

Evaluating the risk assessment approach of the REACH legislation: A case study

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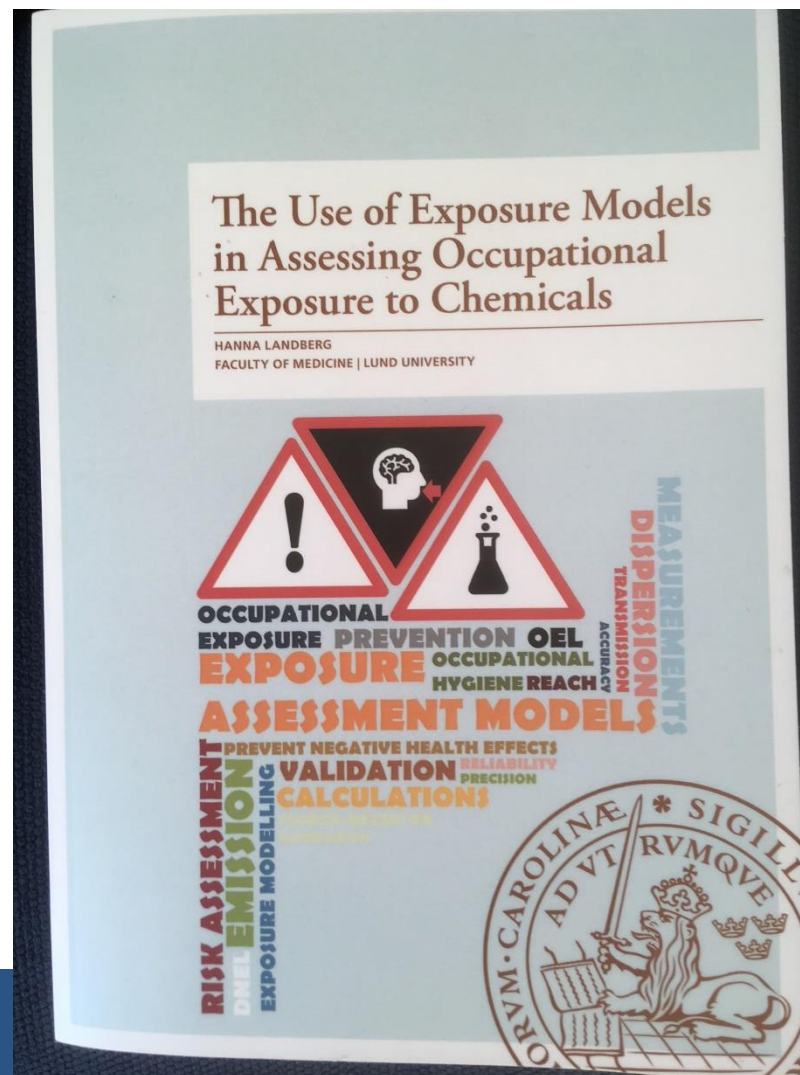


