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Advancing REACH: Strengthening control of emerging risk

Final report

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Advancing REACH: Strengthening control of emerging risk

Final report

by

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Abstract: Advancing REACH: Strengthening control of emerging risk

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

In October 2020, the European Commission launched the Chemicals Strategy for Sustainability that calls to counter emerging risk with preventive action. Against this backdrop, the report aims to place this strategy in the context of the debate on the precautionary principle in the EU and to derive policy options to advance REACH.

The report assesses the general coverage of emerging risk under REACH. To the extent that emerging risk falls into the scope of REACH, it assesses in how far the regulation operationalises the concept of emerging risk with legal instruments and, if relevant, evaluates the practical implementation of such instruments. Based on the findings, it develops policy options responding to the identified deficits in order to advance REACH. The aim of the policy options is to strengthen control of emerging risk under REACH. They are addressing deficits in the provisions of REACH de lege lata. These deficits impede the willingness of actors in industry and authorities and limit them of the framework conditions required to tackle emerging risk. The options at least partially address the identified shortcomings. An overall perspective shows that the foreseeable benefits of the options would outweigh the identified disadvantages.

Kurzbeschreibung: Weiterentwicklung von REACH: Gestärkte Beherrschung von Emerging Risks

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

Im Oktober 2020 stellte die Europäische Kommission die Chemikalienstrategie für Nachhaltigkeit vor, die dazu aufruft, „Emerging Risks", also mehr oder weniger neuartige Risiken, mit präventiven Maßnahmen zu begegnen. Vor diesem Hintergrund zielt der Bericht darauf ab, diese Strategie in den Kontext der Debatte um den Vorsorgegrundsatz in der EU zu stellen und Optionen zur Weiterentwicklung von REACH abzuleiten.

Der Bericht untersucht, ob Emerging Risks allgemein in den Anwendungsbereich der REACH-Verordnung fallen. Soweit dies zu bejahen ist, bewertet er, inwieweit die Verordnung das Konzept der Emerging Risks konkret über Anforderungen operationalisiert und inwieweit die Akteure diese Anforderungen auch praktisch umsetzen. Auf der Grundlage der Ergebnisse entwickelt der Bericht rechtliche Handlungsoptionen, die an die konkret identifizierten Defizite anknüpfen, um REACH in dieser Hinsicht weiterzuentwickeln. Ziel der rechtlichen Handlungsoptionen ist es, die Kontrolle von Emerging Risks im Rahmen von REACH zu stärken. Sie adressieren Defizite in den Bestimmungen von REACH de lege lata. Diese Defizite beeinträchtigen die Motivation von Akteuren in Industrie und Behörden und limitieren die notwendigen Rahmenbedingungen, um neu auftretende Risiken angemessen beherrschen zu können. Die Optionen gehen dabei auf die festgestellten Defizite ein. In einer Gesamtbetrachtung überwiegen die absehbaren Vorteile der Optionen die festgestellten Nachteile.

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AfA	Application for Authorisation
IR	Information Requirements (according to the REACH Annexes)
CJEU	Court of Justice of the European Union
CLH	Harmonised Classification and Labelling
CLP	(EU Regulation on) Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, or Toxic for Reproduction
COM	Communication (from the European Commission)
CoRAP	Community Rolling Action Plan
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
CSS	Chemicals Strategy for Sustainability
DNEL	Derived No Effect Level
D4	Octamethylcyclotetrasiloxane
D5	Decamethylcyclopentasiloxane
ECHA	European Chemicals Agency
EDCs	Endocrine-Disrupting Chemicals
EU	European Union
IUCLID	International Uniform Chemical Information Database
MS	Member State
MSCA	Member State Competent Authority
PBT	Persistent, Bioaccumulative and Toxic
PFHxA	Undecafluorohexanoic acid
PMT	Persistent, Mobile and Toxic
PNEC	Predicted No Effect Concentration
POP(s)	Persistent Organic Pollutant(s)
(Q)SAR	(Quantitative) Structure–Activity Relationship
RAC	Risk Assessment Committee
RCR	Risk Characterisation Ratios
REACH	(EU Regulation on) Registration, Evaluation, Authorisation and Restriction of Chemicals
SDG(s)	Sustainable Development Goal(s)
SEA	Socio-Economic Analysis
SEAC	Socio-Economic Analysis Committee
SVHC(s)	Substance(s) of Very High Concern
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
vPvB	Very Persistent and very Bioaccumulative

Summary

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

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

By its very nature, (legal) control of chemicals is confronted with uncertainties. This, however, does not mean that regulatory measures are not permitted. On the contrary, in line with Principle 15 of the United Nations Rio-Declaration "lack of full scientific certainty" does not hinder risk management measures. This holds true also for emerging risks, a sub-category to the so-called 'known unknowns'.

Emerging risk, for the purpose of this report, is not determined by the "novelty" of a specific risk situation. Rather, it relates to a higher degree of uncertainty as regards the occurrence of an event due to release and exposure (1st order uncertainty) as well as uncertainty with a view to a substances' effects and resulting consequences (2nd order uncertainty). The latter can involve well-known contaminants such as substances with vPvB or endocrine disruptive properties for which it is challenging to establish adverse effects or derive safe levels. Besides, it might refer to substances that are under consideration to be classified as hazardous, e.g. in the case of CMRs where available data is inconclusive and does therefore not provide an appropriate basis for classification. It can, however, also entail recently surfaced properties of a substance and related adverse effects on human health and the environment that are yet unknown.

In October 2020, the European Commission launched the Chemicals Strategy for Sustainability that calls to counter emerging risk with preventive action. Against this backdrop the report aims to place this strategy in the context of the debate on the precautionary principle in the EU and to derive policy options to advance REACH.

The report assesses in chapter 2 the general coverage of emerging risk under REACH. To the extent that emerging risk falls into the scope of REACH, it assesses in how far the regulation operationalises the concept of emerging risk with legal instruments and, if relevant, evaluates the practical implementation of such instruments. Based on the findings, chapter 4 develops policy options responding to the identified deficits in order to advance REACH in this respect.

All assessment steps are mindful that in practice risk control depends on contributions from actors in science, authorities and industry. Therefore, a behavioural perspective underpins the legal analysis, focussing on three behavioural factors: *Willingness* addresses attitudes towards enhanced risk management. This relates to motivational factors (preferences) including the formal and informal rules that govern the organisation that actors belong to, thus (dis)incentivising a particular action. Actors' skills and resources are covered by *capacities*. *Opportunities* refer to external factors providing the right framework conditions (instruments) for action. All three factors are highly interrelated. They influence the extent to which industry

and authorities tackle emerging risk, e.g. when performing the CSA or when developing Annex XV dossiers.

Measured by this standard, REACH provides a general legal duty for industry to take into account emerging risk when assessing and managing risks. Besides, REACH stipulates a general mandate for authorities to tackle emerging risks. Yet, the REACH provisions, notably Section 6 of Annex I on risk characterisation, do not *explicitly* address uncertainty in terms of emerging risk. Rather, the relevance of emerging risk follows from the precautionary principle that underpins REACH as a structural principle. Annex A of the report collects examples for the instrumental design of REACH (shifting burden of proof to industry, using generic risk approaches) anchored in precautionary thinking. Judicature by the EU courts, summarised in Annex B of the report, provide mostly procedural requirements linked to the application of the precautionary principle.

The general coverage of emerging risk under REACH is one aspect relevant in terms of the *willingness* of actors to avoid and mitigate such risks. However, in the absence of explicit legal obligations, the framework could miss out on the willingness of actors from industry, in particular, to tackle emerging risk when applying the provisions of Annex I. Besides, the question arises whether REACH provides the necessary *opportunities* in the form of legal instruments.

The analysis of the registration mechanism shows that, for the time being, the incentives for industrial actors to investigate into emerging risks are quite limited. On the contrary, it is still advantageous to abstain from such efforts. The imprecise wording and the lack of attribution of consequences in case of non-fulfilment lead to this conclusion.

The restriction scheme comprises deficits as well. Since emerging risks implicitly fall into the scope of Annex I, authorities can address emerging risks when proposing restrictions. Due to lack of legal criteria "framing" the precautionary principle in the restriction scheme, authorities however cannot be sure that the Annex XV dossier will eventually be successful. Clearer criteria could help overcome deficits in the legal framework (*opportunities*) by enhancing predictability of the process for all concerned parties and by specifying and thus reducing the resource inputs required by dossier submitters. Reducing these impediments could at the same time increase the *willingness* of MSCA to develop Annex XV dossiers, e.g. to address emerging risk of substances.

Whereas the concept of emerging risk already falls into the scope of REACH de lege lata, it is thus not fully operationalised within the regulatory contexts of registration and restriction, and therefore lacks implementation. Consequently, there is a need to consider policy options aimed at strengthening emerging risk response in REACH. Against this background, section 4.1 develops policy options aimed at strengthening control of emerging risk in REACH. Section 4.2 provides a preliminary evaluation of these options.

Table 1: Advantages and disadvantages of the policy options

Option	Advantages	Disadvantages
Art. 66(a): Restriction Goals	Motivates authorities to draft Annex XV dossiers subject to the legal goals	Disadvantages are not apparent
Annex I Section 6.0: Enhanced	Motivates industry to adequately identify and adequately control emerging risks by creating awareness	Disadvantages are not apparent.

Option	Advantages	Disadvantages
legal clarity on *substantive* scope of CSR in terms of emerging risk	Motivates authorities to draft Annex XV dossiers aimed at preventive control by reducing burden of establishing risk	Clarifying the legal mandate and requirements de lege lata, the option does not incur any additional costs
	Motivates authorities to consider emerging risk in dossier evaluation	
	Facilitates innovation in the direction of sustainable chemistry	
	No changes to scope of judicial review (in substantive terms) if legal action is brought against the restriction	
	Due to all of the above: stronger contributions to normative objectives of REACH: high level of protection, competitiveness and innovation, precautionary principle	
Annex I Section 6.5: Extending duty to minimise exposures and emissions to all emerging risk situations	Legally requires industry to adequately control emerging risks	The duty incurs additional compliance costs on industry
	Yields stronger contributions to normative objectives of REACH: high level of protection, precautionary principle	The duty incurs additional enforcement costs on authorities
Annex I: Operationalise emerging risk in the registration	Legally requires industry to assess relevance of emerging risk	The duty incurs additional compliance costs on industry
	Yields stronger contributions to normative objectives of REACH: high level of protection, precautionary principle	The duty incurs additional enforcement costs on authorities
Annex XV: New tools to tackle emerging risk	Further enhancing legal clarity and thus further reducing burden for authorities (see 2)	Additional *formal* aspects subject to judicial review if legal action is brought against the restriction
	Enhanced transparency of (precautionary) restrictions increases predictability and trust in system	Creating new procedural obstacles which are however minor and can be tackled with guidance

The aim of the policy options is to strengthen control of emerging risk under REACH. They are addressing deficits in the provisions of REACH de lege lata. These deficits impede the *willingness* of actors in industry and authorities and deprive them of the framework conditions *(opportunities)* required to tackle emerging risk. The options at least partially address the identified shortcomings. Table 1 shows that, in an overall perspective, the foreseeable benefits of the options would outweigh the identified disadvantages. In addition, with regard to the objective of a high level of protection, the Commission and the legislative bodies are nevertheless responsible to constantly monitor the handling of emerging risk under REACH.

Zusammenfassung

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

Das Vorhaben REACH-Weiterentwicklung besteht aus insgesamt 18 Teilprojekten, die sich mit unterschiedlichen Aspekten der (Umsetzung der) REACH-Verordnung und Optionen für deren Weiterentwicklung auseinandersetzen. So werden in den jeweiligen Teilprojekten die REACH Prozesse Dossierbewertung, Stoffbewertung, Beschränkung, Zulassung und Konsultationen sowie die Rolle der Widerspruchskammer und das Zusammenspiel der Prozesse analysiert. Auch die Verbindung von REACH zur Nachhaltigen Chemie, die 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.

Es liegt in der Natur der Sache, dass die Regulierung von Chemikalien mit Unsicherheiten behaftet ist. Dies bedeutet jedoch nicht, dass regulatorische Maßnahmen nicht zulässig sind. Im Gegenteil, in Übereinstimmung mit Prinzip 15 der Rio-Deklaration der Vereinten Nationen hindert der „Mangel an vollständiger wissenschaftlicher Gewissheit“ nicht daran, Risikomanagement-Maßnahmen zu ergreifen. Dies gilt auch für „Emerging Risks“, also mehr oder weniger neuartige Risiken. Damit erfasst sind Risiko-Situationen aus dem Bereich der „Known Unknowns“, d.h. es besteht ein generelles Bewusstsein über die risikobedingenden Faktoren, die aber nicht vollständig verstanden werden.

Emerging Risk im Sinne dieses Berichts ergibt sich nicht vorrangig aus der „Neuartigkeit“ einer spezifischen Risikosituation. Vielmehr bezieht sich der Begriff auf einen höheren Grad an Unsicherheit hinsichtlich des Auftretens eines Ereignisses aufgrund von Freisetzung und Exposition (Unsicherheit 1. Ordnung) sowie hinsichtlich der Wirkungen eines Stoffes auf die Schutzgüter und der daraus resultierenden Folgen (Unsicherheit 2. Ordnung). Letzteres kann allgemein bekannte „Problemstoffe“ betreffen, wie z. B. solche mit vPvB oder endokrin wirksamen Eigenschaften, bei denen es schwierig ist, schädliche Wirkungen festzustellen oder sichere Werte abzuleiten. Außerdem kann sich Emerging Risk auf Stoffe beziehen, hinsichtlich deren Gefährlichkeit zwar erste Anhaltspunkte vorliegen, z. B. im Fall von CMRs, bei denen die verfügbaren Daten jedoch nicht schlüssig sind und daher bislang keine geeignete Grundlage für eine Einstufung bieten. Zugleich kann es sich aber auch um wirklich neuartige Bedrohungen handeln, verursacht durch noch unbekannte schädliche Eigenschaften und daraus resultierende Wirkungen auf die Schutzgüter.

Im Oktober 2020 hat die Europäische Kommission die Chemikalienstrategie für Nachhaltigkeit vorgestellt, die dazu aufruft, Emerging Risks mit präventiven Maßnahmen zu begegnen. Vor diesem Hintergrund zielt der Bericht darauf ab, diese Strategie in den Kontext der Debatte um den Grundsatz der Vorsorge in der EU zu stellen und rechtliche Optionen zur Weiterentwicklung von REACH abzuleiten.

Der Bericht untersucht in Kapitel 2, ob Emerging Risks allgemein in den Anwendungsbereich der REACH-Verordnung fallen. Soweit dies zu bejahen ist, bewertet Kapitel 3, inwieweit die Verordnung das Konzept der Emerging Risks konkret über Anforderungen operationalisiert und inwieweit die Akteure diese Anforderungen auch praktisch umsetzen. Auf der Grundlage der

Ergebnisse entwickelt Kapitel 4 rechtliche Handlungsoptionen, die an die konkret identifizierten Defizite anknüpfen, um REACH in dieser Hinsicht weiterzuentwickeln.

Bei allen Bewertungsschritten berücksichtigt der Bericht, dass das Risikomanagement in der Praxis von den Beiträgen der Akteure in Wissenschaft, Behörden und Industrie abhängt. Daher liegt der rechtlichen Analyse eine Verhaltensperspektive zugrunde, die sich auf drei verhaltensbezogene Faktoren fokussiert: Die *Motivation* (auch: Bereitschaft von engl. Willingness) befasst sich mit den Einstellungen zu einem verbesserten Risikomanagement. Dabei relevant sind motivationale Aspekte (Präferenzen) einschließlich der formellen und informellen Regeln von Organisationen, die das Verhalten der darin agierenden Akteure leiten sollen und damit (Fehl-)Anreize für eine bestimmte Handlung setzen. Der Begriff der *Kapazitäten* deckt die Fähigkeiten und Ressourcen der Akteure ab. *Möglichkeiten* beziehen sich auf externe Faktoren, die Rahmenbedingungen (Instrumente) für das Handeln bieten. Alle drei Faktoren sind stark miteinander verknüpft. Sie beeinflussen das Ausmaß, in dem Akteure Risiken angehen, z. B. in dem die Industrie die Stoffsicherheitsbeurteilung durchführt oder Behörden Anhang-XV-Dossiers erarbeiten, etwa zum Erlass von Beschränkungen.

