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Advancing Next Generation Risk Assessment through AI-Augmented Weight-of-Evidence Frameworks

ITTP Summer School

July 8th, 2026

SERS
Safety, Environmental & Regulatory Science




Unilever Policy & Approach
Safe & Sustainable Products without Animal Testing

Unilever

What we believe

- **Every Unilever product must be safe for people and our environment**
- **Animal testing is not needed to assess ingredient & product safety** – there are a wide range of non-animal alternatives grounded in modern science and new technology

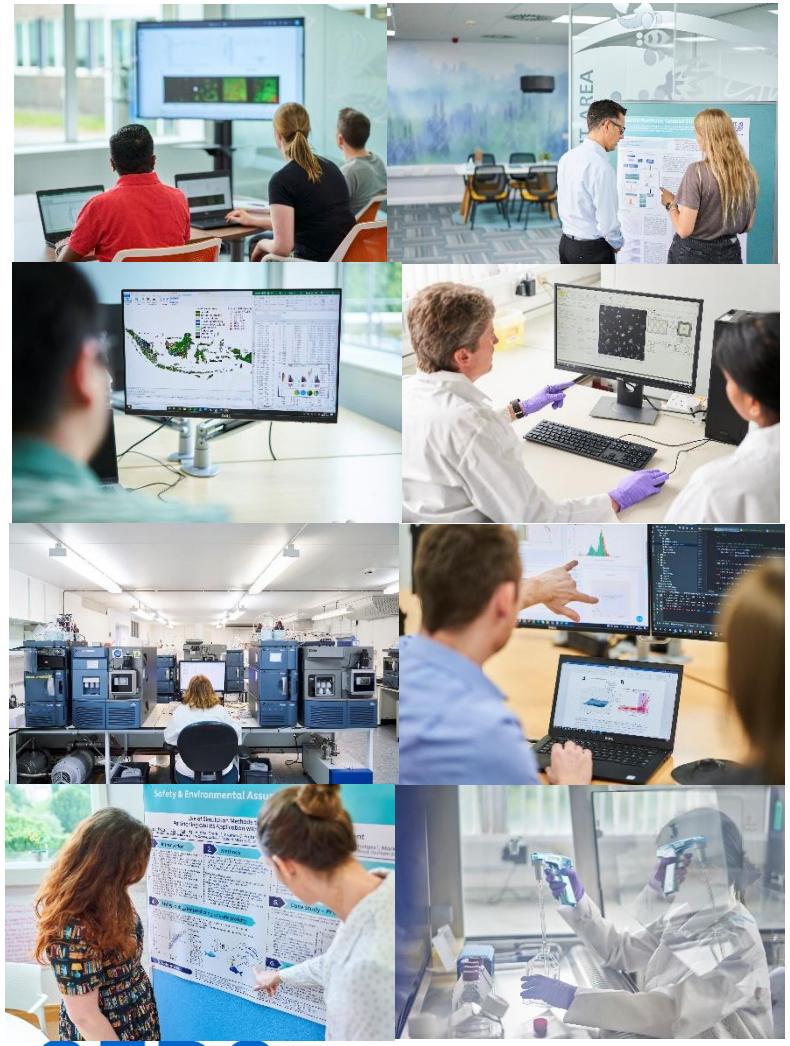
How we do it

40+ years of non-animal safety science

70+ collaborations

600+ publications

SERS Expertise



SERS is a diverse, multi-disciplinary team of ~180 scientists covering:

- Cell & Molecular Biology
- Chemistry
- Computational Modelling
- Environmental Safety
- Environmental Sustainability
- Exposure Science
- Informatics & Data Science
- Mathematics & Statistics
- Microbiology
- Process Safety
- Regulatory Science (chemical & food safety)
- Toxicology

20+ Nationalities
15+ Languages
9 Countries

- Deploy expertise on higher risk business projects
- Collaborate with leading external research teams to develop & apply new scientific capability
- Leverage science & global networks for consumer trust & freedom to operate

Safety Risk Assessments
- Consumers, Workers, Environment

Life Cycle Assessments
- Environmental Impacts

Product Compliance
- Regulatory Data & Dossiers

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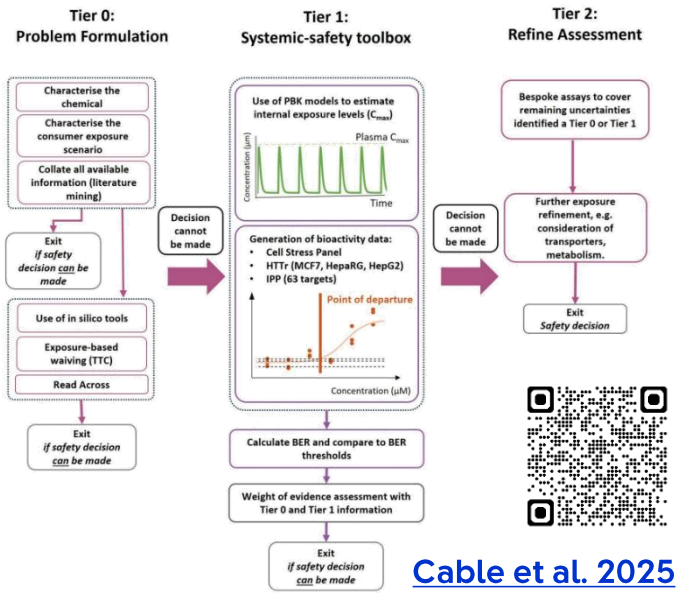
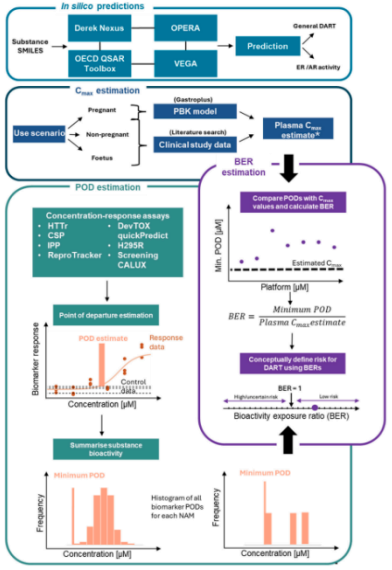
Unilever Next Generation Risk Assessment frameworks

Systemic



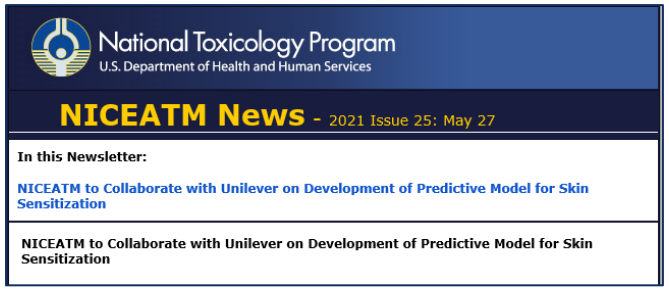
Cable et al. 2025

Developmental & Reproductive

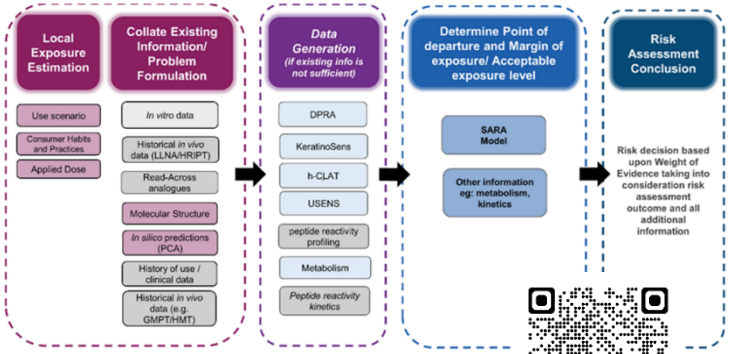


Muller et al. 2025

Ongoing Partnerships

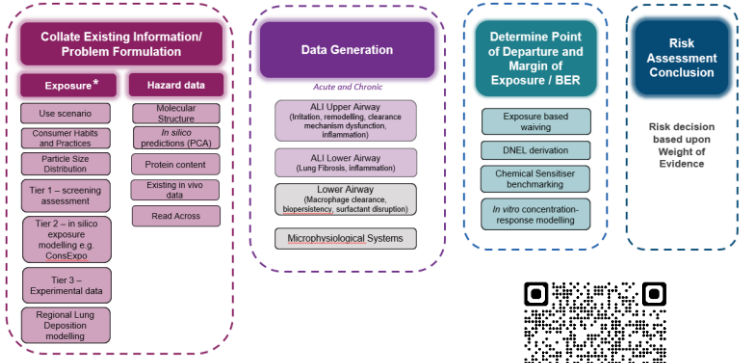


Skin Sensitisation



Reynolds et al. 2021

Inhalation



de Ávila et al. 2025

sers.unilever.com

Safe and Sustainable Products without Animal Testing

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How can we ensure that our products are safe?

Q: Is ingredient X safe to use in product Y at Z%?

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Next Generation Risk Assessment (NGRA) Paradigm Shift

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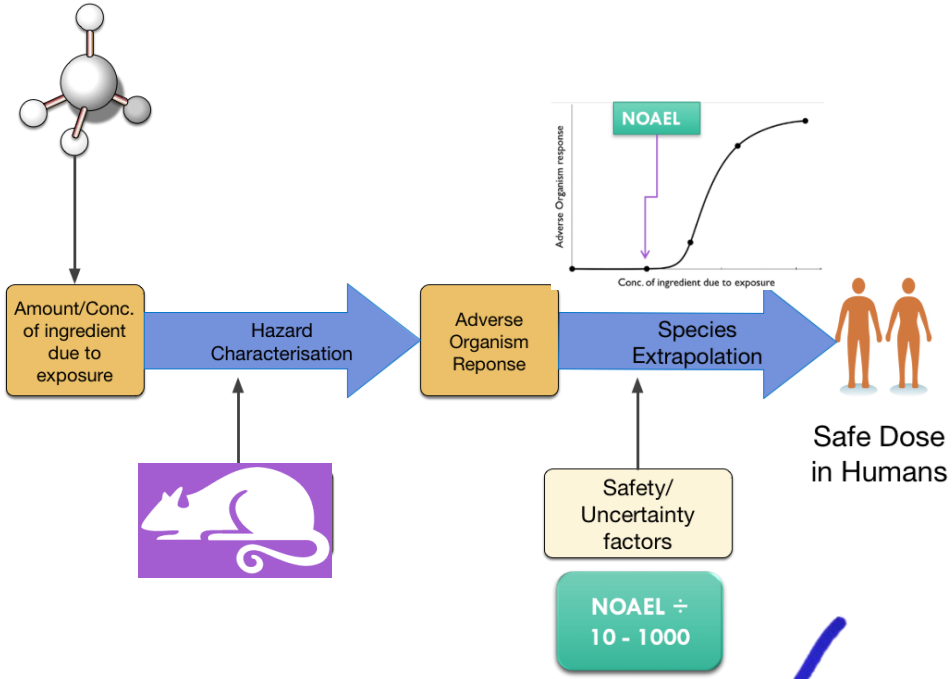
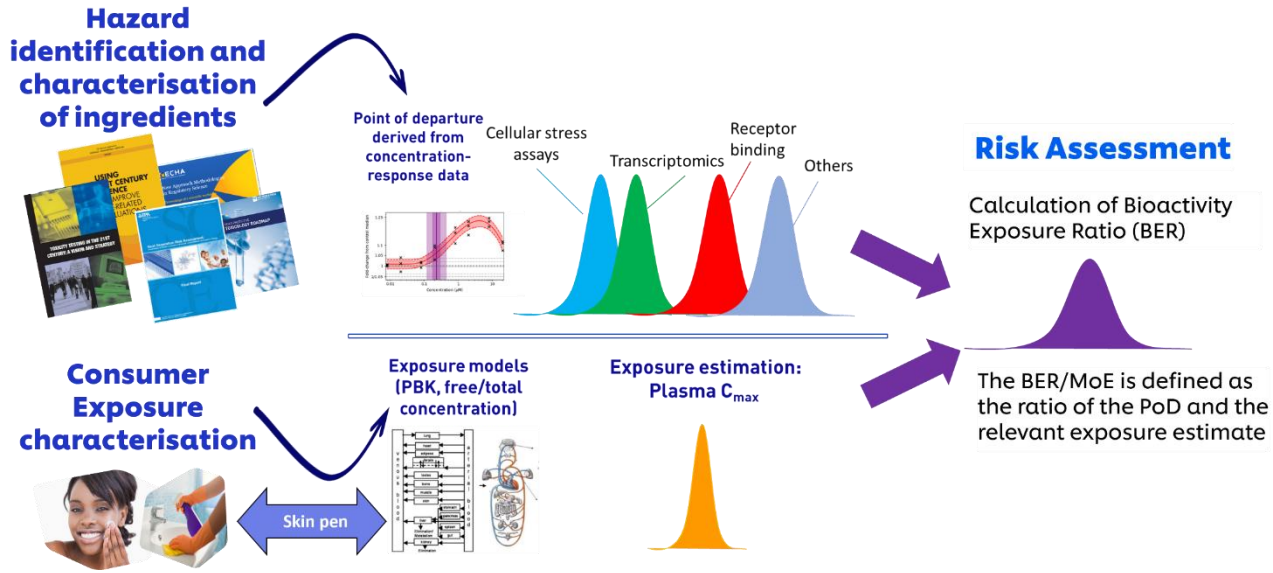
'Traditional' Risk Assessment



