

HUMAN HEALTH ASSESSMENT

Parallel session
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Session 2.1

Reflections from stakeholders

HUMAN HEALTH (HH)

Roadmap-specific technical opportunities and challenges for pesticides and biocides



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Session 2.1 - Human health assessment

HUMAN HEALTH (HH)

Reflections from stakeholders

Roadmap-specific technical opportunities and challenges for pesticides and biocides



Matthias Herzler

Scientific Director

German Federal Institute for Risk Assessment



Tina Mehta

Toxicologist and regulatory leader

British Toxicology Society



Bob van de Water

Professor of Drug Safety Sciences

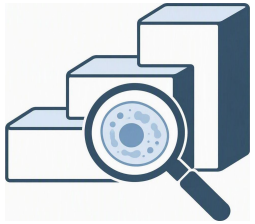
Leiden University

WHAT HAVE WE HEARD

Broad framework	Endpoint application	Specific example
NGRA	**Carcinogenicity**	**Toxicogenomics**
Next generation risk assessment	Tiered approach for complex endpoints	New endpoints for human safety



- **Human-centric** — Non-animal mechanistic assessment
- **Flexible** — Hazard- or exposure-led workflows



- **Tiered testing** — Broad screening then targeted follow-up
- **Mechanisms** — Multiple biological traits



- **Gene expression** — Molecular responses
- **Technology** — New safety endpoints

Broad screening guides targeted testing. Molecular changes require a link to adversity.

Sources: Herzler, NGRA Framework, slides 4–6 and 9–12 (supplied deck); OECD IATA and omics resources.

WHAT'S NEXT

Exposure led scenario	Can we currently move from a hazard-based scenario to an exposure? What are the challenges?
Mechanistic understanding	Using the proposed approaches, is it possible to rely on mechanistic data to ensure safety or where, integrated with in vivo they can be an add of value for assessment?
In silico approaches	Does the development of reliable ADME profiling and parameters/PBK modelling support exposure and prediction of hazard?
Predicting adversity	AOPs are useful but still demanding in terms of *in vivo* data. Quantitative AOPs could help but effort in development.
Regulatory integration	Where in the current Pesticides and Biocides legislations these approaches can be already used or where can we start?

WHAT'S NEXT

Key scientific priorities	Demonstrate human relevance and biological coverage. Develop links between mechanistic changes and adverse outcomes. Increase confidence in new technologies, omics, read-across and NAM-derived PoDs.
Key regulatory priorities	Translate NAM evidence into hazard and risk assessment decisions. Develop harmonised approaches for confidence and uncertainty evaluation. Enable regulatory acceptance across sectors.
Key implementation priorities	Generate regulatory case studies and real-world applications. Strengthen collaboration between regulators, industry and academia. Align scientific innovation with legislative requirements.

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EUROPEAN FOOD SAFETY AUTHORITY

OVERARCHING OPPORTUNITIES FOR NEXT GENERATION RISK ASSESSMENT IN HH AND ERA

Building regulatory confidence in *in silico* predictions, *in vitro* methods and QIVIVE

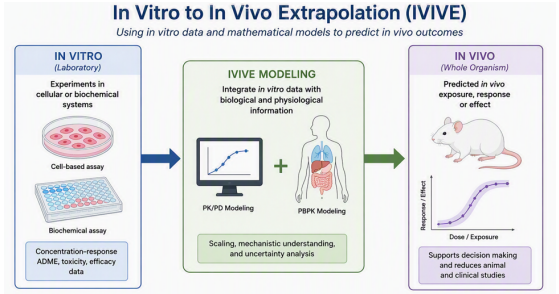
1 QSAR & QAF

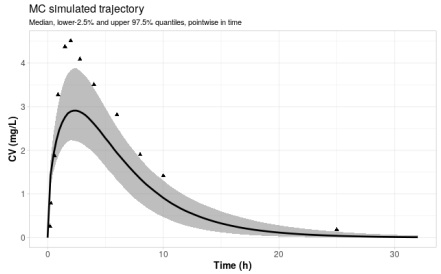
- Enhancing regulatory confidence through reliable QSAR predictions
- Enabling automated QAF-compliant reliability assessments



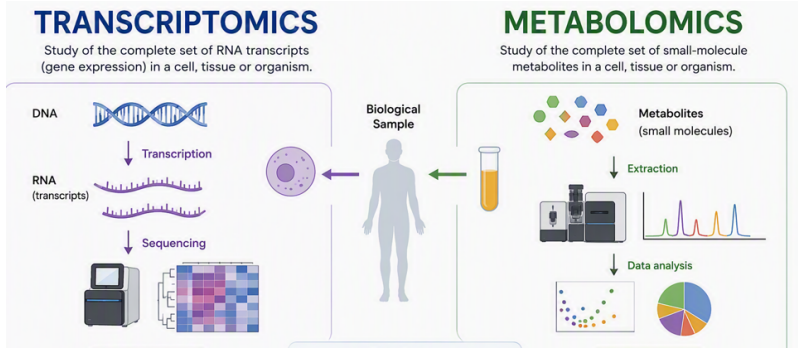
2 TK, ADME, PBK & QIVIVE

- Standardise TK parameters and *in vitro* ADME methods





3 OMICS, PoD & SIGNATURES



4 Nanomaterials and nanoparticle risk assessment

- NMs as a complex materials requiring tailored risk assessment approaches and cross-disciplinary expertise.

➡ Development of *in vitro/in silico* testing batteries, including for nanomaterial assessment

- **Harmonised OECD criteria**
- **Practical tools**

Stronger confidence in NGRA using NAMs