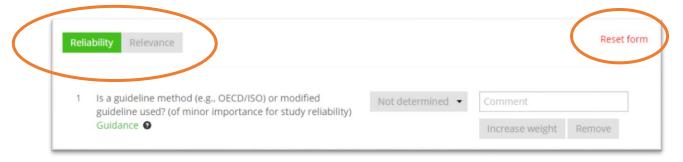
Instructions for reliability and relevance evaluation of **ecotoxicity** studies using the SciRAP tool

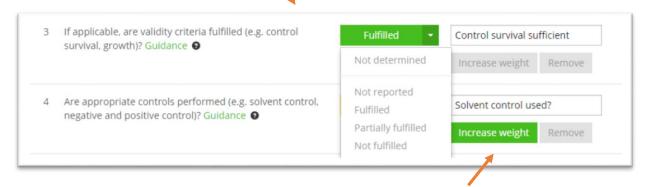
At <u>www.scirap.org</u>, go to the tab "Ecotoxicity studies" at the top of the page, click on "Evaluate reliability & relevance" or "Evaluate reliability & relevance - nano". The reliability/relevance evaluation is conducted in two steps: Evaluating the reliability and relevance of a study (incl. weighing and deselection of criteria), and Assigning the study to reliability and relevance categories (optional).

Evaluate the reliability and relevance

The reliability and relevance criteria can be found under two different tabs.

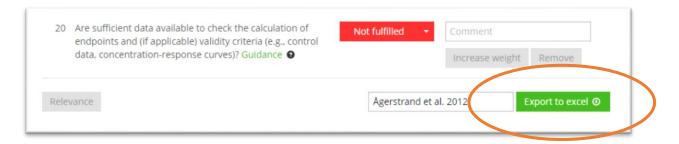


Fill out how well each criterion is met by choosing an alternative from the drop-down menu to the right of each criterion. Choose between "Fulfilled", "Partially fulfilled", "Not fulfilled", "Not reported" and "Not determined". Guidance from Moermond et al. (2016) and Hartmann et al. (2017) (for nanomaterials) is provided by clicking the question mark next to each criterion. Motivations and notes can be added in the comments fields.



The criteria have been given the same default weight, but if certain criteria are considered to be critical for the evaluation this can be adjusted up by clicking "Increase weight". Criteria that are not applicable for the specific study or question being assessed may be removed from the evaluation by clicking "Remove". Motivations for weighing and removing criteria can be provided in the comments fields. Note that your selections for the criteria will be saved on the computer until you click "Reset form".

Once both the reliability and relevance evaluation is completed, name your file and click the green "Export to excel" button. An excel sheet will open up, illustrating the results of your evaluation. This excel sheet can be saved to your computer and shared with others.



The first worksheet in the excel file gives an overall overview of the evaluation in the form of diagrams. This colour profile of the study illustrates where a study's strengths and weaknesses lie, showing green for fulfilled criteria, yellow for partially fulfilled and red for criteria that were not fulfilled. Criteria that were "not determined" will be shown as grey, and criteria that were "not reported" will be dark grey. The bar charts take the weights of criteria into account and do not include criteria that have been removed.

There are also separate worksheets that show the details of the reliability and relevance evaluations. These show lists of the criteria and how each criterion has been evaluated. Any comments made for individual criteria will be listed. The weight of criteria are shown in the first column, and removed criteria are greyed out in the list.

Assign the study to reliability and relevance categories

The output from the SciRAP evaluation can, in combination with expert judgment and the guidance provided in Moermond et al. (2016) and Hartmann et al. (2017) (for nanomaterials), be used as basis for dividing studies into different categories of reliability and relevance. This step is optional. The following categories are recommended:

a. Reliability categories

- Reliable without restrictions: All critical reliability criteria for this study are fulfilled. The study
 is well designed and performed, and it does not contain flaws that affect the reliability of the
 study.
- Reliable with restrictions: The study is generally well designed and performed, but some minor flaws in the documentation or setup may be present.
- *Not reliable:* Not all critical reliability criteria for this study are fulfilled. The study has clear flaws in study design and/or how it was performed.
- Not assignable: Information needed to make an assessment of the study is missing. This
 concerns studies that do not give sufficient experimental details and that are only listed in
 abstracts or secondary literature (books, reviews, etc.) or studies of which the
 documentation is not sufficient for assessment of reliability for one or more vital
 parameters.

b. Reliability categories - nanomaterials

- Reliable without restrictions: All critical and important reliability criteria are fulfilled or
 partially fulfilled. The study is well designed, performed and documented. Nanomaterial
 properties and behaviour in the test system is extensively documented. The experiment has
 been carried out according to methods that are considered scientifically appropriate for
 ecotoxicity testing of nanomaterials and where the physicochemical properties of the
 nanomaterial are considered in the test design. If (when) specific nanomaterial guidance or
 guidelines exist, the use of these may be considered favourable.
- Reliable with restrictions: Most critical and important criteria are fulfilled or partially fulfilled.
 The study is generally well designed, performed and documented, but some minor flaws in
 the documentation or setup may be present. Nanomaterial properties and behaviour in the
 test system is well documented. The experimental design and test method are considered
 scientifically appropriate for ecotoxicity testing of nanomaterials but may contain some
 minor flaws in documentation or setup.
- Not reliable: Not all critical reliability criteria are fulfilled or partially fulfilled. This mainly concerns studies which have clear flaws in study design and study conduction, and/or where the experimental design and test method are considered not to be scientifically appropriate for ecotoxicity testing of nanomaterials.
- Not assignable: Information needed to make an assessment of one or more critical and important criteria is missing. This concerns studies or data from the literature which do not give sufficient experimental details, or reports where the documentation is not sufficient for assessment of reliability for one or more critical parameters.

c. Relevance categories – all substances

- Relevant without restrictions: The study is relevant for the purpose for which it is evaluated.
- Relevant with restrictions: The study has limited relevance for the purpose for which it is evaluated.
- *Not relevant:* The study is not relevant for the purpose for which it is evaluated.
- Not assignable: Studies that do not give sufficient details since the result is presented in abstracts or secondary literature (books, reviews, etc.) or studies of which the documentation is not sufficient for assessment of relevance for one or more vital parameters.

Contact:

For questions or comments, please contact Marlene Ågerstrand, <u>marlene.agerstrand@aces.su.se</u>.

References:

Hartmann NB, Ågerstrand M, Holten Lûtzhoft H-C, Baun A. 2017. "NanoCRED: A transparent framework to access the regulatory adequacy of ecotoxicity data for nanomaterial - Relevance and reliability revisited". NanoImpact, In press.

Kase R, Korkaric M, Werner I, Ågerstrand M. 2016. Criteria for Reporting and Evaluating ecotoxicity Data (CRED): comparison and perception of the Klimisch and CRED methods for evaluating reliability and relevance of ecotoxicity studies. Environmental Sciences Europe 28:7.

Moermond C, Kase R, Korkaric M, Ågerstrand M. 2015. "CRED - Criteria for Reporting and evaluating ecotoxicity Data." Environmental Toxicology and Chemistry 35: 1297-1309.

Molander L, Ågerstrand M, Beronius A, Hanberg A, Rudén C. 2014. "Science in Risk Assessment and Policy (SciRAP): An Online Resource for Evaluating and Reporting In Vivo (Eco) Toxicity Studies." Human and Ecological Risk Assessment. 21 (3), 753-762.