REACH in Belgium: the role of the authorities

1 June 2011

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Role of the National Authorities for REACH

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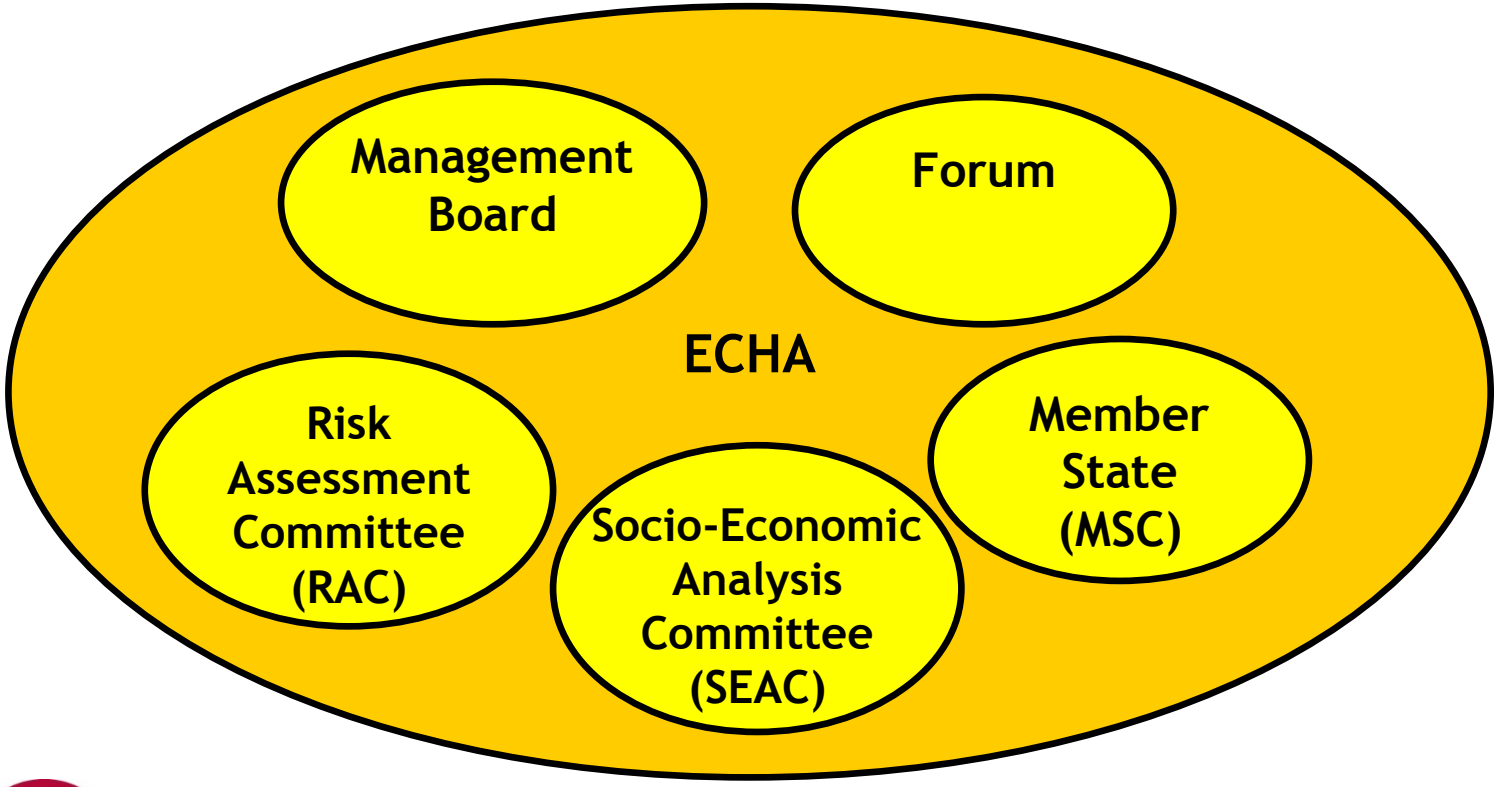
ECHA Committees



REGISTRATION

- Dossier evaluation (by ECHA)

Compliance check of Registrations (5%)

- Does information comply with the requirements of REACH?
Is there sufficient argumentation to waive standard information?
Does Chemical Safety Report comply with Annex I?
- Draft Decision ECHA: (possibly) decision to request additional information

Examination of Testing Proposals

- For tests required by Annex IX & X (>100t/y)
- Draft Decision ECHA: agree/disagree or agree if proposal is ammended

=> Member States (MS) may propose amendments to the draft decision

→ Member State Committee

→ Comitology

EVALUATION

- Substance evaluation (by MS)
  - List of substances to be evaluated prepared by ECHA
    = Community Rolling Action Plan (CORAP)

  based on priorities: exposure, hazard, quantities
  - 1st draft CORAP by Dec 2011
  - MS to select and evaluate substances (within 12months)

