

**Virtual Workshop: Proposal to standardise the analysis and persistence
assessment of non-extractable residues (NER) 17 – 18 February 2021**

Summary and Conclusions

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Summary and Conclusions

EXTRACTION, NER TYPE SEPARATION AND REMOBILISATION

- apply substance specific solvent if available or alternatively use standard solvent mixture
- use solvents with different polarity and start with mild extraction methods that get harsher with every extraction step
- use PLE as terminal step as a standard in a stepwise extraction procedure
- Silylation/EDTA extraction should be used for type I NER characterisation but first prove the method to be applicable
- Remobilization of NER is not routinely investigated

Summary and Conclusions

PERSISTENCY ASSESSMENT AND NER

- A guidance is needed how to follow a stepwise approach; not all steps have to be mandatory in case assessment on P, vP and not P can be already drawn conclusively at an early step without full NER characterization, this should be sufficient
- If only type I NER is of concern for persistence assessment, a standardized approach for determination of type II NER/bioNER vs. type I NER have to be developed
- A concept for simulation tests without full NER characterization and use of non isotope-labelled substances is needed
- Impact of consideration of NER in DT₅₀ derivation for model substances of the project is not that high, necessity of NER characterisation is questionable
- There is concern that NER characterisation cause higher costs for the registrants

Summary and Conclusions

IDENTIFIED RESEARCH NEEDS:

Scientific view:

- Conditions for remobilization of NER
- Chemicals with high type I NER: uptake in organisms?
- Detailed analysis of the EDTA extract (how much xeno/bioNER present)
- When does MTB fail or not apply. Example: MTB `special cases`, no mineralisation but (building block) incorporation into bioNER
- Detailed analysis of the HCl extract after column purification (how much xenoNER left)
- Does the HCl extract contain all bioNER, or should a factor be applied? (like factor 2 for tAA)

Summary and Conclusions

IDENTIFIED RESEARCH NEEDS:

Regulatory view:

- Further validation of the MTB approach for type bioNER determination
- Investigate the role of the consideration of NER in DT_{50} calculation if the degradation does not follow SFO kinetic
- OECD 301 CO₂-formation results suitable for first MTB assessment?

**Thank you for your
attention!**

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