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PBT beoordeling in REACH

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REACH

Registration, Evaluation, Authorisation and restriction of CHemicals

Registration

≥ 1 tonne/yr

Evaluation

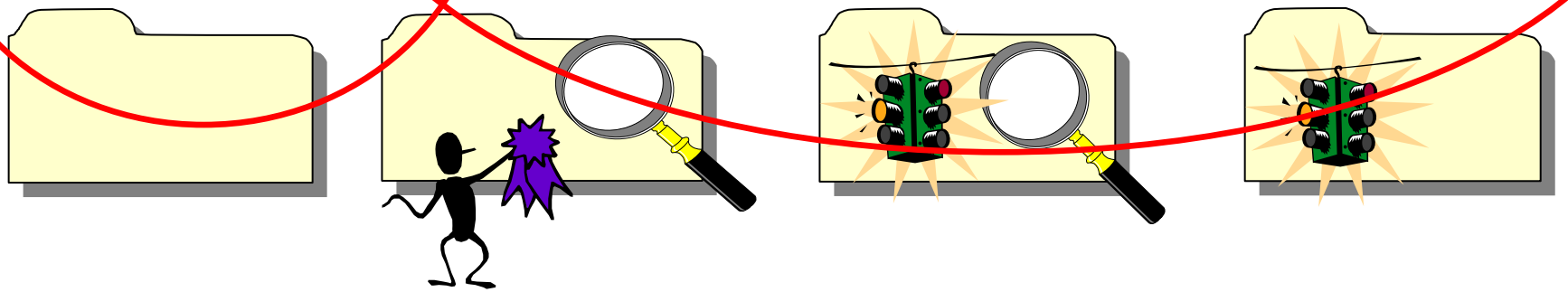