UNIVERSITY OF GOTHENBURG




VÄSTRA
GÖTALANDSREGIONEN

Hanna Landberg thesis



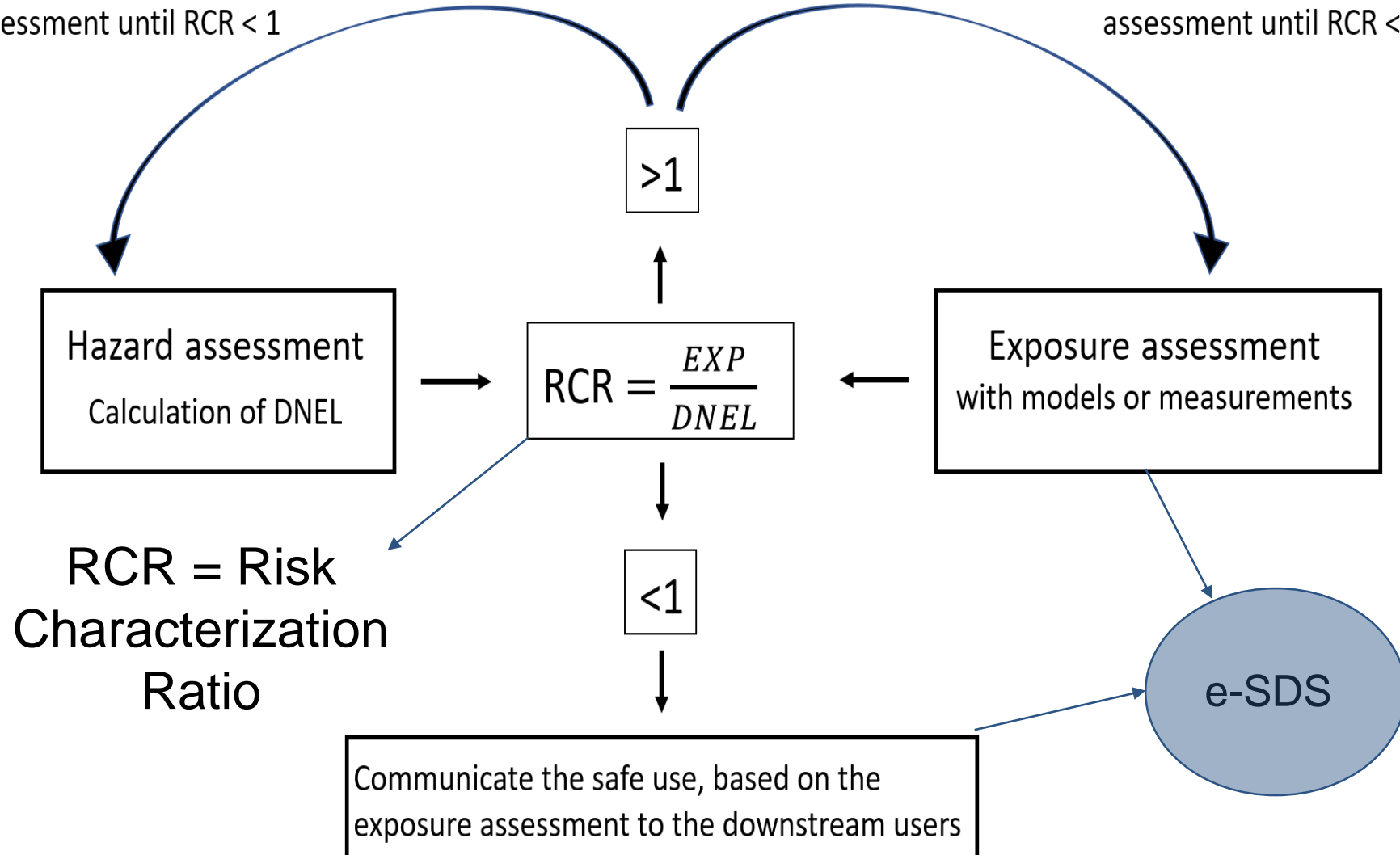
REACH

- Chemicals > 1 ton should be registered to ECHA
- Chemicals > 10 ton and dangerous, PBT or vPvB should be risk assessed in every way they are handled
-  Very high number of risk assessments

Simplified risk assessment approach of REACH

Refine the hazard
assessment until RCR < 1

Refine the exposure
assessment until RCR < 1



e-SDS

- An exposure scenario describes how the exposure of **humans** and the environment to the substance can be controlled to ensure its safe use.
- An exposure scenario refers to an identified use, such as formulation, processing or production. It describes the operational conditions and risk management measures that ensure safe use

Process Categories (PROCs)

Process Categories (PROC)		
	Process categories	Examples and explanations
Proc 2	Use in closed, continuous process with occasional controlled exposure	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions It is not high integrity and occasional exposure will arise e.g. through maintenance, sampling and equipment breakages
Proc 4	Use in batch and other process (synthesis) where opportunity for exposure arises	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure
Proc 5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage
Proc 7	Industrial spraying	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting. Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead to waste water and waste.
Proc 8a	Transfer of substance or	Sampling, loading, filling, transfer, dumping, bagging in



Exposure assessment models

- Available for free to complement exposure measurements
- Models could have different applicability domain and level of complexity
- Calibrated against exposure measurement data

