From bioavailability science to regulation of organic chemicals

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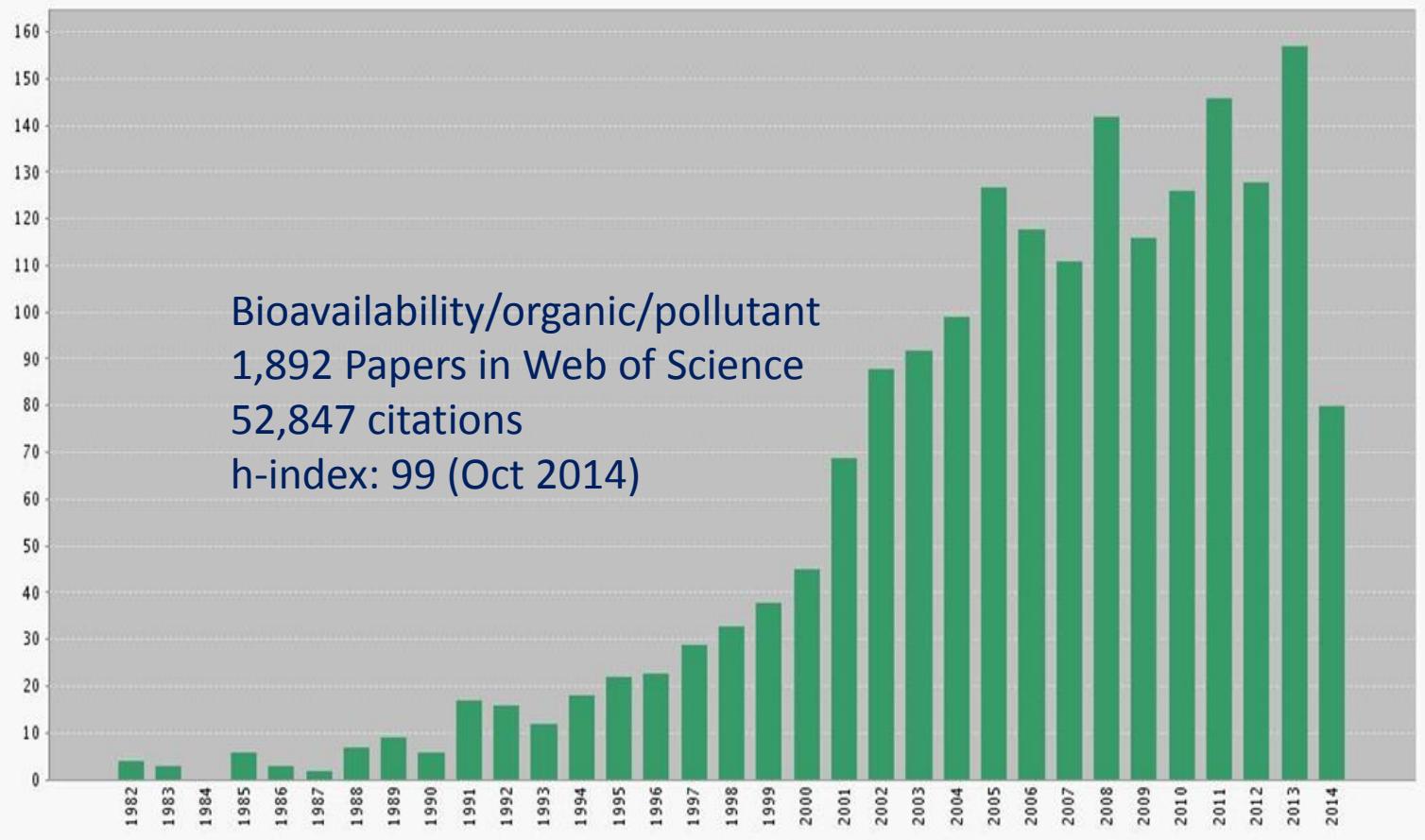
Nanjing, 19-20 October, 2015

Does science know enough?



Application of bioavailability in regulation and soil management is limited

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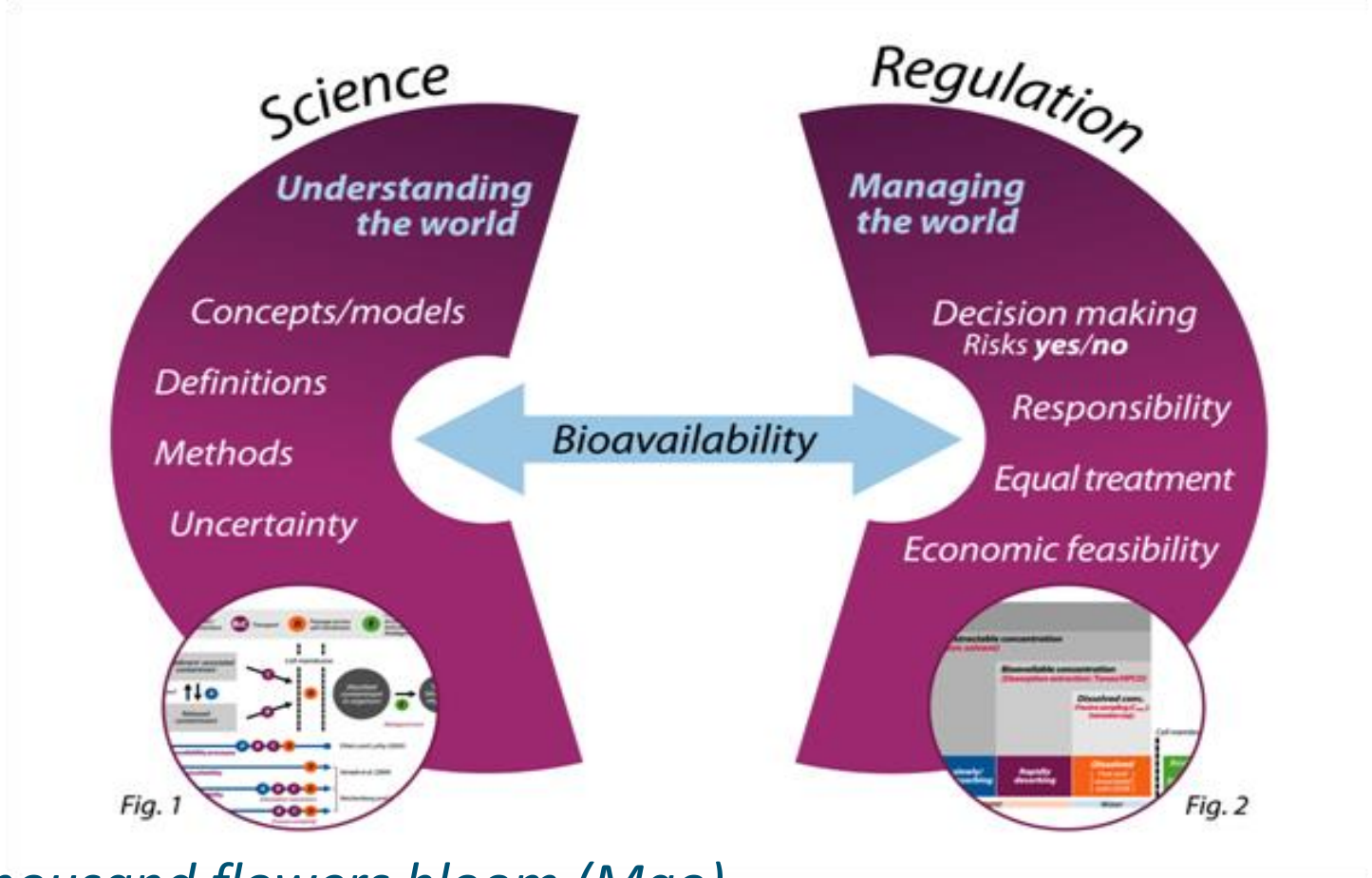
How can we make the step

