Protecting People

Making safety decisions with NAMs

Carl Westmoreland

15th November 2022

Unilever

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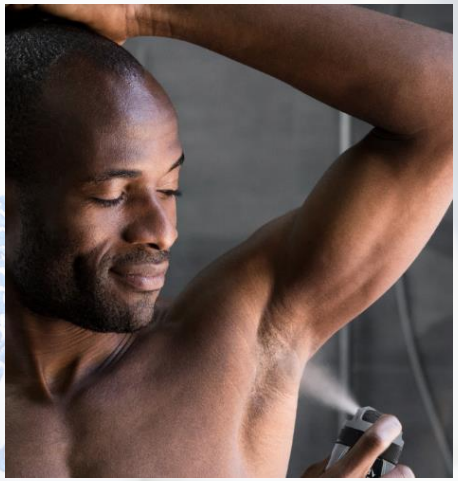

…. and ensuring everyone has trust in the safety decisions

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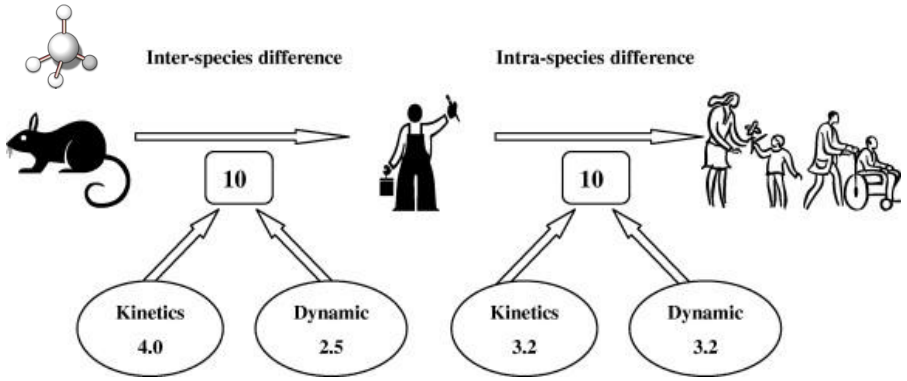
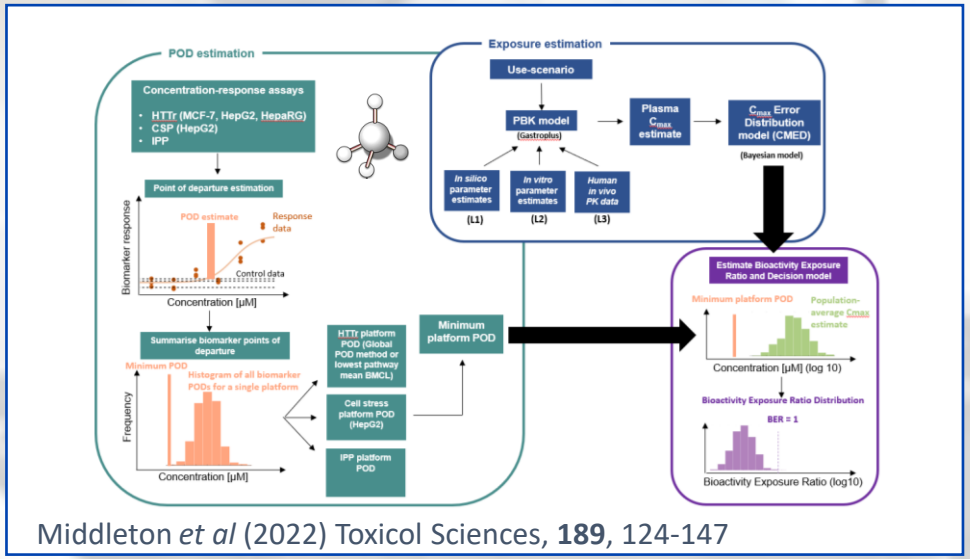


