

# Introductory presentation: The roadmap towards phasing out animal testing for chemical safety assessments –

Commission Communication, commitments, timeline

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# Background

- Article 13 of the Treaty on the Functioning of the European Union recognises the need to protect animals as sentient beings → obligation to consider animal welfare requirements in legislation
- Directive 2010/63/EU sets the goal of phasing out all animal use for research and for regulatory purposes in the EU, as soon as scientifically possible
- Legislations on chemicals define objectives to minimize animal testing
- Resolution of the European Parliament requesting to accelerate the transition to innovation without the use of animals in research, regulatory testing and education (September 2021)

## ❖ **Commission Communication replying to the European Citizens' Initiative (ECI) 'Save cruelty-free cosmetics – Commit to a Europe without animal testing' (C(2023) 5041)**



# Communication replying to the ECI

## Interface REACH-Cosmetics Regulation

- Cosmetics Product Regulation (CPR) bans animal testing for ingredients or products
- No legislative changes (REACH or CPR)
- Further replacement of animal studies with implementation of roadmap

## Transforming chemicals legislation

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

Modernise science – phase out animal testing also in science and education

- No legislative proposal
- Continue with substantial funding of research
- Set of actions, e.g. European Research Area policy action to reduce animal testing in research, exploratory workshop to determine priorities...

# Commitment to develop a roadmap

- Commitment of Commission to prepare a roadmap towards ultimately phasing out animal testing for chemical safety assessments

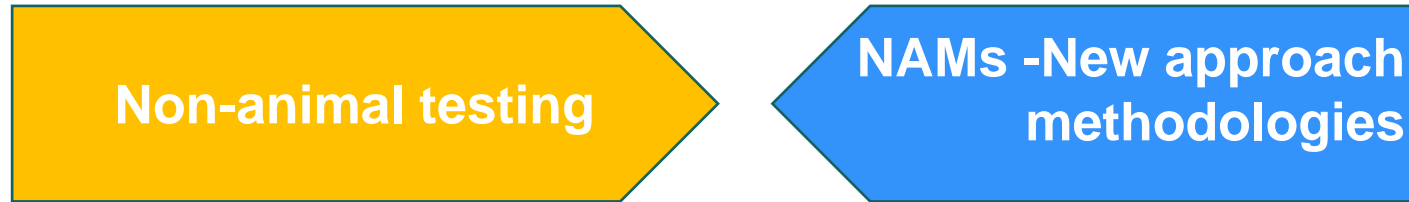
Does not cover animal use for research,  
e.g. bio-medical research

- The roadmap will “outline milestones and specific actions” and address all “relevant pieces of chemical legislation (e.g. REACH, Biocidal Product Regulation, Plant Protection Products Regulation and human and veterinary medicines)”

# Commitment to develop a roadmap

- Commitment of Commission to prepare **a roadmap towards ultimately phasing out animal testing for chemical safety assessments**
- The roadmap will “outline milestones and specific actions” and address all “relevant pieces of chemical legislation (e.g. REACH, Biocidal Product Regulation, Plant Protection Products Regulation and human and veterinary medicines)”
- As part of developing the roadmap:
  - A workshop in the second half of 2023 (11/12 December)
  - A second workshop in the second half of 2024
- Roadmap to be finalised “in the first quarter of the term of the next Commission”

# A roadmap to **non-animal testing** - terminology



- Animal testing corresponding to the scope of Directive 2010/63/EU
  - Live vertebrate animals including independently feeding larval forms and foetal forms of mammals from their last third of development
  - Live cephalopods
- NAM in a broad sense, including
  - In silico (incl. read-across, QSARs...), in chemico and in vitro approaches
  - Integrated approaches to testing and assessment (IATA) and defined approaches (DA)
  - Omics approaches or omic-enhanced studies

# What is a roadmap?

- A policy document (likely in the form of a Communication)
- A navigation plan and schedule listing actions and milestones that are necessary to get towards phasing out animal testing
- It is **not** (necessarily) listing how to replace animal testing, but shows the interim steps and actions that are needed (e.g. need to define non-animal approach for long-term aquatic toxicity; organise expert meeting discussing approach)
- Roadmap to be finalised in the first quarter of the mandate of the next Commission (ca. end of 2025/beginning 2026)
- Reaching the goal of phasing out animal testing for chemical safety assessments in year xyz?



# Communication: several elements of a roadmap

## Action plan to replace animal testing

- Gap analysis
- Short term measures / study replacements
- Long-term measures
- Development needs / research needs

