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PUBLIC CONSULTATION

# VCI Position on the revision of the CLP Regulation

## Summary

On 9 August 2021, the EU Commission published a public consultation on the revision of the CLP Regulation. This revision is one of the 50 actions planned in the Chemicals Strategy for Sustainability, which was adopted on 14 October 2020. In preparation for this consultation, an Inception Impact Assessment was already carried out by the EU Commission in May 2021, which was commented by VCI:

Feedback from: German Chemical Industry Association - VCI (europa.eu)

This new consultation is in the format of a questionnaire and, from the point of view of the German Chemical Industry Association, however, requires - due to the way the questions are posted and the answer options given - more detailed comment. Particularly, some of the multiple-choice questions suggest that a specific answer is desired, or they lead opinions to a certain direction without providing accurate and adequate information. In this context, VCI thanks the EU Commission for the opportunity to comment on the proposed amendments to the CLP Regulation.

The primary objective of the CLP Regulation is to inform actors in the supply chain about potential adverse effects of substances and mixtures by classifying them and labelling them appropriately based on this classification. For data collection, identification, evaluation, and regulation of substances of very high concern (SVHC), e.g. endocrine disruptors, the REACH Regulation provides the right framework and has proven its worth. **A mixing of the tasks of REACH and CLP should be avoided.**

One major target of the proposed revision of the CLP regulation is the implementation of new hazard classes, e.g. for endocrine disruptors. It is the declared aim of the EU Commission to use the proposed new hazard classes to identify substances that are to be subject to the so called “generic approach to risk management” which is so far exclusively applied for CMR substances. The “generic approach to risk management” is essentially a hazard-based approach and means the restriction of substances on the basis of their classification without substance-specific risk assessment. Risk management, however, generally is not in scope of the GHS (and not CLP), and GHS/CLP hazard classification should generally not be used for risk management decisions without additional risk assessment (i.e. no automatism). The proposed introduction of new hazard classes (e.g. endocrine disruptors) as a basis for identification of relevant substances for "automatic" regulatory measures, e.g. restrictions, solely based on the CLP classification, is therefore not supported.
Furthermore, the EU COM aims at “having a leading role and promoting the implementation of existing international instruments” and to “promote, together with industry, the implementation of the Globally Harmonised System of Classification and Labelling of Chemicals

(UN GHS) as the means for identifying chemical hazards".[1] **In this context, any unilateral implementation of e.g. new hazard classes without consultation of the UN GHS is contradictory.** The stated assumption that the GHS may just follow the EU CLP and implement identical criteria is unrealistic and disregards the work of the UN GHS Committee of Experts. Therefore, it is of utmost interest to industry to maintain the achieved harmonisation and not to disregard the work of the UN GHS Committee of Experts by unilateral implementation of new hazard classes without consultation of the UN.

The questionnaire failes to consider the legal consequences of the proposed amendments for downstream or other chemical regulations (e.g. Plant Protection Products and Biocidal Products Regulations), which are associated with **high burden, bureaucracy and costs**.

While the timeline set by the EU Commission for amending the CLP Regulation is very ambitious, an intensive dialogue between industry and authorities is needed before any legal regulations are adapted. We highly recommend to plan sufficient time for stakeholders to evaluate the proposals thoroughly and propose alterations leading to an efficient regulation.

## CLP Revision: VCI position on the proposed amendments of CLP

In its CLP questionnaire, the EU Commission proposes several legislative measures, on which we comment in the following:

**Part I (General questions)**

**Section 1 - New hazard classes**

- **Endocrine disruptors. Endocrine disruptors are chemicals that cause illness by interfering with the hormonal system of human beings or of wildlife (e.g. obesity of children, infertility, etc.);**

We like to comment on the above-mentioned statement, which is part of the introduction to Part I Section 1 of the questionnaire as follows:

- We do not agree with this statement in its absoluteness. Exposure must be taken into account. We refer to the following statements of the BfR (German Federal Institute for Risk Assessment) and the EFSA: "Epidemiological studies have shown an increase in tumor rates in organs that are hormonally regulated such as breast and prostate cancer. The development of such tumors is aided by a number of factors such as overweight or alcohol consumption. Endocrine disruptors are under consideration as an additional potential risk factor. It is also debated whether or not endocrine disruptors are involved in the noted inhibited fertility of men as a result of undescended testicles or decreased sperm counts. However, **to date no causal relationship has been scientifically established between the**

[1] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, Chemicals Strategy for Sustainability, Towards a Toxic-Free Environment.

**exposure to endocrine disruptors through foodstuffs or the environment and adverse health effects."** "Exposure, that is the extent to which humans come into contact with endocrine disrupting substances, is a deciding factor in health risk assessment. **Current data on exposure levels to individual substances** such as bisphenol A or phthalates **have not provided substantial scientific proof of a health hazard**, not even for most susceptible groups of consumers such as small children and adolescents during puberty. Nonetheless, the overall exposure to endocrine disruptors should be reduced as much as possible." (BfR Frequently Asked Questions on Endocrine Disruptors; https://www.bfr.bund.de/en/frequently_asked_questions_on_endocrine_disruptors-50804.html). "Exposure to endocrine disruptors could increase the likelihood of harmful effects in the short-term or later in life. Concern about the possible harmful effects of endocrine disruptors has been growing in recent years because of observations in humans and wildlife. These indicate rising rates of endocrine diseases and disorders, including reproductive and developmental harm in human populations. However, **the scientific basis for linking all such trends to endocrine disruptors (as opposed to other factors such as lifestyle changes and genetic background) is not conclusive."** (EFSA FAQ; https://www.efsa.europa.eu/en/topics/topic/endocrine-active-substances)

- **Question 1 - Please indicate how important it is for you to know a chemical is**

**-An endocrine disruptor with adverse effects on human health**

**-An endocrine disruptor with adverse effects on the environment (e.g. wild life)**

**-Persistent, bio-accumulative and toxic**

**-Persistent, mobile and toxic**

- We answered "important" to all items in question 1. We would like to explain these answers as follows: We understood that the questions posed in section 1 are of a rather general nature. We therefore see these questions predominantly in a context to the general public and the use of consumer products. In this context, we agree that it is important to ensure safety of consumer products with regard to the listed hazards. However, we question that communication of these hazards as such is helpful for consumers. Rather, we would consider it important to inform the consumer about the necessary protective measures and recommended behaviours. Therefore, the answer that it is "important" to know about those hazards should not be misinterpreted in a way that those properties as such are to be communicated to the consumer.

- **Question 2 (Would you be ready to pay more for alternative products that have the same performance, but which do not have that hazards?)**

- The question does not differentiate between hazard and risk. Members of the general public without dedicated knowledge on safety assessment would assume that a hazardous product automatically is less safe – which is not true if the risk is adequately mitigated, e.g. by limitation of exposure. Therefore, this question will necessarily result in biased answers.

## Section 3 - labelling

- **Question 4: In your view, how clear and easy to understand are labels of chemicals in general (think for instance of products you often use, such as detergents, glues, paints, etc.)**
- **Question 5: Considering the example above, if you would like to improve this label, what would you prefer?**

