Für Mensch & Umwelt

Umwelt Bundesamt

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

Outcome Breakout Group ‘Persistency assessment and NER‘

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Outcome Breakout Group ‚Persistency assessment and NER‘

- Different approaches for the determination of DT_{50} values (a-f) with respect to NER formation (b-f) (*Link ‘Half-life derivation’*)→ Basis of the discussion

			Sulfadiazin NER: 82% CO_2: 1.7%	Bromoxynil NER: 63% CO_2: 31%	Isoproturon NER: 51% CO_2: 25%
a)	**Solvent (Sol)-extractable parent**	**current approach** in active substance assessment; NER considered as sink	**5.9**	**7.3**	**44.7**
b)	**Sol_{parent} + total-NER**	according to recommendations in **REACH R.11;** total NER considered remobilisable	**6590.0**	**279.0**	**241.0**
c)	**Sol_{parent} + ASE_{parent}**	**former BfG recommendation**	**10.1**	**8.1**	**53.6**
d)*	**Sol_{parent} + ASE_{parent} + EDTA extractable$_{parent}$**	**ECHA discussion paper and revised BfG recommendation;** consideration of Type I-NER	**10.2**	**7.9**	**48.5**
	Sol_{parent} + ASE_{parent} + Sylilation extractable$_{parent}$		**10.4**	**8.1**	**49.2**
e)*	**Sol_{parent} + ASE_{parent} + $XenoNER_{measured}$**	**ECHA discussion paper;** consideration of bioNER xenoNER = total NER – bioNER -> HCl as proxy for bioNER -> bioNER calculated based on MTB-method (Trapp & Brock-Libonati)	**366.0**	**132.0**	**147.0**
f)	**Sol_{parent} + ASE_{parent} + $XenoNER_{calculated}$**		**467.0**	**161.0**	**140.0**

* calculation based on 6 instead of 10 sampling points

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Is it necessary to have <u>one</u> standardised approach for NER determination and characterisation, i.e. stipulation of the extraction procedure (ASE, EDTA/ Silylation, BioNER, etc.)?

- It would be very useful to have general lines of the methodology of extraction. It helps regulators to know if NER are depending on the extraction even though it is clear that extraction strategy depends on the molecule.
- A guidance is needed, in best case a stepwise approach. In case assessment on P/vP/not P can be already drawn conclusively without full NER characterization, this should be sufficient.
- If only type I NER is of concern for persistence assessment, a standardised approach for determination of type II/III NER vs. type I NER is needed.
- Concept for simulation tests without full NER characterization and use of non isotop-labelled substances needed.
- Concern that NER characterisation cause higher costs for the registrants

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What are the advantages and disadvantages of the presented approaches for c-f for the consideration of NER in DT_{50} calculation?

General:

- Approaches are not protective enough
- Applicable for registrants under REACH, but not meaningful for other purposes, e.g. regulation pharmaceutical, biocides, PPP
- Questionable if approaches d, e or f deliver realistic/relevant DT_{50}
- results of c) and d) seem very similar for the model substances, general tendency for various substances
- in approach e) and f) type II NER are considered in DT_{50} calculation resulting in a kind of worst-case assumption
- Better understanding on NER composition might be needed before incorporating into the PBT assessment, since it has many regulatory implications
- Standardisation of methodology of extraction allows better comparability of study results

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What are the advantages and disadvantages of the presented approachesfor c-f for the consideration of NER in DT_{50} calculation?

DT_{50} based on **parent in Solvent** and **Total NER** (b):

- Approach is probably irrelevant for most substances and deemed too conservative

DT_{50} based on **parent in Solvent and ASE extract** (c):

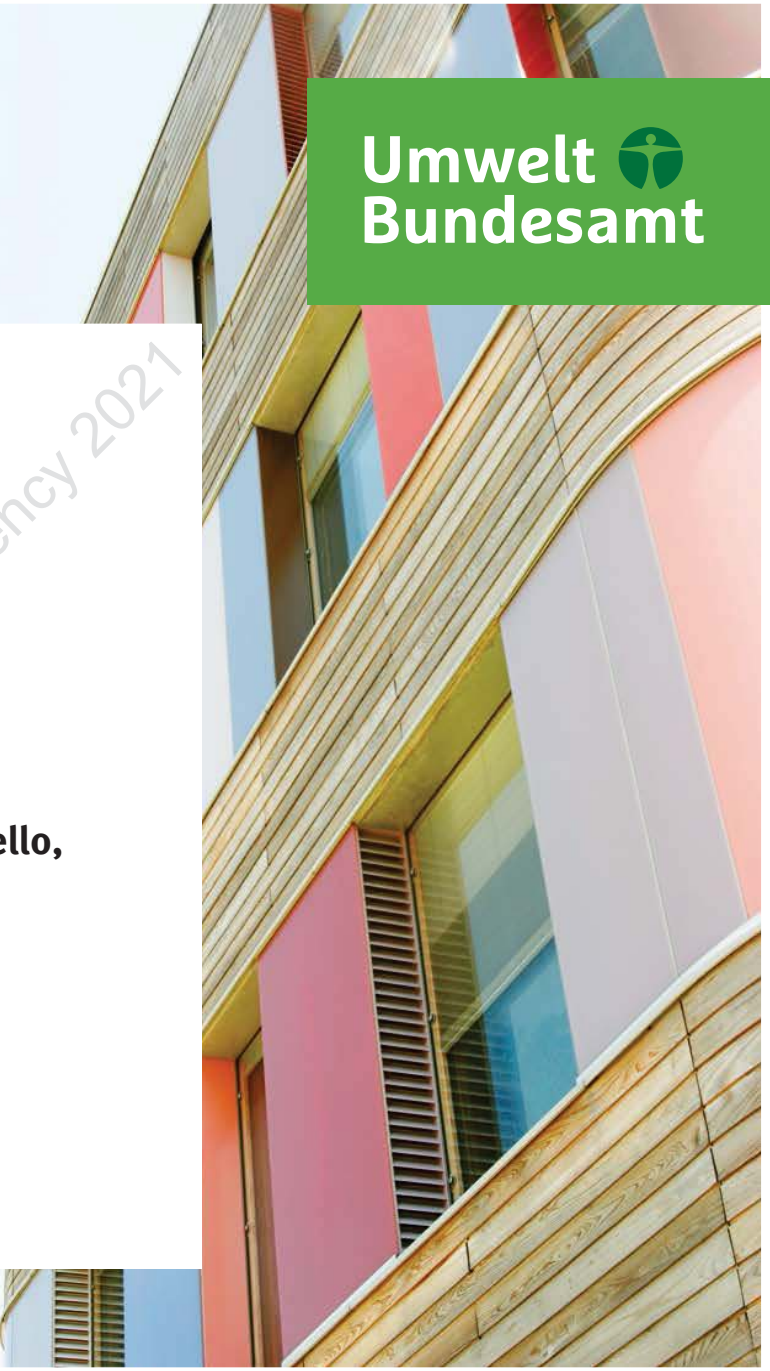
- simplicity with no significant additional cost for the registrant

DT_{50} based on **parent in Solvent and ASE extracts** and **Parent in type I NER** (d):

- additional work/cost for the registrant; regulatory guidance updates needed to interpret the data

DT_{50} based on **parent in Solvent and ASE extracts** and **$XenoNER_{measured}$** (e):

- very cautious about accepting this beyond a screening



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Thank you for your attention!

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