Exposure assessment models

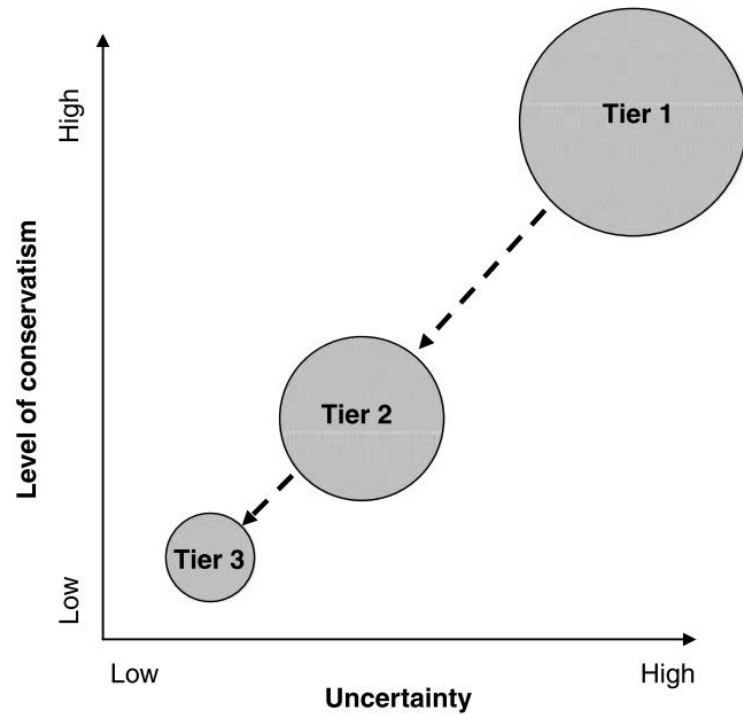
Tier 1

ECETOC TRA

Tier 2

Stoffenmanager (6.1)

Advanced REACH Tool (ART)



Source: Tools for regulatory assessment of occupational exposure: development and challenges
Tielemans et. al (2007)

Recent studies of models validity and reliability

Accuracy Evaluation of Three Modelling Tools for Occupational Exposure Assessment

Andrea Spinazzè, Filippo Lunghini, Davide Campagnolo, Sabrina Rovelli, Monica Locatelli, Andrea Cattaneo, Domenico M. Cavallo

Annals of Work Exposures and Health, Volume 61, Issue 3, 1 April 2017, Pages 284–298, <https://doi.org/10.1093/annweh/wxx004>

Published: 07 February 2017 [Article history](#) ▼

Comparison and Evaluation of Multiple Users' Usage of the Exposure and Risk Tool: Stoffenmanager 5.1

Hanna E. Landberg ✉, Peter Berg, Lennart Andersson, Ulf Bergendorf, Jan-Eric Karlsson, Håkan Westberg, Håkan Tinnerberg

The Annals of Occupational Hygiene, Volume 59, Issue 7, 1 August 2015, Pages 821–835, <https://doi.org/10.1093/annhyg/mev027>

Published: 09 April 2015 [Article history](#) ▼

Original Research Article

Sensitivity Analysis, Dominant Factors, and Robustness of the ECETOC TRA v3, Stoffenmanager 4.5, and ART 1.5 Occupational Exposure Models

R. A. Riedmann, B. Gasic, D. Vernez

First published: 23 January 2015 [Full publication history](#)

DOI: 10.1111/risa.12286 [View/save citation](#)

A Study of the Validity of Two Exposure Assessment Tools: Stoffenmanager and the Advanced REACH T

Hanna E. Landberg, Anna Axmon, Håka

Annals of Work Exposures and Health, Volume 61, Issue 3, 1 April 2017, Pages 575–588, <https://doi.org/10.1093/annweh/wxx004>

Published: 11 March 2017 [Article history](#) ▼

Validation of Lower Tier Exposure Estimates With Available Measurements

Martie van Tongeren ✉, Judith Lamb, John W Cherrie, Laura MacCalman, Ioannis Basinas, Susanne Hesse

Annals of Work Exposures and Health, Volume 61, Issue 8, 1 October 2017, Pages 921–938, <https://doi.org/10.1093/annweh/wxx056>

Published: 18 July 2017 [Article history](#) ▼

Reliability of the Advanced REACH Tool (ART)

Jody Schinkel^{1*}, Wouter Fransman¹, Patricia E. McDonnell², Rinke Klein Entink¹, Erik Tielemans¹ and Hans Kromhout³

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Submitted 6 June 2013; revised 9 December 2013; revised version accepted 16 December 2013.

