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Final report

Advancing REACH - Consultation Procedures

by:
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Abstract: Advancing REACH - Consultation Procedures

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

In this sub-project, the consultation procedures foreseen under REACH were analysed with regard to their effectiveness, efficiency and transparency. In addition, the "Call for Evidence" preceding some of ECHA's restriction proposals and the consultations supporting an RMOA were assessed.

Overall, the consultations are considered as helpful instruments to collect information. However, in particular the data on alternatives gathered through consultations is not sufficient and additional measures may be needed to collect sufficient information.

Kurzbeschreibung: Konsultationsprozesse

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

In diesem Teilprojekt wurden die Konsultationsverfahren nach REACH bzgl. ihrer Effektivität, Effizienz und Transparenz analysiert. Außerdem wurden die „Calls for Evidence", welche die ECHA z. T. vor Beschränkungsvorschlägen durchführt und die Konsultationen von einigen Mitgliedstaaten im Rahmen einer RMOA berücksichtigt.

Insgesamt sind die Konsultationen hilfreiche Instrumente, um Information zu erheben. Allerdings, sind sie insbesondere für die Sammlung von Daten über Alternativen nicht ausreichend, so dass teilweise weitere Maßnahmen zur Erhebung von Informationen notwendig sind.

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List of abbreviations

ADCA	C,C'-azodi(formamide)
AfA	Application for Authorisation
AoA	Assessment of alternatives
BfC	Federal Office for Chemicals (Bundesstelle für Chemikalien)
BPA	Bisphenol A
CAS	Chemical abstract service
C&L	Classification and Labelling (Regulation)
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
CMR	Carcinogen, mutagen, reprotoxic substance
COM	European Commission
CTAC	Chromium Trioxide REACH Authorisation Consortium
DE	Germany
DK	Denmark
DNEL	Derived no effect level
DU	Downstream user
e.g.	For example
EC	European Community
ECHA	European Chemicals Agency
ED	Endocrine Disrupter
EU	European Union
HBCDD	Hexabromocyclododecane
HDDA	Hexamethylene diacrylate
MS	Member State
MSCA	Member State Competent Authority
NL	Netherlands
No.	Number
NGO	Non-governmental organisation
PACT	Public Activities Coordination Tool
PBT/vPvB	Persistent, bioaccumulative, toxic / very persistent, very bioaccumulative
PFOA	Perfluorooctanoic acid
PNEC	Predicted no effect concentration
RAC	Risk assessment committee
REACH	Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMOA	Regulatory management option analysis

ROI	Registry of intention
SE	Sweden
SEA	Socio-economic assessment
SEAC	Socio-economic assessment committee
SME	Small and medium size enterprise
SVHC	Substance of very high concern
UK	United Kingdom
WP	Work Package

Summary

Introduction to the project

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 are analysed and improvement options developed, including potential changes in the regulatory text and its annexes.

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

Background of the sub-study on public consultations

This sub-study assesses the efficiency, effectiveness and the requirements for a transparent procedure of the consultation processes under REACH. Efficiency is a measure of the actors' efforts to participate in a consultation in relation to the outcome achieved through the consultation. The efforts include the stakeholders' activities to transmit information as well as the work of the authorities to organise the consultation, process the data obtained from the consultation and to react on it. Effectiveness is understood as a measure of whether or not the requested information was actually obtained from the stakeholders in the consultation. Finally, transparency addresses the degree to which it is evident to all stakeholders what information has been obtained in the consultation and how it influenced the further decision making process.

The REACH-related and open public consultations analysed included

- Dossier evaluation: consultation of testing proposals
- Restriction: consultation of the initial Annex XV Dossiers submitted to ECHA and of the draft opinions by the Socio-Economic Analysis Committee
- Authorisation: consultation of the proposals for candidate listing, of ECHA's recommendations for Annex XIV inclusion (i.e. substances requiring authorisation) and of the specific applications for authorisation.

In addition to these consultation procedures, which are required according to the REACH text, two further informal consultations, which have been established to gather information from stakeholders at an early stage where included in the study.

The first is a public consultation in the context of the Regulatory Management Option Analysis (RMOA). The RMOA is an informal process enabling the authorities and ECHA to identify a substance's potential risks prior to any official REACH action and to select the most appropriate regulatory instrument within or outside of REACH to control these risks. Since good use information is essential to carry out a well-founded RMOA, many authorities conduct a stakeholder consultation. The German authorities have defined a specific procedure for public consultations that should support their RMOAs. Only this procedure was analysed in the study but practices of other Member States could not be considered.

The second informal consultation process included in the study is the so-called "Call for Evidence", which ECHA may carry out in preparing a restriction proposal. As with the RMOA, the aim of the Calls for Evidence is to broaden the information basis on a substance at an early stage in order to subsequently arrive at more precise analyses and conclusions on a substance's risks.

Both of these informal consultations should support gathering information on uses of chemicals, as the data in registration dossiers is not sufficient for decision making on regulatory measures. The consultations are not limited to any specific type of information, but a broad range of facts and arguments to understand the impact of an envisaged regulation may be gathered.

The study discusses the role of the consultation with regards to the REACH process they should support. Some possible functions of the consultation include gathering information, balancing interests, generating attention or stimulating substitution. In this context, it was particularly important to determine whether the REACH procedures are as transparent as claimed and if the public can be sufficiently involved.

The study includes an analysis of whether or not the primary target groups of a consultation are actually reached by the way consultation requests are currently published. It was assessed if the incentives for participation are sufficient to justify the efforts of providing information, in particular for those information providers that do not have any direct benefits from it. Another angle of the analysis asks if the additional information obtained from a consultation is important enough for the REACH process to justify the effort of the consultation (and the associated time expenditure). In this regard, it was analysed if the information from consultations increased the effectiveness or efficiency of the final regulatory measure. The study also reflected on how the collected information is used in the further work.

Based on these assessments, weaknesses of the consultation processes were identified and, if possible and necessary, improvement options derived.

Main findings and recommendations

The assessed consultations differ with regard to the specificity of their topics (issues) and the range of actors that could respond (target group). All types of assessed consultations should close the data gaps for which the responsible actors (market actors or authorities) cannot gather sufficient information. The data gaps exist because of a lack of respective data requirements for substance registration. The consultation processes were initially designed as an attempt to overcome this deficit for individual REACH processes (dossier evaluation, authorisation and restriction).

At a general level, the analyses show that the assessed consultations are well organised. They are publicly announced on ECHA's website or, in the case of the German RMOAs, on the website of the competent authority. Frequently, further announcements are issued via social media channels or by directly contacting the relevant stakeholders, such as registrants or downstream user associations. Web interfaces facilitate the transmission of comments and guide the users.

Transparency

All official REACH consultations were found to be transparent in all assessed cases, apart from the consultation of testing proposals (dossier evaluation). All submitted information and a document with responses to the comments are published. The "Response to Comments Document" evaluates the relevance of the comments and indicates how it will be used in the further process. Many submissions contain information that is claimed confidential. These submissions are not published and the responses to such comments cannot be understood other than by the original submitter. Consequently, the practice of claiming information as confidential

reduces the transparency of the procedure. Further discussion are needed on how ECHA could (better) balance the interests of information holders and the public.

The information submitted in consultations of testing proposals is not published at all. This may be adequate because mainly the ECHA and the registrant have to find a solution and gather information. However, avoiding animal testing is an important REACH goal and subject to political discussions. Therefore, a more transparent documentation of the arguments supporting or refuting the need to conduct a test would be useful.

Information submitted following a Call for Evidence or in the frame of an RMOA is not currently published. As the ECHA or the member state authorities include it in the RMOA or a restriction proposal, this approach is considered appropriate. In order to ensure transparency about the consultation outcomes, a clear reference to the source of information (i.e. informal consultations) should be provided in the RMOAs or restriction proposals.

Effectiveness and efficiency

A consultation may be considered effective if the desired information is actually collected. Consultations with a narrow scope, i.e. where it is obvious which particular information is requested (e.g. SVHC identification) are more likely to be effective than those with a broad scope and a less specific communication of a particular information need. Regardless of the consultation type and breadth of scope, all examined consultations were found to improve the information basis of the individual REACH process step. Frequently, this resulted in an adjustment of arguments and a changed decision (proposal) of the respective REACH processes.

The main function of the consultations on SVHC identification and on the prioritisation of SVHCs for Annex XIV inclusion is to collect specific information necessary to support the related, specific decision making. Therefore, the consultation scopes for these two processes are narrow. Similarly, the consultation on authorisation applications is limited to comments on alternatives to the SVHC in use. However, this "issue" relates to many different aspects including the availability of alternatives, the technical efforts of implementing an alternative and the economic conditions for introducing the alternative. Therefore, a broader range of information types may be provided within the (narrow) consultation scope.

The consultations in the context of restrictions have a slightly different role. Apart from collecting information on alternatives, comments may address any aspect of the proposal, such as the subject of the regulation, proposed limit values, effects on market players and the presumed improvement for humans and/or the environment. The assessment of the latter receives further input in the second restrictions-related consultation about the SEAC opinion. Hence, the two consultations build on each other and the second may refine the discussion of the first.

It was observed that stakeholders often provide information beyond the actual scope of a consultation in order to influence fundamental rather than specific aspects of a planned regulation. Additionally, they tend to provide the information at a later rather than an earlier stage of the process, e.g. comments are received in the consultation of a SEAC opinion rather than of the initial restriction proposal. At the later process stages the fundamental decisions have already been made (e.g. on the scope of a restriction proposal) and are difficult to revise within the timelines defined by REACH.

In this context, the informal consultation supporting RMOAs or Calls for Evidence takes on special importance. As both consultations are not required by REACH, they add time and efforts for the authorities as compared to the legally foreseen process: The authorities carrying out the consultations and the responding stakeholders invest additional efforts. This would be justified

if the collected information saves time and resources in the subsequent process, i.e. if overall the result is achieved more efficiently, quicker and with fewer controversies. The German authorities are of the opinion that the RMOA consultations are efficient in this regard, increase the data basis on the actual uses of a substance and help identifying the best option to address the risks.

In addition to data collection indicating what specific problem needs addressing, the information from an RMOA consultation should support the selection of the best regulatory measure. The "best measure" in this context is that one, which reduces the risks at least to an acceptable level with the least possible impact on the market actors.

Stakeholder involvement

Despite the procedural differences, all consultations face the same challenge: identifying potential information holders and motivating them to participate. This challenge is even more pronounced, when all legally required data has been provided and the additional information needs can only be satisfied by market actors who are not normally addressed by the consultations.

The participation of stakeholders in all consultations is voluntary, i.e. they have a right not an obligation to comment. Therefore, the effectiveness of a consultation largely depends on its ability to involve those stakeholders, who actually hold the needed information. This may be difficult because frequently the information holders are not directly affected by REACH, such as the downstream users. Therefore, they are much less aware of the possibility to participate than e.g. the registrants. As the authorities also lack knowledge of the identity of the downstream users, they cannot directly contact and invite them to the consultation. This dilemma cannot be solved “in general” and is currently being addressed by ECHA’s and the other authorities’ active communication, including to the broader public and via social media.

The challenges to involve the “right” stakeholders in consultations are of particular concern when asking for information on the availability of alternatives (consultations on AfAs, restriction proposals as well as Calls for Evidence and RMOAs). Providers and users of alternatives frequently do not engage in consultations simply because they are not aware of them. They are neither directly affected by the regulatory process nor do they expect positive market effects from providing comments and information. It is also possible that providers of alternatives also provide the substance under discussion for regulation. Their interest to participate in a consultation is generally low if the market penetration of the alternative product is less economically promising than protecting the market of the “established” product. Another reason for non-involvement in consultations may be a fear that information contributing to the phase-out of a substance's use could “be returned” if the own product is subject to the preparation of a regulatory measure and a related consultation. In addition, the consultations have relatively short time frames. This makes it necessary for third parties who want to provide comments to actively follow the processes and prepare their arguments at an early stage. While this is an obstacle for all potential data submitters, it is particularly relevant for all actors not directly affected by a planned regulatory measure and who have low/no economic interests in the commenting. In summary, non-participation of stakeholders in consultations has many reasons.

Conclusions

In conclusion, the consultations are considered effective, efficient and sufficiently transparent if they concern specific topics and have a narrow scope, e.g. in the scope of an SVHC identification. However, consultations are not sufficient to gather information on alternatives, regardless of the regulatory process they should support. Amongst others, this is due to the fact that the consultations fail to reach the “right” actors as well as that the actors do not sufficiently benefit

from providing information. Therefore, further measures to gather information on alternatives are needed.

One option is to initiate targeted research and investigations to identify and assess potential alternatives and publish the results. This “independent alternatives assessment” could be performed by the member state authorities or by the ECHA, depending on which authority is responsible for the respective regulatory process. It could also be implemented by independent expert panels.

Overall, the majority of stakeholders evaluate consultations in the frame of an RMOA and the Calls for Evidence by ECHA as helpful to clarify fundamental issues from the outset and thus reduce uncertainties in the later formal processes. At the same time, consultations require time and resources, which can only be justified if the obtained information significantly improves the information basis for decision-making and argumentation. Otherwise, these procedures may only lead to a delay in the regulation of substance risks, which would be contrary to the actual objectives of REACH. However, the predominantly positive assessment of the informal consultations prior to the official REACH processes and their increasing use shows that the benefits are so likely that the additional effort is accepted.

Zusammenfassung

Einführung in das Projekt

Der vorliegende Bericht ist ein Teilergebnis des Ressortforschungsplan-Vorhabens „REACH-Weiterentwicklung“, welches im Rahmen des Forschungsplans des Ministeriums für Umwelt, Naturschutz und nukleare Sicherheit gefördert wurde. Im Rahmen dieses Vorhabens wurden verschiedene Aspekte der REACH-Verordnung und ihrer Umsetzung analysiert und Verbesserungsoptionen, einschließlich einer möglichen Veränderung des Verordnungstextes und seiner Anhänge, aufgezeigt.

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

Hintergrund der Teilstudie zu öffentlichen Konsultationen

Diese Teilstudie bewertet die Effizienz, Effektivität und die Anforderungen an ein transparentes Verfahren der Konsultationsprozesse unter REACH. Die Effizienz ist ein Maß für den Aufwand der Akteure, an einer Konsultation teilzunehmen, im Verhältnis zu dem durch die Konsultation erzielten Ergebnis. Der Aufwand umfasst sowohl die Aktivitäten der Akteure zur Übermittlung von Informationen als auch die Arbeit der Behörden zur Organisation der Konsultation, zur Verarbeitung der aus der Konsultation gewonnenen Daten und zur Reaktion auf diese. Effektivität wird als Maß dafür verstanden, ob die angeforderten Informationen tatsächlich von den Stakeholdern in der Konsultation eingeholt wurden oder nicht. Die Transparenz befasst sich mit dem Grad, in dem für alle Beteiligten ersichtlich ist, welche Informationen bei der Konsultation eingeholt wurden und wie diese den weiteren Entscheidungsprozess beeinflusst haben.

Zu den analysierten REACH-bezogenen und öffentlichen Konsultationen gehörten:

- Dossierbewertung: Konsultation der Versuchsvorschläge.
- Beschränkung: Konsultation der Anhang-XV Dossiers, die bei der ECHA eingereicht werden und der Entwürfe von Stellungnahmen des Ausschusses für sozioökonomische Analyse.
- Zulassung: Konsultation der Vorschläge für die SVHC-Identifizierung, der Empfehlungen der ECHA für die Aufnahme in Anhang XIV (d. h. zulassungspflichtige Stoffe) und der konkreten Zulassungsanträge.

Zusätzlich zu diesen Konsultationsverfahren, die gemäß REACH vorgeschrieben sind, wurden zwei weitere informelle Konsultationen analysiert, die der frühzeitigen Erhebung von Informationen von den Interessengruppen dienen.

Die erste ist eine öffentliche Konsultation im Rahmen der Analyse der regulatorischen Managementoptionen (RMOA). Die RMOA ist ein informeller Prozess, der es den Behörden und der ECHA ermöglicht, die potenziellen Risiken eines Stoffes vor einer offiziellen REACH-Maßnahme zu ermitteln und das am besten geeignete Regulierungsinstrument innerhalb oder

außerhalb von REACH zur Kontrolle dieser Risiken auszuwählen. Da gute Verwendungsinformationen für die Durchführung einer fundierten RMOA unerlässlich sind, führen viele Behörden eine öffentliche Konsultation durch. Die deutschen Behörden haben hierfür ein spezifisches Verfahren entwickelt, das ihre RMOAs unterstützen soll. In der Studie wurde nur dieses Verfahren analysiert, Praktiken anderer Mitgliedstaaten konnten nicht berücksichtigt werden.

