



ToxRTool - Toxicological data Reliability Assessment Tool

Instructions for use

Structure of the ToxRTool

The ToxRTool has been developed in the Microsoft Excel® programme and consists of two different parts, one for *in vivo* and one for *in vitro* data.

The tool comprises a list of 21 criteria for *in vivo* studies and 18 criteria for *in vitro* studies. Each criterion can be assigned either a '1' (one point), i.e. 'criterion met', or a '=' (no point), i.e. 'criterion not met'.

Criteria for evaluating *in vivo* or *in vitro* studies were established congruently to the largest extent possible and are grouped into five groups of criteria in both cases:

- I. Test substance identification
- II. Test system characterisation
- III. Study design description
- IV. Study results documentation
- V. Plausibility of study design and results

Groups I to IV contain criteria mainly related to documentation, whereas group V goes beyond documentation and asks for an assessment of the internal plausibility of the approach used in the study.

All criteria must be answered (either by 0 or 1) by the user when evaluating a study.

Some minimum information requirements are thought to be indispensable for a study to be considered reliable. In the tool, these minimum requirement criteria are highlighted in red. Only if these criteria are met, i.e. rated as '1', the tool will assign a data reliability of Category 1 or 2, irrespective of the total score obtained. Due to their high impact on the final outcome, careful evaluation of the 'red' criteria is of crucial importance.

Explanations are available for most of the criteria. These explanations are implemented in Excel as comments to criteria fields. Please, read carefully these explanations. This will ensure a common understanding of the criteria.

The total points assigned to a given study lead to a proposal of a reliability category (1 to 3, see result **A** in table below). This result A may be modified to category 3, if A is category 1 or 2, but not all red criteria were met (result **B**). The evaluator is free to deviate from the tool's categorisation (**C**), but is asked to provide reasoning in such a case (**D**).

A. Numerical result leads to initial Category:	Categories 1, 2 or 3, calculated by the tool
B. Checking red scores leads to revised Category:	Categories 1, 2 or 3, calculated by the tool
C. Evaluator's proposal of Category:	Categories 1, 2 or 3, by the user
D. Justification in case the category proposed by the evaluator deviates from B:	Explanatory text by the user (in case C deviates from B)

How to use the ToxRTool – step by step

1. Open the Microsoft Excel® file.
2. Carefully read the worksheet "Explanations" in the Microsoft Excel® file, which contains explanations on the tool (similar to the information given above).
3. There is one worksheet for *in vitro* studies and one for *in vivo* studies.
Please, choose the worksheets suitable for the study you plan to evaluate!
4. After reading the case study, please start by answering the criteria.
5. Each case study worksheet contains all criteria. Address the criteria one by one and rate each criterion: click on the small green field to the right of the criterion. A drop-down list allows selecting either '0', i.e. criterion not met, or '1', i.e. criterion met, for each criterion. **Please, make sure that all criteria are answered!** Explanations for individual criteria show up as a comment for all fields with a red mark in the upper right corner, when you move the mouse into the criteria fields.
6. Points are automatically summed up both for each of the five criteria groups and the overall total (light blue fields). At the bottom of the criteria list (orange fields) the reliability category resulting from the total points is automatically calculated.
7. Under (A) the category is derived from the sum of points (regardless of whether all red criteria have been met), whilst under
 (B) the category is derived considering the red criteria as essential for the assignment of category 1 and 2.
8. Please fill in the green fields, reading:
 (C) Evaluator's proposal: Category:
 (in case you do not see any specific reason to deviate from the proposed category, just enter category proposed by the tool in (B)
 (D) Justification in case evaluator deviates under C from B:
 (leave empty if you do not deviate)
9. During the course of the quality assessment observations may be made which are important for discussing the relevance of the data for specific purposes. If you would like to document any observation with respect to relevance of the data, please read the text below the list of criteria and use the following green fields.