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ENVIRONMENT DIRECTORATE-GENERAL
Directorate B – Circular Economy & Green Growth
Sustainable Chemicals

INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMEs DIRECTORATE-GENERAL
Directorate D – Chemicals and Consumer Industries
REACH

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CASG-ED/2021/02

4th Meeting of Competent Authorities Sub-Group on Endocrine Disruptors (CASG-ED)

22 March 2021

Topic: Draft proposal on hazard classes for endocrine disruptors in CLP

Agenda Point: **2**

Action Requested: **For discussion**

The Experts of the CASG-ED are invited to send comments by 19/04/2021 to:

ENV-CARACAL@ec.europa.eu **and**

GROW-CARACAL@ec.europa.eu

Draft proposal of hazard classes for endocrine disruptors in CLP

This note contains an initial proposal on the inclusion of hazard classes for endocrine disruptors in the CLP Regulation, as committed in the Chemicals Strategy for Sustainability.

This proposal is intended as a starting point of the discussion and should not be regarded as a final proposal and does not present a final view of the Commission.

In 2020, the Commission published the 'Chemicals Strategy for Sustainability Towards a Toxic-free Environment'[1] which states that *"the Commission will […]·propose to establish legally binding hazard identification of endocrine disruptors, based on the definition of the WHO, building on criteria already developed for pesticides and biocides, and apply it across all legislation;"*

In the action plan of the strategy, it is explained that the Commission will make a *"proposal to amend the CLP Regulation to introduce new hazard classes on endocrine disruptors, PBTs/vPvBs and persistent and mobile substances, and apply them across all legislation"*, with a targeted date fixed in 2021.

Following the discussion with the members of this CASG-ED, the Commission will then develop its final proposal following the better regulation principles as explained in the Strategy:

"The measures presented in this action plan, including legislative proposals and targeted amendments to REACH, will all need to be carried out in line with the better regulation principles and subject to evaluations and impact assessments as appropriate."

The draft proposal of this document is based on the commitment on the Chemicals Strategy for Sustainability, complemented with the discussion and comments received on the document CASG-ED/2020/06 presented during the 2nd meeting of the CASG-ED on 2nd July 2020.

General explanation of the hazard classes

Separate hazard classes for endocrine disruptors (human health/environment)

It was considered a better approach to have separate hazard classes for human health and the environment, mainly for reasons of usability and workability under REACH and downstream legislations.

As it can be envisaged that there will be different implications in downstream legislations as a result of ED human health and/or environment identification, as is already the case today across the legislative framework (for example between Cosmetics Products Regulation and REACH Regulation), such a separation of hazard is preferred.

Furthermore, the Commission also announced that the new criteria in CLP will be built on criteria already developed for plant protection products (PPPs) and biocides. Consequently, as PPPs and biocides legislations already separate human health and environment, a coherent approach under CLP is advantageous.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN

Introduction of category

It is also proposed to introduce categories for each hazard class, mirroring categorisation systems already in place in the CLP or in the GHS as:

- Category 1: Known or presumed endocrine disruptors (ED HH 1 and ED ENV 1)
- Category 2: Suspected endocrine disruptors (ED HH 2 and ED ENV 2)

Indeed, categories are useful to reflect the scientific level of evidence in classification as this allows nuancing, for example, if there is strong evidence supporting the classification or if there is only some indication coming from animal studies.

Such approach will also allow having adequate level of information to the consumers, users, workers and a differentiated approach in the risk management measures in the different pieces of legislation to achieve a high level of protection in a proportionate way.

Finally, it also enables to have better predictability and legal certainty as we currently do for other hazards classes, especially CMR.

Considering the current development, the most favoured option at this stage is not to differentiate (sub-categories) between known and presumed EDs, as currently in most EU downstream legislation, CMR 1A and CMR 1B are regulated the same way.

Finally, to have the same level of flexibility, similar categories will be also introduced for the environmental hazard class, based on the same categories as for the human health hazard class. This will also allow a better coordination of the two hazard classes, as it is expected that some data relevant for human health can also be used for environment, and vice versa.

Further consideration

Regarding potential double classification (*i.e*., same experimental results could be used for classification for CMR as well as for ED), further discussion will be needed. In particular, a way forward could be to put in place rules regarding the wording of hazard statements (e.g., merging of two hazard statements) and labelling requirements, in order to avoid duplication of information for the same adverse effect.

