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Advancing REACH: Substances in Articles

Final report

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Advancing REACH: Substances in Articles

Final report

by

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Abstract: Advancing REACH: Substances in Articles

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

The study analyses, under the perspective of the aims of the REACH Regulation and the requirements formulated in the context of the “circular economy package”, the current legal framework of instruments governing the risk management and related notification and communication obligations concerning “substances in articles” (SiA). The study discusses the definition of the term “article” and its interplay with chemical substances contained in the article or that are an integral element thereof. The subsequent sections analyse the communication obligations in the professional supply chain and towards consumers, the provisions on the registration and notification of SiA as well as the authorisation and restriction schemes.

Each section assesses the respective legal framework (objectives, mechanisms, uncertainties) as well as the state of the art regarding implementation and, based on lessons learned, develops policy options to enhance the framework. Tables at the end of each section summarize the options and the expected effects.

Whilst an in-depth impact analysis of the presented options is beyond the scope of the study, the findings suggest the need to clarify the legal context. This is true for each of the problem areas analysed.

Kurzbeschreibung: REACH Weiterentwicklung – Stoffe in Erzeugnissen

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

Die Studie analysiert unter dem Blickwinkel der Ziele der REACH-Verordnung und der im Rahmen des "Kreislaufwirtschaftspakets" formulierten Anforderungen die aktuell verfügbaren rechtlichen Instrumente des Risikomanagements und der damit verbundenen Melde- und Kommunikationspflichten für "Stoffe in Erzeugnissen". Die Studie untersucht die Definition des Begriffs "Erzeugnis" und seine Wechselwirkung mit chemischen Stoffen, die im Erzeugnis enthalten oder ein integraler Bestandteil davon sind. Die folgenden Abschnitte analysieren die Kommunikationspflichten in der professionellen Lieferkette und gegenüber Verbrauchern, die Bestimmungen zur Registrierung und Notifizierung von Stoffen in Erzeugnissen sowie die Zulassungs- und Beschränkungsregelungen.

Jeder Abschnitt bewertet den jeweiligen rechtlichen Rahmen (Ziele, Mechanismen, Unsicherheiten) sowie den Stand der Umsetzung und entwickelt auf der Grundlage der gewonnenen Erkenntnisse „Policy Options“, die zu einer Verbesserung beitragen können. Tabellen am Ende jedes Abschnitts fassen die Optionen und deren erwartete Auswirkungen zusammen.

Eine eingehende Folgenabschätzung der vorgestellten Optionen ist nicht Gegenstand der Studie. Dennoch legen die Ergebnisse nahe, dass der rechtliche Kontext klarstellender Maßnahmen bedarf. Dies gilt für jeden der analysierten Problembereiche.

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List of abbreviations

AfA	Application for Authorisation
Art.	Article
CARACAL	Competent Authorities for REACH and CLP
CBI	Confidential Business Information
CiP	Chemicals in Products
CJEU	European Court of Justice
CMR(s)	Carcinogenic, Mutagenic, Reprotoxic (substances)
EAN	European Article Number
EDC(s)	Chemical (substance) with Endocrine Disruptive properties
EEE	Electrical and Electronic Equipment
FMD	Full Material Declaration
GPSD	General Product Safety Directive (EU Directive)
IR	Information Requirements (in the context of the REACH registration)
IRS	Integrated Regulatory Strategy (as outlined in the ECHA Annual Report)
MoA	Mode of Action
MS	Member State (of the EU)
MSCA	Member State Competent Authority
NEA	National Enforcement Agency
O5A	Once an article always an article
OR	Only Representative
PAH	Polycyclic Aromatic Hydrocarbons
PBT(s)	Persistent, Bioaccumulative and Toxic (substance)
POP	Persistent Organic Pollutant
PVC	Polyvinyl Chloride
RAC	Risk Assessment Committee
RoHS	Restriction of Hazardous Substances (EU Directive)
RMOA	Regulatory Management Option Analysis
RSL	Restricted Substance List
SEA(C)	(Committee for) Socio-Economic Analysis
SCIP	Substances of Concern In articles, as such or in complex objects (Products), in the context of the WFD database on SiA to be established by ECHA
SDS	Safety Data Sheet
SEv	Substance Evaluation (under REACH)
SiA	Substances in Articles
SoC(s)	Substance(s) of Concern
SVHC(s)	Substance(s) of Very High Concern
SWD	(European Commission) Staff Working Document
vPvB(s)	very Persistent and very Bioaccumulative (substance)
WFD	Waste Framework Directive (EU Directive)

Summary

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

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

REACH predominantly deals with industrial chemicals and mixtures. Chemicals, however, are often not the final goal of the industrial processes. Substances and mixtures, in fact, regularly fulfil a specific function on the way to a final product, which is, probably in the majority of cases, an article (as defined by Art. 3(3) REACH). Descending from Directive 67/548/EEC and the subsequent substance-related legislation on EU level, REACH still carries the eggshells of its genesis. Whilst the regulatory framework governing substances and mixtures is well established, the unintended impacts of substances in articles still lack a coherent legislative response.

The provisions in REACH that concern articles appear more like a foreign body in the regulatory framework. The notion of a harmonious fit would be euphemistic. This observation contrasts sharply with the challenges to be tackled in this field. Substances embedded in articles can be found in infant cord blood and in lipid tissue of humans and animals around the globe regardless whether or not they have ever been in direct contact with the article. Other substances released from articles, e.g. during washing, impair the fertility of fish.

Against this background, the study analyses the article-related requirements laid down in REACH. The yardstick for the assessment is formulated in the normative objectives of the REACH Regulation. Its purpose is "to ensure high level of protection of human health and the environment" (Art. 1(1) REACH) whilst at the same time "enhancing competitiveness and innovation". As articles normally face an "end-of-life"-fate a circular economy perspective provides further normative orientation. In terms of resource efficiency, a circular use of material is advantageous. This would be hindered by problematic substances (or "substances of concern") embedded in the articles causing a "riskcycle"-problem. The 2018 amendment of the Waste Framework Directive aims at addressing this issue with a transparency mechanism linked to supply chain communication requirements laid down in Art. 33(1) REACH. The underlying goals in terms of "circular economy" and "toxic-free environment" are ultimately intertwined with the aims of REACH. They are moreover underpinned by the European Commission "Green Deal" (December 2019), the "New Circular Economy Action Plan" (March 2020) and the process towards a "Chemicals Strategy for Sustainability" (Autumn 2020).

The study discusses the REACH requirements addressing the "substances in article" (SiA) issues. The definition of the term article is subject of section 2.1, followed by the communication duties (section 2.2) and the provisions on the registration and notification of SiA (section 2.3). Subsequently sections 2.4 and 2.5 discuss the authorisation and restriction schemes. Each section assesses the respective legal framework (objectives, mechanism, uncertainties) as well

as the state of the art regarding implementation and, based on lessons learned, develops potential enhancements (policy options). Tables at the end of each section summarize the options and the expected effects. An in-depth impact analysis of the presented options, however, is beyond the scope of the study.

The final chapter provides in the form of a summary table a synopsis of all policy options as well as, to the extent appropriate, a comparative assessment of options.

The work draws on literature research, including documents and studies in the course of the REACH REFIT-process. Besides, expert input by German authority representatives involved in the various procedures of REACH was received on the draft report. Nevertheless, the report presents the opinions of the authors.

In view of the objective of ensuring coherence between substance-related and article-related elements of REACH, both sectors can learn from each other. The consumers' "right to know" in Art. 33(2) REACH does not cover mixtures contained in articles or that are an integral element thereof although the related risk level cannot be regarded substantially lower. On the contrary, unintended effects might occur here to at least the same extent. Hence, the transfer of product-related information requirements should be considered. Closely linked to this policy option is the question how communication on "substances of very high concern" (SVHCs) can be improved. The report discusses more than a dozen approaches in this respect (summarized in Table 1).

Table 1: Overview of policy options addressing the communication on SVHCs in articles

Subject matter	Type	Purpose
Standardised data structure and exchange format allowing harmonised SiA communication	Supportive action, mandate to standardization bodies	Facilitate data transfer along the supply chain
Organisation of supply chain communication	Non-binding guidance	Facilitate data transfer along the supply chain
Proper Enforcement	Administrative action (coordinated, e.g., by ECHA Forum)	Compliance with REACH SiA provisions
Labelling requirement for SVHCs	Amendment of the REACH text; ordinary legislative procedure	Active information of consumers allowing informed purchasing decisions and triggering awareness for safe use instructions
Communication requirements for other substances of concern	Amendment of the REACH text; ordinary legislative procedure	Broadening the scope of SVHC requirements as foreseen in Art. 138(8) REACH
Open SCIP notifications for articles without SVHCs above the 0.1 threshold	Practical level (design and implementation of SCIP by ECHA within existing legal mandate)	Enhanced transparency about SVHC status of articles
Obligatory Response in the context of Art. 33 for articles without SVHCs above the 0.1 threshold	Amendment of the REACH text; ordinary legislative procedure	Avoid uncertainty for suppliers and consumers: Better informed purchasing decisions

Subject matter	Type	Purpose
Reporting obligation in Art. 33(1) after relevant update of candidate list	Clarification of legal situation; implementing annex; comitology procedure	Enhance learning processes in the supply chain: Accurate information of all actors, including consumers
Duty to organize the Art. 33 obligations	Clarification of legal situation; implementing regulation; comitology procedure	Underpin the (at least implicitly already) existing duty formulated in Art. 36 REACH
Shorter period to respond to consumer requests	Amendment of the REACH text; ordinary legislative procedure	Raise the incentive for consumers to use their "right-to-know" under Art. 33(2)
SVHC information in the supply chain before purchasing decision	Clarification of legal situation; implementing annex; comitology procedure	Underpin the obligations already laid down in Art. 33(1)

The findings of the study, however, do suggest that most of the policy options captured in Table 1 are worth pursuing (for details see section 3.1). In order to align the overall substance-related requirements to SiA issues, REACH stipulates notification and registration obligations in this respect. The envisaged additional knowledge base, however, has not yet been established. The report examines the regulatory options at hand (Table 2).

Table 2: Overview of policy options addressing the registration of substances in articles

Subject matter	Type	Purpose
Formalised sameness test (with regard to Art. 7(6)) for article producers, strengthened information requirements for substance manufacturers and modified access to information on exposure data	Amendment of the REACH text and of the Annexes, using implementing legislation on the basis of Art. 7(8), Art. 131 and Art. 132	Clarifying when a substance can be deemed registered for a certain use in order to specify, and thereby curbing, the waivers under the SiA registration
Legal criteria developed by Commission to guide the application of Art. 7(5)	Implementing legislation pursuant to Art. 7(8)	Support ECHA in application of Art. 7(5)
Shifted burden of proof to industry in the application of Art. 7(5)	Modification of Art. 7(5) using the ordinary legislative procedure, and introduction of a new procedure to examine industry data	Lower the bar for ECHA to request SiA registration under Art. 7(5)

Managing risks related to problematic substances in articles is a challenging task for authorities in Europe. This is mainly due to two obvious factors: the sheer quantity and variety of products on the one hand and of the chemicals they contain on the other. Both factors are difficult to oversee and assess. From a regulatory risk management perspective, REACH rests on two main pillars of sovereign instruments: restriction and authorisation. Both have in common the capacity to ban or limit the amount of problematic substances in articles.

From an administrative perspective, the question is relevant which side has to bear the "burden of proof". For a general restriction the public body in its Annex XV dossier has to demonstrate that "there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis" (Art. 68(1) REACH). A restriction, once enacted, can be applicable for all

substances in articles, regardless of whether they were produced in the EU or imported from third countries.

Imposing an authorisation requirement in contrast is linked to generic risk considerations with regard to substances of very high concern. The authorisation regime thus offers a more flexible administrative response that is, however, limited to SVHCs and their use within the EU. Hence, SVHCs embedded in imported articles are, under the current legislation, not covered by the authorisation regime. With an enhanced scope of the term "use" in Title VII of REACH the more targeted authorisation regime would cover imported articles as well (Table 3).

Table 3: Overview of policy option of an extended authorisation scheme

Subject matter	Type	Purpose
Consider in Art. 56 import of articles as use of a substance for the purposes of Title VII; complementing adaptations of Art. 58(2), Art. 62(2), Art. 62(4)(c) and Annex XVI, various procedural adaptations	Amendment of the REACH text, using the ordinary legislative procedure and implementing legislation on (Art. 131 REACH); practical level	Provide another option for regulatory control of SVHCs in imported articles that can be triggered without prior establishing existence of "unacceptable risk" Advance SEA to the extent that only essential uses for society can be granted authorisation via SEA route

For EU based manufacturers this would reduce inequalities by legally harmonising the distribution conditions of domestic and imported articles. As far as SVHCs are incorporated, this option would serve as a functional equivalent to the enhanced restriction option (Table 4). The advantage of the extended authorisation requirement would be that it is up to the applicants to demonstrate "adequate control" of the risks or that the "socio-economic benefits outweigh the risk to human health or the environment" respectively (Art. 60(2) and (4) REACH).

Table 4: Overview of policy options in the context of the restriction scheme

Subject matter	Type	Purpose
Revised criteria for the application of Art. 68(2)	Internal Guideline for the Commission services, taking into account concerns by MS and ECHA	Clarifying the criteria and the procedural steps for the application of Art. 68(2) reflecting a more precautionary approach
Extending the substance scope of Art. 68(2)	Amendment of the REACH text; ordinary legislative procedure	Strengthening the level of protection
Preparatory steps to prepare an Annex XV dossier well in advance of the sunset date	Internal standard operation procedure for the ECHA secretariat	Starting the restriction procedure before the sunset date
Replace "After" in the wording of Art. 69(2) by "At the latest"	Amendment of the REACH text; ordinary legislative procedure	Clearly allow starting the restriction procedure before the sunset date

Section 3.2 summarizes the findings of the study with regard to risk management options.

Zusammenfassung

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

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

REACH befasst sich vorwiegend mit Industriechemikalien und daraus formulierten Gemischen. Chemische Stoffe sind jedoch häufig nicht das finale Ziel der industriellen Prozesse. Vielmehr erfüllen Stoffe und Gemische regelmäßig eine bestimmte Funktion auf dem Weg zu einem Endprodukt, bei dem es sich in den meisten Fällen um ein Erzeugnis handeln dürfte (definiert in Art. 3 Abs. 3 REACH). Als Nachkomme der Richtlinie 67/548/EWG und der anschließenden stoffbezogenen Gesetzgebung auf EU-Ebene trägt REACH noch immer die Eierschalen seiner Entstehungsgeschichte. Während der Rechtsrahmen für Stoffe und Gemische gut etabliert ist, fehlt es für die unbeabsichtigten Auswirkungen von Stoffen in Erzeugnissen noch immer an einer kohärenten legislativen Antwort.

Bestimmungen in REACH, die Erzeugnisse betreffen, erscheinen eher wie ein Fremdkörper im Regelwerk. Diese Beobachtung steht in scharfem Kontrast zu den Herausforderungen, die in diesem Bereich zu bewältigen sind. In Erzeugnissen eingebettete Stoffe finden sich im Nabelschnurblut von Säuglingen und im Fettgewebe von Menschen und Tieren rund um den Globus, unabhängig davon, ob sie jemals in direktem Kontakt mit dem Erzeugnis waren oder nicht. Andere Stoffe, die aus Erzeugnissen freigesetzt werden, z.B. beim Waschen, beeinträchtigen die Fruchtbarkeit von Fischen.

Vor diesem Hintergrund analysiert die Studie die Anforderungen aus REACH an Erzeugnisse. Der Bewertungsmaßstab ist in den normativen Zielen der REACH-Verordnung formuliert. Ihr Zweck ist es, "ein hohes Schutzniveau für die menschliche Gesundheit und die Umwelt sicherzustellen" (Art. 1 Abs. 1 REACH) und gleichzeitig die "Wettbewerbsfähigkeit und Innovation zu verbessern". Da Erzeugnisse in der Regel nach Gebrauch einer Entsorgung zugeführt werden, bietet zudem die Perspektive der Kreislaufwirtschaft weitere normative Orientierung. Im Hinblick auf die Ressourceneffizienz ist eine möglichst zirkuläre Materialverwendung vorteilhaft. Dies würde allerdings beeinträchtigt durch problematische Stoffe (oder "Substances of Concern"), die in die Erzeugnisse eingebettet sind und damit ein "risk cycle"-Problem verursachen. Eine Änderung der Abfallrahmenrichtlinie von 2018 adressiert diese Frage mit einem Transparenzmechanismus, der mit den in Art. 33 Abs. 1 REACH festgelegten Anforderungen an die Kommunikation in der Lieferkette verknüpft ist. Die zugrundeliegenden Ziele in Bezug auf "Kreislaufwirtschaft" und "giftfreie Umwelt" sind letztlich mit den Zielen von REACH verflochten. Sie werden darüber hinaus durch den "New Green Deal" der Europäischen Kommission (Dezember 2019), den neuen "Aktionsplan für die

Kreislaufwirtschaft" (März 2020) und den Prozess hin zu einer "Chemikalienstrategie für Nachhaltigkeit" (Herbst 2020) untermauert.

Die Studie erörtert die Anforderungen von REACH in Bezug auf "Stoffe in Erzeugnissen". Die Definition des Begriffs "Erzeugnis" ist das Thema in Abschnitt 2.1, gefolgt von den Kommunikationspflichten (Abschnitt 2.2) und den Bestimmungen zur Registrierung und Anmeldung von Stoffen in Erzeugnissen (Abschnitt 2.3). Anschließend prüfen die Abschnitte 2.4 und 2.5 relevante Bestimmungen im Zulassungs- sowie im Beschränkungsregime. Jeder Abschnitt untersucht den jeweiligen rechtlichen Rahmen (Ziele, Mechanismen, Unsicherheiten) sowie den Stand der Umsetzung und entwickelt auf der Grundlage der daraus gezogenen Schlussfolgerungen mögliche Verbesserungen („Policy Options"). Tabellen am Ende jedes Abschnitts fassen die Optionen und deren erwartete Auswirkungen zusammen. Eine eingehende Analyse der Auswirkungen der vorgestellten Optionen war nicht Gegenstand der Studie.

Das Schlusskapitel enthält in Form einer zusammenfassenden Tabelle eine Synopse aller Optionen sowie, soweit angemessen, eine vergleichende Bewertung der Optionen.

Die Arbeit stützt sich auf Literaturrecherchen, einschließlich Dokumenten und Studien im Rahmen des REACH REFIT-Prozesses. Zum Berichtsentwurf gingen außerdem Expertenbeiträge von deutschen Behördenvertretern ein, die an den verschiedenen REACH-Verfahren beteiligt sind. Der Bericht stellt die Meinungen der Autoren dar.

Im Hinblick auf das Ziel einer stärkeren Kohärenz zwischen stoff- und erzeugnisbezogenen Elementen von REACH können beide Bereiche voneinander lernen. Das "Right to Know" des Verbrauchers in Art. 33 Abs. 2 REACH gilt nicht für Gemische, die in dem Erzeugnis enthalten sind oder ein integraler Bestandteil davon sind, obwohl das damit verbundene Risiko nicht als wesentlich geringer angesehen werden kann. Im Gegenteil, unbeabsichtigte Wirkungen können hier in mindestens gleichem Umfang auftreten. Daher sollte die Übertragung von produktbezogenen Informationspflichten in Betracht gezogen werden. Eng verbunden mit dieser Option ist die Frage, wie die Kommunikation über "besonders besorgniserregende Stoffe" (SVHC) verbessert werden kann. Der Bericht diskutiert diesbezüglich mehr als ein Dutzend Ansätze (zusammengefasst in Tabelle 1).

Tabelle 1: Überblick der Policy Options für die Kommunikation über SVHC in Erzeugnissen

Gegenstand	Typ	Zweck
Standardisierung von Datenstruktur und Austauschformaten für eine harmonisierte Kommunikation zu Stoffen in Erzeugnissen	Unterstützende Maßnahmen, Mandat an Standardisierungsorganisationen	Erleichtert den Datentransfer entlang der Lieferkette
Organisation der Lieferketten-Kommunikation	Nicht-verbindliche Leitlinien	Erleichtert den Datentransfer entlang der Lieferkette
Gestärkter Vollzug	Behördliche Maßnahmen (koordiniert z. B. durch ECHA Forum)	Compliance bzgl. Anforderungen an Stoffe in Erzeugnissen
Kennzeichnungspflicht für SVHC	Änderung des Haupttextes von REACH; ordentliches Gesetzgebungsverfahren	Aktive Unterrichtung von Konsumenten, ermöglicht informiertere Kaufentscheidungen und stimuliert Bewusstseinsbildung mit Blick auf sichere Verwendung

Gegenstand	Typ	Zweck
Kommunikationsanforderungen für weitere problematische Stoffe	Änderung des Haupttextes von REACH; ordentliches Gesetzgebungsverfahren	Den Anwendungsbereich der Anforderungen an SVHC ausweiten, wie angelegt in Art. 138 Abs. 8
SCIP Notifizierungen für Erzeugnisse ermöglichen, die nicht SVHC oberhalb 0.1 Masseprozent enthalten	Praktische Ebene (Design und Umsetzung von SCIP durch ECHA innerhalb bestehendem rechtlichen Mandat)	Verbesserte Transparenz bzgl. SVHC in Erzeugnissen
In Art. 33 verpflichtende Antwort für Erzeugnisse, die nicht SVHC oberhalb 0.1 Masseprozent enthalten	Änderung des Haupttextes von REACH; ordentliches Gesetzgebungsverfahren	Vermeidet Unsicherheit für Konsumenten und Lieferanten: Informiertere Kaufentscheidungen
In Art. 33 Abs. 1 Mitteilungspflicht bei relevantem Update der Kandidatenliste	Klarstellung der rechtlichen Situation; Durchführungsvorschriften; Komitologie-Verfahren	Verbesserte Lernprozesse in der Lieferkette: Aktuellere Information für alle Akteure, incl. Konsumenten
Organisationspflicht auf Basis der Art. 33 Anforderungen	Klarstellung der rechtlichen Situation; Durchführungsvorschriften; Komitologie-Verfahren	Unterfüttert die (zumindest implizit bereits bestehende) Pflicht aus Art. 36
Kürzere Periode für die Antwort an den Konsumenten nach Art. 33 Abs. 2	Änderung des Haupttextes von REACH; ordentliches Gesetzgebungsverfahren	Stärkere Anreize für Konsumenten ihr Auskunftsrecht nach Art. 33 Abs. 2 zu nutzen
SVHC-Kommunikation in der Lieferkette vor Kaufentscheidung	Klarstellung der rechtlichen Situation; Durchführungsvorschriften; Komitologie-Verfahren	Unterfüttert die bestehenden Verpflichtungen aus Art. 33 Abs. 1

Die Ergebnisse der Studie legen jedoch nahe, dass es sich lohnt, die meisten der in Tabelle 1 erfassten Policy Options zu verfolgen (Einzelheiten siehe Abschnitt 3.1).

REACH sieht für Stoffe in Erzeugnissen Melde- und Registrierungspflichten vor, um diesen Bereich an die generelleren stoffbezogenen Anforderungen anzugleichen. Die erhoffte zusätzliche Wissensbasis ist jedoch noch nicht geschaffen worden. Der Bericht untersucht dazu einige Optionen (Tabelle 2).

Tabelle 2: Überblick der Policy Options für die Registrierung von Stoffen in Erzeugnissen

Gegenstand	Typ	Zweck
Formalisierte Gleichartigkeitsprüfung (im Kontext von Art. 7 Abs. 6) für Erzeugnisproduzenten, gestärkte Informationsanforderungen für Stoffhersteller und angepasster Zugang zu Informationen über Expositionsdaten	Änderung des Haupttextes von REACH sowie der Anhänge, über Durchführungsvorschriften auf Basis von Art. 7 Abs. 8, Art. 131 und Art. 132	Klarstellung, wann ein Stoff als registriert gelten kann für eine bestimmte Anwendung, um die Ausnahmen von der Registrierungspflicht zu präzisieren (und einzuschränken)

Gegenstand	Typ	Zweck
Rechtliche Kriterien der Europäischen Kommission als Orientierung für die Anwendung von Art. 7 Abs. 5	Durchführungsvorschriften auf Basis von Art. 7 Abs. 8	Unterstützung der ECHA bei der Anwendung von Art. 7 Abs. 5
Nachweislast für Industrie bei der Anwendung von Art. 7 Abs. 5	Modifizierung von Art. 7 Abs. 5 über das ordentliche Gesetzgebungsverfahren, und Einführung eines neuen Prüfprozesses bzgl. der eigereichten Daten	Senkung der Anforderungen an ECHA, um nach Art. 7 Abs. 5 die Registrierung von Stoffen in Erzeugnissen verlangen zu können

Der Umgang mit Risiken im Zusammenhang mit problematischen Stoffen in Erzeugnissen ist für die Behörden in Europa eine anspruchsvolle Aufgabe. Dies ist vor allem auf zwei Faktoren zurückzuführen: die schiere Menge und Vielfalt der Produkte einerseits und der darin enthaltenen Chemikalien andererseits. Beide Faktoren sind schwer zu überblicken und zu bewerten. Aus der Perspektive des regulatorischen Risikomanagements basiert REACH auf zwei Hauptpfeilern hoheitlicher Instrumente: Beschränkung und Zulassung. Beiden gemeinsam ist die Möglichkeit, problematische Stoffe in Erzeugnissen zu verbieten oder zu begrenzen.

Aus administrativer Sicht ist die Frage relevant, welcher Akteur die "Beweislast" zu tragen hat. Für eine allgemeine Beschränkung muss die öffentliche Stelle in ihrem Dossier nach Anhang XV nachweisen, dass „die Herstellung, die Verwendung oder das Inverkehrbringen von Stoffen ein unannehmbares Risiko für die menschliche Gesundheit oder die Umwelt mit sich [bringt], das gemeinschaftsweit behandelt werden muss“ (Art. 68 Abs. 1). Eine einmal erlassene Beschränkung kann für alle Stoffe in Erzeugnissen gelten, unabhängig davon, ob sie in der EU hergestellt oder aus Drittländern importiert wurden.

