Reference:

J.Fabre, M.Beekman and F.Vitobello, *Commission Update on the CSS and Recent Developments,* 5th ESA REACH Workshop, ESA ESTEC, Noordwijk, the Netherlands, 19th June 2024

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# Commission update on the CSS and recent developments

## Chemicals Strategy for Sustainability, REACH, PFAS, Chromium (VI) and lead

*DG ENV Julien Fabre*
*DG GROW Martijn Beekman*
*DG DEFIS Fabio Vitobello*

# Update on the Chemicals Strategy for Sustainability

European Commission

# Update on the 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

# CLP revision – Delegated Act

Dec 22

Adds **new hazard classes** in CLP

(OJ 31 March, entry into force 20 April)

- 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)

# CLP Regulation: legislative proposal

## Measures

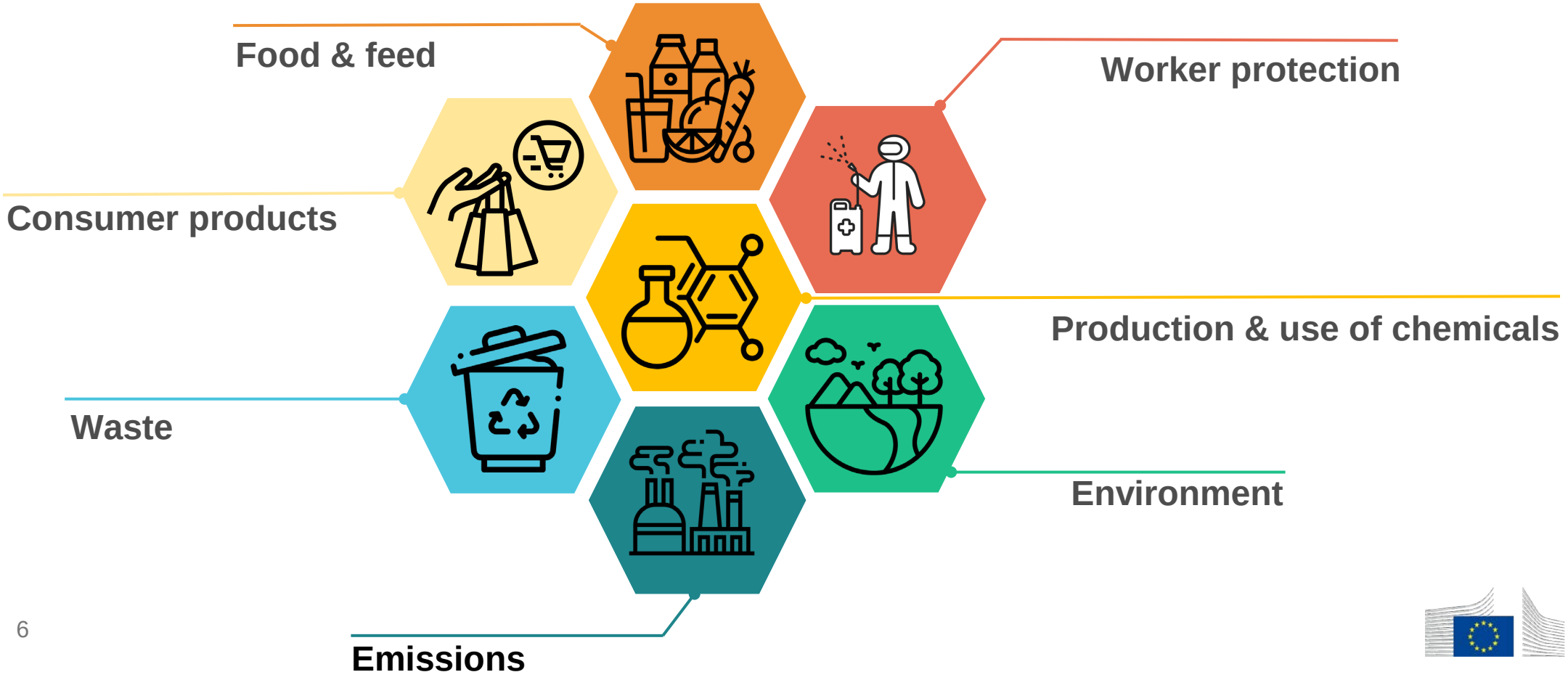
- Updated rules for classifying complex substances (« MOCS »)
  - specific derogation for plant extracts incl essential oils,
  - 5-year review of scientific evidence by the Commission
- Websites selling chemicals online must display hazardous properties of products
- Clearer labelling of hazardous chemicals including online
- Fold-out labels and digital labelling
- Commission gets right to develop classification proposals on hazardous substances (besides industry and Member States)
- Rules for refillable chemicals
- Better information for poison centres

