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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ([1]), and in particular Article 53(1) thereof,

Whereas:

(1) Parts 2 to 5 of Annex I to Regulation (EC) No 1272/2008 contain harmonised criteria for the classification of substances, mixtures and certain articles in hazard classes and in differentiations of those hazard classes and set out provisions on how those criteria are to be met as well as the corresponding labelling requirements. Part 3 of Annex I to Regulation (EC) No 1272/2008 contains criteria on health hazards and Part 4 of that Annex contains criteria on environmental hazards.

(2) The European Green Deal ([2]) sets out the goal to better protect human health and the environment as part of an ambitious approach to tackle pollution from all sources and move towards a toxic-free environment.

(3) The need to establish a legally binding hazard identification of endocrine disruptors, based on the definition established by the World Health Organization in 2002 ([3]) and building on criteria already developed for plant protection products ([4]) and biocidal products ([5]), and to apply it across all Union legislation, is highlighted in the Commission's Communication 'Chemicals strategy for sustainability towards a toxic-free environment' ([6]). That Communication also points to the need to include new hazard classes and criteria in Regulation (EC) No 1272/2008 in order to fully address environmental toxicity, persistency, mobility and bioaccumulation.

(4) The Commission has conducted an impact assessment on the addition of new hazard classes and criteria in Regulation (EC) No 1272/2008, which encompassed an open public consultation, as well as a stakeholder consultation. The Commission has also consulted the European Chemicals Agency's expert group on persistent, bioaccumulative and toxic chemicals, the competent authorities for REACH and CLP (CARACAL), as well as the subgroup on endocrine disruptors of that expert group, on the new hazard classes and criteria for classification and labelling of substances and mixtures, and has taken into account their scientific advice.

([1]) OJ L 353, 31.12.2008, p. 1.

([2]) Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions – The European Green Deal (COM(2019) 640 final, 11 December 2019).

([3]) WHO/IPCS (World Health Organization/International Programme on Chemical Safety), 2002. Global assessment on the state of the science of endocrine disruptors (WHO/PCS/EDC/02.2), https://apps.who.int/iris/bitstream/handle/10665/67357/WHO_PCS_EDC_02.2.pdf.

([4]) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

([5]) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

([6]) Chemicals Strategy for Sustainability, COM(2020) 667 final.

(5) Based on experience and increased scientific knowledge gained in identifying substances as substances of very high concern due to their endocrine disrupting properties as well as in identifying substances as PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative), PMT (persistent, mobile, toxic) and vPvM (very persistent, very mobile) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([7]), it is necessary to adapt Regulation (EC) No 1272/2008 to technical and scientific progress by introducing new hazard classes and criteria. The scientific criteria against which available evidence for classification in those hazard classes are to be assessed should reflect the current state of the science.

(6) Substances and mixtures with endocrine disrupting properties pose a concern to public health and the environment. It has been proven that endocrine disruption can lead to certain disorders in humans, among others birth defects, developmental, reproductive or neurodevelopmental disorders, cancer, diabetes and obesity, and that those disorders have a high and increasing incidence in both children and adults. It has also been demonstrated that endocrine disrupting properties can negatively affect animal populations.

(7) Experience shows that substances and mixtures with PBT or vPvB properties represent a very high concern. They do not easily break down in the environment and tend to accumulate in living organisms across the food web. Accumulation of those substances in the environment is difficult to reverse, as their environmental concentration does not readily decrease by lowering their emissions, and the effects of this accumulation are often difficult to predict in the long-term. Moreover, certain PBT and vPvB substances which undergo long-range transport have the potential to contaminate remote pristine areas. Once those substances are released into the environment, exposure to them is difficult to reverse, which leads to cumulative exposure of both animals and humans via the environment.

(8) PMT and vPvM substances pose concerns as, due to their high persistence together with a high mobility that is a consequence of their low adsorption potential, they can enter the water cycle, including drinking water, and spread over long distances. Many PMT and vPvM substances are only partly removed by wastewater treatment processes and can even break through the most advanced purification processes at drinking water treatment facilities. Such incomplete removal coupled with new emissions mean that the concentration of those PMT and vPvM substances in the environment increase over time. Once released into the environment, exposure to PMT and vPvM substances is difficult to reverse, which leads to cumulative exposure of both animals and humans via the environment. Any effects from this exposure are unpredictable in the long-term.

(9) In light of the increased scientific knowledge and experience gained in identifying endocrine disruptors for human health and the environment as well as PBT, vPvB, PMT and vPvM substances and mixtures, it is appropriate to introduce hazard classes and labelling requirements for those substances and mixtures and the corresponding scientific criteria to identify them.

(10) The level of evidence as regards endocrine disrupting properties may be of different scientific strength. It is therefore appropriate to create two categories of endocrine disruptors: known or presumed endocrine disruptors (category 1) and suspected endocrine disruptors (category 2), both for human health and for the environment.

(11) When developing guidance on the application of the endocrine disruptor criteria, the European Chemicals Agency can benefit from the experience gained from the implementation of legislation on plant protection products and biocidal products and other scientific justifications, in order to provide guidelines that clarify which effects not leading to chronic outcomes for human health and the environment could fall outside the definition of 'adverse effect'.

([7]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(12) The intrinsic properties of PBT and vPvB substances and mixtures display similarities, but they differ substantially with regard to the toxicity criterion. It is therefore appropriate to create a new hazard class, with differentiation, while establishing common rules for the scientific assessment of the intrinsic properties related to persistency and bioaccumulation.

(13) The intrinsic properties of PMT and vPvM substances and mixtures display similarities, but they differ substantially with regard to the toxicity criterion. It is therefore appropriate to create a new hazard class, with differentiation, while establishing common rules for the scientific assessment of the intrinsic properties related to persistency and mobility.

(14) In order to allow for adequate classification of substances and mixtures as PBT and vPvB, whether or not registered under Regulation (EC) No 1907/2006, the existing criteria for identification of PBT and vPvB substances set out in Section 1 of Annex XIII to Regulation (EC) No 1907/2006 should be included in Regulation (EC) No 1272/2008. In this regard, any introduction of hazard categories for PBT and vPvB in Regulation (EC) No 1272/2008 would not be appropriate in view of the high level of scientific strength of the evidence required to fulfil the PBT and vPvB criteria – which mirror those so far laid down in Annex XIII to Regulation (EC) No 1907/2006. Moreover, the screening information laid down in that Annex, to be considered when screening for P, vP, B, vB and T properties, serves a different purpose than hazard identification and classification. In addition, the development of criteria for further hazard categories based on that screening information would lead to overclassification and significant overlaps with existing environmental classification. Therefore, it would not be appropriate to introduce additional hazard categories for PBT and vPvB in Regulation (EC) No 1272/2008.

(15) The classification criteria for M/vM relate, in particular, to the log K_{oc} (soil adsorption coefficient) value. The K_{oc} value is the organic carbon-water partition coefficient and reflects the ability of a substance to be adsorbed on the organic fraction of solid environmental compartments such as soil, sludge and sediment, and is therefore inversely related to the substances' potential of entering into ground water. It is therefore appropriate to assess the mobility criterion against the log K_{oc} value of a substance, a low K_{oc} implying a high mobility.

(16) Providing for new hazard classes entails introducing those classes with their name, their respective hazard statements and their respective hazard category codes. It is therefore necessary to include those hazard classes, hazard statements and category codes in Annexes I, III and VI to Regulation (EC) No 1272/2008. 'EUH statements' – (EU hazard statements) – should be included and they should function as 'H-statements'('main' hazard statements).

