PBT-Assessment: The need for an harmonised guidance across regulations – assessment of persistence -

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Introduction

The PBT-assessment is being established across the various European substance regulations, i.e. for plant protection products (PPPs), biocides, pharmaceuticals and REACH-chemicals, but references between these regulations are sometimes lacking.
A substance should be reliably identified as a PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative) substance – or as not PBT – irrespective of the regulatory framework it is registered under. As a number of substances are registered in more than one regulatory framework, e.g. as a plant protection products (PPPs) and a biocide or a veterinary pharmaceutical, the procedure of PBT assessment needs to be harmonised to avoid conflicting results, especially for the persistence-criterion.

The aim here is to propose consistent guidance on the use of available data across regulations for P-assessment, as well as showing the implications.

The trigger values used for P-assessment are consistent among the mentioned regulations.
However, available data differ in terms of number, type and level of information across regulations.
Guidance for using these data is neither sufficient nor harmonised.
The interpretation of the data will influence the outcome of the P-assessment.

Table 1: Persistence criterion in the PBT and vPvB assessment according to Annex XIII (ECHA, 2008).

	For PBT-assessment	For vPvB-assessment
Trigger-values for the persistence-criterion	• $T_{1/2}$ > 60 days in marine water, or • $T_{1/2}$ > 40 days in fresh- or estuarine water, or • $T_{1/2}$ > 180 days in marine sediment, or • $T_{1/2}$ > 120 days in fresh- or estuarine sediment, or • $T_{1/2}$ > 120 days in soil.	• $T_{1/2}$ > 60 days in marine, fresh- or estuarine water, or • $T_{1/2}$ > 180 days in marine, fresh- or estuarine sediment, or • $T_{1/2}$ > 180 days in soil.

Temperature

REACH guidance suggests temperature normalisation. In PBT assessment of biocides and pharmaceuticals, degradation rates are normalised to 12°C. In risk assessment for PPPs, they are normalised to 20°C. For harmonisation purposes, one temperature should be selected.

Additionally, degradation conditions at 20°C in laboratory tests are not representative for natural conditions in Europe (average temperature of 12°C).

UBA suggests normalising all degradation values to 12°C.

DegT50 evaluation

In some regulatory schemes, one degradation simulation test will be available at the most. Under other regulatory schemes such as PPPs, many more studies are available for substances registered. Expert judgement is needed to evaluate their suitability for assessing the persistence.

For less than 5 values for a single compartment, the maximum value is used (worst case scenario).
If 5 or more studies are available, a statistic approach would be possible.

- The geometric mean of the studies signifies an average degradation rate, which is used in various assessment schemes (e.g. calculation of PEC_{gw} values). However it does not represent the range of degradation rates.
- The 90th percentile is more protective.

The choice of 90th percentile or geometric mean is currently discussed in connection with the level of protectiveness needed for the hazard based PBT-assessment.

Soil studies (field and laboratory)

For comparison with the PBT trigger values, degradation values have to be used, not dissipation values (i.e. in this context, leaching, volatilisation or photodegradation). Laboratory degradation values will be used for P-assessment. Field studies may also be used when conducted or evaluated according to the new EFSA scientific opinion (EFSA, 2010) if this approach has been shown to provide reliable degradation values.

Water sediment studies

Separate reliable DegT50 values for water and sediment can usually not be derived from the study results. DT_{50} values given for the water phase usually only refer to dissipation, as many substances quickly adsorb to the sediment.
Therefore, the DegT50 of the total system should be used for comparison against the two trigger values (water and sediment).
The DegT50 of a substance that is transferred into the sediment should be compared against the trigger value for sediment (120 d).
For substances that mostly remain in the water phase, the DegT50 values should be compared against the water trigger (40d).

Metabolites/ Transformation products

Substances are identified as PBT/vPvB, if they themselves, their components or their metabolites are identified as PBT or vPvB. Metabolites /Transformation products are to be considered in the assessment of all three criteria separately from their parent substances.

Estimated impact assessment

For 64 PPP active substances recently evaluated in UBA, we conducted a preliminary assessment to estimate the numbers of substances that would fulfill the P-criterion and would thus be potential PBT/vPvB substances and also potential candidates for substitution (substances fulfilling 2 of the 3 PBT-criteria).

- data from laboratory studies on degradation in soil (>120 days, table 1; exclusion of field studies since no evaluations according to the new EFSA scientific opinion (EFSA, 2010) are available yet);
- data from laboratory studies on degradation in the total system of water-sediment studies (>120 days);
- maximum value for DT50 (worst-case scenario) or geometric mean, (no consideration of the study number available for one substance);
- Temperature normalized to 12 °C or 20 °C.

Table 2: Estimation of PPP substances that fulfill the P-criteria using different evaluation parameters

Parameters		Percentage persistent in			
DT_{50} value	Temp (°C)	Soil & W/S-System	Only soil	Only W/S-System	Total
Maximum	12	45%	17%	11%	73%
Geometric mean	12	30%	3%	20%	53%
Maximum	20	34%	8%	13%	55%
Geometric mean	20	14%	3%	22%	39%

With the 90th percentile for data normalised to 12°C, about 5% less substances would be classified as persistent in soil laboratory studies compared to using the maximum (58% versus 62% (= 45% and 17%)).

Conclusions

Suggested conditions for persistence within the PBT- assessment :	
Temperature	• normalise to 12°C
DegT50 evaluation	• Expert judgement on suitability of studies • the maximum DegT50 value (worst case scenario) for less than 5 values • The choice of 90th percentile or geo mean, for 5 or more values is currently discussed
Field studies	• may only be used if reliable DegT50 can be derived
Water Sediment studies	• DegT50 of the total system should be used for comparison against water or sediment trigger values, depending on the the distribution of the substance in the compartments
Metabolites	• Always evaluated in the PBT -assessment

Implications: the current P-criteria for PBT-assessment may result in high numbers of substitution candidates for PPPs => further considerations are required.

References:
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