## **Provisional agreement** European Parliament-Council

- Voted in EP 23-04-2024

# One substance one assessment
# EU legal framework on chemicals

**> 100 pieces of legislative pieces dealing with chemicals**



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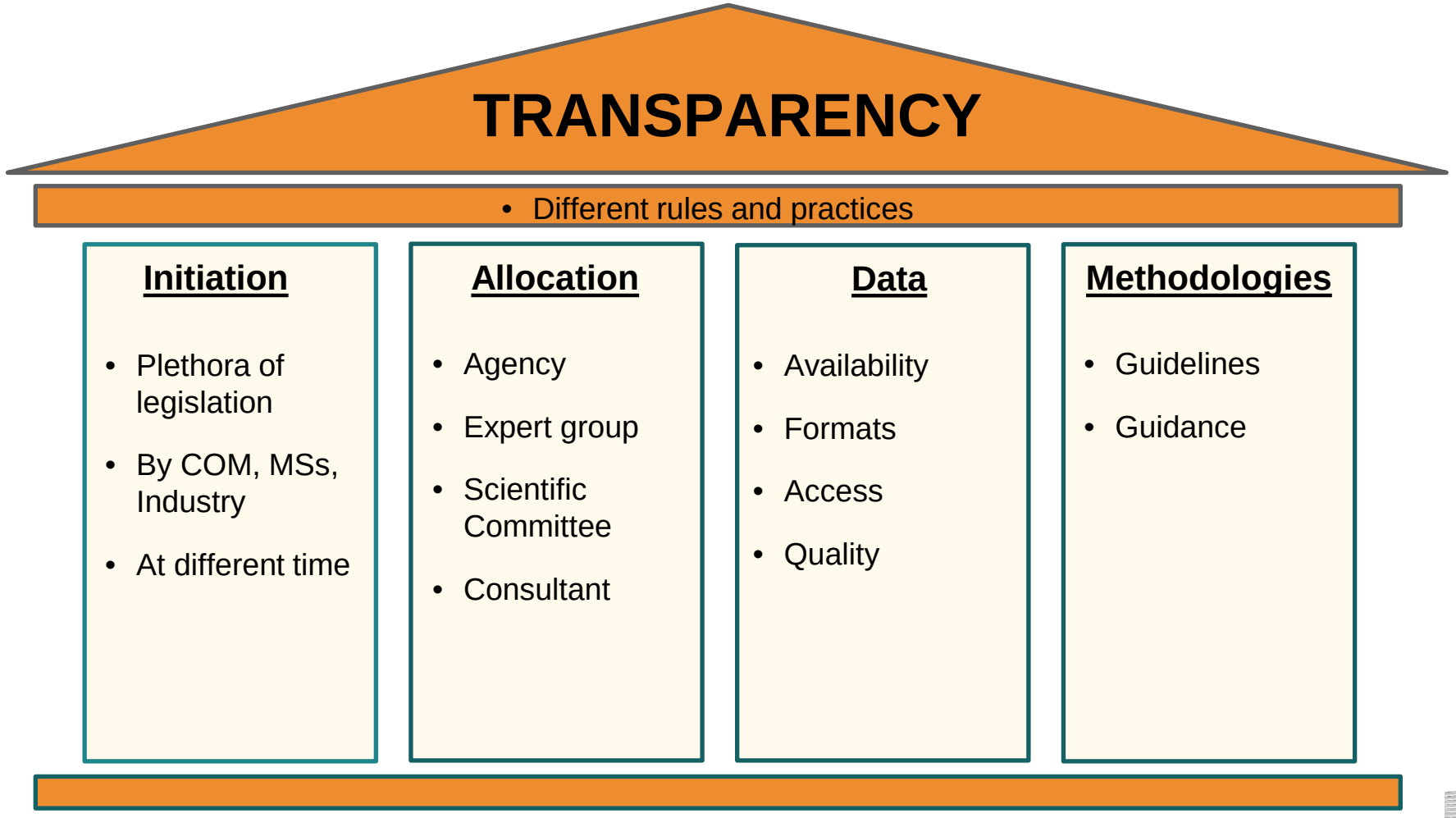
# One substance one assessment - **Today**



