



PBT's and vPvB's: Properties of Concern under REACH

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Overview

- Concept and Specificities of PBT and vPvB properties
- PBT's and vPvB's as Properties of Concern throughout REACH
 - Registration
 - Evaluation
 - Authorisation
 - Restriction
- Take Away Messages
- *Disclaimer: The contents of this seminar are provided for information purposes only. They are not intended as legal advice and should not be relied upon as such.*

Concept of PBT and vPvB Properties

- Definition
- Annex XIII REACH
 - Criteria
 - Information
 - Weight-of-evidence approach
 - Incl. PBT/vPvB properties of
 - Relevant constituents
 - Relevant transformation and/or degradation products
 - Excl. inorganic substances
- ECHA Guidance
 - Chapter R.11 of the Guidance on Information Requirements and Chemical Safety Assessment
 - Updated on 25 November 2014

Specificities of PBT and vPvB Properties

- New concern category
- PBT Expert Group

	Number of substances
On-going assessments (including CORAP substances)	99
Substances discussed by the PBT Expert Group (meetings 1 – 8)	121 ⁽¹⁾ (incl. 3 biocides)
Outcomes of the assessments for discussed substances:	
Sufficient information available - the substance is PBT/vPvB	5
"Not PBT" based on present information	24
Potential PBT/vPvB, further information needed but follow-up not relevant at present	1 ⁽²⁾
Refine assessment/More details on the available information needed/Testing or other new information needed	91 ⁽³⁾

(1) This is the total number of substances for which it is known that the PBT/vPvB assessment is on-going. A small part of these substances have not been discussed in the PBT EG.

(2) This is the total number of substances which have been discussed by the PBT EG, including substances, for which the assessment has already been finalised or is still on-going. Additionally, for several substances counted under the last row the initial assessor has ceased the assessment.

(3) Registered only as intermediate, or similar situation (assessment postponed)

Registration of PBT's and vPvB's

- Registrants of substances manufacturing or importing in quantities ≥ 10 tonnes (Art.14(3) REACH)
- PBT and vPvB assessment (Section 4 of Annex I of REACH)
 - Step 1: Comparison with Annex XIII criteria
 - Step 2: Emission Characterisation
 - Section 8 of CSR
- Exposure Assessment (Section 5) + Risk Characterisation (Section 6)
 - Implementation
 - Communication
 - DU obligations
- SDS (Art.31 REACH)

Evaluation of PBT's and vPvB's

- Substance evaluation
 - Art.44 REACH + selection criteria for prioritisation
 - Suspected PBT and vPvB's
 - « PBT-like substances »
 - « Known PBTs/vPvBs »
 - CoRAP update 17 March 2015
 - main initial ground of concern

- Request for further information

Evaluation of PBT's and vPvB's

- Dossier evaluation
 - Testing proposals (Art.40 REACH)
 - « *priority shall be given to registrations of substances which have or may have PBT, vPvB (...) properties* »
 - Compliance checks (Art.41 REACH)
 - Compliance of CSA / CSR with Annex I
 - New Compliance Check Strategy
 - List of substances potentially subject to compliance checks + CoRAP

- Request for further information

Follow-up to Evaluation of PBT and vPvB's

- Art.42(2) of REACH:
 - « *The competent authorities shall use the information obtained from this evaluation for the purposes of Article 45(5), Article 59(3) and Article 69(4). The Agency shall use the information obtained from this information for the purposes of Article 44. »*
 - Substance evaluation
 - Authorisation
 - Restriction

Authorisation of PBT's and vPvB's

- SVHC Candidate List
 - Art.57(d) REACH (PBT) + Art.57(e) REACH (vPvB)
 - 20 substances on Candidate List
 - SVHC Roadmap to 2020 (23 March 2015)
 - Common screening process
 - Assessment
 - Risk Management Option Analysis (RMOA)

Authorisation of PBT's and vPvB's (cont.)