Das zweite in der Studie enthaltene informelle Konsultationsverfahren ist der sogenannte „Call for Evidence", den die ECHA bei der Vorbereitung eines Beschränkungsvorschlags durchführen kann. Wie bei der RMOA besteht das Ziel des „Calls for Evidence" darin, die Informationsbasis zu einem Stoff in einem frühen Stadium zu verbreitern, um anschließend zu genaueren Analysen und Schlussfolgerungen über die stoffbezogenen Risiken zu gelangen.

Diese beiden informellen Konsultationen sollen die Erhebung von Informationen über die Verwendung von Chemikalien unterstützen, da die Daten in den Registrierungsdossiers für die Entscheidungsfindung über regulatorische Maßnahmen nicht ausreichen. Die Konsultationen sind nicht auf eine bestimmte Art von Informationen beschränkt, sondern es kann ein breites Spektrum an Fakten und Argumenten gesammelt werden, um die möglichen Auswirkungen einer geplanten Regulierung zu verstehen.

Die Studie erörtert die Rolle der Konsultationen im Hinblick auf den jeweiligen REACH-Prozess, den sie unterstützen sollen. Mögliche Funktionen der Konsultation sind das Sammeln von Informationen, der Ausgleich von Interessen, das Erzeugen von Aufmerksamkeit oder das Anregen von Substitution. In diesem Zusammenhang war es besonders wichtig festzustellen, ob die REACH-Verfahren so transparent sind wie behauptet und ob die Öffentlichkeit ausreichend einbezogen werden kann.

Es wurde analysiert, ob die primären Zielgruppen einer Konsultation durch die Art, wie Konsultationen derzeit veröffentlicht werden, tatsächlich erreicht werden. Es wurde untersucht, ob die Anreize für eine Beteiligung ausreichen, um den Aufwand für die Bereitstellung von Informationen zu rechtfertigen, insbesondere für diejenigen Akteure, die keinen direkten Nutzen aus einer Eingabe in die Konsultation ziehen. Ein weiterer Aspekt der Analyse ist die Frage, ob die durch eine Konsultation gewonnenen, zusätzlichen Informationen wichtig genug für den REACH-Prozess sind, um den Aufwand der Konsultation (und den damit verbundenen Zeitaufwand) zu rechtfertigen. In diesem Zusammenhang wurde geprüft, ob die Informationen aus den Konsultationen die Effektivität oder Effizienz der endgültigen Regulierungsmaßnahme erhöht haben. Zudem wurde betrachtet, wie die gesammelten Informationen in der weiteren Arbeit genutzt wurden.

Basierend auf diesen Bewertungen wurden Schwachstellen der Konsultationsprozesse identifiziert und, falls möglich und notwendig, Verbesserungsmöglichkeiten abgeleitet.

Wichtigste Ergebnisse und Empfehlungen

Die analysierten Konsultationen unterscheiden sich hinsichtlich der Spezifität ihrer Themen (Issues) und des Spektrums der Akteure, die antworten könnten (Zielgruppe). Allen bewerteten Konsultationstypen ist gemeinsam, dass sie Datenlücken schließen sollen. Die Datenlücken bestehen, weil es keine entsprechenden Datenanforderungen für die Stoffregistrierung gibt. Die Konsultationsprozesse waren ursprünglich als Versuch konzipiert, dieses Defizit für einzelne REACH-Prozesse (Dossierbewertung, Zulassung und Beschränkung) zu überwinden.

Generell zeigen die Analysen, dass die bewerteten Konsultationen gut organisiert sind. Sie werden öffentlich auf der Website der ECHA bzw. im Falle der deutschen RMOAs auf der Website der zuständigen Behörde angekündigt. Häufig erfolgen weitere Ankündigungen über

die Sozialen Medien oder durch eine direkte Kontaktaufnahme mit den relevanten Interessengruppen, wie z. B. den Registranten oder Verbänden der nachgeschalteten Anwender. Webschnittstellen erleichtern die Übermittlung von Kommentaren und leiten die Nutzerinnen und Nutzer an.

Transparenz

In den analysierten Fällen waren die jeweiligen offiziellen REACH-Konsultationen transparent, mit Ausnahme der Konsultation von Versuchsvorschlägen (Dossierbewertung). Alle eingereichten Informationen und ein Dokument mit Antworten auf die Kommentare wurden veröffentlicht. Das sog. „Response to Comments Document" bewertet die Relevanz der Kommentare und gibt an, wie sie im weiteren Prozess verwendet werden.

Viele Eingaben in die Konsultationen enthalten jedoch Informationen, die als vertraulich eingestuft werden. Diese Eingaben werden nicht veröffentlicht und die Antworten der Behörden können daher nur vom ursprünglichen Einsender verstanden werden. Die Praxis, Informationen als vertraulich zu definieren, reduziert somit die Transparenz des Verfahrens. Hier bedarf es weiterer Diskussionen, wie die ECHA die Interessen der Informationsinhaber und der Öffentlichkeit (besser) ausgleichen könnte.

Die in Konsultationen zu Versuchsvorschlägen eingereichten Informationen werden überhaupt nicht veröffentlicht. Dies mag angemessen sein, da hauptsächlich die ECHA und der Registrant eine Lösung finden und Informationen sammeln müssen. Die Vermeidung von Tierversuchen ist jedoch ein wichtiges REACH-Ziel und Gegenstand politischer Diskussionen. Daher wäre eine transparentere Dokumentation der Argumente, die die Notwendigkeit der Durchführung eines Versuchs unterstützen oder widerlegen, sinnvoll.

Informationen, die in einem „Call for Evidence" oder im Rahmen einer RMOA eingereicht werden, werden derzeit nicht veröffentlicht. Da die ECHA oder die Behörden der Mitgliedsstaaten sie in die RMOA oder einen Beschränkungsvorschlag aufnehmen, wird diese Vorgehensweise als angemessen angesehen. Um die Transparenz der Konsultationsergebnisse zu gewährleisten, sollten in den RMOAs oder Beschränkungsvorschlägen klare Verweise auf die Informationsquelle (d. h. informelle Konsultationen) gegeben werden.

Effektivität und Effizienz

Eine Konsultation kann als effektiv angesehen werden, wenn die gewünschten Informationen tatsächlich gesammelt werden. Konsultationen mit einem engen Anwendungsbereich, bei denen es offensichtlich ist, welche Informationen angefordert werden (z. B. Identifizierung von SVHC), sind mit größerer Wahrscheinlichkeit effektiv als solche die einen breiten Anwendungsbereich haben und bei denen der Informationsbedarf schlechter spezifiziert werden kann. Unabhängig von Art und Umfang wurde bei allen untersuchten Konsultationen eine Verbesserung der Informationsbasis des einzelnen REACH-Prozessschrittes festgestellt. Häufig führte dies zu einer Anpassung der Argumente und einer veränderten Entscheidung (Vorschlag) des jeweiligen REACH-Prozesses.

Die Hauptfunktion der Konsultationen zur Identifizierung und zur Priorisierung von SVHCs für die Aufnahme in Anhang XIV besteht darin, spezifische Informationen zu sammeln, die zur Unterstützung der damit verbundenen, spezifischen Entscheidungsfindung notwendig sind. Daher sind die Konsultationsbereiche für diese beiden Prozesse eng gefasst. In ähnlicher Weise beschränken sich die Konsultationen zu Zulassungsanträgen auf Kommentare zu Alternativen für die verwendeten SVHCs. Dieses „Thema" bezieht sich jedoch auf viele verschiedene Aspekte, einschließlich der Verfügbarkeit von Alternativen, des technischen Aufwands für die Implementierung einer Alternative und der wirtschaftlichen Bedingungen für die Einführung

der Alternativen. Daher kann im Rahmen des (engen) Konsultationsumfangs ein breiteres Spektrum an Informationsarten bereitgestellt werden.

Die Konsultationen im Rahmen von Beschränkungen haben eine etwas andere Rolle. Neben dem Sammeln von Informationen über Alternativen können Kommentare jeden Aspekt des Vorschlags betreffen, wie z. B. den Geltungsbereich, vorgeschlagene Grenzwerte, Auswirkungen auf Marktteilnehmer und die vermutete Verbesserung für Mensch und/oder Umwelt. Die Bewertung der letzteren fließt in die zweite beschränkungsbezogene Konsultation über die SEAC-Stellungnahme ein. Die beiden Konsultationen bauen also aufeinander auf und die zweite kann die Diskussion der ersten verfeinern.

Es wurde beobachtet, dass Stakeholder oft Informationen über den eigentlichen Rahmen einer Konsultation hinaus zur Verfügung stellen, um eher grundsätzliche als spezifische Aspekte einer geplanten Regulierung zu beeinflussen. Außerdem neigen sie dazu, die Informationen eher in einer späteren als in einer früheren Phase des Prozesses bereitzustellen, z. B. werden Kommentare in der Konsultation einer SEAC-Stellungnahme und nicht zum ursprünglichen Beschränkungsvorschlag abgegeben. In den späteren Prozessstadien sind die grundlegenden Entscheidungen bereits getroffen (z. B. über den Umfang eines Beschränkungsvorschlags) und lassen sich nur schwer innerhalb der von REACH festgelegten Fristen revidieren.

In diesem Zusammenhang gewinnen die informellen Konsultationen, die RMOAs oder Beschränkungsvorschläge (Calls for Evidence) unterstützen, besondere Bedeutung. Da beide Konsultationen von REACH nicht vorgeschrieben sind, bedeuten sie für die Behörden einen zusätzlichen Zeit- und Arbeitsaufwand im Vergleich zu dem gesetzlich vorgesehenen Prozess: Die Behörden, die die Konsultationen durchführen, und die antwortenden Interessengruppen investieren zusätzliche Ressourcen. Dies wäre gerechtfertigt, wenn die gesammelten Informationen im weiteren Prozess Zeit und Ressourcen sparen, d. h. wenn das Ergebnis insgesamt effizienter, schneller und mit weniger Kontroversen erreicht wird. Die deutschen Behörden sind der Meinung, dass die RMOA-Konsultationen in dieser Hinsicht effizient sind, die Datenbasis über die tatsächlichen Verwendungen eines Stoffes vergrößern und helfen, die beste Option zur Kontrolle der Risiken zu identifizieren.

Neben der Datenerhebung, die aufzeigt, welches spezifische Problem angegangen werden muss, sollen die Informationen aus einer RMOA-Konsultation die Auswahl der besten regulatorischen Maßnahme unterstützen. Die „beste Maßnahme“ ist in diesem Zusammenhang diejenige, die die Risiken mindestens auf ein akzeptables Niveau mit den geringstmöglichen Auswirkungen auf die Marktakteure reduziert.

Einbeziehung von Interessenvertretern

Trotz der Unterschiede in den Verfahren stehen alle Konsultationen vor der gleichen Herausforderung: die potenziellen Informationsinhaber zu identifizieren und zu motivieren, an der Konsultation teilzunehmen. Diese Herausforderung ist noch größer, wenn alle gesetzlich geforderten Daten zur Verfügung gestellt wurden und der zusätzliche Informationsbedarf nur von Marktakteuren gedeckt werden kann, die normalerweise nicht von den Konsultationen angesprochen werden.

Die Teilnahme der Stakeholder an allen Konsultationen ist freiwillig, d. h. sie haben ein Recht und keine Pflicht zur Stellungnahme. Daher hängt die Wirksamkeit einer Konsultation weitgehend davon ab, ob es gelingt, diejenigen Stakeholder einzubeziehen, die tatsächlich über die benötigten Informationen verfügen. Dies kann schwierig sein, da die Informationsinhaber häufig nicht direkt von REACH betroffen sind (nachgeschaltete Anwender). Daher sind sie sich der Möglichkeit zur Beteiligung viel weniger bewusst als z. B. die Registranten. Da auch die

Behörden die Identität der nachgeschalteten Anwender nicht kennen, können sie diese nicht direkt ansprechen und zur Konsultation einladen. Dieses Dilemma kann nicht „generell“ gelöst werden und wird derzeit durch die aktive Kommunikation der ECHA und der anderen Behörden, auch an die breitere Öffentlichkeit und über soziale Medien, angegangen.

Die Herausforderung, die „richtigen“ Interessengruppen in Konsultationen einzubeziehen, ist ein besonderes Problem, wenn es um Informationen über die Verfügbarkeit von Alternativen geht (Konsultationen zu AfAs, Beschränkungsvorschlägen sowie Calls for Evidence und RMOAs). Anbieter und Nutzer von Alternativen beteiligen sich häufig nicht an Konsultationen, weil sie davon keine Kenntnis haben. Sie sind weder direkt vom Regulierungsprozess betroffen, noch erwarten sie positive Markteffekte durch die Abgabe von Kommentaren und Informationen. Es ist auch möglich, dass Anbieter von Alternativen den zur Diskussion stehenden Stoff für die Regulierung bereitstellen. Ihr Interesse, sich an einer Konsultation zu beteiligen, ist in der Regel gering, wenn die Marktdurchdringung des Alternativprodukts wirtschaftlich weniger erfolgversprechend ist als die Absicherung des Marktes des „etablierten“ Produkts. Ein weiterer Grund für die Nicht-Beteiligung an Konsultationen kann die Befürchtung sein, dass Informationen, die zum Ausstieg aus der Verwendung eines Stoffes beitragen, „zurückgegeben“ werden könnten, wenn das eigene Produkt Gegenstand der Vorbereitung einer Regulierungsmaßnahme und einer damit verbundenen Konsultation ist. Hinzu kommt, dass die Konsultationen relativ kurze Zeitrahmen haben. Dies macht es für Dritte, die Informationen bereitstellen wollen, notwendig, die Prozesse aktiv zu verfolgen und ihre Argumente frühzeitig vorzubereiten. Dies ist zwar ein Hindernis für alle potenziellen Einreicher von Daten, besonders relevant ist es aber für alle Akteure, die nicht direkt von einer geplanten Regulierungsmaßnahme betroffen sind und die ein geringes/kein wirtschaftliches Interesse an der Kommentierung haben. Insgesamt gibt es also viele verschiedene Gründe für eine Nicht-Beteiligung der Akteure an den Konsultationen.

Schlussfolgerungen

Zusammenfassend lässt sich sagen, dass die Konsultationen effektiv, effizient und ausreichend transparent sind, wenn sie spezifische Themen betreffen und einen klar definierten Umfang haben, z. B. im Rahmen einer SVHC-Identifizierung. Allerdings reichen Konsultationen unabhängig davon, welchen Regulierungsprozess sie unterstützen sollen, nicht aus, um Informationen über Alternativen zu sammeln. Der Mangel an Informationen, die für die regulatorische Entscheidungsfindung notwendig sind, insbesondere über Alternativen, kann durch die Konsultationen nicht vollständig kompensiert werden. Dies liegt u. a. daran, dass die Konsultationen nicht die „richtigen“ Akteure erreichen sowie daran, dass die Akteure nicht ausreichend von der Bereitstellung von Informationen profitieren. Daher sind weitere Maßnahmen zur Sammlung von Informationen, besonders über Alternativen, notwendig.

Eine Möglichkeit besteht darin, gezielte Recherchen und Untersuchungen zu initiieren, um mögliche Alternativen zu identifizieren und zu bewerten und die Ergebnisse zu veröffentlichen. Diese „unabhängige Alternativenbewertung“ könnte von den Behörden der Mitgliedsstaaten oder von der ECHA durchgeführt werden, je nachdem, welche Behörde für den jeweiligen Regulierungsprozess zuständig ist. Sie könnte auch von unabhängigen Expertengremien durchgeführt werden.

Insgesamt bewertet die Mehrheit der Stakeholder Konsultationen im Rahmen einer RMOA und die Calls for Evidence der ECHA als hilfreich, um grundlegende Fragen von Anfang an zu klären und damit Unsicherheiten in den späteren formalen Prozessen zu reduzieren. Gleichzeitig sind Konsultationen zeit- und ressourcenaufwändig, was nur dann zu rechtfertigen ist, wenn die gewonnenen Informationen die Entscheidungsfindung und die Argumentationen deutlich

verbessern. Andernfalls können diese Verfahren nur zu einer Verzögerung der Regulierung von Stoffrisiken führen, was den eigentlichen Zielen von REACH zuwiderlaufen würde. Die überwiegend positive Bewertung der informellen Konsultationen im Vorfeld der offiziellen REACH-Prozesse und deren zunehmende Anwendung zeigen jedoch, dass weitgehend akzeptiert wird, dass der mögliche Nutzen den zusätzlichen Aufwand überwiegt.

