The Persistence Assessment Tool (PAT): implementing a methodology for data quality evaluation and weight of evidence in persistence assessments

INTRODUCTION

- Regulatory persistence assessment involves comparing degradation half-lives to criteria in environmental compartments. Other relevant information (e.g. biodegradation screening tests, non-standard experiments, quantitative structure activity relationships (QSARs), field data, etc) should be considered following a weight of evidence (WoE) determination.
- Evaluating data quality (reliability and relevance) and applying it in a robust, transparent and consistent WoE determination presents challenges, especially for challenging substance types.
- To address these challenges, Ricardo developed a free software tool – the Persistence Assessment Tool (PAT) – in conjunction with Concawe and the International Collaboration on Cosmetics Safety.
- The tool provides a step-by-step process that systematically captures, evaluates and combines degradation data to assess persistence in line with global regulatory frameworks. A multimedia fate model is also included to calculate overall persistence (P_{ov}).

AIM: To implement a methodology for the systematic evaluation of data quality and weight of evidence determination, providing support to practitioners for the robust, consistent and transparent assessment of persistence under different regulatory frameworks.

METHODOLOGY

1 Data quality scoring

- Rules have been developed to evaluate the quality of individual studies.
- Scores are produced for **individual fields > categories of fields** (e.g. test system, inoculum, kinetics) > **reliability/relevance >** and **overall quality**.
- Identified **difficult substances** have certain **flags** and considerations during scoring, such as testing volatile substances in an open system.
- Fields are scored according to individual quality criteria. Some fields have potential **'critical fails'**, such as evidence of using a pre-adapted inoculum.

2 Line of Evidence (LoE) evaluation

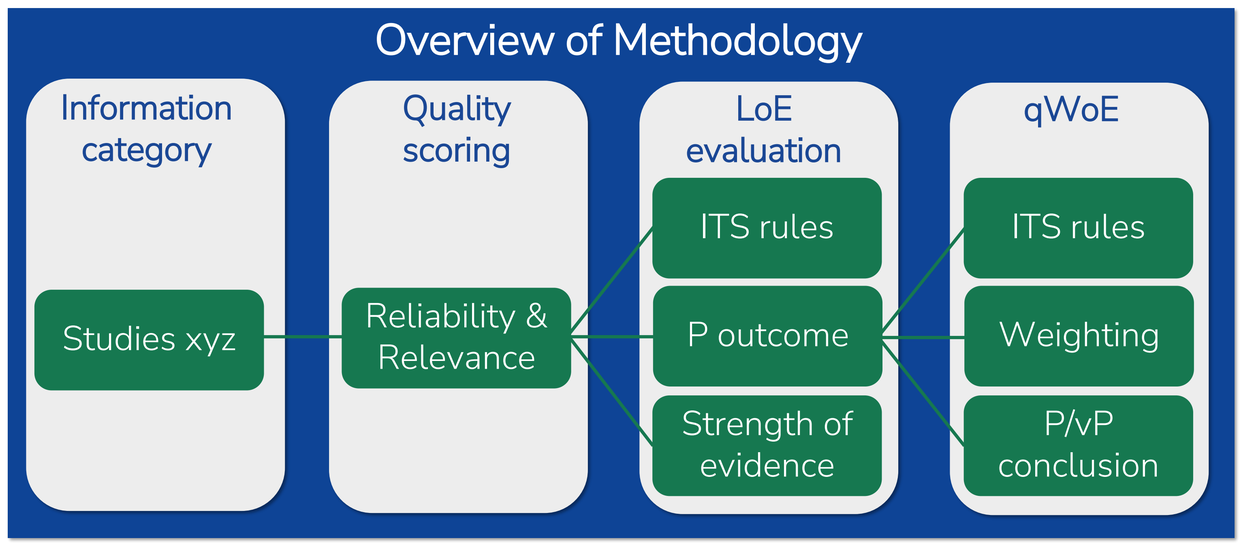
- Each study is combined with other studies from the same line of evidence (LoE) to reach conclusions at the LoE level.
- The LoEs are: simulation tests for water, sediment and soil, screening tests, QSARs, monitoring data, and other relevant data ('other WoE').
- The evaluation includes an assessment of the **persistence outcome** and the **strength of the evidence** for each LoE.
- Depending on the LoE, strength of evidence may incorporate **quantity**, **quality, magnitude** and **consistency**.
- A representative temperature-corrected half-life is produced for the simulation test data. The determination of the representative half-life for the LoE depends on the number of suitable data available.

3 Quantitative Weight of Evidence (qWoE)

- The overall conclusion of the persistence assessment is reached following a step-wise scheme:

1. Simulation test LoE → **2. RBT LoE** → **3. qWoE (all LoEs)** → **4. Consistency check**

- The workflow prioritises the **simulation test LoE** (Step 1) as these generate definitive half-lives for comparison to P/vP criteria, followed by the **ready biodegradability test (RBT) LoE** (Step 2), as per the EU REACH integrated testing and assessment strategy (ITS). Steps 1 or 2 can be switched off.
- If a conclusive outcome cannot be reached from Step 1 or 2, a **qWoE methodology** is applied considering all LoEs together (Step 3).
- The overall score for each LoE determines its **persistence indication** and the size of the score indicates **strength of indication**.
- The overall scores of each LoE are then averaged to determine a mean score and subsequent overall conclusion for the persistence assessment.
- A **consistency check** (Step 4) is also performed to determine how many LoEs align with each persistence outcome.
- The multimedia fate model SimpleRisk4PAT (based on SimpleBox) has been integrated to calculate P_{OV} using representative half-lives from PAT.



CONCLUSION

- The PAT methodology enables a systematic evaluation of data quality and WoE determination of persistence under EU REACH and other regulatory frameworks.
- There is a need for stakeholder input to support further validation, consensus-building and uptake of the methodology.

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