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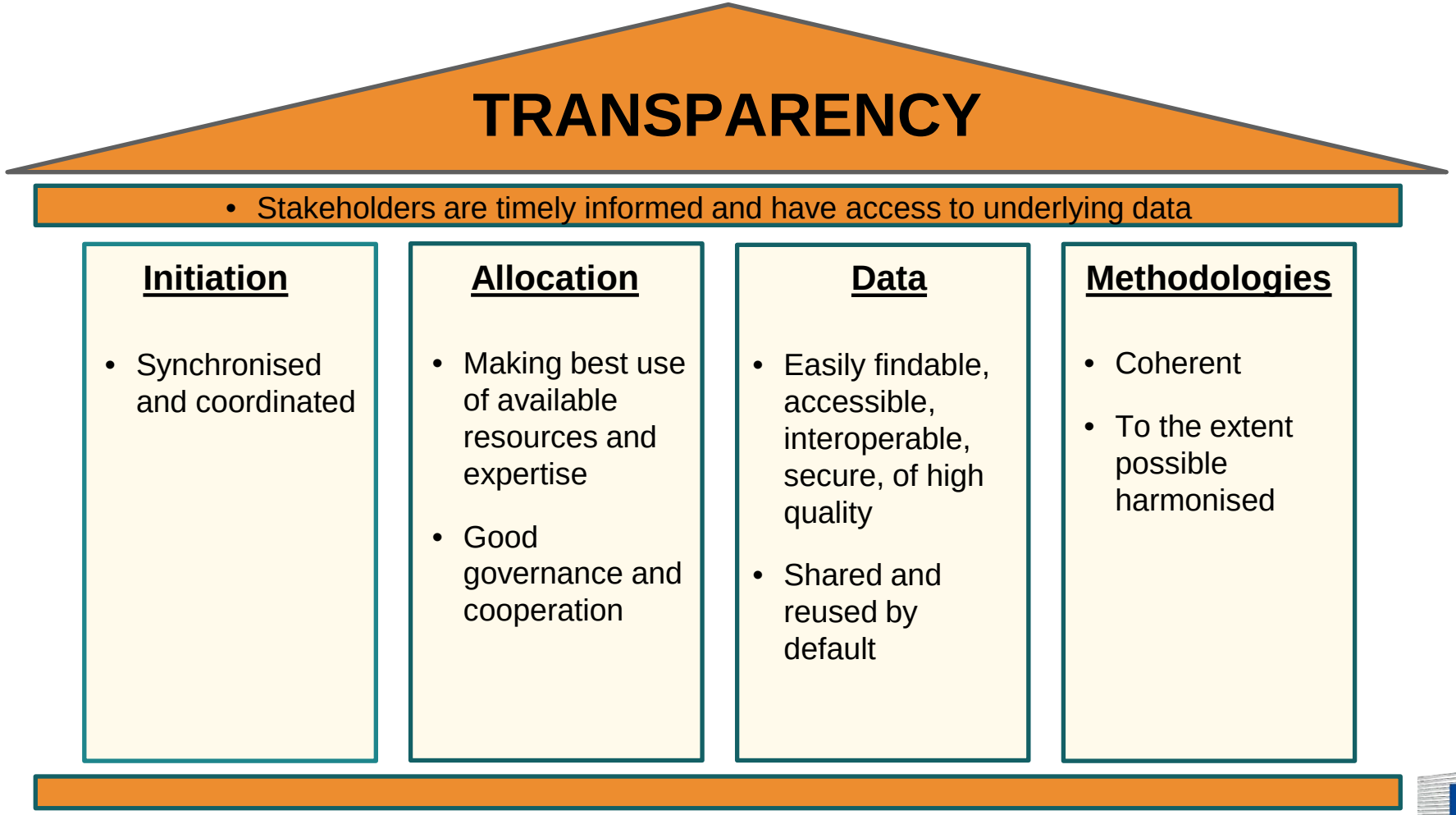
# One substance, one assessment - **Tomorrow**



