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Advancing REACH – The Restriction Procedure

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On behalf of the German Environment Agency

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Abstract: Advancing REACH – The Restriction Procedure

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

Based on a literature review and case studies of selected restrictions, this sub-study assesses the restriction process, identifies deficits in its efficiency and points out options for an improved implementation, including changes in the legal text. Overall, the restriction procedure is evaluated as working well. Nevertheless, the authorities' workload could be reduced and the procedure be accelerated in several aspects.

Kurzbeschreibung: Titel

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 entwickelt.

Auf der Grundlage einer Literaturauswertung und Fallstudien zu ausgewählten Beschränkungen, untersucht diese Teilstudie den Beschränkungsprozess, identifiziert Defizite in der Effizienz des Verfahrens und zeigt Optionen für eine verbesserte Umsetzung auf, einschließlich Veränderungen im Rechtstext. Insgesamt funktioniert das Beschränkungsverfahren gut. Dennoch gibt es einige Aspekte, durch die die Arbeitsbelastung der Behörden verringert und das Verfahren schneller durchlaufen werden könnte.

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List of abbreviations

AoA	Assessment of alternatives
CAS	Chemical abstract service
CLH	Harmonised classification and labelling
CMR	Carcinogen, mutagen, reprotoxic substance
COM	European Commission
CSR	Chemical safety report
D4	Octamethylcyclotetrasiloxane
D5	Decamethylcyclopentasiloxane
DE	Germany
DK	Denmark
DNEL	Derive no effect level
DU	Downstream user
DU CSR	Downstream user chemical safety report
EC	European Community
ECHA	European Chemicals Agency
EFSA	European Food Safety Agency
FR	France
IT	Italy
MS	Member State
NGO	Non-governmental organisation
NL	The Netherlands
NMP	N-methylpyrrolidone
NO	Norway
NP	Nonylphenol
NPEO	Nonylphenol Ethoxylates
OEL	Occupational exposure limit
PBT/vPvB	Persistent, bioaccumulating, toxic / very persistent, very bioaccumulating substance
PFOA	Perfluorooctanoic acid
PNEC	Predicted no effect concentration
RAC	Risk assessment committee
RCR	Risk characterisation ratio
REACH	Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measure
RMO	Regulatory management option
RMOA	Regulatory management option analysis
RoI	Registry of intention
SDS	Safety data sheet
SE	Sweden
SEA	Socio-economic analysis

SEAC	Socio-economic assessment committee
SME	Small and medium size enterprise
SVHC	Substance of very high concern
TDFA	(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and its mono-, di- or tri-O-(alkyl) derivatives
TFEU	Treaty on the Functioning of the European Union
UK	United Kingdom

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 for the Environment, Nature Conservation and Nuclear Safety. Within the project framework, various aspects of the REACH regulation and its implementation are analysed and improvement options developed, including potential changes in the regulatory text and its annexes.

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

The current report provides an analysis of the restriction procedure under the EU Chemicals 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)[1]. The analysis includes an outline of the legislator's original intention regarding the restriction procedure, which is based on the legislation's recitals and the COM's (COM) White Paper on a Future Chemicals Policy[2], a discussion of how this intention was transferred into the REACH text as well as an assessment of its interpretation in guidance documents, practical working procedures and everyday implementation.

The overall aim of this sub-study of the project "Advancing REACH" is to identify improvement areas for the restriction process under REACH and to develop proposals how these improvements can be realised in the future implementation processes of REACH, including the option to implement changes to the regulation itself (articles and annexes). This aim should be achieved by reviewing literature of the current implementation of the restriction process and opinions on deficits and improvement options as well as the development of cases studies of past (and ongoing) restrictions.

The focus of the analysis is set on the efforts needed to develop, substantiate and adopt restrictions under REACH. Amongst others, this includes a discussion of what level of detail is necessary to justify a restriction. In addition, issues are identified which might occur during a restriction process even though it is not intended or foreseen by the legislator, and which create additional burden for the authorities that initiate a restriction. Finally, the analysis reflects on the time needed to come up with new restrictions, the overall duration that is needed from drafting a proposal to a final decision, and the role of the committees at each of the various decision-making steps. Based on several case studies, proposals are derived that could improve the efficiency of the restriction process.

Section 2 of this report outlines the restriction process under REACH and gives background information on the intention of the procedure. Section 3 describes the current implementation of the legal text according to its various steps. The status of the restriction process is outlined in

[1] 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, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

[2] EU Commission (2001): White Paper - Strategy for a future Chemicals Policy /* COM/2001/0088 final */; available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52001DC0088

Section 4 and the case studies are summarised in Section 5. Conclusions and recommendations are provided in Section 6. The assessment scheme applied to develop the case studies is provided in the Appendix of the report.

In the following, the main findings of the (limited number of) case studies and the literature review on the restriction process are summarised according to the core fields of interest of the study. At the end of the chapter recommendations are derived that could support overcoming the identified shortcomings.

Overall findings on the entire restriction process

The restriction process achieves its aims and continues to evolve

The approaches of drafting restriction proposals appear to converge with regard to the content and structure of (information in the) dossiers, the stringency of opinion forming and justification, and the handling of different situations, including the lack of possibilities to demonstrate risks for some hazards, or information gaps leading to uncertainties or triggering qualitative assessment approaches.
The steps of the restriction process were found to fulfil their function in supporting the scrutiny of initial dossiers and improving the focus of a restriction as well as ensuring a good cost benefit ratio of envisaged measures. The opinion forming of the committees in combination with the consultation of stakeholders ensure that unwanted impacts of restrictions are avoided.

The simplified restriction procedure decreases some of the workload

Obviously, the simplified procedure according to Article 68 (2) requires fewer resources to demonstrate an unacceptable risk because this risk is assumed to exist by default for CMRs in consumer articles. The case studies showed that restrictions on CMRs in consumer articles via Article 68 (1) caused largely higher efforts although the use scenarios were similar.

Drivers of workload for the authorities

The scope of a restriction strongly influences the authorities' workload

In general, a broad coverage of substances and/or uses increases the efforts for data collection, demonstration of unacceptable risks, alternatives assessment and socio-economic analyses as well as dealing with stakeholder inputs during consultations. As part of the latter, possible exemptions may have to be discussed.
Narrow restriction scopes tend to allow a more specific information collection and hence efforts are lower to substantiate a proposal. In addition, narrow scoped restrictions appear to be more accepted and therefore less debated by the market actors. This is assumed to be partly due to a lower number of affected stakeholders, a better understanding of the restriction and a clearer concern the restriction aims to address.
A comparison and evaluation of the authorities' efforts to restrict a substance would require matching the efforts with the restriction result. A broad scope requiring a high resource input may be justified if also the risk reduction is high but would not be justified for marginal risk reductions. Such efficiency evaluations were not part of the current study but would be useful to get a complete picture.
In any case, the decision about the scope of a restriction is driven more by the available knowledge and the expected impact than the efforts needed to compile a proposal.

Demonstration of unacceptable risks was observed as resource intensive

The case studies show that the efforts for dossier compilation and opinion forming also depend on the need and abilities to demonstrate a risk and its unacceptability. Relevant drivers are:

- If a group of substances is subject to a restriction, the complexity of the group and the related efforts to justify the grouping (see especially PFOA)
- The hazardous property that is responsible for the risk (e. g. perfluorinated silanes, NP/NPE), which may range from a hazard that is defined via harmonized classification (low effort) to a hazard requiring a case-by-case assessment of a non-standard concern (e. g. PMT, endocrine disruption)
- The need to describe the consequences from continued use, in particular, for environmental relevant substances (PBT/vPvB, ED only P).

The dossier submitters were observed to invest significant resources in the demonstration of an unacceptable risk. In cases where the risk cannot be well substantiated, this may lead to extensive discussions at the level of ECHA, RAC and SEAC, and possibly to revision needs by the dossier submitter.

This was especially due to extensive compilations and evaluations of hazard information and the related review by the RAC and stakeholders. However, for environmental hazards with a low or non-existing effect threshold (e. g. PBT/vPvBs, EDCs) fewer resources were invested because only qualitative risk assessments were generated due to the lack of a suited methodology to quantify effects. A tendency to use qualitative generic approaches to demonstrate the risk and accept an approach of 'minimising emissions' can be observed over time.

Detailed technical and market information is not available to the authorities

Authorities lack detailed information from the economic operators on technical and market issues necessary to compile a restriction dossier. This pertains specifically information on the substance's uses (in products) and key economic figures, as well as information on the availability and feasibility of alternatives. Closing these information gaps requires high efforts from the authorities.

Efforts for socio-economic assessments appear to decrease

Overall and over time, the efforts to compile a detailed SEA appear to have decreased. In the more recent proposals, dossier submitters tended to focus their cost assessments on only the main cost drivers and provide semi-quantitative information if data was insufficient for a full quantification. It seems that the provision of cost-effectiveness assessments is increasingly accepted in cases where damage/benefits cannot be quantified, e. g. for PBTs/vPvBs or EDCs. Here, the emission reduction is used as a proxy for benefits, and costs are evaluated against the achievable emission reduction.

Late introduction of exemptions causes extra work

When drafting restriction proposals authorities frequently have insufficient information to assess whether or not an exemption from the scope is necessary. It is one of the tasks of the public consultations to ensure specific exemptions are considered. However, the opinion forming of RAC and SEAC is then already at an advanced stage. Sometimes exemptions are introduced even only shortly before the Commission's decision making. As a consequence, there is little time for the committees to thoroughly assess the justification and information gaps, resulting in a high level of uncertainty regarding the justification of the requested exemption. Additional resources are needed to (re-)assess partial risks and impacts[3] at the end of the opinion forming process. Additionally, such late exemption requests may delay the COM's

[3] This can be triggered, for example, by the fact that according to Article 77(c) the ECHA executive director requests the SEAC to consider further information on possibly necessary exemptions.

decision-making due to controversial discussions on the justification of the exemptions and a lack of a clear opinion.

Duration of the restriction processes

The main reasons for delays are the REACH committee's and the COM's decision making

The case studies show that the time between the start of drafting a restriction proposal until the opinions are formed is comparatively stable. The timelines of the individual steps are met so that the processing of a dossier from the announcement of the intention to the finalisation of the RAC/SEAC opinions takes between 40 and 50 months[4].
Delays mainly result from the long decision-making processes in the REACH Committee and by the COM (normally about one year, with an observed maximum time of 2-3 years).
No analysis of the duration of restrictions under the "old" Marketing and Use Restrictions Directive was performed in the study. However, with a view to the total duration of more than 52 months of the "quickest cases", one may wonder whether the goal of enacting new restrictions more quickly has been achieved. The considered case of CMR in textiles, which follows the simplified procedure, was only marginally shorter at 46 months. However, it should be noted that the restriction proposal had a very broad scope, which led to lengthy discussions. In addition, only a few cases have been treated using the simplified procedure and a relatively complex procedure was carried out to determine which substances should be covered by the restriction in these cases. It can be assumed that with increasing experience, under the simplified procedure time periods until a new restriction is issued will be further reduced. While the time for developing and scrutinizing a restriction proposal is found appropriate and needed, the time needs for the decision making appear to be an opportunity to speed up the process.

Late exemption requests delay the COM's decision making

As discussed above, late exemption requests not only increase the authorities' workload but may also significantly delay the decision making by the COM.

Choice of the restriction procedure as regulatory measure

Due to a higher acceptance, restriction proposals complementing authorisations can be processed comparatively easily

Especially restrictions addressing SVHCs in imported articles that require authorisation are welcomed rather frequently than contested. Such restriction proposals were observed to trigger fewer discussions among the stakeholders, because they support a level playing field on the EU market and because the existence of an unacceptable risk has already been 'agreed' on in the authorisation process. In addition, such a restriction proposal might have a relatively narrow scope and therefore affect a low number of market actors thus resulting in fewer controversies. Consequently, such restrictions appear to be justified as "low hanging fruits" with the opportunity of risk management with low efforts.

Restriction is well suited and the preferred regulatory measure to address consumer risks

The assessed cases indicate that consumer risks are most frequently addressed by restrictions, i. e. bans of substances or products from the EU market.

[4] Differences essentially arise from the final submission of the Annex XV dossier.

As the restriction procedure is more flexible for managing occupational risks, it may be possible to find regulatory conditions that are acceptable and balance protection and economic impacts

A variety of possible measures exists to manage occupational risks. Next to a complete ban of a use, the implementation of particular (risk reduction) measures at the workplace could also be defined in a restriction that would apply in the same, and hence harmonised, way across the EU. This is not possible under workers protection legislation, as it consists of directives that require transposition in the Member States and would allow interpreting any conditions at EU level differently for the national implementation.
Some of the assessed restriction proposals are innovative in this regard, like the implementation of a legally binding DNEL in combination with the appropriate guidance how to comply with the DNEL or the introduction of training as a measure to limit the exposure of workers[5].
In principle occupational risks can be limited by the following conditions of a restriction:

- Ban: A substance as such, in mixtures or in articles may not be placed on the market or used in the EU.
- Minimisation in mixtures or articles: The concentration or the release of a substance is limited in (certain) mixtures or articles.
- Harmonised technical measure: Quality-assured, harmonised technical measures are to be implemented across the EU when a substance is used.
- Harmonised training: Quality-assured, harmonised and specifically tailored risk reduction strategies are implemented across the EU, such as obligatory training material for employers and employees (cf. diisocyanates case).
- Harmonised limit values combined with safety measures: Binding and harmonised limit values for the occupational setting are prescribed for use in chemical safety assessments and as a basis for deriving risk management measures at the workplace.

Availability and need for information

Use and exposure information is essential but usually not available

The lack of use and exposure information hinders a proper scoping of a restriction proposal, the demonstration of unacceptable risks, the assessment of alternatives as well as the socio-economic analyses. Therefore, this information is essential for any restriction proposal. However, the case studies and the literature review showed that exactly this information is frequently not available to the authorities and that high efforts are needed just to get basic data. The public consultations during the discussion of the restriction dossiers in RAC and SEAC, which are intended as an instrument to close information gaps, were observed as no significant contribution to closing these gaps. In the analysed cases, the lack of use and exposure information resulted in uncertainties about the appropriateness of a restriction scope as well as potential increases in efforts of the overall restriction process.

Available information on alternatives is often very basic

Most of the analysed restriction dossiers contained at least generic information on alternatives. However, the dossier submitters frequently lacked details on the technical performance, the prices of alternative products as well as on the wider impacts of a potential need for substitution. The latter may include process changes, the need to reformulate mixtures or

[5] It has to be mentioned that the decision on this proposal is still pending and the COM has instead instructed ECHA to start the development of an EU-wide occupational exposure limit (OEL) so it can be concluded that such the approach proposed has no clear support.

redesign articles, leading to possible losses in the performance. This lack of information resulted in uncertainties about the potential reaction of market actors on a restriction and hence, the results of the socio-economic analysis.
However, the level of information detail provided in the dossiers reviewed in the case studies appeared reasonable and sufficient to support decision-making. This was further supported by the pragmatic approach of RAC and SEAC to the assessment of alternatives (cf. next Section).

Vague justifications of exemptions cause a high level of uncertainty

As RAC and SEAC have limited information to review an exemption request and develop their opinions, such requests are usually approved by the committees despite uncertainties about the actual need. Due to the uncertainties, the exemptions are time-limited, with reporting requirements based on which the justification for the exemptions is to be reviewed after the time limit has expired.

Role of the Committees

Improved assessment approaches of RAC and SEAC increased the transparency and the efficiency of the restriction process

Over time RAC and SEAC developed and improved their evaluation methods, formats and argumentations. This applies in particular to dealing with information gaps and uncertainties. This resulted in a more stringent, efficient and structured opinion forming process that also makes it easier for the stakeholders to understand the opinions and react to them. Further improvement on the operation of the committees is expected as a result of the restriction task force[6].

The changes in initial scope caused by RAC and SEAC opinions facilitate the further restriction process

RAC and SEAC activities may result in adjustments to the scope of the restriction proposal during the process. Only a narrowing of the scope is possible as a broadening would not ensure sufficient participation of the interested stakeholders at this stage of the evaluation.

The modifications in the restriction scope were partly due to information provided by the stakeholders and partly due to independent considerations by the RAC and SEAC. The changes in scope concerned the coverage of substances, the coverage of uses and exemptions as well as the conditions of a restriction (or exemption), such as the threshold limits. The reasons for the changes included a need for clarification (understanding), practicability (enforcement, compliance monitoring) and essential uses (exemptions due to lack of alternatives).

The Committees' pragmatic approach towards alternatives saves resources and time

In cases where alternatives were already in use for the to-be-restricted substance, RAC and SEAC pragmatically assumed these alternatives available, and therefore considered substitution as an important (or the only) market reaction to a restriction. When it could not be fully confirmed whether alternatives were available, the committees assumed the share of applications, where substitution could happen as well as possible other market reactions. This pragmatic approach was established over time in the various opinion forming processes of RAC and SEAC.
According to the case studies and the literature review, qualitative approaches were accepted to a greater extent in the field of the alternatives assessment than for other parts of a restriction

[6] See ECHA (2018) Recommendations of the Task Force on Restriction Efficiency https://echa.europa.eu/documents/10162/13641/report_task_force_on_restriction_efficiency_en.pdf

proposal. Only in the discussion of exemptions, more in-depth information on alternatives seems to be necessary (and is requested) to enable conclusions on the proposed restriction.

Motivation of stakeholder involvement

Stakeholders - especially the economic actors – are important players in the development of restriction proposals and should have an interest in providing their input. However, it appears that this is not yet happening to a sufficient extent. The following two aspects were observed during the study.

A broad scope incentivises more stakeholder involvement than a narrow one

Defining a broad scope of a restriction regarding the coverage of uses is an option to overcome information gaps by shifting the burden of proving that a risk is (already) controlled or that uses are critical/need longer transition periods to the market actors. It prevents long data collection by the authorities and incentivises the involvement of stakeholders as they aim to prevent their uses being covered by a restriction.

The possibility for late exemption requests discourages (early) stakeholder involvement

It was observed in the case studies that stakeholders were most strongly involved during the later consultations, especially if they wanted to request an exemption. This involvement, although valuable due to additional information being provided, came at a time where changes caused significant efforts and/or could not be scrutinised as thoroughly as other aspects of a restriction proposal.

Recommendations

Overall functioning of the process

From an overall view, the restriction process is well-designed to achieve the aim of reducing unacceptable risks from the use of chemicals. The various activities to streamline the process conducted by all involved actors are implemented in current practice and work routines have been established. These trends are likely to continue and there are no obvious improvement options identified in this regard.

- Therefore, it is recommended **not to make any fundamental changes** to the restriction procedure.

Duration of the process

The duration of the restriction procedures was found to be long but with little potential of shortening without losing quality in the decision preparation and hence efficient and effective risk reduction. The only option identified was the decision making of the REACH committee and the COM, which appears to be inappropriately long. Therefore, it is recommended to

- **Define legally binding deadlines for the decision-making by the COM and the REACH committee**. A time of 6 months appears to be appropriate and proportionate compared to the time RAC and SEAC have to develop their opinions.

Workload of authorities

The workload of the authorities to prepare, scrutinise and decide on a restriction varies depending on many factors, including the type of substances, the availability of information, existing regulation, and the scope of the restriction etc. In order to significantly reduce the workload and make the restriction process more efficient it is recommended to

- **Introduce a simplified procedure to address substances** with hazards **other than CMR** and for which a generic exposure assessment indicates a risk.
  This could be the case for PBTs /vPvBs found in the environmental compartments and/or biota indicating emissions and exposures potentially causing risks. Also endocrine disruption in the environment may be a property rendering a substance suitable for a simplified procedure.

Hence, the project findings support the respective approach of the recently published Chemicals Strategy for Sustainability[7]. However, while the Strategy suggests the simplified procedure for consumer products, a simplified approach also appears justified for environmentally hazardous substances from widely distributed diffuse sources.

- **Streamline the demonstration of unacceptable risks and justification of a restriction in Annex XV dossiers** for substances with hazards with low or missing threshold values. Slim and partly qualitative approaches to the alternatives assessment and the socio-economic analysis may be sufficient and are broadly accepted to support the argumentation of proportionality and effectiveness of measures. For example, the 'emission minimisation approaches' and cost-effectiveness assessments frequently are sufficient. The existing methods and indications of when they are appropriate should be elaborated for transparency and consistency reasons in the guidance document on restriction dossiers.

Lack of information

Information on uses and exposures are essential to develop, target and substantiate a restriction. Hence, if authorities lack this information, the efficiency and effectiveness of a restriction is likely to decrease. If the registrants had better use information in the first place, the chemical safety assessments and recommendations of safe conditions of use could work properly, potentially making restrictions superfluous. Therefore, it is recommended to improve the information basis on uses and exposures of substances to:

- Further develop, improve and establish **approaches to deal with data gaps** and related uncertainties. Pragmatic approaches and reasonable assumptions may be sufficient to evaluate and decide on restrictions, as was observed in the opinion forming of RAC and SEAC. With a view to increased precaution, data gaps may have to be accepted for the sake of (quicker) regulation. Finding (standardized) handling of gaps and uncertainties could be the cost-efficient solution, at least in case where basic data exists and/or more information would not significantly change a decision outcome.

- Implement a **right** for authorities **to request** use and exposure **information** as well as relevant socio-economic data from market actors **and an obligation** of these **to respond** within an appropriate time frame during a regulatory risk management processes. While this approach appears generally viable, targeted questioning is only possible if the relevance of an application is clarified. Completely unknown uses would still not be identifiable. A better coverage of such unknown uses could be achieved by a notification requirement extended to further substances properties in analogy to the REACH Articles 7 and 33 or ECHA's database on substances of concern in products (SCIP) established under the Waste Framework Directive.

- **Consider restrictions with broad scopes regarding uses** especially to address risks from unclear emission sources/uses. If no or only little information is available on uses and

[7] COM(2020) 667 final: Chemicals Strategy for Sustainability Towards a Toxic-Free Environment https://ec.europa.eu/environment/strategy/chemicals-strategy_en

exposures, a broad restriction scope would enable addressing all of them. If communicated early in the process, such broad scope might incentivise stakeholders to provide relevant information without a legal obligation because they intend to be exempted or influence the restriction's condition.

- Combine a broad restriction scope with an **obligatory early time window for submitting exemption requests as a unique opportunity to do so,** i. e. during the dossier preparation period, directly after the announcement in the ROI. This would make stakeholders wanting to prevent regulation provide information and it would allow the authorities to thoroughly assess the request when defining the restriction scope. The exemption requests should be accompanied by defined types of information (e. g. comparable with an application for authorisation) that justifies the deviation from a proposed non-use scenario. Such obligation also would help to avoid time constrains for the evaluation of exemption requests in the RAC/SEAC and enable them to collect additional information, if necessary. The subsequent public consultation could then be used to fill in selective information gaps and gather opinions on the requested exemption.

Zusammenfassung

Der vorliegende Bericht ist ein Teilergebnis des Ressortforschungsplan-Vorhabens „REACH-Weiterentwicklung“, welches im Rahmen des Forschungsplans des Ministeriums für Umwelt, Naturschutz und nukleare Sicherheit gefördert wurde. 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.

Der vorliegende Bericht liefert eine Analyse des Beschränkungsverfahrens nach der EU-Chemikalienverordnung (EG) Nr. 1907/2006 des Europäischen Parlaments und des Rates vom 18. Dezember 2006 zur Registrierung, Bewertung, Zulassung und Beschränkung chemischer Stoffe (REACH)[8]. Die Analyse umfasst eine Darstellung der ursprünglichen Intention des Gesetzgebers bezüglich des Beschränkungsverfahrens, die sich auf die Erwägungsgründe der Verordnung und das Weißbuch der Kommission (KOM)[9] über eine zukünftige Chemikalienpolitik stützt, eine Diskussion darüber, wie diese Intention in den REACH-Text übertragen wurde, sowie eine Bewertung der Interpretation in Leitfäden, praktischen Arbeitsabläufen und der täglichen Umsetzung.

Das übergeordnete Ziel dieser Teilstudie des Projekts „REACH-Weiterentwicklung“ ist es, Verbesserungsbereiche für das Beschränkungsverfahren unter REACH zu identifizieren und Vorschläge zu entwickeln, wie diese Verbesserungen in den zukünftigen Implementierungsprozessen von REACH realisiert werden können, einschließlich der Option, Änderungen an der Verordnung selbst (Artikel und Anhänge) vorzunehmen. Dieses Ziel soll mithilfe einer Literaturrecherche zur aktuellen Umsetzung des Beschränkungsverfahrens und Stellungnahmen zu Defiziten und Verbesserungsmöglichkeiten sowie durch die Erarbeitung von Fallstudien zu vergangenen (und laufenden) Beschränkungen erreicht werden.