- Questions 4 + 5 refer to the clarity and understandability of labels, and how this may be improved. From our point of view, it is important to differentiate between consumer products and professional/industrial products. The GHS was developed mainly for professional/industrial products and is not applied to consumer products in most jurisdictions. For professional/industrial products GHS labels are clear and no improvement is necessary. However, the GHS labels are difficult to understand for consumers and are overloaded with information details without use for members of the general public. Therefore, we see room for improvement for consumer labels, including options for digitization, as stated in the questionnaire – but this does not apply to professional and industrial products
- Any changes of CLP labelling requirements should be done in alignment with the UN GHS only. The GHS system serves as an internationally consistent base for classification, labelling and packaging. Furthermore, the UN GHS Committee of Experts on the GHS itself is currently exploring options to make use of digital labelling. Therefore, all initiatives on streamlining GHS label requirements including the use of digital labelling are welcome to be included into respective UN GHS activities. **Any unilateral changes impacting GHS requirements for professional and industrial use of substances and mixtures should be avoided.**
- In line with the current status of the discussion on UN GHS level, we recommend that for professional and industrial use of substances and mixtures, digital means of labelling are only used in addition to physical labelling, not instead of. It is imperative that safety-relevant information is always applied to product labels physically which can be read without technical aids.
- Digital tools could also be used on a voluntary basis to provide additional end-user targeted information and/or to link information with respect to consumer products, which is already available/published (e.g., composition information on detergents as requested by the EU Detergent Regulation). The way and content of digitised information should be oriented to the respective target group, be it safe use instructions for industrial settings or guidance for consumers. Therefore, any assessment of digital labelling options should clearly differentiate between industrial, professional and consumer use. In this context, sector-specific solutions may be of interest as well. It has to be ensured that physical labels that comply with the UN GHS requirements (according to the building blocks implemented in CLP) can continue to be used in the EU. Further possibilities to simplify labels (e.g. multilingual labels, fold-out labels, reduced requirements for consumer products) and to use digital labels (e.g. partial

shifting of label elements into digital labels) as a voluntary option for the manufacturer should be evaluated and introduced where appropriate.

- Further information can be found in the VCI consultation paper on the Inception Impact Assessment "Simplification and digitalisation of labels on chemicals: Feedback from: German Chemical Industry Association - VCI (europa.eu)

- **Question 5a - Considering the example above, which pieces of the label would you like to keep?**

- As explained for question 5, any changes of labelling requirements need to differentiate between consumer and industrial/professional use. Whereas industrial/professional labels need to provide all relevant hazard information necessary for occupational safety, consumer labels should focus on easily understandable safe use instructions. Because differentiation between consumers and professional/industrial use is not possible in the questionnaire, answers may provide a misleading picture.

- **Question 8: Individual pens are very small items, with little room for a label and information about hazards. What would be the best option for you to inform on the hazardous substances they may contain and the safety instructions?**

- The question does not specify the type of pens, the chemical constituents, the product type (cosmetics, biocides...), or the use conditions. There are labelling regulations on certain product types and for small-volume packaging already available and they work reasonably well. If some aspects of existing regulations need to be addressed, then this question should be made more specific.

## Section 5 - Scope of the CLP regulation

- **Question 10: When buying or using the product categories listed below, you might not be informed that they could be hazardous to the environment. What is your opinion?**

- For good reason, the listed product categories do not cover the environmental hazards via the instruments available in the CLP Regulation. Specific responses to each product category are answered by responding to Question 11. In summary, as a response to Question 10 it can be concluded that all product categories mentioned have their own audience as well as category-specific standards to avoid/minimize environmental risks as fare as possible. Additional elements of hazard communication from the CLP Regulation are therefore neither needed nor useful.

