VERBAND DER MINERALFARBEN INDUSTRIE

Interpretation aid for the revision of the main text of the CLP Regulation

This brief information highlights the most important changes within the CLP Regulation for VdMi members and is intended to prepare for the upcoming changes and consequences. It should be seen as a supplement to the individual examination of the relevant legal text.

The revision of the CLP-Regulation was already announced by the European Commission in 2020 as part of the "Chemicals Strategy for Sustainability". With numerous measures to protect health and the environment, the CSS is an important part of the European Green Deal and will have a significant impact on companies in our industry sector. Already in Q2 2022, the first steps towards the revision of the CLP-Regulation were taken by the European Commission. The plan of the European Commission was to revise the CLP-Regulation in two parts. A delegated act was used to shortcut the normal procedure and to revise the annex as well as introduce new hazard classes. The main text is being revised by means of the ordinary legislative procedure.

The delegated act

The delegated act was published in April 2023 ((EU) 2023/707) and introduced the 6 new hazard classes. Contrary to the usual procedure, these hazard classes were introduced unilaterally by the EU without them being first incorporated into the UN GHS. The new hazard classes include endocrine disruptors for human health and the environment as well as substances that are persistent (P), bioaccumulative (B), mobile (M) and toxic (T). PBT and vPvB substances are already known from the REACH Regulation and ED substances from the Biocide Regulation. Only the PMT and vPvM substances represent a completely new approach and hazard class.

The following transitional periods apply to the new hazard classes:

- 24 and 42 months for substances: From 1 May 2025 onwards, all new substances placed on the market must be labelled according to the new hazard classes. For substances that were previously available, a sale-off period applies until 1 November 2026. After this date all substances must be classified accordingly.
- 36 and 60 months for mixtures: Similar to substances, there are two transitional periods for mixtures. The cut-off dates for these are 1 May 2026 and 1 May 2028.

The European Commission intends to release a guidance document to help with classification with the new hazard classes. The release is expected in Q4 2024. The classification is based on existing data. Therefore, no new studies need to be carried out initially. Only with the planned revision of the REACH-Regulation new studies and further data may be required. The revision of REACH however is currently on hold.

Adaption of the CLP main text

The second part of the Revision is the Revision of the main text. Unlike the introduction of the hazard classes, this is taking place in the ordinary legislative procedure. A fast compromise was reached in the trilogue negotiations, despite the differing positions of Parliament, Commission and Council. The negotiations ended after a short time on December 5, 2023, and this proposal was adopted by the Commission (DG ENVI) on 11 January 2024 and by Parliament on 23 April 2024. After this a corrigendum text, with minor linguistic adaptations was voted on and later accepted. The Text was published in the Official Journal on 20. November 2024 (2024/2865). From VdMi's perspective, the topic of MOCS, the new labelling requirements and the grouping of substances are particularly important.

New classification rules for substances containing more than one constituent (MOCS) (Article 5)

With the new classification rules for substances containing more than one constituent, the Commission is moving away from the conventional approach to substances. According to the new rule, the procedure for classifying MOCS is similar to the procedure for mixtures. It only applies to certain hazard classes (CMR and the 6 new hazard classes). Existing data on the substance itself is no longer relevant, only components are taken into account. Exceptions are possible for substances of plant origin. This exemption will be reviewed again in 5 years. Further exemptions can be obtained if evidence can be presented to the EU Commission that the procedure is not suitable for this type of substance. This could apply, for example, to complex inorganic pigments (e.g. CICPs).

New requirements for labelling and fixed deadline for updating

The Commission is of the opinion that updating the label following a stricter classification is currently not fast enough. The word „immediately" in the text was replaced by a fixed deadline of 6 months. This deadline applies to updating the label in case of a tightening of the classification and begins as soon as the relevant information has been received. In other cases, a period of 18 months is provided (Article 30).

The Commission´s trend of underpinning everything with fixed values continues with the future requirements for the shape of the label. In addition to general requirements such as how the label is attached to a container, the font size, spacing and background are assigned minimum values depending on the container size (Annex 1.2.1).

