
HESI RISK21 Program

RISK21 Case Studies and Implementation



Shake it up...
...and make it
BETTER

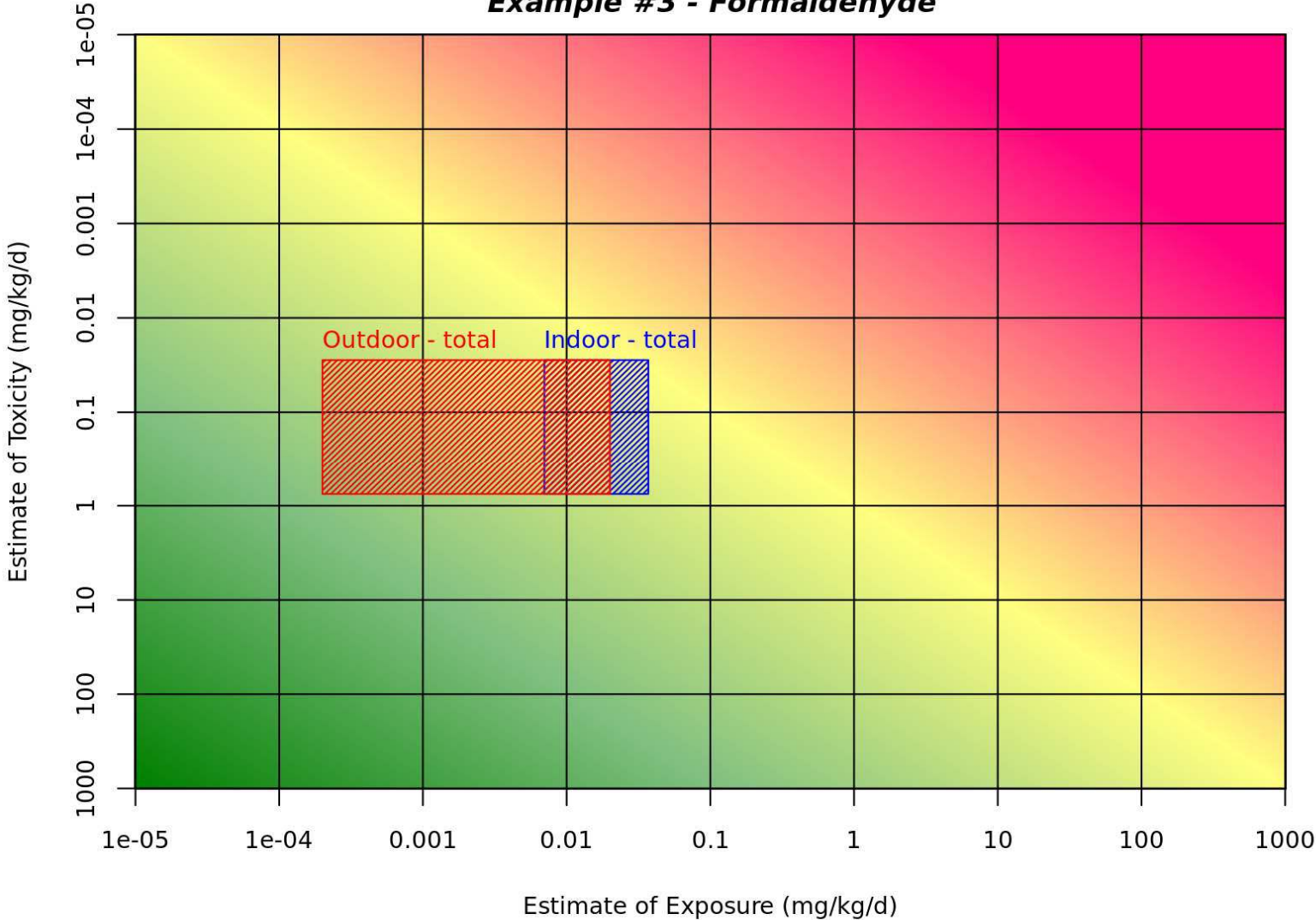
IRIS and Formaldehyde

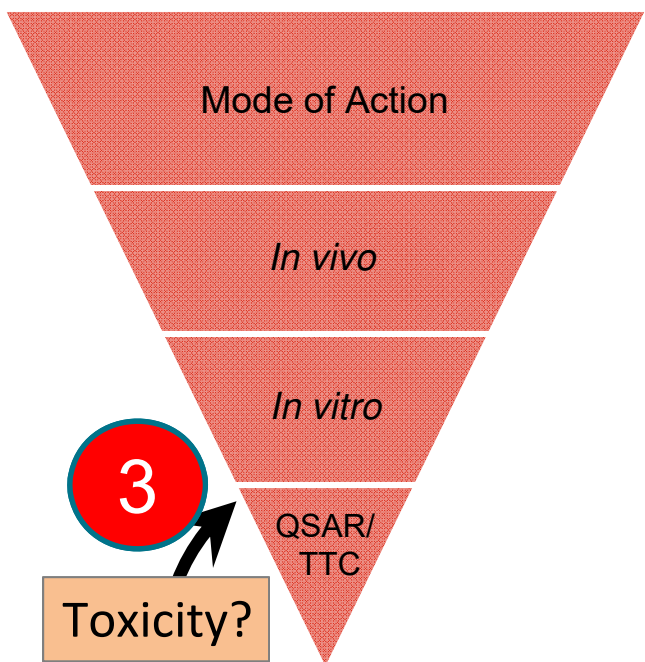
- [Toxicological Review of Formaldehyde-Inhalation Assessment: in Support of Summary Information on the Integrated Risk Information System \(IRIS\) \(PDF\)](#) (1043 pp, 8 MB, [about PDF](#))
- [Tox Review of Formaldehyde, Volume 1: Introduction, Background, and Toxicokinetics \(PDF\)](#) (112 pp, 1 MB, [about PDF](#))
