Contribution from VCI to the Commission consultation

Roadmap Chemicals Strategy for Sustainability

Background

On 9 May 2020, the European Commission published its roadmap for the “Chemicals strategy for sustainability”[1], which the Commission had announced as a constituent of the Green Deal in December 2019.

The roadmap explains the objectives, course of action and timetable for the development of the chemicals strategy. The strategy announced for the 3rd quarter 2020 is intended to take up the results from previous reviews of existing chemicals legislation, improve the protection of citizens and the environment against hazardous chemicals, strengthen Europe's autonomy in the production of essential chemicals and support other "Green Deal" priorities.

The EU Commission is focusing on simplifying and strengthening the existing legal framework. In order to achieve a uniform evaluation of substances, the Commission intends to examine the role of European agencies and advisory bodies in this context. In addition, the strategy is to address scientific findings on risks from endocrine disruptors, combination effects and persistent substances.

A public consultation within the framework of the "Better Regulation" initiative of the EU Commission ("Have your say") runs until 20 June 2020. The VCI contributes to this consultation with the following appraisals and suggestions.

Summary of VCI Cornerstones

The VCI supports the approach outlined in the roadmap: build the chemicals strategy on what has proven its worth and the lessons learned, utilize the potentials for improvement as identified in the evaluations of the chemicals legislation in further implementation, and include new scientific findings.

In considerations how to take up new indications of risks, it is important that this is done on a scientific basis and to take into account all the relevant policies as well as the whole range of aspects that make up sustainability.

[1] Link to the consultation website and the „Roadmap Chemicals Strategy for Sustainability“: http://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12264-Chemicals-strategy-for-sustainability-

The chemicals strategy should comprise the following framework conditions and guiding motives:

- Recognize and strengthen the **key role of the chemical and pharmaceutical industry** regarding health and environmental protection as well as sustainable solutions to achieve the goals of the “Green Deal”.
- **Ensure synergies and consistency** with other “Green Deal” pillars and with the economic recovery plan.
- Further **build on the development work** accounted for and progress achieved in the implementation of the current chemicals regulation.
- **Complex issues** require a thorough analysis of causes and effects as well as of experiences and of links to the existing regulatory overall concept before making decisions.
- Strengthen **certainty in planning** and ensure a **stable regulatory environment** in the chemicals legislation and especially under REACH.
- Recognize and strengthen the **risk-based approach** in the chemicals policy and regulation – for an effective risk management with a sense of proportion.
- The **ECHA database** is a unique database of substances worldwide and should be the starting point for harmonised risk assessments.

The following is essential in efforts to simplify and strengthen the existing legal framework and to incorporate new scientific findings:

- **Roles of agencies and advisory bodies** and “one substance, one assessment” A harmonised method for assessing substance properties is needed which is recognized and applied by all agencies – while it leaves enough scope for more in-depth assessment approaches for specific uses of substances. Industry should be involved in all activities to develop a risk assessment method and in the relevant bodies.
- **Endocrine disruptors (EDs)**: Learning from experiences in the fields of biocidal products and plant protectants to lay down horizontal criteria for ED identification. The potency of the substance, severity and reversibility of adverse effects on an intact organism, and the validity of scientific data must be taken into account.
- **Sustainability and hazardous substances** are not mutually exclusive. It is important to strengthen the safe and sustainable use of classified substances and to identify and exclude specific, unacceptable risks.
- **Combination effects of different substances**: Initially, relevant cases must be identified where a single substance assessment has not sufficiently covered the risks from combined exposure, before developing specific risk management procedures for these scenarios, if necessary.
- **Persistent substances**: No regulation without evidence of risk.

- Ensure **robust test methods** for production safety aspects and bring about improved animal welfare.
- Strengthen **risk management** by making it mandatory to carry out **analyses of regulatory management options**.
- Ensure consistent and efficient **enforcement**.
- Strengthen Europe as a location for chemical production.
- Take into account the effects and synergies with **international chemicals management** when developing the European chemicals strategy.

