

2024 / 03

Human Health Transformational Programme. Programme 2: Development of an Integrated Approach for Chemicals Assessment

Richard Currie on behalf of ECETOC

RESOURCES.

[Staged assessment task force](#)
[Smart Studies task force](#)

[Best practices in Quantitative AOP development – workshop report 38](#)

[Numerous Omics reports and task forces](#)
including those for

- [Applying omics in regulatory toxicology](#)
- Omics data reporting
- Omics data interpretation framework for regulatory applications task force

Modern Science has provided many potentially useful tools and existing data that are not used or reused, respectively.

Animal methods

Non-Animal methods
(NAMs)

New approach
methods
(NAMs)

Old approach
methods
(OAMs)

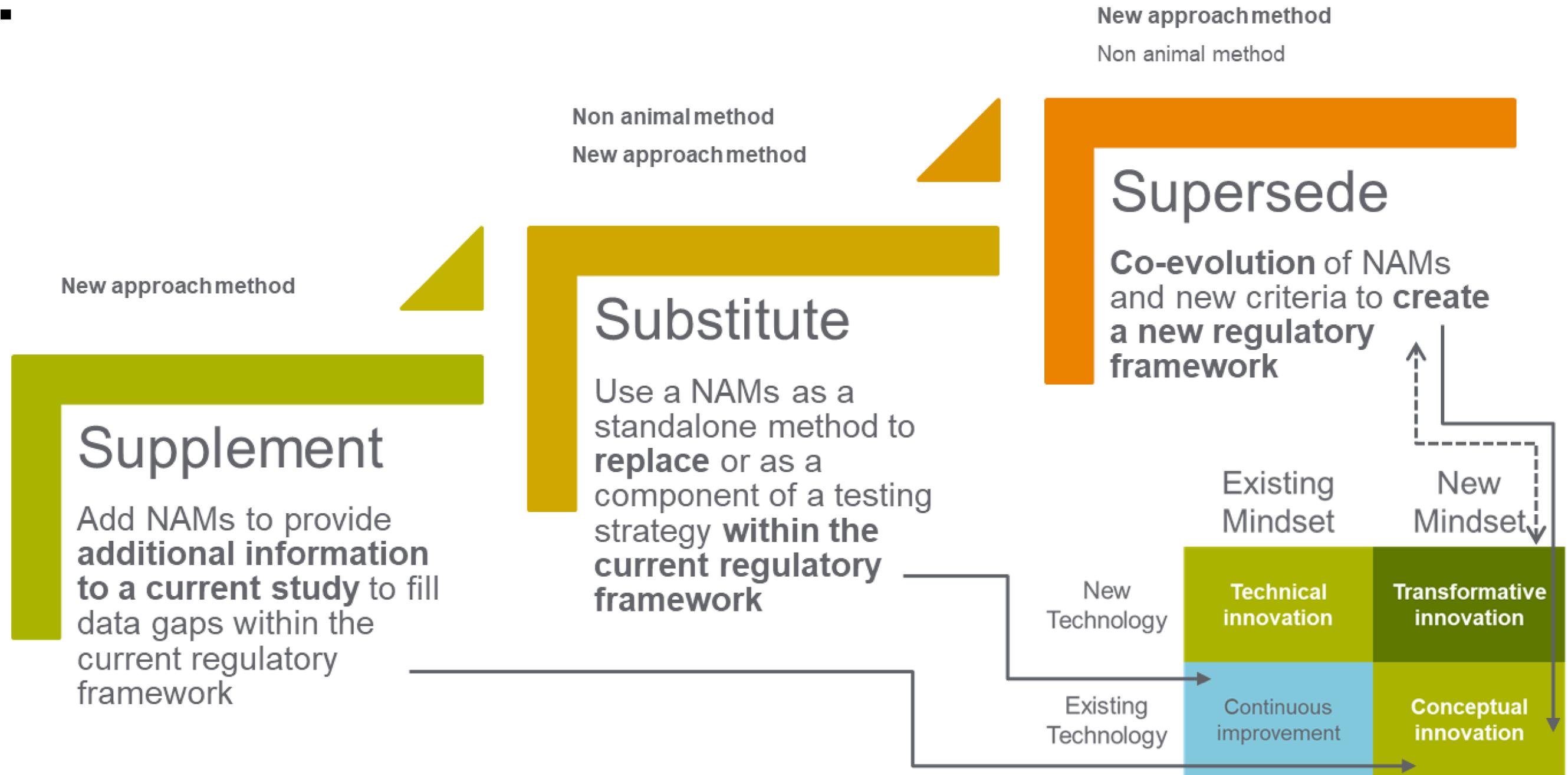
Modern scientific
measurements made on
animal studies,
quantitative systems/AOP
models of adverse effects

Histopathology, behavioural,
etc changes **observed** in
Rodent, Dog, Rabbit, Pig,
Fish, Bird and Primate
models since the 1940s.
MOA studies.