- [Tox Review of Formaldehyde, Volume 2: Hazard Characterization \(PDF\)](#) (570 pp, 4 MB, [about PDF](#))
- [Tox Review of Formaldehyde, Volume 3: Quantitative Assessment, Major Conclusions in the Characterization of Hazard and Dose Response, and References \(PDF\)](#) (253 pp, 2 MB, [about PDF](#))
- [Tox Review of Formaldehyde, Volume 4: Appendices \(PDF\)](#) (108 pp, 1 MB, [about PDF](#))



RISK21 and Formaldehyde

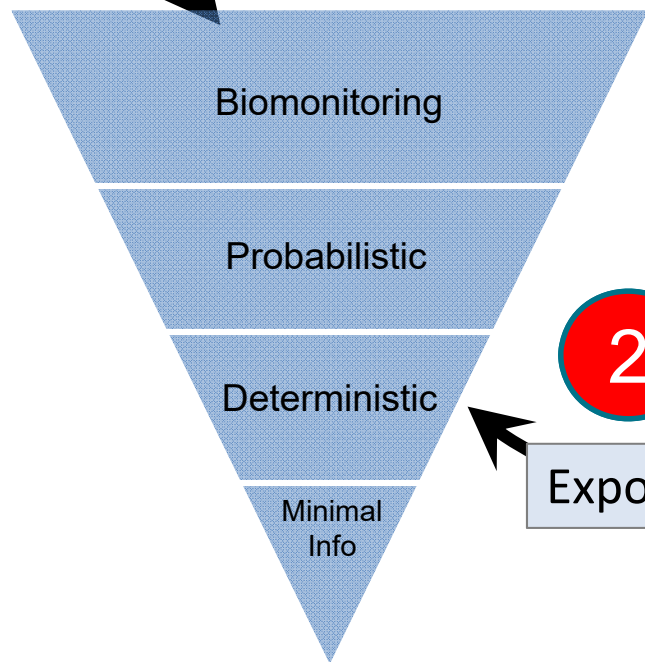
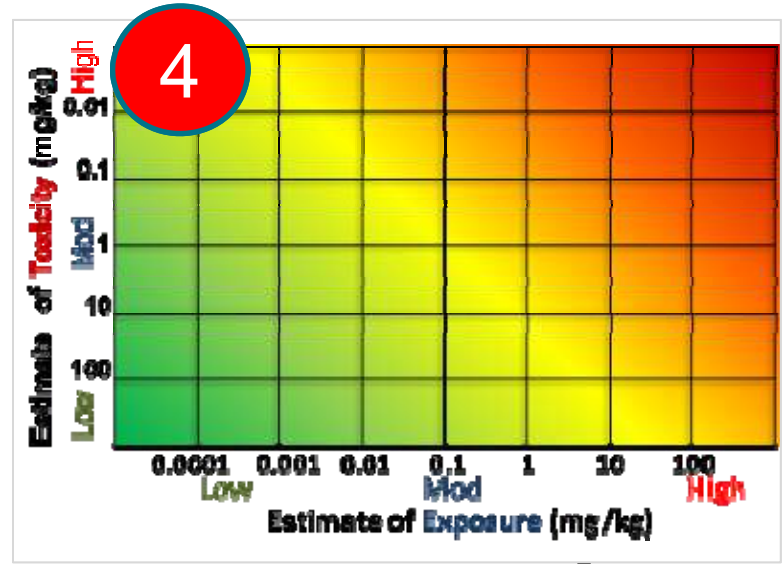
Example #3 - Formaldehyde