Das Zulassungserfordernis ist dagegen an generische Risikoüberlegungen in Bezug auf besonders besorgniserregende Stoffe gebunden. Das Zulassungssystem bietet somit eine flexiblere administrative Antwort, die jedoch auf SVHC und deren Verwendung innerhalb der EU beschränkt ist. Daher sind SVHC, die in importierte Erzeugnisse eingebettet sind, nach der derzeitigen Rechtslage nicht von den Zulassungsregelungen abgedeckt. Mit einem erweiterten Anwendungsbereich des Begriffs "Verwendung" in Titel VII von REACH würde das zielgerichtetere Zulassungssystem auch importierte Erzeugnisse abdecken (Tabelle 3).

Tabelle 3: Überblick der Policy Option einer erweiterten Zulassungspflicht

Gegenstand	Typ	Zweck
In Art. 56 den Import von Erzeugnissen als “Verwendung des Stoffes” im Sinne von Titel VII einordnen; komplementäre Änderungen von Art. 58 Abs. 2, Art. 62 Abs. 2, Art. 62 Abs. 4 lit.c und Anhang XVI; zahlreiche prozedurale Anpassungen	Änderung des Haupttextes von REACH; über das ordentliche Gesetzgebungsverfahren und Durchführungsgesetzgebung (Art. 131); praktische Ebene	Eine weitere Option für die behördliche Kontrolle von SVHC in importierten Erzeugnissen, die ausgelöst werden kann, ohne dass zuvor das Vorhandensein eines "unannehmbaren Risikos" festgestellt werden muss Die sozioökonomische Analyse so vorantreiben, dass nur für die Gesellschaft wesentliche Verwendungszwecke über diese Route zugelassen werden können

Dies würde Vertriebsbedingungen für einheimische und importierte Artikel rechtlich weiter harmonisieren und somit Nachteile für in der EU ansässige Hersteller im Status Quo verringern. Soweit besonders besorgniserregende Stoffe (SVHC) einbezogen werden, würde diese Option als funktionelles Äquivalent zu einer erweiterten Beschränkungsoption dienen (Tabelle 4). Der Vorteil der erweiterten Zulassungspflicht wäre, dass es den Antragstellern obliegt, eine "angemessene Beherrschung" der Risiken nachzuweisen, bzw. dass der "sozioökonomische Nutzen die Risiken überwiegt" (Art. 60 Abs. 2 und Abs. 4 REACH).

Tabelle 4: Überblick der Policy Options im Kontext des Beschränkungsregimes

Gegenstand	Typ	Zweck
Überarbeitete Kriterien für die Anwendung von Art. 68 Abs. 2	Interne Leitlinie für die Dienststellen der Europäischen Kommission, unter Beachtung der Sichtweisen von ECHA und der Mitgliedstaaten	Klärung der Kriterien und der Verfahrensschritte für die Anwendung von Art. 68 Abs. 2, Würdigung eines vorsorgeorientierten Ansatzes
Erweiterung des materiellen Anwendungsbereichs von Art. 68 Abs. 2	Änderung des Haupttextes von REACH; ordentliches Gesetzgebungsverfahren	Stärkung des Schutzniveaus
Vorgezogene Schritte, um ein Anhang XV Dossier mit ausreichendem Vorauf vor dem Ablaufdatum („sunset date“) vorzubereiten	Interne Leitlinie für das Sekretariat der ECHA	Das Beschränkungsverfahren einleiten vor dem Ablaufdatum
Ersetzen von “nach” im Wortlaut von Art. 69 Abs. 2 durch “spätestens nach”	Änderung des Haupttextes von REACH; ordentliches Gesetzgebungsverfahren	Einleitung des Beschränkungsverfahren vor dem Ablaufdatum ausdrücklich gestatten

Die Ergebnisse der Studie in Bezug auf die Optionen des Risikomanagements fasst Abschnitt 3.2 zusammen.

1 Introduction and problem description

Measured by the normative objective of the REACH Regulation to ensure, throughout the life-cycle of chemical substances,[1] a "high level of protection of human health and the environment" (Art. 1(1) REACH)[2] the question arises whether there is a need to enhance the regulatory response to the challenges linked to "substances in articles" (SiA). Several factors contribute to this assumption.

A great variety of everyday products containing SVHCs and other problematic substances[3] can be found on the EU internal market.[4] In the case of exposure (which is partly inevitable[5]), risks for human health (consumers as well as workers in production, distribution and in recycling processes) and the environment may arise:

- Consumers can be exposed to problematic substances present in articles through dermal contact. During normal conditions of use, substances in articles may migrate from the material and penetrate the skin, depending on the quantity and physico-chemical properties of the substance and how it is integrated into the matrix of a given material.[6]
- In the case of small children, the behaviour involved in them exploring their environment by putting objects (e.g. remote control, cables) in their mouth can produce an additional oral pathway of direct exposure to problematic substances in articles.[7]
- Continuous leaking of e.g. (semi) volatile compounds from articles can contribute to concentrations of problematic substances in dust or indoor air, and therefore to exposure to consumers via ingestion or inhalation.[8]
- Exposure via the dermal or the inhalation route are also relevant for workers during the manufacturing of articles, their storage and distribution as well as dismantling or recycling activities.
- Environmental exposure to SiA occurs during manufacturing, in the use phase (article aging, wear and tear etc.) and after disposal. Substances released to the environment are at the same time a potential source of secondary human exposure (exposure route "men via environment").

In addition, considering revived Circular Economy ambitions of the European Commission,[9] societies have to deal with the challenge that problematic substances are found in (consumer) products made from recycled content.[10] One of the goals of Circular Economy is that products and the materials they are made of are free from problematic substances so "that they may be

[1] Cf. Recital 4 of the REACH Regulation, referring to the "Johannesburg Goal" formulated at the World Summit of Sustainable Development (WSSD), i.e. a commitment to the sound management of chemicals throughout their life cycle; see also section 1.1.

[2] Articles, Titles, Annexes without further indication are in this report those of the REACH Regulation.

[3] In this report, the not legally defined term problematic substance means a chemical with intrinsic properties that may cause damage to human health and/or the environment. Substances that meet the criteria of REACH Art. 57 fall under the concept, as well as substances classified as 'hazardous' as defined under the CLP Regulation or other relevant legislation. The term is thus broader than the concept of "Substances of Concern", for which different scopes are discussed, cf. SWD(2018) 20 final, p. 8 et seq.

[4] Klaschka 2017.

[5] See e.g. the case of semi-volatile organic compounds not permanently bound to the polymer which forms part of an article (such as phthalates in PVC), Kemi 2015, p. 61.

[6] For the case of textiles, see Kemi 2014, p. 36 et seq.

[7] For the case of electrical and electronic equipment (EEE), see Kemi 2015, p. 67.

[8] See e.g. Abbasi et al. 2016.

[9] Gaining further momentum through "The European Green Deal", cf. COM (2019) 640 final as well as the 2020 Circular Economy Action Plan, cf. COM(2020) 98 fin.

[10] Cf. on "legislative loopholes" as regards exemptions for POPs in recycled materials Straková et al. 2018.

reused and eventually disposed of in a way that maximises the materials' economic benefits and utility to society while maintaining a high level of human health and environmental protection".[11] REACH contributes to these objectives by encouraging the phase-out of problematic substances and creating incentives to manufacture and use inherently safe chemicals.[12] Accordingly, the updated substitution strategy by ECHA, entitled "Strategy to promote informed substitution of substances of concern", will acknowledge links to the circular economy package.[13]

Consequently, risks to humans (including vulnerable groups such as, e.g. children and the elderly) and the environment may occur from SVHCs and other problematic substances, which are present in or released from articles. Hence, there is a regulatory need to address risks from substances in articles as is also reflected by the normative objectives of REACH and the regulation's instrumental mix.

1.1 REACH normative goals and instruments addressing risks from substances in articles

REACH aims "to ensure a high level of protection of human health and the environment", while "enhancing competitiveness and innovation" (Art. 1(1)). The regulatory approach is based on the two principles laid down in Art. 1(3), i.e. the self-responsibility of economic actors "to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment"[14] and the "precautionary principle". With respect to SiA REACH supports self-responsibility by means of communication obligations covering SVHC (see section 2.2) and registration and notifications requirements (section 2.3). From a regulatory risk management perspective, REACH offers two sovereign instruments: authorisation (section 2.4) and restriction (see section 2.5).

In a globalized economy, many articles are traded internationally. International law and multilateral processes provide further normative orientation. Recital 4 of REACH explicitly mentions the "implementation plan adopted on 4 September 2002 at the Johannesburg World Summit on sustainable development"[15] with its 2020-goal. The latter has been incorporated into the UN Sustainable Development Goals (SDGs),[16] in particular into SDG 12.4, which highlights the "life-cycle" approach embedded in REACH and the related circular economy aspects.[17]

The June 2018 Council Conclusions, with a view to promoting the circularity of products and achieving a high level of protection of human health and the environment, emphasize "the need for information on substances of concern for all actors and to ensure at the latest by 2030 the traceability of substances of concern in materials, including those in imported articles, through the entire supply chain, including end-of-life operations".[18] Additionally, in June 2019, the EU

11 SWD(2018) 20 final, p. 4.

12 Cf. the 2020 "new Circular Economy Action Plan" at COM(2020) 98 fin, p. 13.

13 Mottet 2019.

14 Underpinned by recitals 16, 18, 25, 29, 56, 58 ('chain of responsibilities'), 86, 105; see also Führ and Lahl 2006 and Führ and Schenten 2020.

15 United Nations, Plan of Implementation of the Johannesburg World Summit on Sustainable Development, UN Doc A/Conf.199/20 (2002) (Johannesburg Implementation Plan).

16 United Nations, Transforming our world: The 2030 agenda for sustainable development, UN Doc. A/70/L.1 (2015) (Agenda 2030).

17 SDG 12.4 of the Agenda 2030 (United Nations, Transforming our world: The 2030 agenda for sustainable development, UN Doc. A/70/L.1 (2015)) aims to by "2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment".

18 Council 2018, para. 16.

environment ministers call upon the Commission "to initiate a general discussion" regarding, i.a., "the criticality of uses and the appropriate choice of risk management measures in order to fully exploit authorisation and restriction as means to achieve the phasing out of substances of concern",[19] and recall[20] the need for establishing a level playing field between articles produced within the EU and those imported from third countries.[21]

An explicit regulatory link to REACH has been established with the 2018 amendment of the Waste Framework Directive (WFD). According to the new Art. 9(1)(i), in order to "promote the reduction of the content of hazardous substances in materials and products," the Member States have to "ensure that any supplier of an article as defined in [REACH] … provides the information pursuant to Article 33(1) of that Regulation to the European Chemicals Agency as from 5 January 2021". ECHA has to establish a corresponding database (Art. 9(2) WFD). With this amendment the EU is aiming at the "development of non-toxic material cycles" (recital 38).[22]

Considering the normative objectives of REACH and the crucial role of said regulation as leverage for the Circular Economy (i.e. avoiding recycling of SVHC containing material – "riskcycle" – by means of substitution of SVHCs in articles), there appears to be room for improvement in the context of the existing regulatory approaches on SiA: REACH defines the product group of "articles" as regulatory object (Art. 3(3)) and subsequently addresses SiA via obligations regarding communication (Art. 33), registration (Art. 7.1 and potentially 7.5), notifications (Art. 7.2 and 7.3) and restrictions (Art. 68 f.). The authorisation scheme (Title VII) indirectly affects articles as the incorporation of substances into articles constitutes a use for which authorisation may be required.

This report summarizes potential starting points for enhancements and policy options.

1.2 Complementary regulatory approaches

Besides the REACH Regulation (see the analysis in section 2) there is a great number of regulatory approaches addressing the risks linked to SiA. Products that fall into the scope of REACH articles (in terms of Art. 3(3), c.f. section 2.1.1), as well as the substances present therein,[23] are regulated under several pieces of legislation with slightly different regulatory approaches.[24]

The Directive on General Product Safety (GPSD) complements sector specific legislation (such as specific rules that apply to toys, electrical and electronic goods, cosmetics, chemicals and other specific product groups).[25] It stipulates the overall rule to be transferred into national law that products intended for or likely to be used by consumers may only be placed on the market when they are safe, meaning they do not present any risk or only the minimum risks, consistent with a high level of protection for the safety and health of persons.[26] While in terms of chemical risk the GPSD as such does not provide any substance specific criteria on hazard identification or

[19] Council 2019, para. 19.
[20] Council 2018, para. 18.
[21] Note 19, para. 22.
[22] Recital 38 to Directive 2018/851 continues "it is necessary to promote measures to reduce the content of hazardous substances in materials and products, including recycled materials, and to ensure that sufficient information about the presence of hazardous substances and especially substances of very high concern is communicated throughout the whole life cycle of products and materials. In order to achieve those objectives, it is necessary to improve the coherence among the law of the Union on waste, on chemicals and on products and to provide a role for the European Chemicals Agency to ensure that the information about the presence of substances of very high concern is available throughout the whole life cycle of products and materials, including at the waste stage".
[23] For products that entail not only articles in terms of REACH but also substances as such or mixtures ("combined objects") c.f. section 2.1.3.
[24] For a more detailed assessment, see Reihlen et al. 2017 with further references.
[25] It does not cover pharmaceuticals, medical devices or food, which fall under separate legislation.
[26] Articles 3(1), 2(a), 2(b) Directive 2001/95/EG on general product safety, 2002 OJ L 11, 4.

exposure to be taken into account by producers,[27] standards developed under the directive are addressing such aspects for certain product groups.[28] However, the GPSD does not consider environmental safety[29] and human exposure via the environment; neither are workers[30] among the subjects of protection.

Complementing the general product rules, product specific legislation applies varying approaches to SiA, some of which can be considered as effective:

- Some pieces of legislation restrict the use of a limited number of hazardous substances, see e.g. the End-of life vehicles (ELV) Directive[31] and the Restriction of Hazardous Substances Directive (RoHS),[32] the latter restricting the use of i.a. heavy metals and flame retardants such as lead, cadmium,[33] and polybrominated biphenyls in EEE when substitution is possible from the scientific and technical point of view.[34]
- Pursuant to the Biocidal Products Regulation, articles placed on the market may only be treated with a biocidal product (or intentionally incorporate a biocidal product) containing an active substance which is already approved, listed in Annex I, or under assessment.[35]
- Medical devices legislation (fully effective as of May 2020) stipulates the obligation to state reason for the use of certain problematic substances,[36] combined with a labelling requirement.[37] Combined approaches also apply with respect to articles treated with biocidal products.[38]
- "New approach legislation", such as the Construction Products Regulation (CPR),[39] require conformity with norms and standards as well as "general safety", however such standards rarely contain SiA requirements.[40]
- The Toy Safety Directive[41] limits the content generically (CMR) as well as by lists (allergens) for a number of substances.

27 Postle et al. 2017, p. 84.

28 For a summary list of titles and references of European standards under the directive see European Commission 2020.

29 To the extent products are manufactured in industrial installations, the Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) (Recast), 2010 OJ L 334, 17, cor. 2012 OJ L 158f, 25 (IPPC Directive) aims to reduce industrial emissions into air, water and land and to prevent the generation of waste, in order to achieve a high level of protection of the environment.

30 With a view to safety and health of workers at installations, occupational health provisions oblige employers to ensure that the risk from hazardous chemical agents is eliminated or reduced to a minimum, cf. Art. 6(1) Directive 98/24/EC of 7th April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD).

31 Directive 2000/53/EC of 18th September 2000 on end-of life vehicles - Commission Statements, 2000 OJ L 269, p. 34–43.

32 Directive 2011/65/EU of 8th June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, 2011 OJ L 174, p. 88–110.

33 In August 2018 the "Volkswagen group confirmed that it might have to recall as many as 124,000 electric and hybrid cars from its VW, Audi and Porsche brands due to poisonous cadmium"; c.f. Article by electrek.

34 In addition, following the dynamic requirement to update the list of restricted substances as soon as new scientific evidence is available on more environmentally friendly alternatives, Directive 2015/863/EU amends RoHS to restrict four phthalates.

35 Art. 58 Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, 2012 OJ L 167, 1.

36 Among others, CMRs of category 1A or 1B, EDCs identified as SVHCs under REACH.

37 Regulation (EU) 2017/745 of 5th April 2017 on medical devices, 2017 OJ L 117, 1.

38 Regulation (EU) No 528/2012 of 22nd May 2012 concerning the making available on the market and use of biocidal products 2012 OJ L 167, 1.

39 Regulation (EU) No 305/2011 of 9th March 2011 laying down harmonised conditions for the marketing of construction products and repealing 2011 OJ L 88, 4.4.2011, 5.

40 Cf. Reihlen et al. 2017.

41 Directive 2009/48/EC of 18th June 2009 on the safety of toys, 2009 OJ L 170, 1.

- General packaging legislation requires the minimisation of the use of hazardous substances.[42]

In conclusion, a number of instruments intended to address risks from SiA already exist and some known risks are subject to regulation already. However, the current regulatory framework entails the following shortcomings:

- Scattered restrictions of SiA can be found in various pieces of legislation and are hence challenging to comply with and to control.
- Specific risk management addresses only selected articles and does not sufficiently consider risks to the environment, notably during article use and after disposal.
- Risk management usually fails to adequately address risks from aggregated exposures to multiple substances where these either have the same and therefore fortified mode of action (MoA) or, in the absence of an identical MoA, where there are uncertainties about relevant negative "cocktail effects".
- Emerging (suspected) risks cannot always be effectively regulated, in particular as the burden of proof usually lies with the public authorities who are required to specifically demonstrate the risk.

Moreover, the current, legally required transparency on SiA under REACH is lower than for substances and mixtures (under REACH; but also under some sectoral legislation, e.g., with respect to cosmetics), making informed handling and use of articles (more) difficult (or even impossible).

1.3 Focus and aim of the report

The work draws on literature research, including the documents published by EU bodies. Besides, expert input by German authority representatives involved in the various procedures of REACH was received on the draft report. Nevertheless, the report presents the opinions of the authors.

Taking into account the EU legal framework regarding SiA, the report focuses on how the provisions of the REACH Regulation could be enhanced to provide a more effective risk control. Consequently, possible improvements of other legislation or the interlinks between REACH and other legislation are not discussed, with the exception of the Waste Framework Directive's obligation enacted in 2018 to report SVHCs in articles.

The study describes the REACH legal requirements on SiA, with a focus on the respective normative goals as well as uncertainties and clarification needs. Subsequently, it assesses the implementation status quo with related challenges and, then, develops policy options aimed to yield greater contributions to the normative goals. The study identifies advantages and disadvantages of the options based on qualitative considerations. This will, as far as possible, consider the consequences of different options, where appropriate, in terms of expected contributions to normative objectives, i.e. the high level of protection, effectiveness including legal certainty and thus enforceability, and potential benefits for EU industries (e.g. due to increased legal certainty, due to market chances for proactive companies or due to reduced discriminations compared to imported articles) as well as regarding the additional efforts for authorities and industry to implement additional provisions. Where applicable, also "legislative"

[42] Directive 94/62/EC of 20th December 1994 on packaging and packaging waste 1994 OJ L 365, 10. If packaging comes into food contact, more stringent requirements apply, depending on the material.

arguments (e.g., implementation by the ordinary legislative procedure or comitology) are considered.

The political evaluation of whether or not the achievable risk reduction justifies the (potentially additional) efforts for industry and authorities inherent to the options is not subject to the study.

1.4 Structure of the report

The SiA requirements under REACH are discussed in chapter 2, starting with the article definition in section 2.1, followed by the communication duties (section 2.2) and the provisions on the registration and notification of SiA (section 2.3). Subsequently, the authorisation (section 2.4) and restriction schemes (section 2.5) are presented. Each section assesses the respective legal framework (objectives, mechanism, uncertainties) as well as the state of the art regarding implementation and, based on lessons learned, develops potential enhancements (policy options). Tables at the end of each section summarize the options and the expected effects. An in-depth impact analysis of the presented options, however, is beyond the scope of the study.

Finally, chapter 3 provides first a synopsis of all policy options as well as, to the extent appropriate, a comparative assessment of options.

2 Assessment of article related requirements

The analysis of SiA requirements under REACH focuses on the article definition (see section 2.1), communication duties (section 2.2), provisions on the registration and notification of SiA (section 2.3) as well as the authorisation (section 2.4) and restriction schemes (section 2.5).

2.1 Articles and products in REACH

Section 2.1.1 describes the legal framework with regards to the definition of the term article as a reference for the related obligations. Their implementation and the associated diverse challenges are subject to section 2.1.2. The situation is even more complex when it comes to products containing substances or mixtures that are SVHC not covered by the CLP Regulation (section 2.1.3). Potential enhancements and policy options are discussed in section 2.1.4.
A summary is given in section 2.1.5.

2.1.1 Legal framework: definition of the term article

The term "article" is defined in Art. 3(3) as an "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".[43] Briefly after publication of the regulation in the EU Official Journal a debate started between ECHA, COM und Member States on the interpretation of the term due to the fact that it provides the reference for the 0.1% threshold in Art. 7(2) and Art. 33.[44] This led to the somewhat strange situation that the official ECHA guidance document was published in the internet with a front-page announcing that several states (AT, BE, DE, DK, FR, SE and NY)[45] base their implementation on a different legal interpretation.[46] Those Member States followed the lines described in a presentation by the Danish competent authority as "once an article always an article"-doctrine (O5A).[47]

The CJEU followed the dissenting Member States in the decision of 10th September2015 (C-106/14). The court[48] based its interpretation on the overall aims of REACH laid down in Art. 1(1) and (3) as well as in Art. 55. This led to the conclusion (para 78, emphasis added):

> The duty to provide information is aimed indirectly at allowing those operators and consumers to *make a supply choice in full knowledge of the properties of the products, including those of articles forming part of their composition*. It must be borne in mind in that regard that recital 12 in the preamble to the REACH Regulation states that an 'important objective of the new system to be established by this Regulation is to encourage and in certain cases to ensure that substances of high concern are *eventually replaced* by less dangerous substances or technologies where suitable economically and technically viable alternatives are available', which objective is reflected in

[43] For details see Merenyi 2011, para 73 et subs. and the different versions of the ECHA guidance on SiA (ECHA 2010/2011, Guidance on requirements for substances in articles [ECHA-10-G-08-EN] and ECHA, June 2017 [Version 4.0, ECHA-17-G-19-EN]).

[44] See, i.a., the COM Doc. CA/26/2011 prepared for the 7th Meeting of Competent Authorities for REACH and CLP (CARACAL), 7-9 February 2011.

[45] See the document "Dissenting views on the Guidance on requirements for substances in articles" as of May 2008 compiling the official statements of the dissenting states.

[46] See the letter of the Executive Director of ECHA as of 28th April 2008 (GD/jn D(2008)/1183) and the "note to the reader" as of 01.04.2011:
Dear User of this Guidance,
When reading this ECHA Guidance document, please be aware that it did not find full support by consulted national authorities of EU/EEA Member States in the stage of its final consultation, as reflected in the minutes that you can access via this link. Consequently, companies may face diverging enforcement practices as to some of its aspects.

[47] See the presentation of the Danish Environment Protection Agency under the title "How to apply the 0.1 % trigger limit of REACH article 33 and 7" as of 01.04.2001.

[48] And in line with the Opinion of Advocate General Kokott in the case (as of 12.02.2015), para 26 et subs.

> Article 55 thereof, which provides expressly that substances of very high concern 'are [to be] progressively replaced by suitable alternative substances or technologies where these are economically and technically viable'.

Consequently, the court argued:

> "…in favour of an interpretation which guarantees the effectiveness of the duty to provide information provided for in Article 33 of the REACH Regulation, all along the supply chain through to the final consumer. The duty to provide information imposed on successive operators all along the supply chain is therefore intended to follow the article to which it relates through to the final consumer" (para 79) and concluded: "It would be incompatible with such a duty to take the position that the inclusion of an article as input in a complex product can interrupt the transmission of that duty to provide information to each of the operators along the supply chain, given that that duty relates directly to the presence of a substance of very high concern in that article…" (para 80).

Reflecting on the impact of this interpretation the court in particular rejected the argument that more detailed communication on SiA would lead to an inappropriate burden for industry actors. The court held in para 80:

> As regards the fears expressed by certain parties who have submitted observations to the Court about the compatibility of such a system with the principle of proportionality, it should be noted that the duty to provide information follows from the duty of notification provided for in Article 7(2) of the REACH Regulation whilst completing it by organising, for the benefit of all operators along the supply chain through to the final consumer, the transmission of vital information about the presence of a substance of very high concern. Its scope, however, is limited by Article 33 thereof, which states that 'sufficient information, available to the supplier, to allow safe use of the article [in question]' must include, as a minimum, the name of that substance. That requirement, which is minimal in nature, *cannot be regarded as being an excessive burden*.

In essence, the court decision is led by an argumentation based on the effectiveness of the regulative aims pursued by REACH whilst considering the efforts for the addressees resulting from the interpretation. This benefit/burden-analysis did not trigger concerns with regard to the principle of proportionality; in other words: the legislator did not violate the prohibition of disproportionate measures.[49]

2.1.2 Implementation supported by Guidance Documents

ECHA amended its guidance document[50] along the lines of the court ruling. Due to the great variety of articles and other "products" (see Figure 1) the implementation of the article-related provisions is to a high extent influenced by the explanations, criteria and examples of the document. It contains "guidance" in the first four chapters, whilst chapter 5 assembles "general advice" for duty holders on "obtaining and then evaluating the information needed to comply with their substance in articles obligations".[51] In addition Appendix 5 describes, a "possible step-wise approach" to comply with the legal requirements.[52]

[49] Cf. the analysis of the judgement at Beer and Tietjen 2016.
[50] ECHA 2017c.
[51] ECHA 2017b, 60. For critical review of the amended guidance document see Scheidmann 2017.
[52] It should be noted that Appendix 5 of the document is not part of the guidance as such. The outlined "step-wise" measures (p. 62) thus has to be critically assessed. The guidance points out that they "may be acceptable, as long as they also ensure compliance with the Regulation and achievement of its objectives" (p. 60).