(17) Pictograms are an essential tool to communicate hazard information. They should be added to the hazard information on the new hazard classes, upon their adoption at the UNGHS in order to avoid interference with the use of the existing pictograms covering current hazards. In case new pictograms are created for these new hazard classes, they should be agreed at UNGHS first so that they can apply across the UNGHS members.

(18) To ensure that suppliers of substances and mixtures have time to adapt to the new classification and labelling requirements, provisions on deferred application of the obligation to classify and label substances and mixtures in accordance with this Regulation should be included in Annex I to Regulation (EC) No 1272/2008. That Annex should also provide for the possibility for substances and mixtures which are already placed on the market before the end of that deferral period, to continue being placed on the market without being classified and labelled in accordance with this Regulation, to avoid additional burden on suppliers of substances and mixtures.

(19) In line with the transitional provisions set out in Regulation (EC) No 1272/2008 which allow the application of the new provisions at an earlier stage on a voluntary basis, suppliers should have the possibility of applying the new classification and labelling provisions before the date of application of the obligations to classify and label substances and mixtures in accordance with this Regulation.

(20) Regulation (EC) No 1272/2008 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1272/2008 is amended as follows:

(1) Annex I is amended as set out in Annex I to this Regulation;

(2) Annex II is amended as set out in Annex II to this Regulation;

(3) Annex III is amended as set out in Annex III to this Regulation;

(4) Annex VI is amended as set out in Annex IV to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 December 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annex I to Regulation (EC) No 1272/2008 is amended as follows:

(1) in Part 3, the following Section 3.11 is added:

'3.11. **Endocrine disruption for human health**

3.11.1. ***Definitions and general considerations***

3.11.1.1. *Definitions*

For the purposes of Section 3.11, the following definitions shall apply:

(a) "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;

(b) "endocrine disruption" means the alteration of one or more functions of the endocrine system caused by an endocrine disruptor;

(c) "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;

(d) "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;

(e) "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.

3.11.1.2. *General considerations*

3.11.1.2.1. Substances and mixtures fulfilling the criteria of endocrine disruptors for human health based on evidence referred to in Table 3.11.1 shall be considered to be known, presumed or suspected endocrine disruptors for human health unless there is evidence conclusively demonstrating that the adverse effects are not relevant to humans.

3.11.1.2.2. Evidence that is to be considered for classification of substances in accordance with other Sections of this Annex may also be used for classification of substances as an endocrine disruptor for human health where the criteria provided in this Section are met.

3.11.2. ***Classification criteria for substances***

3.11.2.1. *Hazard categories*

For the purpose of classification for endocrine disruption for human health, substances shall be allocated to one of two categories.

Table 3.11.1.

Hazard categories for endocrine disruptors for human health

Categories	Criteria
CATEGORY 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.
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.

Where there is evidence conclusively demonstrating that the adverse effects are not relevant to humans, the substance shall not be considered an endocrine disruptor for human health.

3.11.2.2. *Basis of classification*

3.11.2.2.1. Classification shall be made on the basis of the criteria outlined above, and a weight of evidence determination of each of the criteria (see Section 3.11.2.3) and an overall weight of evidence determination (see Section 1.1.1). Classification as an endocrine disruptor for human health is intended to be used for substances which cause or may cause an endocrine-related adverse effect in humans.

3.11.2.2.2. Adverse effects that are solely non-specific consequences of other toxic effects shall not be considered for the identification of a substance as endocrine disruptor for human health.

3.11.2.3. *Weight of evidence and expert judgment*

3.11.2.3.1. Classification as an endocrine disruptor for human health is made on the basis of an assessment of the total weight of evidence using expert judgment (see Section 1.1.1). This means that all available information that bears on the determination of endocrine disruption for human health is considered together, such as:

(a) in vivo studies or other studies (e.g. in vitro, in silico studies) predictive of adverse effects, endocrine activity or biologically plausible link in humans or animals;

(b) data from analogue substances using structure-activity relationships (SAR);

(c) evaluation of substances chemically related to the substance under study may also be included (grouping, read-across), particularly when information on the substance is scarce;

(d) any additional relevant and acceptable scientific data.

3.11.2.3.2. In applying the weight of evidence determination and expert judgment, the assessment of the scientific evidence referred to in Section 3.11.2.3.1 shall, in particular, consider all of the following factors:

(a) both positive and negative results;

(b) the relevance of the study designs for the assessment of adverse effects and of the endocrine activity;

(c) the quality and consistency of the data, considering the pattern and coherence of the results within and between studies of a similar design and across different species;

(d) the route of exposure, toxicokinetic and metabolism studies;

(e) the concept of the limit dose (concentration), and international guidelines on maximum recommended doses (concentrations) and for assessing confounding effects of excessive toxicity.

3.11.2.3.3. Using a weight of evidence determination, the link between the endocrine activity and the adverse effects shall be established based on biological plausibility, which shall be determined in light of available scientific knowledge. The biologically plausible link does not need to be demonstrated with substance specific data.

3.11.2.3.4. Using a weight of evidence determination, evidence considered for the classification of a substance as an endocrine disruptor for the environment referred to in Section 4.2 shall be considered when assessing the classification of the substance as an endocrine disruptor for human health under Section 3.11.

3.11.2.4. *Application in time*

From 1 May 2025 at the latest, substances shall be classified in accordance with the criteria laid down in Sections 3.11.2.1 to 3.11.2.3.

However, substances which were placed on the market before 1 May 2025 are not required to be classified in accordance with the criteria laid down in Sections 3.11.2.1 to 3.11.2.3 until 1 November 2026.

3.11.3. ***Classification criteria for mixtures***

3.11.3.1. *Classification of mixtures where data are available for all components or only for some components of the mixture*

3.11.3.1.1. A mixture shall be classified as an endocrine disruptor for human health where at least one component has been classified as a Category 1 or Category 2 endocrine disruptor for human health and is present at or above the appropriate generic concentration limit as shown in Table 3.11.2 for Category 1 and Category 2, respectively.

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]

Note: The concentration limits in this Table shall apply to solids and liquids (w/w units) as well as gases (v/v units).

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.

3.11.3.2. *Classification of mixtures when data are available for the complete mixture*

3.11.3.2.1. Classification of mixtures shall be based on the available test data for the individual components of the mixture using concentration limits for the components classified as endocrine disruptor for human health. On a case-by-case basis, test data on the mixture as a whole may be used for classification when demonstrating endocrine disruption for human health that has not been established from the evaluation based on the individual components. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose (concentration) and other factors such as duration, observations, sensitivity and statistical analysis of the test systems. Adequate documentation supporting the classification shall be retained and made available for review upon request.

3.11.3.3. *Classification of mixtures where data are not available for the complete mixture: bridging principles*

3.11.3.3.1. Where the mixture itself has not been tested to determine its endocrine disruption for human health, but there are sufficient data on the individual components and similar tested mixtures (subject to paragraph 3.11.3.2.1) to adequately characterise the hazards of the mixture, those data shall be used in accordance with the applicable bridging principles set out in Section 1.1.3.

3.11.3.4. *Application in time*

From 1 May 2026 at the latest, mixtures shall be classified in accordance with the criteria laid down in Sections 3.11.3.1, 3.11.3.2 and 3.11.3.3.

