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Advancing REACH - REACH and substitution

Final report

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Advancing REACH - REACH and substitution

Final report

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Abstract: Advancing REACH - REACH and substitution

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) the REACH regulation by analysing various REACH processes and related issues, including substitution, sustainable chemistry, precautionary principle, articles, cost-benefit analyses, socio-economic analyses and financing ECHA.

Substitution is the use of less hazardous alternatives for substances of concern. The support of substitution is an important instrument in REACH to ensure a high level of protection for human health and the environment. It is not only the authorisation and restriction procedures in REACH that address this issue. Other elements of REACH also support substitution – e.g. high-quality data on substance properties and uses from substance registrations and substance evaluations.

What is needed are alternatives that provide better and safer solutions for problematic applications in the long term, and which are economically and technically viable. For this purpose, alternatives are sought which ensure the desired function without simply replacing a substance with a structurally similar but also problematic substance.

This report makes recommendations on how REACH can support functional substitution more than hitherto. They are derived from an analysis of the current impact of REACH on the substitution of problematic substances and from examples. The examples are taken from authorisation and registration. In addition, examples from research projects and other legislation will be evaluated.

The recommendations range from suggestions for making REACH processes more efficient to national monitoring of production and consumption of selected problematic substances. Some can be implemented immediately, others are designed for the medium term.

Kurzbeschreibung: REACH und Substitution

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-Ökomische Analysen, Finanzierung der ECHA) Optionen für eine Verbesserung der (Umsetzung der) REACH-Verordnung entwickelte.

Substitution ist die Verwendung weniger gefährlicher Alternativen für problematische Stoffe. Förderung der Substitution ist ein wichtiges Instrument in REACH, um ein hohes Schutzniveau für die menschliche Gesundheit und die Umwelt sicher zu stellen. Nicht nur das Zulassungs- und das Beschränkungsverfahren in REACH setzen hier an. Auch andere Elemente von REACH unterstützen Substitution – z.B. qualitativ hochwertige Daten über Stoffeigenschaften und Verwendungen aus Stoffregistrierungen und Stoffbewertungen.

Erforderlich sind Alternativen, die für problematische Anwendungen auf Dauer bessere und sicherere Lösungen darstellen, die wirtschaftlich und technisch tragfähig sind. Hierfür werden Alternativen gesucht, die die gewünschte Funktion sicherstellen, ohne einfach einen Stoff durch einen strukturell ähnlichen, aber ebenfalls problematischen Stoff auszutauschen.

In diesem Bericht werden Empfehlungen ausgearbeitet, wie REACH funktionale Substitutionen stärker als bisher unterstützen kann. Sie werden abgeleitet aus einer Analyse der derzeitigen Auswirkungen von REACH auf den Ersatz von problematischen Stoffen und aus Beispielen. Die Beispiele stammen aus der Zulassung und Registrierung. Zusätzlich werden Beispiele aus Forschungsprojekten und anderen Gesetzgebungen ausgewertet. Die Empfehlungen reichen von Möglichkeiten der effizienteren Gestaltung von REACH-Prozessen bis zu einem nationalen

Monitoring von Produktion und Verbrauch ausgewählter problematischer Stoffe. Einige können sofort umgesetzt werden, andere sind mittelfristig angelegt.

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AfA	Application for an Authorisation
AoA	Assessment of Alternatives
CA	Competent Authority
CL	Candidate List
CoRAP	Community Rolling Action Plan
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
C&L	Classification & Labelling
CLP Regulation	Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures
DU	Downstream User
EDC	Endocrine disrupting chemical
ES	Exposure Scenario
Forum	Forum of Exchange for Information on Enforcement
M	Manufacturer
MS	Member State
PACT	Public Activities Coordination Tool
PBT	Persistent, bioaccumulative and toxic
QSAR	Quantitative Structure Activity Relationships
RAC	Committee for Risk Assessment
RMM	Risk Management Measure
RMOA	Regulatory Management Option Analysis
SDS	Safety Data Sheet
SEAC	Committee for Socio-economic analysis
SME	Small and medium sized enterprises
SVHC	Substances of very high concern
WoE	Weight of Evidence
vPvB	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. Various aspects of the REACH regulation and its implementation are analysed and improvement options developed within the project framework, 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 implementation 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 implementtation 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.

How can REACH further support substitution of substances of concern?

1 Introduction: Substitution in legislation and in practice

A central objective of REACH is to ensure a high level of protection of human health and the environment. There are two principal means in REACH to achieve this goal (ECHA 2018):

- Better knowledge on the properties and uses of chemicals, resulting in safe uses of chemicals and reductions of exposures and emissions;
- Substitution: the use of less dangerous alternatives to substances of concern.

Within the context of occupational health and safety, substitution is the most important protective measure to reduce exposures, emissions and adverse effects from chemicals. It is the first option to be assessed and implemented if possible, prior to technical measures, organizational and personal protective equipment (STOP principle). Also, it is an important measure for the protection of consumers and the environment substitution.

The understanding and implementation of the substitution principle as well as the understanding and implementation of this principle have been the subject of discussions and elaborations for decades. A common understanding of this term has been given in ECHA´s substitution strategy:

- The replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures (ECHA 2018, definition cited from Lohse et al. 2003).

Recently there have been a number of national, European and international activities in support of substitution, e.g. the OECD Substitution and Alternatives Assessment Toolbox (http://www.oecdsaatoolbox.org/), the foundation of the ISC3 (International Sustainable Chemistry Collaboration Centre), the Swedish Center for Substitution and the continuation of activities from NGOs, e.g. the ChemSEC Marketplace.

In REACH, the authorisation process is the primary element in which the substitution of substances is explicitly addressed: "Substances of very high concern are progressively replaced

by suitable alternative substances or technologies where these are economically and technically viable". Likewise, however, several other elements of REACH promote substitution by various means. The restriction of specific, problematic uses of a substance (Title VIII), for example, creates the need to find new ways to deliver the desired functionality of the currently restricted use.

Substitution is supported by other chemicals legislations, too. According to ECHA´s substitution strategy, REACH, CLP and the Biocidal Products Regulation together intend to provide a much broader perspective than on SVHCs alone." They are designed to place pressure on and to provide incentives for the industry to try to replace hazardous substances with less hazardous ones" (ECHA 2018).

Since REACH entered into force, authorisations and restrictions have led to an enhanced substitution of SVHC and other substances of concern. These reductions result from a combined effect of various legislations. However, it is difficult to assess substitution quantitatively, due to the lack of precise data on actual production volumes, import volumes and export volumes of substances of concern and their potential substitutes.

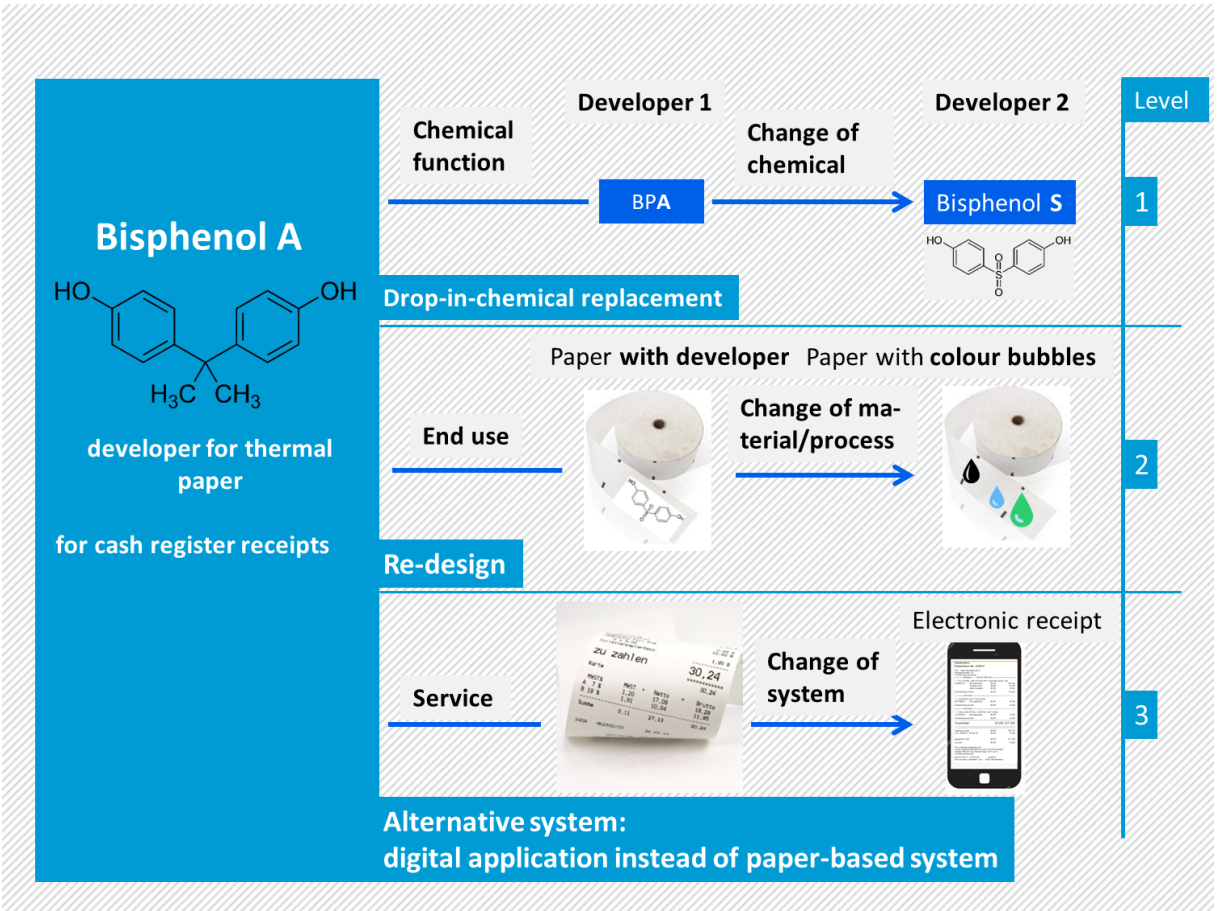
Despite the high priority of substitution in the hierarchy of protection measures, replacement of substances of concern by better and safer substitutions still represents a major challenge for companies. In cases where substitutes were already available, chemicals with a similar structure and similar physico-chemical properties have frequently been selected. This type of replacement is called 1:1 substitution ("drop in chemical replacement").

Examples are the substitution of Bisphenol A by Bisphenol S and the substitution of long chain chlorinated paraffins by middle chain chlorinated paraffins. These alternatives can be used without any major modifications in the production processes. However, these chemicals are also often problematic in terms of adverse effects. Substitutions with major modifications in the processes or technologies are rare.

For the identification and discussion of potential alternatives, the function of a chemical is of central importance. A substitution process which includes the consideration of functional aspects has been defined as "functional substitution". In this approach, a differentiation is made between the technical function of the chemical itself (e.g. as a developer or an optical brightener), the function of the material produced using the chemical (e.g. thermal paper for cash receipts) and the final service that should be delivered, e.g. delivering a receipt to document the purchase of goods.

The following picture gives an example of functional substitutions and the three levels involved. It shows options to substitute Bisphenol A. On level 1, another chemical is used as a developer in thermal paper. On level 2, another type of thermal paper is used, which does not need a developer any longer. On level 3, receipts are delivered, but electronically – therefore, a need to provide thermal paper no longer exists.

Figure 1: Functional substitution: Options to replace Bisphenol A, used as a developer in thermal paper to deliver cash register receipts



Source: own illustration, based on an example from Tickner et al. 2014 (Schweizer und Bunke 2019).

On each of these three levels, alternatives to a given problematic substance can exist. The first level, the technical function of the chemical itself, often leads to “drop in chemical replacements” as described above: substitution by a structural similar substance. The second and third level can offer additional options for substitutions, including changes of materials, processes and systems.

On all three levels, chemicals can be involved. A robust assessment is needed, whether they can pose a risk and whether the alternatives are really better and safer. Therefore, data on substances generated under REACH are required on these levels. In addition, level 2 and 3 require a more in-depth understanding of the function of a product and technical options to realize it. This goes far beyond the tasks of the classical chemicals’ management with a focus on the hazard assessment and exposure assessment of substances. Therefore, the assessment of options of functional substitution needs cooperation and exchange between chemical regulators, technical experts and product designers to find alternatives, which are really better and safer.

Even where case studies of successful substitutions are available, the process to transfer these modifications to the situation existing in other companies (with slight or significant differences in process conditions) can be difficult.

1.2 Aim of the study

The aim of this study is to answer the question how REACH could further support substitution – beyond the present state. The analysis addresses two key questions:

- How does REACH actually support substitution of substances of concern?
- How could changes in REACH or its implementation enhance the support of substitution by REACH?

1.3 Lessons learnt from examples

Many examples of substitution have been assessed for this report. They have been selected from the following fields:

- Restriction under REACH (see section 4.2 and annex section 7.1);
- Authorisation under REACH (see section 4.3 and annex section 7.2);
- Project LIFE Fit for REACH (see section 4.4 and annex section 7.3) and
- Product-related legal provisions (RoHS Directive, Detergent Regulation, Ecodesign Directive and EU Ecolabel Regulation) (see section 4.5 and annex section 7.4).

The objectives of this description have been

- to obtain a better understanding of the influence of REACH on real cases of substitution;
- to identify challenges in the identification and assessment of potential alternatives and
- to derive options in REACH which would allow for an enhanced support of substitution.

The most interesting findings from the analysis of the examples are summarised for each of the four fields in chapter 4. Detailed descriptions of all examples are documented in the annex in sections 7.1 – 7.4.

From each example, lessons have been learnt. They have been used to derive recommendations on how REACH could further support substitution. In this step, we also took into account findings from the project 'Advancing REACH' on the processes of Restriction and Authorisation (work packages 5.1 and 5.4 of the project).

How can REACH further enhance substitution? As an answer to this question, our recommendations are described in the following section. They are based on the findings of the analysis of the examples and an additional literature research on the actual impact of REACH on substitution (see chapter 3 and annex 9 for the results of this research).

1.4 Recommendations

The analysis of the substitution examples as well as the analysis of the present impacts of REACH on substitution have shown many aspects that influence the substitution processes in practice. Several obstacles for substitutions became evident. At the same time we could identify different triggers for substitution and manifold approaches to support substitutions.

The following recommendations (chapter 1.5 and 1.6) show possibilities how REACH could provide stronger triggers and support for substitution than it does at present. Many of them directly refer to specific activities under REACH. For example, future assessments of alternatives

should include a quantitative indication of the "Technical Readiness Level" of each alternative. Recommendations with such a close link to REACH are grouped together in section 1.5 (see Figure 3 for a summary in a nutshell and section 1.5 for a detailed description).

Enhanced future support of substitution requires additional measures, which are not directly related to elements of REACH. An increasing interest of the general public in products free of substances of concern is an example for a development in society which supports substitution. Therefore, the second more general part of our recommendations in section 1.6 addresses politics and society (see Figure 4 for an overview and section 1.6 for more details).

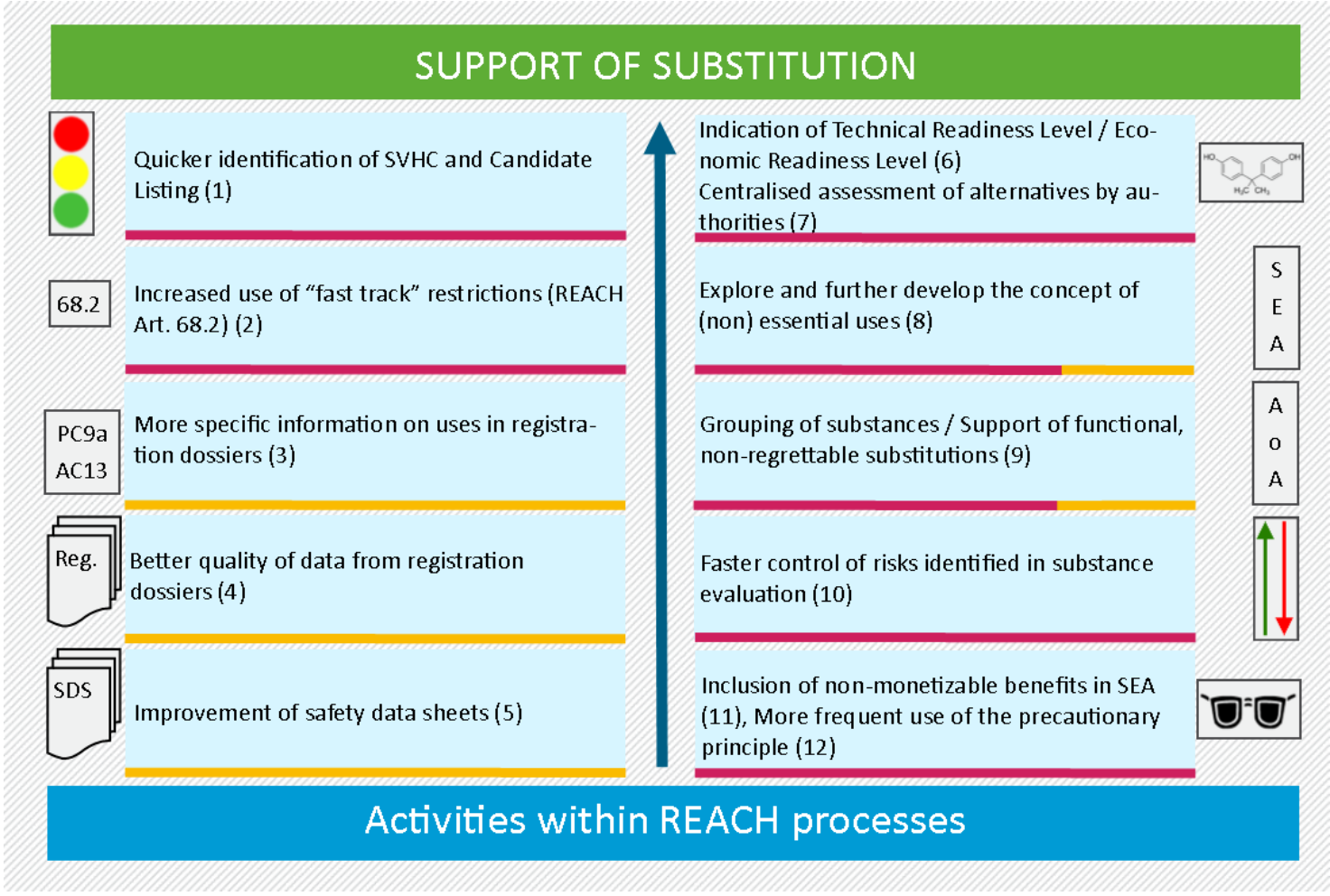
1.5 REACH: Specific recommendations

Several options were identified on how specific REACH activities can be modified for an enhanced support of substitution. The following figure gives an overview.

Figure 2: Activities within REACH to support substitution.

Coloured lines: indication of main actors (**authorities**, **industries**). Numbers: Number of recommendations in section 1.5.

SEA: Socioeconomic analysis; AoA: Assessment of Alternatives



Source: Öko-Institut e.V.

Most of these recommendations are targeted at policymakers/authorities. Most of them should be feasible without changing the legal text of the REACH legislation but would probably require agreement on EU level. The emphasis would be on changing procedures and priorities and integrating concepts. The tasks to improve the data quality of registration dossiers and safety data sheets are in the responsibility of companies producing and importing chemicals and mixtures.

1.5.1 Increase listing of substances

1. Work towards **a more efficient and quicker identification of SVHC and Candidate Listing,** accelerating all related processes. This would require more resources, more stringent discussions and commitments from national authorities and ECHA/Commission to dedicate time to develop more Annex XV proposals for SVHC identification as well as CLH proposals under CLP. Important steps would be improved templates for Annex XV dossiers, a better quality of the data in the registration dossiers (including the PBT assessment), a more efficient process of the discussions in the MS committees and a more efficient handling of comments from public consultations, if they are very comprehensive and repetitive.
2. Increase the use of the "fast-track" option for restrictions granted under Article 68(2). This provision has not been used very often so far and should be used more frequently.

1.5.2 More and better data from registration dossiers and safety data sheets

3. Already ensure in the registration dossiers that the **use categories are more specifically defined** by companies and already indicate the technical function of the substance, with documentation in the dissemination database. This makes it easier to identify substitutes. This is also of particular relevance for restrictions, for applications and for the granting of authorisation of substances, which are intended for very specific uses, rather than a broad variety of uses. A better overview on substances on the market and their uses is needed. This requires additional research – by the MS CA experts, ECHA or technical experts, supplementing the results from the public consultations.
4. Improve the quality of the data on properties and uses of chemicals in the registration dossiers and in the dissemination database. In several cases data was insufficient for classification or totally lacking, which creates uncertainties in the assessment and selection of alternatives; it may also result in regrettable substitution.
5. **Improve the quality of safety data sheets**. Safety data sheets continue to be a core information source for chemicals risk management within the supply chains. Their quality is essential both for identifying substitution needs (hazardous properties, uses advised against, worker protection information, required risk management measures etc.) and potential alternatives. In many cases, the quality of safety data sheets needs further improvement.

1.5.3 Improvement of the Assessment of Alternatives

6. Use the concept of "Technical Readiness Level" for the assessment of alternatives. Assessment of the technological and economic feasibility of alternatives has become a large challenge in many examples of restrictions and authorisations. It would be extremely favourable, if descriptions of alternatives always contained an indication of the use-specific **"Technical Readiness Level"** and the **"Economic Readiness Level".** Such a description could include a middle- and long-term projection and an explanation of factors, which determines the development of these levels.
7. Implement an in-depth-assessment of alternatives to be conducted by authorities on an overarching level, e.g. as part of the RMOA. This would replace the present assessments

carried out by applicants for authorisations, which often aim to show that no suitable alternatives are available, which are technically and economically viable. This would require information provided by companies and additional research to be undertaken by the authorities or by independent technical experts. Under the Stockholm Convention, alternatives for persistent organic pollutants are systematically assessed. These results are published and globally available.

8. Explore and further develop the **concept of 'essential' and 'non-essential uses' under REACH with the aim to promote substitution of essential uses**. This approach to distinguish between essential uses and non-essential uses has been proposed by the Netherlands in the context of the PFAS restriction in December 2019 (see also Cousins et al. 2019). In this context it should be highlighted, that especially for the essential uses the search for alternatives is of high importance.

1.5.4 Grouping, functional substitutions and non-regrettable substitutions

9. **Grouping approaches should be used more frequently for the assessment and regulation of substances** (see also recommendation in Belgium SVHC roadmap study, rdc Environment 2019 and ECHA´s grouping approach to prioritise and de-prioritise substances of the 'the chemicals` universe'[1]). Regulation should not only address individual substances, but wherever possible groups of substances which share a common structure and cause a similar level of concern. Examples are the grouping of bisphenols and the grouping of four phthalates in recent restrictions. The RoHS Directive as well as the Ecodesign Directive give further examples for an effective and far-reaching grouping approach (all PBDEs, the whole group of brominated flame retardants).
   This approach helps to avoid use of substances which are neither better nor safer and which do not lead to an improvement. Such substitutions are called "regrettable substitutions". In most of these cases substances are replaced by substances which are similar in structure but have similar problematic properties as the substances used before. This type of substitution is called "1:1 substitution". It is also called "drop in chemical replacement", because in most cases it does not require a change in the processes.
   A grouping of substances facilitates a more extensive search for alternatives. The analysis of options for so-called "functional substitutions" goes beyond the technical function of a substance. It also considers the function of the materials produced using the respective chemical, and the final service that should be delivered (see end of section 1.1 and Figure 2 for more details on functional substitutions).

1.5.5 Substance evaluation and follow-up activities

10. **Work towards a faster control of risks which have been identified in substance evaluation.** In many substance evaluations, the existence of risks has been established. However, no actual mandatory regulatory follow-up has been initiated for risk control after completion of the regulatory management option analysis (RMOA) (see EEB 2019). Such measures should be based on the results of the RMOA.

1.5.6 SEA and the precautionary principle

11. Change the way SEA is being performed: a pure cost-benefit focus is too narrow and needs to be expanded to **include non-monetizable health benefits for society and environmental benefits** (see EEB restrictions report, EEB 2018) as well as discounting rates that include the potential damage to future generations (see also Arnold 2019). Remark: This

[1] https://echa.europa.eu/de/-/mapping-the-chemical-universe-list-of-substances-by-regulatory-action-published

topic has been analysed more in-depth in work package 5.4 of the project "Advancing REACH". See the final report from that work package for details.

12. Make **more use of the precautionary principle.** More weight should be given to the application of this principle as an argument in the overall assessment. Bisphenol A had been banned in the EU due to a restriction in baby bottles in 2011, after the precautionary principle had been invoked (as pointed out in the recent REACH review, EU 2018). Further examples are discussions of restrictions regarding microplastic and PFAS.
    Remark: The use of the precautionary principle within REACH has been analysed in more detail in work package 9 of the project "Advancing REACH". See report from that work package for details.

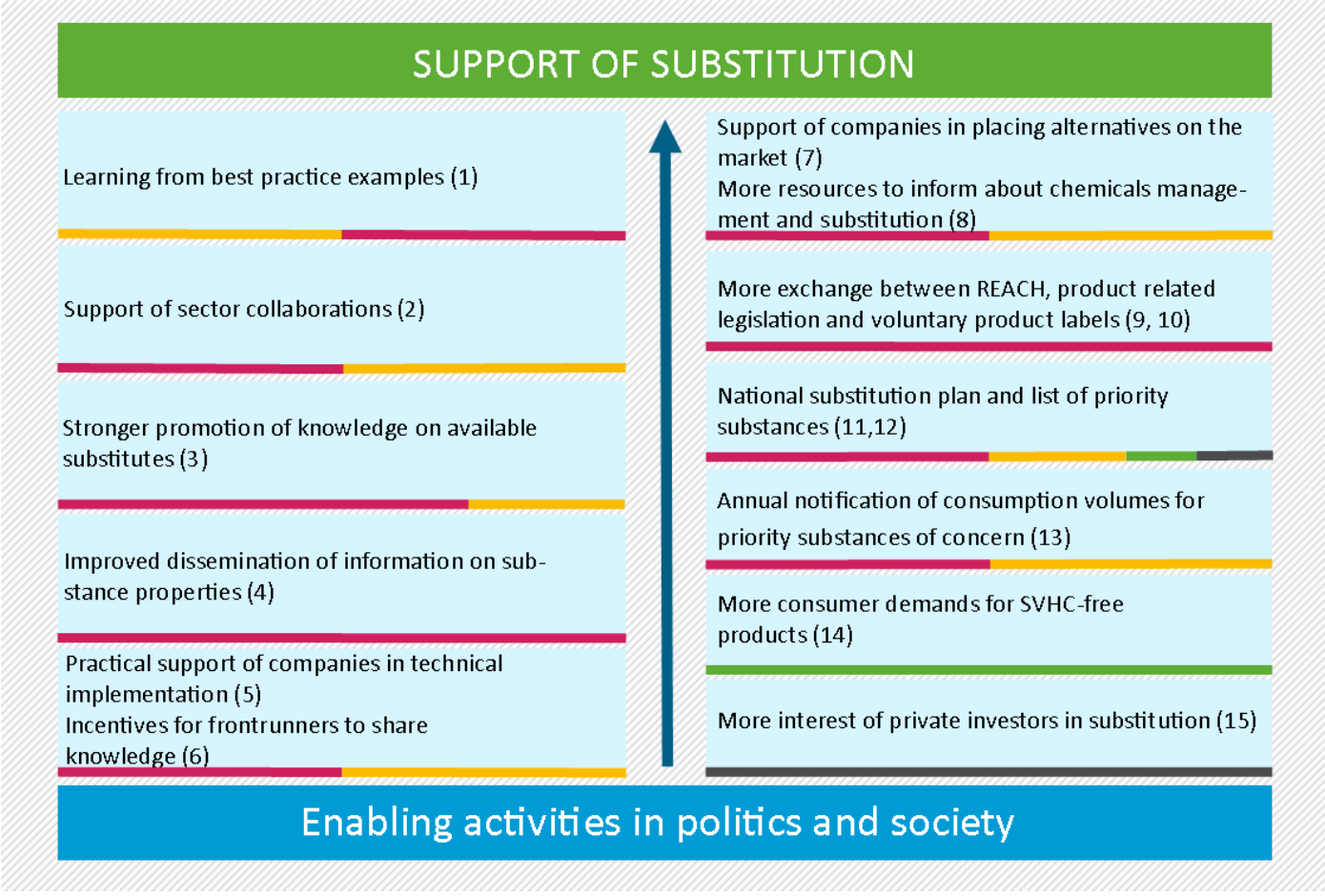
1.6 Recommendations for an enabling environment for substitution

The second group of activities originates from politics. It includes a broader range of societal actors. They are important to form an environment which enables substitution.

An overview of these recommendations is given in the following.

Figure 3: Activities in politics and society to support substitution

Coloured lines: indication of main actors (**authorities**, **industries**, **consumers**, **private financial investors**).
Numbers: Number of recommendations in section 1.6.



Source: Öko-Institut e.V.

1.6.1 Support of companies and sectors

Companies from Baltic States participated in the project LIFE Fit for REACH. The experience from this work emphasises on the importance of supply chain communication and the high quality of data which are available to assess alternatives.

The core challenge of many substitution cases was the lack of suitable alternatives in terms of their technical performance and availability at acceptable costs.

In this situation a higher substitution pressure would create larger markets for potential alternative suppliers. As a consequence, costs for alternatives could decline. This would further support substitution processes.

Based on this experience, three options are seen to overcome the lack of suitable alternatives:

1. stronger regulation in terms of restrictions and authorisation decisions (see recommendation 1 and 2 above (section 1.5.1));
2. targeted support of the development and placing of suitable alternatives on the market and
3. targeted support for penetrating the market with these alternatives.

We gave recommendations for the first point, a stronger regulation, already above in section 1.5.1. The following recommendations address the second and third of these core challenges.

1. Support learning from best practice examples. This seems to be one of the most important support measures. It moves the focus of the discussions and activities to success stories of substitution. Create business cases! It is important to develop new cases and analysis, which show that substitution works and has economic benefits. This encourages other companies to substitute problematic substances in their processes.
2. Encourage sector collaboration to support companies in finding alternatives (see for example the initiative "vecco" on chrome plating)[2]. Collaborations should focus on delivering the function instead of just substituting the chemical (more details on functional substitution are given at the end of section 1.1, see also Figure 2). Knowledge on successful "functional grouping approaches" should be promoted (see the following recommendation).
3. Stronger promote knowledge about available substitutes for substances of concern in the supply chains and support of the use of these substitutes. In addition it is necessary to inform more about successful approaches to group substances according to their function.
4. Improve the dissemination of information about substance properties. At present, many activities under REACH generate information on properties of potential alternatives to hazardous substances (e.g. registration and substance evaluation). However, this information is not systematically compiled and made publicly available.

   Implementation of the last two recommendations would be a significant help to many actors, in particular in lesser developed countries and in economies in transition.

5. Give practical support and financial support to companies who need help for the technical implementation of available substitution cases to their individual processes. This should include information about possibilities to receive public funding for substitution activities.
6. Provide incentives for frontrunners to share their knowledge on successful substitutions (e.g. fees for licenses). Solutions developed in research projects with public funding should be disseminated with creative common licences.

[2] https://www.vecco.info

7. Assist companies (with budgets and knowledge transfer), which developed safer and better alternatives in the difficult phase of placing the alternatives on the market.
8. Inspectors and potentially also industry associations should dedicate more resources to consulting companies on legal compliance, overall chemicals risk management and the identification of substitution priorities.

In all these activities with companies, authorities should highlight the importance of **efficient and meaningful supply chain communication** in chemicals risk management. Cooperation among competitors should be further strengthened in order, for example, to identify alternatives at the sector level, but also along the supply chain, as well as to support substitution, also at the technical level. Direct contacts between companies are an important motivational factor. They are of decisive importance for the reduction of chemical risks.

1.6.2 Use synergies / exchange with product-related regulations

Product-related legal provisions use specific approaches to restrict hazardous substances in products. These approaches vary partly from the approaches used under REACH. Based on the findings from the descriptions of these provisions in section 4.5, the following recommendations are derived. They aim at strengthening of the trigger and support for substitution - under REACH and in the interplay with product legislation.

As already recommended above, a grouping of substances under REACH can be used to cover a broad range of problematic substances in substance evaluation and regulation. The RoHS Directive as well as the Ecodesign Directive give examples for an effective and far-reaching grouping approach (e.g. by regulating all polybrominated diphenyl ethers as one group and all brominated flame retardants as one group).

9. **Promote the exchange between REACH and product group-specific legal provisions** (e.g. RoHS for electrical and electronic equipment), thus taking greater account of the end-of-life phase in chemical safety assessments and in substance evaluations under REACH. REACH generates a large amount of information about critical substance properties and fate, exposures and content in products. Key findings on critical properties (e.g. persistence, bioaccumulation, mobility, endocrine disrupting properties) should be presented to experts from product-related regulations. These legal provisions (e.g. the Detergents Directive) enable authorities by legislation to address specific properties (e.g. biodegradability) of concern independent of the combinations of properties which are laid down in REACH (e.g. REACH Annex XIII, persistence together with bioaccumulation (vPvB substances) or together with bioaccumulation and toxicity (PBT substances)).
10. **Promote the exchange between REACH and voluntary product labels.** This would facilitate the substitution of substances classified as toxic or hazardous for the environment, even if they do not meet the criteria for being classified as substances of very high concern. Consumer demands for harmless and toxic-free products play an important role for certain product groups. Criteria for voluntary product labels can be formulated in such a way, that they exclude problematic substances mentioned above.

1.6.3 National substitution strategy and list of priority substances of concern

A number of additional activities would strongly enhance substitution under the chemicals legislation (not only REACH). They could be started on a national level or on the EU level:

11. Develop a **national substitution strategy** in order to develop options and criteria for substitution on a general level, to prioritise them and to track important substitution processes (see the example from Belgium, rdc Environment 2019).

12. Develop a **national list of priority substances of concern** (and groups). In the Netherlands, the national policy is particularly focussing on priority substances of very high concern, the so-called ZZS substances. This is part of the program "The Netherlands circular in 2050". The Dutch ZZS substances cover a broader range than the SVHC under REACH (RIVM 2017).

1.6.4 Monitor production and consumption of priority substances of concern.

The analysis of the present impact of REACH on substitution has shown that there is no data base with robust empirical evidence which would allow to track the success of substitution (see Chapter 3 and annex section 9.3). At least for priority substances of concern it would be important to know to which extent and in which sectors substitution takes place.

13. For a limited number of identified/defined priority substances of concern, **information on production, import and export volumes** should become available on a national level and throughout the EU (including data on these substances in articles). These figures should be provided on an annual basis specifically for narrowly defined use categories. In order to obtain this information, a voluntary agreement between industry associations and authorities is recommended.

1.6.5 Interest of the general public and investors

The interests of the market (e.g. demands of article producers for SVHC-free raw materials) and of financial investors are most probably the most important non-regulatory drivers for substitution.

14. Support measures to **raise awareness of consumers regarding the problem of substances of concern in articles** and to increase their demands for products free of these substances (e.g. the project AskREACH'[3]).
15. Support measures to **increase the interest of private financial investors in substitution**. They should consider whether companies working for and with better and safer alternatives or not in their investment decisions. This requires measures to raise awareness in society regarding the benefits of replacement of substances of concern.

1.7 Outlook

Enhancing substitution of substances of concern will remain a key challenge for chemicals management in the coming years and is a central aim/element of REACH. The analysis undertaken in the context of this report revealed some progress in substitution due to REACH and the other chemicals legislations, as well as a pressing need for additional efforts – on the part of authorities, industries, consumers as well as private investors.

ECHA's strategy to encourage substitution through innovation in favour of safer chemicals (ECHA 2018) consists of four action areas:

- capacity building;
- facilitating access to funding and technical support;
- facilitating the use of registration, classification and risk management data for sustainable substitution and

[3] https://www.umweltbundesamt.de/en/topics/chemicals/reach-what-is-it/chemicals-in-articles-eu-life-project-askreach

- development of networks related to the substitution of chemicals of concern.

The above recommendations derived from the case studies in the project "Advancing REACH" can directly be aligned to these action areas. This would support the implementation of these recommendations – on a European and on a national level. Successful promotion of substitution requires a public strategy and a strong cooperation with industry, downstream users, visionary companies, innovators and investors. The Belgian roadmap for substitution of SVHC, published in 2019 (rdc environment 2019), provides a very useful vision of what such a strategy might look like.

A national strategy will require years of discussion with all relevant stakeholders. Hard work and commitment in this regard is genuinely worthwhile. The same applies to a voluntary agreement with industry to notify national production volumes for priority substances of concern on an annual basis, similar to the SPIN database in Scandinavia.

In the meantime, many of the recommendations described above can be implemented in on-going processes in the short time. Examples are the inclusion of a technology readiness level in the next analysis of alternatives, an enhanced grouping of substances in restriction proposals, the provision of additional examples for the application of the concept of non-essential uses, or the efforts undertaken to raise consumer awareness, e.g. by the project AskREACH. All these activities are important steps towards an enhanced substitution of substances of concern – by better and safer alternatives.

Looking beyond individual chemicals and their uses, an assessment of benefits and risks should become an early key step in the design of new technologies and materials. This could really reduce the need to look for better and safer alternatives from the beginning.

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 Verbindung von REACH zur Nachhaltigen Chemie, die Umsetzung des Vorsorgeprinzips, die Förderung der Substitution und die Abschätzung des Nutzens der REACH-Verordnung werden untersucht sowie das Verfahren der sozio-ökonomischen Analyse, Optionen zur Regulierung von Stoffen in Erzeugnissen und die Finanzierung der Aufgaben der Chemikalienagentur ECHA.

Wie kann REACH die Substitution von problematischen Stoffen stärker unterstützen?

1.1 Einleitung: Substitution in Gesetzgebung und Praxis

Ein zentrales Ziel von REACH ist es, ein hohes Schutzniveau für die menschliche Gesundheit und die Umwelt sicher zu stellen. Um dieses Ziel zu erreichen, stehen in REACH im Wesentlichen zwei Mittel zur Verfügung (ECHA 2018):

- Bessere Kenntnisse über die Eigenschaften und die Anwendungen von Chemikalien. Beides trägt bei zu einer sichereren Verwendung von Chemikalien und zur Verringerung von Expositionen und Emissionen.
- Substitution: Die Verwendung weniger gefährlicher Alternativen für problematische Stoffe.

Für die Gesundheit und Sicherheit am Arbeitsplatz ist Substitution die wichtigste Schutzmaßnahme zur Verringerung von Expositionen, Emissionen und schädlichen Auswirkungen durch Chemikalien. In der Reihenfolge der Maßnahmen ist sie die erste Möglichkeit, die geprüft und nach Möglichkeit umgesetzt werden soll, noch vor technischen Maßnahmen und vor dem Einsatz organisatorischer und persönlicher Schutzausrüstungen (STOP-Prinzip). Substitution ist auch eine wichtige Maßnahme im Umwelt- und Verbraucherschutz.

Das Prinzip der Substitution, sein Verständnis und seine Umsetzung werden seit Jahrzehnten diskutiert und überarbeitet. Die Substitutionsstrategie der ECHA formuliert das gängige Verständnis dieses Begriffs folgendermaßen:

- Der Ersatz oder die Verringerung von gefährlichen Stoffen in Produkten oder Prozessen durch weniger gefährliche oder ungefährliche Stoffe oder durch das Erreichen einer gleichwertigen Funktionalität durch technische oder organisatorische Maßnahmen (ECHA 2018, Definition zitiert nach Lohse et al. 2003)

In letzter Zeit gab es eine Reihe von nationalen, europäischen und internationalen Aktivitäten zur Förderung der Substitution, z.B. die *Substitution and Alternatives Assessment Toolbox* der OECD (http://www.oecdsaatoolbox.org/), die Gründung des Internationalen Zentrums zur Zusammenarbeit für Nahhaltige Chemie (ISC3), das schwedische Zentrum für Substitution und die Weiterführung von NGO-Aktivitäten wie dem *ChemSEC Marketplace* (Marktplatz für Substitute zu gefährlichen Chemikalien).

In REACH ist das Zulassungsverfahren das Hauptelement, in dem die Substitution von Stoffen explizit behandelt wird: besonders besorgniserregende Stoffe werden schrittweise durch geeignete Alternativstoffe oder -technologien ersetzt, sofern diese wirtschaftlich und technisch tragfähig sind“. Aber auch mehrere andere Elemente von REACH fördern Substitution in unterschiedlicher Weise. So entsteht z.B. durch die Beschränkung bestimmter problematischer Verwendungen eines Stoffes (Titel VIII) die Notwendigkeit, neue Wege zu suchen, um die gewünschten Funktionalitäten ohne den vorher genutzten Stoff zu erreichen.

Auch andere Chemikaliengesetze unterstützen Substitutionen. Gemäß der Substitutionsstrategie der ECHA bieten REACH, die CLP- Verordnung und die Biozid-Verordnung zusammen eine viel umfassendere Perspektive von Substitution, als es der eingeschränkte Blickwinkel auf SVHCs (im Rahmen der Zulassung von REACH) erlauben würde. „Sie sollen Druck auf die Industrie ausüben und Anreize dafür schaffen, dass sie sich bemüht, gefährliche Stoffe durch weniger gefährliche zu ersetzen" (ECHA 2018).

Seit Inkrafttreten von REACH haben Zulassungen und Beschränkungen zu einer verstärkten Substitution von SVHC und anderen problematischen Stoffen geführt. Die gefundenen Verringerungen im Einsatz dieser Stoffe sind das Ergebnis des Zusammenwirkens verschiedener Gesetzgebungen. Allerdings ist es schwierig, Substitution quantitativ zu bewerten. Es fehlen genaue Daten zu den Produktions-, Import- und Exportmengen von problematischen Stoffen und von ihren potenziellen Ersatzstoffen.

Trotz der hohen Priorität der Substitution in der Hierarchie der Schutzmaßnahmen stellt der Ersatz von problematischen Stoffen durch bessere und sicherere Substitutionen immer noch eine große Herausforderung für Unternehmen dar. In Fällen, in denen bereits Ersatzstoffe verfügbar waren, wurden häufig Chemikalien mit einer ähnlichen Struktur und ähnlichen physikalisch-chemischen Eigenschaften gewählt. Diese Art des Ersatzes wird auch als 1:1 Substitution bezeichnet (im englischen Sprachgebrauch als „drop in chemical replacement“).

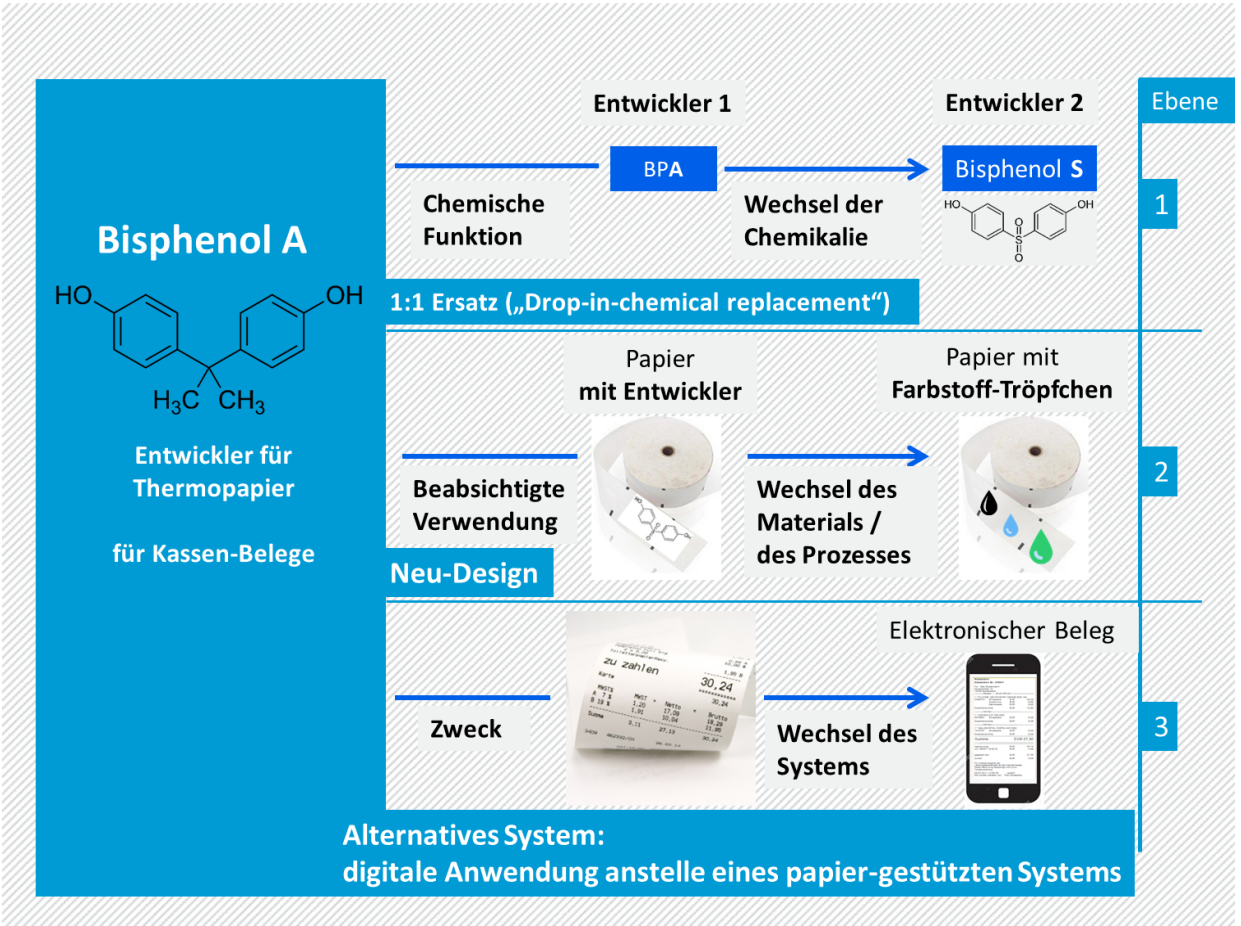
Beispiele sind der Ersatz von Bisphenol A durch Bisphenol S und der Ersatz von langkettigen Chlorparaffinen durch mittelkettige Chlorparaffine. Solche Ersatzstoffe können eingesetzt werden, ohne dass größere Veränderungen in den Produktionsprozessen erforderlich sind. Allerdings sind diese Chemikalien selbst auch oft problematisch aufgrund schädigender Eigenschaften. Substitutionen mit größeren Anpassungen bei Prozessen oder Technologien sind bisher selten.

