The European Partnership on Alternative Approaches to Animal Testing (EPAA) – Activities to Implement the Roadmap

Dr Katia Lacasse, EPAA Industry Co-chair / Cefic

21-22 October 2026, EFSA/ECHA Roadmap Implementation Workshop

Making the Roadmap a Reality: the Role of EPAA

- The Commission presented the roadmap and its ambition
- The challenge is now implementation
- Phasing out animal testing is not only a scientific challenge but also a regulatory, organisational and societal challenge
- EPAA's role is to help bridge these gaps



European Partnership for Alternative Approaches to Animal Testing (EPAA)

The European Partnership for Alternative Approaches to Animal Testing

Collaboration between European Commission and Industry stakeholders from 9 sectors (est. 2005)

Vision: The replacement, reduction and refinement (3Rs) of animal use for meeting regulatory requirements through better & more predictive science (e.g. New Approach Methodologies (NAMs)).

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43 Companies (including 1 SME)

symrise, Gowan, novonesis, L'ORÉAL, DSM, Dow, LVMH, essity, Boehringer Ingelheim, HUNTSMAN, CLARIANT, ExxonMobil, dsm-firmenich, CHANEL, AstraZeneca, EVONIK, Beiersdorf, SERVIER, P&G, Unilever, COLGATE-PALMOLIVE, Henkel, BAYER, ADAMA, CORTEVA agriscience, Reckitt Benckiser, novo nordisk, NOVARTIS, MANE, GSK, MERCK, Takeda, zoetis, SOLVAY, stratiell, REVLON, sanofi, BASF, ESTĒE LAUDER, KANEBO, Johnson & Johnson, syngenta, SHISEIDO

5 DG's of the EC

European Commission

- DG GROW
- DG ENV
- DG SANTE
- DG JRC
- DG RTD

Including Partner Agencies

ECHA EUROPEAN CHEMICALS AGENCY, efsa, EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

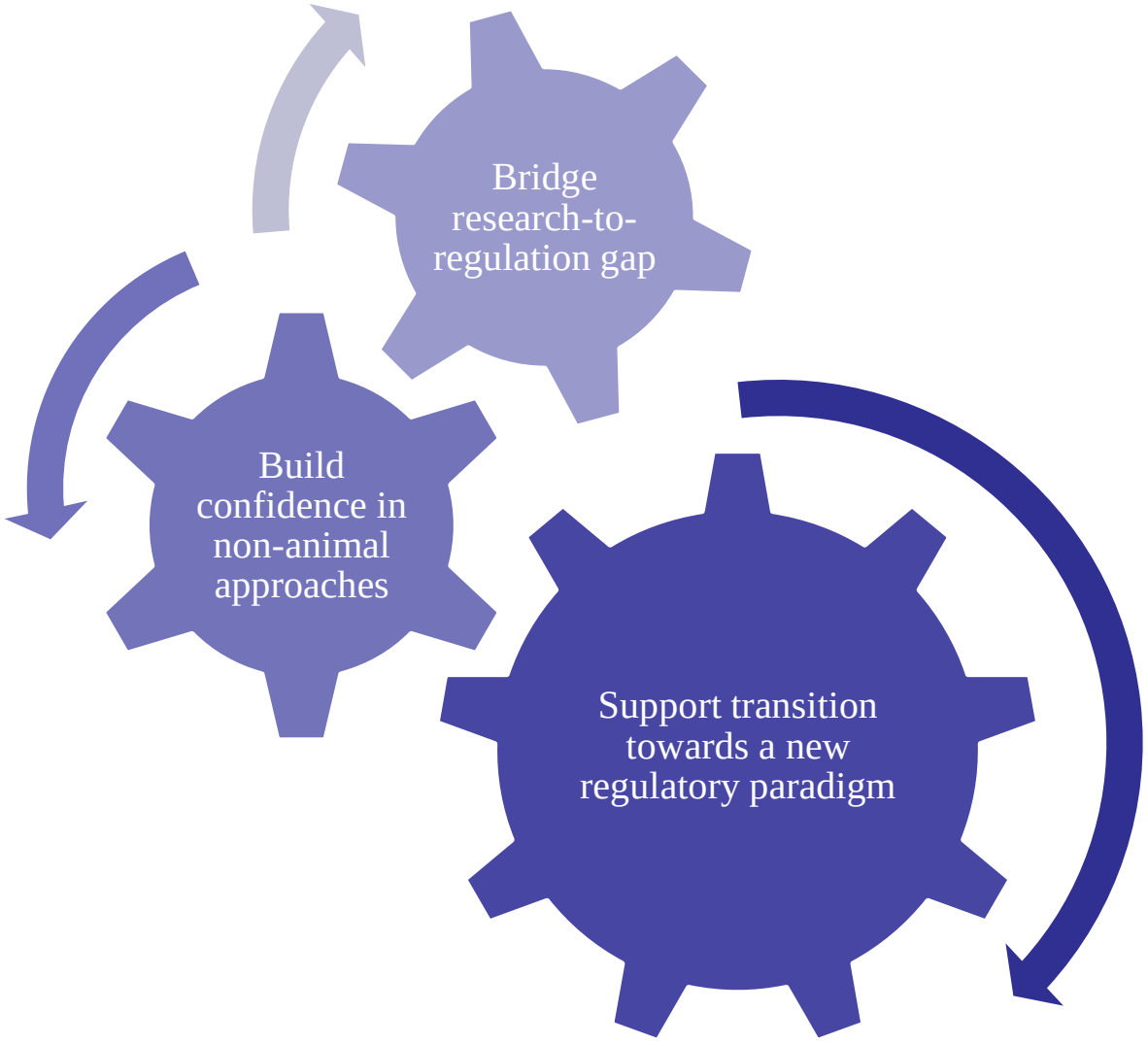
10 Sectoral Associations

animalhealth europe, cefic, Cosmetics Europe the personal care association, CropLife EUROPE, DETERGENTS EUROPE, efpia European Federation of Pharmaceutical Industries and Associations, FOODDRINK EUROPE, ifra, IOFI, sme united

Mirror Group *(Advisory body)*

Experts from national 3Rs organisations, academia, animal welfare NGOs and Sirpa Pietikaïnen (MEP)

Why EPAA matters for the Roadmap?



