AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Proposal for amendments on the revision of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)

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.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

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European Chemicals Agency (ECHA) resources

European Commission proposal	Proposed amendment
[NEW] Recital 36 (a)	
[NEW]	***This revision regulation expands the tasks and remit of the Agency. In order to provide adequate expertise, support and thorough evaluations, the resources of the Agency should be enhanced.***
Justification: ECHA should be granted sufficient resources to properly navigate the added workload detailed on this regulation.	
[NEW] Recital 36 (b)	
[NEW]	***The ECHA Founding Regulation shall take account of these needs.***
Justification: These needs should be clearly reflected in the envisaged standalone ECHA Founding Regulation.	
Article 1 (5) [NEW] [regarding Article 6 (4) of Regulation (EC) No 1272/2008]	
[NEW]	***The Agency shall develop robust and timely guidance to support the abovementioned evaluations.*** ***Once the Guidance is adopted, the abovementioned criteria shall begin to apply.*** ***The Agency shall be provided with the adequate resources to support this work. The ECHA Founding Regulation shall take account of these needs.***
Justification: ECHA should be granted sufficient resources to properly perform the added workload, including the introduction of new hazard classes, as well as the production of clear and robust guidance to support the evaluation of mixtures. This should be clearly reflected in the envisaged standalone ECHA Founding Regulation.	
Article 1 (7) [regarding Article 10(9) of Regulation (EC) No 1272/2008]	
9. The Agency shall provide further guidance for the application of paragraphs 1, 2 and 3.	9. The Agency shall provide further guidance for the application of paragraphs 1, 2 and 3. ***The Agency shall be provided with the adequate resources to support this work. The ECHA***

	Founding Regulation shall take account of these needs.
Justification: ECHA should be granted sufficient resources to produce clear and robust guidance to support this work. This should be clearly reflected in the envisaged standalone ECHA Founding Regulation.	
Article 1 (18) [regarding Article 37 of Regulation (EC) No 1272/2008]	
*(*c) the following paragraph 2a is inserted*:* *'*2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling and, in the case of the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal.	*(*c) the following paragraph 2a is inserted*:* *'*2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling and, in the case of the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal. ***The Agency shall be provided with the adequate resources to support this work. The ECHA Founding Regulation shall take account of these needs.*** […].';
Justification: This right of initiative will create more work for ECHA, and it should therefore be granted sufficient resources to carry out these tasks. This should be clearly reflected in the envisaged standalone ECHA Founding Regulation	
Article 1 (22) [regarding Article 45 of Regulation (EC) No 1272/2008]	
Article 45 is amended as follows: (c) in paragraph 2, point (b) is replaced by the following: '(b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed.';	Article 45 is amended as follows: c) in paragraph 2, point (b) is replaced by the following: '(b) where requested by a Member State, the Commission or the Agency, to undertake a statistical analysis to identify where improved risk management measures may be needed. ***The Agency shall be provided with the adequate resources to support this work. The ECHA Founding Regulation shall take account of these needs.'***;
Justification: Member States may appoint ECHA as the body responsible for receiving information relating to emergency health response and preventative measures. ECHA therefore should be granted sufficient resources to carry out these tasks. This should be clearly reflected in the envisaged standalone ECHA Founding Regulation.	

Article 1 (25) [regarding Article 50 of Regulation (EC) No 1272/2008]	
(b) the following paragraph 3 is added: '3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures.'	(b) the following paragraph 3 is added: '3. Where the Agency acts as an appointed body in accordance with Article 45(1a), it shall put in place the tools necessary to provide access to the information to the relevant appointed body or bodies of the appointing Member State to fulfil their tasks with regard to emergency health response and preventative measures. ***The Agency shall be provided with the adequate resources to support this work. The ECHA Founding Regulation shall take account of these needs.'***
Justification: Article 50 as foreseen provides for the possibility to designate the Agency as the appointed body to receive relevant information for emergency health responses under Article 45. It further tasks the Agency with ensuring the availability of appropriate tools to share information with national appointed authorities so they fulfil their other obligations under Article 45. Therefore ECHA should be granted adequate resources to carry out these tasks.	
Article 1 (29) [regarding Article 54 of Regulation (EC) No 1272/2008]	
Article 54 is replaced by the following: '1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*.'; 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	Article 54 is replaced by the following: '1. The Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011*. ***The committee shall be provided with the adequate resources to support this work. This shall be clearly reflected in The ECHA Founding Regulation.***; 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
Justification: Article 54 references the work of the Agency's Committee for Risk Assessment (RAC). The committee should be provided with adequate resources to carry out future tasks. This should be clearly reflected in the envisaged standalone ECHA Founding Regulation.	

