Translation: Original German, 15 March 2016

Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular CLP and related legislation

Issues and examples from the viewpoint of Verband der Chemischen Industrie (VCI, the association of the German chemical industry)

Since 1 June 2015 the classification, labelling and packing of substances and mixtures at their placing on the market is governed exclusively by the CLP Regulation (REGULATION (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures). The changeover to the CLP Regulation was a major effort for the manufacturers of mixtures, because labels, safety data sheets and all product information had to be adapted to the new labelling rules and changed to the new classification criteria and calculation methods. The new system also changes the elements of hazard communication, and the changed classification criteria, concentration limits and calculation methods can lead to new and tighter classifications and labelling.

The above results in shifts in the reference base for a multitude of legal acts that are directly and automatically linked to classifications. Thus, the regulatory consequences change with the new requirements, also where the data situation of a substance remains the same.

Concerns and uncertainties due to tighter labelling are noted for products for private consumers, especially because of the symbolism “corrosive” instead of the familiar St Andrew’s cross. For example, with the implementation of the GHS (Globally Harmonised System of Classification and Labelling of Chemicals) the general concentration limits for the classification of mixtures – as regards irritant and corrosive effects on skin and eyes – were lowered considerably in the CLP Regulation. In consequence, for formal reasons mixtures that remain unchanged in their composition need to be classified with a more severe hazard and labelled with the matching hazard pictograms and hazard statements. This leads to a situation where consumers assume the existence of new hazards because of more labelling – even though the risk has not

changed. Moreover, inflationary labelling on products can have a "habituation effect", i.e. labelling has no longer the intended effect of a warning. [1]

Harmonised classification and labelling of substances (Annex VI, part 3 of the CLP Regulation) increasingly concern substances with a very wide range of uses, so that the automatic legal consequences have deep impacts into the supply chains and bring extreme challenges, especially for small and medium-sized enterprises (SMEs). Classification decisions should not result in established and safely used substances being no longer available or to disproportionate requirements in occupational health and safety and environmental protection.

Regarding the implementation and putting into practice of the CLP Regulation, we would highlight, in particular, the following issues and problems:

1. No automatic linking of classification under CLP with legal consequences in connected pieces of legislation

The classification of a substance or a mixture is of considerable influence on further legal fields in EU-wide and national legislation. Many legal fields resort to the classification and labelling system when specific measures are to be laid down. Therefore, tightenings in classification lead to tightenings in these numerous legal fields that refer to classification – usually and automatically. The ensuing consequences can be, for example, the costly retrofitting of plants or marketing restrictions and bans. The existing automatism of referring to classification gives no consideration to the fact that the classification criteria of CLP are based on the – intrinsic – properties of substances, with no differentiation by exposure situation and real risk of the respective substance use. Thus, the consequences can be unjustified requirements in the use of a substance/mixture. For this reason, the legal consequences need to be examined as to their proportionality and relevance to risk, and they need to be adapted accordingly.

Some examples of the impacts of classification and labelling under CLP on downstream legal fields:

- **Impacts of CLP on the adaptation of the SEVESO Directive**
  With the application of CLP in the Seveso Directive and the taking over of tighter hazard categories from the CLP Regulation, many more substances will fall under the Seveso Directive in the future. Therefore, clearly more companies will be impacted by the Seveso Directive, with far-reaching obligations and burdens. An evaluation of real risk is necessary, showing whether substances are covered that cannot pose a major-accident hazard in the meaning of the Seveso Directive – irrespective of their hazard classification. For such substances, a proposal should

[1] Consumer organisations, too, criticise inflationary labelling. In the periodical "test" of July 2015 Stiftung Warentest states that hazard symbols and risk/safety phrases need to be printed even on hand dishwashing products. The tighter labelling requirement for this product group is criticised, because many dishwashing agents contain skin-friendly surfactants. This tighter labelling requirement can cause uncertainty among consumers or even decrease their awareness to such a low level that the warnings on products that really pose hazards to health or environment are no longer taken seriously.

be submitted for exclusion from the scope of application of the Directive (also see whereas 11 of the Directive).

