ECETOC TF ‘Moving persistence (P) assessments into the 21st century’

Developing a new paradigm to assess the biodegradation potential of chemicals

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Content of presentation

- Overview of the new ECETOC Task Force ‘Moving persistence (P) assessments into the 21st century’
- Summary of the relevant recent/ongoing research projects
- Some further thoughts on concepts to be considered
Moving P assessment into the 21\textsuperscript{st} century TF - overview

Background

- A range of recently completed and ongoing research activities relating to improving the understanding of persistency and biodegradation (e.g. Cefic LRI, Concawe projects, ECHA NER projects)
- Time dedicated to discussion of the topics of persistency and biodegradation (e.g. 2012 ECETOC workshop\textsuperscript{1}, 2018 Cefic LRI-Concawe workshop\textsuperscript{2})

⇒ Opportunity to consolidate the findings from these activities to develop a practical knowledge base

Deliverables

- Framework documentation (e.g. flow chart backed up by case studies) for best practice in degradation testing and weight of evidence approaches for P assessment
- Potentially a stakeholder workshop, e.g. SETAC Pellston Workshop

Status/timing

- Awaiting final approval from ECETOC Scientific Committee
- Start 2019 with timeline 1 year

\textsuperscript{1} ‘Assessing Environmental Persistence’ Paris 2012
\textsuperscript{2} ‘Recent developments in science supportive to the persistence/biodegradation assessment’ Helsinki Sept 2018
Moving P assessment into the 21st century – relevant projects

Role of microbial community in degradation testing (adaptation, variability)

Cefic LRI ECO 11.3 Ring test to revise OECD 306 in seawater

Hypothesis: Perceived high rate of false negatives in OECD 306, potentially due to high variance in bacteria cell counts and microbial diversity.
Method: Ring-test with 13 CROs and 5 compounds for OECD 306 with two key modifications: 100-fold concentration of seawater to better represent bacterial diversity in sampled environment and increasing test duration (up to 120 days).
Conclusion: Improved OECD 306 test is more reliable.
Next step: SPSF submission to OECD.

Cefic LRI ECO 29 Application of chemostat systems to include adaptation of microbial communities in persistency testing

Hypothesis: Current biodegradation screening protocols underestimate biodegradability.
Method: Expose activated sludge to the test chemical in chemostats for several months. Compare OECD 310 results before and after exposure.
Conclusion: 1. Adaptation of activated sludge community for some chemicals (4-chloroaniline, N-methylpiperazine, metformin) and not for others (diclofenac, carbamazepine). 2. Pre-exposure of sludge to test chemical for one week significantly lowered the variation in degradation potential, initially observed between sludge from 5 different STPs.
Next step: Next steps: 1. How and to what extent should adaptation be incorporated into OECD degradation testing 2. Possibility of pre-exposure to decrease variation in results between sludge sources.
Challenges in conduct and interpretation of simulation degradation tests, including bioavailability considerations

Hypothesis: Dynamic partitioning between the solid aerobic/anaerobic phase and water during incubation confound interpretation of results of OECD 308/309.


Conclusion: 1. Large flexibility of experimental options leads to high variability in outcomes -> need for further standardization.
2. A bioavailability- and biomass-normalized \textit{k'bio parameter} can unify observations from different water-sediment test system setups.

Next step: TBC
Moving P assessment into the 21st century – relevant projects

Challenges in conduct and interpretation of simulation degradation tests, including bioavailability considerations

Cefic LRI ECO 32  *Environmental risk assessment of poorly soluble substances: Improved tools for assessing biodegradation, (de)sorption, and modelling*

**Hypothesis:** Challenges for conducting and interpretation simulation degradation tests with poorly soluble substances. Can we distinguish between bioavailability-limited degradation and intrinsic persistence?

**Method:** Use of passive dosing system and modelling to decouple biodegradation and (de)sorption kinetics.

**Results:**
- Dodecylbenzene = biodegradable, but sorption limited bioavailability (in natural sediment inocula);
- Pyriproxyfen = intrinsic persistence

Evaluating the biodegradation of poorly soluble substances is possible by combining novel testing methods and modelling work, with assessment/simulation of multiple endpoints simultaneously and the application of novel persistence indicators (second order rate constants, considering microbial growth).

