EU CLP Regulation Expands Hazard Classes for Endocrine Disruptors and Persistent Chemicals

Presented by

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The Hidden Threat in Your Home: Endocrine Disruptors

- An endocrine-disrupting chemical (EDC) is defined as: “an exogenous chemical, or mixture of chemicals, that can interfere with any aspect of hormone action”
- These can include natural or manufactured chemicals, such as pesticides, biocides, chemicals in plastic polymers (including breakdown products or constituents), food contact materials, cosmetics, and others

Chemical ingredients in consumer products

Pesticides

Plasticizers

Surfactants

Phenols

Flame retardants

Routes of exposure to EDCs

Picture adapted from Sharpe et. al., BMJ 2004

EDCs mechanisms of action

- Direct action on hormone receptor and receptor function
- Interfere with hormone transport and feedback
- Sex hormone binding globulin
- Thyroid hormone
- Alter hepatic catabolism
- Agonist or antagonist of endogenous nuclear receptors
- Estrogen receptors
- Peroxisome proliferator-activated receptors
- Epigenetic changes through alterations of gene expression
- Non-endocrine-mediated pathways (e.g., immune)
- Systemic toxicity

New hazard classes – what will they look like?

- The hazard classes which will be introduced relate to the identification of endocrine disruptive effects (EDs).
- The European Commission introduced 8 new hazard classes and criteria intended to protect human health and the environment (Regulation (EU) 2023/707). Applies to all chemical substances and mixtures placed on the EU market under REACH
- In force as of 20 April 2023

Need to Insert new hazard classes

Hazards for certain substances and mixtures were not fully addressed via the existing criteria

The new hazard classes target substances and mixtures which are very harmful for human health or the environment

What are the new hazard classes?

- Endocrine disruptors (ED) for human health or the environment
- Persistent, bioaccumulative, and toxic (PBT)
- Very persistent and very bioaccumulative (vPvB)
- Persistent, mobile, and toxic (PMT)
- Very persistent and very mobile (vPvM)

Endocrine Disruptors (ED) for human health

Hazard category	Hazard criteria
Category 1	Known or presumed endocrine disruptors for human health. Must meet all criteria: ✓ Evidence of endocrine activity ✓ Adverse effect in organism or its offspring ✓ Biologically plausible link between endocrine activity and adverse effect.
Category 2	Suspected endocrine disruptors for human health. Meets the criteria for Category 1, but the evidence is not “sufficiently convincing”

Within Annex I to CLP Part 3

→ 3.11 Endocrine Disruptor for Human Health

Endocrine Disruptors (ED) for the environment

Hazard category	Hazard criteria
Category 1	Known or presumed endocrine disruptors for the environment. Must meet all criteria: ✓ Evidence of endocrine activity ✓ Adverse effect in organism or its offspring ✓ Biologically plausible link between endocrine activity and adverse effect.
Category 2	Suspected endocrine disruptors for the environment. Meets the criteria for Category 1, but the evidence is not "sufficiently convincing"

Within Annex I to CLP Part 4

→ 4.2 Endocrine Disruptor for Environment → 4.3 PBT/vPvB → 4.4 PMT/vPvB

Generic concentration limits - EDs

Component classified as:	Generic concentration limits triggering classification of a mixture as:	
	Category 1 ED HH or ENV	Category 2 ED HH or ENV
Category 1 ED	≥0.1%	
Category 2 ED		≥1% [Note 1]

Note 1: If a Category 2 endocrine disruptor for human health is present in the mixture as an ingredient at a concentration ≥0.1%, an SDS shall be available for the mixture upon request.

Label elements – ED HH

Table 3.11.3

Classification	Category 1	Category 2
Pictogram	none	none
Signal word	Danger	Warning
Hazard statement	EUH380: May cause endocrine disruption in humans	EUH381: Suspected of causing endocrine disruption in humans
Precautionary statements	P201, P202, P263, P280, P308+P313, P405, P501	

Label elements – ED HH

Table 4.2.3

Classification	Category 1	Category 2
Pictogram	none	none
Signal word	Danger	Warning
Hazard statement	EUH430: May cause endocrine disruption in the environment	EUH431: Suspected of causing endocrine disruption in the environment
Precautionary statements	P201, P202, P273, P391, P405, P501	

Persistent, bioaccumulative and toxic (PBT)

Persistent if degradation half-life in fresh, marine, or estuarine water, marine or estuarine sediment, or soil is higher than a certain threshold (>40-180 d)

Bioaccumulative if aquatic BCF >2000

Toxic if chronic NOEC <0.01mg/L, a CMR, STOT RE 1 or 2, or an ED HH/ENV 1

Very persistent and very bioaccumulative (vPvB)

Very persistent if degradation half-life in fresh, marine, or estuarine water, marine or estuarine sediment, or soil is higher than a certain threshold (>60-180 d)

Very bioaccumulative if aquatic BCF >5000

Label elements – PBT and vPvB

Table 4.3.1

	PBT	vPvB
Pictogram	none	none
Signal word	Danger	Danger
Hazard statement	EUH440: Accumulates in the environment and living organisms including in humans	EUH441: Strongly accumulates in the environment and living organisms including in humans
Precautionary statements	P201, P202, P273, P391, P405, P501	