# One substance, one assessment package

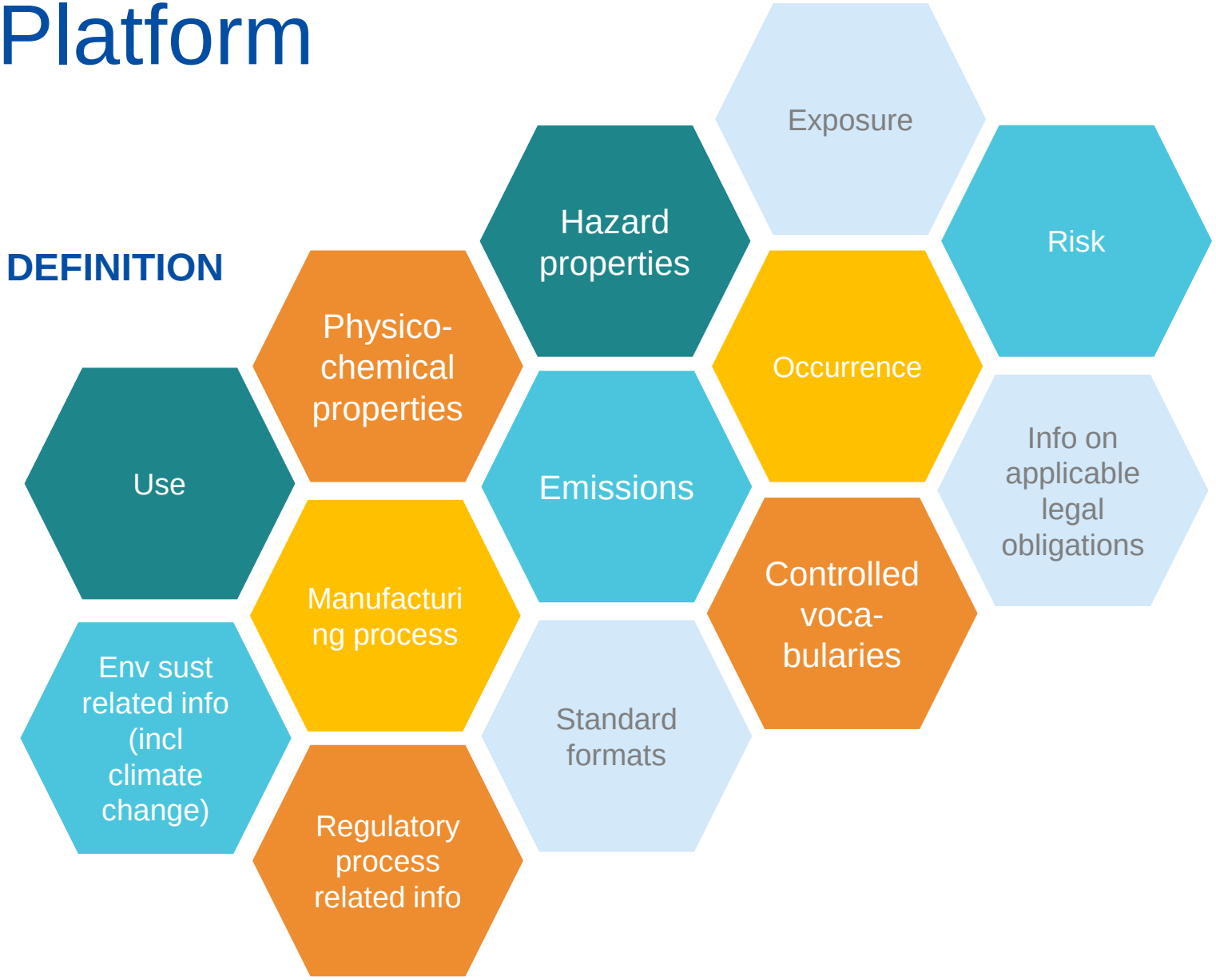
**1. Consolidating work in the EU agencies and improving cooperation**