Der Schwerpunkt der Analyse liegt dabei auf dem Aufwand, der für die Entwicklung, Begründung und Verabschiedung von Beschränkungen unter REACH erforderlich ist. Dies beinhaltet unter anderem eine Diskussion darüber, welcher Detaillierungsgrad notwendig ist, um eine Beschränkung zu rechtfertigen. Darüber hinaus werden Probleme identifiziert, die während eines Beschränkungsverfahrens auftreten können, auch wenn dies vom Gesetzgeber nicht beabsichtigt oder vorgesehen ist, und die einen zusätzlichen Aufwand für die Behörden darstellen, die eine Beschränkung einleiten. Abschließend wird ausgewertet, wie lange die

[8] 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, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

[9] EU Commission (2001): White Paper - Strategy for a future Chemicals Policy /* COM/2001/0088 final */; available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52001DC0088

Erarbeitung neuer Beschränkungen dauert, d.h. vom Beginn der Ausarbeitung eines Vorschlags bis zur endgültigen Entscheidung. Hier wird auch die Rolle der Ausschüsse bei jedem der Schritte analysiert. Anhand mehrerer Fallstudien werden Vorschläge abgeleitet, die die Effizienz des Beschränkungsverfahrens verbessern könnten.

Abschnitt 2 des Berichts erläutert das Beschränkungsverfahren unter REACH und gibt Hintergrundinformationen zur Intention des Verfahrens. Abschnitt 3 beschreibt die derzeitige Umsetzung der im Gesetzestext vorgesehenen Verfahrensschritte. Der Status des Beschränkungsverfahrens wird in Abschnitt 4 dargestellt und die Fallstudien werden in Abschnitt 5 zusammengefasst. Schlussfolgerungen und Empfehlungen werden in Abschnitt 6 gegeben. Das Bewertungsschema, das zur Entwicklung der Fallstudien angewandt wurde, ist im Anhang des Berichts zu finden.

Im Folgenden werden die wichtigsten Ergebnisse der (begrenzten Anzahl von) Fallstudien und der Literaturauswertung zum Beschränkungsverfahren nach den Kerninteressenfeldern der Studie zusammengefasst. Am Ende des Kapitels werden Empfehlungen abgeleitet, die dazu beitragen könnten, identifizierte Defizite zu beheben.

Gesamtergebnisse zum Beschränkungsverfahren

Zielerreichung und Weiterentwicklung des Beschränkungsverfahrens

Die Vorgehensweisen bei der Erarbeitung von Beschränkungsvorschlägen scheinen sich bezüglich des Inhalts und der Struktur der (Informationen in den) Dossiers, der Stringenz der Meinungsbildung und Begründung sowie den Umgang mit unterschiedlichen Situationen, einschließlich der fehlenden Möglichkeiten zum Nachweis von Risiken für einige Gefahren oder Informationslücken, die zu Unsicherheiten oder qualitative Ansätze führen, anzunähern.

Es wurde festgestellt, dass die Schritte des Beschränkungsverfahrens ihre Funktion erfüllen, indem sie die Prüfung der ursprünglichen Dossiers unterstützen und die Ausrichtung einer Beschränkung verbessern sowie ein gutes Kosten-Nutzen-Verhältnis der geplanten Maßnahmen sicherstellen. Die Meinungsbildung der Ausschüsse in Kombination mit der Konsultation von Interessengruppen stellt sicher, dass unerwünschte Auswirkungen von Beschränkungen vermieden werden.

Das vereinfachte Beschränkungsverfahren verringert einen Teil des Arbeitsaufwands

Offensichtlich erfordert das vereinfachte Verfahren nach Artikel 68 (2) weniger Ressourcen für den Nachweis eines unannehmbaren Risikos, da ein solches Risiko bei CMR in Verbraucherprodukten standardmäßig als gegeben angenommen wird. Die Fallstudien zeigten, dass Beschränkungen für CMR in Verbraucherprodukten über Artikel 68 (1) einen wesentlich höheren Aufwand verursachen, obwohl die Anwendungsszenarien ähnlich sind.

Ursachen des Arbeitsaufwands für die Behörden

Der Umfang einer Beschränkung beeinflusst stark den Arbeitsaufwand der Behörden

Im Allgemeinen erhöht ein breiter Geltungsbereich einer Beschränkung bzgl. der abgedeckten Stoffe und/oder Verwendungen den Aufwand für die Datenerhebung, den Nachweis unannehmbarer Risiken, die Bewertung von Alternativen und sozioökonomische Analysen sowie den Umgang mit Stellungnahmen von Interessengruppen während der Konsultationen. Letzteres betrifft u. a. die Diskussion über mögliche Ausnahmen.

Enge Geltungsbereiche einer Beschränkung erlauben tendenziell eine spezifischere Informationssammlung und damit einen geringeren Aufwand für die Begründung eines Vorschlags. Darüber hinaus scheinen Beschränkungen mit engem Geltungsbereich von den

Marktteilnehmenden eher akzeptiert und daher weniger diskutiert zu werden. Es wird angenommen, dass dies zum Teil auf eine geringere Anzahl betroffener Stakeholder, ein besseres Verständnis der Beschränkung und eine klare definierte Besorgnis zurückzuführen ist.

Um den Aufwand der Behörden, einen Stoff zu beschränken zu bewerten, müsste dieser Aufwand mit dem Nutzen einer Beschränkung verglichen werden. Ein breiter Anwendungsbereich, der einen hohen Ressourceneinsatz erfordert, kann gerechtfertigt sein, wenn auch die Minderung des Risikos hoch ist, wäre aber bei marginaler Risikominderung nicht gerechtfertigt. Solche Effizienzbewertungen waren nicht Teil der aktuellen Studie, wären aber nützlich, um ein vollständiges Bild zu erhalten.

In jedem Fall wird die Entscheidung über den Umfang einer Beschränkung mehr durch das verfügbare Wissen und die erwarteten Auswirkungen bestimmt als durch den Aufwand für die Erstellung eines Vorschlags.

Der Nachweis von inakzeptablen Risiken wurde als ressourcenintensiv eingeschätzt

Die Fallstudien zeigen, dass der Aufwand für die Erstellung von Dossiers und die Meinungsbildung auch von der Notwendigkeit und den Fähigkeiten abhängt, ein Risiko und dessen Unzumutbarkeit zu demonstrieren. Relevante Treiber für diesen Aufwand sind:

- Wenn eine Gruppe von Stoffen beschränkt werden soll, die Komplexität der Gruppe und der damit verbundene Aufwand, die Gruppierung zu begründen (siehe insbesondere PFOA)
- Die gefährliche Eigenschaft, die für das Risiko verantwortlich ist (z. B. perfluorierte Silane, NP/NPE). Von der Existenz einer harmonisierten Einstufung (geringer Aufwand) bis hin zu einer Einzelfallbeurteilung einer nicht standardisiert zu ermittelnder Eigenschaft (z. B. PMT, endokrine Wirkung) ist hier eine große Bandbreite möglich.
- Die Notwendigkeit, die Folgen einer weiteren Verwendung zu beschreiben, insbesondere für umweltrelevante Stoffe (PBT/vPvB, ED nur P?)

In den Analysen zeigte sich, dass die MS, welche ein Dossier erstellen, erhebliche Ressourcen in den Nachweis eines inakzeptablen Risikos investieren. In Fällen, in denen das Risiko nicht gut begründet werden kann, kann dies zu umfangreichen Diskussionen auf Ebene der ECHA, des RAC und SEAC führen und Überarbeitungen des Dossiers erforderlich machen.

Dies ist insbesondere auf die umfangreichen Zusammenstellungen und Bewertungen von Gefahreninformationen und die damit verbundene Überprüfung durch den RAC und die Interessengruppen zurückzuführen. Für Umweltgefahren mit einer niedrigen oder nicht vorhandenen Wirkungsschwelle (z. B. PBT/vPvBs, EDCs) wurden allerdings weniger Ressourcen investiert, da aufgrund des Fehlens einer geeigneten Methodik zur Quantifizierung von Wirkungen nur qualitative Risikobewertungen erstellt wurden. Im Laufe der Zeit ist eine Tendenz zu beobachten, lediglich qualitative, generische Ansätze zum Risikonachweis zu verwenden und den Ansatz einer generellen „Emissionsminimierung“ zu akzeptieren.

Detaillierte Technik- und Marktinformationen stehen den Behörden nicht zur Verfügung

Den Behörden fehlen detaillierte Informationen von den Wirtschaftsakteuren zu technischen und marktbezogenen Fragen, die für die Erstellung eines Beschränkungsdossiers erforderlich sind. Dies betrifft insbesondere Informationen über die Verwendungen von Stoffen (in Produkten), wirtschaftliche Kennzahlen sowie über die Verfügbarkeit technisch umsetzbarer Alternativen. Die Schließung dieser Informationslücken erfordert einen hohen Aufwand seitens der Behörden.

Der Aufwand für sozioökonomische Bewertungen scheint abzunehmen

Insgesamt scheint im Laufe der Zeit der Aufwand für die Erstellung einer detaillierten SEA abgenommen zu haben. In den neueren Beschränkungsvorschlägen sind die Kostenbewertungen in den Dossiers nur auf die wichtigsten Kostentreiber konzentriert und werden semi-quantitative Informationen bereitgestellt, wenn die Daten für eine vollständige Quantifizierung nicht ausreichten. Die Bereitstellung von Kosten-Wirksamkeits-Analysen scheint in Fällen, wo Schäden und Nutzen nicht quantifiziert werden können, z. B. für PBTs/vPvBs oder EDCs, zunehmend akzeptiert zu werden. Hier wird die Emissionsminderung als Näherung für den Nutzen verwendet und die Kosten werden anhand der erreichbaren Emissionsminderung bewertet.

Späte Einführung von Ausnahmen verursacht zusätzlichen Aufwand

Bei der Ausarbeitung von Beschränkungsvorschlägen fehlen den Behörden häufig Informationen, um zu beurteilen, ob eine Ausnahme vom Anwendungsbereich notwendig ist oder nicht. Zwar ist es eine Aufgabe der öffentlichen Konsultation, die Notwendigkeit von Ausnahmen zu prüfen, jedoch sind die Diskussionen des RAC und des SEAC dann bereits in einem weit fortgeschrittenen Stadium. Teilweise wird der Wunsch nach einer Ausnahme auch erst während der Entscheidungsfindung der Kommission geäußert. Infolgedessen haben die Ausschüsse wenig Zeit, um die Begründung für die Ausnahme gründlich zu prüfen und die Informationslücke zu bewerten, so dass ein hohes Maß an Unsicherheit hinsichtlich der Rechtfertigung der beantragten Ausnahme besteht. Es werden zusätzliche Ressourcen benötigt, um Teilrisiken und Auswirkungen[10] am Ende des Meinungsbildungsprozesses (erneut) zu bewerten. Darüber hinaus können solche späten Ausnahmeanträge die Entscheidungsfindung der KOM aufgrund kontroverser Diskussionen über die Begründung der gewünschten Ausnahme und in Ermangelung einer klaren Stellungnahme der Ausschüsse verzögern.

Dauer der Beschränkungsverfahren

Der Hauptgrund für Verzögerungen sind die Entscheidungsprozesse des REACH-Ausschusses und der KOM

Die Fallstudien zeigen, dass die Zeit zwischen dem Beginn der Ausarbeitung eines Beschränkungsvorschlags bis zur Formulierung der Stellungnahmen vergleichsweise konstant ist. Die Fristen der einzelnen Schritte werden eingehalten, so dass die Bearbeitung eines Dossiers von der Bekanntgabe der Absicht bis zur Fertigstellung der RAC/SEAC-Stellungnahmen zwischen 40 - 50 Monaten[11] dauert.

Verzögerungen ergeben sich vor allem durch die langen Entscheidungsprozesse im REACH-Ausschuss und bei der KOM (in der Regel ca. ein Jahr, mit einer beobachteten Maximalzeit von 2-3 Jahren).

Eine Analyse der Dauer von Beschränkungsverfahren unter der „alten“ Richtlinie über Beschränkungen des Inverkehrbringens und der Verwendung wurde in der Studie nicht durchgeführt. Mit Blick auf die Gesamtdauer des aktuellen Verfahrens von mehr als 52 Monaten der „schnellsten Fälle“ kann jedoch in Frage gestellt werden, ob das Ziel, neue Beschränkungen schneller zu erlassen, erreicht wurde. Der betrachtete Fall von CMR in Textilien, der dem vereinfachten Verfahren folgt, war mit 46 Monaten nur unwesentlich kürzer. Allerdings ist anzumerken, dass dieser Beschränkungsvorschlag einen sehr breiten Geltungsbereich hatte, was zu langwierigen Diskussionen führte. Außerdem ist zu sagen, dass bisher nur wenige Beschränkungen im vereinfachten Verfahren behandelt wurden und dass diese deshalb relativ

[10] Dies kann z. B. dadurch ausgelöst werden, dass der Exekutivdirektor der ECHA gemäß Artikel 77 (c) den SEAC auffordert, weitere Informationen über möglicherweise erforderliche Ausnahmen zu prüfen

[11] Unterschiede ergeben sich im Wesentlichen aus der endgültigen Einreichung des Anhang-XV-Dossiers.

komplex waren, damit festgestellt werden konnte, welche Stoffe von der Beschränkung erfasst werden sollen. Es ist davon auszugehen, dass mit zunehmender Erfahrung das vereinfachte Verfahren zu einer weiteren Verkürzung der Zeiträume bis zum Erlass einer neuen Beschränkung führen wird. Während die Zeit für die Entwicklung und Prüfung eines Beschränkungsvorschlags als angemessen und notwendig erachtet wird, scheint der Zeitbedarf für die Entscheidungsfindung eine Möglichkeit zu sein, die Entscheidungsfindung zu beschleunigen.

Verspätete Ausnahmeanträge verzögern die Entscheidungsfindung der KOM

Wie zuvor erörtert, erhöhen verspätete Ausnahmeanträge nicht nur den Arbeitsaufwand der Behörden, sondern können auch die Entscheidungsfindung der KOM erheblich verzögern.

Wahl des Beschränkungsverfahrens als Regulierungsmaßnahme

Aufgrund einer höheren Akzeptanz können eine Zulassung ergänzende Beschränkungsanträge vergleichsweise einfach bearbeitet werden

Insbesondere Beschränkungen, die sich auf SVHCs in zulassungspflichtigen Importerzeugnissen beziehen, werden häufig eher begrüßt als angefochten. Es wurde beobachtet, dass solche Beschränkungsvorschläge weniger Diskussionen unter den Stakeholdern auslösen, weil sie gleiche Wettbewerbsbedingungen auf dem EU-Markt unterstützen und das Vorhandensein eines inakzeptablen Risikos bereits im Zulassungsverfahren „vereinbart“ wurde. Darüber hinaus könnte ein solcher Beschränkungsvorschlag einen relativ engen Anwendungsbereich haben und daher eine geringe Anzahl von Marktteilnehmenden betreffen, was zu weniger Kontroversen führt. Folglich scheinen solche Beschränkungen als „niedrig hängende Früchte“ mit der Möglichkeit des Risikomanagements mit geringem Aufwand gerechtfertigt zu sein.

Beschränkungen sind gut geeignet und die bevorzugte Regulierungsmaßnahme, um Verbraucherrisiken zu begegnen

Die bewerteten Fälle zeigen, dass Verbraucherrisiken am häufigsten durch Beschränkungen, d. h. Verbote von Stoffen oder Erzeugnissen auf dem EU-Markt, angegangen werden.

Da Beschränkungen einen flexiblen Umgang mit Arbeitsschutzrisiken ermöglichen, können regulatorisch Bedingungen definiert werden, die breit akzeptiert werden und ein Gleichgewicht zwischen Schutz und wirtschaftlichen Auswirkungen herstellen

Arbeitsschutzrisiken können mittels einer Vielzahl von Maßnahmen reguliert werden. Neben einem vollständigen Verwendungsverbot können z. B. spezifische (risikomindernde) Maßnahmen am Arbeitsplatz in einer Beschränkung festgeschrieben werden, die in der gesamten EU in gleicher und damit harmonisierter Weise gelten würden. Dies ist im Rahmen der Arbeitnehmerschutzgesetzgebung nicht möglich, da diese aus Richtlinien besteht, die in den Mitgliedstaaten umgesetzt werden müssen und somit eine unterschiedliche Auslegung von Bedingungen auf EU-Ebene für die nationale Umsetzung zulassen.

Einige der betrachteten Beschränkungsvorschläge sind in dieser Hinsicht innovativ, wie z. B. die Einführung eines rechtlich verbindlichen DNEL-Wertes in Kombination mit entsprechenden Hinweisen zu dessen Einhaltung und die Einführung von Schulungen als Maßnahme zur Begrenzung der Exposition am Arbeitsplatz[12].

[12] Die Entscheidung über diesen Vorschlag steht noch aus und die KOM hat die ECHA angewiesen, mit der Entwicklung eines EU-weiten Grenzwertes für die berufsbedingte Exposition (OEL) zu beginnen, so dass man zu dem Schluss kommen kann, dass der vorgeschlagene Ansatz keine eindeutige Unterstützung hat.

Grundsätzlich können berufliche Risiken durch die folgenden Bedingungen einer Beschränkung begrenzt werden:

- Verbot: Ein Stoff als solcher, in Gemischen oder in Erzeugnissen darf in der EU nicht in Verkehr gebracht oder verwendet werden.
- Minimierung in Gemischen oder Erzeugnissen: Die Konzentration oder die Freisetzung eines Stoffes wird in (bestimmten) Gemischen oder Erzeugnissen begrenzt.
- Harmonisierte technische Maßnahme: Bei der Verwendung eines Stoffes sind EU-weit qualitätsgesicherte, harmonisierte technische Maßnahmen zu ergreifen.
- Harmonisierte Schulungen: EU-weit werden qualitätsgesicherte, harmonisierte und speziell zugeschnittene Risikominderungsstrategien umgesetzt, wie z. B. verpflichtendes Schulungsmaterial für Arbeitgebende und Arbeitnehmende (vgl. Fall Diisocyanate).
- Harmonisierte Grenzwerte kombiniert mit Sicherheitsmaßnahmen: Für die Verwendung in der Stoffsicherheitsbeurteilung und die Ableitung von Risikominderungsmaßnahmen am Arbeitsplatz sind verbindliche und harmonisierte Grenzwerte für die Arbeitsumgebung vorgeschrieben.

Verfügbarkeit und Bedarf an Informationen

Verwendungs- und Expositionsinformationen sind wesentlich, aber in der Regel nicht verfügbar

Das Fehlen von Verwendungs- und Expositionsinformationen behindert eine fundierte Definition des Geltungsbereiches eines Beschränkungsvorschlags, den Nachweis nicht akzeptabler Risiken, die Bewertung von Alternativen sowie die sozioökonomischen Analysen. Daher sind diese Informationen für jeden Beschränkungsvorschlag unerlässlich.

Die Fallstudien und die Literaturrecherche haben gezeigt, dass genau diese Informationen den Behörden häufig nicht zur Verfügung stehen und dass große Anstrengungen erforderlich sind, um zumindest grundlegende Daten zu erhalten. Es zeigte sich, dass die öffentlichen Anhörungen während der Diskussion der Beschränkungsdossiers im RAC und SEAC, die als Instrument zur Schließung von Informationslücken gedacht sind, keine wesentlichen Beiträge zur Schließung dieser Lücken leisten. In den analysierten Fällen führte das Fehlen von Verwendungs- und Expositionsinformationen zu Unsicherheiten über die Angemessenheit des Geltungsbereiches einer Beschränkung sowie zu einem potenziell erhöhten Aufwand des gesamten Verfahrens.

Oft sind lediglich nur sehr allgemeine Information über Alternativen verfügbar

Die meisten der analysierten Beschränkungsdossiers enthielten zumindest allgemeine Informationen über Alternativen. Allerdings fehlten häufig Angaben zur technischen Leistungsfähigkeit, zu den Preisen alternativer Produkte sowie zu den weitergehenden Auswirkungen eines möglichen Substitutionsbedarfs. Informationen zum Substitutionsbedarf können Prozessänderungen, die Notwendigkeit der Neuformulierung von Gemischen oder die Umgestaltung von Erzeugnissen umfassen, wobei ein neues Design von Produkten Leistungseinbußen mit sich bringen kann. Dieser Informationsmangel führte zu Unsicherheiten über die mögliche Reaktion auf eine Beschränkung im Markt und damit über die Ergebnisse der sozioökonomischen Analyse.

Der Detaillierungsgrad der Informationen in den Dossiers, die in den Fallstudien geprüft wurden, erschien jedoch angemessen und ausreichend, um die Entscheidungsfindung zu unterstützen. Dies wurde auch durch die pragmatische Herangehensweise von RAC und SEAC bei der Bewertung von Alternativen unterstützt (vgl. nächster Abschnitt).

Vage Begründungen von Ausnahmen verursachen ein hohes Maß an Unsicherheit

Da RAC und SEAC nur über begrenzte Informationen verfügen, um Anfragen hinsichtlich einer Ausnahme zu prüfen und ihre Stellungnahme zu entwickeln, werden Anträge auf Ausnahmen in der Regel von den Ausschüssen trotz Unsicherheiten über den tatsächlichen Bedarf genehmigt. Aufgrund der Unsicherheiten sind die Ausnahmen zeitlich begrenzt und mit Berichtspflichten versehen, aufgrund derer die Rechtfertigung für die Ausnahmen nach Ablauf der Frist überprüft werden soll.

Rolle der Komitees

Verbesserte Bewertungsansätze von RAC und SEAC erhöhten die Transparenz und die Effizienz des Beschränkungsverfahrens

Im Laufe der Zeit haben RAC und SEAC ihre Bewertungsmethoden, Formate und Argumentationen weiterentwickelt und verbessert. Dies gilt insbesondere für den Umgang mit Informationslücken und Unsicherheiten. Dies führte zu einem stringenteren, effizienteren und strukturierteren Meinungsbildungsprozess, der es auch den Stakeholdern leichter macht, die Stellungnahmen zu verstehen und darauf zu reagieren. Eine weitere Verbesserung der Arbeitsweise der Ausschüsse wird als Ergebnis der Task Force Restrictions erwartet[13].

Die durch die RAC- und SEAC-Stellungnahmen verursachten Änderungen des ursprünglichen Anwendungsbereichs erleichtern das weitere Beschränkungsverfahren

Die Arbeit des RAC und des SEAC können zu Anpassungen des Geltungsbereichs eines Beschränkungsvorschlags während des Prozesses führen. Dies erfolgt jedoch lediglich als weitere Eingrenzung. Eine Ausweitung des Geltungsbereichs einer Beschränkung ist nicht möglich, da dies in diesem Stadium der Bewertung keine ausreichende Beteiligung der interessierten Stakeholder gewährleisten würde.

Die Änderungen zur Einschränkung von Anwendungsbereichen waren zum Teil auf Informationen der Interessengruppen und zum Teil auf unabhängige Überlegungen des RAC und SEAC zurückzuführen. Sie betrafen die Abdeckung von Stoffen, die Abdeckung von Verwendungen und Ausnahmen sowie die Bedingungen für eine Beschränkung (oder Ausnahmen), wie z. B. die Schwellenwerte. Zu den Gründen für Änderungen gehörten der Bedarf an Klarstellung (Verständnis), Praktikabilität (Durchsetzung, Überwachung der Einhaltung) und wesentliche Verwendungen (Ausnahmen aufgrund fehlender Alternativen).

Die pragmatische Herangehensweise der Ausschüsse zu Alternativen spart Ressourcen und Zeit

Wenn für den zu beschränkenden Stoff bereits Alternativen in Gebrauch waren, gingen RAC und SEAC pragmatisch davon aus, dass diese Alternativen verfügbar waren und betrachteten daher Substitution als wichtige (oder einzige) Marktreaktion auf eine Beschränkung. Wenn nicht hinreichend geklärt werden konnte, ob Alternativen zur Verfügung stehen, gingen die Ausschüsse von dem Anteil der Anwendungen aus, bei denen eine Substitution stattfinden könnte, sowie einem entsprechenden Anteil möglicher weiterer Marktreaktionen. Dieser pragmatische Ansatz hat sich im Laufe der Zeit in der Erarbeitung von Stellungnahmen der Ausschüsse etabliert.

Die Ergebnisse der Fallstudien und Literaturrecherche zeigen auch, dass qualitative Ansätze im Bereich der Alternativenprüfung eher akzeptiert werden als in anderen Teilen eines Beschränkungsvorschlags. Lediglich bei der Diskussion um Ausnahmeregelungen scheinen tiefer

[13] Siehe ECHA (2018) Recommendations of the Task Force on Restriction Efficiency https://echa.europa.eu/documents/10162/13641/report_task_force_on_restriction_efficiency_en.pdf

gehende Informationen über Alternativen notwendig zu sein (und werden auch gefordert), um Schlussfolgerungen über die vorgeschlagene Beschränkung zu ermöglichen.

