Recent Work of ECETOC Task Force (TF):
Moving Persistence (P) Assessments into the 21st Century

Webinar
13.00 – 15.00 CEST
29 September 2020
Webinar practical information

- **This webinar will be recorded** for internal use only (not posted publicly)
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- Please **turn off your camera** 📹
- Please post your **Q&A questions** in the Chat function at anytime as follows: “Name, Affiliation: Question”
- Posted questions will be picked up by the **moderator** in the Q&A session 📒 Chat
- **Slides** will be shared after the event
- Use the **white icon** in the top right corner of WebEx screen to optimise your view - ‘side-by-side view’ may present the best format’
# Webinar agenda

**Objective:** Share recent progress of this ECETOC Task Force with the scientific community, and also to provide timely input to support potential updates to the REACH PBT guidance

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<th>Presenter/Contact</th>
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<td>13.00 – 13.15</td>
<td>Introduction</td>
<td><strong>Aaron Redman</strong>, ExxonMobil (TF Chair)</td>
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<tr>
<td>13.15 – 13.45</td>
<td>Presentation: Conceptual framework for improving P assessments</td>
<td><strong>Delina Lyon</strong>, Concawe (TF member)</td>
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<td>13.45 – 14.00</td>
<td>Q&amp;A</td>
<td><strong>Sylvia Jacobi</strong>, Albemarle (ECETOC PBT EG rep)</td>
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<td>Presentation: Scientific concepts and methods for improving P assessments</td>
<td><strong>Russell Davenport</strong>, Newcastle University (TF member)</td>
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<td><strong>Kathrin Fenner</strong>, EAWAG (TF member)</td>
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<td>14.45 – 15.00</td>
<td>Outlook and close</td>
<td><strong>Pippa Curtis-Jackson</strong>, Environment Agency UK (TF member)</td>
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Introduction

Aaron Redman, ExxonMobil, TF Chair

13.00 – 13.15
ECETOC is a collaborative space for leading scientists from industry, academia and governments to develop and promote practical, trusted and sustainable solutions to scientific challenges which are valuable to industry, as well as to the regulatory community and society in general.
Task force: terms of reference

- **Objective**: Develop an improved *framework* and best practices for persistence and degradation assessments based on *progress* in the scientific understanding of the underlying process

- **Timeline**: 18 months (initiated July 2019)
## Task force

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<tr>
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<td>Redman</td>
<td>ExxonMobil (TF Chair)</td>
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<td>Jens</td>
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<td>Environment Agency UK</td>
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<td>Russell</td>
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<td>Newcastle University</td>
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<td>Kathleen</td>
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<td>Andreas</td>
<td>Schäffer</td>
<td>RWTH Aachen University</td>
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**TF Members**
- Industry
- Academia
- Regulatory body

**TF Stewards**

**TF Scientific Secretary**
Task force: main deliverables

- Two peer-reviewed papers:
  - **Perspectives paper**: strong focus on adapting OECD 2019 Weight-of-Evidence guidance for use in persistence assessment
  - **Methods paper**: review of recent experimental methods and strategies for evaluating absolute and relative degradation of chemicals

- Disseminations:
  - SETAC SciCon 2020: 1 platform & 2 poster presentations
  - Webinar 29 Sept 2020
  - Joint ECETOC/Cefic LRI/Concawe workshop – Helsinki May 2021
Task force: timeline for paper prep

TF Kick-off meeting July 2019

TF drafting papers

Inviting reviews from authorities and key stakeholders

Revision and submission to peer-reviewed journal

Q3 2019

Q4 2019

Q1 2020

Q2 2020

Q3 2020

Q4 2020
Acknowledgements

- Task force members (and Philipp Mayer, DTU)
- External co-authors
  - Erin Maloney, University of Saskatchewan
  - José Julio Ortega-Calvo, Spanish National Research Council
  - Stefan Trapp, DTU
- External regulators and selected experts for review of manuscripts
- ECETOC Secretariat and Scientific Committee
Conceptual Framework for Moving P Assessments into the 21st Century

Aaron Redman, Jens Bietz, John Davis, Delina Lyon, Erin Maloney, Amelie Ott, Jens Otte, Frédéric Palais, John Parsons, Neil Wang

13.15 – 13.45
Definition of persistence

- "Propensity for a chemical to remain in the environment before being transformed by chemical and/or biological processes in a particular emission compartment (e.g., air, water, soil or sediment)"

- Persistence is inversely correlated to degradability

- ‘Degradability’ describes *how completely* and *how quickly* a chemical will degrade in a particular environment
Definition of persistence cont.

