VERBAND DER CHEMISCHEN INDUSTRIE e.V.
WIR GESTALTEN ZUKUNFT.

CONSULTATION ON TARGETED REVISION OF REACH

VCI Position on the REACH Revision

Summary

On 20 January 2022 the European Commission launched a public consultation on options for the revision of the chemicals regulation REACH (deadline for submissions: 15 April 2022). This is intended to implement the REACH related measures announced by the Chemicals Strategy of October 2020.

A REACH revision will have major impacts on both the chemical industry and users of chemicals (substances, mixtures and articles).

The chemical-pharmaceutical industry is a key sector that stands at the beginning of many value and supply chains and plays a major role as a driver in achieving the ambitious goals of the Green Deal, e. g. in climate protection, and in further advancing digitalisation and high-quality supplies of medicines.

Thus, regulatory options for achieving ambitious goals must be designed in such a way that value creation continues to take place in the EU. They must go hand in hand with increasing the ability to innovate and improving the international competitiveness of the industry. Planning security in line with a stable and predictable legal framework is crucial.

Shaping of regulatory options should consider the points below:

- **Information and data requirements** must be proportionate and take into account registration obligations companies must meet in other regions. Where necessary, additional data requirements should be based on a tiered approach considering inter alia, use and exposure.
- More rapid progress in **replacing animal testing** is possible, if the testing scheme is developed towards a more exposure driven one with gradual uptake of new approach methods and acknowledging that these are not replacing current standards one by one.
- Any registration option for certain **polymers** must be based on valid technical and scientific criteria considering the specific properties of polymers compared to other substances as well as workability aspects.
- Possible **combination effects** through exposure to substances should be addressed in a targeted manner, if necessary. Exclusively in the risk assessment of consumer uses mixture assessment factors specific to substances or substance groups might be applied. Supposedly simple regulatory approaches, such as an additional general assessment factor for all substances registered under REACH, do not reflect reality and are not acceptable.

- **Supply chain communication** can be simplified by drawing on the experience of the writers and users of extended safety data sheets to agree on best digitalising practices. Harmonised electronic formats must be compatible with systems already established in companies and requirements in other regions. Pilots are required before decision making on any harmonized format.
- To improve **dossier and substance evaluation**, action plans by the European Commission, ECHA and industry are already being implemented and several implementing regulations have been issued.
- For further developing ECHA's regulatory screening approach, transferring the current **candidate list** for authorisation into a prioritisation tool is discussed. Options for this should pay specific attention on balancing workload and addressees with data absolutely necessary for focused decisions on regulatory needs.
- **Non-REACH options**, e.g., under OSH, should be given **equal rights compared to REACH measures** when assessing regulatory needs. Stakeholders should be involved in assessments of regulatory needs as well as before taking subsequent decisions on potential regulatory options.
- Basically, the **authorisation procedure** should be maintained for industrial, professional and consumer uses. The scope should focus on cases where non-REACH measures or the ordinary restriction procedure are less suitable. The burden of applications for small quantities and process chemicals should be reduced.
- The regular **restriction procedure** allows for balanced and informed risk management, e.g., by stakeholder consultations. Therefore, it should not be replaced by the so-called generic risk approach (GRA) without prior consultation and risk assessment.
- **Professional uses** are subject to occupational health and environmental legislation that has to be implemented by the employer. Thus, in first instance proper implementation and enforcement is key instead of additional regulatory measures. Remaining issues should be addressed outside of the GRA.
- **Export restrictions** for products manufactured in Europe should be based solely on internationally agreed and harmonised requirements.
- REACH **enforcement** must be uniform throughout the EU (level playing field, harmonized analytical methods etc.), consider all actors equally and differentiate between intentional infringements and unintentional errors. Involvement of customs is important, should build on smart approaches and may not disrupt the flow of goods.

REACH Revision: The VCI's comments to the questionnaire

Decisions on regulatory options potentially have major impacts on both the innovation capacity and the competitiveness of European industry. Thus, alongside the measures proposed by the European Commission, first of all, priority should be given to careful examinations of all possible options within the existing chemicals legislation for achieving the CSS objectives.

In this context, the principles of better regulation must be applied, stakeholders must be appropriately involved, and evaluations must be carried out with open outcomes.

The implementation of the EU chemicals legislation, and in particular the complex REACH Regulation, has been and continues to be a step-by-step process - both in terms of the implementation progress and the learning curve for all stakeholders. In particular, implementation of the existing REACH Regulation is far from complete, as the individual processes build on each other (e. g. screenings of data on registered substances to determine whether there is a need for further regulation under REACH or other EU regulations). This must be taken into account when establishing a baseline, shaping options for action, and cost-benefit assessments.

Therefore, the following aspects should be taken into consideration when designing and evaluating possible options:

Section 1 – Registration

Ensure the proportionality of information requirements

Basically, information and data requirements must be workable and take into account animal welfare aspects. Fit-for-purpose replacements for animal testing that have been validated and adopted on international level (OECD) should be considered progressively without invalidating or duplicating testing results already available. If additional data requirements are necessary, they should be based on a tiered approach. Differentiated, substance-specific information requirements for this approach need to be defined on the basis of existing information and depending on substance properties, use, exposure and substance volume. Dossier and substance evaluation under REACH are already established procedures that should be used for this purpose.

Q 1 Increased information on critical hazards

Keep information requirements proportionate and use the substance evaluation for justified individual cases

- For many aspects, the existing tiered information requirements in REACH Annexes VII to X already contain differentiated rules. This means that if certain conditions apply, more data – beyond the standard data set – become necessary for a registration of the substance in question. Thus, additional information can be gathered in justified cases, both through this approach and during a subsequent substance evaluation. This course of action should be

given priority over wide-ranging additional requirements. Especially Annex XI needs to be considered to a larger extent, as it already gives criteria for applying other approaches, e.g. waiving.

Ensure validity of test methods for product safety aspects and bring about more animal welfare

- In practice, regulators so far rely on animal-based assessments and the bar is high for acceptance of alternative methods, "weight of evidence", read-across and grouping of chemicals. This means that industry is increasingly forced to mandate a considerable number of animal tests to fill alleged data gaps, without being convinced that this contributes significantly to safer manufacturing or use of chemicals. Moreover, by testing more and at higher doses, the basic principles of animal welfare are also challenged by this strategy.
  Thus, sound approaches to make progress in replacing animal testing are explicitly supported. Any grouping criteria applied by industry and authorities/ECHA need to be based on sound science and should be harmonized. Such framework should equally apply for groupings from industry and ECHA, whereas differentiation might be foreseen for different phases (e.g., screening phase vs. initiation of a regulatory measure).
- However, we are disappointed that the questionnaire only presents options that contradict safety standards gained under joint efforts of industry and authorities and with international harmonisation of test guidelines. No meaningful and differentiated answer is possible within the framework of those predefined answers. VCI is convinced that a balance between safety, animal testing, and validated alternative methods is possible.
- For this, the REACH test requirements should be strengthened as follows:
  - Develop an improved, innovative testing strategy for product safety in collaboration with EU agencies and the Commission. These tests should limit the use of animals to a measure of last resort, drive forward innovations and promote e.g., the use of new digital technologies for predictive toxicology and allow for exposure-based adaptations.
  - With regard to the potential role of new approach methodologies for replacement of standard information requirements and animal testing we refer to our answers on question 4.
  - Test guidelines should be adopted on international level, as chemicals are marketed globally and companies have to provide data under different legislations in different regions.

