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# Advancing REACH - REACH and sustainable chemistry

Final report



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## **Advancing REACH - REACH and sustainable chemistry**

Final report

by

Dirk Bunke, Andreas Hermann  
Öko-Institut e.V., Freiburg

Dirk Jepsen, Antonia Reihlen  
Ökopol GmbH, Hamburg

On behalf of the German Environment Agency

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## **Abstract: Advancing REACH - REACH and sustainable chemistry**

This report is provided in the scope of the project “Advancing REACH”, funded by the research plan of the German Ministry of the Environment. The project aims to develop options to improve the implementation of REACH by analysing various REACH processes and related issues, including substitution, precautionary principle, articles, cost-benefit analyses, socio-economic analyses and financing ECHA.

Sustainable chemistry contributes to positive, long-term sustainable development. With new approaches, technologies and structures it stimulates technical and social innovations and develops value-creating products and services. Chemicals regulations such as REACH can support several aspects of sustainable chemistry. The main goal of work package 6 in the project “Advancing REACH” has been the development of recommendations how REACH can support sustainable chemistry stronger as it does actually.

The report gives a systematic analysis on the relations between main elements of REACH (e.g. Registration or Information in the supply chain) and main elements of sustainable chemistry (e.g. substitution of hazardous substances or corporate social responsibility of companies). This analysis is a solid basis for the development of recommendations for the improvement of the support. In addition, the analysis helps to get a better understanding of the relations between REACH and sustainable chemistry.

From data on problematic properties of chemicals up to information for consumers on substances of very high concern (SVHC) in articles: REACH supports already today sustainable chemistry in many ways. Weakness of implementation, the weighting of the different goals and limitations in the scope of REACH can reduce the generally possible positive effect of REACH on sustainable chemistry. In specific cases, it can even hinder important objectives of sustainable chemistry. The report describes 12 recommendations for a stronger support of sustainable chemistry by REACH: from a higher efficiency of REACH processes up to an increase in exchange and capacity building.

## **Kurzbeschreibung: REACH und nachhaltige Chemie**

Dieser Bericht ist Teil des Ressortforschungsplan Vorhabens „REACH-Weiterentwicklung“, das basierend auf Analysen verschiedener REACH-Prozesse sowie angrenzender Fragestellungen (Substitution, Nachhaltige Chemie, Vorsorgeprinzip, Erzeugnisse, Kosten-Nutzen Analysen, Sozio-Ökonomische Analysen, Finanzierung der ECHA) Optionen für eine Verbesserung der (Umsetzung der) REACH-Verordnung entwickelte.

Nachhaltige Chemie trägt zu einer positiven, langfristigen Entwicklung in Gesellschaft, Umwelt und Wirtschaft bei. Mit neuen Ansätzen und Technologien schafft sie attraktive Produkte und Dienstleistungen für den zivilgesellschaftlichen Bedarf (Blum et al. 2017). Chemikalienverordnungen wie REACH können mehrere Aspekte der nachhaltigen Chemie unterstützen. Das Hauptziel von Arbeitspaket 6 im Projekt "Advancing REACH" war die Entwicklung von Empfehlungen, wie REACH eine nachhaltige Chemie besser als bisher unterstützen kann.

Der Bericht liefert eine systematische Analyse der Zusammenhänge zwischen den Hauptelementen von REACH (z.B. Registrierung oder Information in der Lieferkette) und den wesentlichen Elementen der nachhaltigen Chemie (z.B. Substitution von Gefahrstoffen oder soziale Verantwortung von Unternehmen). Diese Analyse ist eine tragfähige Basis für die Entwicklung von Empfehlungen zur Stärkung der Unterstützung. Außerdem trägt die Analyse dazu bei, die Zusammenhänge zwischen REACH und der nachhaltigen Chemie besser zu verstehen.

Von Daten über problematische Eigenschaften von Chemikalien bis hin zu Informationen für Verbraucher über besorgniserregende Stoffe (SVHC) in Erzeugnissen: REACH unterstützt bereits heute die nachhaltige Chemie in vielerlei Hinsicht. Eine schwache Durchsetzung von Maßnahmen, die Gewichtung der verschiedenen Ziele und ein eingeschränkter Geltungsbereich von REACH können die generell möglichen positiven Auswirkungen von REACH auf die nachhaltige Chemie mindern. Im Bericht werden 12 Empfehlungen abgeleitet, durch die REACH nachhaltige Chemie noch stärker fördern kann. Sie reichen von der Steigerung der Effizienz der REACH Prozesse bis zum Ausbau von Austausch und Fachkompetenzen.

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## List of abbreviations

|                       |                                                                                                                        |
|-----------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>MS CA</b>          | Member State Competent Authority                                                                                       |
| <b>CoRAP</b>          | Community Rolling Action Plan                                                                                          |
| <b>CSA</b>            | Chemical Safety Assessment                                                                                             |
| <b>CSR</b>            | Chemical Safety Report                                                                                                 |
| <b>C&amp;L</b>        | Classification & Labelling                                                                                             |
| <b>CLP Regulation</b> | Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures |
| <b>DU</b>             | Downstream User                                                                                                        |
| <b>ES</b>             | Exposure Scenario                                                                                                      |
| <b>Forum</b>          | Forum of Exchange for Information on Enforcement                                                                       |
| <b>I</b>              | Importer                                                                                                               |
| <b>ITS</b>            | Intelligent Testing Strategy                                                                                           |
| <b>M</b>              | Manufacturer                                                                                                           |
| <b>MS</b>             | Member State                                                                                                           |
| <b>PACT</b>           | Public Activities Coordination Tool                                                                                    |
| <b>PBT</b>            | Persistent, bioaccumulative and toxic                                                                                  |
| <b>QSAR</b>           | Quantitative Structure Activity Relationships                                                                          |
| <b>RAC</b>            | Committee for Risk Assessment                                                                                          |
| <b>RMM</b>            | Risk Management Measure                                                                                                |
| <b>RMOA</b>           | Regulatory Management Option Analysis                                                                                  |
| <b>SDS</b>            | Safety Data Sheet                                                                                                      |
| <b>SEAC</b>           | Committee for Socio-economic analysis                                                                                  |
| <b>SIEF</b>           | Substance Information Exchange Forum                                                                                   |
| <b>SVHC</b>           | Substances of very high concern                                                                                        |
| <b>WoE</b>            | Weight of Evidence                                                                                                     |
| <b>vPvB</b>           | Very persistent and very bioaccumulative                                                                               |

## Summary

The current report is one of the results of the project “Advancing REACH”, which is funded by the research plan of the German Ministry of the Environment. Within the project framework, various aspects of the REACH regulation and its implementation are analysed and improvement options developed, including potential changes in the regulatory text and its annexes.

The project “Advancing REACH” consists of 18 sub-projects, which discuss different aspects of the regulation and related improvement options. Topics of the sub-projects are the REACH processes dossier evaluation, substance evaluation, restriction, authorisation and consultation, as well as the role of the board of appeal and the interplay of the processes. In addition, the relation between REACH and sustainable chemistry, the implementation of the precautionary principle, the enhancement of substitution and the assessment of benefits of REACH are evaluated, as well as the procedures of the socio-economic analysis, options to regulate substances in articles and the financing of the European chemicals agency’s (ECHA) tasks.

### 1 REACH and sustainable chemistry

Sustainable chemistry contributes to positive, long-term sustainable development. With new approaches, technologies and structures it stimulates technical and social innovations and develops value-creating products and services (Blum et al. 2017). Chemicals regulations such as REACH can support several aspects of sustainable chemistry. The main goal of work package 6 in the project “Advancing REACH” has been the development of recommendations how REACH can support sustainable chemistry stronger as it does actually.

At present no systematic analysis was available on the relations between main elements of REACH (e.g. Registration or Information in the supply chain) and main elements of sustainable chemistry (e.g. substitution of hazardous substances or corporate social responsibility of companies).

Such an analysis can be a solid basis for the development of recommendations how REACH can support sustainable chemistry stronger as it does at present.

- It facilitates the identification of options to foster sustainable chemistry via the implementation of REACH;
- it highlights elements of sustainable chemistry which are out of the scope of REACH and
- it allows to focus proposals for an enhanced exchange between REACH and sustainable chemistry on elements where actual support is realistic.

In addition, the analysis helps to get a better understanding of the relations between REACH and sustainable chemistry. The following sections summarise the main findings of the analysis and documents the recommendations which we developed based on this.

#### 1.1 Relations between REACH and sustainable chemistry

From data on problematic properties of chemicals up to information for consumers on SVHC in articles: REACH can support sustainable chemistry in many ways. For a detailed analysis of relations between these two fields, it has been helpful to describe the main elements of REACH and the main elements of sustainable chemistry.

The twelve main elements of REACH address the following topics:

- **Registration/Data sharing/ Information in the supply chain/ Downstream users/ Dossier evaluation/ Substance evaluation/ Authorisation / Restrictions/ Information. /Agency and Member States Competent Authorities / Fees and charges /Enforcement.**

The twelve main elements of sustainable chemistry refer to:

- **Inherently safer chemicals / Substitution / Reduction of emissions and impact / Resource conservation / Circular economy / Increase of market opportunities / Fair working conditions in the supply chains / Transparency and accessibility of data / Ambitious and enabling legislations / Training and Education / Consumer awareness/ Internalisation of costs**

A short description of these 2x12 main elements is given in chapter 1.2 of this report.

In this analysis of relations between REACH and sustainable chemistry, the line of vision started from REACH. The analysis answered the question, which elements of sustainable chemistry are fostered by REACH.

(Remark: Based on these findings, it is also possible to change the point of view. In chapter 3.3 of the final report it is described, which objectives and basic principles of REACH are mirrored by sustainable chemistry – and which are not. We separated this aspect from the summary in order not to overload the summary with details).

More than 100 relations between main elements of REACH and main elements of sustainable chemistry have been found in this analysis. These relations are described in the twelve tables in chapter 2 of this report. In order to visualise the findings, a matrix has been developed which gives a first impression on the structure and intensity of these relations. This matrix is shown in figure 1 and 2 of this report.

It has not been possible within the scope of this study, to analyse for each of these relations systematically to which extend the relation in practice has been implemented and to which extend it actually promotes sustainable chemistry. This would require for each element a more detailed description of the related chain of actions and a systematic assessment whether data is available to demonstrate the assumed influence. For the same reason we did not weight each of the relations whether it has a low or a high importance to support sustainable chemistry. Only in single cases a comment regarding a high or a low importance of a specific relation is made if this became obvious from the last REACH review and the related studies. An example is the high importance of the substance evaluation to ensure and to promote sufficient quality of data on substance properties and exposures.

Based on this analysis, the following chapters show more the potential of REACH to promote sustainable chemistry than provide a detailed analysis what REACH actually already does in this respect. Even with this restriction, the analysis allows to achieve a clear – and before not available – picture from the (complex) relation between REACH and sustainable chemistry and from the potential of REACH to support sustainable chemistry. In addition, the analysis allows to derive recommendations how REACH could even more support sustainable chemistry in future.

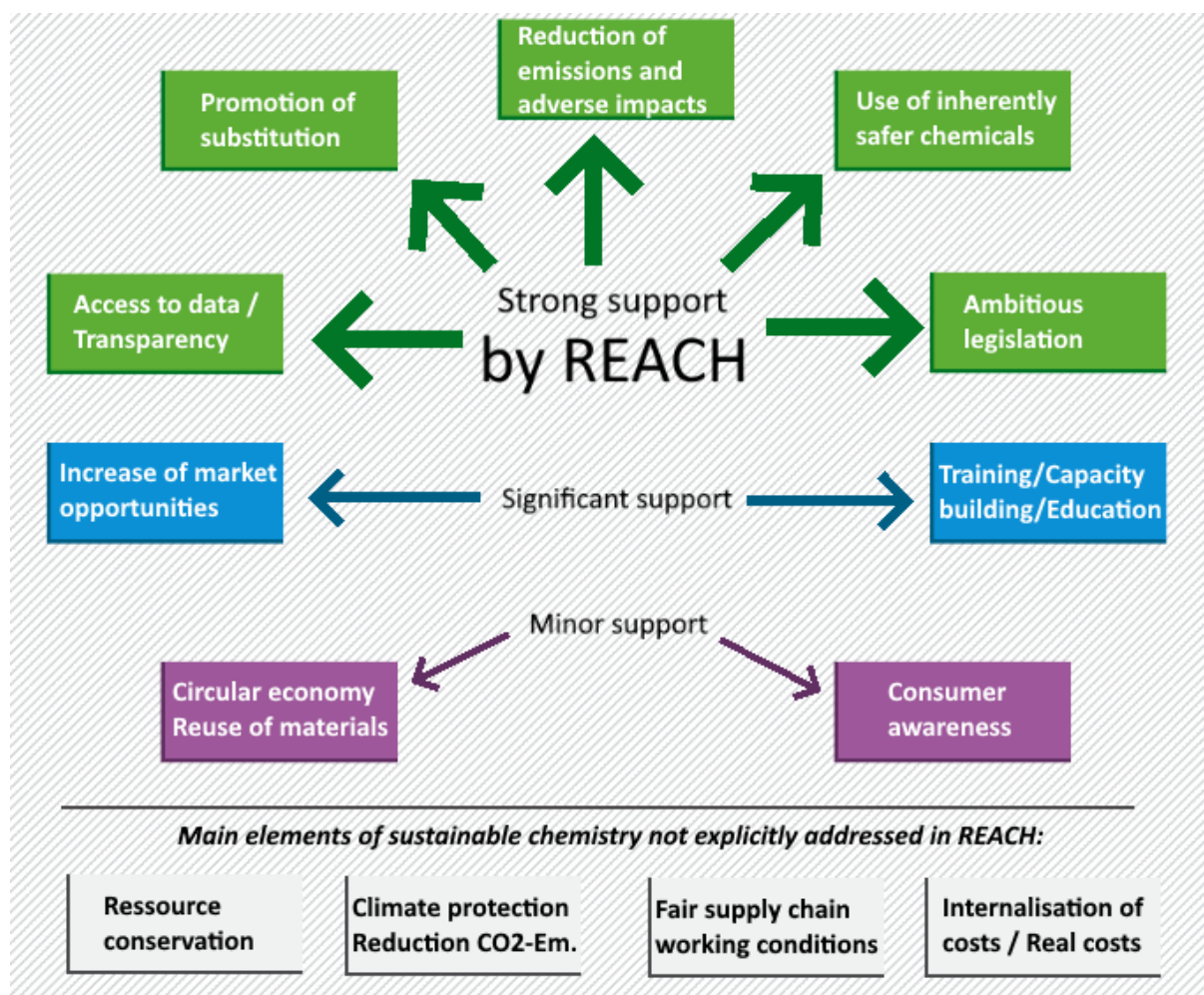
## **1.2 Main elements of sustainable chemistry, supported by REACH**

The following figure illustrates which elements of sustainable chemistry are supported by REACH. The figure arranges the results from the analysis in addition to the matrix in chapter 2 in a more apparent manner. Elements of sustainable chemistry which are supported by REACH are shown in boxes with green colours.

In addition, the figure shows which elements are clearly beyond the scope of REACH. They are shown in the lower part of the figure (below the line) in the four boxes without colouration.

In this figure, the issue of climate protection and reduction of CO<sub>2</sub> emissions is shown as an additional element. This issue belongs to the main element “reduction of emissions and adverse impacts” of sustainable chemistry. At the same time it is an important specific objective of sustainable chemistry, which is not addressed in REACH. Therefore it is described specifically in the analysis and in the figure.

**Figure 1:** Main elements of sustainable chemistry (green boxes) explicitly addressed in REACH and main elements not explicitly addressed (grey boxes).



Source: own illustration, Öko-Institut

The figure shows that REACH as a chemicals regulation supports a large number of main elements of sustainable chemistry. **Nine elements** are supported. **Three elements** and the objective of Climate protection are not explicitly addressed in REACH.

Some elements of sustainable chemistry are supported by REACH by many activities with a high impact, e.g. the reduction of emissions and adverse impacts. Others are supported, but to a minor extend, e.g. consumer awareness.

These differences are illustrated in the figure simply by the thickness and the color intensity of the arrows. This is based on two findings from the matrix analysis:

- the number of activities which support a specific main element of sustainable chemistry;

- ▶ a first estimation of the impact of the relations, if this has been possible (see the remark in section 1.1 of this summary).

**Strong support.** Five main elements of sustainable chemistry are supported by a large number of activities of REACH (more than 10 relations). Some of these activities are implemented since several years (e.g. submission of registration dossiers). The five main elements with strong support are:

- ▶ Reduction of emissions and adverse impacts
- ▶ substitution of hazardous chemicals;
- ▶ use of inherently safer chemicals;
- ▶ access to data and transparency and
- ▶ ambitious legislations.

Sections 3.2.1 – 3.2.5 describe more in detail in which way REACH supports these elements.

**Significant support.** Two main elements of sustainable chemistry are receiving significant support by several activities REACH:

- ▶ Increase of market opportunities (15 relations, at present low implementation) and
- ▶ training/capacity building/ education for sustainable development (less than 10 relations).

This support is described in more detail in sections 3.2.6 and 3.2.7.

**Minor support.** At present, two main elements of sustainable chemistry are explicitly addressed in REACH, however, only in a limited number of activities:

- ▶ Reduction of hazardous substances in materials for circular economy (six relations) and
- ▶ support of consumer awareness regarding products with less problematic chemicals (two relations).

This support is described in more detail in sections 3.2.8 and 3.2.9.

**Some main elements of sustainable chemistry are not addressed in REACH.** From conservation of non-renewable resources up to fundamental social rights – sustainable chemistry covers a very broad range of fields. Four of them are not explicitly addressed by activities within the chemicals regulation REACH:

- ▶ resource conservation,
- ▶ climate protection,
- ▶ standard-based supply chains and fair working conditions, and
- ▶ internalisation of costs.

These elements are described in section 3.2.10.

### 1.3 Aspects of REACH which can hinder sustainable chemistry

The detailed analysis of activities under REACH and their contribution to elements and objectives of sustainable chemistry has shown that REACH is supporting sustainable chemistry in many ways. At the same time, it became apparent that REACH can also be an obstacle for specific objectives of sustainable chemistry – for three reasons:

- ▶ weakness of implementation of specific activities under REACH;
- ▶ conflicting goals which impede an implementation which would foster sustainable chemistry and
- ▶ limitations in the scope of REACH as a whole or of specific activities within REACH.

For more information about these obstacles, see chapter 4.

### 1.4 How can REACH support sustainable chemistry even more effectively?

#### Recommendations

The detailed analysis of REACH and its contribution to sustainable chemistry leads to two major findings:

- ▶ REACH already now provides substantial and important support to the majority of topics of sustainable chemistry. There are many interfaces between REACH and sustainable chemistry. They should be exploited more intensively in order to support the sustainable development goals.
- ▶ Weakness of implementation (see section 4.2) , the weighting of the different goals (see section 4.3) and limitations in the scope of REACH (see section 4.4) can reduce the principally possible positive effect of REACH on sustainable chemistry. In specific cases, it can even hinder important objectives of sustainable chemistry, e.g. substitution of hazardous substances if they are not assessed as being substances of very high concern<sup>1</sup>.

This all in all favourable interaction between the global development goals, respectively the concept of sustainable chemistry, and the REACH Regulation is based on the broad agreement in the overarching goals. However, the role of these documents should not be overlooked. The REACH Regulation sets a framework based on some basic principles that is binding on manufacturers and users of chemicals. The "weakness of implementation" mentioned above is part of the REACH Regulation as of 2006, or rather the preparation of the regulation, but could be overcome more quickly through proactive cooperation between the parties involved.

The chemical industry often refers to its "responsible care" for its products and to its interest in innovations. Consequently, it is important that companies and associations orient their responsibilities towards the Sustainable Development Goals and not towards minimum compliance with legal requirements. As a result, the SDGs and the concept of sustainable chemistry provide the guidelines and guard rails for sound management of chemicals, but

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<sup>1</sup> Within the Concept of Sustainable Chemistry (Blum et al. 2017) it is clearly seen that in many cases the function of a chemical is connected with a hazardous property, e.g. biocidal activity of a disinfectant. Therefore substitution requires a robust analysis whether alternatives are available which fulfil the required function and do not have this or a similar problematic property.

ultimately require the legal basis for implementation. The perspective of the dependencies should be observed.

The REACH Regulation is not *per se* sustainable. Only the persons and institutions that implement REACH achieve sustainable chemicals management. Sustainable chemistry needs the legislative pillar to become effective, not the other way around. This does not rule out the possibility that individual elements of the sustainability goals may be incorporated into chemicals legislation or secondary regulation areas in the medium term. Here, for example, changes in consumer behaviour (reduction of plastic products) and the conservation of resources should be considered.

Based on the findings of the analysis on REACH and sustainable chemistry, the following recommendations are given, how REACH and its implementation can be further developed in order to support sustainable chemistry even more effectively. The recommendations explicitly exclude areas currently not covered by REACH. These recommendations can be implemented within the current legislative scope of REACH.

### **Increase effectivity and efficiency of REACH processes**

1. **Improve the quality of the data on the properties and uses of chemicals.** Hazard and exposure data of high quality are the crucial starting point in sustainable chemistry to reduce emissions in the entire life cycle of a substance to a safe level, to decide on substances with less problematic properties and to find functional substitutes. Incentives should be given for companies which prepare registration dossiers of high quality.
2. **Speed up the process of substance evaluation, including the processes of identification of SVHC and decisions on the most appropriate regulatory option.** This will help to shorten the time period in which emissions of substances of potential concern can occur (before the regulatory decision is taken) and to achieve the related SDG on the safe use of chemicals by 2030.
3. **Support risk reduction measures aiming reducing emissions to a safe level covering the entire substance life cycle. Additional measures that allow to further reduce the total emission of substances with reasonable efforts can minimise uncertainties from a limited quality of risk characterisation data.** Sustainable chemistry is based on the principle of “minimization” of emissions and risks. It would be of great support if under REACH economic actors are motivated to implement risk management approaches that further reduce the total emission if appropriate.
4. **Broaden the present “single substance” perspective of REACH.** Strengthen consideration of mixture effects in Registration, Restriction and Authorisation. Sustainable chemistry aims to reduce the total exposure of men and the environment and considers in the assessment of chemicals also additive effects and other mixture effects.
5. **Use REACH Candidate List, authorisations and restrictions to effectively regulate substances of concern with endpoints which are not in the focus of classification and labelling.** Examples are persistent, mobile and toxic substances, polymers with problematic properties and persistent substances of equivalent concern (REACH Art. 57f. equivalent level of concern).
6. **Improve the socio-economic assessment by addressing adverse effects to individuals and the environment in a holistic approach.** To better take account of sustainable chemistry, the approaches how effects on society and the environment as a whole are addressed should be modified.

