

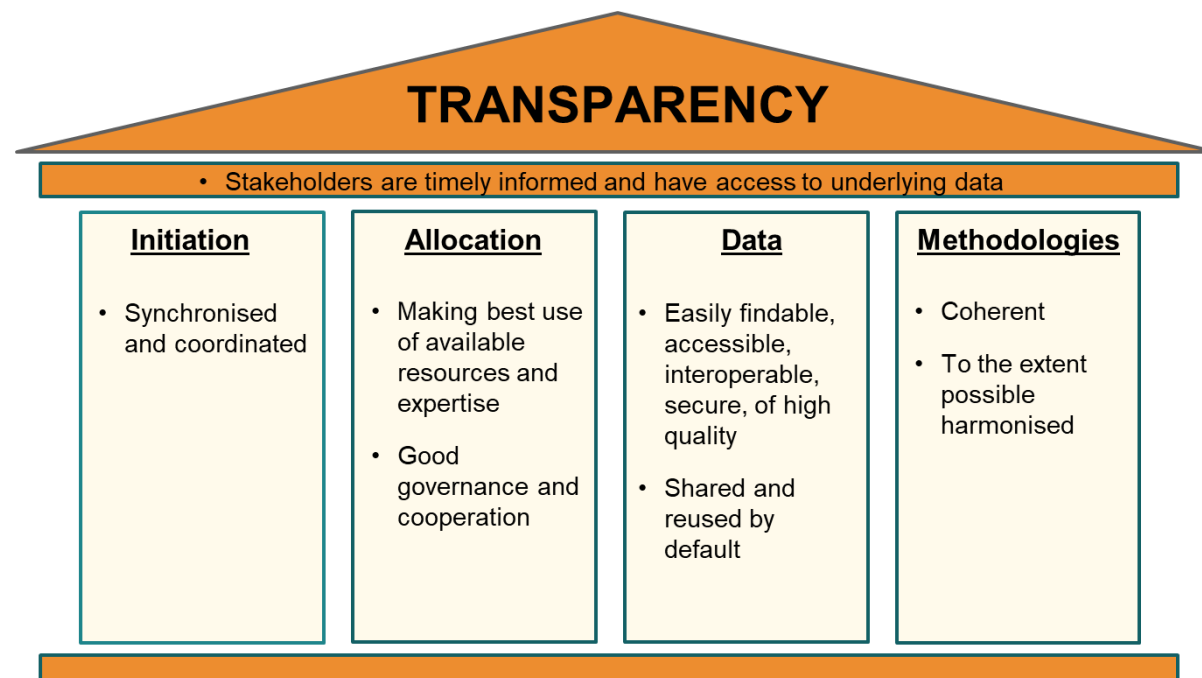
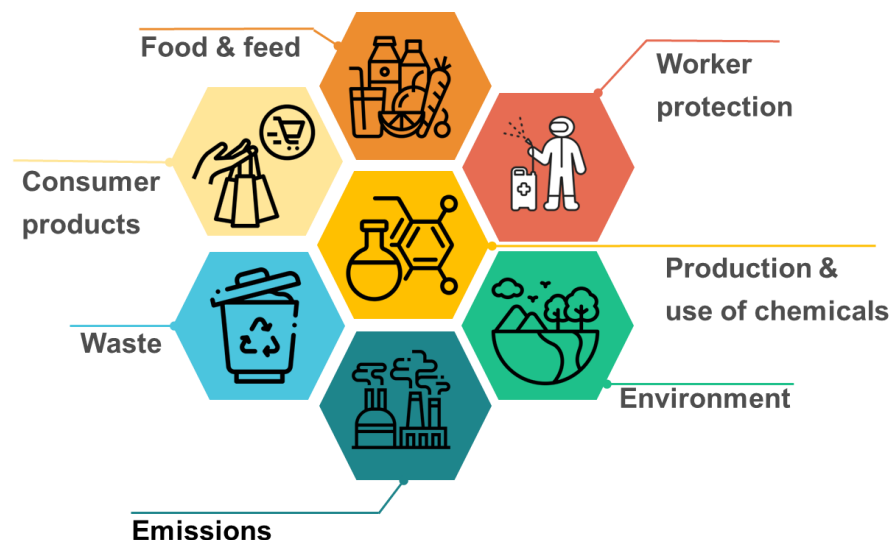