Die Funktion einer Chemikalie ist von zentraler Bedeutung für die Ermittlung und Diskussion möglicher Alternativen. Ein Substitutionsprozess, der funktionelle Aspekte berücksichtigt, wird als „funktionelle Substitution“ definiert. Bei diesem Ansatz wird unterschieden zwischen drei Ebenen: der technischen Funktion der Chemikalie (z.B. als Entwicklersubstanz oder als optischer Aufheller), der Funktion des mit Hilfe der Chemikalie hergestellten Materials (z.B. Thermopapier für Kassenbons) und der zu erbringenden Endleistung, z.B. der Lieferung einer Quittung zur Dokumentation des Warenkaufs.

Die folgende Abbildung zeigt ein Beispiel für funktionelle Substitutionen und die drei oben genannten Ebenen. Es geht hierbei um Möglichkeiten des Ersatzes von Bisphenol A in

Thermopapier für Drucker. Auf Stufe 1 wird eine andere Chemikalie als Entwickler in Thermopapier verwendet. Auf Stufe 2 wird eine andere Art von Druckerpapier verwendet, das überhaupt keinen Entwickler mehr benötigt. Auf Stufe 3 werden Quittungen geliefert, jedoch elektronisch – daher besteht keine Notwendigkeit mehr, Thermopapier bereitzustellen.

Abbildung 1: Funktionelle Substitution: Möglichkeiten des Ersatzes von Bisphenol A, das als chemischer Entwickler in Thermopapier für Kassenbons eingesetzt wird



Quelle: Eigene Darstellung, auf der Grundlage eines Beispiels von Tickner et al. 2014 (Schweizer und Bunke 2019).

Auf jeder dieser drei Ebenen können Alternativen zur problematischen Substanz vorhanden sein. Die erste Ebene, die technische Funktion der Chemikalie selbst, führt häufig zum oben beschriebenen Ersatz des problematischen Stoffes durch einen strukturell ähnlichen Stoff („1:1-Substitution“). Auf der zweiten und dritten Ebene stehen weitergehende Möglichkeiten für Substitutionen zur Verfügung, u.a. Änderungen an Materialien, Prozessen und Systemen.

Auf allen drei Ebenen können Chemikalien eine Rolle spielen. Es bedarf einer soliden Bewertung, um auszuschließen, dass diese Chemikalien ein Risiko darstellen und um zu beurteilen, ob die Alternativen wirklich besser und sicherer sind. Hierfür sind Stoffdaten erforderlich, die unter REACH erstellt werden. Die Ebenen 2 und 3 erfordern zusätzlich ein vertieftes Verständnis der Funktion eines Produkts und der unterschiedlichen technischen Möglichkeiten, diese Funktion zu realisieren. Dies geht weit hinaus über die Aufgaben des klassischen Chemikalienmanagements mit dem Schwerpunkt auf der Gefährdungs- und Expositionsabschätzung von Stoffen. Deshalb ist für die Bewertung von Möglichkeiten der funktionellen Substitution gerade auf den Ebenen 2 und 3 die Zusammenarbeit und der Austausch zwischen

Chemikalienaufsichtsbehörden, technischen Experten und Produktdesignern unabdingbar, um wirklich bessere und sicherere Alternativen zu finden.

Für eine Reihe von problematischen Stoffen und Anwendungen gibt es bereits Beispiele für einen erfolgreichen Ersatz. Sie sind veröffentlicht und verfügbar, Es kann aber für Unternehmen schwierig sein, die in den Beispielen gezeigten erforderlichen Anpassungen umzusetzen, wenn es geringfügige oder größere Unterschiede in den Prozessbedingungen gibt.

1.2 Ziel der Studie

Ziel dieser Studie ist die Beantwortung der Frage, wie REACH die Substitution stärker als bisher unterstützen könnte. Die Analyse befasst sich mit zwei Schlüsselfragen:

- Wie unterstützt REACH derzeit konkret die Substitution von problematischen Stoffen?
- Wie könnten Änderungen an REACH bzw. seiner Umsetzung dazu beitragen, dass REACH die Substitution stärker unterstützt als bisher?

1.3 Erfahrungen aus Praxisbeispielen

Für diesen Bericht wurden zahlreiche Praxisbeispiele zur Substitution ausgewertet. Sie stammen aus den folgenden Bereichen:

- Beschränkung im Rahmen von REACH (siehe Abschnitt 3.2 und Anhang Abschnitt 4.1);
- Zulassung im Rahmen von REACH (siehe Abschnitt 3.3 und Anhang Abschnitt 4.2);
- Das Projekt *LIFE Fit for REACH* (siehe Abschnitt 3.4 und Anhang Abschnitt 4.3) und
- Produktbezogene Rechtsvorschriften (RoHS-Richtlinie, Detergenzien-Verordnung, Ökodesign-Richtlinie und EU-Umweltzeichenverordnung) (siehe Abschnitt 3.5 und Anhang Abschnitt 4.4).

Mit diesen Auswertungen waren folgende Zieleverbunden:

- ein besseres Verständnis des Einflusses von REACH auf reale Substitutionsfälle zu erlangen;
- Herausforderungen bei der Identifizierung und Bewertung potenzieller Alternativen zu ermitteln und
- Möglichkeiten im Rahmen von REACH zu identifizieren, die eine verstärkte Unterstützung der Substitution ermöglichen.

Für jeden der vier Bereiche haben wir die interessantesten Ergebnisse aus der Analyse im Kapitel 3 dieses Berichtes zusammengefasst. Eine ausführliche Beschreibung aller Beispiele findet sich im Anhang in den Abschnitten 4.1 - 4.4.

Aus jedem Beispiel konnten Erfahrungen abgeleitet werden. Sie sind die Grundlage für die Empfehlungen, wie REACH die Substitution weiter unterstützen kann. Für die Empfehlungen wurden auch Erkenntnisse aus zwei anderen Arbeitspaketen des Projektes „*Advancing REACH*“ berücksichtigt. Sie hatten eine genauere Analyse der Beschränkung und der Zulassung unter REACH zum Ziel (Arbeitspakete 5.1 und 5.4 des Projekts).

Wie kann REACH die Substitution problematischer Stoffe stärker unterstützen als bisher? Als Antwort auf diese Frage werden im folgenden Abschnitt unsere Empfehlungen beschrieben. Sie basieren auf den Ergebnissen der Beispielanalyse und einer Auswertung zu den derzeitigen Auswirkungen von REACH auf die Substitution (die Ergebnisse dieser zusätzlichen Literaturrecherche finden Sie im Kapitel 2 und im Anhang 5 dieses Berichtes).

Die Analyse der Substitutionsbeispiele und des aktuellen Einflusses von REACH auf die Substitution hat viele Aspekte aufgezeigt, die Substitutionsprozesse in der Praxis beeinflussen. Es wurden verschiedene Hindernisse deutlich, aber auch unterschiedliche Substitutions-Auslöser und vielfältige Ansätze zur Förderung der Substitution.

1.4 Spezifische and allgemeine Empfehlungen

Die folgenden Empfehlungen (Kapitel 1.5 und 1.6) zeigen Möglichkeiten auf, wie REACH Substitutionen stärker vorantreiben und unterstützen könnte, als es derzeit noch der Fall ist. Viele dieser Empfehlungen beziehen sich unmittelbar auf konkrete Aktivitäten unter REACH. Zum Beispiel sollten zukünftige Bewertungen von Alternativen (AfA) für jede überprüfte Alternative eine quantitative Angabe ihres „*Technical Readiness Level*" („Technologiereifegrads") enthalten. Empfehlungen mit einem solch engen Bezug zu REACH sind gruppiert in Abbildung 1 zusammengefasst und in Abschnitt 0 ausführlicher beschrieben.

Eine verstärkte zukünftige Förderung der Substitution erfordert jedoch darüberhinausgehende Maßnahmen, die nicht in direktem Zusammenhang mit Elementen von REACH stehen. Ein zunehmendes Interesse der Öffentlichkeit an Produkten, die frei von besorgniserregenden Stoffen sind, ist ein Beispiel für eine Entwicklung in der Gesellschaft, die die Substitution unterstützt. Daher richtet sich die zweite Gruppe unserer Empfehlungen in einem weiteren Sinne an Politik und Gesellschaft. Abbildung 2 gibt einen Überblick über diese zweite Gruppe. Abschnitt 1.6 enthält weitere Ausführungen hierzu.

Im Rahmen der Analyse der Substitutionsbeispiele sowie auch der Analyse der gegenwärtigen Auswirkungen von REACH auf die Substitution wurden viele Aspekte aufgezeigt, die Substitutionsprozesse in der Praxis beeinflussen. Dabei wurden mehrere Substitutionshindernisse deutlich, gleichzeitig konnten aber auch unterschiedliche Substitutionsauslöser und vielfältige Ansätze zur Substitutionsförderung identifiziert werden.

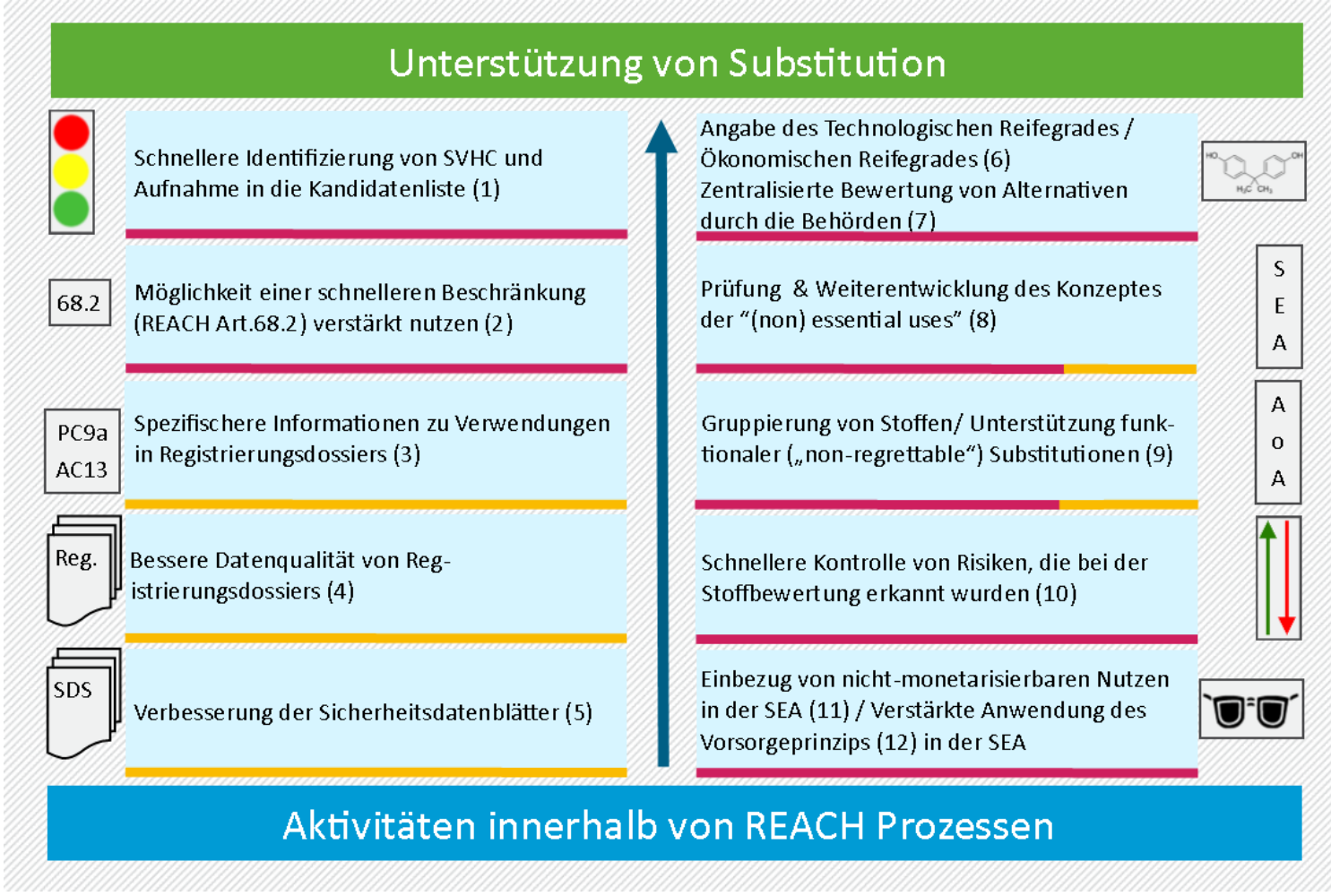
1.5 REACH: Spezifische Empfehlungen

Es konnten mehrere Optionen identifiziert werden, wie konkrete REACH-Aktivitäten im Hinblick auf eine verstärkte Förderung der Substitution modifiziert werden könnten. Die folgende Abbildung gibt einen Überblick darüber

Abbildung 2: Aktivitäten im Rahmen von REACH zur Förderung der Substitution

Farbige Linien: Angabe der Hauptakteure (**Behörden**, **Industrieunternehmen**). Nummern: Nummer der Empfehlung in Abschnitt 1.6.

SEA: Socioeconomic Analysis („Sozio-ökonomische Analyse); AoA: Assessment of alternatives („Bewertung von Alternativen")



Quelle: Öko-Institut e.V.

Diese Empfehlungen richten sich an politische Entscheidungsträger/Behörden. Die meisten von ihnen sollten ohne Änderungen im Gesetzestext der REACH-Gesetzgebung durchführbar sein, würden aber wahrscheinlich die Zustimmung der EU erfordern. Der Schwerpunkt würde auf der Änderung von Verfahren und Prioritäten sowie der Integrierung vorhandener Konzepte liegen. Die Aufgaben zur Verbesserung der Datenqualität der Registrierungsdossiers und der Sicherheitsdatenblätter liegen in der Verantwortung der Firmen, die Chemikalien und Gemische produzieren und importieren.

1.5.1 Vermehrte Aufnahme von Stoffen auf die Kandidaten-Liste und Nutzung von Art. 68

1. Es sollte darauf hingearbeitet werden, **SVHCs schneller und effizienter zu identifizieren und in die Kandidatenliste aufzunehmen.** Dies bedeutet: Beschleunigung der hiermit verbundenen Prozesse. Dies erfordert mehr Ressourcen, manchmal auch stringentere Diskussionen und Verpflichtungszusagen der nationalen Behörden und der ECHA/Kommission. Mit dem Ziel, mehr Zeit für die Entwicklung neuer Vorschläge für Anhang XV zur Identifizierung von SVHCs sowie für CLH-Vorschläge im Rahmen der CLP-Verordnung aufzubringen. Wichtige Schritte sind hier verbesserte Vorlagen für Anhang XV Dossiers, eine bessere Datenqualität in den Registrierungsdossiers (einschließlich der PBT-Bewertung), ein effizienterer Diskussionsprozess in den Ausschüssen der Mitgliedsstaaten und eine effizientere Bearbeitung der Stellungnahmen aus öffentlichen Konsultationen. Dies ist vor allem dann erforderlich, wenn die Stellungnahmen sehr umfassend und repetitiv sind.
2. **Verstärkte Nutzung der "Fast-Track"-Option für Beschränkungen nach Artikel 68 Absatz 2**. Diese Bestimmung wurde bisher nicht sehr oft in Anspruch genommen und sollte zukünftig häufiger genutzt werden.

1.5.2 Mehr und bessere Daten aus Registrierungsdossiers und Sicherheitsdatenblättern

3. Bereits in den Registrierungsdossiers sollten von den Unternehmen die **Verwendungskategorien genauer definiert werden**. Die technische Funktion des Stoffes sollte angegeben und in der öffentlichen Stoffdatenbank der ECHA dokumentiert werden. Dies erleichtert die Identifizierung von Ersatzstoffen. Es ist von besonderer Bedeutung für Beschränkungen, für Zulassungsanträge und Erteilungen von Zulassungen bei Stoffen, die nicht für eine breite Palette von Verwendungen, sondern für sehr spezifische Verwendungszwecke bestimmt sind. Ein besserer Überblick ist notwendig über auf dem Markt vorhandene Stoffe und ihre Verwendungen. Dies erfordert – zusätzlich zu den Ergebnissen der öffentlichen Konsultationen – weitergehende Forschungsanstrengungen der zuständigen Behörden der jeweiligen Mitgliedstaaten, der ECHA und technischer Experten.
4. Verbesserung der Qualität der Daten über Eigenschaften und Verwendungen von Chemikalien in den Registrierungsdossiers und in der öffentlichen Stoffdatenbank der ECHA. In mehreren Fällen waren diese Daten für die Einstufung der Stoffe unzureichend oder fehlten ganz. Dies führt zu Unsicherheiten bei der Bewertung und der Auswahl von Alternativen. Dadurch können Substitutionsentscheidungen getroffen werden, die keine Verbesserung bedeuten (regrettable substitutions).
5. **Verbesserung der Qualität der Sicherheitsdatenblätter**. Sicherheitsdatenblätter sind nach wie vor eine zentrale Informationsquelle für das Risikomanagement von Chemikalien innerhalb der Lieferkette. Ihre Qualität ist sowohl für die Ermittlung des Substitutions-bedarfs (gefährliche Eigenschaften, Verwendungen, von denen abgeraten wird, Informa-tionen zum Arbeitsschutz, erforderliche Risikomanagementmaßnahmen usw.) als auch für

die Bewertung potenzielle Alternativen von sehr hoher Bedeutung. In vielen Fällen muss die Qualität von Sicherheitsdatenblättern weiter verbessert werden.

1.5.3 Verbesserung der Bewertung von Alternativen

6. Verwendung des Konzepts des ***„Technical Readiness Level"*** („Technologiereifegrads") für die Bewertung von Alternativen. Bei vielen Beschränkungen und Zulassungen war die Bewertung der technischen und wirtschaftlichen Durchführbarkeit von Alternativen sehr schwierig. Es wäre äußerst vorteilhaft, wenn Beschreibungen von Alternativen immer einen Hinweis auf den nutzungsspezifischen **"Technologiereifegrad"** und den **"wirtschaftlichen Reifegrad"** enthalten würden. Eine solche Beschreibung könnte eine mittel- und langfristige Projektion und eine Erläuterung der Faktoren enthalten, die die Entwicklung dieser Reifegrade bestimmen.
7. **Vertiefte Bewertung der Alternativen durch die Behörden - auf einer übergeordneten Ebene, z.B. im Rahmen der RMOA** (Analyse der Möglichkeiten des regulatorischen Managements). Diese Bewertungen werden derzeit von den Unternehmen selbst vorgenommen, die einen Zulassungsantrag stellen. Daher zielen sie oft darauf hin, nachzuweisen, dass keine geeigneten Alternativen zur Verfügung stehen, die technisch und wirtschaftlich tragfähig sind. Für eine Bewertung seitens der Behörden müssten Unternehmen Informationen bereitstellen. Außerdem sind für diesen Weg zusätzliche Forschungsanstrengungen durch die Behörden oder durch unabhängige technische Experten erforderlich. Im Rahmen des Stockholmer Übereinkommenswerden Alternativen für persistente organische Schadstoffe systematisch bewertet. Diese Ergebnisse werden veröffentlicht und sind weltweit verfügbar.
8. Prüfung und Weiterentwicklung des Konzeptes der „wesentlichen" und „nicht-wesentlichen" Verwendungen („essential and non-essential uses") in REACH. Das Ziel ist hierbei, die Substitution der „wesentlichen Verwendungen" zu fördern. Dieses Konzept zur Unterscheidung zwischen wesentlichen und nicht wesentlichen Verwendungen wurde von den Niederlanden im Zusammenhang mit der PFAS-Beschränkung im Dezember 2019 vorgeschlagen (siehe auch Cousins et al. 2019).

1.5.4 Gruppierung, funktionelle Substitutionen und fundierte („non-regrettable") Substitutionen

9. **Gruppierungsansätze sollten verstärkt für die Bewertung und Regulierung von Stoffen verwendet werden** (siehe auch Empfehlung in der belgischen SVHC-Roadmap-Studie, rdc Environment 2019 und Gruppierungsansatz der ECHA zur Priorisierung und Depriorisierung von Stoffen aus dem „Universum der Chemikalien"[4]). Die Regulierung sollte sich nicht nur auf einzelne Stoffe beziehen, sondern nach Möglichkeit auf Gruppen von Stoffen, die eine gemeinsame Struktur aufweisen und in vergleichbarem Maße Anlass zu Besorgnis geben. Beispiele sind die Gruppierung von Bisphenolen und von vier Phthalaten in den jüngsten Beschränkungen.
   Sowohl in der RoHS-Richtlinie als auch in der Ökodesign-Richtlinie gibt es weitere Beispiele für einen effektiven und weitreichenden Gruppierungsansatz (alle PBDE, die gesamte Gruppe der bromierten Flammschutzmittel).
   Der Ansatz der Stoffgruppierung trägt dazu bei, Substitutionsentscheidungen zu vermeiden, die nicht sicherer sind und daher keine Verbesserung darstellen (sie werden im Englischen als „regrettable substitutions" bezeichnet). Dies ist in den meisten Fällen der direkte Ersatz von Stoffen durch sog. 1:1-Alternativen: Stoffe, die in ihrer Struktur ähnlich aufgebaut sind,

[4] https://echa.europa.eu/de/-/mapping-the-chemical-universe-list-of-substances-by-regulatory-action-published

aber auch in vergleichbarem Maße problematische Eigenschaften aufweisen wie die zuvor verwendeten Stoffe. Diese Art von Substitution wird auch als „Drop-in-Replacement“ bezeichnet, da mit ihr in der Regel keine Änderungen der Prozessabläufe verbunden sind. Die Gruppierung von Stoffen erleichtert eine umfassendere Suche nach Alternativen. Diese Suche orientiert sich an der erforderlichen Funktion. Möglichkeiten für so genannte „funktionelle Substitutionen“ gehen über die technische Funktion eines Stoffes hinaus. Sie berücksichtigen auch die Funktion der Materialien, die unter Einsatz der jeweiligen Chemikalie hergestellt werden und die endgültige Leistung, die erbracht werden soll (weitere Einzelheiten zu funktionellen Substitutionen: siehe Abschnitt 1.1, am Ende der Einleitung, und die Abbildung dort).

1.5.5 Stoffbewertung und Folgeaktivitäten

10. **Schnellere Kontrolle der Risiken, die bei der Stoffbewertung festgestellt wurden**. Obwohl in vielen Stoffbewertungen das Vorhandensein von Risiken festgestellt wurde, sind häufig nach Abschließen der RMOA („Analyse der Möglichkeiten zum regulatorischen Management“) keine konkreten verbindlichen regulatorischen Folgemaßnahmen zur Risikokontrolle eingeleitet worden (siehe EEB 2019). Solche Maßnahmen sollten auf den Ergebnissen des RMOA basieren. (Hinweis: Dieses Thema wurde im Arbeitspaket 5.4 des Projekts „*Advancing REACH*“ („Weiterentwicklung REACH“) tiefgehender analysiert. Weitere Einzelheiten zu diesem Thema finden Sie im Abschlussbericht zum Arbeitspaket 5.4).

1.5.6 Sozioökonomische Analyse (SEA) und das Vorsorgeprinzip

11. Erweiterung der Methodik der SEA. Ein reiner Kosten-Nutzen-Fokus ist zu eng gefasst. Er sollte erweitert werden, um nicht monetarisierbare gesundheitliche Vorteile für die Gesellschaft und für die Umwelt einzubeziehen (siehe EEB-Beschränkungsbericht, EEB 2018) und Diskontierungssätze, die den potenziellen Schaden für künftige Generationen berücksichtigen (siehe auch Arnold 2019).
12. **Konsequentere Anwendung des Vorsorgeprinzips.** Der Anwendung dieses Prinzips als Argument in der Gesamtbeurteilung sollte mehr Gewicht beigemessen werden. Der einzige Fall, in dem bislang das Vorsorgeprinzip in der EU angeführt wurde, war eine Beschränkung in Form des Verbots von BPA in Babyflaschen im Jahr 2011 (wie in der jüngsten REACH-Überprüfung, EU 2018, dargelegt wurde) Weitere Beispiele sind die Diskussionen um Beschränkungen für Mikroplastik und PFAS. (Hinweis: Die Anwendung des Vorsorgeprinzips im Rahmen von REACH wurde im Arbeitspaket 9 des Projekts „*Advancing REACH*" („Weiterentwicklung REACH“) genauer analysiert. Nähere Einzelheiten finden Sie im Abschlussbericht zum Arbeitspaket 9).

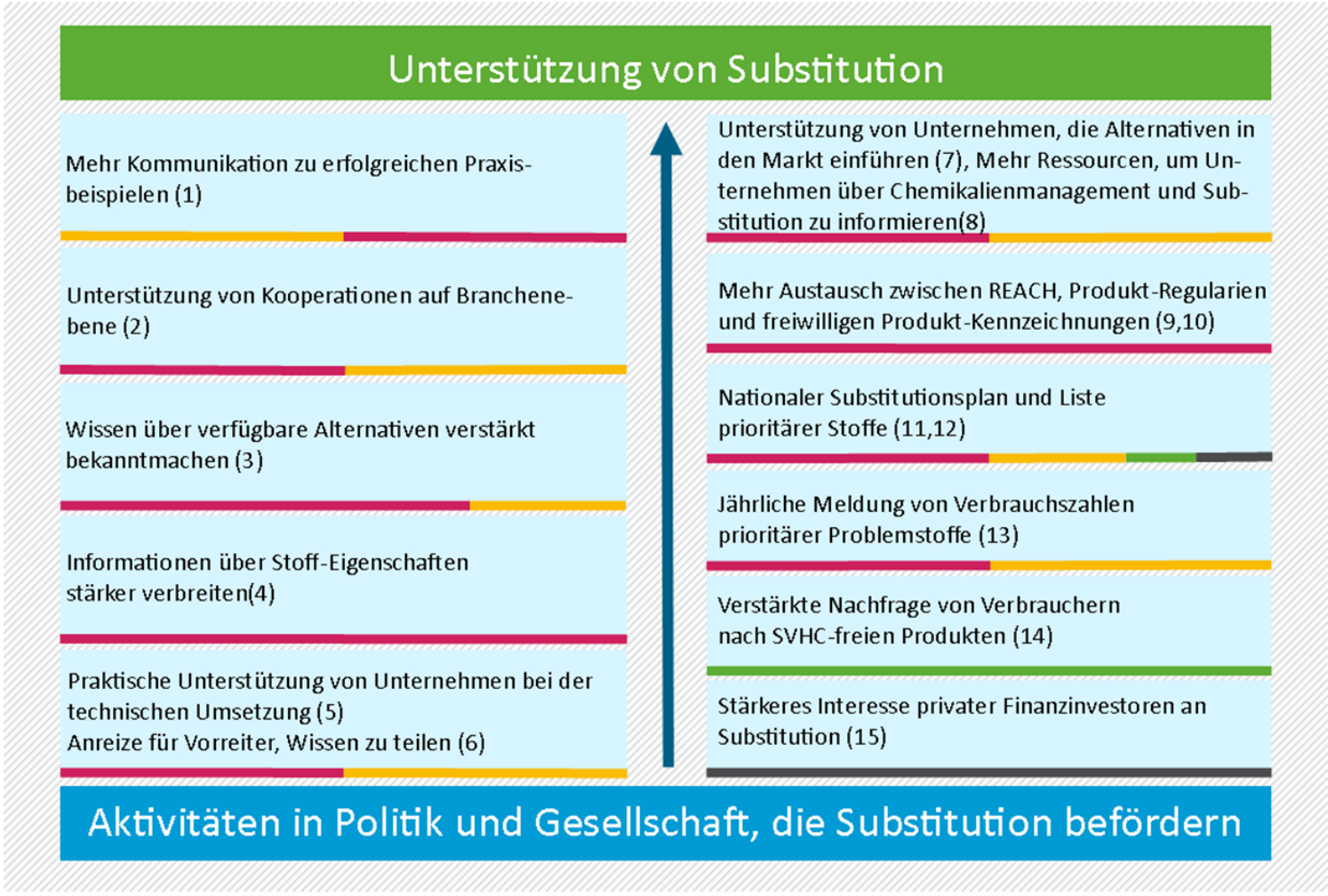
1.6 Empfehlungen für ein günstiges Umfeld für die Substitution

Bei der zweiten Gruppe von Empfehlungen geht es um Handlungsmöglichkeiten in der Politik, die über spezifische Elemente von REACH hinausgehen. Hier ist ein breiteres Spektrum von gesellschaftlichen Akteuren gefordert. Diese Aktivitäten sind wichtig, um ein Umfeld zu schaffen, das Substitution ermöglicht und fördert.

Einen Überblick über diese Empfehlungen gibt die folgende Abbildung.

Abbildung 3: Aktivitäten in Politik und Gesellschaft, die die Substitution fördern

Farbige Linien: Angabe der Hauptakteure (**Behörden**, **Industrieunternehmen**, **Verbaucher*innen**, **private Finanzinvestoren**). Nummern: Nummer der Empfehlung in Abschnitt 1.7.



Quelle: Öko-Institut e.V.

1.6.1 Unterstützung von Unternehmen und Branchen

Am Projekt *LIFE Fit for REACH* waren Unternehmen aus den baltischen Staaten beteiligt. Die hier gewonnenen Erfahrungen zeigen, wie wichtig Kommunikation in der Lieferkette und eine hohe Qualität der verfügbaren Daten zur Bewertung von Alternativen sind.

In vielen Fällen, in denen eine Substitution durchgeführt werden sollte, bestand die wesentliche Herausforderung in einem Mangel an geeigneten Alternativen, bezogen auf die technische Leistungsfähigkeit der Substitute und deren Verfügbarkeit zu akzeptablen Kosten.

In dieser Situation könnte ein höherer Substitutionsdruck größere Märkte für potenzielle Anbieter von Alternativen schaffen. In der Folge sollten die Kosten für die Alternativen sinken. Dies würde Substitutionsprozesse weiter vorantreiben.

Um dem Fehlen von Alternativen entgegen zu wirken, erscheinen nach den Erfahrungen aus den Beispielen drei Wege sinnvoll:

1. Eine stärkere Regulierung mit mehr Beschränkungen und Zulassungsentscheidungen (siehe Empfehlung 1 und 2 weiter oben (Kapitel 1.5.1.)).
2. Die gezielte Förderung der Entwicklung und des Inverkehrbringens geeigneter Alternativen und
3. die gezielte Unterstützung für die Durchdringung des Marktes mit diesen Alternativen.

Empfehlungen für die stärkere Regulierung haben wir bereits im Kapitel 1.5.1 gegeben (s.o.). Die folgenden Empfehlungen befassen sich mit der zweiten und dritten Herausforderung.

1. Die **stärkere Kommunikation zu Beispielen bester Praxis** scheint eine der wichtigsten Unterstützungsmaßnahmen zu sein. Dadurch verschiebt sich der Schwerpunkt der Diskussionen und Aktivitäten auf das Lernen von Erfolgsbeispielen. Wichtig ist auch die Erarbeitung weiterer Beispiele und Analysen, die zeigen, dass sich für ein Unternehmen eine Substitution gelohnt hat („business cases"), Dies wird andere Unternehmen anregen, ihrerseits problematische Stoffe zu ersetzen.
2. **Förderung der Zusammenarbeit innerhalb von Branchen**, um Unternehmen bei der Suche nach Alternativen zu unterstützen (siehe z.B. die Initiative „*vecco*" zur Verchromung).[5]. Ziel der Zusammenarbeit sollte es sein, nicht nur die Chemikalie zu ersetzen, sondern den Erhalt der notwendigen Funktion sicher zu stellen. (für weitere Einzelheiten zur funktionellen Substitution siehe Einleitung (Abschnitt 1.1) und die Abbildung dort
3. **Mehr Informationen über verfügbare Ersatzstoffe** für problematische Stoffe in den Lieferketten und Unterstützung der Verwendung dieser Ersatzstoffe. Es sollte auch mehr informiert werden über bewährte Methoden, um Stoffe aufgrund ihrer Funktion zu gruppieren.
4. **Besserer Wissenstransfer zu Stoffeigenschaften**. Viele Aktivitäten von REACH bringen neue Informationen über die Eigenschaften potenzieller Alternativen gefährlicher Stoffe (z.B. Registrierung und Stoffbewertung). Diese Informationen werden jedoch nicht systematisch zusammengestellt und öffentlich zugänglich gemacht.
   Die Umsetzung der letzten beiden Empfehlungen wäre eine große Hilfe für viele Akteure, insbesondere in weniger entwickelten Ländern und Ländern mit im Übergang befindlichen Wirtschaftssystemen.
5. **Praktische und finanzielle Unterstützung für Unternehmen**, die Hilfe bei der technischen Umsetzung benötigen, um vorhandene erfolgreiche Fallbeispiele von Substitution an ihre individuellen Prozesse anzupassen. Dies sollte auch Informationen

[5] https://www.vecco.info

einschließen über Möglichkeiten, öffentliche Fördergelder für Substitutionsaktivitäten zu erhalten.

6. **Anreize für Unternehmen schaffen, die bei der Substitution federführend sind („Front Runner"), ihr Wissen über erfolgreiche Substitutionen weiterzugeben** (z.B. Gebühren für Lizenzen). Lösungen, die in Forschungsprojekten mit öffentlicher Finanzierung entwickelt wurden, sollten mit Creative Commons-Lizenzen verbreitet werden.
7. **Unterstützung von Unternehmen (mit Budgets und Wissen)**, die sicherere und bessere Alternativen entwickelt haben**, in der schwierigen Phase der Markteinführung der Alternativen**.
8. Inspektoren und auch Industrieverbände sollten **mehr Ressourcen für die Beratung von Unternehmen** einsetzen. Zu Fragen der Einhaltung von Rechtsvorschriften, des Risikomanagements von Chemikalien im Allgemeinen und für Fragen zur Schwerpunktsetzung bei Substitutionen.

Behörden sollten bei all diesen Aktivitäten mit Unternehmen betonen, wie wichtig eine **effiziente und sinnvolle Kommunikation in der Lieferkette** beim Risikomanagement von Chemikalien ist.

Außerdem sollte die Zusammenarbeit zwischen Wettbewerbern weiter verstärkt werden. Z.B., um Alternativen auf Branchenebene, aber auch entlang der Lieferkette zu identifizieren und die Substitution auch auf der technischen Ebene zu unterstützen. Direkte Kontakte zwischen Unternehmen sind ein wichtiger Motivationsfaktor. Sie sind von hoher Bedeutung für die Verringerung chemikalienbedingter Risiken.

1.6.2 Synergien nutzen: Austausch mit produktbezogenen Regelungen

Produktbezogene Rechtsvorschriften verwenden spezifische Ansätze zur Beschränkung gefährlicher Stoffe in Produkten. Sie unterscheiden sich teilweise von den Ansätzen, die unter REACH zum Einsatz kommen. Erfahrungen aus der Analyse dieser Vorschriften ermöglichten es uns, eine Reihe weiterer Empfehlungen abzuleiten. Auch hier ist das Ziel, Substitution zu stärken – sowohl unter REACH als auch im Zusammenspiel mit anderen, produktbezogenen Gesetzen.

Weiter oben (Empfehlung 9 im Kapitel 1.5.5) wurde bereits dargestellt, dass die Bewertung von Gruppen von Stoffen REACH genutzt werden, um ein breites Spektrum problematischer Stoffe in der Stoffbewertung und -regulierung abzudecken. Sowohl die RoHS-Richtlinie als auch die Ökodesign-Richtlinie erläutern, wie ein effektiver und weitreichender Gruppierungsansatz aussehen könnte (z.B. durch gemeinsame Regulierung aller polybromierten Diphenylether und der gesamten Gruppe der bromierten Flammschutzmittel).

Zusätzliche Empfehlungen;

9. **Förderung des Austausches zwischen REACH und produktgruppenspezifischen Rechtsvorschriften (z.B. RoHS für Elektro- und Elektronikgeräte).** Dies unterstützt eine stärkere Berücksichtigung der End-of-Life-Phase in der Stoffsicherheitsbeurteilung und in der Stoffbewertung unter REACH.
   Durch REACH wird eine Vielzahl von Informationen gewonnen über kritische Stoffeigenschaften und schädliche Auswirkungen, über Expositionen und über den Gehalt von Stoffen in Erzeugnissen. Die wichtigsten Erkenntnisse über kritische Eigenschaften (z.B. Persistenz, Bioakkumulation, Mobilität, schädigende hormonelle Wirkung) sollten den Experten für produktbezogene Vorschriften vorgelegt werden. Die gesetzlichen Bestimmungen (z.B. die Detergenzien-Richtlinie) ermöglichen es den Behörden dann, bestimmte bedenkliche Eigenschaften (z.B. das Fehlen einer biologischen Abbaubarkeit) zu regeln, unabhängig von

den in REACH festgelegten Eigenschaftskombinationen (REACH Anhang XIII: Persistenz in Zusammenhang mit Bioakkumulation (vPvB-Stoffe) oder in Zusammenhang mit Bioakkumulation und Toxizität (PBT-Stoffe).

10. **Förderung des Austauschs zwischen REACH und freiwilligen Produktkennzeichnungen**. Diese würde den Ersatz von Stoffen erleichtern, die als giftig oder umweltgefährlich eingestuft sind, auch wenn sie die Kriterien für die Einstufung als besonders besorgniserregende Stoffe nicht erfüllen. Die Forderungen der Verbraucher*innen nach unschädlichen und giftfreien Produkten spielen für bestimmte Produktgruppen eine wichtige Rolle. Die Vergabekriterien für freiwillige Produktkennzeichnungen können so gestalten werden, dass sie die oben genannten Stoffe ausschließen.

1.6.3 Nationale Substitutionsstrategie und Liste prioritärer Stoffe

Zahlreiche weitere Aktivitäten würden die Substitution im Rahmen der Chemikaliengesetzgebung (nicht nur REACH) entscheidend fördern. Sie können auf nationaler Ebene oder auf EU-Ebene initiiert werden:

11. Entwicklung einer **nationalen Substitutionsstrategie**. Sie hat das Ziel, Möglichkeiten und Kriterien für die Substitution auf allgemeiner Ebene zu entwickeln, Prioritäten zu setzen und wichtige Substitutionsprozesse zu verfolgen (siehe Beispiel aus Belgien, rdc Environment 2019).
12. Entwicklung einer **nationalen Liste prioritärer besorgniserregender Stoffe** (und Gruppen). In den Niederlanden konzentriert sich die nationale Politik im Rahmen des Programms „*The Netherlands circular in 2050*“ insbesondere auf prioritäre, besonders besorgniserregende Stoffe, die so genannten ZZS-Stoffe. Diese decken ein breiteres Spektrum von Stoffeigenschaften ab als die SVHC unter REACH (RIVM 2017).

1.6.4 Monitoring der Produktion und des Verbrauchs von prioritären besorgniserregenden Stoffen

Die Analyse der gegenwärtigen Auswirkungen von REACH auf die Substitution hat gezeigt, dass es derzeit keine Datenbasis mit belastbaren empirischen Belegen gibt, auf deren Grundlage beurteilt werden kann, in welchem Umfang Substitutionen erfolgen (siehe Kapitel 3.6). Zumindest bei prioritären Stoffen, die Anlass zur Besorgnis geben, wäre es wichtig zu wissen, in welchem Umfang und in welchen Branchen Substitutionen stattfindet.

13. Für eine begrenzte Anzahl von identifizierten/definierten prioritären Stoffen, die Anlass zur Besorgnis geben, sollten **Informationen über Produktions-, Import- und Exportmengen** auf nationaler Ebene und in der gesamten EU verfügbar sein (einschließlich Daten über diese Stoffe in Erzeugnissen). Diese Zahlen sollten jährlich speziell für eng definierte Verwendungskategorien bereitgestellt werden. Um diese Informationen zu erhalten, empfehlen wir eine freiwillige Vereinbarung zwischen Industrieverbänden und Behörden.

1.6.5 Interesse der allgemeinen Öffentlichkeit und der Investoren

Die Interessen des Marktes (z.B. Forderungen von Produzenten nach SVHC-freien Rohstoffen und Forderungen von Handelsunternehmen nach SVHC-freien Produkten) und das Interesse der Finanzinvestoren sind wahrscheinlich die wichtigsten nicht-regulatorischen Triebkräfte für die Substitution. Dies führt zu zwei weiteren Empfehlungen:

14. Unterstützung von Maßnahmen **zur Sensibilisierung der Verbraucher*innen für die Problematik besorgniserregender Stoffe in Erzeugnissen.** Verbraucher*innen sollen

darüber hinaus darin bestärkt werden, Produkte zu fordern, die frei von diesen Stoffen sind (z.B. durch das Projekt AskREACH'[6]).

15. Unterstützung von Maßnahmen **zur Erhöhung des Interesses privater Finanzinvestoren an der Substitution von Stoffen**. Sie sollten bei ihren Investitionsentscheidungen berücksichtigen, ob Unternehmen für und mit besseren und sichereren Alternativen arbeiten oder nicht.
Ziel ist hierbei, in der Gesellschaft ein Bewusstsein dafür schaffen, welche Vorteile der Ersatz problematischer Stoffe bietet.

1.7 Ausblick

Die Förderung der Substitution problematischer Stoffe wird auch in den kommenden Jahren eine zentrale Herausforderung für das Chemikalienmanagement bleiben. Sie ist ein wichtiges Element innerhalb von REACH. Die hier durchgeführte Analyse ergab, dass dank REACH und anderer Chemikaliengesetze einige Fortschritte bei der Substitution erzielt wurden. Dennoch besteht die dringende Notwendigkeit zusätzlicher Anstrengungen –seitens der Behörden, der Industrie, der Verbraucher*innen und privater Investoren.

Die Strategie der ECHA zur Förderung der Substitution durch Innovation zugunsten sichererer Chemikalien (ECHA 2018) besteht aus vier Aktionsbereichen:

- Kapazitätsaufbau;
- Erleichterung des Zugangs zu Finanzmitteln und technischer Unterstützung;
- Erleichterung der Nutzung von Registrierungs-, Einstufungs- und Risikomanagementdaten für eine nachhaltige Substitution und
- Entwicklung von Netzwerken im Zusammenhang mit der Substitution von besorgniserregenden Chemikalien.

Unsere Empfehlungen im Projekt „REACH Weiterentwicklung" zur Förderung der Substitution wurden aus konkreten Fallbeispielen abgeleitet. Sie können den Aktionsbereichen der Strategie der ECHA zugeordnet werden. Diese Anbindung würde die Umsetzung der Empfehlungen sowohl auf europäischer als auch auf nationaler Ebene erleichtern.

Eine erfolgreiche Förderung der Substitution bedarf einer öffentlichen Strategie und einer starken Zusammenarbeit mit der Industrie, nachgeschalteten Anwendern, visionären Unternehmen, Innovatoren, Investoren und der Bevölkerung. Die belgische Roadmap für die Substitution von SVHC, die 2019 veröffentlicht wurde (rdc environment 2019), enthält ein sehr nützliches Szenario darüber, wie eine solche Strategie aussehen könnte.

Um eine nationale Strategie zu entwickeln, wird es nötig sein, über mehrere Jahre mit allen relevanten Interessengruppen zusammenzuarbeiten. Dieses Engagement lohnt sich. Das Gleiche gilt für eine freiwillige Vereinbarung mit der Industrie, die nationalen Produktionsmengen für prioritäre besorgniserregende Stoffe jährlich zu melden, ähnlich wie dies bei der SPIN-Datenbank in Skandinavien der Fall ist.

In der Zwischenzeit können kurzfristig viele der oben beschriebenen Empfehlungen in laufenden Prozessen umgesetzt werden. Beispiele hierfür sind die konkrete Bezifferung eines Technologiereifegrades und eines wirtschaftlichen Reifegrades in der nächsten Analyse von Alternativen, eine verstärkte Gruppierung von Stoffen in Beschränkungsvorschlägen, die

[6] https://www.umweltbundesamt.de/en/topics/chemicals/reach-what-is-it/chemicals-in-articles-eu-life-project-askreach

Erarbeitung weiterer Beispiele für die Anwendung des Konzepts der wesentlichen Verwendungen und Aktivitäten zur Sensibilisierung von Verbraucher*innen, z.B. durch das *AskREACH*-Projekt. All diese Arbeiten sind wichtige Schritte auf dem Weg zu einer verstärkten Substitution von problematischen Stoffen – durch bessere und sicherere Alternativen.

Über einzelne Chemikalien und deren Verwendung hinaus sollte beim Design von neuen Technologien und Materialien frühzeitig die Bewertung der Vorteile und Risiken ein zentraler Schritt sein. Dies würde die Notwendigkeit maßgeblich verringern, zu einem späteren Zeitpunkt nach besseren und sichereren Alternativen zu suchen.