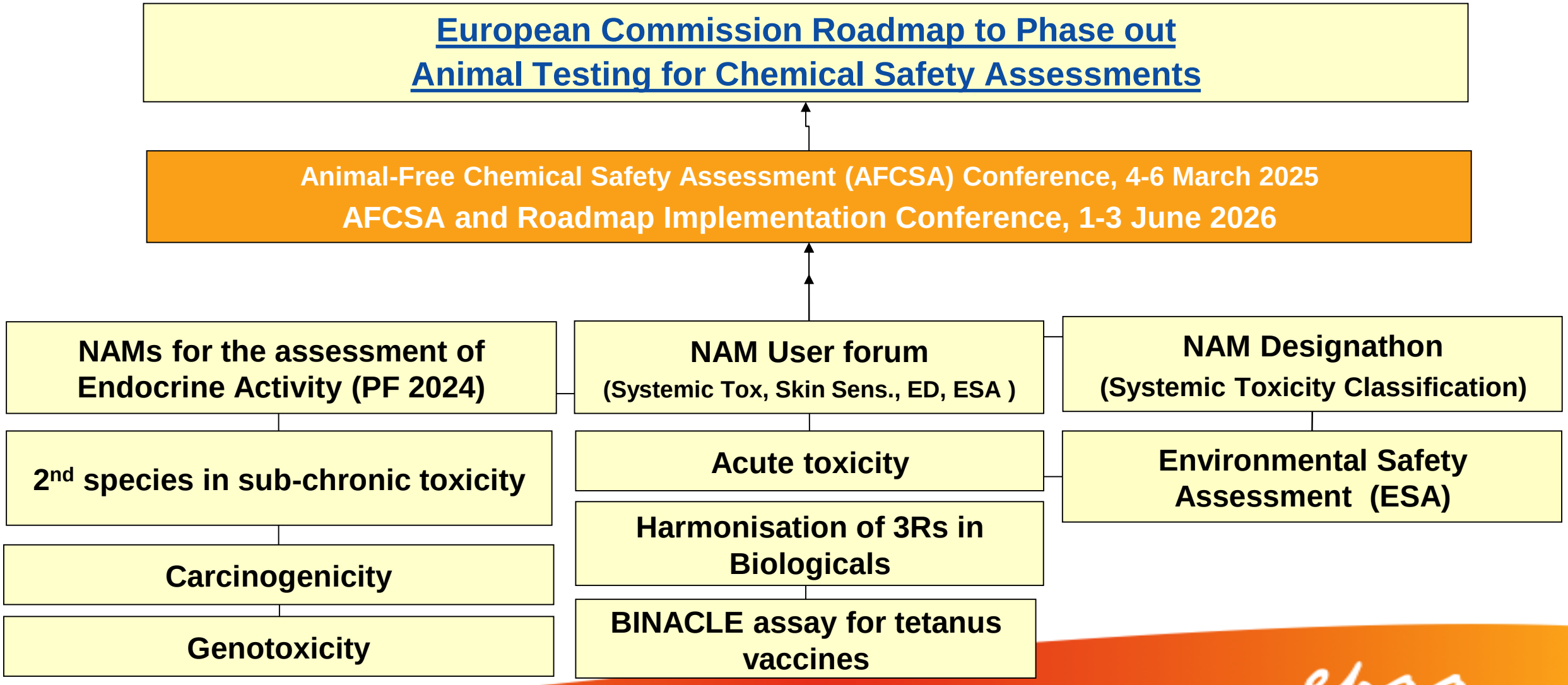
The roadmap identifies what needs to happen

EPAA provides a platform where regulators, scientists and users of the methods can work together to make it happen

