CHCS
CHEMICAL HAZARDS COMMUNICATION SOCIETY

The new CLP hazard classes - Endocrine Disruptors and Persistent Substances; Nanomaterials

Gill Pagliuca
Denehurst Chemical Safety Limited

The EU Green deal and CSS

Aim to better protect human health and the environment and move to a toxic free environment

New hazards being identified through REACH, BPR, etc

Endocrine Disruptors	PBT/vPvB	PMT/vPvM

COM adding these to CLP to improve protection and as part of their target of zero chemical pollution

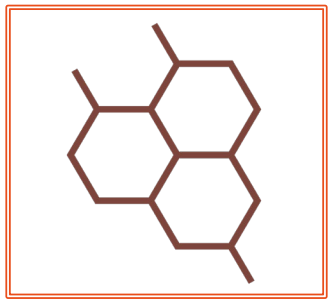
Regulation (EU) 2023/707

Regulation published 31st March 2023

Entered into force 20th April 2023

Transitional measures for substances and mixtures

Transition periods for reclassification and labelling of substances and mixtures



Substances

Substances to be classified and labelled to the new criteria from 1 May 2025

Substances already placed on the before 1 May 2025 must be classified and labelled to the new criteria by 1 Nov 2026

Mixtures

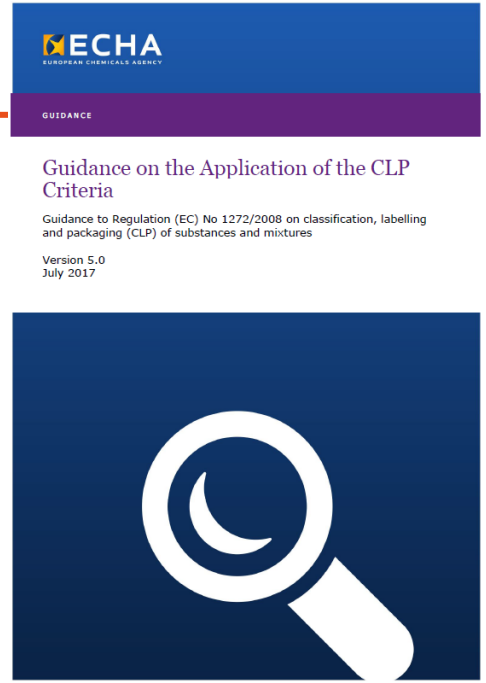
Mixtures to be classified and labelled to the new criteria from 1 May 2026

Mixtures already placed on the before 1 May 2026 must be classified and labelled to the new criteria by 1 May 2028

Timeline


We are here
20th April 2023
Entry into force
1 May 2025 (2 years)
Substances must be classified and labelled using the new criteria
1 May 2026 (3 years)
Mixtures must be classified and labelled using the new criteria
1 Nov 2026 (3 ½ years)
Substances already placed on the market before 1 May 2025 must be classified and labelled using the new criteria
1 May 2028 (5 years)
Mixtures already placed on the market before 1 May 2026 must be classified and labelled using the new criteria