- **Waste classification – Adaptation of hazard criteria for waste referring to CLP**
  The new HP criteria (hazardous properties) must not lead to changes for purely formal reasons – i.e. where the properties of waste have not changed – in the existing classification of hazardousness of waste. This existing classification has proven its worth in practice for many years.
- **Formaldehyde and the impacts on the TA Luft (Technical instructions on air)**
  A risk-adequate implementation of the reclassification of formaldehyde (6th ATP) is called for in the TA Luft (General administrative provision on the German immission control act/Allgemeine Verwaltungsvorschrift zum Bundes-Immissionsschutzgesetz).

Instead of automatically effective legal consequences, initially the real exposure should be examined, and a risk assessment for the uses should be carried out. Where adequate risk management is already in place for consumers, workers or environment, tighter requirements should not apply automatically in downstream pieces of legislation. Instead, options should be provided in all impacted sets of rules, allowing deviations from the “standard legal consequences” (e.g. exemptions from certain obligations).

In the discussion about the legal consequences that arise from the classification or reclassification of substances and that can have considerable impacts on the use of substances and mixtures, the German Federal Ministry of Labour and Social Affairs (BMAS) mandated a legal opinion on the legal consequences of German and European legislation, regarding the classification of substances and mixtures under Regulation (EC) No 1272/2008 and the classification of substances and preparations under Directives 1999/45/EC and 67/548/EEC (“Rechtsfolgen des deutschen und europäischen Rechts aus der Einstufung von Stoffen und Gemischen nach der Verordnung (EG) Nr. 1272/2008, sowie aus der Einstufung von Stoffen und Zubereitungen nach den Richtlinien 1999/45/EG und 67/548/EWG”).

In this opinion, the following is held: Given the large number of European and national legal norms that link legal consequences to the classification of substances and mixtures, it is not predictable for the competent authorities what impacts the legal classification of a substance under the CLP Regulation can have in the practice of companies and monitoring authorities. However, this is necessary to be able to better assess the concerns of industry, in respect of the relevant decision processes. (“Aufgrund der Vielzahl der europäischen und nationalen Normen, welche Rechtsfolgen an die Einstufung von Stoffen und Gemischen knüpfen, ist es für die zuständigen Behörden nicht absehbar, welche Auswirkungen die Legaleinstufung eines Stoffes nach der CLP-VO in der Praxis der Unternehmen und Überwachungsbehörden haben kann. Dies ist jedoch erforderlich, um in Hinblick auf die entsprechenden Entscheidungsprozesse Bedenken von Seiten der Industrie besser bewerten zu können.“) Thus, this opinion serves as a basis for a factual discussion on

existing problems and for the necessary further development of legislation.

One result of the opinion is a database for determining the legal consequences of new or changed classifications. This database builds on search of all directly applicable legal norms in Germany, focusing on EU regulations and German federal laws, ordinances and administrative provisions where legal consequences are linked directly to a classification under the Dangerous Substances/Preparations Directive or the CLP Regulation. Also highlighted are the nature of the respective legal consequences and to whom they are addressed. In total, 41 EU regulations and national legal norms were identified which link legal consequences to the classification of chemicals. This total is broken down into 9 EU regulations, 6 laws, 23 ordinances and 3 administrative provisions. Within the above-mentioned opinion, a database with over 4,000 entries was produced which comprises all EU regulations and German laws, ordinances and administrative provisions that link legal consequences to the classification of chemicals. The database can be found on the website of the Federal Institute for Occupational Safety and Health (BAuA): http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/Einstufung-und-Kennzeichnung/Rechtsfolgen.html

One element of the opinion is the description, by way of example, of results based the classification of formaldehyde (Carc. 1B and Muta. 2), the classification of lead (Repr. 1A) currently under discussion at European level, and the theoretically possible classification of ethanol (Carc. 1A and Repro. 1A) – in order to identify the legal norms and legal consequences under national and European legislation that impact these substances (see final report on the legal consequences of German and European law from the classification of substances and mixtures under Regulation (EU) No 1272/2008 and from the classification of substances and preparations under the Directives 1999/45/EC and 67/548/EEC: “Rechtsfolgen des deutschen und europäischen Rechts aus der Einstufung von Stoffen und Gemischen nach der Verordnung (EG) Nr. 1272/2008, sowie aus der Einstufung von Stoffen und Zubereitungen nach den Richtlinien 1999/45/EG und 67/548/EWG”).

