Probabilistic modelling in exposure and risk assessment – theory, practice and future

GFoRSS, WHO, BfR and ILMERAC Network Meeting

Dubai, 16 November 2025

Matthias Greiner

Probabilistic modelling – indispensable tool for quantifying exposure and health risks

- What is the relevance of the **theory** behind probabilistic modelling?
- What is the current **practice**?
- What is needed now to prepare for the **future**?

This talk focusses on scenario modelling for chemical hazards.

Theory

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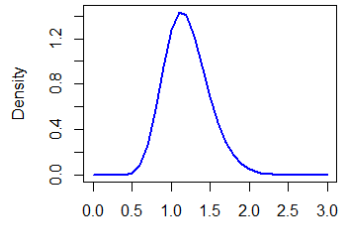
Bayesian concept for parameter uncertainty

Bayesian statistical inference for estimating a population parameter …

Sample

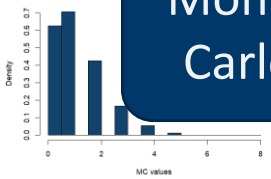


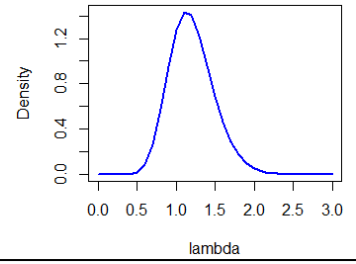
+ prior information (e.g., expert-based)

+ model-based adjustments for bias (e.g., censoring)

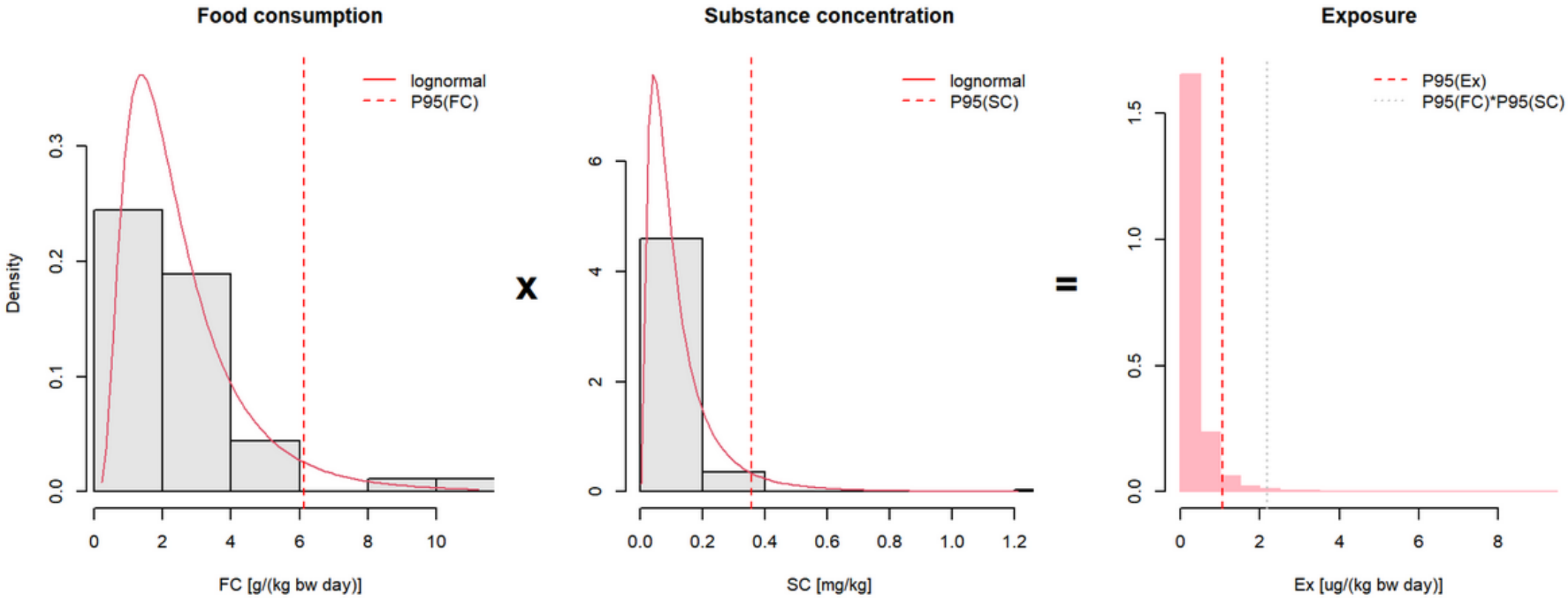
provides input to probabilistic modelling of parameter uncertainty

