3 – 5

IMPLEMENTING NEW APPROACH METHODOLOGIES: CHALLENGES & OPPORTUNITIES

Food & Feed Regulatory Context

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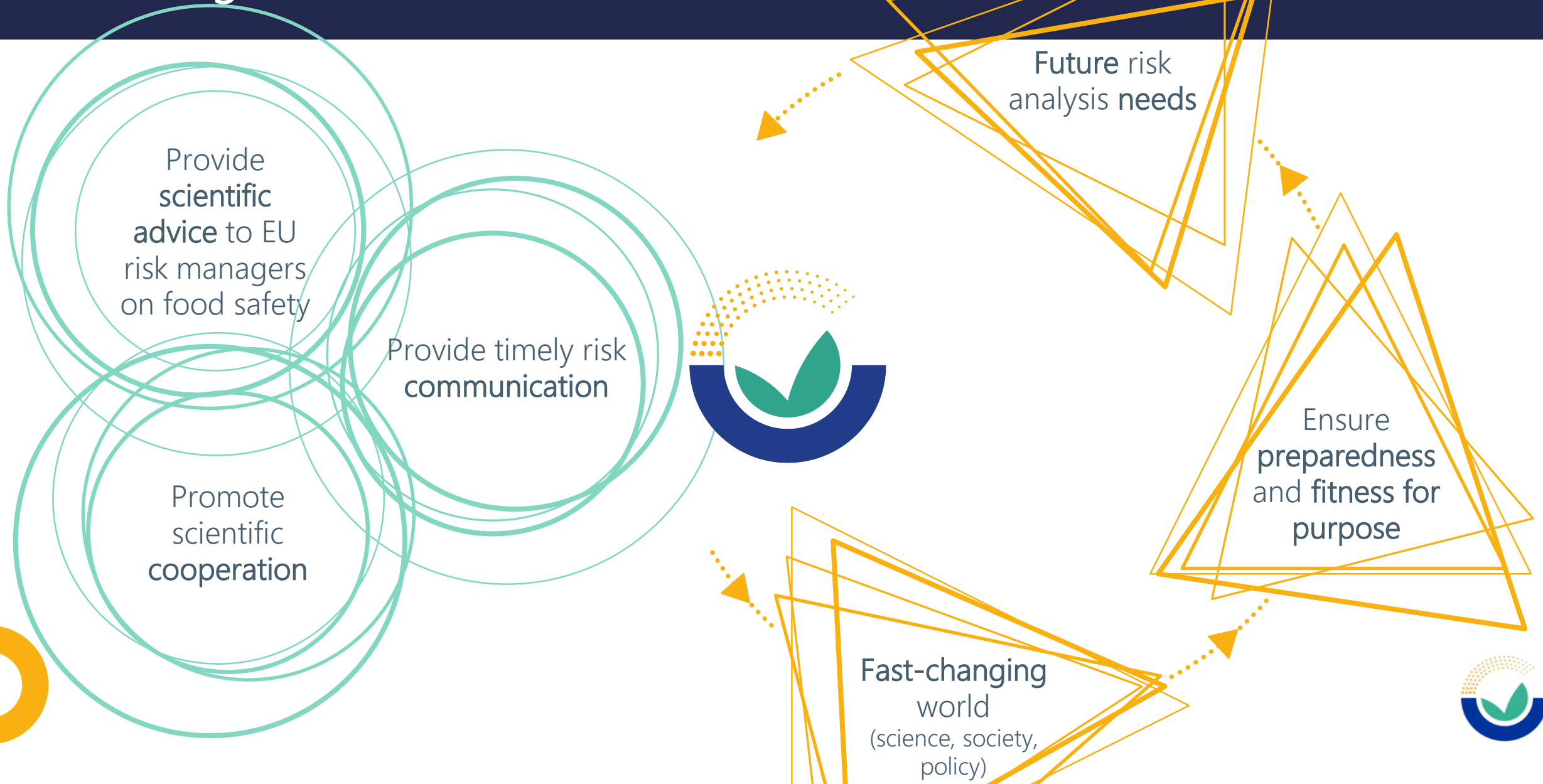
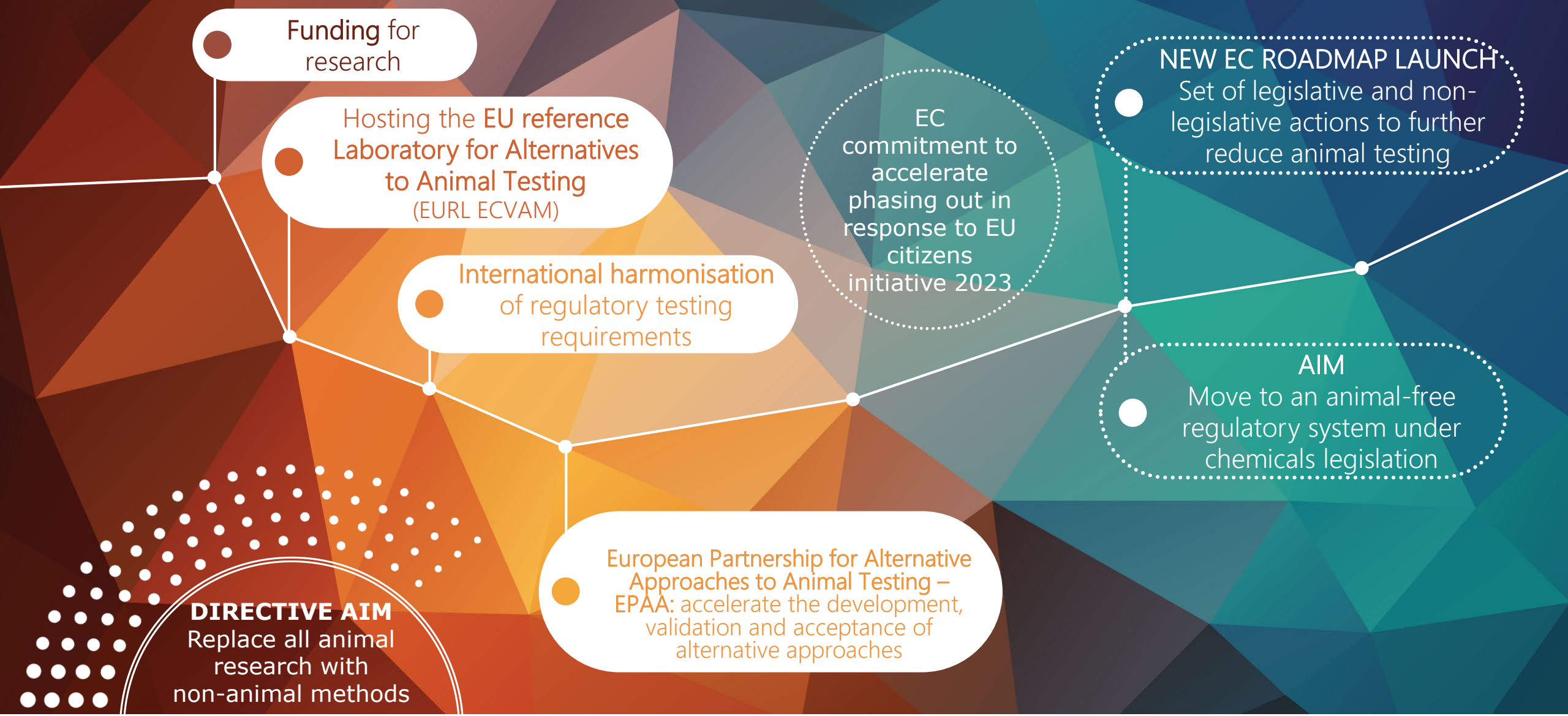
efsa
EUROPEAN FOOD SAFETY AUTHORITY