Container size	Dimension label (mm)	Dimension pictograms (mm)	Minimum font size (x-height in mm)
No more than 3 litres	If possible, at least 52 x74	Not smaller than 10x10 If possible at least 16x16	For containers smaller 0,5 litres: 1,2 For containers 0,5 – 3 litres: 1,4
3 – 50 litres	At least 74x105	At least 23x23	1,8
50 – 500 litres	At least 105x148	At least 32x32	2,0
> 500 litres	At least 148x210	At least 46x46	2,0

The digital label is on its way

The digital label (Article 34) is coming. The VdMi has long campaigned for the introduction of a digital label, which should provide relief for smaller containers in particular. However, it has been decided that the digital label should only be used as an addition. Safety relevant information must continue to be present on the physical label. The digital label can therefore only be used for additional information; this means that it is not helpful for the tight space of small containers which are commonly used for artist and school colours. With this the digital label loses its appeal, especially as relatively high demand is placed on the digital infrastructure and the digital storage of the contents of the corresponding labels.

The use of folded labels, on the other hand, is more supported by the Commission. The use of such labels is possible without major restrictions. Original regulations on the language on the front of the label have been revised. Therefore, a universal label with any language on the front is now possible. This makes it easier to use in all European countries, as it is no longer necessary to produce a separate label for each country depending on the national language (Annex 1.2.1.6). However, hazard labelling and safety-related information must be placed on the first and last page.

Grouping of substances and ATPs (Article 37)

Until now, national authorities have been able to submit dossiers for a harmonized classification of substances or groups of substances. In addition, the European Commission now has the right to request ECHA and EFSA to prepare a proposal for classification. ECHA and EFSA can support this process by providing the Commission with scientific data and recommendations. The grouping of substances must be justified on the basis of scientific data. However, the factors used for grouping are still open to interpretation as currently authorities mainly use structural similarities for grouping.

The publication of ATPs is also to be accelerated. The new CLP-Regulation aims to shorten the current process and publish the ATPs by the end of the following calendar year at the latest.

In order to avoid duplication in work, the Commission is given the right to include substances already identified under REACH and the Biocide Regulation, with the classification relevant properties of the new hazard classes, in Part 3 of Annex VI (harmonized classification) by means of a delegated act.

Classification and labelling inventory (Article 42)

The Commission has decided to add further data to the classification and labelling inventory as well as tidy up. The date of the last update and the identity of the notifier are to be added in the future. In addition, the reason for a deviation from the highest classification should be given, as well as the reason for a higher classification (Article 40). In order to tidy up the inventory, ECHA has been given the right to inform the notifier of old, incomplete or incorrect entries. If these are not subsequently updated, it is possible for these entries to be removed.

Advertising (Article 48)

Advertising in its various forms is a way of marketing a product and bringing it to the customer. However, the Commission believes that advertising should follow certain rules. It was therefore decided that advertising for each product should include the relevant pictograms, signal words, H-phrases and any EUH-phrases. If the product can be purchased directly by the consumer, the