1 Introduction: REACH and substitution

1.1 Introduction: Substitution in legislation and in practice

A central objective of REACH is to ensure a high level of protection of human health and the environment. There are two principal means in REACH to achieve this goal (ECHA 2018):

- Better knowledge on the properties and uses of chemicals, resulting in safe uses of chemicals and reduction of exposures and emissions;
- Substitution: the use of less dangerous alternatives to substances of very high concern.

Within the context of occupational health and safety, substitution is the most important protective measure to reduce exposures, emissions and adverse effects. It is the first option to be assessed, prior to technical measures, organizational and personal protective equipment. Also for the protection of consumers and the environment, substitution is an important measure.

The substitution principle as well as the understanding and implementation of this principle have been the subject of discussions and elaborations for decades. A common understanding of this term has been given in ECHA´s substitution strategy:

- The replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures (ECHA 2018, definition cited from Lohse et al. 2003)

Recently, there have been a number of national, European and international activities in support of substitution, e.g. the OECD Substitution and Alternatives Assessment Toolbox (http://www.oecdsaatoolbox.org/), the foundation of the ISC3, the Swedish Centre for Substitution and the continuation of activities from NGOs, e.g. ChemSEC Marketplace.

In REACH, the authorisation process is the primary element in which the substitution of substances is explicitly addressed: “Substances of very high concern are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable”. Likewise, however, several other elements of REACH promote substitution by various means. The restriction of specific, problematic uses of a substance (Title VIII), for example, creates the need to find new ways to deliver the desired functionality of the currently restricted use.

Substitution is supported by other chemicals legislations too. According to ECHA´s substitution strategy, REACH, CLP and the Biocidal Products Regulation together intend to provide a much broader perspective than on SVHCs alone.“ They are designed to place pressure on and to provide incentives for industry to try to replace hazardous substances with less hazardous ones” (ECHA 2018).

Since REACH entered into force, authorisations and restrictions have led to an enhanced substitution of SVHC and other substances of concern. These reductions result from a combined effect of various legislations. However, it is difficult to assess substitution quantitatively due to the lack of precise data on actual production volumes, import volumes and export volumes of substances of concern and potential substitutes.

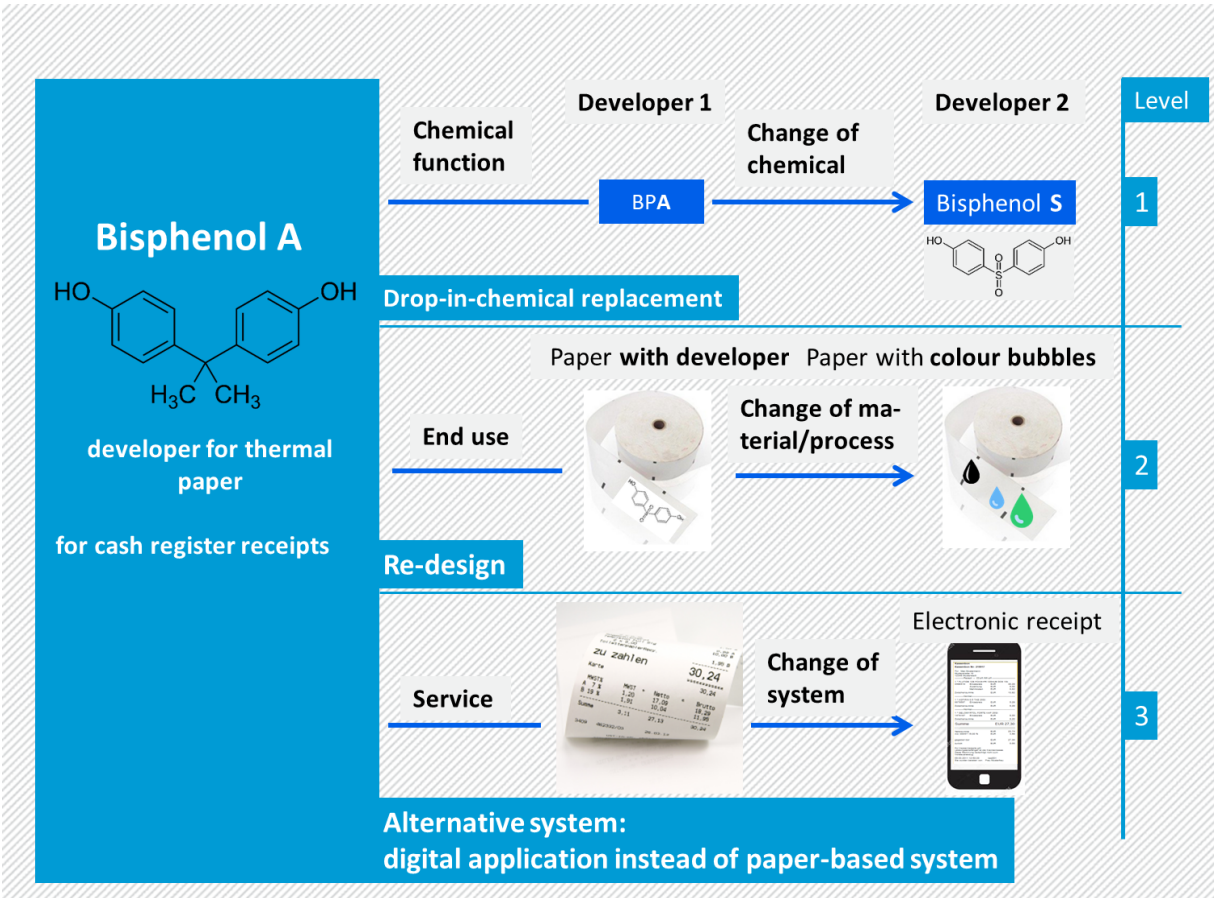
Despite the high priority of substitution in the hierarchy of protection measures, replacement of substances of concern by better and safer substitutions still represents a major challenge for

companies. In cases where substitutes were already available, frequently chemicals with a similar structure and similar physic-chemical properties have been selected (e.g. replacement of Bisphenol A by Bisphenol S, replacement of long chain chlorinated paraffins by middle chain chlorinated paraffins). They can be used without any major modifications in the production processes. However, these chemicals too are often problematic in terms of adverse effects. Substitutions with major modifications in the processes or technologies are rare.

For the identification and discussion of potential alternatives, the function of a chemical is of central importance. A substitution process which includes the consideration of functional aspects has been defined as "functional substitution". In this approach, a differentiation is made between the technical function of the chemical itself (e.g. as a developer or an optical brightener), the function of the material produced using the chemical (e.g. thermal paper for cash receipts) and the final service that should be delivered, e.g. delivering a receipt to document the purchase of goods.

The following picture gives an example of functional substitutions and the three levels involved. It shows options to substitute Bisphenol A. On level 1, another chemical is used as a developer in thermal paper. On level 2, another type of thermal paper is used which no longer needs a developer at all. On level 3, receipts are delivered, but electronically – therefore, a need to provide thermal paper no longer exists.

Figure 4: Functional substitution: Options to replace Bisphenol A, used as a developer in thermal paper to deliver cash register receipts.



Source: own illustration, based on an example from Tickner et al. 2014 (Schweizer und Bunke 2019).

On each of these three levels, alternatives to a given problematic substance can exist. The first level, the technical function of the chemical itself, often leads to drop-in-chemical replacements. The second and third level can offer additional options for substitutions including changes of materials, processes and systems.

On all three levels, chemicals can be involved. A robust assessment is needed as to whether they can pose a risk and whether the alternatives are really better and safer. Therefore, data on substances generated under REACH are required on these levels. In addition, level 2 and 3 require a more in-depth understanding of the function of a product and technical options to realise it. This goes far beyond the tasks of the classical chemicals' management with a focus on the hazard assessment and exposure assessment of substances. As a result, the assessment of options of functional substitution requires stronger cooperation and an enhanced exchange between chemical regulators, technical experts and product designers to find better and safer alternatives.

Even where case studies of successful substitutions are available, the process to transfer these modifications to the situation existing in other companies (with slight or significant differences in process conditions) can be difficult.

1.2 Aim of this study

The aim of this study is to answer the question as to how REACH could support further the principle of substitution **and its application** – beyond the present state. It provides answers to the following two key questions:

- How does REACH actually support substitution of problematic substances?
- How could changes in REACH or in its implementation enhance the promotion of substitution by REACH?

1.3 Structure of the report

The report is structured as follows:

- Chapter 2 describes which elements and requirements of REACH directly or indirectly support substitution. In addition, a definition of the substitution principle is given. Related key terms are described in Annex 8.
- Chapter 3 shows how REACH actually supports substitution of problematic substances. Details of the analysis undertaken for this chapter are given in Annex 9.
- Chapter 4 describes examples for substitution of chemicals and lessons learnt regarding actual and potential impacts of REACH.
- In Chapter 5, recommendations are given as to how REACH could further support the substitution principle and its implementation in practice. In addition, chapter 5 gives an outlook (section 5.5) which goes beyond REACH.

2 Activities in REACH related to the substitution of chemicals of concern

2.1 REACH and the substitution of chemicals of concern

Substitution of substances of concern by suitable alternative substances or processes requires a robust database on substances, processes and uses as well as communication processes regarding these substitutes. Improvement of the database and facilitation of the communication processes are REACH's principal means of supporting substitution. Regarding substitution, REACH gives priority to substances of very high concern (SVHC). In addition, the requirements set for registration, for downstream users and for communication, as well as the restriction process support substitution of hazardous substances even if they are not classified as being SVHCs.

In Working Package 6 of the Project "Advancing REACH", it has been systematically analysed in which way REACH supports main elements of Sustainable Chemistry. A matrix has been developed that shows the relations between individual main elements of sustainable chemistry and main elements of REACH ("Matrix analysis"[7]). Substitution is one of these elements. A large number of activities under REACH – from chemical safety assessments until restrictions of specific uses – support substitution. In the following descriptions of these activities, numbers in brackets refer to the above-mentioned systematic analysis of relation and give the number of the relation.

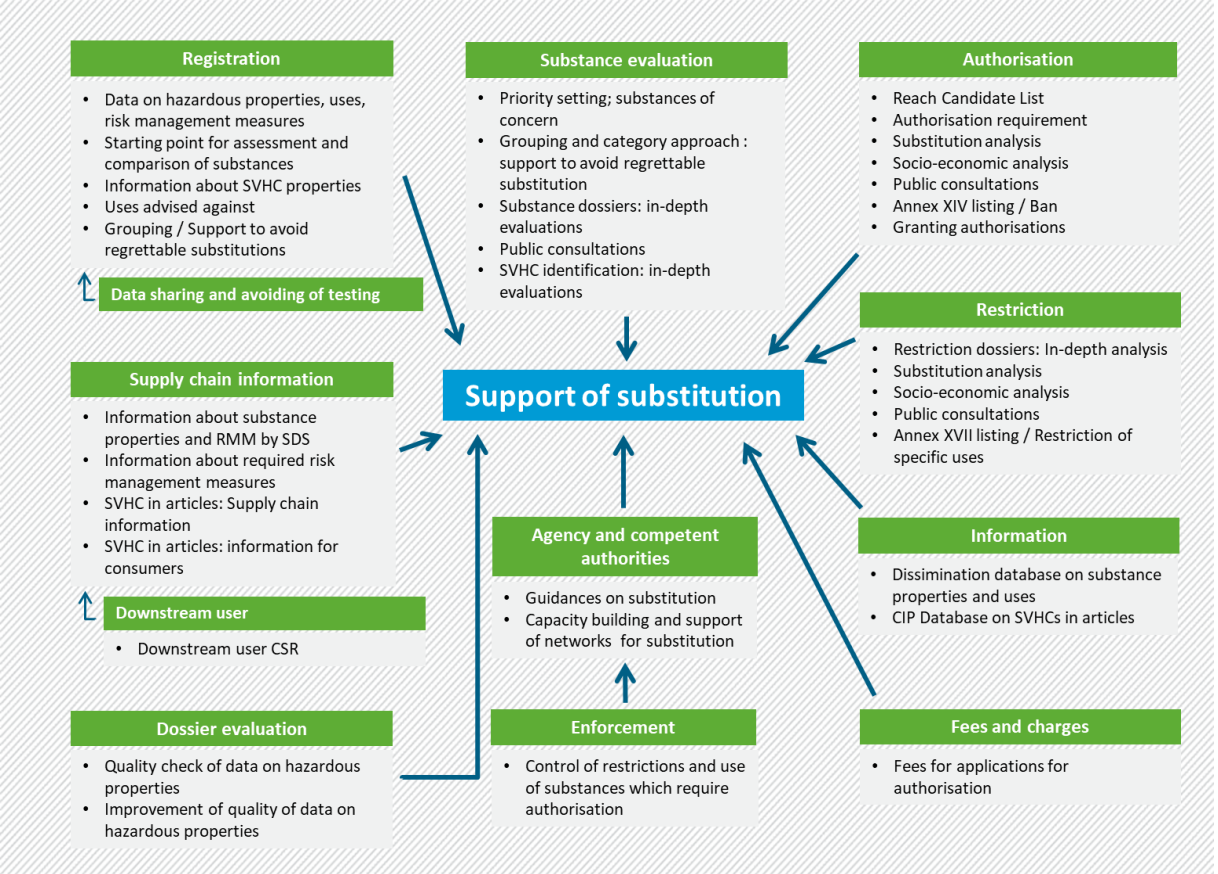
- Chemical safety assessments do not only provide detailed information about substance properties. They also give descriptions of the conditions of use in the exposure scenarios, including information about risk management measures. This is necessary in order to take an informed decision on whether there is a need to search for a less problematic substance or process [5]. The ECHA dissemination database makes this information publicly available [81].
- REACH supports the communication of "uses explicitly advised against" in the safety data sheets, 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 that hazardous substances are substituted by substances of similar structure which have problematic properties too (e.g. substitution of Bisphenol A by Bisphenol S). These so-called "regrettable substitutions" can be avoided provided that the assessment of substances considers substances mainly with structural similarities and similar toxicological profile (grouping, category approach). 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).

[7] Details of this analysis are documented in the final report of work package 6 of the project „Advancing REACH" (see www.uba.de).

- 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 identified 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]. information on SVHC in articles shall be documented by ECHA in the CIP database for information on **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts). This could create an additional support for the identification of articles 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 according to Art. 59 (1) has been found to trigger the search for a substitution of the substance [56]. This is even more the case if a substance becomes subjected to Authorisation (i.e. if taken up in REACH Annex XIV) 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. This can result in better knowledge about alternatives and an enhanced use of alternatives [63]. In case of substances with a low economic value, high fees for 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].

The figure below illustrates for the main elements of REACH which activities are of importance for the substitution of substances of concern. The main elements are the main processes of REACH as expressed in the titles of the regulation.

Figure 5: Main elements of REACH (in boxes) and related activities which can support the substitution of substances of concern.



Source: own illustration, Öko-Institut e.V. (Schweizer, Schöndorf and Bunke 2020).

As already mentioned in the introduction, ECHA´s substitution strategy (ECHA 2018) includes a description in which respect REACH, CLP and the Biocidal Products Regulations are drivers for substitution (ECHA 2018, Annex 1). In the context of authorisation, the replacement of substances of very high concern with safer alternatives or techniques is an important long-term goal. However, the three legislations together intend to have a much broader perspective than SVHCs only. "They are designed to place pressure on and to provide incentives for industry to try to replace hazardous substances with less hazardous ones (ECHA 2018)."

According to ECHA´s substitution strategy, main instruments to support substitution within REACH are registration, supply chain communication, authorisation and restrictions. This is in line with the findings of the matrix analysis shown above.

2.2 Substitution: Key terms

2.2.1 Introduction

Due to the longlasting discussions on the substitution strategy, a broad range of definitions evolved. In the study from Camboni (Camboni 2017) a helpful compilation of terms is available.

In ECHA´s substitution strategy the most important terms are used in a practical manner. "The overall purpose of ECHA´s substitution strategy is to support informed and meaningful substitution of chemicals of concern in the EU and to boost the availability and adoption of safer alternative substances and technologies" (ECHA 2018).

Substitution is defined here as follows:

- The replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures (ECHA 2018, definition cited from Lohse et al. 2003)

In addition, guidance documents from ECHA regarding different steps in authorisation descriptions are given for further terms, e.g." technical feasibility" and "economic feasibility".

In ECHA´s substitution strategy a few terms are used without a definition, e.g. sustainable chemistry, informed substitution, meaningful substitution. Further terms are used in the European and international discussion of the substitution principle, e.g. safe-by-design.

Annex 8 of this report gives definitions for key terms from different references. This aims to support a common understanding of the objectives of substitution and the findings presented in the later chapters of this report.

For the identification and discussion of potential alternatives, the function of a chemical plays a central role. This is reflected in a number of proposals to differ between different levels of functionality. They range from the technical function of the chemical itself (e.g. as a developer or an optical brightener) and the function of the material prepared with help of the chemical (e.g. thermal paper for cash receipts) up to the final service that should be delivered, e.g. delivering a receipt to document the purchase of goods.

A substitution process which includes the consideration of functional aspects has been defined as "functional substitution". This has been explained in more details already earlier in this report in the introduction and in Fig. 1.

3 REACH and its actual impact on substitution

Not only since the REACH Review in 2017, authorities and stakeholders are interested in how REACH and the European chemicals legislation as such have supported the objective of a sound and safe management of chemicals and the substitution of substances of concern. In order to evaluate the actual impact of REACH on substitution we reviewed existing literature on this topic. Apart from findings regarding the actual impact, this review showed difficulties and challenges for substitution and their reasons.

Impressions from the review of these studies contributed to the final recommendations given in chapter 5 of this report on how REACH can stronger support substitution as it does it at the moment.

The main findings of the literature review on the actual impact of REACH on substitution can be summarised as follows:

REACH Authorisation and Restriction

- Authorisation and Restriction under REACH lead to an enhanced substitution of SVHCs and other substances of concern.
- Classification and Labelling of substances under the CLP Regulation is seen as a further important driver for substitution of substances of concern. This regulation has consequences for many other legislations which refer to the result of the classification.
- Most of the identified drivers for substitution (e.g. Candidate List, REACH Annex XIV, need for the assessment of alternatives in case of an application for authorisation) belong to the REACH Authorisation process.

Importance of listing

- Listing of substances under different procedures of REACH (especially Candidate List, Authorisation list (Annex XIV), Restriction List (Annex XVII)) seems to be the most important and most effective trigger for substitution.
- Listing of substances of concern under other legislations and from other activities (e.g. the list of priority substances under the Water Framework Directive, the exclusion criterion under the Biocidal Products Regulation and the SIN list from ChemSec) appears to have a similar effect.

Reduction in use

- For some SVHCs it has been found that production volumes and use volumes decreased. For eight SVHCs this has been shown quantitatively. Emissions to the environment decreased too. However, the degree of reduction and trends differ among the countries.
- Reduction of concentrations of SVHCs in workplace air have been achieved as a consequence of REACH Authorisation.
- The reductions result from a combined effect of various legislations. An enhanced interplay between legal provisions could lead to a further support of substitution

Monitoring substitution

- It is difficult to assess substitution quantitatively due to a lack of precise data on actual production and consumption volumes, on import volumes and export volumes. Furthermore, figures in the chemical safety reports do not need to be updated regularly. Therefore, exact figures on the production tonnages per year are not available – apart from chemicals in Scandinavian countries with reporting obligations to the National Product registers.

Chemicals without SVHC status

- The reviewed studies address chemicals with harmful properties but without SVHC "status" only insofar as they urge to take greater account of them. There are no indications that REACH triggers substitution of these substances' substitution with the exception of restricted substances and substances with harmonised classification. This means: Restrictions and harmonised classifications trigger substitution efforts too.

Intensity of activities

- The intensity of activities aiming to support substitution increased. Different stakeholder groups are engaged with the topic of substitution from different perspectives, e.g. financing substitution, support, decision-making or asking for advancement and giving recommendations.
- A large number of networking activities started at the European level (initiated by ECHA) and at national level, initiated by MS CAs.

Data from REACH Registration and Substance Evaluation

- The data generation under Registration and Substance Evaluation is regarded as a supportive basis for avoiding uninformed, regrettable decisions. Analysing this data for assessment of alternatives is time intensive, and tight timelines of the market actors create a demand for fast substitutions.

Non-regulatory drivers

- The interests of the market (e.g. demands of article producers for SVHC-free raw materials) and of financial investors are most probably the most important non-regulatory drivers.

Drop-in replacement in favour of changes of technology

- Substitution by changes in technology are rare. Most substitutions triggered by REACH lead to a replacement of a substance by another chemical substance representing a 1:1 alternative. Moreover, many of these substitutes are similar in structure to the substances that are substituted. This indicates potential regrettable substitutions: the substitutes cause problematic adverse effects too.

Best practice examples and support of companies

- Learning from best practice examples seems to be one of the most important support measures. It moves the focus of the discussions and activities to success stories of substitution and stimulates further substitutions.

Experience shows that many companies need direct support to adapt available substitution cases to their individual processes.

Annex 9 describes in detail the studies analysed and the findings from the review.

4 Examples of substitution: lessons learnt

4.1 Introduction

This chapter describes several examples of substitution of substances of concern. The objectives of this description have been

- to obtain a better understanding of the influence of REACH on real cases of substitution;
- to identify challenges in the identification and assessment of potential alternatives and
- to identify options in REACH which would allow a stronger support of substitution.

The examples have been selected from different activities:

- Restriction under REACH (see section 4.2 and annex section 7.1);
- Authorisation under REACH (see section 4.3 and annex section 7.2);
- Project LIFE Fit for REACH (see section 4.4 and annex section 7.3) and
- Product-related legal provisions (RoHS Directive, Detergent Regulation, Ecodesign Directive and EU Ecolabel Regulation) (see section 4.5 and annex section 7.4).

For each example, lessons learnt are described. They are used to derive recommendations on how REACH could further support substitution. In this step, we also took into account findings from Work packages (5.1 and 5.4) in the project 'Advancing REACH' on the processes of Restriction and Authorisation under REACH.

In the following section, findings from the analysis of the examples are summarised for each of the four activities. Detailed descriptions of all examples are documented in the annex in sections 7.1– 7.3.

4.2 Restriction under REACH: Examples of substitution

4.2.1 Introduction and overview on examples

In the previous section of this report, restriction under REACH identified as a major driver for substitution. Listing of the restrictions for specific uses of substances in REACH Annex XVII directly creates the need to identify alternatives for uses which are still needed or desired.

Four examples of restrictions under REACH have been analysed in more detail with the aim of developing options on how REACH can further support substitution. These examples are:

1. Bisphenol A in thermal paper (CAS-Nr. 80-05-7);
2. PFOA (Perfluorooctanoic acid, CAS-Nr. 335-67-1) and its salts;
3. Four phthalates (DEHP (diethylhexyl phthalate, CAS-Nr. 117-81-7), DBP (Dibutyl phthalate, CAS-Nr. 84-74-2), BBP (Benzyl butyl phthalate, CAS-Nr. 85-68-7) and DIBP (Diisobutyl phthalate, CAS-Nr. 84-69-5)) in consumer articles and
4. D4 (Octamethylcyclotetrasiloxane, CAS-Nr. 556-67-2) /D5 (Decamethylcyclopentasiloxane, CAS-Nr. 541-02-6) in rinse-off cosmetics.

For the analysis of options to enhance the support of substitution by REACH, findings of work package 5.1 have been taken into account. For this purpose, extracts from the case studies have

been used with the focus on the information available on alternatives and related information from the consultation processes. These extracts are documented in a separate file.

Note: Additional cases of restrictions have been analysed in work package 5.1 of the project "Advancing REACH" with the aim to identify areas for the improvement of the restriction under REACH. A comprehensive documentation of the analysis of the cases of restriction is given here (Annex final report AP 5.1 Restriction, Case Studies Background, January 2019). The case studies have been analysed regarding eight key questions. They addressed important aspects from the initial scope of the restriction up to the methodology of the socio-economic analysis. One of these questions was how alternatives have been assessed.

Overall conclusions and recommendations regarding restrictions are given in chapter 5 of the final report of this work package.

The most important findings from the restriction cases from work package 5.1. regarding substitution have been the following ones:

- Uncertainties in the restrictions reveal the need to obtain a better overview on substances on the market and on their uses;
- In some cases, alternatives were not available (e.g. diisocyanates). In other cases (e.g. four phthalates (DEHP, DBP, BBP and DIBP)), alternatives have already been on the market.
- The overall access for authorities to industry-specific information should be increased in order to overcome data gaps. It would be helpful to introduce a mechanism that gives the authorities more possibilities to request additional data from downstream users, article producers and importers, also for the assessment of the availability of alternatives.

4.2.2 Results from the evaluation of the examples of restrictions

For each example, the following aspects have been characterised d:

- the scope of the restriction
- the submitter of the dossier;
- the decision taken;
- the initial concern and the risks described in the Annex XIV dossier;
- the RAC opinion;
- the impact of REACH on the substitution of the restricted substances;
- changes in monitoring trends;
- ideas for a stronger substitution support by REACH;
- the current state of the play,
- the availability of alternatives and
- lessons learnt.

The comprehensive descriptions of the restriction examples are documented in an annex in sections 7.1.1 - 7.1.4 . In the following table, a summary of the descriptions is given with the focus on five aspects: **scope of the restriction, decision taken, ideas for a stronger substitution support of REACH, availability of alternatives and lessons learnt**.

Table 1: Restriction cases: characteristics and lessons learnt

No.	Characteristics of the example and lessons learnt
[1]	**Restriction of Bisphenol A (BPA, CAS-Nr. 80-05-7) in thermal paper**
	Restriction scope: Use of BPA in thermal paper (took effect on 2nd January 2020). **Decision**: Commission decision in 2016 to restrict BPA in thermal paper in concentrations of 0.02 % or more by weight. **Ideas for a stronger substitution support by REACH**: It would be desirable to accelerate the processes for decision making. Moreover, if the restriction had covered similar bisphenols in a group approach, the substitution by e.g. Bisphenol S (BPS, CAS-Nr. 80-09-1) in thermal paper could have been prevented. **Alternatives available**: As ECHA states, alternative developers such as BPS, Pergafast® 201 (CAS-Nr. 232938-43-1) and D8 (CAS-Nr. 95235-30-6) are available. Given the uncertainties regarding the potentially harmful properties, ECHA encourages companies also to consider technologies and innovations that could remove the need for bisphenols, phenols or non-phenolic substances when developing thermal paper. **Lessons learnt**: Restriction was effective to drive replacement, but possibly to similarly problematic substances (despite RAC flagging this from early on). Discussions of supply chain actors are ongoing. Grouping approaches could be helpful (but not in all cases – hazardous properties of potential alternatives have to be flagged/considered early!)
[2]	**Restriction of PFOA (Perfluorooctanoic acid, CAS-Nr. 335-67-1) and its salts**
	Restriction scope: Production, placing on the market and use of PFOA and its salts and related substances (July 2020 effect date for production). **Decision**: Commission restriction published in June 2017. **Options for a stronger support by REACH**: Group restrictions would be helpful; furthermore, more information in the supply chain about replacements which are equally problematic. The market moved to short-chain replacements like GenX and PFBS (Perfluorbutansulfonsäure, CAS-Nr. 375-73-5). Both were identified as SVHC in 2019. In addition, it is necessary to consider the combined effects from compounds in the same groups, given the known co-exposure of several PFAS substances to ecosystems and humans. **Lessons learnt**: After a very long process, PFOA restriction decreases use, but problem shifted to short-chain PFAS. Discussions for a restriction of non-essential uses (Cousins et al. 2019) of the class of PFAS chemicals are ongoing.
[3]	**Restriction of four phthalates in certain consumer articles**
	Restriction scope: Use of DEHP, DBP, BBP and DIBP when present in any plasticised material in articles at a concentration, individually or in any combination, equal to or greater than 0.1 % by weight of any of such material. **Decision**: Commission published the restriction in December 2018 on bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP). The Commission concluded that the four phthalates pose an unacceptable risk to human health when present in any plasticised material in articles at a concentration, individually or in any combination, equal to or greater than 0.1 % by weight of any of such material. **Ideas for a stronger substitution support by REACH**: The scope of the restriction could be broader to include uses in food contact materials (FCM). They are at present not covered (despite the RA showing large exposure from diet. Additional uptake of phthalates can origin from the

No.	Characteristics of the example and lessons learnt
	food itself which can contain these substances[8]). This omission had been criticised by some NGOs as ineffective and incoherent as there will not be any subsequent substitution trigger for these phthalates in FCM. **Lessons learnt**: Human biomonitoring data can be used to strengthen a restriction proposal, in such a group approach to address combined exposures. Emphasis on substitution should prevent replacement by similar chemicals.
[4]	**Restriction of D4/D5 in rinse-off cosmetics**
	Restriction scope: D4 and D5 in wash-off cosmetic products in a concentration equal to or greater than 0.1 % by weight of either substance, after 31 January 2020. **Decision**: The Commission published the restriction in January 2018 following SEAC's opinion that this is the appropriate Union-wide measure to reduce the discharge of D4 and D5 to wastewater in terms of its socioeconomic benefits and its socioeconomic costs **Ideas for a stronger substitution support by REACH**: The current restriction scope was relatively narrow in terms of substances and uses covered. **Lessons learnt**: It is important to avoid a too narrow scope of any restriction; otherwise additional restriction processes might be needed.

The following table summarized the positive aspects/benefits as well as drawbacks for the environment and human health learned from the restriction examples.

Table 2: Restriction cases: positive aspects and drawbacks learned for an improved substitution (from environment and health perspective)

Example	Positive aspects	Drawbacks
(1) Bisphenol A in thermal paper	The use of BPA in thermal paper declined (partly already before restriction was in place). Companies explore alternatives including non-chemical solutions, e.g. electronic solutions[9]	Replacement with substances of equal/similar concern: this causes a shift to BPS and other bisphenols Narrow scope: other BPAs which may continue be used.
(2) PFOA and its salts	Restriction of group PFOA and salts and related substances leads to decline in use. It illustrates important application of a group approach (PFOA and related substances).	Replacement with equally concerning substances: this causes a shift to shorter chain PFAS (GenX, PFBS).
(3) Four phthalates in consumer articles	Use of phthalates in consumer products is expected to decline further. Group approach for four antiandrogenic phthalate compounds was successful. Human biomonitoring data have been used to demonstrate that the risk is being exceeded based on combined effects. A further positive aspect is that the restriction under REACH influenced further regulations such as Commission Directive 746/05 on	Remaining challenge and enforcement needs: SVHCs in imported consumer articles due to lack of information and difficulties in enforcement. Uses in food contact materials (FCM) is not covered. However, based on the restriction under REACH, EU Commission tasked EFSA to re-evaluate the safety of phthalates in food contact materials.

[8] for details see https://www.bfr.bund.de/de/presseinformation/2013/13/weichmacher_dehp_wird_hauptsaechlich_ueber_lebensmittel_aufgenommen-186791.html

[9] https://newsletter.echa.europa.eu/home/-/newsletter/entry/moving-away-from-bpa-in-thermal-paper

Example	Positive aspects	Drawbacks
	Medical Devices or Commission Directive 10/2011 on Food Contact Materials	Based on the outcome of the EFSA opinion, an amendment of Commission Directive 10/2011 is expected
(4) D4/D5 in rinse-off cosmetics	Restriction for these PBT/vPvB and vPvB chemicals triggered replacements. Restriction leads to increased awareness of impacts of persistent and bioaccumulative compounds in personal care products.	Scope of the restriction was very narrow. ECHA subsequently proposed additional restriction for D4/D5/D6.

4.2.3 Conclusions from restriction examples

The examples of restrictions under REACH evaluated above lead to the following conclusions regarding REACH and substitution:

- Restrictions are an important REACH process to drive substitution and the replacement of hazardous chemicals. Often, the market already reacts before the restriction enters into force (as e.g. seen for BPA in thermal paper) or when other regulatory steps are undertaken. Even at earlier points (classification, identification or previous listing in Annex XIV (as already described in the report from the Danish Ministry from 2019 on effects of some legal interventions under REACH and CLP (Danish EPA 2019) (see also the chapter on the actual impact of REACH above).
- Slowness of regulatory process: In all examples, the concerns for environment (and health) had been known for many years. Nevertheless, it took many more years until a final decision was taken (BPA as case in point). Obviously, procedural reasons and delays can be named and explained, but from a public health and environment perspective, the current situation is not satisfactory. Restriction process needs to be more efficient.
- Need for a sufficiently broad approach of chemicals and uses covered: A too narrow scope of the restriction should be avoided to improve/motivate for a substitution on a broader scale. In addition, this would help to prevent a replacement with chemicals of similarly concerning properties. An example is the restriction for D4, D5 in wash-off products which is now complemented by a second restriction for D4, D5, D6 in several uses.
- Obstacles with the current practice of socio-economic assessment (SEA): This aspect is relevant for both, restriction and authorisation processes. The quantification of known risks (like in the case of the BPA restriction in thermal paper based on the quantified risk for female cashiers) leads to a distortion in the analysis. Its overemphasis on quantitative assessment of risks, benefits, and costs. It omits further effects which are difficult to describe in quantitative terms. The substitution incentive could be enhanced and made clearer if the discussions in RAC and SEAC had a larger focus on societal benefits (including the benefits for human health and the environment) instead of the current narrow understanding of

socio-economic benefit analysis.[10,11]

These aspects already indicate options to improve the REACH processes in order to further support substitution and will be evaluated in more detail in chapter 2.

4.3 Authorisation under REACH: Examples of substitution

4.3.1 Introduction and overview on examples

Authorisation is the central process under REACH which aims to progressively replace substances of very high concern, by suitable alternative substances or technologies where these are economically and technically viable. Manufacturers, importers and downstream users applying for authorisations for specific uses have to analyse the availability of alternatives and have to consider their (potential) hazards, risks, and the technical and economic feasibility of substitution.

By January 2020, for 31 of the 43 substances in Annex XIV, applications for authorisations (AfAs) have been submitted. These applications and authorisations granted or rejected can be analysed to understand how the assessment of alternatives is done in practice and which options exist to further develop this process.

Four examples of granted authorisations under REACH have been analysed in more detail with the aim of developing options on how REACH can further support substitution. These examples are:

- Musk xylene (CAS-Nr. 81-15-2)
- TCEP (Tris(2-chlorethyl)phosphate, CAS-Nr. 115-96-8)
- DEHP (Bis(2-ethylhexyl)phthalate, CAS-Nr. 117-81-7) and
- Octylphenol ethoxylates. (CAS-Nr. 117-81-7)

For the analysis of options to enhance support for substitution by REACH in the present report, findings of work package 5.4 have been taken into account following the same approach as for the cases on restrictions. For this purpose, extracts from the case studies of authorisation from work package 5.4 have been used. The focus of these extracts has been on information on substitution and alternatives (from the Assessment of Alternatives) and related information from the consultation processes and discussions. These extracts are documented in a separate file.

Note: Additional cases of (applications for) authorisations have been analysed in work package 5.4 of the project "Advancing REACH". The aim of work package 5.4 has been to identify areas for the improvement of the authorisation process under REACH. This refers to the identification of SVHCs (see chapter 4, final report work package 5.4) as well as to the application for authorisation and the related reviews (from SEAC, RAC and the public consultations) (see chapter 6, final report of work package 5.4).

An analysis of alternatives (AoA) and a substitution plan are important elements of an application for an authorisation. (The AoA is a mandatory element. If an applicant decides not to prepare a substitution plan, he has to give the reasoning for this in his application) They have

[10] https://chemtrust.org/wp-content/uploads/nef-discounting-future-damage-comp.pdf

[11] https://chemsec.org/publication/authorisation-process,reach/lost-at-sea/

been described for the ten case studies selected in work package 5.4. This includes an overview on the availability of information on substitution and alternatives as well as a documentation of discussions of this topic in the public consultations and the committees (RAC and SEAC).

A comprehensive documentation of the analysis of the cases of authorisations is given in an annex of the report of work package 5.4 (final report AP 5.4, Assessment of the Authorisation process under REACH, March 2019). Overall conclusions and recommendations with relevance to substitution under REACH are given in sections 4.2 and 4.3 (SVHC identification), and in chapters 6 (Authorisation) and 7 (Overall conclusions) of the final report of work package 5.4.

The most important findings from the analysed authorisation cases from work package 5.4. regarding substitution have been the following ones (Wirth 2020):

- Substances that are very similar in structure and have also problematic properties (toxicity and/or ecotoxicity) might be used as alternatives which can substitute each other. Therefore, and as they may have similar properties of concern it might be reasonable to regulate them as a group to avoid regrettable substitution (see. e.g. chromate compounds, lead compound, cadmium compounds, some fluorinated compounds). Currently, they are in most cases identified as SVHCs in separate processes, which multiplies the workload and delays the process to assess/regulate/substitute the relevant ones. This requires a comprehensive assessment which substances belong to such a group. Beyond the structural similarity this assessment has to consider the toxicological and ecotoxicological properties of the potential members of a group.

- Authorisation as an option foreseen by REACH has been used by industry for the majority of the substances of the Authorisation list. One reason was the lack of suitable alternatives acceptable for companies. In some cases, the lack was actually the absence of a suitable technology on hand to produce the type of products needed. In other cases, the alternative has a lower performance and involves higher cost for the introduction. In many cases, it was a mixture of both aspects, discussed in the framework of the application for an Authorisation (AfA).

- The availability of alternatives from a technical and economical perspective is a key argument in the discussions in the SEAC.

- It was sometimes not fully clear if missing technical alternatives cover the full range of downstream uses/products or only parts of this. This became relevant in cases where the range of products affected was very broad (e.g. DEHP primary use and in recyclates) or special knowledge of market actors further down the supply chain was important (Chromates).

- The assessment of alternatives (AoA) is often limited to alternative substances that can be applied in the same or to some extend adapted use as the one currently performed by the applicants. Principal alternatives on the market that might offer a more general (technical?) alternative approach are not assessed (e.g. case study on HBCDD. Here, the alternatives are limited to alternative substances that mediate flame protection to expanded polystyrene (EPS); Alternatives to EPS (e.g. mineral insulation materials) are not discussed).

- Interlinks between AfAs that cover a similar or the same use are not made, neither are they formal relevant to the decision making-process[12].To a large degree, the AoA can vary according to the technical know-how of market actors. Regarding their potential to introduce an alternative, these market actors do not have a better chance to introduce such an alternative than market actors of another AfA that have better technological expertise, provided that there an overall conclusion exists that alternatives are not technically available.
- This lack of expertise in practice is very difficult to overcome for market actors; at least, it is often not possible to gain this expert knowledge within the short term. Partly, this can be addressed by an exchange via databases, information portals and workshop events. Still, these options require at least one person in a company that is a) qualified to use these formats and b) has the time and resources to tackle such questions, which often already is a limiting factor in companies with only a few employees.
- Technical hurdles to implement an alternative are often justified by a claim of non-acceptable loss of quality of resulting products. It could be, for example, that technical requirements make the product in which a substance is used not fit for use. In other cases, the arguments seem to cover rather weak aspects that are more linked to the comfort of the final product user (e.g. the wool dying case, where less intense colour would not lead to a complete loss of dyed wool products).
- Evaluation of the substitution potential of the substances is very much focussed on the applicant's perspective. An exemption from that rule can be observed in the HCBDD case, where after a massive intervention of stakeholders in the public consultation only a very short review period of two years was granted to allow the applicants the fast transition to alternative substances and to realise a phase out. In this case, the perspective of societal stakeholders has been of decisive importance for the decision taken.
- Very broad upstream applications make it difficult to decide in which area a substitution might already be feasible. Different uses can be of different importance for industrial, professional and private users. due to effects on human health and the environment. The discussion on alternatives often remains rather superficial when discussed for a broad range of uses (or specific products) into which the substance is to be incorporated (e.g. in the DEHP cases). It is then hard to assess for authorities (in particular the SEAC) if a technical substitution can be achieved or not). Therefore, upstream applications should include similar uses, which are comparable and can be evaluated together.
- Economic costs should not only cover costs for the applicant but also costs that are linked to the reduction of incentives for innovation: granting of an authorisation might result in market loss to progressive market actors that already apply safer alternatives. It will be difficult to estimate these costs. It could be necessary that this kind of data has to be gathered by external experts which are independent from the applicant.

[12] The new format for the documentation of RAC/SEAC opinions takes note of this question to some degree https://echa.europa.eu/documents/10162/13555/format_rac_seac_opinions_en.pdf/

- It has been proposed in WP 5.4 that applicants, for an authorisation, should receive a list of existing alternatives which have to be assessed in the application. This list could be compiled by the Commission based on all applications received so far and the related public consultations.
- In general, applicants for an authorisation endeavour to demonstrate absence of alternatives in their Assessment of Alternatives (AoA). Often there is large degree of uncertainty as to whether or not alternatives are on the market. It has been proposed that the in-depth-assessment of alternatives should be carried out by authorities responsible at an overarching level, e.g. as part of the RMOA.

4.3.2 Results from the evaluation of the authorisation examples

For each authorisation example, the following aspects have been described:

- Dossier submitter and SVHC property addressed;
- Date of inclusion in the Candidate List, in Annex XIV and sunset date;
- Trends on production volumes observed in SPIN dataset;
- Number of Applications for Authorisations (AfA) received;
- Ideas for a stronger substitution support of substitution/alternatives by REACH and lessons learnt.

The descriptions of the authorisation examples are documented as an annex in sections 7.2.1–7.2.4. In the following table, a summary of the descriptions is given with the focus on three aspects**: applications for authorisations received, ideas for a stronger substitution support by REACH and lessons learnt.**

Table 3: Authorisation cases: characteristics and lessons learnt

No.	Characteristics of the example and lessons learnt
[1]	**Authorisation of Musk xylene (CAS-Nr. 81-15-2)**
	Applications for Authorisation received: None. **Ideas for a stronger substitution support by REACH**: Potentially, an investigation of likely replacement from the same or similar chemical group. **Lessons learnt**: No authorisation applications have been submitted, i.e. substitution has taken place and remaining uses (if any) are now limited to only a few.
[2]	**Authorisation of TCEP (CAS-Nr. 115-96-8)**
	Applications for Authorisation received: None. **Ideas for a stronger substitution support by REACH**: According to the RMOA, the substance is used as an additive plasticiser with the function of a flame retardant. ECHA's screening assessment identified a risk for children from exposure to the flame retardants TCEP, TCPP and TDCP in flexible polyurethane (PUR) foams in childcare articles and residential upholstered furniture. The Commission requested ECHA to prepare a restriction proposal which is now pending as ECHA has withdrawn its original restriction intention in summer 2019 due to the fact that new studies are ongoing at NTP and that it would make sense to wait for the outcome of these studies before further working on the restriction.

No.	Characteristics of the example and lessons learnt
	Lessons learnt: Following the identification as an SVHC and inclusion in Annex XIV, the adoption of an additional restriction to cover the uses in imported articles in order to ensure protection may be necessary.
[3]	**Authorisation of DEHP (CAS-Nr. 117-81-7)**
	Applications for Authorisation received: Yes, and granted for use in PVC in recycled consumer products. ECHA website shows nine authorised uses for DEHP in total. (January 2020) **Ideas for a stronger substitution support by REACH**: There is currently a mismatch between granting authorisations and the desire to create a circular economy (risk of double standards). **Lessons learnt:** An additional restriction was decided necessary to cover use in plastic products (see restriction example of 4 phthalates in consumer plastic articles).
[4]	**Authorisation of Octylphenol ethoxylates (CAS-Nr. 117-81-7)**
	Applications for Authorisation received: 37 (January 2020) **Ideas for a stronger substitution support by REACH:** One could consider shortening the regulatory processes because it took nine years from the inclusion in the Candidate List and the sunset date. **Lessons learnt**: It is an important test case for the consideration of a non-threshold substance with endocrine disrupting properties in the assessment and decisions on authorisation applications

The first two examples below show that for several Annex XIV substances, for which the application deadline already expired applications for authorisation have not been submitted. This means that these substances are no longer on the EU market (unless they are introduced through imported articles, which is illustrated in other examples).

The following table shows positive aspects from the authorisation examples as well as drawbacks for the environment and human health.

Table 4: Authorisation cases: positive aspects and drawbacks learned for an improved substitution (from environment and health perspective)

Example	Positive aspects for environment & health	Drawbacks for environment & health
Musk xylene	No authorisation applications received	Replacements by substances which may have equally problematic properties
TCEP	No authorisation applications received	Exposure from use in imported articles remain (a group restriction is pending)
DEHP	Additional group restriction (four phthalates) adopted for use in plasticisers	Authorisation granted for recycled PVC products
Octylphenol ethoxylates	Applications received; decisions are still pending.	

4.3.3 Conclusions from the Authorisation examples

The REACH authorisation procedure is undoubtedly the central procedure in REACH which aims at achieving substitution by a progressive replacement of substances of very high concern. The examples demonstrate that the impact of the REACH procedure on the use and trends of the substance depends very much on the following aspects:

- If a substance has been recognized and accepted as problematic and alternative substances have been on the market with a similar or better performance at similar prices, it may have become irrelevant to the market already before (e.g. musk xylene). The inclusion of a substance in the REACH Candidate List and Annex XIV has its own value as it triggers discrete legal obligations and it thereby prevents a possible future use of the substance.
- If a substance (such as TCEP and DEHP) is also used in imported articles, the substitution triggered by authorisation might not be sufficient as it does not apply to imported articles. Therefore, it was decided in these cases that an additional restriction is needed in order to reduce consumer and environmental exposure to these SVHCs as this also includes imported articles (referring to REACH Art. 69(2)).
- The time span from the inclusion in the Candidate List until specific applications for authorisation are reviewed and decisions are taken can extend up to many years. For example, in the case of octylphenol ethoxylates, already nine years have passed since their inclusion in the candidate list and applications for authorisation are under review since 2019.