Carcinogenicity and mutagenicity must not be discussed independently

- Carcinogenicity is the major concern for EU Commission and European Parliament. So far, they do not mention mutagenicity/genotoxicity data explicitly, when referring to carcinogenicity information. However, mutagenicity/genotoxicity data is crucial, because a significant proportion of carcinogens acts via a mutagenic mechanism (genotoxic carcinogens).

Annex VII stipulates a well-established screening assay (Ames test). This screening assay has shown a high predictivity and is generally accepted as a first tier of testing for mutagenicity. The test has even shown to give a quite good indication for the results of subsequent in vivo carcinogenicity studies (Matthews EJ et al. Regulatory Toxicology and Pharmacology Volume 44, Issue 2, March 2006, Pages 83-96).

With Annex VIII, a comprehensive set of information on mutagenicity is provided. It covers gene mutations and cytogenetic (i.e., structural or numeric effects on chromosomes). The requested information is based on in vitro studies. Whenever positive results were obtained in one of the in vitro tests, appropriate follow-up tests need to be conducted.

For the further discussion, the interdependencies between mutagenicity/genotoxicity and carcinogenicity need to be considered.

- Carcinogenic effects may be caused by a variety of mutagenic/genotoxic and non-mutagenic/non-genotoxic mechanisms. In order to get more information about potential carcinogenic effects under REACH, validated in vitro methods or new approach methodologies (NAMs) would be necessary. Scientific work is already ongoing for several years. Although the wish for more information is understandable, it needs to be ensured that any additional information is at the same time reliable and predictive. As soon as new validated methods or NAMs will become available, they will have to be evaluated for being integrated into the standard information requirements of REACH.

Q 2 – 3: Information marketed at the lowest tonnage level

Do not increase information requirements across the board – apply a tiered approach

- Information requirements in the volume band of 1 to 10 tonnes per year must remain proportionate. This must not be called into question by disproportionate information requirements and chemical safety report obligations. Otherwise, substance uses would disappear from the market not because of their risk, but because of disproportionate costs (false selection).
  If additional data is required to address a specific concern this might be addressed under current procedures (e.g., substance evaluation under REACH). Thus, the need for a chemical safety assessment for such substances should be derived on a case-by-case basis, depending on use and exposure.

Q 4 New approach

Develop testing scheme towards a more exposure driven one with gradual uptake of new approach methods

- Basically, new approach methodologies (NAMs) building on in vitro, in silico and in chemico tool boxes, on existing data and approaches for prediction of hazard and exposure, can enable to reduce, refine, and replace (3R's) vertebrate animal tests.

- In the last decade progress has been made related to availability, reliability and predictive quality of NAMs. However, under EU REACH the default initial approach is still based on animal testing for filling knowledge gaps, although e.g., required endpoints related to annex VII requirements (except for acute oral toxicity) can already be covered by NAMs.
- NAMs are typically not one to one replacement for existing animal studies. NAMs appropriately validated and accepted at OECD level need to be embedded in a Weight of Evidence (WoE) / Integrated Approaches to Testing and Assessment (IATA) approach to avoid the perception that results from a single NAM can be interpreted as a 'negative' or 'positive' result when taken out of context. A single NAM result is often only part of the equation, and other data/parameters/NAMs have to be brought into the picture to fully evaluate the endpoint. In addition, the decision framework should enable safety assessment based on all the data (including historical data or data which have to be generated for other regions).
- Significant progress towards the adoption of new approach methods will only be possible if the REACH Annex XI requirements for testing are adapted in this respect.
- Single NAMs are rarely applicable to all REACH substances (e.g., due to the specific structure of a substance or physical-chemical properties), it is important to specify endpoints in a generic manner and to develop performance criteria. Thus, the REACH legal text should specify the endpoints in a generic manner to avoid the need for frequent Adaptation to Technical Progress (ATPs), while the selection of methods and test batteries themselves (including applicability domain, interpretation of results) can be specified more efficiently elsewhere.
- Any new safety assessment scheme should not invalidate existing registrations under REACH nor to the volume band approach for previous registrations.
- A precondition to increase the uptake of NAMs is to consider upfront exposure considerations.
- The Organisation for Economic Co-operation and Development (OECD) acknowledges that complex NAMs may require new, flexible approaches for building confidence and a step back from demanding that all methods meet the level of validation currently required for Mutual Acceptance of Data (MAD).

Q 5 Endocrine Disruptors

In the introduction "obesity" and "infertility" are mentioned as examples for negative human health effects of endocrine disruptors. Reference is made to the Commission document COM(2018)734. However, the Commission document does not mention the examples "obesity" and "infertility" in this context. Novel endpoints (e.g., obesity, diabetes) are an area of scientific discussion. However, the link between these diseases and endocrine disrupting substances is still under scientific consideration. Another factor discussed in the context of obesity is e.g., early

life nutrition. There is no robust evidence for any significant adverse health effects in human populations from exposure to endocrine disruptors registered under REACH.

- **Endocrine disruptors: ensure appropriate information requirements**

  Question 5 is difficult to understand and leads to confusion. We assume that what was meant is that registrants should be required to provide to authorities sufficient and appropriate standard information (e. g. data) rather than standard information requirements.

  Existing legislation (REACH) already allows the identification of endocrine disruptors as SVHC. Under REACH, registrants are required to provide information and data on the intrinsic properties of a substance. Additional information can already now be gathered in justified cases in the evaluation procedure under REACH.
  Information and data requirements must be proportionate and take into account animal welfare aspects. VCI is concerned about increasing requirements, in particular in the sense of standard information requirements for hazard identification as a “tick box approach” without proper justification. Extensive vertebrate testing for low tonnage substances (and correspondingly low exposure potential) is not appropriate.

- **Apply a tiered approach for additional data requirements for identification of endocrine disruptors** (Q 5a)

  A tiered approach is the most suitable approach for additional data requirements, where necessary,

  - if there is a reasonable suspicion of endocrine effects,
  - on the basis of available information (WoE including toxicology data),
  - with consideration of use and exposure (e.g. wide dispersive use),
  - related to the individual substance,
  - using internationally accepted and validated test methods.

  Dossier and substance evaluation under REACH are established procedures that should be used for this purpose. This course of action should be given priority over wide-ranging additional standard information requirements in the REACH annexes.

- **Testing strategies should, where possible, minimize animal use** (Q 5b)

  This general principle is currently laid down in article 25 of REACH on the use of vertebrates in experiments.

  The WHO defined an endocrine disrupter as follows:
  “An endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations”
  ‘In vitro screening’ assays can provide information about endocrine activity, but not on

adverse effects. Adverse effects in intact organism can so far only be provided by 'in vivo data'.

In vitro screening assays for endocrine activity need to be fit for purpose. The generation of false positive results should be avoided, in order to avoid unjustified banning of substances and to avoid potential subsequent animal testing to verify questionable in vitro findings. Also, it is not informative to investigate a MoA if no adverse effect related to this MoA is seen in the respective in vivo studies.