**Conclusion:**

**Next step:** TBC
Moving P assessment into the 21st century – relevant projects

Challenges in conduct and interpretation of simulation degradation tests, including bioavailability considerations

Cefic LRI ECO 31.2 A multivariate approach to identify key parameters influencing the degradation rates of organic chemicals in water, water-sediment, and activated sludge systems

Hypothesis: Multivariate approaches can be developed to uncover key parameters influencing degradation rates in different environmental compartments

Method: Regression and classification techniques developed to derive insights from literature-reported degradation data. First phase of project investigated key factors driving aerobic biodegradation rates of pesticides in soil (focus driven by data availability)

Conclusion: 1. Key factors = application history (adaptation), soil texture, biomass concentration, organic carbon content, soil sampling depth; 2. Environmental factors specified in OECD TG are rarely reported and likely do not adequately cover the relevant space.

Next step: 1. Second phase of project will investigate other compartments - water, water-sediment and activated sludge; 2. Consider improvements to OECD TGs to enhance interpretation of results.

ECHA 2018 project: NER formation Improving the interpretation of Non-Extractable Residues (NER) in degradation assessment

Concawe projects at Danish Technical University Effect of concentration, cometabolism and temperature on biodegradation kinetics
Moving P assessment into the 21st century – relevant projects

Interrelating Concawe and Cefic LRI Research activities to develop a new paradigm to improve assessing persistence.
Growth linked versus co-metabolism

Growth linked degradation has several advantages over co-metabolic degradation. Therefore, when assessing persistency, greater emphasis should be placed on tests (experiments) detecting only growth-linked biodegradation in comparison to those also determining biodegradation through co-metabolic transformations.

Robustness and applicability of tests (OECD 301 series and OECD 310) detecting only growth linked biodegradation should be increased in a tiered approach to determine persistency by allowing longer test periods, improved (e.g. more concentrated, diverse) inocula, and especially adaptation (pre-exposure).

Co-metabolic (gratuitous) degradation can only be demonstrated with simulation tests (TG 307 308 309) because of low test substance concentrations and high biomass concentrations. These tests were not developed to assess gratuitous biodegradation.
Moving P assessment into the 21\textsuperscript{st} century – concepts

Biodegradation versus biodegradability

Environmental half-lives of substances supporting growth do change constantly because the number of competent organisms (catalysts) vary with the availability of the substance. The same is true for co-metabolic processes.

Biodegradation = Biodegradability X Environmental conditions. Biodegradability should be used to determine the persistence of chemicals (assigning to bins).

Assessing half-lives should therefore be replaced by assigning substances to categories or bins. Half-lives of categorized chemicals should be determined by default.

Non-persistency of chemicals based on biodegradation mechanisms increases in the following order:

- No degradation detected
- Co-metabolic (gratuitous) degradation (first order kinetics)
- Growth-linked biodegradation (enhanced and inherent biodegradability tests)
- Growth-linked biodegradation (ready biodegradability tests)

Consider developing a weighted point system using results of ECO 31 projects.
To prioritize chemicals supporting growth one should strengthen use tests only detecting growth-linked biodegradation. (extended test duration and exposure of inocula). The opposite occurred because adaptation is thought to be harmful.

**Key message** Adaptation is a natural occurring phenomenon far more important than gratuitous degradation.

Half-lives of chemicals do not exist. All half-lives for regulatory purposes should be assigned by default (bins).

**Key message** bins.

Detecting co-metabolic degradation in “simulation” tests should occur within a few hours to days. Longer duration times detect growth-linked biodegradation.

**Key message** Develop less expensive tests to assess co-metabolic degradation.
Moving P assessment into the 21\textsuperscript{st} century

“All microorganisms are everywhere; conditions and resources determine who flourishes”

M Beijerink 1851-1931

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