Die Untersuchung zeigt, dass REACH eine allgemeine gesetzliche Vorgabe für die Industrie vorsieht, Emerging Risks bei der Risikobewertung und dem Risikomanagement zu berücksichtigen. Außerdem sieht REACH einen allgemeinen Auftrag an die Behörden vor, sich mit solchen Risiken zu befassen. Allerdings gehen die Bestimmungen der Verordnung, insbesondere in Abschnitt 6 des Anhangs I zur Risikobeschreibung, nicht explizit auf die Unsicherheit in Bezug auf neuartige Risiken ein. Vielmehr ergibt sich die Relevanz von Emerging Risks aus dem Grundsatz der Vorsorge, das REACH als Strukturprinzip zugrunde liegt. Anhang A des Berichts sammelt Beispiele für die instrumentelle Gestaltung von REACH (Verlagerung der Beweislast auf die Industrie, Verwendung des Konzepts generischer Risiken), in denen Vorsorge als Strukturprinzip zum Tragen kommt. Die Rechtsprechung der EU-Gerichte, die in Anhang B des Berichts zusammengefasst ist, enthält hinsichtlich der Anwendung des Vorsorgegrundsatzes überwiegend verfahrensrechtliche Anforderungen.

Die genannte allgemeine gesetzliche Vorgabe aus REACH im Hinblick auf Emerging Risks begünstigt bereits die *Motivation* der Akteure, solche Risiken zu vermeiden und zu mindern. In Ermangelung expliziter rechtlicher Verpflichtungen dürfte eine diesbezügliche Bereitschaft insbesondere von Akteuren aus der Industrie jedoch schwach ausgeprägt sein. Außerdem stellt sich die Frage, ob REACH die notwendigen *Möglichkeiten* in Form von Rechtsinstrumenten bietet.

Die Analyse des Registrierungsmechanismus zeigt, dass die Anreize für industrielle Akteure, sich mit Emerging Risks zu befassen, vorerst recht begrenzt sind. Im Gegenteil, ist es nach wie vor vorteilhaft, auf solche Anstrengungen zu verzichten. Unpräzise Formulierungen etwa in Anhang I und die fehlende Zuweisung von Konsequenzen bei Nichterfüllung führen zu diesem Schluss.

Die Regelungen über den Erlass von Beschränkungen weisen ebenfalls Defizite auf. Da Emerging Risks implizit in den Anwendungsbereich von Anhang I fallen, können Beschränkungsvorschläge der Behörden diese Risiken adressieren. Aufgrund fehlender rechtlicher Kriterien zur Anwendung des Vorsorgeprinzips im Beschränkungsregime, können Behörden jedoch nicht sicher sein, dass ihr Anhang XV-Dossier letztendlich erfolgreich sein wird. Klarere Kriterien könnten allerdings helfen, Defizite im rechtlichen Rahmen zu überwinden (*Möglichkeiten*), indem sie die Vorhersehbarkeit des Prozesses für alle Beteiligten erhöhen und den von den Dossiererstellern benötigten Ressourceneinsatz konkretisieren und damit reduzieren. Diese

Hemmnisse zu verringern könnte gleichzeitig die *Motivation* der Behörden erhöhen, Dossiers nach Anhang XV zu entwickeln, z. B. um Emerging Risks zu kontrollieren.

Während das Konzept des Emerging Risk de lege lata bereits in den Anwendungsbereich von REACH fällt, ist es in den regulatorischen Kontexten der Registrierung und Beschränkung nicht vollständig operationalisiert, weshalb es auch eine untergeordnete Rolle in der praktischen Umsetzung spielt. Folglich ist notwendig, Optionen zu erwägen, die darauf abzielen, Emerging Risk in REACH konkreter rechtlich einzuhegen. Vor diesem Hintergrund entwickelt Abschnitt 4.1 rechtliche Optionen, die auf eine Stärkung der Kontrolle von Emerging Risks in REACH abzielen. Abschnitt 4.2 enthält eine vorläufige Bewertung dieser Optionen.

Table 2: Vorteile und Nachteile der Handlungsoptionen

Handlungsoption	Vorteile	Nachteile
Art. 66(a): Ziele für Beschränkung	Motiviert die Behörden, Dossiers nach Anhang XV zu erstellen, die den gesetzlichen Zielen unterliegen	Nachteile sind nicht ersichtlich
Anhang I Abschnitt 6.0: Erhöhte Rechtsklarheit über den *materiellen* Anwendungsbereich des CSR in Bezug auf Emerging Risks	Schaft stärkeres Bewusstsein für Emerging Risks und motiviert dadurch die Industrie, diese Risiken adäquat zu identifizieren und zu beherrschen	Nachteile sind nicht ersichtlich. Klärung des gesetzlichen Auftrags und der Anforderungen de lege lata, die Option verursacht keine zusätzlichen Kosten
	Motiviert die Behörden zur Erstellung von Dossiers nach Anhang XV, die auf für Emerging Risks abzielen, indem der Aufwand für die Feststellung dieses Risikos reduziert wird	
	Motiviert die Behörden, Emerging Risks bei der Dossierbewertung zu berücksichtigen	
	Begünstigt Innovationen in Richtung einer nachhaltigeren Chemie	
	Keine Änderungen am Umfang der gerichtlichen Überprüfung (in materieller Hinsicht), wenn gegen die Beschränkung geklagt wird	
	Durch alle oben genannten Punkte: stärkere Beiträge zu den normativen Zielen von REACH: hohes Schutzniveau, Wettbewerbsfähigkeit und Innovation, Vorsorgegrundsatz	
Anhang I Abschnitt 6.5: Ausweitung der Pflicht zur Minimierung von	Verpflichtet die Industrie gesetzlich, neu auftretende Risiken angemessen zu beherrschen	Die Pflicht verursacht zusätzliche Compliance-Kosten für die Industrie

Handlungsoption	Vorteile	Nachteile
Expositionen und Emissionen auf alle Emerging Risks	Erbringt einen stärkeren Beitrag zu den normativen Zielen von REACH: hohes Schutzniveau, Vorsorgegrundsatz	Die Pflicht verursacht zusätzliche Durchsetzungskosten für die Behörden
Anhang I: Operationalisierung von Emerging Risks in der Registrierung	Verpflichtet die Industrie rechtlich, die Relevanz von Emerging Risks zu bewerten	Die Pflicht verursacht zusätzliche Compliance-Kosten für die Industrie
	Erbringt stärkere Beiträge zu den normativen Zielen von REACH: hohes Schutzniveau, Vorsorgegrundsatz	Die Pflicht verursacht zusätzliche Durchsetzungskosten für die Behörden
Anhang XV: Neue Instrumente zur Bewältigung von Emerging Risks	Weitere Verbesserung der Rechtsklarheit und damit weitere Entlastung der Behörden	Zusätzliche *formale* Aspekte, die einer gerichtlichen Überprüfung unterliegen, wenn gegen die Beschränkung geklagt wird
	Verbesserte Transparenz von (vorsorglichen) Beschränkungen erhöht die Vorhersehbarkeit und das Vertrauen in das Regulierungssystem	Schaffung neuer verfahrensrechtlicher Hindernisse, die jedoch geringfügig sind und mit Anleitung bewältigt werden können

Ziel der rechtlichen Handlungsoptionen ist es, die Kontrolle von Emerging Risks im Rahmen von REACH zu stärken. Sie adressieren Defizite in den Bestimmungen von REACH de lege lata. Diese Defizite beeinträchtigen die Motivation von Akteuren in Industrie und Behörden und sie enthaltenen Ihnen die Rahmenbedingungen (Möglichkeiten) vor, um neu auftretende Risiken angemessen beherrschen zu können. Die Optionen gehen dabei auf die festgestellten Defizite ein. Tabelle 2 zeigt, dass in einer Gesamtbetrachtung die absehbaren Vorteile der Optionen die festgestellten Nachteile überwiegen würden. Darüber hinaus sind die Europäische Kommission und die gesetzgebenden Organe im Hinblick auf das Ziel eines hohen Schutzniveaus dennoch dafür verantwortlich, den Umgang Emerging Risks unter REACH ständig zu überwachen.

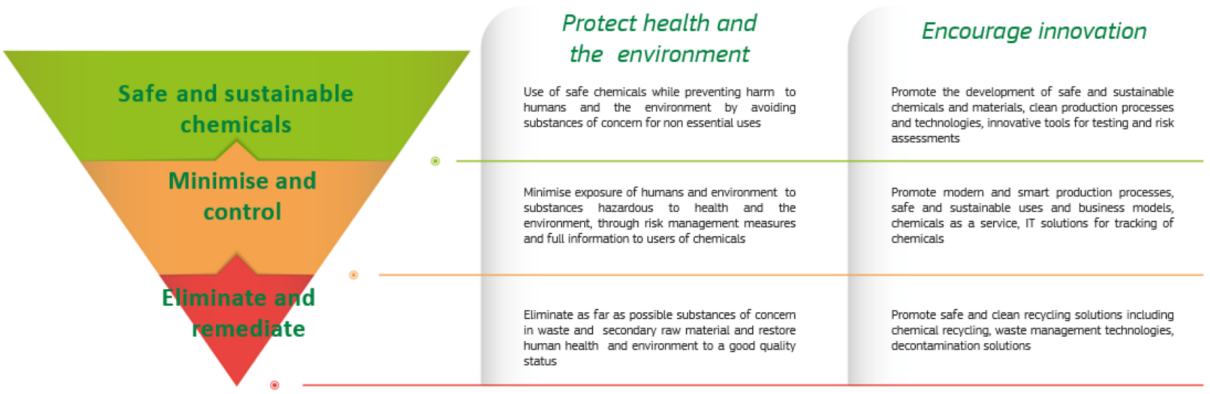
1 Introduction

In October 2020, the European Commission launched the Chemicals Strategy for Sustainability that calls to counter emerging risk with preventive action. Against this backdrop, the report aims to place this strategy in the context of the debate on the precautionary principle in EU and derive policy options to advance REACH.

1.1 Problem impulse

The launch of the Chemicals Strategy for Sustainability (CSS) followed Council Conclusions in 2019[1] under the headline "Towards a Sustainable Chemicals Policy Strategy of the Union" and a respective European Parliament Resolution[2] adopted in July 2020. The CSS formulates a long-term vision for EU chemicals policy that is based on a new "Toxic-free hierarchy" in chemicals management. The hierarchy prioritizes the promotion of safe and sustainable chemicals over minimisation of exposure and risk control and the last resort of elimination (e.g. of contaminated wastes) and remediation. Each of the three levels include specific elements aimed both at protecting human health and the environment and at encouraging innovation (Figure 1).[3] This understanding of innovation not only safeguards but advances existing standards of protection. It also distinguishes new developments that contribute to lowering risks for humans and the environment.[4] All commitments made by the CSS shall contribute to the vision embodied by the hierarchy.

Figure 1: Toxic-free hierarchy as introduced by the CSS



Source: COM(2020) 667, 4.

The CSS asserts that

"Although the EU's approach to chemicals management has been effective in reducing human and environmental exposures to certain problematic substances, ***ongoing and emerging health and environmental concerns*** *call for a strengthening of the legal framework to rapidly respond to scientific findings, making it more coherent, simple and predictable for all actors. In particular, the REACH and CLP Regulations should be reinforced as EU's cornerstones for regulating chemicals*

[1] Council of the European Union (2019).

[2] European Parliament resolution of 10 July 2020 on the Chemicals Strategy for Sustainability (2020/2531(RSP)), P9_TA(2020)0201.

[3] COM(2020) 667, 3.

[4] In this respect, see also Bundesregierung (2016), 143.

and be complemented by coherent approaches to assess and manage chemicals in existing sectorial legislation, especially that regulating consumer products."[5]

Under the headline "Protection against most harmful chemicals", the Commission prioritises substances in consumer products for regulatory risk management measures "that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative" and "further harmful chemicals, including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ".[6]

Additionally, as for the "Chemical pollution in natural environment" the Commission observes that the current frameworks "struggle" to provide for appropriate risk control. The Commission therefore commits to "propose new hazard classes and criteria in the CLP Regulation to fully address environmental toxicity, persistency, mobility and bioaccumulation" as well as to "introduce endocrine disruptors, persistent, mobile and toxic and very persistent and very mobile substances" as SVHC categories.[7] Enhanced information requirements for registrants of chemicals shall contribute to establishing "robust and relevant, up-to-date knowledge" on chemical risks.[8]

Furthermore, these measures are complemented by the commitment to "develop an EU **early warning** and action system for chemicals to ensure that EU policies address **emerging chemical risks** as soon as identified by monitoring and research".[9]

By committing to enhance the capabilities of regulators to react to early warning signs of emerging chemical risk, the strategy calls for a strengthened and more coherent EU chemicals policy.[10] What is more, in recent months and years several Member States as well as the Commission have launched restriction initiatives aimed at taking preventive action against emerging risk, e.g. with respect to PFHxA and intentionally added microplastics.

One can conclude that more recently, also in the context of the Green Deal,[11] a stronger perception of societal challenges linked to ubiquitous exposure to problematic chemicals with associated risks ran rampant and that there is political will to prevent any adverse impacts. At the same time, the strategy indicates that the existing legal framework is not fully capable of appropriately managing the entire range of risks related to chemicals.

1.2 Emerging risk

The Chemicals Strategy for Sustainability uses the term Emerging Risk without clarifying its scope. In EU legislation as well as in the literature there is no consistent concept of emerging risk.[12] A 2016 paper prepared for the European Commission on "Identifying emerging risks for environmental policies" frames the concept as follows:

[5] COM(2020) 667, 9, first paragraph, emphasis added; the original emphasis lies on "strengthening of the legal framework", in particular to "REACH and CLP" as the "cornerstones for regulating chemicals" that should be complemented by "coherent approaches to assess and manage chemicals".

[6] COM(2020) 667, 10.

[7] COM(2020) 667, 13.

[8] COM(2020) 667, 19.

[9] COM(2020) 667, 21, emphasis added.

[10] COM(2020) 667, 9, first paragraph.

[11] COM(2019) 640.

[12] Flage and Aven (2015).

"Emerging risks are, generally, those that have a high degree of uncertainty regarding the probability of occurrence and the amount of potential loss or harm."[13]

Hence, emerging risk appears to describe a certain fraction of situations generally falling into the scope of the precautionary principle. The precautionary principle is enshrined in international law and in EU primary law. Many acts of EU secondary legislation refer to the principle, also the provisions of REACH are, according to Art. 1(3), "underpinned by the precautionary principle". REACH therefore places on industry actors the responsibility "to ensure" that chemicals "do not adversely affect human health or the environment". In addition, regulatory action is based on this principle and the risk management by industry actors has to take it into account as well. Thus, the principle of self-responsibility, laid down in Art. 1(3)1, stipulates the obligation to install precautionary measures during the entire life cycle of chemicals. Yet, across different sectoral legislations there is no horizontally agreed definition of the principle and its legal effects; neither is its role in REACH clearly defined (see on the REACH context section 2.5 and on the context of international and EU primary law Annex II in section B).[14]

What is safe to say, however, is that the precautionary principle addresses risk situations characterized by a high degree of uncertainty i.e. that go beyond the usual uncertainties subject to any risk assessment and which risk assessors are capable to handle by employing "prudential aspects in practice" (cf. section 2.3).[15]

There are different approaches for the systemisation of risk and related uncertainties. First, any risk is characterized by a two-fold uncertainty with respect to the occurrence of an event (1st order uncertainty) and its specific effects and resulting consequences (2nd order uncertainty).[16] Furthermore, in a broader perspective, one can define different knowledge levels whereas uncertainty might reach into the area of "unknown unknowns", describing things we are neither aware of nor understand (Table 3).[17]

Table 3: Categories of uncertainty

	Knowns	**Unknowns**
Known	Things we are aware of and understand	Things we are aware of but do not understand
Unknown	Things we understand but are not aware of	Things we are neither aware of nor understand

The area of emerging risks, in contrast, is allocated to the sphere of 'known unknowns' which stands for things we are aware of but do not fully understand.[18] Air pollution, land degradation and biodiversity loss are given as examples in the field of environment.[19] This is also the particular field of application when the report at hand refers to emerging risk and to precautionary or preventive measures.

Accordingly, emerging risk, for the purpose of this report, is not determined by the "novelty" of a specific risk situation. Rather, it relates to a higher degree of uncertainty as regards the

[13] Science for Environment Policy (2016), 5.

[14] Milieu (2017).

[15] COM(2000) 1, 18.

[16] Führ (2014), para. 45.