- 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




## DEFINITION

## 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

# Consolidation and improving cooperation

| | Individual revisions | 1S1A omnibus proposals |
|---|---|---|
| (re-)attribution of tasks | • Drinking water directive<br>• Cross-border threats to health regulation<br>• Batteries and waste batteries regulation<br>• Industrial emissions directive + Industrial emission portal reg.<br>• Water framework directive and ground water directive<br>• Packaging and packaging waste<br>• End-of-life vehicles directive<br>• Safety of toys regulation<br>• SEVESO III implementing decision<br>• 1S1A proposal on data<br>• Cosmetic Products regulation (*still to be proposed*) | • Regulation on POPs<br>• RoHS directive<br>• Medical devices regulation |
| cooperation | • EMA founding regulation<br>• ECHA basic regulation (*still to be proposed*) | • EEA founding regulation<br>• EFSA founding regulation |

ECHA EUROPEAN CHEMICALS AGENCY

efsa European Food Safety Authority

European Environment Agency

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH



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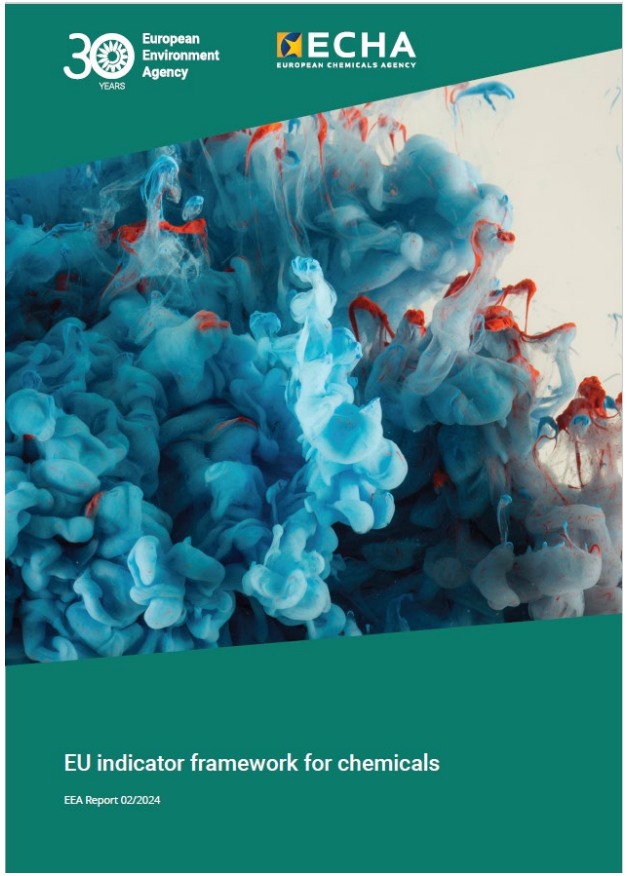
# EU indicator framework for chemicals

**A fact base to support:**

- **Following** the transition to production and use of safe and sustainable chemicals
- **Measuring** the effectiveness of chemicals legislation, past and current measures
- **Identifying** the need and potential impacts of future action



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# Indicator framework – EEA-ECHA report outcome and next steps

- Some progress in transition towards safe and sustainable chemicals
- More work still needed to deliver on achieving the goal of a toxic-free environment
- Further development to fill knowledge gaps
- One substance one assessment legal proposals



