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ANNEXES 1 to 3

ANNEXES

to the

Commission Delegated Regulation

amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures

ANNEX I

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

– in Part 3, the following section 3.11. is added:

3.11. **Endocrine disrupting property 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 disrupting property’ means the hazard posed by an endocrine disruptor;

(c) ‘endocrine disruption’ means the alteration of one or more functions of the endocrine system caused by an endocrine disruptor;

(d) ‘endocrine activity’ means an interaction with the endocrine system that may result in a response of that system, of target organs and/or target tissues, and that confers on a substance or the mixture the potential to alter one or more functions of the endocrine system;

(e) ‘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;

(f) ‘biologically plausible link’ means the correlation between one or a series of biological processes leading to an adverse effect and an endocrine activity, where the correlation is consistent with existing knowledge.

3.11.1.2. General considerations

Substances and mixtures which have altered the function of the endocrine system in well performed experimental studies on animals shall be considered to be known, presumed or suspected human endocrine disruptors unless there is evidence conclusively demonstrating that the adverse effects are not relevant to humans.

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

3.11.2.1. *Hazard categories*

For the purpose of classification for endocrine disrupting properties for human health, substances shall be allocated to one of two categories based on strength of evidence and additional considerations in a weight of evidence determination as referred to in section 1.1.1.

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 human or animal data, or from both human and animal data. 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 and future generations; (c) a biologically plausible link between the endocrine activity and the adverse effect. However, where there is information that raises doubt about the relevance of the biologically plausible link for humans, classification in Category 2 may be more appropriate.
CATEGORY 2	Suspected endocrine disruptors for human health The classification in Category 2 shall be largely based on evidence from human or animal data, or from both human and animal data. A substance shall be classified in Category 2 where all the following criteria are fulfilled: (a) there is evidence of an endocrine activity and an adverse effect in an intact organism or its offspring and future generations; (b) the evidence referred to in (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*

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.). 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.

Where the endocrine-related adverse effects occur together with other toxic effects, endocrine-related adverse effects shall be considered to be present where they are not conclusively demonstrated to be a solely non-specific consequence of the other toxic effects.

3.11.2.3. *Weight of evidence and expert judgment*

3.11.2.3.1. 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, studies performed with adequately validated alternative test systems (in vitro, in silico studies) predictive of adverse effects in humans or animals;

(b) data from analogue substances using structure-activity relationships (SAR), informing about endocrine modes of action;

(c) peer-reviewed published studies;

(d) any additional acceptable 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, and international guidelines on maximum recommended doses and for assessing confounding effects of excessive toxicity.

3.11.2.3.3. Using a weight of evidence determination, the link between the adverse effects and the endocrine activity shall be established based on biological plausibility, which shall be determined in the light of available scientific knowledge. 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.

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. *Specific considerations for classification of substances as endocrine disruptors*
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 where the criteria provided in this section are met.

3.11.2.5. *Application in time*

From … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* at the latest, substances shall be classified in accordance with the criteria laid down in sections 3.11.2.1 to 3.11.2.4.

However, substances which are classified in accordance with this Regulation as applicable on … [*OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* are not required to be reclassified in accordance with the criteria laid down in sections 3.11.2.1 to 3.11.2.4 until … *[OP please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation]*.

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

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-related adverse effects that have 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 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 disrupting properties 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 … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* 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 are classified in accordance with this Regulation as applicable on … [*OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* are not required to be reclassified in accordance with the criteria laid down in sections 3.11.3.1., 3.11.3.2. and 3.11.3.3. until … *[OP please insert the date = the first day of the month following 60 months after the date of entry into force of this Regulation]*.

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 disrupting property for human health).

Table 3.11.3.

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

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3.11.4.2. *Application in time for substances*

From … [*OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* at the latest, substances shall be labelled in accordance with section 3.11.4.1.

However, substances which are labelled in accordance with this Regulation as applicable on … *[OP please insert the date = the day before the date of entry into force of this Regulation] and* which were placed on the market before … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* are not required to be relabelled in accordance with section 3.11.4.1 until … *[OP please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation]*.

3.11.4.3. *Application in time for mixtures*

From … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* at the latest, mixtures shall be labelled in accordance with section 3.11.4.1.