[17] Rumsfeld (2002), cited via Science for Environment Policy (2016), 5.

[18] Science for Environment Policy (2016), 5.

[19] Science for Environment Policy (2016), 6.

occurrence of an event due to release and exposure (1st order uncertainty) or as regards a substances' effects and resulting consequences (2nd order uncertainty). The latter can involve well-known contaminants such as substances with vPvB or endocrine disruptive properties for which it is challenging to establish adverse effects or derive safe levels. Besides, it might refer to substances are under consideration to be classified as hazardous, e.g. in the case of CMRs where available data is inconclusive and does therefore not provide an appropriate basis for classification.[20] It can, however, also entail surfaced properties of a substance and related adverse effects on human health and the environment that are yet unknown.

1.3 Aim and structure of the report

The Chemicals Strategy for Sustainability outlines a wide range of political commitments to take action. Many of these actions address chemicals and risk situations that fall in the scope of the REACH Regulation. Some commitments aim to strengthen the legal framework created by REACH, i.a. by extending the generic approach to risk management introduced by Art. 68(2) REACH to further contexts, and by introducing endocrine disruptors, persistent, mobile and toxic and very persistent and very mobile substances as SVHC categories.[21] Publishing two inception impact assessments on changes in REACH[22] and CLP[23] in early May 2021, the Commission initiates the preparation phase of these prospected legislative changes. ECHA investigates its role in CSS implementation.[24]

Besides, the question arises whether options in addition to those explicitly mentioned by the CSS and its Annex are available to enhance the legal framework to facilitate a more preventive approach. Notably, while **the strategy singles out specific hazard groups to be tackled, it misses the opportunity to draft a more general approach to risk control that could flexibly adapt to future emerging risk situations we are not aware of today, thereby establishing a regulatory system truly capable of reacting to early warning signs.** In particular, such options could aim at improving industry's and the authorities' motivation and framework conditions for risk management.

This notion considers that risk identification and control is not a self-executing process. Rather, it depends on the level of action and inaction by actors in science, authorities and industry. In this view, the three behavioural factors *willingness*, *capacities* and *opportunities* are key.[25] *Willingness* addresses attitudes towards enhanced risk management. This relates to motivational factors (preferences) including the formal and informal rules that govern the organisation actors belong to, thus (dis)incentivising a particular action. Actors' skills and resources are covered by *capacities*. *Opportunities* refer to external factors providing the right framework conditions (instruments) for action. All three factors are highly interrelated. They influence the extent to which industry and authorities tackle emerging risk, e.g. when performing the CSA or when developing Annex XV dossiers.

Against this backdrop, the report assesses in chapter 2 the general coverage of emerging risk under REACH. To the extent emerging falls into the scope of REACH, and mindful of the relevant

[20] Some orientation in this respect follows from category 2 classifications according to GHS and CLP for substances "suspected" of CMR-related toxic effects. In an emerging risk situation available data would not allow for category 2 classifications.

[21] COM(2020) 667, 10, 13.

[22] Ares(2021)2962933.

[23] Ares(2021)2969734.

[24] ECHA (2021a), 14.

[25] On this approach, see Ashford (2000) and (1993), as well as the examples of application in Koch (2005), 128; Führ et al. (2006), 59 et seq..

behavioural factors, chapter 3 assesses in how far the regulation operationalises the concept of emerging risk with legal instruments and, if relevant, evaluates the practical implementation of such instruments. Based on the findings, chapter 4 develops responsive policy options to advance REACH.

2 Coverage of emerging risk under REACH

Pursuant to Art. 1(1) of REACH, the regulation aims to "ensure a high level of protection of human health and the environment". Industry is therefore held responsible that substances as such or in downstream uses "do not adversely affect human health or the environment" as set forth by Art. 1(3) Sentence 1. According to Sentence 2 of this provision, REACH is "underpinned by the precautionary principle". Mindful of these objectives, the regulation provides a legal framework entailing a multitude of provisions on the management of chemical risks, i.e. by activating industry's self-responsibility and providing control instruments to authorities.

2.1 The concept of risk

Chemical risk is, in general, determined using the risk-ratio-model.[26]

*(1) "**Hazard identification** means identifying the biological, chemical or physical agents that may have adverse effects …*

*(2) **Hazard characterisation** consists of determining, in quantitative and/or qualitative terms, the nature and severity of the adverse effects associated with the causal agents or activity …*

*(3) **Appraisal of exposure** consists of quantitatively or qualitatively evaluating the probability of exposure to the agent under study …*

*(4) **Risk characterisation** corresponds to the qualitative and/or quantitative estimation, taking account of inherent uncertainties, of the probability, of the frequency and of the severity of the known or potential adverse environmental or health effects liable to occur. It is established on the basis of the three preceding [components] and closely depends on the uncertainties, variations, working hypotheses and conjectures made at each stage of the process."*[27]

These steps are formalized in REACH Annex I stipulating general provisions for assessing substances and preparing chemical safety reports (CSR). Step (3) on exposure assessment is subject to Section 5 of Annex I, aiming at the determination of any relevant "exposure to the substance [which] is known or reasonably foreseeable" (section 5.2.4 Annex I).[28] As regards emerging risks, steps (1) and (2) on hazard assessment are crucial (Section **Fehler! Verweisquelle konnte nicht gefunden werden.**).

Section 6 of Annex I provides for the risk characterisation (step 4) that integrates the findings from hazard identification, hazard characterisation and exposure assessment. Whereas in REACH there is no definition of the concept of risk,[29] the requirements that come closest to a definition of risk can be found in Section 6. Many legal instruments in REACH refer to Annex I when it comes to the characterisation of risk, in particular Art. 14 providing for substance manufacturers' duty to conduct a CSA, as well as the AfA under authorisation. Likewise, when preparing the Annex XV dossier to establish "unacceptable risk" under Article 68(1) that needs to be tackled with a restriction, authorities are referred to the assessment steps set out in Annex I.

[26] Since its publication in 1983 the risk-ratio-model has evolved into a risk assessment standard, cf. NRC (1983); van Leeuwen (2007), 16.

[27] COM(2000) 1, 33, quoted after EGC, judgment of 9.9.2011, case T-257/07, ECR II-5827, para. 72 – France v Commission *(numbering and emphasis by the authors)*.

[28] Cf. Sections 0.3, 6.2. of Annex I as well as Recital 16 REACH.

[29] Art. 3(37) mentions the term without providing an explanation ("exposure scenario: means the set of conditions, including operational conditions and risk management measures").

It follows that whether there is a risk depends on the risk characterisation ratios (RCR), i.e. the relationship between dose and response for humans, or the concentration and effect for the environment respectively. Only if this ratio does not exceed 1 for either humans or the environment, can the risk be considered adequately controlled. As for properties of substances for which a no-effect threshold cannot be derived, the risk must be deduced by using a semi-quantitative or qualitative analysis, as put forth by Section 6.5. Section 2.3 covers the derogations for PBT and vPvB substances.

2.2 Assessment of standard hazards – and beyond

With regards to emerging risks, steps (1) and (2) on hazard assessment as part of the risk-ratio-model are crucial. To this end, the REACH information requirements (IR) and additional Annexes have to be taken into account. These provisions, on the one hand, define specific assessment steps to determine certain specified hazards. On the other hand, there are no limits to the scope of assessment since "all available information" needs to be taken into account when determining a substance's properties.[30] The same holds true for the CSA, which, pursuant to Section 0.5 of Annex I, "shall be based on the information on the substance contained in the technical dossier and on other available and relevant information". Section 1.0.2. on human health hazard assessment, after listing standard hazard classes to be taken into account, specifies that "[b]ased on all the available information, other effects shall be considered when necessary". Similarly, hazard assessment in the environmental context is "based on all available information", as set out by Section 3.1.1. In addition, the scope of assessment is not limited by the endpoints specified in the standard information requirements under REACH, but other (e.g. neurotoxic) effects can be relevant as well.[31] This extension of the scope at the same time, generally, allows to take into account adverse effects characterised by a higher level of uncertainty.

2.3 Coping with Uncertainty

REACH does not provide general guidance on the role of uncertainty in risk characterisation. REACH acknowledges uncertainties in Annex I Section 1.4.1, where, when establishing the DNEL, "the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation" shall be taken into account. Besides, the regulation provides basic strategies to tackle uncertainties. For instance, in case more than one study on a particular effect is available, risk assessors have to use "normally the study or studies giving rise to the highest concern" to establish the threshold.[32] Additionally, introducing the concept of assessment factors when identifying the PNEC for relevant compartments, Section 3.3.1 provides a tool to rationalize uncertainty.

What is more, ECHA issues distinct guidance on "Uncertainty analysis" as Chapter R.19 of the comprehensive guidance series on IR and CSA.[33] Pursuant to the guidance, uncertainties are inherent to the risk characterisation and all preceding process steps.[34] ECHA lists the following sources of uncertainty: scenario uncertainty, model uncertainty as well as uncertainty as to the parameters used (i.a. measurement errors, sample uncertainty, selection of the data used for

[30] Cf. the related registration obligations in Art. 12 and the introductions to Annexes VII to X.

[31] Cf. Annex I Section 0.10 on "effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in Sections 1 to 6 are impracticable".

[32] Annex I Sections 1.1.4. and 3.1.5 REACH.

[33] ECHA (2012).

[34] ECHA (2012), 7; cf. van Leeuwen (2007), 22 with further references; COM(2000) 1, 17.

assessing the risk, extrapolation uncertainty).[35] A relevant case in which the Agency recommends uncertainty analysis is the substantiation of a RCR close to the regulatory trigger value.[36] A tiered strategy of uncertainty analysis is proposed and ECHA asserts that the "general principles could also be applied if a qualitative or semi-quantitative risk characterisation is conducted".[37]

Besides, Annex XI provides for adaptations of the standard testing regime. If employing strategies such as (Q)SAR and read-across is sufficient to determine adverse effects of substances, additional testing is not deemed scientifically necessary. This also bears some meaning in the context of emerging risk where these strategies might be viable to bridge constraints on the assessment of hazards due to uncertainty. Thus, registrants have to consider a potential concern identified by applying the above-mentioned approaches; and authorities can use those methods in their risk assessment.

As a conclusion, REACH does not specifically define the applicable concept of uncertainty in the context of risk characterisation. From the reflections of uncertainty shown above in the legal text and in the guidance documents, however, it is fair to assume that these relate to the basic element of caution in risk assessment to make sure that any determinations are as robust as possible. In contrast, uncertainties in the realms of emerging risk apply to "situations [where] the scientific data are not sufficient to allow one to apply […] prudential aspects in practice, i.e. in cases in which extrapolations cannot be made because of the absence of parameter modelling and where cause-effect relationships are suspected but have not been demonstrated".[38]

As a conclusion, to the extent uncertainty is taken into account in Annex I and the ECHA Guidance this does not explicitly cover uncertainty in terms of emerging risk. Rather, the relevance of emerging risk follows from the precautionary principle that underpins REACH as a structural principle (section 2.5). However, ambiguity could fail to motivate industry actors in particular to address emerging risk when applying the provisions of Annex I.

2.4 Substances with effects reflecting a higher degree of uncertainty

The standard CSA steps for substances satisfying the PBT and vPvB criteria in Annex XIII that do not fit into the rationale of ecotoxicological endpoints "cannot be carried out with sufficient reliability".[39] Therefore a special regime applies. Substances with vPvB-properties are determined independently from adverse effects because no impact models or sometimes even ideas about possible damage exist.[40] Instead, high concern follows because "[p]ersistence, mobility and the non-natural state extremely expand the possibilities for high exposures and adverse effects in a variety of contexts. They increase the potential exposure immeasurably and are an indication of high interference rates and the fact that emissions are not reversible".[41] There is thus a lack of certainty about the harmful effects of substances with vPvB properties. In addition, Annex XIII acknowledges uncertainties as to the determination of P, B, vP and vB properties which sometimes cannot be detected under lab conditions but observed, e.g. as

[35] ECHA (2012), 8; c.f. van Leeuwen (2007), 22 with further references; c.f. NRC (1983), 11 et seq. COM(2000) 1, 17.

[36] Cf., also on variations of the case, ECHA (2012), 12.

[37] ECHA (2012), 11.

[38] COM(2000) 1, 18.

[39] Annex I Section 4.0.1 REACH.

[40] Von Gleich, Pade and Wigger (2013), 19.

[41] Von Gleich, Pade and Wigger (2013), 19 (authors' translation); Løkke (2006), 346.

results of monitoring and modelling.[42] A regulation addressing these substances can thus be dogmatically attributed to the area of precaution.[43] A similar conclusion can be drawn as regards PBT substances where the (eco)toxic effects are based on Annex XIII Section 1.1.3 lit. (b) (toxic for reproduction), whereas this involves classifications[44] of merely "suspected" hazardous properties.[45]

Consequently, REACH accepts specific adverse effect criteria reflecting a higher degree of uncertainty, triggering risk management measures by industry and authorities.

Section 6.5 para 2 stipulates for PBTs and vPvB derogations from the risk-ratio-model, whilst at the same time, based on the information obtained in the exposure scenario, requiring industry to "minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses". Industry has to take into account this "impetus to minimise" when they prepare the CSR.

Besides, REACH Article 57(d) and (e) stipulate that substances that meet the PBT or vPvB criteria can be identified as SVHCs. Consequently, there is a clear mandate for authorities in Title VII of REACH to control risks posed by substances satisfying the PBT and vPvB criteria. Likewise, "unacceptable risk" in terms of Title VIII can be established by referring to Annex XIII criteria. The European Commission adopted the restriction of Decamethylcyclopentasiloxane (D5) based on the grounds that the substance fulfils the vPvB criteria according to Annex XIII and that, therefore, a "risk to the environment arises from the presence of D4 and D5 in certain cosmetic products that are washed off with water after application".[46] While not directly referring to it, the Commission thus applies the rationale of Annex I Section 6.5 subpara 2 concerning substances satisfying the PBT and vPvB criteria. Consequently, the adopted restriction is based on the rationale that "[e]missions and subsequent exposure, in the case of a PBT/vPvB substance, can be considered as a proxy for unacceptable risk"[47]. Yet, this restriction is currently scrutinized before the court.

Furthermore, Article 57(f) potentially opens the SVHC status for additional substance groups, besides those that meet the Annex XIII criteria, the effects of which reflecting a higher degree of uncertainty. The provision mentions as an example ("such as") substances with PBT/vPvB properties that do *not* fulfil the Annex XIII criteria. For any substance identified on the grounds of Article 57(f) the provision however requires "scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern" to CMR or PBT/vPvB substances. Referring to serious effects, this evidence does not necessarily need to establish hazardous properties – as in the case of vPvB. Whether a substance falls in the scope of Article 57(f) is subject to a case-by-case decision. For instance, in July 2019 substances with PMT properties have been added to the list of SVHCs, whereas the justification for inclusion referred to combined intrinsic properties.[48]

[42] Cf. Annex XIII introductory paragraphs 2 and 3. According to the 5th paragraph, furthermore, the identification "shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products".

[43] Løkke (2006), 347, Zarfl and Matthies (2013), 7 with further references, Von Gleich, Pade and Wigger (2013), 19.

[44] Namely, category 2 classifications according to Regulation EC No 1272/2008.

[45] Cf. Führ et al. (2015).

[46] Recitals 3 and 8 of Commission Regulation (EU) 2018/35.

[47] Annex XV restriction report on D4 and D5, 52; confirmed by the RAC opinion in the procedure. See also section F.9 of the report (p. 81 (in pdf 86) on "Uncertainties" with the overall conclusion "The impact of this uncertainty can thus be considered neutral overall".

[48] Cf. ECHA (2019c): "Persistence, mobility, potential for long-range transport, observed adverse effects (at least the following probable effects for human health: effects on the liver, the kidney, and the haematological and immune systems and effects on development; at least the following probable effects for the environment: population relevant effects on birds and mammals); as

Besides, Article 57(f) mentions substances having endocrine disrupting properties as another example. According to ECHA, "endocrine disruptors interfere with hormone action, and in doing so can produce adverse effects on human and wildlife health".[49] For these substances, one can establish the mode of action, but linking adverse effects to that mode is a challenge. Several substances with endocrine disrupting properties for humans or the environment have been added to the SVHC list.[50]

Concluding on Art. 57(f), the provision allows for the identification of substances linked to emerging risk. As these substances shall qualify as substances of very high concern, the yardstick for assessment is however quite strict ("scientific evidence of probable serious effects").

