



CONCAWE/Cosmetics Europe Long Range Science Strategy (LRSS)/CEFIC Long-range Research Initiative (LRI) **Request for Proposals (RfP)**

Title:

Developing a Persistence Assessment Tool (PAT) for P assessment under REACH

Background

Hazard assessments under REACH include an assessment of PBT properties of substances. Persistence is a prominent element and usually the first tier in PBT assessments. Persistence assessment relies on a tiered assessment of standardized tests, many of which are compared with formal criteria for defined environmental compartments (i.e., freshwater, soil, sediments, etc.). Various recommendations exist in REACH guidance R.11 on the additional lines of evidence for persistence assessment.

However, many chemicals (e.g., volatile compounds, multi-constituent substances, etc.) are not amenable to standardised tests like OECD 307/308/309 and require data developed through non-standard methods. Still, many scientific data generated through non-standard methods are rejected for persistence assessment by European authorities because they do not fit existing standardized test guidelines and are regularly assigned no weight in the persistence assessment. This presents policy barriers to using new science to inform chemicals management, particularly for chemicals that do not fit within the applicability domain of standardised tests.

Inconsistency in the assessment of persistence data in the PBT assessment framework leads to unpredictability in regulatory decisions¹. Therefore, use of R.11 guidance alone does not allow industry to effectively anticipate the rationale applied in decision making.

Weight of evidence (WoE) approaches have the potential to alleviate these challenges in persistence assessments. A WoE approach takes into account all available data, especially those that are conflicting, to arrive at a consensus assessment. OECD² provides guidance for how this may be done in a qualitative fashion, with the following Figure 1 providing an overview of this method.

¹ Hughes, C.B., Brown, D.M., Camenzuli, L. et al. Can a chemical be both readily biodegradable AND very persistent (vP)? Weight-of-evidence determination demonstrates that phenanthrene is not persistent in the environment. *Environ Sci Eur* 32, 148 (2020). <https://doi.org/10.1186/s12302-020-00427-1>

² OECD (2019), Guiding Principles and Key Elements for Establishing a Weight of Evidence for Chemical Assessment, Series on Testing and Assessment No. 311, Environment, Health and Safety Division, Environment Directorate.



Figure 1: OECD 311 Key evidence for Weight of Evidence chemical assessment.

However, all of these factors, including policy considerations and the subjective nature of WoE, can result in inconsistent conclusions on persistence in PBT assessments. Therefore, a transparent WoE framework and decision-making tool is needed to support consistency in decision making and reconcile conflicting data – ergo the proposed Persistence Assessment Tool (PAT). An assessment tool will provide consistency and transparency in the way data is assessed in the currently applied method of Weight of evidence assessment which is based on expert judgement. Similar to the goals of the Bioaccumulation Assessment Tool (<https://arnotresearch.com/bat-reg/>), the PAT should provide a clear assessment of the available lines of evidence factoring in important experimental considerations (e.g., biomass quality and quantity) to facilitate a science-based consensus on the persistence of a substance in water, sediment and soil as requested under annex XIII of the REACH regulation EC 1907/2006. The need for the PAT has been recognised by industry, resulting in the collaboration between Concawe, Cosmetic Europe LRSS and Cefic LRI, with Concawe and Cosmetics Europe LRSS funding this project.

To expand the utility of the PAT for other regulatory regimes, there may also be optional modules to include considerations of multimedia interaction to accommodate an Overall Persistence (Pov) approach.



Objectives

The main objective of this project is to develop a Persistence Assessment Tool (PAT) which should:

1. Provide a transparent mechanism to assess persistence data in a Weight of evidence approach for water, sediment and soil.
2. Clearly communicate how the lines of evidence are gathered and weighed.
3. Should explicitly reference REACH Guidance (and testing guidelines).
4. Allow the inclusion of novel approaches with justifications clearly documented.
5. Optionally include multimedia fate modules to facilitate an Overall Persistence calculation.

This project should include a communications plan to receive and share ideas with the research and regulatory community.

Scope

- Review available guidance (OECD, REACH, Cefic LRI ECO 52, literature) on WoE in persistence assessments and make recommendations for improvement (especially for cases where no clear guidance exists for specific testing information).
- Develop a Persistence Assessment Tool with emphasis on clear documentation of rationale for different lines of evidence in WoE assessment, with transparent quantitative scoring where applicable. The WoE framework should be clearly outlined based on available literature including but not limited to: SCENIHR– weighing of evidence and expression of uncertainty, 2012; Solomon et al. 2013 Env Sci Europe 25:10; OECD WoE principles 2019; ECETOC <https://www.ecetoc.org/taskforce/moving-persistence-p-assessments-into-the-21st-century/>.
- While the applicability of the PAT should focus on petroleum hydrocarbons and cosmetic substance as example chemicals, the PAT should be broad enough to capture multiple chemical classes.
- Depending on the cost of the project, the PAT may include an optional multimedia fate context to organize and interpret the persistence data.
- The guidance associated with the tool should include a brief discussion on the applicability domain of standard OECD tests that are used in REACH Guidance.
- Develop a communications plan to receive and distribute ideas on the PAT with the broader research and regulatory community.

Deliverables

The output of this project will be:

- 1) the Persistence Assessment Tool, consisting of a user-friendly interface such as an Excel sheet, a method for gathering data, a scoring matrix for the lines of evidence for each compartment (water, sediment, soil), an optional multimedia fate context for organizing and interpreting the P data, and a method for collating and interpreting the lines of evidence to produce a consensus persistence assessment.



- 2) At least 2 examples of the operation of the PAT using one petroleum substance and one cosmetic substance, demonstrating a P and non-P conclusion.
- 3) A final report containing an executive summary (2 pages max), a main part (max. 50 pages excluding figures and annexes) and a detailed bibliography. It is expected that the findings will be developed into submission of at least one manuscript for a peer reviewed publication, with optional poster(s) and presentation(s) at suitable scientific conference(s).
- 4) A communications plan including a workshop to disseminate the PAT. The funding for the workshop, open access of publications, and other communications is separate to this RfP.

Cost and Timing

Start in January 2022, duration of 12 months

Budget in the order of €100,000, funded by Cosmetics Europe LRSS and Concawe.

Partnering / Co-funding

Applicants should provide an indication of additional partners and funding opportunities that can be appropriately leveraged as part of their proposal. Partners can include, but are not limited to industry, government/regulatory organisations, research institutes, etc. Statements from potential partners should be included in the proposal package.

Possible regulatory and policy impact involvements / Dissemination

Applicants should provide an indication on how and where they could play a role in the regulatory and policy areas. Dissemination plans should also be laid out.

DEADLINE FOR SUBMISSIONS: October 21th, 2021 at 11:59 PM.

Please submit your application using the “Project Proposal Form” to aott@cosmeticseurope.eu.



PAT-Project-Proposal
-Form-2021.doc

For any questions, please contact delina.lyon@concawe.eu or aott@cosmeticseurope.eu.