Motivation der Stakeholder zur Beteiligung

Stakeholder - insbesondere die Wirtschaftsakteure - sind wichtige Akteure bei der Entwicklung von Beschränkungsvorschlägen und sollten ein Interesse daran haben, ihren Beitrag zu leisten. Es scheint jedoch, dass dies noch nicht in ausreichendem Maße geschieht. Die folgenden zwei Aspekte wurden während der Studie beobachtet.

Ein breiter Geltungsbereich schafft Anreize für eine stärkere Beteiligung der Interessengruppen als ein enger Geltungsbereich

Die Festlegung eines breiten Geltungsbereichs einer Beschränkung hinsichtlich der Abdeckung von Verwendungen ist eine Möglichkeit, Informationslücken zu überwinden, indem die Beweislast, dass ein Risiko (bereits) beherrscht wird oder dass Verwendungen kritisch sind bzw. längere Übergangsfristen benötigen, auf die Marktakteure verlagert wird. Dies verhindert eine langwierige Datenerhebung durch die Behörden und schafft Anreize für die Beteiligung der Marktteilnehmenden, da diese verhindern wollen, dass ihre Verwendungen von einer Beschränkung erfasst werden.

Die Möglichkeit verspäteter Anfragen zu Ausnahmen entmutigt die (frühe) Einbindung der Stakeholder

In den Fallstudien wurde beobachtet, dass die Stakeholder am stärksten während der späteren Konsultationen einbezogen wurden, insbesondere wenn sie eine Ausnahme beantragen wollten. Diese Beteiligung war zwar wertvoll, da zusätzliche Informationen bereitgestellt wurden, kam aber zu einem Zeitpunkt, an dem Änderungen einen erheblichen Aufwand verursachten und/oder nicht so gründlich geprüft werden konnten wie andere Aspekte eines Beschränkungsvorschlags.

Empfehlungen

Allgemeine Funktionsweise des Verfahrens

Insgesamt gesehen ist das Beschränkungsverfahren gut konzipiert, um das Ziel der Verringerung inakzeptabler Risiken durch die Verwendung von Chemikalien zu erreichen. Die verschiedenen Aktivitäten zur Vereinheitlichung des Verfahrens, die von allen beteiligten Akteuren durchgeführt werden, werden in der aktuellen Praxis umgesetzt und es haben sich Arbeitsroutinen etabliert. Diese Trends werden sich wahrscheinlich fortsetzen, und es sind keine offensichtlichen Verbesserungsmöglichkeiten in dieser Hinsicht erkennbar.

- Daher wird empfohlen, **keine grundlegenden Änderungen am Beschränkungsverfahren vorzunehmen.**

Dauer des Verfahrens

Es wurde festgestellt, dass die Dauer des Beschränkungsverfahrens lang ist und nur wenig Potenzial für eine Verkürzung besteht, ohne dass die Qualität der Entscheidungsvorbereitung und damit eine effiziente und effektive Risikominderung verloren geht. Als einzige Option wurde die Entscheidungsfindung des REACH-Ausschusses und der KOM identifiziert, die unangemessen lang zu sein scheint. Es wird daher empfohlen

- **rechtlich verbindliche Fristen für die Entscheidungsfindung der KOM und des REACH-Ausschusses festzulegen.** Eine Zeit von 6 Monaten erscheint angemessen und verhältnismäßig im Vergleich zu der Zeit, die RAC und SEAC für die Erarbeitung ihrer Stellungnahmen haben.

Arbeitsaufwand der Behörden

Der Arbeitsaufwand der Behörden für die Vorbereitung, Prüfung und Entscheidung über eine Beschränkung hängt von vielen Faktoren ab, u. a. von der Art der Stoffe, der Verfügbarkeit von Informationen, bestehenden Regulierungen und dem Umfang der Beschränkung. Um den Arbeitsaufwand deutlich zu reduzieren und das Beschränkungsverfahren effizienter zu gestalten, wird empfohlen

- **ein vereinfachtes Verfahren für Stoffe mit anderen gefährlichen Eigenschaften als CMR einzuführen**, für die eine allgemeine Expositionsbeurteilung ein Risiko anzeigt. Dies könnte für PBTs /vPvBs der Fall sein, die in den Umweltkompartimenten und/oder Biota gefunden werden und auf Emissionen und Expositionen hinweisen, die möglicherweise Risiken verursachen. Auch Stoffe mit endokrinen Wirkungen in der Umwelt könnten für solch ein Verfahren geeignet sein.

Damit unterstützen die Projektergebnisse den Ansatz der kürzlich veröffentlichten Chemikalienstrategie für Nachhaltigkeit[14]. Während die Strategie jedoch das vereinfachte Verfahren für lediglich Verbraucherprodukte vorschlägt, erscheint ein vereinfachtes Verfahren auch für umweltgefährdende Stoffe aus weit verbreiteten diffusen Quellen gerechtfertigt.

- **Vereinfachung des Nachweises unannehmbarer Risiken und der Begründung einer Beschränkung in Anhang XV-Dossiers** für Stoffe mit Gefahren mit niedrigen oder fehlenden Schwellenwerten. Einfache und teilweise qualitative Ansätze bei der Alternativenprüfung und der sozioökonomischen Analyse können ausreichen und sind weitgehend akzeptiert, um die Argumentation der Verhältnismäßigkeit und Wirksamkeit von Maßnahmen zu unterstützen. So sind beispielsweise „Emissionsminimierungsansätze“ und Kosten-Wirksamkeits-Analyse häufig ausreichend. Die vorhandenen Methoden und Regeln, wann deren Anwendung angemessen ist, sollten aus Gründen der Transparenz und Konsistenz im Leitfaden für Beschränkungsdossiers erläutert werden.

Fehlende Informationen

Informationen über Verwendungen und Expositionen sind wesentlich für die Entwicklung, Ausrichtung und Begründung einer Beschränkung. Wenn den Behörden diese Informationen fehlen, werden die Effizienz und die Wirksamkeit einer Beschränkung wahrscheinlich abnehmen. Hätten die Registranten von vornherein bessere Verwendungsinformationen, könnten ihre Stoffsicherheitsbeurteilungen und Empfehlungen für Bedingungen einer sicheren Verwendung in den Sicherheitsdatenblättern angemessen umgesetzt werden und Beschränkungen möglicherweise überflüssig machen. Daher wird empfohlen, die Informationsbasis über Verwendungen und Expositionen von Stoffen zu verbessern:

- Entwicklung, Verbesserung und Etablierung von **Ansätzen zum Umgang mit Datenlücken** und damit verbundenen Unsicherheiten. Pragmatische Ansätze und vertretbare Annahmen können für eine Bewertung von und Beschluss über eine Beschränkung ausreichen. Dies wurde in einigen Stellungnahmen von RAC und SEAC so gehandhabt. Im Sinne einer erhöhten Vorsorge müssen Datenlücken möglicherweise zugunsten einer (schnelleren) Regulierung in Kauf genommen werden. Ein (standardisierter) Umgang mit Lücken und Unsicherheiten könnte eine kosteneffiziente Lösung sein, zumindest in Fällen wo Basisdaten vorhanden sind und/oder mehr Informationen das Entscheidungsergebnis nicht wesentlich verändern würden.

[14] COM(2020) 667 final: Chemicals Strategy for Sustainability Towards a Toxic-Free Environment https://ec.europa.eu/environment/strategy/chemicals-strategy_en

- Implementierung eines **Rechts** für Behörden im Rahmen eines regulatorischen Prozesses, Verwendungs- und Expositionsinformationen sowie relevante sozioökonomische Daten von den Marktakteuren **anzufordern** und eine **Verpflichtung** auf solche Anfragen, innerhalb einer angemessenen Frist zu antworten. Während dieser Ansatz grundsätzlich praktikabel erscheint, ist eine gezielte Befragung nur möglich, wenn die Relevanz einer Verwendung geklärt ist. Völlig unbekannte Verwendungen wären weiterhin nicht identifizierbar. Eine bessere Abdeckung solcher unbekannten Verwendungen könnte durch eine auf weitere Stoffeigenschaften ausgedehnte Meldepflicht in Analogie zu den REACH-Artikeln 7 und 33 oder der unter der Abfallrahmenrichtlinie eingerichteten Datenbank der ECHA über bedenkliche Stoffe in Produkten (SCIP) erreicht werden.

- **Erwägung von Beschränkungen mit breitem Anwendungsbereich**, insbesondere um Risiken aus unklaren Emissionsquellen/Verwendungen zu adressieren. Wenn keine oder nur wenige Informationen über Verwendungen und Expositionen verfügbar sind, würde ein breiter Beschränkungsbereich es ermöglichen, alle Verwendungen und Expositionen zu berücksichtigen. Frühzeitig kommuniziert kann ein breiter Geltungsbereich ein Anreiz für die Beteiligten darstellen, auch ohne eine rechtliche Verpflichtung relevante Informationen bereitzustellen, um von den Beschränkungen ausgenommen zu werden oder die Bedingungen der Beschränkung zu beeinflussen.

- Verknüpfung eines breiten Beschränkungsumfangs mit einem **obligatorischen, frühen Zeitfenster für eine einmalige Gelegenheit zur Einreichung von Ausnahmeanträgen.** Dieses Zeitfenster läge in der Phase, wo das Dossier erstellt wird, direkt nach der Ankündigung im ROI. Dies würde Stakeholder, die eine Regulierung verhindern wollen, dazu bringen, Informationen bereitzustellen, und es würde den Behörden ermöglichen, den Antrag bei der Festlegung des Beschränkungsumfangs gründlich zu prüfen. Den Ausnahmeanträgen sollten eine Reihe von Standardinformationen beigefügt werden (z. B. vergleichbar mit einem Zulassungsantrag), die die Abweichung von einem vorgeschlagenen Beschränkungsszenario begründen. Eine solche Verpflichtung würde auch dazu beitragen, zeitliche Engpässe bei der Bewertung von Ausnahmeanträgen im RAC/SEAC zu vermeiden und den Ausschüssen die Möglichkeit geben, bei Bedarf zusätzliche Informationen zu sammeln. Die anschließende öffentliche Konsultation könnte dann genutzt werden, um punktuelle Informationslücken zu schließen und Meinungen zu der beantragten Ausnahme einzuholen.

1 Background of the study

The current report provides an analysis of the restriction procedure under the EU Chemicals 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)[15]. The analysis includes an outline of the legislator's original intention regarding the restriction procedure, which is based on the legislation's recitals and the COM's (COM) White Paper on a Future Chemicals Policy[16], a discussion of how this intention was transferred into the REACH text as well as an assessment of its interpretation in guidance documents, practical working procedures and everyday implementation.

The overall aim of this sub-study of the project 'Advancing REACH' is to identify improvement areas for the restriction process under REACH and to develop proposals how these improvements can be realised in the future implementation processes of REACH, including the option to implement changes to the regulation itself (articles and annexes). This aim should be achieved by reviewing literature of the current implementation of the restriction process and potential opinions on deficits and improvement options as well as the development of cases studies of past (and ongoing) restrictions.

The focus of the analysis is set on the efforts needed to develop, substantiate and adopt restrictions under REACH. Amongst others, this includes a discussion of what level of detail is necessary to justify a restriction. In addition, issues are identified which might occur during a restriction process even though it is not intended or foreseen by the legislator, and which create additional burden for the authorities that initiate a restriction. Finally, the analysis reflects on the time needed to come up with new restrictions, the overall duration that is needed from drafting a proposal to a final decision, and the role of the committees at each of the various decision-making steps. Based on several case studies, proposals are derived that could improve the efficiency of the restriction process.

Section 2 of the report outlines the restriction process under REACH and gives background information on the intention of the procedure. Section 3 describes the current implementation of the legal text according to the various steps the procedure consists of. The status of the restriction process is outlined in Section 4 and the case studies are summarised in Section 5. Conclusions and recommendations are provided in Section **Fehler! Verweisquelle konnte nicht gefunden werden.**. The assessment scheme applied to develop the case studies is provided in the Appendix of the report.

[15] 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, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

[16] EU Commission (2001): White Paper - Strategy for a future Chemicals Policy /* COM/2001/0088 final */; available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52001DC0088

2 Restrictions under REACH

The aim of the restriction procedure under REACH is to manage unacceptable risks to human health or the environment, which need to be addressed on a Community-wide basis. Restrictions can address the manufacturing, the placing on the market and the use of substances on the European market. They may result in a total ban (i. e. prohibit any manufacture, import or use of a substance (group)), prohibit a specific use, potentially under specific conditions, or may include other conditions that restrict a (particular) use[17].

2.1 History of the restriction process

Restrictions are not a new instrument of European chemicals risk management, but had already been in place well before REACH entered into force. The so-called Marketing and Use Restrictions Directive[18] defined the conditions, procedures and responsibilities in the former restrictions process at EU level. Initially, restrictions were based on proposals at national level. Later restrictions under that Directive were processed by a risk assessment conducted according to the so-called Existing Substances Regulation[19].

In its report on the operation of the chemicals legal framework that had been in place before the development of REACH in 1998[20] the COM identified key problems in the implementation of these legal acts, mainly:

- The COM and the Member States (MS) depended on the chemical industries to provide data on substance hazards or had to conduct testing themselves. As the substance manufacturers and importers were not always (fully) known and incentives for cooperation were missing, information collection on hazards was cumbersome, expensive and time-consuming. In addition, the burden of proof was imposed fully onto the Member State authorities, rather than the industry.
- The COM and the MSs were similarly dependant on the (downstream user (DU)) industries to get information on the use of the substances with an equally challenging access to that information. Hence, exposure data was frequently rough and challenged by the industry in the process.
- A general lack of commitment was observed on the side of the MSs and the industry to implement the provisions of the legal framework.
- Clear procedures, deadlines and impact assessments were missing to justify and target regulatory measures.
- A need was seen to implement the precautionary principle.

[17] For example, conditions could be rules for installations using the substance (group) or a need to wear personal protective equipment or be trained in the use of a particular substance and/or mixture (e. g. diisocyanates restriction).

[18] Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

[19] Regulation (EEC). 793/93 on the evaluation and control of the risks of existing substances

[20] EC (1998) SEC(1998) 1986 final: Commission working document, Report on the operation of Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification\, packaging and labelling of dangerous substances, _as amended; Directive 88/379/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations; Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances;

With regard to Directive 76/769/EEC in particular, the evaluation identified three main areas where the need for improvement was seen:

- The first area identified as a problem was to ensure a harmonised internal market and the possibility for Member States to grant exemptions, which was contrary to this objective.
- Furthermore, it was questioned whether the Directive sufficiently ensures the safety of human health and the environment.
- Finally, various practical aspects of dealing with the Directive were criticised.

All the above aspects resulted in high burdens for the European chemicals risk management and in delays in many of the processes.

In a wider context, the entire chemicals legal framework was criticised and put up for a review, due to more fundamental aspects. These include the unbalanced share of responsibilities between authorities and industries for the safety of chemicals in general, the lack of information on the majority of substances manufactured and used in the EU as well as the insufficient implementation of the precautionary principle in the field of chemicals.

The 'Treaty on the Functioning of the European Union' (TFEU) demands that the precautionary principle be applied in all environmental legal acts. Article 191[21] states:
"[…] *Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay*. […]"

While the TFEU directly addresses the implementation of the precautionary principle, the polluter pays principle can be interpreted as supporting a shift of the burden of proof from the authorities to the market actors. If the consequences of potential damage are the responsibility of the substance users, the prevention of that damage could also be regarded as their scope of responsibility, i. e. the assessment of hazards, exposures and risks as well as (proactively) implementing measures that draw consequences from the findings of such assessments.

According to Recital (1) of REACH, the overarching aim of the regulation is to "[…] *ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in mixtures and in articles, while enhancing competitiveness and innovation.* […]" Following this aim, some fundamental changes to the chemicals legislation as well as the specific deficits identified in the COM report should be remedied by the implementation of REACH and some key principles[22]:.

- No data – no market: without providing at least a minimum of hazard (and use) information, manufacturing and import of substances as such or in mixtures is not allowed.
  This principle addresses the need for hazard and risk information and the problem of missing incentives and tools to require the industry to provide that information
- Shifting of the burden of proof: manufacturers and importers are to assess and ensure, potentially by communicating necessary risk management measures to their customers that

[21] ART THREE UNION POLICIES AND INTERNAL ACTIONS, TITLE XX ENVIRONMENT Article 191 OJ C 326, 26.10.2012, p. 132–133 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12012E191

[22] Additional key changes concerned, amongst others, the equal treatment of existing and new substances (phase-in and non-phase in substances) as well as the introduction of the authorisation process (shifting the burden of proof at least partly to the industries), sharing responsibilities along the supply chain and the simplification of legislation by merging a number of chemicals related legislation into REACH.

the uses of their substances are safe before placing on the market. However, this principle is only applied to a very limited extent with regard to the restriction. The identification of risks and the burden of proof for the justification of the measure is essentially incumbent on the authorities.

- Science, clear procedures including timelines: the REACH procedures and roles and responsibilities of the MSs, the COM, the European Chemicals Agency (ECHA) with Expert Committees and industries were clearly defined and timelines were defined for the processes. Scientific evidence should form the basis for decision making, in form of risk assessments and socio-economic assessments (SEAs) conducted according to an agreed methodology. The latter includes an assessment of costs and benefits of regulatory measures as well as the availability of safer substitutes and their efficacy.
- Identification of substance properties as one of the means to implement the precautionary principle, in particular to prioritise substances for a potential phase out (substances of very high concern (SVHC))[23].

The main specific criticism on the restriction regime that existed before REACH were the undefined timelines for the completion of the risk assessments according to Regulation 793/93 and the very low incentive for the industry to provide essential data.[24] With the introduction of REACH and the therein revised restriction process it was expected to overcome the shortcomings and to accelerate the overall restriction process (Recital (84)). The following provisions under REACH were expected to facilitate the identification and regulatory management of risks from the use of chemicals:

- Safety assessments by substance manufacturers and importers and the potentially derived and recommended risk management measures should limit the risks from the identified uses of the substances. This was expected and intended to significantly reduce the need for restrictions.
- The existence of Chemical Safety Reports (CSRs) should make it easier to identify remaining risks and to subject them to the restriction process in a more focussed way (Recital (86)).
- The notification of SVHCs in articles (REACH Art. 33) should contribute to an improved information basis on the use of these substances and potentially related risks. This may be used, amongst others, as an information basis for restrictions proposals (Recital (29)).
- Restriction proposals should follow the transparency principle and allow stakeholder involvement by making the background information available in form of a dossier (Recital (92)).
- Clear timelines were considered as essential for the acceleration of the restriction procedure (recitals (93) (94)). Therefore, the legislator intended to specify a procedure with defined timelines for the restriction process in the REACH text.

[23] See details on this in the report on the implementation of the precautionary principle and hazard based regulation under REACH published in the frame of the current project.

[24] See European Commission (2001) White Paper - Strategy for a future Chemicals Policy https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52001DC0088

At the time of developing the modified restriction process within REACH, it was clearly expected that its implementation should be based on the precautionary principle. This means, that decision-making should be possible even if data is insufficient to conclude the risks[25].

Furthermore, the introduction of REACH as an EU-regulation instead of the former directives ensured that the requirements for chemical substances, including restrictions, are fully harmonised across the EU MSs (EEA respectively, see Recital (2))[26].

2.2 Legislator's intentions implemented via the restriction process

Although the Marketing and Use Restrictions Directive and its implementation were perceived as insufficient, it was acknowledged that the restrictions developed under that regime should be transferred to REACH. Consequently, the existing restrictions remained valid by including them in the list of restricted substances established by REACH Annex XVII.

Annex XVII should contain all restrictions, whether they are from the past or newly developed, as well as any changes made to them over time, including the conditions for each individual entry (Recital (87)). Furthermore, existing national, more stringent restrictions should be kept valid in a transition period, if notified by the MSs (recital (85)). The intention was to evaluate these measures in the light of a potential EU-wide implementation and thereby harmonising them with these stricter measures.

The restriction procedure under REACH was intended to potentially address any risk originating along the life cycle of a substance including its disposal. It should be able to target substances on its own, in mixtures and/or in articles (recitals (75), (87), (80), (29) – the latter explicitly mentions imported articles). The restriction itself should be flexible to prescribe any condition or measure suited to reduce an identified risk, starting with a total ban and ending with the limitation of (only very) specific uses by measures that reduce the risk to an acceptable level (Recital (23)). Special attention should be given to consumer risks from carcinogenic, mutagenic and reprotoxic substances (CMRs) (Recital (75)).

The MSs or the COM should take the initiative to propose new restrictions (recitals (89) and (91)). The latter should be able to entrust the ECHA to perform the scientific work necessary to develop a dossier justifying a restriction proposal. It was also intended for the ECHA to become active on its own initiative if risks from SVHC in imported articles are identified [27] (recitals (29), (80)). The ECHA was also foreseen to coordinate all tasks related to the development of restriction proposals (Recital (90)), including publication of the dossier, organisation of consultations (92), preparation of draft (93) and final opinions for the COM (Recital (94)).

[25] This is not explicitly stated in a recital but has been implemented via Article 1 (3). The principle is ultimately based on European primary law pursuant to Article 191 TFEU.

[26] In general the Report on the operation of Directive 76/769/EEC concluded there was not a general problem with the acceptance of harmonised measures but some delay when it came to the introduction in the individual member states.

[27] This risk is not covered by the authorisation regime that is usually the instrument to address risks from substances of very high concern in uses in the EU.

3 Translation of intentions into the legal text

3.1 Conditions for restriction proposals

The restriction process is defined in REACH Title VIII and comprises only seven articles (Articles 67-73). If a restriction exists for a substance or substance group, it may only be manufactured and/or used if the conditions specified in that restriction in REACH Annex XVII are met (Article 67 (1)). A restriction may apply only to a particular use of a substance or substance group; in this case all other uses of that substance may be continued.

Two different procedures exist for the development of new restrictions:

- The steps outlined in Article REACH 69 Article should normally be followed (Art. 68 (1)), which includes a public consultation of the restriction proposal and a decision process to be pursued. Art. 68(1) also specifies that the socio-economic effects and the availability of alternatives have to be considered in the decision on a restriction proposal.
- Article 68 (2) defines a simplified restriction procedure that may be applied to address risks from CMRs (cat 1A and 1B) in products that could be used by consumers. In this case, the existence of exposure is assumed and an unacceptable risk is demonstrated by default.[28] Neither the consideration of socio-economic impacts, an assessment of the availability of alternatives, nor a public consultation are required. The COM is entitled to decide if a Committee with representatives from the MS (Article 133(4)) is involved. Although not required, the COM started to perform public consultations on all restriction proposals as part of the 'Better Regulation Initiative'[29]
  Due to the reduced procedural requirements for such restrictions; it is referred to as 'simplified procedure'. This term will also be used below.

The 'simplified procedure' requires fewer elements to substantiate a restriction proposal and is based on substance hazard information and a generic risk assessment/assumption. Due to this simplicity, this procedure is first described in the following section. After this a more detailed description of the standard procedure according to Art. 68(1), which is currently applied in most cases, is given.

3.1.1 Conditions of the 'simplified procedure' (Art. 68(2))

According to REACH Article 68, it is a precondition for any new restriction that an unacceptable risk originating from the presence of a substance on the EU market is demonstrated and that this risk needs to be addressed at Community wide level.

Article 68 (2) implies that a risk is regarded demonstrated if a substance has certain hazards, i. e. fulfils the criteria of a CMR (Cat. 1A and 1B), and if it is known to be present in products (i. e. as such, in mixtures and in articles) that could be used by consumers. Hence, particular hazards are almost sufficient evidence of the need to make a restriction proposal. In a document discussed in the CARACAL Doc. CA/102/2014 additional aspects are mentioned that need to be fulfilled to ensure restrictions can be introduced via the simplified route such as:

[28] In many cases this is linked to a formal harmonised C&L as CMR, but this is not mandatory.

[29] This is mainly based on Article 11 of the TFEU and Protocol No. 2 on the application of the principles of subsidiarity and proportionality annexed to the Treaty stipulates that "*before proposing legislative acts, the Commission shall consult widely* (see EU COM Better regulation: guidelines and toolbox Chapter VII Better regulation guidelines - Stakeholder consultation https://ec.europa.eu/info/sites/info/files/better-regulation-guidelines-stakeholder-consultation.pdf

- Ensure that the substances are contained in consumer products (list of substances/list of articles);
- Evidence must be provided that the substances pose a risk to the health of consumers;
- Evidence must be provided that exposure cannot be technically prevented;
- Sufficient knowledge must be available on the markets concerned (e. g. availability of alternatives)

In this regard, the precautionary principle is implemented here regulation based on generic risk assumption[30]). For cases in which the conditions are not met with sufficient certainty, the document recommends a procedure in accordance with Article 69, in which a detailed proposal is drawn up (see next chapter). The procedure consists of the following steps only (simplified procedure).

