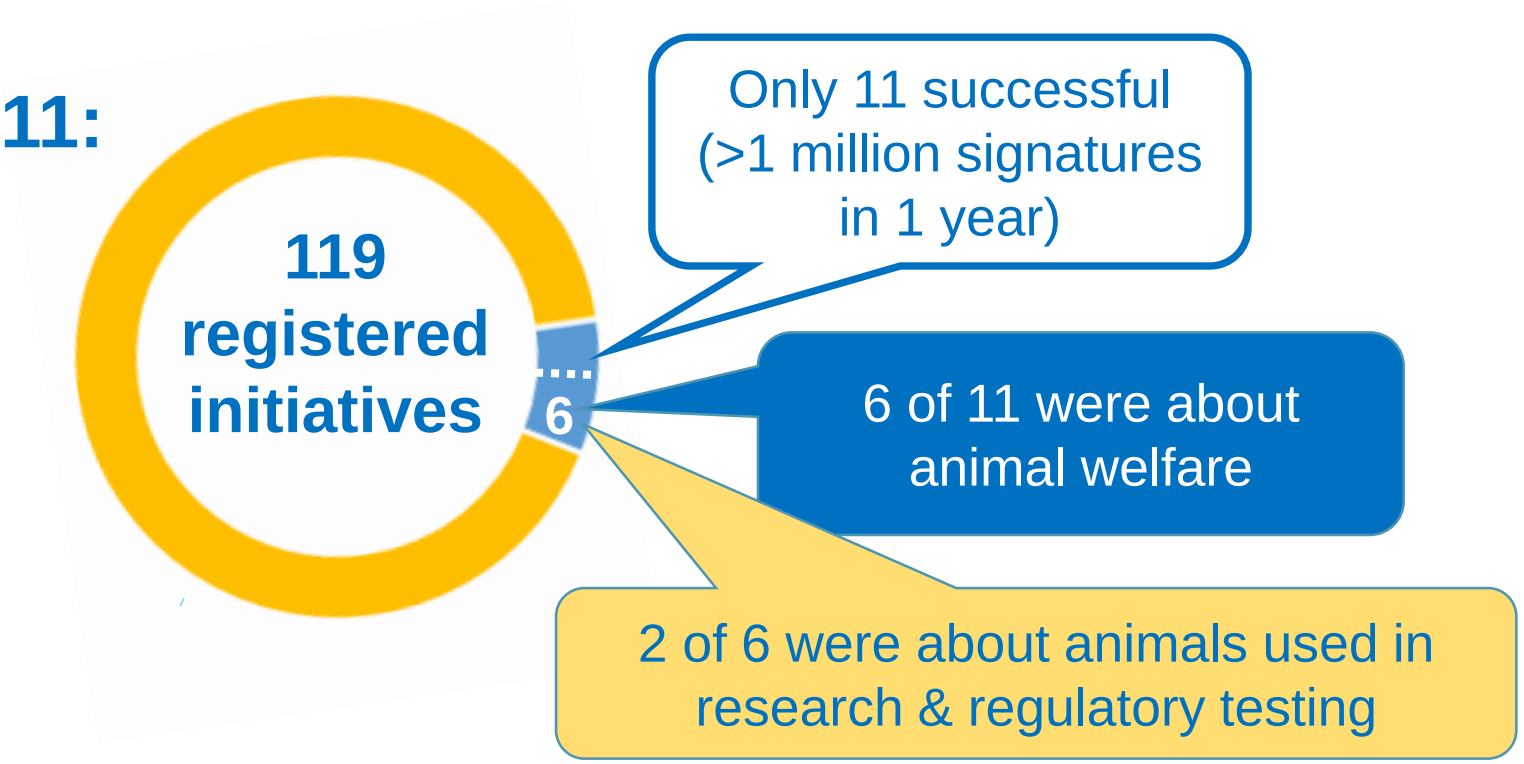
The European Commission Roadmap for phasing out animal testing in chemical safey assessment

Elisabet Berggren, Joint Research Centre, European Commission

The RepRedRef Society Online Seminar, 6 May 2025

European Citizens' Initiative

Since 2011:



https://citizens-initiative.europa.eu/en

European Commission

Save Cruelty Free Cosmetics

1,217,916 signatures

- Commit to a Europe without Animal Testing

COMMISSION'S RESPONSE

1. Enforce the animal testing ban under the Cosmetics Regulation & clarify the interface between the Cosmetics and REACH Regulations

2. Kick off work on a **roadmap towards replacing animal testing in chemical safety assessments** involving all relevant stakeholders

3. Accelerate the reduction of animal testing in research, education and training & continue to support research on alternatives to animal testing with EU funding

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The Roadmap should

provide a plan/schedule to accelerate reaching the goal of phasing out animal testing

&

apply to all relevant pieces of EU chemical legislation that might lead to animal testing for chemical safety assessment
– 15 legislative areas identified

Designed by Freepik

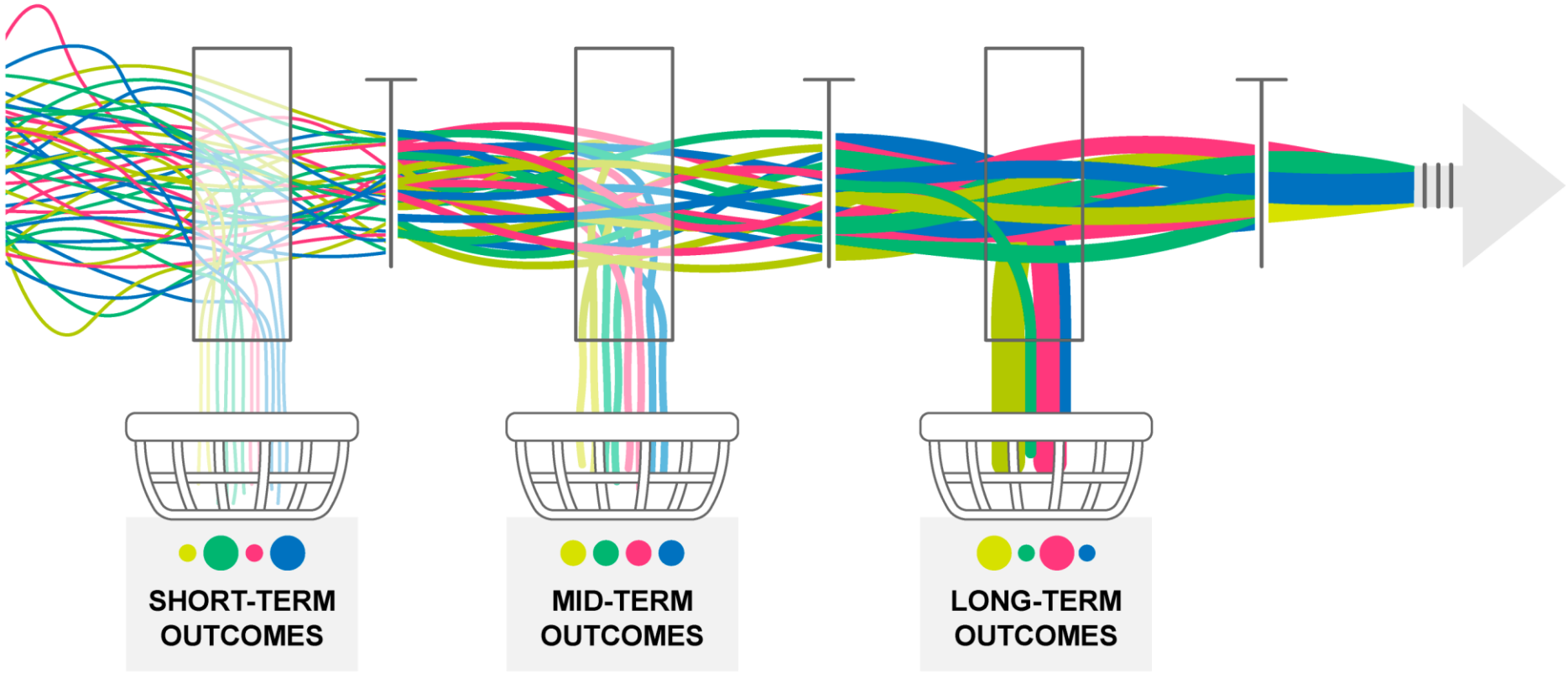
Chemical safety assessments under following legislation are in scope of the Roadmap

1) Chemicals registered under the REACH Regulation (ECHA)
2) Biocides (ECHA)
3) Pesticides (EFSA)
4) Food improvement agents (food additives, food enzymes and food flavourings) (EFSA)
5) Chemicals used in food contact materials (EFSA)
6) Feed additives (EFSA)
7) Human medicinal products (EMA)
8) Veterinary medicinal products and MRLs for active substances in veterinary medicinal products for food-producing animals (EMA)
9) Medical devices
10) Chemicals used in materials/products in contact with drinking water (ECHA)
11) Chemicals covered by the occupational safety directives CAD and CMRD (ECHA)
12) Chemicals used in human nutrition (EFSA)
13) Detergents
14) Classification, labelling and packaging of chemicals (ECHA)
15) Water and Waste legislation (identification of priority substances)

Organisation of the roadmap development

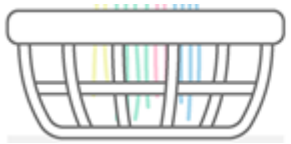
- Interservice Group (DGs and EFSA, ECHA, EMA)
- Three Working Groups (including also stakeholders):
  - Human health (DG ENV)
  - Environmental Safety Assessment (DG GROW)
  - Change Management (JRC, DG GROW)
- Commission workshops on the Roadmap: December 2023, October 2024, 16-17 June 2025, ECHA (for attendance in person register by 15 May)
- Schedule: Publish roadmap early 2026

Roadmap towards phasing out animal testing in chemical safety assessment



Three baskets for short-, medium- and long-term actions

Available methods and approaches



SHORT-TERM

Methods ready to be implemented in current legislation

Methods and approaches in development

MEDIUM -TERM

Methods requiring some further development but still implementable in current legislation

Protection goals and information from animal-free methods

LONG-TERM

New thinking for paradigm shift – transition to animal-free regulatory system

→ Introduction of recommendations into legislation to follow the normal processes (e.g. current infrastructure + legislative procedure)

Human Health (HH) Working Group

- **Overview of animal testing requirements for chemical safety assessments under all legislation in scope**

- **Short-term** solutions for replacing, removing or reducing animal testing discussed:

  - Replacement of **acute oral toxicity** by QSARs / computational methods
  - Replacement of **in vivo toxicokinetics** by in vitro/ in silico toxicokinetics (REACH)
  - Removal of **dog study** (pesticides)
  - Removal of **90-day study for GMO** whole product and enzymes
  - Reduction of **higher tier in vivo studies** (based on suggestions from ECETOC, ASPIS and EMA)

- **Mid-term** solutions for replacing animal testing discussed:
  - DNT in vitro testing battery for pesticides (biocides, REACH)

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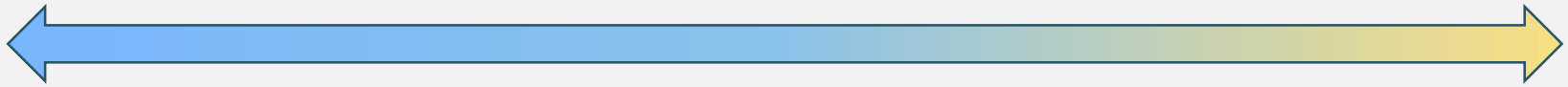
Environmental Safety Assessment (ESA) Working Group

Based on input received from

- ECHA
- EFSA
- EPAA Project Team ESA
- Others

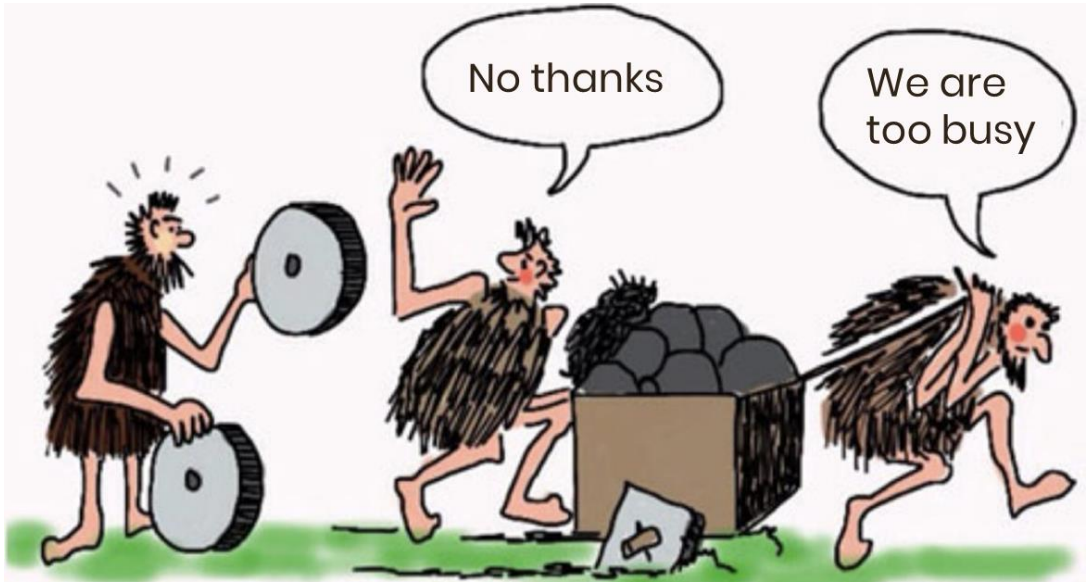
Discussions in the WG ESA on draft recommendations on

- Fish acute toxicity
- Chronic aquatic toxicity
- Long-term switch
- Bioaccumulation
- Endocrine Disruption
- Mammals and birds



1st basket — 3rd basket

The status quo bias – We do not like change



PRECISIONTOX

D6.1 REPORT ON SOCIO-TECHNICAL BARRIERS TO THE UPTAKE OF NAMS

https://precisiontox.org/wp-content/uploads/2024/02/D6.1-Report-on-Socio-Technical-Barriers-26Jan.pdf

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RESEARCH ARTICLE

REVISED **Chemicals regulation and non-animal methods: displacing the gold standard**

[version 2; peer review: 2 approved]

Annamaria Carusi

https://doi.org/10.12688/wellcomeopenres.20581.2

Change Management Working Group – Tasks:

1. Introducing the concept of **transitional initiatives**
2. Developing **indicators** to monitor progress
3. Conducting **bilateral stakeholder discussions** to understand the incentives and concerns from their specific perspective
4. Proposing **collaboration models** to promote trust among stakeholders and develop confidence in non-animal assessment strategies

Scope:

- Informing & inspiring the roadmap construction
- Make the roadmap implementable

Transitional Initiatives

Initiative: a planned course of action including one or more activities, outputs and importantly intended outcomes

Transitional initiative = "unit of change": any initiative contributing directly or indirectly to the replacement or reduction of the use of animals in regulatory assessment of chemicals

Transitional Initiatives – Add your unit of change to the Roadmap!

Number of Notified Initiatives 30 April 2025

20

Required information

1. Title
2. Contact details of notifier
3. Short description
4. Planned output(s)
5. Planned date of output(s)
6. Intended outcome
7. Indicative date of outcome
8. Source(s) of funding

EUSurvey

Optional

9. Suggested indicators
10. Additional information
11. Upload outputs

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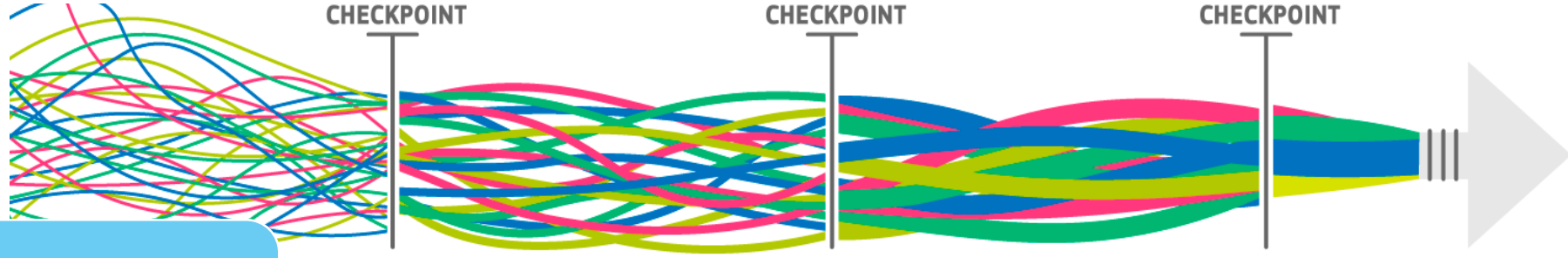
Transitional Initiatives – the process

Anyone – an inclusive process!

Notification of Transitional Initiative



Completeness & clarity check

JRC

Publication in the Catalogue

Monitoring and non-binding recommendations

Publication in the Catalogue provides visibility, but does not imply endorsement by the Commission

Complete with information on transitional initiatives identified, but not notified

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Indicators - Measuring change so we can manage it

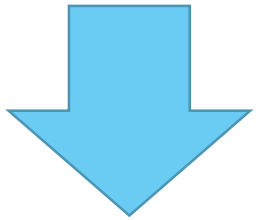
- What does success look like to you?
- What makes an effective indicator?
- Who should host and report on indicators?

Discussed with stakeholders at the EPAA Conference in March

One source of information:

Bilateral Stakeholder Discussions

- Commission Interservice group met 20 stakeholders in a safe space discussion
- Focussing on listening & understanding, no specific Q&A
- Inspiring open discussion/confidence building, no minutes



Inspiring roadmap construction

Informing on how to create trust & better collaboration models

1	EFPIA
2	CEFIC
3	Animal Health Europe
4	ICCS + Cosmetics Europe
5	Ncad
6	Consultant
7	Eurometaux
8	Food Drink Europe
9	IFRA
10	Crop Life Europe
11	CRO
12	Animal welfare NGOs
13	CONCAWE
14	AISE
15	PrecisionTox (ASPIS)
16	SMEs
17	NL ministries & authorities
18	SCCS
19	NAMWISE
20	Health&Environmental NGOs

Bilateral Stakeholder Discussions – Next Steps

- Make a Summary of outcome
- Present back to everyone that participated
- Finalise & present at the Commission Roadmap Conference in June

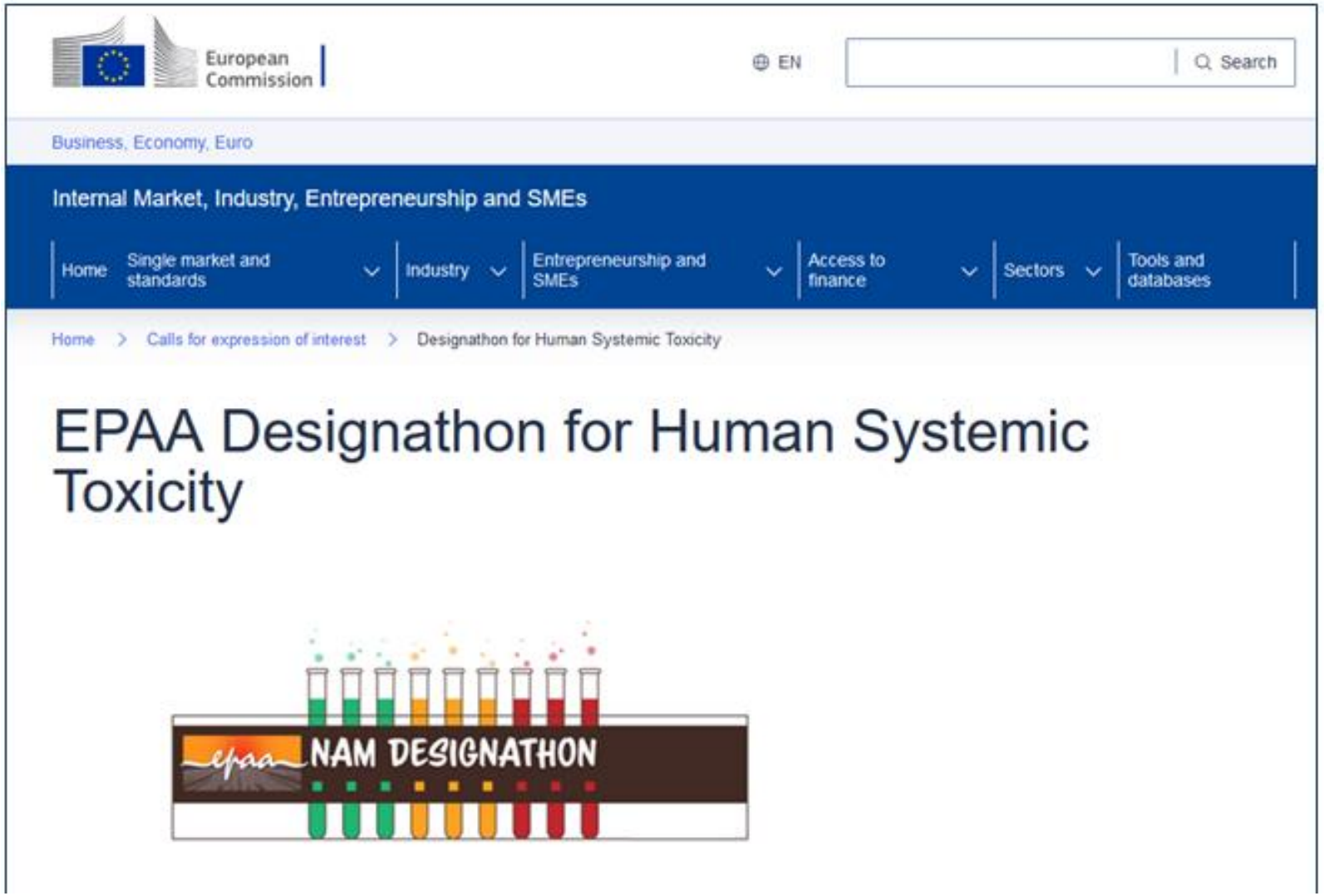
Input to the Commission Actions creating the Roadmap

Collaboration Models

- Safe spaces
- Open communication
- All stakeholders involved
- No-one left behind
- Building on what works already

Create Networks
Allow for Flexibility
Efficient use of Time & Resources

Transitional Initiatives – an Example



https://single-market-economy.ec.europa.eu/calls-expression-interest/epaa-designathon-human-systemic-toxicity_en

From Classification to Protection

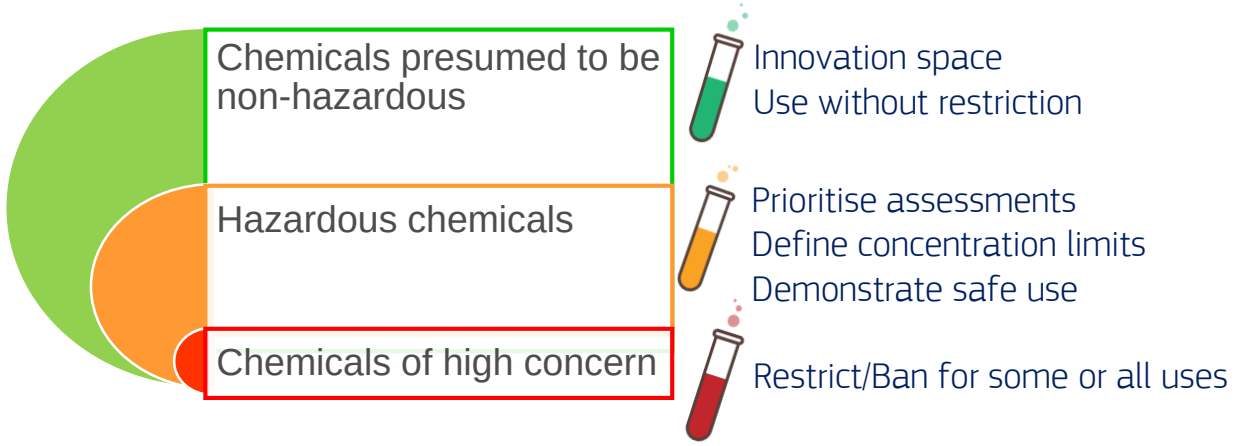
Conceptual development

NAMs-based systemic toxicity classification matrix

		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

Risk management outcomes:

From current to future



Designathon Strategy:

- Create and calibrate the system based on already classified chemicals → same decisions (equivalent protection)
- Apply to additional chemicals → more decisions (overall higher level of protection)

Steps of the Transformational Vision

Concept of a NAMs-based human systemic toxicity classification

		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

Inform future systemic toxicity GHS class: From animal-based criteria to non-animal based criteria

Outcomes

Acute Tox	Muta	Carc	Repro	STOT SE	STOT RE	(ED, not GHS)

Expected development of current GHS classes

Continuous mutual exchange of progress

Systemic Toxicity

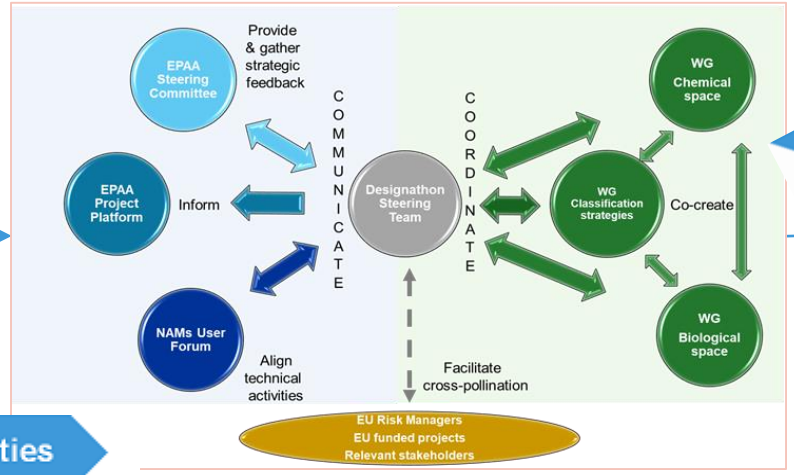
The Challenge

Activities

Pilot Phase

Outputs

Co-creation Phase



Activities

Outputs

Activities

Testing

Implementation Phase

Integration: 2 to 3 Co-created Solution(s)