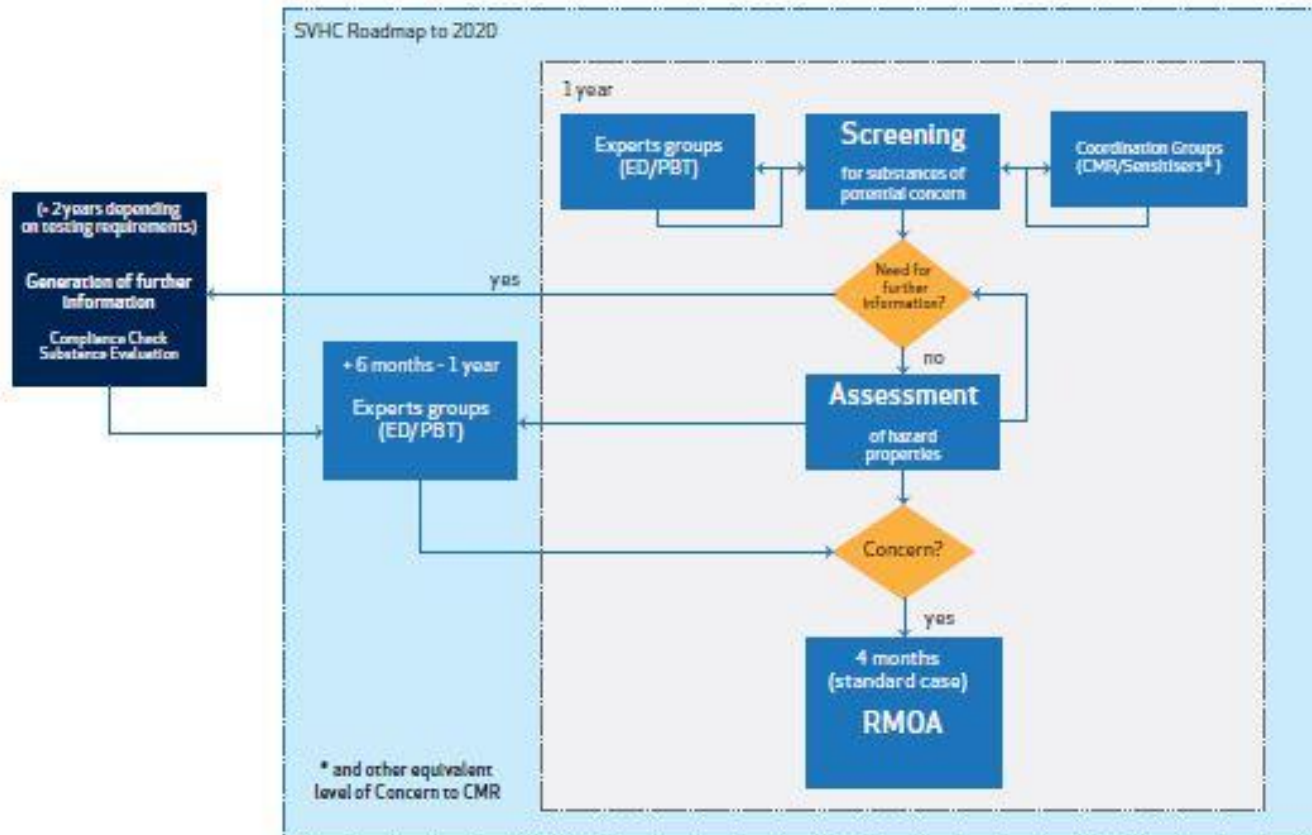


Figure 1: Overview of activities under the Roadmap with indicative timelines and links to closely related activities (compliance check, substance evaluation).

Authorisation of PBT's and vPvB's (cont.)

- Prioritisation for inclusion on the Authorisation List
 - Highest inherent property score
- Authorisation List (Annex XIV REACH)
 - 1 PBT, 1 vPvB
 - HBCDD
 - 2 PBT's/vPvB's in Draft 6th recommendation
- Application for Authorisation
 - Art.60(2): « *an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled* »
 - Not applicable to PBT/vPvB substances
 - Art.60(4): « *an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies* »

Restriction of PBT's and vPvB's

- No specific provision for PBT/vPvB's
- PBT/vPvB assessment part of Annex XV restriction dossier
- Applied: 2 ongoing processes
- Confirmation of PBT/vPvB properties?
 - Restriction following/in parallel to Authorisation
 - « The final conclusion and confirmation on the PBT and ED properties can only be achieved through the SVHC identification process. » (SVHC Roadmap)
- Assessment criteria?
 - « *When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis* » (Art.68 REACH)

Take Away Messages

- PBT/vPvB properties trigger obligations and processes throughout REACH
- Regulatory focus
- Processes feed into one another – build up a consistent scientific/technical/legal argumentation early on
- Opportunities to comment and remedies are available

Questions?