Persistence = Intrinsic properties of the substance (intrinsic persistence) + Environmental conditions (environment-dependent persistence)
How is persistence currently evaluated in Europe?

- Compartment-specific half-life criteria, with half-lives determined by biodegradation testing

### Table R.11—5: Persistence (P/vP) criteria according to Annex XIII to the REACH Regulation and related simulation tests.

<table>
<thead>
<tr>
<th>According to REACH, Annex XIII, a substance fulfils the P criterion when:</th>
<th>According to REACH, Annex XIII, a substance fulfils the vP criterion when:</th>
<th>Biodegradation simulation tests from which relevant data may be obtained include:</th>
</tr>
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<tbody>
<tr>
<td>The degradation half-life in marine water is higher than 60 days, or The degradation half-life in fresh- or estuarine water is higher than 40 days, or</td>
<td>The degradation half-life in marine, fresh- or estuarine water is higher than 60 days, or</td>
<td>OECD TG 309: Simulation test – aerobic mineralisation in surface water</td>
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<td>The degradation half-life in marine sediment is higher than 180 days, or The degradation half-life in fresh- or estuarine water sediment is higher than 120 days, or</td>
<td>The degradation half-life in marine, fresh- or estuarine sediment is higher than 180 days, or</td>
<td>OECD TG 308: Aerobic and anaerobic transformation in aquatic sediment systems</td>
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<td>The degradation half-life in soil is higher than 120 days</td>
<td>The degradation half-life in soil is higher than 180 days</td>
<td>OECD TG 307: Aerobic and anaerobic transformation in soil</td>
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</table>
Challenges with current P assessment

1. Compartmental half-lives based POPs, from old studies

2. Screening and higher tier test methods are not broadly applicable to all chemical types

3. Half-lives are variable, depending on measurement method and test parameters

4. Single compartment behaviour does not reflect persistence in overall environment

5. Other degradation/fate processes overlooked, e.g., photolysis
Task force objective

- Propose an integrated assessment framework that combines multimedia approaches to organize and interpret data using a clear WoE approach to allow for a more consistent, transparent and thorough assessment of persistence.
Weight-of-Evidence is recommended for P assessment in Europe

1. Substance is readily biodegradable?
   - yes → Not P/vP
   - no → Substance is potentially P/vP. Is there other information which coherently provides proof of non-persistence or persistence?

2. Screening information (Table R.11-4):
   - Positive enhanced ready biodegradation test and other data supporting?
   - Specific inherent test positive with non-adapted inoculum → Not P and not vP
   - Negative enhanced ready biodegradation test?
   - Specific inherent biodegradation test negative → Potentially P and vP

3. Other information useful in a weight-of-evidence approach:
   - Abiotic degradation
   - Applicable QSARs
   - Monitoring data
   - Simulation test results
   - In situ/field degradation study results
   - Other (testing and non-testing information)
Re-introducing the concept of overall persistence ($P_{ov}$)

- $P_{ov} \rightarrow$ environment as a single, unified set of connected media

- $P_{ov}$ calculation using multimedia fate and transport models (MFTMs)
  - multi-phase partitioning and environmental fate properties to determine residence time, predict persistence ($P_{ov}$)
  - assume mass conservation across the entire system, while accounting for thermodynamics, inter-media transfer, input processes (emissions), and degradation

- Concept of $P_{ov}$ raised many times since introduction in 1979 (incl. ECETOC 2003 Technical Report No. 90)

- OECD $P_{ov}$ and LRTP Screening Tool - 2007

- $P_{ov}$ recently proposed as suitable replacement for compartment-specific half-lives in P assessment (ECCC, 2016)
Data to feed into WoE for overall persistence

- Hydrolysis rates
- Photolysis rates
- Oxidation rates
- Phys-chem properties supporting degradation
- QSAR/modeling results
- Behavior of analogous substances
- Field, monitoring data
- Existence of biodegradation pathways
- Biodegradation rates, half-lives

Substance manufacture, use, disposal + Phys-chem properties
Proposed schematic of a WoE approach adapted for P assessment
(adapted from (OECD, 2019))

<table>
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<tr>
<th>Problem formulation</th>
<th>Evidence collection</th>
<th>Evidence evaluation</th>
<th>Evidence weighing</th>
<th>Evidence integration/reporting</th>
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</table>
| ▪ Set the hypothesis  
  ▪ Specific endpoints and/or final decisions | ▪ Assemble all lines of evidence  
  ▪ Use unit world model concept to identify relevant lines of evidence and data gaps | ▪ Use established data quality metrics to screen evidence  
  ▪ Determine data relevance using unit world or MFTM (P_{ov}) | ▪ Score relevant lines of evidence  
  ▪ Assign weight to evidence | ▪ Evaluate consistency in evidence  
  ▪ Assess impact of residual uncertainty |
| ▪ Establish relevant lines of evidence  
  ▪ Identify knowledge gaps | | ▪ Determine data reliability and uncertainty  
  ▪ Determine relevance | | |
Obtaining the right level of data for $P_{ov}$ assessment