Modern scientific
measurements made on *in
vitro* assays, even more
computational toxicology
than in the OAMs,
integrated via NGRAs,
quantitative systems/AOP
models of adverse effects

Historic Read across, *in vitro*
tests and SAR/qSAR.
MOA studies.
Traditional conceptual
framework

Modern Science could be applied in different ways.



Development of an Integrated Approach for Chemicals Assessment (Transformational Programme 2)

Why

- Much of the technology for new approach methodologies (NAMs) exists, but standardized agreed implementation frameworks required

Objectives

- Identify opportunities for application of NAMs in next generation risk assessment (NGRA)

Deliverables

- Two peer-reviewed manuscripts: [Ball et al. 2022](#) (framework for incorporating NAMs in REACH); [Botham et al., 2023](#) (use of NAMS for low tonnage chemicals in REACH)
- Two Task Forces initiated 2023: Staged assessment for low tonnage chemicals TF; Smart in vivo studies TF

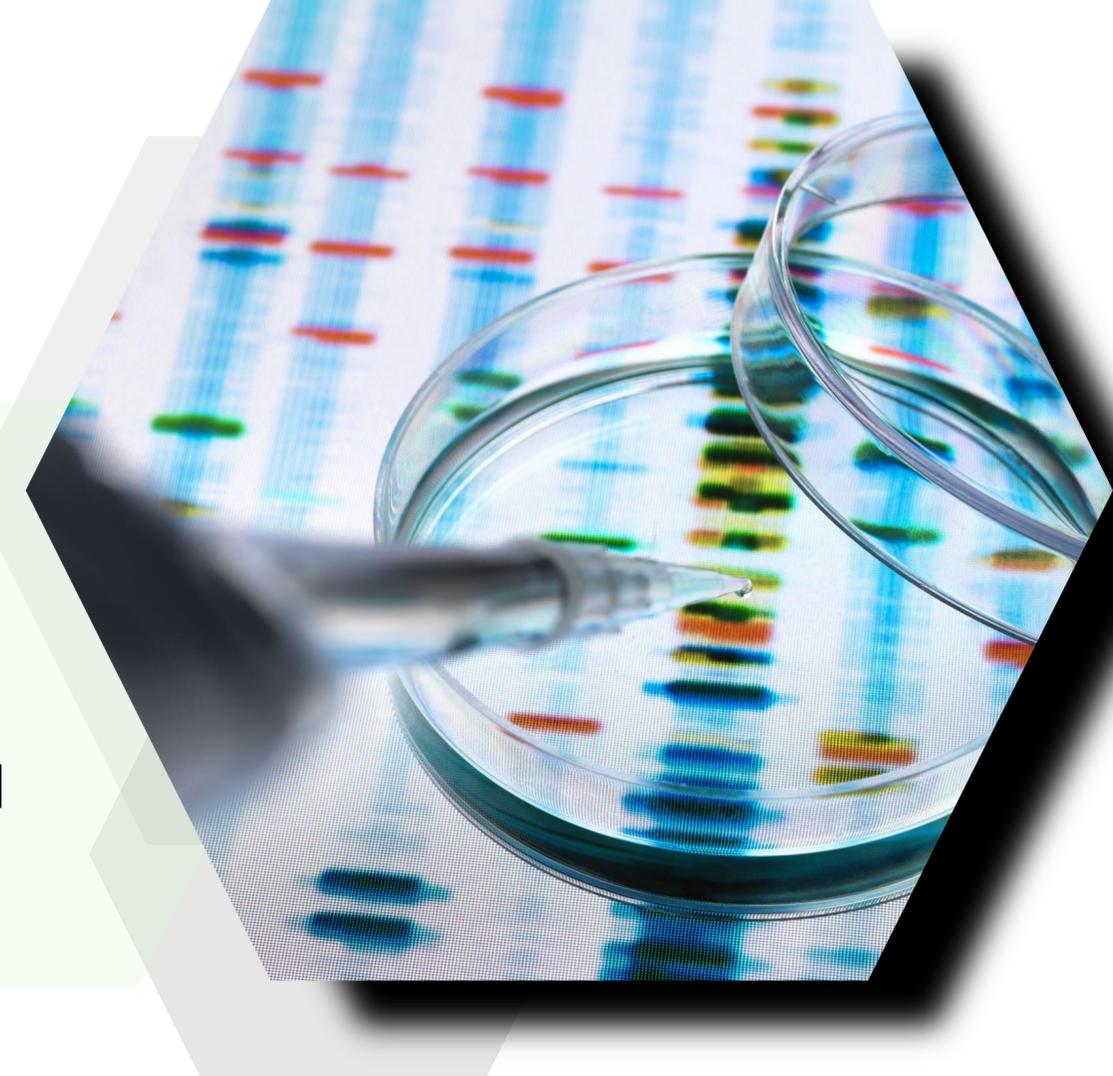
Timeline

Aug 2018:
Kick-off
meeting

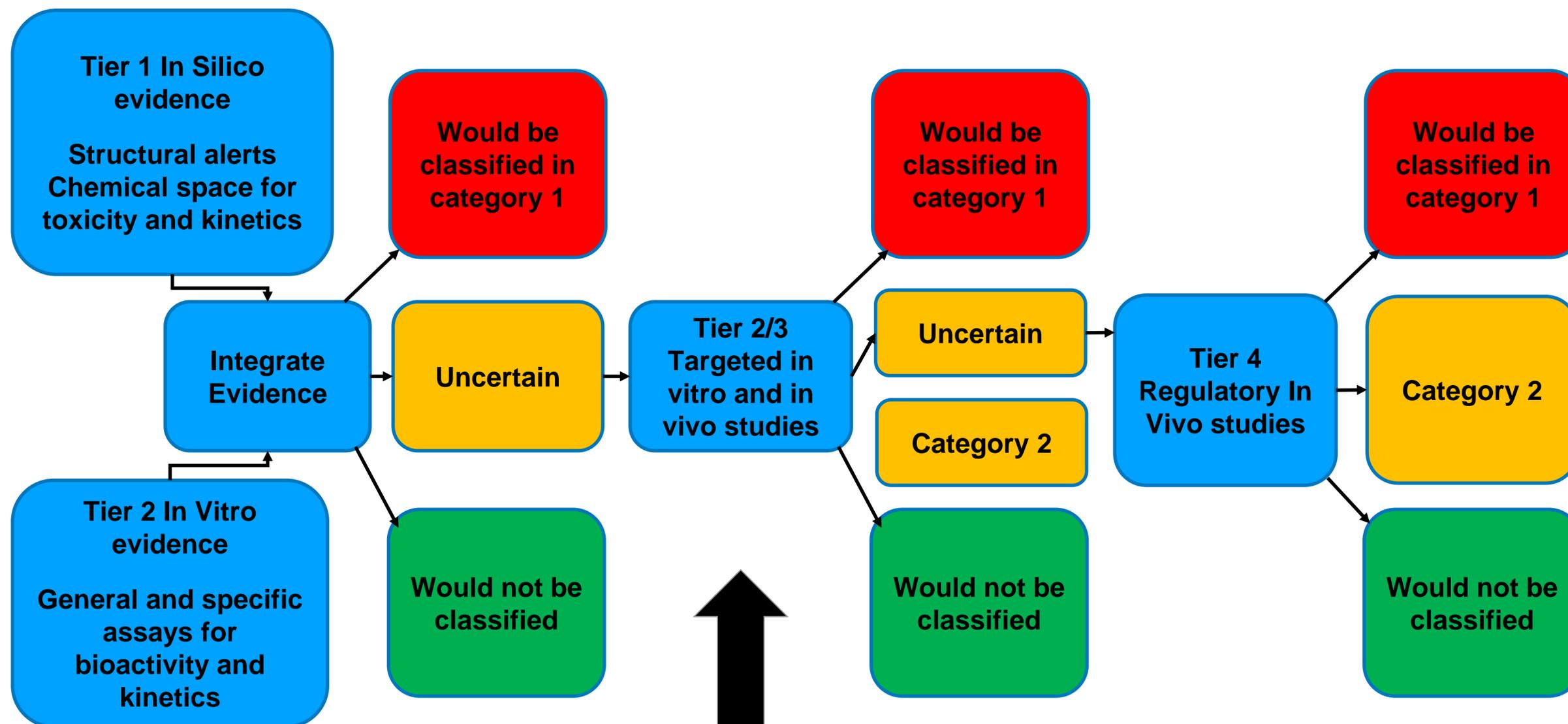
Sept 2023:
2nd
manuscript
published

Feb 2022:
1st
manuscript
published

2023-2024:
TP ongoing



ECETOC Human Health Staged Evaluation aims to use modern science and tiered testing to reduce uncertainty to enable a decision

