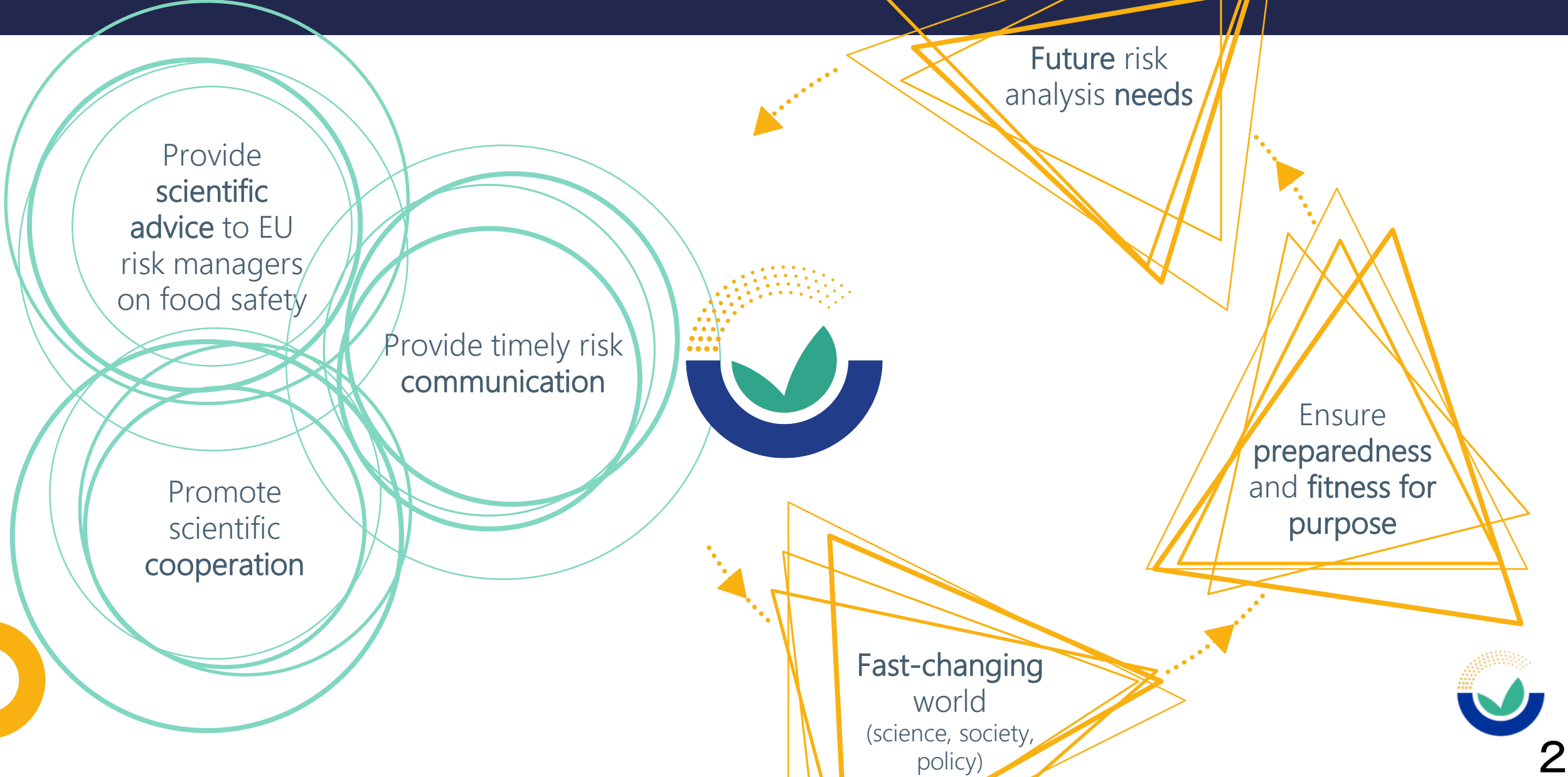


IMPLEMENTING NEW APPROACH METHODOLOGIES: CHALLENGES & OPPORTUNITIES

Food & Feed Regulatory Context

Carlos das Neves
Chief Scientist

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)

Evolve methods/models/tools

To Increase knowledge and improve risk assessment

Support paradigm shift



Scientific Development

Fast growth

Quick advancement

Increase of available toolbox



EC Policy ► EU Chemical Strategy for Sustainability

"[...] to reduce dependency on animal testing but also to improve the quality, efficiency and speed of chemical risk assessment."

