CONSULTATION ON THE ROADMAP/INCEPTION IMPACT ASSESSMENT

VCI Position on the REACH Revision

Summary

The EU Chemicals Strategy intends large numbers of amendments and extensions of the existing chemicals legislation. These 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 can play 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 with a stable and predictable legal framework is crucial.

Fundamental aspects

- The goals of the Chemicals Strategy should be achieved primarily within the framework of existing legislation.
- To shape the Chemicals Strategy, a knowledge-based and open-ended dialogue with all stakeholders is needed, in order to prepare and evaluate various options for action, including cost-benefit impact assessments. Rushed action is not appropriate in relation to the size of the project.
- The further development of the chemicals legislation should be based on the precautionary principle, which provides for comprehensive scientific assessments, risk assessments and the involvement of stakeholders (cf. Commission communication on the precautionary principle).
- The diversity of chemicals, research and free market decisions are a basic prerequisite for innovative solutions.
- Options should not exclude the use of hazardous substances right from the start but should allow an evaluation with open results. The functionality or reactivity of chemical substances needed for certain uses and processes are often inextricably linked to their hazardous properties.

Shaping of regulatory options

- **Information and data requirements** must be proportionate and take into account animal welfare aspects. Where necessary, additional data requirements should therefore be based on a tiered approach that takes into account, inter alia, use and exposure.
- In order to consider possible **combination effects** in the exposure to substances in a targeted manner, if necessary, exclusively in the risk assessment of consumer uses mixture assessment factors specific to substances or substance groups should be applied. Supposedly simple regulatory approaches, such as an additional general assessment factor for all substances registered under REACH, 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.
- To improve **dossier and substance evaluation**, action plans by public authorities and industry are already being implemented and several implementing regulations have been issued.
- The **best option for risk management** should be identified in transparent procedures with sufficient involvement of relevant stakeholders.
- The scope of the **authorisation procedure** should be focused on specific suitable cases, and the burden of applications for small quantities should be reduced.
- The regular **restriction procedure** allows for balanced risk management and consultations. Therefore, it should not be replaced by the so-called generic approach. Moreover, it must be taken into account that professional uses take place in different conditions than consumer uses.
- **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, consider all actors equally and differentiate between intentional infringements and unintentional errors.

REACH Revision: The VCI's comments on the planned impact assessment of the EU Commission

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 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 results.

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:

1. Revision of information requirements

Ensure the proportionality of information requirements

Information and data requirements must be workable and take into account animal welfare aspects. If additional data requirements are necessary, they should therefore be based on a tiered approach, according to which differentiated, substance-specific information requirements are 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.

- **Registration of certain polymers: a workable, cost-efficient concept based on valid technical and scientific criteria is needed**

  When developing a registration option for certain polymers ("polymers requiring registration", PRR), the framework conditions specified in Art. 138 (2) of the REACH Regulation must be fulfilled.

  Criteria for identifying polymers requiring registration (PRR) and polymers not requiring registration ("polymers of low concern", PLC) must be developed. Furthermore, exemptions for certain PRRs based on risk-based approaches (e.g., polymeric precursors) are needed. To make polymer registration feasible and cost-effective, it is essential to also develop appropriate solutions for grouping PRRs (to reduce, among other things, the burden and

number of animal tests as well as costs). In this context, instead of the principle of "Sameness" known from non-polymeric substances, the principle of "Similarity" should be applied for the grouping of PRR. This is also necessary to ensure proportionality of information requirements for polymers, considering substance properties and exposure.

- **“Hazards of concern”: keep information requirements proportionate and use the substance assessment 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 otherwise needed 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 in a substance evaluation subsequently to the registration.

  This course of action should be given priority over wide-ranging additional requirements.

- **Endocrine disruptors: ensure a harmonised legal framework**

  The endocrine disruption is the causal linkage of adverse effects with a hormone-like mechanism of action, but not a novel adverse effect. Therefore, where necessary, additional data requirements - going beyond existing REACH information requirements - should be established on a substance-specific basis where there is a justified suspicion of endocrine effects and based on existing information depending on use and exposure.