Further changes will be needed based on how the hazard classes will be developed. In particular, hazard class and category codes will need to be updated in Annex VI, Table 1.1.

It is important to note that it is expected in any case that a guidance will be developed to further explain how to apply the criteria for the new hazard classes. However, the new hazard classes to be included under Annex I of CLP should be as detailed as possible to avoid any problem on interpretation. The guidance will take into account existing guidance under the Biocidal Product Regulation and the Plant Protection Products Regulation.

Annex I: Proposal of hazard class for human health

Text proposal	Comments
3.11 Endocrine disrupting property for human health	To follow CLP naming, it should be the name of the hazard (and not the substance) as for example “carcinogenicity”
3.11.1 Definitions and general considerations	Wording from Repro. 3.7.1
3.11.1.1 Endocrine disruptor means a substance or a mixture of substances that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.	Definition from WHO/PCS/EDC/02.2: https://www.who.int/ipcs/publications/en/ch1.pdf?ua=1
3.11.1.2 A substance is considered to be an endocrine disruptor if it meets all of the following criteria : (1) it shows an adverse effect in an intact organism or its progeny; (2) it shows endocrine activity; (3) the substance has an endocrine disrupting mode of action, i.e. there is a biologically plausible link between the endocrine activity and the adverse effect”.	
3.11.1.3 An adverse effect is defined in this context as a change in morphology, physiology, growth, development, reproduction or lifespan of an organism, system or (sub)population 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.	Definition from WHO/IPCS Environmental Health Criteria 240, Principles and Methods for the Risk Assessment of Chemicals in Food. Environmental Health Criteria 240: https://apps.who.int/iris/bitstream/handle/10665/44065/WHO_EHC_240_13_eng_Annex1.pdf?sequence=13 (Glossary)
3.11.1.4 An endocrine activity is defined as an interaction with the endocrine system that can potentially result in a response of	Definition from the ECHA/EFSA guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 [2].

[2] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5311

<table>
<tr><td>the endocrine system, target organs and tissues. A substance that has an endocrine activity has the potential to alter the function(s) of the endocrine system.</td><td></td></tr>
<tr><td>3.11.2 Classification criteria for substances</td><td></td></tr>
<tr><td>3.11.2.1 Hazard categories
For the purpose of classification for endocrine disrupting properties for human health, substances are allocated to one of two categories based on strength of evidence and additional considerations in a weight of evidence approach.</td><td></td></tr>
<tr><td>Table 3.11.1
Hazard categories for endocrine disruptors for human health
<table><tr><th>Categories</th><th>Criteria</th></tr><tr><td>CATEGORY 1</td><td>Known or presumed endocrine disruptors for human health

A substance is classified in Category 1 for endocrine disrupting properties for human health if it is known or presumed to meet the criteria defined in 3.11.1.2.

The classification in Category 1 is based on evidence from human and/or on data from animal studies. Such data shall provide clear evidence of an adverse effect, endocrine activity and that the adverse effect is a consequence of the endocrine activity.

However, when there is information that raises doubt about the relevance of the endocrine disrupting mode of action for humans, classification in Category 2 may be more appropriate.</td></tr></table></td><td>Wording adapted from Repro. 3.7.2.1.1 (Table 3.7.1(a))</td></tr>
</table>

CATEGORY 2	Suspected endocrine disruptors for human health A substance is classified in Category 2 for endocrine disrupting properties for human health when there is some evidence of an adverse effect, which is a consequence of the endocrine activity, and where the evidence is not sufficiently convincing to place the substance in Category 1.	Wording adapted from Repro. 3.7.2.1.1 (Table 3.7.1(a))
Where there is evidence demonstrating that the adverse effects identified are not relevant to humans, the substance should not be considered an endocrine disruptor for human health.		
3.11.2.2 Basis of classification		
Classification is made on the basis of the appropriate criteria, outlined above, and an assessment of the total weight of evidence (see 1.1.1). Classification as an endocrine disruptor for human health is intended to be used for substances which have an intrinsic, specific property to produce an endocrine-related adverse effect. Endocrine-related adverse effects shall have been observed in the absence of other toxic effects, or if occurring together with other toxic effects the endocrine-related adverse effect is considered not to be solely secondary non-specific consequence of the other toxic effects.		Wording adapted from Repro 3.7.2.2.1
3.11.2.3 Weight of evidence		
Classification as an endocrine disruptor for human health is made on the basis of an assessment of the total weight of evidence, see section 1.1.1. This means that all available relevant scientific data (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro, or, if applicable, in silico		Wording adapted from Repro 3.7.2.3.1 For further information, please refer to ECHA/EFSA guidance on in silico prediction methods and read-across approaches and categories (page 52-53)