  OUTCOME:
  - MS may draft decision to request for further information
  - MS may submit Annex XV dossier
    - *for identification of a substance of very high concern (SVHC)*
    - *introduction of a restriction in the EU*
    - *proposal for harmonised Classification and Labelling (CLH)*

AUTHORISATION

- Purpose

- ensure that risks of substances of very high concern (SVHC) are controlled

- gradually replacing SVHC by suitable alternative substances or technologies (when economically viable and technically feasible)

Identification of SVHC via Annex XV-dossier

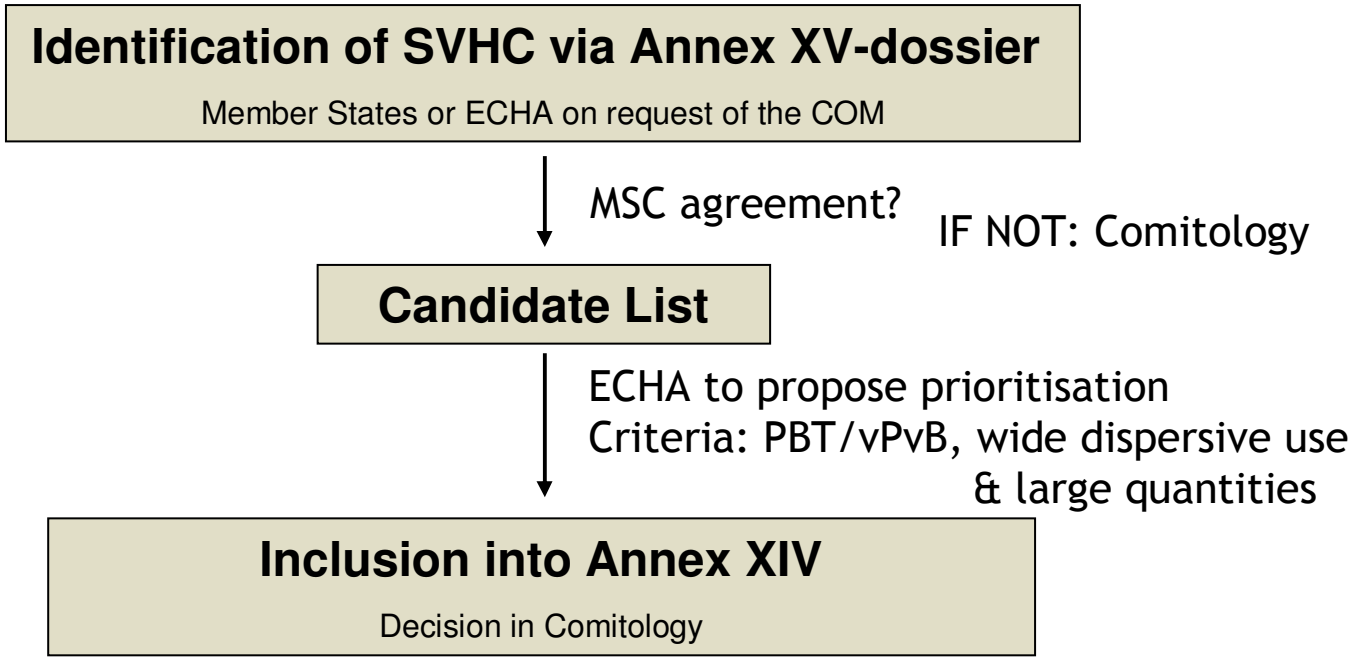
Member States or ECHA on request of the COM

SVHC:

- carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 or 2
- persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB)
- substances of equal concern (e.g. endocrine disruptors)

AUTHORISATION

- Procedure



AUTHORISATION

- Granting of authorisations
  - Use and placing on the market is not allowed unless authorisation granted by COM

2 possibilities:

1. Shall be granted IF RISK IS ADEQUATELY CONTROLLED

2. For PBT/vPvBs, non-threshold CMRs, endocrine disruptors... or if risk is not adequately controlled:
ONLY IF SOCIO-ECONOMIC BENEFITS OUTWEIGH THE RISK AND IF NO SUITABLE ALTERNATIVE SUBSTANCES OR TECHNOLOGIES EXIST

