Presentations from the break-out groups

ECHA/EFSA
Topical Scientific Workshop on Soil Risk Assessment

7-8 October 2015

Disclaimer:
This presentation is a summary of the discussions in the break-out groups and is not an official position of the organisations or their representatives present at the workshop.

Group 1

Problem definition and conceptual model for soil risk assessment

Chairs: Marc S. Greenberg, Kees Romijn, Janet Cermak

7 Oct Protection goals and ecosystem services

8 Oct Analysis plan and conceptual model

ECHA/EFSA

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Protection goals

1. Relevance of setting Specific PGs under REACH and BPR for soil organisms.
2. Relevance of the ecosystem services approach.
3. Where would harmonisation of the approaches bring added value in the soil risk assessment?

Proposed issues for further discussion
• Similarities and differences
• Elements to be considered
• Foreseen adaptation needs and regulatory boundaries
• Calibration from reference tiers

Protection goals

1. Relevance of setting Specific PGs under REACH and BPR for soil organisms.

- Most participants thought setting specific Protection Goals (SPG) within the approach of Environmental Services was relevant – within the limits of policy set general PG's
- We as Risk Assessors should sieze the opportunity to develop SPG's based on our 'science' and what we can actually measure
- Development of SPGs is needed across the industries (e.g., biocides, pesticides, industrial chemicals, veterinary medicines, fertilizers) and regions (EU/NA) should include clear definition of:
  - Land/soil use
  - Product use
  - Exposure scenario and time scale

Protection goals

2. Relevance of the ecosystem services approach.

- ESS approach considered useful in defining what are we want to protect (what do we value ?) (good communcation tool !)

- It was suggested that SPGs could be used in the context of describing trade-offs if chemical, pesticide or biocide use posed a given risk—this idea speaks to acceptability of the risk

- How to deal with Uncertainty – does this increase when adopting SPG's under ESS ? Especially for data-poor substances beyond Tier "1?
  - Approach of calbirating lower Tiers from a reference Tier is considered usefull – also for Biocides and REACH,
  - ... even when this may be more difficult than for PPP's (data availability & lack of defined reference Tiers)

Protection goals

2. Relevance of the ecosystem services approach.

- Biodiversity as protection goal ?

  - We need to define what definition of biodiversity is and important to define it as something you can actually measure

Analysis plan and conceptual model

1. Equilibrium Partitioning Method
   - Scientific basis/uncertainty
   - When/how/to-whom?

2. Species Sensitivity Distributions
   - Species/taxa/functions selection & integration in a PNECsoil

3. Ecological modelling
   - Prediction of population/functional effects
   - Addressing spatial and temporal variability in exposure and response

4. Current approaches for linking exposure and effects (REACH/BPR/PPP):
   - Similarities, divergences
   - Harmonisation

5. Updating/integration the conceptual model

Analysis plan and conceptual model

1. Equilibrium Partitioning Method
   - Scientific basis/uncertainty
   - When/how/to-whom?

   - Recommendations:
     - Analyse further the 40% that EPM didn't work for (Case study 3 8 Oct 2015)
     - Mode of action/chemical groups

       Mode of exposure

       Species similarities

       Limitations of the method

   Comparison of collected microbial data for determining if EPM is applicable

   There may be need for revising/rethinking the applicability of current assessment factors

Analysis plan and conceptual model

2. Species Sensitivity Distributions
   - Species/taxa/functions selection & integration in a PNECsoil
   - Soil differs from aquatic condition – heterogeneity

Differences in opinion

- Species selection
  - Combine taxa or split? Species selection should be led by mode of action (MoA)

Agreement

- SSD is a tool for assessment and part of a tiered risk assessment
- Learn, improve and evolve method (eg. Water Quality development approach may not be applicable to all product evaluation)
- Should link to Protection Goal and legislative requirement
- Recommendations : think about applicability

Analysis plan and conceptual model

3. Ecological modelling
   - Prediction of population/functional effects
   - Addressing spatial and temporal variability in exposure and response