2.5 Legal principle strengthens political room to manoeuvre

Pursuant to Art. 1(3) Sentence 2 of REACH, the regulation's "provisions are underpinned by the precautionary principle". In terms of the 2001 white paper "Strategy for a future Chemicals Policy", this principle is "fundamental to achieving" the goal of a high level of protection of human health and the environment.[51]

By stating that the regulation's "provisions are underpinned by the precautionary principle", Art. 1(3) REACH makes clear that this principle serves as a structural principle thus guiding all legal instruments. Generic risk approaches and allocation of the burden of proof to industry are two out of many examples of REACH mechanisms that structurally anchor the precautionary principle (see Annex A in section A). Further, the principle particularly gains momentum with respect to provisions referring to the concept of risk and related uncertainties.[52] This derives from the link between Art. 1(3) Sentence 2 (cited above) and Art. 191(2) TFEU (cf. Annex B in section B on the context of EU primary law and international law).[53] Besides, some of the highest (national) courts in the EU are interpreting constitutional law from an inter-generational perspective.[54] Accordingly, Art. 3(3) TEU and Art. 11 TFEU) are to be interpreted in such a way that the precautionary principle comes into play. This calls for prudence, especially in the case of non-reversible effects. Otherwise, one would burden future generations with unclear risks instead of contributing to reducing them now.

In the context of REACH, the precautionary principle shall guide industry and authorities when determining risk pursuant to Annex I of REACH. It follows that, when establishing "unacceptable risk" according to Article 68(1), authorities are legally mandated to base their assessment on this principle as well.

Taking into account the findings of the preceding sections, the REACH Regulation is based upon the risk concept that is common in EU law. That means that the regulation does not conceptually separate prevention against "well characterised risk" and precautionary measures against emerging risk.[55] Rather, REACH applies a uniform concept of risk, covering the full range of risk

well as low adsorption potential and high water solubility rendering the substance fully bioavailable for uptake via (drinking) water. Together, these elements lead to a very high potential for irreversible effects."

[49] ECHA (2021d).

[50] You can find the ECHA candidate list here.

[51] COM(2001) 88, 5. Besides, Recital 9 of REACH notes that the application of the precautionary principle is key to overcome "problems in the functioning of Community legislation on chemicals" predating REACH.

[52] Rehbinder (2008), Art. 1, para. 29; Rehbinder (2012a), para. 17, 22; Rehbinder (2012b), para. 17.

[53] Rehbinder (2008), Art. 1, para. 29 m. w. N.; Winter (2006), 56 (60); Schenten (2017).

[54] See e.g. the decision of 24 March 2021 by the Federal Constitutional Court at ECLI:DE:BVerfG:2021:rs20210324.1bvr265618.

[55] Annex I Section 0.5 REACH refers to "well-characterised risk" and "potential risk", whereas in both cases the general rule applies that risk "need[s] to be characterised precisely"; see also Annex XI, Section 1.4.

situations, and only the socially accepted residual risk falls out of scope.[56] In terms of the regulation, a risk triggering the obligation to install measures with the aim to reach a level of "adequate control" is either present or it is not. Emerging risk falls into the scope of this range as well.

Yet, it is not clear what exactly follows from this conclusion. To the extent the principle has been operationalized by the case-law of the EU courts, this particularly relates to procedural requirements – in regulatory contexts other than REACH. A 2017 review on the precautionary principle in EU environmental policies found many manifestations of the precautionary principle alongside different legal frameworks. It follows that there are no clear criteria, but the normative content of the precautionary principle can be flexibly adapted to the particular regulatory context.[57]

Against this background, there is no legal basis prescribing that any risk situation under REACH must not be interpreted in the light of the precautionary principle. Political impetus, on the other hand, can significantly affect the practical relevance of the precautionary principle in the implementation of REACH.

The CSS answers to Conclusions by the Council explicitly highlighting the precautionary principle:[58]

"UNDERLINES the need to improve and mainstream the chemical risk assessment and management of chemicals across EU legislation in order to avoid unnecessary burden and to increase the coherence and effectiveness of the EU chemicals-related legislation to achieve a high level of protection for human health and the environment, especially with respect to the precautionary principle and to the effective protection of workers; SUPPORTS the development and implementation of an early warning system at EU level for identifying new, emerging chemical risks that allows to undertake appropriate actions to protect human health and environment and to implement measures to prevent or control issues of concern."

The CSS also answers to a Resolution by the European Parliament stressing[59]

"that the Strategy should fully reflect the precautionary principle and the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay, as well as cornerstone principles of the European chemicals legislation such as the placing of the burden of proof on manufacturers, importers and downstream users, and that it should effectively apply those principles.

The CSS literally refers to prevention instead of precaution; however, its subject matter and methodological approach as well as the legal and policy context make it indisputable that the strategy – in line with Art. 11 TFEU – aims at "integrating" the precautionary principle "into the definition and implementation of the Union's policies and activities".

2.6 Conclusion

REACH provides a general legal duty for industry to take into account emerging risk when assessing and managing risks. Besides, REACH stipulates a general mandate for authorities to tackle emerging risk. Considering the behavioural factors outlined in section 1.3, the general

[56] Schmolke (2014), 83; Rehbinder (2008), Art. 1, para. 32; Rehbinder (2012b), para. 24; Nettesheim (2011), Art. 191 AEUV, para. 89; similarly Appel (2003), 167 (168).

[57] Milieu (2017).

[58] Council of the European Union (2019).

[59] European Parliament resolution of 10 July 2020 on the Chemicals Strategy for Sustainability (2020/2531(RSP)), P9_TA(2020)0201, para. 14.

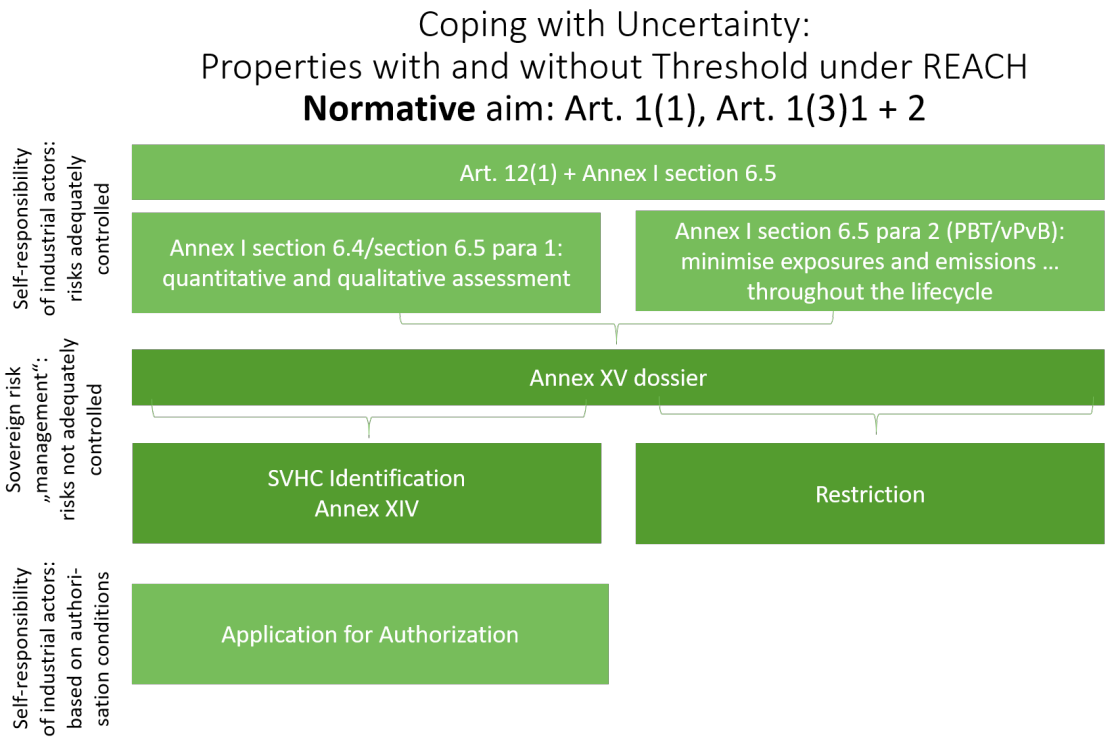
coverage of emerging risk under REACH is one aspect relevant in terms of the *willingness* of actors to avoid and mitigate such risks. The strength of the motivational impulses remains to be seen, though. Besides, the question arises whether REACH provides the necessary *opportunities* in the form of legal instruments. The next section therefore looks at the operationalisation and implementation of emerging risk in the REACH regulatory mechanisms.

3 Operationalisation and implementation of emerging risk

The risk characterisation pursuant to Annex I Section 6 introduces two categories of properties, namely those for which it is possible to derive an effect threshold and where this is not the case. This "logic" embedded in Annex I is relevant for the entire risk management system established by REACH. It provides the benchmark for industrial actors to "adequately control" the substance related risk as stipulated by Art. 14(6) and Art. 37(5). Evidence of compliance with this obligation shall be provided in the registration dossier. Uses for which the registrant cannot provide an exposure scenario that is in line with Annex I shall not be part of the scope of registration. Consequently, for those uses the market barrier of Art. 5 (no data, no market) applies. These requirements operationalise self-responsibility as the underlying regulative approach of REACH.[60]

The REACH mechanisms, however, are not built solely on this approach. As a "safety net", authorities may additionally install risk "management" measures in cases where they come to the conclusion that industry`s activities to control risks are insufficient. Authorities may then impose restrictions.[61] A different set of legislative measures apply to "substances of very high concern" (Art. 57), i.e. "substances (…) for which there is scientific evidence of probable serious effects to human health or the environment". Both sovereign mechanisms build upon the same "logic" embedded in Annex I (see Figure 2). The common denominator of all aforementioned measures addressing the risks related to chemical substances can be seen in the fact that they have to cope with different levels of uncertainties.

Figure 2: Coping with uncertainty – properties with and without threshold under REACH



Source: own illustration, sofia

[60] Most prominently formulated in Art. 1(3)1 REACH and further reinforced by recitals 16, 18, 25, 29, 56, 58 ('chain of responsibilities'), 86, 105. See also Führ and Schenten (2020), 344 (348 et subs.).

[61] Recital 86 of REACH.

Against this background, this chapter assesses to what extent the REACH regulatory mechanisms registration (section 3.1), authorisation (3.2) and restriction (3.3) operationalise the concept of emerging risk and whether the actors are implementing this concept by actually addressing emerging risk as part of their respective management measures. These

3.1 Registration

Section **Fehler! Verweisquelle konnte nicht gefunden werden.** shows that REACH, according to Art. 12(1) and the introductions to Annexes VII to X, requires registrants to take into account "all available information" when determining a substance's properties. Besides, in the context of the CSA, Section 0.10 of Annex I clarifies that the scope of assessment is not limited by the endpoints specified in the standard IR under REACH, but other effects can be relevant as well. These provisions seek to stimulate self-responsibility of industry when thoroughly compiling the registration dossier. Considering that the REACH provisions "are underpinned by the precautionary principle", this framework could motivate registrants to ensure full coverage of emerging risk.

Hence, theoretically, the dossier should address all risks arising from manufacture and use of chemicals. In practice, however, this outcome appears unrealistic. In this respect, one has to take into account that there is no clear obligation for registrants in this respect. Consequently, in terms of dossier evaluation efforts by ECHA, it is highly unlikely that deficits regarding emerging risk are detected. The question arises whether de lege lata REACH creates incentives for industry to undertake risk management above the obligatory (minimum) level. In this respect, one has to take note of the considerable rate of non-compliance with REACH, which put pressure on ECHA and on industry to improve measures aimed at ensuring compliance[62] and, to this end, also induced legislative changes to the legal framework (more precise dossier update requirements, higher compliance check target).[63] It is therefore fair to assume that large parts of industry usually tend to comply only with the indispensable minimum requirements.[64] There are three main reasons for this. First, the testing capacities to identify the entire range of (potentially) adverse properties of a chemical or a mixture are limited. Secondly, the incentive situation of registrants leads to them not fully identifying all negative properties respectively overestimating the effectiveness of risk mitigation measures. Thirdly, the competent authorities have limited resources to close the gap created by the first two reasons.

Against this background, to assure that industry provides meaningful data on emerging issues and controls associated risks adequately, the European Commission does not rely on the general provision of Art. 12(1) of REACH but intents to amend the REACH information requirements "to enable an effective identification of substances with critical hazard properties, including effects on the nervous and the immune systems".[65]

In conclusion, for the time being the incentives for industrial actors to further investigate into emerging risks are quite limited. On the contrary, it is still advantageous to abstain from such efforts. In order to motivate registrants to proactively tackle emerging risk, the legal framework needs to be advanced. To this end, chapter 4 develops policy options.

[62] ECHA and European Commission (2019).

[63] See the overview at Führ et al. (2020a).

[64] In this respect, see already Führ et al. (2006).

[65] COM(2020) 667, 20.

3.2 Authorisation

Section 2.4 establishes that substances in the realms of emerging risk with effects reflecting a higher degree of uncertainty can meet the criteria according to Article 57 of REACH on the identification of SVHCs. Any of these substances may eventually be added to Annex XIV, which triggers the duty to apply for authorisation. As an example, Musk xylene is a substance listed in Annex XIV (entry no 1) due to its vPvB properties[66], for which the sunset date expired. Consequently, it is not possible anymore to legally place this substance on the market or use it, subject to the exemptions listed in Article 56 of REACH. Moreover, entries 42 and 43 comprise groups of substances considered EDCs for the environment.[67] These examples show the authorisation regime operationalises emerging risk.

In addition, Art. 55 stipulates as one "aim of this Title" on authorisations that SVHCs "are progressively replaced". This commitment was "fundamental"[68] for the development of a SVHC Roadmap that ever since its launch in 2013 steers the EUs activities to phase out SVHCs.[69] The legal framework therefore creates incentives to implement the rules on SVHCs, also as regards emerging risk substances.

The question to what extent the authorisation regime needs improvement in terms of ensuring a high level of protection is not in the scope of the report.[70] Yet, the brief overview shows that in general it provides the *opportunities* for public authority actors to tackle emerging risk and that it at least to some extent manages to create the required *willingness*. At the same time, only few MSCA appear to be in the position to develop Annex XV dossiers.[71]

3.3 Restriction

Art. 68(1) allows to introduce 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. Pursuant to Annex XV Section II.3 "[t]he risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I".[72]

Art. 68(2) introduces a so-called "fast track" procedure to restrict CMRs (category 1A or 1B) that "could be used by consumers".[73] The CSS commits to expand the scope of Art. 68 (2) to additional substance groups (endocrine disruptors, PBT/vPvB substances, immunotoxicants,

[66] You can find the ECHA authorization list here.

[67] You can find entry 42 of the ECHA authorization list here and entry 43 here.

[68] See Council of the European Union (2013), 5: "In defining the Roadmap, it is fundamental to remind that the aim of the authorisation process, as stated in Article 55 of REACH, is 'to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable'.".

[69] See ECHA (2021d).

[70] Wirth et al. (2021).

[71] By the end of May 2021, only 13 States (of EU-27, Norway and United Kingdom) have ever issued an Annex XV proposal for SVHC identification; only 8 of them did this at least 5 times.

[72] The dossier can also provide a comprehensive impact assessment of the restriction measure, especially if the dossier submitter choses to conduct a socio-economic assessment, which is not mandatory.

[73] This generic approach can be deemed a reflection of the precautionary principle, see Annex A; cf. on the relevance for substances in articles Führ et al. (2020b), 69.

neurotoxicants, respiratory sensitisers and substances that affect specific organs) and to add professional users as protection target.[74] Additional options that the European Commission looks into include "operationalising the concept of essential use in restrictions".[75]

MS experts perceive, due to information requirements by RAC and SEAC, the restriction procedure as more burdensome compared to the pre-REACH situation.[76] In fact, only few MSCA appear to be in the position to develop Annex XV dossiers. As of April 2021, only nine MS have ever notified an intention to (sometimes cooperatively) prepare a restriction dossier, with only six of them doing so more than three times.[77] In this context it is, however, also relevant to note that, unlike Title VII on the authorisation mechanism, Title VIII on restrictions does not formulate particular normative objectives[78] that could drive *willingness*.

