

The PBT Assessment of Veterinary Pharmaceuticals

A reason for equivalent concern



Ines Prutz, Jens Schönfeld, Section IV 2.2
Federal Environment Agency Dessau, Germany
Contact: ines.prutz@uba.de, jens.schoenfeld@uba.de

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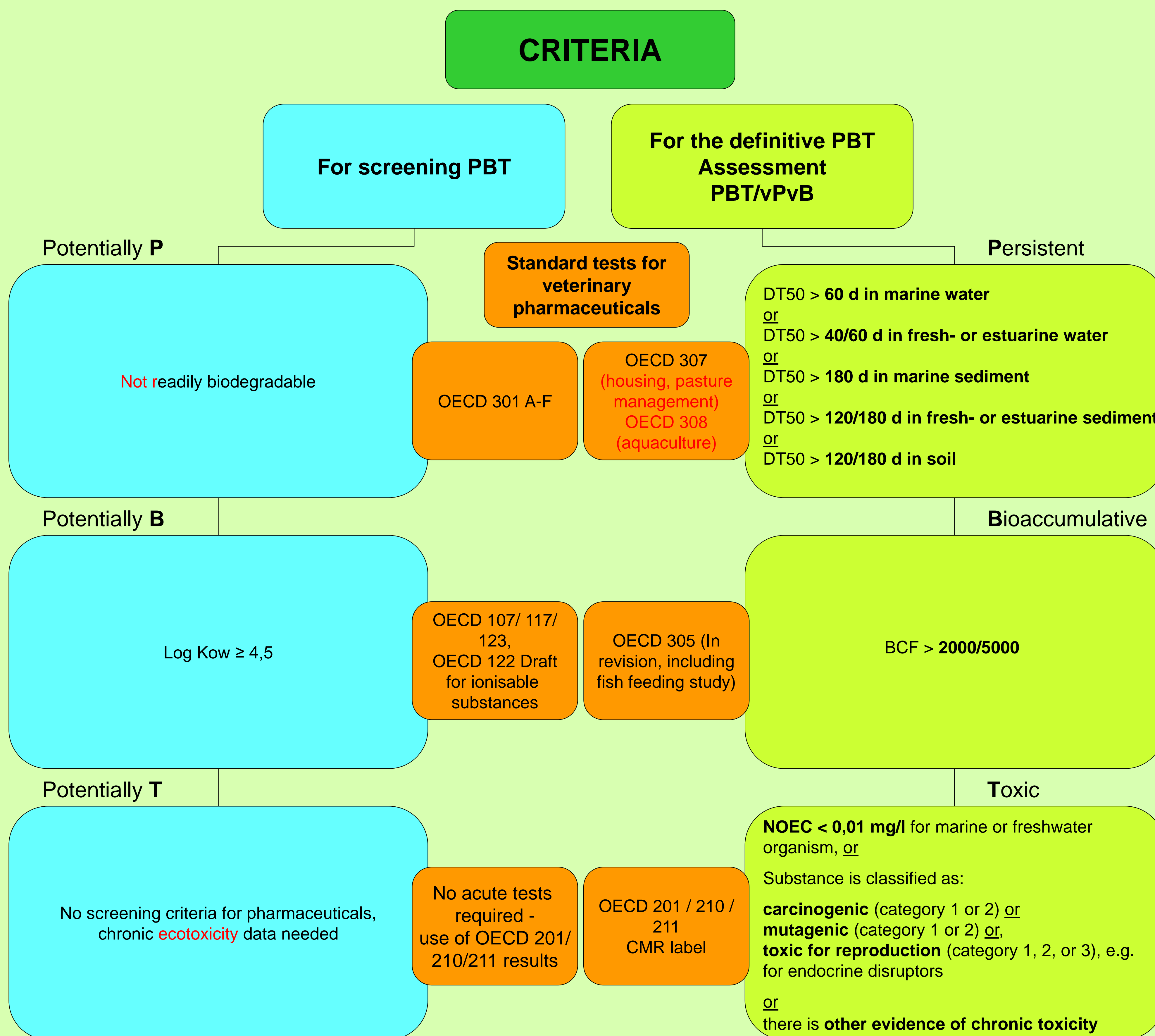
What is PBT or vPvB?

