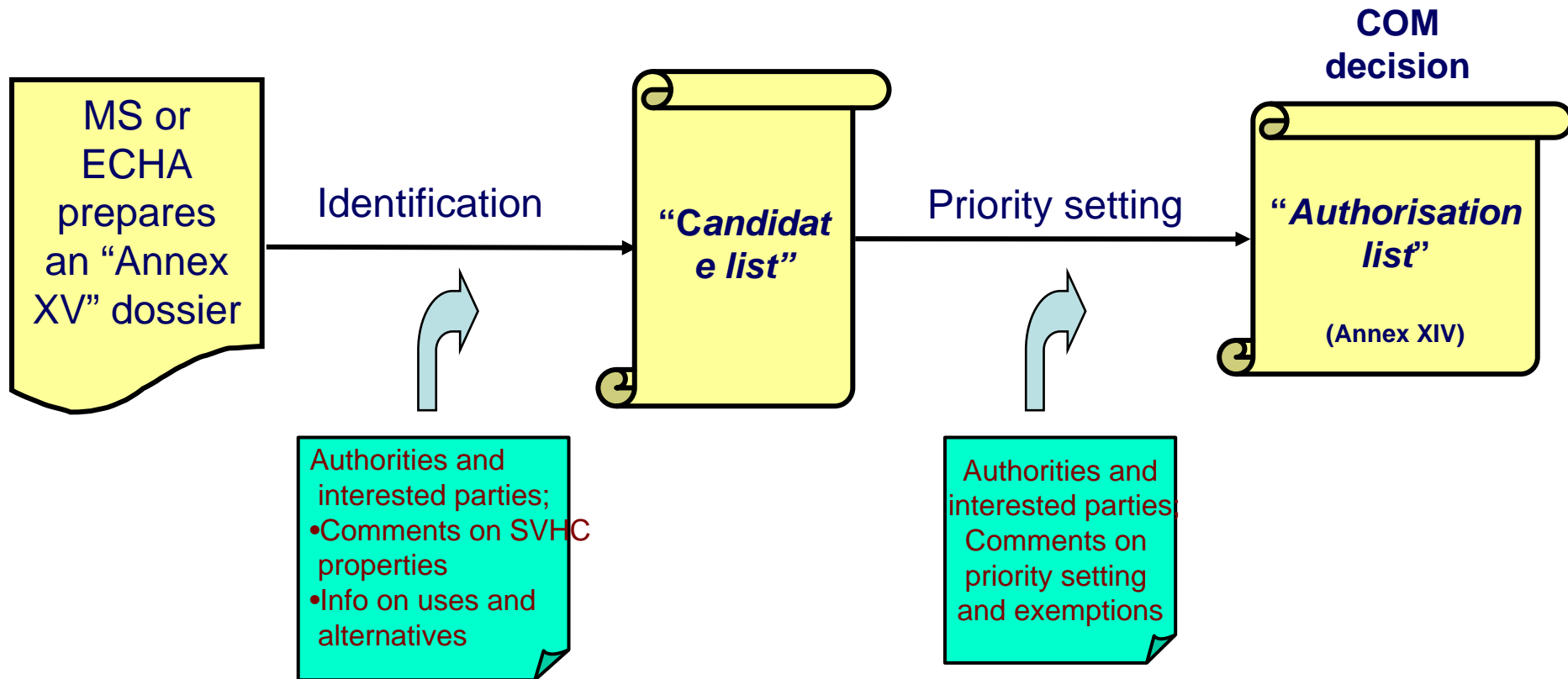
# Some upfront observations

- Authorisation is a new process, with many unknown factors but high (political) expectations
- Need for a common understanding of the aim and scope of authorisation, compared e.g. to restriction
- Legislation defines the process in (very) great detail:
  - many formal steps to be followed
  - many actors involved
  - long process but with tight deadlines for many parts
- Type and quality of information available at different steps in the process is a key factor