In addition to the general points illustrated by these examples above, the following more specific findings regarding the authorisation procedure should be mentioned here (see also results from work package 5.4 of the project "Advancing REACH").

- Although many of the submitted applications are use-specific and well-defined, applications cover very broad uses of SVHC involving thousands of tonnes and potentially hundreds of downstream users (e.g. for the use of DEHP in raw and recycled PVC, HBCDD (1,2,5,6,9,10-Hexabromcyclododecanm, CAS-Nr. 3194-55-6) in flame retarded expanded polystyrene (EPS), lead chromates in paints and chromium(VI)oxide. These broad use definitions are challenging because they require a comprehensive analysis of the availability of alternatives for all of these uses.
- Granting authorisations despite the existence of alternatives hinders substitution. The authorisations for lead chromate pigments were granted although EU manufacturers had already moved to safer alternatives.[13]
- Socio-economic assessments which prioritise the applicant's perspective instead of society's, including human and environmental benefits, are misleading and counterproductive. Due to disagreements over these approaches, several resolutions in the EU Parliament have been triggered over the years; in 2017, the German Environment Ministry had suggested a political debate about the socio-economic analysis, risks and benefits. This has been published as a position paper of the Federal Government.[14] Authorisations should be rejected or granted only under specific and stricter conditions if data in the socio-economic assessment were insufficient for a comprehensive assessment of risks and benefits.

[13] https://chemicalwatch.com/23102/eu-paint-associations-oppose-lead-pigments-authorisation

[14] German Environment Ministry 2017, Position paper on REACH authorisation

4.4 The EU-project LIFE Fit for REACH: Examples of substitution

The EU-project LIFE Fit for REACH[15] aims at getting a better understanding of obstacles to substitutions in supply chains and ways to overcome them. 12 selected substitution cases from this project have been analysed to learn from this experience and to recommend appropriate actions to enhance substitution in the context of REACH.

4.4.1 Brief description of the project and overview on examples

The activities of the EU project "LIFE Fit for REACH" aimed at supporting small and medium sized enterprises in Estonia, Latvia and Lithuania in implementing their obligations under REACH, especially regarding substitution of substances of very high concern (SVHC) and an overall better chemicals management. Among the main objectives of the project were:

- preparing small and medium sized enterprises (SME) which are downstream users under REACH for (future) challenges in chemicals management, including a pro-active management of restriction and authorisation processes;
- capacity building for downstream user SMEs on chemicals (risk) management, including on classification, labelling and packaging, safety data sheets, chemicals inventories and following the legal obligations for SVHCs;
- supporting the substitution of SVHCs and other substances of concern in the companies' products and processes and implementing options to increase resource efficiency.

In the frame of the project, several other activities took place, such as national round tables, information events and capacity building, e.g. on green claims, as well as assessments of the socio-economic and environmental impacts of substitution. Furthermore, information leaflets and guidance were developed, as well as practical tools to support chemicals risk management in enterprises.

The project took place from 2014 to the end of 2020. The actual substitution supports activities in the project ended by mid-2020. All project results are published on the project website[16].

In total, more than 90 companies participated in activities, of which many at least screened the chemicals they use and identified those that could be regarded as priority for substitution. Six of the participating partner companies identified substitution needs before the project start and identified, tested and in the majority of cases also implemented the use of alternatives during the project.

In addition to the six partner companies, a large number of enterprises in the three Baltic States were contacted during the project and motivated to improve their chemicals management and, if relevant, substitute substances of concern. Twelve examples of the LIFE Fit for REACH have been analysed from the current report.

In the following sections and the related annex, section 7.3, detailed information is given on some of the results obtained in this project.

[15] https://www.fitreach.eu/article/welcome-lifefit-reach

[16] http://fitreach.eu/content/project; as the core target group of the project are enterprises in Latvia, Lithuania and Estonia, the English version of the website contains less information and tools than the national ones.

4.4.2 Results from the analysed examples from the project LIFE fit for REACH

For each example, the following aspects are summarized:

- name of substance and specific function and use;
- person/ institution responsible for the substitution process
- initial trigger/ initial concern for companies to search for alternatives and further circumstances of the starting situation;
- alternatives which have been assessed, alternatives chosen and challenges in the substitution process;
- impact of REACH and options to improve the process;
- ideas for a stronger substitution support by REACH and lessons learnt.

An overview on the analysis can be found in the following table with a focus on 3 aspects (substance, alternatives, lessons learnt) and details are given in an annex in sections 7.3.1 – 7.3.9.

Table 5: Project LIFE Fit for REACH: Summary of examples for substitution and lessons learnt

No.	Characteristics of the example and main findings
[1]	**Substitution of methylene dichloride (CAS-Nr. 5-09-2) in polyurethane foam production.**
	Specific function: Cleaning agent. Methylene dichloride is used to clean a filling and dosing station of pre-polymers for the production of PU-foams. **Alternative chosen**: The originally chosen alternative had been removed from the market after change of the ownership of the producing company. A second alternative (resin-based cleaner) was identified as second best and is now used despite some disadvantages in handling and operational conditions. **Lessons learnt**: Substitution only happens, if there are suitable alternatives available, which requires a critical demand/market perspective for alternatives producers. Changes on ownership of companies may lead to alternatives being withdrawn from the market.
[2]	**Substitution of BPA (Bisphenol A, CAS-Nr. 80-05-7) in metal cans for dairy products (food contact material, FCM).**
	Specific function: Component of epoxy resins which are used as can coating and linings. **Alternative chosen**: Solution 1: The epoxy resin-based lacquer for the can is replaced by a resin based on benzoguanamine-formaldehyde. Solution 2: procurement of already (non-BPA-based) pre-coated metals, i.e. omitting the lacquering at site. Solution 3: For the can caps, an alternative supplier was identified whose caps are based on a vinyl-organosol lacquer. Solution 4: the side stripe lacquer is being replaced by a solid (powder) polyester-based coating (development ongoing). **Lessons learnt:** REACH can support substitution decisions that are triggered by obligations under other legislation (EU FCM legislation). Information on hazardous properties and environmental fate generated under REACH is useful for alternatives assessment. Comprehensive (group) restrictions may support the development of better and safer alternatives and could hence also enhance substitution and avoid regrettable substitution.
[3]	**Substitution of ethanol (CAS Nr. 64-17-5) in winter windshield agents.**

No.	Characteristics of the example and main findings
	Specific function: Anti-freezing agent in windshield wiping agents. **Alternative chosen**: A recipe was developed using propylene glycol (CAS Nr. 57-55-6). Practical tests showed that the windshield wiping agent did not evaporate at a sufficient rate, resulting in decreased visibility for the driver. In addition, the product costs increased considerably. As a consequence, the substitution process was stopped. **Lessons learnt**: Substitution may not be possible and implemented in practise within the existing technology path.
[4]	**Substitution of sodium perborate (CAS Nr.15120-21-5) in washing agents.**
	Specific function: Bleaching agent in washing powders and washing liquids. **Alternative chosen**: A combination of specific enzymes, citrates and percarbonate was selected as alternative. **Lessons learnt**: The Candidate List is a powerful trigger for substitution, because it helps companies in priority setting and because customers start requesting the use of products free from SVHCs. An immediate inclusion of an SVHC into Annex XIV is not always needed to initiate substitution. In short supply chains, e.g. in the manufacture of chemical products, a complex communication along many actors is not essential for successful substitution
[5]	**Substitution of a phthalate and an organotin compound in sealants**
	Specific function: DINP (Diisononyl phthalate, CAS-Nr. 28553-12-0/ 68515-48-0): plasticiser, DBTL (Dibutyltin dilaurate, CAS-Nr. 77-58-7): catalyst. **Alternative chosen**: DINP has been substituted by DINCH (CAS Nr. 166412-78-8); dibutyltin dilaurate (CAS Nr.3648-18-8) was substituted by dioctyltin dilaurate **Lessons learnt**: The Candidate List, the CoRAP-list and substance evaluations aimed at SVHC identification due to endocrine disruption, raise awareness and may be considered early in a company's decision making. The ECHA registration database as well as the classification and labelling inventory are generally useful to assess alternatives. However, information is often not sufficient, in particular for low-volume chemicals, which challenges the assessment of hazards and risks and also the suitability of alternatives.
[6]	**Reuse of production wastes from polyurethane foams**
	Specific function: PU foams are used as construction products. **Alternative chosen**: In this case, the use of chemicals was reduced (resource efficiency increased) by optimising the timing of the quality control measurements in the foam production process, and thereby reducing the amount of production wastes. Attempts to identify users of the (clean) PU foam wastes were not successful. **Lessons learnt**: Use reduction is one way to decrease environmental burdens of the use of hazardous chemicals and can also be achieved by a reuse of production wastes. To make production wastes available to other companies, a marketplace would be needed as well as a clarification of registration obligations (and/or exemptions).

No.	Characteristics of the example and main findings
[7]	**Substitution of nonylphenol (CAS Nr. 25154-52-3) in epoxy floorings**
	Specific function: It is part of the curing component of a flooring lacquer. **Alternative chosen**: A recipe was developed, where nonylphenol could be fully eliminated by the use of, among others, a diglycidyl ether of bisphenol-A (CAS Nr. 25068-38-6) and increasing a number of aminic components. The product performance was increased (no cracks or discoloration without significantly altering the floor laying process (e.g. similar viscosity, same or lower level of workers exposure to chemicals, same or decreased mixing times). The production costs did not increase. **Lessons learnt**: Substitution may be supported by inclusion of an SVHC in the Candidate List and if alternatives are available on the market. Due to the substitution the product performance may even be improved, potentially also increasing sales volumes. Hence substitution can be an overall benefit and a win-win situation.
[8]	**Substitution of volatile organic compounds VOCs in lacquering of metal sheets**
	Specific function: Solvents in primers and lacquers. **Alternative chosen**: The alternative to the primer/lacquer system selected for substitution was obtained from the same producer and tested with respect to its practical feasibility. The overall VOC content is reduced. While one VOC aimed for substitution could not be reduced (Xylene (CAS-Nr. 1330-20-7)), the other (2-methoxypropanol (CAS Nr. 1589-47-5)) was eliminated. **Lessons learnt:** Substitution may be triggered by requirements from industrial legislations (VOCs). In this sense incentives for substitution exist beyond REACH. If mixtures are concerned, downstream users are limited to either identifying alternative substances for their own mixtures or to cooperate with customers/others to specifically develop a product for their needs. If customers with strong demands regarding quality and/or the use of specific products are involved, companies have to invest extensively in communication and testing to show that alternatives achieve the same results as the original product. Already the classification as CMR and/or listing of a substance in the CoRAP for further evaluation sends signals to the users and may contribute to a decision to substitute.
[9]	**Substitution of ink-jet printer for electronic components** **Specific function:** Substance (or technical process) required to permanently identify cables of electronic components. **Alternative chosen:** Thermal transfer printer using a printing technology that does not require the use of hazardous solvents. **Lessons learnt:** Technology changes may decrease/eliminate emissions of hazardous substances into workplace air. The REACH registration database allows to assess the substances contained in the polymeric marking.
10	**Substitution of a textile dye (mixture)** **Specific function**: Dying of textile. **Alternative chosen**: Another mixture which is not classified as sensitising. **Lessons learnt:** Classification may be a substitution trigger. Several information sources are used by downstream users to find alternatives, including safety data sheet, communication with suppliers, the REACH Candidate List and the CoRAP
11	**Substitution of chemicals used for production of jewellery**
	Specific function: Hazardous substances are needed for several processes in the production of jewellery. **Alternatives chosen**: Use of alternative substances and mixtures, changes of technologies and process organisation.

No.	Characteristics of the example and main findings
	Lessons learnt: Hazard information under REACH has been crucial for these substitutions. Main triggers have been awareness during the project (potential risks for workers), together e.g. the need for an application for authorisation, existing restrictions, "uses advised against" in the CSR, a withdrawal of substances from the market, demands from customers on information on implementable risk reduction measures in the SDS(existing ones where often not implementable).
12	**Substitution of 1,2-Benzisothiazolin-3-one (CAS-Nr. 2634-33-5) and 2-Methyl-3(2H)-isothiazolone (CAS-Nr. 2682-20-4)**
	Specific function: Preservation of a household chemical mixture. **Alternative chosen**: Other chemicals (not further specified). **Lessons learnt:** Main trigger for substitution was the intention to avoid self-classification of the mixture and the wish to apply for an ecolabel (which does not allow the content of isothiazoles). The alternative chemical was identified via communication with the supplier of the isothiazolones (CAS-Nr. 1003-07-2).

4.4.3 Conclusions from the Baltic States examples in the LIFE fit for REACH project

The main (combination of) factors triggering substitution observed in the LIFE Fit for REACH project in companies operating in the Baltic States are (in the order of importance):

- (non-) compliance with legislation (e.g. existing restrictions, occupational exposure limit values); also outside REACH
- the inclusion of a substances on the Candidate List as SVHC; CoRAP-list and substance evaluations;
- the classification of a substance as hazardous (which may be triggered by (new) information generated under REACH) and/or the fact that a substance causes a (consumer mixture) to be classified;
- customer requests and the expectation to enter new markets with a new/better substance and/or mixture.
- company policies aiming at reducing the use of hazardous substances and/or providing safe products to the market;
- the fact that a substance is already regulated, even if this does not apply to the own sector, ongoing discussions about classification, SVHC identification and/or the existence of endocrine disrupting properties

Most of the companies of which substitution cases were analysed (cases described under sections 7.3.1 to 7.3.7) were well aware of chemical hazards and/or risks and had respective management systems and tools in place. However, small and medium-sized companies, in particular those operating at the end of the supply chain, revealed a generally low awareness on chemical risks and lack of respective management systems and tools. For these (SME) companies, the core substitution trigger was the higher awareness raised, which helped to organise chemical inventories in the companies and supported priority setting. This was needed to create motivation and understanding for the need to substitute. In this regard, the classification plays a very important role. Compliance with REACH in general was a trigger to initiate substitution in some cases but not the only one.

REACH provided support to the substitution process because:

- Information is available on substance properties that is needed to assess alternatives.
- The Candidate List, CoRAP and the PACT are used as indicators of potential future regulation and hence support the search for alternatives and avoidance of substances that are under scrutiny of authorities

In most cases, safety data sheets for the alternatives to the hazardous substances and mixtures were the main information source for DUs to assess the potential alternatives and to decide, based on the given information in the SDS, whether or not to check the feasibility of the respective substance and/or mixture. Mainly information on the hazardous properties was used as well as data on workers protection and/or the needed risk management measures. The influence of the REACH regulation on the quality of safety data and safety data sheets compared to prior chemical legislation cannot be judged from the examples.

Several of the companies highlighted that too little communication took place in the substitution process. This may be due to that most of the analysed companies are formulators but also due to the experience that information requests are partly not well answered[17].

Generally, the existence of REACH as such seems to have raised awareness on chemical hazards and risks and the need to manage them. This is partly due to increased supply chain communication, and partly because of an overall increased awareness on chemicals. This is a general supportive factor and is difficult to measure or directly deduce from the project's substitution cases.

In the context of the project a direct consulting on chemicals risk management and substitution was offered by the project group to interested companies and money was made available to those, which agreed on specific measures. These two support activities together with the concerted action of the project team with national and regional authorities and different awareness raising campaigns, including for consumers, seems to have paved the ground for companies to decide to involve in substitution.

The core challenge of many substitution cases was the lack of suitable alternatives for companies in terms of their technical performance and availability at acceptable costs. This suggests that a higher substitution pressure, which would create larger markets for potential alternative suppliers, would further support substitution processes. This could mean stronger regulation in terms of restrictions and authorisation decisions as well as targeted support to the development and placing on the market as well as penetrating the market of suitable alternatives.

4.5 Approaches for substitution under Product-related legal provisions

Substitution of substances of concern is an important topic not only in substance-oriented chemicals legislation. Several product-related legal provisions regulate the content of chemicals in specific products, e.g. the RoHS Directive for Electrical and Electronic Equipment. Some of these provisions have been in place already before REACH entered into force. They trigger substitution of substances of concern by mandatory and voluntary measures. In many cases, they refer to data on substance properties, which have been generated under REACH.

[17] There were also cases where communication with suppliers was found very helpful and supporting. Furthermore, some suppliers also provided alternatives to hazardous substances and mixtures.

Product-related legislations have been addressing problematic substances in different ways for many years. Experience from these provisions can help to further support substitution of problematic substances in future – within and beyond REACH. Therefore, four important product-related provisions have been described regarding their approach to address substitution:

1. the RoHS Directive (section 4.5.1, for details see annex, section 7.4.1);
2. the Detergent Regulation (section 4.5.2, for details see annex, section 7.4.2);
3. the EcoDesign Directive (section 4.5.3, for details see annex, section 7.4.3) and
4. the EU Ecolabel Regulation (section 4.5.4, for details see annex section 7.4.4).

The description of the provisions followed a similar structure for the analysis of examples from the previous sections:

- Description of the legislation and scope;
- Initial trigger/initial concern to set up the provisions and further characteristics of the starting situation
- Person/institution responsible for the substitution process
- Assessment of alternatives and challenges in the substitution process
- Interrelationship with REACH (including ideas for a stronger substitution support by REACH) and lessons learnt from the example.

The detailed descriptions of the four provisions are documented in the annex (section 7.4.1–7.4.4) of this report. In the following sections, a shortened report is given with a focus on the lessons learnt.

4.5.1 Substitution under the RoHS Directive

Description of the legislation

The RoHS Directive restricts the use of certain hazardous substances in electrical and electronic equipment (EEE) that are placed on the European market. The first RoHS 1 Directive[18] 2002/95/EC banned "the dirty six", i.e. lead, mercury, cadmium, hexavalent chromium, poly-brominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE). This ban became effective on 1 July 2006.

Meanwhile, the initial RoHS Directive (RoHS1) has been replaced by the RoHS 2 Directive 2011/65/EU[19] , which entered into force on 21 July 2011. The list of restricted substances in Annex II has most recently been amended by 31 March 2015: Accordingly, the four phthalates Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) have been added to Annex II and the restriction applies to most EEE products (including computers) from 22 July 2019 on.

Exemptions from these restrictions can be granted for specific applications if substitution is scientifically or technically impracticable or the reliability of substitutes is not ensured.

[18] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:037:0019:0023:en:PDF

[19] See the consolidated version and all amendments of the Annexes at: http://ec.europa.eu/environment/waste/rohs_eee/legis_en.htm

Scope

RoHS is applicable to all products placed on the European market and therefore covers imported products as well. Thus, RoHS provides a level playing field between EU and non-EU manufacturers.

The example of PBDEs

In addition to restricting certain substances, RoHS has also been restricting groups of substances, e.g. lead and all lead compounds as well as all PBDE congeners since 1 July 2006. This grouping led to a comprehensive ban. It addresses not only one, but several substances. Therefore, it was more effective compared to other legal provisions for this group which address only a single substance

For example, the grouping of PBDEs under RoHS entailed an early ban of decaBDE (CAS-Nr. 1163-19-5) – besides the ban of commercial penta- (CAS-Nr. 32534-81-9) and octaBDE (CAS-Nr. 32536-52-0) under the former dangerous preparation Directive 76/769/EEC.[20] However, the use of decaBDE in electrical and electronic equipment has been the subject of legal controversy because it was temporarily permitted again under the RoHS Directive as exemption 9a "DecaBDE in polymeric applications".[21] On 1 April 2008, however, the European Court of Justice in its judgement dated 1 April 2008 ruled that DecaBDE was no longer permitted to be used as a flame retardant in new electrical and electronic equipment placed on the market as of 1 July 2008.

In contrast, it ruled out that DecaBDE should be covered by the Stockholm Convention until 2017 in Annex A[22] (decabromodiphenyl ether (BDE-209) present in commercial decabromodiphenyl ether therein, with specific exemptions for the production and use of commercial decabromodiphenyl ether).[23]

[20] Commercial penta- and octaBDE have been restricted in their marketability since 2004 under Directive 76/769/EEC; these restrictions were taken over in Regulation (EC) No. 1907/2006 (REACH) in Annex XVII. The commercial penta- and octaBDE was taken up on Annex A of the Stockholm Convention by the 4th Conference of the Parties in May 2009 and required amendments to the POPs Regulation, which were implemented by Regulations (EU) No 757/2010 and have been applicable since 26 August 2010. With Regulation (EU) No. 207/2011, the entry on pentaBDE was deleted from Annex XVII to avoid double regulation in the EU. Entry 45 on octaBDE remained in REACH Annex XVII.

[21] The justification of the exemption was published in Commission Decision 2005/717/EC (13 October 2007), (3) Since the risk assessment of DecaBDE, under Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, has concluded that there is at present no need for measures to reduce the risks for consumers beyond those which are being applied already, but that additional studies are required under the risk assessment, DecaBDE can be exempted until further notice from the requirements of Article4(1) of Directive 2002/95/EC. Should new evidence lead to a different conclusion of the risk assessment, this decision would be re-examined and amended, if appropriate. In parallel, industry is implementing a voluntary emissions reduction programme.

[22] Eighth Meeting of the Conference of the Parties to the Stockholm Convention in Geneva, Switzerland from 24 April to 05 May 2017; http://www.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP8/tabid/5309/Default.aspx

Decisions SC-8/10, on the listing of decabromodiphenyl ether (commercial mixture, c-decaBDE), and SC-8/13, on the review of information related to specific exemptions for decabromodiphenyl ether, as adopted by the Conference of the Parties, are set out in annex I to the present report.

[23] The specific exemptions are:

- Parts for use in vehicles specified in paragraph 2 of Part IX of this Annex
- Aircraft for which type approval has been applied for before December 2018 and has been received before December 2022 and spare parts for those aircraft
- Textile products that require anti-flammable characteristics, excluding clothing and toys
- Additives in plastic housings and parts used for heating home appliances, irons, fans, immersion heaters that contain or are in direct contact with electrical parts or are required to comply with fire retardancy standards, at concentrations lower than 10 per cent by weight of the part
- Polyurethane foam for building insulation

Initial trigger/initial concern to set up the provisions

According to the recitals in the RoHS 1 Directive, concerns from the end-of-life stage have triggered substance restrictions in order:

- To contribute to the protection of human health and the environment, as well as the sound recovery and disposal of waste of electrical and electronic equipment;
- To reduce waste management problems linked to the identified and restricted heavy metals and flame retardants of concern;
- To combat environmental pollution by cadmium (CAS-Nr. 7440-43-9);
- To decrease the negative impact of chemical exposure on workers' health in recycling plants.

Alternatives

The RoHS 2 Directive states that not only a substitution of a chemical should be taken into consideration but also a change of material or change of system ("*elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II*").

The alternatives that are applied for lead in electrical and electronic equipment (EEE), for example, do not have to be disclosed in the RoHS context.

Interrelationship with REACH

It is interesting to note that the legal controversy on the ban of decaBDE was also based on different decision schemes than under REACH? that were applied to justify an exemption under RoHS: [24] Whereas the justification of the exemption 9a on "DecaBDE in polymeric applications", published in the Commission Decision 2005/717/EC (13 October 2007), was based on risk assessment considerations, the European Court of Justice (ECJ) argued that according to RoHS a ban of a substance may only be lifted if no viable technical alternatives exist.

Lessons learnt from the RoHS directive example

An important aspect is that the RoHS directive, as common for other product-related regulations, is also applicable to imported products and hence provides a level playing field for all actors/companies in EU and non-EU.

A grouping of substances was introduced due to environmental and human health concerns in the waste phase and in order to strengthen recycling. However, the possibility of a further re-use after recycling was left open by applying for specific exemptions.

The availability and reliability of substitutes is given highest priority in further decisions on the restricted substances, e.g. as core criteria for granting an exemption of the restriction.

In retrospect, this grouping of substances based on end-of-life concerns can be considered as being ahead of its time compared to other provisions, e.g. as shown for the PBDE example.

[24] See the evaluation of exemption 9a in the Oeko-Institut report: Gensch, C.-O.; Zangl, S.; Groß, R.; Weber, A. in collaboration with Deubzer, O. (2009): Adaptation to scientific and technical progress under Directive 2002/95/EC. October 2007 – October 2008; Oeko-Institut e.V. in cooperation with Fraunhofer Institut für Zuverlässigkeit und Mikrointegration (IZM); Commissioned by: EU Commission, DG Environment, Brussels; https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IV/final_report_oeko-2009.pdf

4.5.2 Example 2: Substitution under the Detergent Regulation

Description of the legislation

The detergent regulation currently in force is Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents.[25] This regulation has been in force since 8 October 2005 and has replaced earlier legislative measures that already covered the requirement that surfactants should be biodegradable in order to protect the aquatic environment.

Scope

All detergents placed on the EU market must comply with this regulation; thus, it applies to imported products as well. This entails a level playing field between EU and non-EU manufacturers.

Initial trigger/initial concern to set up the provision

The recitals of the regulation explain that appropriate measures concerning detergents should ensure a high level of environmental protection, especially of the aquatic environment.

Therefore, the need to set up requirements on biodegradability for all surfactants arose because the former legislation only covered primary biodegradability and was only applicable to anionic and non-ionic surfactants. The main emphasis on ultimate biodegradability was explained to be due to concerns related to the potential toxicity of persistent metabolites.

Alternatives

The Detergents Ingredients Database (DID-list) Part A. List of Ingredients 2016[26] contains information about properties of surfactant. It compiles data on their acute and chronic toxicity as well as on degradation, readily biodegradability and possibility for anaerobic degradation. The DID-list was set up to calculate the critical dilution volume of detergents mainly in the context of ecolabels.

Interrelationship with REACH

The detergent regulation does not contain any reference to the REACH regulation, which is due to the fact that it was published and became effective before REACH.

Lessons learnt from the example

The detergent regulation is a result of a longer history of former, also national approaches on how to deal with detergents polluting the aquatic environment.

For this environmental emission scenario, a unique approach was set up that neither restricts certain surfactants nor bans for specific properties such as persistence and bioaccumulation, but that defines the substance property – in this case biodegradability - which is permitted. Biodegradability is required irrespective of other substance properties such as aquatic toxicity.

This product-related regulation also applies to imported products and therefore provides a level playing field.

[25] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32004R0648#document1

[26] https://ec.europa.eu/environment/ecolabel/documents/DID%20List%20PART%20A%202016%20FINAL.pdf

4.5.3 Example 3: Substitution under the Ecodesign Directive

Description of the legislation

The Ecodesign Directive 2009/125/EC[27] provides a framework for setting minimum mandatory requirements for energy-related products to improve the environmental performance of products and to reduce their energy and resource consumption.

Ecodesign, in principle, can define substance-related requirements (or benchmarks) for products that help to improve any of the following aspects in any life cycle phase:

- Consumption of materials, of energy and of other resources such as fresh water,
- Emissions to air, water or soil,
- Pollution through physical effects such as noise, vibration, radiation, electromagnetic fields,
- Generation of waste material,
- Possibilities for reuse, recycling and recovery of materials and/or energy.

For electronic displays and televisions, the Commission Regulation (EU) 2019/2021 has been published in the Official Journal of the European Union on 5.12.2019.[28] Considerations to strengthen circular economy und enhance the recycling of enclosures have for example led to a substance restriction for halogenated flame retardants.

Scope

The above-mentioned Commission regulation covers the placing on the market and putting into service of electronic displays, including televisions, monitors and digital signage displays. Thus, it applies to imported products as well.

The specific requirements are laid down in the Annexes,[29] where it is stipulated in section "D. Material Efficiency Requirements" that "*the use of halogenated flame retardants is not allowed in the enclosure and stand of electronic displays.*" The requirements shall apply from 1 March 2021.

Initial trigger/initial concern to set up the provisions

In its recitals, the Commission Regulation underlines the importance of using the Ecodesign framework to support the shift towards a more resource efficient and circular economy, arguing that appropriate non-energy-related requirements contributing to circular economy objectives should be laid down.

According to recital 15, the "presence of halogenated flame retardants represents a major issue in the recycling of plastics of electronic displays. Some halogenated compounds have been

[27] Directive 2009/125/EC, Annex 1, Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of Ecodesign requirements for energy-related products; https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009L0125

[28] COMMISSION REGULATION (EU) 2019/2021of 1 October 2019 laying down Ecodesign requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EC) No 642/2009; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.315.01.0241.01.ENG&toc=OJ:L:2019:315:TOC

[29] ANNEXES to the COMMISSION REGULATION (EU) .../...laying down Ecodesign requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008and repealing Commission Regulation (EC) 642/2009, Brussels, 1.10.2019 C(2019) 2122 final ANNEXES 1 to 5; https://ec.europa.eu/energy/sites/ener/files/documents/c-2019-2122_1_en_annexe_acte_autonome_part1_v6.pdf

restricted by Directive2011/65/EU because of their high toxicity but may be still found in old displays while others are still permitted. A monitoring of the maximum content of non-permitted compounds in recycled plastic is not cost-effective, which leads to them all being incinerated. Alternative solutions would exist for the bulk of the plastic part in an electronic display, such as the enclosure and the stand, permitting higher yields of recycled plastics. Use of halogenated flame retardants in these parts should be limited."

Further characteristics of the starting situation

The WEEE Directive[30] requires that plastics used in EEE containing brominated flame-retardants must be removed from any separately collected WEEE according to Annex VII on the selective treatment for materials and components of waste electrical and electronic equipment referred to in Article 8(2).

Interrelationship with REACH

Halogenated flame retardants comprise a large number of substances. The International Electrotechnical Commission provides an International Standard for the exchange of material composition data, the IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry. For substance groups in the "IEC Declarable Substance List", the IEC provides reference substances. For the substance group of brominated flame retardants (other than PBBs, PBDEs, or Hexabromocyclododecane), 63 substances are listed[31] that substantially differ in their molecular structure, e.g. Dibromo-propanol (CAS-Nr. 116499-75-3, 204570-16-1) and TBBPA (CAS-Nr. 79-94-7).

Thus, the grouping provided here based on waste-related considerations goes beyond grouping that has so far been applied in REACH, which is e.g. based on read across.

This restriction will also lead to a large phase out of diantimony trioxide which is used as a synergist of halogenated flame retardants. Diantimony trioxide has for some time been under regulatory scrutiny for its use in EEE.

Lessons learnt from the example

The restriction comprises halogenated flame retardants as a very large group of substances whereas under the European legal provisions such as RoHS, REACH and POP rather single substances are restricted.

Compared to restriction and authorisation under REACH, this restriction has to be considered as a unique short cut based on considerations relating to waste management and recycling.

The requirements apply to imported products as well, and therefore provide a level playing field for EU and non-EU manufacturers and service providers.

[30] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast); https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012L0019&from=EN, last viewed 02.07.2018

[31] http://std.iec.ch/iec62474/iec62474.nsf/Index?open&q=141329

4.5.4 Example 4: EU Ecolabel Regulation

Description of the legislation

The Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel[32] lays down rules for the **voluntary** EU Ecolabel scheme. Here it is described how environmental requirements shall be developed that products have to meet in order to carry the EU Ecolabel. The criteria for product groups are published in the form of Commission Decisions.

The regulation states that "the EU Ecolabel should aim at substituting hazardous substances by safer substances, wherever technically possible" (recital 7). Article 6 (6) stipulates that:

"The EU Ecolabel may not be awarded to goods containing substances or preparations/ mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (1), nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency."

Scope

The implementation of Article 6 (6) of the ecolabel regulation usually takes place by banning substances or mixtures that meet the criteria for classification of the CLP Regulation 1272/2008 for

- carcinogenic, mutagenic or toxic for reproduction,
- hazardous to the aquatic environment,
- acute toxicity, specific target organ toxicity, respiratory and skin sensitization.

Thus, the criteria for the products list the restricted hazard classifications (see e.g. for hard surface cleaners,[33] rinse-off cosmetic products[34] and paints and varnishes[35]).

Besides, the substances listed on the REACH Candidate List are banned as well.

Exemptions from the hazard classification for specific substances can be applied for, in the context of the EU Ecolabel; this is called derogation.

Initial trigger to set up the provision

The EU Ecolabel aims to promote products with a reduced environmental impact during their entire life cycle. The EU Ecolabel enables consumers to choose products with the best overall environment performance. Thereby, the EU Ecolabel shall provide an incentive for producers to make their production and products more sustainable and contribute to transform the EU market towards more sustainable products and services.

[32] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02010R0066-20171114

[33] Commission Decision (EU) 2017/1217of 23 June 2017establishing the EU Ecolabel criteria for hard surface cleaning products; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017D1217-20190315

[34] Commission Decision of 9 December 2014establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014D0893-20181023

[35] Commission Decision of 28 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014D0312-20180502

Alternatives

The Ecolabel regulation states that the substitution of hazardous substances by safer substances should include not only a change of chemicals, but that also a change of material or a change of system should be taken into consideration: "*the substitution of hazardous substances by safer substances, as such or via the use of alternative materials or designs, wherever it is technically feasible*".

Challenges in the substitution process

In case of unresolvable challenges in the substitution process, it is possible to grant a derogation from specific hazard statements. A derogation request is individually assessed, however, there are no further specifications in terms of criteria for the assessment.

For several product groups, derogations have been set in the development of the criteria e.g.

- for rinse off cosmetics, the functional substance groups surfactants, fragrances and preservatives are exempted from the obligation in Article 6(6) as well as for one specific substance (zinc pyrithione (CAS-Nr. 13463-41-7) used in anti-dandruff shampoos being classified for H400 Very toxic to aquatic life); the surfactants have a derogation for the environmental hazards of Category 3 and 4 (H412: Harmful to aquatic life with long-lasting effects and H413: May cause long-term adverse effects to aquatic life).

In hard surface cleaners, the derogated substances are surfactants and enzymes as well as one specific substance (NTA (Nitrilotriacetic acid, CAS-Nr. 139-13-9) as an impurity in MGDA (Trisodium dicarboxymethyl alaninate, CAS-Nr. 164462-16-2) and GLDA (Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate, CAS-Nr. 51981-21-6) exempted from the hazard statement H351 Suspected of causing cancer); surfactants here are derogated from a different hazard classification compared to the rinse-off cosmetics (H400 Very toxic to aquatic life and H412 Harmful to aquatic life with long- lasting effects) due to technical performance requirements of the cleaning product.

- For paint and varnishes, the derogations are complex and are set out in the Appendix where for substance groups, e.g. a certain preservative such as in-can preservatives, the scope of restriction and/or derogation is specified, also detailing concentration limits (where applicable).

An evaluation of the implementation of the EU Ecolabel regulation carried out in 2015[36] concluded that the provisions of the EU Ecolabel on hazardous substances hamper the acceptance by producers for some product groups and result in the situation that there are no license holders in some product groups, e.g. for computers and laptops:[37] The criterion on hazardous substances and mixtures in the product, sub-assemblies and component parts is a complex system providing the usual list of hazardous classifications that, however, applies to defined sub-assemblies and component parts as well as to substance groups. For some substance groups such as flame retardants and plasticizers, derogations are defined that cover some hazard classifications. Besides, there are additional substance restrictions specified for substance groups or materials. According to the evaluation report mentioned above, industry

[36] Nuttall, Chris; Gasbarro, Federica; Iraldo, Fabio; Nucci, Bennedetta; Paglialunga, Anna; Evans, Louise; Barberio, Michele; Rosenow, Jan (2017): Project to Support the Evaluation of the Implementation of the EU Ecolabel Regulation, Synthesis Report, October 2015; https://op.europa.eu/en/publication-detail/-/publication/67ba4716-5499-11e7-a5ca-01aa75ed71a1

[37] Commission Decision of 9 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for personal computers; https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32011D0337

reported these requirement *"to be both too stringent to be met and based on unfamiliar verification processes associated with hazardous classifications."*

Interrelationship with REACH

The only explicit link to the REACH regulation consists in the ban of the SVHCs of the Candidate List.

Lessons learnt form the example

Although the EU Ecolabel is a voluntary scheme, it is an example for directing substitution on a voluntary basis in order to avoid regrettable substitution. Instead of blacklisting individual substances, the EU Ecolabel is based on exclusion of specific hazard classifications that forms the benchmark for human health and the environment. A non-achievement of this benchmark needs an explicit permission by a derogation.

There are a number of license holders in product groups that have to be considered as mixtures in the sense of REACH and CLP, e.g. rinse-off cosmetics, hard surface cleaners and paints and varnishes. However, in product groups consisting of a number of sub-components (complex articles), it seems to be more difficult for industry to fulfill the requirements of the EU Ecolabel on hazardous substances. This demands a sufficient knowledge about the substances contained in the product. This knowledge is often not there.

4.5.5 Conclusions from the product-related legal provisions

The analysis of four legal product-related provisions has revealed different approaches to restrict the use of hazardous substances and to support their substitution. Some elements of these approaches are different from the current practice in REACH. They can stimulate the discussion on how to further improve substitution under REACH.

- The RoHS Directive and the Ecodesign Directive address large groups of substances, e.g. lead and all its compounds, all PBDE congeners and the whole group of brominated flame retardants.
- Adverse impacts for health and the environment during recovery and disposal of waste have been the initial concerns for restrictions of substances of concern in the RoHS Directive.
- Support of the transition to a more resource-efficient and circular economy has been an important objective of the Ecodesign Directive.
- Concerns related to the potential toxicity of persistent metabolites have been the initial concern to compile data on degradability in a Detergents Ingredients Database (DID-list). This allows direct comparison of detergents and calculation of critical dilution volumes.
- The Detergent Regulation defines criteria for a substance property which is allowed: the biodegradability. This is irrespective of other substance properties, e.g. aquatic toxicity.
- Voluntary schemes as the EU ecolabel aim to exclude and avoid not only substances of very high concern, but all substances classified as toxic, hazardous to the environment or CMR from getting this label.
- The requirements of these product-related legal provisions all apply to imported products as well and therefore provide a level playing field for EU and non-EU manufacturers and service provider.

5 Recommendations: How can REACH enhance substitution?

The analysis of the substitution examples in the previous chapter has shown many aspects that influence substitution processes in real life practise. Several obstacles for substitutions become visible as well as different triggers for substitution and manifold approaches to support substitutions.

This chapter contains recommendations on how REACH can provide stronger triggers and support for substitution than it does at present. They are based on the lessons learnt from the examples described above and arranged in the same order:

- REACH Restriction and Authorisation (section 4.2, 4.3);
- Substitution examples from the EU project Fit for REACH in the Baltic States (section 4.4) and
- Product-related regulations (section 4.5).

An additional recommendation to quantitatively monitor the impact/benefits of substitution is given based on the findings from the analysis of the present impact of REACH on substitution (chapter 3).

For a structured overview of all recommendations given below, see the summary and Figure 3 and Figure 4 at the beginning of this report (page 12ff).

5.1 Recommendation from the analysis of examples from REACH restrictions and authorisations

The following recommendations are targeted at policymakers/authorities. Most proposals should be feasible without the need of changes in the legal text of the REACH legislation. The emphasis would be on changing procedures and priorities, but would probably require EU agreement:

1. Work towards **a more efficient and quicker identification of SVHC and Candidate Listing** accelerating all related processes. This would require more resources, more stringent discussions and commitments from national authorities and ECHA/Commission to dedicate time to develop more Annex XV proposals for SVHC identification as well as CLH proposals under CLP. Important steps would be improved templates for Annex XV dossiers, a better quality of the data in the registration dossiers (including the PBT assessment), a more efficient process of the discussions in the MS committees and a more efficient handling of comments from public consultations if they are very comprehensive and repetitive.
2. Ensure already in registration dossiers that the **use categories are more specifically defined** by companies and indicate already the technical function of the substance, with documentation in the dissemination database. This makes it easier to identify substitutes. This is also of particular relevance for restrictions, for applications and for the granting of authorisation of substances which are intended for very specific uses rather than a broad variety of uses. A better overview is needed on substances on the market and their uses. This requires additional research – by the MS CA experts, ECHA or technical experts, supplementing the results from the public consultations.

3. **Grouping approaches should be used more frequently for the assessment and regulation of substances** (see also recommendation in Belgium SVHC roadmap study, rdc Environment 2019 and ECHA´s grouping approach to prioritise and de-prioritise substances of the 'the chemicals` universe'[38]). Regulation should not only address individual substances, but wherever possible groups of substances which share a common structure and which cause a similar level of concern. Examples are the grouping of bisphenols and the grouping of four phthalates in recent restrictions. The RoHS Directive as well as the Ecodesign Directive give further examples for an effective and far-reaching grouping approach (all PBDEs, the whole group of brominated flame retardants).

   This approach helps to avoid regrettable substitutions: the "drop-in-replacement" of substances by 1:1 alternatives which are similar in structure but have similar problematic properties as the substances used before. A grouping of substances facilitates a more extensive search for alternatives. The analysis of options for so-called "functional substitutions" goes beyond the technical function of a substance. It also considers the function of the materials produced using the respective chemical, and the final service that should be delivered (see section 1.9 for more details on functional substitutions).

4. Increase the use of the "fast-track" option for restrictions granted under Article 68(2). This provision has not been used very often so far and should be used more frequently.
5. Change the way SEA is being performed: a pure cost-benefit focus is too narrow and needs to be expanded to **include non-monetizable health benefits for society and environmental benefits** (see EEB restrictions report, EEB 2018) as well as discounting rates that include the potential damage to future generations (see also Arnold 2019). Remark: This topic has been analysed more in depth in work package 5.4 of the project "Advancing REACH". See the final report of this work package for details.
6. **Work towards a faster control of hd risks which have been identified in substance evaluation.** In many substance evaluations, the existence of risks has been established. However, no actual mandatory regulatory follow-up has been initiated for risk control after completion of the regulatory management option analysis (RMOA) (see EEB 2019). Such measures should be based on the results of the RMOA.
7. Explore and further develop **the concept of 'essential uses' and 'non-essential uses' under REACH with the aim to promote substitution of essential uses**. This approach to distinguish between essential uses and non-essential uses has been proposed by the Netherlands in the context of the PFAS restriction in December 2019 (see also Cousins et al. 2019).
8. Make **more use of the precautionary principle.** More weight should be given to the application of this principle as an argument in the overall assessment. Bisphenol A had been banned in the EU due to a restriction in baby bottles in 2011, after the precautionary principle had been invoked (as pointed out in the recent REACH review, EU 2018). Further examples are discussions of restrictions regarding microplastic and PFAS. Remark: The use of the precautionary principle within REACH has been analysed in more detail in work package 9 of the project "Advancing REACH". See report from this work package for details.

A further recommendation regarding a "centralised assessment of alternatives" has been developed in work package 5.4 on Authorisation in the project "Advancing REACH":

9. Implement an in-depth-assessment of alternatives to be conducted by authorities on an overarching level, e.g. as part of the RMOA. This would replace the present assessments

[38] https://echa.europa.eu/de/-/mapping-the-chemical-universe-list-of-substances-by-regulatory-action-published

carried out by applicants for authorisations which often aim to show that no suitable alternatives are available, which are technically and economically viable. This would require information provided by companies and additional research to be undertaken by the authorities or by independent technical experts. Under the Stockholm Convention, alternatives for persistent organic pollutants are systematically assessed. These results are published and globally available.

A number of activities which would strongly support substitution under REACH can be started on a national level:

10. Develop a national SVHC substitution strategy in order to develop options and criteria for substitution on a general level, to prioritise them and to track important substitution processes (see the example from Belgium, rdc Environment 2019).
11. Develop a national list of priority hazardous substances and groups. In the Netherlands, national policy is particularly focussing on priority substances of very high concern, the so-called ZZS substances. This is part of the program "The Netherlands circular in 2050". The Dutch ZZS substances cover a broader range than the SVHC under REACH (RIVM 2017).
12. **Encourage sector collaboration** to support companies in finding alternatives (see for example the initiative "vecco" on chrome plating)[39]. Collaborations should focus on delivering the function instead of just substituting the chemical (more details on functional substitution are given in chapter 1.1. and figure 3). Knowledge on successful "functional grouping approaches" should be promoted (see the following recommendation).
13. Use the concept of "Technical Readiness Level" for the assessment of alternatives. Assessment of the technological and economic feasibility of alternatives has become a large challenge in many examples of restrictions and authorisations. It would be extremely favourable if descriptions of alternatives always contained an indication of the use-specific **"Technical Readiness Level"** and the **"Economical Readiness Level"** for each potential alternative which has been assessed. Such a description could include a middle- and long-term projection and an explanation of factors, which determine the development of these levels.

Substitution of substances of concern is an important objective of REACH and of sustainable chemistry. Recently, an analysis has been performed regarding the relations between REACH and sustainable chemistry (work package 6 of the project "Advancing REACH". See final report of this work package for more details). It included a set of recommendations on how REACH could provide further support for sustainable chemistry. The following recommendations aim to support substitution, are in line and complement the recommendations given above:

14. Improve the quality of the data on the properties and uses of chemicals in registration dossiers and data bases.
15. Speed up the process of substance evaluation, as well as the processes of identification of SVHC and decisions on the most appropriate regulatory option (see recommendation 1 above) (e.g. by shortening the time periods needed for the assessment of results from additional tests which have been requested from the registrants);
16. Stronger promote knowledge about available substitutes for substances of concern in the supply chains and support the use of these substitutes. Authorisations should only be granted, if no substitutes are available (which are technically and economically feasible at the given time point and do not pose unacceptable hazards/risks to human health or environment). At present, many activities under REACH generate information on properties of potential alternatives to hazardous substances (registration and substance

[39] https://www.vecco.info

evaluation). 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 in economies in transition;

17. Support functional substitutions and avoid unregrettable substitutes by regulating not only individual substances one by one, but groups of substances which share a common structure, MOA and similar concerns (category approach) (see recommendation 3 above);
18. Improve the socio-economic assessment by addressing adverse effects to human 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 and improved. The precautionary principle should be applied to support the SEA. A stronger focus and weight should be given to the application of this principle as an argument in the overall assessment (see recommendation 5 and 8 above);

5.2 Recommendation from the analysis of substitution examples of substitution from the project LIFE Fit for REACH

Based on the experience of the project LIFE Fit for REACH for the Baltic States, a number of recommendations can be derived on how to support substitution processes, which are complementary to those in the previous section. In addition, the experience from the companies involved in the project put emphasis on the importance of supply chain communication and of a high quality of the data available to assess alternatives.