2. Legal consequences of harmonised classification and labelling

See VCI position paper: Impacts of classification under the CLP Regulation on other pieces of legislation - on the example of ethanol
See BDI-DIHK-BDA-BGA position paper: Fundamental position of BDI, DIHK, BDA and BGA on dealing with the classification of chemical substances and its legal consequences

Harmonised classification and labelling of substances (Annex VI, part 3 of the CLP Regulation) increasingly concern substances with a very wide range of uses, so that the automatic legal consequences have deep impacts into the supply chains and bring extreme challenges, especially for small and medium-sized enterprises (SMEs). Classification decisions should not result in established and safely used substances being no longer available or to disproportionate requirements.

By no means must classification decisions lead to automatically applicable tightenings

in downstream pieces of legislation. Instead, options should be provided in all impacted sets of rules, allowing deviations from the "standard legal consequences" (e.g. exemptions from certain obligations). Classification decisions on substances with well-established risk management should be suspended until downstream legislation has been adapted based on the real risk.

3. Overlaps between the requirements of CLP Regulation (EC) No 1272/2008 and Biocidal Products Regulation (EU) No 528/2012

There are overlaps between several parts of the CLP Regulation and the Biodical Products Regulation (BPR), which cause problems in practice.

The CLP Regulation *"should ensure a high level of protection of human health and the environment"*. The BPR is based on the same idea. The introduction of additional labelling, exclusion criteria or extra conditions and rules leads to a very large number of products that require labelling and of numerous products displaying large numbers of labelling items. A flood of labelling does not result in a more careful handling by private consumers and professional users of those products that require special care. Rather, the consequences are a decreasing awareness of hazards and all products being deemed equally "hazardous". The fundamental thought underlying the CLP Regulation – i.e. *"a high level of protection of human health and the environment"* – can be eroded very easily by the rising number of labelling. Therefore, it should be determined in each individual case which labelling items are conducive to improving the level of protection. This should include the question whether the substances or products at stake are used industrially or by the public at large.

The application of additional labelling items or an adaptation of existing ones, that become necessary due to changes in the classification of active substances, involve much work and cost for industry. A harmonisation of classification and labelling in the various EU Member States and one identical labelling of products with identical specification, irrespective of their intended (biocidal) use, would keep such work and cost as low as possible and enable a comparability of products manufactured inside the EU and imported treated articles.

The following examples are meant to highlight the problem:

- **Evaluation of active substances, exclusion criteria and restrictions**

Pursuant to Article 5 *("Exclusion criteria")*, BPR in principle excludes the approval of an active substance if it meets certain classification criteria (carcinogen category 1A or 1B, mutagen category 1A or 1B, toxic for reproduction category 1A or 1B, endocrine-disrupting properties, PBT or vPvB) or if it is thus classified. This is totally independent from the concentration of the active substance at stake in the ensuing biocidal product.

Also in the assessment of respiratory sensitisers and of substances meeting two of the PBT criteria, the legal requirements go beyond that of the CLP Regulation: Such active substances are approved only after a positive *"comparative assessment"* in the evaluation, with the approval of the active substance being granted only for a reduced

period of time. Moreover, the use in consumer products is restricted.

In contrast to the above, the CLP Regulation identifies certain hazards by taking into account the concentration, limits are laid down, and potential hazards are communicated by way of pictograms, signal words and H- and P-phrases.

This means that the BPR requirements go much further than the CLP Regulation. They constitute an unequal treatment of substances intended for biocidal uses, as compared with the same or comparable substances that just fall under CLP requirements.

- **Labelling of treated articles**

Where an active substance meets certain classification criteria (e.g. respiratory sensitiser, two PBT criteria), special rules for the labelling of treated articles (mixtures and articles) are included in the implementing regulation for the approval of the active substance. These rules do not depend on the concentration of the active substance in the treated article. For mixtures this means a tightening of existing labelling provisions under the CLP Regulation.

For example, the special rules for the approval of IPBC as preservative demand information about the risk of skin sensitisation in the label of articles treated with IPBC, regardless of the IPBC concentration in the end product. There are numerous further examples.