Chapter 5 reflects the fact that most supply chain actors are still struggling with the challenge to align their supply chain communication to the requirements formulated in REACH; i.e. the granular level of the article definition. On the other hand, a growing number of suppliers are recognizing the benefits of an enhanced supply chain communication (see section 2.2); not only in terms of REACH but also with a view towards general product safety and product quality, including product liability.[53]

2.1.3 Combined objects as interface problem

From an everyday products perspective, it has to be acknowledged that goods available on the EU common market consist not only of (sub-)articles in terms of REACH[54] but also entail often substances as such and mixtures (and thus are described in this chapter as "combined objects"). Thus, the problem at hand should be framed in a broader sense as "chemicals in products" (CiP)[55]. As outlined above, REACH is focussing on "substances in articles" (SiA). The information requirements laid down in Art. 33 REACH are applicable for articles "containing" an SVHC. This condition is met when the SVHC is embedded in a material that fulfils the definition of an "article" (Art. 3 (3) REACH, see section 2.1.1). If this is not the case, material that is part of a product placed on the market remains – under the REACH definitions – a substance (Art. 3 (1) REACH) or mixture of two or more substances (Art. 3 (2) REACH). Thus, the question arises whether "combined objects" are comprehensively addressed. In this respect (but without using the term "combined objects") the ECHA guidance addresses borderline cases (emphasis by ECHA) "between[56]

a) *articles* with an integral substance/mixture, and

b) combinations of an *article* (functioning as a container or a carrier material) and a *substance/mixture*."

From a legal perspective, the interplay between REACH and CLP is relevant. REACH provides for communication requirements on SVHC in articles (section 2.1.1) whilst CLP addresses classified substances and triggers information requirements for substances as such or mixtures thereof (i.a. in Art. 31 REACH). However, with respect to the core question of this study, the scope of the relevant provisions differ:

- Art. 33 REACH covers substances from the candidate list embedded in the material structure of articles.
- On the other hand, substances as such (and mixtures thereof) with classified properties under CLP (Art. 31(1)(a)) as well as PBT/vPvB (Art. 31(1)(b)) and other SVHCs (Art. 31(1)(c)) have to be communicated by means of a SDS for professional recipients (in some cases upon request, c.f. Art. 31 (3[57] and 4)) and by means of warning signs and precautionary statements to the consumer.

For all "combined objects" this split system applies. In legal terms this can be phrased as an interface problem.[58]

53 This beneficial aspect was part of the argumentation in the Opinion delivered by Advocate General Kokott in the case (as of 12.02.2015), para 121.

54 Sub-article refers to the articles contained in a complex object, which remain articles in terms of REACH with all related legal obligations, cf. the CJEU jurisprudence summarized supra section 2.1.1.

55 See the CiP-Programme in the SAICM here: CiP-Programme in the SAICM context.

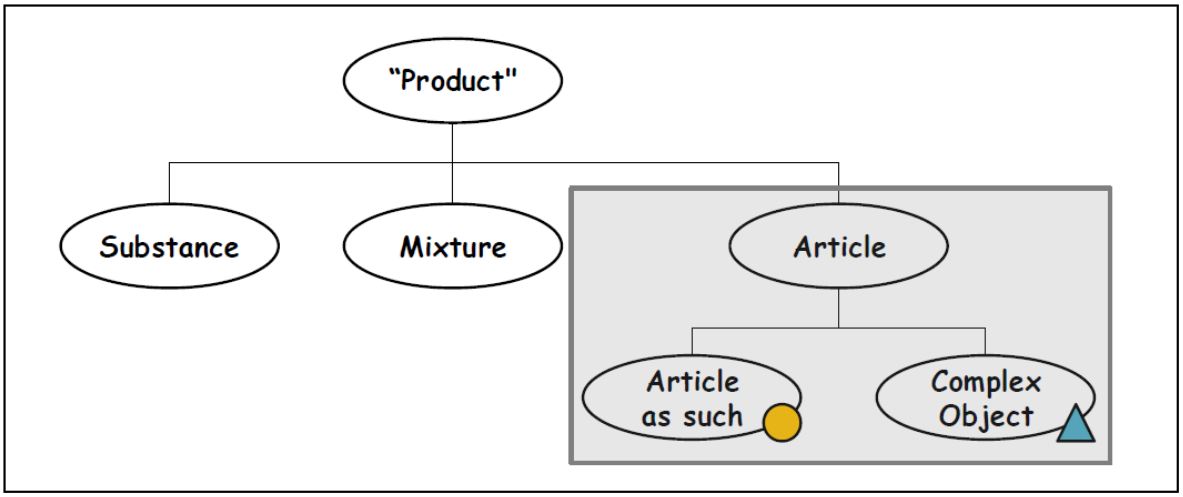
56 For the whole range of possible borderline case see ECHA 2017c, section 2.3 and subs. as well as Annex 3 (p. 70-77).

57 Above the concentration thresholds laid down in Art. 31(3)(a) and (b); the latter refer to SVHC.

58 Structurally similar interface problems occur between different sectoral pieces of legislation. For "options to address the interface between chemical, product and waste legislation" in the context of circular economy initiatives see COM(2018) 32 final and SWD(2018) 20 final.

An illustration of the points of reference for information requirements can be found in a document on the SCIP database.[59]

Figure 1: Scope of the SCIP database (to be established by ECHA) illustrating the points of reference for legal obligations



Source: ECHA 2019b, p. 4.

Figure 1: Scope of the SCIP database (to be established by ECHA) illustrating the points of reference for legal obligation

A so-called product can be a substance, mixture or an article. An article in turn can be an article as such or a complex object. The SCIP database will cover articles, including articles as such and complex objects. Substances and mixtures will not be covered.

From a REACH perspective, the split system leads to the effect that a consumer can request the name of a SVHC embedded in the material structure of an article (indicated in the grey shaded area in Figure 1). The SiA requirements are also applicable for option a) where the substance/mixture is seen as an "integral" element of the (sub-)article (option a of the two options outlined by ECHA).[60] With regard to option b) where the article functions "as a container or a carrier material" for substances as such and mixtures contained in the article the consumer might see (at best) warning symbols,[61] but he is not entitled to ask the supplier for the name of the SVHC.

This twofold differentiation is already difficult to justify when comparing one type of article with another type. In a systemic view, moreover, it leads to a situation where it is possible for articles as such to collect SVHC data on a European level[62] and make them available to consumers as well as to actors at the end-of-life stage of products. For SVHCs in mixtures, linked to an article, the REACH intention that "EU citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions"[63] is met in quite a

59 ECHA 2019b, p. 4.

60 However, the question remains which sub-component of the final product serves as the reference to apply the 0.1% threshold of the substance/mixture; e.g. in case where the mixture includes a SVHC. No indication is given, as far as conceivable, in this respect by the Guidance (ECHA 2017c).

61 If applicable: hazard pictogram(s), signal word(s), hazard statement(s) and precautionary statement(s).

62 See the SCIP-database (ECHA 2019b) to be established by ECHA and the AskREACH database established in the framework of an EU LIFE project.

63 Recital 117 REACH.

different manner, thus providing a significant lower level of information. This influences the possibilities of digitalized support. Since determining substances in articles is challenging for all supply chain actors, and in particular for consumers, a digitalized access would reduce transaction costs substantially. The same applies for distributors (retailers supplying mixtures and/or articles) who play an important role as intermediaries in the supply chain. The differentiation, consequently, leads to a situation where the aims of REACH are only met in suboptimal manner; – notably in cases where warning symbols are not attached to the article/its packaging.

Against this background, it can be set forth that the problem at hand, i.e. "chemicals in products", is broader than the regulatory mechanisms addressing “substances in articles” provided by REACH. With a view to the aims of REACH, the question arises how REACH can be enhanced in a way that the problem situation is addressed properly.

2.1.4 Potential enhancements/Policy options

The scope of the regulative approach of REACH concerning “substances in articles” causes limitations that are not yet overcome by the clarification concerning the term “article” provided by the CJEU ruling. In order to address these limitations, several options might be considered bearing in mind the aim of REACH, as the CJEU coined it (see section 2.1.1), that supply chain actors and consumers are in a position to “make a supply choice in full knowledge of the properties of the products”.

REACH defines the term “article” in differentiation to substances and mixtures. In this perspective, the definition is useful. An approach to broaden the scope of the term “article” in a way that covers products that contain substances as such and mixtures would undermine the intended effect creating different legal objects and formulate specific obligations. Thus, the different terms fulfil necessary functions in the regulatory approach towards chemicals. This does not allow to merge the terms.

From a terminological perspective two options are available: Firstly, a meta-definition might be introduced assembling all sub elements and link legal obligations to this new definition (e.g. by introducing the term “combined object” as a functional equivalent REACH term for “product”, see Figure 1); secondly, the distinction between the different terms is maintained, but certain legal obligations are linked to the “non-article” elements of a product. The latter option upholds the established terminology and therefore seems preferable. Nevertheless, the first option is briefly outlined below.

Solution 1:
As a meta-definition that covers (on a separate horizontal level) all material elements of a “product” placed on the market, the term “combined object” might be added to the set of definitions in Art. 3 REACH. This would allow to link the information requirements laid down in Art. 31[64] to all material elements covered by the term, whilst upholding the O5A-doctrine.[65] Alternatively the term might also be introduced to the ECHA Guidance on SiA. As already mentioned at the beginning of the previous section, the ECHA guidance already uses a similar formulation for products supplied to consumers entailing a “combination”[66] of (complex) articles, mixtures and substances.

64 Subsequently it might be worthwhile to consider using the term also in Art. 7 REACH as well.
65 See supra section 2.1.1.
66 See, e.g., ECHA 2017c, p. 20: “combination of an article and a substance/mixture”.

The level of terminology, however, is not sufficient to close the gap with regard to information requirements. The latter would need to be linked to the meta-term which might lead to new interpretation disputes and associated uncertainties.

Solution 2:
The least intrusive option thus would be to rely on the existing definitions (standing side by side on a vertical level) whilst enhancing the "consumer right to know" and the preceding "supply chain information" to substances and mixtures that are part of a combined object. To this end the information flow provided for by Art. 33 should cover substances and mixtures present in combined objects.

Thus, a future Art. 33(3) wording might read as follows:

> Paragraphs 1 and 2 also apply to substances and mixtures that are an integral element of an article or to substances and mixtures for which the article functions as a container or a carrier material.

There should be no need to adopt the related communication mechanisms in the professional supply chain; at least not in terms of SVHC communication since the obligation to provide information on substances and mixtures by means of safety data sheets is already covering this issue. Thus, for compliant industry actors no additional burden would occur. On the other hand, the new wording would put consumers in a position to make informed purchasing decisions also with regard to mixtures/substances incorporated in a product.

Beyond the scope of this study, moreover, it appears worthwhile considering to extend the consumers' right to know also to mixtures. However, in practical terms consumers mostly purchase mixtures in packed form; thus the suggested new Art. 33(3) would cover these cases.

2.1.5 Summary

The following table summarizes the preferable policy option outlined in this section.

Table 5: Policy option enhancing the communications obligations in Art. 33 to all article related substances/mixtures

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
1 sect. 2.1.4	Scope of Art. 33 enlarged in a new para 3 to substances and mixtures linked to an article	Amend-ment of the REACH text; ordinary legislative procedure	SVHC com-munication obligations cover all article related substances/ mixtures on the market	Supply chain actors and consumers: Informed purchasing decisions also with regard to all combinations of an article and a substance / mixture	Borderline cases (see guidance on SiA) with regard to Art. 33 are no longer relevant. The related clarification efforts can be avoided. Industry: Supply chain communication for mixtures containing SVHCs above 0.1% is already foreseen via SDS; in this respect all information should be already available to suppliers of mixtures

For other potential enhancements in the context of Art. 33 see the legal options outlined in section 2.2.3.2.

2.2 Improved communication on SVHCs in articles

This section addresses the REACH requirements concerning the communication of SVHCs along the article supply chains and with regard to the consumer.

2.2.1 Legal framework

The legal framework governing the communication on SiA is designed in a way that contributes to the general aims of REACH with a view to an increased transparency on the uses of SVHCs and thereby enhancing the eventual replacement of SVHCs, where this is possible.

The scope of application with regard to communication on SVHCs (and classified substances under CLP) is limited due to the exceptions laid down i.a. by Art. 2(6) REACH with respect to mixtures. In particular cosmetics (Art. 2(6)(b) REACH) are excluded due to the specific requirements laid down in Directive 1223/2000. This leads to inconsistencies, e.g. in terms of the environmental hazard classification requirements[67] and the classification and labelling of personal care products.[68]

2.2.1.1 Objectives

As outlined already in section 2.1, REACH aims to progressively replace SVHCs with "suitable, alternative substances or technologies where these are economically and technically viable" in order to, i.a., "ensure a high level of protection of human health and the environment", and to foster innovation and competitiveness, whilst at the same time contribute to "the good functioning of the internal market".[69] Against this background, REACH applies a tiered regulatory approach to SVHCs: transparency on the use of these substances in articles, thereby putting consumers in the position to "make informed decisions",[70] shall unfold market incentives for article producers to abstain from SVHC use, and for retailers to consider SVHCs in the listing and delisting of articles. In addition (see section 2.4), authorities may impose authorisation requirements on prioritised SVHCs, thus reinforcing these incentives.

2.2.1.2 Legal mechanisms and requirements

Within the article supply chain, pursuant to Art. 33(1), "suppliers[71] of articles[72]" containing SVHCs above 0.1% w/w must "provide the recipients[73] with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance". According to Art. 33(2), the same information has to be provided to a consumer upon request, free of charge, within 45 days of receipt of the request.

The SVHC (legal) status of a substance becomes effective upon publication of the so-called candidate list on the internet.[74] In 2008, ECHA added the first 15 entries to the candidate list. The 2013 SVHC Roadmap[75] expected several hundred substances on the candidate list in 2020. By January 2020, it had grown to 205 substances (and substance groups).

67 For the latter cf. Sobek et al. 2013, discussing Inconsistencies in EU environmental hazard classification requirements for UV-filters.

68 Klaschka 2012.

69 Art. 1(1), 55; Recital 12, 70.

70 Recital 117. In the words of the European Commission, the consumer 'right to know' was included in REACH so that "[c]onsumers can play an active role in the process by taking an interest in the safety of the products they buy", see explanation by the European Commission (9.5.2019).

71 The term "placing on the market" defines Art. 3 (12) as "supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market". Thus, no purchasing act is needed to fulfil the definition.

72 For the term and the related legal and implementation issues see section 2.1.

73 Art. 3(35) states that the term ""recipient of an article" applies to "an industrial or professional user, or a distributor, being supplied with an article but does not include consumers". Thus retailers are covered, since – according to Art. 3(14) – "distributor: means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties".

74 Cf. candidate list by ECHA (03.04.2020).

75 ECHA 2013.

In addition, under the EU Waste Framework Directive (WFD) as amended in 2018,[76] new obligations regarding SVHCs in articles arise for EU Member States and for ECHA, the latter having the task to create a database to collect and provide information about articles that contain SVHCs above 0.1% by weight. At the beginning of 2020, ECHA launched a test version of the (SCIP) database foreseen in Art. 9(2) WFD.[77] When transposing the Directive into national legislation, Member States have to "ensure that any supplier of an article" (as defined by REACH) provides the information on SVHCs in articles to ECHA from 5th January 2021.[78] The scope of the requirements refers to REACH Art. 33.

The reporting obligations mentioned in this section concern all articles supplied on the EEA market, including imported articles.

2.2.1.3 Legal uncertainties and clarification needs

Measured by the normative objectives, this section summarises, from a legal perspective, uncertainties in the interpretation of the relevant provisions of REACH and indicates the subsequent clarification needs.

Art. 33(1) obliges suppliers to provide SVHC information to the professional recipients of articles while it does not oblige explicitly the latter to actively request this information or to investigate this issue, in case no or only doubtful information was provided. However, article recipients such as brands and retailers remain fully responsible for the legal conformity of the articles they place on the market.

The notion in Art. 33(1) and (2) "available to the supplier" is embedded in the wording describing the first communication requirement "sufficient information (…) to allow safe use of the article". The notion is not applicable to the second requirement ", as a minimum, the name of that substance." Voices in literature argue that the duty of the supplier to provide information on SVHCs is stipulated by the Art. 33(1) information he received from his upstream supplier.[79] The European Court of Justice (CJEU), however, concludes[80] as follows (emphasis added):

> Article 33 of Regulation No 1907/2006, as amended, must be interpreted as meaning that, for the purposes of application of that provision, *it is for the supplier* of a product one or more constituent articles of which contain(s) a substance of very high concern identified in accordance with Article 59(1) of that regulation in a concentration above 0.1% weight by weight of that article, *to inform the recipient* and, on request, *the consumer*, of the presence of that substance *by providing them, as a minimum, with the name of the substance in question.*

The ruling clarifies that the duty to provide the name of the SVHC is a minimum requirement that has to be followed strictly. Each supplier of an article remains fully responsible for the accuracy of the provided information.

Art. 33 REACH thus should encourage suppliers of articles to build up organisational capacities, which allow them to determine whether their articles or components thereof contain SVHCs above 0.1% (w/w). In fact, keeping the legal principle of proportionality in mind, the CJEU ruled that this requirement "which is minimal in nature, cannot be regarded as being an excessive burden".[81] A strategy of relying on legitimate expectations of their suppliers' compliance[82] would

76 Directive 2008/98/EC on waste 2008 OJ L 312/3, amended by Directive (EU) 2018/851, 2018 OJ L 150/109.
77 Cf. section 1.1 and https://echa.europa.eu/de/scip-database (03.04.2020).
78 Führ 2018.
79 See Scheidmann 2017, p 11.
80 CJEU as of 10.09.2015, see section 2.1.1 above.
81 CJEU as of 10.09.2015, see section 2.1.1 above.
82 Scheidmann 2017, p. 7.

put professional recipients at risk. Whilst there is no explicit requirement under REACH to set up management systems,[83] suppliers face the factual need to establish an internal organisational structure assuring that these requirements are actually met (this could be clarified in an implementing annex, see section 2.2.3.2.6). This interpretation is in line with the explicit duties laid down in Art. 36 REACH which does not only contain the "obligation to keep information", as indicated by the title of the provision. Rather, as a logical first step each "distributor shall assemble (…) all the information he requires to carry out his duties under this Regulation". The provision thus formulates the general "duty to organize" which is ultimately embedded in the principle of self-responsibility of commercial actors as laid down in Art. 1(3)1. Thus, REACH actors have to actively organize the information, communication and cooperation (IC&C) processes in the supply chain on which the functioning of the various REACH mechanisms is based upon.[84]

Art. 33(1) is not clear on the exact date when suppliers need to provide SVHC information to the recipient. The latter is defined in Art. 3 Number 35 as "an industrial or professional user, or a distributor, being supplied with an article". Thus, the question arises under which conditions the term "supplied with an article" is applicable. In this respect, reference can be made to Number 33 of Art. 3 defining "supplier of an article" as any "actor in the supply chain placing an article on the market". Supply in the context of Art. 33 could therefore mean "placing on the market", defined in Number 12 of Art. 3 as "supplying or making available" to a third party,[85] including importing. Consequently, merely making available of articles could trigger the reporting obligation. In order to bring the recipient into a position where he can make an informed purchasing decision, a potential professional buyer of an "available" article should be actively informed about the fact that the article contains a SVHC above 0.1% (w/w). In practical terms, this would mean that in a catalogue or an online shop this information should be provided in relation to the respective article before the purchasing decision is made.

Indeed, Art. 33(2) is applied accordingly: suppliers have to provide consumers with SVHC information upon request, whereas this obligation applies irrespective of any purchasing activity since consumers can apply their right to know to any article made available. The reason for this interpretation of Art. 33(2) is to allow consumers to avoid articles containing SVHCs above 0.1% - the overarching normative goal of Art. 33. This provision does not aim to put professional recipients at a less favourable position than consumers. Consequently, it should be clarified that professional recipients are provided SVHC information before the purchase is done (see section 2.2.3.2.8).

On the other hand, a different interpretation is possible: Number 35 of Art. 3 defines recipient of an article as a professional actor "being supplied with an article". This wording might be read in the sense that a specific supply activity is necessary, in contrast to mere "holding available". Under that notion, Art. 33(1) requires suppliers to provide relevant SVHC information at least "upon supply" to the recipient. ECHA apparently supports this legal view when stating that in the professional supply chain the "information is to be provided to the recipient of the article when the article is supplied for the first time".[86] In this scenario, some recipients such as retailers may have the capacities to contractually oblige their suppliers to (exclusively) provide articles without SVHCs triggering the legal threshold (section 2.2.2.2). However, other recipients lacking

[83] See also ECHA 2019e, p. 9.

[84] For details see Führ 2008 and Führ 2011a, para 4, 50, 108, 113 and subs.; Führ 2011b, para 8 et subs.

[85] It follows that physical transfer is covered by the term but it is also sufficient to have the article on stock or list it in a catalogue or an online shop. Since both definitions mention the term "supply" REACH offers a somewhat circular definition. This creates legal uncertainties. Considering the legislative intention of informed purchasing decisions the fact whether a SVHC is present or not should be visible before the decision is taken.

[86] ECHA 2017c, p. 26.

such capacities could be deprived of making an informed purchase choice in accordance with the normative objectives.

Closely related is the question which status of the candidate list has to be considered. In the "upon supply" scenario, some actors interpret the reporting requirement as to referring only to the SVHCs present on the candidate list as of the date of supply. For instance, the ECHA guidance quoted above proceeds "when the article is supplied for the first time after the inclusion of the substance into the Candidate List".[87] In this view, the supplier does not have to provide an update of his report to reflect any (bi-annual) update of the candidate list, potentially affecting the SVHC status of the article. This interpretation deprives article suppliers, notably retailers of articles with a longer (i.e. more than 6 months) shelf life, of knowing the actual SVHC contents of those articles. This interpretation consequently hampers the cascade of information requirements as foreseen in Art. 33(1) and leaves the recipients with the factual duty to perform tests for each (sub-)article likely to contain a SVHC above 0.1%. At the latest, this would be required when a consumer requests SVHC data for this article since Art. 33(2) is applicable to the retailer during the entire period he is "making available" the article (see below; for a proposal to clarify this issue see section 2.2.3.2.5).

If an article contains no SVHCs or SVHCs below the threshold, suppliers of articles are not obliged to report to their recipients/reply to the consumer's right to know requests.[88] No answer therefore could mean both that SVHCs are not included (above the threshold) or that the supplier simply has not (yet) reported/answered to the request. These uncertainties reduce the reliability of the reporting mechanisms, both for professional recipients and consumers. In addition, they create costs for the implementation processes performed by the recipient and for the enforcement activities by the national enforcement agencies who must first clarify what "no answer" means (see section 2.2.3.2.4).

There are also uncertainties regarding the temporal scope of Art. 33(2). One can only assume that authorities most likely will not enforce information requests addressed at articles that have been placed on the market before REACH entered into force on 1st June 2007. For articles placed on the market thereafter, the right to know applies. At least since 28th October 2008, when ECHA published the first version of the candidate list, suppliers of articles placed on the market thereafter are obliged to communicate information on candidate list substances pursuant to Art. 33. However, REACH does not stipulate whether the Art. 33(2) communication duty is determined by the candidate list in effect at the time of request or at the time of the first market placement. The wording of the paragraph indicates that, as the list evolves, so do the communication duties of article suppliers. This would be the adequate interpretation in light of the normative objectives.

However, the German REACH-CLP-Biozid Helpdesk holds the legal view that for articles already delivered, in the event of a candidate list update Art. 33 does not require suppliers to update SVHC information provided in the past;[89] whilst all subsequent suppliers now have to comply with the new candidate list with regard to the same article.[90] The same applies in the case of a consumer request under Art. 33(2): here the supplier has to comply with the current candidate

87 ECHA 2017c, p. 26.

88 Proactive suppliers however use this opportunity to inform their customers of the absence of SVHCs. For instance, the LIFE AskREACH project encourages suppliers of articles, with or without SVHCs above the threshold, to upload information on such articles to a database set up by the project to support Art. 33 implementation.

89 In cases in which the first supplier have the article on stock after the update of the candidate list.

90 See REACH-CLP-Helpdesk answer No 0077: "There is no legal obligation to provide updated information for products already supplied if the candidate list is extended.
However, commercial recipients who supply the article after the candidate list has been updated in the supply chain are subject to the relevant information obligations that are now in force" (own translation), (11.06.2020).

list of the request date. The consumer can address his request to any supplier; he is not limited to retailers. And he is not obliged to purchase the article or to have the intention of doing so. Thus, all actors in the supply chain need to be in a position to reply to the request, given that they are placing the article on the market.

It can be stated that, for the time being, uncertainties exist in the interpretation of Art. 33(1), since, as mentioned above, the subsequent suppliers, including retailers, face severe difficulties to comply with Art. 33(2). This situation hinders smooth implementation of the supply chain communication requirements on SVHCs. The same is true for the Art. 33(1) obligation of downstream suppliers receiving articles during an update of the candidate list or having them on stock during this period with the effect that the company is "making available" the article after the update and is subsequently delivering them to its customers. Furthermore, any uncertainty with regard to Art. 33(1) also impedes the optimal implementation of the SCIP database, since the respective reporting obligations under the WFD are expressly linked to that provision.

The 45 days period set out in Art. 33(2), which seems surprisingly long given the fact that within the supply chain article suppliers have the duty to provide the SVHC information at least upon supply, usually deprives consumers of the chance to receive relevant information they need in purchase situations, e.g. at the point of sale, including online shopping (see section 2.2.3.2.7).