Following the analysis of the 2nd REACH Review published in 2018,[79] the Commission identified the need to "(f)rame the application of the precautionary principle" in the context of restriction.[80] Meanwhile, new sections on uncertainty have been added to the templates for the Annex XV restriction report and the Committees' Opinion, in order to enhance transparency on preventive action.[81] These templates are administrative guidelines without direct legal effect. Besides, section 2.4 of this report concludes that restriction proposals may address emerging risk, as seen in the case of the substance D5 with vPvB properties. This derives from the precautionary principle underpinning the provisions of REACH. Consequently, it is possible to enact restrictions addressing emerging risk. However, the legal framework does not frame the specific conditions and criteria under which a restriction dossier may address emerging risk. In the words of the General Court, the Annex XV dossier needs to provide a "sufficiently reliable and cogent information" basis for the Commission to decide on a "as thorough a scientific evaluation of the risks as possible, account being taken of the particular circumstances of the case at issue".[82] Because REACH does not provide legal criteria what this means in practice, submitters put a lot of effort into the scientific reasoning of dossiers addressing emerging risks of chemical substances.

Authorities used to be reluctant to impose restrictions based on a precautionary approach. In the recent past, however, there are signs of change: according to MS experts, the pending restriction initiatives on Undecafluorohexanoic acid (PFHxA), its salts and related substances, and on intentionally added microplastics are addressing emerging risk control in the context of Title VIII REACH. According to the Annex XV dossier on PFHxA, what is known with some certainty is that PFHxA is "extremely" persistent – exceeding the Annex XIII p and vP criteria[83] –, mobile and linked to long-range transport potential[84] and that, while PFHxA does not occur naturally, it is already ubiquitously present[85] in the environment. Once PFHxA is released, it will

[74] COM(2020) 667 final, ANNEX, 2; Ares (2021)2962933, 3.

[75] Ares (2021)2962933.

[76] Kemi (2015), 26.

[77] See the list here (05.05.2021).

[78] Neither do the Recitals provide normative orientation guiding the implementation of Title VIII. One possible explanation for this omission is that the legislators, mindful of the existence of restrictions in the legislation preceding REACH, were of the impression that the objective of this mechanism could be expected to be known in general.

[79] SWD(2018) 58 fin, PART 5/7, 111; SWD(2018) 58 fin, PART 1/7, 44.

[80] See "Action 10" at COM(2018) 116 fin, 8; SWD(2018) 58 fin, PART 1/7, 44.

[81] Based on the work of the Task Force on Restriction Efficiency, see ECHA (2020b), 28.

[82] Judgment of the General Court of 14 November 2013 in ICdA and Others v Commission, T-456/11, ECLI:EU:T:2013:594, para. 52.

[83] ECHA (2019b), 31.

[84] ECHA (2019b), 32.

[85] ECHA (2019b), 41 e.g. contamination of soil in Rastatt, Germany and uptake of PFHxA in plants.

thus remain in the environment for decades to centuries because of the extreme persistence.[86] Beyond that, the dossier refers to some major uncertainties when assessing hazards, bioaccumulation and exposure in the context of the determination of risk. The dossier establishes PFHxA risks and calls for preventive action on the basis that "the extreme persistence, the mobility and the long-range transport potential of PFHxA as well as the difficulty to remove PFHxA lead to unpredictable and irreversible adverse effects on the environment and human health over time".[87] Therefore, the dossier continues that "PFHxA should be treated as a non-threshold substance for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment and environmental monitoring data regarded as a proxy for an unacceptable risk.[88]

Similarly, in the "microplastics" restriction dossier ECHA finds "extreme persistence" and ubiquitous emissions which make continuous accumulated exposure probable.[89] Whereas due to lack of data a specific risk cannot be established, any potential negative effects will most likely be irreversible.[90]

The outcome of these restriction procedures is open. As for PFHxA, notwithstanding the acknowledgement of substances with PMT properties in the context of Article 57(f) (see section 2.4) and by the CSS, the dossier submitters, due to lack of legal criteria, cannot be sure that the dossier will eventually lead to restriction. Clearer criteria could help overcome deficits in the legal framework (and thus enhance the *opportunities*) by enhancing predictability of the process for all concerned parties and by specifying and thus reducing the resource inputs required by dossier submitters. Reducing these impediments could at the same time increase the *willingness* of MSCA to develop Annex XV dossiers, e.g. to address emerging risk of substances with severe effects that are more controversial than PMT. Providing clearer criteria as regards restrictions of emerging risks is therefore amongst the policy options discussed in chapter 4.

[86] ECHA (2019b), 24.

[87] ECHA (2019b), 32.

[88] ECHA (2019b), 40.

[89] ECHA (2019a).

[90] ECHA (2019a), 13, 129 et subs.

4 Policy options

By its very nature, the regulation of chemicals is confronted with uncertainties. This, however, does not mean that regulatory measures are not permitted. On the contrary, in line with principle 15 of the Rio Declaration[91], "lack of full scientific certainty" does not hinder risk management measures. This holds true also for emerging risks, a sub-category to the so-called 'known unknowns', i.e. situations we are aware of but do not fully understand (e.g. air pollution, land degradation and biodiversity loss).[92]

Whereas the concept of emerging risk already falls into the scope of REACH de lege lata (chapter 2), it is not fully operationalised within the regulatory contexts of registration and restriction, and therefore lacks implementation (chapter 3). Consequently, there is a need to consider policy options aimed at strengthening emerging risk response in REACH. Any such option needs to take into account that risk control is not a self-executing process. Rather, it depends on the level of action and inaction by actors in authorities and industry, underpinned by scientific findings. This has to be reflected in the design of the institutional context based on a "responsive regulation" approach;[93] i.e. the regulatory mechanisms with their substantive requirements and their translation into procedural elements should be adjusted to those factors that are most relevant for the intended contributions of the core risk control actors. In this view, the three behavioural factors *willingness*, *capacities* and *opportunities* are key (section 1.3).

Capacities of actors are mostly determined by their individual scientific and administrative skills and the resources provided by the organisations in which they operate. Consequently, advancements of REACH could not have a direct impact on *capacities*. In contrast, REACH determines the framework conditions and hence the *opportunities* in the field of regulatory risk control. Besides, REACH can have a rather strong effect on actors' *willingness*, both by creating conditions allowing for smooth work flows and by creating incentives in the form of normative goals. The policy options therefore should address the current lack of *willingness* and *opportunities*. Advancements as regards these factors could, in addition, create impetus for a change of *capacities,* e.g. when organisations adapt their allocation of resources corresponding to changes in the legislation. Furthermore, and from a scientific researcher's perspective, the likelihood that the research results lead to regulatory impact might stimulate their research efforts on emerging risks.[94]

Against this background, section 4.1 develops policy options aimed at strengthening control of emerging risk in REACH. Section 4.2 provides a preliminary evaluation of these options.

In addition, complementary measures providing incentives for companies to design substances that are inherently safe (benign-by-design) could underpin the policy options. These measures are not in the scope of the report. In this respect, the CSS comprises a series of helpful commitments, addressing improved information requirements for registrants under REACH (low tonnage substances, EDC),[95] more cooperation by Agencies undertaking chemical

[91]United Nations (1992a): "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

[92] See section 1.2.

[93] Ayres and Braithwaite (1992).

[94] Agerstrand et al., (2017).

[95] COM(2020) 667, 11, 20.

assessments[96] and leverage the Science-Policy-Interface[97]. It is furthermore crucial to acknowledge the full picture of chemical transition, which cannot be achieved by imperative law in isolation. For instance, REACH does not directly stipulate specific provisions addressing the early design phase of substances. Suggestions have thus been formulated to ensure normative orientation during substance design.[98] Additional policy options aim at facilitating "sustainable chemistry" in REACH.[99]

4.1 Strengthening control of emerging risk in REACH

To strengthen industries' and policy-makers' motivation and framework conditions to tackle emerging risk, several options are conceivable (Table 4).

Table 4: Overview of policy options

Policy option	Regulatory scheme(s) effected	See Section
Art. 67: Add goals to restriction	Restriction	4.1.1
Art. 3: Add definitions of risk and uncertainty	Registration (and Evaluation), Authorisation, Restriction	4.1.2
Annex I, 6.0: Clarify scope for emerging risk in general	Registration (and Evaluation), Authorisation, Restriction	4.1.3.1
Annex I, 6.5: Clarify scope for minimisation of emissions and exposure	Registration (and Evaluation), Authorisation	4.1.3.2
Annex I: Operationalisation of emerging risk in registration	Registration (and Evaluation)	4.1.4
Annex XV: Added tools	Restriction	4.1.5

4.1.1 Legislative provision defining the aim of the restriction scheme

The REACH Title VIII does not include an Article defining the programmatic goal to the restriction scheme (section 3.3). Such a goal, however, would provide specific normative orientation besides the general aims of the Regulation laid down in Art. 1.

Such a provision would underpin the legislator´s intention and thus guide the application of the Title as well as the interpretation by the European Courts. Thus, it could create impetus on the part of authorities to take efforts, creating verifiable milestones etc. to pursue these goals.

4.1.1.1 Art. 55 as a model

There are examples for the driving effects of normative objectives. For instance, Art. 55 could serve as a model (section 3.2). Adding a programmatic goal to the restriction scheme is therefore one policy option. Aligning the restriction regime with the goal of Art. 55 could be one coherent option, which would moreover acknowledge the various interlinks between authorisation and restriction.[100] While it would still be possible to impose restrictions regarding basically "all

[96] COM(2020) 667, 14 subs.

[97] COM(2020) 667, 21.

[98] Führ et al. (2019), 34, 86.

[99] Bunke et al. (2020).

[100] See. e.g., Art. 69(2).

substances falling within the scope of this Regulation",[101] this goal would focus activities on substances that meet the criteria laid out in Art. 57 of REACH. This would entail the precaution oriented SVHC categories PBT, vPvB as well as "equivalent concern" substances, including those with PMT or endocrine disruptive properties. Such policy option could therefore create impetus to tackle emerging risk. The introduction of additional categories to Art. 57[102] as envisaged by the CSS[103] would create additional impulses.

4.1.1.2 Scope of application

Title VIII addresses "Certain dangerous substances, mixtures and articles". The wording itself does not define which types of substances are covered. Implicitly, however, the scope of application is defined in Art. 67(1) by opening the restriction scheme under the condition that an "unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances" has been identified.

4.1.1.3 Aim of restriction and considerations for substitution

Following the example of Art. 55 with its heading "Aim of authorisation and considerations for substitution" a new Art. 66(a) might be inserted under the headline "Aim of restriction and considerations for substitution". A possible wording, along the lines of Art. 55, might include the following elements.

It could stipulate that the aim of this Title (on restrictions) is to ensure the good functioning of the internal market while assuring that unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances is adequately controlled. The provision could proceed that to this end the Commission and the Member States competent authorities shall systematically analyse the impact of all substance with the properties referred to in Art. 14(4) and Art. 57(f). Compared to Title VII on authorisations this would constitute a wider substantive scope. Besides, the provision could stipulate that authorities shall propose proportionate restriction measures whereas the fact should be considered that the "sunset effect" of a restriction gives room for market dynamics developing solutions for the function that the substance has had fulfilled so far. In contrast to the wording of Article 55 (…"that these substances are progressively replaced"…), this formulation does not only highlight replacement but is open to a wider understanding of innovation. In an economic perspective the expectation that "problematic substances" are gradually deprived of their market access in a mid- and long-term perspective triggers research and development measures of all actors involved.[104] Furthermore, with a view to incentivizing control of emerging risks, the provision could explicitly refer to the precautionary principle.

4.1.2 Definitions on risk and uncertainty

The legal text might also be amended by introducing stand-alone definition(s) on the concepts of risk and immanent uncertainties. Art. 3 on "Definitions" could be the appropriate place in the legal text. This however raises the question why the legislators did not add to Art. 3 a definition of risk in the first place (section 2.1). One reasonable explanation for this could be that the legislators wished to maintain a certain degree of flexibility regarding the interpretation of risk

[101] Recital 75 of REACH.

[102] Endocrine disruptors, persistent, mobile and toxic and very persistent and very mobile substances.

[103] COM(2020) 667 final, 13. The inception impact assessment based on the CSS does however not mention this option, see Ares(2021)2962933.

[104] Harvard Economist Michael Porter has argued that – contrary to widespread assumption – stricter regulation on a national level leads to a competitive advantage for those companies that fall under the jurisdiction, see Porter (1998).

in the different REACH mechanisms. This omission can thus be deemed a significant feature of the overall regulatory design of REACH. From this perspective, adding definitions to Art. 3 would at least depart from the initial intentions of the legislators. Considering the complexity of risk situations,[105] a legal definition would be a real challenge in terms of "added value" to the motivation of the relevant actors. Thus, this option does not appear advisable.

4.1.3 Clarify coverage of emerging risk in Annex I

As outlined in chapter 2 (sections 2.2 et subs.), the provisions in Annex I provide very limited guidance and even fewer incentives for registrants to invest in measures addressing emerging risks, and potentially hampers authorities in tackling these risks. Against this backdrop, explicitly introducing the significance of emerging risk in Annex I could clarify the already existing legal mandate to invoke preventive risk control actions, thereby reinforcing incentives – and reducing impediments – of actors to take account of such risks. From the perspective of the conceptual design of REACH, such an enhancement of Annex I would directly link to where risk is "defined" in the status quo.

When further developing Annex I, the aim is to qualitatively describe emerging risk and thereby adding it explicitly to the scope of CSA, preferably by using an approach that appears widely accepted and by using language already familiar in the REACH legal text. Since REACH does not differentiate categories of risks, any reference to emerging risk should remain general to allow for some flexibility and at the same time provide the achievable maximum of precision so there is legal clarity and thus a more robust duty for registrations and mandate for authorities. This could entail the addition of a Section 6.0 to Annex I (section 4.1.3.1). Besides, in the light of this newly added section aiming to induce enhanced risk control by industry, modifications of Annex I Section 6.5 appear advisable as well (4.1.3.2).

4.1.3.1 New Section 6.0

With regard to the evaluation of risk, an introductory section to the chapter "risk characterisation" in Annex I would automatically adjust not only the scope of risk analysis in the registration dossier but furthermore the focus of the assessment frameworks for RAC and SEAC.

A formulation used by the 2001 White Paper "Strategy for a future Chemicals Policy"[106] appears to provide all necessary elements to determine emerging risk. The White Paper created the initial impulse setting off the legislative procedure that eventually led to the adoption of REACH. It entails the following formulation in the context of the precautionary principle that the Paper deems "fundamental" to "ensure a high level of protection of human health and the environment":[107]

*"Whenever **reliable** scientific evidence is available that a substance may have an adverse **impact** on human health and the environment but there is still scientific uncertainty about the precise **nature** or the magnitude of the **potential damage [...]**."*[108]

This wording provides an appropriate basis for defining emerging risk in REACH. Some adaptations should be considered, though, to better align it with the legal text and architecture of REACH and thereby ensure coherence. The terms "impact" and "potential damage" should be

[105] For a systemic description of different levels of uncertainties, based on the wording laid down in ISO 31.000, see Führ (2014) with the figure in para 65.

[106] COM(2001) 88. See also Winter (2000a) and the contributions in Winter (2000b).

[107] COM(2001) 88, 5.

[108] COM(2001) 88, 5 (emphasis added).

replaced by the expression "adverse effect"[109] that conveys a very similar meaning and is more familiar in REACH, for instance in Section 0.3 of Annex I ("potential adverse effects").[110] In conjunction with the predicate "may have" ("a substance may have an adverse effect")"), it is clear that the provision covers potential adverse effects as well. The term "nature" lacks precision. In order to operationalise relevant uncertainty referring e.g. to the more specific *mechanisms* (of the adverse effect) appears more appropriate. This concept is subject to the CLP Regulation (e.g. Annexes I and III) and is also referred to by Annex XI REACH.

