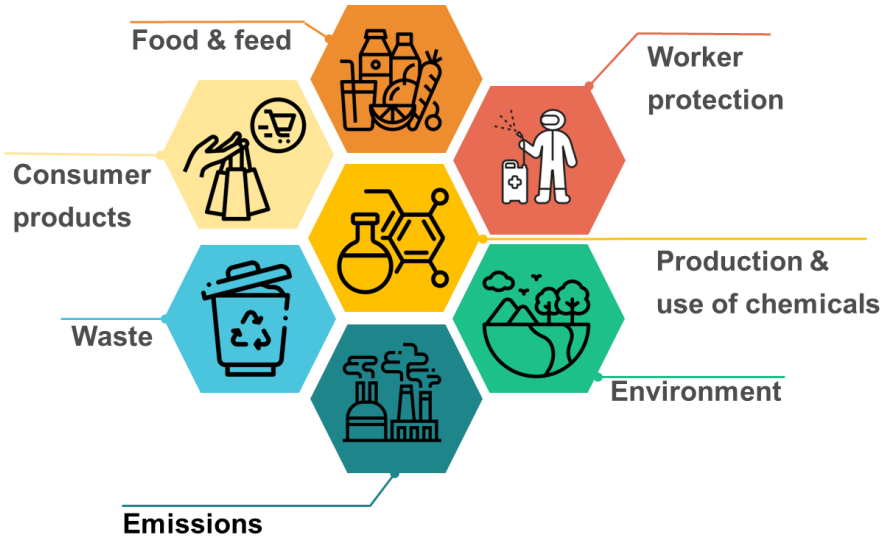
OSOA supporting legislation and MS involvement

EFSA Advisory Forum – 4 March 2026
COM, DG ENV, Unit C4 – Safe & Sustainable Chemicals

One substance, one assessment

Improve efficiency, effectiveness and coherence of the EU legal framework on chemicals consisting of more than 40 pieces of legislation dealing with chemicals



TRANSPARENCY

- Stakeholders are timely informed and have access to underlying data

Initiation	Allocation	Data	Methodologies
• Synchronised and coordinated	• Making best use of available resources and expertise • Good governance and cooperation	• Easily findable, accessible, interoperable, secure, of high quality • Shared and reused by default	• Coherent • To the extent possible harmonised

European Commission

One substance, one assessment package

1. Consolidating work in the EU agencies and improving cooperation

REGULATION (EU) 2025/2457
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

DIRECTIVE (EU) 2025/2456
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
amending Directive 2011/65/EU of the European Parliament and of the Council as regards the reattribution of scientific and technical tasks to the European Chemicals Agency

