Capacity building on compliance with chemicals legislation, with emphasis on REACH/CLP linked to Industrial Emission Directive – Technical aspects
ECRAN - 60146

PBT & vPvB Assessment

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ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE

Guidance on Information Requirements and Chemical Safety Assessment

Part C: PBT/vPvB assessment

Version 2.0

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Why PBTs and vPvBs ?

- Specific concerns occur specifically for substances that are highly accumulative and persistent
- Very high uncertainty in predicting PEC and/or PNEC
- A "safe" concentration cannot be established
- Traditional risk assessment may not address the risks adequately
- Draw parallel with known dangerous substances
- Early identification and fast implementation of risk reduction measures necessary to prevent future generations from long-term exposure

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Why PBTs and vPvBs ?

- Persistent chemicals can reach remote regions
- Bioaccumulative substances can contaminate animals at the top of food chains – long-term effects are difficult to predict
- Exposure is difficult to stop due to long half-life

➢ Current risk assessment methods considered inadequate

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PBT Assessment (TGD, 2003)

Part of the marine risk assessment

Protection targets:

- Aquatic ecosystem (incl. Sediment)
- Top predators (e.g. whales, marine birds)

Additional concerns:

- Accumulation
  - **a) effects unpredictable in the long-term**
  - **b) difficult to reverse**
- Remote areas should remain untouched

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Testing Strategies for PBTs (TGD, 2003)

P: Use of standard biodegradation testing methods and (Q)SARs

B: Use of log Kow and QSARs for BCF

T: Use of short-term toxicity data or other indicators for toxicity

How to proceed when screening data indicate potential concern

- Test first P, then B, then T (reduce animal testing)

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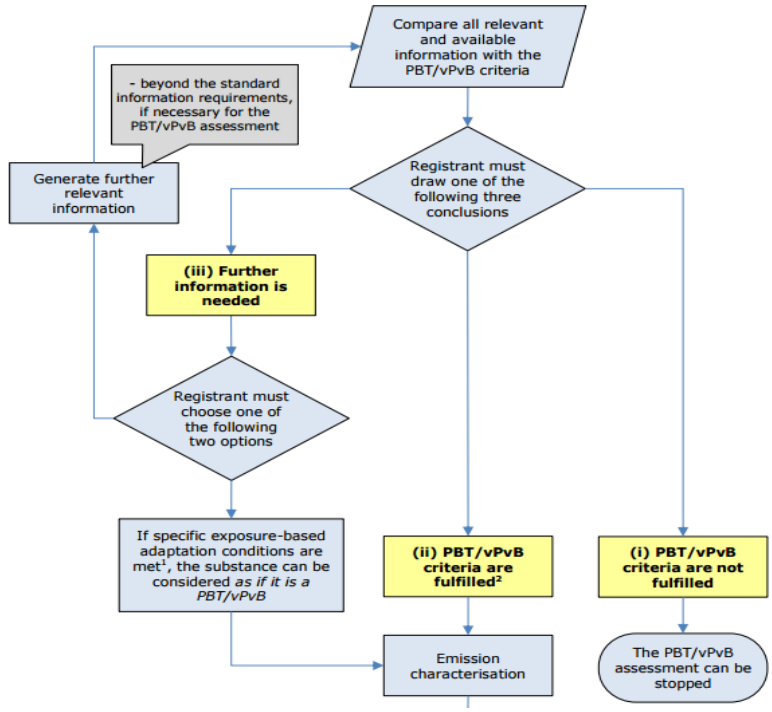
PBT/vPvB Assessment

REACH

- is required for all substances for which a chemical safety assessment (CSA) must be conducted and reported in the chemical safety report (CSR).
- in general all substances M/I in amounts of ≥10 t/a that are not exempted from the registration requirement under REACH.
- exemptions apply as described in Article 14(2), e.g. for substances present in a preparation if the concentration is < 0.1 % weight by weight (w/w), for on-site or transported isolated intermediates, and for Product and Process Oriented Research and Development.



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The objective of PBT/vPvB Assessment

REACH

- to determine if the substance fulfils the criteria given in Annex XIII, and if so, to characterize the potential emissions of the substance to the different environmental compartments during all activities carried out by the registrant and all identified uses.
- In addition, it is necessary to identify the likely routes by which humans and the environment are exposed to the substance.
- **PBT substances** = substances that are persistent, bioaccumulative and toxic,
- **vPvB substances** = are characterised by a particular high persistency in combination with a high tendency to bio-accumulate, but not necessarily proven toxicity.

These properties are defined by the criteria laid down in Annex XIII of the REACH Regulation.

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PBT/vPvB Assessment - steps

REACH

- **Step 1:** Comparison with the criteria in Annex XIII
  - 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 of his substance.
- **Step 2:** Emission Characterization (EC)
- **Step 3:** Risk Characterization (RC)

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Guidance on information requirements and chemical safety assessment Chapter R.11: PBT Assessment

This guidance describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, in the context of the chemical safety assessment.