In addition, the phrase "reliable scientific evidence" is not used in REACH.[111] One can refer to Art. 57(f) bearing some structural similarity in that it opens the SVHC status for substances of "equivalent concern", including hazards or effects not yet defined by specified criteria. This provision refers to substances "for which there is scientific evidence of probable serious effects". The reliability of such evidence is thus assumed. Both Art. 57(f) and the policy option discussed in this section have in common that they rely on scientific evidence; the difference is that the policy option more broadly covers scientific uncertainty over the adverse effect while Art. 57 is reserved for substances of very high concern. Scientific uncertainty over the adverse effect, however, relates to another criterion of the policy option and not to the availability of scientific evidence. Linking preventive measures to scientific evidence would exclude a "purely hypothetical approach to risk, founded on mere suppositions which are not yet scientifically verified", as the CJEU demands.[112] It appears therefore to be justified to omit the word "reliable". Another argument in favour of that omission is that Annex XI on adaptations of the standard testing regime – which bears some meaning in the context of emerging risk (section 2.3) – also provides general rules on scientific rigor thus ensuring quality standards. ECHA Guidance provides additional – limited – orientation to assess reliability.[113]

Based on these considerations, the following modified version of the White Paper text appears appropriate. It describes the scope of emerging risk and related uncertainties (as defined in section 1.2) rather than defining (limits of) the term conclusively:

Modified version of the White Paper text describing the scope of emerging risk

Risk can also be determined in relation to situations where scientific evidence is available that a substance may have an adverse effect on human health and the environment, but there is still scientific uncertainty over the precise mechanisms or the magnitude of this effect.

In addition, with a view to increasing legal clarity, the legal text should provide guidance as to the type of evidence that might be taken into account. In this respect, one option is to use wording from the amended Annex XIII stipulating criteria for the identification of PBT and vPvB substances:

[109] There is no legally binding definition for the expression "adverse effect". ECHA defines it on its website in the context of REACH and CLP as follows: "Change in morphology, physiology, growth, development or lifespan of an organism, which results in impairment of its functional capacity or impairment of its capacity to compensate for additional stress or increased susceptibility to the harmful effects of other environmental influences".

[110] See also Recital 4 (with a reference to the "Johannesburg goal" adopted 2002 at the World Summit on Sustainable Development), Recital 17 (outlining the implications of the principle of self-responsibility laid down in Recital 16) and Recital 70 (with reference to SVHCs highlighting the need to "minimising the likelihood of adverse effects" for substances with properties without an effect threshold).

[111] Art. 138(2) and Recital 41 refer to „sound technical and valid scientific criteria" with a view to regulating polymers; Art. 40(2) and Recital 64 refer to "scientifically valid information" to be captured via public consultations. Both phrases however appear context-specific and therefore do not provide guidance for emerging risk.

[112] CJEU, case C-236/01, para. 106, 113; EGC, case T-13/99, para. 144; EGC, case T-257/07, para. 75; cf. Annex B.

[113] Cf. ECHA (2011), 3.

Guidance as to the type of evidence

This shall be based on all available information such as the results of monitoring and modelling, suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well-documented case reports and observations.

Precisely, these two paragraphs could be inserted as new Section 6.0 of Annex I, providing orientation for the subsequent provisions in this section. This would clarify the mandate of authorities to impose restrictions based on emerging risk. Besides, it would clarify the duties of industry to manage emerging risk.

4.1.3.2 Extend Section 6.5

To warrant effective emerging risk management by industry, one could introduce an additional policy option extending the duty to minimise exposures and emissions pursuant to Section 6.5 of Annex I. Risks identified pursuant to the suggested Section 6.0 are linked with a higher degree of uncertainty with regards to the potential adverse effect on human health and the environment. From the perspective of the legislator, it is not possible to tell in advance whether for (emerging) hazards in the particular risk characterisation situation a 'safe' dose for humans and a 'safe' concentration in the environment can be established. This could be due to a lack of methods that are sufficiently reliable when performing the characterisation; "adequate control" of risks can thus not be established.

Similarly, REACH assumes that for substances satisfying the PBT and vPvB criteria adequate risk control cannot be established. Section 6.5 of Annex I therefore requires industry to minimise exposures and emissions to humans and the environment throughout the lifecycle of these substances (see section 2.4).[114] An extended Section 6.5 could generically address situations where it is not possible to reliably derive a DNEL or PNEC due to uncertainties of emerging risk. It could stipulate that, in addition to complying with any provisional PNEC or DNEL, industry is required to minimise exposures and emissions to humans and the environment. The following wording could be considered for this.

Possible wording for an extended Section 6.5

When for a particular substance there is scientific uncertainty over the precise mechanism or the magnitude of the adverse effect on human health and the environment, the manufacturer or importer shall comply with any provisional PNEC or DNEL. In addition, it shall implement on its site, and recommend for downstream users, risk management measures which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses.

Substances with endocrine disruptive properties, for instance, could fall into the scope of this provision. It could be added as the last subparagraph to Section 6.5 of Annex I.

4.1.3.3 Impact on the authorisation scheme

This section assesses the potential effects of the policy options discussed in the two previous sections on the conditions laid down in Annex XIV, the AfA and the evaluation of AfA by RAC and

[114] See also Articles 60(3) and 60(4) of REACH in the context of authorisation provisions. Authorisation for the use of a PBT or vPvB substance cannot be granted under Art. 60(2) because the risk cannot be adequately controlled in accordance with Section 6.4 of Annex I to REACH.

SEAC. Before that, in direct comparison to the potential impact on the restriction scheme, a systemic argument has to be taken into account.

Implementing the policy option would, to some extent, lower the burden to justify preventive restriction measures. In contrast, this would not be the case for the authorisation regime. The Art. 57 criteria for SVHCs are the entry point for the authorisation scheme. Changes to Section 6 on risk characterisation of Annex I would not affect these criteria.[115] This appears justified since the category of "substances of very high concern" should under no circumstances be diluted. As has been shown in section 2.4, the SVHC categories also cover effects linked to a higher degree of uncertainty which can be deemed falling into the scope of emerging risk. Yet, the restriction scheme by referring to risk that is "unacceptable" but without providing any further guidance as to the interpretation of that term, provides more flexibility to reflect the socio-political context.[116]

The policy option of a new Section 6.0 could provide normative orientation to use the restriction mechanism to address the risk situation and insofar do not include the uses covered by the restriction into Annex XIV. This follows from Art. 58(2), which allows stipulating exemptions in cases where due to legislation other than REACH "the risk is properly controlled". The practical relevance of this nexus is, however, very minor in nature since Art. 58(2) exemptions are very rare,[117] even without the possibility to consider emerging risk.

There are two routes available for granting authorisation. According to Art. 60(2), an authorisation shall be granted if the risk arising from the Annex XIV SVHC is adequately controlled in accordance with Section 6.4 of Annex I. Besides, for non-threshold substances an authorisation may only be granted if it is shown pursuant to Art. 60(4) that socio-economic benefits outweigh the risk. The adequate control route will most likely not be available to emerging risks, because the lack of quantifiable relations between a substance's properties and its human and environmental impact is usually one major element of emerging risk. The impact of the policy option on Art. 60(2) therefore appears negligible. In the context of the Art. 60(4) assessment, comprising a more qualitative weighing of risks and benefits, arguments based on emerging risk might provide additional grounds in favour of not granting the application.

4.1.4 Operationalise emerging risk in the registration

The overview in section 3.1 concludes that, for the time being, the incentives for industrial actors to further investigate into emerging risks are quite limited. The policy option outlined in section 4.1.3, in conjunction with the existing duty to take into account uncertainties i.e. "all available data" (cf. section **Fehler! Verweisquelle konnte nicht gefunden werden.**), could encourage industry to self-responsibly address such risks.

According to Art. 14(1), registrants of substances in quantities of 10 tonnes or more per year have to submit a CSR documenting CSA conducted in accordance with Annex I. Consequently, both policy options on Section 6.0 and on Section 6.5 of Annex I guide the registrants' risk assessment in situations characterized by a higher degree of uncertaintyThe policy option of Section 6.0 would increase the registrant's awareness of emerging risk. In addition, Section 6.5 would introduce a clearer obligation on how to adequately control these risks, i.e. by minimising emission.

[115] Note that Annex XV Section 2 provides a template dossier for the identification of SVHCs which as regards the justification recurs to hazard-related Sections 1 to 4 of Annex I.

[116] Cf. Wirth et al. (2018) for a comparison of advantages and disadvantages of the authorisation and restriction schemes.

[117] Of the 54 entries on Annex XIV only in three cases use exemptions are granted, see the ECHA authorization list here.

In addition, to reinforce the outlined incentives, a section could be added to Annex I, stipulating a clearer obligation to take into account emerging risk while conducting the CSA and afterwards. This could take the form of a procedural requirement to specify in which databases a search was conducted, when and with which search terms. To this end, IUCLID should be enhanced to add those data in a structured manner.

Any identified indication of emerging risk would then be subject to the update requirement according to Art. 22. The WikiREACH concept suggested in literature,[118] which entails IT tools and incentivising mechanisms to make better use of scientific findings from (academic) research for the REACH system, and which is reflected by the CSS as "a common open data platform on chemicals to facilitate the sharing, access and re-use of information on chemicals coming from all sources",[119] could be a relevant source for information.

Obviously, the policy option would also affect the Agency's activities in Dossier Evaluation and in the recently Enhanced (manual) Completeness Check since the Agency may evaluate whether the registrant has undertaken the appropriate measures targeting emerging risk. The "open data platform" could also facilitate compliance activities targeted at emerging risk. Furthermore, additional guidance would be needed for registrants and for the Agency to enhance legal clarity when implementing this new provision.[120]

At the same time, the registrants are given an opportunity to act proactively and thereby differentiate themselves from their competitors.

4.1.5 Add tools to Annex XV

Clarifying that emerging risk falls into the scope of Annex I could already contribute to the *willingness* of actors in authorities to tackle these risks. Besides, Annex XV operationalises the risk assessment by the authority preparing the restriction proposal. Additional options could therefore aim to introduce new instruments to Annex XV addressing emerging risk, thereby enhancing the *opportunities* of public authority actors.

Annex XV Section II.3 lays down general principles for preparing a dossier to propose and justify restrictions. Such a dossier comprises the following elements:

1. Proposal
2. Information on hazard and risk
3. Information on alternatives
4. Justification for Restrictions at Community Level
5. Socio-economic assessment
6. Information on stakeholder consultation

The 2nd element creates the link to Annex I by stipulating that "risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I". The policy option described in section 4.1.3 clarifies the mandate in Section 6.5 of Annex I; consequently, it guides the path to addressing emerging risk with the restriction proposal.

In the context of Annex XV, moreover, this could be underpinned by additional measures. To increase legal clarity for the dossier submitter this mandate could be operationalized.

[118] Agerstrand et al. (2017); see also Führ et al. (2020a), 34.

[119] COM(2020) 667 final, 18; see also COM(2020) 667 final, ANNEX, 4: "Establishment of an open platform on chemical safety data and tools for accessing relevant academic data".

[120] E.g., ECHA (2012), 8 should be revised since more differentiated wording is required as to when "uncertainty analysis […] will be a matter of judgement for the [CSR] author(s)".

Furthermore, preventive measures might need to derogate to some limited extent from the standard procedures outlined in elements 2 to 6 of Annex XV. All these legal effects could be achieved by adding further elements in Annex XV Section II.3. The following paragraphs outline the changes deemed necessary to that effect:

a) The new element(s) could be introduced by a general clause providing the overall context, along the following lines:

Introduction of the new element(s)

For proposals targeting a risk situation where scientific evidence is available that a substance may have an adverse effect on human health and the environment, but there is still scientific uncertainty over the precise mechanism or the magnitude of this effect, the following additional requirements apply.

By referring to "additional" requirements, the clause would clarify that the existing Annex XV provisions apply, in general, to emerging risk situations as well.

b) As is current practice, the submitter of an Annex XV dossier would have to identify and explain any uncertainties in the dossier. In addition, in order to trigger derogations, where appropriate, and to trigger a focused evaluation by the ECHA Committees (section 4.1.6), the dossier submitter would need to state if the proposed restriction aims to be preventive in nature, e.g.:

Obligation to state whether the proposed restriction aims to be preventive in nature

The proposal shall state whether it aims at taking preventive action.

Corresponding to that, adding a tick box with the option for additional explanations to the Annex XV dossier template could be an easy implementation solution.

c) With a view to increasing legal clarity, specific criteria could be provided clarifying the uncertainties covered by this provision. This could be done by providing examples based, for instance, on the experience gathered in pending restriction procedures (section 3.3). This would create legal certainty in structurally related future restriction initiatives. At the same time, the wording must not limit the scope with a view to any other future uncertainty criterion one is not aware of today, e.g.:

Examples for uncertainties covered by the provision

Preventive action may be justified if, for instance, scientific evidence is available that a substance is very persistent in accordance with the criteria set out in Annex XIII and that any adverse effect on human health and the environment is most likely not reversible, irrespective of the scientific uncertainty over the precise nature or the magnitude of this effect.

In addition, the suggested Annex I amendment lists potential data sources to establish emerging risk. It would also be possible to adapt this provision in accordance with scientific progress. One could, for instance, consider a review clause requiring the Commission to analyse every 5 years whether this provision reflects the current state of science as regards substance properties linked to emerging risk. Such a clause could link to the existing reporting obligations pursuant to Art. 117(4) of REACH.

d) Administrative guidelines by the European Commission suggest that precautionary measures should be "subject to review, in the light of new scientific data".[121] A similar notion can be found in Art 129 REACH concerning precautionary measures by MS. Reflecting this legal context, to justify proportionality of the planned preventive restriction invoking the precautionary principle, legal provisions indicating the provisional nature of the proposal could be considered. In this respect, several options are conceivable. The first option would be simply maintaining the legal status quo as the procedure laid out in Art. 68 et subs. already stipulates the option "amending current restrictions", providing thus the framework to adapt restrictions in view of e.g. new scientific findings. This option would, however, lack an external trigger to assess any adaptation needs but would rely on the proactive review by authorities. Another option could therefore take the form of a review clause in which the Commission commits to reassess the risk after due time in the light of then available evidence, as has been practiced already.[122] Such review clause may also refer to specific monitoring mechanisms.[123] Cloning large parts para. 8 of Art. 60 stipulating the conditions for granting authorisations could be an option, e.g.:

Review clause for reassessment of risks

By way of derogation, the proposal shall be subject to a time-limited review without prejudice to any decision on a future review.

Alternatively, a more general mechanism linked to the review activities according to Art. 117 of REACH could be considered as well. It could stipulate, for instance, that the Commission when assessing "experience acquired with the operation of this Regulation" according to Art. 117(4) also considers the effectiveness of existing restrictions and whether there is a need to modify these restrictions.

4.1.6 Adjusting the evaluation framework for RAC and SEAC

RAC assesses, according to Art. 70, whether "suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier". Next, SEAC formulates "an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact", pursuant to Art. 71. Under the policy option, the existing framework for these evaluations will not change, but particularly entail whether

"methods and parameters used for risk assessment and impact assessment are appropriate, following the guidance documents and applied consistently;

quality of the scientific data is sufficient;

conclusions are reached logically, in a consistent way;

evidence is robust and focussed to the concern identified; and

all relevant issues have been included and well justified."[124]

[121] COM(2000) 1, 4; European Commission (2018), 76; see also Annex B.

[122] See e.g. in Annex XVII entries 18a on Mercury and 23 on Cadmium.

[123] For an example of monitoring criteria, designed in the context of authorisation according to the "no adequate control"- route (Art. 60(4)), see Führ et al. (2011), Annex C.

[124] ECHA (2015), 23.

Additionally, as usual, RAC will evaluate uncertainties in the risk assessment.[125]

On SEA Annex XV stipulates that "the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole". In practice, the "Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals" clearly states that "[f]or SEAC, the cost of moving to alternatives is often the most important part of the overall cost of the proposal".[126] In order to reach the normative goal, it is crucial to ensure that in situations of emerging risk, the balance of concern and cost does not, by default, tend to be at the expense of concern. One could therefore consider adjusting the framework in a way that SEAC conclusions (opinions) by default assign prima facie high relevance to the concern's associated, often uncertain, health and environmental benefits over, probably more tangible, costs for industry due to a substance's phase-out. The deliberations by SEAC in the draft opinion on the microplastic restriction proposal could serve as a template:

"Even though a clear conclusion on proportionality is not possible recognising the uncertainties of the impacts of the restriction, SEAC considers that the irreversibility of microplastic emissions is a key argument in favour of proportionality of the proposed restriction."[127]

4.2 Evaluation of policy options

For each option introduced above, this section identifies the relevant legislative implementation procedures (section 4.2.1) and summarizes advantages and disadvantages (4.2.2).

4.2.1 Legal implementation

Section 4.1 introduces two categories of policy options, i.e. those addressing changes to the REACH Annexes and others (see overview in Table 4).

4.2.1.1 Amendments to the annexes

Pursuant[128] to Art. 131, the Annexes may be amended in accordance with the procedure referred to in Art. 133(4), i.e. regulatory procedure with scrutiny. This procedure laid down in Art. 5a Council Decision 1999/468/EC[129] reflects the normative content of Art. 290 TFEU.[130] Consequently, amendments to the REACH annexes are subject to the requirements of Art. 290 TFEU. 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".