1 Background and Scope

1.1 The Role of Public Consultation under REACH

Before REACH entered into force a key requirement for a new chemicals legislation was the establishment of efficient processes (see COM (2001) 88 final WHITE PAPER "Strategy for a Future Chemicals Policy"). Furthermore, the REACH text urges the ECHA to become a trustful agency (see recital 95) and guarantee transparent processes to gain that trust from all stakeholders.

Therefore, the legislator incorporated several public consultation procedures as part of different REACH processes. An important characteristic of all public consultations discussed in the frame of this study is that they are completely voluntary. There are no mechanisms established in the processes looked at, which oblige certain actors to submit information[1].

Two functions can be seen as the main tasks of such public consultations:

- **Information collection - facts:** One function of the public consultation is to gather facts that allow authorities to assess the needs and options for further regulatory action under REACH[2]. Such facts are e.g. data that support a substance property, as is the case when new substances of very high concern are identified, candidate list substances are recommended for uptake on Annex XIV or new or existing restrictions are issued. Here it is very important for authorities to get the full picture of intrinsic substance properties, the way the substance is used, potential substitution issues and economic impacts of a measure. In these cases, third parties can provide additional information to what has already been collected by the authorities and support a more profound decision making. In some processes, individuals or groups of actors (usually manufacturers, importers, or downstream users of substances) need to interact with ECHA. As part of such interactions, they provide an argumentation based on the actors' knowledge (e.g. when a test is proposed for investigating an endpoint according to Annex IX or X or when Applications for Authorisations (AfA) are submitted). In such situations, public consultations are used to gather more information from third parties not included in the argumentation originally filed to ECHA (e.g. on already existing tests, alternative test methods, or alternative substances or technologies in case of authorisation).
- **Information collection – argumentation (validity of rationale)**: A second aspect of public consultations is the increase of transparency on the argumentation in the decision process and the opportunity for third parties to express their views on the proposed rationale for a decision. This becomes in particular relevant in cases where the activities lead to a market intervention. A part of such processes is also the evaluation of available information. This is not always a yes or no situation but often a controversial discussion with a range of arguments e.g. driven by market interests or a party´s focus on environmental or human health protection. In these cases, a public consultation is the opportunity to provide the individual position of a stakeholder and at the same time

[1] Examples of mandatory information submissions to ECHA are e.g. the notifications implemented in REACH (e.g. for SVHC in Articles according to Article 7 or as a downstream user of a substance covered by an upstream authorisation under Article 66 (1))

[2] Or in the specific case of the Risk Management Option Analysis (RMOA) under other optional regulations

make it available to a broader audience, which can then also develop an own view of the ongoing process and provide further arguments. Such public consultations are issued in the frame of the restriction, especially on the SEAC draft opinion and, with some limitation, the public consultation in the frame of an AfA[3]. The collection of such argumentations results in different weighting of facts, which might lead to a balancing of interests when controversial arguments contribute to decision making.

1.2 Scope of Work

This sub-study deals with the public participation options within the framework of REACH. These are analysed with regard to their efficiency, their effectiveness and their requirements for a transparent procedure. The efficiency is to be seen as a measure of the effort required by the actors to carry out the participation procedure. This includes the effort of the stakeholders to transmit information, but also the effort of the authorities to organise the procedure, to process the information and, if necessary to react to it. The effectiveness is understood as a measure for obtaining the information that is requested within the framework of the respective participation option. Finally, transparency is the measure by which it becomes clear what information has been obtained in the procedure and how this further influences the process.

This report includes the analysis of public consultations in the context of the REACH processes, which are open to all stakeholders. This includes commenting on testing proposals in the context of the dossier evaluation. It also includes the two consultations in the restriction process, the first on the initial restriction proposal submitted to ECHA with the Annex XV Dossier and the subsequent one on the draft opinion by the Socio-Economic Analysis Committee. Three consultations are considered in the authorisation process. Firstly, the public consultation on the candidate list proposals, then on ECHA's subsequent recommendation on the substances that will ultimately be subject to mandatory authorisation and finally on the consultation of concrete applications for authorisation.

In addition to these official procedures provided for in the REACH text, further public informal consultations have been established to gather information from stakeholders at an early stage, which are analysed in this study.

The first is a public consultation within the framework of the so-called Risk Management Option Analysis (RMOA). The RMOA was established as an informal tool for authorities and ECHA to investigate the potential risks posed by a substance prior to any official REACH action and then select the most appropriate instrument in REACH or beyond to eliminate these risks. As the RMOA takes a holistic view of substances to support the selection of the most appropriate risk management measure, it is necessary to obtain a good information base on the uses of the substances. Therefore, many authorities have established some form of stakeholder consultation. In Germany, the authorities have established a public consultation for their own

[3] It should be noted that in the REACH text in Article 64 (2) the public consultation is limited to information related to alternatives. Nevertheless Article 64 (3) highlights that committees (RAC and SEAC) should consider all information that became available to them in the process when making up their opinion.

RMOA procedures through a defined process. This was considered in the context of the research project. Other practices of other Member States were not analysed[4].

The second informal consultation process included in the study is the so-called "Calls for Evidence", which can be carried out by ECHA for the preparer of a restriction proposal. As with the RMOA, the aim here is to broaden the information base at an early stage in order to subsequently arrive at more precise analyses and conclusions with regard to substance risks.

Both consultations are not limited to a certain type of information but have the aim to collect a broad range of facts and arguments to understand the impact of an envisaged regulation before an official regulatory pathway has been entered. They were motivated by a lack of detailed use information, which contrary to the original expectations when REACH was established is not contained in the registration dossiers but is crucial for deciding whether and how a substance should be regulated.

In the context of the research carried out here, it was discussed which role the respective consultation takes on for the respective REACH process (gathering information, balancing interests, generating attention or stimulating substitution). In this context, it was particularly important to determine whether REACH's procedures meet its claim of far-reaching transparency and whether the public is sufficiently involved. Special attention is paid to existing hurdles and obstacles. It was analysed which actors would be the primary target groups of a consultation and how publicising the consultation would be suitable to reach the desired target group. In the next step, it was important to analyse whether the effort for providing information is in line with the possible incentives for participation. This was a particularly relevant question if the transmitters of information do not directly benefit from the activity. At the same time, it is also relevant to analyse whether the additional information generated is sufficiently relevant for the respective REACH process to justify the effort of a consultation (and the associated time expenditure). Additionally, it was considered whether the information contributes to an increase in efficiency of the results of the respective REACH process' products and how the information is used in the further course of the work. Finally, the analysis was linked to the identification of possible weaknesses and, if necessary the derivation of suggestions for improvement.

[4] The RMOA is an informal preliminary stage of the actual REACH risk management procedure. For this reason, there is no formalised procedure for the extent and way in which a public consultation is to be carried out. Slightly different procedures have therefore been established in the individual Member States that carry out RMOAs (cf. BMWi 2019). At the time of writing, most RMOAs were prepared by a few Member State authorities (six) and ECHA. Most of the authorities had established some form of stakeholder consultation or at least had not completely excluded the transmission of information. Germany had already defined a process at this stage, which established a clear procedure for consultation. Therefore, the analysis here focuses on the approach of the German authorities, which conduct a formalised public consultation as part of each RMOA.

2 Characterisation of the Different Public Consultations

In the following section the different public consultations taken into consideration are briefly described with regard to their main objectives and some key characteristics. The aspects relevant for further assessment are derived from this first analysis of the different consultation procedures.

2.1 Testing Proposals

The registration process under REACH obliges manufacturers and importers to collect data according to the Annexes VII to X for the substance they manufacture/import, depending on the tonnage. Some data that need to be generated according to Annex IX and X are based on animal testing with invertebrates. Since REACH tries to limit such animal testing (see recitals 13, 33, 47 and Article 25) and allows the performance of new invertebrate testing only as a last resort, registrants have to submit testing proposals only with their registration dossier, in case data for a specific endpoint are missing for a full assessment. According to Article 40 ECHA has the task to evaluate the need for this new test. Therefore, Article 40 (2) prescribes a public consultation to give third parties that are not involved in the registration the opportunity to provide information on this testing proposal.

Key characteristics of the public consultation on testing proposals are shown in the following Table.

Table 1: Key characteristics of public consultations on testing proposals

Parameter	Key information
Scope	Scientific evidence that helps to evaluate the need for a new invertebrate test
Target group	Data holders for specific endpoints that are not involved in registration
Announcement	Via ECHA website starting page and on special overview site (overview of all ongoing public consultations) • https://echa.europa.eu/ • https://echa.europa.eu/public-consultations)
Execution of consultation	Table with all open consultations in own section (https://echa.europa.eu/information-on-chemicals/testing-proposals/current)
Data submission	Web form
Documentation of closed consultations	Table with all closed consultations in own section (https://echa.europa.eu/information-on-chemicals/testing-proposals/previous/outcome)
Outcome of consultation	No list of comments published, remark that commenting was performed in a process outcome document (not always)
Information requested	• Information on already existing data • Information on alternatives to animal testing
Duration	45 days from publication
Outcome	Decision document, publicly available (PDF) https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status

Parameter	Key information
Remarks	Website overview and additional explanation on ECHA website "Testing proposals consultation" (https://echa.europa.eu/information-on-chemicals/testing-proposals)

Remarks and specific questions for further assessment:

Since the appropriateness of an animal test is part of the negotiations between registrants and ECHA, only the decision documents are made public. These do not contain information if any actor participated in the public consultation and whether the submitted information was helpful for the process. Therefore, for this study it was necessary to contact ECHA and discuss amongst others the following research questions with them:

- To which extent do third parties participate in the consultations on testing proposals? Do they participate at all?
- How can the transparency of this consultation and the further processing of the results be ensured?
- Do third party comments lead to less testing (e.g. animal testing)?

2.2 Information Gathering in the Frame of a Risk Management Option Analysis (RMOA) – German Process

The German REACH authorities implement a public consultation in the frame of the drafting of an RMOA. The public consultation aims to collect relevant information that enables the authorities to evaluate the needs and options for further action. To facilitate this public consultation the leading authority, the "Bundesstelle für Chemikalien" (BfC) offers its own section at the German REACH-CLP-Biocide Helpdesk website in German and in English.[5] Furthermore, the overall approach is explained in an additional part of the website.[6] The public consultations usually start close to the date of publicising the intention to investigate a substance in the Public Activities Coordination Tool (PACT).

Table 2: Key characteristics of public consultations in preparation of an RMOA (German approach)

Parameter	Key information
Scope	Commenting on a regulation intention
Target group	Interested third parties
Announcement / Execution Documentation	Via website starting page (overview of all ongoing and closed public consultations) https://www.reach-clp-biozid-

[5] https://www.reach-clp-biozid-helpdesk.de/DE/REACH/Verfahren/SVHC-Verfahren/Stoffliste-DE/Stoffliste-DE_node.htm (German) and https://www.reach-clp-biozid-helpdesk.de/DE/REACH/Verfahren/SVHC-Verfahren/Stoffliste-EN/Stoffliste-EN.html (English)

[6] https://www.reach-clp-biozid-helpdesk.de/DE/REACH/Verfahren/SVHC-Verfahren/Roadmap-DE/Roadmap-DE_node.html (German)

Parameter	Key information
	helpdesk.de/DE/REACH/Verfahren/SVHC-Verfahren/Stoffliste-DE/Stoffliste-DE_node.html
Outcome of consultation	RMOA outcome document
Information requested	Generally all relevant information that could support opinion making, especially information not available in the registration dossiers. In particular the following information is highlighted: • Tonnage • Use type, operational conditions, information on production process, concentration ranges and resulting expected exposure, information on risk reduction measures • Information on alternatives and socio-economic impacts • Information from other regulatory contexts (e.g. water framework directive) Content or migration measurements or monitoring data/exposure measurements (e.g. at the workplace)
Duration	Two months
Outcome	Comments are not published
Remarks	

2.3 Authorisation

The authorisation process can be divided into three steps. Part of each step is a public consultation. The steps are:

a) Identification of SVHCs;

b) Recommendation for inclusion in the Authorisation List; and

c) Application for Autorisation.

During each step of the process, different types of information are relevant for the assessment. While in the first step the hazardous properties of a substance are discussed exclusively some additional information on the use pattern and tonnage become relevant in the second step. In the third step, during the discussion of a specific AfA the public consultation covers the availability of alternatives (technically and economically).

2.3.1 SVHC-Identification (Candidate Listing)

Article 59 (4) of the REACH text stipulates the public consultation in the frame of the identification of substances of very high concern (SVHC). The scope of this consultation is determined by the content of the Annex XV Dossier that needs to be prepared in order to identify a new SVHC. This is limited to hazardous properties that are included in Article 57 of REACH. Data that either show the presence of a certain property or its absence are mainly of interest. The need for such information can vary depending on the specific property under assessment. In case the substance shall be listed on the basis of Article 57 (a-c) and already has a harmonised classification for this property, the need for additional data is limited as an assessment has already been made with other legislation and new information that disburdens the substance is not very likely. This might be different if it is not fully clear whether a criterion

is fulfilled[7]. In such cases weight of evidence approaches needs to be applied, which can be controversial and might involve data that show the presence of a hazardous effect and other data that show the opposite. In such cases it is likely that participation in the consultation is higher than in other cases.

Table 3: Key characteristics of public consultations on an Annex XV Dossier for the SVHC identification

Parameter	Key information
Scope	Commenting on an Annex XV Dossier on SVHC identification
Target group	Third parties
Announcement	Via website starting page (overview of all ongoing public consultations)
Execution of consultation	Table with all open consultations in own section https://echa.europa.eu/substances-of-very-high-concern-identification
Documentation of closed consultations	Documentation of the entire process on own website section https://echa.europa.eu/identification-of-svhc Details on received comments on substance specific sub-sites in word documents. Also public available decisions as document.
Outcome of consultation	List of all comments and responses to comments (Word format due to integrated additional files such as EXCEL, PDF, Word) https://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations
Information requested Intrinsic properties of the substance	Identity of the substance and intrinsic properties relevant for the identification (unless identification is based on harmonised classification and labelling and cannot be challenged in this context).
Information requested Additional information (requested in practice not foreseen in REACH text)	Additionally, information on uses, exposure potential and alternatives • Is the substance used on its own or in mixtures by professionals or consumers in the EU, and if yes in which applications, in which concentration (range) is the substance present in the mixture, what is the volume per use; • Is the substance present in articles, and if yes, which types of articles; • Is there information on other substance(s) on the Candidate List which could be used as an alternative to the proposed substance in its uses, or; • Is there other relevant information which illustrates the wide dispersiveness of the uses in the EU, e.g., significant monitoring/epidemiological data?
Duration	45 days for the general public[8]
Outcome	MSC agreement, update of candidate list
Remarks	In practice, ECHA already asks for use information (see above). This is not in the scope of the consultation as defined by REACH. Nevertheless, this information

[7] There have been different interpretations in the past when a substance can be considered as bioaccumulative based on Annex XIII of REACH, or whether toxicity can be shown sufficiently to show equivalent concern. Similar is the situation when endocrine properties shall be demonstrated in a case by case discussion.

[8] not defined in Reach text. Article 59 (4) only uses the terminology "within a specified deadline". The 45 days period is then specified by ECHA, REACH only sets a defined deadline of 60 days for comments from MSCAs or ECHA (Article 59(5)).

Parameter	Key information
	is used to decide on the next steps in the process or if it might be reasonable to switch to an alternative regulatory measure. The consultations have been set from March-April and September-October of each year.

Remarks and specific questions for the further assessment:

- What is the typical number of comments usually submitted?
- What is the composition of stakeholders that contributed?
- What information was considered to change the proposal?
- What information was submitted but rejected as irrelevant?
- Are there differences between the number of comments received, which depend on the property under concern (57 a-f)?
- Do contributors limit their comments to the scope of the process?

2.3.2 Prioritisation (Recommendation of SVHC for Annex XIV))

The public consultation on the recommendation for an inclusion of a substance in Annex XIV is defined by Article 58(4). In this article, comments on uses that might qualify for an exemption are highlighted. Nevertheless, the scope is not limited to this question but might also cover other areas, like e.g. the latest information on tonnage or uses that have been included in the opinion making[9].

