



Analytical challenges and issues of biological active substances in Environmental fate and Ecotoxicological testing regimes

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Analytical challenges are important!

- Regulatory studies are required
- Financial implications
- The science must be sound
- Pioneering products



Dialogue needed in order for the science to advance

Algal polysaccharide test item - 1

Environmental Fate Study

OECD 307 - Degradation in soils

Data is used to predict the likelihood of environmental persistence

Key Challenges:

- Rapid degradation of test item
- Exact adherence to guideline impossible

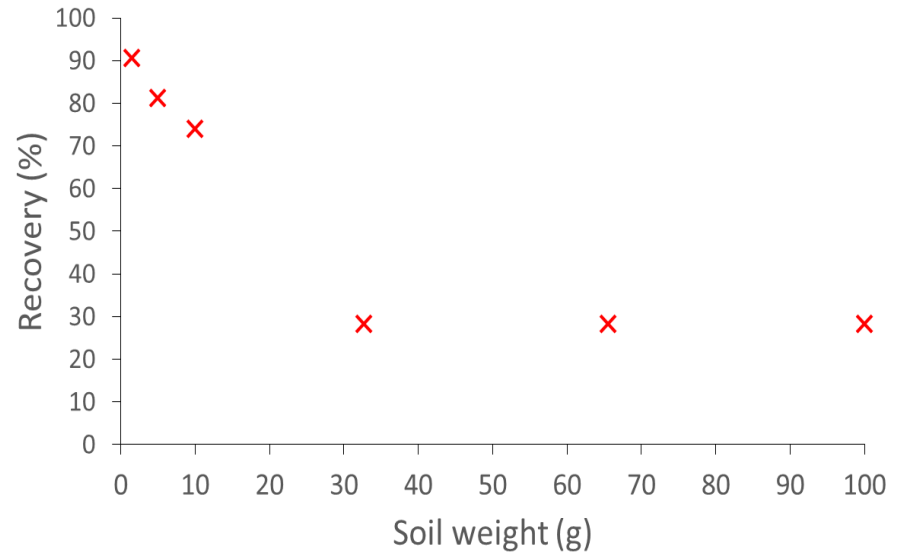
Solutions:

- Careful planning
- Study design modifications



Study design modification: very instable test item

- Small soil aliquots
- Modified extraction method
- Omit sample concentration
- Exaggerated application rate
- Immediate freezing



Similar modifications for parallel adsorption/desorption (OECD 106) study

Algal polysaccharide test item – 2

Aquatic Ecotox Study

OECD 221- *Lemna* growth inhibition test

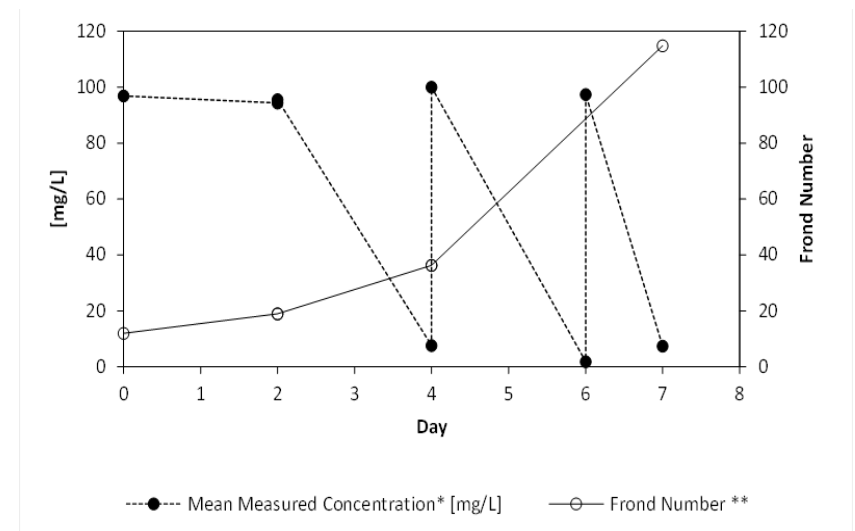
Data is used to assess toxicity to *Lemna* (duckweed)

Key Challenges:

- Utilisation of test item as a carbon source by the plants
- Rapid degradation of test item
- Suitable analytical method

Solutions:

- Semi-static test design
- Tailor made HPLC/MS method (detecting multiple charged ions)



Botanical extract test item – Organic acids

Another OECD 221- *Lemna* growth inhibition test

Key Challenges:

- Extensive bacterial growth was induced by the test item
- Test item itself was significantly bacteriologically degraded
- Concentrations of the test item in the test media could not be maintained
- Not possible to handle the test item under standard static, semi-static or flow-through conditions

Botanical extract test item – Organic acids

Aquatic Ecotox Study

OECD 211- *Daphnia magna* reproduction test

Survival, growth, and reproduction of *Daphnia magna* investigated over 21 days

Key Challenges:

- Oxidation of the unsaturated fatty acids
- Adsorption to feed/separation from water

Solutions:

- Extensive stability assessment, exhaustive recovery from test vessels
- Flow through conditions



Microbial test item – Fungal spores

Pollinator Study

GD 239 - Chronic toxicity to honey bee larvae

Key Challenges:

- Artefacts
- Enumeration method
- Statistical analysis

Solutions:

- Interdisciplinary approach
- Dialogue



Conclusions

- Rapid test item degradation is common across diverse compounds and study types
- Stability issues require expert handling, rapid communication and action
- Experience is everything
- Need for dialogue – share the challenges

Thank you for listening!



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