- Part C: PBT and vPvB Assessment (Chapter R.11)

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REACH PBT criteria

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Persistence

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant. -

- T1/2 > 60 days in marine water, or
- T1/2 > 40 days in fresh- or estuarine water, or
- T1/2 > 180 days in marine sediment, or
- T1/2 > 120 days in fresh- or estuarine sediment, or
- T1/2 > 120 days in soil.

Bioaccumulation

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

- BCF > 2000 L/kg

Toxicity

- **NOEC (long-term) < 0.01 mg/L for marine or freshwater organisms, or**
- substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3), or
- there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC. -

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vPvB criteria

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Persistence

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.

- T1/2 > 60 days in marine, fresh- or estuarine water, or
- T1/2 > 180 days in marine, fresh- or estuarine sediment, or
- T1/2 > 180 days in soil.

Bioaccumulation

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

- BCF > 5000 L/kg

Table C.3-1: PBT and vPvB criteria according to Annex XIII to REACH

Property	PBT-criteria	vPvB-criteria
Persistence	A substance fulfils the persistence criterion (P) in **any** of the following situations: • $T_{1/2}$ > 60 days in marine water; • $T_{1/2}$ > 40 days in fresh- or estuarine water; • $T_{1/2}$ > 180 days in marine sediment; • $T_{1/2}$ > 120 days in fresh- or estuarine sediment; • $T_{1/2}$ > 120 days in soil.	A substance fulfils the "very persistent" criterion (vP) in **any** of the following situations: • $T_{1/2}$ > 60 days in marine, fresh- or estuarine water; • $T_{1/2}$ > 180 days in marine, fresh- or estuarine sediment; • $T_{1/2}$ > 180 days in soil.
Bioaccumulation	A substance fulfils the bioaccumulation criterion (B) when: BCF > 2000	A substance fulfils the "very bioaccumulative" criterion (vB) when: BCF > 5000
Toxicity	A substance fulfils the toxicity criterion (T) in **any** of the following situations: • NOEC or EC_{10} < 0.01 mg/L for marine or freshwater organisms; • substance is classified as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2); • there is other evidence of chronic toxicity, as identified by the classifications: STOT (repeated exposure), category 1 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) or category 2 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) according to the CLP Regulation.	-

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Screening criteria

For many substances the available data may not allow a definitive conclusion on the PBT or vPvB properties. In this case so-called screening criteria may be used as surrogate information to decide whether a substance may potentially fulfil the PBT or vPvB criteria.

Persistence

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Type of data	Criterion	Screening assignment	See section
Persistence			R.11.1.3.1
Ready biodegradability test	readily biodegradable	Not P and not vP	
Enhanced ready biodegradability test	readily biodegradable	Not P and not vP	
Specified tests on inherent biodegradability			
Zahn-Wellens (OECD 302B)	≥70 % mineralisation (DOC removal) within 7 d; log phase no longer than 3d; removal before degradation occurs below 15%; no pre-adapted inoculum	Not P	
MITI II test (OECD 302C)	≥70% mineralisation (O2 uptake) within 14 days; log phase no longer than 3d; no pre-adapted inoculum	Not P	
Biowin 2 (non-linear model prediction) and Biowin 3 (ultimate biodegradation time) **or** Biowin 6 (MITI non-linear model prediction) and Biowin 3 (ultimate biodegradation time)	Does not biodegrade fast (probability < 0.5)[3] and ultimate biodegradation timeframe prediction: ≥ months (value < 2.2) **or** Does not biodegrade fast (probability < 0.5)[1] and ultimate biodegradation timeframe prediction: ≥ months (value < 2.2)	P P	

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Bioacumulation and toxicity

Type of data	Criterion	Screening assignment	See section
Convincing evidence that a substance can biomagnify in the food chain (e.g. field data [4])	e.g. BMF > 1	B or vB, definitive assignment possible	R.11.1.3.2
Octanol-water partitioning coefficient (experimentally determined or estimated by valid QSAR)	Log Kow ≤ 4.5	Not B and not vB	
Toxicity			R.11.1.3.3
Short-term aquatic toxicity (algae, daphnia, fish)	EC50 or LC50 < 0.01 mg/L	T, criterion considered to be definitely fulfilled	
Short-term aquatic toxicity (algae, daphnia, fish)	EC50 or LC50 < 0.1 mg/L	T	
Avian toxicity (subchronic or chronic toxicity or toxic for reproduction)	NOEC < 30 mg/kg food	T	

Guidance on information requirements and chemical safety assessment ,Chapter R.11: PBT Assessment

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Outcomes from PBT/vPvB Assessment

1. The data show that **the properties of the substance meet the specific criteria**,

or

do not allow a direct comparison with all the criteria, but nevertheless indicate that the **substance is likely to have these properties**.