Schroeder *et al* (2011) Toxicol in Vitro, **25**, 589-604



Middleton *et al* (2022) Toxicol Sciences, **189**, 124-147

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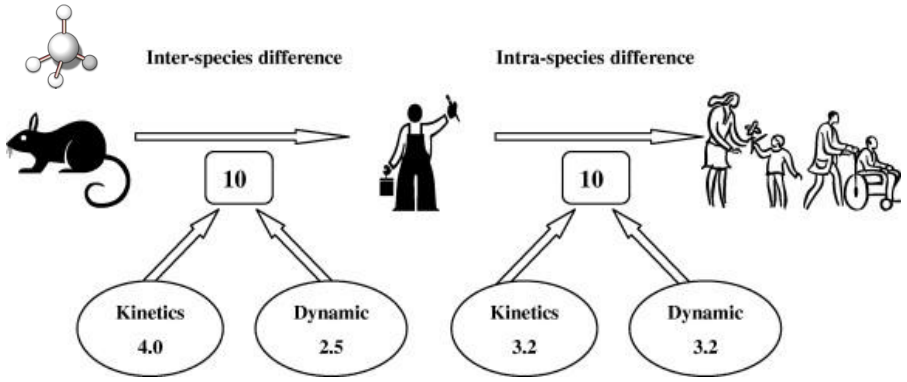


Schroeder *et al* (2011) Toxicol in Vitro, **25**, 589-604

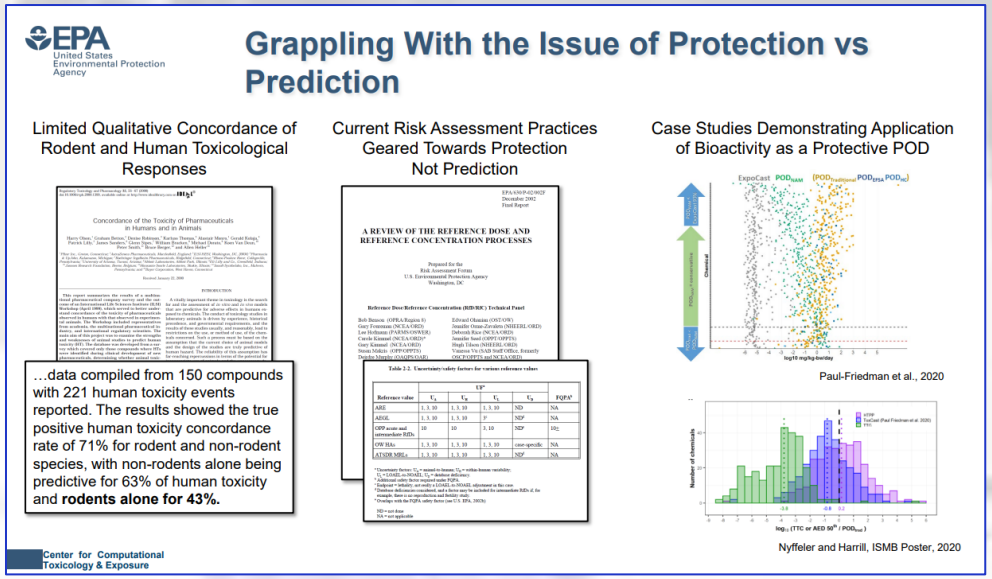
Tests at high doses in rodents

The gold standard for protecting people?

Do rodents predict what might happen in people?

Margins of Safety (MoS) can allow us to protect people

National Academies of Sciences, Engineering and Medicine (2022)
doi.org/10.17226/26496



Rusty Thomas, US EPA (2021)

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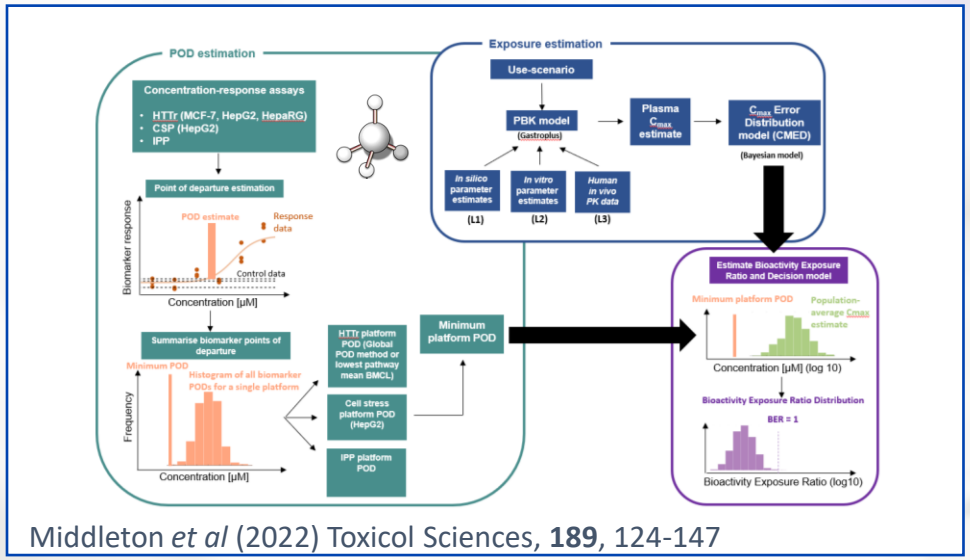


