



Experiences with Innovative legal instruments on risk assessment: the European Union

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European Commission DG ENV

Reversal of the burden of proof

REACH Regulation: burden of proof (1/3)

- REACH Regulation (Registration, Evaluation, Authorization, and Restriction of Chemicals): protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry.
- REACH places the burden of proof on industry, rather than on regulatory authorities or the public.

REACH Regulation: burden of proof (2/3)

- Registration: before a substance is manufactured or placed on the market into the EU, the manufacturer or importer must register it. The company must provide information, in particular on the chemical properties and uses and.
- The amount and type of data required for registration depend on the volume of the chemical produced or imported.

REACH Regulation: burden of proof (3/3)

- Authorization: For certain chemicals, companies may need to obtain authorization from the EU before they can be used. Otherwise, the uses of the substances is not authorized.



Generic risk assessment

REACH Regulation: generic risk assessment

- The generic risk management approach: Article 68(2) of the REACH Regulation
- Simplified procedure which the Commission may use in relation to substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), categories 1A and 1B on their own, in mixtures or in articles that could be used by consumers.
- Examples of restrictions: several CMRs in clothing, textiles and footwear and 8 polycyclic-aromatic hydrocarbons (PAHs) in rubber and plastic

Thank you



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Back-up Slides



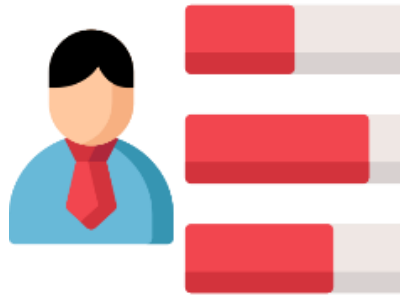
Use of available data: The EU Common data platform on chemicals

The EU chemicals acquis

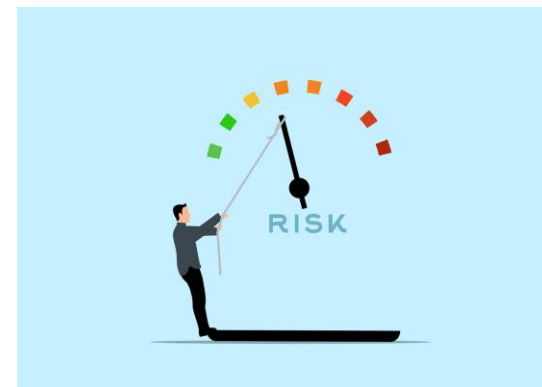
- EU chemicals regulatory framework is vast
- Important objective = to protect human health and the environment



Data

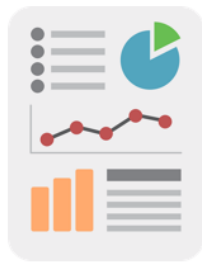


Scientific bodies



Assessment outcome

Who is involved, where does all this data go?