Table 4: Key characteristics of public consultations on the draft proposal of SVHC for inclusion into Annex XIV

Parameter	Key information
Scope	Commenting on a draft a proposal to define in which order substances from the Candidate List are included in the Authorisation List (Annex XIV).
Target group	Third parties
Announcement	Via website starting page (overview of all ongoing public consultations)
Execution of consultation	Table with all open (and closed) consultations in own section https://echa.europa.eu/recommendation-for-inclusion-in-the-authorisation-list
Documentation of closed consultations	Documentation on the website section and an additional website section where the entire process is documented https://echa.europa.eu/previous-recommendations
Outcome of consultation	Final ECHA proposal on the inclusion of SVHC on the Annex XIV
Information requested Scope	All uses of the substance within the scope of the authorisation requirement

[9] The main source for such information is usually the registration dossier. In practice this source has been proven to be unreliable to a certain degree as it might contain outdated information (e.g. in case a use is not relevant anymore) or is missing use specific tonnage information that might lead to worst-case assumptions by ECHA that overestimate risks that lead to a prioritisation of a substance, but does not reflect the real situation.

Parameter	Key information
Information requested Check if basis for proposal is up to date	Confirmation on • Uses and • Volumes used; • Views on the transitional arrangements and • Possible exemptions.
Duration	3 months at varying times of the year
Outcome	• List of all comments and responses to comments (MS Word® format due to integrated additional files such as MS EXCEL®, PDF® and MS Word®) • Final recommendation to the commission on the uptake of substances on Annex XIV
Remarks	REACH text defines that a proposal should be made at least every two years. ECHA defined as a general rule that a proposal is made every year or one and a half years (this lead to varying starting times).

Remarks and specific questions for further assessment:

- What is the typical number of comments usually submitted?
- What is the composition of stakeholders that contributed?
- What information was considered to change the proposal?
- What information was submitted but rejected as irrelevant?
- Is the provided input appropriate to support the process of developing the recommendation?

2.3.3 Applications for Authorisation (AfA)

When developing an AfA the potential to substitute the SVHC from a use is evaluated in a so-called Analysis of Alternatives (AoA). Therefore, the applicant is obliged to assess all known alternatives (chemicals and technical alternatives) for their potential to be introduced in the use applied for. This also includes assessing the impact from substitution on other members in the supply chain that are supplied with the products of the applicant.

To be able to evaluate the full picture regarding the substitution potential, it is important for the RAC and SEAC to know whether or not there are alternatives that the applicants for authorisation have not been considered at all or if the assumptions regarding the introduction are correct (e.g. suitability for the process, availability, economic feasibility for the applicant etc.).

One key feature of the consultation on AfAs is, that the received information is forwarded to the applicant who can then respond to the comments (also published in the response to the comments document) and give further arguments or clarification why an alternative is not considered suitable or the argumentation is accepted and the application adapted accordingly. After this, the committees finalise their opinions.

Table 5: Key characteristics of public consultations on an AfA

Parameter	Key information
Scope	Commenting on the AoA[10] included in an AfA, information on alternative substances or technologies" (Article 64(2)) and other arguments in favour or against a continuation of a use
Target group	Interested third parties (in particular such that have information on alternatives)
Announcement	Via website starting page (overview of all ongoing public consultations)
Execution of consultation	Table with all open consultations in own section https://echa.europa.eu/applications-for-authorisation-consultation
Documentation of closed consultations	Documentation on the website section and an additional website section where the entire process is documented. https://echa.europa.eu/applications-for-authorisation-previous-consultations
Outcome of consultation	Opinion documents of RAC and SEAC
Information requested Alternative substances or technologies	Information on alternatives (Article 64 (2))
Duration	Eight weeks
Outcome	List of all comments (table on website section) Response to the comments document from the applicant RAC and SEAC opinion
Remarks	ECHA issued a guidance document on this consultation, developed a web format and a template (for upload)

Remarks and specific questions for further assessment:

- What is the typical number of comments usually submitted?
- What is the composition of stakeholders that contributed?
- What information was considered to change the opinion?
- What information was submitted but rejected as irrelevant?
- Is there a sufficient level of detail available for the assessment of the suitability of alternatives?

2.4 Restriction Proposals

When developing new restrictions according to Article 68 (1) two public consultations are foreseen. The first consultation covers all information provided in the Annex XV Dossier (Article 69 (6)). Third parties are asked to provide comments e.g. on the included risk assessment, potential additional exemptions and limit values for the restriction or on the evaluation of included alternatives or the socio economic consequences of the proposed restriction. These

[10] Sometimes combined with the socio-economic analysis (SEA) as one main issue with substitution is the economic impact an introduction of an alternative has.

comments have relevance for the evaluation of the proposal and are considered in the work of the committee for risk assessment (RAC) and the committee for socio-economic analysis (SEAC), and can influence the opinion making.

In a second step, the draft opinion of the SEAC is published for a public consultation and can be commented on by third parties (Article 71 (1)). Here the aim is to gather comments on socio-economic effects and to discuss the appropriateness of the SEAC argumentation.

2.4.1 Annex XV Dossiers

Table 6: Key characteristics of public consultations on Annex XV Dossiers

Parameter	Key information
Scope	Commenting on an Annex XV Dossier on • Proposal of a new restriction • Change of an existing restriction under Article 68 (1)[11]
Target group	All interested parties (EU and non-EU stakeholders)
Announcement	Via website starting page (overview of all ongoing public consultations)
Execution of consultation	Table with all open consultations in own section (https://echa.europa.eu/restrictions-under-consideration) With link to proposal specific sub-page in a web format
Documentation of closed consultations	Documentation of the entire process in the registry of intentions (https://echa.europa.eu/registry-of-restriction-intentions)
Outcome of consultation	List of all comments and responses to comments (Word format due to integrated additional files such as EXCEL, PDF, Word) RAC opinion, draft SEAC opinion
Information requested Scope of restriction, analysis of restriction options	• Information on products (substances, mixtures, articles) • Information on activities that are a potential subject of the restriction (manufacturing, placing on the market, use) • Restriction options (e.g. total ban, limit values such as maximum concentration, migration limits, labelling, restricted sales practices such as sale only for professionals etc., training) Proposals should be justified based on either risk or socio-economic elements (or both). ECHA highlights that RMOs other than restrictions (e.g. different EU wide legislation) need to be supplemented with both risk and socio-economic arguments, as these will be forwarded to the COM without further processing of RAC and SEAC (since their mandate only covers REACH).
Information requested Hazard or Exposure	Intrinsic substance properties • Studies that have not been considered • A wider analysis of the hazard to enable RACs understanding of the impact of the new information (in case the study does not result in a complete revaluation by the dossier submitter). • Exposure information (measured or modelled)
Information requested Environmental emissions	Emission to the environment Monitoring data in various environmental media

[11] In the frame of a new restriction following the procedure of Article 68 (2) a public consultation is not formally prescribed.

Parameter	Key information
	Monitoring data from specific industrial plants, a national or EU sector Information on emission factors (e.g. assumptions on releases, effectiveness of risk management measures)
Information requested Baseline	Responses on assumptions on the baseline (what is the current situation without the restriction)
Information requested: Description of analytical methods	Available testing methods in regard to the scope of the proposed restriction and related limit of detection and limit of quantification (what can be suitable restriction limits)
Information requested Information on alternatives	Identification of technical or economic alternatives Related risk or hazard information Evidence on the suitability of alternatives (already discussed in the dossier or new ones)
Information requested Information on costs	Cost of proposed restriction (direct, indirect in the supply chain) • Cost of substitution • Testing cost • Remediation cost
Information requested Information on benefits	Comments on benefits human health and the environment (qualitatively or quantitatively)
Information requested Other SEA issues	• Affordability • Effects on SME • Effects on stocks or recycling • Supply chains • Spare parts • Market analysis
Information requested Transitional period /deferred entry into force	Transitional periods or entry into force (minimisation of costs and maximisation of benefits Sufficient for supply chains affected
Information requested Request for exemption	Responses that propose new exemptions (with justification) Information on already proposed exemptions (risk, cost)
Duration	6 months from publication
Outcome	Final restriction proposal, publicly available (PDF), sometimes with additional background document Documentation of the entire process in the registry of intentions (https://echa.europa.eu/registry-of-restriction-intentions)
Remarks	If information has been evaluated as relevant, the opinions of RAC and SEAC might recommend an adapted version of the original restriction proposal (or even recommend not putting a restriction in place). Other information is discussed in the outcome document.

Information requested based on ECHA „public consultation guidance" (retrieved August 2019)

Remarks and specific questions for further assessment:

The consultation process and all information submitted is public (except for parts that have been claimed as confidential).

The outcome documents can be analysed by the following key questions (informed by case studies generated in the frame of WP 5.1):

- What is the typical number of comments usually submitted?
- What is the composition of stakeholders that contributed?
- What information was considered to change the proposal?
- What information was submitted but rejected as irrelevant?

2.4.2 SEAC Draft Opinion

While the risk-related questions of a restriction proposal more or less allow the identification of a risk, the socio-economic interpretation of the effects of that risk and a potential restriction might be subject to intensive discussion and interpretation. Therefore, REACH foresees a second round for commenting on the SEAC's draft opinion and the assumptions that formed the basis of it. This additional consultation can further influence the final outcome of opinion making.

Table 7: Key characteristics of public consultations on the SEAC draft opinion (restriction proposal)

Parameter	Key information
Scope	Commenting on the SEAC draft opinion for a • Proposal of a new restriction • Change of an existing restriction under Article 68 (1)[12]
Target group	Third parties (EU and non-EU stakeholders)
Announcement	Via website starting page (overview of all ongoing public consultations)
Execution of consultation	Table with all open consultations in own section (https://echa.europa.eu/restrictions-under-consideration) With link to proposal specific sub-page
Documentation of closed consultations	Documentation of the entire process in the registry of intentions (https://echa.europa.eu/registry-of-restriction-intentions)
Outcome of consultation	List of all comments and responses to comments (Word format due to integrated additional files such as EXCEL, PDF, Word)
Information requested Scope of restriction	Comments can be given on any issues related to the scope, such as • Substances covered, • Any relevant concentrations limits and • Any derogations proposed (or not proposed).
Information requested Justification that an EU wide measure is needed	Comments can be given, if an EU wide measure is needed
Information requested Justification that the restriction is the most	Comments may be given on the proposed restriction option related to • Effectiveness, • Enforceability,

[12] In the frame of a new restriction following the procedure of Article 68 (2) the SEAC is not involved.

Parameter	Key information
appropriate EU wide measure	• Monitorability, • Cost or benefit.
Duration	2 months from publication
Outcome	Final SEAC opinion Documentation of the entire process in the registry of intentions (https://echa.europa.eu/registry-of-restriction-intentions)
Remarks	

As with the public consultation of the restriction proposal, the commenting on the SEAC draft opinion can be assessed. An additional aspect to focus on could be an assessment on whether the information submitted in this commenting round is new or just repetitive arguments and information that was already submitted in the first public consultation of the proposal (this could be an indicator for the efficiency of the second consultation in the frame of the restriction). So some key questions would be:

- What is the typical number of comments usually submitted?
- What is the composition of stakeholders that contributed?
- What information was considered to change the proposal?
- What information was submitted but rejected as irrelevant?
- What information is doubling the public consultation on the restriction proposal (the initial public consultation on the Annex XV Dossier)?

2.4.3 Call for Evidence in the Frame of the Development of an Annex XV Dossier for a Restriction Proposal

The Call for Evidence is a voluntary public consultation in preparation of a restriction proposal. It is voluntary for all stakeholders including the authorities. Nevertheless, all actors have a certain interest in that process.

The authorities need extensive data to show the risk, which is a precondition for a restriction, to specify the scope of the restriction and to evaluate the consequences of a restriction. The more data they have at this pre-processing stage, the more precise the actual Annex XV Dossier can be.

On the other hand the interaction with other stakeholders also allows information holders to support the restriction and to prevent unwanted developments. They can e.g. provide information on the lack of alternatives in certain uses or the high socio-economic impact in order to get an exemption. They can also help to define the level of control, adjust assumptions on tonnages etc. On the other hand, stakeholders can also introduce particular problems they are aware of which would need to be addressed. It would be even possible to consider a "no regulation" or a regulation under a different legislation in the light of the additional information.

As a result, a broad participation in this consultation could reduce the need to comment on the resulting Annex XV Dossier at a time where the authorities have a wider range of options to deal with a substance without having invested all the efforts in preparing a restriction proposal.

Table 8: Key characteristics of Calls for Evidence (preparing a restriction proposal)

Parameter	Key information
Scope	Commenting on a potential restriction proposal (before an official process is initiated)
Target group	Interested third parties
Announcement	Via website starting page (overview of all ongoing public consultations)
Execution of consultation	Table with all open consultations in own section https://echa.europa.eu/calls-for-comments-and-evidence
Documentation of closed consultations	Only documentation of the activity on a website section and an additional substance specific website section, comments are not published. https://echa.europa.eu/previous-calls-for-comments-and-evidence
Outcome of consultation	Depending on results, potentially an Annex XV Dossier with a restriction proposal
Information requested Scope of potential restriction, analysis of restriction options	• Information on products (substances, mixtures, articles) • Information on activities that are a potential subject of the restriction (manufacturing, placing on the market, use) • Restriction options (e.g. total ban, limit values such as maximum concentration, migration limits, labelling, restricted sales practices such as sale only for professionals etc., training) • Proposals should be justified based on either risk or socio-economic elements (or both).
Information requested Hazard or Exposure	Intrinsic substance properties • Studies • A wider analysis of the hazard to enable RAC's understanding of the impact of the planned restriction • Exposure information (measured or modelled)
Information requested Environmental emissions	• Emission to the environment • Monitoring data in various environmental media • Monitoring data form specific industrial plants, a national or EU sector • Information on emission factors (e.g. assumptions on releases, effectiveness of risk management measures)
Information requested Baseline	Information on the baseline (what is the current situation without the restriction)
Information requested Description of analytical methods	Available testing methods for the substance under consideration and related limits of detection and limit of quantification (what can be suitable restriction limits).
Information requested information on alternatives	• Identification of technical or economic alternatives • Related risk or hazard information • Evidence on the suitability of alternative (already discussed in the dossier or new ones)
Information requested Information on costs	Cost of a potential restriction (direct, indirect in the supply chain) • Cost of substitution • Testing cost • Remediation cost

Parameter	Key information
Information requested Information on benefits	Comments on benefits for human health and the environment (qualitatively or quantitatively)
Information requested other SEA issues	• Affordability • Effects on SME • Effects on stocks or recycling • Supply chains • Spare parts • Market analysis
Information requested / Transitional period / deferred entry into force	Transitional periods or entry into force (minimisation of costs and maximisation of benefits) Sufficient for supply chains affected
Information requested / request for exemption	Responses that propose exemptions (with justification)
Duration	Not defined (usually between 2-3 months)
Outcome	Comments are not published and are used internally.
Remarks	The intention is usually supported by a short background document that defines the initiative.

3 Assessment of the Different Public Consultations

In the following sections, the assessment of the different public consultations under consideration will be described. The various processes will be assessed according to the key parameters

- Efficiency,
- Effectiveness and
- Transparency.

Before details of the assessment for the individual public consultations are presented, the general approach of the assessment is described in more detail.

The efficiency of the process in the understanding of this report covers an assessment of the way the consultation process is organised. It will be assessed what type of information is requested (facts, argumentation, both), how the data can be submitted and used for the particular process. The assessment of the efficiency also covers aspects regarding the efforts needed to execute the public consultation. This covers efforts to arrange the consultation, collect the information, and to process it. It also covers the efforts to generate or gather information and provide it to the consultation process.

Regarding the effectiveness of the consultations, it will be assessed to what extent the additional information contributes to the outcome of the REACH processes or their individual steps which the particular public consultation contributes to. In practice we will investigate the initial proposal document and compare this status with the final outcome and whether or not the provided information was incorporated.

The last aspect also covers the transparency aspect of the study. Besides the question of how authorities communicate the public consultations, the explanation and guidance provided to specify which type of information should be provided how, it will also be investigated how data are further processed and whether it becomes clear to the information providers how the information is considered and integrated (or not).

For all the processes a description will be made that characterises the type of information requested and the way it is submitted.

It should be taken into account that content is only included in the analysis in order to be able to assess to what extent the function of public consultations is fulfilled. Due to the size of the documents to be considered, it is not possible to analyse in depth whether the individual contributions were appropriate and correct.

The following parameters will be assessed to the degree the public information allows its analysis:

- EFFICIENCY:
  - One parameter for the efficiency of the consultations is the extent to which stakeholders participate in the consultations. Where feasible a differentiation of the different stakeholder groups is made.

- Another parameter for the efficiency of the consultation is the framework in which the consultations are carried out, such as the way in which comments are submitted or the form of the announcement.
- A further parameter is the pre-structuring of the expected information for the orientation of potential participants. This is contrasted with an assessment of the extent to which thematically appropriate comments were provided.