Document the application of the precautionary principle and support its use in the SEA. A

stronger focus and weight should be given to the application of this principle as an argument in the overall assessment.

### **Better consider substances of concern in mixtures, articles and waste**

7. **Give more guidance to adequately address the end-of-life stage in chemical safety assessments.** This allows reducing burdens from wastes and can contribute to a strengthening of circular economy by avoiding the entry of substances of concern in materials and wastes
8. **Increase the knowledge of SVHC in articles and the possibilities for consumers to obtain information** about this issue. More efforts should be made to further raise awareness on SVHC in articles in the EU and worldwide. The REACH provisions could be used as a basis for global (communication) standards on SVHC in articles, leading to more transparency and awareness

### **Improve substitution of substances of concern**

9. Stronger promote knowledge about available substitutes for substances of very high concern in the supply chains and support their substitution. Authorisations should only be granted, if no substitutes are available (which are technically and economically feasible). At present, many activities under REACH generate information on potential alternatives to hazardous substances. However, this information is not systematically compiled and made publicly available. This could be of significant help to many actors, in particular in countries in lesser developed countries and economies in transition.
10. Support functional substitutions by regulating not only individual substances, but groups of substances which share a common structure and similar concerns (category approach). Substitution of substances of concern by alternatives, which are similarly hazardous is a problem at global level. Under REACH, the scope of several processes could address groups of substances. Options to implement category approaches should be further implemented and developed methodologies should be made available also globally, to facilitate learning from REACH experience.
11. Provide incentives for a substitution of substances classified as hazardous going beyond the substitution of substances of very high concern. Under REACH, focus of the substitution processes within authorization is on SVHC. Sustainable chemistry aims to replace in a broader scope hazardous substances (even if they do not fulfill the criteria of Annex XIII).

### **Exchange and capacity building**

12. **Strengthen Capacity building especially in developing countries and in countries in transition.** This is of crucial importance for the sound management of chemicals and waste, for the transition to a more sustainable chemistry and for progress regarding the sustainable development goals. In fact, the implementation of REACH is already supporting these efforts. To further support capacity building, it is recommended to enhance the transfer of learnings and experiences regarding risk management decision making and implementation from the EU to other countries but also within the supply chains and sectors inside the EU.

For references of the recommendations to the underlying analysis see chapter 5.

## Zusammenfassung

Der vorliegende Bericht ist ein Teilergebnis des Ressortforschungsplan-Vorhabens „REACH-Weiterentwicklung“. Im Rahmen dieses Vorhabens wurden verschiedene Aspekte der REACH – Verordnung und ihrer Umsetzung analysiert und Verbesserungsoptionen, einschließlich einer möglichen Veränderung des Verordnungstextes und seiner Anhänge, aufgezeigt.

Das Vorhaben REACH-Weiterentwicklung besteht aus insgesamt 18 Teilprojekten, die sich mit unterschiedlichen Aspekten der Umsetzung der REACH Verordnung und Optionen für deren Weiterentwicklung auseinandersetzen. So werden in den jeweiligen Teilprojekten die REACH Prozesse Dossierbewertung, Stoffbewertung, Beschränkung, Zulassung und Konsultationen sowie, die Rolle der Widerspruchskammer und das Zusammenspiel der Prozesse analysiert. Auch die Umsetzung des Vorsorgeprinzips, die Förderung der Substitution und die Abschätzung des Nutzens der REACH-Verordnung werden untersucht sowie auch das Verfahren der sozio-ökonomischen Analyse, Optionen zur Regulierung von Stoffen in Erzeugnissen und die Finanzierung der Aufgaben der Chemikalienagentur ECHA.

### 1 REACH und nachhaltige Chemie

Nachhaltige Chemie trägt zu einer positiven, langfristigen Entwicklung in Gesellschaft, Umwelt und Wirtschaft bei. Mit neuen Ansätzen und Technologien schafft sie attraktive Produkte und Dienstleistungen für den zivilgesellschaftlichen Bedarf (Blum et al. 2017). Chemikalienverordnungen wie REACH können mehrere Aspekte der nachhaltigen Chemie unterstützen. Das Hauptziel von Arbeitspaket 6 im Projekt "Advancing REACH" war die Entwicklung von Empfehlungen, wie REACH eine nachhaltige Chemie besser als bisher unterstützen kann.

Derzeit liegt keine systematische Analyse der Zusammenhänge zwischen den Hauptelementen von REACH (z.B. Registrierung oder Information in der Lieferkette) und den wesentlichen Elementen der nachhaltigen Chemie (z.B. Substitution von Gefahrstoffen oder soziale Verantwortung von Unternehmen) vor.

Eine solche Analyse bietet eine tragfähige Basis für die Entwicklung von Empfehlungen dazu, wie REACH die nachhaltige Chemie besser als bisher unterstützen kann.

- Sie erleichtert die Identifizierung von Optionen zur Förderung einer nachhaltigen Chemie durch die Umsetzung von REACH;
- Sie hebt Elemente der nachhaltigen Chemie hervor, die nicht in den Anwendungsbereich von REACH fallen und
- Sie ermöglicht eine Fokussierung der Vorschläge für einen verbesserten Austausch zwischen REACH und der nachhaltigen Chemie auf Elemente, bei denen eine tatsächliche Unterstützung realistisch ist.

Darüber hinaus trägt die Analyse dazu bei, die Zusammenhänge zwischen REACH und der nachhaltigen Chemie besser zu verstehen. Die folgenden Abschnitte fassen die wichtigsten Ergebnisse der Analyse zusammen und stellen die auf der Grundlage dieser Ergebnisse aufbauenden Empfehlungen, die von uns entwickelt wurden, dar.

#### 1.1 Zusammenhänge zwischen REACH und der nachhaltigen Chemie

Von Daten über problematische Eigenschaften von Chemikalien bis hin zu Informationen für Verbraucher über besorgniserregende Stoffe (SVHC) in Erzeugnissen: REACH kann die nachhaltige Chemie in vielerlei Hinsicht unterstützen. Für eine detaillierte Analyse der

Zusammenhänge zwischen diesen beiden Bereichen war es hilfreich, die wesentlichen Bestandteile von REACH und die zentralen Elemente der nachhaltigen Chemie zu beschreiben.

Die zwölf Kernelemente von REACH beziehen sich auf die folgenden Themenfelder:

- **Registrierung / Datenweitergabe / Informationen in der Lieferkette/ Nachgeschaltete Anwender/ Dossierbewertung / Stoffbewertung / Zulassung / Beschränkung / Informationen / die Agentur und die zuständigen Behörden der Mitgliedstaaten / Gebühren und Abgaben / Durchsetzung.**

Die zwölf Hauptelemente der nachhaltigen Chemie beziehen sich auf:

- **Inhärent sicherere Chemikalien / Substitution / Reduzierung von Emissionen und Auswirkungen / Ressourcenschonung / Kreislaufwirtschaft / Erhöhung der Marktchancen / Faire Arbeitsbedingungen in den Lieferketten / Transparenz und Zugriff auf Datenbestände / Weitreichende und sekundäre Rechtsvorschriften / Aus- und Weiterbildung / Verbraucherbewusstsein / Internalisierung der Kosten**

Kapitel 1.2 dieses Berichts enthält eine kurze Beschreibung dieser 2 x 12 Kernelemente.

In der Analyse der Zusammenhänge zwischen REACH und der nachhaltigen Chemie wurde zunächst die Perspektive von REACH eingenommen. Die Analyse beantwortete die Frage, welche Elemente der nachhaltigen Chemie durch REACH gefördert werden.

(Anmerkung: Auf der Grundlage dieser Erkenntnisse kann man auch eine andere Blickrichtung einnehmen. In Kapitel 3.3 des Endberichts wird beschrieben, welche Ziele und Grundsätze von REACH sich in der nachhaltigen Chemie widerspiegeln – und welche nicht. Wir haben diesen Aspekt in der Zusammenfassung außen vorgelassen, um die Zusammenfassung nicht mit Details zu überladen).

Die Analyse ergab mehr als 100 Zusammenhänge zwischen den Hauptelementen von REACH und den Kernelementen der nachhaltigen Chemie. Diese Zusammenhänge werden in den zwölf Tabellen in Kapitel 2 dieses Berichts beschrieben. Um die Ergebnisse zu visualisieren, wurde eine Matrix entwickelt, die einen ersten Eindruck über die Struktur und Intensität dieser Zusammenhänge vermittelt. Diese Matrix ist in den Abbildungen 1 und 2 dieses Berichts dargestellt.

Im Rahmen dieser Studie war es nicht möglich, für jeden dieser Zusammenhänge systematisch zu analysieren, inwieweit der Zusammenhang in der Praxis umgesetzt wurde und inwieweit er tatsächlich eine nachhaltige Chemie fördert. Dazu wäre es notwendig, für jedes Element die damit verbundene Handlungskette genau zu beschreiben und systematisch zu bewerten, ob Daten zum Nachweis des angenommenen Einflusses verfügbar sind. Aus dem gleichen Grund haben wir nicht jeden der Zusammenhänge danach gewichtet, ob er eine geringe oder eine hohe Bedeutung für die Unterstützung einer nachhaltigen Chemie hat. Nur in Einzelfällen kommentierten wir die hohe bzw. geringe Bedeutung eines bestimmten Zusammenhangs, wenn diese in der letzten REACH-Überprüfung und den damit verbundenen Studien zutage trat. Ein Beispiel ist die Stoffbewertung, die von großer Bedeutung ist, um eine ausreichende Qualität der Daten über Stoffeigenschaften und -expositionen zu gewährleisten und zu fördern.

Auf der Grundlage dieser Analyse haben wir in den folgenden Kapiteln eher das Potenzial von REACH zur Förderung der nachhaltigen Chemie aufgezeigt als genau zu analysieren, was REACH in dieser Hinsicht bereits tut. Trotz dieser Einschränkung erlaubt die Analyse, ein klares und bisher nicht verfügbares Bild über die (komplexen) Zusammenhänge zwischen REACH und der nachhaltigen Chemie und über das Potenzial von REACH zur Förderung der nachhaltigen

Chemie zu erlangen. Darüber hinaus lassen sich aus der Analyse Empfehlungen ableiten, wie REACH die nachhaltige Chemie in Zukunft noch besser unterstützen könnte.

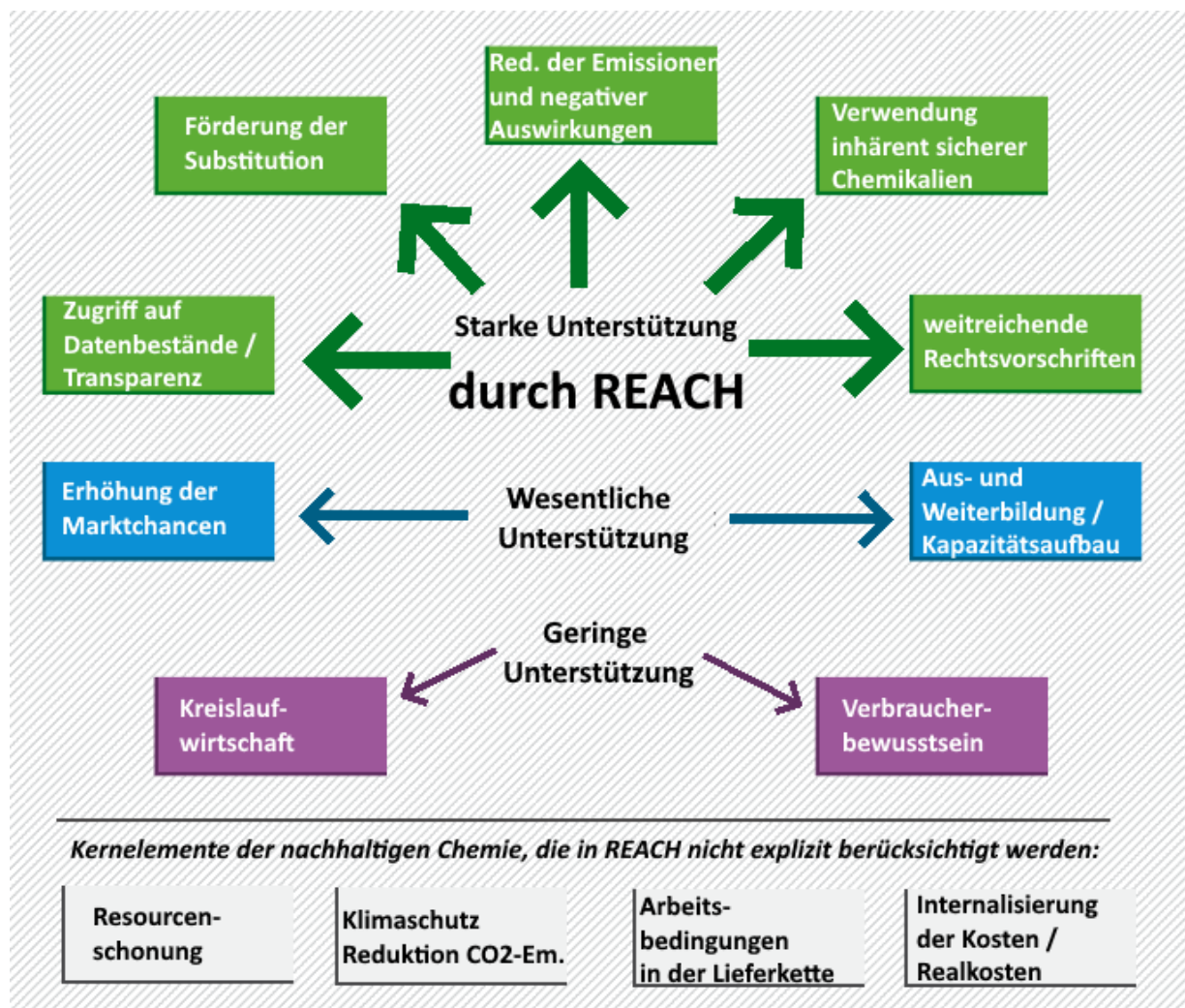
## **1.2 Kernelemente der nachhaltigen Chemie, die von REACH unterstützt werden**

Die folgende Abbildung veranschaulicht, welche Elemente einer nachhaltigen Chemie durch REACH unterstützt werden. Die Abbildung zeigt die Ergebnisse der Analyse noch einmal übersichtlicher angeordnet als bei der in Kapitel 2 dargestellten Matrix. Elemente der nachhaltigen Chemie, die durch REACH unterstützt werden, sind in grünfarbigen Kästen dargestellt.

Darüber hinaus zeigt die Abbildung, welche Elemente deutlich über den Rahmen von REACH hinausgehen. Sie sind im unteren Teil der Abbildung (unterhalb der Linie) in den vier Kästen dargestellt, die nicht farbig hinterlegt sind.

In Abbildung 1 wird das Thema Klimaschutz und Reduktion der CO<sub>2</sub>-Emissionen als zusätzliches Element dargestellt. Dieser Bereich ist dem Kernelement „Reduzierung von Emissionen und negativen Auswirkungen“ der nachhaltigen Chemie zuzuordnen. Gleichzeitig handelt es sich dabei um ein wichtiges spezifisches Ziel der nachhaltigen Chemie, das nicht in REACH verankert ist. Daher findet es entsprechend Niederschlag in der Analyse sowie in Abb. 1.

**Abb. 1:** Kernelemente der nachhaltigen Chemie (grüne Kästen), die in REACH ausdrücklich angesprochen werden, und Kernelemente, die nicht ausdrücklich angesprochen werden (Kästen mit grauer Farbfüllung).



Quelle: eigene Darstellung, Öko-Institut

Die Abbildung zeigt, dass REACH als Chemikalienverordnung eine Vielzahl von Kernelementen der nachhaltigen Chemie unterstützt. **Neun Elemente** werden unterstützt. **Drei Elemente** und das Ziel des Klimaschutzes sind in REACH nicht explizit verankert.

Einige Elemente der nachhaltigen Chemie werden von REACH durch viele weitreichende Aktivitäten gefördert, z.B. die Reduzierung von Emissionen und negativen Auswirkungen. Andere wie z. B. Verbraucherbewusstsein werden zwar unterstützt, allerdings nur in geringem Umfang.

Diese Unterschiede werden in der Abbildung einfach durch die Dicke und die Farbintensität der Pfeile veranschaulicht. Die folgenden beiden Erkenntnisse aus der Matrixanalyse bilden die Grundlage für diese Darstellung:

- die Anzahl der Aktivitäten, die ein bestimmtes Kernelement der nachhaltigen Chemie unterstützen;
- eine erste Abschätzung der Auswirkungen der Zusammenhänge, wo eine solche durchgeführt werden konnte (siehe dazu die Bemerkung in Abschnitt 1.1 dieser Zusammenfassung).

**Starke Unterstützung.** Fünf Kernelemente der nachhaltigen Chemie werden durch eine Vielzahl von REACH-Aktivitäten gefördert (mehr als 10 Zusammenhänge). Einige dieser Aktivitäten werden bereits seit mehreren Jahren durchgeführt (z.B. Einreichung von Registrierungs-dossiers). Die fünf Kernelemente, die stark gefördert werden, sind folgende:

- ▶ Reduzierung von Emissionen und negativen Auswirkungen
- ▶ Substitution gefährlicher Chemikalien;
- ▶ Verwendung inhärent sichererer Chemikalien;
- ▶ Zugriff auf Datenbestände und Transparenz und
- ▶ Weitreichende Rechtsvorschriften.

In den Abschnitten 3.2.1 - 3.2.5 wird näher beschrieben, wie REACH diese Elemente unterstützt.

**Wesentliche Unterstützung.** Zwei Hauptelemente der nachhaltigen Chemie werden durch mehrere REACH-Aktivitäten erheblich gefördert:

- ▶ Erhöhung der Marktchancen (15 Zusammenhänge, derzeit geringe Umsetzung) und
- ▶ Ausbildung/ Kapazitätsaufbau/ Bildung für nachhaltige Entwicklung (weniger als 10 Zusammenhänge).

Diese Förderung wird in den Abschnitten 3.2.6 und 3.2.7 näher beschrieben.

**Geringe Unterstützung.** Derzeit werden von REACH zwei Kernelemente der nachhaltigen Chemie explizit abgedeckt, allerdings werden diese nur durch eine begrenzte Anzahl von Aktivitäten gefördert:

- ▶ Reduzierung von Gefahrstoffen in Materialien für die Kreislaufwirtschaft (sechs Zusammenhänge) und
- ▶ Unterstützung des Verbraucherbewusstseins für Produkte mit weniger problematischen Chemikalien (zwei Zusammenhänge).

Diese Unterstützung wird in den Abschnitten 3.2.8 und 3.2.9 näher beschrieben.

**Einige Kernelemente der nachhaltigen Chemie werden in REACH nicht behandelt.** Von der Schonung nicht erneuerbarer Ressourcen bis hin zu sozialen Grundrechten – die nachhaltige Chemie deckt ein sehr breites Spektrum ab. Für vier dieser Bereiche sind keine Aktivitäten im Rahmen der Chemikalienverordnung REACH explizit vorgesehen:

- ▶ Ressourcenschonung,
- ▶ Klimaschutz,
- ▶ standardbasierte Lieferketten und faire Arbeitsbedingungen, und
- ▶ Internalisierung der Kosten.

Diese Elemente sind in Abschnitt 3.2.10 beschrieben.

### 1.3 Aspekte von REACH, die eine nachhaltige Chemie behindern können.

Die detaillierte Analyse der Aktivitäten im Rahmen von REACH und der Beitrag dieses Regelwerks zu den Elementen und Zielen einer nachhaltigen Chemie hat gezeigt, dass REACH die nachhaltige Chemie in vielerlei Hinsicht unterstützt. Gleichzeitig wurde deutlich, dass REACH auch ein Hindernis für spezifische Ziele einer nachhaltigen Chemie darstellen kann – aus drei Gründen:

- ▶ Schwache Umsetzung spezifischer Maßnahmen;
- ▶ Widersprüchliche Ziele, die eine Umsetzung, die eine nachhaltige Chemie fördern würde, behindern und
- ▶ Beschränkungen des Geltungsbereichs von REACH als Ganzes oder bestimmter Aktivitäten im Rahmen von REACH.

Weitere Informationen zu diesen Hindernissen finden Sie in Kapitel 4.

### 1.4 Wie kann REACH eine nachhaltige Chemie noch effektiver unterstützen?

#### Empfehlungen

Als Ergebnis der detaillierten Analyse von REACH und dem Beitrag dieses Regelwerks zur nachhaltigen Chemie sind zwei wesentliche Erkenntnisse festzuhalten:

- ▶ REACH unterstützt bereits jetzt in großem Umfang die meisten Themen der nachhaltigen Chemie. Es gibt viele Schnittstellen zwischen REACH und der nachhaltigen Chemie. Diese sollten intensiver genutzt werden, um die Ziele der nachhaltigen Entwicklung zu unterstützen.
- ▶ Eine schwache Durchsetzung von Maßnahmen (siehe Abschnitt 4.2), die Gewichtung der verschiedenen Ziele (siehe Abschnitt 4.3) und ein eingeschränkter Geltungsbereich von REACH (siehe Abschnitt 4.4) können die generell möglichen positiven Auswirkungen von REACH auf die nachhaltige Chemie mindern. In Einzelfällen können diese Faktoren sogar wichtige Ziele einer nachhaltigen Chemie behindern, z.B. die Substitution von Gefahrstoffen, die nicht als besonders besorgniserregend eingestuft werden<sup>2</sup>.

Diese insgesamt günstige Wechselwirkung zwischen den globalen Entwicklungszielen bzw. dem Konzept der nachhaltigen Chemie und der REACH-Verordnung beruht auf einer breiten Übereinstimmung, was die übergeordneten Ziele angeht. Die Rolle dieser Dokumente darf dabei nicht außer Acht gelassen werden. Die REACH-Verordnung gibt einen auf einigen Grundprinzipien basierenden Rahmen vor, der für Hersteller und Anwender von Chemikalien verbindlich ist. Die oben erwähnte „schwache Umsetzung“ geht mit der REACH-Verordnung 1907/2006 bzw. der Vorbereitung der Verordnung einher, könnte aber durch eine proaktive Zusammenarbeit zwischen den beteiligten Parteien schneller überwunden werden.

