
EU Chemicals Strategy
for Sustainability
Jordane WODLI, DG Environment
European Commission
#ChemicalsStrategy
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THE CHEMICALS STRATEGY FOR SUSTAINABILITY

A legislative framework still in evolution, with a need of test methods to assess endocrine disruptors

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Chemicals Strategy for Sustainability

Boosting innovation

- Strategic R&I plan for chemicals and materials (Oct 22)
- Commission recommendation on safe and sustainable by design criteria (Dec 22)
- Research funding
- Taxonomy delegated acts (Jun 23)

Strengthening legislation for better protection

- Water Package (Oct 22)
- Eco-design regulation (Mar 22)
- Industrial Emissions (Apr 22)
- REACH restriction roadmap (Apr 22)
- CLP regulation (Dec 22; provisional agreement Dec 23)
- Maximum levels for food contaminants (Lead, Cadmium, Aug 22); PFAS (Dec 22)
- REACH
- Essential use (Apr 24)
- Cosmetics product regulation
- Toy safety regulation (Jul 23)

Simplification & coherence

- Horizontal proposal on (re-)attribution of technical work on chemicals to EU Agencies (Dec 23)
- Horizontal proposal on improving access, sharing and re-use of chemical data (Dec 23)
- Proposal for a basic regulation of the European Chemicals Agency

Knowledge and science

- Strategic research and innovation plan for chemicals – Oct 22
- European partnership for the assessment of risks from chemicals (PARC) – May 22
- Indicator framework (Apr 24)

Global

- Proposal of new hazard classes to UN Global Harmonised System for Classification – Jan 23
- International Framework on Chemicals – Sep 23
- Funding for developing countries
- Export ban on chemicals banned in the EU

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CLP revision – Delegated Act Dec 22