However, mixtures which were placed on the market before 1 May 2026 are not required to be classified in accordance with the criteria laid down in Sections 3.11.3.1, 3.11.3.2 and 3.11.3.3 until 1 May 2028.

3.11.4. ***Hazard Communication***

3.11.4.1. Label elements shall be used in accordance with Table 3.11.3 for substances and mixtures meeting the criteria for classification in this hazard class (Endocrine disruption for human health).

Table 3.11.3.

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

3.11.4.2. *Application in time for substances*

From 1 May 2025 at the latest, substances shall be labelled in accordance with Section 3.11.4.1.

However, substances which were placed on the market before 1 May 2025 are not required to be labelled in accordance with Section 3.11.4.1 until 1 November 2026.

3.11.4.3. *Application in time for mixtures*

From 1 May 2026 at the latest, mixtures shall be labelled in accordance with Section 3.11.4.1.

However, mixtures which were placed on the market before 1 May 2026 are not required to be labelled in accordance with Section 3.11.4.1 until 1 May 2028.';

(2) in Part 4, the following Sections 4.2, 4.3 and 4.4 are added:

'4.2. **Endocrine disruption for the environment**

4.2.1. ***Definitions and general considerations***

4.2.1.1. *Definitions*

For the purposes of Section 4.2., the following definitions shall apply:

(a) "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;

(b) "endocrine disruption" means the alteration of one or more functions of the endocrine system caused by an endocrine disruptor;

(c) "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 mixture the potential to alter one or more functions of the endocrine system;

(d) "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;

(e) "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.

4.2.1.2. *General considerations*

4.2.1.2.1 Substances and mixtures fulfilling the criteria of endocrine disruptors for the environment based on evidence referred to in Table 4.2.1 shall be considered to be known, presumed or suspected endocrine disruptors for the environment unless there is evidence conclusively demonstrating that the adverse effects identified are not relevant at the population or subpopulation level.

4.2.1.2.2 Evidence that is to be considered for classification of substances in accordance with other Sections of this Annex may also be used for classification of substances as an endocrine disruptor for the environment where the criteria provided in this Section are met.

4.2.2 ***Classification criteria for substances***

4.2.2.1 *Hazard categories*

For the purpose of classification for endocrine disruption for the environment, substances shall be allocated to one of two categories.

Table 4.2.1.

Hazard categories for endocrine disruptors for the environment

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 biologically plausible link between the endocrine activity and the adverse effect.

Where there is evidence conclusively demonstrating that the adverse effects identified are not relevant at the population or subpopulation level, the substance shall not be considered an endocrine disruptor for the environment.

4.2.2.2. *Basis of classification*

4.2.2.2.1 Classification shall be made on the basis of the appropriate criteria outlined above, and a weight of evidence determination of each of the criteria (see Section 4.2.2.3) and an overall weight of evidence determination (see Section 1.1.1). Classification as an endocrine disruptor for the environment is intended to be used for substances which cause or may cause an endocrine-related adverse effect at population or subpopulation level.

4.2.2.2.2 Adverse effects that are solely non-specific consequences of other toxic effects shall not be considered for the identification of a substance as endocrine disruptor for the environment.

4.2.2.3. *Weight of evidence and expert judgment*

4.2.2.3.1. Classification as an endocrine disruptor for the environment is made on the basis of an assessment of the total weight of evidence using expert judgment (see Section 1.1.1). This means that all available information that bears on the determination of endocrine disruption for the environment is considered together, such as:

(a) in vivo studies or other studies (e.g. in vitro, in silico studies) predictive of adverse effects, endocrine activity or biologically plausible link in animals;

(b) data from analogue substances using structure-activity relationships (SAR),

(c) evaluation of substances chemically related to the substance under study may also be included (grouping, read-across), particularly when information on the substance is scarce;

(d) any additional relevant and acceptable scientific data.

4.2.2.3.2. In applying the weight of evidence determination and expert judgement, the assessment of the scientific evidence referred to in Section 4.2.2.3.1 shall, in particular, consider all of the following factors:

(a) both positive and negative results;

(b) the relevance of the study design for the assessment of adverse effects and its relevance at the population or subpopulation level, and for the assessment of the endocrine activity;

(c) the adverse effects on reproduction, growth/development, and other relevant adverse effects which are likely to impact on populations or subpopulations;

(d) the quality and consistency of the data, considering the pattern and coherence of the results within and between studies of a similar design and across different species;

(e) the route of exposure, toxicokinetic and metabolism studies;

(f) the concept of the limit dose (concentration), and international guidelines on maximum recommended doses (concentrations) and for assessing confounding effects of excessive toxicity;

(g) where available, adequate, reliable and representative field or monitoring data or results from population models.

4.2.2.3.3. Using a weight of evidence determination, the link between the endocrine activity and the adverse effects shall be established based on biological plausibility, which shall be determined in light of available scientific knowledge. The biologically plausible link does not need to be demonstrated with substance specific data.

4.2.2.3.4. Using a weight of evidence determination, evidence considered for the classification of a substance as an endocrine disruptor for human health referred to in Section 3.11 shall be considered when assessing the classification of the substance as an endocrine disruptor for the environment under Section 4.2.

4.2.2.4. *Application in time*

From 1 May 2025 at the latest, substances shall be classified in accordance with the criteria laid down in Sections 4.2.2.1 to 4.2.2.3.

However, substances which were placed on the market before 1 May 2025 are not required to be classified in accordance with the criteria laid down in Sections 4.2.2.1 to 4.2.2.3 until 1 November 2026.

4.2.3. ***Classification criteria for mixtures***

4.2.3.1. *Classification of mixtures where data are available for all components or only for some components of the mixture*

4.2.3.1.1. A mixture shall be classified as an endocrine disruptor for the environment where at least one component has been classified as a Category 1 or Category 2 endocrine disruptor for the environment and is present at or above the appropriate generic concentration limit as shown in Table 4.2.2 for Category 1 and Category 2, respectively.

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]

Note: The concentration limits in this Table apply to solids and liquids (w/w units) as well as gases (v/v units).

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.

4.2.3.2. *Classification of mixtures where data are available for the complete mixture*

4.2.3.2.1.

Classification of mixtures shall be based on the available test data for the individual components of the mixture using concentration limits for the components classified as endocrine disruptor for the environment. On a case-by-case basis, test data on the mixture as a whole may be used for classification when demonstrating endocrine disruption for the environment that has not been established from the evaluation based on the individual components. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose (concentration) and other factors such as duration, observations, sensitivity and statistical analysis of the test systems. Adequate documentation supporting the classification shall be retained and made available for review upon request.

4.2.3.3. *Classification of mixtures where data are not available for the complete mixture: bridging principles*

4.2.3.3.1. Where the mixture itself has not been tested to determine its endocrine disruption for the environment, but there are sufficient data on the individual components and similar tested mixtures (subject to paragraph 4.2.3.2.1) to adequately characterise the hazards of the mixture, those data shall be used in accordance with the applicable bridging principles set out in Section 1.1.3.

4.2.3.4. *Application in time*

From 1 May 2026 at the latest, mixtures shall be classified in accordance with the criteria laid down in Sections 4.2.3.1 to 4.2.3.3.

However, mixtures which were placed on the market before 1 May 2026 are not required to be classified in accordance with the criteria laid down in Sections 4.2.3.1, 4.2.3.2 and 4.2.3.3 until 1 May 2028.