1. The Com has the sole right of proposal.
2. Subsequently, a public consultation with interested parties is carried out in order to refine the regulatory text, if necessary.
3. Finally, the Regulatory Committee discusses the proposal and the Commission can take a decision on the basis of these discussions.

In practice, this means that the two committees, Committee for Risk Assessment (RAC) and the Committee for Socio Economic Analysis (SEAC), that usually evaluate restriction proposals are not involved and a decision can be taken immediately at the level of the Com.

As a consequence, the information needed to substantiate a new restriction is comparatively low and is limited to substance properties and the knowledge about the consumer products that contain the substance. Although this seems to be a rather simple way to protect consumers from exposures to substances causing the most severe adverse health effects, in practice several obstacles limit a broad application of the simplified procedure:

1. Due to (significant) data gaps in the registration dossiers it is not possible to conclude on the CMR endpoints[31]. Although the data availability for phase-in substances has improved due to the registration obligation, for many substances relevant data for the evaluation of CMR properties have not been provided by registrants. Therefore, data has to be requested during compliance checks or substance evaluations before a restriction proposal can be elaborated.
2. Information on products is scarce and generic in registration dossiers. Usually very broad product categories are specified, making it difficult to scope restrictions.[32] First examples of 'simplified restrictions' revealed a need for additional discussions with the stakeholders to define a list of substances that are used in certain type of products (see Chapter 5.4 on the restriction of CMR in textiles).

3.1.2 Conditions of the 'regular procedure' (Art. 68(1))

Restrictions proposals according to Article 68 (1) have to fulfil two conditions:

1. Demonstration of an unacceptable risk in combination with the need to address the risk on an EU-wide level

[30] This describes situations where a risk can be assumed as default without further evidence.

[31] UBA (2020) REACH Compliance: Data availability in REACH registrations – Part 3: Evaluation of 100 to 1000 tpa substances, https://www.umweltbundesamt.de/publikationen/reach-compliance-data-availability-in-reach-0
UBA (2018) REACH Compliance: Data availability in REACH registrations Part 2: Evaluation of data waiving and adaptations for chemicals ≥ 1000 tpa https://www.umweltbundesamt.de/publikationen/reach-compliance-data-availability-in-reach

[32] This also applies to 'regular' restriction proposals according to Art. 68(1)

2. The impacts assessment shows that the restriction is justified because the benefits outweigh the costs. It has to include an assessment of:
   a. alternatives to the current situation
   b. economic impacts and benefits for the society (socio-economic analysis (SEA)).

These two aspects will be reflected a bit more in detail in the following.

3.1.2.1 Description of an unacceptable risk

REACH does not provide any criteria that clearly define the term 'demonstration of an unacceptable risk'; hence, different than for Article 68 (2), it is unclear when this condition is fulfilled.
Two aspects require clarification: the term 'unacceptable' and the term 'demonstration', as according to the general understanding of chemicals risk assessors, a RCR exceeding 1 would indicate a risk. Neither the REACH guidance document on developing Annex XV dossiers for restrictions[33] nor the guidance on chemical safety assessment[34] contain any respective clarification or interpretation of the term 'unacceptable risk'. Similarly, while the 'demonstration of safety' is defined and interpreted as deriving RCRs for one or any use of a substance below the value of 1 in the frame of a CSR, the 'demonstration of an unacceptable risk' by a MS authority in the context of the restriction procedure is not described in the related guidance document. This is due to the fact that the assessment of a risk being acceptable or not is essentially a political assessment in a social context, for which it is neither possible nor desirable to derive any standardised criteria or guidelines for decision making. It is one of the benefits of the restriction procedure that the assessment of a necessity and the definition of the restriction scope allow some flexibility.

The hazard assessment in demonstrating an unacceptable risk is currently implemented as follows: In practice, health related restrictions under Art. 68(1) frequently concern CMRs and environment related risks persistent, bioaccumulative and toxic substances/very persistent, very toxic substances (PBT/vPvBs). Both types of hazards may be the reason to identify substances as SVHCs based on REACH Article 57. While the formal SVHC identification process is part of the authorisation process such substances can still be relevant for the restriction, especially in areas that are not in the scope of the authorisation. Restriction proposals for such substances are frequently a follow-up of a harmonised classification (CMRs) or a candidate listing (CMR and PBT/vPvB). Although a formal determination of SVHC status is not necessary for a restriction, in practice ECHA welcomes this step for PBT substances or endocrine disruptors with an effect in the environment. Similarly, a harmonised classification[35] and/or candidate listing frequently precedes a restriction proposal for the following hazards:

- Sensitisation (corresponding classification)
- Irreversible damage to organs (corresponding classifications)

[33] ECHA (2007): Guidance for the preparation of an Annex XV dossier for restrictions. Interestingly, Chapter 5.2 providing guidance on the demonstration of risk talks about 'adequate control' of risks or risks that are 'not sufficiently managed' rather than of unacceptable ones and refers to the CSR according to REACH Annex I and the related guidance documents for methodology to conduct the risk assessment.

[34] In particular ECHA (2008): Guidance on information requirements and chemical safety assessment Part E: Risk Characterisation

[35] Harmonised classification is possible for CMR properties and respiratory inhalation. For all other end-points, a harmonised classification is possible on a case-by-case basis if a need for Union-wide harmonised classification and labelling is demonstrated.

- Endocrine disruptors - ED (partly corresponding classification as toxic to reproduction, not applicable in the area of environmental ED)[36]

In addition, restrictions can be used to address other substance properties which are not directly related to the classification or SVHC as other human health or environmental properties posing a risk (e. g. physical appearance of substances like asbestos, microplastics, other human health or environmental properties).

As a conclusion from current practice, the type of hazard does not limit the scope of an unacceptable risk or, vice versa, as a wide range of hazards can in principle cause an unacceptable risk.

In addition to the identification of hazards, the demonstration of a risk also requires an exposure assessment. There are no criteria on the acceptability of exposure levels (e. g. a maximum number of affected people) in REACH to guide decision-making on an unacceptable risk.

In contrast to Article 68, Article 69 defines that, in case the COM or a MS considers that adequate control is not ensured from a process performed with a substance, there might be the need to prepare a restriction proposal. But again it remains unclear what this means in a specific case. In the frame of risk assessment, as already mentioned, this is understood as a situation where a RCR > 1. According to current practice, exposures are modelled based on generic information which causes a high degree of uncertainty due to the unspecific assessment and partly rough assumptions. Therefore, such an approach seems insufficient to substantiate a restriction.

The lack of a clear and unambiguous interpretation of the term 'unacceptable risk' is especially is challenging, but at the same time offers the possibility to apply the instrument of restriction flexibly and broadly for adverse effects that cannot be directly linked to a particular exposure, which is the case for most of the above mentioned hazards. Deciding on the acceptability of risk is further exacerbated because measured exposure data are frequently available only for a certain group of persons or for a defined region in the EU (e. g. one MS). Even if a risk can be demonstrated for a specific situation (persons, geography), it must be shown that this situation is representative for the EU, i. e. a similar risk level exists, at least potentially, across several MSs and/or in other groups of persons.

Analysing the already adopted restrictions, the following conditions can be seen as examples of possible criteria indicating that a restriction is justified (i. e. a risk can be considered as unacceptable).

- There is evidence provided by epidemiological studies that parts of the population (in particular vulnerable groups) suffer from adverse effects due to exposure to a substance (see e. g. restriction on Phthalates Annex XVII 51, which addresses risks from childcare articles and toys that originate from mucus contact (mouthing)). [37]
- Substance concentrations in the environment are increasing over time in the environmental compartments, including organisms. In such cases assumed effects may also support a restriction proposal, even though no specific effect has been described (e. g. based on

[36] In the CARACAL sub-group meeting on EDs in July 2020 a paper was circulated that proposed the extension of CLP by inclusion of two new hazard classes for EDs in the CLP Regulation, one for human health and one for the environment (see CASG-ED/2020/06 https://circabc.europa.eu/sd/a/b0d53977-123e-4b27-8af3-b88ca8aa738b/CASG_ED_2020_06_COM_reflections_CLP.docx)

[37] Already addressed in the recitals of Directive 76/769/EEC and continued in subsequent political strategies issued by the COM e. g. DECISION No 1386/2013/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' Nr. 71. (4). Furthermore such groups are given special attention in risk assessments, e. g. when safe threshold levels are derived, see Annex I section 1.4.1. and the relevant Guidance on Annex XV for restrictions Section 5.3 (p.50)
https://echa.europa.eu/documents/10162/23036412/restriction_en.pdf/d48a00bf-cd8d-4575-8acc-c1bbe9f9c3f6

laboratory and monitoring data). Here, REACH allows regulatory action based on the precautionary principle if there is an indication of a high likelihood of damage (in the future). To demonstrate the relation between the use of such a substance or its presence in articles on the EU market can be very difficult and gives reason for substantial controversial discussion (e. g. in public consultation), and insufficient data might lead to a discontinuation of the restriction process. As consequence MS and ECHA are investing lots of resources to collect this kind of information.

- Effects have been shown under laboratory conditions (e. g. in animal testing) and exposure of human or the environment can be demonstrated

In conclusion, the demonstration of an unacceptable risk is crucial to developing a restriction proposal, because it is a pre-condition of the entire process. While information on hazards and uses may be available, at least, to a certain extent from registration dossiers and other EU risk assessment documents, the derivation of specific risks due to several exposure sources and the collection of evidence showing the existence of (relevant) damage that is occurring (in a representative manner) across the EU is an extensive task of the authorities. The high resource demands are considered discouraging to even start the process. Despite the improvements in data availability, authorities still have significant data gaps on specific uses of substances, in particular in consumer articles, and lack possibilities to 'formally request' such information from the industry stakeholders. Finally, the idea of implementing the precautionary principle is counteracted by the need to provide evidence of damage that can be considered representative or similar in other populations or regions.[38]

3.1.2.2 Impact assessment

The second condition for the restriction proposal is the consideration of consequences of an envisaged restriction. According to REACH Annex XV, restriction proposals should include an evaluation if alternatives to the restricted substances exist for the applications which are planned to be restricted. The impact assessment covers two main areas:

- An Assessment of Alternatives (AoA)
- An assessment of the socio-economic consequences of the intended measure, a so-called socio economic analysis (SEA)

The role of the two elements and some key questions/challenges are described in the next paragraphs.

AoA

When a new restriction is introduced the use of a substance may not be allowed in a number of applications or products. Production and use of a substance may be entirely banned or changes may be needed to the technology to which the substance is applied in order to reduce exposures to humans or the environment. This can have significant consequences for the market actors using the substance if there is no alternative they can apply in order to adapt their current practice. Therefore, REACH obliges the submitter of a restriction proposal to perform an AoA

[38] See also Communication from the Commission on the precautionary principle COM/2000/0001 final https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52000DC0001, this document states that a factor triggering the use of the principle "[…] *is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data.* […] ". So it clarifies that it might not be up to the risk assessor to eliminate all doubts linked to the risk assumption and justifies a political decision on risk measures to ensure a high level of protection.

based on available information for all substance uses and/or products covered in the scope of the intended restriction.

Some alternatives may be other substances that have the same or a similar function as the one to be restricted (drop-in substitution), but some may also be completely different products or processes that are suitable to replace the use of the substance and achieve an equal outcome/functionality. In this context, it can also be an option to do without a functionality altogether, even if no alternatives exist and the social benefit does not appear to be given. Depending on the extent of technology adaptation it can be very easy for market actors to move to an alternative. In the case of some drop-in substitutions processes might only need minor adaptations, but other key parameters can remain stable (e. g. process can be continued in same installation, product performance is not lowered etc.). In other cases, the shift to alternatives can be more difficult, e. g. when an entire technology change needs to be performed. In such cases market actors will need to invest lots of time and money to expand expertise and to implement technical preconditions for the technology. Consequently, the AoA does not only cover a collection of theoretical alternatives, but also an assessment of the feasibility for market actors currently using the substance that is intended to be restricted. The feasibility assessment on the one hand covers the technical feasibility (can market actors switch to the alternative and how long will this potentially take). On the other hand, an economic assessment of the alternative is part of the analysis (is it financially feasible to introduce a technology given the economic operation the market actor performs). This aspect is closely linked to the SEA, where these financial considerations are part of the analysis, as well. These AoA tasks result in some challenges for the dossier submitters when preparing the restriction proposal, as there are:

- **Technical knowledge of the processes** that involve the substance under consideration is needed (what does the substance do in the process or product it is currently used for).
  In practice the authorities developing a restriction proposal are usually focussed on regulatory issues, exposure, fate and (eco-)toxicology rather than engineering. Therefore, they frequently lack knowledge and understanding of the technical aspects, which is the core competence of the market actors that actively use the substance (formulators or end users). These are not necessarily the ones (most) affected by a restriction (e. g. in case of an import of an article or mixture).
  The market actors that might be affected by a restriction do not have an obligation to provide technical details to authorities. The registration process has shown that product related information is included in only a very generic way. Often only product categories are indicated, e. g. plastic products, which could be a plastic chair or the part of a highly complex electronic product, which obviously might have entirely different consequences, but cannot be derived from the description.
  Thus, the collection of technical information on the current use of the substance under consideration can be very burdensome for dossier submitters and often bares the risk of insufficient understanding.

- An overview of **possible alternative** needs to be generated.
  Based on the assessment of technical functions of the substance that is intended to be restricted, potential alternatives need to be identified. Given potential uncertainties on the technical functions of the substance under concern, it is difficult to evaluate the technical suitability of a potential alternative. Companies developing potential alternatives are often not easy to identify, because they are not involved in pre-discussions on a restriction proposal and not aware there might be an opportunity for their product on the market. Hence, it is very difficult to involve such actors and gain understanding on technical details of the alternative (even more if these alternatives are linked to confidential issues) and again

there is no legal requirement for these market actors to get involved in the development of the restriction proposal.

- The **economic and financial consequences** of an introduction of the alternative needs to be determined.
  Again the knowledge of the costs for the introduction of an alternative is an information type that is mainly something market actors might be able to generate. In many cases this does not only cover the market price of an alternative substance (e. g. when a drop-in substitution is possible), but also other costs such as investments in technical equipment, process adaptations etc. Frequently, this is difficult to estimate even for companies that consider the introduction of an alternative and, therefore, is often a source of uncertainty in restriction proposals.

All aspects described above are linked to difficulties for authorities to get access to relevant key information from market actors and a lack of a mechanism to request these data in a legally binding way. To overcome these difficulties, the elaboration of a restriction proposal is accompanied by informal calls for evidence, where market actors are requested to provide relevant information on a voluntary basis. It is important to note that companies which do not provide information on their uses risk their interests not being considered in any subsequent regulation. Nevertheless, the main incentive for market actors to provide data is to prevent regulation or at least to obtain an exemption. The provision of information to justify the restriction is not usually in the interest of market participants. Apart from this some of the information is collected via contracted research by consultancies and research institutions. Nevertheless, work on the AoA can be considered as burdensome for the Annex XV authors and a source of significant uncertainty.

SEA

The SEA is an instrument to evaluate impacts that might result from a regulatory measure. As a general rule for REACH processes, the societal benefits of a regulatory measure should outweigh the risks associated with a continued use of a substance, i. e. no change in regulation.

Annex XVI specifies basic information on how socio-economic analyses may be performed in the context of restrictions or authorisation. A guidance document exists for SEAs provided in the frame of a restriction proposal.[39] The SEA guidance for the restriction process mentions four purposes the SEA has in the context of the restriction process:

- Purpose 1: Justification that community-wide action is required;
- Purpose 2: Assessing whether the proposed restriction is the most appropriate community-wide action compared to other regulatory management options (RMOs);
- Purpose 3: Refining the scope of the proposed restriction;
- Purpose 4: Assessing the proposed restriction in terms of:
  - The net benefits to human health and the environment and
  - The net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

Different types of SEA information may be relevant to these different purposes. For example, in relation to Purpose 1, the SEA may be important to determining whether action at the member

[39] ECHA (2008): Guidance on Socio-Economic Analysis – Restrictions

state rather than the Community level would result in significantly different impacts on business across the EU, could cause an unfair playing field or could potentially distort competition or create barriers to trade.

For Purpose 2, the SEA is likely to be more focused on comparing the effectiveness, costs and benefits of different risk management options. The aim here is to determine whether restrictions would appear to be the 'best' option, taking into account the full range of socio-economic impacts; only this level of analysis is obligatory for authorities under REACH. It can be noted that this purpose, to large extend, has been moved to the informal process of the regulatory management option analysis (RMOA). By doing so, it was the authority's intention to perform this assessment before a measure is initiated and to avoid potential double work by selecting a sub optimal measure. Nevertheless, since the RMOA is an informal procedure, even though widely accepted by authorities and also industry stakeholders, an argumentation has to be incorporated in the restriction proposal itself.

The aim of the SEA would be similar for Purpose 4, although in this case the focus would be on identifying the costs and benefits of the proposed restriction, rather than undertaking a more comprehensive and systematic comparison across the range of potential risk management options (and this type of analysis will have to be carried out by the COM). In public discussions, this aim is often stressed to be the main aim of the SEA. It is even more linked to the impacts of the market intervention, like e. g. loss of profits, loss of products and disturbances in supply chains. The main challenge on this process part is that discussion is often limited to financial aspects and, thus, suffers from methodological shortcomings on how to evaluate damage in environmental compartments[40]. Furthermore, distributional effects of costs and benefits across different actors or sectors are not always sufficiently transparent. For example disparities manifesting in one sector having all the costs and others need consideration and require detailed descriptions rather than averaging figures, if these exist.

For Purpose 3, the SEA is focused more on refining the proposed restriction measure so as to improve the balance of costs and benefits, for example, by examining how changes in the scope of the activities covered or the timing of requirements might reduce costs. This is also very important to substantiate exemptions in the frame of the restriction proposal. Practice shows that the need for exemptions is often claimed very late by the industry; i. e. during the public consultation. In such cases it is particularly difficult to assess costs and benefits for society as stakeholders again mainly focus on the perspective of the individual company/sector. This aspect is closely related to the evaluation of alternatives in the frame of the restriction proposal, as in addition to the question whether alternatives are available on a technical basis, it is important for submitters of restriction proposals to evaluate, if the introduction of potential alternatives can be justified on an economic level or in which timeframe this is possible. Usually, these types of considerations would be part of any SEA carried out for Purposes 2 or 4, for example as iteration within the overall SEA process.

Some of the information to assess impacts on the EU market are systematically missing when authorities intend to prepare a restriction proposal, so that cost benefit assessments or, more often, cost effectiveness assessment suffer from a high level of uncertainty. The market actors currently have no obligation to provide such data. Moreover, by not providing such data they can even hinder an initiative from an authority. On the other hand one could argue that the restriction in first place aims to remove identified unacceptable risks and that the

[40] See e. g. EEB (2017) Restricted Success - EEB's appraisal of restriction under REACH, June 2017 https://eeb.org/publications/31/chemicals/33788/restricted-success-eebs-appraisal-of-restriction-under-reach.pdf, ECHA (2016) Cost and benefit assessments in the REACH restriction dossiers, April 2016 https://echa.europa.eu/documents/10162/13630/cost_benefit_assessment_en.pdf/b780a657-b4aa-4274-8c74-3a80bae8e883

demonstration of a substance risk might already be sufficient to trigger further regulatory action (even when there is no sufficient socio economic information available, the risk remains and cannot be ignored). This can be partly overcome by the authorities by initiating their own research activities to prepare the restriction, either with their own staff or by making use of consultants or research institutions with specific expertise. In this regard the restriction and in particular the SEA can be seen as procedures where the burden of proof has not been shifted to market actors as originally foreseen by the introduction of REACH. This is especially true for market actors at the end of supply chains (end users of substances, article importers/producers/assemblers) where information requirements from safety data sheets do not apply and information on articles is highly unspecific.

3.2 Developing a 'regular' restriction proposal

According to Article 69, two actors may initiate a restriction proposal: The COM (Art. 69(1)), which commissions ECHA to perform the scientific and formal work and the MSs (Art. 69(4)). There is one condition, under which ECHA is entitled to assess if a restriction is needed to control risks. This is the case, when a substance is subject to authorisation (listed in REACH Annex XIV) and risks might originate from the use of that substance in articles, in particular from imported articles as this is not covered by the authorisation requirement. Hence, ECHA should assess and decide if the remaining risks from articles should be addressed by a restriction. This assessment should be performed after the sunset date in Annex XIV (Article 69 (2) in combination with Article (58) (c)(i)).

Any restriction proposal according to REACH Art. 69, is to be prepared in form of an Annex XV Dossier (Article 69 (1) and (4)).

If an MS intends to initiate a restriction, it first informs the ECHA thereof. The ECHA checks the list of 'restriction intentions' (commonly referred to as 'registry of (restriction) intentions' – ROI), which it hosts, to check if another regulatory initiative has already been announced. The ROI enables ECHA to fulfil its coordination tasks imposed by the legislator in order to coordinate the implementation of new risk reduction measures.

The ECHA updates the ROI with that restriction intention and also does so for its own intended restriction proposals. This ensures transparency about planned activities among the MSs and the ECHA as well as towards interested third parties. In case more than one MS plans to propose a restriction, it is the ECHA's task to coordinate their work and ensure that only one dossier is prepared. One submitter may take over the dossier preparation or several actors (various MSs and the ECHA) may collaborate in this. Although it is not legally forbidden that several interested parties submit an individual restriction proposal[41], this is unlikely to happen in practice.

The deadline for submitting the restriction dossier is 12 months from the request by the COM for ECHA (Article 69 (3)) and from the date of its announcement for the MSs (Article 69 (4))[42]. This timeline should avoid delays in the dossier preparation and ensure a strict time management of the dossier submitters.

Article 69 (4) specifies that Annex XV restriction dossiers should refer to and consider:

[41] If a substance already has been listed on the according to Article 69 (5). Which means there is already an ongoing process to prepare a restriction proposal for the substance, no new restriction intention may be started according to Article 69 (4) sentence 2.

[42] It should be noted that exceeding the deadline has no direct legal consequences. In practice, the declaration of intent could be withdrawn and resubmitted.

- Every dossier, CSR or risk assessment prepared under REACH, e. g. CSRs provided as part of registration dossiers or applications for authorisations, Annex XV dossiers to identify SVHCs or the outcomes of substance evaluations.
- Risk assessments submitted under other EU legislation. If these risk assessments were performed by other EU bodies (e. g. the European Food safety Agency (EFSA) responsible for the assessment of food contact materials[43]), these have to provide the information to ECHA on request.

After submission of the Annex XV restriction dossier to the ECHA, the Committee for Risk Assessment (RAC) and the Committee for Socio Economic Analysis (SEAC) check its conformity (Article 69 (4)) and inform the dossier submitter within 30 days about the outcome. If a dossier is in conformity with the requirements, ECHA publishes it on its website without delay (Article 69 (6)).

If a dossier is found not to be in conformity with the requirements of REACH Annex XV, the Committees inform the dossier submitter about the reasons of non-conformity within 45 days after receipt of the dossier. After receipt of the information about the non-conformity, the dossier submitter may adjust the dossier into conformity within 60 days. If the dossier submitter fails to do so, the procedure of the restriction proposal is terminated. Dossiers brought into conformity by a revision are published by ECHA without delay.

After publication of the dossier, the stakeholders are invited to and may participate in a consultation of the proposal. ECHA informs third parties of the 6 months period for submitting comments (Article 69 (6)). According to Article 69 (6), the stakeholders may submit the following types of information in the consultation of the restriction proposal:

- General comments on the dossier or the proposed scope of the restriction
- A SEA (or information that contribute to one) that either supports the restriction (or parts thereof) or provides evidence that a restriction might be disproportionate (regarding its benefits and drawbacks).

In summary, the REACH provisions improved the design of the restriction process as compared to the Marketing and Use Restrictions Directive. It defines clear steps for the development of a restriction proposal, assigns responsibilities to the various actors, including to the Committees assessing the conformity of the proposals, specifies deadlines for conducting each of the steps and ensures stakeholder involvement. However, it does not provide means to overcome the lack of (use and exposure) data on the side of the authorities.

3.3 Development of opinions and submission to the COM

The RAC and SEAC evaluate the restriction proposals and each develops an opinion for the issues within their remit.

Article 70 specifies the scope of the RAC's opinion and the RAC's timeline: the RAC must develop its opinion within nine months after publication of the proposal. The opinion should conclude on the appropriateness of the proposal to reduce the risks to human health and/or the environment. The opinion should be based on the relevant sections in the dossiers and the comments received during public consultation. Article 70 does not mention any further

[43] See EFSA http://www.efsa.europa.eu/en/science/scientific-committee-and-panels

information sources that the RAC should consider nor does it require the RAC to ask for additional data in order to underpin justifications in the dossiers or the comments.

