PFAS/2023/02 Annex 1

In this guide

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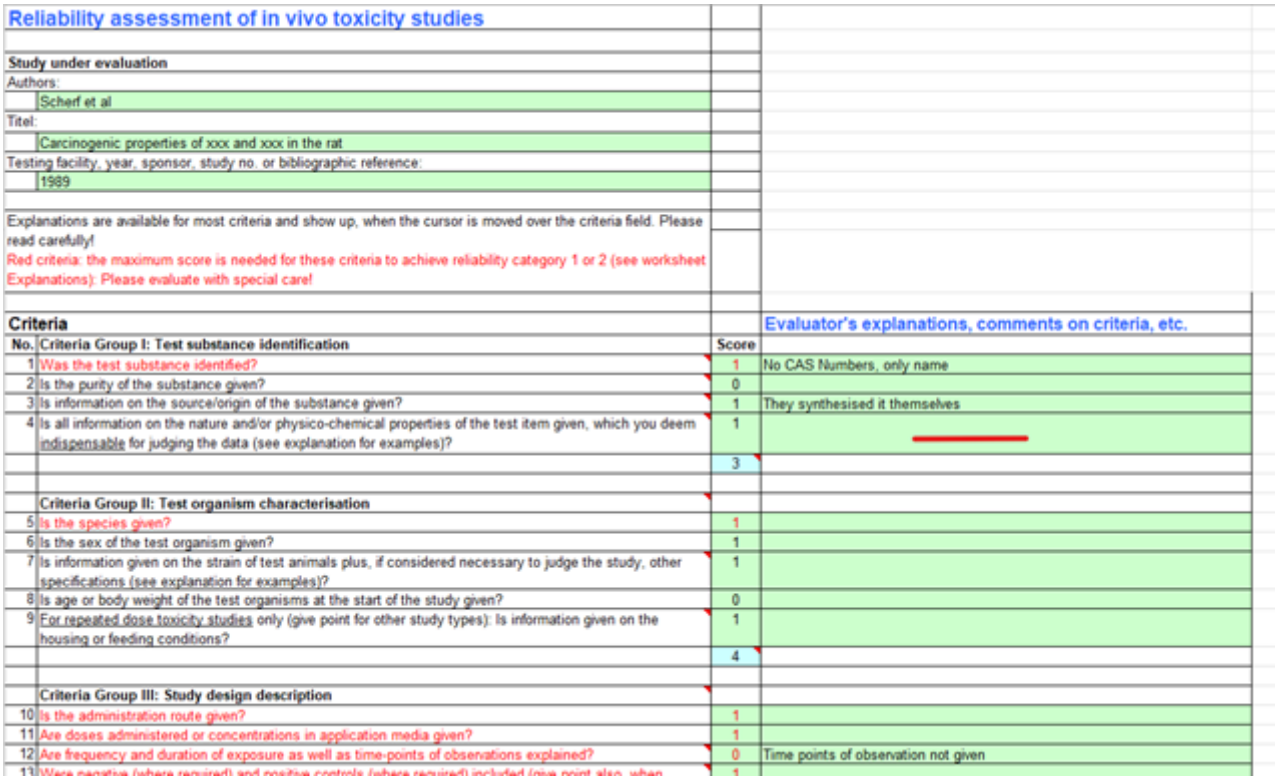
Reliability scoring

Should papers undergo reliability scoring or quality assessment to assess reliability prior to inclusion into the narrative/table? The subgroup may wish to consider providing specific guidance on epidemiology, *in vivo* and *in vitro* studies, respectively?

To ensure data used in all reports are of adequate quality all *in vivo* and *in vitro* papers could undergo Klimisch scoring using the ToxRTool (Figure 1). Similarly, epidemiology data could undergo quality assessment e.g. using Newcastle Ottowa Score (NOS) (Figure 2), or Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) assessment (Figure 3), or based on Annex 1 of the SETE report..

Screening papers for reliability could reduce the number of papers used in the assessments and may impact on the subgroup decision-making on presentation of data i.e. if data are presented in a narrative, tabular or graphical format.

Figure 1. Example of ToxRTool.



