RÉPUBLIQUE FRANÇAISE
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anses

# CURRENT APPLICATIONS – A REGULATORY AUTHORITY PERSPECTIVES

**SANDERS PASCAL – Scientific director « Exposure and Toxicology »**

# Current Use of New Approach Methodologies at Anses

Regulatory domains at Anses : Reach Regulated substances, Biocides, Pesticides, Veterinary Drugs

Use of some integrated strategies for regulatory purposes when regulations allow it

Use of NAMs at least partially, when needed on a case-by-case basis

- Specific endpoints : Topical toxicity, genotoxicity, sensitisation
- Mechanistic exploration
- Veterinary drugs: 3Rs, interspecies extrapolation

Limits : No explicit provisions about their use in the regulations.

Endocrine disrupter (ED) potential for active substances (biocides or pesticides)
ECHA/EFSA Guidance for ED assessment

- *In vivo* data : One or Two generation studies
- NAMs for mechanistic exploration

# Research activities at Anses

**Hazard assessment**

Laboratory of Fougères

Genotoxicity, cell toxicity studies for toxins, nanomaterials, mixtures

Case study in collaboration with risk assessors teams

**Exposure assessment**

Integration of HBM data

Mixture of interest in food

PBPK Modelling

qIVIVe for ab initio PBPK modelling

# Uncertainty

All types of limitations in available knowledge that affect the range and probability of possible answers to an assessment questions. - Efsa

Any stakeholder has a different view on what uncertainy is.

Need to reach a mutual understanding (EFSA Guidance on Uncertainty Analysis in Scientific Assessments)

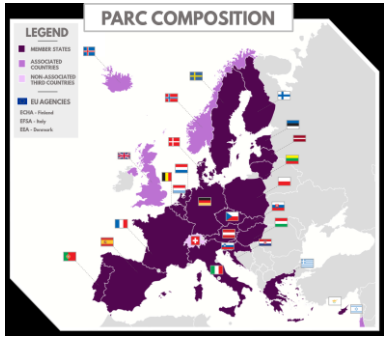
Uncertainties relating to

- Assessment inputs (e.g. relevance & reliability of data, data gaps, reliability of assumptions)
- Assessment methods (e.g. modelling, literature search, statistical analysis, expert judgement)

# Confidence

Construction through case studies to ensure scientific correctness and relevance for regulatory needs.

# Partnership for Assessment of Risks from Chemicals - PARC




**Horizon Europe**

**GLOBAL CHALLENGES & EUROPEAN INDUSTRIAL COMPETITIVENESS • Health**

Public-Public Partnership – Proposal submitted to EC – September 2021

Objectives : to build a high-level network between EU and National Risk Agencies, Universities, Public Research Organisations to commit to **jointly support the development and implementation of a programme** of research and innovation activities in relation with **the assessment of risk from chemicals.**

Hazard assessment

Innovation in regulatory risk assessment

**For NAMS and Omics**

- To contribute to the consideration of new approaches and methods of HA and provide data to fill gaps in knowledge on poorly characterised contaminants or new emerging hazards.
- To also aim to promote the use of innovative methods and tools and contribute to integration of new technologies.
- To implement some case studies for Integrated Approaches on Testing and Assessment.
- To work on data and knowledge management to promote open science and FAIRness.
- To work on concept and toolboxes in relation with the chemical strategy for sustainability

# Conclusion

“Shifting the current risk assessment paradigm from animal-centred *in vivo* testing to human, mechanism-informed, NAM-based assessment strategies is necessary because human relevant test systems and strategies are increasingly needed to continue protect health as much as possible and with all available scientific knowledge in a high speed evolving world.”

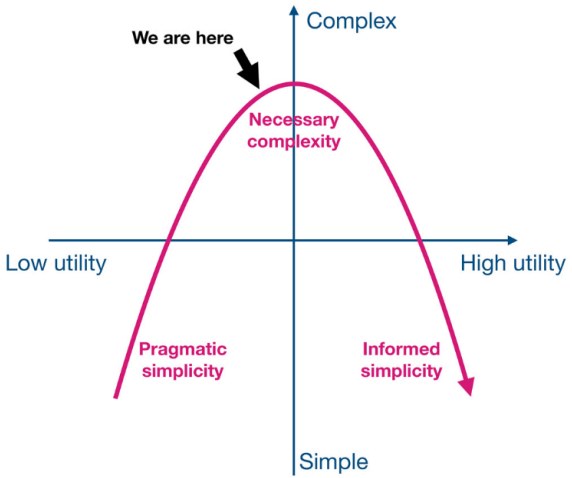



**FIGURE 1:** Evolution of the adverse outcome pathway framework from pragmatic to informed simplicity.

Knapen, D. (2021). Env. Tox. & Chem