4.2.4. ***Hazard Communication***

4.2.4.1. Label elements shall be used in accordance with Table 4.2.3 for substances and mixtures meeting the criteria for classification in this hazard class (Endocrine disruption for the environment).

Table 4.2.3.

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

4.2.4.2. *Application in time for substances*

From 1 May 2025 at the latest, substances shall be labelled in accordance with Section 4.2.4.1.

However, substances which were placed on the market before 1 May 2025 are not required to be labelled in accordance with Section 4.2.4.1 until 1 November 2026.

4.2.4.3. *Application in time for mixtures*

From 1 May 2026 at the latest, mixtures shall be labelled in accordance with Section 4.2.4.1.

However, mixtures which were placed on the market before 1 May 2026 are not required to be labelled in accordance with Section 4.2.4.1 until 1 May 2028.

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

4.3.1. *Definitions and general considerations*

4.3.1.1. For the purposes of Section 4.3 the following definitions shall apply:

"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.

4.3.1.2. The hazard class Persistent, Bioaccumulative and Toxic or Very Persistent, Very Bioaccumulative properties is differentiated into:

— PBT properties and,

— vPvB properties.

4.3.2. *Classification criteria for substances*

4.3.2.1. *Classification criteria for PBT*

A substance shall be considered a PBT substance when it fulfils the persistence, bioaccumulation and toxicity criteria set out in Sections 4.3.2.1.1 to 4.3.2.1.3 and assessed according to Section 4.3.2.3.

4.3.2.1.1. *Persistence*

A substance shall be considered to fulfil the persistence criterion (P) where any of the following conditions is met:

(a) the degradation half-life in marine water is higher than 60 days;

(b) the degradation half-life in fresh or estuarine water is higher than 40 days;

(c) the degradation half-life in marine sediment is higher than 180 days;

(d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days;

(e) the degradation half-life in soil is higher than 120 days.

4.3.2.1.2. *Bioaccumulation*

A substance shall be considered to fulfil the bioaccumulation criterion (B) where the bioconcentration factor in aquatic species is higher than 2 000.

4.3.2.1.3. *Toxicity*

A substance shall be considered to fulfil the toxicity criterion (T) in any of the following situations:

(a) the long-term no-observed effect concentration (NOEC) or ECx (e.g. EC10) for marine or freshwater organisms is less than 0,01 mg/l;

(b) the substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2) according to Sections 3.5, 3.6 or 3.7;

(c) there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Section 3.9;

(d) the substance meets the criteria for classification as endocrine disruptor (category 1) for humans or the environment according to Sections 3.11 or 4.2.

4.3.2.2. *Classification criteria for vPvB*

A substance shall be considered a vPvB substance when it fulfils the persistence and bioaccumulation criteria set out in Sections 4.3.2.2.1 and 4.3.2.2.2 and assessed according to Section 4.3.2.3.

4.3.2.2.1. Persistence

A substance shall be considered to fulfil the "very persistent" criterion (vP) where any of the following conditions is met:

(a) the degradation half-life in marine, fresh or estuarine water is higher than 60 days;

(b) the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days;

(c) the degradation half-life in soil is higher than 180 days.

4.3.2.2.2. *Bioaccumulation*

A substance shall be considered to fulfil the "very bioaccumulative" criterion (vB) where the bioconcentration factor in aquatic species is higher than 5 000.

4.3.2.3. *Basis of classification*

For the classification of PBT substances and vPvB substances, a weight of evidence determination using expert judgement shall be applied, by comparing all relevant and available information listed in Section 4.3.2.3 with the criteria set out in Sections 4.3.2.1 and 4.3.2.2. That weight of evidence shall be applied in particular where the criteria set out in Sections 4.3.2.1 and 4.3.2.2 cannot be applied directly to the available information.

The information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions.

The identification shall also take account of the PBT/vPvB properties of relevant constituents, additives or impurities of a substance and relevant transformation or degradation products.

This hazard class (Persistent, Bioaccumulative and Toxic (PBT) or Very Persistent, Very Bioaccumulative (vPvB) properties) shall apply to all organic substances, including organo-metals.

The information set out in Sections 4.3.2.3.1, 4.3.2.3.2 and 4.3.2.3.3 shall be considered for the assessment of P, vP, B, vB and T properties.

4.3.2.3.1. *Assessment of P or vP properties*

The following information shall be considered for the assessment of P or vP properties:

(a) results from simulation testing on degradation in surface water;

(b) results from simulation testing on degradation in soil;

(c) results from simulation testing on degradation in sediment;

(d) other information, such as information from field studies or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.

4.3.2.3.2. *Assessment of B or vB properties*

The following information shall be considered for the assessment of B or vB properties:

(a) results from a bioconcentration or bioaccumulation study in aquatic species;

(b) other information on the bioaccumulation potential, provided that its suitability and reliability can be reasonably demonstrated, such as:

(i) results from a bioaccumulation study in terrestrial species;

(ii) data from scientific analysis of human body fluids or tissues, such as blood, milk or fat;

(iii) detection of elevated levels in biota, in particular in endangered species or in vulnerable populations or subpopulations, compared to levels in their surrounding environment;

(iv) results from a chronic toxicity study on animals;

(v) assessment of the toxicokinetic behaviour of the substance.

(c) information on the ability of the substance to biomagnify in the food chain, where possible expressed by biomagnification factors or trophic magnification factors.

4.3.2.3.3. *Assessment of T properties*

The following information shall be considered for the assessment of T properties:

(a) results from long-term toxicity testing on aquatic invertebrates;

(b) results from long-term toxicity testing on fish;

(c) results from growth inhibition study on algae or aquatic plants;

(d) the substance meeting the criteria for classification as carcinogenic in Category 1A or 1B (assigned hazard statements: H350 or H350i), germ cell mutagenic in Category 1A or 1B (assigned hazard statement: H340), toxic for reproduction in Category 1A, 1B or 2 (assigned hazard statements: H360, H360F, H360D, H360FD, H360Fd, H360fD, H361, H361f, H361d or H361fd), specific target organ toxic after repeated dose in Category 1 or 2 (assigned hazard statements: H372 or H373);

(e) the substance meeting the criteria for classification as endocrine disruptor (Category 1) for human health or the environment (assigned hazard statements: EUH380 or EUH430);

(f) results from long-term toxicity testing on terrestrial organisms; invertebrates and plants;

(g) results from long-term toxicity testing on sediment organisms;

(h) results from long-term or reproductive toxicity testing with birds;

(i) other information, provided that its suitability and reliability can be reasonably demonstrated.

4.3.2.4. *Weight of evidence and expert judgment*

4.3.2.4.1. In applying the weight of evidence determination using expert judgment as referred to in Section 1.1.1 all available relevant scientific data shall be considered together, such as:

(a) in vivo studies or other studies (e.g. in vitro, in silico studies);

(b) information from the application of the category approach (grouping, read-across);

(c) data from analogue substances using structure-activity relationships (SAR), informing about P, vP, B, vB and T properties;

(d) results of monitoring and modelling;

(e) human experience such as occupational data and data from accident databases;

(f) epidemiological and clinical studies;

(g) well documented case reports, peer-reviewed published studies and observations;

(h) any additional acceptable data.

The quality and consistency of the data shall be given appropriate weight. The available results regardless of their individual conclusions shall be assembled together in a single weight of evidence determination.

