Stärkt reglering av kemikalier i konsumentprodukter genom förbättrad användning av forskningsdata

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Folkhälsomyndigheten

Kemikalier i konsumentprodukter

- Innehåller och emitterar kemikalier med farliga och okända egenskaper
- Hormonstörande kemikalier och lågdoseffekter
- Bristfällig reglering, framför allt i *varor*
- Global och ökad konsumtion

Syfte

Bidra till en stärkt reglering av kemikalier i konsumentprodukter

- Analys av strategier för reglering av kemikalier i varor
- Metod för förbättrad användning av all tillgänglig och relevant data i hälsoriskbedömning

Reglering av kemikalier i varor

- Stora skillnader i hur kemikalier regleras i olika varor
- Produktspecifika regler viktiga komplement till Reach
- Kemikalier som ska fasas ut i miljön regleras i liten utsträckning i varor

Molander et al. 2012a; 2012b

Användning av forskningsdata i hälsoriskbedömning

- All tillgänglig och relevant data för ett ämne ska beaktas i riskbedömning
- Standardiserade studier används framför icke-standardiserade forskningsstudier
- Icke-standardstudier kan bidra med viktig information
- Utvärdering av icke-standardstudier sällan strukturerad, systematisk eller transparent

Reliability and relevance

Reliability = inherent quality of a study

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

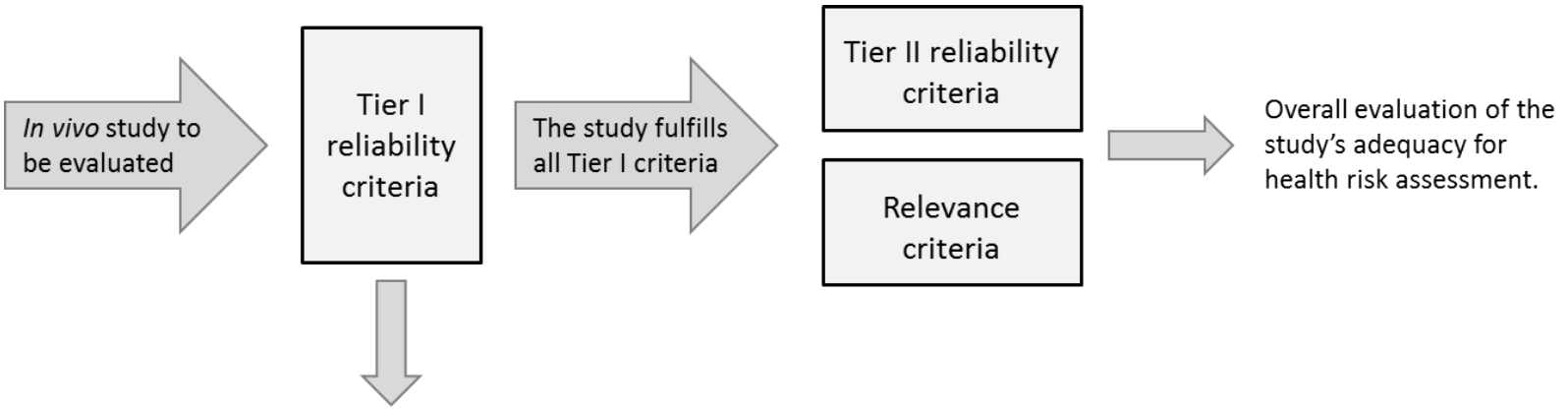
Adequacy = reliability + relevance

Klimisch et al. 1997; OECD 2005; ECHA 2011

Ny metod för utvärdering av toxicitetsstudier

- Främja systematisk och transparent bedömning av tillförlitlighet OCH relevans av *in vivo*-studier
- Kvalitativ approach
- Transparent användning av “expert judgment”
- Användarvänlig