- Belief that **science** on bioavailability of organic chemicals is mature enough to be used by **REGULATORS** and **INDUSTRY**. **BRING THEM TOGETHE**R
- The main objective of the Symposium is to identify and provide **solutions** to the problems faced by users in handling bioavailability concepts during risk assessment and regulation of organic chemicals.
- Implications for authorisation of chemicals (REACH), soil & sediment regulation, remediation industry.

Bring different worlds together



Let thousand flowers bloom (Mao)

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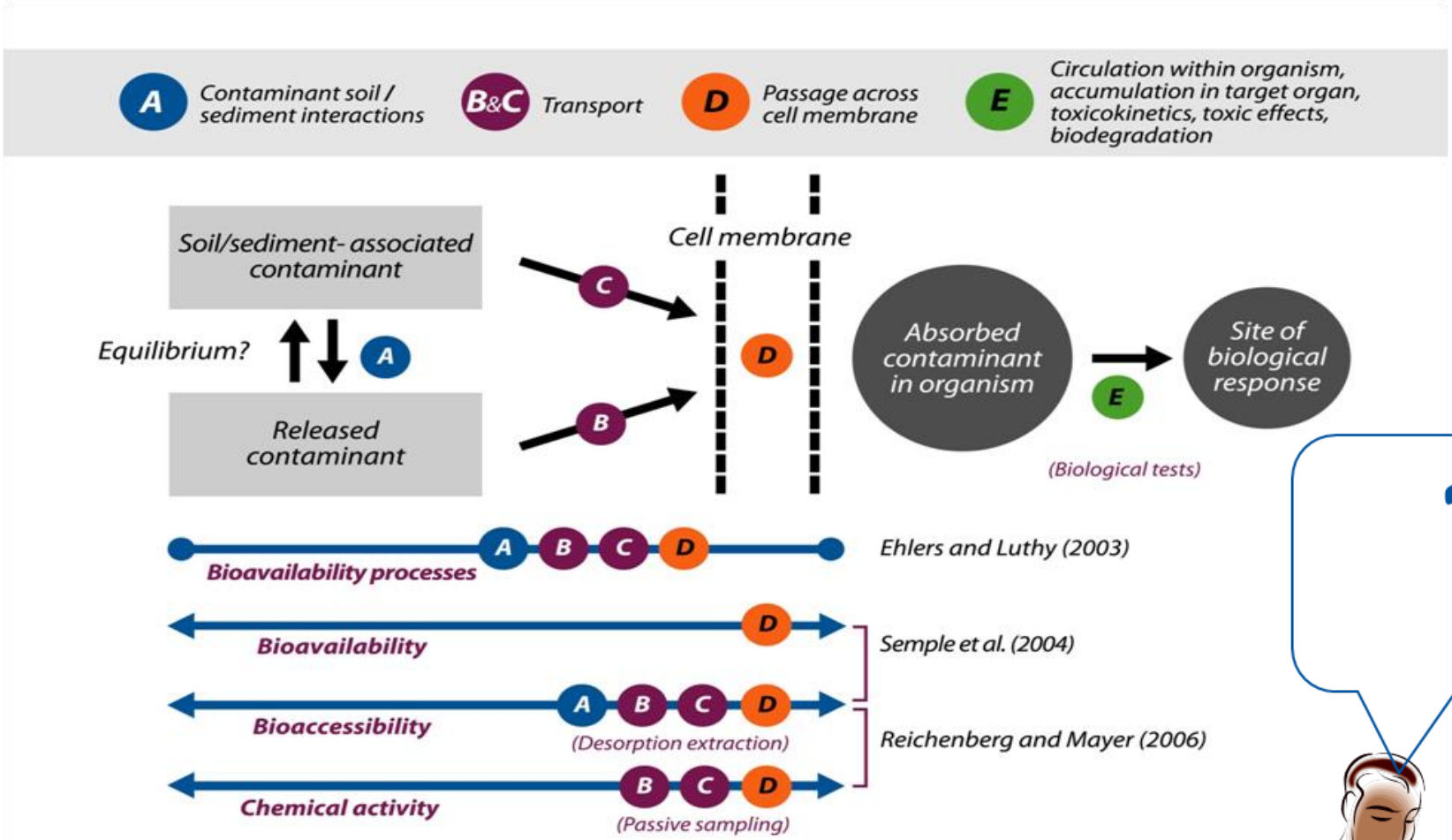
Scientific definition/concept of Bioavailability



Ortega-Calvo et al., 2015

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SESSS10 OUTPUT

- SESSS10 website updates with presentations, wrap-up sessions http:/sess10.setac.eu
- Session in Barcelona SETAC Europe AM
- Position paper to be published in 2015