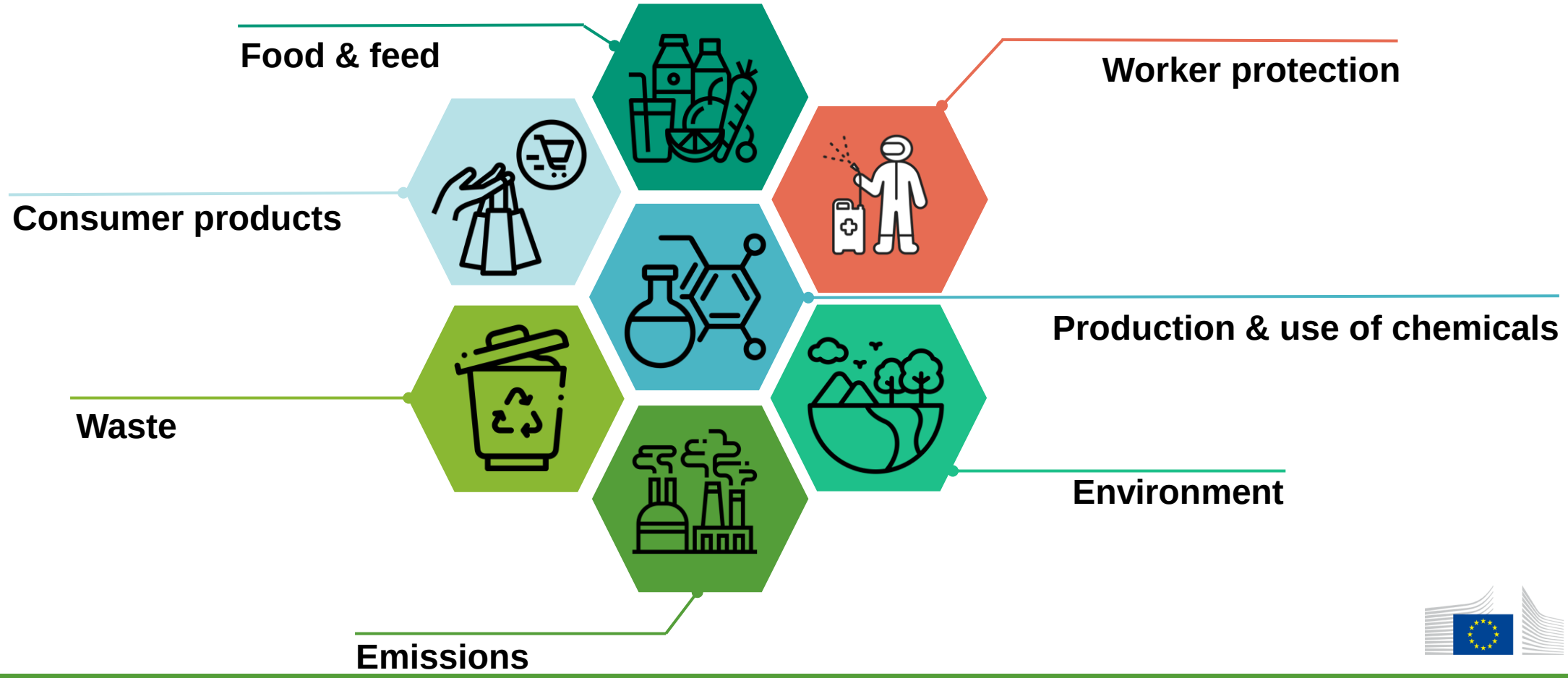
Adds **new hazard classes** in CLP

(OJ 31 March 23, entry into force 20 April 23)

- Endocrine disruption for human health in Category 1 and Category 2
- Endocrine disruption for the environment in Category 1 and Category 2
- PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative)
- PMT (persistent, mobile, toxic), vPvM (very persistent, very mobile)

One substance one assessment
EU legal framework on chemicals

> 100 pieces of legislative pieces dealing with chemicals



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One substance one assessment - *Today*

Initiation

- Plethora of legislation
- By COM, MSs, Industry
- At different time

Allocation

- Agency
- Expert group
- Scientific Committee
- Consultant

Data

- Availability
- Formats
- Access
- Quality

Methodologies

- Guidelines
- Guidance

Fit for purpose, but different rules and practices

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One substance, one assessment - *Tomorrow*

Initiation

- Synchronised and coordinated

Allocation

- Making best use of available resources and expertise
- Good governance and cooperation

Data

- Easily findable, accessible, interoperable, secure, of high quality
- Shared and reused by default

Methodologies

- Coherent
- To the extent possible harmonised

Stakeholders are timely informed and have access to data

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One substance, one assessment package

