REVISION OF THE CLP REGULATION

Comments on the Commission proposal for the revision of CLP and suggestions for additional amendments to improve protection of people's health and the environment

May 12, 2023

GENERAL COMMENTS

The European Environmental Bureau (EEB) welcomes the Commission proposal on the revision of the CLP regulation (Regulation 1272/2008). **The proposal presented by the Commission supports the toxic-free environment vision of the European Green Deal and the Chemicals Strategy for Sustainability (CSS).** Therefore, we call on the European Parliament and the Council to adopt the revision of the CLP regulation as a matter of urgency, during the mandates of this Commission and Parliament.

The EEB also highly appreciates the draft compromise proposals by the Swedish Presidency. These proposals will contribute to greater clarity on how to classify and label hazardous substances and mixtures and will increase legal certainty. However, we do see opportunities for further strengthening of the CLP regulation and we do hope that **Member States will show more ambition to increase the protection of people and the environment** against hazardous chemicals through the Council proposal. Please find below our proposals for improving the CLP regulation in this respect.

The proposals include amendments to:

- Expand the scope of CLP to cover environmental hazards of cosmetics (art 1.5)
- Remove the new definition of multi-constituents (art 2)
- Remove the escape clause for classification of MOCS (art 5.3)
- Use data on the whole mixture for classification if they demonstrate persistent, mobile or bioaccumulation properties (like already stipulated for CMR properties) (art 6.4)
- Include the new hazard classes (EDCs, PBT/vPvB, PMT/vPvM) in the product identifier for mixtures (art 18.3)

- Include explicit provision of the use of group approaches in the procedure for harmonization of classification and labelling (art 37.1)
- Introduce time limit for the Commission to act on ECHA's (RAC) opinion (art 37.5)
- Introduce fee for industry requesting a change of existing harmonised classification and labelling (art 37.6)
- Include PMT/vPvMs for the prioritization for harmonised classification and labelling (art 37.7)
- Include deadline for the harmonised classification and labelling of already identified SVHCs (art 37.8)
- Introduce new article on access to justice
- Promote the development of criteria for neurotoxic and immunotoxic chemicals (art 53.2)
- Include gender equality in the CLP regulation (recital 39)

PROPSALS FOR ADDITIONAL AMENDMENTS TO THE COMMISION PROPOSAL:

The changes from the Commission proposal (or CLP 1272/2008 text) are marked in ***bold italics*** for additions and ~~**striked through**~~ for deletions.

Article 1.5 - Scope of CLP regulation

Ref.	Regulation 1272/2008	EEB proposed amendments
1.5	5. This Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user: (a) medicinal products as defined in Directive 2001/83/EC; (b) veterinary medicinal products as defined in Directive 2001/82/EC; (c) cosmetic products as defined in Directive 76/768/EEC;	5. This Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user: (a) medicinal products as defined in Directive 2001/83/EC; (b) veterinary medicinal products as defined in Directive 2001/82/EC; (c) cosmetic products as defined in Directive 76/768/EEC ***for human health hazard classes***;
	Justification	
Extent the scope of the CLP regulation to cover environmental hazards of cosmetics. The Cosmetics regulation does not cover environmental hazards. Therefore, these hazards should be covered within the scope of CLP (in analogy with the REACH regulation).		

Article 2 - Definitions - delete new definition multi-constituents

Ref.	Commission proposal	EEB proposed amendments
(2)	(2) in Article 2, the following points 7a and 38 are added: '7a. 'multi-constituent substance' means a substance that contains more than one constituent.	(2) in Article 2, the following point~~s 7a and~~ 38 ~~are~~ ***is*** added: ~~***'7a. 'multi-constituent substance' means a substance that contains more than one constituent.***~~
	Justification	

Delete the new definition for multi-constituent substances. This definition is not in line with REACH and ECHA guidance.