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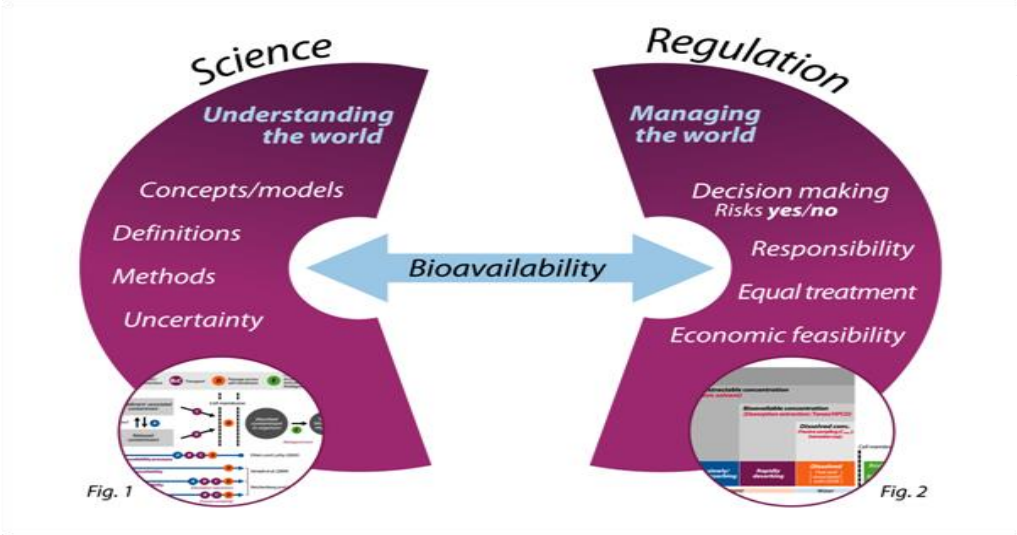
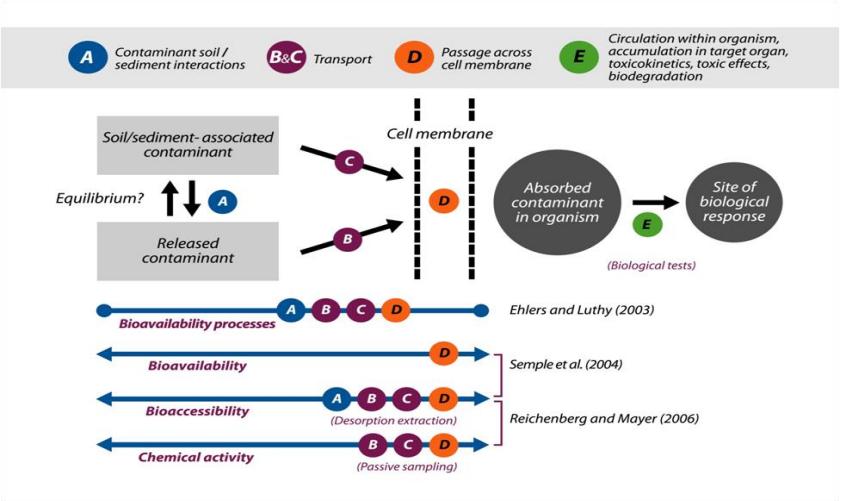
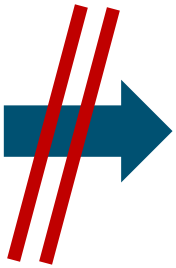
[⋈]European Commission, DG for Internal Market, Industry, Entrepreneurship and SMEs, REACH Unit, B-1049 Bruxelles, Belgium

Present: confusion







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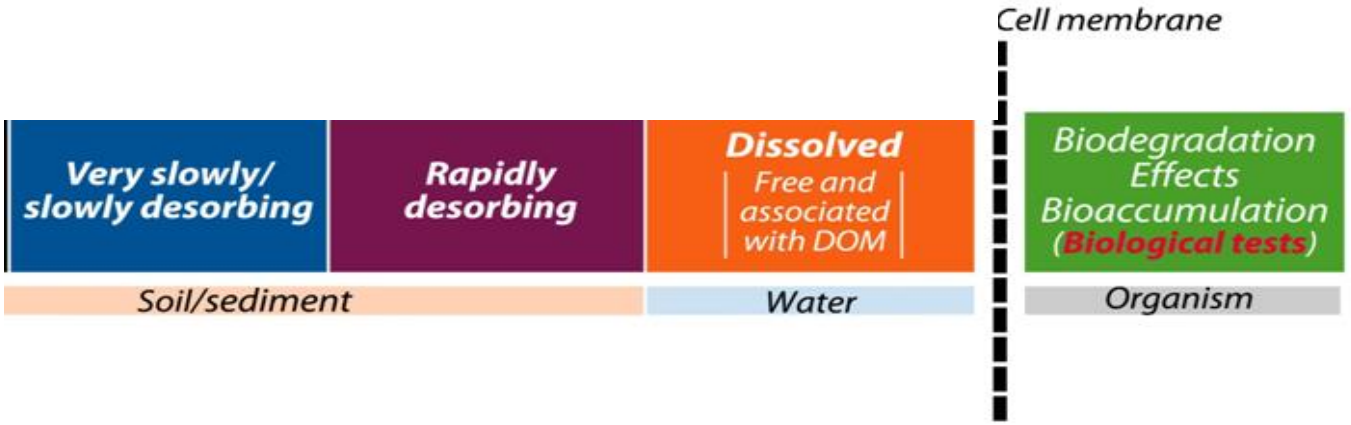
Simple concept (1)

Simple concept

Contaminant distribution in soil/sediment
Retrospective risk assessment

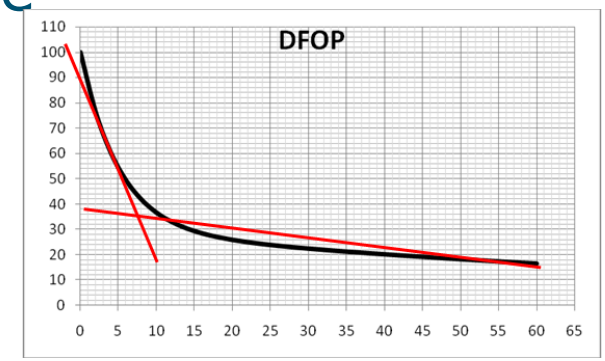


Regulation

- Prospective (looking ahead)
  - Prevent pollution
  - Acceptation of chemicals/pesticides
  - European legislation
- Retrospective (looking backwards)
  - Contaminated area
  - National legislation

Prospective regulation

- Acceptation of new chemicals
  - **Use of pesticides**
  - **Reach**
  - Supply of sufficient and reliable data
  - Fate modelling, based on **one** available fraction (K_{OC}) and **one** degradation rate
  - ^{14}C-tests



Oliver, 2014

Bioavailability' in the REACH Regulation

Bioavailability not really mentioned but links present

- Short-term aquatic

  "mitigating factors indicating that aquatic toxicity is unlikely to occur…highly insoluble in water…"

