

SciRAP Webinar:

Applying the CRED criteria for evaluating reliability and relevance of ecotoxicity studies for regulatory assessment

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Today's webinar

Evaluation of **ecotoxicity** studies

- Tomorrow: Evaluation of **toxicity** studies

Purpose: Show the SciRAP platform and the CRED evaluation method, and invite you to give feedback

40 min presentation followed by questions

Webinars will be recorded and 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 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



Resources at SciRAP

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

www.scirap.org

Experts disagree!

Assessment of chemicals: Easy in theory, difficult in practice.

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)

Methods give different result

Table 13 Summary of the reliability evaluation of non-standard test data

Reference	Evaluation method			
	Klimisch	Durda	Hobbs	Schneider
Andreozzi <i>et al.</i> [14]	-	-	-	-
Ferrari <i>et al.</i> [15]	-	-	-	-
Huggett <i>et al.</i> [16]	-	-	+	-
Robinson <i>et al.</i> [17]	+	-	+	-
Schmitt-Jansen <i>et al.</i> [18]	+	-	+	-
Quinn <i>et al.</i> [19]	-	-	+	-
Metcalfe <i>et al.</i> [20]	-	-	+	+
Nentwig [21]	+	-	+	++
Halm <i>et al.</i> [22]	+	-	+	++

- Unacceptable quality/not reliable, + acceptable quality/reliable with restrictions, ++ high quality/reliable without restrictions.

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

The CRED evaluation method

CRED= Criteria for Reporting and Evaluating **ecotoxicity** Data

Moermond *et al.* 2015. ET& C; Kase *et al.* 2016. Environmental Science Europe.

Klimisch-method

Recommended for ecotoxicity and toxicity studies

Few reliability criteria

No relevance criteria

No additional guidance

Standard tests are favoured

Developed by BASF

CRED-method

For aquatic **ecotoxicity** studies

Developed from OECD tests and other evaluation methods

Both reliability and relevance criteria

Additional guidance to each criteria

Does not favour standard studies

Developed by Stockholm University, Dutch RIVM, Swiss Centre for Applied Ecotoxicology, Swiss EAWAG

Examples of criteria

20 reliability criteria

- Is a sufficient number of organisms per replicate used for all controls and test concentrations?
- Is the experimental system appropriate for the test substance?