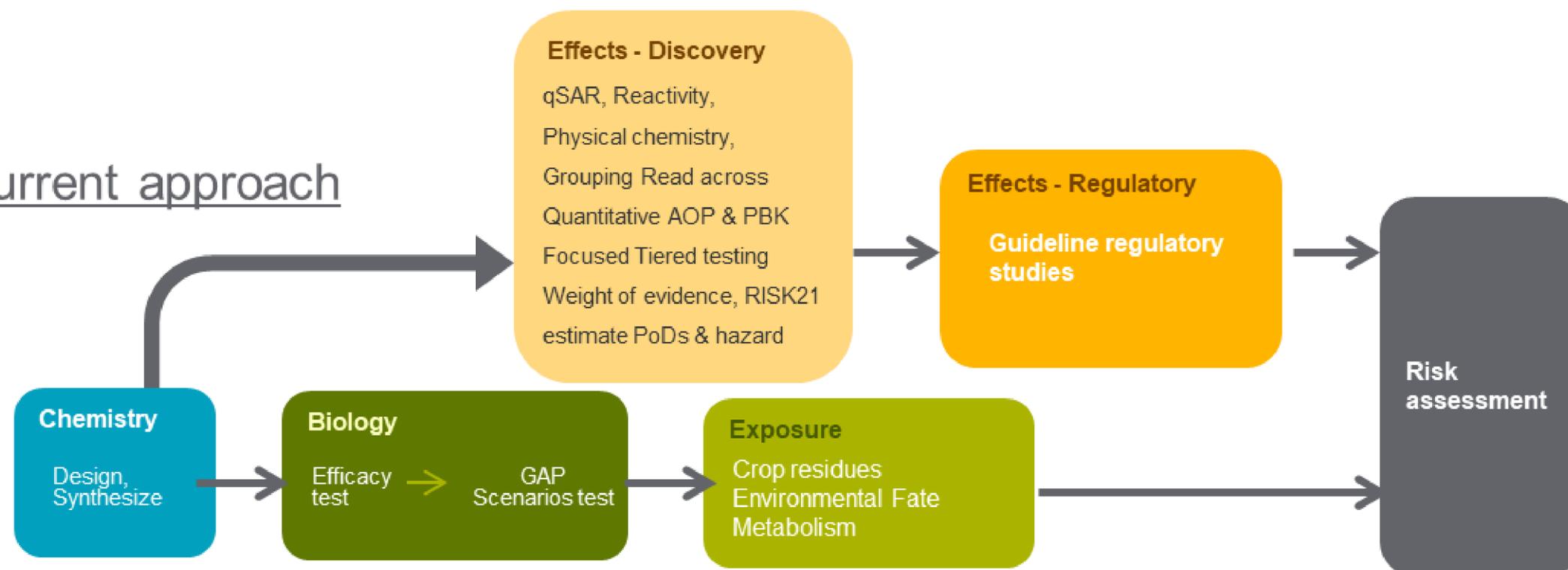


SMART studies using additional endpoints including omics data, interpreted for regulation (collaboration with others e.g. HESI eSTAR committee)

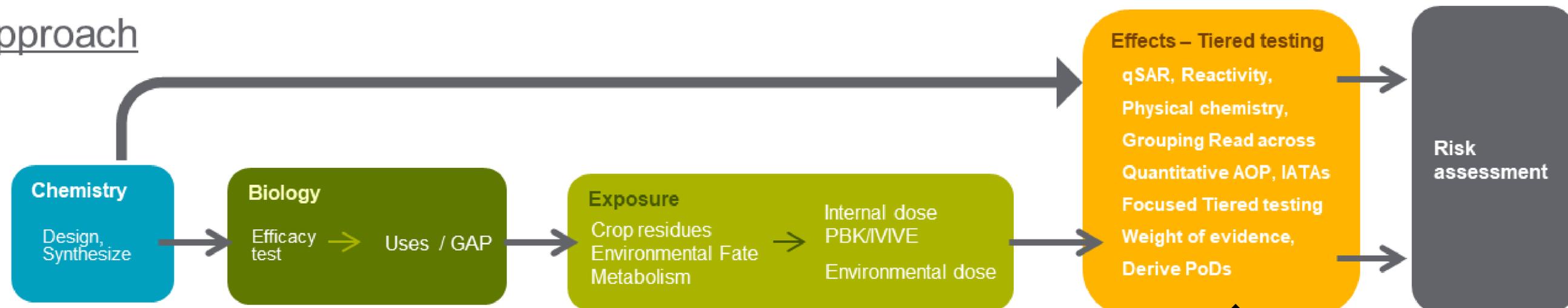
Quantitative AOPs using mathematical modelling

How might a modernised approach be built?