VCI Cornerstones

FRAMEWORK CONDITIONS FOR THE CHEMICALS STRATEGY

1. THE CHEMICAL AND PHARMACEUTICAL INDUSTRY SUPPORTS THE CREATION OF A FRAMEWORK, AS PRESENTED, IN THE DEVELOPMENT OF THE PLANNED CHEMICALS STRATEGY

The VCI supports the approach outlined in the roadmap to build the chemicals strategy on what has proven its worth and to fully utilize the experiences gained in recent evaluations of existing chemicals legislations as well as the identified potentials for improvement in further implementation efforts. Also, new scientific findings are to be included.

The roadmap announces simplifications and a strengthening of the legal framework. The VCI has already made concrete proposals for this in the context of the REFIT evaluations of the chemicals legislation.

In all deliberations on taking up new indications of risks of substances for humans and environment, it is important that these are based on scientific findings and to take into account all relevant regulations and the entire range of aspects that make up sustainability. A balance must be struck between claims that may not be fully compatible, e.g. sufficient testing of chemicals, animal welfare and the cost-benefit ratio of further tests.

2. THE CHEMICAL AND PHARMACEUTICAL INDUSTRY ENABLES SUSTAINABLE SOLUTIONS

With research and development and innovative products, the industry enables for our society today a high level of health and environmental protection. Together with other economic players, the industry with its products makes decisive contributions to the quality of life and value creation in Europe.

The chemical industry is a system provider and/or at least a supplier of building blocks for many solutions to achieve the "Green Deal" goals (e.g. for wind turbines, solar energy generation, energy storage, building modernisation and insulation, digitalisation).

At the same time, the industry is facing a comprehensive transformation process that calls for adequate location conditions.

3. ENSURE SYNERGIES AND CONSISTENCY WITH OTHER “GREEN DEAL” PILLARS AND WITH THE ECONOMIC RECOVERY PLAN

The opportunity should be used to achieve the greatest possible synergies – or, at least, to avoid conflicting goals – in implementing the various pillars and measures of

the Green Deal. In particular, this applies to the EU industrial strategy, circular economy, the transformation of the chemical industry, and the digitisation strategy. Furthermore, the priorities and timetables of the Green Deal and the Economic Recovery Plan should be attuned to each other and the opportunity to preserve or build up essential chemicals and supply chains in Europe should be taken.

4. BUILD ON THE DEVELOPMENT WORK ACCOUNTED FOR AND PROGRESS ACHIEVED

The European Commission's reports on reviews and evaluations[2] provide a good overview of the current state of implementation of the European chemicals policy and in particular its key regulation, i.e. REACH. They document the extensive development work and progress achieved by public authorities and industry. Compared with previous reviews, it was possible to show that process improvements have been brought about and that the individual procedures are gradually becoming better attuned to each other. But the reports also make quite clear that further work is needed to increase effectiveness and efficiency. In this context, a more holistic approach must be pursued than in the past, which takes into account all protection goals of relevant legislations as well as aspects of sustainability. This applies not only for synergies and interactions between policy areas of the "Green Deal", but also to the approach in the evaluation of substances (cp. 11.) and the choice of the most appropriate regulatory management option (cp. 15.).

5. COMPLEX ISSUES REQUIRE A THOROUGH ANALYSIS OF CAUSES AND EFFECTS, EXPERIENCES AND LINKS TO THE REGULATORY OVERALL CONCEPT

Complex issues require a thorough analysis of hazard, exposure and risk potentials, of the results of relevant safety research and of links to the existing regulatory overall concept.

As experience with nanomaterials shows[3], progress in such issues can be made and suitable solutions can be implemented if the following questions are clearly answered before decisions are made or the best suited regulatory option is initiated:

- What scientifically proven effects and impacts are there;

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2 Commission General Report on the operation of REACH and review of certain elements, COM(2018) 116 final; Report from the Commission about findings of the Fitness Check on the most relevant chemicals legislation (excluding REACH), COM(2019) 264 final; Communication from the Commission on options to address the interface between chemical, product and waste legislation, COM(2018) 32 final

3 Regulation (EC) 2018/1881 amending annexes I, III, VI, VII, VIII, IX, X, XI and XII of the REACH regulation (EC) No 1907/2006

- How are these already addressed directly or indirectly in existing regulation (here, other fields beside the chemicals legislation must be taken into account);
- What options for action are there in principle, especially through integration in existing approaches or regulations;
- Which methods, tools etc are needed – and what will become available when;
- What benefit can be achieved at what cost/effort, and which socio-economic aspects must be given consideration (impact assessment).