Article 71 defines the timeline for and the scope of the SEAC opinion. SEAC has 12 months to form its opinion. It prepares a draft opinion based on the relevant parts of the dossier and the information from the public consultation according to Article 69 (b). Such information may be the dossier submitter's SEA or information by a third party contributing to a SEA or comments on the impacts of the proposed restriction.
According to REACH, the SEAC should use relevant information if there is any. This implies that an active request by the SEAC for additional information (i. e. not in the dossier or received in the consultation) is not foreseen. As a consequence, SEAC is not intended to collect 'new' information to close information gaps or to reduce uncertainties from any actor involved in the process (or which is not involved, yet).
The SEAC's draft opinion is immediately published by ECHA for another consultation lasting for 60 day (Article 71 (1)).
After the consultation, the SEAC finalises its opinion taking into account all socio-economic arguments received during the process.
As the opinion-making may be difficult if the RAC's opinion significantly diverges from the dossier submitter's conclusions on the (level of) risk and the proposed measure, the ECHA is entitled, according to Article 71 (3), to extend the deadline for the SEAC's opinion-making by a maximum of a further 90 days.

ECHA forwards the finalised opinions to the COM (Article 72) as well as all information collected in additional documents or as comments that are considered in the opinions. If one or both opinions cannot be finalised within the given timelines, the ECHA informs the COM and provides the reasons for the delay and prepares the opinion in the time frame indicated. ECHA is also to publish the final opinions on its website.

Both Committees have established their rules of procedure and guidelines on how to form opinions. According to reports, the processes have improved regarding the efficiency and consistency over time, with several issues still remaining to be solved, in particular regarding the socio-economic assessments.

3.4 Decision process

The COM shall prepare a draft amendment to Annex XVII within three months of receiving the SEAC opinion (Article 73(1)) or in case there is no opinion of the SEAC the deadline specified in Article 71 if it concludes that a restriction is justified based on the provided information and the opinions. This deadline is often not met in practice, whereby this also has no direct consequences, but leads to a delay in the completion of the process.

In case the draft amendment to Annex XVII diverges from the original restriction proposal or if it does not take into account the Committees' opinions, the COM has to provide its reasons together with the draft amendment. According to REACH, the COM makes the final decision taking into account the vote of a Committee according to Article 133 (REACH-Committee[44]) and after the deadlines of the EU Parliament and the Council to interfere in the process have passed. The latter may scrutinise and reject the amendment in accordance with Article 133(4) of REACH. The COM may react to a negative vote in the REACH Committee and/or a rejection of the

[44] Representatives of MS governments are members of this committee, not to be mixed up with the member state committee according to Article 76 (e), which has decision function in REACH processes not linked to a legal act (e. g. the identification of an SVHC).

proposal by Parliament or Council by proposing changes to the amendment and resubmitting for another vote.

4 Facts about Restrictions

In 2009[45], the first substances were included into Annex XVII of REACH according to Art. 137 by transferring the already existing restrictions adopted under the Marketing and Use Restrictions Directive (76/769/EEC) into the list of restricted substances. In 2010, the first dossiers were managed under REACH and 52 restriction proposals were announced in the ROI. Since then,[46] 47 dossiers have been submitted and treated according to Article 68 (1). Five additional ones have been announced for submission in 2020. An overview of the restriction activities until mid-2020 is provided in Table 1.

Table 1: Restriction activities documented in the ROI (until May 2020)

Status in the REACH Process	Number of Dossiers/restriction proposals
Entries in the ROI	52[47]
Commission decided[48]	21
Withdrawn intention	6
Non-conforming dossiers	4[49]
Opinion development of the committees	9
Opinions adopted (awaiting decision of COM)	7
Intentions	5

The table shows the current status of the different entries in the ROI at the time the data were retrieved and does not reflect the history of restriction proposals. This means e. g. four dossiers were not in conformity at the time of extracting the information from the ROI (and have been revised and re-submitted). However, RAC or SEAC rejected more than only those four dossiers as not conforming to requirements. Similarly, RAC and SEAC were working on a total of 9 opinions at the time of documenting the restriction activities in the ROI (as of May 2020). In total, many more opinions have been formed (at least 28 – decided restrictions and adopted opinions).

Of the 21 decisions made by the COM, only two rejected the proposal; i. e. no restriction was included in Annex XVII.

In 2014 the COM rejected Denmark's proposal to restrict four phthalates in consumer products based on a risk resulting from combined consumer exposures from multiple sources. Here, the COM followed the RAC opinion, which did not support the risk conclusion, based on the presented data. In 2016, Denmark in cooperation with ECHA submitted a revised proposal with a specified scope on consumer articles with direct contact to consumers. The revised proposal was accepted and the existing entry was changed in Annex XVII for the four phthalates (entry 51).

[45] This was foreseen this way by the legislator as from the beginning of REACH it was the plan that Title VIII and Annex XVII entered into force three years after REACH entered into force.

[46] See ROI (data retrieved on May 12th 2020) https://echa.europa.eu/de/registry-of-restriction-intentions

[47] Represents 38 unique substances/entries, since it can be the case that some substances/entries of Annex XVII have been issued several times, e. g. after resubmission after revision of a non-conforming dossier.

[48] A new restriction has been implemented or an existing one has been changed.

[49] These dossiers were resubmitted later and were then processed.

In 2015 Sweden proposed to ban cadmium compounds in artist paints based on a demonstrated risk due to releases to the environment and resulting risks to human health (man via environment). The RAC found the human health risk from that use negligible compared to other sources and therefore did not support the restriction proposal. The Commission followed this argumentation and did not propose a restriction.

The (level of) human health risk demonstrated in the initial Danish proposal[50] and the Swedish proposal was linked to a high degree of uncertainty. In addition, RAC, SEAC and the COM did not see that the dossier submitters sufficiently showed that the expected benefits justify the proposed restrictions.

In all the other 19 cases, the Committees supported the restriction proposals and the COM implemented a respective amendment to REACH Annex XVII. However, in the course of the discussions, changes were made to the initial proposal. These often concerned the restriction's scope (coverage of substances), concentration thresholds for the restricted substances in products or specific exemptions from the restrictions based on technical or socio-economic reasons.

The nature of the proposed restrictions varied from very specific ones (e. g. methanol in windshield fluids (entry 69) or 1,4-dichlorobenzene in air fresheners and toilet blocks (entry 64)) to ones with a wider scope (e. g. bis(pentabromophenyl) (entry 67), which was restricted in all mixtures and articles placed on the market (without any exemptions)).

To date, all proposals have been developed by nine different member States and the ECHA (cf. Table 2). The table highlights that ECHA has the highest number of restriction proposals, including revisions of existing Annex XVII entries and restrictions resulting from the obligatory assessment of potential risks from SVHCs listed in Annex XIV in (imported) articles (cf. Article 58 (6) in combination with Article 69 (2)).

Table 2: Number of restriction proposals per country (including ECHA) (until May 2020)

Country/Institution	Number of restriction proposals
ECHA	22 (1 with DK, IT, NO; 1 with DK; 1 with NO
Sweden (SE)	7 (1 with FR; 1 with DE)
France (FR)	6 (1 with SE)
Norway (NO)	6 (1 together with ECHA, IT, DK; 1 with DE, 1 with ECHA)
Denmark (DK)	5 (1 with ECHA, IT, NO; 1 with ECHA)
Germany (DE)	4 (1 with SE; 1 with NO)
Italy (IT)	4 (1 together with ECHA, DK, NO 2 resubmissions for the same substance)
Netherlands (NL)	3
Poland (PL)	2 (1 resubmission for the same substance)
United Kingdom (UK)	1

[50] Obviously, these deficits of the Danish restriction proposal were improved in the revised version, as there the restriction was accepted.

5 Case Studies

Several case studies were developed to review the restriction activities under REACH in order to identify obstacles to the efficient implementation of restrictions and control of unacceptable risks. The case studies aimed to answer the following questions:

- How was the restriction scope defined in the initial proposal and at the end of the procedure (for implemented restrictions)?
- Which arguments were discussed to widen/narrow the scope (this includes justifications for exemptions)?
- How was the unacceptable risk substantiated?
- How were alternatives assessed?
- Which socio-economic arguments were included in the dossier submitter's SEAs and discussed in the further process?

The case studies were selected with the aim of covering the range of different situations of a restriction under REACH. The following criteria were used to select the cases:

- All subjects of protection are covered by the cases, i. e. human health (workers, consumers) and the environmental
- All possible regulatory options to implement a restriction are covered:
  - 68 (1) – 'regular' restriction
  - 68 (2) – 'simplified' restriction (CMR (cat 1A and 1B) in products used by consumers)
  - 69 (2) – presence of SVHC on Annex XIV triggers restriction proposal
- Preference is given to proposals made by the German authorities (as there is better access to background information than for proposals from other MS)
- The restrictions should cover single substances as well as groups of substances.

The list of cases to select from included finalised restrictions as well as open restriction proposals as of April 2019. The selected cases are provided in Table 3.

Table 3: Restriction processes selected as cases for the study

No.	Case	Reasoning for selection
1	Diisocyanates	Human health – occupational safety, 68 (1), grouping, DE
2	NMP	Human health – occupational safety, individual substance, 68 (1) NL proposal, defines DNEL[51] as binding threshold for occupational risk management
3	Phthalates	Human health – consumer protection, grouping, 69 (2) DK /ECHA proposal (proposal was updated)
4	CMR in textiles	Human health – consumer protection, grouping, 68 (2)

[51] Derived no effect level

No.	Case	Reasoning for selection
		ECHA
5	perfluorinated Silane	Human health – consumer protection, individual substance, 68 (1) – DK, respiratory sensitizer
6	PFOA	Environment, grouping, DE, 68 (1) PBT with not classical B
7	Nonylphenol and ethoxylate	Environment, grouping, 68 (1) SE, environmental ED
8	D4/D5 (rinse off)	Environment, grouping, 68 (1) UK
9	Microplastics	Environment, grouping, 68 (1) Completely different approach, scope defined by shape, physical occurrence of substances (plastics), ECHA, broad scope with several use specific restriction conditions (assumed to be descriptive rather than conclusive, since it is not expected to be finalised by the end of the project time)

For each of the restriction cases, the respective documents were analysed. In the following chapters, the main observations from the case study work are presented.

5.1 Diisocyanates

In 2016, Germany submitted a proposal to restrict diisocyanates under REACH Article 68 (1) to prevent workers risks from the professional use of isocyanate-containing products. Table 4 provides key information on the restriction process.

Table 4: Key steps in the restriction process of diisocyanates

Process parameter	Information from case (duration from previous process step [Months])
Type of restriction	Art. 68 (1)
Subject of protection	Workers (direct exposure of users as well as bystanders[52])
Restriction scope	Group of diisocyanates used as such or in mixtures for industrial or professional use in concentrations > 0.1% unless a) The label indicates a training need (by 2022) b) The users have been adequately trained (by 2023)
Submitter(s)	Germany
Substance	Diisocyanates EC / List no: - CAS no: - (group of various substances)
Date of intention	07/10/2015 (0)
Expected date of submission	07/10/2016 (12)
Date of submission/date of Annex XV dossier	06/02/2017 (4)

[52] Bystanders are persons not using a substance themselves but might still be exposed, because they are present in the same area (e. g. a room) where the use is performed. While direct users might be protected by risk management measures (e. g. PPE), bystanders often lack such protection, because they are not in the focus of on-site risk assessment.

Process parameter	Information from case (duration from previous process step [Months])
RAC Opinion adopted	05/12/2017 (10)
SEAC Opinion adopted	15/03/2018 (13,5)[53]
REACH Committee vote	04/02/2020, in favour (23)
Outcome of restriction process	Regulation (EU) 2020/1149 of 3 August 2020 http://data.europa.eu/eli/reg/2020/1149/oj
Entry into force	24.02.2022 / 24.08.2023
Overall process duration	58 Months

5.1.1 Scope of the restriction

The diisocyanates are addressed by the restriction proposal as a group because the (double) isocyanate group is a structural element of all group members and is regarded responsible for the 'molecular initiating event' of the sensitisation effect. The grouping approach and addressing the entire group in the restriction has not been questioned during the restriction process.

The subject of protection is workers in an industrial and professional setting of the substances as such or in mixtures as well as bystanders at the place of use. This has not been changed in the course of the process until the final decision. The restriction proposal aims to reduce the risk by the following:

- The producers of diisocyanate containing products reduce the concentration of all substances (as singles substance and as the sum of all substances of the group) in the scope below a limit value (< 0.1 % by weight) or
- The users have to undergo appropriate training on how to use diisocyanate containing products before they work with them (organisation of training facilitated by producers of products).

The measures to adapt the organisation of training are elaborated extensively in the final proposal of the restriction (including Annexes with clear specification of key characteristics of the measures).

The proposed restriction conditions were slightly modified and worded differently in the final decision.

5.1.2 Demonstration of an unacceptable risk

All substances (of the group) have a harmonised or self-classification[54] as respiratory and skin sensitiser category 1. Hence, the respiratory sensitisation that is addressed by the proposal can be regarded as generally accepted and proven.

Due to the broad use spectrum, the proposal lists generic application areas and provides observed exposure levels as ranges on an exemplary basis for specific (mainly construction) products. These are derived from workplace measurements (concentration in air) and

[53] Note previous step is the submission not the RAC opinion.

[54] Not all group members in the scope of the proposal are already subject of a harmonised classification. Further activities have been or will be initiated to implement these classifications.

supported by biomonitoring data. No RCRs were derived due to the lack of threshold values for the endpoint of respiratory sensitisation.

The occurrence of occupational asthma due to the use of these substances is stated to be 'commonly known'. Two approaches were used to demonstrate the exposure-effect relation at the workplace based on statistics and epidemiological studies, including observations from workplaces, where diisocyanate containing products are applied. Respective monitoring data existed on the phenomenon from the occupational setting.

From the beginning of the restriction process, there was almost no disagreement on the fact that the use of isocyanates poses a risk to workers that needs to be addressed. The RAC agreed with the dossier submitters argumentation, including on demonstrating the risk based on incidences of asthma cases.

5.1.3 Assessment of alternatives

The different diisocyanates belonging to the group can be used to substitute each other. As they are all of similar hazard, it is reasonable to address them as a group in the restriction proposal, i. e. to prevent substitution of one with another (with a similar hazard profile).

The assessment of alternatives in the restriction proposal is generic and summarises that

- There are very many uses of diisocyanates (in polyurethane) implying a need for many different alternatives rather than just a few
- There are alternatives to polyurethane on the market in particular in the construction sector, however with a lower technical performance and/or with associated similar or even higher health concerns
- Overall, stakeholder indicate a lack of suitable alternatives

It is concluded from this brief assessment that a shift to alternative products (i. e. substitution) is not expected at a large scale in the near future. The SEAC agreed to the conclusion that suitable alternatives are generally not available.

5.1.4 Socio-economic assessment

Based on the assumption that in most cases, companies will implement training programmes rather than substituting diisocyanates use, the dossier submitter's impact assessment balances the prevented health treatment costs of occupational asthma with the costs of implementing training measures for workers, assuming an effectiveness of preventing occupational asthma between 50-70%.

The SEAC allocated some costs differently (sectoral costs / societal costs) and requested clarification for some calculations that were insufficiently transparent. SEAC consented to some simplifications of describing the baseline situation (average EU situation rather than Member State level, consideration of existing training activities etc.). SEAC disagreed on the type of drivers of socio-economic costs (type of training, number of workers concerned) and the estimation of costs for e-learning trainings. SEAC questioned the assumed effectiveness of the training and, overall, found the description of benefits acceptable. A minority opinion was filed considering the assumed effectiveness of training measures in reducing the number of occupational asthma incidents strongly questionable.

5.1.5 Choice of risk management measure

At the beginning, the dossier submitter considered using the authorisation process because diisocyanates are primarily used in mixtures on the EU market, which was the main cause of concern. The change in regulatory instrument was triggered by stakeholder information received during the consultation. This information was also important for the definition of the restriction conditions. Key issues leading to proposing a restriction rather than starting an authorisation process were:

- Diisocyanates are used in a wide range of medium to small scale, wide dispersive uses[55], implying significant distortions on the market or a need for either authorisation applications by manufacturers with a broad scope or a very high number of (specific) DU applications to ensure important uses with low risks can continue. An application of the DUs themselves can be considered highly unlikely, as these actors in this particular case are assumed to lack the necessary resources and expertise to provide a meaningful application for authorisation.
- A high number of professional end users, often in SME companies, indicated significant impacts on SMEs with low capacities to ensure the necessary and important continued use under safe conditions.
- The limited availability of alternatives suggests that the aim of substitution[56] can hardly be realised by the companies. Hence, all users would have to apply for authorisation and it was assumed that in most cases, authorisation could not be refused due to the lack of viable alternatives.

Other measures, like voluntary 'self-regulatory initiatives' by the industry, were seen as a potential alternative option. They were evaluated as problematic due to a lack of legal means to approach companies that refuse to join such an initiative.

Based on these arguments the restriction proposal does not aim to eliminate the use of diisocyanates in the EU but to require binding risk management measures that significantly reduce the adverse effects on human health. The envisaged restriction was assumed to reduce the number of annual new occupational asthma cases due to the handling diisocyanates by 50-70 per cent.

5.1.6 Overall evaluation of the restriction process

The case exemplifies a restriction that does not aim at the complete phase-out of the addressed substances, but at the implementation of a mandatory and EU-wide harmonised risk management. The approach seems possible, as only professional users are targeted, which allows good monitoring opportunities. Statistics on staff training can be used, whenever already existing, or newly developed, to monitor the implementation. In the longer term, the reported incidents of occupational asthma collected in the course of occupational health management may be used to monitor the success of the restriction.

Some generalised learnings from the case could be:

- Targeting an entire substance group clearly signals that the entire group must be replaced, as minor differences in hazard among the group members is not seen a substantial improvement (i. e. grouping reduces regrettable substitution and enables targeting many

[55] Amongst others, these uses are: production and use of polyurethane materials and polyurethane composites, manufacture and use of foam materials (flexible and spray foam), manufacture and use of coatings, manufacture and use of glues.

[56] One explicit aim of the Authorisation process is the phase out of substances of very high concern from uses.

substances with one effort). In the current case, the efforts to document individual hazards, exposure levels and damage cases could be generalised and hence the workload was reduced for drafting and assessing the proposal. Also substance users will take one effort to manage all substances in the same way, either by substituting or by implementing the training.

- A clearly defined scope regarding the chemical group based on structure causing hazard, the products containing the substances and the affected group of workers, which corresponds to available effect data reduces the likelihood that the scope is questioned in the restriction process.
- For substances without effect thresholds, evidence of damage related to the use of the substance may be sufficient to prove an unacceptable risk.
- Generic assessments of alternatives may be sufficient in the (broadly acknowledged) absence of technically feasible, lower risk alternatives for the majority of applications, in particular where the restriction does not aim at a complete phase-out.
- If substitution can reasonably be excluded as the expected reaction of market actors, assessing adaptation costs can be comparatively lean.

In this particular case, the restriction was considered a better regulatory measure to improve workers protection than the European occupational safety and health legislation[57] and its daughter directives[58], including Directive 98/24/EC, which is the basis for the introduction of harmonised EU occupational exposure limits values (OEL). Only a few EU wide OELs exist but several national limit values were established, resulting in different limits across the EU. As workers legislation requires national transpositions, ensuring an EU-wide harmonised set of measures to control exposure could be better established by a REACH restriction.

As obligatory training measures prior to handling hazardous mixtures is a new and unique approach under REACH, it estimates the actually achievable degree of risk reduction. Therefore, the German authorities initiated a study to generate exposure data of workers handling diisocyanates under the restriction conditions[59].

5.2 N-methylpyrrolidone

In 2013, the Netherlands proposed to restrict N-methylpyrrolidone (NMP) to limit workers' exposure and risks, in particular from coatings and cleaners for professional and consumer use. NMP is a solvent that is mainly used under industrial conditions but also in a wide range of (products for) professional applications.

Table 5: Key steps in the restriction process of N-methylpyrrolidone

Process parameter	Information from case
Type of restriction	Art. 68 (1)
Subject of protection	Workers

[57] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work

[58] For overview see EU agency for occupational safety and health https://osha.europa.eu/en/safety-and-health-legislation/european-directives

[59] BAuA (ongoing): Investigations into the feasibility of a cohort study among workers exposed to diisocyanates to accompany new regulations for diisocyanates under chemicals legislation https://www.baua.de/EN/Tasks/Research/Research-projects/f2458.html

Process parameter	Information from case
Restriction scope	Original proposal: Manufacture and use of NMPs unless worker exposure levels remain under defined workplace air concentrations and/or dermal exposure is avoided Final decision: Placing on the market restricted above concentrations of 0.3%, unless CSRs of manufacturers, importers or DUs relate to DNELs of 14.4 mg/m^3 (inhalation) and 4.8 mg/kg/day (dermal).
Submitter(s)	Netherlands
Substance	1-methyl-2-pyrrolidone EC / List no: 212-828-1 - CAS no: 872-50-4
Date of intention	04/06/2012 (0)
Expected date of submission	09/08/2013 (12)
Date of submission/date of Annex XV dossier	09/08/2013 (0)
RAC Opinion adopted	05/06/2014 (10)
SEAC Opinion adopted	25/11/2014 (15) [60]
REACH Committee vote	24/10/2017, in favour (35)
Outcome of restriction process	Regulation (EU) No 2018/588 of 18/04/2018 (Annex XVII entry 71) (6) http://data.europa.eu/eli/reg/2018/588/oj
Entry into force	09/05/2018; transition period 09/05/2020[61]
Overall process duration	70 Months

5.2.1 Scope of the restriction

The restriction scope did not include consumer products due to existing regulatory measures, in particular the classification as toxic to reproduction cat. 1B which has a concentration threshold of 0.3% and makes it subject to the CMR restriction in consumer products in REACH Annex XVII (Entry 30[62]), and its inclusion in the candidate list.

In the public consultation several market actors proposed exempting their specific processes. The arguments for the exemptions included the existence of a high level of process control and difficulties to substitute in general, and in particular due to installation permits requiring the use of NMPs in the particular processes. The latter would cause significant follow-up costs in case of a substitution (pharmaceuticals, biocides, plant protection products).

Exemptions for entire sectors were not granted in the restriction process. Instead, the originally proposed exposure limits forming part of the restriction conditions, which should have been monitored via workplace air measurements, were discussed.
The RAC discussed the validity and practicality of the originally suggested occupational

[60] Note previous step is the submission not the RAC opinion.

[61] Four more years are given as derogation for use as solvent or as reactant in wire coating.

[62] After inclusion to Appendix 6 of the respective Annex XVII entry 30 via Commission Regulation (EU) No 109/2012 http://data.europa.eu/eli/reg/2012/109/oj

exposure limit values. They suggested using the REACH DNELs derived according to the respective guidance documents to limit both the inhalation and the dermal exposure. Instead of measuring workplace air concentrations, RAC proposed requiring the use of the DNELs they derived (higher value than the originally proposed) in the CSRs. As only safe uses are allowed, RCR >1 would force registrants to derive operational conditions and RMMs ensuring safe use and to communicate these with the SDSs as binding use conditions for the DUs. This would also ensure enforceability of the restriction.

5.2.2 Demonstration of an unacceptable risk

The hazard of NMP was demonstrated based on the harmonised classification as reprotoxic Cat. 1 and the respective candidate listing. The targeted endpoints were repeated dose toxicity and developmental toxicity

The use/exposure information of NMP was derived from the registration dossiers, literature studies and monitoring data. The unacceptability of the risks was demonstrated via RCRs for workers and pregnant workers, based on specifically derived DNELs and modelled exposure levels using EASY TRA. RMMs were assumed based on industry information. The RCRs exceeded the value of 1.

The RAC supports the risk assessment provided in the restriction proposal.

5.2.3 Assessment of alternatives

The restriction proposal includes an extensive list of possible alternatives for different uses of NMP. The availability was assessed per sector, considering the consultation inputs and literature. It is specified that for many applications alternatives might be generally available, however mostly displaying lower technical performance and/or having a similar or even higher toxic profile, as judged from classification and labelling data. Hence, in conclusion for the majority of uses, technically feasible alternatives are regarded as not readily available.

A key discussion issue in the restriction process was the feasibility of introducing suitable alternatives for the various uses. While in some cases substitution was evaluated to be a relatively easy and low costs measure without relevant consequences (drop in substances) other cases appeared to be very difficult with significant adaptations to the current production processes, resulting in very high costs in the affected sectors.