'Next Generation' Risk Assessment



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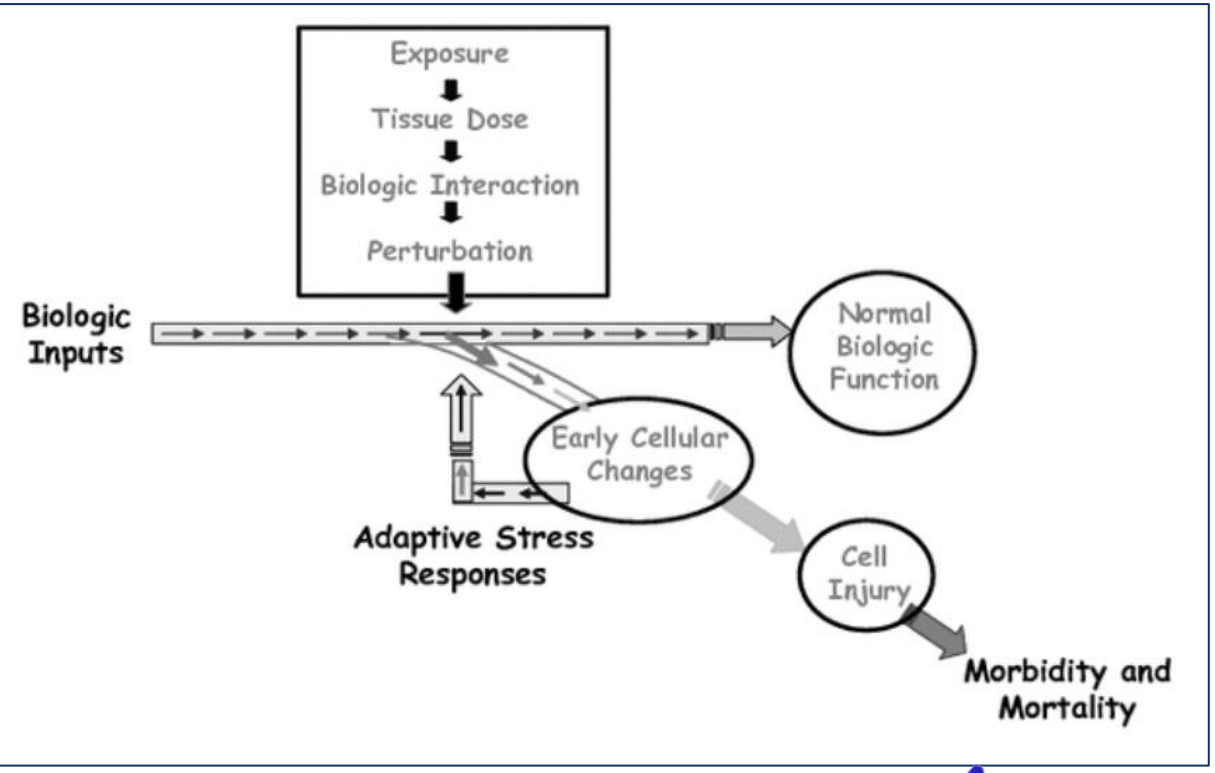
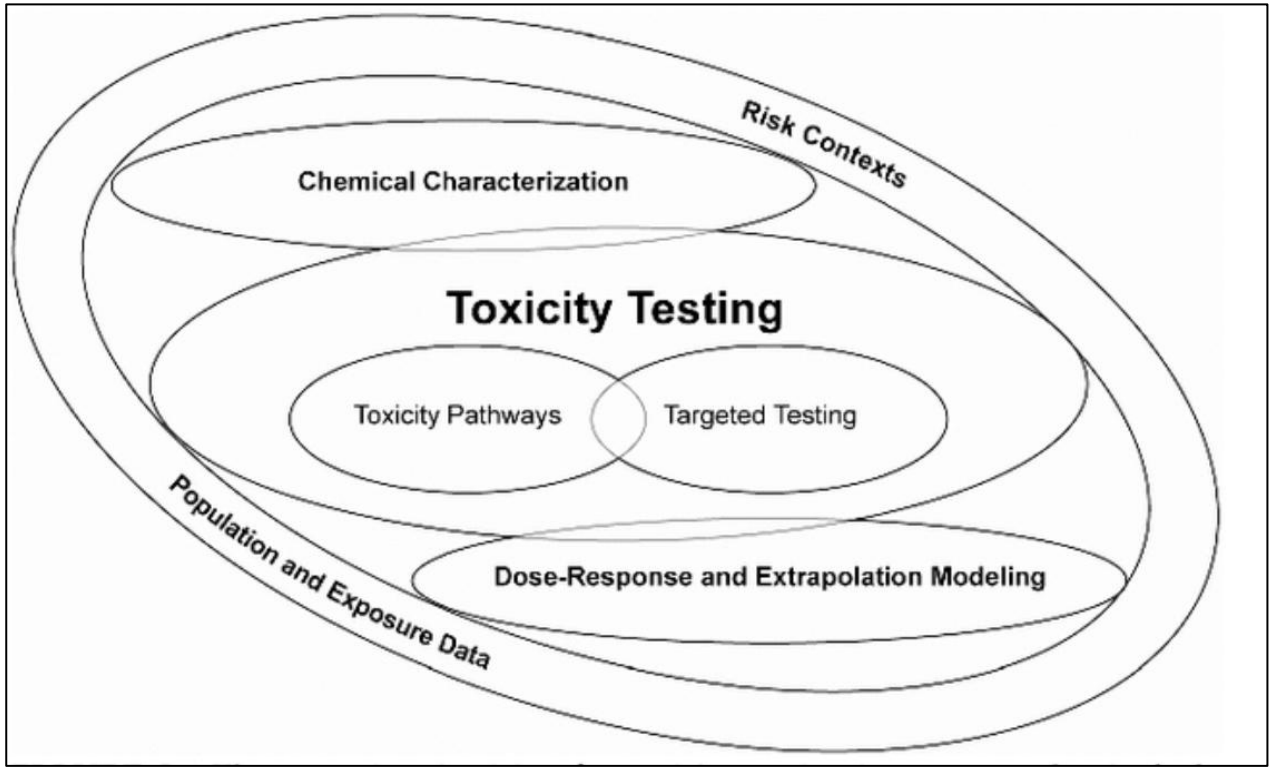
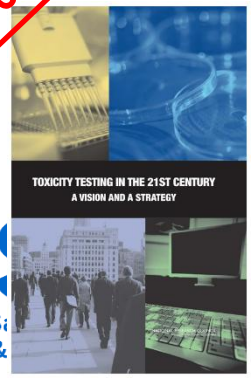
Next Generation Risk Assessment concepts





2007



[Toxicity Testing in the 21st Century: A Vision and a Strategy | The National Academies Press]

The Need for Implementation of Non-animal Safety Assessments

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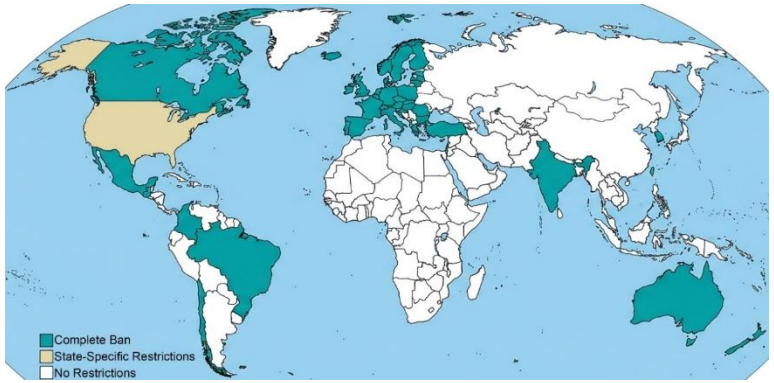
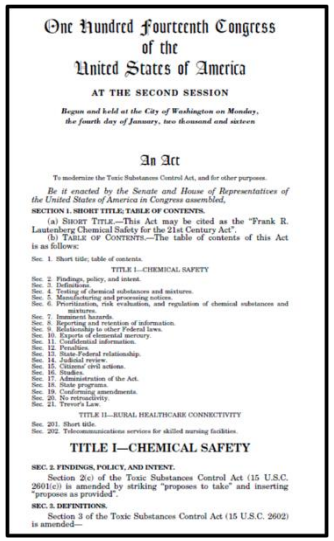


Rusyn et al, 2026 (submitted)



One Hundred Fourteenth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Monday, the fourth day of January, two thousand and sixteen

An Act

To modernize the Toxic Substances Control Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—CHEMICAL SAFETY

Sec. 2. Findings, policy, and intent.
Sec. 3. Definitions.
Sec. 4. Testing of chemical substances and mixtures.
Sec. 5. Manufacturing and processing notices.
Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.
Sec. 7. Imminent hazards.
Sec. 8. Reporting and retention of information.
Sec. 9. Relationship to other Federal laws.
Sec. 10. Exports of elemental mercury.
Sec. 11. Confidential information.
Sec. 12. Penalties.
Sec. 13. State-Federal relationship.
Sec. 14. Judicial review.
Sec. 15. Citizens' civil actions.
Sec. 16. Studies.
Sec. 17. Administration of the Act.
Sec. 18. State programs.
Sec. 19. Conforming amendments.
Sec. 20. No retroactivity.
Sec. 21. Trevor's Law.

TITLE II—RURAL HEALTHCARE CONNECTIVITY

Sec. 201. Short title.
Sec. 202. Telecommunications services for skilled nursing facilities.

TITLE I—CHEMICAL SAFETY

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended by striking "proposes to take" and inserting "proposes as provided".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

PETA APPROVED
Global Animal Test Policy

Next Generation Risk Assessment (NGRA)

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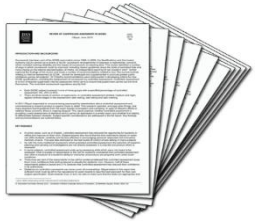
Existing Data

ECOTOX Knowledgebase

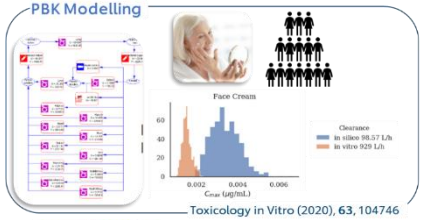
A-O-P-Wiki

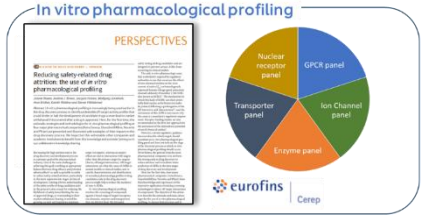
Knowledge Bases

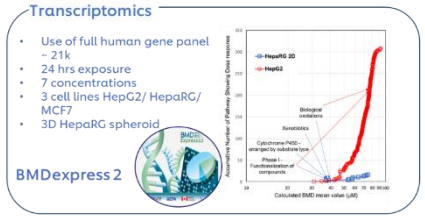


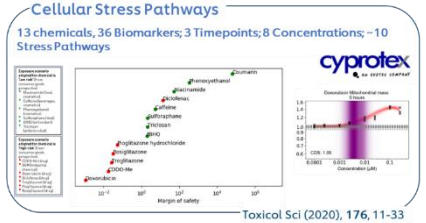
Scientific literature

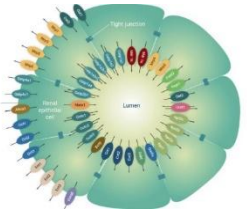
New (NAM) in vitro data



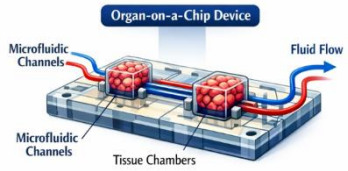








[Credit: Newcells aProximate™ platform](#)



GEO Gene Expression Omnibus

CompTox Chemicals Dashboard
Search 1,200,063 Chemicals

ChEMBL

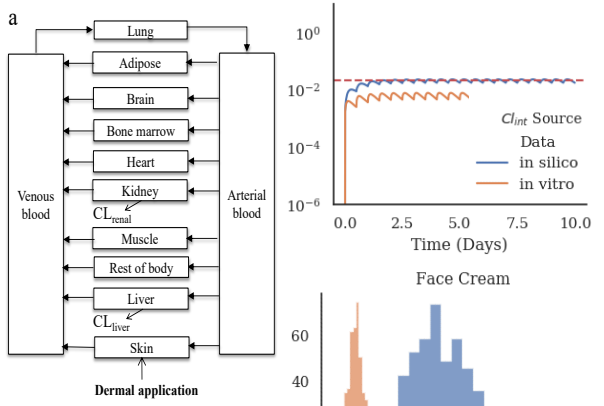
External Data

FDA U.S. FOOD & DRUG ADMINISTRATION

Regulatory Guidance

Safety Decision

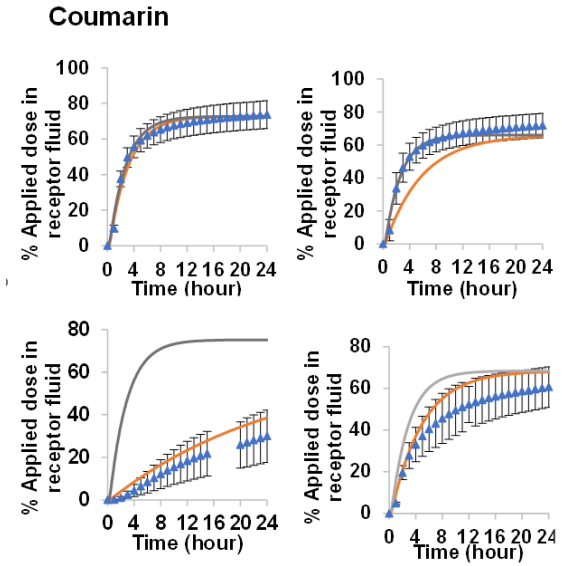
Exposure modelling



Computational Modelling in NGRA

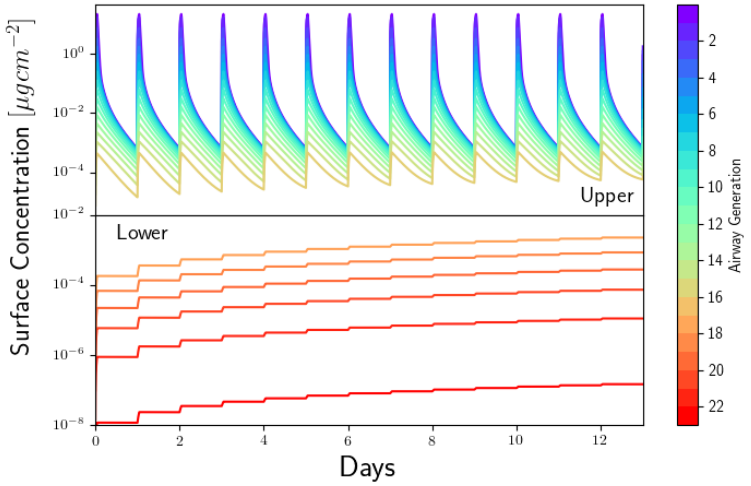
Exposure modelling

Dermal



- Diffusion through skin
- Partitioning from complex mixtures into stratum corneum