- Opinion of RAC & SEAC, decision in Comitology

RESTRICTIONS

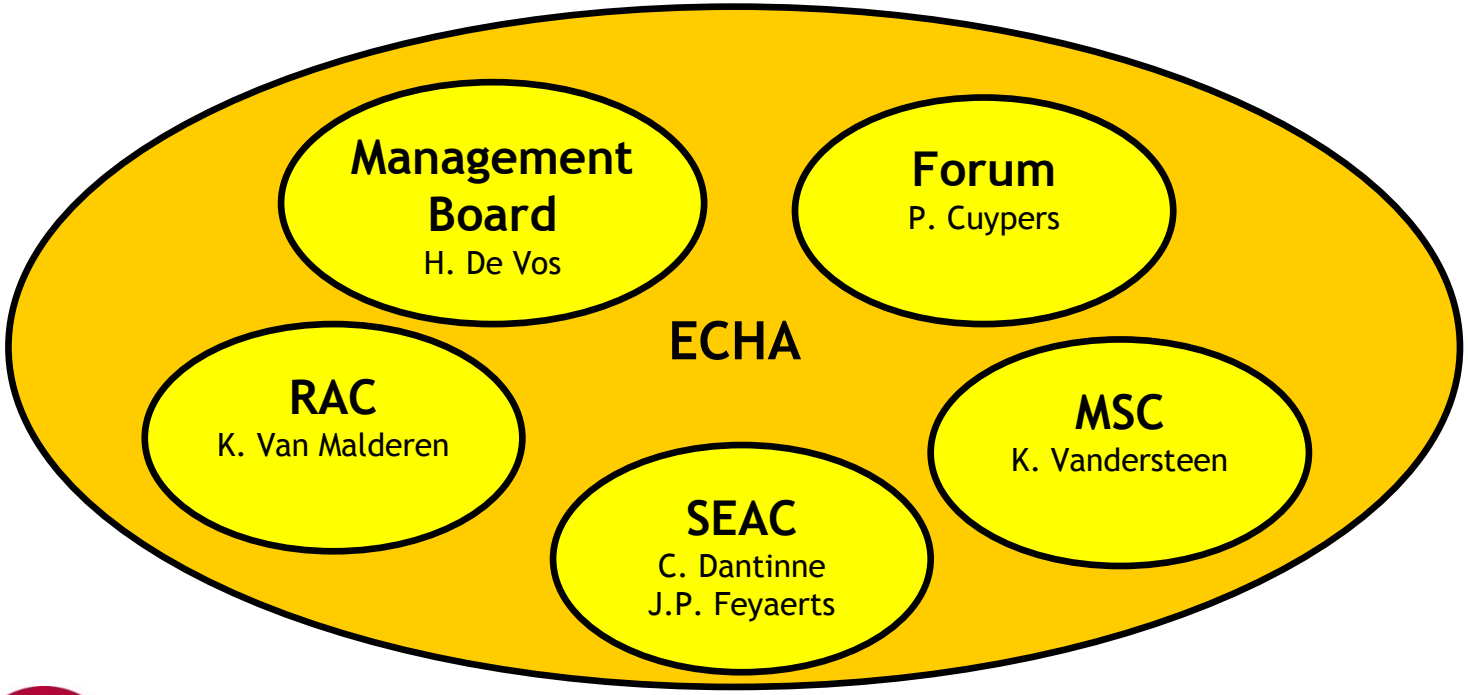
• A substance for which a restriction applies (Annex XVII) shall not be manufactured, marketed or used unless the conditions of that restriction are met

• Procedure to introduce a restriction in Annex XVII:
  - Annex XV-dossier by Member State or by ECHA
  - Opinion of RAC & SEAC
  - Decision in Comitology → inclusion Annex XVII

• Fast-track procedure for CMRs Cat.1 or 2 in consumer products: COM makes a proposal to include in Annex XVII

•Important with respect to imported articles (out of scope authorizations)

Representation in ECHA Committees



Representation in ECHA Committees

• Management Board (MB): adopting the work plan, the budget, appointment of the Director, appointment of the members of the committees,...

• Member State Committee (MSC): resolving divergences of opinions on draft decisions regarding dossier evaluation and proposals for the identification of SVHC, advice on the prioritisation of substances for inclusion in Annex XIV

• Risk Assessment Committee (RAC): opinions on restriction proposals, applications for authorization and proposals for harmonized C & L

•Socio-Economic Analysis Committee (SEAC): opinions on restriction proposals and applications for authorization (socio-economic effects and analysis of alternatives)

• Forum: coordination and harmonization of a network of enforcement authorities

Tasks coordinated by the Commission

Competent Authorities for REACH And CLP (CARACAL)

- Advises the European Commission and ECHA on questions related to REACH and CLP
- Composed of representatives of the competent authorities for REACH and CLP + stakeholders
- Former REACH competent authorities (CA REACH)

- ## Comitology ('REACH Committee')

  - Art. 133 of REACH
  - Regulatory procedure -> Regulation (EC) 182/2011
  - Implement changes to REACH and its annexes, decision in case no unanimous MSC agreement, decision on restrictions after RAC/SEAC opinion…

Other tasks…

- National Helpdesk for REACH → Federal Public Service Economy
- Enforcement
- Protection of confidential information
- Inform the public on REACH, on the risks of substances…

Thank you for your attention!

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