

The Persistence Assessment Tool (PAT): Implementing a Methodology for Data Quality Evaluation and Weight of Evidence in Persistence Assessments



Megan Griffiths¹, Chris Hughes², Simon Cook¹, Dik van de Meent³, John Parsons³, Blanca Serrano Ramón⁴, Katherine Santizo⁵, Delina Lyon⁵, Amelie Ott⁶
1: Ricardo, Harwell, UK | 2: Embark Chemical Consulting, Chester, UK | 3: Association of Retired Environmental Scientists (ARES), Odijk, NL | 4: ECETOC, Brussels, BE | 5: Cefic-LRI, Brussels, BE | 6: Concawe, Brussels, BE | 7: International Collaboration on Cosmetics Safety (ICCS), New York, USA

Email contact: megan.griffiths@ricardo.com

Background

- Regulatory persistence assessments require the comparison of degradation half-lives to set criteria in environmental compartments, with all relevant lines of evidence (LoE) considered together in a weight-of-evidence (WoE) approach.
- However, current guidance is lacking in supporting the evaluation of data quality and the integration of data into a transparent and consistent WoE determination.
- There are also issues for substances whose properties or compositions render them difficult to evaluate using standard methods.
- To address these challenges, a free software tool – the **Persistence Assessment Tool (PAT)** – was developed to support the evaluation of persistence.
- The PAT follows a stepwise methodology to systematically capture, evaluate and combine information to reach robust conclusions for persistence assessments.
- The methodology has been developed in accordance with principles of the EU REACH regulatory framework, test guidelines and guidance, whilst being customisable to accommodate different regulatory practices.
- A multimedia fate model, SimpleRisk4PAT, is also included to optionally calculate overall persistence (P_{ov}).



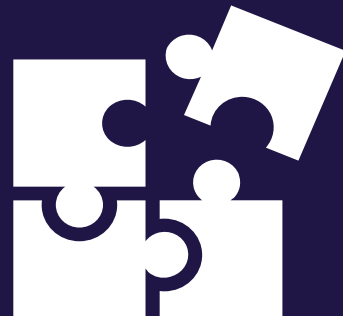
Information gathering

Information on the substance and its persistence data (screening tests, soil/sediment/water simulation tests, monitoring data, QSARs, and other relevant data) is input



Study quality evaluation

The reliability, relevance, and overall quality of diverse persistence data is numerically scored and then rated as low, medium, or high



Line of evidence evaluation

Different studies are combined to derive P/vP conclusions for each LoE, considering strength, P/vP outcome, and consistency of evidence. Representative half-lives are also determined from simulation data



Weight-of-evidence determination

Information from different LoEs are weighted and integrated into a single persistence conclusion, with consistency assessed

The PAT is identified as a **weight-of-evidence tool for persistence assessments** in the new ECHA **Guidance on the Application of the CLP Criteria**. To ensure its continued relevance and effectiveness, it is important to improve the tool based on user feedback. **An updated version of the PAT is currently being developed.**

Upcoming Updates to the PAT

MORE FLEXIBILITY

- Enable **temperature correction of half-lives to be disabled**.
- Provide a **free text field for assessor comments** in the results sheet.
- Change **water test volume input to a numerical value** instead of just >100 mL or <100 mL.

ROBUST METHODOLOGY

- Ensure all **critical fails and study quality flags** are working.
- Indicate where only a **single study is available** for a line of evidence.
- Ensure all **geomean half-life rules** are correct.
- Reflect the use of **lag (not log) phase** for inherent biodegradability in the most recent ECHA R.11 guidance.

BETTER USEABILITY

- Widen the column widths** of some tables to ensure all study quality flags are readable.
- Add the **settings that have been used** to the Export files.
- Increase the **clarity of the LoE conclusions** summary graph.

Further stakeholder input is needed to support consensus-building and uptake of the methodology. Scan the QR code to download the PAT!

