THE ROLE OF MESOCOSM DATA IN ECOTOXICOLOGICAL LEGISLATION

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INTRODUCTION

Mesocosm studies serve as a regulatory accepted study, seen as bridging a gap between lower tier laboratory-based toxicity tests and dynamic natural ecosystems. They represent standardised experimental systems that aim to capture the interactions, variability, and recovery dynamics of aquatic communities and populations under realistic environmental conditions. Within the context of environmental risk assessment for plant protection products (PPPs), mesocosms provide higher-tier data that go beyond individual species response, generating ecologically relevant data into population, community, and functional-level effects.
In regulatory frameworks, mesocosm studies can be used to simulate real-world exposure scenarios while maintaining reproducibility and scientific consistency. Understanding how endpoints are interpreted within regulatory evaluations is key to determining how mesocosm data influence final legislative outcomes.

However, the complexity of mesocosm datasets presents challenges for interpretation across studies and the integration of mesocosms into regulatory decision-making. Whilst EFSA 2013[1] provides EU guidance on the interpretation of mesocosms in an effort toward standardisation and to increase comparability and transparency across studies, differences in design that are required for chemical loading, behaviour, sediment characteristics, species composition, and environmental conditions can all affect study outcomes and regulatory interpretation.

REGULATORY TRIGGER FROM AUTHORITIES

COME TO BOOTH 35 TO DISCUSS HOW A MESOCOSM CAN SUPPORT YOUR REGULATORY SUBMISSION!

GLP Lower-tier laboratory studies:

- Single species tests
- Standardised OECD testing
- EC50, EC10, NOEC
- Targeted and specific but don't reflect ecological realism
- Conservative exposure

GLP Mesocosm design:

- Communities set up and composition data gathered
- Sediment and Water Characterisation
- Exposure modelling – e.g. EPAT. Design application regime
- Difficulty replicating real world scenarios in a controlled environment, suitable replication

GLP In-Life Phase:

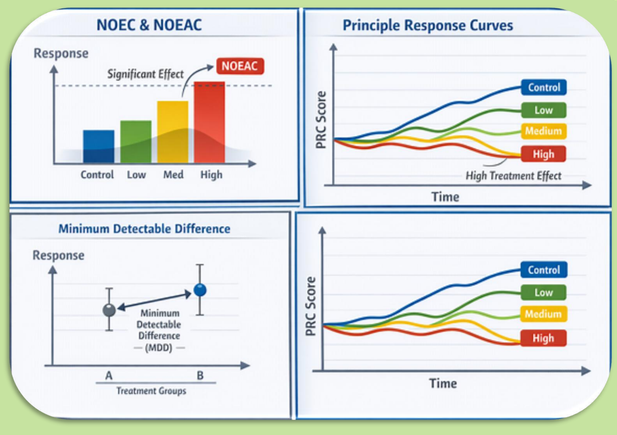
- Application of PPP
- Biological monitoring (taxonomic abundanc sampling, macrophyte health)
- Analytical degradation monitoring
- Time and resource consuming
- Unpredictable complications of natural conditions

GLP Data collection:

- Macrophyte wet/dry weights
- Macrophyte mapping area
- Taxonomic identification
- Degradation analytics

GLP Data analysis:

- NOEC, NOEAEC,
- Principal Response Curves
- Minimum Detectable Difference
- EFSA 2013 requirements



Refine Risk assessment:

- Assessment factors
- Derive RACs - ETO & ERO
- Broad lack of success rate

Regulatory Decision:

- EFSA 2013 assessment
- High levels of reg scrutiny of design & results
- No/unlikely acceptance of ERO

ISSUES

- Difficult substances – hard/impossible to match EPAT in real-world conditions
- Not always possible to include (lab) sensitive spp/taxa in natural systems
- Lack of standardisation in mesocosm design
- Limited guidance on data interpretation

PROPOSALS

- Evaluation of mesocosms should be more holistic – including assessment of exposure profiles
- ERO should be considered as part of WoE
- Modified designs to account for difficult substances should be accepted alongside more standardised mesocosm design
- Results still used to support weight of evidence
- Risk assessment for where EFSA 2013 requirements not met

CONCLUSION

Mesocosm studies provide ecologically relevant insights for PPP risk assessment, but their complexity and variability create challenges for consistent interpretation and regulatory acceptance. Differences in study design, environmental conditions, and community composition can limit comparability across experiments, even when standardisation efforts are applied. Regulatory requirements on GLP studies further increases the resource demands associated with generating acceptable higher-tier data. The interpretation of ecological endpoints can remain subjective, influencing how results are integrated into risk assessments. Continued refinement of analytical approaches and guidance will be essential to strengthen the use of mesocosm data in PPP risk assessment. If the proposals outlined above were taken on board, they would support more consistent interpretation and evaluation of mesocosm data and enable a greater number of mesocosm studies to be accepted within regulatory decision-making which provides more ecologically relevant data for real world scenarios.

References: Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013; 11(7): 3290.