It follows that, as the (basic) legislative act presupposes the objectives of relevant delegated acts, such delegated acts may not pursue objectives not in line with those laid down the basic act. Likewise, the content and scope of the delegated act are determined by the basic act.

[125] ECHA (2015), 25.

[126] ECHA (2015), 25.

[127] ECHA (2020b), 63.

[128] Large parts of the analysis in section 4.2.1.1. are taken from Schenten and Führ (2016), 11 et subs.

[129] Council Decision 1999/468/EC of 28 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 17 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."

[130] C.f. Recital 7a Council Decision 1999/468/EC.

Guidance as to the determination whether legislative changes are essential or non-essential in relation to the basic act is given by a Legal Service opinion on the application of Article 290, derived inter alia from judicature of the EU courts.[131] In summary, the following legal criteria have to be taken into account:

Proposed measures have to cumulatively be

1. in line with the objectives of the basic act,
2. in line with the objectives, content, scope and duration of the delegation of power explicitly defined in the basic act, and
3. limited to modifying non-essential elements of the basic act, whereas the respective evaluation is subject to an overall view of all relevant aspects (no violation of fundamental guidelines and obligations imposed, margins of discretion etc.).

Considering these criteria, Table 5 briefly appraises the relevant options.

Table 5: Legislative implementation procedures

Option	In line with the objectives of the basic act?	In line with the delegation of power explicitly defined in the basic act?	Limited to modifying non-essential elements?
Annex I, 6.0: Clarify scope for emerging risk in general	**Yes -** REACH aims to ensure a high level of protection, while stimulating competitiveness and innovation. The provisions are "underpinned by the precautionary principle". REACH aims to control emerging risk.	**Yes -** Article 131 of REACH mandates any amendments to the annexes without providing any additional requirements.	**Yes** – The suggested amendments do not add new obligations but simply clarify the existing mandate for authorities and duties for industry.
Annex XV: Added tools			
Annex I, 6.5: Clarify scope for minimisation of emissions and exposure			**Yes** – While the suggested amendments add new obligations for industry actors, these are of a rather minor nature and have therefore to be regarded as non-essential. This assessments takes into account the margins of discretion by the legislators as well as crucial role the precautionary principle plays in REACH.
Annex I: Operationalisation of emerging risk in registration			

The table shows that all options are subject to the regulatory procedure with scrutiny and can be implemented in this manner.

4.2.1.2 Other options

As for the other options targeting Art. 3 and of Art. 66(a) more than one implementation scenario is conceivable.

The options could fall under implementing legislation according to Art. 132, applicable to measures necessary to put the provisions of REACH efficiently into effect. Creating impetus for implementation of the existing restriction provisions is the main function of the suggested legislative provision defining the aim of the restriction scheme. This option can therefore be

[131] Council of the EU, Opinion of the Legal Service, Application of Articles 290 (Delegated Acts) and 291 (Implementing Acts) TFEU, 8970/11, LIMITE, 11.4.2011.

deemed covered by the mandate of Art. 132 and can thus be adopted in accordance with the procedure referred to in Article 133(3).

In contrast, section 4.1.2 assumes that adding definitions of the terms risk and uncertainty to Art. 3 would at least depart from the initial intentions of the legislators. These amendments could therefore not be considered to be of implementing nature. Therefore, the ordinary legislative procedure applies.

4.2.2 Advantages and disadvantages

This section compares the advantages and disadvantages of the policy options (Table 6). In this respect, several aspects are taken into account. This includes the contribution to the normative goals of REACH and related benefits to health and environment, as well as market chances for industry. Administrative cost for authorities and costs for industry are considered cursorily as well.[132] Likely implications on litigation are considered as well, given that political decisions by EU bodies based on scientific facts have broad discretion de lege lata.[133]

The required legal implementation procedure is not considered for the following reasons. An Annex to the CSS lists legislative proposals it intends to present (mostly in 2022) with a view to advancing REACH.[134] Some of these entries (e.g. update of information requirements) refer to comitology as appropriate legislative procedure, while others don't (e.g. changes to Art. 57 and 68(2)). The latter indicates that the commission plans to initiate the ordinary legislative procedure. Against this background, when a policy option triggers the ordinary procedure (section 4.2.1.2), this is not construed as a disadvantage since this more cumbersome procedure will – according to the information available until July 2021 – be launched in any case.

Table 6: Advantages and disadvantages of the policy options

Option	Advantages	Disadvantages
Art. 66(a): Restriction Goals	Motivates authorities to draft Annex XV dossiers subject to the legal goals	Disadvantages are not apparent
Annex I Section 6.0: Enhanced legal clarity on *substantive* scope of CSR in terms of emerging risk	Motivates industry to adequately identify and adequately control emerging risks by creating awareness	Disadvantages are not apparent. Clarifying the legal mandate and requirements de lege lata, the option does not incur any additional costs
	Motivates authorities to draft Annex XV dossiers aimed at preventive control by reducing burden of establishing risk	
	Motivates authorities to consider emerging risk in dossier evaluation	
	Facilitates innovation in the direction of sustainable chemistry	
	No changes to scope of judicial review (in substantive terms), if legal action is brought against the restriction	

[132] A fully-fletched assessment of benefits and costs is of course not possible. Note, however, that an assessment by ECHA of restriction cases between 2010 and 2020 shows that were the benefits of restriction could be monetised, "the annual benefits amount to €2.1 billion – four times higher than the associated costs of €0.5 billion", see ECHA (2021b), 7.

[133] CJEU Case 199/13 P on acrylamide: ECLI:EU:C:2014:205; cf. Bergkamp et al. (2013), para. 10.56 et subs.

[134] COM(2020) 667, ANNEX.

Option	Advantages	Disadvantages
	Due to all the above: stronger contributions to normative objectives of REACH: high level of protection, competitiveness and innovation, precautionary principle	
Annex I Section 6.5: Extending duty to minimise exposures and emissions to all emerging risk situations	Legally requires industry to adequately control emerging risks	The duty incurs additional compliance costs on industry
	Yields stronger contributions to normative objectives of REACH: high level of protection, precautionary principle	The duty incurs additional enforcement costs on authorities
Annex I: Operationalise emerging risk in the registration	Legally requires industry to assess relevance of emerging risk	The duty incurs additional compliance costs on industry
	Yields stronger contributions to normative objectives of REACH: high level of protection, precautionary principle	The duty incurs additional enforcement costs on authorities
Annex XV: New tools to tackle emerging risk	Further enhancing legal clarity and thus further reduce burden for authorities (see 2)	Additional *formal* aspects subject to judicial review if legal action is brought against the restriction
	Enhanced transparency of (precautionary) restrictions increases predictability and trust in system	Creating new procedural obstacles which are however minor and can be tackled with guidance

The aim of the policy options is to strengthen control of emerging risk under REACH. They are addressing deficits in the provisions of REACH de lege lata. These deficits impede the *willingness* of actors in industry and authorities and deprive them of the framework conditions (*opportunities*) required to tackle emerging risk. The options at least partially address the identified shortcomings. Table 6 shows that, in an overall perspective, the foreseeable benefits of the options would outweigh the identified disadvantages. In addition, with regard to the objective of a high level of protection, the Commission and the legislative bodies are nevertheless responsible to constantly monitor the handling of emerging risk under REACH.

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A Appendix: Indications of the precautionary principle in REACH

Annex A shows links to the precautionary principle in REACH. Normative goals and specific legal mechanisms both can be a reflection of the precautionary principle. Taking into account findings from literature, this Annex aims to provide a general overview on indications of the precautionary principle in REACH.

Table 7: Indications of the precautionary principle in REACH

Context		Provision(s)	Actor(s)	Comments on precautionary principle indications
1.	Normative objectives	Art. 1(1) and 1(3)	All	The purpose of REACH is to ensure a high level of protection of human health and the environment while enhancing competitiveness and innovation. To this end, the REACH "provisions are underpinned by the precautionary principle". As a structural principle it particularly gains momentum with respect to provisions referring to the concept of risk and related uncertainties (cf. section 2.5).[135]
2.	Registration	Art. 5: "No data no market" rule, general registration obligations with tiered IR	Industry	Instrumental design: manufacturing / importing quantities as a proxy for risk and trigger for the intensity of IR[136] as the mere "lack of knowledge about the impact of many chemicals on human health and the environment is a cause for concern".[137] Based on a generic risk[138] assumption in situations when there is a need to obtain and pass on information to enable [further/specific] risk assessment or risk management.[139] Tonnages also trigger dossier evaluation level of scrutiny (by ECHA).

[135] Rehbinder (2008), Art. 1, para. 29; Rehbinder (2012a). para. 17, 22; Rehbinder (2012b) para. 17.

[136] Recital 34 REACH; critical of this: Appel (2003), 167 (168); Kogan (2012), 8, 39.

[137] COM(2001) 88 fin, 4 ; see also Recital 34 of REACH.

[138] The regulatory "Fitness Check" of the most relevant (40+ pieces of) chemicals legislation (excluding REACH) identifies two in principle complementing approaches to EU chemicals risk management: one approach is based on specific risk assessment and the other one based on generic risk considerations. The main difference, according to the Commission Services, "is the point in time when the exposure assessment is considered and the specificity of the exposure assessment". Under the generic approach, the legislator anticipates a certain risk calling for regulatory action, based on plausible assumptions, cf. SWD(2019) 199 fin, PART 3/3, p. 316.

[139] SWD(2019) 199 fin, PART 3/3, 316 establishes this category.

Context		Provision(s)	Actor(s)	Comments on precautionary principle indications
3.		Art. 6 et seq; Annexes: Duty to identify hazards, exposure, risk, and mitigation measures (IR/CSR)	Industry: registrants	Instrumental design: burden of proof lays with industry[140]. Assessment of scientific data: as "underpinned by the precautionary principle" uncertainty of precise effects / damage no excuse for inaction.
4.		Art. 14(5)/37(5) duty to "adequately control the risks" based on the "risk characterisation" (Annex I Section 6)	Industry: supply chain	Instrumental design: burden of proof and minimisation principle concerning exposures and emissions of substances with PBT/vPvB properties; assessment of scientific data: quantitative (DNEL/PNEC-ratio) or qualitative (e.g., non-threshold effects) (see line 3)
5.		Art. 7(5): Request to submit registration for substances in articles	ECHA	Assessment of scientific data, see line 3; burden of proof however lays with ECHA[141]
6.	Evaluation	Art. 41: Compliance Check	ECHA	Instrumental design: level of scrutiny linked to tonnages, see line 2; assessment of scientific data, see line 3
7.		Art. 43: Testing Proposal Examination	ECHA	Assessment of scientific data, see line 3
8.		Art. 44(2):, Identifying substances for evaluation (CoRAP)	ECHA	Instrumental design, i.e. applicable to "suspected" risks, industry has to proof that risk is not relevant / under control
9.		Art. 45: Substance Evaluation	MS/ECHA	Assessment of scientific data, see line 3
10	Authorisation	Art. 55: Aims at "assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced"	Industry: supply chain, MS/ECHA	Substitution objective structurally reflects precautionary principle[142]
11		Art. 57: SVHC criteria	MS/ECHA	Assessment of scientific data (Higher degree of uncertainty inherent to some criteria, in particular, i.e. vPvB[143], possibly Art. 57(f) (see section 2.4)

[140] v. Holleben and Schmidt (2002); Calliess and Lais (2005); Hansen, Carlsen and Tickner (2007); Kogan (2012), 8, 39.

[141] Cf. the analysis and policy options at Führ et al. (2020b), 53, 58.

[142] Hansen, Carlsen and Tickner (2007); Rehbinder (2008), Art. 1, para. 11, 34 et seq..

[143] Cf. Løkke (2006), 347, Zarfl and Matthies (2013), 7 with further references; v. Gleich,Pade and Wigger (2013), 19.

	Context	Provision(s)	Actor(s)	Comments on precautionary principle indications
12		Art. 58: (legal effects of) Inclusion in Annex XIV	ECHA, COM	Instrumental design: SVHC properties trigger the need to apply for authorisation, indicating a generic risk approach. Industry can then lift the ban subjec6t to a specific risk assessment.[144]
13		Art. 58(3): Prioritisation criteria		Considers PBT or vPvB properties with inherent uncertainties, line 11, as well as wide dispersive use (generic risk assumption)[145] and high tonnages (proxy for risk, see line 2)
14		Art. 62: Applications for authorisations	Industry: supply chain	Assessment of scientific data, see line 3 (especially concerning adequate risk control / benefits outweighing risks)
15		Art. 64: Assessment of Applications	ECHA	Assessment of scientific data, see line 14
16		Art. 60: Authorisation Decision	COM	Normative decision can be based on precautionary principle, especially for non-threshold substances pursuant to Art. 60(3)
17		Art. 60: Review phase	COM	Instrumental design: burden of proof to acknowledge progress in scientific knowledge
18	Restriction	Informal "Call for Evidence"	Industry, all	Instrumental design: Authority announces intention to propose a restriction, all interested parties can provide supportive or exculpatory evidence
19		Art. 68(1), Annex XV: Preparing Restrictions	COM (ECHA), MS	Normative decision (submit Annex XV dossier) interpreting "unacceptable risk", based on assessment of scientific data, see line 3
20		Art. 69-72: Assessment of dossier	ECHA	Assessment of scientific data, see line 3
21		Art. 73: Commission Decision	COM	Normative decision (adoption of restriction)
22		Art. 68(2): Restriction for products that "could be used by consumers"	COM	See line 19. Instrumental design, generic risk approach: simplified procedure for CMRs listed in entries 28 – 30 of Annex XVII in chemical mixtures because exposure[146] to

[144] Cf. the legal analysis at Führ et al. (2015), 78.

[145] SWD(2019) 199 fin, PART 3/3, 316.

[146] Including exposure of vulnerable groups (e.g. children), see SWD(2019) 199 fin, PART 3/3, 316.

Context		Provision(s)	Actor(s)	Comments on precautionary principle indications
				consumers is assumed.[147] As regards CMRs in articles the Commission rather follows a specific risk approach.[148]
23	Communication	Art. 31, 33: SDS, supply chain communication and consumer request on SVHCs in articles	Industry	Instrumental design, i.e. generic risk approach to enable [further/specific] risk assessment or risk management, and as use in consumer products may result in exposure of vulnerable groups (e.g. children).[149]

[147] 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, COM(2003) 644, 37.

[148] Cf. the analysis and policy options at Führ et al. (2020b), 69, 73.

[149] SWD(2019) 199 fin, PART 3/3, 316.

B Appendix: The precautionary principle in EU and international law

After a longer period of debate,[150] the precautionary principle permeates the entire legal system.[151] It entered the level of international law (section B.1B.1) as well as the treaties establishing the European Communities and the EU (section B.2). As already discussed, it underpins the regulatory approach of the REACH Regulation (section 2.5).

B.1 International Law

Since the 1980s, several international environmental agreements[152] rely on the precautionary principle or a precautionary approach.[153] However, the agreements use different formulations and instrumental configurations. Thus, no universal understanding has emerged regarding the content and scope of the principle itself.[154] Generally, the precautionary principle is seen as a risk management tool.[155] Based on this understanding, a state may or possibly must, within its abilities, act carefully and proactively regarding activities that may have a harmful effect on the environment or human health.[156]

On the level of non-binding declarations, the precautionary principle gained increasing recognition. This applies in particular to Principle 15 of the Rio Declaration:[157]

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[158]

With a view towards unintended effects of chemicals, the post-Rio conference in Johannesburg formulated in 2002 a chemicals-related "Johannesburg Goal"[159] and related processes. In 2015, the UN General Assembly adopted the Sustainable Development Goals (SDGs), reaffirming that goal in SDG 12 by seeking to achieve, by 2020, "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".[160]

Against this background, the precautionary principle pursuant to Principle 15 of the Rio Declaration states that protective measures to prevent serious or irreversible damage can be taken without full scientific certainty about the *possible* extent of damage. This understanding is

[150] Rehbinder (1991).

[151] Hoffmann-Riem (2016), 18 et subs.

[152] On a local level, e.g. in Germany and Sweden, this occurred in the 1970s, Rehbinder (1991), 7, 183.