   - Should have a clear linkage between species model and function
   - Models are a tool and help explain and communicate, but should be used as the driver – clear linkage between model and PG formulation
   - Data requirements might be restricting
   - Think before you use

Analysis plan and conceptual model

4. Current approaches for linking exposure and effects (REACH/BPR/PPP):
   - Similarities, divergences
   - Harmonisation

   - Better communication required between exposure and effects assessors (during problem formulation)
   - Question Where's the uncertainty?
     - Diverse answers
   - Determine where the most uncertainty lies before the next tier

Analysis plan and conceptual model

5. Updating/integration the conceptual model

- Should be integrated and drive risk assessment
  - Need to get together and derive conceptual model first
- Useful communication tool between exposure and effects assessors

Group 2a

Environmental exposure and fate assessment

Chair: Willie Peijnenburg

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1. What are the key elements and processes to be considered in the environmental exposure and fate assessment?

- Key physico-chemical parameters to be considered in soil exposure and fate assessment.
  - Common parameters that we normally use are still valid
  - A few new suggestions that could be considered; **desorption**, lab to field extrapolation
  - Plant uptake (relevance to be assessed as compared to other uptake routes in case of grazing cattle as additional endpoint)
  - Characterisation of SOM – analogue to black carbon in aquatic media
  - Matrix in which chemical is applied; different matrices may change the properties/reactivity of the chemical
  - Dependence of microbial community on the soil pH and its effect on the fate of the chemicals
- Release, transfer/partitioning, aging of the different type of substances; metals, ionisable substances, surfactants,..
  - Perfluorinated compounds currently not covered - as are weak acids and especially weak bases.
  - Analyses needed at the beginning and end of the ecotox tests, applying appropriate analytical techniques to make sure that the same fractions are compared (dose metrics allowing for extrapolation lab-field and field-field)

1. What are the key elements and processes to be considered in the environmental exposure and fate assessment?

- Which processing steps/operational conditions/set of physico-chemical properties would indicate high potential for indirect exposure (e.g. deposition from air or via sludge from WWTPs etc.) of the soil?

  - Matrix and its effect on the properties of the compounds in question: overestimation of risk possible, dependent on matrix
  - Exposure scenarios need to take indirect exposure into account – these need to be developed

1. What are the key elements and processes to be considered in the environmental exposure and fate assessment?

- What are the key aspects to be taken into account in degradation/dissipation assessment e.g. triggers for testing degradation in soil (simulation testing), relevant temperature for assessing degradation rate, information relevant for Weight of Evidence (WoE)?

  - **Need to harmonise the approaches across legislations**; for example test temperature and chemicals legislations (for instance: PBT assessment) vs pesticides ➔ balance needed
  - Length of the equilibrium period should be harmonised regarding choice of proper analytical methods: different methods needed at start and end of analytical assessment to quantify same fraction
  - Moving target/ reference temperature complicates comparison of studies
  - Multiple/co-exposure of (for instance) pesticides (see slide Prof. Schaeffer)

Agricultural field (Jülicher Börde, Germany)

Crop rotation: pasture (2013), winterwheat (2014), potatoes (2015)

→ 12 active ingredients used within 6 weeks

	Product	Amount	Application date
Herbicide	Broadway	130 g/ha	20.03.14
	+ Arelon (IPU)	2 l/ha	
Fungicide	Matador	0,75 l/ha	14.04.14
	Capalo	1,5 l/ha	05.05.14
	Skyway	1,25 l/ha	30.05.14
Growth regulator	CCC	1 l/ha	20.03.14
	Moddus	0,2 l/ha	05.05.14

1. What are the key elements and processes to be considered in the environmental exposure and fate assessment?

- What are the key aspects to be taken into account in soil bioaccumulation assessment in regulatory decision making (e.g. bioavailability, test environment, reliability and relevance)?

