

State of play on the ‘candidate list’
of Substances of Very High Concern

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- What is the ‘candidate list’?
- How will it be developed?
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The 'candidate list'

- Establishment of the 'candidate list' is part of the authorisation procedure
- Consists of substances that have been identified as meeting the criteria for being Substances of Very High Concern (Art. 57)
- These substances are candidates for eventual inclusion in Annex XIV (the 'authorisation list') following a prioritisation process
- The 'candidate list' has not yet been established!

Authorisation procedure



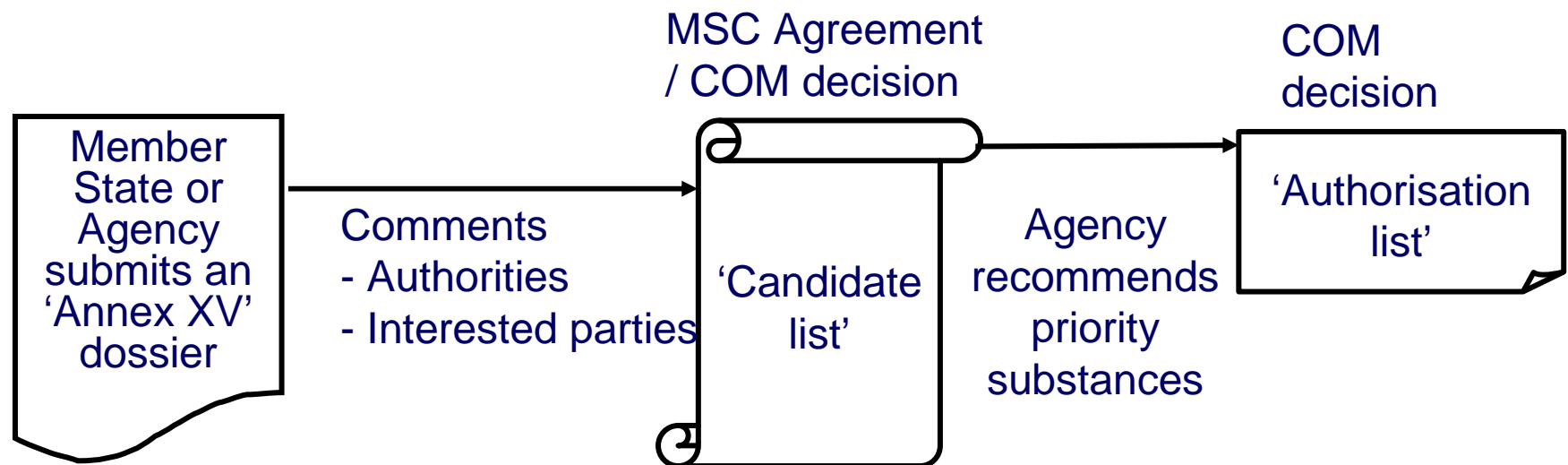
Step 1:

- Identification of substances for the 'candidate list'
- Prioritisation of substances
- Inclusion of substances on 'authorisation list'

Step 2:

- Application for authorisation
- Granting of authorisation
- Review of authorisation

Identification of SVHCs, inclusion in the 'Candidate list' and inclusion of substances in the 'Authorisation list' (Annex XIV)



Identification of SVHC for 'candidate list'



- MS (or ECHA on behalf of COM) includes substance in Registry of Intentions
- Submission of Annex XV dossiers (focussing on hazardous properties)
- Accordance check by ECHA
- Publication of Annex XV reports for comments
- Development of Support Document (incl. responses to comments) by MS and ECHA
- Agreement on identification by ECHA's Member State Committee (if comments are received)
- Inclusion in 'candidate list'

Approximately 4.5 - 5 months

Where are we now?



- MSs have submitted proposals for 16 substances by early June, 2008
- Consultation period: 30 June – 14 August, 2008
- Comments have been received on all substances
 - 7 MSCAs
 - National and international NGOs, industry associations, companies, national authorities, individuals from EU, US and Japan

Comments received



- In general the comments received by MSCAs support the proposal of identifying the substance as a SVHC
 - Except for one substance where one MSCA does not support the proposal
- Many comments on use and exposure (not relevant for the identification discussion, but will be considered for prioritisation for inclusion in the ‘authorisation list’)
- General questions raised by some MSCAs regarding scope of some of the entries and necessity to place the substance on the ‘candidate list’ have been referred to the REACH CA meeting

MSC agreements

- Member State Committee meeting 7-8 October 2008:
 - Confirmed 1 substance as SVHC without discussion, as no comments on identification had been received
 - Confirmed 10 substances as SVHC without discussion after written consultation
 - Reached agreement on 4 substances as SVHC after discussion
 - Reached agreement on 1 substance (cyclododecane) that insufficient information is available to judge the fulfilment of the criteria

Substances identified as CMR



- 4,4'-Methylene dianiline (C)
 - Bis(2-ethylhexyl)phthalate (R)
 - Dibutylphthalate (R)
 - Benzylbutylphthalate (R)
 - Cobalt dichloride (C)
 - Triethyl arsenate (C)
 - Lead hydrogen arsenate (CR)
 - Diarsenic trioxide (C)
 - Diarsenic pentaoxide (C)
 - Sodium dichromate (CMR)
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Substances identified as PBTs, vPvBs



- Alkanes, C10-13, chloro- (SCCP) (PBT & vPvB)
- Anthracene (PBT)
- Bis(tributyltin)oxide (TBTO) (PBT)
- Hexabromocyclododecane (HBCDD) (PBT)
- Musk xylene (vPvB)

What's next?



