

Initiative towards improving our understanding of persistence in the 21st century



Key findings from Sept 2018 Workshop held in Helsinki

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Abstract and background

Recent developments in the understanding of factors which influence the outcome of persistence (P) assessments of chemicals (particularly biodegradation) are not being fully recognised in existing regulations and environmental risk assessments. This combined with failure to recognise limitations of existing biodegradation tests can potentially lead to chemicals being incorrectly labelled as 'P', 'vP' or not P.

A key challenge is to reach consensus on how new scientific knowledge and test improvements can be incorporated into existing regulatory frameworks to ensure appropriate classification of the hazards posed by a wide range of chemicals. To explore opportunities to address this issue a multi-stakeholder Persistence Workshop was held which provided an opportunity to-

- Initiate a process to re-examine the fundamentals of biodegradation and what existing test methods can achieve
- Disseminate key findings from recent research projects and ongoing initiatives to assess how these interrelate and can be used to improve persistence assessments.
- Develop proposals and opportunities regarding how the current situation can be improved

Multi stakeholder participation

6 representatives from consultancies/Contract Research Organisations, 17 from industry, 16 from academia and 36 from European regulatory bodies

Workshop structure

Divided into 3 principle sessions on:-

- 1) Role of microbial community in degradation testing (adaptation, variability, growth & cometabolism)
- 2) Impact of environmental factors on bioavailability and degradation
- 3) Interpretation of the OECD simulation test results and identified challenges

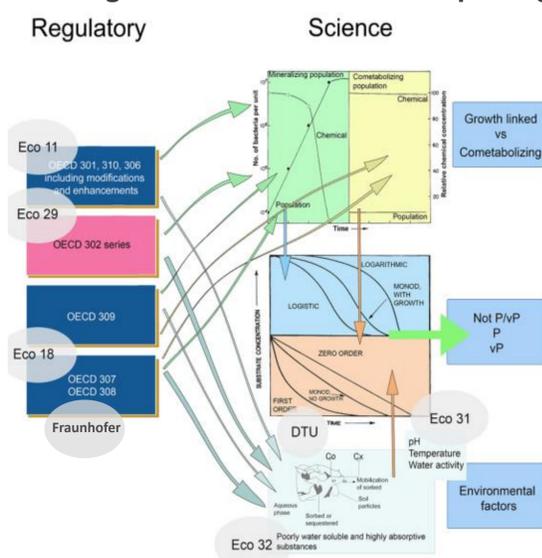
For each session

- Q&A based on session summaries to distil key messages and propose how these could be incorporated and/or used to improve guidance

Plus poster session

- Posters assessed on their relevance for risk assessment

Linking research activities to help bridge the gap to ensure sound science

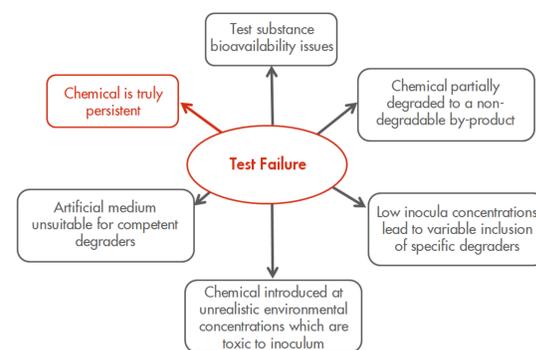


Schematic prepared to try to link Cefic LRI 'Eco' persistence (see <http://cefic-lri.org/projects/>) with Concawe (e.g. Danish Technical University (DTU) and Fraunhofer projects).