4.3.2.4.2. In applying the weight of evidence determination, the following information, in addition to the information referred to in Sections 4.3.2.3.1, 4.3.2.3.2 and 4.3.2.3.3, shall be considered as part of the scientific assessment of the information relevant for the P, vP, B, vB and T properties:

(a) Indication of P or vP properties:

(i) Results from tests on ready biodegradation;

(ii) Results from other degradation screening tests (e.g. enhanced ready test, tests on inherent biodegradability);

(iii) Results obtained from well-developed and reliable biodegradation (Q)SAR models;

(iv) Other information provided that its suitability and reliability can be reasonably demonstrated.

(b) Indication of B or vB properties:

(i) Octanol-water partitioning coefficient experimentally determined or estimated by well-developed and reliable (Q)SAR models;

(ii) Other information provided that its suitability and reliability can be reasonably demonstrated.

(c) Indication of T properties:

(i) Short-term aquatic toxicity (e.g. results from acute toxicity testing on invertebrates, algae or aquatic plants or fish, in vitro acute toxicity testing on fish cell line);

(ii) Other information provided that its suitability and reliability can be reasonably demonstrated.

4.3.2.5. *Application in time*

From 1 May 2025 at the latest, substances shall be classified in accordance with the criteria laid down in Sections 4.3.2.1 to 4.3.2.4.

However, substances which were placed on the market before 1 May 2025 are not required to be classified in accordance with the criteria laid down in Sections 4.3.2.1 to 4.3.2.4 until 1 November 2026.

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).

4.3.3.2. *Application in time*

From 1 May 2026 at the latest, mixtures shall be classified in accordance with the criteria laid down in Section 4.3.3.1.

However, mixtures which were placed on the market before 1 May 2026 are not required to be classified in accordance with the criteria laid down in Section 4.3.3.1 until 1 May 2028.

4.3.4. ***Hazard communication***

4.3.4.1. Label elements shall be used in accordance with Table 4.3.1 for substances or mixtures meeting the criteria for classification in this hazard class.

Table 4.3.1.

Label elements for PBT and vPvB properties

	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

4.3.4.2. *Application in time for substances*

From 1 May 2025 at the latest, substances shall be labelled in accordance with Section 4.3.4.1.

However, substances which were placed on the market before 1 May 2025 are not required to be labelled in accordance with Section 4.3.4.1 until 1 November 2026.

4.3.4.3. *Application in time for mixtures*

From 1 May 2026 at the latest, mixtures shall be labelled in accordance with the provisions laid down in Section 4.3.4.1.

However, mixtures which were placed on the market before 1 May 2026 are not required to be labelled in accordance with Section 4.3.4.1 until 1 May 2028.

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

4.4.1. *Definitions and general considerations*

4.4.1.1. For the purposes of Section 4.4 the following definitions shall apply:

"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.

"log K_{oc}" means the common logarithm of the organic carbon-water partition coefficient (i.e. K_{oc}).

4.4.1.2 The hazard class Persistent, Mobile and Toxic or Very Persistent, Very Mobile properties is differentiated into:

— PMT properties and,

— vPvM properties.

4.4.2. *Classification criteria for substances*

4.4.2.1. *Classification criteria for PMT*

A substance shall be considered a PMT substance when it fulfils the persistence, mobility and toxicity criteria set out in Sections 4.4.2.1.1, 4.4.2.1.2 and 4.4.2.1.3. and assessed according to Section 4.4.2.3.

4.4.2.1.1. *Persistence*

A substance shall be considered to fulfil the persistence criterion (P) in any of the following situations:

(a) the degradation half-life in marine water is higher than 60 days;

(b) the degradation half-life in fresh or estuarine water is higher than 40 days;

(c) the degradation half-life in marine sediment is higher than 180 days;

(d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days;

(e) the degradation half-life in soil is higher than 120 days.

4.4.2.1.2. *Mobility*

A substance shall be considered to fulfil the mobility criterion (M) when the log K_{oc} is less than 3. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest log K_{oc} value for pH between 4 and 9 is less than 3.

4.4.2.1.3. *Toxicity*

A substance shall be considered to fulfil the toxicity criterion (T) in any of the following situations:

(a) the long-term no-observed effect concentration (NOEC) or ECx (e.g. EC10) for marine or freshwater organisms is less than 0,01 mg/l;

(b) the substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2) according to Sections 3.5, 3.6 or 3.7;

(c) there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification as specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Section 3.9;

(d) the substance meets the criteria for classification as endocrine disruptor (category 1) for human health or the environment according to Sections 3.11 or 4.2.

4.4.2.2. *Classification criteria for vPvM*

A substance shall be considered a vPvM substance when it fulfils the persistence and mobility criteria set out in Sections 4.4.2.2.1 and 4.4.2.2.2 and assessed according to Section 4.4.2.3.

4.4.2.2.1. *Persistence*

A substance shall be considered to fulfil the "very persistent" criterion (vP) in any of the following situations:

(a) the degradation half-life in marine, fresh or estuarine water is higher than 60 days;

(b) the degradation half-life in marine, fresh or estuarine water sediment is higher than 180 days;

(c) the degradation half-life in soil is higher than 180 days.

4.4.2.2.2. *Mobility*

A substance shall be considered to fulfil the "very mobile" criterion (vM) when the log K_{oc} is less than 2. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest log K_{oc} value for pH between 4 and 9 is less than 2.

4.4.2.3. *Basis of classification*

For the classification of PMT substances and vPvM substances, a weight of evidence determination using expert judgment shall be applied, by comparing all relevant and available information listed in Section 4.4.2.3 with the criteria set out in Sections 4.4.2.1 and 4.4.2.2. That weight of evidence shall be applied in particular where the criteria set out in Sections 4.4.2.1 and 4.4.2.2 cannot be applied directly to the available information.

The information used for the purposes of assessment of the PMT/vPvM properties shall be based on data obtained under relevant conditions.

The identification shall also take account of the PMT/vPvM properties of relevant constituents, additives or impurities of a substance and relevant transformation or degradation products.

This hazard class (PMT and vPvM properties) shall apply to all organic substances, including organo-metals.

The information set out in Sections 4.4.2.3.1, 4.4.2.3.2 and 4.4.2.3.3 shall be considered for the assessment of P, vP, M, vM and T properties.

4.4.2.3.1. *Assessment of P or vP properties*

The following information shall be considered for the assessment of P or vP properties:

(a) results from simulation testing on degradation in surface water;

(b) results from simulation testing on degradation in soil;

(c) results from simulation testing on degradation in sediment;

(d) other information, such as information from field studies or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.

4.4.2.3.2. *Assessment of M or vM properties*

The following information shall be considered for the assessment of M or vM properties:

(a) results from adsorption/desorption testing;

(b) other information, such as information from leaching, modelling or monitoring studies, provided that its suitability and reliability can be reasonably demonstrated.

4.4.2.3.3. *Assessment of T properties*

The following information shall be considered for the assessment of T properties:

(a) results from long-term toxicity testing on aquatic invertebrates;

(b) results from long-term toxicity testing on fish;

(c) results from growth inhibition study on algae or aquatic plants;

(d) the substance meeting the criteria for classification as carcinogenic in Category 1A or 1B (assigned hazard statements: H350 or H350i), germ cell mutagenic in Category 1A or 1B (assigned hazard statement: H340), toxic for reproduction in Category 1A, 1B or 2 (assigned hazard statements: H360, H360F, H360D, H360FD, H360Fd, H360fD, H361, H361f, H361d or H361fd), specific target organ toxic after repeated dose in Category 1 or 2 (assigned hazard statements: H372 or H373);

(e) the substance meeting the criteria for classification as endocrine disruptor (Category 1) for human health or the environment (assigned hazard statements: EUH380 or EUH430);

(f) results from long-term toxicity testing on terrestrial organisms; invertebrates and plants;

(g) results from long-term toxicity testing on sediment organisms;

(h) results from long-term or reproductive toxicity testing on birds;

(i) other information provided that its suitability and reliability can be reasonably demonstrated.