Question 5b is a theoretical question and can only be answered case by case. Risk considerations, based on use and exposure, should be taken into account, before additional testing is required.

Furthermore, the question probably is not asked correctly: Instead of "protection of laboratory animals", should it not rather be "use of laboratory animals" as of course even if animal tests are required, the animal protection rules should be respected.

Q 6 - 7 Information requirements for polymers

As some of our responses to the survey questions might be perceived as contradictory, we would like to point out that the options provided do not allow for more differentiated responses. Thus, it is essential that discussions and contributions, e.g., those made in the CASG Polymers are taken into account. In brief, some of our main positions from this discussion include:

Consider principles and achievements of the current REACH regulation for polymers

- The CLP and REACH regulations apply to all chemicals, including polymers.
- Polymers are exempted from REACH Title II (registration) and Title VI (evaluation) only; all other provisions also apply for polymers.
- Instead of the polymer the more reactive monomers, which are usually intermediates, are subject to more extensive registration requirements than regularly applicable for intermediates under REACH.
- As a result, a comprehensive safety status for human health and the environment has been achieved by the ongoing REACH process related to polymers.

Conditions specified in REACH Article 138 (2) for any polymer registration must be considered

- Article 138 (2) provides the basic, risk-based framework under which REACH mandates the Commission to assess whether certain polymers should become subject to registration.
- VCI considers article 138 (2) as essential prerequisite for any polymer registration option, including:
  - Proof of a practicable and cost-efficient way of selecting polymers subject to registration
  - Sound technical and valid scientific criteria as well as the following risk-based considerations,

- Report(s) that credibly demonstrate that certain types of polymers pose an increased risk compared to other substances and polymers.
- These report(s) have to take into account competitiveness and innovation aspects on the one hand and the protection of human health and the environment on the other.

Qualified impact assessment by the European Commission needed

A robust impact assessment of polymer registration options by the European Commission is required, based on the following approach:

- The basis for the impact assessment must be a completely elaborated/described concept for a polymer registration in line with principles of the REACH regulation. We do not consider it possible to develop such a concept on-the-fly or in parallel to an impact assessment.
- All costs within the supply chain must be considered and differentiated. Manufacturers of polymers with high tonnages are subject to different economic consequences than SMEs that produce special polymers in small tonnages.
- Baseline of any impact assessment should be the current legal situation, where polymers are exempted from registration, but not from the other provisions of the REACH framework, and monomers are registered with regular data sets instead of the polymers.

Grouping: Develop classification based on certain characteristic properties to assign a polymer into a predefined polymer group.

- The term ‘polymer’ covers a multitude of different substances which may have diverse properties.
- Grouping of these polymers is a challenging task, and at the same time one of the core prerequisites for any polymer registration scheme to be developed by the European Commission. Only a successful grouping approach, preferably by hazard similarity, might provide a suitable frame for assessing heterogeneous groups of polymers.
- Such a grouping requires close cooperation with different experts (e.g., scientists, regulatory affairs managers) to develop a workable grouping framework.
- ECETOC has already addressed this issue in detail in its technical reports (ECETOC TR 133-1 and TR 133-3), which should be considered when drafting any upcoming legislation.
- Such a grouping within REACH should be based on available data. In this regard, we refer to the current proposal of ECETOC in the CASG-Polymers.[1]
- A "one-fits-all" and/or box-ticking solution is neither feasible nor justified, taking into account the heterogeneity of the polymers.

[1] E.g., ECETOC, September 2021, Assessing the safety of polymers: Examples of grouping approach, https://www.youtube.com/watch?v=ltUa_DEKcmo

Substance identity / sameness: Similarity rather than sameness approach recommended to differentiate between two different substances

- If the current rules on identity of substances would also be applied for polymers this would maximise the number of polymers to be considered: Polymers do not consist of one identifiable substance but are a mixture of various combinations of its monomers.
- “Similarity” of polymers needs to be considered instead of “sameness” when identifying common properties and defining polymeric substances.
- Most of these properties are confidential business information, as they represent the polymer product more than the actual polymer.
- From the perspective of the chemical industry, a clear distinction between substances and polymers under REACH is necessary and tailor-made solutions are required.

PLC/PRR criteria: Potential risk and non-risk polymers

- As indicated in the survey, we do not see any general need to introduce a polymer registration under REACH due to the measures already established.
- Nevertheless, PLC / PRR criteria should be used when identifying polymers that might cause a potential risk to "humans and environment".
- First approaches of PLC/PRR criteria have been proposed by the EU Commission and presented in the CASG Polymers. Here we would like to point out, similar to our response in the questionnaire, that a high degree of harmonization with other regulations, global as well as EU regulations, is essential.
- Such criteria must be efficient and practicable. Therefore, real-life testing of the criteria should be carried out before taking any decision, e.g., by pilot studies.

Polymeric Precursor: Acknowledge methods applied for risk management

- Within the chemical industry, specific chemicals with an increased reactivity are required for certain applications. However, this does not cause an increased risk to human health or the environment.
- In addition to the intrinsic properties of a chemical substance (hazard), risk management also considers other factors such as the type or the duration of exposure when assigning risk management measures. This ensures that the risk can be managed effectively despite the inherent hazard of a substance.
- This also applies to polymers. For example, many polymers used in industrial production are reactive polymers (polymeric precursor). Here, operational safety measures etc. are already in place under the current OSH and environmental legislation.
- Experiences prove, that no uncontrolled risks are associated with handling of polymers in industrial settings or later in the supply chain (where usually molecular weight is increasing).
- Therefore, we advocate for a risk-based differentiation of such cases, and for an exemption or reduced registration requirements for polymeric precursors in any polymer registration scheme.

Q 8 Environmental footprint

Environmental footprint does not fit in the registration step under REACH

The Product Environmental Footprint (PEF) concept was developed as a standard method for providing information on the environmental footprint for end-use products in the context of green claims and pursues a cradle-to-grave approach. On a voluntary basis VCI supports the promotion of sustainable products, procedures and advice for consumers to achieve environmental and climate goals.

The Chemical industry represents both suppliers of substances (chemical raw material) and their customers, the formulators. Thus, we acknowledge a need for data collection for the calculation of the PEF. However, we are critical regarding the provision of information on environmental performance in the registration step of REACH.

REACH registration is substance related and focusses on physical-chemical and toxicological data for substances and use patterns aiming to derive conditions of safe use for the whole lifecycle of a substance. Companies are obliged to provide these data in joint registrations for the same substance by submission to ECHA. In addition, certain information is communicated to downstream users via the safety data sheet. On the other hand, data on environmental performance are product specific and depend very much on the production process, the raw materials and the pre-cursors used. Therefore, performance parameters for the same substance might differ and may often have to be revised due to adjustments in production and raw material supply. In addition, certain performance raw data might rely on process specific data that require consideration of antitrust rules or are confidential business information (e.g., individual energy consumption might allow conclusions on production process) and thus might not be shared with competitors. This would lead to high complexity and efforts in terms of drafting and updating the REACH dossiers and will most likely disqualify such performance information from being included in the joint data set of a registration under REACH.