  - Dissolved concentration can be used as a trigger for bioaccumulation
  - Feeding habits and exposure routes need to be taken into account
  - Desorption and inclusion of fast dissolving fraction
  - May not work for metals due to regulation of internal concentrations
  - Need to make sure equilibrium is reached in the test
  - Use of ecologically relevant, non-toxic concentrations
  - Links or protocols needed between bioaccumulation protocols and standardized bioavailability measurements

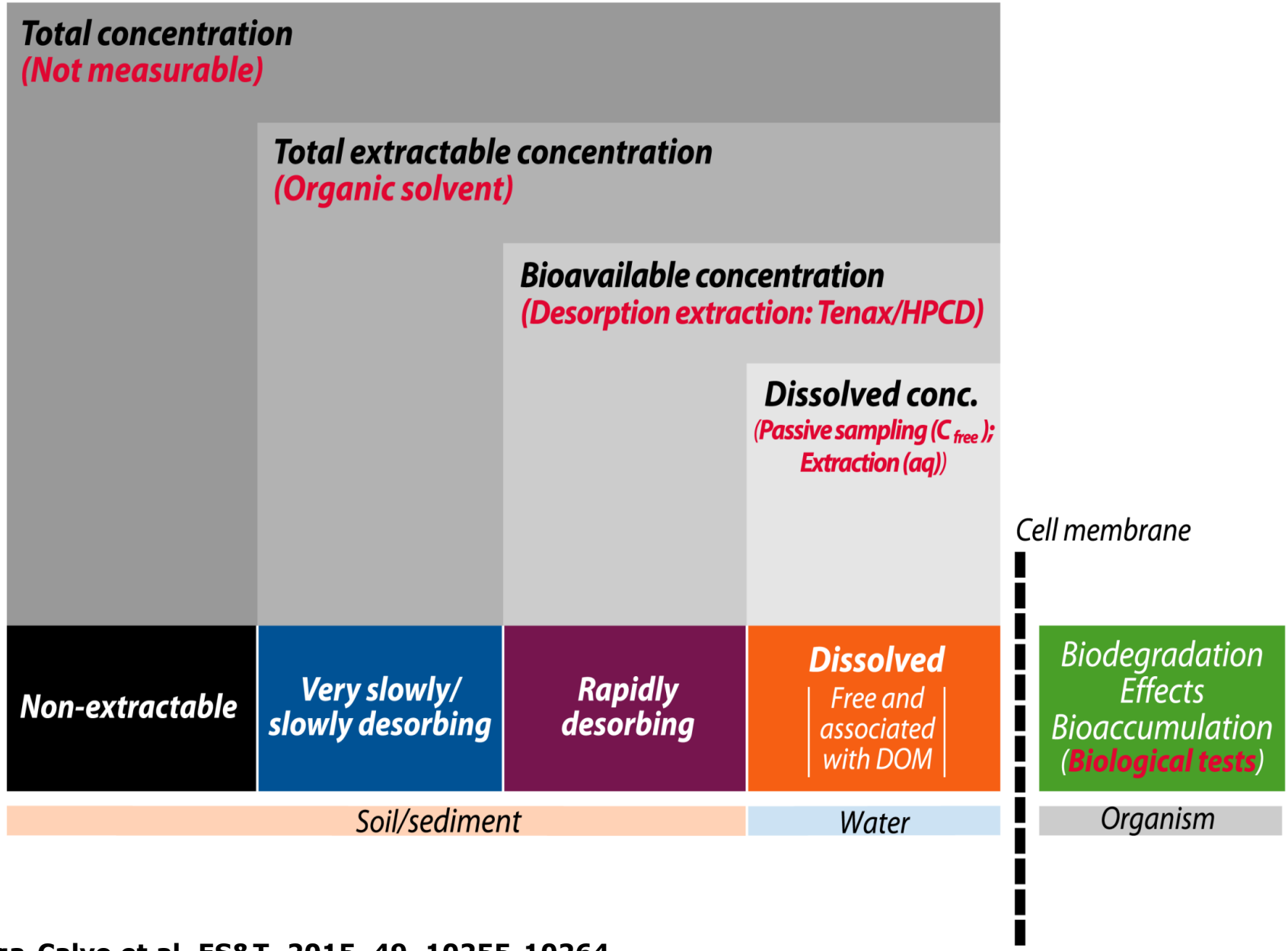
1. Conclusions from Group 2a

Key issues

- Need of harmonization of testing needs across regulations (general issue)
  - Making sure the tests are fit for purpose given the context of the regulations