These experiences should be used, as a matter of principle, when approaching complex issues such as combination effects and persistent substances – and, more generally, in the context of the chemicals strategy as a whole.

6. STRENGTHEN CERTAINTY IN PLANNING IN THE CHEMICALS LEGISLATION AND ESPECIALLY UNDER REACH, AND ENSURE A STABLE REGULATORY FRAMEWORK

Implementing the complex REACH requirements is a step-by-step process that must be managed by companies and public authorities well beyond 2020. For example, the joint EU Commission/ECHA action plan for evaluating registrations is geared to the period up to 2027.

To make the implementation of existing complex requirements a success, companies need planning certainty and a stable regulatory environment. With its relevant conclusion in the REACH report 2018,[4], i.e. that there is no reason to change the enacting terms of the Regulation, the Commission provides an important basic prerequisite for further REACH implementation – with good prospects of success for the protective goals of REACH. The same objective should be pursued for the next review in 2022, and it should be respected in the shaping of the chemicals strategy.

Simplifications and a strengthening of the REACH building blocks should be further pursued, as set out in the 16 measures of the EU Commission. Our industry is contributing to this process, e.g. by participating in the Cefic action plan to check and update registration dossiers[5], the Exchange Network on Exposure Scenarios[6] and projects on specific issues (e.g. interface of REACH and occupational health and safety).

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4 Commission General Report on the operation of REACH and review of certain elements, COM(2018) 116 final

5 Cefic REACH Dossier Improvement Action Plan: https://cefic.org/our-industry/reach-dossier-improvement-action-plan

6 Exchange Network on Exposure Scenarios : https://echa.europa.eu/de/about-us/exchange-network-on-exposure-scenarios; Cefic/VCI have jointly developed, inter alia, the LCID method (LCID: Lead Component Identification), so that exposure scenarios of substances can be used for determining the safe use conditions of mixtures.

If planned refinements to requirements are made during the ongoing implementation of chemicals regulations, e.g. during the implementation of the biocidal products regulation, this must not delay or even prevent authorisations, but transitional periods for their application should be provided for, where appropriate.

7. THE ECHA DATABASE IS A UNIQUE DATABASE OF SUBSTANCES WORLDWIDE AND SHOULD BE THE STARTING POINT FOR HARMONISED RISK ASSESSMENTS

Under REACH, companies have to date submitted comprehensive substance data sets – in over 100,000 registration dossiers for 23,000 substances – to the European Chemicals Agency ECHA. This took place in parallel to the further development of regulatory requirements and interpretations, methods and evaluation processes, which led to criticism on being up-to-date and quality of dossiers and was reason enough for the EU Commission and ECHA to initiate an action plan with 15 measures to improve the data situation by 2027. Chemical companies participate in the action plan of the European Chemical Industry Council (Cefic), which was published in mid-2019 and provides for the review and, where necessary, updating of dossiers.

Now, It is important to complete and make use of this enormous wealth of data, instead of continuing to demand more (beyond REACH) physical-chemical and toxicological information, especially since an adaptation has already been made regarding nanomaterials. However, the chemical industry supports scientifically justified adjustments to the information requirements in Annexes VI-X.

8. RECOGNIZE AND STRENGTHEN THE RISK-BASED APPROACH IN THE CHEMICALS POLICY AND REGULATION – FOR AN EFFECTIVE AND PROPORTIONATE RISK MANAGEMENT

Policies and regulations require a fine balance between hazard-based and risk-based processes and rules. While a hazard-based approach may be or appear to be simpler and more transparent because of its lower complexity, often only a risk-based approach enables equally effective, efficient and proportionate risk management measures.

The above balance was largely achieved in the shaping of the REACH Regulation, but is increasingly being questioned at present, particularly in the restriction procedure (e.g. restriction proposal on microplastics). Furthermore, the EU Commission has newly introduced the term "generic risk consideration" in its communication on the REFIT assessment of the chemicals legislation. However, such considerations are not a real risk assessment; they would merely be an upgraded hazard evaluation – as substance- or use-dependent exposure levels/release potentials are not taken into account. Therefore, "generic risk considerations" can and must not replace valid risk assessments.