Work and cost are immense for applying additional labelling, without bringing about any higher protection level for consumers. Quite the contrary: The flood of additional labelling can cause a loss of awareness among consumers who incorrectly appraise the risks.

- **Evaluation of active substance releasers**

The approval of biocidal active substances according to BPR comprises the determining of a harmonised classification of the active substance according to the CLP Regulation and inclusion in Annex VI to the latter. Pursuant to the exclusion criteria laid down in Article 5 BPR[2] active substances classified as CMR category 1A or 1B cannot be approved as a matter of principle. For biocidal products containing these active substances, an authorisation is rendered clearly more difficult: They can be authorised only under certain conditions. Consequently, a substance evaluation by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) for harmonised classification pursuant to CLP has a direct influence on the active substance approval (or refusal) under BPR.
According to BPR also systems releasing biocidal active substances *in situ* need to undergo an authorisation procedure for biodical products. Here, an assessment is

[2] **Exclusion criteria:**

- Carcinogen (category 1A or 1B)
- Mutagen (category 1A or 1B)
- Toxic for reproduction (category 1A or 1B)
- Endocrine-disrupting properties
- PBT or vPvB

made of the released active substances, of potential by-products and original substance(s) – by examining the entire *"in situ* system" as a whole.

One of the possibilities for *in situ* generation is the formation of the active substance from so-called releasers. These are substances which release the active substance – by themselves or under the impact of atmospheric oxygen or moisture. In contrast to other *in situ* systems, where only the released active substance is examined in active substance approval, for releasers the precursor substance needs to be approved as active ingredient. Consequently, here the "exclusion criteria" – which are based on the harmonised CLP classification – apply to the precursor substances.

The RAC has already classified several releasers as CMR 1B. Thus, these releasers fall under the exclusion criteria and can be no longer approved without further steps as active substances according to BPR. However, this RAC classification is expressly made on the basis of the existing relevant classification of the released active substance. The differentiation between releasers and other *in situ* systems, as established within BPR for the evaluation either of the released active substance or of the entire system, is not taken into account for the harmonised classification by the RAC.

Consequently, the assessment by the RAC according to the CLP Regulation directly influences other regulatory fields too, without sufficiently taking into account the specific criteria of the latter (here: evaluation of active substances and biocidal products pursuant to BPR). For this reason, the harmonised classification according to the CLP Regulation should not be taken as an absolute exclusion criterion in other regulatory fields. Instead, this harmonised classification should be included in the upcoming risk assessment with an open (i.e. not foregone) decision. Concretely, this means for releasers that a detailed risk assessment – as intended within the BPR authorisation procedure – should be carried out, without any anticipatory decision through the RAC classification.

- **Different calculation of endpoints**

The evaluation of active substances under BPR follows other approaches than the CLP Regulation. For calculating DNELs (Derived No-Effect Level) and AOELs (Acceptable Operator Exposure Level), different scenarios are taken as a basis, and they lead to different values. Examples for this are glutaraldehyde and copper.

- **Changes in classification through harmonisation of classification and labelling**

In the EU a harmonised classification and labelling is intended for biocidal active substances. With changes in classification, this can lead to a new notification or to changes to existing authorisations of the concerned biodical products becoming necessary in the individual Member States or – for Union authorisations – at ECHA.

During the process of active substance approval, the decision on how to implement possible changes in classification lies with the individual Member States. This can result in different classifications in the various Member States which do not conform

with the CLP Regulation.

For the companies, changes in the classification of substances and a possibly ensuing reclassification of mixtures mean much administrative work and high costs. Harmonised classification and labelling should be implemented equally and the same time in all Member States.

- **EU manufacturers at a disadvantage against importers**

BPR enables a simplified procedure for the authorisation of biocidal products if certain criteria of Article 25 are fulfilled. Inter alia, exclusively substances from Annex I to BPR can be used. However, the active substances listed under category 1 of Annex I (e.g. lactic acid, sodium benzoate), which are authorised as food additives, can be used as active substances in biocidal products only in concentrations that are so low that this use does not require classification of the biocidal product according to CLP. Otherwise, such biocidal products do not qualify for authorisation in the simplified procedure.
In consequence, active substances of category 1 cannot be used as preservatives for non-biocidal end products – due to their classification inside the EU. By contrast, articles which were treated (in this case, preserved) with these active substances can be imported into the EU without authorisation of the biodical products and without restrictions.