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# Guiding criteria and principles for the essential use concept in the EU legislation

*Commission Communication (C(2024)1995 final) adopted 22 April*

## What is the purpose of the Communication?

- Deliverable under the Chemicals Strategy for Sustainability
- To provide guiding criteria and principles for the essential use concept for **incorporating** the concept in the EU legislation in a harmonised way
- To bring this concept as a tool for assessing when it is justified from a societal point of view to use a **most harmful substance**
- **Only has a legal effect once included in the legislation**

# Guiding criteria and principles for the essential use concept in the EU legislation

*Commission Communication (C(2024)1995 final) adopted 22 April*

**Guiding criteria: The use of a most harmful chemical is essential for society only if both cumulative criteria are met:**

1. It is **necessary for health, safety** or it is **critical for the functioning of society**, AND
2. There are **no acceptable alternatives** to the use of that chemical

# Guiding criteria and principles for the essential use concept in the EU legislation

*Commission Communication (C(2024)1995 final) adopted 22 April*

**Aim of the essential use concept: increase the protection of health and the environment**:

- **A faster phase-out** of the most harmful substances in **non-essential uses**
- Allowing **more time** for the phase-out in **uses that are essential for society**
- When used in the legislation, it can **increase regulatory efficiency**, **facilitate decision-making** and **increase predictability**
- Providing **incentives to invest into safer and more innovative solutions, increase competitiveness**

# Guiding criteria and principles for the essential use concept in the EU legislation

*Commission Communication (C(2024)1995 final) adopted 22 April*

## Introduction of the essential use concept in a particular legislation:

- After an Impact Assessment
- To set legal definitions, consider the appropriate procedures, actors and bodies for the assessment and decision-making, explore the simplification potential of the concept in the framework of the particular legal instrument
- To consider specificities of the particular legal instrument

## In the meantime, for businesses:

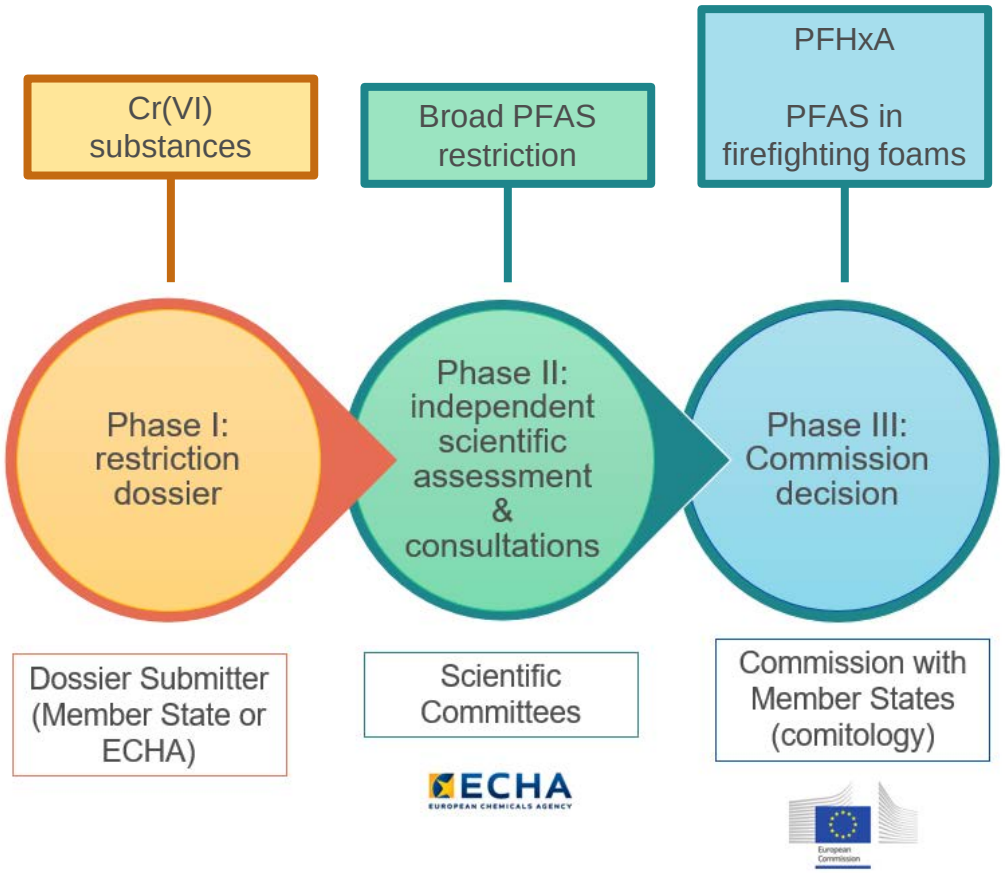
- clear signals on where investment and substitution efforts shall be directed
- incentives for more research and innovation into safer and more sustainable alternatives for the most harmful substances