Availability of guidance etc



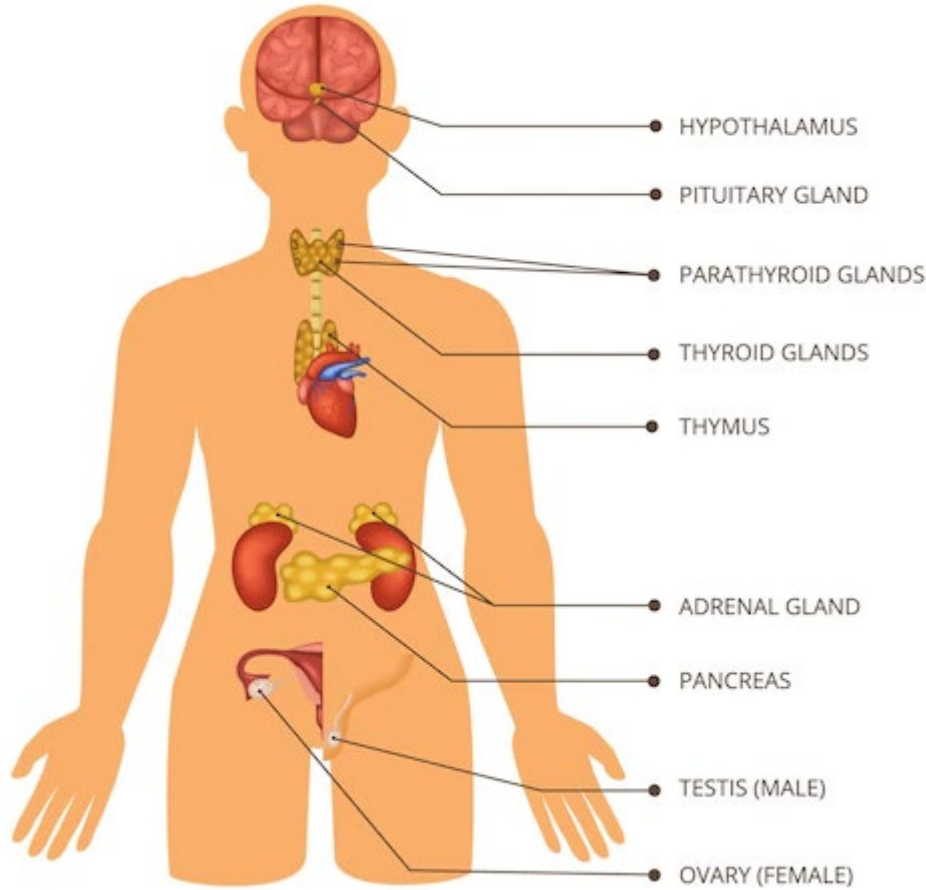
- Updated Guidance on the Application of the CLP criteria expected to be published mid 2024
- Until then can use
  - EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and EC No 1107/2009 https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5311
  - Guidance on Information Requirements and Chemical Safety Assessment, Part C: PBT/vPvB assessment (R11), Version 3.0, June 2017 https://echa.europa.eu/documents/10162/17235/information_requirements_part_c_en.pdf
  - See also https://echa.europa.eu/new-hazard-classes-2023

Guidance

- Existing guidance covers
  - ED HH1, ED Env 1, PBT/vPvB
- New guidance needed for
  - ED HH 2, ED Env 2, M part of PMT/vPvM
- First drafts of new guidance published at https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-clp

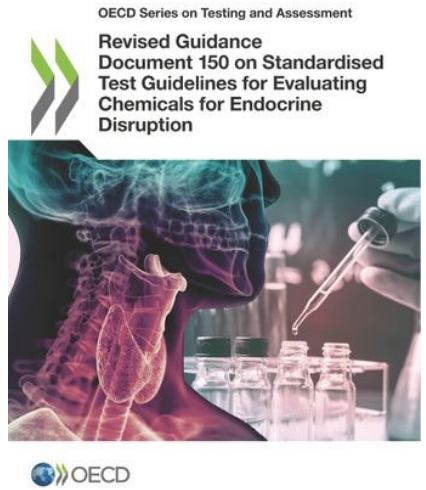
Endocrine disruption for human health (3.11)

- Natural or synthetic chemicals that mimic, block or interfere with hormones in humans / animals / wildlife
- Endocrine disruption can lead to, amongst other effects, birth defects, developmental, reproductive or neurodevelopmental disorders, cancer, diabetes and obesity
- Primary focus is on ED with EATS pathways
  - EATS = Estrogenic, Androgenic, Thyroidal and Steroidogenic modalities



Testing

- CLP requires no new testing, only assessment of existing available data
  - Other regulations such as REACH may require new testing
  - REACH Annexes VII-X are being updated
- Guidance on testing
  - EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and EC No 1107/2009 https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5311
  - OECD Guidance Document 150 https://www.oecd-ilibrary.org/environment/guidance-document-on-standardised-test-guidelines-for-evaluating-chemicals-for-endocrine-disruption-2nd-edition_9789264304741-en