Challenge the current legislation on data requirements with the inclusion of alternative methods to replace animal testing

For areas not yet covered by legal bases on NAMs' use

ROADMAP FOR ACTION ON NAMs

TEST
(multi-omics, in silico, in vitro, AOPs, organoids, grouping, PBPK, human models)

INTEGRATE
Conclusions on MoA/thresholds into an IATA system

NAMs Landscape
EFSA collaborations

EFSA STRATEGY 2027

Strategic Objective 2 – Key Actions
Develop and integrate new approach methodologies (NAMs) and omics for regulatory risk assessment

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)*

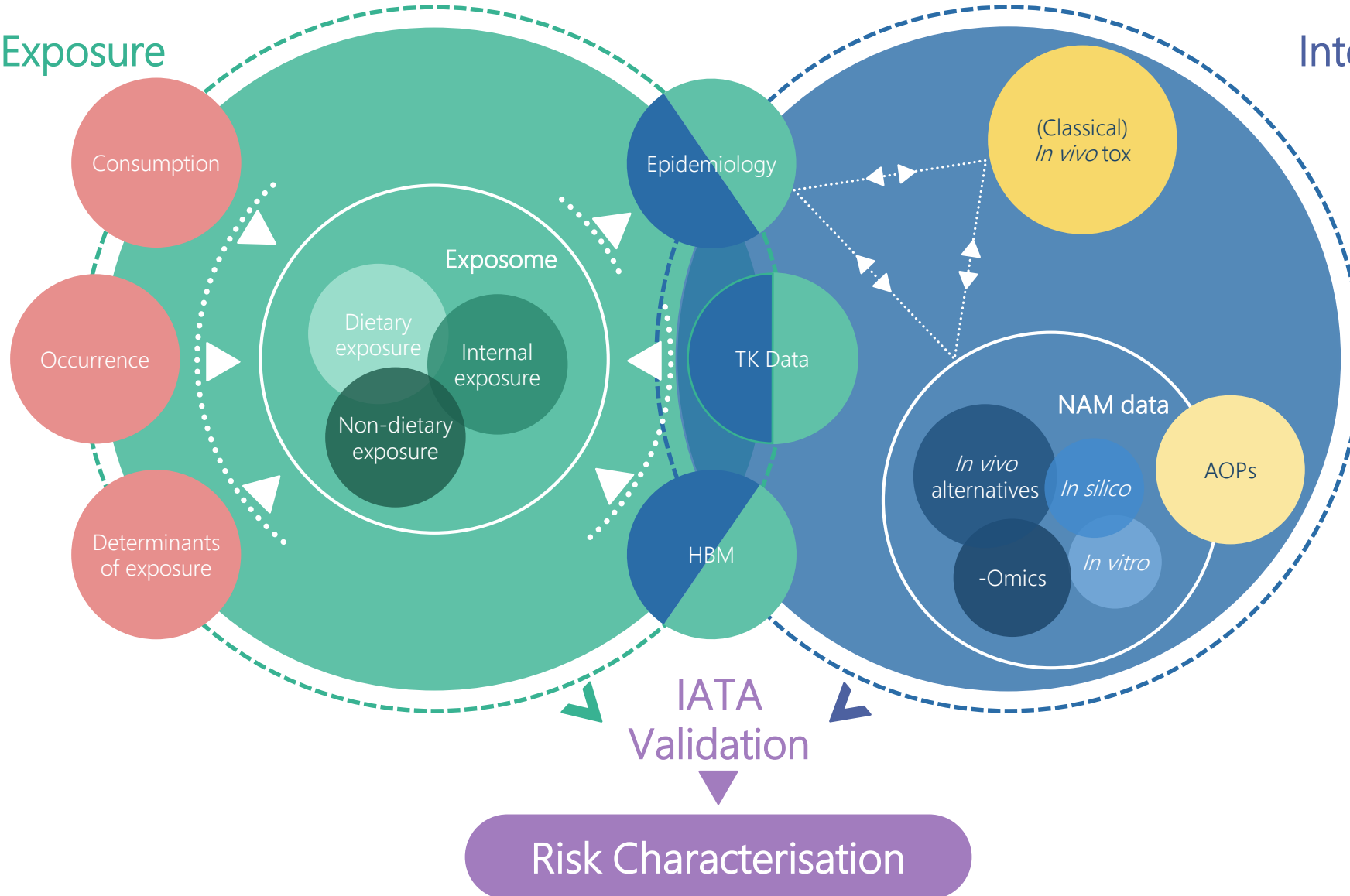
NAM for the assessment of developmental neurotoxicity