Article 5.3 - Hazard classification of substances with more than one constituent

Ref.	Commission proposal	EEB proposed amendments
(4)	(4) in Article 5, the following paragraph 3 is added: '3. A multi-constituent substance containing at least one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance, unless Annex I lays down a specific provision.	(4) in Article 5, the following paragraph 3 is added: '3. A substance containing ***more than*** ~~***at least***~~ one constituent, in the form of an individual constituent, an identified impurity or an additive for which relevant information referred to in paragraph 1 is available, shall be examined in accordance with the criteria set out in this paragraph, using the available information on those constituents as well as on the substance~~***, unless Annex I lays down a specific provision***~~.
	Justification	
The newly introduced derogation "unless Annex I lays down a specific provision" is vague and not consistent with the criteria for the classification of mixtures set in Article 6, nor with the information provided in recitals 2 and 3. More-over a derogation for setting specific concentration limits is already granted in article 10.1 based on "adequate, reliable and conclusive scientific information". In case the Council prefers to keep the proposed provision in Annex I, an explanatory note should be added to Recital (2) specifying that derogations can be granted only in exceptional circumstances based on adequate, reliable and conclusive scientific information. In that scenario, the third paragraph of article 10.1 can be removed.		

Article 6.4 - Mixture classification - use of information on persistent, mobile and bioaccumulation properties

Ref.	Commission proposal	EEB proposed amendments
(5)	(5) in Article 6, paragraphs 3 and 4 are replaced by the following: [...] 4. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very persistent and very	(5) in Article 6, paragraphs 3 and 4 are replaced by the following: [...] 4. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'biodegradation, persistency, mobility and bioaccumulation' properties within the 'hazardous to the aquatic environment', 'persistent, bioaccumulative and toxic', 'very persistent and very bioaccumulative', 'persistent, mobile and toxic' and 'very

	mobile' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself ';	persistent and very mobile' hazard classes referred to in sections 4.1.2.8, 4.1.2.9, 4.3.2.3.1, 4.3.2.3.2, 4.4.2.3.1 and 4.4.2.3.2 of Annex I, the manufacturer, importer or downstream user shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture and not for the mixture itself '; ***However, where the available test data on the mixture itself demonstrates persistent, mobile or bioaccumulation properties which have not been identified from the relevant available information on the individual substance referred to in the first subparagraph, that data shall also be taken into account for the purposes of the evaluation of the mixture referred to in the first subparagraph.***
Justification		
Add new paragraph 2 to article 6.4, in analogy with paragraph 2 of article 6.3. Information on the whole mixture that demonstrates persistent, mobile or bioaccumulation properties, should be taken into account for the classification of the mixture. in analogy with article 6.3 paragraph 2 for CMR properties, article 5.3 for PMB properties and recital (3).		

Article 18.3 - Introduce new hazard classes

Ref.	Regulation 1272/2008	EEB proposed amendments
	3. The product identifier for a mixture shall consist of both of the following: (a) the trade name or the designation of the mixture; (b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard.	3. The product identifier for a mixture shall consist of both of the following: (a) the trade name or the designation of the mixture; (b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT), aspiration hazard, ***endocrine disruption for human health, endocrine disruption for the environment, persistent, bioaccumulative and toxic, very persistent, very bioaccumulative, persistent, mobile and toxic, or very persistent and very mobile properties.***

	Justification
	The product identifier for a mixture shall also consist of the identity of the substances belonging to the newly introduced hazard classes for endocrine disruption, and PBT/vPvB, PMT/vPvM hazard classes.