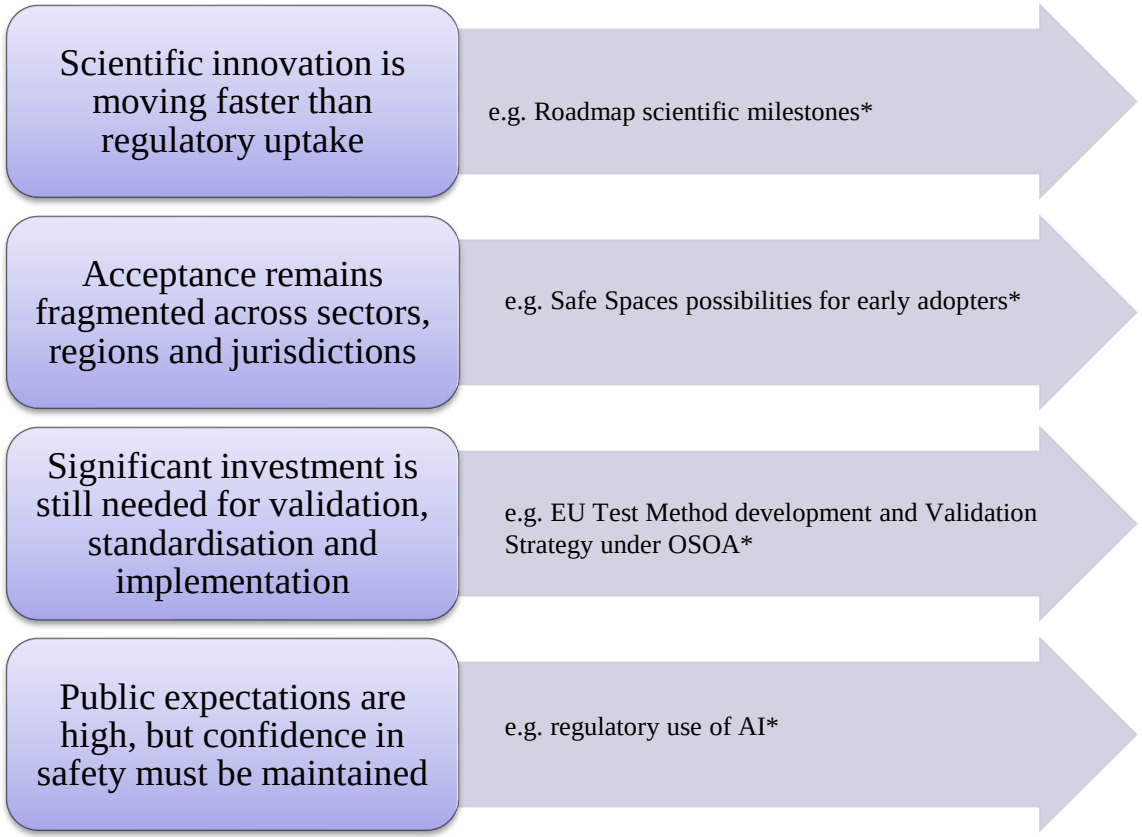
Key contributions:

- **Landscaping scientific developments** of New Approach Methodologies (NAMs) and their **fitness-for-regulatory use**
- Generating regulatory **case studies**
- **Sharing** practical experience across industry sectors and regulatory frameworks
- Enabling regulatory **dialogue**, e.g. contributing to ECHA Collaborative Platform to Alternatives to Animal Testing (CP-AAT) and Roadmap Steering Committee

EPAA 2026 activities



Challenges that still need solving

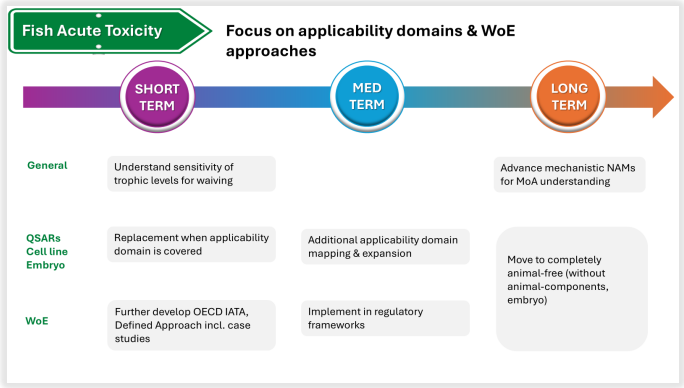


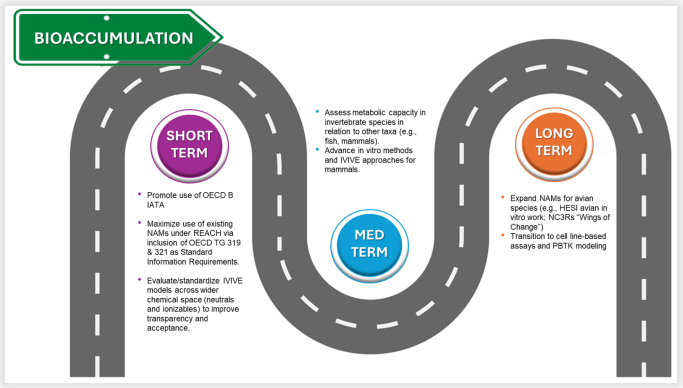
Success will not rest on science alone.

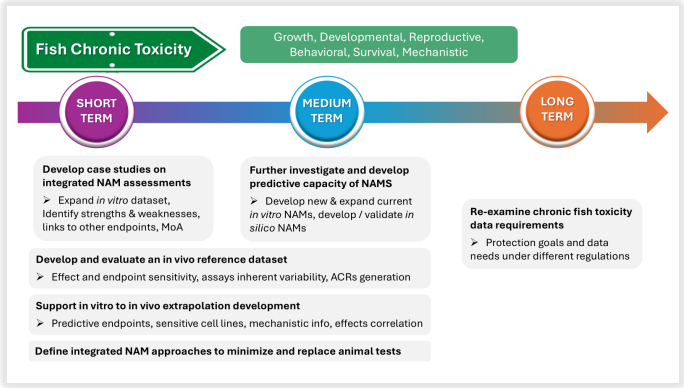
It depends just as much on sustained political support to turn evidence into regulation, funding and lasting implementation.