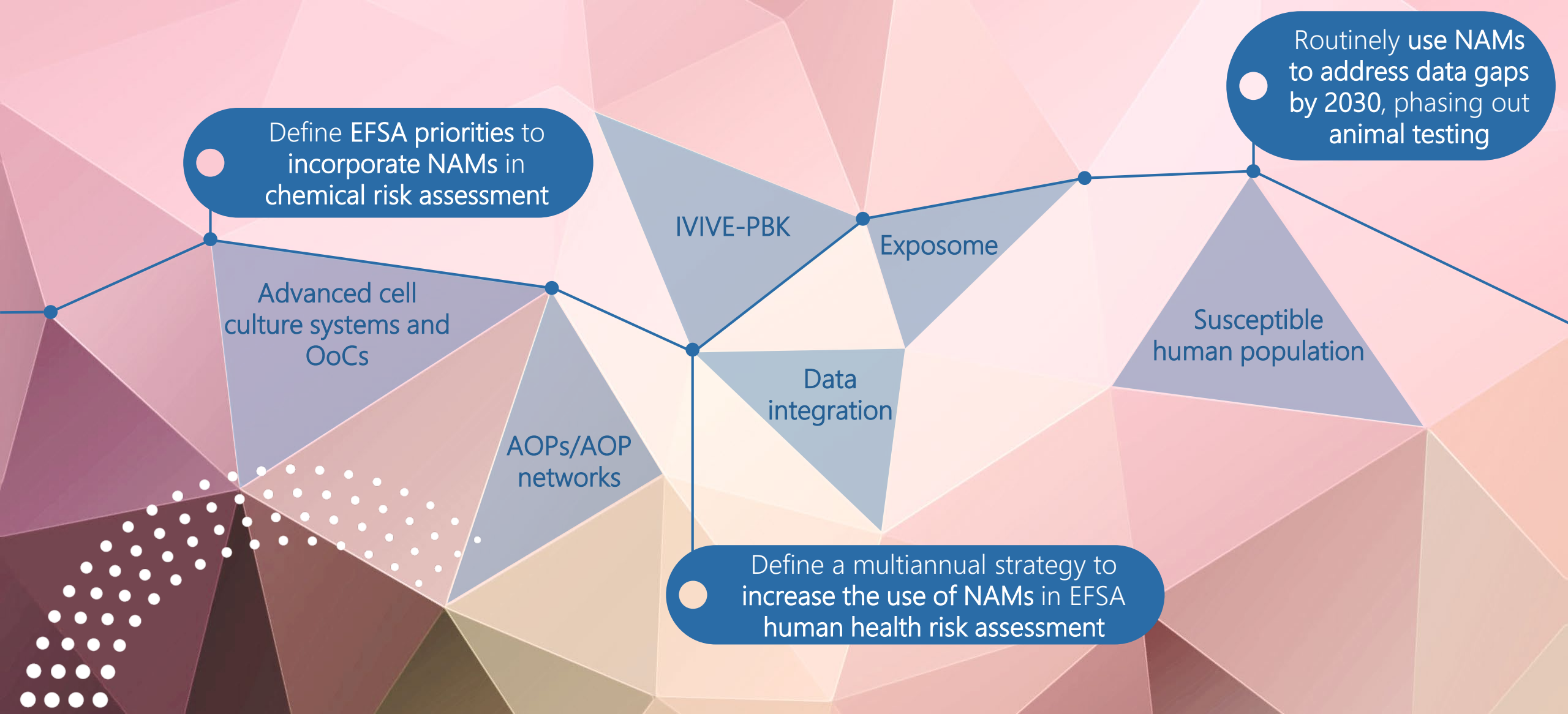


EFSA's VISION

Integration of Exposure Assessment

Integration of Hazard Identification And Characterisation





