

# EU Chemicals Strategy for Sustainability

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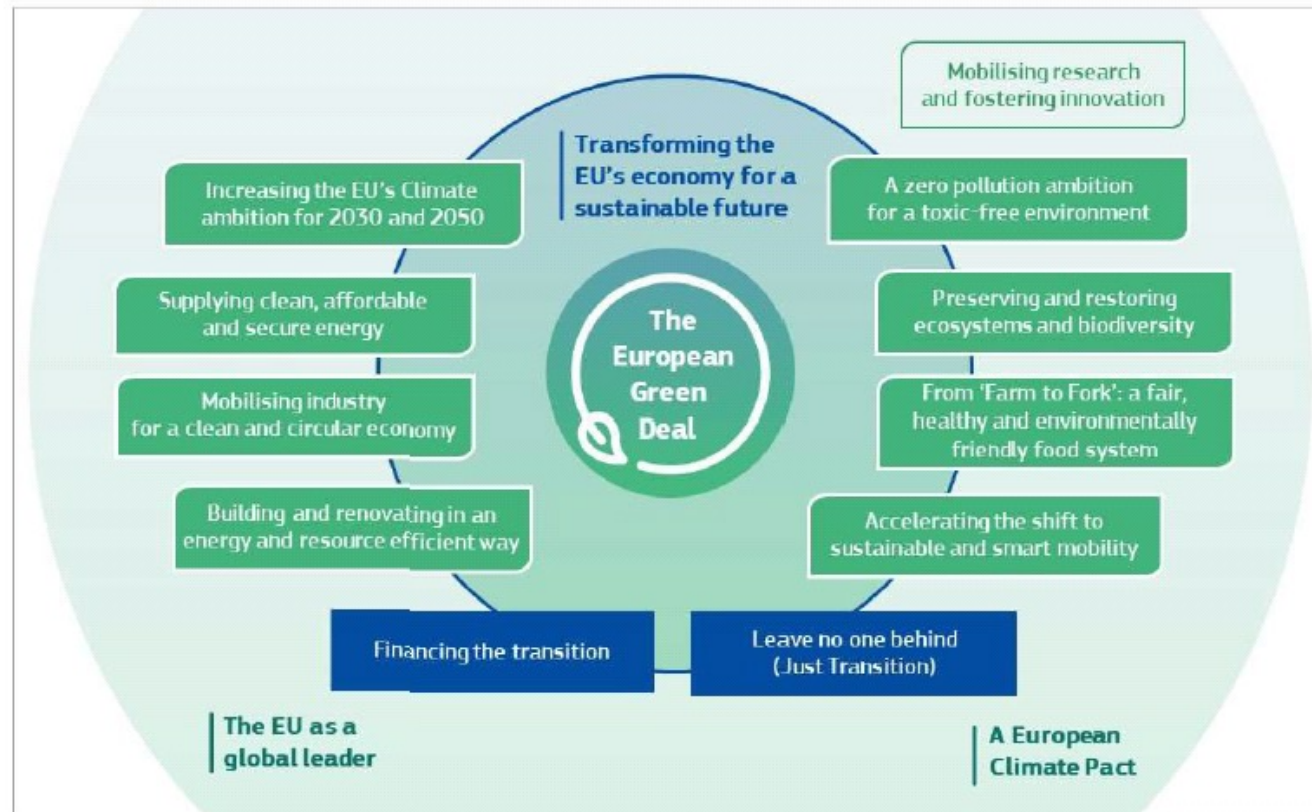
Endocrine disruptors: state of play in REACH and CLP

#ChemicalsStrategy  
#EUGreenDeal

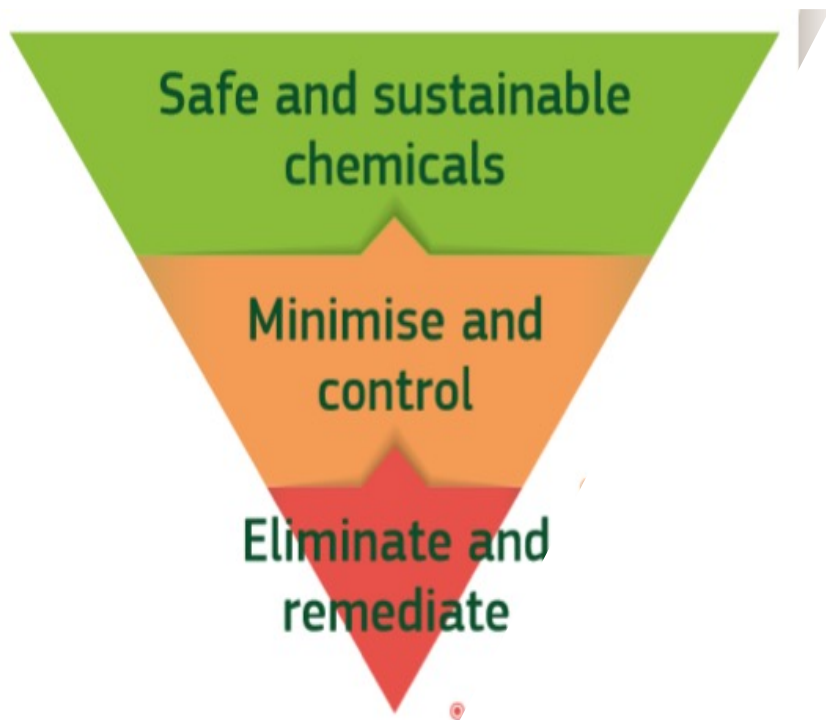


European  
Commission

# Chemicals Strategy for Sustainability



# 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

# Strengthening legislation

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



Endocrine  
disruptors

PFAS

Mixtures

Environmental  
impact

New hazard classes

Concept of 'essential uses'

# REACH update on ED information requirements

**Objective:** Updating the REACH Annexes to include data requirements on endocrine disruption (Annex I and Annexes VII to X).