Respiratory

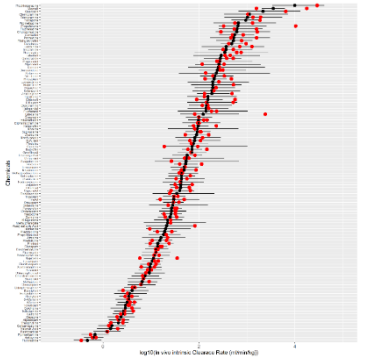


- Particle deposition modelling
- Clearance mechanism modelling; mucous transport, trans-epithelial diffusion

Estimation of key model parameters

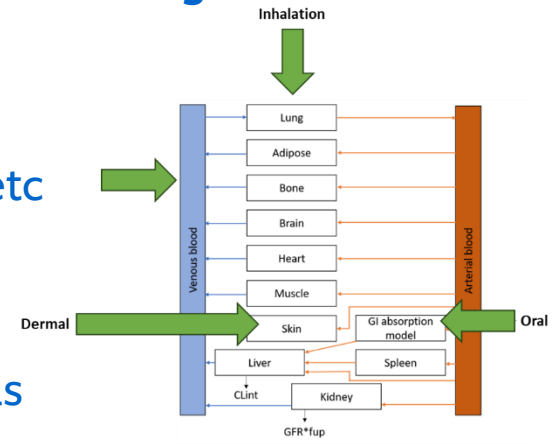
Dawei Tang

- Estimation of e.g., intrinsic clearance.
- Hierarchical Bayesian statistical model



Systemic exposure modelling

- Applicable to humans, fish etc
- ODE-based models
- Bespoke vs generic models



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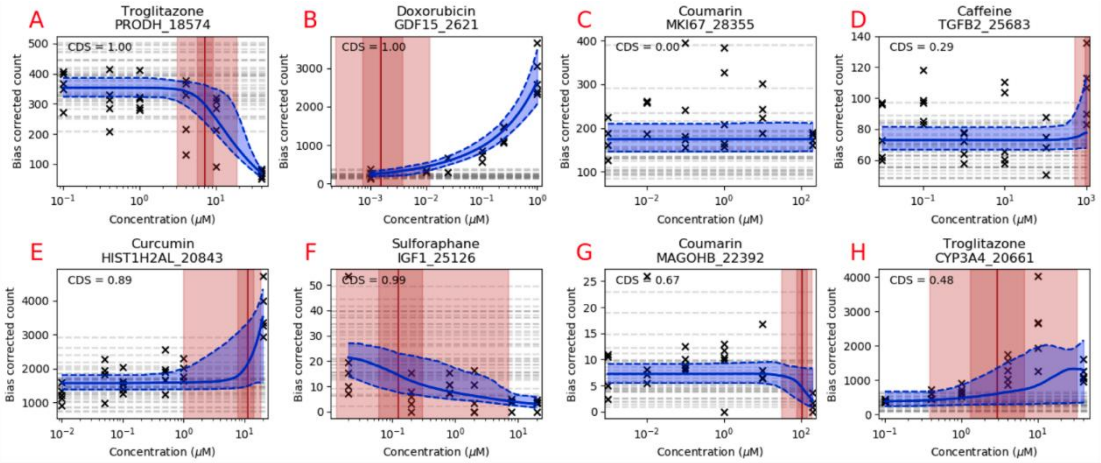
Pendlington et al. 2024, De Avila et al. 2024, Barrett et al. 2022

Computational Modelling in NGRA

Hazard modelling



- Modelling of concentration response data
- Estimation of point of departure (PODs)
- Various approaches being used:
  - Maximum likelihood/parametric models
  - Bayesian non-parametric models

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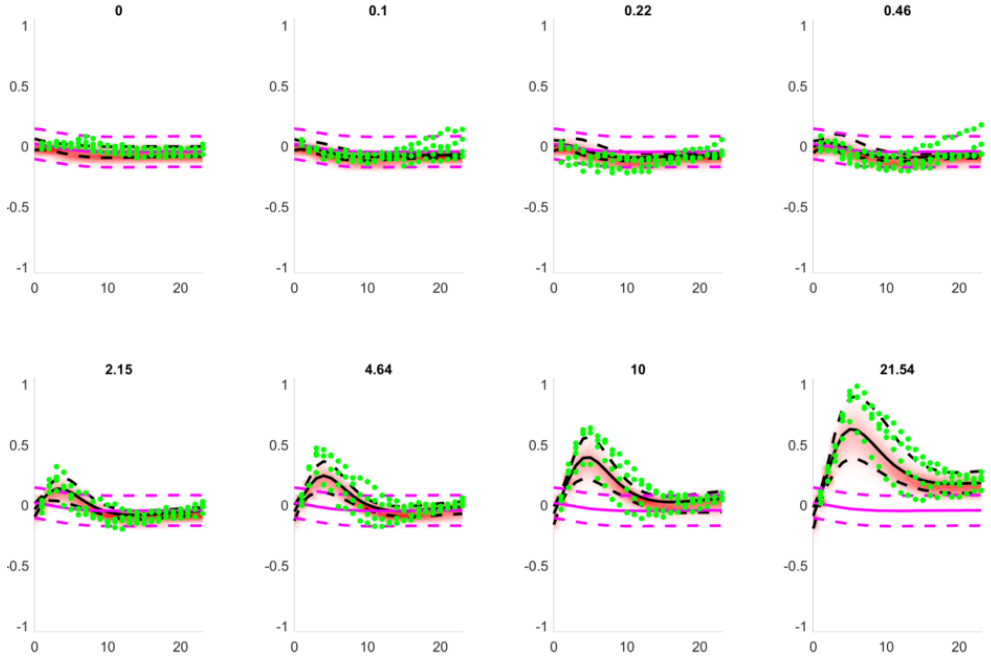
Reynolds et al. Comp. Tox 2019

NRF2 response

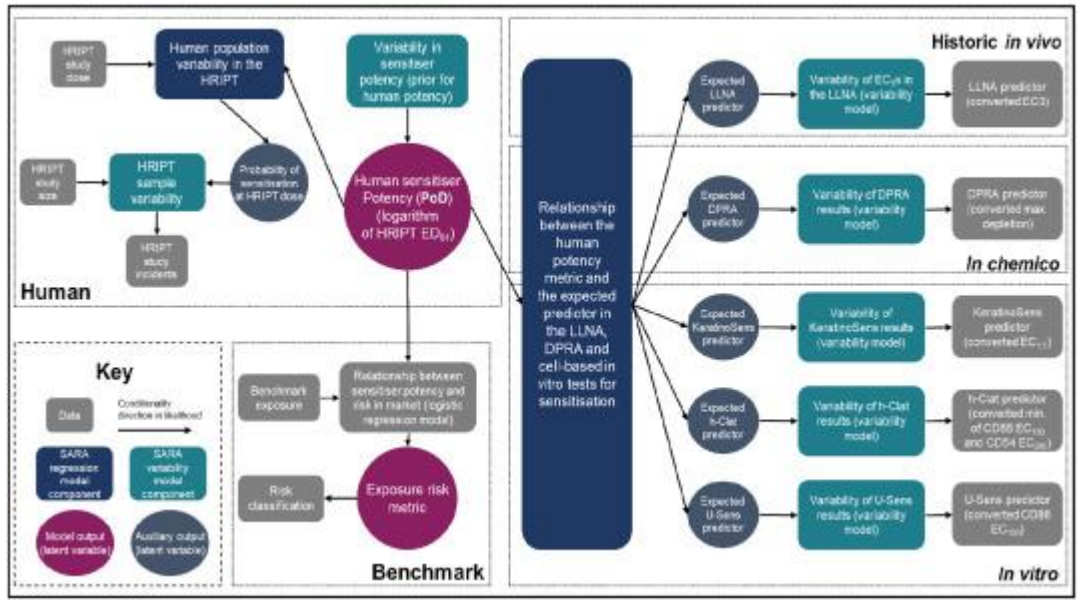


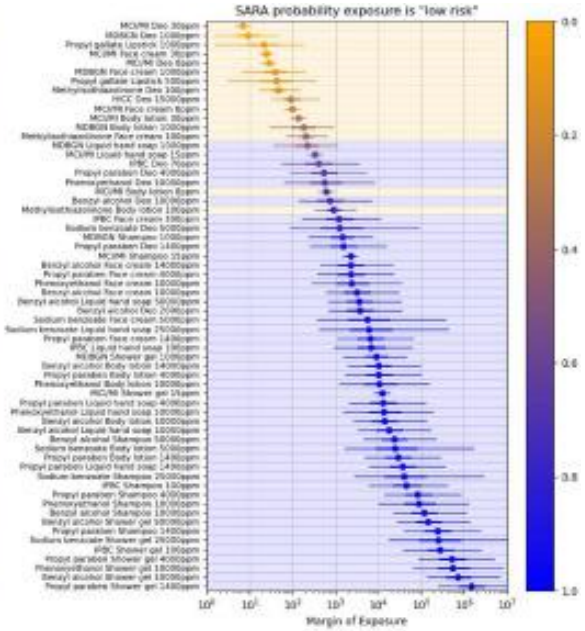
- Time series analysis of biological response
- Using mechanistic ODE models
- Gaussian process state space models

Middleton et al. (in prep)

Computational Modelling in NGRA

Quantifying risk





- Example: Skin Allergy Risk Assessment (SARA) model
- Hierarchical Bayesian statistical model
- Uses training data from benchmark exposure scenarios and safety decisions.
- Variant of the model being developed in collaboration with US federal agency (NICEATM)

National Toxicology Program
U.S. Department of Health and Human Services

Integrated Chemical Environment

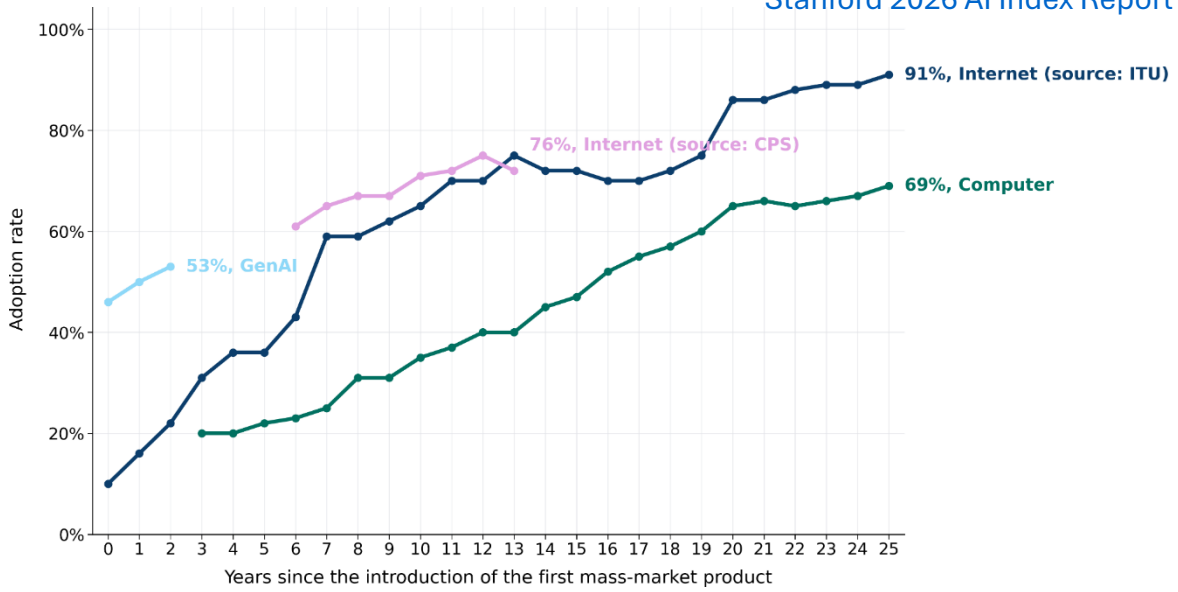
Reynolds et al. Regulatory Toxicology and Pharmacology 2022

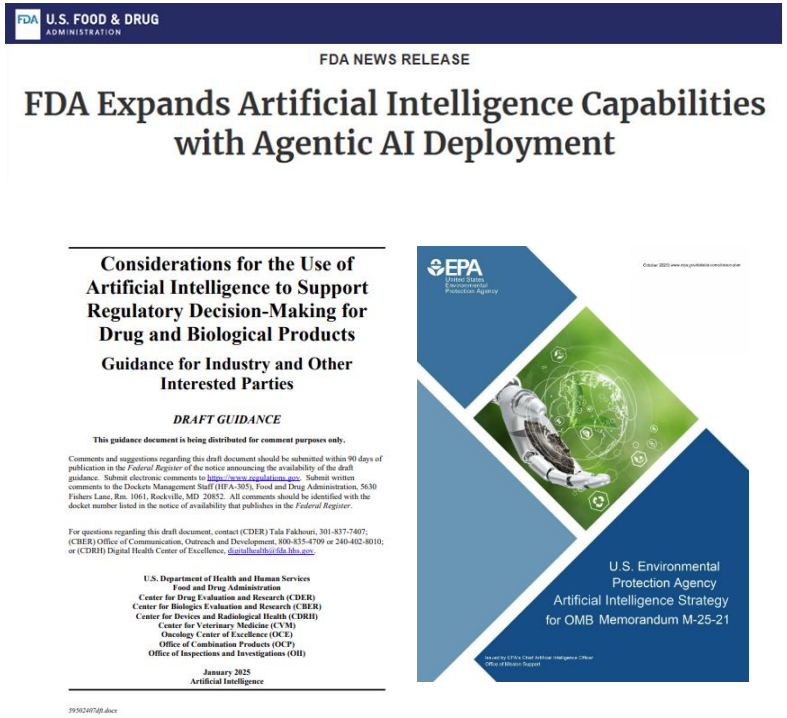
AI in Safety Critical Systems

Unilever

Speed of AI adoption by technology

Stanford 2026 AI Index Report





U.S. FOOD & DRUG ADMINISTRATION

FDA NEWS RELEASE

FDA Expands Artificial Intelligence Capabilities with Agentic AI Deployment

Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry and Other Interested Parties

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Tala Fakhouri, 301-837-7407; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Digital Health Center of Excellence, digitalhealth@fda.hhs.gov.

