

# Persistent Bioaccumulative and Toxic substances (PBT/vPvB) under REACH



*Chrystèle Tissier (ECHA/ Directorate B)*

*Roma, 10 April 2008*

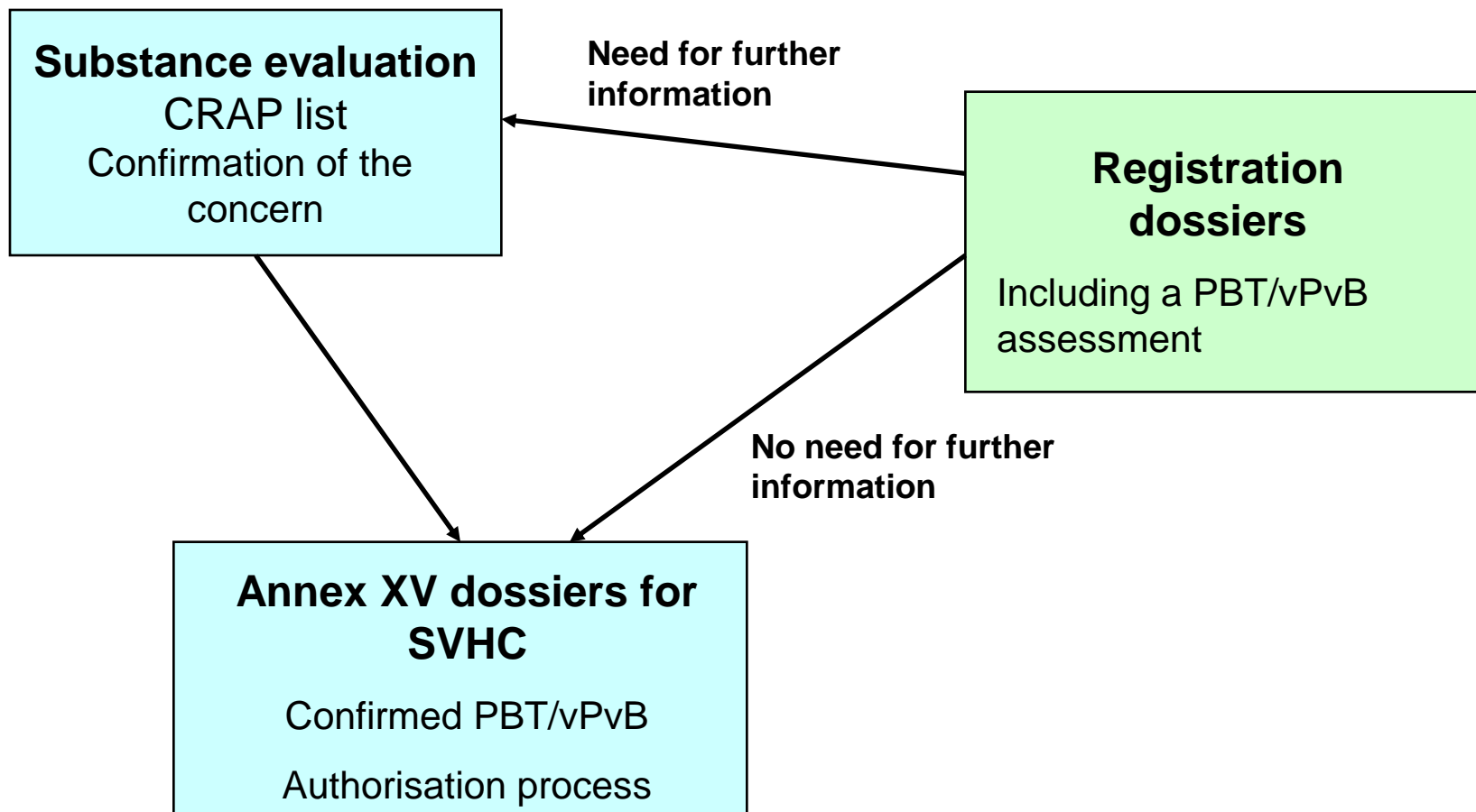
- Which processes in REACH ?
  - Preparation of Annex XV dossiers for identification of SVHC (articles 57, 59)
  - Chemical Safety assessment in registration dossier (article 14 (3d))
  - Substance evaluation (article 44a)
  