2.2.2 Implementation

In the first years of REACH, legal uncertainties hindered the practical implication since Art. 33 does not specify whether the 0.1% value in case of articles that are complex objects (e.g. car, mobile phone, shoe) refers to the whole product or to each article it is composed of. In September 2015, the European Court of Justice decided in favour of the 'once an article always an article' (O5A) approach (see section 2.1.1), according to which the 0.1% threshold applies to each article of a complex object made up of more than one article, which were joined or assembled together. Since 2017, the ECHA "Guidance on requirements for substances in articles" is comprehensively addressing the ruling and consequential action needs for suppliers (for details see section 2.1.2).

Assessments on the question how Art. 33 is applied in practice observe a lack of implementation partly due to lack of awareness, both on the part of article suppliers and of consumers, as well as challenges in supply chain communication and related data gaps. The findings are coherently pointing in this direction (section 2.2.2.1), linked with a lack of awareness and a – perceived – lack of legal clarity[91] and appropriate means to act compliant (section 2.2.2.2). This also affects the perspective of circular economy (section 2.2.2.3).

2.2.2.1 Reports and studies on the overall implementation of Art. 33

Several studies and documents of e.g. ECHA and the Commission Services, as well as civil society actors, observe a number of problems in the implementation of Art. 33. In its second General Report on the Operation of REACH, the European Commission found companies "struggle"[92] to respond to (the limited number of) consumers' right to know requests.[93]

In this respect, the CJEU's ruling on the 0.1% threshold ("O5A") caused complaints by industry actors as reporting obligations have increased substantially. The CJEU, however, has considered

[91] For details, see section 2.2.1.3.
[92] COM (2018) 116 fin, p. 4.
[93] Cf. CSES 2015, p. 155; SWD(2018) 58 fin., PART 5/7, p. 59.

the issue in terms of proportionality in its reasoning and stated that the requirement of Article 33, "which is minimal in nature, cannot be regarded as being an excessive burden".[94]

The quality of answers replied to consumer requests is often not adequate,[95] which may demotivate consumers to use the tool. At the same time, if consumers do not ask, an important incentive for supply chain communication is missing.

The Commission concludes that it "remains difficult for actors in the supply chain to retrieve, verify and communicate information on SVHCs in articles".[96] For instance, only 47% of the 174 companies participating in a survey performed in the context of an EU LIFE project (LIFE AskREACH) feel well informed or quite well informed about the presence of SVHCs in their articles.[97]

One obvious reason for this is the lack of appropriate supply chain communication on SVHCs pursuant to Art. 33(1).[98] ECHA reports on "clear indications" that SVHC information is not adequately communicated along the article supply chains.[99] In fact, only single sectors (e.g. automotive)[100] or companies (e.g. Apple)[101] with highly professionalised procurement structures can assure a minimum level of confidence that their suppliers have reported the actual SVHC contents – at least at the date of supply.

Meanwhile, first enforcement experience based on an EU wide horizontal assessment of Art. 33 compliance is available. The Forum (Art. 76(f) REACH) completed a so-called 'pilot project' on the harmonised enforcement of substances in articles. According to the project report, 15 Member States participated in the operational phase of the pilot project.[102] The total amount of inspected articles was 682. Out of these, 55 articles contained SVHCs above 0.1% w/w. From these 55 articles the information obligation of Art. 33(2) was fulfilled in 24 cases and was not fulfilled in 31 cases (56%). Relating these findings to firms, 43 companies were obliged to answer from which 21 companies fulfilled this obligation and 22 companies (51%) did not.[103] The results also show a high non-compliance rate of 89% for the articles with information obligations according to Art. 33(1).[104] However, it is not possible to draw general conclusions on the situation of articles on the EU markets from these figures, as the project focused on high risk products or materials, and targeted only a few SVHCs.[105]

2.2.2.2 Lack of awareness and means to act compliant

As for consumer awareness, data from a representative Eurobarometer poll indicates that consumers are aware of a generic right to know, as they mostly agree with the statement "if you ask whether a product contains particularly hazardous chemicals, the seller is required by law to

94 CJEU, Case 106/14, o.c., para 81.

95 See e.g. the examples of inadequate company replies received by BUND via the "ToxFox" App in this article by ToxFox (10.5.2019).

96 SWD (2018) 58 final, part 1, p. 30.

97 Schenten et al. 2019.

98 Reihlen and Halliday 2017, p. 24.

99 ECHA 2016, p. 120.

100 The International Material Data System (IMDS) employed by the automotive sector, including most major original equipment manufacturers (OEMs), is an information exchange system (database) providing the technical means report 'full material declarations' in terms of chemical content of supplied (part) products. It is designed to ensure compliance with chemical-substance-related requirements, at the same time facilitating circular mass flows, see information on IMDS(accessed 1.12.2018); but cf. on the constraints Winkler-Portmann (2019) and related development perspectives Winkler-Portmann (2020).

101 Guzzo et al. 2016.

102 ECHA 2019e, p. 6.

103 ECHA 2019e, p. 26 et seq.

104 ECHA 2019e, p. 26

105 ECHA 2019e, p. 6, 36.

provide you with this information".[106] However, such a response does not mean that consumers are aware of the specific right to know as laid down in Art. 33.[107] Rather, a 2016 ECHA report on the operation of REACH found consumers largely unaware of their right to ask for information on SVHCs in articles.[108]

Article suppliers refrain from providing SVHC information due to different reasons, such as that they

- lack the data they should supply themselves;
- are not aware of (all) legal obligations;
- lack the means to collect data along the supply chain and provide it to their recipients;
- hesitate to provide information because they perceive it as confidential.[109]

Closely related to a lack of means, complexity is another impediment. In practice, companies are facing various legislations besides REACH, applicable in different jurisdictions and relevant for specific articles and substances. They often collect SiA requirements applicable for them in (manufactured) restricted substance lists (M)RSL, against which suppliers need to declare conformance of their articles (negative reporting of the substances not included in articles, or processes). Few sector standards exist for such lists;[110] besides companies tend to create their own[111] lists thus contributing to a high complexity in SiA requests to suppliers.

At the same time, as for data quality and reliability, information provided in such compliance declarations usually is too scarce to check even plausibility.[112] In fact, to verify compliance, companies perform excessive testing, e.g., risk-based testing of materials in every article (e.g., phthalates in plastics). For instance, Nike in 2015 carried out almost 500,000 chemical tests in its supply chains to make sure articles do not contain restricted substances.[113]

In practice, suppliers may report declarations of conformity regarding certain substances regulated such as SVHCs, perhaps supported by chemical testing. Presuming the accuracy of such statements, they ensure compliance with respect to specific substances. However, such declarations indicate the article properties upon the date of delivery and thus refer only to the substances listed on a RSL or e.g., on the SVHC list by this date. It follows that with every new identification of SVHCs the compliance declaration is potentially partly outdated. An additional declaration, probably accompanied by chemical testing and taking into account the newly added substances, is then required.

Thus, notwithstanding the uncertainties as to interpreting the legal obligations discussed above, also the way market actors organize their purchasing conditions and the (absence of) automated communication processes create practical problems with a view towards Art. 33 compliance. Thus, companies face a variety of organisational challenges in the supply chains.

106 European Commission 2017.

107 Schenten et al. 2019.

108 ECHA 2016, p. 120.

109 Reihlen and Halliday 2017.

110 E.g., ZDHC MRSL, see MRSL by ZDHC (24.05.2019).

111 In fact, even in sectors having standards established, companies tend to add their "individual" substances to the list, as this might reflect requirements of specific markets and/or to yield competitive advantages. For instance, in the automotive sector one RSL ("GADSL") is shared by all OEMs, while each OEM adds certain substances on top.

112 Reihlen and Halliday 2017.

113 See (14.11.2018).

2.2.2.3 Circular economy perspective

From the circular economy perspective, presuming declarations are communicated to recyclers after all,[114] the recyclers in most case will only have the information on 'yes' or 'no' with regard to the 0.1% threshold for SVHCs. Thus, uncertainties as to the actual toxic load of end-of-life articles still would remain. In general, mere negative reporting thus deprives recyclers of their possibilities to bring materials from end-of-life articles back into the material streams, since they do not know the composition of the articles delivered to their recycling facilities. In this respect, a register with all products containing SVHCs would be helpful (see section 2.2.3.2.3).

It remains to be seen whether the future notification obligation on SVHCs in articles under Art. 9 WFD will foster transparency and thus communication on SVHCs, with positive spill-over effects to Art. 33 compliance.[115]

2.2.3 Potential enhancements/Policy options

A tiered approach to address the implementation deficits and legal shortcomings appears reasonable. In this respect, the impact of recent regulatory changes (WFD) which will become effective as of 2021 (given the transposition of the directive to national legislation takes place in time) should be considered. Beside enhanced efforts to stipulate the implementation of the existing legal framework (see section 2.2.3.1), options to alter the legal framework also could be considered (2.2.3.2). Section 2.2.4 summarizes the implications of the different options.

2.2.3.1 Implementation support

The least invasive option would be to support companies in their efforts to act compliant (see sections 2.2.3.1.1 - 2.2.3.1.3). Proper enforcement activities by the regional authorities would provide additional incentives in this direction (2.2.3.1.4).

2.2.3.1.1 Supportive tools

A study on behalf of the European Commission provides information on the availability of different tools to enhance communication on SiA in the supply chains as well as vis-á-vis the consumer.[116] As regards business to consumer communication, some MS smartphone apps are available for consumers to scan article barcodes and automatically generate Art. 33(2) requests. Answers provided by suppliers are stored in a database and available for other consumers scanning the same article. Such tools have the potential to significantly lower the transaction costs for consumers and suppliers in the implementation of Art. 33(2).[117] In the EU LIFE AskREACH project, such a tool is developed and offered to authorities and NGOs in all MS, backed by comprehensive awareness campaigns aimed at consumers and article suppliers.[118] However, design flaws in the legal basis (notably no obligation to answer if SVHCs above 0.1% are not present in articles) put the success of such tools at risk, as empirical data suggest that not getting an answer to a request discourages consumers from further using their right to know.[119]

In addition, a company's reply to a consumer's request is only as good as the flow of SVHC information according to Art. 33(1) in the supply chains of such articles. In this respect, the mentioned study for the Commission assesses the availability and usefulness of different

114 Which is rather doubtful under REACH, cf. Bernard 2017, 54, however the WFD stipulates a new reporting mechanism on SVHC in articles, addressed specifically at recyclers.
115 Führ 2018.
116 Reihlen and Halliday 2017.
117 Hellinger 2019, p. 169; Schenten and Schönborn 2018.
118 See information on LIFE AskREACH.
119 Schenten, Brenig, Führ, Bizer 2020 (submitted).

business to business communication approaches.[120] According to ECHA, companies running systems ensuring traceability of supplied raw materials and article compositions are less challenged to comply with Art. 33 obligations.[121] IT-based solutions offer opportunities to establish a systematic approach to transparency and traceability of SiA within complex (global) supply chains. In order to "be prepared"[122] for future legislation, the long-term vision of a Full Material Declaration (FMD) is a promising approach. FMD implies the generation of a structure tree of all materials present in a certain final article (Bill of materials – BOM) subject to reporting, which is usually a complex object (incorporating more than one individual article). The structure follows the different stages in the production process of an article, e.g. from semi-finished article (e.g. plastic sheet), further processed component (e.g. machining, coating), to incorporation in the final article. This way firms can meet present requirements from law as well as from sectoral or company specifications and can prepare for future requirements.[123]

The possibility of easy and quick information transfer between different tools appears essential to increase the efficiency of communication and thereby the acceptance of such tools. Thus, a standardised data structure and exchange format is recommended, ideally agreed upon at global level.[124]

2.2.3.1.2 Reduce impediments through harmonised SiA communication

Lack of supplier cooperation is one main obstacle for proper Art. 33(1) implementation, whereas the supply chain complexity and the (globally) growing number of article-related requirements put increasing pressure on article suppliers. Proliferation of sector requirements could be reduced, and suppliers' willingness to cooperate in turn increased, if sector approaches were interoperable and data easily interchangeable. Hence, inter-sector cooperation based on harmonised SiA reporting requests would reduce burdens placed on all supply chain actors (principle: report data once, use several times). Besides, the more common data demands are, the stronger is the voice of the different sectors to obtain a sufficient level of information by their suppliers. The same rationale can be found in the "mission statement" of the inter-sectoral[125] "Proactive Alliance", initiated in 2018, which sets out to define recommendations for a global cross-sector standard for communicating SiA information, also supporting FMD and taking into account the "once an article always an article" (O5A) principle (see section 2.1.1) for articles in terms of REACH.[126]

Thus, as indicated by the 2020 Circular Economy Action Plan,[127] EU policies could support harmonisation efforts concerning SiA communication as increased effectiveness and efficiency will have a direct positive impact on compliance.

2.2.3.1.3 Guidance on organisation of supply chain communication

One option to support supply chain actors would be to provide guidance on how to organise communication along the supply chain and how to document related activities and data to ensure compliance, by fostering development of a respective standard. As model for this

120 Reihlen and Halliday 2017.
121 ECHA 2017c.
122 In contrast to the current practice of "negative reporting" (section 2.2.2), knowing which substances are present in articles would allow companies to control compliance of their products also in terms of future regulations and would at the same time satisfy the needs of circular economy.
123 Cf. Schenten et al. 2018.
124 Reihlen and Halliday 2017, p. 26.
125 The group gathers representatives from automotive, chemicals, furniture, electrical and electronic, mechanical, metalworking and metal articles, home textiles, textiles and sporting goods and medical devices.
126 Cf. information on the proactive alliance (05.04.2020).
127 Cf. COM (2020) 98 fin. After that, the European Commission seeks to "co-operate with industry to progressively develop harmonised systems to track and manage information on substances identified as being of very high concern and other relevant substances", p. 13.

supportive instrument could serve the technical documentation defined in an international standardization document[128] for economic operators under RoHS.

This option would help article suppliers to design their purchasing conditions along the supply chain in a way that they contain clear provisions on quality management and communication of substances in articles by means of private law. It would reduce the transaction costs of industry actors.

2.2.3.1.4 Enforcement

Art. 125 obliges the Member States "to maintain a system of official controls and other activities as appropriate to the circumstances". Art. 126 states that the "penalties provided for must be effective, proportionate and dissuasive". Although in wide areas REACH is based on the regulatory approach of "self-responsibility",[129] a certain level of administrative enforcement is foreseen. With enforcement activities, the MS stipulate incentives for companies to implement Art. 33. In the first years of implementing REACH, there have been legal uncertainties as to the reference point of the 0.1% (w/w) threshold in Art. 33. For this reason, apparently, article suppliers were granted a "period of grace" by national enforcement agencies. However, the CJEU's judgement clarifying the "once an article always an article" interpretation is five years old as of September 2020. Hence, under the rule of law and with a view to the principle of equal treatment, it would be beneficial if national authorities were to intensify their efforts in assuring that firms comply with their information obligations regarding SVHCs.

This is particularly important as market-based incentives can only advance the intended policy objective, if the disclosed information is correct (for insights from the Forum pilot-project cf. section 2.2.2.1).

However, legal uncertainties of Art. 33 create challenges for enforcement agencies (section 2.2.1.3)which could be reduced by modifications of the legal text (section 2.2.3.2).

2.2.3.2 Legal options

With regard to the existing legal framework (see section 2.2.1) and the implementation by the relevant actors so far (section 2.2.2), considering enhancements of the legal requirements seems appropriate. The following legal options[130] are at hand with regard to the normative aims pursued by the provisions on communication on SVHCs in articles. The considerations are based on the assumption that ECHA establishes the SCIP-database (see section 1.1) with the functionality outlined at the ECHA website.[131]

2.2.3.2.1 Labelling for SVHCs in articles

Under the current legislative framework, consumers face the problem that a response to a request based on Art. 33(2) is to be expected after a relatively long period of up to 45 days. A labelling requirement would allow the consumer to check directly at the point of sale whether the article contains SVHCs above the 0.1% limit. A similar requirement could also apply to online shops. Based on this information, the consumers would be in a position to make an informed

[128] Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances (IEC 63000:2016), DIN EN IEC 63000:2019-05; VDE 0042-12:2019-05.

[129] Cf. section 1.1; underpinned by recitals 16, 18, 25, 29, 56, 58 ('chain of responsibilities'), 86, 105; see also Führ and Lahl 2006 and Führ and Schenten 2020.

[130] See also Hermann and Bunke 2015, p. 93 subs on the regulatory options (1) Standardised communication format for articles (inter alia proposing criteria for "sufficient information"), (2) Labelling for SVHCs in articles, (3) Extension of the communication requirements to other substances, and (7) Register for articles containing SVHC.

[131] See SCIP prototype by ECHA (06.04.2020).

purchasing decision. It would also serve as a trigger to consider safe use instructions, where available and appropriate.

In practical terms, it is noticeable that a product label, in the moment it is printed on the article, is static in nature whilst the candidate list dynamically evolves, usually every six months. A label indicating the presence of a specific SVHC would become misleading if after a candidate list update another substance present in the article now falls in the scope of Art. 33(2). A generic label such as "includes SVHC(s)" would thus be preferable.

Another element of the option could oblige suppliers falling under the labelling duty to use appropriate means to inform interested consumers of the precise name(s) of the SVHC(s) and of safe use instruction, if relevant. For instance, the supplier could provide a QR code on the article or its packaging which forwards consumers to a website providing the information. With this option, it would be possible to update the website whilst the QR code functions as a (unique) product identifier. A growing number of retailers offers scanning devices at the point of sale, which would allow to access the information on a larger screen. Online shops can provide a link to the respective section of the website for each product that contains SVHCs.

This option would transpose the minimum answer under Art. 33(2) – i.e. the name of the substance – into a labelling requirement. Given that the supplier already acts in compliance with REACH the additional burden is "minimal in nature", whilst the benefit for the consumer as well as for the overall substitution goal is substantial.[132]

This option requires an adaption of the legal text of REACH in the ordinary legislative procedure.[133]

In order to assess the impact of a labelling obligation for SVHCs in articles, implementing measures for "energy-related" products in the context of the Ecodesign Directive (ED)[134] could be used as a test case, since the ED provides for setting e.g. design and communication obligations linked to "legislation on the marketing and use of specific substances" such as SVHCs.[135]

2.2.3.2.2 Communication requirements to other substances of concern

Art. 138(8) REACH stipulates that by "1 June 2019, the Commission shall carry out a review to assess whether or not to extend the scope of Article 33 to cover other dangerous substances, taking into account the practical experience in implementing that Article. On the basis of that review, the Commission may, if appropriate, present legislative proposals to extend that obligation".

Against this background an extension of the communication requirements to other "substances of concern"[136] might be envisaged in a proposal to amend the scope of Art. 33. Consequently, the same requirements are to be met for those substances. The possible benefits and additional burdens will be assessed in an impact assessment performed by the Commission services.

In order to make use of that option the EU legislative bodies have to amend the text of REACH.

132 A SVHC labelling scheme could also aim to support professional recipients of articles and thus be applicable to all (sub-)articles subject to Art. 33(1), cf. Hermann and Bunke 2015, p. 99.

133 An alternative implementation route could go via a modification of the CLP legal text, which to the end of a SVHC labelling obligation of articles would require, i.a., additional classification criteria for SVHCs that are PBT and vPvB, see Hermann and Bunke 2015, p. 103 et subs. Due to the link of CLP to the GHS one can assume, however, that the implementation route via the REACH context would more likely be available in a short-term perspective.

134 Directive 2009/125/EC of the European Parliament and of the Council of 21st October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products.

135 Cf. Führ et al. 2019.

136 In this respect, see the options already discussed at Hermann and Bunke 2015, p. 100 et subs.

2.2.3.2.3 Improvement of the SCIP database for articles

The EU is on the way to advance the legal requirements that facilitate and stipulate change processes towards a more circular economy. One of the recent developments is the SCIP-database under Art. 9(1) WFD. All suppliers of articles (included in complex objects) containing SVHCs have to provide data to ECHA accordingly (see section 1.1). The data then would be accessible by operators of recycling installations and by consumers.

In practical terms, ECHA is planning to make the information submitted to SCIP publicly available.[137] Authorities can use the database as a tool to monitor and help identify the substances of concern that are present in articles. It will also allow them to consider the need for further regulatory actions. The data would support, moreover, economic actors with business models aiming at a "second life"; be it directly as "second-hand" shop or indirectly after refurbishment of any kind. For those actors and for their potential customers, it would be helpful to have access to a database that in a user-friendly manner provides information as for the composition of the product at hand and the (sub-)articles incorporated therein. Accurate data should include a number for each batch[138] in the sense of a unique product identifier.

For consumers, the database would offer information that would help them to make more informed purchase decisions, given that the entries in SCIP can easily be linked to products on the market. In the current conception of SCIP, notifiers "must insert other names of the articles or complex objects to be supplied to consumers, when such names are key to allow them to search the information in the SCIP database (e.g. brand and model)", whilst this only applies "when such identifiers are available to them".[139] In this respect, the EAN (European Article Number) could be a useful indication for consumers, in particular when SCIP incites suppliers to assign batch specific EAN to their articles to allow for precise SVHC information.[140]

Yet, from the perspective of the user, some uncertainty remains as to any article not mentioned in the database. Against the background of first experiences made in the enforcement of Art. 33 REACH, verifying significant rates of non-compliance (section 2.2.2.1), users may not be in the position to reasonably conclude that any article not included in SCIP does not contain SVHCs above the threshold. These uncertainties however may impede the objective of the tool to support consumers' purchasing choices. With a view to reducing these impediments, ECHA could create the option for suppliers to voluntarily notify articles not containing SVHCs above 0.1% w/w. This option would also acknowledge efforts of suppliers analysing their article portfolio in order to identify those products that (do not) fall under the notification requirement. Enhancing user-friendliness, ECHA could also provide an opportunity for potential users to simultaneously browse SCIP and the article database set up under the LIFE AskREACH project when searching for article information.[141]

No legislative changes would be needed for the implementation of these options as it would not constitute any additional legal obligations but merely enhance the service function of SCIP for a variety of actors.

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137 Cf. information on SCIP database (03.04.2020); Questions and Answers ID 1714 (Version 1.0 as of 09.09.2019): "The information submitted to the SCIP database will be publicly available and therefore readily available to waste operators to bridge the current gap in the information flow. ECHA will publish the information, as received, on its website. The quality of the data remains the responsibility of each duty holder".

138 Several approaches are available to define batch.

139 ECHA 2020, 32 et subs.

140 Currently it is not common practice to assign a new EAN when the SVHC status of an article changes, cf. Schenten and Schönborn 2018.

141 In cases in which the first supplier have the article on stock after the update of the candidate list.

2.2.3.2.4 Response obligatory also in cases where SVHCs are not present above 0.1%

Currently recipients of an article in most cases do not receive a notice providing the information foreseen in Art. 33(1). This might have two reasons: the article contains no SVHCs above 0.1% or the supplier is unaware of his obligation to communicate the fact that there is a SVHC present above 0.1%. The professional recipient then faces the problem to address the aforementioned uncertainty in order to comply with his own Art. 33 requirements. In addition, his capacity to make an informed purchasing decision is undermined and thus, the benefits linked to the provision are not harvested.

The same applies to consumers; they also have to deal with the possibility that a missing reply can mean several things. Unlike a professional recipient of an article, consumers do not have a realistic capacity to clarify the factual basis.

Both problems would be addressed with the regulative option to make Art. 33(1) and (2) information obligatory also in cases where SVHC are not present above 0.1% in an article.

For suppliers that are already compliant, the additional burden would be minimal. They just have to add the explicit notion "no SVHC above 0.1%" in the article (respectively in no sub-article). The other market actors would lose their competitive advantage from acting non-compliant.

For this option, the EU legislators need to amend the text of the REACH Regulation under the ordinary legislative procedure.

2.2.3.2.5 Reporting obligations after candidate list update

Among the supply chain actors, there are different views with regard to the question which reporting obligations are applicable after the list of SVHCs has been updated. The German REACH-CLP-Biozid Helpdesk does not see the need to update the SVHC notice by the upstream supplier after an update of the candidate list regarding an article that has been delivered before the update. At the same time, the FAQ answer No. 0077 states:[142]

> However, commercial recipients who supply the article after the candidate list has been updated in the supply chain are subject to the relevant information obligations that are now in force.

Whilst the quoted statement is correct in a legal perspective de lege lata, the question arises how de lege ferenda the "subsequent supplier" can be put into a better position to act compliant. The least invasive way would be to explicitly oblige the upstream supplier to feed in the information on SVHCs with regard to the new candidate list. This would be in line with the REACH principle to collect data "at source"; i.e. the actor that is located closest to the origin of the data. It would create additional burden to the subsequent supplier if he has to verify the SVHC status of all his articles on stock after each update of the candidate list.

Similar to the legal duty already in place for updates of the SDS,[143] the regulatory option at hand would be to clarify that the article supplier has the legal duty to update the SVHC communication for a certain time period after he has delivered the article to the recipient. The time frame has to be decided by the legislator. Art. 36 can give orientation in this respect in stipulating that the distributor has to "keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last (…) supplied" an item. This provision underlines the general product monitoring duty in terms of REACH requirements as laid down,

142 See REACH-CLP-Helpdesk answer No 0077 (own translation), (11.06.2020).
143 Art. 31(9).

i.a., in Art. 5(1) subpara 1 GPSD. It indicates that the duties of a supplier or a distributor does not cease the moment an article has been delivered to the recipient.

To implement this option, an implementing annex to REACH based on Art. 132 appears sufficient to be adopted in the comitology procedure. Legislative measures in the context of Art. 138(8) process could also provide a possibility to clarify the updating obligation.