Risk? Safety?

3
Toxicity?

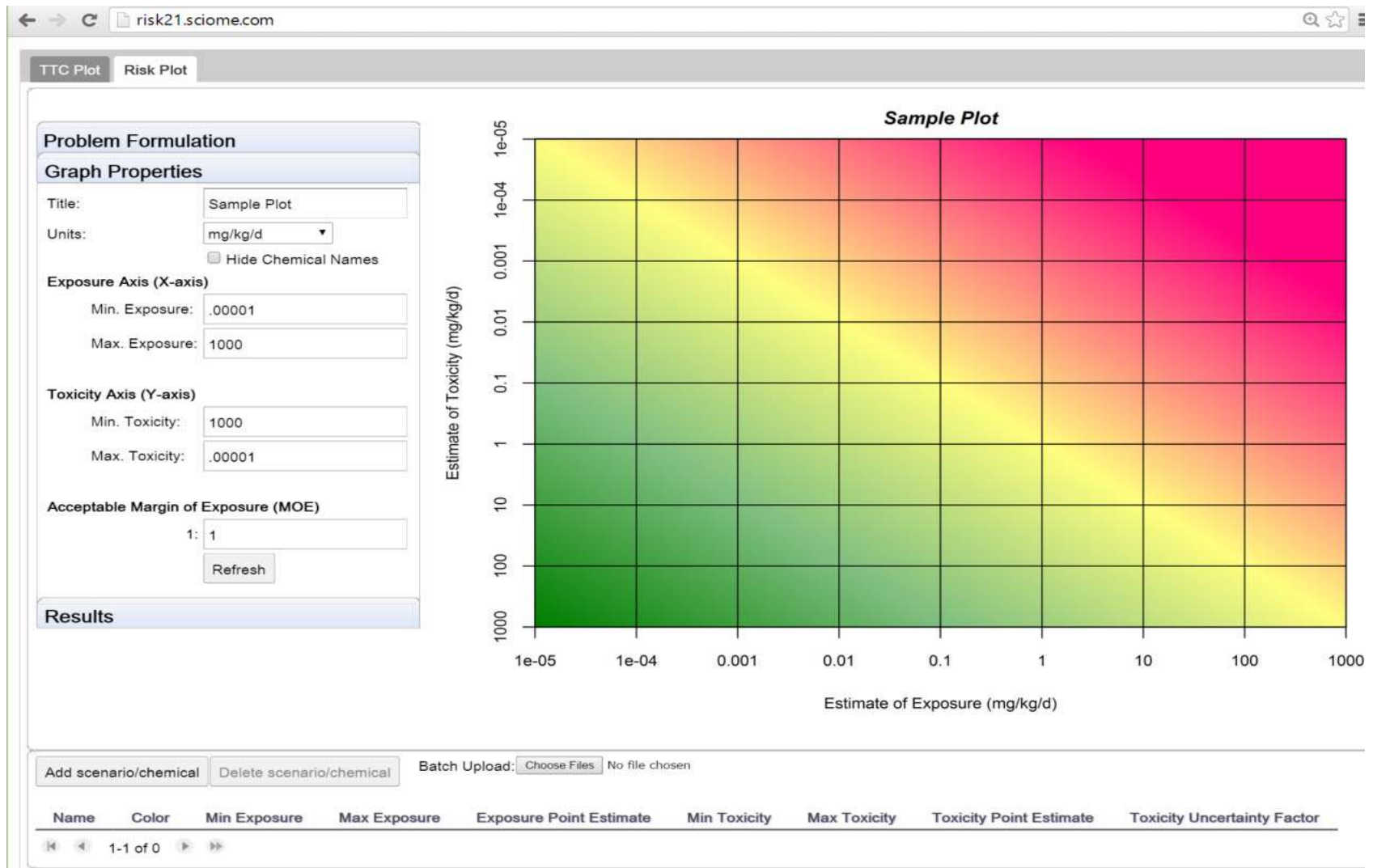


2
Exposure?

1
Problem Formulation

Conclude

WEB-Based Tool: www.risk21.org



<http://informahealthcare.com/txc>
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REVIEW ARTICLE

A 21st century roadmap for human health risk assessment

Timothy P. Pastoor¹, John E. Doe², Nancy G. Doerr³, Nina Heard⁴, Ronald N. Hines⁵, Anna B. Lowit⁶, Timothy Pastoor⁴, Richard D. Phillips⁷, Dana Sargent^{8a}, James H. Sherman⁹, Jennifer Young Tanir³ & Michelle R. Embry³

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REVIEW ARTICLE

Risk assessment in the 21st century: Roadmap and matrix

Michelle R. Embry³, Ian C. Dewhurst³, J. Craig Rowlands¹

¹VLSI Health and Environmental Sciences Institute, Washington, DC, USA, ²Syngenta Crop Protection LLC, Greensboro, NC, USA, ³US Environmental Protection Agency, NHEERL, Research Triangle Park, NC, USA, ⁴ExxonMobil Biomedical Sciences, Inc., Annandale, NJ, USA, ⁵Arysta LifeScience North America, Cary, NC, USA, and ⁶Monsanto Company, Saint Louis, MO, USA

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REVIEW ARTICLE

The use of mode of action information in risk assessment: Quantitative key events/dose-response framework for modeling the dose-response for key events

Ted W. Simon¹, Penelope A. F. Subteam¹¹

¹Ted Simon LLC, Washington, DC, USA, ²US Environmental Protection Agency, NHEERL, Research Triangle Park, NC, USA, ³US Environmental Protection Agency, Office of Pesticide Programs, Washington, DC, USA, ⁴ExxonMobil Biomedical Sciences, Inc., Annandale, NJ, USA, ⁵Arysta LifeScience North America, Cary, NC, USA, and ⁶Monsanto Company, Saint Louis, MO, USA

