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Advancing REACH: Interplay of the REACH Processes

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Abstract: Advancing REACH: Interplay of the REACH Processes

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

The interfaces between the processes registration, dossier evaluation, substance evaluation, authorisation and restriction are described and analysed with regard to the intended interactions, existing instruments to support the interplay, observed deficits and improvement ideas. Based on this, findings on the main deficits and options to improve the interplay are summarised.

Overall, the interplay between processes is assessed as working sufficiently well, with some improvement potential in the area of dossier and substance evaluation. An overarching deficit negatively affecting all process is the lack of hazard and use information at sufficient quality and level of detail in the registration dossiers.

Kurzbeschreibung: Weiterentwicklung von REACH: Zusammenspiel der REACH-Prozesse

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

In diesem Bericht werden die Schnittstellen zwischen den Prozessen Registrierung, Dossierbewertung, Stoffbewertung, Zulassung und Beschränkung beschrieben und bezüglich des intendierten Zusammenspiels, der beobachteten Defizite und Herausforderungen sowie Verbesserungsmöglichkeiten analysiert. Auf dieser Grundlage werden die zentralen Defizite und Verbesserungsoptionen zusammengefasst.

Insgesamt funktionieren die Schnittstellen zwischen den Verfahren ausreichend gut, wobei einige Verbesserungspotenziale im Bereich der Dossier- und Stoffbewertung identifiziert wurden. Der Mangel an Daten über Stoffeigenschaften und Verwendungen in ausreichend hoher Qualität und Detailtiefe in den Registrierungsdossiers ist ein übergreifendes Defizit, welches sich auf alle Prozesse direkt oder indirekt negativ auswirkt.

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AfA	Application for Authorisation
AoA	Assessment of Alternatives
BoA	Board of Appeal
BOEL	Binding Occupational Exposure Limit value
C&L	Classification and Labelling (Regulation)
CCH	Compliance CHeck (dossier evaluation)
CMR	Carcinogenic, Mutagenic, Reprotoxic Substance
COM	EU Commission
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
CSS	Chemicals Strategy for Sustainability
ECHA	European Chemicals Agency
IRS	Integrated Regulatory Strategy
MS	Member State
MS CA	Member State Competent Authority
PACT	Public Activities Coordination Tool
PBT/vPvB	Persistent Bioaccumulative and Toxic substance/very Persistent, very Bioaccumulative substance
RAC	Risk Assessment Committee
RCR	Risk Characterisation Ratio
REACH	Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMOA	Regulatory Management Option Analysis
RP	Restriction proposal
SCIP	Substances of Concern In Products
SEAC	Socio-Economic Assessment Committee
SEv	Substance Evaluation
SID	Substance Identity
SVHC	Substance of Very High Concern
TCC	Technical Completeness Check

Summary

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

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

The current sub-project is aimed at identifying deficits in the interplay of the REACH processes registration, evaluation, authorisation and restriction in order to point out potential obstacles in meeting the regulation's goal of achieving a high level of protection in an efficient way. In general, a 'deficit in interplay' is understood as any 'issue' that hinders or prevents achieving a high level of protection by making risk assessment and risk management less effective or efficient as it could be. In practice, these deficits could consist of insufficient information availability or an inappropriate coordination of measures. Either of the two may have different reasons, such as provisions in the REACH text, insufficient communication and coordination among the actors or a lack of guidance and methods. The direct consequences of these deficits could be that the risk management process overlooks risks, is delayed or unnecessarily demands high resources.

To analyse the interface, a separate table was prepared to match each of the individual REACH processes with each of the remaining ones. In doing so, the authorisation process was separated into the steps 'Identification of substances of very high concern (SVHC)', 'Inclusion of SVHC into Annex XIV', 'Development of Applications for Authorisation', 'Opinion forming on Applications for Authorisation' and 'Decision making on Authorisation' because at each stage different actors are concerned. Similarly, the restriction process was sub-divided into the proposal drafting, the opinion forming and the decision making step.

For each of the interfaces in the resulting tables it was described

- how the interplay at the specific interface is intended by REACH or, where this is not explicitly defined in the legal text, how it should be to ensure the processes work properly
- which instruments have been introduced (recently) to support the interplay at the specific interface, such as additional legislation, guidance updates, templates, consultations
- observations about deficits in the interplay of process, as explained above
- ideas for improvement that address the observed deficits.

It should be noted that these ideas for improvement have only been derived from the perspective how a deficit could be overcome but have not been assessed with regard to their costs and benefits. If any of these ideas should be considered for further action, such assessment would be needed to identify whether or not the expected improvements in risk management

justify the additional burdens an option would create for the authorities and the industry actors under REACH.

The analysis of interplay of REACH processes revealed no major deficits which would significantly hamper prioritisation, risk assessment and risk management of chemicals. However, a lack of sufficient information on substance properties and uses was identified as a recurring challenge at all interfaces with the registration process. For some aspects, specific options to improve the interplay were derived.

The lack of sufficient data in registration dossiers on substance properties and the uses of substances could be overcome, amongst others by: an improved technical completeness check which would to a higher degree include the chemical safety report, the revision of data requirements on substance properties and uses or the introduction of a new, slim process to request missing data from registrants, similar to the substance evaluation process, but less formalised and would also cover use information. Additionally, further possibilities to close the gap on use information include improved guidance documents on how use information should be provided in registration dossiers, by focussing more on the chemical safety report during dossier evaluation, introducing a notification requirement for (specific) uses of (specific) substances or an enhanced implementation of REACH Article 34. The options have different implications on the burdens and costs for the various actors as well as the possible benefits that could be achieved through the availability of better data. These costs and benefits were not evaluated during the study.

In the recent years, ECHA and the member states have discussed the delineation between dossier and substance evaluation. Amongst others, it was revealed that there are three options, on how the evaluation processes could be conducted efficiently: the substance evaluation starts after the dossier evaluation (if it is necessary or if data from the dossier evaluation are needed to decide on the need of a substance evaluation), all information needs are covered by a substance evaluation (this would require clarification/adaption of whether or not standard data may be requested during a substance evaluation (which would implement the rules of the dossier evaluation)) or the simultaneous implementation of both processes (COMBO approach).

The interfaces between authorisation and restriction are legally defined which ensures that generally no gaps or overlaps exist in their implementation. However, on gap exists regarding the entry into force of a restriction on SVHCs in (imported) articles complementing an authorisation requirement. If ECHA was able assess the need for a respective restriction and start dossier preparation earlier, the time gap between entry into force of the authorisation and the (potentially needed) restriction could be closed.

A core issue in the interplay of REACH processes which does not evolve from the analysis of individual interfaces between processes is the question on how to identify the most relevant substances (prioritisation), ensure coverage of all possible risks (efficacy) with a minimum of burdens for all actors (efficiency) in the overall regulatory process. ECHA's Integrated Regulatory Strategy (ECHA 2019) illustrates the possible pathways a substance could take from the selection of substances for regulatory action until the implementation of the most appropriate regulation, and lists the criteria guiding the respective decision making. The Integrated Regulatory Strategy seems to be a good approach to identify chemical risks but a subsequent (political) step appears to be necessary, which would identify those risks which should be reduced as a priority.

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 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.

Dieses Teilprojekt soll Defizite im Zusammenspiel der REACH-Prozesse Registrierung, Bewertung, Zulassung und Beschränkung identifizieren, um mögliche Hindernisse für die effiziente Erreichung des REACH-Ziels, ein hohes Schutzniveaus für Mensch und Umwelt, aufzuzeigen. Jeder „Aspekt“, der das Erreichen eines hohes Schutzniveaus erschwert oder verhindert, indem die Bewertung oder das Managements von Risiken weniger effektiv und effizient umgesetzt werden können, als dies prinzipiell möglich wäre, wird als „Defizit im Zusammenspiel“ angesehen. Praktisch entstehen Defizite durch eine mangelnde Informationsverfügbarkeit oder eine inadäquate Koordinierung von Aktivitäten. Beides kann unterschiedliche Gründe haben, wie z. B. Vorgaben im REACH-Text, eine unzureichende Kommunikation und Kooperation der Akteure oder fehlende Leitlinien oder Methoden. Direkten Folgen dieser Defizite wären z. B. das Übersehen von Risiken, Verzögerungen in Bewertungs- und Managementprozessen oder ein hoher Bearbeitungsaufwand.

Für die Analyse der Schnittstellen wurde für jeden REACH-Prozess eine Tabelle angelegt, in der jeder weitere Prozess als Zeile aufgeführt ist. Da bei jeder Station unterschiedliche Akteure beteiligt sind, wurde der Zulassungsprozess in seine Teilschritte unterteilt: „Identifizierung besonders besorgniserregender Stoffe (SVHC)“, „Aufnahme von SVHCs in den Anhang XIV“, „Erstellung von Zulassungsanträgen“, „Stellungnahmen über Zulassungsanträge“ und „Entscheidung über Zulassungen“,. In ähnlicher Weise wurde der Beschränkungsprozess in die Schritte „Erstellung eines Vorschlages“, „Stellungnahme“ und „Entscheidung“ unterteilt. Für jede der so definierten Schnittstellen wurde in den Tabellen beschrieben:

- Wie der REACH-Text das Zusammenspiel intendiert und, wo dies nicht explizit gesetzlich definiert ist, wie die Schnittstelle für ein reibungsloses Vorgehen funktionieren müsste.
- Welche Instrumente (kürzlich) eingeführt wurden, um das Zusammenspiel der Prozesse an der jeweiligen Schnittstelle zu verbessern, z. B. zusätzliche Gesetze, Aktualisierungen von Leitlinien, Veröffentlichung von Vorlagen, Konsultationen etc.
- Beobachtungen über Defizite an den Schnittstellen (s.o.).
- Ideen, wie die beobachteten Defizite behoben werden könnten.

Es ist zu beachten, dass die Verbesserungsoptionen nur aus der Sicht einer möglichen Behebung von Defiziten entwickelt und die mit einer Option verbundenen Kosten und Nutzen nicht

bewertet wurden. Im Fall, dass eine der Optionen für weitere Aktivitäten vorgesehen wird, sollten Kosten-Nutzen-Bewertungen durchgeführt werden, um zu prüfen, ob die erwarteten Nutzen durch ein verbessertes Risikomanagement die möglichen Kosten/den Aufwand für Industrie und Behörden rechtfertigen.