studies and data from analogous substances using structure-activity relationship (SAR), informing about endocrine modes of action) are considered together, including peer-reviewed published studies and additional acceptable data.	"peer-reviewed …" from Carc. 3.6.2.2.1
In applying the weight of evidence determination, the assessment of the scientific evidence 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 mode of action; (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;	
Using a weight of evidence approach, the link between the adverse effect(s) and the endocrine activity shall be established based on biological plausibility, which shall be determined in the light of current scientific knowledge.	
Evidence used for the classification of a substance as an endocrine disruptor for the environment in section 4.2 should be considered to assess the classification of the substance as endocrine disruptor for human health in the current section 3.11.	
3.11.2.4 [List of evidences that can be used for classification]	This is a placeholder for a future list of evidence that can be used in the weight of evidence to assess the classification. This list will be developed in a second step on the basis of the discussion on the hazard categories.

3.11.2.5 Evidence considered not to support classification for endocrine disruption It is recognised that evidence may be seen in humans, animals and/or in vitro that do not justify classification. Such effects include, but are not limited to: (a) evidence on adversity, endocrine activity or biological plausibility such as i. the available information is sufficient to postulate a non - endocrine MoA where an endocrine MoA can conclusively be excluded; ii. the structural or functional relationship between the KEs is not understood and considered unplausible. (b) substance-induced species-specific mechanisms of toxicity, i.e. demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.	
3.11.3 Classification criteria for mixtures	Wording from Repro
3.11.3.1 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture	Wording from Repro
3.11.3.1.1 The mixture shall be classified as an endocrine disruptor for human health when at least one ingredient 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.	Wording adapted from Repro
Table 3.11.2	Wording adapted from Repro

<table>
<tr><td colspan="2">Generic concentration limits of ingredients of a mixture classified as endocrine disruptor for human health that trigger classification of the mixture</td><td></td></tr>
<tr><td colspan="2"><table>
<tr><td rowspan="2">Ingredient classified as:</td><td colspan="2">Generic concentration limits triggering classification of a mixture as:</td></tr>
<tr><td>Category 1 endocrine disruptor for human health</td><td>Category 2 endocrine disruptor for human health</td></tr>
<tr><td>Category 1 endocrine disruptor for human health</td><td>≥ 0.1 %</td><td></td></tr>
<tr><td>Category 2 endocrine disruptor for human health</td><td></td><td>≥ 1 %</td></tr>
</table>
Note: The concentration limits in Table 3.11.2 apply to solids and liquids (w/w units) as well as gases (v/v units).</td><td>Wording adapted from Carc.
This table defines the GCL (Generic Concentration Limit). However SCL (Specific Concentration Limit) could be set on a case-by-case basis.</td></tr>
<tr><td colspan="2">3.11.3.2 Classification of mixtures when data are available for the complete mixture</td><td>Wording from Repro</td></tr>
<tr><td colspan="2">3.11.3.2.1 Classification of mixtures will be based on the available test data for the individual ingredients of the mixture using concentration limits for the ingredients classified as endocrine disruptor for human health. On a case-by-case basis, test data on mixtures may be used for classification when demonstrating effects that have not been established from the evaluation based on the individual ingredients. 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 endocrine disrupting test systems. Adequate documentation supporting the classification shall be retained and made available for review upon request.</td><td>Wording adapted from Repro</td></tr>
</table>