Die chemische Industrie verweist oft auf ihren „verantwortungsbewussten Umgang (responsible care)“ mit ihren Produkten und auf ihr Interesse an Innovationen. Daher ist es wichtig, dass Unternehmen und Verbände ihre Verpflichtungen an den Zielen der nachhaltigen Entwicklung

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<sup>2</sup> Das Gesamtkonzept der nachhaltigen Chemie (Blum et al. 2017) macht deutlich, dass in vielen Fällen die Funktion einer Chemikalie mit einer gefährlichen Eigenschaft verbunden ist, z.B. der bioziden Aktivität eines Desinfektionsmittels. Daher erfordert die Substitution eine verlässliche Analyse darüber, ob es Alternativen gibt, die die geforderte Funktion erfüllen und nicht die jeweilige gefährliche Eigenschaft oder eine ähnlich problematische Eigenschaft aufweisen.

orientieren und nicht an einer Minimal- Einhaltung der gesetzlichen Vorgaben. Die SDGs und das Konzept der nachhaltigen Chemie stellen dabei zwar die Richtlinien und Leitplanken für einen umweltverträglichen Umgang mit Chemikalien zur Verfügung, für ihre Umsetzung ist letztlich jedoch eine rechtliche Grundlage erforderlich. Hierbei sollten die vorhandenen Abhängigkeiten berücksichtigt werden.

Die REACH-Verordnung ist nicht per se nachhaltig. Allein die Personen und Institutionen, die REACH umsetzen, können ein nachhaltiges Chemikalienmanagement erzielen. Nachhaltige Chemie braucht die gesetzgeberische Säule um wirksam zu werden, nicht andersherum. Das schließt nicht aus, dass einzelne Elemente der Nachhaltigkeitsziele mittelfristig in das Chemikalienrecht oder in sekundäre Regelungsbereiche aufgenommen werden. In diesem Zusammenhang sind z.B. Veränderungen im Verbraucherverhalten (Reduzierung von Kunststoffprodukten) und die Schonung von Ressourcen zu berücksichtigen.

Basierend auf den Ergebnissen der Analyse zu REACH und zur nachhaltigen Chemie werden folgende Empfehlungen gegeben, wie REACH und seine Umsetzung weiterentwickelt werden können, um die nachhaltige Chemie noch effektiver zu unterstützen. In den Empfehlungen werden Bereiche, die derzeit nicht unter REACH fallen, ausdrücklich ausgenommen (siehe Abschnitt 3.2.10). Diese Empfehlungen können im Rahmen der aktuellen Gesetzgebung von REACH umgesetzt werden.

### **Steigerung der Effektivität und der Effizienz der REACH-Prozesse**

1. **Verbesserung der Qualität der Daten über die Eigenschaften und Anwendungen von Chemikalien.** Gefährdungs- und Expositionsdaten hoher Qualität sind der entscheidende Ausgangspunkt in der nachhaltigen Chemie, um die Emissionen über den gesamten Lebenszyklus eines Stoffes auf ein sicheres Niveau zu senken, sich für Stoffe mit weniger problematischen Eigenschaften zu entscheiden und zweckmäßige Ersatzstoffe zu finden. Für Unternehmen, die Registrierungsdossiers von hoher Qualität erstellen, sollten Anreize geschaffen werden.
2. **Beschleunigung des Prozesses der Stoffbewertung, einschließlich der Prozesse zur Identifizierung von SVHCs und der Entscheidung über die am besten geeignete Regulierungsoption.** Diese wird dazu beitragen, die Zeitspanne, in der Emissionen von Stoffen mit Gefahrenpotenzial auftreten können, zu verkürzen (bevor die regulatorische Entscheidung getroffen wird) und das damit verbundene SDG über die sichere Verwendung von Chemikalien bis 2030 zu erreichen.
3. **Unterstützung von Maßnahmen zur Risikominderung mit dem Ziel, die Emissionen auf ein sicheres Niveau zu reduzieren, und zwar über den gesamten Lebenszyklus der Stoffe. Durch zusätzliche Maßnahmen, mithilfe derer die Gesamtemissionen von Stoffen mit vertretbarem Aufwand weiter reduziert werden können, lassen sich die Unsicherheiten verringern, die auf eine unzureichende Qualität der Risikobeschreibungsdaten zurückzuführen sind.** Die nachhaltige Chemie basiert auf dem Prinzip der „Minimierung“ von Emissionen und Risiken. Es wäre sehr hilfreich, wenn die Wirtschaftsakteure im Rahmen von REACH motiviert wären, Risikomanagementkonzepte umzusetzen, die die Gesamtemissionen gegebenenfalls weiter reduzieren.
4. **Erweiterung der aktuellen „Einzelstoff“-Perspektive von REACH.** Stärkere Berücksichtigung von Mischungseffekten bei der Registrierung, Beschränkung und Zulassung. Die nachhaltige Chemie zielt darauf ab, die Gesamtexposition von Mensch und Umwelt zu verringern und berücksichtigt bei der Bewertung von Chemikalien auch additive Effekte und andere Mischungseffekte.
5. **Verwendung der REACH-Kandidatenliste sowie Zulassungen und Beschränkungen im Rahmen von REACH, um besorgniserregende Stoffe, die nicht im Fokus der Einstufung und Kennzeichnung stehen, durch Endpunkte wirksam zu regulieren.** Beispiele sind

mobile Stoffe, Polymere mit problematischen Eigenschaften und schwer abbaubare Stoffe, die in gleichem Maße Anlass zur Sorge geben (REACH Art. 57f. gleichwertiger Grad der Besorgnis).

6. **Verbesserung der sozioökonomischen Bewertung, um schädlichen Auswirkungen auf Mensch und Umwelt in einem ganzheitlichen Ansatz entgegenzuwirken.** Um stärker nachhaltige Chemie zu berücksichtigen, sollte die Vorgehensweise wie die Effekte auf Gesellschaft und Umwelt als Ganzes angegangen werden, modifiziert werden. Dokumentierung der Anwendung des Vorsorgeprinzips und Unterstützung seiner Anwendung im Rahmen der sozioökonomischen Analyse. Die Anwendung dieses Prinzips sollte als Argument in der Gesamtbewertung stärker in den Vordergrund gestellt und gewichtet werden.
7. **Bessere Prüfung besorgniserregender Stoffe in Gemischen, Artikeln und Abfällen. Eine bessere Orientierungshilfe zur angemessenen Adressierung der End-of-Life-Lebensphase bei Stoffsicherheitsbewertungen.** Dies ermöglicht eine Verringerung der Belastungen durch Abfälle und kann zu einer Stärkung der Kreislaufwirtschaft beitragen, indem der Eintrag von besorgniserregenden Stoffen in Materialien und Abfälle vermieden wird.
8. **Erweiterung des Wissens über SVHC in Erzeugnissen und der Möglichkeiten für Verbraucher, sich über dieses Thema zu informieren.** Es sollten weitere Anstrengungen unternommen werden, um das Bewusstsein für SVHC in Erzeugnissen in der EU und weltweit weiter zu schärfen. Die REACH-Bestimmungen könnten als Grundlage für globale (Kommunikations-)Standards für SVHC in Erzeugnissen dienen, was zu mehr Transparenz und Bewusstsein führen würde.

#### **Verbesserung der Substitution von besorgniserregenden Stoffen**

9. **Stärkere Förderung einer Wissensbasis über verfügbare Ersatzstoffe für besonders besorgniserregende Stoffe in den Lieferketten und Förderung ihrer Substitution. Zulassungen sollten nur erteilt werden, wenn keine (technisch und wirtschaftlich tragfähigen) Ersatzstoffe zur Verfügung stehen.** Derzeit liefern viele Maßnahmen unter REACH Informationen über mögliche Alternativen zu Gefahrstoffen. Diese Informationen werden jedoch nicht systematisch zusammengestellt und öffentlich zugänglich gemacht. Dies könnte für viele Akteure, insbesondere in weniger entwickelten Ländern und Schwellenländern, eine wichtige Hilfe sein.
10. **Förderung des Ersatzes durch geeignete Alternativstoffe durch Regulierung nicht nur einzelner Stoffe, sondern auch von Stoffgruppen, die eine einheitliche Struktur aufweisen und zu ähnlichen Problemen führen (Kategorieansatz).** Die Substitution von bedenklichen Stoffen durch Alternativen, die ähnlich gefährlich sind, ist ein globales Problem. Unter REACH könnte der Anwendungsbereich mehrerer Prozesse auf Stoffgruppen ausgedehnt werden. Optionen zur Umsetzung von Kategorieansätzen sollten weiter umgesetzt und entwickelte Methoden auch weltweit verfügbar gemacht werden, um das Lernen aus den Erfahrungen mit REACH zu erleichtern.
11. **Schaffung von Anreizen für die Substitution von als gefährlich eingestuften Stoffen, die über die Substitution von besonders besorgniserregenden Stoffen hinausgehen.** Unter REACH liegt der Schwerpunkt der Substitutionsprozesse im Rahmen der Zulassung auf SVHC. Die nachhaltige Chemie zielt jedoch darauf ab, Gefahrstoffe in größerem Rahmen zu ersetzen (auch wenn sie die Kriterien des Anhangs XIII nicht erfüllen).

## **Austausch und Kapazitätsaufbau**

- 12. Stärkung des Aufbaus von Kapazitäten, insbesondere in Entwicklungsländern und in Schwellenländern.** Dies ist von entscheidender Bedeutung für die ordnungsgemäße Handhabung von Chemikalien und Abfällen, für den Übergang zu einer nachhaltigeren Chemie und im Hinblick auf Fortschritte, was die Ziele der nachhaltigen Entwicklung angeht. Die Umsetzung von REACH unterstützt diese Bemühungen bereits jetzt. Um den Aufbau von Kapazitäten weiter zu unterstützen, wird empfohlen, den Transfer von Erkenntnissen und Erfahrungen in Bezug auf die Entscheidungsfindung und Umsetzung des Risikomanagements von der EU in andere Länder, aber auch innerhalb der Lieferketten und Sektoren innerhalb der EU, zu verbessern.

Für Verweise zwischen den einzelnen Empfehlungen auf die ihnen zugrunde liegenden Ergebnisse der Analyse siehe Kapitel 5.

# 1 Introduction: Relations between REACH and sustainable chemistry

## 1.1 Background and aim

Sustainable chemistry contributes to positive, long-term sustainable development. With new approaches, technologies and structures it stimulates technical and social innovations and develops value-creating products and services (Blum et al. 2017). Chemicals regulations such as REACH can support several aspects of sustainable chemistry. The main goal of work package 6 in the project “Advancing REACH” has been the identification of concrete options which allow to enhance this support within the existing REACH regulation.

At present no systematic analysis has been available on the relations between main elements of REACH (e.g. Registration or Information in the supply chain) and main elements of sustainable chemistry (e.g. substitution of hazardous substances or corporate social responsibility of companies).

- Such an analysis is a solid basis for the development of recommendations how REACH can support sustainable chemistry stronger as it does at present. It facilitates the identification of options to foster sustainable chemistry via the implementation of REACH;
- It highlights elements of sustainable chemistry which are out of the scope of REACH and
- It allows to focus proposals for an enhanced exchange between REACH and sustainable chemistry on elements where actual support is realistic.

In addition, the analysis helps to get a better understanding of the relations between REACH and sustainable chemistry

The following chapters show in detail the results of a systematic search for relations between REACH and sustainable chemistry. Starting point are 12 main elements of REACH and 12 main elements of sustainable chemistry. These elements are described in section 1.2. The approach chosen for the analysis of the relations between these elements is described in section 1.3

Before the results of the analysis and the conclusions from this work are described in chapters 2 – 5, additional information from a legal perspective on relations between REACH, sustainability and sustainable chemistry is given in section 1.4.

The results of the analysis of relations between REACH and sustainable chemistry are visualised as a matrix in chapter 2.1. Individual relations are described in twelve tables in chapter 2.2

Findings from this analysis regarding the question how REACH can support sustainable chemistry are the content of chapter 3. A limited number of obstacles in REACH for specific objectives of sustainable chemistry are explained in chapter 4.

Based on the results presented in chapter 2 – 4, recommendations have been elaborated how REACH could support sustainable chemistry even more effectively. They are described in chapter 5 of this report.

## 1.2 Main elements of REACH and of sustainable chemistry

The following “main elements” of REACH reflect the main processes of REACH and largely correspond to the titles of the regulation.

- ▶ **R1: Registration.** This element covers the activities from manufacturers (M) and importers (I) of substances who are obliged to register their substances. It includes among others, the preparation of a registration dossier with respective hazard data and a chemical safety report, if required. As a central element, it is the basis for most of the elements of REACH.
- ▶ **R2: Data sharing.** Data sharing under REACH aims to avoid unnecessary testing of animals and to reduce the registration costs. Formation of SIEFS and application of specific methods such as read across are examples of activities in this element which are related to specific elements of sustainable chemistry.
- ▶ **R3: Information in the supply chain.** Communication between manufacturers/importers of substances and downstream users (formulators and end users of substances and mixtures, manufacturers and supplier of articles, retailers) are of central importance to ensure safe use of chemicals. Main activities in this field are the receipt and the use of safety data sheets. This element also includes information about substances of very high concern in articles.
- ▶ **R4: Downstream users.** According to the principle of shared responsibility, downstream users (DU) of substances have specific obligations under REACH. One central activity is the comparison of the own uses with the identified uses as described in the safety data sheets. Further activities can result from information of the DU on hazardous properties and the implementation of risk management measures in case these deviate from the information in the safety data sheet of the suppliers. These activities are supplementary to the activities within the supply chain (see previous point).
- ▶ **R5: Dossier evaluation.** This element is crucial for a quality control for the registration dossiers. It aims to ensure that the data in the registration dossiers, e.g. on substance properties, are of sufficient quality to derive appropriate risk management measures for a safe use of substances. Beyond this, it is of central importance to have a robust data base for substance evaluation and following elements such as Authorisation and Restriction.
- ▶ **R6: Substance evaluation.** Based on a prioritization of substances according to suspected concerns, substance evaluation improves the quality of substance data related to the particular concern under question. Activities such as grouping of substances and regulatory management option analyses aim to avoid regrettable substitutions and to identify the most appropriate regulatory management option, considering REACH and other legislations.
- ▶ **R7: Authorisation.** Substances of very high concern have to be substituted under REACH, if less problematic substitutes (substances or processes) are available and technically and economically feasible. Activities in this field reach from placing of substances on the Candidate List and public consultations on alternatives until granting of authorisations. If applying for an authorization, industry has to demonstrate that the risks can be controlled even for substances of very high concern (SVHC), including a socio-economic analysis.
- ▶ **R8: Restrictions.** Specific uses of substances with unacceptable risks which cannot be adequately controlled can be restricted under REACH. This requires preparation of restriction dossiers by member state competent authorities, decisions about restriction

proposals as well as listing of restrictions in REACH Annex XVII. Restriction dossiers include a socio-economic analysis on the costs and benefits of specific uses of the substance under evaluation.

- **R9: Information.** This element consists of reporting obligations of ECHA and member states as well as communication activities from ECHA to MS and to the general public. It does not refer to information in the supply chain which is the topic of element R3. The review on the operation of REACH and CLP, the report on alternatives for animal testing and the dissemination database for non-confidential data from registration dossiers belong to this element.
- **R10: Agency and Member States Competent Authorities.** ECHA has specific obligations to support European and international cooperations as well as to support developing countries, if requested by the Commission. Member States have to build national helpdesks to help enterprises to be compliant with REACH. In addition, preparation of information about risks of substances for the general public belongs to this element. These activities are described in REACH Title X (Agency) and XIII (Competent authorities).
- **R11: Fees and charges.** Fees and charges as given in the REACH legislation could be incentives which support sustainable chemistry. Examples for important activities in this field are reduction of fees for SMEs (lowering the economic burdens) and adaptation of fees for authorisations to the amount of assessment work which has to be done by the authorities. High fees for applying for an authorization can trigger a more intense search for less problematic substitutes.
- **R12: Enforcement.** Competent authorities of the member state have to establish a national system of controls and related infrastructure. They have to enforce the obligations, to penalise incompliance and to report about implementation. These are elements of an ambitious legislation which can support sustainable chemistry in different aspects.

A similar structure is not available for the field of sustainable chemistry. Sustainable chemistry addresses a broad field of topics. For further information on sustainable chemistry, its relation to Green Chemistry and its importance for the Strategic Approach on International Chemicals Management (SAICM) see Blum et al. (2017), IPEN (2017), WECF/IPEN (2017), UNEP (2018), Clark and Kümmerer (2016), Friege (2017), Friege and Lahl (2017) and ISC3 (2019).

For the analysis of relations between REACH and sustainable chemistry 12 main elements of sustainable chemistry have been identified which cover the main topics of this field. The selection of these elements has been based on the recent publications of Blum et al. 2017 and IPEN/WECF 2018 and the knowledge of the actual discussions in this field. [Main elements S1 – S7 are described in Blum et al. 2017 as objectives and guiding principles of sustainable chemistry (Blum et al. 2017, chapter 1, p. 4). Main elements S 8 and S 9 are described in the same reference as general aspects of sustainable chemistry (Blum et al. 2017, chapter 4.1, p.7). Main elements 10 and 11 are described in the same reference as important action steps (Blum et al. 2017, chapter 4.8 and 4.7, p. 9). Main element 12 has been addressed in the same reference (Blum et al. 2017, chapter 4.4) and in IPEN/WECF 2018]].

The 12 main elements of sustainable chemistry are:

- **S1: Inherently safer chemicals.** This means the design and use of chemicals which are not classified as hazardous and which do not have other problematic properties (such as persistency or bioaccumulation) is a central element of sustainable chemistry. These chemicals should have been sufficiently tested in order to ensure that they indeed are less hazardous than others. (Nevertheless, for many applications only chemicals with hazardous properties will be available. In other cases it can be that a certain degree of persistence during the use phase is required in order to fulfil the desired function. In these cases sustainable chemistry tries to find chemicals which are non-persistent outside and after their desired application (e.g. if they are released in the environment)) (Clark and Kümmerer 2016).
- **S2: Substitution.** Development and use of alternative solutions for problematic applications which have less adverse effects. Regrettable substitutions of regulated hazardous substances by other substances or methods which are not yet regulated, but have similar problematic properties must be avoided (ECHA 2018. Fantke 2015).
- **S3: Reduction of emissions and impact.** Reduction of impacts to avoid adverse effects on health and the environment along the entire life cycle of a substance (i.e. production, services involving chemical substances, application and disposal of products) or product. This includes e.g. emissions of greenhouse gases, nutrients and photooxidants (Reihlen et al. 2016).
- **S4: Resource conservation.** Conservation of natural resources by deploying energy and raw materials required for production and application of chemical products and services in the most efficient way possible. In addition, scarce resources are conserved and renewable raw materials are sustainably generated (EU COM 2018). (The term “resources” in this context does not mean human resources at the work place. Resource conservation through the use of recovered/recycled materials is covered under S5).
- **S5: Circular economy.** Promotion of reuse and recycling of materials by avoiding the entry of substances of concern in material flows and stocks and to reduce the need to eliminate such substances from economic cycles. This facilitates recycling and disposal of materials in cases where a reuse is not any longer possible (Friege 2017).
- **S6: Increase of market opportunities.** Applications of substances that have hitherto been recognized as problematic should trigger market chances for enterprises which offer alternative innovative solutions (Friede et al. 2015). Ambitious standards for occupational safety and environmental protection will result in less or even no regulatory interventions. This element also refers to new business models with further improvements in the performance of products (Moser et al. 2014).
- **S7: Fair working conditions in the supply chains.** Application of corporate social responsibility to balance people, planet and profit in all decisions and investments in a company as well as with the value chain partners. Fundamental social rights should be in place not only in one single company, but in the whole supply chains of chemical industry and the related sectors of economy (OECD 2011, CSR Netherlands 2015).

- **S8: Transparency and accessibility of data.** In order to comprehensively evaluate the sustainability of products, stakeholders need information on the impact of raw materials extraction, production, processing, transportation, use and disposal of substances, materials and products. This includes knowledge about the hazardous properties of substances, about exposures and risks. In addition, transparency refers to the decision processes which take place in assessing chemicals, to the use patterns of substances and the composition and structure of the chemical sector (Reihlen et al. 2016).
- **S9: Ambitious and enabling legislations.** In a globalized world, all companies should be compliant with comparably ambitious legislative frameworks and act responsibly. Besides that, regulation should enable companies to develop new, more sustainable approaches and should reward companies that are frontrunners in terms of sustainability (PIANOo 2019).
- **S10: Training and Education.** Education for sustainable chemistry and sustainable development is the basis for generating an understanding of sustainability in different fields, including chemistry. State-of-the-art knowledge on sustainable chemistry needs to be better integrated into education at school, university training and professional trainings in many disciplines. This includes capacity building and knowledge transfer (Collins 2017).
- **S11: Consumer awareness.** Products of sustainable chemistry need success in the markets. They have to be bought by consumers and public authorities. Consumer have to be aware of the real impact of products produced without respecting sustainability demands. They have to be convinced to pay the price a sustainable product is worth and to reflect about alternative options which are more sustainable than buying a product (Blum et al. 2017).
- **S12: Internalisation of costs.** According to the “polluters pay” principle, all costs which are connected to hazardous properties of chemicals should be included in the price of the chemicals. At present, several costs which are caused by chemicals are externalised, e.g. public health costs for health damages or costs for the restauration of contaminated areas (Arnold 2019). (In this context the term “Internalisation of costs” refers to costs caused by adverse effects. It does not refer to fees which have to be paid for registration of chemicals or assessment of chemicals).

### 1.3 Working steps for the analysis

Each of the twelve main elements of REACH consists of several activities, e.g. preparation of a chemical safety assessment as part of the registration process. In order to analyse the relations between REACH and sustainable chemistry, these activities have been listed in the following tables. It is briefly indicated which results are expected from such an activity, e.g. description of conditions of safe use. Then it is analysed whether these results are important for one or more main elements of sustainable chemistry. For example, descriptions of safe use of a substance are important to reduce emissions and adverse impacts. (In some cases, comments are given whether such a support can be considered a high or low. However, this has been only possible in some obvious cases),

For each main element of REACH, the activities are described in one table. The activities and their relations are consecutively numbered.

In addition to the tables, the numbers of relations are transferred to a matrix (see Fig. 1 and 2 in chapter 2). It shows the main elements of REACH and of sustainable chemistry.

