Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction

Final Report

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Final Report
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1 Introduction

1.1 Scope of work

This study supports the European Commission’s wider impact assessment for amendments of the REACH Regulation. This will be based on several separate technical studies, each addressing different proposed changes to REACH. The current report considers three illustrative implementation scenarios to extend the Generic Risk management Approach (GRA) to further hazard classes and uses. It also examines three options to reform the REACH authorisation and restriction processes. The study comprised eight main tasks, according to the Terms of Reference:

- Task 1 - Develop a methodology;
- Task 2 - Mapping uses of the substances that will be subject to the generic approach to risk management (hereafter referred to as “use mapping”);
- Task 3 - Assess impacts of current uses of those substances affected by an extended generic approach to risk management;
- Task 4 - Assess the impacts of options to revise the REACH authorisation and restriction processes;
- Task 5 - Support the Commission in organising four ad-hoc workshops;
- Task 6 - Support the Commission in conducting the Public Consultation, in relation to subjects concerning authorisations and restrictions;
- Task 7 - Support the Commission in addressing comments from the Regulatory Scrutiny Board; and
- Task 8 – Presentation material.

The geographical scope of this study is all EU-27 Member States plus the EEA countries. The study has three objectives:

- To establish and assess the baseline scenario. This is how the REACH Regulation has developed from June 2007 and how it was expected to develop, in the absence of legislative changes, over the next 30 years. Note, the impact assessment assumes the following indicative appraisal period:
  - First, that the adoption of revised REACH Regulation occurs in 2025;
  - The revisions come into effect (i.e., the first GRA restriction and all measures for authorisation and restriction reform) from 2026;
  - Thereafter, the baseline estimates current and future costs and benefits that would be expected to occur for various stakeholders from the current REACH Regulation processes. These are based on estimates of future workload provided by ECHA. These are compared to estimated costs, savings and other benefits over a 30-year appraisal period (2026-2055 inclusive);
- To assess the significant socioeconomic costs and benefits of a wider application of the GRA.
- To assess the significant socioeconomic costs and benefits of three options for reforming the authorisation and restriction processes of REACH, compared to the baseline scenario.
1.1.1 GRA Implementation

The Chemicals Strategy for Sustainability (CSS) announced that use of the GRA for proposing restrictions would be extended from carcinogenic, mutagenic or toxic for reproduction (CMR) substances to a larger group of hazard classes, gradually. The additional hazard classes considered in this study are:

- Persistent, Bioaccumulative and Toxic (PBT);
- very Persistent and very Bioaccumulative (vPvB) substances;
- endocrine disruptors (ED) with effects on human health and the environment;
- Substances with specific Target Organ Toxicity, Single (STOT SE) and Repeated Exposure (STOT RE); and
- immunotoxic substances, neurotoxic substances, and respiratory sensitisers.

Note, the CSS does not specify that PMT/vPvM substances should be subject to the extended GRA. However, after discussions in the scoping phase and in agreement with the European Commission, they were included in the assessment to understand their uses and the potential impacts of including this hazard class.

The generic approach to risk management will also be extended from consumer uses to professional uses.

As such, the existing potential for restrictions using the GRA (i.e. via Article 68(2)) would be extended. For all substances, restrictions under Article 68(1) would remain possible, but this procedure would mainly be used for substances or uses not otherwise regulated. As part of this study use potentially subject to the extended GRA under REACH as well as under the Cosmetics Regulation and the Toy Safety Directive have been mapped (see section 1.2.2). The resulting economic, social and environmental effects have been screened and the significant effects assessed (see section 1.2.3).

1.1.2 Options for authorisation and restriction reform

The three options assessed in this report were initially identified by the European Commission in the inception impact assessment. They have been further refined via consultation with Member States in CARACAL meetings alongside a series of workshops organised for the purposes of this study. The four options under consideration are:

- The baseline scenario. The baseline is the continuation of how REACH has worked from June 2007 until April 2021. The appraisal period over which costs and benefits are assessed is 30 years (2026 and 2055). These are based on assumptions provided by ECHA on its expected future workload. Baseline costs and benefits are compared to three potential reform options;
- Option 1: Streamline the authorisation and restriction provisions (while keeping authorisation and restriction processes separate). This option would involve modifying elements of the authorisation and restriction process through legal changes, to address weaknesses identified;
- Option 2: Merge authorisation and restriction provisions into one system. Under this option Annex XIV (the authorisation list) would be integrated into Annex
XVII (restrictions), which would be retained. Presence of substances in articles would be covered in new section of Annex XVII for listed SVHCs, which would also make Article 69(2) redundant. Derogations from restrictions would effectively replace applications for authorisation. There would be three possible ways to do this, which includes a new method, a derogation of general applicability:

- **Option 3: Removing the authorisation title from REACH.** Risks arising from chemical substances would be addressed by generic and specific restrictions under REACH (Articles 68(1) and 68(2)) and by other legislation (e.g., worker’s protection legislation, industrial emission legislation, etc., both at EU and national levels). Annex XIV (the authorisation list) would disappear and applications for authorisation would cease, and

- **Under all the options, grounds for granting authorisations and/or derogations from restrictions would also be considered based on one or two routes.** Either the Essential Use Concept (ESU) and/or on demonstration of “minimal exposure”. The Essential Use Concept is under development in a separate study, which is running in parallel. At the time this study was carried out, details of how precisely the Concept may apply in practice, the information requirements required and hence how it may interact with the options in this study was not known. The current study considers the specific implications from the ESU at a high level, and these are associated with significant uncertainty.

### 1.1.3 Structure of the report

This report follows the structure recommended in Tool #11 of the Better Regulation Toolbox, November 2021. The preferred option may comprise elements of one or more options listed above. As such, the assessment of each option in this study comprises several measures each examined individually. Moreover, given the interplay between the extended use of the GRA, authorisation and restriction reform options, following individual assessment of measures the options alongside GRA and ESU are assessed in combination to identify the key costs, benefits and trade-offs.

The remainder of section 1 describes the methodology employed for the study. Thereafter:

- **Section 2 covers the political and legal context** to the impact assessment of the REACH reform;

- **Section 3 explores the problem,** drawing on various background information and targeted stakeholder interviews; this section explores why the reforms are being considered, discussing the key drivers behind them;

- **Sections 4 explores why the EU should act,** detailing the appropriate legal basis and the need/benefits of action at EU rather than Member State level;

- **Sections 5 discusses what should be achieved** via discussion of the general policy objectives of REACH reform and the specific objectives of extending the GRA and reforms to REACH authorisation and restriction;

- **Section 6 details the various options to achieve the objectives.** This includes the baseline (Do nothing)’ and more details on options for extending the use of the GRA and reform of REACH authorisation and restriction;

- **Section 7 examines impacts of individual measures from each option as well as three potential GRA implementation scenarios.** The options for authorisation

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and restriction reform comprise various measures which are explained in detail, along with the implications of each potential change. Three implementation scenarios for the extension of the GRA are also examined:

- **Section 8** consolidates the analysis above and assesses aggregate impacts of the current policy options and implementation scenarios. The precise combination of measures, and hence the final policy options, was not determined in this study. It may involve a combination of measures from several different options; and

- **Section 9** provides monitoring and evaluation recommendations.

- **Annex 1** contains in a separate document the approach and final report for Task 2 – the use mapping;

- **Annex 2** contains in a separate document the summary report on the stakeholder engagement activities; and

- **Annex 3** contains the summary reports of the four workshops organised on the reform of authorisations and restrictions and on the extension of GRA.
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2 Political and legal context

This section examines the political and legal context to the GRA extension and reforms to authorisation and restriction. First, the REACH Regulation is described with a focus on authorisation and restriction. Second, the wider context of the European Green Deal, the Zero Pollution Action Plan for Water, Air and Soil, and the Chemicals Strategy for Sustainability.

2.1 REACH

Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) aims to ensure a high level of protection of human health and the environment, including the promotion of alternative test methods, as well as the free circulation of substances on the internal market, while enhancing competitiveness and innovation. It applies directly in all Member States and the EEA. Given the aims of REACH and the extensive EU trade in chemicals, a harmonised EU-level approach was deemed the most suitable for regulating chemicals under REACH in 2006.

The REACH Regulation itself includes an obligation for a review every five years to monitor progress in the achievement of its objectives. The first such review, “the first REACH Review” was published in 2013. The results of the second review, “the second REACH review” were published in March 2016. This was a Regulatory Fitness and Performance (REFIT) review undertaken in line with the Better Regulation Guidelines. The second REACH Review was undertaken alongside a fitness check on the most relevant chemicals legislation (excluding REACH). This included an assessment of the interplay between REACH and several related legislations.

The second REACH review concluded REACH was achieving its goals but highlighted some important areas by which the process could be improved. This included reducing the complexity and burden associated with authorisation processes, and improving the speed of restriction processes.

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28 This is intended as a useful Commission report on the operation of REACH and an evaluation report. These documents support and are used in the analysis of a large number of detailed supporting technical studies on specific chemicals issues. These included the Cumulative Chemical Assessment for the EU Chemicals Industry: https://ec.europa.eu/environment/chemicals/reach/review/reach-chemical-assessment-results_en/2a446770cc631301


The analysis influenced the subsequent development of the European Green Deal (EGD)\(^2\), the Zero Pollution Action Plan for 2050 (ZPAP)\(^3\) and the Chemicals Strategy for Sustainability (CSS)\(^4\).

### 2.1.1 The European Green Deal

The European Green Deal (EGD) is a package of policy measures and initiatives to transform the EU into a resource efficient and competitive economy. The overall aim is to achieve climate neutrality in the European Union by 2050 with an interim milestone of reducing greenhouse gas emissions by 55% compared to 1990 levels by 2030\(^5\). The EGD comprises seven themes, which include:

- Transforming the EU economy and society; including creating new opportunities for innovation, investment, and jobs;
- Leading the third industrial revolution by creating markets for clean technologies and products; and
- Working with nature to protect our planet and health; to improve living conditions, maintain a healthy environment, create quality jobs, and provide sustainable energy resources\(^6\).

The EGD involves both reviewing existing European law to ensure compatibility with this ambition, but also introducing new legislation across the circular economy, biodiversity, farming, and innovation\(^7\). Initiatives span energy, climate, agriculture and food, environment, industry, transport and finance. Specific strategies under the environment include the Zero Pollution Action Plan and the Chemicals Strategy for Sustainability.

### 2.1.2 The Zero Pollution Action Plan

The Zero Pollution Action Plan (ZPAP) proposes that pollution elimination measures are incorporated into all policy developments and steps are taken to further decouple economic growth from increases in pollution. Pollution includes the negative externalities associated with chemicals causing cancer, ischaemic heart disease, obstructive pulmonary disease, strokes, mental and neurological conditions, diabetes for example, with the most harmful impacts typically being borne by the most vulnerable groups, including children\(^8\). These externalities are also a main driver of biodiversity loss. This forms the public health, environmental, moral, and socioeconomic case for EU-level action on pollution.

The zero-pollution vision for 2050 is:

\(^{4}\) [https://ec.europa.eu/info/strategy/ZDriorities-2019-2024ZeuroDean-green-deal/delivering-eurooean-green-deal]
\(^{5}\) [https://eur-lex.europa.eu/infopages/2022-2024zeuroDean-green-deal/delivering-eurooean-green-deal]
\(^{6}\) [https://ec.europa.eu/info/strategy/2020-2024-forest-action-plan/forest-action-plan_en]
\(^{7}\) [https://ec.europa.eu/info/strategy/2020-2024-forest-action-plan/forest-action-plan_en]
\(^{8}\) [https://ec.europa.eu/info/strategy/2020-2024-forest-action-plan/forest-action-plan_en]
\(^{9}\) [https://ec.europa.eu/info/strategy/2020-2024-forest-action-plan/forest-action-plan_en]

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Air, water and soil pollution is reduced to levels no longer considered harmful to health and natural ecosystems and that respect the boundaries our planet can cope with, thus creating a toxic-free environment.

The ZPAP complements other strategy areas, including climate-neutrality, the circular economy and restored biodiversity goals. It also contributes to the UN 2030 Agenda for Sustainable Development, specifically Sustainable Development Goals (SDGs) 3, 6, 11, 12, 14 and 15. Its main objective is to include pollution prevention in all relevant EU policies, maximising synergies in an effective and proportionate way.

2.1.3 The Chemicals Strategy for Sustainability

The Chemicals Strategy for Sustainability (CSS) is a key component of the EGD. Its aim is to better protect citizens and the environment from harmful chemicals, and boost innovation by promoting the use of safer and more sustainable chemicals. The CSS states: 'In order to develop and deploy the sustainable chemicals that enable the green and digital transitions and to protect the environment and human health, [...] innovation for the green transition of the chemical industry and its value chains must be stepped up and the existing EU chemicals policy must evolve and respond more rapidly and effectively to the challenges posed by hazardous chemicals. This includes ensuring that all chemicals are used more safely and sustainably, promoting those chemicals having a chronic effect for human health and the environment - substances of concern - are minimised and substituted as far as possible, and phasing out the most harmful ones for non-essential societal use, in particular in consumer products.'

It also highlights the need 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 the EU’s cornerstones for regulating chemicals.'

2.1.4 Other initiatives in the CSS and associated studies

To fulfil the toxic-free environment ambitions outlined in the European Green Deal and in the aligned CSS, a series of thematic studies are being undertaken by the European Commission. These are associated with a number of proposed reforms to the REACH Regulation. These are closely linked to the extension of the GRA and reforms to restriction and authorisation that are the focus of this report. The studies are summarised below. Coherence between the studies is ensured via a coordinating study: ‘Scientific and technical support to the impact assessment for the proposal for revision of REACH’. The results of these studies will feed into the European Commission impact assessment accompanying the REACH revision.

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[2] Page 2
2.1.5 UN Sustainable Development Goals

Revising the REACH Regulation is an opportunity to ensure that the functioning of the REACH Regulation helps deliver on the UN SDGs. The objectives of REACH link closely to the following goals:

- 3 - Good health and well-being: 6 - Clean water and sanitation: 14 - Life below water: 15 - Life on land
  - Hazardous chemicals and pollutants are continually produced, used, and released in significant quantities rendering them ubiquitous in humans and the environment.

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the environment. Costs of inaction (including the burden of disease from chemical exposure) and the benefits of minimising adverse impacts emphasise the need to act on chemical pollution at a global scale.

- Revision of the REACH Regulation intends to help minimise future impacts of chemicals in the environment, whether that is on land or in water, and on human health and wellbeing. The second REACH review also noted that REACH had influenced chemicals policy outside of the EU.

- 11- Sustainable cities and communities; 12 - Responsible consumption and production

- Many chemicals have the propensity to accumulate in both humans and the environment. It is this mode of action, paired with the continued growing use of chemicals in materials, articles and products which highlights the need to avoid legacy effects through sustainable management, consumption and production of chemicals encouraging circularity at the design stage.

- With global supply chains becoming increasingly complex, the sound management of chemicals by companies and organisations adhering to the REACH Regulation will contribute to the broader global goals of resource efficiency, sustainability, and waste reduction.
3 What is the problem and why is it a problem?

This section provides extensive analysis of the problems encountered with REACH processes to date. It also highlights where those processes have delivered significant benefits. Readers familiar with the conclusions of the second REACH review in 2018, for example, may wish to proceed directly to the visual problem trees in section 3.1.2.

3.1 Problem definition – key messages

<table>
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<tr>
<th>The evidence indicates that both REACH authorisation and restriction are meeting their objectives. However, two central problems have been identified:</th>
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<tbody>
<tr>
<td>• First, the authorisation process is complex, slow, and costly. It places a high administrative burden on authorities at several stages of the process and on companies. Improving its efficiency could accelerate decision making, hence improving the risk management of SVHCs at a faster rate and increasing the overall level of protection to human health and the environment, while reducing administrative costs.</td>
</tr>
<tr>
<td>• Second, the current Article 6(1) restriction process places a high burden on authorities and is proving too slow to adequately protect both consumers and professionals from the risks posed by several classes of chemicals.</td>
</tr>
<tr>
<td>These problems reflect various interrelated sub-problems. These include:</td>
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<tr>
<td>• Practical challenges in authorisation procedures have occurred in two key dimensions. First, complex “cotinine applications” submitted with broad scope applied for covering a large number of downstream users have created a significantly greater workload than expected, particularly for authorities. Second, applications from downstream users, although their assessment is usually technically more straightforward, have resulted in a large number of similar applications with a relatively limited scope. This has placed a significant burden on opinion forming committees and decision-making authorities more generally.</td>
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<tr>
<td>• Concerns have arisen of negative effects to SMEs and a lack of a level playing field for EU companies, because authorisation requirements do not apply to articles imported to the EU.</td>
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<tr>
<td>• Constraints on technical resources in Member States, the European Commission and ECHA, including Committees as well as deficiencies in some of the applicants have meant decision making for both authorisation and restriction has been slow. These issues have also adversely affected the rate at which substances have been added to the Candidate List and Annex XIV.</td>
</tr>
<tr>
<td>• Restrictions have proceeded at a slower pace than expected and requirements for Article 6(1) restrictions are resource intensive and technically challenging for authorities.</td>
</tr>
<tr>
<td>The context for the above problems includes:</td>
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<tr>
<td>• A higher level of ambition for human health and environmental protection envisioned in the EGD, ZPAAP and CSR than when REACH was established in 2006.</td>
</tr>
<tr>
<td>• Evidence of significant damage occurring from several classes of chemicals that are a) associated with various human health and environmental harms, b) that are used extensively in the EU and EEA by professionals as well as consumers, and c) that persist and accumulate in the environmental compartments and/or the human body and which are difficult or impossible to reverse after release.</td>
</tr>
<tr>
<td>• As a consequence of the complexity and slow progress in the implementation of authorisations and restrictions and the corresponding administrative burden, the protection of human health and the environment has not progressed at a satisfactory speed. For example, evidence suggests that average benefits of restrictions in terms of risk reduction (or avoided damage to human health and the environment) have exceeded their costs by a ratio of four to one, hence why increasing the speed of decision making is considered important.</td>
</tr>
<tr>
<td>The above challenges are expected to persist in the absence of reforms to the REACH Regulation to more efficiently and effectively address the risks posed by chemicals.</td>
</tr>
</tbody>
</table>
3.1.1 What is the problem?

3.1.1.1 Overview of the problems identified

The Inception impact assessment (IIA)\(^1\) provides an initial summary of several problems and drivers that a targeted revision of REACH aims to address. These seek to be addressed by the reform of REACH and are covered in several technical studies. Below, we summarise those most relevant to the current study.

3.1.1.1.1 Complexity and burden associated with authorisation processes

Specific problems have been identified in the authorisation process that need to be addressed. These have impacted industry, Member States, ECHA and the European Commission. The IIA concludes that "The authorisation procedure is too heavy and inflexible. The authorisation process has imposed a heavy burden on both companies and authorities. A multitude of applications for the use of small quantities of substances, unclear criteria for authorisation and information gaps (for uses where competent authorities have already implemented alternatives), as well as unclear information in applications (in particular from applicants up the supply chain and from only representatives), have led to prolonged discussions and delays in decision making. In many cases, this has placed EU-based companies at a competitive disadvantage compared to their non-EU competitors".

3.1.1.1.2 Speed of restriction processes and level of protection

In terms of restriction, a key issue is the need to increase the speed of introducing restrictions and hence increase the level of protection, as per the higher level of ambition set out in the EGD and CSS. The IIA states "The current restriction process is too slow to sufficiently protect consumers and professional users against risks from the most hazardous substances. The normal restriction procedure, through specific risk assessment, puts a high burden on authorities to document unacceptable risk for health or the environment. Although REACH already enshrines the use of a generic approach (i.e., assuming that the use constitutes a risk) for restricting certain carcinogenic, mutagenic or toxic (CMR) substances in consumer products, this procedure cannot be used for other critical hazard classes including endocrine disruptors, persistent, bioaccumulative and toxic (PBT/vPvB) substances, immunotoxins, neurotoxins, respiratory sensitisers or substances that affect specific organs. Moreover, professional users\(^2\) are often using the same products as consumers, but much more frequently and during longer periods of time. Yet, they are unlikely to benefit from the same risk management as in industrial settings. Hence, they should get a level of protection at least at the level of consumers\(^3\)."