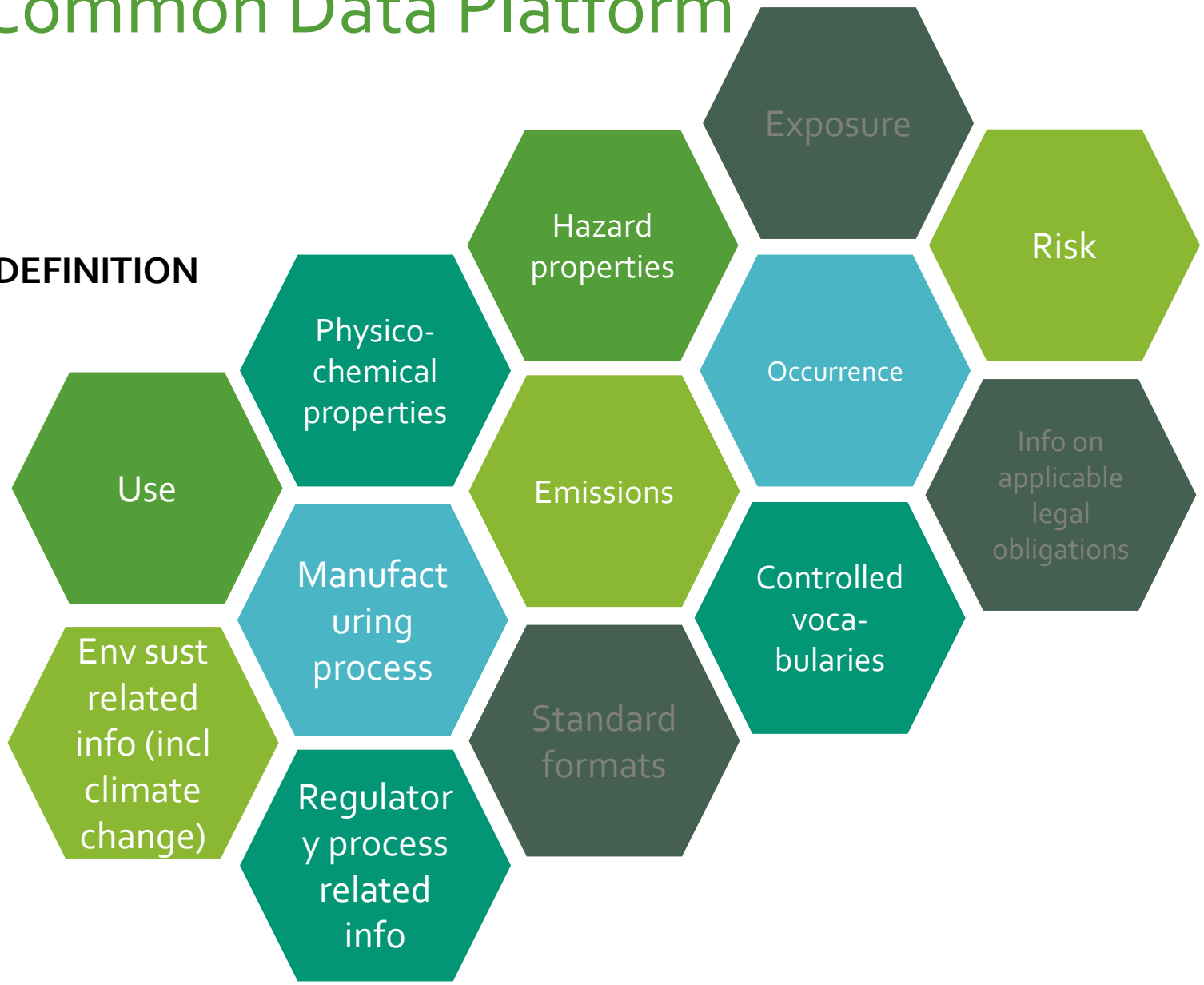
1. Consolidating work in the EU agencies and improving cooperation

- Proposal for a regulation on the re-attribution of tasks and improving cooperation among agencies
- Proposal for a directive on the re-attribution of tasks amending RoHS directive

2. Removing barriers to reusing of data and establishing monitoring and outlook framework for chemicals

- Proposal for a regulation establishing a common data platform on chemicals and establishing a monitoring and outlook framework for chemicals

Common Data Platform



SOURCES

- From implementation of EU chemicals legislation (Annex)
- Monitoring data from IPCHEM
- Human biomonitoring data
- Selected datasets from research or (inter)national implementation programmes

Not only 'input' data, but also output, such as assessment reports, agencies' opinions, reference values

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PROCESSES AT INTERNATIONAL LEVEL

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GHS work on ED

- GHS informal working group on potential hazards issues (PHI-IWG)
- Active since 2023, with 3 main streams of work:
  - EDs;
  - Persistence and mobility;
  - Hazardous to the terrestrial environment
- On ED, adoption last year of a mandate to OECD on ED (ST/SG/AC.10/C.4/2023/6) and adoption of the 2023-2024 workplan of the working group
- Work of OECD on-going with an ad-hoc group for GHS ED
- Aims: to review the science needed for classification and labelling of substances and mixtures that have endocrine disrupting properties

Update of the EDCs State of the Science Report

- UNEA resolution 5/7 adopted by the United Nations Environment Assembly on 2 March 2022.
- "Request UNEP, subject to the availability of resources, and in cooperation with the World Health Organization, to update the report entitled State of the Science of Endocrine Disrupting Chemicals 2012 [...]"
- Start of the project in 2024
- EDC Expert Group launched
- With collaboration of WHO, but also OECD and GHS, to align the 2 processes and avoid duplication of works