## Part II (Questions for experts)

## Section 1 - New hazard classes

**General Comments:**

- We would like to emphasise that the introduction of new hazard classes for endocrine disruptors and PBT/vPvBs or PMT/vPvM substances is not necessary, since a high level of health and environmental protection and the improvement of environmental quality are already sufficiently provided by existing legislation.
- Endocrine disruption is not a separate toxicologically defined endpoint. For this reason, a separate hazard class is not justified and does not serve the purpose. Furthermore, adverse effects triggered by endocrine disruptors, such as carcinogenic or reproductive toxic effects are already covered by existing CLP hazard classes. The introduction of new hazard classes for endocrine disruptors may result in double classification, which would lead to confusion. Double regulation should be avoided. In addition, the introduction of a category of "Suspected Endocrine Disruptors" based solely on in vitro data is not scientifically justified.
- Persistence, bioaccumulation, or mobility properties do not in themselves justify the definition of new hazard classes. Persistence and bioaccumulation are parameters that help to weigh according to the fate of a substance in the environment. So far bioaccumulation and degradation parameters are used to weigh acute or chronic toxicity in the classification of "hazards due to the aquatic environment". Any class including a toxicity element as defined under REACH Annex XIII in addition to persistence, bioaccumulation or mobility would overlap with the existing hazard class for aquatic toxicity. Basically, for regulatory management the regular restriction procedure under REACH is applicable for of PBT(vPvB)/PMT(vPvM) substances as well as substances with other critical hazard properties (such as immunotoxicity, neurotoxicity, organ toxicity, respiratory sensitisation).
- ED/PBT and PMT are combinations of different effects/multiple endpoints. The GHS system does not provide for such an approach. There are no suitable tests available.
- The scope of the UN GHS is hazard classification and communication. The scope of the UN GHS explicitly excludes any risk management decisions "which generally require some risk assessment in addition to hazard classification". As a conclusion, GHS hazard classification is generally considered not sufficient to automatically, i.e. without further risk assessment, result in risk management decisions, e.g. restrictions or bans of substances. However, this is exactly the meaning of the generic risk management approach proposed by the Commission. The introduction of new hazard classes (such as endocrine disruptors) is proposed as a basis for extending the generic approach to risk management to those new hazard classes, with the aim of automatically banning the use of chemicals classified for those new hazards for the use in consumer products. In conclusion, the idea of introducing new hazard classes into the GHS as a means to identify chemicals to be automatically restricted or banned for certain uses without any risk assessment is in clear contradiction to the internationally agreed principles of the GHS and therefore cannot be supported.

- Hazard classes in the UN GHS and the CLP Regulation should continue to be reserved for hazards according to the OECD "hazard" definition[2], i.e. should be defined exclusively for relevant intrinsic hazardous substance properties (including toxic properties such as aquatic toxicity). In this context the definition of new hazard classes, if necessary at all, should first take place within the framework of the GHS. The implementation of the UN GHS building blocks into the CLP Regulation could then take place in a second step.
- Furthermore, definition of additional hazard classes within CLP while no adequate and scientifically sound measurement methods are available would result in considerable loss of reputation for this highly recognized regulation.

- **Question 13 - For known endocrine disruptors, do you think...?:**

- Endocrine disruption is not a separate toxicologically defined endpoint. For this reason, a separate hazard class is generally not justified and does not serve the purpose. Furthermore, adverse effects triggered by endocrine disruptors, such as carcinogenic or reproductive toxic effects are already covered by existing CLP hazard classes. The introduction of new hazard classes for endocrine disruptors may result in double classification, which would lead to confusion. Double classification should be avoided as well as double regulation.
- Whereas adversity is part of the hazard identification, aspects such as severity, (ir)reversibility and potency are part of the hazard characterisation. Any criteria for endocrine disruptors, if so, should include those aspects: To decide whether a substance is an endocrine disruptor, consideration must be given to the potency of the substance, the severity of the adverse effects on an intact organism, the reversibility of an adverse effect, and the strength of the scientific data.

- The introduction of a category of “Suspected Endocrine Disruptors” based solely on in vitro data is not scientifically justified.

- Overall, the VCI considers that for chemicals REACH offers the right framework to identify and assess endocrine disruptors as is being done today via Article 57(f).

[2] Hazard definition: Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub)population is exposed to that agent.
OECD (2020), Test No. 491: Short Time Exposure In Vitro Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage, OECD Guidelines for the Testing of Chemicals, Section 4, OECD Publishing, Paris, https://doi.org/10.1787/9789264242432-en.

