Commission Roadmap towards phasing out animal testing for chemical safety assessment

State of play of the roadmap development – for REMA / Human World for Animals event

20 February 2025

Introduction

- The roadmap provides a **plan/schedule** to accelerate reaching the goal of phasing out animal testing
- Commission Communication
- Roadmap to be **finalised latest in Q1 2026**
- **Implementation phase** – long-term undertaking

- Applicable to **all relevant pieces of EU chemical legislation** that might lead to animal testing for **chemical safety assessments**
  – 15 legislative areas identified

Designed by Freepik

Introduction

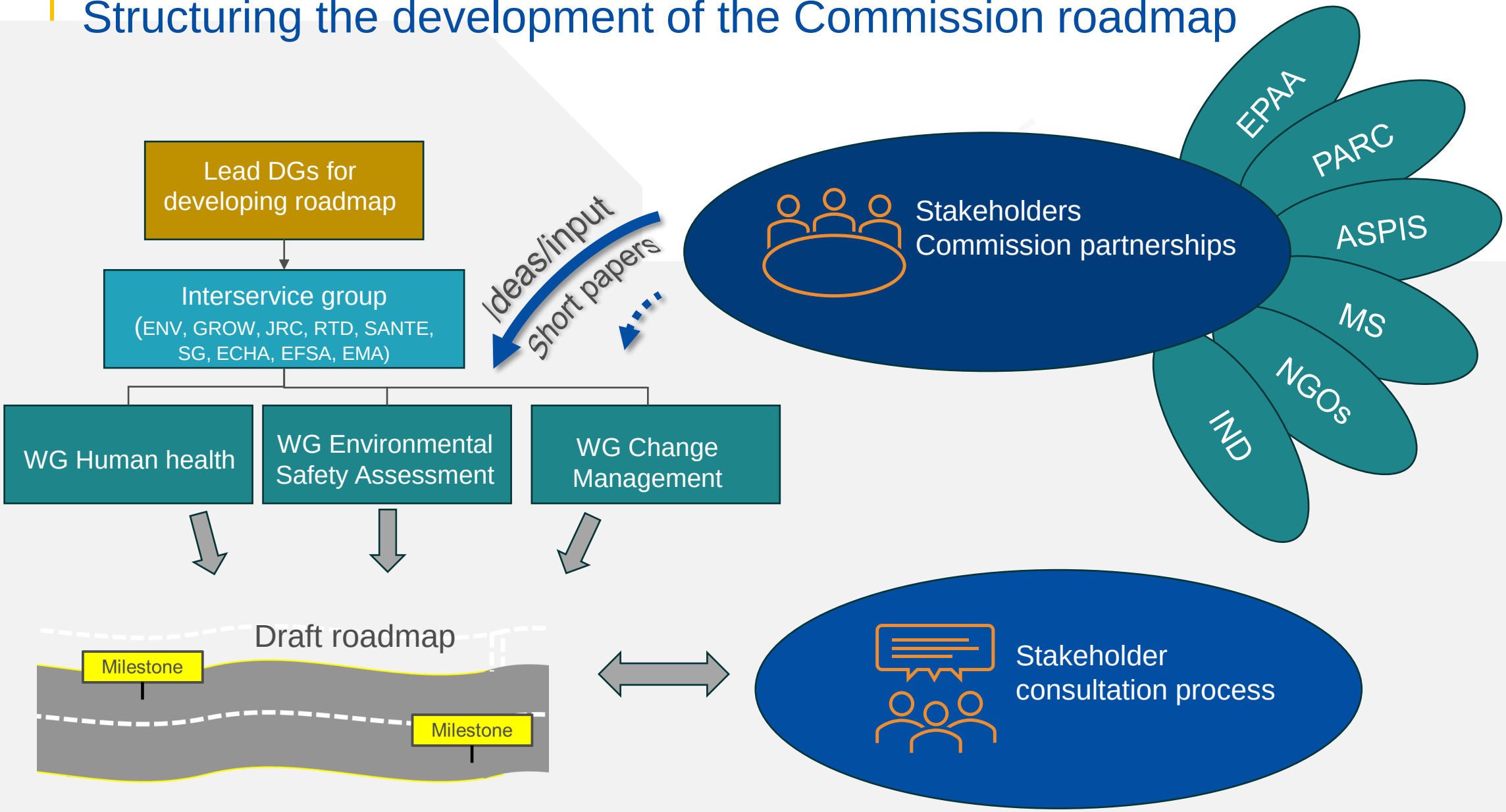
The roadmap will

- List **concrete action points** (e.g. recommendation on how to replace/reduce/refine animal testing for certain endpoint / area of concern)
- Contain **milestones** (e.g. agreement on regulatory needs for complex endpoints)
- Define **indicators** that help to monitor the progress of the implementation
- Recommend and possibly define **organisational structures** that are necessary for the implementation process

Designed by Freepik

Organisation of the roadmap development

Structuring the development of the Commission roadmap

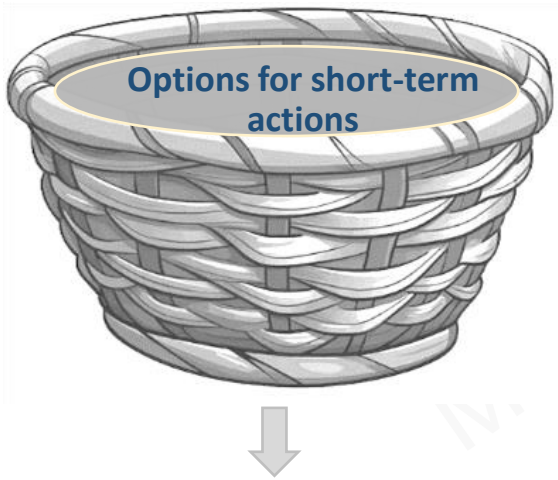


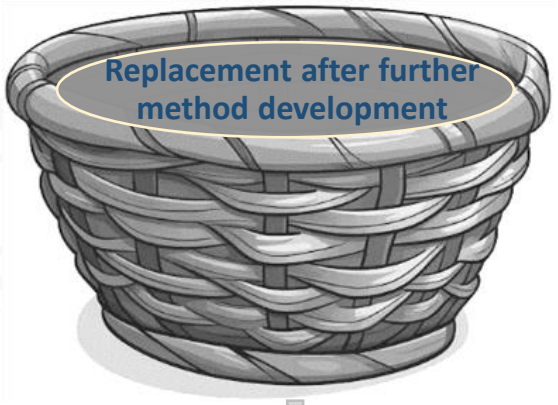
Elements of the roadmap – three baskets

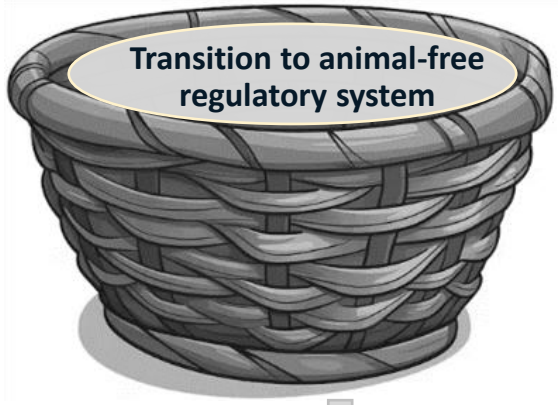
Available methods/approaches
Methods/approaches in development
Expansion/Improvement of method

Starting points:

Protection goals and information from animal-free methods







Recommend short-term replacements

Prioritise methods for further development
Expansion of domain of applicability
Recommend to validate method

Define protection goals – action to develop animal-free approach

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Elements of the roadmap – three baskets

- Currently, COM WGs on Human Health and Environmental Safety Assessments are identifying potential methods/approaches for 1st and 2nd basket and discuss the way forward to fill the 3rd basket

- Expectation for roadmap:
  - 1st basket: Recommendations for short-term replacements
  - 2nd basket: Recommendations for methods/approaches to be further developed or expanded
  - 3rd basket: Recommendations for performance criteria for future methods/approaches
    Identification of the necessary organisational structures for sustaining the development of animal-free system

→ **Introduction of recommendations into legislation to follow the normal processes (e.g. discussion in MS competent authorities subgroup under pharma legislation + legislative procedure)**

State of play of the roadmap development

Update from the WG on Human Health

Discussion points – Human Health

- **HH WG met 4 times in 2024, once in 2025**

- **Overview of animal testing requirements for chemical safety assessments under all legislation in scope:** Current requirements with some info on replacement suggestions has been catalogued.

