

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](#)

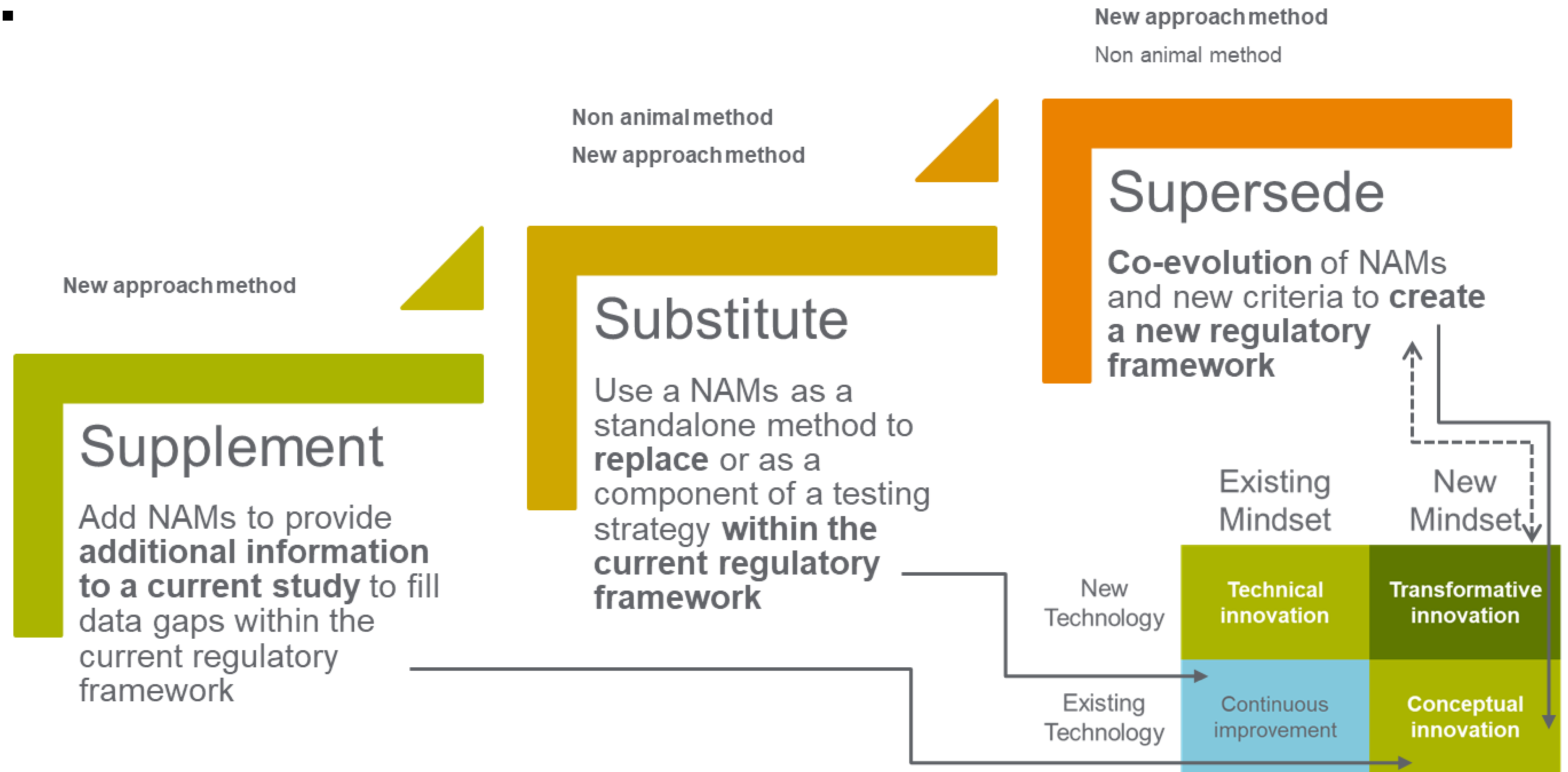
[Numerous Omics reports and task forces](#)
including those for

- [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.