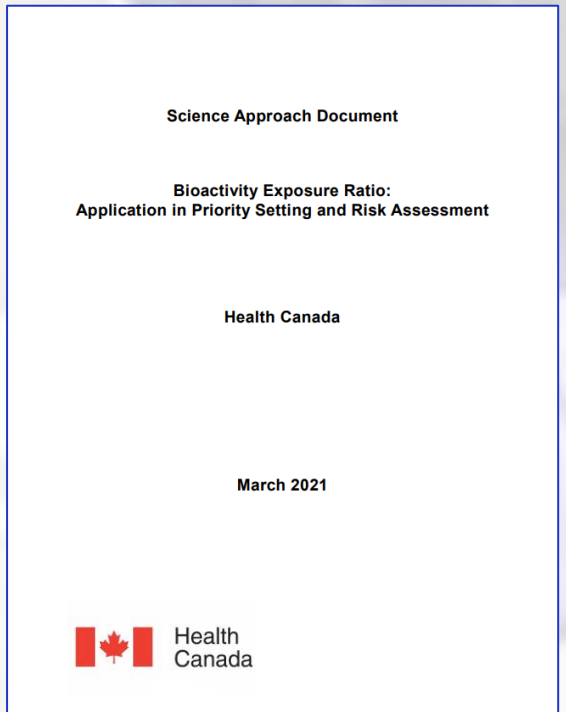
Middleton *et al* (2022) Toxicol Sciences, **189**, 124-147

Use of human biology to protect people

- A large toolbox of NAMs developed over many years
- There isn't a lack of tools, just experience with using them to make decisions

Do NAMs predict what might happen in high dose animal studies?

Bioactivity Exposure Ratios (BER) can allow us to protect people



Science Approach Document

Bioactivity Exposure Ratio:
Application in Priority Setting and Risk Assessment

Health Canada

March 2021

Health Canada

APCRA
ACCELERATING THE PACE OF CHEMICAL RISK ASSESSMENT

Archives of Toxicology (2022) 96:2865–2879
https://doi.org/10.1007/s00204-022-03365-4

REVIEW ARTICLE

A framework for establishing scientific confidence in new approach methodologies

Anna J. van der Zalm[1] · João Barroso[2] · Patience Browne[3] · Warren Casey[4] · John Gordon[5] · Tala R. Henry[6] · Nicole C. Kleinstreuer[7] · Anna B. Lowit[6] · Monique Perron[8] · Amy J. Clippinger[1]

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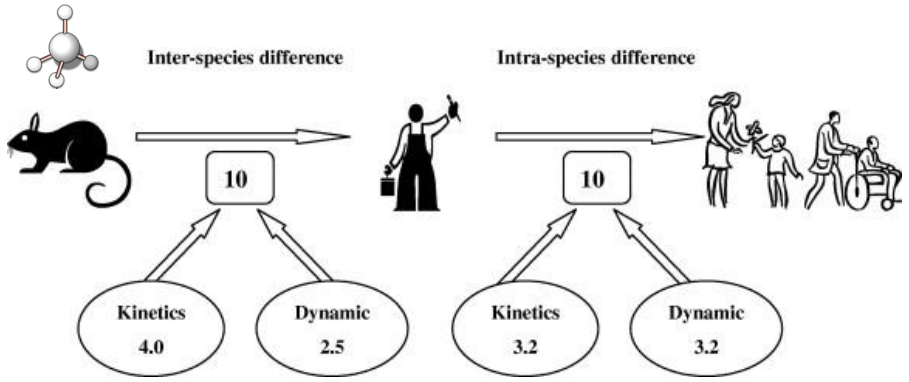
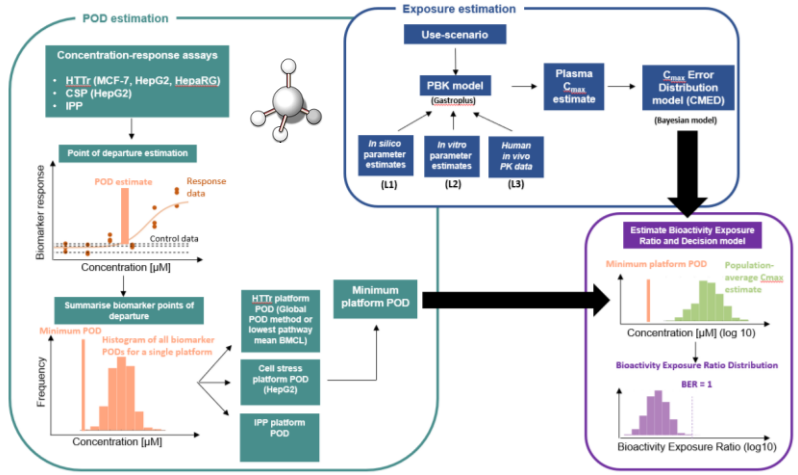