4.4.2.4. *Weight of evidence and expert judgment*

4.4.2.4.1. In applying the weight of evidence determination using expert judgment as referred to in Section 1.1.1, all available relevant scientific data shall be considered together, such as:

(a) in vivo studies or other studies (e.g. in vitro, in silico studies);

(b) information from the application of the category approach (grouping, read-across);

(c) data from analogue substances using structure-activity relationships (SAR), informing about P, vP, M, vM and T properties;

(d) results of monitoring and modelling;

(e) human experience such as occupational data and data from accident databases;

(f) epidemiological and clinical studies;

(g) well documented case reports, peer-reviewed published studies and observations;

(h) any additional acceptable data.

The quality and consistency of the data shall be given appropriate weight. The available results regardless of their individual conclusions shall be assembled together in a single weight of evidence determination.

4.4.2.4.2. In applying the weight of evidence determination, the following information, in addition to the information referred to in Sections 4.4.2.3.1, 4.4.2.3.2 and 4.4.2.3.3 shall be considered as part of the scientific assessment of the information relevant for the P, vP, M, vM and T properties:

(a) Indication of P or vP properties:

(i) Results from tests on ready biodegradation;

(ii) Results from other degradation screening tests (e.g. enhanced ready test, tests on inherent biodegradability);

(iii) Results obtained from well-developed and reliable biodegradation (Q)SAR models;

(iv) Other information, provided that its suitability and reliability can be reasonably demonstrated.

(b) Information relevant for the M or vM properties:

(i) Organic carbon to water partition coefficient (K_{oc}) estimated by well-developed and reliable (Q)SAR models;

(ii) Other information, provided that its suitability and reliability can be reasonably demonstrated.

(c) Information relevant for the T properties:

(i) Short-term aquatic toxicity (e.g. results from acute toxicity testing on invertebrates, algae or aquatic plants or fish, in vitro acute toxicity testing on fish cell line);

(ii) Other information provided that its suitability and reliability can be reasonably demonstrated.

4.4.2.5. *Application in time*

From 1 May 2025 at the latest, substances shall be classified in accordance with the criteria laid down in Sections 4.4.2.1 to 4.4.2.4.

However, substances which were placed on the market before 1 May 2025 are not required to be classified in accordance with the criteria laid down in Sections 4.4.2.1 to 4.4.2.4 until 1 November 2026.

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).

4.4.3.2 *Application in time*

From 1 May 2026 at the latest, mixtures shall be classified in accordance with the criteria laid down in Section 4.4.3.1.

However, mixtures which were placed on the market before 1 May 2026 are not required to be classified in accordance with the criteria laid down in Section 4.4.3.1 until 1 May 2028.

4.4.4. ***Hazard communication***

4.4.4.1. Label elements shall be used in accordance with Table 4.4.1 for substances or mixtures meeting the criteria for classification in this hazard class (PMT and vPvM properties).

Table 4.4.1.

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

4.4.4.2. *Application in time for substances*

From 1 May 2025 at the latest, substances shall be labelled in accordance with Section 4.4.4.1.

However, substances which were placed on the market before 1 May 2025 are not required to be labelled in accordance with Section 4.4.4.1 until 1 November 2026.

4.4.4.3. *Application in time for mixtures*

From 1 May 2026 at the latest, mixtures shall be labelled in accordance with Section 4.4.4.1.

However, mixtures which were placed on the market before 1 May 2026 are not required to be labelled in accordance with Section 4.4.4.1 until 1 May 2028.'

ANNEX II

In Part 2, Section 2.10, first paragraph, of Annex II to Regulation (EC) No 1272/2008

the following indent is added:

‘— ≥ 0,1 % of a substance classified as endocrine disruptor for human health category 2; or

— ≥ 0,1 % of a substance classified as endocrine disruptor for the environment category 2.’

ANNEX III

Part 1 of Annex III to Regulation (EC) No 1272/2008 is amended as follows:

(1) the following points (c) and (d) are added:

'(c) if the hazard statement 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;

(d) if the hazard statement 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.'

(2) in Table 1.2, the following rows are added:

'EUH 380	Language	
	BG	Може да причини нарушение на функциите на ендокринната система при хора
	ES	Puede provocar alteración endocrina en los seres humanos
	CS	Může způsobit narušení činnosti endokrinního systému u lidí.
	DA	Kan forårsage hormonforstyrrelse hos mennesker
	DE	Kann beim Menschen endokrine Störungen verursachen
	ET	Võib põhjustada inimesel endokriinseid häireid
	EL	Μπορεί να προκαλέσει ενδοκρινική διαταραχή στον άνθρωπο
	EN	May cause endocrine disruption in humans
	FR	Peut provoquer une perturbation endocrinienne chez l'être humain
	GA	D'fhéadfadh sé a bheith ina chúis le suaitheadh inchríneach sa duine
	HR	Može uzrokovati endokrinu disrupciju u ljudi
	IT	Può interferire con il sistema endocrino negli esseri umani
	LV	Var izraisīt endokrīnu disrupciju cilvēka organismā
	LT	Gali ardyti žmonių endokrininę sistemą
	HU	Endokrin károsító hatású lehet az embereknél
	MT	Jistgħu jikkawżaw tfixkil fis-sistema endokrinali fil-bnedmin
	NL	Kan hormoonontregeling bij de mens veroorzaken
	PL	Może powodować zaburzenia funkcjonowania układu hormonalnego u ludzi
	PT	Pode causar desregulação endócrina nos seres humanos
	RO	Poate cauza dereglări endocrine la oameni
	SK	Môže spôsobiť endokrinnú disrupciu u ľudí
	SL	Lahko povzroči endokrine motnje pri ljudeh.
	FI	Saattaa aiheuttaa hormonitoiminnan häiriöitä ihmisissä
	SV	Kan orsaka hormonstörningar hos människor

EUH 381	Language	
	BG	Вероятно причинява нарушение на функциите на ендокринната система при хора
	ES	Se sospecha que provoca alteración endocrina en los seres humanos
	CS	Podezření, že vyvolává narušení činnosti endokrinního systému u lidí.
	DA	Mistænkt for at forårsage hormonforstyrrelse hos mennesker
	DE	Steht in dem Verdacht, beim Menschen endokrine Störungen zu verursachen
	ET	Arvatavasti põhjustab inimesel endokriinseid häireid
	EL	Ύποπτο για πρόκληση ενδοκρινικής διαταραχής στον άνθρωπο
	EN	Suspected of causing endocrine disruption in humans
	FR	Susceptible de provoquer une perturbation endocrinienne chez l'être humain
	GA	Ceaptar go bhfuil sé ina chúis le suaitheadh inchríneach sa duine
	HR	Sumnja se da uzrokuje endokrinu disrupciju u ljudi
	IT	Sospettato di interferire con il sistema endocrino negli esseri umani
	LV	Domājams, ka var izraisīt endokrīnu disrupciju cilvēka organismā
	LT	Įtariama, kad ardo žmonių endokrininę sistemą
	HU	Feltételezhetően endokrin zavart okozhat az embereknél
	MT	Suspettati li jikkawżaw tfixkil fis-sistema endokrinali fil-bnedmin
	NL	Wordt ervan verdacht hormoonontregeling bij de mens te veroorzaken
	PL	Podejrzewa się, że powoduje zaburzenia funkcjonowania układu hormonalnego u ludzi
	PT	Suspeito de causar desregulação endócrina nos seres humanos
	RO	Suspectată că ar cauza dereglări endocrine la oameni
	SK	Podozrenie, že spôsobuje endokrinnú disrupciu u ľudí
	SL	Domnevno povzroča endokrine motnje pri ljudeh.
	FI	Epäillään aiheuttavan hormonitoiminnan häiriöitä ihmisissä
	SV	Misstänks orsaka hormonstörningar hos människor'