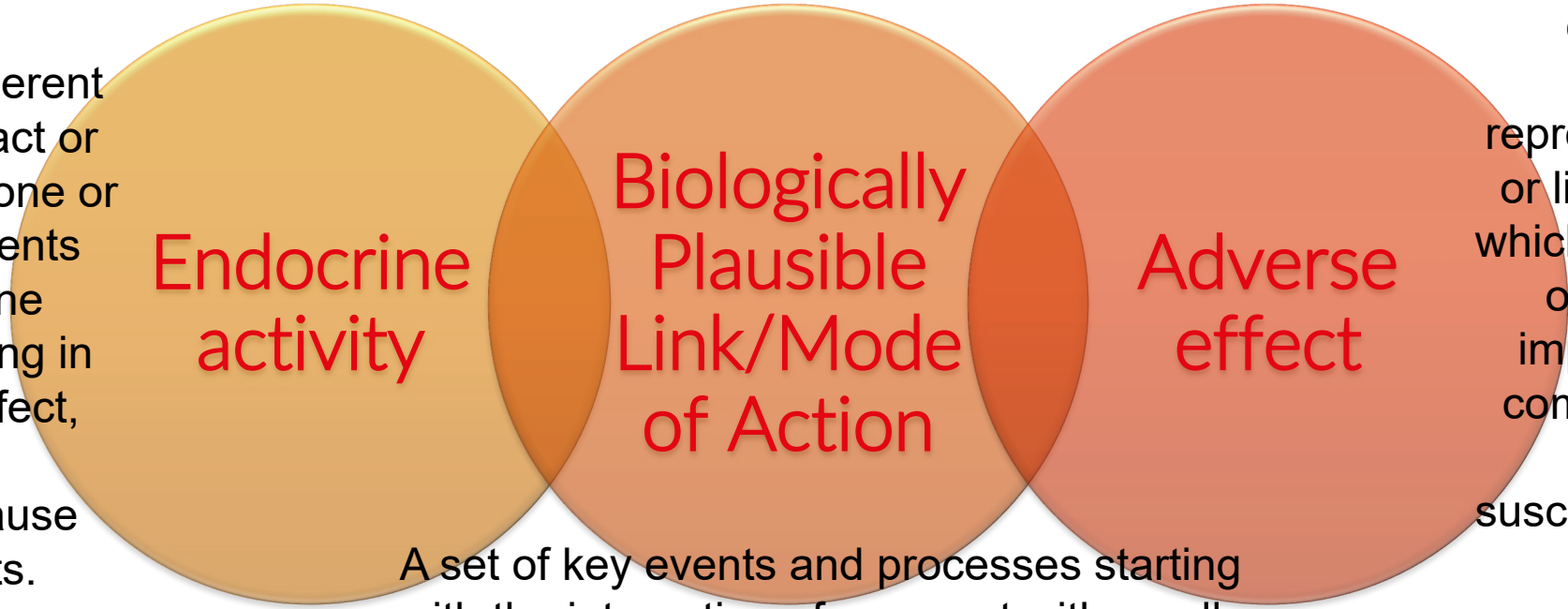
Hazard categories for endocrine disruptors for human health (ED HH 1 & 2)

Categories	Criteria
Category 1	Known or presumed endocrine disruptors for human health Classification in Cat. 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.
Category 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.

Endocrine Disruptor Assessment

Three conditions for identification of an endocrine disruptor

having the inherent ability to interact or interfere with one or more components of the endocrine system resulting in a biological effect, but need not necessarily cause adverse effects.



A set of key events and processes starting with the interaction of an agent with a cell, through physiological and tissue or organ changes, potentially resulting in an adverse outcome.

change in morphology, physiology, growth, reproduction, development or lifespan of an organism which results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increased susceptibility to the harmful effects of other environmental influences.