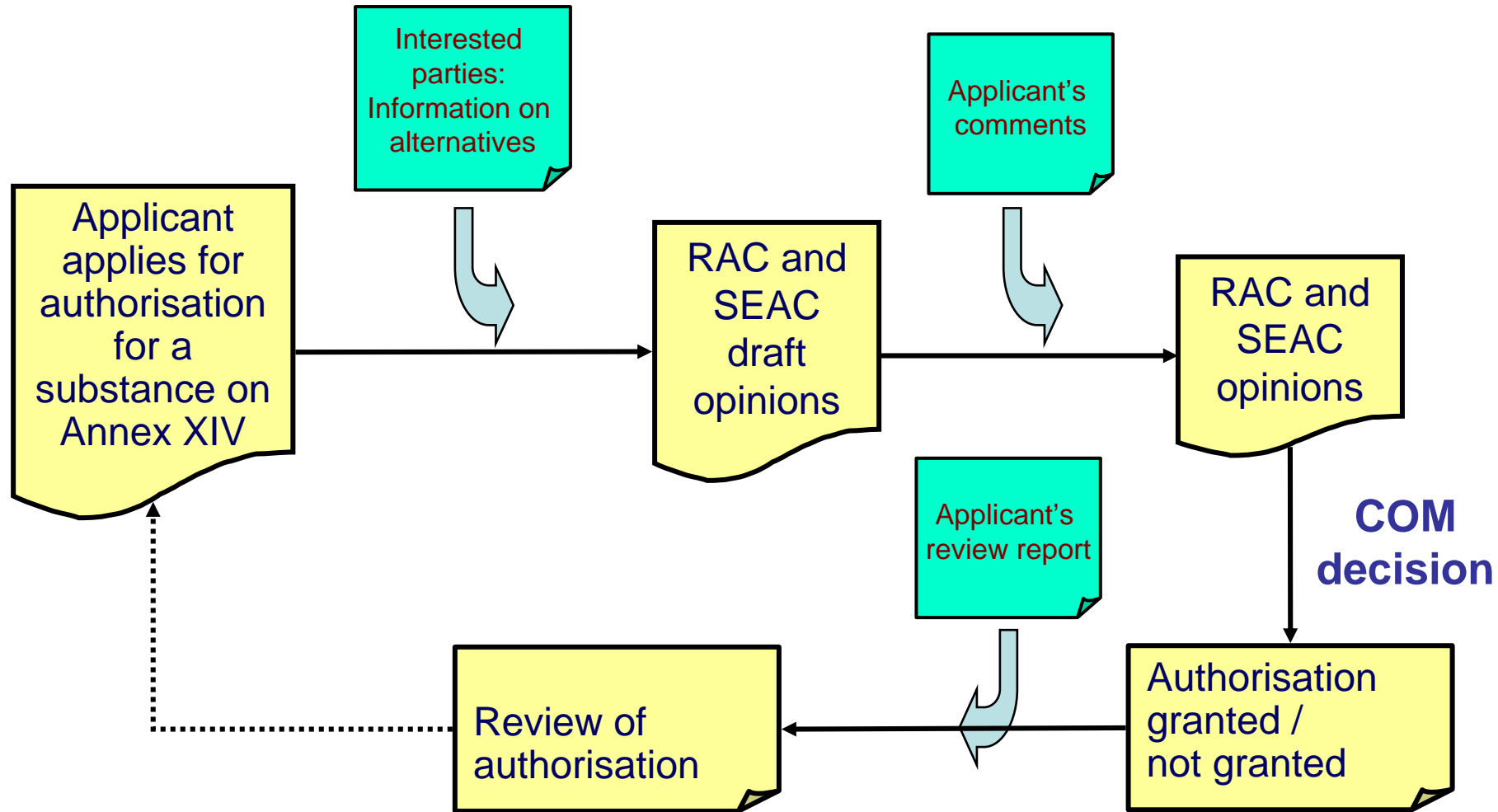
# The authorisation procedure: a 2-step approach

- Step 1: "Selection" of substances for the authorisation process
- Step 2: Application for authorisation, granting of authorisation and review of authorisation

**‘Step 1’ : Identification of SVHCs, inclusion in the “Candidate list” and inclusion in the ‘Authorisation list’ (Annex XIV)**