## Taken into consideration :

- OECD Conceptual Framework (CF) for Testing and Assessment of Endocrine Disrupting Chemicals (GD 150, 2018)
- Update of Biocides Regulation and Plant Protection Product Annexes to include mandatory ED tests to assess Biocides/PPP active substances
- REACH Registration has a tiered approach (volumes)

**NB: Endocrine disruptors = Substances of Very High Concern (SVHC)**

# REACH update on ED information requirements

- Two options were developed and discussed at meetings of the Competent Authorities Subgroup for ED (CASG-ED).
- Options cover EATS modalities (not enough standardized test methods available for other modalities) and vertebrates (EATS: Estrogen, androgen, thyroid hormone, steroidogenesis)
- The two options were used as policy options in a study to support the REACH Impact Assessment, finalised in July 2022.

# REACH Revision – Evaluation



**Substance evaluation** is the tool to confirm or clear a potential concern for a substance, informing the need for further risk management

**Streamline** substance evaluation procedures

- **Clarify** how to establish concern, what can be asked; streamline the rolling action plan (CoRAP)
- Support to **grouping**

**Testing by authorities:** under assessment as one tool across sectors

# REACH Revision

## Adapting the restriction process:

Extending the **generic risk management approach** to restrictions to endocrine disruptors, PBT/vPvB substances, immunotoxicants, neurotoxicants, respiratory sensitisers and substances that affect specific organs

- Extending the generic risk approach to products marketed for professional use
- Restrictions/bans by default with possibility of derogations for **essential uses**



# REACH Revision – Indicative timing of actions

- Supporting actions and studies – **Q1 2021 to Q4 2022**
- Impact Assessment – **Autumn 2021 to Autumn 2022**
- Drafting proposal for revision of REACH – **2022/2023**
- Commission adoption of proposal – **Q4 2023**

# CLP New Hazard classes

- Endocrine Disruptors  
→ (categorisation system)
- Persistent Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB)
- Persistent Mobile and Toxic (PMT) and very Persistent and very Mobile (vPvM)

# ED Hazard classes

- Based on the definition of the WHO
- Building on criteria already developed for pesticides and biocides
- To be applied across all legislation
- Separate classes: human health and environment
  - Distinction of ED for human health or environment already exists today across the legislative framework

# ED Hazard classes – Text Human Health

## Definitions:

- **'endocrine disruptor'** means a substance or a mixture that alters one or more functions of the endocrine system and consequently causes adverse effects in an intact organism, its progeny, populations or subpopulations;
- **'endocrine disruption'** means the alteration of one or more functions of the endocrine system caused by an endocrine disruptor;
- **'endocrine activity'** means an interaction with the endocrine system that may result in a response of that system, of target organs or target tissues, and that confers on a substance or the mixture the potential to alter one or more functions of the endocrine system;
- **'adverse effect'** means a change in morphology, physiology, growth, development, reproduction or lifespan of an organism, system, population or subpopulation that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
- **'biologically plausible link'** means the correlation between an endocrine activity and an adverse effect, based on biological processes, where the correlation is consistent with existing scientific knowledge.

# ED Hazard classes – Text Human Health Cat. 1

## Known or presumed endocrine disruptors for human health

The classification in Category 1 shall be largely based on evidence from at least one of the following:

- a) human data;
- b) animal data;
- c) non-animal data providing an equivalent predictive capacity as data in points a or b.

Such data shall provide evidence that the substance meets all the following criteria:

- (a) endocrine activity;
- (b) an adverse effect in an intact organism or its offspring or future generations;
- (c) a biologically plausible link between the endocrine activity and the adverse effect.

However, where there is information that raises serious doubt about the relevance of the adverse effects to humans, classification in Category 2 may be more appropriate.

# ED Hazard classes – Text Human Health Cat.2

## **Suspected** endocrine disruptors for human health

A substance shall be classified in Category 2 where all the following criteria are fulfilled:

- (a) there is evidence of:
  - i. an endocrine activity; and
  - ii. an adverse effect in an intact organism or its offspring or future generations;
- (b) the evidence referred to in point (a) is not sufficiently convincing to classify the substance in Category 1;
- (c) there is evidence of a biologically plausible link between the endocrine activity and the adverse effect.

# ED Hazard classes – Human Health (labelling)

Classification	Category 1	Category 2
Symbol/pictogram		
Signal Word	Danger	Warning
Hazard Statement	EUH380: May cause endocrine disruption in humans	EUH381: Suspected of causing endocrine disruption in humans
Precautionary Statement Prevention	P201 P202 P263 P280	P201 P202 P263 P280
Precautionary Statement Response	P308 + P313	P308 + P313
Precautionary Statement Storage	P405	P405
Precautionary Statement Disposal	P501	P501

# Timeline

- Draft published for consultation on “Have your say” 20 September – 18 October 2022  
[https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13578-Introducing-new-hazard-classes-CLP-revision\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13578-Introducing-new-hazard-classes-CLP-revision_en)
- Adoption: 19 December 2022



# Setting the example globally

- Propose the new hazard classes for the **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)**
- 43<sup>rd</sup> session of the GHS Sub-Committee (7 to 9 December 2022): agreement on the EU Proposal to include work on unaddressed hazards in the programme of work for the biennium 2023-2024
- The work will start in early 2023



# Thank you

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