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

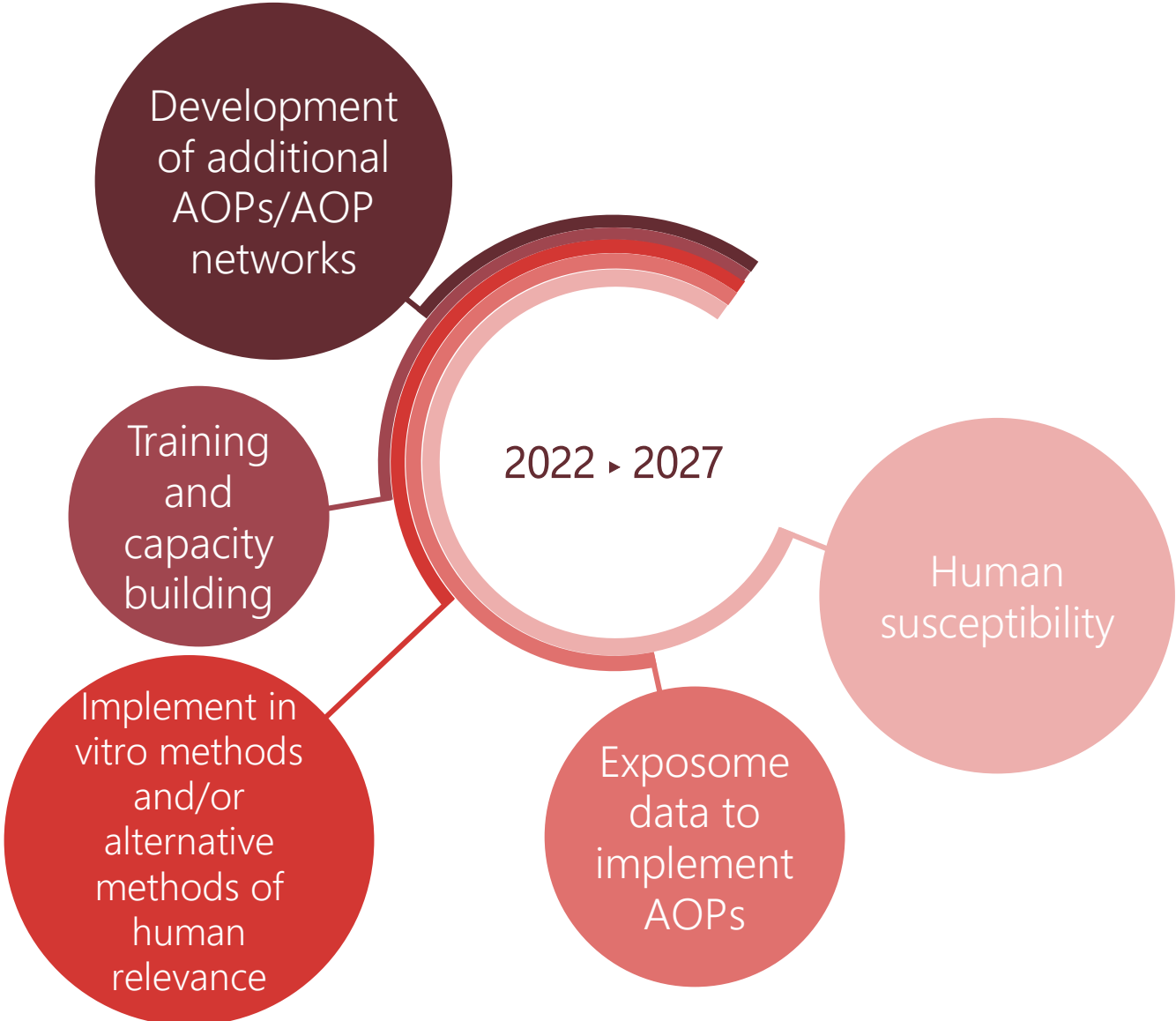
Strong scientific collaboration with US EPA, OECD, JRC,

