

SC 7: Statistical issues in the design and analysis of ecotox experiments

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Abstract

Course covers statistical considerations of experimental design and statistical analysis used to evaluate toxicity of chemicals in the environment. Both NOEC determination and EC_x estimation from regression models are developed in detail, with assessment of their applicability and use in risk assessment. The lead instructor works closely with OECD and USEPA, is an active member of the OECD Validation Management Group for Ecotoxicity and was instrumental in developing several new OECD Test Guidelines and new methodology and these will be discussed. All instructors have worked on several other multi-disiplinary teams developing regulatory statistical guidance. Continuous, quantal, severity score (histopath), time-to-event data (e.g., time to reach NF stage 62), and experiments with multiple controls will be explored. The instructors have decades of practical experience designing and analyzing ecotoxicity experiments, performing risk assessments, and dealing with related regulatory issues and drew on that experience in developing this class. Underlying principles will be discussed, but the focus will be on practical issues. All topics will be illustrated by real laboratory ecotoxicity data demonstrating the relevant points and techniques. Logical flow-charts for NOEC determination and for regression model fitting will be presented, as well as some discussion of software to conduct analyses.

Course objectives

The course is intended to identify and explore techniques both statistically sound and acceptable to the regulatory communities for analyzing laboratory ecotoxicity experiments to meet current or near-term future guidelines. The course will identify problematic data that may call for specialized approaches. It is intended to provide practical advice and make specific recommendations, as well as alternatives and when they might be appropriate. It will also introduce statistical methods in recently adopted OECD Test Guidelines.

Course level

Intermediate