CRITICAL REVIEWS IN TOXICOLOGY, 2016
 VOL. 46, NO. 1, 43-53
<http://dx.doi.org/10.3109/10408444.2015.1082973>

REVIEW ARTICLE

Illustrative case using the RISK21 roadmap and matrix: prioritization for evaluation of chemicals found in drinking water

Douglas C. Wolf¹, Angelo Moretto² & Michelle R. Embry³

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CRITICAL REVIEWS IN TOXICOLOGY, 2016
 VOL. 46, NO. 1, 54-73
<http://dx.doi.org/10.3109/10408444.2015.1082974>

REVIEW ARTICLE

Use of the RISK21 roadmap and matrix: human health risk assessment of the use of a pyrethroid in bed netting

John E. Doe¹, Deborah R. Lander², Nancy G. Doerr³, Nina Heard⁴, Ronald N. Hines⁵, Anna B. Lowit⁶, Timothy Pastoor⁴, Richard D. Phillips⁷, Dana Sargent^{8a}, James H. Sherman⁹, Jennifer Young Tanir³ & Michelle R. Embry³

¹Parker Doe Partnership LLP, Frodsham, Cheshire, UK, ²DuPont Haskell Global Centers for Health & Environmental Sciences, Newark, DE, USA, ³VLSI Health and Environmental Sciences Institute, Washington, DC, USA, ⁴Syngenta Crop Protection LLC, Greensboro, NC, USA, ⁵US Environmental Protection Agency, NHEERL, Research Triangle Park, NC, USA, ⁶US Environmental Protection Agency, Office of Pesticide Programs, Washington, DC, USA, ⁷ExxonMobil Biomedical Sciences, Inc., Annandale, NJ, USA, ⁸Arysta LifeScience North America, Cary, NC, USA, and ⁹Monsanto Company, Saint Louis, MO, USA