Insgesamt hat die Analyse des Zusammenspiels der REACH-Prozesse gezeigt, dass es keine größeren Defizite gibt, die die Priorisierung, Risikobewertung und das Risikomanagement von Chemikalien wesentlich verhindern. Allerdings wurde z.B. der Mangel an ausreichenden Informationen über Stoffeigenschaften und Verwendungen als wiederkehrende Schwierigkeit an allen Schnittstellen mit dem Registrierungsprozess identifiziert. Für einige Aspekte wurden spezifische Verbesserungsmöglichkeiten für das Zusammenspiel gefunden:

Der Mangel an ausreichenden Daten in den Registrierungsdossier sowohl über die Eigenschaften von Stoffen als auch über deren Verwendungen könnte z. B. behoben werden durch: eine verbesserte technische Vollständigkeitsprüfung, die auch den stärker Stoffsicherheitsbericht einbezieht, eine Überarbeitung der Datenanforderungen für Stoffeigenschaften und Verwendungen oder die Einführung eines neuen, schlanken Verfahrens, um gezielt fehlende Informationen von den Registranten einzufordern, ähnlich wie in der Stoffbewertung aber weniger formalisiert und Verwendungsinformationen einschließend. Zudem gäbe weitere Möglichkeiten, den Mangel an Verwendungsinformationen zu beheben, u. a. verbesserte Leitfäden zur Angabe von Verwendungen im Registrierungsdossier, Veränderung des Fokus bei der Dossierbewertung auf den Stoffsicherheitsbericht, die Einführung einer Notifizierungspflicht für (bestimmte) Verwendungen von (bestimmten) Stoffen oder eine verstärkte Umsetzung von REACH Artikel 34. Die Optionen haben unterschiedliche Implikationen auf die Belastungen und Kosten der unterschiedlichen Akteure sowie die möglichen Nutzen, die durch die bessere Verfügbarkeit von Daten erzielt werden können. Diese wurden im Rahmen der Studie nicht bewertet.

In den letzten Jahren haben ECHA und die Mitgliedsstaaten die Abgrenzung zwischen Dossier- und Stoffbewertung diskutiert. Dies hat u. a. ergeben, dass es drei Optionen gibt, wie die beiden Bewertungsprozesse effizient durchgeführt werden können: die Stoffbewertung beginnt nach der Dossierbewertung (wenn diese notwendig ist oder Daten aus der Dossierbewertung gebraucht werden, um über die Stoffbewertung zu entscheiden), alle Informationsbedarfe werden über eine Stoffbewertung bearbeitet (dies würde es eine Anpassung/Klärung erfordern, ob Standarddaten in einer Stoffbewertung (unter Einhaltung der Anforderungen der Dossierbewertung) erfragt werden dürfen) oder die parallele Implementierung beider Prozesse (COMBO Ansatz).

Zulassung und Beschränkung haben gesetzlich definierte Schnittstellen, die sicherstellen, dass es keine Lücken oder Überschneidungen bei der Umsetzung der Verfahren gibt. Allerdings wurde könnte das Zusammenspiel bezüglich des Inkrafttretens von Beschränkungen von SVHC in importierten Erzeugnissen, die eine Zulussung ergänzt, verbessert werden. Könnte die ECHA bereits vor dem im Anhang XIV spezifizierten Ablaufdatum eines SVHC prüfen, ob eine Beschränkung in (importierten) Erzeugnissen sinnvoll ist und mit der Erstellung eines Anhang XV-Dossiers früher beginnen, so könnte ggf. die zeitliche Lücke zwischen dem Inkrafttreten der Beschränkung und der Zulassung eines SVHC geschlossen werden.

Eine zentrale Frage zum Zusammenspiel der REACH-Prozesse, die nicht aus der Analyse der einzelnen Schnittstellen hervorgeht, ist, wie im Gesamtprozess die relevantesten Stoffe identifiziert (Priorisierung) und alle möglichen Risiken (Effektivität) mit einem Minimum an Belastungen für alle Akteure (Effizienz) angemessen reguliert werden können. In ECHAs Integrierter Regulatorischer Strategie (ECHA 2019) werden mögliche Wege von der Auswahl

regulierungsbedürftiger Stoffe bis zur Durchführung der am besten geeigneten Regulation aufgezeigt und die Kriterien aufgeführt, die diesen Weg leiten. Die Integriert Regulatorische Strategie erscheint ein guter Ansatz zur Identifizierung von Chemikalienrisiken zu sein, jedoch müsste sich hieran noch ein (politischer) Schritt zur Entscheidung anschließen, welche der identifizierten Risiken prioritär gemindert werden müssen.

1 Introduction

Among the aims of the REACH legislation is to ensure a **high level of protection of human health and the environment**. The main instruments by which this should be achieved are the REACH processes of registration, evaluation, authorisation and restriction. The current report focuses on the activities conducted by the authorities under REACH and does not include the activities by industry, such as the communication of conditions of safe use along the supply chain and the communication on SVHCs in articles.

The objectives of registration and the evaluation processes are to develop a sound information basis for risk assessments and risk management activities. The objectives of the authorisation and the restriction process are to enable the authorities to control and at best eliminate unacceptable risks, which they identify from generic or specific risk assessments.

The REACH processes should complement each other in achieving a high level of protection in an effective and efficient way. They are linked by the information flows / knowledge about substances as well as the actors involved in the assessment and management of risks. It is assumed that improvements in the linkage between the REACH mechanisms would result in improvements in the effectiveness and efficiency of achieving a high level of protection.

Further aims of REACH include the **increase of competitiveness and innovation** of the EU industries and the prevention of unnecessary animal testing. Despite all REACH goals being at an equal footing, the current report evaluates the deficits of the interplay of processes mainly from the perspective of improving human health and the environment.

The aim of this sub-study is to identify deficits in the interplay of REACH processes and options to increase the level of environmental and human health protection from chemicals in a (more) resource-efficient and effective way. The study complements the other sub-studies of the project, which analyse the effectiveness and efficiency of the processes as such and in more detail. Consequently, aspects of whether or not individual REACH processes as such work well may also influence the processes interfaces but have not been analysed in detail in this report.

In this sub-study the goal of REACH is assumed to be an 'optimal risk management process'. Such 'optimal risk management' is understood as a process where:

- Sufficient data are gathered to identify all relevant potential risks; i.e. not necessarily only those which give rise to the highest concern and hence are the reason to implement a risk management measure, but also those related to other hazards[1] and which may be considered, as well.
- Data are gathered and assessed in the manner that is most efficient to reach the protection goals. This implies that the resource needs of the authorities and the industry actors are as low as possible. However, the analysis of this study focuses on the resource input of the, authorities (Commission (COM), European Chemicals Agency (ECHA) and Member States (MS)).

[1] The scope of risk assessments may have consequences for a) the design of risk management measures and b) for any socio-economic assessments supporting the decision making on whether or not a measure should be implemented. If the exposure pathways for different effects are different, the risk management strategy for one hazard may not cover the other. If hazards and risks are not assessed and integrated in SEAs, the benefits of taking a measure may be (significantly) underestimated. This may particularly be the case for environmental risks that are not normally considered in authorisation processes related a CMR concern.

- The most appropriate risk management measure is selected, i.e. that measure, where the balance between implementation costs and achievable benefit in terms of risk control is best, with the minimum of adequate risk control being implemented.

Consequently, anything that hinders an optimal risk management process is considered a deficit in the interplay of processes.

The focus of the analysis is set onto the interplay of substance evaluation, dossier evaluation, authorisation, and restriction and the generation and use of data via the registration process.

The following research questions guided the assessment:

- At which links between REACH processes is an optimal risk management aggravated, delayed or impeded? Where does the interplay function well?
- How can the deficits in the interplay be overcome?
- How can links between substance evaluation and dossier evaluation as well as the limitation of uses by authorisations and restrictions be optimised?
- What opportunities are there to extend the data generation by linking it to other chemicals assessment and management processes?

2 Methodology

The current study is based on the outcomes of the sub-projects conducted under the project 'Advancing REACH' and compiles learnings and expertise from the involved experts.

The interfaces between each of the (steps of the) REACH processes to be analysed are presented in table form. Each table relates to one specific process or process step. It is filled analysing the influence of all the other processes and process steps onto that particular process, by proving one separate row per process / process step. The reversed 'direction' of how the addressed process influences the other processes is NOT covered in that table. The template of the tables is provided below for further explanation.

The tables were completed based on the understanding that each process should contribute to the goals of REACH, in particular to achieving a high level of protection of human health and the environment.

Table 1: Explanation of tables to describe interfaces between processes

Impacting process	Impact of … on the process, e.g. authorisation	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Name of process (step)	Description how the process in the 1st column (left) should influence the addressed process (here: authorisation) The description is either based on the legal provisions or logically derived considering the needs of implementing a risk assessment or risk management process	Any formal or information procedure or tool, such as templates, consultations, guidance or legislation that improve the interplay between processes	Observations from the project team and the authorities participating in the sub-project on deficits	Ideas how the deficits could be overcome/improved These ideas have neither been defined in detail nor been assessed regarding their costs and benefits.

The tables were completed by the consultant team of the project and further input was provided by the representatives of the involved German authorities[2]. The tables were then evaluated and summarised. The indicated improvement options were slightly further developed to make them more understandable for further discussion.

It is sometimes challenging to decide whether an observed shortcoming is an 'interface issue' or a challenge that occurs 'within a process'. For example, are delays caused by the need to generate hazard data via SEvs inherent to the SEv process. These delays may affect decision making in another processes and hence also concern the processes' interfaces.

For the purpose of the detailed assessment, the authorisation process was separated into distinct steps to better analyse the information flows within the process. As several documents are being prepared and various actors are involved at each step this separation is considered useful. However, this created interfaces within the overall process, which could also be regarded as challenges that are inherent to the authorisation as such.

[2] German Environment Agency (UBA), German Ministry of the Environment (BMU), Federal Office for Chemicals (BfC), Federal Institute for Occupational Health and Safety (BAuA), Federal Institute for Risk assessment (BfR)

As a pragmatic approach and as the identification of deficits may be helpful in the overall project context, the interfaces between the various steps of authorisation and restriction were described separately in the tables.

No literature review was performed to gather further information on the interplay of processes. Hence, the analysis is based on the experience and expert judgement of the involved consultants and authorities.

3 Overview on the interplay of REACH processes

In this chapter the interplay of the four REACH processes is described in table form. For each process, and partly individual steps of that process, one table has been created. The details of the individual processes are not described in the report but it is anticipated that the reader is informed of the legal basis and the implementation of the processes. If any of these procedures are not fully known, ECHA's webpage should be consulted for general information[3], or the reports of the sub-studies performed during the project for further details.