However, mixtures which are labelled in accordance with this Regulation as applicable on … *[OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* are not required to be relabelled in accordance with section 3.11.4.1 until … *[OP please insert the date = the first day of the month following 60 months after the date of entry into force of this Regulation]*.';

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

'4.2. **Endocrine disrupting property 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 disrupting property' means the hazard posed by an endocrine disruptor;

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

(d) 'endocrine activity' means an interaction with the endocrine system that may result in a response of that system, of target organs and/or target tissues and that confers on

a substance or mixture the potential to alter one or more functions of the endocrine system;

(e) '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;

(f) 'biologically plausible link' means the correlation between one or a series of biological processes leading to an adverse effect and an endocrine activity, where the correlation is consistent with existing knowledge.

4.2.1.2. General considerations

Substances and mixtures which have altered the function of the endocrine system in well performed experimental studies on animals 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 (sub)population level.

4.2.2 ***Classification criteria for substances***

4.2.2.1 *Hazard categories*

For the purpose of classification for endocrine disrupting properties for the environment, substances shall be allocated to one of two categories based on strength of evidence and additional considerations in a weight of evidence determination.

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 animal data. 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 and future generations; (c) a biologically plausible link between the endocrine activity and the adverse effect. However, where there is information that raises doubt about the relevance of the endocrine disrupting adverse effects for the population or subpopulation level, classification in Category 2 may be more appropriate.

CATEGORY 2	Suspected endocrine disruptors for the environment The classification in Category 2 shall be largely based on evidence from animal data. A substance shall be classified in Category 2 where all the following criteria are met: (a) there is evidence of an endocrine activity and an adverse effect in an intact organism or its offspring and 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.

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

4.2.2.2. *Basis of classification*

Classification shall be made on the basis of the appropriate criteria set out in section 4.2.2.1, and an assessment of the weight of evidence of each of the criteria (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 (sub)population level.

Where the endocrine-related adverse effects occur together with other toxic effects, endocrine-related adverse effects shall be considered to be present where they are not conclusively demonstrated to be a solely non-specific consequence of the other toxic effects.

4.2.2.3. *Weight of evidence and expert judgment*

4.2.2.3.1. 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, studies performed with adequately validated alternative test systems (in vitro, in silico studies) predictive of adverse effects in humans or animals;

(b) data from analogue substances using structure-activity relationships (SAR), informing about endocrine modes of action;

(c) peer-reviewed published studies;

(d) any additional acceptable data.

4.2.2.3.2. In applying the weight of evidence determination, 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 taxonomic groups;

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

4.2.2.3.3. Using a weight of evidence determination, the link between the adverse effects and the endocrine activity shall be established based on biological plausibility, which shall be determined in the light of available scientific knowledge. 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.

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 in section 3.11. shall be considered to assess the classification of the substance as endocrine disruptor for the environment in section 4.2.

4.2.2.4. *Specific consideration for classification as environmental endocrine disruptor*

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 where the criteria provided in this section are met.

4.2.2.5. *Application in time*

From … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* at the latest, substances shall be classified in accordance with the criteria laid down in sections 4.2.2.1 to 4.2.2.4.

However, substances which are classified in accordance with this Regulation as applicable on … [*OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* are not required to be reclassified in accordance with the criteria laid down in sections 4.2.2.1 to 4.2.2.4 until … *[OP please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation]*.

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

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-related adverse effects that have 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 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 disrupting properties 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 … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* 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 are classified in accordance with this Regulation as applicable on … [*OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* are not required to be reclassified in accordance with the criteria laid down in sections 4.2.3.1, 4.2.3.2 and 4.2.3.3 until … *[OP please insert the date = the first day of the month following 60 months after the date of entry into force of this Regulation]*.

4.2.4. ***Hazard Communication***

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

Table 4.2.3.

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

4.2.4.2. *Application in time for substances*

From … [*OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* at the latest, substances shall be labelled in accordance with section 4.2.4.1.

However, substances which are labelled in accordance with this Regulation as applicable on … [*OP please insert the date = the day before the date of entry into force of this Regulation*] and which were placed on the market before … [*OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation*] are not required to be relabelled in accordance with section 4.2.4.1 until … [*OP please insert the date*

= the first day of the month following 42 months after the date of entry into force of this Regulation]

4.2.4.3. *Application in time for mixtures*

From … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* at the latest, mixtures shall be labelled in accordance with section 4.2.4.1.