The core challenge of many substitution cases was the lack of suitable alternatives in terms of their technical performance and availability at acceptable costs. This suggests that higher substitution pressure, which would create larger markets for potential alternative suppliers, would further support substitution processes. This could **mean stronger regulation** in terms of restrictions and authorisation decisions as well as **targeted support to the development and placing of suitable alternatives on the market as well as penetrating the market with these alternatives**. The first two of the following recommendations address this core challenge;

19. Authorities should continue to work on the identification of SVHCs, because this already triggers substitution or elimination of these substances (see recommendation 1 above).
20. In all activities of authorities with companies the (role of) efficient and meaningful supply chain communication in chemicals risk management as well as creating business cases should be highlighted. Cooperation among competitors should be further strengthened in order, for example, to identify alternatives at sector level, but also along the supply chain as well as to support substitution also at technical level (see recommendation 12 above).
21. The data provided especially from the registration dossiers should be further improved; in several cases data was insufficient for classification or totally lacking, which creates uncertainties in the assessment and selection of alternatives; it may also result in regrettable substitution.
22. Safety data sheets continue to be a core information source for chemicals risk management. Their quality is essential both for identifying substitution needs (hazardous properties, uses advised against, worker protection information required risk management measures etc.) and potential alternatives. In many cases quality of safety data sheets needs further improvement.
23. Direct contacts between companies are an important motivational factor in chemicals risk reduction. Inspectors and potentially also industry associations should dedicate more resources to consulting companies on legal compliance, overall chemicals risk management and the identification of substitution priorities (see recommendation 12).

5.3 Recommendations from the analysis of product-related legal provisions

Product-related legal provisions use specific approaches to restrict hazardous substances in products. These approaches vary partly from the approaches used under REACH. Based on the findings from the descriptions of these provisions in section 4.5, the following recommendations can be provided. They aim at a strengthening of the trigger and support for substitution - under REACH and in the interplay with product legislation.

24. Cover a broad range of problematic substances by grouping substances of concern under REACH for assessment and regulation. The RoHS Directive as well as the Ecodesign Directive give examples for an effective and far-reaching grouping approach (all PBDEs, the whole group of brominated flame retardants).
25. Endorse the exchange between REACH and product group-specific legal provisions (e.g. RoHS for electrical and electronic equipment), thus taking greater account of the end-of-life phase in chemical safety assessments and in substance evaluations under REACH. REACH generates a large amount of information about critical substance properties and fate, about exposures and content in products. Key findings on critical properties (e.g. persistence, bioaccumulation, mobility, endocrine disrupting properties) should be presented to experts from product-related regulations. These legal provisions (e.g. the Detergents Directive) enable authorities by legislation to address specific properties (e.g. biodegradability) of concern independent of the combinations of properties which are laid down in REACH (e.g. REACH Annex XIII, persistence together with bioaccumulation (vPvB substances) or together with bioaccumulation and toxicity (PBT substances)).

26. Promote the exchange between REACH and voluntary product labels. This would facilitate the substitution of substances classified as toxic or hazardous for the environment, even if they do not meet the criteria for being classified as substances of very high concern. Consumer demands for harmless and toxic-free products play a role for certain product groups.

5.4 Recommendations from the analysis of the actual impact of REACH on substitution

Findings from the analysis of the actual impact of REACH on substitutions are described in Chapter 3 of this report. They allow to give a number of additional recommendations how REACH can further support substitution.

The interests of the market (e.g. demands of article producers for SVHC-free raw materials) and of financial investors are most probably the most important non-regulatory drivers for substitution. This leads to the following two recommendations:

27. Support measures to **raise awareness of consumers regarding the problem of substances of concern in articles** and to increase their demands for products free of these substances (e.g. the project AskREACH'[40])).
28. Support measures to **increase the interest of private financial investors in substitution**. They should consider in their investment decisions whether companies are working for and with better and safer alternatives or not.

The analysis of several studies containing information on the impact of REACH on substitution (for references see chapter 9.6.2 of this report) has shown that there is no data base with robust empirical evidence which would allow to track the success of substitution. At least for

[40] https://www.umweltbundesamt.de/en/topics/chemicals/reach-what-is-it/chemicals-in-articles-eu-life-project-askreach

substances of very high concern it would be important to know to which extend and in which sectors substitution takes place. This knowledge would be substantial to monitor the success of substitution measures and to identify areas where further activities are required. At present, only in Scandinavian countries a database on the amounts of chemicals and mixtures for specific uses already exists: the Nordic Product Registers and the related SPIN database. In order to track the success of substitution efforts, similar data would be of great significance (Sackmann et al. 2018, Bunke et al. 2020). In contrast to the Nordic Product Registers, it would not be necessary to receive such data for thousands of chemicals, but to focus on a limited number of substances to the substitution of which high priority should be given. This leads to the following recommendation:

29. For identified/defined priority substances of concern, information on production, import and export volumes should become available on a national level and EU wide (including data on these substances in articles). These figures should be provided for specifically/narrowly defined use categories. In order to obtain this information, a voluntary agreement between industry associations and authorities is recommended.

In addition, discussions of the analysis of several studies on REACH and substitution show the importance of best practice examples and of support of companies. This is reflected in the following recommendations:

30. Learning from best practice examples should be supported. This seems to be one of the most important support measures. It moves the focus of the discussions and activities to success stories of substitution. More business cases should be created. This stimulates further substitutions.
31. Companies who need help for the technical implementation of available substitution cases to their individual processes should get practical support and financial support. This should include information about possibilities to receive public funding for substitution activities.
32. Frontrunners should get incentives to share their knowledge on successful substitutions (e.g. fees for licenses). Solutions developed in research projects with public funding should be disseminated with creative common licences.
33. Companies who developed safer and better alternatives need assistance (with budgets and knowledge transfer) in the difficult phase of placing the alternatives in the market.

For a structured overview of all recommendations given above, see the summary and Figure 3 and Figure 4 at the beginning of this report (page 12ff).

5.5 Outlook

Enhancing substitution of substances of concern will remain a key challenge for chemicals management in the coming years and is a central aim/element of REACH. The analysis undertaken in the context of this report revealed some progress in substitution due to REACH and the other chemicals legislations, as well as a pressing need for additional efforts – on the part of authorities, industries, consumers as well as private investors.

ECHA's strategy to encourage substitution through innovation in favour of safer chemicals (ECHA 2018) consists of four action areas:

- capacity building;
- facilitating access to funding and technical support;

- facilitating the use of registration, classification and risk management data for sustainable substitution and
- development of networks related to the substitution of chemicals of concern.

The above recommendations derived from the case studies in the project "Advancing REACH" can directly be aligned to these action areas. This would support the implementation of these recommendations – on a European and on a national level. Successful promotion of substitution requires a public strategy and a strong cooperation with industry, downstream users, visionary companies, innovators and investors. The Belgian roadmap for substitution of SVHC, published in 2019 (rdc environment 2019), provides a very useful vision of what such a strategy could look like.

A national strategy will require years of discussion with all relevant stakeholders. Hard work and commitment in this regard is genuinely worthwhile. The same applies to a voluntary agreement with industry to notify national production volumes for priority substances of concern on an annual basis, similar to the SPIN database in Scandinavia.

In the meantime, many of the recommendations described above can be implemented in on-going processes in the short term. Examples are the inclusion of a technology readiness level in the next analysis of alternatives, an enhanced grouping of substances in restriction proposals, the provision of additional examples for the application of the concept of non-essential uses, or the efforts undertaken to raise consumer awareness, e.g. by the project AskREACH. All these activities are important steps towards an enhanced substitution of substances of concern – by better and safer alternatives.

Looking beyond individual chemicals and their uses, an assessment of benefits and risks should become a key step early in the design of new technologies and materials. This could reduce right from the beginning the need to look for better and safer alternatives.

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7 Annex: Detailed analysis of the examples

The following sections contain the detailed descriptions of the selected examples. The examples refer to the activities:

- Restriction under REACH (section 7.1, for a summary: see section 4.2 above);
- Authorisation under REACH (section 7.2, for a summary see section 4.3 above);
- the project LIFE Fit for REACH (section 7.3, or a summary see section 4.4 above) and
- four product-related legal provisions (RoHS Directive, Detergent Regulation, Ecodesign Directive and EU Ecolabel Regulation) (section 7.3, for a summary see section 4.5 above).

7.1 Restriction under REACH: examples of substitution

7.1.1 Example 1: Restriction of Bisphenol A in thermal paper

Restriction scope: Use of BPA (Bisphenol A, CAS-Nr. 80-05-7) in thermal paper (took effect on 2nd January 2020)

Dossier submitter: France (2014)

Decision: Commission decision in 2016 to restrict BPA in thermal paper in concentrations of 0.02 % or more by weight[41]

Initial trigger and Annex XV dossier: There have been many years of concern regarding BPA`s endocrine disrupting properties and effects on humans and wildlife. Following the identification of BPA as a compound toxic to reproduction and inclusion in the REACH Candidate List, France submitted a restriction dossier in 2014. The Annex XV dossier indicated a risk for workers (primarily cashiers) and consumers exposed to bisphenol A when handling thermal papers.

RAC opinion: RAC concluded in 2015 that the risk for consumers is adequately controlled but confirmed the risk for workers. [42] Moreover, RAC noted that bisphenol S (BPS), the most likely substitute according to France, may have a toxicological profile similar to BPA and might cause similar adverse health effects. Therefore, ECHA was tasked to monitor the use of BPS in thermal paper.

Impact of REACH: Substitution was triggered following the adoption of the restriction: An ECHA survey from 2018 showed that BPA is being replaced by BPS (Bisphenol S, CAS-Nr. 80-09-1) in thermal paper already before the official entry into force of the restriction in January 2020. [43] In March 2019 Belgium and ECHA hosted a workshop on alternatives for BPA in thermal paper. [44] The workshop focused on the alternatives available, e.g. whether there are any suspected issues related to their safety and the challenges for the supply chain in adopting them.

Changes in monitoring trends: It is probably too early to evaluate the impact of this restriction in terms of human and environmental exposures. Also, in future it will be difficult to assess the specific contribution of this restriction as there are many other uses of BPA resulting in human and environment exposure.

[41] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R2235&from=EN

[42] https://echa.europa.eu/documents/10162/30eddda4-b27c-659e-d6d2-7b8ef02320a9

[43] https://echa.europa.eu/de/-/bpa-being-replaced-by-bps-in-thermal-paper-echa-survey-finds

[44] https://www.health.belgium.be/en/supply-chain-substitution-workshop-alternatives-bisphenol-thermal-paper

Ideas for a stronger substitution support by REACH: The substitution incentive would be stronger if more uses were covered and also substances with equally concerning properties were included. If the restriction had addressed similar bisphenols in a group approach the substitution by e.g. BPS in thermal paper could have been prevented[45,46]

Current state of play: Currently BPA is still on the market for many applications and further restrictions are under investigation. Germany has submitted a CLH dossier to update the harmonised classification. [47] Belgium has meanwhile started the classification process for identifying BPS as a substance toxic to reproduction[48], while still continuing the CoRAP process.

Alternatives available: As ECHA states, alternative developers are available such as BPS Pergafast® 201 and D8. [49] Given the uncertainties regarding the potentially harmful properties, ECHA recommends companies to also consider technologies and innovations that could remove the need for bisphenols, phenols or non-phenolic substances when developing thermal paper.

Lessons learnt: The restriction is effective in driving the replacement of BPA, but in many cases probably to similarly problematic substances, despite early indications from RAC during the opinion development. The scope is very narrow and further restrictions might be needed for other applications and exposure routes, as currently evaluated by UBA. Discussions of the supply chain actors for various alternatives are ongoing. Grouping approaches could be helpful (but not in all cases – hazardous properties of potential alternatives have to be flagged/considered early!)

7.1.2 Example 2: Restriction of PFOA and its salts

Restriction scope: Production, placing on the market and use of PFOA (Perfluorooctanoic acid, CAS-Nr. 335-67-1) and its salts and related substances (July 2020 effect date for production, transition periods for specific uses are detailed in the restriction[50])

Dossier submitter: Germany and Norway (2014)

Decision: Commission restriction published in June 2017[51]

Initial trigger and Annex XV dossier: For many years there have been concerns regarding the PBT properties and widespread use in applications, such as special finishing to textiles and paper to achieve water, grease, oil and/or dirt repellency. The first discussion on an EU restriction for PFOA already took place in 2006 in the context of the EU PFOS restriction. In 2013, PFOA was identified as a Substances of Very High Concern (SVHC) because of its persistence, bioaccumulative and toxic property (PBT), and was included in the Candidate List. In June 2017, over 10 years after the first EU discussion, the restriction on PFOA and its salts and related substances was published in the EU Official journal.

RAC and SEAC opinion: RAC proposed two different concentration limits: namely 25 ppb for PFOA and its salts and 1 000 ppb for one or a combination of PFOA-related substances, in other substances, mixtures or articles, reflecting the possible presence of unavoidable impurities and

[45] https://www.chemtrust.org/wp-content/uploads/chemtrust-toxicsoup-mar-18.pdf

[46] https://www.kemi.se/en/news-from-the-swedish-chemicals-agency/2017/new-report-37-bisphenols-may-be-endocrine-disruptors/

[47] https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18280184f

[48] https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e182ed4414

[49] https://newsletter.echa.europa.eu/home/-/newsletter/entry/moving-away-from-bpa-in-thermal-paper

[50] https://echa.europa.eu/documents/10162/7a04b630-e00a-a9c5-bc85-0de793f6643c

[51] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1000&from=EN

unintended contaminants, and taking account of the capabilities of analytical methods. SEAC agreed with the approach and with the exemptions proposed by RAC and suggested several referral periods to allow the sectors time for transitions. The restriction also exempts the unavoidable production of PFOA during the manufacture of fluorochemicals with a carbon chain equal to or shorter than six atoms. The concentration limits were criticized as too high by NGOs who also criticized the exemptions as being counterproductive to achieve a strong substitution trigger. [52]

Impact of REACH: Substitution was triggered following the announcement of the restriction and other substances were used instead of PFOA, mostly short chained PFAS. It can be assumed that also the process of listing PFOA under Stockholm convention will have added to this effect, as discussions have been going on for many years in parallel.

Changes in monitoring trends: It is still too early for a final judgement, but some research papers have found a slight decline in PFOS and PFOA in wildlife. [53] On the other hand, levels of short-chain PFAS are on the rise. Moreover, the knowledge about impacts from aggregate exposures is increasing, which is currently neglected in the risk assessments of the individual substances, as highlighted by the RIVM. [54]

Ideas for a stronger substitution support by REACH: In order to trigger substitution at a larger scale, a broad restriction covering the whole group of PFAS chemicals was recommended (see below). Following the regulatory focus on PFOA, industry has moved to short chain replacements like GenX and PFBS, both identified as SVHC in 2019. In addition, it would be desirable to consider combined effects from compounds in same groups to better protect environment and health. Research has highlighted known co-exposures of several PFAS substances to ecosystems and humans. [55]

Current state of play: In December 2019, the Netherlands have announced to consider a REACH restriction for all non-essential uses of PFAS. [56] Meanwhile Germany has submitted a restriction proposal for undecafluorohexanoic acid (PFHxA), its salts and related substances. Norway plans to restrict Perfluorohexane-1-sulphonic acid, its salts and related substances.

Lessons learnt: The PFOA restriction achieved a reduction of PFOA uses and applications, but the problem has now shifted to increasing exposure to short- chain PFAS. Discussions for a restriction of non-essential uses of the class of PFAS chemicals are ongoing at EU level. The development of a concept for only allowing `essential uses` could become an interesting new angle for triggering substitution efforts more efficiently.

7.1.3 Example 3: Restriction of four phthalates (DEHP, DBP, BBP and DIBP) in certain consumer articles

Restriction scope: Use of bis(2-ethylhexyl) phthalate (DEHP, CAS-Nr. 117-81-7), dibutyl phthalate (DBP, CAS-Nr. 84-74-2), benzyl butyl phthalate (BBP, CAS-Nr. 85-68-7) and diisobutyl phthalate (DIBP, CAS-Nr. 84-69-5) when present in any plasticised material in articles at a concentration, individually or in any combination, equal to or greater than 0,1 % by weight of any of such material.

[52] EEB Report: Restricted success, 2017

[53] CHEM Trust PFAS briefing, 2019, https://chemtrust.org/wp-content/uploads/PFAS_Brief_CHEMTrust_2019.pdf

[54] https://www.rivm.nl/bibliotheek/rapporten/2018-0070.pdf

[55] https://www.healthandenvironment.org/assets/images/Conley_1-15-2020_webinar_slides.pdf

[56] https://www.endseurope.com/article/1669232/netherlands-working-proposal-ban-pfas-europe

Dossier submitter: ECHA (in cooperation with Denmark), 2016

Decision: The restriction relating to DEHP, DBP, BBP and DIBP was published in December 2018. [57] The Commission concluded that the four phthalates pose an unacceptable risk to human health when present in any plasticised material in articles at a concentration, individually or in any combination, equal to or greater than 0,1 % by weight of any of such material.

Initial trigger and Annex XV dossier: There had been longstanding concerns about endocrine disrupting and reprotoxic effects of these substances. All 4 phthalates are already on Annex XIV with a sunset date of 21 February 2015. The restriction dossier aims at restricting the use in relevant consumer articles. The dossier built on an earlier restriction proposal from Denmark from 2011. New human biomonitoring data from Democophes project supported the concern and became the basis for the joint restriction for 4 phthalates. RAC considered that a restriction related to the combined concentration of the four phthalates is needed to address the risk to human health.

Impact of REACH: While it is not easy to determine the exact trigger for substitution (in some case the classification or identification as SVHC, or the inclusion in Annex XIV) it was found that the use in certain phthalates dropped over the last years. This new restriction covers the gap also for the use of 4 phthalates in any plasticised material in articles.

Changes in monitoring trends: Although the use of certain phthalates have been replaced, the majority of the plasticizer`s market is still phthalates compounds, e.g. phthalates such as DINP, DPHP and DIDP are still produced in the EU and used in many applications. For example, DEHP is nowadays much less used in EU but in the rest of the world, DEHP continues to be the dominant plasticizer (still 70% of global production).[58] Human biomonitoring data for children in Germany showed decreasing trends for DEHP and other phthalates but an increase in other phthalates like DPHP (di-(2-propylheptyl) phthalate).[59]

Ideas for a stronger substitution support by REACH: The effectiveness of this restriction to trigger substitution could be increased by broadening the scope. They are at present not covered (despite the RA showing large exposure from diet)(Additional uptake of phthalates can origin from the food itself which can contain these substances[60]) This omission had been criticized by some NGOs as ineffective and incoherent as there will not be any subsequent substitution trigger for these phthalates in FCM. **Current state of play:** There are several other reprotoxic phthalates on the REACH Candidate List and on Annex XIV.

Lessons learnt: Human biomonitoring data can be used to strengthen a restriction proposal, in particular when using a group approach to address combined exposures of similarly acting substances. The scope of the restriction proposal should include all significant exposure routes identified.

7.1.4 Example 4: Restriction of D4/D5 in rinse-off cosmetics

Restriction scope: Octamethylcyclotetrasiloxane (D4, CAS-Nr. 556-67-2) and decamethylcyclopentasiloxane (D5, CAS-Nr. 541-02-6) in wash-off cosmetic products in a

[57] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R2005&from=EN

[58] https://chemsec.org/app/uploads/2019/09/Replacing-Phthalates-%E2%80%93-ChemSec-190911.pdf

[59] https://www.sciencedirect.com/science/article/pii/S1438463919306066

[60] for details see https://www.bfr.bund.de/de/presseinformation/2013/13/weichmacher_dehp_wird_hauptsaechlich_ueber_lebensmittel_aufgenommen-186791.html

concentration equal to or greater than 0.1 % by weight of either substance, after 31 January 2020. [61]

Dossier submitter: UK (2015)

Decision: The Commission published the restriction in January 2018 following SEAC`s opinion that this is the appropriate Union-wide measure to reduce the discharge of D4 and D5 to wastewater in terms of its socioeconomic benefits and its socioeconomic costs

Initial trigger and Annex XV dossier: There have been long-standing concerns about persistence and bioaccumulation about these substances. In March 2016 RAC concluded that D4 meets the REACH criteria as PBT and vPvB substance and that D5 fulfils the criteria for the identification of a vPvB substance. RAC confirmed that the hazard properties of D4 and D5 give rise to specific concerns for the environment when present in cosmetic products that are used or disposed of with water. It also concluded that the proposed restriction is a targeted and appropriate Union-wide measure to minimize emissions caused by washed off products.

Impact of REACH: The regulatory discussions and restriction triggered substitution, as can be seen from advertisements for alternatives. [62]

Changes in monitoring trends: It is rather too early for a detailed assessment and little data are available. The silicone industry claims that recent monitoring data show decreasing trends of D4 and D5 in wastewater.[63]

Ideas for a stronger substitution support by REACH: The current restriction scope was very narrow in terms of substances and uses covered. Therefore, ECHA has started an additional restriction process.

Current state of play: In June 2018 D4, D5 and D6 (Dodecamethylcyclohexasiloxane, CAS-Nr. 541-02-6) were identified as SVHCs and included in the REACH Candidate List. Subsequently ECHA has proposed a restriction to restrict the placing on the market of D4, D5 and D6 as substances, as constituents of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w of each substance. The committee opinions are scheduled for March 2020. [64]

Lessons learnt: Important to avoid a too narrow scope of a restriction, otherwise additional restriction processes might be needed.

7.2 Authorisation under REACH: examples of substitution

7.2.1 Example 1: Musk xylene (CAS-Nr. 81-15-2)[65]

Dossier submitter: The Netherlands

SVHC property: vPvB

Date of inclusion in Candidate List and Annex XIV: 28.10.2008 and 17.2.2011

Sunset date: 21.8.2014

[61] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0035&from=EN

[62] https://www.cosmeticsandtoiletries.com/formulating/category/haircare/Replacements-for-Silicone-in-Shampoo-Formulations-393431431.html

[63] https://www.silicones.eu/industry-update/echa-committees-should-take-into-account-recent-monitoring-data-during-their-upcoming-evaluation-of-d4-d5-and-d6/

[64] https://echa.europa.eu/documents/10162/1705e46e-0629-f177-d109-ffd208fccbec

[65] https://echa.europa.eu/substance-information/-/substanceinfo/100.001.210

Trends observed in SPIN database: very low volumes indicate that musk xylene is used in very low percentages in products or that data on tonnage are confidential (see page 31 of Danish report)

Authorization applications received: none[66]

Ideas for a stronger substitution support by REACH: potentially an investigation of likely replacement from the same or similar chemical group

Lessons learnt: No authorization applications have been submitted, i.e. substitution has taken place and remaining uses (if any) are very small.

7.2.2 Example 2: TCEP (Tris(2-chloroethyl) phosphate, CAS-Nr. 115-96-8)[67]

Dossier submitter: Austria

SVHC property: Toxic to reproduction

Date of inclusion in Candidate List and Annex XIV: 13.1.2010 and 14.8.2012

Sunset date: 21.8.2015

Trends observed in SPIN database: no data in the SPIN database

Authorisation applications received: none

Ideas for a stronger substitution support by REACH: According to the RMOA the substance is used as an additive plasticizer with the function of a flame retardant. ECHA's screening assessment identified a risk for children from exposure to the flame retardants TCEP, TCPP and TDCP in flexible polyurethane (PUR) foams in childcare articles and residential upholstered furniture. The Commission requested ECHA to prepare a restriction proposal which is now pending as ECHA has withdrawn its original restriction intention in summer 2019) [68]

Lessons learnt: Following the identification as an SVHC and inclusion in Annex XIV it can still be needed to adopt an additional restriction to cover the uses in imported articles in order to ensure protection.

7.2.3 Example 3: DEHP (Bis(2-ethylhexyl) phthalate, CAS-Nr. 117-81-7)[69]

Dossier submitter: Sweden

SVHC property: Toxic to reproduction and endocrine disruption

Date of inclusion in Candidate List and Annex XIV: 28.10.2008 and 17.2.2011

Sunset date: 21.2.2015

Trends observed in SPIN database: Clear decrease in use (p.33). The first important trigger was the harmonised classification for reprotoxicity). This had also been reported in previous studies such as the report `Driving innovation`.[70]

[66] https://echa.europa.eu/received-applications

[67] https://echa.europa.eu/substance-information/-/substanceinfo/100.003.744

[68] https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e1829a30b8

[69] https://echa.europa.eu/substance-information/-/substanceinfo/100.003.829

[70] Baskut Tunkat. Driving Innovation. How stronger laws help bring safer chemicals to market. Center for International Environmental Law (CIEL), 2013. *http://www.ciel.org/Publications/Innovation_Chemical_Feb2013pdf*

Authorisation applications received: Yes, and granted for use in PVC in recycled consumer products. ECHA website shows 9 authorised uses for DEHP in total (January 2020).[71]

Ideas for a stronger substitution support by REACH: There is currently a mismatch between granting authorisations and the desire to create a circular economy (risk of double standards).

Lessons learnt: Additional restriction was decided necessary to cover the use in plastic products (see restriction example of 4 phthalates in consumer plastic articles).

7.2.4 Example 4: Octylphenol ethoxylates[72]

Dossier submitter: Germany

SVHC property: Endocrine disruption (for the environment)

Date of inclusion in Candidate List and Annex XIV: 19.12. 2012 and 13.6.2017

Sunset date: 4.1.2021

Trends observed in SPIN database: decreasing uses except for Sweden (but inclusion in Annex XIV was after the investigated period).

Authorisation applications received: 37 (January 2020)[73]

Ideas for a stronger substitution support by REACH: It could be desirable to shorten the regulatory processes because it took 9 years from the inclusion in the Candidate List and the sunset date.

Lessons learnt: still to come! It might become an important test case for the consideration of a non-threshold substance with endocrine disrupting properties in the assessment and decisions on authorisation applications.

7.3 Project LIFE Fit for REACH: examples of substitution

7.3.1 Example 1: Substitution of methylene chloride in polyurethane foam production

Name of substance: methylene dichloride (CAS 75-09-2); dichloromethane

Specific function: cleaning agent; methylene chloride is used to clean a filling and dosing station of pre-polymers for the production of PU-foams.

Company information: The company produces construction products and employs 76 persons. Its management system is certified according to ISO 9001, ISO 14001 and OHSAS 18001 standards.

Initial trigger / initial concern to search for alternatives: workers protection, classification as suspected carcinogen, restriction under REACH Annex XVII for paint strippers (indication of potential further regulation)

Further characteristics of the starting situation: Various parts of the pre-polymer dosing system have to be cleaned. Due to high adhesiveness and low solubility of the pre-polymer materials, the cleaning agents must be strong and require time to act (up to 60 hours). An increase of the cleaning time would potentially lead to decreases in the production capacity.

[71] https://echa.europa.eu/du-66-notifications

[72] https://echa.europa.eu/substance-information/-/substanceinfo/100.239.147

[73] https://echa.europa.eu/received-applications

Alternatives which have been assessed: six alternative mixtures for cleaning were tested at laboratory scale. Of these, one was selected for testing in the production line. All alternatives were found to require longer cleaning times, to have worse cleaning results for the dried residues and to be associated with higher costs.

Alternative chosen: The originally chosen alternative had been removed from the market after change of the ownership of the producing company. A second alternative was then selected, tested and is now used.

Challenges in the substitution process: A longer cleaning time is necessary for the alternative to achieve a comparable result. This is compensated by heating the alternative product during the cleaning process. This increased odours, which are a nuisance to the employees and therefore, improvements in ventilation were needed.

Impact of REACH: The classification of methylene chloride and the related workers exposure triggered the substitution process. The fact that methylene chloride is on the CoRAP further enhances the substitution pressure due to an expectance of potential regulatory action.
The safety data sheet was an important source of information in the identification and assessment of alternatives; hence good quality of these documents supports substitution (and prevents regrettable substitution).

Options to improve the process: In this case, no alternatives were available that provide an equal functionality and performance to methylene chloride. Hence, incentives to develop alternatives for methylene chloride as cleaning agent would be helpful for the company.

Ideas for a stronger substitution support by REACH: Inclusion of methylene chloride on the Candidate List and potentially also on REACH Annex XIV would initiate a collective search for alternatives and related market demands, which would potentially also enhance research in developing suitable alternatives.

Lessons learnt from the example: substitution may be triggered by classification and workers protection issues. Suitable alternatives may not be available and their development may require a critical demand/market perspective for alternatives producers. Alternatives may require changes in the process (heating) and have other disadvantages (odour).

7.3.2 Example 2: Substitution of BPA in metal cans for dairy products

Name of substance: bisphenol A (BPA, CAS 80-05-7)

Specific function: Component of epoxy resins which are used as can coating and linings.

Company information: The company produces dairy products. As part of their activities, they use pre-manufactured metal cans to fill canned milk and seal them. Here, a BPA-containing epoxy resin was used for the can lining.

Initial trigger / initial concern to search for alternatives: the decision to substitute had two steps: first – the French ban of BPA in all foodstuffs and later the stricter migration limit value under the EU food contact materials legislation. While the French ban resulted in a partial change to other coatings (just for French customers), the change at EU level initiated the change of the entire production to a BPA-free alternative. Also, the fact that BPA is being discussed for (further) regulation under REACH played a role in the decision making.

Further characteristics of the starting situation: No specific characteristics.

Alternatives which have been assessed: several alternatives were assessed that were provided by different producers on the EU market, ranging from the use of different mixtures to

entirely changing the type of packaging materials (e.g. to glass). The company assessed SDSs, information from ECHA's databases (evaluated as helpful) and available literature. It experienced that communication with alternatives suppliers was cumbersome and slow, even answering requests for SDSs. Several alternatives were tested but proved to be problematic for different reasons, including release of (other) hazardous substances, reduced shelf-life of the product and technical incompatibilities of materials. The final selection of the alternatives was based on the results from performance testing.

Alternative chosen: Solution 1: The epoxy resin-based lacquer for the can is replaced by a resin based on benzoguanamine formaldehyde.
Solution 2: Procurement of already (non-BPA-based) pre-coated metals, i.e. omitting the lacquering at site.
Solution 3: For the can caps, an alternative supplier was identified whose caps are based on a vinyl-organosol lacquer.
Solution 4: The side stripe lacquer has been successfully replaced by a solid (powder) polyester-based coating. A switch to a new equipment was needed.

Challenges in the substitution process: there were a number of challenges, including a lack of (sufficient data to assess) suitable alternatives, slow communication, compatibility of coatings with the (existing) equipment, challenges in sourcing and with customer demands (e.g. regarding the colour of the coating), incompatibility of coatings with the milk (resulting in changed shelf-lives of the product) and last but not least substitution costs.

Impact of REACH: The main trigger for substitution came from other legislation. Information provided under and due to REACH helped assessing alternatives.

Options to improve the process: better communication with alternative suppliers and swifter supply of (safety) information.

Ideas for a stronger substitution support by REACH: a comprehensive restriction of the use of BPA and potentially the group of bisphenols could lead to the development of more and cheaper as well as better-performing alternatives to BPA – containing chemicals; this would have supported the substitution process.

Lessons learnt from the example: REACH can support substitution decisions that are triggered by obligations under other legislation. Information generated under REACH is useful for alternatives assessment. Comprehensive (group) restrictions may support the development of better and safer alternatives and could hence also enhance substitution and avoid regrettable substitution. Substitution of chemicals may require changes in processing.

7.3.3 Example 3: Substitution of ethanol in winter windshield agents

Name of substance: Ethanol (CAS 64-17-5)

Specific function: Anti-freezing agent in windshield wiping agents

Company information: The company produces household chemicals, car chemicals and cleaning products. It produces powdered and liquid products and also has some eco-labelled product lines.

Initial trigger / initial concern to search for alternatives: The company policy aims to use only substances that are safe to human health and the environment. Substitution should avoid classification of products and increase safety during transport and storage.

Further characteristics of the starting situation: pre-condition that the price of the possible alternative should be similar to that of ethanol.

Alternatives which have been assessed: Several substances were assessed as alternatives, including propylene glycol (CAS 57-55-6), butylal (CAS 2568-90-3), butyl diglycol (CAS 112-34-5), methanol (CAS 67-56-1), propanol (CAS 71-23-8), isopropanol (CAS 67-63-0), butanol (CAS 71-36-3), pentanol (CAS 71-41-0), polyvinyl alcohol (CAS 9002-89-5).
The assessment criteria were: good cleaning properties, good evaporation rate (i.e. no blurs remaining on the windshield after wiping), low density and viscosity, absence of sensitising or irritating and lower flammability than ethanol, lack of dissolution of plastics, freezing point below -21°C, acceptable prices.

Alternative chosen: a recipe was developed using propylene glycol (CAS 57-55-6). Practical tests showed that the windshield wiping agent did not evaporate at a sufficient rate, resulting in decreased visibility for the driver. In addition, the product costs increased considerably. As a consequence, the substitution process was stopped.

Challenges in the substitution process: No suitable alternative with less hazardous properties and a similar technical performance as ethanol was found.

Impact of REACH: the trigger to substitute was classification; the alternatives have been identified long time ago; hence, REACH did not have an impact on the process

Options to improve the process: No improvement opportunities identified in this case

Ideas for a stronger substitution support by REACH: No support options by REACH identified

Lessons learnt from the example: Substitution may not be possible and implemented in practise within the existing technology path.

7.3.4 Example 4: Substitution of sodium perborate in washing agents

Name of substance: Sodium perborate (CAS 15120-21-5)

Specific function: Bleaching agent in washing powders and washing liquids

Company information: The company produces household chemicals, car chemicals and cleaning products. It produces powdered and liquid products and also has some eco-labelled product lines.

Initial trigger / initial concern to search for alternatives: The company policy aims to use only substances that are safe to human health and the environment. Sodium perborate is included on the REACH Candidate List as reprotoxic.

Further characteristics of the starting situation: In parallel, sodium carbonates were assessed for phase-out.

Alternatives which have been assessed: Hypochlorites (CAS 14380-61-1), Peracetates, Enzymes (CAS 9000-90-2; CAS 9014-01-1), Carbonates (CAS 3812-32-6), acidic and alkali salts (citrates, tartrates, carbonates). Assessment criteria were:

Good stain removal from fabric of any colour (or of no colour)

No damaging properties to the fabric or colour

Usability range from: 30–60 ˚C, or even better 20–90 ˚C

High water solubility, also in hard water

Low costs

Low hazard profile to the environment and human health

Alternative chosen: A combination of specific enzymes, citrates and percarbonate was selected as alternative.

Challenges in the substitution process: Long testing phase to achieve a satisfactory technical performance

Impact of REACH: REACH was an additional trigger to substitute the substances and enhanced the implementation of the company policy to use only safe chemicals. The potential inclusion of perborates into the authorisation list did not play an important role. However, customers also demanded substitution which was considered in priority setting on substitution. The company used ECHA's database of registered substances with respect to hazard data to support their evaluation of alternatives.

Options to improve the process: for the company the availability of internal experts that could compose new recipes with the alternative substances was crucial. No communication or other processes were actually needed.

Ideas for a stronger substitution support by REACH: There were no aspects identified how REACH could have more strongly supported the process.

Lessons learnt from the example: The Candidate List is a powerful trigger for substitution, because it helps companies in priority setting and customers start requesting the use of products free from SVHC. An immediate inclusion of an SVHC into Annex XIV is not always needed to initiate substitution; classification may already be a sufficient trigger. In short supply chains and in the manufacture of chemical products, a complex communication may not be necessary.

7.3.5 Example 5: Substitution of a phthalate and an organotin compound in sealants

Name of substance: Di-isononylphthalate (DINP, CAS 28553-12-0); dibutyltin dilaurate (DBTL, CAS 77-58-7)

Specific functions: DINP: plasticiser, DBTL: catalyst

Company information: The company formulates construction products, in particular sealants and adhesives. It has approximately 100 employees and the products are exported both to the EU and the global market.

Initial trigger / initial concern to search for alternatives:
DINP is restricted for (other) uses; at present and according to ECHA notifications, the substance is not classified but there are indications that DINP may be an endocrine disrupter.
DBTL is classified as reprotoxic and skin sensitizer and may also be an endocrine disrupting chemical. Hence, there is a risk of it being identified as an SVHC

Further characteristics of the starting situation: The sealant is a construction product and hence requires conformity assessments under the Construction Products Regulation. As it is used to affix glass within insulation windows, changes in the formulation require conformity assessment of the final product. The company also exports to France, which has stricter requirements on the products and hence, these requirements were used for performance testing.

Alternatives which have been assessed: for DINP: DINCH (CAS 166412-78-8) and for DBTL: dioctyltin dilaurate (CAS 3648-18-8). No additional alternatives were assessed. The assessment criteria were:

Product quality: comparable technical parameters as current products

Handling during use should be unchanged, i.e. viscosity or curing speed should be similar

Alternatives are no SVHC and are less hazardous than current substances

Production costs should not increase

Alternative chosen: DINP has been substituted by DINCH and dibutyltin dilaurate was substituted by dioctyltin dilaurate.

Challenges in the substitution process: Large number of tests had to be conducted to identify and adapt the quality of the product. The research laboratory invested significant shares of their resources into the re-formulation process.

Impact of REACH: REACH was the core driver of the process, as the company policy includes to avoid the use of SVHC. Furthermore, customers of the company increasingly demand products free of SVHCs if the quality level can be maintained with the substitute.

Options to improve the process: No options for improvement were identified

Ideas for a stronger substitution support by REACH: data for dioctyltin dilaurate is lacking or not sufficient for classification. Therefore, there is some uncertainty on whether or not this alternative is actually better and safer than DBTL.

Lessons learnt from the example: The Candidate List as well as the CoRAP-list and following substance evaluations with respect to the identification of substances as SVHC (e.g. endocrine disruption) raise awareness and are integrated early into the companies' decision making. The ECHA registration database as well as the inventory for classifications is generally useful to assess alternatives but sufficient information is often missing in particular for low-volume chemicals. This is a challenge for the assessment of hazards and risks and also the suitability of alternatives.

7.3.6 Example 6: Reuse of production wastes from polyurethane foams

Name of substance: MDI (Methylene diphenyl diisocyanate, CAS 101-68-8), polyols, polyurethane foams; use reduction "cross-company"

Specific function: use as/for construction products

Company information: The medium-sized company produces construction products and has certified management systems.

Initial trigger / initial concern to search for alternatives: the idea of the company was to reduce waste from polyurethane production by introducing improved quality control of the constituting substances, namely the polyols and identifying a market for the (still) remaining (extruded) solid polyurethane wastes that cannot be reduced.

Further characteristics of the starting situation: Some potential uses of the waste foams had already been identified.

Alternatives which have been assessed: the company researched different options to use the production wastes, which have a defined composition, in other sectors and for different uses, such as filler materials in flooring etc. Finally, no market for the material could be created and the company chose to optimise their process.

Alternative chosen: Optimization of the process control and improved timing of product quality monitoring resulted in lower amounts of production wastes.

Challenges in the substitution process: ensuring regular quality control requires high competences and sufficient (laboratory) capacities; hence own equipment was needed and

scientific support in the development of the necessary analytical methodology. Due to lack of knowledge on how solid production wastes can be used in other sectors, it was difficult to find a "starting point" for opening a new market. PU foams change the fire safety of the intended products (use in concrete) and could hence not be used (indirect use restriction due to fire safety).

Impact of REACH: The process was driven by resource concerns.

Options to improve the process: A transparent marketplace for the reuse of production wastes does not exist; this might be an option for implementation under the circular economy work of the EU Commission rather than under REACH. However, clarification of the status of waste materials and/or the need to register and/or provide information with the products is necessary.

Ideas for a stronger substitution support by REACH: part of the factors influencing the amount of production wastes were changing qualities of the input materials (i.e. purity and concentration ranges of substances in the MDI and polyol mixtures). If the definitions of these substances were tighter, these fluctuations in composition might be lower. It is unclear if this is a problem at larger scale.

Lessons learnt from the example: Use reduction is one way to decrease environmental burdens from hazardous chemicals. To make production wastes available to other companies, a marketplace would be needed as well as a clarification of registration obligations (and/or exemptions) as well as knowledge on the ingredients of these waste.

7.3.7 Example 7: Substitution of nonylphenol in epoxy floorings

Name of substance: Nonylphenol (CAS 25154-52-3) is a suspected PBT/vPvB, very toxic to aquatic life, suspected of damaging fertility and the unborn child, and an EDC

Specific function: part of the curing component of a flooring lacquer

Company information: The company produces construction products, mainly in the area of epoxy resin flooring materials. It employs 3 persons (micro enterprise).

Initial trigger / initial concern to search for alternatives: Candidate listing of nonylphenols and a reduced availability of other product components (although not being restricted and/or hazardous) required reformulation of the product.

Further characteristics of the starting situation: Nonylphenols were included in the Candidate List for authorisation in 2012. The REACH Annex XVII restrictions are not relevant for the specific case. The company expected that phasing out nonylphenols from the recipe would attract new customers.

Alternatives which have been assessed: Various changed recipes of the epoxy resin were tested in which nonylphenol was replaced by a combination of other substances.

Alternative chosen: A recipe was developed, where nonylphenol could be fully eliminated by the use of, among others, a diglycidyl ether of bisphenol-A (CAS 25068-38-6) and increasing a number of aminic components which were contained in the mixture before the substitution, already. The successful option resulted in quality flooring (no cracks or discoloration developed in time) without a significantly altered floor laying process (e.g. similar viscosity, same or lower level of workers exposure to chemicals, same or decreased mixing times). The production costs were not significantly increased.

Challenges in the substitution process: The recipe had to be fully changed from an initial composition of 10 different substances to a final composition of (only) 5 substances of which 4 were also contained in old formula. The substitution is also contained in the epoxy resin itself.

Impact of REACH: Candidate listing and classification triggered substitution

Options to improve the process: Potential alternatives were identified and evaluated with the help of (some) supplier communication and using SDSs. Some of the communication was slow.

Ideas for a stronger substitution support by REACH: No obvious possibilities for support identified.

Lessons learnt from the example: Substitution may be initiated by different aspects, among which the Candidate List is one and the availability of substances on the market may be another. In this case, the substitution improved the product performance, which resulted in an increase of sales.

7.3.8 Example 8: Substitution of volatile organic compounds (VOCs) in lacquering of metal sheets

Name of substance: Various VOCs, including xylene (CAS 1330-20-7) and 2-methoxy propanol (CAS 1589-47-5)

Specific function: solvents in primers

Company information: The company is part of a larger corporate group and its main activities are the cleaning, priming and cutting of steel sheets and profiles. A large application area of the steel sheets and profiles is the metal constructions, shipbuilding and repair sector.

Initial trigger / initial concern to search for alternatives: According to the Industrial Emissions Directive (IED) (2010/75/EU) two emission limit values for stack emissions apply: for the drying processes 50 mg C/ m3 and for the coating processes: 75 mg C/ m3. Among the VOCs were xylene, which is included in the CoRAP and 2-methoxypropanol which is classified as toxic to reproduction Cat. 1B. According to the IED, VOCs fulfilling the classification criteria of CMRs should be substituted.

Further characteristics of the starting situation: The company's customers have high demands regarding the quality of the metal surface coatings they obtain from the company. Most of the customers specify which particular primer (trade name) should be used. The primers are usually sold as "systems", i.e. primer and final coatings are to be used as "a package" to obtain optimal results.

Alternatives which have been assessed: a market analysis was conducted to identify alternative primer systems. The safety data sheets of potential alternative primers and primer systems were analysed with the aim of identifying products with less hazardous VOCs and an overall lower VOC content.

Alternative chosen: An alternative solvent provided by the same supplier as the one to be substituted was chosen, so the established primer/lacquer system could still be used. The alternative solvent was tested with respect to its practical feasibility. The overall VOC content was reduced, 2-methoxypropanol is not contained anymore but Xylene is still included in the same concentration, according to safety data sheet.

Challenges in the substitution process: Unless the technology is changed from solvent-based to water-based products, the total VOC content in primers and the related emissions are unlikely to be significantly reduced. As a change to water-based products would involve longer drying

times of the coated metal sheets and potentially different application procedures of the primer, substitution would have strong implications on the production processes.

As the company is an end-user, it analysed the mixtures market, i.e. the availability of primer/coating systems, rather than conducting a substance-wise search. Providers of respective products referred them to the available alternatives and gave "regular" customer support.

Impact of REACH: the substitution process was mainly driven by requirements of the IED. The extent to which REACH and a potential future identification of 2-methoxypropanol as SVHC on the Candidate List contributed to the composition of the chosen alternative could not be determined.

Options to improve the process: the main improvement option appears to be a better/more closely targeted support by the providers of primer products to the (SME) customers applying them. Here, more advice and support appeared to be possible.

Ideas for a stronger substitution support by REACH: there are no apparent options of how REACH could have more strongly supported the substitution process.