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\(^2\) Note: while not quoted in the CSS, this would increase the protection of vulnerable groups, such as hairdressers, if pregnant women were risk assessed at work (e.g., hairdressers).
\(^3\) Inception impact assessment, Annex (2021)126/0333
3.1.1.2 Evidence for the problems identified

This section summarizes the evidence supporting the above problems.

3.1.1.2.1 Levels of protection must be increased to meet the EGD and CSS ambitions and current processes are not efficient.

The second REACH review comprised various supporting documents and technical studies. Whilst this body of information is now several years old, it remains the most comprehensive information on the overall functioning of the REACH Regulation at the time of writing. Many specific actions and objectives identified from the second REACH review have been adopted and several important processes in REACH have changed since its publication in 2018. However, several fundamental problems remain. At the same time, since the second REACH review has been published, the objectives of the European Commission, the level of ambition for health and environmental protection in the EU and EEA, specified in the EGD and CSS, have increased. This section specifies several problem drivers identified in the second REACH review along with supporting evidence.

This evidence is based on the above supporting studies, the REACH review Staff Working Document (SWD), the EGD and CSS. This has been supplemented by stakeholders views gathered via two specific workshops on authorisation and restriction reform, held with Member States both online and in Slovenia on 5 November 2021 and with other stakeholders online and in Brussels on 12 November 2021. A public consultation between 20 January 2022 and 15 April 2022 was also undertaken. This public consultation covered several areas for potential reform to the REACH Regulation that are examined in several different studies (Table 5). As part of this study, another smaller, targeted consultation was undertaken via a survey instrument and in-depth interviews with industry, Member State Competent Authorities (CAs), ECHA and NGOs in May 2022. These focussed only on the potential extension of the GRA and reforms to authorisation and restriction. A further
stakeholder workshop was held on 27 May 2022 to present emerging findings from the study concerning the extension of the GRA.

The key findings from the second REACH review were noted in the European Commission General Report Conclusion and Actions (SWD (2018) 59 final)\(^2\). Several of these are summarised below and, together with the EGD, the CSS and other inputs, provided a basis for consideration of the implementation of the GRA and revisions to authorisation and restriction processes. In a workshop with representatives from industry, NGOs, trade unions, public authorities, and other stakeholders held in November 2021, there was an overall consensus on the need to revise the current authorisation and restriction procedures\(^3\). A report from the European Environmental Bureau published in 2022 was critical of the time taken for action on chemical substances through REACH\(^4\).

In terms of the achievement of objectives, REACH is delivering results but the speed of progress towards the objectives is lagging initial expectations. The authorisation and restriction processes impose significant costs, both to industry and authorities. The main costs to industry are compliance costs associated with the preparation of Applications for Authorisation (AfA) and from the requirements of Articles 68(1) and 68(2) restrictions. These processes result in costs to authorities arising at various steps with two main implications. First, they take up resources (primarily the time of specialist staff) in the European Commission, ECHA and Member States, including technical committees. This adversely impacts the speed of regulatory decision making and hence of achieving the expected level of the environmental and health protection. Second, the resources spent on these processes create an opportunity cost; those resources cannot be used in alternative activities, such as developing additional restrictions\(^5\).

Member States endorsed this overall description of the problems identified, in a workshop held in November 2021. They agreed on the necessity to accelerate the substitution of hazardous chemicals in the EU and that strengthening incentives for faster substitution of the most harmful substances was important\(^6\). A workshop with representatives from industry, NGOs, trade unions, public authorities, and other stakeholders held in November 2021 similarly stressed the importance of "problems due to the slowness of the authorisation and restriction processes"\(^6\). Targeted interviews with NGO, public authorities and industry representatives also identified a need to simplify the authorisation system and reduce the burden (including from high numbers of individual applications for very similar uses)\(^7\). These put a high resource demand on ECHA Committees and the European Commission. Therefore, a simplification of the authorisation process or reduction in the number of individual applications for authorisation could increase the speed of the process and help relieve decision making bottlenecks.

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\(^2\) https://ec.europa.eu/growth/content/2018-06-07/growthbrief-12nov2022_en

\(^3\) European Commission "Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses and to reform REACH authorisation and restriction, Stakeholder workshop report, 12 November 2021.

\(^4\) https://eeb.org/guides/need-for-speed-on-chemical-regulations-in-europe/


\(^6\) European Commission "Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses and to reform REACH authorisation and restriction, Member States workshop report, 9 November 2021.

\(^7\) European Commission "Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses and to reform REACH authorisation and restriction, Stakeholders workshop report, 12 November 2021.

\(^8\) Targeted stakeholder interviews, National Competent Authorities, NGOs and industry, May 2022.
3.1.1.2.2 Further action is required to increase the speed of decision making and reduce administrative costs

Numerous opportunities and actions were identified as a result, and these have influenced the development of the options assessed in the current study. These are summarised below.

**Simplification of Authorisation and Restriction Process – opportunities and actions identified**

The second REACH review identified specific shortcomings of REACH and several areas "requiring the most urgent action". These related to inefficiencies in its operation. It noted that the authorisation process needed to be simplified and to ensure a level playing field between EU companies and importers of products produced by non-EU companies. This reflected concerns that current authorisation requirements could be harming competitiveness of EU companies, because authorisation requirements do not apply to articles imported to the EU where SVHCs are not present in the final product. This could be achieved via subtracting imported articles to authorisation requirements, more effective restrictions and enforcement, while clarifying the interface between REACH and other EU legislation, in particular Occupational safety, and Health (OSH).

Any such simplification should not impair reductions in the level of protection of human health and the environment.

As such, further efficacy in the implementation of the authorisation system was needed, further reductions to the administrative burden and greater certainty for companies applying for authorisation, particularly Small and Medium-sized Enterprises (SMEs) was required. Member States agreed these issues posed problems during the November 2021 workshop. Similarly, participants in a wider stakeholder workshop on 12 November 2021 also identified inefficiencies in the current authorisation system as a key problem.

Resource constraints in Member States, the European Commission and agencies have affected activities under authorisation and restriction. These constraints have "reduced the number of substances that are assessed and registered and has slowed down progress". Further improvements in the efficiency of the restriction system were also identified, although some focus was placed here on an authorisation. The meeting also concluded the interface between REACH and OSH legislation needed to be improved, which "calls for systemic solutions to address the main overlaps and discrepancies".

Several opportunities and actions were identified aimed to address the shortcomings:

- Slow progress of risk assessment and implementation of risk management for existing substances. The restriction and authorisation processes need to be implemented more efficiently and with quicker decision making.
- The SVHC roadmap and early assessment of possible regulatory measures through a voluntary regulatory management option assessment (VARMA) had proved to be an effective tool to identify and manage risk associated with “known relevant SVHCs”.
- The existing authorisation process is an effective driver for substituting SVHCs along the supply chain. But practical challenges and concerns were identified. Efforts to further simplify the process should continue, with a focus on clarifying the requirements and providing greater predictability to applicants. This would involve closely monitoring and addressing difficulties raised in applications for authorisation covering multiple operators (Action 6) and consideration of options to develop and use early socioeconomic information for possible regulatory measures (Action 7).
- Since the second REACH review was published, several actions have been taken forward, but the need for further improvements has been noted subsequently. For example, Member States at a November 2021 workshop noted that there was insufficient information exchange between applicants for authorisation and alternative providers in the existing system.2
- Challenges with the interplay between authorisation and restriction were also raised in the second REACH review. Action 11 requested ECNA to consider “systematically preparing restriction database.

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2 European Commission, "Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform REACH authorisation and restriction: Member States workshop report, November 2021."
3.1.1.2.3 Candidate listing and inclusion in Annex XIV is effective, but progress is too slow.

An SVHC Roadmap\textsuperscript{17} was introduced in 2012 in collaboration with ECHA and the European Commission in response to perceived slow progress on Candidate Listing prior to 2012. At the start of the SVHC Roadmap in 2012, the Candidate List contained around 140 substances. In the decade since, around 70 more entries were added, for which a voluntary Regulatory Management Option Analysis (RMOA) has been undertaken. RMOA was judged to be an effective tool which had increased transparency and predictability for industry\textsuperscript{18}. Participants at a workshop with representatives from industry, NGOs, trade unions, public authorities, and other stakeholders held in November 2021 endorsed that it should continue to be used\textsuperscript{19}.

The implementation of the SVHC Roadmap was concluded to have improved coordination and efficiency, via a common screening approach and joint undertaking of RMOAs. This also helped efficient development of Annex XV dossiers for the identification of SVHC (as well as the development of restriction proposals), as they improved knowledge of the substances, hazards, and exposure\textsuperscript{20}. A total of 211 substances (or groups) had been identified from 2008 to 2020, with the majority (139) of these being CMRs (Figure 1, Figure 2).


\textsuperscript{18} Since 2013, the SVHC Roadmap 2020 sought to identify substances of very high concern (SVHCs) and manage their risks where required. The objective was to identify necessary lower SVHCs and include them on the Candidate List by 2030. It sought a consistent, transparent, and efficient approach for identifying and addressing SVHCs. As part of this approach, ECHA and Member States began to systematically screen registered substances and use RMOAs to decide whether regulatory action was needed and if so, the most appropriate ways to manage their risks.


\textsuperscript{20} European Commission "Study to support the impact assessment for potential amendments to the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform REACH authorisation and restriction, stakeholders' workshops report, 22 December 2021.


\textsuperscript{23} By 2021, 24 RMOAs had been carried out on these substances, which had increased to 139 by 2021. Of those judged to be best addressed under REACH, 24 were addressed via authorisation and 6 via restrictions. For other substances, it was concluded that no regulatory action was needed at the time. COM (2018) 116 Final Annex 4 (Table 4.7).
Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction

Figure 1: Substances or group of substances included in the Candidate list (2008-2020)

Figure 2: Hazard properties of all substances or groups of substances identified in the Candidate List (2020)

It was originally expected that 137 substances would be added to the Candidate List by 2010, with a further 25 added per year\(^1\). The actual numbers of substances added to the Candidate List were lower and the rate slowed between 2013 (13) and 2016 (5)\(^2\). The reasons for this included that many of the remaining cases were more complex (for

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\(^1\)See COM (2016) 116 Final Annex 4 (Table 4.8)
\(^2\)See COM (2016) 116 Final Annex 4 (Table 4.8)

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
example with PBTs, vPvBs, where more detailed RMOA dossiers and, in some cases, generation of new data would be required; non-compliance of many registration dossiers and lack of data in the dossier; and a lack of newly classified CMR and other substances under the CLP Regulation, reflecting a lack of resources to develop new harmonised classification and labelling (CLH) dossiers. It was originally expected that the first Annex XIV entries would start in 2011 with eight substances, that 12 more would be added in 2012 and 25 per year thereafter.\(^\text{[9]}\)

As of June 2017, Annex XIV contained 43 substances, but decisions on several more were postponed (for example, more recent information on Annex XIV substances is in the baseline in section 6.2). The postponements were driven by several factors, which had adversely affected the resources that could be allocated to processing applications for authorisation (and other activities) at ECHA and Member State level. Specifically:

- Experience with complex applications for authorisation that covered a broad range of downstream industries submitted by upstream operators (manufacturers and importers), the so-called “upstream applications”, revealed important challenges with the process. The main reason for these complexities and challenges was the very broad uses applied for, as well as uncertainties on the level of details required for such upstream applications.
- ECHA’s workload was substantially greater than expected, driven by the number of such complex authorisations, which compounded the problem.

Other decisions on inclusion in Annex XIV were postponed, as it was not clear whether authorisation or restriction were the most appropriate regulatory process to address the risk.\(^\text{[10]}\)

The REACH review found evidence that the inclusion of substances into the Candidate List or in Annex XIV functioned as a driver for at least some companies to engage in substitution. A 2015 survey found that 19% of companies responded to the placing of a substance on the Candidate List by launching research and development activities (R&D) to develop new substances. 35% launched initiatives to find alternative formulations of existing substances and 24% requested a substitution from the supplier. The response of companies to inclusion of substances in the Authorisation List was similar.\(^\text{[11]}\) Note more recent data on the effects of authorisation and restriction is in the baseline in section 6.2.

In summary, the evidence indicates inclusion on the Candidate List acts as a driver for substitution and is perceived as an effective tool. Despite concerted effort, the rate of substances added to the Candidate List remains slower than expected. This has been compounded by the increasing complexity of the substances being added as well as resource constraints in authorities developing CLH dossiers. Other resource pressures (particularly associated with the burdens from the authorisation process) have compounded delays in the addition of more substances both to the CL and to Annex XIV.

During the November 2021 workshop, Member States noted that generating a clear understanding of uses and exposure earlier in the process, for example at Candidate Listing stage, may help

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\(^{[11]}\) See COM (2016) 116 final Annex 4, via a survey conducted in the study to monitor the impacts of REACH on innovation, competitiveness, and SMEs.
facilitate identification and prioritisation of risks and allow exchange of information on alternatives earlier in the process\(^2\).

3.1.1.2.4 Implementation of the authorisation process has resulted in problems

Overall, the second REACH review concluded that the authorisation process\(^3\) had contributed to the progressive replacement and eventual phase out of SVHCs. Moreover, the process ensures that the risks are better identified and properly controlled when SVHCs are used in authorised uses\(^4\). Many companies have also reduced usage or substituted SVHCs. For example, no applications were received for over half the SVHCs on Annex XIV, suggesting these are no longer used or have been substituted\(^5\). Several measures to improve the authorisation process and make it more predictable for applicants have been undertaken since the publication of the first REACH review\(^6\). However, several related issues remain problematic\(^7\).

**Issue 1: Upstream applications for authorisation have proved challenging and burdensome**

Specific challenges had been encountered with applications submitted by upstream operators in the supply chains. This has both increased the time taken to make decisions and affected the quality of those decisions, with concerns raised by Member States, Non-Governmental Organisations (NGOs) and the European Parliament and with the first cases of case law. Two particular weaknesses of such “upstream” applications were identified:

- Lack of representativeness of the data supporting the exposure assessment for all the companies covered by the applications. This made assessing risks to workers particularly challenging. This, in turn, reflects challenges in collecting such data from downstream users and in setting conditions for granting authorisations by authorities.
- Too broad description of uses in the applications, including sub-uses or utilizations with different substitution profiles and possibilities, where the substances are used in several different sites, in different sectors and in different articles. This makes the analysis of alternatives overly complex and challenging to prepare and assess\(^8\).

**Issue 2: Downstream applications for authorisation for certain uses have also proved inefficient and burdensome**

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\(^{2}\)European Commission "Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform REACH authorisation and restriction", DG Environment and Maritime, 2016.

\(^{3}\)Authorisations are granted if the applicant can demonstrate that the risks posed by the use of the substance is adequately controlled (Article 12 of REACH). If not, an authorisation may still be granted if it is demonstrated that the socio-economic benefits of using the substance outweigh the risks to human health or the environment and that there are no suitable alternative substances or technologies (Article 12(4) of REACH).

\(^{4}\)See COM(2018) 136 final, Annex 6, Page 6

\(^{5}\)European Commission "Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform REACH authorisation and restriction", DG Environment and Maritime, 9th November 2021.

\(^{6}\)This includes eliminating the frequency of amendments of the Authorization list, simplifying the authorization process for some specific uses (e.g., in legacy cases) and consideration of socio-economic impacts when excluding new substances in the Authorization list.

\(^{7}\)European Commission "Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform REACH authorisation and restriction", DG Environment and Maritime, 9th November 2021.

\(^{8}\)See COM(2018) 136 final, Annex 6, page 87. Further guidance was published to aid development of the description of uses, of the representative exposure scenarios, and on the socioeconomic analysis to try and mitigate risks.
Where downstream users applied individually, while the assessment and decision-making processes were often relatively straightforward, but this resulted in a large number of individual applications for the same or very similar uses. These often related to small volumes of controlled substances (e.g., some uses in medical applications) generating limited risk reduction at the EU level, compared to the burden associated with the processing of applications. For example, some 50% of the uses applied for, as of March 2017, related to Chromium VI compounds. As of March 2022, applications related to uses of chromium trioxide accounted for over 25% of all received applications and accounted for 78% of costs. Similarly, applications for uses of 4-(1,1,3,3-tetramethylbutyloxy)phenol, ethoxyxylated, accounted for a further 21% of applications and a similar proportion of RAC and SEAC applications. This is not judged to be an efficient use of the time of specialists in the ECHA, RAC and SEAC, and expensive and time consuming for applicants.

The problems described above were endorsed by Member States in the November 2021 workshop. In addition to the problems identified, the basic trigger for the potential number of applications is dependent on what substances (and what uses, if any) have been included in Annex XIV and whether authorisation was the most appropriate regulatory tool.

**Issue 3: Costs to all stakeholders from authorisation processes are high**

Applications for authorisation are complex and time consuming, with extensive data needs and complex analysis (e.g., exposure assessments, analysis of alternatives etc.). Whilst the average cost of applying for authorisation decreased from EUR 220 000 (on average per substance, use and applicant for the first applications in 2015) to around EUR 120 000 in 2016, they remained high for individual companies (note more recent data obtained via ECHA provide further breakdown of these costs, by use and the levels of complexity of the application. See baseline in section 6.2).

Direct costs for companies applying for authorisations include the fees to ECHA (typically accounting for between 19% to 20% of the overall costs). But the largest source of costs is associated with the preparation of the application, including the costs of technical analysis, often prepared by consulting companies.

There are further follow-up costs for companies, including those from compliance with the conditions set out in the granted authorisations, which are often nontrivial. R&D costs, adaptation of the production processes and costs associated with implementation of the

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10 European Commission: Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform REACH authorisation and restriction, Member States workshop report, 9 November 2021. See also Background paper: Workshop on the reform of the REACH Authorisation and Restriction System, Ankara (2018) 96585, 29 November 2021.


12 European Commission: Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform REACH authorisation and restriction, Member States workshop report, 9 November 2021.

13 See COM (2018) 8 Final Annex 4, page 107. Note there are reduced from the SMEs. The source data does not specify the equivalent figure for SMEs.

14 Experience with authorisation to date has resulted in efficiency gains, as authorities and applicants gained experience with the process and vice versa (e.g., gained by 2016 and beyond). Whilst the data indicates a sharp decline in typical costs per applicant per use from 2013 to 2015 (which largely stems from a lower average cost for the preparation of the analysis of alternatives), there was only a much smaller decreases in average costs from 2014 and 2015. See COM (2018) 116 Final Section “Authorisation”, figure 4 on page 77.
alternative(s), where these were adopted, are also incurred. These costs are unlikely to be included in the cost estimates above.

The costs of applications can be shared between the various applicants when applying jointly. Upstream applications can be submitted either by one applicant or several, sharing costs in the latter case. While some of the most complicated joint "upstream" applications submitted had a large number of applicants, they were extremely expensive. They were estimated to cost some EUR 2 million for the preparation and submission of the applications, with a further EUR 2 million on consortium management. This reflects the size and complexity, but also the challenges in processing and decision-making. This estimate excludes the associated resource burden and challenges in decision making for authorities. These costs for upstream applications reflect various complexities, which differ case by case. This has led to potentially very broad uses applied for, comprising vast numbers of specific sub-uses, even for the same substance and "use". This in turn meant different alternatives (since there were different substitution profiles within one use applied for) and risk management measures needed to be considered. There have also been different effects from substitution on end product functionality in each case. Assessing whether such differences in functionality are merely "acceptable" or seriously hamper (e.g., safety), is challenging and time consuming both for applicants and for authorities. Furthermore, assessing the costs and benefits of specific uses is time consuming and technically challenging.

These issues are considered to be one of the central reasons for delays in decision making, with knock-on effects for the realisation of benefits and the ability of ECHA, in particular, to progress with other issues, including the development of Annex XV restriction proposals (discussed further below). They are also considered to be one of the reasons why industry has been arguing in some cases, in favour of using OSH and/or restriction for a particular substance, rather than the authorisation process, given their lower administrative burden for companies.

Issue 4: Greater certainty for industry may improve outcomes

The REACH review notes that "from industry's perspective, the biggest cost driver is the uncertainty about the future legislative requirements for the substances that companies manufacture or use. Such uncertainty arises already at the stage of placing a substance on the Candidate List and is in general associated with potential negative effects on investment decisions and/or the choice by companies on where to locate their production facilities". The review acknowledges evidence of this is anecdotal.

