Guidance on the selection of cohorts for extended one-generation reproduction toxicity study (OECD 443)

Alan Poole
European Centre for Ecotoxicology & Toxicology of Chemicals, Belgium

The extended one-generation reproduction toxicity study (EOGRRTS; OECD test guideline 433) is a new and technically complex design to evaluate the putative effects of chemicals on fertility and development, including effects upon the developing nervous and immune systems. In addition to offering a more comprehensive assessment of developmental toxicity, the EOGRTS provides important improvements in animal welfare through reduction and refinement of use of experimental rodents in a modular study design. The challenge to the practitioner however is to know how the modular aspects of the study should be triggered on the basis of prior knowledge of a particular chemical, or on earlier findings in the EOGRTS itself, requirements of specific regulatory frameworks not withstanding. The purpose of this document is to offer guidance on science-based triggers for these extended evaluations.

Biography

Alan Poole earned his PhD from the University of Surrey and is a Fellow of the Royal College of Pathologists. He worked for the UK Medical Research Council before moving to Smith Kline and French to lead a team involved in preclinical development of pharmaceuticals. He was later employed by Dow Chemical in Switzerland where he worked addressing safety of industrial chemicals. He has published widely and is currently the Secretary General of the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC).

alan.poole@ecetoc.org

Notes: