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Final report

# Assessment of the Authorisation Process under REACH

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On behalf of the German Environment Agency

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**Abstract: Assessment of the Authorisation Process under REACH**

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

The study analysed all steps of the authorisation processes with the aim of identifying options to increase the effectiveness and efficiency of the process. Based on a literature analysis and an assessment of example cases, it is concluded that the aims of authorisation are generally achieved. Nevertheless, several improvement options are identified amongst others regarding the selection of the process as risk management option, the availability of use information or the time-lines for processing and decision making on an application for authorisation.

**Kurzbeschreibung: Überprüfung des Zulassungsprozesses unter REACH**

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

In dieser Studie wurden die Schritte des Zulassungsprozesses mit dem Ziel der Identifizierung von Optionen, die Effektivität und Effizienz des Prozesses zu erhöhen untersucht. Aus den Ergebnissen einer Literaturstudie sowie von Fallbeispielen wird geschlossen, dass die Ziele des Zulassungsverfahrens insgesamt erreicht werden. Dennoch wurden verschiedene Möglichkeiten, den Prozess zu optimieren herausgearbeitet, u.a. bezüglich der Auswahl des Prozesses als beste regulatorische Maßnahme, der Verfügbarkeit von Verwendungsinformationen sowie der Zeitläufe für die Bearbeitung und Entscheidungsfindung über Zulassungsanträge.

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| | |
|---|---|
| **ADCA** | C,C'-azodi(formamide) |
| **AfA** | Application for Authorisation |
| **AoA** | Analysis of Alternatives |
| **CARACAL** | Competent Authorities for REACH and CLP |
| **CLP** | Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 |
| **CMR** | Carcinogenic, mutagenic and toxic to reproduction |
| **COM** | European Commission |
| **CSR** | Chemical safety report |
| **CTAC** | Chromium Trioxide REACH Authorization Consortium |
| **DBP** | Dibutyl phthalate |
| **DEHP** | Bis(2-ethylhexyl) phthalate |
| **DNEL** | Derived No Effect Level |
| **DU** | Downstream User |
| **EC** | European Commission |
| **ECHA** | European Chemicals Agency |
| **EDs** | Endocrine Disruptive |
| **EEC** | European Economic Community |
| **EIoC** | Equivalent Level of Concern |
| **EPS** | Expanded polystyrene |
| **ES** | Exposure Scenario |
| **HBCDD** | Hexabromocyclododecane |
| **HDDA** | Hexamethylene diacrylate |
| **MoA** | Mode of Action |
| **MS** | Member states |
| **MSCA** | Member State Competent Authorities |
| **No.** | Number |
| **NPEs** | Nonylphenol ethoxylates |
| **OC** | Operational Conditions |
| **OPEs** | Octylphenol ethoxylates |
| **PACT** | Public Activities Coordination Tool |
| **PBT/vPvB** | Persistent, Bioaccumulative and Toxic/ very Persistent, very Bioaccumulative |
| **PFOA** | Pentadecafluorooctanoic acid |
| **PMT** | Persistent, mobile and toxic |
| **PNEC** | Predicted No Effect Concentration |

| | |
|---|---|
| **PPORD** | Product and Process Orientated Research and Development |
| **PPP** | Plant Protection Products |
| **PVC** | Polyvinyl chloride |
| **RAC** | Committee for Risk Assessment |
| **REACH** | 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 |
| **REEG** | REACH Exposure Expert Group |
| **RiME** | Risk Management and Evaluation platform |
| **RMM** | Risk Management Measure |
| **RMOA** | Regulatory Management Option Analysis |
| **SDS** | Safety Data Sheet |
| **SEA** | Socio-Economic Analysis |
| **SEAC** | Socio-Economic Analysis |
| **SR&D** | Scientific research and development |
| **STOT** | Specific target organ toxicity |
| **SVHC** | Substances of Very High Concern |
| **WHO/IPCS** | World Health Organization/International Programme on Chemical Safety |

## Summary

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

The project "Advancing REACH" consists of 18 sub-projects, which discuss different aspects of (the implementation of) the regulation and related improvement options. Topics of the sub-projects are the REACH processes dossier evaluation, substance evaluation, restriction, authorisation and consultation, as well as the role of the board of appeal and the interplay of the processes. In addition, the relation between REACH and sustainable chemistry, the 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.

**Introduction to this report**

An analysis of the authorisation process under Regulation (EC) No 1907/2006 (in the following referred to as REACH) is provided with this report. Authorisation under REACH was introduced as a new legal instrument to reduce risks that originate from the use of Substances of Very High Concern (SVHC) in the EU by a stepwise elimination of such substances from the market as far as possible, with the option to grant temporary specific exemptions based on individual applications. The chemicals legislation before REACH did not comprise a similar process.

The aim of the analysis was to investigate the efficiency of the authorisation process with regard to the aims defined in the REACH text: The ultimate goal of authorisation is the eventual phase-out of SVHCs and, if this is technically and economically not feasible, to minimise the risks originating from their use. A special focus is set on the impacts of the authorisation process on the workload of authorities.

The analysis covers all steps of the authorisation process from the identification of SVHCs over the recommendation issued by the European Chemicals Agency (ECHA) that prioritises substances from the candidate list for an uptake onto the Annex XIV of REACH to the application for authorisations (AfA), and the processing of AfAs until the decision on granting an authorisation. Furthermore, additional processes that have been established to improve the REACH implementation and particularly the authorisation process are included in the assessment. This covers the regulatory management option analysis (RMOA) and the screening for substances that might qualify for the authorisation process.

The following questions are addressed:

1. Is the general aim of the REACH authorisation accomplished? How can the effectivity and efficiency be increased?
2. What are the main drivers that determine the workload during the identification of SVHCs, the prioritisation and the processing of the AfAs, including the preceding informal steps?
3. Are there possibilities to reduce the workload caused by the individual steps?
4. Is the prioritisation approach introduced by ECHA useful, in principle? Should further criteria be developed or additional actors be included in the process?
5. How can the speed of the individual procedures be increased?

Efficiency in this regard is also understood, as the "best way to achieve the aims" of authorisation with the investment of the given resources of member state competent authorities (MSCA) and the European Chemicals Agency (ECHA).

**Methodology**

The present study comprised an assessment of the REACH text itself, related studies and reports (e.g. from ECHA or prepared for the REACH Review) as well as an analysis of past examples in form of case studies for SHVC identification and AfAs. For all case studies publicly available documents, in particular Annex XV Dossiers, RMOA outcome documents, background reports on substances or groups of substances and the response to comments documents were analysed. For the AfA case studies also draft and final opinions of the committees, public AfA documents, and comments from public consultations were analysed.

Ten case studies were analysed with regard to the effectiveness and efficiency of SVHC identification and to exemplify potential shortcomings or achievements of the current SVHC identification. The case selection considered that the following should be represented:

- various hazard end points linked to Article 57 a-f
- substances with multiple SVHC endpoints
- at least one substance group
- "special situations" understood as: substances with impurities (Basic Violet), substances that qualify as SVHC based on the degradation products (OPEs)

Furthermore, another ten case studies were analysed with regard to the effectiveness and efficiency as well as workloads and improvement potentials related to the processing of AfAs.

The cases should cover various types of AfAs and the following was considered in their selection:

- AfA decisions exist, i.e. cases are already finalised
- Different risks are covered (occupational, consumers, environment). However, as only completed cases were assessed, occupational aspects are overrepresented because only few cases addressing other risks at the time of the assessment
- Both upstream and individual applications are covered (also in comparison)
- Coverage of bridging applications, where alternatives are already known
- Different types of risk levels are represented, e.g. low tonnage, controlled conditions

Furthermore, some exceptional situations were included in the examples, e.g. the "Roche Diglyme AfA, which covers a new production installation.

**Conclusions and recommendations**

The conclusions and recommendations on the possible improvements of SVHC identification and authorisation procedures are compiled according to the research questions.

**(1) Is the general aim of the REACH authorisation accomplished? How can the effectiveness and efficiency be increased?**

In general, the current study indicates that the overall aims of the authorisation have been achieved. The procedures are established, functioning and regarded a significant driver for a phase-out of substances. This is true for SVHCs on the candidate list[1] as well as substances listed in Annex XIV, i.e. subjected to authorisation.

Although it is very difficult to quantify the effect of authorisation on substitution, it is evident that awareness on SVHC increased and market actors tend to avoid such substances if possible. For a relevant number (currently 22 out of 54) of substances, no or only few AfAs have been submitted, which indicates that these are of no or low relevance for the EU market. This can have different reasons:

- Substances could be easily substituted
- Substances are still in use outside the EU and former EU production has shifted to non-EU countries. In these cases there even might be the potential that substances still enter the EU market in articles or in mixtures below certain threshold limits
- Substances already had no relevance before they were regulated and regulatory action was based on insufficient information.

However, it is not clear if this was already the case before the authorisation requirement under REACH. To the authors' knowledge no reports exist that could clarify the reasons for this inaction (no applications), hence it remains unclear if the authorisation requirement was very effective (triggering substitution very effectively) or has been very ineffective (investment of large bureaucratic burden for preparatory steps of an authorisation requirement, without triggering a substantial change in risks from chemicals).

On the other hand there are substances for which very many AfAs have been submitted or where a large number of DUs are covered. Only some of these AfAs indicate a substitution aim in the short- or mid-term. The gained value of these applications would be the increased risk management until the use is ended. Risk management consists of the measures described in the ESs and any potential additional measures defined in authorisation decisions, which become mandatory and EU wide harmonised standards for the substance use. Nevertheless, it can also be discussed if such an effect would also be achievable with other measures, such as e.g. restrictions.

The RMOA is a valuable instrument that can help to anticipate whether or not the aim of authorisation can be achieved for a particular substance and the market functioning be ensured at the same time (in the most effective way). To increase the efficiency of RMOAs in depth information on substance uses would be needed but is frequently missing, which hinders getting a clear picture of the implications of a measure. Furthermore, information on alternatives and market impacts are scarce and limit the possibility for authorities to decide on a measure. Measures to overcome this lack of information could cover stakeholder voluntary commitments to provide this type of information. However, experiences show that such processes often do not close all data gaps. A legally binding mechanism for authorities to request the information might be a better solution to overcome information shortcomings at an early stage of the strategic selection of a suited regulatory approach.

[1] See also DG Growth (2017) Study on the Impacts of REACH Authorisation

In contrast to the lack of use information, substance property data from registrations and evaluations is usually better to identify substances as SVHC. This is especially true if substance properties correspond to CLP classifications categories and can be subjected to harmonised classifications. However, for some properties (e.g. endocrine disrupter for the environment (ED ENV)) data become only available after time/effort-consuming requests during a substance evaluation since these data are not part of the standard information to be provided with the registration. Here an extension of the information requirements might help to reduce the efforts for authorities when evaluating the hazardous properties of a substance. ECHA's screening processes and the increasing efforts to use grouping approaches support the identification of substances that might qualify for an authorisation and might also support the prevention of regrettable substitutions.

A problem identified in AfAs is the evaluation of assessments of alternatives (AoAs). Applicants mainly argue that alternatives are not available and often it is highly uncertain whether or not alternatives are on the market. The complexity of an assessment of alternatives is certainly dependant on the "type" of alternative, i.e. whether a very similar "drop in" substance, a different substance which requires completely different technical installations, or also different (non-chemical) technical solutions are under consideration. As REACH requires the applicants to describe the alternatives and the potential to introduce them, certain problems arise:

- In upstream applications mainly alternatives for DUs are discussed and it is difficult to transfer respective knowledge from them to the applicant's AfA. Hence knowledge transfer needs to be improved.
- Some DUs are in fact just "substance users" (but still potential applicants of an AfA). Such users (often SME) lack background knowledge on alternatives on the expected scientific level and cannot fulfil the authorities' expectations regarding the knowledge on alternative processes.
- Some market actors have unrealistic expectations on their ability to use alternatives. For example, an operator of a specific installation will not be able to change to an alternative unless it is a drop-in chemical that works within the same installation. From the user's perspective other alternatives are only a theoretical option.

In such situations, applicants may not be able to provide realistic in-depth assessments of alternatives and the benefit of such analyses for the overall application is questionable. One way forward could be to assess alternatives on an overarching level by authorities. Still, information has to be compiled and communicated from alternative providers and users. As information on alternatives is relevant to decide on the best regulatory option and the design of a later regulatory measure, the RMOA may be an appropriate process for this. Based on this information, use-specific sunset dates could be considered to encourage substitution and to avoid further AfAs as far as possible. This might lead to an overall increase of the efficiency of the authorisation and enhance substitution instead of authorisations.

**(2) Drivers of the authorities' workload for authorisations**

Overall, the main driver of the authorities' workload in all steps of the authorisation is the lack of information on uses and alternatives as well as on the socio-economic impacts of a non-use scenario.

Information on uses, alternatives and socio-economic impacts are needed in any decisions. They are most important to support the RMOA, the evaluation of AfAs, and for prioritisation, the latter

with lower importance. Currently, no process exists for authorities to collect that information from the market actors, apart from the authorisation decision itself. Here, the conditions of an authorisation may require DUs at the end of the supply chain to report the implemented operational conditions (OCs) and risk management measures (RMMs) as well as exposure levels, thus improving the information for a stronger fact-based evaluation at the time of reviewing the authorisation. If authorities want to obtain this information earlier, currently the only option is to invest own resources and start research activities, such as making measurements, starting surveys or contacting stakeholders.

In contrast, the SVHC identification exclusively concerns substances properties. The process may be burdensome, when the information basis is not clear e.g. information is missing, there is disagreement about the interpretation of data or case-by-case evaluations need to be prepared. This is in particular the case for substances identified under Article 57 (f), where data often do not yet fall under standard data requirements compared to the other SVHC criteria under Article 57 a-e. The decision process itself is well-structured and can usually be finalised in the foreseen time frames. The decision on the SVHC often follows a harmonised classification and pre-discussions among experts in the RIME+, expert groups and the CARACAL, where disagreements between MS can be solved a priori.
In addition to the assessment of data and preparation of the dossier, the number and quality of comments provided in the public consultation is the main determinant of workload for SVHC identification because the authorities need to answer and transparently document their replies to all submissions in a RCOM.

One key driver determining the workload in the authorisation of a particular substance is the number of submitted AfAs and their complexity, especially when upstream applications are submitted. It should be highlighted that upstream applications are an instrument to implement harmonised OCs and RMMs across entire sectors. Therefore, those uses are clearly distinguished in order to clarify which market actors are covered and what measures should be enforced. The authorities benefit from upstream applications because they reduce the number of applications for one substance and because they can be handled relatively easily if a limited number of uses is covered in one application. To optimise the effect of upstream applications, further improvement of the instrument is needed, for example in the form of guidance.

**(3) Reducing the workload for the individual authorisation steps?**

Since the authorisation process entered into force, standards and guidance have been developed to support the implementation of the individual authorisation steps, which reduced the workload of all actors.

The workload for SVHC identification is determined by the available evidence to demonstrate an SVHC property. The initiated measures seem suitable to increase the process efficiency, although this does not automatically decrease the authority's workload:

- **Grouping** allows discussing several substances that
  - follow the same MoA and cause similar effects and/or
  - may be used as alternatives to each other or for other substances on the candidate list.

  While the first aspect can lead to more focussed work and therefore increase the efficiency of SVHC identification by including similar argumentations into one Annex XV dossiers. The second aims at increasing the overall effectiveness by preventing substitution of one substance by a structurally similar one with comparable properties.

- **Property specific expert groups** discuss standards and criteria how a particular SVHC property can be demonstrated in case the standard set of criteria cannot be applied and a stronger case sensitive weight of evidence approach is needed. Here the development of guidance and exemplifying case studies are important elements to establish a standard that is widely accepted by MSCAs and thereby defines the minimum data set sufficient for the demonstration of SVHC properties.

The authorities' workload for evaluating AfAs (also) originates from insufficient information provided in the Chemical Safety Report (CSR), the AoA, or the SEA because RAC and SEAC often take an active role to improve the assessments. REACH places the burden of proof onto the market actors who want to continue a use. One can argue that the committees automatically participate in developing the argumentation of the AfA when discussing the suitability and availability of alternatives or adjusting economic impact considerations of non-use and continued use scenarios, for example. However, active information collection and assessment go beyond evaluation. Rules and quality standards that limit these activities should be established that allow RAC and SEAC to reject low quality proposals. This should especially be the case, when the committees would need to invest resources to generate own additional information.

An exemption is the derivation of overreaching reference values for the risk assessment (margin of risks). Such harmonised reference values for the quantification of the risk would support the objectivity of the assessment and reduce the workload for the evaluation of many individual argumentations on the adequate reference level. Furthermore, defining safety thresholds can be considered as an authority responsibility. A similar role could be assigned to a list of reference alternatives that defines the minimum scope of an AoA and provide basic information on the alternatives as input to the assessment. This may assist committees to initiate conditions or to reject AfAs. Reference values can also be used to define a margin of risks level which if exceeded leads to rejection or shorter review periods – margins should be regardless of the potential economic benefits for the company or the supply chain.

If the committees revise an applicant's argumentations one could discuss whether a full quantitative reassessment is needed or if qualitative discussions are sufficient to understand the changes and to draw conclusions. A qualitative approach can even more be justified in cases where the overall argumentation is not significantly changed, when certain costs are corrected but the order of the magnitude is not changed and other costs exceed them by far[2], for example.

Cut-off criteria for certain conditions in an AfA could be developed to simplify the application and its evaluation. These could concern the emission or exposure levels of an SVHC in a use but also particular cost-benefit relations in SEAs or be qualitative and refer to protection goals, for example. It should be discussed if such criteria could be developed, also to the uncertainties of assessments, especially in the area of the SEA and the suitability of alternatives. This might also reduce the strong focus of AfAs on methods assigning a monetary value to the authorisation impacts. Such criteria would represent a political standard on "what can be accepted and what is unacceptable" not in monetary terms but with a stronger focus on the exposed subject of protection. Such criteria would also assist the final decision process of the COM and the REACH Committee and increase the predictability of the decision itself. Since such criteria would have the status of a political determination they should be enacted by the COM and the REACH committee (as representation of the MS). Other areas where criteria could be relevant are low

[2] This can e.g. be seen when impacts on workers are assessed and compared with economic impacts on supply chains. The number of workers using the substance is in most application relatively low and corrections rarely change an overall picture, while economic impacts are often overweigh these effects by a hundred fold.

volume of substances (volumes of insignificance) or, the overall benefit of a use for the society (e.g. essential uses).

**(4) Suitability of ECHA's prioritisation approach**

The process as such how ECHA prioritises SVHC for inclusion in Annex XIV is very clear and concise. Since most information is available at least for a basic evaluation, it can be applied in a straight forward way. Nevertheless, as the information basis may not be up-to-date or certain information missing, the prioritisation outcome might over- or underestimate the relevance of an individual substance. The workload of prioritisation increases if ECHA needs to actively research the information basis. It is therefore essential that registration dossiers are regularly updated.

One improvement option could be that ECHA does not include all SVHCs of the candidate list in each prioritisation round because the task will grow as the number of new authorisation candidate substances is assumed to grow faster than the number of SVHCs on Annex XIV. Therefore, the partly performed practice in RMOAs of explicitly stating whether a later inclusion of a substance in Annex XIV is the ultimate goal should be a standard process. Substances not foreseen for authorisation could be excluded from the prioritisation process, resulting in reduced workloads for ECHA for preparing recommendations.

Overall it can be questioned if the prioritisation criteria currently used by ECHA are sufficient to put forward the substances for which the authorisation requirement provides significant risk reduction. It is for example questionable if SVHCs need to be prioritised for Annex XIV if general aims of the authorisation cannot be achieved in mid-term. For example, if SVHCs may not be substituted with reasonable likelihood it might be more effective to control potential risks via alternative measures (e.g. a restriction or other pieces of legislation). However, there might be some benefit to facilitating a candidate listing to prepare these alternative measures or to use this as a measure on its own. For example, if an RMOA recommends restriction as the best regulatory measure for a substance after SVHC identification, no prioritisation would be needed. In such cases, the candidate list would have the role to manifest the SVHC status officially, together with the aim to trigger information generation on SVHCs in articles according REACH Art. 7 of REACH and the Waste Framework Directive's[3] Art. 9 new database (SCIP).

Another aim that can be considered may be to ensure the functioning of the market, in case substitution seems difficult, at least in some areas. Here additional prioritisation criteria could address the market structure for the substance and the likely numbers of application for authorisation or their complexity. A large number of market actors that are using a substance might indicate either a large number of applications or highly complex upstream applications, which might lead to market disruptions especially if a high number of SMEs are involved in such activities.

**(5) Acceleration of individual procedures**

Overall and according to the findings of this study, the timelines defined by the REACH text seem to be appropriate to manage the processing of AfAs by the respective ECHA departments as well as by the RAC and SEAC, even if AfAs are submitted in a high number. Still it needs careful monitoring of the resources needed to manage these processes as Annex XIV will be more and more extended and numbers of applications may increase even more. Probably more resources are then needed to handle applications in a shorter time. Currently, the time critical step in handling AfAs is the final decision process of the COM and the REACH committee. Even though

[3] DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives

there is no fixed timeline defined in the REACH text the current durations until final decisions are taken often seem disproportionate (sometimes several years after the final RAC/SEAC opinions). Clear timelines for this final step of the handling of AfAs would give affected industry stakeholders more security for planning their business activities and investments.

The speed of processes preceding the official authorisation procedures, such as the RMOA or substance screenings as well as the development of Annex XV dossiers strongly depend on the availability of data and complexity of the individual case. The following measures might accelerate these processes:

- Further improvement of the quality of registrations dossiers, in particular to close data gaps and ensure data is up to date. This is in particular important for information on use patterns and specific use amounts. Registrants should e.g. be encouraged to provide information on use specific volumes. Currently, this is foreseen in the frame of the registration, but the way information is included there is often to unspecific and aggregated. This could be further elaborated so that information really supports decision making. Implementing an obligation under REACH for downstream users to provide certain information (either in supply chains or towards authorities) could even be considered.
- Involve DU if possible already at the stage of the RMOA, in particular those, which would be affected to the greatest extent by an (non-)authorisation.
- Analyse already in the RMOA which sectors may be affected by an authorisation, size and capacities of affected companies to deal with substitution and the number of expected AfAs. This should improve decision making on whether or not authorisation is the best regulatory measure, as indications of the possibility to substitute with moderate efforts or at mid-term would be gathered.

Political decision criteria would help speed up decisions in the REACH Committee, which is the process currently causing the largest delays. One core question to be addressed in this context is the extent to which the EU COM and the REACH committee need additional information for their decision not already obtained by the application and addressed in the RAC/SEAC opinions (Is there an information level seen as relevant and currently missing in the RAC/SEAC opinions?). Currently, improvements for the availability of alternatives are being discussed and the judgement of the EU court of justice is assigning more responsibility to the EU COM in this area. Another area which is often a basis for public debates, are the economic impacts on sectors, which are often indirect impacts. Also, the appropriateness of a refusal of an application is often discussed on the policy level in the context of certain protection aims (like e.g. protection towards endocrine disruptors). To improve this situation the following approaches could be useful:

- Support by technical experts, this can either be the existing committees RAC and SEAC or separate expert groups.
- Definition of (political) decision criteria that are agreed by member state authorities and COM to clarify or set a clear frame for refusal or approval of AfAs. These would define in which situations it might be justified to
    - grant an authorisation even if there are various uncertainties or relevant remaining risks

- refuse an authorisation although an individual application shows good arguments to grant it for this one market actor, but an authorisation nevertheless seems not justified (e.g. in case a large share of market actors already moved to an alternative or the use as such seems non-essential to justify the continued use of an SVHC even though the economics of the use would justify this in the SEA).

# Zusammenfassung

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

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

**Einleitung zu diesem Bericht**

Mit diesem Bericht wird eine Analyse des Zulassungsverfahrens nach der Verordnung (EG) Nr. 1907/2006 (im Folgenden als REACH bezeichnet) vorgelegt. Die Zulassung unter REACH wurde als neues Rechtsinstrument eingeführt, um Risiken aus der Verwendung von SVHC in der EU durch eine schrittweise Eliminierung solcher Stoffe zu reduzieren, wobei vorübergehende und spezifische Ausnahmen auf der Grundlage einzelner Anwendungen gewährt werden können. Die Chemikaliengesetzgebung vor REACH beinhaltete keinen ähnlichen Prozess.

Ziel der Analyse war es, die Effizienz des Zulassungsverfahrens im Hinblick auf die im REACH-Text definierten Ziele zu untersuchen: Das oberste Ziel der Zulassung ist der Ausstieg aus der Verwendung von SVHCs und, falls dies technisch und wirtschaftlich nicht machbar ist, die Minimierung der Risiken, die von ihrer Verwendung ausgehen. Ein besonderer Schwerpunkt lag auf der Betrachtung der Auswirkungen des Zulassungsverfahrens auf die Arbeitsbelastung der Behörden.

Die Analyse umfasst alle Schritte des Zulassungsverfahrens von der Identifizierung eines Stoffes als besonders besorgniserregend (SVHC) über die Empfehlung der Europäischen Chemikalienagentur (ECHA), die Stoffe aus der Kandidatenliste für eine Aufnahme in den Anhang XIV von REACH priorisiert, bis hin zum Zulassungsantrag (AfA) und der Bearbeitung von AfAs bis zur Entscheidung über die Erteilung einer Zulassung. Darüber hinaus werden zusätzliche Prozesse, die zur Verbesserung der Umsetzung von REACH und insbesondere des Zulassungsverfahrens eingerichtet wurden, in die Bewertung einbezogen. Dazu gehören die Analyse der Optionen für das Regulierungsmanagement (RMOA) und das Screening nach Stoffen, die für das Zulassungsverfahren in Frage kommen könnten.

Die folgenden Fragen werden behandelt:

1. Wird das allgemeine Ziel der REACH-Zulassung erreicht? Wie kann die Effektivität und Effizienz gesteigert werden?
2. Was sind die Hauptfaktoren, die die Arbeitsbelastung während der Identifizierung von SVHCs, der Priorisierung und der Prüfung der AfA, einschließlich der vorangegangenen informellen Schritte, bestimmen?
3. Gibt es Möglichkeiten, den durch die einzelnen Schritte verursachten Arbeitsaufwand zu reduzieren?

4. Ist der von der ECHA eingeführte Priorisierungsansatz prinzipiell sinnvoll? Sollten weitere Kriterien entwickelt oder zusätzliche Akteure in den Prozess einbezogen werden?
5. Wie kann die Geschwindigkeit der einzelnen Verfahren erhöht werden?

Effizienz wird in diesem Zusammenhang auch als der „beste Weg zur Erreichung der Ziele“ der Zulassung unter Einsatz der gegebenen Ressourcen der zuständigen Behörden der Mitgliedsstaaten (MSCA) und der Europäischen Chemikalienagentur (ECHA) verstanden.

**Methodik**

Die vorliegende Studie umfasste eine Bewertung des REACH-Textes selbst, der Auswertung relevanter Studien und Berichte zum Zulassungsverfahren (z. B. von der ECHA oder vorbereitet für den REACH-Review) sowie eine Analyse von Prozessbeispielen als Fallstudien zur SHVC-Identifizierung sowie zu Zulassungsanträgen (AfA). Für alle Fallstudien wurden öffentlich zugängliche Dokumente, insbesondere Dossiers nach Anhang XV, RMOA-Ergebnisdokumente, Hintergrundberichte zu Stoffen oder Stoffgruppen und die Antworten auf die Kommentare (Response to Comments, RCOM) analysiert. Für die AfA-Fallstudien wurden auch Entwürfe und endgültige Stellungnahmen der Ausschüsse, öffentliche AfA-Dokumente und Kommentare aus öffentlichen Konsultationen analysiert.

Zehn Fallstudien wurden im Hinblick auf die Effektivität und Effizienz und zur Veranschaulichung möglicher Mängel oder Erfolge der aktuellen SVHC-Identifizierung analysiert. Bei der Fallauswahl wurde berücksichtigt, dass die folgenden Fälle vertreten sein sollten:

- Verschiedene Gefahren-Endpunkte im Zusammenhang mit Artikel 57 a-f
- Stoffe mit mehreren SVHC-Endpunkten
- Mindestens eine Stoffgruppe
- „Besondere Situationen“ verstanden als: Stoffe mit Verunreinigungen (Basic Violet), Stoffe, die aufgrund der Abbauprodukte (OPEs) als SVHC qualifiziert sind

Darüber hinaus wurden weitere zehn Fallstudien hinsichtlich der Effektivität und Effizienz sowie der Arbeitsbelastung und Verbesserungspotenziale bei der Bearbeitung von AfA analysiert.

Die Fälle sollten verschiedene Arten von AfA abdecken und bei ihrer Auswahl wurde Folgendes berücksichtigt:

- AfA-Entscheidungen liegen vor, d.h. die Fälle sind bereits abgeschlossen
- Es werden verschiedene Risiken abgedeckt (Arbeitsplatz, Verbraucher und Umwelt). Da jedoch nur abgeschlossene Fälle bewertet wurden, sind Fälle zum Arbeitsschutz überrepräsentiert, da es zum Zeitpunkt der Bewertung nur wenige Fälle gab, die sich mit anderen Risiken befassten.
- Es werden sowohl „upstream“ als auch individuelle Anträge abgedeckt (auch im Vergleich)
- Abdeckung von Anwendungen zur Überbrückung, bei denen Alternativen bereits bekannt sind
- Verschiedene Arten von Risikoniveaus werden dargestellt, z. B. niedrige Tonnage, kontrollierte Bedingungen.

Darüber hinaus wurden einige Ausnahmesituationen abgedeckt. Ein Beispiel ist die „Roche Diglyme AfA“, die eine neue Produktionsanlage umfasst.

**Schlussfolgerungen und Empfehlungen**

Die Schlussfolgerungen und Empfehlungen zu möglichen Verbesserungen der Verfahren zur Identifizierung und Zulassung von SVHC werden im Folgenden entsprechend der Forschungsfragen zusammengestellt.

**(1) Ist das allgemeine Ziel der REACH-Zulassung erreicht? Wie kann die Effektivität und Effizienz gesteigert werden?**

Die Analyse zeigt, dass die allgemeinen Ziele der Zulassung erreicht werden. Die Verfahren sind etabliert, funktionieren und werden als wesentliche Triebkraft für einen Ausstieg aus der Verwendung von Stoffen angesehen. Dies gilt sowohl für SVHC der Kandidatenliste[4] als auch für Stoffe, die in Anhang XIV aufgenommen werden und einer Zulassung unterliegen.

Obwohl es sehr schwierig ist, die Auswirkungen der Zulassung auf die Substitution zu quantifizieren, ist es offensichtlich, dass das Bewusstsein für SVHC gestiegen ist und die Marktakteure dazu neigen, solche Stoffe nach Möglichkeit zu vermeiden. Für eine relevante Anzahl von Stoffen (derzeit 22 von 54) sind keine oder nur wenige AfA eingereicht worden, was darauf hindeutet, dass diese für den EU-Markt keine oder nur geringe Relevanz haben. Dies kann verschiedene Gründe haben. Die Stoffe:

- konnten leicht ersetzt werden
- werden nach wie vor außerhalb der EU verwendet, und die frühere EU-Produktion hat sich in Nicht-EU-Länder verlagert. In diesen Fällen besteht sogar die Möglichkeit, dass Stoffe in Erzeugnissen oder in Gemischen unterhalb bestimmter Schwellenwerte noch auf den EU-Markt gelangen
- hatten schon vor ihrer Regulierung keine Relevanz, und die Regulierungsmaßnahmen basierten auf unzureichenden Informationen.

Es ist jedoch nicht klar, ob dies bereits vor der Zulassungspflicht unter REACH der Fall war. Es gibt nach Kenntnis der Autoren keine Berichte, die die Gründe für dieses Nichthandeln erklären (keine Anträge). Daher bleibt unklar, ob die Zulassungspflicht in dieser Hinsicht sehr wirksam (führt zu umfassenden Substitutionsaktivitäten) oder sehr unwirksam war (hoher bürokratischer Aufwand für vorbereitende Schritte einer Zulassungspflicht, ohne eine wesentliche Veränderung der Risiken von Chemikalien auszulösen).

Auf der anderen Seite gibt es Stoffe, für die sehr viele AfA eingereicht wurden oder bei denen eine große Anzahl von DU abgedeckt ist. Nur einige dieser AfA weisen auf ein kurz- oder mittelfristiges Substitutionsziel hin. Der Zugewinn bei diesen Anträgen wäre die erhöhte Risikokontrolle bis zur Beendigung der Verwendung. Das Risikomanagement besteht aus den in den Expositionsszenarien (ES) beschriebenen und allen potenziellen zusätzlichen Maßnahmen, die in Zulassungsentscheidungen definiert werden, die zu verbindlichen und EU-weit harmonisierten Standards für die Verwendung des Stoffes werden. Es kann jedoch sein, dass eine solche Wirkung auch mit anderen Maßnahmen, wie z. B. Beschränkungen, erreichbar wäre.

Die RMOA ist ein wertvolles Instrument, das dazu beitragen kann vorauszusehen, ob für einen bestimmten Stoff das Ziel der Zulassung erreicht und gleichzeitig das Funktionieren des Marktes (auf die effektivste Art und Weise) sichergestellt werden kann. Um die Effizienz von RMOA zu

[4] Siehe auch DG Growth (2017) Study on the Impacts of REACH Authorisation

erhöhen, sind vertiefte Informationen über die Stoffverwendungen erforderlich, die jedoch häufig fehlen. Das erschwert das Verständnis der Auswirkungen einer Maßnahme. Darüber hinaus gibt es oft kaum Informationen über Alternativen und Auswirkungen von Maßnahmen auf den Markt, was die Möglichkeit der Behörden einschränkt, über eine Maßnahme zu entscheiden. Zur Überwindung dieses Informationsmangels könnten unter anderem freiwillige Selbstverpflichtungen beitragen. Die Erfahrung hat jedoch gezeigt, dass diese oft nicht alle Datenlücken schließen können. Ein rechtsverbindlicher Mechanismus für Behörden zur Anforderung der Informationen könnte eine bessere Lösung sein, um Informationsdefizite in einem frühen Stadium der strategischen Auswahl eines geeigneten Regulierungsansatzes zu überwinden.

Im Gegensatz zum Mangel an Verwendungsinformationen sind Daten zu Stoffeigenschaften aus Registrierungen und Bewertungen in der Regel besser verfügbar und dazu geeignet, Stoffe als SVHC zu identifizieren. Dies gilt insbesondere dann, wenn die Stoffeigenschaften den CLP-Einstufungskategorien entsprechen und die Stoffe harmonisierten Einstufungen unterzogen werden können. Für einige Eigenschaften (z. B. hormonähnliche Wirkung bzgl. der Umwelt (ED ENV)) werden Daten jedoch erst nach länger andauernden und aufwendigen Datenanforderungen während einer Stoffbewertung verfügbar, da diese nicht zu den Standardinformationen gehören, die mit der Registrierung bereitgestellt werden müssen. Hier könnte eine Erweiterung der Informationsanforderungen helfen, den Aufwand für die Behörden bei der Bewertung der gefährlichen Eigenschaften eines Stoffes zu reduzieren. Die Screening-Prozesse der ECHA und die zunehmenden Bemühungen um die Verwendung von Gruppierungsansätzen unterstützen die Identifizierung von Stoffen, die für eine Zulassung in Frage kommen könnten, und könnten bedauerliche Substitutionen vermeiden helfen.

Ein in den AfA identifiziertes Problem ist die Bewertung von AoAs. Antragsteller argumentieren hauptsächlich damit, dass keine Alternativen zur Verfügung stehen und es oft unklar ist, ob Alternativen überhaupt auf dem Markt sind. Die Komplexität einer Bewertung von Alternativen hängt sicherlich von der „Art“ der Alternative ab, d.h. davon, ob es sich um einen sehr ähnlichen „drop-in“ Stoff handelt, einen anderen Stoff, der völlig andere technische Prozesse und ggf. Maschinen erfordert, oder auch um unterschiedliche (nicht-chemische) technische Lösungen. Da REACH von den Antragstellern verlangt, die Alternativen und die Möglichkeiten ihrer Einführung zu beschreiben, ergeben sich gewisse Probleme:

- In Upstream Anträgen werden hauptsächlich Alternativen für DUs diskutiert und es ist schwierig, das entsprechende Wissen aus diesen Alternativen in die AfA des Antragstellers zu übertragen. Daher muss der Wissenstransfer verbessert werden.
- Einige DUs sind in der Tat nur „Stoffanwender“ (aber immer noch potenzielle Antragsteller einer AfA). Diesen Anwendern (oft KMU) fehlt es an Hintergrundwissen über Alternativen auf dem erwarteten wissenschaftlichen Niveau und sie können die Erwartungen der Behörden bezüglich des Wissens über alternative Verfahren nicht erfüllen.
- Einige Marktakteure haben unrealistische Erwartungen an ihre Möglichkeiten, Alternativen zu nutzen. Zum Beispiel wird ein Betreiber einer bestimmten Anlage wahrscheinlich nur dann in der Lage sein, eine Alternative zu nutzen, wenn dies eine „drop-in“ Chemikalie ist, die innerhalb derselben Anlage funktioniert. Aus der Sicht der Anwender sind andere Alternativen nur eine theoretische Option.

In solchen Situationen kann es sein, dass Antragsteller nicht in der Lage sind, realistische, detaillierte Bewertungen von Alternativen vorzulegen, und der Nutzen solcher Analysen für die Gesamtanwendung ist fraglich. Ein Weg nach vorn könnte darin bestehen, Alternativen auf

übergreifender Ebene durch die Behörden zu bewerten. Dennoch müssen Informationen von alternativen Anbietern und Nutzern zusammengetragen und kommuniziert werden. Da Informationen über Alternativen für die Entscheidung über die beste regulatorische Option und die Gestaltung einer späteren Regulierungsmaßnahme relevant sind, könnte die RMOA ein geeignetes Verfahren hierfür sein. Auf der Grundlage dieser Informationen könnten nutzungsspezifische Endzeitpunkte für die Anwendung in Betracht gezogen werden, um die Substitution zu fördern und weitere AfA so weit wie möglich zu vermeiden. Dies könnte zu einer allgemeinen Steigerung der Effizienz der Zulassung führen und die Substitution anstelle von Zulassungen fördern.

**(2) Treiber der Arbeitsbelastung der Behörde für Genehmigungen**

Insgesamt ist die Hauptursache für die Arbeitsbelastung der Behörden in allen Schritten der Zulassung der Mangel an Informationen über Verwendungen und Alternativen sowie über die sozioökonomischen Auswirkungen eines Szenarios der Nichtverwendung,

Informationen über Verwendungen, Alternativen und sozioökonomische Auswirkungen sind für alle Entscheidungen erforderlich. Sie sind am wichtigsten zur Unterstützung der RMOA, zur Bewertung der AfA und zur Festlegung von Prioritäten, wobei letzteres die geringste Bedeutung hat. Gegenwärtig gibt es, abgesehen von der Genehmigungsentscheidung selbst, kein Verfahren, mit dem die Behörden diese Informationen von den Marktakteuren einholen könnten. Hier können die Bedingungen einer Zulassung verlangen, dass die nachgeschalteten Anwender am Ende der Lieferkette die implementierten OC und RMM sowie die Expositionsniveaus melden müssen, wodurch die Informationen für eine stärker faktenbasierte Bewertung zum Zeitpunkt der Überprüfung der Zulassung verbessert werden. Wenn die Behörden diese Informationen früher erhalten wollen, besteht derzeit die einzige Möglichkeit darin, eigene Ressourcen zu investieren und mit Forschungsaktivitäten zu beginnen, wie z. B. Messungen durchzuführen, Umfragen zu starten oder Kontakt zu Interessengruppen aufzunehmen.

Im Gegensatz dazu betrifft die Identifizierung von SVHC ausschließlich die Stoffeigenschaften. Das Verfahren kann aufwendig sein, wenn die Informationsgrundlage nicht klar ist, z. B. wenn Informationen fehlen, Uneinigkeit über die Interpretation der Daten besteht oder Einzelbewertungen vorgenommen werden müssen. Dies gilt insbesondere für Stoffe nach Artikel 57 (f), bei denen die Daten im Vergleich zu den anderen SVHC-Kriterien nach Artikel 57 a-e oft noch nicht unter die Standarddatenanforderungen fallen. Der Entscheidungsprozess selbst ist gut strukturiert und kann in der Regel in den vorgesehenen Zeiträumen abgeschlossen werden. Die Entscheidung über die besonders besorgniserregenden Stoffe erfolgt häufig nach einer harmonisierten Einstufung und nach Vorgesprächen zwischen den Expertinnen und Experten in RIME+ und CARACAL, in denen Meinungsverschiedenheiten zwischen den Mitgliedstaaten a priori gelöst werden können.

Neben der Bewertung der Daten und der Erstellung des Dossiers ist die Anzahl und Qualität der Kommentare, die im Rahmen der öffentlichen Konsultation abgegeben werden, der wichtigste Bestimmungsfaktor für die Arbeitsbelastung bei der Identifizierung von SVHC, da die Behörden antworten und ihre Antworten auf alle eingereichten Kommentare in einem RCOM transparent dokumentieren müssen.

Ein Hauptfaktor, der die Arbeitsbelastung bei der Zulassung eines bestimmten Stoffes bestimmt, ist die Anzahl der eingereichten AfA und deren Komplexität, insbesondere wenn es sich um upstream Anträge handelt. Es ist hervorzuheben, dass upstream Anträge ein Instrument zur Umsetzung harmonisierter OCs und RMMs über ganze Sektoren hinweg sind. Daher ist es so, dass die Verwendungen klar unterschieden werden, um zu klären, welche Marktakteure abgedeckt sind und welche Maßnahmen durchgesetzt werden sollten. Die Behörden profitieren

von upstream Anträgen, weil sie die Anzahl der Anträge für einen Stoff reduzieren und weil sie relativ einfach gehandhabt werden können, wenn eine begrenzte Anzahl von Verwendungen in einem Antrag abgedeckt ist. Um die Wirkung von upstream Anträgen zu optimieren, ist eine weitere Verbesserung des Instruments erforderlich, zum Beispiel in Form von Leitlinien.

**(3) Verringerung des Arbeitsaufwands für die einzelnen Genehmigungsschritte?**

Seit dem Inkrafttreten des Zulassungsverfahrens wurden Standards und Leitlinien entwickelt, um die Umsetzung der einzelnen Zulassungsschritte zu unterstützen, wodurch sich der Arbeitsaufwand für alle Akteure bereits verringert hat.

Der Arbeitsaufwand für die Identifizierung von SVHC wird durch die verfügbaren Daten für den Nachweis einer SVHC-Eigenschaft bestimmt. Die bereits eingeleiteten Maßnahmen scheinen geeignet, die Prozesseffizienz zu erhöhen, was jedoch nicht automatisch die Arbeitsbelastung der Behörden verringert:

- Durch die **Gruppierung** können mehrere Stoffe diskutiert werden, die den gleichen Mode of Action (MoA) und ähnliche schädliche Wirkungen haben und/oder die als Alternativen füreinander oder für andere Stoffe auf der Kandidatenliste verwendet werden.
- Der erste Aspekt kann die Effizienz der SVHC-Identifizierung erhöhen indem ähnliche Argumentationen in ein Dossier nach Anhang XV aufgenommen werden. Der zweite Aspekt zielt darauf ab, die Gesamtwirksamkeit einer Zulassung zu erhöhen, indem die Substitution eines Stoffes durch einen strukturell ähnlichen Stoff mit vergleichbaren toxischen Eigenschaften verhindert wird.
- **Expertengruppen zu spezifischen Stoffeigenschaften** diskutieren Normen und Kriterien, wie eine bestimmte SVHC-Eigenschaft nachgewiesen werden kann, falls der Standard-Kriterienkatalog nicht angewendet werden kann und eine stärker fallbezogene Argumentation gemäß „Weight of Evidence“ erforderlich ist. Hier ist die Entwicklung von Leitlinien und beispielhaften Fallstudien ein wichtiges Element, um einen Standard zu etablieren, der von den zuständigen Behörden der Mitgliedstaaten weitgehend akzeptiert wird und damit den, für den Nachweis von SVHC-Eigenschaften ausreichenden Mindestdatensatz definiert.

Der Arbeitsaufwand der Behörden für die Bewertung von AfA entsteht (auch) durch unzureichende Informationen im Stoffsicherheitsbericht (CSR), der AoA oder der sozio-ökonomischen Analyse (SEA), da der Ausschuss für Risikobewertung (RAC) und der Ausschuss für sozio-ökonomische Analysen (SEAC) oft eine aktive Rolle bei der Verbesserung der Bewertungen übernehmen. REACH überträgt die Beweislast auf die Marktakteure, die eine Verwendung weiterführen wollen. Man kann argumentieren, dass die Ausschüsse automatisch an der Entwicklung der Argumentation einer AfA mitwirken, wenn sie z. B. die Eignung und Verfügbarkeit von Alternativen diskutieren oder die Überlegungen zu den wirtschaftlichen Auswirkungen von Nichtverwendungs- und Weiterverwendungsszenarien anpassen. Eine aktive Informationssammlung und -bewertung geht jedoch über die Bewertung hinaus. Es sollten Regeln und Qualitätsstandards festgelegt werden, die diese Aktivitäten einschränken und es den RAC und SEAC ermöglichen, Vorschläge von geringer Qualität abzulehnen. Dies sollte insbesondere dann der Fall sein, wenn die Ausschüsse Ressourcen investieren müssten, um eigene zusätzliche Informationen zu generieren.

Eine Ausnahme ist die Ableitung von Referenzwerten für die Risikobewertung. Solche harmonisierten Referenzwerte für die Quantifizierung des Risikos würden die Bewertungen objektivieren und den Bewertungssaufwand für die einzelnen Argumentationen in den Anträgen

verringern. Darüber hinaus kann die Festlegung von Referenzwerten als Verantwortung der Behörde betrachtet werden. Eine ähnliche Rolle könnte einer Liste von Referenzalternativen zugewiesen werden, die den Mindestumfang einer AoA definiert und grundlegende Informationen über die Alternativen als Input für die Bewertung liefert. Dies kann den Ausschüssen helfen, Bedingungen zu initiieren oder AfA abzulehnen. Referenzwerte können auch verwendet werden, um die Höhe der Risikomarge zu definieren, deren Überschreitung zur Ablehnung oder zu kürzeren Überprüfungszeiträumen führt - die Margen sollten unabhängig vom potenziellen wirtschaftlichen Nutzen für das Unternehmen oder die Lieferkette sein.

Wenn die Ausschüsse die Argumentation eines Antragstellers verändern, könnte man fragen, ob eine vollständige, quantitative Neubewertung erforderlich ist oder ob qualitative Diskussionen ausreichen, um die Änderungen zu verstehen und Schlussfolgerungen zu ziehen. Ein qualitativer Ansatz kann insbesondere dann gerechtfertigt sein wenn die Gesamtargumentation nicht wesentlich verändert wird, also z. B. bestimmte Kosten korrigiert, die Größenordnung aber nicht verändert wird und andere Kosten diese bei weitem übersteigen[5].

Um den Antrag und seine Bewertung zu vereinfachen, könnten Cut-Off Kriterien für bestimmte Bedingungen in einer AfA entwickelt werden. Diese könnten die Emissions- oder Expositionswerte eines besonders besorgniserregenden Stoffes in einer Verwendung, aber auch bestimmte Kosten-Nutzen-Relationen in SEAs betreffen oder qualitativ sein und sich z. B. auf Schutzziele beziehen. Es sollte diskutiert werden, ob solche Kriterien entwickelt werden könnten, auch im Hinblick auf die Unsicherheiten von Bewertungen, insbesondere im Bereich der SEA und der Eignung von Alternativen. Dies könnte auch den starken Fokus der AfA auf Methoden verringern, die den Auswirkungen der Genehmigung einen monetären Wert zuweisen. Solche Kriterien würden einen politischen Standard dafür darstellen, „was akzeptiert werden kann und was inakzeptabel ist“, nicht in monetärer Hinsicht, sondern eher hinsichtlich des Schutzniveaus. Solche Kriterien würden auch den endgültigen Entscheidungsprozess der COM und des REACH-Regelungsausschusses unterstützen und die Vorhersehbarkeit der Entscheidung selbst erhöhen. Da solche Kriterien den Status einer politischen Entscheidung hätten, sollten sie von der COM und dem REACH-Ausschuss (als Vertretung der Mitgliedsstaaten MS) erlassen werden. Andere Bereiche, in denen Kriterien relevant sein könnten, sind geringe Anwendungsmengen von Stoffen (vernachlässigbare Mengen) oder der Gesamtnutzen einer Verwendung für die Gesellschaft (z. B. wesentliche Verwendungen).

**(4) Eignung des Priorisierungsansatzes der ECHA**

Das Verfahren der ECHA zur Priorisierung von SVHC für die Aufnahme in Anhang XIV ist sehr klar und prägnant. Da die meisten Informationen zumindest für eine grundlegende Bewertung zur Verfügung stehen, können sie auf einfache Weise angewendet werden. Da die Informationsbasis jedoch möglicherweise nicht aktuell ist oder spezifische Informationen fehlen, könnte das Ergebnis der Priorisierung die Relevanz eines einzelnen Stoffes über- oder unterschätzen. Der Arbeitsaufwand für die Priorisierung steigt, wenn die ECHA die Informationsgrundlage aktiv überprüfen muss. Es ist daher unerlässlich, dass die Registrierungsdossiers regelmäßig aktualisiert werden.

Eine Verbesserungsmöglichkeit könnte darin bestehen, dass die ECHA nicht alle SVHCs der Kandidatenliste in jede Priorisierungsrunde einbezieht. So könnte die Priorisierungaufgabe handhabbar bleiben, auch wenn die Zahl der Kandidatenstoffe schneller wachsen wird als die Zahl der SVHCs, die in Anhang XIV aufgenommen werden. Daher sollte auch die teilweise bereits

[5] Dies zeigt sich z. B., wenn die Auswirkungen auf die Arbeitnehmer bewertet und mit den wirtschaftlichen Auswirkungen auf die Lieferketten verglichen werden. Die Zahl der Arbeitnehmer, die den Stoff verwenden, ist in den meisten Anwendungsbereichen relativ gering, und Korrekturen ändern selten ein Gesamtbild, während die wirtschaftlichen Auswirkungen diese Auswirkungen oft um das Hundertfache überwiegen.

eingeführte Praxis in den RMOAs explizit anzugeben, ob eine spätere Aufnahme in Anhang XIV intendiert ist, zum Standardverfahren werden. Stoffe, die nicht für eine Zulassung vorgesehen sind, könnten vom Priorisierungsprozess ausgeschlossen werden, was den Arbeitsaufwand der ECHA für die Erstellung von Empfehlungen verringern würde.

Insgesamt kann in Frage gestellt werden, ob die derzeit von der ECHA verwendeten Priorisierungskriterien ausreichen, um genau die Stoffe vorzuschlagen, für die die Zulassungspflicht eine erhebliche Risikominderung zur Folge hätte. Es ist zum Beispiel fraglich, ob SVHCs für Anhang XIV priorisiert werden müssen, wenn die allgemeinen Ziele der Zulassung mittelfristig nicht erreicht werden können. Wenn z. B. eine Substitution unwahrscheinlich ist, könnte es wirksamer sein, potenzielle Risiken durch alternative Maßnahmen (z. B. eine Beschränkung oder andere Rechtsvorschriften) zu kontrollieren. Es könnte jedoch von Vorteil sein, die Aufnahme von Kandidaten in die Liste zu fördern, um diese alternativen Maßnahmen vorzubereiten oder die SVHC-Identifizierung als eigenständige Maßnahme zu nutzen. Wenn z. B. eine RMOA eine Beschränkung als beste regulatorische Maßnahme für einen Stoff nach der Identifizierung von SVHC empfiehlt, wäre keine Priorisierung erforderlich. In solchen Fällen würde die Kandidatenliste den SVHC-Status offiziell bestätigen und dazu führen, dass Informationen über SVHCs in Erzeugnissen gemäß REACH Art. 7 der REACH-Verordnung und der Abfallrahmenrichtlinie[6] Art. 9 der neuen Datenbank (SCIP) generiert werden.

Ein weiteres zu betrachtendes Ziel, kann der Erhalt der Funktionsfähigkeit des Marktes sein, falls eine Substitution zumindest in einigen Bereichen schwierig erscheint. Hier könnten zusätzliche Priorisierungskriterien die Marktstruktur für den Stoff und die wahrscheinliche Anzahl von Zulassungsanträgen oder deren Komplexität anzeigen. Eine große Anzahl von Marktteilnehmern, die einen Stoff verwenden, könnte entweder auf eine große Anzahl von Anwendungen oder auf hochkomplexe upstream Anträge hindeuten, was insbesondere dann zu Marktstörungen führen könnte, wenn eine große Anzahl von KMU an solchen Aktivitäten beteiligt ist.

**(5) Beschleunigung einzelner Verfahren**

Insgesamt und gemäß der Ergebnisse dieser Studie scheinen die durch den REACH-Text festgelegten Zeitvorgaben angemessen zu sein, um AfA durch die jeweiligen Abteilungen der ECHA sowie durch den RAC und SEAC zu bearbeiten, auch wenn AfA in hoher Zahl eingereicht werden. Dennoch bedarf es einer sorgfältigen Überwachung der Ressourcen, die für die Verwaltung dieser Prozesse erforderlich sind, da der Anhang XIV immer weiter ausgedehnt wird und die Zahl der Anträge noch weiter steigen könnte. Wahrscheinlich werden mehr Ressourcen benötigt, um die Anträge dann in kürzerer Zeit zu bearbeiten. Gegenwärtig ist der zeitkritische Schritt bei der Bearbeitung von AfA der endgültige Entscheidungsprozess der COM und des REACH-Regelungsausschusses. Auch wenn im REACH-Text kein fester Zeitrahmen definiert ist, erscheinen die Zeiträume bis zur endgültigen Entscheidung oft unverhältnismäßig lang (manchmal mehrere Jahre nach den endgültigen Stellungnahmen des RAC/SEAC). Klare Zeitvorgaben für diesen letzten Schritt der Behandlung von AfA würden den betroffenen Industrieakteuren mehr Sicherheit für die Planung ihrer Geschäftsaktivitäten und Investitionen geben.

Die Geschwindigkeit der Prozesse, die den behördlichen Zulassungsverfahren vorausgehen, wie z. B. die RMOA oder das Stoffscreening sowie die Entwicklung von Dossiers nach Anhang XV,

[6] DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives

hängt stark von der Datenverfügbarkeit und der Komplexität des Einzelfalls ab. Die folgenden Maßnahmen können diese Prozesse beschleunigen:

- Fortsetzung der Aktivitäten zur Verbesserung der Qualität der Registrierungsdossiers, insbesondere um Datenlücken zu schließen und die Aktualität der Daten sicherzustellen. Dies ist vor allem für Informationen über Verwendungsmuster und spezifische Verwendungsmengen wichtig. Registranten sollten ermutigt werden, Informationen über verwendungsspezifische Mengen bereitzustellen. Gegenwärtig ist dies im Rahmen der Registrierung vorgesehen, aber die Art und Weise, wie die Informationen dort aufgenommen werden, ist oft zu unspezifisch oder zu stark zusammengefasst. Dies könnte weiter ausgearbeitet werden, so dass die Informationen wirklich die Entscheidungsfindung unterstützen. Es könnte sogar erwogen werden, im Rahmen von REACH eine Verpflichtung für nachgeschaltete Anwender einzuführen, bestimmte Informationen zur Verfügung zu stellen (entweder in Lieferketten oder gegenüber Behörden).
- Einbeziehung von nachgeschalteten Anwendern, wenn möglich bereits in der Phase der RMOA, insbesondere diejenigen DU, die am stärksten von einer (Nicht-)Zulassung betroffen wären.
- Bereits im Rahmen der RMOA sollte analysiert werden, welche Branchen von einer Zulassung betroffen sein könnten, die Größe und die Kapazitäten der betroffenen Unternehmen und die Anzahl der erwarteten AfA. Dies dürfte die Entscheidungsfindung darüber, ob eine Zulassung die beste Regulierungsmaßnahme ist oder nicht, verbessern, da Hinweise auf die Möglichkeit einer Substitution mit mäßigen Anstrengungen oder mittelfristig gesammelt würden.

Politische Entscheidungskriterien würden dazu beitragen, die Entscheidungen im REACH-Ausschuss zu beschleunigen, da dieser Prozess derzeit die größten Verzögerungen verursacht. Eine in diesem Zusammenhang zu klärende Kernfrage ist, inwieweit die EU-COM und der REACH-Regelungsausschuss für ihre Entscheidung Informationen benötigen, die nicht bereits durch den Antrag erhalten wurden und die nicht in den Stellungnahmen des RAC/SEAC behandelt werden (Gibt es einen Informationsstand, der als relevant angesehen wird und derzeit in den Stellungnahmen des RAC/SEAC fehlt?). Derzeit werden Verbesserungen für die Verfügbarkeit von Alternativen diskutiert und das Urteil des EU-Gerichtshofs weist der EU-COM mehr Verantwortung in diesem Bereich zu. Ein weiterer Bereich, der oft Grundlage für öffentliche Debatten ist, sind die wirtschaftlichen Auswirkungen auf Branchen, die sich meistens indirekt auswirken. Auch die Angemessenheit der Ablehnung eines Antrags wird oft auf politischer Ebene im Zusammenhang mit bestimmten Schutzzielen (wie z. B. dem Schutz vor endokrin wirksamen Substanzen) diskutiert. Um diese Situation zu verbessern, könnten folgende Ansätze nützlich sein:

- Unterstützung durch technische Expertinnen und Experten. Dies können entweder die bestehenden Ausschüsse RAC und SEAC oder eigenständige Gruppen mit entsprechender Expertise sein.
- Definition von (politischen) Entscheidungskriterien, die von den Behörden der Mitgliedsstaaten und der COM zur Klärung vereinbart werden, um einen klaren Rahmen für die Ablehnung oder Genehmigung von AfA zu setzen. Diese könnten beschreiben in welchen Situationen es gerechtfertigt sein könnte:
  - eine Genehmigung zu erteilen, auch wenn es verschiedene Unsicherheiten oder relevante Restrisiken gibt bzw.

- eine Zulassung zu verweigern, obwohl ein Einzelantrag gute Argumente enthält, diesem einen Marktakteur eine Zulassung zu erteilen, da dies aber dennoch nicht gerechtfertigt erscheint. Dies könnte zum Beispiel dann der Fall sein, wenn ein großer Teil der Marktakteure bereits eine Alternative verwendet oder wenn die Verwendung so unwichtig erscheint, dass sie die weitere Verwendung des SVHC nicht rechtfertigt, selbst wenn die SEA hierfür wirtschaftliche Vorteile nachweist.

# 1 Introduction

With this report an analysis of the authorisation process under 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 (in the following referred to as REACH) is provided. The analysis covers all steps of the authorisation process from the identification of a substance as of very high concern (SVHC) over the recommendation issued by the European Chemicals Agency (ECHA) that prioritises substances from the candidate list for an uptake onto the Annex XIV of REACH to the application for authorisations (AfA) and the processing of AfAs until the decision. Furthermore, additional processes that have been established to improve the REACH implementation and particularly the authorisation process, are included in the assessment. This covers the regulatory management option analysis (RMOA) and the screening for substances that might qualify for the authorisation process.

The aim of the analysis was to investigate the efficiency of the authorisation process with regard to the aims defined in the REACH text: The ultimate goal of authorisation is the eventual phase-out of SVHCs and, if this is technically and economically not feasible, to minimise the risks originating from their use. A special focus is set on the impacts of the authorisation process on the workload of authorities.

The following questions are addressed:

- Is the general aim of the REACH authorisation accomplished? How can the efficiency be increased?
- What are the main drivers that determine the workload during the identification of SVHCs, the prioritisation and the processing of the AfAs, including the preceding informal steps?
- Are there possibilities to reduce the workload caused by the individual steps?
- Is the prioritisation approach introduced by ECHA useful, in principle? Should further criteria be developed or additional actors be included in the process?
- How can the speed of the individual procedures be increased?

Efficiency in this regard is also understood, as the “best way to achieve the aims” of authorisation with the investment of the given resources of member state competent authorities (MSCA) and the European Chemicals Agency (ECHA).

Authorisation under REACH was introduced as a new legal instrument to reduce risks that originate from the use of SVHC in the EU by a stepwise elimination of such substances from the market as far as possible, with the option to grant temporary specific exemptions based on individual applications. The chemicals legislation before REACH did not comprise a similar process.

# 2 Overview on the Authorization Process

In the frame of REACH, authorisation is covered by Title VII, which is divided into three chapters[7]:

- Chapter 1 Authorisation requirement
- Chapter 2 Granting of authorisations
- Chapter 3 Authorisations in the supply chain

Apart from the authorisation process, also the informal preparatory processes that might lead to an authorisation requirement are introduced in the following.

## 2.1 Authorisation Requirement

The first chapter of REACH Title VII defines the scope of the authorisation regime. Article 55 defines the aim(s) of the authorisation procedure.

[…] "*The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution*. "[…]

To achieve this aim a process was introduced that can be divided into three steps:

- Step 1: SVHC identification: SVHCs are substances with certain hazardous properties that may cause adverse effects either to human health or the environment and are therefore of "very high concern" (Article 57). These are:
  - Carcinogenic, mutagenic and toxic to reproduction cat. 1a/b (CMR) according to Annex I of the CLP Regulation[8] (Art. 57 a-c)
  - Persistent, bioaccumulative and toxic (PBT) and very persistent very bioaccumulative (vPvB) (Art. 57 d and e). The substances are identified according to REACH Annex XIII.
  - Substances giving rise to an equivalent level of concern (Eloc) as those falling under the points (a) to (e). Authorities need to identify these substances on a case-by-case basis and compile scientific evidence of probable serious effects to human health or the environment, which substantiate the level of concern. Substances considered could be:
    - Endocrine disrupters (EDs), which are currently identified via the definition of the World Health Organisation/International Panel on Chemical Substances (WHO/IPCS). This approach follows the conceptual framework of the OECD Guidance document 150 (2018), establishing a link between the Mode of Action (MoA) and the

[7] A detail flow chart of all steps during an authorisation procedure from first identification of a substance as SVHC to a granted or denied authorisation can be found on the ECHA website under https://echa.europa.eu/authorisation-process (visited 07.02.2020)

[8] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1272

observed adverse effects on organisms/populations[9]. Recently, criteria were established for the identification of these substances in the frame of the Regulations for Biocides[10] and Plant Protection Products (PPP)[11]. Under REACH such criteria have not been established in the REACH text or other implementing legal act.

- Substances with persistent, bioaccumulative and toxic or very persistent and very bioaccumulative properties, which do not fulfil the criteria (d) or (e).

It should be noted that Art. 57 (f) is not limited to these two substance groups, as it is not defined which information is required to demonstrate an EloC. EDs (environmental, human health), sensitising (respiratory) properties or properties that affect other organs (corresponding to a classification as "specific target organ toxicity" (STOT)) could also be included. On 16.01.2020, the first persistent, mobile and toxic (PMT) substance was identified according to Article 57 (f)[12]

The identification of SVHCs and their inclusion into the so-called REACH candidate list (Art. 59(1)) is a continuous process.

- Step 2: Prioritisation of SVHCs on the candidate list for authorisation: the potential risks from SVHCs on the candidate list are screened and those with the highest risk potential are selected for inclusion in the "authorisation list" (REACH Annex XIV). Three criteria explicitly mentioned in REACH Art. 58 (3)) are considered in the prioritisation:
  - PBT/vPvB properties (in accordance with the SVHC identification process),
  - wide dispersive uses
  - high market volumes.

  The latter two criteria exceed the information needs for SVHC identification, but can usually be obtained from the registration dossiers. It should be noted that the REACH text states […] "*Priority shall normally be given to substances with*" […]. This means, ECHA may also consider other reasons when assessing SVHCs on the candidate list. ECHA's overall prioritisation approach is described in a document published in 2014[13].

  An additional aspect to the criteria defined in the REACH text that is considered in the prioritisation of SVHCs is the "interchangeability" of a substance with another one already prioritised or listed on Annex XIV. This should prevent a regrettable substitution. ECHA also assesses if an SVHC is already subject to other regulatory activities to avoid interference with this process.

[9] See also CASG-ED/2020/03

[10] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.301.01.0001.01.ENG&toc=OJ:L:2017:301:TOC

[11] Adopted criteria for PPP Commission Regulation (EU) 2018/605 of 19 April 2018, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018R0605

[12] See ECHA website on Perfluorobutane sulfonic acid (PFBS) and its salts https://echa.europa.eu/de/candidate-list-table/-/dislist/details/0b0236e183da8013

[13] https://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf/e18a6592-11a2-4092-bf95-97e77b2f9cc8

- Step 3: Inclusion of substances in the authorisation list (Annex XIV). This last step establishes the actual authorisation requirement and consist of an EU Commission (COM) decision to change Annex XIV via a legislative procedure. The change is enacted by a delegated regulation. The entry in the Annex XIV includes an identification of the SVHC and a sunset date from which it may not be used anymore unless the use is covered by an authorisation. It may define substance specific exemptions if a use is considered acceptable after having been sufficiently evaluated in the frame of another regulatory activity.

If no applications for authorisation are submitted for an SVHC on Annex XIV, the authorisation procedure ends at this point. From an overall efficiency perspective, this would be a desirable situation assuming the use of the substance being successfully phased out, while at the same time products formerly produced with that substance have been successfully substituted without any notable disruption of the EU-market.

Since this was not expected to be the case for all SVHC the possibility to apply for an authorisation was introduced under REACH. This phase of the authorisation procedure will be briefly reflected in the next chapter.

## 2.2 Applying for Authorisation

If it is not possible to substitute a substance on REACH Annex XIV, market actors can apply for an authorisation to use the substance beyond the sunset date. The COM may grant an authorisation if an applicant demonstrates certain conditions[14]:

6. **Adequate control route:** The applicant demonstrates that risks are adequately controlled in all uses covered by the application. This means all human and environmental exposures are below the threshold under which no adverse effects are expected and that is derived based on (eco-) toxicological data. For human health effects the limit value is called Derived No Effect Level (DNEL) and for environmental effects it is called Predicted No Effect Concentration (PNEC). If no DNELs and PNECs can be derived, the second route can be followed.
7. **Socio-economic analysis route:** The applicant demonstrates that the socio-economic benefits of using the substance outweigh the risks and that there are no suitable alternative substances or technologies to substitute the use of the substance.

In cases where adequate control can be demonstrated it is important to note that potential exposure of humans and/or the environment needs to be minimised in the best possible way. This needs to be described in the application in the form of an exposure scenario (ES) detailing a set of operational conditions (OC) and risk management measures (RMM), if necessary.

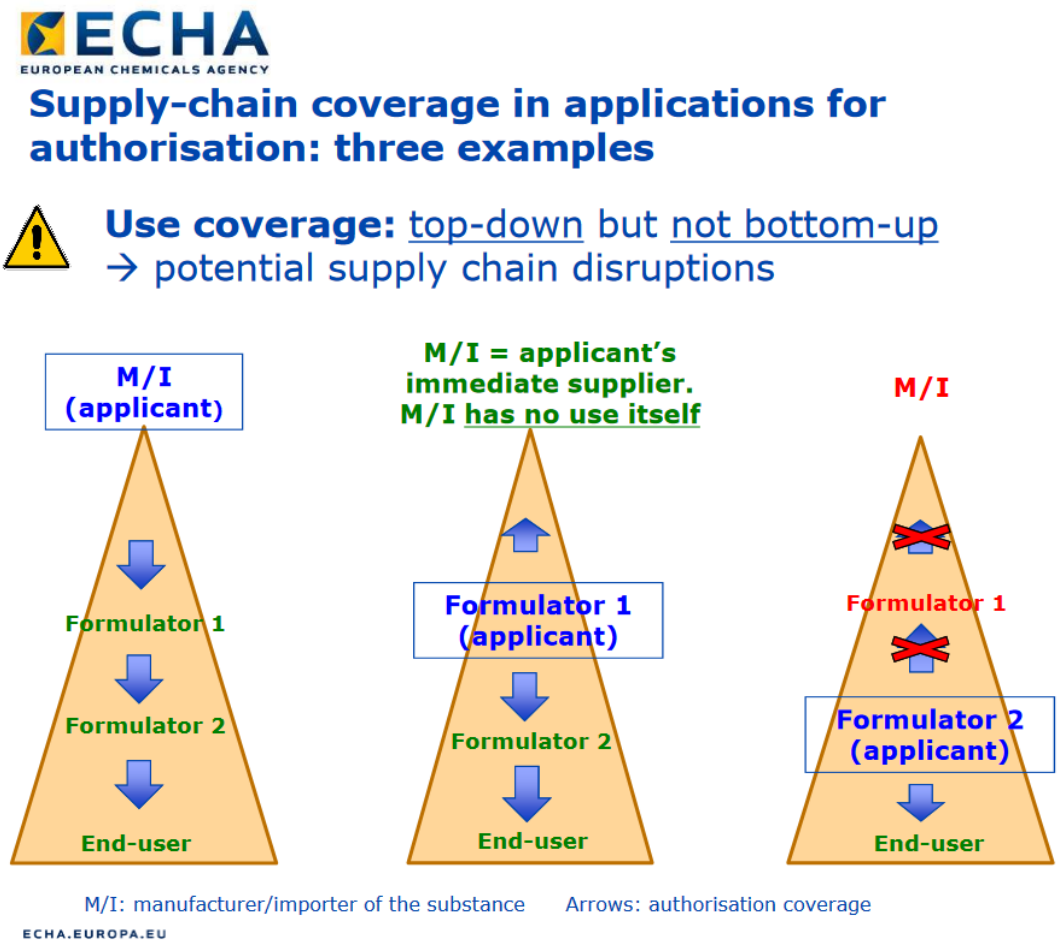
Applicants have to submit their AfA to ECHA, which first checks if all formal requirements are fulfilled. Then, the AfA is evaluated by two expert committees: the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC). The committees, after evaluating the provided assessments and argumentations, each provide an opinion document regarding the AfA. Based on these opinions, the COM drafts a decision proposal. The REACH Committee, consisting of Member State (MS) representatives, vote on the Commission's decision proposals for each application. After the vote, the Commission adopts a respective Commission implementing decision. With the decision the Commission not only approves or rejects authorisation for the applied uses, but it can also define conditions to be followed for an authorised use. Each authorisation has to be reviewed after a time period defined in the decision

[14] See also ECHA Website under https://echa.europa.eu/applying-for-authorisation/start-preparing-your-application

with the aim to reassess the arguments in particular the need for a continued use of the substance. Authorisations can be reviewed at any time in case new information on the risks and/or the substitution potential of a substance in a particular use becomes available.

An AfA may cover one or several uses as well as one or several substances. Furthermore, market actors higher in the supply chain may cover the uses of their customers (downstream users (DU)) in their application (see Figure 1). Such so-called upstream applications cover all DUs that perform a use in the application's scope when they receive the substance either directly from the application holder or the covered supply chain. However, all DUs must implement the OCs and RMMs described in the AfA in order to ensure that the risk assumptions in the AfA match reality. In any case, all uses in a supply chain must be covered by the authorisation.

**Figure 1: Options to cover uses in the supply chain of a substance in an AfA**




Source ECHA https://echa.europa.eu/documents/10162/13637/afa_supply_chain_coverage_en.pdf/ade54fb6-5451-4259-8814-e207b6783120, visited 07.02.2020

Chapter 3 of Title VII (Authorisation) defines the rules that the supply chain members are to follow after an authorisation has been granted.

Authorisation holders covering DU-uses are required to communicate the OCs and RMMs of all uses along the supply chain via the chemical safety data sheet (SDS), as well as any potential additional conditions of the authorisation. DUs who are not the authorisation holders must implement all OCs and RMMs as well as the additional conditions communicated to them. They

may either only source a substance as such or in mixtures only from suppliers who have a valid authorisation or make an own AfA for their use. Furthermore, DUs who are not authorisation holders must notify ECHA of their (authorised) use and make themselves known to the authorities to enable effective enforcement on the adequate performance of the uses.

## 2.3 Informal Processes linked to Authorisation

In practice, the REACH authorisation is not an isolated process but is interlinked with other REACH processes, namely the registration, the dossier and substance evaluation and the restriction.

Restrictions are the second option under REACH to limit the use of hazardous substances in the EU. In principle, a restriction may have the same scope as an authorisation if an unacceptable risk can be demonstrated in a restriction proposal. Vice versa, this is not true because the scope of a restriction can be broader[15]. Besides authorisation and restriction under REACH, there are also other regulatory options to limit adverse effects of substances on human health or the environment, such as harmonised classifications und the CLP-regulation[16].

The implementation practice has shown that an early decision for a particular regulatory option may have unintended consequences. Therefore, potential impacts of a regulatory measure "authorisation" may be identified before a respective decision and its appropriateness be justified.

The SVHC identification is solely based on the intrinsic properties of a substance. However, although substances may fulfil the criteria of candidates for authorisation, the respective aims of the authorisation process may not be achievable. If a substance cannot be substituted in many uses (in a short or mid-term perspective) all market actors affected will have to apply for an authorisation. It is possible that either very many market actors will assume (and rely on) that an upstream application will cover their use or very many market actors will make an individual AfA. In the former case, very complex AfAs will be submitted and in the latter, a large number of AfAs will be applied for. Both create high burdens for market actors and authorities, which could possibly be avoided by a different regulatory measure, if it can be foreseen before the decision on the regulatory option.

All REACH processes to a large degree are based on registration data. The data quality and appropriateness is assessed in the dossier evaluation and detailed assessments of substance properties can be performed during substance evaluation. If the evaluation[17] reveals data gaps preventing conclusions on substance hazards, additional information can be requested from the registrants.

Since most of the REACH processes are interlinked and in order to identify the best regulatory options, additional informal processes and expert groups have been established. All formal and

[15] The scope of restrictions differ in that they not only cover SVHCs but any type of unacceptable risk from substances on the EU market including the placing on the market. As this is not relevant for the current analysis, it is not further discussed.

[16] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. A classification under CLP also impacts several other pieces of EU legislations as these refers to classification categories defined here. Thereby a new classification of a substance can result in a situation where another legislation becomes relevant for a substance. An example e.g. is the toy directive which prohibits the use of carcinogenic, mutagenic or substances toxic to reproduction (CMR) in toy materials (Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys)

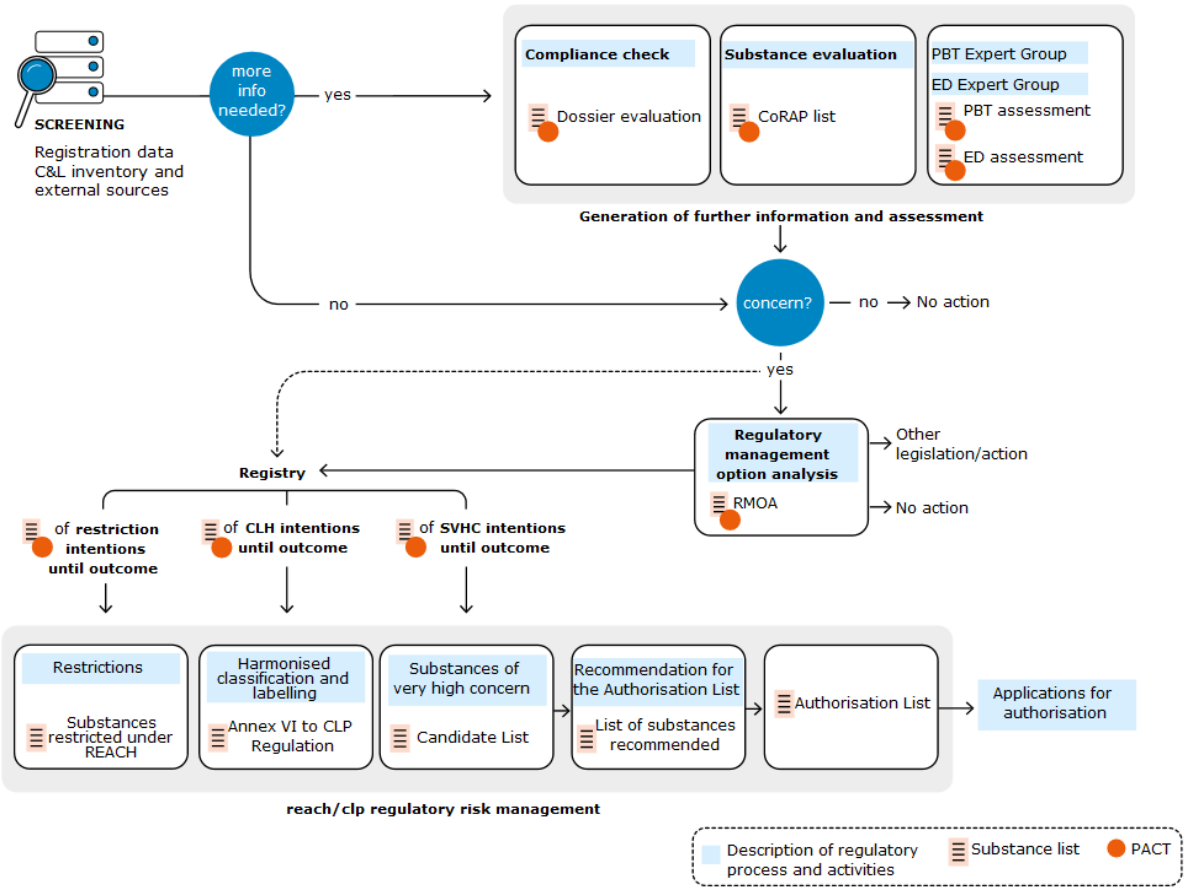
[17] During dossier evaluation, data request can only cover standard information that need to be included in the dossiers, while the substance evaluation can also request additional data.

informal processes and their interlinks are reflected in ECHA's Integrated Regulatory Strategy, which aims

- to efficiently identify substances of concern
- select the most suitable measure to reduce potential risks and
- to inform and involve stakeholders in this process.

ECHA's website gives an overview on the links between the procedures under https://echa.europa.eu/de/substances-of-potential-concern.

**Figure 2: ECHA's Integrated Regulatory Strategy**




(Source: European Chemicals Agency, http://echa.europa.eu/ as of February 2020)

Some of the procedures and involved bodies are briefly presented in the next chapters and their importance for the authorisation process is described.

### 2.3.1 Competent Authorities for REACH and CLP

The expert group of the Competent Authorities for REACH and CLP (CARACAL) advises the Commission and ECHA on the implementation of REACH and CLP. CARACAL members represent the national Competent Authorities for REACH and CLP. In addition, observers from non-EU countries as well as industry and trade associations, non-governmental organisations (NGOs), trade unions, and international organisations[18] participate.

[18] https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=39424&no=2

The CARACAL discusses various issues related to REACH and CLP and prepares recommendations to assist the Commission in the implementation of the regulations. With regard to the authorisation procedure, the interpretation of Article 57 (f)[19] has been discussed several times. The CARACAL also pre-discusses delegated acts or reflects on scientific opinions during their making (e.g. relevant for the inclusion of SVHC on Annex XIV and decisions on AfA).

**Workload for Authorities related to the CARACAL**

As part of their participation in the CARACAL, the authorities have to participate in several meetings over the year and comment on multiple documents before and after each meeting. In addition, they may bring forward own subjects for discussion. The meeting schedules are usually rather tight despite an extension of the meetings to two days (one for REACH and one for CLP).

**Conclusion**

The CARACAL is a very important exchange panel especially to discuss practical implementation issues and interpretations of the REACH where this is ambiguous. Regarding authorisation, some of the discussed issues include the SVHC Roadmap[20] and the interpretation of ELoC under Art. 57 (f)[21]. It supports the development of a common understanding on scientific and procedural questions among the MSCAs, ECHA the Commission as well as with the stakeholders (from industry, NGOs and scientists). Since observers can participate in the open session, the CARACAL meetings are also an opportunity for stakeholders to provide their opinions on the REACH processes and discuss with ECHA and the MSCAs. Thematic sub-groups may be formed such as the sub-group on EDs, which aims to describe how these substances should be approached under REACH[22].

Although the discussion time has already been extended, more time (and resources) would be needed to discuss all relevant issues in sufficient detail. This indicates a need for more/better written preparation before and documentation after the meetings.

### 2.3.2 Screening the Chemical Universe for Substances of Concern

ECHA performs screening processes to identify potential concern[23] using automated tools assisted by manual data analyses. While in the beginning, the screening should identify individual substances that might need regulation, ECHA increasingly identifies groups of substances with the aim of regulating the group members in a coordinated way and thereby reducing the risk that a substance is replaced by a similar and equally or even more hazardous substance. This is the substitution of a substance by another with the same problematic substance properties and thus does not lead to an overall improvement for human health or the environment.

[19] In 2020 a new sub group of the CARACAL was established to develop a framework for the treatment of endocrine disruptors under REACH and CLP

[20] The SVHC Roadmap describes the overall strategy for the identification of SVHC and the way risk management measures will be introduced in a future REACH implementation. It has been developed in 2013 and implementation plans have been published ever since by ECHA, see https://echa.europa.eu/svhc-roadmap-to-2020-implementation

[21] The ECHA approach on "Identification of substances as SVHCs due to equivalent level of concern to CMRs (Article 57(f)) – sensitisers as an example" has e.g. been pre-discussed in the CARACAL before it has become a guideline document for the identification of SVHC https://echa.europa.eu/documents/10162/13657/svhc_art_57f_sensitisers_en.pdf/a50728cc-6514-486c-9108-193a88b4bc9e

[22] See also CASG-ED/2020/03 "1st Meeting of Competent Authorities Sub-Group on Endocrine Disruptors (CASG-ED), 7 February 2020 https://circabc.europa.eu/ui/#

[23] The screening activities have a somewhat wider scope than to identify substances that fulfil the criteria to be a SVHC. It aims also for the identification of other substances that might need additional risk management and that are outside a potential scope of the authorisation.

ECHA's screening and identification of potential SVHCs is supported by informal independent expert groups. In the context of authorisation the expert group on PBTs[24] and the one on EDs[25] is relevant. The mandate of the expert group on EDs is as follows:

[…] "*The expert group provides informal and non-binding scientific advice on matters related to the identification of endocrine-disrupting properties of chemicals, in particular:*

- *Matters related to screening methods or activities to identify potential endocrine disruptors (e.g. for the CoRAP list or the Candidate List).*
- *Matters related to the development of integrated approaches to testing and assessment of endocrine-disrupting properties.*
- *Feedback and recommendations on complex (specific/generic) scientific issues related to information and (tiered) testing needs for potential endocrine disruptors (e.g. under dossier or substance evaluation, or under biocidal active substance evaluation).*
- *Specific questions on the interpretation of test data or other relevant information in relation to the identification of endocrine-disrupting properties (e.g. during SVHC dossier development or a biocidal active substance evaluation).*"

The mandate of the PBT expert group basically covers the same tasks for the PBT properties.

Both expert groups may be relevant especially in the SVHC identification. The expert groups consist of experts from MSCAs and the industry but also include independent experts and experts from industry organisations and NGO.

#### Workload for Authorities related to Expert Groups

The work of expert groups may facilitate the development of SVHC identification dossiers and hence, the respective workload of the preparing MS. It supports consolidating scientific data, identifying potential data gaps and resolving controversial interpretations of data (which may reveal additional research needs), Data generation can be facilitated by other REACH processes (e.g. the substance evaluation) or own additional data generation before the official process starts.

Consequently, the expert group is an additional process for potential participation by authorities, which facilitates a structured data analysis that would have to be performed, e.g. if an SVHC should be officially identified. The critical data review in the expert groups makes the outcome of official REACH processes more predictable as potential gaps or disagreements are already known. This might increase the overall efficiency of the SVHC identification and actually reduce the overall work on documents later on.

### 2.3.3 Regulatory Management Options Analysis

REACH authorisation is not the only process by which substance risks in the EU can be managed. To prevent unintended consequences, it is important to identify the most suitable regulatory measure that eliminates potential risks with the least efforts early in the risk management process.

[24] https://echa.europa.eu/pbt-expert-group

[25] https://echa.europa.eu/endocrine-disruptor-expert-group

Since an overreaching process to decide between regulatory alternatives was missing, the MSCA and ECHA introduced a respective informal instrument, the RMOA. ECHA (at the request of the Commission) or a MS can carry out this case-by-case analysis in order to conclude on the best regulatory measure for a certain substance risk.

The RMOA was introduced partly due to the stakeholders' criticism of the authorisation process when its implementation started. Authorisation was claimed to be burdensome and not effective with regard to the envisaged aims. It was also stated that

- Some SVHCs could not be substituted and the AfAs would put a large workload on applicants without real risk reduction and
- A risk reduction could be achieved by other regulatory options with lower efforts by all stakeholders.

For authorities, documenting the RMOA allows sharing information and promoting early discussion, in particular on whether or not a substance should be identified as SVHC. This should create a common understanding of the action pursued. An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g., harmonised classification and labelling, inclusion in the Candidate List or Annex XIV, restrictions, regulation under other EU legislation) or that no regulatory action is required at EU level.

Any subsequent REACH processes include consultations of interested parties and decision making by MSCAs and the European Commission, usually including Committee work as defined in REACH and CLP.

The substances for which an RMOA is either under development or has been completed since the implementation of the SVHC Roadmap commenced in February 2013 are included in the Public Activities Coordination Tool (PACT).

**Workload for Authorities related to RMOAs**

The generation of an RMOA involves significant additional work for the preparation of the document and potential consultations with stakeholders. In Germany, a formalised and defined public consultation procedure was established, where stakeholders can provide input to an RMOA. The input is evaluated and may be followed by an in-depth consultation, e.g. to clarify the uses, tonnages and the use conditions as well as the socio-economic impacts of a regulatory measure of substances that might qualify for an authorisation requirement.

Some of the RMOA information is not formally relevant for the SVHC identification or the prioritisation for authorisation. Hence, their collection causes additional workloads for the authorities.

Nevertheless, it seems reasonable to generate the information at this stage of the preparatory process to better understand if the aims of authorisation can be achieved and what impacts the requirement might cause in the supply chains if the SVHC cannot be substituted. This is especially important if it is foreseeable that a substitution is unlikely and exposure reduction measures should be implemented instead. Furthermore, an assessment of supply chains might provide an overview on the expected number of AfAs. This may support deciding between authorisation and restrictions in terms of effectiveness and efficiency. Restrictions could also be implemented under suitable product-specific regulation. This can even be reasonable, although the workload may be larger for a particular authority that initiates the later regulation, as if the substance would be subjected to an authorisation requirement.

### 2.3.4 Public Activities Coordination Tool

The main purpose of the PACT is the coordination of the regulatory activities of the various MSCAs and ECHA. In addition, the PACT can be seen as an instrument to communicate information on substances undergoing an RMOA so that stakeholders and the general public can better predict what substances may be addressed by formal risk management routes in the future. The PACT is published on ECHA's website[26].

The PACT gives registrants the opportunity to ensure that their registration data is up-to-date, to consider the best business strategy to address substances of potential concern, and to get prepared for public consultation during any subsequent regulatory processes.

ECHA highlights that the PACT also provides the contact details of the national authority performing an RMOA, which gives the possibility for stakeholders to feed the RMOA development process with their contributions and comments. It is important to note, however, that it remains the decision of the national authority how to take into account any input from stakeholders.

Bearing this in mind, it is also important to highlight that RMOAs or RMOA conclusions published on the PACT reflect only the views of the authority preparing the RMOA. ECHA further makes clear that this does not preclude the European Commission or other Member States from considering or initiating regulatory risk management measures which they deem appropriate.

#### Workload for Authorities in the Frame of the PACT

The PACT is in first instance an additional task for ECHA. The Pact increases the administrative workload for ECHA. It does not directly deliver an additional value for an authorisation but is an instrument that makes stakeholders aware of the various processes ongoing on substances. This enables them to prepare for formal or informal consultations and allows registrants to update registration information early enough for any assessments in the course of the authority activities. If the stakeholders use the PAC accordingly, the authorities' assessments could be improved.

### 2.3.5 Risk Management and Evaluation Platform (RiME+)

On the ECHA Website the RiME+ is described as "The informal Risk Management and Evaluation (RiME+) platform facilitates voluntary coordination and discussion on activities related to the implementation of the integrated regulatory strategy, covering the different REACH/CLP processes."[27]

In this exchange panel the MSCAs, COM and ECHA representatives discuss strategic issues regarding the regulation of substances without any formal commitment. If issues are identified that need a formal discussion, subjects can be focussed by e.g. preparatory studies, discussion papers etc. and included into the meetings of CARACAL

The role of the RiME+ platform is described on ECHA´s website:

- *"Support the implementation of the integrated regulatory strategy focusing on preparatory steps to regulatory risk management actions. This includes screening and regulatory management option analysis (RMOA) activities and how to best generate further information to identify substances for which further risk management is needed.*

[26] See: https://echa.europa.eu/de/pact

[27] https://echa.europa.eu/de/rime

- *Enhance common understanding on and promote further integration and efficient use of the different REACH/CLP processes, so that substances of concern are moved without undue delay to regulatory risk management.*
- *Identify needs for the setting up of ad-hoc groups to discuss and further develop generic approaches for priority topics or to work on (large) group of substances. Agree on the aim, scope, resources and timelines for such work groups.*
- *Reporting from the different ad-hoc groups (e.g. working on groups of substances) and existing working groups.*
- *Support the further development and enhance the use of tools to help authorities carry out their tasks and track ongoing activities (e.g. ACT, interact) and stakeholders follow progress (e.g. PACT) under the integrated regulatory strategy.*
- *Ensure that items are brought to CARACAL for discussion and endorsement, where relevant, and adequate reporting to CARACAL."*

RiME's work can be seen as a basis for future regulatory proposals[28] under REACH. Subjects are often related to ECHA´s, the COM's or a MS´s research. For example, if a thematic study has been prepared, the outcome and findings may be discuss including whether they should be considered in ongoing actions such as risk management measures.

The RiME+ also collaborates with the REACH Exposure Expert Group (REEG), which consists of representatives from the MSs and ECHA. Its work focusses on uses of hazardous chemicals and the related human (workers and consumers) and environmental exposures in the context of REACH. The group aims to enhance discussions, collaboration and coordination of activities among experts from authorities on related issues and may provide scientific input to the RiME+.

**Workload for Authorities in the Frame of the RiME+**

The workload for these informal activities (not foreseen by the REACH text) results in additional meeting capacity and the generation and commenting of meeting documents. Nevertheless, these meetings provide a chance to pre-discuss technical or strategic questions without the involvement of stakeholders. As a result officially foreseen meetings benefit from one or very few agreed options which can then be prepared and be discussed with a wider audience. To the consultants knowledge there are no other REACH related exchange formats for authorities to discuss open questions and the development of new approaches for the REACH implementation. So the efficiency of the overall process might be increased if only proposals are brought forward that have the support of a larger number of authority experts.

[28] Specific discussions on the overall regulatory strategy is not the main objective of the RIME+. Such issues are discussed within the CARACAL where all competent authorities for the REACH implementation are represented.

# 3 Status Quo of the Authorisation Process

## 3.1 Substances on Candidate List and Annex XIV

As of 1st of June 2008, Title VII on Authorisation under REACH entered into force. In October of the same year ECHA published the first SVHC candidate list (15 substances) and one year after entering into force the first recommendation for an inclusion in Annex XIV was issued (7 substances). In 2011, the first six substances were included in Annex XIV by a Commission delegated act[29]. In the meantime, the candidate list contains 209 substances (status June 2020) and ten recommendations were prepared by ECHA. Annex XIV covers 54 substances in the meantime and has been changed five times since its initial listing[30]. An overview on the composition of the candidate list and the current Annex XIV regarding the number of substances and the intrinsic properties linked to them is shown in Figure 3.

[29] Commission Regulation (EU) No 143/2011 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L .2011.044.01.0002.01.ENG&toc=OJ:L:2011:044:TOC

[30] Commission Regulation (EU) 2020/171 of 6 February 2020 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32020R0171

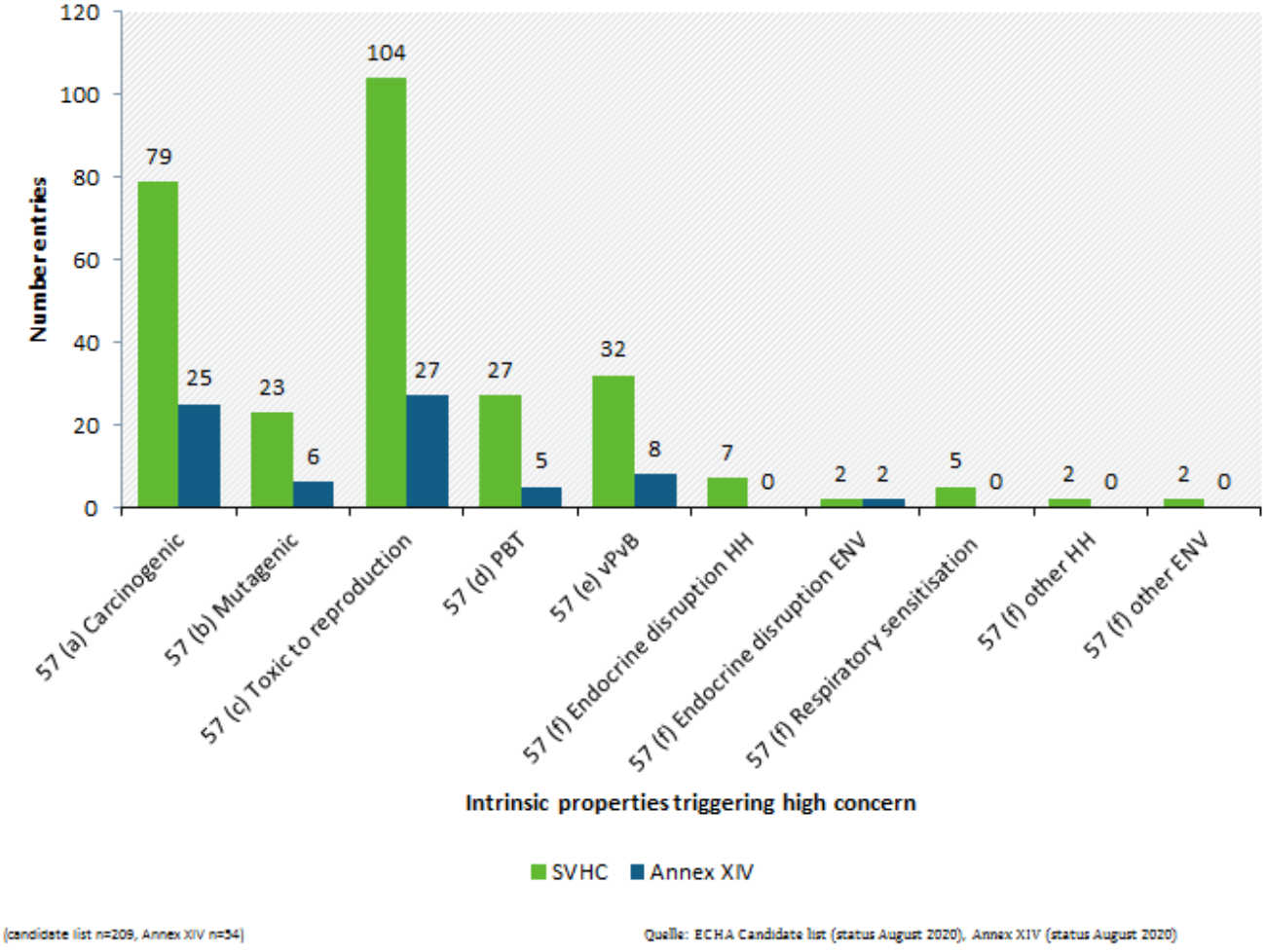
Commission Regulation (EU) No 2017/999 of 13 June 2017 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1497425502745&uri=CELEX:32017R0999

Commission Regulation (EU) No 895/2014 of 14 August https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32014R0895

Commission Regulation (EU) No 348/2013 of 17 April 2013 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32013R0348

Commission Regulation (EU) No 125/2012 of 14 February 2012 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32012R0125

**Figure 3: Types of substances on the candidate list and Annex XIV**




Source: own illustration

## 3.2 Applications for Authorisations

An analysis prepared by ECHA (Table 1) shows that for 32 of the 54 substances on Annex XIV, at least one AfA for one use has been submitted. In some cases AfAs were submitted by only one applicant and sometimes AfAs for such single uses were submitted by several applicants. This means, for 22 substances no AfAs have been submitted. Therefore, it can be assumed that these substances are not used anymore in the EU and that

- They have not been used in the EU before either or,
- They have been substituted by other processes or chemicals or
- The uses have moved outside the EU; i.e. products are produced with the substances elsewhere.

In the last case, the authorisation's ultimate aim of eventually phasing out the use of SVHC should not be seen as realised since a real shift to safer alternatives has not been introduced but the uses of potential high concern have just been relocated outside the geographical scope of REACH. Further it still led to unwanted effects on human health and/or the environment, including later import into the EU in articles, which is out the scope of an authorisation requirement but still might contribute to an exposure of humans or the environment throughout the life cycle.

**Table 1: Applications for authorisation per substance**

| Substance | Number of received[1] applications (applicants) | Number of uses | RAC and SEAC opinions per use[2] | RAC and SEAC opinions per use and per applicant[3] | Commission decisions per use and per applicant[4] |
|---|---|---|---|---|---|
| Bis(2-ethylhexyl) phthalate (DEHP) | 5 (7) | 10 | 10 | 14 | 7 |
| Dibutyl phthalate (DBP) | 3 (3) | 5 | 5 | 5 | 5 |
| Bis(2-ethylhexyl) phthalate (DEHP) and Dibutyl phthalate (DBP) | 1 (1) | 3 | 3 | 3 | 3 |
| Lead sulfochromate yellow (C.I. Pigment Yellow 34) and Lead chromate molybdate sulphate red (C.I. Pigment Red 104) | 1 (1) | 12 | 12 | 12 | 12 |
| Hexabromocyclododecane (HBCDD) | 1 (13) | 2 | 2 | 26 | 26 |
| Diarsenic trioxide | 4 (4) | 5 | 5 | 5 | 5 |
| Trichloroethylene | 13 (15) | 19 | 19 | 21 | 21 |
| Lead chromate | 1 (1) | 1 | 1 | 1 | 1 |
| Chromium trioxide | 43 (88) | 69 | 56 | 127 | 49 |
| Sodium dichromate | 21 (27) | 27 | 27 | 39 | 36 |
| Chromium trioxide, Sodium dichromate and Potassium dichromate | 1 (6) | 3 | 3 | 18 | 18 |
| Chromium trioxide, Sodium dichromate | 1 (2) | 1 | | | |
| Sodium chromate | 3 (5) | 4 | 4 | 7 | 8 |
| Sodium chromate; Potassium chromate | 1 (1) | 4 | 4 | 4 | 4 |
| 1,2-Dichloroethane (EDC) | 16 (18) | 20 | 20 | 22 | 22 |

| Substance | Number of received[1] applications (applicants) | Number of uses | RAC and SEAC opinions per use[2] | RAC and SEAC opinions per use and per applicant[3] | Commission decisions per use and per applicant[4] |
|---|---|---|---|---|---|
| Potassium dichromate | 4 (4) | 7 | 7 | 7 | 7 |
| Ammonium dichromate | 3 (5) | 4 | 4 | 5 | 5 |
| Dichromium tris(chromate) | 2 (3) | 3 | 3 | 5 | 5 |
| Chromium trioxide; Dichromium tris(chromate); | 1 (2) | 4 | 4 | 5 | 5 |
| Strontium chromate | 2 (13) | 3 | 3 | 23 | 20 |
| Potassium hydroxyoctaoxodizincatedichromate | 1 (5) | 2 | 2 | 10 | 10 |
| Bis(2-methoxyethyl) ether (Diglyme) | 10 (10) | 12 | 10 | 10 | 8 |
| Arsenic acid | 1 (1) | 1 | 1 | 1 | 1 |
| Chromic acid | 1 (1) | 1 | 1 | 1 | 1 |
| Formaldehyde, oligomeric reaction products with aniline (technical MDA) | 1 (1) | 2 | 2 | 2 | 2 |
| 2,2'-dichloro-4,4'-methylenedianiline (MOCA) | 1 (1) | 1 | 1 | 1 | |
| Pentazinc chromate octahydroxide | 2 (3) | 4 | 4 | 6 | 6 |
| 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated | 50 (69) | 76 | 23 | 29 | |
| 4-Nonylphenol, branched and linear, ethoxylated | 5 (6) | 6 | 2 | 2 | |
| 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated; 4-Nonylphenol, branched and linear, ethoxylated | 6 (22) | 21 | | | |
| Pitch, coal tar, high-temp. | 4 (4) | 4 | 1 | 1 | |
| Pitch, coal tar, high-temp.; Anthracene oil | 4 (4) | 4 | 1 | 1 | |

[1] An application/review report is received in terms of Article 64(1) of REACH when ECHA has received the application fee.

[2] One opinion refers to a compiled version of the final opinions of RAC and SEAC for each use.

[3] This refers to compiled final opinions of RAC and SEAC for each use and applicant/authorisation holder. For instance, if one application has been submitted by 3 applicants/authorisation holders for 1 substance and 2 uses there will be (3×1×2=) 6 RAC and SEAC opinions and subsequent Commission decisions. If another application/review report is submitted by 1 applicant/authorisation holder for 1 substance and 3 uses, there will be (1×1×3=) 3 RAC and SEAC opinions and Commission decisions. In total there would be 9 RAC and SEAC opinions and 9 Commission decisions.

[4] Final decisions for each use and applicant/authorisation holder.

(Source: ECHA August 2020 https://echa.europa.eu/de/received-applications )

The above three cases could also occur for all other SVHCs on Annex XIV for which applications have been submitted. The AfAs only show that there are some uses that are considered necessary at least in the short- or mid-term. To date no profound information is available to what degree the authorisation regime really increased substitution activities. A study prepared for the REACH review 2018 on the "Impacts of REACH Authorisation" (EU COM, 2017)[31] found that market actors rather reported that they experienced some market effects from the authorisation obligation, but this did not lead to an increase in the market for alternatives or products produced with alternatives. Effects were more linked to:

- "*a reduction in the number of suppliers of SVHCs,*
- *reduced availability of the SVHC for their use,*
- *an increase in the price of the SVHC, and*
- *conditions being imposed on safe handling and use of an SVHC*."

These answers indicate that it became somewhat more burdensome for market actors to operate with SVHCs from Annex XIV, but substitution was not first choice[32] (at least at the time the study was prepared).

A recent study prepared by ECHA[33] on the impacts of authorisation and restriction indicated that a restriction is seen as a main driver for substitution followed by market demands to replace hazardous substances in products. An authorisation requirement itself was not necessarily seen as a strong driver for substitution since costs for the replacement were estimated to be high[34] while market advantages due to the replacement were considered to be low. On the other hand the listing of SVHCs on the candidate list is a key process for market actors to identify substances that should be replaced in products. Therefore this part of the authorisation is a strong driver for market demands. Also several substances subjected to a restriction later on were first included in the candidate list as a first step of regulatory activity, thus authorisation might have an indirect effect on substitution even though it is not perceived in this way by all stakeholders.

[31] Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (December 2017) "Study on the Impacts of REACH Authorisation" Economics for the Environment Consultancy Ltd (eftec) in association with Apeiron-Team NV, Peter Fisk Associates Limited (PFA) and The Economics Interface Limited
https://ec.europa.eu/docsroom/documents/26847/attachments/1/translations/en/renditions/native

[32] At least before 2017 at the time the study was prepared.

[33] ECHA (July 2020), "Impacts of REACH restriction and authorisation on substitution in the EU"
https://echa.europa.eu/documents/10162/24152346/impact_rest_auth_on_substitution_en.pdf/7c95222f-5f84-57f7-4cba-65b8463c79d4 ,

[34] Although ECHA noted there might be an overestimation of the costs of substitution by stakeholders.

# 4 SVHC-Identification

## 4.1 Overview

REACH Article 57 defines the hazardous properties a substance must fulfil to qualify being subjected to the authorisation process. Art. 59 defines the identification procedure and the responsibilities for the individual steps. An overview on the steps to be taken to include a substance on the candidate list is given in Table 2.

**Table 2: Steps and timeline for the identification of an SVHC**

| Step #[35] | Article | Task | Timeline |
|---|---|---|---|
| 1.1 | 59 (2) | Preparation of an Annex XV Dossier by ECHA on request of the Commission | Not specified |
| 1.2 | 59 (3) | Preparation of an Annex XV Dossier on MSCA initiative | Not specified |
| 2.1 | 59 (2) | Circulation of Dossier to MSCAs (dossier preparation by ECHA) | Not specified |
| 2.2 | 59 (3) | Circulation of Dossier to other MSCAs (dossier preparation by MSCA) | 30 days from receipt |
| 3 | 59(4) | Publication of a note on ECHA's website that an Annex XV dossier has been prepared, invitation of interested parties to submit comments and subsequent commenting phase by stakeholders | Not specified in regulation (45 days set by ECHA) |
| 4 | 59 (5) | Commenting by MSCAs`15 | 60 days |
| 5.1 | 59(6) | Inclusion into candidate list without further discussion if no comments are received. | not specified publication without undue delay (Art. 59(10) |
| 5.2.1 | 59 (7) | Forwarding of dossier and received comments to Member State committee (MSC) to decide on inclusion | 15 days |
| 5.2.2 | 59(8) | MSC decision | 30 days |
| 5.2.3 | 59(8) | Inclusion into candidate list if unanimous agreement on the identification is reached | not specified (twice a year specified by ECHA) |
| 5.3.1 | 59(9) | In case of disagreement in the MSC, the EU COMmission prepares a draft proposal on the inclusion | 3 months (after receipt of the MSC opinion) |
| 5.3.2 | 59(9) | Final decision by EU Com and REACH-Committee | not specified |

[35] Steps with same numbers belong to the same step and are alternatives, e.g. if different actors can perform the step.

| Step #[35] | Article | Task | Timeline |
|---|---|---|---|
| 5.3.3 | 59 (10) | Update of candidate list after final (positive) decision | not specified (without delay) |

## 4.2 Authorisation Scope

Art. 56 defines the general conditions of the authorisation process. It defines a clear phase-out scenario for SVHCs listed in Annex XIV of the regulation and hence require authorisation. For each substance a sunset date is provided in the annex, which defines the date from which a substance may not be used anymore, unless certain conditions apply. These conditions are also part of Art. 56 and Art. 2:

- the use is covered by a granted authorisation
- the use is covered by a specific exemption that is incorporated in Annex XIV
- the sunset date has not yet passed
- the sunset date has passed and an application has been made 18 months before that date but a decision on the application for authorisation has not yet been taken
- the use is covered by a general exemption according to Article 56 (3-6)
- the substance is excluded from the scope of REACH or Title VII according to Art. 2, in particular intermediates are excluded based on Article 2(8).

In addition, situations are described, where the legislator considers an authorisation disproportionate. These exemptions from the requirement to apply for authorisation are:

- Art. 56 (3) "research and development": This exemption covers substance uses which have not been commercialised, yet. The REACH text generally exempts scientific research and development (SR&D)[36] as it is assumed that the tonnages are rather small and handling is performed with special care by researchers along the life cycle. A threshold for SR&D has been specified at 1 ton per year (Art. 3 (23)). It should be noticed that also standard measurements and analysis can be seen as SR&D[37]. If specified in the Annex XIV entry, also Product and Process Orientated Research and Development (PPORD) may be exempted. Up to now this exemption has not been used.[38]
- Art. 56 (4) "other authorisations schemes already apply": The four exemptions of this paragraph have been included because the legislator considered risks already sufficiently assessed under other legislation, namely that on PPPs, biocides, engine fuels and other

[36] See also ECHA 2017 Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD) Version 2.1October2017 http://echa.europa.eu/documents/10162/23036412/ppord_en.pdf/22a12900-ad27-454c-aedd-82972ef2f675

[37] See ECHA Q&A ID: 0585 Version: 1.2 (retrieved 28.01.2019) https://echa.europa.eu/de/support/qas-support/browse/-/qa/70Qx/view/ids/585

[38] The PPORD exemption allows the use of relatively small amount of a substance (1ton per year). This is often not enough for the development of an application under industrial condition. Furthermore the authorisation requirement would put pressure on such a use from the beginning and an argumentation that would justify a use of such an SVHC would be very challenging. So there is very little incentive to use this rule under REACH, which is clearly intended by title VII.

fuels.[39] Here, the legislator found it disproportionate to subject the uses to a second approval scheme (PPP, biocides) or socio economically justified (fuels).

- Art. 56 (5) "other authorisations schemes already apply for human health": Substances subject to authorisation due adverse effects on human health (57 (a-c) and f) if human health)) already having undergone an evaluation under EU legislation are exempted. This concerns in particular legislation on cosmetics and food contact materials.[40]
- Art. 56 (6) "Mixtures that contain substances subjected to authorisation below a threshold": Substances contained in mixtures below the listed thresholds need not be subjected to authorisation. The thresholds do not refer to the volumes per use of a market actor but address the concentration of substances in mixtures. For CMR substances the thresholds refer to the thresholds applying to their classification (Article 57 (a-c)). For substances requiring authorisation based on Article 57 (d-f) a generic threshold of 0.1 % weight by weight (w/w) applies. This exemption can be interpreted as an attempt to ensure proportionality between the burden of substitution and the preparation of an AfA if the c substance concentrations in a mixture are low. It should be noted that the thresholds are no safe levels derived from toxicological data, which would be needed to justify an authorisation based on adequate control of risks. A threshold value exempting substances from authorisation based on low amounts does not exist.

## 4.3 SVHC Identification

The identification of new SVHCs according to REACH starts with the preparation of a dossier in line with the requirements of REACH Annex XV on the initiative of MSCA or by ECHA on request of the COM.

To identify a substance as SVHC, information related to the substance identity and its intrinsic hazardous property (-ies) are compiled. The key information on the substance's uses, potential alternatives and use volumes have to be provided in the second part of the dossier. This dossier part is confidential. The extent of required information varies across substances, in particular related to the property that causes the concern. It is highly dependent on the available information provided by industry or public literature on exposures, uses, and alternatives.

For substances that are identified as SVHC according to Article 57 (a-c) the dossier can be limited to a CLP harmonised classification if this already exists (REACH Art. 59 (2) and (3)). This option does not exist for PBTs/vPvBs due to a lack of a corresponding classification category. For SVHC identifications based on Article 57 (f) reference to a classification category may be useful, but is not sufficient to demonstrate the equivalent concern. Further arguments have to be included in the dossier that describes the impact on human health or the environment in more detail (e.g. irreversibility of exposure/effect, severity of effect). For some hazards that could lead to an SVHC identification no corresponding classification exists, e.g. environmental EDs[41] or PMT substances.

If no harmonised classification exists or if this is not sufficient, the Annex XV dossier should document evidence that demonstrates the substances has a particular hazardous property.

[39] Note: there are also some more exemption of similar type included in Article 2 of the REACH regulation.

[40] CMR substances cat. 1a/b are e.g. restricted in cosmetics by Article 15 of Regulation (EC) No. 1223/2009. Cat 2 substances are only allowed in case an evaluation of a scientific committee concluded the risk is justifiable. (https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF)

[41] Endocrine disruptors that impact the human health are currently always classified as toxic to reproduction.

Registration dossiers should contain the data on the substance properties, tonnages and at least a generic use pattern. If this is not the case, e.g. due to data waiving or low registration volumes (tests not required), ECHA could request it in the course of compliance checks (dossier evaluation) or by Member States in the course of substances evaluations if standard information according the REACH Annexes VII – X are concerned. According to REACH Art. 46, MSCAs are entitled to request additional information beyond the standard information requirements to close data gaps, during substance evaluation.

Dossier and substance evaluation cannot be used for data generation if the requirement to register a substance does not apply. This could be the case in the following situations:

- A substance is manufactured or imported in amounts below 1 ton per year,
- A substance is a polymers (REACH Art. 2(9))[42].

As a consequence, for non-registered substances the burden of proof is that a substance fulfils at least one of the criteria of REACH Art. 57 lies with the dossier submitter (see also Figure 4). In such situations the authorities have to rely on available information in the literature. If no or insufficient data are available, they may research the relevant properties to generate the needed data for SVHC identification and potentially further regulatory measures.

Polymers may be included in the registration obligation under the condition that it is possible to describe suited technical and scientific criteria (review clause of REACH Art. 138 (2)). In the past, the COM has contracted several studies to develop a framework for registering polymers under REACH (RPA 2012[43], Bio 2015[44]). The ongoing third study is expected to define a registration obligation that may be introduced by 2022. Such an obligation might help to overcome several problems related to authorisation:

- SVHC Identification of polymers: Currently, authorities have no or little knowledge of some polymers on the market. Since regulated substances must be clearly identified a registration obligation would enable taking inventory of polymers on the market.
- Generation of key toxicological data: Data necessary to identify polymers as SVHC would be provided in the registration dossier.

Therefore and regarding the efficiency of authorisation, a registration requirement for polymers would reduce the authorities' burdens for SVHC identification as well as for introducing adequate risk management measures.

For substances placed on the market in volumes below 1000 kg per year and manufacturer/importer a registration is currently not foreseen as it is considered disproportionate. This leaves the burden of proof with the authorities in case they suspect SVHC properties go along with a substance. Such a burden could be reduced if the needed data could be requested from market actors if sufficient evidence of concern exists. Such right to ask for data would need criteria to define the level of evidence to prove an indication of concern. Overall it might decrease the efforts of the authorisation process for MSCAs as less data generation has to be performed by them and a higher number of substances could be targeted with existing

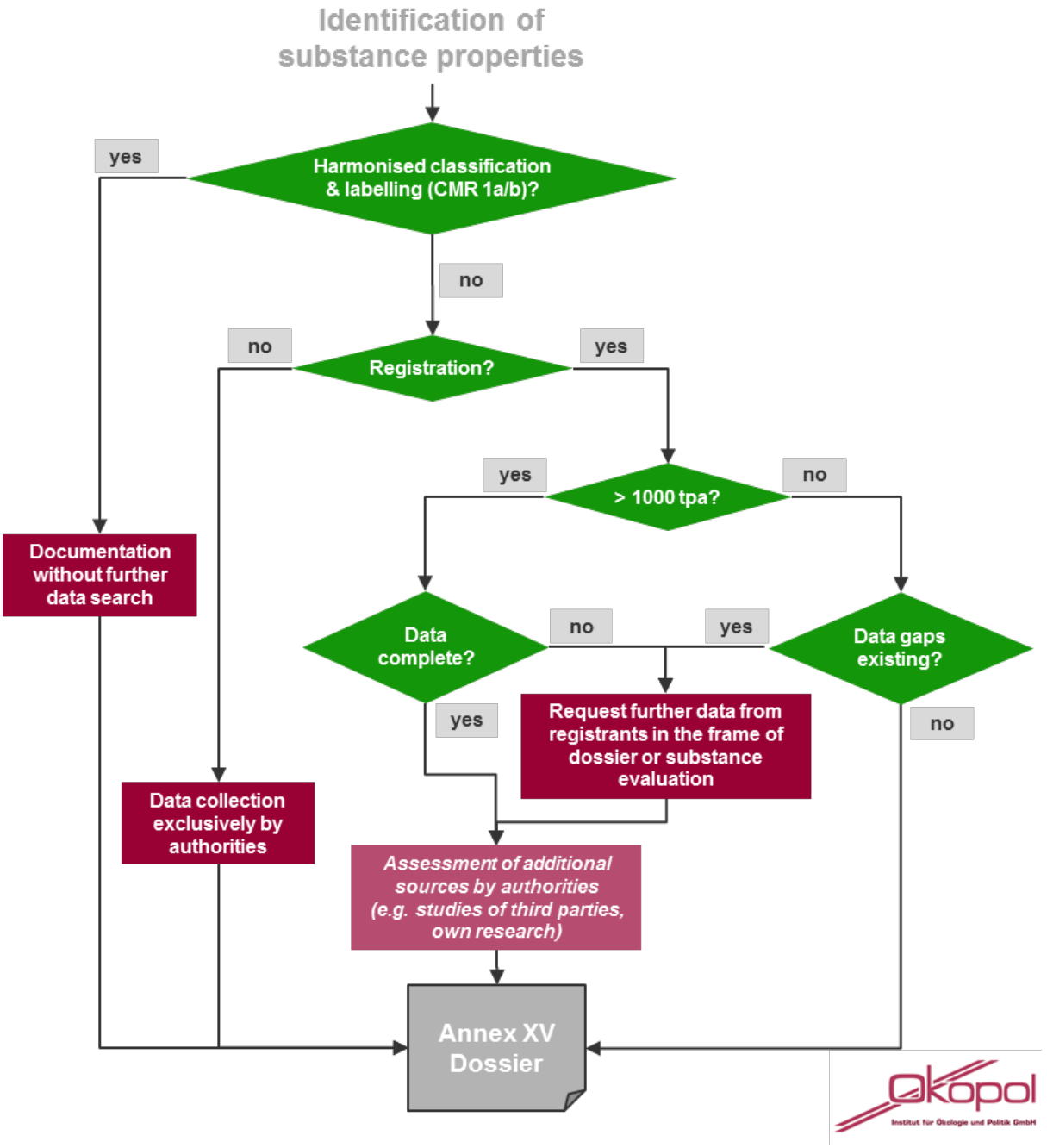
[42] The exemption for registering polymers is currently under scrutiny on the basis of REACH Art. 138 (2).

[43] Review of REACH with regard to the Registration Requirements on Polymers and 1 to 10 Tonne Substances 070307/2011/602175/SER/D3 https://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study10.pdf

[44] Technical assistance related to the review of REACH with regard to the registration requirements on polymers, Final report https://ec.europa.eu/environment/chemicals/reach/pdf/FINAL%20REPORT%20POLYMER%20SI671025.pdf

resources. On the other hand it might be more efficient from an overall perspective, if the data are generated by the authority instead of investing resources to identify market actors that place the substance on the market and request the data from them. If the data generation should be performed by stakeholders, a notification obligation for low tonnage substances might be recommendable to identify potential duty holders.

**Figure 4: Approaches to generate hazard data for Annex XV dossiers**




Source: BMWi 2019

## 4.4 Case Studies on SVHC Identification

Ten of case studies were developed to analyse the effectiveness and efficiency of SVHC identification and to exemplify potential shortcomings or achievements of the current SVHC identification. Publicly available documents, in particular Annex XV Dossiers, RMOA outcome

documents, background reports on substances or groups of substances and the response to comments documents were analysed. The case selection considered that the following should be represented:

- various hazard end points linked to Article 57 a-f
- substances with multiple SVHC endpoints
- at least one substance group
- "special situations" understood as: substances with impurities (Basic Violet), substances that qualify as SVHC based on the degradation products (OPEs)

An overview in the selected cases is shown in Table 3.

**Table 3: Cases selected to analyse SVHC identification**

| # | Substance name | Description | EC / List no | CAS no | Scope |
|---|---|---|---|---|---|
| 1 | [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (Basic Violet) | with ≥ 0.1% (w/w) of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2) | 208-953-6 | 548-62-9 | Carcinogenic (Article 57a) |
| 2 | 2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol, UV-328 | | 247-384-8 | 25973-55-1 | PBT (Article 57d)#vPvB (Article 57e) |
| 3 | 4-(1,1,3,3-tetramethylbutyl)phenol (Octylphenol) | | 205-426-2 | 140-66-9 | Endocrine disrupting properties (Article 57(f) - environment) |
| 4 | 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (OPEs) | covering well-defined substances and UVCB substances, polymers and homologues | - | - | Endocrine disrupting properties (Article 57(f) - environment) |
| 5 | Bis(2-ethylhexyl) phthalate (DEHP) | | 204-211-0 | 117-81-7 | Toxic for reproduction (Article 57c)#Endocrine disrupting properties (Article 57(f) - environment)#Endocrine disrupting properties (Article 57(f) - human health) |
| 6 | C,C'-azodi(formamide) ADCA | | 204-650-8 | 123-77-3 | Respiratory sensitising properties (Article 57(f) - human health) |
| 7 | Hexamethylene diacrylate (HDDA) | | 235-921-9 | 13048-33-4 | Skin sensitising properties (Article 57(f) - human health) |
| 8 | Pentadecafluorooctanoic acid PFOA | | 206-397-9 | 335-67-1 | Toxic for reproduction (Article 57c)#PBT (Article 57d) |
| 9 | 4,4'-isopropylidenediphenol | Bisphenol A; BPA | 201-245-8 | 80-05-7 | Endocrine disrupting properties (Article 57(f) - environment); Endocrine disrupting properties (Article 57(f) - human health); Toxic for reproduction (Article 57c) |
| 10 | Cadmium | | 231-152-8 | 7440-43-9 | Carcinogenic (Article 57a)#Specific target organ toxicity after repeated exposure (Article 57(f) - human health) |

| # | Substance name | Description | EC / List no | CAS no | Scope |
|---|---|---|---|---|---|
| | Cadmium carbonate | | 208-168-9 | 513-78-0 | Carcinogenic (Article 57a)#Mutagenic (Article 57b)#Specific target organ toxicity after repeated exposure (Article 57(f) - human health) |
| | Cadmium chloride | | 233-296-7 | 10108-64-2; 35658-65-2 | Carcinogenic (Article 57a)#Mutagenic (Article 57b)#Toxic for reproduction (Article 57c)#Specific target organ toxicity after repeated exposure (Article 57(f) - human health) |
| | Cadmium fluoride | | 232-222-0 | 7790-79-6 | Carcinogenic (Article 57a)#Mutagenic (Article 57b)#Toxic for reproduction (Article 57c)#Specific target organ toxicity after repeated exposure (Article 57(f) - human health) |
| | Cadmium hydroxide | | 244-168-5 | 21041-95-2 | Carcinogenic (Article 57a)#Mutagenic (Article 57b)#Specific target organ toxicity after repeated exposure (Article 57(f) - human health) |
| | Cadmium nitrate | | 233-710-6 | 10325-94-7; 10022-68-1 | Carcinogenic (Article 57a)#Mutagenic (Article 57b)#Specific target organ toxicity after repeated exposure (Article 57(f) - human health) |
| | Cadmium oxide | | 215-146-2 | 1306-19-0 | Carcinogenic (Article 57a)#Specific target organ toxicity after repeated exposure (Article 57(f) - human health) |
| | Cadmium sulphate | | 233-331-6 | 10124-36-4; 31119-53-6 | Carcinogenic (Article 57a)#Mutagenic (Article 57b)#Toxic for reproduction (Article 57c)#Specific target organ toxicity after repeated exposure (Article 57(f) - human health) |
| | Cadmium sulphide | | 215-147-8 | 1306-23-6 | Carcinogenic (Article 57a)#Specific target organ toxicity after repeated exposure (Article 57(f) - human health) |

## 4.5 Key Findings from the Case Studies

### 4.5.1 Findings on CMR Substances

- **Harmonised classifications shift the workload from SVHC identification to classification.** All cases of SVHC identification according to REACH Art. 57 (a-c) concerned substances with harmonised classifications. This is in line with an agreed strategy between ECHA and the MSCAa[45]. It is an advantage that besides ECHA and the MSCAs, the RAC is also involved in a harmonised classification and therefore the evidence proving that the relevant intrinsic property is fulfilled was not questioned.
  It should be noted that the workload for the SVHC identification is low, but that corresponding efforts have been invested into the harmonised classification.

- **Grouping of CMRs would be more effective by reducing the risk of substitution with similarly hazardous substance and more efficient by reducing efforts of compiling Annex XV dossiers**. Structurally similar CMR substances might be used as alternatives for each other. To avoid that a substance is replaced by a similar and equally or even more hazardous substance, it could be an option to regulate them as a group (see. e.g. chromate compounds, lead compound, cadmium compounds, some fluorinated compounds). Even if the similarity is very high, substances are currently identified as SVHCs in separate processes. This multiplies the workload for dossier preparations, public consultations, and opinion development on the MSC etc.

- **Differentiating adverse effects for individual members of a group would reduce workloads of SVHC identification while still enabling inclusion of different relevant endpoints.** Cadmium compounds are an example where all group members fulfil the carcinogenicity criterion (REACH Art. 57 (a)). This property alone would be sufficient to include all substances in the candidate list and make them subject to authorisation. Nevertheless, all cadmium compounds were also identified as substances of equivalent concern according to Article 57 (f)[46]. The mutagenicity and toxicity to reproduction of cadmium differs, with some fulfilling the criteria for classification 1a/b and others not. Dossier data shows that the effect is caused by the extent to which the compounds release free cadmium ions.

- **Clear criteria when impurities with CMR substances trigger an SVHC identification are needed, also to reduce efforts related to consultations.** The substance 4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (Basic Violet) is considered an SVHC only if it contains a CMR impurity in the substance in concentrations exceeding 0.1% (w/w) (i.e. content of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2) equal to or above 0.1% (w/w)). The public

[45] See ECHA (2013) „SVHC Roadmap to 2020 Implementation Plan9 December 2013, Annex 2: Screening for potentially relevant SVHCs – CMRs“ https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf/66ba723a-d2e4-4d1a-ae89-a78c4db4d621

[46] due to their effects on the kidneys and the bones (harmonised classification as STOT RE1 - hazard statement H372: Causes damage to organs through prolonged or repeated exposure)

consultation showed that it was important to clarify that a pigment with a lower concentration of Michler´s ketone than 0.1% (w/w) is not considered an SVHC and that the reference for a formulated mixture would be the final concentration of the impurity in the mixture (not the concentration of the pigment). Many inputs to the consultation were due to a misunderstanding and caused unnecessary work to address them.

### 4.5.2 Findings on PBT/vPvB Substances

- **SVHC identification of PBT/vPvB substances requires higher efforts by authorities but leads to a formally agreed PBT/vPvB status and may differ from the respective conclusions of the registrants.** In general, the identification of an SVHC according to REACH Art. 57 (d) or (e) requires more efforts than for CMRs, because it cannot rely on a harmonised classification (even though some harmonised classifications can be used to demonstrate the T criterion[47]). It involves the development of a weight of evidence approach by the dossier submitter. According to the registration dossier, UV-328 is not a PBT/vPvB. In this regard these additional efforts assist additional measures needed to ensure adequate risk management for the substances (authorisation/restriction) and the generation of additional information (e.g. by supply chain or notification obligations), which ensured REACH aims can be realised.

- **Demonstration of persistence can be straight forward.** The case studies show that persistency can be demonstrated in a clear and concise way based on registration data and/or models on persistence[48]. In the case of UV-328, read-across to the substance's main degradation products was used, where it was known that data show a high persistence. By this, it was possible to generate new additional data on the UV-328 itself.

- **Identification of the B-criterion may require considerable efforts.** More disagreement can be observed between dossier submitters and other involved experts (MSCA and stakeholders), when the B criterion is discussed (see case on UV-328, PFOA). The standard method to discuss bioaccumulation, the bio-concentration factor is assessed. This is usually determined via the oil/water partitioning coefficients. This endpoint involves some uncertainties, as it is often not determined experimentally but modelled. In case of PFOA the bio-concentration factors do not meet the numeric criteria of Annex XIII. However, the weight of evidence argumentation demonstrates that the substance accumulates in food webs via bio-magnification and can therefore be considered to fulfil the B criterion. This is in line with Annex III Chapter 3.2.2. in cases, where the bio-concentration is not the most representative parameter to describe the bioaccumulation potential.

[47] See REACH Annex XIII section 1.1.3. Toxicity points 2 and 3:

[…] *"(b) the substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B, or 2) according to Regulation EC No 1272/2008;*
*(c) there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008.*" […]

[48] Even though it needs to be highlighted that this could be different in cases where data do not show such a clear picture.

### 4.5.3 Findings on Substances of Equivalent Concern

Article 57 (f) has been used for substances considered to be endocrine disruptors with the differentiation of whether there is relevance for human health or the environment. All assessed substances identified as endocrine disruptors for human health are already classified as reproductive toxicants.

All dossiers cover an individual case by case weight of evidence approach with the special case of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (OPEs) where a group of polymeric substances is covered that can degrade to octylphenol, which is an identified SVHC because of its endocrine disrupting properties (environment), and where the polymeric substances themselves do not show the endocrine effect.

- **SVHC identification as EloC is labour intensive due to extensive stakeholder commenting on the Annex XV dossier.** The comments on Article 57 (f) substances were often very extensive. Many comments questioned the weight of evidence arguments and the relevance the substance has in regard to the equivalent concern (is the concern obvious or large enough to be regulated). Arguments brought forward are e.g. linked to:
  - The relationship between an effect and the exposure towards a substance (effect not linked to substance use)
  - The level of control and in conclusion
  - The extend of the effect, it is questioned that an effect can be demonstrated frequently and might therefore be negligible
  - The irreversibility of effects (see also next aspect)
- **A lack of agreement on approaches to demonstrate an EloC (for skin sensitisers) increases workloads or leads to unsuccessful SVHC proposals.** Case-by-case approaches for sensitisers followed a scheme ECHA proposed in a paper (ECHA 2012)[49], where they exemplified a comparison between CMR substances and sensitisers according to 6 criteria:
  - Health effects
    - Type of possible health effects
    - Irreversibility of health effects
    - Delay of health effects
  - Other factors
    - Quality of life affected
    - Societal concern
    - Possibilities to derive a “safe concentration”

[49] https://echa.europa.eu/documents/10162/13657/svhc_art_57f_sensitisers_en.pdf/a50728cc-6514-486c-9108-193a88b4bc9e

- For ELOC effects in the environment the following parameters can be considered (not conclusive)[50]
  - Delay of effects
  - Inter-generational effects
  - Impact on migratory species (spatial effects)
  - Impact of short-term exposure (long-term effects)
  - Potential to impair population level structure and recruitment or ecosystem function and stability

In the case of HDDA, the MSC decision was split, since some MS were not convinced that the criteria sufficiently support an SVHC identification based on an EloC. In particular, they questioned the irreversibility of the effect and the extent to which the quality of life is reduced by potential effects. They did not generally question the possibility of skin sensitisers being considered SVHCs nor that HDDA is a highly potent skin sensitiser. However, they did not support the argumentation along the six criteria.

### 4.5.4 General Overarching Observations

- **Data in addition to that generated under REACH may be required to substantiate an SVHC identification.** A better data basis on adverse effects, especially to use the weight of evidence approach, is needed to show the criteria of an SVHC property are fulfilled. Additional information sources could be EU Risk Assessment Reports (RAR)[51] or the OECD Screening Information Datasets (SIDS). In the assessed cases, very extensive data was presented (except where SVHC identification was based on harmonised classifications[52]) to substantiate the weight of evidence arguments. If data gaps exist, an efficient process to generate these data is needed. Under REACH this could be the Evaluation. Currently, the processes in the frame of evaluation are considered to be very time consuming and do not deliver data within an appropriate timeframe.
- **Information that is not essential for SVHC identification may be included in an Annex XV dossier, resulting in efforts being shifted from later stages of the authorisation process to the SVHC identification.** Apart from hazard information, data on tonnage (imported, manufactured, used), sectors or areas of use were included in the analysed Annex XV dossiers. While not needed for the SVHC identification, ECHA later used it for its recommendation on Annex IV inclusion. This addition may originate from RMOAs and may

[50] See ECHA Annex XV SVHC report template, chapter 6.3.2.2 Environment https://echa.europa.eu/documents/10162/13638/annex_xv_svhc_report_template_en.doc/906b4cd5-383e-4e68-b0d1-7fd5c7dd6e20 or

[51] https://echa.europa.eu/en/information-on-chemicals/information-from-existing-substances-regulation

[52] It should be noted that in these cases substantial work has also been invested to demonstrate the harmonized classification is justified. In consequence this means authorities will need to invest less efforts in an overreaching perspective.

also support the selection of the best regulatory measure (i.e. before SVHC identification). In the cases assessed hardly any RMOAs were prepared[53].

- **SVHC identification may also result in restriction proposals.** Some SVHCs were not included in Annex XIV but subjected to a restriction because of the (additionally submitted) information on amounts and uses (in different sectors) as well as the inability of the authorisation process to properly address the risks (e.g. PFOA due to its low concentrations in other substances or in articles).

- **RMOAs can help deciding how to share the burden of proof and selecting the best regulatory option early in the process.** In case of HDDA (skin sensitiser) the RMOA concluded that in principle a restriction addresses potential risks. However, it was as expected difficult to demonstrate and describe HDDA's human health impacts due to a lack of relevant data (especially for consumers). As a consequence, it was decided to require authorisation and place the burden of proof to market actors that intended to continue the use.

- **Using registration information prevents unnecessary discussions**. In some cases it was discussed if authorisation is the most appropriate regulatory pathway. In all cases, the dossier submitters showed that an authorisation obligation would limit the substance's use and would therefore (positively) change the current situation. For ADCA, stakeholders questioned the use pattern described in the Annex XV dossier, but argued that data from registration dossiers and must therefore be taken seriously and cut the discussions short.

- **Public consultations are currently not efficient.** In many of the cases data on uses and exposure were submitted during public consultation rather than information on the substance properties. This information is not needed for SVHC identification and has only a very limited effect on the potentially following inclusion to Annex XIV. Therefore and in the assessed cases, consultations increased the authorities' workload without measurable improvements for the Annex XV dossier and further process.

  The authorities involved in the project reported that the SVHC identification drives some market actors to provide more detailed information on the uses and products of the respective substances. This information may be useful if substances are then not introduced into the further authorisation steps, but enter a restriction process or other measures. However, when the focus lies only on the authorisation itself, it would be better from a perspective that bears the authorities' workload in mind, that the efforts for a formal SVHC procedure are avoided. It would be more useful to receive such information in the beginning of the regulatory process (e.g. during RMOA) where it can be used to decide on the best regulatory measure (e.g. in regard to eliminate risks, timelines, burden for involved actors etc.).

[53] Mainly, because substances were listed before the introduction of the instrument.

## 4.6 Conclusions SVHC Identification

The process of SVHC identification is the initial official step and the basis to submit substances to the authorisation requirement. As such, the aim of initiating phase-out of SVHC has been accomplished for 209 substances[54]. Overall, the process can be considered as efficient with the workload being lowest in cases, where a harmonised classification exists and highest in cases, where an equivalent level of concern is to be demonstrated.

Drivers of the workload are the collection (and generation) of data and developing argumentations in all "non-standard" cases as well as replying to consultation inputs.

The informal steps preceding an SVHC identification, in particular the RMOA as well as the supporting steps, like expert group meetings, appear to decrease the workload of the authorities with a view to an overall risk management process under REACH. However, viewing the authorisation process in isolation, the workload for a particular step may also increase. In this regard, also ECHA's screening process is considered helpful.

Whereas the individual timelines of the SVHC identification process appear to be appropriate and are generally kept by all actors, some potentials for increasing the efficiency of individual steps were identified, including by developing guidance to identify SVHCs for which no clear criteria exist how to identify the SVHC property and reach an agreement on how to demonstrate EloC and grouping of similar substances with an SVHC property caused by the same mode of action.

### 4.6.1 Workload

The workload for SVHC identification significantly varies in relation to the specific endpoints addressed (Article 57 a-f) and also depends on the state of the regulation. The case studies show that SVHC proposals based on properties covered by REACH Art. 57 (a-c) can be rather short if a harmonised classification already exists.

For substances either identified as PBT/vPvB according to Article 57 (d, e) or as EloC (57f), significantly higher workloads are needed. The cases imply that mainly two reasons are responsible for the additional workload:

- Data is insufficient to demonstrate whether or not a substance fulfils the criteria of the respective hazardous property
- There is uncertainty about whether or not the adverse effects of a substance give enough reason to conclude on an "equivalent level of concern". This can be also the case, when there are no doubts about the hazardous property but it is not clear how serious the effects might be (e.g. as the case on HDDA).

A higher workload usually arises from the need to apply a weight of evidence approach.

In general it can be concluded that the SVHC identification is efficient for registered substances because the authorities can close potentially existing data gaps using REACH processes[55]. Informal pre-processes, such a screening and the use of expert groups support the first identification of potential SVHCs and during RMOA it can be decided if authorisation is an effective tool to address assumed risks. The SVHC identification procedure has clearly defined

[54] Status July 2020

[55] Even though this can take considerable time due procedures that are linked to these processes (e.g. the dossier and the substance evaluation).

timelines and opinion making follows a clear structure. Once the dossier was submitted in all cases the decision was taken within the 4 months foreseen. Most SVHC identifications took from about 6 months to 10 months from the first declaration of an intention in the PACT until the decision[56]. For those substances which need more preparation time (e.g. PFOA) or several dossier revisions (UV-328, DEHP due to two different SVHC properties) the increased workload results from the need to resolve disagreements or consolidate the evidence base and can hence be regarded as necessary and useful rather than an inefficiency of the process.

As generally no significant needs to reduce the workload were identified, no improvement recommendations are made for the process as such.

### 4.6.2 Proof of Hazardous Property

If a substance does not fulfil a clearly defined endpoint criterion the efforts to show that an SVHC property is fulfilled increases. For example, PFOA did not fulfil the numerical bioaccumulation criterion according to REACH Annex XIII, but was identified as an SVHC via an alternative assessment based on a weight of evidence approach. In this example, some discussion could be observed during consultation but also between Member States on whether or not the substance could be identified as PBT. Here, this uncertainty increased the efforts for the dossier submitter:

- For the dossier preparation and
- In the response to comments after the public consultation.

Similar controversies are observed in the identification of endocrine disruptors, but also for the classification of new CMR substances under CLP. This is due to the underlying data often being ambiguous and allowing different interpretations on whether or not a certain property exists. In accordance with the SVHC roadmap implementation plan a harmonised classification and labelling process should be entered (and/or other REACH processes) if data gaps are identified.

This challenge was also identified by MSs and ECHA and triggered the establishment of various expert groups over the years (e.g. for STOT RE, ED or Skin Sens.). The expert groups were mandated to reflect on the controversial properties for a defined time-period. The expert group on EDs is based on the respective guidance documents established for biocides and PPPs based on the respective OECD method for the identification of endocrine disruptors[57].

The clarification of criteria and processes as well as agreement on whether or not a particular concern is sufficient to trigger regulation (skin sensitisers) are the main improvement potentials identified for the SVHC identification process regarding the work on demonstrating hazardous properties of a substance exists. This clarification could be in form of guidance documents or consist of formalised discussions in expert meetings, if the need for clarification arises.

Non-standard hazard properties could be identified that might need additional guidance or criteria on how to demonstrate the existence of a hazardous property. For example, this could concern other ways than following Annex XIII for identifying PBTs or criteria for the identification of endocrine disruptors.

In specific cases, the arguments that support an assignment of a property could be pre-discussed among MS and additional experts. CLP classifications could be discussed in the RAC, which would already be in the process and ensuring a link to the harmonised classification. In others

[56] Although it can be assumed that there is already some preparatory work done before this announcement.

[57] OECD (2018), *Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption*, OECD Series on Testing and Assessment, No. 150, OECD Publishing, Paris, https://doi.org/10.1787/9789264304741-en

there is no formalised procedure but the CARACAL or MSC could be tasked with such discussions. Collaboration of MSa should also be intensified to overcome potential resource constrains. Currently, the overall burden for SVHC identification (and also preparation of RMOAs) is carried by a limited number of MSCAs. Hence, better distributions of the burdens might speed up the overall process of SVHC identification and increase the number of substances that can be subjected to an authorisation requirement. Furthermore, the experience and competences gained by MSs engaging in the development of SVHC identification proposals could contribute to more stringency in discussions.

### 4.6.3 Demonstration of an Equivalent Level of Concern

Uncertainties for dossier submitters and discussions among stakeholders arise from the need to demonstrate an equivalent level of concern. Additional information on the type and severity of effects, the extent of exposure and the irreversibility of exposure or effects are needed. As for other properties, additional overreaching and agreed guidance may be needed to avoid diverging opinions, as occurred in the case of Hexamethylene diacrylate (HDDA)[58]. ECHA's criteria intended to help dossier submitters in building their argumentation of why sensitisers which can be considered as substances of equivalent concern, but were not accepted by all MSC members. Four criteria were considered to be too general[59], in a way that each substance under discussion might fulfil them even though these criteria have previously been discussed in RiME, MSC and CARACAL.

To clarify the equivalent concern of sensitisers, further development and coordination seems necessary, to be sure the weight of evidence approach is accepted by all MS-authorities and dossiers are not rejected. Similar processes will be needed if other properties are discussed under article 57 (f). Currently, a paper is being discussed, which defines criteria rendering a substance persistent and mobile[60]. Such substances have the potential to enter water bodies and lead to an equivalent level of concern. How such concern can be demonstrated can be subject to further activities. Such processes are followed by ECHA with contribution from MS.

### 4.6.4 Screening and Grouping

A significant workload for authorities originates from the fact that SVHC need to be identified via a substance-by-substance approach. Even if structurally similar substances have the same hazardous property that qualifies them as an SVHC and that is based on the same mode of action, each substance has to be individually identified as an SVHC via a separate Annex XV Dossier, which undergoes the complete process of public consultation. This was shown with the example of carcinogenicity of cadmium compounds[61] caused by the release of cadmium ions.[62]

[58] HDDA was intended to be identified as an SVHC according to Art. 57 (f). The property of concern investigated was skin sensitization.

[59] From minority opinion document of the MSC (MSC, 2015) … four of these (derivation of a safe level of exposure, delay of health effects, quality of life and societal concern), as addressed in the support document, are relatively generic in nature and could in fact be applied to all skin sensitisers. Therefore, we question whether such a generic assessment is sufficient to complete this comparison between CMRs and skin sensitisers and contribute to the equivalent level of concern argument. https://echa.europa.eu/documents/10162/27da08c4-3da3-e1a4-94b9-188ec825128c

[60] A proposal is discussed in the CARACAL (CA/MS/93/2019) and might lead to an agreement between authorities that such substances are considered to be SVHC according to Article 57 (f).

[61] The argumentation was based on the same main studies prepared by the Swedish KemI and some overreaching work on Cadmium (the EU RAR and work performed by IARC), all dossiers were submitted by the Swedish authorities.

[62] As some cadmium compounds are not only carcinogenic but also have other SVHC properties, still a number of individual dossiers may be necessary if all properties should be identified.

The preparation of individual dossiers for similar and similarly acting substances may lead to an inclusion into the candidate list with different timelines and regrettable substitution may occur.

Increases in the efficiency of the SVHC identification as well as avoiding substitutions with substance with similar concerning properties could hence be achieved by identifying similar substances in only one dossier that discusses the particular SVHC property, which all compounds have in common. Even if additional properties may have to be identified for individual group members, this grouping approach will reduce

a) The burden for the preparation of dossiers

b) The administrative burden for ECHA and the MSCAs to undergo the official process several times

c) Increase the efficiency for stakeholders to provide comments only once for the SVHC property.

If a group of substances is addressed in the SVHC identification the dossier may either have to be limited to the one hazardous property all substances have in common or it would have to include subchapters for properties that only some of the group members have. Alternatively, separate dossiers could be prepared for additional properties (see DEHP).

An advantage of grouping is that it informs the market actors that all substances in the group will be regulated. This will discourage regrettable substitutions and thereby increase the overall efficiency of the process: Alternatives will not be sought within the group and the aim to reduce risks can be realised with a higher likelihood (see also e.g. chromate compounds, phthalates, fluorinated substances, bisphenols). Other advantages of grouping can occur when an equivalent level of concern needs to be justified, as it can help in demonstrating the similarity of severity of effects or similarity if no exposure-effect relationship can be demonstrated[63]. It seems important that a lack of data for some potential group members does not block the entire regulatory process. Instead, an adjusted group should be used to regulate some substances immediately and to be able to add others at a later stage. Alternatively, a substance by substance option is always a way to start with some members in case of the lack of data to substantiate the group.

### 4.6.5 Need for Additional Information on Use Pattern and Substitution Potential

Information needs on use patterns and substitution potentials may increase the workload in the SVHC identification process but their collection early in the process, e.g. in the context of an RMOA may save considerable resources because it supports choosing the best regulatory option and because it facilitates the further processes of authorisation, e.g. prioritisation.

In the assessed case studies, information needs of Chapter 2 of the Annex XV dossier covering uses, volumes and substitution potentials of a substance contributed to the workload of dossier preparation. Overall, Chapter 2 is rather short and information can be retrieved relatively easily from the registration dossiers. But this information can give rise to extensive comments from stakeholders during the consultation if they assume that the data is not correct and not appropriate (e.g. in the case of ADCA).

On the one hand manufacturers and importers and - regarding the use information - also downstream users are responsible for the correctness of data in the registration dossier and authorities should trust in that dossiers are correct and up-to-date. On the other hand, several reports show that numerous dossiers are neither up to date nor describe the real (specific) use

[63] See Annex XV document for ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate(FRD-902) EC Number:700-242-3 CAS Number:62037-80-3 (GenX), ELOC was justified with the combined exposure of various fluorinated substances in the environment https://echa.europa.eu/documents/10162/41086906-eeb6-a963-f0b9-af1d0e27efc2 .

pattern. Furthermore, registration dossiers do not cover the aspect of the substitution potential[64].

The RMOA can play an important role in verifying and potentially correcting registration information on uses early in the process, as authorities can discuss use information as well as the substitution potential of a substance with stakeholders. Then the data will already have been reviewed when the regulation option authorisation is chosen. This does not necessarily decrease the overall workload since the information has to be discussed in the generation of the RMOA, but it may avoid deciding to put a substance to the authorisation regime where this is not the best regulatory option.

It is recommended, as is already performed in the majority of cases, to keep Chapter 2 of the Annex XV dossier as it is and to use the RMOA to verify that information, in order to prevent extensive commenting during SVHC identification and support selection of the best regulatory option.

[64] The only indication for a need of substitution could be unsupported uses that are considered not safe.

# 5 Inclusion of Substances in Annex XIV

## 5.1 Description of the Process and Findings

ECHA prepares a proposal on the inclusion of SVHCs in Annex XIV of REACH to the COM.[65] Before submission to the COM, this proposal first undergoes a public consultation and is then adopted by the MSC, which takes the comments from the consultation into account[66]. Table 4 lists the tasks and timelines of preparing a proposal for Annex XIV inclusion.

**Table 4: Timeline for the inclusion of substances in Annex XIV**

| Step #[67] | Article | Task | Timeline |
|---|---|---|---|
| 1. | 58 (3) | ECHA drafts recommendation for inclusion of candidate substances in Annex XIV, taking into account the opinion of the MSC. | not specified<br>(at least every two years) |
| 1a | 58 (3) | MSC prepares an opinion on the draft recommendation | For each recommendation after the public consultation to enable taking note of comments |
| 2 | 58(4) | Public consultation of draft | three months<br>(from publication of draft) |
| 3 | 58(4) | ECHA updates the draft recommendation and forwards the final draft to the COM | not specified |
| 4 | 58(1) | Decision by the COM and the REACH-Committee on the inclusion of SVHCs in Annex XIV | not specified |

Information needs to prioritise substances for the recommendation, are determined by the prioritisation criteria laid down in Article 58 (3) of REACH. These are:

- A substance has PBT/vPvB properties: This concerns SVHC identified on the basis of Article 57 (d, e). As ECHA refers to the properties in the Annex XV dossier for SVHC identification and no additional hazardous properties outside the scope of Article 57 (a-f) are considered, all necessary information is available from the SVHC identification.
- A substance has wide dispersive uses: For registered substances this information can usually be obtained from the registration dossiers. In the past, there have been experiences that such uses were either reported false positive (a use has been included in dossier, but was not performed in practice[68]) or false negative (not all uses were included in dossiers[69]). In cases where no registration exists this information is not available to ECHA. In such cases additional information sources need to be used (e.g. reports, public consultations).
- A substance is present on the market in high volumes: For registered substances this information can be obtained from the registration dossiers. However, in many cases tonnage

[65] According to Article 133 (4) of REACH

[66] See also ECHA web site under https://echa.europa.eu/de/role-of-the-member-state-committee-in-the-authorisation-process

[67] Steps with the same number are belong to the same step and are alternatively, e.g. if different actors can perform the step.

[68] This has e.g. been an issue with ADCA where there was a use reported that linked the substance to consumer spray applications

[69] Such examples could be seen in cases where AfA were submitted for unknown uses like e.g. the chromates in cooling systems.

information is incomplete and not updated. If several uses outside the scope of authorisation (e.g. intermediates) are covered in one dossier but are specifically differentiated, this can be a challenge in identifying the volumes which could undergo authorisation and if this would be a good regulatory option.
The market volumes of a substance maybe overestimated if registration dossiers are not updated and uses have already been phased out.
An underestimation of market volumes is less likely because registration data from all registrants can be summed up and used to assess this criterion. The only theoretical scenario where market volumes could be underestimated consists of a very high number of importers and manufacturers placing the substance on the market below 1 ton per year.

According to ECHA's methodology, the prioritisation information is used for scoring (see Table 5 to Table 7).

**Table 5: Scoring scheme to prioritise SVHC for Annex XIV according Art. 58 (3a)**

| Inherent property | Category | score |
|---|---|---|
| 57(a) and/or 57(b) and/or 57(c) and/or 57(f)<br>• 57(f) in this category relates to substances not being endocrine disruptors.<br>• In case of PBT-like substances identified under Article 57(f), these should be considered in the PBT score. | low | 1 |
| 57(f) (ED) | medium | 7 |
| 57(d) or (e) | high | 13 |
| 57(d) and (at least) one other SVHC property | high | 15 |
| 57(e) and (at least) one other SVHC property | high | 15 |

The highest scores are assigned to substances that are PBT or vPvB as defined by REACH Art. 58 but other SVHC properties are also considered. PBT like substances also get a high score equal to PBT/vPvB.

**Table 6: Scoring scheme to prioritise substances for Annex XIV according Art. 58 (3b)**

| Tonnage | Category | Score |
|---|---|---|
| No volume | zero | 0 |
| <10 t/y | very low | 3 |
| 10 to <100 t/y | low | 6 |
| 100 to <1,000 t/y | medium | 9 |
| 1,000 to <10,000 t/y | high | 12 |
| ≥ 10,000 t/y | very high | 15 |

The tonnages correspond to the tonnage bands relevant for registration – no registration, registration without CSR, higher information requirements. Only for the highest category more

detailed information from registration dossiers are necessary (> larger 1000) to be able to differentiate further.

**Table 7: Scoring scheme for prioritisation of substances for Annex XIV according Art. 58 (3c)**

| Use type | Category | Score |
|---|---|---|
| No use | zero | 0 |
| Industrial | low | 5 |
| Professional | medium | 10 |
| Consumer | high | 15 |

The most complex criterion is the assessment of the risk from a wide dispersive use and is based on the following two general assumptions[70]:

- Release control: CONSUMER < PROFFESSIONAL < INDUSTRIAL
- Wide-spread use
  i.e. number (and distribution) of sites: CONSUMER > PROFFESSIONAL > INDUSTRIAL

These assumptions are based on several guidance documents on exposure estimation under REACH, which ECHA acknowledges as being "*simplistic and coarse*". Nevertheless, registrants are responsible for the correct and up-to-date description of uses. Incorrect coverage of consumer uses can (falsely) lead to a high score, in particular because the volume is not relevant but only the fact that it is used by consumers. This should be a strong argument to keep the life cycle description of dossiers up to date, but in practice many registrants cover uses with a very broad range, which can result in an over or (more unlikely) in an underestimation of potential risks.

ECHA opens the prioritisation criterion for further refinement in case more detailed information is available on use-specific volumes. For example, based on such information it could be determined if only very low volumes enter professional or consumer uses while the largest share enters an industrial use. In such cases a medium score would be set.
Another relevant aspect for the criterion is the use in articles. Integration of substances in articles where releases cannot be excluded during service life and the waste phase, may result in higher prioritisation scores compared to if only the use description in the registration dossier would be used. Refinement in any case increases ECHA´s workload, but is only possible if relevant information is available in the registration dossiers.

After an assessment of the three criteria (with or without refinement) a total score is assigned to each substance on the candidate list and the ones with the highest scores are recommended for inclusion into Annex XIV. It should be noted that the scores can change from one prioritisation round to the next one as the information basis may change if the tonnage decreases, uses are phased-out or if new uses are stared that lead to higher scores, for example. Therefore, ECHA has to assess each substance on the list in every round.

REACH Art. 58 states: […] "*Priority shall normally be given to substances with"* […]. This indicates that also other criteria could be considered than just the ones shown above. Further

[70] See ECHA (2014), Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) Editorial update: 5March 2020
https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930

considerations are given to aspects such as if substances could be used as substitutes for an already included SVHC or one that is recommended for prioritisation in the same round (interchangeability), or if other regulatory activities are already ongoing..

It is most important for the overall effectiveness of the authorisation process under REACH that only substances are selected for inclusion in Annex XIV, for which the aim of substitution can be achieved at least in the mid-term, i.e. market actors would rather substitute than apply for authorisation. Otherwise, the authorities will receive a high number of applications that exceed their current capacity for handling such applications without a respective benefit e.g. clear risk minimisation in the described use conditions or perspective for a substitution on short-/mid-term. Another aspect that should potentially be considered is a second aim of the authorisation procedure to ensure a functioning market. This aspect should also be reflected in the prioritisation by assessing the market structure and aspects like the number of potential applicants (substance users) effects on the downstream supply chain of these users and the extent of SMEs affected that might struggle with the technical needs of an AfA etc. It seems important in this regard, that there is a decision on the regulatory route even before ECHA starts their prioritisation process, like e.g. when the candidate listing occurs or even earlier in the RMOA.
Currently[71], the high number of applications for NPEs and OPEs forced ECHA to treat them in three tranches to be able to perform all formal checks and to organise public consultations and for the committees to evaluate the proposals, properly. It can be assumed that the MSCAs exceeded their resources to prepare comments and draft opinions for the final decisions in the REACH Committee.

To prevent a high number of AfAs, it might be an option to shift to another regulatory measure and prepare a restriction[72]. Again, to anticipate the number of AfAs some level of information on the actual uses is needed, which may not always be available in the registration dossiers. Therefore, ECHA assessed the potential application areas of substances in the latest recommendation in an additional research activity[73]

Besides the assessment of the three criteria ECHA needs to include the following issues in the recommendation:

- The identity of the substances according to REACH Annex VI, Section 2:
  This information will (at least partly) already have been generated during the SVHC identification, as substance identity is also part of the Annex XV dossiers (confidential part B). For registered substances this information should also be available in the registration dossiers.
- The intrinsic property that was the reason for inclusion into the candidate list: This information is available from the Annex XV dossier and does not require additional activities at this stage.
- A proposed sunset date: This date should take into account, when appropriate, the production cycles for the covered uses to assume when substitution could reasonably be

[71] February 2020

[72] A restriction proposal is also linked significant workload in particular for the authorities. Still from an overall perspective it can be an option especially if risks are assumed from life cycle stages (e.g. article service life, intermediate use) that are not in the scope of the authorisation and can be covered by a restriction.

[73] ECHA (2020) "Estimating the number and types of applications for 11 substances added to the Authorisation List in February2020 February 2020"
https://echa.europa.eu/documents/10162/13634/applications_for_11_substances_Authorisation_List_February_2020.pdf/66fd8424-5f57-9c33-f3e5-265f01f754ba

implemented. This requires more detailed use information, which is not necessarily contained in registration dossiers and would therefore require e.g. stakeholder input during public consultation (or even earlier in informal processes).

- A proposed "latest application date" by when the applications have to be sent to ECHA to ensure continued use without disruption.

Further information to be considered in recommendations for Annex XIV inclusions is the number of expected AfAs and the related transitional arrangements.

The draft recommendation is subject to a public consultation. Apart from the industry and NGOs, also the MSCAs are invited to provide comments, thus having an active role in this step. Based on the comments a final draft recommendation will be prepared and forwarded to the COM for decision making. If the draft is adopted, an amending regulation will implement the changes of Annex XIV.

In recent years, the COM started additional public consultations on the recommended substances, in particular by applying a more holistic approach and looking from a broader perspective at the consequences of an authorisation obligation.[74] Therefore one could argue that the additional aspects of the inclusion of a substance onto Annex XIV could be directly parts of ECHA´s prioritisation procedure. In the end, the inclusion of an SVHC in Annex XV is also a political decision of the COM and the MSs that are represented in the REACH Committee. As there are often different opinions on such decisions, there were long time periods between the prioritisation and the inclusion of substances in the Annex. Some substances that were recommended in the early prioritisation rounds have still not been included.

## 5.2 Recommendations for the Inclusion of Substances in Annex XIV

ECHA's prioritisation approach seems to be straight forward and justified. Currently, most of the necessary data is available either in the Annex XV dossier or the registration dossiers. This is in line with the requirement set out in the REACH text (Annex XV Chapter II.2.). However, the additional activities of COM and the REACH Committee indicate that this approach in not sufficiently far reaching to select candidates efficiently enough. Therefore, it might be reasonable to discuss additional available information[75] early in the process towards a potential SVHC-identification to ensure its validity. Even more if the assessment in this process is based on use information that might not be up to date in the registration dossiers.

In addition to the currently applied process, a BMWi report[76] proposes to add additional aspects to the recommendation for inclusion in Annex XIV. These are linked to additional functions of the candidate list, which some authorities assign to it. These functions are:

- Generation of additional information on the occurrence of SVHCs in articles in order to assess the need for or define a restriction.
- Substitution trigger - experience shows that once a substance is on the candidate list, market actors start avoiding it.

[74] The need for a broader view on the regulation of substances was also a reason to introduce the RMOA.

[75] It must be noted that some information are often lacking at this stage, especially, information on uses and exposure data

[76] Ökopol & RPA: REACH nach 2018 – Unter besonderer Berücksichtigung der Regulierungsalternativen „Beschränkung" und „Zulassung". Full report in German https://www.bmwi.de/Redaktion/DE/Publikationen/Studien/reach-nach-2018-gesamtbericht.html

- Formalised demonstration of a particular hazardous property not covered by a classification category, analogous to a harmonised classification, e.g. for PBTs/vPvBs or EDs[77]. In such cases, often the proposal of a restriction is intended after completion of this formal procedure. The SVHC identification would ensure that the existence of the hazardous property as an absolute basis for the demonstration of an unacceptable risk in restriction dossiers is challenged. Thereby, the risk of unsuccessful restriction dossiers is reduced.

The report proposes making such intentions explicit when a substance is identified as SVHC and ECHA taking this underlining motivation into account in the prioritisation rounds. Substances intended to be restricted could be excluded from the prioritisation process, which would avoid unnecessary work for ECHA and the market actors, who might find themselves confronted with a need to apply for authorisation even though this was never the intention of the authority that proposed the substance for the candidate list.

Also in cases where inclusion in the candidate list is intended as a measure on its own, i.e. no authorisation or restriction is intended; substances could be excluded from the prioritisation by ECHA. Here, an additional RMOA should be prepared according to the report if a need for further regulation arises.

An indication on the intention of SVHC identification would increase the predictability and transparency of (future) regulatory measures and would help market actors to prepare. Authorities involved in the prioritisation could focus their resources on substances that are really intended for introduction into the authorisation process.

[77] An optional process to achieve a similar result would be the use of Article 77 (3c) where the ECHA's director can ask the RAC to assess the risk that might originate from a certain substance. Up to now this option has only been used for CMR properties and not for properties that are not reflected by a classification. https://echa.europa.eu/de/about-us/who-we-are/committee-for-risk-assessment/opinions-of-the-rac-adopted-under-specific-echa-s-executive-director-requests

# 6 Application for and granting of Authorisations

## 6.1 Overview

The last step of the authorisation procedure consists of the market actors submitting AfAs followed by two expert panels evaluating them and a final decision by the COM. The subsequent implementation of potential additional risk management measures can be seen as an optional step.

Regarding the overall efficiency of the authorisation process the optimal situation for a substance listed on Annex XIV would be that no AfAs are submitted, because all uses can be assumed phased out and no additional efforts are needed. This has been the case for 12 substances up to now[78].

If AfAs are submitted, the aim of phase-out is not achieved right away (not fully effective) and further efforts are needed (decrease in efficiency for risk reduction). The preparation of the AfA requires not only high efforts on the side of the industry but also their evaluation creates very high workloads for ECHA, the REACH Committees and the MSCAs. Furthermore, preparing the final decision requires efforts by the COM and the MS that prepare their own positions for the REACH Committee discussions.

The authorisation is an alternative option to substitution foreseen by REACH and has been used by the industry for the majority of substances on Annex XIV. One of the reasons for the industry applying for authorisation is the lack of suitable alternatives, which could mean several things:

- There was really no suitable alternative to the SVHC
- Available alternatives perform worse (i.e. not technically feasible)
- Costs of available alternatives are disproportionate (i.e. not economically feasible)

In many cases it was a mixture of these aspects which are discussed in the AfAs.

## 6.2 General Conditions for granting Authorisations

### 6.2.1 Adequate Control Route

REACH defines two basic scenarios for granting an authorisation: In the first scenario, called "adequate control route" it is possible to demonstrate adequate control of risk via a safety assessment (REACH Art. 60 (2)). Control of risk refers to any risk that originates from the intrinsic property referred to in the Annex XIV entry. The article lists information to be considered in the decision process and which should as a consequence be part of an AfA. These are […] "*all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision*". The risk assessment needs to be documented in a chemical safety report (CSR). If an applicant can demonstrate adequate control of risks in the AfA, the COM must grant an authorisation. In this case the authorisation procedure does not result in a situation where there is any substitution pressure on users.

REACH Art. 60 (3) clarifies that the adequate control route cannot be applied to all substances. Substances for which no safe level can be derived, shall not follow the adequate control route. This can be the case for CMR and PBT/vPvB substances as well as substances of equivalent

[78] Status as of February 2020

concern (Article 57 a-c and f)[79]. A case-by-case assessment may be needed on whether or not safe levels can be derived. Deriving a safe level is not possible by definition for PBTs/vPvBs or EloC substances according to REACH Art. 57 (f). Here, the applicant always has to establish his AfA on REACH Art. 60 (4).

### 6.2.2 Socio-Economic Route

REACH Art. 60 (4) describes the approach of the second scenario, the so called socio-economic route, which is strongly based on the socio-economic impacts of a potential authorisation as compared to a non-use scenario of the substance. This assessment is performed from a perspective of the applicant, in particular when aspects are discussed such as impact on business and economic feasibility of alternatives. These have to be proportionate for the individual applicant(s), not for the EU economy in total.

Authorisation via the socio-economic route may be refused under certain conditions, namely if risks outweigh the benefits or if suitable alternatives exist. However, these criteria are not mandatory and authorities are much more flexible in deciding on an application. AfAs based on the socio-economic route also contain a CSR that describes the level of all risks under the use conditions of a substance. This includes a description of the adequacy and effectiveness of RMMs implemented to control risks as far as possible.

## 6.3 Content of Authorisation Applications

Additional elements to consider in deciding on an AfA that follows the socio-economic route are:

- Socioeconomic impacts of a discontinued use on the market actors and society outlined in the application, e.g. on consumers,
- The availability of alternative substances or technologies for the use(s) covered by the AfA, including a plan how substitution might be realised in the future,
- Comments from third parties submitted in the consultation process and
- Information on the risks that might originate from the use of alternatives.

The evaluation of socio-economic impacts of the use of alternatives is very challenging for authorities. Among others, this is due to the fact that alternatives are very specific to the applying market actors. Therefore, the respective information is often not available early in the authorisation process, i.e. at the time of strategically deciding on the best regulation pathway in the RMOA or during prioritisation. Even if this information is presented in an AfA, an evaluation must be based on many assumptions, on the impacts in supply chains or implementation costs for using an alternative, for example. In addition, an extensive explanation is needed to understand the complex context of using the alternative.

REACH Art. 62 specifies the content of AfAs in more detail. Besides some formal aspects, like the applicant(s) identity, the substance(s) identity, a description of the scope of the authorisation is needed including a specification […] "*for which use(s) the authorisation is sought and covering the use of the substance in mixtures and/or the incorporation of the substance in articles, where this is relevant*".

Other mandatory elements of an AfA are, regardless of the scenario for granting authorisation:

[79] There are also examples for CMR od ED substances where it is possible to derive such safe levels (at least theoretically) and AfAs that follow the adequate control route.

- A CSR that covers the hazards and risks originating from substance properties referred to in Annex XIV, in case it has not been submitted as part of a registration[80].
- An analysis of alternatives[81], including the applicant's research and development activities. The inclusion of information on alternatives is also required, when adequate control of risk can be demonstrated.
- A substitution plan, in case the analysis of alternatives has shown viable alternatives exist.

No minimum standards on the type and level of detail of the submitted information and analyses are defined in REACH and the responsibility for the appropriateness of AfAs is placed on the applicants. However, ECHA assesses the completeness and admissibility of an AfA and RAC/SEAC discuss their content.

## 6.4 Socio-Economic Analyses in Authorisation Applications

AfAs based on the socio-economic route have to include a socio economic analysis (SEA), which should follow the relevant guidance document and format defined by ECHA, according to REACH Annex XVI. REACH Art. 111 requires ECHA to define IT formats, which are implemented via IUCLID and most of the AfA content is provided as an annex to the respective IUCLID dossier.

REACH Annex XVI contains some information about potentially relevant information for a SEA:

- Impacts from the authorisation or non-authorisation, which include:
  - Impacts on industry (manufacturers, importers or other members of the supply chain(s)), which are mainly various types of economic effects and changes in production processes,
  - Impacts on consumers (e.g. increase of market prices, product performances)
  - Impacts on society (e.g. changes of human health or environmental impacts)
  - Availability and feasibility (technically and economically) of alternative substances and technologies for the applicant and time planning of potential introduction of the alternatives
  - Wider implications on trade, competition and economic development (in particular for SMEs and in relation to third countries)
  - Benefits for human health and the environment as well as the social and economic benefits in case of the refusal of an authorisation
  - Others effects that seem relevant for the applicant or affected parties.

Due to the uncertainties about the content and level of detail of information in a SEA provided in the AfA, clarifications are frequently needed during the evaluation and opinion forming process, which creates additional workloads for the authorities.

[80] Even in cases where a CSR already exists it usually has to be revised before inclusion in an AfA because its level of detail is not sufficient to demonstrate "no risk" or at least minimised exposure/emissions.

[81] The applicants' analysis of alternatives is much less extensive than the evaluation of alternative substances and technologies that is required of the authorities as part of the SEA according to REACH Annex XVI.

## 6.5 Timelines of the Authorisation Process

The REACH regulatory text does not define a date, by when the aims of the authorisation process should be realised, neither the identification of the SVHCs nor the listing on Annex XIV or the phase-out or continued use based on the conditions of authorisation. The timelines only refer to the gathering and documentation of relevant information for the individual procedural steps, which is described in more detail in the below sub-chapters.

### 6.5.1 Application for Authorisation and Review Periods

After the inclusion in REACH Annex XIV, a substance may be used until the sunset date (transition period) after which continuation requires a valid authorisation. The duration of the transitional period between Annex XIV inclusion and sunset date is not defined, but REACH Art. 58 (1. (c) (i)) states: […] "*which should take into account, where appropriate, the production cycle specified for that use*." This allows some flexibility to consider the needs of the market actors[82]. The following interpretations of how long a transitional period could last exist:

- The sunset date is defined by the use requiring the shortest time to be adapted (e.g. phase out in products, redesign etc.). As a consequence, all users that are not able to change their production during the transitional period would need to apply for authorisation, at least for an additional transition period.
- The sunset date is related to the use requiring the longest time to adapt (e.g. phase out in products, redesign etc.). As a consequence, market actors that could substitute faster might have little incentive to do so, delaying the phase-out and hence the achievement of the authorisation aim.
- The sunset date is use specific. This would require in depth knowledge of all uses.
- The transitional period is defined as an average of the time all uses need to substitute. This approach seems most realistic and does not require too much in depth knowledge of the authorities.

REACH does not define a starting point for the preparation of an AfA and potential applicants could even start their preparatory work to substitute instead of preparing an application before an official inclusion of a substance in Annex XIV. In the logic of the authorisation mechanism this seems consistent as the AfA is rather intended to be an exception, while the phase out should be, sooner or later, the default. The entire preparatory process from RMOA over SVHC identification and prioritisation increases the time market actors have to substitute.

However, REACH defines the date by which an AfA has to be completed and sent to ECHA. This date should ensure the continued use of a substance and anticipates the time authorities need to decide on the AfA. In practice this date is an important feature of the authorisation decision process, as there are several examples where no decision was taken until the sunset date but the use could still be continued as an AfA had already been submitted. Hence, this date ensures the functioning of the EU common market, which is another aim of the authorisation process (c.f. REACH Art. 55). According to REACH Art. 58 (1. (c) (ii)) this date has to be at least 18 months before the sunset date and is therefore called "latest application date", although it is possible to apply for an authorisation whenever market actors want to.

An authorisation granted by the COM is valid indefinitely but subject to defined review periods. COM may decide to amend or withdraw it anytime but especially as a result of a review. The

[82] In practice this are usually 2-3 years.

review periods are defined in the authorisation decision and not defined in the REACH text. Standard review periods have been introduced by RAC and SEAC in the beginning of the authorisation.[83] The review report needs to be submitted 18 months before the review period expires.[84]

The procedure of processing AfAs is defined in the REACH text and the individual steps are shown in the table below.

