

Request for data on multi-generation reproductive toxicity studies

Deadline: 15 February 2009

The OECD is developing a Test Guideline on an Extended One Generation Reproductive Toxicity Study. According to the draft Test Guideline, the second generation (F2) is not performed in every cases but triggered if early findings from the study or data from previous studies raise concern for possible effects on reproduction or if equivocal effects on reproduction are obtained in the P animals.

The possibility to stop the study after the first generation (F1) is supported by two retrospective analyses respectively performed in the Netherlands (2007) and in the US (2008), on industrial chemicals and on pesticides. These analyses indicate that the impact of the second generation on the overall NOAEL or Classification and Labelling is very limited. However, the US retrospective analysis shows that if the triggers proposed in the draft Test Guideline are used, the study will go to the 2nd generation in 43% of the cases.

The triggers, as defined in the current draft Test Guideline, need to be refined, so that they can better focus on the identification of relevant cases. This will be done through a data analysis of available databases (US, Netherlands and Canada) that will be merged into the US EPA's Toxicity Reference Database (ToxRefDB). As this will be a major work, critical for the protection of human health, it is important that the dataset be as comprehensive as possible.

Therefore anyone having relevant data should first contact David Dix and Matt Martin (US EPA), and check with them if the study is not already in ToxRefDB. Then, if appropriate, US EPA (Dix and Martin) should be provided with the data in whatever form they are, e.g.: the study report itself, a summary of the study report, a publication based on the study report. Since ToxRefDB is publicly accessible, only non-confidential data for which the identity of the compound can be included are suitable for entry into this database.

The request includes all types of multi-generation studies (including extended one generation reproductive toxicity studies if an F2 has been triggered), studies submitted or not to Competent Authorities, studies in the public domain or not, studies with positive or negative results.

You can contact David Dix and Matt Martin at the following e-mail addresses: Dix.David@epamail.epa.gov ; Martin.Matt@epamail.epa.gov.

All data should be submitted **by 15 February 2009**.