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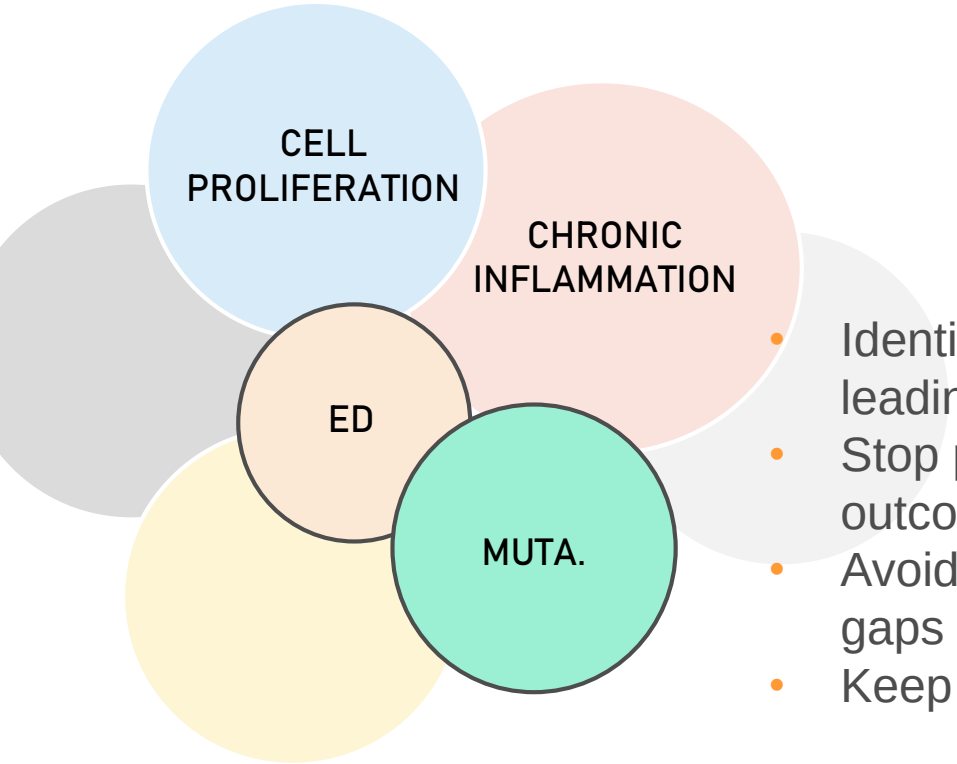
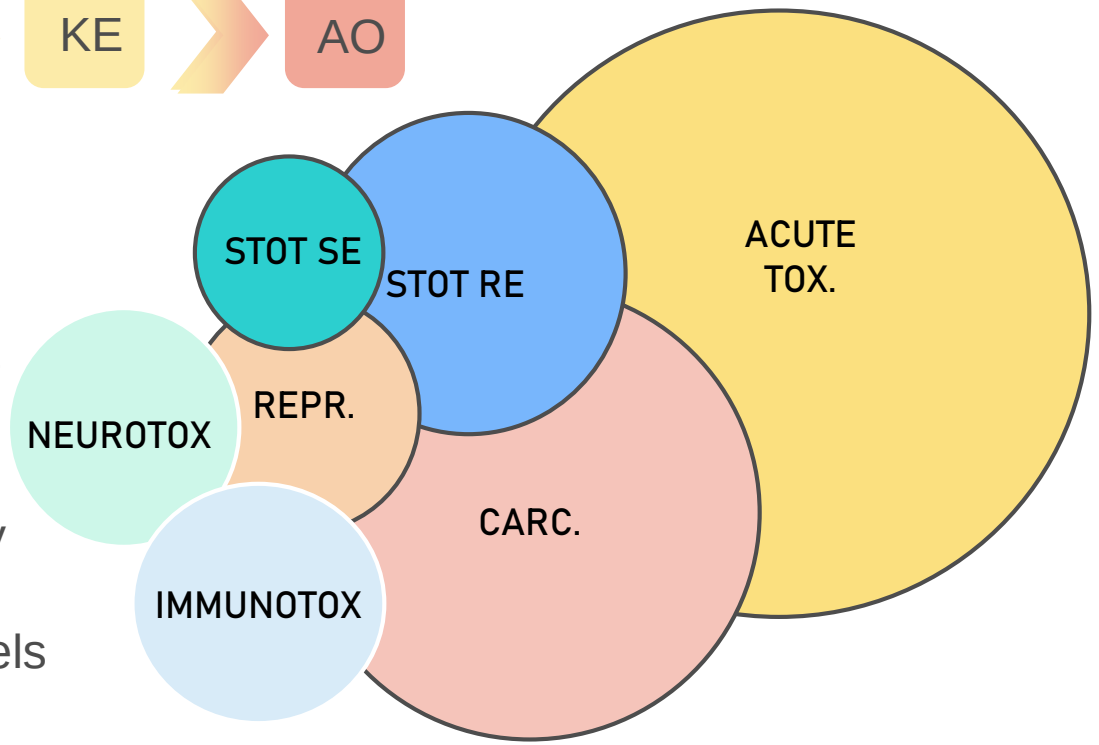


- Identify intermediate effects leading to adverse outcome
- Stop predicting adverse outcome
- Avoid redundancy & identify gaps upstream
- Keep current protection levels



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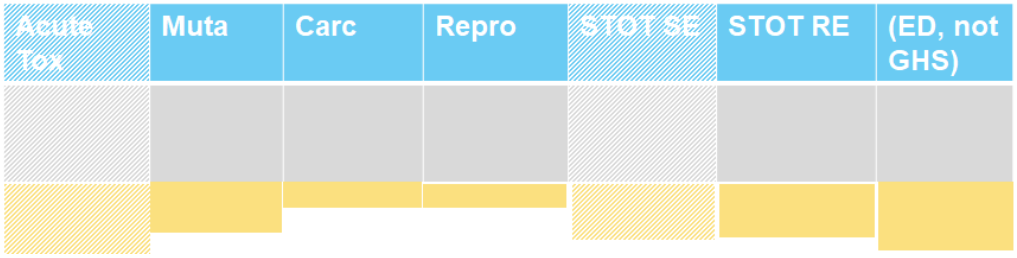
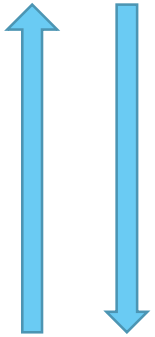
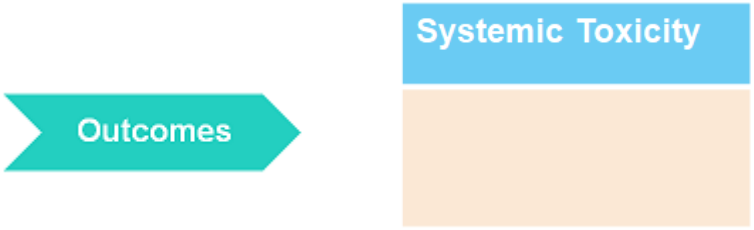
FROM ANIMAL-BASED CRITERIA TO NON-ANIMAL BASED CRITERIA