- **Question 14a - Please detail why and how a subcategorisation should be provided. Please indicate whether there should differences between human health and the environment.**

- Differences in protection goals between human health assessments (individuals) and environmental assessments (populations of species) should be considered.

- **Question 19a &22a - Please provide alternative labelling option**

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|---|---|
| Symbol/pictogram | None, alternatively GHS07 |
| Signal word | None, alternatively 'warning' |
| Hazard Statement | EUHxxx: |
| Precautionary Statements | P203, P273, P391, P501 |

- **Question 26: The CLP regulation requires to use all available data to identify hazards in chemicals. Data may come from REACH registration(s) or public scientific literature. To what extent do you think that the data currently available on chemicals are sufficient to perform an assessment for the foreseen hazard classes mentioned above?**

- In our view, there is no need to extend the scope of the REACH Regulation with regard to data generation and evaluation to support classification and labelling under CLP. The primary objective of the CLP Regulation is to inform actors in the supply chain about potential adverse effects of substances and mixtures by classifying them and labelling them appropriately based on this classification. For data collection, identification, evaluation, and regulation of substances of very high concern (SVHC), e.g. endocrine disruptors, the REACH Regulation provides the right framework and has proven its worth. The existing data requirements under REACH, together with the various other methods available, are sufficient to enable an appropriate assessment to be made.

- **Question 27 - Considering the suggested new criteria for additional hazard classes, do you foresee a need to invest significant resources to get the expertise to assess the hazards of chemicals?**

- This question is unclear. Do "resources" refer to having the necessary expertise/knowledge, or does it include data availability/generation? Data generation is regulated within the scope of the REACH Regulation. Additional standard information requirements will lead to additional effort without contributing to more safety. The assessment of data with regard to new hazard classes will result in significant workload for experts in (eco-)toxicology and extension of testing laboratories and thus require high investments.

- **Question 28 - Do you or your organisation/company already have an estimate of the number of impacted chemicals due to the potential new hazard classes?**

The number of chemicals that will be classified by one or more of the proposed new hazard classes may strongly differ between companies, depending on sectors and applications. However, it needs to be emphasized that any new hazard classes, especially when combined with new REACH information requirements, basically require the **re-assessment of all chemicals on the market** for those new hazard classes. Therefore, all chemical would be impacted by any new hazard classes.

## Section 2 – Classification

- **Question 29 - In order to increase the number of substances with harmonised classification, to what extent do you agree to the following statements?**
  **- The European Commission should also have the right to initiate European classification for some substances?**

This proposal is not supported for two reasons, a more formal one and a political one. For industry, it is very important that the CLH process is predictable, based on sound science and appropriate with regard to risk reduction and socioeconomic impact. Formally speaking, according to article 37 (5), CLP, the role of the Commission includes an assessment whether or not a proposed harmonised classification is "appropriate". This obligation provides the Commission with a certain margin of discretion, which requires assessment of appropriateness beyond fulfilment of the classification criteria, as assessed by RAC. In case the Commission would become an actor in the CLH process by initiating CLH dossiers, the Commission would lose the independency to assess "appropriateness" - or would need to assess and judge on their own proposal. Especially, combined with the intention of the Commission to set priorities for the CLH process based on "concern", e.g. on endocrine disruptors (see question 32), industry is worried that the CLH process will be biased by political agendas and public debates, and by this would exactly not be scientific based, appropriate and predictable any more.

