My view on Good Quality Data

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SETAC

promotes……

- the advancement and application of **scientific research** related to contaminants and other stressors in the environment

- the use of science in environmental **policy and decision-making**

- **education** in the environmental sciences

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Revisiting Communication Strategies at SETAC Europe

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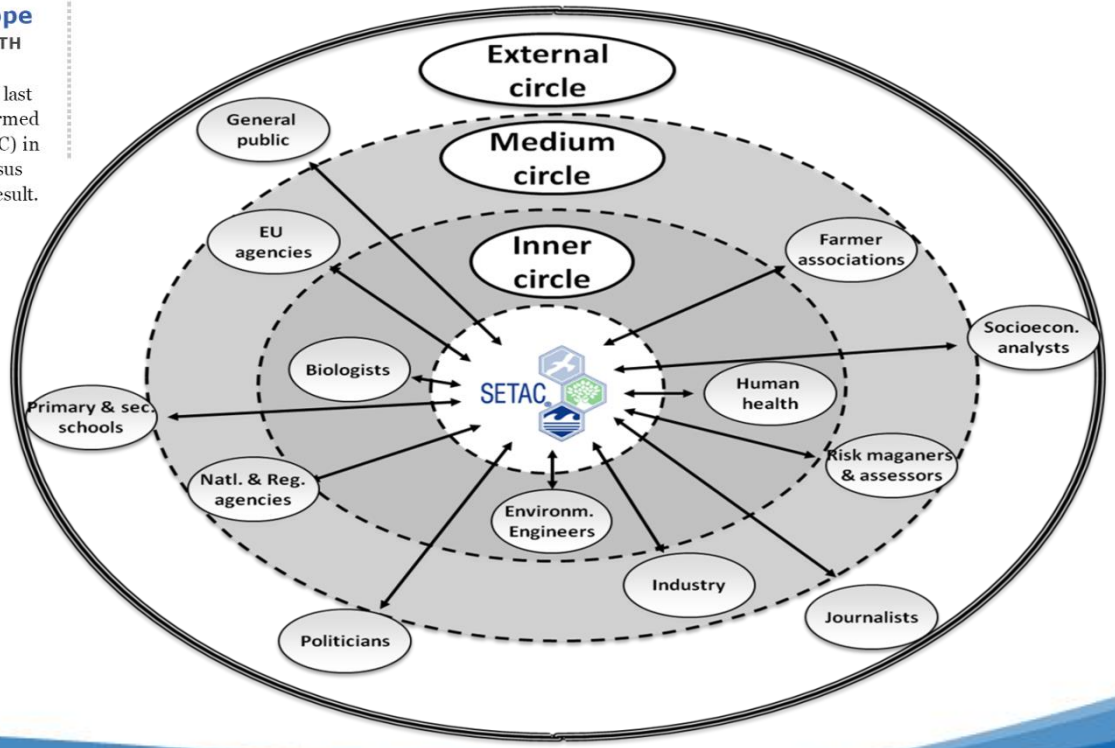
SETAC Europe started a process for strengthening communication strategies last September during the long-range planning (LRP) meeting with the newly formed SETAC Europe Advisory Group on Science and Risk Communication (SCIRIC) in Antwerp, Belgium. Following this dialogue, the participants achieved consensus on several major initiatives and developed actions for implementation as a result.



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Ortega-Calvo et al.
ES&T, 2015. 49, 10255-10264

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From Bioavailability Science to Regulation of Organic Chemicals