The manufacture of treated articles – like in-can preserved products or preserved wood – in the EU is subject to stricter regimentation than imports. Consequently, EU manufacturers are at a disadvantage against importers while there is no possibility to differentiate for consumers.

4. Contribution of the CLP Regulation to international harmonisation

With the entry into force of the CLP Regulation, the EU implements into European law the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals, as elaborated by the United Nations. The GHS was developed to improve for chemicals their safety in handling, occupational health and safety and environment. This is to be achieved by means of harmonised criteria for the classification of substances and mixtures and harmonised elements for hazard communication (label, safety data sheet). At the same time, harmonisation should enhance legal certainty for companies and eliminate formal trade barriers. Meanwhile, the GHS has been implemented also in all major trading partners of the EU (USA, Japan, China, Korea and others).

However, regarding the implementation into national law the GHS allows not to take over individual “building blocks”. Usually, such “building blocks” are individual hazard categories. For example, the EU did not take over hazard category 5 for acute toxicity – while the EU adopted some additional supplementary items of hazard information that are not yet part of the GHS, in order to maintain the existing high level of protection. This “modular system” is bound to bring systematic differences in the hazard labelling of chemical substances/mixtures. Moreover, some individual countries, which have introduced the GHS, prescribe binding hazard classifications for defined

substances (“substance lists”). Such substance lists are not agreed between these countries. Against this backdrop, UN pilot projects are under way to look into introducing a globally harmonised substance list in the UN-GHS. Finally, different countries use different revision numbers of the UN-GHS as the basis for their respective national legislations (UN-GHS is revised every two years).

But beside these relatively well-documented differences in the nationally implemented versions of the GHS text itself, major differences arise in practice in the application of the classification rules. Due to the “cultural imprint” – attributable to frequently very different existing rules for the classification of hazardous substances – quite often different data sources are used (e.g. nationally available databases). The comparison between the USA and the EU is just one example. Existing data are assessed and weighted differently (e.g. human experiences from occupational health and safety versus standardised animal testing) and different test methods are deemed valid or not for classification (e.g. OECD methods versus other methods). Even with the same regulatory requirements, this leads to major differences in the resulting hazard classification.

With a view to driving forward the global harmonisation of the hazard classification of chemicals and the connected goals as stated above, intensive cooperation between the competent national authorities should be demanded. Such cooperation should serve to harmonise the expectations of public authorities regarding the data to be used for classification and their assessment and – in result – for the transparency of the relevant available data and the ensuing classifications, possibly up to a globally harmonised substance list.

GHS is applied in the European Union for products for private consumers that fall in the scope of the CLP Regulation, but it is not applied in many other countries and regions of the world. Therefore, the ratio between the costs and workload through “global harmonisation” and the benefits is extremely unfavourable for manufacturers of these products.

5. Adaptation of the CLP Regulation to changes in the UN-GHS

The text of the UN-GHS is continually further developed by the “ECOSOC Sub-Committee of Experts on the GHS” at UNECE. A revised version of the UN-GHS text is published every two years. Resulting changes are incorporated in CLP by way of “Adaptations to technical progress” (ATPs). Furthermore, there are ATPs to update the substance list in Annex VI to the CLP Regulation. In consequence, also the users need to check their product labels and safety data sheets at least in two-year intervals, in order to adapt them to the latest version of CLP (corresponding to the current version of the UN-GHS). But many changes in the UN-GHS are only about purely formal aspects, such as editorial changes of the binding phrases for precautionary statements (e.g. 8th ATP, P502 new: “Refer to manufacturer or supplier for information on recovery or recycling” instead of P502 old: “Refer to manufacturer/supplier for information on recovery/recycling”;

P502 old “Informationen zur Wiederverwendung oder Wiederverwertung beim Hersteller oder Lieferanten erfragen” instead of P502 old: “Informationen zur Wiederverwendung/Wiederverwertung beim Hersteller/Lieferanten erfragen”). However, even such editorial changes generate considerable work and cost for the changeover at the users – without improving safety for the relevant products.