Persistent, mobile, and toxic (PMT)

Persistent if degradation half-life in fresh, marine, or estuarine water, marine or estuarine sediment, or soil is higher than a certain threshold (>40-180 d)

Mobile if log K_{oc}<3

Toxic if chronic NOEC <0.01mg/L, a CMR, STOT RE 1 or 2, or an ED HH/ENV 1

Very persistent and very mobile (vPvM)

Very persistent if degradation half-life in fresh, marine, or estuarine water, marine or estuarine sediment, or soil is higher than a certain threshold (>40-180 d)

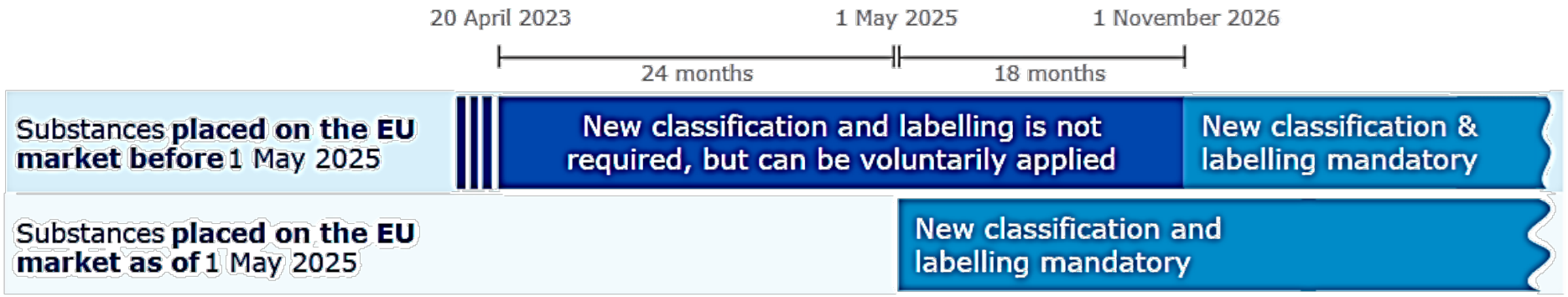
Very mobile if log K_{oc}<2

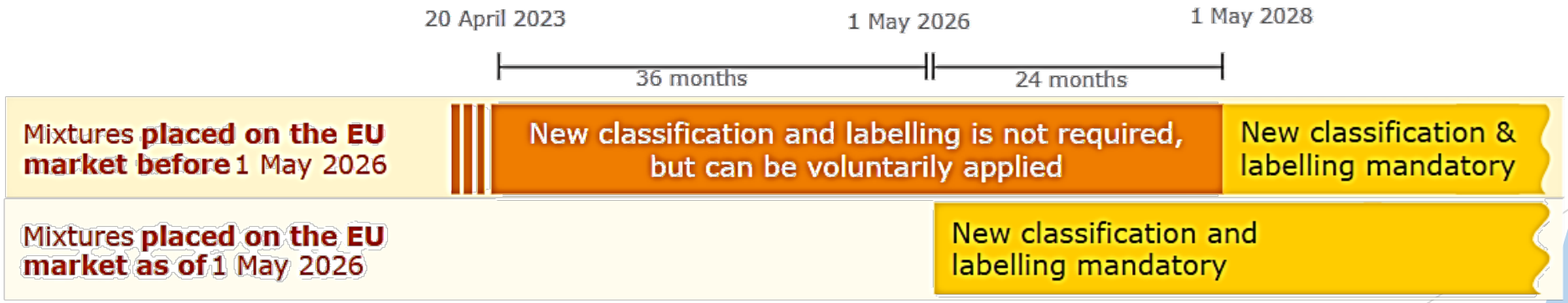
Label elements – PMT and vPvM

Table 4.4.1

	PMT	vPvM
Pictogram	none	none
Signal word	Danger	Danger
Hazard statement	EUH450: Can cause long-lasting and diffuse contamination of water resources	EUH451: Can cause very long-lasting and diffuse contamination of water resources
Precautionary statements	P201, P202, P273, P391, P405, P501	

Timeline for transition





European Chemicals Agency (ECHA). New hazard classes 2023. https://echa.europa.eu/new-hazard-classes-2023

Conclusion

The need to insert new hazard classes and their criteria into the CLP Regulation is part of the commitments made by EU COM under the chemicals strategy for sustainability, part of the European Green Deal

THANK YOU

Any questions?

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Bergeson & Campbell. (2023, May 9). Regulatory Developments: EC Implements New Hazard Classes to CLP. https://www.actagroup.com/regulatory-developments/entry/ec-implements-new-hazard-classes-to-clp

European Chemicals Agency (ECHA). New hazard classes 2023. https://echa.europa.eu/new-hazard-classes-2023

European Commission (2022, December 19). Questions and Answers: revision of the Regulation on classification, labelling and packaging of chemicals. https://ec.europa.eu/commission/presscorner/detail/en/qanda_22_7776

European Commission (2023, 31 March). COMMISSION DELEGATED REGULATION (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R0707&from=EN

Timeline for transition