The PEF is highly dependent on the formulation of the product, the manufacturing process and the raw materials used, which might be bought from different suppliers ensuring supply, being cost competitive and being able also to buy on the spot market from non-EU countries. Changes there would lead to a continuous revision of the PEF. Also, it would be mandatory to reference to the REACH dossiers upstream (pre-cursors) and even downstream to reflect the various Life Cycle Assessment profiles for supply and use. That will be even more complex and almost impossible for imported substances and mixtures with only representatives and distributers involved. Therefore, a REACH registration in IUCLID with its rigid format to manage substance related toxicological and ecotoxicological profiles and use conditions with regard to risk management is not the appropriate legal framework for this type of information.

Therefore, the German Chemical Industry objects to any collection of PEF-relevant data via REACH registrations. A more efficient approach is needed which considers that even though the PEF covers cradle-to-grave performance, information on the environmental footprint of substances can only be provided from cradle-to-gate in order to be open to as many different downstream uses as possible. The missing "... to grave"-information will be added by the

different downstream users for their specific uses and end of life scenarios. Moreover, learnings from the current work on safe and sustainable-by-design criteria should be considered.

Q 9(a - e) Information requirements on use and exposure

Documentation of safe use: right sense of proportion is needed

- Basically, the current registration scheme to address uses, has shown that it is fit for purpose. Extending notification requirements towards ECHA would extend bureaucracy and costs for companies and authorities. Moreover, REACH processes already include means to collect additional information if in a specific case additional information is required (use notifications to suppliers and downstream user chemical safety assessment according to Art. 37 and 38; evaluation procedures; calls for evidence; consultation within various REACH and other processes).
- For use information under REACH, the balance must be maintained between what the registrant can specify for the totality of users and what is specific to certain users or workplaces. If more or different information is needed in special cases, e. g. if a substance has been prioritized for further regulatory action in ECHA's regulatory screening a more targeted approach considering registrants as well as downstream users should be chosen, e.g., a request for specific additional available information. For other needs, e.g., recycling issues, a targeted exchange between the parties concerned is more expedient than comprehensive additional documentation requirements. The standard registration procedure should not be overstrained by this. On the other hand, an option for providing a dossier update upon inclusion of a substance in PACT (Public Activities Coordination Tool of ECHA) would be welcome, when update requirements focus on the substances foreseen for the next assessment cycle and a reasonable timeframe is foreseen for the update if additional information is available.
- Even if not perfect, use descriptors should not be touched, as the system is already complex, numbers of related exposure scenarios might be high and sectors have elaborated specific use maps to complement the current system.
- **Keep update requirements focussed to relevant changes**

  As a matter of principle, updates of registrations are required in cases specified according to REACH Article 22 and implementing legislation. This covers tonnage band updates and updates of the chemical safety report. Thus, it has no added value to stipulate updates on tonnage information within a certain timeframe, if this would not change conclusions on safe handling of the substance. For proper risk management the current approach that addresses tonnages within the chemical safety assessment is more substantiated. However, the option "If a trigger according to REACH Art. 22 c or g applies" is missing in the questionnaire.
- **Extremely high efforts, major limitations and no uniform method for tonnage per use estimation**

  Tonnage information is essentially available at downstream users (DUs); transparency towards the registrant depends on the length and the complexity of the supply chain. Within a project under the umbrella of the joint CSR/ES Roadmap from authorities and industry a

Cefic/VCI group assessed available approaches on estimating tonnages per use (report available on request). Despite several approaches having been developed by sectors facing severe regulatory constraints on their substances, there is no uniformly applicable method for identifying and aggregating information on tonnage per use and any method is labour-intensive. Thus, such information should never become a standard information requirement and may only be provided by industry in specific cases. Competition law and the fact that distributors are much involved in the chemical sector further limit options for identification and aggregation of such information.

- **Grouping must be based on sound scientific rationales and case-specific**

  Any use of data from one substance for initiating or taking regulatory decisions on another substance requires sound rationales. Even substances with similar chemical structure and same or similar technical function might have different use patterns, volumes and exposure situations. Case-by-case assessments are required to provide for proper grouping of substances.

Q 9(f - h) Derived Minimal Effect level for non-threshold substances

- **Optional DMEL derivation for CM (carcinogenic, mutagenic) substances is well received by industry**

  We support a risk-based approach for non-threshold carcinogenic substances. Basically, deriving DMELs under REACH for such substances classified is in principle possible and we welcome this as an option. There are some important prerequisites for DMEL calculations, such as e. g. a comprehensive database, detailed knowledge about Mode of Action (MoA), high quality studies to derive a dose response and an appropriate starting point for DMEL calculations. In addition, animal welfare / 3R principles (replace, reduce, refine) should be considered, as there are no validated new approach methods for carcinogenicity in place, yet.

  Thus, case specific decisions have to be taken, whether scientific dose response relationships allow for sound DMEL derivation or a qualitative and holistic assessment resulting in a minimization principle should be chosen.

- **DMEL-approach tailored for non-threshold endpoints / mutagenic carcinogens**

  The DMEL-approach is meant for non-threshold endpoints / mutagenic carcinogens and should not be used without the explicit knowledge that a substance exerts a non-threshold toxicity. Thus, we are against widening the DMEL-concept to further hazard categories beyond carcinogens with a primary mutagenic mechanism. Endocrine disrupters, neurotoxicants, immunotoxicants and respiratory sensitisers are not per-se based on non-threshold mechanisms. Even if it may be - in some cases - difficult to quantify the threshold, they should not be treated as non-threshold substances.

- **Acceptable risk determination must take into account substance-specific aspects**

  Concerning the question which excess risk is acceptable: The determination of a default acceptable risk cannot be carried out across all substances, as substance-specific aspects, an impact assessment and evaluation of the feasibility are required.

Rather, REACH should be used to prioritize CM-substances e. g. for the identification of binding occupational exposure limit values under the Directive on the protection of workers from the risks related to exposure to carcinogens with primary mutagenic mechanisms at work.

Q 10(a - c) Introduction of a Mixtures Assessment Factor (MAF)

Address combination effects in a targeted and substance-specific manner

Parameters such as exposure pathways, exposure levels, relevant toxicological endpoint, mode of action, potency, etc. of different substances limit the likelihood of combination effects occurring. Therefore, supposedly simple regulatory approaches, such as an additional general assessment factor for all substances registered under REACH, are not acceptable – because in this case, substances or uses without relevant detectable combination effects would be discontinued without improving the protection of humans and the environment or any (socio)economic benefits (Q 10b).

A generic MAF is not scientifically justified and neither proportionate nor an appropriate tool to take into account potential combination effects of chemicals. So far, reviews and assessments (e.g., those presented during the MAF workshop in November 2021) indicate that combination effects only occur in a limited number of cases in the environment. Moreover, in such cases findings are dominated by a few substances and strongly depend on local factors.

Thus, all regulatory options presented in the questionnaire (Q10c) are neither backed by scientific findings nor proportionate. Instead, in order to take into account combination effects that may occur in the exposure of the environment to substances in a targeted manner, concepts must be developed with which extrapolation factor(s) can be derived – substance-specific or substance-group-specific - as part of the risk assessment, if necessary.