Moreover, the linguistic differences between H- and P-phrases within CLP and between CLP and GHS cause implementation problems in practice. These problems are intensified by faulty translations and continuous corrections in the different language versions of the CLP Regulation. Due to such deviations, the labelling of products in the market will not always have exactly the same wording, also with the information necessary for safe handling and use being given in terms of content.

Example of the correction of Regulation (EC) No 1272/2008 of 10 April 2015 for the combination phrase “P305 + P351 + P338”:

> “Vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.”
>
> now reads
>
> “Eventuell vorhandene Kontaktlinsen nach Möglichkeit entfernen. Weiter spülen.“

Cost and effort for the changeover could be reduced considerably and without quality loss for product labels and safety data sheets if clearly longer transitional periods were granted for incorporating editorial changes to the UN GHS into CLP.

Urgently needed is an acceptance by public authorities of minor text deviations of H- and P-phrases, because the manufacturers cannot put into practice immediately and equally the full application of such continuous adaptations.

6. Annex VI to the CLP Regulation – Classifications by manufacturers and minimum classifications

Unlike the earlier Annex I to the Dangerous Substances Regulation (67/548/EEC), which laid down the classification across all available endpoints for the listed substances, the present procedure departs from this approach. Article 4(3) CLP stipulates the following: Where a substance is subject to harmonised classification and labelling through an entry in part 3 of Annex VI, that substance shall be classified in accordance with that entry for all hazard classes covered. For the listed hazard classes or differentiations, no classification under Title II CLP shall be carried out by manufacturers or importers. However, where the substance also falls within one or more hazard classes not covered by an entry in part 3 of Annex VI, classification for these hazard classes by manufacturers or importers becomes necessary. Thus, for substances listed in Annex VI the hazard classes not covered there need to be added. This leads to different classifications on the market of the substances in part 3 of Annex VI CLP.

Also problematic is the determination of so-called minimum classifications (CLP Regulation, Annex VI, 1.2.1 “Minimum classification”) in Annex VI, part 3, table 3.1

CLP. When translating classifications under Directive 67/548/EEC to classifications under CLP, the translations based on the data were not always exact. For certain hazard classes, including acute toxicity and specific target organ toxicity (repeated exposure) the classification according to the criteria of Directive 67/548/EEC does not correspond directly to the classification in a hazard class and category under CLP. In these cases, the classification in this Annex shall be considered as a minimum classification. Where the manufacturer or importer has access to data or other information that lead to classification in a more severe category compared to the minimum classification, classification in the more severe category must then be applied.

Annex VI was designed as a listing of substances with harmonised classifications and labelling elements at Community level. Therefore, the goal should be to lay down in a binding manner the classification and labelling of these substances for all endpoints. The entries in Annex VI should be harmonised fully, also with a view to a future, globally harmonised substance list.

7. Information to poison centres: Article 45 CLP

According to Article 45 CLP, information is to be provided about the ingredients of mixtures, which are classified as hazardous on the basis of their health or physical effects, to bodies appointed by the Member States. In consequence of this provision, manufacturers and importers, who place substances and mixtures on the market in Europe, are faced with different national systems and information requirements of the various Member States, even though this obligation arises under Article 45 of the CLP Regulation.

According to Article 45(4) CLP, the Commission is mandated to establish the harmonisation of the information requirements and the format for the submission of information, by way of an EU regulation. Industry supports the fast adoption of harmonised requirements, in order to approximate the different submission systems in the EU Member States to each other and to make submission manageable for companies. It would be target-oriented to set up one central body which receives information from manufacturers and importers and subsequently passes on this information to the bodies appointed by the Member States. In this exercise, the safety data sheet should be taken as the basis for harmonising the information requirements for mixtures that are used exclusively industrially or commercially. It is necessary to lay down Europe-wide uniform information requirements and to make available one uniform, language-independent format for data submission. Here, information should be submitted in English language or it should be translated automatically in other official languages.