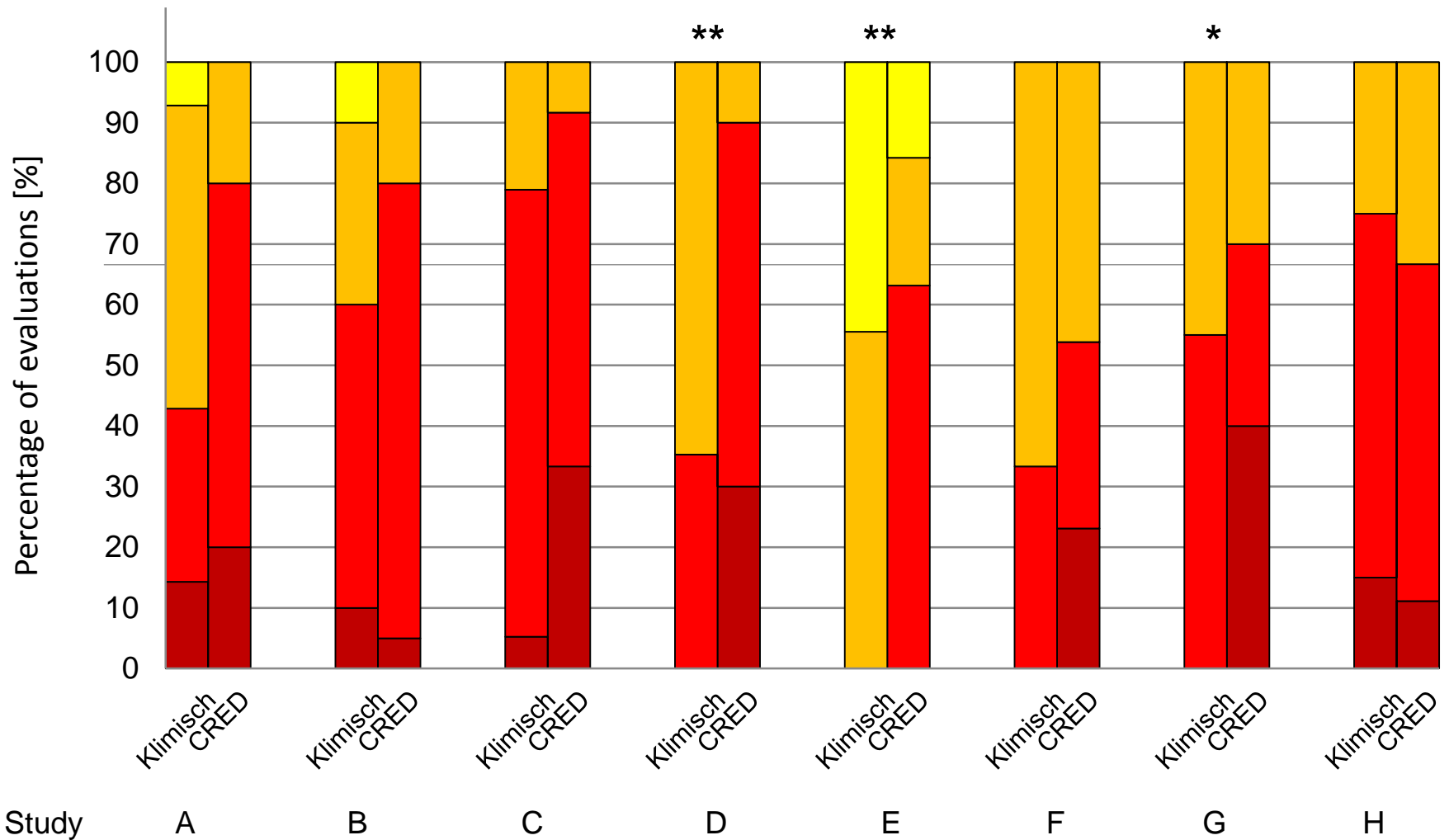
13 relevance criteria

- Is the species tested relevant for the compartment under evaluation?
- Are appropriate life stages studied?

Comparison of Klimisch and CRED

International "ringtest" with >70 risk assessors from academia, industry and governmental agencies.

- Evaluation of eight ecotoxicity studies
- Risk assessors' opinions about the methods