BRIDGING HORIZONS IN ENDOCRINE DISRUPTORS RESEARCH

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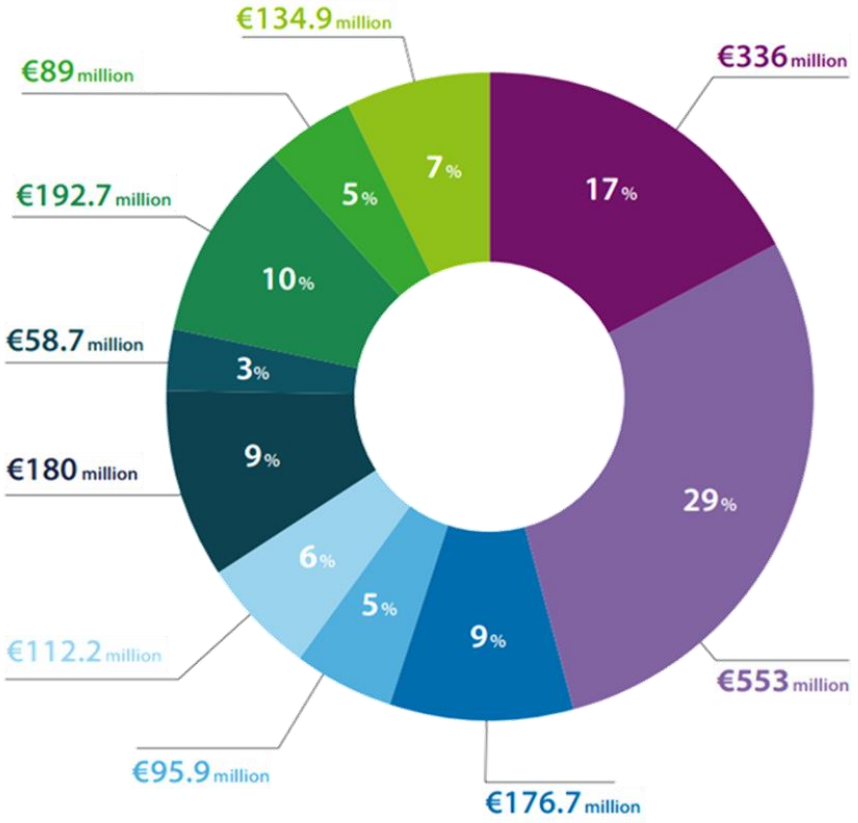
Horizon Europe provides funding for research and innovation in chemicals and health



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EURION: the first European cluster on EDC research

In 2019, the Commission funded the first project cluster on EDCs

- Consolidating 8 EDC-related projects under one initiative to develop new testing and screening methods for the identification and assessment of risk from EDCs.
- Funded with 49 million EUR.
- Set up in order to:
  - Facilitate synergies between related projects.
  - Streamline feedback to policy.
  - Publish and attend conferences jointly.
  - Collaborate on specialised scientific topics as part of WGs.
  - Organise joint events and workshops that benefit the ED and regulatory communities.

GOLIATH Testing metabolism disrupting chemicals
OBERON
ERGO Endocrine Guideline Optimisation
ENDpoiNTs
athena
SCREENED Screening for Endocrine Disruptors
freia PROJECT
edcmet

EURION
European Cluster to Improve Identification of Endocrine Disruptors

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ENKORE: a new cluster on EDCs and health

ENKORE

Funded from 2024 to 2028 with €40M from Horizon Europe.

- 5 projects: EDC-MASLD, ENDOMIX, HYPIEND, MERLON and NEMESIS.
- Working together to better understand the health impacts of EDCs:
  - In the context of chemical mixtures and looking beyond the organ level.
  - Featuring a strong New Approach Methodologies (NAMs) component.
  - Different areas of focus: immune system, metabolic systems and disorders, neuroendocrine system, etc.
- ENKORE aims to close the gap between science and policy by generating health-relevant knowledge that informs regulators and protects our health

EDC-MASLD

ENDOMIX

HYPIEND

Merlon

NEMESIS

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NAMS FOR ED-IDENTIFICATION AND CHARACTERISATION

Update from EC Roadmap WS

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Introduction

- The roadmap provides a **plan/schedule** to accelerate reaching the goal of phasing out animal testing
- 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

Core elements

- **Core of the roadmap**
  - Analysis/description of the **steps to replace** (reduce/refine) animal testing
  - Outline the path to expand and **accelerate the development, validation and implementation of non-animal methods**
  - Outline the path for **uptake across legislations**.