► EFFECTIVENESS
The main indication of the effectiveness of the consultation is whether the information needed by the questioners was received.
This depends on the

- Clarity about what information was needed (sender instructions) and
- The necessity of transmitting extensive papers with a differentiated presentation of the information e.g. differentiation according to roles, types of information, necessity of additional explanation of the relevance of the information (sender's effort for the answer).

► TRANSPARENCY

- The transparency of the public consultation is assessed based on the type of announcement and whether and how the results of the consultation are published afterwards.
- Furthermore, a measure of transparency is the extent to which it is made known that the information received is included in the process steps to be commented on, or in the associated documentation (e.g. Annex XV Dossiers, results documents).

3.1 Assessment of the Public Consultation on Testing Proposals

Efficiency

This consultation supports deciding on whether a vertebrate test in accordance with Annexes IX and X must be provided. The consultation target group is not limited, i.e. all stakeholder groups can participate. However, the fact that only very few actors have relevant information on the substance does limit the actual target group. As indicated in section 2.1 the number of inputs and whether or not there are any comments is not indicated in the outcome document of the testing proposal decision. In their report on "The use of alternatives to testing on animals for the REACH Regulation" (June 2020)[13], ECHA reports having received comments to almost all public consultations launched before 2015. However, the amount of comments decreased to one third of all consultations initiated after 2015.

[13] https://echa.europa.eu/documents/10162/0/alternatives_test_animals_2020_en.pdf/db66b8a3-00af-6856-ef96-5ccc5ae11026

Effectiveness

The discussion on testing proposals is a very specific expert discussion. Despite this, the ECHA report indicated regular contributions from third parties. However, it is unclear to what extent these comments contribute to reducing animal testing. The ECHA report specifies about the comments: "[…] *Many comments received from third parties are about potential strategies that the registrant could use, for example, information supporting weight of evidence, references to open literature and, seldom, potentially relevant studies.* […]"

This might be even more complicated as a collection of existing studies has already been carried out for the registration so that the potential number of scientific studies that have not yet been included in the assessment will be very low.

Furthermore, problems arise from the following points:

- If a test strategy is proposed, the registrant has the opportunity to challenge the alternative approach. According to the ECHA report, the information is often not sufficiently documented to be able to assess whether the endpoints concerned can be conclusively evaluated.
- Another problem is to gain access to any studies mentioned in the input (and to compensate the information owner financially) in order to assess whether they can fill the data gap.

Efficiency/Effectiveness

The number of actors that might be able to contribute to the consultation is generally small. Therefore, the overall number of contributions to the public consultation is also expected to be low. This might be even more so as independent scientists are usually not systematically included in discussions on REACH and therefore might not follow the calls for such public consultations.

Due to the frequently general nature of the comments submitted (apart from references to existing studies), their influence on the testing proposal decision is often low. The ECHA report states that there are, however, a few examples where the comments have led to an adjustment of the registrants' testing strategy and thus contributed (albeit to a small extent) to a reduction in animal testing. However, according to ECHA's report, it is difficult to establish a principle causality between the consensus and the final decision on the test proposals, as in many cases it was decided to carry out the tests.[14]

Transparency

The transparency of the consultation can be evaluated as adequate with some limitations since it is mainly a scientific expert discussion, even though there is less background provided on the individual calls or the outcome of the public consultation. An overall process outcome document is published. It is neither indicated if there was information provided nor what the information was. Consequently, there is no response to the comments document that indicates if and how information was included in the final decision on the testing proposal. In that regard some room for an increase of transparency can be seen (at least regarding the number and type of submissions to the consultation could be published) and could improve stakeholder exchange.

[14] Between 2009 and 2019 in total 1348 tests were conducted. Not all were animal tests as sometimes a tiered testing approach was proposed in the decision, so again it is difficult to assess if the consultation leads to an effective reduction of animal testing.

The documents are easy to find. The only source that could be identified was the above mentioned ECHA report from 2020.

Conclusion

A key problem of the consultation is the fact that assumed data holders that could provide relevant new information are considered to be a relatively small stakeholder group and not necessarily the ones that are already involved in the REACH processes. Nevertheless, the consultation does not cause extraordinary efforts, hence it should remain as an option to introduce new information, in particular, because of REACH´s aim to reduce animal testing to the bare minimum. Room for improvement could be made by investigating alternative announcement mechanisms specific for actors from academia.

3.2 Assessment of the Public Consultation on Information Gathering in the Frame of an RMOA

The overall comparison of the RMOA implementation across EU shows[15] that stakeholder consultations are an important instrument in many member states and also for ECHA. Even though, differences can be observed regarding the way the instrument is implemented. Some MSs organise consultations as a targeted process with selected stakeholders to collect information needed. Others do not have a dedicated structured process but are open to input when the RMOA is prepared. The evaluation in the following is limited to an assessment of the situation as it has been implemented in Germany and as it has been described in chapter 2.2.

Efficiency

The consultation has a strong focus on the market actors. After opening the public consultation, registrants of the substance under consideration, sector associations in relevant use areas as well as notifiers to the classification and labelling inventory according to the CLP Regulation are actively informed about the opportunity to comment and provide information, as described in a general explanatory statement on the website. This seems particularly important as the public consultation is organised by an individual national authority, which might not be noticed in other MSs. Still, as in any public consultation, not all stakeholders that might be affected by the process may be informed properly. One measure to overcome this is the publication of the RMOA intention in the public activities coordination tool (PACT) hosted by ECHA, which provides an overview on all regulatory activities under REACH, including the RMOA process.

Market players appreciate the possibility to provide information at an early stage of the regulatory process to ensure their specific situation is taken into account. Therefore, industry stakeholders and sector associations do contribute to the public consultation organised in this process. It is a particularly good instrument for DUs to provide complex information before the regulatory pathway is chosen. On the other hand, this is precisely where a core problem of such informal consultation lies. The relevant information holders must feel addressed by the consultation and recognise the meaningfulness of participation at this early stage. However, it often turns out that only a regulation activity that imposes a limitation on one's own commercial activity leads to actors becoming aware of a regulatory activity and giving it the priority it merits, so that resources are made available for the preparation of the information.

The incentive for stakeholders of the civil society to participate in the public consultation may vary. Similar to the official public consultation processes they might rather have information on the hazardous properties of a substance than detailed use information. So it is assumed that

[15] See BMWi (2018) REACH beyond 2018 – Restriction and authorisation as regulatory alternatives (Projekt Nr. 021/16) https://www.bmwi.de/Redaktion/EN/Publikationen/Studien/reach-after-2018-complete-report.html

their contribution often has a more general character. Moreover, the process as established in Germany does not explicitly call on these stakeholders to participate in the consultation. The main reason for this is the assumption that the risk-determining information of the commercial uses essentially lies in the hands of the market actors and that this information is required as a matter of priority.

The public consultation is usually structured via an online questionnaire. It is also possible to submit supplementary information.

Effectiveness

The collection of technical information on substance uses and exposures helps authorities to specify initial considerations on the most suitable risk management option and get a better picture of the requirements for future regulation. Experiences from the German activities show that, as a rule, the situation regarding the use of substances was much clearer after the consultation. This enabled a decision to be made as to whether a substance needs to be regulated and how a regulation can be designed, if necessary. This improves the specificity of a later regulation proposal (e.g. under REACH) and may reduce the need for stakeholders to introduce relevant information in official public consultations foreseen under REACH for the first time, which might result in a high administrative burden for the involved parties in opinion-making (usually ECHA secretariat, RAC and SEAC).

An additional feature that might increase the efficiency of the consultation is the option that the involved authorities may organise a follow-up process (e.g. in form of stakeholder meetings or written follow-up) with selected stakeholders to request more data or to clarify the input.

Efficiency/Effectiveness

The public consultation in the RMOA process has the potential to introduce relevant information necessary for the selection of an optimal regulatory (or other) measure to control risks that might originate from a substance. Although extra efforts need to be taken to perform the consultation (as for the entire RMOA), it may increase the efficiency of follow-up steps authorities take, such as:

- Preparations of dossiers for the selected measure. Since additional information supports the definition of the intended scope of a measure, it becomes easier to substantiate it in the necessary documents and the opinion-making and decision process will gain reduced uncertainty.
- Handling comments in foreseen measures (depending on the selected measure) may become less burdensome as stakeholders already made their contributions. Comments then might focus on specific details but not impact the overall picture concerning the assumed risk situation linked to the substance´s use.

In principle, the evaluation of efficiency must be preceded by the recognition that the RMOA (or the public consultation in the frame of its preparation) is an additional informal procedure which causes additional organisational and substantive work for the authorities involved. Overall, it must be stated that the RMOA delays the time it takes to regulate potential risks about one year (in more complex cases even longer, see BMWi 2019). Therefore, it can generally be seen as consuming additional time, delaying the start of formal regulatory actions and thus reducing the efficiency of the overall REACH process. On the other hand, it should also be taken into account that the analysis helps to select the appropriate procedure and that a pre-sorting of the information already takes place on the content level, so that the subsequent work can be

carried out in a targeted manner and, if necessary, more efficiently so that the process as a whole is not prolonged. Ultimately, however, this is also very dependent on the complexity and informational nature of the individual case. Nevertheless, the process is generally accepted and considered helpful when preparing a measure, thus increasing the effectiveness by the collection of relevant information.

Transparency

Compared to the official consultations foreseen by REACH the process is less transparent. Only the announcement is published on the website of the REACH-Helpdesk and is accessible for all stakeholders. Registrants of the substance, C&L notifiers and already known market sectors are actively contacted, which reduces the risk that the consultation is not taken note of. In addition, the intention to prepare an RMOA is published on the ECHA website (PACT).

Neither comments nor the way they have been handled in the RMOA process are published. It is not even published if stakeholders did comment. Also, there is no information if follow-up consultations with selected stakeholders have taken place. Only the RMOA outcome document is available which does not address the consultation at all.

Conclusion

The consultation in the frame of the RMOA can help to overcome the general problem that often insufficient information is available to the authorities on the actual uses of substances and the products (article and mixtures) they end up in. The information as included in the registration dossiers is often too generic to derive decisions on the regulatory pathway needed to control risks in a way that a high level of protection for human health and the environment are achieved and at the same time the market interventions are limited as far as possible. However, this is not always the case and therefore, an RMOA may be generated based on information which already exists and the RMOA's function of information gathering which is performed through the consultation does not come into play (in addition to the actual main task of identifying the best regulatory management option).

At the same time, the information gathered can support the follow-up measures and also might help focus on other public consultations necessary (to assist the generation of questions to address specific data needs).

The more informal process of the consultation in the RMOA might encourage stakeholders to also provide sensitive data. Even more so, as this information is not published by default, (in contrast to most other public consultations officially held under REACH where a specific confidentiality claim needs to be established). Also, the option to clarify the information provided can be seen as a benefit that justifies additional efforts to collect the information.

3.3 Assessment of the Public Consultation in the Frame of Authorisation

3.3.1 Assessment of the Public Consultation on SVHC Identification

In the assessment of the public consultations in the frame of the SVHC identification, ten cases have been analysed in detail (Table 9).

Table 9: Cases selected to analyse the consultation for SVHC identification

#	Substance name	Description	EC/List no	CAS no
1	[4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (Basic Violet)	With ≥ 0.1% (w/w) of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)	208-953-6	548-62-9
2	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol, UV-328		247-384-8	25973-55-1
3	4-(1,1,3,3-tetramethylbutyl)phenol (Octylphenol)		205-426-2	140-66-9
4	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (OPEs)	Covering well-defined substances and UVCB substances, polymers and homologues	-	-
5	Bis(2-ethylhexyl) phthalate (DEHP)		204-211-0	117-81-7
6	C,C'-azodi(formamide) ADCA		204-650-8	123-77-3
7	Hexamethylene diacrylate (HDDA)		235-921-9	13048-33-4
8	Pentadecafluorooctanoic acid PFOA		206-397-9	335-67-1
9	4,4'-isopropylidenediphenol	Bisphenol A; BPA	201-245-8	80-05-7
10	Cadmium		231-152-8	7440-43-9
	Cadmium carbonate		208-168-9	513-78-0
	Cadmium chloride		233-296-7	10108-64-2; 35658-65-2
	Cadmium fluoride		232-222-0	7790-79-6
	Cadmium hydroxide		244-168-5	21041-95-2
	Cadmium nitrate		233-710-6	10325-94-7; 10022-68-1
	Cadmium oxide		215-146-2	1306-19-0
	Cadmium sulphate		233-331-6	10124-36-4; 31119-53-6
	Cadmium sulphide		215-147-8	1306-23-6

Efficiency

The aim of the Annex XV Dossier in the SVHC identification is to clarify the substance property of concern. As a result, comments are often limited in number. In the cases analysed, numbers often range from only 7 to 24. Only in some particular controversial cases were numbers higher and then dependent on the assumed extent of affected users. Higher numbers were observed in the cases of HDDA (32) ADCA (73) and Bisphenol A (173). In these particular cases, a high share of industry stakeholders (associations and individual companies) participated in the consultations. In the cases with a lower number of commenting parties and with less controversial discussion on the hazardous substance properties market actors were less involved in the consultation, sometimes no market actor or a sector association commented. In many cases, other MS authorities were the largest contributor group, either by just showing support for the proposal or providing additional evidence to support the arguments in the dossier. Also, there are some contributions from environmental or human health NGOs, sometimes 4 to 7 contributions more than from the industry.

The consultation is already structured by the input format that requests specific information areas from stakeholders.

Effectiveness

Stakeholders often only get involved in this consultation if the hazardous property is controversial. For a wide range of SVHC proposals, the low number of comments from the industry shows a general agreement on these cases. This confirms other investigations on this process where it is postulated that substance data can be generated in the REACH system with high reliance and thus gives no reason for disagreement. The requested information is usually linked to test data for a particular endpoint to justify an intrinsic property. It can be seen that such information can be considered as expert information and in most cases, there is only little additional evidence that can be provided. In these cases, the dossier submitter can be quite confident that the data presented in the dossier lack relevant gaps and the result of the consultation can be considered highly efficient.

Efficiency/Effectiveness

The SVHC identification process seems to be actively followed by the stakeholders. In the case of controversial discussions, stakeholders have the opportunity to get involved and they actively do so. Sometimes contributions are not fully focussed on the intrinsic properties. Nevertheless, this additional information can be used to adapt the further regulation pathway from a regulation via an authorisation requirement (listing in Annex XIV) towards other measures (e.g. the selection of the restriction under REACH). Hence, it is considered to be relevant (even though it increases the workload for the handling of the comment). Even though stakeholders are involved in the consultation with high effectiveness (sectors organise prepare contributions etc.) a relevant number of contributions does not meet the core aspect of the SVHC identification process.

Transparency

The transparency of the process can be evaluated as generally high. As far as possible, all information is made publicly available. Furthermore, a response to the comments document is prepared including responses from the dossier submitter that indicates which relevance the comment has for the proposal.

The documents are easy to find and all process steps of the authorisation process are collected in one substance-specific internet resource. ECHA continuously tries to improve the traceability of such information, e.g. by including links to the overview in the Registry of Intentions, which

was extended by ECHA beyond the originally defined scope to use it for restriction proposals[16]. It is further linked to in the "Substance Infocards" and several other spots on the website that are linked to the authorisation process in general. All documents, including the ones from past processes, can be accessed.

Some submitters are anonymous so it is not fully transparent towards the broader public who contributed to the consultation.

Conclusion

The public consultation in the frame of the SVHC identification is a purely hazard focussed process and thus a strongly expert focussed discussion. In most cases the discussion on the substance properties is limited due to clear evidence being provided. Only when there is some larger controversy and the argumentation in the dossier is based on a strong weight of evidence approach (e.g. in case of endocrine disruptors (ED)), more contributions from market actors are submitted. Regardless of these observations, there have been no examples in the cases assessed where the SVHC status was not formally established, showing that none of the consultations altered the argumentation significantly.

Nevertheless, the consultation is seen as an important instrument that allows the participation of directly affected stakeholders. Furthermore, in many cases additional information relevant for later stages of the regulatory pathway was submitted and could already be fed into the processes, which ECHA systematically does. Among other things, this finding was an impetus to establish the RMOA. If the information were submitted in one of the official consultations, their particular (narrow) scope might prevent it being taken into account. A holistic approach of asking for different types of information, as it is possible in an informal RMOA consultation, is therefore useful and supports the selection of the most appropriate measure before starting a measure. This could also reduce the number of comments submitted during the subsequent official consultation(s).

3.3.2 Assessment of the Public Consultation on Recommendations of SVHC for Inclusion on Annex XIV

Efficiency

The proposals for the inclusion of SVHCs on Annex XIV are extensively commented by industry stakeholders as well as human health and environmental NGOs.