Setting the EFSA scene



Setting the EFSA scene


Funding for research
Hosting the EU reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)
International harmonisation of regulatory testing requirements
EC commitment to accelerate phasing out in response to EU citizens initiative 2023
NEW EC ROADMAP LAUNCH
Set of legislative and non-legislative actions to further reduce animal testing
AIM
Move to an animal-free regulatory system under chemicals legislation
European Partnership for Alternative Approaches to Animal Testing – EPAA: accelerate the development, validation and acceptance of alternative approaches
DIRECTIVE AIM
Replace all animal research with non-animal methods

EFSA SCIENTIFIC PROJECTS FOCUS

- R for Replacement of animal tests with non-animal tests
- Support regulatory processes
- Building partnerships with other EU Agencies on working towards technical validation of studies

'The 3 Rs ALTERNATIVES'

Replacement, Reduction, and Refinement of animals used in research, teaching, and exhibition.

REPLACEMENT – THE USE OF NEW APPROACH METHODOLOGIES (NAMs)

Variety of applicable studies

In vitro, in vivo, in chemico, in silico - measure of Key Events (KE)

AOP-informed Integrate Approach Test Assessment (IATA)

To

Evolve **methods/models/tools**

Increase knowledge and **improve** risk assessment

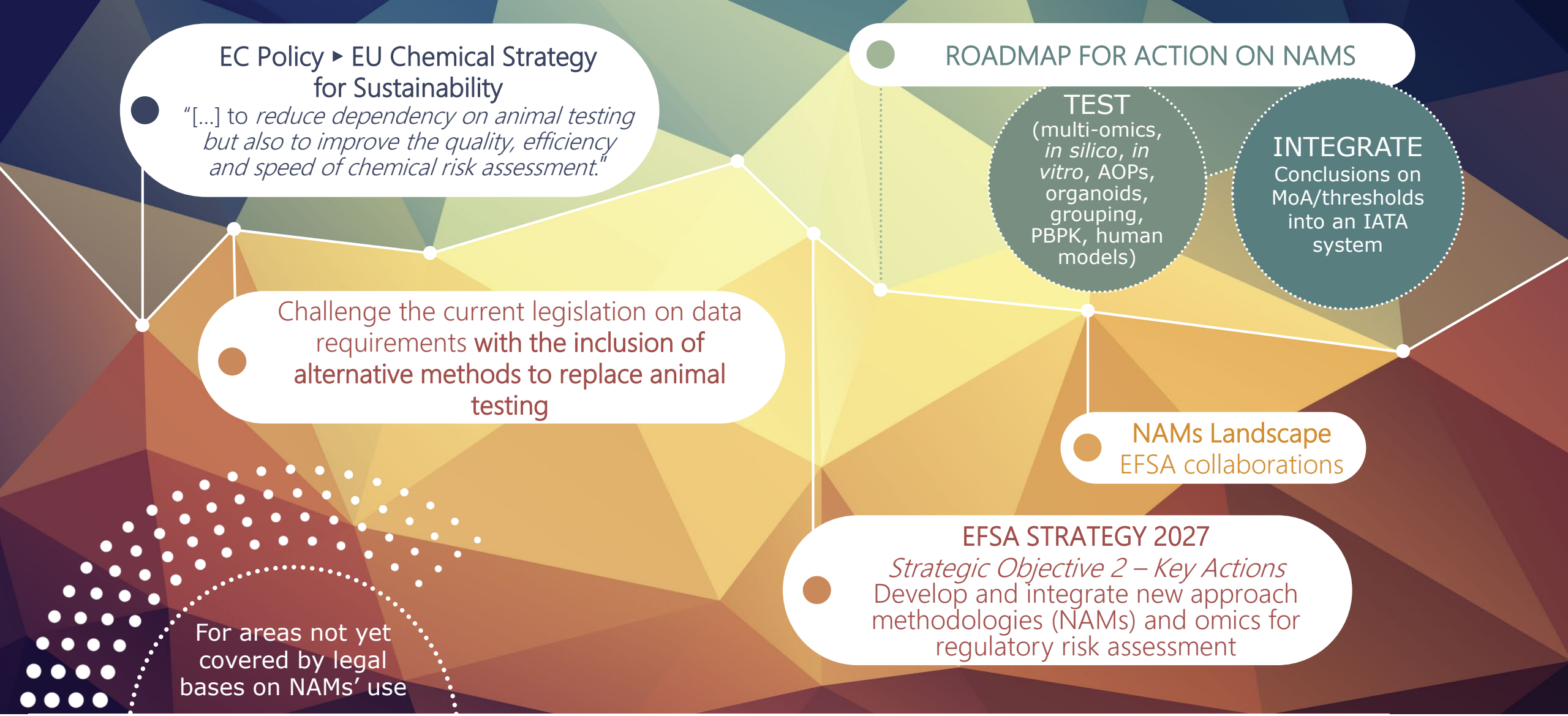
Support **paradigm shift**

Scientific Development

Fast growth

Quick advancement

Increase of available toolbox



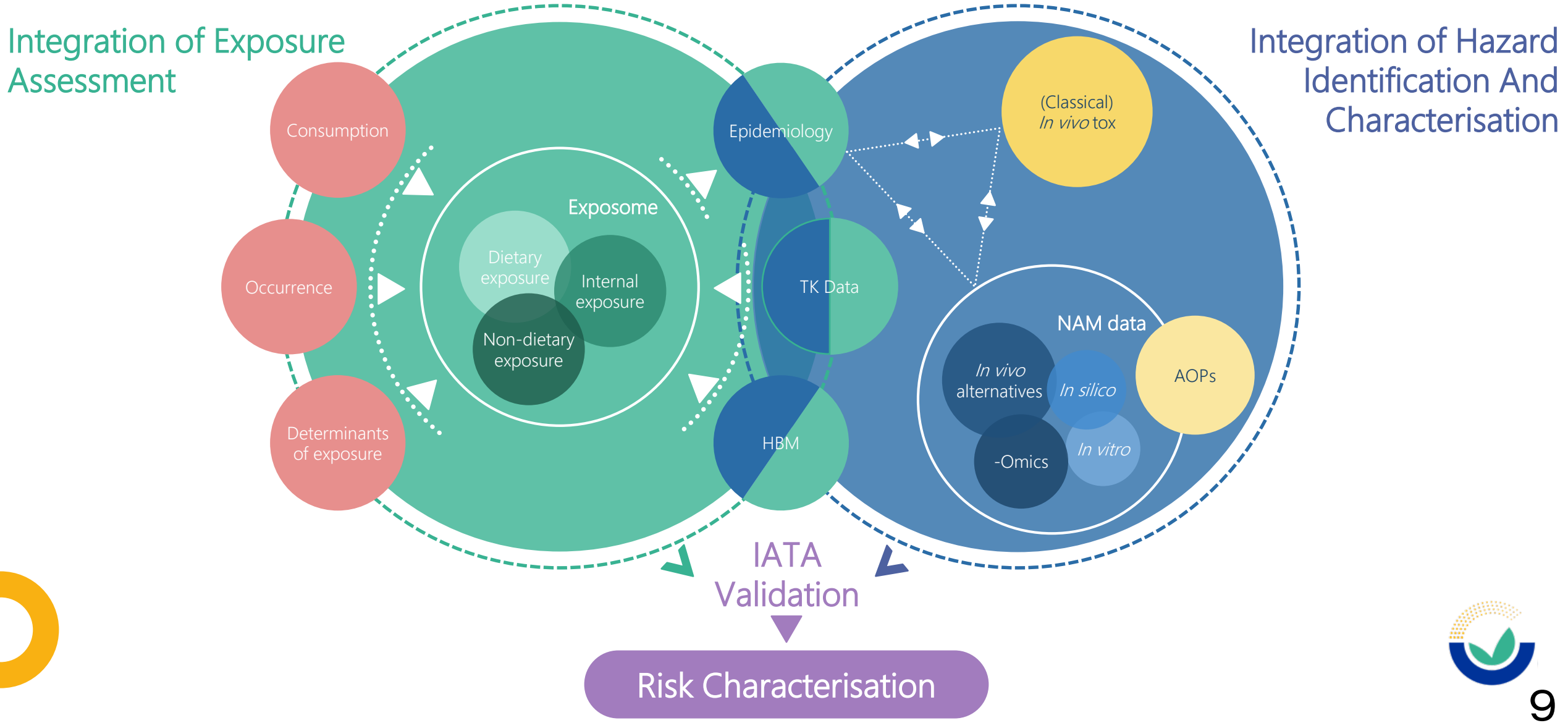
EC Science Policy Interface – Set the ambition!

