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Our position

AmCham EU comments – Classification, labelling and packaging (CLP) Delegated Act introducing new hazard classes

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3.4 trillion in 2021, directly supports more than 4.9 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

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Executive summary

Recommendations for improving the European Commission's proposed updated rules on classification, labelling and packaging (CLP) hazard classes include:

- alignment with UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS);
- more precise wording, particularly in the endocrine disruptors (ED) draft text;
- allowing the consideration of additional data in the bioaccumulation and mobility criteria; and
- removing the signal word 'danger'.

Introduction

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness. It aims to ensure a growth-orientated business and investment climate in Europe. The following suggestions, and detailed comments in the attachment, aim to provide clarity, workability and consistency when it comes to the proposed CLP hazard classes.

CLP must be consistent with UN GHS

The Chemicals Strategy for Sustainability should be implemented in a targeted, proportionate and science-based manner. It is important to address new hazard classes first under UN GHS. This would help promote an international level playing field, prevent barriers to trade and remove the risk imposed on industry through the need to comply with significantly different rules on classification and labelling across different jurisdictions, all moving at different speeds. The 'targeted impact assessment' accompanying the draft CLP hazard classes acknowledges that moving under CLP prior to the UN GHS' decision could cause technical barriers to trade. It also acknowledges that previous EU proposals to introduce new hazard classes under UN GHS have not been successful. The European Commission should re-evaluate this point and work to secure support at UN GHS before embarking on the new hazard classes under EU CLP. Nevertheless, we note with concern the Commission's intention to proceed with the current draft delegated act prior to securing agreement at UN GHS.

Weight of Evidence (WoE) terminology should be consistent across ED and persistent, bioaccumulative and toxic (PBT)/ persistent, mobile and toxic (PMT) hazard classes

According to Organisation for Economic Co-operation and Development (OECD) No. 311, 'Guiding Principles and Key Elements for Establishing a Weight of Evidence for Chemical Assessment', all evidence – and how it was collected, evaluated and weighted – should be systematically and comprehensively documented. The quality and consistency of the data shall be given appropriate weight. Currently, wording on weight of evidence is not consistent across the various hazard classes being tabled by the Commission. As a solution, we propose to amend the PBT/PMT WoE wording by

leveraging the terminology in the ED classes, which is consistent with existing ED criteria for plant protection and biocidal products.

More precise wording is required throughout the ED draft text

Certain paragraphs and definitions of the ED draft text are vague and open to interpretation, which could undermine legal certainty. The text should be improved to avoid lengthy and complicated guidance development and bottlenecks during the harmonised classification process. Otherwise, stakeholders will not be able to come to an agreement on the interpretation of the legal text. The definitions in this section do not consistently reflect the World Health Organization (WHO) definition, as key aspects are omitted. The criteria to distinguish between Category 1 and 2 are inconsistent and unclear, both for human health (HH) and Environment (ENV). Detailed comments are provided in the attachment. A key principle is that since toxicology deals with the adverse effects of chemicals on living organisms, then criteria for categories should start with the adverse effect. Only then is it necessary to consider the mode of action or how the adverse effect is brought about. We therefore suggest that under Category 1 a) should address the adverse effect and b) the endocrine activity, rather than the other way around. This is also how it is done in the Plant Protection Products and Biocide criteria and gives consistency of approach across EU regulations. Under Category 2 adverse effect should also be given primary importance since mode of action is irrelevant if there is no clearly identified adverse effect.

Current wording for the bioaccumulation and mobility criteria is too limiting

The formal classification criteria for B and M should allow additional data to be considered where there is evidence convincingly demonstrating its relevance. Despite previous acknowledgement at Additional tools

Competent Authorities for REACH and CLP (CARACAL), the Bio-Concentration Factor (BCF) occasional applicability for bioaccumulation via the diet for the PBT/ very persistent and very bioaccumulativ (vPvB) class is not reflected in the text. Similarly, by better referencing leachability as part of the criteria for mobility, the challenge of identifying substances with a potential to concentrate in drinking water and present a risk to human health, would be addressed. Without a more formal integration of leachability metrics, proposed PMT criteria lack specificity based on a high number of false positive and false negative findings.