The matrix shows for each cell which relations are relevant. In addition, it allows a first qualitative description which elements of REACH show the strongest relations to sustainable chemistry, which elements of sustainable chemistry are strongly supported by REACH and which are not.

The picture given in the matrix together with the underlying information from tables 1 – 12 allows to identify further options to support sustainable chemistry by REACH in a focused and efficient manner.

Chapter 3 describes these findings more in detail for each of the central elements of REACH.

## 1.4 Additional information / REACH and sustainable chemistry: legal background

Environmental policy in compliance with the criteria of sustainability and the precautionary principle (Art. 191 para 2 Treaty of the Functioning of the European Union – TFEU (OJ EU 2012, p.47)) and a high level of protection in the areas of health, safety, environmental and consumer protection (Art. 114 para 3 TFEU) are legal pillars of the European Union (Epiney, A. 2019, p. 95 ff). A high level of environmental protection and the improvement of the quality of the environment are an equivalent and equal-ranking task alongside the other tasks of the Union mentioned in Art. 3 TEU (OJ EU 2012, p.13).

In particular, sustainable development is an objective, a principle and a rule of European primary legislation that has to be followed in defining secondary legislation like the REACH Regulation. As a general applicable principle of the TFEU, sustainable development is to be promoted by effective incorporation of the requirements of environmental protection in policies and measures that are outside the field of environmental policy (cf. the cross sectional clause in Art. 11 TFEU).

When setting up environmental policies, the following principles must be observed (cf. Art. 191 para 2 TFEU) (Epiney, A. (2019), p. 95 ff):

- ▶ a high level of protection of the environment,
- ▶ the precautionary principle,
- ▶ the principle of combating pollution at source and
- ▶ the polluter-pays principle.

The high level of protection of the environment and the precautionary principle are reflected as main objectives in Art. 1 REACH (see chapter 3.3). Both objectives are also part of sustainable chemistry (see chapter 3.3).

Sustainable chemistry is considered beyond REACH: Chemical substances are regulated in a broad range of the EU chemical acquis (covering around 40 pieces of legislation) (cf. EC 2019). The chemical acquis covers for example regulation on the workers' health and safety, regulations on pharmaceutical, veterinary and food additives. In this context REACH serves as a source for (eco-)toxicity information on substances and mixtures used in environmental and product regulation of the EU. For example the information generated in REACH is used for the classification of waste under the Waste Framework Directive or to identify prioritised substances for Annex X of the Water Framework Directive 2000/60/EG.

REACH has made an important step to support sustainable chemistry – compared to the previous substance legislation - by shifting the responsibility for the management of the risks of substances “to the natural or legal persons that manufacture, import, place on the market or use these substances” (cf. Recitals 18 and 25 REACH). This paradigm shift implements the polluter-pays principle and the principle of combating pollution at the source (see above Art. 191 para 2 TFEU) throughout the down-stream supplier chain – thus creating a “chain of responsibility” (cf. Recitals 56 and 58) (Führ 2011, Rn.51),

Regarding the objective of REACH to protect human health and the environment from hazardous substances and to enhance innovation, REACH was a legislative innovation that reformed the chemical legislation in the EU. Before REACH entered into force in 2007, chemicals were regulated by several pieces of legislation: the Council Regulation (EEC) No 793/933 (Existing Substances Regulation (ESR)), Directive 76/769/EEC<sup>4</sup>, Directive 1999/45/EC<sup>5</sup>, Directive 1991/155/EC<sup>6</sup> and the Directive 67/548/EEC<sup>7</sup> (Directive 92/32/EC)<sup>8</sup>. De-facto the legislation before REACH privileged existing substances over new substances and thus hampered the innovation of new substance (Führ 2011, Chapter 1, Rn. 7). Moreover, the continued access of existing substances to the market without efficient knowledge about possible hazardous properties put human health and the environment at risk.

The REACH Regulation starting with the Commission’s Proposal from 2003<sup>9</sup> and enacted in 2006 was developed without a reference to SDGs (adopted 2015) (United Nations 2015) but against the background of the World Summit of Sustainable Development WSSD and the Johannesburg Plan of Implementation (JPOI).

On the WSSD in Johannesburg 2002 the European Union and its Member States committed themselves to the sound management of chemicals throughout their life cycle as expanded upon in Paragraph 23 of JPOI. Accordingly, the EU stated that by 2020 “chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment” (EU 2013). REACH has incorporated that commitment as a legislative goal (cf. Recital 4)<sup>10</sup>. Beyond that, REACH aims at sustainable development in general as Recital 3 of the REACH preamble states: “A high level of human health and environmental protection should be ensured in the approximation of legislation on substances, with the goal of achieving sustainable development.”

<sup>3</sup> Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, OJ L 84, 5.4.1993, p. 1.

<sup>4</sup> Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, OJ L 262, 27.9.1976, p. 201.

<sup>5</sup> Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJ L 200, 30.7.1999, p. 1.

<sup>6</sup> Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC, OJ L 76, 22.3.1991, p. 35.

<sup>7</sup> Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967, p. 1.

<sup>8</sup> Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 154, p. 1.

<sup>9</sup> Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) (EC/2003/0644 final).

<sup>10</sup> “[...] chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment.”

With a view to the further development of EU environmental policy, development in the EU is guided by the environmental action programmes (EAP). The 7th EAP which entered into force 2014<sup>11</sup> and extends until 2020 calls for a *“Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions, building on horizontal measures to be undertaken by 2015.”* The non-toxic environment strategy which was supposed to be set by the end of 2018 has not been approved by the Commission, yet (Chemical Watch 2018).

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<sup>11</sup> Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 “Living well, within the limits of our planet”, OJ L 354, 28.12.2013, p. 171: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013D1386>.

## 2 Relations between REACH and sustainable chemistry

### 2.1 Matrix on relations between REACH and sustainable chemistry

The following figure gives an overview, which main elements of REACH are related to main elements of sustainable chemistry. Details on individual relations are given in tables 3 – 14 in the following section 2.2.

**Table 1: Matrix on relations between elements of REACH (1-12) and elements of sustainable chemistry (1 – 12)**

One relation; Two relations or Three or more or very important relations

| REACH                             | 1<br>Regis-<br>tration | 2<br>Data<br>sharing            | 3<br>Infor-<br>mation/<br>supply<br>chain | 4<br>Down-<br>stream<br>users | 5<br>Dossier<br>Evalua-<br>tion | 6<br>Substance<br>Evaluation | 7<br>Authori-<br>sation         | 8<br>Restric-<br>tions | 9<br>Infor-<br>mation | 10<br>Agency /<br>Authority | 11<br>Fees and<br>charges       | 12<br>Enforce-<br>ment | Num-<br>ber of<br>rela-<br>tions |
|-----------------------------------|------------------------|---------------------------------|-------------------------------------------|-------------------------------|---------------------------------|------------------------------|---------------------------------|------------------------|-----------------------|-----------------------------|---------------------------------|------------------------|----------------------------------|
| <b>Sustain. Chemistry</b>         |                        |                                 |                                           |                               |                                 |                              |                                 |                        |                       |                             |                                 |                        |                                  |
| 1 Inherently safer chemicals      | Two                    | Two                             | One                                       | One                           | One                             | One                          | Two                             | One                    | One                   |                             |                                 |                        | 12                               |
| 2 Substitution                    | One                    | One                             | Two                                       |                               | One                             | One                          | Three or more or very important | One                    | Two                   |                             | One                             |                        | 14                               |
| 3 Reduction of impacts            | Two                    |                                 | Three or more or very important           | One                           |                                 | One                          | Three or more or very important | One                    | One                   |                             |                                 |                        | 12                               |
| <b>4 Resource conservation</b>    |                        |                                 |                                           |                               |                                 |                              |                                 |                        |                       |                             |                                 |                        |                                  |
| <b>5 Circular economy</b>         | One                    |                                 | Two                                       |                               |                                 |                              | One                             |                        | One                   |                             |                                 |                        | 6                                |
| 6 Market opportunities            |                        | Three or more or very important | Three or more or very important           | One                           | One                             |                              | One                             | One                    |                       | One                         | Three or more or very important | One                    | 15                               |
| <b>7 Corporate Social Respon.</b> |                        |                                 |                                           |                               |                                 |                              |                                 |                        |                       |                             |                                 |                        |                                  |

| REACH                                                    | 1<br>Regis-<br>tration                   | 2<br>Data<br>sharing | 3<br>Infor-<br>mation/<br>supply<br>chain | 4<br>Down-<br>stream<br>users | 5<br>Dossier<br>Evalua-<br>tion | 6<br>Substance<br>Evaluation | 7<br>Authori-<br>sation                  | 8<br>Restric-<br>tions | 9<br>Infor-<br>mation                    | 10<br>Agency /<br>Authority              | 11<br>Fees and<br>charges | 12<br>Enforce-<br>ment | Num-<br>ber of<br>rela-<br>tions |
|----------------------------------------------------------|------------------------------------------|----------------------|-------------------------------------------|-------------------------------|---------------------------------|------------------------------|------------------------------------------|------------------------|------------------------------------------|------------------------------------------|---------------------------|------------------------|----------------------------------|
| <b>Sustain. Chemistry</b>                                |                                          |                      |                                           |                               |                                 |                              |                                          |                        |                                          |                                          |                           |                        |                                  |
| 8 Accessible /<br>transparent ... data                   | Three or<br>more or<br>very<br>important | Two                  | One                                       | One                           | One                             | One                          | Three or<br>more or<br>very<br>important | One                    | Three or<br>more or<br>very<br>important | One                                      |                           | One                    | 22                               |
| 9 Ambitious<br>legislation                               | One                                      | One                  | One                                       | One                           | One                             | One                          | One                                      | One                    | One                                      | Two                                      | One                       | One                    | 14                               |
| <b>10 Training<br/>/Education/ Capacity<br/>building</b> | One                                      | One                  |                                           |                               |                                 |                              |                                          |                        |                                          | Three or<br>more or<br>very<br>important |                           |                        | 7                                |
| <b>11 Consumer<br/>awareness</b>                         |                                          |                      | One                                       |                               |                                 |                              |                                          |                        |                                          | One                                      |                           |                        | 2                                |
| <b>12 Internalisation of<br/>costs</b>                   |                                          |                      |                                           |                               |                                 |                              |                                          |                        |                                          |                                          |                           |                        |                                  |
| Number of relations                                      | <b>14</b>                                | <b>10</b>            | <b>15</b>                                 | 5                             | 5                               | 5                            | <b>15</b>                                | 7                      | <b>10</b>                                | <b>10</b>                                | 5                         | 3                      |                                  |

Source: own illustration, Öko-Institut

The following figure gives the additional information which relations refer to the individual cells.

**Table 2: Matrix on relations between elements of REACH (1-12) and elements of sustainable chemistry (1 – 12). Alignment of activities to cells.**

Numbers in this figure: Relations from tables 1 – 12 belong to individual cells. Details on Relations: see lines of tables 3 – 14 in section 2.2.

| REACH                                       | 1<br>Regis-<br>tration | 2<br>Data<br>sharing | 3<br>Infor-<br>mation/<br>supply<br>chain | 4<br>Down-<br>stream<br>users | 5<br>Dossier<br>Evalu-<br>ation | 6<br>Sub-<br>stance<br>evalu-<br>ation | 7<br>Authorisation | 8<br>Re-<br>stric-<br>tions | 9<br>Infor-<br>mation | 10<br>Agency /<br>Authority | 11<br>Fees<br>and<br>charges | 12<br>Enforce-<br>ment | Number<br>of<br>relations |
|---------------------------------------------|------------------------|----------------------|-------------------------------------------|-------------------------------|---------------------------------|----------------------------------------|--------------------|-----------------------------|-----------------------|-----------------------------|------------------------------|------------------------|---------------------------|
| <b>Sustain. Chemistry</b>                   |                        |                      |                                           |                               |                                 |                                        |                    |                             |                       |                             |                              |                        |                           |
| <b>1 Inherently safer chemicals</b>         | 1, 4                   | 18, 21               | 25                                        | 43                            | 45                              | 50                                     | 55, 61             | 70                          | 80                    |                             |                              |                        | <b>12</b>                 |
| <b>2 Substitution</b>                       | 5, 8                   | 22                   | 26, 35                                    |                               | 46                              | 51                                     | 56, 60, 63         | 75                          | 81, 83                |                             | 101                          |                        | <b>14</b>                 |
| <b>3 Reduction of impacts</b>               | 6, 9                   |                      | 28, 30,<br>32                             | 42                            |                                 | 52                                     | 57, 59, 67         | 73                          | 84                    |                             |                              |                        | <b>12</b>                 |
| 4 Resource conservation                     |                        |                      |                                           |                               |                                 |                                        |                    |                             |                       |                             |                              |                        |                           |
| 5 Circular economy                          | 7                      |                      | 29, 36                                    |                               |                                 |                                        | 58                 | 74                          | 85                    |                             |                              |                        | 6                         |
| <b>6 Market opportunities</b>               |                        | 16, 19,<br>20        | 27, 33,<br>37                             | 41                            | 47                              |                                        | 64                 | 76                          |                       | 92                          | 98,99,102                    | 104                    | <b>15</b>                 |
| 7 Corporate Social Respon.                  |                        |                      |                                           |                               |                                 |                                        |                    |                             |                       |                             |                              |                        |                           |
| <b>8 Accessible/transparent<br/>data</b>    | 2, 3, 10,<br>11, 12    | 15, 17               | 31, 34                                    | 40                            | 48                              | 53                                     | 62, 65, 69         | 71                          | 78, 79,<br>82, 86     | 90                          |                              | 106                    | <b>22</b>                 |
| <b>9 Ambitious legislation</b>              | 14                     | 24                   | 39                                        | 44                            | 49                              | 54                                     | 68                 | 77                          | 87                    | 89, 91                      | 103                          | 105                    | <b>14</b>                 |
| 10 Training/Education/<br>Capacity building | 13                     | 23                   |                                           |                               |                                 |                                        |                    |                             |                       | 88, 93, 95,<br>96, 97       |                              |                        | 7                         |
| 11 Consumer awareness                       |                        |                      | 38                                        |                               |                                 |                                        |                    |                             |                       | 94                          |                              |                        | 2                         |
| 12 Internalisation of costs                 |                        |                      |                                           |                               |                                 |                                        |                    |                             |                       |                             |                              |                        |                           |
| <b>Number of relations</b>                  | <b>14</b>              | <b>10</b>            | <b>15</b>                                 | 5                             | 5                               | 5                                      | <b>15</b>          | 7                           | <b>10</b>             | <b>10</b>                   | 5                            | 3                      |                           |

Source: own illustration, Öko-Institut

## 2.2 Description of the individual relations between REACH and Sustainable Chemistry

The following 12 tables list the relations which have been found between main elements of REACH (R1 – R12) and main elements of sustainable chemistry (s1 – S12). Each table refers to one of the main elements of REACH, e.g. Registration (R1) in table 1.

**Table 3: Relations between REACH Registration (R1) and elements of sustainable chemistry (S1-S12)**

| Nr. | Code         | Activities                                                                                                                                                                                                                   | Results                                                                                                        | Effect on / support of                                                                                                                                                              | Comment                                                   |
|-----|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| 1   | R1/1<br>→ S1 | Submission of registration dossier for all substances above 1 t/a (including assessment of substance identity and contaminations), unless substances are exempted                                                            | Available hazard data and basic use information are evaluated and compiled                                     | Basic information to assess hazards and risks of substances/ basis to decide for inherently safe chemicals (S1)                                                                     | Use information are very basic for substances below 10t/a |
| 2   | R1/2<br>→ S8 | Submission of registration dossier for all substances above 1 t/a. ECHA gives registration number                                                                                                                            | Registration number is given                                                                                   | Substance becomes “visible”, support of Data accessibility and transparency (S8)                                                                                                    |                                                           |
| 3   | R1/3<br>→ S8 | as above                                                                                                                                                                                                                     | Manufacturers (M)and importers (I) are identified.                                                             | Transparency who is producing or importing substances (S8)                                                                                                                          |                                                           |
| 4   | R1/4<br>→ S1 | Chemical safety assessment (CSA)/ hazard and PBT/vPvB assessment / compilation of use and exposure data including exposure scenarios (ES)/ risk assessment and derivation of suitable risk management measures (RMM) per use | Chemical safety report (CSR); detailed information on hazardous properties, exposures, uses and related risks. | More extensive property and use information (compared to substances without CSA); basic information to decide whether a substance can be considered as inherently safer or not (S1) |                                                           |
| 5   | R1/5<br>→ S2 | as above                                                                                                                                                                                                                     | as above                                                                                                       | More extensive property and use information; basic information to trigger substitution (S2)                                                                                         |                                                           |
| 6   | R1/6<br>→ S3 | as above                                                                                                                                                                                                                     | CSR; detailed information on conditions of safe use per substance use and the required RMMs.                   | Basic condition to reduce emissions during production and use (S3)                                                                                                                  | Strongly depending on the quality of the data             |

| Nr. | Code           | Activities                                                                                                                         | Results                                                              | Effect on / support of                                                                                 | Comment                                                                                                                                                             |
|-----|----------------|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7   | R1/7<br>→ S5   | Performing CSA / Assessment of the waste phase                                                                                     | Recommendations for the disposal of wastes                           | Assessment of waste phase could be relevant for circular economy (S5)                                  | Implementation is not very ambitious                                                                                                                                |
| 8   | R1/8<br>→ S2   | Identification of uses advised against                                                                                             | M/I decide not to take responsibility for a particular (un-safe) use | Triggers phase out of a use and therefore stimulates substitution (S2)                                 | Only, if other M/I do not support this use                                                                                                                          |
| 9   | R1/9<br>→ S3   | as above                                                                                                                           | as above                                                             | Triggers phase out of a use and therefore reduces emissions and impacts (S3)                           | Only, if other M/I do not support this use                                                                                                                          |
| 10  | R1/10<br>→ S8  | Submitting information on tonnage band                                                                                             | Rough indication about amounts used                                  | First impression on the magnitude of substance flows increases transparency (S8)                       | Only data on tonnage band, no detailed figures on production volume MS CAs have access to more precise information (confidential data in the registration dossiers) |
| 11  | R1/11<br>→ S8  | Submitting information on producers                                                                                                | Manufacturers are identified                                         | Increase of transparency regarding the structure of the market (S8))                                   |                                                                                                                                                                     |
| 12  | R1/12<br>→ S8  | Submission of non-confidential data                                                                                                | Non-confidential data becomes publicly available.                    | Basic information on properties and uses of substances becomes publicly available and transparent (S8) |                                                                                                                                                                     |
| 13  | R1/13<br>→ S10 | Development of guidance for the different tasks of substance registration                                                          | Guidance documents are available for M, I and DU                     | These guidelines support education/training (S10)                                                      | Very specific guidance                                                                                                                                              |
| 14  | R1/14<br>→ S9  | Be compliant with registration requirements                                                                                        |                                                                      | Ambitious legislation (S9)                                                                             |                                                                                                                                                                     |
| -   |                | Submission of registration dossier for all substances above 1 t/a. Registrants pay for the generation of data and the work by ECHA | Registration fee                                                     |                                                                                                        | This is an example for internalisation of costs related to the assessment of                                                                                        |

| Nr. | Code | Activities                                                          | Results | Effect on / support of | Comment                                               |
|-----|------|---------------------------------------------------------------------|---------|------------------------|-------------------------------------------------------|
|     |      | to process and potentially evaluate it. See Table 11 (element Fees) |         |                        | chemicals, not related to damages caused by chemicals |

**Table 4: Relations between REACH Data sharing and avoiding of testing (R2) and elements of sustainable chemistry (S1 – S12)**

| Nr. | Code         | Activities                                                                                                                                                      | Results                                                                                                                                             | Effect on / support of                                                                                                          | Comment                                                                                                  |
|-----|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|
| 15  | R2/1<br>→ S8 | Preregistration of substances by M/I (done)                                                                                                                     | Information on substances which are intended to be registered and on total number of substances which can be expected / Substances become “visible” | First impression on the universe of chemicals which could be on the market/ Increase of transparency (S8)                       | Only temporary effect (before registration takes place) / No requirement to register later               |
| 16  | R2/2<br>→ S6 | Bringing together all manufacturers and importers of one substance                                                                                              | SIEF (Substance Information Exchange Forum); joint registration dossier                                                                             | Registration efforts and costs are reduced; cooperation between companies are enhanced. This improves market opportunities (S6) | SIEFs/joint registration dossiers may enable SMEs to register                                            |
| 17  | R2/3<br>→ S8 | Bringing together all manufacturers and importers of one substance; compilation of available data, discussion of studies and classification and labelling (C&L) | Data are compiled and extended agreed classifications / studies become prioritized                                                                  | More data become accessible / improvement of data accessibility (S8)                                                            | Information from all M/I is merged and evaluated Entries for the C&L inventory come from the same source |
| 18  | R2/4<br>→ S1 | Bringing together all manufacturers and importers of one substance; compilation of available data, discussion of studies and classification and labelling (C&L) | Studies have been evaluated / improved data on substance properties, uses and risks in registration dossiers                                        | Improvement of the data basis to select inherently safer chemicals (S1)                                                         |                                                                                                          |
| 19  | R2/5<br>→ S6 | Share of data on animal testing in SIEFs                                                                                                                        | Protection of animal welfare, reduction of costs for testing                                                                                        | Less costs for registration, Improvement of market opportunities (S6)                                                           | Animal welfare is an important objective of REACH                                                        |

| Nr. | Code          | Activities                                                                                                                                                     | Results                                                                                                                             | Effect on / support of                                                                        | Comment                                 |
|-----|---------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-----------------------------------------|
| 20  | R2/6<br>→ S6  | Use of data from alternative testing (Read across, grouping, QSAR approaches, weight of evidence approach (WoE)), use of an intelligent testing strategy (ITS) | Reduction of costs because tests can be waived                                                                                      | as above (S6)                                                                                 | linked with registration (R1)           |
| 21  | R2/7<br>→ S1  | Application of read across, QSAR approaches and grouping of substances                                                                                         | Completion of Information about substance properties                                                                                | Better information about substance properties allow to select inherently safer chemicals (S1) |                                         |
| 22  | R2/8<br>→ S2  | Grouping of substances                                                                                                                                         | Information on substances of similar structure, avoidance of substitution of a substances of concern by other substances of concern | Support of non-regrettable substitutions (S2)                                                 |                                         |
| 23  | R2/9<br>→ S10 | Development of guidance how to use read across-, QSAR-, grouping- and weight of evidence – approaches                                                          | Guidance how to use alternative testing methods                                                                                     | Support of (SM)E in application of alternative methods (Education/ Training) (S10)            | Very specific guidances, for expert use |
| 24  | R2/10<br>→ S9 | Assessing substances with use of alternative data                                                                                                              |                                                                                                                                     | Example for ambitious regulation (S9)                                                         |                                         |