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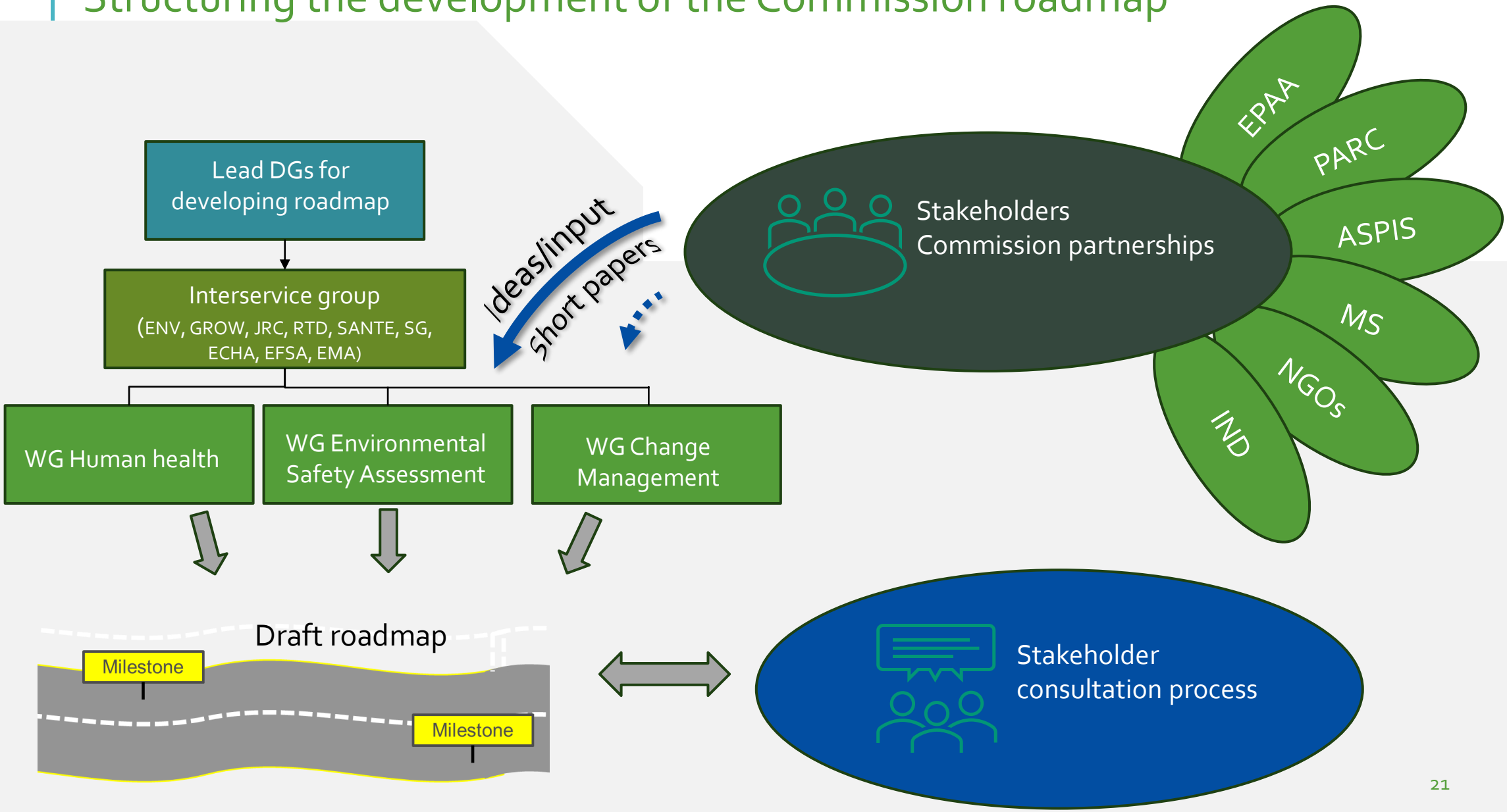
Structuring the development of the Commission roadmap



Status of the Commission roadmap development

- 9 Interservice Group meetings have been held → terminology, structure, organization of the roadmap development discussed
- Scope of EU-legislation included in the Roadmap development has been agreed → 15 areas of legislation/pieces of legislation in scope
- Dedicated meeting on how to accelerate validation (May '24)
- Stakeholder consultation - Call for evidence Sept-Oct '24; targeted consultation in Q4/2024-Q2/2025)
- Commission workshop for stakeholder input 25 October 2024
- Commission workshop 16-17 June 2025

TEST METHOD DEVELOPMENT

Acceleration of Validation

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Test Method Development, Validation, Standardisation, Qualification

Points identified at **Interservice Group meeting on 21 May 2024:**

- Mutual acceptance of data is an important principle
- How to accelerate the validation process?
- Options for (better) funding for validation (range EUR 100 Millions)
- Consider regulatory needs in research and funding of research
- Prioritisation of method developments to meet regulatory needs?
- Learnings from the qualification process (pharma sector)?