Hazard communication for PBT/vPvB and PMT/ very persistent and very mobile (vPvM)

The proposed signal word in the Commission's text is 'danger'. To limit disturbances in international trade, avoid confusion in the supply chain and limit the divergence from GHS, we propose to include no signal word, or alternatively 'warning', as well as specific hazard statement phrases.

Annex I: Detailed proposals for improvement

Page	Section number	Comment
1	3.11.1.1. Definitions	(b) states: '"endocrine disrupting property" means the hazard posed by an endocrine disruptor' That sentence will mean that for example a flammability hazard or skin irritation caused by an 'endocrine disruptor' is an endocrine disrupting property. As it seems unlikely that this was the intention, we suggest rewording the definition.
1	3.11.1.1. Definitions	(c) states '"endocrine disruption" means the alteration of one or more functions of the endocrine system caused by an endocrine disruptor' This definition is too broad, as most substances (both endocrine disruptors and those which are not) are likely at high doses to cause multiple different alterations of one or more functions of the endocrine system, of which for endocrine disruptors, one leads to an adverse effect which has the causal link, but other endocrine activities of an 'endocrine disruptor' will not be linked to adverse effects. Hence, it is not logical to assume that all endocrine activities of an endocrine disruptor represent 'endocrine disruption'. Therefore, this definition may in fact lead to confusion, however, if necessary it must refer to the link between adverse effect and mode of action, in line with the WHO definition.
1	3.11.1.2. General Considerations	The paragraph states: '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.' This sentence **lacks sufficient reference to the adverse effect and causal link between the endocrine activity and the adverse effect, in line with the WHO definition**. We suggest adding wording accounting for the adverse effect and the causal link upfront, not just at the end.

2	Table 3.11.1	There seems to be a **logical contradiction** between the proposed criteria text on Category 1 and Category 2 regarding which cases should belong to Category 1 versus 2. The criterion suggested in the category 1 text is the strength of evidence for a biologically plausible link in humans, while the criterion of the Category 2 text is the strength of evidence for adverse effects and for endocrine activity. This creates a situation where the Category 2 text requires strong evidence for a biologically plausible link, while the Category 1 text suggests placing substances into Category 2 where there is doubt about that link. For Category I the differentiation between known EDs and suspected EDs is unclear. Suspected EDs should fall under category II. The wording 'adverse effect in an intact organism' in combination with 'largely based on' does not guarantee an exclusion of the possibility to classify any substance solely on the basis of in vitro data.
3	3.11.2.1 Hazard Categories	The sentence beneath the table states '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.' Should this sentence not refer to the weight of evidence required by 3.11.2.2? Additionally, in case the adverse effects were assumed relevant for humans but not the mode of action, it cannot be the intention to classify as endocrine disruptor for humans, but rather another hazard class reflecting the adverse effect should be in scope, eg reproductive toxicity.
3	3.11.2.2. Basis of Classification	The last sentence states: '...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.' We note that this phrase requires a proof of negative and enormous amounts of mode of action and physiology knowledge, which in practice means that the intention is to classify for secondary unspecific effects. If that is not the intention, the

		phrase should be reworded to refer to the Weight of Evidence assessment outcome.
3	3.11.2.3.2.	Under point (b), we suggest to add reference to human relevance.
3	3.11.2.3.4.	The overall wording of the HH section as drafted is likely to lead to classification of all ENV EDs as HH Cat 2 as well, even when eg, the endocrine-related adverse effects are observed only in snails, but not in fish or rats or mice or rabbits. This is because the text does not clarify a hierarchy of experimental animals in terms of relevance for humans, and the sentence under Table 3.11.1 requires a proof of a negative, which is technically impossible.
4	3.11.2.4. Specific considerations for classification of substances as endocrine disruptors	This section states: '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.' This means that also hazards such as skin irritation can be used as basis for human endocrine disruptor classification and SVHC status. Is this the intention, as up to now, we had worked on the basis of the communication by the Commission that SVHCs or 'the most harmful' substances meet certain hazard characteristics, ie severity, delay, irreversibility etc (jrc96572-identification svhc reach article 57f.pdf)? This could be avoided by making reference to the STOT RE criteria description for classifiable **'significant toxicity'** from section 3.9.2.7. of CLP: Effects considered to support classification for specific target organ toxicity following repeated exposure, and section 2.9.2.8.: Effects considered not to support classification for specific target organ toxicity following repeated exposure.
4	Table 3.11.2.	By analogy to other CLP hazards, it is suggested to add in Category 2 column a requirement to provide SDS on request when Category 2 ED HH classified component is present at 0.1% or more. Support an update of CLP Annex II where such mixtures should require the EUH210 on label .

