

Organisation Team

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Photo: silylation workstation at Fraunhofer IME

Miscellaneous

Target group:

Regulators and registrants/applicants from different chemical regulations as well as academics/researchers and consultants who are involved in experimental studies and dossier preparation.

Venue:

The meeting will be held virtually on the WebEx videoconference platform.

A link will be sent by e-mail to all registered participants within one week before start of the workshop.

Registration:

Please send an email with reference line "NER Workshop" to

Daniel.Richter@uba.de and cc Annett.Sawatzki@uba.de

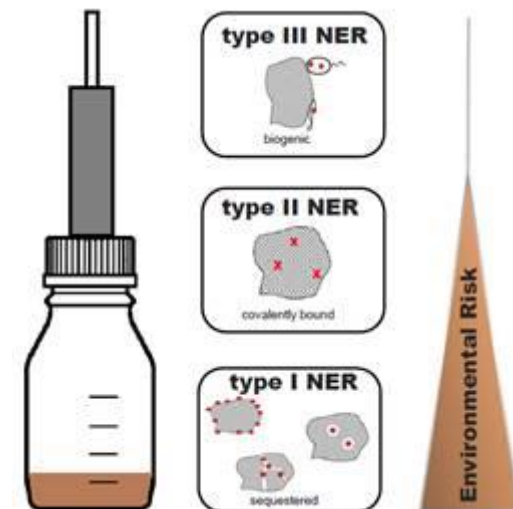
and please state:

- your first and family name,
- company or affiliation
- country
- field of interest (*to which breakout group would you like to participate*)

by January 31st, 2021 at the latest.

Costs:

Workshop free of charge!



Virtual Workshop: Proposal to standardise the analysis and persistence assessment of non-extractable residues (NER)

17 – 18 February 2021

on behalf of:

Umweltbundesamt Dessau-Roßlau,
Germany

Danmarks
Tekniske Universitet



INSTITUTE
FOR
ENVIRONMENTAL
RESEARCH



RWTH AACHEN
UNIVERSITY

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IME

Umwelt
Bundesamt

Virtual Workshop: Proposal to standardise the analysis and persistence assessment of non-extractable residues (NER)

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NER are formed during transformation tests in soils, water/sediment systems and water (e.g. OECD 307, 308, 309). The relevance of NER formation depends on substance properties and characteristics of the solid matrix (soil, sediment etc). Extraction methods impact the amount of NER formed but are difficult to standardise. Thus, the boundary between the extractable fraction and non-extractable residues is currently not precisely specified.

The ECHA R.11 guidance, 2017 highlights the importance of NER for assessment of persistence for PBT, vPvB and POP classification. NER can either be reversibly bound to the soil/sediment and pose a potential risk to be released into the environment or be irreversibly bound or even degraded and transformed into biomass which is assessed as safe sink.

For regulatory use, classification of different NER types according to their binding status is proposed. Extraction schemes for experimental determination of those NER types in laboratory testing are proposed but a standardised, commonly accepted extraction routine is not yet available.

The fraction of biogenic NER (safe sink) can be calculated beforehand from a few, readily available data. This allows a first characterization of the significance of NER for the P assessment.

A research and development project funded by UBA has compared different approaches to determine total NER and the different types and developed a refined proposal for routine testing.

The aim of the workshop is to present and discuss the proposal to achieve a harmonised concept to be used in regulatory assessment of the environmental persistence of REACH chemicals, pesticides, biocides and pharmaceuticals.

Programme

Wednesday, 17th February 2021

13:00 – 13:30 **Welcome note and introduction** (Matthias Honnacker, UBA)
Background to NER from regulatory perspective (Astrid Wiemann, Ulrich Jöhncke, UBA)

13:30 – 14:00 **Determination of non-extractable residues in soils: Towards a standardised approach** (Dirk Löffler, BfG)

14:00- 14:30 **NER assessment – ECHA discussion paper** (ECHA and A.Schäffer, RWTH Aachen/ M.Kästner, UFZ Leipzig/ S.Trapp, DTU Lyngby)

14:30-15:00 **NER assessment - the current approach for medicinal products** (Rene van Herwijnen, RIVM, NL)

15:00 – 15:15 **Break**

15:15 – 15:45 **NER assessment – an industry's perspective** (Doris Ebert, on behalf of ECETOC)

15.45 – 16.30 **Presentation results of the UBA R+D project including the MTB-approach** (Dieter Hennecke, Fraunhofer IME/ Stefan Trapp, DTU Lyngby)

16:30 –17:00 **Discussion day 1 (in breakout groups)**

Thursday, 18th February 2021

09:00 – 09:45 **Proposal of a harmonised approach to consider the NER in P/ PBT assessment – open questions** (D.Hennecke/ A.Schäffer/ M.Kästner/ S.Trapp, UBA)

09:45 – 10:30 **Open questions, discussion and presentation of outcome from breakout groups**

10:30 – 10:45 **Break**

10:45- 11:15 **Summary and conclusions** (UBA, Hennecke, Schäffer, Kästner, Trapp)

11:15 **End**

Breakout groups (17th February 2021, 16.30 - 17.00 h)

- 1. Extraction, NER type separation and remobilisation**
A. Schäffer, M. Kästner, D. Hennecke
- 2. Persistence assessment and NER**
U.Jöhncke, A.Wiemann, S.Trapp, J.Schmidt
- 3. Questions from registrants and applicants** cancelled