Schroeder *et al* (2011) Toxicol in Vitro, **25**, 589-604



Middleton *et al* (2022) Toxicol Sciences, **189**, 124-147

Animal Technician

Statistician

Pathologist

Veterinarian

Clinical Chemist

Study Director

CRO

Haematologist

QA

Histologist

Cell Biologist

Bayesian Statistician

Molecular biologist

Bioinformatician

PBK Modeller

QA

Immunologist

Study Director

CRO

Computational Chemist

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Protecting People without Animal Testing

The toolbox of NAMs will keep evolving

Ensuring we continue to use the best new science for protecting people as it emerges

We will keep learning together

Building experience, gaining confidence

Building capability and capacity

Continue sharing and publishing

NAMs in regulations

Guidance on NAMs vs. specific lists of tests

Opportunities to embrace NAMs vs. ‘waiving animal tests’

Flexibility and scientific dialogue

Maximising opportunities within Annex XI of REACH

Cosmetics

ICCR International Cooperation on Cosmetics Regulation (2018)

European Commission: Scientific Committee on Consumer Safety (2021)

OECD (2021)

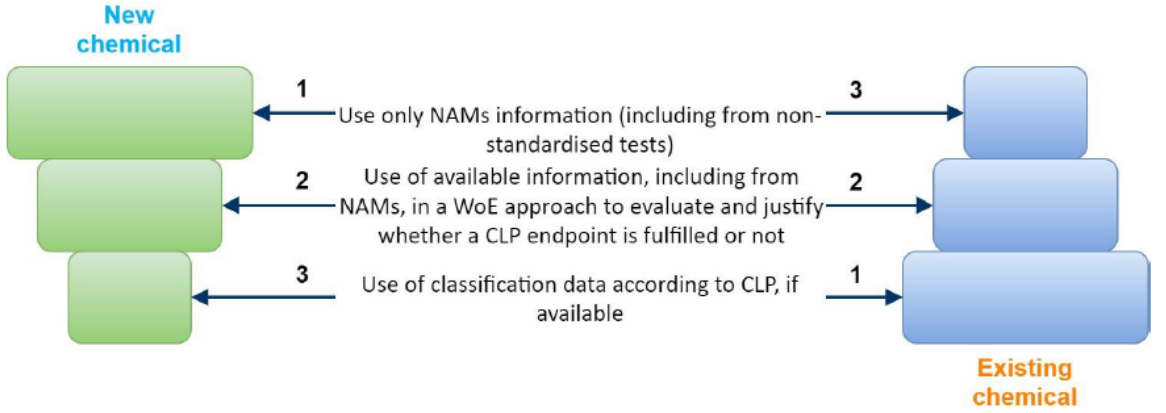
Chemicals

ECETOC (2022)

EPAA (2022)

Protecting People without Animal Testing

Figure 24. Tiered approach regarding the information requirements and use of NAMs data for new or existing chemicals



In general, NAMs provide an opportunity for rapid and reliable toxicological profiling of chemicals and materials, including in the design phase. Further consideration should be given to the use of NAM-derived data within the SSbD framework, including the many cases where NAMs provide mechanistic information which is not directly comparable to endpoints from traditional *in vivo* studies.

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