- Need of harmonization across regulations of testing and reference conditions (example: T, 'aging issue')
- Similar dose metrics (or: extraction/analytical methods) as basis for extrapolations: use actual concentrations, be aware that different analytical methods might be needed when testing in order to assess the same dose metrics
- Make sure to match extraction methods with the assessment question for both exposure and effects assessment (examples: different methods in case of NER-assessment, persistence, degradability, ……)
- Need of protocols for standardized bioavailability measurements

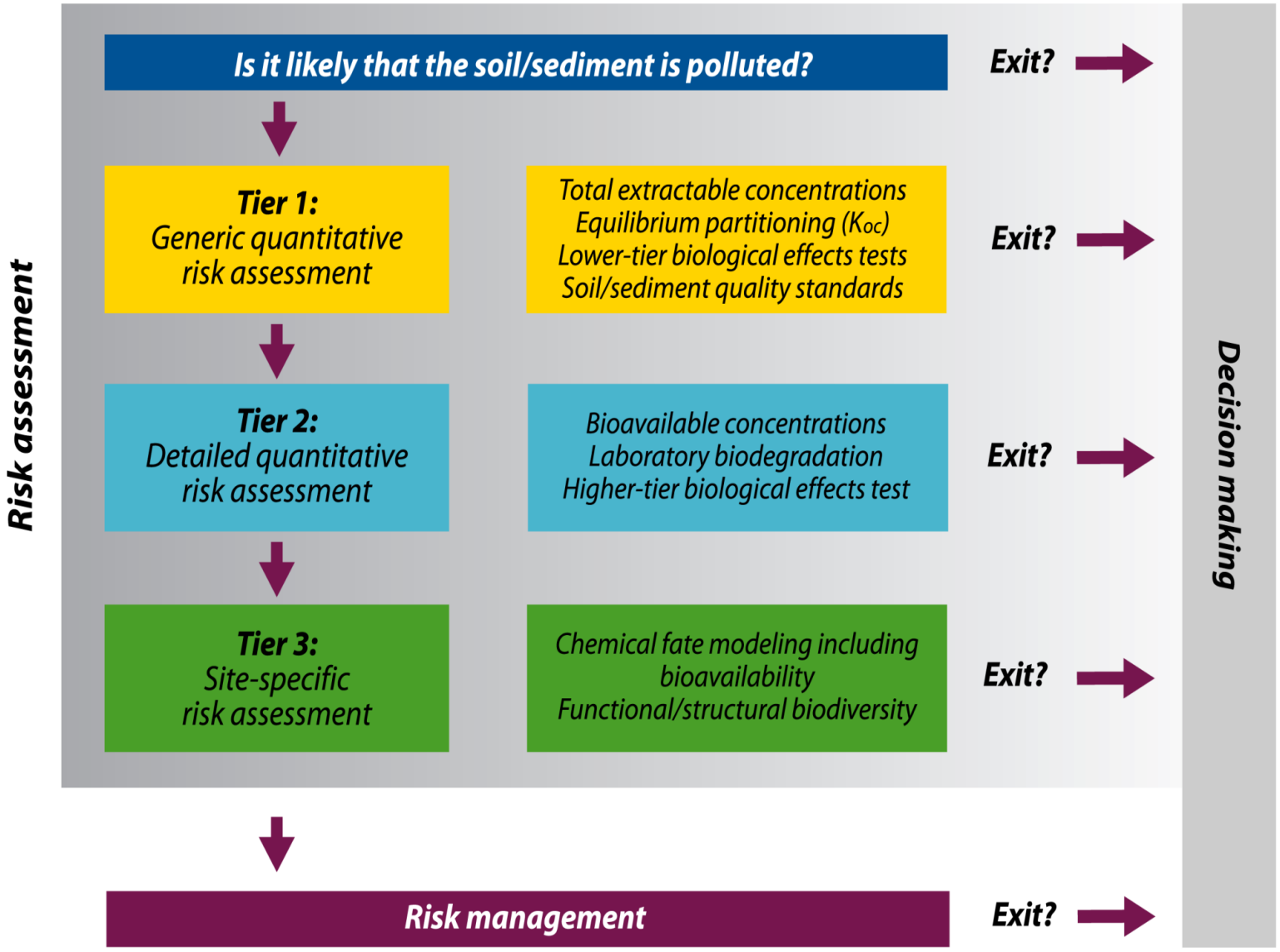
2. How to take bioavailability and NER formation into account in soil exposure and fate assessment