Monte Carlo





Probabilistic modelling is the gold standard for working with functions of random variables (“Monte Carlo integration”)

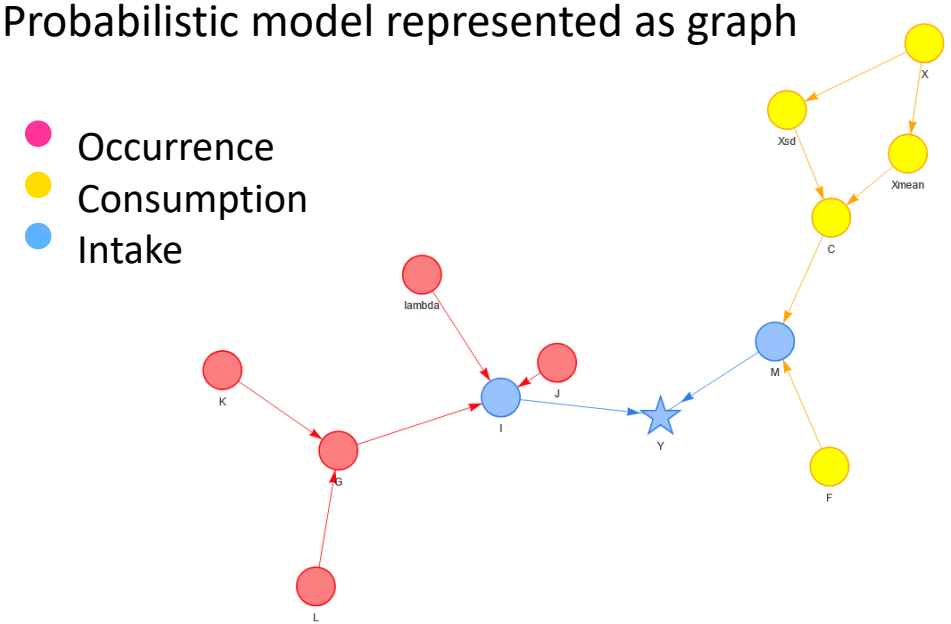


Greiner, 2022 (unpublished course notes)

Causation in probabilistic modelling and epidemiology

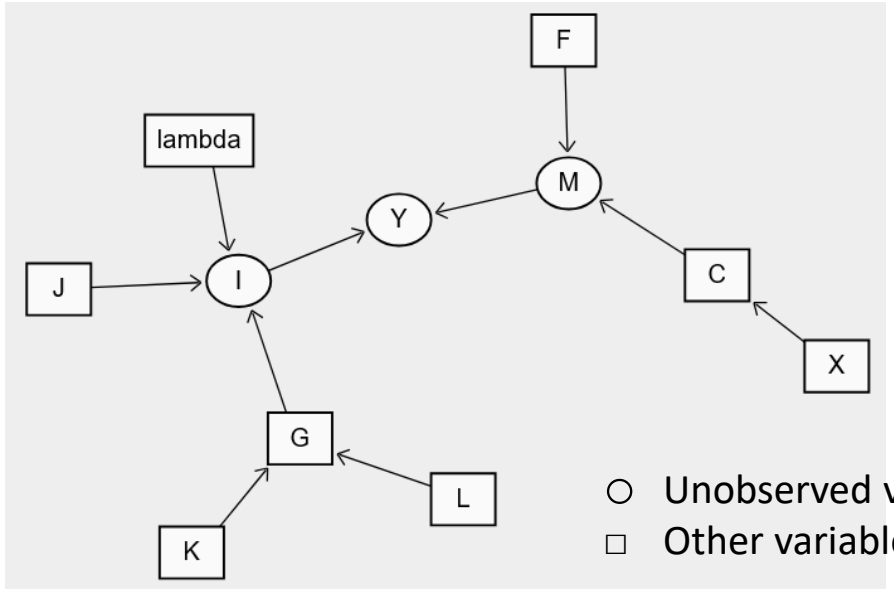
Probabilistic modelling for knowledge integration is consistent with modern epidemiological concepts for causation