**Initial $P_{ov}$ assessment**
- Using available or estimated parameters (Bonnell et al 2018; Gouin et al 2012)

**Evaluation of $P_{ov}$ result**
- Identify the relevant compartments/processes
- Compare against benchmark, e.g., $P_{ov}$ for POPs $\geq 195$ days (Scheringer 2009)
- Uncertainty can be evaluated by sensitivity analysis and/or risk profile or proximity to thresholds

**Refine $P_{ov}$**
- Incorporate higher tier data as informed by intermediate analysis step
Previous examples of the use of WoE and $P_{ov}$

- **Giesy et al. (2014)** – chlorpyrifos
  - Plenty, variable data – Used geometric mean of half-lives
  - Field data

- **Brandt et al. (2016)** – substituted phenolic benzotriazoles
  - QSARs, biodegradation models, Environmental monitoring, Sediment core analysis
  - Summary narrative approach

- **Bridges & Solomon (2016)** – cyclic volatile methyl siloxanes
  - Environmental monitoring, laboratory data, field studies, MFTM
  - Proposed quantitative WoE (next slide)

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**Learnings & Comparison to OECD WoE approach**

- Must first evaluate quality of studies (e.g., Klimisch scoring)
- Weight is to differentiate data sources, not for evaluating quality
- Final decision must be transparent
Quantitative WoE approach
(Bridges & Solomon, 2016)
Goal: consistent, transparent and thorough P assessment

**Problem formulation**
- Set the hypothesis
- Specific endpoints and/or final decisions

**Evidence collection**
- Establish relevant lines of evidence
- Identify knowledge gaps

**Evidence evaluation**
- Determine data reliability and uncertainty
- Determine relevance

**Evidence weighing**
- Score relevant lines of evidence
- Assign weight to evidence

**Evidence integration/reporting**
- Evaluate consistency in evidence
- Assess impact of residual uncertainty

**Evidence evaluation**
- Use established data quality metrics to screen evidence
- Determine data relevance using unit world or MFTM ($P_{ow}$)

**Evidence weighing**
- Consider quantitative WoE

**Evidence integration/reporting**
- Complete Persistence Assessment based on unit world concept and WoE,
- Determine persistence of substance using appropriate metrics ($P_{ow}$ half-life, other relevant endpoints)

**Problem formulation**
- Hypothesis: substance is degradable (biotic or abiotic, any compartment)
- Endpoints: $P_{ow}$ half-life in standard or nonstandard tests (Davenport et al 2021)

**Evidence collection**
- Assemble all lines of evidence
- Use unit world model concept to identify relevant lines of evidence and data gaps

**Evidence evaluation**
- Use established data quality metrics to screen evidence
- Determine data relevance using unit world or MFTM ($P_{ow}$)

**Problem formulation**
- Specific endpoints and/or final decisions

**Evidence evaluation**
- Determine relevance

**Evidence weighing**
- Assign weight to evidence

**Evidence integration/reporting**
- Complete Persistence Assessment based on unit world concept and WoE,
- Determine persistence of substance using appropriate metrics ($P_{ow}$ half-life, other relevant endpoints)
Co-authors on “Conceptual Framework for Moving P Assessments into the 21st Century”

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Q&A

Moderator: Sylvia Jacobi, Albemarle

13.45 – 14.00
Scientific Concepts and Methods for Moving P Assessments into the 21st Century

Russell Davenport, Pippa Curtis-Jackson, Philipp Dalkmann, Jordan Davies, Kathrin Fenner, Laurence Hand, Kathleen McDonough, Andreas Schäffer, Cyril Sweetlove, José Julio Ortega-Calvo, Amelie Ott, John Parsons, Stefan Trapp, Neil Wang, Aaron Redman

14.00 – 14.30
Content

- Introduction
- Major challenges by theme
  - Microbial characteristics
  - Obstacles with test substance
  - Testing/abiotic factors
  - Linking lab to field
  -----------------------
  Modelling
- Current and future options
- Translating science into policy
- Conclusions
Introduction
chemicals – an Earth system threat

- > 350,000 chemical & mixtures\(^1\)
- Planetary Boundaries for Chemicals\(^2-4\)
- Persistence central proxy for exposure\(^2-4\)