(3) in Table 1.3, the following rows are added:

'EUH 430	Language	
	BG	Може да причини нарушение на функциите на ендокринната система в околната среда
	ES	Puede provocar alteración endocrina en el medio ambiente
	CS	Může způsobit narušení činnosti endokrinního systému v životním prostředí.
	DA	Kan forårsage hormonforstyrrelse hos miljøet
	DE	Kann endokrine Störungen in der Umwelt verursachen
	ET	võib põhjustada endokriinseid häireid keskkonnas
	EL	Μπορεί να προκαλέσει ενδοκρινική διαταραχή στο περιβάλλον
	EN	May cause endocrine disruption in the environment
	FR	Peut provoquer une perturbation endocrinienne dans l'environnement
	GA	D'fhéadfadh sé a bheith ina chúis le suaitheadh inchríneach sa chomhshaol
	HR	Može uzrokovati endokrinu disrupciju u okolišu
	IT	Può interferire con il sistema endocrino nell'ambiente
	LV	Var izraisīt endokrīnu disrupciju vidē
	LT	Būdama aplinkoje gali ardyti endokrininę sistemą
	HU	Endokrin károsító hatású lehet a környezetben
	MT	Jistgħu jikkawżaw tfixkil fis-sistema endokrinali fl-ambjent
	NL	Kan hormoonontregeling in het milieu veroorzaken
	PL	Może powodować zaburzenia funkcjonowania układu hormonalnego w środowisku
	PT	Pode causar desregulação endócrina no ambiente
	RO	Poate cauza perturbări endocrine la nivelul mediului
	SK	Môže spôsobiť endokrinnú disrupciu v životnom prostredí
	SL	Lahko povzroči endokrine motnje v okolju.
	FI	Saattaa aiheuttaa hormonitoiminnan häiriöitä ympäristössä
	SV	Kan orsaka hormonstörningar i miljön

EUH 431	Language	
	BG	Вероятно причинява нарушение на функциите на ендокринната система в околната среда
	ES	Se sospecha que provoca alteración endocrina en el medio ambiente
	CS	Podezření, že vyvolává narušení činnosti endokrinního systému v životním prostředí.
	DA	Mistænkt for at forårsage hormonforstyrrelse hos miljøet
	DE	Steht in dem Verdacht, endokrine Störungen in der Umwelt zu verursachen
	ET	Arvatavasti põhjustab endokriinseid häireid keskkonnas
	EL	Ύποπτο για πρόκληση ενδοκρινικής διαταραχής στο περιβάλλον
	EN	Suspected of causing endocrine disruption in the environment
	FR	Susceptible de provoquer une perturbation endocrinienne dans l'environnement
	GA	Ceaptar go bhfuil sé ina chúis le suaitheadh inchríneach sa chomhshaol
	HR	Sumnja se da uzrokuje endokrinu disrupciju u okolišu
	IT	Sospettato di interferire con il sistema endocrino nell'ambiente
	LV	Domājams, ka var izraisīt endokrīnu disrupciju vidē
	LT	Įtariama, kad būdama aplinkoje ardo endokrininę sistemą
	HU	Feltételezhetően endokrin zavart okozhat a környezetben
	MT	Suspettati li jikkawżaw tfixkil fis-sistema endokrinali fl-ambjent
	NL	Wordt ervan verdacht hormoonontregeling in het milieu te veroorzaken
	PL	Podejrzewa się, że powoduje zaburzenia funkcjonowania układu hormonalnego w środowisku
	PT	Suspeito de causar desregulação endócrina no ambiente
	RO	Suspectată că ar cauza perturbări endocrine la nivelul mediului
	SK	Podozrenie, že spôsobuje endokrinnú disrupciu v životnom prostredí
	SL	Domnevno povzroča endokrine motnje v okolju.
	FI	Epäillään aiheuttavan hormonitoiminnan häiriöitä ympäristössä
	SV	Misstänks orsaka hormonstörningar i miljön

EUH 440	Language	
	BG	Натрупва се в околната среда и в живите организми, включително в човешкия организъм
	ES	Se acumula en el medio ambiente y en los organismos vivos, incluidos los humanos
	CS	Hromadí se v životním prostředí a živých organismech včetně člověka
	DA	Ophobes i miljøet og levende organismer, herunder i mennesker
	DE	Anreicherung in der Umwelt und in lebenden Organismen einschließlich Menschen
	ET	Akumuleerub keskkonnas ja elusorganismides, sealhulgas inimestes
	EL	Συσσωρεύεται στο περιβάλλον και σε ζωντανούς οργανισμούς, συμπεριλαμβανομένου του ανθρώπου
	EN	Accumulates in the environment and living organisms including in humans
	FR	S'accumule dans l'environnement et dans les organismes vivants, y compris chez l'être humain
	GA	Carnann in orgánaigh bheo lena n-áirítear sa duine agus bíonn éifeachtaí fadtéarmacha acu
	HR	Nakuplja se u okolišu i živim organizmima, uključujući ljude
	IT	Si accumula nell'ambiente e negli organismi viventi, compresi gli esseri umani
	LV	Uzkrājas vidē un dzīvos organismos, tai skaitā cilvēka organismā
	LT	Kaupiasi aplinkoje ir gyvuose organizmuose, įskaitant žmones
	HU	Felhalmozódik a környezetben és az élő szervezetekben, beleértve az embereket is
	MT	Jakkumulaw fl-ambjent u fl-organiżmi ħajjin inkluż fil-bnedmin
	NL	Accumulatie in het milieu en levende organismen, met inbegrip van mensen
	PL	Akumuluje się w środowisku i organizmach żywych, w tym u ludzi
	PT	Acumula-se no ambiente e nos organismos vivos, inclusive no ser humano
	RO	Se acumulează în mediu și în organismele vii, inclusiv la oameni
	SK	Akumuluje sa v životnom prostredí a živých organizmoch vrátane ľudí
	SL	Se kopiči v okolju in živih organizmih, tudi v ljudeh.
	FI	Kertyy ympäristöön ja eläviin eliöihin, myös ihmisiin
	SV	Ackumuleras i miljön och i levande organismer, inbegripet människor.

