



The European Partnership
for Alternative Approaches to Animal Testing



European Partnership for Alternative Approaches to Animal Testing (EPAA)

Our 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)**). The partners are pooling knowledge and resources to accelerate the development, validation and acceptance of alternative approaches at national, European and global levels.

Our structure

EPAA Steering Committee takes strategic decisions on EPAA activities and is composed of representatives of the member companies and of services of the European Commission.

The EPAA covers **eight industry sectors** encompassing animal health, chemicals, cosmetics, fragrances, food and drinks, pharmaceuticals, soap and detergents and crop protection products. The co-chairs from industry and the European Commission convene the quarterly meetings.

39 Companies (including 1 SME)



5 DG's of the EC



Including Partner Agencies



Mirror Group (Advisory body)

Tuula Heino, Christiane Hohensee, Helena Kandarova, Sirpa Pietikäinen (MEP), Vera Rogiers, Emma Grange, Julia Baines, Winfried Neuhäus, Monique Janssens

9 Sectoral Associations



The **EPAA strategy** is defined by a 5-year Action Programme; the current programme runs from 2021 to 2025. The EPAA reports progress against the strategy to its members and 3Rs-concerned stakeholders during the EPAA Annual Conference.

The **EPAA Mirror Group** consists of experts from the civil society including academia, animal welfare, laboratory animal science, 3Rs centres, and other third-party organizations. It acts as a consultation forum in an advisory capacity to the Steering Committee for the implementation of the Action Programme, providing comments from a broader societal perspective.



EPAA Annual Conference 2023

Our mission

Launched in 2005, EPAA is a unique partnership between industry and the European Commission with the aim of:

- **Promoting the development & validation of animal alternatives** for regulatory animal testing.
- **Accelerating regulatory use of animal alternatives** at member state, European, and global levels through fostering knowledge exchange among partners and stakeholders.
- **Providing a platform for stakeholder dialogue** on scientific, regulatory, and policy developments that impact regulatory animal testing.

In fulfilling its mission, EPAA also considers innovation, protection of intellectual property, and overall competitiveness of European industry.

In recent years EPAA has also sought to facilitate a successful implementation of the **European Green Deal, Chemical Strategy for Sustainability, Pharmaceutical Strategy for Europe, and EU Commission roadmap** towards ultimately phasing out animal testing for chemical safety assessments.



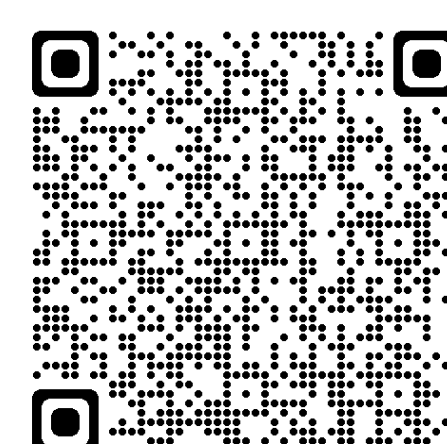
Our activities

EPAA projects are overseen by a Projects Platform & cover:

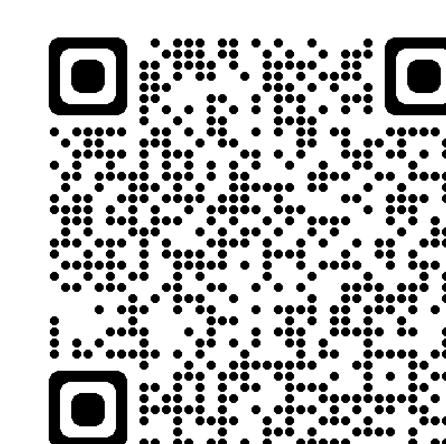
- **Acute toxicity**
- **Harmonisation of 3Rs in Biologicals**
- **Carcinogenicity of Agrochemicals**
- **Skin sensitization NAM User Forum**
- **NAMs in regulatory decisions for chemical safety**
 - NAM Designation (challenge for chemicals classification)
 - NAM User Forum
- **Environmental Safety Assessment**

The EPAA also provides student travel grants and an annual prize for either lab technicians (Refinement Prize) or young scientists (3Rs Science Prize).

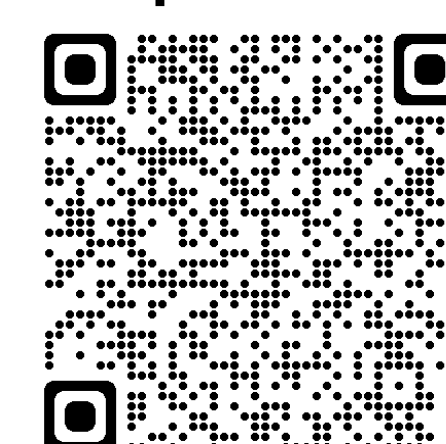
EPAA
website



EPAA
LinkedIn



EPAA Annual
report 2023



The Commission roadmap towards ultimately phasing out animal testing for chemical safety assessments

European Commission, DG GROW and DG ENV

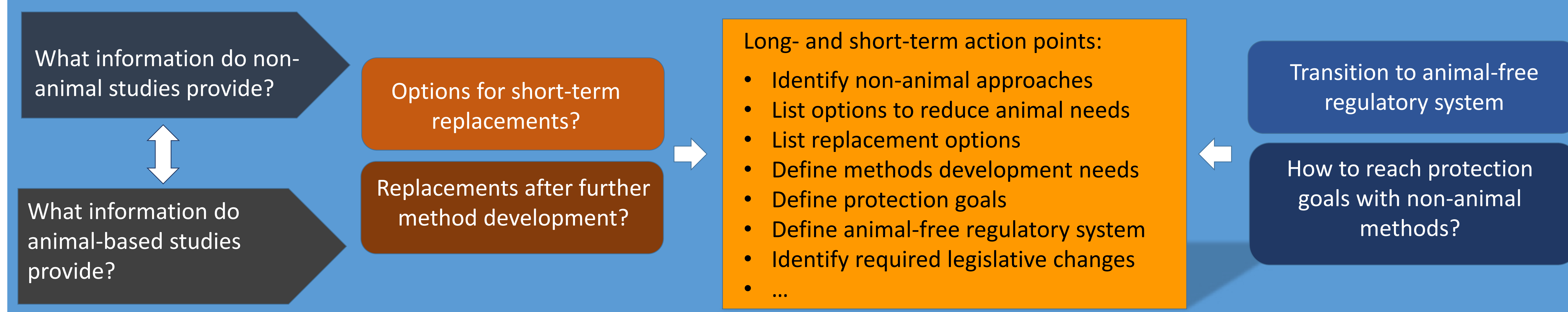
Sofia Camorani, Marco Fabbri, Katrin Schutte, Georg Streck



COMMISSION ROADMAP

With Commission Communication C(2023) 5041 replying to the European Citizens' Initiative (ECI) 'Save Cruelty-free Cosmetics - Commit to a Europe without Animal Testing' the Commission announced the development of a roadmap towards ultimately phasing out animal testing for chemical safety assessments. The roadmap will

- Be finalised in the first quarter of the term of the next Commission (Q4 2025/Q1 2026).
- Outline milestones and specific actions, to be implemented in the short to longer term, to reduce animal testing and describe the transition towards an animal-free regulatory system.
- Analyse and describe the necessary steps to replace animal testing in all relevant pieces of chemical legislation (e.g. REACH, Biocidal Product Regulation, Plant Protection Products Regulation and human and veterinary medicines).
- Describe the path to expand and accelerate the development, validation and implementation of non-animal methods as well as means to facilitate their uptake across legislations.

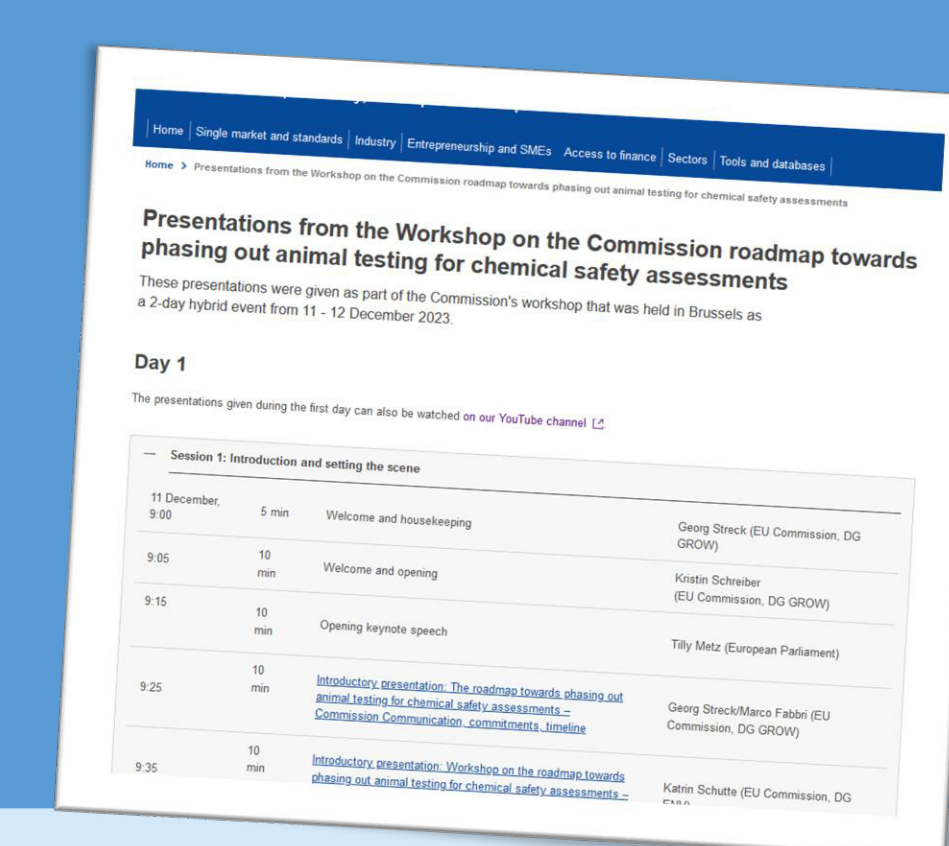


Further elements of the roadmap

1. Analysis of strengths and weaknesses of the landscape of agencies, committees and working groups that provide advice on non-animal methods.
2. Analysis of the need and feasibility of an advisory expert scientific committee to provide advice on the development of non-animal approaches and their uptake and use in the regulatory context.
3. Analysis of possibilities to accelerate the validation and acceptance of new non-animal methods.
4. Analyse how to facilitate access to information such as upcoming events, calls, but also on guidance, e.g. through dedicated platforms and interactive communication tools.
5. A proposal on 'Streamlining EU scientific and technical work on chemicals through the EU agencies' that has the purpose to enhance the collaboration of the agencies and to increase their efficiency by making full use of synergies in the assessment of chemicals.
6. An analysis, in close collaboration with the agencies, of the possibilities to increase the agencies' visibility and impact in international forums.
7. Outline ways to improve outreach activities in the international dimension (e.g., GHS, OECD, ICH/VICH, ISO).
8. A proposal for a Regulation on chemicals data to improve accessibility to information on chemicals (proposal submitted).

OUTREACH AND INVOLVEMENT OF STAKEHOLDERS

Involving stakeholders is crucial for pooling the scientific knowledge that forms the basis of the roadmap and essential to receive support from Member States, agencies and all stakeholders, including Commission Partnerships such as the European Partnership for Alternative Approaches to Animal Testing (EPAA) or the Partnership for the Assessment of Risks from Chemicals (PARC), both during development of the roadmap and in the implementation phase. The roadmap development is therefore accompanied by multiple stakeholder activities and a stakeholder consultation plan according to the Better Regulation rules.



- Public consultation on the initiative on Have-your-say (https://ec.europa.eu/info/law/better-regulation/have-your-say_en)
- Targeted stakeholder consultations in meetings/surveys
- Information of MS and stakeholders via Committees and Expert Groups
- Outreach activities with non-EU partners and international organisations

Organisation of workshops:

- A workshop end of 2023 to kick off the work on the roadmap
- A workshop in the second half of 2024 on the progress of the roadmap (25 Oct. 2024)
- Possible further workshops on scientific and regulatory aspects

Workshop on the Commission roadmap towards phasing out animal testing in chemical safety assessments (11/12 December 2023)

- Presentations and discussions with stakeholders (MS, EU agencies, industry, research community, NGOs) on ideas and approaches for the roadmap.
- Session in cooperation with the Partnership for the Assessment of Risks from Chemicals (PARC), WP2.2, on the Next Generation Risk Assessment.
- Presentations and recordings: https://single-market-economy.ec.europa.eu/presentations-workshop-commission-roadmap-towards-phasing-out-animal-testing-chemical-safety_en



Transparency – a working tool to make progress together!

The European Commission (DG Environment) publishes data on the use of animals for scientific purposes based on information reported by the 27 Member States according to Directive 2010/63/EU. The Alures statistical and the Alures Non-Technical Summary databases provide not only reliable statistics but also insights into why and how animals are used in science. These transparency tools are crucial for knowing where our efforts to reduce or replace animal use in science would be most effective.

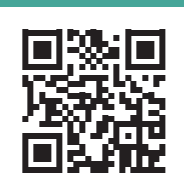
ALURES databases, world's most comprehensive depository on animal use taking transparency to another level!

Reliable statistics with the understanding and openness in animal use allow

- **The Public** to have a complete overview of when and how animals in Europe are being used in science.
- **Researchers and funders** to determine urgent focus areas for the development of new alternative approaches
- **Policy makers** to make evidence-based, informed policy decisions

1. ALURES Statistical Database

What information is available?



SECTION 1	SECTION 2	SECTION 3
Numbers of animals (conventional and genetically altered) used for the first time for research, testing, routine production, and education and training	All uses and reuses of animals for research, testing, routine production, and education and training Reason for use (e.g. specific research area, type of testing) Actual severity (mild, moderate, severe) experienced by animals Genetic status Use of animals to meet legislative requirements	Numbers, uses and reuses of animals for the creation and maintenance of genetically altered animals (mostly mice and fish)
Species Origins		

2. ALURES NTS Database

Gaining insight into the use of animals in science.