The following REACH processes (and some of their individual steps) are covered:

a) **Registration**
Submission of registration data by the registrants via the REACH IT

b) **Dossier Evaluation** (DEv)

b.1 **Completeness Check** (TCC)[4]
Ascertain that all elements mentioned in Art. 20(2) have been provided by the registrant followed by the granting of a registration number (ECHA).
Although the TCC is formally not part of the DEv according to Title VI of REACH, it is included here due to its close relation to the dossier evaluation process.

b.2 **Compliance Check** (CCH)
Ascertain that all elements mentioned in Art. 20(2) have been provided by the registrant and assessment of compliance of the registration dossiers, including assessment of testing proposals (ECHA). Compared to the TCC, the data quality and adequacy are more thoroughly assessed in the scope of a CCH.

c) **Substance Evaluation** (SEv)
Targeted assessment of suspected risks by a Member State Competent Authority (MS CA) and whether or not additional data are needed to prove or disprove the initial concern.

d) **Identification of substances of very high concern** (SVHC)
Demonstration that at least one of the criteria of REACH Art. 57 is fulfilled in an Annex XV dossier (MS CA, ECHA).

e) **Authorisation**

e.1 **Inclusion in Annex XIV**
Assessment of SVHC according to ECHA's prioritisation criteria/process and proposal for Annex XIV (ECHA); decision making on Annex XIV inclusion (COM with MSs).

e.2 **Application for Authorisation** (AfA)
Development of an application for authorisation for substances included in Annex XIV (Industry).

e.3 **Opinion forming on AfAs**
Assessment of AfAs by the Committee for Socio-Economic Analyses (SEAC) and the Risk Assessment Committee (RAC) and development of an opinion on the arguments provided by the applicants (ECHA).

[3] www.echa.europa.eu

[4] The completeness check is an assessment of whether meaningful information is included in a IUCLID field and hence a step in the acceptance of registration dossiers and allowing market entry via the registration number. The completeness check is separately included in the first table but covered under the row "dossier evaluation" in the following ones.

e.4 Decision making on AfAs
Assessment of AfA, SEAC and RAC opinions and decision making on whether or not an authorisation should be granted (COM with MSs).

f) **Restrictions**

f.1 Drafting a restriction proposal
Development of an argumentation demonstrating unacceptable risks from one or several uses of a substance that require Community wide action and proposal of specific measures to manage the risk in form of a restriction dossier (MS CA or ECHA an request of COM).

f.2 Restriction: opinion forming
Assessment of restriction proposals and opinion forming by RAC and SEAC (ECHA).

f.3 Restriction: decision making
Assessment of the restriction proposal and SEAC/RAC opinions and decision making on a restriction (COM, MS).

3.1 Interplay with registration

The registration dossiers are the information basis of all risk assessment and risk management processes under REACH. However, the obligation to keep registration dossiers up to date require that new information from any information source inside and outside REACH is reflected and included, where relevant. Hence, the main influence from other processes onto the registration process and registration dossiers is mediated via the updating requirement.

A large number of actions were implemented to support the generation of high quality registration dossiers, including the development of extensive guidance documents, the establishment of the REACH helpdesk(s) or the publication of evaluation reports indicating core challenges in the data provision. Recently, an implementing act was adopted to clarify the timelines of and obligations for dossier updates.

Table 2: Impacts of different REACH processes on the registration of substances

Impacting process	Impact of … on the registration process Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Completeness Check[5]	The CC ensures that chemicals can only access the market if registrants provide meaningful information on all data requirements ('no data-no market').	ECHA has enhanced the technical completeness check (TCC) procedure twice[6] in the last years. In addition to the TCC-plugin the registrants should now be aware that manual verification of the data entries might occur.	The backlog of the manifestly incomplete dossiers appears to be still relevant. The attempts to withdraw the registration number in these cases are still pending.	Establish an internal routine (based on – automated - deficit criteria) to detect incomplete dossier (ECHA). Establish an internal routine to withdraw the registration number (based on the 'acquis communautaire'[7]) (ECHA). Introduce an explicit legal provision clarifying the competence of ECHA to withdraw the registration number (EU legislator) at a later stage. Enhance transparency and awareness among registrants on the new manual verification and its outcome (regular

[5] The Completeness Check is included in this table because of its high relevance for the data quality in registration dossiers. In the following tables the CCH is included in the row on dossier evaluation.

[6] A further revision of the TCC concerning the CSR was postponed.

[7] Cf. UBA Texte 207/2020, section 6.2.5.1.

Impacting process	Impact of … on the registration process Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
				reports by ECHA) and a dissemination strategy in this respect.
Dossier evaluation	Ensures quality of the registration information by requesting improvements in case of non-compliance. • Substance identity • Standard information required for the tonnage band (Annexes VII - X) • Risk assessment (chemical safety report (CSR)) • Specific risk management measures to ensure safe use	ECHA is committed to checking the compliance of 20% of the registration dossiers rather than 5%. COM proposed legislation to clarify requirements in Annex VII to X[8]; further changes may be proposed. The Board of Appeal's (BoA) decision making clarifies ambiguous requirements and competences, thus preventing repeated disputes over data requirements.	• A different understanding on the use of data waving and read across between registrants and authorities causes incompliant dossiers and/or unnecessary disputes between ECHA and the registrants and/or between authorities. • The industry frequently delays the DEv by responding to ECHA's data claims at the very end of the deadlines and/or using all opportunities to extend them. • ECHA decisions are partly appealed at the BoA; decision making of BoA delays dossier update. • The focus of the evaluation is on hazard data, not data on the uses. Therefore, the registrant's conclusions on risks remain vague.	• Improve and increase the evaluation of the CSR, including DNELs and exposure scenarios, not only in the TCC, but also in the (manual) CCH itself. • Analysing examples of rapid delivery of data and main reasons for long delays. • Revision of guidance documents on information requirements to clarify any diverging interpretations on the nature of data and options to provide it, including based on learnings from BoA assessments. • Assessment of adequacy of the timelines for testing/data provision as well as whether or not simultaneous testing would be useful to accelerate the process. • Assessment of the impacts and feasibility of changes in data requirements introduced only through updates to guidance. • Toxicology Dashboard WikiREACH[9] acts as a catalyst to (1) enable ECHA to initiate (eco)toxicological studies by academic research laboratories, (2) raise awareness among academic

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM:Ares(2020)5643171

[9] Cf. UBA Texte 207/2020 section 6.2.2.

Impacting process	Impact of … on the registration process Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
				researchers on the prerequisites for the relevance of their studies for regulatory processes and (3) leverage relevant substance data from academic research for the purpose of registration.[10] • Increased transparency as to (1) which parts of a dossier ECHA has addressed in a CCH and what has been the outcome of the CCH and as to (2) the identities of registrants failing CCH or completeness check.[11] • Avoid delay in updating of registration dossiers due to appeals to BoA by modifying the procedural framework for BoA. [12]
Dossier evaluation (Testing Proposal Examination)	Testing proposals are consulted, examined and decided on, higher-tier data is contributed to the registration dossier while avoiding unnecessary and unsuitable tests from being conducted.		• Little input from third parties on existing data (e.g. from academia) → consultation not effective. • ECHA sometimes disagrees with the industry on the validity of data from alternative test methods, which may contradict the REACH aim of preventing animal tests.	• Clarification of consultation scope, e.g. by more targeted questions. • Analyse if the full examination of testing proposals should continue or if it could be replaced by a less resource intensive procedure without the loss of the protection level.[13]

[10] Cf. UBA Texte 207/2020, section 6.2.2.

[11] Cf. UBA Texte 207/2020, section 6.2.3. and 6.2.5.2.

[12] Cf. sub-study on the Board of Appeal (not yet finalised). Agerstrand et al., DOI: 10.1039/c7em00422b and the Annex to the "Chemicals Strategy for Sustainability", COM(2020) 667 final mentioning the measure "Establishment of an open platform on chemical safety data and tools for accessing relevant academic data" due for 2023.

[13] Depending on the assessment result, a change in the requirements on evaluating testing proposals might be necessary

Impacting process	Impact of … on the registration process Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
				• Avoid delay in updating of registration dossiers due to appeals to BoA.[14]
Dossier evaluation (Testing Proposal Examination)	Testing proposals are consulted, examined and decided on, higher-tier data is contributed to the registration dossier while avoiding unnecessary and unsuitable tests from being conducted.		• Little input from third parties on existing data (e.g. from academia) → consultation not effective. • ECHA sometimes disagrees with the industry on the validity of data from alternative test methods, which may contradict the REACH aim of preventing animal tests.	• Clarification of consultation scope, e.g. by more targeted questions. • Analyse if the full examination of testing proposals should continue or if it could be replaced by a less resource intensive procedure without the loss of the protection level.[15] • Avoid delay in updating of registration dossiers due to appeals to BoA.[16]
Substance evaluation	For substances subject to SEv, registrants should particularly reflect the information in their registration dossier relating to the initial concern prior to or early in the SEv process. Registrants should include additional (non-standard) information due to SEv decision into their dossiers (i.e. registration update).	Repeated advice from ECHA to registrants to update registration dossiers of substances that are subject to SEv (irrespective of whether a SEv decision is issued or not).	• Registration dossiers are of low quality and registrants sometimes update them late in the SEv process. • SEv may improve dossier quality through formal and informal interaction, but this depends very much on the stance taken by registrants. • Long duration of SEv delays registration dossier updates with the requested information. • ECHA decisions are partly appealed and decision making of	• Even more focused advice or else a change to the legal text preventing late dossier updates during SEv, i.e. obligation for the registrants to review the state of science regarding the initial concern and potentially update the registration dossiers with that information after a substance is included in the CoRAP. • Implementation of sanctions in case of non-delivery of (appropriate) data; e.g. withdrawal of registration number or penalties at MS level. • Require registrants to indicate ongoing SEvs in the SDS and to communicate

[14] Cf. sub-study on the Board of Appeal (not yet finalised)

[15] Depending on the assessment result, a change in the requirements on evaluating testing proposals might be necessary

[16] Cf. sub-study on the Board of Appeal (not yet finalised)

Impacting process	Impact of … on the registration process Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
			the BoA delays SEv conclusion and dossier updates.	RMMs needed if the assumed risk is verified as long as the decision is pending. • Avoid delay in updating of registration dossiers due to appeals to BoA [17]
SVHC Identification	Registrants should update hazard information in their registrations if new information becomes available and/or in order to indicate an identified SVHC property in their dossier.	Implementing act specifies term 'without undue delay' and clarifies timelines for dossier updates (upcoming implementing regulation)[18].	• It is assumed that registrants do not always update their PBT-assessments and related sections of the registration dossier after an SVHC identification. • It is unclear if registrants of substances containing (newly identified) SVHCs (PBTs/vPvBs and others) identify their substance as PBT/vPvBs or consider this in their classification.	• Monitor impact of COM implementing regulation on dossier updates (studies, SVHC properties etc.); consider additional measures if insufficient. • Clarify in the REACH guidance documents how PBT/vPvBs and other SVHCs 'in substances' influence that substance's hazard and classification and how to update registrations after SVHC identification of a substance's constituent.
SVHC Identification	Registrants should assess and update the information on uses of SVHCs to facilitate decision-making on a future authorisation. Registrants should reassess uses after SVHC identification and advise against uses where risks are not controlled and/or update the safe conditions of use.	The RMOA-process (assessment of the possible risk management measures and choice of the most appropriate measure) was made more prominent and transparent in order to potentially trigger dossier updates by registrants providing more information on uses and exposure.	• Information on uses and on the conditions of safe use is often not updated after substances are identified as SVHC. • Lack of early MS consultation with downstream supply chain as part of RMOA to establish what regulatory measures are in place and what measures could readily be adopted.	• Update guidance on information requirements (and IUCLID) to further specify and detail information requirements on uses. • Review the REACH text or related guidance to require more specific use information and a dossier update regarding information on uses after SVHC identification.

[17] Cf. sub-study on the Board of Appeal (not yet finalised)

[18] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L .2020.331.01.0024.01.ENG&toc=OJ:L:2020:331:TOC

Impacting process	Impact of … on the registration process Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Annex XIV Inclusion	Registrants should reassess their uses and advise against if risks are not properly controlled after Annex XIV inclusion.	Implementing act specifies term 'without undue delay' and clarifies timelines for dossier updates (implementing regulation)[19].	• It is unclear if registrants reassess uses and advise against unsafe ones. • Registrants assume unrealistic use tonnages to identify safe uses when compiling and updating their registration dossiers.	• Include a requirement in the REACH text to advise against uses in the registration dossier and in the SDSs (adaptation REACH Annex II), unless an authorisation is granted or uses are exempted.
AfA	Registrants should update information on uses, exposures and/or risk management measures according to the assessments in their AfAs or in the AfAs of their customers if these are published (new information).		• The AfAs reveal that the real uses are not always covered by the registration dossiers. • It is unclear if AfA information is included in registration updates[20]	• Monitor impact of COM implementing regulation on the requirements to update registrations; consider additional measures if insufficient. • Implement (automatic) checks that AfA information on uses is included in registration dossiers e.g. more specific CSRs.
Opinion on AfAs	Registrants update information on uses, exposures and/or risk management measures if an opinion is published		• It is unclear if information in the opinions is included in registration updates as 'new information'.	• Monitor impact of COM implementing regulation on requirement to update registrations; consider additional measures if insufficient.
Decision on AfAs	If authorisation for a specific use is denied, use information in the registration dossier should be updated; i.e. not an intended use anymore but a use advised against.		• It is unclear if registration information on uses are updated with uses advised against if authorisation is denied.	• Monitor impact of COM implementing regulation on requirement to update registrations; consider additional measures if insufficient. • Include a requirement in the REACH text to advise against uses in the

[19]https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2020.331.01.0024.01.ENG&toc=OJ:L:2020:331:TOC

[20] Uses discovered in the development of an AfA which are not identified in the registration dossier are 'new information' and should trigger an update of the registration dossier with undue delay. From the economic perspective, updating the registration dossier during the AfA development and before the COM decides may be contested because, depending on the outcome of the COM's decision, another update of the registration may be unnecessary or a deletion of non-authorised uses.

Impacting process	Impact of … on the registration process Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
				registration dossier and in the SDSs (adaptation REACH Annex II), unless an authorisation is granted or uses are exempted.
Decision on AfAs	Conditions of use in granted authorisations should be incorporated in CSRs and only uses identified for which an authorisation exists or which are exempted from authorisation (dossier updates).		• It is unclear if updating takes place.	• Monitor impact of COM implementing regulation on requirement to update registrations; consider additional measures if insufficient.
Restriction proposal (RP)	Registrants should update their dossiers with more precise use information when an intention to restrict a substance is published.	The RMOA should help identify the best regulatory measure and understand the main impacts before a formal process starts.	• The information on the life cycle is often too vague to support impact assessment of a proposed restriction.	• Monitor impact of COM implementing regulation on requirement to update registrations; consider additional measures if insufficient.
Restriction proposal	Registrants update their dossiers if the Annex XV dossier includes new information.		• It is assumed that no updates take place before the final decision is taken.	• Monitor impact of COM implementing regulation on requirement to update registrations; consider additional measures if insufficient. • Require registrants to update their registration dossier after the intention to draft a restriction proposal is announced in the PACT or ROI.
Opinion on RP	No impact			
Decision on RP	Registrants should update their dossiers by adapting/excluding the intended uses.		• Unclear if registration dossiers are updated and restricted uses are advised against or excluded.	• Monitor impact of COM implementing regulation on requirement to update registrations; consider additional measures if insufficient.

3.2 Interplay with dossier evaluation

The dossier evaluation is only influenced by the registration process; i.e. the initial dossier quality determines the resource needs to achieve a certain level of confidence in the data. The processes of substance evaluation, authorisation and restriction do not have an influence on the dossier evaluation process.

Table 3: Impacts of different REACH processes on the dossier evaluation

Impacting process	Impact of … on dossier evaluation Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Registration	The quality of registration dossiers determines the resource needs for dossier evaluation (assessing information and requesting updates in case of non-compliance).	The implementing act specifies the term 'without undue delay' and clarifies timelines for dossier updates[21] COM proposed a first legislation to clarify requirements in Annex VII to XI[22]	• The incorrect description of SIDs and the partly insufficient quality of dossiers create significant workloads for ECHA. • Different understanding of data waving and read-across between registrants and ECHA may cause extra work and potential delays in decision making.	• Monitor impact of new regulations on dossier quality; review related guidance and update if necessary; consider additional measures on updating if the existing ones are not sufficient. • Analyse main reasons for insufficient descriptions of the SID and develop instruments to improve this. SID checks should take place before the registration number is granted. • Apply the enhanced completeness check in the updating process.
Substance evaluation	In most cases, first a CCH is done by which standard information is requested and then an SEv may take place. In the exceptional cases where an SEv precedes a CCH,	ECHA implements a screening process to identify data gaps and priorities for clarifying concerns of registered substances. Integrated Regulatory Strategy (IRS) and other ECHA/COM initiatives	• In many cases, SEVs are started only after a CCH has taken place, but this may not always be the quickest and most efficient option to get the necessary hazard information.	• MS could address standard information request under SEv, i.e. there would be no need to have a separate CCH. • Decide on the best evaluation instrument and/or the sequence of SEv and DEv on a case-by-case basis.

[21] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2020.331.01.0024.01.ENG&toc=OJ:L:2020:331:TOC

[22] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM:Ares(2020)5643171

Impacting process	Impact of … on dossier evaluation Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
	the evaluated endpoints could be omitted in the latter.	('Joint Action Plan') expected to resolve problems in the interplay.	• Partly insufficient communication between ECHA and MSCAs in parallel assessment processes resulted in conflicts and inefficiency. • Delays and inefficient evaluation due to the need for several subsequent decisions.	• Consider combining SEv and DEv (COMBO approach) • Improve communication between ECHA and MSCAs in case of (partly) parallel evaluation processes.
SVHC Identification	ECHA could consider de-prioritisation of identified SVHC if they are regarded as sufficiently regulated. SVHC identification may trigger CCH if they reveal data gaps for other endpoints.		• Frequently, SVHCs are identified based on already evaluated registration dossiers.	
Annex XIV Inclusion	ECHA could consider de-prioritisation of substances subject to authorisation			
AfA	No impacts			
Opinion on AfA	No impacts			
Decision on AfA	No impacts			
Restriction proposal	No impacts			
Opinion on RP	No impacts			
Decision on RP	ECHA could consider de-prioritisation of substances subject to restrictions			

3.3 Interplay with substance evaluation

The substance evaluation is an instrument to generate data that is necessary to assess a risk. It involves the assessment of registration dossiers and other relevant information and frequently leads to (non-standard) information requests from the ECHA to the registrants. The scope and content of the substance evaluation is largely determined by the information availability and quality of the registration dossiers. As the process is intended to clarify the need for further risk management, an influence of other processes on the SEv is rather low, with the exception of the DEv.

Table 4: Impacts of different REACH processes on substance evaluation

Impacting process	Impacts of … on substance evaluation Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Registration	Registration information is the basis to prioritise substances for evaluation and defining the initial concern.[23] The quality of the registration dossier has an impact on the efficiency and effectiveness of the SEv process	ECHA implements a screening process to identify data gaps and priorities for clarifying concerns of registered substances. The quality of registration dossiers should be improved by implementing regulations on dossier updates and clarification of information requirements by the pending revision of REACH Annexes VII-X.	• The current information requirements are not always sufficient to identify substances for which a concern can be established. This regards hazard data, in particular about PBT/vPvB, endocrine disruption (ED) or carcinogenicity, mutagenicity and reprotoxicity (CMR), where registrants only seldom generate further information on a voluntary basis. It also concerns the CSR which may not clearly point out potential risks or uses/use amounts that could give rise to a prioritisation. • Depending on tonnage, registration information is	• Monitor impact of COM implementing regulation on updating dossiers. • Require registrants to further assess a potential concern upon indications in the required standard data, even beyond the required information in the applicable REACH Annex. • Review information from prior assessments on the opportunities to increase (certain) information requirements, including for low volume substances, to enable a better initial assessment of crucial SVHC endpoints at least at screening level[25]; adapt the REACH annexes accordingly. • Check dossier quality during screening and define most adequate instrument in the context of IRS (e.g. do not perform SEv on poor quality dossiers)

[23] Also other information is used in the prioritisation process.

[25] Obviously additional data requirements would cause additional costs to industries and such adaptations to the Annexes would require assessing which types of information would be useful and justifiable. It may be an option to develop tiered requirements and/or to prioritise certain data which allow better initial screening to limit the industries' efforts.

Impacting process	Impacts of … on substance evaluation Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
			incomplete in order to define the initial concern. It is unclear if risks and SVHC hazards are overlooked.[24] • Low dossier quality may require lengthy and extensive evaluation processes that could be more efficient if data were better in the first place.	
Dossier evaluation	Standard information requirements, which are the basis for the SEv should be quality assured. No compliance issues would have to be raised in the SEv. A full CCH is expected to increase the efficiency of the (subsequent) SEv process.	Integrated Regulatory Strategy (IRS) and other ECHA/COM initiatives ('Joint Action Plan') expected to resolve problems in the interplay.	• In many cases, but not always, SEvs are started after completion of a CCH. • Miscommunication between ECHA and the MSCAs in parallel evaluation processes has given rise to conflicts and inefficiencies in the past. • A CCH prior to every SEv may not necessarily be better, as it takes a long time to complete both processes. The need for resources may reduce the overall number of substances evaluated by CCH and SEv.	• Apply the enhanced completeness check before starting the SEv. • Decide on the right instrument on a case-by-case basis on the best sequence of the evaluation processes. • Improve communication between ECHA and MSCAs in case of (partly) parallel evaluation processes.

[24] In the negotiations about REACH, the legislators decided to use the registration volume as a proxy for the expected risks and therefore as a suitable trigger of registration requirements regarding hazard data. Whether or not this initial assumption leads to risks being overlooked is unclear as yet. In any case it causes difficulties in identifying substances of concern because basic indicators of hazards are not available for low volume substances. Additionally, the decision not to require extensive information for low volume substances should prevent that substances are not registered and hence withdrawn from the market merely due to economic reasons.

Impacting process	Impacts of … on substance evaluation Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
SVHC Identification	Information gaps in preparing a dossier for SVHC identification may trigger a substance evaluation.			
Annex XIV Inclusion	No impact			
AfA	No impact			
Opinion on AfA	No impact			
Decision on AfA	No impact			
Restriction proposal	Information gaps in preparing a restriction proposal may trigger a substance evaluation.			
Opinion on RP	No impact			
Decision on RP	No impact			

3.4 Interplay with SVHC Identification

To identify SVHCs on the candidate list for authorisation, the respective properties of a substance are assessed and documented. The information collection is based on the registration dossier and further information sources and, where necessary, may trigger evaluation processes to enable (further) data requests to the registrants. Consequently, the registration data determine the efforts for SVHC identification and the evaluation processes support it. Other REACH processes have no impact on the SVHC identification.

Table 5: Impacts of different REACH processes on the identification of SVHCs

Impacting process	Impacts of … on SVHC identification Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Registration	Registration dossiers should contain basic and key information to assess the SVHC criteria. Registrants should make a PBT/vPvB assessment and/or classify CMRs allowing selecting these directly for SVHC identification processes.	Integrated regulatory strategy and substance screening.	• Data to identify potential SVHCs are partly missing in registration dossiers, e.g. for substances in volumes of 1-100 t/a (Annexes VII and VIII not required) or because information has been (inappropriately) waived or derived by read-across (Annex XI)[26]. • Substances exempted from REACH or from registration (e.g. volume < 1 t/a) cannot be included in any screening of ECHA, i.e. no indications that they could be SVHC. • Registrants' PBT/vPvB assessments may come to different conclusions than the authorities. • Registrants have no interest in highlighting SVHC properties (e.g. PBT). Therefore, known PBT/vPvBs are not assessed as such in the registration dossiers.	• Review information (from studies) on the opportunities to increase information requirements, including for low volume substances to enable an assessment of the SVHC endpoints at least at screening level and adapt the REACH annexes accordingly[27]. • Develop legislation on polymers (as ongoing) and ensure that polymers that could have SVHC properties are covered by a future registration requirement. • Provide better guidance and hold training sessions for registrants on how to assess SVHC properties in substance registrations. • Assess options to reverse the burden of proof in the REACH text for substances, which fulfil certain information triggers (e.g. regarding persistence): such substances should be automatically flagged as 'potential SVHCs' unless the registrants prove

[26] The volume-based registration requirements were agreed among the legislators during the REACH negotiations and may be reviewed in the light of challenges to prioritise substances for risk management measures. The possibilities to waive data requirements are generally justified and, amongst others, serve the purpose of preventing unnecessary animal testing and reducing burdens. However, ECHA still reports the application of data waiving and read-across as frequently not compliant. Vice versa, industries challenge ECHA's acceptance of their justification. In any case, the data waving and options to use alternative data defined in Annex IX may hinder the identification of SVHC properties and/or the prioritisation of substances for evaluation and/or risk management.

[27] Obviously additional data requirements would cause additional costs to industries and such adaptations to the Annexes would require assessing which types of information could be justified.

Impacting process	Impacts of … on SVHC identification Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
				(with additional data in a tiered process) that this is not the case.[28]
Dossier evaluation	The quality of registration data should be assured, i.e. a sound information basis exists and all compliance issues have been resolved.	ECHA's integrated regulatory strategy and substance screening helps to identify substances for SVHC identification.	• Only required information can be evaluated; for some SVHC endpoints key data may be missing.	• Review available information (from studies) on the opportunities to increase information requirements, including for low volume substances to enable an assessment of the SVHC endpoints at least at screening level and adapt the REACH annexes accordingly.
Substance evaluation	SEvs may trigger SVHC identification if Art. 57 criteria appear to be fulfilled and SVHC identification is considered a good follow-up. If data is missing to identify an SVHC, an SEv can be initiated to request the missing data. To clarify a concern, use information may be gathered in an SEv that could influence whether or not SVHC identification is the best regulatory option.	ECHA's integrated regulatory strategy and substance screening helps to identify substances for SVHC identification.	• Some substances proposed for SVHC identification in SEv could have been identified more efficiently by other means. • Long durations between SEv and the proposal for SVHC identification and actual initiation of this process. • SEvs triggered to clarify an SVHC property may delay the SVHC identification due to the lengthy data generation process.	• Increase speed of SVHC identification after corresponding SEv conclusion, e.g. by requiring either ECHA or the MS to follow-up such SEv conclusions within a certain time frame.
Annex XIV Inclusion	No impact			
AfA	No impact			

[28] This suggestion will cause considerable additional costs for registrants, in particular for low volume substances where higher tier tests are not normally required. Hence, it should be assessed if tiered approaches could be developed to increase knowledge (for some substances with particular properties indicating a potential SVHC concern) at acceptable costs. Depending on the legal consequences of such flagging, the pressure to disprove the SVHC property increases; i.e. if communication in articles would be required also for substances flagged as 'potential SVHC'.

Impacting process	Impacts of … on SVHC identification Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Opinion on AfA	No impact			
Decision on AfA	No impact			
Restriction proposal	No impact.			
Opinion on RP				
Decision on RP	No impact			

3.5 Interplay with Annex XIV inclusion

SVHC on the candidate list may be included in Annex XIV, i.e. subject to authorisation. ECHA applies its prioritisation process based on a set of criteria and the information from registration dossiers. Hence, the SVHC identification determines the scope of this process and the registration information is crucial for the prioritisation. Evaluation processes have an impact via the registration information while the authorisation and restriction processes do not have a relevant impact on the process.

Table 6: Impacts of different REACH processes on the inclusion of SVHCs into Annex XIV

Impacting process	Impacts of … on including SVHCs into Annex XIV Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Registration	Registration information on uses is applied to assess the prioritisation criteria for Annex XIV inclusion, in particular on volumes, uses and exposures.	Formalised prioritisation process based on ECHA's methodology and criteria.	• Registration information on uses is partly insufficient to implement in ECHA's prioritisation criteria. Sometimes only the use patterns are available, which do not always reflect the reality. This may	• Develop options to retrieve use information from the SCIP database and consider it in prioritisation. • Develop legislation requiring downstream users to report their use of an SVHC after its candidate listing,

Impacting process	Impacts of … on <u>including SVHCs into Annex XIV</u> Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
			result in incorrect prioritisation decisions (overestimation and underestimation of potential risks).	in particular for uses not covered by the SCIP. • Reassess ECHA's prioritisation criteria in the light of experiences from the past and check if they could be improved.
Registration	Information on uses should be considered in the conditions of the Annex XIV entry, e.g. sunset date, latest date for application or exemptions.		• Use information is insufficient to support decision making on Annex XIV inclusion.	• Develop options to retrieve use information from the SCIP database. • Develop legislation requiring downstream users to report their use of an SVHC after its candidate listing, in particular for uses not covered by the SCIP.
Dossier evaluation	If the CSR is assessed during the CCH, it will support prioritising of substances for Annex XIV inclusion, as it is then quality assured.	ECHA planning to include the CSR in the TCC.	• The CSR is currently not sufficiently assessed during Dev and it is unclear when this will happen, at least in a basic form as part of the TCC. • Dossier evaluation has little means to improve use information as neither the authorities nor the registrants have good access to DU information on uses.	• Include the CSR evaluation not only in the TCC, but also in the (manual) CCH itself. • Develop options and assess how registrants could be supported in collecting use information from DUs in the scope of a (manual) CCH. This could include changes in the legal text on reporting uses upstream (Art 34) with consideration of potential CBI issues. • Develop and assess an obligation for DUs to report use information to ECHA during a CCH. • Require more detailed information from the registrants on uses during the CCH, including volumes per uses and functions of the substances.

Impacting process	Impacts of … on <u>including SVHCs into Annex XIV</u> Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Substance evaluation	Information from an SEv supports the prioritisation of SVHCs for Annex XIV inclusion, in particular regarding identified risks and/or use and exposure data. Information from SEv may be used in defining the Annex XIV entry, e.g. sunset date, latest date for application (or exemptions).			• Ensure SEv conclusions and other relevant published (use) information is included in the registration dossiers.
SVHC Identification	Only identified SVHCs can be included into Annex XIV.	Considerations under the CSS to develop new hazard categories under the CLP regulation might facilitate the assessment of PBT/vPvB and EDCs in the future (similar to CMR) if classification criteria exist.		
SVHC Identification	Information from the SVHC identification dossier and the consultation support the prioritisation process of the Annex XIV dossier and / or the conditions of the entry in Annex XIV, e.g. sunset date, latest date for application or exemptions **Note**: use information is not requested in the consultation but frequently provided if available to facilitate the further process	Calls for information input clearly define the scope of comments, structured questionnaires.	• Stakeholder expectations of influencing the decision on priority setting for Annex XIV lead to high efforts in responding to the consultation inputs • Consultation on prioritisation proposals should provide use information but fails to do so	
AfA	No impact			

Impacting process	Impacts of … on including SVHCs into Annex XIV Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Opinion on AfA	No impact			
Decision on AfA	No impact			
Restriction proposal	Substances proposed for restriction are postponed from prioritisation to Annex XIV until the restriction process is finalised	The PACT publishes all intentions for regulatory measures early in the process, aimed at preventing double efforts.		• Include an automatic flag/prohibition to initiate parallel regulatory processes for one substance, ensure that this includes the groups a substance is included in.
Opinion on RP	No impact			
Decision on RP	If all uses of a substance are already restricted, they need not be subject to authorisation	RMOA clarifies the regulatory route for a specific substance (SVHC)		

3.6 Interplay with applications for authorisation

SVHCs included in Annex XIV may only be used if an authorisation for that use has been granted. Applicants for authorisation are to compile information to justify an authorisation and provide it to the ECHA for assessment in the Committees and the further decision making process. The drafting of AfAs is based on the registration dossiers and complemented with further, more detailed information on the uses. Hence, the other processes under REACH have a limited influence on the AfA development.

Table 7: Impacts of different REACH processes on applications for authorisation

Impacting process	Impacts of … on applications for authorisation Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Registration	Registrations identify manufactures and importers and thereby support	Manufacturers and importers are published in ECHA's	• Coordination between stakeholders is difficult since	• Enable providing contact details in ECHA's database to facilitate

Impacting process	Impacts of … on <u>applications for authorisation</u> Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
	consortia formation and/or getting access to and support on CSRs and drafting AfAs covering all or just the particular downstream uses.	database; however, without contact persons. Information is partly confidential.	registrants often do not have a strong incentive to prepare AfAs while DU often do not understand the full task and the need for their contribution to such a process.	cooperation between companies on a voluntary basis.
Registration	Registration information should be a good basis of the AfA, including scoping all uses of an SVHC. REACH allows referring to the CSR prepared for registration to describe the risk in an AfA.		• Current practice shows that neither the use description nor the safety assessments are sufficiently detailed for use in the AfA.	• All actions to improve the quality of registration dossiers will help (cf. above). However, additional information is needed.[29]
Dossier evaluation	Standard information in the registration should be quality assured and provide a sound basis for developing AfAs.	ECHA plans including the CSR in the TCC but it is unclear, when this will actually take place.	• Only available information can be quality assured; if more detail is needed and/or uses are missing/incorrectly described, the CCH is not of much help.	• All actions to improve the quality of registration dossiers will help (cf. above). However, additional information is needed which is not covered by the CCH.
Substance evaluation	Improved information in the registration dossiers should help developing AfAs (particularly the risk assessment); requires dossier updates (cf. above).		• Information transfer works from SEv to registration dossiers and hence for AfA development works. • Current practice shows that the use description and CSRs are not sufficiently detailed for AfAs.	• All actions to improve the quality of registration dossiers will help (cf. above).
SVHC Identification	Identified SVHC properties define the scope of the risk assessment in the AfA (only required for properties of concern).	Guidance documents on AfAs specify the necessary content of AfAs.	• From the perspective of an optimal risk management, all relevant risks should be considered and hence, the	• Assessment of past authorisation cases to identify if the lack of addressing all known hazard endpoints in the AfA required regulation in addition to the

[29] The information needs to compile an AfA go beyond what is needed for a regular registration dossier and hence does not concern an interface between the two processes.

Impacting process	Impacts of … on <u>applications for authorisation</u> Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
			exclusion of non-SVHC hazards is counterproductive. • From the perspective of human health and the environment, greater consideration should be given to the impacts that would arise from the adoption of alternatives and result in shifts in risks, e.g. due to increases in transport and energy use (linked to recyclability), increase in water use and increase in other raw materials use, in particular critical raw materials, etc.	authorisation. If this were the case, assessment of the additional regulation could have been prevented if the AfA (and respective opinion forming and decision making) had addressed all hazards/risks. Conclude whether or not consideration of all hazards in AfAs would be useful. • Consider revising the AfA guidance with an explanation why addressing additional hazard endpoints in the authorisation process and possible approaches to do that could be useful to prevent later (additional) regulation, at least on a voluntary basis.
SVHC Identification	Identified SVHC properties define the route on which the AfA aims to demonstrate a need for continued use (SEA route or adequate control route).		• AfAs frequently include a SEA also for SVHCs that should be treated according to the adequate control route. • Derivation of reference DNELs for SVHC is challenging for applicants and may lead to different applicants deriving different values.	• Assess options to allow applicants for authorisation to develop a SEA (with appropriate deadlines) if their argumentation on adequate control is not followed by the RAC to avoid unnecessary work by the industries and Committees. • Reference DNELs for use in the AfA (and CSRs) could be derived in the SVHC identification processes by the authorities.
Annex XIV Inclusion	Conditions specified in the entry of Annex XIV determine timeline (application and sunset date) and scope of the application (exemptions).		• Timelines should be as short as possible and as long as necessary for industry to adjust, this is difficult to judge and may put either high time pressure on	• Consider options how to make better decisions on appropriate authorisation deadlines, e.g. allow greater flexibility than just 4, 7 and 12 years.

Impacting process	Impacts of … on <u>applications for authorisation</u> Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
			applicants (resulting in insufficient AfAs) or leave too much time (resulting in unnecessary delays of risk management). • There are cases that AfAs are submitted "quick and dirty" to allow continued use after sunset date (gain some time). • Companies initiate the AfA procedure and through this identify alternatives leading to substitution; sufficient time before the sunset date facilitates this.	• Consider options to make better decisions on appropriate sunset dates, e.g. establish sunset periods to increase the likelihood of substitution without the need to apply for authorisation. • Simplify the requirements for legacy parts[30].
Opinion on AfA	The fact that AfAs of insufficient content or quality can be rejected by the Committees motivates applicants for authorisation to deliver good quality AfAs.		• AfAs sometimes lack relevant information, are of low quality/incompliant. This creates high workloads for the Committees and the opinion forming processes. • ECHA's committees change the criteria that they use in their assessment without making the basis for these known, leading to an increased number of questions from Rapporteurs.	• Define clear criteria that justify rejection of an authorisation proposal of (very) low quality with the option of resubmission within a specific deadline[31] . • ECHA should update published guidance and justifications for how RAC and SEAC are assessing AfAs to reduce the potential for questions and unnecessary time costs.

[30] Discussions are ongoing in the COM on this issue at the time of writing the report.

[31] This option would also require defining how production and use of the substance should be handled during that period; the respective provision should not lead to using low quality applications to prolong the deadline of the sunset date; i.e. without the intention to re-submit the AfA.

Impacting process	Impacts of … on <u>applications for authorisation</u> Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Opinion on AfA	RAC and SEAC request additional information and provide comments to an AfA, triggering improvements and changes to the application.		• The AfAs are improved according to the RAC and SEAC requests. • There is a lack of transparency and justification for some of the 'rules of thumb' that are being adopted by e.g. SEAC.	• RAC/SEAC could request revised assessments rather than additional information to reduce their workload. • Develop approaches to collect information on alternatives more efficiently than via the consultations and from AfAs. • Clarify e.g. in the guidance documents on AfAs and SEAs the basis for the 'rules of thumb' that are being adopted by the Committees so that applicants are able to challenge or adopt them as appropriate.
Decision on AfA	No impact			
Restriction proposal	A restriction proposal might narrow the scope of AfAs (only non-restricted ones). It may discourage DUs to apply for uses if these concern products covered by the intended restriction.		• Parallel processes for the same endpoint are impossible (except regarding articles). • There is a low likelihood that a restriction proposal for endpoints other than those addressed by the authorisation run in parallel to the AfA development.	
Opinion on RP				
Decision on RP	The restriction of substances in products narrows the scope for viable uses that can be authorised and might focus the authorisation process on a limited number of essential uses.			

3.7 Interplay with opinion forming on AfAs

The Committees form their opinions based on the AfAs and request additional information from the applicants, where this is necessary and possible. The other REACH processes link with the AfA in that the registration information may be used for plausibility checking and that the SVHC identification and Annex XIV entry define the conditions within which an authorisation may be granted. The restriction processes is not considered to interact with this step, except by limiting the potential authorisation conditions.

Table 8: Impacts of different REACH processes on the opinion forming process on AfAs[32]

Impacting process	Impacts of … on opinion forming on AfAs Intended/ necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Registration	RAC and SEAC use the AfA as information basis and the registration dossier is not normally of relevance in the opinion forming process.		Ideally the registration dossier could be part of the AfA, but in practice the description of uses and risk management measures do not include sufficient details.	Improvements in Registration dossiers could support the process of preparing an AfA (see table above).
Dossier evaluation	As registration dossiers are not normally consulted by RAC and SEAC, the DEv is not relevant for this process.			
Substance evaluation	If the substance was evaluated, information is used to cross-check the AfAs.			
SVHC Identification	Benefits and costs of continued use or ended use are allocated to the effects caused by the identified SVHC properties.		• From the perspective of improving the level of protection, also the decision-making on authorisation via the adequate control route, which is triggered by the identified SVHC property, may consider the	• Change the REACH text to allow considering the availability of alternatives for authorisations on the adequate control route.

[32] As the information needs to form opinions on AfAs in many ways resemble those needed to prioritise SVHCs for Annex XIV inclusion, reference is made to Table 6 rather than repeating the evaluation of interplay and ideas for improvement.

Impacting process	Impacts of … on <u>opinion forming on AfAs</u> Intended/ necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
			availability of alternatives as a potential reason for refusing authorisation, even if RCR < 1.	
Annex XIV Inclusion	Potential exemptions in Annex XIV limit the scope of the opinion forming; timelines impact on the SEA results.			
AfA	The AfAs are the basis for SEAC and RAC to form an opinion on granting an authorisation. The quality and the scope of an AfA determine the scope and resource needs of the Committees to form their opinion.	Guidance document for industry on how to develop AfAs, opportunity to consult with ECHA on AfAs early in the process.	• Low quality AfAs are frequently not rejected but RAC/SEAC request additional information (and make own assessments) resulting in high workloads and a partial shift of responsibility. • Assessments of Alternatives (AoA) are frequently difficult for SEAC to assess, information may have to be collected in addition to what is provided in the AoA.	• RAC/SEAC could reject AfAs of insufficient quality based on clear quality criteria, potentially with a period for allowed resubmission despite the date for application having passed. • Develop clear guidance on what information on the alternatives must be provided by the applicants. • Identify options to more strongly involve potential producers of alternatives into the consultations. • Ensure, e.g. by rules of procedure, that RAC/SEAC during the evaluation of AoAs only collect the information which is necessary to validate it but not to make one on their own.[33]
Decision on AfA	Decision making follows opinion forming → limited impact.	Based on the experiences and to better support the COM's decision making, the		

[33] From the environmental and health perspective this proposal could also be argued as critical as it reduces the opportunities of identifying alternatives that were not mentioned by the applicant. However, it appears that consultations and individual information collection by the Committees did not change the overall view on the availability of suitable alternatives up to now.

Impacting process	Impacts of … on opinion forming on AfAs Intended/ necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
		templates of the opinions have been adapted.		
Restriction proposal	No impact			
Opinion on RP	No impact			
Decision on RP	No impact			

3.8 Interplay with decision making on AfAs

The COM decides on whether or not an authorisation can be granted based on the AfA and the Committee opinions. Hence, registration and evaluation do not directly interact with that step of the authorisation process. The borderlines of decision making are defined by the SVHC properties (route for granting an authorisation) and the Annex XIV entry. The registration process does not interact with the decision making.

Table 9: Impacts of different REACH processes on the decision making on AfAs

Impacting process	Impacts of … on decision making on AfAs Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Registration	No impact			
Dossier evaluation	No impact			
Substance evaluation	No impact			
SVHC Identification	No impact		From the perspective of improving the level of protection, also the decision-making on authorisation via the adequate control route, which is triggered by the identified SVHC property, may consider the availability	• Change the REACH text to allow considering the availability of alternatives for authorisations on the adequate control route.