Probabilistic model represented as graph



Exposure to alizarin red S (ARS) by consumption of marked eel (Schendel et al., 2018), re-implemented as demo model using https://shiny.bfr.bund.de/apps/shiny-rrisk/ (v18.4)

Causal model represented as directed acyclic graph (DAG)



Same model, visualised using DAGitty https://www.dagitty.net/dags.html (v3.1)

Conclusions from theoretical aspects

- Theory behind probabilistic modelling is consistent with Bayesian inference and modern concepts of causation.
- Common biases can be remedied (e.g., adjusted parameter estimates).
- Probabilistic modelling helps to focus on the range of quantitative results that are consistent with the state of knowledge in the presence of uncertainties.

Practices

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Probabilistic modelling in a tiered approach

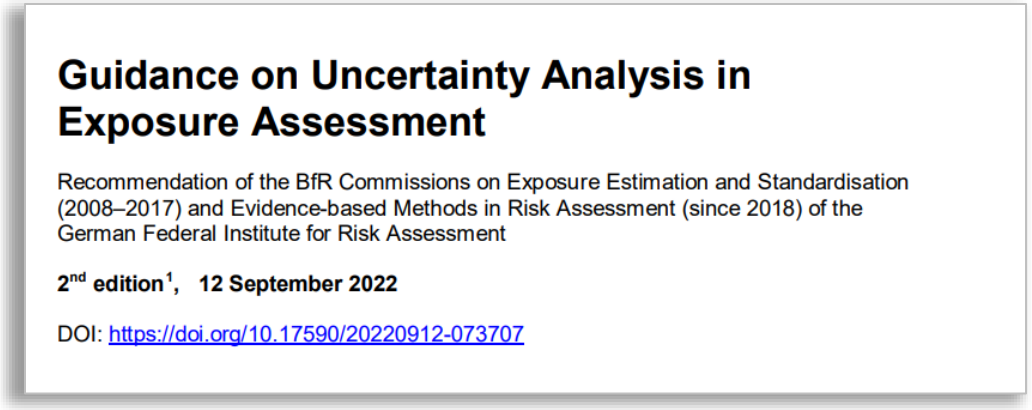
Lower tier

- To save time and effort, start simple
- Deterministic model
- Conservative assumptions regarding scenario
- Conservative default values (e.g., body weight, exposure factors)
- Avoid underestimation of risk

If estimate is of concern, use higher tier

Higher tier

- Use of (more) actual data
- Refined Scenarios
- Probabilistic assessment



Guidance on Uncertainty Analysis in Exposure Assessment

Recommendation of the BfR Commissions on Exposure Estimation and Standardisation (2008–2017) and Evidence-based Methods in Risk Assessment (since 2018) of the German Federal Institute for Risk Assessment

