



REACH Post Registration: Next Challenges

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Authorisation

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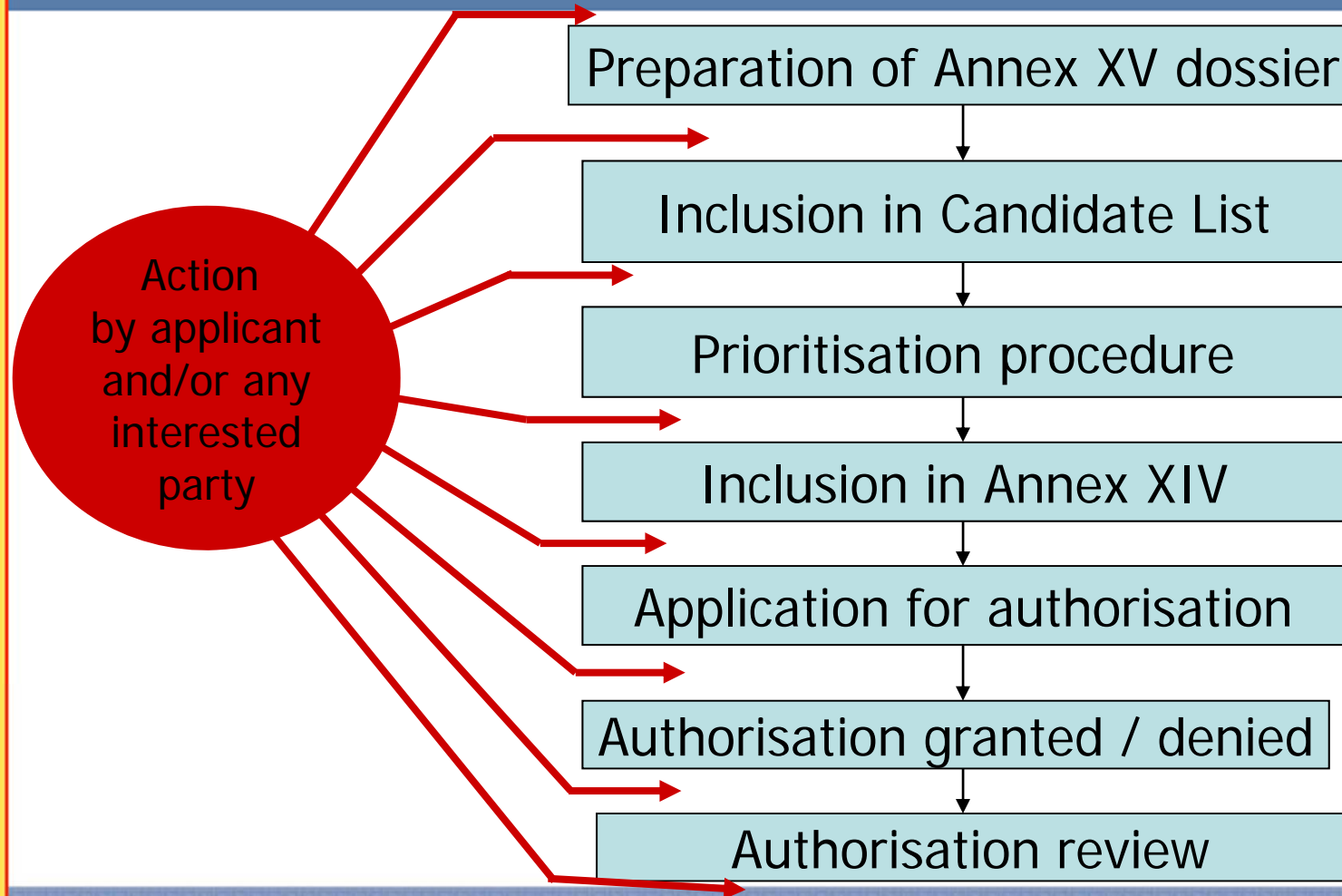
Authorisation

- Objectives
- Main steps of the process
- Points of public intervention
- Compliance with competition law
- Recommendations

