

Nye fareklasser og merkekrav i CLP

Eco Onlines sommerseminar 2023

EU Chemicals Strategy for Sustainability

#ChemicalsStrategy
#EUGreenDeal



European
Commission

(EU) 2023/707 Innfører nye fareklasser i CLP-forordningen

- Hormonforstyrrende egenskaper
 1. Stoffer som er kjent eller antatt å være hormonforstyrrende for menneskers helse eller i miljøet
 2. Stoffer som er mistenkte å være hormonforstyrrende for menneskers helse eller i miljøet
- Miljøfarlige egenskaper
 - PBT persistent, bioakkumulerende og giftig
 - vPvB svært persistent og svært bioakkumulerende
 - PMT persistent, mobil og giftig
 - vPvM svært persistent og svært mobil
- Kunngjort 31. mars 2023



De nye reglene gjelder fra

- 1. mai 2025 klassifisering og merking av nye stoff
- 1. november 2026 klassifisering og merking av gamle* stoff
- 1. mai 2026 klassifisering og merking av nye stoffblandinger
- 1. mai 2028 klassifisering og merking av gamle* stoffblandinger

**"gamle" stoff ble omsatt før 1. mai 2025*

**"gamle" stoffblandinger ble omsatt før 1. mai 2026*



CLP vedlegg I, kapittel 3.11:

Endocrine disruption for human health



Kriterier hormonforstyrrende for helse

«Known or presumed»

«Suspected»

Hazard categories for endocrine disruptors for human health

Categories	Criteria
CATEGORY 1	<p>Known or presumed endocrine disruptors for human health</p> <p>The classification in Category 1 shall be largely based on evidence from at least one of the following:</p> <ul style="list-style-type: none"> a) human data; b) animal data; c) non-animal data providing an equivalent predictive capacity as data in points a or b. <p>Such data shall provide evidence that the substance meets all the following criteria:</p> <ul style="list-style-type: none"> (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. <p>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.</p>
CATEGORY 2	<p>Suspected endocrine disruptors for human health</p> <p>A substance shall be classified in Category 2 where all the following criteria are fulfilled:</p> <ul style="list-style-type: none"> (a) there is evidence of: <ul style="list-style-type: none"> 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.

Klassifiseringsgrenser for blandinger

Table 3.11.2.

Generic concentration limits of components of a mixture classified as endocrine disruptor for human health that trigger classification of the mixture

Component classified as:	Generic concentration limits triggering classification of a mixture as:	
	Category 1 endocrine disruptor for human health	Category 2 endocrine disruptor for human health
Category 1 endocrine disruptor for human health	≥ 0,1 %	
Category 2 endocrine disruptor for human health		≥ 1 % [Note 1]

Merkeelementer

Label elements of endocrine disruption for human health

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

CLP vedlegg I, kapittel 4.2:

Endocrine disruption for the environment



Kriterier hormonforstyrrende for miljø

«Known or presumed»

«Suspected»

Hazard categories for endocrine disruptors for the environment	
Categories	Criteria
CATEGORY 1	<p>Known or presumed endocrine disruptors for the environment</p> <p>The classification in Category 1 shall be largely based on evidence from at least one of the following:</p> <ul style="list-style-type: none"> a) animal data; b) non-animal data providing an equivalent predictive capacity as data in point a. <p>Such data shall provide evidence that the substance meets all the following criteria:</p> <ul style="list-style-type: none"> (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. <p>However, where there is information that raises serious doubt about the relevance of the adverse effects identified at population or subpopulation level, classification in Category 2 may be more appropriate</p>
CATEGORY 2	<p>Suspected endocrine disruptors for the environment</p> <p>A substance shall be classified in Category 2 where all the following criteria are met:</p> <ul style="list-style-type: none"> (a) there is evidence of: <ul style="list-style-type: none"> 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.

Klassifiseringsgrenser blandinger

Table 4.2.2.

Generic concentration limits of components of a mixture classified as endocrine disruptor for the environment that trigger classification of the mixture

Component classified as:	Generic concentration limits triggering classification of a mixture as:	
	Category 1 endocrine disruptor for the environment	Category 2 endocrine disruptor for the environment
Category 1 endocrine disruptor for the environment	≥ 0,1 %	
Category 2 endocrine disruptor for the environment		≥ 1 % [Note 1]

Merkeelementer hormonforstyrrende for miljø

Label elements of endocrine disruption for the environment		
Classification	Category 1	Category 2
Symbol/pictogram		
Signal Word	Danger	Warning
Hazard Statement	EUH430: May cause endocrine disruption in the environment	EUH431: Suspected of causing endocrine disruption in the environment
Precautionary Statement Prevention	P201 P202 P273	P201 P202 P273
Precautionary Statement Response	P391	P391
Precautionary Statement Storage	P405	P405
Precautionary Statement Disposal	P501	P501



CLP vedlegg I, kapittel 4.3:

Persistent, Bioaccumulative and Toxic or

Very Persistent, Very Bioaccumulative properties



PBT - kriterier

Persistence

- (a) DegT50 > 60 days, marine water;
- (b) DegT50 > 40 days, fresh or estuarine water;
- (c) DegT50 > 180 days, marine sediment;
- (d) DegT50 > 120 days fresh or estuarine water sediment;
- (e) DegT50 > 120 days in soil.
-eller overvåkingsdata

Bioaccumulation

- BCF in aquatic species > 2000.
-eller andre typer data på bioakkumulering

Toxicity

- (a) (NOEC) or EC10 for marine or freshwater organisms < 0,01 mg/l;
- (b) CMR 1A eller 1B;
- (c) STOT RE kategori 1 or 2;
- (d) ED kategori 1 (helse eller miljø)
-eller andre typer toksdata



vPvB - kriterier

Very persistent:

(a) DegT50 > 60 days in marine, fresh or estuarine **water**;

(b) DegT50 > 180 days marine, fresh or estuarine water **sediment**;

(c) DegT50 > 180 days in **soil**.

-eller overvåkingsdata

Very bioaccumulating

BCF in aquatic species > 5 000.

-eller andre typer data på bioakkumulering



Klassifiseringsgrenser PBT/vPvB

4.3.3. *Classification criteria for mixtures*

- 4.3.3.1. A mixture shall be classified respectively as a PBT or vPvB when at least one component contained in the mixture has been classified respectively as a PBT or vPvB and is present at or above 0,1 % (weight/weight).

0.1 vektprosent

Merkeelementer PBT/vPvB

	PBT	vPvB
Symbol/pictogram		
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 Statement Prevention	P201 P202 P273	P201 P202 P273
Precautionary Statement Response	P391	P391
Precautionary Statement Disposal	P501	P501



CLP vedlegg I, kapittel 4.4:

Persistent, Mobile and Toxic or
Very Persistent, Very Mobile properties



PMT- kriterier

Persistence:

- (a) DegT50 > 60 days in marine water;
- (b) DegT50 > 40 days in fresh or estuarine water;
- (c) DegT50 > 180 days in marine sediment;
- (d) DegT50 > 120 days in fresh or estuarine water sediment;
- (e) DegT50 > 120 days in soil.
-eller overvåkingsdata

Mobility:

Log Koc < 3

Ioniserbare stoffer: laveste log Koc < 3 for pH mellom 4 og 9
-eller data fra f.eks. utlekkingsstudier, overvåking

Toxicity:

- (a) (NOEC) eller EC10 for marine or freshwater organisms < 0,01 mg/l;
- (b) CMR 1A eller 1B
- (c) STOT RE kategori 1 or 2
- (d) ED helse eller miljø kategori 1
-eller andre typer toksdata



vPvM- kriterier

Very Persistent

- (a) DegT50 > 60 days in fresh or estuarine water;
 - (b) DegT50 > 180 days in marine, fresh or estuarine water sediment;
 - (c) DegT50 > 180 days in soil.
- eller overvåkingsdata

Very Mobile

$\log K_{oc} < 2$

Ioniserbare stoffer; laveste $\log K_{oc} < 2$ ved pH mellom 4 og 9
-eller data fra f.eks. utlekkingsstudier, overvåking



PMT/vPvM klassifiseringsgrenser

4.4.3. *Classification criteria for mixtures*

- 4.4.3.1 A mixture shall be classified as a PMT or vPvM where at least one of its components has been classified as a PMT or vPvM and is present at or above 0,1 % (weight/weight).

0.1 vektprosent

PMT/vPvM merkeelementer

Label elements for PMT and vPvM properties

	PMT	vPvM
Symbol/pictogram		
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 Statement Prevention	P201 P202 P273	P201 P202 P273
Precautionary Statement Response	P391	P391
Precautionary Statement Disposal	P501	P501



Draft plan

→ Starting point for the plan



Q1-Q2 2023	Delegated act publication/entry into force
Q1 2023	ECHA experts to initiate work on the guidance text
Q2 2023	Interim "info package" on ECHA website
Q2 2023	ED/PBT expert group consultations until 31 May
Q3 2023	Launch of PEG and RAC consultations
Q1 2024	CARACAL consultation
Q2 2024	Guidance publication
Q2 2025-Q4 2026	Transitional period ends for substances

EFSA provided valuable support during drafting

Oppsummering

- (EU)2023/707
- 1.mai 2025 - 1. mai 2028
- Nye fareklasser i CLP vedlegg I:
 - Hormonforstyrrende for helse, kategori 1 og 2 (kapittel 3.11)
 - Hormonforstyrrende for miljø, kategori 1 og 2 (kapittel 4.2)
 - Persistent, bioakkumulerende og giftige stoffer (kapittel 4.3)
 - Svært persistente og svært bioakkumulerende stoffer (kapittel 4.3)
 - Persistent, mobile og giftige stoffer (kapittel 4.4)
 - Svært persistente og svært mobile stoffer (kapittel 4.4)
- ECHA jobber med veiledningsmaterialet