A safe operating space for humanity in the “Anthropocene”

Rockström et al., 2009 Nature

\(^{1}\)Wang et al., 2020 EST  \(^{3}\)MacLeod et al., 2014 EST
\(^{2}\)Diamond et al., 2015 EI  \(^{4}\)Persson et al., 2013 EST
Introduction: importance and regulatory use

Persistent Organic Pollutants (POPs)*

- Soil (6 months)
- Sediment (6 months)
- Water (2 months)

Persistent, Bioaccumulative, Toxic (PBT)* / very Persistent, very Bioaccumulative (vPvB)*

- Soil (>120/180 d)
- Sediment (>120/180 d)
- Water (>40/60 d)

Stockholm Convention (2001)

- Plant Protection Products (1107/2009)
- Industrial Chemicals (REACH)
- Biocidal Products (528/2012)

Persistence

Screening Tests (e.g., OECD TGs 307, 308, 309)

Simulation Tests (e.g., OECD TGs 307, 308, 309)

* Additional criteria to fulfill POP or PBT / vPvB classification: Bioaccumulation, long-range transport, (POP only), toxicity (PBT only)
Introduction: issues

- Current P assessment based on:
  - methods developed >30 years ago
  - a narrow range of chemical properties

- Persistence not a single fixed physico-chemical property
  \[= \text{intrinsic substance property} + \text{environmental conditions}\]

- One test-one environmental condition ≠ real environment

Evaluate recent progress and future directions for improving such test methods
Challenge: microbial source, sampling & characteristics

10³⁻¹⁰¹² “species”

10³⁰ bacteria

Microbial community similarity

Lifestyles and processes tests exclude:
Biofilms (40-80% of communities)³
Anaerobic³
Adaptation⁴,⁵

Approx. cell concentrations:

10¹⁻¹⁰⁷/mL

10⁴⁻¹⁰⁷/mL (OECD TG309)

10⁸/mL

10⁸⁻¹⁰⁹/mL

10⁵⁻¹⁰⁷/mL

10¹⁰/g

Biodeg test:

Screening¹
Simulation

Outcome

Outcome

t₁/₂ varies > x 10 (²)

Wu et al., 2019 Nat.Microbiol.

¹Kowalczyk et al., 2015 EES
²Latino et al., 2017 ESPI
³Flemming & Wuertz 2019 NRM
⁴Poursat et al., 2019 CEST
⁵Itrich et al., 2015 EST
Accounting for microbial abundance to improve tests

## Screening tests

- OECD 306 test
- OECD306CB
- Revised test mBST
- New test mBST

## Simulation tests

- OECD 308
- DegT_{50,\text{sed}}
- DegT_{50,\text{w}}
- DT_{50,w}
- DegT_{50,\text{system}}

## Methods

- Flow cytometry

### Characterising microbial diversity

- DNA → mRNA → Ribosome (rRNA) → Protein (enzymes)

---

1. Ott et al. 2020 EST
2. Honti et al., 2016 CEST
3. Brown et al., 2019 JMM
Obstacles with test substance

Simultaneous parallel processes to biodegradation

Additional issues

- Low substance concentrations
- Multiconstituent substances (e.g. UVCBs)$^4$
- Substance toxicity$^5$

1. Shrestha et al., 2019 EST
2. Ortega-Calvo et al., 2015 EST
3. Schäffer et al., 2018 ESE
4. Hammershøj et al., 2019 EST
5. Timmer et al., 2020 Chemos.
Overcoming obstacles with substances

Passive dosing for low solubility\(^1\)

Desorption extraction for bioavailable fractions\(^2\)

Silylation derivatisation for type 1 and 2 NER\(^3\)

NER type 1: sequestered, entrapped, strongly sorbed
NER type 2: strongly, covalently bound
NER type 3: biogenic, partly contained also in types 1 and 2

Total concentration (Not measurable)

Total extractable concentration (Organic solvent)

Bioavailable concentration (Desorption extraction: ISO/TS 16751)

C\(_{\text{free}}\) (Passive sampling)

Biodegradation (OECD tests 307 & 308)

Soil or sediment

Water

Microorganism

Microbial membrane

Tenax

\(^1\)Birch et al., 2018 EST
\(^2\)Ortega-Calvo et al., 2020 EST
\(^3\)Schäffer et al., 2018 ESE
\(^4\)ECETOC, 2013
Testing & abiotic factors

Siloed tests

Hydrolysis
pH

Photolysis

Biodegradation

Combined test

Biodegradation

Irradiated OECD TG 308\(^1\)
Irradiated OECD TG 309\(^2\)