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

REGULATION (EU) 2025/2455
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

Consolidation and improving cooperation

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

ECHA EUROPEAN CHEMICALS AGENCY

efsa European Food Safety Authority

European Environment Agency

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

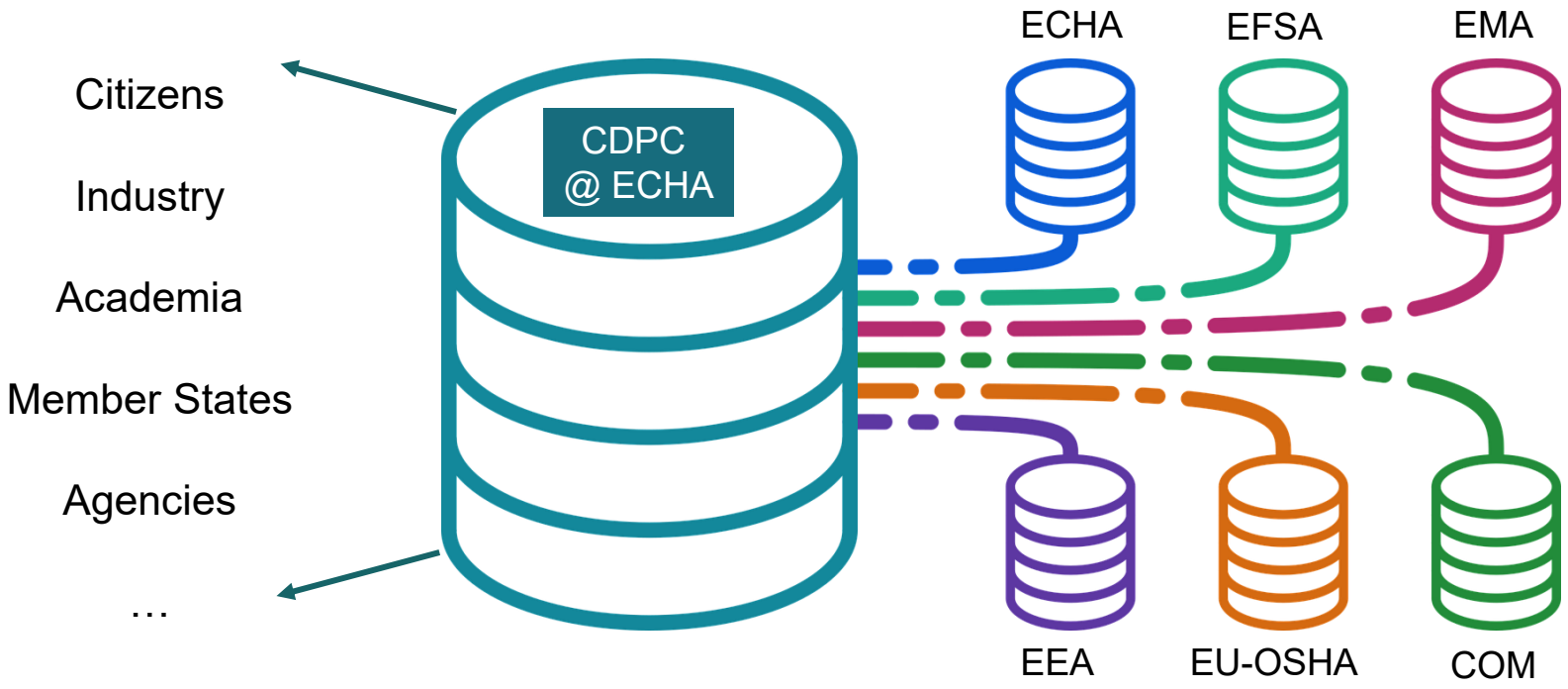
European Agency for Safety and Health at Work