Original Article

Between-User Reliability of Tier 1 Exposure Assessment Tools Used Under REACH

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¹Institute of Occupational Medicine, Research Avenue North, Riccarton, Edinburgh, EH14 4AP, United Kingdom; ²The Royal Zoological Society of Scotland RZSS Edinburgh Zoo, Edinburgh, EH12 6TS United Kingdom; ³Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Nikolai-Fuchs-Strasse 1, 30625 Hannover, Germany; ⁴Centre for Occupational and Environmental Health; Centre for Epidemiology; Division of Population Health, Health Services Research and Primary Care; School of Health Sciences; Faculty of Biology, Medicine and Health; The University of Manchester, Manchester Academic Health Science Centre, Manchester M13 9PL, UK.

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Abstract

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Aim

The aim of this case study was to evaluate the risk assessment approach of the REACH legislation in 10 industrial chemical departments with a focus on the use of three models to calculate exposures.

Method

We compared the RCRs of registered ES with the observed RCRs using Stoffenmanager[®], ART, and ECETOC TRA.

Workplaces

Collection of e-SDS

Selection of e-SDS

Extracted RCRs

Or calculated RCRs

Registered
RCRs

Visits

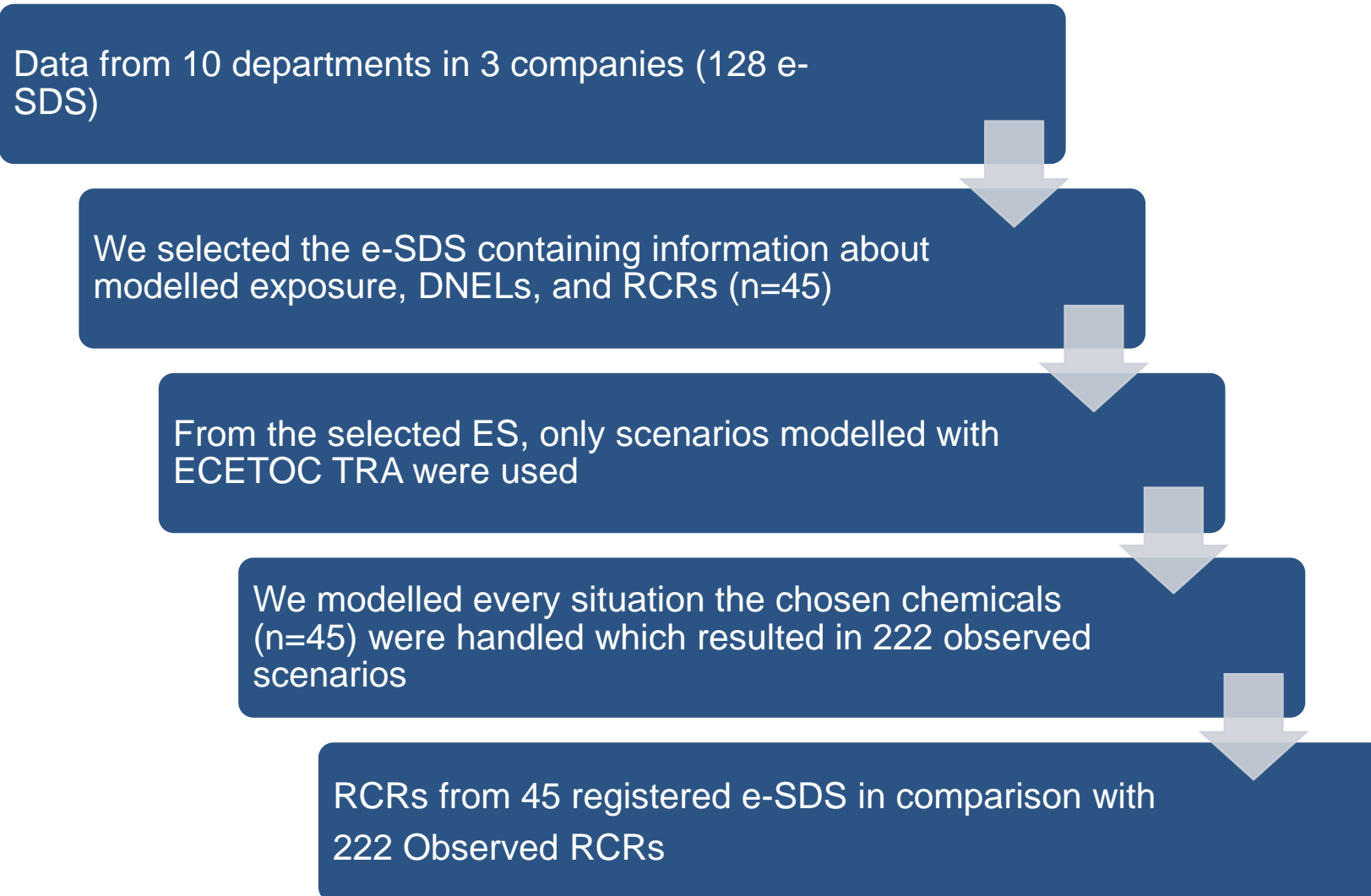
Studied each situation

Used the three
models

Calculated RCRs

Observed RCRs

Data



Results

Risk characterisation ratios (RCR)

PROC

2

4

5

7

8a

8b

9

15

Results

Risk characterisation ratios (RCR)

PROC	n
2	13
4	2
5	10
7	4
8a	7
8b	76
9	40
15	70

Results

Risk characterisation ratios (RCR)

PROC	n	Registered ES
		Median (min–max)
2	13	0.20 (0.020–0.67)
4	2	0.76 (0.76–0.76)
5	10	0.21 (0.014–0.76)
7	4	0.52 (0.0070–0.80)
8a	7	0.50 (0.010–0.50)
8b	76	0.17 (0.0010–0.75)
9	40	0.21 (0.0030–0.90)
15	70	0.10 (0.0030–0.80)