The number of substances included in Annex XIV were fewer than expected (43 substances by June 2017, compared to a baseline assumption of 120 by 2016).

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15 See COM(2018) 136 final Section "Authorisation", Page 76 and 77. However, it must be noted that the alternative would be re-authorisation and higher costs in terms of sharing out the substance, releasing mutual benefits the EU, or obliging the business (or affected product line). Hence, these avoided costs are effectively the downstream benefits of the authorisation. Similar data and benefits are also derived by these companies who do not apply for authorisation via sharing out the SVHC.


17 Background paper Workshop on the reform of the REACH Authorisation and Restriction System, Annex (2021)6676028 – 29/11/2021. Some workshop participants considered that the background paper was an accurate overview of the problems encountered, but this statement was not made by participants directly.


Applications for authorisation were received for only 68% (21 of the 31) of the substances in Annex XIV (2017 data), suggesting phase out or substitution in whole or in part for the remaining 10. However, even where substitution was not possible, the second REACH review identified that the authorisation process typically resulted in improvements in their risk management and, in turn, to reduced occupational and environmental exposure, even where use was authorised to continue. As of May 2022, the number of entries stood at 59 and at 24 entries in Annex XIV, no applications for authorisation were received in most of the applications for authorisations assessed, the applicants requested time to substitute the SVHC with a safer alternative(s). The REACH review indicated that about a quarter of the opinions related to so-called “bridging” applications, where the applicant had identified its substitution strategy and applied for a specific period, identifying when the substitution would take place.

Issue 5: Current processes may have contributed to contested decisions

The process has also resulted in several contested decisions as well as court cases. This has compounded the costs, complexity, delays in authorisation decision making, and uncertainty for industry. These included:

- Case T-637/16 Sweden vs. Commission: which challenged the decision granting an authorisation for uses of lead sulfochromate yellow 546 and lead chromate molybdate red. The decision granting an authorisation was annulled mainly due to the uncertainties of the assessment of the alternatives which were not considered by the Commission in its decision. This judgment was appealed in certain points by the Commission, and the Court confirmed that judgment (Case C-399/19P Sweden vs. Commission).

- Case T-106/17 Client Earth vs. Commission: challenging the response to an internal review of the decision to grant an authorisation for uses of DEHP in Polyvinyl chloride (PVC). The request was dismissed, and this was confirmed in an appeal case brought by Client Earth (C-458/19 P).

- Case T-346/17 Client Earth against the Commission on lead chromate pigment authorisation, challenging the response to an internal review request.

- Case C-144/21 European Parliament vs. Commission, challenging the decision to partially grant an authorisation of chromium trioxide ("CT_Chemservice")

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53 See COM (2019) 116 final, section 5.6
54 https://europa.eu/eya/about/curia_entractor/epdf_getDoc?docid=246643&pagelndex=0&dodang=EN&mode=req&dfr=&occ=first&part=1&d=3023810
due to the uncertainties in the risk assessment and of the analysis of alternatives. The case is ongoing.

**Issue 6 - Stakeholders have raised other process concerns**

- Some applications for authorisation affect only a small number of companies, sometimes operating in only one Member State, where the use is associated only with localised risks. In these cases, it is questioned whether the subsidiarity principle is met and the involvement of European institutions is proportionate. Member States in the November 2021 workshop were not in favour of national level authorisation to ameliorate these issues, given the adverse effects on the Internal Market and likely increase to the administrative burdens of national authorities.

  Stakeholders in a similar workshop on 12 November shared the same concerns but noted potential benefits for SMEs in streamlined procedures and faster decision-making.

- Information presented in the second REACH review also suggested some stakeholders viewed applicants who applied later for such substances/uses were unfairly able to benefit from the lessons of those that applied earlier.

- More generally, NGO stakeholders have criticised the public third-party consultation process under authorisation as it unfairly prioritises the interests of applicants over those producing possible alternatives. NGOs argue that this penalises those companies that have substituted SVHCs without applying for authorisation at all. In contrast, many applicants consider the extent of additional information required by ECHA committees at the opinion forming stage to be excessive and unnecessary.

**Issue 7: Despite these challenges, the authorisation process has resulted in significant benefits**

In terms of socioeconomic effects of the authorisation decisions themselves, the "benefits", where authorisations are granted, correspond to avoided costs for industry (opportunity costs borne by society) if the applicant could no longer use the substance in the use applied for. Costs in this context are the expected damages to humans or the environment that would occur from an unauthorised use, before that substance and use was substituted for an alternative. A refused authorisation results in the removal of the affected SVHC quantities from the market immediately upon the notification of the refusal decision, with the associated compliance costs borne by industry. Analysis of authorisations granted for the first 30 uses (of a total of 17 substances) indicates that on average such benefits were expected to amount to between EUR 32 and EUR 38 million, per applicant, per use. The average application cost noted above therefore represents 0.2% of the avoided costs (benefits) per applicant, per continued use. However, the review noted costs for applying

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92 Background paper: Workshop on the reform of the REACH Authorisation and Restriction System, Maastricht, 9 November 2021.
93 European Commission: Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses and to reform REACH authorisation and restriction, Member States workshop report, 9 November 2021.
94 European Commission: Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the generic risk management approach to further hazard classes and uses and to reform REACH authorisation and restriction, Stakeholders workshop report, 12 November 2021.
95 See COM (2016) 116 final Annex 1
may still be significant for SMEs19. A more detailed assessment of 60 uses in a study on the impacts of authorisation for ECHA indicated benefits of continued use amounted to between EUR 4.6 billion to EUR 6.4 billion, per year16 of up to 366 tonnes of 17 different substances. This corresponded to monetized risks of between EUR 230 to EUR 340 million per year from continued use15.

In summary, the authorisation process has led to an accelerated reduction and progressive phase out of SVHCs. Where they are used by companies who hold an authorisation, the risks are better controlled. However, so-called “upstream” applications have revealed significant problems. Downstream users applying individually have also submitted large numbers of applications for the same or very similar uses, often for small volumes. Both these approaches have incurred significant burdens to industry and to authorities in data collection, clarification and in decision-making. This burden has impacted progress on other regulatory activities. Based on the above, the REACH review concluded that simplification of the authorisation process required urgent action. This action should “further streamline and simplify the process with a view to reducing the administrative burden, particularly for SMEs”, clarifying requirements and making the process more predictable16.

3.1.1.2.5 Restrictions have delivered benefits, but the number implemented has lagged expectations

REACH restrictions are a key regulatory “safety net” for managing the risk from chemicals in the EU. They have provided a structured approach to addressing unacceptable risks arising from the manufacture, use or placing on the market of substances, under Article 68(1). Restrictions can target distinct aspects; for example, some restrictions relate to conditions (e.g., training, warnings, limits), or prevent the placing on the market of specific uses, leaving others unaffected (where risk is not deemed unacceptable). In addition, restrictions of CMR substances, Category 1A & 1B, on their own, in mixtures and in articles based on generic risk management under Article 66(2) have shown to be a powerful tool for the protection of consumers.

The second REACH review concluded that the restriction process for substances and groups had contributed to lowering human and environmental exposure to harmful substances20. However, new restrictions have been proposed and introduced at a slower pace than expected. This was attributed to a lack of information to identify appropriate candidates, alongside a burden on authorities that dis-incentives Member States from making restriction proposals. There are concerns that this undermines protection of human health and environmental protection and means that the system has been unable to respond quickly to emerging risks20. For instance:

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21 European Parliament and European Council. Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform the REACH authorisation and restriction system. Ares (2021) 6760328 - 26/11/2021
Between January 2011 and December 2016, a total of 13 restrictions (an average of 2.6 per year) were adopted under Article 68(1). This fell well short of the 11 expected per year at the time of the adoption of REACH.

A restriction adopted under Article 68(2) related to four phthalates (DEHP, DBP, BBP and DIBP) in certain articles, submitted in 2016 was adopted in 2018.

Restrictions under Article 68(2) include PAHs in rubber and plastic articles (2013); several newly classified CMR substances and mixtures for supply to the public (entries 28-30). (Note, this has been updated several times and covers a large number of substances); and CMRs in textile articles (the initial proposal was made in 2015 with the restriction adopted in 2018)\(^2\).

3.1.1.2.6 Challenges in Article 68(1) restriction procedures and experience to date with Article 68(2)

The underlying reasons for the slower pace of Article 68(1) restriction proposals include challenges in data availability for risk assessment and prioritisation for authorities, who bear the burden of proof in preparing restriction dossiers\(^2\). This in turn reflects a general lack of data on the substance’s use and exposure contained in registration dossiers. While improvements have been made via the Restrictions Task Force (RTF), development of an Article 68(1) Annex XV (restriction) dossier is still considered by some Member States to be technically challenging. It requires large amounts of data, and typically receives challenging reviews/critique and requests for further analysis from ECHA Committees during opinion making stages. Several Member States and NGOs noted that conformity checks were overly strict, and the level of evidence required in a restriction proposal was too high\(^2\). Member States in the November 2021 workshop\(^2\) agreed that the demonstration of uncontrolled risk in restriction dossiers, as per Article 68(1), was highly complex and time consuming.

The cost of preparing an Article 68(1) restriction was estimated by one Member State to be between EUR 0.5 and 1 million\(^2\). Other estimated costs for a “particularly complex” dossier for PFOA of 2.5 Full Time Equivalents (FTE) per year plus EUR 635,000 in consultancy support. The corresponding costs estimated by ECHA for the development of an Annex XV dossier amounted to 1 FTE per year, alongside the costs of approximately EUR 65,000 for consultancy support per dossier (depending on its complexity)\(^2\). Note this is discussed further in the baseline in section 6.2.

Dossiers prepared by ECHA need to be submitted within one year of notification of intention under Articles 68(1), (2) and (4) of the REACH Regulation. Member States may take longer...
and notify 12 months before submission\textsuperscript{127}. Reflecting these challenges, only a small number of Member States have initiated the Article 58(1) restriction process (a total of eight), and only four have done this more than once. This was a smaller number than had prepared comprehensive risk assessments in the pre-REACH existing substances system\textsuperscript{109}.

The second REACH review concluded that producers of articles in the EU are at a competitive disadvantage in relation to non-EU producers and EU importers of articles that contain SVHCs subject to authorisation in the EU. In these cases, the introduction of a restriction covering CMRs (Categories 1A and 1B) in consumer articles would prevent the introduction of articles containing these CMR substances into the EU market via the simplified procedure in Article 68(2). This would then provide a level playing field between EU and non-EU companies, but only in the context of consumer articles that contain these CMRs. This approach cannot be used for imported articles intended for professional and industrial uses, and neither can it be used for imported articles containing other substances subject to authorisation due to other hazards (e.g., PBTs, endocrine disruptors). These uses and substances can be restricted via Article 69(2). But that can only apply for those articles where the substance is causing a risk that is not adequately controlled\textsuperscript{107}.

While improving, the Article 68(1) restriction process has also not met original expectations for efficiency. The drafting of Annex XV dossiers is perceived as an excessive burden by Member States, in part due to the lack of specific expertise, namely on the socioeconomic assessment, the costs associated with their preparation and the high number of requests for additional information from ECHA committees. This remains a concern despite a Restriction Efficiency Task Force set up in 2014, with 71 recommendations implemented by Member States, RAC and SEAC and ECHA\textsuperscript{110}.

Reflecting these challenges, there has been increased use of the grouping approach in more recent restriction proposals\textsuperscript{111}. This approach increases the risk reduction potential of any one restriction by expanding the scope of substances (risks) that can be addressed, while seeking to mitigate risk of regrettable substitution. It also increases the efficiency of the process for the dossier submitter, using read across, for example, for the assessment of several substances in the group. Although the analysis required in dossier preparation can be more challenging, the information requirements for the analysis of alternatives and SEA also do not necessarily increase in direct proportion to the scope of the restriction. The benefits of this approach can also include greater certainty for industry, avoiding or mitigating regrettable substitution, avoiding investment developing alternatives that are subject to authorisation or restriction, alongside a level playing field between producers and importers of a substance\textsuperscript{112}.

It is important to note that the second REACH review concluded, based on SEAC analyses, that several broader restrictions (DecaBDE, PFOA and PFBA-related substances) were estimated to have delivered similar levels of cost effectiveness (i.e., cost of avoiding...

\textsuperscript{129} See COM (2019) 316 final, section G.1.
\textsuperscript{130} See COM (2019) 316 final, page 96.
\textsuperscript{131} See for example: https://echa.europa.eu/documents/10162/137474/strategic_theme_assessment_en.pdf/75384735-cd54-42b3-88f9-a376f42e9e8b
emissions, per kilo) to other restrictions, hence the action was considered proportionate to the risk.\textsuperscript{13}

In contrast, Article 68(2) restrictions do not have explicit data requirements, but “practical experience has been that information gathering for restrictions in articles, here too has been complicated and taken considerable time.”\textsuperscript{14, 15} Related to this, a lack of information for grouped restrictions also creates further substantial burdens on authorities and makes determining grounds for derogations more challenging. Efforts to collate improved data via calls for evidence have not always resulted in more detailed information on uses and possible exposures, potentially due to fears of a restriction on those uses as well.\textsuperscript{16}

The second REACH review noted that “application of the ‘simplified’ restriction procedure established under Article 68(2) remains a challenge for consumer articles and, so far used in a limited number of cases when, against the initial expectations, it has not been more efficient than the normal procedure under Article 68(1)”. It should be noted that this reflected specific complexities of the restriction on CMR substances in consumer articles (conditions, nature and duration of contact, concentration limits etc.). The identification of which CMR substances could potentially be present in articles was a particular challenge and slowed down the process considerably. These challenges have been mitigated via the introduction of a systematic approach on when to apply Article 68(2) restrictions and a general approach and criteria for the use of such restrictions.\textsuperscript{17} However, this systematic approach may need to be redefined if the GRA is extended.

The second REACH review also noted further improvements:

- ECHA should act more swiftly in accordance with Article 69(2) and consider the preparation of a restriction dossier (Annex XV dossier) before the sunset date to avoid possible distortion of the internal market and penalisation of European producers vis-à-vis non-European producers of (consumer) articles containing such substances. It should be noted that ECHA increased their work related to Article 69(2) after the second REACH review, but there are still resource constraints given other priorities in the restriction roadmap.
- The need for restriction should be considered in all steps of the implementation of the regulatory strategy (screening, follow-up of the evaluation processes, RMOA) to allow initiation of the restriction work as soon as there is sufficient information available to support the use of this instrument.
- More Member States should be involved (either individually or jointly) in the preparation of restriction dossiers (Annex XV dossier).\textsuperscript{18} Note, after this recommendation was made, several Member States jointly developed the

\textsuperscript{14} Background paper Workshop on the reform of the REACH Authorisation and Restriction System, Nov (2007) 5676073 - 25/11/2011
\textsuperscript{15} Note, the initial and expiry date and there is a clear difference between the PAH/CMR in terms of restrictions and exemptions of newly classified CMR on the other, in the latter case there is an extensive information gathering and analysis phase, this action is triggered by CLP classifications.
\textsuperscript{17} See COM (2018) 336 final, Annex 4, page 13
restriction proposals for DecabDE, PFOS and tattoo inks. Five Member States are currently working on a proposal for a restriction on PFAS, for example.\(^\text{10}\)

The main sources of indirect costs associated with restrictions differ based on the scope of the restrictions itself and the conditions imposed. They can include those caused by the withdrawal of a substance from the market. The main cost drivers of restrictions for industry are substitution of substances with alternatives (or the compliance with the newly set thresholds or concentration limits). Total substitution costs linked to Article 8(1) restrictions were estimated in the second REACH review to be EUR 250 million per year. Variation between cases is however significant, between EUR 0 and EUR 100 million per year, per case. Five of the restrictions contributed to around 88% of the total costs. A total of nine of the restrictions submitted and adopted during the review period under Article 8(1) for the introduction and amendment of new and current restrictions have an estimated cost of approximately EUR 170 million per year. More recent analyses by ECHA published in 2021 indicate that the cost per restriction proposed between 2016-2020 was EUR 6 million per year (median) and EUR 53.3 million per year (mean).\(^\text{11}\)

Similar data are not available for Article 68(2) restrictions of CMRs, given the absence of a restriction dossier and analysis of socioeconomic costs and benefits.

The second REACH review also highlighted key differences in opinion on the merits of using generic (Article 68(2)) or specific (Article 8(1)) risk-based approaches to risk management. Industry generally favoured specific risk-based approaches. Non-industry stakeholders (mostly NGOs) generally wished to strengthen the generic based approach.\(^\text{12}\)

Public consultations undertaken by ECHA on restrictions were also criticised by some stakeholders as being insufficiently publicised, typically available only in English and generating disappointing evidence on alternatives. The number of such consultations are considered a burden and participation in them by SMEs is particularly low.\(^\text{13}\) Some NGOs and Member States also consider that SEAC is overly lenient on those seeking derogations from restrictions and has recommended transition periods that are too long. They argue the information sought to justify such derogations “typically falls below that required for applications for authorisation.”\(^\text{14}\)

The overall conclusion of the REACH review noted that further action to create a “level playing field with non-EU companies” was one of four issues requiring the most urgent action. In addition, it noted that the number of restrictions implemented to date had not met original expectations. While the process has been improved, this constituted a “further issue to address.”\(^\text{15}\)

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3.1.1.2.7 When adopted, the average benefits of restrictions have been around four times their cost

The second REACH review concluded that the expected health and environmental benefits of restrictions amounted to EUR 380 million per year. While not all benefits could be quantified, they heavily outweigh the estimated costs (EUR 170 million per year)\(^\text{126}\). As above, more recent data by ECHA on restrictions proposed between 2016-2020 amounted to over EUR 2.1 billion per year in health benefits (where such benefits could be monetised); an annual reduction of about 95,000 tonnes of substances of concern; and positive health impacts (or removed risk) for over 7 million consumers and workers. In 12 cases where both costs and benefits were monetised, the monetised cost estimates comprised EUR 460 million and the benefits EUR 2.1 billion. As such, the monetised benefits were around four times higher than the costs. Moreover, the costs of restrictions where benefits are calculated in reduced emissions were estimated at EUR 1.1 billion per year, associated with a reduction of about 95,000 tonnes per year. Therefore, the cost per tonne of reduced/avoided emission of hazardous substances was about EUR 12,000 per tonne. The study also compared trends over time and concluded that since 2016, the proposed restrictions have become more costly, but the estimated benefits in terms of monetised health impacts as well as reduced emissions have grown at an even faster rate\(^\text{127}\).

3.1.1.2.8 Authorisation and restriction pose ongoing challenges to SMEs and downstream sectors

The second REACH review noted that the business activity of SMEs had generally been more affected by REACH than larger companies\(^\text{128}\). Most of the quantified costs data for SMEs relate to registration requirements. The review concluded that there had not been enough experience at the time of publication for a full assessment of the impacts of the authorisation process on SMEs, but they appeared to be less affected, both from placing of substances on the Candidate List and the authorisation procedure. However, data from the SME Panel of the second REACH review indicated that the costs of the application for authorisation are a concern for approximately one quarter to one third of participating SMEs and broadly similar figures applied to the restriction process\(^\text{129}\). The review’s conclusion notes caution in this interpretation as these data were based on limited sample sizes.

Data from the public consultation undertaken for the second REACH review noted that one of the issues most frequently raised by the downstream sectors concerned the general complexity and administrative burden related to the authorisation process (as well as to the obligations to communicate information across the supply chain). It also noted “a few examples provided by industry indicating that uncertainty and recurring costs associated with the authorisation process have been an important factor for decisions on whether to locate the manufacture of certain products in the EU or not”\(^\text{130}\). A workshop with industry,


\(^{127}\) https://echa.europa.eu/documents/10162/17228/costs_benefits_reach_restictions_2016_en.pdf/4b1a63e4-5b0c-466a-8169-9b5c8d5c164f

\(^{128}\) See COM (2018) 136 final, section 6.7.2. This reflects that typically larger businesses are better at risk assessment and regulatory staff is better able to assist smaller businesses.

\(^{129}\) See COM (2018) 136 final, p.84.