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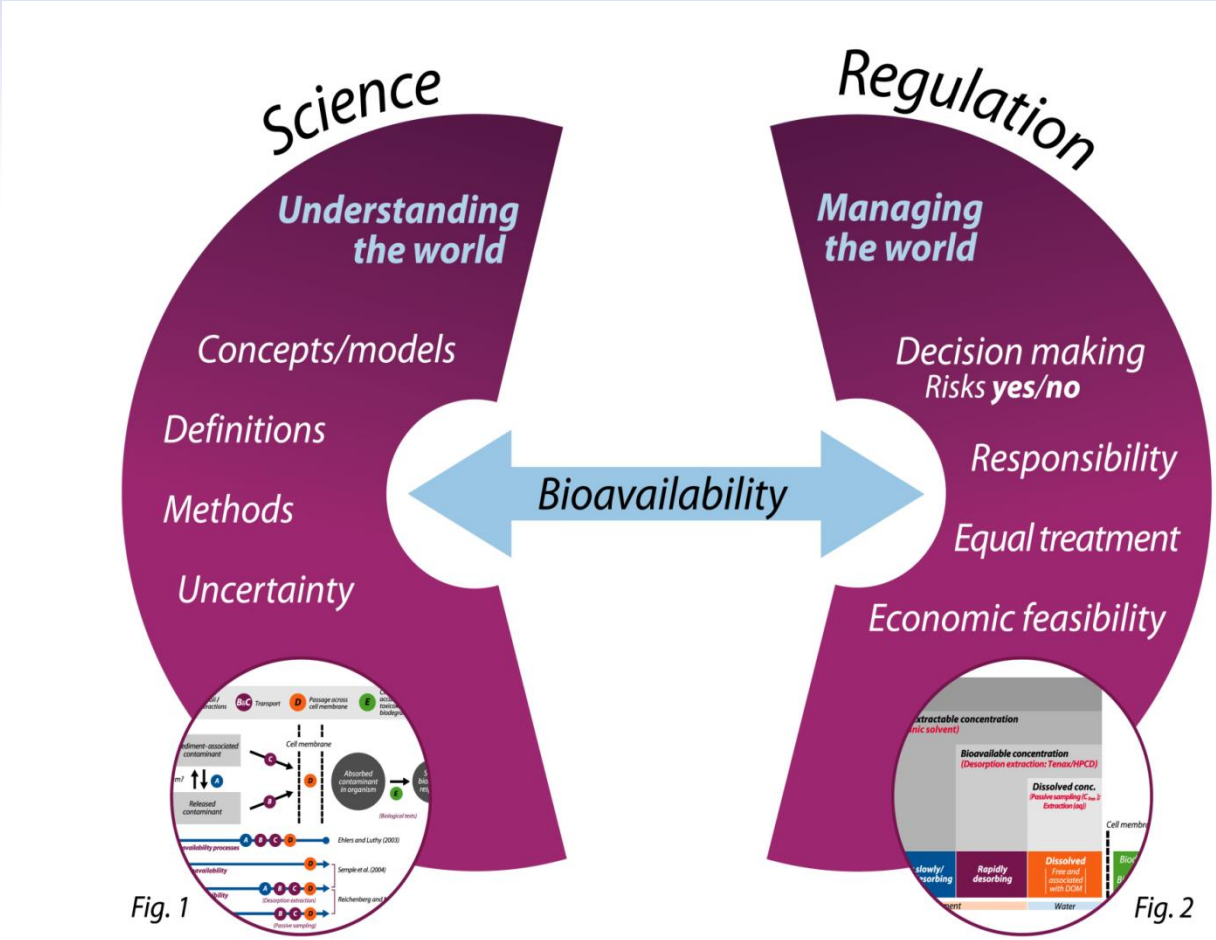
Bringing different worlds together



Open Call Collection OC-2016-2

Proposal Reference OC-2016-2-21324

Title: From Bioavailability Science to Regulation of Organic Chemicals

Acronym: Bio-AV

Summary

The bioavailability of organic chemicals (persistent organic pollutants or POPs, pesticides, biocides, pharmaceuticals and others) in soil and sediment is an important area of scientific research. However, this area remains only partially recognized by regulators and industries working in the environmental sector. Based on the positive experiences from the previous implementation with metals, regulators have recently started to consider bioavailability within retrospective risk assessment (rRA) and remediation frameworks for organic chemicals. In this regard, realistic decision-making in terms of hazard definition and priority considerations that result in optimised cost allocation while ensuring protection of the environment and public health can be achieved. However, the implementation of bioavailability for rRA remains difficult because scientific developments on bioavailability do not always translate into practical approaches for regulators.

The human, material and economic resources needed to perform bioavailability research already exist within Europe. In this COST Action, different disciplines will be integrated to create a 'virtual institute', where the strategic aspects of bioavailability science and regulation are covered. The Action is divided into four interactive working groups focusing on (i) implementation, (ii) methodologies, (iii) environmental risks from regulatory decisions, and (iv) remediation. Regular meetings, workshops, training schools, short-term scientific missions and a robust dissemination plan will enable a platform for research synergies and communication with relevant stakeholders. The goal is to provide an integrated approach to enable the implementation of existing bioavailability concepts and methods into environmental risk assessment and regulation, including parameters and modelling for their innovative application and standardization.