OPEN ACCESS – links at www.risk21.org



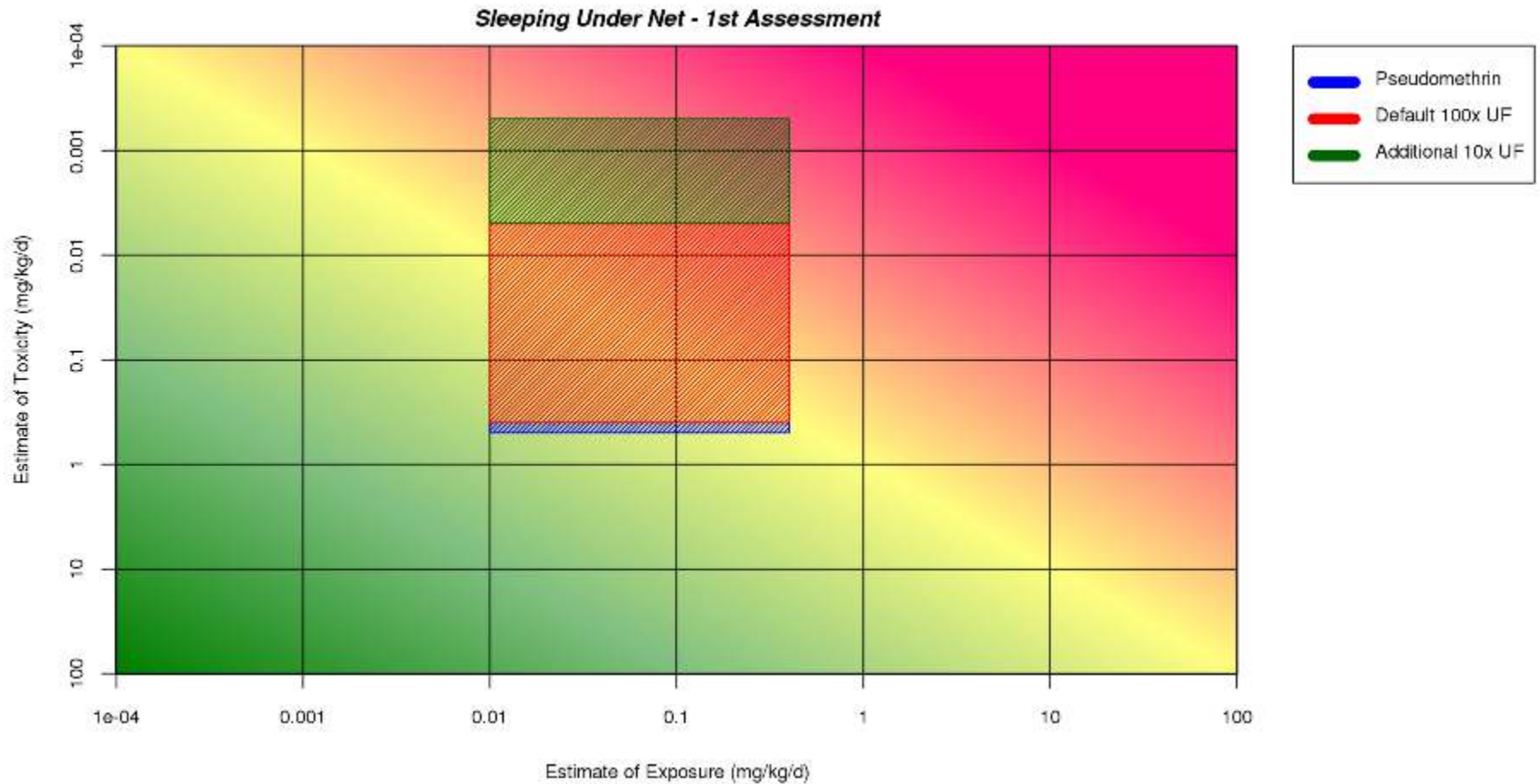
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Critical Reviews in Toxicology, 2014; **44**(S3): 17–43
Critical Reviews in Toxicology, 2016; **46**(1): 43–53
Critical Reviews in Toxicology, 2016; **46**(1): 54–73