\(^{130}\) See COM (2018) 136 final, p.84.
NGOs, trade unions, public authorities, and other stakeholders held in November 2021 emphasised the extent of the burden from the authorisation and restriction procedures on SMEs, not just in preparing application for authorisation, but also in complying with conditions in authorisation decisions and in restriction."13.

3.1.1.2.9 Member State resourcing for REACH is an ongoing concern

There are 42 REACH Competent Authorities (CAs) operating in the 27 EU Member States and the three EEA countries (seven Member States have more than one CA).13 The second REACH review notes that while generally satisfied with their technical expertise, some CAs consider that, despite good cooperation between CAs at Member State level, their individual financial and human resources are not sufficient to achieve all activities required under REACH.13. The authorisation process results in costs at various stages, starting with Member States Competent Authorities or ECHA proposing substances for SVHC identification, the inclusion in the Candidate List, and the inclusion of substances in Annex XIV (list of substances subject to authorisation), all of which are drivers of costs for duty holders.13.

3.1.1.2.10 Effects of REACH on industry innovation and competitiveness

Assessing the direct effects of REACH authorisation and restriction on innovation is challenging. The conclusion of the second REACH review noted mixed effects. For some companies, REACH has led to an increase in resources spent on R&D and to the use of information generated for compliance with REACH being used in the conception of new products. At the same time, compliance has led to the diverting of some R&D resources, which would otherwise have been available for innovative activities.

Listing of substances in the Candidate List or in Annex XIV triggers communication across the supply chain, initiates substitution activities at all supply chain levels, and triggers consideration of reformulation for some products and the withdrawal of others. However, concerns have been noted that the continuous inclusion of new substances in the Candidate List and in Annex XIV is perceived as a challenge for international competitiveness. Despite this, there has been a continuous flow of new substances on the EU market over the same period. A survey noted that for 85% of companies’ obstacles to innovation arose from “a lack of information on the hazards and risks of some of the alternatives and uncertainty concerning the regulatory requirements applicable to those alternatives.”13.

The second REACH review concluded that the vast majority of companies (between 80% and 85%) had reported that no effects (neither positive nor negative) on trade of chemical substances with the EUEEA had arisen from the REACH Regulation, but that important benefits had been achieved in the harmonisation of legislation and the integration of the

13 European Commission, “Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction, 22 November 2021.”
13.1 https://echa.europa.eu/authorities-candidate-listing-
A survey by the European Commission (2017) found that R&D, innovation, and investment spending was impacted by authorisation for more than 80% of respondents (46 total). For the majority of respondents, authorisation resulted in an increase in spending. Overall, 67% of respondents identified an increase in innovation and investment spending and 72% identified an increase in R&D spending.

In terms of external competitiveness, economic data indicate a continued surplus in the extra EU trade balance for chemicals. The data indicate this surplus is driven by specialty chemicals (58%), followed by consumer chemicals and polymers. The EU’s share on the global market has been decreasing over the last 20 years (the period included the 10 years before the introduction of REACH). The rate of that decrease did accelerate after 2007, although raw material (particularly oil), energy, labour and capital costs were expected to have played a significant role.

As the authorisation process does not cover imported articles, respondents noted that it penalises EU versus non-EU companies, while also leaving insufficient time to identify and develop alternatives. A level playing field can be established through the use of Article 69(2), but this has not been possible when the concerned substance is not present in the final article or where its presence does not constitute a risk. There is a risk in such cases that production is relocated outside the EU, with the finished product then imported back into the EU. Concerns have been raised that once companies have submitted an application for authorisation there are weak incentives for that company to engage in substitution, as it may weaken their case. This issue was not explicitly discussed during stakeholder workshops and the existing evidence is anecdotal. This risk would be compounded by the above-mentioned delays to decision making which may cement the status quo rather than support companies with the ongoing trial and error process of innovation.

3.1.1.2.11 Interface with occupational safety and health (OSH) legislation

The overall conclusion of the REACH review noted that further clarification in the coherence between REACH and OSH and waste legislation was one of four issues requiring most urgent action. Similarly, the evaluation of the OSH legislation concluded that while there

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131 Background paper: Workshop on the reform of the REACH Authorisation and Restriction System, Addendum 2011/074/EN – 25/11/2011 Note: some of the workshop participants concluded that the background paper was an accurate description of the problems encountered, but this document was not made by participants directly.
132 Background paper: Workshop on the reform of the REACH Authorisation and Restriction System, Addendum 2011/074/EN – 25/11/2011 Note: some of the workshop participants concluded that the background paper was an accurate description of the problems encountered, but this document was not made by participants directly.
were synergies and complementarities between OSH and REACH, there was a need to further clarify the interface to remove uncertainties and overlaps.\(^\text{144}\)

One key overlapping area is the setting of Occupation Exposure Limits (OELs) under OSH, and Derived No-Effect Limits (DNELs) under REACH for threshold substances. Where DNELs and OELs (and EU Binding Occupational Exposure Limit Values (BOELs)) have diverged, this has caused confusion for companies who need to apply the stricter limit and poses problems for enforcement.\(^\text{145}\) Member States in the November 2021 workshop felt that the REACH-OSH interface was the most important, but the interface between REACH and the Industrial Emissions Directive was also recognised. Participants noted there was potential for regulatory conflicts between OSH and REACH, affecting both authorisation and restriction. The majority of participants were in favour of harmonised limit values to prevent divergence between OSH legislation and REACH, for example.\(^\text{146}\) Similar views were reported in a stakeholder workshop on 12 November 2021; here participants considered that OSH should be the main legislation for worker protections, while REACH supplements this with protections for consumer uses, for example.\(^\text{147}\)

3.1.2 Problem trees and intervention logic

The interventions discussed in this section are complex, have multiple drivers and involve technical subject matter. The problem trees and intervention logic models below provide an overview of the problems and their drivers, interrelationships, and the policy objectives.

Figure 3 provides detail for the problem drivers related to the extension of the GRA and reforms to the restrictions process. Figure 4 provides the same for potential options to reform the REACH authorisation process.


\(^{146}\) European Commission. “Study to support the impact assessment for potential amendments to the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform REACH authorisation and restriction. Member States workshop report. 9th November 2021.

\(^{147}\) European Commission. “Study to support the impact assessment for potential amendments to the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform REACH authorisation and restriction. Stakeholders workshop report, 12 November 2021.”
Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction.

**Figure 3: Problem tree – GRA and restriction reform**

Drivers

- Limited incentives for companies to provide information
- Registrations do not always contain all the required information
- SMEs lack resources to contribute to restriction consultations
- Specific risk assessments require large amount of data on uses, exposure/emissions and alternatives
- SMEs lack resources to comply with restrictions

Problems

- Limited data upon which to generate restrictions
- Lack of access to detailed information on uses, exposure/emissions and alternatives
- Restriction dossiers are resource intensive to prepare
- High burden on authorities in restriction development
- Slow pace of restrictions being proposed and implemented resulting in insufficient protection of consumers and professional users
- Difficult to assess and conclude on justifications for derogations
- Limited enforceability and enforcement of restrictions

Specific objectives

- Increase the efficiency of restrictions by increasing the speed of restricting critical hazard classes
- Prevent manufacture, placing on the market or use of substances (on their own, in mixtures and in articles) in critical hazard classifications and in uses for consumers and by professionals
- Increase the efficiency of restriction (decrease the cost and increase the proportionality of costs to benefits)
- Extend the protection provided to consumers to professional users
- Reduce administrative burden on Competent Authorities and companies, specifically SMEs

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Figure 4: Problem tree – authorisation reform

Drivers
- Resources and expertise in Member States, ECHA and COM are constrained
- REACH does not define the precise level of detail required in AIs
- Downstream user applications: cases with a multitude of often repetitive individual applications for similar uses of sometimes very small quantities of SVHCs
- Some legal definitions are unclear and/or there is lack of criteria to support the interpretation of certain definitions or concepts
- Upstream actors may not have detailed information on downstream uses
- SMEs lack resources/knowledge to apply for authorisation
- Authorisations do not apply to imported articles

Problems
- Applications prepared with varying levels of detail
- High administrative burden on companies, especially on SMEs
- Delays in decision-making
- Complexity leading to controverses and court cases
- Uncertainty for companies
- Specific challenges with authorisations for SMEs
- Unfair playing field between EU producers and importers of articles
- Insufficient incentives for substitution

Specific objectives
- Simplify the authorisation processes
- Provide clearer and more focussed legal requirements for applications for authorisations
- Reduce the administrative burden on Competent Authorities
- Reduce administrative burden on companies, in particular SMEs
- Facilitates decision-making on hazardous substance, so as to free competent authority resources to tackle other chemical regulatory risks
- Increase the efficiency and effectiveness of the authorisation process

P2 Processes in REACH are not fit for purpose
3.1.3 What is the estimated scale of the problem?

3.1.3.1 Specific Problem 1: the pace of Article 68(1) restrictions is not sufficient to ensure that consumer and professional uses of the most harmful substances are adequately regulated

The previous sections provide an indication that the slow progress on Article 68(1) restrictions has potentially resulted in insufficient levels of protection for consumer and professional uses of the most harmful substances. However, where there has been a restriction proposal, average benefits in terms of better protection have been large for both consumers and professionals. This section explores the available evidence on the nature and scale of concern associated with uses of the chemical hazard classes affected by the potential GRA extension. Where data are sufficient to do so, quantitative, and monetary information on the impacts are provided.

Exposure to these substances is associated with a wide range of human health and environmental effects, the evidence presented below suggests these effects present a significant welfare cost to the EU. These effects manifest themselves in the short, medium, and long term, near and far from the point of release. Exposure can occur during substance manufacture, use (including for the manufacture of mixtures and articles) and at the end of life and in secondary materials when these are recycled. This presents risk to different types of users, based on the lifecycle stages of the use of a substance, as well as the level of occupational health and safety protection that may apply. While not explicitly defined in REACH, the three main different types of uses are:

- **Uses at an industrial site** (e.g., those employed in the manufacture of paper, cars or electronic components).
- **Uses by professionals** (e.g., hairdressers and nail technicians, those providing cleaning services, construction workers, workers in garages). They often carry out their work outside of a single site and are less likely to be protected by RMMs, despite potentially high and repeated exposure. Many are self-employed (hence are not covered by CAD/CMD or OELs, as these protections are the duty of the employer). Many lack access to specialist advice on the safe handling of chemicals.
- **Uses by consumers** (e.g., those purchasing products for use in the home).

The hazard classes under the scope of the GRA extension are those of greatest concern. The human health and environmental effects (both physical effects and the associated socioeconomic costs) associated with exposure to substances in these hazard classes are discussed below. Socioeconomic costs to human health include excess mortality and morbidity, direct health care costs (e.g., time of specialist staff, medication and treatment), and reduced productivity. Various stated or revealed preference studies seek to price negative externalities related to the most harmful chemicals using "willingness-to-pay" methods. Damage to the environment from chemical exposure also presents significant societal costs, but these are typically harder to quantify. These include damages to various

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Section 7.4 provides details on the number of substances, their associated hazard status and estimates of the associated tonnages and uses affected by the potential extension of the GRA to provide a further indication of the extent of current environmental and human health concerns.

3.1.3.1.1 Endocrine disruptors with effects for human health

**Human health effects**

Exposure to endocrine disrupting chemicals can create a range of human health effects due to their interference with hormone action. EDs are known to have a range of effects including impacts on male and female reproduction, breast development and cancer, prostate cancer, neuroendocrinology, thyroid, metabolism and obesity, and cardiovascular endocrinology. Endocrine disrupters in humans occurs through a variety of mechanisms including nuclear receptors, non-nuclear steroid hormone receptors, non-steroid receptors, enzymatic pathways involved in steriod biosynthesis and/or metabolism and through various other mechanisms. EDs and potential EDs can be found in a wide variety of products which result in human and environmental exposure, via diet, air, skin, and water.

**Current regulatory protection**

The 2018 REACH review identified two main challenges for categorising EDs as SVHC. Firstly, in identifying whether the substance is of "equivalent level of concern", and secondly, related to the availability of relevant scientific data to identify substances using the WHO/IPCS (2002) definition.

Identification of endocrine disruptors is required by the Plant Protection Products Regulation (PPPR) and the Biocidal Products Regulation (BPR) according to criteria established, respectively, in 2017 and 2018. REACH does not contain identification criteria for EDs, but these are identified as substances of very high concern (SVHCs) on a case-by-case basis, following the IPCS/WHO definition and the application of the "equivalent level of concern" carried out by the REACH Member State Committee.

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156 According to the WHO/IPCS (2002) definition, a chemical endocrine disruptor is "an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or a population". World Health Organization, "Risk Assessment of the State of the Science of Endocrine Disruptors". 2003. http://www.who.int/ipcs/publications/environmental_disruptors/en/


The ED assessment list comprises substances and groups of substances undergoing an ED assessment under REACH or the BPR, and that have been brought for discussion to ECHA’s ED Expert Group.\textsuperscript{[10]} The list comprises 105 entries, 101 referring to individual substances and four referring to groups of substances. Some substances and groups of substances have also been added to the Candidate List of SVHCs for authorisation\textsuperscript{[1]} and in the Authorisation List\textsuperscript{[10]} (as of July 2022) for endocrine disrupting properties for human health, the environment or both.

Table 10: Number of substances in the ED assessment list as of July 2022

<table>
<thead>
<tr>
<th>Outcome/status</th>
<th>Substance</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>ED – Human Health (HH)</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>ED – Environment (ENV)</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>ED HH &amp; ENV</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Inconclusive</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Not ED</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Under development</td>
<td>23 BPR; 42 SEV\textsuperscript{*}; 6 others</td>
<td>1 substance evaluation; 1 other</td>
</tr>
<tr>
<td>Total number of entries</td>
<td>101</td>
<td>4</td>
</tr>
</tbody>
</table>

\textsuperscript{*SEV: Substance evaluation}

Table 11: Number of substances in Candidate List and Authorisation List for ED properties as of July 2022

<table>
<thead>
<tr>
<th>Candidate List</th>
<th>Authorisation List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance</td>
<td>Group</td>
</tr>
<tr>
<td>ED – Human Health (HH)</td>
<td>6</td>
</tr>
<tr>
<td>ED – Environment (ENV)</td>
<td>4</td>
</tr>
<tr>
<td>ED HH &amp; ENV</td>
<td>3</td>
</tr>
<tr>
<td>Total EDs</td>
<td>12</td>
</tr>
</tbody>
</table>

Moreover, a number of EDs (entry 46a: nonylphenol, branched, ethoxylated; entry 51: Dibutyl phthalate (DBP); Benzyl butyl phthalate (BBP); Bis(2-ethylhexyl) phthalate (DEHP); entry 66: Bisphenol A) have been restricted through REACH Annex XVII\textsuperscript{[11]}.\textsuperscript{[12]}

Evidence on the associated welfare costs to the EU

A series of papers published by Trasande et al. identified 15 possible exposure-outcome associations between various EDCs and human health. The effects considered include: IQ loss and intellectual disability, attention deficit disorder (ADHD), autism spectrum disorder 151

\textsuperscript{10} https://echa.europa.eu/ed-assessment
\textsuperscript{11} https://echa.europa.eu/candidate-list-table
\textsuperscript{12} https://echa.europa.eu/authorisation-list

\textsuperscript{10} Although the reason for their restriction was their reproductive

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Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction

Table 12 outlines the human health effects associated with exposure to EDs considered in Trasande et al. (2016) analysis, the endocrine-disrupting mechanism causing the effect, and the associated substances. Estimates of the associated costs are also provided. These estimates are methodologically problematic, which is discussed later in this section.

Note a small number of the substances covered in the analyses include pesticides. Costs linked to pesticides should be excluded from any analyses for REACH as they are regulated via the Plant Protection Products Regulation. Moreover, studies by Trasande et al. (2015, 2016) indicate the costs related to organophosphate pesticides (which represent a significant share of the costs associated to ED exposure). The analysis also includes some substances regulated via REACH (e.g., certain phthalates). The section is intended to illustrate the overall scale of the problem only and is discussed further in the benefits section of the impact assessment.

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Table 12: Identified effects, associated EDCs and costs

<table>
<thead>
<tr>
<th>Health impact category</th>
<th>Human health effect</th>
<th>Endocrine disrupting mechanism</th>
<th>Examples of associated substances</th>
<th>Estimated welfare costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurodevelopmental effects</td>
<td>IQ loss and intellectual disability, ADHD and ASD</td>
<td>Endocrine disruption can have adverse consequences on a developing brain through mechanisms including thyroid hormone or sex steroid actions or through other hormonal pathways.</td>
<td>Polychlorinated biphenyls (PCBs), Polybrominated diphenyl ethers (PBDEs) and organophosphate pesticides interfere with thyroid hormone action, evidenced through human and laboratory studies. Substances including lead, methylmercury, arsenic and pesticides have been linked to ASD and ADHD.</td>
<td>Neurodevelopmental disabilities have been associated with IQ losses, and hence productivity losses and other associated health and societal costs. Trasande et al., follows the approach of previous authors to estimate the cost of an IQ point lost as $19,269 (2010) in discounted lifetime costs. Other costs are estimated for intellectual disability, autism, and ADHD. This is discussed further below.</td>
</tr>
<tr>
<td>Obesity and metabolism effects</td>
<td>Childhood and adult obesity and adult diabetes</td>
<td>Toxicological studies have shown various endocrine-disrupting mechanisms by which EDCs contribute to obesity and diabetes. For example, disrupting peroxisome proliferator-activated receptors (PPARs) and BPA as a synthetic estrogen.</td>
<td>Epidemological and toxicological evidence suggest that substances including tributyltin, organophosphate pesticides, fungicides, phthalates, environmental phthalates, heavy metals. Persistent organic pollutants are associated with obesity and diabetes.</td>
<td>Obesity and diabetes present significant healthcare costs to society and can result in various related conditions and subsequent reductions in life expectancy. Costs considered include medical expenditures in children and adults and DALYs associated with obesity in adulthood.</td>
</tr>
</tbody>
</table>

162 Attane IY, Trasande L. 2015 Economic costs of childhood lead exposure in low and middle-income countries. Environ Health Perspect 2013;121:1037-1042
164 Bellanger et al. 2013 Economic benefits of methylmercury exposure control in Europe: Discounted value of neurobehavioral prevention. Environmental Health 12
165 Note, in recent REACH restrictions x £11 per IQ point value is used, based on labor market evidence

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<table>
<thead>
<tr>
<th>Health category</th>
<th>Human health effect</th>
<th>Endocrine disrupting mechanism</th>
<th>Examples of associated substances</th>
<th>Estimated welfare costs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male reproductive health effects</strong></td>
<td>Male reproductive health effects associated with exposure to EDs include hypospadias, cryptorchidism, testicular cancer, prostate cancer, low testosterone, and poor semen quality.</td>
<td>EDs impact semen quality through various mechanisms, with substances affecting different parts of the endocrine system.</td>
<td>EDs associated with male reproductive disorders include phthalates, including dibutyl phthalate (DBP) and D(2-ethylhexyl) phthalate (DEHP), pesticides, including prochloraz, vinclozolin, linuron, and prochloraz; bisphenol A (BPA); the dichlorodiphenyltrichloroethane (DDT) and D(2,4,5-trichlorophenol) compounds, and UV filters, such as octyl methoxycinnamate and 4-methylbenzyldecy camphor.</td>
<td>There are significant individual and societal costs associated with male reproductive health problems, with costs including medical and fertility treatment. Trasande et al. report significant costs associated with PEDE-attributable cryptorchidism, phthalate-attributable male infertility, PEDE-attributable testicular cancer, and phthalate-attributable decreases in testosterone. Direct and indirect costs associated with assisted reproductive technology were estimated at EUR 6,607 per couple from a study in Denmark. The costs for mortality due to reductions in testosterone in lifetime economic productivity loss were obtained from a US source and updated to EUR in 2013 prices.</td>
</tr>
<tr>
<td><strong>Female reproductive health effects</strong></td>
<td>Female reproductive health effects associated with exposure to EDs include polycystic ovary syndrome.</td>
<td>Whilst there is a growing body of evidence linking EDs to female reproductive health problems, characterising these effects presents a significant challenge.</td>
<td>There is evidence for associations between various EDs and impacts on the developing ovary and reproductive tract including BPA, phthalates, pesticides, and persistent organic pollutants (POPs).</td>
<td>Significant costs are associated with female infertility and a range of other conditions, including healthcare costs, work disturbances and lost productivity. Trasande et al. carried out a cost estimation from a</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Health impact category</th>
<th>Human health effect</th>
<th>Endocrine disrupting mechanism</th>
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<th>Estimated welfare costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>endometriosis, uterine fibroids, and cancers at reproductive sites.</td>
<td>challenge, largely as a result of the inability to observe early reproductive endpoints in females without invasive procedures.</td>
<td>endometriosis, uterine fibroids, and cancers at reproductive sites.</td>
<td>societal perspective including treatment costs and indirect costs such as productivity loss.</td>
</tr>
</tbody>
</table>
Monetary valuation

While the costs of endocrine disruptors on human health are difficult to quantify, and hence uncertain, since 2015 Trasande et al. published a series of inter-related papers which estimate the socioeconomic costs of exposure to EDS in the EU. Originally, four related papers were published in the *Journal of Clinical Endocrinology and Metabolism* (Trasande et al. 2015), Bellanger et al. 2015, Hauser et al. 2015, Legler et al. 2015). These were followed by a fifth paper (Hunt et al. 2016) addressing estimated costs of female reproductive disorders and diseases attributable to ED exposure. Trasande et al. (2016) then presented an update to the original cost estimates, including estimates for individual EU countries. Kahn et al. (2020) provides an update to the exposure-outcome relationships, identifying newly published epidemiological and toxicological evidence published since the previous estimates published in Trasande et al. (2016), however no update to the cost estimates were made.