	New approach methods (NAMs)	Old approach methods (OAMs)
Animal methods	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.
Non-Animal methods (NAMs)	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, <i>in vitro</i> 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

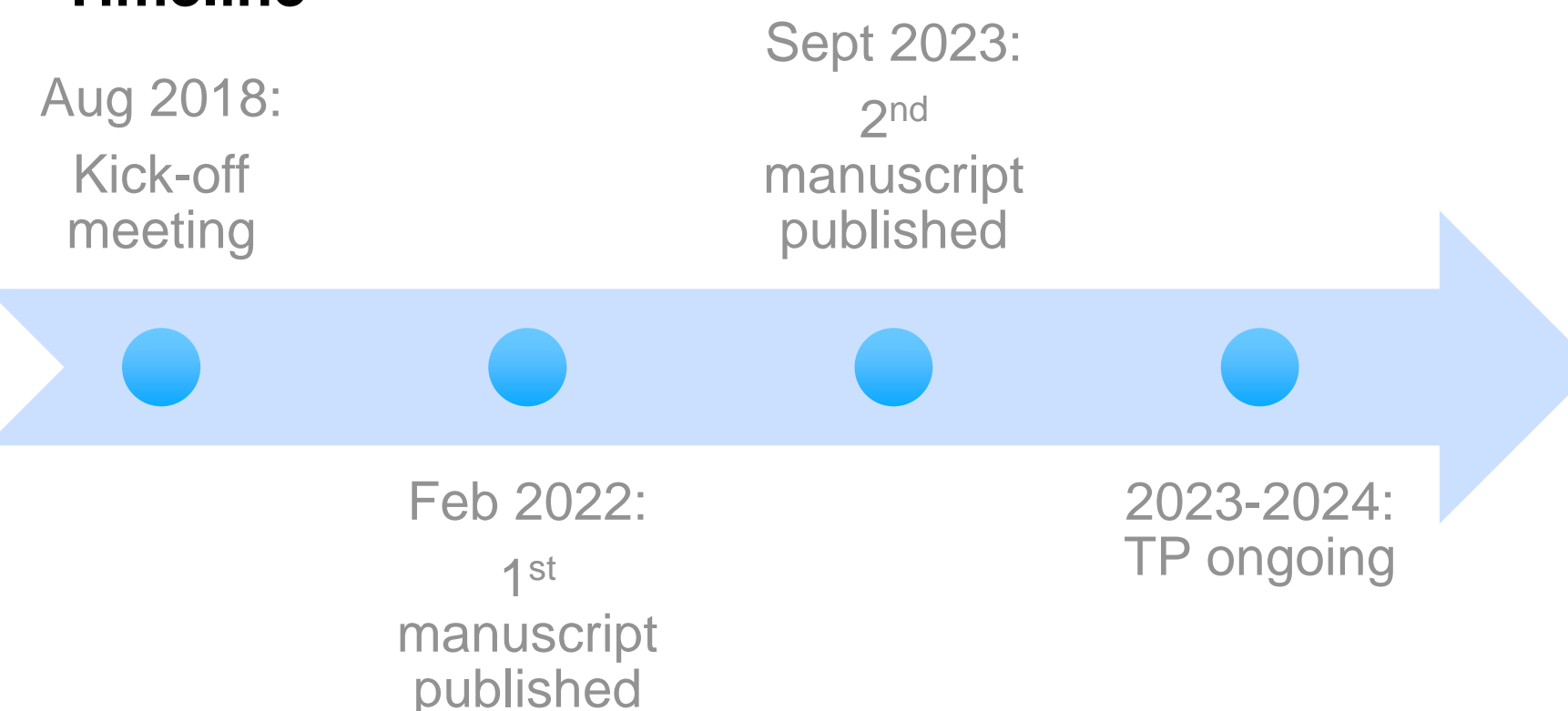
Objectives

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

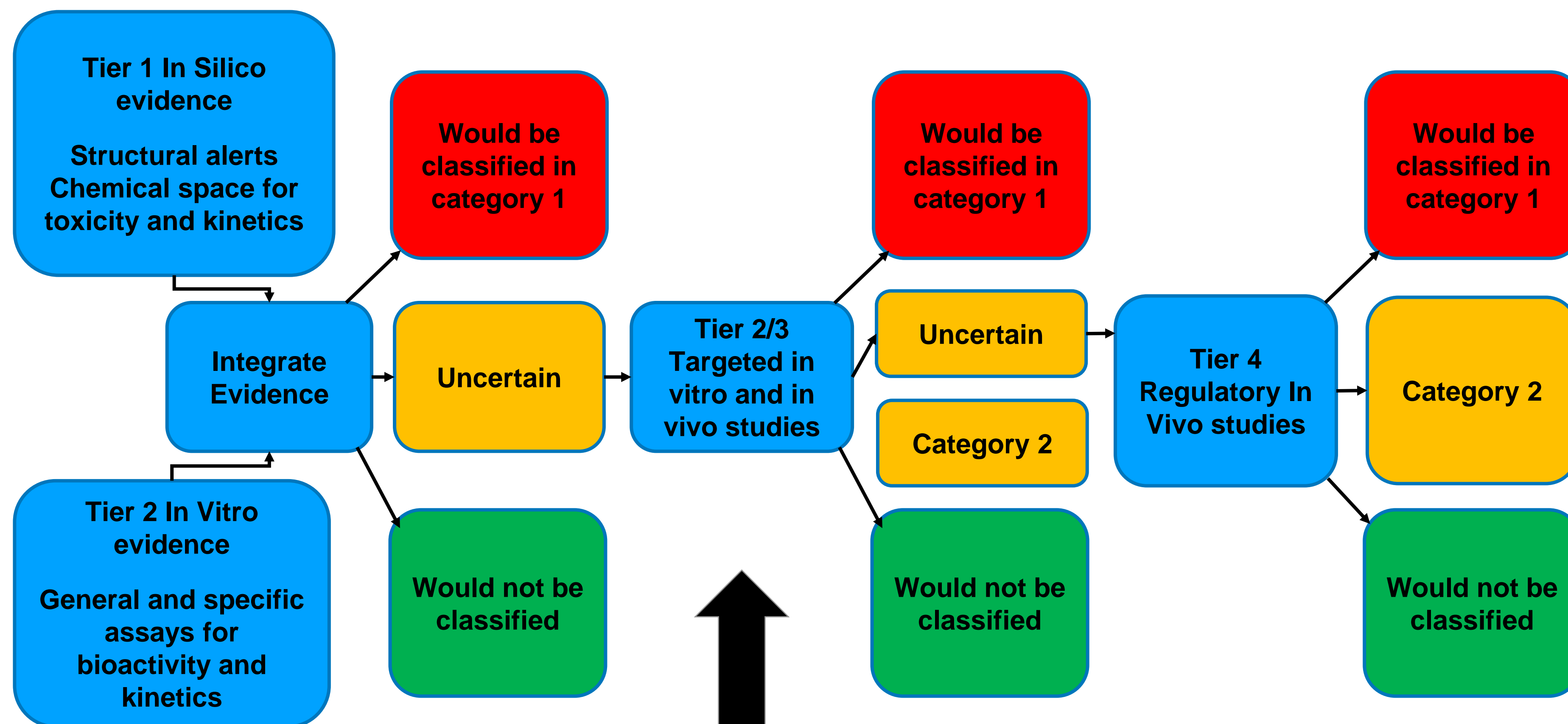
Deliverables

- 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



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

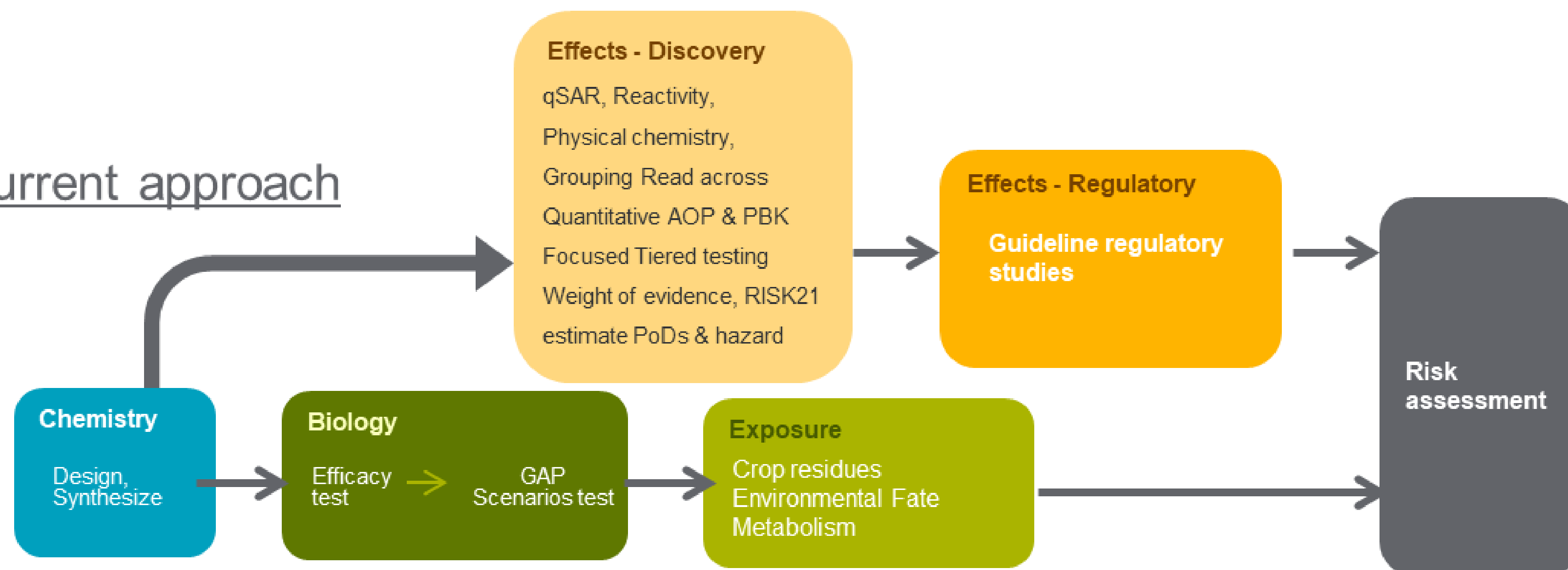