Q 10d Simplifying communication in the supply chain

- **Digitalization of safety data sheets must take into account existing systems, diversity of supply chains, the role of software providers, the timeline and global perspectives**

  Supply chains differ regarding actors, already available electronic tools, skills, adaptation potential and other parameters. Success of introducing any harmonised electronic tool would thus heavily depend on whether needs and adaptation potential (content, velocity) at different stages in the diversity of supply chains affected is considered.

  Any potential electronic exchange using harmonised formats should be compatible with systems already established in companies and the available ESCom XML. This is decisive, as companies and service providers have invested significant effort in SDS authoring software and other IT systems, often tailored to one company. The needs of non-industrial recipients of the safety data sheets, such as craft businesses, service providers or institutional users without corresponding IT systems, must also be taken into account.

In addition, harmonisation should not be limited to the EU market, but should also consider global markets.

Furthermore, the timeline is critical for cost-benefit assessments. Both investment cycles and necessary adaptations of company systems should be adequately considered in the EU Commission's options.

- **Sound impact assessment and pilot projects needed**

  Only pilot projects might enable informed estimates of the impact and feasibility of any tool option. Therefore, such projects involving registrants and downstream users should inform the impact assessment.

- **Improving safety data sheets: attune best practices**

  A prerequisite for any harmonisation is a common understanding of content and degree of detail to be processed. This includes the interplay between the current safety data sheet sections and exposure scenario annexes. For the extended safety data sheet, so far only an incomplete common understanding has developed as to which risk management information should be provided in the main sections and which in the annex. Furthermore, redundancies and inconsistencies at the interface between REACH and occupational health and safety must be avoided. Experience in the VCI and related recommendations are summarized in a report that was already shared with German authorities and might support in addressing key topics. For more explanation see: The extended Safety Data Sheet under REACH and Risk Assessment in Occupational Health and Safety – Evaluation of a VCI Expert Workshop

  In addition, it should be made clear in the REACH text that relevant assessments and documentation based on other legislations, in particular OSH (e. g. risk assessments at the workplace), are recognized by public authorities with regard to compliance with obligations of downstream users (e. g. as a conformity check of a use or (part of) the downstream user's chemical safety assessment).

- **Build on ENES activities and improve workability**

  Much build-up work for improving supply chain communication has already been done jointly by industry and authorities under the umbrella of the ENES work programme and network. Now it is decisive to combine these building blocks to a holistic concept. The association and its members contributed to the ENES network, inter alia, through project work as part of the joint work programme.

Section II Evaluation

Q 11 – 12 Changes to the provisions on the evaluation process

It is undisputed that dossiers should be compliant with all REACH provisions.
Registration dossiers have to be compliant at the time of submission according to respective REACH Articles and be updated according to Art. 22.
Nevertheless, the actual approach to differentiate between a completeness check at the time of submission and a subsequent compliance check with the option to take decisions on adaptation

needs is reasonable. Dossiers might include thousands of pieces of information and require expert judgements. Thus, only for cases of misuse of the submission system a clear decision on non-compliance might be easily taken. For the other dossiers acknowledgment of what is already in line with requirements and the current process for resolving the remaining issues via the compliance check procedure basically is a proportionate, effective and efficient tool.

- **Companies show responsibility and review their registration dossiers**
  So far, companies have submitted comprehensive substance datasets to the European Chemicals Agency (ECHA) for around 23,000 different substances in roughly 100,000 registration dossiers under REACH, creating a database which is unique worldwide. This took place in parallel with the further shaping of regulatory requirements and regarding interpretations, methods and evaluation processes.
  Following the end of the last transition period for registrations in 2018, the subsequent review of dossiers and substances goes further on as a step-by-step and continuous process. For example, the joint action plan of the EU Commission and ECHA for the evaluation of registrations is oriented to the period until 2027. In 2020, the EU Commission also issued an implementing regulation to concretize the update obligations for existing registrations.

- **Companies participate in Cefic Dossier Improvement Action Plan**

  Many chemical companies are taking part in the implementation of the Cefic action plan for the review and update of registration dossiers which runs to 2026. The latest Cefic report (published in March 2022) shows the progress made.

- **The EU Commission has already anticipated a revision of the requirements for registration dossiers and data quality by way of implementing regulations**

  Implementing Regulation EU 2020/1435 on the duties of registrants to update their registrations under REACH has been in force since December 2020.

  The annexes to the REACH information requirements have been amended several times in the applicable comitology procedure, including those relating to nanomaterials, and further amendments are about to be published or are being worked on. These amendments concern both clarifications of how to interpret requirements and adaptations based on new findings, e. g. to test methods.

- **Revocation of the registration number: differentiate between intentional infringements and unintentional errors / deviating interpretations**

  Already now, ECHA has the possibility to revoke registration numbers in case of persistently incomplete dossiers. If further competences are transferred to ECHA for the follow-up of evaluation decisions, it is important that a distinction is made between intentional infringements and unintentional errors / deviating interpretations.

  Furthermore, suitable communication options should be established between the public authority and affected parties to ensure that any inadequacies can be remedied quickly. In the case of such a highly important decision, the company concerned must be heard and have the opportunity to lodge an appeal. In addition, the impact on supply chains should be considered.

- **Responsibility for substance data lies with the companies - parallel testing commissioned by public authorities is not justified**

  A cornerstone of the REACH Regulation is that the responsibility for generating substance data lies with the substance manufacturers or importers.

  Particularly in the context of substance evaluation, the Commission can make justified demands for additional data from companies. Relevant testing is carried out according to the standards provided for under REACH (often international test methods) by laboratories that require additional certification for many tests. In the dossier evaluation, public authorities can check the information received and, if necessary, demand subsequent improvements or impose sanctions if non-compliance with requirements is found.

  Furthergoing possibilities for public authorities to commission tests / studies for obtaining additional data are not expedient, since the knowledge about the substances is primarily available in the companies and not on the part of the authorities. Unilateral commissioning by the authorities would leave out the companies' own testing strategies. In addition, there would also be a lack of coordination with the consortia. Last but not least, regulatory study requirements in other regions of the world where the companies are active would not be taken into account. This would put at stake the planning certainty needed by companies and the appropriateness / proportionality of data requirements and is, therefore, not acceptable.

- **Waiving requires a case-specific rationale - do not replace this by predefined tick-boxes**
  Justifications of waiving are case-specific. Thus, any limitations to waivers being established by public authorities would unnecessarily reduce options for avoiding animal testing and application of tailor-made testing strategies by registrants.

- **Keep completeness and compliance check separate – do not change ECHA's empowerment**
  Obvious cases of misuse may already now be rejected during dossier submission due to lack of completeness. Any further reaching compliance check should stay to be a separate process as this requires recognition of the overall data situation. It would be neither proportionate nor efficient to reject dossiers and disrupt manufacture/import or delay start of manufacture/import due to simple mistakes. For this, spontaneous updates as well as ECHA's compliance check decisions are more proportionate means.

- **Sound decisions require consultation and inclusion of newly available information**
  Limiting of the number of decision-making cycles addressing specific information requirements: It is important to allow full consideration of data, alternative approaches and comments from companies during decision making. Otherwise, superfluous (animal) testing and unnecessary burdens might result for companies. As any submission / intervention by companies is potentially labour-intensive and only substantial data would qualify for being considered there is no real danger of overloading the system with too many cycles.