These papers identify 15 possible exposure-outcome associations between various EDS and human health. The latest figures produced in 2016 estimate concern-attributable costs to the EU from polybrominated diphenyl ether and lost cognition; organophosphate and lost cognition, autism, ADHD, cryptorchidism, assisted reproductive technology, low testosterone-induced early mortality, fibroids, DBE-Childhood obesity; DBE-Adult diabetes; phthalate-adult obesity; phthalate-adult diabetes—biphenyl A-childhood obesity; testicular cancer and endometriosis. The estimated cost of impacts attributable to endocrine-disrupting chemicals in the 2016 paper was in the order of EUR 160 billion per year after accounting for the probability of causation, which is approximately 1.28% of the 2016 EU Gross Domestic Product (GDP).

**Criticisms of the methodology**

It should be noted that there has been criticism of the Trasande et al. (2015) methodology and conclusions. Bond and Dietrich (2017) present a bluntly written, critical review of the methodology used, stating that the costs estimated were “highly speculative” and should be interpreted as an upper bound on costs. In the methodology used, there is a potential for bias, as Bond and Dietrich (2017) note that the studies selected “were not linked to a cohort to assess the incidence from exposure to alleged EDS and adverse health outcomes.” A
these limitations, the conclusions reached by the recent COI studies analysed should be taken with great caution and viewed as suggestive about the costs of diseases related to exposure to EDs.

3.1.3.1.2 Endocrine disruptors with effects on the environment

**Effects on the environment**

EDs are associated with various adverse effects on wildlife, including disrupted reproductive function and development in birds, fish, amphibians, and molluscs. Species can be impacted through mechanisms including male and female reproductive dysgenesis and thyroid gland dysfunctions. A number of chemicals are capable of altering hormonal function through a wide range of mechanisms of action. While trends have shown clear reductions in species diversity and ecosystem health/resilience, attributing exposure to EDs in these trends is challenging. Many other causal factors (e.g., habitat destruction/degradation) are also associated. A further challenge comes from the delay in effects (or identification of those effects) following exposure to EDs.

Despite these challenges, there is a wide body of evidence demonstrating the impacts of EDs on wildlife. One of the most extensively studied impacted species is fish, with various studies demonstrating the impact of EDs, focusing mainly on oestrogenic effects. There are extensive chronological studies on the effects of organotin compounds on populations of marine molluscs and oestrogenic disruption in marine and freshwater fish living in the coastal and riverine waters of the United Kingdom (UK).

Bond and Eckstein (2017) also criticise the criteria used by the Steering Committee for evaluating laboratory and animal evidence of endocrine disruption, originally proposed by the Danish Environmental Protection Agency (DBF). The GRADE Working Group (2014) was tasked to evaluate human epidemiology evidence, termed "Hearing of Evidence for Public Health Interventions" (HEPHI). The original GRADE methodology was extended to include "between system reliability" (BTR) as an additional method to assess evidence. The BTR method was developed to be applied to scientific evidence on inter-oral pollutants which is obtained from animal models, as it is often not possible to assess the overall probability of causation in human populations. The BTR method employs a system of 0-19% estimates, which are used to identify studies that are "not representative of general populations" and are used to assign a probability of causation. The use of this method is considered to reach a consensus. The GRADE framework for evaluating evidence is based on a weighted average of multiple studies and is designed to be "transparent, weak and controlling evidence". They state that HEPH is acceptable as a model for causation when 30% or more of the evidence is rated as "high". However, the authors claim that the framework is "not representative of general populations" and that the evidence should be interpreted with caution, as they lack the probability of causation estimates for specific species. The information in the article is presented in such a way that it is difficult to draw conclusions from the data provided, but the authors claim that the evidence is "not representative of general populations" and that the evidence should be interpreted with caution, as they lack the probability of causation estimates for specific species.
poorpoises, dolphins, whales, and polar bears. However, evidence on endocrine disruption in mammals remains sparse given the significant challenges in studying them ethically.

Current regulatory protection:

Table 10 and Table 11 above show the number of substances and groups of substances included in the ED Assessment List, Candidate List and Authorisation List as of July 2022. Three substances with endocrine disrupting properties for the environment have also been restricted (entry 46a: nonylphenol, branched, ethoxylated; entry 51: Bis(2-ethylhexyl) phthalate (DEHP); entry 66: Bisphenol A).

Evidence on welfare costs to the EU

While evidence of endocrine disruption in wildlife is widespread, it is difficult to quantify effects given limited understanding of how physiological changes affect the individual animal and how individual responses affect wider populations.\cite{Jobling, decontamination} While available studies have demonstrated examples of effects, the level of quantification is low. Where monetary valuation is available, this has typically been developed for specific cases and mostly for blockades and pesticides (e.g., the regulation of the anti-fouling agent tributyltin (TBT) has resulted in an estimated increased revenue to commercial fishing across the EU of between EUR 2.2 million – EUR 158 million per year; estimated benefits of nutrient cycling\cite{Tyler} at EUR 0.1 – EUR 126 billion and remediation costs across EU harbours estimated at EUR 21-237 million. Estimates are also available for industrial chemicals such as polychlorinated biphenyls (PCBs) in terms of avoided clean up, decontamination costs, avoided healthcare costs and productivity losses. Amec et al. (2017) reports that the reduction in waste containing PCB thanks to their phase out was estimated at resulting in the avoidance of clean up and decontamination costs of around EUR 180 million per year.

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### Example: Per- and polyfluorinated alkyl substances

Per- and polyfluorinated alkyl substances (PFAS) are a group of more than 4,700 widely used, non-made chemicals. PFAS can accumulate over time in humans and the environment presenting a significant concern. While some of the more prevalent and regulated PFAS (e.g., PFOA and PFOS) are seen levels decrease, lesser known PFAS remain unregulated and their levels are on the rise. Most of the PFAS which have been well-studied (limited number) have been shown to be moderately to highly toxic.\cite{decontamination, decontamination}

Atmospheric transport in particular has resulted in PFAS pollution in remote regions including the arctic, exposing the local wildlife. Concentrations of PFAS including PFOS and other PFAS have been detected in invertebrates, fish, amph始建es, reptiles, birds and mammals across the globe.\cite{decontamination, decontamination} PFAS have been shown to disrupt reproductive function in animals. Multiple studies on mice and rats have shown reproductive...
3.1.3.1.3 Persistent, bioaccumulative and toxic substances (PBT) and very persistent and very bioaccumulative substances (vPvB)

**Effects and current regulation**

PBT/vPvB substances cover a range of chemicals with varying effects which can be damaging to human health and the environment. As of April 2022, ECHA's PBT assessment list for example, contained 225 unique substances/entries130.

PBTs and vPvBs persist in the environment for long periods of time. They accumulate in living organisms, and can be transported long distances to remote areas. Exposure is very difficult to reverse, as reducing emissions may only result in a reduction in environmental concentrations many years later. As such, a particular concern with vPvB substances is that effects may occur even when not demonstrated in laboratory testing130. PBT/vPvB substances cover a range of chemicals with varying effects which can be damaging to human health and the environment. As of April 2022, ECHA's PBT assessment list for example, contained 225 unique substances/entries130.

Reflecting the level of concern from PBT/vPvB substances, specific attention is placed on them under the current REACH Regulation, which envisages that they may be included in Annex XIV as SVHC, aiming for their substitution where alternatives are technically and economically feasible. Where substances fulfill the criteria, registrants must conduct a specific PBT/vPvB assessment and adopt various specific RMMs, communicating these to downstream users. The PBT and vPvB criteria is given in Section 1 of Annex XIII to the REACH Regulation. Properties assessed under these criteria include: persistence, bioaccumulation, toxicity, indication of P and vP properties, indication of B and vB properties, and indication of T properties130. Further actions may be undertaken during substance evaluation with such substances listed as SVHCs and included in the Authorisation List or be subject to restriction130.

**Approach to evaluation**

In restriction proposals and in applications for authorisation for PBT and vPvB substances133, SEAC notes that “data on P, B and T properties do not often allow for quantitative assessment of human health or environmental impacts. The valuation of benefits via the assessment of the impacts on the environment and human health (the

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132 https://echa.europa.eu/ebc
134 https://echa.europa.eu/ebc
136 https://echa.europa.eu/ebc
137 https://echa.europa.eu/ebc
139 Directorate-General for Internal Market, Industry, Enterprise and SMEs
standard 'impact pathway' approach is not possible, and other options for a benefits assessment need to be considered. Accordingly, SEAC pursued a cost-effectiveness analysis-based approach, proposing to establish a benchmark for the proportionality/disproportionality of action to reduce emissions of PBTs/vPvBs, based on the cost of past actions. Within such an approach, cost-effectiveness could be informed by the development of benchmarks.

In 2015, IVM conducted a study (IVM, 2015) to provide SEAC with information that could be used in the development of such a benchmark. This was based on past regulatory action. The study gathered information on the past (and current) cost of PBT emission reductions or on reductions in the use of, or exposure to, PBTs/vPvBs to provide an indication of the implied 'public willingness-to-pay' for such reductions. Note that this value reflects how much government agencies and other organisations (not the public) have been willing to spend on clean-up, remediation/restoration and disposal activities (service life and or waste stage), or how much it has cost to substitute a PBT/vPvB.

The IVM (2015) study identified a very wide 'grey zone' of somewhere between EUR 1,000 and EUR 50,000 per kg of PBT substance substituted, remediated or emission reduced. Within this 'grey zone', measures may be deemed either proportionate or disproportionate from a cost-effectiveness perspective (depending on the PBT/vPvB substance). Other studies include work by Gubbett (2014) and other papers which argue that it is necessary to account for the 'stock pollution effects' (i.e., the nature of their cumulative release and persistence in the environment over time). Moreover, a limited number of stated preference-based studies have been undertaken with the aim of developing monetary estimates of people's Willingness to Pay (WTP) to accept a precautionary approach with respect to PBTs and vPvBs.

3.1.3.1.4 Substances with Specific Target Organ Toxicity. Single Exposure (STOT SE) and substances with Specific Target Organ Toxicity, Repeated Exposure (STOT RE)

Human health effects

STOT SE refers to specific, non-lethal effects on organs or organ systems in the body following a single exposure to a chemical. All significant health effects occurring after exposure (immediate or delayed) are included in the hazard class, whether reversible or irreversible. Significant effects to a target organ after repeated exposure are classified as STOT RE. Quantitative information on population level effects is limited, but indicative values for specific effects are available and can be used for illustrative purposes.

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Footnotes:

1. i.e., assessment of the adverse and its associated attributable damage does to specific receptors in a defined study area.
2. There may be based on studies on obtainable for persistence (excluding information on the cost of post regulations; existing data on remediation to clean up costs for PBTs and vPvBs, and/or economic analysis studies that have been used in the process of reducing exposure for PBTs and vPvBs for similar substances.
6. Certain non-health effects excluded from this classification, for example respiratory or skin sensitisation, cancerogenicity or reproductive toxicity. Regulation (EC) No 1272/2008 of the European Parliament and of the Council.
Monetary valuation

A report by ECHA presents indicative WTP valuation data for kidney failure and kidney disease which illustrates the value individuals place on avoiding the exposure-related illness. The costs presented in the report are based on a multi-Member State survey of just over 3,000 respondents. Later cross referenced with grey and academic literature alongside a further peer review. As well as estimating the associated costs, the report also provides a critical review of the study. The kidneys can be impacted by exposure to heavy metals, as well as certain organic solvents and polyaromatic hydrocarbons (PAHs). Other contaminants of concern include: cadmium, pentachlorophenol, methyl chloride, toluene, pyrene, fluoranthene, ethylbenzene, nitrobenzene, and pentachlorobenzene. The WTP valuation study estimated a cost of just over EUR 530 for avoiding one episode of acute kidney failure and around EUR 2,760 for avoidance of one case of chronic kidney disease (2012 prices). However, a peer review conducted as part of the study suggests that these results are significantly lower than previous WTP estimates of mild morbidity symptoms and long-term conditions and should be used with caution in the impact assessment.

3.1.3.1.5 Immunotoxic substances

These substances can impact the functionality of the immune system directly, resulting in reduced resistance to infections and tumours from immunosuppression. Direct action can also result in dysregulation of homeostasis, causing allergic or autoimmune phenomena from exaggerated immune responses. Chemicals can also be recognised as foreign by the immune system, resulting in allergy or autoimmunity. The prevalence of allergic and autoimmune diseases has risen over the past few decades, resulting in increased healthcare costs for the EU. While most autoimmune diseases cannot be cured, most of them can be managed. An increase in autoimmune diseases will increase costs directly, and indirectly through increased susceptibility to other illnesses. While no quantitative studies on the cost of immunotoxic substances have been identified, immunotoxicity assessments have identified various immunotoxic effects of chemicals. Veraldi et al. (2006) assess the immunotoxicity of 20 chemicals of concern, and consider whether the costs of increased vulnerability to other human health effects could improve the quantitative assessment of immunotoxic substances. In this study benzene, trichloroethylene, PAHs, asbestos, and styrene impact the immune system through suppression. Trichloroethylene can also cause immune disturbances.

33 The overall conclusion is that the kidney disease values from the ECHA study should not be used in practical impact assessment. ECHA, (2016). Valuing related health impacts of chemicals. Available at: https://echa.europa.eu/documents/10162/39455/46354/20160106t tex_european.pdf

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hypersensitivity and asbestos can result in immune enhancement. Crystalline silica causes dysregulation of the immune system.\(^{210}\)

### 3.1.3.1.6 Neurotoxic substances

#### Effects and substances of concern

Over 200 chemicals are known to be neurotoxic in humans and over 1,000 are known to be neurotoxic in animals. The most well-studied and well-regulated substances are lead and mercury which are known to cause intelligence quotient (IQ) loss (predominantly in children aged 7 or younger), alongside PBDEs, organohalophosphates and arsenic. Perfluorinated compounds (PFCs) and pesticides have been linked to attention deficit hyperactivity disorder (ADHD).\(^{211}\) Those neurotoxic substances which are less well-studied and less regulated present a further potential concern to human and wildlife health.

The neurodevelopmental effects with the most extensive evidence associated with chemicals exposure are the loss of IQ points and an associated increased incidence of mild mental retardation (MMR), and ADHD.

Intelligence quotient (IQ) is a widely used scoring system representing human intelligence, typically determined through a series of standardised tests. Numerous substances, including lead and mercury, are linked with declines in intellectual ability which can be expressed as a loss of IQ points. While IQ loss in itself is not classed as a disease, it can result in a classification of MMR where IQ scores fall below 70. This is associated with higher risk of developing mental health, behavioural and academic difficulties and of experiencing socioeconomic disadvantages.\(^{212}\) In childhood, MMR may not be easily identifiable, but may manifest in delayed speech.\(^{213}\) ADHD is a behavioural disorder manifesting in inattentive, hyperactive, and impulsive behaviours. Most cases are diagnosed between ages 3 – 7 years old\(^{214}\) where it can be observed through impaired behavioural function at home and school, as well as academic performance.\(^{215}\)

Estimates vary worldwide, but prevalence has been increasing over time. ADHD is still relatively under-recognised and underdiagnosed in most countries, particularly in girls and older children.\(^{216}\) There is a strong genetic component to one’s risk of developing the condition, but those born prematurely, with low birthweight and/or with epilepsy are at higher risk.\(^{217}\)

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(8) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3809299/

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Monetary valuation

Various quantitative assessments have been undertaken to assess the impact of neurotoxic substances. Quantitative and monetary estimates have been identified only for a small number of extensively regulated substances; notably lead and mercury and do not capture possible effects from the larger number of substances above. Moreover, evidence is emerging that damage could be caused in children, including in the womb, at levels previously thought to be safe. Some assessments assume a threshold for effects, while others do not, meaning that damage could be occurring even at low levels of exposure.224,225 European Commission (2017)226 provides estimates of the on-going burden of neurotoxic disease attributable to chemical exposure. It is estimated that in the EU around 30,000 Disability Adjusted Life Years (DALYs) related to neurotoxic disease could be resulting from chemical exposure, and 250,000 DALYs attributable to chemical exposure combined with underlying genetic predisposition. Using a cost per DALY of about EUR 135,000 (2017)221, the estimated cost of DALYs related to neurotoxic disease effects in 2017 was around EUR 4 billion attributable to chemical exposure and up to EUR 34 billion attributable to chemical exposure combined with underlying genetic predisposition.

Similarly, Hanninen et al. (2014)222 provides estimates for the number of DALYs attributable to IQ loss and MMR in children under 5 years old. This study provides burden of disease estimates for nine risk factors, including lead. Lead represents 4% of the estimated burden of disease attributed to the 9 risk factors. Most other risk factors considered in this study are not relevant under EU REACH. The results of this study suggest that lead contributes to 100-900 DALYs per million people in Europe, note, however, that this includes hypertensive diseases and increased blood pressure from exposure. The population of the EU28 in 2014 was 507.24 million223, resulting in a total DALYs estimate of around 51,000 to 457,000 DALYS attributable to lead for neurodevelopmental and other human health effects, including hypertensive diseases and increased blood pressure from exposure. Using a cost per DALY of EUR 130,564 (2014)224, the estimated cost of human health effects, including but not limited to neurodevelopmental effects, attributable to lead

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221 WHO (2022), and prioring: https://www.who.int/ceh/news-room/detail/lead-exposure-and-opportunites-and-threats


224 DALY value of £130,564 per DALY adjusted to 2017 prices from the 2015 figure in the "Study on the cumulative health and environmental benefits of chemical legislation" (2017) for the European Commission, available here: http://ec.europa.eu/environment/health/pubs/chemicals-health/Social/e24717d9b-99fb-11e4-a73a-01aa75ed7181/health-benefits.pdf. Original cost per DALY analysis is from Krull et al. and Bell (2016): 2016, 293, E113-E121. Costs are given in 2017 prices and these are the latest DALY estimates available.


D tasted as a constant 130,564 DALYs per DALY adjusted to 2017 prices from the 2015 figure in the "Study on the cumulative health and environmental benefits of chemical legislation" (2017) for the European Commission, available here: https://op.europa.eu/en/publication-detail/-/publication/8d7e7d9b-99fb-11e4-a73a-01aa75ed7181/language-en. Original data per DALY analysis is from Krull et al. and Bell (2016): 2016, 293, E113-E121. Costs are given in 2017 prices and these are the latest DALY estimates available. Note the note differs here and in the footnotes above as the DALY data relates to different years, hence different GDP deflators were used in the original analysis.
exposure would correspond to somewhere between EUR 7 and EUR 60 billion in 2014, for example.