European Commission

Common data platform on chemicals

Bringing together all chemicals related data into one database

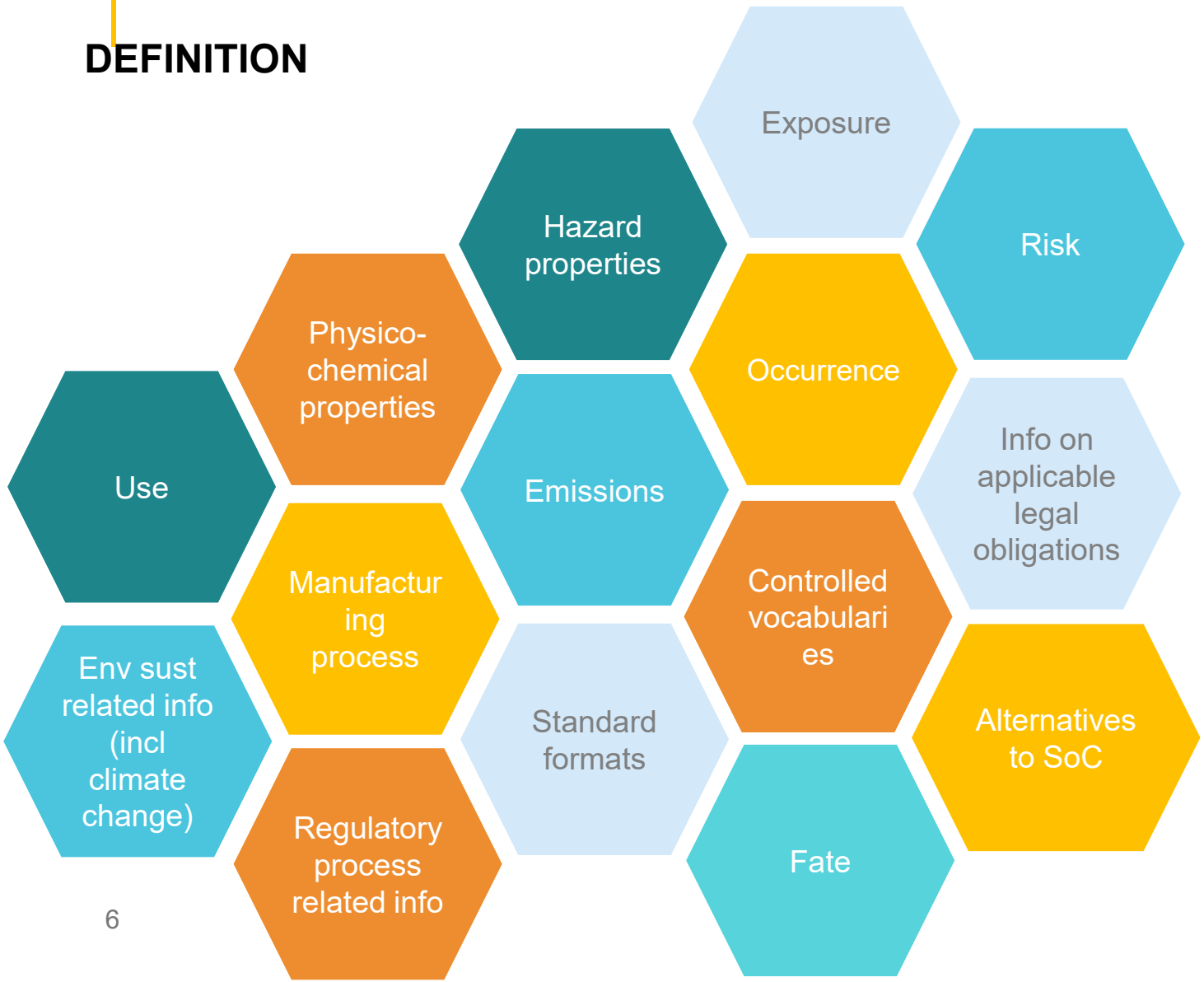
- ECHA to establish platform
- Agencies (ECHA, EEA, EFSA, EMA, EU-OSHA) + COM to provide chemicals data to ECHA (+ 1 obligation on MS; 1 obligation on industry)
- Voluntary data provision possible by anyone



European Commission

What is ‘chemicals data’, which data are included in CDPC?

DEFINITION



SOURCES

- From implementation of EU chemicals legislation (Annex I)
- Monitoring data from IPCHEM
- Human biomonitoring data
- Selected datasets from research or (inter)national implementation programmes
- Voluntarily provided by MS, national agencies, research institutes or third countries' organisations, and accepted by one of the Agencies

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

Also legacy data

What will you find in the platform and when?

WHAT?

- All chemicals data in scope
- Public and non-public data including confidential data
- Legacy data and 'new' data

WHEN?