Article 1 (18) [regarding Article 37 of Regulation (EC) No 1272/2008]	
(d) paragraph 3 is replaced by the following: '3. Where the proposal of the manufacturer, importer or downstream user concerns the harmonised classification and labelling of substances in accordance with Article 36(3), it shall be accompanied by the fee determined by the Commission in accordance with the procedure referred to in Article 54(2).'	(d) paragraph***s*** 3 ***and 4 are ~~is~~*** replaced by the following: '3. Where the proposal of the manufacturer, importer or downstream user concerns the harmonised classification and labelling of substances in accordance with Article 36(3), it shall be accompanied by the fee determined by the Commission in accordance with the procedure referred to in Article 54(2). ***4. The Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 and the Agency's Committee for Socio-Economic Analysis set up pursuant to Article 76(1)(d) of Regulation (EC) No 1907/2006 shall adopt opinions on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment on both the proposal and the draft opinions of the Committees. In developing their opinion, the Committees shall ensure a thorough scientific review of any proposal submitted pursuant to paragraphs 1 or 2, following a weight of evidence approach where all available information bearing on the assessment is considered together, including positive and negative results. The Commission, the Agency and Member States shall strive to ensure that members of the Committees have the necessary expertise to assess substances meeting the criteria in Article 36, paragraph 1. Where necessary due to the complexity of the proposal under consideration, the Agency shall be empowered to organise additional meetings of the Committees to discuss specific scientific or technical aspects. These may include discussions with independent scientific experts chosen by the Agency, in consultation with the parties concerned. The Agency shall forward these opinions and any comments to the Commission.'***

Justification:

The proposed new wording in paragraph 4 in Article 37 (Procedure for harmonisation of classification and labelling of substances) would strengthen the thoroughness of the opinion development process of ECHA's committees. Key proposals include:

- Better consultation opportunities on both the harmonised classification dossier and the draft opinions.
- The opportunity for the Socio-Economic Analysis Committee to deliver an opinion, which is particularly important in light of the planned extension of the generic approach to risk management under the Registration, Evaluation, Authorisation and Restriction of Chemicals regulation (REACH).
- Formal opportunities for ECHA to involve independent experts on specific issues.
- More rigorous requirements for the expertise of ECHA committee members.

These changes are necessary due to the increasing complexity and workload from the introduction of new hazard classes, particularly in areas where RAC has yet to develop in-depth expertise (eg persistent, mobile and toxic (PMT), very persistent, very mobile (vPvM) substances and endocrine disruptors). The planned extension of the generic approach to risk management under REACH also warrants including the Committee for Socio-Economic Analysis in the process at the harmonised classification stage.

Grouping

European Commission proposal	Proposed amendment
Recital 18	
(18) Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where such similarity allows for similar classification of all substances in the group. The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances when similar substances can be classified as a group.	(18) Harmonised classification and labelling proposals need not necessarily be limited to individual substances and could cover a group of similar substances, where ~~***such***~~ ***structural*** similarity, ***complemented by similar evidence-based hazard and risk profiles***, allow~~s~~ for similar classification of all substances in the group. ***The grouping process shall be scientifically robust, coherent and transparent for all stakeholders.*** The purpose of such grouping is to alleviate the burden on manufacturers, importers or downstream users, the Agency and the Commission in the procedure for harmonisation of classification and labelling of substances. It also avoids testing of substances when similar substances can be classified as a group.
Justification: Clear scientific criteria must guide the grouping of substances in a harmonisation of classification and labelling procedure. The allowed grouping criteria should be clearly defined as established under REACH. Although chemical structure is the appropriate starting point to consider when grouping substances, it is not conclusive. Similar family names or backbones should not be confused with similar hazard profiles. Grouping based merely on structural similarity may lead to inadequate worst-case classification. Rather, it must be complemented by an assessment of the hazard properties of the group's various substances to identify similarities and differences. The assessment of hazard profiles should be carried out in a Weight of Evidence manner to prioritise actual robust experimental data. All grouping practices must be scientifically robust, coherent and transparent.	
Article 1 (18)(b) [regarding Article 37 of Regulation (EC) No 1272/2008]	
*(*18) Article 37 is amended as follows: (b) in paragraph 2, the first subparagraph is replaced by the following: '2. Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, provided that there is no entry in Part 3	(18) Article 37 is amended as follows: (b) in paragraph 2, the first subparagraph is replaced by the following: '2. Manufacturers, importers or downstream users of substances may submit to the Agency a proposal for harmonised classification and labelling of those substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, provided that there is no entry in Part 3

