Part II: Non-Extractable Residues (NER) in Soil – A Regulatory View

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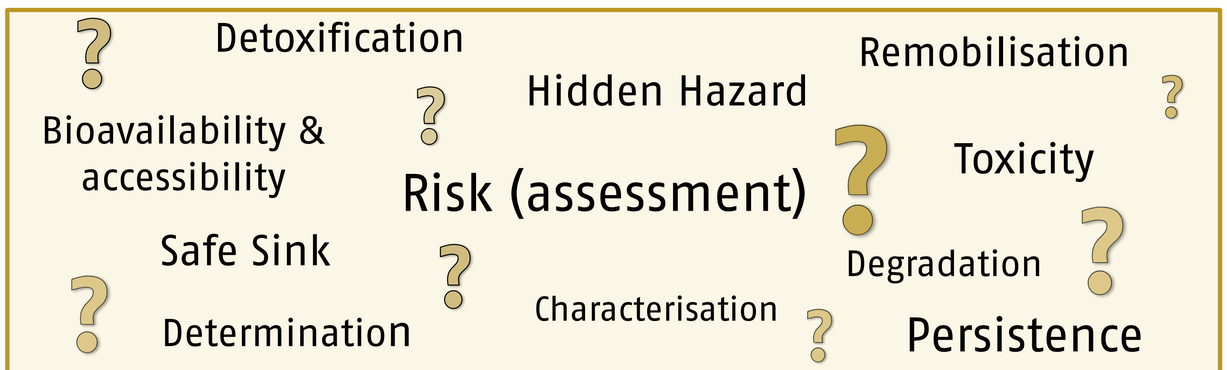
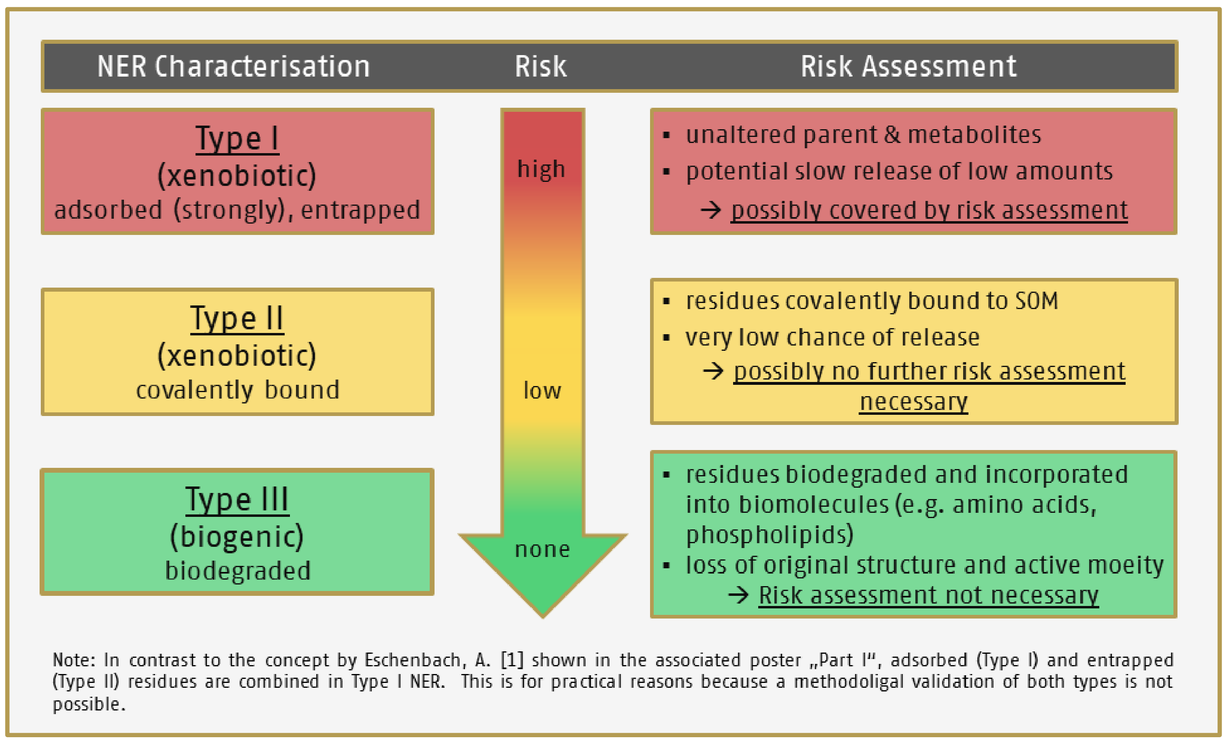
Background