5	Table 3.11.3.	It is suggested to rephrase the text of the EUH statement for endocrine disruptors. The term 'endocrine disruption' (ED) cannot be assumed to be familiar to the end users. It is suggested to refer to 'disruption of hormonal systems' instead.
5	Table 3.11.3.	It is suggested to reconsider the proposed Generic Concentration Limits (GCLs) for classification of mixtures for ED HH. Endocrine disruption is in majority of cases a mode of action for existing GHS hazards, for example reprotoxicity. In case the GHS hazard caused by the endocrine mode of action has a different GCL than the GCL indicated in Table 4.2.2., then the GCL of the GHS hazard class should be used also for the ED HH classification of mixtures. This will ensure consistency of classifications and will adequately reflect the available information on substance. It should also be considered whether additional provisions are required that would require deviation from GCLs listed in Table 4.2.2, in case the GHS hazard caused by the endocrine mode of action has been assigned an SCL. In such case the ED hazard should be triggered as of the SCL of the triggered GHS hazard (that SCL can be higher or lower than the GCLs from Table 4.2.2).
6	4.2.1.1.	(b) states: '"endocrine disrupting property" means the hazard posed by an endocrine disruptor;' That sentence will mean that for example a flammability hazard or skin irritation caused by an 'endocrine disruptor' is an endocrine disrupting property. As it seems unlikely that this was the intention, we suggest rewording the definition. (c) states '"endocrine disruption" means the alteration of one or more functions of the endocrine system caused by an endocrine disruptor;'. This definition is too broad, as most substances (both endocrine disruptors and those which are not) are likely at hight doses to cause multiple different alterations of one or more functions of the endocrine system, of which for endocrine disruptors, one leads to an adverse effect which has the causal link, but other endocrine activities of an 'endocrine disruptor' will not be linked to adverse effects. Hence, it is not logical to assume that all

		endocrine activities of an endocrine disruptor represent 'endocrine disruption'. Therefore, this definition may in fact lead to confusion, however, if necessary it must refer to the link between adverse effect and mode of action.
7	4.2.1.2 General considerations	The current draft text is inconsistent with the definition, as reference to the causal link to the adverse effect is lacking.
7/8	Table 4.2.1.	This table has similar inconsistencies as the human health criteria table in that it suggests different criteria for the decision on whether to put a substance into Cat 1 or Cat 2, and the user then does not know which criterion to use: is it doubt about the population relevance (Cat 1 text) or doubt about the evidence for adverse effects and endocrine activity (Cat 2 text)?
8	4.2.2.1. Hazard categories	The sentence below **table 4.2.1. is inconsistent with the wording of 4.2.1.2.** (General considerations).
10	Table 4.2.2.	By analogy to other CLP hazards, it is suggested to add in Category 2 column a requirement to provide SDS on request when Category 2 ED ENV classified component is present at 0.1% or more.
11	Table 4.2.3.	It is suggested to rephrase the text of the EUH statement for endocrine disruptors. The hazard 'endocrine disruption' (ED) is not familiar to the end users. It is suggested to refer to 'disruption of hormonal systems' instead.
11	Table 4.2.3.	It is suggested to reconsider the proposed Generic Concentration Limits (GCLs) for classification of mixtures for ED ENV. In cases where aquatic toxicity is caused by the endocrine mode of action, the GCLs resulting from CLP Annex I Table 4.1.1 and Table 4.1.2 should apply instead of the GCLs from Table 4.2.3.
12	4.3.1	It is suggested to define key terminology used in the hazard class, similar to what is done for ED.