- Basis
  - Criteria in Annex XIII of REACH

# What is a PBT/vPvB under REACH?

## Criteria for the identification of PBT/vPvB under Annex XIII of the REACH regulation

PBT-criteria	vPvB-criteria
<ul style="list-style-type: none"><li>- <math>T_{1/2} &gt; 60</math> days in marine water, or</li><li>- <math>T_{1/2} &gt; 40</math> days in fresh- or estuarine water, or</li><li>- <math>T_{1/2} &gt; 180</math> days in marine sediment, or</li><li>- <math>T_{1/2} &gt; 120</math> days in fresh- or estuarine sediment, or</li><li>- <math>T_{1/2} &gt; 120</math> days in soil.</li></ul>	<ul style="list-style-type: none"><li>- <math>T_{1/2} &gt; 60</math> days in marine, fresh- or estuarine water, or</li><li>- <math>T_{1/2} &gt; 180</math> days in marine, fresh- or estuarine sediment, or</li><li>- <math>T_{1/2} &gt; 180</math> days in soil.</li></ul>
BCF > 2000 L/kg	BCF > 5000 L/kg
<ul style="list-style-type: none"><li>- NOEC (long-term) &lt; 0.01 mg/L</li><li>- substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3), or</li><li>- there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.</li></ul>	-