Lessons learnt from the example:

Also, beyond REACH, incentives for substitution exist

If mixtures are concerned, downstream users are limited to either identifying alternative substances for their own mixtures or to cooperate with customers/others to specifically develop a product for their needs.

If customers with strong demands regarding quality and/or the use of specific products are involved, companies have to invest extensively in communication and testing to show that alternatives achieve the same results as the original product.

Already the classification as CMR and/or listing of a substance in the CoRAP for further evaluation sends signals to the users and may contribute to a decision to substitute.

7.3.9 Additional substitution cases

"Small scale" substitution activities were undertaken in a number of companies within the LIFE Fit for REACH project. Among these were the following cases:

An ink jet printer used to permanently identify cables with a code-number in a company producing electronic components was replaced by a thermal transfer printer. The substitution trigger was that the printing inks contained toluene and butanone, for which occupational exposure limit values exist. In addition, workers complained about headaches.
The alternative printer and chemicals were offered by the supplier of the original printer. The safety data sheet provided by the supplier and the REACH registration database were used to assess the substances contained in the polymeric marking of the new, thermal transfer printer.

A company of the textile sector ended the use of a textile dye (mixture) which was classified as sensitising and toxic to the aquatic environment. The main substitution trigger was the classification identified from the safety data sheet of the mixture. The information sources for the assessment of alternative mixtures were safety data sheets and communication with suppliers, but also the CoRAP, authorisation consultations and different "REACH lists", such as the Candidate List or the CoRAP were used.

A jewellery producer used several chemicals, including boric acid and different solvents, the hazards of which she was unaware of. The awareness raising work of the project was the main

trigger to substitution because the potential workers risks became obvious to the responsible manager. In addition, several other factors contributed to the decision to replace a number of hazardous substances and mixtures, among others: one substance requires authorisation[74] and restrictions apply, for some substances there is a "use advised against" in the SDS, chemicals were withdrawn from the market, there were demands from customers on information on implementable risk reduction measures in the SDS (existing ones where often not implementable). Substitution involved the use of alternative substances and mixtures as well as changes of technologies and process organisation. The information sources to identify and assess alternatives included: consultation of CoRAP, Pact and Candidate List, use of the registration database (substance data and legal information), safety data sheets (in particular the description of the products), as well as other (scientific) literature, which was assessed by the project team. Overall, there was little communication with suppliers as the documentation of alternatives was comparably good. Overall, hazard information under REACH is regarded as crucial in this case, as the awareness of potential damage and the availability of data was most important for the company's decision making.

A producer of consumer household chemicals substituted 1,2-Benzisothiazolin-3-one and 2-Methyl-3(2H)-isothiazolone to avoid self-classification of the mixture. In addition, there were plans to apply for an eco-label, the criteria of which are very critical and low for the content of isothiazoles. The alternative substances were identified via communication with suppliers of benzoisothiazolinone and methyl-isothiazolone and with different other preservative suppliers.

7.4 Product-related legislation: examples of substitution

7.4.1 Example 1: RoHS Directive

Description of the legislation

The RoHS Directive restricts the use of certain hazardous substances in electrical and electronic equipment (EEE) that is placed on the European market. The first RoHS 1 Directive[75] 2002/95/EC banned the dirty six - lead, mercury, cadmium, hexavalent chromium, poly-brominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE); this ban became effective on 1 July 2006.

Meanwhile, the initial RoHS 1 Directive has been replaced by the RoHS 2 Directive 2011/65/EU[76], which entered into force on 21 July 2011 repealing the RoHS 1 Directive 2002/95/EC on 3 January 2013. The former list of the restricted substances in Article 4 of RoHS 1 was moved to Annex II. The restriction of additional substances is now possible by an amendment of the Annex II of the Directive by the Commission in form of a delegated act.

The list of restricted substances in Annex II has most recently been amended by the Commission Delegated Directive (EU) 2015/863 of 31 March 2015: Accordingly, the four phthalates Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) have been added to Annex II and the restriction applies for most product EEE (including computers) from 22 July 2019 on. The restriction of DEHP, BBP, DBP and DIBP shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019.

[74] Although the comparably low use amounts suggest that an exemption from the authorisation requirement could most likely be applied.

[75] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:037:0019:0023:en:PDF

[76] See the consolidated version and all amendments of the Annexes at: http://ec.europa.eu/environment/waste/rohs_eee/legis_en.htm

Exemptions from these restrictions can be granted for specific applications if substitution is scientifically or technically impracticable or the reliability of substitutes is not ensured. These exemptions should not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006, e.g. they should consider the processes of authorisation and restriction.

Scope

RoHS is applicable to all products placed on the European market and therefore covers imported products as well. Thus, RoHS provides a level playing field between EU and non-EU manufacturers.

In addition to restricting certain substances RoHS restricts groups of substances, e.g. lead and all its compounds as well as all PBDE congeners since 1 July 2006. This grouping led to a comprehensive ban. It addresses not only one, but several substances. Therefore, it was more effective earlier compared to other legal provisions for this group.

which address only a single substance.

For example, the grouping of PBDEs entailed an early ban of decaBDE – besides the ban of commercial penta- and octaBDE under the former dangerous preparation Directive 76/769/EEC.[77] Though the use of decaBDE in electrical and electronic equipment has been the subject of legal controversy because it was interim permitted again under the RoHS Directive as exemption 9a "DecaBDE in polymeric applications".[78] But on 1 April 2008, the European Court of Justice in its judgement dated 1 April 2008 ruled that DecaBDE may no longer be used as a flame retardant in new electrical and electronic equipment placed on the market as of 1 July 2008.

In contrast, it took under the Stockholm Convention until 2017 to take up DecaBDE in Annex A[79] (decabromodiphenyl ether (BDE-209) present in commercial decabromodiphenyl ether therein, with specific exemptions for the production and use of commercial decabromodiphenyl ether).[80]

[77] Commercial penta- and octaBDE have been restricted in their marketability since 2004 under Directive 76/769/EEC; these restrictions were taken over in Regulation (EC) No. 1907/2006 (REACH) in Annex XVII. The commercial penta- and octaBDE was taken up on Annex A of the Stockholm Convention by the 4th Conference of the Parties in May 2009 and required amendments to the POPs Regulation, which were implemented by Regulations (EU) No 757/2010 and have been applicable since 26 August 2010. With Regulation (EU) No. 207/2011, the entry on pentaBDE was deleted from Annex XVII to avoid double regulation in the EU. Entry 45 on octaBDE remained in REACH Annex XVII.

[78] The justification of the exemption was published in Commission Decision 2005/717/EC (13 October 2007), (3) Since the risk assessment of DecaBDE, under Council Regulation (EEC) No 793/93 of23 March 1993 on the evaluation and control of the risks of existing substances, has concluded that there is at present no need for measures to reduce the risks for consumers be-yond those which are being applied already, but additional studies are required under the risk assessment, DecaBDE can be exempted until further notice from the requirements of Article4(1) of Directive 2002/95/EC. Should new evidence lead to a different conclusion of the risk assessment, this decision would be re-examined and amended, if appropriate. In parallel industry is implementing a voluntary emissions reduction programme."

[79] Eighth Meeting of the Conference of the Parties to the Stockholm Convention in Geneva, Switzerland from 24 April to 05 May 2017; http://www.pops.int/TheConvention/ConferenceoftheParties/Meetings/COP8/tabid/5309/Default.aspx

Decisions SC-8/10, on the listing of decabromodiphenyl ether (commercial mixture, c-decaBDE), and SC-8/13, on the review of information related to specific exemptions for decabromodiphenyl ether, as adopted by the Conference of the Parties, are set out in annex I to the present report.

[80] The specific exemptions are:

Parts for use in vehicles specified in paragraph 2 of Part IX of this Annex

- Aircraft for which type approval has been applied for before December 2018 and has been received before December 2022 and spare parts for those aircraft
- Textile products that require anti-flammable characteristics, excluding clothing and toys
- Additives in plastic housings and parts used for heating home appliances, irons, fans, immersion heaters that contain or are in direct contact with electrical parts or are required to comply with fire retardancy standards, at concentrations lower than 10 per cent by weight of the part
- Polyurethane foam for building insulation

Bis(pentabromophenyl)ether(decabromodiphenyl ether; decaBDE) was taken up in REACH Annex XVII (entry 67) stating that it shall not be manufactured or placed on the market as a substance on its own after 2 March 2019 and shall not be used in the production of, or placed on the market in (a) another substance, as a constituent; (b) a mixture and (c) an article, or any part thereof, in a concentration equal to or greater than 0,1 % by weight, after 2 March 2019.

Further paragraphs specify the exemptions as defined by the Stockholm Convention and further specifications to provide consistency in EU legislation, e.g. to the RoHS Directive by also exempting electrical and electronic equipment within the scope of Directive 2011/65/EU.

Initial trigger / initial concern to set up the provisions

According to the recitals in the RoHS 1 Directive, concerns from the end-of-life stage have triggered substance restrictions in order:

To contribute to the protection of human health and the environment as well as the sound recovery and disposal of waste of electrical and electronic equipment;

To reduce waste management problems linked to the identified and restricted heavy metals and flame retardants of concern;

To combat environmental pollution by cadmium;

To decrease the negative impact of chemical exposure on workers' health in recycling plants.

Further characteristics of the starting situation

An additional recital in the recast RoHS 2 Directive described the concern of informal treatment of EEE waste: "In spite of those measures, however, significant parts of waste EEE will continue to be found in the current disposal routes inside or outside the Union. Even if waste EEE were collected separately and submitted to recycling processes, its content of mercury, cadmium, lead, chromium VI, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) would be likely to pose risks to health or the environment, especially when treated in less than optimal conditions."

Person/ Institution responsible for the substitution process

RoHS obliges the manufacturer not to use the restricted substances respectively substance groups. From the publication of the RoHS 1 Directive in the Official Journal of the European Union on 13.2.2003 until the date when the restrictions became effective (1 July 2006) provided a transition period of more than three years to find substitutes.

For the four phthalates, there was a transition period of more than four years from the date of publication to the date of effectiveness.

If manufacturers are not able to substitute the restricted substances, they can apply for an exemption.

Alternatives

The alternatives that are used for e.g. lead in EEE do not have to be disclosed in the RoHS context.

The RoHS 2 Directive states that not only a substitution of a chemical should be taken into consideration but also change of material or change of system (*"elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II").*

Challenges in the substitution process

As shortly mentioned in the description of the legislation, challenges in the substitution process are addressed by the RoHS Directive for specific applications *"if substitution is not possible from the scientific and technical point of view, taking specific account of the situation of SMEs or if the negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the environmental, health and consumer safety benefits of the substitution or the reliability of substitutes is not ensured."*

Exemptions for the use of the restricted substances are listed in Annex III of the RoHS 2 Directive. Article 5 of the Directive on the Adaptation of the Annexes to scientific and technical progress stipulates the criteria for providing an exemption. An exemption can be justified if at least one of the following criteria is fulfilled:

the elimination or substitution of the restricted substance via design changes or materials and components is scientifically or technically impracticable, meaning that a substitute material, or a substitute for the application in which the restricted substance is used, is yet to be discovered, developed and, in some cases, approved for use in the specific application;

the reliability of substitutes is not ensured, meaning that the probability that EEE using the substitute will perform the required function without failure for a period comparable to that of the application in which the original substance is included, is lower than for the application itself;

the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

Once one of these conditions is fulfilled, the evaluation of exemptions, including an assessment of the duration needed, shall consider the availability of substitutes and the socio-economic impact of substitution, as well as adverse impacts on innovation, and life cycle analysis concerning the overall impacts of the exemption. All exemptions need to have an expiry date and they can only be renewed upon submission of a new application. The maximum duration of an exemption is set at five years, except for medical devices and monitoring and control instruments including industrial monitoring and control instruments; there a maximum duration of seven years can be grated.

The periodic exemption review assesses whether substitutes are available and reliable in quite short cycles compered to periods granted under REACH. As an outcome of an assessment, the scope of an exemption might be narrowed down and the application still needing the restricted substances might further be specified.

Interrelationship with REACH

It is interesting to note that the legal controversy on the ban of decaBDE was also based on different decision schemes than under REACH that were applied to justify an exemption under RoHS: [81] Whereas the justification of the exemption 9a on "DecaBDE in polymeric applications", published in the Commission Decision 2005/717/EC (13 October 2007) was based on risk assessment considerations, the European Court of Justice (ECJ) argued that according to RoHS a ban of a substance may only be lifted if no viable technical alternatives exists.

[81] See the evaluation of exemption 9a in the Oeko-Institut report: Gensch, C.-O.; Zangl, S.; Groß, R.; Weber, A. in collaboration with Deubzer, O. (2009): Adaptation to scientific and technical progress under Directive 2002/95/EC. October 2007 – October 2008; Oeko-Institut e.V. in cooperation with Fraunhofer Institut für Zuverlässigkeit und Mikrointegration (IZM); Commissioned by: EU Commission, DG Environment, Brussels; https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IV/final_report_oeko-2009.pdf

Commission Decision 2005/717/EC (13 October 2007) stated that "since the risk assessment of DecaBDE, under Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, has concluded that there is at present no need for measures to reduce the risks for consumers beyond those which are being applied already, but additional studies are required under the risk assessment, DecaBDE can be exempted until further notice from the requirements of Article4(1) of Directive 2002/95/EC. Should new evidence lead to a different conclusion of the risk assessment, this decision would be re-examined and amended, if appropriate. In parallel industry is implementing a voluntary emissions reduction programme." The ECJ concluded on these considerations that the possibility of substituting DecaBDE has not been considered by the EU Commission when adopting the exemption for DecaBDE and that the Commission infringed Article 5(1) of Directive 2002/95.

Lessons learnt from the RoHS directive example

An important aspect is that the RoHS directive, as common for all product-related regulations is also applicable on imported products and hence provides a level playing field for all actors/companies in EU and non-EU...

A grouping of substances was introduced due to environmental and human health concerns in the waste phase and in order to strengthen recycling. However, the possibility of a further re-use after recycling was left open and is only possible when applying for specific exemptions.

The availability and reliability of substitutes is the given highest weight in further decisions on the restricted substances, e.g. as core criteria for granting an exemption of the restriction.

In retrospect, this grouping of substances based on end-of-life concerns can be considered as being ahead of its time compared to other provisions, e.g. as shown for the PBDE example.

7.4.2 Example 2: Detergent Regulation

Description of the legislation

The detergent regulation currently in force is Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents.[82] This regulation is in force since 8 October 2005 and replaced earlier legislative measures that already addressed the need that surfactants should be biodegradable in order to protect the aquatic environment.

Scope

All detergents placed on the EU market must comply with this regulation, thus, it applies to imported products as well. Thus, this provides a level playing field between EU and non-EU manufacturers.

The current detergent regulation introduced a wider scope and addresses all surfactants including anionics, non-ionics, cationics and amphoterics. Besides it introduced stricter requirements regarding the biodegradability of the surfactants than the legislative measures before. Article 4 on "Limitations based on the biodegradability of surfactants" stipulates the following:

The surfactants must show ultimate aerobic biodegradability. For the ultimate aerobic biodegradation of surfactants of industrial or institutional detergents derogations can be requested; this is further detailed below, in the section on challenges in the substitution process.

[82] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32004R0648#document1

If ultimate aerobic biodegradation tests are failed, the level of primary biodegradability shall be measured for all surfactants in detergents. If the level of primary biodegradability is lower than that stipulated in Annex II, derogations shall not be granted.

Test methods and analytical methods are specified in the Annexes of the regulation referring to OECD methods and ISO standards.

Initial trigger/initial concern to set up the provision

The recitals of the regulation explain that appropriate measures concerning detergents should ensure a high level of environmental protection, especially of the aquatic environment.

Therefore, the need to set up requirements on biodegradability for all surfactants arose because the former legislation only covered primary biodegradability and was only applicable to anionic and non-ionic surfactants.

The main emphasis on ultimate biodegradability was explained to be due to concerns related to the potential toxicity of persistent metabolites.

Further characteristics of the starting situation

The former EU detergents legislations were set up because poorly biodegradable detergents formed large quantities of foams in rivers in the 1960s and adversely affected the aquatic environment.[83]

The detergent regulations reflect the specific emission pathway into wastewater and provide measures in the form of requiring biodegradability of substances so that in wastewater treatment plants the detergent emissions can be treated, and the surfactants can be degraded.

Thus, it represents a legislative measure based on one substance property and the specific emission scenario.

Person/Institution responsible for the substitution process

Manufacturers placing detergents on the EU market are responsible that the surfactants comply with the biodegradability requirements. If manufacturers have difficulties to substitute certain surfactants in specific products, they can apply for a derogation.

Alternatives

The Detergents Ingredients Database (DID-list) Part A. List of Ingredients 2016[84] contains information about properties of surfactants. It compiles data on their acute and chronic toxicity as well as on degradation, ready biodegradability and possibility for anaerobic degradation The DID list was set up to calculate the critical dilution volume of detergents mainly in the context of ecolabels.

Challenges in the substitution process

As mentioned above, for surfactants in industrial and institutional detergents, derogations are possible.

Article 5 details the conditions for granting a derogation; the surfactants that have obtained derogation, with the corresponding conditions or limitations of use, are provided in Annex V. Annex V however only contains one entry which use has been expired 27 June 2019.

[83] Wagner, G. (2017): Waschmittel, Chemie, Umwelt, Nachhaltigkeit, 5. vollständig überarbeitete und aktualisierte Auflage, Wiley-VCH Verlag GmbH und Co. KGgA, Germany

[84] https://ec.europa.eu/environment/ecolabel/documents/DID%20List%20PART%20A%202016%20FINAL.pdf

Interrelationship with REACH

The detergent regulation does not contain any reference to the REACH regulation, furthermore as it was published and became effective before REACH.

Lessons learnt form the example

The detergent regulation is a result from a longer history of former also national approaches for dealing with detergents polluting the aquatic environment.

For this environmental emission scenario, a unique approach was set up that does not restrict certain surfactants nor bans for specific properties e.g. persistence and bioaccumulation but defines the substance property – in this case biodegradability – that is allowed. The biodegradability is required irrespective to other substance properties e.g. aquatic toxicity.

This product-related regulation also applies to imported products and therefore provides a level playing field.

7.4.3 Example 3: Ecodesign Directive for halogenated flame retardants

Description of the legislation

The Ecodesign Directive 2009/125/EC[85] provides a framework for setting minimum mandatory requirements for energy-related products to improve the environmental performance of products and to reduce their energy and resource consumption.

The Ecodesign Directive is implemented through product-specific regulations, directly applicable in all EU countries. Ecodesign legislations are published for various household appliances and information and communication technologies.86

Ecodesign, in principle, can define substance related requirements (or benchmarks) for products that help to improve any of the following aspects in any life cycle phase:

Consumption of materials, of energy and of other resources such as fresh water,

Emissions to air, water or soil,

Pollution through physical effects such as noise, vibration, radiation, electromagnetic fields,

Generation of waste material,

Possibilities for reuse, recycling and recovery of materials and/or energy.

For electronic displays and televisions, Commission Regulation (EU) 2019/2021 has been published in the Official Journal of the European Union on 5.12.2019.87 Considerations to strengthen circular economy und enhance the recycling of enclosures have for example led to a substance restriction for halogenated flame retardants.

[85] Directive 2009/125/EC, Annex 1, Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of Ecodesign requirements for energy-related products; https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009L0125

[86] https://ec.europa.eu/energy/en/topics/energy-efficiency/energy-efficient-products/list-regulations-product-groups-energy-efficient-products

[87] COMMISSION REGULATION (EU) 2019/2021of 1 October 2019 laying down Ecodesign requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EC) No 642/2009; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L .2019.315.01.0241.01.ENG&toc=OJ:L:2019:315:TOC

Scope

The above-mentioned Commission regulation covers the placing on the market and putting into service of electronic displays, including televisions, monitors and digital signage displays. Thus, it applies to imported products as well.

The specific requirements are laid down in the Annexes,[88] where under section "D. Material Efficiency Requirements" it is stipulated that "*the use of halogenated flame retardants is not allowed in the enclosure and stand of electronic displays.*"

The requirements shall apply from 1 March 2021.

Initial trigger / initial concern to set up the provisions

The Commission Regulation in its recitals underlines the importance of using the Ecodesign framework to support the move towards a more resource efficient and circular economy and argues that therefore appropriate non-energy related requirements contributing to circular economy objectives should be laid down.

According to recital 15, the "presence of halogenated flame retardants represents a major issue in the recycling of plastics of electronic displays. Some halogenated compounds have been restricted by Directive2011/65/EU because of their high toxicity but may be still found in old displays and others are still allowed. Control on maximum content of non-permitted compounds in recycled plastic is not cost-effective, resulting in all being incinerated. Alternative solutions would exist for the bulk of the plastic part in an electronic display, such as the enclosure and the stand, permitting higher yields of recycled plastics. Use of halogenated flame retardants in these parts should be limited."

Further characteristics of the starting situation

The WEEE Directive[89] requires that plastics used in EEE containing brominated flame-retardants must be removed from any separately collected WEEE according to Annex VII on the selective treatment for materials and components of waste electrical and electronic equipment referred to in Article 8(2).

In the course of an assessment of diantimony trioxide (ATO) conducted by Oeko-Institut with a view to the review and amendment of the RoHS Annex II list of restricted substances,[90] the waste management for EEE plastics from enclosures was described as follows:

ATO is stated to be used as synergist together with halogenated flame retardants and, specifically in plastics, with brominated flame retardants. The separation process of brominated flame retardants as applied in Europe is established on density-based sink-float sorting techniques after size reduction by shredding. Post-shredder sorting techniques separate plastics that contain a diantimony trioxide-based flame retardant combination with a high efficiency from other non-flame retardant plastic types, because of the high density of antimony trioxide (ρ

[88] ANNEXES to the COMMISSION REGULATION (EU) .../...laying down Ecodesign requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008and repealing Commission Regulation (EC) 642/2009, Brussels, 1.10.2019 C(2019) 2122 final ANNEXES 1 to 5; https://ec.europa.eu/energy/sites/ener/files/documents/c-2019-2122_1_en_annexe_acte_autonome_part1_v6.pdf

[89] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast); https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012L0019&from=EN, last viewed 02.07.2018

[90] RoHS Annex II Dossier for Diantimony trioxide (flame retardant). Restriction proposal for substances in electrical and electronic equipment under RoHS; Version 2, 04/12/2019; https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Diantimony_trioxide_RoHS_Dossier_V2_final_20191204.pdf

= 5,7 g/cm³).[91] According to the KU Leuven, X-ray fluorescent based optical sorting techniques are also used alternatively or in combination with density based sink-float sorting techniques after size reduction by shredding as state of the art recycling processes in Europe.

This fraction is as of today's state of the art not recycled but sent to incineration with energy recovery as there is no further post-shredder sorting of different plastic materials to obtain a required purity, e.g. to separate the plastic material ABS and HIPS containing brominated flame retardants.

It has to be noted that for halogenated flame retardants another concern has long been raised which is the formation polybrominated and polychlorinated dioxins and furans (PBDD/F, PCDD/F) if the plastic is combusted at lower temperatures (<900°C) or not well functioning incinerators. This happens because still significant parts of EEE waste will continue to be found in the disposal routes outside the Union where it is treated and disposed of by means of very crude technologies that entail environment and human health damage.

Person/ Institution responsible for the substitution process

Manufacturer and service provides are responsible that their electronic displays, including televisions, monitors and digital signage displays comply with the requirements.

Alternatives

It will be possible to monitor the substitution of the halogenated flame retardant because a labelling of plastic components heavier than 50 g is required: The polymer needs to be specified as well as the used flame retardant: "Components containing flame retardants shall additionally be marked with the abbreviated term of the polymer followed by hyphen, then the symbol "FR" followed by the code number of the flame retardant in parentheses. The marking on the enclosure and stand components shall be clearly visible and readable."

Challenges in the substitution process

In the course of an assessment of tetrabromobisphenol A (TBBP-A) conducted by Oeko-Institut with a view to the review and amendment of the RoHS Annex II list of restricted substances,[92] it was concluded for the additive use of TBBP-A as a flame retardant that common substitutes for TBBP-A in housings are halogen-free organo-phosphorus compounds. Oeko-Institut further pointed out that the human health hazards of the organophosphate esters differ depending on the side group of the phosphate. Some arylated organophosphates meet the PBT criteria or are suspected of being potential endocrine disruptors (e.g. triphenyl phosphate).

[91] KU Leuven-University of Leuven (2018): Contribution submitted by Jef Peeters, Department of Mechanical Engineering, Faculty of Engineering & Engineering Technology, KU Leuven-University of Leuven on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_KU_LEUVEN_Diantimony_Trioxide_20180615.pdf, and
Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI) (2018): Contribution submitted on 14.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_diantimony_trioxide__ZVEI_Answers_RoHS_Pack_15_Fragebogen_ATO.pdf,

[92] RoHS Annex II Dossier for TBBP-A, Restriction proposal for substances in electrical and electronic equipment under RoHS, Tetrabromobisphenol A (TBBP-A, flame retardant); Version 2, 04/12/2019; https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/TBBPA_RoHS_Dossier_V2_final_20191204.pdf

The environmental and human health risks of several of the organophosphorus compounds suggest that additional data is needed concerning the available alternatives to allow conclusions to be drawn as to their hazard level.

Interrelationship with REACH

Halogenated flame retardants comprise a large number of substances. The International Electrotechnical Commission provides an International Standard for the exchange of material composition data, the IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry. For substance groups in the "IEC Declarable Substance List", the IEC provides reference substances.

For the substance group of brominated flame retardants (other than PBBs, PBDEs, or Hexabromocyclododecane), 63 substances are listed[93] that substantially differ in their molecular structure, e.g. Dibromo-propanol and TBBPA.

Thus, the grouping provided here based on waste related considerations goes beyond grouping that has so far been performed under REACH, which is e.g. based on read-across.

This restriction will also lead to a large phase out of diantimony trioxide which is used as a synergist of halogenated flame retardants. Diantimony trioxide has since quite time been under regulatory scrutiny for its use in EEE.

Lessons learnt from the example:

The restriction comprises only the halogenated flame retardants as a very large group of substances whereas under the European legal provisions such as RoHS, REACH and POP, rather single substances are restricted.

Compared to restriction and authorisation under REACH, this restriction has to be considered as a unique short cut based on considerations that regards waste management and recycling.

The requirements apply to imported products as well and therefore provides a level playing field for EU and non-EU manufacturers and service providers.

7.4.4 Example 4: EU Ecolabel Regulation

Description of the legislation

The Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel[94] lays down rules for the voluntary EU Ecolabel scheme. Here it is described, how environmental requirements shall be developed that products have to fulfil in order to carry the EU Ecolabel. The criteria for product groups are published in the form of Commission Decisions.

The regulation states that "the EU Ecolabel should aim at substituting hazardous substances by safer substances, wherever technically possible" (recital 7). Article 6 (6) stipulates that:

"The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (1), nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18

[93] http://std.iec.ch/iec62474/iec62474.nsf/Index?open&q=141329

[94] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02010R0066-20171114

December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency."

Scope

The implementation of Article 6 (6) of the ecolabel regulation is usually achieved place by banning substances or mixtures that meet the criteria for classification of the CLP Regulation 1272/2008 for

carcinogenic, mutagenic or toxic for reproduction,

hazardous to the aquatic environment,

acute toxicity, specific target organ toxicity, respiratory and skin sensitization.

Thus, the criteria for the products list the restricted hazard classifications (see e.g. for hard surface cleaners,[95] rinse-off cosmetic products[96] and paints and varnishes[97]).

Besides, the substances listed on the REACH Candidate List are banned as well.

Exemptions from the hazard classification for specific substances can be applied for, in the context of the EU Ecolabel, this is called derogation.

Initial trigger to set up the provision

The EU Ecolabel aims to promote products with a reduced environmental impact during their entire life cycle. The EU Ecolabel enables consumers to choose products with the best overall environment performance. Thereby, the EU Ecolabel shall provide an incentive for producers to make their production and products more sustainable and contribute to transform the EU market for more sustainable products and services.

Person/ Institution responsible for the substitution process

The institution responsible for the substitution process are the companies that apply for the EU Ecolabel.

An application for a derogation must be submitted by industry.

Alternatives

The Ecolabel regulation states that the substitution of hazardous substances by safer substances should include not only a change of chemicals but also a change of material or a change of system should be taken into consideration: "*the substitution of hazardous substances by safer substances, as such or via the use of alternative materials or designs, wherever it is technically feasible*".

Challenges in the substitution process

In case of unresolvable challenges in the substitution process, it is possible to grant a derogation from specific hazard statements. This is specified in Article 6 (7) as follows:

"For specific categories of goods containing substances referred to in paragraph 6, and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall

[95] Commission Decision (EU) 2017/1217of 23 June 2017establishing the EU Ecolabel criteria for hard surface cleaning products; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017D1217-20190315

[96] Commission Decision of 9 December 2014establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014D0893-20181023

[97] Commission Decision of 28 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014D0312-20180502

environment performance compared with other goods of the same category, the Commission may adopt measures to grant dero-gations from paragraph 6. No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 and that are identified according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (weight by weight)."

A derogation request is individually assessed, however, there are no further specifications in terms of criteria for the assessment.

In the above-mentioned product groups, derogations have been set in the development of the criteria e.g.

for rinse off cosmetics the functional substance groups surfactants, fragrances and preservatives are exempted from the obligation in Article 6(6) as well as for one specific substance (zinc pyrithione used in anti-dandruff shampoos being classified for H400 Very toxic to aquatic life); the surfactants have a derogation for the environmental hazards of Category 3 and 4 (H412: Harmful to aquatic life with long-lasting effects and H413: May cause long-term adverse effects to aquatic life).

In hard surface cleaners, the derogated substances are surfactants and enzymes as well as one specific substance (NTA as an impurity in MGDA and GLDA exempted from the hazard statement H351 Suspected of causing cancer); surfactants here are derogated from a different hazard classification compared to the rinse-off cosmetics (H400 Very toxic to aquatic life and H412 Harmful to aquatic life with long- lasting effects) due to technical performance requirements of the cleaning product.

For paint and varnishes, the derogations are complex and are set out in the Appendix where for substance group, e.g. a certain preservatives such as in-can preservatives, the scope of restriction and/or derogation is specified, also detailing concentration limits (where applicable).

An evaluation of the implementation of the EU Ecolabel regulation carried out in 2015[98] concluded that the provisions of the EU Ecolabel on hazardous substances hamper the acceptance by producers for some product groups and result in the situation that there are no license holders in some product groups, e.g. for computers and laptops:[99] The criterion on hazardous substances and mixtures in the product, sub-assemblies and component parts is a complex system providing the usual list of hazardous classifications that however applies to defined sub-assemblies and component parts as well as substance groups. For some substance groups such as flame retardants and plasticizers, derogations are defined that cover some hazard classifications. Besides there are additional substance restrictions specified for substance groups or materials. According to the evaluation report, industry reported these requirements *"to be both too stringent to be met and based on unfamiliar verification processes associated with hazardous classifications."*

Interrelationship with REACH

The only explicit link to the REACH regulation consists in the ban of the SVHCs of the Candidate List.

[98] Nuttall, Chris; Gasbarro, Federica; Iraldo, Fabio; Nucci, Bennedetta; Paglialunga, Anna; Evans, Louise; Barberio, Michele; Rosenow, Jan (2017): Project to Support the Evaluation of the Implementation of the EU Ecolabel Regulation, Synthesis Report, October 2015; https://op.europa.eu/en/publication-detail/-/publication/67ba4716-5499-11e7-a5ca-01aa75ed71a1

[99] Commission Decision of 9 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for personal computers; https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32011D0337

Lessons learnt form the example

Although the EU Ecolabel is a voluntary scheme, it is an example for directing substitution on a voluntary basis in order to avoid regrettable substitution. Instead of blacklisting individual substances, the EU Ecolabel is based on exclusion of specific hazard classifications that forms the benchmark for human health and the environment. A non-achievement of this benchmark needs an explicit permission by a derogation.

There are a number of license holders for product groups that have to be considered as mixtures in the sense of REACH and CLP, e.g. rinse-off cosmetics, hard surface cleaners and paints and varnishes. However, in product groups consisting of a number of sub-components (complex articles), it seems to be more difficult for industry to fulfill the requirements of the EU Ecolabel on hazardous substances. This demands a sufficient knowledge about the substances contained in the product. This knowledge is often not there.

8 Annex: Key terms and definitions related to substitution

This section gives definitions for key terms from different references. It aims to support a common understanding of the objectives of substitution and the findings presented in chapter 5 of this report.

Alternative: (1) substance, material, process, product or service to replace a substance of concern (Tickner et al. 2015). (2) related to REACH Authorisation, definition from ECHA 2011a: alternative is a possible replacement for an Annex XIV substance. It should be able to replace the function that the Annex XIV substance performs. The alternative could be another substance(s) or it could be a technology (i.e. a process, procedure, device, or modification in an end-product) or a combination of technical and substance alternatives. For example, a technical alternative could be a physical means of achieving the same function of the Annex XIV substance or perhaps changes in production, process or product that removes the need for the Annex XIV substance altogether (additional remark: the function needs to be clearly described)/ see also available alternative and suitable alternative.

Analysis of alternatives (AoA): related to REACH Authorisation, definition from ECHA 2011c: A systematic search for alternatives that can be documented and presented in an application for authorisation. This analysis is the applicant's evidence to show that the technical and economic feasibility of the possible alternatives has been analysed and their risks compared to those of the Annex XIV substance. The aim of this analysis should be to determine if use of the alternative would lead to an overall reduction in risk. Guidance on conducting an analysis of alternatives can be found in the Guidance on the preparation of an application for authorisation (ECHA, 2011a). See also alternatives assessment.

Application: see use.

Assessment of alternatives: a process for identifying, comparing and selecting safer alternatives to chemicals of concern (including those in materials, processes or technologies) on the basis of their hazards, performance, and economic viability. A primary goal of the assessment of alternatives is to reduce risk to humans and the environment by identifying safer choices (biznGo 2013). In this process, function and application not only are general used as a baseline for assumptions regarding exposure to a chemical, but are also important for identifying the universe of potential alternatives and narrowing the scope of the assessment, in the case of multifunctional chemicals (Tickner et al. 2014) (3) OECD: Alternatives assessment: A process for identifying and comparing potential chemical and non-chemical alternatives that can be used as substitutes to replace chemicals or technologies of high concern. See also analysis of alternatives.

Available alternative: related to REACH Authorisation, definition from ECHA 2011c: Accessible and able to replace the Annex XIV substance, e.g. can be accessed in sufficient quantity and quality) [Remark: in the context of REACH Authorisation related to Annex XIV substances only]. (Related to REACH Authorisation, definition from ECHA 2011c). See also alternative and suitable alternative.

Benefits: The positive implications, both direct and indirect, resulting from an action. This includes both financial and non-financial elements (related to REACH Authorisation, definition from ECHA 2011c).

Chemical alternatives assessment: see alternatives assessment.

Chemical function: the task or job a substance performs (definition derived from definition of "substance function" given by ECHA 2011c ("The function of the Annex XIV substance for the

use(s) being applied for is the task or job that the Annex XIV substance performs") how and why a chemical is used (Tickner et al.2014). While the concept of function may not be a key consideration in chemicals assessment and management today, chemists and designers regularly focus on function when identifying cost-effective, highly performing options for a particular product or manufacturing process (Tickner et al. 2014).

Chemical function: The potential function of a chemical is driven by the chemical´s structure (functional groups size, shape, geometry, electron density etc.) (Tickner et al. 2014).

Chemical grouping: see grouping.

Chemicals assessment see chemicals management and chemical safety assessment.

Chemicals management, solutions-oriented approach: This approach starts with considerations of functions, rather than characterising and managing a particular risk associated with the use of a chemical. It is an additional tool, which complements existing tools to chemicals management (Tickner et al. 2014). It is a ree-orientation of chemicals management approaches from time-intensive risk assessment and risk management based on single chemical substances to a comparative evaluation of the best option to fulfill a specific function (Tickner et al. 2014).

Chemicals management, traditional approach: collect information on chemical hazards, uses and exposures, evaluate risks, and determine appropriate risk reduction management measures, such as use restrictions or exposure controls (Tickner et al. 2014). In this process, information on use provides critical information on potential exposures. See also: Chemical safety assessment (CSA).

Chemical Safety Assessment (CSA): Process laid down in REACH Art. 14 aimed at determining the risk posed by a substance and, as part of the exposure assessment, developing exposure scenarios including risk management measures to control the risks. Annex I to the REACH Regulation contains general provisions for performing a CSA. The CSA consists of the following steps: Human health hazard assessment / Human health hazard assessment of physicochemical properties / Environmental hazard assessment; and PBT and vPvB assessment. If, as a result of this hazard assessment, the registrant concludes that the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC Remark: replaced by CLP Regulation EC 1272/2008) (for substances) or has PBT/vPvB properties, this triggers further steps in the chemical safety assessment: Exposure assessment and Risk characterisation (related to REACH Registration, definition from ECHA 2011c).

Drop-in chemical replacement: replacement of a chemical by a functionally equivalent chemical substitute (Tickner et al. 2014).

End Use Function: Function relates to the specific purpose that a chemical serves in a product or process. The particular end use of a chemical is known, including product/process properties and performance characteristics for which a chemical is needed (product/process end use level). E.g: flexible film that protects food. Option 1: phthalates to make polyvinylidine chloride flexible. Option 2: use of flexible low density polyethylene (Tickner et al. 2014).

Economic feasibility: a situation where the economic benefits exceed the economic costs (definition from ECHA 2011c, related to REACH authorisation ("Analysis of the economic implications of the adoption of an alternative. Economic feasibility is normally defined as a situation where the economic benefits exceed the economic costs. For more details on how the concept is applied in authorisation applications; see Section 3.7 in the Guidance on the preparation of an application for authorisation." (ECHA 2011c).

Economical impacts: Costs and benefits to manufacturers, importers, downstream users, distributors, consumers and society as a whole (related to REACH Authorisation, definition from ECHA 2011c).

Environmental impacts: Impacts on all environmental compartments. Covers all use and non-use impacts on the affected environmental compartments (related to REACH Authorisation, definition from ECHA 2011c).

Feasibility: see economical feasibility and technical feasibility.

Function as Service: Function relates to the broad "service" that a chemical provides or which is desired in a material, product or process (e.g. microbial resistance, flexibility). That service may be provided through chemical, material, or process/design changes, which are not necessarily dependent on specific chemistries. Importantly, at the level "function as service" the question of the need for the function can also be considered (or the need of a specific functionality). (Tickner et al. 2014).

Function: the task or job a substance / material / product performs (definition derived from definition of "substance function" given by ECHA 2011c ("The function of the Annex XIV substance for the use(s) being applied for is the task or job that the Annex XIV substance performs"). See also chemical function.

Functional substitution: (1) "Functional substitution describes the application of information on function to identify, evaluate, and select safer alternatives that achieve a particular result" (Tickner et al. 2014): Different from traditional approaches it does not consider primarily other chemical structures. It considers simultaneously three distinct conceptual levels of substitution: chemical function, end use function, and function as service. It goes beyond simply drop-in chemical substitutes (that may have similar toxicity profiles as the substituted chemical) and, as a result, supports a considered transition to safer, functionally equivalent alternatives (Tickner et al. 2014). It is a functional approach to chemicals management (Tickner et al. 2014). Functional substitution can take place at the chemical level (chemical function level, chemical change), at the "end use function" level (material, product, process change) or at the "function as service" level (system change) (Tickner et al. 2014). The three levels of functional substitutions provide a broader view which potential alternatives could be considered to achieve a desired end result. It increases the range of substitution options available.
(2) Approach for substitution which sets the focus on the (technical) function of the substance rather than on its chemical structure and associated risk. This is the key to allow a wider range of substitution solutions. Functional substitution helps to avoid regrettable substitution. (Definition cited from ECHA 2018 (referring to Tickner 2014)).

Functional use: see function, see chemical function, see substance function.

Fundamental substitution which really means a large progress compared with the situation before (regarding reduction of adverse impacts). Opposite to incremental substitution, term used in Fantke et al. 2015 without a clear definition.

Grouping: the general approach for considering more than one chemical at the same time. It can include formation of a chemical category or identification of (a) chemical analogue(s) with the aim of filling data gaps as appropriate (read-across). The category or the analogue approach makes it possible to extend the use of measured data to similar untested chemicals, and reliable estimates that are adequate for classification and labelling and/or risk assessment can be made without further testing. In this way, both approaches are important since they provide an alternative to testing individual chemicals and as a result should lead to a decrease in the use of animal testing. In addition, it will increase the knowledge of the hazard properties of chemicals

that may otherwise remain untested and provide for an increased level of protection for human health and the environment (OECD 2014). Remark: In the last sentence, the word "untested" can be replaced by "unassessed". This expresses that grouping and read across allow to close data gaps without testing.

Health impacts: Impacts on human health including morbidity and mortality effects. Covers health related welfare effects, lost production due to workers' sickness and health care costs (related to REACH Authorisation, definition from ECHA 2011c).

Impact: All possible effects – positive or negative – including economic, human health, environmental, societal and wider effects on trade, competition and economic development (definition from ECHA 2011c), see also economic impacts, environmental impacts, health impacts.

Incremental substitution: substitution which results only in a minor progress (term used from Fantke et al. 2015 without clear definition), opposite to fundamental substitution: See also fundamental substitution.

Informed substitution: (considered) transition from chemicals that may pose risks in production processes or products to less hazardous alternatives (Tickner et al. 2014)

Meaningful substitution: term used in ECHA´s substitution strategy (ECHA 2018) without further definition. It is used as contradiction to a regrettable substitution.

One-to-one substitution: Replacement of one substance by another with the aim of achieving a lower level of risk.

Product use: see use.

Regrettable substitution: (1) Substitution of a chemical of concern (e.g. a restricted substance (which is under severe regulatory control)) by a structurally related drop-in substitute which have similar toxicity profiles (Tickner et al. 2014). (2) Substitution of a chemical of concern by a substitute or a process which also causes unwanted exposures or risks (WP 10 working group). (3) Substitution focusing on similar chemical drop-in substitutes which may lead to substitution with alternatives that have similar toxicology profiles (Definition given in ECHA 2018 with reference to Tickner et al. 2014). (4) Replacement of a toxic substance with one that has unknown – if not greater – toxic effects. (WSDE 2015). Note: Focus in this definition is on the missing knowledge of the properties of the substitute. Opposite could be an "informed" substitution.

Safer alternative: An option, including the option of not continuing an activity, that is healthier for humans and less detrimental for the environment than the existing means of meeting that need. For example, safer alternatives to a particular chemical may include a chemical substitute or a re-design that eliminates the need for any chemical addition (biznGo 2013).

Social costs: Denotes the opportunity cost to society and includes also external costs or externalities (related to REACH Authorisation, definition from ECHA 2011c).

Social impacts: Denotes the opportunity cost to society and includes also external costs or externalities (related to REACH Authorisation, definition from ECHA 2011c).

Solutions oriented approach: see chemicals management, solutions-oriented approach.

Sustainable substitution: term used in ECHA´s substitution strategy (ECHA 2018) without further definition. It is used as contradiction to a regrettable substitution.

Substitution, substitution principle: (1) the replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures (Definition used in ECHA´s substitution strategy, cited from Lohse et al. 2003). (2) Replacement of one substance by another with the aim of receiving a lower risk (Lofstedt 2014, cited in Camboni 2017). For further definitions, see Camboni 2017, Appendix A1.1.1.

Substitution principle: see substitution.

Suitable alternative: An alternative that is technically and economically feasible for replacement of the Annex XIV substance where transferal to the alternative results in reduced overall risks to human health and the environment (as compared to the Annex XIV substance) taking into account risk management measures and operational conditions. It must also be available (e.g. can be accessed in sufficient quantity and quality) (related to REACH Authorisation, definition from ECHA 2011c). See also unsuitable alternative.

Technical feasibility: Relates to an alternative substance or technology which is capable of fulfilling or replacing the function of the Annex XIV substance, without compromising the functionality delivered by the substance and its use in the final product. See also the Guidance on the preparation of an application for authorisation (ECHA, 2011a) (related to REACH Authorisation, definition from ECHA 2011c).

Unsuitable alternative: An alternative that has been analysed as part of the analysis of alternatives in which it is shown that the alternative is not technically or economically feasible, is not available for use or does not reduce risks (related to REACH Authorisation, definition from ECHA 2011c)**.** See also suitable alternative.

Use: see function, see chemical function, see technical function.

Additional terms related specifically to authorisation and restriction under REACH:

Adequate control route: (related to REACH Authorisation, definition from ECHA 2011c): An authorisation shall be granted if it is shown that the risk to human health and the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I {Art. 60(2)} and taking into account Article 60(3). (See also the Guidance on the preparation of an application for authorisation (ECHA, 2011a)).

Socio-economic route: (related to REACH Authorisation, definition from ECHA 2011c): An authorisation may be granted if it can be shown that the risk to human health or the environment from the use of the Annex XIV substance is outweighed by the socio-economic benefits and if there are no suitable alternative substances or technologies (Article 60(4)).

Socio-economic analysis: (related to REACH Authorisation, definition from ECHA 2011c): The socio-economic analysis (SEA) is a tool to evaluate what costs and benefits an action will create for society by comparing what will happen if one action is implemented compared to the situation where it is not. Under the REACH authorisation procedure, an SEA is a compulsory part of an application for authorisation whenever the risks to human health or the environment from the use of an Annex XIV substance are not adequately controlled. An SEA may be undertaken by an applicant in support of an application when adequate control is proposed. An SEA may also be produced by any third party in support of information on alternatives.