Key Expertise needed for evaluation

Earth and related Environmental sciences

Environment chemistry

Keywords

Bioavailability

Regulation

Chemicals

Risk

Communication

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COST - Network Bioavailability

- **Retrospective RA & Regulation**
- **52 proponents, 17 countries**
- **Tripartite (ACAD, IND, REG), EFSA & ECHA EoIs**
- **Networking (Working Groups, Workshops, Courses), 4 years**
- **Decision June 2017**
- **B Plan: Interest Group SETAC, ECETOC**

Data Quality & RA: Data should be "adequate"

Adequacy = reliability + relevance

Reliability = inherent quality of a study

Relevance = data and tests are appropriate for a particular hazard or risk characterization

Courtesy of Marlene Ågerstrand, ACES, Stockholm University

CRED-project

Criteria for Reporting and Evaluating ecotoxicity Data

1. Developed the CRED-evaluation method with Dutch RIVM, Swiss Centre for Applied Ecotoxicology and Swiss Eawag
2. 75 risk assessors evaluated ecotoxicity studies using
   - Klimisch et al. (1997)
   - CRED-evaluation method
3. Comparison of results and refinement of the CRED-evaluation method
4. Developed the CRED-reporting recommendations for authors of peer-reviewed studies

Courtesy of Marlene Ågerstrand, ACES, Stockholm University

Klimisch

- Recommended for ecotoxicity and toxicity studies in Europe and USA
- Few reliability criteria
- No relevance criteria
- No additional guidance
- Standard tests are favoured
- Developed by BASF