Industrial stakeholders/associations and individual companies are represented in high numbers (>30). Also NGOs are regularly represented in a relevant number of about five (given the usually far lower overall number that follows chemicals questions across EU). MSs have been represented regularly about five times.

The expected input is to some degree already structured by the outcome of the recommendation. The following areas are of relevance for the consultation:

- General comments on the recommendation to include the substances in Annex XIV and the related prioritisation, including information on tonnages and use patterns. The hazardous properties are not questioned because this is finally clarified in the SVHC identification,

[16] Further extension was made on harmonised classification and labelling requirements which are not in the scope of this report, since they are not a REACH process.

- Comments on transitional arrangements as there are the sunset date and the latest application date,
- Comments on uses that should be exempted from authorisation, including the reasons,
- Comments on uses for which review periods should be included in Annex XIV, including the reasons.

Effectiveness

Many industry stakeholders usually comment in this consultation. However, their information is not always helpful as many comments question the authorisation route in general or request exemptions that are not justified. This is one of the reasons to do consultations before an official process, when the relevant information can be used to target a measure, as is the case in the RMOA. Some examples of exemption arguments include the lack of releases of substances, the lack of possibilities to substitute or a claim that risks have already been addressed and properly controlled by other pieces of legislation (EU wide or national). Such comments in many cases lack justification as foreseen in the legal text[17] (or are at least not a subject in the recommendation process ECHA performs). Nevertheless, ECHA provided extensive responses to all comments, which causes a high bureaucratic burden. Partly they reduce this burden as they refer to answers already given to other comments or answers by an already prepared standard rationale for subjects they expect during the consultation. Only some comments substantially provide input in the requested areas.

NGOs usually welcome the recommendation on a general level. In addition, the main area for comments are the transition arrangements, where usually shorter periods are requested due to the level of risk from using the substances. In some cases, NGOs also indicate that authorisation should not be the regulatory instrument to treat risks as they demand that no uses at all should be authorised (total ban).

Efficiency/Effectiveness

The consultation seems to be very burdensome compared to the amount of information that is provided in the areas that actually should be discussed. Since many market actors want to avoid the burden of an AfA many contributions to the consultation are rather political and do not meet the aim of the consultation or the claims are not justified. Some reasons for the latter can be a lack of understanding of what can be granted as an exemption under the authorisation. One comment often repeated is that the risks are “potentially” covered in other regulation, which usually is actually not the case. Also requests for general exemptions are made for example like the one for scientific research and development, which does not need a specific inclusion in the Annex XIV entry. Other comments like the low potential to achieve substitution (lack of alternatives) are rather issues that need to be discussed in the AfA and do neither affect the recommendation by ECHA nor must they be dealt with in decision making by the EU Commission. Alternatively, such issues could have already been addressed during the preparation of the RMOA (in case one was prepared).

Transparency

The transparency of the consultation can be evaluated as generally high. As far as possible, all information is made publicly available. Furthermore, a Response to Comments Document is

[17] See Article 62 (5, 6), the here mentioned situations refer to the risk assessment in the later application for authorisation. The argumentation often includes a reference to one of these laws (often in relation to the Water Framework Directive and the priority substances identified there) and the claim that the substances are sufficiently regulated there.

prepared including responses from ECHA that indicate which relevance the comments have for the proposal. Since comments that cannot be considered are also included in the document, decision-makers can later take notice of concerns brought forward on the principle authorisation obligation.

The documents are easy to find and all process steps of the authorisation process are collected in one substance-specific internet resource.

Some submitters are anonymous so it is not fully transparent towards the broader public who contributed to the consultation.

Conclusion

The consultations on recommendations for inclusion in Annex XIV result in a high number of comments. Often these comments are politically motivated and do not focus on the input that is expected to be provided. Therefore, the workload for ECHA becomes very high as the process, as agreed by member states, is seen as far more technical/fact-based. The motivation for this behaviour can be explained as a consequence that a much more general debate on the question of which substances should be subjected for authorisation is not foreseen in REACH. Once the substance has been included in the candidate list, the subsequent steps are more or less in the hands of the authorities. MS or ECHA could at that point also decide to prepare a restriction, but this is not something that is foreseen to be discussed with the stakeholders. As a reaction to this situation, the EU COM started to initiate its own parallel consultations to be able to discuss such political evaluations of the suitability and the proportionality of an authorisation obligation and to be able to include other arguments. Still, the official consultation seems to be overloaded with a huge amount of information that is not relevant or justified and thus not proportionate regarding the outcome.

3.3.3 Assessment of the Public Consultation on AfAs

In the assessment of the public consultations of specific applications for authorisation, ten cases have been analysed in detail.

Table 10: Case studies for the application for authorisation

#	Case name	substance
1	Chromium Trioxide *REACH* Authorization Consortium (CTAC)	Chromium trioxide
2	Hans-Grohe	Chromium trioxide
3	Blue Cube	Trichloroethylene
4	Illario Ormezzano oder Gruppo Colle	Sodium dichromate
5	Deza/Grupa Azoty	Bis(2-ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP)
6	Micrometal	Ammonium dichromate
7	Roche Diagnostics	Bis(2-methoxyethyl) ether (Diglyme)
8	Plastic Planet srl	Bis(2-ethylhexyl) phthalate
9	INEOS Styrenics Netherlands BV	Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-

#	Case name	substance
		hexabromocyclododecane, gamma-hexabromocyclododecane
10	DCC Maastricht B.V. OR	Lead sulfochromate yellow (C.I. Pigment Yellow 34) Lead chromate molybdate sulphate red (C.I. Pigment Red 104)

Efficiency

The contributions on the commenting phase of the AfA were sometimes very low to none (e.g. Diglyme) or only a few comments (Ammonium dichromate). Only in exceptional cases, more than 20 contributions were made (e.g. HBCDD).

Most contributions were submitted by NGOs and some also by academia that comment on the existence of alternatives. Only in exceptional cases, comments on alternatives were submitted from industry stakeholders, as has been the case for HBCDD. One reason for industry stakeholders, especially from downstream user sectors, to participate in this consultation is to support the arguments of the applicant, e.g. by indicating the validity of applicability or timelines for substitution.

MS authorities are usually not represented in this consultation as they are mostly represented via the experts in RAC/SEAC[18] or support the later decision in the REACH committee. Furthermore, it is unlikely that information relevant for the AfA is available to a MS authority, such as on alternatives, socio-economic data, etc.

On other aspects of the application, almost no comments could be identified. It is assumed that this might have two reasons:

- An AfA describes a very applicant-centred situation, so it is difficult to comment on risk or socio-economic assumptions (which are furthermore only partly publicly available).
- There is a low incentive for market actors to get involved in the discussion on other market actors' AfAs, except it is obvious that a large share of the industry has already phased out a substance. In this case, granting an authorisation is not acceptable as the level of protection for human health or the environment would be lower than that established throughout the sector (as has been the case for HBCDD).

It is worth noting that producers of potential alternatives hardly appear in the consultations, unless they perform the same process as the applicant or they introduced the alternative and made it available on the market (cf. the cases of HBCDD). The reasons for this observation are unclear but one could be that such market actors do not know about the process or have no incentive to get involved due to a perceived lack of positive market effects.

Effectiveness

Since the AfA is very applicant-centred and large parts are often claimed as confidential it is difficult for third parties in many cases to comment specifically on certain parts (the discussion on alternatives can be seen as an example). The HBCDD examples shows that effective commenting on alternatives was possible as several companies could already report successful substitution. Thus, it was impossible for the applicant to claim the alternative is not available or suitable. Such situations are very rare. Other interest groups like NGOs/academia usually lack

[18] Note: formally the experts are independent. Still many of them have been delegated from the national authorities.

such practical information. As a consequence, the applicant is often able to reject the arguments from the consultation and the arguments of the submitters are hardly considered[19].

Efficiency/Effectiveness

Usually, the participation in the public consultation of AfAs is limited. The lack of participation can be interpreted in different ways or may be a combination of two conditions:

- The representation within the application is accurate. This includes, above all, the analysis of the availability and suitability of alternatives. In some cases, even very few but insistent comments on the existence of additional alternatives than those specified in the application had a relevant impact. The efficiency of the consultation would therefore be very high, as it would reassure SEAC that the information in the application is correct.
- The providers and/or users of potential alternatives are not aware of the consultation or have no incentive to participate in it. In this case, the first interpretation would lead to a false conclusion, which is ultimately caused by the lack of motivation of the actors to participate (or possibly also on unfamiliarity with the processes). Hence, a basic problem of all consultations comes into play, namely that in many cases actors are not reached who are not directly affected by the consequences of banning one or several uses of a substance.

Transparency

The transparency of the consultation can be evaluated as not very transparent because it is possible (and often done) to keep relevant parts of the application documents confidential. This is understandable, as the market actors indeed frequently have to include sensitive business data in their application for authorisation to justify their argumentation. However, this makes it very difficult to comment on specific parts (even more as comments are not limited to a particular subject).

Nevertheless, all information is made publicly available to the extent possible, as foreseen by the REACH text (apart from the testing proposals). Furthermore, a response to the comments document is prepared where the dossier submitter indicates, which relevance the comment has for the AfA and can give a rationale on their opinion.

The documents are easy to find and all process steps of the authorisation process are collected in one substance-specific internet resource. All documents, including the ones from past processes, can be accessed.

Conclusion

Overall, the aim of the consultation on AfAs is to challenge the argumentation of the applicant. It focusses on the termination of the use applied for and to introduce an alternative. Key actors that contribute to this type of consultation are NGOs that aim to increase the level protection of human health and the environment by contributing arguments that support not granting an authorisation. In exceptional cases, this role has also been taken by market actors in a sector, where large shares of the market already introduced an alternative and continued the use of an SVHC is considered not state of the art. While this latter situation has a huge impact on the

[19] It should be noted that the adequateness of an alternative is also a difficult discussion in the opinion making of the SEAC, as it basically faces the same problem that it needs to evaluate them only from a applicants perspective, as it is currently interpreted not from a perspective of other market actors that might have already implemented the alternative but might have other pre-conditions (technically and economically).

opinion-making, mainly of the SEAC, and may result in very short authorisation review periods or potentially to total refusal of the authorisation, contributions by NGOs to date have had less impact, as they are often more general and are not substantiated with technical and economic background information.

The strong applicant oriented evaluation of arguments makes it generally difficult for third parties to challenge the arguments. Over time ECHA has tried to reduce the number of confidentiality claims. Still, this is an additional obstacle for stakeholders to check argumentations in more detail. Furthermore, it seems questionable from an overall perspective, which stakeholders can systematically follow the AfA process since it can be assumed applications will increase over the next years (including review reports). The following general considerations result from this assumption:

- If they contribute to the consultations, the main incentive for NGOs is to prevent an authorisation as they assume continued use would be disproportionate for human health or the environment. Usually, they do not focus on a particular substance or technology, but in general favour the substitution approach. It is unlikely that they can prepare comments for specific AfA due to resource constraints.
- Industrial stakeholders have mainly two incentives to contribute to the consultation on an AfA:
  - They want to support the arguments of the applicant(s): This kind of comment is often submitted by DU sectors that depend on products that contain the SVHC or are produced by using it. These contributions assist opinion-making, especially of the SEAC, but may also bear some risk of being biased due to economic interests.
  - They want to promote a different standard of technology: When large parts of a sector have already substituted an SVHC and by that changed the status quo it can be an incentive for market actors to contribute to the consultation. The reasons could be economic and/or improvements for human health and the environment (sector image).

In many cases there are only few contributions to the AfA consultations. Overall the comments have some value to reduce uncertainties. The preparation of comments that are specific for the AfA can be burdensome and in many cases, the incentive for stakeholders to prepare such input is limited due to resource constraints. Only in exceptional cases where, in the view of a large majority of stakeholders, the use of an SVHC would be authorised that is in opposition of a widely accepted alternative already in practice, the consultation is used to argue against an authorisation. Hence, the consultation rather provides an extra control level not to grant disproportionate authorisations, but in many cases does not provide new information. Still, as the example of HBCDD shows, it may influence the decision strongly. Therefore, it must be seen as an important control instrument during the authorisation process where market sectors and the civil society can balance arguments brought forward by applicants. It is also important to underline some arguments by showing support and confirming some statements made, so RAC and SEAC get a higher level of certainty in their decision.

The main challenges arise from the absence of stakeholders that can provide more details on alternatives, as this information is systematically missing in the process, but should be one main element for the opinion-making.

3.4 Assessment of the Public Consultation in the Frame of the Restriction

In the assessment of the public consultations in the frame of the restriction, eight cases have been analysed in detail (see Table 11)[20].

Table 11: Restriction processes selected as cases for the study

#	Case	Reasoning for selection
1	Diisocyanates	Human health – occupational safety, 68 (1), grouping, DE
2	NMP	Human health – occupational safety, individual substance, 68 (1) Other aspects: NL proposal, defines DNEL[21] as a binding threshold for occupational risk management.
3	Phthalates	Human health – consumer protection, grouping, 69 (2) Other aspects: DK/ECHA proposal (proposal was updated)
4	perfluorinated Silane	Human health – consumer protection, individual substance,68 (1) – Other aspects: DK, respiratory sensitiser
5	PFOA	Environment, grouping, DE, 68 (1) Other aspects: PBT with not classical B
6	Nonylphenol and ethoxylate	Environment, grouping, 68 (1) Other aspects: SE, no PBT, environmental ED
7	D4/D5 (rinse off)	Environment, grouping, 68 (1) Other aspects: UK
8	Microplastics	Environment, grouping, 68 (1) Other aspects: Completely different approach, scope defined by shape, physical occurrence of substances (plastics), ECHA, broad scope with several use specific restriction conditions (assumed to be descriptive rather than conclusive, since it is not expected to be finalised by the end of the project time).

In the following, key findings from the different consultation processes are presented.

3.4.1 Assessment of the Public Consultation on Annex XV Dossiers

Efficiency

Depending on the individual case the contribution from stakeholders in the consultations varied. Contributions ranged from only 13 (perfluorinated Silanes) to 175 (PFOA) with an average of 55 and a geometric mean of 31 (7 proposals excluding microplastics). This general variance is to some extent predictable as it is at least in parts related to the scope of the restriction proposal and the affected number of uses and consequently the number of affected stakeholders. This becomes very obvious when the restriction proposal on microplastic is assessed which has a very broad scope and likewise introduces a different approach to regulate a group of substances. Furthermore, the consultation was organised by topics with two different deadlines. At the time the assessment was done only the first half of the consultation was finalised, but there were already 473 contributions. This shows that the overall engagement of stakeholders might

a) Depend on the substance or group of substances that are intended to be restricted and

[20] In contrast to the sub-study on restrictions, the case on CMR in textiles was excluded as the regulatory pathway following Article 68 (2) does not foresee a public consultation.

[21] Derived no effect level

b) The number of affected industry sectors and the depth of the market intervention resulting from the planned measure.

The largest stakeholder group that contributed to the public consultations were individual companies and sector associations. It was often not possible to assign contributions to individual life cycle steps of the substance use (manufacturer/importer, downstream user or producers/importers of articles). Sometimes it was not even possible to decide at all who contributed to the consultation as the stakeholders have been anonymised entirely (even though one can assume that such contribution was rather made by industry stakeholder. ECHA is fully aware of the identity of each contributor. In that regard there is full transparency towards the core authority that manages the REACH processes, but not towards the broader public.

Many submissions are accompanied by extensive documents that are partly publicly available and partly confidential (fully or redacted).

The public consultations were structured by at least a questionnaire/set of questions. Also, several consultations were accompanied by a background document with an additional explanation on the kind of information that was seen as particularly important to the case under discussion (scientific, technical, impacts on business).

Some information provided was rather general and described impacts on stakeholders, industry sectors on a rather general level. Others were very specific and provided additional background information on specific scientific studies and/or reports.

Effectiveness

In general, the complexity of the information that is requested and provided in the consultations on a restriction proposal is high. To structure the public consultation process ECHA defined focus areas where information should be provided. The microplastics proposal even had a different timeline set for the preferred submission of input. The stakeholders were requested to provide risk-related information first and for a second deadline, information on exemptions and socio-economic impacts to be able to feed the provided information to the respective committee process. In addition, the consultations are more and more prepared by background documents that provide key aspects of the Annex XV Dossier (e.g. explanations on the scope or already identified areas for specific additional information).