Emission and risk characterisation is required (i.e. characterisation of all emissions throughout the lifecycle of the substance and implementation, respectively recommendation of RMM and operational conditions (OC) that minimise exposure of humans and the environment).

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Outcomes from PBT/vPvB Assessment

2. The data show that the properties of the substance **do not meet the specific criteria**

or

do not allow a direct comparison with all the criteria but nevertheless indicate that **the substance is not likely to have these properties** and, consequently, that **the substance is not considered a PBT/vPvB.**

The PBT/vPvB assessment stops.

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Outcomes from PBT/vPvB Assessment

3. The data on the **properties of the substance do not allow a direct comparison with all the criteria and further information is needed**.

Registrant has two options:

- The registrant generates the required information (depending on the information needed, the submission of a testing proposal may be required) and concludes on the PBT/vPvB properties of the substance concerned once the lacking data are available (i.e. conclusion (1) or (2)); or
- The registrant refrains from generating further information and treats his substances as if it were a PBT/vPvB

Outcomes from PBT/vPvB Assessment

4. **Further information would be needed** to conclude on the PBT/vPvB properties of the substance. However, the registrant (for several reasons) has decided not to conduct confirmatory testing.

- If a clear decision on the properties of a substance cannot be made, either because it is not possible to characterise a substance, or since it is technically not possible to conduct testing, this lack of a clear decision does not obviate the requirement on a registrant to propose appropriate and proportionate RMMs and OCs.

Substances containing PBT/vPvB

- *A substance having a constituent with PBT or vPvB properties, which is present at a concentration of ≥80 % ;*
- *A substance having one or more constituents or impurities with PBT or vPvB properties in individual amounts equal or above 0.1 % (but less than 80%).*
- *If any constituent/impurity of a substance degrades, or is transformed into substances which have PBT or vPvB properties and if these transformation or degradation products are formed in individual amounts above 0.1% (of the weight of the initial substance). The percentage of degradation or transformation products may be indicated as for impurities or constituents with PBT- or vPvB- properties, if applicable.*

- RMM have to be considered as soon as a substance contains or degrades to PBT or vPvB substances above the threshold of 0.1%, irrespective of which of the three groups described above the substance belongs to.

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PBT/vPvB substance

- Substances are considered as PBT or vPvB substances when they fulfil the criteria for all three (or two) inherent properties P, B and T or vP and vB, respectively.

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EPA's PBT Criteria

Persistence		Bioaccumulation	Toxicity
Half-Life:		BCF:	Fish ChronicValue:
(Orange) Moderate	(Red) High Concern	Moderate (Orange) ≥ 1,000	Moderate (Orange) < 10 mg/L
Water: ≥ 2 months	> 6 months		
Soil: ≥ 2 months	> 6 months	High Concern (Red) ≥ 5,000	High Concern (Red) < 0.1 mg/L
Air: -	> 2 days		
Sed: ≥ 2 months	> 6 months		

ECHA European Chemicals Agency

ECRAN

Recommendation of the European Chemicals Agency (ECHA)

of 1 June 2009

for the inclusion of substances in Annex XIV (the list of substances subject to authorisation) of Regulation (EC) No 1907/2006

(4) ECHA has developed a paper presenting ECHA's approach for prioritising, pursuant to Article 58(3) of the REACH Regulation, substances for inclusion in Annex XIV[5]. On the basis of this approach ECHA has prioritised the following seven substances for inclusion in Annex XIV:

- 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) **vPvB**
- 4,4'-Diaminodiphenylmethane (MDA)
- Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins - SCCPs)
- Hexabromocyclododecane (HBCDD) **PBT**
- Bis(2-ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP)
- Dibutyl phthalate (DBP)

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Candidate List of Substances of Very High Concern for authorisation – PBT/vPvB substances

Name	EC Number	Reason for inclusion
Anthracene oil	292-602-7	Carcinogenic,PBT and vPvB
Anthracene oil, anthracene-low	292-604-8	Carcinogenic, mutagenic, PBT and vPvB
Anthracene oil, anthracene paste	292-603-2	Carcinogenic, mutagenic, PBT and vPvB
Anthracene oil, anthracene paste, anthracene fraction	295-275-9	Carcinogenic, mutagenic, PBT and vPvB
Anthracene oil, anthracene paste,distn. lights	295-278-5	Carcinogenic, mutagenic, PBT and vPvB
Pitch, coal tar, high temp.	266-028-2	Carcinogenic, PBT and vPvB
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	201-329-4	vPvB
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	287-476-5	PBT and vPvB
Anthracene	204-371-1	PBT
Bis(tributyltin)oxide (TBTO)	200-268-0	PBT
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified:	247-148-4 and 221-695-9	PBT