**Table 5: Relations between REACH Information in the supply chain (R3) and elements of sustainable chemistry (S1 – S12)**

|    | Nr.          | Activities                                                             | Results                                                                    | Effect on / support of                                                                                       | Comment         |
|----|--------------|------------------------------------------------------------------------|----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-----------------|
| 25 | R3/1<br>→ S1 | Delivery of a safety datasheet by substance M/I, receipt and use by DU | DU receives information on substance properties                            | Necessary information to identify or select inherently safer chemicals (S1)                                  | Central element |
| 26 | R3/2<br>→ S2 | As above                                                               | DU can receive information about very problematic properties of substances | Information that substances are very problematic (e.g. CMR substances or SVHC) can trigger Substitution (S2) |                 |

|    | Nr.          | Activities                                                                                                                                              | Results                                                                                                                          | Effect on / support of                                                                                                 | Comment                                                                                                                                                                                                                                                                                                                   |
|----|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 27 | R3/3<br>→ S6 | As above / Comparison of own use with identified uses in SDS/ check of uses advised against                                                             | DU can start to look for suppliers which offer non-regrettable substitutes for substances of concern or for uses advised against | These requests support innovative business models which develop alternatives for the use of substances of concern (S6) | Awareness on intended use and own use regarding conditions of safe use This could lead to the need to perform a DU CSR (see below)                                                                                                                                                                                        |
| 28 | R3/4<br>→ S3 | Receipt of SDS by DU, implementation of exposure scenario (ES) by DU / Comparison of own use with identified uses in SDS/ check of uses advised against | Implementation of conditions of safe use (as described in the exposure scenarios (ES) in the safety data sheet) by the DUs.      | Use of appropriate risk management measures by the DU leads to reduction of emissions (S3) in the supply chain.        | Central element; Awareness on intended use and own use regarding conditions of safe use This could lead to the need to perform a DU CSR (see below)/ CoU mostly very general and difficult to understand for DU; DU CSR is a clear mechanism to allocate responsibility on own uses deviating from identified uses in SDS |
| 29 | R3/5<br>→ S5 | DU: Implementation of waste management practices as described in the SDS                                                                                | Reduction of wastes and problematic impacts of wastes                                                                            | Support of a circular economy with less amounts of hazardous substances in materials and waste streams (S5)            | National provisions on waste management are normally followed CSR and SDS normally not                                                                                                                                                                                                                                    |

|    | Nr.            | Activities                                                                                                                             | Results                                                                                   | Effect on / support of                                                                                                  | Comment                                                 |
|----|----------------|----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
|    |                |                                                                                                                                        |                                                                                           |                                                                                                                         | elaborated enough to generate really useful information |
| 30 | R3/6<br>→ S3   | DU, Formulator: merging of information from exposure scenarios of single substances to information on safe use for mixtures            | SDS for mixtures, conditions of safe use for mixtures                                     | SDS for mixtures are the basis to select appropriate risk management measures for mixtures and to reduce emissions (S3) |                                                         |
| 31 | R3/7<br>→ S8   | as above                                                                                                                               | as above                                                                                  | SDS for mixtures give transparent data on safe use of mixtures (support of data availability and transparency) (S8)     |                                                         |
| 32 | R3/8<br>→ S3   | DU: identification, implementation and communication of <b>additional</b> risk management measures, including information to consumers | Additional information on safe use and implementation of related risk management measures | Reduction of emissions in the supply chain (DU and uses by consumers) (S3)                                              | Real relevance unclear                                  |
| 33 | R3/9<br>→ S6   | as above                                                                                                                               | Enhanced communication in the supply chain                                                | More communication in the supply chain improves business opportunities (S6)                                             |                                                         |
| 34 | R3/10<br>→ S8  | Getting and giving information about SVHC in articles in the supply chain and to the public (Art.33.1 + 33.2)                          | Information on SVHC in articles                                                           | Transparency on the presence of SVHC in materials (S8)                                                                  |                                                         |
| 35 | R3/11<br>→ S2  | Selection of alternative materials without SVHC                                                                                        | Replacement of substances of concern in materials                                         | Support of substitution of SVHC in materials (S2)                                                                       |                                                         |
| 36 | R3/12<br>→ S5  | as above                                                                                                                               | Reduction of SVHC in materials                                                            | Decrease of substances of concern supports recycling of materials, support of Circular economy (S5)                     | For SVHC only                                           |
| 37 | R3/13<br>→ S6  | as above                                                                                                                               | Need for suppliers which offer alternative materials.                                     | Enhanced request for innovative alternatives, increase of market opportunities (S6)                                     |                                                         |
| 38 | R3/14<br>→ S11 | Consumers: requesting and getting information on SVHC in articles according to Art.33.2                                                | Consumers are informed on SVHC in products                                                | Consumer are more aware about substances of concern in products (S11)                                                   |                                                         |

|    | Nr.           | Activities                                                                                  | Results | Effect on / support of                | Comment |
|----|---------------|---------------------------------------------------------------------------------------------|---------|---------------------------------------|---------|
| 39 | R3/15<br>→ S9 | Communication in the supply chain including use pattern of substances and SVHCs in articles |         | Example for ambitious regulation (S9) |         |

**Table 6: Relations between REACH Downstream users (R4) and elements of sustainable chemistry (SC). The activities in this element are strongly linked to the activities in the element “Supply chain information” (R3). In order to avoid redundancies, relations are mentioned in the comments if they have been described already above.**

| Nr. | Code         | Activities                                                                                                                                          | Results                                                                                    | Effect on / support of                                                                                        | Comment                                                                                                                                                   |
|-----|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 40  | R4/1<br>→ S8 | Providing information on the own uses to registrants                                                                                                | Communication up the supply chain in order to ensure that uses are registered and assessed | Manufacturers get knowledge on the uses of their substance, increase of transparency in the supply chain (S8) | Weak effect due to implementation deficits / Registration of uses of DU due to this communication ensures safe use of the substances and reduce emissions |
| 41  | R4/2<br>→ S6 | as above                                                                                                                                            | Enhanced communication in the supply chain                                                 | Improvement of business opportunities due to more exchange (S6)                                               |                                                                                                                                                           |
| 42  | R4/3<br>→ S3 | Conducting a Downstream User Chemical Safety Assessment / Report (DU CSA/ CSR) and implementation of the identified risk management measures (RMMs) | Identification of conditions of safe use for DU uses                                       | Reduction of emissions due to implementation of appropriate RMMs (S3)                                         |                                                                                                                                                           |
| 43  | R4/4<br>→ S1 | Identification of deviating hazard classification and information of ECHA                                                                           | Improved information on substance properties                                               | Better data base to assess whether a substance is inherently safer (S1)                                       | Real relevance unclear / improved information can support substitution                                                                                    |

| Nr. | Code         | Activities                                                    | Results                                                                                | Effect on / support of                                                                    | Comment |
|-----|--------------|---------------------------------------------------------------|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|---------|
| 44  | R4/5<br>→ S9 | Performing the activities described above by downstream users | Improved communication in the supply chain, DU takes responsibility for deviating uses | These activities show the ambitious and demanding character of the REACH legislation (S9) |         |
|     |              |                                                               |                                                                                        |                                                                                           |         |

**Table 7: Relations between REACH Dossier evaluation (R5) and elements of sustainable chemistry (S1 – S12)**

| Nr. | Code         | Activities                                                 | Results                                                                                                                    | Effect on / support of                                                                                           | Comment                                                                                                           |
|-----|--------------|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| 45  | R5/1<br>→ S1 | Evaluation of registration dossiers                        | Compliance of dossiers checked. Incompliant data or lacking data are requested.                                            | Improvement of database to decide on inherently safer chemicals (S1)                                             | Dossier evaluation is of crucial importance to ensure sufficient quality of the data in the registration dossiers |
| 46  | R5/2<br>→ S2 | as above                                                   | Assure sufficient quality of data on substance properties, base for comparison of substances and substitution              | Improvement of database allows to identify adequate substitutes (S2)                                             | s.a.                                                                                                              |
| 47  | R5/3<br>→ S6 | as above                                                   | Assure sufficient quality of data on safe use                                                                              | Level playing field for all enterprises, thereby increase of market opportunities for compliant enterprises (S6) | s.a.                                                                                                              |
| 48  | R5/4<br>→ S8 | Evaluation of testing proposals                            | Decision on testing needs; optimal strategy to generate missing information identified (Intelligent Testing Strategy, ITS) | The testing strategy show availability of data and supports transparency (S8)                                    | In addition, this relation supports animal welfare                                                                |
| 49  | R5/5<br>→ S9 | Evaluating dossiers according to the criteria set in REACH | Important quality assurance for registration dossiers.                                                                     | These activities show the ambitious and demanding character of the REACH legislation (S9)                        |                                                                                                                   |

**Table 8: Relations between REACH Substance evaluation (R6) and elements of sustainable chemistry (S 1 – S 12)**

| Nr. | Code         | Activities                                                                                                             | Results                                                                                               | Effect on / support of                                                                                                                                               | Comment                                                                                                                                 |
|-----|--------------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| 50  | R6/1<br>→ S1 | Evaluation of prioritized substances based upon concerns                                                               | Improved information about substance properties and uses.                                             | Improvement of database to decide on inherently safer chemicals (S1)                                                                                                 | Integrated Regulatory Strategy as tool for priority setting                                                                             |
| 51  | R6/2<br>→ S2 | as above, and: application of grouping approach in substance evaluation                                                | Improved information on substance properties and uses / database to find less hazardous substitutes / | Information on substances which are structurally related and have similar concerns, thereby avoidance of regrettable substitutions and support of substitutions (S2) | Grouping approach has the potential to become an important tool (impact reduction)                                                      |
| 52  | R6/3<br>→ S3 | as above                                                                                                               | Improved information on substances for which more stringent risk management measures are required     | Improved risk management measures and reduction of emissions (S3)                                                                                                    |                                                                                                                                         |
| 53  | R6/4<br>→ S8 | as above                                                                                                               | Transparent assessment of (specific) risks, evaluation report and evaluation decisions                | Increase of data accessibility and transparency of assessment steps (S8)                                                                                             |                                                                                                                                         |
| 54  | R6/5<br>→ S9 | Performing a regulatory management option analysis (RMOA) (see comment, RMOA is not mentioned in the REACH legal text) | Identification of the best suitable option to control risks of a substance                            | Crosslinks between regulations are considered; this is a characteristic of an ambitious and demanding legislation (S9)                                               | RMOA is not mentioned in the REACH legal text<br>However, it is an important part of the substance evaluation process organized by ECHA |

**Table 9: Relations between REACH Authorisation (R7) and elements of sustainable chemistry (S1 - S12)**

| Nr. | Code         | Activities                                                                        | Results                                                               | Effect on / support of                                                                                                 | Comment                                                                                                                                                                                                                                                                                                                                                                      |
|-----|--------------|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 55  | R7/1<br>→ S1 | Placing a substance on the Candidate List (and later listing in Annex XIV)        | Information on very problematic properties of the substance.          | Improvement of data base to decide on inherently safer substances (S1), improvement of data availability for SVHC (S8) |                                                                                                                                                                                                                                                                                                                                                                              |
| 56  | R7/2<br>→ S2 | as above                                                                          | Request for alternatives to SVHC                                      | Trigger to search for substitutes (S2)                                                                                 | REACH Art. 57f (equivalent level of concern) allows to address substances for which there is scientific evidence of serious effects to HH or ENV which give rise to equivalent level of concern as substances listed in Art 57 (a-e) , e.g. endocrine disruptors, PBT, vPvB not fulfilling the criteria of Art. 57 d or e, persistent and mobile bioakkummulative substances |
| 57  | R7/3<br>→ S3 | as above                                                                          | Reduced use of SVHCs                                                  | Reduction of emissions and impacts (S3)                                                                                |                                                                                                                                                                                                                                                                                                                                                                              |
| 58  | R7/4<br>→ S5 | as above                                                                          | Reduced amounts of SVHCs in materials                                 | reduced content of substances of concern in materials, support of recycling of materials (circular economy) (S5)       |                                                                                                                                                                                                                                                                                                                                                                              |
| 59  | R7/5<br>→ S3 | Inclusion of substance in Annex XIV, definition of sunset date, ban of substances | Ban of substances for all uses for which no authorisation is granted. | Reduction of use leads to reduction of emissions and impacts (S3)                                                      | Import of articles containing the respective chemicals not covered                                                                                                                                                                                                                                                                                                           |

| Nr. | Code           | Activities                                                                                               | Results                                                                             | Effect on / support of                                                                                                                                                                           | Comment                                                                            |
|-----|----------------|----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| 60  | R7/6<br>→ S2   |                                                                                                          | Pressure to substitute or to request an authorization                               | Need to find alternatives, support of substitution (S2)                                                                                                                                          | Granting of authorization despite of existence of substitutes hampers substitution |
| 61  | R7/7<br>→ S1   |                                                                                                          | Pressure to use less problematic substances.                                        | Trigger to check whether inherently safer chemicals can be used (S1)                                                                                                                             |                                                                                    |
| 62  | R7/8<br>→ S8   | Application for authorization (M/I/DU)                                                                   | Information about applicants/users                                                  | Increase of transparency regarding use pattern and producers/users of SVHC (S8)                                                                                                                  |                                                                                    |
| 63  | R7/9<br>→ S2   | Consultation on alternatives                                                                             | Compilation of alternatives which are on the market.                                | Trigger for an enhanced use of available substitutes (S2)                                                                                                                                        | Granting of authorization despite of existence of substitutes hampers substitution |
| 64  | R7/10<br>→ S6  | as above                                                                                                 | Possibility of contribution for enterprises which are offering substitutes.         | Improvement of market opportunities for suppliers of alternatives (S6)                                                                                                                           |                                                                                    |
| 65  | R7/11<br>→ S8  | Development of substitution plan analysis                                                                | Schedule for testing or developing alternatives for substances of very high concern | Increase of transparency regarding future use and substitution of SVHC (S8)                                                                                                                      |                                                                                    |
| 66  | R7/12<br>→ S12 | Performance of a socioeconomic analysis                                                                  | Indication of costs and benefits which are connected with a specific use            | Discussion of costs related to a specific use could be starting point to identify costs which are externalised, support of approaches to include these costs in the price of the chemicals (S12) | Potential to include externalised costs                                            |
| 67  | R7/13<br>→ S3  | Decision making on application authorization, prescription of use conditions; setting revision deadlines | Authorisation decision, authorization number                                        | Reduction of emissions and impacts due to strict risk management measures (S3)                                                                                                                   |                                                                                    |
| 68  | R7/14<br>→ S9  | as above                                                                                                 | as above                                                                            | Example for an ambitious regulation (S9)                                                                                                                                                         |                                                                                    |

| Nr. | Code          | Activities                                                                                                 | Results                                        | Effect on / support of                                                        | Comment |
|-----|---------------|------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------------------------------------------------|---------|
| 69  | R7/15<br>→ S8 | DUs notify the ECHA, if authorized substances are used; ECHA prepares register and grants access to the MS | Registers of DU that use authorized substances | Transparency and accessibility of data on users of authorized substances (S8) |         |

**Table 10: Relations between REACH Restriction (R8) and elements of sustainable chemistry (S1 – S12)**

|    | Code          | Activities                                                         | Results                                                                                           | Effect on / support of                                                                                                                                                                          | Comment                                               |
|----|---------------|--------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| 70 | R8/1<br>→ S1  | MS CA: Preparation of a restriction dossier                        | Information on substance properties and uses, exposures and risks                                 | Improvement of database to decide on inherently safer chemicals (S1)                                                                                                                            |                                                       |
| 71 | R8/2<br>→ S8  | as above                                                           | Information on substance properties and uses, exposures and risks                                 | Increase of data on substances of concern which are publicly available, is generated in a transparent approach (S8)                                                                             |                                                       |
| 72 | R8/3<br>→ S12 | as above                                                           | Socio-economic analysis, indication of costs and benefits which are connected with a specific use | Discussion of costs related to a specific use could be starting point to identify costs which are externalised, support of approaches to include this costs in the price of the chemicals (S12) | Potential to include costs which are externalised yet |
| 73 | R8/4<br>→ S3  | Agreement on a restriction and listing of substances in Annex XVII | Stop of specific uses                                                                             | Reduction of emissions and impacts (S3)                                                                                                                                                         | Can include imported articles                         |
| 74 | R8/5<br>→ S5  |                                                                    | as above                                                                                          | Reduction of hazardous substances in materials, thereby support of reuse of materials and support of circular economy (S5)                                                                      | Restrictions can include imported articles            |
| 75 | R8/6<br>→ S2  | as above                                                           | Need for substitutes                                                                              | Trigger to develop substitutes (S2)                                                                                                                                                             |                                                       |

|    | Code         | Activities                      | Results                 | Effect on / support of                                                                                                           | Comment |
|----|--------------|---------------------------------|-------------------------|----------------------------------------------------------------------------------------------------------------------------------|---------|
| 76 | R8/7<br>→ S6 | as above                        | as above                | Support of innovative business (models) which offer alternatives, improvement of market opportunities for such enterprises (S 6) |         |
| 77 | R8/8<br>→ S9 | Assessing restriction proposals | Decision on restriction | Example for a requirement of an ambitious regulation (S9)                                                                        |         |

**Table 11: Relations between REACH Information (R9) and elements of sustainable chemistry (S1 – S12)**

| Nr. | Code         | Activities                                                                                                            | Results                                                                                                  | Effect on / support of                                                                                                                                               | Comment                                                                                                                            |
|-----|--------------|-----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| 78  | R9/1<br>→ S8 | Reviewing the implementation of REACH + CLP (every 5 years) (MS CA + ECHA) (+ Review alternatives for animal testing) | Documentation of progress, challenges and needs for further development /Indicators on work and progress | Indicators give an overview on the implementation of a regulation, this enhanced the transparency of the chemical sector (e.g. number of substances registered) (S8) |                                                                                                                                    |
| 79  | R9/2<br>→ S8 | Implementing access to information to the MS and to the public, supporting exchange between MS CA                     | Dissemination database available with non-confidential data from registration dossiers                   | Data on properties and uses for a large number of chemicals becomes publicly available, support of availability and transparency (S8)                                |                                                                                                                                    |
| 80  | R9/3<br>→ S1 | as above                                                                                                              | as above                                                                                                 | Database as important starting point to find inherently safer chemicals (S1)                                                                                         |                                                                                                                                    |
| 81  | R9/4<br>→ S2 | as above                                                                                                              | as above                                                                                                 | Database as important starting point to find substitutes (substances, processes) for substances of concern (S2)                                                      | A substitute for a substance of concern can be another substance, another process or another approach to achieve the same function |

| Nr. | Code          | Activities                                                                | Results                                                                  | Effect on / support of                                                                                                     | Comment                                             |
|-----|---------------|---------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|
| 82  | R9/5<br>→ S8  | Starting 2021: Notification / Database on SVHC in raw materials /articles | Data on SVHC in raw materials                                            | Data on SVHC in materials becomes publicly available, support of availability and transparency (S8)                        | Impact depending on degree of information requested |
| 83  | R9/6<br>→ S2  | as above                                                                  | Replacement of SVC in materials                                          | Database as important starting point to find substitutes for substances of concern in materials (S2)                       |                                                     |
| 84  | R9/7<br>→ S3  | as above                                                                  | as above                                                                 | Reduction of emissions of SVHCs from materials (S3)                                                                        |                                                     |
| 85  | R9/8<br>→ S5  | as above                                                                  | as above                                                                 | Reduction of hazardous substances in materials, thereby support of reuse of materials and support of circular economy (S5) |                                                     |
| 86  | R9/9<br>→ S8  | Clarification which information cannot be confidential (Art. 118/119)     | Clear distinction between confidential and non-confidential information. | Support of publication of data and of transparency regarding confidentiality issues (S8)                                   |                                                     |
| 87  | R9/10<br>→ S9 | Fulfilling reporting obligations                                          | High quality information on the implementation of REACH and CLP.         | Example for a requirement of an ambitious regulation (S9)                                                                  |                                                     |

**Table 12: Relations between REACH Agency and member state competent authorities (Titles X and XIII of REACH) (R10) and elements of sustainable chemistry (S1 – S12)**

| Nr. | Code           | Activities                                                                                                     | Results                                                      | Effect on / support of                                                | Comment |
|-----|----------------|----------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|-----------------------------------------------------------------------|---------|
| 88  | R10/1<br>→ S10 | MS CA: support of national networks, cooperation between MS CA and ECHA / contact to stakeholder organisations | Enhanced cooperation, improved training and mutual learning. | Training and capacity building for authorities and stakeholders (S10) |         |

| Nr. | Code            | Activities                                                                                                                                                                                                                                                                        | Results                                                                                                | Effect on / support of                                                                                                                                                       | Comment                                                                        |
|-----|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| 89  | R10/2<br>→ S9   | as above                                                                                                                                                                                                                                                                          | as above                                                                                               | Example for a requirement of an ambitious regulation (S9)                                                                                                                    |                                                                                |
| 90  | R10/3<br>→ S8   | Founding and managing the Committee for Socio-economic analysis (SEA), the Committee on for Risk Assessment (RAC), the Forum for Exchange of Information on Enforcement (FORUM)/ Public consultations/ Community Rolling Action Plan / Public Activities Coordination Tool (PACT) | Basis for robust, transparent decisions and transparency regarding scheduling of regulatory activities | Increase of transparency regarding regulatory decisions (S8)                                                                                                                 | In addition important elements to ensure high quality of substance evaluations |
| 91  | R10/4<br>→ S9   | as above                                                                                                                                                                                                                                                                          | as above                                                                                               | Example for requirements of an ambitious regulation (S9)                                                                                                                     |                                                                                |
| 92  | R10/5<br>→ S6   | National helpdesks<br>Support of companies for registration<br>Development of formats and software for data transfer (IUCLID)                                                                                                                                                     | Support for companies                                                                                  | Increase of market opportunities for enterprises which are compliant with an ambitious legislation and can offer support regarding this legislation to their customers (S 6) |                                                                                |
| 93  | R10/6<br>→ S10  | Dissemination of substance specific data and development of guidance and guidelines                                                                                                                                                                                               | Training/ capacity building for (SM) enterprises                                                       | Training of enterprises, use of guidance documents for training at universities (S10)                                                                                        |                                                                                |
|     | Already covered |                                                                                                                                                                                                                                                                                   | Dissemination database                                                                                 | Access to data and transparency (S8), already expressed in REACH element “Information” (R 9)                                                                                 | This activity has already been covered in element R 9 (Information)            |
| 94  | R10/7<br>→ S11  | Supporting information about REACH for interested organisations and the general public / Information about risks of substances to the general public                                                                                                                              | Information in non-technical language (e.g. flyers / social media)                                     | Information support consumer awareness regarding substances of concern(S11)                                                                                                  |                                                                                |

| Nr. | Code            | Activities                                        | Results                | Effect on / support of                                                                        | Comment |
|-----|-----------------|---------------------------------------------------|------------------------|-----------------------------------------------------------------------------------------------|---------|
| 95  | R10/8<br>→ S10  | As above                                          | as above               | Information can be used for training at schools, universities and professional training (S10) |         |
| 96  | R10/9<br>→ S10  | Support of European and international cooperation | Training and guidance. | Training/Education for sustainable development and capacity building (S10)                    |         |
| 97  | R10/10<br>→ S10 | Support of developing countries                   | as above               | Training/Education for sustainable development and capacity building (S10)                    |         |