RISK21 Case Studies



1. “Pseudomethrin”
2. 20 Chemicals in Drinking Water

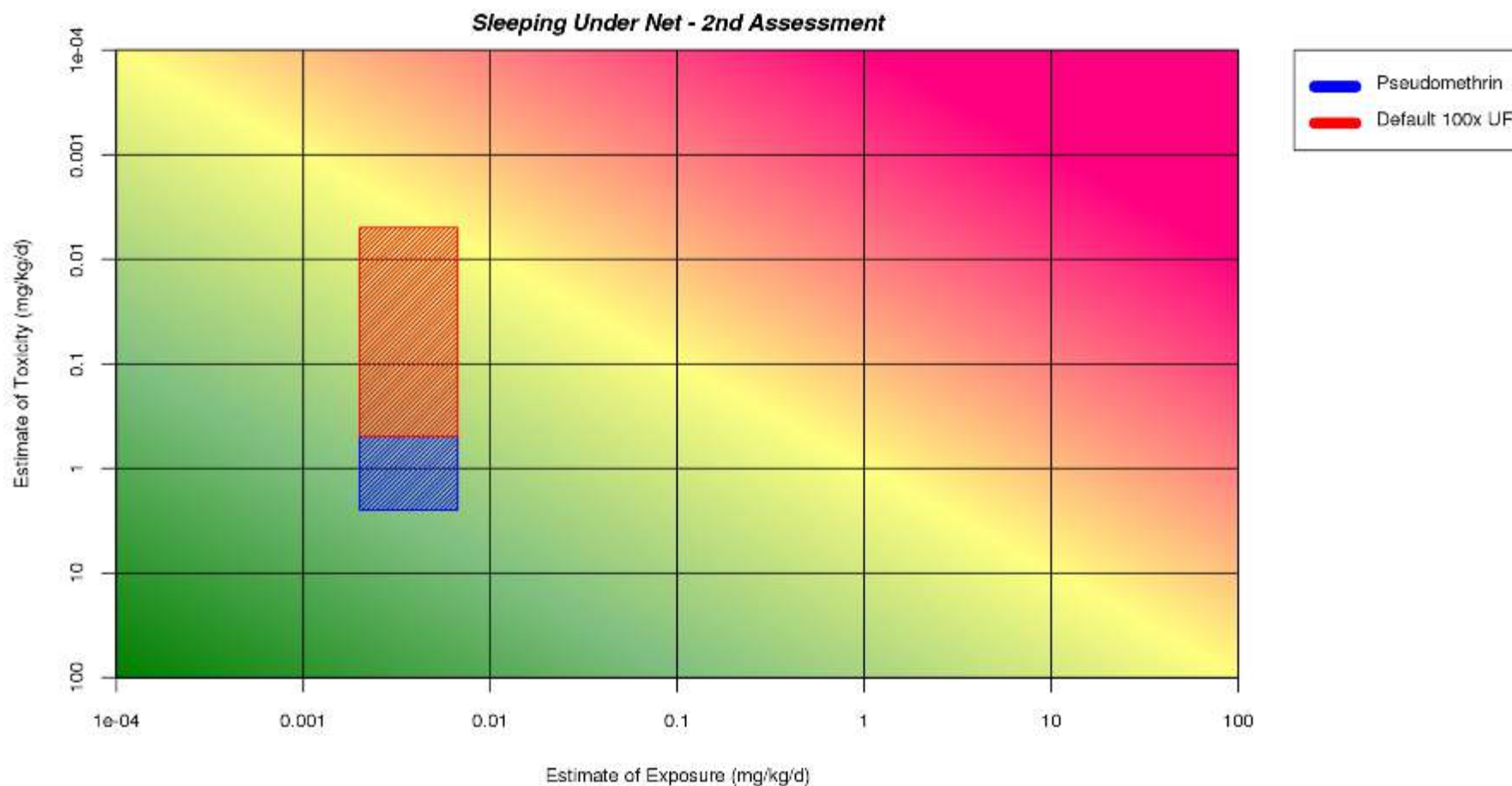
Sleeping under net: Tier 0



Exposure range: 0.1 – 0.443 mg/kg/d (infant, aggregate, sleeping)