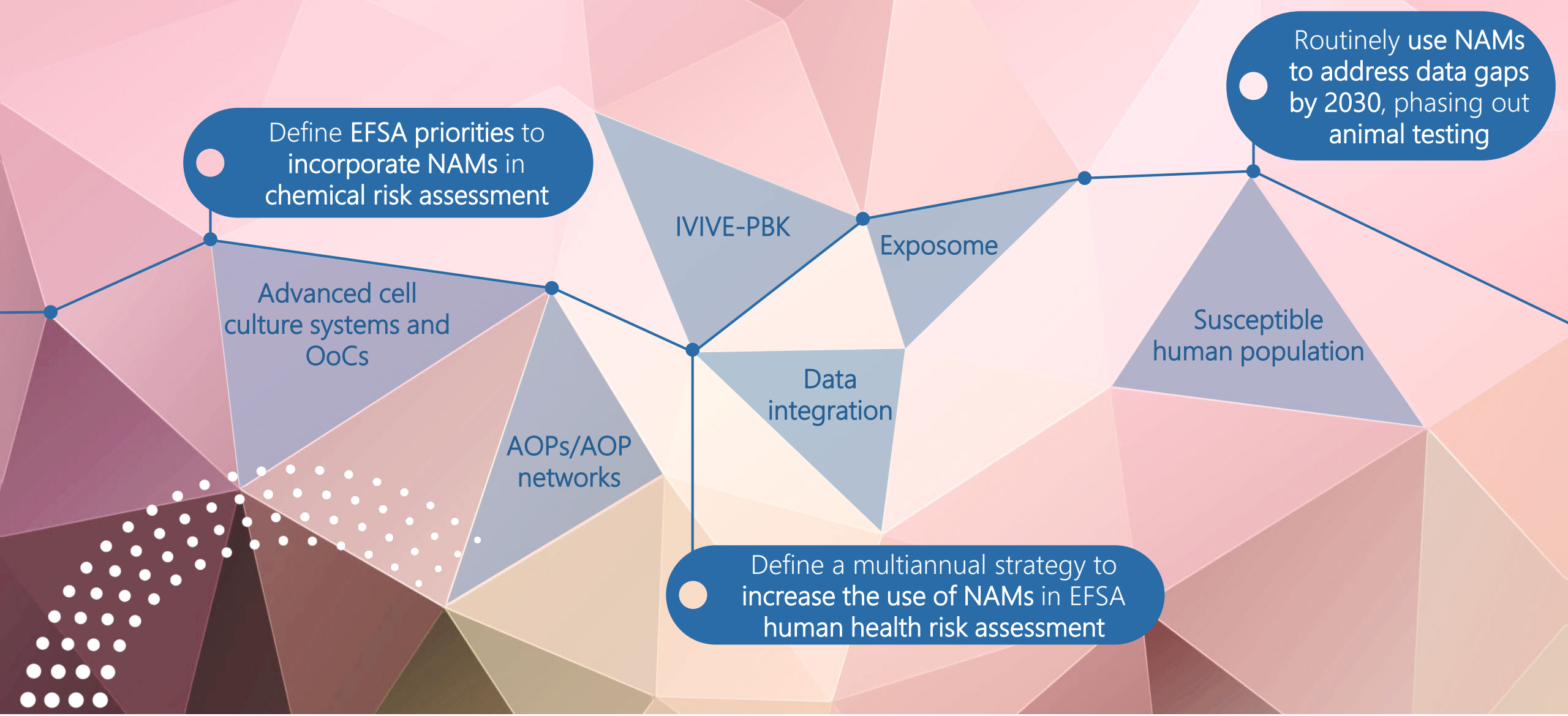
*" The Commission will foster multidisciplinary research and digital innovations for **advanced tools, methods and models, and data analysis capacities** to also move away from animal testing."*

EFSA's current use of NAMs in risk assessment

Regulatory case studies available	NAM is the assessment of comparative metabolism
	NAM for the assessment of developmental neurotoxicity
	NAM for the assessment of chronic neurotoxicity focus on Parkinson diseases
	NAM for the assessment of the endocrine activity using in vitro studies for the evaluation of the ED properties of pesticides
	Chemical mixtures
EFSA Guideline (OECD DNT IVB)	NAM for the assessment of developmental neurotoxicity