- **Question 30 - Setting toxicological/ecotoxicological values such as DNEL/DMEL, PNEC is part of the hazard assessment. These values are currently derived in accordance with REACH or specific sectorial regulations (e.g. food contact materials, cosmetics, biocidal products, workers protection). As part of the 'One substance, one assessment' concept, the Commission intends to include a procedure to harmonise values for some toxicological/ecotoxicological parameters in CLP. Such harmonised values could be then used for risk assessment in the different EU chemicals legislations**

- **Question 31 - How would you assess the possible impact of the harmonisation of toxicological/ecotoxicological parameters (e.g. DNELs or PNECs)?**

- Any procedures on setting harmonised environmental and safety values would be clearly beyond the scope of the GHS, and would mix up hazard classification and risk assessment decisions. Harmonisation of e.g. PNEC/DNEL values as established under REACH, and/or OELs, should not be regulated under CLP, but under REACH or OSH legislation.
- Furthermore, the UN GHS clearly states that it is "not intended to harmonise risk assessment procedures or risk management decisions (such as establishment of a permissible exposure limit for employee exposure), which generally require some risk assessment in addition to hazard classification" (1.1.2.6 Other scope limitations).
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  - **Question 32 - Currently CLH dossiers can be submitted by national competent authorities and in some cases by companies. Once received, the dossiers are checked for accordance.**
    **What is your opinion about the three following statements?**

  - **The system should allow prioritisation of substances for which serious concerns are raised (e.g. priority given to substances highly suspected of being an endocrine disruptor, once the criteria are adopted).**
  - **The system should allow low prioritisation of substances of lower concerns.**
  - **No need to modify the current approach as the system already contained a prioritisation mechanism (National Authorities' priorities, ECHA screening)**

- Based on the regulatory risk management approach, the Commission can directly feed prioritised substances from the Chemical Universe, which are also determined by group assessment, into the process of harmonised classification. This means that the focus here is more on regulatory risk management and not on new findings on intrinsic substance properties that lead to a new/adapted harmonised classification and labelling. In our view, the process for obtaining harmonised entries should instead emphasize sound scientific exchange that incorporates the latest findings. This, of course, involves prioritisation, but at the same time opposes the use of group approaches. Regarding the prioritisation of the substances with serious concerns or lower concerns, we believe that the existing prioritisation mechanisms are efficient and appropriate, therefore we do not consider the additional prioritisation mechanism necessary.

  - **Question 33 - Currently economic operators (manufacturers, importers, downstream users, distributors) are not allowed to submit a proposal to ECHA to revise an existing harmonised classification for an Annex VI entry. Only Member states can submit such a proposal.**

- While the question posed talks about economic operators (manufacturers, importers, downstream users, distributors), the selection of answers provided in the questionnaire talks about stakeholders. We would therefore like to state our answer as follows due to this deviation. The revision request by e.g. stakeholders and economic operators (manufacturers,

importers, downstream users, distributors) should be allowed once new peer-reviewed information is available.

- **Question 34 - To derive the correct classification of certain chemicals, the use of animal testing is still necessary. Would you be confident to classify (your) products on the basis of alternative methods only?**
    - In the case the result of a test performed with an alternative method is positive, to classify (your) chemicals accordingly: Yes or No?

- This question depends on the toxicological endpoint under consideration. There should be a validation/quality/appropriateness check of the study. In particular the systematic availability needs to be verified before an in vitro finding can be taken forward. As chemical Industry we are committed to replacing, reducing and refining animal testing. Under REACH, animal testing can only be used as a last resort, which is why the Industry has been using, where possible and applicable, alternative methods and approaches (e.g. grouping, read-across, validated in vitro assays), to demonstrate the safety of a substance in REACH dossiers. To enable a full transition to alternative methods as the preferred option compared to animal studies, New Approaches Methodologies (NAMs) need to meet highest performance standards, they must be fully validated and accepted by competent authorities. Only the endorsement of a new method by e.g. ECHA will allow the chemical industry to amend their testing schemes.

- **Question 37 – How do you rate the economic impact (cost savings) of the following five policy options?**

- Please be aware: Under the existing legislation, bulk chemicals are non-packaged goods and carry dangerous goods labels, but not the CLP labels. Therefore, this question is misleading and cannot give a meaningful answer.

## Section 3 – Labelling

- General VCI-comments on this section can be found on page 4.