**Table 13: Relations between REACH Fees and charges (R11) and elements of sustainable chemistry (S1 – S12)**

| Nr. | Code           | Activities                                           | Results                                                                                         | Effect on / support of                                                                                                             | Comment                                                                                                                            |
|-----|----------------|------------------------------------------------------|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| 98  | R11/1<br>→ S6  | Reduction of fees for SMEs                           | Less costs for SMEs                                                                             | Improvement of market opportunities for SMEs (S6)                                                                                  |                                                                                                                                    |
| 99  | R11/2<br>→ S6  | No fees for substances with 1- 10 t/a                | Less costs for small volume chemicals                                                           | Improvement market opportunities for all companies manufacturing or importing small volume chemicals (S6)                          | This is only a positive effect if the small volume chemicals do not pose a risk in their uses                                      |
| 100 | R11/3<br>→ S12 | Fees for registration, evaluation and authorisations | Internalisation of higher costs for complex evaluation tasks such as applications authorisation | Height of fees could depend on time needed for task by MS CA. These costs have to be paid by the applicant, they are Internalised. | This is an example for Internalisation of costs related to the assessment of chemicals, not related to damages caused by chemicals |
| 101 | R11/4<br>→ S2  | High fees for authorisation                          | Incentive to use or develop substitutes                                                         | Substitution (S2)                                                                                                                  | Objective cannot be reached if authorisations                                                                                      |

| Nr. | Code          | Activities                                         | Results                  | Effect on / support of                                                             | Comment                                        |
|-----|---------------|----------------------------------------------------|--------------------------|------------------------------------------------------------------------------------|------------------------------------------------|
|     |               |                                                    |                          |                                                                                    | are granted even if alternatives are available |
| 102 | R11/5<br>→ S6 | as above                                           | as above                 | Improvement of market chances for incentive enterprises offering alternatives (S6) |                                                |
| 103 | R11/6<br>→ S9 | Setting adequate fees for complex assessment tasks | System of adequate fees. | Example for a requirement of a ambitious regulation (S9)                           |                                                |

**Table 14: Relations between REACH Enforcement (R12) and elements of sustainable chemistry (S1 – S12)**

| Nr. | Code          | Activities                                                                                                 | Results                                                      | Effect on / support of                                                  | Comment |
|-----|---------------|------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|-------------------------------------------------------------------------|---------|
| 104 | R12/1<br>→ S6 | MS CA: Establish and implementation of a system of controls and authorities / penalties for non-compliance | Level playing field for companies, control of non-compliance | Increase of market opportunities for companies which are compliant (S6) |         |
| 105 | R12/2<br>→ S9 | as above                                                                                                   | Clear and demanding tasks for companies                      | Example for a requirement of an ambitious legislation (S 9)             |         |
| 106 | R12/3<br>→ S8 | National reporting on the experience with REACH and CLP / every 5 years                                    | Information about implementation, progress and challenges.   | Increase of transparency regarding the chemical sector (S8)             |         |

## 3 How can REACH support sustainable chemistry? Findings from the matrix analysis

### 3.1 Introduction

From data on problematic properties of chemicals up to information for consumers on SVHC in articles: REACH can support sustainable chemistry in many ways. The following chapter 3.2 summarises the results of a detailed analysis of relations between main elements of REACH and main elements of sustainable chemistry. (These relations are described in the twelve tables in chapter 2.2 above).

- In this analysis, the line of vision started from REACH. The analysis answered the question, which elements of sustainable chemistry are fostered by REACH.
- Based on these findings, it is also possible to change the point of view. In Chapter 3.3 it is described, which objectives and basic principles of REACH are mirrored by sustainable chemistry – and which are not.

More than 100 relations between main elements of REACH and main elements of sustainable chemistry have been described in our analysis. It has not been possible within the scope of this study, to analyse for each of these relations systematically to which extend the relation in practice has been implemented and to which extend it actually promotes sustainable chemistry. This would require for each element a more detailed description of the related chain of actions and a systematic assessment whether data is available to demonstrate the assumed influence. For the same reason we did not weight each of the relations whether it has a low or a high importance to support sustainable chemistry. Only in single cases a comment regarding a high or a low importance of a specific relation is made if this became obvious from the last REACH review and the related studies. An example is the high importance of the substance evaluation to ensure and to promote sufficient quality of data on substance properties and exposures.

Based on this, the following chapters show more the potential of REACH to promote sustainable chemistry than providing a detailed analysis what REACH actually already does in this respect. Even with this restriction, the analysis allows to achieve a clear – and before not available – picture from the (complex) relation between REACH and sustainable chemistry and from the potential of REACH to support sustainable chemistry. In addition, the analysis allows to derive recommendations how REACH could even more support sustainable chemistry in future.

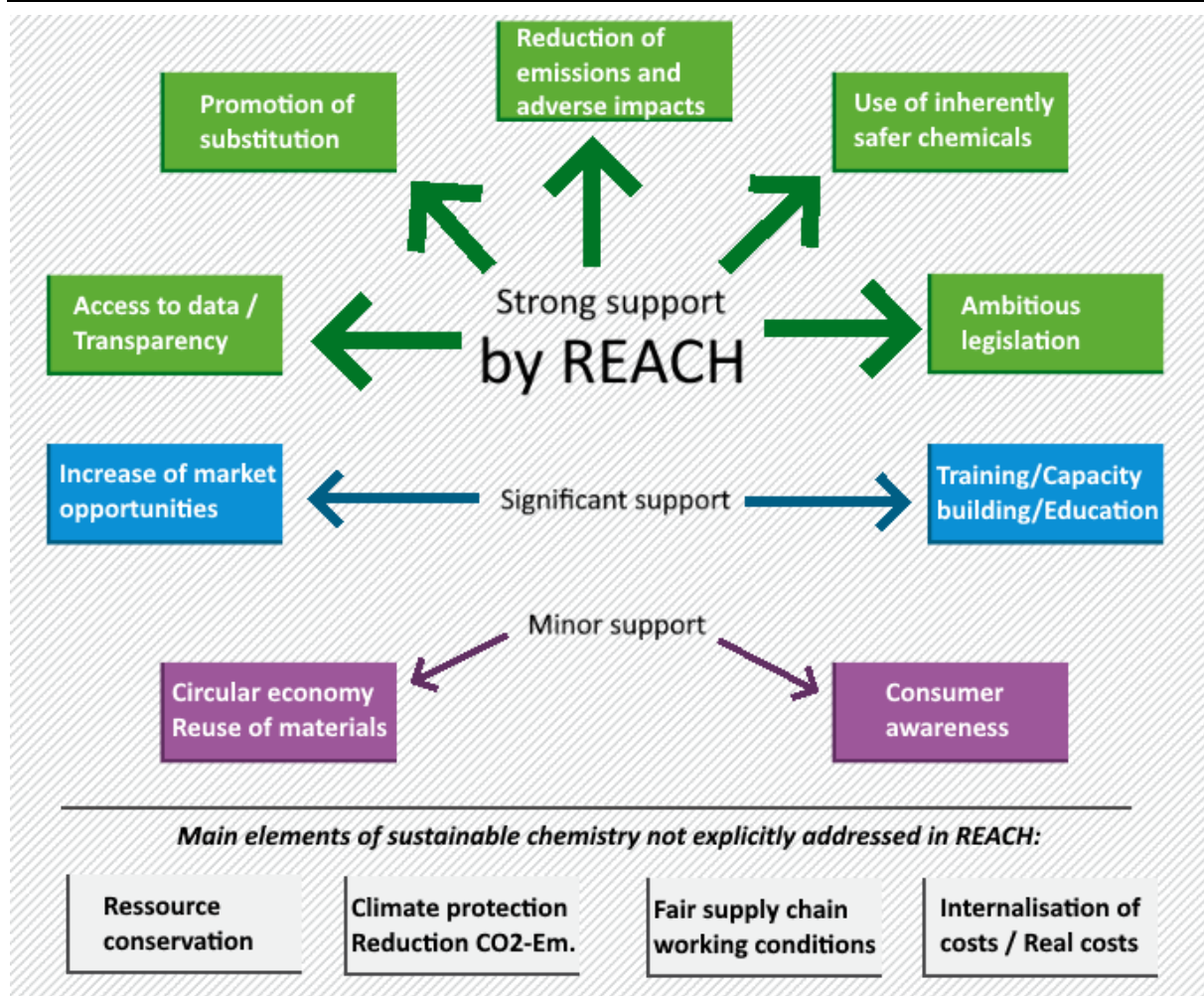
### 3.2 Main elements of sustainable chemistry, supported by REACH

The following figure illustrates which elements of sustainable chemistry are supported by REACH and arranges the results from the analysis in addition to Fig. 1 and Fig. 2 in a more apparent manner. These elements are shown in boxes with green colours.

In addition, it shows which elements are clearly beyond the scope of REACH. They are shown in the lower part of the figure (below the line) in the four boxes without colouration.

In this figure, the issue of climate protection and reduction of CO<sub>2</sub> emissions is shown as an additional element. This issue belongs to the main element “reduction of emissions and adverse impacts” of sustainable chemistry. At the same time it is an important specific objective of sustainable chemistry, which is not addressed in REACH. Therefore it is described specifically in the analysis and in the figure.

**Figure 1:** Main elements of sustainable chemistry (green boxes) explicitly addressed in REACH and main elements not explicitly addressed (white boxes).



Source: own illustration, Öko-Institut

The figure shows that REACH as a chemicals regulation supports a large number of main elements of sustainable chemistry. **Nine elements** are supported. **Three elements** and the objective of Climate protection are not explicitly addressed in REACH.

Some elements of sustainable chemistry are supported by REACH by many activities with a high impact, e.g. the reduction of emissions and adverse impacts. Others are supported, but to a minor extend, e.g. consumer awareness.

These differences are illustrated in the figure simply by the thickness and the color intensity of the arrows. This is based on two findings from the matrix analysis:

- ▶ the number of activities which support a specific main element of sustainable chemistry;
- ▶ a first estimation of the impact of the relations, if this has been possible (see the remark in the introduction (section 3.1).

**Strong support.** Five main elements of sustainable chemistry are supported by a large number of activities of REACH (more than 10 relations). Some of these activities are implemented since several years (e.g. submission of registration dossiers). The five main elements with strong support are: Reduction of emissions and adverse impacts, substitution of hazardous chemicals,

inherently safer chemicals, access to data/ transparency and ambitious legislations. **Sections 3.2.3 - 3.2.5** describe in which way REACH supports these elements.

**Significant support.** Two main elements of sustainable chemistry are receiving significant support by several activities REACH: Increase of market opportunities (15 relations, at present low implementation) and training/capacity building/ education for sustainable development (less than 10 relations). This support is described in more detail in sections 3.2.6 and 3.2.7.

**Minor support.** At present, two main elements of sustainable chemistry are explicitly addressed in REACH, however, only in a limited number of activities: Reduction of hazardous substances in materials for circular economy (six relations) and support of consumer awareness regarding products with less problematic chemicals (2 relations). This support is described in more detail in sections 3.2.8 and 3.2.9.

**Some main elements of sustainable chemistry are not addressed in REACH.** From conservation of non-renewable resources up to fundamental social rights – sustainable chemistry covers a very broad range of fields. Four of them are not explicitly addressed by activities within the chemicals regulation REACH: resource conservation, climate protection, standard-based supply chains and fair working conditions, and internalisation of costs. These elements are described in section 3.2.10.

In the following sections, these findings are explained individually more in detail. Numbers in brackets (e.g. [6])) indicate in which line of the tables in chapter 2.2 a specific relation is addressed. As said above, additionally the issue climate protection and reduction of CO<sub>2</sub> was included, which is a specific aspect of the element “reduction of emissions and adverse impacts”, however not addressed individually in the matrix.

### 3.2.1 REACH and the reduction of emissions and adverse impacts

The safe use of chemicals is one of the core objectives of REACH. Art. 1 para 1 REACH states that REACH aims “to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances”. Thus the objective serves the overarching goal of a sustainable development (cf. Recital 3 and 131 REACH). The high level of protection is highlighted by the application of the precautionary principle (Art. 1 para 3 REACH). According to a Communication from the Commission of the EU, the precautionary principle is to be applied in practice especially “where preliminary objective scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community.” (EC 2000, p.3) The European Court of Justice (ECJ) has ruled in connection with the precautionary principle that “where there is scientific uncertainty as to the existence or extent of risks to human health the Community institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent.”<sup>12</sup> On this basis, precaution can be understood as overcoming a risk situation which is defined by inconclusiveness and uncertainty (Calliess/Ruffert, Article 174 TEC, paragraph 26ff.). However, a measure based on the precautionary principle must comply with the principle of proportionality, too, in other words it must be appropriate, necessary and proportional (Epiney 2005, p.130ff.)

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<sup>12</sup> ECJ Case C-157/96, National Farmer’s Union and Others [1998] ECR I-2211, (cited as NFU judgement), paragraph 63, and ECJ Case C-180/96, United Kingdom v Commission [1998] ECR I-2265 (cited as BSE judgement), paragraph 99.

To achieve a high protection level for humans and the environment, reductions of emissions, exposures and adverse impacts are necessary. These reductions are also a main objective and a main element of sustainable chemistry.

Sustainable chemistry and REACH aim to reduce emissions of substances to a safe level. Under REACH, for substances for which no threshold values for adverse effects can be derived, especially for PBT and vPvB substances the reduction should be minimised as far as possible. For the large majority of substances with threshold level, the objective of “safe use” can be demonstrated by a risk characterisation ratio below 1 on the basis of reliable hazard and exposure data.

Many activities in REACH are related to the central aim of ensuring “safe use” and the reduction of emissions and adverse effects:

Description of the conditions of safe use is an essential task in the chemical safety assessment. It is the basic condition to achieve reduction of emissions during production and use and to avoid adverse impacts [6]. Registrants have the possibility to explicitly inform about unsafe uses and to advise against them. It is reasonable to assume that such uses will be phased out sooner or later and that the emission of these substances will decrease [9]. Otherwise, downstream users have to take responsibility for these uses and have to conduct their own chemical safety assessment. This results in descriptions of safe use and, if relevant, in a reduction of the emissions and adverse impacts by implementation of the appropriate risk management measures [42]. Securing a high level of protection for human health needs to include the protection of vulnerable groups like children, ill or old people. In this respect it is important that REACH explicitly pays attention to relevant human population groups and possibly to certain vulnerable sub-populations (cf. Recital 69 REACH)

- ▶ Conditions of safe use for substances are communicated to the downstream users in the safety data sheets. The use of the proposed risk management measures should result in a reduction of emissions and adverse impacts – at the production site as well as in the supply chains [28]. The same applies to mixtures based on the safety data sheets prepared by formulators [30].
- ▶ Downstream users can identify, implement and communicate additional risk management measures (compared to the information from the registrant). This may include information to the consumer. This further supports the safe use of the substances and mixtures and a further reduction of emissions and adverse impacts [32].
- ▶ Substance evaluation identifies the need for more stringent risk management measures for substances of concern. The application of these measures can result in a reduction of emissions [52].
- ▶ The placing of a substance on the REACH Candidate List and on the Authorisation list in many cases triggers the substitution of this substance. As a consequence, emissions of this substance can decrease [57, 59]. Additional information about SVHC in articles can support substitution of these SVHC in these articles. This could result in reduced releases of SVHC from articles [84].
- ▶ The Authorisation includes the prescription of strict risk management measures to minimise emissions as far as possible, resulting in a reduction of emissions and impacts [67].

- The restriction of a specific use means that this use should no longer be permitted. Consequently, related emissions and adverse impacts will cease [73].

### 3.2.2 REACH and the substitution of chemicals of concern and problematic processes

The concept of sustainable chemistry demands substitutes and alternative processes in order to avoid adverse effects. Substitution requires a technically available alternative, a robust database on substances, processes and uses as well as communication processes. Improvement of the database and facilitation of the communication processes are REACH's principal means of supporting substitution:

- Chemical safety assessments do not only provide detailed information about substance properties. They also give descriptions of the conditions of use in the exposure scenarios, including information about risk management measures. This is necessary in order to take an informed decision on whether there is a need to search for a less problematic substance or process [5]. The ECHA dissemination database makes this information publicly available [81].
- Within the supply chain, REACH supports the communication of uses explicitly advised against in the safety data sheet, making it clear that the manufacturer/importer of the substance does not take responsibility for an unsafe use. In this situation, downstream users themselves have to prepare chemical safety assessments, if they want to use a substance in such a way. This stimulates the search for substitutes for uses advised against [8].
- There are several examples for the substitution of hazardous substances which are restricted through regulation by other hazardous substances which are not yet restricted (e.g. substitution of Bisphenol A by Bisphenol S). In many cases these substitutes have similar chemical structures. These regrettable substitutions can be avoided, provided that the assessment of substances comprises a grouping of substances due to structural similarities. Data sharing between registrants of the same substance within SIEFs and intense exchange on options to use read across supports this grouping [22]. (Regrettable substitution can also take place if a technical solution is chosen which has (other) adverse effects.
- Safety data sheets are used to communicate information about substance properties in the supply chain. This allows downstream users to identify substances which should be substituted due to their problematic properties, e.g. CMR substances or substances otherwise assessed as SVHCs [26]. Downstream users receive information about SVHCs in articles according to REACH Art. 33.1. This can trigger them to use different articles, which fulfill the same functionality but do not contain these substances [35]. In future, information on SVHC in articles will be documented by ECHA in a specific database. This could create an additional support for the identification of materials which should be substituted by less problematic ones [83].
- Dossier evaluation improves the quality of data on substance properties. This supports a robust decision on substitution [46]. The same applies to the evaluation of specific substances by Member States. If this substance evaluation applies grouping approaches,

additional information is generated about structurally similar substances. This supports non-regrettable substitutions [51].

- ▶ Already the placing of a substance on the REACH Candidate List has been found to trigger the substitution of the substance [56]. REACH Art. 57f allows to include substances on the Candidate List which are of equivalent concern as CMR, PBT and vPvB substances. This covers problematic substance properties which are at present not addressed in the classification criteria of the CLP Regulation [56]. High mobility of substances is an example for such a property recently under discussion as equivalent level of concern.
- ▶ Such a trigger effect for substitution is even stronger if a substance becomes subjected to authorisation and cannot be used any longer in the majority or all of its uses. This increases the pressure to find substitutes [60]. Consultation on alternatives is an important step in the authorisation procedure which could generate knowledge about substitutes and could result in an enhanced use of alternatives [63]. In case of substances with a low economic value, high fees for authorisation and high costs for the preparation of an applications for an authorisation can be an effective incentive to search intensively for substitutes for SVHCs listed in Annex XIV [101].
- ▶ Restriction of a specific use increases the need to find and use appropriate substitutes [75].

As shown in the matrix in section 2, in total, nine of the twelve main elements of REACH can support the substitution element of sustainable chemistry. All these activities generate information on potential alternatives to hazardous substances. However, this information is not yet systematically compiled and not made publicly available.

### **3.2.3 REACH and the use and development of chemicals with less problematic properties (inherently safer chemicals)**

The design and use of chemicals which are not classified as hazardous and which do not have other problematic properties (such as persistency or bioaccumulation potential) is a central element of sustainable chemistry. These chemicals should have been sufficiently tested in order to ensure that they indeed are less hazardous than others. Nevertheless, for many applications only chemicals with hazardous properties will be available. In other cases, a certain degree of persistence during the use phase is required in order to fulfil the desired function. In these cases sustainable chemistry tries to find chemicals which are non-persistent outside and after their desired application (e.g. if they are released in the environment).

By different means, REACH contributes to the implementation of this objective:

- ▶ Registration provides information on hazards and risks of substances – the most important requirement to decide whether a substance is of concern or not [1]. This decision always has to take into account the context of the intended use. More detailed information is available from the chemical safety reports for substances, including a PBT/vPvB assessment [4]. The requested sharing of data between all registrants of the same substances leads to a more intense evaluation of studies and an improved data set on substance properties [18]. The application of the read-across approach, QSAR approaches and grouping of substances allows for a more complete overview for the substance under consideration and related

similar substances. This facilitates the selection of substances with less problematic properties [21].

- After clarification of the substance properties, this information is shared in the supply chain. This enables downstream users to compare different substances and to choose a less problematic one [5]. If downstream users have deviating information regarding the hazard classification of a substance (compared to the information contained in the safety data sheet), they have to inform ECHA. This improves in many cases the data bases on chemicals – and supports the selection of less problematic ones. Dossier evaluation [45] and – even more pronounced – substance evaluation [50] and the preparation of a restriction dossier [70] are further activities which improve the amount and the quality of data which is available for the assessment of substances.
- Identification of substances of very high concern is a crucial step in the authorisation process. By placing substances on the REACH Candidate List (and later listing in Annex XIV), information about very problematic substance properties is made available. This helps users to deselect these substances during the search for less problematic substances for a specific use [55]. The authorisation requirements lead to the ban of a substance for all uses for which no authorisation has been granted. This triggers substitution – and can trigger the search for less problematic substances [61].
- In addition, the dissemination database published by ECHA is an important information source to identify less problematic substances [80].

