
Workshop Report

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

17. / 18. February 2021

On February 17 and 18, 2021, an international online workshop entitled “Proposal to standardize the analysis and persistence assessment of non-extractable residues (NER)” took place (see link ‘[Leaflet Workshop](#)’). It was organized by the German Environment Agency and Fraunhofer IME.

More than 70 participants (see link ‘[Participants](#)’) from authorities, industry and science, including members of ECHA's PBT Expert Group, discussed the future consideration of NER in persistence assessment. As a basis for the discussion, the ECHA discussion paper for NER assessment (see link ‘[Literature](#)’) was presented by the authors, as well as the results of the current UBA research project "Consideration of non-extractable residues (NER) in the PBT assessment" (FKZ 3718 65 407 0).

The aim of the workshop was to present and discuss a practical approach for a harmonised test procedure for NER characterisation. In this discussion, the industry's point of view was an important indicator for determining the acceptance and practical applicability of the proposed approach. In addition, regarding the effects of NER characterisation on the PBT assessment, the contributions of the regulators were necessary in order to get a reliable statement.

Questions related to details of the practical laboratory procedure and to suggestions regarding additions or modifications to the presented procedure were raised during the workshop. Moreover, the regulatory context was discussed (see link ‘[FAQ](#)’). On the second day, the questions focused more on the chemical analysis of silylation extracts. Most laboratories have no experience with this extraction method and the extracts have the reputation of being difficult to analyse. This was rebutted by the results of the current research project. In cases where the test substance is sensitive to silylation, EDTA extraction offers an alternative procedure. A suggestion for a further alternative method (pyrophosphate extraction) was included and will be investigated on the present sample set as part of a Bachelor thesis.

The two main topics “laboratory practice” and “NER in persistency assessment” were discussed in more detail in breakout groups (see links ‘[Breakout Group Laboratory Practice](#)’, ‘[Breakout Group Persistence Assessment](#)’).

Based on the results of the first day, two flow charts were drafted which present two different ways to take into account NER in the persistence assessment (see links ‘[Proposal 1](#)’, ‘[Proposal 2](#)’). This was explained using a practical example with data from the research project (see link ‘[Extraction procedure and Half-life derivation](#)’). Both flow charts

represent a stepped approach with increasing laboratory effort in each step, but at the same time a higher degree of reality or decreasing conservatism.

It was concluded that, e.g. PLE should be the final step in a stepwise extraction procedure (see link '[Summary and Conclusions](#)'). Further conclusions were that guidance is needed on how to proceed in a stepwise approach for NER characterisation and persistence assessment. In addition, the practical determination of "bioNER" (type III NER) was found to be still not fit for practice. However, a modelling approach (MTB) is proposed which should give a good estimate of bioNER.

Workshop presentations

Day 1

- Determination of non-extractable residues in soils: Towards a standardised approach (Löffler D.)
- NER assessment – ECHA discussion paper (ECHA and Schäffer A., Kästner M., Trapp S.)
- NER assessment - the current approach for medicinal products (van Herwijnen, R.)
- NER assessment – an industry's perspective (Ebert D., on behalf of ECETOC)
- Presentation results of the UBA R+D project including the MTB-approach (Hennecke D., Trapp, S.)

Day 2

- Proposal of a harmonised approach to consider the NER in P/ PBT assessment – open questions (Hennecke D., Schäffer A., Kästner M., Trapp S.)
- Open questions
- Discussion and presentation of outcome from breakout group 1 'Extraction, NER type separation and remobilisation'
- Discussion and presentation of outcome from breakout group 2 'Persistence assessment and NER'
- Summary and conclusions (UBA)