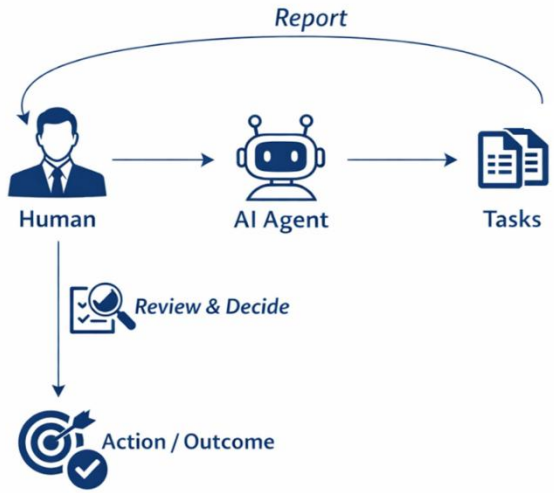
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Veterinary Medicine (CVM)
Oncology Center of Excellence (OCE)
Office of Combination Products (OCP)
Office of Inspections and Investigations (OII)

January 2025
Artificial Intelligence

59502405dft.docx

EPA United States Environmental Protection Agency

U.S. Environmental Protection Agency
Artificial Intelligence Strategy
for OMB Memorandum M-25-21



Moving towards AI-augmented safety frameworks

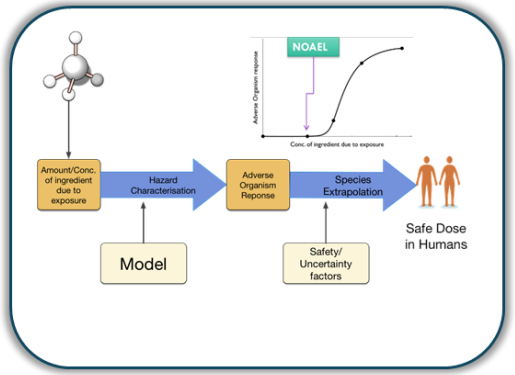
Traditional Toxicology = Empirical science focused on observations from animal studies

Increased focus on the use of exposure science and understanding of human biology (NAMs, PBK, DAs, IATAs, protection of human health, AOPs…)

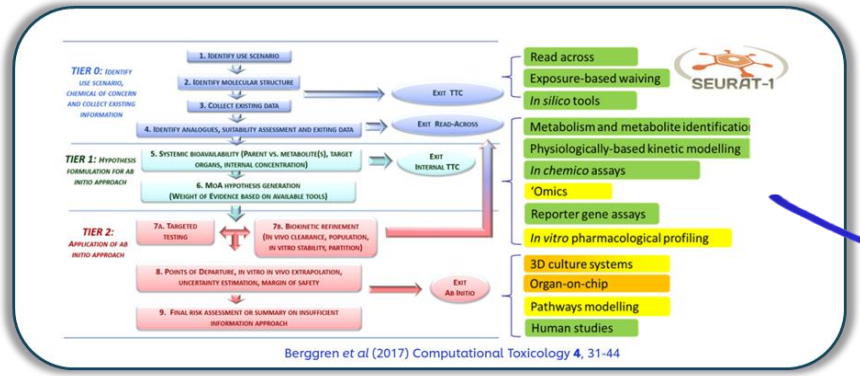
Augmentation of Next Generation Risk Assessment using AI-based technologies and approaches

Time

'Traditional' Risk Assessment

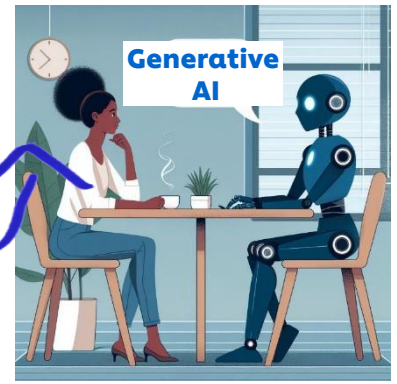


Next Generation Risk Assessment (NGRA)



Berggren *et al* (2017) Computational Toxicology **4**, 31-44

AI-augmented NGRA



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Current Non-Animal Protective Frameworks for Safety Decisions

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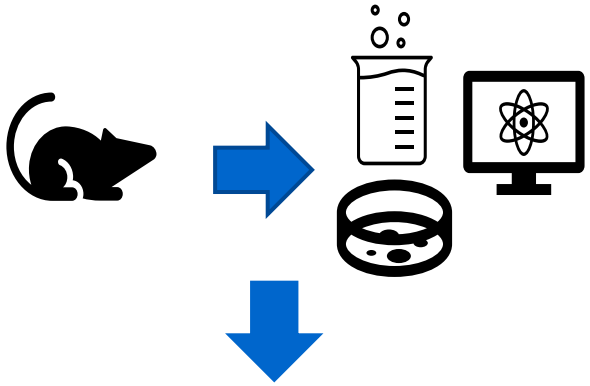
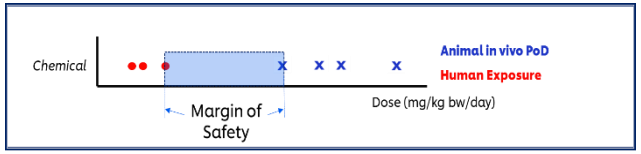
Non-animal NAMs strategies for 1-2-1 replacement – prediction of animal outcome

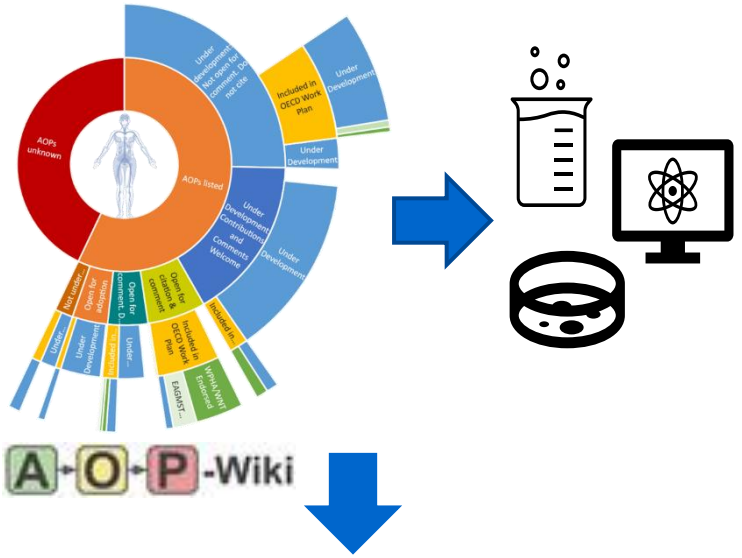


Prediction of an animal test is not necessarily relevant to assess human safety

Rodent studies have been used in a protective manner with the use of uncertainty factors rather than in a predictive way



Development of battery of assays aligned to AOPs



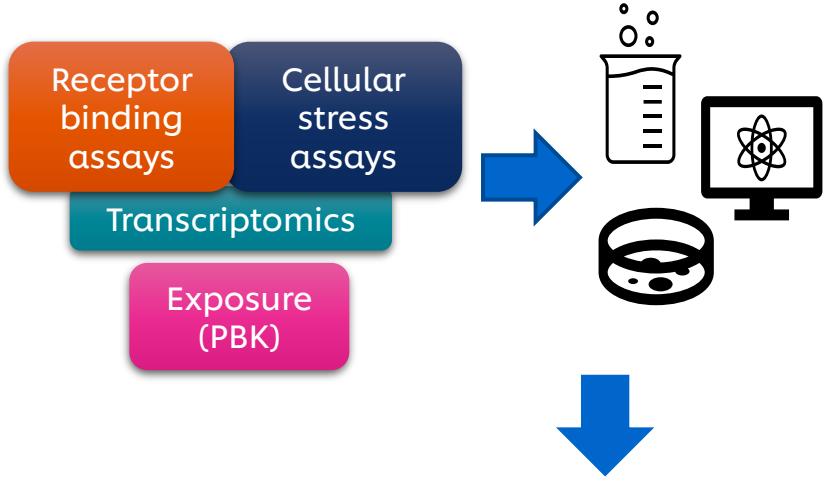
~ Multiple 1000s of assays need to be if multiple AOPs are covered

How to identify the relevant AOP?

Not feasible as a Tier 1 approach

Useful for Tier 2/bespoke safety assessment when differentiation between bioactivity & adversity is needed

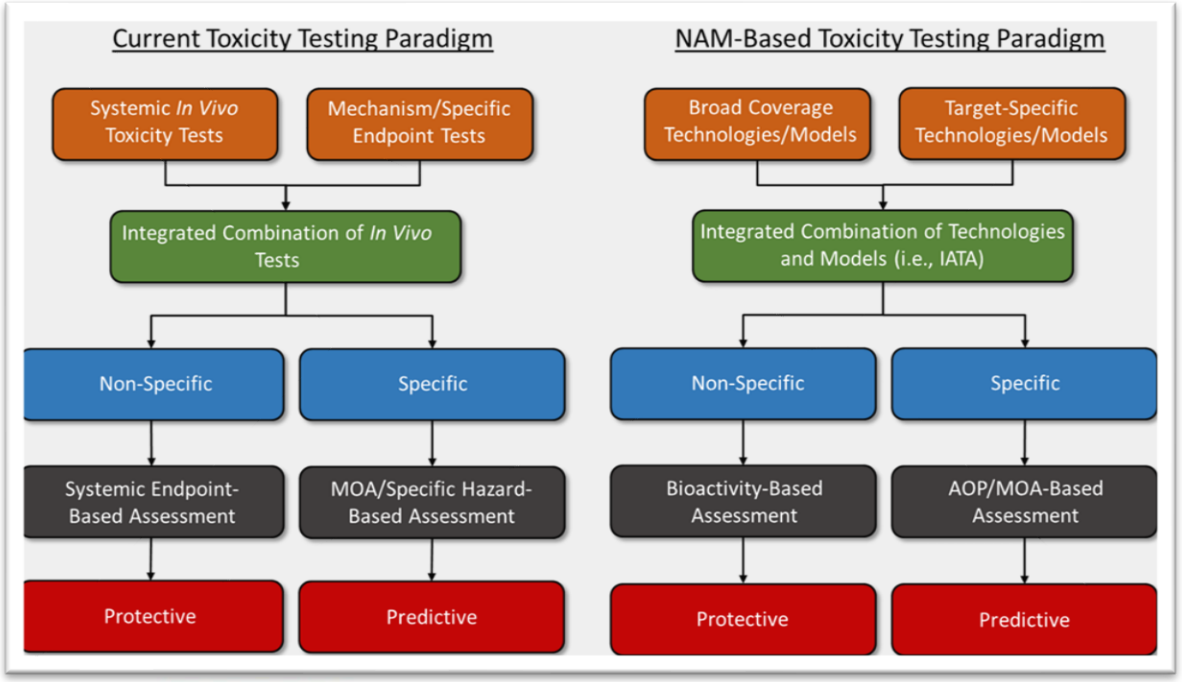
Development of high-throughput & broad coverage set of non-animal NAMs



Protection Hypothesis:

If biological activity measured using a broad suite of human-relevant test systems is above the predicted exposure in humans, then systemic adverse effects are highly unlikely