<table>
<tr><td>3.11.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles</td><td>Wording from Repro</td></tr>
<tr><td>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 ingredients and similar tested mixtures (subject to paragraph 3.11.3.2.1) to adequately characterise the hazards of the mixture, these data shall be used in accordance with the applicable bridging rules set out in section 1.1.3.</td><td>Wording adapted from Repro</td></tr>
<tr><td>3.11.4 Hazard Communication</td><td>Wording from Repro</td></tr>
<tr><td>3.11.4.1 Label elements shall be used in accordance with Table 3.11.3, for substances or mixtures meeting the criteria for classification in this hazard class.</td><td>Wording from Repro</td></tr>
<tr><td>Table 3.11.3
Label elements of endocrine disrupting properties for human health</td><td>Wording adapted from Repro</td></tr>
<tr><td>
<table>
<tr><td>Classification</td><td>Category 1</td><td>Category 2</td></tr>
<tr><td>Symbol/pictogram</td><td>  </td><td>  </td></tr>
<tr><td>Signal Word</td><td>Danger</td><td>Warning</td></tr>
<tr><td>Hazard Statement</td><td>EUHXXX: May cause endocrine-related adverse effects on human health</td><td>EUHXXX: Suspected of causing endocrine-related adverse effects on human health</td></tr>
<tr><td>Precautionary Statement Prevention</td><td>P201
P202
P260</td><td>P201
P202
P260</td></tr>
</table>
</td><td>Table based on “ozone layer” hazard class before entering into GHS: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008R1272-20101201 Section 5.1

EUH statement based on similar wording as Carc.

P Statements adapted from Repro.
P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and</td></tr>
</table>

	P263 P264 P270 P280	P263 P264 P270 P280	understood. P260: Do not breathe dust/fume/gas/mist/vapours/spray. P263: Avoid contact during pregnancy and while nursing. P264: Wash … thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P280: Wear protective gloves/protective clothing/eye protection/face protection. P308 + P313: IF exposed or concerned: Get medical advice/attention. P405: Store locked up. P501: Dispose of contents/container to …
Precautionary Statement Response	P308 + P313	P308 + P313	
Precautionary Statement Storage	P405	P405	
Precautionary Statement Disposal	P501	P501	

Annex II: Proposal of hazard class for the environment

Text proposal	Comments
4.2 Endocrine disrupting property for the environment	
4.2.1 Definitions and general considerations	
4.2.1.1 Endocrine disruptor means a substance or a mixture of substances that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.	
4.2.1.2 A substance is considered to be an endocrine disruptor if it meets all of the following criteria : (1) it shows an adverse effect in an intact organism or its progeny; (2) it shows endocrine activity; (3) the substance has an endocrine disrupting mode of action, i.e. there is a biologically plausible link between the endocrine activity and the adverse effect".	
4.2.1.3 An adverse effect is defined in this context as a change in morphology, physiology, growth, development, reproduction or lifespan of an organism, system or (sub)population 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.	
3.11.1.4 An endocrine activity is defined as an interaction with the endocrine system that can potentially result in a response of the endocrine system, target organs and tissues. A substance that has an endocrine activity has the potential to alter the function(s) of the endocrine system.	
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 are allocated to one of two categories based on strength of evidence and additional considerations in a weight of evidence approach.

Table 4.2.1

Hazard categories for endocrine disruptors for the environment

Categories	Criteria
CATEGORY 1	Known or presumed endocrine disruptors for the environment A substance is classified in Category 1 for endocrine disrupting properties for the environment if it is known or presumed to meet the criteria defined in 4.2.1.2. The classification in Category 1 is based on evidence from human and/or on data from animal studies. Such data shall provide clear evidence of an adverse effect that is relevant for the (sub-)population level and which is a consequence of the endocrine activity. However, when there is information that raises doubt about the relevance of the effect for the (sub-)population level, classification in Category 2 may be more appropriate.
CATEGORY 2	Suspected endocrine disruptors for the environment A substance is classified in Category 2 for endocrine disrupting properties for the environment when there is some evidence of an adverse effect that is relevant for