12	4.3.1.	Since a substance / mixture may be considered at the same time a PBT and a vPvB it is suggested to clarify at the beginning of this hazard class, that the classification must be done for each class separately.
12	4.3.2.1.	To make the legal text consistent and remove interpretation doubts it is suggested to make the text in section '4.3.2.1. Classification criteria for PBT' more precise, by including a reference to section 4.3.2.3. Basis of classification. While section 4.3.2.1. lists selected numerical criteria with cut-offs, section 4.3.2.3. requires a Weight of Evidence approach and consideration of all information going beyond the parameters listed in section 4.3.2.1. It is recommended to clarify the importance of including all relevant information already upfront.
13	4.3.2.1.2.	BCF will not always be a good indicator of B. To account for these scenarios, the criterion for B should allow consideration of additional data where there is evidence convincingly demonstrates its relevance.
13	4.3.2.2.	See above the comment on 4.3.2.1 PBT. We support the same solution for vPvB.
13	4.3.2.2.2.	By analogy to the comment on 4.3.2.1.2. it is also suggested to rephrase section 4.3.2.2.2.
13/14	4.3.2.3	According to OECD, a weight of evidence assessment involves 'integrating all evidence and indicating how evidence was collected, evaluated and weighed' It is proposed to reword section 4.3.2.3 by leveraging wording from the ED classes.
15	4.3.2.4.1	Available information should include fate studies to support the Persistence assessment

		Suggest to add (i) environmental fate studies.
15	4.3.2.4.1	Suggest leveraging wording from the WoE wording 4.2.2.3.2 from the ED classification category, in particular around positive and negative results, the relevance of study designs, the quality and consistency of data.
15	4.3.2.3.3	Lines f to h; We suggest to remove long-term effects in other species than the aquatic compartment, as relevant thresholds are not yet defined. The guidelines were developed to inform risk assessment. In the aquatic classification, findings in long-term studies lead to classification at higher levels than those relevant in a PBT assessment. Similarly, long-terms effects on other species should reflect the intent to inform on long-term adverse effects.
16	4.3.2.4.2 (c)	Toxicity considered in a PBT assessment is chronic toxicity. It is proposed to remove reference to acute toxicity which supports the existing CLP aquatic classification.
17	Table 4.3.1.	The proposed EUH440 and EUH441 statements seem to not follow the GHS approach for the H-statements. E.g. the proposed EUH440 'Accumulates in living organisms including in humans with long- lasting effects' effectively states the hazard will always manifest itself, which is not the case and is also not how GHS H statements are phrased. The statement EUH441 similarly states that the chemical will always accumulate in living organisms, which also is not the case. Further, it uses the word 'possible' for long lasting effect, while the most appropriate statement would have been that 'the long-lasting effects could not have been excluded' (since based on toxicity information currently they are no known long-lasting effect, otherwise PBT would have applied too). These statements should be reviewed to ensure they are readable, understandable and translatable.
18	4.4 Persistent, Mobile and Toxic (PMT) or Very Persistent, Very Mobile (vPvM) properties	In the hierarchy of information on mobility, leachability should have a higher weight, to achieve the intended benefit of the classification. The PMT concept is based on limited number of publications, which indicate that the suggested PMT criteria could lack specificity based on a high number of false positive and false negative findings.

		• Germany's PMT concept 'not fit for purpose', says Cefic (chemicalwatch.com) • Industry analysis concludes mobility part of PMT criteria 'too simplistic' (chemicalwatch.com) Inclusion of publicly available information in the Persistence assessment and comparison to monitoring data have shown that the proposed PMT criteria do not support the identification of substances likely to occur in drinking water. Those findings are in alignment with a prior review from ECETOC, which concluded that the substance profile of water contaminants demonstrate that PM substances do not have a higher likelihood than non-PM substances to be detected in surface or groundwater (see reference below): ECETOC (2021). Persistent chemicals and water resources protection. Technical Report No. 139. Brussels, May 2021. Collard, Marie and Camenzuli, Louise and Saunders, David and Vallotton, Nathalie and Curtis-Jackson, Pippa, Persistence and Mobility (Defined as Organic-Carbon Partitioning) Do Not Correlate to the Detection of Substances Found in Surface and Groundwater: Criticism of the Regulatory Concept of Persistent and Mobile Substances. Available at SSRN: https://ssrn.com/abstract=4235131
18	4.4.1. Definitions	We suggest to define key terminology used in the hazard class, similar to ED.
18	4.4.1.	Since a substance / mixture may be considered at the same time a PMT and a vPvM it is suggested to clarify at the beginning of this hazard class, that the classification must be done for each class separately.
18	4.4.2.1.	To make the legal text consistent and remove pause for interpretation the text in 'section 4.4.2.1. Classification criteria for PMT' should be refined by including a reference to section 4.4.2.3. Basis of classification.