Next Generation Risk Assessment (NGRA) – Protection not Prediction




Regulatory Toxicology and Pharmacology 148 (2024) 105579

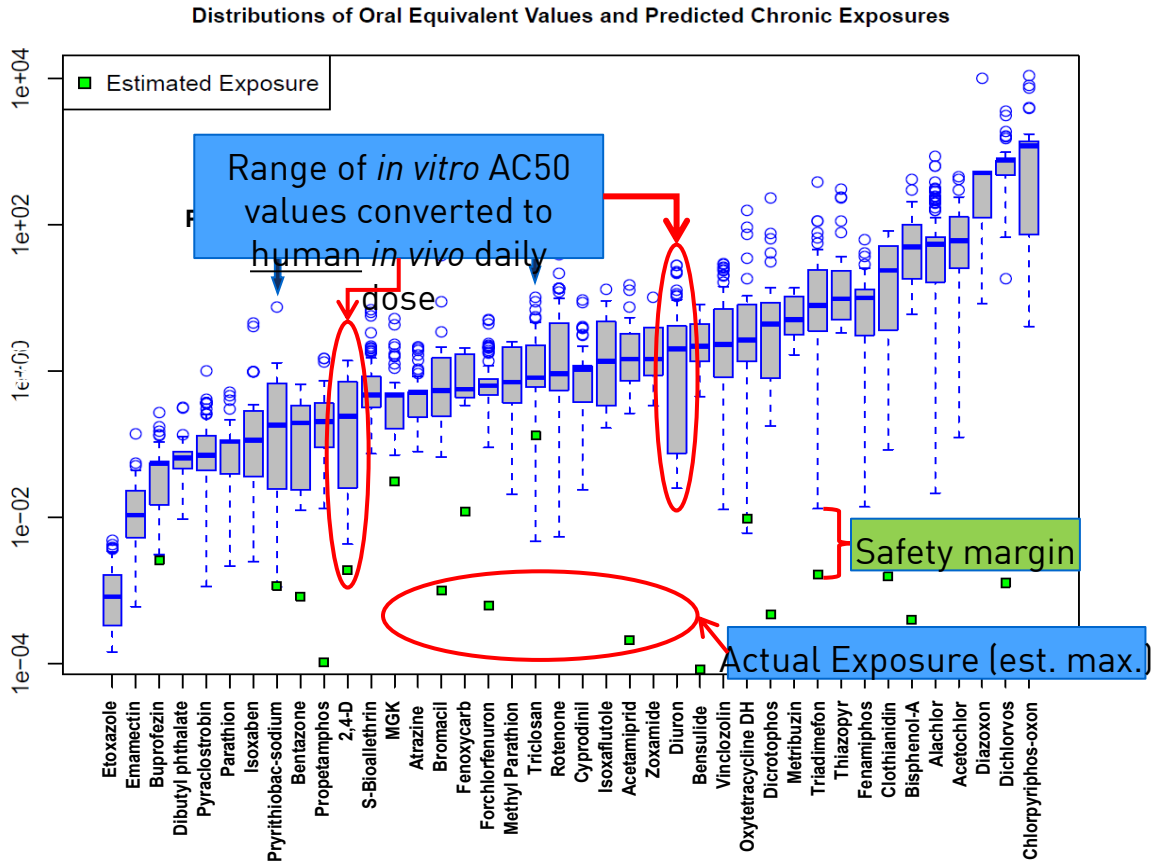
Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

Adverse effects in traditional and alternative toxicity tests

Patience Browne[a,*], Katie Paul Friedman[b], Kim Boekelheide[c], Russell S. Thomas[b]



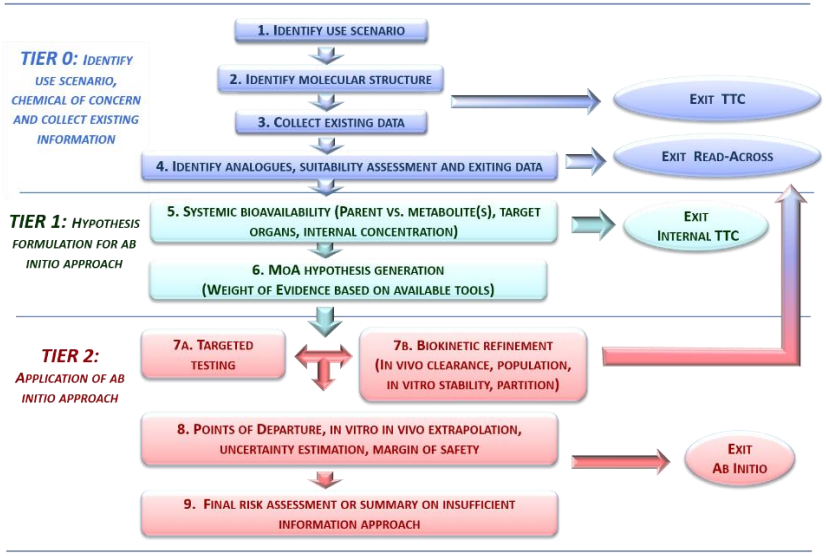
Thomas RS et al., 2019. Tox Sci. 1;169(2):317-332.

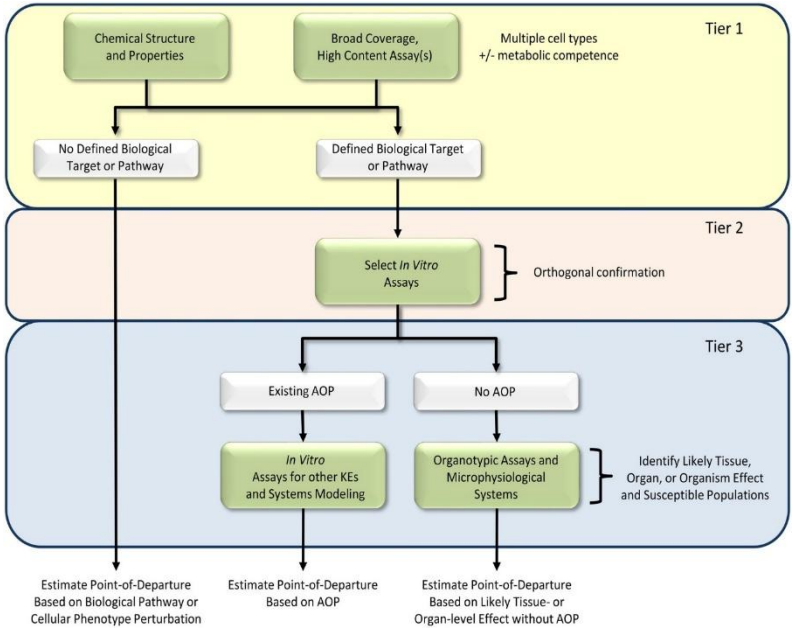
Decision focuses on **Protection of human health**

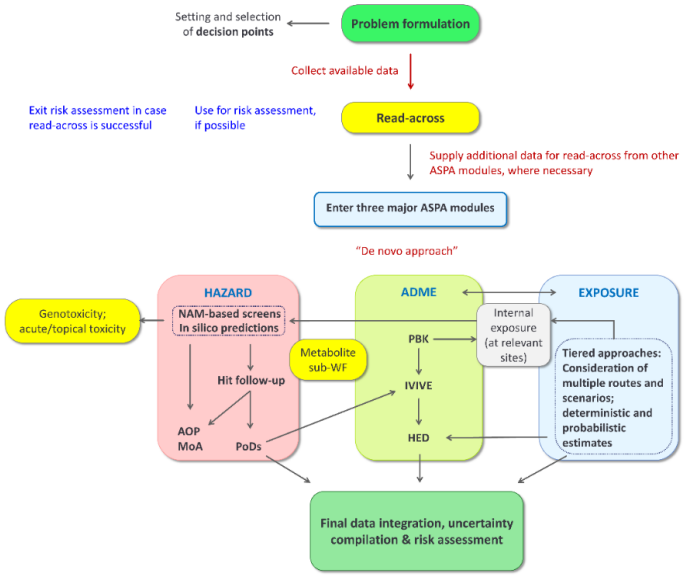
The hypothesis underpinning this type of NGRA is that **if there is no bioactivity observed at consumer-relevant concentrations, there can be no adverse health effects.**

Decision frameworks in NGRA – Tiered approaches

Problem formulation – Tier 0 → **Bioactivity : Exposure Ratio – Tier 1** → **Refine Bioactivity:Exposure– Tier 2**







Seurat-1 Berggren et al., 2017

EPA Blueprint Thomas et al., 2019

ASPA Leist et al 2025

Safety Decision

Decision frameworks in NGRA – Putting theory into practice

Unilever

Existing Data

ECOTOX Knowledgebase

A-O-P-Wiki

Knowledge Bases

Scientific literature

CompTox Chemicals Dashboard Search 1,200,063 Chemicals

ChEMBL

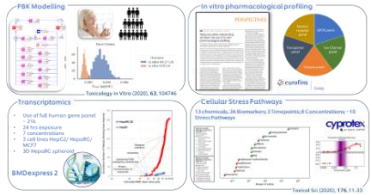
External Data

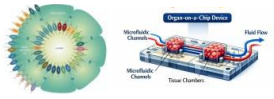
SCCS Opinion

U.S. FOOD & DRUG ADMINISTRATION

Regulatory Guidance

New in vitro data

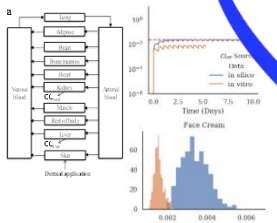




Credit: Newcells aProximate™ platform

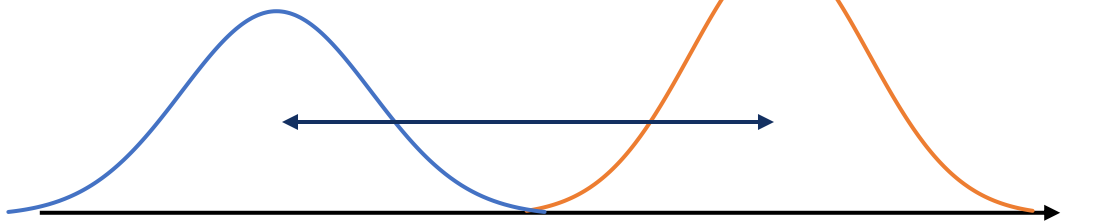
Safety Decision

Exposure modelling



C_{max}

POD



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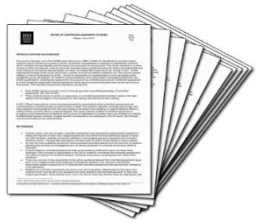
Problem formulation – Tier 0

ECOTOX Knowledgebase

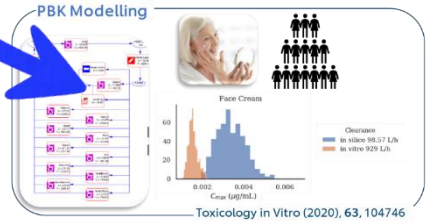
A-O-P-Wiki

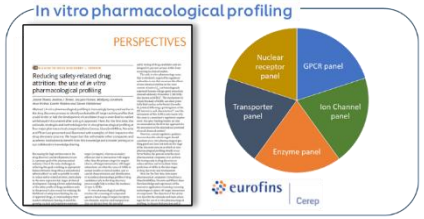


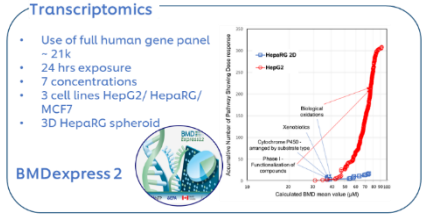
CompTox Chemicals Dashboard Search 1,200,063 Chemicals

ChEMBL

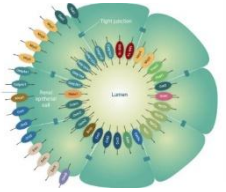
Bioactivity : Exposure Ratio – Tier 1

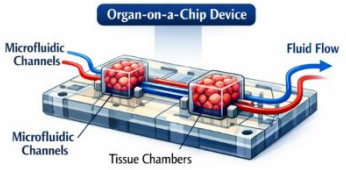






Refine Bioactivity:Exposure– Tier 2





Safety Decision

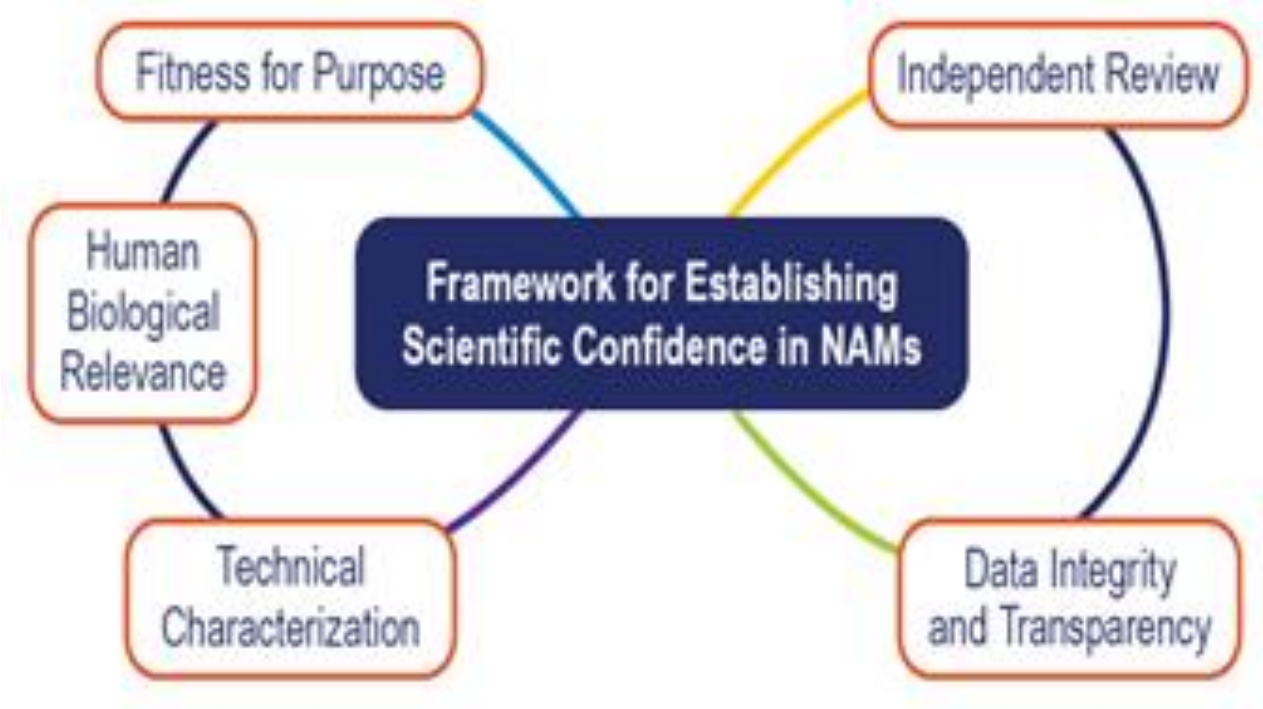
A framework for establishing scientific confidence in new approach methodologies