## Analyses of how to improve acceptance, validation, organisation

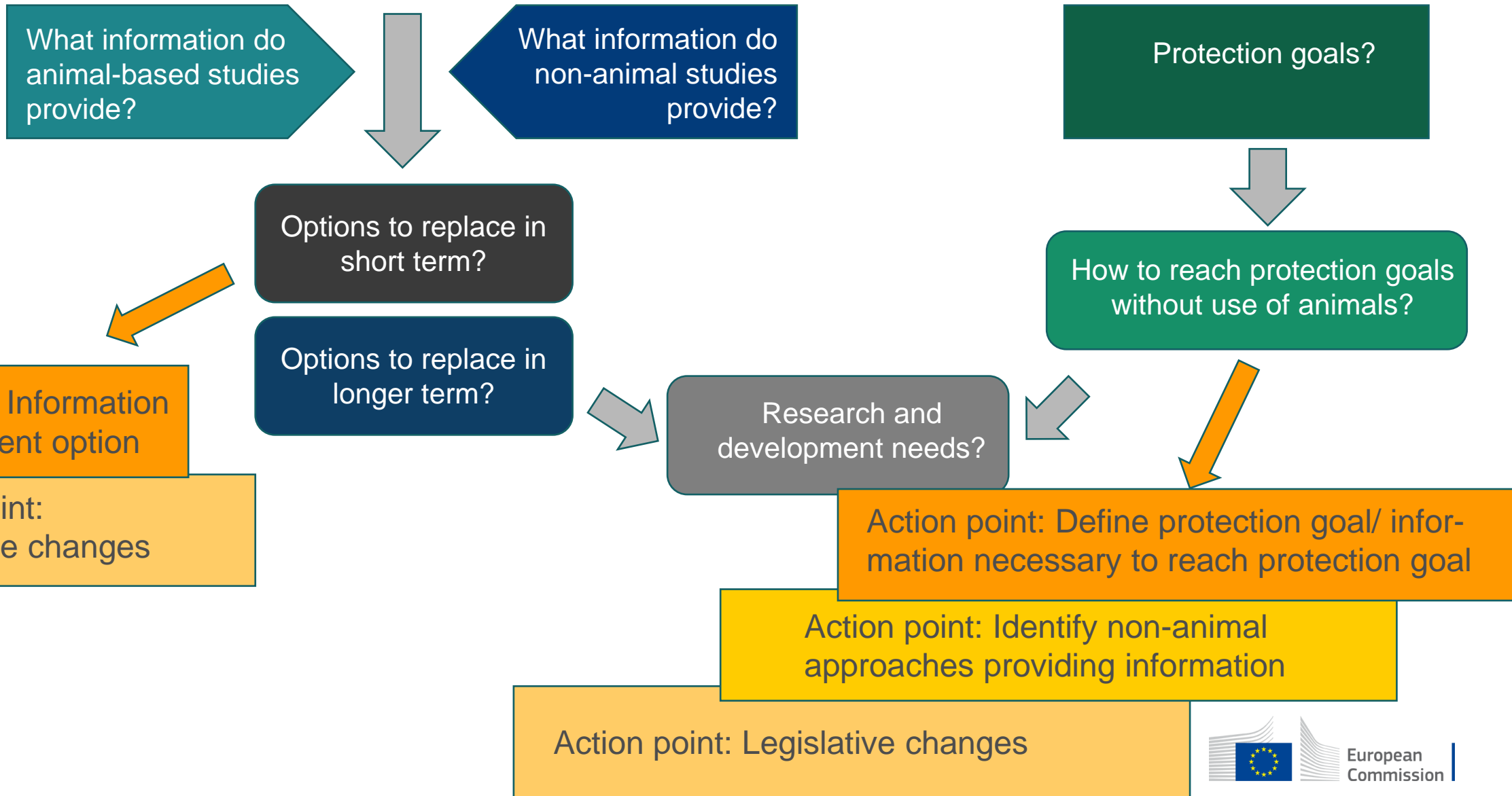
- Analysis of how to accelerate acceptance of methods + validation
- Analyse need/feasibility of an advisory scientific committee
- Analyse current landscape of working groups etc. providing advice on non-animal methods

## Outreach and involvement of stakeholders

- Stakeholder involvement
- Workshops
- Strengthen collaboration of agencies and expert committees
- Outreach to non-EU partners/international organisations – UN GHS
- Increase impact in international forums



# Action plan to replace animal testing



# Elements of a roadmap (1)

- ❖ Indicated in Commission Communication replying to the European Citizens' Initiative (C (2023) 5041)
- **Action plan to replace animal testing**
- **Joining forces - stakeholder involvement in developing the roadmap:** e.g. with workshops
  - First workshop in the second half of 2023
  - Second workshop in the second half of 2024
  - Further workshops/activities focusing on scientific and regulatory aspects organised in collaboration with the EPAA, the agencies, other partners
- **Strengthen collaboration of agencies and expert committees:**
  - Commission proposal entitled 'Streamlining EU scientific and technical work on chemicals through the EU agencies' – Purpose: Enhance the collaboration of the agencies and to increase their efficiency by making full use of synergies in the assessment of chemicals
  - Analysis of strengths and weaknesses of the current landscape of agencies, committees and working groups that provide advice on non-animal methods.
  - Explore opportunities for a stronger collaboration and analyse possibilities to accelerate the transfer of available scientific expertise to legislation.

## Elements of a roadmap (2)

- **Advisory scientific committee on non-animal methods:** Analyse the need/feasibility of an expert scientific committee to provide advice on the development of non-animal approaches and their use in the regulatory context.
- **Acceptance of methods:** Analyse ways to accelerate the acceptance of new non-animal methods, while taking into account the importance of mutual acceptance of data across different jurisdictions. This includes the need to increase validation but also the regulatory uptake of non-animal methods.
- **International dimension:**
  - Outreach to non -EU partner countries and multilateral organisations to foster the development and acceptance of non-animal testing methods for regulatory purposes,
  - UN Globally Harmonised System of Classification and Labelling of Chemicals.
- **Agencies involvement in international forums:** Analyse how to increase the agencies' visibility and impact in international forums, such as OECD, WHO, APCRA ...

# Elements of a roadmap (3)

- **Improve availability and accessibility of information:**
  - Proposal on a Regulation on chemicals data that will improve accessibility to information on chemicals
  - Analysis of how to facilitate access to information such as upcoming events, calls, but also to guidance
- **Outreach to scientific community and stakeholders:** Increase outreach to stakeholders and the scientific community, with support of its agencies, to receive the necessary input on how to replace animal testing with non-animal approaches, e.g. via the organisation of workshops, the annual conference under the umbrella of EPAA or contributions to conferences.

# Thank you



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