Article 37.1 – Harmonisation of classification & labelling - use of group approach

Ref.	Commission proposal	EEB proposed amendments
(18)	(18) Article 37 is amended as follows: (a) paragraph 1 is replaced by the following: '1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The Commission may ask the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC) No 178/2002* to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The Commission may subsequently submit the proposal to the Agency.	(18) Article 37 is amended as follows: (a) paragraph 1 is replaced by the following: '1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of ***a*** substance~~s~~ ***or group of substances*** and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The Commission may ask the Agency or the European Food Safety Authority established in accordance with Article 1(2) of Regulation (EC) No 178/2002* to prepare a proposal for harmonised classification and labelling of ***a*** substance~~s~~ ***or group of substances*** and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof. The Commission may subsequently submit the proposal to the Agency.
	Justification	
	Promote the harmonisation of classification and labelling based on group considerations. The current approach of dealing with substances one-by-one takes too much time and should be replaced by using group approaches. The use of group approaches for harmonised classification & labelling allows to improve protection of public health and the environment, while reducing the need for animal tests, increasing consistency, predictability, and preventing regrettable substitution. The Commission proposed to add the possibility to initiate harmonised classification and labelling proposals for several substances at once by replacing the references to 'substance' by 'substances'. We call for the introduction of an explicit and strong clarification to promote and prioritise the use of group approaches in article 37 for the purpose of harmonised classification and labelling by the authorities, to provide legal certainty.	

Article 37.5 - Harmonised classification and labelling - deadline for COM to act

Ref.	Commission proposal	EEB proposed amendments
(18)	(e) paragraphs 5 and 6 are replaced by the following:	(e) paragraphs 5 and 6 are replaced by the following:

	'5. The Commission shall adopt without undue delay, delegated acts in accordance with Article 53a to amend Annex VI by inclusion of substances together with the relevant classification and labelling elements and, where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI.	'5. The Commission shall adopt ~~**without undue delay**~~ ***within 12 months of receipt of the RAC opinion***, delegated acts in accordance with Article 53a to amend Annex VI by inclusion of substances together with the relevant classification and labelling elements and, where appropriate, the specific concentration limits, M-factors or acute toxicity estimates in Table 3 of Part 3 of Annex VI.
	Justification	
Make harmonised classification & labelling faster and more efficient. Put an end to delays in harmonised classification & labelling introduced by the Commission. Article 37.5 allows the Commission to act "without undue delay" after receipt of ECHA's RAC opinion. However, it takes on average 21 months for the Commission to process ECHA's opinion[1]. Almost two-fold longer than the development of the CLH proposals by member states and the development of the opinion by the RAC Committee. Therefore, we propose the introduction of a strict deadline in article 37.5 for the Commission to act after receipt of ECHA's scientific and technical opinion, in analogy with similar provisions in the Cosmetics regulation and REACH. OR alternatively: consider making ECHA responsible for this administrative action, given that CLP is a purely scientific process about the intrinsic properties of chemical substances. The current procedure by the Commission is used by Industry to re-open and repeat the discussion on harmonised classification and labelling, thereby delaying harmonised classification and labelling.		

Article 37.6 - Introduce fee for industry requests for change of existing harmonised classification and labelling

Ref.	Commission proposal	EEB proposed amendments
(18)	(e) paragraphs 5 and 6 are replaced by the following: 6. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market.';	(e) paragraphs 5 and 6 are replaced by the following: 6. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI shall submit a proposal in accordance with paragraph 2, second subparagraph, to the competent authority in one of the Member States in which the substances are placed on the market.'; ***The proposal of the manufacturer, importer or downstream user for a change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI shall be accompanied by the fee determined by the***

[1] The Need for Speed, EEB report, 2022.

		Commission in accordance with the procedure referred to in Article 54(2).
	Justification	
If manufacturers, importers or downstream users who have new information submit a proposal requesting a change of the harmonised classification and labelling elements of substances in Part 3 of Annex VI, such request should be accompanied by a fee to compensate for the costs involved for authorities. (Text suggestion is copied and amended from new art 37.3).		