- Minimum viable product within 3 years (Art. 3(14), Annex IV)
- Implementation plan (specific datasets + timing) (Art. 4(1)))
- All legacy data within 10 years (Art. (ECHA) (Art. 3(14))
- New data from a dataset already included in platform: within 90 days of receipt by ECHA (Art. 3(14))

Obligations on MS

Data hosting

Business as usual

'Authorities' means the Commission, the competent authorities of the Member States as referred to in any of the Union legal acts as listed in Annex I or III, and the Agencies, excluding their management boards; (Art. 2(2))

Explicit reference to national agencies in specific articles (Art. 3(2)(c); 5(2); 5(7); 5(9); 10(1); 15(2); 17(4));

Data provision

Business as usual	+	Obligatory data provision	+	Voluntary data provision
E.g. reports or monitoring data currently already made available to agencies or COM under underlying Union acts		Article 10 – Information on regulatory processes on chemicals		Explicit mentions in Art. 3, 11, 12, 15

Obligatory data provision

Article 10 – Information on regulatory processes on chemicals

- Make information on regulatory process or activity available to Union agency responsible under the respective Union act listed in Annex III

- Information to be provided:
  - Chemical identity
  - Union legal act + regulatory process
  - Person or body responsible
  - Status or process or activity
  - Outcome (+ report/opinion)
  - Intended start date, data of completion, latest progress update

~ (Public) Activities Coordination Tool, but expanded to Annex III

MS access to/use of data

ACCESS

Authorities **have access to**:
- All chemicals data contained in the platorm, including non-public data (Art. 19(2))

Authorities **shall**:
- Take necessary measures, incl security measures, to ensure that non-public data in the platform is not made available to the public (Art. 19(3))

USE

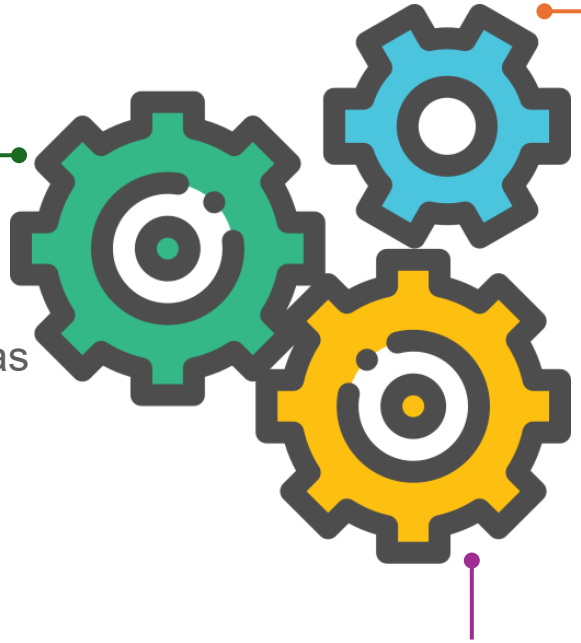
Authorities **may** use data:
- In the performance of any of their activities, where those activities support the development, implementation or enforcement of Union law and policy (Art. 20(1))

Authorities **shall not** use data:
- To fulfill any legal obligations of duty holders (Art. 20(2))

(except for the assessment of the completeness of data or where existing provisions provide for the sharing and use of data under the legal acts listed in Annex I)

When using data, Authorities **shall**:
- Respect the marking of data as not being made available to the public (Art. 20(3))

Monitoring and outlook framework



1. Framework of indicators

- Framework is already established, but shall be managed and updated as appropriate, in consultation with the Member States (Art. 21(1))

2. Early warning and action system

- EEA to draw up annual report, including info from national early warning systems, and present to Authorities
- Within 9 months of the presentation of each annual report, Authorities shall consider undertaking regulatory, policy or enforcement actions accordingly and provide a justification if they decide not to proceed with any action (Art. 23(4))

3. Observatory for specific chemicals

- COM to select chemicals for further scrutiny under the observatory. List of selected chemicals to be adopted via comitology ➔ consultation of MS and vote by MS (Art. 23(3))

Data generation mechanism

- ECHA may commission studies (Art. 24(1))
  - ➢To support implementation of Union chemicals legislation
  - ➢To contribute to supporting, evaluation and developing Union chemical policy
  - ➢In context of EUON
- The ECHA shall seek to avoid duplication with Member State or Union research or implementation programmes (Art. 24(5))
  - Overview of Member State programmes?
- ECHA shall commission scientific studies only after it has consulted the Member States (Art. 24(6))
  - ➢Consultation in EG?