- **Documentation of safe use: right sense of proportion is needed**

  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. for an authorisation application or for recycling issues, a targeted exchange between the parties concerned or, for example, the formation of know-how platforms is more expedient than comprehensive additional documentation requirements. The standard registration procedure should not be overstrained by this.

  In particular, 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 reports. Otherwise, substance uses would disappear from the market not because of their risk, but because of disproportionate costs (false selection).

- **Information on the environmental footprint: develop concepts together with interested parties**

  Consideration on information requirements regarding the overall environmental footprint of chemicals is at the very beginning. Here, concepts and criteria need to be discussed and developed together with all interested parties that have been tested for their impact and workability (e. g. in pilot projects) and find general acceptance (inter alia, through extensive consultation, appropriate adjustments and consideration thresholds).

2. Introduction of a mixture 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.

In order to take into account combination effects that may occur in the exposure of humans and/or 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.

3. Simplification of supply chain communication

Build on ENES activities and improve workability

The VCI welcomes that the EU Commission wants to simplify supply chain communication. The association and its members are already contributing to the ENES network, inter alia, through project work as part of the joint work programme.

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

  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 shows that workshops and practical instructions, among other things, help here.

  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).

- **Harmonised formats: Digitalizing safety data sheets, taking into account the role of software providers, existing systems and the timeline**

  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.

4. Revision of requirements in dossier and substance evaluation

Companies show responsibility and review their registration dossiers - parallel testing commissioned by public authorities is not justified

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 continues 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 2021) 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**

  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.

  Further going 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.

5. Reform of the authorisation procedure

Simplify the procedure and bring the scope of application into focus

- **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 restrictions on 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.

- **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.

- **A procedure is needed to ensure that the best and most efficient risk management option is chosen in each individual case**

  The reform of REACH authorisation and restriction procedures must establish a transparent method that ensures that the best and most efficient risk management option can be chosen in each individual case. The authorisation procedure should be limited to cases where it has demonstrable advantages over a restriction procedure. In this respect, we welcome that the European Commission wants to examine various options, even an abolition or merger of the authorisation and restriction procedures.

- **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.

  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.

6. Reform of the restriction procedure

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

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

  The primarily hazard-based "general 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 respective activities (e. g. through occupational health and safety measures) during their activities.

  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.

- **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.

  The evaluation of essential conditions could be included at the end of existing REACH procedures, e.g., the restriction/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 diverse societal groups, including industry.

- **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.

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

  The general concept for 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.

- **Roadmap for prioritising substances for the restriction procedure brings transparency**

  A roadmap for prioritising substances with certain properties within the regular REACH restriction procedure is supported, as this brings transparency and facilitates coordination between the public authorities involved.

- **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.

- **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**

  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.

7. 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 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 and internet sales as well as a zero-tolerance policy for infringements. The following points should be taken into account 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. Otherwise, European companies will be at a competitive disadvantage vis-à-vis their non-EU competitors and also within the EU. Appropriate qualifications of enforcement authorities, the provision of suitable analytical methods and involvement of customs in import controls and further harmonisation efforts in inspections within EU-wide projects should make an important contribution to this.

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

  For example, checks could be carried out downstream of import processing by the competent enforcement authority. The issue of "offers and sales via the internet" must also be given greater consideration in enforcement.

- **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.

8. 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 some examples (the list is not exhaustive):

- Planned new CLP hazard classes and SVHC criteria under REACH
- Planned new CLP hazard classes and generic approach to risk management under REACH
- Impact of the generic approach on 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 the Circular Economy Action Plan
- Impact of a concept to identify "Essential Uses".
- Impact of the introduction of the "One Substance - One Assessment" concept

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The VCI represents the politico-economic interests of over 1,700 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.