Impacting process	Impacts of … on decision making on AfAs Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
			of alternatives as a potential reason for refusing authorisation, even if RCR < 1.	
Annex XIV Inclusion	No impact			
AfA	Scope, quality and consistency of argumentation is the basis for the COM to get an overview of the situation and decide.	Guidance document on AfAs.	• It is unclear how the COM makes use of the AfA information in detail.	
AfA	AoAs proving the existence of suitable alternatives should lead to the denial of an authorisation (SEA route). If an authorisation is granted, the substitution plan and other information in the AfA are considered in defining review periods and authorisation conditions.	Guidance document on AfAs.	• Sometimes, AoAs (in combination with the SEA) appear to be insufficient to support decision making, including on review periods.	• Define minimum criteria on the information content of AoAs (guidance document) to ensure the COM receives sufficient information for decision making.
Opinion on AfA	The RAC and SEAC opinion should guide the COM's decision making.	Formal process defined how opinions are provided and processed. COM sometimes initiates additional calls for information. Based on the experiences and to better support the COM's decision making the templates of the opinions have been adapted.	• The COM has to address uncertainties in opinions when taking their decisions without an information basis as compared to the committees. • The facts in the RAC/SEAC opinion are politically evaluated/interpreted by the COM (e.g. what is an acceptable risk or an economic argument for the continuation of a use?). As RAC/SEAC cannot anticipate all information needs related to the interpretation in	• Assess if and how opinions could be improved to satisfy all of the COM's information needs. • Develop approaches for the COM to conclude on authorisations, thereby considering all relevant information relating to the need for continued use and to particularly document separately and transparently any reasons politically justifying an authorisation which go beyond or are

Impacting process	Impacts of … on decision making on AfAs Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
			the decision making stages, delays may occur to gather that (additional) data. • Additional consultations delay the decision making process but may lead to better decisions monitoring and other conditions may be included in the opinion with little consideration of their feasibility, potential for double regulation or costs.	in conflict with the RAC/SEAC opinions. • Define clear deadlines for COM decision making to prevent unnecessary delays. • Where authorisation conditions would create a significant burden, especially for downstream users, RAC and SEAC should be required to demonstrate that they have also considered the feasibility and need for those conditions where there is also other relevant legislation (e.g. a BOELV).
Restriction proposal.	No impact			
Opinion on RP	No impact			
Decision on RP	No impact			

3.9 Interplay with restriction proposals

Restriction proposals are developed based on registration dossiers and hence link with the registration process and indirectly with all other REACH processes that contribute to its data quality.

Table 10: Impacts of different REACH processes on drafting restriction proposals

Impacting process	Impacts of … on drafting restriction proposals Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Registration	Registration dossiers should provide the key information on substances upon which the restriction proposal can be based.	ECHA and MSCA have implemented the possibility for a call for evidence to collect information to substantiate a restriction proposal.	• Often the description of uses and products is too vague to define the exact restriction scope. • Not all substances relevant for restriction are registered.	• Implement legislation empowering ECHA/MS to request use information on substances for which restrictions are intended from DUs (via the registrants, directly to ECHA or to the MS). • Consider options to require registration or at least notification of (specific) substances that are suspected to cause risks but currently are exempted from registration (e.g. less than 1 t/a, polymer, substances in articles).
Dossier evaluation	Quality assurance of registration information should lead to more credible/revised information for developing the restriction proposal.		• Registration dossiers are updated after CCH; even after a dossier updates its quality, it is often not sufficient for restriction proposals.	• Apply the enhanced completeness check in the updating process.
Substance evaluation	Substance evaluations identifying risks that have to be addressed at community level trigger discussions and support decision making on the development of a restriction proposal. If data gaps are identified, an SEv may be initiated to close them. Non-standard information from SEv support the risk assessment in the restriction proposal.		• Dossiers are updated after SEv. • SEv documents are used in preparing restriction proposals. • As SEvs take a long time, they may delay the preparation of restriction dossiers if initiated to close data gaps.	• Apply the enhanced completeness check in the updating process. • Enable / implement reference to relevant SEv conclusions in restriction proposals and omitting discussion of hazards and risks.

Impacting process	Impacts of … on drafting <u>restriction proposals</u> Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
SVHC identification	SVHC identification initiates discussions about the possibility to develop a restriction proposal. Information from the SVHC identification dossier and the consultation supports risk assessment in the restriction proposal. Note: use information is not required in the dossier or requested in the consultation but frequently provided if available to facilitate the further process.		• SVHC identification dossier is used in preparing restriction proposal.	
Annex XIV Inclusion	SVHCs on Annex XIV cannot be restricted, except in articles: Listing in Annex XIV triggers risk assessment of remaining risks from (imported) articles (after sunset date) and the initiation of an additional restriction if unacceptable risks are identified.	Guidance on restriction proposals discusses how existing regulation must be considered.	• ECHA implements its obligation to assess restriction needs in practice. • As the assessment of a restriction need and the development of a restriction dossier may start only after the sunset date, there is a gap between the authorisation requirements and the restriction of SiA in (imported) articles if a restriction is developed for the SVHC (delayed protection)	• Assess options to ensure necessary restriction proposals are initiated early in order to ensure a level playing field in the area of articles; e.g. change the legal text to allow ECHA starting activities already before the sunset date.
Annex XIV Inclusion	Authorisation is considered in the proposal of a restriction.	Guidance on restriction proposals discusses how		

Impacting process	Impacts of … on drafting restriction proposals Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
		existing regulation must be considered.		
AfA	No impact			
Opinion on AfA	Opinions may be considered in developing and targeting restriction proposals.		• AfA opinions are used as an information source for restriction proposals.	
Decision on AfA	Granted authorisations leading to inclusion of SVHCs in articles should be considered by ECHA when assessing the need to restrict the use of SVHCs in articles.		• AfA decisions are considered when assessing if a restriction is needed on SVHCs in articles.	
Opinion on RP	If a restriction proposal is rejected, the opinion should be taken into account if that proposal is revised.			
Decision on RP	If a restriction proposal is rejected, the reasoning of that decision is taken into account in revising the restriction proposal.			

3.10 Interplay with opinion forming on restriction proposals

The RAC and SEAC form their opinions on restriction proposals based on these and possibly using additional information from the registration dossiers. Hence, links exist to registration and indirectly to all processes that contribute to the data quality and coverage.

Table 11: Impacts of different REACH processes on the opinion forming on restriction proposals

Impacting process	Impacts of … on opinion forming on restriction proposals Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Registration	The committees should use the registration information to check the restriction proposal and form their opinion.	Several activities to improve registration dossiers (updating, information requirements etc.).	• Registration information is currently insufficient for a thorough assessment of restriction proposals.	• Cf. proposals in Table 6 and Table 10.
Dossier evaluation	Basic data should be quality assured, increasing the credibility and the quality of that information.		• Use information and CSRs are not (sufficiently) assessed and hence not improved in quality via the DEv and therefore not available for opinion forming.	• Cf. proposals in Table 6 and Table 10.
Substance evaluation	If an SEv precedes the restriction proposal, the content and results of that process should be used to support opinion forming.		• SEv documents are used as information source for opinion forming.	• Cf. Table 10.
SVHC Identification	SVHC properties have been agreed to and should be considered in the opinion forming.		• SVHC identification documents are not always used in the opinion forming, leading to double work for discussing hazards (and risks).	• Assess if the committees could simply refer to SVHC identification and omit all discussion on related hazards, unless there is new information. If this is not possible according to current legislation, consider changing the REACH text.
Annex XIV Inclusion	Existing risk management measures should be considered in the opinion forming on the necessity of a restriction.	Guidance on drafting restriction proposals.	• The impact of authorisation is considered in the opinion forming in practice, i.e. this works well.	
AfA	If a substance proposed for restriction (in articles) has also undergone an		• AfAs are used as an information source by the Committees in their opinion forming, i.e. this works well.	

Impacting process	Impacts of … on <u>opinion forming on restriction proposals</u> Intended/necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
	authorisation process, the AfAs should be used, too.			
Opinion on AfA	If a substance proposed for restriction (in articles) has also undergone an authorisation process, the opinions should be consistent with those formed on the AfA.		• It is unclear to which extent opinions are consistent.	Assess if the opinions for substances on potentially several authorisations and on a restriction proposal are consistent and, if this is not the case, develop approaches to ensure consistency.
Decision on AfA	If a substance proposed for restriction (in articles) has also undergone an authorisation process, the AfA decisions should be cross-checked with potential impact assessments in the opinions.		• It is unclear to which extent the AfA decisions are used in the opinion forming.	
Restriction proposals	Scope, quality and content of the restriction proposal define the scope of the Committees' work.	Guidance on drafting restriction proposals.	• The information content of restriction proposals varies; some trigger unnecessary work on issues of low importance.	
Decision on RP	No impact			

3.11 Impacts of other processes on the decision making on restriction proposals

The COM decides on restriction proposals based on the initial dossiers and the Committees' opinions. There are no links to other processes.

Table 12: Impacts of different REACH processes on deciding on restriction proposal

Impacting process	Impacts of … on the decision making on restriction proposals Intended/ necessary for RMM	Instruments supporting interplay	Evaluation of the interplay	Ideas for improvement
Registration	No impact			
Dossier evaluation	No impact			
Substance evaluation	No impact			
SVHC Identification	SVHC status of a substance is considered in the decision making.			
Annex XIV Inclusion	Existing risk management measures are considered in the decision making.			
AfA	No impact			
Opinion forming on AfA	No impact			
Decision on AfA	No impact			
Drafting RP	Restriction proposal is the basis for the COM to decide.			
Opinion on RP	Opinions on the RP are the basis for the COM to decide.			

4 Findings on the interplay of the REACH processes

At which links between REACH processes is an optimal risk management aggravated, delayed or impeded? Where does the interplay function well?

Overall, the interplay between the REACH processes works well. No major deficits were identified at the interfaces of the processes that hinder the prioritisation, risk assessment and risk management of chemicals. However, improvement potentials for some specific aspects were identified (cf. tables in Section 3). Additionally, the lack of hazard and use information was identified as a recurring issue for the interfaces of evaluation, restriction and authorisation with the registration process, as all of these are based on information collected in the registration dossier. The lack of correct descriptions of the SID is a challenge for all processes and roots in deficits of the registration dossiers.

Substance evaluation and dossier evaluation contribute to an improvement in data quality and completeness of registration dossiers. As it is not fully clear whether or not ECHA may request standard or non-standard data in SEV/CCH there were several related debates in the past. However, this appears to be mainly clarified by now[34].
A deficit in the interplay between the two evaluation processes is their sequential conduction, because this is time-consuming and may therefore prevent a 'quick' introduction of risk reduction activities. Delays may also result from information requests under dossier evaluation that are refuted via appeals to the BoA and then reiterated in SEvs if that process is started afterwards.

Restrictions and authorisation increase the level of protection for human health and the environment. The SVHC identification may initiate substitution, thus accelerating risk reduction or avoiding further risk management. The legally defined scopes of restriction and authorisation exclude the possibility of 'double regulation'. The requirement for ECHA to assess the need for a restriction of authorised substances in articles ensures that potential gaps in risk management are addressed, however due to the start of these activities only after the sunset data, with a delay. As SVHC identification is a precondition to authorisation but does not limit the possibilities to use a substance, there is no regulatory overlap.