Data



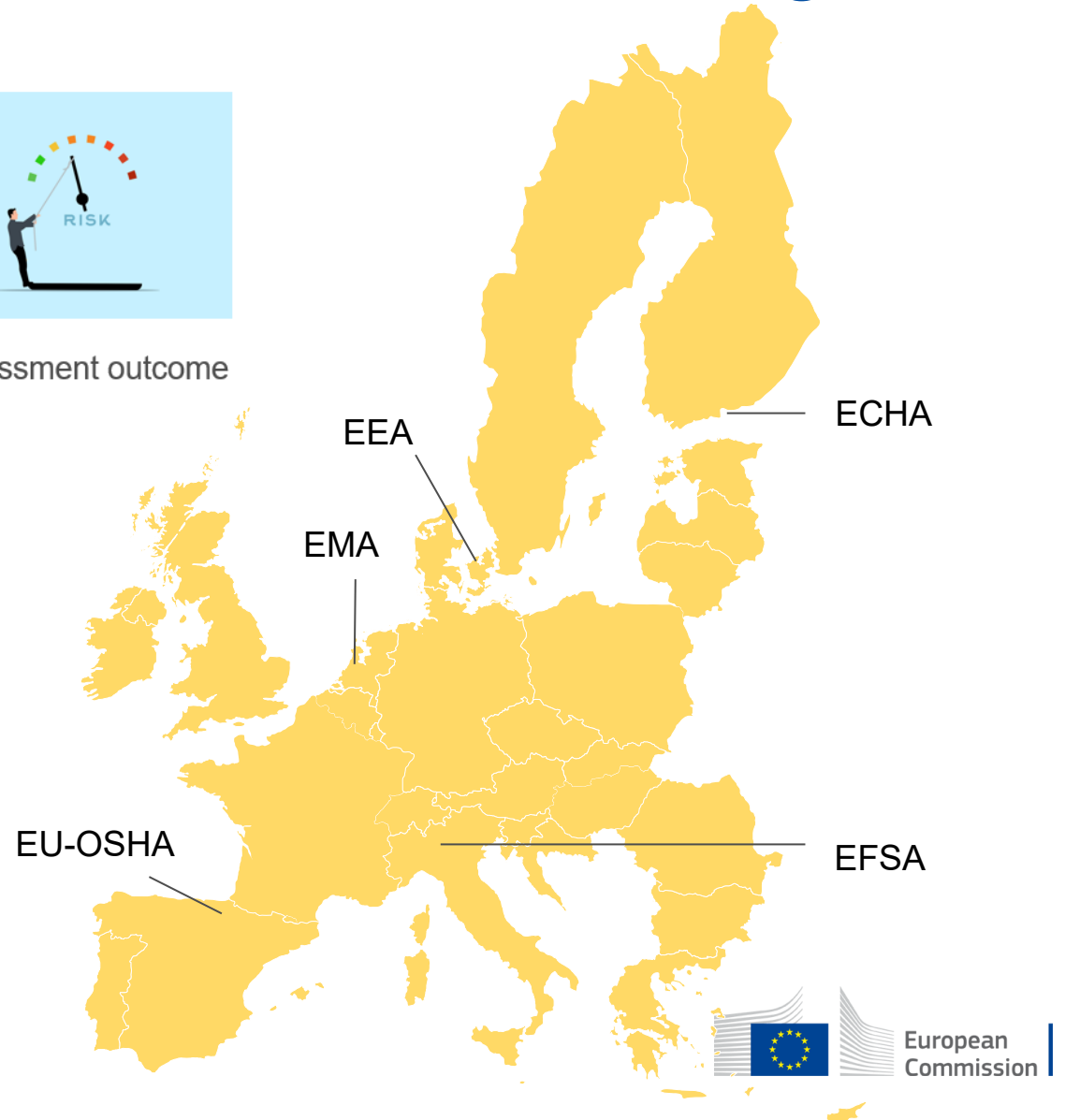
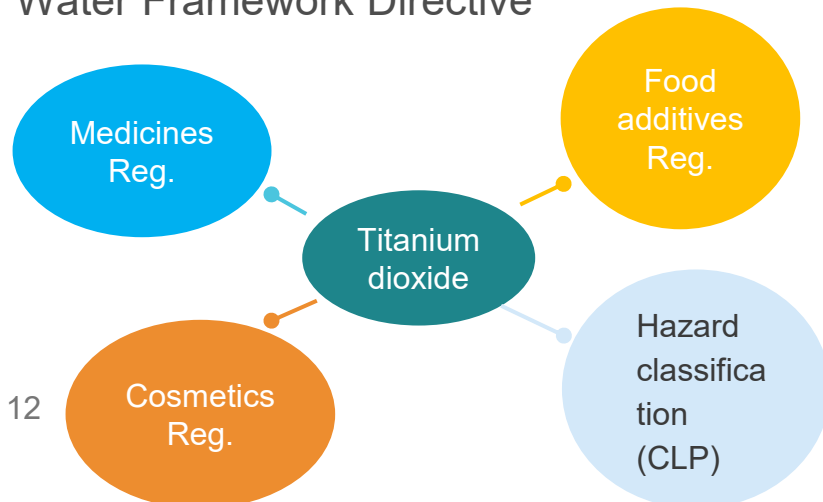
Scientific bodies