- How to take into account the bioavailability in soil in relation to effects assessment?
- Whether and how NERs should be considered in soil exposure/risk assessment?
- Does stabilisation of a substance (NER) always mean a loss of effects on non-target organisms?
- How is the formation of bound residues currently taken into account within the different regulations as part of the soil risk assessment (trigger values for further characterisation of the non-extractable residues (NER) and field studies)?
- How to reliably identify and quantify NERs within degradation simulation testing in soil?



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

Tiered Risk Assessment-Management Framework



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

2. How to take bioavailability and NER formation into account in soil exposure and fate assessment

- Bioavailability has a place in second and third tier of retrospective assessment and following management of contaminated sites
- Keep it simple, limit to measurable parameters (total extractable chemical and bioavailable fraction).
- Update assessment models with bioavailability
- Use validated and preferably standardized chemical and biological methods.
  - Agreement needed on the definition of bioavailability

Conclusion: topic has potential for implementation.

2. How to take bioavailability and NER formation into account in soil exposure and fate assessment

NER

1 – Sequestered

2 – Chemically bound

3 – Metabolized residues

Fractions 1 and 2 can be (slowly) released, key question: is there a concern? A safe sink?

Fraction 3: methods in place to quantify this fraction.

NER formation matters with regard to regulation, does not matter in interpretation test results

Time scale needs to be taken into account

Key issue: Generalized model needed to allow for implementation in regulation.

Conclusions

- **Topic has potential for implementation**
- **Harmonization effort needed, involving regulators and scientists.**

3. How are exposure and effect assessments linked today? How could they be better linked in the future?

- More realism needed
- Exposure assessment often very artificial and conservative
- Tiered process required in both exposure and effects assessment to protect the environment
- A plea for the formulation of relevant concepts
- This would help in distinguishing the relevant tests and deciding on how to use the data
- Modification of data requirements, but this is recognized as a time-consuming process

4. Measuring of exposure in ecotox media/studies?

- What analytical tools are available at the moment, what are their limitations, and how to improve exposure assessment in ecotox media/studies?
  - Passive sampling
  - DGT method
  - Modified LC-MS and GC-MS
  - Measurement of actual concentrations in analogy to aquatic compartment
  - Interpretation of results; perhaps use time-weighed averages?
- What is the feasibility of testing of exposure concentrations also of metabolites in the standard soil tox/fate strategies?
  - Can be done but the method has to be tailored to the compounds being measured
  - Need to define what metabolites are meaningful
    - Trigger values? 5 or 10 % ? Or below 5 % in case of toxic metabolites

Group 2b

Environmental exposure and fate assessment

Chair: Mark Egsmose

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1. Modelling tools in soil exposure assessment

a. How are modelling tools used within different regulations today?

- Modelling tools and simple calculation sheets are used to calculate exposure in soil for biocides, REACH chemicals and PPPs
- Models are used in data poor substances but work best for data rich substances (on exposure) (REACH)
- Modelling results to be used by regulators in REACH need to be accompanied by a proper justification.
- There seems to be a varying range of expertise amongst national authorities with regards to the use of different models for the same regulation (PPP, BPR, REACH)
- Models usually determine total conc. but it would be helpful to determine the poor water conc.