Substitution plan: (related to REACH Authorisation, definition from ECHA 2011c): (1) Proposal including a timetable detailing the replacement of an Annex XIV substance by a suitable alternative substance or technology. The substitution plan must be included in the application

for authorisation if suitable alternatives are available. It might also be required within the review of a given authorisation. / (2) A commitment to take the actions needed to substitute the Annex XIV substance with an alternative substance or technology within a specified timetable (ECHA 2011a).

9 Annex: REACH and its actual impact on substitution

9.1 Introduction

Not only since the REACH Review in 2017, authorities and stakeholders have been interested in how REACH and the European chemicals legislation as such have supported the objective of a sound and safe management of chemicals and the substitution of substances of concern. In order to evaluate the actual impact of REACH on substitution we have undertaken a review of existing literature on this topic. Apart from findings regarding the actual impact, this review revealed a number of difficulties and challenges encountered due to substitution and highlights the corresponding reasons thereof. Impressions from the review of these studies contributed to the final recommendations given in this report on how REACH can stronger support substitution as it is the case at present.

The main findings of the literature have been summarised in Chapter 3 above. The following sections describe in detail the studies analysed and the findings from the review.

9.2 Study review

15 studies from different authors and stakeholder groups have been analysed in this review.[100] The following section 9.2.1 gives an overview aiming to introduce these studies. The evaluations in sections 9.2.2 - 9.3 have been focused on

- observable effects & impacts of REACH on substitution;
- (REACH) activities to explain the observed effects;
- barriers to substitution;
- support strategies as well as
- challenges in the assessment of impact of REACH on substitution.

Conclusions from these findings on the impact of REACH on substitution are drawn in section 9.4.

9.2.1 Introduction of reviewed studies

In total, 15 studies were analysed with regard to their findings on REACH's actual impact on substitution. They are listed in Table 6. Most useful information has been found in three studies focussing on authorisation: These are *Monitoring Authorisation under REACH* (Austrian Environmental Agency 2017), *Impact of Authorisation* (EC 2017a) and *Effects of legal interventions* (DEPA 2019)[101]. Seven studies refer to REACH without a special focus on one regulatory sub-process[102]; finally, another five studies discuss substitution either with REACH as a side issue[103] or in the broader context of chemicals as such[104]. Thus, it can be distinguished between studies that have no regulatory focus and those which focus specifically on

[100] Starting points for the selection of the studies have been the ECHA Substitution Strategy (ECHA 2018) and the studies performed for the REACH Review 2017. Further studies and key references have been mentioned in these reports.

[101] Numbers according to numbering in Table 6: 4, 8.15

[102] Numbers according to numbering in Table 6: 1, 2, 3, 5, 9, 10, 12

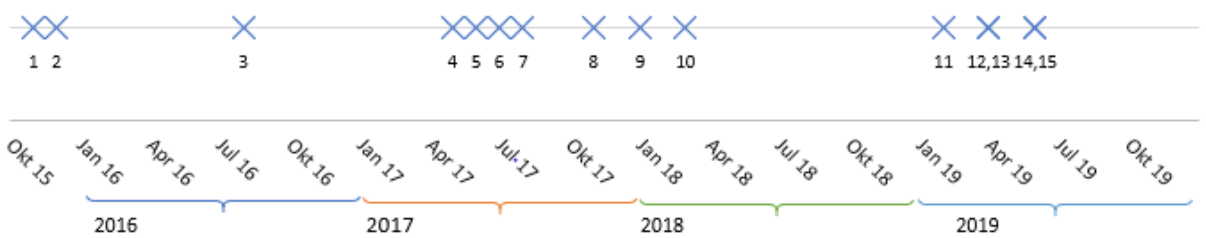
[103] Numbers according to numbering in Table 6: 6, 11, 13

[104] Numbers according to numbering in Table 6: 7, 14

authorisation. This fact allows to draw the following conclusions: firstly, a pre-assumption is made that authorisation plays the major role when addressing REACH's impact on substitution; secondly, this entails a narrowing of the perspective. In addition, the focus on authorisation reflects the intense public debate of this process due to the far-reaching consequences which this element of REACH has for the availability of substances of concern.

The following figure and the related Table 6 show the publication dates of the studies covered here along a timeline starting in autumn 2015. According to the publication date, the reviewed studies can be grouped into two with some harbingers in 2015 and 2016. Those (No. 1-3) and studies from the first group (No. 4 to 10) were published aiming to support and contribute to the REACH Review carried out in 2017. Publications of the second group (No. 11 to 15) pick up the conclusions from the REACH Review process and develop recommendations, further steps and actions, as can be seen already from their titles, e.g. *Roadmap for the Substitution of SVHC* (Belgium Ministries, No. 13) and *Chemicals Innovation Action Agenda* (European Commission, No. 14). In addition, the table differentiates between the following study types (in order of decreasing degree of scientific details): (a) analytical report, (b) roadmap with concrete goals and recommendations, (c) statement of intent, or (d) expression of opinion.

Figure 6: Publication dates of studies covered by this review



Source: own illustration, Öko-Institut e.V.

Note: Numbered publication dates match the study information in the following table.

Table 6: Matching numbered publishing dates from Figure 6 above to study information

No.	Publishing Authority	Title of Study	Publishing date	Degree of scientific detail
1	European Environmental Bureau (EEB)	A roadmap to revitalise REACH	Nov 15	Expression of opinion (d)
2	EU Commission (EC)	Impacts of REACH on Innovation, Competitiveness and SMEs	Dec 15	Analytical report (a)
3	Lowell Center	Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH	Aug 16	Analytical report (a)
4	Austrian Environmental Agency	Monitoring Authorisation under REACH	May 17	Analytical report (a)
5	EEB	Restricted success	June 17	Expression of opinion (d)

No.	Publishing Authority	Title of Study	Publishing date	Degree of scientific detail
6	Lowell Center	Accelerating Substitution under REACH	July 17	Roadmap with concrete goals / recommendations (b)
7	EC	Study for a non-toxic environment	Aug 17	Statement of intent (c)
8	EC	Impact of Authorisation	Nov 17	Analytical report (a)
9	ECHA	Substitution Strategy	Jan 18	Statement of intent (c)
10	EC	Conclusions from REACH Review	March 18	Analytical report (a)
11	OECD	Approaches to Support Alternatives Assessment	Feb 19	Analytical report (a)
12	EEB	Conclusions after a decade of REACH	Apr 19	Expression of opinion (d)
13	Belgium Ministries	Roadmap for the substitution of SVHC	Apr 19	Roadmap with concrete goals (b)
14	EC	Chemicals innovation action agenda	June 19	Statement of intent (c)
15	Danish Environmental Protection Agency	Effects of legal interventions	June 19	Analytical report (a)

The following table summarises the reviewed studies in light of their contribution to the evaluation question: REACH's impact on substitution. This compilation gives an indication of each report and its point of view on substitution.

Table 7: Summary of reviewed studies focussing on REACH's impact on substitution

Reference	Main message on REACH's impact on substitution
Impact of Authorisation - COM (2017) [8]	In an industry survey, 44% (n=37/83) of survey participants indicated to have substituted SVHCs. It was found that authorisation drives substitution even though substitution costs can be higher than authorisation costs mainly due to uncertainties and internal substitution policies. Barriers to substitution are a lack of alternatives that are worth investigating further or a lack of technically feasible alternatives as revealed by investigations. Benefits of substitution are seen mainly in the reduction in worker exposure to SVHCs and reduction in emissions. Due to limited data, it is difficult to assess the costs related to substitution. REACH authorisation has little impact on the intermediate use of SVHC (as such uses are exempted from the authorisation process.).
Effects of legal interventions - DEPA (2019) [15]	Eurostat/Prodcom and REACH registration data are currently no suitable indicators for assessing trends in use of SVHC substances. The SVHC tonnages in Nordic countries have declined, but most probably due to combined effects of several legislative measures and market drivers for substitution. It is indicated that effects of legislation on chemicals may differ between substances, applications and countries.
ECHA Substitution Strategy (2018) [9]	Better knowledge on physico-chemical, toxicological and ecotoxicological properties of substances and their uses is being generated through the REACH processes. Based on these data, priorities can be determined, and better-informed choices can be made with respect to substitution. Concrete support for substitution is provided owing to the need

Reference	Main message on REACH's impact on substitution
	for communication on SVHCs in articles, to mandatory requirements for analysis of alternatives and due to public consultation. In addition, a possible trend is seen with regard to purchasing decisions where SVHC-free products are preferred. Time-limited reviews of authorisations ensure that industry needs to continue its efforts on substitution. Both a ban of substances through restriction under REACH and the exclusion criteria under the Biocidal products regulation will directly lead to substitution.
Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs - COM (2015) [2]	With respect to substitution, the report – due to its focus – identifies mainly limits and challenges for substitution. It was found that a substance's placing on the Candidate List may decrease an investor's interest in companies producing or handling these substances. Less R&D measures were undertaken where there were no substitutes readily available. In addition, it should be realised that substitution does not necessarily lead to products with better characteristics and lower costs. The request for immediate substitution (in order to keep products on the market) means that producers have less time for developments. Consequently, substitutes will be selected from the set of substances available and affordable. How far substitution can be realised depends on downstream user processes. Therefore, it is more probable that substitution is established on the level of the formulator or article producer. In total, the withdrawing of a substance from the market depends on the criticality of the substance (needs on the market to use a substance). Finally, this report gathers several information on how to support substitution.
Monitoring Authorisation under REACH – Austrian Environmental Agency (2017) [4]	A proposed assessment method, the RiME[105] indicators, were tested with respect to their effectiveness in monitoring authorisation under REACH. As an overall conclusion it was found that the RiME indicators are insufficient according to the authors' opinion. Instead, a list of recommendations was developed to better assess authorisation under REACH: • move the focus of assessment to success stories of substitution/ learning from best practice; instead of aiming at identifying indicators to assess all at once. • for listed SVHC: analyse use indicators over the time for a consistency check • increase efforts to encourage or enforce registrants to update production volume information • find appropriate indicators to assess reduction of SVHC-containing articles in the EU as a start for concerted monitoring action • creation of a competence centre or focal point on alternative assessment to overcome the lack of information on existing alternatives and (eco)tox data • E-PRTR can be used to clarify reasons for emission reductions (risk reduction measures or application of alternatives)
Conclusions and Actions summarized from the REACH Review – COM (2018) [10]	In this compilation of conclusions and actions summarised from the REACH Review in 2018, the substitution-related focus is rather set on the measures to improve REACH, i.e. capacity building, collaborative networks, R+D investments and the interplay between Authorisation and Restriction. Independently, the role of SMEs in the transition towards safer alternatives is highlighted together with the need for knowledge as well as financial support. Another field of action should be the non-restricted uses of SVHC.
Study for a non-toxic environment - COM (2017) [7]	With respect to substitution and in addition to what was already found in the other studies, two aspects are put forth that so far have not been adequately considered: first, there is an inconsistency in the legislation on SVHC in articles and requirements for providing information on the content of SVHC in articles. This information is be poorly compiled and the obligations are rarely enforced. Second, as the authorisation process

[105] Indicators proposed by the Risk Management Expert (RiME) Meeting 2015 in Brussels. The RiME is a subgroup of the advisory expert group CARACAL (Competent Authorities for REACH and CLP).

Reference	Main message on REACH's impact on substitution
	under REACH does not cover SVHC in imported articles, these will continue to exist in the use, waste stream and will remain in recycled material. As an important conclusion, the report identifies insufficient attention paid to hazardous chemicals in material flows, which is an important condition for a Circular Economy.
Chemicals Innovation Action Agenda – COM (2019) [14]	First of all, this report is an action plan that is meant to support other studies, some of them analysed here. However, several aspects of substitution are highlighted too. I The support of substitution limited by the complexity of global supply chains as the transmitted information about down-stream businesses is insufficient. This leads to a higher probability of regrettable substitution; in addition, chemicals-to-chemicals substitution is more likely than a substitution that provides the same function, which is achieved, however, by application of a different technology or process. When trying to compile the required amount of information on SVHC and safer alternatives, in many cases authorities are hindered by protection of confidential business information and especially too little knowledge on SVHC in articles and mixtures. An area of tension identified consists of aiming at the achievement of the circular economy goals of longevity and recyclability of a product on one side and the use of safer (or smaller quantities of) chemicals in that product on the other. An overall recommendation of the Chemicals Innovation Agenda is the reframing of REACH from being primarily a regulatory compliance activity to an innovation opportunity.
Roadmap for the substitution of SVHC - Belgium Ministries (2019) [13]	While being a roadmap with concrete goals, the introduction of this roadmap highlights the need for action especially as "existing regulations alone were insufficient". Reasons are namely the lack of certainty that (1) substitution is promoted, (2) that enough investments are undertaken in finding, testing and implementing alternatives; and (3) that the authors found that some stakeholders were not sufficiently aware of their obligations.
EEB reports (published in 2015, 2017 and 2019) [1;5;12]	From the three EEB reports, the following can be concluded with respect to substitution: Outdated registration data leads to mistakes and wasted time and resources of ECHA and the Member States when preparing draft decisions. The EEB calls for a strong implementation of REACH Article 22 requiring mandatory updates of registration dossiers when new data becomes available. Furthermore, an acceleration of Candidate Listing and Authorisation is requested. Article 68(2) gives the Commission power to "fast-track" a restriction proposal in case of CMR substances (carcinogenic, mutagenic, toxic for reproduction) in consumer products. These restriction proposals only have to assess in which way the risk can be adequately addressed, a. EEB suggests that the BPA restriction might have fallen into this category.
Needs and opportunities to enhance substitution efforts within the context of REACH - Lowell Center (2016) [3]	According to Lowell Center, the following weaknesses of REACH call for action: The authors find that information collected under REACH is not readily usable to identify alternatives and that the principle of substitution is not strongly connected to the resourcing and implementation of programs and activities to promote substitution. The Lowell Center sees a lack of public or private investments to support the needed R&D measures. The authors identify a disconnection between industry's needs and the research base in academia. In addition, most of the authorities do not consider the evaluation of technical feasible alternatives to fall within the scope of their mandate.

The following sections describe the main findings from the analysis of the studies. They are structured in such a way that they address five key questions:

- what impacts of REACH on substitution can be seen? (section 9.2.2);
- what are drivers/ triggers in REACH for substitution? (section 9.2.3);

- what are barriers and difficulties for substitution? (section 9.2.4);
- which support strategies exist? (section 9.2.4) and
- what makes it difficult to assess impacts of REACH on substitution? (section 9.3).

9.2.2 What impacts of REACH on substitution can be seen?

9.2.2.1 Overview of impacts

- Since the REACH regulation has been in force, the production volume and the use of SVHCs have been reduced within the European Union.
- Substitution of SVHC has led to lower levels of emissions to the environment and lower levels of occupational exposure.

These are the first two important findings of the literature review. Furthermore, less prominent findings are:

- Where SVHCs have been reduced, it is reasonable to assume that they have been substituted by alternatives in the supply chains.
- In the studies which have been analysed, chemicals with harmful characteristics but without SVHC-"status", without restrictions or without harmonised classifications have only been addressed. in such a way that they should be taken more closely into account. However, it should be noted that these substances of concern (even if they have not yet been identified as SVHCs) are intensively assessed by Competent Authorities regarding their classification. In addition, at present the concept of "equivalent concern" is being developed further in order to cover problematic substance properties beyond the ones listed in REACH Art. 57 a-e
- It has been suggested by reviewed reports that another impact is that strengthening substitution has become a task of authorities, Member States, environmental NGOs, research institutes and industry.
- Substitution is also in the focus of some private investors that have highlighted the importance of strengthening the chemicals companies' activities in and reporting on product stewardship, substitution and management of substances of concern.
- Withdrawal of substances from (some) markets is influenced by (future) Authorisation needs and/or Restrictions, and the related possibility of their substitution as well as the importance of a particular substance for a company. Another option beside substitution could be that companies consider the relocation of their activities outside Europe.
- According to industry stakeholders, significant differences in employment and revenue due to substitution processes were not substantial.
- In the view of the industry stakeholders who participated in the reviewed reports, REACH is a compliance instrument instead of a motivator for innovation or a trigger for a mind-set change. The compliance focus leads to a strategy in which the substitution of substances of concern is a "problem" that asks for a quick solution. There is not much understanding for

the need to find an alternative without adverse effects for man and the environment. Consequently, it could be seen that less R&D measures were started and financed where there were no substitutes readily available.

The following sections describe these findings in more detail.

9.2.2.2 Substitution of SVHC and reduction of the volume of SVHCs

In an industry survey undertaken in the context of the impact evaluation of REACH Authorisation (EC 2017a), 44% of the respondents[106] indicated that they had substituted a use of a SVHC and therefore avoided the need to apply for Authorisation. 61 examples of SVHCs were provided for which substitution was applied for by the respective industry stakeholders. Ten examples are shown in the following table (the list of examples can be accessed in the Impact of Authorisation report (EC 2017a) and are documented in this report in Annex 9.7.2). The examples have been selected in such a way that they show the range of alternatives chosen: from chemical alternatives up to changes in technologies (see e.g. example 1, dichloroethane, alternative nr 3).

Table 8: Examples of substitution: SVHC, uses and alternatives (industry survey).

No	Substance	CAS number	N	Use of (possible) SVHC	Alternative
1	1,2-dichloroethane	107-06-2	5	• Softener for PVC • Solvent • Swelling agent	• 2-methylcyclohexanone • 4-methylpentan-2-one • Alternative technology • Not stated
2	1-methyl-2-pyrrolidone	872-50-4	1	• Solvent	• Not stated
3	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	1	• Stabiliser	• Bumetrizole
4	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	1	• Stabiliser	• 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
5	4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated	923-960-0	1	• Surfactant	• Not stated
7	Aluminosilicate Refractory Ceramic Fibres (RCF)	n/a	2	• Insulation material • Protective / heat insulating layer	• Glass, oxide, chemicals • Not stated

[106] 44%, i. e. 37 of 83 respondents in total; see also footnote 110 (page 32)

No	Substance	CAS number	N	Use of (possible) SVHC	Alternative
8	Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	2	• Plasticiser	• Di-''isononyl'' phthalate (DINP) • Not stated
9	Bis(2-methoxyethyl) ether (Diglyme)	111-96-6	1	• Solvent	• Dimethyl sulfoxide
10	Bis(pentabromophenyl) ether	1163-19-5	1	• Flame retardant	• Phosphinic acid, P,P-diethyl-, aluminium salt (3:1)

Source: EC 2017a.

Of those companies who reported a substitution, 77% indicated the REACH Authorisation to be the major driver for their substitution activities. The study found that the Authorisation process leads to substitution where it is technically feasible, even if the cost of applying for Authorisation could have been lower.

Addressing the question of a reduction in the volume of SVHC in articles, 59% of 17 respondents[107] indicated that they had either substituted or reduced the volume of SVHCs in their articles.[108]

9.2.2.3 Reduction in use of individual SVHCs: Quantitative findings

In general, the evaluated reports contained only few quantitative figures describing the effects of substitution. Reasons for this will be addressed in chapter 9.3.

In the study DEPA 2019, 43 exemplary substances are presented showing a reduction of either the production volumes (in tonnes per year) or the number of mixtures within the addressed time period (1990s to 2016) based on the Nordic SPIN database for Denmark, Sweden, Finland and Norway[109]. An overall trend is that within the Nordic countries, reduction of substances has already started before Candidate Listing and Listing on Annex XIV. Therefore, this trend may have been supported, but not initiated by REACH.

Here, only those examples are shown where a direct link between use reduction and the REACH listing is deemed to be likely by the authors. In total, eight examples were found in the list of SVHCs evaluated by DEPA for which, in at least one country, the reduction can be assumed to be triggered by REACH activities. These substances are listed in the following table including information on the individual SVHC properties and REACH listing dates (Remark: Since, in all cases, several legal provisions are in place in parallel, it has to be assumed that these reductions are an impact of the overall chemicals legislation).

[107] Referring to the same survey, but this question had less participants due to incomplete questionnaire replies; see also footnote 110 (page 32)

[108] Note that these responses relate to cases of substitution which occurred before the application stage of the Authorisation process (e.g. inclusion on the Candidate List or the Authorisation List).

[109] Substances in Preparations in Nordic Countries

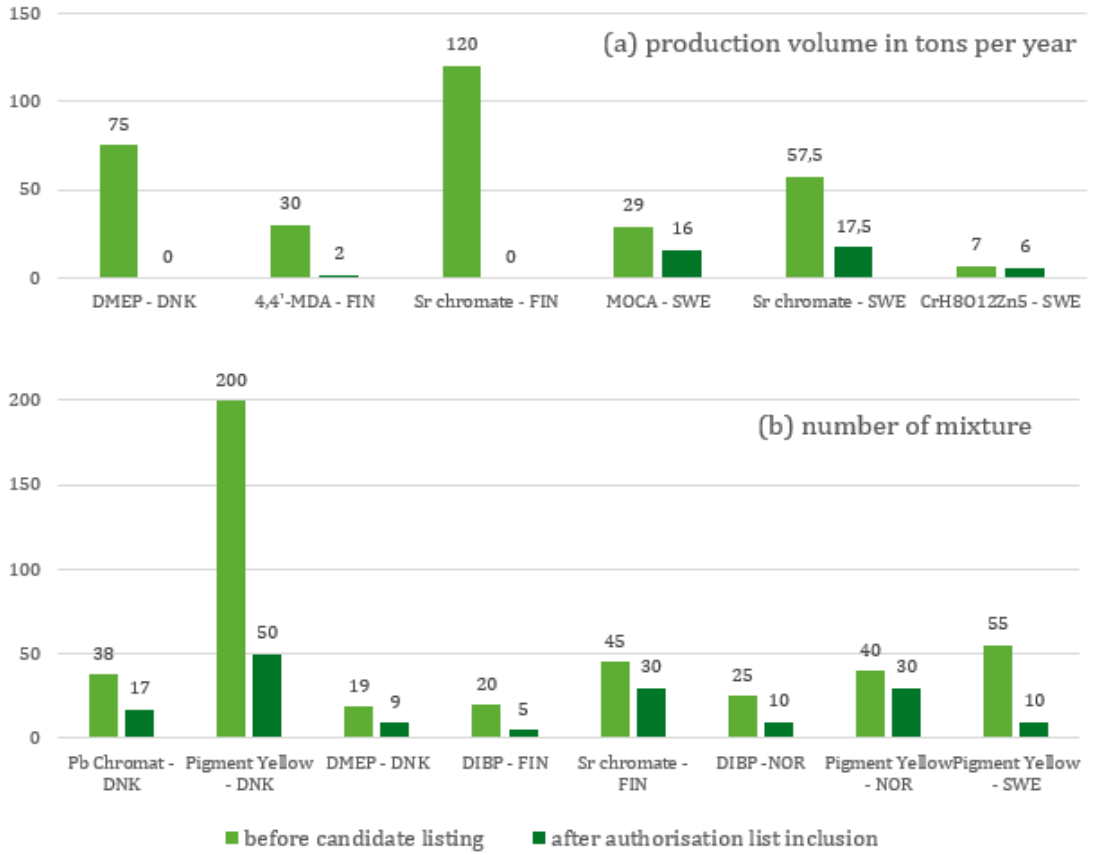
Table 9: Description of examples from DEPA 2019 for which reductions in production volume or number of mixtures can be attributed to REACH activities

No.	Substance	SVHC Property	Countries in which reduction was found	REACH listing dates	
				Candidate List	Inclusion in Authorisation List
1	Diaminodiphenylmethan (4,4'-MDA)	Carcinogenic	DK	28-10-2008	17-02-2011
2	DIBP	Toxic for reproduction	FI, NO	13-01-2010	14-02-2012
3	Pb Chromat	Carcinogenic, toxic for reproduction	DK	13-01-2010	14-02-2012
4	Pigment Yellow	Carcinogenic, toxic for reproduction	DK, NO, SE	13-01-2010	14-02-2012
5	2,2'-dichloro-4,4'-methylenedianiline (MOCA)	Carcinogenic	SE	19-12-2011	14-08-2014
6	Strontium chromate	Carcinogenic	FI, SE	20-06-2011	14-08-2014
7	Pentazinc chromate octahydroxide	Carcinogenic	SE	19-12-2011	14-08-2014
8	DMEP	Toxic for reproduction	DK	19-12-2011	13-06-2017

The following figure presents the use reduction of the eight selected SVHC in individual countries disclosed separately per reduction indicator (production volume or number of mixtures). The initial indicators' values (first columns) date back to one year before the Candidate Listing, while the values originating from the period of one to two years after the Authorisation List Inclusion were chosen as "arrival dates" (second columns). The difference between Candidate Listing and inclusion in Annex XIV was five to seven years. The reduction of the production volume ranged from 100% for DMEP in Denmark as well as Strontium chromate in Finland to minus 14% for Pentazinc chromate octahydroxide in Sweden. The reduction of the number of mixtures was highest for Pigment Yellow in Sweden (minus 82%) and lowest for Pigment Yellow in Norway (minus 25%).

As can be seen from the following figure, the reduction as such differs a lot both between the substances as well as the countries. It has to be noted that the exact reduction numbers are estimates from SPIN data graphs given in the Annex (Annex 9.7.1).

Figure 7: Reductions in production volume (a) and reductions in number of mixtures (b) before listing on the Candidate List and after inclusion into the Authorisation List for several SVHC in the Nordic Countries



Data: based on SPIN Data estimated from DEPA 2019; for details see Annex

Notes: (1) Country abbreviations: DNK – Denmark; FIN – Finland; SWE- Sweden; NOR – Norway

(2) Sr cromate - SWE values are divided by 10 for the reason of presentability on the same y axis with the others;

(3) $CrH_8O_{12}Zn_5$ = Pentazinc chromate octahydroxide

However, DEPA concludes that in general "it is not possible to distinguish between trends that occur because of Candidate Listing or Authorisation List Inclusion". Neither can it "be ruled out that the classification trigger itself can affect volumes for long periods. [...] In addition, there is no clear trend as to whether patterns change before or after any of the two regulatory interventions; moreover, the observed trends vary from country to country."

9.2.2.4 Impacts of REACH related to substitution with qualitative descriptions

Reduced emissions to the environment: The industry survey undertaken for the report on the *Impact of Authorisation* (EC 2017a) indicates that the substitution of SVHC led to reduced emissions to the environment. The compartments benefiting most from these reduced emissions are wastewater streams as well as the atmosphere. According to the majority of responses which indicated that emissions were reduced, the annual reduction in emissions of SVHC was estimated to be up to 0.1 ton per year. The solid waste generated from SVHC containing material was also reduced when SVHCs were substituted.

Reduced emissions at workplaces: Substitution of SVHCs can lead to a reduction of emissions at workplaces. The concentrations of SVHCs at workplaces and the number of exposed persons can decrease due to a reduction of production or handling of these substances. Respondents to

the industry survey claimed that even in cases where a substitution was currently not possible, the REACH Authorisation had nevertheless led to improved risk management at workplaces.

Changes in number of employees: For the majority of companies which participated in the industry survey and indicated that they substituted substances of concern, substitution has not led to any changes in the number of employees in their organisations. Only four respondents stated that substitution resulted in a reduction in the number of employees. Most companies reported an increase in employment by 1 to 9 workers. It has to be noted that these findings refer to a very small number of companies with only a few employees. Therefore, the data provided can only be seen as first indications, not as robust quantitative results.

Changes in volume of products sold: The EU 2017a report on *Impacts of Authorisation* outlined that one third of the respondents who indicated that they had implemented substitution due to REACH Authorisation "did not know whether substitution by alternative substances and/or technologies had an effect on the volume or revenue generated from the sale of their products". Most reported a decrease in the revenue from products with alternative substances and/or technologies following from a reduction in volume. Seventeen percent of the respondents indicated that they had not seen any change in revenue generated from products manufactured with alternative substances and/or technologies.

It should be noted that the authors of this study could not evaluate the completeness of the picture drawn by the industry survey presented in the study. The number of respondents to the different questions varied as incomplete questionnaires were included in the analysis.[110] Although this study is the most detailed analysis which is available on the impact of authorisation under REACH so far, it is based on a very limited number of responses.

9.2.3 What are triggers and drivers for substitution?

The studies analysed in this review describe several factors which initiate and support substitutions – called triggers and drivers. Any activity which supports substitution can be understood as "driver". If such an activity results in the initiation of a new substitution activity, it can be called a "trigger" (at the same time it is also a driver). It is not always possible to distinguish clearly between these terms.

The following two sections explain regulatory and non-regulatory triggers and drivers with a focus on REACH-specific factors. In most cases, substitution specifically deals with SVHCs, substances which are restricted or substances with a harmonised classification.

9.2.3.1 Regulatory triggers and drivers

Activities under REACH

Several activities under REACH initiate and support substitution. This has been analysed in detail in three studies covered by this review: the study *Monitoring Authorisation under REACH* (Austrian Environmental Agency 2017), the study *Impact of Authorisation* (EC 2017a) and the study *Effects of legal interventions* (DEPA 2019). Further aspects on triggers and drivers have been discussed briefly in the other twelve studies of this review.

The following table lists REACH activities and elements which support substitution. They have been identified in the studies analysed for this review.

[110] The total industry survey analysis is based on 63 complete and 21 partial responses. The questionnaire was sent to 240 individuals of which, in some cases, several individuals belonged to the same company.

Table 10: REACH Activities and elements that trigger substitution

Registration & Dossier Evaluation	Authorisation	Restriction	Substance Evaluation
• Generation of better knowledge on substance properties • Making better informed choices	Announcement effect[111]: • Listing on Candidate List • Listing in Annex XIV • Pressure to search for alternatives Time limits in authorisations (with need for revisions) • Assessment of alternatives • Consumer demand according to REACH Art. 33	Announcement effect: • Listing in Annex XVII • Pressure to search for alternatives	Announcement effect: • CoRAP listing • Uncertainty effect[112] • Grouping approach (in order to avoid regrettable substitutions) • Making better informed choices • Support of priority setting

Note: Own compilation according to reviewed studies.

According to the reviewed reports, Authorisation is the most important process for the support of substitution by REACH. (In addition, Authorisation is a subject of intense public discussion due to its far-reaching consequences for the availability of SVHCs. This can be an additional explanation for the focus of the studies). The triggers for substitution under the process of Authorisation are listed in the table in chronological order: the entry of intention of SVHC identification into the PACT, the actual placement on the Candidate List and the inclusion in Annex XIV. With each step, the pressure (which can be seen as an incentive) for research and development for substitution rises. At the latest when it is decided that Authorisation must be applied for a certain substance, an assessment of alternatives must be carried out. Already before, classification and labelling of a substance (and mixtures) or other regulatory actions such as the Risk Management Options Analysis can start discussions on substitution in companies which are following the REACH activities.

Review periods are defined for granted authorisations with the aim of checking, whether or not the availability of suitable alternatives has changed. The need to review AfAs (and the recurring related costs) as well as the possibility of suitable alternatives developing in the future are also incentives to immediately invest into R&D and/or substitute and not to invest in review activities. Finally, the consumer demand for information according to REACH Art. 33 could become a market-driven incentive for substitution.

The reports containing the in our view most useful information regarding impact of REACH on substitution had a focus on evaluating the effects of Authorisation. This can be due to the fact that this element of REACH has far reaching consequences for the ban of substances and is therefore under intense public discussion (REACH Review 2017, EC 2018).

Further elements of the Registration and Dossier Evaluation that can promote substitution are the additional knowledge gained about substance properties. It allows to make better informed choices. Restriction under REACH (with listing of the substances in Annex XVII) leads to an

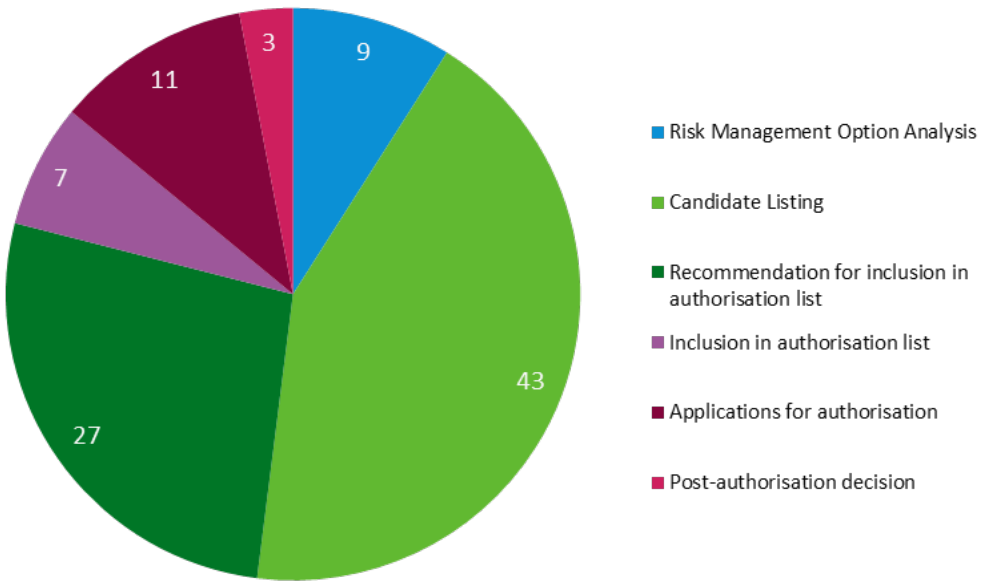
[111] Describes the effect that key announcements like Candidate Listing, Authorisation Listing and the sunset date entail early substitution, improvement of exposure conditions and market disturbance (*Impact of Authorisation,* EC 2017)

[112] According to the study Impact of Authorisation (EU 2017), it is observable that uncertainties for business continuation including the rely on granted authorisation have an impact on substitution decisions of companies. To avoid misunderstanding: in relation to the discussed topic, the uncertainty effect has no official or scientific definitions.

enhanced substitution of substances of concern. Substance Evaluation drives substitution in the sense of an "early warning system" on possible later regulation. For example, information gathered in the Substance Evaluation Dossiers and Listing on the CoRAP list support better informed choices of companies shedding light on future Authorisation or Restriction candidates.

The report on *Impact of Authorisation* (EC 2017a) evaluated the responses to an industry survey on the most important legislative incentives. The results are presented in Figure 8. Most often, the answer was that Candidate Listing is the legislative incentive triggering companies to substitute certain substances (34%), followed by the recommendation for inclusion in the Authorisation List (27%) and the actual inclusion to the Authorisation List. This result supports the finding of listing being the most important driver for substitution.

Figure 8: Distribution of answers on the question of the most important legislative incentive for substitution in %



Source: Impact of Authorisation (EC 2017a)
Note: The number of respondents was 56.

Of all incentives provided by REACH, the listing on different lists (Candidate List, Annex XIV, Annex XVII, CoRAP) appears to be the most effective trigger for initiating substitution activities in industry.

Activities under other legal provisions

The reviewed studies also list chemical legislations other than REACH which play a role when substances of concern are substituted. The ECHA Substitution Strategy (ECHA 2018) especially highlights the CLP regulation[113] and the Biocidal Products Regulation (BPR) [114]in addition to REACH.

[113] Regulation on classification, labelling and packaging of substances and mixtures, EC No. 1272/2008

[114] REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal

- The Regulation on Classification, Labelling and Packaging (CLP) supports substitution in the way of knowledge generation on hazardous properties of substances and – as a consequence – classification and labelling of substances (and mixtures). This regulation has consequences for many other legislations which refer to the result of the classification.
- The exclusion criterion under the BPR (Art. 5) directly entails the need for substitution, following a blacklisting strategy – as it is the case for restrictions under REACH.

ECHA listed more than 20 EU regulations and directives that currently are linked to the existing rules on classification and labelling ("downstream legislations"). These legislatives are covering policy areas such as consumer products, occupational health and safety, waste and end -of-life products, and general legislation on control of dangerous or hazardous chemicals in legal provisions for air and water quality. ECHA concludes that, as a result of more information becoming available through the registration process under REACH and the CLP requirements, further risk management measures might be initiated in line with all of these legal provisions, thus providing a higher consistency for more chemical safety and for a high protection level for humans and the environment.

- Other parts of chemicals regulations supporting a safer chemicals management are the Regulation on Plant Protection Products (pesticides)[115], the Directive on carcinogens and mutagens at work and the Directive on risks related to chemical agents at work [116] [117]. In addition, the POP regulation[118] aims to ban persistent organic pollutants globally. This includes a comprehensive assessment of alternatives.
- The restriction of substances in Annex II of the RoHS Directive[119], the restrictions of substances regarding their use in toys according to the Toys Directive and restrictions according to the Cosmetic Regulation are further drivers for substitution from products legislation.
- The Water Framework Directive (WFD)[120] leads to the identification of priority substances "presenting a significant risk to or via the aquatic environment" asking for a risk assessment. Even if the directive itself does not prescribe direct measures to substitute these substances, it supports substitution indirectly by aiming to avoid the release of these substances into water bodies.

9.2.3.2 Other drivers beyond regulation

Besides the regulatory drivers, the review of studies revealed other factors that support substitution:

[115] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market

[116] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

[117] Directive 98/24/EC - risks related to chemical agents at work https://osha.europa.eu/en/legislation/directives/75

[118] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

[119] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

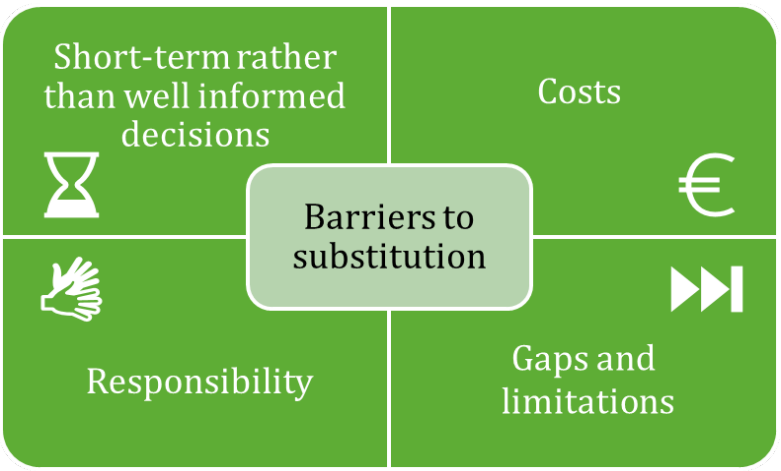
[120] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy

- Private investors demand for reporting on product stewardship, substitution and management of substances of concern. According to ECHA 2015, these investors are interested in investing in forward-looking companies that are taking the initiative offered by the REACH Regulation. They search for companies that are successfully investing in innovative, greener substitutes, which can take the lead in other regions and countries where the chemical regulations are seeking to follow REACH.
- The demands of large retailers and article producers for SVHC-free products and raw materials are important drivers especially for consumer goods.
- Image issues: Internal policies and substitution strategies in order to create an external picture as frontrunners due to a change of mindset in consumers (DEPA (2019) cited from REACH Review (2018); COM *Impact of Authorisation* (2017a); ECHA Substitution Strategy (2018)).
- The reduction of the concentrations of substances of concern in materials and waste streams is an important objective to reach a more circular economy. (*Study for a non-toxic environment*, EC 2017). This requires the substitution of substances of concern in many uses. Recently, the Netherlands published a national list of priority substances of concern as an element of their national strategy for a circular economy (Wassenaar et al 2018).

9.2.4 Barriers to and difficulties for substitution

Next to the drivers, this review of the studies on REACH and substitution also reveals a larger number of barriers which make substitution more difficult at present. They range from data gaps and limitations in the assessment of alternatives up to costs connected with a substitution process. Four groups of barriers are shown in the following Figure 9. Each group addresses several aspects.

Figure 9: Barriers to substitution.



Source: own illustration, Öko-Institut e.V.

9.2.4.1 Solutions with a short implementation time instead of well-informed decisions

A first group of barriers are time constraints. When substitutes have been already available, they have been used. Frequently chemicals have been selected as substitutes with a similar structure. This often allows a replacement without larger changes in the production process. In several

cases, this so-called „drop-in-chemical replacement" has led to „regrettable substitutions": the use of substances which also have been or are suspected to have problematic properties. Examples are the substitution of Bisphenol A by other bisphenols and the substitution of long-chain chloro paraffines by medium- and short-chain chloroparaffines (Fantke et al. 2015).

There is no indication for a strategic interest of companies in general to systematically develop alternatives for substances of concern whose is more complex. This is especially the case for all changes that require a larger modification of the process conditions or even the move to another technology. Development of such alternatives is expected to require significant time and resources for research and development. Therefore, alternatives in processes and supply chains demand will, effort and time-intense assessments and developments.

Even when case studies of successful substitution are available, the process to transfer these changes to the situations in other companies (with slighty or significantly different process conditions) is not an easy one.

In addition, it was noticed that the substitution decision and the withdrawal of a substance from the market depends on the importance of the substance in the eyes of the company. Therefore, economic criteria are most relevant for these decisions. At present there is no indication that companies in general decide to substitute a substance of concern pro-actively and without external (mostly regulatory) pressure in order to reduce adverse impacts on men and the environment

The reports on substitution of SVHCs show that, in most cases, companies see substitution only as a need to be compliant with legislation. At present, substitution involves a disproportionate effort for companies which see few benefits.

Several studies concluded that substitution at present does not necessarily lead to better products. Industrial stakeholders most probably think of drop-in replacements of chemicals which have been available already while functional alternatives on the level of technology played a minor role. Several cases for substitutions were reported which could be achieved in the short term. Later, they have been found to be problematic too.

9.2.4.2 Gaps and limitations

Several gaps and limitations which hamper substitution have been discussed in the reviewed studies.

Robust information about alternatives. Assessment of alternatives requires inter alia sufficient information about the toxicological and ecotoxicological properties of the potential alternatives. The report *Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH* (Lowell Center 2016) points out that information collected under REACH is certainly useful for this kind of information. However, the registration data in its current form is not readily usable to identify alternatives. This is due to the fact that it has not been the intention of the registration process to present data in such a way. Therefore, the data from the ECHA dissemination database requires further processing to become a more useful tool for the assessment of alternatives.

Budgets. The Lowell Center Report of 2017 raises attention to another limitation. The principle of substitution is frequently discussed. However, development of alternatives and implementation of substitution is generally not a priority topic in programs and activities in industry. Existing support strategies as described below can be very important to further strengthen substitution. However, they should be connected to national and EU-wide programs (R&D and others) to ensure that the necessary budgets for these activities are available.

Substances of concern not yet listed. According to the reviewed studies, substitution activities so far focused on substances which

- already have been identified as SVHC,
- have a harmonised classicisation as CMR substances or
- are restricted.

For other substances of concern (e.g. structurally related substances with problematic properties) without such a legal pressure, substitution, in generally has not occurred as it seems.

Information gaps on SVHCs in articles. Even under REACH there are large information gaps regarding the occurrence of SVHC in articles, their emissions during the use phase of the articles, their occurrence in waste streams and (in future) in recycled material. It is one objective of the implementation of the SCIP database to improve the knowledge on SVHCs in articles. This would help to identify further needs for substitution of SVHCs in articles.

Inconsistencies in the regulation of articles in the EU. Import of SVHC-containing articles into the EU is one important source for SVHCs. Import of such articles is actually not covered by the Authorisation process under REACH, but restrictions under REACH can prohibit the import of articles with restricted substances (see also REACH Art. 69.2). Requirements of some other legal provisions such as the RoHS Directive apply to imported products as well, and therefore provide a level playing field for EU and non-EU manufacturers and service providers.

9.2.4.3 Lack of a sense of responsibility

Evaluation of technical feasibility of alternatives. Reduced emissions of hazardous chemicals at workplace and to the environment is an essential aim in declarations of authorities and industry. However, implementation of a real substitution project can be a time-demanding process in a company. The identification of potential alternatives and the evaluation of their technical and economic feasibility is one of largest challenges within this process. Support of this step would be highly appreciated by companies. Unfortunately, it was found that most of the authorities scarcely have the possibilities to support the development of technically feasible alternatives. One reason is that only few of them have engineering expertise in this field of action. (Belgium Ministries 2019)

Shifting of responsibilities and activities within the supply chains. Most supply chains are complex. The degree to which substitution can be implemented, in some cases depends on downstream user processes, in other cases on the market power of the producer of the substance or their alternatives. It is more probable that substitution is established on the level of the formulator rather than the article producer (who has less knowledge about the chemical composition of the raw materials which he uses). As a consequence, responsibility for substitution decisions is likely to be fruitlessly shifted up and down the supply chain. (*Chemicals Innovation Agenda,* EC 2019).

Interest of investors. Private and public investors can influence in-house decisions of companies. Provided that investors are interested in those companies which implement substitution strategies, this would be a trigger for substitution, as companies align themselves with the investors' conditions. If only decisions and R&D measures in favour of substitution would arouse the interest of investors, the companies would substitute SVHCs. However, at present, there are no indications that private investors support substitution activities in this way. On the contrary, the authors of the study "Impact of REACH Authorisation" came to the conclusion that the placing of a substance on the Candidate List even reduces private investors'

interests in companies producing or handling these substances (EU 2017a) .There is a need for investor leadership in the sense that investors recognize the importance of their role. In addition, incentives and regulations are required for investors to include substitution of hazardous substances in their investment decisions.

9.2.4.4 Costs and obligations

The implementation of substitution involves costs, especially costs for research and development (R&D) and the adaption of technologies and production sites. In the absence of private investors promoting substitution through financing, companies have difficulties to afford such expenses. From a business point of view, expenses only make sense if they are absolutely necessary for external reasons or result in a (mostly economic) benefit. This is especially true for SMEs, as noted in a special report by the EU Commission (EC 2015). As long as an expenditure is not absolutely necessary for external reasons or does not bring an (economic) advantage, it will not be made for business reasons. At the moment, external reasons or incentives are lacking that would provide an advantage for companies to opt for substitution for business reasons. However, promoting technologies that are free of substances of concern through external "pressure" or incentives could reduce future costs incurred by companies and in connection with the adverse effects of the emissions of substances of concern on human health and the environment.