5.2.4 Socio-economic assessment

Four risk management options[63] are proposed and their health benefits qualitatively described. For each option, reactions of the use sector were assumed (substitution, exposure reduction, relocation and termination of use) and costs as well as wider socio-economic impacts derived. The information sources were industry contributions, partly cross-checked with publicly available data from literature etc. The figures are specified as indicative of the order of magnitude of costs. Despite some uncertainty on the actual extend the impacts might have on business there was general acceptance of the assessment performed. In fact, market intervention was not the most important aspect of the proposed measure but the realisation of a harmonised protection level (limit value) that is accompanied with mandatory safety measures, which can be considered as a limited economic burden.

[63] Total ban, restriction with derogations, binding DNELs (two options) and authorisation

5.2.5 Choice of risk management measure

The approach of the restriction includes the derivation of a DNEL, the use of which is obligatory for any mixture, where NMP is contained above 0.3%. In using those DNELs, registrants are to derive the safe conditions of use, which are to be communicated with the SDS and implemented by the user. Hence, the restriction uses the regular, industry-based risk assessment and management process to ensure exposure and risk reduction and only interferes by prescribing which DNEL to use. This approach was used for the first time in a restriction process.

This approach prevents conflicts with existing workers protection legislation and is in line with the share of responsibilities under REACH (registrants, or DUs if they deviate and prepare a DU-CSR, derive safe conditions of use). In practice, however, the challenge with regard to the enforcement of the restriction is that a dermal DNEL is not directly monitorable due to a lack of measurement methods[64]. This enables the market actors to consider special needs that stem from the different uses and enables DUs to adjust the exposure scenarios so as to match the local requirements of an individual site.

The restriction is accompanied by a guidance document specifying the conditions in column 2 of Entry 71 in REACH Annex XVII[65]. The guidance follows the steps a DU should implement after receiving an exposure scenario, but it is important to note that this is not legally binding. Other than in the 'normal procedure', the implementation of the operational conditions and RMMs may be understood as even more (legally) binding for the DUs. Furthermore, the guidance introduces potential RMMs for exemplary processes (e. g. filling, unloading, and sampling). It can be regarded as the first EU-authored document under REACH providing good practice examples in managing risks related to the handling of hazardous chemicals, which could be a benefit beyond the specific impacts of the restriction on risk levels.

The restriction lacks an accompanying evaluation process (e. g. some kind of monitoring exposure levels under the proposed operational conditions). Such evaluation would support the identification of the remaining risks and potentially needed improvements of the good practice measures that DUs should apply in order to ensure the DNELs are met. Hence, a mechanism providing data needed for a revision of the restriction conditions is not implemented.

5.2.6 Overall evaluation of the restriction process

Generalised learnings from the case study are:

- It is difficult to implement exemptions from the scope of a restriction via a public consultation even if plausible technical and economic arguments are provided.
- The unacceptability of risks may be demonstrated based on modelled exposure data, in particular if a large number of applications are covered by a restriction and individual data is unlikely to be collectable.
- Even detailed assessments of alternatives may not be sufficient to clarify the possibility to replace a substance in one or several uses.

[64] See BAuA (2020, in German) Umsetzung der Beschränkung 1-Methyl-2-pyrrolidon (NMP) in nationales Recht https://www.baua.de/DE/Themen/Arbeitsgestaltung-im-Betrieb/Gefahrstoffe/REACH-Bewertungsstelle-Arbeitsschutz/pdf/NMP.pdf?__blob=publicationFile&v=2

[65] ECHA (July 2019) How to comply with REACH Restriction 71, guideline for users of NMP (1-methyl-2-pyrrolidone) https://echa.europa.eu/documents/10162/13641/entry_71_how_to_comply_en.pdf

- Semi-quantitative assessments of socio-economic impacts, even involving a high level of uncertainty about industry responses to a restriction, may be a sufficient information basis to decide on the most efficient measure to reduce a risk.
- A restriction can be designed to support and enhance an existing REACH mechanism (here based on registration risk assessment).

5.3 Phthalates (DEHP, DBP, DIBP, and BBP)[66]

Two closely related restriction proposals were submitted for these phthalates. The first proposal was submitted by Denmark but failed to demonstrate a risk according to the RAC opinion. The proposal was resubmitted by ECHA and Denmark in cooperation and resulted in a restriction. The following two tables show the process of the restriction for the first and the second proposal.

Table 6: Key steps in the restriction process of phthalates, first dossier

Process parameter	Information from case
Type of restriction	Art. 68 (1)
Subject of protection	Consumers
Restriction scope	Placing on the market of articles containing the four phthalates (individual or in sum) above 0.1% in plasticised materials that are intended for indoor uses or which may come into contact with the skin or mucous membranes
Submitter(s)	Denmark
Substance	Diisobutyl phthalate (DIBP); Dibutyl phthalate (DBP); Benzyl butyl phthalate (BBP); Bis(2-ethylhexyl) phthalate (DEHP) EC / List no: - CAS no: - (group of various substances)
Date of intention	20/10/2010 (0)
Expected date of submission	14/04/2011 (6)
Date of submission/date of Annex XV dossier	12/08/2011 (4)
RAC Opinion adopted	12/06/2012 (10)
SEAC Opinion adopted	05/12/2012 (16) [67]
REACH Committee vote	--
Outcome of restriction process	Communication 2014/C 260/01 of 09/08/2014 (18)
Overall process duration	26 (+18 for Com communication) – total 44 Months

A second restriction proposal was initiated by ECHA to investigate the risk that might originate from the placing on the market by consumer products. The main difference to the initial one is that it was focussed on a more sensitive exposure scenario, the direct contact of the phthalate containing material with skin or mucous membranes.

[66] DEHP = Diethylhexyl phthalate, DBP = Dibutyl phthalate, DIBP = Diisobutyl phthalate and BBP = Benzylbutyl phthalate

[67] Note previous step is the submission not the RAC opinion.

The second restriction proposal was initiated according to Article 69 (2) after the phthalates were included in Annex XIV for authorisation, as a result of ECHA's duty to assess remaining risks from articles that might be addressed by a restriction.

Table 7: Key steps in the restriction process of phthalates, revised proposal

Process parameter	Information from case
Type of restriction	Art. 68 (1)
Subject of protection	Consumers
Restriction scope	Placing on the market of articles containing the four phthalates (individual or in sum) above 0.1% in plasticised materials that are intended for indoor uses or which may come into contact with the skin or mucous membranes Exemptions for toys, childcare articles, medical uses
Submitter(s)	ECHA, Denmark
Substance	DIBP, DBP, BBP, DEHP EC / List no: - CAS no: - (group of various substances)
Date of intention	03/03/2015 (0)
Expected date of submission	01/04/2016 (13)
Date of submission/date of Annex XV dossier	01/04/2016 (0)
RAC Opinion adopted	10/03/2017 (11)
SEAC Opinion adopted	15/07/2017 (15) [68]
REACH Committee vote	11/07/2018 (in favour) (12)
Outcome of restriction process	Regulation (Eu) No 2018/2005 of 17/12/2018 (Annex XVII entry 51) (5) http://data.europa.eu/eli/reg/2018/2005/oj
Overall process duration	45 Months

5.3.1 Scope of the restriction

The restriction proposal covers a closed group of four mono constituent substances[69], which are used in the production of articles.

Workers may be exposed to the phthalates during production and consumers may be exposed via the articles they use (service life) and the food they ingest. An unacceptable risk was expected due to a combined exposure to the phthalates from multiple sources. The restriction should prevent that consumers are exposed at levels causing adverse effects.

The scope of the initial restriction proposal was changed in the second proposal by exempting already regulated articles (toys, food contact materials, electronic equipment) and uses in the

[68] Note previous step is the submission not the RAC opinion.

[69] Different from open groups like e. g. the diisocyanates of the perfluorinated silanes where not all substances are explicitly listed as part of the proposal.

medical sector. The final regulation also exempts uses in food contact materials[70] as well as for maintenance and repair of vehicles and aircraft, where this is essential for the function and safety.

5.3.2 Demonstration of an unacceptable risk

In both Annex XV dossiers, the demonstration of the unacceptable risk was based on the same argumentation.

The hazards have been demonstrated and agreed at EU level in the SVHC identification process. All phthalates addressed had a classification as reprotoxic category 1B (H360 FD). The main effect responsible for this classification was the so-called '*phthalate syndrome'*[71]. The dossier submitters assumed that this endpoint might not be the most sensitive and other severe effects might need to be considered (effects on the immune system, metabolic system and neurological development).

The substances have a similar mode of action. Therefore, the dossier submitters assumed that a combined exposure to the four substances might trigger risks that are not identified if substance risks are only evaluated on the individual level.

The uses of phthalates were described as very broad, ranging from construction products, every-day articles and toys to food contact materials. Phthalates may also accumulate in house dust. Exposures were stated to occur from multiple sources and to all four phthalates. Information on the content of phthalates in articles was provided. Exposure levels from biomonitoring data were used to calculate the average daily intake and conclude on risk levels. Exposure models for articles, food and indoor air were used to characterise the main sources of exposure.

The discussion on the most sensitive endpoint and the similarity of the mode of action justifying the combined risk assessments caused large efforts in preparing restriction dossiers that comply with the requirements of REACH.

In its opinion on the first restriction proposal, the RAC argued that no unacceptable risk was demonstrated in the initial restriction proposal. It criticised that

a) the phthalates' contribution to reproductive and endocrine risks cannot be determined (lack of clear cause-effect relationship),

b) DNELs and modelled exposure level were overestimated,

c) monitoring data were outdated,

d) EU regulation had entered into force that should have already reduced exposure levels; this was substantiated by data on a decrease of the average phthalate-content in articles on the EU market,

e) trends to substitute the phthalates were observed, which was expected to be further increased by the inclusion of the substances in the candidate list.

In the second restriction dossier, the DNELs were accepted by the RAC[72]. The newer and more representative biomonitoring data and related exposure modelling were found more reasonable than in the first dossier. The argumentation that imported articles are the main source of

[70] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food requires authorisation of substances.

[71] Syndrome shown to affect the genital development and several other effects on male mice during embryonal development, see also Annex XV dossier.

[72] All but one corresponded to those derived by the RAC and they were stated to probably underestimate risks due to uncertainties, nevertheless, they were accepted as pragmatic way forward.

exposure was accepted, i. e. the projection of imported phthalate volumes outpacing substitution activities triggered by the authorisation requirements and other regulatory measures (e. g. RoHS) were found reasonable. In addition, a different exposure modelling approach was taken based on average migration limits and assumed proportions of articles containing the phthalates.

Overall a very extensive weight of evidence argumentation was needed to show the existence of an unacceptable risk, even though the main concern is the consumer and vulnerable groups like e. g. children.

5.3.3 Assessment of alternatives

Both restriction proposals evaluate the economic and technical feasibility and availability of alternatives to the four phthalates and conclude that sufficient alternatives are in principle available for consumer products.

5.3.4 Socio-economic assessment

The socio-economic assessment in the second restriction proposal is based on a 'non-use' scenario assuming that market actors would either substitute or search external markets for their products. Hence, cost estimates focused on costs of substitution.

Overall, the SEAC agreed with the assessment.

5.3.5 Overall evaluation of the restriction process

Generalised learnings from the restriction process are:

- It is possible to address a 'closed group' of substances in the scope of a restriction.
- An unacceptable risk may originate from combined exposures of substances with a similar mode of action; the justification may be very extensive.
- Uncertainties of hazard levels may not be a problem in demonstrating risks as long as they point to an underestimation rather than an overestimation of risks.
- Biomonitoring data can be a good basis to define the risk level if recent.
- Market projections may be a valid information source to demonstrate trends in the occurrence of substances in articles.
- It may be better to apply a broad and generic scope regarding the covered uses/articles and exempt uses which are already regulated or are expected to fail to appropriately react to the restriction.
- If alternatives are available at reasonable cost, SEAs may focus on substitution costs.

As the four phthalates were already included in Annex XIV at the time of preparing the (first) restriction proposal, the scope was automatically limited to articles. Large efforts were needed to demonstrate unacceptable risks although the restriction mainly covered consumer products, which most companies excluded from their authorisation applications due to assumed consumer risks and the availability of potential alternatives. These large efforts can be attributed both to the broad scope and the approach to address risks from combined exposures.

Grouping based on a common mode of action enabled the dossier submitters to demonstrate that risks from combined exposure, in particular with a view to the targeted vulnerable group of children.

5.4 CMRs in textiles

This restriction proposal is the first one implemented according to the simplified procedure of REACH Art. 68 (2). Although not required the COM collected stakeholder information via a public consultation (22 October 2015 to 22 March 2016) and a workshop (February 2017 – with the opportunity of providing written comments also after the workshop), in particular to develop a list of substances (groups) covered by the restriction.

Table 8: Key steps in the restriction process of CMRs in textiles

Process parameter	Information from case
Type of restriction	Article 68 (2)
Subject of protection	Consumers
Restriction scope	CMRs cat. 1A and 1B in clothing, textiles likely to come into contact with the skin is comparable to clothing
Submitter(s)	Commission
Substance	Substances which are classified as carcinogenic, mutagenic or toxic for reproduction, category 1A or 1B (Entry 72) EC / List no: - CAS no: - (group of various substances)
Date of intention	Not relevant (N.R.) for procedure according Article 68 (2)
Expected date of submission	N.R.
Date of submission/date of Annex XV dossier	N.R.
RAC Opinion adopted	N.R.
SEAC Opinion adopted	N.R.
REACH Committee vote	26/04/2018 (in favour)
Outcome of restriction process	Regulation (EU) No 2018/1513 of 10/10/2018 http://data.europa.eu/eli/reg/2018/1513/oj
Overall process duration	About 46 Months (Beginning 2015 was estimated as starting date[73]

5.4.1 Scope of the restriction

The initially proposed scope of the restriction covered

a) Textiles (material)

b) Which are in close contact with the human skin (exposure exists); mainly clothing but also other textiles used indoors

[73] From the Commission website: Implementing the approach developed in 2014, the Commission started to work on a potential restriction of CMRs 1A and 1B in textiles." https://ec.europa.eu/growth/sectors/chemicals/reach/restrictions_en

c) Substances with carcinogenic, mutagenic and/or reprotoxic properties (cat. 1A or 1B).

The material part of the scope, i. e. the focus on textiles and the understanding/definition of textiles was not discussed at any time.

The exposure conditions were discussed among the stakeholders and the COM. The inclusion of textiles was not questioned, whereas the definition of the nature of contact to the skin (duration, intensity etc.) was addressed. In addition, derogations were discussed, such as textiles for workers protection.

The relevance of the covered (types of) substances for the textiles (clothing) sector was the main subject of controversy as the industry found that some of the initially listed substances are no longer in use (phased out already for some time ago). It could be argued that for these substances a restriction would not affect current production. However, it may create burdens on the market actors and for enforcement because compliance checking would require testing the full list. This would need large efforts and potentially additional testing capacity. Therefore, the related discussions aimed at focussing the substance list on the relevant substances (groups) and to identify existing testing protocols needed to assess compliance with the concentration thresholds in the restriction.

5.4.2 Demonstration of an unacceptable risk

The initial scope of the restriction covered substances where hazardous properties (CMR) have already been demonstrated, amongst others due to existing harmonised classification, listing on the candidate list or via (other) restrictions which already existed. No (additional) efforts had to be taken to demonstrate the substances fulfil this pre-condition of Article 68 (2) and the hazard as such was not discussed.

With regard to the products that were intended to fall under the restriction, the textiles were a clear case where direct contact to the skin of consumers could be assumed without additional efforts. Hence, the generic exposure and risk assessment were also not intensely discussed.

5.4.3 Assessment of alternatives

Not relevant under the simplified procedure.

5.4.4 Socio-economic assessment

Not relevant under the simplified procedure.

5.4.5 Overall evaluation in regard to the restriction process

The main, generalised learnings from the case study are:

- It is possible to implement a restriction with a very broad scope regarding the application area, however this may require focussing on the side of substance coverage.
- As intended, the process under Art. 68 (2) simplifies the development of restrictions by allowing to omit the demonstration of an unacceptable risk based on hazard and generic risk considerations.
- Although not legally foreseen, consultations with stakeholders are important to ensure that the restriction scope targets the relevant substances which actually occur on the market and hence, limit compliance and enforcement efforts in particular related to testing.
- The simplified restriction procedure is not necessarily quick.

In the phthalate restriction, which is also a case where CMRs in a broad range of consumer articles are addressed, the efforts needed to demonstrate the unacceptable risk was a very resource consuming and lengthy process. If phthalates had been regulated via Art. 68 (2), also the discussion about toxicity endpoints other than reproductive toxicity would not have been necessary.

Overall, the simplified procedure may enhance the speed of the restriction process in general.

5.5 Perfluorinated Silanes[74]

The following table summarises key information about the case study.

Table 9: Key steps in the restriction process of perfluorinated silanes

Process parameter	Information from case
Type of restriction	Article 68(1); 'regular' restriction proposal
Subject of protection	Human health (consumers)
Restriction scope	Ban of perfluorinated silanes in mixtures with organic solvents and in consumer sprays above 2 ppb by weight
Submitter(s)	Denmark
Substance	(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silanetriol and any of its mono- di- or tri-O-(alkyl)derivatives EC / List no: - CAS no: - (group of various substances)
Date of intention	25/11/2014 (0)
Expected date of submission	02/10/2015 (11)
Date of submission/date of Annex XV dossier	20/04/2016 (6)
RAC Opinion adopted	10/03/2017 (11)
SEAC Opinion adopted	15/07/2017 (15) [75]
REACH Committee vote	11/12/2018, in favour (16)
Outcome of restriction process	Regulation (EU) No 2019/957 of 11/06/2019 (Annex XVII entry 73) http://data.europa.eu/eli/reg/2019/957/oj
Entry into force of the restriction	01.07.2019
Overall process duration	48 Months

5.5.1 Scope of the restriction

In the original proposal, (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives (abbreviation TDFAs) were proposed for restriction in the (formulation of) mixtures with organic solvents in concentrations exceeding 2ppb in spray products intended for supply to the general public.

[74] (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives (abbreviation TDFAs) EC no. n.a.; CAS-no n.a.; Index no. n.a

[75] Note previous step is the submission not the RAC opinion.

The RAC proposed slightly changing the wording of the restriction, exempting professional users and implementing two communication obligations (labelling and communication in the SDS).

As the substances were not registered, it was difficult to get a clear understanding of which share of the substances' uses are covered by the restriction, i. e. whether or not a relevant contribution to the overall risk is addressed.

5.5.2 Demonstration of an unacceptable risk

The restriction was initiated because several incidences of serious respiratory health effects were reported across Europe after consumers used sprays containing these substances in combination with one or more organic solvents. The sprays were used to impregnate surfaces of various consumer articles (textiles, walls etc.).

The demonstration of an unacceptable risk included two arguments:

- The hazard of perfluorinated silanes was demonstrated mainly based on results from laboratory testing (mice), which showed serious lung damage following short-term exposure.
- 713 incidents of respiratory illness requiring hospitalisation for treatment after exposure to proofing/impregnating sprays were reported by the poison centres. A total of 20-40% of these incidents is considered to be directly related to products containing perfluorinated silanes and organic solvents.

The main uncertainties discussed in relation to the risk were the causality between the observed incidents and the use of the spray products because the information on the composition of the spray products was incomplete with regard to the content and identity of the perfluorinated silanes[76] and the other components of the products and their hazards. In addition, the hazard information was mainly based on animal testing. In the end risk was considered unacceptable for consumers because acceptable alternatives were identified (see below), but professional users were allowed to continue use.

5.5.3 Assessment of alternatives

In the restriction dossier, alternatives to the proposed restriction were identified and described:

a) water-based mixtures (i. e. not containing organic solvents), in which the silanes are expected not to cause the adverse effects

b) application of impregnating solutions using different application methods (e. g. brush)

c) products not containing fluorinated alternatives instead of the perfluorinated silanes.

All alternative types assessed were selected, because it is possible to accomplish the same or at least similar functionalities of the final treated surface and whether or not they are available on the market.

For the alternatives under c) it was not clarified in the dossier if these alternatives would actually reduce the human health risks. The dossier states that the alternatives are already available; i. e. a lack of alternatives would not prevent the implementation of a restriction.

[76] As these would not normally trigger classification, they did not have to be listed in the list of ingredients/safety data sheets.

5.5.4 Socio-economic assessment

In the socio-economic assessment the illness-related costs were calculated (hospitalisation, productivity loss, individual welfare loss) and the benefit defined as the prevention of these costs. Environmental impacts were disregarded as negligible.

The costs of providing alternatives were qualitatively assessed and concluded to be relevant but comparatively small. Some arguments were the possibility to change the application techniques (type of packaging) and the availability of drop-in alternatives (assumed simple re-formulation) and, from the consumer perspective, the use of water-based products.

Social costs (employment losses) were considered negligible. No change in (consumer) prices was expected.

Discussions evolved around the lack of information on which alternatives would be adopted and on their respective hazards and risks. At the end, some of the SEAC members formulated a minority opinion based on the argument that this information gap prevented a proper assessment of socio-economic effects and left the assumptions that alternatives would have an unproven lower impact. Nevertheless, the SEAC opinion supported the restriction because it was regarded as most effective in eliminating the consumer risk and because sufficient alternatives were available to substitute the spray application. The restriction was also seen as a suitable measure because it addresses risks from imported and EU-manufactured spray products at the same time.

Despite the uncertainties regarding the impacts of the restriction on market actors, the restriction was considered sufficiently cost-effective based on the assumed relatively low reformulation costs and market share losses for current producers of the products. This could be interpreted in a way that the SEAC weighted the need for risk reduction and the plausibly argued low negative market impacts as more important than the clarification of the remaining information gaps; i. e. an implementation of the precautionary principle in the wider sense.

5.5.5 Overall evaluation in regard to the restriction process

The case of perfluorinated silanes shows that health risk for consumers can be effectively addressed by the restriction procedure under REACH. Generalised learnings from the process are:

- A specific (narrow) scope of a restriction proposal can be useful to address an immediate problem and the scope is unlikely to be altered during the discussions.
- Incidents of damage observed in relation to a consumer use of chemical products (reports by poison centres) can be sufficient to demonstrate an unacceptable risk (even though there was remaining uncertainty about causality).
- If the available alternatives are briefly described and qualitatively assessed with regard to their suitability and efforts for the market actors, the argumentation may already be sufficiently plausible for a SEAC opinion and show the potential extent of market impacts.
- The SEA may be lean and address the direct benefits (consumer well-being and prevented health and work-related costs) and efforts to react to the restriction (costs to apply an alternative). If it is plausible that the number of actors and products are limited, this information may be a sufficient basis for the SEAC opinion.

Despite several uncertainties regarding the number of affected products and actors as well as the actual application of alternatives and related costs, the SEAC formed a supportive opinion as the benefits and impacts appeared to outweigh the disadvantages of a restriction.

This case is an example of a risk originating from toxic effects caused the combination of two substances in a mixture: without the solvents, which transport the silanes to the location of the activity, the adverse effect would not occur. The properties of the silanes are only relevant when they come in contact with the right target tissue.

The case also allows concluding that a precautionary approach may influence the decision making: The restriction was supported despite the lack of information, as consumer protection was considered most important. As the 'continued use scenario' showed safe use to be impossible, a restriction seemed to be the most efficient measure to eliminate the risk.

5.6 Perfluorooctanoic acid (PFOA) and related substances

Germany and Norway proposed the restriction in order to improve the protection of human health and the environment from the covered group of substances, which are PBTs.

Table 10: Key steps in the restriction process of perfluorooctanoic acid

Process parameter	Information from case
Type of restriction	Article 68 (1)
Subject of protection	Human health and the environment
Restriction scope	The initial restriction proposal covers PFOA including its salts and any substance(s) that may degrade to PFOA (based on certain C-F structural elements). Restrictions concern the manufacture, placing on the market and use as such, in mixtures or in articles above a concentration of 2 ppb. In the adopted restriction, the concentration thresholds were increased (25 ppb for PFOA and 1000 ppb for PFOA-related substances)
Submitter(s)	Germany, Norway
Substance	Perfluorooctanoic acid and its salts EC / List no: - CAS no: - (group of various substances) Any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula C_7F_{15}- directly attached to another carbon atom, as one of the structural elements. Any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula C_8F_{17}- as one of the structural elements. The following substances are excluded from this designation: • C_8F_{17}-X, where X = F, Cl, Br • C_8F_{17}-C(=O)OH, C_8F_{17}-C(=O)O-X' or C_8F_{17}-CF_2-X' (where X' = any group, including salts).
Date of intention	19/02/2014 (0)
Expected date of submission	17/10/2014 (8)
Date of submission/date of Annex XV dossier	17/10/2014 (0)
RAC Opinion adopted	08/09/2015 (11)

Process parameter	Information from case
SEAC Opinion adopted	04/12/2015 (14)[77]
REACH Committee vote	07/12/2016 (in favour) (34)
Outcome of restriction process	Regulation (EU) No 2017/1000 of 13/06/2017 (Annex XVII entry 68) http://data.europa.eu/eli/reg/2017/1000/oj
Entry into force of the restriction	04/07/2020
Overall process duration	56 months

5.6.1 Scope of the restriction

The restriction proposal not only covers PFOA, including its salts, but also all substances that might degrade to PFOA and/or have certain structural elements[78]. PFOA is the stable end product of biological and non-biological degradation of perfluorinated substances of longer chain lengths, and highly persistent. It was not questioned by the stakeholders or the committees that the degradation actually takes place.