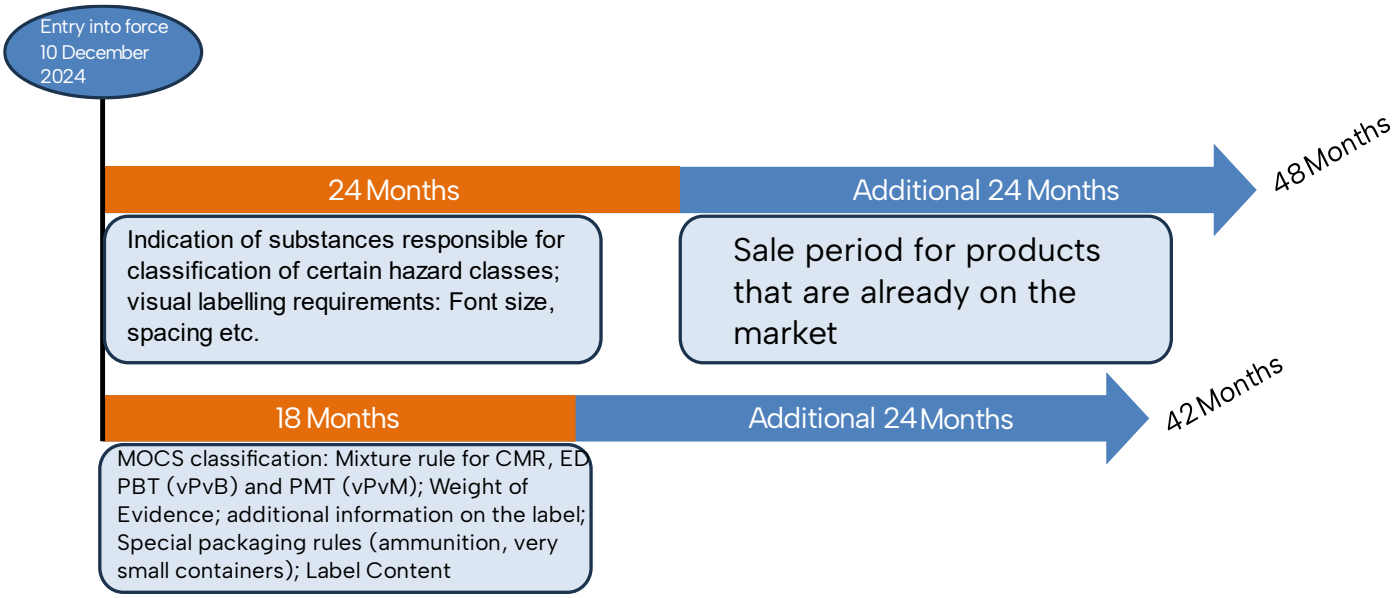
sentence *"Always follow the information on the product label"* must also be included. These requirements include catalogues but also flyers handed out at trade fairs. These requirements apply in particular to online retail, where the classifications must be clearly recognizable. Special exceptions apply to non-visual advertising, e.g. radio.

In addition to the safety instructions, special terms may be no longer used for classified substances or products containing these. These include, for example, "non-toxic", "harmless" or "ecological". This measure is already a first step towards the Green Claims Regulation announced by the Commission.

Additional hazard classes (Article 53)

Following the outcry from industry and justified criticism of the unilateral introduction of new hazard classes within Europe, the Commission is trying to do better with other new hazard classes. While it is too late for the 6 hazard classes already introduced by the delegated act and the introduction into the GHS taking more time, the Commission is taking the right path for hazard classes for neurotoxicology and immunotoxicology. For these two newly planned hazard classes, it has been decided that the Commission will first introduce them into the GHS and then transfer them to the CLP-Regulation.

Transition periods for labelling and classification elements



VERBAND DER MINERALFARBEN INDUSTRIE

Further transitional periods and references

18 months after the 1st of the month following entry into force	24 months after the 1st of the month following entry into force
Article 5: MOCS Article 6: New Approach Methods Article 9: Weight of Evidence und Bridging Article 10: Concentration limits, M-factor and acute toxicity Article 25: Requirements for additional information on the label Article 29: Special rules for very small and special containers, as well as no packaging and ammunition Article 30: Label-Update Article 31: Requirements for folding and digital labels Article 34: Digital label Article 35: Refill requirements Article 40: Reason for deviation from classification Article 42: Cleaning up and new data in the C&L Inventory Article 48: Advertisement Article 50: ECHA's task and funding Annex I: Requirements for folding label Label on inner packaging Label elements digital label Annex II: Refill	Article 18: New hazard classes in product identifiers Article 31: Label requirements and features Article 45: ECHA can become the contact point for health emergencies and prevention; can receive all the data needed to fulfil this task Annex I: Label requirements: Font size, symbol size and more Annex III: Dossiers for harmonised classification

The Verband der Mineralfarbenindustrie e. V. represents German manufacturers of inorganic (e. g. titanium dioxide, iron oxides), organic and metallic pigments, fillers (e. g. silica), carbon black, ceramic and glass colours, food colourants, artists' and school paints, masterbatches and products for applied photocatalysis.

The VdMi is listed in the Lobbying Register for the Representation of Special Interests vis-à vis the German Bundestag and the Federal Government (Lobbyregister des Deutschen Bundestags, number R000760) as well as in the Transparency Register of the EU Commission (number 388728111714-79).

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