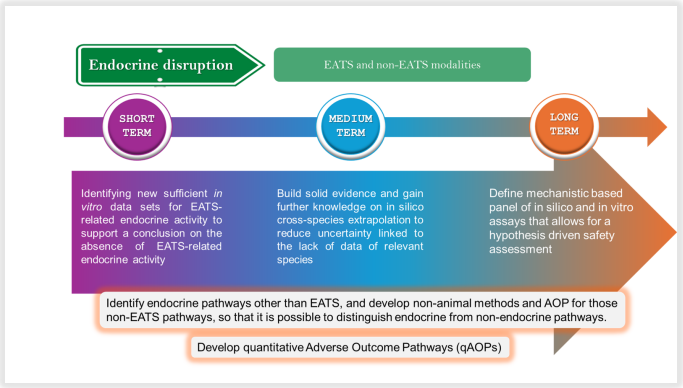
*These key themes were covered at recent EPAA Animal Free Chemical Safety Conference (AF-CSA)

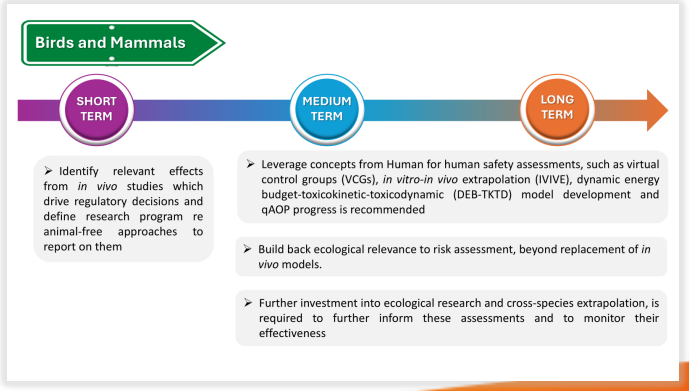
Environmental Safety Assessment (ESA)

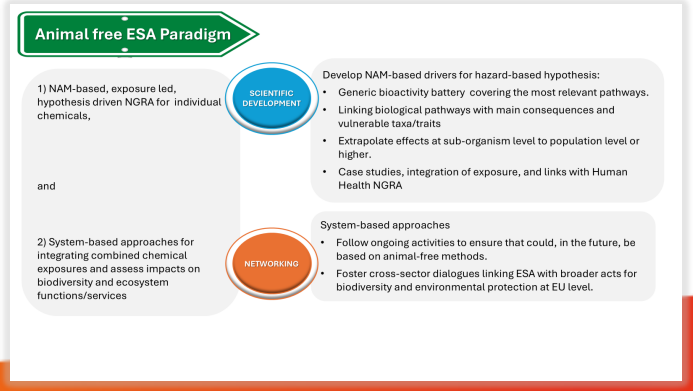












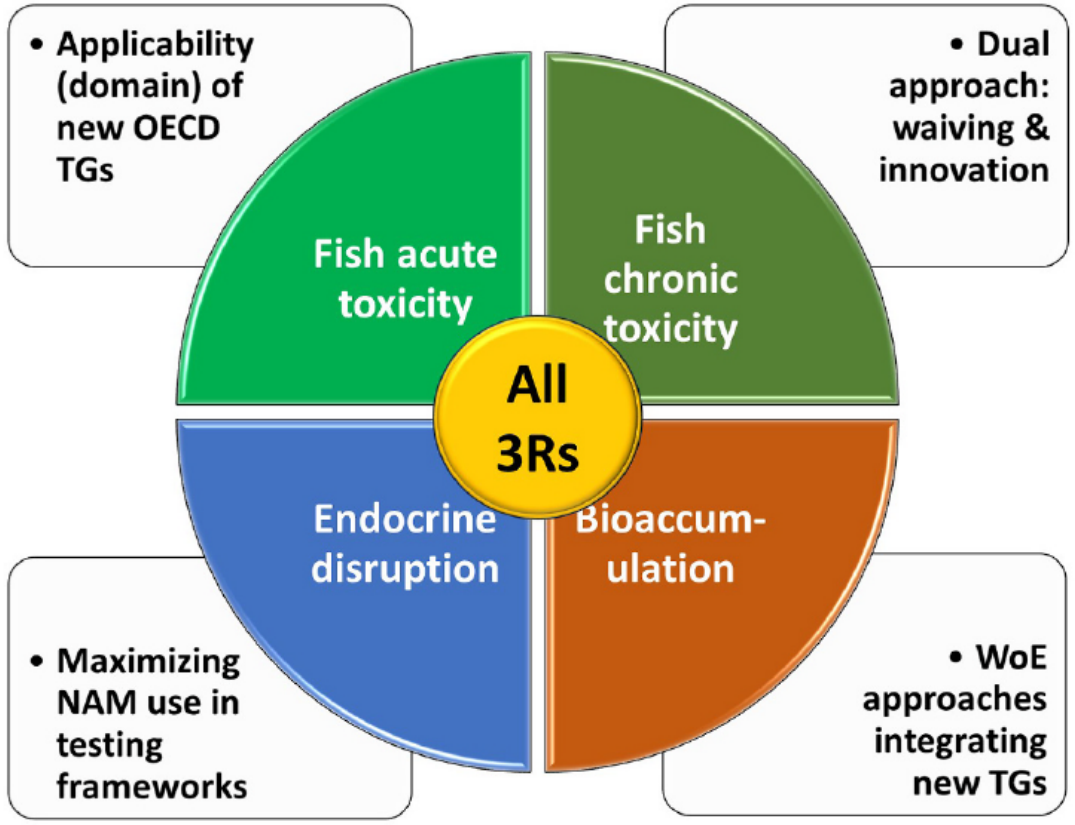
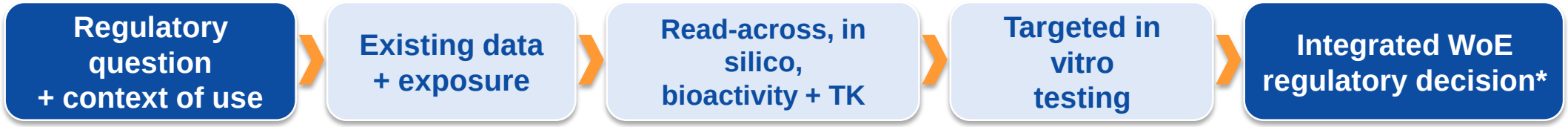