The group was defined with an open scope because

- It is not clear which substances of the group are on the EU market (on its own, in mixture or in articles[79]) and
- It was considered more efficient to address the group rather than to regulate individual substances and add relevant compounds to a list.

Substances were named only as examples but it was clear that these do not represent the full restriction scope (demonstrated in the dossier).

The coverage of substance as a group and the inclusion of precursors under the restriction scope were discussed, including on how to clarify the scope (changes proposed in RAC's opinion) and thus created a significant workload. The key challenge was that neither the dossier submitter nor RAC could investigate a closed list with substances covered due to the high variability of the substance group in total. Finally, the restriction proposal was processed with an open wide scope.

The conditions of the restriction were changed in that the concentration thresholds were increased to 25 ppb for PFOA and 1000 ppb for one or a combination of PFOA-related substances. This was due to comments provided during the public consultation that the limit values would be difficult to meet because they were lower than the background concentrations in the surroundings of installations.

Exemptions from the restriction were included for safety-relevant or health applications (e. g. firefighting foams, implanted medical products), where closed conditions were assumed (photolithographic applications), and where the assessment revealed that feasible alternatives are missing.

[77] Note previous step is the submission not the RAC opinion.

[78] Linear or branched perfluoroheptyl group with the formula C7F15 or C8F17, with the exception of substances with the designation — C8F17-X, where X = F, Cl, Br. — C8F17-C(=O)OH, C8F17-C(=O)O-X′ or C8F17-CF2-X′ (where X′ = any group, including salts)

[79] While there have been rather good information on the use of PFOA itself these information was lacking for its presence in mixtures and articles, as it is usually present in concentration below information need to be provided on these products, so other measures initiated like candidate listing did not help to improve the information basis.

5.6.2 Demonstration of an unacceptable risk

The PBT hazard was demonstrated by recurring to the SVHC identification. It should be noted that in the SVHC identification process according to Art. 57 (f) the demonstration of bioaccumulation did not follow the classical concept of accumulation but a weight of evidence argumentation was used.
In addition, it was specified that PFOA is classified as Carc. Cat. 2, Repr. Cat. 1B, and STOT RE 1 (liver), which is the basis for the toxicity criterion.

A high degree of uncertainty existed on the use and emission part of the risk demonstration: Some of the covered substances are placed on the market only as isolated (transported or on-site) intermediates. Therefore, no detailed CSR is included in the registration dossier and information on uses is missing. Some substances are not registered because they fulfil the polymer definition and are therefore not included in ECHA's registration database. The lack of data is probably the main reason why they are also not included in the classification and labelling inventory.

Due to a lack of a solid database on products containing PFOA and PFOA-related substances, discussions were difficult regarding the main emission sources and their contribution(s) to the overall risk.

However, relevant exposure levels to PFOA and PFOA-related substances were demonstrated by the ubiquitous occurrence in the environment and humans shown by environmental and human biomonitoring data.

Due to the above challenges and the high workload unsuccessfully invested in the respective clarifications, the RAC concluded that no relevant quantitative risk assessment is possible for the environment. Therefore, the restriction should aim at minimising emissions in general. Similarly, the assessment of human health risks did not show a clear picture. Despite a sufficiently clear information basis, it was concluded that potential risks cannot be excluded for workers handling substances under the restriction's scope.

5.6.3 Assessment of alternatives

The restriction proposal includes an overview of alternatives for uses according to sectors and functionalities, differentiating fluorinated from non-fluorinated alternatives. Some of the alternatives, such as fluorotelomer-based short-chain chemistry are stated to already be in use on the market. However, the information detail on these alternatives was limited to some main processes (e. g. direct use of PFOA in the production of fluoropolymers[80]).

For the main groups of alternatives, hazard data was compiled and a general appraisal of the technical and economic feasibility provided was based on literature research and the stakeholder comments. Many of the identified alternatives, are fluorinated substances outside the scope of the restriction proposal. It was acknowledged that their hazard profiles are of 'lower concern' than that of PFOA and PFOA-related substances.

The availability of alternatives was commented on during consultation, indicating a generally lower performance, higher costs and potentially higher use amounts are needed for many of the alternatives. In the end there was a fundamental difference of opinion between stakeholders and authorities regarding what could be considered as adequate substitute, especially when consumer products were discussed. As an outcome from the discussion on risk, the discussion

[80] It should be noted that these alternatives were also fluorinated substances outside the scope of the proposal and are currently also under investigation whether they might qualify as PBT substances so it must be considered to be a regrettable substitution, see RMOA issued by the Netherlands (June 2019) https://echa.europa.eu/documents/10162/a69d536b-4274-ff51-800a-65e6af17d0fa

focus was on the identification of areas where PFOA and PFOA-related substances could by no means be replaced and/or where exemptions from a total ban would be needed.

5.6.4 Socio-economic assessment

The SEAC focussed strongly on the hazard profile of the substances covered under the restriction proposal. They highlighted the PBT status of the substance and in addition to that the wide dispersive characteristics of their uses. In addition to that they noted the potential for long-range transport and that a global solution should actually be a more favourable action but agreed that a start under REACH seems justified so as to not lose time. This high severity of anticipated effects was used to justify a far reaching market intervention even though assessments might suffered from a high level of uncertainty with regard to the assessment of economic impacts for market actors. The key issue in SEACs opinion was the conclusion that compliance cost for meeting a 2 ppb limit value might be unjustified and therefore accepted the higher value of 25 ppb in the final restriction.

5.6.5 Overall evaluation of the restriction process

General learnings from the current restriction process are:

- It is generally possible to include precursors of the substances that are targeted by a restriction into the restriction scope if it can be shown with certainty that degradation to that substance takes place to a relevant extent.
- It can be very burdensome to demonstrate unacceptable risks for PBT/vPvB substances, in particular if these have a broad use spectrum (high assumed environmental cost from continued use assumed).
- However, a broad scope of regulation seems appropriate, as the substance is used in numerous applications and not one of them is the dominant source of emissions.
- Use information is highly important to demonstrate risks; closing information gaps, in particular for low-volume substances, intermediates (with impurities) and polymers can be very important but challenging.
- Regulation is possible and an unacceptable risk could be substantiated event though arguments were based on numerous assumptions at least if PBT/vPvB substances are concerned. In this case a general emission minimisation could be the aim of the restriction.
- A broad scope with regard to the uses of a substance may require (lengthy) discussions about exemptions but can be successful and effective, in particular when emission sources and their contributions to a risk are unclear

The restriction proposal on PFOA and PFOA-related substances was an extensive effort of the authorities. Despite the large resources invested, the risk needed to be substantiated on several assumptions. Although the dossier was carefully prepared, significant changes were triggered by information provided in the public consultation. It seems very likely that similar issues will occur when other PBT/vPvB substances are targeted that also have a broad use and can even be more associated with a group of substances that can be degraded to the key substance of concern.

5.7 Nonylphenol and Nonylphenol Ethoxylates (NPs and NPEOs)

Sweden proposed restricting the content of nonylphenol (NP) and nonylphenol ethoxylates (NPEOs) in textile articles thereby complementing an existing restriction on the use of these substances in textile processing, as well as a related authorisation requirement.

Table 11: Key steps in the restriction process of nonylphenol and nonylphenol ethoxylates

Process parameter	Information from case
Type of restriction	Art. 68 (1)
Subject of protection	Environment (aquatic compartment)
Restriction scope	Initial proposal: NPs and NPEOs contained in concentrations above 0.01% in textile articles that are likely to be washed. Adopted regulation: scope limited to NPEs
Submitter(s)	Sweden
Substance	4-Nonylphenol, branched and linear and 4-Nonylphenol, branched and linear, ethoxylated EC / List no: - CAS no: - (group of various substances)
Date of 1st intention	02/09/2011
Withdrawal date	07/02/2013 restriction dossier did not conform to the requirements of Annex XV dossier
Date of 2nd intention	17/04/2013 (0)
Expected date of submission	02/08/2013 (4)
Date of submission/date of Annex XV dossier	29/07/2013 (resubmission) (0)
RAC Opinion adopted	03/06/2014 (11)
SEAC Opinion adopted	09/09/2014[81] (14)
REACH Committee vote	07/07/2015 (in favour) (27)
Entry into force	3 February 2021
Outcome of restriction process	Regulation (EU) No 2016/26 of 13/01/2016 (Annex XVII entry 46a) http://data.europa.eu/eli/reg/2016/26/oj
Entry into force	03/02/2021
Overall process duration	51 months

5.7.1 Scope of the restriction

The initial restriction proposal covered NP and NPEOs in textile articles, which are likely to be washed with water above a concentration of 0.01% w/w.

NP was eliminated from the scope in the final restriction because no intentional use of NP was identified. Hence, RAC and SEAC concluded that market actors would have no means to reduce NPs other than reducing one of their known sources in textiles – the use of NPEOs. Additionally, the effectiveness including NPs in the scope was considered minimal as only (negligible) trace amounts were found in textiles.

The application area of textiles that are likely to be washed and the concentration threshold were not changed during the process. However, the wording was modified and the definitions

[81] Note previous step is the submission not the RAC opinion.

made more explicit and precise so to clarify that also raw and semi-finished textiles are covered by the scope.

This proposal 'extends' an existing restriction for textiles (including semi-finished products and yarns – general rule articles that can be washed and in this way release the substances).

5.7.2 Demonstration of an unacceptable risk

The main aim of the restriction was to limit risks to the aquatic compartment from the adverse effects of NPs, which are released from NPEOs under environmental conditions.

Large parts of the Annex XV dossier are dedicated to demonstrating the hazards of NP, in particular its endocrine disrupting properties. Despite the use of a large data set, it was concluded that no Predicted No Effect Concentration (PNEC) can be derived and hence, no safe environmental concentrations be determined. The RAC concluded that a PNEC could only be derived for traditional aquatic toxicity, which does not cover additional risks due to an endocrine disruption and potential additive effects due to the presence of several compounds in EU water bodies.

Monitoring data on concentrations in EU water bodies were used to compare the derived 'minimum PNEC' with actual exposure levels by the RAC and an unacceptable risk was regarded as demonstrated for several water bodies in different EU countries.

Textiles, in particular imported ones, were identified as a significant emission source because they can release NPEOs which can degrade to NP and short chain NPEOs/NPECs. Market data on textile imports and average NP/NPEO concentrations were used to derive the substance amounts that might be released during washing.

5.7.3 Assessment of alternatives

Several alternatives to the use of NPEOs were described and evaluated in the restriction proposal, which were found to already be in use due to the existing use restriction. It was said that several alternatives may be needed for different application areas but that the performance of many available alternatives was considered equal to NPEOs. The costs of the alternatives were identified as slightly higher than those of the NPEOs. Also stakeholder comments indicated that alternatives are already in use. The RAC did not identify significant concerns about the alternatives.

All in all, the availability and costs of alternatives (inside and outside the EU) were not a major discussion issue.

5.7.4 Socio-economic assessment

It was estimated that the restriction would reduce NPEO emissions to the environment by approximately 21%. This benefit has not been monetised, and hence, no value for cost-benefit assessments was available.

The cost assessment specified substitution costs incurred outside the EU but passed on to the textile importers as well as compliance costs arising from the need to test and ensure imported textiles do not contain NPEOs above the concentration thresholds.

Overall, SEAC concluded that the restriction could be cost effective, as the efforts were considered low and the benefits significant.

5.7.5 Choice of measure

The main discussions about the restriction proposal questioned its effectivity in reducing emissions to water bodies. Although the dossier provided only limited information on the share of textiles that would be affected by the restriction (assumed 20 %), the committees supported the restriction. This was due to them finding

a) Other risk management options less well suited

b) That a positive effect on EU water bodies could not be excluded.

As endocrine effects may already occur at low concentrations, a strict minimisation approach was regarded justified.

Further, it was doubted that the effects of the measure could be monitored sufficiently well because a candidate listing was initiated in parallel. The contribution of either measure to a potential environmental improvement could therefore hardly be distinguished.

5.7.6 Overall evaluation of the restriction process

Generalised learnings from the case include:

- When defining the scope of the restriction it is easier to include only substances that are actually used in the scope of a restriction; if possible, impurities and degradation products should be addressed by covering the substances/products that contain them or which may degrade into them.
- It should be possible and a standard approach to rely on hazard assessments from other processes to save resources; information should only be updated and/or complemented with new/other hazards to save resources and avoid double work.
- For substances with effects that have no or very low threshold values, like an endocrine disrupter, it may be possible to substantiate risks based on the fact that exposure cannot be excluded, in particular for the environment where it is challenging to observe effects (cf. discussion on PFOA in Section 5.6). Whether or not the identified level of risk is acceptable should be subject to the SEA.
- It may be well justified to apply a set of regulatory measures to control a risk (use restriction, authorisation and a further restriction for placing on the market). In particular here, hazard and risk assessment approaches may be shared to reduce the workload for each measure.

In the context of this restriction, there were discussions on whether or restrictions and other regulatory measures should be initiated in parallel or if the effect of one should be awaited before starting the other. While considering the assessment of a need for another measure and the ability to monitor the effects of each regulatory measure independently, creating a level playing field could be an argument to apply more than one measure at a time, in particular in the context of complementing inclusion of SVHCs into Annex XIX.

5.8 Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5)

Table 12: Key steps in the restriction process of Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5)

Process parameter	Information from case
Type of restriction	Article 68 (1)
Subject of protection	Environment
Restriction scope	D4 and D5 should not be placed on the market in wash-off personal care products above concentrations of 0.1%
Submitter(s)	United Kingdom
Substance	Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) EC / List no: - CAS no: - (group of various substances)
Date of intention	10/06/2014 (0)
Expected date of submission	17/04/2015 (10)
Date of submission/date of Annex XV dossier	10/06/2015 (2)
RAC Opinion adopted	10/03/2016 (9)
SEAC Opinion adopted	09/06/2016 (12)[82]
REACH Committee vote	10/05/2017 (in favour) (13)
Outcome of restriction process	Regulation (EU) No 2018/35 of 10/01/2018 (Annex XVII entry 70) http://data.europa.eu/eli/reg/2018/35/oj
Entry into force	31/01/2020
Overall process duration	37 months

5.8.1 Scope of the restriction

The initial proposal aimed to restrict D4 and D5 in rinse-off personal care products above concentrations of 0.1% w/w.

The initial proposal contained an indicative list of products that should be covered by the scope of the restriction. This was extended during the evaluation by replacing the list with a link to the cosmetics regulation; this also resulted in a change of terminology to 'cosmetic' wash-off products.[83]

[82] Note previous step is the submission not the RAC opinion.

[83] Based on this initial restriction with a narrow scope a second restriction was brought forward with the aim to extend the scope https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade

5.8.2 Demonstration of an unacceptable risk

For D4 it was demonstrated that the criteria of Annex XIII REACH are met, i. e. that it is a PBT and vPvB. D5 was shown to be vPvB and a PBT due to its content of D4. In addition, D4 has a harmonised classification (CLH) as toxic to reproduction Cat. 2. It also has toxic effects on aquatic organisms and mammals. The registrants had not identified D4 and D5 as PBT or vPvB due to a different interpretation of the bioaccumulation data.

Based on the scope on cosmetic wash-off products discharge to wastewater and ambient air was assumed to occur. Wastewater treatment plants were assessed as not (sufficiently) eliminating /destroying D4/D5, resulting in their release to the environment. The data underpinning the exposure assessment stemmed from market data as well as measured emission concentrations from waste water treatment plants as well as environmental monitoring data.

Due to D4 and D5 being PBT and vPvB, both the dossier submitter and the RAC stated a risk assessment be inappropriate. Instead a minimisation strategy for substance emissions should be adopted.

5.8.3 Assessment of alternatives

The restriction proposal contains little information on alternatives; it is neither clear if and which alternatives are available and suitable nor whether or not they are less problematic than the (fully investigated) D4 and D5. Some potential alternatives seem to have a less problematic hazard profile.

The stakeholders indicated not all cosmetic (wash-off) products contain D4 and D5, implying an availability of suitable alternatives. However, the need for (a combination of) various alternatives was highlighted in order to replace the functionalities of D4 and D5.

Alternatives registered under REACH were considered commercially available while others were evaluated as not readily available in sufficient quantities to replace D4 and D5. Nevertheless, they were indicated as potentially relevant in the longer term. Furthermore, it was indicated that potential polymeric alternatives are unlikely to be registered but may be available in significant amounts.

5.8.4 Socio-economic assessment

The assessment of socio-economic impacts is hindered by the lack of information on relative prices and required loading rates (i. e. concentration needed to achieve the functional requirement) of the alternatives. Substitution cost calculations and cost-effectiveness estimates (€ per kg of emission reduced) are presented based on a range of assumptions regarding required 'use ratio' loading rates. No information was presented about costs for changing production processes.

It was assumed that reformulation of the affected products would be possible but might create some development costs. The cost effectiveness calculations justified the restriction (mean cost per reduced kg about 400€). The comparisons with similar regulatory activities for other PBT showed that this value was at the lower end.

5.8.5 Choice of measure

In the restriction process, some discussion was held about other potential options to reduce the emissions of D4 and D5. One of these was to 'update the registration dossiers' advising against the use of D4/D5 in cosmetic wash-off products. The option was not chosen because DUs were

assumed to prepare a DUCSR and continue their use. The proposition of D4 and D5 for inclusion in an Annex of the Stockholm Convention was also considered. However, in the end the restriction was considered the most effective option.

5.8.6 Overall evaluation of the restriction process

The generalised learnings of from this example are:

- If it can be argued that a specific application of a substance (group) contributes to an overall exposure/risk, it may be better to restrict that (narrow) use with comparably low efforts than aiming at a broad restriction covering a larger share of the emissions. However, the RAc noted that the scope of the regulation was too narrow and therefore suggested its widening.[84]
- There is a strategy change regarding the efforts to demonstrate an unacceptable risk from PBTs; the submitter of this (later) proposal put less efforts to quantitative risk assessments, which was (also) acceptable for RAC than e. g. in the case of PFOA but also in the case of NP, which is an endocrine disruptor that effects organisms in the environment.
- If a significant share of products within a particular product group does not contain the substance (group) addressed by a restriction proposal, it may be sufficient justification to assume alternatives as available.
- SEA may focus on the most relevant cost items, such as substitution and compliance costs.
- The lack of polymer registrations may contribute to uncertainties regarding the availability of alternatives.

Overall, the restriction process was straight forward, as it was based upon clear data, well-founded information on the uses and the potential socio-economic effects. Only a few comments were provided that were not in favour of a measure for this scope.

5.9 Microplastics

ECHA prepared the restriction proposal upon request of the COM. It is the first proposal submitted that covers a chemical group (polymers) defined by its form, i. e. physical characteristics. The following table shows the key steps in the restriction process.

Table 13: Key steps in the restriction process of microplastics

Process parameter	Information from case
Type of restriction	Article 68 (1)
Subject of protection	Primarily environment but possibly also human health via the food chain accumulation
Restriction scope	Microplastics intentionally added to products for consumer or professional use. The initial proposal defines the term microplastics as ‘particles containing polymers’, amongst other specifying threshold concentrations and particle sizes
Submitter(s)	ECHA

[84] This resulted in a second restriction proposal, as indicated above.

Process parameter	Information from case
Substance	Microplastics EC / List no: - CAS no: - (group of various substances)
Date of intention	17/01/2018 (0)
Expected date of submission	11/01/2019 (12)
Date of submission/date of Annex XV dossier	20/03/2019 (7)
RAC Opinion adopted	11/06/2020 (10)
SEAC Opinion adopted	Not yet adopted[85]
REACH Committee vote	Not yet voted on
Outcome of restriction process	Not yet published

5.9.1 Scope of the restriction

The initial Annex XVI document specified that polymers in the form of microplastics should not be placed on the market as such or in mixtures in concentrations above 0.01% w/w. Hence, a group of substances is addressed (polymers), which are defined by their physical form (particle and size-related criteria).

As the term 'microplastics' is not defined, the proposed scope describes how this is to be understood: polymer-containing particles (including additives or other substances added) where≥ 1% w/w of particles specific criteria regarding size and diameter.[86]

The proposal includes a number of exemptions, which either relate to the polymer properties (occurring in nature, biodegradable) or the use conditions preventing release (industrial sites, containment). In addition, notification and labelling obligations are proposed for exempted products to enable informed decision making of product users.

Industry stakeholders criticised the proposal as not being in line with REACH and reacted to the scope in two directions: some found it not properly defined and too broad (almost any polymer) and others believed it too narrow due to the high number of exemptions and the potential lack of including particles at nanosize. On the other hand environmental and consumer non-governmental organisations (NGOs) argued that the exemptions proposed are too broad. These stakeholders interpreted REACH in a broader way arguing that microplastics can be understood as a group of persistent substances that require an EU-wide measure.

In general, the RAC supported the proposed scope of the restriction but suggested deleting the lower size limitation of the definition of particles and modifying the criteria specifying 'biodegradation'.

5.9.2 Demonstration of an unacceptable risk

The main concern of this proposal is the irreversible release of microplastics and the resulting negative effects in the food chain. This type of assumed risk is not fully in line with the substance

[85] Note previous step is the submission not the RAC opinion.

[86] Either all dimensions 1nm ≤ x ≤ 5mm, or for fibres, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3.
At the beginning of their dossier preparation, ECHA used the following definition in a call for evidence: "any polymer , or polymer-containing, solid or semi-solid particle having a size of 5mm or less in at least one external dimension. The definition in the Annex XV dossier resulted from handling the stakeholder feedback on that first working definition.

properties that have formerly been used to substantiate restrictions. The main argument is that the release of microplastics can be interpreted as a release of highly persistent substances to the environment. However, it fits in with the COM's intention to classify emissions from plastics as an environmental problem and to reduce such emissions via activities foreseen in the plastics strategy[87]. Hence, the restriction broadens the scope of properties that may trigger the need for a restriction under REACH.

ECHA describes a range of associated (but not unambiguously demonstrated) adverse effects of microplastic particles, including: physical/mechanical hazards, (eco)toxicological hazards of the polymers, and the potential content of additives or environmental pollutants accumulating in the particle matrices. The available evidence is insufficient to conclude on the potential risks from microplastics, although ingestion and accumulation in the food chain are observed.

In the dossier, the uses of microplastics are described as well as the general release pathways to the environment, including their impact on the share of microplastics eventually reaching the environment (including e. g. elimination in wastewater treatment plants or incineration with solid municipal waste).

ECHA provides information from several sources about the occurrence of microplastics in different environmental compartments across the globe as well as forecasts of a continuous increase in exposure levels. In addition, for the marine environment, evidence quoted shows that current exposure levels have an adverse effect on marine organisms.

While the occurrence was not debated, the relevance of hazards was subject to extensive discussions with the stakeholders. Many interventions pointed out a lack of clear evidence of adverse effects, but ECHA found the persistence and irreversibility of the release of microplastics sufficient grounds for an unacceptable risk. As for other persistent substances, no PNEC was derived to demonstrate unacceptable risks.

Despite the uncertainties in supporting evidence, RAC agreed that the persistence of microplastics constitutes an unacceptable risk due to the build-up of an irreversible environmental stock.

Consequently, ECHA strongly follows the precautionary principle proposing regulatory measures in the absence of sufficient data to unambiguously demonstrate a risk. As a risk is probable even though there might be some uncertainty due to data gaps, the restriction aim is minimisation of emissions to prevent negative effects as far as possible in the future. This conclusion is shared by the RAC.

5.9.3 Assessment of alternatives

For each of the sectors where microplastics are used, the availability of alternatives was assessed and documented in the Annex of the restriction dossier. Alternatives were generally found to be available, though with different limitations regarding performance, costs and supply volumes as well as transition times to use them as substitutes. In some sectors alternatives are found to already be in use.

Generally, the use of alternatives has been of lower importance in the overall restriction proposal.

[87] See also COM/2018/028 final, A European Strategy for Plastics in a Circular Economy, https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516265440535&uri=COM:2018:28:FIN

5.9.4 Socio-economic assessment

The impact assessment was conducted according to sectors (and partly even at product group level) due to the many different applications of microplastics and the differences in availability of alternatives.