Assessment outcome

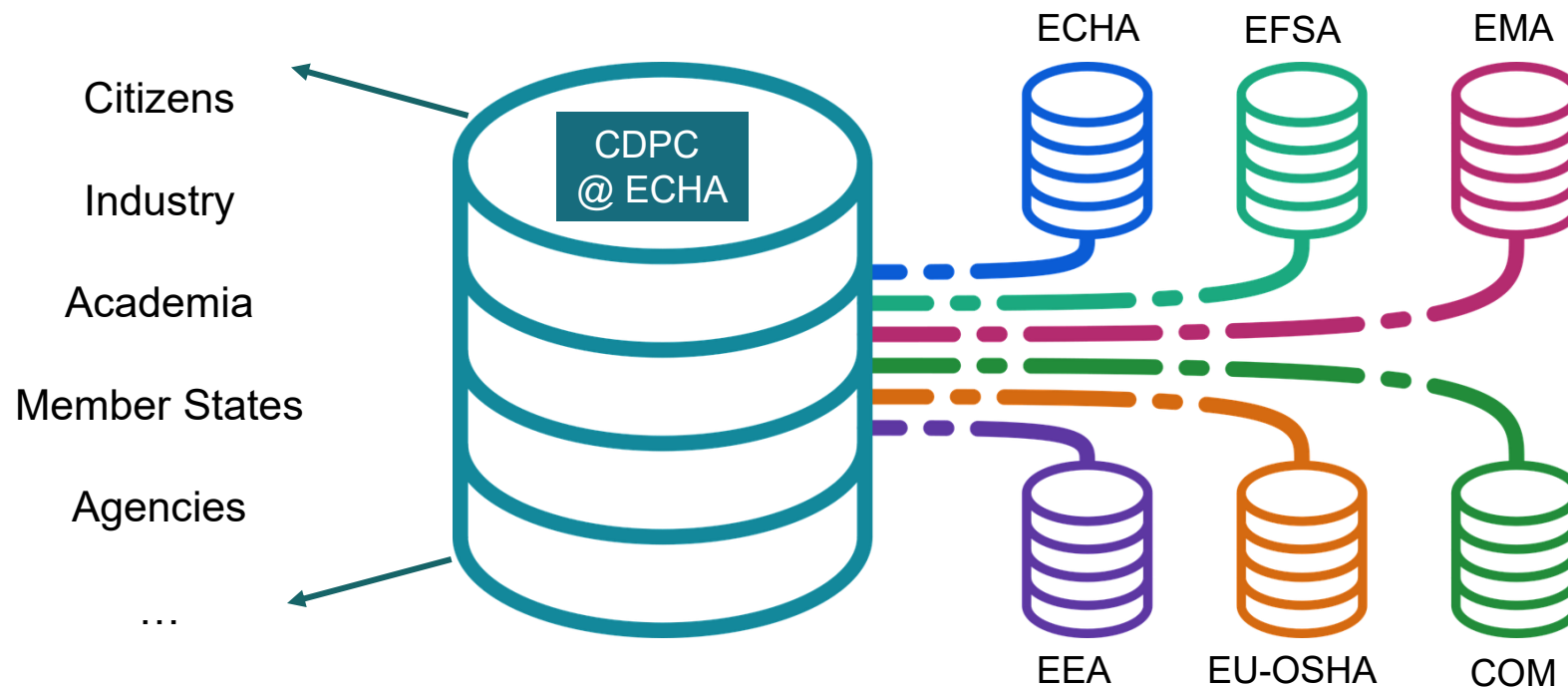
- Industry placing chemical on the market
- Member States, e.g. monitoring data under Water Framework Directive

- MS
- Agencies (COM)