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

- Not an additive process, if > 1 ED substance, each is compared to the concentration threshold separately
- Proposed CLP Revision: A negative result in a tested mixture will not be able to trump classification based on ingredients (will bring into line with existing provisions for CMRs)

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]

Note 1: If a Category 2 endocrine disruptor for human health is present in the mixture as an ingredient at a concentration ≥ 0,1 % a SDS shall be available for the mixture upon request.

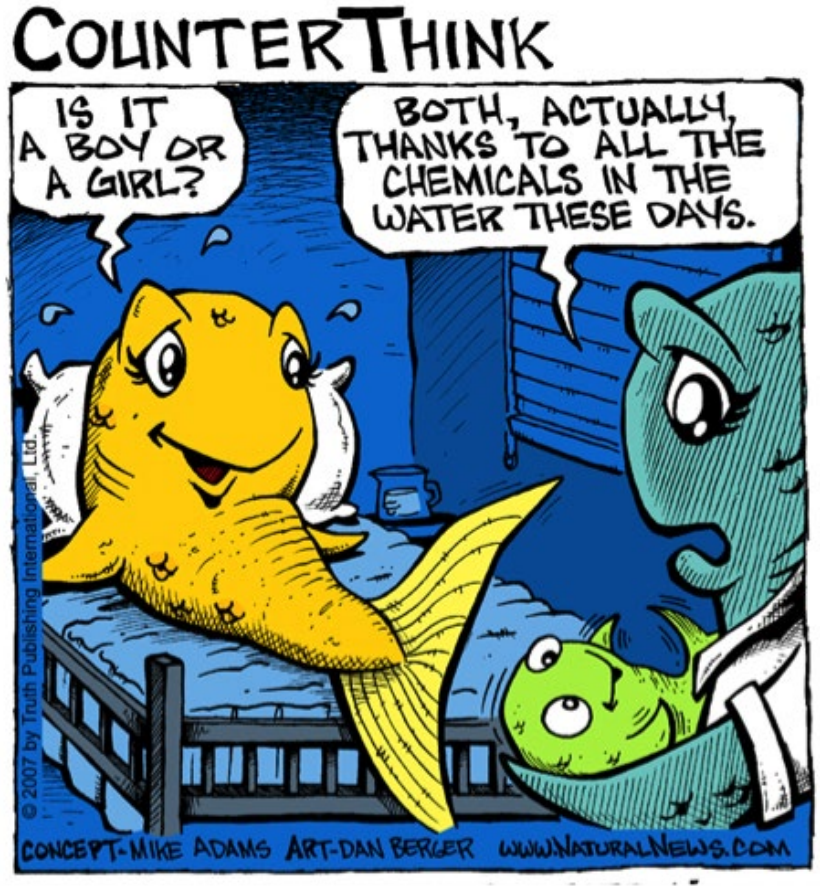
Label elements of endocrine disrupting properties for human health

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

* EUH210 "Safety data sheet available on request" if mixture contains ED Cat 2 ≥0.1% and not intended for the general public.

Endocrine disruption for the environment (4.2)

- Similar to ED HH, but for non-target organisms (NTO) (aquatic organisms, fish, birds, ….) rather than humans



Hazard categories for endocrine disruptors for the environment (ED ENV 1 & 2)

Categories	Criteria
Category 1	Known or presumed endocrine disruptors for the environment The classification in Category 1 shall be largely based on evidence from at least one of the following: a) animal data; b) non-animal data providing an equivalent predictive capacity as data in point a. 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 identified at population or subpopulation level, classification in Category 2 may be more appropriate.
Category 2	Suspected endocrine disruptors for the environment A substance shall be classified in Category 2 where all the following criteria are met: (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 plausible biological link between the endocrine activity and the adverse effect.

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

- Not an additive process, if > 1 ED substance, each is compared to the concentration threshold separately
- Proposed CLP Revision: A negative result in a tested mixture will not be able to trump classification based on ingredients (will bring into line with existing provisions for CMRs)

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]

Note 1: If a Category 2 endocrine disruptor for the environment is present in the mixture as an ingredient at a concentration ≥ 0,1 % a SDS shall be available for the mixture upon request.