- **Collecting suggestions for short - medium – long-term actions with their motivation**

- **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) - ongoing
  - **Removal** of 90-day study for GMO whole product and enzymes – considered

  - ECETOC - three projects that aim to reduce in vivo studies
  - ASPIS & EMA - reduction strategy for carcinogenicity studies (based on 90-day study and in vitro)

Discussion points - continued

- **What's still required to make existing Alternatives the default choice?**

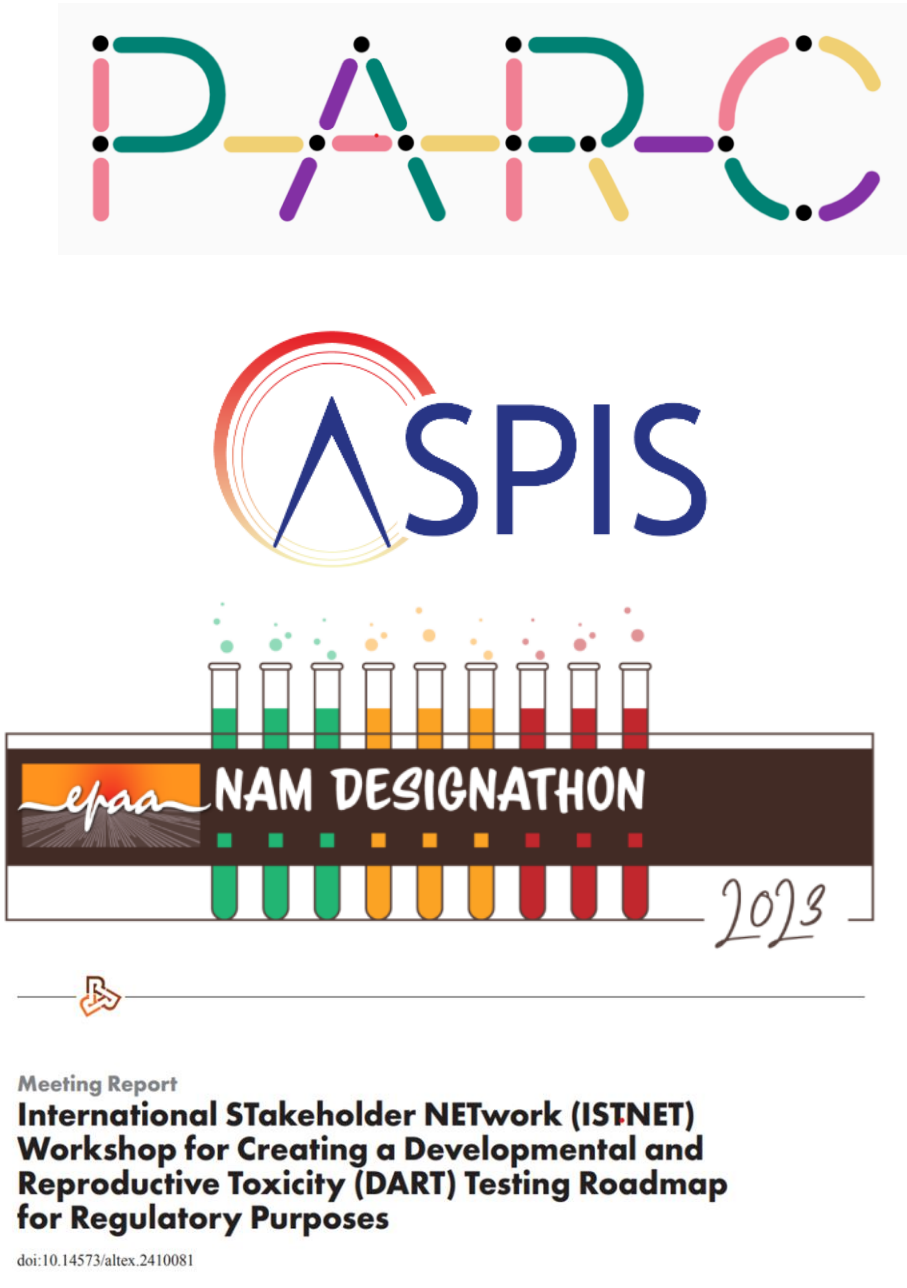
  - Acute toxicity test replacement by QSAR as a model case for describing which steps are needed for the actual use of the alternative per legislation.