However, mixtures which are labelled in accordance with this Regulation as applicable on … *[OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* are not required to be relabelled in accordance with section 4.2.4.1 until … *[OP please insert the date = the first day of the month following 60 months after the date of entry into force of this Regulation]*.

4.3. Persistent, Bioaccumulative and Toxic (PBT) or Very Persistent, Very Bioaccumulative (vPvB) properties

4.3.1. ***Definitions***

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.

4.3.2. ***Classification criteria for substances***

4.3.2.1. *Classification criteria for PBT*
A substance that fulfils the persistence, bioaccumulation and toxicity criteria set out in sections 4.3.2.1.1. to 4.3.2.1.3 shall be considered a PBT substance.

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 2000.

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 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 4.1;

(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 that fulfils the persistence and bioaccumulation criteria set out in sections 4.3.2.2.1 and 4.3.2.2.2. shall be considered a vPvB substance.

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 or impurities of a substance and relevant transformation and/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.

4.3.2.3.1. *Assessment of P or vP properties*

The following information shall be considered for the assessment of P 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, 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 aquatic plants;

(d) the substance meeting the criteria for classification as carcinogenic in Category 1A or 1B (assigned hazard phrases: H350 or H350i), germ cell mutagenic in Category 1A or 1B (assigned hazard phrase: H340), toxic for reproduction in Category 1A, 1B and/or 2 (assigned hazard phrases: 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 phrase: H372 or H373);

(e) the substance meeting the criteria for classification as endocrine disruptor (Category 1) for human health or the environment (assigned hazard phrases: 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) suitable in vivo tests or adequately validated alternative test systems (in vitro, in silico studies) in humans or animals;

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

(c) (Q)SAR results 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 biodegradation (Q)SAR models in accordance with Section 1.3 of Annex XI to Regulation (EC) No 1907/2006;

(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 (Q)SAR models in accordance with Section 1.3 of Annex XI to Regulation (EC) No 1907/2006;

(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, 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 … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* 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 are classified in accordance with this Regulation as applicable on … [*OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* are not required to be reclassified in accordance with the criteria laid down in sections 4.3.2.1 to 4.3.2.4 until … *[OP please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation]*.

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 … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* at the latest, mixtures shall be classified in accordance with the criteria laid down in sections 4.3.2.1 to 4.3.2.4.

However, mixtures which are classified in accordance with this Regulation as applicable on … [*OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of*

the month following 36 months after the date of entry into force of this Regulation] are not required to be reclassified in accordance with the criteria laid down in sections 4.3.2.1 to 4.3.2.4 until … *[OP please insert the date = the first day of the month following 60 months after the date of entry into force of this Regulation]*.

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 living organisms including in humans with long- lasting effects	EUH441: Strongly accumulates in living organisms including in humans with possible long-lasting effects
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 … [*OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* at the latest, substances shall be labelled in accordance with section 4.3.4.1.

However, substances which are labelled in accordance with this Regulation as applicable on … *[OP please insert the date = the day before the date of entry into force of this Regulation] and* which were placed on the market before … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* are not required to be relabelled in accordance with section 4.3.4.1 until … *[OP please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation]*.

4.3.4.3. *Application in time for mixtures*

From … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* at the latest, mixtures shall be labelled in accordance with the provisions laid down in section 4.3.4.1.

However, mixtures which are labelled in accordance with this Regulation as applicable on … *[OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* are not required to be relabelled in accordance with section 4.3.4.1 until … *[OP please insert the date = the first day of the month following 60 months after the date of entry into force of this Regulation]*.

4.4. **Persistent, Mobile and Toxic (PMT) or Very Persistent, Very Mobile (vPvM) properties**

4.4.1. ***Definitions***

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

4.4.2. ***Classification criteria for substances***

4.4.2.1. *Classification criteria for PMT*

A substance that fulfils the persistence, mobility and toxicity criteria set out in sections 4.4.2.1.1., 4.4.4.1.2. and 4.4.2.1.3. shall be considered a PMT substance.

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 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 4.1;

(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 that fulfils the persistence and mobility criteria set out in sections 4.4.2.2.1. and 4.4.2.2.2 shall be considered a vPvM substance.

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 or impurities of a substance and relevant transformation and/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 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.

4.4.2.3.1. *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 studies, provided that its suitability and reliability can be reasonably demonstrated.