≥ 10 tonnes/yr
+ substances of concern

Authorisation

CMR & PBT & equivalent concern

Restrictions

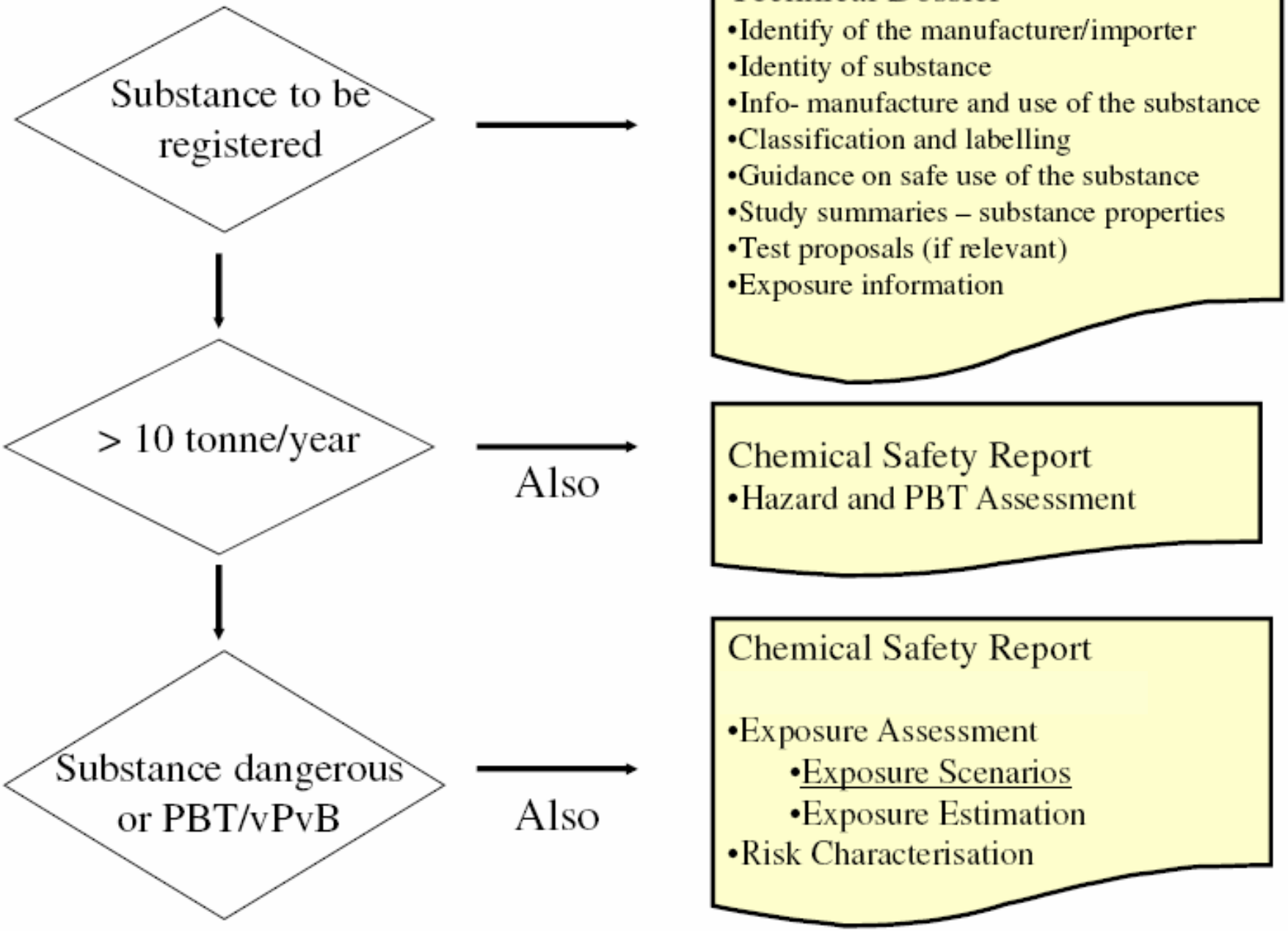
Substances of concern



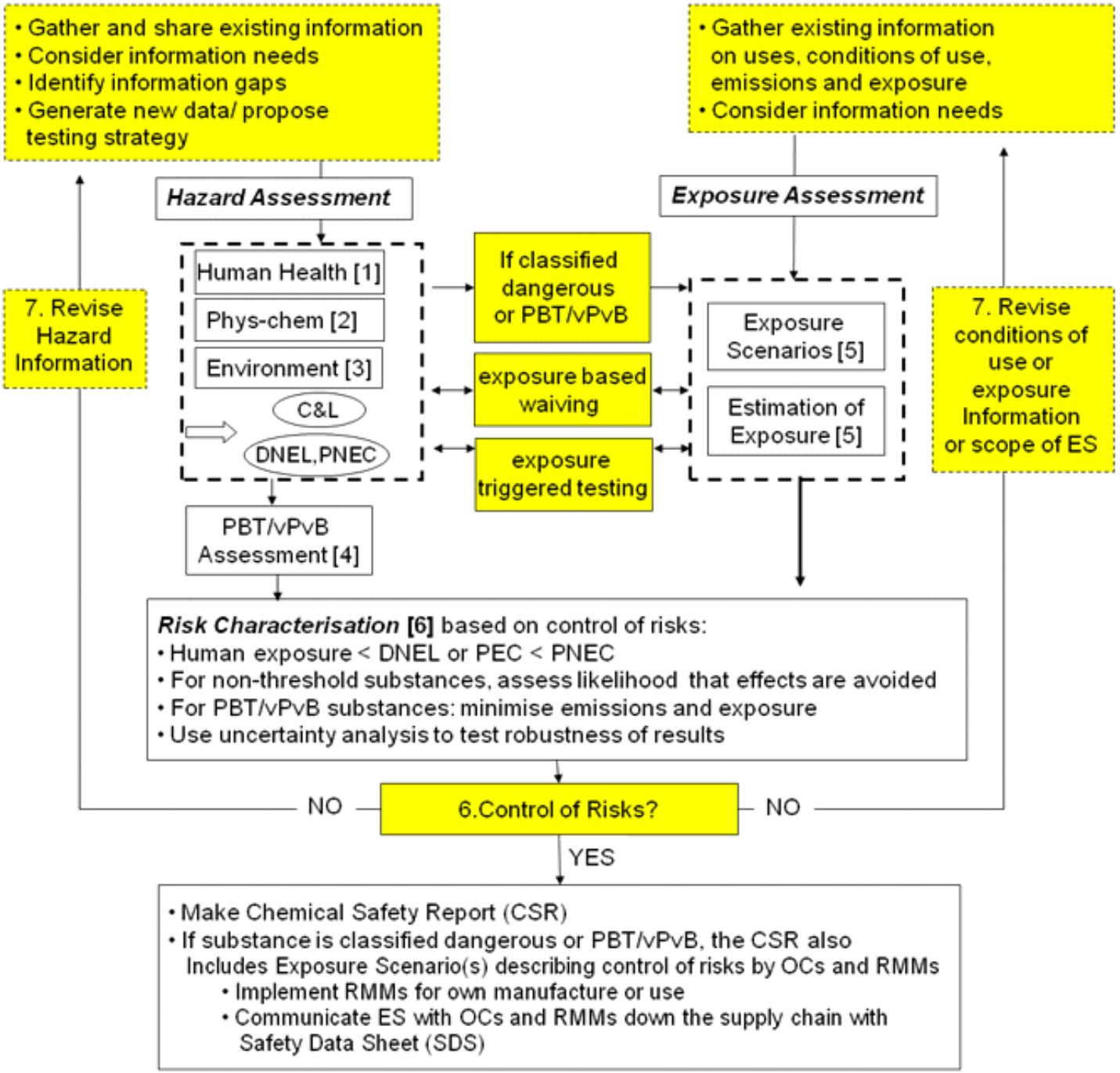
What should a registrant do in REACH on PBTs/ vPvBs?