## Section 4 – Online Sales

- We welcome a clarification of the responsibilities for compliance for online sales, but due to the complexity of implementation we would like to emphasise at this point that this should be done in close dialogue with industry.

- **Question 39 - Some chemicals purchased online from non-EU countries often do not comply with EU law (e.g. are not providing obligatory safety information). In those cases, it is very difficult to identify the responsible company and take corrective measures.**

**In such a case, do you think the online service providers, platforms should be considered responsible?**

- We would like to add here, that from industry perspective, enforcement is the Achille's heel of chemicals legislation today. With REACH and 40+ pieces of EU chemical legislation, the EU has the most comprehensive chemical legislation in the world. However, the constant flow of illegal imports into Europe and the current poor enforcement system undermines the level of protection it is set to offer. We call on the EU Commission to ensure full and harmonised enforcement of **existing** EU rules both within the internal market borders and at EU borders. Likewise, enforcement must not discriminate between traditional and online markets. Ensuring a level playing field on the EU market is a critical prerequisite for the success of the Chemicals Strategy for Sustainability and for maintaining the trust of society in the ability of enforcement and regulators to effectively protect them from dangerous chemical products.

## Section 5 – Scope of the CLP Regulation

- **Question 45 - Do you consider that there are gaps or overlaps between Article 1(5) of the CLP regulation and provisions in other legislations or that the wording is unclear?**

- If products have already specific labelling requirements according to EU regulations that are complementary to CLP, then they should remain subject to that regulatory regime to avoid confusion with labelling obligations from CLP.

- **Question 46 - Currently neither the CLP nor the specific ('sectorial') legislation applying to the products listed in the table below require that information on classification and labelling of environmental hazards is provided to the users.**

  **In your view, what would be the best option to make users aware of these environmental hazards?**

- Medicines:

- Within the framework of the authorisation of medicinal products for human use, an environmental risk assessment has been mandatory for many years and must be submitted with the application for authorisation. Therefore, the statement that information on environmental hazards is not identified is not correct. They are included in the package leaflet. In addition, within the framework of the federal government's trace substance strategy for Germany, an improved disposal notice for the product information (package leaflet) of medicinal products has been developed; this makes it possible to inform patients without confusing them with a label according to the CLP Regulation on the medicinal product package, which may possibly lead to non-compliance with the drug therapy: "Never dispose of medicines in the waste water (e.g. not in the toilet or sink). Ask your

pharmacy how to dispose of the medicine when you are no longer using it. By doing so, you are helping to protect the environment. You can find more information at *www.bfarm.de/arzneimittelentsorgung.“*
Furthermore, additional labelling for environmental hazards might have negative impact on therapeutic compliance. Patients should have clear instruction on how to use and dispose unused medicinal products. That is already covered in the package leaflet.

- Veterinary Medicines:

- The statement that information on environmental hazards is not identified in specific regulation is not correct for veterinary medicinal products (VMPs) as there is already information for the user in place. Within the framework of the authorisation of veterinary medicinal products an environmental risk assessment is mandatory for many years. In case potentially harmful effects are identified risk management measures are defined to reduce those risks. These are also addressed in the package leaflet as well as instructions for disposal. If the risks for the environment are considered unacceptable and outweigh the therapeutic benefit the veterinary medicinal product cannot be authorised. More information *https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/environmental-risk-assessment-veterinary-medicines* The statement introducing question 46 is also not correct for Veterinary Medicinal Products as there is already information for the user in place.

- Medical devices:

- Medical devices in the form of substances and mixtures intended for the final user, especially those devices that are invasive or used in direct physical contact with the human body, are excluded in the current CLP Regulation (Art. 1. Par. 5 (d)). A revision of the exemption – if it is considered - would impact strictly regulated labelling materials. Provision of information for safe handling and use is sufficiently ensured for these devices by existing sectoral legislation, e.g. the Medical Device Regulation (MDR). This covers human health as well as environmental aspects, like advice on adequate and safe waste disposal (MDR Annex I, Chapter II, Section 14.7). As there is already adequate legislative control in place, we do not see a reason why the current exemption from the hazard communication requirements under CLP for such products might be adapted/revoked. If these exemptions were nonetheless withdrawn, sufficiently long transitional periods would be required, as any change of labelling of medicines and medical devices is strictly regulated by the MDR and requires significant efforts, time and approval.