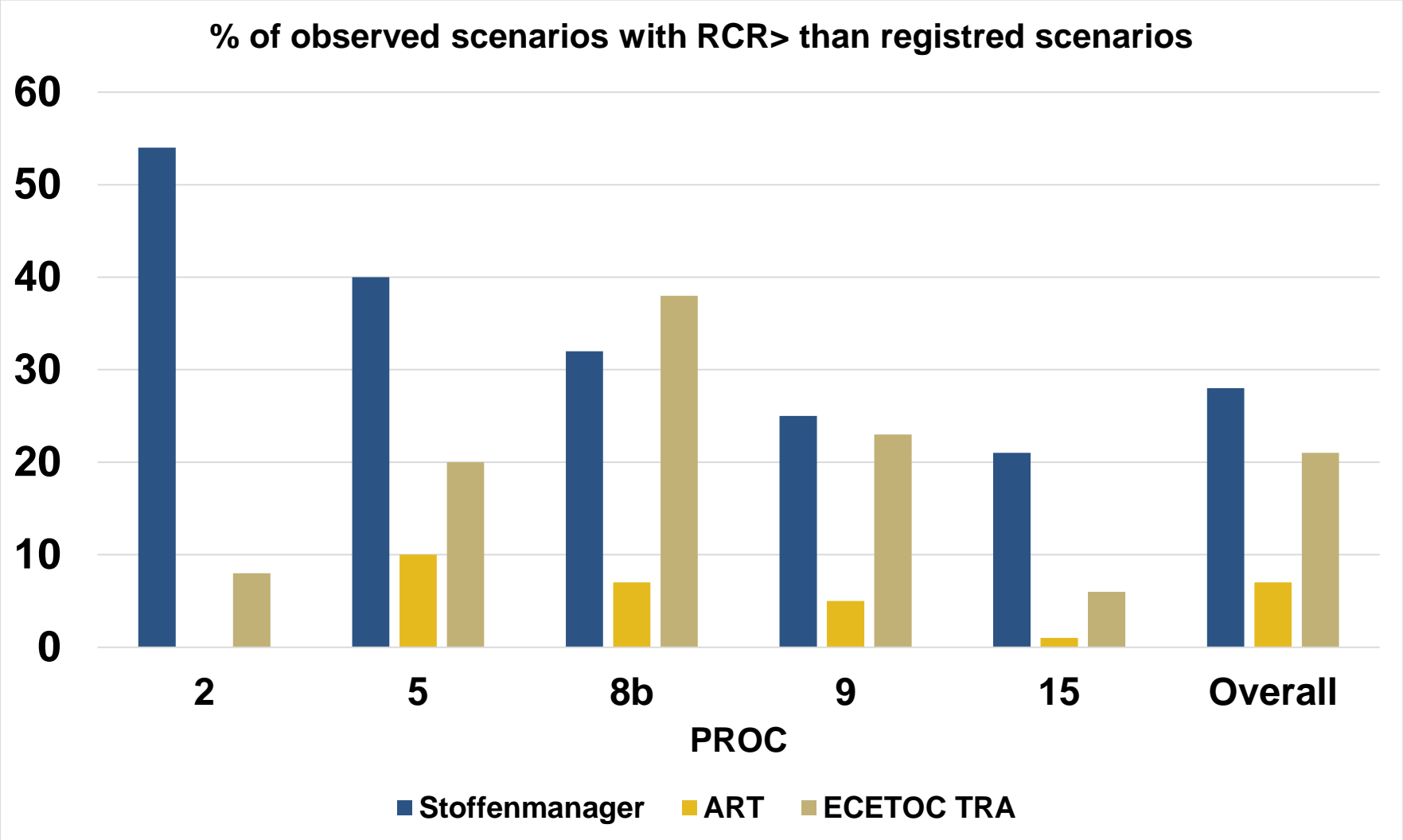
Results

Risk characterisation ratios (RCR)					
PROC	n	Registered ES	Stoffenmanager®	ART	ECETOC TRA
		Median (min–max)	Median (min–max)	Median (min–max)	Median (min–max)
2	13	0.20 (0.020–0.67)	0.39 (0.0010–17)	0.000076 (4*10 ⁻¹⁰ –0.0030)	0.0030 (0.000060–11)
4	2	0.76 (0.76–0.76)	2.4 (0.46–4.3)	0.46 (0.34–0.59)	0.00050 (0.000090–0.00090)
5	10	0.21 (0.014–0.76)	0.080 (0.010–3.2)	0.00060 (0.00011– 1.6)	0.060 (0.030–3.2)
7	4	0.52 (0.0070–0.80)	0.00090 (0.000010–0.020)	0.0020 (0.000050–0.0070)	0.010 (0.00090–0.20)
8a	7	0.50 (0.010–0.50)	0.030 (0.020–0.10)	0.020 (0.000030–0.20)	0.0040 (0.00030–0.060)
8b	76	0.17 (0.0010–0.75)	0.020 (0.00000090–55)	0.00039 (5*10 ⁻⁶ –17)	0.050 (0.000030–110)
9	40	0.21 (0.0030–0.90)	0.010 (0.0000020–9.3)	0.00060 (2*10 ⁻⁸ –2.5)	0.040 (0.000030–7.7)
15	70	0.10 (0.0030–0.80)	0.010 (0.000010–3.2)	0.00020 (1*10 ⁻⁸ –0.56)	0.0030 (0.00010–0.50)