2.2.3.2.6 Duty to organize with regard to supply chain communication on SVHCs

Legal provisions formulating material requirements towards companies or other organisations factually force them to set up and maintain an organisational structure that is capable of coping with these legal obligations; thus, every material provision comes with an implicit "duty to organize". This observation holds true in particular in the context of a legal framework that is built upon the regulatory principle of self-responsibility (see section 1.1). In the context of REACH, the requirements laid down in Article 36(1), Sentence 1, underpin this finding. The provision formulates explicitly a "duty to organize" for the actors in the supply chain.[144] The provision also mentions "distributors" as an addressee of the duty; a term that is part of the definition "supplier of an article" (Art. 3(33)). Thus it has to be concluded that a "duty to organize" with respect to the SiA requirements already exists under REACH.

The addressees of the duty, however, are often not aware of the related obligations. Thus, it would be helpful in the process of reducing the implementation deficits to formulate this duty in more detail. An implementing regulation based on Art. 132 provides more legal certainty than a mere guidance document issued by ECHA. It should formulate in detail – whilst abstaining from operational details[145] – the legislative intentions and goals to be reached by the "duty to organize".

The annex would clarify the outcome in terms of communication along the supply chain as well as the information flow inside a company. It should also point out to which extent the related activities and data have to be documented to ensure compliance. In this context, international developments on standardised SiA communication should be taken into account.

The implementing annex has to go through the comitology procedure. It would not formulate additional burdens; rather, it would help to gain the benefits pursued by REACH to a higher extent.

2.2.3.2.7 Shorter period to respond to consumer requests

With the current response period of 45 days the incentive for consumers to make an Art. 33(2) request is quite limited. Given that – after more than 10 years of REACH – the supply chain actors should be in the position to establish an effective Art. 33(1) communication, the response period could be reduced substantially. This can also be applied to the retailers since they are part of the information flow stipulated by Art. 33(1). Since they are the direct link to the consumer, they also have the greatest incentive to keep the SVHC information accurately up to date. The bigger retailers in most cases rely on enterprise resource planning (ERP) systems capable of identifying and tracing every article on stock. The same applies to wholesale traders distributing articles to smaller shops which they can provide, based on an article number, with the SVHC data. Thus, a time period of e.g. three working days appears appropriate from the supplier perspective. In addition, an immediate electronic reply (based on the measures outlined above) appears desirable. This intention can be formulated in the accompanying recitals.

144 See the deliberations in the context of Führ 2008 and Führ 2011a, para 4, 50, 108, 113 and subs.; Führ 2011b, para 8 et subs.

145 For an – somewhat ambiguous – attempt in this direction, see chapter 5 of the ECHA 2017c.

For this option, the EU legislators need to amend the text of the REACH Regulation under the ordinary legislative procedure.

2.2.3.2.8 Providing SVHC information in the supply chain before purchasing decision

As outlined in section 2.2.1.3, legal uncertainty may occur insofar as the question arises whether a commercial recipient of an article has to be informed under Art. 33(1) only in parallel to the delivering of the article or before the purchasing act. The wording might be read in a way that the data have to be provided only "on supply". In order to allow the (potential) recipient an informed purchasing decision, it should be clarified that Art. 33(1) obliges the supplier to include the SVHC information in any information system that is used to support the "making available" of the article (e.g. a catalogue or an internet store) and that he has to reply to any request by potential recipients. In this respect, a potential customer should be in the same position like a consumer under Art. 33 (2).

This clarification would support the overall aim of Art. 33(1) and thus contribute to the related benefits. Since the data have to be provided anyhow, the additional burden is almost not existing.

An implementing annex appears sufficient to deliver the proposed clarification.

2.2.4 Summary

The following table summarizes - in continuation of Table 5– the policy options discussed in this section.

Table 6: Policy options addressing the communication on SVHC in articles

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
2 sect. 2.2.3.1.1/ 2.2.3.1.2	Standardised data structure and exchange format allowing harmonised SiA communication	Supportive action, mandate to standardization bodies	Facilitate data transfer along the supply chain	Industry: Foundation to comply with Art. 33(1) and (2) is laid; reduce transactions costs; contribute to manageability of product safety; reduce liability and reputational risks.	Industry: Adopt the communication patterns in the supply chains; set up and maintenance of the system.
3 sect. 2.2.3.1.3	Organisation of supply chain communication	Non-binding guidance	Facilitate data transfer along the supply chain	See No. 2	See No. 2
4 sect. 2.2.3.1.4	Proper enforcement	Administrative action (coordinated by ECHA forum?)	Compliance with REACH SiA provisions	Industry: Level playing field for all companies; non-compliant actors lose their free-rider advantage and have to invest into compliance management Consumers: Foundation for right to know, Art. 33(2) improved. Health & Environment: ultimately emissions from SVHC in articles reduced.	Industry: No additional burden for compliant actors. Authorities: Resources needed (as foreseen in Art. 125/126 REACH)
5 sect. 2.2.3.2.1	Labelling requirement for SVHCs	Amendment of the REACH text; ordinary legislative procedure	Active information of consumers allowing informed purchasing decision and triggering awareness for safe use instructions	Industry, Health & Environment: See No. 4 Consumers: Reduced transaction costs to identify SVHCs in articles	Industry: Compliant actors: Development and attachment of label to articles and complex objects by placers on the market; Non-compliant actors: Lose their free-rider advantage and have to invest into compliance management.

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
6 sect. 2.2.3.2.2	Communication requirements for other substances of concern	Amendment of the REACH text; ordinary legislative procedure	Broadening the scope of SVHC requirements as foreseen in Art. 138(8) REACH	Equivalent benefits as for communication on SVHCs	Equivalent burden as for communication on SVHCs (CJEU: "minimal in nature")
7 sect. 2.2.3.2.3	Open SCIP notifications for articles without SVHCs above the 0.1% threshold	Practical level (design and implementation of SCIP by ECHA within existing legal mandate)	Enhanced transparency about SVHC status of articles	Consumers, retail, second-hand businesses: Reduced transaction costs to identify SVHC status of articles Industry: Market chances linked to transparency	No additional burden beyond voluntary notification of articles without SVHC above 0.1%
8 sect. 2.2.3.2.4	Obligatory response for "SVHC-free" article.	Amendment of the REACH text; ordinary legislative procedure	Avoid uncertainty for suppliers and consumers: Better informed purchasing decision	Industry: Level playing field for all article suppliers; enhance trust and reputation as supplier. Consumer: Certainty about the content of SVHCs in articles Health & Environment: ultimately emissions from SVHCs in articles reduced.	Industry: Art. 33(2) Additional responses to consumer request in cases where no SVHC is present.
9 sect. 2.2.3.2.5	Reporting obligation after SVHC update	Clarification of legal situation; implementing annex; comitology procedure	Enhance learning processes in the supply chain: Accurate information of all actors, including consumers	See No. 4, plus: Consumer: Certainty about the content of SVHC in articles	Industry: Additional assessment of and communication on SVHC in articles supplied prior to the candidate list update.
10 sect. 2.2.3.2.6	Duty to organize the Art. 33 obligations	Clarification of legal situation; implementing regulation; comitology procedure	Underpin the (at least implicitly already) existing duty formulated in Art. 36 REACH	In a mid-term perspective the transaction costs for supply chain communication will be reduced; thus, the benefits described in No. 3 will occur.	See No. 2.
11 sect. 2.2.3.2.7	Shorter period to respond to consumer requests	Amendment of the REACH text; ordinary legislative procedure	Raise the incentive for consumers to use their "right-to-know" under Art. 33(2)	Industry: Level playing field for all companies. Consumer: Information availability for purchasing decision improved	See No. 8.

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
				Health & Environment: Ultimately emissions from SVHCs in articles reduced.	
12 sect. 2.2.3.2.8	SVHC information in the supply chain before purchasing decision	Clarification of legal situation; implementing annex; comitology procedure	Underpin the obligations already laid down in Art. 33(1)	Support informed purchasing decisions of commercial actors. Market benefits for "SVHC-free" articles. Health & Environment: Emissions from SVHCs in articles reduced.	Industry: Information under Art. 33(1) has to be provided anyhow; additional incentive to standardize internal processes to handle customer requests will lead to reduced additional burden.

All options aim at enhancing transparency on SiA and practicability of the related information flow. They support each other mutually. For all options a tentative comparison of benefits and efforts, as outlined in Table 6, leads to the conclusion that benefits outweigh the limited additional burden for economic actors.

Some of the options require an amendment of the legal text of REACH in the ordinary legislative procedure; in other cases, an implementing annex appears sufficient. A proper enforcement of the duties laid down in Art. 33 is already required by Art. 125 and 126 REACH.

2.3 Registration and notification of substances in articles

This section analyses the requirements laid down in Art. 7(5) and 7(6). Subsequently, options to enhance the requirements are considered.

2.3.1 Legal framework

The article-related obligations in Art. 7 are part of the REACH registration scheme, i.e. the central mechanism to transpose the "No data, no market" rule under Art. 5 and thus one precondition to ensure a high level of protection for humans and the environment.

2.3.1.1 Objectives

The specific goal of Art. 7 is to cover uses of substances in articles which are not inside the scope of the substance registrations as such. One intention is to cover imported articles containing substances not yet registered under REACH. Some obligations refer to SVHCs in articles, reiterating related phase-out goals (section 2.2.1.1). The SVHC-related obligation in particular intends to collect data on imported articles.[146] To the extent imported articles are covered, the provisions also contribute to a level playing field with regards to SiA and reduce distortions in terms of competitiveness respectively.

2.3.1.2 Legal mechanisms and requirements

The article-related requirements laid down in Art. 7 can be summarized as follows:[147]

Art. 7(1), concerning the registration of substances in articles to be submitted by producers or importers of the article, states that the registration for any substance contained in an article only has to be submitted by the producer or the importer of the article if certain conditions are met:

- If the substance is present in those articles in quantities totalling over 1 t/a/producer or importer;
- If the substance is intended to be released under normal and reasonably foreseeable conditions of use;
- If the substance has not already been registered for that specific use (Art. 7(6) REACH).

Art. 7(2), on the notification to the Agency on the part of the producer or importer of the article, provides an obligation to notify SVHCs included in the candidate list,

- If the substance is present in those articles in quantities totaling over 1 t/a/producer or importer;
- If the substance is present in those articles above a concentration of 0.1% weight per weight (w/w)
- If the substance has not already been registered for that specific use (Art. 7(6) REACH);

146 Such data is also relevant in the context of RMOA.

147 Cf. Hermann and Bunke 2015, p. 111.

- If an exposition during the application and disposal cannot be excluded (Art. 7(3) REACH).

Unlike registration obligations under REACH (cf. Art. 22(2)), REACH does not require notifiers to update any submitted notifications.[148] Moreover, notifications do not fall into the scope of ECHA's compliance check activities (Art. 41(1)(a)) and are therefore exclusively subject to national enforcement.

Art. 7(5) enables the Agency to request, in justified individual cases, a separate registration for an included substance from the producer or importer of the article. However, a set of conditions has to be met:

- If the substance is present in the article(s) in quantities totaling over 1 t/a/producer or importer;
- If there are grounds for suspecting that the substance is released from the article(s);
- If there are grounds for suspecting that the release presents a risk to human health or the environment;
- If no registration is required pursuant to Article 7(1);
- If the substance has not already been registered for that specific use (Art. 7(6) REACH);

Hence, unlike the registration obligation under Art. 7(1), Art. 7(5) is also applicable when releases are not intended.[149]

Art. 7(6) shall release the producer or importer of an article from the obligations pursuant to Art. 7(1) and Art. 7(2) – provided that he is able to demonstrate that his use has already been registered. The registrant has to provide information on substance use in three different sections of the registration dossier:

- In the technical dossier in accordance with Art. 10(a)(iii) REACH in conjunction with Annex VI, Section 3.5 (for all registered substances, regardless of the production or import volume). In this context, only a brief general description on the use(s) is required. In addition, the production process of the article should be shortly described (Annex VI, Section 3.2). Furthermore, the quantities (tonnages) of the substance in articles made available to downstream users is to be indicated (Annex VI, Section 3.4).
- In Part B, Section 2 of the CSR according to Annex I REACH. This report is required for registered substances with a production/import volume of above 10 t/a. This requirement likewise involves only a brief general description of all identified uses.
- In the exposure scenarios (Part B, Section 9 of the CSR according to Annex I REACH), mandatory for registered substances with properties specified in Art. 14(4)[150] and with a production/import quantity of above 10 t/a per producer/importer, very precise information is required to prove that the use of the substance is safe. ECHA developed the "use descriptor" scheme to support companies in generating exposure scenarios (cf. the following section).

2.3.1.3 Legal uncertainties and clarification needs

According to Art. 7(6), the registration and notification obligations for producers and importers of articles under Art. 7(1), (2), as well as ECHA's mandate pursuant to 7(5) to require case

148 ECHA 2017c, p. 52.
149 See e.g. ECHA 2017c, 57.
150 In any case Art. 14(6) applies according to which "any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment". To this end, registrants of substances not fulfilling the criteria of Art. 14(4) might be factually required to assess exposure.

specific registration, do not apply to substances in articles that have already been registered for that use. However, the clause does not provide any criteria for article producers/importers to determine whether a substance use in articles is already registered; thus, challenging the practical implementation – including enforcement – of this provision.

Instead, the ECHA guidelines provide assessment criteria. According to the Agency, article producers/importers may rely on the Art. 7(6) waiver if

- the substance is the same as the substance already registered, and
- the use is the same as the use described in a registration of the substance, i.e. the registration refers to the use in the article.[151]

Substance sameness can be determined based on the identifiers referred to in Annex VI of REACH, Section 2.[152] When deciding whether a substance can be regarded as already registered for that use, ECHA recommends companies to compare

- the function of the substance in the article (e.g. pigment, flame retardant),
- the process by which the substance is included in the articles (i.e. tasks, or process types from the occupational perspective, e.g. "dipping and pouring"),[153] and
- the type of article.[154]

With respect to all three criteria, ECHA refers[155] to the application of the "use descriptor system"[156]. ECHA initially created this system to streamline the development of exposure scenarios in REACH. It is therefore applicable to all substance uses in all industries, based on very simplified assumptions. For instance, all plastic articles and all electronic applications are covered by only one article category in each case.[157] In IUCLID registrants voluntarily can pick additional sub-article categories, which are still broad in scope though (e.g. small plastic articles). At the same time, since the REACH registration scheme aims to ensure a high level of protection (section 2.3.1), substance data must allow for assessment of the safe use. ECHA therefore emphasizes that substance use in the context of Art. 7(6) cannot be determined exclusively by referring to the use descriptor information, instead more detailed information is needed.[158]

In addition, limited data access rights might compromise the downstream users' sameness assessment as outlined above. ECHA does not by default provide access to all use data received by registrants via the dissemination portal. Rather, Art. 118(2)(b) "normally" deems "the precise use, function or application of a substance" confidential information (however, "without prejudice to Article 7(6)"; see section 2.3.3.1.3). Usually only information on the article categories is available. Downstream users might thus not have all information needed to determine sameness of uses and whether Art. 7(6) applies.

In conclusion, while assessment criteria is absent in the legal text, the criteria provided in the ECHA guidance falls short of the actual data needs, measured by the regulatory objectives. In addition, Art. 7(6) presupposes that data provided by substance manufacturers/importers is of sufficient quality to allow for the necessary determination. In practice, however, a significant

151 ECHA 2017c, p. 46.
152 Cf. ECHA 2017b.
153 ECHA 2015, 49.
154 ECHA 2017c, p. 46.
155 ECHA 2017c, p. 46.
156 ECHA 2015.
157 Cf. Hermann and Bunke 2015, p. 113
158 See, in bold letters, ECHA 2017c, p. 46.

share of dossiers is not compliant with the data requirements.[159] In fact, experience from SEv shows that substance manufacturers lack understanding of their DU's use conditions.[160] Consequently, use information provided may lack accuracy and relevance. Article manufacturers/importers relying on the available data might thus risk being non-compliant, too. However, in such a situation, relying on the derogation provided by Art. 7(6) would not be justified.

Given the Art. 7(6) derogation does not apply, the duty to register substances in articles according to Art. 7(1) only applies if, among other conditions, these substances are "intended to be released under normal or reasonably foreseeable conditions of use". The legal text does not provide any assessment criteria in this respect while the ECHA guidelines provide additional orientation.

According to ECHA,[161]

- release of substances from articles is "intended" if it fulfils an "accessory function", e.g. a fragrance deliberately added to an article. Other releases that do not provide such function (but unintentionally occur e.g. due to ageing, wear and tear) are out of scope and so are releases fulfilling the main function of the object (e.g. ink in a pen, considered as a combination[162] of an article and a substance/mixture).
- Intended release occurs under "conditions of use" only during service life of the article; release during the production or disposal phase of the article are therefore excluded.
- Such conditions of use are furthermore "normal or reasonably foreseeable" if associated with the main function of an article. "Normal" uses applies e.g. to those described in the article's instructions for use. Additionally, any conditions of use that can be anticipated as likely to occur because of the function and physical form of the article can constitute "reasonably foreseeable" use. In this respect, ECHA flags the example of a small child not aware of an article's function but using it for e.g. biting or licking.

ECHA concludes that "a release which does not occur under normal or reasonably foreseeable conditions of use is not considered to be an intended release".[163] The question therefore arises if from this quotation one may in turn draw that "reasonably foreseeable" use in the child scenario can be construed as intended release and would then trigger the registration obligation.[164] The guidance however refrains from drawing this latter conclusion, leaving thus uncertainties as to the application of the criteria.

As for Art. 7(2) on the notification of SVHCs in articles, pursuant to Art. 7(3) there is no duty to notify if the producer or importer can "exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal." As for the definition of "normal or reasonably foreseeable conditions", assessment criteria are missing, however the observations made in context with Art. 7(1) apply accordingly. The ECHA guidelines provide information on how producers and importers can establish that there is no exposure, taking into account the substances' and the articles' physical and chemical properties as well as the conditions of use and disposal.[165] REACH does not foresee a specific mechanism to ensure

159 See, e.g., ECHA and European Commission 2019.

160 The use descriptions in the registration dossiers often lack clarity and consistency, due to, i.a., the rather unspecific use descriptor system. Consequently, the exposure scenarios and the derived operational conditions and risk management measures remain quite generic and thus are not in line with REACH Annex I section 5.1

161 See e.g. ECHA 2017c, p. 53.

162 Regarding these cases, see section 2.1.3.

163 See e.g. ECHA 2017c, p. 53.

164 Other view: Herbatschek et al. 2013, 4.15.

165 ECHA 2017c, p. 49.

compliance with Art. 7(2) and (3). Rather, such activities are subject to national enforcement. For National Enforcement Agencies (NEA), however, in the absence of clear enforceable criteria it might be challenging to determine compliance, particularly in the case of complex cases regarding substances in articles. ECHA recommends economic actors to document the results of their internal Art. 7(3) assessment to be prepared in the case of enforcement inquiries.[166]

Further legal uncertainties relate to the application of the registration in Art. 7(5), notably the yardstick to determine whether the risk-related requirements are met. In this respect, the legal text requires for the Agency to have "grounds for suspecting" there will be substance release and risk, thus referring to mere "suspicion" while it does not explicitly require to identify "proof". REACH does not define criteria for the Agency to consider whether any "grounds for suspicion" are given; neither does ECHA guidance.[167] These legal uncertainties constitute barriers to the application of the provision.

Put into context with other REACH mechanisms, one may conclude that the regulation requires "proof" when authorities directly limit the ability of placing a substance on the market, e.g. by imposing restrictions or authorisation requirements or by assigning legal classifications (CLH, SVHC). In contrast, based on Art. 7(5) a company can be required to submit a dossier, considering the "no data, no market" general rule. Hence, the provision only indirectly limits the marketing abilities if the registration is not submitted accordingly or if the registration data show that no measures are available to "adequately control the risks identified in the chemical safety assessment", Art. 14(6).

The wording "grounds for suspecting" establishes thus a standard that has been commented as "particularly low".[168] In the implementation ECHA may invoke the precautionary principle,[169] as it underpins the provisions of REACH (Art. 1(3)). In this respect, in line with CJEU jurisprudence, the Agency's assumptions that the criteria in 7(5)(b)(i) and (ii) are met are not sufficient only in cases where they appear "purely hypothetical".[170]

Moreover, Art. 7(5) does not clearly stipulate the procedure under which ECHA can render decisions under that provision. Art. 7(8) stipulates that "any measures for the implementation of paragraphs 1 to 7 shall be adopted in accordance with the procedure referred to in Article 133(3)", i.e. comitology. Since comitology as mode for decision-making is reserved to the Commission, it is not the procedure to render decisions under Art. 7(5).[171] Hence, REACH does not establish procedural requirements for the formation of such decisions.

2.3.2 Implementation

The scope of Art. 7(1) is very restricted. As the definition of intended release is rather narrowly construed, only few use cases are conceivable (e.g. scented articles) that would be covered by the registration rules. The relevance in terms of registration numbers based on that provision is not clear since the ECHA dissemination portal does not flag data from registration dossiers transmitted by producers or importers. It may, however, reasonably be assumed that for substances which are intended to be released from articles, the use in the article has generally already been registered by the manufacturer or importer and that therefore no registrations are required under Art. 7(1). At the same time, according to the European Commission, amount and

166 ECHA 2017c, p. 48.
167 See e.g. ECHA 2017c, 57.
168 Herbatschek et al. 2013, 4.16.
169 Fischer 2008, para. 59.
170 CJEU Case C-236/01, Monsanto and others v Presidenza del Consiglio dei Ministri and Others, ECLI:EU:C:2003:431, para. 106.
171 Other view: Herbatschek et al. 2013, 4.16.

adequacy of information in registration dossiers for the safe use of substance in articles is very limited.[172]

On the practical implementation of Art. 7(2) obligation, the European Commission observes:

> "ECHA has made substantial efforts to facilitate the submission of such notifications by providing easy-to-understand guidance to duty holders as well as by making available a web form for users that are not familiar with the IUCLID format. Despite these efforts, the number of notifications [lies at] 365 notifications on 39 SVHCs by 16 December 2016. While it is difficult to estimate how many notifications there should be, this number is likely to indicate a low level of compliance."[173]

Three years later, on 20th December 2019, ECHA reports on 481 notifications (ever) received.[174] Measured by the main function of Art. 7(2) to provide data on SVHCs in imported articles, the low numbers cannot satisfy.

Besides lack of awareness of duty holders and difficulties to get appropriate information from (third country) suppliers, the European Commission identifies "very broad descriptions of uses in articles in registration dossiers, which may (incorrectly) lead duty holders to the conclusion that their articles are exempt from the obligation to notify" as probable reason for the low number of notifications.[175] The Forum pilot enforcement project on "Substances in Articles"[176] meanwhile found that the Art. 7(2) "notification obligation did not apply in most inspected cases, and where it did, the company complied with the obligation". Due to its small scale scope, however, the report disclaims that "results presented in the report are not necessarily representative of the situation in the EU-EEA market as a whole". Besides, as "checks of the compliance with the notification obligation rely on the information provided by the companies", some uncertainties as to the results may prevail.

In addition, until today, the agency has not requested a registration dossier on substances in articles according to Art. 7(5).

In conclusion, Art. 7 appears not to contribute to the generation of new data and, together with the information requirements in the substance registration, consequently not to provide for an adequate picture of the substances used in articles placed on the EEA market.

2.3.3 Potential enhancements and policy options

Hermann and Bunke (2015) analysed different policy options to strengthen the REACH obligations regarding substances in articles. Among these options was amending Art. 7(1) to the effect that registration is mandatory, if release of substances from articles is foreseeable under normal or reasonably conditions of use, while an intention for such release would not be needed to trigger the requirement. The report however concluded that such amendment would most likely have little practical effect as it can be assumed that in the vast majority of cases, at least formally, the substance use in question is already covered by a substance registration, thus triggering the Art. 7(6) waiver.[177] Therefore, Hermann and Bunke (2015) recommend clarifying and extending the information requirements for substance manufacturers and importers if substances are used in articles (section 2.3.3.1).[178]

172 SWD (2018) 58 fin, Part 1/7, 29.
173 SWD (2018) 58 fin, Part 5/7, 58 ; cf. ECHA 2016, p. 120.
174 ECHA 2019d.
175 SWD (2018) 58 fin, Part 5/7, 58.
176 ECHA 2019e, p. 2, 35; cf. on the pilot project section 2.2.2.1.
177 Hermann and Bunke, p. 129.
178 Hermann and Bunke, p. 129.

Additional options (section 2.3.3.2) intend to strengthen ECHA's mandate to require registration according to Art. 7(5).

Besides, the analysis found implementation challenges with respect to the obligations to notify SVHCs (lack of legally binding assessment criteria, in particular). However, the WFD requires Member States to ensure that as of January 2021 article suppliers notify all articles placed on the EEA market which contain SVHCs above 0.1% to a database. This mechanism could therefore provide oversight of the articles containing SVHCs on the market which goes even beyond the limited scope of Art. 7(2) (i.e. tonnage threshold condition, availability of Art. 7(6) waiver, no update obligation). It therefore remains to be seen how the new regulatory mechanism will work in practice and, depending on this, options to strengthen Art. 7(2) may be developed.[179]

2.3.3.1 Specifying the waivers under Art. 7(6)

As outlined in section 2.3.1.3 two aspects, in particular, are challenging the practical implementation of Art. 7(6):

1. The clause does not provide any criteria for article producers/importers to determine whether a substance use in articles is already registered for the use in this specific article.
2. It presupposes that data provided by substance manufacturers/importers are of sufficient quality to allow for such determination.

Accordingly, policy options should address both aspects (see sections 2.3.3.1.1 and 2.3.3.1.2). Such options would reframe the article producers'/importers' opportunities to the benefit of the REACH legislators' intentions of ensuring a high level of protection, as they either make sure that waiving from registration/notification is indeed justified or motivate the company to actually register/notify the substances in articles as this option becomes less of a burden than claiming the derogation.

In addition, to ensure that the two complementary options provide the intended effects, access to information rules enshrined in Title XII might need to adapt as well (section 2.3.3.1.3).

2.3.3.1.1 Formalising the sameness test for article producers

This policy option intends to clarify that a substance can be deemed registered for a certain use pursuant to Art. 7(6) only to the extent that is the result of an adequate test of the sameness, both of the substance and its use in the article context.