- ECHA adds the SVHC substances to the 'candidate list' by end of October, 2008
 - Immediate obligations following inclusion in the 'candidate list'
 - Any supplier of an article containing the substance >0.1% (w/w) shall provide information to professional users on safe use incl. name of substance (Art. 33(1))
 - Any supplier of an article containing the substance >0.1% (w/w) shall, within 45 days of request, provide sufficient information to consumers on safe use incl. name of substance (Art. 33(2))
-

What's next



Further obligations:

- Producers and importers of articles containing substances on the 'candidate list' in a concentration >0.1% and in total >1 t/y must notify the substance to ECHA (Art. 7(2), applies from 1 June 2011)
- Suppliers shall provide an SDS for substances or preparations containing substances on the 'candidate list' (Art. 31(1)(c), essentially only substances identified as being of an equivalent level of concern, i.e. Art. 57(f))

Next steps

- Priority setting and preparation of the Annex XIV proposals in October-November
- MSC consultation in December-January
- Public consultation from January-April
- Review of comments in May
- MSC consultation end of May
- Recommendation to COM before June

Approximately 7 months

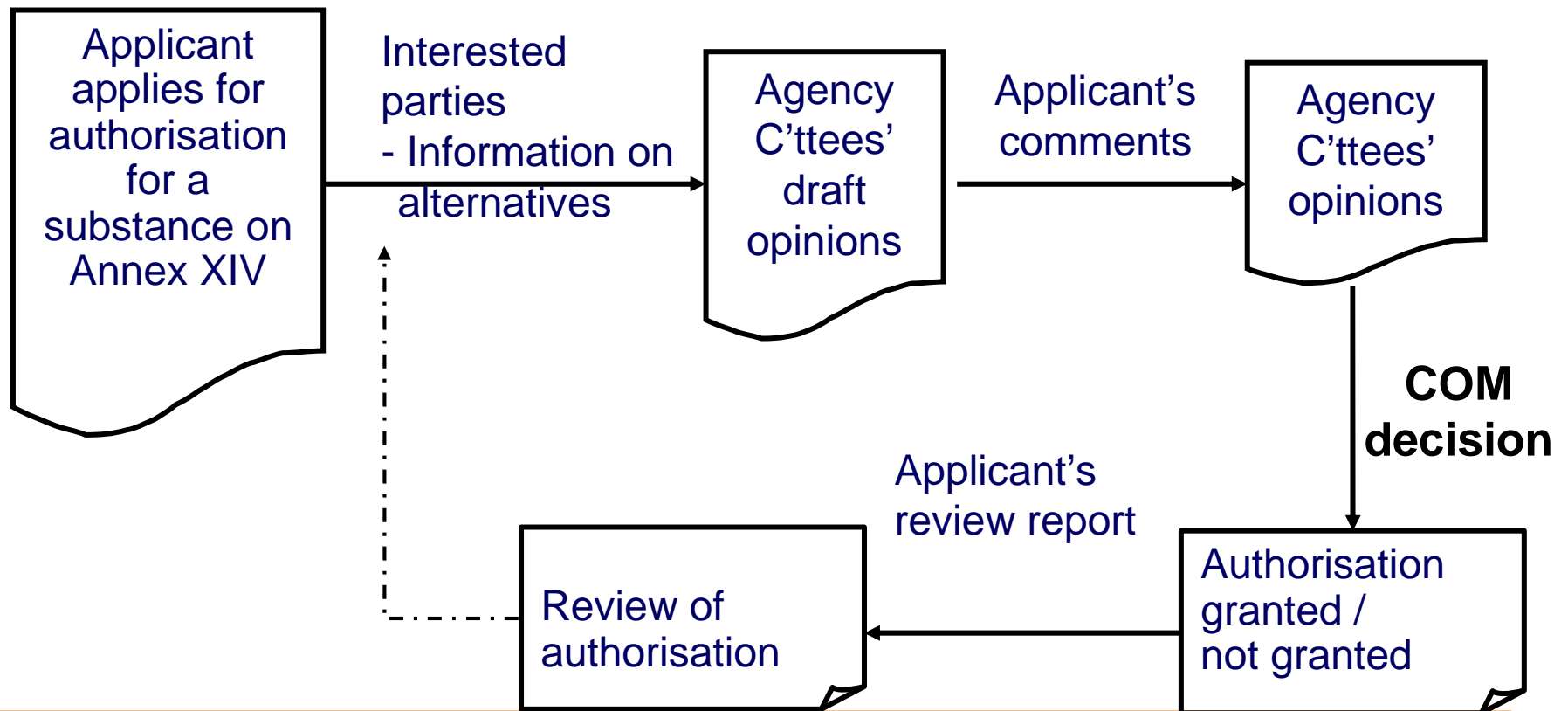
Annex XIV entries



‘Authorisation list’ entries contain (cf. Art. 58(1)):

- Identity of the substance
- Intrinsic properties of the substance referred to in Art. 57 (CMR, PBT, vPvB, equivalent concern)
- Transitional arrangements
 - The sunset date
 - Application date (at least 18 months before the sunset date)
- Review periods for certain uses, if appropriate
- Uses or categories of uses exempted from the authorisation requirements, if any, and conditions for such exemptions, if any

Granting (or refusing) the authorisation



Timelines for first authorisations



- First 'Candidate list' Oct 2008
- First Annex XIV proposals June 2009
- Annex XIV published [Autumn 2009]
- First application date [Spring 2011]
- COM draft proposal [Autumn 2012]
- First approvals [Early 2013]

Conclusions

- Authorisation is a complex and heavy process
- We are still at the start, there are many points to explore and hurdles to overcome
- Guidance has been developed but this new process will need learning-by-doing
- The ‘candidate list’ is a ‘living’ list
- ECHA’s mission is to get the whole REACH ‘machinery’ to work efficiently and effectively
- Authorities should carefully consider the best risk management option

Thank you

for your attention