From the date of its entry into force, REACH has become a unique data source on properties and uses of chemicals. There is an urgent need for such data in order to find chemicals which have less adverse effects.

### **3.2.4 REACH and the accessibility of data and transparency**

Sustainable chemistry is based on comprehensive information about substance properties, conditions of use, impacts of chemicals and processes, market opportunities, consumer attitudes, social corporate responsibility of companies and more issues. This requires good accessibility of data for the different stakeholders and a high transparency of information in the supply chains and in society. Several activities of REACH result in a large increase of data accessibility and transparency.

- Registration of a substance makes comprehensive information about its properties and uses accessible [12]. After dissemination by ECHA, the non-confidential data are publicly available [79]. Clarification about confidentiality of data takes place in a transparent way aiming to ensure minimisation of confidentiality issues to the necessary extent [86]. In addition, the registration number makes the substance “visible” and trackable for further actions [2]. It becomes transparent who is producing and importing a substance [3, 11]. The production volumes are known – as tonnage bands and, in more precise terms, as figures in the chemical safety report [10] (data from the CSRs are only accessible for Competent Authorities). Downstream users can support the registrants by supplying information about their uses. This enhances the transparency of use patterns of substances and groups of substances [40].

- ▶ The preregistration of substances gave a first indication of the substances which have been intended to be registered. This created more transparency of the total number and the variety of the chemicals which can be expected to be on the market [15]. The cooperation of registrants of the same substance within a consortium (i.e. SIEF) improves the data availability for the members of the consortium [17].
- ▶ Safety data sheets for mixtures makes information about safe use of mixtures available in the supply chain [31]. More transparency about the presence of SVHCs in articles results from the information requirements of REACH Art. 33.1 and Art. 33.2 [34]. Transparency in this aspect will be further enhanced through the SCIP database for information on **Substances of Concern** in articles as such or in complex objects (**Products**) established under the Waste Framework Directive (WFD) [82]. Companies supplying articles containing SVHCs on the Candidate List in a concentration above 0.1% weight by weight (w/w) on the EU market have to submit information on these articles to ECHA, as from 5 January 2021 (ECHA 2019b).
- ▶ Evaluation of testing proposals by ECHA and the development of intelligent testing strategies provide more clarity regarding the availability of experimental studies [48]. A detailed assessment of individual substances in the process of substance evaluation [53] and preparation of a restriction proposal [71] increases the availability of information on hazardous properties, uses and exposures. The methodology applied and the results obtained are documented in a transparent manner.
- ▶ Several activities within authorisation support transparency on uses of SVHC (even if very specific information on individual conditions of use is in most cases declared as confidential business information and not publicly available). Applications for an authorisation indicate producers and users and the intended uses of an Annex XIV substance [62]. In addition, downstream users have to inform ECHA if they use authorised substances. This makes the present use of these substances more transparent [69]. Regarding future uses of the substances for which an authorisation is requested, the substitution plan provides transparency on the planned future uses as well as on the availability of substitutes [65].
- ▶ Indicators on the implementation of REACH provide more transparency about the chemical sector. Such indicators are part of the REACH Review Process [78]. The national reporting about the experience with REACH and the CLP Regulation supports this review [106]. ECHA developed a set of numerical indicators to track progress in several processes of REACH (e.g. percentage of registration dossiers included in dossier evaluation by ECHA to assess compliance with the registration obligations and to ensure a sufficient quality of the data submitted).
- ▶ Transparency on regulatory decision processes (decisions are taken by the Commission) including the supporting discussions in the committees is an important aim of the scientific committees involved in substance evaluation, authorisation and restriction (SEAC, RAC, Commission). The Community Rolling Action Plan, as well as the Public Activities Coordination Tool and the Registry of Intentions (ROI) inform in a transparent manner

about planned activities and document the results obtained so far in an easily accessible way [90].

All of these activities under REACH will help to improve the accessibility of data and increase transparency on the properties, uses and risks of chemicals, contributing also to sustainable chemistry.

### **3.2.5 REACH as an ambitious regulation**

In order to reach the objectives of sustainable chemistry, companies in a globalized world should be compliant with comparably ambitious legislative frameworks. In addition regulation should stimulate and enable companies to develop more sustainable approaches which are successful in the markets. Therefore sustainable chemistry needs ambitious and encouraging regulations. Due to its wide scope, REACH is one of the most complex and most ambitious chemical regulations worldwide. This is reflected by the complex structure of the REACH regulation as well as by individual elements and tasks:

- Compliance with the registration requirements is an example for an ambitious task for producers and importers of substances [14]. Other examples are the communication on (complex) patterns of use for downstream users, the identification of SVHC in articles within the supply chain, the evaluation of a registration dossier and of a restriction proposal and reporting obligations regarding the implementation of REACH [39,44,49,77,87].

Each of the main processes of REACH, e.g. Registration or Authorisation, contains one or more specific demanding tasks. These tasks require experience as well as expert knowledge from all actors which are involved in its implementation. Examples are:

- The assessment of substances with use of alternative data in a weight-of-evidence approach [24].
- The performance of an RMOA to identify the best options in place to control the risks of a substance. Being a complex task, this requires knowledge of scope and constraints of several chemicals regulations [54].
- The decision about an application for an authorisation. This includes assessment of data from a socio-economic analysis as well as prescription of conditions of use for a maximum reduction of emissions [68].
- Cooperation between MS CA, ECHA and stakeholder organisations to enhance cooperation and to establish networks including the supply chains and authorities, e.g. ESES [89].
- The setting-up and managing of expert committees involved in complex assessment tasks, e.g. the Committee for Socio-Economic Analysis (SEA), the Committee for Risk Assessment (RAC) and the expert groups (EGs) and working groups (WG) (e.g. ED EG, PBT EG, PETCO Working Group, REACH Exposure EG) [91].
- The implementation of an efficient system for enforcement by MS CA [105] and the setting of adequate fees for complex assessment tasks [103].

From registration until enforcement: REACH sets ambitious requirements for authorities and industry with regard to the fulfilment of its objectives. This is an important contribution to sustainable chemistry.

### **3.2.6 REACH and an increase of market opportunities**

In order to replace existing problematic processes and products, new approaches in sustainable chemistry have to be economically successful. REACH can support this development if it increases market opportunities for companies which have committed themselves to a higher protection level for humans and the environment. In addition, REACH triggers cooperation which can result in reduced costs for individual companies, which may then lead to better market access or higher competitiveness of the products. Several activities under REACH have such effects:

- ▶ Manufacturers and importers of the same substance have to work together in Substance Information Exchange Forums (SIEF) to ensure data sharing in joint registrations (cf. Art. 11, 27, 33, 53 REACH), (Führ 2011, Chapter 1, Rn.32). This reduces costs for the individual company and can enhance cooperation [16, 19]. Avoidance of animal testing by use of alternative testing methods can also reduce costs for testing (cf. Art. 25 para 1 REACH) [20]. A further reduction of costs results from lower registration fees for SMEs [98] and from the decision to take no or less fees for the registration of low volume chemicals [99].
- ▶ However, the REACH Regulation has harmonised standards and requirements for the market access of substances, mixtures and articles to the internal market (by harmonised rules on Registration, Evaluation, Authorisation and Restriction – and the processes underlying these mechanisms). Thus it has reduced barriers for substances, mixtures and articles. REACH seems not to have hindered competitiveness on the whole but rather improved it according to economic figures (EC 2019, p.12; CEFIC 2017; CEFIC 2018, p.12; EC 2018, p.2; EC 2015, p.196).
- ▶ For a successful registration, in many cases an intense exchange of information with downstream users is required for most of the actual uses. At the same time, this increased communication can intensify the customer/client relations and increase market opportunities [41].
- ▶ REACH exempts substances manufactured for the purpose of product and process orientated research and development from several registration obligations, e.g. Art. 5, 6 and 7 REACH for five years (cf. Art. 9 para 1 REACH). Thus REACH intends to support innovation by manufacturers of a substance as well as downstream users (cf. Art. 37 para 4 lit. f REACH) (cf. Recital 28).
- ▶ Downstream users have to comply with the conditions of use communicated to them in the safety data sheets. In addition, downstream users have to communicate about additional risk management measures if required by their uses [32]. All of these activities are time-consuming. For problematic uses which require extensive risk management measures, this will contribute to creating a demand for alternatives. This should increase market opportunities for companies offering such alternative products and processes [27].

- Identification of substances as SVHC and inclusion on the REACH Candidate List may initiate substitution processes in the market. These activities automatically create interest in and increase market opportunities for companies offering alternatives to REACH Candidate List Substances [37, 64]. High fees for authorisations and high costs for the preparation of an application for an authorisation are another incentive to use more intensively existing alternatives and to support companies offering those [102]. The same applies to the restriction of specific uses of a substance which also triggers the need to find alternatives [76].
- National helpdesks aim to support companies in registration and other REACH processes. This helps companies which take the necessary efforts to be compliant with REACH. In addition, these companies can offer their customers support for REACH tasks as a service [92].
- Careful evaluation of dossiers and national control systems for the implementation of REACH ensure a level playing field for all enterprises under REACH. This increases the market opportunities for companies which are compliant with REACH [47,104].

All these activities make a significant contribution in terms of increasing market opportunities for companies which are compliant with REACH and keeping non-compliant companies from the market. Many of them only refer to the substitution of substances of very high concern, however. Although this influence is considered as significant, it is not as strong as e.g. the support of the element “reduction of impacts” which refers to all substances under REACH.

### **3.2.7 REACH and capacity building, training and education for sustainable development**

Capacity building, mutual knowledge transfer as well as training and education are important elements of sustainable chemistry. They are supported by several activities under REACH. Most but not all of them belong to the tasks of ECHA and the related authorities:

- A large number of guidance documents have been developed, with the participation of many stakeholders, for the different REACH tasks. They are important instruments for capacity building and training. The comprehensive guidance on information requirements is an important example for this support [13]. The practical guide on how to use alternatives to animal testing shows clearly that this training is in many cases very specific and has a strong focus on technical questions [23].
- MS CAs have to support national networks and to cooperate with stakeholder organisations. This results in an improved knowledge transfer [88]. ECHA is responsible for the dissemination of substance-specific data and of guidance – important information sources for the in-house training of experts in companies [93]. These sources could also be used at universities. In addition, ECHA provides support information about REACH for interested parties and the general public. This is done by various means, including social media, using a non-technical language [95]. These materials can be used for different training purposes.
- REACH is supplying science and public with information on hazards of substances but important measures to support sustainable chemistry lie beyond the scope of REACH. The

knowledge of known hazards and persistency must be applied in the design phase of chemicals and products and there should be a focus on education and Research & Innovation across chemicals and product development fields (EEA 2017, p.17). Tasks such as read across or the robust comparison of alternatives require additional skills. Therefore chemists and product developers working for the manufacturers and down-stream users should get additional support and training to make use of the knowledge REACH produces, e.g. in the integrating principles of safe-by-design<sup>13</sup> and sustainable chemicals in the design phase (EEA 2017, p11).

- ECHA has to foster European and international cooperation. A further task is the support of developing countries. For many countries this is a crucial requirement to implement sound management of chemicals and waste. Often basic constituents such as classification and labelling of chemicals are missing. Therefore capacity building and training worldwide are important objectives of these tasks [96, 97].

### **3.2.8 REACH and circular economy: re-use of materials**

- Within registration, the chemical safety assessment explicitly has to address the waste phase of a chemical. This includes recommendations for a safe handling of waste, aiming to improve the knowledge about where the life cycle of a substance ends [7]. The recommended waste management practices have to be implemented by downstream users. This should reduce the amount of wastes generated, as well as the content of substances of concern within wastes [29].
- The inclusion of SVHCs on the REACH Candidate List triggers information flows in the article supply chains [36] and supports the substitution of these substances in articles and related waste streams [58]. The new ECHA database on SVHC in articles (SCIP: database for information on **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts)) is expected to further support this replacement and thereby to further reduce the amount of these substances in waste streams [85] (ECHA 2019b).
- Similar to the effect of the authorisation process, the restriction of a substance inhibits specific uses and the related content of the substance in articles and waste streams [74].

In total, these activities could significantly contribute to move towards non-toxic material cycles and support a more circular economy in the EU. This is also one objective of the Strategic Plan of ECHA for 2019-2023 (ECHA 2018c).

### **3.2.9 REACH and consumer awareness**

Consumers play an important role within the concept of sustainable chemistry. For many sectors of the chemical industry and the related supply chains, they are the final customers - as individual persons or as institutions (public procurement). For sustainable (chemical) products to be successful on the market, consumers have to be aware of the real impact of non-sustainable products.

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<sup>13</sup> Safe-by-design is a concept to reduce and eliminate the use or generation of hazardous substances in the design, manufacture and application of chemical products. It has important links to occupational health and safety, pollution prevention, and sustainable development patterns. (IPEN 2017, p.60ff "Green Chemistry and Sustainable Chemistry")

Although REACH excludes consumers from the definition of a down-stream user (cf. Art. 3 para 13 and 35 REACH), REACH contains several provisions for consumers.

Within the complex field of consumer awareness, REACH can support the awareness for problems related to hazardous chemicals, and for options which consumers have in terms of selecting less problematic ones:

- ▶ Consumers have the right to know whether any SVHCs are present in articles (REACH Art. 33. (2), Recital 56 REACH). A good information base keeps consumers better informed about these most problematic substances. If the information is provided already prior to the purchase of the product, an alternative product with less substances of less concern can be chosen [38]. However, it is not easy for the consumer to find supplier of an article which does not contain SVHC or to know what to ask for. Additionally, due to the limitations of REACH (cf. chapter 4.4) consumers cannot ask for hazardous substances in articles in general. (This topic is further addressed in work package 8 of the project Advancing REACH).
- ▶ ECHA has to develop supporting information about REACH also for the general public. This is done in a non-technical language, including the use of social media. The materials create more awareness regarding substances of concern in daily life [94].

### **3.2.10 Out of scope: Main elements and objectives of sustainable chemistry that are not addressed in REACH**

Three main elements of sustainable chemistry are not explicitly addressed in the REACH regulations:

- ▶ Resource conservation;
- ▶ Internalisation of external costs;
- ▶ Fair working conditions in the supply chains (beyond occupational safety and environmental protection).

Besides that, one central objective of sustainable chemistry is out of scope of REACH:

Reduction of greenhouse gas emissions for climate protection.

**Resource conservation:** Sustainable chemistry aims to reduce significantly the rate of consumption of raw materials (energy, water, renewable and non-renewable resources). Therefore it assesses options for an enhanced use of renewable raw materials which have been produced in a sustainable manner. It supports chemicals which can be produced with fewer raw materials. This has already been addressed in the principles of Green Chemistry ("Principle of atom efficiency" (Anastas and Warner 1998).

A core principle of REACH is the safe use of chemicals, not less use of chemicals. Neither the amounts of raw materials required for the production of a chemical, nor the resource efficiency of a chemical process are being addressed in the regulations.

**Internalisation of costs / real costs:** Unsafe use of chemicals can lead to huge costs for the treatment of related diseases and the recreation of polluted areas. Sustainable chemistry provides that the costs for these actions are included in the socio-economic analysis of chemicals and their use. At present, in most cases these costs are not paid by the producers or users of the

chemicals, but by other groups of society. This externalisation of costs prevents that the real costs of the use of problematic chemicals become visible. The socio-economic analysis in REACH provides a methodology to document and assess such costs. However, the internalisation of such costs in the prices of chemicals is not a topic of REACH.

**Fair working conditions in the supply chain.** Establishment of international standards for working conditions is an important aim of sustainable chemistry. It goes beyond occupational health and environmental protection related to the production and use of chemicals (which are a central aspect in REACH and addressed in the objective “reduction of emissions and adverse impacts”). It explicitly includes aspects such as accident prevention and safe work places, minimum wage and fair salaries, working time and vacation time regulations, overtime compensation, right to social agreements, no discrimination, no child work. According to the concept of sustainable chemistry, these fundamental social rights should be in place not only in one single company, but in the whole supply chains of chemical industry and the related sectors of economy. These aspects are outside the scope of REACH.

**Climate protection.** Reduction of greenhouse gas emissions by successful climate change mitigation measures is a central objective of sustainable chemistry. For this purpose, the calculation of CO<sub>2</sub> equivalents for the production of chemicals as well as for chemicals processes is an important method. It is one element of the life cycle assessment of substances and products which is an important tool in sustainable chemistry. REACH assesses in detail the hazardous properties of substances for human health and the environment. However, this does not include the amount of greenhouse gases which are emitted for the synthesis of a substance, nor the greenhouse gases related to a specific process. This is beyond the scope of REACH, but very well in the scope of agencies and authorities which implement chemicals safety as well as general environmental protection.

### 3.3 Additional information: Objectives and principles of REACH : which are supported by sustainable chemistry?

The previous sections described which elements of sustainable chemistry are supported by REACH.

Based on the findings of the analysis, it is also possible to assess which objectives and basic principles of REACH are reflected and supported by sustainable chemistry. Two answers can be given:

- ▶ **Most objectives and principles of REACH are supported by sustainable chemistry.**  
From the high protection level for human health up to the precautionary principle – sustainable chemistry supports the majority of the objectives and principles of REACH. This is described in the following section 3.3.1.
- ▶ **The REACH objective “Animal welfare” is out of the scope of sustainable chemistry.**  
One objective of REACH is not discussed within sustainable chemistry: the promotion of alternative methods for the assessment of hazards of substances and the sharing of toxicological information to avoid unnecessary testing. This is described in the following section 3.3.2 .

### 3.3.1 Objectives and principles of REACH addressed by sustainable chemistry

REACH has four main objectives:

- ▶ high level of protection for human health and the environment (Art. 1 para 1 REACH);
- ▶ animal welfare by promotion of alternative methods for assessments of hazards of substances (Art. 1 para 1 and Recitals 37 and 40 REACH);
- ▶ free circulation of substances on the internal market (Art. 1 para 1 REACH);
- ▶ enhancing competitiveness and innovation (Art. 1 para 1 REACH).

In addition REACH is based on a number of basic principles which together with the objectives form the “backbone” for the main elements of REACH, from registration up to enforcement:

- ▶ responsibility of industry for data on properties and on uses of substances (Art. 1 para 3 REACH);
- ▶ “No data, no market” (cf. Art. 5 REACH);
- ▶ shared responsibility within the supply chains for safe use of substances and
- ▶ the precautionary principle (Art. 1 para 3 REACH).

These objectives and basic principles represent the “backbone” of REACH, from registration up to enforcement. Most of these objectives and principles of REACH have corresponding elements in the concept of sustainable chemistry.

- ▶ The REACH objective to achieve a **high protection level for human health and the environment** corresponds to the central objective of sustainable chemistry, which consists in reducing adverse impacts as far as possible.
- ▶ The REACH objective “Support of the chemical industry and the related economic sectors” (by **free circulation of substances on the internal market while enhancing competitiveness and innovation**) corresponds to an important objective of sustainable chemistry. “Increase of market opportunities and encouraging regulations”
- ▶ “**No data, no market**” describes in short words the condition set out by REACH to first register a substance (documenting and communicating safe use), and then to sell it. Sustainable chemistry requires that the properties of substances are well-known and calls for ambitious regulations to meet this requirement.
- ▶ “**Responsibility of industry**”. REACH is based on the principle that it is up to manufacturers, importers and downstream users to ensure that no adverse effects of their chemicals occur, i.e. safe use is possible. This is one important aspect of the ambitious regulations which are requested in the concept of sustainable chemistry.
- ▶ “**Shared responsibility**” under REACH means that registrants and downstream users have to work together in order to ensure a safe use of substances in the supply chain. The concept

of sustainable chemistry emphasises that cooperation between many actors is needed to develop and implement more sustainable approaches.

- The provisions of REACH are underpinned by the **precautionary principle**. Sustainable chemistry is based on the same principle.

### 3.3.2 Objectives of REACH not addressed by sustainable chemistry

As shown in the previous chapter, most of the main objectives and principles of REACH have corresponding elements in the concept of sustainable chemistry. However, for one objective this does not apply: **support of animal welfare**.

- REACH has the aim of promoting alternative methods for the assessment of hazards of substances and to share toxicological information. The main reason for this aim is to promote animal welfare and to avoid unnecessary testing of animals. Testing on vertebrate animals for the purposes of REACH shall be undertaken only as a last resort. Measures have to be taken to limit duplication of tests. In the guidance documents developed for registrants, opportunities for using alternatives to animal testing are described. Alternative methods outlined in REACH are a weight-of-evidence approach, in vitro methods, quantitative structure-activity relationship (QSAR) models and read-across/categories) (ECHA 2016).
- Avoidance of unnecessary testing of animals is not addressed in the concept of sustainable chemistry.

## 4 How can REACH hinder sustainable chemistry?

### 4.1 Introduction

The detailed analysis of activities under REACH and their contribution to elements and objectives of sustainable chemistry has shown that REACH is supporting sustainable chemistry in many ways. At the same time, it became apparent that REACH can also be an obstacle for specific objectives of sustainable chemistry – for three reasons:

- ▶ weakness of implementation of specific activities;
- ▶ conflicting goals which impede an implementation which would foster sustainable chemistry and
- ▶ limitations in the scope of REACH as a whole or of specific activities within REACH.

### 4.2 Weakness of implementation

Regarding its principles, objectives and main elements, REACH has a large potential to support sustainable chemistry. In order to realise this potential, REACH has to be implemented properly. 10 years' experience with REACH reveals several fields where implementation fails to meet the expectations. Important examples are:

**Quality of data in registration dossiers** is decisive for the correct assessment and classification of a substance, the identification of uses advised against and adequate risk management measures in order to reduce emissions during the use and potentially the waste treatment of the substance (see section 2.2, table 1, section 3.2.4). Robust data on substance properties form the basis for the identification and communication of hazards and risks, as well as for necessary RMMs. Furthermore, it provides the basis for the identification of functional substitutes for hazardous substances/SVHC and/or of substances with less adverse effects. Deficiencies in the quality of registration data endanger the entire chemicals risk management chain. They can lead to wrong decisions regarding priority setting, substitutions and risk management measures. Within REACH, dossier evaluation aims to ensure a sufficient quality of the data which have been submitted by the registrant. The REACH review 2018 has clearly shown that a majority of registration dossiers have insufficient data quality (EC 2018).

**The end-of-life stage in the life cycle of a chemical is often not addressed** (in detail) in the chemical safety assessments (see section 2.2, table 1, [8] and section 3.2.8). Despite the existence of detailed guidance and clear legal requirements, the lack of competences and capacities within the industry and the low priority assigned to the waste life stage resulted in the fact that registration dossiers and chemical safety assessments are accepted that contain only a minimum information<sup>14</sup>.