While there is significant evidence demonstrating the harmful effects of neurotoxic substances, there is limited evidence of the costs of ongoing exposure to neurotoxic substances in the EU. Naclelec and Rabl (2016)[20] have estimated the cost of a lost IQ point at EUR 16,300 (2013 prices), based on a review of IQ and lifetime earnings in the US. Some of the more recent monetary assessments for neurotoxic substances are based on marginal average changes in IQ at the level of each child. These changes are then valued, based on the long-term relationship between exposure and IQ and from that to productivity and earnings potential, resulting in a cost per (fraction of) an IQ point lost. However, the assumption of an empirical link between marginal changes in IQ; productivity and earnings is disputed and estimated values should be treated with caution.

3.1.3.1.7 Respiratory sensitisers

Effects and risk factors

Respiratory diseases are a significant problem in the EU, representing approximately 7.5% of deaths in 2016[21,22]. While there is an extensive scientific literature on associations between air pollution and respiratory diseases[23,24], the evidence on specific chemical exposures and their effects is less detailed. Respiratory diseases identified as being potentially caused or exacerbated by chemical substances include asthma, asbestos-related chronic obstructive pulmonary disease (COPD) and allergic rhinitis, among others[25]. Various occupations are associated with an increased risk of asthma, such as domestic and equipment cleaners[26], animal health, cosmetology, farming and food production, healthcare, industrial, manufacturing or construction, laboratory and some office and educational work[27]. Occupations known to have an increased risk of COPD include mining, construction, foundry, welding, steel, textiles (especially cotton) and farming[28].

Monetary valuation

European Commission (2016)\(^{223}\) and European Commission (2017)\(^{224}\) both include calculations of the cost impact of occupational asthma. Valuations are based on case data, treatment costs, lost workdays, and output. European Commission (2016) extrapolates data from the United Kingdom and Germany to estimate the prevalence of occupational asthma attributable to chemical exposure. The estimated prevalence of occupational asthma reduced in the EU over the period 2004-2014 from around 26,000 to 7,000 cases. This reduction has resulted in total cost savings to the EU in the region of EUR 250 million. In 2013, environmentally attributable childhood asthma was estimated to cost the EU approximately EUR 1.6 billion per year\(^{224}\). However, the role of respiratory sensitisers in this is unknown.

There are still significant gaps in understanding the causes of asthma, making it difficult to accurately assess the burden of asthma attributable to chemical exposure. The majority of cost data is available for occupational exposure to respiratory sensitisers with a lack of data available on the costs related to consumer exposure.

The next sections of this report focus on specific challenges with the authorisation and restriction processes (Problem 2) which interlink and follow on from the problems highlighted above for problem 1.

### 3.1.3.2 Specific Problem 2: the authorisation process is not efficient, is burdensome and does not provide enough incentives for substitution

The nature and significance of the problems with the authorisation processes is discussed at length in Section 3. The scale of costs to industry, Member States, the European Commission and agencies, as well as the implications in terms of the speed of decision making, is discussed in the baseline (Section 6.2). These costs have been quantified based on reasonable estimates provided by ECHA on its future authorisation workload. Given the extent of data, the key elements of the baseline are summarised in section 6.3.

Overall, the estimated administrative costs of maintaining the current system are expected to be somewhere in the order of between EUR 14 million and EUR 20 million per year. Over the next 30 years, the present value of these costs is expected to be somewhere in the order of EUR 275 million to EUR 395 million. Most of these costs would be incurred by applicants (industry), but with significant costs falling to ECHA. Member States and the European Commission, respectively, in order of the size of cost expected.

#### 3.1.3.2.1 How might the problems evolve?

Specific Problems 1 and 2 are interrelated. The problems identified in Section 3 of this report reflect the authorisation process as it is currently applied. They also reflect the current use of Article 68(1) restrictions and the current scope of Article 68(2) restrictions in addressing risks from the most harmful chemicals.

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\(^{224}\) European Commission, Amos Foster Wheeler Environment & Infrastructure UK (2017) Study on the cumulative health and environmental benefits of chemical regulation. https://ec.europa.eu/environment/publication-detail/?publication_id=g36259e5-9db0-11e7-85f0-01ae77e6718a\(\text{language}=en\).

Several stakeholder groups endorsed the description of the problems identified with the current REACH authorisation processes. In the absence of changes, the costs are expected to persist over the appraisal period for this impact assessment. As noted above, the estimated costs are expected to be substantial. While the majority would be incurred by industry (in line with the objectives of REACH), significant costs fall to ECHA, Member States and the European Commission. The evidence presented above indicates that authorisation has made significant contributions to SVHC substitution, as well as to improved risk management measures where SVHC uses are authorised. These benefits would be expected to continue in the future, alongside the costs, in line with the number of AfAs and decisions.

The indirect effect of this burden has also adversely impacted regulatory activities and decision making in several other areas, in recent years. This is judged to have affected the ability of authorities to propose and decide on new restrictions. In the absence of changes (and with expected workloads and existing resources in authorities) this is anticipated to continue with the knock on effects accumulating over the next 30 years. Based on the available evidence, this would be expected to have ongoing adverse effects on the speed at which substances are added to the authorisation list and of restriction development and decision making under Articles 68(1) and 68(2).

Section 3.1.1.2.10 indicated that production and use of the most harmful chemicals in the EEA are substantial. These substances are used by industry as well as by professionals and consumers, in various articles. While restrictions under Article 68(1) are estimated to have resulted in significant net benefits (Section 3.1.1.2.5), they have proved to be resource intensive and technically challenging to prepare and decide upon. As such, the number of restriction decisions and hence realisation of protections to human health and the environment has been constrained. It is expected that this would continue with the associated ongoing damage to human health and the environment in the EEA.
4 Why should the EU act?

Article 4 of the Treaty of the Functioning of the European Union (TFEU) states that the environment is an area of shared competence between the EU and its Member States. The regulation of chemicals has been harmonised at EU level to preserve the good functioning of the internal market, in line with Article 114 of the TFEU. As the EU has exercised its competence in this area, the subsidiarity principles of subsidiarity and proportionality must be respected as per Article 5 of the Treaty on European Union (TEU).

The objectives of the REACH Regulation include ensuring a high level of protection of human health and the environment [...] to promote [...] the free circulation of substances on the internal market while enhancing competitiveness and innovation. Given these aims and the extensive intra and extra EU trade in chemical substances, mixtures and articles, a harmonised EU level approach was used when the REACH Regulation was adopted in December 2006. The current reforms concern a revision to the existing REACH Regulation. As such, the objectives of this intervention cannot be achieved by Member States alone, respecting the conditions laid out in Article 4 of the TFEU.

Moreover, the second REACH review concluded that there is clear added value from regulating chemicals at EU level through REACH, and that the system has provided benefits in terms of effectiveness and avoiding a fragmented approach in a cross-border market.

The paper from the Ad-hoc Meeting of Competent Authorities for REACH and CLP (CARACAL) in March 2022 also states that there was a "general consensus on the need to revise the current process of authorisation and restriction amongst Member States". There was agreement on the need to deal with this at an EU level, rather than a national level approach.

There is also evidence that exposure to harmful chemicals is an ongoing concern to the general public. A 2017 Special Eurobarometer survey aimed to gauge public opinion on chemicals and safety in the EU. It asked participants about levels of concern about being exposed to hazardous chemicals. Over 25% indicated they were very concerned, and just under 40% a little concerned about this. Opinions on whether the current level of regulation and standards in the EU is protecting human health and the environment should be
Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses and to reform REACH authorisation and restriction.

increased. Across the EU, 50% of respondents indicated that they perceived the current level of chemicals regulation as not high enough and that it should be increased, although this varied across Member States (72% in Greece and only 33% in Poland). Some 32% indicated they felt it was at the right level and 7% felt it was already sufficiently high and could be even lower. A similar survey was also conducted in 2019, where 90% of respondents agreed that they were worried about the impact of chemicals present in everyday products on the environment. Slightly less (85%) agreed that they were worried about the impact of chemicals on products on their health. These findings are almost identical to those from the 2017 survey and indicate an ongoing concern for EU citizens.


5 What should be achieved?

5.1 What are the objectives?

5.1.1 General objectives – REACH

Article 1(1) of the REACH Regulation lays out its objectives:

"The purpose of [REACH] is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."

As noted earlier, the second REACH review concluded that REACH was fit for purpose and delivering results towards achieving its objectives, but that progress towards the objectives is lagging behind initial expectations. It identified several areas where the REACH Regulation could be improved. The Zero Pollution Action Plan and the Chemicals Strategy for Sustainability build on the findings of the second REACH review and call for strengthening of the legal framework for addressing pressing environmental and health concerns through a targeted revision of the REACH Regulation. The second REACH review also identifies opportunities for simplifications of the existing processes.

5.1.2 General and specific objectives – REACH revision

The revision of REACH seeks to reinforce the general objectives of the existing REACH Regulation by achieving a higher level of protection of human health and the environment, while ensuring a better functioning, competitive internal market. The specific objectives to address the problems identified for authorisations and restrictions are:

- To simplify the REACH authorisation and restriction processes, reducing administrative costs and accelerating regulatory decision making on chemical risks;
- To increase the efficiency and effectiveness of REACH authorisation and restrictions (i.e., improve and increase the rate at which they meet their objectives) and increase the risk reduction capacity of individual restrictions;
- To provide clearer and more focused requirements for requests for derogations from restrictions and/or requirements and legal clarifications for applicants for authorisation;
- To provide further incentives for substitution of substances of concern, whilst incentivising innovation in the chemicals industry within the EU; and

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To increase the speed at which protection of human health and the environment can be enhanced via REACH authorisation and restriction.

The general and specific objectives of REACH, its revision (in general and in terms of authorisation and restriction reform) including the proposed extension of the GRA are summarised below (Table 13).
Table 13: General and specific objectives, REACH processes and proposed REACH revisions

<table>
<thead>
<tr>
<th>General objectives – REACH (Article 1)</th>
<th>General objectives of authorisation in REACH</th>
<th>General objectives of restriction in REACH</th>
<th>General objectives – REACH revision</th>
<th>Specific objectives – GBA extension</th>
<th>Specific objectives – authorisation and restriction reform</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure a high level of protection of human health and the environment.</td>
<td>Ensure the good functioning of the internal market while assuring the risks from SVHCs are properly controlled and that those substances are progressively replaced with suitable alternative substances or technologies where those are economically and technically viable (Article 56).</td>
<td>Prevent manufacture, placing on the market or use of substances posing an unacceptable risk to human health or the environment, or in a community wide basis (Article 67-73).</td>
<td>Increase the level of protection for human health and the environment.</td>
<td>Increase the speed at which protection of human health and the environment can be enhanced via REACH authorisation and restriction, especially from the most harmful substances.</td>
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</tr>
<tr>
<td>The promotion of alternative methods for assessment of hazards of substances</td>
<td>Prevent use and placing on the market of articles containing substances included in AXIV, where risk is not</td>
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<tr>
<td>The free circulation of substances on the internal market</td>
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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
<table>
<thead>
<tr>
<th>General objectives - REACH (Article 1)</th>
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<th>General objectives of restriction in REACH</th>
<th>General objectives - REACH revision</th>
<th>Specific objectives - GRA extension</th>
<th>Specific objectives – authorisation and restriction reform</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhancing competitiveness and innovation</td>
<td>adequately controlled (Article 69(2)).</td>
<td></td>
<td></td>
<td></td>
<td>• Greater flexibility to use the right instrument to regulate relevant substances/substance groups.</td>
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</tbody>
</table>
6 What are the various options to achieve these objectives?

6.1 Introduction

This section provides more details on:

- Three implementation scenarios for the extension of the GRA (Section 6.4). As noted earlier, this is expected to be implemented gradually.
- Three options under consideration for reforms to authorisation and restriction. These would be adopted alongside the GRA extension:
  - Option 1: clarifications, simplification and streamlining in the authorisation and restriction processes intended to address challenges observed in their implementation.
  - Option 2: the authorisation and restriction processes would be merged, with various possible options for derogation from restrictions.
  - Option 3: the authorisation provisions would be removed from REACH (but the Candidate List would be kept).
Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction.
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6.4 Description of Policy Options - Part 1: Implementation scenarios for the GRA extension

6.4.1 Current empowerment and procedure

According to REACH Article 68(1), the European Commission can introduce a new restriction amending Annex XVII if there is an "unacceptable risk" originating from the manufacture, use or placing on the market of a substance in the EU and that this risk needs to be addressed at Community wide level.

Article 68(2) currently empowers the European Commission to propose a restriction based on generic risk considerations if a substance has certain hazards, (i.e., fulfils the criteria of being carcinogenic, mutagenic or repro toxic (CMR) (cat. 1A or 1B)), and if exposure to it can generically be assumed, meaning that substance on its own, in mixtures or in articles could be used by consumers. Hence, hazardous properties of the substance and generic exposure considerations are sufficient for the European Commission to propose and substantiate new restrictions for uses of CMRs by consumers at the current time.

In this regard, risk management is enabled based on a generic risk assumption\(^{357}\). The European Commission is using Article 68(2) in REACH to regularly restrict CMR substances (Cat. 1A or 1B), on their own or in mixtures, for supply to the general public by adding newly classified CMR substances to the appendices to entries 28-30 of Annex XVII of REACH. When it comes to CMR cat. 1 substances in articles used by consumers, generic restrictions have been used to a limited extent: a restriction of certain CMR substances in textiles (entry 72 of Annex XVII)\(^{358}\) and certain PAH compounds in rubber and plastic (entry 50 of Annex XVII). In product specific legislation, there are also generic restrictions for CMR substances with relevance for consumers (e.g., the Toy Safety Directive\(^{359}\) and the Cosmetic Products Regulation\(^{360}\)).

6.4.2 Scope of potential future empowerment

In the CSS, the European Commission identifies the GRA as one of the actions to increase the level of protection of human health and the environment against chemicals with lasting harmful effects more efficiently. Making GRA a default approach for consumer and professional uses and extending it to further hazards classes and uses seeks to enable a more preventive approach, as well as to increase the speed of regulatory action and decision making, alongside providing stronger incentives for substitution.

The first aim is to increase protection from hazards already identified as being of concern, i.e., CMRs, PBTs/vPvBs and ED substances. An extension of the GRA to further hazard classes, including those affecting the immune, neurological, or respiratory systems and chemicals toxic to a specific organ is being considered.

In addition to the extension of the GRA to other hazard classes, the CSS also recognises the need to establish the same level of protection as applies to consumers to professional

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357 This describes situations where a risk can be assumed as defaults without the need for further evidence.

358 The restriction was not imposed on all consumer products, but on a clearly defined group of products. In addition, the substances were specifically identified and not all combinations with a classification to CMR 1A or 1B were included in the restriction.


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users, i.e., to certain categories of workers outside industrial settings and self-employed workers (see Table 26).

**Table 26: Comparison of current scope of the GRA under REACH and plans for its extension according to the CSS**

<table>
<thead>
<tr>
<th>Uses covered</th>
<th>Current scope of GRA (Article 68(2))</th>
<th>Envisaged scope of GRA in REACH revision</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• Consumer uses</td>
<td>• Consumer uses</td>
</tr>
<tr>
<td></td>
<td>o Substances</td>
<td>o Substances</td>
</tr>
<tr>
<td></td>
<td>o Mixtures</td>
<td>o Mixtures</td>
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<tr>
<td></td>
<td>o Articles</td>
<td>o Articles</td>
</tr>
<tr>
<td></td>
<td>• Professional uses (with similar exposure patterns for consumers)</td>
<td>• Professional uses (with similar exposure patterns for consumers)</td>
</tr>
<tr>
<td></td>
<td>o Substances</td>
<td>o Substances</td>
</tr>
<tr>
<td></td>
<td>o Mixtures</td>
<td>o Mixtures</td>
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<tr>
<td></td>
<td>o Articles</td>
<td>o Articles</td>
</tr>
<tr>
<td></td>
<td>• CMR cat. 1A and 1B</td>
<td>• CMR Cat. 1A and 1B</td>
</tr>
<tr>
<td></td>
<td>• ED (HH and Env) Cat. 1</td>
<td>• ED (HH and Env) Cat. 1</td>
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<tr>
<td></td>
<td>• STOT (SE and/or RE) Cat. 1</td>
<td>• STOT (SE and/or RE) Cat. 1</td>
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<tr>
<td></td>
<td>• Resp. Sens Cat. 1</td>
<td>• Resp. Sens Cat. 1</td>
</tr>
<tr>
<td></td>
<td>• Substances affecting the immune or neurological systems</td>
<td>• Substances affecting the immune or neurological systems</td>
</tr>
<tr>
<td></td>
<td>• PBT/vPvB (see below)</td>
<td>• PBT/vPvB (see below)</td>
</tr>
</tbody>
</table>

The CSS does not specify that **PMT/vPvM substances** should be subject to the extended Generic Risk Management Approach. However, after discussions in the scoping phase and in agreement with the European Commission, they were included in the assessment to understand their uses and the potential impacts of including this hazard class. This hazard class is not part of the main scenarios, but the impacts are described as part of the sensitivity assessment.

### 6.4.3 Implementation scenarios

The GRA extension concerns consumer uses and uses performed by certain categories of professionals where greater exposure or emissions (e.g., such as farmers, construction workers, hairdressers) are expected to be similar to those of consumers. The implementation of the GRA restrictions is assumed to be based on prioritisation of uses. The principles and criteria assumed in this impact assessment are described in the following sub-sections.

#### 6.4.3.1 Prioritisation assumptions

**In terms of professional uses**, many products aimed at professionals are also available to consumers. The assumption made is that such “consumer like” uses by professionals, taking into account potential exposure and emissions, would be prioritised for restrictions. Figure 16 illustrates this potential overlap between professional uses (“P”) consumer uses (“C”) (and also and industrial uses (“I’)). It has been assumed priority for GRA restrictions would be placed on those uses which fall in the intersection between “C” and “P” (i.e. the blue arrow).

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98 It is not explicitly stated in the CSS that both 36 and 368 will be part of the future system. However, in the context of this study, both categories are examined in order to be able to consider the impacts of both options. This does not, however, represent an anticipation of the final scope of the SME restrictions in Article 68(2) of the revised REACH.
In terms of articles, prioritisation for GRA restrictions has been assumed to be based on generic exposure/emission considerations based on three aspects:

- High potential for direct exposure to humans (with an emphasis on vulnerable groups, such as pregnant women);
- And/or high potential for emissions to the environment (across the article’s whole lifecycle, more emphasis may be given to the use phase); and
- Article types posing problems for recycling for production/use of new articles.

6.4.3.2 Assumptions on implementation timescales

To reflect the gradual implementation of the GRA extension, three scenarios have been examined. Various further assumptions have been agreed with the European Commission. It is not possible at the time of writing to estimate in any detail the scope of future restrictions. The approach here is to make high level indicative assumptions about phasing to give an order of magnitude to the costs and benefits.

- The start year for implementation of restrictions under the extended GRA is assumed to be 2026

- The extended GRA will apply to substances with a harmonised classification under CLP and/or identified SVHCs. The results therefore differentiate substances currently with and without harmonised classification. As such, the future scope of the GRA will reflect
  a) the prioritisation of substances described above
  b) substances with harmonised classifications in the hazard classes included in the extension of GRA as well as
  c) the rate at which new harmonised classifications can be determined. Hence, various “phase in” periods and shares of uses have been assumed.

- Substances already with a harmonised classification or SVHC may be subject to GRA as of the start date. They are assumed to be covered by GRA over a five-year period. After that, the substances currently without harmonised classification will, if and when they obtain a classification, gradually be subject to GRA restrictions. The number of substances that might receive a harmonised classification in turn depends on capacity to prepare and assess CLH dossiers. For this study, capacity has been estimated between lower and upper bounds. The lower bound based on the current “capacity” of authorities to prepare and process CLH dossiers is around 28 substances classified under CLP every year\(^{120}\). The upper bound is based on the results of an impact assessment of revisions to CLP. This estimated that in the future

\(^{120}\) Based on information from ECHA, it is assumed that about 80 substances can be processed including grouping and then only about half of the proposed classification is retained. This leaves around 27-28 substances per year. Here, 28 is used as the model assessment in the lower bound.

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs.
an additional 120 CLH dossiers might be prepared per year. Assuming that only 50% retain the proposed classification, results in around 60 new substances being classified under CLP every year. Therefore, for the assessment, it is assumed that a range between 28 and 60 substances receive a harmonised classification every year.