Continuous mutual exchange of progress in non-animal methodologies during parallel development of the existing classes and the new additional common animal-free class





Criteria based on human evidence and animal methods will remain to avoid obligation to re-evaluate already classified chemicals and allow for use of existing data

Criteria based on non-animal methods increase, as pushed into the system step by step

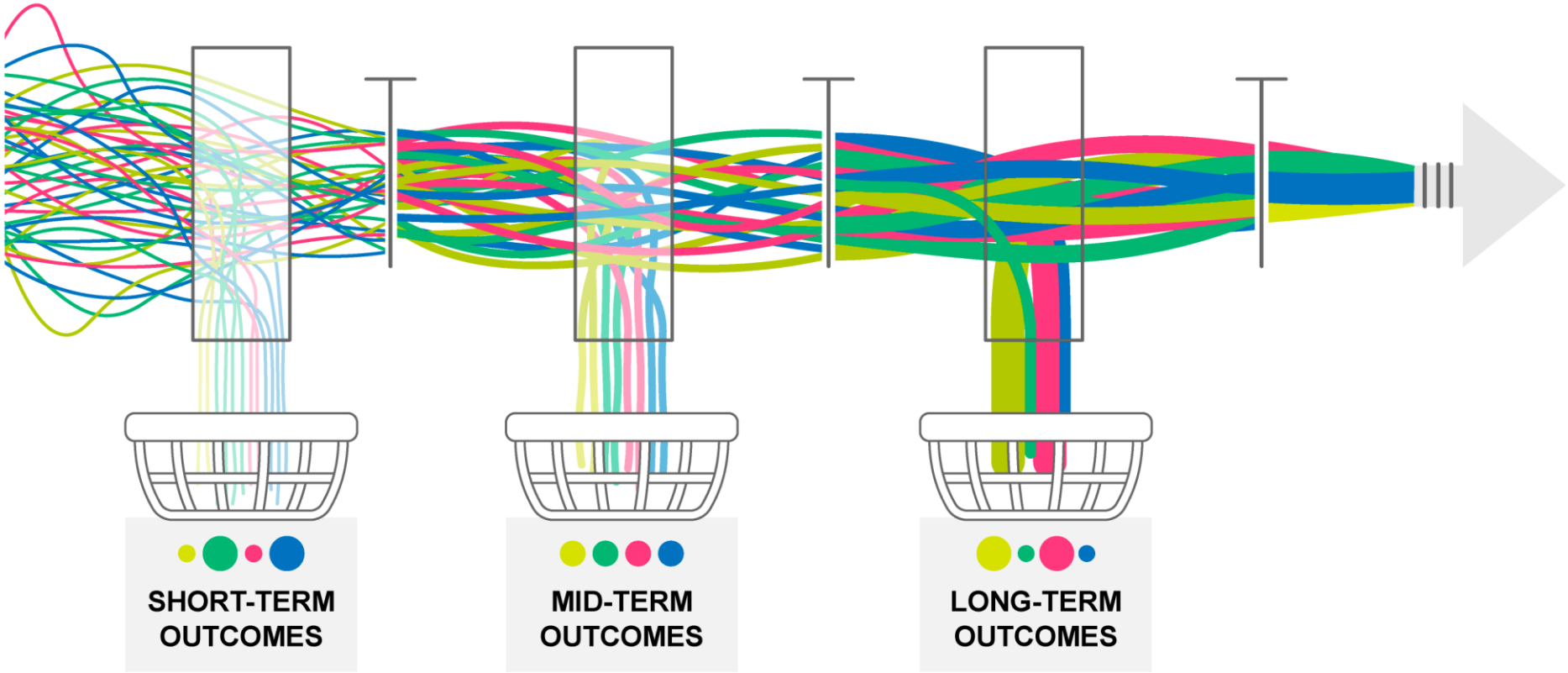
- *to provide partial replacement,*
- *to strengthen weight of evidence considerations,*
- *to cover additional health concerns*

Criteria based only on non-animal methods are developed on evidence from bio-activity and systemic availability, respecting the concept of equal protection gained by calibrating the system with already classified chemicals.

Non-animal methods are pulled into the system, as more reliable and relevant methods, providing an added value, become availble.

Impact

…phasing out animal testing in chemical safety assessment for human health systemic toxicity



Thank you

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