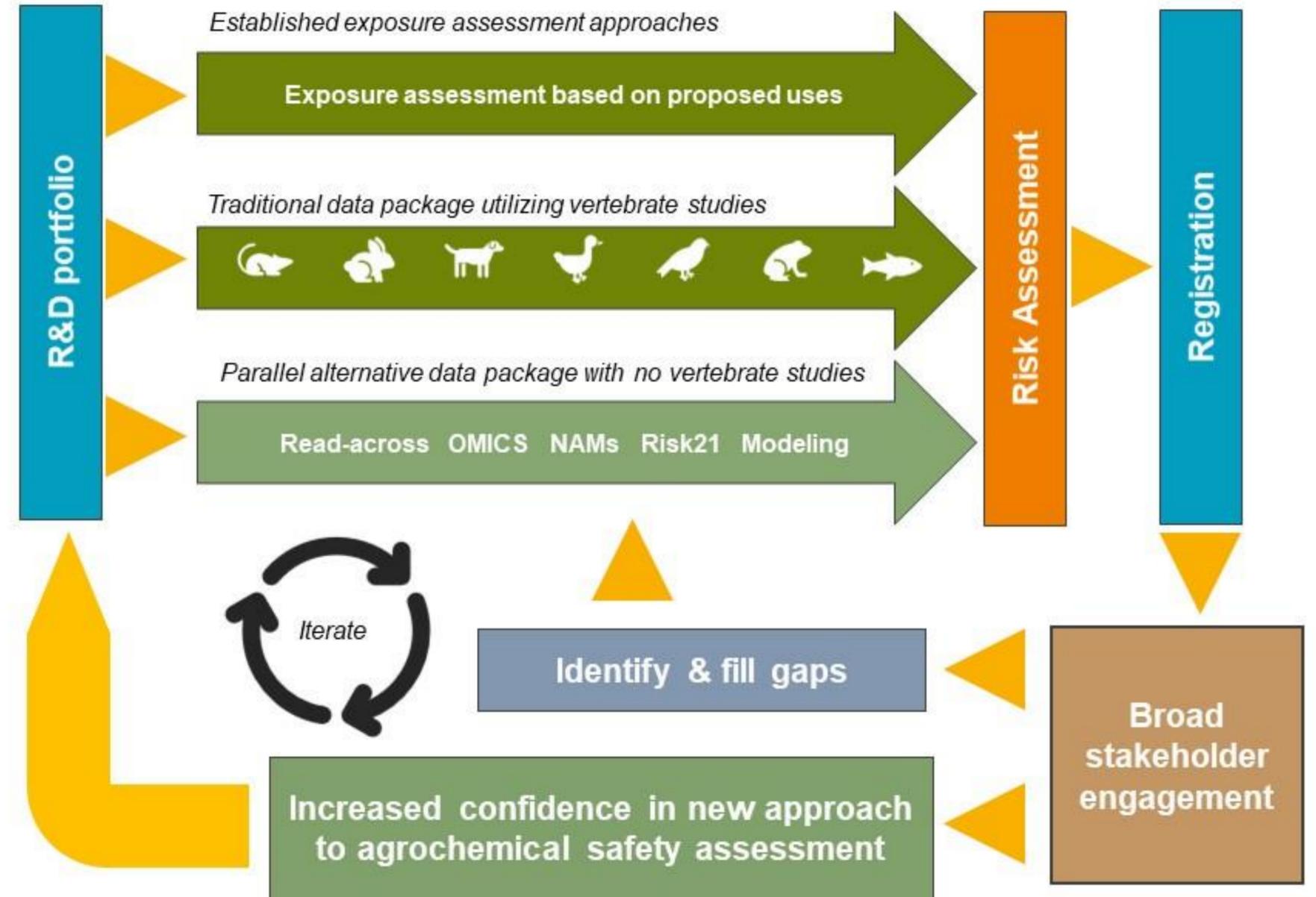
Historic current approach



Modern approach



Industry case study – suggesting adaptations needed to build a trusted change by iterative exploration & learning



<https://www.altex.org/index.php/altex/article/view/2671>

Thank you.