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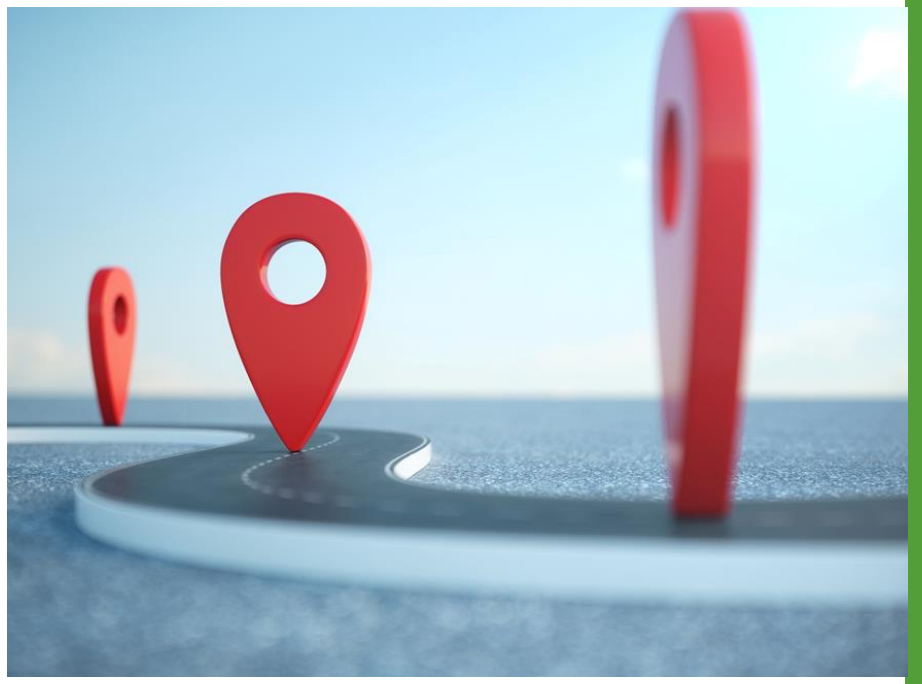
Test Method Development, Validation, Standardisation, Qualification

- Part of the (development of the) roadmap are **analyses** and **recommendations**
  - On **potential priorities** for method development needs for animal-free methods
  - 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)



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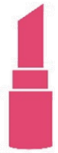
Test Method Development, Validation, Standardisation, Qualification

- Consideration on organisational structure for method development and validation / standardisation


Plant Protection


REACH


Cosmetics


Biocides


Pharma-ceuticals


Other

Expert level	Input on regulatory needs for development of animal-free methods/approaches
Policy level	Prioritisation / decision on funding of animal-free method/approach developments

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Test Method Development, Validation, Standardisation, Qualification

➢ Consideration on organisational structure for method development and validation / standardisation

- Need to flag early on regulatory needs
- Collection of input from different legislative areas
- Scientific expertise from different areas relevant for animal-free methods and approaches (NAMs)
- Input from stakeholders including research community
- Sustainable organisational structure that allows continuous input (or input in annual cycles) to prioritisation of method development and identifying validation / standardisation needs

- Policy level deciding on priority setting
- Allocation of funding

- Grant / tender management and administration
- Success monitoring and feedback mechanism

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Test Method Development, Validation, Standardisation, Qualification

➢ **Considerations specific on validation / standardisation**

- Different options for funding to be analysed (e.g. EU budget, industry fees, mixed funding (EU, MS, public-private partnerships)
- Funding needed
- EURL ECVAM and PEPPER as existing models for organisational structures supporting validation

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