Workshop provided the opportunity to:-

- Improve links between key 'persistence' research activities
- Recognise importance of linking specific research projects to provide a more holistic persistence assessment
- Assess how key messages and links from this research can be disseminated to improve persistence assessments
- Discuss how new knowledge can be used in regulations
- Recognise the links between persistence (P), Bioaccumulation/bioavailability (B) and Toxicity (T)
- Assess and address specific challenges posed by UVCBs⁽¹⁾

REASONS WHY OECD READY BIODEGRADATION TESTS CAN FAIL



Key outcomes/main messages from each of the sessions

Session 1 Role of microbial community

Need for robust screening (enhanced) biodegradability tests

Use widely different fresh water inocula, more concentrated seawater inocula?	Not widely accepted by regulators. Need to improve/revise guidance? OECD 306 could have used enhanced inocula concentrations if reliable methods were available when original guidance was written
Include adaptation as tool to improve screening test?	Not widely accepted by regulators, but need for discussion as adaptation can be a key removal mechanism Exposure methods need to be environmentally relevant Assess influence on pre-exposed inocula on simulation (e.g. OECD 309) test results
Use of specific analyses at low concentrations in an OECD 309 test set-up	Required to assess UVCB and multi-constituent substances Consider use in combination with ready biodegradation tests (RBTs) or enhanced test (mineralization)

Session 2 Impact of environmental factors

Status and considerations for current OECD tests

- OECD tests do not adequately cover the space of environmental factors that are important for degradation – how can this be resolved?
- More research & guidance needed on effects of exposure history, microbial community biomass/composition, soil properties etc. on test outcomes
- As it is unlikely that all variability of testing outcomes can be removed how can the issue of inherent variability be redressed?
- Biodegradability indicators (e.g. half-lives) derived from current simulation tests do not adequately describe 'true' biodegradation rates of poorly soluble substances due to influence of bioavailability limitations
- Consider risk-based approach using bioavailability/activity?
- Combine novel testing methods with modelling incorporating biodegradation and partitioning to assess compartment specific biodegradability?

Session 3 Interpretation of simulation tests

Potential considerations

- Improving study reproducibility, reliability and comparability will allow consistent comparison for benchmarking and interpretation of P data
- Need for robust modified studies to support and help interpret current OECD tests especially for multi-constituent/UVCB testing
- Regulatory studies need to be performed within the scope of the intrinsic properties of a substance e.g. high K_{ow}/high K_{aw} substances will increase the number of chemicals that can be assessed for P
- Correct half-life (t_{1/2}) based on bioavailable fraction K_{BIO}?
- 1. Need to reduce reliance on assumptions and better define K_{BIO} to increase its use and interpretation in P assessments
- 2. Currently drivers of degradation both abiotic and biotic cannot be quantified to refine this value
- Need new test criteria? Standardised sediment?

Posters and discussions

The workshop and parallel poster sessions indicated that a lot of previous research findings plus concerns raised by industry and leading academics had not been recognised in the ECHA guidance. In fact some posters provided data to directly contradict recent changes in guidance from the EU ECHA PBT Expert Group notably on the influence of temperature on degradation in simulation studies, persistence of some poly aromatic hydrocarbons and importance of taking adaptation into account. These issues need to be openly discussed and where decisions are deemed to be questionable a mechanism established so these can be appropriately challenged and where necessary subject to independent evaluation. The challenge is to provide alternatives and improvements to the current testing paradigm to increase confidence that the persistence properties of chemicals are correctly classified. This workshop was seen as an important step in identifying opportunities to try and improve understanding of factors affecting persistence of chemicals (particularly UVCBs) and assess how the current regulatory system can be improved to identify 'persistent' chemicals of real concern.

Next steps

- The key findings from the workshop will be published
- An ECETOC Task Force (TF) will work on areas of interest identified during the workshop (<http://www.ecetoc.org/taskforce/moving-persistence-p-assessments-into-the-21st-century/>)
- The TF terms of reference for this will be refined at a kick off meeting in Q3/2019

Other opportunities?

- SETAC focussed symposium - extend beyond EU as this is a global issue
- Develop collaborative (e.g. EU Framework) projects aimed at better defining persistence

The workshop identified limitations of existing methods and the need to agree on how ongoing research can help to move persistence assessments of all chemicals into the 21st Century

⁽¹⁾ Unknown or Variable Composition, Complex Reaction Products and Biological Materials