- The scenarios include different subsequent start dates for restrictions of different hazard classes. CMR (for professional uses), EDs, PBT and vPvBs are assumed to have the highest priority. The start year is assumed to be 2026. For scenario 1, the other hazard classes will start to be covered by GRA restrictions in the same start year. For scenario 2 and 3, the start date for the other hazard classes is assumed to be five years later, i.e., 2031.

- For the limited number of EDs, PBT and vPvBs that also have harmonised classification (CLH) under CLP and/or are identified as SVHC, it is assumed that they are already regulated. For the later assessment of costs and benefits, no impacts are assumed for this group.

- In the tables below, when referring to “consumer use” and “professional use”, the implementation scenarios assume use of a substance on its own or in a mixture. When referring to “articles”, the scenarios assume use of articles by consumers and/or professionals. The data does not allow consideration of articles used by consumers and articles used by professionals separately.

- For scenario 1, the start date for restrictions of consumer and professional uses (substances and mixtures) is the same, while restriction in articles is assumed to start two years later. For scenarios 2 and 3, professional uses will be phased-in with a two year delay.

- The table below also refers to “implementation period”. Here this refers to how many years it will take to introduce GRA restrictions for the particular hazard classes and uses. For example, if there are 100 substances in a given hazard class and the implementation period is 10 years, then 10 substances are assumed to be restricted each year. It is assumed that adoption of a restriction dossier is implemented in one year, to simplify the calculations. In practice the adoption of a GRA restriction may take longer, but the impact of this on the cost assessment is expected to be minor in view of the overall uncertainties.

- The “share of uses included” (i.e. covered by the GRA) are assumptions made to reflect the uncertainty about the prioritisation of uses as well as the effects of possible derogation provisions, based on the essential use criteria. These have been discussed with the European Commission as indicative assumptions suitable for scenario building in the impact assessment.

- Different hazard classes have been assessed and have been grouped, as set out below. The grouping reflects the availability of the underlying data in the use maps (see Section 1.2.2).

**Table 27: The implementation scenarios in numbers - CMRs**

<table>
<thead>
<tr>
<th>CMR</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professional use</strong></td>
<td>Start year</td>
<td>2026</td>
<td>2026</td>
</tr>
<tr>
<td></td>
<td>Implementation period</td>
<td>5y</td>
<td>5y</td>
</tr>
</tbody>
</table>
Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction.

**Table 28: The implementation scenarios in numbers – ED, PBT and vPvB substances**

<table>
<thead>
<tr>
<th>CMR</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Share of uses included</td>
<td>75%</td>
<td>80%</td>
</tr>
<tr>
<td></td>
<td>Substances without CLH</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Start year</td>
<td>2031</td>
<td>2031</td>
</tr>
<tr>
<td></td>
<td>Implementation period</td>
<td>15y</td>
<td>15y</td>
</tr>
<tr>
<td></td>
<td>Share of uses included</td>
<td>75%</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>Substances with CLH</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Start year</td>
<td>2031</td>
<td>2031</td>
</tr>
<tr>
<td></td>
<td>Implementation period</td>
<td>15y</td>
<td>15y</td>
</tr>
<tr>
<td></td>
<td>Share of uses included</td>
<td>75%</td>
<td>50%</td>
</tr>
<tr>
<td>Articles (for professional use with high exposure/emissions)</td>
<td>Share of uses included</td>
<td>50%</td>
<td>10%</td>
</tr>
<tr>
<td></td>
<td>Substances without CLH</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Start year</td>
<td>2031</td>
<td>2031</td>
</tr>
<tr>
<td></td>
<td>Implementation period</td>
<td>15y</td>
<td>15y</td>
</tr>
<tr>
<td></td>
<td>Share of uses included</td>
<td>75%</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>Substances with CLH</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Start year</td>
<td>2031</td>
<td>2031</td>
</tr>
<tr>
<td></td>
<td>Implementation period</td>
<td>15y</td>
<td>15y</td>
</tr>
<tr>
<td></td>
<td>Share of uses included</td>
<td>75%</td>
<td>50%</td>
</tr>
<tr>
<td>Consumer use</td>
<td>Share of uses included</td>
<td>50%</td>
<td>10%</td>
</tr>
<tr>
<td></td>
<td>Substances without CLH</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Start year</td>
<td>2031</td>
<td>2031</td>
</tr>
<tr>
<td></td>
<td>Implementation period</td>
<td>15y</td>
<td>15y</td>
</tr>
<tr>
<td></td>
<td>Share of uses included</td>
<td>75%</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>Substances with CLH</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Start year</td>
<td>2031</td>
<td>2031</td>
</tr>
<tr>
<td></td>
<td>Implementation period</td>
<td>15y</td>
<td>15y</td>
</tr>
<tr>
<td></td>
<td>Share of uses included</td>
<td>75%</td>
<td>50%</td>
</tr>
<tr>
<td>Professional use</td>
<td>Share of uses included</td>
<td>50%</td>
<td>10%</td>
</tr>
</tbody>
</table>

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Table 28: The implementation scenarios in numbers – Other hazard classes assessed

<table>
<thead>
<tr>
<th>Articles</th>
<th>Substances without CLH</th>
<th>Substances with CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
<td>2028</td>
<td>2028</td>
</tr>
<tr>
<td>Implementation period</td>
<td>5y</td>
<td>5y</td>
</tr>
<tr>
<td>Share of uses included</td>
<td>75%</td>
<td>50%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances with CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Articles</th>
<th>Substances without CLH</th>
<th>Substances with CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
<td>2033</td>
<td>2033</td>
</tr>
<tr>
<td>Implementation period</td>
<td>10y</td>
<td>20y</td>
</tr>
<tr>
<td>Share of uses included</td>
<td>50%</td>
<td>10%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances with CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances without CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>All other hazard classes</th>
<th>Substances with CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
<td>2026</td>
</tr>
<tr>
<td>Implementation period</td>
<td>5y</td>
</tr>
<tr>
<td>Share of uses included</td>
<td>90%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances without CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances with CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances without CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances with CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances without CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances with CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances without CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances with CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances without CLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
</tr>
<tr>
<td>Implementation period</td>
</tr>
<tr>
<td>Share of uses included</td>
</tr>
</tbody>
</table>
Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction

<table>
<thead>
<tr>
<th>All other hazard classes</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
<td>2031</td>
<td>2036</td>
<td>2036</td>
</tr>
<tr>
<td>Implementation period</td>
<td>15y</td>
<td>16y</td>
<td>16y</td>
</tr>
<tr>
<td>Share of uses included</td>
<td>75%</td>
<td>50%</td>
<td>25%</td>
</tr>
</tbody>
</table>

Articles

<table>
<thead>
<tr>
<th>Substances with CLH</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
<td>2028</td>
<td>2033</td>
<td>2033</td>
</tr>
<tr>
<td>Implementation period</td>
<td>10y</td>
<td>20y</td>
<td>30y</td>
</tr>
<tr>
<td>Share of uses included</td>
<td>50%</td>
<td>10%</td>
<td>1%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substances without CLH</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start year</td>
<td>2033</td>
<td>2033</td>
<td>2033</td>
</tr>
<tr>
<td>Implementation period</td>
<td>10y</td>
<td>20y</td>
<td>30y</td>
</tr>
<tr>
<td>Share of uses included</td>
<td>50%</td>
<td>10%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
6.5 Description of Policy Options - Part 2: authorisation and restriction reform options

This section of the report provides more detail on the options, the reasons behind their development and their implications. It is aimed at readers requiring an operational explanation. Section 6.6 provides a more basic summary of the key elements. Therefore, for the purposes of the impact assessment, section 6.7 provides greater detail still, of proposed changes within each option. This section is aimed at those requiring more intricate detail on each potential change.

Table 30: Overview of options and key processes implications

<table>
<thead>
<tr>
<th>Option</th>
<th>Overview and key implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1: Streamline the authorisation and restriction provisions</td>
<td>REACH authorisation places the burden of proof on industry and aims at progressive substitution of SVHC by suitable alternatives, while aiming to ensure that the risks for specific authorised uses are properly controlled until substitution can occur.</td>
</tr>
<tr>
<td></td>
<td>• Option 1 involves maintaining the existing authorisation system but modifying a series of elements of the process to address weaknesses identified during its current implementation. As such the focus of changes proposed are on the authorisation system with a subset of improvements proposed for the restriction system.</td>
</tr>
<tr>
<td></td>
<td>• The process of identifying SVHCs (candidate listing) and making them subject to authorisation/generic bans (Annex X V listing) would remain the same, including all types of uses (as well as industrial uses). No major changes (but still improvements) are envisaged for the restriction process under REACH Article 68(1) for this option.</td>
</tr>
<tr>
<td></td>
<td>• As for the other options, the scope of Article 68 (2) would be extended and the essential use concept implemented, in particular for professional and consumer uses.</td>
</tr>
<tr>
<td></td>
<td>• Implementation of the essential use concept in REACH is also being considered as the context of the modification of the existing authorisation system, derogations from restrictions (following Article 68 (1) and 68 (2) under Option 1, but also under Options 2 and 3, with some differences in scope) to increase efficiency and speed of authorisations and restrictions. Different options for how the essential use concept could be incorporated in REACH restrictions and authorisations are being considered in a separate study.</td>
</tr>
<tr>
<td></td>
<td>• National requirements regarding industrial uses under workers and environmental regulation remain in place for those substances that are not regulated at EU level.</td>
</tr>
<tr>
<td></td>
<td>• As is currently the case, with the exception of derogations under Article 68 (2), continued use of substances subject to authorisation could only be granted through authorisations per applicant.</td>
</tr>
<tr>
<td></td>
<td>• Continued use of substances restricted under Articles 68 (1) or 68 (2) could only be granted through derogations proposed by authorities as part of the preparation of the restriction. Nevertheless, industry has the (informal) possibility to flag the need for derogations during the consultations on the restriction dossier and on the SEAC opinion.</td>
</tr>
</tbody>
</table>

| Option 2: Merging the authorisation and restriction processes           | This option was developed on the assumption that the modifications of the authorisation system in Option 1 are insufficient to address the identified weaknesses, in particular to reduce the administrative burden on companies and authorities, disadvantages for EU | 110 |
Option | Overview and key implications
--- | ---
companies and delays in substitution and application of necessary risk management measures. The main measures of Option 2 are the following:

- To replace Annex XIV listing (all the substances where uses are subject to an authorisation in the EU) with restrictions of SVHCs, either in a revised form of Annex XIV ("Annex XIV bis") or in a specific section of Annex XVII, and to broaden and align the possibilities for derogations for both SVHCs (ex-Annex XIV) and restrictions under Articles 68(1) and 68(2). In this context, it needs to be noted that the current authorisation requirement is already de facto a generic restriction, and authorisations are de facto a way to derogate from this generic restriction. While the change from the authorisation requirement to a generic restriction would be only nominal, without any change in practical implications (in other words, a substance listed on Annex XIV bis will be banned in principle, just as it is currently the case for Annex XIV), there would be more ways to derogate from this generic restriction than currently is the case for the authorisation requirement in Annex XIV. In practice, there will be more possibilities for authorities to exclude certain uses or categories of uses, and there will be the possibility for derogations of general applicability requested by industry, in addition to authorisation.

- The process of identifying SVHCs (candidate listing) and making them subject to authorisation/generic basis (currently Annex XIV listing) would remain the same, including all types of uses (as well as industrial uses). Under Option 2, either Annex XIV would be retained with modifications or Annex XIV would become a specific section of Annex XVII. No major changes, but still improvements, are envisaged for the restriction process under REACH Article 68(1) under this option.

- As for the other options, the scope of Article 68(2) will be extended and the essential use concept implemented, in particular for professional and consumer uses.

- Different options for how the essential use concept could be incorporated in REACH restrictions and authorisations are being considered in a separate study.

- National requirements regarding industrial uses under workers and environmental legislation remain in place for those substances that are not regulated at EU level.

- Under this option, there would be three ways to introduce derogations from the restrictions (applying to all three forms of restrictions, Annex XIV/XVII listing of SVHCs, Articles 68(1) and 68(2)):

  - Derogations could already be included as part of the restriction, as proposed and adopted by authorities (as in the existing restriction system with the burden of proof on authorities). Industry has the (informal) possibility to flag the need for derogations during the consultations on the restriction dossier and on the SEAC opinion.

  - After the restriction is adopted, and if the Commission introduced such a possibility in that particular restriction, companies could formally request:
    
    - Generally applicable (joint) derogations to a specific use and cover all the companies that perform that use (note this would be a new element with the burden of proof on industry). "Generally applicable derogations" are derogations in Annex XVII for certain uses of a substance, no matter which user has applied for the derogations (i.e., it is generally applicable). 
    
    - Individual derogations/authorisations (similar to existing REACH authorisations with the burden of proof on industry) would be possible only in specific circumstances. Note "individual derogations" are decisions addressed to the applicant for authorisation and only apply to applicants.

---

The disadvantages for EU companies are that Annex XIV substances may still be present in imported articles even if not authorised for such uses in the EU. With the extension of the scope of generic restrictions to cover all (or most) of the hazard classes subject to authorisation, such uses in imported articles will be restricted without the need for documentation of an unacceptable risk.
<table>
<thead>
<tr>
<th>Option</th>
<th>Overview and key implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 3: Removing the authorisation title from REACH</td>
<td>The development of this option has assumed that the weaknesses of the current REACH authorisation system outweigh its benefits and that restrictions following Article 68(1) and the extension of the scope of Article 68(2) (in line with the CSS) would be sufficient to address the risks of the use of SVHCs.</td>
</tr>
<tr>
<td>a)</td>
<td>Option 3 involves maintaining candidate listing of SVHCs but removing the remainder of the authorisation system.</td>
</tr>
<tr>
<td>b)</td>
<td>The process of identifying SVHCs (candidate listing) would remain the same. No major changes, but still improvements, are envisaged for the process under REACH Article 68(1) under this option, as with the other options.</td>
</tr>
<tr>
<td>c)</td>
<td>As for the other options, the scope of Article 68(2) will be extended and the essential use concept implemented, in particular for professional and consumer uses.</td>
</tr>
<tr>
<td>d)</td>
<td>Different options for how the essential use concept could be incorporated in REACH restrictions and authorisations are being considered in a separate study.</td>
</tr>
<tr>
<td>e)</td>
<td>National requirements regarding industrial uses under workers and environmental legislation remain in place for those substances that are not regulated at EU level, and would need to address risks related to SVHCs that would otherwise have been regulated under REACH provisions for SVHCs (authorisation under Option 1, generic restrictions under Option 2), and which would not be regulated under REACH restrictions under Articles 68(1) and 68(2) or other EU legislation.</td>
</tr>
</tbody>
</table>

**Continued use of substances restricted under Articles 68(1) or 68(2) could only be granted through derogations proposed by authorities as part of the preparation of the restriction.** Nevertheless, Industry has the (informal) possibility to flag the need for derogations during the consultations on the restriction dossier and on the SEAC opinion.

- a) | Compared to policy Options 1 and 2, Option 3 does not include formal options for industry to submit requests for derogations/authorisations from restrictions. Nevertheless, Industry has the possibility to flag the need for derogations during the consultations on the restriction dossier and on the SEAC opinion. A possibility to formally submit requests for derogations/authorisations under Article 68(2) restrictions is not envisaged in this option (i.e., neither for essential uses). |
- b) | Under Option 3, risks arising from chemical substances used by consumers and professionals would be addressed via Article 68(2) restrictions under REACH and/or via Article 68(1) for industrial uses. |
- c) | Substances that are currently included in Annex XIV (Authorisation List) would be transferred to Annex XVII (Restriction List) as bans. |
- d) | Risks arising from the use of chemicals in industrial settings would be addressed either by REACH restrictions if EU-wide action is needed or by (national) measures under Occupational Safety and Health legislation (OSH) for concerns related to workers’ safety and by the Industrial Emissions Directive 2010/75/EU (IED) concerning emissions to the environment. This is not different from the current provisions for substances not already regulated at EU level. |

Even though the authorisation title would be removed under this option, the Candidate List would be retained. In such cases, prioritisation for regulatory actions under REACH could be made by ECHA or Member States based on the information collected on the substances included in the Candidate List. The Candidate List could also contribute to prioritisation for regulatory actions under non-REACH processes (noting that proposed modifications for inclusion of substances in the Candidate List discussed below would be fully applicable in this case).
<table>
<thead>
<tr>
<th>Option</th>
<th>Overview and key implications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horizontal measures (applies to all options)</td>
<td>Under all the options, the Candidate List would be maintained but used for prioritisation for regulatory action in general. As such, it may be linked to additional obligations for companies. These are:</td>
</tr>
<tr>
<td>Downstream users have to notify authorities and provide information (e.g., uses, tonnage, exposure) on substances included in the Candidate List.</td>
<td>The ability to grant authorisations and derogations from restrictions of specific uses could be based on whether these uses are judged essential (the EEU). (Note: this concept is currently being developed under a separate study but assumes a use is essential if it is necessary for health, safety, or is critical for the functioning of society and there are no alternatives that are acceptable from the standpoint of environment and health). This essential use concept could replace or complement the current criteria, in particular socio-economic analysis, for granting an authorisation (Article 62) and would set the criteria for granting derogations from Article 62(2) “GRA restrictions” and restrictions under Article 68(1).</td>
</tr>
<tr>
<td>Downstream users have to pay a notification fee for substances in the Candidate List.</td>
<td>Complementary to the essential use concept, the European Commission is also considering, for exceptional cases, the possibility of granting derogations from GRA restrictions for uses where there is “minimal exposure”. The minimal exposure concept would be applicable for uses of substances in articles subject to GRA restrictions and for industrial uses of substances in mixtures. In exceptional cases, the Commission, as part of their restriction proposal, may grant a derogation if there is evidence that the exposure/ emissions throughout the whole lifecycle of the substance (i.e., not only from the use-phase of the article) is absent or minimal. This will include considerations of the potential for long-range transport, mobility characteristics, potential to contaminate natural resources, exposure/emissions from recycled materials and there are no suitable alternatives.</td>
</tr>
<tr>
<td>The role of the Forum on enforceability of authorisations and restrictions is also being reviewed to consider the following alternative measures:</td>
<td>The role of the Forum on enforceability of authorisations and restrictions is also being reviewed to consider the following alternative measures:</td>
</tr>
<tr>
<td>Making the Forum a Committee providing an opinion with the equivalent status of RAC and SEAC. The Forum would give an opinion on enforceability with equivalent status as the “Agency Opinion” of RAC and SEAC, as defined in Article 70 and 71 REACH, with subsequent changes in Article 76, 87, 73 (1) of REACH. The Forum would give an opinion on AIAs general derogation requests/ individual derogation requests and on restrictions proposals under Article 68(1). The procedure for the Forum Working Group on enforceability would be the starting point to set up the Committee procedures in REACH, but this procedure would need to be expanded if Forum advice was to become a “third” Agency opinion. This would necessitate changes to the status and composition of the Forum of</td>
<td></td>
</tr>
<tr>
<td>The Forum gives advice on both proposed restrictions and (as a new element) authorisations which could be provided when draft opinions are uploaded for comments by the Committee members. This would mean that the Forum would be involved in the enforceability aspects whenever RAC and SEAC give an opinion (e.g., always for restriction proposals and where necessary for individual derogations/ authorisations). Note this may not always be necessary and this should not prolong the opinion-making process of RAC and SEAC. Their advice would focus on enforceability of recommendations for authorisation and RMMs operational conditions proposed by RAC or other conditions proposed by SEAC at draft opinion stage. This would be done for groups of substances or uses. This requires a change of Article 77 (4) sub h) (adding Forum advice on enforceability of authorisation conditions)</td>
<td></td>
</tr>
<tr>
<td>Option</td>
<td>Overview and key implications</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------</td>
</tr>
</tbody>
</table>

and revised (stronger) text in Articles 70 and 71 (e.g., “the RAC/SEAC opinions take into account the Forum advice” which is currently missing). It may possibly include an obligation for the European Commission to take the advice into account in Article 73 (1).
### 6.6 Authorisation and restriction reform - options summary

#### Table 31: Comparison of options and components

<table>
<thead>
<tr>
<th>Step</th>
<th>Substances</th>
<th>Baseline (no changes to REACH)</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
</tr>
</thead>
</table>
| Candidate List                          | Substances with the hazard properties listed in Article 57 of REACH        | CMR, PBT, vPvB substances + ELoC\(^{364}\) for other substances | • Add ED, PBT, vPvM to hazard classes where reference to harmonised classification is sufficient to be able to include substances on the Candidate List (i.e., no ELoC is necessary);  
• Add requirements for downstream users to provide information on use, exposure, alternatives, and waste management when the substance is included in the candidate list;  
• Add fees linked to this notification obligation linked to the SVHC entry of substances to the Candidate List |
| Type of risk management instrument      | SVHC on Annex XIV                                                          | Authorisation requirement/Annex XIV | Restriction/Annex XVII (incl. integration of ex-Annex XIV) | None |
| applying by default (i.e., unless there is a derogation on authorisation) | Other substances                                                           | Restriction/Annex XVII          | Restriction/Annex XVII |          |
| Derogation proposed by authorities      | SVHC on Annex XIV                                                          | Article 58(2) Only for uses where risks are properly controlled by other legislation. | Part of restriction proposal | n/a |
|                                          | Other substances                                                           | Part of restriction proposal    | Part of restriction proposal |          |
| Derogation of general applicability\(^{365}\) | None                                                                      |                                 | Possible where envisaged in restriction | None |
| on formal industry request (applicable to all users) | Possible where envisaged in restriction |                                 | None |

\(^{364}\) Equivalent level of concern

\(^{365}\) i.e., applying to anyone using the substance according to the conditions of the derogation, independently from being an applicant or not.