Label elements of endocrine disrupting properties 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

* *EUH210 "Safety data sheet available on request" if the mixture contains ED Cat 2 ≥0.1% and not intended for the use of the general public.*

Persistent, Bioaccumulative and Toxic or Very Persistent, Very Bioaccumulative properties

- Definitions
  - “PBT” means a persistent, bioaccumulative and toxic substance or mixture that meets the classification criteria set out in Section 4.3.2.1.
  - “vPvB” means a very persistent and very bioaccumulative substance or mixture that meets the classification criteria set out in Section 4.3.2.2.
- Why are they of concern
  - Do not break down, difficult to remove
  - Effects are cumulative
  - Some may be transported around the world, contaminating pristine areas
  - Don’t always know what the long-term effects are

PBT/vPvB Criteria for substances

Needs to meet criteria for P + B + T

Persistence	a. half-life in marine water is > 60 d; or b. half-life in fresh or estuarine water is > 40 d; or c. half-life in marine sediment is > 180 d; or d. half-life in fresh or estuarine sediment is >120 d; or e. half-life in soil is >120 d
Bioaccumulation	Bioconcentration factor >2000 (measured in aquatic species)
Toxicity	a. Long-term no-observed effect concentration (NOEC) or EC10 for marine or freshwater organisms <0.01 mg/l; or b. Classified as carcinogenic (Cat. 1A or 1B), mutagenic (Cat. 1A or 1B), or toxic for reproduction (Cat. 1A, 1B, or 2); or c. Other evidence for chronic toxicity: STOT (repeated exposure) Cat. 1 or 2; or d. Meets the criteria for ED for health or the environment

Needs to meet criteria for vP + vB

Very Persistent	a. half-life in marine, fresh, or estuarine water is > 60 d; or b. half-life in marine, fresh, or estuarine sediment is > 180 d; or c. half-life in soil is >180 d
Very Bioaccumulative	Bioconcentration factor >5000

Classification of mixtures containing PBT or vPvB substances

- Not an additive process, if > 1 PBT/vPvB substance, each is compared to the concentration threshold separately
- 0.1% threshold consistent with REACH SVHC requirements

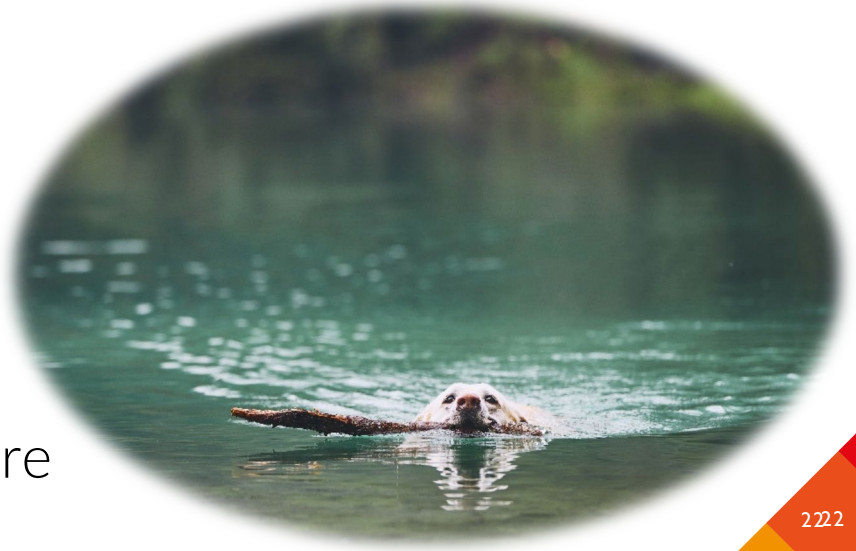
Component Classified as	Concentration limits triggering classification of a mixture as:	
	PBT	vPvB
PBT	≥ 0.1 % w/w	
vPvB		≥ 0.1 % w/w

Label elements for PBT and vPvB

Classification	PBT	vPvB
Symbol/pictogram	—	—
Signal Word	Danger	Warning
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