SMART studies using additional endpoints including omics data, interpreted for regulation (collaboration with others e.g. HESI eSTAR committee)

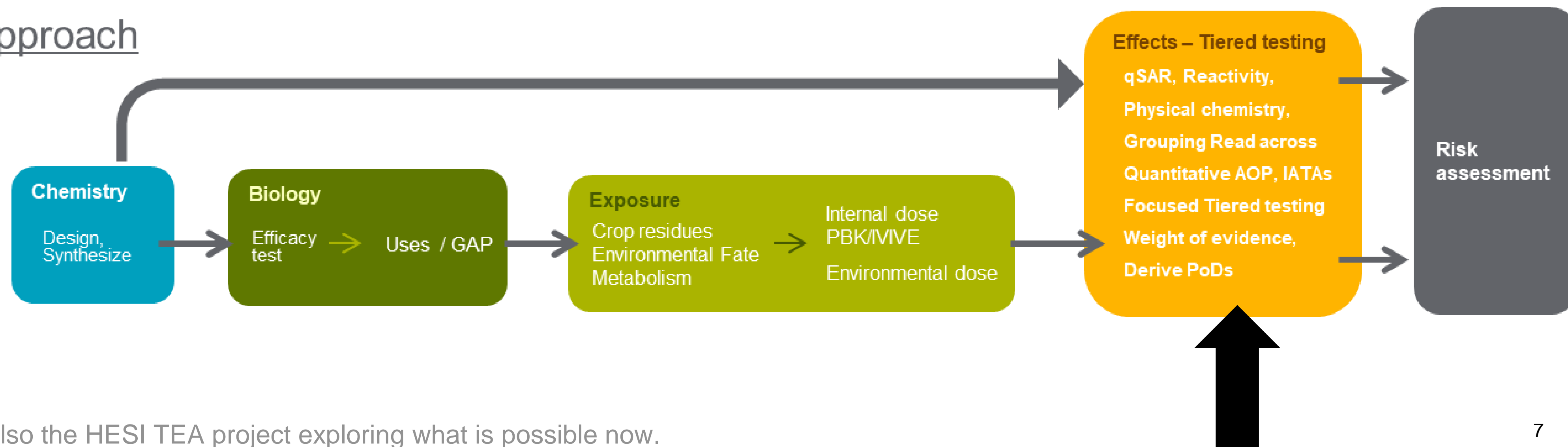
Quantitative AOPs using mathematical modelling

How might a modernised approach be built?