EU-wide Human biomonitoring study

- ECHA and EFSA, with EEA, commission Union-wide HBM study covering all MS, within 4 years after EiF (Art. 25(1))
- Budget: 15 Mio (EFSA) + 5 Mio (ECHA DGM) for two years
- MS to cooperate in the planning and organisation of the HBM study and provide technical assistance and admin support (Art. 25(2))
  - ➢EG sub-group on HBM to discuss planning an organisation?
- COM to review whether HBM studies should be done regularly, within 2 years after finalisation of 1st HBM study (Art. 32(3))

Enforcement and penalties

- Agencies to **cooperate** with MS enforcement authorities and exchange info on compliance of businesses with study notification obligation (Art. 30(1))
- MS to **lay down penalties** for non-compliance with notification obligation

  --> **notify** COM within 22 months after entry into force of regulation(Art. 31)

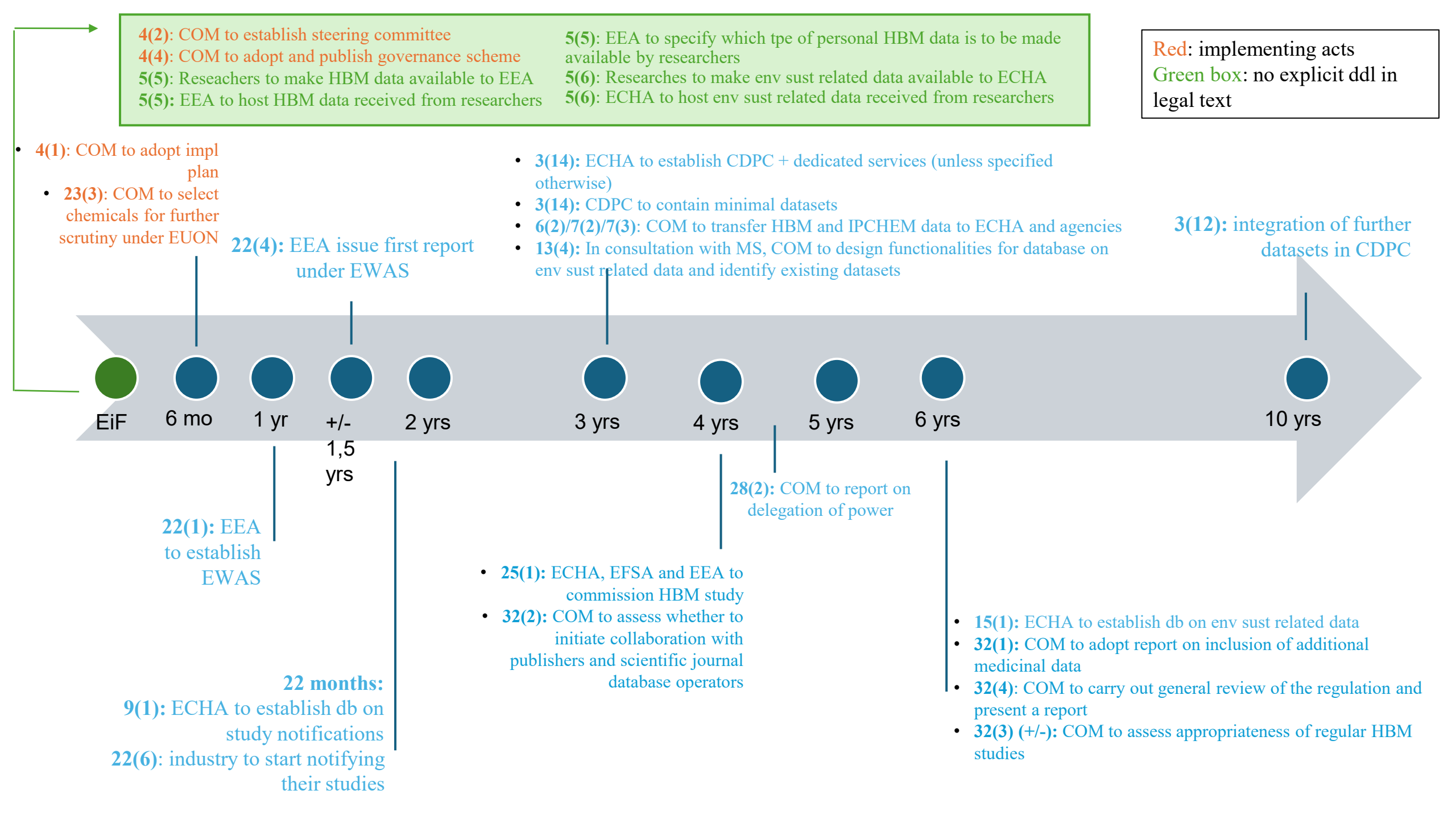
Consultations

Legal

- Database of environmental sustainability related data: COM to design database functionalities and identify existing datasets, in consultation with MS, within 3 years after entry into force (Art. 15(4))
- Framework of indicators: Agencies to establish and manage framework of indicators, in consultation with MS (Art. 21(1))
- Data generation mechanism: ECHA to commission scientific studies only after it has consulted MS (Art. 24(6))
- Adoption of implementing acts (recital 22 + Art. 23(3))
- Adoption of delegated acts (to amend annexes or expand medicinal data scope) by COM after consultation of MS (Art. 28(4))

Beyond legal

- Expert group on one substance, one assessment
  - to inform MS on development and operation and to consult them as users andcontributors
  - reimbursement of 2 people travelling; indefinite number of people can attend online
  - !! Internal coordination in MS – mapping of who does what?


4(2): COM to establish steering committee
4(4): COM to adopt and publish governance scheme
5(5): Reseachers to make HBM data available to EEA