ECHA specified that it is not possible to quantify the benefits of the restriction, justifying a cost-effectiveness approach for the SEA assuming emission reduction is a good proxy for potential benefits. The cost assessment focuses on compliance costs (reformulation, changed raw materials, enforcement) as well as other costs such as market impacts due to loss of performance in certain technologies and the costs of unemployment. ECHA concluded the restriction would effectively limit emissions in a very cost effective way (23/kg per year ranging from €1/kg to €820/kg per year). While overall aiming at emission minimisation, exemptions are foreseen to enable continued use in some areas, in particular where release is considered controlled.

Besides several exemptions alleviating the impacts of the restriction, long transition periods are proposed to allow market actors adapting their products and processes to either substitute or control release.

Some market actors claimed the labelling and notification obligations as a disproportional burden especially for SME. Others generally found the efforts unjustified with a view to the by far larger proportion of unintentionally released microplastics. This was also addressed in the restriction dossier; however, as REACH can only address intended uses and the fact that other sources might be more problematic does not justify non-action. In addition, the restriction is complemented by other measures at EU level targeting the non-intended release implemented in the frame of the EU plastics strategy. The RAC stated that the estimated emission reductions are significant.

5.9.5 Overall evaluation in regard to the restriction process

The proposal to restrict microplastics is an example of an attempt to regulate a group of substances proven to be persistent and with indications of bioaccumulative and toxic effects based on precautionary considerations. Although the process is not yet finalised, it can be learnt from the example that:

- It is likely but cumbersome that extremely large groups of substances can be restricted, where the group is rather defined by physical parameter than by chemical ones.
- The acceptance that a risk is very likely if substances with environmental concerns are released to the environment for certain types of substances has increased over time (here substances with persistent properties, others may be persistent mobile and toxic substances (PMT) or endocrine disruptors).

The restriction may lead to a ban of microplastics from the market where a release to the environment is unavoidable, i. e. no exemption applies. Some examples are rinse-off cosmetics, agricultural goods like seeds or plant protection products[88]. It appears that alternatives are available and could be implemented with acceptable efforts. This is partly based on the assumption that alternatives do exist for applications, while in other cases there might not be alternatives available (yet) but a longer transition period should encourage the development of such. In some cases the low contribution to the overall emissions, while at the same time a high

[88] Fertilisers are excluded as the new EU regulation on fertilisers already has a rule that prevents the use of polymers that are persistent under use conditions.

benefit for society was discussed as a basis for granting exemptions as in the case for in vitro diagnostics.

6 Conclusions and recommendations

In the following, the main findings of the (limited number of) case studies and the literature review on the restriction process are summarised according to the core fields of interest of the study. At the end of the chapter recommendations are derived that could support overcoming the identified shortcomings.

6.1 Overall findings on the entire restriction process

The restriction process achieves its aims and continues to evolve

The approaches of drafting restriction proposals appear to converge with regard to the content and structure of (information in the) dossiers, the stringency of opinion forming and justification, and the handling of different situations, including the lack of possibilities to demonstrate risks for some hazards, or information gaps leading to uncertainties or triggering qualitative approaches.

The steps of the restriction process were found to fulfil their function in supporting the scrutiny of initial dossiers and improving the focus of a restriction as well as ensuring a good cost benefit ratio of envisaged measures. The opinion forming of the committees in combination with the consultation of stakeholders ensure that unwanted impacts of restrictions are avoided.

The simplified restriction procedure decreases some of the workload

Obviously, the simplified procedure according to Article 68 (2) requires fewer resources to demonstrate an unacceptable risk because this risk is assumed to exist by default for CMRs in consumer articles. The case studies showed that restrictions on CMRs in consumer articles via Article 68 (1) caused largely higher efforts although the use scenarios were similar.

6.2 Drivers of workload for the authorities

The scope of a restriction strongly influences the authorities' workload

In general, a broad coverage of substances and/or uses increases the efforts for data collection, demonstration of unacceptable risks, alternatives assessment and socio-economic analyses as well as dealing with stakeholder inputs during consultations. As part of the latter, possible exemptions may have to be discussed.

Narrow restriction scopes tend to allow a more specific information collection and hence efforts are lower to substantiate a proposal. In addition, narrow scoped restrictions appear to be more accepted and therefore less debated by the market actors. This is assumed to be partly due to a lower number of affected stakeholders, a better understanding of the restriction and a clearer concern the restriction aims to address.

A comparison and evaluation of the authorities' efforts to restrict a substance would require matching the efforts with the restriction result. A broad scope requiring a high resource input may be justified if also the risk reduction is high but would not be justified for marginal risk reductions. Such efficiency evaluations were not part of the current study but would be useful to get a complete picture.

In any case, the decision about the scope of a restriction is driven more by the available knowledge and the expected impact than the efforts needed to compile a proposal.

Demonstration of unacceptable risks was observed as resource intensive

The case studies show that the efforts for dossier compilation and opinion forming also depend on the need and abilities to demonstrate a risk and its unacceptability. Relevant drivers are:

- If a group of substances is subject to a restriction, the complexity of the group and the related efforts to justify the grouping (see especially PFOA)
- The hazardous property that is responsible for the risk (e. g. perfluorinated silanes, NP/NPE), which may range from a hazard that is defined via harmonized classification (low effort) to a hazard requiring a case-by-case assessment of a non-standard concern (e. g. PMT, endocrine disruption)
- The need to describe the consequences from continued use, in particular, for environmental relevant substances (PBT/vPvB, ED only P?)

The dossier submitters were observed to invest significant resources in the demonstration of an unacceptable risk. In cases where the risk cannot be well substantiated, this may lead to extensive discussions at the level of ECHA, RAC and SEAC, and possibly to revision needs by the dossier submitter.

This was especially due to extensive compilations and evaluations of hazard information and the related review by the RAC and stakeholders. However, for environmental hazards with a low or non-existing effect threshold (e. g. PBT/vPvBs, EDCs) fewer resources were invested because only qualitative risk assessments were generated due to the lack of a suited methodology to quantify effects. A tendency to use qualitative generic approaches to demonstrate the risk and accept an approach of 'minimising emissions' can be observed over time.

Detailed technical and market information is not available to the authorities

Authorities lack detailed information from the economic operators on technical and market issues necessary to compile a restriction dossier. This pertains specifically information on the substance's uses (in products) and key economic figures, as well as information on the availability and feasibility of alternatives. Closing these information gaps requires high efforts from the authorities.

Efforts for socio-economic assessments appear to decrease

Overall and over time, the efforts to compile a detailed SEA appear to have decreased. In the more recent proposals, dossier submitters tended to focus their cost assessments on only the main cost drivers and provide semi-quantitative information if data was insufficient for a full quantification. It seems that the provision of cost-effectiveness assessments is increasingly accepted in cases where damage/benefits cannot be quantified, e. g. for PBTs/vPvBs or EDCs. Here, the emission reduction is used as a proxy for benefits, and costs are evaluated against the achievable emission reduction.

Late introduction of exemptions causes extra work

When drafting restriction proposals, authorities frequently have insufficient information to assess whether or not an exemption from the scope is necessary. It is one of the tasks of the public consultations to ensure specific exemptions are considered. However, as the opinion forming of RAC and SEAC is already and advanced discussion stage this is very late in the process. Sometimes exemptions are introduced even shortly before the Commission's decision making. As a consequence, there is little time for the committees to thoroughly assess the justification and information gap to a high level of uncertainty regarding justification of the requested exemption. Additional resources are needed to (re-)assess partial risks and impacts[89] at the end of the opinion forming process. Additionally, such late exemption requests may delay

[89] This can be triggered, for example, by the fact that according to Article 77(c) the ECHA executive director requests the SEAC to consider further information on possibly necessary exemptions.

the COM's decision-making due to controversial discussions on the justification of the exemptions and a lack of a clear opinion.

6.3 Duration of the restriction processes

The main reason for delays are the REACH committee's and the COM's decision making

The case studies show that the time between the start of drafting a restriction proposal until the opinions are formed is comparatively stable. The timelines of the individual steps are met so that the processing of a dossier from the announcement of the intention to the finalisation of the RAC/SEAC opinions takes between about 40 – 50 months[90].
Delays mainly result from the long decision-making processes in the REACH committee and by the COM (normally about one year, with an observed maximum time of 2-3 years).
No analysis of the duration of restrictions under the marketing and use restrictions directive was performed in the study. However, with a view to the total duration of more than 52 months of the 'quickest cases', one may wonder whether the goal of enacting new restrictions more quickly has been achieved. The considered case of CMR in textiles, which follows the simplified procedure, was only marginally shorter at 46 months. However, it should be noted that the restriction proposal had a very broad scope, which led to lengthy discussions. In addition, only a few cases have been treated using the simplified procedure and that a relatively complex procedure was carried out to determine which substances should be covered by the restriction. Here it can be assumed that with increasing experience, the simplified procedure can lead to a further reduction of the time periods until a new restriction is issued. While the time for developing and scrutinizing a restriction proposal are found appropriate and needed, the time needs for the decision making appear to be an opportunity to speed up decision making.

Late exemption requests delay the COM's decision making

As discussed in Section 6.2, late exemption requests not only increase the authorities' workload but may also significantly delay the decision making by the COM.

6.4 Choice of the restriction procedure as regulatory measure

Due to a higher acceptance, restriction proposals complementing authorisations can be processed comparatively easily

Especially restrictions addressing SVHCs in imported articles that require authorisation are welcomed rather frequently than contested. Such restriction proposals were observed to trigger fewer discussions among the stakeholders, because they support a level playing field on the EU market and because the existence of an unacceptable risk has already been 'agreed' on in the authorisation process. In addition, such a restriction proposal might have a relatively narrow scope and therefore affect a low number of market actors thus resulting in fewer controversies. Consequently, such restrictions appear to be justified as 'low hanging fruits' with the opportunity of risk management with low efforts.

Restriction is well suited and the preferred regulatory measure to address consumer risks

The assessed cases indicate that consumer risks are most frequently addressed by restrictions, i. e. bans of substances or products from the EU market.

[90] Differences essentially arise from the final submission of the Annex XV dossier.

As the restriction procedure is more flexible for managing occupational risks, it may be possible to find regulatory conditions that are acceptable and balance protection and economic impacts

A variety of possible measures exists to manage occupational risks. Next to a complete ban on a use, the implementation of particular (risk reduction) measures at the workplace could also be defined in a restriction that would apply in the same, and hence harmonised, way across the EU. This is not possible under workers protection legislation, as it consists of directives that require transposition in the Member States and would allow interpreting any conditions at EU level differently for the national implementation.
Some of the assessed restriction proposals are innovative in this regard, like the implementation of a legally binding DNEL in combination with the appropriate guidance how to comply with the DNEL and the introduction of training as a measure to limit the exposure of workers[91].
In principle occupational risks can be limited by the following conditions of a restriction:

- Ban: A substance as such, in mixtures or in articles may not be placed on the market or used in the EU.
- Minimisation in mixtures or articles: The concentration or the release of a substance is limited in (certain) mixtures or articles.
- Harmonised technical measure: Quality-assured, harmonised technical measures are to be implemented across the EU when a substance is used.
- Harmonised training: Quality-assured, harmonised and specifically tailored risk reduction strategies are implemented across the EU, such as obligatory training material for employers and employees (cf. diisocyanates case).
- Harmonised limit values combined with safety measures: Binding and harmonised limit values for the occupational setting are prescribed for use in chemical safety assessments and derive RMMs at the workplace.

6.5 Availability and need for information

Use and exposure information is essential but usually not available

The lack of use and exposure information hinders a proper scoping of a restriction proposal, the demonstration of unacceptable risks, the assessment of alternatives as well as the socio-economic analyses. Therefore, this information is essential for any restriction proposal. However, the case studies and the literature review showed that exactly this information is frequently not available to the authorities and that high efforts are needed just to get basic data. The public consultations during the discussion of the restriction dossiers in RAC and SEAC, which are intended as an instrument to close information gaps, were observed as no significant contribution to closing these gaps. In the analysed cases, the lack of use and exposure information resulted in uncertainties about the appropriateness of a restriction scope as well as potential increases in efforts of the overall restriction process.

Available information on alternatives is often very basic

Most of the analysed restriction dossiers contained at least generic information on alternatives. However, the dossier submitters frequently lacked details on the technical performance, the prices of alternative products as well as on the wider impacts of a potential need for

[91] It has to be mentioned that the decision on this proposal is still pending and the COM has instead instructed ECHA to start the development of an EU-wide occupational exposure limit (OEL) so it can be concluded that such the approach proposed has no clear support.

substitution. The latter may include process changes, the need to reformulate mixtures or redesign articles, leading to possible losses in the performance. This lack of information resulted in uncertainties about the potential reaction of market actors on a restriction and hence, the results of the socio-economic analysis.
However, the level of information detail provided in the dossiers reviewed in the case studies appeared reasonable and sufficient to support decision-making. This was further supported by the pragmatic approach of RAC and SEAC to the assessment of alternatives (cf. next Section).

Vague justifications of exemptions cause a high level of uncertainty

As RAC and SEAC have limited information to review an exemption request and develop their opinions, such requests are usually approved by the committees despite uncertainties about the actual need. Due to the uncertainties, the exemptions are time-limited, with reporting requirements based on which the justification for the exemptions is to be reviewed after the time limit has expired.

6.6 Role of the Committees

Improved assessment approaches of RAC and SEAC increased the transparency and the efficiency of the restriction process

Over time RAC and SEAC developed and improved their evaluation methods, formats and argumentations. This applies in particular to dealing with information gaps and uncertainties. This resulted in a more stringent, efficient and structured opinion forming process that also makes it easier for the stakeholders to understand the opinions and react to them. Further improvement on the operation of the committees is expected as a result of the restriction task force[92].

The changes in initial scope caused by RAC and SEAC opinions facilitate the further restriction process

RAC and SEAC activities may result in adjustments to the scope of the restriction proposal during the process. This only pertains to narrowing the as its broadening would not ensure sufficient participation of the interested stakeholders at this stage of the evaluation.

The modifications in the restriction scope were partly due to information provided by the stakeholders and partly due to independent considerations by the RAC and SEAC. The changes in scope concerned the coverage of substances, the coverage of uses and exemptions as well as the conditions of a restriction (or exemption), such as the threshold limits. The reasons for the changes included a need for clarification (understanding), practicability (enforcement, compliance monitoring) and essential uses (exemptions due to lack of alternatives).

The Committees' pragmatic approach towards alternatives saves resources and time

In cases where alternatives were already in use for the to-be-restricted substance, RAC and SEAC pragmatically assumed these alternatives available, and therefore considered 'substitution' as an important (or the only) market reaction to a restriction. When it could not be fully confirmed whether alternatives were available, the committees assumed the share of applications, where substitution could happen as well as possible other market reactions. This pragmatic approach was established over time in the various opinion forming processes of RAC and SEAC.
According to the case studies and the literature review, qualitative approaches were accepted to

[92] See ECHA (2018) Recommendations of the Task Force on Restriction Efficiency https://echa.europa.eu/documents/10162/13641/report_task_force_on_restriction_efficiency_en.pdf

a greater extent in the field of the alternatives assessment than for other parts of a restriction proposal. Only in the discussion of exemptions, more in-depth information on alternatives seems to be necessary (and is requested) to enable conclusions on the proposed restriction.

6.7 Motivation of stakeholder involvement

Stakeholders - especially the economic actors – are important players in the development of restriction proposals and should have an interest in providing their input. However, it appears that this is not yet happening to a sufficient extent. The following two aspects were observed during the study.

A broad scope incentivises more stakeholder involvement than a narrow one

Defining a broad scope of a restriction regarding the coverage of uses is an option to overcome information gaps by shifting the burden of proving that a risk is (already) controlled or that uses are critical/need longer transition periods to the market actors. It prevents long data collection by the authorities and incentivises the involvement of stakeholders as they aim to prevent their uses being covered by a restriction.

The possibility for late exemption requests discourages (early) stakeholder involvement

It was observed in the case studies that stakeholders were most strongly involved during the later consultations, especially if they wanted to request an exemption. This involvement, although valuable due to additional information being provided, came at a time where changes caused significant efforts and/or could not be scrutinised as thoroughly as other aspects of a restriction proposal.

6.8 Recommendations

Overall functioning of the process

From an overall view, the restriction process is well-designed to achieve the aim of reducing unacceptable risks from the use of chemicals. The various activities to streamline the process conducted by all involved actors are implemented in current practice and work routines have been established. These trends are likely to continue and there are no obvious improvement options identified in this regard.

- Therefore, it is recommended **not to make any fundamental changes** to the restriction procedure.

Duration of the process

The duration of the restriction procedures was found to be long but with little potential of shortening without losing quality in the decision preparation and hence efficient and effective risk reduction. The only option identified was the decision making of the REACH committee and the COM, which appears to be inappropriately long. Therefore, it is recommended to

- **Define legally binding deadlines for the decision-making by the COM and the REACH committee**. A time of 6 months appears to be appropriate and proportionate compared to the time RAC and SEAC have to develop their opinions.

Workload of authorities

The workload of the authorities to prepare, scrutinise and decide on a restriction varies depending on many factors, including the type of substances, the availability of information, existing regulation, and the scope of the restriction etc. In order to significantly reduce the workload and make the restriction process more efficient it is recommended to

- **Introduce a simplified procedure to address substances** with hazards **other than CMR** and for which a generic exposure assessment indicates a risk.
  This could be the case for PBTs /vPvBs found in the environmental compartments and/or biota indicating emissions and exposures potentially causing risks. Also endocrine disruption in the environment may be a property rendering a substance suitable for a simplified procedure.

Hence, the project findings support the respective approach of the recently published Chemicals Strategy for Sustainability[93]. However, while the Strategy suggests the simplified procedure for consumer products, a simplified approach also appears justified for environmentally hazardous substances from widely distributed diffuse sources.

- **Streamline the demonstration of unacceptable risks and justification of a restriction in Annex XV dossiers** for substances with hazards with low or missing threshold values. Slim and partly qualitative approaches to the alternatives assessment and the socio-economic analysis may be sufficient and are broadly accepted to support the argumentation of proportionality and effectiveness of measures. For example, the 'emission minimisation approaches' and cost-effectiveness assessments frequently are sufficient. The existing methods and indications of when they are appropriate should be elaborated for transparency and consistency reasons in the guidance document on restriction dossiers.

Lack of information

Information on uses and exposures are essential to develop, target and substantiate a restriction. Hence, if authorities lack this information, the efficiency and effectiveness of a restriction is likely to decrease. If the registrants had better use information in the first place, the chemical safety assessments and recommendations of safe conditions of use could work properly, potentially making restrictions superfluous. Therefore, it is recommended to improve the information basis on uses and exposures of substances to:

- Further develop, improve and establish **approaches to deal with data gaps** and related uncertainties. Pragmatic approaches and reasonable assumptions may be sufficient to evaluate and decide on restrictions, as was observed in the opinion forming of RAC and SEAC. With a view to increased precaution, data gaps may have to be accepted for the sake of (quicker) regulation. Finding (standardized) handling of gaps and uncertainties could be the cost-efficient solution, at least in case where basic data exists and/or more information would not significantly change a decision outcome.

- Implement a **right** for authorities **to request** use and exposure **information** as well as relevant socio-economic data from market actors **and an obligation** of these **to respond** within an appropriate time frame during a regulatory risk management process. While this approach appears generally viable, targeted questioning is only possible if the relevance of an application is clarified. Completely unknown uses would still not be identifiable. A better coverage of such unknown uses could be achieved by a notification requirement extended to further substances properties in analogy to the REACH Articles 7 and 33 or ECHA's database on substances of concern in products (SCIP) established under the Waste Framework Directive.

- **Consider restrictions with broad scopes regarding uses** especially to address risks from unclear emission sources/uses. If no or only little information is available on uses and

[93] COM(2020) 667 final: Chemicals Strategy for Sustainability Towards a Toxic-Free Environment https://ec.europa.eu/environment/strategy/chemicals-strategy_en

exposures, a broad restriction scope would enable addressing all of them. If communicated early in the process, such broad scope might incentivise stakeholders to provide relevant information without a legal obligation because they intend to be exempted or influence the restriction's condition.

Combine a broad restriction scope with an **obligatory early time window for submitting exemption requests as a unique opportunity to do so,** i. e. during the dossier preparation period, directly after the announcement in the ROI. This would make stakeholders wanting to prevent regulation provide information and it would allow the authorities to thoroughly assess the request when defining the restriction scope. The exemption requests should be accompanied by defined types of information (e. g. comparable with an application for authorisation) that justifies the deviation from a proposed non-use scenario. Such obligation also would help to avoid time constrains for the evaluation of exemption requests in the RAC/SEAC and enable them to collect additional information, if necessary. The subsequent public consultation could then be used to fill in selective information gaps and gather opinions on the requested exemption.

7 Literature review on the restriction process

Table 14: List of studies assessed in the literature review

Study title	Link to the report
Technical assistance related to the extension of the obligation of a CSA /CSR for CMR 1A/1B substances < 1-10 tonnes per year	http://ec.europa.eu/environment/chemicals/reach/pdf/1-10t%20P2%201-10t.pdf
Study on the impact of REACH on innovation, competitiveness and SMEs	http://ec.europa.eu/growth/sectors/chemicals/reach/studies_en
Evaluation of ECHA	http://ec.europa.eu/docsroom/documents/24301
REACH-Review report EU-Commission 2017/2018	REACH-Review report EU-Commission 2017/2018
ECHA Report on the operation of REACH 2016	https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf
ECHA: General report 2016	https://echa.europa.eu/documents/10162/23133404/mb-45_general_report_2016_en.pdf/799e7f88-78e1-13a4-b4e0-86f3b172214a
ECHA: General report 2017	https://echa.europa.eu/documents/10162/21877836/general_report_17_en.pdf/953322a8-793c-636a-c251-fdbee96249e1
ECHA: Evaluation Progress Report 2016	https://echa.europa.eu/documents/10162/13628/evaluation_report_2016_en.pdf/f43e244f-7c90-75bd-e1b2-3771bcb1f8e8
ECHA: Evaluation Progress Report 2017	https://echa.europa.eu/documents/10162/13628/evaluation_under_reach_progress_en.pdf/24c24728-2543-640c-204e-c61c36401048
BMWi: Forschungsprojekt REACH nach 2018	https://www.bmwi.de/Redaktion/DE/Publikationen/Studien/reach-nach-2018-gesamtbericht.html
ECHA: Assessment of the current substance evaluation process under REACH	https://echa.europa.eu/documents/10162/13628/sev_survey_2015_en.pdf
PBT – Quo vadis? Prüfung und Fortschreibung des PBT-Bewertungskonzepts zur Identifizierung von Umwelt-SVHC. FKZ 3715 65 415	https://www.umweltbundesamt.de/publikationen/pbt-quo-vadis-examination-and-further-development
Schenten, J., Führ, M. 2016: SVHC in imported articles: REACH authorisation requirement justified under WTO rules, Environ Sci Eur (2016) 28:21, DOI 10.1186/s12302-016-0090-9;	https://enveurope.springeropen.com/articles/10.1186/s12302-016-0090-9
Projekt „Stärkung der Regelungen für (Import-) Erzeugnisse in der Chemikalienverordnung REACH“	https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_40_2015_staerkung_der_regelungen_fuer_import-erzeugnisse_in_reach.pdf
Restricted Success EEB’s appraisal of restriction under REACH	https://circabc.europa.eu/sd/a/e1cfbd29-7435-4db5-bef5-c93b78d08c2d/21%20-%20Agenda_point_10_2_restricted_success_EEBs_appraisal_restriction_under_reach.pdf

Study title	Link to the report
COMMISSION STAFF WORKING DOCUMENT on the REPORT FROM THE COMMISSION in accordance with Article 117(4) REACH and Article 46(2) CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(3) and 138(6) of REACH	http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0049
Workshop on the implementation of ECHA´s integrated regulatory strategy. Proceedings. 28 February - 1 March 2017	https://echa.europa.eu/documents/10162/13628/regulatory_strategy_workshop_2017_report_en/2dafd9be-74ab-d154-a305-cb79113f8328
A roadmap to revitalise REACH, EEB	https://eeb.org/library/a-roadmap-to-revitalise-reach/
IDENTIFYING THE BOTTLENECKS IN REACH IMPLEMENTATION	https://www.documents.clientearth.org/wp-content/uploads/library/2012-10-01-identifying-the-bottlenecks-in-reach-implementation-coll-en.pdf
ECHA (2020) Recommendations of the Task Force on Restriction Efficiency	https://echa.europa.eu/documents/10162/13641/report_task_force_on_restriction_efficiency_en.pdf/68ba2a4f-5c93-4b55-a061-b69fd2795a21