Fig. 1. Main priority areas and proposed actions, to be complemented with a long-term initiative for developing a new ESA paradigm.

Human Health Safety Assessment (HH)

From endpoint replacement to integrated, exposure-informed and hypothesis-driven assessment



*Follow up animal testing not an option for all sectors!

EPAA implementation priorities

Acute toxicity	Genotoxicity	Carcinogenicity	Repeated-dose systemic toxicity	DNT / DART
Explore waiving opportunities, remove roadblocks for refinement strategies, support implementation of computational approaches	Build confidence in targeted strategies to reduce *in vivo* follow-up	Coordinate a cross-sector NAM-based framework and route to regulatory use	Connect Designathon, TK/PBK, OECD and case-study activities	Support DART ISTNET and Roadmap activities that build on DNT maturity and map gaps and frameworks for DART

Cross-cutting enablers (e.g. User Forum): regulatory case studies • applicability domains and uncertainty • regulator engagement • data sharing • international alignment

Sources: EPAA June 2026 AFCSA Roadmap Implementation Conference report

Activities of specific relevance for PPP/BPR

- Acute toxicity testing
- Skin Sensitisation User Forum (applying non-animal strategies for assessing skin sensitisation)
- Carcinogenicity of Agrochemicals, expanded to carcinogenicity assessment framework project
- 2nd species for sub-chronic toxicity
- Tools to support application of physiologically-based kinetic modelling (PBK) (completed project)
- …..

- More on projects and activities
  - on Project platform - Internal Market, Industry, Entrepreneurship and SMEs
  - 2026 Annual Report (soon to come, stay tuned)
  - Publications in NAM Journal Special Issue (soon to come)



2026 Annual conference of the European Partnership for Alternative Approaches to Animal Testing (EPAA)

Implementing the Roadmap: Working together in the EU and beyond

CONFERENCES AND SUMMITS

Register here

Book your seat, 3 weeks left to register, registration will end on Monday 2 November 2026, 17:00 (CET)

animal experimentation | chemicals legislation

Tuesday 17 November 2026, 10:00 - 17:00 (CET)

Live streaming available

Practical information

When	Tuesday 17 November 2026, 10:00 - 17:00 (CET)
Where	Albert Borschette Congress Center, Rue Froissart 36, 1040 Brussels, Belgium
Livestream	Starts on Tuesday 17 November 2026, 10:00 (CET)

Thank you!

- EPAA connects scientific progress with targeted regulatory implementation
- Human Health and Environmental projects translate Roadmap actions into practical case studies
- Confidence will grow through shared evaluation and learnings, early dialogue and international alignment