- **Replacing animal testing for complex (systemic) endpoints**

  - Aim to propose **performance and acceptance criteria** for new approaches (universal)
  - Aim to propose **uncertainty criteria** (likely sector dependent). RISKHUNT3r is developing an uncertainty framework (in a specific context).
  - Aim to define more clearly what information regulators need from a new, non-animal-based testing system

Related projects – Collaboration

- **PARC NGRA-Route**:
  proposal for “Next- Generation Risk Assessment” becoming the default risk assessment approach in various EU chemical legislations
- ASPIS EU-research project cluster:
  Alternative Safety Profiling Algorithm (ASPA), a NGRA-framework
- **EPAA projects**
  - Acute Toxicity, Skin Sensitization, Carcinogenicity
  - Endocrine Disruption
  - NAM User Forum
  - NAM Designathon Challenge
- **INternational STakeholder NETwork** on Developmental and Reproductive Toxicity - Roadmap for **DART**-assessments



Update from the WG on Environmental Safety Assessment

WG on Environmental Safety Assessment (ESA)

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

Update from the WG on Change Management

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

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Transitional Initiatives – Units of Change

Transitional initiative

Any initiative contributing directly or indirectly to the replacement or reduction of animal use in regulatory assessments.

Output:

concrete deliverable resulting from an activity.

Intended Outcome:

the change we hope it will contribute to.

Transitional Initiatives – the process

Notification of Transitional Initiative

Anyone – an inclusive process!

Completeness & clarity check

JRC

Publication in the Catalogue

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Publication in the Catalogue provides visibility

but does **not** imply endorsement by the Commission

Monitoring and non-binding recommendations

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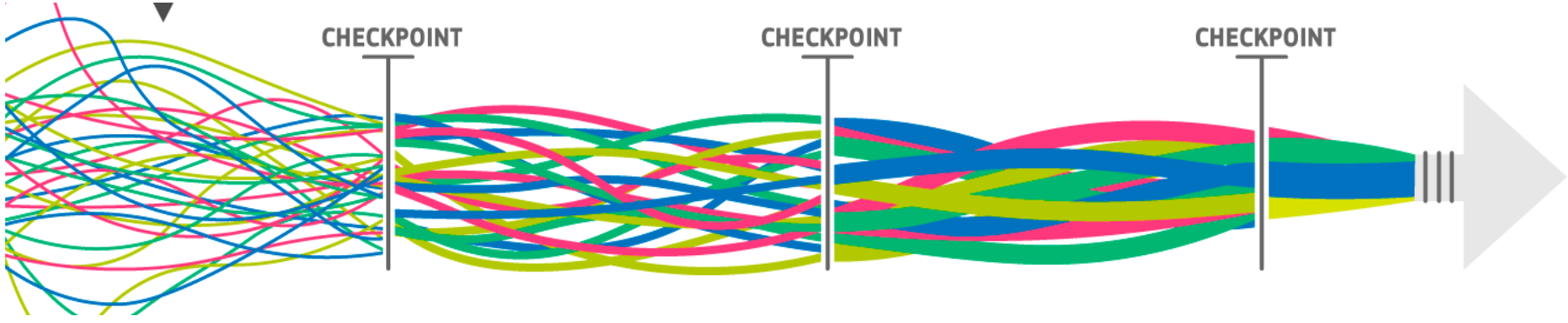

Notify transitional initiatives via EUSurvey

Required field

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

Optional field

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

EUSurvey

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Test Method Development

Acceleration of Validation

Test Method Development, Validation, Standardisation, Qualification

- Commission commitment with Communication C(2023)5041 replying to the European Citizens' Initiative:
  - 'Core of the roadmap will be to analyse and to describe the necessary steps to replace animal testing in pieces of legislation that currently require animal testing for chemical safety assessments. The roadmap will outline 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.'