8. Classification & Labelling Inventory

The C&L Inventory lists classifications and labelling, as notified by manufacturers and importers according to Article 40 of the CLP Regulation. It is emerging that the notified

classifications and labelling show huge differences for many substances. The goal is a "purge" of contradictory entries, where there are no underlying factual reasons like different compositions or impurities and differences in physical state and form of a substance. However, in the "purge" of entries the relevant framework conditions need to be taken into account:

- The registration process, including agreeing on the classification in the consortium, constitutes a major part of the harmonisation process. By the end of the last registration period, one jointly agreed classification will be available for a large number of substances. Preferred standing should be given to entries that are included in the Inventory by way of joint registrations: because for these substances, agreeing on their classification has already taken place.
- ECHA should directly correct or delete obvious mistakes. Should this not be possible on legal grounds, for procedural reasons only ECHA can directly contact the respective notifier/registrant, in order to initiate a correction.
- Highly diverging entries for import products could be attributable to an extra-European manufacturer, who imports the substance into the EU, orienting himself to the GHS of the United Nations (UN-GHS) or to the classification requirements of his country of origin. This can explain why hazard categories of UN-GHS, which were not taken over into European law, come up in the C&L Inventory. ECHA should delete such entries. Here, ECHA could achieve further harmonisation by way of targeted information to importers.
- The lacking "threshold of low volume" for notification to the Inventory is among the factors contributing to the wide band of classifications. It makes sense that data requirements are clearly reduced for low-volume substances, as compared with high-volume substances. In the overall perspective, this leads to a variation in classification. Here, too, further approximations can be made after the end of the last registration period in 2018.
- It is unclear how to deal with entries made by companies that have ceased to exist. ECHA should be given the possibility to delete such entries to keep the Inventory up-to-date.

9. Impacts of the CLP Regulation on the determination of water hazard classes (WGKs) under the ordinance on plants for the handling of water-polluting substances (AwSV) in Germany

With the planned replacement of the administrative ordinance on water-polluting substances (VwVwS) by the ordinance on plants for the handling of water-polluting substances (AwSV), the CLP Regulation is used for deriving the water hazard class of mixtures. Here, the M-factors for aquatoxic substances need to be taken into account – with no differentiation being made between substances with acute and chronic M-factor, as was introduced in the 2nd ATP of the CLP Regulation.

Where an M-factor needs to be taken into account for a substance of WGK 2 or WGK 3 due to its high aquatic toxicity, the percentage share of this substance is multiplied by this factor. The result is used for determining the percentage by mass. Consequently,

with a share of 3% or more of WGK 3 substances in the mixture, the mixture as a whole is classed as WGK 3 under the VwVwS. Where a mixture contains a WGK 3 substance with an M-factor of 10, already with a content of 0.3% of this substance the mixture would need to be classed as WGK 3 under the AwSV.

The taking into account of M-factors in the determination of water hazard classes brings clearly higher WGKs for mixtures containing substances with M-factors. Because of the technical requirements and conditions for mixtures in higher WGKs, this has highly cost-intensive impacts on production and storage facilities. Especially in low concentration ranges, this leads to assessments which clearly constitute a tightening, as compared with the CLP classification as hazardous to the aquatic environment. For example, with a substance with an M-factor of 10 in the mixture, already from a concentration of 0.3% the highest WGK is reached for this mixture. According to CLP, the highest classification can be made only from a content of 2.5%.

The planned taking into account of M-factors brings a problematic tightening which is not congruent with CLP in this form. A mathematical determination of WGKs under AwSV without taking into account M-factors would usually result in better congruence with the assessment of aquatic toxicity under CLP.

10. Navigator of Chemical Substance Regulation (see "Cefic PROPOSAL FOR A CENTRAL EUROPEAN NAVIGATOR OF CHEMICAL SUBSTANCE REGULATION")

VCI – together with its European umbrella organisation Cefic – considers a so-called "Navigator of Chemical Substance Regulation" as a good start to identify overlaps and help chemicals producers to find their way through complex and overlapping regulations. We suggest that a European substance-regulation navigator provides – after entering e.g. the substance name or CAS no. – answers, inter alia, to the following questions:

- How is the substance regulated?
- What substance-relevant items of information are available at European and national authorities?

In fact, the European Chemicals Agency (ECHA) has created a database where information can be retrieved about substances registered under REACH. However, this database is not sufficient, because it covers neither the entire regulatory framework on chemicals in the European Union/Member States nor the results from the European research programmes.