# Relations between the different processes

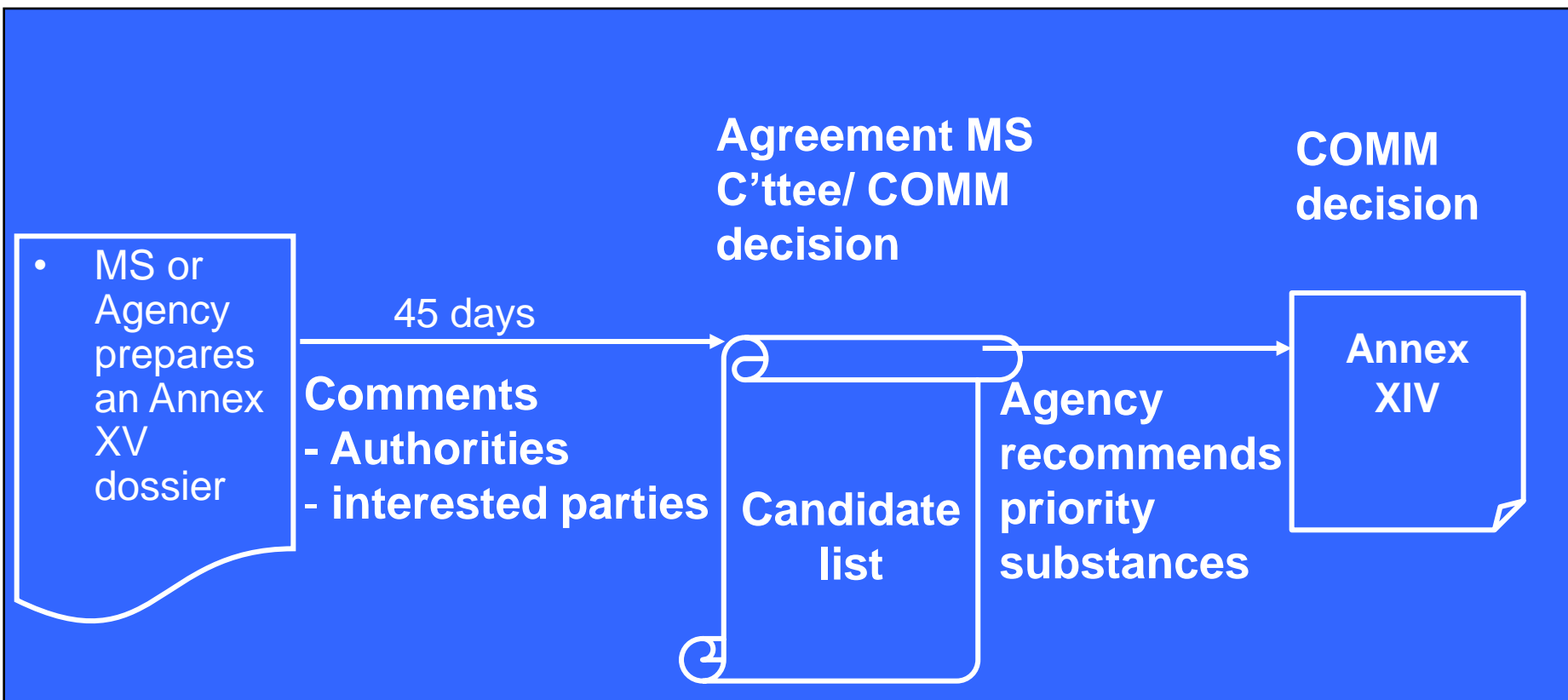


# Annex XV dossier : identification of SVHC.



- Aim
  - Authorisation (art. 55) :  
*‘To ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable’*
- Who?
  - Member States or
  - ECHA on request by the Commission
- What?
  - SVHC (art.57): **PBT/vPvB**, CMR, equivalent level of concern
- More information
  - Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern
    - Available on the ECHA website (<http://echa.europa.eu/>)

# Annex XV dossier: Identification of SVHC process



# Registration dossier: Chemical Safety Assessment



- Objective (Annex I(4))
  - Determine if the substance fulfils the criteria in Annex XIII and if so characterise the potential emissions to the different environmental compartments for all identified uses (no usual risk characterisation)
  - Implementation by registrants of Risk Management Measures (RMM) which minimise emissions and subsequent exposures of humans and the environment
- Who?
  - Registrants of substances manufactured/imported at more than 10 tonnes per year
- What?
  - PBT/vPvB assessment section in the Chemical Safety Assessment
- More information
  - Guidance on information requirements and chemical safety assessment
    - Chapter R11 on PBT and vPvB assessment
      - To be published in June 2008 on the ECHA website

# Information to use for the assessment: intrinsic properties

- All relevant and available information
  - Including assessment performed under other fora
  - Global portal (OECD)
- For registrants as a minimum the information required under Annexes VII to X + alternatives methods (A.XI)
- Integrated testing strategies (ITS)
- If the available information doesn't allow a direct comparison with the criteria then (Annex I(4.1)) requires the registrant to:
  - Consider on a case by case basis, other available evidence like monitoring data giving rise to an equivalent level of concern and
  - Consider all information relevant for screening of the P, B and T properties

- **Persistence**
  - Ready biodegradability (A.VII): screening criteria
  - Hydrolysis, further degradation test (A.VIII): screening criteria
  - Simulation tests (A.IX and X): definitive criteria
- **Bioaccumulation**
  - Partition coefficient (Kow) (A.VII): screening criteria (>4.5)
  - Bioaccumulation in aquatic species (fish) (A.IX): definitive
- **Toxicity**
  - Short term toxicity on invertebrates, growth inhibition study on algae (A.VII): screening criteria (L(E)C50 < 0.1 mg/L)
  - short term toxicity on fish (A.VIII): screening criteria (L(E)C50 < 0.1 mg/L)
  - Long term toxicity on invertebrates, fish (A.IX): definitive criteria

# Information on exposure

- Annex XV dossiers
  - Information on uses, exposure and alternatives in order to facilitate the prioritisation later on
- Chemical Safety Assessment/PBT
  - Identify emissions to the environment
  - Identify exposure routes by which humans and the environment are exposed to the substance

Performed as for a normal risk assessment when developing exposure scenarios but the objective is to show that the RMMs recommended or implemented aimed at *minimising exposures and emissions to humans and the environment throughout the lifecycle of the substance that results from manufacture or identified uses (Annex I (6.5))*

# Publication of information

- Article (119, 77(2e))
- Publicly available
  - Name for dangerous substances
  - C&L
  - Physico chemical data
  - Pathways and environmental fate information
  - Results of toxicological and ecotoxicological
  - DNEL, PNEC
  - Guidance on safe use
  - Analytical methods

- Current regulation for new and existing chemicals: **PBT working group** (sub group of the TCNES)
  - Remit of the group
    - Assess PBT/vPvB properties of new and existing chemicals
    - Assess PBT/vPvB properties of biocides evaluated under Directive 98/8/EEC
    - Assess PBT/POP properties of POP candidates in the frame of the Stockholm Convention (before POP Review Committee)
  - PBT already evaluated in this forum:
    - Summary of the evaluation of 127 existing chemicals available on the ECB website (<http://ecb.jrc.it/esis>)
- REACH:
  - Evaluation by the Member State Committee of Annex XV dossiers submitted
  - Possibility of PBT working group? Remit of this group? Link to CLRTAP?

**Thank you for your attention**