One Substance, One Assessment

*EFSA Management Board
26 March 2026*

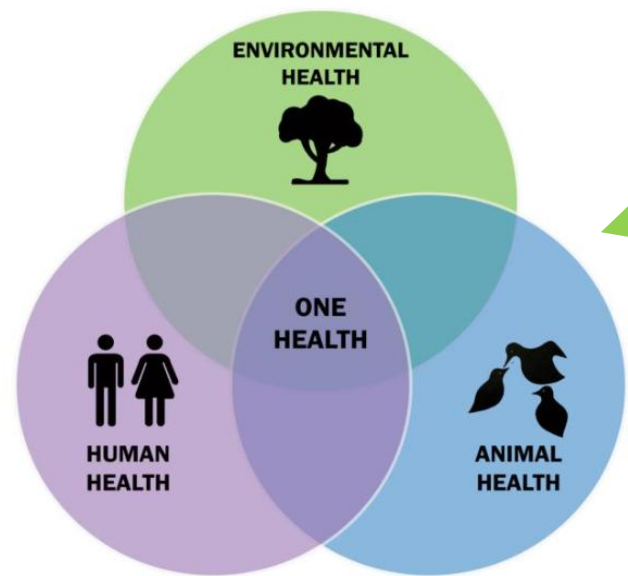
One substance, one assessment

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



One substance, one assessment in support of EU policies

#DigitalEU



Consolidating technical work in EU Agencies

	Individual revisions or new legislation	1S1A omnibus proposals
(re-)attribution of tasks	<ul style="list-style-type: none"> • 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 regulation • End-of-life vehicles directive • Safety of toys regulation • SEVESO III implementing decision • Regulation establishing common data platform of chemicals • Cosmetic products regulation (<i>as part of ECHA's basic act</i>) • OEL derivation (<i>as part of ECHA's basic act</i>) 	<ul style="list-style-type: none"> • Regulation on POPs • RoHS directive • Medical devices regulation



Improving cooperation among EU Agencies

	Individual revisions	1S1A omnibus proposals
	<ul style="list-style-type: none"> • EMA founding regulation • ECHA founding regulation 	<ul style="list-style-type: none"> • EEA founding regulation • EFSA founding regulation



Introducing generic obligation on the Agencies requiring cooperation (Art 23(m) of the GFL)

The Authority shall cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and with other scientific bodies established under Union law, in particular the ECHA, the EMA, and the EEA,

- *on the provision of relevant scientific opinions,*
- *on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and*
- *on the development of scientific methodologies for the assessment of chemicals.*

Strengthening provisions on solving divergent scientific opinion (Art 30 of the GFL)

- Stronger obligation to monitor and identify potential source of divergence
- Obligation to attempt solving the divergence and only if unsuccessful to refer to the Commission
- Divergence in hazard identification to be solved via a harmonised classification developed by the ECHA

Coordination and cooperation mechanism



Commission Interservice Group on One Substance, One Assessment

- ENV, GROW, SANTE, EMPL, RTD, JRC
- ECHA, **EFSA**, EMA, EEA, EU-OSHA
- Meetings at least 2 times per year

Expert working group of Member States, Commission Services and EU Agencies on One Substance, One Assessment

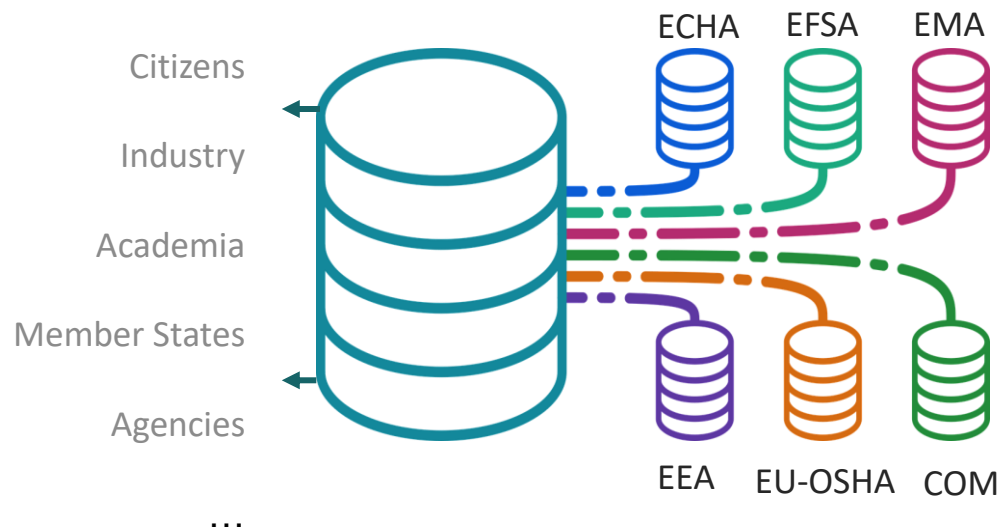
- On-going and planned work on chemicals
- Ongoing and planned initiatives on methodologies
- Repository of inconsistencies and inefficiencies
- Meetings at least 2 times per year

A new **database containing information on regulatory processes** on individual substances or groups of substances that are planned, ongoing or have been completed