- **Clarifications related to cease-of manufacture might improve awareness on Board of Appeal decision consequences**
  Clarifying requirements for registrants in case manufacturing is ceased or the registered volume changed during the evaluation procedure or in any follow-up registration according

to BoA decisions 9-2020 and 6-2020 might be helpful. However, options for manufacturers to declare cease of manufacture or to adapt tonnage bands resulting in reduced duties may not be limited any further.

- **Modifying procedural requirements requires due care**
  Any modification of current processes requires due care. The impact would depend on the details of each change. Thus, no overall rating is possible. As a guiding principle for thoughts about potential modifications, velocity should not be gained at the expense of proper consultation and assessments. We would be available to discuss pros and cons of concrete well founded proposals.
- **Testing proposal process helps to avoid unnecessary, non-accepted animal and other testing**
  If submission of testing proposals would be skipped, no alignment of the companies intended testing set-up with expectations of authorities would happen. Even for standard testing without column 2 adaptations there are certain decisions to be taken on the concrete test design that might in case of diverging views from companies and authorities be rejected later-on by authorities. Basically, this equally applies for non-animal as well as animal testing.

SECTION III AUTHORISATION AND RESTRICTION

Q 13 (-13b) Application of the essential use concept specifically under REACH

- **Assess the aspects really decisive for the impact of any essential use concept**
  The options provided do not allow a valid judgement related to essential uses and handling of the most harmful substances. Phase-out should remain a stepwise process and substitution options must take into account technical as well as economic feasibility. Simplicity, and velocity are no sound criteria for decisions on banning uses as the decisive question is whether the use of the substance would cause an unacceptable risk. Wrong / unsubstantiated decisions remain wrong, even if they would be fast, predictable und simple. Moreover, the ordinary restriction procedure already allows for effective bans in case this is scientifically justified.
- **Bring the concept of essential use in such a shape that it facilitates decisions on exemptions in the restriction procedure**

  Currently, there are many questions how decisions about what is essential should be made and by whom. How can such an approach be integrated into existing chemicals legislation, in particular REACH processes, in a practicable way and without contradicting EU law and WTO requirements?

  We support an "essential use" approach that is based on scientific risk assessment, in line with the application principles of the precautionary principle and underpinned by workable criteria. Here, safe uses must not be categorically excluded.

Any definition of essentiality should consider the much broader application range and not be narrow, as what might fit for the Montreal protocol's implementation is not fit for REACH purposes. Whereas health, safety and an intact environment might basically easily be agreed to be essential in Europe, views are expected to be much more diverse with regard to products supporting Green Deal goals and the modern way of life.

The evaluation of essential conditions could be included at the end of existing REACH procedures, e.g., the restriction of unacceptable risks or the authorisation procedure, in order to consider an exemption in a restriction proposal or to facilitate the decision to grant an authorisation for such a use. Since it is a societal decision and not a chemical law decision, what would be essential, a new committee could be set up for this purpose with the participation of representatives of various societal groups, including industry.

However, as unsafe uses might already be banned today, we do not see any real environmental, health, socio-economic or economic benefits.

The key question to be answered by the impact assessment remains whether the concept would allow efficiency gains while keeping proportionality. Furthermore, the demonstration of essentiality would very likely be of such high complexity that it would eat up any efficiency gains of the GRA or even worse add an additional burden on industry and authorities.

Q 13c - d Reform of the authorisation and restriction procedure

Keep the authorisation procedure, bring the scope of application into focus and simplify the process

- As the Commission indicated to make use of different sub-options of the main options 1 to 3, in their later-on preferred option, we do not discuss the impact of the overall options 1 to 3 but of their decisive aspects and the set-up of relevant sub-options.
- Basically, the authorisation procedure should be maintained for industrial, professional and consumer uses where this procedure is more suitable than other REACH or Non-REACH processes for avoiding negative ecological and economic impacts. The scope should be focused to cases where non-REACH measures (e.g. OSH) or the restriction procedure are less suitable than an authorisation.
  It should - at least for industrial and professional uses - never be replaced by the generic restriction procedure. Clarification, simplifications and such focussing on cases where no other measures would be equally suitable, would reduce burdens – even if efforts for an application for authorisation stay to be high - and basically provide legal certainty. As conditions of use are designed and granted case specific, also human health and environment profit from this approach.
- Compared to restrictions only the authorisation procedure balances substitution pressure and the right of companies to continue uses adequately controlled if no suitable alternative is available for the company in a reasonably transparent process.
- A merger of restriction and authorisation, and especially one where authorisation would be limited to essential uses under the generic restriction according to Art. 68 (2), would have a

strong negative impact on legal certainty, innovation and research, competitiveness, transparency and would add administrative burdens, due to the essential use assessment as an additional step and potential banning of safe uses. Additionally, the merger of the two processes as it has been outlined by the EU Commission would very likely result in increased complexity of the overall process.

- Non-REACH options should be given equal rights compared to REACH measures when assessing regulatory needs. This applies for judgements on what is already sufficiently addressed as well as for how to address additional regulatory needs. We request to consider this point in any of the options assessed to reform the authorisation and restriction scheme.
- In addition to options explicitly mentioned in the questionnaire we would like to address other aspects of potential regulatory options mentioned in the introduction.
  - For further developing ECHA's regulatory screening approach, the current candidate list for authorisation is intended to be transferred into a priorisation tool. Experiences with calls for evidence and other means for collecting data relevant to confirm potential concerns and regulatory needs as well as to allow differentiation between uses in this regard show that case specific data on use and exposure support tailor-made decision making. However, it would be too early in the process and too inefficient to collect such data already in registrations or for a broader number of substances or from all downstream users on a regular basis.
    For authorities as well as for companies an option to collect available data on use patterns for a limited number of substances with a limited set of basic data (fields) and, if relevant, additional case-specific questions constitute smarter options and should thus be considered in the Commission' s impact assessment.
  - Options for collecting relevant data on uses and exposure should pay specific attention on balancing workload and addresses of potential notification requirements with absolute needs for focused decision making on regulatory needs. This means: limit the number of candidate substances identified / affected, narrow down for which uses additional information on use and exposure should be provided, check upfront whether uses are covered already under other legislation (e.g. OSH, IED/BREF), foresee a deselection mechanism for the candidate list, usually limit reporting to one cycle and limit the number of cycles if repeated reporting is well justified.
- **Examine all options for simplifying the procedure with an open mind to the outcome**

  In order to limit the burden of authorisation and restriction procedures under REACH, all realistic possibilities for simplifying procedures should be used to the full - without limitations of scientific justifications, risk assessments and consultations. This includes appropriate timeframes for reviewing authorisations as well as exemptions for substances already regulated via other EU regulations and for applications with negligible exposure. However, with regard to potential procedural changes it is crucial to maintain at least the current consultations (e.g., of Stakeholders, Member State Committee) and exemptions (e.g., Art. 58 (2)). Also reviews of authorisations should be subject to the same rules as initial applications.