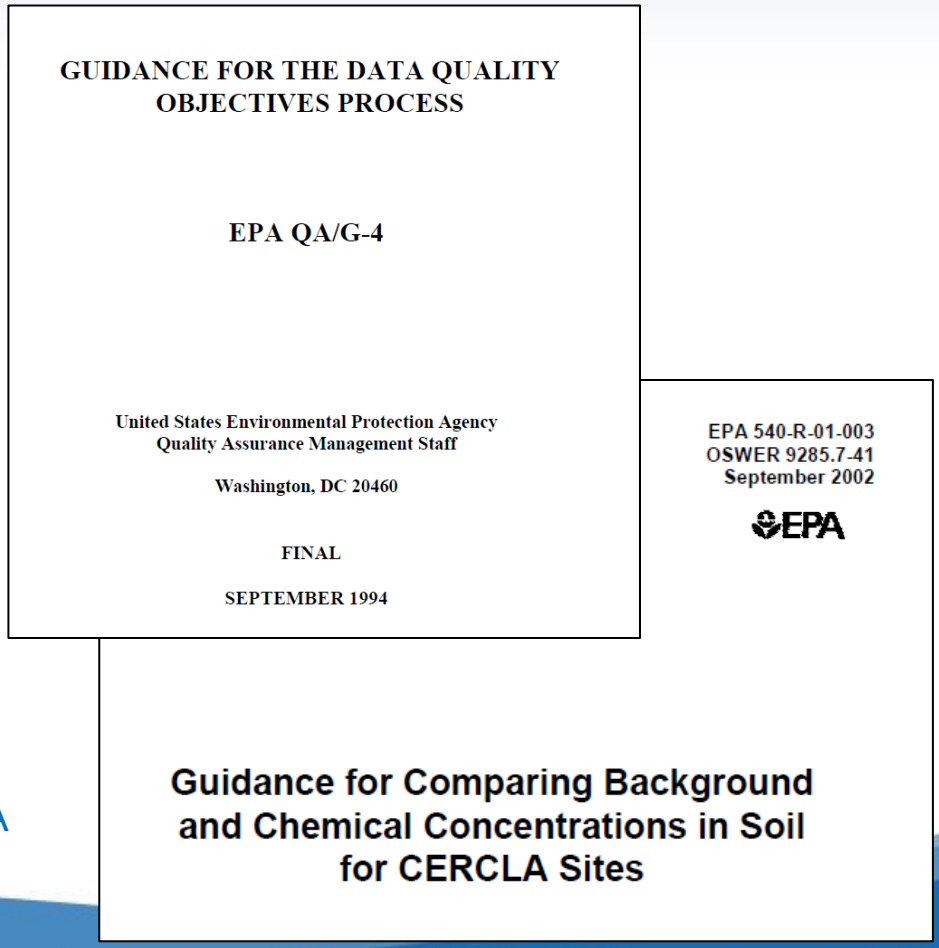
CRED

- For aquatic ecotoxicity studies
- Developed from OECD tests and other evaluation methods
- Reliability and relevance criteria
- Additional guidance
- Does not favour standard studies
- Developed by researchers and risk assessors

Courtesy of Marlene Ågerstrand, ACES, Stockholm University

US Environmental Protection Agency

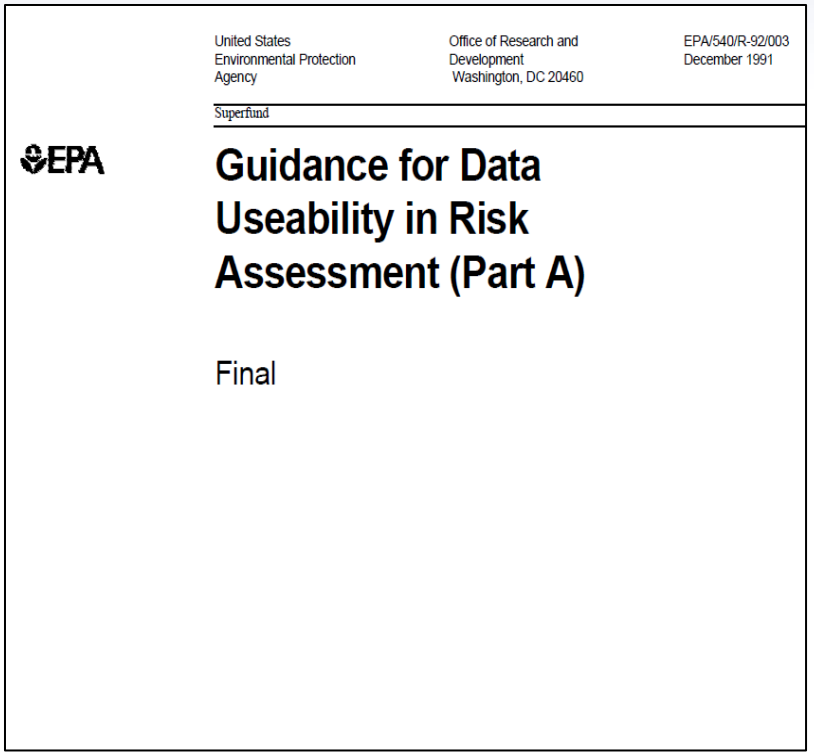
- These guidance documents provide frameworks for considering data quality objectives prior to data collection, such as:
  - Identify problems and decisions
  - Identify inputs to the decision
  - Define the boundary of the study area
  - Develop decision rules
  - Specify tolerance limits
  - Establishing background data



Courtesy of Jane Staveley, Exponent, USA

US Environmental Protection Agency

- Once data are collected, this guidance discusses elements of data quality for use of data in risk assessment
- For example:
  - Data sources
  - Detection limits
  - Data validation
  - Use of background data



United States Environmental Protection Agency | Office of Research and Development Washington, DC 20460 | EPA/540/R-92/003 December 1991