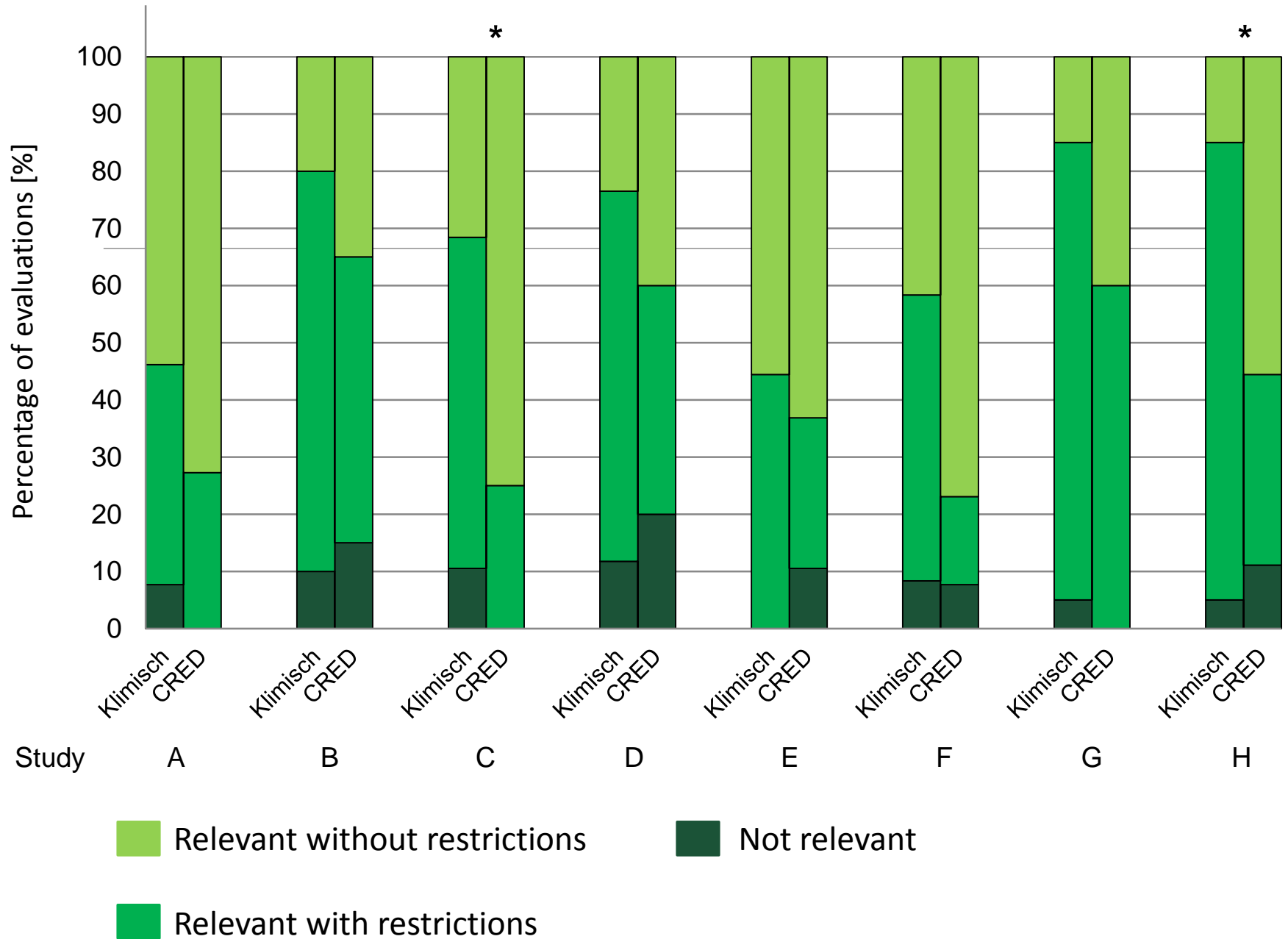


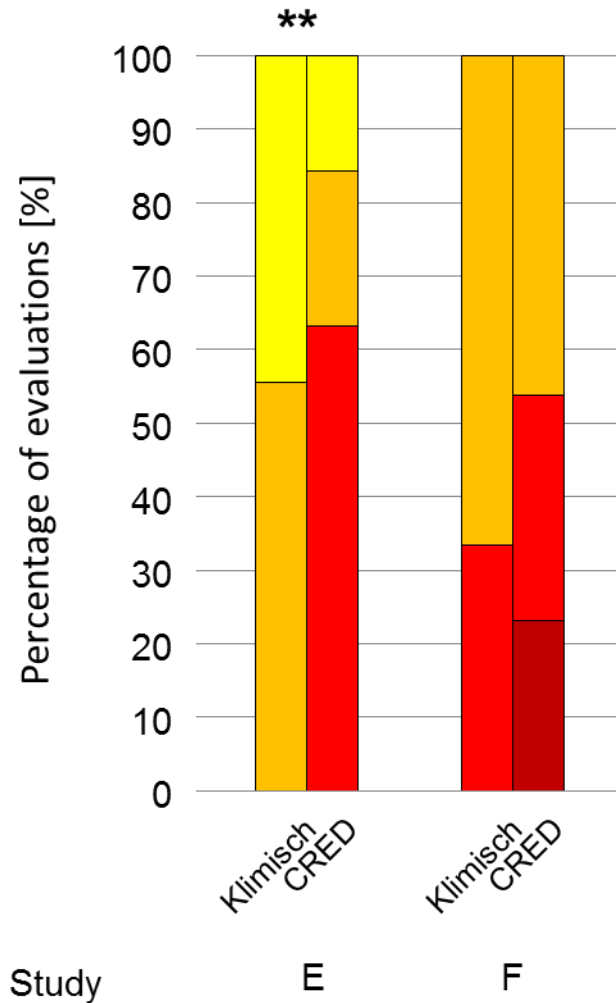
Reliable without restrictions

Not reliable

Reliable with restrictions

Not Assignable





- Reliable without restrictions
- Reliable with restrictions
- Not reliable
- Not Assignable

- *Flaws in study design related to dosing and potential loss of tested substance*
- *Missing solvent control data*

Klimisch → CRED

Improved criteria leads to:

- More consistent results
- More transparent evaluations

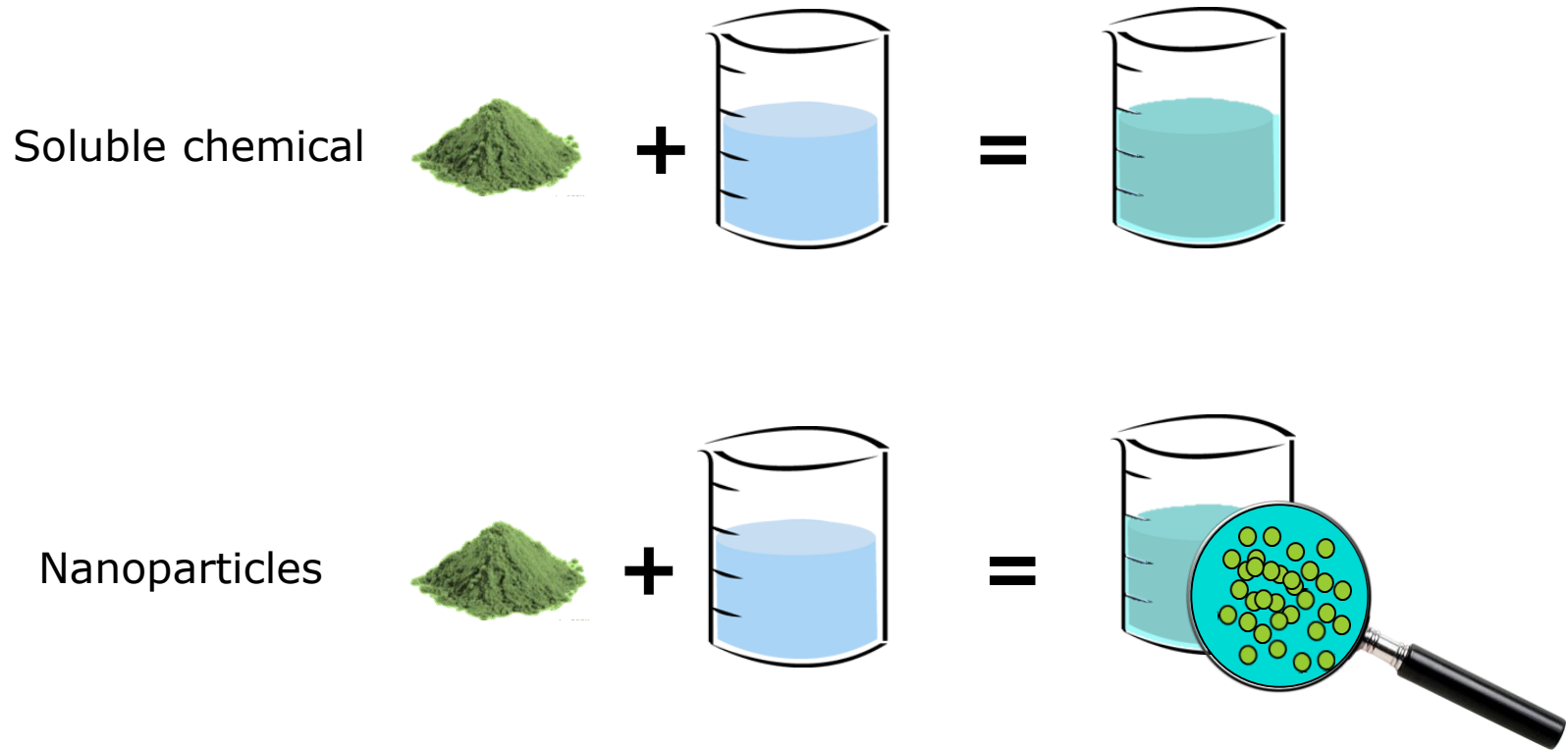
Risk assessors' opinions about CRED

- More consistent and accurate evaluations
- Easy and applicable for routine use
- Less dependence on expert judgment
- More transparent

Who is using CRED?

- Recommended in WFD guidance document when setting EQS-values
- NORMAN network & other research initiatives
- Consultancy firms

NanoCRED with DTU, Denmark



Hartmann et al. 2017. NanoImpact.

Insufficient reporting of peer-reviewed studies

- Frustrating! Waste of knowledge, resources and tax payers money.
- Insufficiently reported or bad science? Credibility of research?
- Why? Different traditions and low regulatory awareness among researchers.
- Efficient solution? Reporting requirements in journals.

Reporting checklist

- Intended for researchers
- Can be used as template for supplemental material

Report ecotoxicity studies

This reporting checklist was developed to help researchers design, perform and report ecotoxicity studies in a transparent way that fulfill the **reliability** criteria for regulatory risk assessment. Not all criteria apply to all studies.

1 General information

a Purpose of study

b Description of endpoints

2 Test setup

a Performed according to standard/modified standard (e.g., OECD, US EPA)

b Performed according to Good Laboratory Practices (GLP)

c Description of used control(s): negative control, solvent control, positive control

d Control(s) mortality, growth, morbidity and other observed non-standard effects like behavior and coloring

e Comparison to validity criteria (e.g. control survival, growth) from appropriate standard test method

3 Test compound

a Identification (e.g. name, CAS-number, specify if the salt or the base is tested)

Tour of the SciRAP website

www.scirap.org

Thanks! Questions? www.scirap.org

References:

Hartmann NB, Ågerstrand M, Holten Lützhoft 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.

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

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.

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.