- **Specific solutions for small quantities required**

  Insofar as the authorisation procedure is to be maintained overall and also for small quantities, in particular, the procedure for small quantities (e.g., 100 kg/year) must be simplified. The same applies for processing agents.

- **Improve workability for SMEs**

  Furthermore, it should be examined how the efficiency, transparency, proportionality and workability of the regular restriction procedure under Article 69 can be improved, particularly for medium-sized enterprises.

- **Coordinate export regulations internationally**

  A point not addressed in the questionnaire is restrictions on exports. Export restrictions for products manufactured in Europe should generally not be imposed unilaterally but based on internationally coordinated and harmonised requirements. At present, the prerequisite safety is ensured by existing requirements to the manufacture of chemicals in the EU in combination with the EU Regulation on Prior Informed Consent (PIC Regulation). If necessary, it should therefore be examined not under REACH but under the leadership of international institutions whether there is a need to adapt international rules.

Q 14 (- 14 b) GRA

The regular restriction procedure for risk management better meets the precautionary principle than a generic approach

The regular restriction procedure allows for balanced risk management and consultations. Therefore, it should not be largely replaced by the so-called generic approach without prior consultation and risk assessment. Moreover, it must be taken into account that professional uses take place in different conditions than consumer uses.

- **Generic approach to risk management: Consider exposure and risk, keep up the scientific risk assessment as core element for chemicals management**

  The primarily hazard-based "generic approach to risk management" proposed in the Chemicals Strategy must be designed taking into account benefits, risks and safe conditions of use.

  Decisive for the protection of consumers is the safe use of a substance and not exclusively its intrinsic substance properties. It is also important that the procedure is transparent and includes appropriate opportunities for involvement of the companies and industries concerned.

  With an option that provides for a hazard-based approach for bans and restrictions, it is not sufficient to assess only the impacts in the REACH context; it is also essential that impacts of an indirect nature, in supply chains and other jurisdictions, are assessed too.

- **Professional uses are not consumer uses and, therefore, must not be regulated as such**

  The term "professional use" is used for professional activities that do not take place at an industrial site. However, the use conditions can be similar or even identical to those in the industrial sector. Professional users, compared to consumers, have specific qualifications and possibilities to limit risks during their respective activities (e. g. through occupational health and safety measures).
  Companies with business models relying on professional uses, are responsible that such uses are performed in line with conditions of use identified in registrations and communicated in the supply chains as identified safe uses. Equally relevant information from safety data sheets of mixtures has to be considered.

  We do not object that in enforcement projects some issues have been identified. However, where current legislation is not observed yet, training and enforcement is the more sustainable approach compared to bans that would also equally target those working in line with obligations and those with deficiencies. This applies across uses, different member states and sectors of use.

  If necessary, use conditions and risk management measures can be selectively restricted in a regular restriction procedure within the existing legal framework (REACH). Because of the situation described, it is neither necessary nor appropriate to equal professional use with use by private end users.

- **Restrictions must be proportionate - the generic approach lacks important aspects**

  The generic approach to risk management proposed in the Chemicals Strategy, with a ban on the use of particularly hazardous substances in the consumer sector or in open uses in the environment, must leave room for consideration of benefits, risks and possible safe use conditions. It is also important to establish transparent procedures with appropriate opportunities for involvement of the companies and industries concerned.

  Measures that are assessed as proportionate for the avoidance of the greatest risks must not be adopted for lesser risks without examination. It is explicitly stated that “Non-discrimination means that comparable situations should not be treated differently, and that different situations should not be treated in the same way, unless there are objective grounds for doing so.” (cf. Guidelines for applying the precautionary principle).

  For example, pure organ toxicity has a different quality than CMR effects. PBT substances cannot be compared with substances that only meet the P or the PB criteria.

- **Protection against particularly harmful chemicals can be achieved on the basis of existing regulation**

  Adaptations should include an examination of different options in the possibilities for the design of relevant provisions and of the respective impacts – especially in the supply chains. These options should be discussed in an open-ended dialogue with all stakeholders.

  For the restriction of PBT substances and substances with other hazard properties (such as immunotoxicity, neurotoxicity, organ toxicity, respiratory sensitisation), the regular

restriction procedure should apply as a matter of principle. Such substances must not be restricted without risk assessment and sufficient consultation with the parties concerned.

- **Simplify the restriction procedure – but not to the detriment of due care, risk assessment and proportionality**

  In risk management decisions, due care must take precedence over speed.

  The proven concept of scientific risk assessment must remain the central element for the application of the precautionary principle and for decisions in chemicals management.

  A transparent and comprehensible procedure is needed that is suitable for identifying the best risk management option and provides for sufficient stakeholder involvement.

- **Transparency in the procedure and involvement of companies**

  It is also important that the companies concerned are closely involved in all procedural steps and that appropriate consultations are provided for. In addition, submitted information must be given sufficient consideration.

  For public authorities and companies concerned, it must always be transparent in all assessment activities which substance is being processed when by whom and with what intention. Direct contact persons are needed too.

  All agency decisions affecting the registrant must be appealable.

- **Existing SVHC criteria already allow the identification of endocrine disruptors and other substances of similar concern as SVHC**

  Alongside the substance properties concretely named in the REACH Regulation, also all substances with similar serious effects on the environment or human health can be identified as SVHC (REACH Article 57 f). Several substances with endocrine disrupting or sensitising properties have already been identified as SVHC. Also, immuno- and neurotoxic substances may already now be identified as SVHC either according Art. 57 a-c or f).

  However, persistence and mobility or combinations of these parameters are not hazard properties and do not justify an adding of potential SVHC criteria. Should persistent or mobile substances qualify for SVHC identification in individual cases due to other serious properties (e. g. additional toxicity) their identification can be made within the existing legal framework.

- **Group approach could contribute to an efficient procedure and fair decision-making**

  Group approaches in regulation are supported, provided that no substances or uses are restricted without specific prior evidence of unacceptable risk and without grouping being substantiated by scientific data. Individual group members must be named, including appropriate identifiers. Here, completeness and quality of Annex XV dossiers, sound risk assessments and consultations as well as appropriate consideration of socio-economic aspects must be further prerequisites for proportionate regulatory decisions.

SECTION IV ENFORCEMENT

Q 14(c – l) Revision of requirements for checks and enforcement

Ensure level playing field by EU-wide, harmonised enforcement that gives equal consideration to all actors

Already now, the REACH Regulation provides a framework for suitable sanctions, inter alia, in conjunction with national legislation. In the interest of a level playing field in competition, the chemical industry welcomes better controls on imports, particularly E-Commerce imports, as well as a zero-tolerance policy for infringements. The following views should be considered or reconciled, respectively, in the concrete design of rules:

- **Enforcement authorities across the EU should enforce the chemicals legislation in a uniform manner**

  Fair enforcement must give equal consideration to manufacturers, traders, downstream users, importers and only representatives throughout the whole supply chain until private end consumer level. Otherwise, European companies will be at a competitive disadvantage vis-à-vis their non-EU competitors and within the EU. Appropriate qualifications of enforcement authorities, the provision of suitable analytical methods, the involvement of customs authorities in controls and further harmonisation efforts in inspections within EU-wide projects should make an important contribution to the purpose mentioned above.