- Chemicals form non-extractable residues (NER) in environmental compartments (e.g. soil)
- Quantification possible using isotope-labelled test substances
- Characterisation difficult if possible at all
- Process leading to reduced compound (bio)availability and decelerated degradability



Regulatory Views & Implementation in Risk Assessment

- Based on **methodical definition** (non-extractability)
- **Different and contrasting views** of role of NER formation and their subsequent **persistence/toxicity** (e.g. EU: REACH (EC_1907_2006), Biocides (EC_528_2012) and plant protection products (PPP; EC_1107_2009)
- For PBT assessment characterisation is often requested however without standardised guidance or testing guidelines



Note: In contrast to the concept by Eschenbach, A. [1] shown in the associated poster „Part I", adsorbed (Type I) and entrapped (Type II) residues are combined in Type I NER. This is for practical reasons because a methodoligal validation of both types is not possible.

EU

- Industrial Chemicals (ECHA):
  - NER regarded as non-degraded substance for P/vP assessment unless it can be shown that residues are irreversibly bound (REACH)
- Biocides (ECHA):
  - If NER >10% should be characterized „as far as possible"
  - Organic matter characterization (humic fractions)
  - Quantification after acetone/methanol-ultrasonic extraction
  - **Authorization declined** if **NER >70%** and **Mineralisation <5%** after **100 days** (see also PPP)
- Pharmaceuticals
  - No specific mention or guidance
  - Guidance for pharmaceutical companies (FASS.se): NER considered not bioavailable and can be removed from system for DT_{50} calculations
- PPP (EFSA):
  - NER in determination of **fate and behaviour in soil, water and sediment** (7.1.1. route of degradation in soil, 7.2.2.2. aerobic mineralisation in surface water and 7.2.2.3. water/sediment)
  - **Identify** individual components which at any time account for more than 10% of the amount of active substance added, including, **if possible**, non-extractable residues (for soil only)
  - Considered as **degradation**, **sink** and **detoxification** process
  - Usually accounted for in the description of **dissipation kinetics**
  - **Authorization declined** if **NER >70%** and **Mineralisation <5%** after **100 days** (Guidance Document on Persistence in Soil), unless...
    - **Unless** clause: scientific demonstration that there is no accumulation in soil under field conditions at such levels that:
      - Unacceptable **residues** in **succeeding crops** occur
      - Unacceptable **phytotoxic effects** on succeeding crops occur
      - Unacceptable **impact** on the **environment** occurs

US (PPP)

- Guidance for Addressing Unextracted Pesticide Residues in Laboratory Studies [2]
- **NER >10%:** screening for **adequate extraction methods**:
  - Use of polar and nonpolar solvent systems (range of dielectric constants) in order to:
    - Quantify degradation of parent and
    - Avoid double-counting sorption in exposure models
- If NER **cannot** be **excluded** from the residues of **concern** (assuming similar toxicity as parent) different **aquatic exposure modelling approache**s with DT_{50} values including and excluding NER should be used:
  - DT_{50} values including unextracted residues result in no level of concern (LOC) exceedances for risk: may be used in the exposure assessment in the absence of DT_{50} values that exclude unextracted residues
  - DT_{50} values including unextracted residues result in an LOC exceedance: both DT_{50} values including and excluding unextracted residues may be used with the Total Residue (TR) kinetics approach in the exposure assessment to produce bounding exposure estimates for the residues of concern.
  - If the unextracted residues may include a transformation product that is known or suspected to be more toxic than the test compound, then
    - They may be assessed with the Residue Summation (RS) kinetics approach if the transformation product shares a similar mechanism of action as the parent compound; or
    - They may be assessed separately from the parent compound if the transformation product has a mechanism of toxicity different from that of the parent compound.

Regulatory Challenges & Future Requirements

- Lack of knowledge about **chemical nature** of NER
- Formation & occurrence not linked to **bioavailability** & **bioaccessibility**
- Qualitatively and quantitatively not linked with **potential effects**

→ Further **information** on the **nature** of NER
→ Reliable methods and experimental or modelling tools to **evaluate** NER **toxicity**, environmental **impact** and residue **carry-over**
→ **Evaluation** of **relevance** for tox and ecotox as non-point source pollution of water bodies through slow release

[1] Eschenbach A. (2013): Characterization of non extractable residues for their risk assessment in soil with special regards to pharmaceuticals. International Workshop Pharmaceuticals in Soil, Sludge and Slurry, Dessau.
[2] EPA (2014): https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-addressing-unextracted-pesticide-residues.