Article 37.7 - Harmonised classification and labelling of substances already identified as SVHC under REACH (EDC, PBT/vPvB, PMT/vPvM)

Ref.	Commission proposal	EEB proposed amendments
	(f) The following paragraphs 7 and 8 are inserted: '7. The Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI to this Regulation by inclusion of substances as endocrine disruptor category 1 for human health properties, endocrine disruptor category 1 for environment properties, as persistent, bioaccumulative and toxic or as very persistent and very bioaccumulative together with relevant classification and labelling elements where, on … [OP: please insert the date = the *date of entry into force of Commission Delegated Regulation (EU) …i.e. delegated act on the new hazard classes - reference to be added once adopted*], those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006. The inclusion of the substances, referred to in the first subparagraph, in Table 3 of Part 3 of Annex VI to this Regulation shall be carried out on the basis of the respective criteria for which those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.'	(f) The following paragraphs 7 and 8 are inserted: ***By 31 December 2025, t***~~T~~he Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI to this Regulation by inclusion of substances as endocrine disruptor category 1 for human health properties, endocrine disruptor category 1 for environment properties, as persistent, bioaccumulative and toxic**,** ~~or~~ as very persistent and very bioaccumulative**, *as persistent, mobile and toxic, or very persistent and very mobile*** together with relevant classification and labelling elements where, on ***1 January 2025***~~…~~ ~~[OP: please insert the date = the *date of entry into force of Commission Delegated Regulation (EU) …i.e. delegated act on the new hazard classes - reference to be added once adopted*~~], those substances have been included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006.'
	Justification	
	- Prioritise harmonised classification & labelling of Endocrine disrupting and Persistent chemicals that are already identified under REACH. 22 EDCs and 49 Persistent chemicals (PBT/vPvB and PMT/vPvM) are already identified as Substance of Very High Concern (SVHC)	

	under REACH. These substances meet the criteria for the new hazard classes under CLP and we support the obligation for the Commission to adopt delegated acts to amend Annex VI in order to include in Table 3 of Part 3 of that Annex substances already identified under REACH, without redoing an assessment. We propose to include a deadline for their harmonised classification & labelling by delegated act by end of 2025 in article 37.7. - The Commission did not propose the prioritisation of the persistent, mobile and toxic or very persistent and very mobile chemicals (PMT/vPvM). PMT and vPvM chemicals are of very high concern due to carcinogenic, mutagenic, reprotoxic or ED properties in combination with persistence and mobility in the environment, causing irreversible, long-lasting effects and pollution of drinking water resources now and for future generations, across Europe. Therefore, already identified PMT/vPvM chemicals under REACH should also be included in Part 3 of Annex VI in the same way as proposed for EDCs, PBTs and PMTs. We note in this respect that EDCs and PMT/vPvM have the same legal status under REACH (SVHC identification according to article 57(f)). Therefore, we do not see a reason for not prioritising the PMT/vPvM for harmonised classification and labelling.

Article 37.8 Introduce deadline for Harmonised classification and labelling of substances already identified as belonging to the new hazard classes under BPR and PPPR

Ref.	Commission proposal	EEB proposed amendments
	8. The Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI by inclusion of substances together with relevant classification and labelling elements where, on … [OP: please insert the date = *the date of entry into force of Commission Delegated Regulation (EU) …i.e. the delegated act on the new hazard classes - reference to be added once adopted*] those substances have not been approved, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 or have been approved with derogation in accordance with the relevant provisions of those Regulations, due to either of the following characteristics:	8. ***By 31 December 2025, t***~~T~~he Commission shall adopt delegated acts in accordance with Article 53a to amend Table 3 of Part 3 of Annex VI by inclusion of substances together with relevant classification and labelling elements where, on ***1 January 2025***~~… [OP: please insert the date = *the date of entry into force of Commission Delegated Regulation (EU) …i.e. the delegated act on the new hazard classes - reference to be added once adopted*]~~ those substances have not been approved, under Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 or have been approved with derogation in accordance with the relevant provisions of those Regulations, due to either of the following characteristics:
	Justification	
COM added Paragraph 8 to Article 37 to insert an obligation on the Commission to adopt delegated acts to amend Annex VI in order to include in Table 3 of Part 3 of that Annex substances that have not been approved under the Plant Protection Products Regulation and the Biocidal Products Regulation and those that have been approved because they fulfilled the conditions for derogation.		