**Table 8: Timeline for the processing of an AfA**

| Step #[85] | Article | Task | Timeline |
|---|---|---|---|
| 1. | 64 (1) | ECHA confirms receipt of the AfA | not specified |
| 2.1 | 64 (3) | RAC and SEAC check the completeness of the AfA regarding the information required in Art. 62 | not defined |
| 2.2 | 64 (3) | If incomplete, the committees may request further information / a revision of the AfA<br>The SEAC may request the applicant or third parties to submit additional information on alternatives | not specified<br>(case by case to be defined) |
| 3.1 | 64 (2) | The non-confidential parts of the AfA are published and third parties may submit information on alternative substances or technologies | not specified |
| 3.2 | 64 (1) | RAC / SEAC prepare draft opinion on the AfA | 10 months[86]<br>(from receipt) |
| 4.1 | 64 (5) | ECHA forwards the draft opinions to the applicant | end of deadline for draft opinions |
| 4.2 | 64 (5) | Receipt of draft opinions assumed (default, without explicit confirmation). | 7 days after sending |
| 4.3.1 | 64 (5) | The applicant announces that he will comment on the draft opinions | 1 month after receipt |
| 4.3.1.1. | 64 (5) | The applicant comments on the opinion | 2 months after receipt |
| 4.3.1.2 | 64 (5) | RAC / SEAC revise their draft opinions based on comments and prepare final opinions | 2 months after receiving comments |

[83] Two documents define the way RAC and SEAC define these period in practice. The first one covers general cases while the second is uses for long review periods SEAC/20/2013/03 (Agreed at SEAC-20) https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf/c9010a99-0baf-4975-ba41-48c85ae64861, CA/101/2017 https://echa.europa.eu/documents/10162/13580/ca_101_2017_criteria_longer_review_period_afa_en.pdf/4cda0778-02c3-c949-f1c2-6deb1622a754

[84] Besides that, the COM is entitled to review any authorisation at any time during the review period if new information is available that change the basis for the authorisation (e.g. new information on risk, availability of alternatives etc.)

[85] Steps with the same number belong to the same step and are alternative options, e.g. if different actors can perform the step.

[86] This applies to the standard AfA case. In case a later AfA is made by an applicant according to Article 63 (2) which makes reference to an existing authorization the period is only 5 months.

| Step #[85] | Article | Task | Timeline |
|---|---|---|---|
| 4.3.2 | 64 (5) | The applicant announces that he has no wish to comment on the draft opinions | the longest 1 month after receipt of draft opinions |
| 5 | 64 (5) | ECHA forwards the final opinions to the COM | 15 days after finalising opinions. |
| 6 | 64 (8) | The COM prepares a draft authorisation decision | 3 months after receipt of opinions[87] |
| 7 | 64 (8) | The COM and REACH Committee take a final decision | not specified |

## 6.6 Case Studies

Ten case studies were developed to further analyse the effectiveness and efficiency as well as workloads and improvement potentials related to the processing of AfAs. Due to resource constraints, the information collection was limited to the following information sources: Annex XV Dossiers, RMOA outcome documents, background reports on substances or groups of substances, draft and final opinions of the committees, public AfA documents, comments from public consultations and response to comments documents. The cases should cover various types of AfAs and the following was considered in their selection:

- AfA decisions exist, i.e. cases are already finalised
- Different risks are covered (occupational, consumers, environment). However, as only completed cases were assessed, occupational aspects are overrepresented due to a lack of cases addressing other risks at the time of the assessment.
- Both upstream and individual applications are covered (also in comparison)
- Coverage of bridging applications, where alternatives are already known
- Different types of risk levels are represented, e.g. low tonnage, controlled conditions

Furthermore, some exceptional situations were covered. One example is the “Roche Diglyme AfA”, which covers a new production installation. This is not an indication that in the short to mid-term a substitution is intended because an investment into new facilities would be a strong argument for a continued use of the substance in this process due to socio economic arguments. The selected cases are shown in Table 9.

[87] Currently, exceeded in many cases.

**Table 9: Case studies for the application for authorisation**

| # | Case name | substance | Reasoning for selection | comments |
|---|---|---|---|---|
| 1 | Chromium Trioxide REACH Authorization Consortium (CTAC) | Chromium trioxide | Relevance: occupational health and safety<br>Highly complex supply chains, complex scope, risk assessment and alternative assessment, upstream application that covers lots of DU<br>Criticised due to lack of detail in DU supply chains | 6 AfAs submitted by a consortium of importers and first level formulators |
| 2 | Hans-Grohe | Chromium trioxide | Relevance: occupational health and safety<br>Considered to be a good quality example, based on CTAC, specification of several assumptions from that application complex | comparison CTAC |
| 3 | Blue Cube | Trichloroethylene | Relevance occupational health and safety<br>Relevance assessment of alternatives – responsibility carried over to DU and enforcement | 5 AfAs submitted by manufacturer of substance |
| 4 | Illario Ormezzano oder Gruppo Colle | Sodium dichromate | Relevance occupational health and safety/ consumer<br>Application on the background of existing alternatives, argumentation based on final customers' requirements and availability of alternatives | Sodium Dichromate as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings |
| 5 | Deza/Grupa Azoty | Bis(2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP) | Relevance occupational health and safety/consumer<br>Interlink with existent restrictions | 6 AfAs |
| 6 | Micrometal | Ammonium dichromate | Relevance occupational health and safety<br>Low volume substance, low risk level | The use of Ammonium dichromate (ADC) as a photosensitizer for production of micro components |
| 7 | Roche Diagnostics | Bis(2-methoxyethyl) ether (Diglyme) | Example application after sunset date to start a process in a new installation, extension of current use (conflict with substitution aim?) | Use of diglyme as a process chemical in the manufacture of one specific type of Dynabeads® used in immunodiagnostic assays (in vitro diagnostic) |

| # | Case name | substance | Reasoning for selection | comments |
|---|---|---|---|---|
| 8 | Plastic Planet srl | Bis(2-ethylhexyl) phthalate | Relevance consumer<br>distribution of legacy SVHC into a wide range of articles through recycling | Industrial use of recycled soft PVC containing DEHP in polymer processing |
| 9 | INEOS Styrenics Netherlands BV | Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane | Relevance environment, bridging application as alternatives are available | Niche application flame retardants EPS insulation material |
| 10 | DCC Maastricht B.V. OR | Lead sulfochromate yellow (C.I. Pigment Yellow 34)<br>Lead chromate molybdate sulphate red (C.I. Pigment Red 104) | Relevance occupational health and safety<br>Authorisation although alternatives are available | 12 individual applications of similar scope, detailed differentiation in Uses |

## 6.7 Key Observations from the Case Studies

In the following, key observations from the case studies are described. Details on the individual cases can be retrieved in a separate document.

### 6.7.1 Applications for Authorisation

- **None of the AfAs assessed in the case studies followed the adequate control route.** All cases except DEHP for consumer uses were based on the socio-economic route from the beginning, although safe levels can be established for several of the SVHC.
  In the AfA on the use of DEHP in consumer products, which covered the formulation of mixtures containing DEHP, applicants concluded that adequate control is demonstrated in the risk assessment. The RAC confirmed that adequate control could be shown because a safe level could be derived for reprotoxic effects of the substance[88]. However, as the RAC also questioned that the workplace conditions ensuring risk control are always realised, it concluded that the AfA should be based on the socio-economic route.

- In several of the cases, **the RAC could not get a clear view of the OCs and RMMs described in the risk assessment** and to what extent these are state-of-the-art at all market actor´s sites. This was particularly true for upstream AfAs.
  One example is the upstream AfA for chromium trioxide. The RAC concluded that there was a high level of uncertainty originating from too general descriptions of OC and RMM as the application intended to cover a broad range of downstream users. In contrast to this, the AfA by HansGrohe included very specific descriptions of OCs and RMMs for only for two sites, but also highlighting in how far and for which of these all other sites differ. This was sufficient evidence for the RAC/SEAC to conclude on the degree of implementation of the risk assessments' conditions. Up to now, only one AfA was rejected and the authorisation refused because of a too low quality of the application documents[89]. However, the discussions about the quality of the scientific analysis, which were partly expressed in the RAC/SEAC opinions, caused:
  - multiple enquires during the evaluation process and
  - additional conditions in the authorisation decision, mainly on monitoring and reporting requirements including by the downstream users

- **When the RAC was uncertain about OCs and RMMs, it frequently proposed conditions as part of their opinion.** One core condition for applicants and DUs was a monitoring requirement to improve the information on the actual use of the substances on-site and resulting risk levels (e.g. as part of the upstream AfA for chromium). Monitoring became very characteristic for the authorisation. This was frequently linked to a requirement for DUs to derive exposure reduction measures and report them to the applicant, so that he could

[88] At that time, DEHP had not been identified also as ED and therefore, this effect was not included in the AfA

[89] The Commission specified that as well RAC and also SEAC concluded that, the application did not include all the necessary information specified in Article 62(4) and rejected the authorisation https://ec.europa.eu/docsroom/documents/36022/attachments/1/translations/en/renditions/native

consider them in the review report. This was the case in several of the case studies, particular for trichloroethylene.

The improvement of risk reduction shifts parts of the responsibility of the applicant to recommend an exposure scenario which shows no risk or at least a minimised risk[90]to the DUs. As a consequence, the definition of an optimised risk management is only possible in the review report, i.e. after the additional information is retrieved from the DUs. Hence, the actual level of risk is assessed only then at the individual DU and the implementation of optimised measures may be delayed as compared to an application which prescribes stricter OCs and RMMs from the start in an exposure scenario that is approved by the RAC as appropriate and applies to all DU covered. In addition, it is difficult to enforce the (vague) OCs and RMMs described in the general exposure scenario in the AfA in practice. Furthermore, it is uncertain if AfAs with a high level of uncertainty can be rejected if socio-economic effects and absence of alternatives are described sufficiently. This might undermine the actual aim of, at least, risk minimisation and decrease the overall efficiency of the authorisation process.

- **The cases confirm that the SEAC's opinion may overwrite concerns of the RAC.**
  If the RAC is concerned or uncertain about the OCs and RMMs in an AfA, SEAC's opinion was found to overrule the RAC´s opinion. The relevant key arguments why an authorisation was granted despite the RAC's concern were the non-availability of technically feasible alternatives for the applicant (or its covered users) and the usually monetised comparison of the costs and benefits under the most likely non-use scenario showing overall net benefits for society of a continued use. This practice enables authorisation of uses despite a lack of adequate control based on socio economic arguments. Nevertheless, the RAC´s opinion was important to derive the general conditions of the authorisation such as the review period or the implementation of additional risk management and reduce remaining risks.

- At the moment, **the substitution potentials are evaluated mainly from the applicant's perspective.**
  An exemption was observed in the HCBDD case, where stakeholders massively intervened in the public consultation resulting in a very short review period of two years. This should allow the applicants a fast transition to alternative substances and to realise a phase-out. In other applications the review periods were at least four years to give the applicants more time to investigate the alternatives in detail. Review periods of seven years (and not for longer periods) were justified by a need to evaluate the availability of alternatives and identify any progress made on alternatives that need additional research at the time of the submission of the AfA. This was the case for the Blue Cube complex and the application on asphalt testing. A recent ruling of the court of justice on the substance lead chromate assigns a larger responsibility to the EU COM, to consider alternatives with a wider view when taking its decision on an authorisation application[91].

[90] The applicants' own uses were considered to already ensure adequate control.

[91] See ECLI:EU:T:2019:144, JUDGMENT OF THE GENERAL COURT (Fifth Chamber), 7 March 2019 (*), (REACH — Commission Decision authorising the use of lead sulfochromate yellow and of lead chromate molybdate sulfate red –Article 60(4) and (5) of Regulation (EC) No 1907/2006 — Examination of the lack of availability of alternatives — Error of law) http://curia.europa.eu/juris/document/document.jsf?text=&docid=211428&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=11327665

- **Some AfAs can be seen as bridging applications to realise substitution.**
  In some AfAs a time planning was included by when an alternative was considered to be implemented. Review periods requested were adapted specifically to these timelines and AfAs only had the function to grant a bridge until substitution is realised. In one case, that of the flame retardant HBCDD, this became important as not the applicant identified an alternative but it was brought forward during public application and the RAC/SEAC defined the AfA as a bridge to implement the alternative. For these AfAs the relevance of the non-use scenario can be seen as less important, as it is seen as an acceptable aim and can therefore be seen as an effective option to realise the authorisation aim.

- **SEAC may be unable to evaluate if the assessment of alternatives in upstream AfAs is complete.**
  In some of the assessed upstream applications it was not fully clear if the stated lack of technical alternatives concerned the full range of downstream uses/products or only parts of them. This is relevant in the cases where a broad range of products is affected, such as the primary and secondary use of DEHP, or where the SEAC would need special and detailed knowledge of the processes conducted by the market actors down the supply chain to understand the requirements and applications where a substance is used (chromates).

- **Usually only drop-in alternatives are assessed**.
  The assessment of alternatives (AoA) is often limited to alternative substances that can be applied in the same or an adapted use as the one currently performed by the applicants or their downstream users. The main alternatives on the market that might offer a more general alternative approach are not assessed, as illustrated in the case study on HBCDD, where the alternatives are limited to substances that mediate flame protection to EPS rather than discussing also alternative materials, like mineralic insulation materials. Nevertheless, REACH offers options to include further alternatives, e.g. when identified during public consultation or when SEAC asks for a broader assessment from the applicant. This includes in particular alternative functional or technical non-chemical alternatives[92].

- **The monetised cost-benefit assessment of a continued use may be questioned due to imbalances and in information availability and the comparison of different cost categories.**
  If AfAs cover substances with adverse human health effects posing risks to workers, the number of affected workers in a continued use can usually be determined very well, even though there might be uncertainties in very complex supply chains. Since the number of workers at risk is often low compared to the total number of persons employed in the affected companies the monetised health effects are often a magnitude lower than those caused on the business as a consequence of the non-use scenario. The latter covers persons suffering from unemployment in the companies using the substance or in downstream

[92] See also working package 10 of the overall research project "advancing REACH" on REACH and substitution**.** This study analyses the support of the so-called substitution, which is the use of less hazardous alternatives for substances of concern, by instruments of the REACH regulations and elaborates concrete recommendations (not yet published). An overview on all individual studies prepared in the frame of the project given here https://www.umweltbundesamt.de/en/topics/chemicals/reach-what-is-it/advancing-reach

sectors that rely on a product produced using the substance of concern.[93]
Overall, monetarisation of such effects is complex and involves a high level of uncertainty due to the many underlying assumptions. Therefore, and if strictly focused on the applicant level, the SEAs tend to demonstrate that the benefits of a continued use outweigh the risks by far. It can be questioned if such different cost categories are comparable or should be the only categories considered.
In addition, other impacts like potential benefits for competitors are usually discussed only qualitatively or are not considered at all. The same is true for potential environmental impacts. The strong focus on monetarisation of the impact of granting or rejecting the authorisation seems to have its limitations when it comes to impacts on environmental compartments (water, air etc.) or human health effects with a more ethical perspective (e.g. death[94]). This being even if established methods are applied in a correct way because the underlying principle can be questioned and potentially the comparison of the different effects may not be adequate, from a conceptual perspective[95].

- **The RAC and SEAC form their opinions on each AfA individually.**
  The AoAs of AfAs covering similar uses may differ to a large degree depending on the technical know-how of the applicants. Regarding their possibility to assess an alternative and potentially to introduce it later on, market actors with low technical (background) expertise on a technology will provide less elaborated AoAs. This lack of expertise in practice is very difficult to overcome for market actors and often not possible within a short-term. Partly, this can be addressed by databases, information portals and workshop events. Still, these options require at least one person in a company that is a) qualified to use these formats and b) has the time and resources to be engaged in such questions, which often already is a limiting factor in companies with only a few employees.

- **The inability to substitute is often justified by a claimed loss of product quality, which would not be accepted by customers of the substance users.**
  Sometimes the lower acceptance is attributed to subsequent technical requirements making the product unfit for purpose, e.g. in case of hard chrome plating and functional chrome plating in the aviation sector. In other cases, arguments cover aspects of convenience for the final product user, illustrated in the wool dying case, where a less intense colour would avoid the complete loss of dyed wool products, for example. There are no clear criteria indicating

[93] The indication of closure of businesses which applicants sometimes give can frequently not be substantiated if inquired by the SEAC but partial closure may be plausible, which limits the number of affected persons in a non-use scenario, too. Nevertheless, usually benefits outweigh the risks despite SEAC allowing only conservative assumptions, partly because the remaining risks are comparatively low.

[94] Currently established methods are applicable to put a monetised value on health effects, even though these approaches can be discussed as they often compare very different aspects (e.g. loss of economic success – turnover, with loss of workers life)

[95] Further investigation of the relationship between human health effects and impacts of non-use scenarios should be made to confirm this observation. If this observation can be verified, it could be discussed to describe these effects more qualitatively to reduce the burden for the argumentation in the SEA and the efforts put into the verification of the assumptions made and the recalculation of effects in case there are uncertainties (e.g. as happened in the SEA prepared as part of the CTAC application complex, here the SEAC made an own calculation but the result did not change the evaluation at all, since the deviation from the results of the applicants calculation were very close and the impacts of the non-use scenario were over tenfold higher). Such outcomes give the impression that such assessment have the character of self-fulfilling prophecy to some degree.

to what extent convenience aspects could be relevant from an overall socio-economic perspective. REACH currently defines a case by case basis for such evaluations.

- **The final decision process by the EU COM takes disproportionately long in many cases.** In the assessed cases the last step of the authorisation procedure, after the committees have adopted the final opinions, i.e. the COM taking a decision with support of the REACH-Committee, takes significant time (an overview of the duration for the steps for the cases assess is given in Table 11).
  In the cases assessed the step took up to as long as all other steps together: 6-9 months Sodium dichromate and Ammonium Dichromate when the decision was taken rather fast and several years in more complex cases (about 1-2 years up to here and over 5 years in the extreme case of the DEHP application which was finally withdrawn by the applicant). It should also be noted that not all cases have been decided, yet and some have been pending for over 30 months now.

### 6.7.2 Information Requirements and Data Quality of AfAs

#### 6.7.2.1 Chemical Safety Report (CSR)

As mentioned in Chapter 6.2, several AfA suffer from an insufficient description of OCs and RMMs. In many cases it is difficult for the RAC to understand to what extent an exposure scenario (ES) reflects the reality of all substance users potentially covered by an AfA or to what degree it rather reflects an idealised reasonable worst case or even a worst case scenario. Sometimes the RAC established own ESs and provided risk assessments in order to determine the risk level of a continued use.

In the DEHP application, which was designed to show adequate control, the applicant's reference values were higher than the default values provided by RAC in advance of the AfA. The RAC had to evaluate the applicant's approach and concluded that it was founded on old data and therefore not acceptable. Again, the RAC recalculated all assessments and corrected the estimation of the remaining risk. In the specific case of DEHP, the application shifted from the adequate control route to the socio-economic route as adequate control of risks could not be demonstrated with the RAC's threshold values.

It is now common practice that the RAC makes its own risk assessments or at least adapts the existing ones in the applications, if their evaluation of the applicant's risk assessment shows it is insufficient. This causes a very high workload for the RAC. It can be argued that the RAC takes over responsibility for the adequacy of the risk assessment from the applicant. A benefit of such approach consists in the possibility to conclude and decide on the AfA. A disadvantage consists of the resource limitations in case many AfAs have to be managed.

There are two options to reduce the RAC's burden for evaluating low quality risk assessments in AfAs:

- The applicants' risk assessments are considered unreasonable and the risk of a use is derived from rather simple (reasonable) worst case assumptions. The risk level derived this way is the input for the subsequent evaluation steps, a cost benefit analysis for example.
  If the AfA follows the adequate control route and a risk is determined, the AfA should be rejected unless it includes a SEA to evaluate the AfA via the socio economic route, instead.

The applicant has to accept a potential overestimation of risks and resulting either in short review periods or even a refusal of authorisation.

- Applications are rejected and applicants need to improve the applications. This proposal would reassign the responsibility for the revision of the CSR back to the applicant and reduce the burden for the RAC. This would be in line with the overall principle of authorisation under REACH to shift the responsibility for risk assessments from the authorities to the market actors.

The revision of the risk assessment can be time consuming, especially for upstream applications that cover a wide range of DUs. Therefore, potential deficiencies of a CSR should already be identified during the conformity check of the AfA, resulting in its rejection, if the quality is too low. This approach would avoid that AfAs of low quality enter the committee evaluation and reduce the burden for the assessments in the committees, which is limited by the comparably low number of experts.

If an AfA were rejected, the production may be interrupted at applicant or DU stage. As this is not an intention of REACH, time limited "transition" authorisations might be needed to give the applicant enough time to resubmit an improved application. Realistic time periods should be no shorter than 2 years and the transitional arrangement should have a different status as a COM authorisation under review. It should be clearly a one-time opportunity and re-application with another low-quality assessment would lead to a final rejection.

Finally, it can be considered what adverse health and environmental effects of a continued use are included in the assessment. In the case of DEHP it was discussed whether only its reprotoxicity should be considered or also its other adverse effects, including endocrine disruption. In a non-use scenario obviously all adverse effects are eliminated and might therefore cause benefits for future human health and the environment. At the same time, the continued use will cause health and environmental damage from all of a substance's hazardous properties.

#### 6.7.2.2 Assessment of Alternatives (AoA)

The broader the use (patterns) and the range of different products is that they are covered by an AfA, the more uncertainty results for the related AoA as all these have different subsequent technical requirements. This is illustrated in the AfA of hard chrome for machine parts or chrome as a purely decorative element. Furthermore, the suitability of an alternative is often only evaluated from the substance user´s perspective, rather than from the perspective of the competitors. Although this is in line with REACH Art. 60 (5b), it may allow continued use despite the downstream market sectors having already substituted (e.g. the use of chromates in wool mordant or the production of pigments for paints). In the case of lead pigments, only the higher raw material costs and the shorter revision periods for maintenance of painted surfaces (economic arguments) on behalf of the applicants caused the rejection of an alternative, although the competitors already relied on the use of alternatives.

NGOs claim (ClientEarth & chemsec, 2018[96] EEB, 2019[97]) that economic assessments should not only cover the applicant's costs but also costs that are linked to the reduction of incentives for

[96] ClientEarth & ChemSec (2018) "*How to find and analyse alternatives in the Authorisation Process*" https://chemsec.org/app/uploads/2018/03/180612-Alternatives-in-the-authorisation-process.pdf

[97] European Environmental Bureau (2019) "*A Roadmap to Revitalise REACH*" https://eeb.org/library/a-roadmap-to-revitalise-reach/

innovation[98]. This might create losses to progressive market actors who already apply safer alternatives. If such additional aspects were included, the result of assessments might change and certain alternatives might become feasible. In such cases, there would be no basis to grant an authorisation and a review could only reflect the time needed to introduce the alternative in the uses applied for (and potentially the time needed for some market actors to qualify products that are produced with an alternative according to other requirements, e.g. the airworthiness in the aviation sector or requalification in the health sector).

#### 6.7.2.3 Socio Economic Analysis (SEA)

The SEA in AfAs is dominated by approaches to monetise impacts and relate costs to benefits. Alternatively, the costs for the reduction of emissions are discussed under a "willingness to pay approach"[99].

One recurring issue in discussions on SEAs are the types of incorporated costs and the extent of a certain impact, such as the number of job losses in a sector and the duration of unemployment, the market losses of applicants and their and customer. SEAC often corrects the assumptions in the AfA and the RAC may correct underestimated health effects both resulting in changes of the calculated impacts of the continued use scenario. The impacts of a non-use scenario were often overestimated in the view of the SEAC experts[100]. At the same time benefits are allocated to the directly affected persons (e.g. workers in contact with a substances). The benefits for society in a wider view are often not considered or only qualitatively.

Overall, in the cases assessed in this project, the additional work of the committee did not change the situation described in the AfA. As in the assessed cases the human health impacts were mainly limited to worker risks, the overall number of damage cases (cancer, skin sensitivity etc.) was rather limited despite the corrections, so the calculated impacts remained in the same order of magnitude, while the impacts of the non-use scenario also remained in a similar order but often outweighed the health impacts by a hundredfold. This seems to be linked to a generally low number of workers handling SVHC and rather large impacts on the economic side. In none of the cases where workers' risks have been compared with economic impacts were the health effects even close to outweighing the economic impacts. At the same time the SEAC often confirmed that the overall approaches chosen by the applicants were appropriate to present the socio-economic effects. In conclusion, it seems questionable whether there will ever be a case that shows that the no-use scenario will be beneficial. This poses the following key questions:

- Do additional criteria apart from monetisation need to be assessed in AfAs, when only workers' risks are in the scope of the analysis?
- Is it sufficient to have a qualitative argumentation?
- Can clear cut-off criteria be defined for the workplace, above which risks are so high that an authorisation cannot be granted (also under consideration of a precautionary approach – especially for a very broad unspecific upstream application)?

[98] Even though this might not be foreseen by the REACH text, currently.

[99] See e.g. ECHA website "willingness to pay to avoid certain health impacts" https://echa.europa.eu/de/support/socio-economic-analysis-in-reach/willingness-to-pay-to-avoid-certain-health-impacts or IVM Institute for Environmental Studies (2015) "Benchmark development for the proportionality assessment of PBT and vPvB substances" https://echa.europa.eu/documents/10162/13647/R15_11_pbt_benchmark_report_en.pdf/a695a7fd-e2bd-4dc5-b69a-bc02f9f98fef

[100] This usually results in adapted estimates on impacts. Cost of unemployment are often only accepted partly or estimates on losses are only considered for short timelines (e.g. one year instead of 12 years).

- Which criteria can be used to evaluate the importance of a use for society in cases, where an AfA cannot demonstrate adequate control of risk[101]?
- Would a qualitative discussion of impacts be sufficient in RAC/SEAC to evaluate an applicant's calculations? Is an own assessment necessary when there is a clear indication that fundamental changes in the assessment can be expected? Can it be better in such cases to redirect the AfA back to the applicant to revise it and implement indicated changes (burden of proof remains with the applicant)?
- To overcome limitations in the AoA lists of potential alternatives should be generated after the initial application across all AfAs (including those brought forward during public consultations) that have been issued for a certain substance in a specific use. This list should
  - assist future substitution activities of the market actors and
  - define the minimum scope of the AoA for the review report in case continued use is seen necessary by the authorisation holder or market actors that initially apply later when such a list already has been generated.

This last point would help market actors with less technical experience to get a clear view of what is expected as a minimum and would increase comparability of applications, still the burden of proof will remain with the applicants.

[101] In the frame a document issued by the Norwegian EPA on a regulatory strategy on PFAS the concept of "essential uses" was proposed that justify the use of SVHC despite the risk linked to it, "Elements for an EU-strategy for PFASs" (https://www.regjeringen.no/contentassets/1439a5cc9e82467385ea9f090f3c7bd7/fluor---eu-strategy-for-pfass---december-19.pdf) The concept was first proposed in Cousins et al. (2019). The concept of essential use for determining when uses of PFASs can be phased out. Environmental Science Processes & Impacts. https://pubs.rsc.org/en/content/articlelanding/2019/em/c9em00163h#!divAbstract .

# 7 Conclusions and Recommendations

The conclusions from the study on whether or not and how the SVHC identification and authorisation procedure could be enhanced or improved are compiled according to the research questions (an overview on proposals is given in Table 10).

## 7.1 Is the General Aim of the REACH Authorisation accomplished? How can the Effectiveness and Efficiency be increased?

In general, the current study indicates that the overall aims of the authorisation are have been achieved. The procedures are functioning and regarded a significant driver for a phase-out of substances subjected to authorisation. This is true for substances listened in Annex XIV and also for SVHCs on the candidate list[102].

Although it is very difficult to quantify the effect of authorisation on substitution, it is evident that awareness on SVHC increased and market actors tend to avoid such substances if possible[103]. For a relevant number (currently 22 out of 54) of substances, no or only few AfAs have been submitted, which indicates that these are of no or low relevance for the EU market. This can have different reasons:

- Substances could be easily substituted
- Substances are still in use outside the EU and former EU production has shifted to non EU countries. In these cases, there might even be the potential that substances still enter the EU market in Articles or in mixtures below certain threshold limits
- Substances had no relevance prior to being regulated and regulatory action was based on insufficient information.

However, it is not clear if this was already the case before the authorisation requirement under REACH. No reports, to the authors knowledge, exist that could clarify the reasons for this inaction (no applications), hence it remains unclear if the authorisation requirement was very effective in this regard (triggering substitution very effectively) or has been very ineffective (investment of large bureaucratic burden for preparatory steps of an authorisation requirement, without triggering a substantial change in risks from chemicals)

On the other hand, there are substances for which very many AfAs have been submitted or where a large number of DUs are covered. Only some of these AfAs indicate a substitution aim in the short- or mid-term. The gained value of these applications seems to be the increased risk management until the use is ended, which consists of the measures described in the ESs and any potential additional measures defined in authorisation decisions, which become mandatory and EU wide harmonised standards for the substance use. Nevertheless, it can also be discussed whether such a harmonised risk management approach would also be achievable with other measures (e.g. a restriction) that might be less resource demanding.

The RMOA is a valuable instrument that can help to anticipate whether or not the aim of authorisation can be achieved for a particular substance and the market functioning be ensured

[102] See also DG Growth (2017) Study on the Impacts of REACH Authorisation

[103] See also working package 10 of the overall research project "advancing REACH" on REACH and substitution. This study analyses the support of the so-called substitution, which is the use of less hazardous alternatives for substances of concern, by instruments of the REACH regulations and elaborates concrete recommendations (not yet published). An overview on all individual studies prepared in the frame of the project given here https://www.umweltbundesamt.de/en/topics/chemicals/reach-what-is-it/advancing-reach

at the same time (in the most effective way). To increase the efficiency of RMOAs in depth, information on substance uses would be needed but is frequently missing, which hinders getting a clear picture of the implications of a measure. Furthermore, information on alternatives and market impacts are scarce and limit the possibility for authorities to decide on a measure. Measures to overcome this lack of information could cover stakeholder voluntary commitments to provide this type of information in the future. However, experiences have shown that such processes often do not close all data gaps. A legally binding mechanism for authorities to request the information might be a better solution to overcome information shortcomings in an early stage of the strategic selection of a suited regulatory approach.

In contrast to the lack of use information, substance property data from registrations and evaluations are usually better to identify substances as SVHC. This is especially true if substance properties correspond to CLP classifications categories and can be subjected to harmonised classifications. However, for some properties (e.g. ED ENV) data become only available after time-/effort-consuming data requests during a substance evaluation since these data are not part of the standard information to be provided with the registration. Here, an extension of the information requirements might help to reduce the efforts for authorities when evaluating the hazardous properties of a substance. ECHA's screening processes and the increasing efforts to use grouping approaches support the identification of substances that might qualify for an authorisation and to ensure regrettable substitution is improved.

A problem identified in AfAs is the evaluation of AoAs. Applicants mainly argue that no alternatives are available and often it is highly uncertain whether or not alternatives are on the market. The complexity of an assessment of alternatives certainly depends on the "type" of alternative, i.e. whether a very similar "drop in" substance, a different substance which requires completely different technical installations, or also different (non-chemical) technical solutions are under consideration. As REACH requires the applicants to describe the alternatives and the potential for them to introduce the aforementioned, certain problems arise:

- In upstream applications mainly alternatives for DUs are discussed and it is difficult to transfer respective knowledge from them to the applicant's AfA
- Some substance users (potential applicants of an AFA) are in fact just users and the authorities' expectations regarding the knowledge on alternative processes are too high. Such users (often SME) lack background knowledge on alternatives on the expected scientific level.
- Some market actors have unrealistic expectations on their ability to use alternatives. For example, if a user has got a certain type of installation, he will not be able to change to an alternative unless it is a drop in chemical that works within the same installation. From the user's perspective other alternatives are only a theoretical option.

In such situations, applicants may not be able to provide realistic in-depth assessments of alternatives and the benefit of such analyses for the overall application is questionable. One way forward could be to assess alternatives at an overarching level by the authorities. Still, information has to be compiled and communicated from alternative providers and users. As information on alternatives is relevant for deciding on the best regulatory option and the design of a later regulatory measure, the RMOA may be an appropriate process for this. Based on this information, use-specific sunset dates could be considered to encourage substitution and to avoid further AfAs as much as possible. This might lead to an overall increase of the efficiency of the authorisation and enhance substitution instead of authorisations.

## 7.2 Drivers of the Authorities' Workload for Authorisations

Overall, the main driver of the authorities' workload in all steps of the authorisation is the lack of information on uses and alternatives as well as on the socio-economic impacts of a non-use scenario.

Information on uses, alternatives and socio-economic impacts are needed in any decisions. They are most important to support the RMOA, the evaluation of AfAs, and for prioritisation, the latter with lower importance. Currently, no process exists for authorities to collect that information from the market actors, apart from the authorisation decision itself. Here, the conditions of an authorisation may require DUs at the end of the supply chain to report the implemented OCs and RMMs as well as exposure levels, thus improving the information for a stronger fact-based evaluation at the time of reviewing the authorisation. If Authorities want to obtain this information earlier, the only option is to invest own resources and start research activities, such as making measurements, starting surveys or contacting stakeholders.

In contrast, the SVHC identification exclusively concerns substances properties. The process may be burdensome, when the information basis is not clear e.g. information is missing, there is a disagreement about the interpretation of data or case-by-case evaluations need to be prepared. This is in particular the case for substances identified under Article 57 (f), where data are often not yet falling under standard data requirements compared to the other SVHC criteria under Article 57 a-e. The decision process itself is well-structured and can usually be finalised in the foreseen time frames. The decision on the SVHC often follows a harmonised classification and pre-discussions among experts in the RIME+, expert groups and the CARACAL, where disagreements between MS can be solved a priori.
In addition to the assessment of data and preparation of the dossier, the number and quality of comments provided in the public consultation is the main determinant of workload for SVHC identification because the authorities need to answer and transparently document their replies to all submissions in a RCOM.

One key driver determining the workload in the authorisation of a particular substance is the number of submitted AfAs and their complexity, especially when upstream applications are submitted. It should be highlighted that upstream applications are an instrument to implement harmonised OCs and RMMs across sectors. Therefore, uses are clearly distinguished in order to clarify which market actors are covered and what measures should be enforced. The authorities benefit from upstream applications because they reduce the number of applications for one substance and because they can be handled relatively easily if a limited number of uses is covered in one application. Therefore, upstream applications can also be a very valuable tool to reduce the number of applications and thereby the burden for both market actors and authorities. To optimise the effect of upstream applications, further improvement of the instrument is needed, for example in the form of guidance, e.g. what installation or use types may be aggregated as a use to be representative in the AfA.

## 7.3 Reducing the Workload for the Individual Authorisation Steps

Since the authorisation process entered into force, standards and guidance have been developed to support the implementation of the individual authorisation steps, which already reduced the workload of all actors.

The workload for SVHC identification is determined by the available evidence to demonstrate an SVHC property. The initiated measures seem suitable to increase the process efficiency, although this does not automatically decrease the authorities' workload:

- **Grouping** allows discussing several substances that

  d) follow the same MoA and cause similar effects and/or

  e) may be used as alternatives to each other or for other substances on the candidate list.

  While the first aspect can lead to a more focussed work and therefore increases the efficiency of SVHC identification by including similar argumentations into one Annex XV dossier. The second aim is increasing the overall effectiveness by preventing substitution of one substance by a structurally similar one with comparable properties.

- **Property specific expert groups** discuss standards and criteria how a particular SVHC property can be demonstrated in case the standard set of criteria cannot be applied and a stronger case sensitive weight of evidence approach is needed. Here, the development of guidance and exemplifying case studies are important elements to establish a standard that is widely accepted by MSCAs and thereby defines the minimum data set sufficient for the demonstration of SVHC properties.

The authorities' workload for evaluating AfAs (also) originates from insufficient information provided in the CSR, the AoA, or the SEA because the RAC and SEAC often take an active role to improve the assessments. REACH places the burden of proof onto the market actors who want to continue a use. One can argue that the committees automatically participate in developing the argumentation of the AfA when discussing the suitability and availability of alternatives or adjusting economic impact considerations of non-use and continued use scenarios, for example. However, active information collection and assessment go beyond evaluation. Rules and quality standards that limit these activities should be established that allow the RAC and SEAC to reject low quality proposals. This should especially be the case, when the committees need to invest resources to generate own additional information.

An exemption is the derivation of overreaching reference values for the risk assessment (margin of risks). Such harmonised reference values for the quantification of the risk would support the objectivity of the assessment and reduce the workload for the evaluation of many individual argumentations at the adequate reference level. Furthermore, defining safety thresholds can be considered as an authority responsibility. A similar role could be assigned to a list of reference alternatives that defines the minimum scope of an AoA and provide basic information on the alternatives as input to the assessment. This may assist committees to initiate conditions or to reject AfAs. Reference values can also be used to define the margin of risks level which, if exceeded, leads to rejection or shorter review periods – margins should be regardless the potential economic benefits for the company or the supply chain.

If the committees revise an applicant's argumentations one could discuss whether a full quantitative reassessment is needed or if qualitative discussions are sufficient to understand the changes and to draw conclusions. A qualitative approach can be justified even more in cases where the overall argumentation is not significantly changed, when certain costs are corrected but the order of the magnitude is not changed and other cost exceed them by far[104], for example.

Cut-off criteria for certain conditions in an AfA could be developed to simplify the application and its evaluation. These could concern the emission or exposure levels of an SVHC in a use but also particular cost-benefit relations in SEAS or be qualitative and refer to protection goals, for

[104] This can e.g. be seen when impacts on workers are assessed and compared with economic impacts on supply chains. The number of workers using the substance is in most application relatively low and corrections rarely change an overall picture, while economic impacts are often overweigh these effects by a hundred fold.

example. It should be discussed if such criteria could be developed, also regarding the uncertainties of assessments, especially in the area of the SEA and the suitability of alternatives. This might also reduce the strong focus of AfAs on methods assigning a monetary value to the authorisation impacts. Such criteria would represent a political standard on "what can be accepted and what is unacceptable" not in monetary terms but with a stronger focus on the exposed subject of protection. Such criteria would also assist the final decision process of the COM and the REACH Committee and increase the predictability of the decision itself. Since such criteria would have the status of a political determination they should be enacted by the COM and the REACH committee (as representation of the MS). Other areas where criteria could be relevant are:

- low volume of substances (volumes of insignificance)
- overall benefit of a use for the society (e.g. essential uses).

## 7.4 Suitability of ECHA's Prioritisation Approach

The process as such how ECHA prioritises SVHC for inclusion in Annex XIV is very clear and concise. Since most information is available at least for a basic evaluation, it can be applied in a straight forward way. Nevertheless, as the information basis may not be up-to-date or certain information missing, the prioritisation outcome might over- or underestimate the relevance of an individual substance. The workload of prioritisation increases if ECHA needs to actively check research the information basis. It is therefore essential that registration dossiers are regularly updated.

One improvement option could be that ECHA does not include all SVHCs of the candidate list in each prioritisation round because the task will grow as the number of new authorisation candidate substances is assumed to grow faster than the number of SVHCs on Annex XIV. Therefore, the partly performed practice in RMOAs of explicitly stating whether a later inclusion of a substance in Annex XIV is the ultimate goal should be a standard process. Substances not foreseen for authorisation could be excluded from the prioritisation process, resulting in reduced workloads for ECHAs for preparing recommendations.

Overall, it can be questioned if the prioritisation criteria currently used by ECHA are sufficient to put forward the substances for which the authorisation requirement provides significant risk reduction. It is for example questionable if SVHCs need to be prioritised for Annex XIV if general aims of the authorisation cannot be achieved in mid-term. If substitution e.g. may not be realised with reasonable likelihood it might be more effective to control potential risks via alternative measures (e.g. a restriction or other pieces of legislation). However, there might be some benefit to facilitate a candidate listing to prepare these alternative measures or to use this as a measure on its own. For example, if an RMOA recommends restriction as the best regulatory measure for a substance after SVHC identification, no prioritisation would be needed. In such cases, the candidate list would have the role to manifest the SVHC status officially, together with the aim to trigger information generation on SVHCs in articles according REACH Art. 7 of REACH and the Waste Framework Directive's[105] Art. 9 new database (SCIP).

## 7.5 Acceleration of Individual Procedures

Overall and according to the findings of this study, the timelines defined by the REACH text seem to be appropriate to manage the processing of AfAs by the respective ECHA departments as well

[105] DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives

as by the RAC and SEAC, even if AfAs are submitted in a high number. Still it needs the careful monitoring of the resources needed to manage these processes as Annex XIV will be more and more extended and numbers of applications may increase even more. Probably more resources are needed to then handle applications in a shorter time. Currently, the time critical step in handling AfAs is the final decision process of COM and the REACH committee. Even though there is no fixed timeline defined in the REACH text, the current durations until final decisions often taken seem disproportionate (sometimes several years after the final RAC/SEAC opinions). Clear timelines for this final step of the handling of AfAs would give affected industry stakeholders more security for planning their business activities and invests.

The speed of processes preceding the official authorisation procedures, such as the RMOA or substance screenings as well as the development of Annex XV dossiers strongly depend on the availability of data and complexity of the individual case. The following measures might accelerate these processes:

- Activities to improve the quality of registrations dossiers, in particular to close data gaps and ensure data is up to date. This is in particular important for information on use patterns and specific use amounts. Registrants should e.g. be encouraged to provide information on use specific volumes. Currently, this is foreseen in the frame of the registration, but the way information is included it is often too unspecific and aggregated. This could be further elaborated so that information really does support decision making. It could even be considered to implement an obligation under REACH for downstream users to provide certain information (either in supply chains or towards authorities).
- Involve DU users, if possible at the stage of the RMOA, which would be affected to the greatest extent by an (non-)authorisation.
- Analyse in the RMOA which sectors may be affected by an authorisation, size and capacities of affected companies to deal with substitution and the number of expected AfAs. This should improve decision making on whether or not authorisation is the best regulatory measure, as indications of the possibility to substitute with moderate efforts or at mid-term would be gathered.

Political decision criteria would help to speed up decisions in the REACH Committee, which is the process currently causing the largest delays. One core question to be addressed in this context is the extent to which the EU COM and the REACH committee need additional information for their decision not already obtained by the application and addressed in the RAC/SEAC opinions (Is there an information level seen as relevant and currently missing in the RAC/SEAC opinions?). Currently, improvements for the availability of alternatives are being discussed and the judgement of the EU court of justice assigns more responsibility to the EU COM in this area. Another area which is often a basis for public debates are the economic impacts on sectors, which are often indirect impacts. Also, the appropriateness of a refusal of an application is often discussed at the policy level in the context of certain protection aims (like e.g. protection towards endocrine disruptors). To improve this situation following approaches could be useful:

- Support by technical experts, this can either be the existing committees RAC and SEAC or separate expert groups.

- Definition of (political) decision criteria that are agreed by member state authorities and COM to clarify setting a clear frame for refusal or approval of AfAs. This would define situations where it might be justified to
  - grant an authorisation even if there are various uncertainties or relevant remaining risks
  - refuse an authorisation although an individual application shows good arguments to grant it for this one market actor, but an authorisation nevertheless seems not justified (e.g. in case a large share of market actors already moved to an alternative or the use as such seems non-essential to justify continued use of an SVHC even though the economics of the use would justify this in the SEA).

**Table 10: Overview on proposed measures to improve the authorisation process**

| Nr. | Proposed measure | Affected Process step(s), (supported stakeholder group) | Potential improvements and challenges |
|---|---|---|---|
| 1 | Technical assessment of alternatives on a higher level by authorities (with involvement of stakeholders) | • RMOA (ECHA, MSCA)<br>• Listing on Annex XIV (ECHA, EU COM)<br>• AfA (applicants) | • May support selection of best RMO in regard to the substitution aim of the authorisation under REACH<br>• Does ensure a harmonised approach on the assessment of alternatives (at least for the technical part)<br>• Does support the generation of AoA as part of AfA (set of minimum alternatives to be considered)<br>• May support substitutions by market actors formerly unaware of such alternatives, instead of AfA (resulting in less workload in the AfA decision making process)<br>• Does support market actors with limited scientific knowledge on technical processes (good practitioners) to prepare AfAs, if needed (helps to overcome application hurdles and too low quality for RAC and SEAC assessment)<br>• Challenge: would strongly depend on information that is made available to authorities (from DUs or branches, in particular providers of alternatives) |
| 2 | Improve documentation of OC and RMM in application for authorisation (preferably also in registration documents) by implementation of mandatory reporting obligations along supply chains (in particular for upstream-applications) | • AfA (applications, ECHA, RAC) | • Reduction of number of single applications by increased use of the instrument “upstream applications” (in practice this might always be a trade-off between increasing complexity and lower application numbers) |
| 3 | Promotion of current ECHA activities in screening | • ECHA Screening (ECHA, applicants, MSCA) | • Increases awareness for potential concern for substitution of hazardous substances (also among DU)<br>• Can trigger incentive to update information in registration dossiers |
| 4 | Increase use of grouping for structurally related substances with properties of concern | • RMOA (ECHA, MSCA, DU and further downstream supply chain)) | • Can improve efficiency if toxicology/ecotoxicology argumentation can be used for several substances due to similar MoA (reduces efforts for preparation of documents and repeated interaction with stakeholders) |

| Nr. | Proposed measure | Affected Process step(s), (supported stakeholder group) | Potential improvements and challenges |
|---|---|---|---|
| | | • SVHC identification (ECHA, MSCA)<br>• Listing on Annex XIV (ECHA, EU COM) | • Supports more strategical approaches for the selection of risk management measures.<br>• Provides early and synchronised signal for stakeholders on potential regulation and gives opportunity to provide consolidated information for a group.<br>• Prevents selection of substances that have a similar concern |
| 5 | Increase use of grouping for substances with properties of concern that can have the same function in a use/product even though structurally unrelated | • RMOA (ECHA, MSCA, DU and further downstream supply chain))<br>• SVHC identification (ECHA, MSCA)<br>• Listing on Annex XIV (ECHA, EU COM) | • Supports more strategical approaches for the selection of risk management measures.<br>• Provides early and synchronised signal for stakeholders on potential regulation and gives opportunity to provide consolidated information for a group.<br>• Prevents selection of substances that have a similar concern |
| 6 | Strengthen role of property specific expert groups | • Screening (MSCA, ECHA)<br>• SVHC identification (MSCA, ECHA) | • Supports identification of substances of concern by establishing standards and criteria widely accepted by MSCA and ECHA when standard set of criteria cannot be applied and a stronger case sensitive weight of evidence approach is needed to demonstrate the (equivalent) concern. |
| 7 | Establish minimum quality criteria for the inclusion of AoA and SEA information in AfA? | • AfA opinion making (ECHA, RAC/SEAC) | • Reduce extensive data requests or own assessments by RAC and SEAC during opinion making |
| 8 | Establish overreaching reference values to characterise risks and to establish margin of risks that can be accepted (can either be quantitative or qualitative) | • AfA opinion making (RAC, applicants)<br>• AfA Decision making process (EU COM) | • Ensures comparability of risk levels<br>• Assists Committees to initiate conditions or to reject AfAs. Can be used to define margin of risks level which if exceeded leads to rejection or shorter review periods – margins should be regardless the potential economic benefits for the company or the supply chain |
| 9 | Establish tonnage levels where risks may be considered insignificant with a high likelihood | • AfA preparation of application (applicants) | • Enables applicants to use the adequate control route (reduces efforts to prepare and check documents and assessments) |

| Nr. | Proposed measure | Affected Process step(s), (supported stakeholder group) | Potential improvements and challenges |
|---|---|---|---|
| | | • AfA opinion making (RAC, applicants)<br>• AfA Decision making process (EU COM) | |
| 10 | Establish uses where risks may be acceptable due to high overall benefits for society (define essential uses, potentially time limited with review periods) | • AfA opinion making(RAC/SEAC, applicants)<br>• AfA Decision process (EU COM) | • Changes authorisation aim from short mid-term substitution to risk minimisation: Supports the establishment of high quality risk management via authorisation conditions<br>• Challenge: Reach agreement on concept of “essential for society”, this is not likely to be something that can be discussed in the frame of an AfA but will need an overreaching technical and political process |
| 11 | Exclude substances from prioritisation process (can already be defined in RMOA – candidate listing ultimate RMO, other RMOs) | • RMOA (ECHA, MSCA)<br>• Prioritisation (ECHA) | • Reduction of workload<br>  ○ Substances on candidate list more likely to be regulated via other RMOs can be excluded from prioritisation process<br>  ○ Substance where there was no need for an update of basic information (no registration update, no new information from public consultations) may not need to be reassessed<br>• Challenge: implement a process (either voluntarily or legally binding) that allow authorities to request data at the time this decisions are taken |

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# A Timelines for granting an Authorisation in the Cases selected

**Table 11: Application for Authorisation, steps and timeframe needed until decision (date of start of a step and duration in months until next step in brackets)**

| Substance<br>Submitter<br>EC Number<br>CAS-Number<br>ID | Submission Date (listed in RAC/SEAC Opinion and Commission Decision) | Consultation Period (listed in RAC/SEAC Opinion and Commission Decision) | Date of RAC/SEAC Opinion adopted (Compiled RAC and SEAC opinions) | Adopted Commission Implementing Decision (or: Status) |
|---|---|---|---|---|
| **Chromium trioxide**<br>Submitter: LANXESS Deutschland GmbH in its legal capacity as Only Representative of LANXESS CISA (Pty) Ltd<br>EC Number: 215-607-8<br>CAS Number: 1333-82-0<br>ID: 0032-01; ID: 0032-02; ID: 0032-03; ID: 0032-04; ID: 0032-05; ID: 0032-06 | 11/05/2015 (3) | 12/08/2015 – 07/10/2015 (2) | 16/09/2016 (11) | Pending decision[106] (47)[107] |
| Submitter: Hansgrohe SE<br>ID: 0114–01, ID: 0114–02 | 15/11/2016 (3) | 08/02/2017 – 04/04/2017 (2) | 21/08/2017 (4) | 14/02/2019 (17) |
| **Trichlorethylene**<br>Submitter: Blue Cube Germany Assets GmbH & Co. KG [application transferred from original Applicant: DOW DEUTSCHLAND ANLAGENGESELLSCHAFT mbH due to a notified legal entity change]<br>EC Number: 201-167-4<br>CAS Number: 79-01-6<br>ID: 0024-01; ID: 0024-02; ID: 0024-03; ID: 0024-04; ID: 0024-05 | 18/08/2014 (3) | 12/11/2014 – 07/01/2015 (2) | 11/09/2015 (8) | 10/08/2018 (36) |
| **Sodium dichromate**<br>Submitter: Gruppo Colle.S.r.l. | 27/10/2016 (4) | 08/02/2017 – 05/04/2017 (2) | 07/07/2017 (3) | 15/12/2017 (6) |

[106] See document: EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SME's Chemicals and Consumer Industries REACH, REACH Authorisation Decisions Last update: 03/07/2020 https://ec.europa.eu/docsroom/documents/42566/attachments/1/translations/en/renditions/native

[107] Reference August 2020)

| Substance<br>Submitter<br>EC Number<br>CAS-Number<br>ID | Submission Date (listed in RAC/SEAC Opinion and Commission Decision) | Consultation Period (listed in RAC/SEAC Opinion and Commission Decision) | Date of RAC/SEAC Opinion adopted (Compiled RAC and SEAC opinions) | Adopted Commission Implementing Decision (or: Status) |
|---|---|---|---|---|
| EC Number: 234-190-3<br>**CAS Number**: 7789-12-0; 10588-01-9<br>ID: 0113-01 | | | | |
| **Bis(2-ethylhexyl) phthalate (DEHP)**<br>Submitter Grupa Azoty Zakłady Azotowe Kędzierzyn S.A.<br>EC Number: 204-211-0<br>CAS Number: 117-81-7<br>ID: 0003-01; ID: 0003-02 | 08/08/2013 (3) | 13/11/2013 – 08/01/2014 (3) | 23/10/2014 (9) | (Status: Withdrawn 01/04/2020) (65) |
| Submitter: DEZA a.s.<br>ID: 0004-01; ID: 0004-02 | 12/08/2013 (3) | 13/11/2013 – 08/01/2014 (3) | 27/01/2015 (12) | (Status: Pending Decision) (31) |
| Submitter: DEZA a.s.<br>ID: 0004-03 | 12/08/2013 (3) | 13/11/2013 – 08/01/2014 (3) | 28/11/2014 (10) | (Status: Pending Decision) (32) |
| Submitter: VINYLOOP FERRARA S.p.A.; Stena Recycling AB; Plastic Planet srl<br>ID: 0008-01; ID: 0008-02 | 13/08/2013 (3) | 13/11/2013 – 08/01/2014 (3) | 22/10/2014 (9) | 16/06/2016 (21) |
| **Dibutyl phthalate (DBP)**<br>Submitter: DEZA a.s.<br>EC Number: 201-557-4<br>CAS Number: 84-74-2<br>ID: 0005-01; ID: 0005-02; ID: 0005-03 | 23/08/2013 (3) | 13/11/2013 – 08/01/2014 (3) | 28/11/2014 (10) | 08/04/2016 (17) |
| **Ammonium dichromate**<br>Submitter: Micrometal GmbH<br>EC Number: 232-143-1<br>CAS Number: 7789-09-5<br>ID: 0049-01 | 09/12/2015 (2) | 10/02/2016 – 06/04/2016 (2) | 06/09/2016 (5) | 22/05/2017 (9) |

| Substance<br>Submitter<br>EC Number<br>CAS-Number<br>ID | Submission Date (listed in RAC/SEAC Opinion and Commission Decision) | Consultation Period (listed in RAC/SEAC Opinion and Commission Decision) | Date of RAC/SEAC Opinion adopted (Compiled RAC and SEAC opinions) | Adopted Commission Implementing Decision (or: Status) |
|---|---|---|---|---|
| **Bis(2-methoxyethyl) ether (Diglyme)**<br>Submitter: Roche Diagnostics GmbH<br>EC Number: 203-924-4<br>CAS Number: 111-96-6<br>ID: 0084-01 | 18/02/2016 (2) | 27/04/2016 – 22/06/2016 (2) | 06/06/2017 (12) | 14/05/2019 (23) |
| **Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane**<br>Submitter: INEOS Styrenics Netherlands BV<br>INEOS Styrenics Ribecourt SAS<br>INEOS Styrenics Wingles SAS<br>Synthos Dwory 7 spółka z ograniczoną odpowiedzialnością spółka komandytowo-akcyjna.<br>Synthos Kralupy a.s.<br>StyroChem Finland Oy<br>Monotez SA<br>RP Compounds GmbH<br>Synbra Technology bv<br>Sunpor Kunststoff GmbH<br>Dunastyr Polystyrene Manufacturing C. Co. Ltd<br>Versalis SpA<br>Unipol Holland bv<br>**EC Number**: 221-695-9; 247-148-4<br>**CAS Number**: 3194-55-6; 25637-99-4;134237-50-6; 134237-51-7, 134237-52-8<br>ID: 0013-01; ID: 0013-02 | 13/02/2014 (3) | 14/05/2014 – 09/07/2014 (2) | 08/01/2015 (6) | 08/01/2016 (12) |
| **Lead sulfochromate yellow** (C.I. Pigment Yellow 34)<br>Submitter: DCC Maastricht B.V. OR<br>EC Number: 215-693-7 | 19/11/2013 (listed in Commission Decision)(3) | 12/02/2014 – 09/04/2014 (2) | 11/12/2014 (8) | 07/09/2016 (22) |

| Substance<br>Submitter<br>EC Number<br>CAS-Number<br>ID | Submission Date (listed in RAC/SEAC Opinion and Commission Decision) | Consultation Period (listed in RAC/SEAC Opinion and Commission Decision) | Date of RAC/SEAC Opinion adopted (Compiled RAC and SEAC opinions) | Adopted Commission Implementing Decision (or: Status) |
|---|---|---|---|---|
| CAS Number: 1344-37-2<br>ID: 0012-01; ID: 0012-03; ID: 0012-05; ID: 0012-07; ID: 0012-09; ID: 0012-11 | | | | |
| **Lead chromate molybdate sulphate red (C.I. Pigment Red 104)**<br>Submitter: DCC Maastricht B.V. OR<br>EC Number: 235-759-9<br>CAS Number: 12656-85-8<br>ID: 0012-02; ID: 0012-04; ID: 0012-06; ID: 0012-08; ID: 0012-10; ID: 0012-12 | 19/11/2013 (3) | 12/02/2014 – 09/04/2014 (2) | 11/12/2014 (8) | 07/09/2016 (22) |