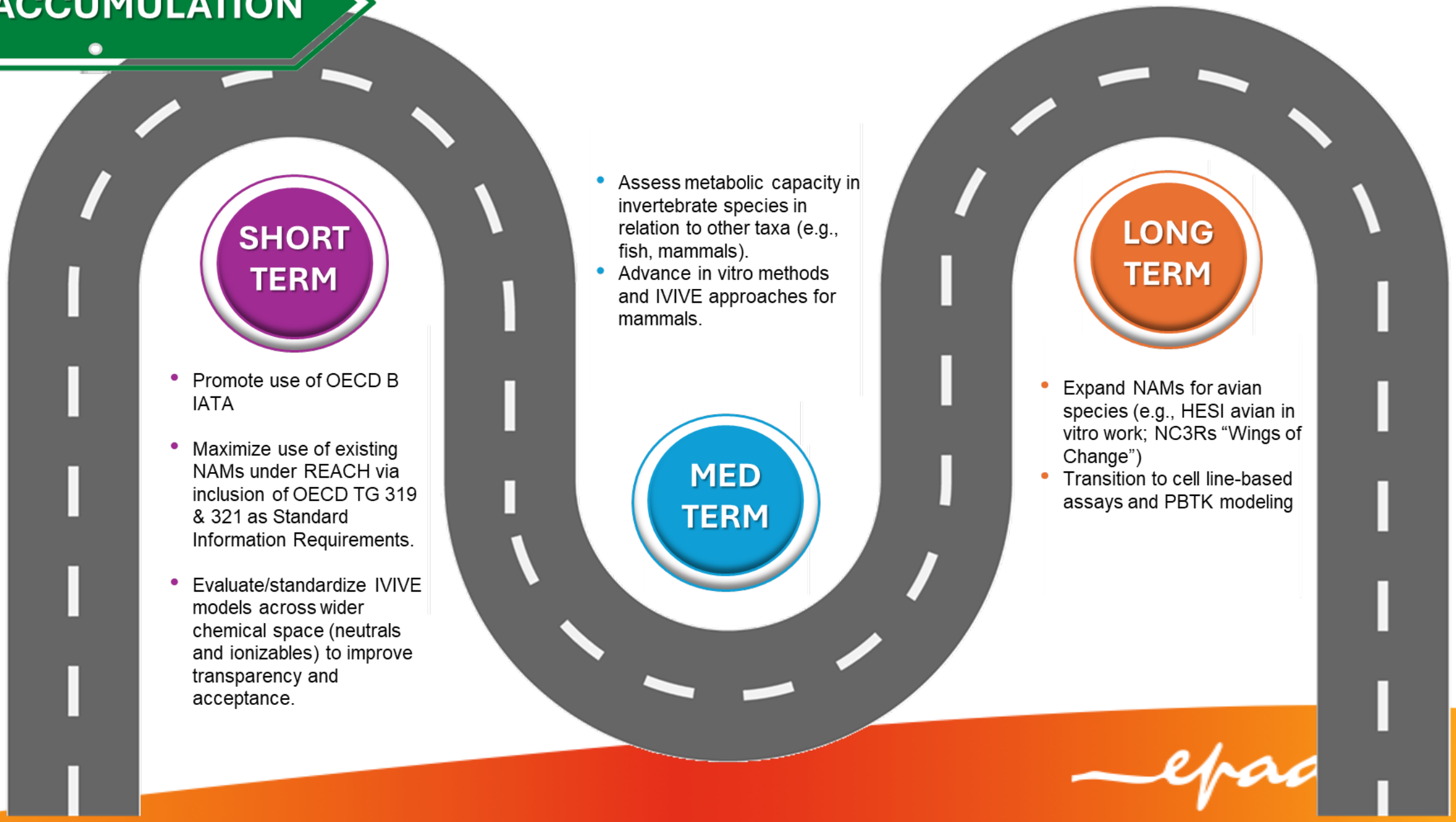
Back up slides

Fish Acute Toxicity

Focus on applicability domains & WoE approaches

	SHORT TERM	MED TERM	LONG TERM
General	Understand sensitivity of trophic levels for waiving		Advance mechanistic NAMs for MoA understanding
QSARs Cell line Embryo	Replacement when applicability domain is covered	Additional applicability domain mapping & expansion	Move to completely animal-free (without animal-components, embryo)
WoE	Further develop OECD IATA, Defined Approach incl. case studies	Implement in regulatory frameworks	

BIOACCUMULATION



SHORT TERM

- Promote use of OECD B IATA
- Maximize use of existing NAMs under REACH via inclusion of OECD TG 319 & 321 as Standard Information Requirements.
- Evaluate/standardize IVIVE models across wider chemical space (neutrals and ionizables) to improve transparency and acceptance.

MED TERM

- Assess metabolic capacity in invertebrate species in relation to other taxa (e.g., fish, mammals).
- Advance in vitro methods and IVIVE approaches for mammals.

LONG TERM

- Expand NAMs for avian species (e.g., HESI avian in vitro work; NC3Rs “Wings of Change”)
- Transition to cell line-based assays and PBTK modeling

Fish Chronic Toxicity

Growth, Developmental, Reproductive, Behavioral, Survival, Mechanistic

SHORT TERM

MEDIUM TERM

LONG TERM

Develop case studies on integrated NAM assessments

- Expand *in vitro* dataset, Identify strengths & weaknesses, links to other endpoints, MoA

Further investigate and develop predictive capacity of NAMS

- Develop new & expand current *in vitro* NAMs, develop / validate *in silico* NAMs

Re-examine chronic fish toxicity data requirements

- Protection goals and data needs under different regulations

Develop and evaluate an in vivo reference dataset

- Effect and endpoint sensitivity, assays inherent variability, ACRs generation

Support in vitro to in vivo extrapolation development

- Predictive endpoints, sensitive cell lines, mechanistic info, effects correlation

Define integrated NAM approaches to minimize and replace animal tests

Endocrine disruption

EATS and non-EATS modalities

SHORT TERM

Identifying new sufficient *in vitro* data sets for EATS-related endocrine activity to support a conclusion on the absence of EATS-related endocrine activity

MEDIUM TERM

Build solid evidence and gain further knowledge on in silico cross-species extrapolation to reduce uncertainty linked to the lack of data of relevant species

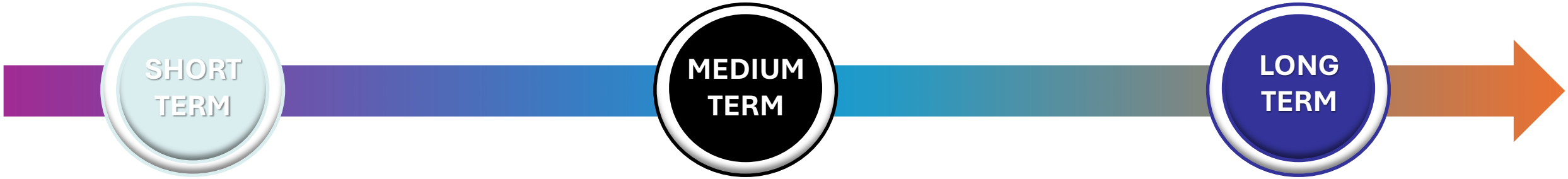
LONG TERM

Define mechanistic based panel of in silico and in vitro assays that allows for a hypothesis driven safety assessment

Identify endocrine pathways other than EATS, and develop non-animal methods and AOP for those non-EATS pathways, so that it is possible to distinguish endocrine from non-endocrine pathways.