Article 53.2 - Add provision for development of criteria for neurotoxic and immunotoxic properties

Ref.	Commission proposal	EEB proposed amendments

(26)	(b) paragraph 2 is replaced by the following: '2. The Commission or the Member States acting in the interest of the Union shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as well as for alternative test methods at the level of the UN.';	(b) paragraph 2 is replaced by the following: '2. The Commission or the Member States acting in the interest of the Union shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of endocrine disruptors for human health, endocrine disruptors for the environment, persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as well as ***the development of criteria for immunotoxic and neurotoxic substances and*** for alternative test methods at the level of the UN.';
	Justification	
Development of criteria for specific neurotoxicity and immunotoxicity. The CSS committed to address chemicals with immunotoxic and neurotoxic properties. CLP's hazard class STOT RE cat.1, includes some immunotoxic and neurotoxic substances, but not all are properly covered. In order to promote the future introduction of new specific criteria for neurotoxicity and immunotoxicity, we recommend a new provision to article 53 requiring the development of criteria for classification and labelling of neurotoxic and immunotoxic substances.		

Article 41 - Improve the classification and labelling inventory

Ref.	Commission proposal	EEB proposed amendments
	Article 41 - Agreed entries Where the notification in Article 40(1) results in different entries on the inventory referred to in Article 42 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Agency accordingly.	Article 41 - Agreed entries Where the notification in Article 40(1) results in different entries on the inventory referred to in Article 42 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Agency accordingly. ***Add new paragraph: introducing automatic harmonisation of diverging self-classifications, where the most hazardous self-classification becomes the one harmonised, in case no justification is provided for the divergence as foreseen in the new point (g) under Article 40.***

Justification
Improve the quality and transparency of ECHA's classification & labelling inventory. The classification & labelling inventory is hampered by erroneous, obsolete, and diverging classifications. The introduction of an automatic harmonisation of diverging self-classifications, where the most hazardous self-classification, in case the reason for divergence from the most severe classification is not justified. (as requested under the new point (g) introduced under article 40.1

New Article: Include Access to Justice

Ref.	Commission proposal	EEB proposed amendments
	Justification	
Include a new Article providing access to justice for any natural or legal person. See proposals from the NGO Clientearth		

Recital 39 - Integrate gender issues

Ref.	Commission proposal	EEB proposed amendments
39	(39) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary and the citizens of the Union should benefit from an equal protection of their health and environment and because substances and mixtures should circulate freely on the Union market , but can rather, by reason of their scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,	Since the objectives of this Regulation cannot be sufficiently achieved by the Member States, because environmental pollution is transboundary, and the citizens of the Union should benefit from an equal protection of their health and environment. ***Equality of citizens across the Union should also take into account gender equality, recognising that chemical pollution affects gender, ages and sexes differently.*** ~~***and because s***~~ ***Also recognising that s***ubstances and mixtures should circulate freely on the Union market , but can rather, by reason of their scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,
	Justification	
Gender equality should be integrated in the CLP regulation, for example in recital 39 by recognising that equality of citizens across the EU should also take into account gender equality, as chemical pollution can have different effects dependent on gender and age. Women's health is differently		

impacted by chemicals. Physiological, anatomic, and other biologic differences influence susceptibility to chemicals. Many examples are reported in a joint report by WECF and EEB[2]. For example, different body composition results in a higher capacity of women to accumulate toxic chemicals as women have higher average body fat percentage than men. Women and men have different metabolism and intestinal microbiota and therefore, different capacities to absorb and metabolise chemicals. Different hormone systems with higher levels of oestrogens result in higher susceptibility to exposure to xenoestrogens such as plastic ingredients and pesticides. Therefore, legal provisions should be introduced in CLP to properly address the differences in biological sex and age and their implications for variation in potential effects that must be considered in the hazard assessment.

4. Contacts

tatiana.santos@eeb.org
helene.loonen@eeb.org

[2] https://eeb.org/wp-content/uploads/2021/07/Report-16.pdf