Efficiency/Effectiveness

It is difficult to decide if a large share of potentially affected market actors do respond to the consultations on restrictions as there is no baseline known for a specific proposal. Some representativeness can nevertheless be assumed across the industry, as several different sector associations usually participate. There are several public consultations during which position papers of a more general character that expressed concerns regarding a new restriction proposal have been submitted. Sometimes such documents have been provided by several market actors, repeatedly. Hence, no additional new information was provided but still, this information had to be processed several times by ECHA. While on the one hand such behaviour gives some idea on the number of affected stakeholders, it decreases the overall efficiency of information collection.

Concerning the socio-economic effects, the data gap could often be closed with the information provided by the market actors. In many cases, the information provided by market actors or the sector associations was also linked to a request for an exemption from the proposed scope of a restriction or the adaptation of limit values to be able to meet restriction conditions. Such information was well suited to avoid unintended effects. Nevertheless, it was not always clear if

exemption claims were properly justified. That revealed some level of uncertainty to the evaluation, but often requested exemptions were implemented, at least partly.

NGO information was often more general and in support of proposed restrictions as potential chemical risks were emphasized. In some cases, specific exemption proposals were criticised and a stricter measure was requested. Nevertheless, these contributions are important to reflect the effect a measure for society and to adjust a naturally, somewhat biased contribution by market actors that have some interest to continue the use of a substance.

Another strategy to provide information was often chosen by environmental or consumer NGOs. Here information that was intended to be provided was often pre-discussed and approved by several NGOs. As a consequence, the overall number of contributions from this group was rather low but represented a larger share of an NGO community.

Submissions by member states are very much to the point. Many contributions are made to support the general restriction proposal. Information is specifically aimed to propose changes or add new information to support already included claims (e.g. additional studies on a hazardous property).

Transparency

The transparency of the process can be evaluated as generally high. As far as possible all information is made publicly available. Furthermore, a response to a comments document is prepared where both responses from ECHA and the dossier submitter are included. This response indicates, which relevance the comment has for the restriction proposal and if it contributes to the ongoing refinement of the proposal.

The documents are easy to find and all process steps of the restriction process are collected at one substance-specific internet resource. ECHA continuously tries to improve the traceability of such information, e.g. by including links to the overview in the Registry of Intentions, in the Substance Infocards, and several other spots on the website that are linked to the restriction process in general. All documents, including the ones from past processes, can be accessed.

As a larger share of information submitters – it is valid to assume these are all industry stakeholders from the content of the submissions – tends to be anonymous it is not fully transparent towards the broader public who contributed to the consultation.

Conclusions

In general, the public consultation is essential for the preparation of a restriction as it is the only official process step to introduce and discuss major changes to a proposal, such as the restriction's scope and the potential introduction of (new) exemptions, limit values relevant for later enforcement or other conditions of the intended restriction (.g. risk reduction and/or remediation measures). In this context, it is important to note that amendments that have not been discussed in the consultation cannot become part of the decision, as this would undermine the right to stakeholder participation specified in REACH. The main problem is the strict timelines defined by REACH for the opinion-making of RAC and SEAC. More complex comments like e.g. argumentations that substantiate an exemption have to be evaluated under time constraints and might lead to sub-optimal results (in the exemplified question the generation of an unjustified exemption or potentially over stringent regulation and negative effects on market actors). This is one of the main justifications for additional stakeholder consultations earlier in a restriction procedure, such as during RMOAs and/or the Calls for Evidence issued by ECHA.

3.4.2 Assessment of the Public Consultation on SEAC Draft Opinions

Efficiency

Overall it can be stated that the number of contributions decreases compared to the initial public consultations. Several contributions were made by stakeholders that already provided comments in the first consultation on the restriction proposal. This partly created a type of dialogue in which agreement/disagreement with changes after the initial commenting round were expressed. So in many cases, it can be seen as a follow-up of the initial information exchange.

The contributions to the SEAC draft opinions were generally more focused on the socio-economic impacts of the planned measure. They often specified information already submitted in the general consultation. In other cases, specific comments to proposed changes of the restriction scope were provided (e.g. adaptations on limit values, exemptions).

Usually, the SEAC structures the consultation with specific questions.

Effectiveness

Due to the follow-up nature of the process, the stakeholders are effectively involved and discussion is often to the point. Nevertheless, sometimes participants repeat input from the initial consultation, which is more linked to risk-related aspects (e.g. derived threshold limits for the determination of a risk – DNEL/PNECs). Such information is not relevant for this process step. Nevertheless, SEAC responds to such contributions and clarifies the situation, thus reducing the efficiency of data collection.

Efficiency/Effectiveness

The contributions to the SEAC draft opinions were generally more focused on the socio-economic impacts of the planned measure. They often specified information already submitted in the general consultation. In other cases, specific comments to propose changes of the restriction scope were provided (e.g. adaptations on limit values, exemptions).

Transparency

The transparency of the process can be evaluated as generally high. As far as possible all information is made publicly available. Furthermore, a Response to Comments Document is prepared where both responses from ECHA and SEAC are included. This response indicates, which relevance the comment has for the restriction proposal and if it contributes to the ongoing refinement of the proposal (or the opinion).

The documents are easy to find and all process steps of the restriction process are collected at one substance-specific internet resource. ECHA continuously tries to improve the traceability of such information, e.g. by including links to the overview in the Registry of Intentions, in the Substance Infocards, and several other spots on the website that are linked to the restriction process in general. All documents, including the ones from past processes, can be accessed.

As a larger share of information submitters tends to be anonymous (from the content of the submissions it is plausible to assume these are very often industry stakeholders) it is not fully transparent towards the broader public who contributed to the consultation.

Conclusion

The commenting phase on the SEAC draft opinion is an important step to fine-tune the proposal also regarding the initial commenting phase and changes to the proposal that resulted from this. Different to the first public consultation that is prescribed in the frame of the restriction, the time frame is more suitable because the main arguments (usually) have already been

introduced. Therefore, comments are mainly about final changes (or support) of the envisaged measures. The process appears is established and, as it follows on from the previous consultation, the stakeholders are in many cases already engaged in the process.

3.4.3 Assessment of the Public Consultation in a Call for Evidence

Efficiency

The Call for Evidence has a clear aim to inform a specific restriction proposal. It is accompanied by a short description of the planned proposal and gives all stakeholders the chance to comment on the process. Depending on the planned proposal the information specifically needed may vary. All affected stakeholders, in particular, DU can provide information on uses and potentially needs for exemptions early in the process which is usually welcomed (similar as for consultations in the frame of the RMOA).

Effectiveness

The information collected during the Call for Evidence has the potential to improve and target the initial idea of the restriction proposal and may reduce the need for stakeholders to introduce relevant information in official public consultations for the first time. This may result in less administrative burden for the involved parties in opinion-making (usually ECHA secretariat, RAC and SEAC).

Efficiency/Effectiveness

The Call for Evidence has the potential to introduce relevant information necessary for the generation of a restriction proposal. Although extra efforts need to be taken to perform the consultation, it may lead to increased efficiency of the authorities' follow-up steps, such as the:

- Preparation of dossiers to substantiate the restriction proposal. Since additional information supports the definition of the intended scope, it may be easier substantiated in the Annex XV Dossier. There may be less uncertainty in the opinion-making and decision process.
- Handling of comments during the public consultation of the restriction proposal might become less burdensome as stakeholders already made their contributions. Comments then might focus on specific details but not impact the overall picture concerning the assumed risk situation linked to the substance´s use.

Transparency

The announcement of the call is facilitated via ECHA´s online resources (website, newsletter). No announcement is made in the RoI or the PACT (different from other consultations) which somewhat contradicts efforts to collect information on ongoing processes for a substance in an overview.

Information received during the call is not published nor are the names of the stakeholders who participated (or if there were comments at all). Nevertheless, the information will most likely appear in the Annex XV Dossier and the source of such information is usually documented there.

Conclusion

Similar to the consultation in the frame of the RMOA, the Call for Evidence helps to overcome the overreaching problem, that often insufficient information is available to authorities on the actual uses of substances and the products (article and mixtures). The information gathered supports the generation of the later restriction proposal and might also assist in focussing the subsequent

public consultations necessary (assist the generation of questions to address specific data needs).

Again, the more informal format of this consultation may encourage the submission of information. The incentive might even be higher for market actors, as the regulatory measure and potential market effects are already clear.

4 Summary, Conclusions and Recommendations

4.1 General Observations

In general, the different consultations considered in this study are different depending on the REACH process they should support. This relates to the specificity of the topic under consideration and, on the other hand the range of possible actors who can be considered as target group. In addition, some consultations are rather "isolated" participation processes (testing proposals, applications for authorisation), while others build on each other. The latter applies, for example, to the RMOA followed by a possible Call for Evidence, the consultation on a restriction proposal and the subsequent SEAC draft opinion. Another example can be the RMOA which triggers an authorisation procedure, including the consultations on the SVHC identification and the prioritisation for Annex XIV inclusion.

Despite these procedural differences, **the same challenge** exists for all consultations**: identifying and motivating potential information holders to participate**. This challenge arises in particular when the REACH core actors have fulfilled their legally binding information obligations (e.g. registration is completed well) and further information is needed that is not directly available to the norm addressees of consultations.

The core difficulty consists in that the actors who hold the necessary information are not aware of the opportunity to contribute and/or have no incentive to do so and can also not be directly addressed by the authorities because they are not known to them. These actors are either the downstream users of the substance under consideration or the providers of alternatives to it. Both groups of actors are frequently not aware that a regulatory action is ongoing that may endanger their business activities (DUs) or provide a good chance to increase the market of their product (alternative providers). Hence, they simply do not know that they could influence the process to their benefit by providing information. It is too high a burden for them (as well as e.g. academia that generate REACH-relevant information) to monitor the regulatory processes under REACH and compile information for the consultation during their day-to-day business. This dilemma of not reaching the "right actors" cannot be solved in a general way and is currently being addressed through active information efforts by ECHA and other authorities.

4.2 Testing Proposals

The consultation on the testing proposals is relatively isolated, although often endpoints are concerned which may also be relevant in the context of SVHC identification. The primary purpose is to prevent unnecessary testing of vertebrates and to use existing data where possible. Basically, this consultation complements the efforts that the registrants should already make to compile all data on a substance in the registration dossier and to determine the hazardous properties on the basis of this data. The identification of new studies should therefore at best only occur in exceptional cases and in these cases only confirm the registrant's own searches in the registration dossier.

This seems to confirm ECHA's observations that in very rare cases additional concrete studies are identified that help to finally assess endpoints. However, it was also observed that fewer and fewer contributions have been received in the more recent consultations. One can only speculate about the reasons. One reason could be that in the early days of REACH, more high tonnage substances were registered, which are/were possibly used by a larger number of stakeholders and were therefore better studied, so that more stakeholders could provide information. More

recent testing proposals concern substances registered in smaller tonnages and are therefore of interest to only a few actors. This may mean that the consultation still reaches information holders with comparable efficiency, but the process becomes less effective because there is simply less data.

Alternatively, it could be that more data is held by actors who are not directly involved in REACH (e.g. researchers at universities) for whom participation generates limited benefit and leads to additional work. In this case, the procedure as such would not be particularly efficient in identifying new sources of information and its effectiveness in reducing testing on vertebrate animals would also decrease. Which situation is more likely cannot be concluded from the available information.

Overall, the approach of the authorities to inform the public as much as possible about the process by announcing the consultation through their communication channels (website, social media) and to clarify further information on and the role of REACH in relation to animal testing is considered appropriate. It is recommended **to increase in transparency about the number and type of consultation inputs**.

4.3 Public consultation in the frame of the RMOA generation

Consultation as performed in Germany within the framework of the RMOA can at best provide the information necessary to

- Make a well-reasoned decision on whether and which risks exist in the handling of a substance and which is the best regulatory option to address these risks, and furthermore,
- Ensure that the subsequent scope of a regulation is sufficiently well defined either through the choice of instruments or the concrete design and can be implemented by the authorities.

Overall, the RMOA consultation is **initially associated with an additional effort (as is the RMOA as a whole) and it can also lead to a delay of the actual REACH process**. Therefore, the consultation (and RMOA) are only justified if this effort leads to efficiency and/or effectiveness gains during further steps towards a legal regulation of substance risks (in REACH or under other legal instruments). However, the analyses carried out do not allow any conclusions to be drawn on how possible follow-up activities develop (e.g. whether information was provided in the RMOA and then redundantly reintroduced in a follow-up activity). Such an analysis is also difficult to carry out because there is no harmonised procedure for consultation in the RMOA. Some stakeholders who have been involved in the preparation of the RMOA have stated that a consultation should not be excluded in principle (BMWi 2019).

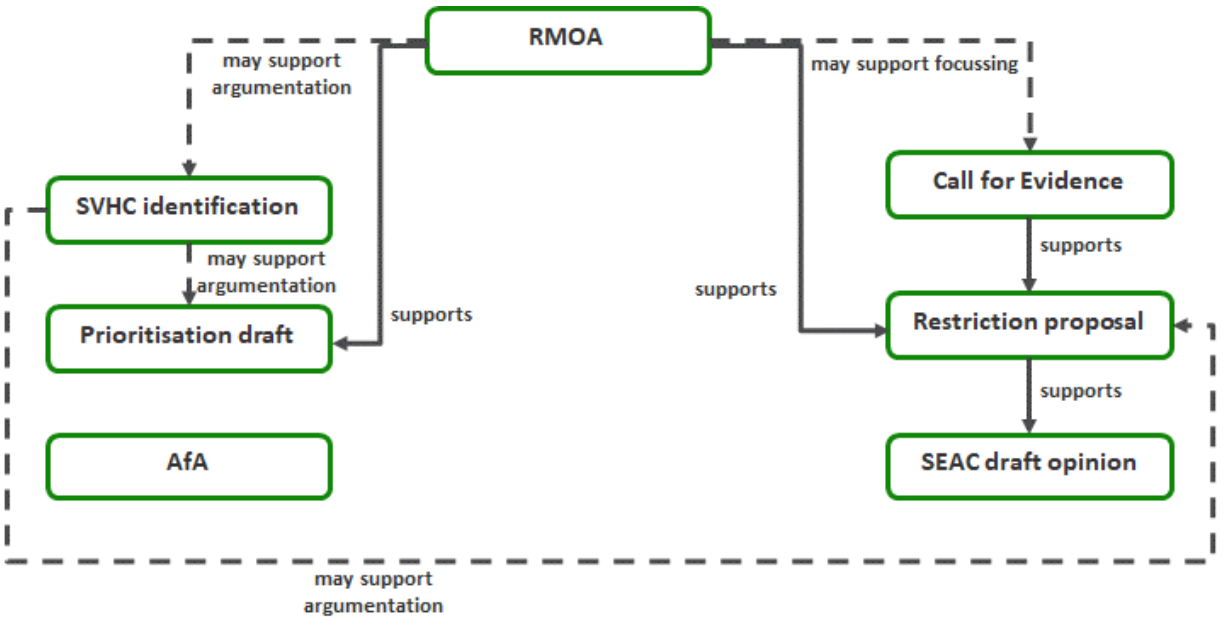
The implementing German authorities stated that **additional helpful information was often provided by market actors.** This made it possible to assess the overall situation in the RMOA and the information could also be used in the follow-up measures.

Similar to the Call for Evidence, the **main advantage of the consultation in the RMOA is that a certain flexibility in terms of timing is possible and, if necessary, individual important aspects that come up can be dealt with in greater depth**. In the official consultations the authorities have to determine the relevance of the provided information, close potential data gaps or challenge claims that have been provided within deadlines of only a few months. This might result in the implementation of sub-optimal measures, where e.g. exemptions have been

granted without appropriate reasoning or have been rejected although needed by certain market actors.

A significant advantage of the consultation in the RMOA results from its upstream nature. In many of the other consultations examined, the stakeholders felt the need to provide additional information, which was not the subject of the respective participation opportunity. Often, this information could be fed into later procedural steps, but then it was not possible, or only possible with difficulty, to revise fundamental decisions. For example, it was not possible to switch to another regulatory instrument within REACH or beyond. The following figure shows how information collected in the RMOA can also be used in other process steps and thus possibly contribute to reducing the need for third-party involvement in these steps.

Figure 1: Potential positive impacts of the RMOA-related public consultation on other REACH processes and public consultations



Source: Own illustration, Ökopol

Despite the described advantages, the RMOA-related consultation bears the risk of only reaching stakeholders who are already involved with the substance (focus of the German procedure initially are the registrants) or who are aware of the use/utilisation of the substance. Another problem preventing the involvement of stakeholders in a consultation exists, where the consulting authority is located in a member state with a different language. This may be true especially in the case of SMEs.