of Annex VI for such substances in relation to the hazard class or differentiation covered by that proposal.’;	of Annex VI for such substances in relation to the hazard class or differentiation covered by that proposal.’; ***In case of a proposal for harmonised classification and labelling of a group of substances, those substances shall be grouped based on clear and cumulative scientific criteria. These criteria shall include structural similarity and similar evidence-based hazard and risk profiles. The assessment of the hazard and risk profile shall be carried out in a Weight of Evidence manner.***
Justification: Grouping of substances going into a harmonised classification and labelling of a group of substances must be based on clear scientific criteria. The allowed grouping criteria should be clearly defined as established under REACH. Although chemical structure is the appropriate starting point to consider when grouping substances, it is not conclusive. Similar family names or backbones should not be confused with similar hazard profiles. Grouping based merely on structural similarity may lead to inadequate worst-case classification. Rather, it must be complemented by an assessment of the hazard properties of the group's various substances to identify similarities and differences. The assessment of hazard profiles should be carried out in a Weight of Evidence manner to prioritise actual robust experimental data.	
Article 1 (18)(c) [regarding Article 37 of Regulation (EC) No 1272/2008	
(c) the following paragraph 2a is inserted: ‘2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling and, in the case of the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal. Within one week from receipt of the notification, the Agency shall publish the name and, where relevant, the EC and CAS numbers of the substance(s), the status of the proposal and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).	(c) the following paragraph 2a is inserted: ‘2a. Before submitting a proposal to the Agency, a competent authority, manufacturer, importer or downstream user shall notify the Agency of its intention to submit a proposal for harmonised classification and labelling and, in case of the Commission, the request to the Agency or the European Food Safety Authority to prepare such proposal. Within one week from receipt of the notification, the Agency shall publish the name ~~***and, where relevant***~~, the EC and CAS numbers of the substance(s) ***and where relevant***, the status of the proposal and the name of the submitter. The Agency shall update the information on the status of the proposal after completion of each stage of the process referred to in Article 37(4) and (5).

Where a competent authority receives a proposal in accordance with paragraph 6, it shall notify the Agency and provide any relevant information on its reason for accepting or refusing the proposal. The Agency shall share that information with the other competent authorities.’;	Where a competent authority receives a proposal in accordance with paragraph 6, it shall notify the Agency and provide any relevant information on its reason for accepting or refusing the proposal. The Agency shall share that information with the other competent authorities.’;
Justification: The substance(s) subject to regulatory actions must be clearly and individually identified to provide legal certainty and ensure enforcement. In addition, missing identification of group members leaves responsibility for the substances’ correct identification and classification to the industry, which will necessarily result in deviating classifications and runs contrary to the Regulation's harmonised classification objectives. Also, a precise substance identification can support digitalisation.	

Transition times

European Commission proposal	Proposed amendment
Article 1 (12) [regarding Article 30 of Regulation (EC) No 1272/2008]	
Article 30 is replaced by the following: *'Article 30* **Updating information on labels** 1. In case of a change regarding the classification and labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier shall ensure that the label is updated within 6 months after the results of the new evaluation referred to in Article 15(4) were obtained. 2. Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier shall ensure that the label is updated within 18 months after the results of the new evaluation referred to in Article 15(4) were obtained. 3. Paragraphs 1 and 2 shall not apply where a change regarding the classification and labelling of a substance or a mixture was triggered by a harmonised classification and labelling of a substance set out in a delegated act adopted pursuant to Article 37(5) or by a provision set out in a delegated act adopted pursuant to Article 53(1). In such cases, the supplier shall ensure that the label is updated by the date set out in the respective delegated act. 4. The supplier of a substance or mixture that falls within the scope of Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 shall update the label in accordance with those Regulations';	Article 30 is replaced by the following: *'Article 30* **Updating information on labels** 1. In case of a change regarding the classification and labelling of a substance or a mixture, which results in the addition of a new hazard class or in a more severe classification, or which requires new supplemental information on the label in accordance with Article 25, the supplier shall ensure that the label is updated within ***24*** ~~***6***~~ months after the results of the new evaluation referred to in Article 15(4) were obtained. ***Labels on substances and mixtures that have been placed on the market before the change in classification and labelling do not have to be updated.*** 2. Where a change regarding the classification and labelling of a substance or a mixture is required other than that referred to in paragraph 1, the supplier shall ensure that the label is updated within ***24*** ~~***18***~~ months after the results of the new evaluation referred to in Article 15(4) were obtained. ***Labels on substances and mixtures that have been placed on the market before the change in classification and labelling do not have to be updated.*** 3. Paragraphs 1 and 2 shall not apply where a change regarding the classification and labelling of a substance or a mixture was triggered by a harmonised classification and labelling of a substance set out in a delegated act adopted pursuant to Article 37(5) or by a provision set out in a delegated act adopted pursuant to Article 53(1). In such cases, the supplier shall