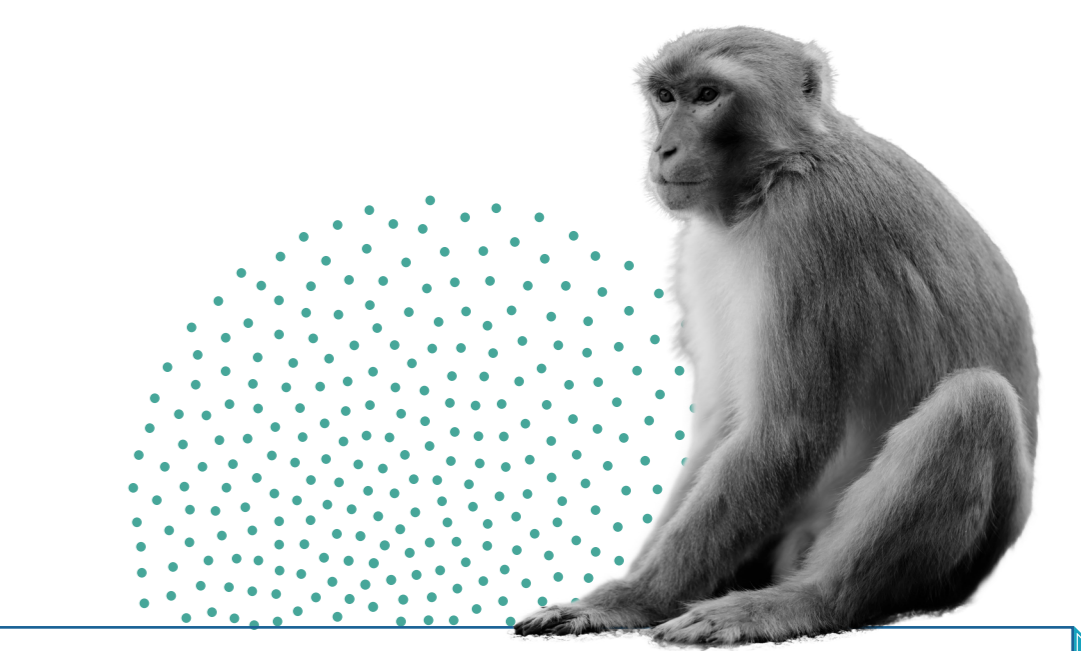
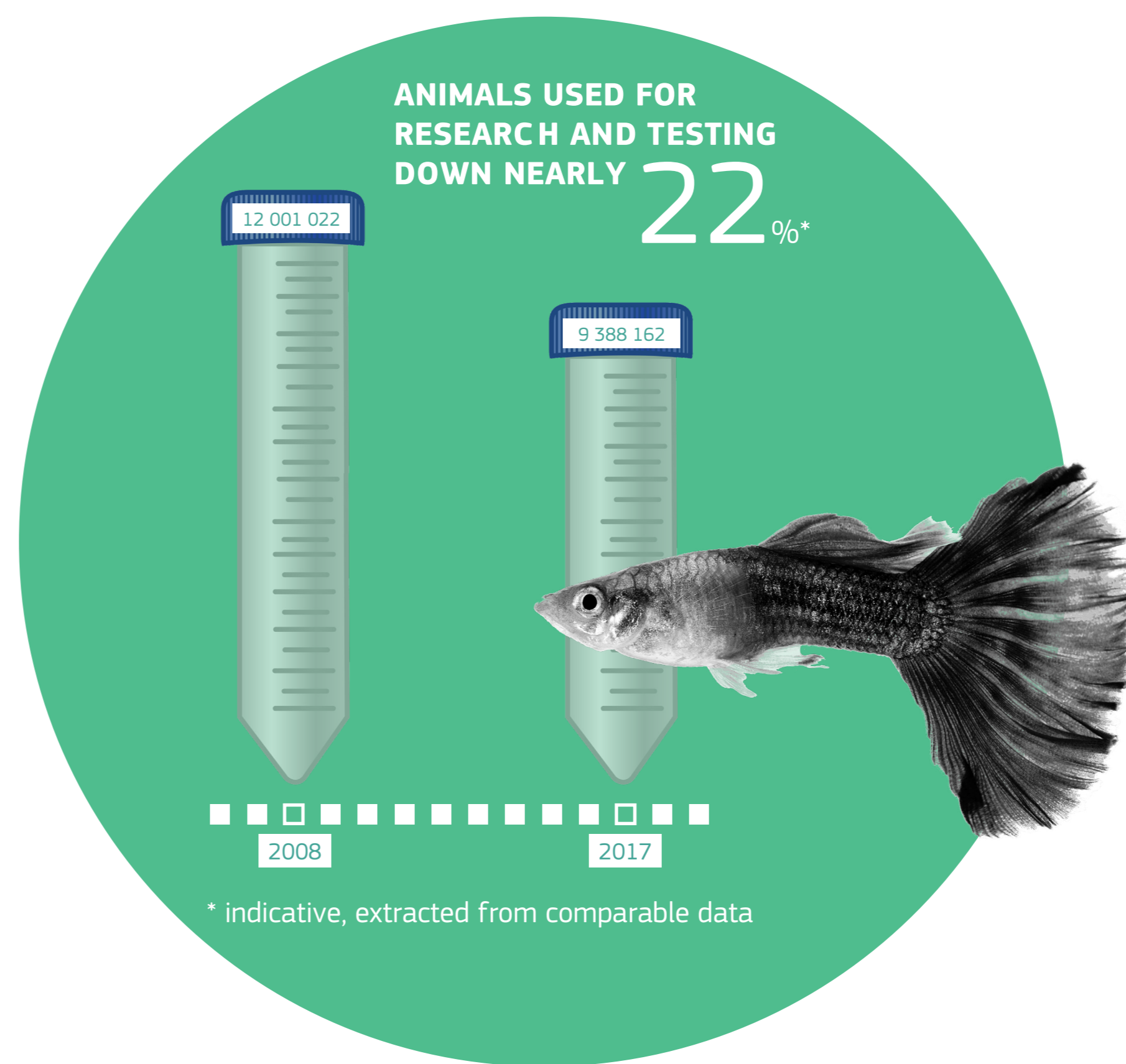
Non-technical project summaries (NTS)

- provide clear and concise descriptions of authorised animal projects in the EU
- facilitate understanding of why and how animals are used and how the work is done
- explain how the Three Rs are applied and what limitations they have



Making the EU a global leader in transparency

The EU is committed to phasing out the use of animals in science when it is scientifically possible to do so. It is working towards the ultimate goal of replacing all animals used for scientific purposes, but more time is needed to develop alternative approaches that do not involve animals.



WHAT ARE SCIENTIFIC PURPOSES?

All uses of animals for basic, translational and applied research, regulatory testing and production, education and training, as well as the creation and maintenance of genetically altered animal lines

Protecting and improving the welfare of animals in scientific research

Why is it still necessary to use animals in research?

Animals have played key roles in medical advancements of the last century. We would not enjoy better health, improved quality of life and longer life expectancy without the knowledge gained from animal research.

Technological advances, computer simulations and test tube methods already greatly reduce the number of animals used, but are not yet able to fully replicate living organisms' complexities and reactions.

Hence, alternative solutions are not yet always available.

It is the EU's ultimate goal to completely replace animals in science. Until this becomes reality, it is committed to reducing the number of animals and respecting the welfare of the animals used for scientific purposes.

How are animals protected?

In Europe, all living animals used in science are protected by very strict legislation, Directive 2010/63/EU. All animal studies must comply with this legislation. Animals cannot be used for scientific purposes without prior authorisation. Authorities can only allow the use of animals when there are no alternative, non-animal methods available. In addition, the use of the animals must be justified by the expected benefits, also taking into account ethical considerations.

The Three Rs, to Replace, Reduce and Refine the use of animals, at the heart of the EU legislation

- There is a legal obligation to eliminate or minimise pain, suffering, distress and lasting harm on animals to a minimum level possible.
- All efforts to minimise pain, suffering and distress have to be made from the planning stage.
- Every establishment must have a named person responsible for the welfare and care of animals, as well as a designated veterinarian.



This poster



Animals in science EC website

Luxembourg: Publications Office of the European Union, 2024

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EURL ECVAM

Non-animal methods in science and regulation

FOR OVER 30 YEARS THE JRC HAS BEEN WORKING ON THE THREE RS

R
Replacement

use alternatives
instead of animals

R
Reduction

use fewer
animals

R
Refinement

minimise pain
and distress

The mandate of EURL ECVAM is set out in EU legislation to protect animals used for scientific purposes and includes the following duties



research and
development



method
validation



knowledge
sharing



promotion
of the three Rs



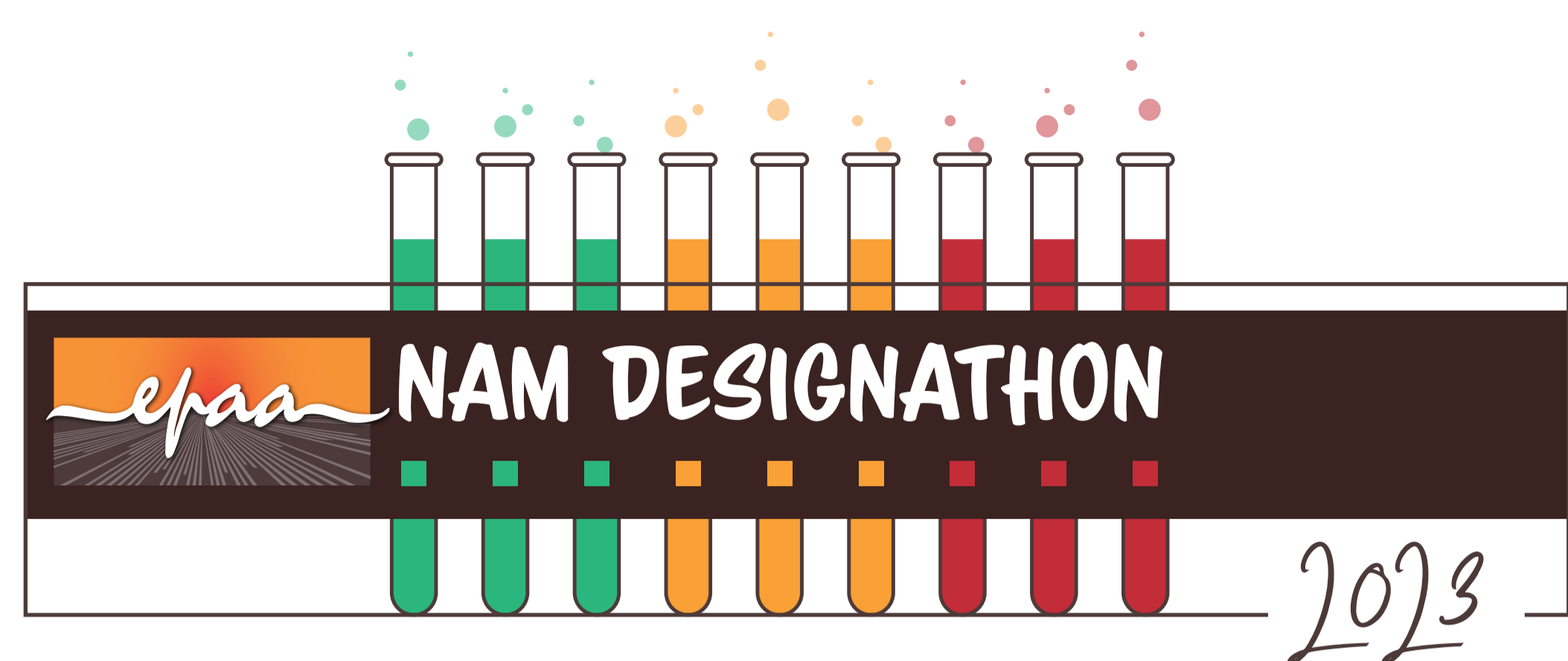
[EU Reference Laboratory for alternatives to animal testing \(EURL ECVAM\)](https://joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam_en)

joint-research-centre.ec.europa.eu/eu-reference-laboratory-alternatives-animal-testing-eurl-ecvam_en



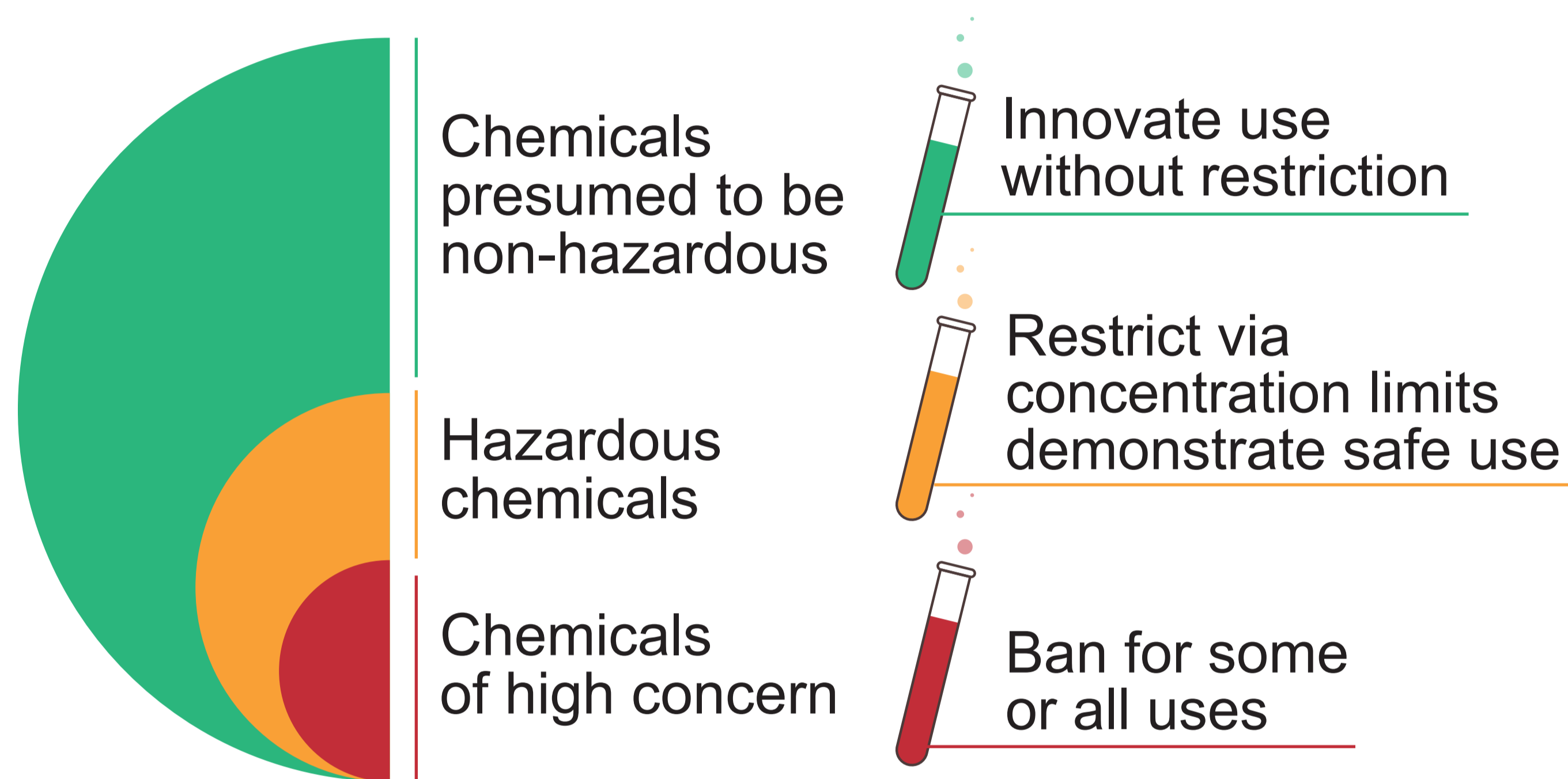
[NEW Status Report](#)

NAM DESIGNATHON



In 2023, the European Partnership for Alternative Approaches to Animal Testing (EPAA) invited the research community developing **New Approach Methodologies (NAMs)** to submit NAM-based solutions to inform the development of a future **classification system for systemic toxicity in humans**.

PRINCIPLE OF EQUIVALENT PROTECTION: MAKE THE SAME DECISIONS, NOT NECESSARILY THE SAME PREDICTIONS



Assign chemicals to groups 1-3 (low, medium & high concern)

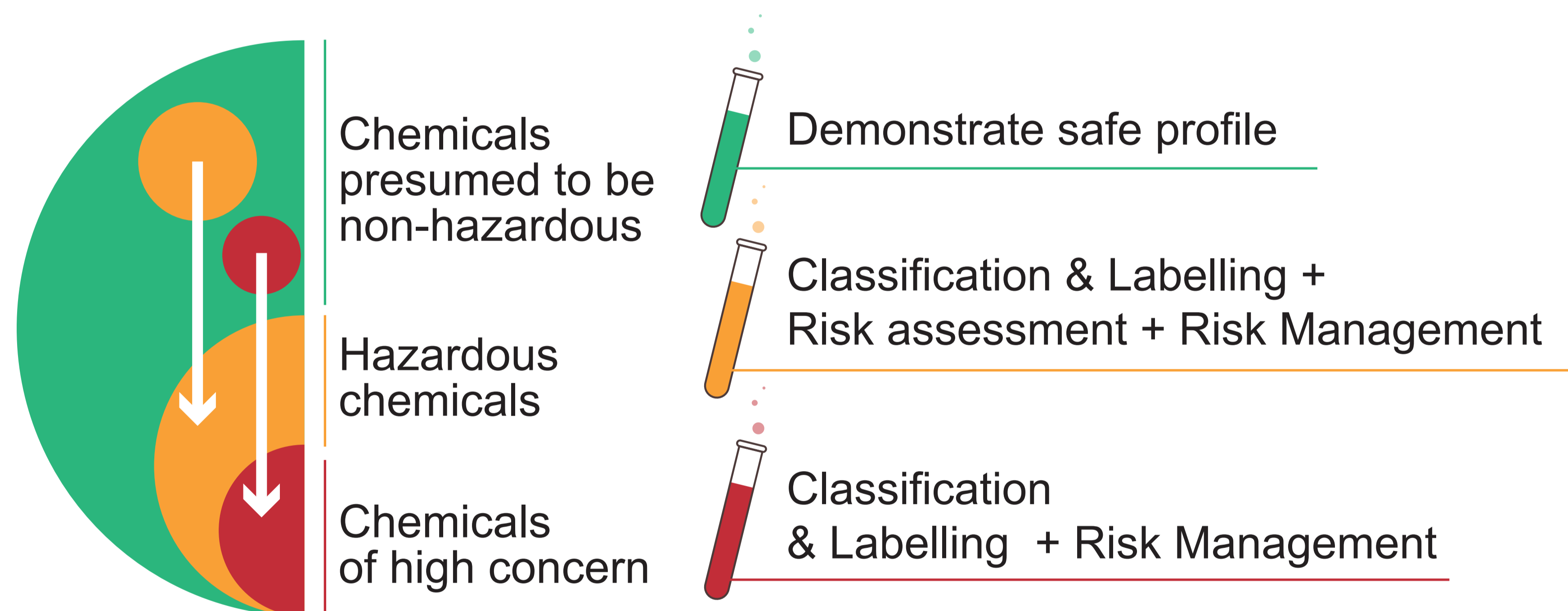
Existing data for already classified chemicals (high & medium concern) are used to calibrate the classification scheme resulting in equivalent protection

		Activity (NAM-based toxicodynamics)		
		HIGH	MEDIUM	LOW
Potential Systemic Availability (NAM-based toxicokinetics, based on ADME properties)	HIGH	H	H	M
	MEDIUM	H	M	L
	LOW	M	L	L



From Berggren & Worth (2023), Regul. Toxicol. Pharmacol. 142, 105431. <https://doi.org/10.1016/j.yrtph.2023.105431>

NAMS CAPTURE CHEMICALS CURRENTLY TREATED AS GREEN, BUT BASED ON NO OR LIMITED INFORMATION



Besides identifying unknown chemicals of concern, we hope to identify low concern chemicals supporting replacement and sustainable by design.

We received 23 NAM-based solutions to inform the development of a future classification system for human systemic toxicity.

In March we met with all contributors to compare and contrast the different solutions and co-create!

Now we are starting Phase 2 of the EPAA NAM Designathon.

If you are curious about our progress or want to contribute,
CONNECT TO US HERE:





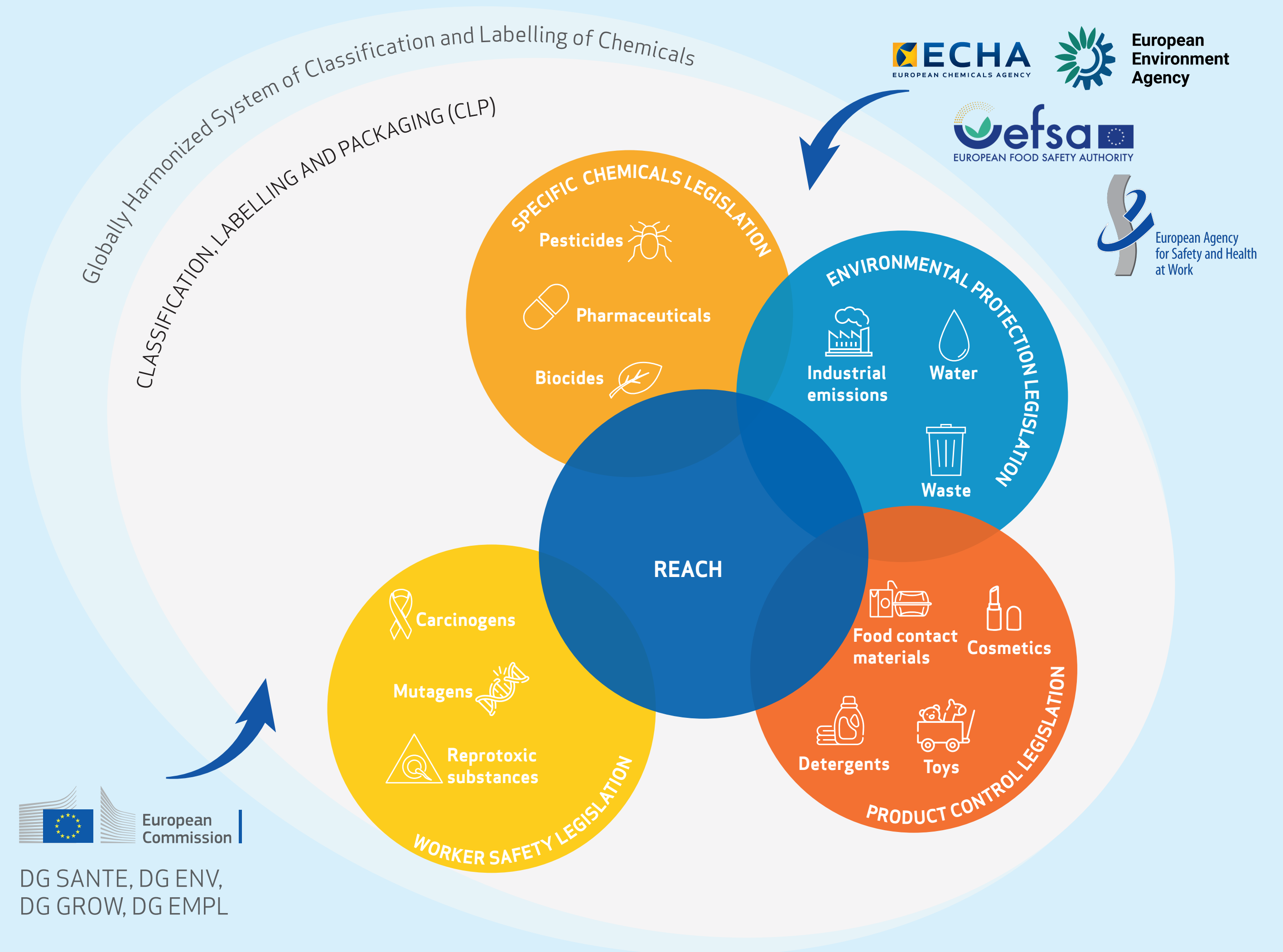
Towards an animal testing-free system for industrial chemicals

Identifying the needs and working to replace animal testing within the current chemicals management system

EU chemicals management system

To protect Human health and the environment, we rely on a horizontal generic approach with some fundamental elements:

- defined hazard classes
- clear criteria for consistent classification
- standard information requirements for hazard assessment
- quality data for decision making
- consistent regulatory actions within chemicals legislation



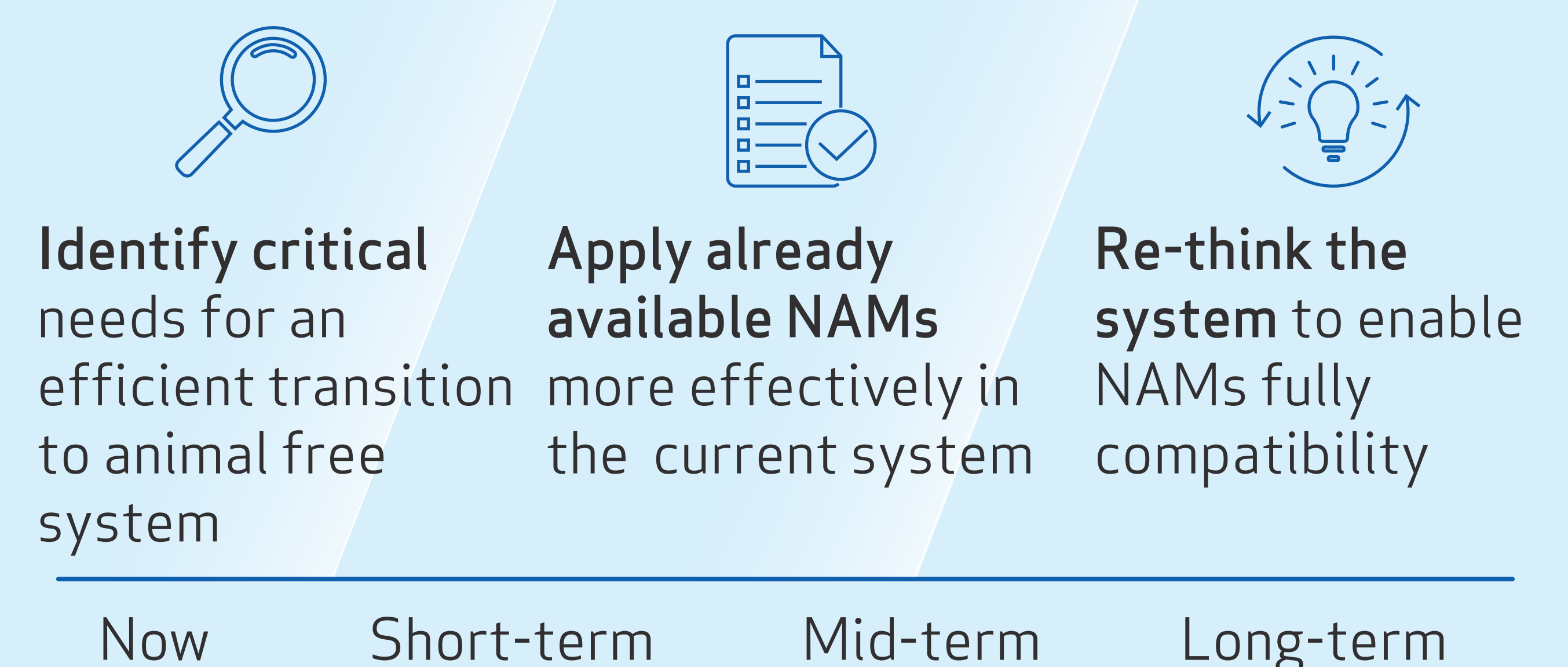
Critical needs

To achieve an animal testing-free regulatory system, we need to consider elements of chemical assessment:

- Hazard identification** NAMs should allow a conclusive outcome on the (lack of) hazard
- Hazard characterization** NAMs should identify hazard based on new information (e.g. at molecular/cellular level)
- Extrapolation** NAMs data should lead to set safety levels, to communicate the hazard and assess the risks

A way forward

1. to close major gaps
2. to gain experience and confidence
3. to propose a NAMs compatible system



Areas for development

- Application of **toxicokinetics** in chemical assessments
- Development of improved **in silico methods** (e.g. QSARs) for lower tier endpoints (e.g. Acute oral toxicity)
- Utilisation of NAMs to support **read-across and grouping**
- Inclusion of 'omics in current test guidelines for higher tier endpoints (e.g. Repeated dose toxicity)

Learn more

- Read ECHA's report on the use of alternatives to testing on animals
- Read ECHA's report on the key areas of regulatory challenges
- Alternatives to animal testing. <https://echa.europa.eu/animal-testing-under-reach>

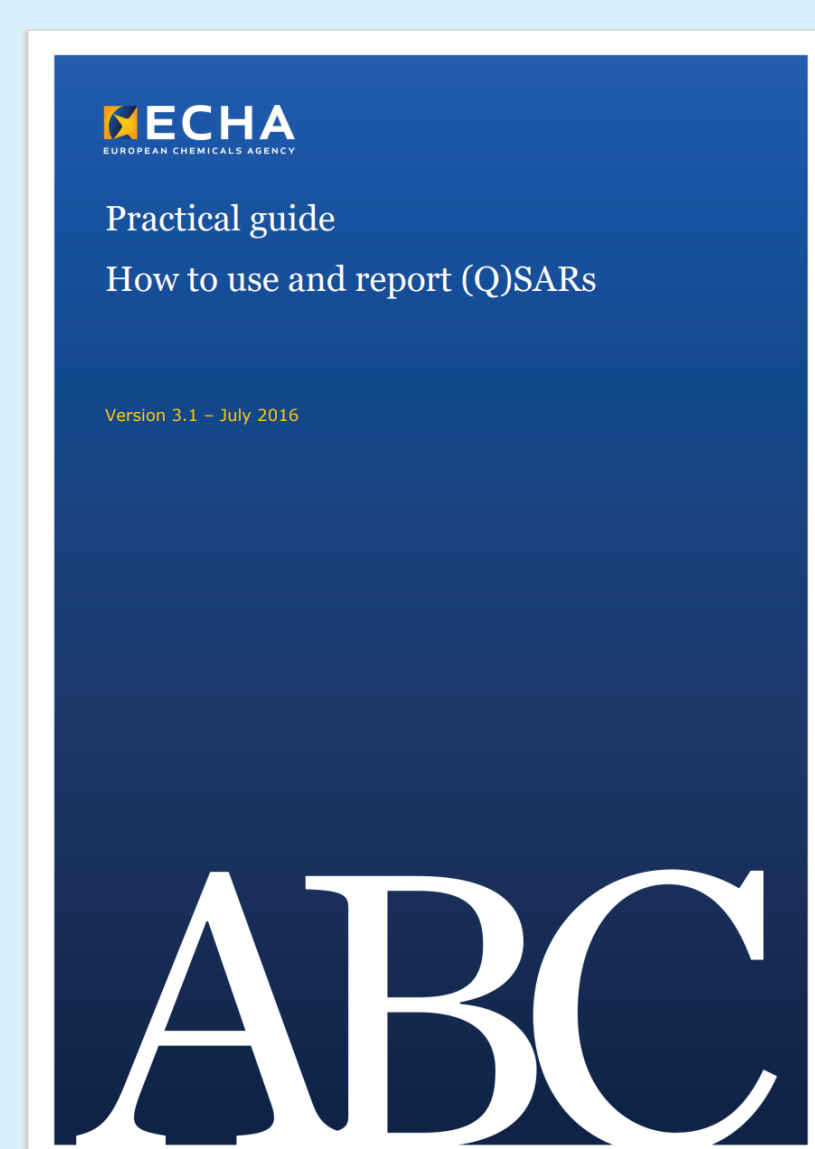
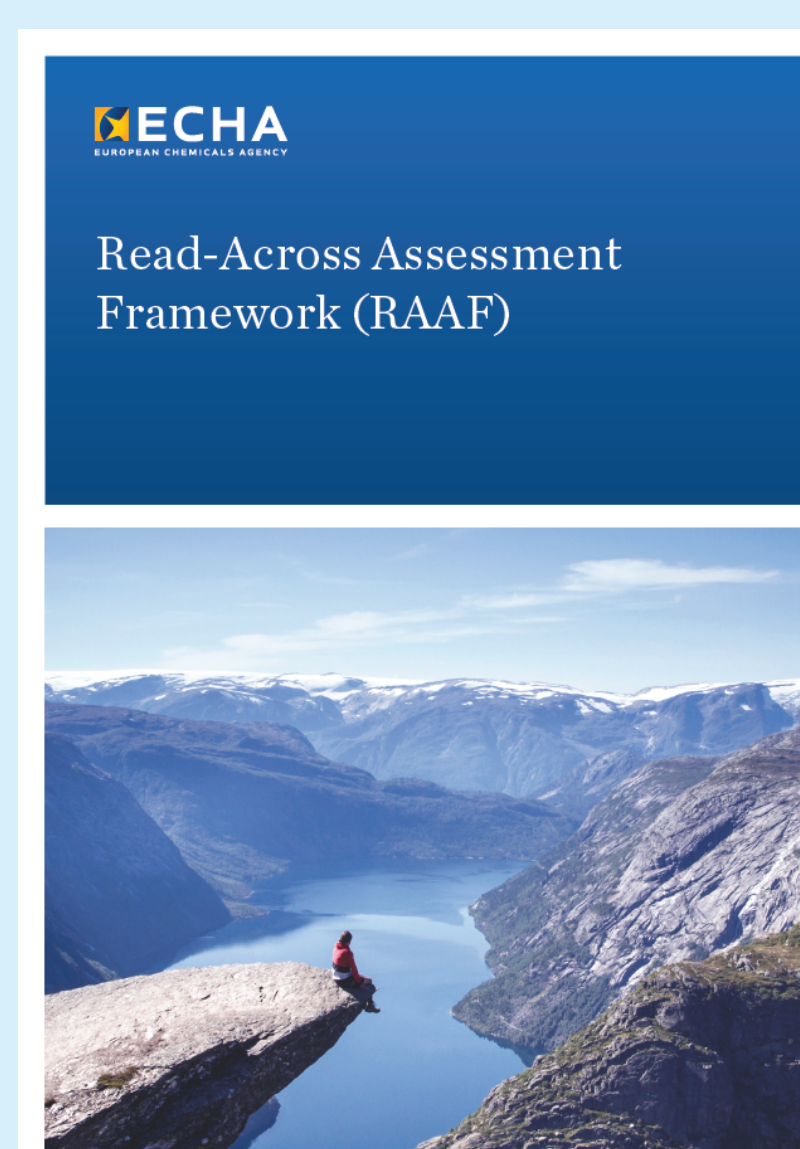


ECHA Activities to promote New Approach Methodologies - NAMs

ECHA is committed and active in promoting alternatives to animal testing

Guidance and standardisation

- We provide practical guidance and training to registrants
- We support the development of harmonised guidance and assessment frameworks at OECD



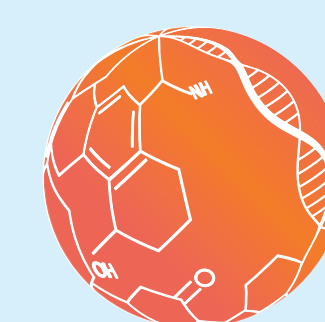
Collaboration

We collaborate in research projects and case studies

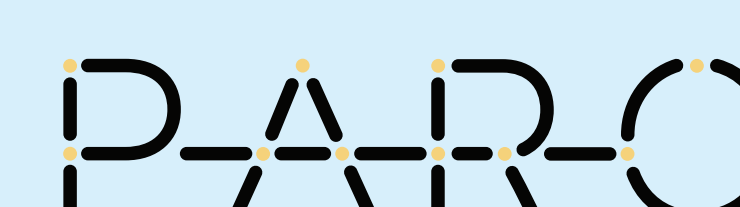
Globally

Within EU Research consortia

With academia and industry



APCRA
ACCELERATING THE PACE OF
CHEMICAL RISK ASSESSMENT



Partnership
for the
Assessment
Risks
from
Chemicals



Long-Range
Research Initiative



MetAbolomics ring-Trial
for CHEMical groupING
(MATCHING)




Making data available


We facilitate access to non-confidential data in IUCLID format

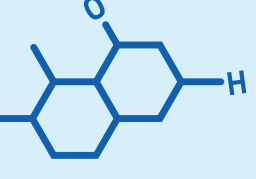
- Development of predictive computational models.
- Correlation and concordance analyses
- Safety data sheets and classification and labelling of chemicals

REACH registration  IUCLID 6

 [www](http://www.echa.europa.eu)
ECHACHEM



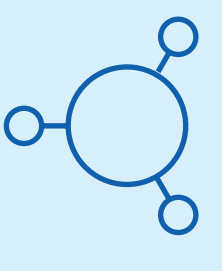
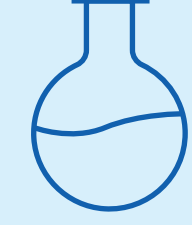
 REACH study results

 eChemPortal

 QSAR Toolbox

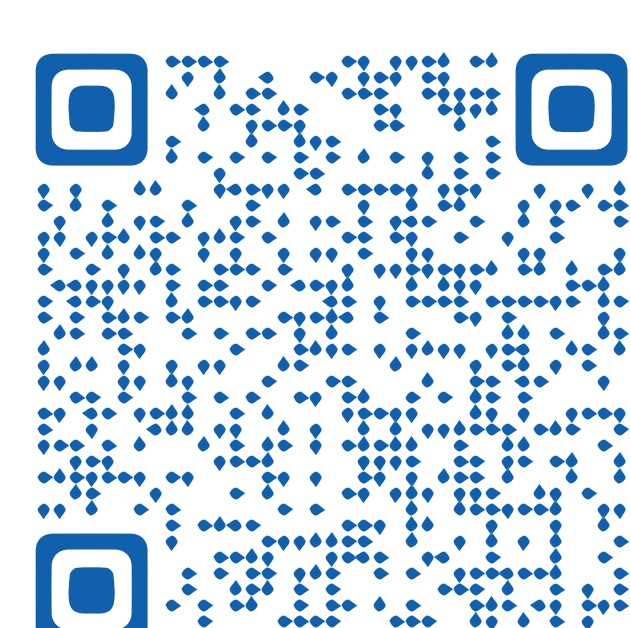
ECHA projects

We invest in services related to methodological developments of NAMs related to addressing critical needs in regulatory hazard assessment

-  Developments of QSARs and their assessment framework
-  Guidance on sample cryopreservation for omics measurement
-  Better utilisation of 'omics to support read-across and grouping
-  Toxicokinetics for industrial chemicals

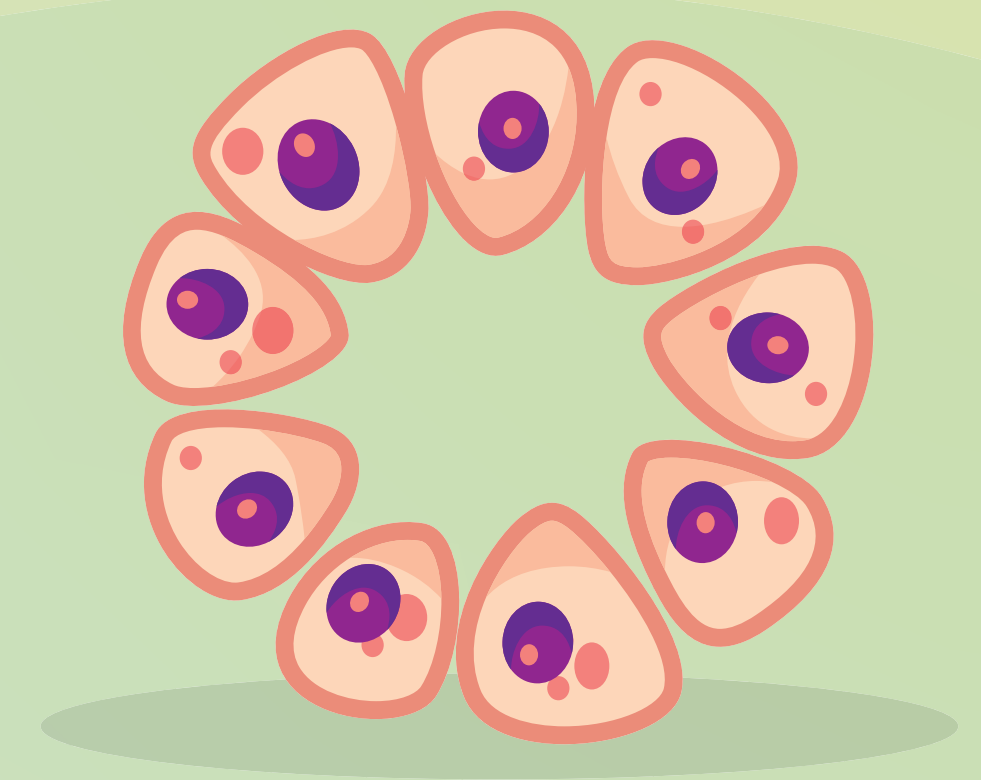
Learn more

Read ECHA's workshop report on New Approach Methodologies





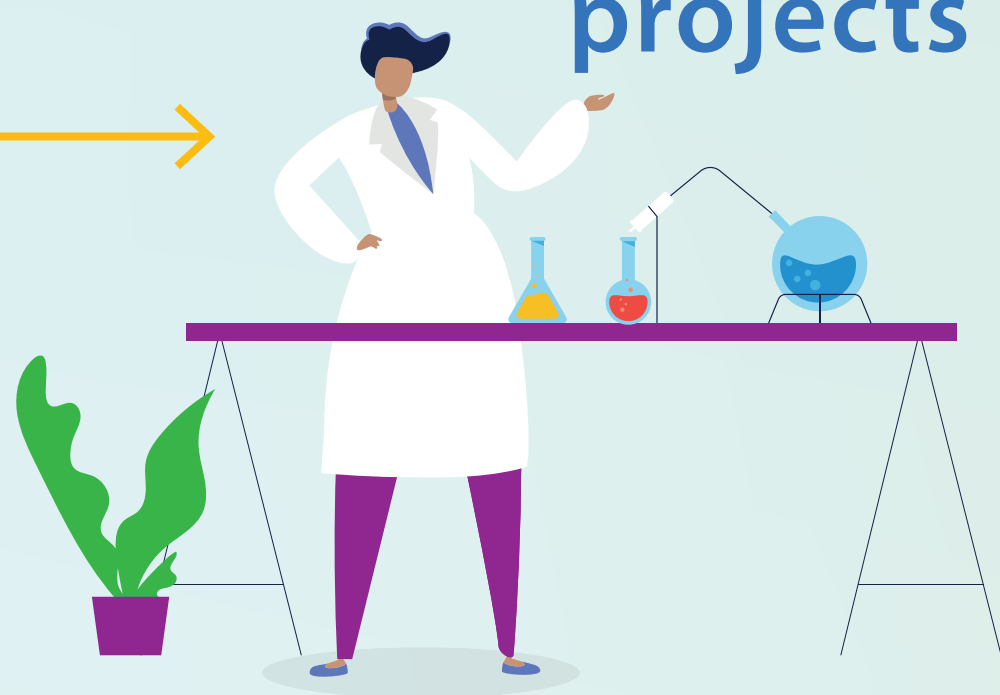
ALTERNATIVES TO ANIMAL TESTING



THE COMMISSION INVESTED

> €1 billion

> 300 projects



Over the last two decades, the European Commission has substantially supported alternatives to animal testing

AVERAGE ANNUAL BUDGET

11M€
FP5
5th Framework Programme

32M€
FP6
6th Framework Programme

48M€
FP7
7th Framework Programme

76M€
H2020
Horizon 2020

■ Projects supported by the European Commission

WHAT DO WE WANT TO DO WITH IT ?

Changing the paradigm in safety testing of chemicals and drugs and developing efficient complementary tools for biomedical research

WHY THEY ARE IMPORTANT ?

HUMAN-RELEVANT
Improve predictability and robustness of studies for scientists and regulators

VERSATILE
Answer questions that current methods cannot address

ETHICAL
Animal protection: replace/reduce/refine animals (3Rs)

SUSTAINABLE/AUTONOMOUS
Independent of shortage/quality with animals



WHY IS UPTAKE OF ALTERNATIVES TO ANIMAL TESTING SLOW ?

Limited awareness of and confidence in **Alternatives to animal testing** from regulators

Insufficient availability of **Alternatives to animal testing** to cover complex regulatory endpoints or all aspects of biomedical sciences

Lack of investment in Member States to fund additional **Alternatives to animal testing** and dedicated infrastructures

Lack of resources in Member States to qualify/standardize/validate **Alternatives to animal testing**

Limited coverage in university teaching



IT TAKES TIME ...

Example of in vitro method for skin sensitisation
From FP6 SENS-IT-IV project to GARD Method (Genomic Allergen Rapid Detection)

START
2005

END
2011

VALIDATION
(EURL ECVAM)
2017-2021

EU LEGISLATION
2023
Regulatory Approval

SENS-IT-IV
Development

2014
SPIN-OFF
Lund University

GARD Method
Market

2022
OECD
Test Guideline

WE CONTINUE INVESTING IN RESEARCH

for the development of animal-free safety assessment, and expand it beyond

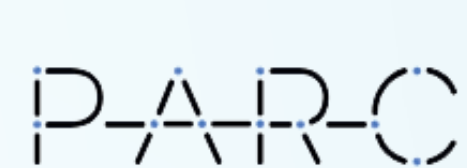
INCREASED DIALOGUE WITH STAKEHOLDERS (INDUSTRY, REGULATORS, CROs)

H2020



Animal-free Safety
Project cluster for Implementation
of novel Strategies

Horizon Europe



Partnership for the Assessment
of Risk from Chemicals



Innovative Health Initiative

DISCOVER
FUNDING
OPPORTUNITIES:



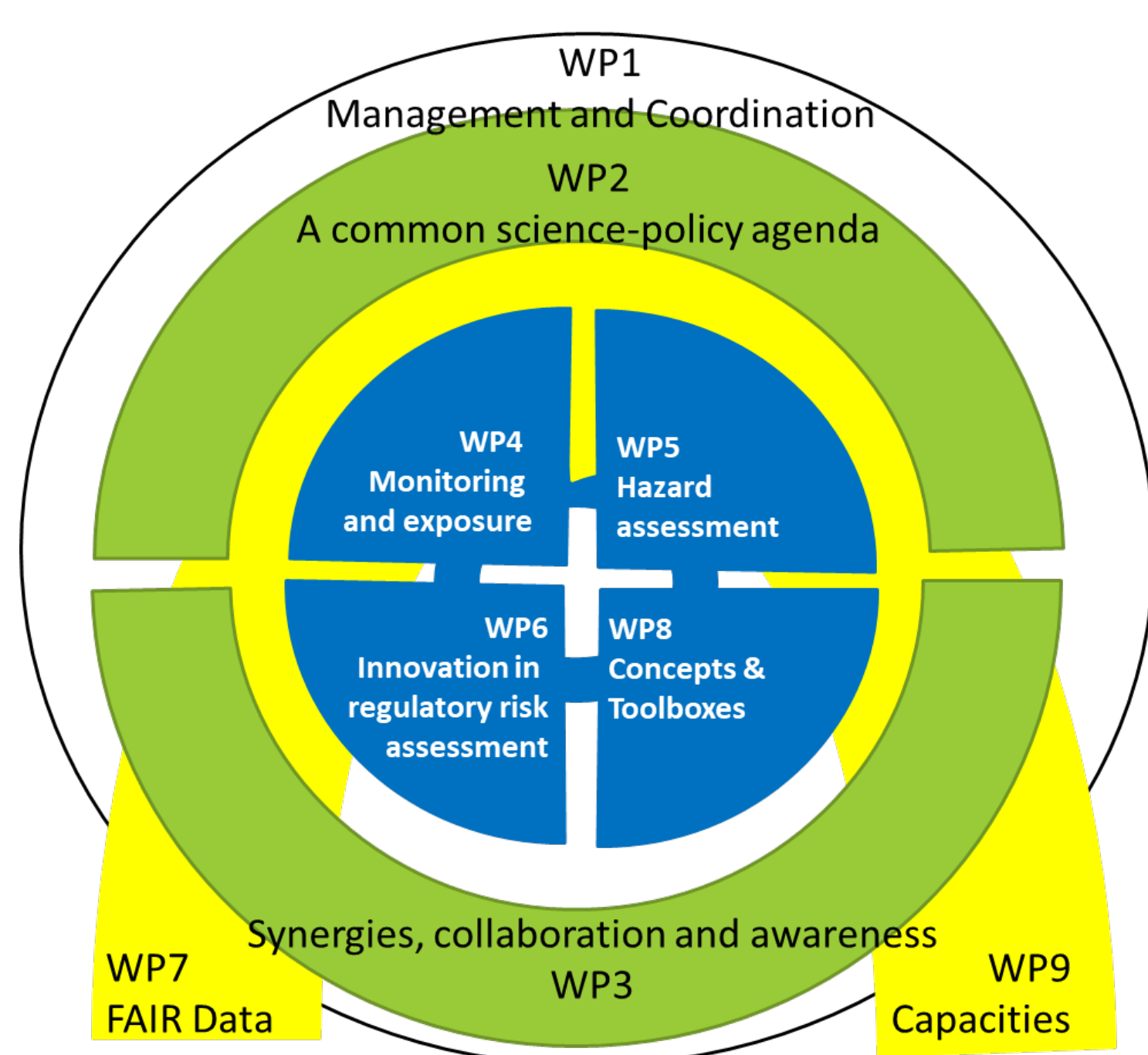
PARTNERSHIP FOR THE ASSESSMENT OF RISKS FROM CHEMICALS



PARC Coordination Team, T2.2 co-leaders
ANSES, BfR

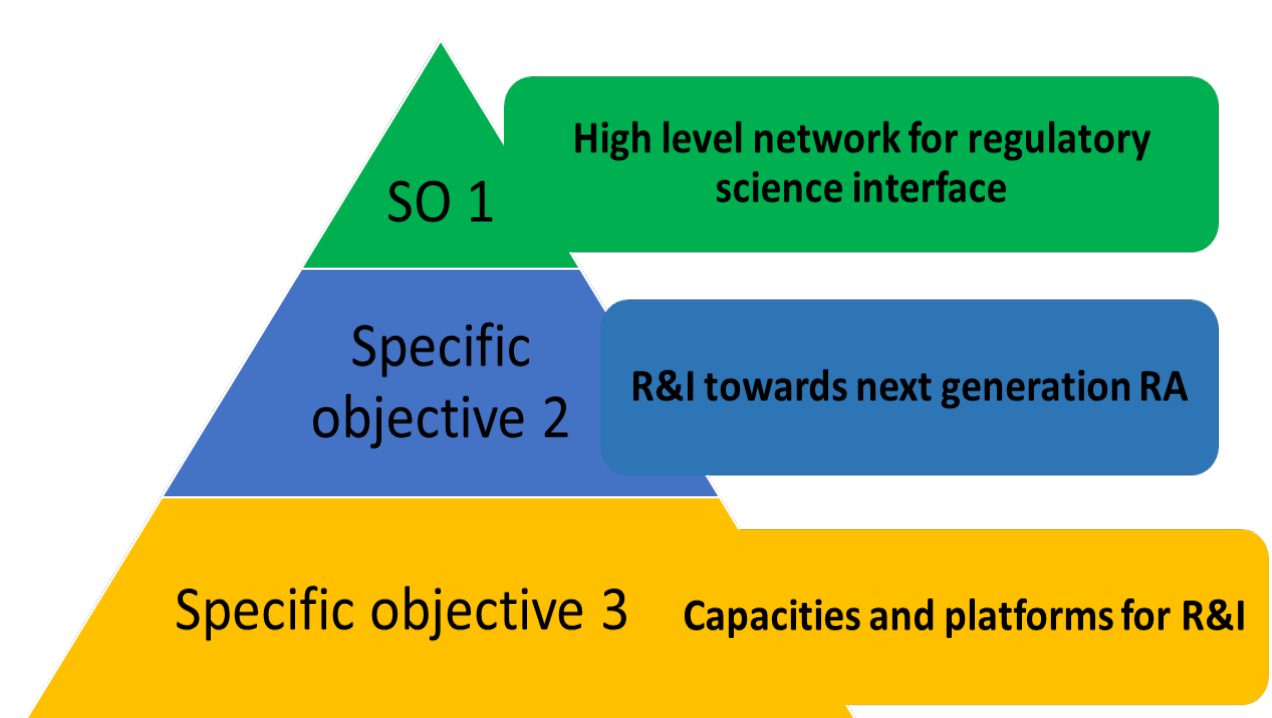
PARC in a nutshell

- **Public-public** European partnership under Horizon Europe
- **7 years** length - launched in May 2022
- **Cofunded** 50/50 by the European Commission and PARC partners
- **400M€ budget**, max 200M€ reimbursed by the European Commission
- **198 partners from 28 countries** - 23 member states, 3 associated countries, 2 non associated countries (Switzerland, UK), **3 European Agencies (EFSA, ECHA et EEA)**



PARC actively contributes to the **Chemicals Strategy for Sustainability**:

- Dialogue at the EU level,
- Development of a strong network
- Innovative methods and tools



Challenges	R&I needs	Objectives	Actions	Outcomes
<ul style="list-style-type: none"> Number & diversity of chemicals Gaps in toxicology Incomplete occurrence and exposure data Separate policy frameworks Need for new risk paradigms Restricted data access Lack of skills High public concern Environmental and public health costs 	<ul style="list-style-type: none"> Science - Policy dialogue to drive regulatory innovation Innovating toxicology: new methods and approaches Monitoring and impact assessment Cooperation across sectors New risk assessment approaches and decisions support tools FAIR data and open and connected platforms Training for new skills Improved communication 	<ul style="list-style-type: none"> Consolidate and strengthen the R&I capacity for chemical risk assessment EU & national risk assessors and regulatory entities come together with the scientific community in a cross-disciplinary network to set priorities for R&I in chemical RA EU & national RA entities and their scientific networks carry out a joint R&I programme to respond to the agreed priorities in chemicals RA European risk assessors, their scientific network and the wider stakeholder community have access to the R&I capacities required to implement innovative chemical RA 	<ul style="list-style-type: none"> Support a common science policy agenda Evolve hazard assessment Advance monitoring and exposure assessment Create and strengthen synergies & collaborations Drive innovation in regulatory risk assessment Define new concepts and toolboxes Support and contribute to FAIR data Enhance capacities: infrastructure and skills Foster communication across stakeholder groups 	<ul style="list-style-type: none"> A sustainable Europe-wide R&I platform for chemical risk assessment Establish synergies with relevant activities from other EU Green Deal policy areas for shared understanding & addressing needs to better protect environment & health Empower the Common European Green Deal Data Space by providing FAIR data on chemicals. Enhance collaboration & move towards 'one substance - one assessment' with shared evidence, tools & methodologies. Zero Pollution Enhance the protection of workers from chemical risks. Support public authorities & industry in developing a circular economy including better waste management

IMPACT
Establish the EU as an internationally recognised driver of innovative chemical risk assessment with an optimal protection of human health and the environment

From scientific innovation to policy: NGRARoute

- To provide a **concrete and applicable roadmap proposal for implementing Next-Generation Risk Assessment (NGRA) as the default approach** to chemical risk assessment in EU chemicals legislation
- In scope: **all European chemicals legislation** with a risk assessment component of its own. **Human health and environmental** risk assessment.

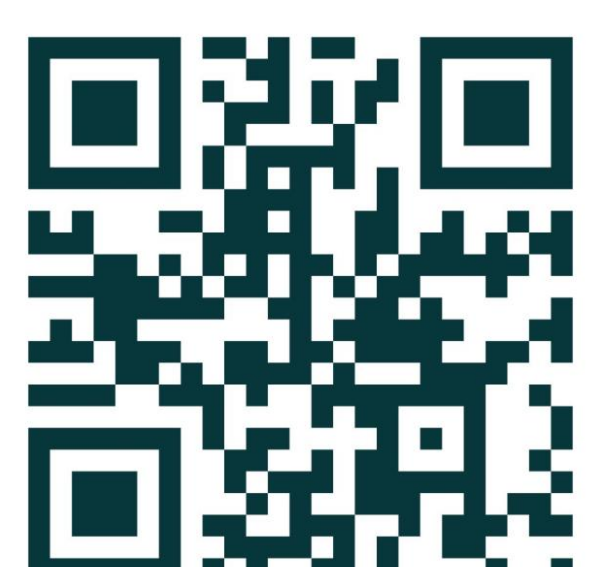
Workshop on Commission roadmap for phasing out animal testing in chemical safety assessments
 (Dec 11/12, 2023)

- Ongoing **collaboration with EU Commission and EPAA**, roadmap proposal expected for 2025

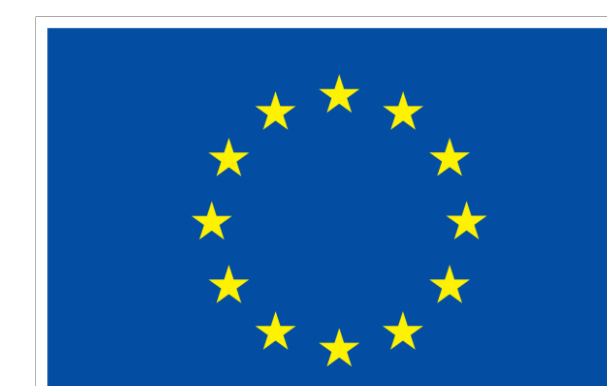
A new co-operative space for the risk assessment community

PARCopedic

Knowledge management and community platform for chemical risk assessment professionals in and beyond PARC

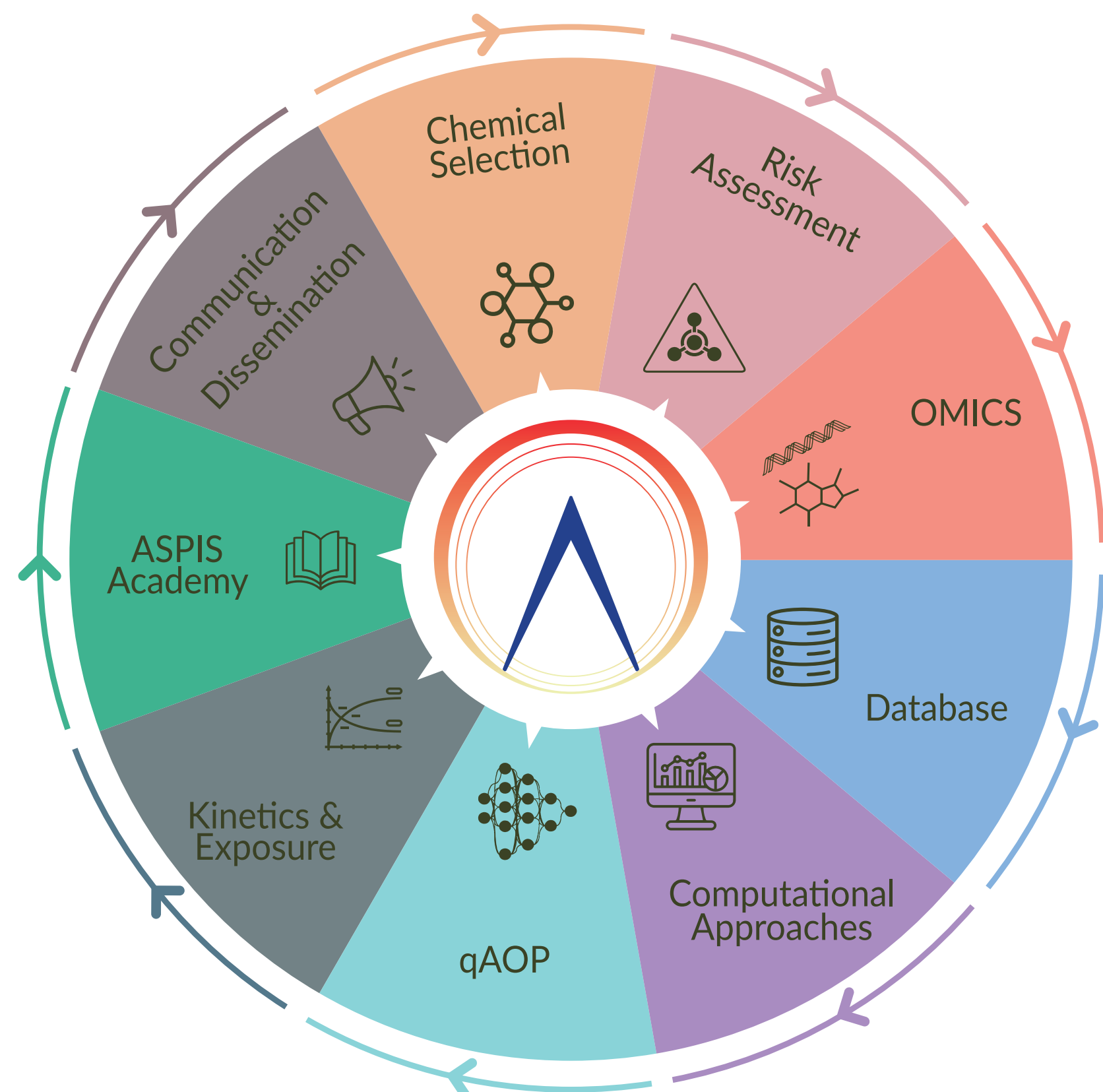


Partnership FOR THE Assessment OF Risks FROM Chemicals



Co-funded by the European Union

Working groups



Mission

To establish a next generation risk assessment (NGRA) framework based on new approach methodologies (NAMs), encompassing in vivo to in silico technologies. Its goal is to **unite three distinct ideas** to better understand chemical toxicity and provide, together, innovative methods of assessing and regulating hazardous chemicals without traditional toxicity testing using laboratory animals.

Background

ASPIS is a confluence of three Horizon 2020-funded projects: **PrecisionTox**, **ONTOX** and **RISK-HUNT3R**. It represents Europe's effort towards the sustainable, animal-free, and reliable chemical risk assessment of tomorrow. It includes more than 70 institutions across the European Union, United Kingdom and United States.

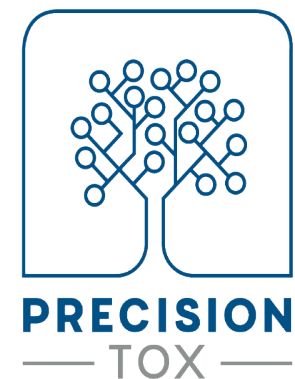
Consortium



Human-centric chemical safety assessment utilizing systems toxicology (www.risk-hunt3r.eu)



Synthesizing toxicology knowledge to support next-generation risk assessment (ontox-project.eu)



Leveraging evolutionary diversity to reveal the molecular basis of toxicity (precisiontox.org)

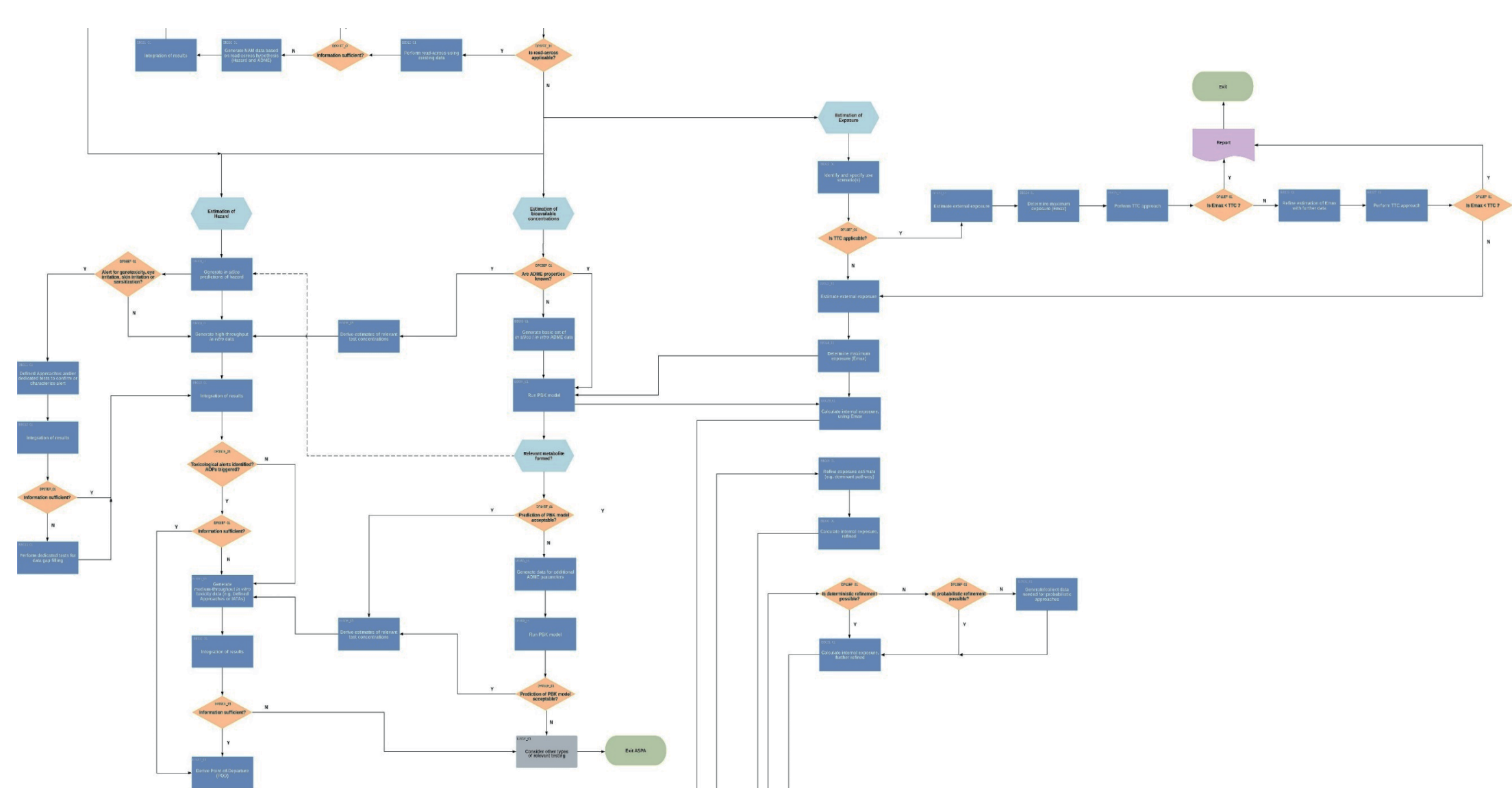
Activities and Perspectives

- ASPIS is a unique partnership consolidating the regulatory science research community by producing innovative and pragmatic solutions for industry, policy makers (EU Commission) and regulators (PARC)
- ASPIS takes an active role in the societal aspects by generating tools to replace and reduce the use of laboratory animals in regulatory science
- ASPIS contributes to the discussion on the EU Commission roadmap to phase out animal testing, as well as participating at EPAA designathon 20-22 March 2024

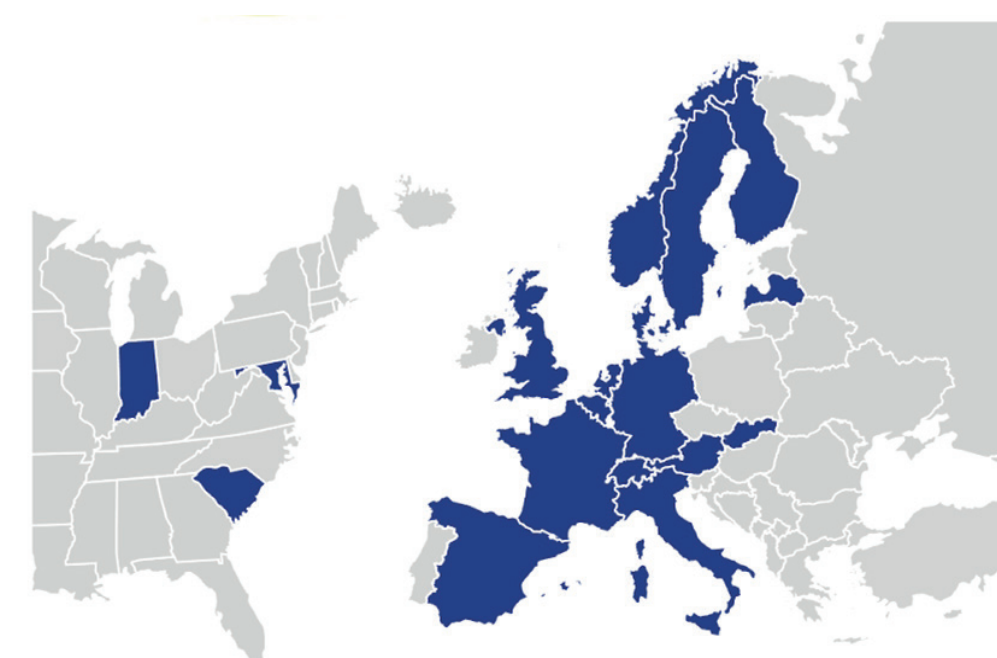
Inter-ASPIS Activities

ASPIS Next Generation Risk Assessment framework (ASPA)

- ASPIS is developing case studies to **operationalize NGRA**, by developing a well-guided workflow for safety assessment of chemicals
- ASPA defines a **tiered approach** on what tools/methods to use; at which steps to obtain and evaluate data; and how to put data into a context of a hazard or risk assessment scenario.
- ASPA defines a **decision logic** with one entry but multiple exit points, activating/deactivating specific modules, and prioritizing and filtering of information.
- Currently being applied to static chemicals and DNTs



ASPIS Academy



Established in March 2023, the ASPIS Academy is a network of >120 early-stage researchers (ESRs) from 65 partners in the EU, UK and USA interested in developing and using New Approach Methodologies (NAMs) in toxicology. The goal of the Academy is build a viable ESR network focused on the use of NAMs for chemical risk assessment, to improve the careers of ESRs through training, championing their needs while setting up a space where ideas and dreams of a new generation of young scientists can shine. Additionally, creating an ASPIS legacy by training a new generation of young scientists.

Programs



In person trainings at ASPIS Open Symposia, project meetings, and online webinars and workshops. This includes science communication, effective presentations, AI in Risk Assessment and Summer School.



Involvement of ESRs in ASPIS working groups. Goals include gaining specialized insights, expanding network, exposure to diverse perspectives, and co-authorship opportunities.



Career development sessions and mentorship pairs across the three consortia. Mentors and mentees work together to build a path to success, innovation, and excellence in toxicology



ESR mobility facilitation among the cluster partners. Goals include sharing of knowledge and expertise and accelerating collaborations.

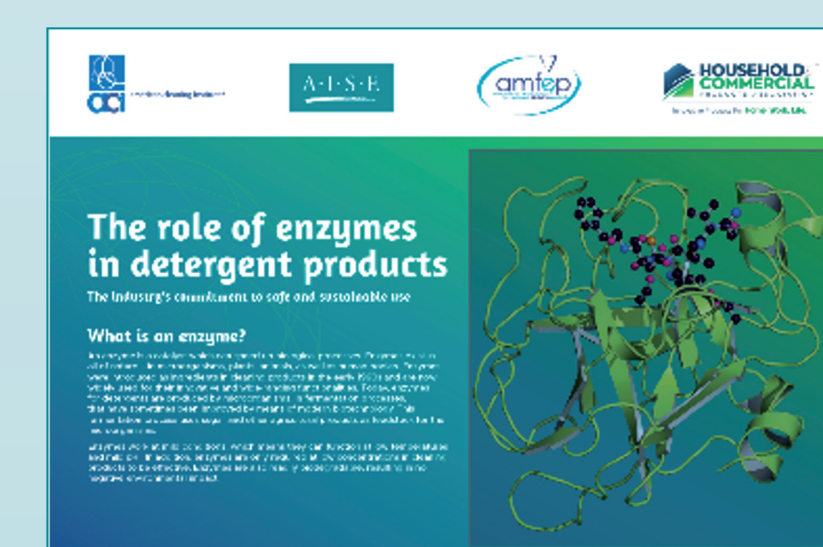
Join us at the **ASPIS Open Symposium at EUROTOX 2024**

1 For additional information contact the ASPIS Working Group Coordinator at Jon.Freedman@wormtox.org



The European detergents industry is committed to closing the gap between science and regulation to prevent unnecessary animal testing

- No animal tests are carried out on finished detergent products.
- A.I.S.E. has a long history of pro-active product stewardship projects, e.g. on safe handling and use of enzymes.
- The safety of detergent ingredients is regulated under REACH. A.I.S.E. advocates for the proper use of New Approach Methodologies (NAMs) in the revision of REACH, which offer opportunities to prevent unnecessary animal testing.
- A.I.S.E. and its members contribute to activities on NAMs through refinement of use and exposure and other alternative approaches to animal testing.



REGULATORY CHALLENGES FOR DETERGENT INGREDIENTS INCLUDE:

- Current & upcoming changes to REACH (hazard data - PBT/vPvB / PMT/vPvM and safety assessment)
- REACH surfactant category registrations (endpoint data requests vs. use of Weight of Evidence (WoE) and read-across)
- Classification schemes used:
 - Globally Harmonised System of Classification and Labelling of Chemicals (GHS)
 - EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC No 1272/2008) - new hazard classes introduced by Commission Delegated Regulation (EU) 2023/707



A.I.S.E.'s commitment to finding alternatives to animal testing is implemented through our scientific engagement with partners in a variety of research initiatives.



- Non-animal science in regulatory decisions for chemical safety



with



- Eye Damage & Irritation
- Physiologically-Based Kinetic (PBK) Model validation for surfactants
- Assessing Membrane-Water Partitioning of Surfactants
- Suitability of the RTgill-W1 cell line assay (OECD 249) for surfactants

UN Sub-Committee of Experts on the GHS - Informal Working Group on Non-Animal Testing Methods



- Classification of health hazards, in particular skin corrosion/irritation, serious eye damage/irritation and respiratory or skin sensitisation



A.I.S.E. has new & ongoing projects on alternative tests for eye and skin irritation as well as several scientific publications.



Collaboration with other formulating sectors to contribute to the successful implementation of the requirements of the REACH and CLP Regulations



ABOUT A.I.S.E.

A.I.S.E. has been the voice of the detergents and maintenance products industry to EU regulators since 1952, representing over 900 companies supplying household and professional cleaning products and services across Europe. A.I.S.E. has pursued scientific research to finding alternatives to animal testing for over three decades. www.aise.eu/alternativestoanimaltesting

Read more about:
**A.I.S.E.'s
commitment**





Modern science to protect people and environment



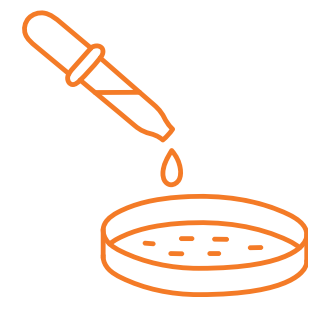
The European Partnership for Alternative Approaches to Animal Testing

A commitment to progressively transition to New Approach Methods (NAMs) and phase out animal testing

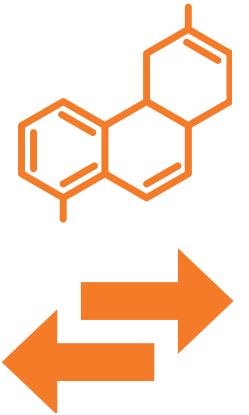
The chemicals industry is developing non-animal testing methods and innovating new and sustainable chemicals.



Computational models



In vitro assays & predictive screening



Grouping of chemicals & read-across



Exposure-driven and regulatory-relevant concepts in (eco)toxicology



Cefic's Long-range Research Initiative (LRI) advances scientific assessment of chemicals safety through rigorous research.



25 years of funding



200+ projects



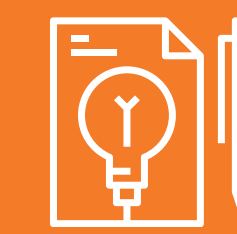
100 million euros for research, studies & awards



NAMs research since 2016



6+ million euros



15+ projects



5+ on environment



10+ on health

Find out more about Cefic-LRI projects:



What is needed to build confidence and increase deployment of NAMs in REACH?

NOW

Regulatory acceptance & policy uptake of available & reliable NAMs.

VISION

Paradigm shift in REACH: Decisions on testing is based on exposure and the extent to which a chemical becomes available to a biological system.

- ▶ A safe space for knowledge exchange & to create trust
- ▶ International alignment & global standards

About Cefic

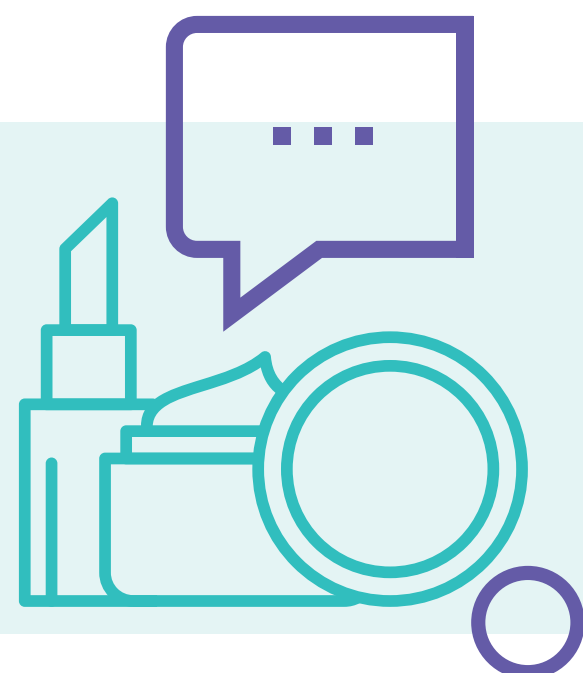
Cefic, the European Chemical Industry Council is the voice chemical companies across Europe, which provide 1.2 million jobs and account for 14% of world chemicals production.

www.cefic.be - info@cefic.be

Cosmetics Europe's key achievements in advancing Non - Animal Methods (NAMs)



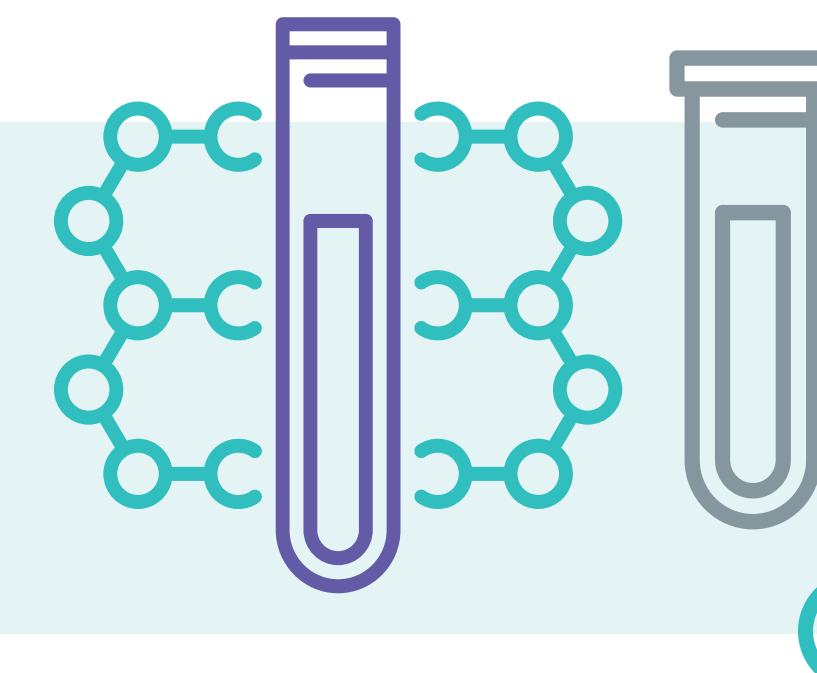
COSMETICS EUROPE, THE VOICE OF THE COSMETICS INDUSTRY SINCE 1962



Cosmetics Europe represents cosmetics and personal care manufacturers, as well as associations advocating for our industry at national level, right across Europe.



FOR OVER 30 YEARS, THE COSMETICS SECTOR HAS LED THE ADVANCEMENT OF NAMs



Ensuring the safety of cosmetic products and promoting the development and acceptance of alternatives to animal testing are key priorities for our sector. The industry's dedication to upholding the highest safety standards is reflected in the continuous refinement of testing and assessment capabilities for all our cosmetic product ingredients.

THE LONG-RANGE SCIENCE STRATEGY (LRSS): RESEARCH AND SCIENCE PROGRAMME ON NAMs (2016 -2022)



The LRSS programme drove our specific research programme on alternatives to animal testing. It was founded on multidisciplinary partnerships between cosmetics companies and other groups that have a deep interest in NAMs and Next Generation Risk Assessment (NGRA), including the international regulatory community, validating agencies, academia, research institutes and industry partners.



THE GOAL OF THE LRSS PROGRAMME

TO ENABLE ANIMAL-FREE SAFETY ASSESSMENTS OF COSMETIC INGREDIENTS

3 PILLARS

Filling critical science gaps related to specific endpoints of toxicity and the use of NAMs to understand biological mechanisms of adverse effects caused by a substance to which the body or environment is exposed to.



Areas in which The LRSS programme scientists evaluated the safety of cosmetic ingredients using NAMs:

- Skin Sensitization
- Eye Irritation and Severe Eye Damage
- Genotoxicity/ Mutagenicity
- Toxicokinetics (absorption, distribution, metabolism and elimination (ADME))
- Toxicodynamics
- Dermal and Inhalation Exposure
- Environment

Implementation of NAMs in NGRAs, to show, through case studies, that safety assessments are possible on multiple toxicity endpoints, especially systemic toxicity.



- Case studies have been instrumental in the LRSS program, guiding the practical implementation of scientific workflows
- These case studies demonstrated the feasibility of safety assessment solely relying on non-animal data, integrating findings from *in silico* and *in vitro* NAMs
- LRSS led ~20 case studies to highlight the practical application of NAMs in tiered NGRAs

Development and validation of NAMs as well as confidence building in the NGRA framework to advocate uptake by industry and gain regulatory acceptance.



- Several scientific contributions from Cosmetics Europe were included in the Scientific Committee on Consumer Safety (SCCS) Notes of Guidance (NoG) for testing the safety of ingredients
- Only within the LRSS program, Cosmetics Europe delivered >15 OECD documents

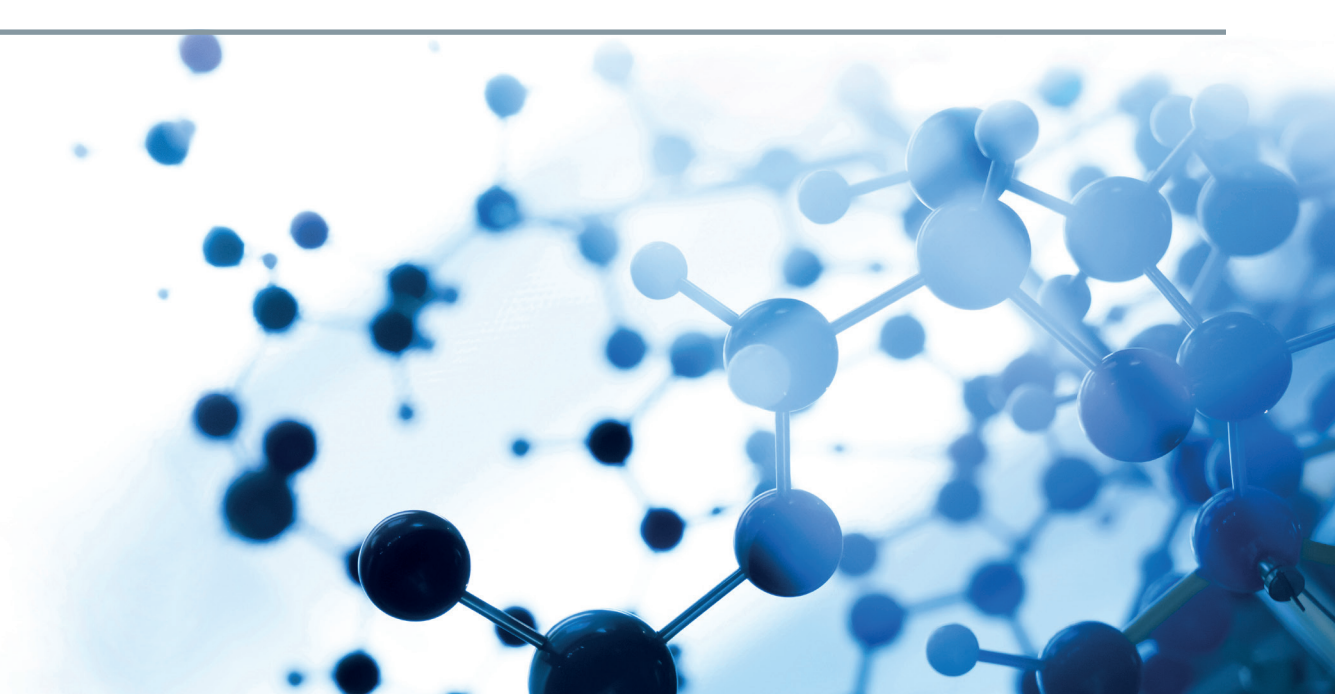
Outside LRSS, Cosmetics Europe submitted the 1st regulatory NGRA dossier to evaluate the systemic safety of Benzophenone- 4 (Under evaluation by the SCCS)