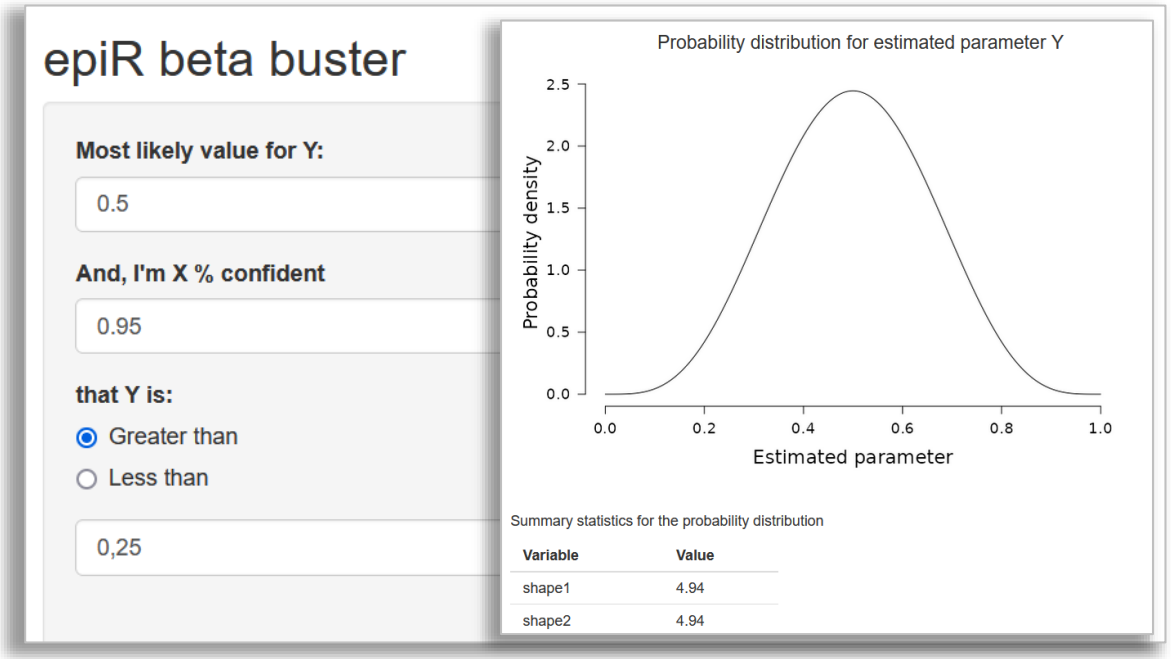
2nd edition[1], 12 September 2022

DOI: https://doi.org/10.17590/20220912-073707

Heinemeyer et al. (2022)

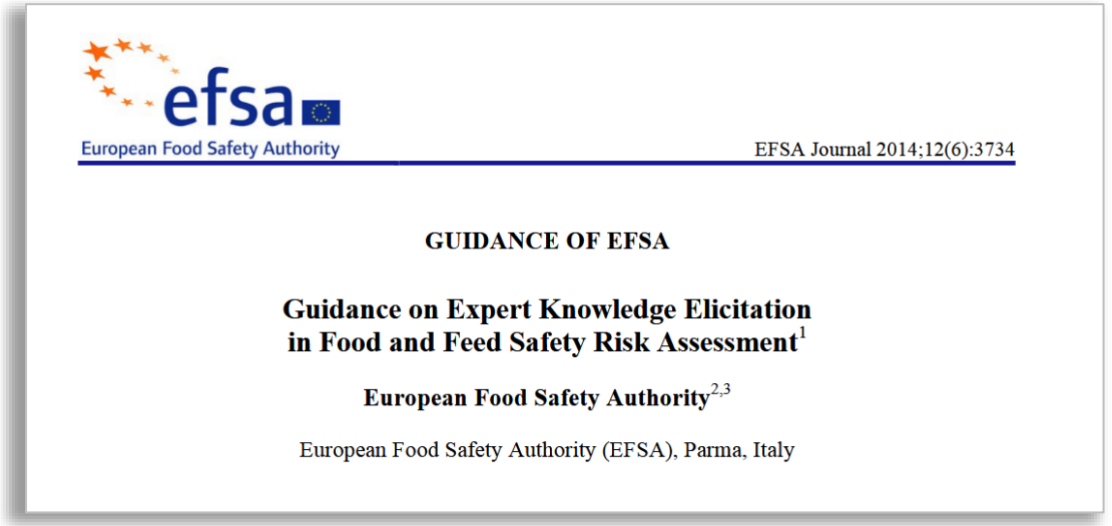
Probability distributions can be derived from expert knowledge

