

EU Chemicals Strategy for Sustainability

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Revision of EU chemicals regulations

- Classification, Labelling and Packaging (CLP)

- REACH

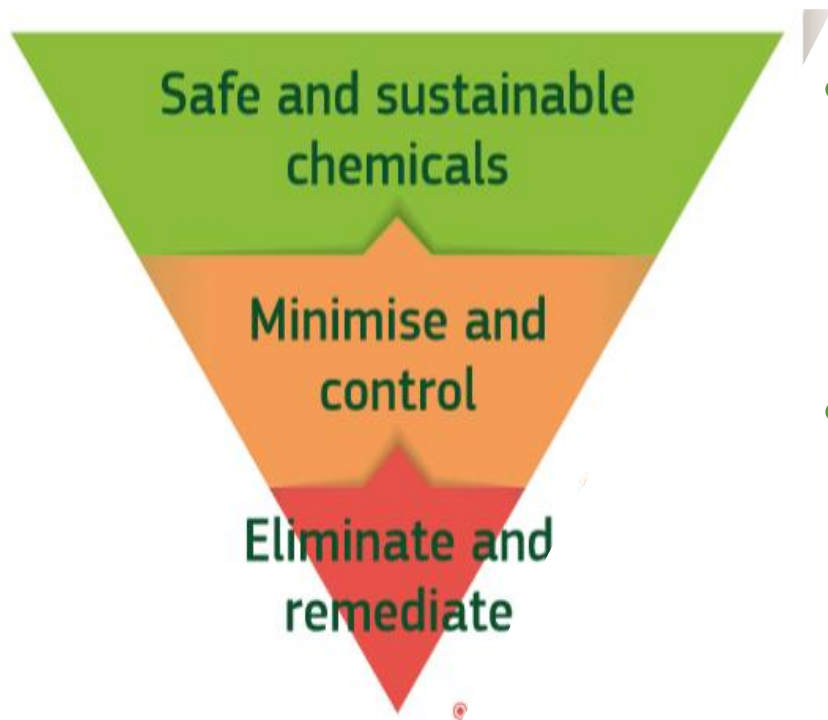
#ChemicalsStrategy

#EUGreenDeal



European
Commission

2030 vision – towards a toxic-free environment



- Chemicals are produced/used in a way that **maximises their benefits to society** while **avoiding harm to planet & people**
- Production and use of *safe and sustainable chemicals* becomes the EU market norm and a global standard

TOXIC-FREE ENVIRONMENT: 5 building blocks

Innovation,
competitiveness,
recovery

Strengthen
legislation for
better protection

Simplification &
coherence

Knowledge and
science

Global

2. Strengthening legislation

- **All chemicals** on the market to be used safely and sustainably.
- Substitute and minimise as far as possible **substances of concern**
- Avoid the **most harmful chemicals** in consumer products esp. for vulnerable groups



Endocrine
disruptors

PFAS

Mixtures

Environmental
impact

New hazard classes

Concept of 'essential uses'

Classification Labelling and Packaging Regulation (CLP)



CLP: “cornerstone” of chemicals safety (based on UN Globally Harmonised system):

- **identifies hazards** in chemicals (e.g. to classify as flammable, carcinogen)
- **communicates hazards** and safety precautions on the label (e.g. 'wear gloves')
- **set out packaging rules** of hazardous chemicals (e.g. tactile warnings, child resistant fastenings)
- **requests information** being sent to EU Poison centres (chemicals information in case of intoxication)

CLP users: consumers, workers, companies and authorities

CLP Revision – New Hazard classes

- Introduce new hazard classes for
 - Endocrine disruptors
 - Persistent Bio-accumulative and Toxic / very Persistent and very Bio-accumulative (PBTs/vPvBs)
 - Persistent Mobile and Toxic / very Persistent and very Mobile (PMTs/vPvMs)

to apply across all legislation (chemicals, specific products)

CLP Revision – Endocrine Disruptors (1)

- Discussions with Member States ongoing
- Based on the definition of the WHO.
- Building on criteria already developed for pesticides and biocides.
- To be applied across all legislation.

CLP Revision - Endocrine Disruptors (2)

- Separation of classes: **human health** and the **environment**.
- Introduction of categories
 - Category 1: Known or presumed endocrine disruptors (ED HH 1 and ED ENV 1)
 - Category 2: Suspected endocrine disruptors (ED HH 2 and ED ENV 2)
- Development of **new labels elements** (H- and P-statements) potentially combined with existing ones.

CLP Revision – Harmonised Classification

- A mandate for European Commission to request European Chemicals Agency (ECHA) to initiate, develop and submit a proposal for harmonised classification
- Harmonisation of human health and environment-based safety values
 - *(for example: predicted no-effect concentration (PNEC), derived no-effect level (DNEL))*

CLP Revision – Next steps

- **Impact assessment**
- **Proposal** by the Commission in 2022.
- After adoption, ED criteria to be proposed under **UN Globally Harmonised System**
- Each **downstream legislation** will need to be modified to take into account the new criteria when establishing risk management measures (implementation of the Chemicals Strategy).

REACH – the instruments

- **Registration** of substances produced or imported ≥ 1 tonne/year => manufacturer or importer submit dossier with hazard and uses/exposure info to European Chemicals Agency (ECHA)
 - **Over 26,000 substances in database**
- **Evaluation** of dossiers (ECHA) and of substances (Member States)
- **Restrictions** of substances of very high concern when they pose unacceptable risk to health and/or the environment
- **Authorisation** for substances of very high concern with the aim of substituting by chemicals of lower concern or non-chemical methods

REACH Revision – Registration

- More information on **critical hazard properties** (carcinogenicity, endocrine disruption etc.) to **ensure hazard identification and risk assessment**
- Registration of **certain polymers** of concern
- Request information on **environmental footprint**
- More information on use and exposure.



REACH Revision – Registration and communication

- Request **Chemical Safety Assessment** for **1-10 tonnes/year** substances
- Introduce a **Mixtures Assessment Factor**
- Introduce a **Derived Minimal Effect Level** for non-threshold substances with a dose-response relationship
- Revise requirements for **supply chain communication** and **e-safety data sheets (e-SDS)**

REACH Revision – Evaluation



- **All registrations** must comply with the legal requirements
- Allow **revocation** of registration numbers
- Improve procedures for **filling of data gaps**, incl. by group assessment and mandating testing
- Streamline **substance evaluation procedures**

REACH Revision – Authorisation



- Extend definition of **Substances of Very High Concern** (Article 57)
 - **Endocrine disruptors** (without *Equivalent Level of Concern*)
 - **Persistent, mobile & toxic (PMT)**
 - **Very persistent, very mobile (vPvM)**
 - General reference to CLP classifications
- Reform of **authorisation & restriction** processes

REACH Revision – Restrictions



- Extend the use of the **Generic Approach for Risk Management** (Article 68(2) on consumer products)
 - **First: Endocrine disruptors, PBT/vPvBs**
 - **Later: Immunotoxicants, neurotoxicants, respiratory sensitisers, specific target organ toxicity (STOTs)**
- Extend to products for **professional use**
- Exempt **essential uses** (to be defined)

REACH Revision – Indicative timing of actions

- Inception Impact Assessment (roadmap) for 4 weeks stakeholder consultation – **May 2021**
- Supporting actions and studies – **Q1 2021 to Q1 2022**
- Public consultation – **open until 15 April 2022**
- Impact Assessment – **Autumn 2021 to Autumn 2022**
- Drafting proposal for revision of REACH – **2022**
- Commission adoption of proposal – **end 2022**

Thank you

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