Annex A evaluation of reliability of results of genotoxicity studies – general considerations

In this guide

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1. Reliability is defined as “evaluating the inherent quality of a test report or publication relating to preferably standardized methodology and the way that the experimental procedure and results are described to give evidence of the clarity and plausibility of the findings” (Klimisch et al., 1997).

2. In assigning the reliability score, the compliance with the Organization for European Economic Cooperation and Development (OECD) Test Guidelines (TGs)

or standardized methodology and the completeness of the reporting as detailed below were considered.

3. The reliability scores were:

1) reliable without restriction : This includes studies or data from the literature or reports which were carried out or generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to Good Laboratory Practice (GLP)) or in which the test parameters documented are based on a specific (national) testing guideline (preferably performed according to GLP) or in which all parameters described are closely related/comparable to a guideline method.

2) reliable with restrictions: This includes studies or data from the literature or reports (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.

3) insufficient reliability: testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.

4) reliability cannot be evaluated: This includes studies or data from the literature, that do not give sufficient experimental details and that are only listed in short abstracts or secondary literature (books, reviews, etc.).

5) reliability not evaluated, since the study is not relevant and/or not required for the risk assessment (in case the study is reported for reasons of transparency only): The study is not relevant and/or not useful for the risk assessment.