Test Method Development, Validation, Standardisation, Qualification

- Part of the (development of the) roadmap are **analyses** and **recommendations**
  - On **potential priorities** for method development needs for animal-free methods (2nd/3rd basket)
  - On **organisational structures** necessary for continued prioritisation of method development and validation during the implementation phase
  - ➢ Options for (better) **funding** for validation
  - ➢ Possibilities for **accelerating** the **validation** process
  - ➢ Learnings from the **qualification** process (EMA, EFSA)

Outreach and stakeholder involvement

Stakeholder Consultation – Call for Evidence

- Call for Evidence was open 17 Sept. – 15 October 2024 (91 contributions received)

High-level statements on call for evidence as summarised by consultant

- More work needed on (or significant challenges associated with) the development and validation of non-animal methods for **complex hazard endpoints**, including endocrine disruption, carcinogenicity, reproductive toxicity, repeated dose toxicity, and developmental effects.
- Stakeholders widely acknowledged the need to speed up the **validation process**.
- Many stakeholders emphasised the need for **collaboration** between actors and sectors for the success of the roadmap.
- Stakeholders widely acknowledged the need for **both regulatory and non-regulatory actions**.

→ Report on call for evidence will be published and uploaded on CircaBC later once approved

Targeted Consultations - 1st survey

- **1st survey: Collecting input on topics relevant for development of roadmap**
  - General part
  - Options for animal-free test methods for human health and environmental safety assessment (3 baskets model)
  - Non-animal test methods under development
  - Option for Reduction/Refinement
  - Test method development and validation
  - Training needs

- Consultation of MS authorities, EU agencies, businesses, non-governmental organisations and the scientific community through **online survey**
- Survey from 29 November 2024 to 24 January 2025
- **193 responses are currently analysed by consultant**

Targeted Consultations - 2nd survey

- **2nd survey: Requesting feedback on draft action points, milestones… of the roadmap**
  - Main topic will be the draft roadmap (as far as developed)

- Consultation of MS authorities, EU agencies, businesses, non-governmental organisations and the scientific community
- Planned to be send out: **End of March/beginning of April**
- Open for ca. 6 weeks

- Likely to be followed up by targeted interviews

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Commission Workshops

3rd Com Workshop

- 16-17 June 2025, Helsinki
- Topic: Presentation of the draft roadmap
- Feedback from stakeholders on actions and milestones
- https://echa.europa.eu/-/third-workshop-to-discuss-the-roadmap-to-phase-out-animal-testing-for-chemical-safety-assessments

2nd Commission Workshop on 25 Oct. 2024

Report, pre-reads, presentations: https://single-market-economy.ec.europa.eu/events/roadmap-phasing-out-animal-testing-chemical-safety-assessments-second-workshop-2024-10-25_en

1st Commission Workshop on 11/12 Dec. 2023

together with PARC (NGRA route)

Report, presentations and recordings: https://op.europa.eu/en/publication-detail/-/publication/e350d987-3820-11ef-b441-01aa75ed71a1/language-en

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Animal-Free Chemical Safety Assessment (AF-CSA) Conference

4-6th March 2025

Brussels

Objectives/content:

- Specific focus on how long-term change – scientific vision of Next Generation Risk (NGRA) approaches
- Human Health and Environmental Safety Assessment
- Priorities for development of test methods/approaches
- Validations strategies

➔ To recommend actions on short, medium, long-term roadmap goals

4 and 6th: discussion in plenary (hybrid format)

5th: breakout sessions (in person only)

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Thank you

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Backup slides

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)