Priors in Bayesian inference, e.g. for a Beta distribution

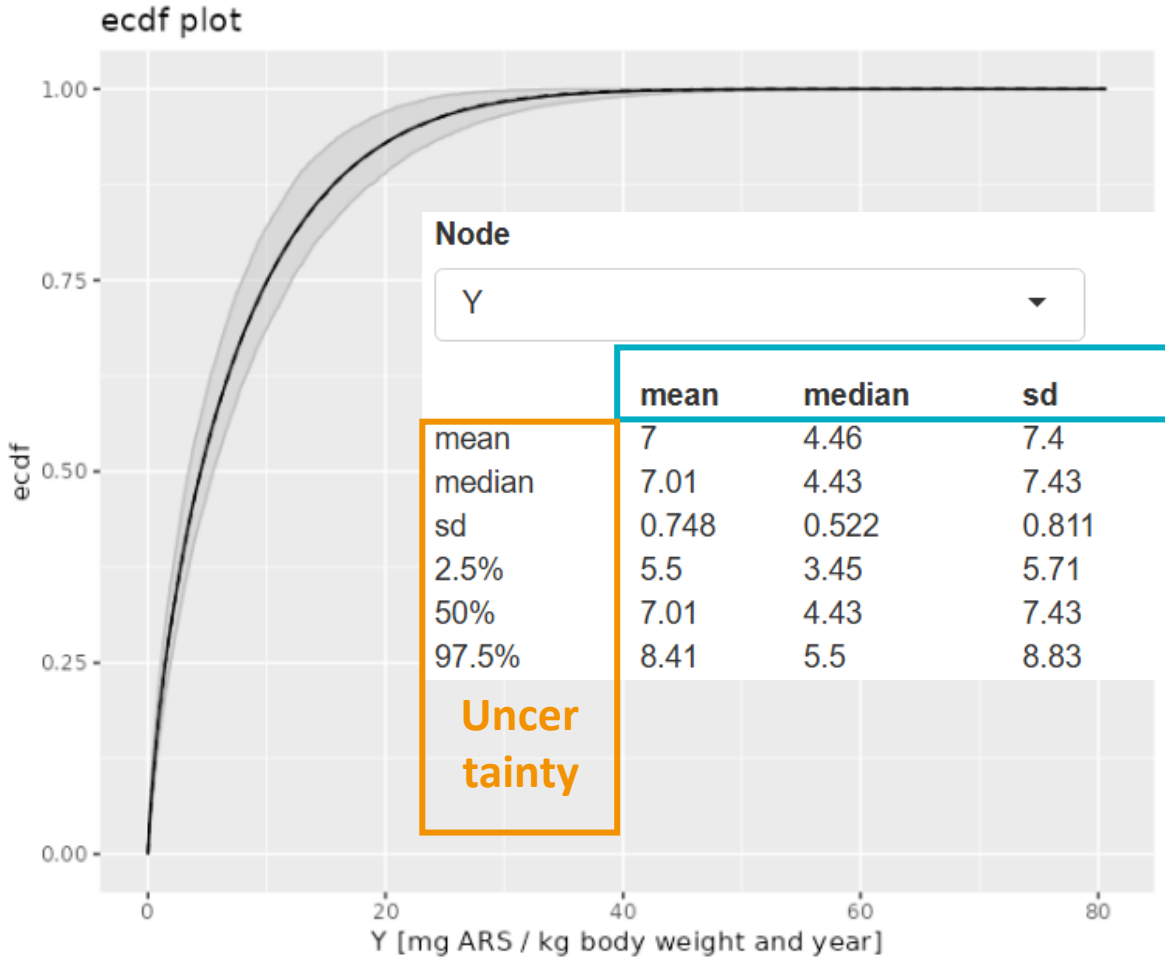


https://shiny.vet.unimelb.edu.au/epi/beta.buster/
Stevenson et al. (2015)

"Elicit from knowledgeable experts quantitative parameters and their uncertainties in a probabilistic way" (EFSA, 2014)



Quantifying the impact of parameter uncertainty on the model results by two-dimensional (2D) simulation



	mean	median	sd	5%	25%	50%	75%	95%	unit
mean	7	4.46	7.4	0.174	1.49	4.46	10.1	22.4	mg ARS / kg body weight and year
median	7.01	4.43	7.43	0.171	1.48	4.43	10.1	22.5	mg ARS / kg body weight and year
sd	0.748	0.522	0.811	0.0307	0.194	0.522	1.1	2.44	mg ARS / kg body weight and year
2.5%	5.5	3.45	5.71	0.117	1.12	3.45	7.95	17.3	mg ARS / kg body weight and year
50%	7.01	4.43	7.43	0.171	1.48	4.43	10.1	22.5	mg ARS / kg body weight and year
97.5%	8.41	5.5	8.83	0.239	1.91	5.5	12.1	26.9	mg ARS / kg body weight and year