# PFAS, Chromium(VI) and Lead

# REACH restriction

Title VIII, articles 67 – 73

- Unacceptable **risk** to human health or the environment
- Needs to be addressed on a Community-wide bases
- Taking into account the **socio-economic impact**, including the **availability of alternatives**



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# PFHxA, its salts and PFHxA related substances (phase III)

Proposal from the Commission to be adopted soon

Restriction on the placing on the market and use in:

(transitional period ranging from 18M to 5Y)

→ Clothing and other textiles for the general public
→ Food contact materials made from paper and cardboard
→ Consumer mixtures
→ Cosmetics products
→ Firefighting foam used for training/testing, by public fire services and for civil aviation



Comitology Register (europa.eu)

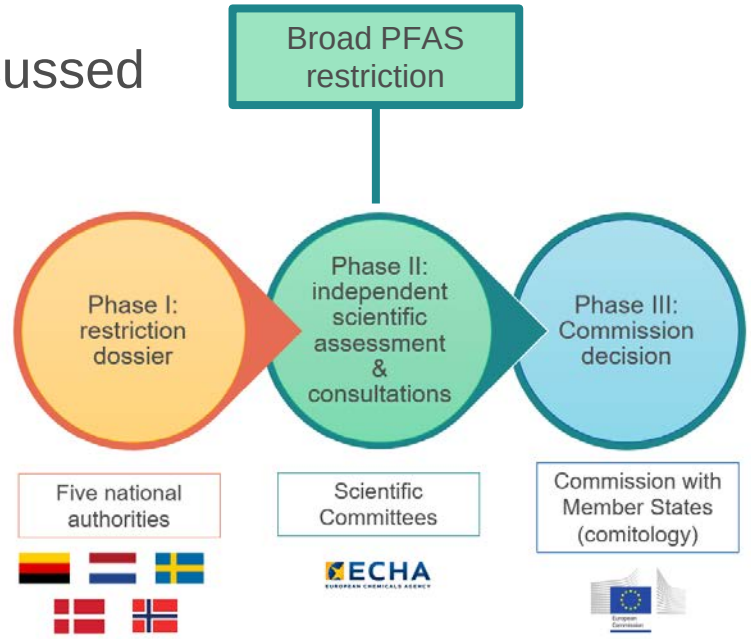
# PFAS in firefighting foams (phase III)

- RAC and SEAC opinions finalized:
  - Proposing to restrict placing on the market, formulation and use of PFAS (as a group)
  - Different transitional periods per sector
  - Additional risk reduction measures
- Commission draft proposal under preparation

| Sector | Emissions (t/y) |
|---|---|
| Oil/chemical industry (Seveso establishments) | 200 |
| Other industries | <10 |
| Civilian aviation | 40 |
| Defence | 20 |
| Municipal fire services | 50 |
| Hand-held fire extinguishers | <10 |
| Marine applications | 50 |
| Training and testing | 80 |
| **All sectors** | ~470 |

# Broad PFAS restriction (phase II)

- PFAS serious human health and environmental concern, many polluted areas in Europa (and globally)
- Restriction dossier triggered many comments (>5600) and concerns
- Derogations are already indicated and will be further discussed
- Important elements:
  - Emissions during life-cycle (as proxy for the risk)
  - Availability of alternatives
  - Economic impacts



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# COM role and some considerations

- At this stage, COM is an observer in RAC and SEAC.
- The Commission envisages that there will be derogations for **critical uses where no alternatives are currently available**.
- Based on the RAC and SEAC opinion, the Commission is committed to work as fast as possible on this dossier and put forward a **balanced restriction of PFAS**.
- Important to **minimise emissions of PFAS in the entire life cycle** for any use that is derogated.
- Encourage innovation into **safe and sustainable alternatives**.