- Simulation testing in water

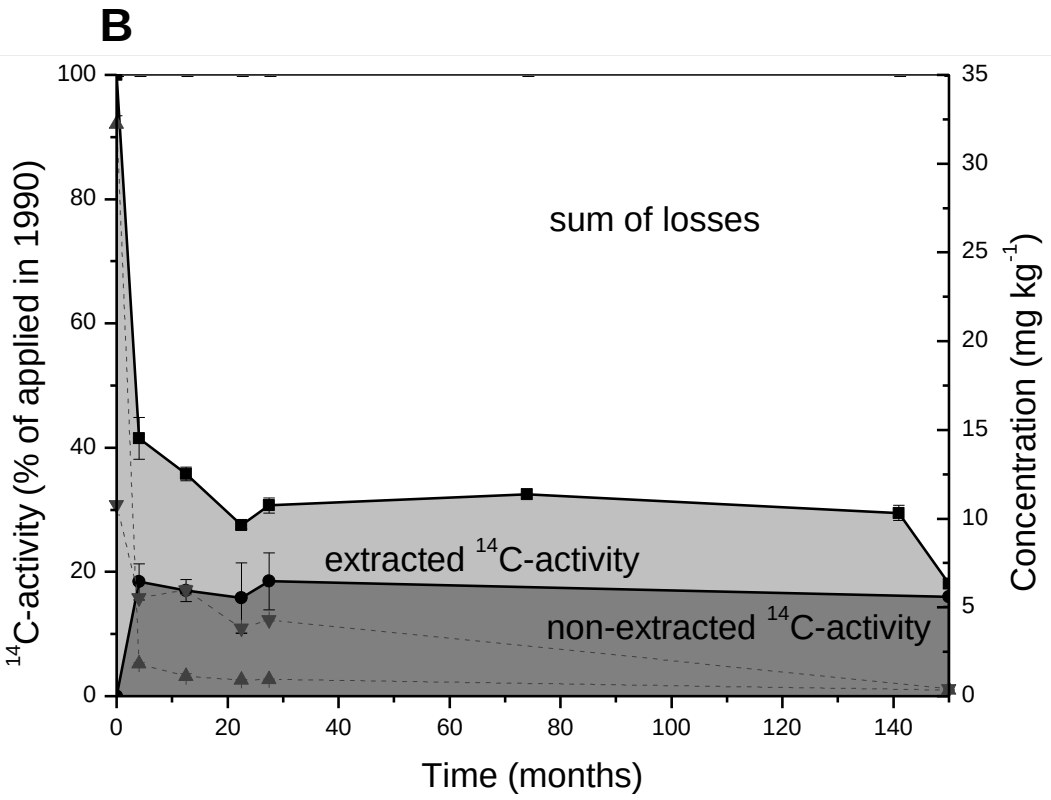
  "…highly insoluble in water…"

- Bioaccumulation

  "…low potential to cross biological membranes…"

- Conversely: high (bio?)availability in compartment triggers testing

Result of research with ^{14}C



Doick et al. 2005

Non-extractable residue (measured as ^{14}C)

- The chemical itself associated with mineral and/or organic matter fractions
- Transformation product
- Microbial biomass
- Carbonates

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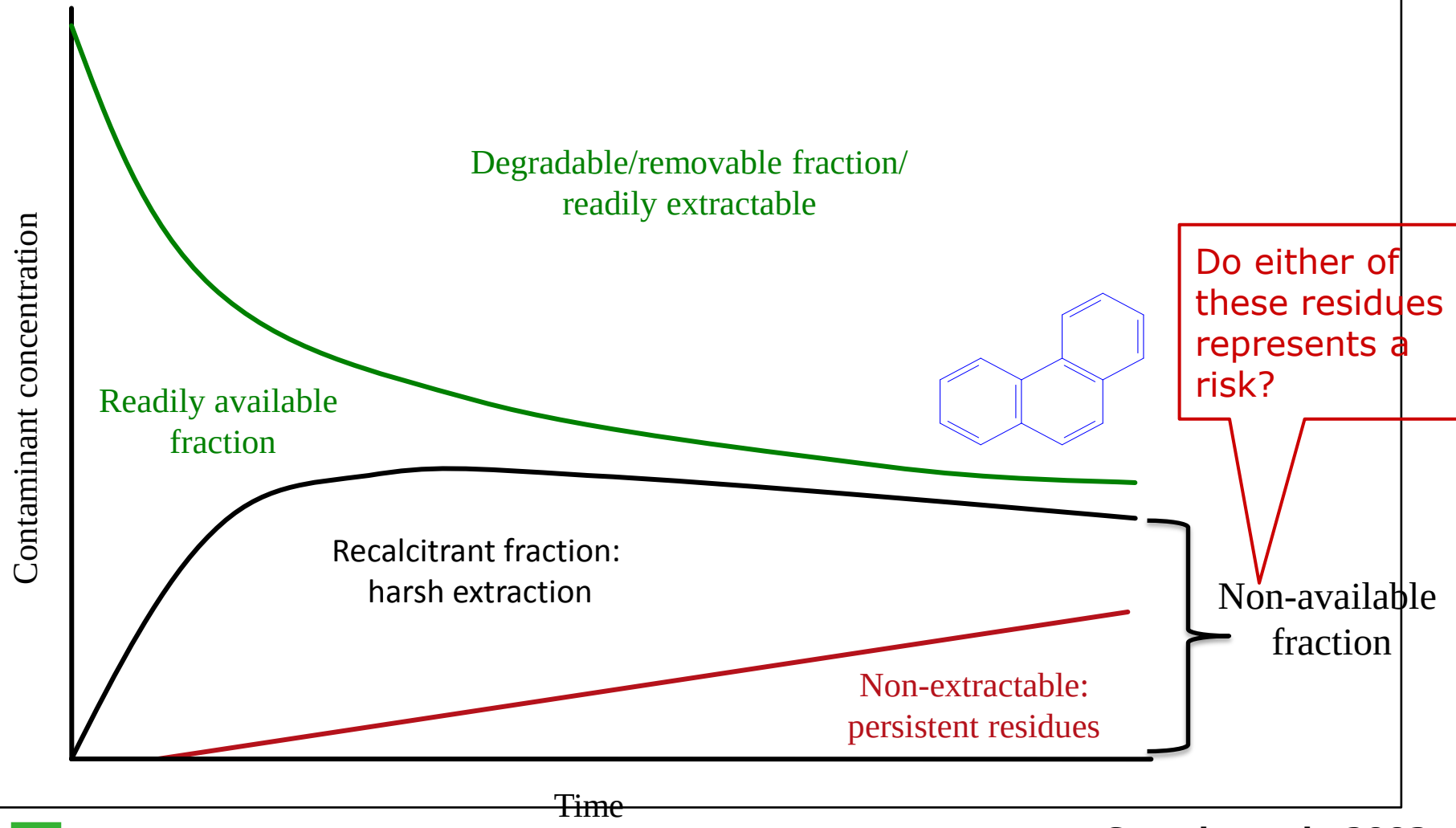
Fate and behaviour of organic contaminants in soil