To make sure article producers/importers adequately assess the sameness of registered substances vis-à-vis substances in articles, integrating the assessment steps developed by ECHA[180] into the legal text is one available policy option.

In order to assess the sameness of uses, the substances' functions in the article, and the types of articles, are useful criteria already covered by the "use descriptor system" (section 2.3.1.2). ECHA acknowledges that the categories provided by this system are too broad. As there are efforts at OECD level to globally harmonise (at least) parts of the system,[181] any developments of this system most likely are subject to deliberations at OECD level. Hence, adding more specific (sub-)categories (e.g. greater level of detail than "plastic articles" or "small plastic articles") to the system is another long-term option.

179 In addition, in ECHA 2016, p. 122, the Agency mentions "one possibility would be to consider extending the scope of Article 7(2) to cover all hazardous substances" to facilitate identification of "substances of potential concern in imported articles and to initiate action in a proactive manner."

180 Based on the Guidance on Substance Identification, see section 2.3.1.2.

181 See e.g. ECHA 2015, p 6; OECD 2017.

Apart from the use descriptor system, to determine safe article use, additional information is needed. In particular, the concentration of the substance in the article, and additional conditions of exposure (e.g. migration and release potential).[182] More precisely, this information would be needed, first, with respect to the substance registration (see next section 2.3.3.1.2). Second, the article producer/importer has to consider the relevant information for his article. Hence, an implementing act introducing a sameness test for the purpose of Art. 7(6) should also provide for respective specifications. Moreover, considering the current lack of understanding to what extent actors make use of the waiver, they should have the duty to notify this to ECHA.

The wording of the implementing regulation taking into account the various aspects mentioned in this section (e.g. new Art. 7a) could read as follows:

(1) For the purpose of Art. 7(6) REACH, the producer or importer of the article shall determine sameness of the substance and of its use in the article with the information provided in existing registration dossiers. It shall take account of the following information:

- substance identification;

- the function of the substance in the article;

- the process by which the substance is included in the article;

- the type of article;

- the concentration of the substance in the article;

- other relevant conditions of exposure *[placeholder for additional specific requirements to be formulated on the basis of enforcement experience on what is relevant and feasible]*.

(2) Referring to all criteria set out in Paragraph (1), the producer or importer of the article shall notify the Agency if it finds the substance has already been registered for that use.

The question arises how to enforce the new notification scheme in a way that creates incentives for the economic actors to comply. In this respect, one can draw on experience from the (lack of) compliance with Art. 7(2) on the notification of SVHCs in articles. In the latter case, enforcement duties lie exclusively with national authorities who might lack expertise needed for complex substance in articles assessments. For the regulatory option discussed, one complementing approach therefore might be to create an additional "completeness check" and "compliance check" mandate for the Agency which has the expertise to deal with such complex issues. Furthermore, ECHA would need to allocate resources for this new task.

As for the legal implementation of the policy option, Art. 7(8) provides that any "measures for the implementation of paragraphs 1 to 7 shall be adopted in accordance with the procedure referred to in Article 133(3)". Pursuant to Art. 132, the aim of such measures is "to put the provisions of this Regulation efficiently into effect". The aim of the policy option is to efficiently flesh out the obligation provided in Art. 7(6) and can thus be deemed covered by the legal mandate of Art. 133(3).

Besides, for article producers/importers to be able to compare the information on their articles with existing registration data, additionally, the suggested modifications must be reflected by the information requirements for substance manufacturers and importers (section 2.3.3.1.2).

[182] Cf. Hermann and Bunke, p. 130.

2.3.3.1.2 Strengthening information requirements for substance registrants

Under Art. 7(6), the article producer/importer has to establish that the substance use is already covered by a registration. This therefore depends on the quality of the dossier information. However, in the substance registration requirements to specify information concerning use in articles are vague (section 2.3.1.2). Hermann and Bunke (2015) found that more precisely defining the registration requirements as to information on the use of a substance in an article would probably significantly enhance the exposure scenarios in the registration dossiers. As a result, this would increase the informative value of exposure scenarios for the protection of consumers and the environment, but also for occupational safety in industrial and professional settings in which articles are produced and used. In addition, it would put article producers/importers in the position to compare substance registration data with their own article information.

Hence, Hermann and Bunke (2015) recommended clarifying the information requirements for the registered use of a substance in an article with respect to exposure scenarios of Section 9 of the chemical safety report and the technical dossier.[183] Consequently, in Sections 0.7, 0.8 and 5 of Annex I and Section 3.5 of Annex VI it should be explicitly stated that the registrant has to specify the concentration of the substance in the article, and provide additional exposure conditions (e.g. migration and release potential) whereas enforcement experience should be taken into account when developing the specific information requirements.

Pursuant to Art. 133(1), the REACH Annexes may be amended in accordance with the procedure referred to in Article 133(4), i.e. the regulatory procedure with scrutiny laid down in Art. 5a Council Decision 1999/468/EC.[184] This procedure reflects the normative content of Art. 290 TFEU.[185] Art. 290(1) TFEU provides that a "legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act". The provision continues that the "objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts".[186] The amendments covered by the respective policy option only specify existing information requirements in terms of substance uses in articles and therefore can be deemed to be covered by the legal mandate of Art. 133(4).

2.3.3.1.3 Access to information

Under Art. 118(2)(b) "the precise use, function or application of a substance" shall "normally be deemed to undermine the protection of the commercial interests" of the registrant. Given substance registrants would provide more detailed exposure data in terms of section 2.3.3.1.2, ECHA might therefore not have a general legal mandate to provide public access to such data. Consequently, article producers and importers would not be in the position to refer easily to this data when assessing sameness of their substance in article scenarios in terms of section 2.3.3.1.2.

In order to support the intended legal effects, the Agency could re-evaluate how it construes "precise" in the realms of Art. 118(2)(b). Notably, this provision de lege lata applies "without prejudice to Article 7(6)". Therefore, with a view to the practical implementation of Art. 7(6), ECHA might have some room to maneuver adapting a more open dissemination policy on

183 Hermann and Bunke 2015, p. 130.

184 Council Decision 1999/468/EC of 28th June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, 1999 OJ L 184/ 23, amended by Council Decision 2006/512/EC of 17th July 2006, 2006 OJ L 200/ 11, repealed by Regulation (EU) No 182/2011 of 16.2.2011, 2011OJ L 55/ 13. However, according to Art. 12 Regulation 182/2011 the "effects of Article 5a of Decision 1999/468/EC shall be maintained for the purposes of existing basic acts making reference thereto."

185 C.f. Recital 7a Council Decision 1999/468/EC.

186 Cf. for the application of such criteria Council of the EU, Opinion of the Legal Service, Application of Articles 290 (Delegated Acts) and 291 (Implementing Acts) TFEU, 8970/11, LIMITE, 11.04.2011.

substance use data related to the information requirements on exposure of substances in articles.

If leeway for the Agency does not appear to exist, another option would be clarifying 118(2)(b) accordingly, e.g. by adding in an implementing regulation derogations to the effect that the information items referred to above fall out of the scope of the term "normally" in the provision. As a result, the policy option would more precisely frame the relationship between Art. 7(6) and Art. 118(2). As for the legal implementation, it would thus be covered by Art. 132 mandating "measures necessary to put the provisions of this Regulation efficiently into effect".

2.3.3.2 Strengthening ECHA's mandate under Art. 7(5)

There are no known cases in which the Agency made use of its mandate to require registration under Art. 7(5). This section therefore develops options regarding the practical implementation and further development of the legal mandate provided in Art. 7(5).

2.3.3.2.1 Support application in status quo

Currently there is a lack of experience with Art. 7(5) because ECHA never tested it in practice. In line with the intended "safety net" function of that provision, its legal text confers to ECHA a wide margin of discretion as to its implementation – in order to contribute to the normative goals. ECHA probably is reluctant to invoke Art. 7(5) because if the Agency requires an economic actor to submit a dossier based on that provision, this decision would be eligible for legal review by the European courts.

In order to reduce legal uncertainties impeding the application of Art. 7(5), one option is for the Commission to develop criteria providing orientation for the margin of discretion. This could take the form of an implementing act pursuant to Art. 7(8).

The outlined option does not create any new obligations for industry.

2.3.3.2.2 Reversal of the burden of proof

Reversing the burden of proof would significantly lower the bar for ECHA to require registration on the grounds of Art. 7(5). Different variations of such an option are conceivable. From the perspective of the intended "safety net" function of the legal mandate, a more effective approach appears appropriate. Hence, the option discussed here releases ECHA from the obligation to establish that registration shall be required due to substance release and risk. Instead, ECHA may request dossier submission for substances present in articles above of 1 ton. The article producer/importer may then invoke exculpatory evidence on lack of substance release and (thus) risk – and subsequently might be relieved of his duties.

Proposal for amendments *(in italics)* in the current legal text of Art. 7(5):

[subpara 1] The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

[(b) deleted and replaced by the wording previously found under (c)]

(b new) the substance is not subject to paragraph 1.

[subpara 2] A submission for registration shall be accompanied by the fee required in accordance with Title IX.

[subpara 3] In the cases of this paragraph the producer or importer of an article is not obliged to submit a registration if he can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal.

Considering the regulatory context of Art. 7, the proposed waiver uses the wording of Art. 7(3) ("exclude exposure") concerning the waiver from the SVHC notification obligation. This also entails a reduced focus (exposure) compared to the legal status quo (release and risk), which can however be considered appropriate given the shift of the burden of proof from ECHA to industry. To reduce legal uncertainties, the assessment criteria developed in the ECHA guidance (section 2.3.1.3) could be added to the legal text in another paragraph, providing orientation for the economic actors. The latter would need comprehensive data to establish that exposure can be excluded. The modifications detailed in section 2.3.3.1.2 could be supportive as they contribute to an enhanced data source in registration dossiers.

Moreover, a process needs to be defined for ECHA to assess submitted applications for waivers. This process would start off with a (perhaps tailored) completeness check. Additionally, it might copy procedural elements established in the authorisation or restriction contexts, e.g. involving RAC in the exposure assessment. In addition, the competencies of the Board of Appeal could be extended to provide legal protection to industry actors.

This option may not be implemented via Art. 7(8) as it not merely puts the REACH provisions efficiently into effect but modifies the structural element of burden of proof allocation. To this end, Art. 7(5) needs to be amended, which would be subject to the ordinary legislative procedure.

2.3.4 Summary

The following table summarizes the policy options discussed in this section.

Table 7: Policy options addressing the registration of substances in articles

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
13 sect. 2.3.3.1.1 2.3.3.1.2 2.3.3.1.3	Formalised sameness test for article producers, strengthened information requirements for substance manufacturers and modified access to information on exposure data	Amendment of the REACH text, using implementing legislation on the basis of Art. 7(8), Art. 131 and Art. 132	Clarifying when a substance can be deemed registered for a certain use in order to specify, and thereby curbing, the waivers under the SiA registration	All: Legal certainty; more transparency on exposure regarding substance in articles Consumer and Environment: Better risk control Authorities: Better understanding of substances in articles (and related risks)	Industry: More intense application of registration obligations, which is however in line with the original intention of Art. 7 REACH
14 sect. 2.3.3.2.1	Legal criteria developed by Commission to guide the application of Art. 7(5)	Implementing legislation pursuant to Art. 7(8)	Support ECHA in application of Art. 7(5)	See No. 13	No additional efforts/burden

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
15 sect. 2.3.3.2.2	Shifted burden of proof to industry in the application of Art. 7(5)	Modification of Art. 7(5) using the ordinary legislative procedure, and introduction of a new procedure to examine industry data	Lower the bar for ECHA to request SiA registration under Art. 7(5)	All: Legal certainty Consumer and environment: Better risk control Authorities: Reduced cost of requesting SiA registration	Industry: Burden of proof that exposure can be excluded Authorities: Examination of industry data needed

2.4 Enhanced authorisation scheme concerning (imported) articles

Managing risks related to problematic substances in articles is a challenging task for European authorities. This is mainly due to two obvious factors: the sheer quantity and variety of products on the one hand and of the chemicals they contain on the other. Both factors are difficult to oversee and assess. From a regulatory risk management perspective, REACH rests on two main pillars of sovereign instruments: restriction and authorisation. Whilst, compared to the adoption of a restriction, the burden for authorities to impose an authorisation requirement is lower, the authorisation regime, however, is limited to the use of SVHCs within the EU.

SVHCs are applied during the production process and might – or might not – be found in the supplied article. Both uses are covered by the authorisation regime. REACH affects the use in the production process only inside the EU. This creates a tension for the second type of use, the article level, which is relevant for those products manufactured within the EU as well as for imported products. For the time being, SVHCs in imported articles[187] are not covered by the authorisation regime. This leads to a situation where articles produced inside the EU have to follow stricter rules than those imported from abroad (given that no restriction is in place accompanying the authorisation regime). Section 2.4 will thus focus on the regulatory option of an extended authorisation scheme covering SVHCs in imported articles.

According to Eurostat data, in 2015, products worth more than 3 trillion EUR have been produced and sold within the EU market while during that same period products worth more than 1.7 trillion EUR have been imported into the EU-28 from third countries. A high share of these products are articles in terms of REACH.[188] In addition, recent growth of import of goods into the European Union could be observed, it almost tripled between 2000 and 2015, with a large share being imported from countries with less strict legislation on chemicals control.[189]

Section 2.4.1 outlines why the legal framework of the authorisation scheme does not provide for regulatory control of SVHCs in imported articles. For this reason, there is no need for a section on the implementation in the status quo. However, section 2.4.2 – when elaborating the extended authorisation mechanism – also reflects on shortcomings in the status quo implementation of the authorisation scheme[190] and how those relate to the regulatory option.

[187] Imported substances and mixtures, on the other hand, are subject to the authorisation regime; for the example of paints containing SVHC pigments (lead chromates) see Judgment of the General Court, 7.3.2019 - Case T-837/16 (Sweden v Commission), ECLI:EU:T:2019:144.

[188] Schenten and Führ 2016.

[189] Reihlen et al. 2017, p. 20.

[190] See also Wirth et al. 2020.

2.4.1 Legal framework

This section puts the authorisation scheme into the normative context of REACH (section 2.4.1.1), outlines its legal mechanisms, and thereby explains why it is not applicable to SVHCs in imported articles (sections 2.4.1.2 and 2.4.1.3).

2.4.1.1 Objectives

The authorisation scheme, according to Art. 55, aims to "ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable". This scheme is thus paramount with a view to the objective of REACH to ensure a high level of protection and contribute to innovation (section 2.2.1.1). By imposing the obligation to apply for authorisation for the use of a SVHC, it constitutes a severe market barrier for this substance. In addition, since any SVHC may become subject to the authorisation requirement, already the identification of a substance as SVHC and subsequent addition to the "candidate list" sends a strong substitution impulse into the supply chains. Besides, according to Art. 1(1) REACH aims to enhance competitiveness of European economic actors in the international arena.

2.4.1.2 Legal mechanisms and requirements

The authorisation scheme regulates the uses of substances; uses of articles themselves are not subject to authorisation.[191] Following Art. 56(1) REACH, a "manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV," unless the respective actor attained an authorisation for the corresponding use or this use is exempt from the authorisation requirements. However, REACH regulates only the use of SVHCs within the EEA. Whenever the producer of an article incorporates the substance outside the EEA, Art. 56(1) does not apply. An article may therefore be imported into the EEA, subject to the requirements of Art. 7 REACH (section 2.3). Further developing the legal mechanism, section 2.4.2 provides details on the status quo procedures both to establish an authorisation obligation as well as to apply for authorisation.

2.4.1.3 Legal uncertainties and clarification needs

The authorisation scheme[192] does not cover SVHCs present in imported articles; it does therefore not properly control any risks arising from these substances and, to that extent, falls short of the objective of REACH to ensure a high level of protection. In addition, it is compromising the normative goal of enhanced competitiveness as EEA "domestic" producers of articles are subject to stricter requirements than those, which are produced "abroad", thus potentially "harming" EU companies.[193]

2.4.2 Potential enhancement of an extended authorisation scheme

Addressing the legal shortcomings, one option could be to extend the legal effect of Title VII REACH to SVHCs present in imported articles. This option is also envisaged as a "medium-term" regulatory option by the preparatory study for the EU "Non-Toxic Environment" strategy.[194]

191 ECHA 2011, p.32.

192 Section 2.5 discusses the options offered by the restriction regime.

193 COM (2018) 116 fin, p. 4.

194 Reihlen et al. 2017, p. 82 (Table 4: Overview of identified responses).

A legal appraisal concluded that such an extended authorisation scheme would be consistent with the specifications of international trade rules, arising from the relevant World Trade Organization's (WTO) Technical Barriers to Trade (TBT) agreement.[195]

For the purpose of an extended authorisation scheme, Art. 56 REACH could be modified to the effect that Paragraph 1 also covers the import[196] and subsequent uses of an Annex XIV substance when incorporated in articles. To this end, a sentence along the lines "for the purposes of Title VII of this Regulation the import of articles is considered use of a substance" could be added to Art. 56(1)(a), complemented by additional modifications of the legal text (summarized in Table 8). Such an extension would aim to ensure that articles containing Annex XIV substances and originating from third countries can only be imported into the EEA given the conditions of Annex XIV are met or given this incorporation is authorised in accordance with Articles 60 to 64. This enhancement serves as a functional equivalent for a restriction. It avoids a separate restriction procedure (see section 2.5); from an enforcement perspective, it entails the advantage that applicants for authorisation carry the burden of proof.

By that, the legal instrument could make sure that risks arising from SVHCs in imported articles are properly controlled. Yet, the suggested option cannot completely wipe out any inequalities of authorisation conditions for domestic articles vis-à-vis those imported from third countries, since any operations taking place in third countries elude the jurisdiction of REACH. Notably, after the sunset date expired, EU article producers have to apply for authorisation *before* they may use the SVHC for incorporation into an article. In contrast, the suggested option does not impede third country actors from using the SVHC during article production. Likewise, the scope of the AfA[197] differs since the EU based applicants in that context have to take into account e.g. worker safety in their CSR, while third country actors would not have to consider in the CSR exposure scenarios related to production operations outside the EU. Nevertheless, the option reduces one of the most severe inequalities by legally harmonising the distribution conditions of domestic and third country articles. In other words, said articles can only be placed on the market if the use, or import as component of an article, respectively, of the SVHCs complies with the Annex XIV entry or is justified by a granted authorisation. The option therefore contributes to the REACH objective of enhanced competitiveness.

Table 8: Overview of legal and procedural elements part of an extended authorisation scheme

Subject matter	Context of authorisation scheme	Specific implementation steps
Legal basis to cover SVHC in imported articles	Art. 56(1)(a)	Modification needed (ordinary legislative procedure)
Obligation for legislator to consider case-by-case whether the authorisation requirement should be linked to a concentration limit	Art. 58(2)	Modification needed (ordinary legislative procedure)

195 Führ and Schenten 2015.

196 Import according to Art. 3(10) "means the physical introduction into the customs territory of the Community"; import, moreover, "shall be deemed to be placing on the market" (Art. 3(12)).

197 Cf. section 2.4.2.3.

Subject matter	Context of authorisation scheme	Specific implementation steps
Consider SVHC in imported articles, import volumes for inclusion in Annex XIV	Art. 58(3)	Administrative activity/practical level
More targeted stakeholder consultation	Art. 58(4)	Practical level
AfA: Extend list of actors entitled to apply for application;	Art. 62(2)	Modification needed (ordinary legislative procedure)
AfA: Material scope of the AfA	Art. 62(4)(c)	Modification needed (ordinary legislative procedure)
AfA: ECHA support to third country actors involved in applications	Consortium management	Practical level
AfA: More targeted SEA	Annex XVI	Comitology (Art. 131)

All changes of the legal text mentioned in the following sections are subject to the ordinary legislative procedure, while for modifications of Annexes the comitology procedure is available.

2.4.2.1 Considering SVHCs in imported articles for inclusion in Annex XIV

ECHA coordinates the temporal sequence in which candidate SVHCs are included in Annex XIV, considering the Art. 58(3) criteria (i.e. PBT or vPvB properties, wide dispersive use, high volumes). It recommends to the European Commission which substances should be treated as a priority.[198] For each priority substance, the Agency issues a report substantiating the prioritisation and defining the exact conditions for inclusion in Annex XIV pursuant to Art. 58(1). The report is mostly based on the original Annex XV dossier for each substance.[199] According to Number 2 of that Annex, the "available use and exposure information and information on alternative substances and techniques shall be provided". This can include occurrences of the substance in question in imported articles already de lege lata.

For the prioritisation under the extended scheme, ECHA could consider the presence of SVHCs in imported articles – and so should the initial Annex XV report for SVHC identification. The SCIP database and similar initiatives[200] are expected to be useful sources in this respect.[201] Furthermore, data collected under the registration or notification schemes concerning chemical substances as already established or under development in various third countries might, to the extent publicly available, give insights as to relevant article uses of SVHCs.[202] Besides, to assess priorities, import volumes to the EU of relevant articles might play a role.

In addition, in practice, complexity of the supply chains using SVHCs has become another criterion ECHA considers when developing its recommendations; an aspect that also bears some meaning with respect to imported articles (section 2.4.2.5).

198 In accordance with REACH Art. 58(3), these are usually substances that have certain characteristics (PBT or vPvB) or fulfil the criteria of "wide dispersive use" or "high volumes".

199 This was drawn up by a Member State or the Agency to identify a substance as SVHC.

200 E.g. the SVHC databases set up by the LIFE AskREACH project (section 2.2.2) and by the BUND (Friends of the Earth Germany); SVHC database (30.08.2019).

201 When notifying articles to SCIP firms can voluntarily provide the information concerning "is the article produced or assembled in the EU?", see ECHA 2020, p. 34.

202 Some regulatory systems also intend to regulate substances in articles. For instance, the Korean Ministry of Environment proposed on 3rd May 2018 a mandatory system for tracking chemicals including mixtures under its Chemicals Control Act. This system is meant to trace substances along their supply chain including downstream uses, apparently also in articles, see OECD 2018.

2.4.2.2 Defining the scope of the authorisation

Information collected by ECHA in the prioritization process also serves to identify uses or categories of uses which, pursuant to Art. 58(2), "may be exempted from the authorisation requirement" as existing legal provisions ensure adequate control.[203] Before ECHA delivers its final recommendations, the Agency makes "available on its website" the collected information for comments by "interested parties" in accordance with Article 58(4). These are invited to submit information on possible exemptions but can also communicate exculpatory information regarding the risks of a substance, thus avoiding the inclusion in Annex XIV. In addition, they might provide information on available alternatives, thus supporting the substitution aim laid down in Art. 55.

Moreover, the legislator should be obliged to consider whether the authorisation requirement should be linked to a concentration limit – for practical purposes, and to avoid creating an unnecessary barrier to circular material flows. It should do so, however, on a case-by-case basis, so it can take into account substance specific peculiarities. One option[204] would therefore be to add to Art. 58(2) a sentence conveying that the authorisation requirement can be linked to a concentration limit of the SVHC in articles,[205] provided that one may expect that below that threshold the risk is properly controlled. Such exemptions would then automatically be subject to public consultation pursuant to Art. 58(4).

Under the extended scheme, third country producers of articles would be a particular group of interested parties in terms of Art. 58(4). To make sure all justified arguments are considered, the agency should, taking into account experience gathered under the implementation of the RoHS Directive, actively approach such actors, instead of only passively offering the opportunity to get involved via internet consultation.[206]

As REACH provides to interested parties a right to be heard, Annex XIV entries already in place before the extension of REACH will not apply to imported articles. These legacy cases could be addressed via the procedure set out in Art. 69(2), given the Agency can establish that the substance in articles poses a risk to human health or the environment that is not adequately controlled.

2.4.2.3 AfA in view of SVHCs in imported articles

As for AfA in view of SVHCs in imported articles, several legal and procedural aspects require consideration, i.e. the personal and the material scope of the AfA and the availability of joint applications.

Personal scope

According to REACH, a company needs to be established within the community (EEA) to place substances, mixtures or articles on the market. With regard to imported articles, in most cases an importer (REACH Art. 3(11)) is the addressee of legal requirements under REACH. In cases where the importer is not "established within the Community" an only representative (OR, Art. 8) has to be appointed to carry out legal acts under the REACH Regulation.

[203] For the time being, as far as evident, this option did not play a relevant role.

[204] Art. 56(6) generally excludes SVHCs present in mixtures in certain concentrations from the authorisation requirement. Establishing an analogy for SVHCs present in articles could thus be considered an alternative option. However, a general exemption might deprive the regulators of their capability of ensuring a high level of protection while at the same time to avoid creating an unnecessary barrier to circular material flows.

[205] This provision would be applicable to both domestic and imported articles.

[206] For the proposal to apply the RoHS approach in finding alternative substances and technologies in the context of Art. 64(2), see Schenten and Führ 2015.

Currently, according to REACH Art. 62(2), manufacturer(s), importer(s) and/or downstream user(s) of a substance are entitled to apply for authorisation. Besides, according to ECHA, also the OR of a non-EU manufacturer (of a substance) can submit an AfA;[207] whereas this scenario is not explicitly mentioned in Title VII.[208]

Manufacturers and importers of substances may apply to cover the use of their downstream users, whereas this scenario is not relevant for the extended authorisation scope; rather, it covers situations where e.g. an SVHC is imported to the EEA and then incorporated into an article. Neither relevant is the application by downstream users as the incorporation of SVHCs in articles abroad is not downstream use in terms of REACH.[209]

In conclusion, to provide for the option of importers of an article and ORs representing a third-country producer of an article to apply for authorisation, a respective modification of the existing provisions (e.g. Art. 62(2)) explicitly mentioning these actors is needed.