COLLABORATION, PARTNERSHIPS AND THE FUTURE



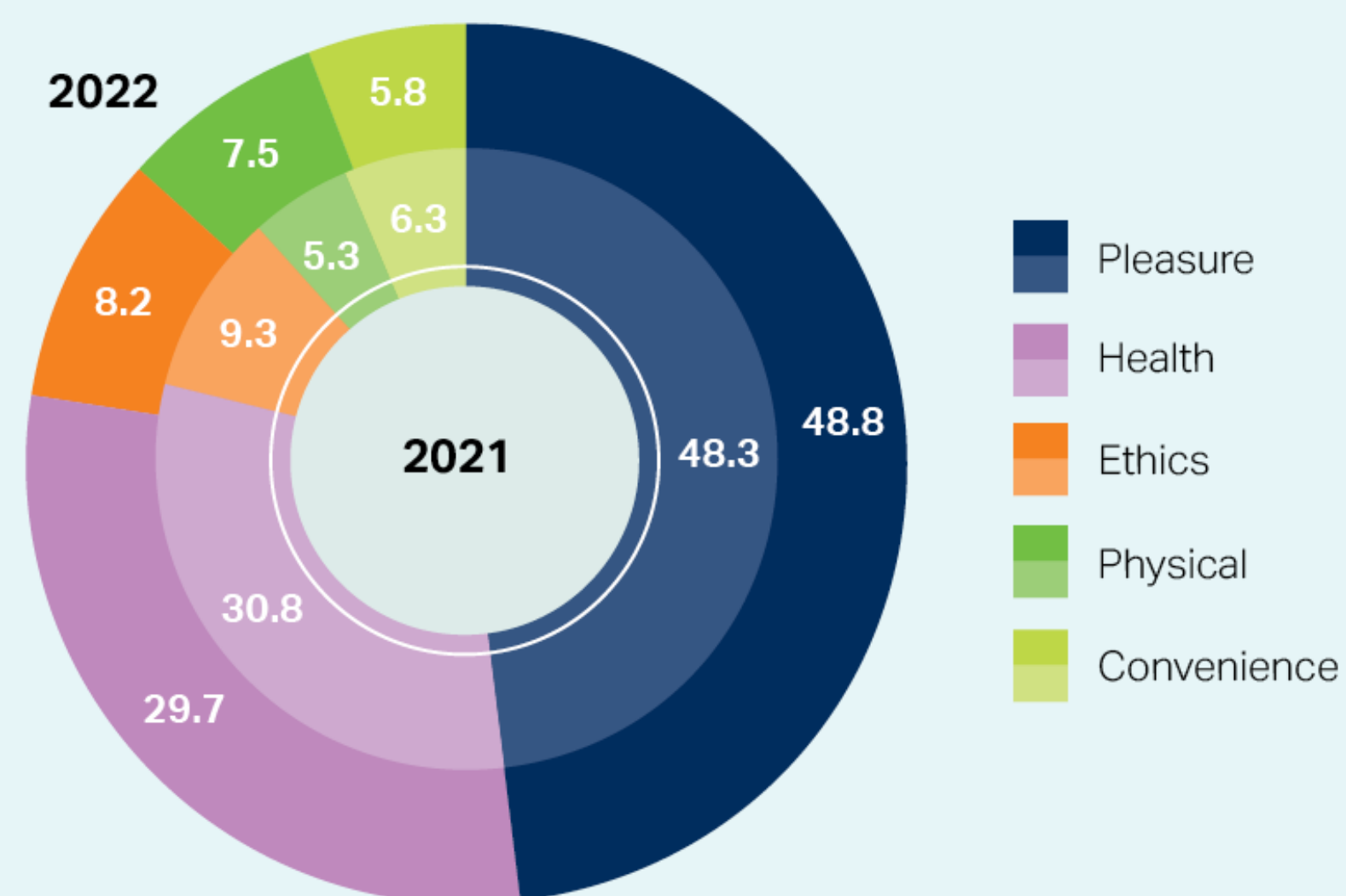
- Cosmetics Europe continuously engages in partnerships with organizations (EPAA, ICCR) and collaborations (RiskHunter, ONTOX, PARC, VHP4Sfatey) with similar initiatives and goals.

- Cosmetics Europe played a key role in the establishment of the International Collaboration on Cosmetics Safety (ICCS), a global initiative focused on advancing the adoption of animal-free assessments of cosmetics, and their ingredients, for human health and environmental safety. Since its establishment, Cosmetics Europe has been actively involved in various projects of the organisation in its capacity as an ICCS member.



Towards the integration of new approach methodologies (NAMs) in food safety risk assessments

Drivers of innovation in Europe (%)



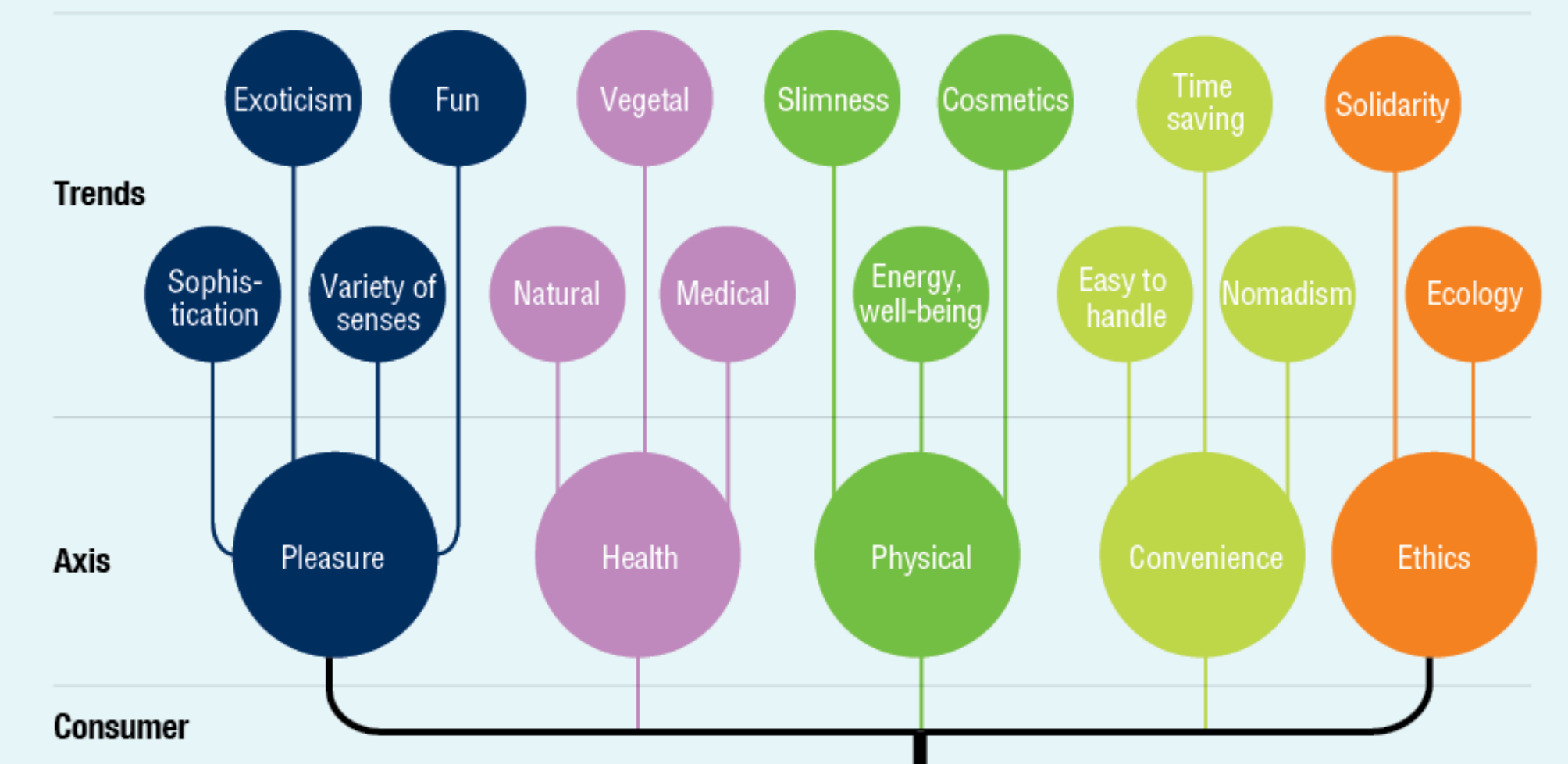
Source: World Food Innovation Barometer by ProtéinesXTC
Copyright © ProtéinesXTC

Novel foods and food ingredients can help meet consumer needs and expectations, improve health, and contribute to sustainable food systems.

All 'food and food ingredients' must be demonstrated to be safe following their consumption and prior to their placement on the market.

Application of NAMs can improve the relevance of data available for food safety assessment and avoid unnecessary animal use.

Food innovation trends



Source: World Food Innovation Barometer by ProtéinesXTC
Copyright © ProtéinesXTC

WHY?

- Next generation or non-animal approaches have advantages over animal approaches e.g. mechanistic investigations
- Risk assessment questions can be better tailored to the human situation
- Political and societal calls to phase out animal testing
- Increasing popularity of vegan foods
- Current EU Regulatory framework allows for the use of NAMs
- Need for more consistency in use of NAMs for food safety risk assessments
- Time associated with traditional studies impacts competitiveness of European businesses and speed to market
- EFSA guidance documents in food safety risk assessments must reflect the new science and provide flexibility for use of NAMs



OUR POSITION

FoodDrinkEurope¹ calls for the routine application of NAMs in scientific and regulatory food safety assessment in Europe²:

Need to close the gap between modern safety science and regulatory requirements

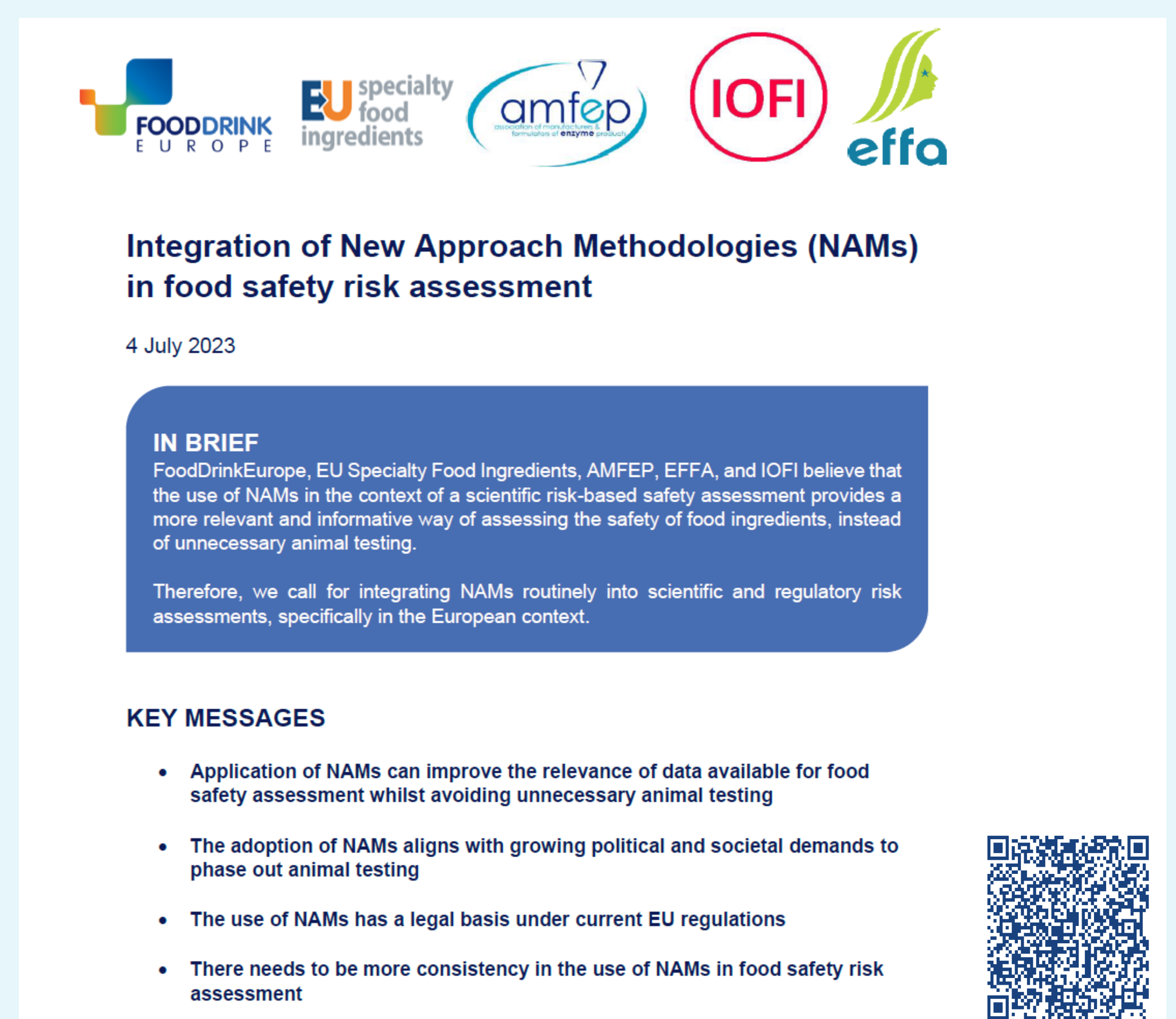
- More flexibility to use fit-for-purpose NAMs within regulatory framework
- Focus on specific human centric safety questions and avoid check list of animal studies

Innovation requires the right regulatory setting and a NAMs approach is important for innovation in the food industry

- NAMs provide more informative high-quality data (e.g. mechanistic understanding), and can be quicker to perform
- Risk of innovation in the EU food sector slowing or stopping without regulatory acceptance of NAMs

The food industry welcomes partnership with the broad base of stakeholders

- Partnership with academia, industry and regulatory authorities to progress adoption of NAMs
- Opportunity to feedback on latest EFSA guidance documents and pilots launched for integrating NAMs in risk assessment



¹ FoodDrinkEurope represents the food and drink manufacturing industry, made up of 291,000 businesses, of which 99% are SMEs, with 4.6 million employees. Contact:

² Position paper co-signed by FoodDrinkEurope, EU Specialty Food Ingredients, the Association of Manufacturers and Formulators of Enzyme Products (AMFEP), the European Flavour Association (EFA), and the International Organization of the Flavor Industry (IOFI)



Accelerating the transition Towards animal-free, sustainable innovation



The International
Fragrance Association

Close cooperation

Enhancing **regulatory application of NAMs** through close cooperation with stakeholders and collaboration in various scientific coordination platforms.



The European Partnership
for Alternative Approaches to Animal Testing

ICCS

INTERNATIONAL
COLLABORATION ON
COSMETICS SAFETY



CAAT

Center for Alternatives
to Animal Testing

Fragrance initiatives

Actively supporting the development and **regulatory acceptance of animal-free approaches** for the advancement of fragrance safety.



Research Institute Fragrance Materials (RIFM)- An independent nonprofit scientific organization that uses historical data, NAMs and advanced exposure tools to the greatest extent possible to evaluate the safe use of fragrance ingredients. Realistic exposure data in consumer products are derived via the Creme-RIFM Aggregate Exposure Model. RIFM's safety assessment conclusions inform the IFRA Standards.



IFRA Standards – IFRA's safe use policy restricting the use of certain fragrance ingredients based on the RIFM safety assessments.



International Dialogue for the Evaluation of Allergens (IDEA) - An industry-driven multi-stakeholder forum developing a NAM-based framework for Quantitative Risk Assessment for skin sensitisation. Find out more: ideaproject.info



Safe and Sustainable by Design (SSbD) - IFRA supports the SSbD framework development as active partner within IRISS, to use NAMs in fragrance innovation and the evaluation of alternatives.



www.ifrafragrance.org