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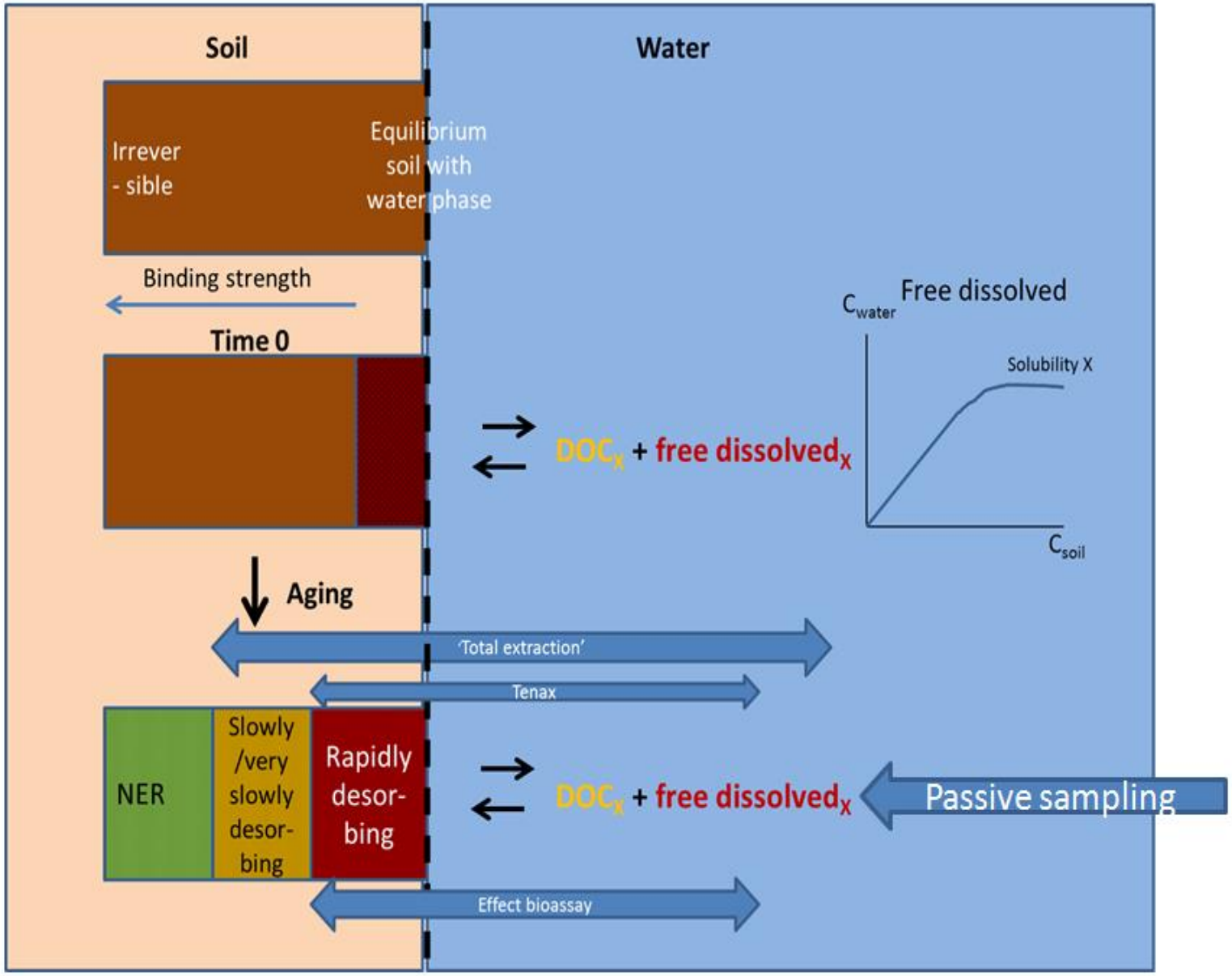
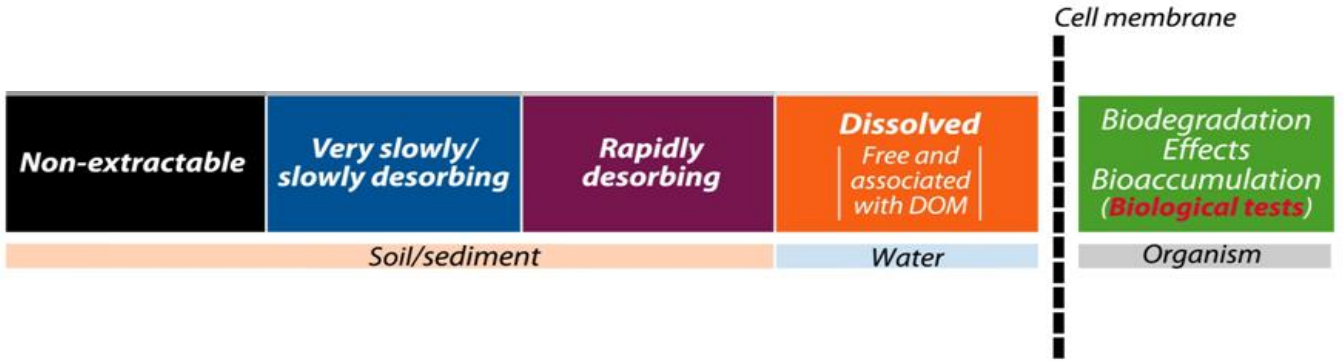
Semple et al., 2003


Soil
Water
Irrever
- sible
Equilibrium
soil with
water phase
Binding strength
Time 0
Aging
C_{water} Free dissolved
Solubility X
C_{soil}
DOC_X + free $dissolved_X$
'Total extraction'
Tenax
NER
Slowly
/very
slowly
desor-
bing
Rapidly
desor-
bing
DOC_X + free $dissolved_X$
Passive sampling
Effect bioassay