Persistent, Mobile and Toxic or Very Persistent, Very Mobile properties (4.4)

- Definitions
  - “PMT” means a persistent, mobile and toxic substance or mixture that meets the classification criteria set out in Section 4.4.2.1.
  - “vPvM” means a very persistent and very mobile substance or mixture that meets the classification criteria set out in Section 4.4.2.2.
- Why are they of concern
  - Contamination of water supplies
  - Difficult and expensive to clean up, not always removed even by advanced filtration processes
  - Some spread over long distances
  - Don’t always know what long term health effects are



PMT/vPvM Criteria for substances

Needs to meet the criteria for P + M + T	Persistence	a. half-life in marine water is > 60 d; or b. half-life in fresh or estuarine water is > 40 d; or c. half-life in marine sediment is > 180 d; or d. half-life in fresh or estuarine sediment is >120 d; or e. half-life in soil is >120 d
	Mobility	Log Koc < 3 (for ionisable substances, use lowest Koc between pH 4 and 9)
	Toxicity	a. Long-term no-observed effect concentration (NOEC) or EC10 for marine or freshwater organisms <0.01 mg/l; or b. Classified as carcinogenic (Cat. 1A or 1B), mutagenic (Cat. 1A or 1B), or toxic for reproduction (Cat. 1A, 1B, or 2); or c. Other evidence for chronic toxicity: STOT (repeated exposure) Cat. 1 or 2; or d. Meets the criteria for ED for health or the environment
Needs to meet the criteria for vP + vM	Very Persistent	a. half-life in marine, fresh, or estuarine water is > 60 d; or b. half-life in marine, fresh, or estuarine sediment is > 180 d; or c. half-life in soil is >180 d
	Very Mobile	Log Koc < 2 (for ionisable substances, use lowest Koc between pH 4 and 9)

Classification of mixtures containing PMT or vPvM substances

- Not an additive process, if > 1 PBT/vPvB substance, each is compared to the concentration threshold separately
- 0.1% threshold consistent with REACH SVHC requirements

Component Classified as	Concentration limits triggering classification of a mixture as:	
	PMT	vPvM
PMT	≥ 0.1 % w/w	
vPvM		≥ 0.1 % w/w

Label elements for PMT and vPvM

Classification	PMT	vPvM
Symbol/pictogram	—	—
Signal Word	Danger	Warning
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

Precedence of Statements

Added to Annex III:

- If EUH441 ‘Strongly accumulates in the environment and living organisms including in humans’ is assigned, the statement EUH440 ‘Accumulates in the environment and living organisms including in humans’ may be omitted;
- If EUH451 ‘Can cause very long-lasting and diffuse contamination of water resources’ is assigned, the statement EUH450 ‘Can cause long-lasting and diffuse contamination of water resources’ may be omitted.’

Updates to Annex VI (Harmonised classifications)

- CLH template updated by ECHA
- First priority to include substances identified as ED HH, ED Env, PBT, vPvB, PMT, vP,VM under other regulations
  - REACH Candidate List of SVHC
  - Biocides and PPP
  - CLP Revision – by 1 Jan 2026???
- In future, process may be CLP before SVHC identification
  - Aim to reduce risk of diverging view between RAC and MSC
  - NGOs concern over delays in identifying SVHC

Nanomaterials

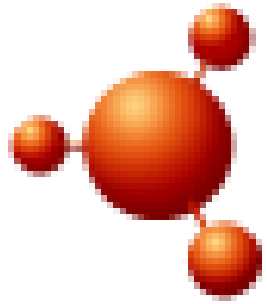
- EU revised definition of nanomaterials in 2022
- REACH
  - Updated guidance for NMs under REACH
  - Some chapters still undergoing revision (e.g R.11)
  - Specific hazard communication requirements for NM in SDS since 31.12.2022
    - Identification in sections 1, 3
- CLP
  - Nanomaterials are included, but no specific classification or labelling requirements (yet!)