EFSA Guidance Documents

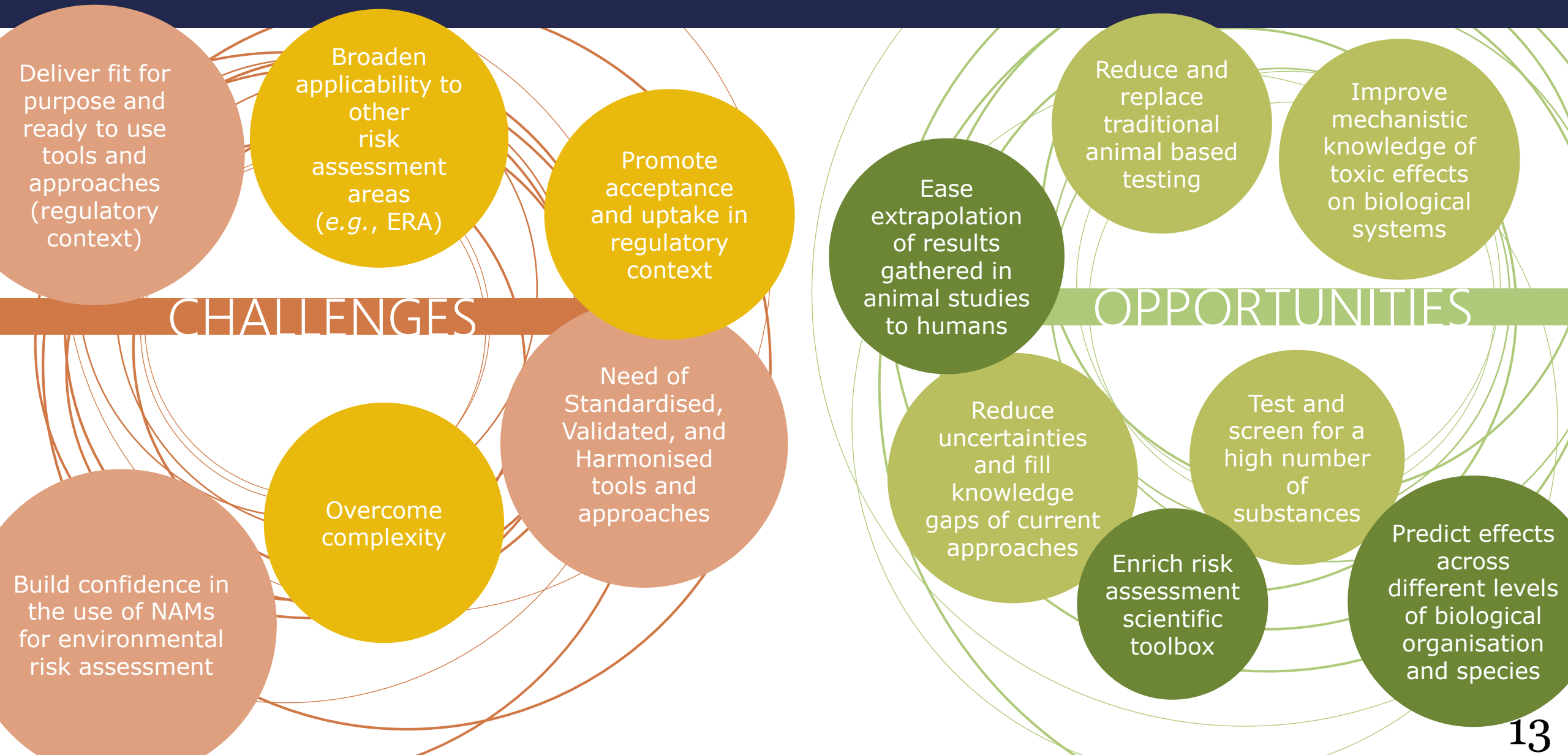
OECD DNT IVB: *in vitro* assays for developmental neurotoxicity



THE FUTURE: EFSA projects on NAMS – Multi annual plan



NAMs – CHALLENGES AND OPPORTUNITIES



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



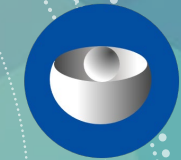
KIC Coordinator
Carlos das Neves



KIC Manager
Andrea Terron



EU MS Food Safety Agencies



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



World Health Organization



APCRA
ACCELERATING THE PACE OF
CHEMICAL RISK ASSESSMENT



STRONGER TOGETHER
EFSA EUROPEAN AND INTERNATIONAL ENGAGEMENT LANDSCAPE
on NAMS



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