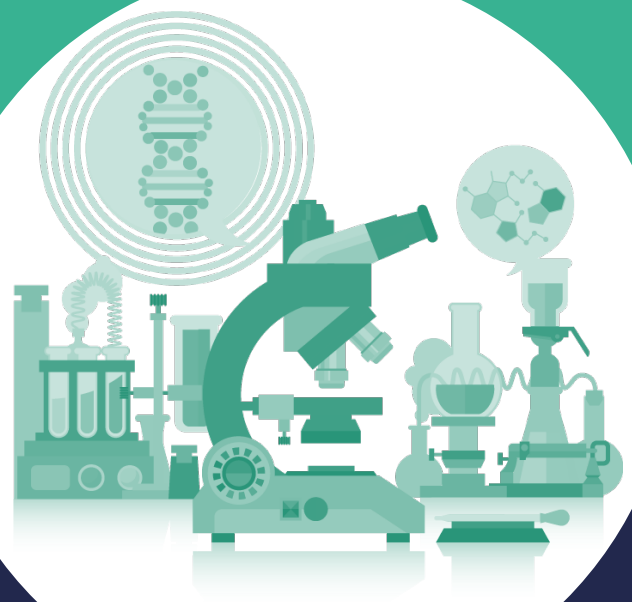
EFSA's VISION





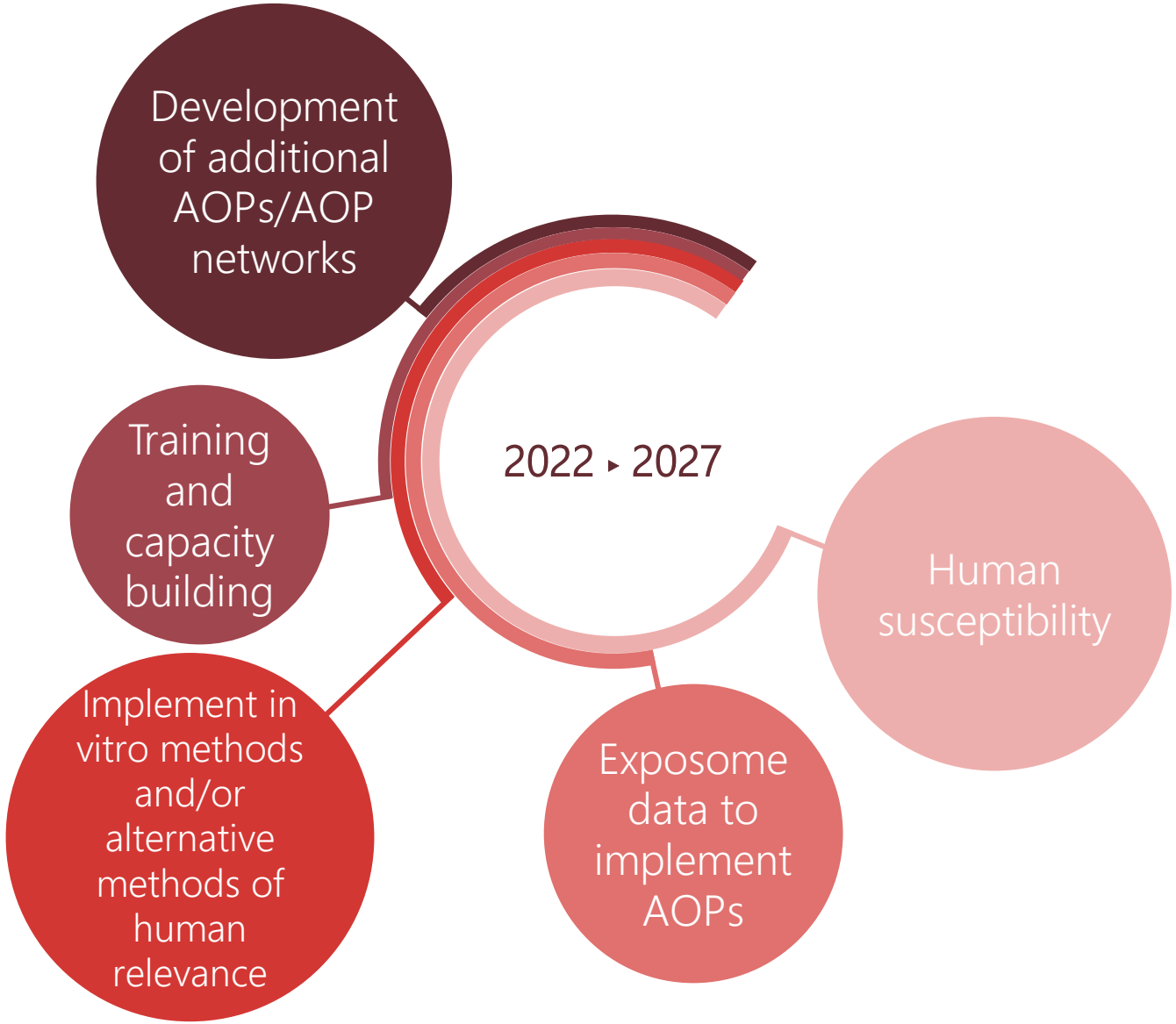
THE PRESENT – NAMS Roadmap for action for development and implementation (Escher *et al.* 2022)

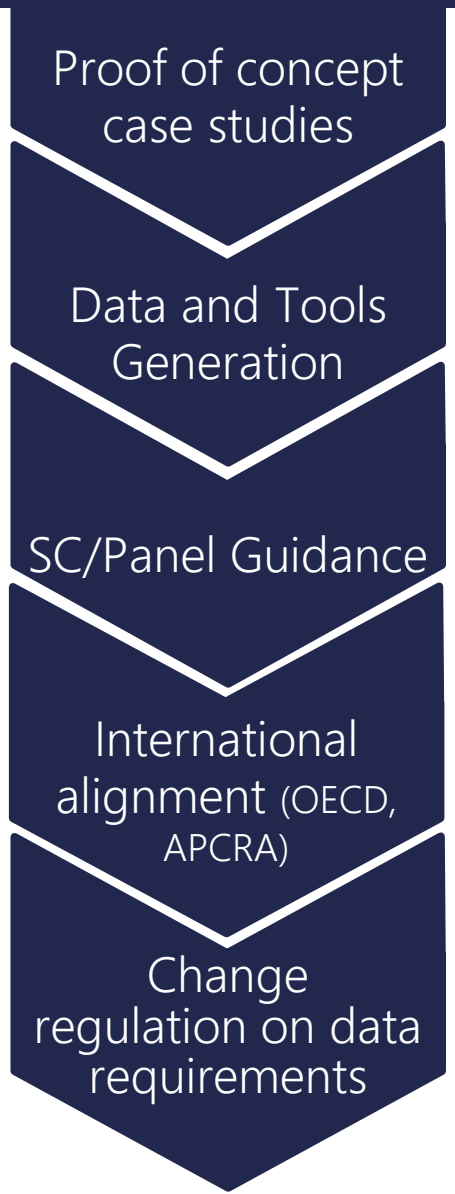
ROADMAP IMPLEMENTATION - WHERE IS EFSA NOW WITH NAMs?