Greater **harmonisation in the approach** between the member states with regard to stakeholder involvement in the RMOA would therefore certainly be an **option**

- **To promote this possibility for the transmission of information and**
- **To create trust in such an informal process (and then also to formalise it to some extent)**.

If necessary, it would also be a good option to **create a common platform for all RMOA activities, possibly located within ECHA, and thus to centralise the collection of information and also to standardise the approach to stakeholders and to use the large reach of ECHA**.

With regard to transparency, there is no need to initiate additional processes, as **relevant information can be included in the follow up documents itself and its origin can be made transparent there** (comparable to thematic studies that are also used to collect information).

4.4 Public consultations in the frame of the authorisation process

In contrast to the consultations for restrictions, the consultations under the authorisation process build on each other less strongly and there is no refinement of arguments. However, the subject matter of each consultation is also much narrower and more focused. A direct link between SVHC identification and prioritisation only exists if the discussed property addresses PBT/vPvB properties, as these are prioritised.

In the case of consultations on specific applications for authorisation, the comments refer to the specific use and possibly emerging non-use scenarios, available alternatives, etc. Thus, there is no interrelation to the identification or prioritisation of SVHCs.

4.4.1 Public consultation on SVHC identification

The consultation on SVHC identification is narrowly limited to information on the hazardous property under discussion. Due to the use of the candidate list in numerous supply chain processes, the inclusion of new substances is of great importance for many market players. This results in a **high level of awareness of the SVHC identification process**, which leads to stakeholders following the process closely and, if necessary, actively accompanying it. The SVHC identification, is a particularly important element in the entire REACH system and is possibly better perceived than, for example, the consultation on prioritisation for Annex XIV inclusion or the consultation on the testing proposals, which also concerns hazardous properties (often also similar endpoints), but which does not result in any direct obligations for stakeholders. The content side of the consultation is apparently (now) **well understood by the stakeholders** invited to comment and the comments often relate to the interpretation of toxicological data, the addition of new data or argumentation on a weight of evidence approach. It can therefore be considered very efficient, as only a **small amount of information not related to the subject matter** of the consultation is submitted. **The targeted feedback is also promoted by the format of the comments**, which again clarifies which data are expected. The use of such formats should be further developed and also extended to other, possibly more complex consultations (restriction, RMOA) in order to further promote the focus on relevant information and also to be able to bundle duplications (cf. section on restrictions).

In terms of transparency, a full response to the comments document is published and all information on a procedure is documented in one place on the ECHA website. **No need for further adjustments regarding the transparency is seen here**.

4.4.2 Public consultation on recommendations for inclusion on Annex XIV

A **core problem of the consultation on the Annex XIV recommendations is the effectiveness with which the quite numerous comments support the process**. Prioritisation is carried out by ECHA on the basis of a few well-defined evaluation criteria. These criteria are in most cases **sufficiently backed up with information** (tonnage scale, use patterns - wide dispersive, point sources) or already clarified in the SVHC identification (PBT, vPvB). Therefore, the **need for further information for the process is already limited**.

However, numerous stakeholders (companies and associations use the consultation to question the appropriateness of the authorisation route to achieve substitution that is technically and economically feasible. Since this is not the task of this process and was not foreseen in REACH,

the effectiveness is reduced by off-target input. However, it should be noted that arguments addressing issues beyond the subject of SVHC identification and prioritisation are not requested at any point so that stakeholders do not have the opportunity to introduce them. When prioritisation of SVHCs for Annex XIV began, it became evident that the decision-making would benefit from a broader information base. Therefore, the Commission carried out its own additional information gathering in order to prepare the political decision. Although improving the information base, the consultations were carried out late in the processes and fundamental decisions could either not be revised or only by pursue a completely new approach (i.e. already invested resources were largely in vain). **This problem has been taken up by the authorities and the COM and the RMOA has been introduced**. Here, the practice of enabling stakeholders to participate in the form of information transfer was established.

In terms of transparency, a full response to the comments document is published and all information on a procedure is documented in one place on the ECHA website. **No need for further adjustments regarding the transparency is seen here**.

4.4.3 Public consultation on AfA

In the consultation on the AfAs, it could be observed that the arguments were not exclusively limited to the actual subject of consultation, the availability of alternatives. However, this formed the core of the discussions, so that the total number of comments was relatively low in many cases (approx. < 20). This can be explained by the fact that with **a broad availability of alternatives, the granting of authorisation should only be successful in a few cases**. Many **AfAs take a corporate or sectoral perspective** and therefore cover a relatively narrow scope and also reflect a certain state of the art. **Commentaries by third parties (NGOs, academia) therefore often have the character of theoretical references** without addressing details of the concrete technical process. This is particularly true when additional alternatives are to be discussed. Comments containing this level of detail are not very effective for the further process, as they can easily be challenged by the applicant. From the Committees' point of view, a more in-depth examination of the information means additional work. **Only in individual cases do other market actors also urge changes in the use of substances and contain therefore a more sophisticated in depth argumentation**.

Overall, it is therefore **relatively difficult to comment specifically on individual aspects of concrete AfAs**, which results in rather less participation by third parties. Furthermore, comments questioning the continuation of substance use are often not in the interest of market actors, either because they themselves carry out comparable uses or because they are profiteers of the uses. Furthermore, the comments **often lack actors who have already realised a successful substitution of the substance or offer alternatives to the market**, perhaps simply because they are not aware of the process, since they are not affected and do not hope for an additional positive market effect from a comment. Another reason may be that alternatives providers also market the products under review and even then have little incentive to comment against their own established products and therefore do not participate. In addition, market actors may find it difficult to provide information that would lead to a discontinuation of the use of substances when they might be the target of a similar activity in another case and then hope that no third party submits comments (e.g. for another substance subject to authorisation). Thus, a fundamentally passive behaviour could rather lead to substances continuing to be used, which could be a systematic problem of a voluntary participation option. Therefore, there is not much motivation to question an application. Rather, it can be observed that in individual cases even companies or associations speak out in favour of a continuation of uses and thus follow more of an interest-oriented commentary approach. It should also be noted that the entire

consultation only has a time frame of 8 weeks, which means that third parties who might be able to comment need to follow current authorisation activities and, if necessary, prepare their arguments at an early stage. This does not appear to be feasible for many actors, as they may not initially be affected by the authorisation requirement themselves and overall there is little interest in the transmission of information.

Therefore, the current assessment of the **AfA consultation is that its effectiveness in influencing opinion formation is limited or rather has its effect in terms of continuing its use rather than questioning it.** Ultimately, it is **uncertain to what extent potential information owners are efficiently addressed to participate**. The above considerations suggest that necessary knowledge is limited (and may need to be complemented with additional research) or that participation in the consultation does not necessarily yield benefits and is therefore not undertaken. Therefore, it seems beneficial to initiate further measures to better feed information on alternatives into the approval process (but also into other regulatory processes). One possibility here could be to initiate targeted research and investigation activities that bear the cost of identifying information and carry out an independent assessment of the alternatives and make this available. This could be a task for the assessment authorities of the Member States and ECHA or could be organised via independent expert panels.

In terms of transparency, a full response to the comments document is published and all information on a procedure is documented in one place on the ECHA website. **No need for further adjustments regarding the transparency is seen here**. One aspect that could be questioned is the widespread practice of declaring (too) many details as confidential (which also applies to application documents). In some cases, it is difficult for third parties to understand how arguments are justified within the framework of the commentary, as background information is not publicly available. Finding a balance here is difficult, but is already well moderated by ECHA. This could be better formalised in the future, e.g. through a clear specification of which data must be included and may not be considered confidential under any circumstances.

4.5 Public consultation in the restriction process

Two formal consultations take place in the restriction process. The first concerns the Annex XV Dossier with the initial restriction proposal and the second concerns the draft opinion of the SEAC. In addition, the Call for Evidence and a consultation within the framework of RMOA generation are directly related to the public consultation in preparation of a restriction proposal. The Call for Evidence is discussed here, as it already takes up some of the suggestions identified and may contribute to overcoming shortcomings.

4.5.1 Public consultation on the Annex XV Dossier

A restriction proposal on its own in many cases **gives stakeholders some incentive to participate in the process** to:

- **Support the proposal or even to call for a stricter regulation**, as the scope of the regulation is not perceived to be broad enough. – often seen for environmental NGOs, national authorities, and sometimes market actors
- To **oppose the proposal, either as a whole or in relation to (the conditions of) individual uses of the substance**, the accompanying conditions of use including the process-related risk management measures or to the higher limit values that form the

framework of the restriction – observed by market actors or industry associations, less frequently by authorities.

The overall **high number of stakeholders taking part** in the consultations on restrictions suggests a **high level of efficiency**. However, one danger of this consultation is that **niche applications are not sufficiently taken into account** when relatively broad scopes are discussed. This problem exists in principle if a broad market intervention is planned, i.e. also in the initial preparation of the dossier, but also in other REACH procedures in which fundamental regulations are made (inclusion in Annex XIV or in the RMOA).

The **information provided in the consultation often leads to adjustments of the original restriction proposals** and can thus be considered relevant and the consultation effective in terms of the ultimate goal of finding an appropriate regulation.

The increased **structuring of the consultation** on the basis of concrete questions, especially in the case of complex restriction projects, also supports the **increase in efficiency** through the systematic collection of information by topic (e.g. affected uses, limit values, effects on companies and markets).

The **multiple submissions of the same recurring arguments reduce efficiency**. It would be desirable to bundle and consolidate the arguments in advance.
This could be done on the part of the submitters by the stakeholders organising their submissions in such a way that the representation of the submission is shown by a co-signature of the individual actors, but the information is only transmitted once. This should be supported by clear communication from the authorities, elucidating that the number of submissions does not determine the relevance of the arguments. There may of course be exceptions, for example when it comes to the individual economic impact on individual market actors. More consolidation on the submitters end might require an earlier pre-announcement of the intended measure. Alternatively stronger promotion of the announcement of the planned regulation within the framework of the ROI could already be sufficient to support stakeholder organisation. There could also be a stronger consolidation of submissions on the part of the authorities, e.g. through automated text recognition and the resulting identification of identical content. In this way, comments with the same content could be aggregated and dealt with once in the Response to Comments Document. Such a measure might have to be linked to a stronger specification of the input formats. At present, it is possible to submit individual and stack-protected documents, which makes such processing difficult.

The **transmission of information at an early stage would** also be desirable (e.g. if information is already being collected in the RMOA in a public consultation or the restriction proposal is being prepared with a Call for Evidence). This concerns, in **particular the desire for exemptions to the restriction and related justifications** of the absence of risk in this area or the socio-economic effects that make regulation unjustifiable when faced with an unacceptable risk. At the same time, this would possibly increase the **effectiveness** of the entire restriction procedure, as the information could be used to adjust the scope right from the start. However, this is difficult in cases where no organisation of the various market players can carry out such information consolidation. An additional general obstacle to participate in the consultation is the lack of the market actors' expertise and resources to provide the information (e.g. SMEs).

A recurring theme in the development of a restriction proposal (but also in the RMOA) is the **lack of knowledge on specific uses and products containing the substances**. One possibility to improve this situation could be to **impose a notification obligation for users of the substance as such, in mixtures or articles when a restriction is announced in the ROI**. This

would impose a legally binding obligation on market players to cooperate, which could increase the **effectiveness of the procedure for the authorities**. At the same time, it should be noted that this could be associated with a considerable effort for market actors. Furthermore, this requires additional time, which could delay the establishment of a measure. Nevertheless, it could close a gap that exists between the actors who already participate voluntarily in the consultations and therefore already expend a considerable amount of effort and those who currently (consciously or unconsciously in the absence of knowledge of the process) do not participate in the consultations.

In terms of transparency, the consultation on the restriction proposals seems to be **sufficiently balanced in terms of protection of confidential information and clarity on the impact in terms of adjustments to the proposal.** The bundling of contributions suggested above would also reduce the burden of replying to comments and still achieve the high level of transparency.

4.5.2 Public consultation on SEAC draft opinions

It should be noted that the consultation on the SEAC draft opinion is based exclusively on arguments that were included in the original restriction proposal or were submitted in the consultation on the latter. Thus, it is emphasised that the range of issues on which the consultation takes place is narrow. **Stakeholders who have already participated in the first consultation will presumably also follow this process and, if necessary, seek additions and clarifications.** Therefore, the efficiency here can be considered very high. Nevertheless, there is an inherent risk that some actors will not (be able or willing to) participate in these voluntary consultations and this could possibly be eliminated with a mandatory obligation to participate. As the **comments are usually very closely related to the SEAC assessments**, the effectiveness is often very high.

The comments may be associated with a **higher level of specificity of information, which makes it necessary to submit individual comments** (e.g. on the availability of alternatives, or economic effects, which may vary considerably and may also be confidential). However, this increases the effectiveness of the consultation. Ultimately, however, **the two-stage consultation in the restriction procedure makes it possible to balance efficiency and effectiveness**.

The transparency of the procedure is comparable to that of the Annex XV Dossier and seems appropriate. All comments are published (within the rules of confidentiality) and their further impact on the development of the restriction will be clarified in the response documents.

4.5.3 Public Consultation in a Call for Evidence

The main contribution of the Call for Evidence is that it offers the possibility to introduce information already before the official restriction procedure starts and thus **improves the information basis for the dossier-creating authority**. This additional effort for the implementation of the additional consultation **leads above all to a temporal deferral of the activities and enables a thorough preliminary examination of arguments regarding an extension of the regulatory scope or possible exemptions**. In addition, the **stakeholders become aware of the procedure at an early stage** and the efficiency of the overall procedure can be increased, as stakeholders as a whole have the opportunity to provide information and, if necessary, to further refine the arguments. Thus, this consultation can contribute to both efficiency and effectiveness.

With regard to transparency, **relevant information can be included directly in the dossier itself and its origin can be made transparent there** (comparable to thematic studies that are also used to collect information). Additional activities for the publication of the information

submitted or in relation to the evaluation of the data, therefore, appear dispensable and would not justify a further workload for these activities.

5 List of References

BMWi (2019): REACH nach 2018 – Unter besonderer Berücksichtigung der Regulierungsalternativen „Beschränkung“ und „Zulassung“ https://www.bmwi.de/Redaktion/DE/Publikationen/Studien/reach-nach-2018-gesamtbericht.html

COM (2001): COM(2001) 88 final “*WHITE PAPER Strategy for a future Chemicals Policy*” https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001DC0088&from=EN

ECHA (2020) The use of alternatives to testing on animals for the REACH Regulation, Fourth report (2020) under Article 117(3) of the REACH Regulation https://echa.europa.eu/documents/10162/0/alternatives_test_animals_2020_en.pdf/db66b8a3-00af-6856-ef96-5ccc5ae11026

ECHA (2018): Strategy to promote substitution to safer chemicals through innovation, main report https://publications.europa.eu/en/publication-detail/-/publication/a5932f85-0571-11e8-b8f5-01aa75ed71a1/language-en

ECHA (2017): Strategy to promote substitution to safer chemicals through innovation, Final Annex MB/58/2017–15/12/2017, https://echa.europa.eu/documents/10162/2792271/mb_58_2017_2_annex_strategy_substitution_safer_alternatives_en.pdf/d1c31c63-4047-e7be-75d1-12320a4a8489

ECHA (2015): Submission of information on alternatives by interested third parties for the public consultations on alternatives for Applications for Authorisation, Instructions & Format, ECHA-13-G-02-EN https://echa.europa.eu/documents/10162/13555/instructions_third_parties_afa_en.pdf/7bcfcfc7-e189-4e65-8e95-3c93520344c3

ECHA (2018): ECHA’s general responses on issues commonly raised in public consultations on draft recommendations, https://echa.europa.eu/documents/10162/13640/recom_general_responses_doc_en.pdf/44e192e5-ac72-4458-b4f5-c016754a1d4c

ECHA (unknown): Public Consultation Guidance (Restrictions) https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c

ECHA (2019): Public consultations in the authorisation process (website), https://echa.europa.eu/public-consultation-in-the-authorisation-process

ECHA (several years), General Report and Consolidated Annual Activity Report

EEB (2017): Restricted Success -EEB’s appraisal of restriction under REACH https://eeb.org/publications/31/chemicals/33788/restricted-success-eebs-appraisal-of-restriction-under-reach.pdf

EEB (2015): A Roadmap to Revitalise REACH - REACH AUTHORISATION PROCESS - A Critical Assessment https://eeb.org/publications/31/chemicals/2349/roadmap-to-revitalise-reach-2.pdf

Ministerie van Infrastructuur en Milieu (MinIenM) (2016): REACH FORWARD - priorities for effective regulation, Discussion paper policy conference Brussels 1 June 2016 – final version