Add NER, but keep the concept simple

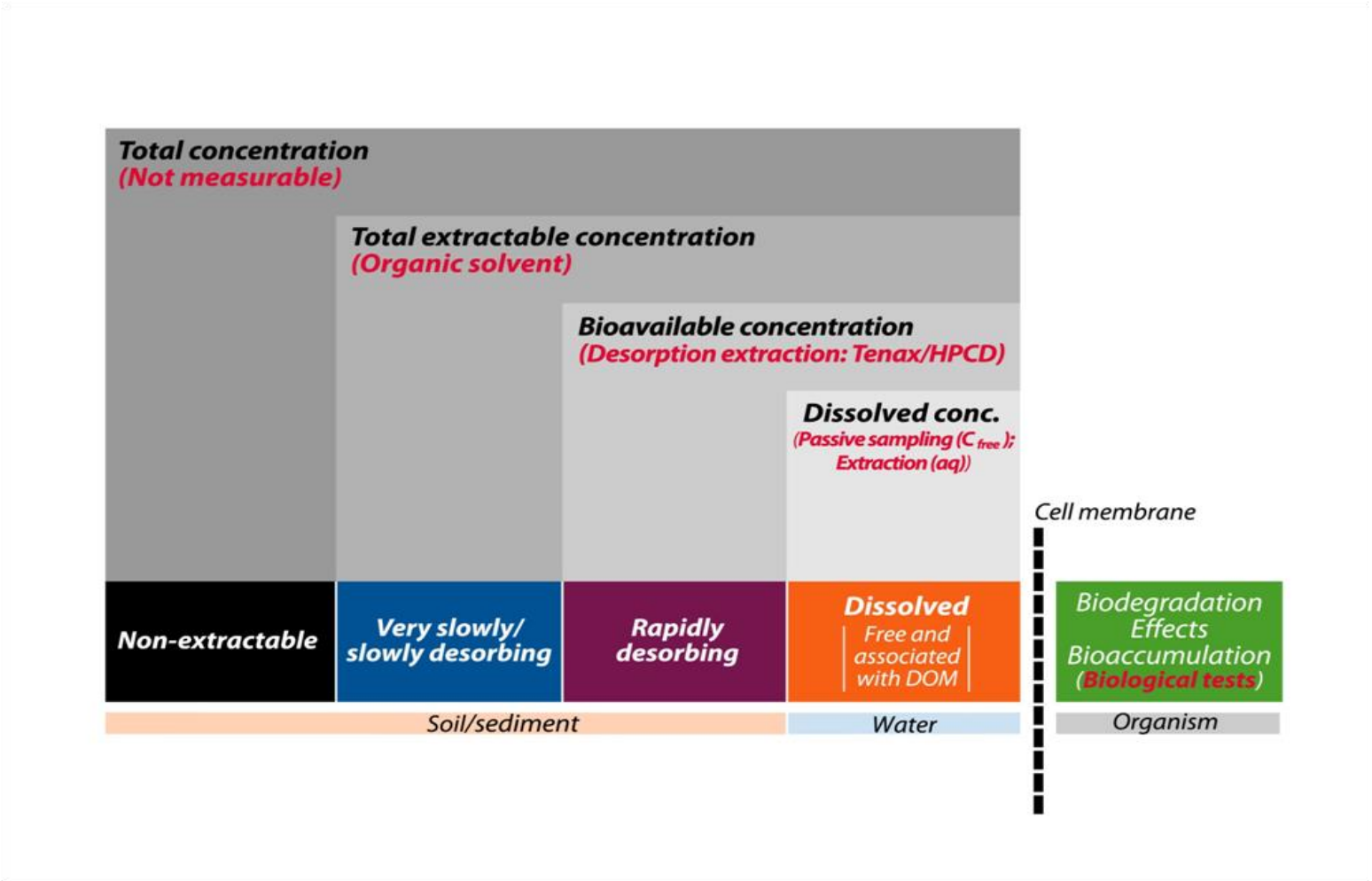
Contaminant distribution in soil/sediment
Prospective risk assessment



Measurement of bioavailability

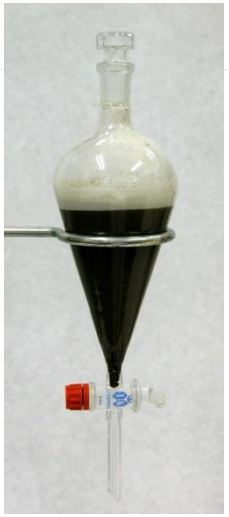
- Regulators decide on facts;
- Measurable result;
- Clear meaning of result;
- Use standard methods, if possible.

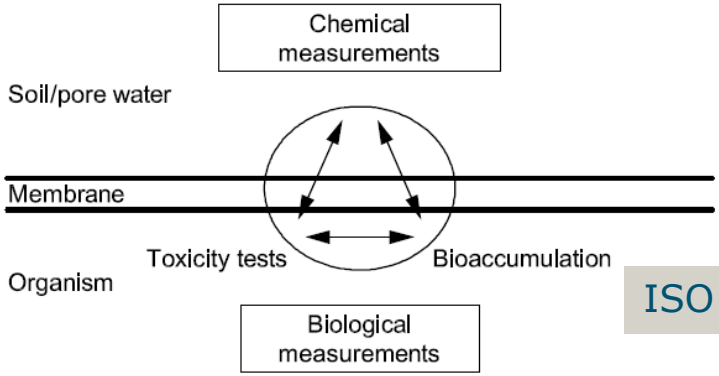
Simple and measurable concept



Measurement of bioavailability

- Bases on desorption of chemical using an infinite sink. Cyclodextrin/Tenax (ISO/DIS 16751)
- (Free) solved in the water phase. Passive sampling.