Simple hazard-based triggers should be maintained for some aspects of regulation; however, a regulatory decision must necessarily be more risk-based the more specific and relevant it becomes. Bans, restrictions and authorisations should rely exclusively on robust and scientifically sound risk assessments.

9. ROLES OF AGENCIES AND ADVISORY BODIES AND "ONE SUBSTANCE – ONE ASSESSMENT": A HARMONIZED METHOD IS NEEDED

Evaluation methods for substances have been established and further developed in all relevant chemical legislations (REACH, biocides, plant protection and certain product-specific provisions). So far, however, there is only limited cooperation between the European agencies/advisory bodies with their evaluation concepts. At the same time, it must be taken into account that established agencies and bodies (such as ECHA and EFSA) have specific competences and are not interchangeable at will. Regarding the assessment of the risk posed by a substance, the uses of this substance are essential, as they determine exposure pathways and levels. It is important to avoid duplication of work, conflicting opinions and inconsistencies as far as possible, as these cause uncertainty among public authorities, the public at large and industry – and they impair planning security.

Therefore, a harmonised methodology is needed, which is recognised and applied by all agencies – while giving scope for more in-depth assessment approaches for specific substance uses. In this way, scarce expert resources in public authorities and industry can be used efficiently, as parallel processing of the same issues could be avoided.

Industry should be involved in all work on a risk management methodology and in relevant bodies.

10. ENDOCRINE DISRUPTORS (ED): LEARNING FROM EXPERIENCES IN THE FIELDS OF BIOCIDES AND PLANT PROTECTANTS TO LAY DOWN HORIZONTAL CRITERIA FOR ED IDENTIFICATION

Endocrine disruptors (EDs) have been identified and regulated under the biocides and plant protection legislation, using criteria based on the WHO definition.[7] They have also been identified for several years as candidate substances for the authorisation procedure under REACH[8], and since 2014 a dedicated expert group has been providing scientific support. As with other candidate substances, once they have been identified, they are prioritized regarding the need for further regulation. Thus, there is already an increasingly used legal basis under REACH for the identification of endocrine disrupters, relying on a case-by-case assessment (general, no specific ED

[7] Cp. ECHA/EFSA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009

[8] Legal basis: identification of SVHC under REACH according to Article 57 f in conjunction with Article 59

criteria). Furthergoing regulatory risk management measures under REACH, such as restrictions (bans/restrictions on manufacture and use) and authorisation requirements (no use without specific authorisation) are fully applicable to endocrine disrupters. There is still a need for coordination concerning the scientific criteria for identifying these substances. The legal foundations for risk management options are already comprehensively implemented.

Consequently, the "one substance - one assessment" approach should also be applied to the identification of endocrine disrupters, so that horizontal criteria under REACH and biocides and plant protection legislation are equally applied and duplication and contradictions are avoided.

However, proposals to introduce horizontal criteria – in the form of a new hazard class in the CLP Regulation – are not target-oriented, as endocrine disrupting properties do not describe a toxicological endpoint (as e.g. carcinogenicity), but a mode of action. Furthermore, there is no such hazard class in the UN GHS[9], the harmonised application of which has been agreed by regions and countries through the incorporation of UN hazard classes into their regulations.

When establishing criteria for the identification of EDs, the following should be taken into account:

- As a general rule, it should also be possible, as part of the risk assessment, to set thresholds or limit values for endocrine disrupters below which no harmful effects are to be feared during use.
- EDs should be identified as those substances which, even in low quantities or dosages, cause adverse effects in humans or the environment. Here, consideration must be given, inter alia, to the potency of the substance, the severity of the adverse effects on an intact organism, the reversibility of an adverse effect and the validity of scientific data.

Before legislation is developed further, experiences with the practical implementation and possible impacts of existing legislations should be evaluated. In particular, this applies to the recently adopted criteria for biocidal products and plant protectants regulation and to the procedures under REACH. In our view, meaningful results can only be achieved after five years of experience at the earliest.