Reliability assessment of in vivo toxicity studies

Study under evaluation

Authors:
Scherf et al

Titel:
Carcinogenic properties of xxx and xxx in the rat

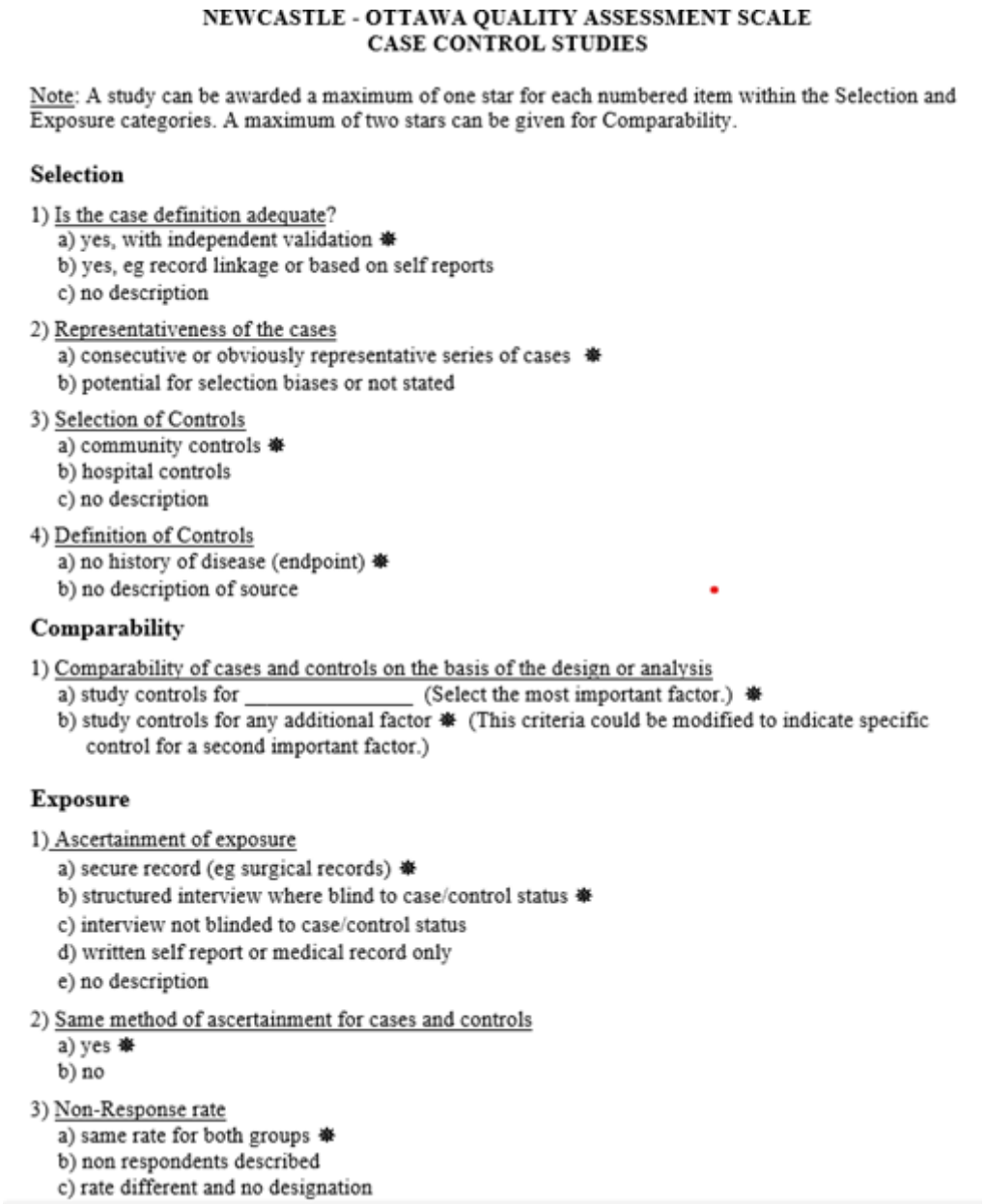
Testing facility, year, sponsor, study no. or bibliographic reference:
1989

Explanations are available for most criteria and show up, when the cursor is moved over the criteria field. Please read carefully!
Red criteria: the maximum score is needed for these criteria to achieve reliability category 1 or 2 (see worksheet Explanations). Please evaluate with special care!

Criteria			Evaluator's explanations, comments on criteria, etc.
No.	Criteria Group I: Test substance identification	Score	
1	Was the test substance identified?	1	No CAS Numbers, only name
2	Is the purity of the substance given?	0	
3	Is information on the source/origin of the substance given?	1	They synthesised it themselves
4	Is all information on the nature and/or physico-chemical properties of the test item given, which you deem indispensable for judging the data (see explanation for examples)?	1	
		3	
	Criteria Group II: Test organism characterisation		
5	Is the species given?	1	
6	Is the sex of the test organism given?	1	
7	Is information given on the strain of test animals plus, if considered necessary to judge the study, other specifications (see explanation for examples)?	1	
8	Is age or body weight of the test organisms at the start of the study given?	0	
9	For repeated dose toxicity studies only (give point for other study types): Is information given on the housing or feeding conditions?	1	
		4	
	Criteria Group III: Study design description		
10	Is the administration route given?	1	
11	Are doses administered or concentrations in application media given?	1	
12	Are frequency and duration of exposure as well as time-points of observations explained?	0	Time points of observation not given

A screenshot of the ToxRTool. The image shows a form with multiple sections and lines of text and highlighted sections in green. Text varies in colour black, red and blue.

Figure 2. Example of NOS



NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE
CASE CONTROL STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Selection

1) Is the case definition adequate?
   a) yes, with independent validation ✸
   b) yes, eg record linkage or based on self reports
   c) no description

2) Representativeness of the cases
   a) consecutive or obviously representative series of cases ✸
   b) potential for selection biases or not stated

3) Selection of Controls
   a) community controls ✸
   b) hospital controls
   c) no description

4) Definition of Controls
   a) no history of disease (endpoint) ✸
   b) no description of source

Comparability

1) Comparability of cases and controls on the basis of the design or analysis
   a) study controls for _____ (Select the most important factor.) ✸
   b) study controls for any additional factor ✸ (This criteria could be modified to indicate specific control for a second important factor.)

Exposure

1) Ascertainment of exposure
   a) secure record (eg surgical records) ✸
   b) structured interview where blind to case/control status ✸
   c) interview not blinded to case/control status
   d) written self report or medical record only
   e) no description

2) Same method of ascertainment for cases and controls
   a) yes ✸
   b) no

3) Non-Response rate
   a) same rate for both groups ✸
   b) non respondents described
   c) rate different and no designation

An example of NOS, shows a screenshot of a black and white document with multiple headings and numbered sections.

Figure 3. Example of STROBE

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/	8*	For each variable of interest, give sources of data and details of methods of

Example of Strobe, is a screenshot of a black and white text document. The document has multiple sections with headings, item numbering and notes.