Impact on other regulations

REACH Revision

- Will need to be updated to make it consistent with CLP
- New testing may be needed
  - Update to Annexes VII to X in progress
    - New CARACAL sub group formed to review information requirements
    - Increase use of NAMS to reduce reliance on animal tests
- Updates to IUCLID required

IUCLID



- IUCLID update spring 2024 to include new hazard classes
  - Optional to include once released
  - Mandatory to include in new REACH Registration dossiers, PPORDS, CLP Notifications, PCN Notifications, etc from end of relevant transition periods (including spontaneous update)

Other regulations

- Pesticides/biocides
  - already implemented (ED can't be approved unless negligible risk or essential)
- Cosmetics
  - ED not specifically mentioned, but many also CMR
  - May be targeted for Restriction
  - SCCS evaluation (risk rather than hazard based)

Other regulations

- Toys
  - Proposed revision of toy safety regulation included prohibiting use of ED
- Food packaging
  - Public consultation completed, proposed revision of FCM regulations (delayed to 2025?)
- Water quality
  - Not specifically mentioned but could become important criterion

What to do now

- The introduction of the new hazard classes will require a considerable effort for many companies. Planning for the implementation of them will help make the process go more smoothly.

- Make sure your plan includes the necessary resources to manage these additional obligations.

Start identifying raw materials and products that may be affected

- Check the Candidate List of SVHC to see if any of the substances you use are listed there as endocrine disruptors, PBT, vPvB, PMT or vPvM (you should already be aware of these!!)
- Check REACH dossiers for PBT/vPvB assessments
  - If not PBT/vPvB but meets the criteira for P, vP, T, consider if M, vM is a possibility

Check screening lists to see if a chemical may be of concern

N.B. just because a chemical is on such a list does not automatically mean it is a problem, but there should either be data available, or data will be being generated to help make assessments in future).

- Some useful lists include:
  - A list of PBT/vPvB assessments made under the previous EU chemicals legislation on the ECHA website at https://echa.europa.eu/information-on-chemicals/pbt-vpvb-assessments-under-the-previous-eu-chemicals-legislation and a list of substances undergoing assessment for endocrine disrupting properties at https://echa.europa.eu/ed-assessment
  - Endocrine Disruptor Lists (collaboration of some EU Member State national authorities) https://edlists.org/the-ed-lists

Check screening lists to see if a chemical may be of concern

- US EPA screening lists for endocrine disruptors https://www.epa.gov/endocrine-disruption
- US EPA PBT List https://www.epa.gov/toxics-release-inventory-tri-program/persistent-bioaccumulative-toxic-pbt-chemicals-covered-tri
- UN list of identified endocrine disruptors (included in this report) https://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=n
- Japan List of Suspected Endocrine Disruptors https://www.env.go.jp/en/chemi/ed/speed98/sp98t3.html
- CHEMSEC SIN List https://sinlist.chemsec.org/

Working with suppliers

- If you are a formulator, you will be dependent on receiving information on the new classifications of your raw materials from your suppliers. This could leave you with a very short timescale to implement the new rules, especially if you are producing mixture-in-mixture products.
- Talk to your suppliers to see how quickly they anticipate implementing the new classification and labelling criteria, and if there are any products that they expect will be affected.

Timing

- Consider how changes in classification may affect pre-printed label stocks, packaging, etc. and manage stocks accordingly.
- Although time will be given for implementation in EU, any ‘new’ information on hazards must be acted on ‘without delay’
- Although GB has not adopted, GB supply must also react to new information ‘without delay’

For substances

- Update C & L notifications if necessary
- Prepare to update REACH registrations
  - Contact the Lead Registrant if part of a joint submission to make sure this is in hand
- Prepare new or update existing labels if necessary
- Prepare new or update SDS if necessary
- New testing not needed for CLP
  - May be needed for other regulations to re-evaluate screening data showing concern

For mixtures

- Consider all components
- Prepare new or update existing labels if necessary
- Prepare new or update SDS if necessary
- Prepare new or update Poison Centre Notifications
- Remember limits for minor ingredients are typically 0.1%

Any questions?