		While section 4.4.2.1. lists fixed criteria, section 4.4.2.3. requires Weight of Evidence approach and consideration of information going beyond the parameters listed in section 4.4.2.1. It is recommended to make this clear already upfront.
18	4.4.2.1.2.	log Koc will not always be a good indicator of mobility. To account for these scenarios, the criterion for M should allow consideration of additional data where there is evidence convincingly demonstrates its relevance.
18	4.4.2.1.2.	Log Koc is not applicable for ionisable substances. Log Kd is the best parameter for these compounds. To be consistent with substances that are non-ionisable under environmentally relevant pH values, we suggest a threshold of 1 for LogKd. This corresponds to Koc-values being in the range of 2 orders of magnitude greater than Kd-values.
19	4.4.2.2.	See above the comment on 4.4.2.1 PMT. This is analogous suggestion for vPvM.
19	4.4.2.2.2.	By analogy to the comment on 4.4.2.1.2. it is also suggested to rephrase section 4.4.2.2.2.
19	4.4.2.2.2.	log Koc is not applicable for ionisable substances. Log Kd is the best parameter for these compounds. To be consistent with substances that are non-ionisable under environmentally relevant pH values, we suggest a threshold of 0 for LogKd for vM. This corresponds to Koc-values being in the range of 2 orders of magnitude greater than Kd-values.
19	4.4.2.3	According to OECD, a weight of evidence assessment involves 'integrating all evidence and indicating how evidence was collected, evaluated and weighed'. It is proposed to reword section 4.3.2.3 by leveraging wording from the ED classes.

20	4.4.2.3.1	Suggest referring to leaching models and studies, provided that their suitability and reliability can be reasonably demonstrated.
20	4.4.2.3.2	We suggest to remove long-term effects in other species that the aquatic compartment as relevant thresholds are not yet defined. The guidelines were developed to inform risk assessment. In the aquatic classification, findings in long-term studies lead to classification at higher levels high than those relevant in a PBT assessment. Consistently long-terms effects on other species should reflect the intent to inform on long-term adverse effects.
21	4.4.2.4.1	Suggest leveraging wording from the WoE wording 4.2.2.3.2 from the ED hazard class.
21	4.4.2.4.2 (b)	Suggest including: • In silico leachability model. • Experimental leaching studies.
23	'Part 1 of Annex III ...'	For substances classified simultaneously as PBT and vPvB there is a need to have a joint EUH statement for presentation on the labels. There is two reasons for this, saving space on the labels and avoiding potentially contradicting information. Therefore, we suggest implementing a joint EUH440/441 statement for labels. If this is done, it will then need to be reflected in CLP Annex III Part 1.
23	Table 4.4.1.	The statements as proposed in the draft include the word 'substance', this should not be the case since the statement will also be applicable to mixtures. To remain in line with GHS H-statements, it is recommended to use the word 'may' instead of 'can'. In addition, for EUH451 is it proposed to add the word 'potentially' since vPvM substances/mixtures do not meet any toxicity criteria and they are classified as vPvM as due to their high persistence and high mobility a hazard in long term could not have been excluded even when toxicity data supporting this are not available.

		Therefore, a reference to drinking water sources should be kept as this is the protection goal of this hazard class, and the text should be reviewed to ensure it can be meaningfully translated into other languages.
23	'Part 1 of Annex III ...'	For substances/mixtures classified simultaneously as PMT and vPvM there is a need to have a joint EUH statement for presentation on the labels. There are two reasons for this, saving space on the labels and avoiding potentially contradicting information. Therefore, we suggest implementing a joint EUH450/451 statement for labels. If this is done, it will then need to be reflected in CLP Annex III in its Part 1.
5 6 19 23	Table 3.11.3. Table 4.2.3. Table 4.3.1. Table 4.4.1.	For all new hazard classes it is suggested not to require a signal word. This would help to limit disturbances to international trade, avoid confusion in the supply chain and limit the divergence from GHS. If however, there is a need to include signal words for the new hazards, we suggest that for PBT and vPvB hazard communications (table 4.3.1) the signal word 'warning' is used, which would be consistent with the 'Aquatic Chronic' classification.