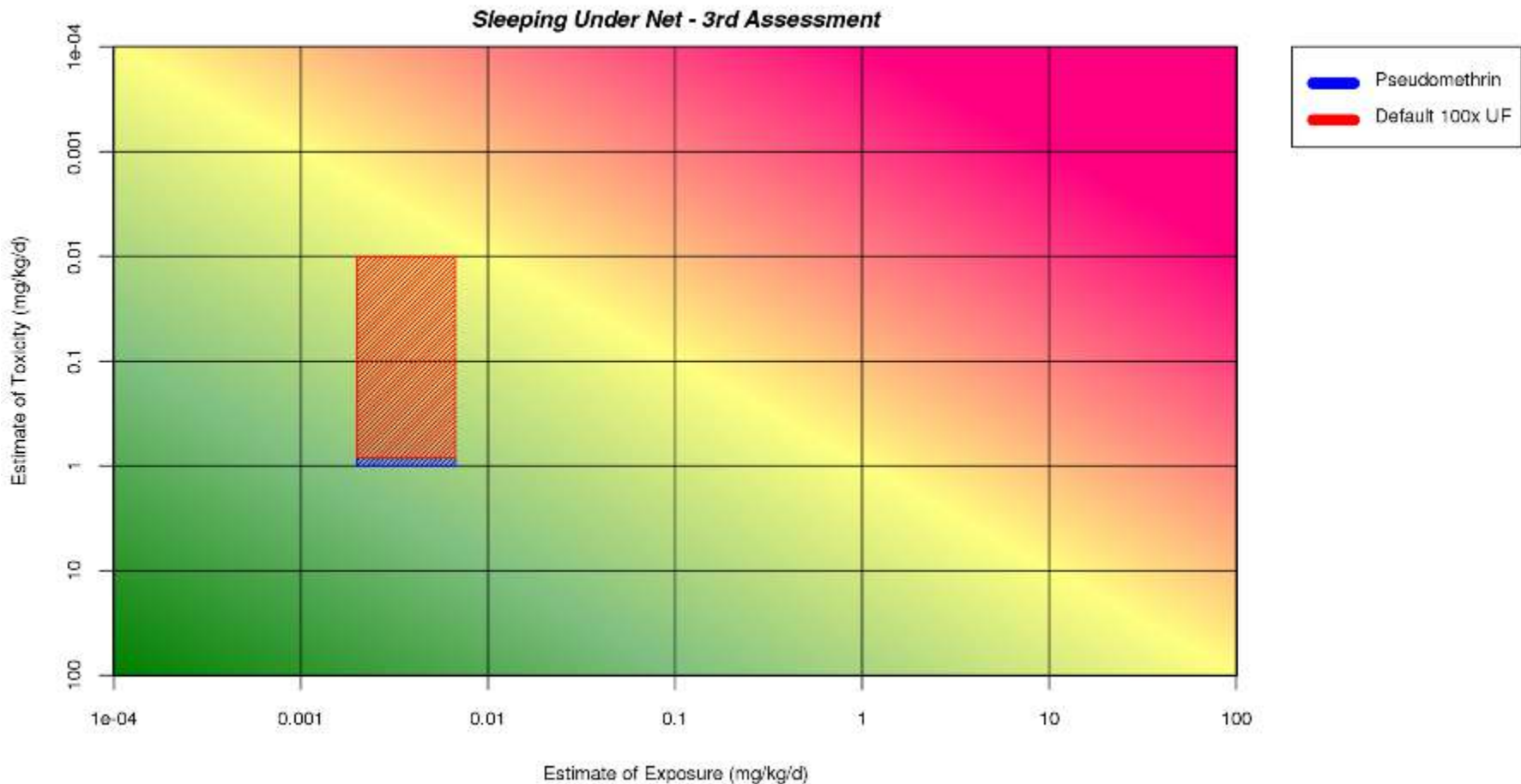
Toxicity value: most potent chronic NOAEL (lambda-cyhalothrin): 0.5 + UFs

Sleeping under net: 2nd Assessment



Exposure range: 0.002 – 0.0067 (infant, aggregate, sleeping) –dermal absorption estimates
Toxicity range: 0.5 – 2.5 [derived from most potent chronic NOAEL (lambda-cyhalothrin) and 5-fold lower potency of pseudomethrin based on MEA IC50] + UFs