	ensure that the label is updated by the date set out in the respective delegated act. 4. The supplier of a substance or mixture that falls within the scope of Regulation (EC) No 1107/2009 or Regulation (EU) No 528/2012 shall update the label in accordance with those Regulations’;

Justification:
In many cases, it is not technically feasible to update labels within six months or even 18 months. Industry requires a longer transition period of 24 months to ensure that more complicated label updates can be completed within regulatory deadlines.

For example, in the case of pre-printed labels or packaging with label elements pre-printed on it, having new labels designed, ordered, produced and supplied to production plants can take at least 12 months, if not even longer. A 24-month transition period is necessary to ensure that certain complex label update scenarios are not inadvertently noncompliant.

Additionally, it is necessary to clarify that labels on products which have been placed on the market do not have to be updated. It is impossible for companies to update labels on products that have already been placed on the market and distributed throughout the supply chain.

Advertising

European Commission proposal	Proposed amendment
Article 1 (23) [regarding Article 48 of Regulation (EC) No 1272/2008]	
Article 48 is replaced by the following: *'Article 48* **Advertisement** 1. Any advertisement for a substance classified as hazardous shall indicate the relevant hazard pictogram, the signal word, the hazard class and the hazard statements. 2. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) shall indicate the hazard pictogram, the signal word, the hazard class and the hazard statements.	Article 48 is replaced by the following: *'Article 48* **Advertisement** 1. Any advertisement for ***the sale to the general public of*** a substance classified as hazardous shall ***request the user to 'always read and follow product label information'*** ~~***indicate the relevant hazard pictogram, the signal word, the hazard class and the hazard statements.***~~ 2. Any advertisement for ***the sale to the general public of*** a mixture classified as hazardous or covered by Article 25(6) shall ***request the user to 'always read and follow product label information'*** ~~***indicate the hazard pictogram, the signal word, the hazard class and the hazard statements.***~~
Justification: The advertisement requirements currently proposed would place disproportionate burdens on companies without improving human health and environmental protection. Hazardous substances offered to industrial and professional users must be accompanied by comprehensive safety data sheets. More specific requirements for advertisements should therefore only be directed to the general public. For the general public, a request to 'always read and follow product label information' is a more effective way to draw attention to the hazards and precautionary information on the label. It would also be more efficient to add to advertisements, which would otherwise always need to be updated following changes in labels. This is particularly important as 'any advertisement' covers a broad range of materials, including company websites, television commercials, internet videos, customer presentations, brochures and weekly supermarket circulars, among others. Such advertisements are often not made specifically for jurisdictions subject to the CLP Regulation's provisions on hazard communication. Incorporating CLP label elements into a global promotional video would be confusing to non-EU viewers. The provision may also have unexpected negative consequences. For example, it could lead to deselection by consumers of overall more sustainable products, eg a more concentrated dish soap or laundry detergent carrying a CLP label but providing more resource and energy efficiency.	

Distance sales

European Commission proposal	Proposed amendment
Article 1 (24) [regarding Article 48a of Regulation (EC) No 1272/2008]	
The following Article 48a is added: *'Article 48a* **Distance sales offers** Suppliers placing substances or mixtures on the market through distance sales shall clearly indicate the label elements referred to in Article 17.';	The following Article 48a is added: *'Article 48a* **Distance sales offers** Suppliers placing substances or mixtures on the market through distance sales ***to the general public*** shall clearly indicate the label elements referred to in Article 17.';
Justification: Hazardous substances offered to industrial and professional users must be accompanied by comprehensive safety data sheets. Including a copy of the CLP label in business-to-business ordering systems would therefore not improve human health and environmental protection. In such cases, the label would often be visible to a procurement agent who has no connection to how the purchased hazardous substances and mixtures are used by the employees of the purchasing company. The proposed amendment therefore targets the new requirements for distance sales to the general public.	