Modelling tools used in different regulations

PPP –

- national excel calculations, models and scenarios;
- models and excel calculations used EU wide (5cm depth as one standard EU scenario);
- ESCAPE I and ESCAPE II (linked PPP guidance).
- Simple Treat (looking at STPs)
- *EFSA GD PECs in soil for future regulatory use - PECsoil will be derived from PERSAM, PEARL and PELMO*

Modelling tools used in different regulations cont./

Biocides – choice of model is based on *direct* or *indirect* exposure depending on the product type e.g.

- Simple Treat model for distribution and degradation processes in STP in EUSES (indirect exposure);
- models based on the TGD ;
- Emission scenario documents are used for exposure assessment for Product Type specific situations

REACH –

- EUSES; Chesar
- ECETOCTRA
- national excel calculations - captured in relevant technical guidance

Contaminated sites – ASTM-RBCA modelling

b. What would be the available tools and tests to be used as *intermediate tiers* from lab to field in the exposure assessment?

Intermediate tiers:

1. Pesticides – (moist column) – slide 14 of PW
2. REACH – may be STP simulation test; field studies are not part of the REACH information requirements but only simulation studies like surface water, sediment or soil simulation tests.
3. Biocides - lab tests (screening or simulation triggered by biodegradability, if a.s are directly applied or emitted to soil)
4. National procedure (Italy) – aerobic and anaerobic digestion for biogas production and indirect use of sludge in soils.

c. Which *type of chemicals* would require specific soil exposure assessment i.e. modelling tools available for neutral organic chemicals would not be applicable or would need to be adapted? Triggers for specific attention?

- Some chemical groups that require specific soil exposure assessment:

  e.g Inorganics; ionic substances; surfactants; organometallics; UVCBs

- Input parameters and selection of input scenarios needs to be adapted for modelling these type of chemicals.
- No generic triggers for specific attention could be identified however, it was stressed that the scope and the limits of the applicability of the model. Special considerations are needed for some chemical groups where the standard modelling approach can not be used.

c. Potential of the methods and modelling tools in the future?
What are the possibilities for use of modelling tools for regulatory purposes?

For future:

1. Harmonisation possibility of the models between legislation (especially for comparable intended uses).
2. Models used in one area eg PERSAM for PPPs may be used (with care) in other scenarios for other legislation, even though data requirements might be different.
3. If protection goal is clearly defined and current models are fit for purpose then there is no need to have more complex IT models, except for refinement.
4. Validation of models should be carried out e.g. by comparing with similar models or with good field data
5. It would be useful to have a ring test of the model users

2. How are exposure- and effect assessments linked today? How could they be better linked in the future?

HOW?

- Max initial PEC is compared with PNEC (for some scenarios).
- For PPP accumulated PEC is compared with effect concentration.
- A workshop on how to link exposure with effect was proposed.

QUESTIONS RAISED:

- Are there tools to assess whether the recovery period between pulses of exposure is enough for the population to recover?
- What is the effect on the whole population of a spatially limited exposure like a perimeter of a field in comparison to the whole field?

FUTURE

- Measuring concentrations in effects studies/ understanding which concentrations are used in the effect assessments
- Review the state of the art of modelling for linking exposure and effect and integrated assessment since already a lot of resources have been used on EU level for this.
- Effect assessment in some cases is based on bioassays. In the future bioassays could also be used for exposure assessment?
- Bioavailability is a way how to link exposure and effect. Models like TKTD (toxicokinetic-toxicodynamic model) could be used which models what the internal dose in organism could be.

3. What methodology and tools are available today to carry out exposure assessments at landscape level? What data and tools are needed to make it possible in the future?

- Definition of landscape level for soil exposure assessment is needed. What scale are we talking about?
- To reduce uncertainty EU wide datasets are needed for landscape level assessments.
- Better understanding of the processes that determine the exposure, could lead to better input parameters used in the current models.
- Potential for spatial and temporal GIS approaches are already available

- Concern was raised that current models provide a lot of data but only 10-20% is used.
- Spatial and temporal modelling (Landscape?) may provide better ways of using data for refined EA.
- EFSA guidance document is using EU wide spatial, temporal data for soil, weather and crops
- Georeferenced data needs to be made available for use.
- Additionally it is useful to have data not only on soil properties but also on soil species to know which species lives in which eco-region.