Sleeping under net: 3rd Assessment



Exposure range: same as previous

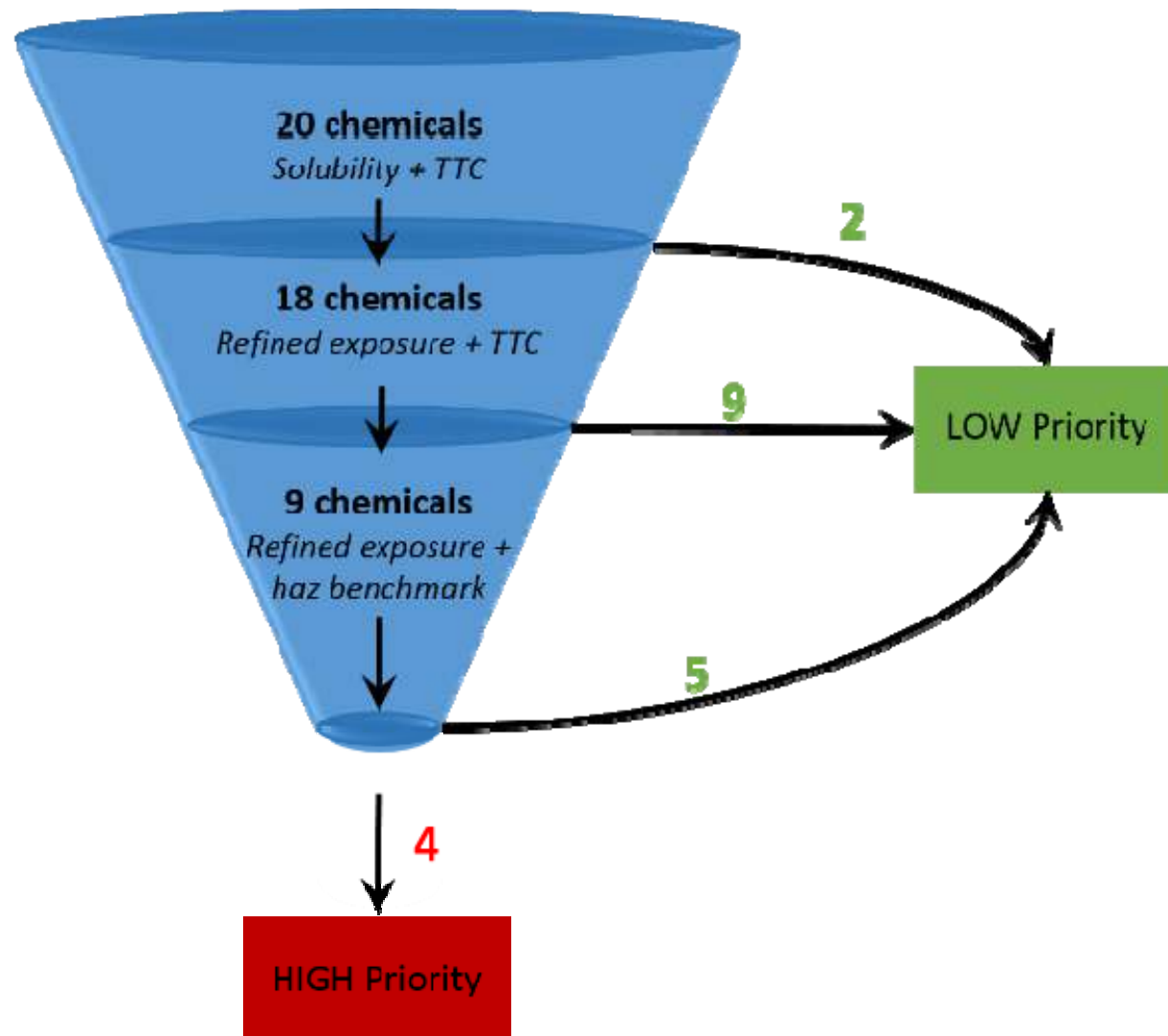
Toxicity range: Used 5-day dog study (neurological NOAEL of 1 mg/kg/d) with UF and in vitro screens

RISK21 Case Studies



1. “Pseudomethrin”
2. 20 Chemicals in Drinking Water

Water Case Study – Overview of Results



FDA/CFSAN (May 2015)



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health



Taiwanese Office of Food Safety (Taipei; October 2015)



China National Center for Food Safety (Nanjing; October 2015)



RISK21 and the Future...



Shake it up... ...and take your pick...