How can the deficits in the interplay be overcome?

Several options could be derived to overcome the lack of hazard and use information that affects all of the REACH processes. Improved **hazard** information could be achieved via

- improved information and guidance for registrants, improved TCC (increased compliance) this is ongoing work by all actors and could be further intensified.
- revising and/or extending data/registration requirements
  the Commission is reviewing these issues, including the respective annexes, requirements for low volume substances and the registration of polymers.
- implementing a lean procedure to request hazard data from the industry in a targeted way, similar to the SEv but less formalised.

While supporting registrants in providing better data would increase data quality, the type and scope of information that is available is unlikely to change. Revising or extending data

[34] Further clarification on the delineation of CCH and SEv is expected from the 2nd phase of the adaptations of Annex VI – X.

requirements would create substantial additional burden to the industry and should therefore be justified by a proportionate increase in the level of protection through the gained knowledge.

Not only the authorities lack **information on the uses** but also the registrants frequently do not have full knowledge of the applications of their substances. Gathering use information could include the following activities:

- Focussing more strongly on the improvement of use information in registration dossiers and CSRs to improve IT-based concepts for CSRs checking and to include it in the evaluation processes
- A general obligation for DUs to notify their uses to ECHA, which could be limited to substances with specific hazardous properties and/or use areas
- An enhancement of REACH Art. 34 with stricter requirements for the DUs to communicate their uses to the registrant
- An obligation to update use information in registration dossiers after a substance is included into the PACT or other announcement tools (CoRAP, ROI…)
- Improvements of guidance documents and consultation approaches
- An obligation for the industry to answer specific information requests from authorities conducting a risk assessment or risk management process on their or their customers' uses

All of the above options would increase the knowledge on uses. The options differ in the workload they create to the industry and the authorities (costs) and the extent of their potential effect, i.e. if they contribute data to any REACH process, including prioritisation, or only to a particular one (benefits). Furthermore, some options are more difficult to implement and enforce than others. For example, a 'general use notification', even if limited to certain substance properties or use patterns, would create an extensive workload for the industry but might also significantly improve the information basis for risk assessment and risk reduction activities. A targeted information request results in much lower efforts but is bound to be incomplete and suffers from authorities not knowing the identity of (all) DUs. Either option requires smart approaches to enforce information requests and a more detailed and systematic description of uses.

A decision on whether or not a systematic or targeted information collection on uses is justified and how such information collection could be designed and applied requires a political decision, considering the costs and benefits of any such option.

How can links between substance evaluation and dossier evaluation be optimised?

At a general level, the interplay between processes would be facilitated by a better (automated) completeness check, a thorough and specific assessment, which evaluation process is most appropriate for a particular substance as well as improved cooperation and communication between ECHA and the Member States.

To avoid delays in the evaluation process and ensure resources are most efficiently used, optimisation potentials exist. While it is obvious that a DEv is most adequate if only standard information is needed and an SEv should be implemented if the data to be requested may only be obtained via the SEv, different options exist in cases of mixed data needs:

- Implementation of a DEv first, followed by an SEv (upon need and/or if data collection via Dev is necessary to decide if an SEv is needed)
- Directly implementing an SEv covering all information needs
  this may require adaption/clarification of the REACH requirements regarding the possibilities to request standard data in an SEv (in accordance with the CCH requirements)
- Parallel implementation of the two processes (COMBO approach), as is increasingly implemented in practice.

Which of these options is most appropriate remains to be assessed and discussed and may be subject to individual considerations.

How can links between authorisations and restrictions be optimised?

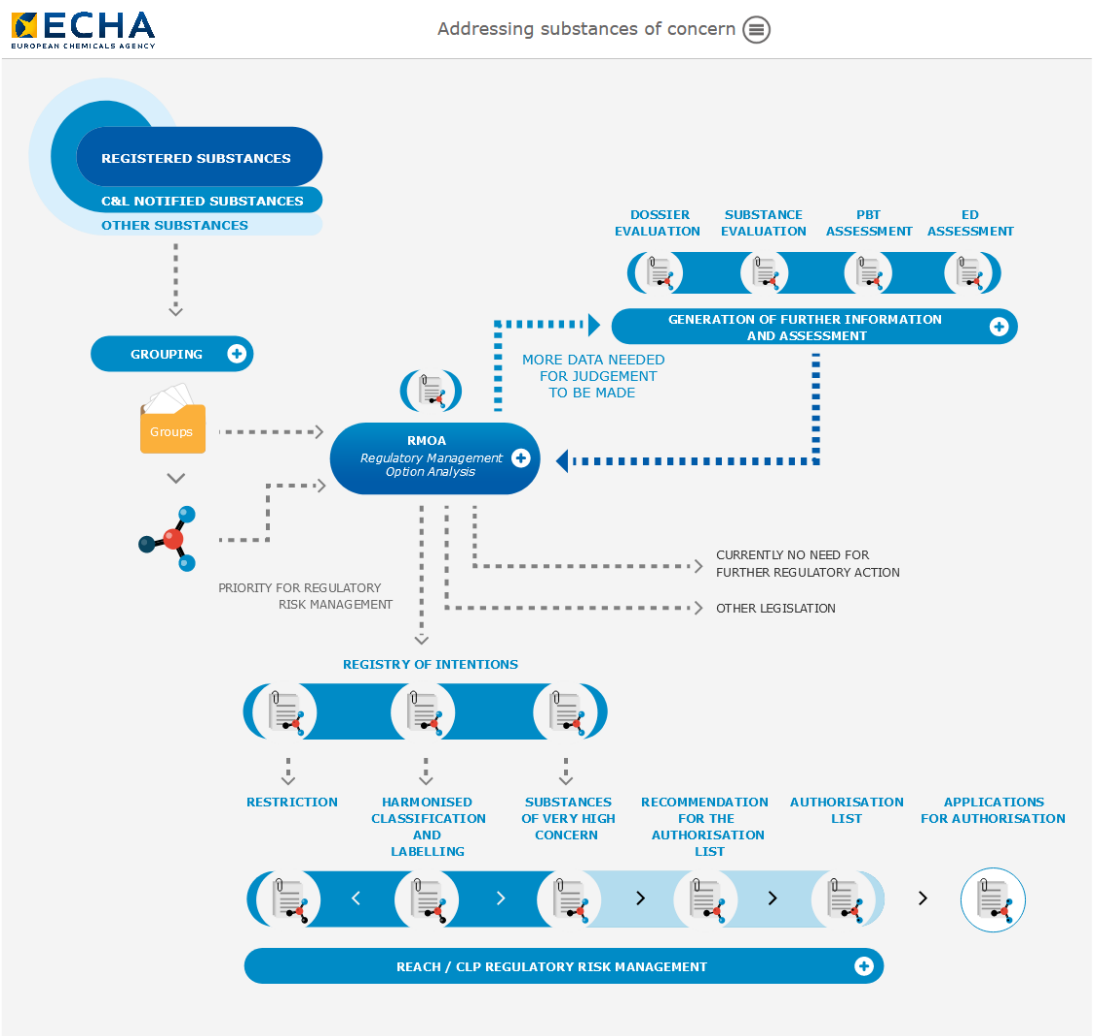
Generally, no major optimisation needs for links between authorisation and restriction were identified. The only improvement option refers to the delay in managing risks from SVHC in (imported) articles that is a result of REACH[35] requiring ECHA to start its activities only aftzer the sunset data in Annex XIV has passed. If ECHA could start their work ealier, the time gap could be closed. This may require a change in the legal text and a change in ECHA's working procedures.

Selection of appropriate risk management measures

A core question about the interplay of REACH processes, which does not evolve from the assessment of individual interfaces is how the most relevant substances (priority setting) can be identified and all possible risks be covered (effectiveness) at a minimum of burdens for all actors (efficiency) under REACH. The possible routes a substance could take and the criteria for directing it are provided in ECHA's integrated regulatory strategy (ECHA 2019).

[35] Cf. UBA Texte 194/2020 for further details

Figure 1: The Integrated Regulatory Strategy (IRS)



Source: ECHA, https://echa.europa.eu/irs-infographic

In the analysis of interfaces, the RMOA was confirmed to play a key role in identifying appropriate measures to deal with a substance, despite not being a formalised process under REACH.

ECHA's screening of substances registered above 100 t/a results in substance lists for five categories (mapping of the chemicals universe). As the screening is based on substance groups, also substances in the lower volume registrations are covered. The registration information is used to derive the need for further action or conclude that a substance is not of priority at the time of screening. The substances in the lower tonnage bands will be screened after the 'universe of the higher volume substances' is sorted out.

The IRS appears to be a good approach to identify chemical risks within the REACH process. From the implementation perspective, another prioritisation step is needed to select those substances which should be addressed first by evaluation or for risk reduction. Such prioritisation within the lists requires a more detailed assessment of relevance, i.e. an evaluation of health and environmental, societal benefits, the availability of alternatives and the essentiality of a use as well as a political decision about addressing a particular (group of) substances, or both. While the former could theoretically be implemented by ECHA, information on uses is not

available at the moment. The political decisions on addressing particular substances or substances groups are not in ECHA's remit but could be implemented either by the Commission or the Member States.

Which opportunities exist to extend the data generation by linking it to other chemicals assessment and management processes?

REACH is embedded into the EU chemicals policy framework and hence overlaps with several pieces of legislation, such as the CLP regulation, legislation on pesticides, biocides, pharmaceuticals or cosmetics, for example. Additionally, links exist between REACH and product, environmental, workers and installation-related legislation. Finally, the EU launched the Chemicals Strategy for Sustainability (CSS), which suggests a new context and a stronger emphasis on precaution and risk reduction from the use of chemicals.

While the current analysis focussed on the links between processes within REACH, also the links to other legal areas are important to achieve an optimal overall chemicals risk management. The following observed deficits appear to be addressed by the actions planned under the CSS:

- Lack of information: a common data platform will be established merging information on chemicals from different legislation and sources that should improve information availability on hazards. It is unclear if use information will be covered by that platform. Additionally, methods and tools will be developed to improve the availability and use of data from scientific research for regulatory purposes.

- Avoiding gaps and overlaps: it is currently unclear how the 'one substance one assessment' principle will actually be implemented. In the ideal case it would lead to commonly accepted assessment results, preventing multiple risk assessments for one substance. Nevertheless, specific assessments pertaining to a particular use and individual design of risk management measures are likely to still be implemented in the various regulatory contexts.
  The use of one common PACT is likely to improve coordination and cooperation in general. Furthermore, a Commission internal coordination mechanism as well as the establishment of a respective working group with the MSs, the Commission services and the Agencies should contribute to an efficient common risk assessment process. These instruments should not delay risk management measures.

- Handing-over regulatory action: whether or not and to what extent the handing-over of regulatory action is needed will not be necessary anymore once a common assessment process is established will remain to be seen.

5 Literature

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