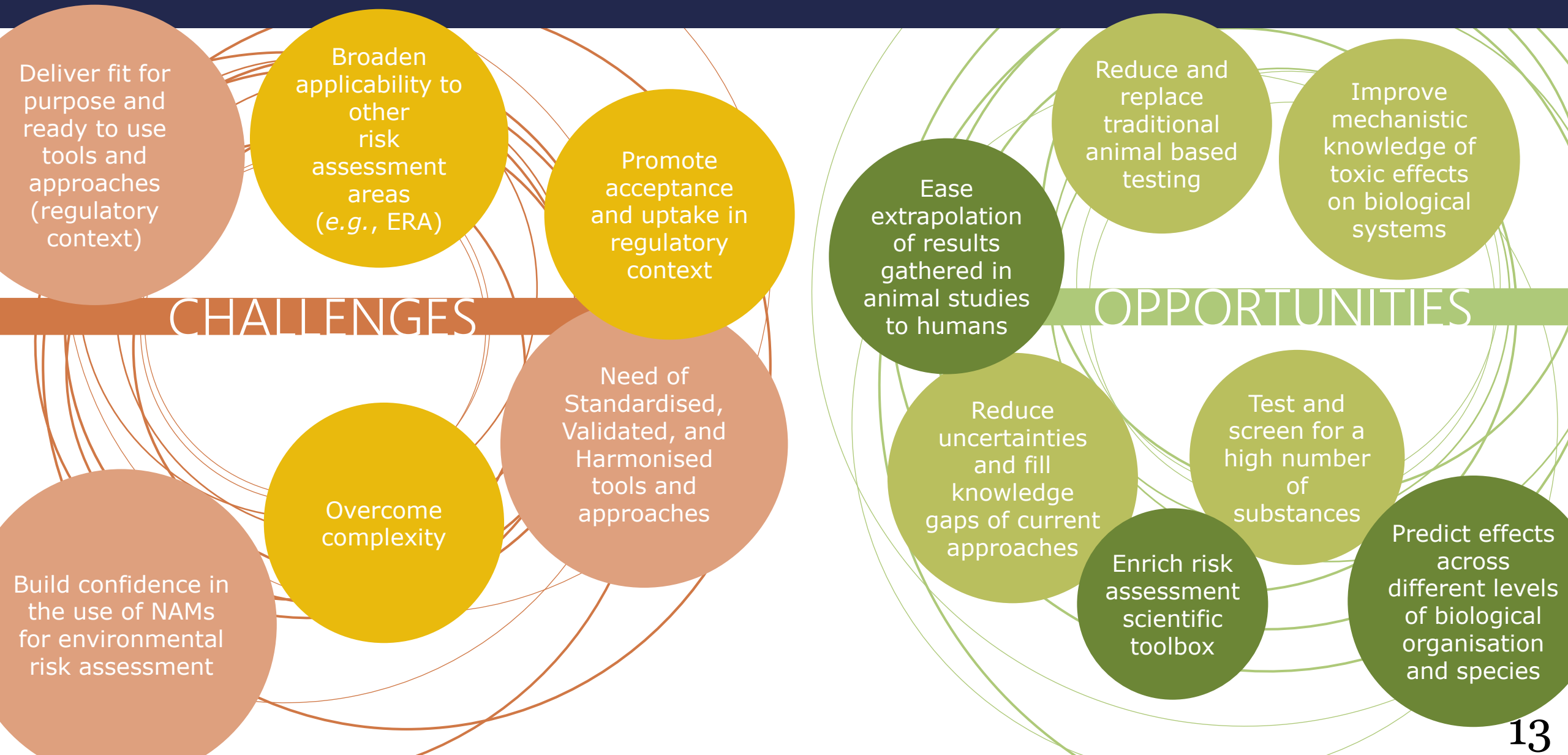
INVESTMENTS	32 EFSA-launched projects
	APCRA, PARC
	Areas addressed: toxicokinetics, toxicodynamic, systems' toxicology, modelling, read-across, data management → **Emphasis on case studies**
	Strong scientific collaboration with US EPA, OECD, JRC,
EFSA Guidance Documents	**OECD DNT IVB**: *in vitro* assays for developmental neurotoxicity