Superfund

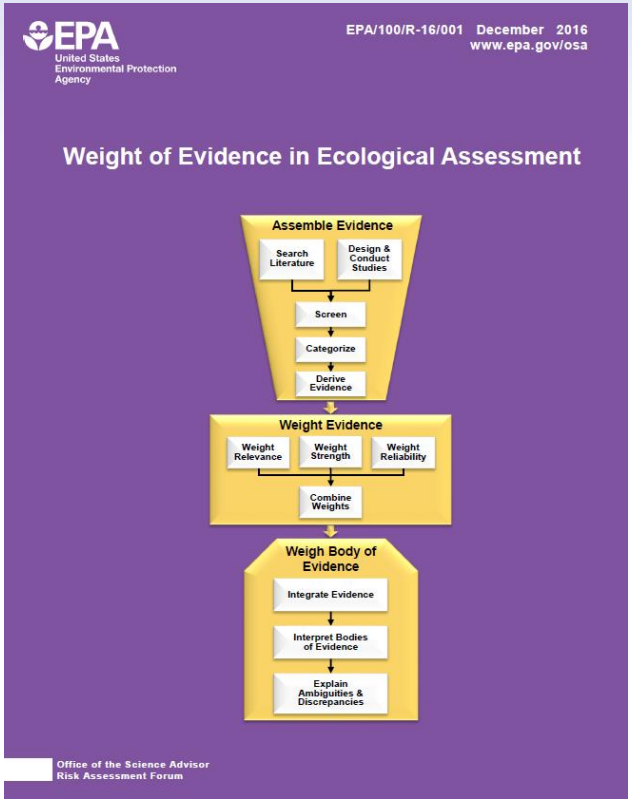
EPA

Guidance for Data Useability in Risk Assessment (Part A)

Final

Courtesy of Jane Staveley, Exponent, USA

Weight of Evidence Considerations



- At the end of the risk assessment, the data are then evaluated again to compare the weight of evidence (WOE) to evaluate multiple lines of evidence, especially if conflicting results are seen. This guidance speaks of issues in terms of:
  - **Relevance** – how close is the study to the problem at hand?
  - **Strength** – does the study show a strong positive or negative relationship?
  - **Reliability** – are sample size and statistical analysis acceptable?

Courtesy of Jane Staveley, Exponent, USA

Actions for increased regulatory awareness and impact

1. Identify applicable legislation and guidance documents
2. Identify relevant regulatory procedures and their outcomes
3. Identify relevant assessments from non-regulatory stakeholders
4. Evaluate chemical assessments
5. Report studies in a way that enables regulatory use
6. Place academic studies in a regulatory context
7. Submit studies and comment on current assessments and processes
8. Create a dialogue with stakeholders
9. Write for policy makers
10. Train the next generation

Courtesy of Marlene Ågerstrand, ACES, Stockholm University

CONCLUSIONS

- **Tripartite communication is important – a role for SETAC**
- **Reliability and relevance are not the same thing**
- **The way forward: regulatory exposure of academic researchers**

SETAC resources on data quality & RA

- Papers at SETAC Journals (ET&C and IEAM). Examples:
  - Moermond C, Kase R, Korkaric M, Ågerstrand M. 2015. "CRED - Criteria for Reporting and evaluating ecotoxicity Data." Environmental Toxicology and Chemistry 35: 1297-1309.
  - Moermond CTA, Beasley A, Breton R, Junghans M, Laskowski R, Solomon K, Zahner H. 2017. Assessing the reliability of ecotoxicological studies: An overview of current needs and approaches. Integrated Environmental Assessment and Management. DOI: 10.1002/ ieam.1870. 3.
  - Ruden C, Adams J, Ågerstrand M, Brock T, Poulsen V, Schlekat C, Wheeler J, Henry T. 2017. Assessing the relevance of ecotoxicological studies for regulatory decision-making. Integrated Environmental Assessment and Management. DOI: 10.1002/ieam.1846.

- SETAC Workshops & Meetings:
  - Workshop "**Closing the Gap Between Academic Research and Regulatory Risk Assessment of Chemicals**", SETAC Glasgow Annual Meeting. 2013. http://glasgow.setac.eu/
  - SETAC Pellston Workshop "**Improving the Usability of Ecotoxicology in Regulatory Decision-Making**". 2015. https://www.setac.org/?page=SETACWorkshopSum

- SETAC Europe Certified Risk Assessors
  - Course **"Evaluation of ecotoxicity and degradation studies for use in environmental risk assessment of chemicals**". SETAC Brussels Annual Meeting. 2016. https://certification.setac.org/courses/course-list/

- SETAC Interest Groups
  - Global Ecological risk assessment IG. https://www.setac.org/group/IGEcoRisk

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Environmental Toxicology and Chemistry Journal
Allen Burton (Chief Editor)

SETAC is looking forward to interact with other stakeholders here in EFSA!

Thank you for your attention