

# How to progress PBT assessment of petroleum UVCB substances

Online workshop on testing and assessment of petroleum UVCB substances

21 June 2021

Vincent Bonnomet  
European Chemicals Agency

## **Background: Annex XIII of REACH**

- Required for registrations >10 tpa
- Tiered assessment is possible: "screening information" (Annex XIII 3.1) and "assessment information" (Annex XIII 3.2)
- *"relevant constituents of a substance and relevant transformation and/or degradation products"*
- *"data obtained under relevant conditions"*

## Screening information

- screening studies, QSAR, ...
  - (v)P: e.g. ready, inherent, or enhanced biodeg. tests if applicable
  - (v)B: e.g.  $\log K_{ow} > 4.5$ ,  $\log K_{ow} > 2$  &  $\log K_{oa} > 5$
- Must be documented, relevant (for the information requirement) and reliable (e.g. applicability domain, uncertainties)
- Whenever available, assessment information prevails over screening information

## Assessment information

- Higher tier studies
  - (v)P: e.g. simulation tests
  - (v)B: e.g. bioaccumulation studies
  - Long-term/chronic aq. tox on 3 trophic levels and HH endpoints
- QSAR are not assessment information
- Weight of evidence: higher tier studies >> other information

## Petco substances are UVCBs

- Guidance R.11.4.2.2:
  - “Known constituents” –approach, if feasible
  - “Fraction profiling” (or “block profiling”) approach: the PBT/vPvB-properties are assumed to be the same in the fraction or to follow a regular and predictable pattern
  - Whole substance approach, if adequate
  - A combination of those approaches
- For the known constituents or block approaches:
  - assess each constituent (or block), or
  - assess one lead constituent (or one lead block)

## **In any case, the information must be relevant (and reliable)**

- The information requirement should be met
  - E.g. for (v)P, (bio)degradation should be assessed, not dissipation (potential volatilisation, NER, or other losses should be quantified)
  - Conditions should be relevant for the PBT/vPvB assessment (e.g. half-lives for a temperature of 12°C)

Thank you!