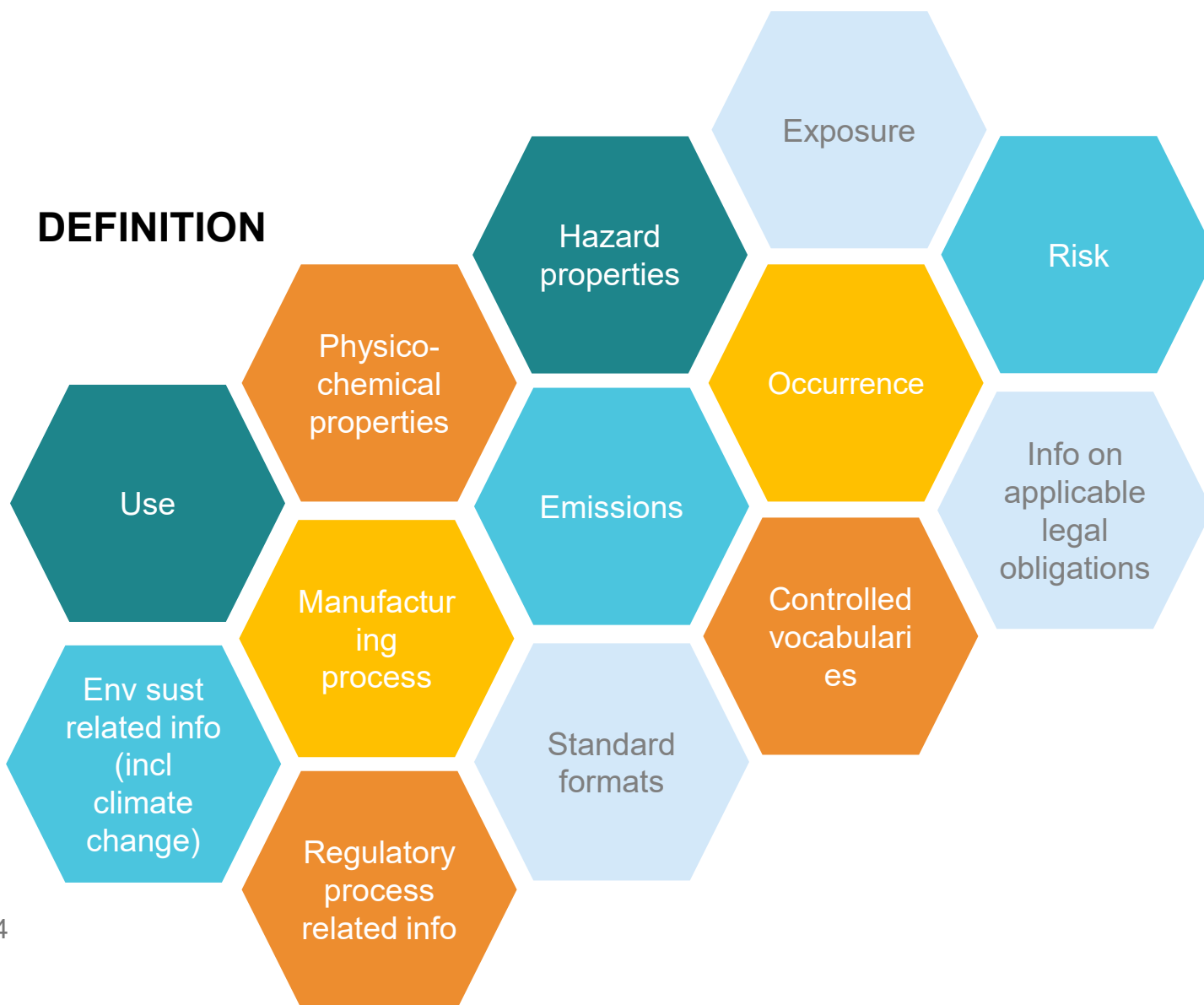


Common data platform on chemicals

- Fitness check: difficulties for MS and assessors to know which information exists, where to find it and how to access it
- Legislative proposal establishing common data platform on chemicals (CDPC): bring together all chemicals related data into one database



What is 'chemicals data', which data are included in CDPC?



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

Data needs to be findable and interoperable

STANDARD DATA FORMATS



CONTROLLED VOCABULARIES



Access to data in the CDPC



TRANSPARENCY

- Different pieces of legislation with different transparency rules
- How to deal with confidential data in the CDPC coming from specific pieces of legislation ?



ORIGINATOR PRINCIPLE

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

DIFFERENTIATED ACCESS

Authorities
(MS CA,
Agencies,
COM)



All others