11. SUSTAINABILITY AND HAZARDOUS SUBSTANCES ARE NOT MUTUALLY EXCLUSIVE

The manufacture of many chemicals requires a specific reactivity of their starting materials, even if innovative processes are used or less hazardous or non-unclassified substances are produced.

[9] UN GHS: Globally Harmonized System of Classification and Labelling of Chemicals (GHS): https://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

As a matter of principle, also hazardous substances can be handled safely, especially in industrial uses. Therefore, it is important not to ban substances solely due to any classification under the CLP Regulation[10], but to exclude unacceptable risks from their uses and to strengthen the safe and sustainable use of classified substances. This can be done, for example, by better aligning REACH safety information and occupational health and safety practice and by using IT tools that support the generation and communication of safety information.

At least in the medium-term, classified substances will continue to have an important role in production and supply chains, and they will continue to make decisive contributions to digitalisation (electronic components), climate change ambitions (e-mobility, storage technologies for solar and wind energy etc) and other “Green Deal” goals. This must be taken into account in the definition of the term “toxic-free environment". A risk-based approach allows to distinguish safe and sustainable uses from unsafe uses of a substance. The sustainability of uses of chemicals should be assessed in a holistic way, taking into account the specific product uses during the entire life cycle of the substance.

Regarding the interface between chemicals and waste legislation, the EU Commission wants recovery operators to receive information on substances that could cause problems in recycling. An obligation to declare SVHC in articles was already introduced by the Waste Framework Directive, even before the completion of relevant studies. Declaration obligations must be clearly distinguished from substitution requirements. The VCI has submitted its comments on the role of substances that are classified and possibly problematic in recovery processes within the EU Commission's consultation on the above-mentioned interface.

12. COMBINATION EFFECTS OF DIFFERENT SUBSTANCES: PRIORITIZE RISKS BASED ON RELEVANT DATA SOURCES

In the discussion about combination effects, it is important to clearly specify which substances and combinations are meant (cp. 5.). In this respect, the term "combination effects of different chemicals" used in the roadmap only gives a rough orientation.

Intentionally produced mixtures are already regulated under the REACH and CLP regulations and, where applicable, under product-specific rules. If unintentional combinations are to be considered, it must be taken into account that no product contains a random number of chemicals and that no plant uses arbitrary numbers of chemical substances. Therefore, the question arises as to which combined exposures realistically occur and, moreover, represent a risk to humans and/or the environment that is not already addressed by existing risk management.

[10] Furthermore, according to the CLP Regulation, the term “hazardous” is used for a wide range of substance properties (e.g. irritant, instable, toxic). This is primarily about deriving safety information depending on the assigned classification – so that no harmful effects occur.

Parameters such as exposure pathways, exposure levels, relevant toxicological endpoint, mode of action, potency etc. of different substances limit the probability of combination effects occurring at all. Therefore, supposedly simple regulatory approaches (such as a recently proposed additional assessment factor for all substances registered under REACH) are not appropriate. Instead, relevant data sources should be used to identify those combinations with the highest risks.

13. PERSISTENT SUBSTANCES: NO REGULATION WITHOUT EVIDENCE OF RISK

Increasingly, public authorities are currently trying to undermine risk-based procedures and to regulate substances based on their persistence (cp. 8.). While REACH provides for an evaluation approach for substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, persistence alone is not a hazard characteristic. It is also argued that the likelihood of emissions occurring should replace evidence of a risk. This stands in contradiction to the mandatory requirement of an unacceptable risk as a trigger for a restriction under REACH.

Further discussions are about the attempt to establish persistence in combination with mobility (and possibly also toxicity) quasi as a hazard criterion. It is important to recognise that mobility is not synonymous with hazard or risk. The parameter "mobility" might provide information on the potential presence of a chemical in the environment (in a compartment). However, this parameter is not suitable to inform on exposure in biota, nor the potential to accumulate in biota. The scientific community holds that the potential hazard associated with the presence of a chemical in the environment can only be defined by an appropriate complex evaluation of the combination of fate properties and risk. In particular, an improved management of local sources and contaminations can contribute to better protection of drinking water. For this purpose, analytical methods need to be developed or validated – so that source-oriented measures can be elaborated where appropriate.