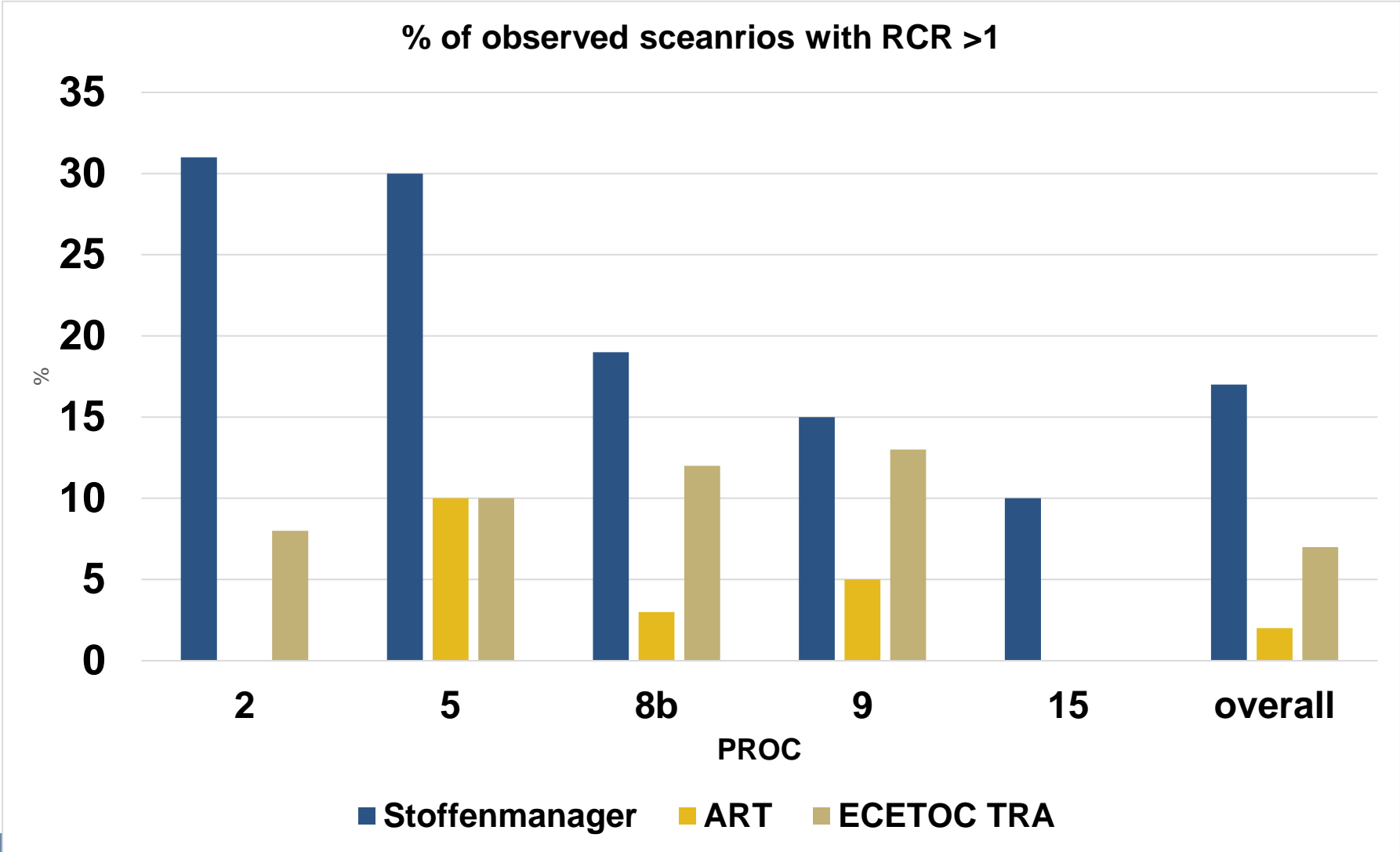
Results

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		Median (min–max)	Median (min–max)	Median (min–max)	Median (min–max)
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8a	7	0.50 (0.010–0.50)	0.030 (0.020–0.10)	0.020 (0.000030–0.20)	0.0040 (0.0020–0.060)
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9	40	0.21 (0.0030–0.90)	0.010 (0.0000020–9.3)	0.00060 (2*10 ⁻⁸ –2.5)	0.040 (0.000030–7.7)
15	70	0.10 (0.0030–0.80)	0.010 (0.000010–3.2)	0.00020 (1*10 ⁻⁸ –0.56)	0.0030 (0.00010–0.50)