- Register their chemical
- Perform a PBT assessment as part of the Chemical Safety Assessment
- If PBT/vPvB:
  - Emission characterisation
  - Demonstrate emission minimisation

Registration dossier - content



Ch
PB


• Gather and share existing information
• Consider information needs
• Identify information gaps
• Generate new data/ propose testing strategy
• Gather existing information on uses, conditions of use, emissions and exposure
• Consider information needs
Hazard Assessment
Exposure Assessment
Human Health [1]
Phys-chem [2]
Environment [3]
C&L
DNEL,PNEC
If classified dangerous or PBT/vPvB
exposure based waiving
exposure triggered testing
Exposure Scenarios [5]
Estimation of Exposure [5]
7. Revise Hazard Information
7. Revise conditions of use or exposure Information or scope of ES
PBT/vPvB Assessment [4]
Risk Characterisation [6] based on control of risks:
• Human exposure < DNEL or PEC < PNEC
• For non-threshold substances, assess likelihood that effects are avoided
• For PBT/vPvB substances: minimise emissions and exposure
• Use uncertainty analysis to test robustness of results
NO
6.Control of Risks?
NO
YES
• Make Chemical Safety Report (CSR)
• If substance is classified dangerous or PBT/vPvB, the CSR also Includes Exposure Scenario(s) describing control of risks by OCs and RMMs
• Implement RMMs for own manufacture or use
• Communicate ES with OCs and RMMs down the supply chain with Safety Data Sheet (SDS)

PBT and vPvB assessment

- According to Annex I of EC 1907/2006, the PBT and vPvB assessment consists of the following two steps, which are identified as such in Part B, Section 8 of the Chemical Safety Report:

  - Step 1: Comparison with the Criteria given in Annex XIII or other evidence of equivalent concern

  - Step 2: Emission Characterisation
    - Identification of emissions to the environment;
    - Identification of exposure routes by which humans and the environment are exposed

Further actions for PBT/vPvB substances identified by a Registrant

- Characterisation of the emissions
  - Estimation of the amounts of the substance released to the different environmental compartments
  - Identification of the likely routes by which humans and the environment are exposed to the substance.
  - The registrant needs to develop Exposure Scenarios for all identified uses of his PBT/vPvB substance, unless he concludes to advise in his technical dossier against certain uses of his substance.
- Risk Management
  - Implement or recommend (to DU) of appropriate and effective risk management measures to eliminate or minimize the emissions to as low a level as is technically and practically possible

What can authorities do on PBT/vPvB substances?