- Agencies, Commission and MSs authorities to provide information on planned work on chemicals

Common data platform on chemicals (CDPC)

Common Data Platform on Chemicals @ ECHA



- 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

Access to and use of data in the CDPC

ACCESS

DIFFERENTIATED ACCESS

Authorities
(MS CA,
Agencies,
COM)



All others



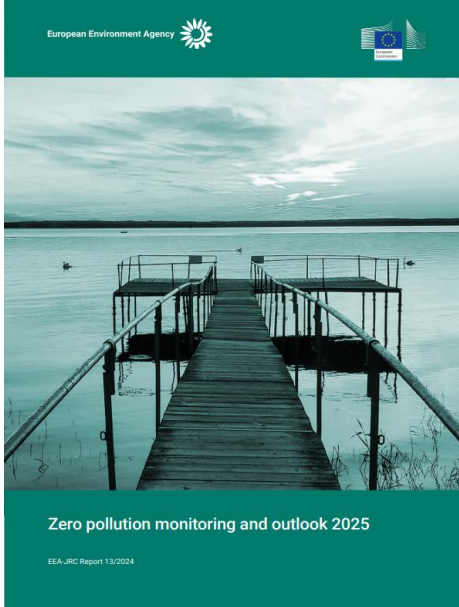
USE

EU COM + Agencies + MS CA can use:

- Public + confidential data
- To support development or implementation of chemicals legislation and policy
- Not to fulfil the legal obligations of duty holders; burden of proof remains!

ORIGINATOR PRINCIPLE

- Confidentiality marking under originating legislation is respected throughout when data is accessed or used through CDPC
- Confidentiality flag = part of contextual data when data is provided to CDPC



Monitoring and outlook framework for chemicals

EFSA to collaborate

Framework of indicators (EEA)

- monitor drivers of chemical pollution
- measure effectiveness of chemicals legislation
- measure transition towards production of safe and sustainable chemicals
- Info through dashboard in CDPC
- Include aggregated territory-based risk indicator

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EFSA to

- Identify relevant data
- Consider action based on report

Early warning and action system (EEA)

- Based on existing systems, info from agencies, literature, ...
- Annual report, for COM, MS, agencies
- Info available through CDPC
- Authorities to consider undertaking action

Observatory for specific chemicals (ECHA)

- = giving formal status to EUON (European Union Observatory for Nanomaterials) and providing possibility to expand scope
- Observatory for specific chemicals identified as potential contributors to new and emerging chemicals risks

Benefits of One Substance, One Assessment

- Identification of emerging chemical risks
- Improved assessments
 - Consistency through access and re-use of data
 - Consistency through cooperation obligation
 - Efficiency through task distribution
- View on planned and ongoing regulatory actions
 - Companies have access to data on actions
- Improved enforcement
 - MS have access to all chemicals data

PROTECTION

PREDICTABILITY

TRUST

Timeline

MVP (Minimum Viable Product)

Article 4:

COM to adopt:

- Implementation plan
- Governance scheme

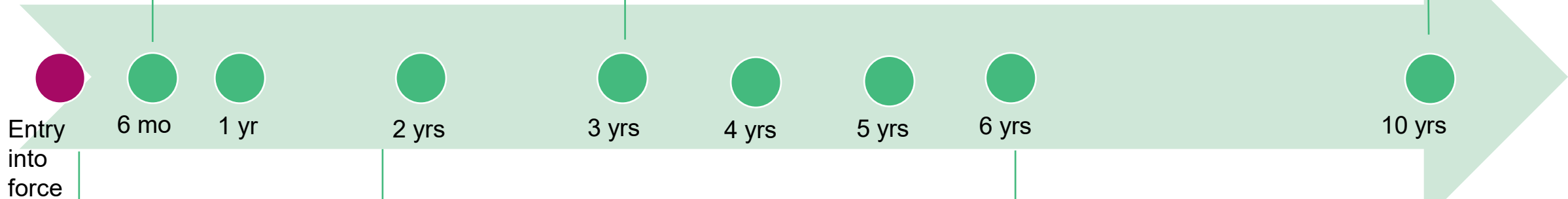
Article 3:

ECHA to establish CDPC + dedicated services (unless specified otherwise)
CDPC to integrate minimal datasets (Annex IV)

- Public and non-public data
- Legacy data and 'new' data
- Dedicated services fully functional

Article 3 (12):

All data integrated in the CDPC



Article 4

COM to establish steering committee

Article 9 and 22:

22 months from entry into force:

- ECHA to establish database on study notifications
- industry to start notifying their studies

Article 15:

ECHA to establish database on env sustainability related data

Article 32:

COM to adopt report on inclusion of additional medicinal data

2 January
2026

2 January
2036

Thank you



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