Develop quantitative Adverse Outcome Pathways (qAOPs)

Birds and Mammals



- Identify relevant effects from *in vivo* studies which drive regulatory decisions and define research program re animal-free approaches to report on them

- Leverage concepts from Human for human safety assessments, such as virtual control groups (VCGs), *in vitro-in vivo* extrapolation (IVIVE), dynamic energy budget-toxicokinetic-toxicodynamic (DEB-TKTD) model development and qAOP progress is recommended

- Build back ecological relevance to risk assessment, beyond replacement of *in vivo* models.

- Further investment into ecological research and cross-species extrapolation, is required to further inform these assessments and to monitor their effectiveness

Animal free ESA Paradigm

1) NAM-based, exposure led, hypothesis driven NGRA for individual chemicals,

and

2) System-based approaches for integrating combined chemical exposures and assess impacts on biodiversity and ecosystem functions/services

SCIENTIFIC DEVELOPMENT

Develop NAM-based drivers for hazard-based hypothesis:

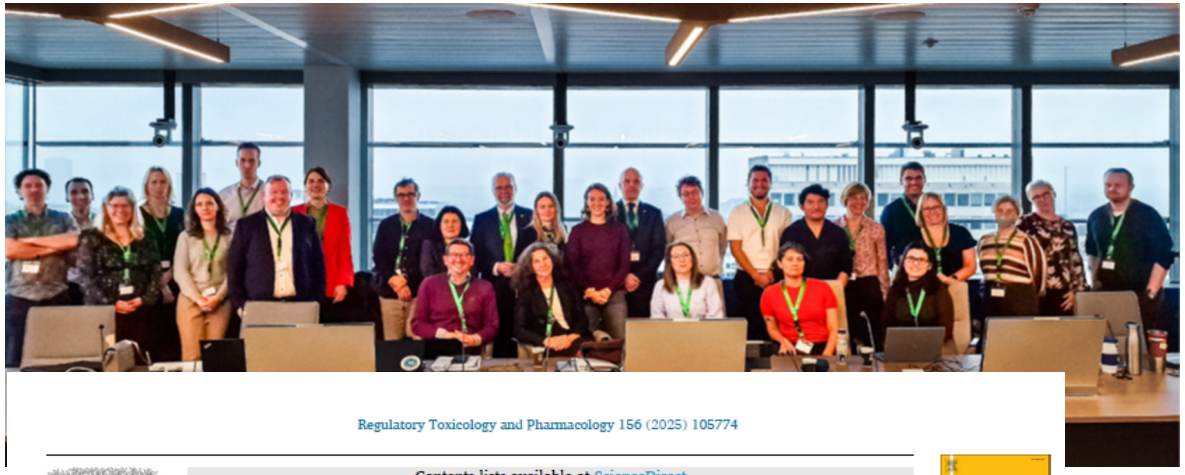
- Generic bioactivity battery covering the most relevant pathways.
- Linking biological pathways with main consequences and vulnerable taxa/traits
- Extrapolate effects at sub-organism level to population level or higher.
- Case studies, integration of exposure, and links with Human Health NGRA

NETWORKING

System-based approaches

- Follow ongoing activities to ensure that could, in the future, be based on animal-free methods.
- Foster cross-sector dialogues linking ESA with broader acts for biodiversity and environmental protection at EU level.

Background: EPAA Partners Forum on ESA



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Contents lists available at ScienceDirect

Regulatory Toxicology and Pharmacology

journal homepage: www.elsevier.com/locate/yrtph

Use of alternatives to animal testing for Environmental Safety Assessment (ESA): Report from the 2023 EPAA partners' forum

Jose V. Tarazona [a,*], Ana Fernandez-Agudo [a], Ondrej Adamovsky [b], Marta Baccaro [c], Natalie Burden [d], Bruno Campos [e], Björn Hidding [f], Karen Jenner [g], David John [h], Katia Lacasse [i], Adam Lillicrap [j], Delina Lyon [k], Samuel K. Maynard [l], Amelie Ott [m], Veronique Poulsen [n], Mike Rasenberg [o], Katrin Schutte [p], Marta Sobanska [o], James R. Wheeler [q]