[153] A selection: Vienna Convention for the Protection of the Ozone Layer in 1985, the Montreal Protocol of 1987, Framework Convention on Climate Change of the United Nations, Convention on Biological Diversity and the Convention for the Protection of the Marine Environment of the North-East Atlantic in 1992, the Cartagena Protocol on Biosafety of 2000, Stockholm POP Convention of 2001 etc.

[154] OECD (1995), 16 et seq., Sands and Peel (2012), 217 et seq., 222.

[155] Atapattu (2007), 283 with further references.

[156] Sands and Peel (2012), 222.

[157] Sands and Peel (2012), 217 et seq., 222.

[158] United Nations (1992a).

[159] United Nations (1992b), para. 23.

[160] United Nations (2015), para 59, target 12.4.

thus to be distinguished from the largely consented principle of preventive environmental protection, according to which states take preventive measures to guard against damage which is *likely* to occur on the basis of scientific knowledge.[161]

In addition, there are some binding multilateral agreements applying the precautionary principle in the context of chemicals control. For example, the Stockholm Convention on persistent organic pollutants ('POP') provides restriction measures regarding the production, use and release of specific substances.[162] Pursuant to its Art. 1 "[m]indful of the precautionary approach as set forth in Principle 15 of the Rio Declaration […], the objective of this Convention is to protect human health and the environment from [POP]".[163] In order to list a new substance in one of the Convention's annexes, the Conference of the Parties shall decide "in a precautionary manner" while taking due account of "any scientific uncertainty".[164] According to *Sands* and *Peel,* the "Convention increasingly moves to regulate POPs whose toxicity is not uniformly accepted".[165] There are also chemicals-related provisions of international law on the protection of the maritime area, many of which implement the precautionary principle in terms of risk prevention.[166]

As reflected by the binding multilateral agreements, the constitutive elements of the precautionary principle within the meaning of Principle 15 include risk, damage and scientific uncertainty. Another element is the "capabilities" of states, indicating that precautionary measures must obviously consider the relation between benefits and efforts. There is no international scientific or political consensus on the definition of these constitutive elements. There is also no general guidance on how to identify risks and calculate the damages.[167] What degree of scientific certainty is required or *vice versa*, how much scientific uncertainty is allowed to act on the basis of precaution, can also only be determined in each individual case and in view of the potential and possible extent of the damage.

In summary, international (environmental) law often refers to the precautionary principle in the sense that state actors may be legally entitled to act upon the identification of a cause for concern. It thus creates a framework for regional legislation (e.g. EU).

B.2 EU primary law

On the level of EU primary law, Article 191(2) Sentence 1 of the TFEU states that the Union's environmental policy is based, inter alia, on the precautionary principle. The integration clause laid down in Art. 11 TFEU provides that "[e]nvironmental protection requirements must be integrated into the definition and implementation of the Union policies and activities, in particular with a view to promoting sustainable development." By means of this clause, the principle is transmitted into each and every policy and activity performed by the EU. This holds true not only for the legislative definition of the policies and activities but also with regard to their administrative implementation. The European Commission and ECHA, for instance, in

[161] Atapattu (2007), 203; Sands and Peel (2012), 201 et seq.

[162] Cf. the UNECE Aarhus Protocol on Persistent Organic Pollutants (POP) as well as the UNEP Rotterdam convention on certain hazardous chemicals and pesticides in international trade, both from 1998.

[163] Cf. Recitals 8, 9 POP-Convention.

[164] Art. 8(9) POP-Convention.

[165] Sands and Peel (2012), 526; McLaren et al. (2021) comment that the EU is the "most active Party in proposing new POPs for listing", 7.

[166] WBGU (2013), 85.

[167] Atapattu (2007), 206 et seq.

enacting their competences, are bound by primary law. The same applies to Member State bodies acting at the EU level. Furthermore, since the Union policies are mainly implemented by national or regional competent authorities, Art. 11 TFEU[168] obliges them as well.

Accordingly, the CJEU held that the precautionary principle is a "fundamental principle of environmental protection".[169] It follows that the principle does not only bind measures based on Art. 192 TFEU to achieve environmental policy objectives, but also, according to Art. 114(3) TFEU, measures aimed at achieving the internal market, in particular if they serve to protect human health.[170] Besides its enabling function[171] to shape e.g. legal frameworks, the principle can unfold legal obligations in cases such as frameworks falling short of its substantive requirements (see below).[172]

According to the CJEU, the precautionary principle allows the EU legislator – or, where appropriate, a decision-maker authorised by it – "where there is uncertainty as to the existence or extent of risks […] take protective measures without having to wait until the reality and seriousness of those risks become fully apparent".[173] In essence, this definition describes a risk situation characterised by a higher degree of uncertainty, i.e. emerging risk. With regard to chemical substances, the element of uncertainty may refer to the intrinsic properties of the substance and to the possibility of exposure.

The courts of the Union have based a large number of their decisions on the precautionary principle and have outlined its scope mainly through specific procedural requirements.[174] On that basis, a Communication from the European Commission in 2000 aims to "establish Commission guidelines for applying [the precautionary principle]" and "build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully"[175]. Communications from the Commission are not legally binding. On the political level, the Council and the European Parliament supported the document.[176] The Union Courts referred to it in several rulings.[177] Thus, it can be stated that this particular document has gained considerable practical relevance.[178] The Communication is also of interest for the analysis as the Commission's original draft on REACH explicitly referred to the Communication's

[168] Underpinned by Art. 4(3)1 TEU.

[169] CJEU, Opinion 2/00, coll. 2001 I-9717, para. 29; cf. on the significance of the principle, giving structure and guidance to EU policies, Rehbinder (2012a), para. 17, 22; Calliess and Ruffert (2011), art. 191, para. 26.

[170] CJEU, judgment of 5.5.1998, case C-157/96, coll. I-2211, para. 64 – National Farmer's Union; judgment of 5.5.1998, case C- 180/96, coll. I-2265, para. 100 – United Kingdom/Ireland (BSE); judgment of 9.9.2003, case C.236/01, coll. I-8105, para 111 – Monsanto; General Court, judgment of 11.9.2002, case T-13/99, coll. II-3305, para. 114 – Pfizer Animal Health; General Court, judgment of 26.11.2002, case T-74/00, coll. II-4045 para. 183 f. – Artegodan; General Court, case T-257/07, para. 66, also see COM(2000)1, 3 and the discussion at Heselhaus (2010), 91 (99 f).

[171] Winter (2003), 137 f. There is a wide margin of judgement with regard to the decision of "whether" and "how" to apply the precautionary principle.

[172] For example, the General Court declared the inclusion of a plant protection active substance in the positive list of Directive 91/414/EEC null and void, as the European Commission did not adequately assess the available scientific data in the light of the precautionary principle, see General Court, Judgment of 11.7.2007, case T-229/04, coll. II-2437 Sweden/Commission (pending before the CJEU as case C-102/04).

[173] CJEU, case C-180/96, para. 112 – United Kingdom/Ireland (BSE).

[174] Heselhaus (2010), 91 (97); Arndt (2012), 46, 49; see also SRU (2011), para. 436 f.

[175] COM(2000)1, 10f.

[176] See No 3 of Council Resolution 1999/C 206/01 of 28.6.1999 on Community consumer policy 1999-2001, OJ C 206 of 21.7.1999, 1.

[177] CJEU, case C-236/01, para. 79; General Court, case T-257/07, para. 72.

[178] See e.g. Appel (2005), 206 f. Calliess and Lais (2005), 290 (292); Milieu (2017).

guidance with regard to the conceptual importance of the precautionary approach to the Regulation,[179] which the Commission also confirmed after the adoption of REACH.[180]

The precautionary principle sets out procedural requirements for risk management in the broader sense, which is structured along the three steps of scientific risk identification, normative risk evaluation and risk management in the narrower sense. Precautionary aspects are particularly important in steps 2 and 3.[181] This approach makes it possible to deal in regulatory or e.g. corporate contexts rationally with uncertainties. The following sections give an overview of which guidelines apply for the individual steps.

B.2.1 Risk identification

The scientific risk assessment is based on the four-step "risk-ratio model", which is also implemented in REACH, and which comprises determination of (1) the hazard potential and (2) the quantitative or qualitative dose-effect relationship, (3) exposure assessment and (4) risk characterisation.[182] All four steps inevitably entail uncertainties.[183] Primary law enriches the individual steps with specific procedural requirements. For example, risk assessment – as codified in a similar manner in Art. 191 TFEU – must be "taken in the light of the best scientific information available" and based on the "most recent results of international research".[184] Even in situations where risk assessment proves impossible due to the "inadequate nature of the available scientific data", "sufficiently reliable and cogent" conclusions must be developed to allow decision-makers to make a normative assessment of the facts in the next step.[185] As a result, taking account of "the particular circumstances of a given case", precautionary measures can also be taken if the risk assessment proves to be practically impossible,[186] for example if the necessary tests are not available at the time of the analysis.[187] If the incomplete data situation does not permit a detailed analysis of the facts, a risk can consequently also be assessed on the basis of a preliminary risk determination.[188]

B.2.2 Normative risk evaluation

In normative risk evaluation, the legislator or another legitimate body analyses the scientifically described risks. Precaution is particularly important in situations where the risk assessment

[179] See COM(2003) 644 fin, 19, 68 as well as critical Hansen, Carlsen and Tickner (2007), 395 (397).

[180] See the „Questions & Answers" to the regulation at European Commission 2007, 3: „The REACH Regulation is based on the precautionary principle, its requirements implement the principle as set out in the Communication from the Commission on the Precautionary principle (COM(2000)1)".

[181] While every risk assessment is characterised by various uncertainties, only the precautionary risk assessment derives options for action from this.

[182] COM(2000)1 fin, 33; General Court , case T-257/07, para. 72; se already section 2.1.

[183] COM(2000)1 fin, 14.

[184] CJEU, Judgement of 28.1.2010, case C-333/08, coll. I-757, para. 92 – Commission/France, Judgement of 8.7.2010, case C-343/09, para 60 – Afton Chemical Limited; General Court, case T-13/99, para. 158; General Court , Judgement of 11.9.2002, case T-70/99, coll. II-3495, para 171 – Alpharma, General Court, case T-257/07, para 74; see also for test depth CJEU, Judgement of 5.2.2004, case C-24/00, coll. I-1277, para. 65 – Red Bull.

[185] General Court, case T-13/99, para. 160 et seq.; General Court, case T-70/99, para. 173 et seq.; General Court, case T-257/07, para. 77.

[186] CJEU, case C-236/01, para. 112.

[187] CJEU, Judgement of 22.12.2012, case C-77/09, coll. I-13533, para 45, 68 et seq. – Gowan Comércio.

[188] Referring to the case-law Rehbinder (2008), Art. 1, para. 30; SRU (2011), para. 36 et sec.

does not allow a clear assessment of the risk due to insufficient or inaccurate data[189] – it is therefore not possible to clearly allocate the situation to the areas of risk that are understood and require action or residual risk that is understood but deemed negligible, but there is emerging risk.

According to Art. 191(3) TFEU, the assessment is based not only on scientific analysis but also on aspects such as benefit-cost considerations or the availability of alternatives. In addition, the evaluation always depends on the objectives of a measure, e.g. as stipulated by a legal act. In this respect, in the chemicals context, the goal of (ensuring) a high level of protection with regard to health and the environment gains momentum. Conversely, EU courts rejected "zero risk" as a yardstick for the achievement of any objectives.[190]

Risk evaluation can override scientific conclusions.[191] However, speculative considerations cannot be the basis for a cause for concern triggering precautionary action: a "purely hypothetical approach to risk, founded on mere suppositions which are not yet scientifically verified" is not sufficient; rather, the evaluation must "provide[…] specific evidence which, without precluding scientific uncertainty, makes it possible reasonably to conclude" that there is a cause for concern.[192] Minority opinions in the scientific community may provide grounds for the assumption of emerging risk.[193] As a result, there is a reduction in the level of evidence[194] required for the determination of emerging risk.

B.2.3 Risk management in the narrower sense

The identification of emerging risk establishes a situation falling into the scope of the precautionary principle. This is followed by a 'political' decision on the appropriate response.[195] This can consist of waiting "until […] results of more detailed scientific research become available".[196] However, if the normative evaluation concludes that a concern cannot be considered socially adequate, the decision-maker is required, for example in the food sector, "by reason of the precautionary principle, to adopt provisional risk management measures necessary to ensure a high level of protection".[197] In this context, emerging risk also legitimises those measures which may infringe the fundamental rights of third parties.[198] There is a wide range of risk management instruments and measures, some of which can be combined.

- These include the promotion of research, monitoring of the cause of concern, the provision of information to consumers or the general public, e.g. on product labelling or product registers, recommendations.

[189] COM(2000)1 fin, 18.

[190] General Court, case T13/99, para. 152; General Court, case T-257/07, para. 78 et seq.. Besides, "zero risk" is not to bemixed up with the "zero pollution" goal pursued by EU policies, cf. COM(2021) 400.

[191] Calliess and Ruffert (2011), Art. 191, para. 26 with reference to the General Court ruling; COM(2000)1 fin, 25.

[192] CJEU, case C-236/01, para. 106, 113; General Court, case T-13/99, para. 144; General Court, case T-257/07, para. 75.

[193] COM(2001) 88 fin, 29; Nettesheim (2011), Art. 191, para. 92, but see also there the reference to General Court, case T-74/00, para. 200 ("most representative scientific statements").

[194] CJEU, case C-236/01, para. 108 et seq.

[195] COM(2000)1 fin, 18.

[196] General Court, case T-13/99, para. 161; COM(2001) 88 fin, 20.

[197] General Court, case T-257/07, para. 81.

[198] General Court, case T-13/99, para. 170; Epiney 2012, Art. 191, para 28.

- Notification and registration obligations can increase transparency on chemical substances in circulation.
- General or individual authorisation procedures and restrictions are available for substances with increased potential for concern.[199]

Like all regulative risk management measures, precautionary measures are bound by substantive and procedural requirements stipulated by the rule of law, particularly the principles of proportionality, of equal treatment (non-discrimination) and of coherence.[200]

This also comprises an assessment of the advantages and disadvantages of (non-)action, including an economic analysis of the intended benefits and the related efforts.[201] However, according to settled case-law the judicature of the CJEU allows the legislator and those mandated by legislators a wide margin of discretion for normative decisions based on an interpretation of scientific data:

"[I]n an area of evolving and complex technology such as that relating to the evaluation and monitoring of the risks posed by chemical substances, the European Union institutions have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts, in order to determine the nature and scope of the measures which they adopt, and that review by the European Union judicature has to be limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether the authorities have manifestly exceeded the limits of their discretion."[202]

[…European Union institutions have] *"broad discretion, which implies limited judicial review of their exercise of that discretion, applies not only to the nature and scope of the measures to be taken but also applies, to some extent, to the finding of the basic facts."*[203]

If the decision-maker takes *provisional* risk management measures, he has a duty to examine them "within a reasonable period" and to follow the scientific development, but also, for example, the change in risk perception.[204]

[199] See these and other examples SRU (2011), para 439.

[200] General Court, case T-13/99, para. 410 et seq.; in detail COM(2000)1, 20 et seq.; Decker (2009), 123 et seq.; Milieu Ltd et al. (2011), 49 et seq.

[201] See in this respect also the Better Regulation "Toolbox" complementing the Better Regulation Guideline, SWD(2017) 350, and stating that a "proportionate [impact assessment] should also be carried out for every decision invoking the precautionary principle which should set out the elements necessary for the exercise of the principle", European Commission (2018), 73.

[202] CJEU, case 199/13 P on acrylamide: ECLI:EU:C:2014:205., para. 26

[203] CJEU, case 199/13 P on acrylamide: ECLI:EU:C:2014:205., para. 28

[204] CJEU, case C-157/96, para. 65; General Court, case T-257/07, para. 83; see also SRU (2011), para. 437.

C Summary

International law provides some normative context for the application of the precautionary principle. While not stipulating specific requirements applicable in the scope of REACH, the international framework outlines a basic approach in the sense that „lack of full scientific certainty“ should not hinder public bodies to enact measures protecting human health and the environment in situations where „threats of serious or irreversible damage“ might occur. Likewise, in such a situation, industry should take appropriate measures to ensure adequate risk control.

EU primary law, and the judicature of the EU courts, establish a legal framework for the application of the precautionary principle, guiding the objectives and implementation of secondary legislation. This holds true for REACH, in particular, since the provisions of this regulation are “underpinned by the precautionary principle”, as stipulated by Art. 1(3) Sentence 2 of REACH.