Authorisation: Title VII of REACH

- Objectives:
 - Ensures the functioning of the internal market
 - Assures that risks from Substances of Very High Concern (SVHCs) are properly controlled (SVHCs are CMR, PBT or vPvB, or equivalent concern)
 - SVHCs are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable
- Guidance on the preparation of application for Authorisation published in OJ on 28 January 2011

Overview of the Authorisation Process



Preparation of Annex XV Dossier

Aim:

- Identification of substance as an SVHC for potential inclusion in the Candidate List (CL)

Procedure:

- Member States' competent authorities and ECHA (on the request of the EC) post intentions to submit Annex XV dossiers on the 'Registry of Intentions'
 - **Advocacy:** interested parties (manufacturers / importers of substance or alternatives) have the opportunity to contact the sponsor of the dossier and provide information

Inclusion of Substance in the Candidate List

- The submitted Annex XV reports are posted on the ECHA website

→ **Formal comments:** interested parties have 45 days from the date of publication to provide comments to ECHA

Comments should relate to the identification of the substance as an SVHC as well as further information related to use, exposure, alternatives and risks

- Member State Committee (MSC): unanimous agreement on inclusion (if not, final decision is by the Commission)

Effect of Inclusion of a Substance in the Candidate List (CL)

- Communication: articles with a CL substance >0.1% provide information right away
- Notification: within 6 months of inclusion but only starting from 1 June 2011
- SDS is required for substances on CL

Legal challenge: interested parties have chosen to challenge ECHA before the Court – interim relief is unlikely

Prioritisation Procedure

Aim:

- Recommendation of priority substances for inclusion in Annex XIV by ECHA

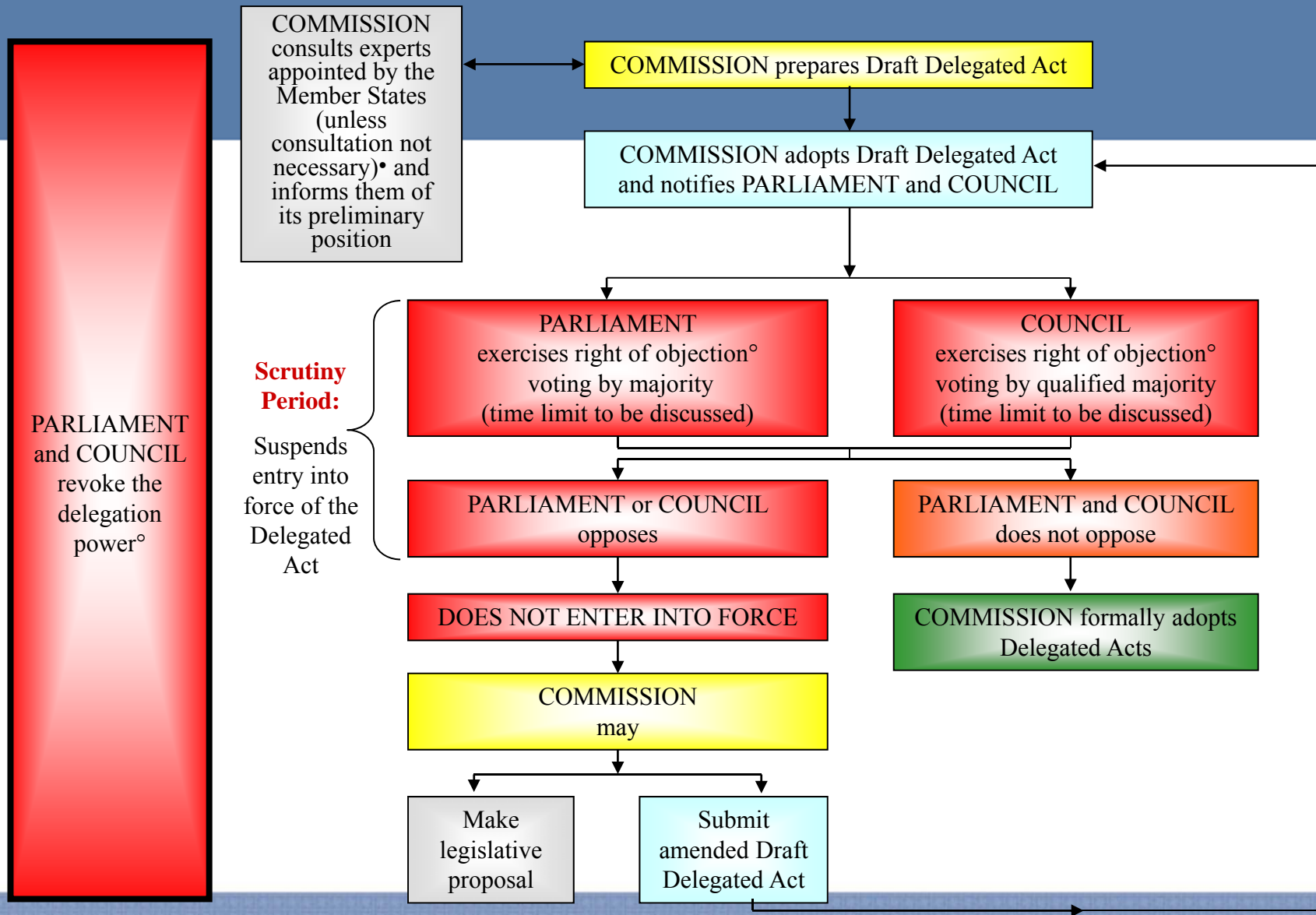
Procedure:

- 2-tier system (improve efficacy and transparency):
 - Scoring system (based on PBT and vPvB properties, wide-dispersive uses and releases, and high volumes)
 - Regulatory effectiveness and coherence
- Draft recommendation is published on ECHA's website
 - **Formal comments:** interested parties may submit comments within 3 months of the date of publication (CBI protected, if justified)

Prioritisation Procedure

- MSC gives its opinion on updated recommendation
- ECHA makes its recommendation to the Commission (also considering MSC opinion)
- Commission uses regulatory procedure with scrutiny (later delegated act procedure) to issue decisions
- Substance is listed in Annex XIV (subject to authorisation)
 - Opportunity to intervene?

Delegated Act Procedure



Status of Annex XIV

- First recommendation of priority substances for inclusion in Annex XIV was adopted by ECHA on 1 June 2009 for 6 SVHCs.
- Draft Commission Regulation amending Annex XIV received a favourable opinion in the REACH Committee on 21 September 2010.
- Still subject to scrutiny by the European Parliament and the Council. The text of the draft Regulation is publicly accessible through the Comitology Register.

Application for Authorisation

- Required for substances on Annex XIV before placing them on the market or using
 - Information that MUST be included:
 - Identity of the substance and applicant; description of use(s); CSR (unless already submitted); analysis of possible alternatives; substitution plan (if alternative is available)
 - Information that MAY be included:
 - Socio-economic analysis
- **Formal comment** by interested parties on alternative substance(s) / technique(s)
- ECHA's Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) will give their draft opinions within ten months – based on information from the applicant, interested parties and other relevant sources
- **Formal comment** by the applicant; following written notice of the intention to comment

Authorisation Granted / Denied

- Granted, if:
 - Risk is adequately controlled based on opinion of RAC (except PBT and vPvB substances and other SVHCs where no threshold can be determined)
 - Socio-economic benefits outweigh the risk and there is no suitable alternative based on the opinions of RAC and SEAC

- Actions by authorisation holder:
 - Include authorisation number on label
 - Update SDS / inform downstream user (has to notify ECHA within 3 months of first supply)
 - Submit review report

Compliance with Competition Law Rules

- Potentially sensitive issues when working in cooperation
- Same types of rules apply as during the registration process, but further:
 - ❑ Do not share information which may prevent or restrict competition, such as costs and sources of supply, inventories, market design for substitution, etc.
 - ❑ Be careful about sharing plans on switching to alternatives or discontinuing uses
 - ❑ Document your discussions
 - ❑ Use trustee when dealing with issues considered CBI

Recommendations

- Authorisation is a complex process; be aware of very tight deadlines and strict rules
- Be vigilant; follow Registry of Intentions
 - as manufacturers / importers of a given substance
 - as downstream user
 - as manufacturers / importers of alternative
- Collect data and other information in readiness for action
- When working with other interested parties be aware of competition rules