	the (sub-)population level and which is a consequence of the endocrine activity, and where the evidence is not sufficiently convincing to place the substance in Category 1.	
~~Where there is evidence demonstrating that the adverse effects identified are not relevant at the (sub)population level for non-target organisms, the substance should not be considered an endocrine disruptor for the environment.~~		This paragraph coming from PPP criteria is not relevant for a horizontal system in CLP.
4.2.2.2 Basis of classification		
Classification is made on the basis of the appropriate criteria, outlined above, and an assessment of the total weight of evidence (see 1.1.1). Classification as an endocrine disruptor for the environment is intended to be used for substances which have an intrinsic, specific property to produce an endocrine-related adverse effect. Endocrine-related adverse effects shall have been observed in the absence of other toxic effects, or if occurring together with other toxic effects the endocrine-related adverse effect is considered not to be solely secondary non-specific consequence of the other toxic effects.		
4.2.2.3 Weight of evidence		
Classification as an endocrine disruptor for the environment is made on the basis of an assessment of the total weight of evidence, see section 1.1.1. This means that all available relevant scientific data (in vivo studies or adequately validated alternative test systems predictive of adverse effects in humans or animals; as well as in vivo, in vitro, or, if applicable, in silico studies and data from analogous substances using structure-activity relationship (SAR), informing about endocrine modes of action) is		

considered together, including peer-reviewed published studies and additional acceptable data.	
In applying the weight of evidence determination, the assessment of the scientific evidence 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 (sub-)population level, and for the assessment of the endocrine mode of action; (c) the adverse effects on reproduction, growth/development, and other relevant adverse effects which are likely to impact on (sub-)populations. Adequate, reliable and representative field or monitoring data and/or results from population models shall as well be considered where available; (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; (f) the concept of the limit dose, and international guidelines on maximum recommended doses and for assessing confounding effects of excessive toxicity;	
Using a weight of evidence approach, the link between the adverse effect(s) and the endocrine activity shall be established based on biological plausibility, which shall be determined in the light of current scientific knowledge.	
Evidence used for the classification of a substance as an endocrine disruptor for human health in section 3.11 should be considered to assess the classification of the substance as endocrine disruptor for the environment in the current section 4.2.	

4.2.2.4 [List of evidences that can be used for classification]	This is a placeholder for a future list of evidence that can be used in the weight of evidence to assess the classification. This list will be developed in a second step on the basis of the discussion on the hazard categories.
4.2.2.5 Evidence considered not to support classification for endocrine disruption It is recognised that evidence may be seen in humans, animals and/or in vitro that do not justify classification. Such effects include, but are not limited to: (a) evidence on adversity, endocrine activity or biological plausibility such as i. the available information is sufficient to postulate a non - endocrine MoA where an endocrine MoA can conclusively be excluded; ii. the structural or functional relationship between the KEs is not understood and considered unplausible. (b) substance-induced species-specific mechanisms of toxicity, i.e. demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.	
4.2.3 Classification criteria for mixtures	
4.2.3.1 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture	
4.2.3.1.1 The mixture shall be classified as an endocrine disruptor for the environment when at least one ingredient 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 ingredients of a mixture classified as endocrine disruptor for the environment that trigger classification of the mixture

Ingredient 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 Table 4.2.2 apply to solids and liquids (w/w units) as well as gases (v/v units).

4.2.3.2 Classification of mixtures when data are available for the complete mixture

4.2.3.2.1 Classification of mixtures will be based on the available test data for the individual ingredients of the mixture using concentration limits for the ingredients classified as endocrine disruptor for the environment. On a case-by-case basis, test data on mixtures may be used for classification when demonstrating effects that have not been established from the evaluation based on the individual ingredients. 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 endocrine disrupting test systems. Adequate documentation supporting the classification shall be retained and made available for review upon request.

<table>
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<tr><td>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 ingredients and similar tested mixtures (subject to paragraph 4.2.3.2.1) to adequately characterise the hazards of the mixture, these data shall be used in accordance with the applicable bridging rules set out in section 1.1.3.</td><td></td></tr>
<tr><td>4.2.4 Hazard Communication</td><td></td></tr>
<tr><td>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.</td><td></td></tr>
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<tr><td>Hazard Statement</td><td>EUHXXX: May cause endocrine-related adverse effects on the environment</td><td>EUHXXX: Suspected of causing endocrine-related adverse effects on the environment</td></tr>
<tr><td>Precautionary Statement Prevention</td><td>P273</td><td>P273</td></tr>
</table>
</td><td>P Statements from long-term (chronic) aquatic hazard.
P273: Avoid release to the environment.</td></tr>
</table>

Precautionary Statement Response	P391	P391	P391: Collect spillage. P501: Dispose of contents/container to …
Precautionary Statement Storage			
Precautionary Statement Disposal	P501	P501	