PBT Pharmaceuticals are compounds that possess the following three inherent properties as indicators of hazard:

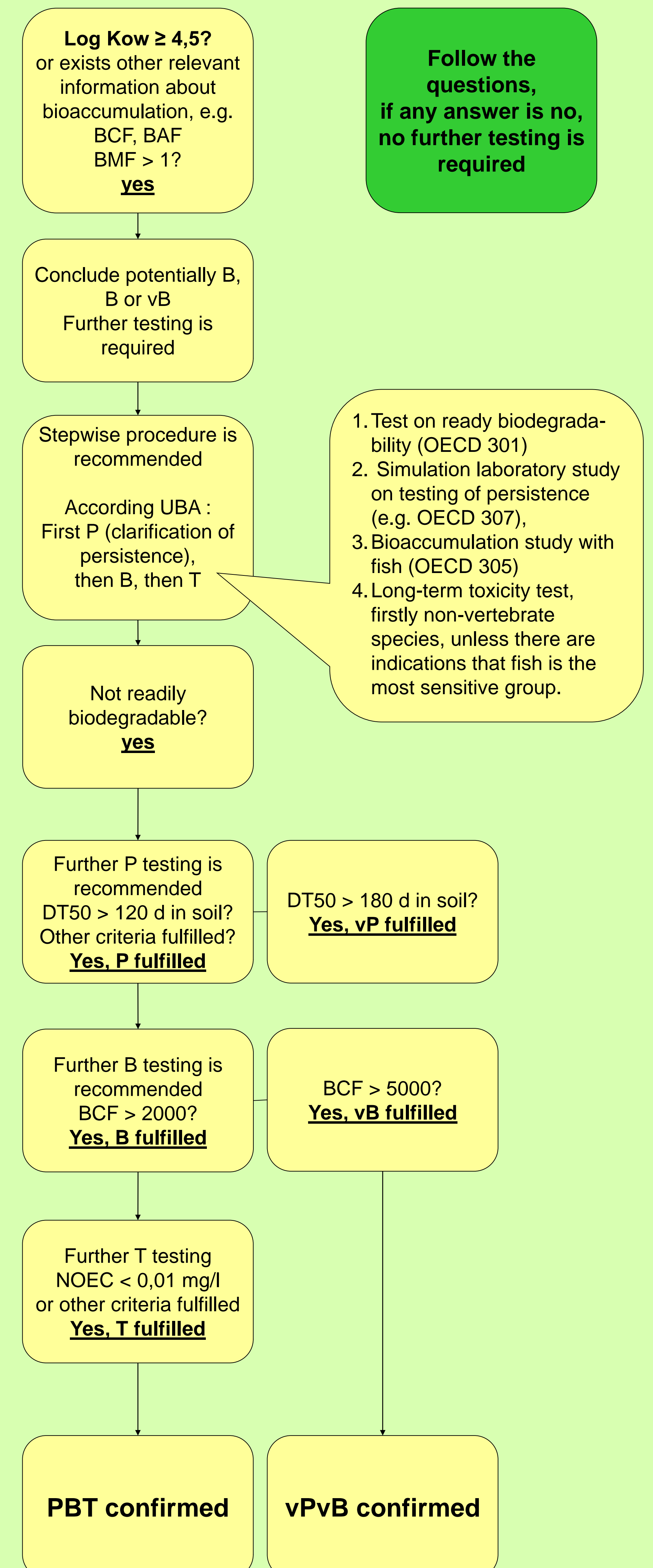
- Persistent or very persistent,
- Bioaccumulative or very bioaccumulative,
- Toxic

For PBT substances a „safe“ concentration in the environment cannot be established with sufficient reliability.
Therefore, for PBT/vPvB substances the main focus shifts from exposure to the inherent safety of a substance.
This way of thinking is called hazard assessment.

Current procedure



STEPWISE APPROACH



Open issues

Generally

- No guidance is given where in the risk assessment of VMP and how to perform the PBT assessment
- **No consequences for authorisation**
- Relevant data are submitted only in phase II, Tier B

Practically

- For determination of logD for ionisable substances no finalised guidance exists (only draft version, OECD 122)
- Indicators like BCF calculated from monitoring data can provide supplementary information on bioaccumulation

Pay attention to

- Normalisation of the DT50 values to the average European outdoor temperature of 12 °C (see TGD, point 2.3.6)
- Normalisation of BCF data to lipid content of 5 %
- Additional criteria for toxicity, e.g. endocrine disruptors, CMR substances, etc.

Outlook

- EU wide harmonisation of PBT assessment and its consequences for authorisation (ongoing discussions in CVMP and ECHA)
- Revision of VICH guidelines in view of data requirements (PBT assessment in phase I)