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]

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

Received: 17 May 2022 / Accepted: 11 August 2022 / Published online: 20 August 2022

REVIEW ARTICLE



Evaluation of an Early Tier Toolbox for Systemic Safety

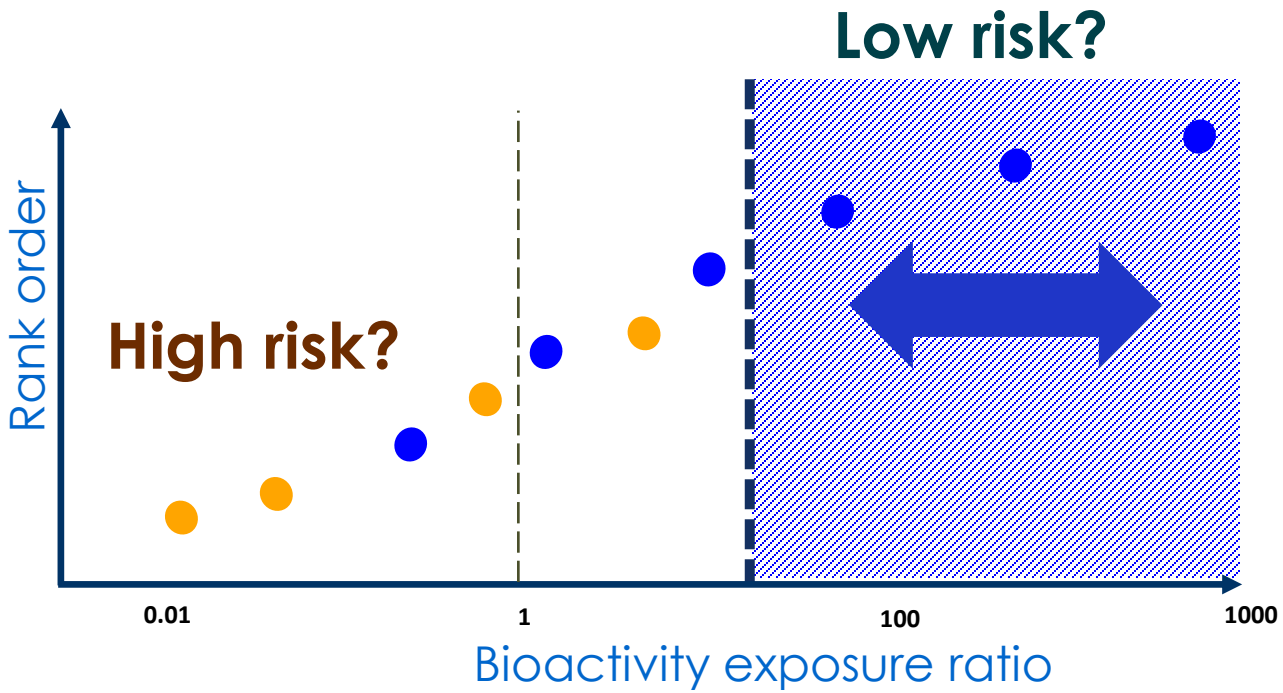
AIM: Use robust/reproducible NAMs to ensure the protection of consumers: can the approach be used to confidently identify low risk chemical exposure scenarios?

1. **Define the toolbox components** Choose and evaluate a set of NAMs covering exposure modelling and bioactivity investigations
2. **Select test chemicals** Choose as many as practicable to maximise coverage of different chemistries and biological effects/toxicity
3. **Set performance criteria** Define the 'truth' that the performance of the toolbox will be compared to

Performance Criteria

Benchmarking using chemical-exposure scenarios

- Chemicals with well-defined human exposures
- Traditional safety assessment available
- High certainty in the risk classification for each chemical-exposure scenario from a consumer goods perspective
- Risk class is relative to consumer health (N.B. drugs = high-risk)



‘Low’ risk for consumers from systemic perspective

‘High’ risk for consumers from systemic perspective

Protectiveness

How many of the high-risk exposure scenarios are identified as uncertain/high risk?
(i.e. BER < threshold)

Utility

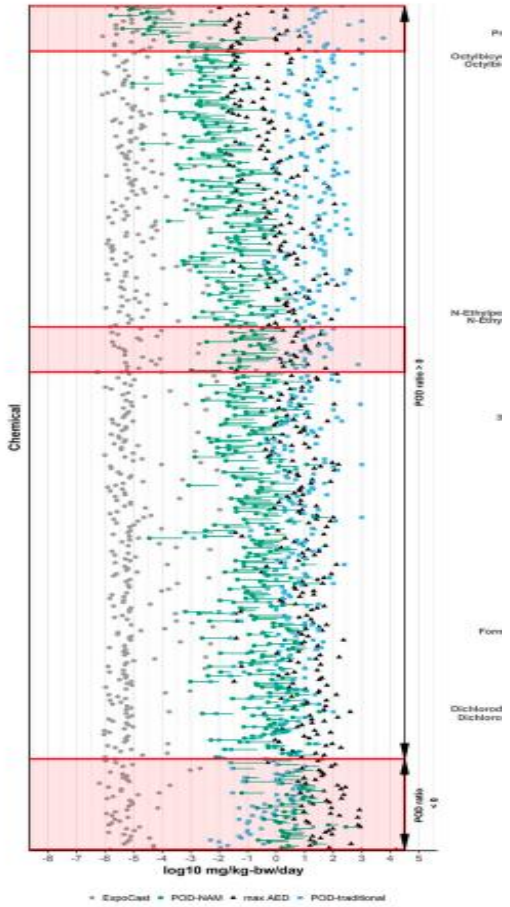
How many of the low-risk scenarios are identified as low-risk at this early tier stage in a risk assessment framework?
(i.e. BER > threshold)

In vitro cell assay (NAM) data are generally protective…

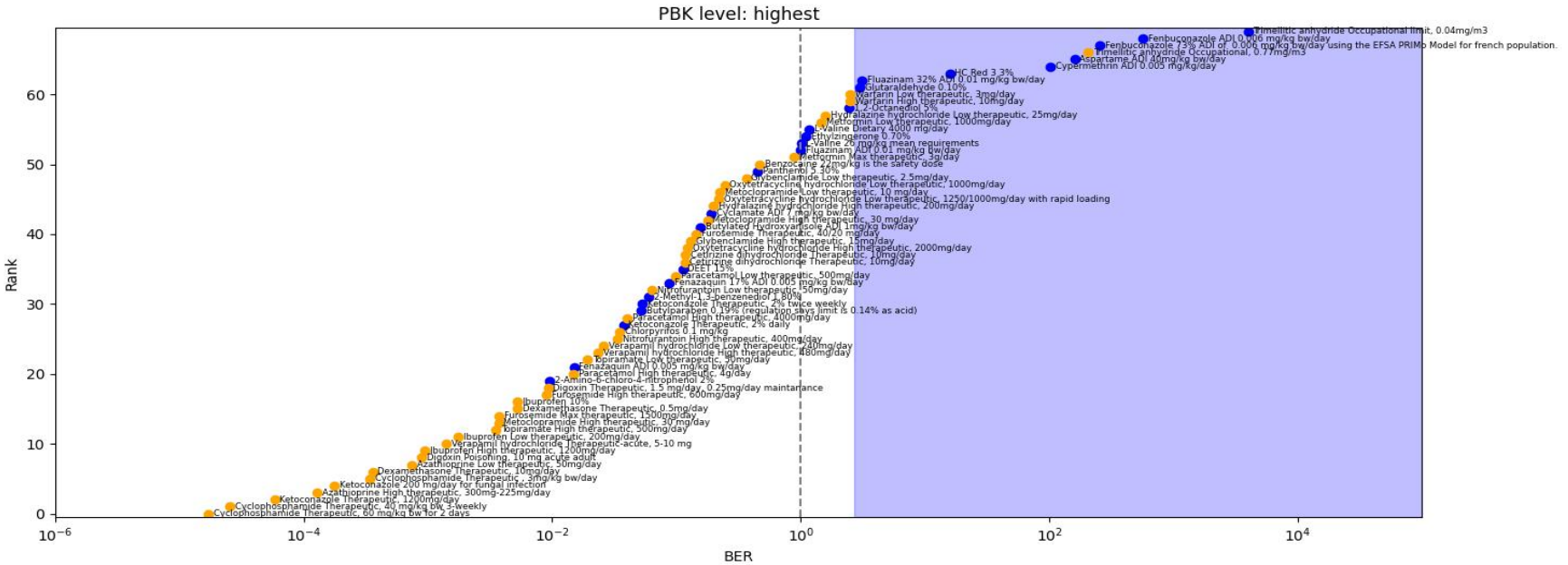
Unilever

Protectiveness **98% (45 out of 46)**

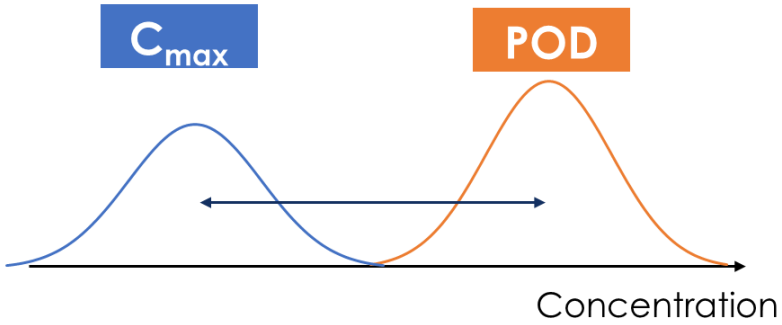
Utility **33% (8 out of 24)**



Paul-Friedmann et al 2020



Middleton et al., 2022; Cable et al., 2025



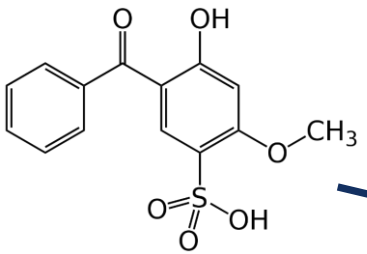
- High protectiveness (>90%, i.e., conservative)
- In many cases, need to go to Tier 2 if ingredients are active or exposures are high

APCRA
ACCELERATING THE PACE OF CHEMICAL RISK ASSESSMENT

Case Study: BP-4 as an ingredient in sunscreens

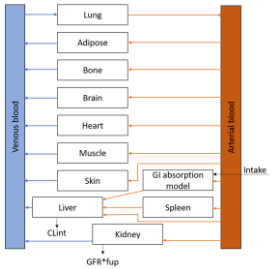
Unilever

Is Benzophenone-4 safe in a sunscreen product at the maximum approved level of 5%?



BP-4

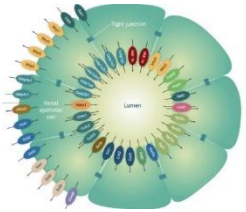
Exposure scenario



PBK modelling

Limited Hepatic Clearance

Renal clearance



Tier 2 cell assays

Newcells aProximate™ platform

In silico tools

Estrogen-Androgen-Thyroid-Steroidogenesis Assays

Targeted assays

Receptor binding assays

Cellular stress assays

Transcriptomics

Broad coverage assays

SERS
Safety, Environmental & Regulatory Science

Conclusion
Low risk considering weight of evidence and model/POD relevance

Research Article
Making Safety Decisions for a Sunscreen Active Ingredient Using Next-Generation Risk Assessment: Benzophenone-4 Case Study

Maria T. Baltazar[1], Sophie Cable[1], Richard Cubberley[1], Nicola J. Hewitt[2], Jade Houghton[1], Predrag Kukic[1], Hequn Li[1,3], Sophie Malcomber[1], Beate Nicol[1], Ruth Pendlington[1], Ans Punt[1], Joe Reynolds[1], Sharon Scott[1], Sandrine Spriggs[1] and Matthew P. Dent[1]

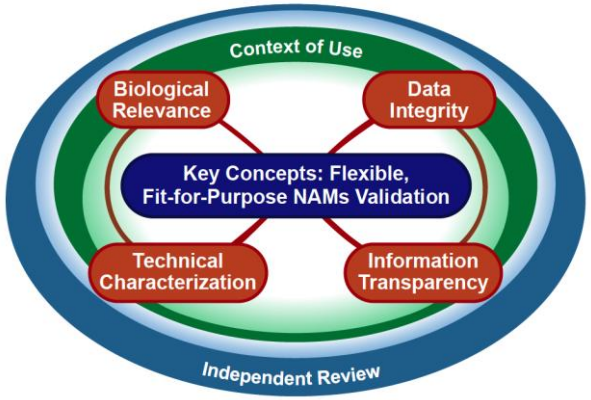
[1]Safety, Environmental and Regulatory Science (SERS), Unilever Colworth Science Park, Shambrook, UK; [2]Cosmetics Europe, Auderghem, Belgium; [3]current affiliation: Certara Predictive Technologies, Certara UK Limited, Sheffield, UK

Baltazar et al., (2025)