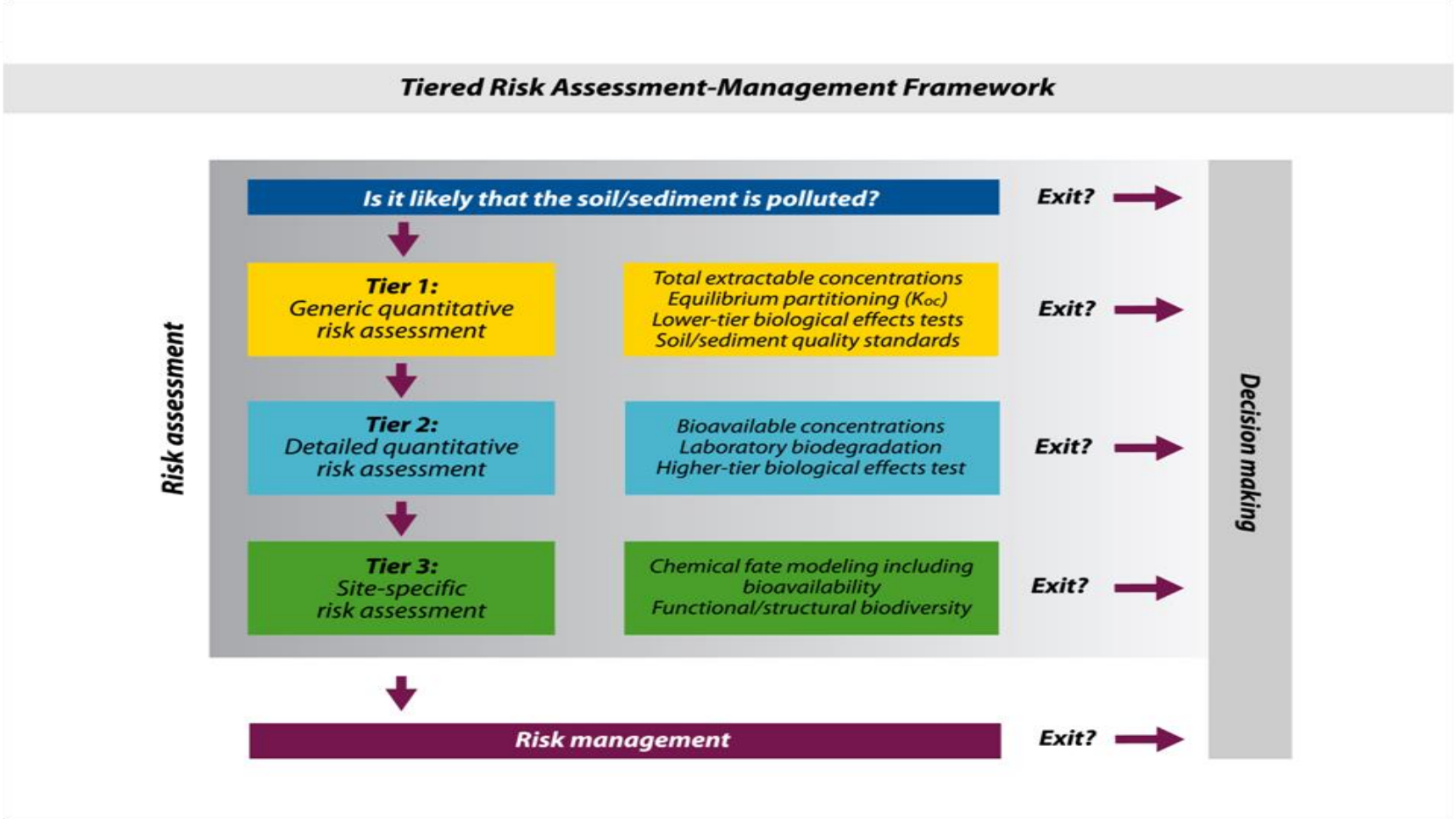




ISO 17402

- Focussed on pathways causing risks
- Many ISO and OECD methods are available

Bioavailability in a Tiered Risk Assessment-Management Framework



Example TRIAD approach (ISO/CD 19204)

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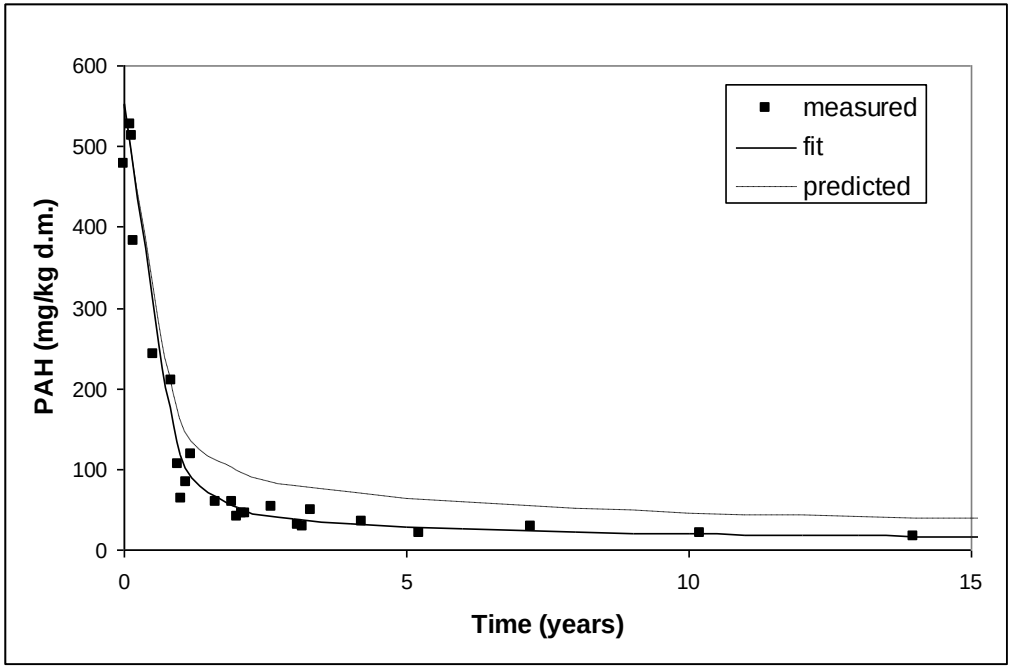
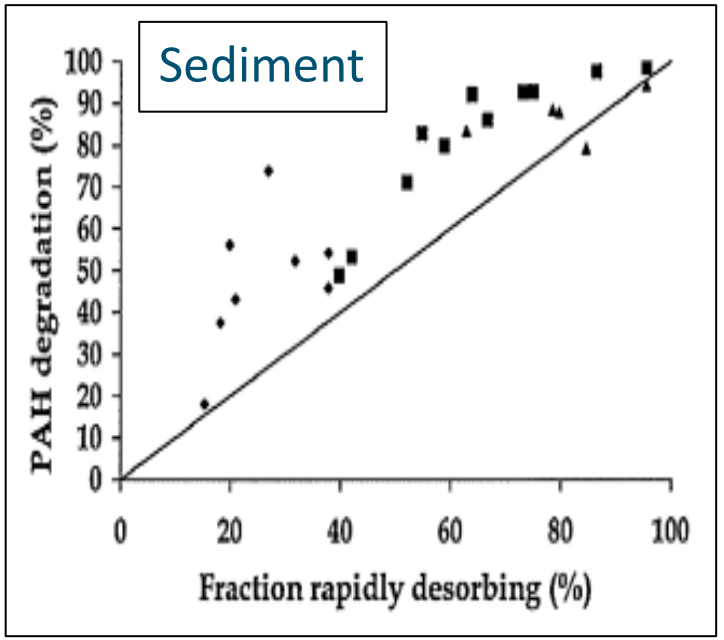
Bioavailability and biodegradation

- Increase bioavailability
  - Presentation Jose Julio Ortega-Calvo
- Predict biodegradation