Joint applications

Under the current scheme, Art. 62(2) provides for joint applications of manufacturers, importers or ORs for the uses of their downstream users. Groups of downstream users undertaking the same use can prepare a joint application, too.[210] Another option is cooperation of different actors only on parts of the application (e.g. CSR). These shared responsibilities are intended to help applicants reduce costs, and may also improve adequacy and consistency of the documents supporting the application. At the same time, joint applications, particularly when formulated precisely, can help reduce the burden of authorities tasked to scrutinize the AfA.

With a view to the extended scheme, importers and ORs, both representing third country producers of similar articles (see below), should be allowed to cooperate as well. Third country actors could also cooperate with upstream EEA applicants. Another cooperation scenario is conceivable: EU based article producer applies for authorisation of an SVHC incorporated into an article which then would also cover imported articles – and vice versa. All cooperation scenarios, legally speaking, will be possible if the REACH legal text confers to them the right to apply for authorisation (cf. – modified – Art. 62(2)). ECHA could provide targeted guidance to support inter-continental AfA consortia;[211] third countries with high article import volumes to the EEA could be encouraged to develop cooperation platforms in their countries.[212]

Material scope

Art. 62(4)(c) requires applicants to describe any uses of the substance for which authorisation is sought, including the "incorporation of the substance in articles, where this is relevant". To reduce legal uncertainties as to whether subsequent uses of the imported article are covered by the authorisation requirement, one available option is to amend (in italics) the legal text as follows: "the incorporation of the substance in articles, *including substances in imported articles*; where this is relevant".

207 ECHA Q&As, "Can an Only Representative apply for an authorisation"? ID: 0568, Vers.: 1.1, modified date: 04/06/2015, ECHA Q&As (01.03.2018).

208 See however Art. 8(2) "the representative shall also comply with all other obligations of importers under this Regulation".

209 This legal situation does not change even if the import scenario is added to Art. 56(1)(a).

210 Cf. on different scenarios ECHA 2017d, p. 16.

211 Cf. ECHA support: applying for authorisation (30.08.2019) as well as ECHA 2017d.

212 This would allow domestic article producers to join forces with a view to upcoming needs to apply for authorisation for their similar articles. ECHA could bring in its experience gained in the work with importers of articles under REACH and gained in the third country-related work under the framework of the PIC Convention.

For the purposes of Art. 62(4)(c), according to ECHA, reference to the use descriptor system is to be made,[213] which defines very broad and generic use categories[214] (e.g. plastic articles, electronics applications); the technical function of the substance is additional "minimum information" of the application.[215]

When determining similarity of articles subject to joint submission these two criteria should also apply in the context of the extended scheme. From a risk management perspective, specific use description is pivotal in terms of defining the relevant scope of the CSR (see next section). From an economic perspective, the criteria allow applicants to define the desired scope of authorisation sufficiently broad so that a certain number of applications can be commercialised, and that concerned industries can pool their resources for application. At the same time such a strategy can ensure feasibility of tasks on the side of authorities.

The authorisation decisions remain effective also after modifications of the articles as long as the use of the substance in the article remains within the use description of the AfA and the requirements laid down in the authorisation.

2.4.2.4 Granting authorisation for SVHCs in imported articles

Art. 62(4) defines the information to be provided in the AfA. As one main rationale behind the extended authorisation is to reduce unequal article distribution conditions for domestic and third-country article producers, in principle the same provisions should also apply to imported articles.

In general, any AfA includes a CSR covering all risks to human health and the environment along the substance life cycle that are relevant in the use scenarios for which authorisation is sought (Art. 62(4)(d)).[216] Other mandatory elements of the AfA include the alternatives assessment and proposals to monitor the effectiveness of the risk management measures and the fate of the SVHCs in the environmental compartments and the impact on human health. In addition, pursuant to Art. 62(5)(a), the AfA may include a socio-economic analysis (SEA).

Regarding SVHCs for which effect thresholds can be derived, in accordance with Art. 60(2), the Commission will grant the authorisation if the CSR as part of the AfA provides proof of adequate risk control. Evidence of adequate control is provided when, according to Annex I, Section 6.4 REACH in the relevant phases throughout the life cycle of the substance in use and for each exposure scenario the estimated exposure and concentration levels do not exceed the respective DNEL[217] or PNEC[218] values.[219] If this does not succeed, authorisation may also be granted if the applicant demonstrates that the socio-economic benefits outweigh the risks linked to the use and that no less concerning alternative substances and technologies are available. For substances for which deriving effect thresholds is scientifically not appropriate (Art. 60(3)), as proof of adequate control cannot be provided, only the socio-economic "authorisation route" is available.

In view of the AfA for SVHCs in imported articles, only the risks for humans and the environment during service life (use phase) and at the waste stage fall into the scope of the CSR; the

213 ECHA 2011, p. 32.

214 For details see above, section 2.3.1.3.

215 See the overview at ECHA 2019c, p. 76.

216 For the assessment steps in chemical safety assessment, refer to Art. 14 as well as Annex I REACH.

217 Derived No-Effect Level for effects toxic to humans.

218 Predicted No-Effect Concentration for ecotoxic effects.

219 In addition, "the likelihood and severity of an event occurring due to the physicochemical properties of the substance" has to be negligible.

production phase taking place in a third country would not be relevant. In that context, Art. 60(2) could apply accordingly for SVHCs eligible for quantitative risk assessment.

For other SVHCs – i.e. any PBT and any vPvB substances, as well as certain CMRs and other substances of "equivalent concern" – the question arises, how applicants could show as part of the socio-economic analysis that benefits of the third country articles outweigh the risks. ECHA guidance, in accordance with Annex XVI, supports applicants to identify relevant factors to be considered by SEA.[220] Thereafter, socio-economic benefits relate to the value added of the continued substance use, including wider social impacts, such as the functioning of the market and the securing of jobs. Experience from the implementation of the authorisation scheme de lege lata shows that the applicants usually compare costs related to worker health with effects on employment – and are usually capable of establishing that the SVHC use scenario is beneficial, i.e. outweighing the risks.[221] Obviously, employment effects in third countries, where article producers operate, are beyond the geographic scope of REACH. Yet, article import might as well have positive effects on EU employment, even when the supply chain for these articles operates outside of Europe. One plausible scenario would be the import of a component (article) for a complex object assembled in the EEA, thus enabling value creation with regard to that object. In any case, third country actors can rely on employment related arguments only to a certain limited extent.

From the international trade perspective, under current SEA strategies, authorities could treat third country and domestic applicants differently. This however would most likely not be in line with WTO rules. Hence, other approaches to SEA could be considered.

For instance, the SVHC presence in such articles may unleash e.g. technical functions which are essential for society and therefore required in certain use contexts. The application approach could aim to show such uses are indispensable. This would best reflect the goal of the authorisation scheme to phase out SVHCs. Research and public debate would be needed, as similarly requested already by the Council,[222] to identify and agree on criteria when uses are to be considered "essential".[223]

These considerations could at the same time create momentum to provide more normative orientation to the authorisation scheme as a whole, i.e. also with respect to AfA strategies of domestic applicants, and the work of SEAC.

Changes of Annex XVI REACH could reflect an advanced SEA approach focussed on essential uses.

2.4.2.5 Additional considerations on implementation

According to enforcement experience, non-compliance with REACH of imported products appears to be above average.[224] Authorities should thus give appropriate attention to imported articles subject to the requirements of REACH. This equally applies to articles under the scope of an extended authorisation scheme as to articles for which other REACH obligations apply. Besides, for enforcement the same routines would apply as have been established in the context of activities monitoring compliance of imported products with restrictions or with the rules on communication and notification of SVHCs.

220 Cf. ECHA 2017d, p. 51 as well as ECHA support: SEA (01.03.2019).

221 Cf. the case study analysis by Wirth et al. 2020.

222 Council 2019, para. 19, cf. section 1.1.

223 Cf., for instance, Cousins et al. 2019 with proposals concerning the concept of essential use for determining when uses of PFASs can be phased out.

224 SWD (2018) 58 fin, Part 1/7, p. 61.

The low numbers of Art. 7(2) notifications for imported articles (section 2.3.2), the frequent struggle of EU actors to receive data of SVHC presence in supplied articles (section 2.2.2), and the comparatively high level of non-compliance of imported products indicate a low level of awareness of the REACH rules on the part of importers. This seems to be the case for all REACH mechanisms relevant for third country actors, potentially including the extended authorisation scheme. Hence, if the EU intends to control the risks of SVHC in imported articles, no matter which measure it adopts, its representatives (ECHA, European Commission and Member States) need to contribute to awareness raising at international level, notably at countries with high import rates to the EU.

AfA can be very complex and therefore challenge the work of ECHA and the committees. This is the case e.g. when applications are "covering a broad range of different industries [and] are submitted by upstream operators (in particular by manufacturers and importers) on behalf of the downstream users or submitted by multiple downstream users".[225] However, AfAs for SVHCs in imported articles are not necessarily overly complex. The extended authorisation scheme adds one entirely new, and arguably hardly complex, AfA scenario to the system: third country article producer uses SVHC produced in third country and imports the article to the EU. Complexity increases, though, when several actors, including those from third countries, submit a joint application (section 2.4.2.3). In quantitative terms, AfAs for SVHCs in imported articles may or may not involve a high number of actors and so do today's AFAs.

Another new challenge is more qualitative in nature since involving third country actors in the process often entails additional cultural aspects to be considered. It as well entails regulatory aspects: not in every jurisdiction article producers can make use of a regulatory framework for chemicals such as REACH providing for transparency of the substance produced and used. In practice, article importers operating in such jurisdictions could therefore struggle to identify SVHCs in their articles subject to authorisation. While a trend can be observed that legislators worldwide, notably in Asia, are enacting legislations which share some key principles with EU REACH (e.g., different variations of "no data, no market"), such legislations often establish their own nomenclature and do not, e.g., reflect the SVHC definition. Hence, some "translation efforts" might be needed for third country actors to identify SVHCs in their articles and allow for submission of an AfA. However, existing SVHC obligations for imported articles (see above) obviously require the same efforts and thus the co-legislators of the REACH Regulation apparently do not deem these efforts disproportionate.

2.4.3 Summary

The following table summarizes the policy options discussed in this section.

Table 9: Policy option of an extended authorisation scheme

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
16 sect. 2.4.2	Consider in Art. 56 import of articles as use of a substance for the purposes of Title VII; complementing adaptations of Art. 58(2), Art. 62(2),	Amendment of the REACH text, using the ordinary legislative procedure and implementing legislation on	Provide another option for regulatory control of SVHCs in imported articles that can be triggered without prior establishing existence of "unacceptable risk"	Authority: Additional risk control instrument with comparatively low-threshold trigger Consumer and Environment: Better risk control Industry: Reduced inequalities between domestic and third country	Third country industry: Need to apply for authorisation (where needed via an "only representative") Authorities: Need to process submitted AfAs

[225] SWD (2018) 58 fin, Part 5/7, p. 94.

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
	Art. 62(4)(c) and Annex XVI, various procedural adaptations	(Art. 131 REACH); practical level	Advance SEA to the extent that only essential uses for society can be granted authorisation via SEA route	actors, while retaining the possibility to lift the ban based on an AfA (compared to restriction)	

2.5 Restrictions regarding substances in articles

Since the authorisation scheme de lege lata does not apply to SVHCs in imported articles (section 2.4.1.2), Art. 69(2) offers a hinge between the restriction and authorisation schemes for substances in articles. Besides, Art. 68(2) provides a specific legal basis to restrict CMR substances in consumer products, including articles.[226]

2.5.1 Legal framework

The following sections focus on the restriction mechanisms subject to REACH Art. 68(2) and Art. 69(2).[227]

2.5.1.1 Overall objectives

In line with the overall objective of REACH ("provisions are underpinned by the precautionary principle", Art. 1(3), Sentence 2), the "restriction provisions should allow the manufacturing, placing on the market and use of substances presenting risks that need to be addressed, to be made subject to total or partial bans or other restrictions, based on an assessment of those risks".[228] In addition, Art. 69(2) is to be put in context with the regulatory objectives concerning SVHCs (2.2.1.1) as well as the overall objective to enhance competitiveness, i.e. by reducing inequalities as regards the right to place on the market articles manufactured in the EEA vis-á-vis those imported from third countries. The normative intention of the restriction pursuant to Art. 68(2) is to provide for a leaner and simplified procedure for CMRs in consumer products. It thus reflects a precautionary approach.

2.5.1.2 Legal mechanisms and requirements

2.5.1.2.1 Restrictions under Art. 68(2)

In general, Art. 68(1) provides for the introduction of new and the amendment of current restrictions for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles "when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis". The procedural steps in this respect, including preparation by ECHA or a Member State of an Annex XV dossier, expert appraisals by ECHA's RAC and SEAC and a multi-tier public consultation, are set out in Articles 69 to 73 (Figure 2).

226 Moreover, authorities may address SVHCs using the ordinary restriction procedure set out in Art. 68(1).

227 Cf. on Title VIII REACH Herbatschek et al. 2013, 4.198 et subs.

228 Recital 23 of REACH.

Figure 2: Restriction procedure

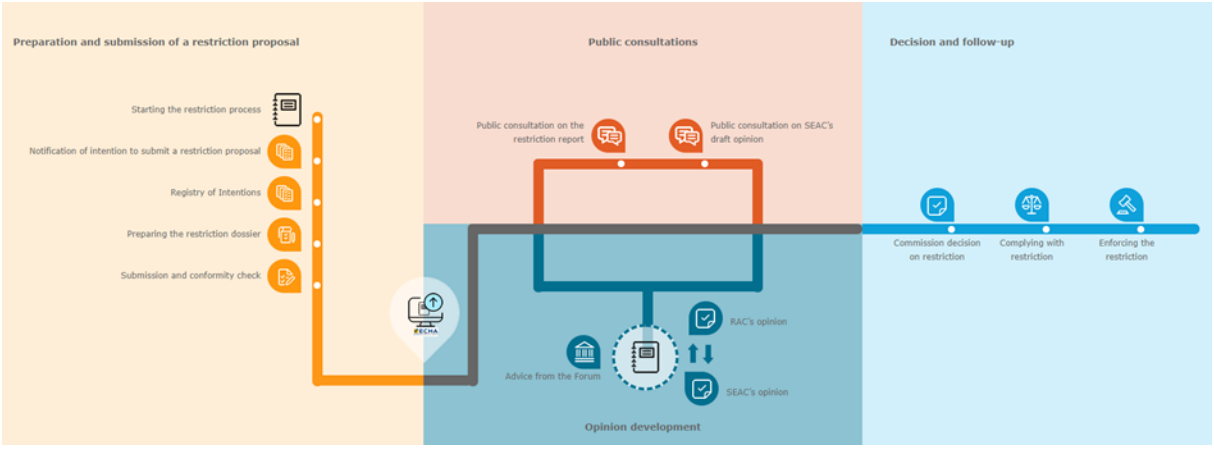

Figure 2: Restriction procedure

The restriction process of the manufacture, placing on the market or use of substances is divided into three phases. The first phase is called "preparation and submission of a restriction proposal" and includes five steps: starting the restriction process, notification of intention to submit a restriction proposal, registry of intentions, preparing the restriction dossier, submission and conformity check. The second phase is divided into two subphases. The first subphase is called "public consultations" and includes the public consultation on the restriction report and the public consultation on SEAC's draft opinion. The second subphase is called "opinion development" and includes three steps: advice from the forum, RAC's opinion and SEAC's opinion. The third and last phase is called "decision and follow up", consisting of the commission decision on restriction, complying with the restriction and enforcing the restriction.

These procedural requirements, however, shall not apply subject to the conditions laid down in Art. 68(2):

> "For a substance on its own, in a mixture or in an article which meets the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the [regulatory comitology procedure with scrutiny]."

In its October 2003 REACH proposal, the Commission justifies the regulatory "short-cut" of Art. 68(2) on the grounds that the classifications referred to imply that a sound scientific basis has already been provided.[229]

One procedural limitation is that Art. 68(2) formally mandates only the Commission.

2.5.1.2.2 Restrictions under Art. 69(2)

Art. 69(2) establishes a link to the authorisation procedure. It allows to impose restrictions once the sunset date (Article 58(1)(c)(i)) has expired. According to Art. 69(2), SVHCs from Annex XIV may become subject to restrictions to the extent these substances are parts of articles:[230]

> "After the date referred to in Article 58(1)(c)(i) for a substance listed in Annex XIV, the Agency shall consider whether the use of that substance in articles poses a risk to human health or the

[229] COM (2003) 644 fin, p. 37.

[230] The specific need to address substances listed in Annex XIV in an article perspective is reflected in Art. 58(6); see section 2.5.3.2.

environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV."

However, this requires ECHA to prepare an Annex XV dossier, while – according to the legal text – only after the "sunset date", as specified in Art. 58(1)(c)(i) REACH, the agency shall begin to determine whether the use of that substance in articles poses a risk to human health or the environment "that is not adequately controlled." If a risk is identified, the procedure according to Art. 69 – 73 needs to be followed. As a result, a restriction would constitute a ban[231] on the placing on the market which would, however, only come into effect at a later date and – unlike in Art. 68(2) – only after a further regulatory process.

2.5.1.3 Legal uncertainties and clarification needs

Legal uncertainties and clarification needs are relevant for both restriction routes discussed in this section.

2.5.1.3.1 Prerequisites for the application of Art. 68(2)

REACH does not provide any guidance on the implementation of Art. 68(2). According to the Commission, the first restriction procedure on that legal grounds with respect to PAH[232] pointed at uncertainties as to:

- when this procedure could be applied, considering reduced scientific scrutiny and the fact that, according to the legal text, a socio-economic impact assessment is not required;
- the type of information and the level of detail needed in the documentation supporting the restriction proposal;
- the assessment to ensure that the draft restriction is scientifically sound and proportionate, including consultation of stakeholders and, where necessary, consultation of a scientific expert body.[233]

The legal text, thus, does not provide guidance in terms of the level of scrutiny, documentation and procedural steps. Acknowledging this gap, the Commission developed application and prioritisation criteria in terms of Art. 68(2) as well as an implementation procedure, shared with CARACAL in November 2014.[234] In this latter note, the Commission dismisses the option of a semi-automatic restriction of CMRs in consumer articles in analogy to mixtures because one could not assume potential (or sometimes theoretical) exposure from the presence of such substances in articles.[235]

Entries 28-30 of Annex XVII to REACH prohibit the sale and use of substances and mixtures classified CMR 1A or 1B for supply to the general public. It is a long established practice to amend these entries every time substances get newly classified accordingly.[236] A SWD for the 2012 REACH Review finds this "simplified" restriction for CMR in substances and mixtures

231 Furthermore, there would be no possibility to remove the ban in order to use the substance in articles by applying for authorisation.
232 Commission Regulation (EU) No 1272/2013 of 6th December 2013 as regards polycyclic aromatic hydrocarbons.
233 CA/102/2014, 3.
234 CA/102/2014.
235 CA/102/2014, 2.
236 Cf. ECHA's answer on FAQ "Are substances classified as CMRs, and included in Annex VI to CLP but not yet included in the Appendices 1-6 of Annex XVII to REACH, covered by the restrictions in entries 28-30 of Annex XVII to REACH?" at ECHA Q&As (07.09.2019): When substances are classified for the first time as CMR and included in an "Adaptation to Technical Progress (ATP)" of the CLP Regulation, the European Commission prepares a draft amendment to include these substances in the Appendices of REACH Annex XVII. The amendment then has to be adopted in accordance with Article 68(2) of REACH, before the new substances are covered by entries 28-30.

justified i.a. by the potential wide exposure (from combined sources); whereas, for CMR in articles, this approach "should not result in a systematic prohibition of the sale of all articles containing any newly classified CMR substances to the general public."[237]

The CARACAL paper further notes general difficulties to obtain information about the presence of substances in articles and/or migration from the same.[238] It then elaborates on the two probable routes in terms of implementing Art. 68(2) with a view to articles, i.e.

- targeting individual CMR substance or groups of substances with a similar structure/mode of action, present in potentially different categories of consumer articles, and
- targeting specific categories of consumer articles and aiming at restricting the potential presence or migration of CMR substances in them.[239]

As for the procedure, the Commission proposes steps resembling to a large extent those steps subject to the ordinary restriction procedure. For instance, the CARACAL paper suggests launching

> "a public consultation for the identified articles / CMR substances, requesting information on their presence or likelihood of presence in the specified consumer articles and, to the extent possible, their concentration/migration, their function, the frequency of contact with the article, the availability of alternatives, possible socio-economic impacts of a ban/restriction and enforceability of the possible restriction".[240]

2.5.1.3.2 Prerequisites for the application of Art. 69(2)

Art. 69(2) requires ECHA to assess whether SVHC use in articles poses "a risk to human health or the environment that is not adequately controlled" and to, based on this assessment, consider the need of a restriction. In contrast, Art. 68(1) defines as legal trigger for restrictions that an "unacceptable risk to human health or the environment, … which needs to be addressed on a Community-wide basis" exists. Therefore, the question arises, whether both provisions are using different yardsticks. This seems however not to be the case as both procedures start off with the preparation of an Annex XV dossier and therefore uniform criteria (referring to the risk assessments steps set out in Annex I) apply. It should also be considered that the inclusion into the candidate list and a fortiori into Annex XIV already entails the conclusion that the risk has to be "addressed on a community-wide basis". In this respect, the prerequisite stipulated in Art. 68(1) is already met; at least insofar as the Annex XIV covers the presence of the substance in articles.

2.5.2 Implementation

As for the implementation of Art. 68(2), the CARACAL paper concludes with the outlook of selecting textile and clothing articles as a first test case using the 2nd of the two routes deemed available (section 2.5.1.2).[241] In October 2015, the Commission launched a consultation on a possible restriction of hazardous substances in textile articles and clothing for consumer use focussing initially on 286 CMRs. Adoption of such restriction followed three years later while its scope was reduced to 33 CMRs.[242] Whilst looking at the numbers of substances subject to

237 SWD (2013) 25, p. 77 (emphasis added).
238 CA/102/2014, 2.
239 CA/102/2014, 4.
240 CA/102/2014, 11.
241 CA/102/2014, 13.
242 Commission Regulation (EU) 2018/1513 of 10th October 2018 as regards certain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B.

scrutiny, this procedure surely involved some efficiency, but it was not significantly faster compared to the PAH restriction process.[243]

However, some lessons how to increase efficiency might be learned from the restriction procedure on textiles. Commission staff considers the procedure a success to which a high level of stakeholder involvement contributed. Other success factors are more textiles specific, including availability of reported information (MS/NGO work identifying relevant substances) and a high degree of self-regulation in the sector (certification, RSLs).[244]

From 2009 until 2017 ECHA prepared nine proposals for restrictions in total,[245] only one[246] was based on Art. 69(2).[247] It has to be noted that the Annex XV dossier was not prepared by ECHA alone (as foreseen in the legal text), but rather in cooperation with Denmark based on a previous dossier and additional results from an EU biomonitoring project.[248]

Thus, it can be questioned whether the regulatory option offered in Art. 69(2) has proven to be an effective measure to address problems arising from SVHCs in imported articles. The "lessons learnt" from the first plasticizer dossier might serve as a basis for future restriction efforts under Art. 69(2).

It also has to be taken into account that with regards to SiA restrictions the aim of REACH "to ensure a high level of protection of human health and the environment" can also be achieved on the general statuary source provided in Art. 68(1), given that the conditions formulated there are met.

The number of restrictions (16 between 2009 and December 2018)[249] enacted under REACH falls short of estimates by the Commission before the adoption of REACH that Member States would prepare 11 Annex XV dossiers for restriction per year, given the (at this point of time expected) boost in availability of risk data.[250]

2.5.3 Potential enhancements/Policy Options

2.5.3.1 Strengthening the simplified restriction procedure in Art. 68(2)

The restriction route established by Art. 68(2) is indolent in the application to articles.[251] This instrument does therefore not yet provide a "fast-track" safe guard in terms of consumer risk; the Commission Services consider it not more efficient than the ordinary procedure.[252] Whether the approach tested in the "CMRs in textiles" restriction is capable of yielding faster results if applied in a less complex case (involving e.g. less substances) remains to be seen.

One key challenge apparently is the general lack of data on substances in articles, impeding, in the Commission's view, the establishment of a sound scientific basis for regulatory proposals. However, criteria developed by the Commission provide the benchmark for establishing this basis.

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243 Germany asked the Commission in June 2010 to initiate the simplified restriction process for PAH, see (29.02.2019).

244 Kilian 2019, p. 9.

245 ECHA 2018b, p. 59. Eight other Annex XV dossiers for restrictions are in the ECHA pipeline (p. 58).

246 Restriction under Article 69(2) on the four classified phthalates in articles; c.f. COMMISSION REGULATION (EU) 2018/2005 of 17th December 2018, O.J. No. L 322/14 as of 18.12.2018 (recital 2).

247 A list of all Annex XV dossiers prepared by ECHA is available here(26.01.2019).

248 Cf. OJ No. L 322/14 as of 18.12.2018 (recital 3): "The dossier built on a previous restriction proposal submitted by Denmark in 2011. (…) The 2016 Annex XV dossier took into account new information on exposure from different sources including human biomonitoring data from the Union-wide DEMOCOPHES project (project partners of DEMOCOPHES) which measures the presence of the four phthalates in urine samples".

249 ECHA 2019a, p. 59.

250 SWD (2018) 58 fin, PART 1/7, p. 43.

251 See, referring to Commission Regulation (EU) 2018/1513.

252 SWD (2018) 58 fin, PART 1/7, p. 94.

One available option is to review these criteria – considering the very objective of Art. 68(2) – i.e. providing a regulative "short cut" in cases where classified CMR are concerned whereas the scenario CMR in articles is expressly mentioned – and also considering the precautionary principle underpinning all REACH provisions.[253] The reviewed criteria could reflect that, in the absence of any requirements on the implementation of Art. 68(2) as regards articles, the provision mandates the Commission to introduce restrictions in CMRs in articles even in cases where comprehensive data with regard to the presence of such substances in the articles, or on socio-economic considerations, are not at hand.