14. ENSURE VALIDITY OF TEST METHODS FOR PRODUCTION SAFETY ASPECTS AND BRING ABOUT MORE ANIMAL WELFARE

The REACH Regulation and its associated guidance documents describe the items of information required to establish a common understanding of both the hazards of and exposure to chemicals. By combining information on hazard and exposure, risks to human health and the environment are assessed. The current regulation is largely based on the traditional approach of animal testing to gain knowledge about such potentially dangerous effects. However, the REACH Regulation also promotes the use of alternative assessment methods without animal testing. This includes applying “weight of evidence” approaches, read-across and grouping of chemicals. This is a prerequisite for achieving the animal welfare objective of EU Directive 2010/63/EU on the protection of animals used for scientific purposes, which is also reflected in Article 25(1) of REACH: *“In order to avoid animal testing, testing on vertebrate animals for the*

purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests."

In practice, regulators 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.

Therefore, 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 avoid the use of animals, drive forward innovations and promote e.g. the use of new digital technologies for predictive toxicology.
- Work with the EU Commission to reduce the time required for research and development of new and safer substances. This would deliver more cost-effective innovations, bring products to market faster, prepare for future regulatory challenges and be accepted by consumers.
- Apply sound scientific principles that result in safer chemicals being brought on the market.
- Give priority to available measured exposure and emission data over modelled data, focus on high quality and reliable existing information and application/recognition of findings on mode of action of substances.

15. STRENGTHEN RISK MANAGEMENT BY MAKING IT MANDATORY TO CARRY OUT ANALYSES OF RISK MANAGEMENT OPTIONS

So far, public authorities of the EU Member States have been carrying out analyses of regulatory management options on a purely voluntary basis as part of their SVHC roadmap 2020. They determine what risk management already exists for a substance or its uses, whether additional regulation is necessary and which option is suited best for this purpose (e.g. restriction, authorisation, harmonised classification, workplace exposure limit etc.). This provides a basis for informed decisions on which regulatory route to take if necessary.

However, the national authorities' approach in this matter is not uniform to date. Therefore, the existing legal framework should be strengthened by introducing a mandatory analysis of regulatory management options with a harmonised approach. This is because it must be ensured – in the interest of better and sustainable regulation – that the most appropriate risk management measure is taken and that EU law is applied consistently. It is imperative that the industry concerned be involved in this process.

16. ENSURE CONSISTENT AND EFFICIENT ENFORCEMENT

Enforcement of chemicals legislation must be carried out uniformly throughout Europe by the supervisory authorities. Fair enforcement should equally take into account manufacturers, distributors, users, importers and only representatives. Otherwise, European companies will have competitive disadvantages compared to their non-European competitors and also within Europe. Further developing staff, the involvement of customs in import controls and further harmonisation efforts in inspections within the framework of EU-wide projects can make important contributions to this. Control instruments and checks must be designed in such a way that they do not impede the movement of goods on import. Checks should therefore preferably be carried out downstream of the import process by the competent supervisory authority. The issue of "internet offers and sales" must be considered in enforcement even more.

17. STRENGTHEN EUROPE AS A LOCATION FOR CHEMICAL PRODUCTION

According to the roadmap, the chemicals strategy should also support Europe's autonomy in the production of essential chemicals in key sectors in an overarching manner and promote research and development, in order to bring about a sustainable transformation of the chemical industry.

During the corona pandemic it has become clear how closely supply chains are interlinked and that the international division of labour and trade creates dependencies between the European economy and its global partners. At the same time, the chemical and pharmaceutical industry generates considerable export surpluses. Value creation and innovation are heavily dependent on trade.

It is difficult and might be subject to dynamic changes to define what essential chemicals are. The production of a medicine can require many ingredients and feedstocks as well as specific technology. Specializations have emerged; alliances make production efficient and enable the use of by-products.

In the described setting, the aim cannot be Europe’s autonomy for certain chemicals. Instead, the chemical and pharmaceutical industry must be able to adapt quickly and flexibly to changing framework conditions and requirements. Overly one-sided dependencies in the supply chains should be identified and resilience must be increased with a sense of proportion (e.g. by diversifying suppliers). There is no such thing as a "one size fits all" solution for companies.