With respect to the costs, companies may consider the benefits of either paying the costs for substitution or for the application for authorisation. Costs for the development and implementation of a new alternative can be much higher than the costs for application for an authorisation.

In addition, companies have obligations to fulfil towards their customers regarding technical properties of their products which are determined by the processes used. They have to ensure or even guarantee that these properties will be maintained, sometimes for years. Thus, modifications due to substitution are sometimes impossible. Some companies even consider the moving of their production location outside the EU in order to avoid authorisation obligations (EU 2015). To what extend this really happen is uncertain. No valid data or specific examples do exist on this issue.

9.2.5 Support Strategies

The studies reviewed for this analysis described support strategies to overcome existing barriers which at present hamper substitution.

At first, the reports underline the important supportive role of the European Chemicals Agency (ECHA) as the central European institution to ensure the implementation of this regulation. Through information dissemination via the ECHA Website, the agency acts as facilitator for data access and coordinator of related stakeholders.

A second support strategy is networking as e.g. in the ECHA Network on Substitution[121] and the Network of REACH SEA[122] and Analysis of Alternatives Practitioners (NeRSAP). Workshops on substitution in non-formalised contexts may also be an opportunity for networking on the topic. In this regard, the Austrian Environment Agency proposes to appoint a person on Member State level to manage substitution of SVHC, taking the requested action on the installation of a

[121] https://echa.europa.eu/substitution-networks

[122] SEA = socio-economic analysis

substitution focal point. This is a possibility to counter the proposal of the REACH Review for further capacity building on MS level (EC 2018).

In addition to ECHA´s activities to support substitution, on a national level, several MS CA started performing and supplementing similar activities on REACH and substitution, e.g. Sweden and the Netherlands. An overview of such activities launched by ECHA is given in the following section. More details on national activities from MS CA are provided in section 4.6.

(Additional information: The study *Impact of Authorisation* (EC 2017a) contains a helpful list of portals and tools for substitution and the assessment of alternatives. A similar compilation can be found in the Occupational Safety and Health Wiki[123]. Examples are the portal SubsPort, the substitution support program of ChemSEC under the EU Life Programme[124], the QSAR Toolbox[125], the Eco-innovation observatory[126], NORDEN[127] and Subst-cmr (French EPA)[128],e[129].

The demand of financing substitution has already been discussed before. Already, several investor groups support substitution strategies. Thus, companies can apply for (co-)funding for R&D of SVHC-free formulations and technologies.

An implicit support for substitution can be seen in the fact that Candidate Listing and the process of authorisation as such are known outside the EU. This helps EU companies and producers to cooperate with non-EU partners.

Finally, **learning from best practice examples is highlighted as one of the most important support measures:** this moves the focus of the discussions and activities to success stories of substitution and stimulates further substitutions (Austrian Environment Agency 2017). Experience shows that many companies need direct support to adapt available substitution cases to their individual processes. This goes beyond participation in EU or national workshops and networking.

9.2.6 ECHA: Initiatives on substitution in general under REACH

In 2018, the European Chemicals Agency (ECHA) launched its substitution strategy to increase capacity building, support and use of ECHA database in substitution processes (https://echa.europa.eu/de/substitution-news-and-activities/events2019). The focus lies on explicitly connecting substitution to innovation in safer chemicals, materials and technologies and advocating a wider change in industry practice and in outlook to address the risks associated with substances of concern. It acknowledges that REACH pushes companies to search for and move to safer alternatives, directly: authorisation, restriction (regulatory risk management encourages substitution), indirectly: CLP, registration, communication in supply chain (CLP identification first step and important driver for companies to avoid consequences). Over the last years, ECHA has organised several supply chain workshops to discuss substitution options with companies and to exchange knowledge on available tools. Examples are flame retardants in home textiles (2018), metal substitution, and antifouling paints. ECHA intends to trigger a shift in companies' mindset so that substitution is seen as part of innovation to safer

[123] https://oshwiki.eu/wiki/Substitution_of_hazardous_chemicals#Success_stories (accessed 20.12.19)

[124] https://www.subsportplus.eu/(accessed 04.02.2020)

[125] https://qsartoolbox.org/(accessed 04.02.2020)

[126] https://www.eco-innovation.eu/ (accessed 04.02.2020)

[127] https://www.nordicinnovation.org/(accessed 04.02.2020)

[128] https://substitution.ineris.fr/en(accessed 04.02.2020)

[129] To find in Study for the strategy for a non-toxic environment of the 7th EAP- Sub-study a: Substitution, including grouping of chemicals & measures to support substitution, Table 1. https://ec.europa.eu/environment/chemicals/non-toxic/pdf/Sub-study%20a%20substitution%20grouping%20NTE%20final.pdf

chemicals. In addition, the grouping of substances has become an important regulatory approach within substance evaluation. An important reason for this has been the aim to avoid regrettable substitutions in the future.

Remark: More details on national initiatives from EU member states are given in section 4.5 and annex section 9.5 of this report.

9.3 Methodological challenges in monitoring substitution

At present, there is no robust data base available which would allow to quantify the impact of REACH on the substitution of Substances of Concern in Europe. This would require detailed quantitative information about the use of these substances. Statistical data on the production and consumption of chemicals hazardous to human health and the environment in Europe are published on an annual base by EUROSTAT (Oltmanns et al. 2020). However, these figures are based on data from PRODCOM, the European production statistics. The large majority of these data sets refer to group entries and do not allow a substance-specific monitoring of substitution processes as it can be done on the basis of data from the Nordic SPIN database (Oltmanns et al. 2020, Bunke et al. 2020, Sackmann et al. 2018). Findings from the REACH Baseline study (Bunke et al. 2012, Bunke et al. 2017) show a clear increase in the quality of data on substance properties due to REACH. For a set of more than 240 reference substances, this study contains a quantitative description of the situation before REACH. This baseline allows a comparison with the situations at several subsequent time points. However, the scope of this study does not include assessment of substitution processes. The data from the Nordic SPIN database allow a similar comparison for individual substances and the monitoring of substitution. However, such data exist only for four Scandinavian countries.

Apart of the concrete examples for eight SVHC taken from DEPA 2019, the reviewed studies did not contain further examples for explicitly REACH triggered reduction in product volumes or numbers of mixtures of any SVHCs. The Austrian Environmental Agency reported the reduction in the product volume for several substances in Nordic countries commenting that success stories weren't due to REACH but most likely due to Nordic Chemicals legislation in the time before REACH came into force. An.

The majority of the evaluated reports agree in the finding that REACH generated and generates knowledge on chemicals at least through registration (especially chemical safety assessment), dossier evaluation and substance evaluation. Although, the study review showed that at present no data exist which allow monitoring of substitution processes in Europe over time in a quantitative way. Studies of the Austrian Environment Agency (2017) and DEPA (2019) use SPIN data in order to monitor authorisation under REACH and the effect of legal interventions, respectively. Such data on product volumes is missing under REACH as registered volumes are indicated in the registration dossiers in tonnage bands only and is not regularly updated by registrants. When reductions or increase in consumption of chemicals were determined those effects could not be assigned to individual pieces of legislation (e.g. health or chemicals legislation) or aligned to a specific regulatory action (e.g. the REACH Authorisation). As can be seen in DEPA (2019) for the Nordic countries alone, trends already differ per country, substance and application. Thus, it is uncertain whether such trends could be evaluated EU wide in a meaningful way.

It is not yet clear which indicators may be suitable for assessing a reduction in the exposure of human beings and environment. Possible indicators could be for example article categories, product categories, sector of end-uses, IUCLID tonnages, data from human biomonitoring and environmental species banks. In the eyes of the authors of the report of the Austrian

Environment Agency in 2017, mapping those over a certain time period would be a good consistency check given that data on those indicators are available. Due to the missing monitoring regime, it is also not yet clear how much effect the regulatory actions already had. As can be seen from Impact of Authorisation (EC 2017a), to substitute a substance takes several years.[130]

Also missing to draw a more complete picture of the impacts REACH had on substitution are e.g. detailed substitution costs, or sales numbers for SVHCs or alternatives (EC 2017a, Impact of Authorisation).

Accessing the data is even more difficult as there are non-registered uses of and companies often consider the required precise data on volumes and uses as confidential business information (Chemicals Innovation Agenda, EC 2019). One example for difficulties in data assessment is the industry survey conducted in EC 2017a (*Impact of Authorisation*) with a response rate of 35% only.

As can be seen from the sections above on the reduction of the use of SVHCs (use volumes and number of mixtures, see chapter 9.2.2.2 and 9.2.2.3) it is certain that substitution takes place. But, seeing the quantity of data available for accessing SVHC reduction, the authors of this study (DEPA 2019) conclude that further effort is needed to develop appropriate assessment methods.

9.4 Conclusions: Actual impacts of REACH on substitution

The reports analysed in this review show that REACH actually has a number of impacts on the substitution of substances of concern.

- Authorisation and Restriction under REACH lead to an enhanced substitution of SVHCs and other substances of concern.
- Classification and Labelling of substances (and mixtures) under the CLP Regulation are seen as a further important driver for substitution of substances of concern. This regulation has consequences for many other legislations which refer to the result of classification and labelling.
- Most of the identified drivers for substitution (e.g. Candidate List, REACH Annex XIV, need for the assessment of alternatives in case of an application for authorisation) belong to the REACH Authorisation process.
- Listing of substances under different procedures of REACH (with different legal consequences) (especially Candidate List, Authorisation List (Annex XIV), Restriction List (Annex XVII)) seems to be the most important and most effective trigger for substitution.
- Listing of substances of concern under other legislations and from other activities (e.g. the list of priority substances under the Water Framework Directive, the exclusion criterion under the Biocidal Products Regulation and the SIN list from ChemSec) seems to have a similar announcement effect.
- For some SVHCs it has been found that production volumes and the number of uses decreased. For eight SVHCs this has been shown quantitatively. Emissions to the

[130] The number of years to achieve substitution ranges between one year and four years (53%), another 27% counted five to ten years (n=49)

environment decreased in these cases, too. However, intensity of reduction and trends differ among the four Scandinavian countries assessed. (It has to be noted that these reductions are probably caused by the overall chemical legal provisions which are in place.

- Reduction of concentrations of certain SVHCs at the workplace have been achieved as a consequence of REACH Authorisations.
- The reduction of substances of concern results from a combined effect of various legislations. An enhanced interplay between legal provisions could lead to a further support of substitution.
- In the studies covered by this review, chemicals with harmful characteristics but without SVHC "status" have only been addressed insofar as it was stated that these chemicals should be taken more closely into account. There are no indications that, for these substances, substitution is triggered by REACH. An exception are restricted substances and substances with a harmonized for which substitution efforts would be undertaken. This triggers substitution efforts too.
- The intensity of activities aiming to support substitution increased. Different stakeholder groups are dealing with the topic of substitution, analysing it from different perspectives, e.g. financing substitution, support, decision-making or dedicating their efforts to advancement and giving recommendations in this respect.
- A large number of networking activities have been launched at the European level (initiated by ECHA) and on the national level, initiated by MS CAs.
- The data generation under Registration and Substance Evaluation can be regarded as a supportive basis for avoiding uninformed, regrettable decisions. However, analysing this data is a time-intensive task, and tight time frames in the market are calling for substitutions which can be realised in the short term.
- The interests of the market (e.g. demands of article producers for SVHC-free raw materials) and of financial investors are most probably the most important non-regulatory drivers.
- Substitution by changes in technology are rare. Most cases triggered by lead to the use of other chemicals (drop-in-alternative, 1:1 alternative). Moreover, many of these substances are similar in structure to the substances that are replaced. This indicates potential regrettable substitutions: the alternatives which may cause similar problematic effects, too.
- It is difficult to monitor substitutions quantitatively as registration dossiers include public data on production volumes only as tonnage bands. Furthermore, figures in the chemical safety reports do not need to be updated regularly. Therefore, exact figures on the production tonnages per year are not available – apart from chemicals in Scandinavian countries with reporting obligations to the National Product registers.
- Learning from best practice examples seems to be one of the most important support measures. It moves the focus of the discussions and activities to success stories of substitution and stimulates further substitutions.

- Experience shows that many companies need direct support to adapt available substitution cases to their individual processes.

9.5 Additional information: National initiatives on substitution support from MS CA

Several countries started their national activities on substitution support:

- Sweden: Swedish Chemical Substitution Center (https://www.ri.se/en/popfree/swedish-centre-chemical-substitution) and creation of databases, e.g. BASTA for construction sector
- Belgium: Adoption of a Belgian strategic roadmap to substitution of SVHC in 2018. Includes subsidies for RnD activities and research on substitutes, organisation of sector-specific workshops e.g. supply chain substitution workshop on alternatives to bisphenol A in thermal paper, 26 March 2019, Brussels, Presentations, outcome of the discussion groups and workshop report are available here: https://www.health.belgium.be/en/supply-chain-substitution-workshop-alternatives-bisphenol-thermal-paper
- The Netherlands: Chemical Innovation Agenda released in 2018 which proposes 7 areas where RnD needed to stimulate development of safer alternatives: https://www.chemischestoffengoedgeregeld.nl/content/workshop-towards-safe-chemicals-innovation-agenda-substitution-safe-design
- France: There is no formal strategy for substitution, but several related initiatives are in place, e.g. the obligation to substitute CMR 1A and 1B in the workplace.

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9.6.2 Links to studies covered in the study review in chapter 9.2

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Commission study for a non-toxic environment (incl. relevant case studies)
https://ec.europa.eu/environment/chemicals/non-toxic/pdf/NTE%20main%20report%20final.pdf

Commission Study: Impact of Authorisation https://ec.europa.eu/docsroom/documents/26847"

ECHA webpages on substitution, including work carried out to promote substitution in the context of ECHA`s substitution strategy https://echa.europa.eu/de/substitution-news-and-activities/events2019

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9.7 Annexes

9.7.1 Supportive information on SVHC reduction from DEPA (2019)

The data in the following two tables is the basis for the graphs in Figure 10 of this section which shows the reduction in production volume and number of mixtures before inclusion in the Candidate List and after inclusion in the Authorisation List for several SVHC[131] in the Nordic

[131] Abbreviations and details for Substances can be read of Table (page 30).

Countries[132]. It is important to notice that the following numbers estimates, this means that they are derived from of the graphs given below.

Table 11: Reduction in production volumes and number of mixtures for selected SVHCs in Scandinavia: Production volumes

Substance name	Before Candidate Listing Year	Before Candidate Listing Amount/t	After inclusion in Authorisation List Year	After inclusion in Authorisation List Amount/t	Country	Reduction of	Within years
DMEP -	2010	75	2016	0	DK	-100	6
4,4'-MDA -	2007	30	2012	2	FI	-93	5
Sr chromate -	2010	120	2015	0	FI	-100	5
MOCA -	2010	29	2015	16	SE	-45	5
Sr chromate -	2010	57,5	2015	17,5	SE	-70	5
CrH8O12Zn5 - S	2009	7	2016	6	SE	-14	7

Note: These figures are estimated numbers from the graphs given below.

Table 12: Reduction in production volumes and number of mixtures for selected SVHCs in Scandinavia: Number of mixtures

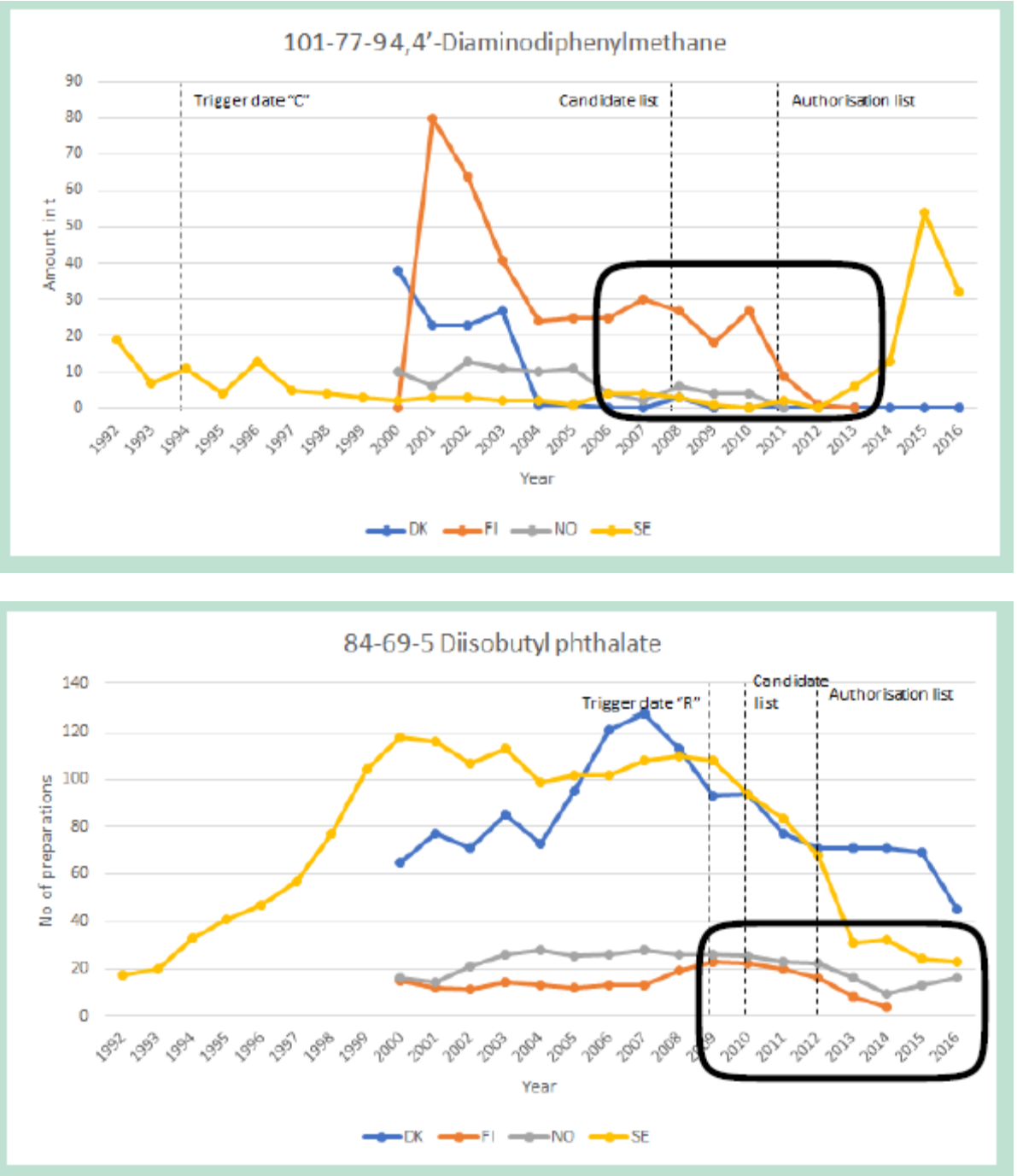
Substance name	Before Candidate Listing Year	Before Candidate Listing Nr of mixtures	After inclusion in Authorisation list Year	After inclusion in Authorisation list Nr of mixtures	Country	Reduction of	Within years
Pb Chromat -	2007	38	2014	17	DK	-55	7
Pigment Yellow -	2009	200	2014	50	DK	-75	5
DMEP -	2010	19	2016	9	DK	-53	6
DIBP -	2008	20	2014	5	FI	-75	6
Sr chromate -	2010	45	2015	30	FI	-33	5
DIBP -	2008	25	2014	10	NO	-60	6
Pigment Yellow - NO	2009	40	2014	30	NO	-25	5
Pigment Yellow - SE	2009	55	2014	10	SE	-82	5

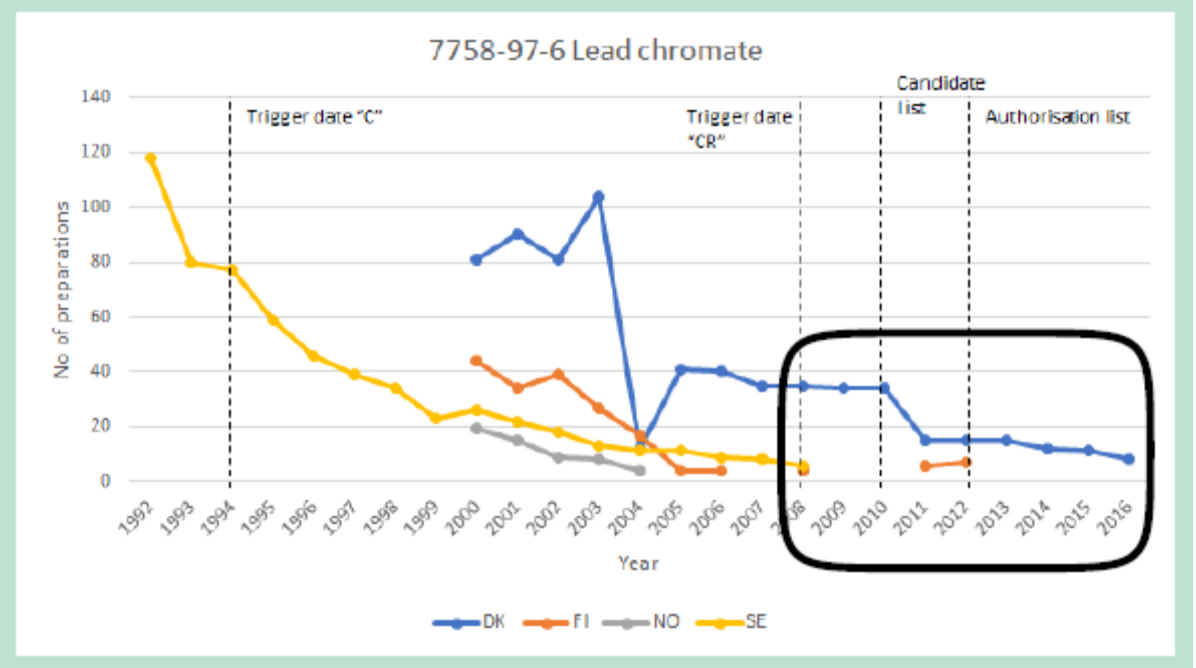
Note: These figures are estimated numbers from the graphs given below.

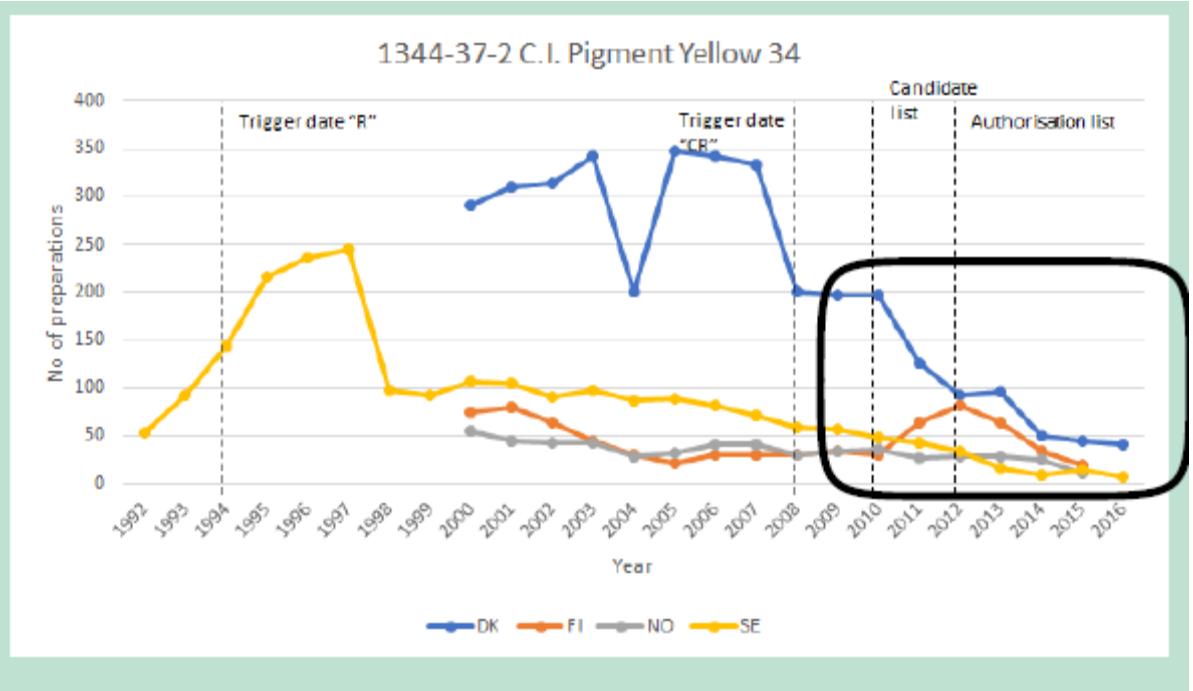
[132] The following abbreviations are used for the countries: SWE/SE – Sweden, DNK/DK – Denmark, NOR/NO – Norway, FIN/FI – Finland whereof triplets of letters are used in the table, double letters are used in the graph.

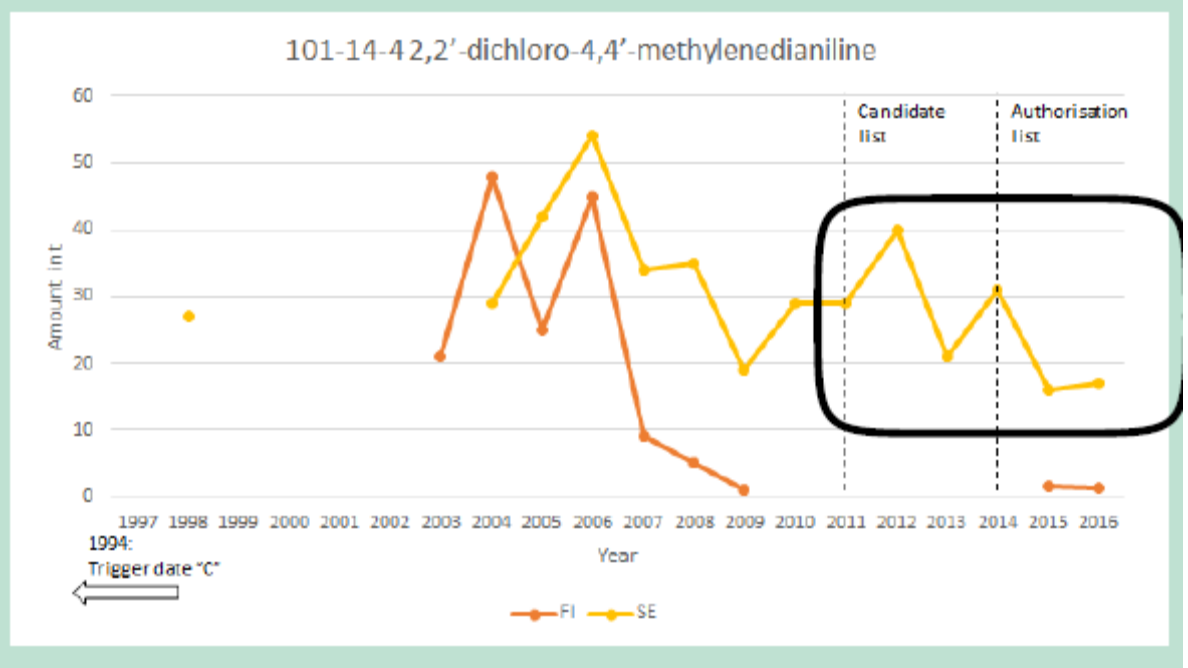
The following Figure 10 contains the base data for the individual reduction numbers of eight SVHC taken from DEPA 2019. Black boxes in the graphs indicate the time period in which reductions in the indicator (y axis) can be attributed to REACH activities. The figure consists of 10 individual graphs.

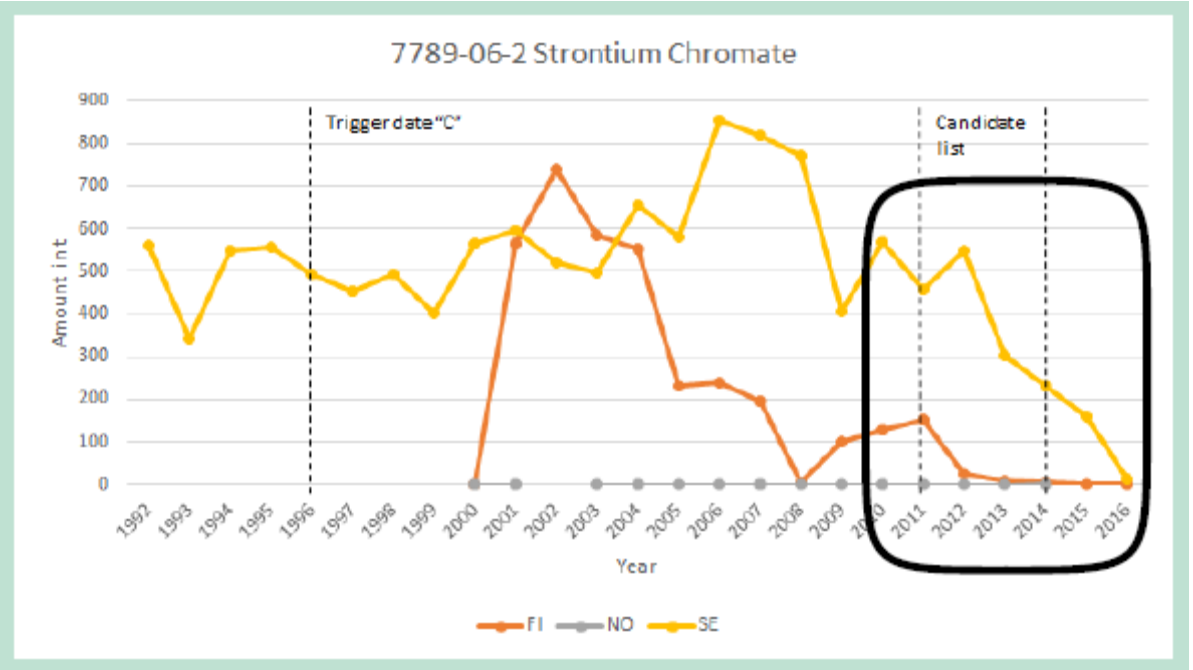
Figure 10: Production volumes (in tons) *or* number of mixtures over time for eight SVHC in Scandinavia.

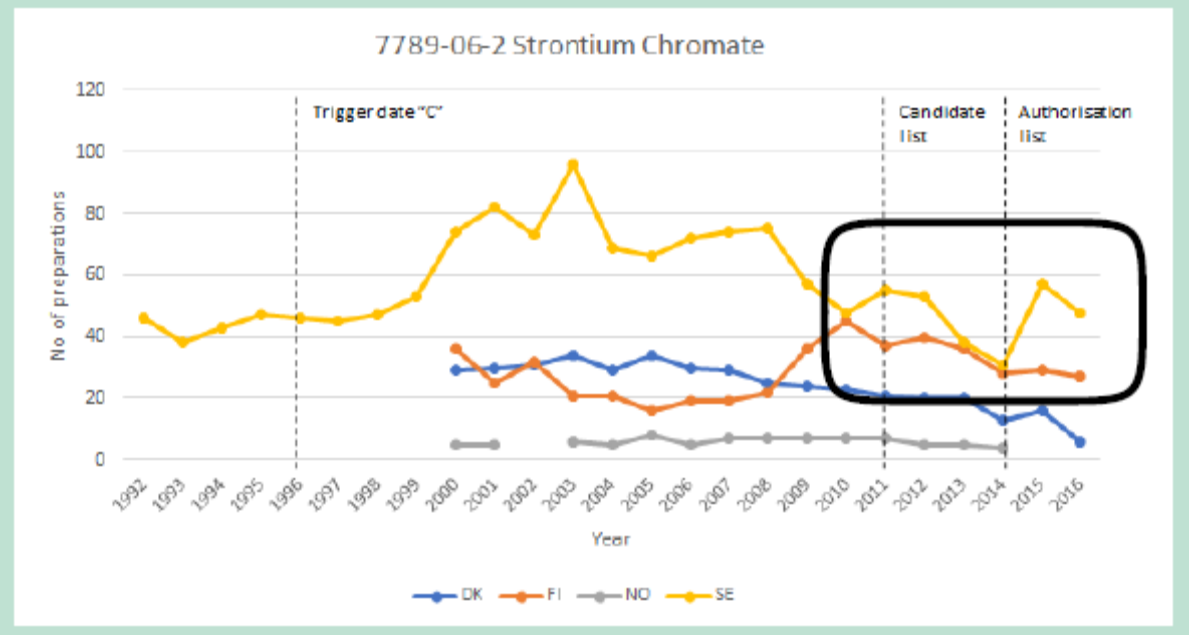


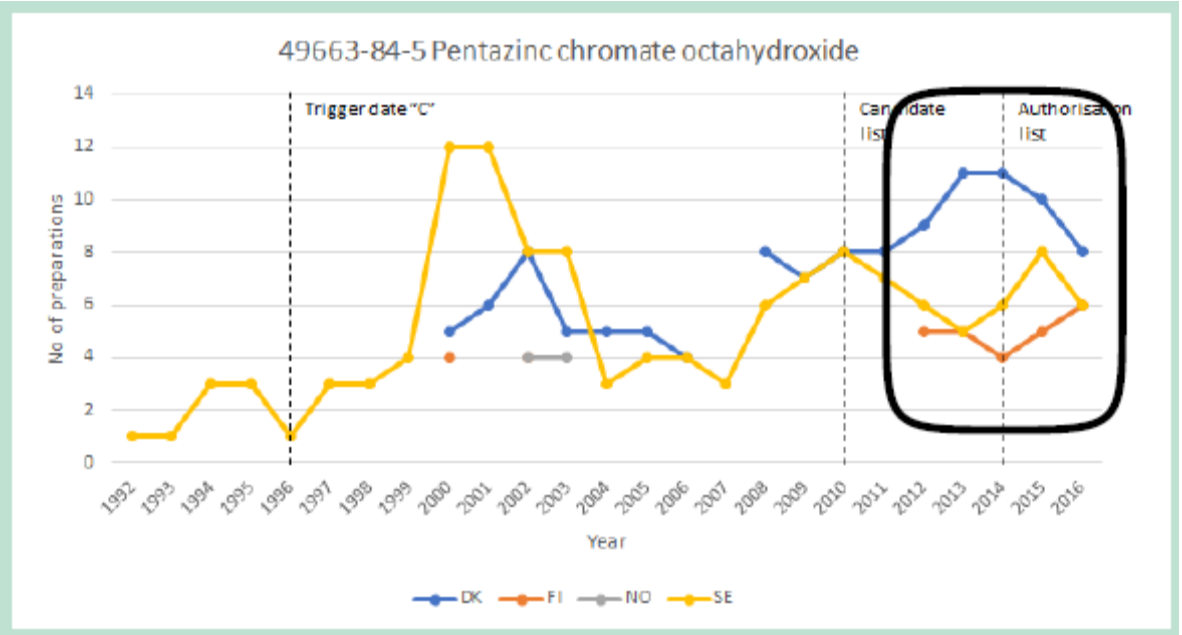

7758-97-6 Lead chromate
Trigger date "C"
Trigger date "CR"
Candidate list
Authorisation list
No of preparations
Year
DK
FI
NO
SE

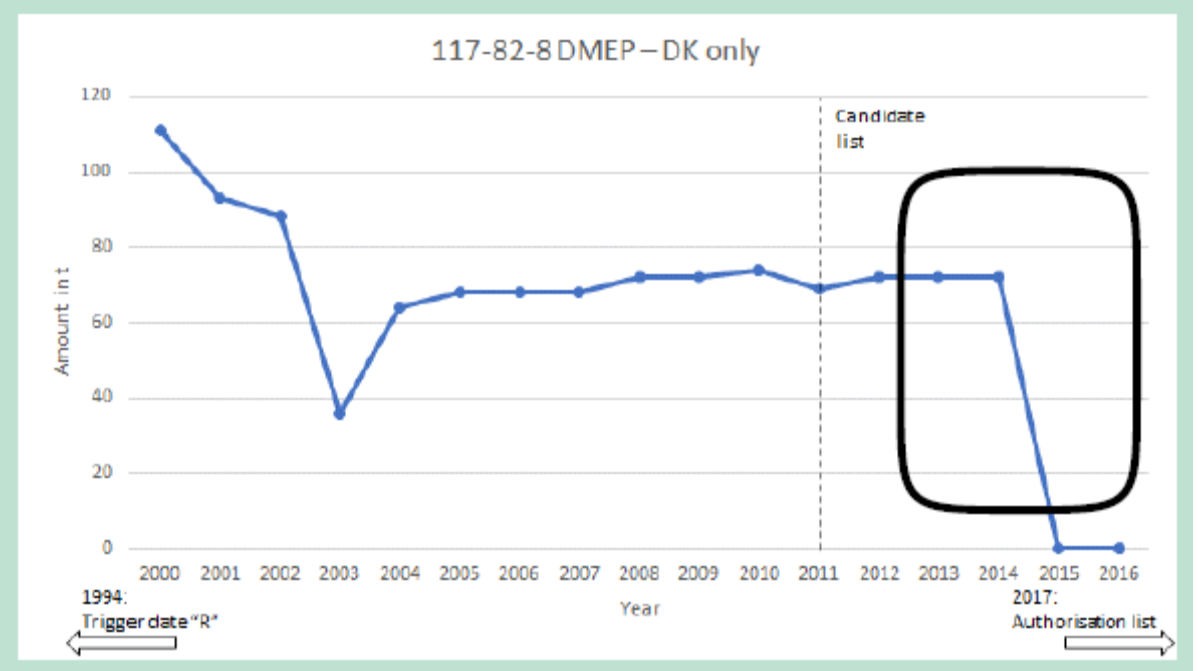

1344-37-2 C.I. Pigment Yellow 34
Trigger date "R"
Trigger date "CR"
Candidate list
Authorisation list
No of preparations
Year
DK
FI
NO
SE

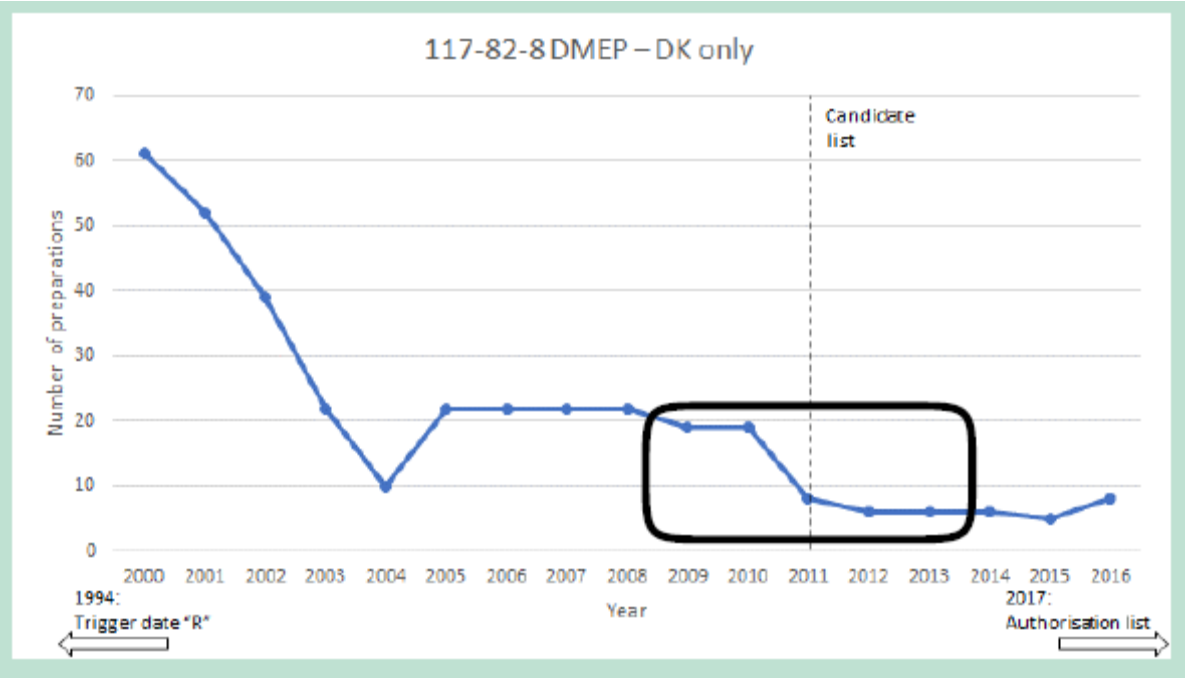

101-14-4 2,2'-dichloro-4,4'-methylenedianiline
Amount int
Year
Candidate list
Authorisation list
1994:
Trigger date "C"
FI
SE


7789-06-2 Strontium Chromate
Amount int
Year
Trigger date "C"
Candidate list
FI
NO
SE


7789-06-2 Strontium Chromate
Trigger date "C"
Candidate list
Authorisation list
No of preparations
Year
DK
FI
NO
SE


49663-84-5 Pentazinc chromate octahydroxide
Trigger date "C"
Authorisation list
No of preparations
Year
DK
FI
NO
SE





This is the end of Figure 10.
Source: Öko-Institut, figures based on data from DEPA 2019

9.7.2 Examples of substitution from the study: Impacts of REACH Authorisation (EC 2017a).

The following table shows the examples for substitution gathered in an industry survey. It has been published in the study "Impact of REACH Authorisation" (EC 2017a).

Table 13: Examples of substitution – (Possible) SVHCs, uses and alternatives (industry survey).

No	Substance	CAS number	N	Use of (possible) SVHC	Alternative
1	1,2-dichloroethane	107-06-2	5	Softener for PVC Solvent Swelling agent	2-methylcyclohexanone 4-methylpentan-2-one Alternative technology Not stated
2	1-methyl-2-pyrrolidone	872-50-4	1	Solvent	Not stated
3	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	1	Stabiliser	Bumetrizole
4	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	1	Stabiliser	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate
5	4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated	923-960-0	1	Surfactant	Not stated
6	4-Nonylphenol, branched and linear	n/a	1	Costabilizer for plasticized PVC	Triisotridecyl phosphite
7	Aluminosilicate Refractory Ceramic Fibres (RCF)	n/a	2	Insulation material Protective / heat insulating layer	Glass, oxide, chemicals Not stated
8	Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	2	Plasticiser	Di-''isononyl'' phthalate (DINP) Not stated
9	Bis(2-methoxyethyl) ether (Diglyme)	111-96-6	1	Solvent	Dimethyl sulfoxide
10	Bis(pentabromophenyl) ether	1163-19-5	1	Flame retardant	Phosphinic acid, P,P-diethyl-, aluminium salt (3:1)
11	Boric acid	11113-50-1	2	Buffer substance Plating	Not stated
12	C,C'-azodi(formamide) (ADCA)	123-77-3	1	Smoke ammunition	Alternative technology

No	Substance	CAS number	N	Use of (possible) SVHC	Alternative
				and illuminating ammunition	
13	Cadmium	7440-43-9	3	Manufacture of solder Plating Protection of aerospace hardware	Alternative technology Not stated
14	Chromic acid	7738-94-5; 13530-68-2	1	Etching of copper	Disodium peroxodisulphate (Sodium persulfate)
15	Chromium trioxide	1333-82-0	7	Anodising process Anti-corrosive Catalyst Chrome plating Electro-plating Pre-treatment at colour-coating line Not stated	2-ethylhexanoic acid, chromium salt Alternative technology Sulphuric acid Titanium Not stated
16	Chromium VI; Chromium, ion (Cr6+); Hexavalent chromium	18540-29-9	4	Chromate conversion coating Decorative function Plating	Chromium III Not stated
17	Dibutyl phthalate (DBP)	84-74-2	1	Plasticiser	Not stated
18	Hexabromocyclododecane (HBCD)	25637-99-4	3	Flame retardant Not stated	1,3 Butadiene/styrene copolymers Polymeric flame retardant Not stated
19	Lead	7439-92-1	1	Manufacture of solder	Alternative technology
20	Lead chromate	7758-97-6	2	Pigments	Polymeric flame retardant Not stated
21	Lead sulfochromate yellow	1344-37-2	1	Pigments	Various lead-free pigments
22	Perboric acid; sodium salt	10332-33-9; 11138-47-9; 12040-72-	1	Bleach/bleach precursor in consumer	Disodium carbonate, compound with hydrogen peroxide (2:3) (Sodium percarbonate)

No	Substance	CAS number	N	Use of (possible) SVHC	Alternative
		1; 37244-98-7		laundry tablets and powder	
23	Potassium dichromate	7778-50-9	1	Plating	Not stated
24	Sodium chromate	7775-11-3	3	Descaling Passivation of metals Sensitiser in light-sensitive lacquer	4-(phenylamino)benzenediazonium hydrogen sulfate formaldehyde (1:1) (Diazo) Alternative technology Chromium oxide
25	Sodium dichromate	10588-01-9; 7789-12-0	3	Passivation Softener	Nitric acid Not stated
26	Trichloroethylene	79-01-6	2	Degreasing parts in manufacture Solvent	Alternative technology Tetrachloroethylene (perchloroethylene)
27	Trilead Dioxide Phosphonate	12141-20-7	1	Acid scavenger as part of stabilizer	Triisotridecyl phosphite
28	Not stated	-	8	Passivation Plastisiser Solvent Not stated	2-methoxy-1-methylethyl acetate Not stated
			Total: 61		alternative substance: 24 alternative Technology:7 not stated: 14

Source: EC 2017a.