At present, a long time period of several years is required for substance evaluation and possibly following implementation of risk management (see section 3.2.1 and section 2.2, table 6). This

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<sup>14</sup> Consideration of substance amounts in wastes was explicitly discussed by ECHA and industry associations, among others, in the development process of specific environmental release categories (spERCs). Here, submission of rough amount estimates from waste processing using spERCs were “generally accepted” (however, without any legal implications regarding any validation of the spERCs). Nevertheless, according to personal communication with ECHA, current practice appears to hardly ever consider substance risks from waste processing, which may also be due to the fact that specific waste legislation exists and no added value is seen in REACH information. It is not clear whether or not stronger consideration of risks from the waste stage will be required in the future.

process starts with the placement of the substance in the Community Rolling Action Plan. It may end with a decision for the proper regulatory management option and the implementation of measures - which is a time-consuming process as well (in other cases, the decision can be that there is no need for additional risk management measures). Several factors cause the long duration, e.g. the time needed to get further information on substance properties during substance evaluation. Throughout this long time period, the respective substances will still be used – causing further emissions and exposures in some cases. Options to shorten the required time span for substance evaluation e.g. in the PBT assessment are discussed since several years in the ECHA PBT Expert Group (Scheringer et al. 2018).

The main goal of the authorisation process is to end the use of the most hazardous substances and to promote their replacement by less hazardous substitutes (see section 2.2, table 7 and section 3.2.2). This requires a comprehensive analysis of alternatives. Authorities and the ECHA Committees in some cases lack information to evaluate the applicants' assessments of alternatives and the socio-economic implications of phasing out a use.<sup>15</sup> Furthermore, the practice of **granting authorisations despite the availability of technically feasible alternatives in cases where there are claims that these are not economically feasible for the applicant might** decrease the market opportunities for manufacturers of less hazardous chemical substitutes or alternative products and processes.

**Restriction proposals addressing only individual substances** could lead to regrettable substitutions, replacing a regulated substance by a structurally related one (see section 2.2, table 8 and section 3.2.2). This shifts the emissions from one substance to another, without really avoiding problematic exposures (c.f. example of Bisphenol A being replaced by other bisphenols.) (Fantke et al. 2015, ECHA 2019).

Notification of substances of very high concern in articles takes place. However, at present, the **knowledge of the presence of these SVHC in articles in the European market is still limited (ECHA 2018a)**. This is due to deficits in the implementation of supply chain communication on SVHC in articles (Art. 33(1)) (see section 2.2, table 3). This results in a lack of transparency. As described in the next section, this is also an example for a conflicting goal between increase of knowledge and amount of time needed to get it from (often global) supply chains.

As regards SEAC's decisions (see section 2.2, table 7 and 8), in many cases it is **not clear to which extent the precautionary principle has been applied**. At present in a restriction proposal an unacceptable risk has to be proven, which has to be addressed at EU level (REACH Art. 68(1)). It is not sufficient to show the risk for one or two member states and to assume a similar situation in the others as then, addressing the risk at national level would be appropriate. Framing of the application of the precautionary principle is one of the key action points resulting from the REACH review 2018 (EC 2018, sec. 3.2, Action 10).

In the socio-economic analysis (see section 2.2, table 7, [66]), **adverse effects to individuals and the environment are only addressed to a lesser extent than costs**. SEA is dominated by short-term costs and benefits. The currently used methodology enables large economic benefits to outweigh severe health risks. Benefits for human life and environmental health often cannot be quantified and are given less weight than economic benefits (cf. results from Work Package 4 of the project). This is contradictory to the aim of sustainable chemistry to assess costs and benefits in a holistic approach (For more details on these aspects, see results of work package 4 of the project).

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<sup>15</sup> The authorities' lack of information on substance uses was one of the reasons to develop and implement REACH. While generic information is now available from registrations, specific data on which alternatives could be used in which particular process is proprietary knowledge of the manufacturing industries.

**Risks of mixture toxicity are not addressed in the registration dossiers.** REACH refers to substances as such, in mixtures and in articles. In their chemical safety assessment, registrants have to consider all relevant information regarding potential adverse effects (REACH Annex I). This should include information about mixture toxicity. At present, it is not clear how this could be implemented under REACH (Bunke et al. 2014). Here, the key requirement for demonstration of “safe use” is an exposure level of a single substance below the no-effect levels (risk characterisation ratio of 1). Sustainable chemistry aims to reduce the total burden of exposures, taking mixture toxicity into account.

### 4.3 Balancing of conflicting goals

The overall goals of REACH are to improve the level of protection of human health and the environment, while increasing competitiveness and innovation of the EU industry, as well as limiting the number of animal tests performed (REACH Art.1).

These goals are not necessarily contradictory, but they frequently need to be balanced when the legal provisions are interpreted. For example, REACH cannot pursue the objective to ensure a high level of protection of human health and environment in an absolute manner but must act in accordance with its other legal objectives to enhance competitiveness and innovation as well as the free circulation of goods. Furthermore the provisions to protect human health and the environment must follow the proportionality principle. As a general principle of EU law (cf. Art. 5 para 4 EU Treaty (OJ EU 2012, p.13)) it restricts authorities in the exercise of their powers by requiring them to strike a balance between the means used and the intended aim.

The change of the weight assigned to the economic goals (competitiveness, partly innovation) and the protection goals would lead to stricter (interpretations of) requirements in many cases. Examples, where the weighting of goals leads to a less strong fostering of sustainable chemistry are:

#### Registration:

The tiered information requirements for substance registration (REACH Annex VII – X) are based on the assumption that the potential level of risk from substances increase with increasing manufacturing and use amounts. This means that the risk level influenced the requirements. The industry is assumed to more easily recover registration costs for high volume substances than for low volume substances. Hence, economic considerations do not contradict increasing registration requirements. The tiered information requirements are a reasonable approach to protect industry from high costs but prevents the existence of complete hazard data, in particular on long-term effects for low volume substances<sup>16</sup>.

Animal testing should be prevented (see section 3.3.2). Therefore, other options are defined to generate hazard data, such as QSARs, read-across and weight of evidence. ECHA's dossier evaluations, as well as other projects assessing data quality for substances registered in amounts exceeding 1000 t/a (BfR 2015)) show that experimental data is lacking to a very large extent for the higher tier endpoints. Frequently, the information submitted has been deficient. In many cases, read across and deviations from the standard testing requirements have been wrong or done with an inadmissible reasoning. On the one hand, this results in a high uncertainty

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<sup>16</sup> The lack of information on low volume substances may be particularly regrettable, if they are used as substitutes for substances of very high concern, as no obvious hazards are identified by the companies. However, they have to deal with uncertainty (no information) and, if the missing data is generated at a later time showing a hazard or risk, may have to substitute again. The extent to which data is not existing is documented for example in ECHA's evaluation reports (ECHA 2018b).

regarding the actual hazards of the assessed substances. On the other hand, it weakens the evidence base for use of read-across and grouping.

### **Authorisation**

The authorisation decisions taken by the COM and the length of the review period of authorisations among others are attributable to the assessment of alternatives performed by the applicant and the presented substitution plans. The assessment of alternatives includes an evaluation of technical and economic feasibility, which should protect the industry from too strict or too fast phase-out of substances. However, as it may be in the interest of industry to prolong their use of SVHCs, the proposed phase-out timelines imply that until the use is ended, damage occurs to either humans or the environment, hence contradict the goals of health and environmental protection (cf. EC 2017; EEB 2015). On the other hand, without the review period given in authorisation decisions, a stricter regulation could lead to unintentional effects like a transfer of production (and risk) to non-EU countries. This would also contradict the goals of sustainable chemistry. This also concerns the process length of opinion forming in the RAC and SEAC for applications for authorisation.

In case of substances for which “adequate control of risk” can be demonstrated, authorisation shall be granted according to REACH Art. 60(2) (despite the availability of alternatives; c.f. above). This allows flexibility for the industry to continue a use and improve their substance handling. However, the goal of health and environmental protection may be underrepresented, it is likely that several (SME) users of the authorised substances have only limited capacities for controlling emissions from these uses to the workplaces and the environment. In these cases, risks would not be adequately controlled and adverse effects could take place.

The scope of the authorisation process is limited to SVHC as defined under Art. 57. This increases predictability and the extent to which substance uses may be reduced in the (near) future for the industry. However, risks may also arise from substances which do not fulfill the criteria of REACH Art. 57 and for which authorisation is not possible as they cannot be included on the candidate list (at present). However, for some of these substances, identification as SVHC may be possible under Article 57(f) (equivalent level of concern), e.g. for persistent, bioaccumulative and toxic substances. It is discussed to apply this also for persistent, mobile and toxic substances.

### **Restriction**

The industry’s competitiveness and innovation capacity are affected by the availability of substances for their products and processes. Therefore, the hurdles to restrict or ban the use of a (group of) substance are considerably high and include the demonstration of a risk that needs to be addressed at EU level (REACH Art. 68(1)). In principle the precautionary principle can be used from the Commission as an argument for a restriction proposal, if the risk of a substance is not adequately controlled and the socio-economic analysis does not come to contradicting conclusions. In such a case MS have to decide whether they follow this argumentation. In practice such a case did not occur yet, although it would be protective of human health and the environment. (Further details on REACH and the precautionary principle are provided in the report of the work package 9).

### **Information about substances in articles**

Responsible choices require information about a product. Generating and communicating information about (hazardous) substances in articles (REACH Art. 33.1 and 33.2, see section 2.2, table 3) may be considered confidential information, e.g. if the particular article/location of an

SVHC in a product should be communicated.<sup>17</sup> In addition and according to industry, the communication on SVHC in articles requires considerable resources by the supply chain actors, in particular as the candidate list is continuously updated, requiring evaluation of the SVHC communication as well (cf. Reihlen and Halliday 2017). At this point, the limited scope of Art. 33 and the requirement to communicate to consumers only on request and only, if an SVHC is contained in an article, are the result of conflicting goals of REACH, too.

These issues show that the different REACH goals may be in conflict and the actual implementation depends on the weight assigned to the different goals. Whether the current balance between economic and health/environmental interest is struck well depends of course on the stakeholder perspective. In addition, the conflicting goals do not necessarily require adaptation of the REACH regulation, as this may lead to incoherences within REACH.

#### 4.4 Limitations in the scope of REACH

As described in section 3.2.10, a few of the main elements of sustainable chemistry are obviously out of the scope of REACH: Resource conservation, reduction of emission of greenhouse gases, fair social working conditions within the supply chains and increase in prices for chemicals due to internalisation of costs. Therefore, REACH cannot support these elements. It does not mean that these elements are less important than the elements addressed in REACH.

Some limitations result directly from the scope of individual elements of REACH:

1. Registration is not required for substances with a production volume below 1 ton/year. Chemical safety assessment is only required for substances with a production volume of 10 tons/year or more (see section 2.2, table 1). This limits the amount of data available for low volume chemicals.

Polymers are exempted from REACH Registration (REACH Art. 2, 9), but KOM should review this exemption (Art. 138 (2) REACH). However, monomers are included and problematic polymers can be regulated by authorisations or restrictions. Several studies have been undertaken and activities are on-going evaluating how (groups of) polymers can be identified which require registration (Wood 2019).

Less obvious are three limitations in the scope of individual activities of REACH which could hinder more ambitious objectives of sustainable chemistry:

2. **Substitution of hazardous substances.** In REACH, substitution is requested explicitly only for substances of very high concern (REACH Art. 55, see section 3.2.2). In the concept of sustainable chemistry, a hazardous substance should be substituted by a less hazardous one wherever possible. This also refers to hazardous substances which are not identified as SVHC according to REACH Art. 57 a-f. In this respect, the scope of the substitution objective of sustainable chemistry is much broader than of REACH. REACH requires “only” safe use for these substances. REACH does not impose any obligations to check whether substitutes are available for “non-SVHC”- substances or not and to use them if possible.
3. **Reduction of emissions** (see section 3.2.1).

Sustainable chemistry is based on the principle of “minimization” of risk, as e.g. stated in the SDGs for the use of chemicals. Minimization of risk means that any source of exposure to

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<sup>17</sup> See related position papers by e.g. the automotive and the aircraft industries who fear loss of CBI from providing such information. In a [chemical watch article](#), the ECHA database was stated to be an opportunity for industry espionage (see ACEA 2018).

hazardous substances is actually eliminated or reduced as much as possible and if feasible and not creating other types of unacceptable adverse impacts. This principle of sustainable chemistry is, among others, based on the assumption that chemicals interact and enhance their effects as well as that any exposure reduction contributes to human and environmental health.

In contrast to this, REACH is based on the principle that for all substances that have a threshold below which no adverse effect is expected, may be managed so that exposure levels remain “just” under that threshold value. This means if a RCR of less than 1 is achieved, no further risk reduction need exists and can be required of the economic actors. But the reliability of exposure scenarios is often weakened due to a limited quality of exposure data.

However, the “principle of emission and exposure minimization” does apply also under REACH for all substances that do not have an effect threshold, such as PBT/vPvBs or non-threshold carcinogens.

These diverging approaches and views upon risk reduction beyond the “safe level” of threshold substances should be further discussed and solutions are found to overcome these, partly contradictory philosophies.

4. REACH does not support system innovation: Since the focus of the REACH mechanisms lies on the single substance, its properties, risk assessment and risk management, innovations that require changes in the entire value-chain are not stimulated by REACH. Therefore REACH falls short to support sustainable chemistry when it comes to the transformation of value chains as well as institutional and financial structures that might hinder sustainability. The mechanisms of REACH to authorise or restrict the use of substances of (very high) concern does not offer enough incentives to implement system innovations. However, the diffusion success of a product (i.e. will it gain market share) is influenced by following: compatibility with routines (no behavioural change necessary); prices, costs, profitability; minor uncertainties; availability of service offerings; reputation of providers; and the role of market leaders (the sooner they offer the innovation, the greater the diffusion dynamics (Fichter, Clausen 2013, p.209 ff.)).

## 5 How can REACH support sustainable chemistry even more effectively? Recommendations

The detailed analysis of REACH and its contribution to sustainable chemistry leads to two major findings:

- ▶ REACH already provides substantial and important support to the majority of topics of sustainable chemistry now. There are many interfaces between REACH and sustainable chemistry. They should be exploited more intensively in order to support the sustainable development goals.
- ▶ Weakness of implementation (see section 4.2) , the weighting of the different goals (see section 4.3) and limitations in the scope of REACH (see section 4.4) can reduce the generally possible positive effect of REACH on sustainable chemistry. In specific cases, it can even hinder important objectives of sustainable chemistry, e.g. substitution of hazardous substances if they are not assessed as being substances of very high concern<sup>18</sup>.

This all in all favourable interaction between the global development goals, respectively the concept of sustainable chemistry, and the REACH Regulation is based on the broad agreement in the overarching goals. However, the role of these documents should not be overlooked. The REACH Regulation sets a framework based on some basic principles that is binding on manufacturers and users of chemicals. The "weakness of implementation" mentioned above is part of the REACH Regulation as of 2006, or rather the preparation of the regulation, but could be overcome more quickly through proactive cooperation between the parties involved.

The chemical industry often refers to its "responsible care" for its products and to its interest in innovations. Consequently, it is important that companies and associations orient their responsibilities towards the Sustainable Development Goals and not towards minimum compliance with legal requirements. As a result, the SDGs and the concept of sustainable chemistry provide the guidelines and guard rails for sound management of chemicals, but ultimately require the legal basis for implementation. The perspective of the dependencies should be observed.

The REACH Regulation is not per se sustainable. Only the persons and institutions that implement REACH achieve sustainable chemicals management. Sustainable chemistry needs the legislative pillar to become effective, not the other way around. This does not rule out the possibility that individual elements of the sustainability goals may be incorporated into chemicals legislation or secondary regulation areas in the medium term. Here, for example, changes in consumer behaviour (reduction of plastic products) and the conservation of resources should be considered.

Based on the findings of the analysis on REACH and sustainable chemistry, the following recommendations are given, how REACH and its implementation can be further developed in order to support sustainable chemistry even more effectively. The recommendations explicitly exclude areas currently not covered by REACH (see section 3.2.10). These recommendations can be implemented within the current legislative scope of REACH.

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<sup>18</sup> Within the Concept of Sustainable Chemistry (Blum et al. 2017) it is clearly seen that in many cases the function of a chemical is connected with a hazardous property, e.g. biocidal activity of a disinfectant. Therefore substitution requires a robust analysis whether alternatives are available which fulfil the required function and do not have this or a similar problematic property.

## **Increase effectivity and efficiency of REACH processes**

- 1. Improve the quality of the data on the properties and uses of chemicals.** Hazard and exposure data of high quality are the crucial starting point in sustainable chemistry to reduce emissions in the entire life cycle of a substance to a safe level, to decide on substances with less problematic properties and to find functional substitutes. It is therefore recommended and of high importance that the quality of data made accessible via ECHA's registration database is improved as much as possible to provide the best possible basis for risk assessment and the assessment of alternatives in the context of substitution of substances of concern (see chapter 4.2 (1)).  
Incentives should be given for companies which prepare registration dossiers of high quality. (Further details on how data quality could be improved under REACH are provided in the reports of the work packages 1, 3 and 5.3).
- 2. Speed up the process of substance evaluation, including the processes of identification of SVHC and decisions on the most appropriate regulatory option.** This will help to shorten the time period in which emissions of substances of potential concern can occur (before the regulatory decision is taken) and to achieve the related SDG on the safe use of chemicals by 2030 (see chapter 4.2. (3)). (Further recommendations for substance evaluation and SVHC identification are provided in more detail in the reports of the work packages 5.3, 5.4 and 5.6).
- 3. Support risk reduction measures aiming reducing emissions to a safe level covering the entire substance life cycle. Additional measures that allow to further reduce the total emission of substances with reasonable efforts can minimise uncertainties from a limited quality of risk characterisation data.** Sustainable chemistry is based on the principle of "minimization" of emissions and risks. It would be of great support if under REACH economic actors are motivated to implement risk management approaches that further reduce the total emission if appropriate (see chapters 3.2.1 and 4.4 (4)).
- 4. Broaden the present "single substance" perspective of REACH.** Strengthen consideration of mixture effects in Registration, Restriction and Authorisation. Sustainable chemistry aims to reduce the total exposure of men and the environment and considers in the assessment of chemicals also additive effects and other mixture effects (see chapter 4.2(9)).
- 5. Use REACH Candidate List, authorisations and restrictions to effectively regulate substances of concern with endpoints which are not in the focus of classification and labelling.** Examples are persistent, mobile and toxic substances, polymers with problematic properties and persistent substances of equivalent concern (REACH Art. 57f. equivalent level of concern) (see chapter 3.2.2 and 4.3 (5)).
- 6. Improve the socio-economic assessment by addressing adverse effects to individuals and the environment in a holistic approach.** This assessment is the core instrument to identify impacts and assess the "cost-benefit ratio" of a measure. To better take account of sustainable chemistry, the approaches how effects on society and the environment as a whole are addressed should be modified.  
Document the application of the precautionary principle and support its use in the SEA. A stronger focus and weight should be given to the application of this principle as an argument in the overall assessment (see chapters 3.2.2, 4.2 (4), 4.2 (7) and 4.2 (8)). (Further information about SEA are provided in more detail in the report of the work package 4).

## **Better consider substances of concern in mixtures, articles and waste**

- 7. Give more guidance to adequately address the end-of-life stage in chemical safety assessments.** This allows reducing burdens from wastes and can contribute to a strengthening of circular economy by avoiding the entry of substances of concern in

materials and wastes. The respective provisions should be strengthened, among others by enforcing the implementation of existing guidance. Furthermore, awareness should be increased that waste treatment practices may be implemented differently in other regions of the world, which would be another argument not to include SVHCs in products, which are likely to be disposed of outside the EU, if possible (see chapter 4.2 (2)).

8. **Increase the knowledge of SVHC in articles and the possibilities for consumers to obtain information** about this issue. More efforts should be made to further raise awareness on SVHC in articles in the EU and worldwide. The REACH provisions could be used as a basis for global (communication) standards on SVHC in articles, leading to more transparency and awareness (see section 3.2.4 and 4.2 (5)). (Further recommendations regarding the regulation of articles under REACH are provided in more detail in the report of the work package 8. An overview on the current status of this topic is given in the documentation of the joint ECHA/ DE CA workshop on substances of concern in articles, held in October 2019 in Berlin).

#### **Improve substitution of substances of concern**

9. **Stronger promote knowledge about available substitutes for substances of very high concern in the supply chains and support their substitution** (see section 3.2.2). **Authorisations should only be granted, if no substitutes are available (which are technically and economically feasible)** (see chapter 3.2.2 and chapter 4.2 (4)). At present, several activities under REACH generate information on potential alternatives to hazardous substances. However, this information is not systematically compiled and made publicly available. This could be of significant help to many actors, in particular in countries in lesser developed countries and economies in transition. (Further recommendations how REACH can strengthen substitution are provided in more detail in the report of the work package 10).
10. **Support functional substitutions by regulating not only individual substances, but groups of substances** which share a common structure and similar concerns (category approach). Substitution of substances of concern by alternatives, which are similarly hazardous is a problem at global level. Under REACH, the scope of several processes could address groups of substances. Options to implement category approaches should be further implemented and developed methodologies should be made available also globally, to facilitate learning from REACH experience (see chapter 3.2.2).
11. **Provide incentives for a substitution of substances classified as hazardous going beyond the substitution of substances of very high concern.** Under REACH, focus of the substitution processes within authorization is on SVHC. Sustainable chemistry aims to replace in a broader scope hazardous substances (even if they do not fulfill the criteria of Annex XIII). The substitution strategy of ECHA has already a broader scope than SVHC only (see chapter 3.2.2 and ECHA 2018c) (Further recommendations how REACH can strengthen substitution are provided in more detail in the report of the work package 10).

#### **Exchange and capacity building**

12. **Strengthen Capacity building especially in developing countries and in countries in transition.** This is of crucial importance for the sound management of chemicals and waste, for the transition to a more sustainable chemistry and for progress regarding the sustainable development goals. In fact, the implementation of REACH is already supporting these efforts. To further support capacity building, it is recommended to enhance the transfer of learnings and experiences regarding risk management decision making and implementation from the EU to other countries but also within the supply chains and sectors inside the EU (see chapter 3.2.7).

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