Evaluating non-animal toolboxes and workflows

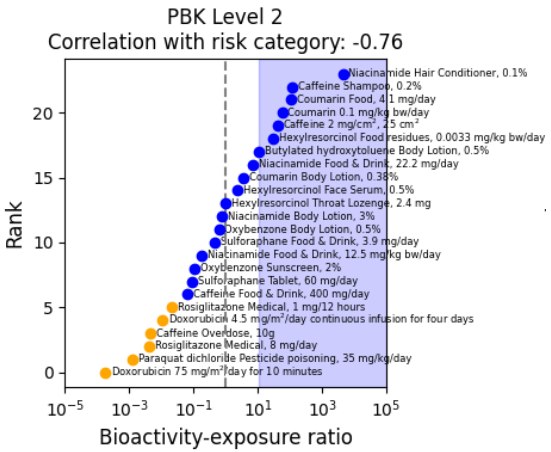
Unilever

Validation Frameworks



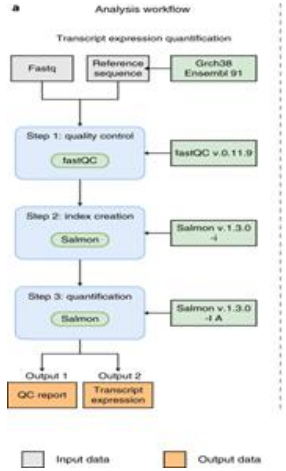
ICCVAM Validation Report, Figure 1
(adapted from van der Zalm et al. 2022 Arch Tox)

Protectiveness & Utility

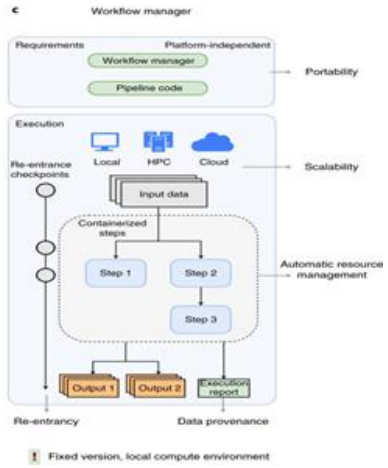


Middleton et al., 2022

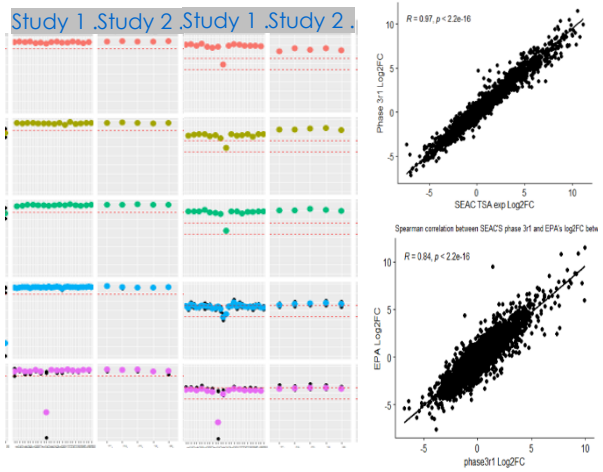
Computational reproducibility/portability



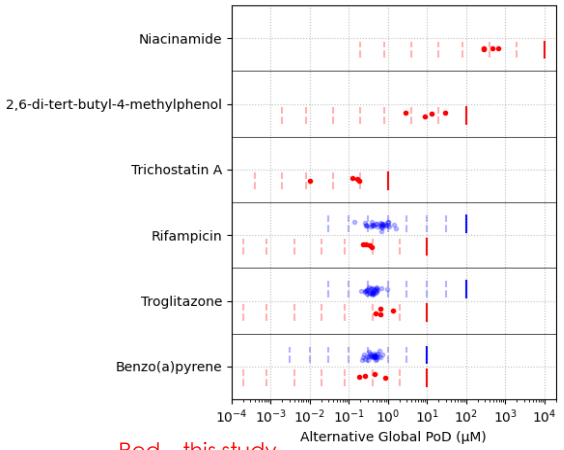
https://www.nature.com/articles/s41587-020-0439-x



Assess Quality

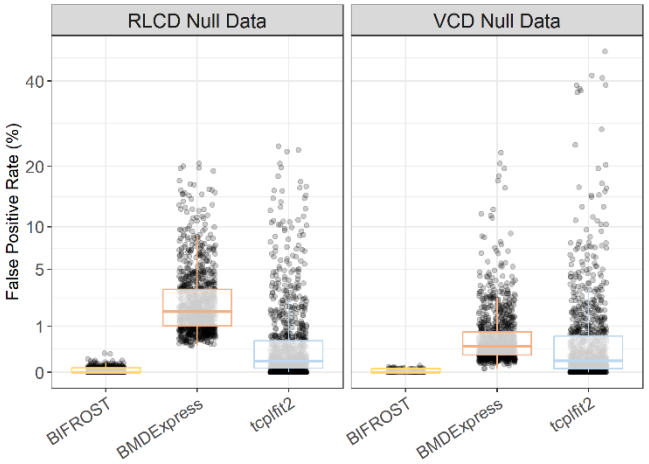


Assess reproducibility



Red – this study
Blue – EPA HepaRG screen
(Rogers et al. EHP 2025 - GSE284321)

Assess Specificity



Factors limiting broad uptake of NGRA approaches

Unilever

Problem formulation– Tier 0

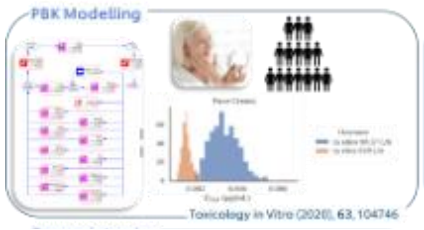
ECOTOX Knowledgebase

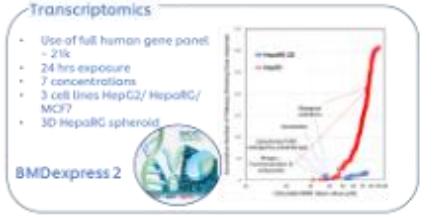
A-O-P-Wiki

CompTox Chemicals Dashboard
Search 1,200,063 Chemicals

ChEMBL

Bioactivity : Exposure Ratio– Tier 1





Refine Bioactivity:Exposure– Tier 2

Safety Decision

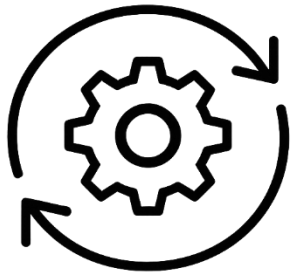
- Requires **multidisciplinary** teams, covering:
  - Risk assessment & business partnering
  - Toxicology
  - Chemistry
  - Statistical modelling
  - Bioinformatics
  - Data Engineer
  - PBK modellers
- Current toolboxes are **protective of human health**, but assessments can be **overly conservative**.
- **Mechanistic interpretation** of data and distinguishing between bioactivity and adversity is an **on-going challenge**.
- **Limited integration and interpretation** of different data types and **sources of information**.

Where can AI add value to NGRA?

Unilever

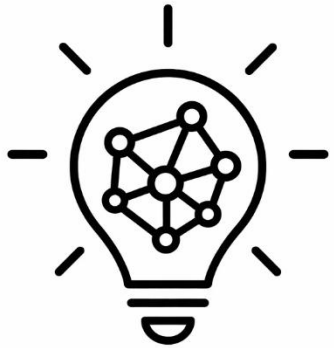
Standardisation and automation

- Automation of **existing processes and workflows**
- Focus: saving time performing routine tasks associated with a risk assessment.
- Example: agentic aids for e.g., REACH submission.



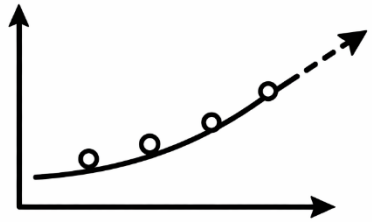
Knowledge and insights

- Extracting **new insights** from multiple data sources
- Focus: supporting risk assessors to **generate structured hypothesis** or **mechanistic interpretations** of the available data.



Predictive modelling

- **Generating predictions** based on available information.
- Focus: Modelling and simulation of **hazard** and **exposure** data.
- Examples: **quantifying risk**, estimating uncertainty, generating **synthetic data** (*filling data gaps*).



Application of AI in Safety Science: Agentic workflows

Unilever

Problem formulation– Tier 0

ECOTOX Knowledgebase

A-O-P-Wiki

CompTox Chemicals Dashboard
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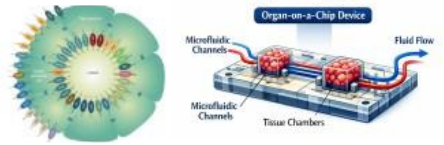
ChEMBL

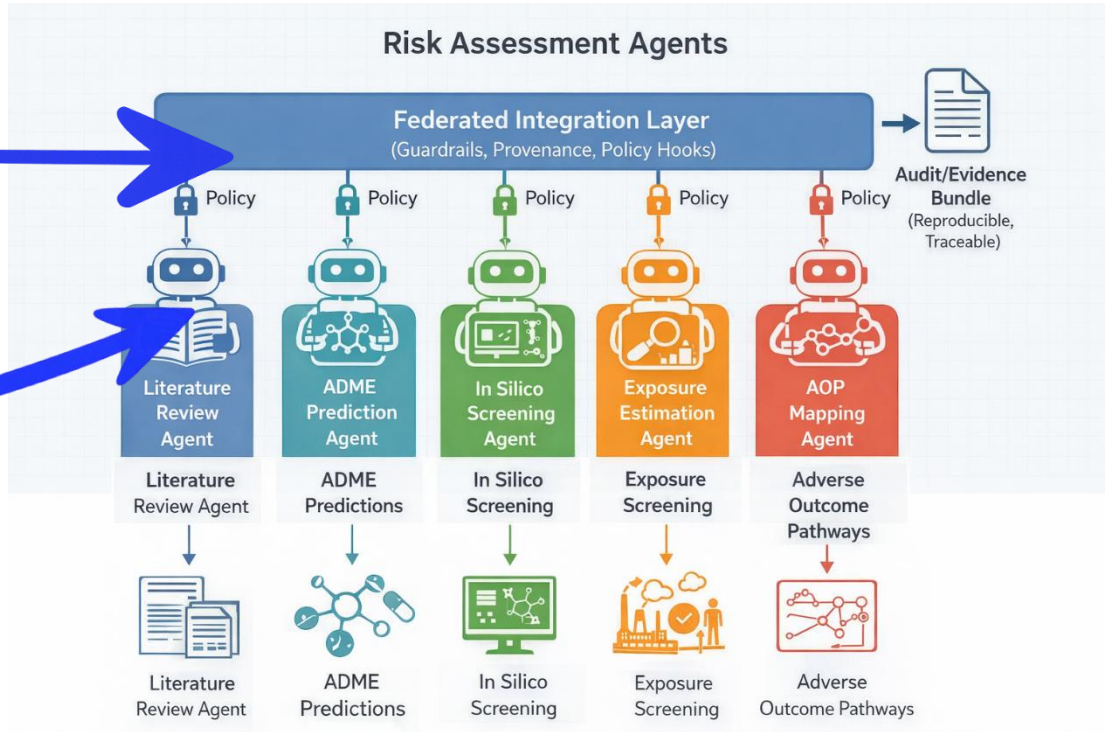
Bioactivity : Exposure Ratio– Tier 1

Refine Bioactivity:Exposure– Tier 2



Safety Decision

Automation of Tier 0 and Tier 1 workflows



Based on Ivo Djidrovski, 2026

- Increased productivity
- Holistic integration across expertise teams
- Consistency and tractability of outcomes & decisions

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Safety, Environmental & Regulatory Science

Keshav Gubbi

Application of AI in Safety Science: Integrating knowledge across data modalities

Unilever

Problem formulation– Tier 0

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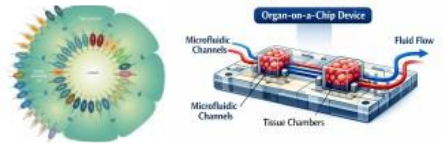
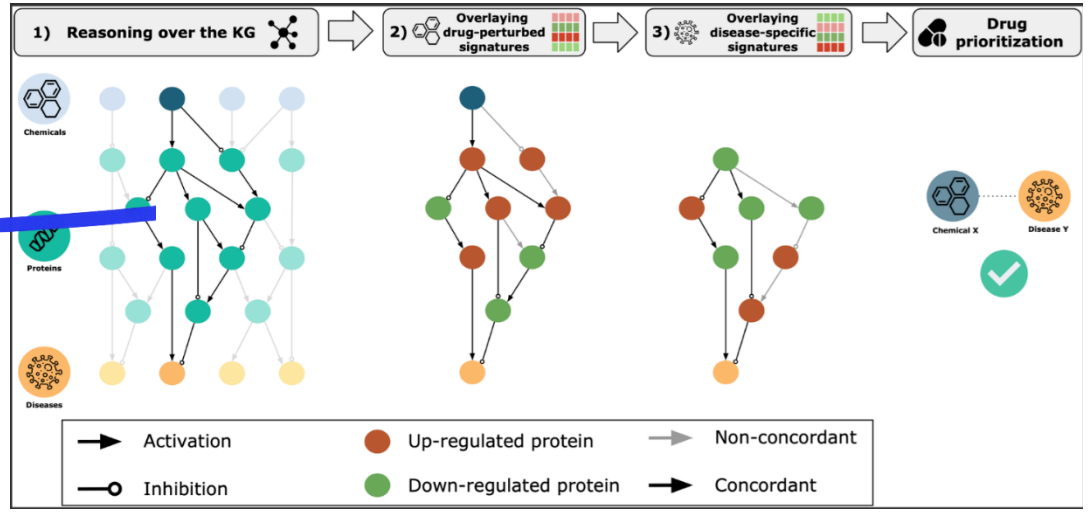


Safety Decision

Integration of structured and unstructured data

Example: *Causal reasoning & hypothesis generation*



Daniel Domingo-Fernández et al, 2022

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Safety, Environmental & Regulatory Science