4.4.2.3.2. *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 aquatic plants;

(d) the substance meeting the criteria for classification as carcinogenic in Category 1A or 1B (assigned hazard phrases: H350 or H350i), germ cell mutagenic in Category 1A or 1B (assigned hazard phrase: H340), toxic for reproduction in Category 1A, 1B and/or 2 (assigned hazard phrases: 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 phrase: H372 or H373);

(e) the substance meeting the criteria for classification as endocrine disruptor (Category 1) for human health or the environment (assigned hazard phrases: 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*

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) suitable in vivo tests or adequately validated alternative test systems (in vitro, in silico studies) in humans or animals;

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

(c) (Q)SAR results 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 addition to the information referred to in sections 4.4.2.3.1., 4.4.2.3.2. and 4.4.2.3.3., in applying weight of evidence determination, the following information shall be considered as part of the scientific assessment:

(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 biodegradation (Q)SAR models in accordance with Section 1.3 of Annex XI to Regulation (EC) No 1907/2006;

  (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 (Q)SAR models in accordance with Section 1.3 of Annex XI to Regulation (EC) No 1907/2006;

  (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, 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 … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* 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 are classified in accordance with this Regulation as applicable on … [*OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* are not required to be reclassified in accordance with the criteria laid down in sections 4.4.2.1 to 4.4.2.4 until … *[OP please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation]*.

4.4.3. ***Classification criteria for mixtures***

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).

From … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* at the latest, mixtures shall be classified in accordance with the criteria laid down in sections 4.4.2.1 to 4.4.2.4.

However, mixtures which are classified in accordance with this Regulation as applicable on … [*OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* are not required to be reclassified in accordance with the criteria laid down in sections 4.4.2.1 to 4.4.2.4 until … *[OP please insert the date = the first day of the month following 60 months after the date of entry into force of this Regulation]*.

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: Persistent substance which can pollute water resources	EUH451: Very persistent substance which can pollute 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 … [*OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* at the latest, substances shall be labelled in accordance with section 4.4.4.

However, substances which are labelled in accordance with this Regulation as applicable on … *[OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 18 months after the date of entry into force of this Regulation]* are not required to be relabelled in accordance with section 4.4.4 until … *[OP please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation]*.

4.4.4.3. *Application in time for mixtures*

From … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* at the latest, mixtures shall be labelled in accordance with section 4.4.4.

However, mixtures which are labelled in accordance with this Regulation as applicable on … *[OP please insert the date = the day before the date of entry into force of this Regulation]* and which were placed on the market before … *[OP please insert the date = the first day of the month following 36 months after the date of entry into force of this Regulation]* are not required to be relabelled in accordance with section 4.4.4 until … *[OP please insert the date = the first day of the month following 60 months after the date of entry into force of this Regulation]*.’

ANNEX II

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

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

‘EUH 380	Language	

	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	May cause endocrine disruption in humans
	FR	
	GA	
	HR	
	IT	
	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV	

EUH 381	Language	
	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	Suspected of causing endocrine disruption in humans
	FR	
	GA	
	HR	
	IT	
	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	

	SL	
	FI	
	SV’;	

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

‘EUH 430	Language	
	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	May cause endocrine disruption in the environment
	FR	
	GA	
	HR	
	IT	
	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV	

EUH 431	Language	
	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	Suspected of causing endocrine disruption in the environment
	FR	
	GA	
	HR	
	IT	

	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV	

EUH 440	Language	
	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	Accumulates in living organisms including in humans with long lasting effects
	FR	
	GA	
	HR	
	IT	
	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV	

EUH 441	Language	
	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	

	EN	Strongly accumulates in living organisms including in humans with possible long lasting effects
	FR	
	GA	
	HR	
	IT	
	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV	

EUH 450	Language	
	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	Persistent substance which can pollute water resources
	FR	
	GA	
	HR	
	IT	
	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV	

EUH 451	Language	

	BG	
	ES	
	CS	
	DA	
	DE	
	ET	
	EL	
	EN	Very persistent substance which can pollute water resources
	FR	
	GA	
	HR	
	IT	
	LV	
	LT	
	HU	
	MT	
	NL	
	PL	
	PT	
	RO	
	SK	
	SL	
	FI	
	SV’.	

ANNEX III

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’.

’.