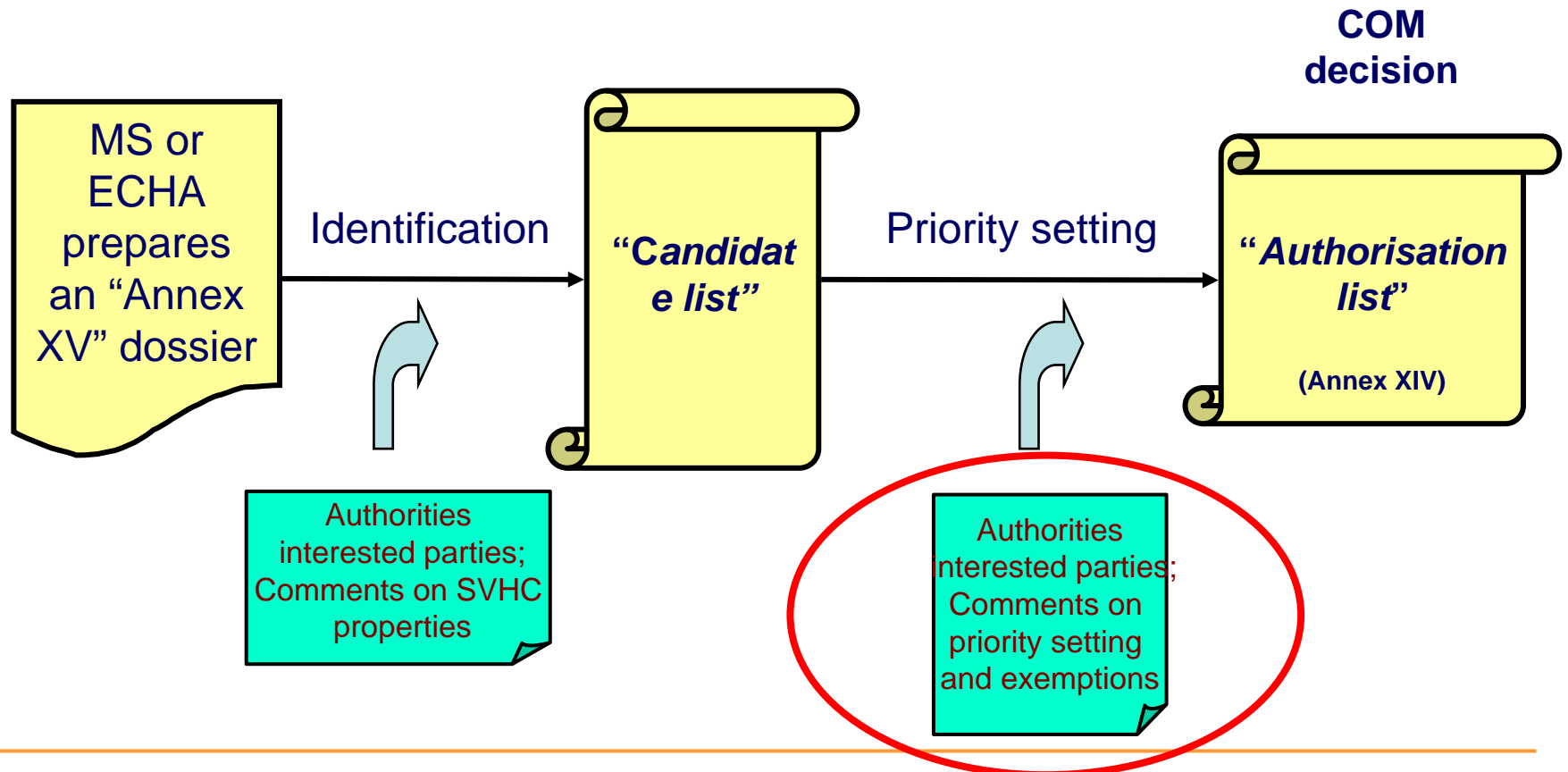
## 'Step 2': Granting (or refusing) the authorisation



# Issues considered in the Authorisation process

<b>Stage in the authorisation process</b>	<b>Actor</b>	<b>Considered issues</b>
Before the submission of an Annex XV dossier	MS / COM	The most appropriate risk management instrument
Identification of a SVHC / inclusion on the Candidate List	MS/ECHA -> MSC	Hazardous properties
Prioritisation and Annex XIV recommendation	ECHA / MSC	PBT/vPvB Indication of exposure Other factors (e.g. grouping) Justified exemptions
(Authorisation application) Authorisation decision	(applicant->) RAC/SEAC -> COM	Control of risks? Suitable alternatives available? Socio-economic benefits of the continued use?
<a href="http://echa.europa.eu">http://echa.europa.eu</a>		7

## 'Step 1' : Identification of SVHCs, inclusion in the "Candidate list" and inclusion in the 'Authorisation list' (Annex XIV)



# First experiences with Annex XIV recommendation

- Consultation period; 14 January – 14 April 2009
- Announced via press release
- Web pages with general background information
- Background papers to explain approach followed
- Web forms for submitting comments
- Possibility to provide confidential info
- Structured (this time only) to solicit for comments on:
  - Priority setting (incl. non-prioritised substances)
  - Uses which could be exempted from authorisation
- Comments to ECHA, responses provided to MSC for developing their opinion
- Responses will be published by June 1

# Results (1)

- ca. 365 comments submitted on all substances currently on the Candidate List
- From 25 countries (19 EU-countries + Norway; Switzerland, Japan, US, Egypt, Turkey)

But;

- Many comments submitted several times, either for the same (group of) substances (e.g phthalates) or for several (or even all) substances
- Web forms quite often misinterpreted and therefore not used correctly, complicating the work of ECHA and MSC
- Consequences of confidentiality claims (for names, information and documents submitted) not always realised.

→ ECHA to draw conclusions/make proposals to technically improve the next consultations

## Results (2)

- **General / policy-level comments, e.g.:**
    - Concerns about the appropriateness of authorisation
    - Concerns about import of (semi)-finished articles
    - Better consideration of cumulative effects/synergistic toxicity of substances
- Relevant, but not at this stage of the process or not specifically related to authorisation!

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# Results (3)

## Specific comments on exemptions:

- Use out of scope of authorisation, e.g. R&D, Intermediates
- Use covered or already regulated by other legislation:
  - **Community legislation**
  - recommended exemptions: **Annex XVII**
  - National legislation
  - Standards, agreements
  - Not specified
- Low level of risk and/or suitable alternatives not available

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# Conclusions

- Authorisation is a complex and lengthy process but ECHA is dedicated to turn it into a success and implement it efficiently and transparently
- There's a need to improve the understanding of the aim and scope of authorisation (e.g. to restriction)
- Consultation worked reasonably well but process could be (technically) improved
- Need to further improve communication on the exact aim of the various consultations
- Need help of all stakeholders!

Thank You  
for your attention

