

SciRAP Webinar:

Using the SciRAP tool to evaluate reliability and relevance of *in vivo* toxicity studies for regulatory assessment

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Today's webinar

- Presentation of the SciRAP platform and the SciRAP approach for evaluating *in vivo* toxicity studies
- Tour of the website and demonstration of the tool
- Concluding remarks
- Q and A (use the chat function!)

Note: recording of webinar and pdf of presentation will be made available online



Who are we?



Dr Marlene
Ågerstrand



Prof Christina
Rudén



Dr Anna
Beronius



Prof Annika
Hanberg

SciRAP = Science in Risk Assessment and Policy

- Promote structure and transparency when evaluating toxicity and ecotoxicity studies for hazard and risk assessment
- Bridge the gap between academic research and chemicals regulation
- Be flexible for use in different regulatory frameworks
- Free of charge

www.scirap.org



Data should be “adequate”

Adequacy = reliability + relevance

Reliability = inherent quality of a study

Relevance = data and tests are appropriate for a particular hazard or risk characterization

Experts disagree

Expert judgment – an integral and necessary part of hazard and risk assessment

- May introduce value-based assumptions
- Needs to be transparent

For example, selection and evaluation of toxicity and ecotoxicity studies

- Brominated flame retardant decaBDE (Alcock et al. 2011)
- Herbicide atrazine (Boone et al. 2014)
- Herbicide glyphosate (Portier et al. 2016)
- Industrial chemical bisphenol A (Beronius et al. 2010)

Resources at SciRAP.org

- Method for evaluation of ecotoxicity + nano ecotoxicity studies
- Method for evaluation of toxicity studies (*in vivo*)
- Reporting recommendations
- Publications (often open access)
- Information about webinars, seminars, workshops, etc.

www.scirap.org

Development of SciRAP *in vivo*

- Based on recommendations and requirements in OECD test guidelines regarding:
 - Animal model
 - Housing and feeding conditions
 - Administration of test substance
 - Methods
 - Observations and measurements
 - Reporting
- Available methods, e.g. Klimisch, ToxRTool
- Compliance with standardised test guidelines or GLP not a requirement

Development of SciRAP *in vivo*

- First version published 2014
 - Beronius A, Molander L, Ruden C, Hanberg A: **Facilitating the use of non-standard *in vivo* studies in health risk assessment of chemicals: a proposal to improve evaluation criteria and reporting.** *J Appl Toxicol.* 2014; **34**(6):607-617.
- Ringtest among end-users 2015 (manuscript)
- Nordic workshop 2016
 - Beronius A, Ågerstrand M, Rudén C, Hanberg A: **SciRAP workshop report: Bridging the gap between academic research and chemicals regulation - the SciRAP tool for evaluating toxicity and ecotoxicity data for risk assessment of chemicals.** Nordic Working Papers. Nordic Council of Ministers. Copenhagen, 2017, 33 pp.
- Current version online March 2017
- Continuous development – feedback welcome!

Structure of the SciRAP approach to evaluate in vivo toxicity studies:

Evaluate reliability

Reporting quality

30 criteria

Judge as “fulfilled”,
“partially fulfilled”, “not fulfilled”

Possibility to remove criteria or increase weight

Methodological quality

19 criteria

Judge as “fulfilled”,
“partially fulfilled”, “not fulfilled”

Possibility to remove criteria or increase weight

Evaluate relevance

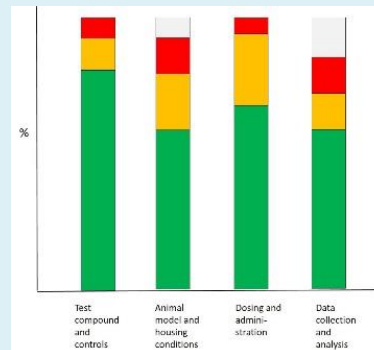
List of 8 items to consider

All listed items do not have to be fulfilled for the study to be considered relevant

Colour-coding tool

Exported excel file:

- Evaluation summary
- SciRAP score
- Colour profile



Qualitative assessment

Tour of www.scirap.org

Interpreting evaluation results

$$\text{SciRAP score} = \% \text{ fulfilled units} + \frac{\% \text{ partially fulfilled units}}{2} - \% \text{ not fulfilled units}$$

Note!

- A partially fulfilled criterion only contributes half of a fulfilled criterion.
- If the weight of a criterion has been increased it is worth 1.5 times a “regular” criterion.
- If many criteria are left as “not determined” it may affect the score negatively.
- **Consider SciRAP score and colour profile together!**

Interpreting evaluation results

How can the results of the evaluation be used?

For example:

- To rank studies according to their reliability (and relevance)
- To categorise studies into reliability categories (e.g. Klimisch)
- To facilitate discussion (agreement) between evaluators
- To summarise/compare/combine evaluation results for several studies

Future developments

- Enable evaluation of relevance in the colour-coding tool
- Criteria for the evaluation of *in vitro* studies
 - Prototype available this summer
 - Ringtest
- Criteria for the evaluation of epidemiological studies

Thank you for your attention!

Please contact us with any questions: anna.beronius@ki.se

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Useful references

- Beronius A, Molander L, Rudén C, Hanberg A: **Facilitating the use of non-standard in vivo studies in health risk assessment of chemicals: a proposal to improve evaluation criteria and reporting.** *J Appl Toxicol.* 2014: **34(6):607-617.**
- Beronius A, Ågerstrand M, Rudén C, Hanberg A: **SciRAP workshop report: Bridging the gap between academic research and chemicals regulation - the SciRAP tool for evaluating toxicity and ecotoxicity data for risk assessment of chemicals.** Nordic Working Papers. Nordic Council of Ministers. Copenhagen, 2017, 33 pp.
- Molander L, Hanberg A, Rudén C, Ågerstrand M, Beronius A. **Combining web-based tools for transparent evaluation of data for risk assessment: developmental effects of bisphenol A on the mammary gland as a case study.** *J Appl Toxicol.* 2017: **37(3):319-330.**

More on the website!