- 

REACH Evaluation

Objective

- To verify lack of adverse effects to human health and the environment
- To prevent unnecessary use of animal tests

Two types of evaluations

- Dossier evaluation (initiated by ECHA, mandatory)
  (Priority to dangerous substances, CMR, resp sensitizers, PBT, vPvB, > 100 tpa)

- **Substance evaluation (initiated by MSCA / COM, voluntarily)**
  - Selection criteria, amongst others:
    - › Suspected PBTs, vPvBs and PBT-like substances
    - › Known PBTs/vPvBs

Authorisation and Restriction under REACH

Free circulation of substances on the internal market

Chemical safety is responsibility of INDUSTRY

Interference in the internal market

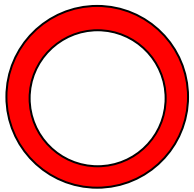
Community wide action is responsibility of AUTHORITIES

Registration

Dossier/substance evaluation

Authorisation

Annex XIV



Restriction

Annex XVII

Authorisation and Restriction under REACH (2)

- Objective: special instruments to regulate dangerous substances and to ensure that risks are properly controlled (substitution); by member states or Commission.

Authorisation:

  - substances of very high concern (CMR, PBT, vPvB or equivalent concern)

- **Restrictions:**
  - an unacceptable risk to human health or the environment
  - arising from manufacture, use or placing on the market of substances
  - which needs to be addressed on a community wide basis
- **Annex XV Dossiers:**
  - Principles for preparing dossiers for authorisation and restriction

Where are we with PBTs in REACH (1)?

- 53 Annex XV SVHC dossiers submitted by Member States and accepted as SVHCs -> on candidate list for Annex XIV

- First round of substances, as an example (underlined substances are PBTs listed in Annex XIV):

Triethyl arsenate	Anthracene	MDA
DBP	Cobalt dichloride	Diarsenic pentaoxide
Diarsenic trioxide	Sodium dichromate	**Musk xylene**
DEHP	**HBCDD**	**SCCP**
TBTO	DBP	Lead hydrogen arsenate

Where are we with PBTs in REACH (2)?

- No restriction dossiers yet on PBTs
- No authorisations granted as yet (as of 2013)

- The substance evaluation process has not yet started, but intentions to evaluate 27 potential PBT/ vPvB substances, from a total of 91 substance evaluations planned between 2012 and 2014

- European Chemicals Agency (ECHA) will start with a new PBT working group in February 2012

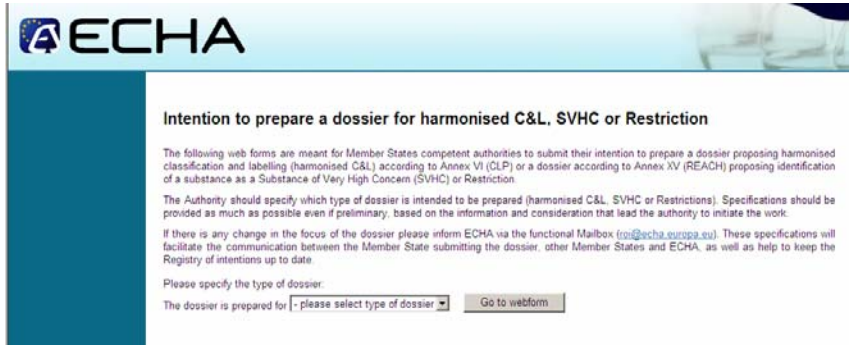
What can NGOs/ Universities do?

- ECHA goes public!
  - Information
  - Consultations Annex XV/XIV

- You can submit comments via a webform:
- Confirmed intentions are visible on the registry on Intentions

  http://echa.europa.eu/chem_data/reg_intentions_en.asp

- The Annex XV dossiers can be found on the ECHA website: http://echa.europa.eu/consultations/authorisation/svhc_en.asp



Conclusions

- PBT/vPvB assessment in REACH is in principle the responsibility of Industry
- Authorities can evaluate registration dossiers on the quality of the PBT assessment and ask for additional information

- Authorities, in cooperation with ECHA, will actively pursue screening for potential PBTs/vPvBs and regulate, if needed, PBTs/vPvBs

- NGOs and Universities can contribute data and insights via the public consultations on Annex XV dossiers and priority setting for authorisation (Annex XIV list).

Thank you for your attention!