- Cosmetics:

- To guide use and disposal, information on products must be meaningful and understandable for consumers. Indicating the damage that a chemical mixture could cause under unrealistic, worst-case conditions (i.e. hazard) is not an effective way to communicate and should be reserved to situations where the real-life use/disposal cannot

be foreseen by the manufacturer. When use/disposal are strictly pre-determined, there is clear evidence that targeted information and warnings are more easily understood by consumers. This principle has been successfully implemented for many years in the Cosmetics Product Regulation (CPR) for human safety of cosmetic products. The upcoming revision of the CPR and the Sustainable Products initiative provide an opportunity to introduce relevant consumer information on the environmental impact of cosmetic products, going beyond (eco)toxicological hazard information. Simple extension of CLP labelling to cosmetics would not add any useful consumer information and would often contradict the intended use/disposal.

- Food additives

- Food additives are fully regulated in the EU by Regulation (EC) No. 1333/2008. This regulation lays down rules on food additives to ensure the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, where appropriate, the protection of the environment (Art. 1). The protection of the environment for the use of food additives in foods is clearly in the scope of the food additives regulation. According to Art. 6 of the said regulation a food additive may only be included in the Community list of approved food additives if it meets several conditions, including environmental factors. In our opinion Regulation (EC) No. 1333/2008 fully covers environmental risks originating from the use of food additives.

- Feed additives:

- There is also an environmental risk assessment in place in the authorisation process for feed additives. Feed additives (unless those that are on the market as finished products for the end user) do fall under CLP legislation and are therefore labelled according to CLP. Feed additives that are used in compound feed as well as feed and compound feed in general have also detailed labelling rules laid down in regulation 1831/2003 and 767/2009. This does cover all necessary information for users and consumers to ensure a high level of safety. (767/2009: „The objective of this Regulation, in accordance with the general principles laid down in Regulation (EC) No 178/2002, is to harmonise the conditions for the placing on the market and the use of feed, in order to ensure a high level of feed safety and thus a high level of protection of public health, as well as to provide adequate information for users and consumers and to strengthen the effective functioning of the internal market.").

**Section 6 – Notifications to Poison Centres**

- We would welcome a clarification of the role of distributors in the supply chain regarding to poison centre notification of relevant mixtures. Notification of substances is not necessary, as relevant information is available due to REACH registration. Furthermore, we support the

inclusion of the role of an only representative in the CLP Regulation if it is precisely defined for which articles in the CLP Regulation this should apply here.

- **Question 47a - Why would C&L inventory notifications for substances only not be sufficient to fulfil the objective of granting adequate emergency health response?**

- Expanding the PCN notification obligation from mixtures to substances would not bring any added value on safety for human health and environment perspective as the information on the substance(s) is already available in the ECHA substance information tool. This would lead to duplicating information in C&L inventory, PCN tool and REACH databases. If combination of these data is deemed necessary to make them useable for emergency health centres, ECHA has all the prerequisites available.

Note to the reader:
- **Bold:** Questions raised by the Commission
- VCI Position

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- Identification no. in the EU Transparency Register: 15423437054-40
- The VCI is registered in the "public list on the registration of associations and their representatives" of German Parliament (Deutscher Bundestag).

*The VCI represents the politico-economic interests of over 1,700 German chemical and pharmaceutical companies and German subsidiaries of foreign businesses in contacts with politicians, public authorities, other industries, science and media. In 2020, the industry realised sales of nearly 190 billion euros and employed around 464,000 staff.*