4. Background concentrations

a. How might the background concentrations (i.e., natural and/or anthropogenic 'ambient' levels) of soil contaminants be incorporated into the risk assessment process?
b. How to take into account the background concentrations in risk assessment (PEC)?

Challenges identified:

- Background concentration are not always known
- They are mostly established through a political decision as in the case of the WFD.
- This needs to be defined
- In heavy metal modelling this is overcome by monitoring an area known to be low in heavy metals and use that concentration as the background
- Otherwise, background concentrations can be identified through modelling or else by taking the concentration in your control, since there is no pristine area.
- Data needs to be robust and representative.
- Background concentration is sometimes added to the PEC

Group 3

Effect assessment

Chair: Véronique Poulsen
Chair: Paulo Sousa

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1. Would better links between exposure and effect improve the risk assessment for soil?

- How to account for bioavailability in toxicity testing. Is the application of a default correction factors fully supported?
  - General agreement that the bioavailable fraction of a chemical should be used in ERA – but which one?
  - What can we learn from experiences with metals in prospective (REACH) and retrospective (site-specific) ERA?
  - Further needs in this context: Validation of any surrogate chemical methods needed, influence of environmental (soil) factors to be clarified, complexity of the issue not to be mirrored 1 : 1 in ERA, other?

- What about analytical verification of test substance concentration during tox testing?

1. Would better links between exposure and effect improve the risk assessment for soil?

- **Lower Tier**
  - ✓Adjusting for OM content, if applicable, without using the correction factor
  - ✓Recommendations to use of natural soil (LUFA) for test system without additional correction factor
  - ✓Need for more data to justify the use of the correction factor at lower tiers, even in case of a test with 5% OM content
  - ✓Estimate the pore water concentration from first tier test
  - ✓Not all the experts agreed on total soil concentration measurement at the beginning of the test
- **Higher tier**
  - ✓For higher tier assessments, it was agreed that pore water concentration could be measured, taking into account the phys-chem properties of a substance

2. Are we selecting the relevant species for soil toxicity testing

- What is the relevance of OECD 217 (carbon transformation test) in regulatory hazard assessment?
- Does OECD 208 with 6 species predict long-term toxicity to plants?
- How many and which soil invertebrate species should be covered in hazard assessment?
- How to consider "positive" effects e.g. increase in growth, microbial activity etc.?
- Number of species versus applied AFs.

2. Are we selecting the relevant species for soil toxicity testing

- **Recommendations**

✓Data on additional species could be used for covering difference sensitivity and the SSD could be used in the risk assessment of soil organisms

✓Being the test on carbon transformation rather insensitive, the nitrogen transformation test could also cover effects on the carbon transformation

✓Recommendations to refer back to the workshop on NTTPs

✓Positive effects were discussed but how to consider them in the RA is unclear.

✓AF can be decreased when additional data on different species are available. SSD could be used when at least 8 data point are available. The AF to apply to the HC_5 could be replaced by using the $LLHC_5$. However, there are cases whether the LLHC5 cannot be used.

✓The calibration of the AF using existing database to lower the uncertainty when extrapolating from lab to field considering field data was also discussed

3. What are the boundaries of the applicability of the EPM –based model to predict hazard in soil?

- EPM is used for hydrocarbons applying a solubility cutoff (from logPow=6) considering that the water solubility is a limitation in using that method.
- Considering that microorganisms are not covered to derive PNEC screen and in soil, microbial processes are crucial, additional test on microorganisms might be requested
  a) Nitrogen transformation test is considered a useful and relevant test, however the use of BIOLOG was mentioned when criteria on the interpretation of results are well established.