- **Control instruments and inspections must be designed to ensure the swift movement of goods upon import**

  In case of suspicion by customs inspectors in B2B transactions, the chemical industry believes that the most efficient strategy for customs authorities is to alert national enforcement agents of a possible non-compliance and have them investigate once the shipment has reached its destination rather than blocking imports at the border. This would shift the burden of checking conformity with REACH for imported products onto a team of specialised local inspectors who will be more familiar with the complexities of REACH than the recipient of the goods. In principle, checks should be carried out downstream of import processing by the competent enforcement authority.

  The issue of ”E-Commerce imports", especially for B2C, must also be given greater consideration in term of enforcement. For instance, a priori controls could be conducted in the warehouses, and distribution / sorting centres of couriers like service providers handling ecommerce-sales to EU consumers. For the purpose of targeted controls special criteria need to be designed. In this context, VCI agrees with the suggested solutions to address problems with checking online purchases (internet trade) and small parcels under Option 14l and favours their further development and implementation.

- **Enable a differentiation between intentional infringements and unintentional errors / deviating interpretations as well as communication**

  ECHA already has the possibility to revoke registration numbers in case of persistently incomplete dossiers. If further competences are to be transferred to ECHA for the follow-up

of evaluation decisions, it is important that a distinction is made between intentional infringements and unintentional errors / deviating interpretations.

Furthermore, appropriate communication channels between the public authority and stakeholders should be established, which give the possibility to remedy inadequacies quickly. A right to be heard is required in the procedure.

- **Strengthen cooperation between customs and REACH enforcement agencies within the EU**

  There is a need for enhanced cooperation to improve data exchange between customs and REACH enforcement agencies and to ensure all Member States have the same means to release the goods at their borders. However, one of the key concerns of manufacturers of chemical products is the protection of confidential business information (CBI).

  There should not be additional procedures at the borders that will negatively impact the flow of legitimate and compliant / registered goods. The chemical industry welcomes the solutions tabled to introduce REACH-related parameters in the customs risk assessment to achieve a uniform risk assessment approach throughout Member States and the aim to provide support to customs authorities in Member States, e.g. training and suitable equipment (options 14j and 14k). We consider the further development of the European Customs Inventory of Chemical Substances (ECICS) database to show the link between CUS number and REACH requirements as a possible path forward, albeit CAS numbers are more commonly used in chemical industry and international chemical trade.

- **Ensuring knowledge regarding REACH requirements upon importation**

  VCI notes that limited knowledge about REACH is indeed a daily challenge for a compliant importation and placement of goods produced in third countries. Without doubt, it would be fruitful to make more information publicly available by sharing (non-sensitive) information on REACH online and by publishing newsletters with relevant information for importers and end-users. Such solutions would provide equal access to information across the value chain until consumer level.

  To ensure proper knowledge on REACH among importers or their representatives it is essential to organise regular awareness raising and training sessions. Hereby, customs authorities, enforcement agencies and associations could collaborate and join efforts to achieve this common goal. Such measures will certainly have positive effects, especially if there are synergies with already existing formats. The same applies for an inter-institutional platform if industry is involved.

- **Placing effective and balanced measures to address the risks of non-compliance at the border**

  The chemical Industry in Germany attaches great importance to a compliant behaviour in everyday business. Thus, VCI is seriously concerned about some of the suggested measures which, in our experience, could turn out to be inadequate and burdensome throughout customs procedures and the release into free circulation. For example, the introduction of a mandatory submission of chemical analysis certificates, safety data sheets (SDSs) and new

"standard information sheets" from third country producers upon importation will generate additional administrative costs for shipments into the EU and will require substantial changes of IT systems within companies and customs authorities, not least because a single shipment may contain several different REACH-related goods. In principle, VCI stands against attempts to introduce cumbersome and bureaucratic requirements into the importation procedure and strongly calls Member States and the European Commission to conduct proper cost-benefit assessments of options 14f (3; 4), 14g (2; 4), 14h (2; 3; 4) before taking any final decisions. For example, although it has been already demonstrated (e.g.**REF-8 project report**) that articles sold online have a high non-compliance rate, a mandatory requirement to submit SDSs would not tackle this issue due to the fact that SDSs are provided according to REACH only for substances and mixtures sold to industrial or professional users but not for articles or goods sold to consumers.

Furthermore, it is questionable whether embedding REACH in the AEO solution would have any added value to avoid non-compliance. Companies that have been granted an AEO authorisation are considered trusted economic operators which have already demonstrated that reliable internal compliance processes are in place and work efficiently. Moreover, importers that have not subjected themselves under such a strict regime should be the main target of a potential measure encouraging companies to reflect on REACH.

The German chemical industry emphasizes the need for practical measures that allow automated mass-processing of customs formalities mirroring the reality of industrial production whilst ensuring that unjustified blockage and delays of goods at the border are avoided (unless there is justified concern for public health or environment). Currently, however, the introduction of additional codes and the ongoing integration of REACH into the TARIC database goes the opposite direction since it adds complexity to the procedure by obliging the importer to conduct in-depth case-by-case assessments upon importation. We recognize that the involvement of customs authorities is necessary to be able to detect possible fraudulent cases of REACH imports and we take this issue seriously. For that reason, VCI advocates for an efficient and effective approach where the importer certifies by declaration, based on a unique REACH-related TARIC-and EU-wide applicable code, that the shipment conforms to the REACH regulation. This solution could be quickly implemented without major burdens for all goods in the combined nomenclature, irrespective of their status as substances, mixtures or articles under REACH, and at the same time it would raise awareness among importers about REACH requirements.

In order to avoid inconsistency and confusion among shippers and importers, genuine harmonisation among EU countries with regard to the customs involvement is crucial, in both scope and procedures. VCI opposes national measures as, for example, national codes that could potentially undermine a level playing field within the EU.

Last but not least, in our opinion the mandatory inclusion of the REACH registration numbers or CUS numbers in the customs declaration is not a feasible option and does not necessarily ensure compliance with REACH. In addition, some products might not even have such identifiers at the time of import for entirely valid reasons or may never have such an

identifier because e.g., they are out of the current scope of REACH (e.g., polymers, substances which occur in nature, exempted substances etc.).

Elements lacking in the planned impact assessment

The Chemicals Strategy contains many references to other elements of the Green Deal and between the planned changes to various pieces of chemicals legislation such as the REACH and CLP regulations.

The real effects of the REACH revision depend on this, so that such effects should be considered additionally in the impact assessment.

Here are some examples (the list is not exhaustive):

- Planned new CLP hazard classes and SVHC criteria and generic approach to risk management under REACH
- Impact of the generic approach to risk management and other measures, as regards other pillars or Green Deal objectives (e. g. climate protection, electromobility)
- Impact of definitions/concepts such as "safe and sustainable chemicals" or "substances of concern" within the implementation of the Circular Economy Action Plan
- Impact of the introduction of the "One Substance - One Assessment" concept

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The VCI represents the politico-economic interests of over 1,900 German chemical and pharmaceutical companies and German subsidiaries of foreign businesses in contacts with politicians, public authorities, other industries, science and media. In 2021, the industry realised sales of nearly 220 billion euros and employed around 530,000 staff.