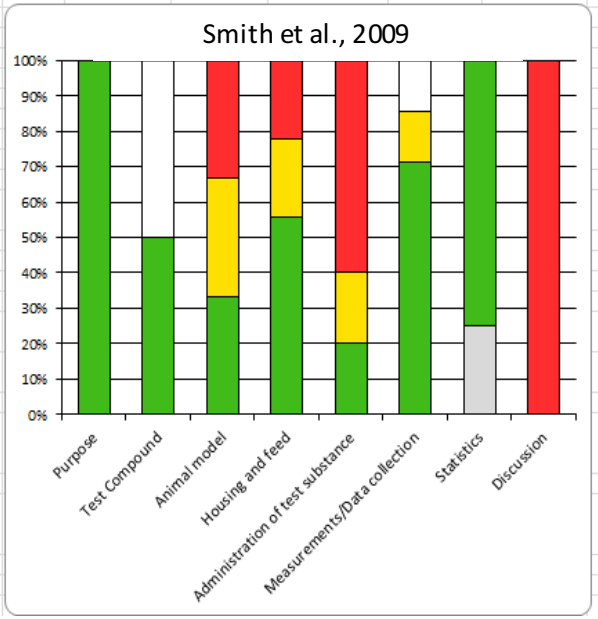
Metod för utvärdering av toxicitetsstudier



Beronius et al. 2014
Molander et al. 2015

Web-baserat färgkodningsverktyg

Not determined	1	
Fulfilled	18	
Partially fulfilled	5	
Not fulfilled	7	
Not applicable	2	
	Purpose	
	The purpose of the study has been stated.	Fulfilled
	The endpoints to be investigated have been stated.	Fulfilled
	Test Compound	
	The vehicle is described.	Fulfilled
	Any fluorescent- or radiolabelling, etc. is described.	Not applicable
	Animal model	
	The motivation behind the choice of animal model (species and strain) is given, i.e. why one species or strain is preferred above	Not fulfilled
	Animals have been individually identified.	Fulfilled
	The method for individual identification of animals is stated.	Partially fulfilled
	Housing and feed	
	Housing conditions are described, i.e. temperature, relative humidity, light-dark cycle and number of animals per sex in each cage.	Fulfilled
	Cage materials, including any physical enrichment, and water bottle materials are described.	Fulfilled
	The bedding material used is described.	Not fulfilled
	Considerations have been made to minimize the content of substances in the selected bedding material that may affect the toxicity of the compound being investigated, such as	Partially fulfilled
	The type and source of feed are reported.	Fulfilled
	The feed has been analyzed for contaminants that could impact study objectives, such as pesticide residues, persistent organic pollutants, heavy metals and mycotoxins.	Partially fulfilled
	The feed has been analyzed for phytoestrogen content.	Fulfilled
	The source of drinking water is reported.	Fulfilled
	The drinking water has been analyzed for contaminants that could	



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Otillräcklig rapportering

Category	Items to be described
Purpose and endpoint	Purpose of study
	Description of endpoints
Protocol	Standard / modified standard / non-standard
Test compound	Identification (e. g. name, CAS-number)
	Physico-chemical data (e.g. volatility, stability, solubility, degradability, adsorption)
	Source
	Purity
	Vehicle
	Radiolabelled
Dosing system	Tested doses or concentrations
	Measured doses or concentrations.
	Exposure duration

Reporting checklist

Fallstudie

- Hur väl fungerar den föreslagna utvärderingsmetoden?
  - Utvärdering av *in vivo*-studier som undersökt effekter av bisfenol A på bröstkörtelutveckling
- Metoden uppfyller sitt syfte
  - Systematisk, strukturerad och transparent bedömning
  - Brister i tillförlitlighet och rapportering synliggjorda
- Underlag för vidareutveckling av metoden

Molander et al. *submitted manuscript*

Ringtest

- Feedback från tänkta användare
- Ca 50 deltagare (akademi, myndigheter, konsulter, industri)

  - Positiv respons!
  - Guide för bedömning av enskilda kriterier och för tolkning av resultaten efterfrågas

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Science in Risk Assessment and Policy

SciRAP (Science in Risk Assessment and Policy) is a web-based reporting and evaluation resource developed to facilitate and increase the use of peer-reviewed toxicity and ecotoxicity literature in regulatory risk assessment of chemicals. The intention is to bridge the gap between academic research and chemicals regulation and policy.

This project is a collaboration between the Department of Environmental Science and Analytical Chemistry (ACES), Stockholm University, the Institute of Environmental Medicine (IMM), Karolinska Institutet in Stockholm, and the research programme MistraPharma. Please contact us if you have questions or comments.

Stockholm University

Karolinska Institutet

MistraPharma

News!

We are UPDATING our evaluation criteria!

We are currently working on further improving the criteria and tool for evaluating *in vivo* toxicity studies. The current version will remain available online until the updates are complete. Click here to learn more or contact us with any questions.

Recent publications:

Kase et al. 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.

Beronius & Vandenberg. 2016. "Using systematic reviews for hazard and risk assessment of endocrine disrupting

Tack för uppmärksamheten!