# Cr(VI) substances under REACH

- Currently: uses of certain Cr(VI) substances subject to authorisation
  - 2018-2020: COM granted several authorisations to Cr(VI) substances suppliers
    - to cover uses by their (many) downstream users
  - 2020-2024: increasing number of downstream user applications for authorisation
    - heavy burden for RAC/SEAC/ECHA/COM, backlog in decisions
  - 2023: annulment of ‘Chemservice’ upstream authorisation
    - Includes ‘use 4’: use of chromium trioxide in surface treatments in aeronautics/aerospace industries
    - Uses covered by the annulled decision are still allowed until new COM decision is taken
  - 2024: ADCR and CTACSub2 upstream review reports and new applications under evaluation by ECHA
    - ADCR = Aerospace and Defence Chromates Reauthorisation consortium
    - COM committed to provide legally robust decisions asap

# Cr(VI) substances under REACH

- Authorisation approach for regulating Cr(VI) substances is no longer appropriate to control the risk to human health posed by these substances

- COM asked ECHA to prepare a restriction dossier

  - ECHA is preparing a restriction dossier (by April 2025)
    - ECHA holding second Call for Evidence (June-August 2024).
    - Stakeholders encouraged to provide information on their uses.
    - Participation of aerospace/defence industry in 1st Call for Evidence (Q1 2024) was very limited.

  - After April 2025: 1) ECHA opinion making, 2) COM decision making.
    - If all goes well, restriction could be adopted end 2026.

  - Authorisation regime remains in force for Cr(VI) substances listed in Annex XIV in the mentime
    - Cr(VI) restriction's entry-into-force → authorisation obligation will be withdrawn for substance covered by the restriction.
    - Until then:
      - ECHA and COM continue to treat applications for authorisation for Cr(VI) substances.
      - Conditions of current authorisations remain applicable.

# EU Space R&D – Lead free transition

- SnPb solders are extensively used in electronics for space applications to inhibit the growth of whiskers. Lead-free transition could create a serious risk for space projects that may result in catastrophic failure in the satellite due to whiskers growth.
- Lead has been recommended for inclusion in Annex XIV. The Commission is not obliged to follow this recommendation and does not intend to include lead in the authorisation list. Inclusion in Annex XIV is not a prohibition of use. The Commission is assessing all available risk management measures, to address the concerns related to the remaining non-regulated uses of lead in the most appropriate way
- As part of the EU Call covering Critical Space Technologies for EU non-dependence, in 2022 and 2023 DG-DEFIS has opened a call for projects focused on:
  - Replacement solutions for metallic lead (Pb) used in solder paste, assembly, finishings, terminations
- The project LETTERSS has been selected and kicked-off

# LETTERSS

## Lead-free Transition For The European Space Sector

HORIZON-CL4-2023-SPACE – Critical Space Technologies for EU non-dependence

01/01/2024 ➔ 31/12/2026 Budget: 2.7 ME

## Objectives:

- Find solutions to the issues that slow down using COTS with existing SnPb Assembly Technology
- Finding and validating **suitable replacement(s) for the SnPb solder**, workhorse of the Space Electrical Assembly for 60 years
- **Reducing the risks of the Pb-free transition** by advancing the state-of-the- art in our **understanding of Tin-whisker formation and growth.**

## Achievements & Milestones up to date:

- Completed the revision of the existing normative regarding Pb-free requirements/restriction
- Literature research completed
- European Space SMEs Survey has been launched
- Test Vehicles Designs in progress

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# Thank you





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