Consequently, fully exhausting the opportunities of Art. 68(2), the criteria could allow for a general restriction of (certain) CMRs in certain categories, e.g. of articles above a (default) threshold value – without any obligation to, prior to the restriction, establish the relevance of these substances in these articles. Indeed, notification and communication obligations of Art. 7(2) and Art. 33 demonstrate that, under REACH, it is possible to prescribe one default legal threshold value for a range of substances (any SVHCs) in any articles on the market.[254] To avoid negative effects of the planned restriction, i.e. the effect that for a banned substance no less problematic alternative is available, the criteria should still foresee a public consultation, which should however be focussed in accordance with the actual information needs. If the Commission concentrated the consultation on the availability of alternatives and in contrast refrained from detailed assessments of the (likelihood of) presence of certain CMRs in the specified articles as well as concentration/migration, the frequency of contact with the article etc., the procedure could be shortened significantly. However, from an enforcement and monitoring perspective, a broad scope of the restriction not specifically addressing technical details such as migration limits and related analytical methods would confront NEAs with very similar challenges as do Art. 7(2) and Art. 33.

In this understanding, a more precautious restriction would indeed provide for a "fast track" restriction as intended by the co-legislators; additionally, it would arguably[255] yield strong positive effects in terms of a high level of protection and at the same time, this would provide clarity for producers and enforcement agencies, the latter facing the same monitoring routines as related to the mentioned provisions on SVHCs.

Finally, having issued a restriction, evidence may come to the attention of the legislators that for some articles the default threshold is too high to ensure a high level of protection. In such cases, they could lower the thresholds using the same simplified procedure.

In this context, it should be noted that the proposal to extend the authorisation requirement to imported articles (see section 2.4) may serve as a functional equivalent of the above outlined proposal. The advantage of the extended authorisation requirement would be that it is up to the applicants to demonstrate "adequate control" of the risks or that the "socio-economic benefits outweigh the risk to human health or the environment" respectively (Art. 60 (1) and (4)).

Appreciating the role of Art. 68(2) in its regulatory context, comprising additional risk management options, during revision of the criteria, the Commission should take into account concerns brought up by ECHA as well as by Member States.

In addition, the restriction route established by Art. 68(2) is rather narrow in scope as it excludes other problematic substances such as PBTs, vPvBs, endocrine disrupters or

253 It should also be taken into account that for entries 28-30 of Annex XVII the potential presence of CMRs in mixtures is not relevant.

254 Hence, since a restriction constitutes a more invasive marketing condition, like any other legal measure it must respect the principle of proportionality – justified; in particular in terms of avoiding consumer risk. In this respect, the "precautionary principle" gives the legislator a certain amount of discretion; see work package 9 in the context of this project.

255 Notwithstanding unintended rebound effects such as regrettable substitution.

sensitisers.[256] Thus, a regulatory option would be to add to the scope substances that fulfil the criteria of Art. 57 and have been added to the candidate list. The extended scope would apply to candidate list substances in articles, as well as in mixtures and regarding the substances as such. For the implementation of this option, amending the legal text of REACH is necessary, thus triggering the ordinary legislative procedure.

2.5.3.2 Strengthening restrictions of SVHCs in articles under Art. 69(2)

A policy option to strengthen the restriction route in Art. 69(2) would mandate ECHA to start preparing a restriction dossier before the sunset date. This option would be in line with Art. 58(6).

According to current legislation, with regard to SVHC in imported products no risk reduction is expected when the authorisation requirement takes effect. This is a concern also raised in the REACH Review 2017:[257]

> ECHA should act more swiftly in accordance with Article 69(2) and consider the preparation of a restriction dossier (Annex XV dossier) before the sunset date in order to avoid possible distortion of the internal market and penalisation of European producers vis-à-vis non-European producers of (consumer) articles containing such substances;

Thus, the SWD underpinning the REACH Review concludes:[258]

> An additional issue to consider is the effect of delays in the adoption of restrictions of substances of very high concern subject to authorisation, when present in articles placed on the EU market. In particular, the delay in the adoption of restrictions for imported articles containing those substances after the sunset date could affect negatively the level of protection of human health and environment as well as create a competitive disadvantage for EU producers of articles.

Consequently, the REACH Review, as summarized in the "Commission General Report", formulates the following conclusion:[259]

> The interplay between authorisation and restriction is enshrined in REACH. It foresees that for substances subject to authorisation, ECHA should consider after the sunset date whether the use of such substances in articles poses risks to human health or the environment that is not adequately controlled and, if so, should start a restriction procedure. There is a need to expedite the assessment of the need for restrictions on imported articles containing substances subject to authorisation in order to ensure a level playing field between economic operators in and outside the EU. It should be explored if and how applying the authorisation procedure for the non-restricted uses of SVHCs to achieve comparable risk management and substitution more efficiently and predictably.

As a result of this analysis the following action is foreseen:

> Action 11: Interplay between authorisation and restriction
>
> (1) ECHA is requested to consider systematically the preparation of a restriction dossier before the sunset date of each substance that is subject to authorisation and present in articles in accordance with Article 69(2).

256 ANEC/BEUC 2016, p. 4.
257 SWD (2018) 58 final, p. 94.
258 SWD (2018) 58 final, p. 45.
259 COM (2018) 116 final, accompanied by SWD (2018) 58 final [references to Art. 69(2) are to be found on p. 35, 45, 94].

(2) The Commission, ECHA and Member States will assess the interplay between restriction and authorisation to achieve a comparable risk reduction more efficiently through risk management and substitution.

In its "Strategic Plan 2019 – 2023" ECHA considers this action in a rather generic manner:[260]

REACH, BPR: Support capacity building in companies and Member States, in particular through the development of networks that can coordinate and help advancing the practice of substitution. Promote carrying out analyses of alternatives to substances of concern – through showing concrete examples, as appropriate.[14]
The respective footnote 14 states: "This links to Action 11 of the REACH Review. (using Art. 69(2) early) – Analyses of alternatives is one of the key issues in this."

Earlier in the document – and also in quite general wording – ECHA promises (p. 12) to execute its regulatory duties "in an integrated manner":

REACH, CLP: Execute the required regulatory actions for prioritised groups of substances using evaluation, harmonised classification and labelling, restrictions and authorisation in an integrated manner.[12]
The respective footnote 12 reads as follows: "See Actions 2, 7, 8, 9, 10, 11 and Action 13(2) of the REACH Review"

It remains to be seen in how far ECHA will be able to implement its ambitions into the regulatory processes in the next years. One option is to take preparatory steps for a restriction basis in Art. 69(2) well in advance of the sunset date in cases where a forecast shows that this is most likely the appropriate regulatory response to the risk constellation. The legal text de lege lata does not ask for those preparatory steps but at the same time this option is not excluded. Thus, ECHA is in a position to develop an administrative strategy in order to be prepared for regulatory actions at the moment the sunset date expires. However, one can argue that the involvement of RAC and SEAC only can be started after the sunset date. To overcome this procedural hurdle, the text could be altered by replacing the first words in Art. 69(2) ("After the date …") by "At the latest at". This would allow ECHA to gain input from "third parties" during the process to expand Annex XIV. In addition, data provided in the AfA procedure might contribute to the factual basis.

2.5.4 Summary

The following table summarizes the policy options discussed in this section.

Table 10: Policy options in the context of the restriction scheme

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
17 sect. 2.5.3.1	Revised criteria for the application of Art. 68(2)	Internal Guideline for the Commission services, taking into account concerns by MS and ECHA	Clarifying the criteria and the procedural steps for the application of Art. 68(2) reflecting a more precautionary approach	Authority: Additional risk control instrument with comparatively low-threshold trigger Consumer and environment: Better risk control	NEAs are obliged to enforce restrictions

260 ECHA 2018a, p. 14.

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
18 sect. 2.5.3.1	Extending the substance scope of Art. 68(2)	Amendment of the legal text requiring the ordinary legislative procedure	Extend the scope of Art. 68(2) to substances other than CMR, which have been added to the candidate list	See No. 17	Industry: Consumer products containing candidate list SVHCs can be subject to restrictions
19 sect. 2.5.3.2	Preparatory steps to prepare an Annex XV dossier well in advance of the sunset date	Internal standard operation procedure for the ECHA secretariat	Starting the restriction procedure before the sunset date	Level playing field also for imported articles, providing the same benefits with regard to human health and the environment	No additional burden; the preparation of the Annex XV dossier and the procedural steps take place earlier
20 sect. 2.5.3.2	Replace “After” in the wording of Art. 69(2) by “At the latest”	Amend the legal text	Clearly allow starting the restriction procedure before the sunset date	Timely creating the benefits described in the field above	See field above

3 Synopsis

There is a general risk for EU citizens and their environment of being exposed to SVHCs and other problematic substances that are present in or released from articles. Taking into account the normative objectives of REACH, notably to ensure a high level of protection, there is a regulatory need to address risks from substances in articles.

This chapter provides, first, an overview of all options developed in the context of the assessed regulatory mechanisms (Table 11). The respective sections in chapter 2 (to be found in the first column) give more details on the options. Second, to the extent appropriate, a comparative assessment of options is provided with regard to consumer transparency (section 3.1) and with regard to risk management options (section 3.2).

Table 11: Overview of all developed policy options

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
Coverage of "combined objects" in article related requirements					
1 sect. 2.1.4	Scope of Art. 33 enlarged in a new para 3 to substances and mixtures linked to an article	Amendment of the REACH text; ordinary legislative procedure	SVHC communication obligations cover all article related substances/mixtures on the market	Supply chain actors and consumers: Informed purchasing decisions also with regard to all combinations of an article and a substance/mixture	Borderline cases (see guidance on SiA) with regard to Art. 33 are no longer relevant. The related clarification efforts can be avoided. Industry: Supply chain communication for mixtures containing SVHCs above 0.1% is already foreseen via SDS; in this respect all information should be already available to suppliers of mixtures
Improved Communication on SVHCs in articles					
2 sect. 2.2.3.1.1/ 2.2.3.1.2	Standardised data structure and exchange format allowing harmonised SiA communication	Supportive action, mandate to standardizatio n bodies	Facilitate data transfer along the supply chain	Industry: Foundation to comply with Art. 33(1) and (2) is laid; reduce transactions costs; contribute to manageability of product safety; reduce liability and reputational risks.	Industry: Adopt the communication patterns in the supply chains; set up and maintenance of the system.
3 sect. 2.2.3.1.3	Organisation of supply chain communication	Non-binding guidance	Facilitate data transfer along the supply chain	See No. 2	See No. 2
4 sect. 2.2.3.1.4	Proper enforcement	Administrative action (coordinated by ECHA forum?)	Compliance with REACH SiA provisions	Industry: Level playing field for all companies; non-compliant actors lose their free-rider advantage and have to invest into compliance management	Industry: No additional burden for compliant actors. Authorities: Resources needed (as foreseen in Art. 125/126 REACH)

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
				Consumers: Foundation for right to know, Art. 33(2) improved. Health & Environment: ultimately emissions from SVHC in articles reduced.	
5 sect. 2.2.3.2.1	Labelling requirement for SVHCs	Amendment of the REACH text; ordinary legislative procedure	Active information of consumers allowing informed purchasing decision and triggering awareness for safe use instructions	Industry, Health & Environment: See No. 4 Consumers: Reduced transaction costs to identify SVHCs in articles	Industry: Compliant actors: Development and attachment of label to articles and complex objects by placers on the market; Non-compliant actors: Lose their free-rider advantage and have to invest into compliance management.
6 sect. 2.2.3.2.2	Communication requirements for other substances of concern	Amendment of the REACH text; ordinary legislative procedure	Broadening the scope of SVHC requirements as foreseen in Art. 138(8) REACH	Equivalent benefits as for communication on SVHCs	Equivalent burden as for communication on SVHCs (CJEU: "minimal in nature")
7 sect. 2.2.3.2.3	Open SCIP notifications for articles without SVHCs above the 0.1% threshold	Practical level (design and implementation of SCIP by ECHA within existing legal mandate)	Enhanced transparency about SVHC status of articles	Consumers, retail, second-hand businesses: Reduced transaction costs to identify SVHC status of articles Industry: Market chances linked to transparency	No additional burden beyond voluntary notification of articles without SVHC above 0.1%
8 sect. 2.2.3.2.4	Obligatory response for "SVHC-free" article	Amendment of the REACH text; ordinary	Avoid uncertainty for suppliers and consumers: Better informed purchasing decision	Industry: Level playing field for all article suppliers; enhance trust and reputation as supplier.	Industry: Art. 33(2) Additional responses to consumer request in cases where no SVHC is present.

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
		legislative procedure		Consumer: Certainty about the content of SVHCs in articles Health & Environment: ultimately emissions from SVHCs in articles reduced.	
9 sect. 2.2.3.2.5	Reporting obligation after SVHC update	Clarification of legal situation; implementing annex; comitology procedure	Enhance learning processes in the supply chain: Accurate information of all actors, including consumers	See No. 4, plus: Consumer: Certainty about the content of SVHC in articles	Industry: Additional assessment of and communication on SVHC in articles supplied prior to the candidate list update.
10 sect. 2.2.3.2.6	Duty to organize the Art. 33 obligations	Clarification of legal situation; implementing regulation; comitology procedure	Underpin the (at least implicitly already) existing duty formulated in Art. 36 REACH	In a mid-term perspective the transaction costs for supply chain communication will be reduced; thus, the benefits described in No. 3 will occur.	See No. 2.
11 sect. 2.2.3.2.7	Shorter period to respond to consumer requests	Amendment of the REACH text; ordinary legislative procedure	Raise the incentive for consumers to use their "right-to-know" under Art. 33(2)	Industry: Level playing field for all companies. Consumer: Information availability for purchasing decision improved Health & Environment: Ultimately emissions from SVHCs in articles reduced.	See No. 8.
12 sect. 2.2.3.2.8	SVHC information in the supply chain before purchasing decision	Clarification of legal situation; implementing annex; comitology procedure	Underpin the obligations already laid down in Art. 33(1)	Support informed purchasing decisions of commercial actors. Market benefits for "SVHC-free" articles. Health & Environment: Emissions from SVHCs in articles reduced.	Industry: Information under Art. 33(1) has to be provided anyhow; additional incentive to standardize internal processes to handle customer requests will lead to reduced additional burden.

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
Registration and notification of substances in articles					
13 sect. 2.3.3.1.1/ 2.3.3.1.2/ 2.3.3.1.3	Formalised sameness test for article producers, strengthened information requirements for substance manufacturers and modified access to information on exposure data	Amendment of the REACH text, using implementing legislation on the basis of Art. 7(8), Art. 131 and Art. 132	Clarifying when a substance can be deemed registered for a certain use in order to specify, and thereby curbing, the waivers under the SiA registration	All: Legal certainty; more transparency on exposure regarding substance in articles Consumer and Environment: Better risk control Authorities: Better understanding of substances in articles (and related risks)	Industry: More intense application of registration obligations, which is however in line with the original intention of Art. 7 REACH
14 sect. 2.3.3.2.1	Legal criteria developed by Commission to guide the application of Art. 7(5)	Implementing legislation pursuant to Art. 7(8)	Support ECHA in application of Art. 7(5)	See No. 13	No additional efforts/burden
15 sect. 2.3.3.2.2	Shifted burden of proof to industry in the application of Art. 7(5)	Modification of Art. 7(5) using the ordinary legislative procedure, and introduction of a new procedure to examine industry data	Lower the bar for ECHA to request SiA registration under Art. 7(5)	All: Legal certainty Consumer and environment: Better risk control Authorities: Reduced cost of requesting SiA registration	Industry: Burden of proof that exposure can be excluded Authorities: Examination of industry data needed
Enhanced authorisation scheme concerning (imported) articles					
16	Consider in Art. 56 import of articles as use of a substance for the purposes of Title VII;	Amendment of the REACH text,	Provide another option for regulatory control of SVHCs in imported articles that can be	Authority: Additional risk control instrument with comparatively low-threshold trigger	Third country industry: Need to apply for authorisation (where

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
sect. 2.4.2	complementing adaptations of Art. 58(2), Art. 62(2), Art. 62(4)(c) and Annex XVI, various procedural adaptations	using the ordinary legislative procedure and implementing legislation on (Art. 131 REACH); practical level	triggered without prior establishing existence of "unacceptable risk" Advance SEA to the extent that only essential uses for society can be granted authorisation via SEA route	Consumer and Environment: Better risk control Industry: Reduced inequalities between domestic and third country actors, while retaining the possibility to lift the ban based on an AfA (compared to restriction)	needed via an "only representative") Authorities: Need to process submitted AfAs
Restrictions regarding substances in articles					
17 sect. 2.5.3.1	Revised criteria for the application of Art. 68(2)	Internal Guideline for the Commission services, taking into account concerns by MS and ECHA	Clarifying the criteria and the procedural steps for the application of Art. 68(2) reflecting a more precautionary approach	Authority: Additional risk control instrument with comparatively low-threshold trigger Consumer and environment: Better risk control	NEAs are obliged to enforce restrictions
18 sect. 2.5.3.1	Extending the substance scope of Art. 68(2)	Amendment of the legal text requiring the ordinary legislative procedure	Extend the scope of Art. 68(2) to substances other than CMR, which have been added to the candidate list	See No. 17	Industry: Consumer products containing candidate list SVHCs can be subject to restrictions
19 sect. 2.5.3.2	Preparatory steps to prepare an Annex XV dossier well in advance of the sunset date	Internal standard operation procedure for the ECHA secretariat	Starting the restriction procedure before the sunset date	Level playing field also for imported articles, providing the same benefits with regard to human health and the environment	No additional burden; the preparation of the Annex XV dossier and the procedural steps take place earlier

No.	Subject matter	Type	Purpose	Benefit	Effort/Burden
20 sect. 2.5.3.2	Replace “After” in the wording of Art. 69(2) by “At the latest”	Amend the legal text	Clearly allow starting the restriction procedure before the sunset date	Timely creating the benefits described in the field above	See field above

All options summarized in Table 11 are generally standing side-by-side, thus complementing each other. Some options taken together however may create a certain redundancy with a view to the desired regulatory effects. Some options might to some extent overlap in their scopes. To the extent one may consider these options in a competitive relationship, benefits and efforts assigned to each option in the last two columns can give orientation in weighing advantages and disadvantages, and so can the (legislative) procedure necessary to implement the option (which is in turn linked to transposition periods). In addition, the question arises which rather qualitative considerations could be relevant in determining whether one option may be preferred over the other.

Specifically, there are two clusters of options which require a comparative view:

- Certain options aimed at enhancing the transparency for consumers on SVHCs in articles (1, 5, 7, 8 and 11) are at least to some extent competing with each other. Section 3.1 provides a first comparative assessment.
- For SiA risks, both the restriction and the (extended) authorisation scheme provide risk management options. Section 3.2 contains an initial comparative assessment in this respect.

3.1 Comparative consideration of consumer transparency options

All mentioned options (see first indent above) have a common goal to enhance the transparency of SVHCs in articles for the consumers. The options 8 “obligatory response” and 11 “shorter period” aim to advance the existing Art. 33(2) mechanism, while entailing active involvement of consumers to use their right to know. The SCIP database, on the other hand, establishes a register for articles placed on the EU market that contain SVHCs above 0.1% w/w. Data stored in this repository will be available to the public, including consumers. In ECHA’s conception of SCIP, notifying suppliers should provide together with their SVHC report sufficient information putting consumers in the position to identify specific (end-)products – if such identifiers are available. Compared to the Art. 33(2) active request scenario, the register would thus be the option causing the lowest transaction costs, both for consumers and suppliers. It remains, however, to be seen whether the SCIP database, after the reporting obligation becomes mandatory in January 2021, will indeed provide meaningful article data for consumers. In this respect, one may not reasonably expect that SCIP indeed gives the full picture of SVHC articles on the market. Against this background, aiming to reduce uncertainties as to the SVHC status of articles, option 7 “more open SCIP notifications” targets opening the SCIP reporting scheme also for suppliers keen to – on a voluntary basis – indicate in the database their articles that do not contain SVHCs above the threshold. Taking into account that this option could be implemented without any additional law making required, it could provide a good short-term solution in terms of advancing the article related requirements. At the same time, the legislator could already position options 8 “obligatory response” and 11 “shorter period” as a mid-term option in case the voluntary, more open SCIP approach does not attain a sufficient degree of transparency. This outlook of stricter future regulation might incite more active use of reporting possibilities under option 7.

Option 5 “labelling for SVHCs in articles” has to be seen in the light that it shares the same scope with SCIP (de lege lata), i.e. it applies only to articles with SVHCs. Moreover, the label concept outlined in this report would require the supplier to link it with up-to-date online information on the actual SVHC(s) present in the article, i.e. this option would bring only little “offline” added value in terms of an enhanced information basis. Implementing both options would thus clearly create redundancies. Since the legal mandate for SCIP already exists and suppliers are preparing to comply, there is no additional need for implementing option 5. This would even be the case if

SCIP in the current conception fails to enhance transparency on SVHCs, because in that scenario it would not be plausible that the labelling option would achieve higher supplier acceptance.

Option 1 would enlarge the scope of Art. 33 to all everyday products (given that the "combined objects" do not fall under one of the exemptions in Art. 2). This would not only be compatible to the options discussed above but also enhance the related benefits.

3.2 Comparative consideration of risk management options

The authorisation and restriction schemes provide complementary regulatory options, stipulate different requirements for authorities and cause different effects. In this report, one main focus is regulatory control of substances, including SVHCs, in imported articles.

As regards imported articles, REACH creates a link to the restriction scheme in Art. 69(2): for each Annex XIV entry, ECHA shall assess whether, to ensure adequate risk control, it is necessary to impose a restriction on those substances in articles. Addressing the regulatory omission as regards SVHCs in imported articles is the main intention of this hinge between the authorisation and restriction schemes. The practical impact of that provision, however, has been quite limited (section 2.5.3.2).

With a view to regulatory control of SVHCs in imported articles, both mechanisms entail advantages and disadvantages. Authorities may impose an authorisation requirement based on the known hazardous properties of a substance of very high concern. It is the subsequent task of applicants for authorisation to show that they are capable of adequate risk control and to propose appropriate monitoring measures,[261] or, depending on the available authorisation route(s), that the benefits outweigh the risks. This also means that every AfA is subject to scrutiny by authorities. In contrast, before they may adopt a restriction, authorities have to establish that an "unacceptable risk to human health or the environment" exists. REACH provides a broad margin of discretion to formulate fit-for-purpose restrictions. In this context it should be noted that, while in first 10 years of REACH restriction activities focussed on substances for which risks could be quantified, recently more open approaches emerged[262] – which are yet to be finally approved and adopted by the legislators. In any case, economic actors may not lift the ban, i.e. after adoption of the restriction no more administrative procedures are required. With a view to the legal principle of proportionality, the legal effects caused by authorisation are depriving economic actors to a lesser extent of their business opportunities compared to a general restriction banning the respective use completely.[263]

Whether an (extended[264]) authorisation requirement or a restriction is the best option depends on the specific risk scenario to be regulated. The available risk knowledge, the particular article group in question as well as the available time to achieve effective regulatory control are important aspects which need consideration. In this respect, the following conclusions can be drawn:

If the authorities possess evidence that an "unacceptable risk" arises from the presence of SVHCs in an article , the restriction path appears to be the most suitable option. If there are concerns that the presence of SVHCs in an article poses a risk, but, even under emerging more open

261 Cf. Führ et al. 2011 for further details.

262 Such as non-threshold approaches using emissions as proxy for risk/reduction in emissions (lead in PVC), semi-quantitative assessments (skin sensitisers in textiles), as well as a restriction imposing a reporting requirement to improve the quality of information available to assess potential future risks (microplastics).

263 Cf. Führ and Schenten 2015, p. 52 et subs.

264 As proposed in section 2.4.2.

approaches, the high standard established by the restriction scheme to impose a ban is likely not be met, different options are available in the context of RMOA:

- Authorities may trigger dossier evaluation or, particularly, substance evaluation, intended to generate suitable risk data. This may substantiate any restriction initiative or may also show that no action is needed due to negligible risk.[265] However, usually lack of the exposure information impedes the restriction initiative, not lack of hazard data. Exposure data is difficult to request in the mentioned evaluation schemes. Attempting to obtain further information through RMOA is thus another option.[266]
- Alternatively, if immediate action is perceived necessary, the European Commission may trigger the (extended) authorisation scheme, benefiting from the shifted burden of proof.

With a view to procedural efficiency, the authorisation scheme can be advantageous in particular in cases were suitable alternatives are already available for all or the majority of the SVHC uses subject to authorisation,[267] since in such a scenario economic actors will most likely prefer substitution over the authorisation procedure. First indications whether alternatives do exist could be found in the Annex XV dossier employed to propose substances for inclusion in the candidate list, which should provide "information on alternative substances and techniques" that is moreover substantiated by a public consultation of interested parties pursuant to Art. 59(4).

At the same time, notwithstanding the availability of suitable alternatives the (extended) authorisation scheme can – provided there is political will – be the best option in a scenario where urgent action is required (e.g. to address seasonal articles) with respect to article categories addressing vulnerable groups (e.g. children's toys).[268]

In the latter scenario, a "fast-track" restriction could also be a suitable regulatory response, if options related to Art. 68(2) (i.e. option 17, in particular, better allowing for precautionary action) are implemented.

In addition, available decision trees[269] may provide further orientation for the choice of the regulatory option.

The options aimed at improving the restriction scheme (17, 18, 19 and 20 as the formalised version of 19) are complementing each other and are standing side by side the option of an extended authorisation scheme (option 16). Hence, when considering opportunities to enhance the legal framework of REACH, the legislator does not necessarily need to choose one option over the other but could adopt all of them.

265 At this point one could also consider Art. 7(5), notably in its further developed manifestation as set out in option 16.
266 RMOA invites authorities to share information with other authorities and stakeholders.

267 Wirth et al. 2018.
268 Besides, Member States may impose national restrictions by invoking the "safeguard clause" of Art. 129 REACH.

269 Wirth et al. 2018.

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