RESEARCH NEEDS

- Use of pore water concentration in RA
- How to normalise effect data across soils and chemicals
- Data collection of toxicity data on soil organisms in order to better define AFs
- Development of criteria for interpreting and draw conclusion based on BIOLOG results

4. Biodiversity for soil organisms community

- **Would considering the change in the biodiversity of soil organisms improve the soil risk assessment?**
  - Definitions:
    - Soil organisms are microbes, invertebrates and plants
  - Overall perspective biodiversity is important
  - For PPPs exposure and therefore diversity on-field, edge of field and off-field are different and should have different levels of protection
  - For REACH exposure areas and non–exposed areas are not clearly definable
  - Reference level needs to be defined
  - Key drivers/indicator species from different taxonomy groups are needed
  - We are missing higher tier tests applied to risk assessment
- **Can functional diversity be considered as providing a sufficient level of protection, incl. structural diversity?**
  - Both structure and function are important
  - We need methods tackling both function and structure to be discussed in regulatory context - Are there any methods that could be applied in the regulatory context?

4. Biodiversity for soil organisms community

- **How to assure the protection of biodiversity (especially in case of microorganisms)? When is the change in the (microbial) community significant enough to raise the concern?**
  - Measure both structure and function is important
  - DNA based and PLFA methods available to measure structures
  - To measure functions:
    - Nitrogen fixations (e.g. zinc) and ammonia transformations over short time period
    - Multienzyme and BIOLOGs / microresp
    - Focus on functions performed by a small part of microbial community

- **When is the change in the microbial community significant enough to raise the concern?**
  - To know normal operating range (NOR) for microbial community
  - To define when deviation from NOR is relevant for function of the system

5. How to improve applicability and test design of higher-tier testing (semi field/field studies) in regulatory context? What are the new/applicable higher tier methods?

- Inclusion of "intermediary" (= complex) lab studies: multiple generation tests; multispecies tests?
  - Good approach
    - Where to include them in the test strategy
    - Tackle direct and indirect effects
    - Statistical considerations,
    - How to interpret the results (competition?)
    - Which species to use but also for which chemicals?
    - Need for ring test and guidance for standardisation

5. How to improve applicability and test design of higher-tier testing (semi field/field studies) in regulatory context? What are the new/applicable higher tier methods?

- Use SSD approach in soil. Do we have enough data? Can we combine different organism groups?
  - There is data need to implement the approach
  - We can combine different organisms/trophic levels, but we should be aware of biases
  - other important factors to be considered (e.g. different soil types)
  - What kind of effects can be combined (focus on chronic effects)
  - **Guidance for SSD approaches for soil is needed**

5. How to improve applicability and test design of higher-tier testing (semi field/field studies) in regulatory context? What are the new/applicable higher tier methods?

- Mesocosm (e.g. TMEs) and Field tests
  - TMEs can mimic field variation
  - Could be a good surrogate reference tier
  - Guidance is needed:
    - Experimental design (e.g. statistical power; how to tackle recovery)
    - Site selection (regionalisation issues)
    - How to deal with data? How to deal with false positives and negatives?
  - For calibration of lower tiers we need more data

5. How to improve applicability and test design of higher-tier testing (semi field/field studies) in regulatory context? What are the new/applicable higher tier methods?

- Development and validation of modelling approaches
  - Data needs for modelling: reproduction, avoidance, full life-cycle etc.; for the same chemicals and same organisms
  - IBM model for earthworms exists

- Further needs: Improvement of basic ecological and biogeographical data sets, ideally by EU-wide connected databases, other? Ecoregions?
  - Mapping of ecoregions
  - Database combination, open data sharing? Problems with getting data combined?
  - **Need for data mapping**
  - Open access, but is also costs

Research needs

- **Future research needs on biodiversity and higher tier testing;**
  - Regional ecological differences have to be considered (e.g. to refine PECs, PNECs)
    - Need more research on regionalisation (e.g. mapping species and natural soils, data from existing data bases)
    - Need for collection and data sharing on biogeographical data
  - More data on the NOR for soil organisms
  - Guidance on application on SSD approach
  - Guidance on the performance of TMEs or similar approaches