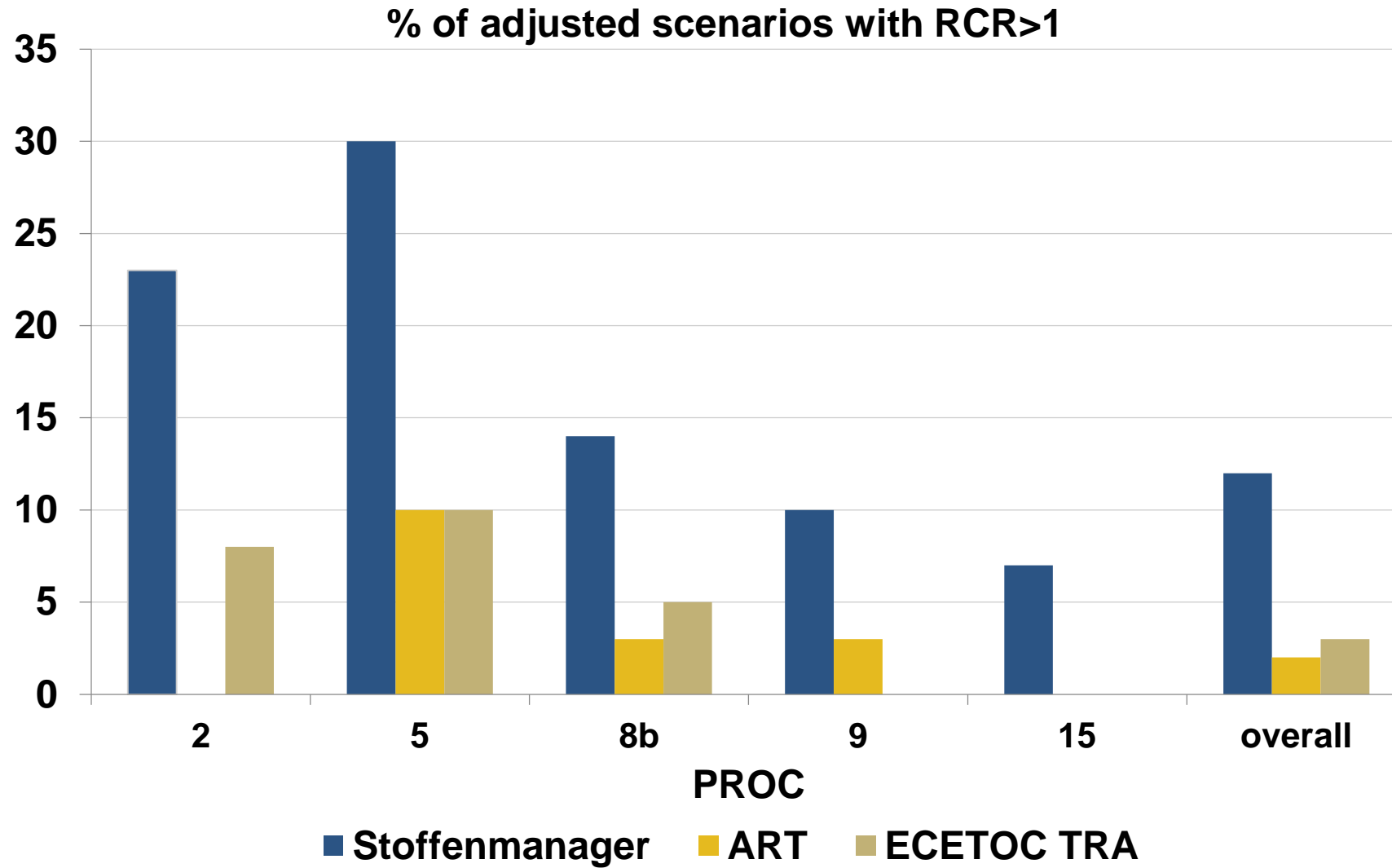
Results



Results



Results



Results

- ES with RCR>1 using Stoffenmanager in comparison with ES RCR<1:
- Lower DNEL-values (RCR>1 had median 1 and RCR<1 had median 24.5)
- Higher vapour pressure (RCR>1 had median 2500 and RCR<1 had median 89)

Results

- 58 % of all modelled ES with Stoffenmanager[®] gave a higher modelled outcome than ECETOC TRA.
- Stoffenmanager identified 25 ES with $RCR > 1$ whilst the ECETOC TRA had $RCR < 1$ for the same ES.
- => The Tier approach recommended by ECHA is not working according to the results in this study. Tier 1 models supposed to be more conservative and should give higher RCR than Tier 2

Conclusions

- Observed RCRs had generally lower calculated exposures than registered RCRs. But 12 % of the ES using Stoffenmanager[®], had $RCR > 1$
- Tier 2 models identified 25 ES with $RCR > 1$ whilst the Tier 1 model (ECETOC TRA) had $RCR < 1$ for the same ES.
- Overall, exposure models for chemicals with low DNELs and high vapour pressures should be used with caution.
- To decrease false safe scenarios, Stoffenmanager[®] could be used as a Tier 1 model instead of ECETOC TRA. It may be troublesome to use very generic exposure scenarios. More specific exposure scenarios are preferred.

Scientific publication – accepted (AWEH)

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Thank you