Alberto Locca

Keshav Gubbi

Application of AI in Safety Science: Quantifying biological similarity at scale

Unilever

Problem formulation– Tier 0

ECOTOX Knowledgebase

A-O-P-Wiki

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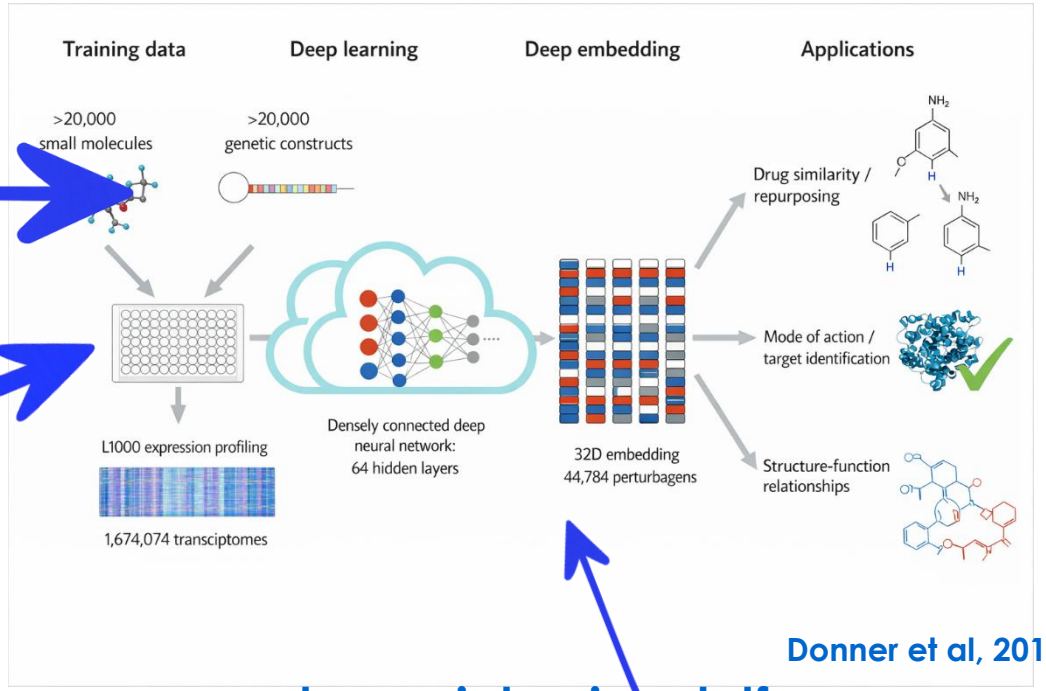
ChEMBL

Bioactivity : Exposure Ratio– Tier 1

Refine Bioactivity:Exposure– Tier 2

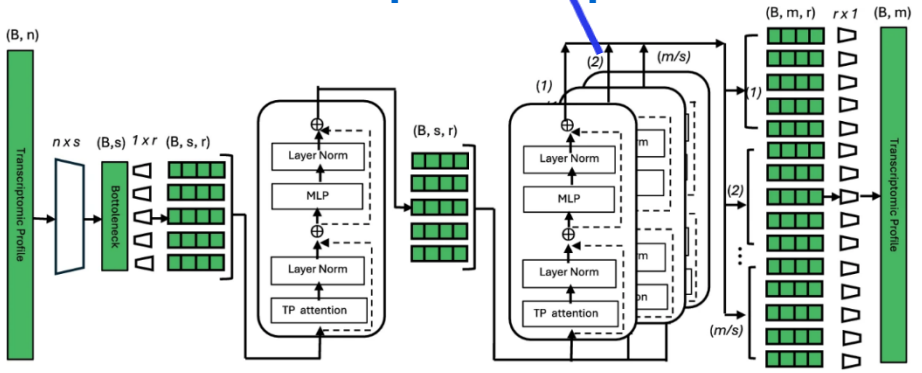
Safety Decision

Metric learning …



Donner et al, 2018

… across transcriptomics platforms



Cong et al, 2026

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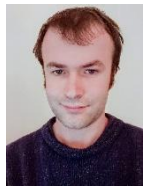
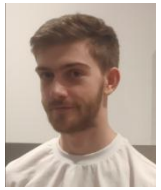


Hugh Barlow



Patrik Engi

Application of AI in Safety Science: Synthetic data & Foundation Models

Unilever

Problem formulation– Tier 0

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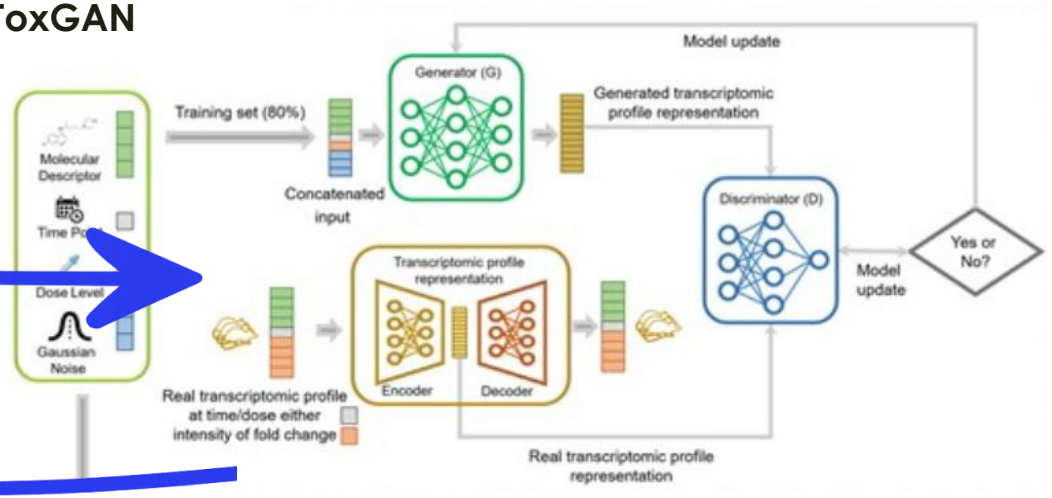
ChEMBL

Bioactivity : Exposure Ratio– Tier 1

Refine Bioactivity:Exposure– Tier 2

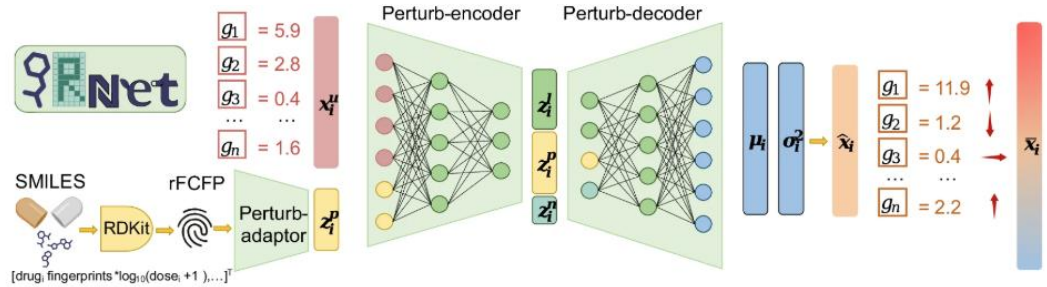
Safety Decision

ToxGAN



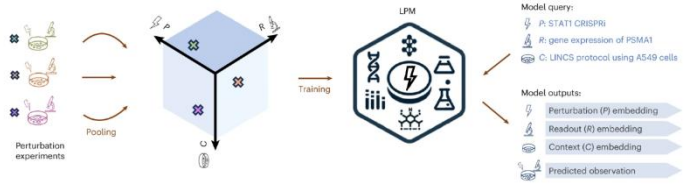
Chen et al, 2022

PRNet



Qi et al, 2024

Large-perturbation model



Miladinovic et al, 2025

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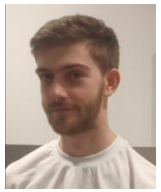
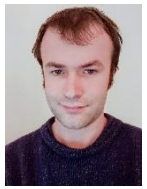


Patrik Engi



Hugh Barlow

Building confidence in AI augmented systems

Unilever

Proportionate Governance

Adoption of AI requires proportional validation and governance based on potential scientific and regulatory impact.

Traceability

AI-supported outputs should remain traceable to underlying evidence.

Reproducibility and Change control

AI outputs should remain governable over time and variability should be monitored and controlled.

Human Accountability

AI should assist decisions with human oversight, clear responsibilities, and communication of uncertainty.

Use **case studies** to build shared understanding and **practical guidance** on how to evaluate AI-augmented frameworks.

Vadlapati et al, 2026

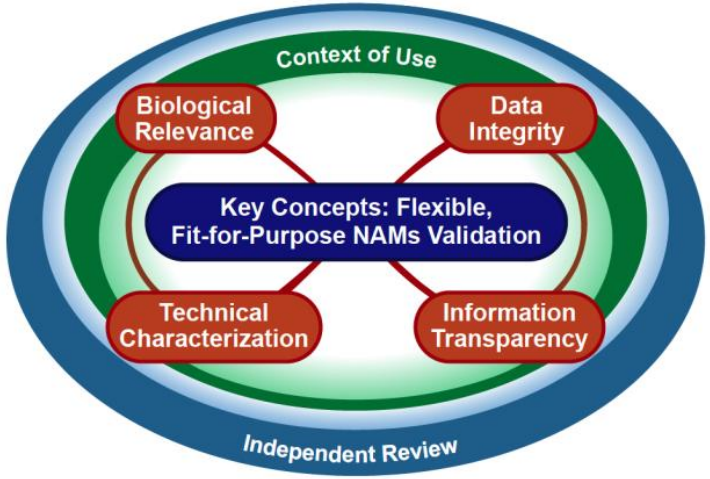
Failure Class	Description	Critical Impact
Epistemic Hallucination	Fabrication of plausible but factually incorrect content	Erroneous medical or military decisions based on false information
Overconfidence Failure	High-confidence presentation of incorrect outputs	Human operators accept errors without scrutiny
Abstention Failure	Inappropriate refusal to respond when a response is needed	System paralysis at critical decision points
Prompt Fragility	Output instability across semantically equivalent phrasings	Unpredictable system behavior in diverse operational conditions
Temporal Drift	Performance changes across model versions and time	Undetected reliability regression following post-deployment updates
Reasoning Collapse	Incoherence, repetition, or truncation under complex reasoning demands	Failure during time-critical operational tasks
Agentic Escalation	Autonomous execution of unsafe or unintended actions	Irreversible operational or physical consequences
Adversarial Manipulation	Prompt injection causing deviation from intended instructions	Command hijacking by deliberate adversaries

Towards AI-augmented safety frameworks: Build Confidence Step by Step

Unilever

Increased industry: academia: regulatory exchange to amplify positive impact of AI on future toxicology, while also managing governance challenges.

- Leverage scientific and technological progress to advance exposure science, understanding of human biology and risk assessment.



- Guidance and guidelines that will pave the way for regulatory acceptance.

ICCVAM Validation Report, Figure 1 (adapted from van der Zalm et al. 2022 Arch Tox)

- Design educational programmes.
- Training and access to information that will support confidence in the use of AI.

Application of AI in Safety Science: Future Trends

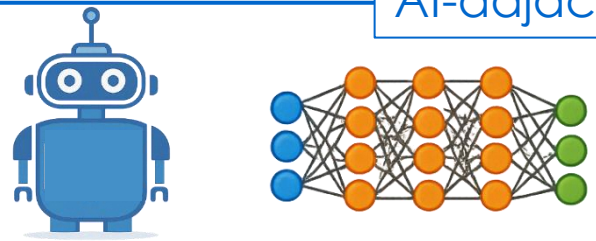
Unilever

- Increased access to chemical, biological, exposure and toxicological data that are FAIR (expected exponential increase in global data volumes*).
- Access to agentic AI workflows will increase uptake of NGRA-based approaches by making them more accessible and transparent
- Data-driven approaches that strengthen and enhance expert based decision making

* Source: Statista, Bernard Marr & Co

Bioactivity vs adversity

AI-adjacent approaches



Agentic AI | Representation learning | Knowledge Graphs

Risk Quantification & Uncertainty analysis | Key drivers & pathways | Next steps (e.g., hypothesis generation) | Weighing and scoring different sources of information

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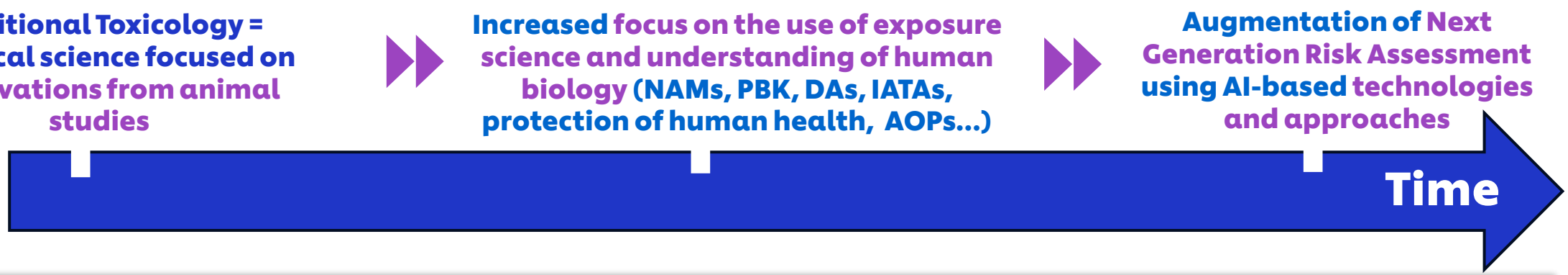

Conclusions

1. Leveraging human-in-the-loop AI-driven approaches in future will be crucial to further advance the use of Next Generation Risk Assessment.
2. Increased industry: academia: regulatory exchange is necessary in future to amplify positive impact of AI on toxicology.
3. Managing governance challenges early in the process will be needed, including FAIR use of NAM data, democratisation of AI models, increased international collaboration, including strategic plans, guidance & guidelines.
4. AI will further democratise Next Generation Risk Assessment as multidisciplinary science that brings together toxicologists and scientists with engineers, statisticians and mathematicians.

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