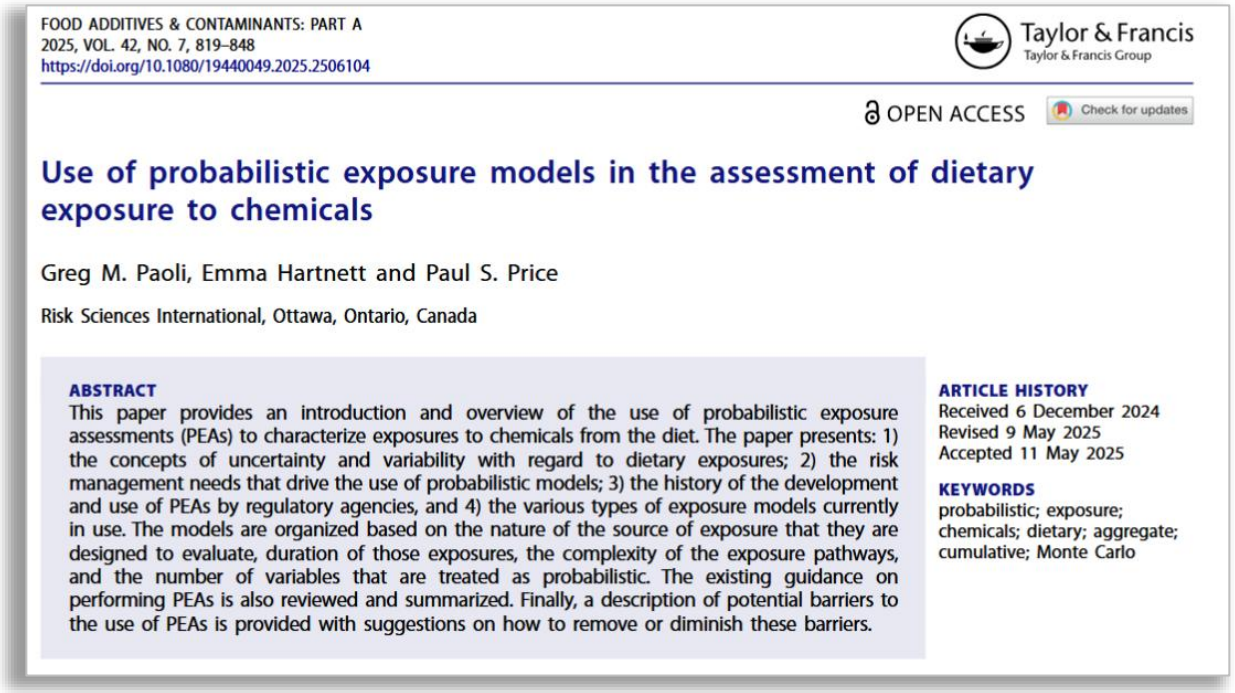
Uncertainty

Variability

Exposure to alizarin red S (ARS) by consumption of marked eel (Schendel et al., 2018), re-implemented as demo model in shiny rrisk (https://shiny.bfr.bund.de/apps/shiny-rrisk/)

Software for probabilistic modelling for specific questions and regulatory needs or to supporting generic approaches

Dietary exposure to chemicals



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Use of probabilistic exposure models in the assessment of dietary exposure to chemicals

Greg M. Paoli, Emma Hartnett and Paul S. Price

Risk Sciences International, Ottawa, Ontario, Canada

ABSTRACT

This paper provides an introduction and overview of the use of probabilistic exposure assessments (PEAs) to characterize exposures to chemicals from the diet. The paper presents: 1) the concepts of uncertainty and variability with regard to dietary exposures; 2) the risk management needs that drive the use of probabilistic models; 3) the history of the development and use of PEAs by regulatory agencies, and 4) the various types of exposure models currently in use. The models are organized based on the nature of the source of exposure that they are designed to evaluate, duration of those exposures, the complexity of the exposure pathways, and the number of variables that are treated as probabilistic. The existing guidance on performing PEAs is also reviewed and summarized. Finally, a description of potential barriers to the use of PEAs is provided with suggestions on how to remove or diminish these barriers.