Investment decisions against the EU usually have several rational reasons. Therefore, the EU and the national governments should make the location conditions in the EU so attractive for domestic and foreign investors that they once again invest more in Europe.

Research, e.g. within the European Partnership for Chemicals Risk Assessment under Horizon 2020, should involve chemical, biotechnology and life science companies in order to take account of cross-sectoral regulatory burdens when products from these

fields enter the market, so that the sectors' innovation potential and competitiveness are not restrained.

Strengthening Europe's position as a location for chemicals and pharmaceuticals will create the necessary know-how as well as human and financial resources to enable public authorities and industry to make sovereign decisions, in order to limit risks (e.g. supply shortages) and to facilitate investment in R&D.

18. TAKE INTO ACCOUNT INTERNATIONAL CHEMICALS MANAGEMENT

Global chemical production is expected to double by 2030[11] - with most production activities, especially for basic chemicals, taking place outside Europe.

Supply chains are internationally oriented and complex. Therefore, an effective and sustainable European chemicals strategy must include and support capacity building for chemicals management (infrastructure, know-how) outside the EU. In order to keep trade barriers and burdens on industry and public authorities concerned as low as possible, it is desirable that the already established and demanding regulations are compatible with emerging systems. The consistent and coherent implementation of the United Nations' "Globally Harmonized System of Classification, Labelling and Packaging of Chemicals" (UN GHS) is seen as the basis. In conducting and using studies on chemicals and the subsequent risk assessments, synergies should be utilised as far as possible. Decisive contributions and methods for this have been provided by OECD, ICCA and other institutions. The following elements are considered particularly important for chemicals management:

- Recognize and maintain the UN GHS on classification and labelling of chemicals: The international compatibility of the system must not be put into question by going-it-alone actions, because only such a harmonized system can achieve gradual implementation in developing regions in the long term.
- Mutual recognition of data: The OECD has developed a system that allows participating countries to share the results of studies and risk assessments carried out in accordance with OECD methods or guidelines. This allows reductions in cost and effort.
- Support to emerging regions through cooperation, sharing pragmatic "best practice" approaches and providing tools that help to build high quality, yet workable management systems at reduced cost and complexity, using the know-how of the world's leading regulators (e.g. ICCA Toolbox).[12]

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[11] UN Environment, Global Chemicals Outlook II (2019): http://www.unenvironment.org/resources/report/global-chemicals-outlook-ii-legacies-innovative-solutions

[12] International Council of Chemical Associations (ICCA), Regulatory Toolbox 2.0: http://www.icca-chem.org/wp-content/uploads/2018/04/ICCA-Regulatory-Toolbox-Version-2-0-FINAL-03-27-2018.pdf

- Continuation of the Multi-Stakeholder Strategic Approach on International Chemicals Management (SAICM) beyond 2020, as this process lays the necessary foundations for sustainable chemicals management worldwide.
- Make EU contributions to regulatory tools such as the OECD eChemPortal[13]
- Harmonisation and simplification of safety data sheets for consistent communication on the safe handling of substances and products, first from and to Europe, later worldwide.
- Establishment of an international chemicals navigator oriented to existing databases such as the European IUCLID database and those of the USA, Canada and Japan as well as the OECD eChem portal; in a second step extended to include legal regulations.
- Voluntary initiatives such as the chemical industry's Responsible Care® programme help promote sustainable practices and a continuous improvement process.

The European chemicals strategy should be designed in such a way that it fits as a building block into global trade and global management of chemicals. Concretely, this means to drive forward internationally agreed definitions, methods and quality-assured data requirements – while avoiding duplication of work and unnecessary animal testing. This would contribute to the continuous improvement of chemical safety.

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

The VCI represents the politico-economic interests of around 1,700 German chemical companies and German subsidiaries of foreign businesses. For this purpose, the VCI is in contact with politicians, public authorities, other industries, science and media. In 2019 the German chemical industry realised sales of over 198 billion euros and employed around 464,000 staff.

[13] OECD eChemPortal – The Global Portal to Information on Chemical Substances: https://www.echemportal.org/echemportal/