THE FUTURE: EFSA projects on NAMS – Multi annual plan





NAMs – CHALLENGES AND OPPORTUNITIES



EFSA's KNOWLEDGE & INNOVATION COMMUNITY (KIC) ON NAMs

Scientific Consensus

Provide a space of discussion

New methodologies for risk assessment

Their potential contribution to the overall strategic goals of EFSA

Research

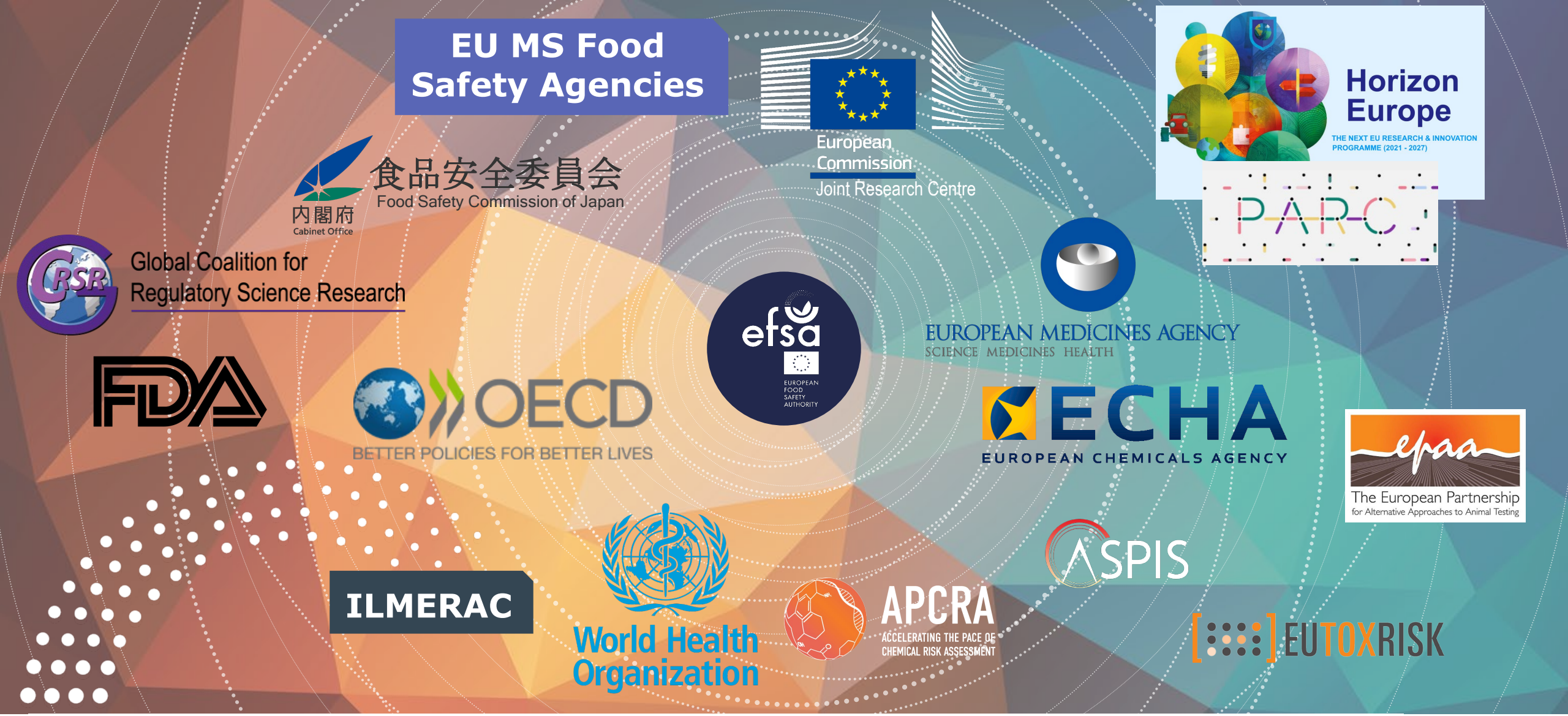
Develop a plan for future activities of NAMs in EFSA

Engagement

Work together with national and international partners, stakeholders, and communities

KIC Coordinator
Carlos das Neves

KIC Manager
Andrea Terron



STRONGER TOGETHER
EFSA EUROPEAN AND INTERNATIONAL ENGAGEMENT LANDSCAPE on NAMS

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