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KEYWORDS
probabilistic; exposure; chemicals; dietary; aggregate; cumulative; Monte Carlo

See review by Paoli et al. (2025)

1D simulation

- CalTox TM
  https://dtsc.ca.gov/caltox/
- CARES NG
  https://caresng.org/
- ConsExpo TM
  https://www.rivm.nl/en/consexpo/consexpoweb
- DEEM-FCD
  https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/deem-fcidcalendex-software-installer
- LifeLine TM
  https://archive.epa.gov/ncer/ej/web/pdf/lifeline.pdf
- PACEM
  https://www.pacemweb.nl/simulation/assessment-settings
- SHEDS
  https://www.epa.gov/chemical-research/stochastic-human-exposure-and-dose-simulation-sheds

2D simulation

- MCRA
  https://www.rivm.nl/en/food-safety/chemicals-in-food/monte-carlo-risk-assessment-mcra

Bayesian models

- Advanced Reach Tool
  https://www.advancedreachtool.com/
- BIKE
  https://doi.org/10.3390/foods10112520

Generic approaches (1D/2D)

- @RISK
  https://lumivero.com/products/at-risk/
- ModelRisk
  https://www.vosesoftware.com/Risk-In-Excel/
- Oracle Crystal Ball
  https://www.oracle.com/uk/middleware/technologies/crystalball.html
- Shiny rrisk
  https://shiny.bfr.bund.de/apps/shiny-rrisk/

Disclaimer: not comprehensive, not based on systematic review

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Conclusions regrading practices

- Although probabilistic modelling is often considered for refined models it can also accommodate data poor situations.
- Tools and protocols exist to derive distributions from expert knowledge.
- Joint models for uncertainty and variability require software capable of 2D Monte Carlo simulation or Bayesian models.

Future

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AI-assisted risk and exposure modelling

Getting prepared for:

- Secure, accessible and sustainable IT environments.
- Validation protocols and benchmarking for AI-generated models.
- Closer cooperation between risk modellers, domain experts and AI specialists.

Deliver model-based decision support in exposure and health risks

Getting prepared for:

- Complex interactions between natural disasters/climate change and hybrid warfare.
- Extreme epistemic uncertainties occurring through elevated exposure levels in combination with disrupted infrastructures for monitoring and reporting and strategic disinformation.
- Absence of tailor-made models and inapplicability of empirical model validation.

Conclusions for discussion

We need to maintain modelling expertise through training at different levels

- Knowledge-based objectives: statistical/mathematical concepts, system thinking and knowledge of key principles in epidemiology such as causation and bias.
- Skill-based objectives: capability to define and set up a model from scratch in an interdisciplinary team and to interpret the results.

References

EFSA (European Food Safety Authority), 2014. Guidance on Expert Knowledge Elicitation in food and feed safety risk assessment. EFSA Journal 2014; 12(6):3734, 278 pp. https://doi.org/10.2903/j.efsa.2014.3734

Heinemeyer G, et al. (2022). Guidance on Uncertainty Analysis in Exposure Assessment - Recommendation of the Commissions on Exposure Estimation and Standardisation (2008–2017) and Evidence-based Methods in Risk Assessment (since 2018) of the German Federal Institute for Risk Assessment (BfR). https://doi.org/10.17590/20220912-073707, https://www.bfr.bund.de/cm/349/guidance-on-uncertainty-analysis-in-exposure-assessment.pdf. Accessed Sep 24, 2025.

Paoli, G. M., Hartnett, E., & Price, P. S. (2025). Use of probabilistic exposure models in the assessment of dietary exposure to chemicals. Food Additives & Contaminants: Part A, 42(7), 819–848. https://doi.org/10.1080/19440049.2025.2506104

Schendel T, Jung C, Lindtner O and Greiner M (2018). Guidelines for Uncertainty Analysis: Application of the respective documents of EFSA and BfR for exposure assessments. EFSA supporting publication 2018: EN-1472. 113 pp. https://doi:10.2903/sp.efsa.2018.EN-1472

Stevenson M, Nunes T, Heuer C, Marshall J, Sanchez J, Thornton R, Reiczigel J, Robison-Cox J, Sebastiani P, Solymos P, Yoshida K, Firestone S. (2015) epiR: An R package for the analysis of epidemiological data. R package version 0.9-69.

Credits

Adrian Cieszynski (Unit Exposure to Chemicals and Transport of Dangerous Goods), Anna Jäger and Christian Jung (Unit Exposure Assessment and Exposure Standardisation), all Department Exposure at BfR, provided material for these slides.

Thank you for your attention!

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