How to perform REACh studies in a smart way? A case study with Industrial Chemicals on aquatic systems highlighting challenges and solutions

Katrin Weber[1], Marco Candolfi[1],

[1] Eurofins Agroscience Services Ecotox GmbH, Eutinger Str. 24, 75223 Niefern-Öschelbronn, Germany

E-mail contact: KatrinWeber@eurofins.com

Background

The regulatory framework of REACH [1] (Registration, Evaluation, Authorisation and Restriction of Chemicals) has transformed the landscape of ecotoxicological testing, necessitating robust methodologies for assessing the environmental impact of a wide range of industrial chemicals. Historically, testing focused on plant protection products were simpler in terms of molecule complexity and behavior in aquatic environments. However, with the inclusion of diverse substances under REACH, new analytical and methodological challenges have emerged, requiring innovative solutions.

Objectives

The aim is to elucidate the challenges faced in aquatic ecotoxicology testing under the REACH framework. It focuses on the complexities introduced by novel substances, outlines the limitations of traditional testing methods, residue analysis and proposes a strategic approach to streamline testing processes while ensuring regulatory compliance.

Methods

Achieving a systematic testing approach to aquatic testing includes the following steps:

1. Test Item Preparation: Developing reliable methods for dissolving and administering test substances that are poorly soluble, volatile, or chemically unstable.

2. Exposure Systems: Using different test systems, tailored to the specific characteristics of the test substance. Adjustments to the test system design are often required to mitigate issues like biofilm formation or chemical degradation.

3. Analytical Challenges: Highlighting the inadequacies of standard methods (e.g., TOC analysis) and advocating for the use of advanced analytical techniques such as HPLC, GC-MS/MS, and LC-MS/MS for precise measurement, particularly at low concentrations.

4. Feasibility Studies: Conducting preliminary assessments based on OECD 23[2] to evaluate the chemical properties and potential issues before starting the main biological tests. This proactive step aims to refine the testing strategy and improve overall efficiency.

Results

The findings emphasize the critical role of customized test setups and advanced analytical techniques in overcoming the challenges of aquatic ecotoxicology testing under REACH. Key results include:

- Enhanced Accuracy in Dosing and Measurement: Adapted methods allow for better control of substance concentrations, even with volatile or unstable chemicals.

- Reduction in Testing Failures: By conducting feasibility studies and tailoring the exposure systems, the incidence of failed tests due to biofilm formation or analytical issues was significantly reduced.

- Improved Compliance with Regulatory Requirements: The adoption of state-of-the-art analytical methods addressed the heightened accuracy demands of REACH, leading to more robust data and greater regulatory acceptance.

Discussion

The shift from testing plant protection products to a broader array of industrial chemicals under REACH has highlighted substantial gaps in traditional ecotoxicology testing methodologies. Substances with complex physical and chemical properties (e.g., UVCBs, polymers, volatile compounds) present unique challenges in terms of solubility, stability, and analytical detection. The presentation argues for a paradigm shift towards “smart testing” — a strategic approach that integrates comprehensive feasibility studies, enhanced communication between stakeholders, and the application of cutting-edge analytical techniques.

The proposed methodology not only addresses the technical challenges but also aligns with the regulatory objectives of REACH by reducing unnecessary animal testing and streamlining the overall process. By improving test accuracy and data reliability, this approach supports better decision-making regarding the environmental impact of industrial chemicals.

Conclusions

The complexities introduced by the expanded scope of REACH testing necessitate a re-evaluation of traditional ecotoxicology methodologies. A tailored, adaptive approach is essential for handling the diverse range of test substances encountered. Through feasibility studies, enhanced analytical methods and customized exposure systems, the proposed strategy effectively meets the stringent regulatory requirements while minimizing costs and resource use. Continued innovation and collaboration in advancing ecotoxicological testing practices are important to ensure the safe use of industrial chemicals in the environment.

Keywords

REACH, Aquatic Ecotoxicology, Analytical Challenges, Feasibility Studies, Test System Adaptation, Advanced Analytical Techniques, Industrial Chemicals, Biofilm Formation, Regulatory Compliance.

1. References

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)Text with EEA relevance

[2] OECD (2019), Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, OECD Series on Testing and Assessment, OECD Publishing, Paris