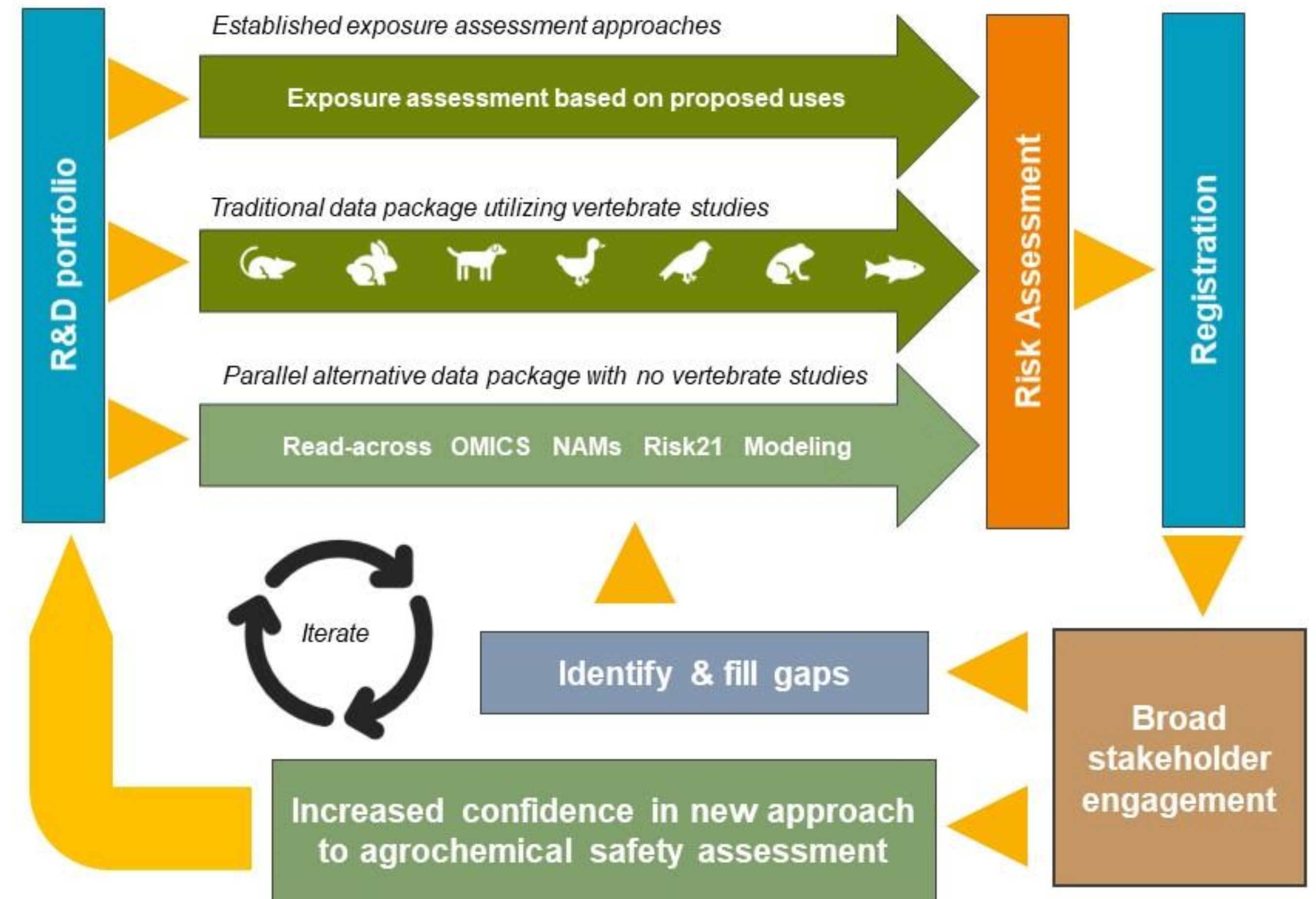
Historic current approach



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.