EUH 441	Language	
	BG	Натрупва се в значителни количества в околната среда и в живите организми, включително в човешкия организъм
	ES	Acumulación elevada en el medio ambiente y en los organismos vivos, incluidos los humanos
	CS	Silně se hromadí v životním prostředí a živých organismech včetně člověka
	DA	Ophobes i høj grad i miljøet og levende organismer, herunder i mennesker
	DE	Starke Anreicherung in der Umwelt und in lebenden Organismen einschließlich Menschen
	ET	Akumuleerub rohkelt keskkonnas ja elusorganismides, sealhulgas inimestes
	EL	Συσσωρεύεται έντονα στο περιβάλλον και σε ζωντανούς οργανισμούς, συμπεριλαμβανομένου του ανθρώπου
	EN	Strongly accumulates in the environment and living organisms including in humans
	FR	S'accumule fortement dans l'environnement et dans les organismes vivants, y compris chez l'être humain
	GA	Carnann go mór in orgánaigh bheo lena n-áirítear sa duine agus d'fhéadfadh éifeachtaí fadtéarmacha a bheith acu
	HR	U velikoj se mjeri nakuplja u okolišu i živim organizmima, uključujući ljude
	IT	Si accumula notevolmente nell'ambiente e negli organismi viventi, compresi gli esseri umani
	LV	Izteikti uzkrājas vidē un dzīvos organismos, tai skaitā cilvēka organismā
	LT	Gausiai kaupiasi aplinkoje ir gyvuose organizmuose, įskaitant žmones
	HU	Nagymértékben felhalmozódik a környezetben és az élő szervezetekben, beleértve az embereket is
	MT	Jakkumulaw ħafna fl-ambjent u fl-organiżmi ħajjin inkluż fil-bnedmin
	NL	Sterke accumulatie in het milieu en levende organismen, met inbegrip van mensen
	PL	W znacznym stopniu akumuluje się w środowisku i organizmach żywych, w tym u ludzi
	PT	Acumula-se fortemente no ambiente e nos organismos vivos, inclusive no ser humano
	RO	Se acumulează puternic în mediu și în organismele vii, inclusiv la oameni
	SK	Výrazne sa akumuluje v životnom prostredí a živých organizmoch vrátane ľudí

EUH 441	Language	
	SL	Se močno kopiči v okolju in živih organizmih, tudi v ljudeh.
	FI	Kertyy voimakkaasti ympäristöön ja eläviin eliöihin, myös ihmisiin
	SV	Ackumuleras kraftigt i miljön och i levande organismer, inbegripet människor.

EUH 450	Language	
	BG	Може да причини дълготрайно и дифузно замърсяване на водните ресурси
	ES	Puede ser causa de una contaminación difusa y duradera de los recursos hídricos
	CS	Může způsobit dlouhodobé a difúzní znečištění vodních zdrojů
	DA	Kan forårsage langvarig og diffus forurening af vandressourcer
	DE	Kann lang anhaltende und diffuse Verschmutzung von Wasserressourcen verursachen
	ET	Võib põhjustada veevarude pikaajalist ja hajusat saastumist
	EL	Μπορεί να προκαλέσει μακροχρόνια και διάχυτη μόλυνση υδάτινων πόρων
	EN	Can cause long-lasting and diffuse contamination of water resources
	FR	Peut provoquer une contamination diffuse à long terme des ressources en eau
	GA	Substaint mharthanach ar féidir léi acmhainní uisce a thruailliú
	HR	Može uzrokovati dugotrajno i raspršeno onečišćenje vodnih resursa
	IT	Può provocare la contaminazione duratura e diffusa delle risorse idriche
	LV	Var izraisīt ilgstošu un difūzu ūdens resursu kontamināciju
	LT	Gali sukelti ilgalaikę ir pasklidąją vandens išteklių taršą
	HU	Tartós, diffúz szennyezést okozhat a vízkészletekben
	MT	Jistgħu jikkawżaw kontaminazzjoni dejjiema u diffuża tar-riżorsi tal-ilma
	NL	Kan langdurige en diffuse verontreiniging van watervoorraden veroorzaken
	PL	Może powodować długotrwałe i rozproszone zanieczyszczenie zasobów wodnych
	PT	Pode causar uma contaminação prolongada e difusa dos recursos hídricos
	RO	Poate cauza contaminarea difuză și de lungă durată a resurselor de apă

EUH 450	Language	
	SK	Môže spôsobiť dlhotrvajúcu a difúznu kontamináciu vodných zdrojov
	SL	Lahko povzroči dolgotrajno in razpršeno kontaminacijo vodnih virov.
	FI	Voi aiheuttaa vesivarojen pitkäkestoista hajakuormitusta
	SV	Långlivat ämne som kan förorena vattenkällor

EUH 451	Language	
	BG	Може да причини особено дълготрайно и дифузно замърсяване на водните ресурси
	ES	Puede ser causa de una contaminación difusa y muy duradera de los recursos hídricos
	CS	Může způsobit velmi dlouhodobé a difúzní znečištění vodních zdrojů
	DA	Kan forårsage meget langvarig og diffus forurening af vandressourcer
	DE	Kann sehr lang anhaltende und diffuse Verschmutzung von Wasserressourcen verursachen
	ET	Võib põhjustada veevarude väga pikaajalist ja hajusat saastumist
	EL	Μπορεί να προκαλέσει πολύ μακροχρόνια και διάχυτη μόλυνση υδάτινων πόρων
	EN	Can cause very long-lasting and diffuse contamination of water resources
	FR	Peut provoquer une contamination diffuse à très long terme des ressources en eau
	GA	Substaint an-mharthanach ar féidir léi acmhainní uisce a thruailliú
	HR	Može uzrokovati vrlo dugotrajno i raspršeno onečišćenje vodnih resursa
	IT	Può provocare la contaminazione molto duratura e diffusa delle risorse idriche
	LV	Var izraisīt ļoti ilgstošu un difūzu ūdens resursu kontamināciju
	LT	Gali sukelti labai ilgalaikę ir pasklidąją vandens išteklių taršą
	HU	Rendkívül tartós, diffúz szennyezést okozhat a vízkészletekben
	MT	Jistgħu jikkawżaw kontaminazzjoni dejjiema u diffuża ħafna tar-riżorsi tal-ilma
	NL	Kan zeer langdurige en diffuse verontreiniging van watervoorraden veroorzaken
	PL	Może powodować bardzo długotrwałe i rozproszone zanieczyszczenie zasobów wodnych
	PT	Pode causar uma contaminação muito prolongada e difusa dos recursos hídricos

EUH 451	Language	
	RO	Poate cauza contaminarea difuză și de foarte lungă durată a resurselor de apă
	SK	Môže spôsobiť veľmi dlhotrvajúcu a difúznu kontamináciu vodných zdrojov
	SL	Lahko povzroči zelo dolgotrajno in razpršeno kontaminacijo vodnih virov.
	FI	Voi aiheuttaa vesivarojen erittäin pitkäkestoista hajakuormitusta
	SV	Mycket långlivat ämne som kan förorena vattenkällor’

ANNEX IV

In Part 1, Section 1.1.2.1.1 of Annex VI to Regulation (EC) No 1272/2008, Table 1.1 is amended as follows:

(1) the following row is inserted after the row for hazard class 'Aspiration hazard':

'Endocrine disruptor for human health	ED HH 1 ED HH 2;'

(2) the following rows are inserted after the row for hazard class 'Hazardous to the aquatic environment':

'Endocrine disruptor for the environment	ED ENV 1 ED ENV 2
Persistent, bioaccumulative and toxic Very persistent and very bioaccumulative	PBT vPvB
Persistent, mobile and toxic Very persistent and very mobile	PMT vPvM.'