\(^1\)EU, 2013
\(^2\)Hand & Moreland, 2014 ETC
Testing & abiotic factors - temperature

- Chemical reaction temperature-dependence predicted by the Arrhenius equation
- ECHA guidance states OECD TG 309 to be carried out at 12 °C
- $Q_{10}$ of 2.58 to correct for tests carried out at other temperatures (developed for pesticides in soil)
- Assumes a single $E_a$ value for all environments and complex microbial communities

Brown et al., 2020 STOTEN

Meynet et al., 2020 EST
Linking lab P assessment to the field

- Persistence
  \[=\text{intrinsic substance property} + \text{environmental conditions}\]
- Lab assessments constrained by test design and conditions

McDonough et al., 2018 STOTEN

McLachlan et al., 2017 EST
Comber & Holt, 2010

Q: How can we measure persistence?
A: Relativity!

Fold-difference in amine oxide effluent concentrations

Lab assessed predictions and field measurements
Modelling

• Predict microbial biotransformation half-lives
• Predict microbial biotransformation products
  • Metabolites
  • NER

Databases

• Requirement for metadata
• Pathway data e.g. Eawag-BBD/PPS & envipath.org
  Latino et al., 2017 ESPI

Inverse modelling for biotransformation rates

Honti et al., 2016 EST
Trapp et al., 2018 EST

QSBRs

• Improvements in machine-learning
• Strategies to widen datasets through normalization e.g. biomass concentration.
• Group substances based on enzymatic transformation\(^1\)\(^-\)\(^3\).

\(^1\)Achermann et al., 2018 EST
\(^2\)Nolte et al 2018 ESPI
\(^3\)Wang et al., 2018 Chemos.
Translating science into policy

- Method validity and ratification
  - Reliability scores
  - Limitations in current test
  - Time to ratification

- Knowledge, skills and data discrepancies
  - Academia/industry versus guidelines
  - Contract Research Organisations (CROs)
  - Data reporting

- Early engagement
Conclusions

- Persistence is non-trivial and complex
- Scientific advances could improve the precision and accuracy of P assessments
- Time of implementing advances needs to be accelerated (< 10 years)
- More efficient collaboration between academia, regulators and industry
Q&A

Moderator: Kathrin Fenner, EAWAG

14.30 – 14.45
Outlook

Pippa Curtis-Jackson, UK Environment Agency

14.45 – 15.00
Regulatory perspective

- Demonstrating the safety of a substance is the responsibility of the Registrant
- Persistence assessment evolves slowly
  - Integrated testing strategy (ECHA guidance)
  - Testing, Weight-of-Evidence, read-across
  - Guidance on interpretation (R7 and R11)
Regulatory perspective

- A global appetite for change amongst regulatory bodies must be inspired

- Regulators do recognise that advances have been made in science underpinning persistence assessment that may not be in the guidance

- Regulators realise that to assist in this change we must prioritise supporting the development of additional standardized intermediate tests (potentially ring tested at an OECD level), that could be read-across to the legal criteria, and do not undermine legacy conclusions
Regulatory perspective

- Always remember when working to improve the science of persistence assessment
  - The current assessment approach is precautionary
  - Any replacement standard and interpretation must be similarly precautionary
  - Before acceptance any new study or way of working must be proved i.e. introducing chemical benchmarking to studies and improving our microbial population understanding will need validating
Regulatory perspective

- Applicability, standardisation and agreement on interpretation between both registrants and regulators must be agreed

- Ideally new/replacement tests should ideally be quicker, more reproducible, accurate, reliable and comparable than that currently used for conclusion
OUTLOOK

- Set precedent
- Use the improved *framework*
- Use the improved *scientific understanding* and new methods

**MOST CHEMICAL REGULATORS ARE SCIENTISTS TOO**

*We share a common language*
Aims of this Task Force

- Develop an improved *framework* and best practices for persistence and degradation assessments based on *progress* in the scientific understanding of the underlying process.
Ongoing & future work by ECETOC and Cefic LRI

- **ECETOC/Cefic LRI/Concawe joint workshop** on Moving P assessments into the 21st century – May 2021 - TBC

- **Cefic LRI ECO 52**: ‘Bioavailability, complex substances and overall persistence (BCOP): Three themes to deliver a step-change in persistence assessments’ - Christopher Hughes, Ricardo, UK

- **Cefic LRI ECO 55**: RfP title ‘Assessing the impact of sample collection on microbial population and validity criteria in the OECD 309 surface water mineralisation test’

- Persistence Assessment Tool – next step to improve consistency, transparency & implementation of WoE
Thank you

ECETOC Task Force: Moving persistence assessments into the 21st Century

For more information, please contact:

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