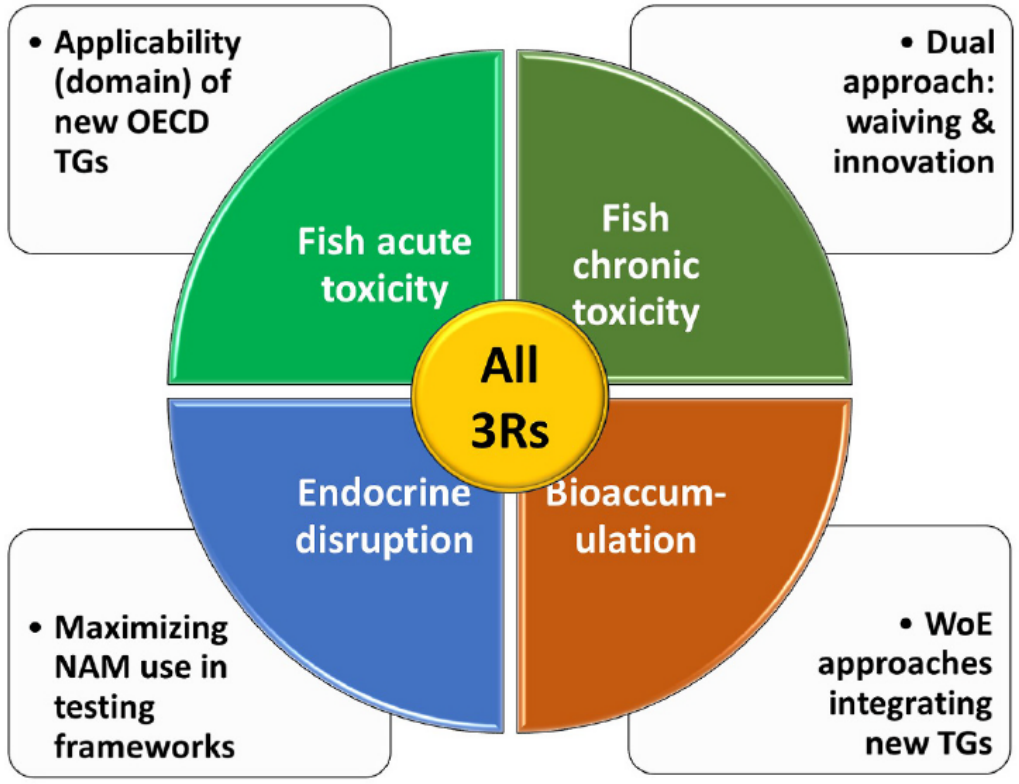


Fig. 1. Main priority areas and proposed actions, to be complemented with a long-term initiative for developing a new ESA paradigm.

DOI:10.1016/j.yrtph.2025.105774

Bruno

Acute toxicity

Human Health roadmap implementation project

Roadmap objective	Workshop priorities	EPAA implementation focus
Move from traditional acute animal tests towards computational and weight-of-evidence approaches that can support regulatory decisions.	Map how acute toxicity information is used across EU legislation Complete evaluation of computational approaches such as CATMoS Identify substances outside current model applicability domains Address remaining regulatory and scientific gaps	Support dissemination, training and practical case studies Engage with ECHA CP-AAT and Member State assessors Contribute implementation evidence for Annex XI and future UN GHS discussions Promote refined testing only where non-animal evidence is insufficient

Near-term opportunity: focus on implementation, usability domains and regulatory learning.

Sources: June 2026 HH breakout conclusions and EPAA AFCSA conference report

Genotoxicity

Human Health roadmap implementation project

Roadmap objective	Workshop priorities	EPAA implementation focus
Expand the regulatory use of non-animal strategies and reduce in vivo follow-up testing across sectors.	Review where legislation still triggers in vivo follow-up Map ongoing European and international non-animal initiatives Explore expanded use of in silico and targeted testing strategies Build evidence around successful sector-specific applications	Use the EPAA Genotoxicity project as the coordination hub Develop cross-sector regulatory case studies Connect with PARC, OECD activities and method developers Translate project learning into practical implementation recommendations

Implementation pathway: mapping → case studies → shared evaluation → regulatory guidance.

Sources: June 2026 HH breakout conclusions and EPAA AFCSA conference report

Carcinogenicity

Human Health roadmap implementation project

Roadmap objective	Workshop priorities	EPAA implementation focus
Create a coherent, cross-sector framework for NAM-based carcinogenicity assessment and a clear route to regulatory use.	Coordinate the many active initiatives and clarify regulatory needs Define mechanistic coverage and weight-of-evidence expectations Evaluate how NAM-based approaches can support classification and risk assessment Promote international alignment from the outset	Map Roadmap actions and complementary PARC/EPAA roles Use EPAA for cross-sector exchange on industry best practice Work with CP-AAT and other regulatory platforms Develop case studies that test the framework in real decisions

EPAA value: connect science initiatives with implementation, classification and global acceptance.

Sources: June 2026 HH breakout conclusions and EPAA AFCSA conference report

Repeated-dose systemic toxicity

Human Health roadmap implementation project

Roadmap objective	Workshop priorities	EPAA implementation focus
Develop integrated human-health assessment strategies that combine exposure, toxicokinetics, bioactivity and targeted testing.	Link short-term replacement opportunities with long-term paradigm change Strengthen IVIVE, ADME, toxicokinetics and PBK modelling Broaden exposure-based waiving approaches across relevant routes Coordinate evaluation criteria for systemic toxicity frameworks	Connect the NAM Designathon, OECD IATA work and NAM User Forum Use case studies to compare protection and confidence Explore a dedicated EPAA TK/PBK implementation activity Support phasing out non-rodent second-species testing where justified

Core principle: tiered, hypothesis-driven assessment with higher tiers only when confidence is insufficient.

Sources: June 2026 HH breakout conclusions and EPAA AFCSA conference report

Developmental neurotoxicity and DART

Human Health roadmap implementation project

Roadmap objective

Advance non-animal assessment for developmental neurotoxicity and developmental and reproductive toxicity at different maturity levels.

Workshop priorities

Treat DNT and DART separately because readiness differs

Build on OECD guidance and growing experience with in vitro DNT batteries

For DART, define applicability domains and broader testing frameworks

Map initiatives, gaps and links with endocrine and systemic toxicity

EPAA implementation focus

Organise targeted workshops and information-sharing activities

Include DNT and DART case studies in future NAM User Forums

Connect to ISTNET-DART, PARC, OECD and relevant regulators

Clarify where EPAA coordination can accelerate regulatory experience

Phased approach: implement mature DNT tools while developing the evidence base and framework for DART.

Sources: June 2026 HH breakout conclusions and EPAA AFCSA conference report