Cornelissen et al., 1998

Prediction based on measurement of rapidly and Slowly available fractions

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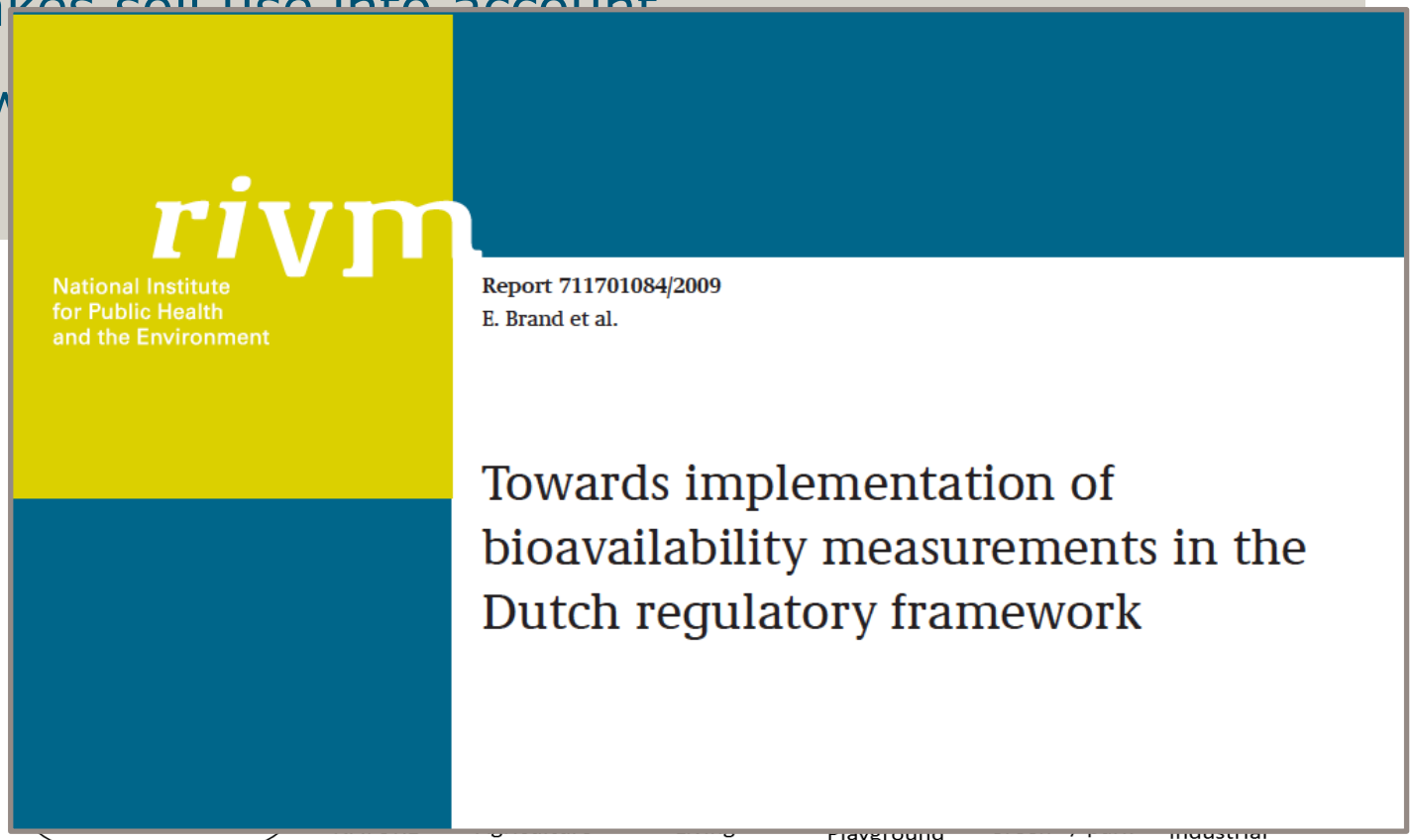
Bioavailability in Dutch policy

- Recalculate to 10% organic matter
- Takes soil use into account
- Aw



Small scale home farming | Garden | Playground | + Env. value | Industrial

Soil function classes

Soil use
(→ decreasing "sensitivity")

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Peijnenburg, 2014

Australia: if we can't get rid of it, why not lock it away?

- Removal risk by physical means (dig and dump) which can be prohibitively expensive and may not ultimately prove effective- leaving for future generations

Ravi Naidu

Key to a bioavailability-based guideline is:

- Science underpinning bioavailability
- Reliable tools for measuring bioavailable fraction
- Recognition and acceptance by regulators
- Careful consideration of liability inc. community acceptance
- Policies and bioavailability-based guidelines

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The way forward

- Prospective (EU) and retrospective (National) regulations need a straight forward approach;
- Bioavailability has a place in the second tier of retrospective assessment and following management of contaminated sites;
- Keep it simple, limit to measurable parameters (total extractable chemical and bioavailable fractio;.
    - Hazard is not coming from NER
- Update assessment models with bioavailability;
- Use validated and preferably standardized chemical and biological methods.

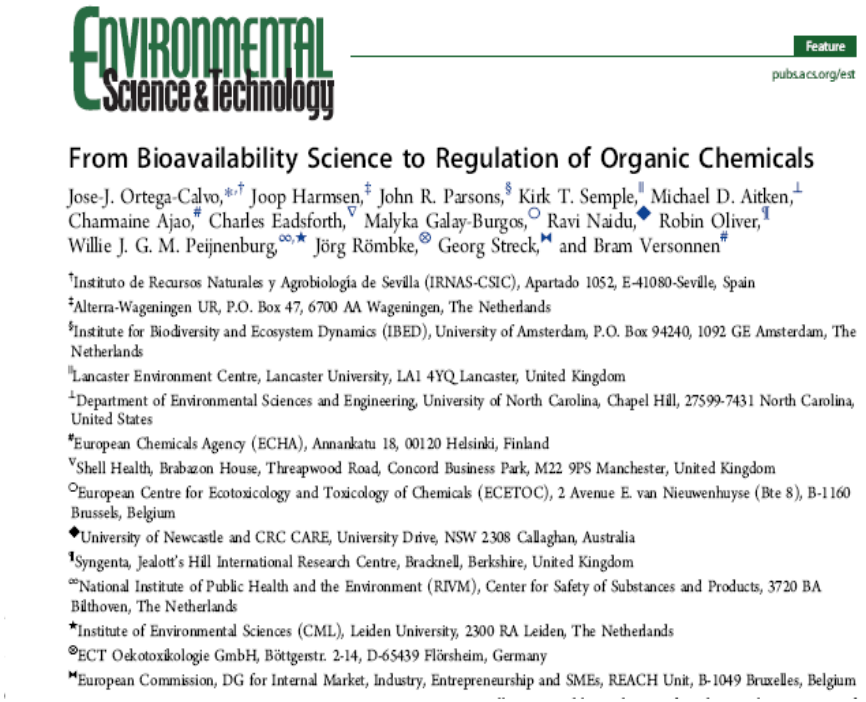
Ortega-Calvo et al., 2015

From Brussels to Sevilla…..to Nanjing (1)

- The 10th SETAC Europe Special Science Symposium,, Brussels, Belgium. A two-day meeting on 14-15 October 2014.
  - Bioavailability of organic chemicals: Linking science to risk assessment and regulation;
  - The main objective is to identify and provide scientifically-based solutions to the challenges faced by regulators and industries in handling bioavailability issues during risk assessment and regulation of organic chemicals;
  - Ambition: View point paper on how bioavailability might be incorporated in to contaminated soil/sediment risk assessment.
- March draft paper, goal Feature in Es&T (13 Authors)

From Brussels to Sevilla……to Nanjing (2)

- Sevilla, 13th-15th April at Institute of Natural Resources and Agrobiology (CSIC) Jose Julio, Kirk, John and Joop
- Barcelona – 4th – 8th May, Fine tuning with most authors
- May 12 Submission
- August On-line
- September Publication



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EXTRA: Take home message to come to a successful paper

- If you have a good idea, find people having ideas on the subject, not necessary your ideas;
- Trust each other, look for possibilities to meet and discuss. Be open, agree and disagree;
- Find a leader and support him with a core group;
- It is not a democratic process;
- Write together;
- Rewrite and shorten each others text;
- Have fun and celebrate the result.

Acknowledgements

Co-authors:

- **Dr Jose Julio Ortega-Calvo**
- **Dr John R. Parsons**
- **Prof. Kirk T. Semple**
- Prof Michael D. Aitken
- Dr Charmaine Ajao
- Dr Charles Eadsforth
- Dr Malyka Galay-Burgos
- Prof Ravi Naidu
- Dr Robin Oliver
- Prof Willie J.G.M. Peijnenburg
- Dr Jörg Römbke
- Dr Georg Streck
- Dr Bram Versonnen

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