5(5): EEA to host HBM data received from researchers
5(5): EEA to specify which tpe of personal HBM data is to be made available by researchers
5(6): Researches to make env sust related data available to ECHA
5(6): ECHA to host env sust related data received from researchers
Red: implementing acts
Green box: no explicit ddl in legal text
4(1): COM to adopt impl plan
23(3): COM to select chemicals for further scrutiny under EUON
22(4): EEA issue first report under EWAS
3(14): ECHA to establish CDPC + dedicated services (unless specified otherwise)
3(14): CDPC to contain minimal datasets
6(2)/7(2)/7(3): COM to transfer HBM and IPCHEM data to ECHA and agencies
13(4): In consultation with MS, COM to design functionalities for database on env sust related data and identify existing datasets
3(12): integration of further datasets in CDPC
EiF
6 mo
1 yr
+/- 1,5 yrs
2 yrs
3 yrs
4 yrs
5 yrs
6 yrs
10 yrs
22(1): EEA to establish EWAS
22 months:
9(1): ECHA to establish db on study notifications
22(6): industry to start notifying their studies
25(1): ECHA, EFSA and EEA to commission HBM study
32(2): COM to assess whether to initiate collaboration with publishers and scientific journal database operators
28(2): COM to report on delegation of power
15(1): ECHA to establish db on env sust related data
32(1): COM to adopt report on inclusion of additional medicinal data
32(4): COM to carry out general review of the regulation and present a report
32(3) (+/-): COM to assess appropriateness of regular HBM studies

Next steps

- COM is establishing steering committee and regulatory committee
- COM is drafting governance scheme and implementation plan

  -->consultation of MS in EG
- COM will start work on implementing act identifying substances for further scrutiny under the observatory

  --> consultation of MS in EG and regulatory committee
- Next EG meeting: Q2 2026
- Ad hoc EG meeting before, to discuss governance scheme, implementation plan and act on observatory

Thank you

European Commission