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<table>
<thead>
<tr>
<th>Step</th>
<th>Substances</th>
<th>Baseline (no changes to REACH)</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorisation applicant(s) only</td>
<td>(applicable to) SVHC on Annex XIV Other substances</td>
<td>Uses for which authorisation is granted</td>
<td>Possible when foreseen in Annex XVII, no upstream applications</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>None</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6.7 Description of Policy Options - Part 3: measures in each authorisation and restriction reform option

Each option comprises various measures. The assessment of impacts is carried out on all measures. Each measure is discussed in sections 6.7 to 6.10 along with unique reference numbers. The purpose of this approach is to enable the European Commission to select a final option(s), based on a combination of measures. For example, the measure to allow companies to apply for derogation requests from GRA restrictions (under Option 2) could be combined with other measures in Option 1 and/or Option 3 to define the final 'preferred option'.

6.7.1 Horizontal measures — apply to all options

6.7.1.1 Candidate List measures (horizontal)

Potential modifications of the Candidate List (CL) are presented separately, as they apply to all options being considered. At present the Candidate List is linked to the obligation for ECHA to prioritise and recommend substances for inclusion in the Authorisation List (Annex XIV). In Options 1, 2 and 3, the Candidate List could remain as a tool to prioritise substances for regulatory action, for example in REACH restrictions but also in other non-REACH processes such as under Occupational Safety and Health (OSH) legislation or the Industrial Emissions Directive 2010/75/EU (IED).

In addition, it could be used to trigger requests for additional information on uses, exposure, emissions and waste management of SVHCs and their alternatives. This would be used by authorities in their development of proposals for regulatory action, minimising the need for specific requests for this during the preparatory steps of the regulatory proposals. A series of alternative measures to Candidate List process have been assessed (Table 32).

<table>
<thead>
<tr>
<th>Ref no.</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>CL1</td>
<td>Identification of substances as SVHC when they meet the criteria for classification, as regards their ED, PBT/vPvB, PMT/vPvM properties, would follow the same procedure as currently used for CMRs. i.e., when there is a harmonised classification, a reference to the CLP Regulation would be sufficient in the Annex XV (SVHC) identification dossier as the hazard confirmation is done through CLP (there would be no more reference to Annex XIII of REACH). There would be no need for an MSC opinion in these cases.</td>
</tr>
<tr>
<td>CL2</td>
<td>The demonstration of an Equivalent Level of Concern (ELoC) (similar procedure to Article 56) would be needed for hazards other than CMR, ED, PBT, vPvB, PMT and vPvM. This would maintain the current approach of Annex XV (SVHC) dossier and MSC opinion.</td>
</tr>
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</table>

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<th>Ref no.</th>
<th>Detail</th>
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<tbody>
<tr>
<td>CL3</td>
<td>A new procedure/criterion would be added to the CL which addresses the situation when the harmonised classification of the substance listed in the CL has changed due to new information, so that criteria of Article 57 are no longer fulfilled (similar to Article 58(6)).</td>
</tr>
<tr>
<td>CL4</td>
<td>An improved link would be established with CLP so that the hazard properties of substances on the Candidate List would be automatically updated in cases where the substance classification as CMR, ED, PBT, vPvB, PMT or vPvM is established or revised under CLP.</td>
</tr>
</tbody>
</table>
| CL5 | To strengthen the usefulness of the Candidate List, new requirements could be introduced for industry to regularly (e.g., on an annual basis) provide more detailed information on e.g., uses, tonnages and exposure/emission patterns, waste management, possible alternatives for substances on the list. Note a range of options are being considered and are assessed in this report for the type, detail and frequency of such requirements, from "light touch" low burden, to more detailed information. This information would first be requested after 18 months from inclusion in CL, then require periodic update. Downstream users would need to provide some or all of the following information for substances used above the cut-off quantity (150 kg/yr, 1 kg/yr, 10 kg/yr, 100 kg/yr to be assessed) on the list periodically (1, 3 or 5 years to be assessed)) to ECHA e.g., via IUCLID:  
  - Description of their uses and technical function of the CL substance;  
  - Tonnages;  
  - Human exposure/emissions to the environment (e.g., workers' exposure, emissions to air);  
  - Waste management (e.g., details on wastewater treatment);  
  - Screening of alternatives (based on easily accessible and available information, e.g., based on literature review, web search – but no request for on-site research and testing; this would be less detailed than AoA in AAs). |
| CL6 | As a result of the additional information requested above, a new public ECHA database with notification information would be established. This would need to be designed and maintained by ECHA. |
| CL7 | Allow alternative providers to submit information directly to ECHA on available alternatives. This additional information would need to be screened and processed by ECHA. |
| CL8 | The addition of an initial notification and update “fee” for substances in the Candidate List to incentivise substitution. This would be a tonnage-based fee and paid every time there is a notification and an update. Fees would be used to fund ECHA activities on processing the information submitted, projects on substitution activities and could also cover all risk management related activities in ECHA and Member States. |
| CL9 | Upon request by Member States enforcement authorities, DUs should be obliged to provide proof of notification (IUCLID statement) and payment of notification fees (ECHA receipt of paid fee). Use is exempted from notification requirements due to low quantities; a proof of the quantity should be provided. In turn, Member States should lay down the provisions on penalties applicable for the infringement of new obligations on notification of substances in CL. The scale of penalties is up to MS, not defined by REACH. |
6.7.1.2 Essential use and “minimal exposure” (horizontal)

Two potential bases for derogations from restrictions and granting authorisations are assessed (Table 33). These are based on the essential use (ESU) concept, in line with the sub-options assessed in a separate contract, or ESU as the main route, but with the possibility of minimal exposure derogations for non-essential uses, in exceptional cases for substances in articles subject to GRA restrictions. Note that under Article 68(1), a restriction is processed if there is an unacceptable risk. So, for Article 68(1) restrictions, uses for which there is no unacceptable risk (uses that can be considered safe) would not be restricted.

<table>
<thead>
<tr>
<th>Ref no.</th>
<th>Detail</th>
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<tbody>
<tr>
<td>ESU</td>
<td>The essential use concept would replace the current criteria for granting an authorisation (Article 67) and would set the criteria for granting derogations from Article 68(1) and 68(2) restrictions. The use of substances would only be permitted “if they are necessary for health, safety, or are critical for the functioning of society and there are no alternatives that are acceptable from the standpoint of environment and health”. This concept is under development in a separate study and has not been finalised at the time of writing.</td>
</tr>
<tr>
<td>Minimal exposure</td>
<td>For exceptional cases, for uses of substances in articles and for industrial uses of substances in mixtures, authorisations/derogations from restrictions may be granted based on “minimal exposure”: it would need to be proven that exposure/emissions throughout the whole lifecycles of the substance is absent or minimal, including considerations of the potential for long range transport, mobility characteristics, potential to contaminate natural resources, exposure/emissions from recycled materials and that there are no suitable alternatives.</td>
</tr>
</tbody>
</table>

6.7.1.3 The role of the Forum (horizontal - F1/F2 are alternatives)

<table>
<thead>
<tr>
<th>Ref no.</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td>The Forum becomes a Committee providing “Agency Opinions” with a similar status of RAC and SEAC. Opinions would be provided on enforceability of Article 68 general derogation requests' individual derogation requests and on restriction proposals under Article 68(1). Note for ARA's, the advice would be on the enforceability of additional conditions proposed by RAC or SEAC and not likely to be required in all cases.</td>
</tr>
<tr>
<td>F2</td>
<td>The Forum continues to give advice on enforceability of restrictions but also for authorisations (note this is not relevant for all options). These would be provided when draft opinions are uploaded for comment by the Committee members. Hence the Forum would be involved whenever RAC and SEAC give an opinion (e.g., always for restrictions and when necessary for individual authorisations). The advice would focus on enforceability of recommended conditions for authorisation and RM/operational conditions proposed by RAC or other conditions proposed by SEAC at the draft opinion stage. This would be done...</td>
</tr>
</tbody>
</table>
Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction

<table>
<thead>
<tr>
<th>Ref no.</th>
<th>Detail</th>
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<tbody>
<tr>
<td></td>
<td>for groups of substances or uses, rather than for every ARA. Note this may not always be necessary and this should not preter the opinion-making process of RAC and SEAC.</td>
</tr>
</tbody>
</table>
6.8 Option 1 measures: Streamline the authorisation and restriction provisions

For Option 1, the emphasis is placed on adjustments to the authorisation process, with improvements to the restriction process.

6.8.1 Authorisation process

6.8.1.1 Prioritisation and inclusion of substances into Annex XIV (Authorisation List)

REACH authorisation places the burden of proof on industry. The prioritisation of substances from the Candidate List and their inclusion in Annex XIV is a starting point for the authorisation requirement and there are indications that certain elements could be improved. The introduction of notification obligations (and their subsequent update) by industry for uses of substances included in the Candidate List could result in:

a) ECHA being able to take more informed decisions on which substances to suggest for inclusion into Annex XIV;

b) The consultation on the ECHA prioritisation and draft ECHA recommendation could be limited to confirming information from DU notifications and gathering additional information from interested parties (including providers of alternatives); and

c) Companies with access to information on the use of substances in the Candidate List, using this to prepare joint applications for authorisation for the same use.

<table>
<thead>
<tr>
<th>Ref no.</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Op1 A1</strong></td>
<td>Including presence of Annex XIV substances in articles in authorisation scope to address risk arising from SVHC in articles. This would extend the scope of current provisions on authorisation requirements to cover not only use of substances but also their presence in articles and bring the authorisation system closer to restrictions. This would also make Article 68(2) redundant, as authorisation for SVHC in articles would automatically cover presence of substances in articles and there would be no need for such restrictions. This may however increase the number of applications expected, resulting in additional burden on both industry and authorities, although it is anticipated that this burden is minor as it has not been assessed quantitatively. In fact, as integrating substances in articles in the EU is subject to authorisation, this would cover mainly imported articles which still may contain SVHCs subject to authorisation. On the other hand, as the SVHCs in some articles for consumers and professionals may be restricted via the extended use of Article 68(2), it is anticipated that the number of additional applications will be minor. As such this has not been assessed quantitatively in this study, as there would be no need to apply for authorisation for those prioritised uses.</td>
</tr>
</tbody>
</table>

Table 35: Option 1 authorisation measures (Op1 A#)

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6.8.1.2 Application for authorisation phase

Upstream applications submitted by actors higher in the supply chain contribute to the problems identified in the current authorisation system. In many cases, issues arise due to broad, poorly defined and described uses applied for, deficiencies in information provided by downstream users, including operational conditions, risk management measures and possibilities for substitution. This has made the assessment, opinion and decision making of such applications difficult and lengthy, has led to court cases and resolutions by the European Parliament.

Under Option 1, a series of measures are being considered focused on clarifications of definitions and legal wording within the regulation which detail these information requirements. The measures aim to provide additional clarity and detail on the authorisation requirements, while not necessarily increasing burden for the applicant, but instead making the process clearer and more consistent.

<table>
<thead>
<tr>
<th>Ref no.</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Op1 A5</td>
<td>The definition of intermediate uses would be clarified in Article 3.15</td>
</tr>
<tr>
<td>Op1 A6</td>
<td>Within the GR&amp;D exemption, there would be a new definition of ‘controlled conditions’ in Article 3 added to the current text.</td>
</tr>
<tr>
<td>Op1 A7</td>
<td>For applications for authorisation, clarifications would help to specify the level of granularity required in relation to use description, technical function, and representativeness of DU information.</td>
</tr>
</tbody>
</table>

---

Table 36: Option 1 authorisation measures (Op1 A#)
### 6.8.1.3 Opinion making phase

Within the opinion making phase it is possible (if necessary) for the Committees to make a joint request to the applicant for additional information to bring the application into conformity with the requirements of Article 62. However, the legislation currently contains no clear description for this. A formalised procedure for the completeness/conformity checks could be adopted and introduced at the beginning of the application evaluation.

---

**Ref no.** | **Detail**
---|---
Op1 A8 | Either add or delete “adequate control route” text (i.e., Article 60(2), 60(3) and review wording of 60(4) accordingly.
Op1 A9 | A new provision would be included in the text which would prevent the authorisation of uses to produce articles/mixtures for export that are banned in the EU.
Op1 A10 | Clarification of the definition of **suitability of alternatives** for the applicant. For example, additional detail would be provided on how to conclude whether a suitable alternative is available for the same/similar use, also taking into account the technical function and level of performance provided.
Op1 A11 | Clarify the **substitution plan requirement**, indicating that a substitution plan or R&D plan is always required as part of the application. The specific information requirements for a substitution plan would also be introduced possibly in an Annex to REACH.
Op1 A12 | Further clarification of which actors in the supply chain can apply for an authorisation. For example, this would include downstream users, their immediate upstream actors, manufacturers/ importers (Article 62(d)).
Op1 A13 | Addition of an extra bullet point in Article 60(3) stating that: (c) whether other actors in the EU have already carried out a substitution for similar uses.
Op1 A14 | Clarification of the requirements for submission and evaluation of review reports (e.g., type of information to be submitted, assessment of non-compliance of with conditions to granted authorisations, possibility of merging review reports by several authorisation holders of the same use, etc.). These details would be specified in an implementing act, while the key points would be included in Article 61.
Op1 A15 | In cases of refused authorisation, there would be the possibility for the European Commission to set up a transitional period of up to 18 months and ad-hoc arrangements to facilitate ceasing of the use. The aim of this measure is to allow companies a smooth transition away from the substance and also avoid problems of disposal of the unused substance.

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*This article deals with the grounds for granting of an authorisation. It currently contains explicit consideration of the risk to human health and the environment and the technical and economic feasibility of alternatives.*

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process, similar to the one currently outlined in REACH Article 69(4) for restrictions. These measures are proposed to provide clarity and formality on the completeness/conformity process.

### Table 37: Option 1 authorisation measures (Op1 A#)

<table>
<thead>
<tr>
<th>Ref no.</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Op1 A16</td>
<td>When the A# is submitted, the ECHA Secretariat first checks for completeness (i.e., all required elements are included) before issuing an invoice. Checks and verifications currently being completed by ECHA remain the same, but the procedure is clearer.</td>
</tr>
<tr>
<td>Op1 A17</td>
<td>Further clarifications to the conformity procedure (Article 64(3)) are proposed to define the conditions for a dossier to be in conformity. This would include the introduction of a “stop-the-clock” mechanism for the deadlines of opinion making which can be imposed until additional information submitted at the request of the Committee is provided by the applicant. If the application remains non-conformant, within [x] days of the date of receipt of the reasons from the Committees, the procedure shall be terminated, application fee non-refundable.</td>
</tr>
<tr>
<td>Op1 A18</td>
<td>If the application conforms, the respective ECHA Committees (RAC/SEAC) devise an opinion. Following this opinion, under Article 64(5) the applicant then has one month to comment. If no comments are received, then the draft opinion becomes final. If there are comments, the Committees then have two months to finalize the opinion, with the possibility to extend to three months if the applicant’s comments are extensive.</td>
</tr>
<tr>
<td>P2</td>
<td>As mentioned above, proposed changes to the role of the Forum would mean that they can be consulted (this may not always be necessary) on the enforceability of the summary of the proposed conditions set out in the opinions of the Committees for major groups of substances. This measure ties into the revised role of the Forum as described in the horizontal measures section above and would increase their involvement in the evaluation and opinion making process.</td>
</tr>
</tbody>
</table>

#### 6.8.1.4 Decision-making phase

Currently under REACH Article 64(3), the Commission is expected to prepare a draft authorisation decision within three months of receipt of the opinions from the agency. However, in most cases, the Commission has not been able to meet this target due to the sheer number and complexity of decisions. Therefore, a series of options for improvement are proposed.

### Table 38: Option 1 authorisation measures (Op1 A#)

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Op1 A20  Extend the European Commission deadline to within 12 months, with possible deadlines of 6, 9 or 12 months being considered in this impact assessment. This would prolong the time for preparing a Commission proposal, but the burden would likely remain the same.

Currently, under REACH it is not clear how and by whom the elements that could potentially trigger a review of a granted authorisation should be notified, collected, and assessed. Changes to the legal provisions would provide better specificity of the exact information required and who should provide it. A series of further measures are being proposed under Option 1 specifically for the review of granted authorisations (under Article 81)\(^7\).

Op1 A21  Proposed introduction of a new legal obligation for the authorisation holder to notify to the relevant authorities (ECHA and/or MS Competent Authorities) any relevant changes to tonnages, HMIs and operational conditions and legal entity.

Op1 A22  Notified changes to authorisations would be assessed by ECHA (no Committee opinion) and would submit this information to the Commission for potential review. This may increase the burden on ECHA somewhat.

Op1 A23  Further clarification would be added to the legislation detailing the type and granularity of information to be submitted as part of the review report and scope of uses.

Op1 A24  Assessment of non-compliance of conditions/monitoring arrangements of the original decision would be undertaken by ECHA.

Op1 A25  Clarification of the rules on the possibility of merging review reports for different authorisation holders.

Op1 A26  Possibility to set out a 'one-time' or 'phasing out' authorisation (without review report) in cases where alternatives are technically feasible, but where time is needed to implement these.

Op1 A27  Information requirements and submission fees for authorisation holders could gradually increase with every subsequent review report. This could aid to speed up substitution by discouraging multiple review reports\(^8\).

Op1 A28  Clarify the way an authorisation may be reviewed according to Article 61(4) and (5)\(^9\). The COM review would be triggered directly by notification from Member State Competent Authority (MSCA) responsible for Directive 96/61/EC (IPPC) and Directive 2000/60/EC (WFD).

\(^7\) Note: in this case, it was concluded that such a task could also be established via an Implementing Act.

\(^8\) Note: fees are addressed in a separate regulation, not in REACH. So this change may require changes to the fees regulation.

\(^9\) Note: to date this has never been used. It is understood that one of the reasons for this is a lack of clarity around how exactly it could be done.
6.8.2 Restriction process (applies to Options 1, 2 and 3)

6.8.2.1 Article 68(1)

Under Option 1 there are no major changes foreseen. The measures being proposed concern minor changes to the timing of various stages of the restriction process. The burden of proof of demonstrating unacceptable risk is on authorities and the justification will be assessed by ECHA’s Committees. Authorities will still be able to scope their restriction proposals by proposing derogations from the restriction. The dossier submitter (Member State or ECHA, on behalf of COM) can propose derogations from restrictions and the burden of proof for such derogations will still lie on the dossier submitter, as currently.

Implementation of the essential use concept in REACH is being considered in the context of the exemptions from restrictions (following 68(1) and 68(2) under all options to increase efficiency and speed of restrictions (see “ESU” in Table 33).

Table 39: Option 1 restriction measures (Op1 R#)

<table>
<thead>
<tr>
<th>Ref no.</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Op1 R1</td>
<td><strong>Article 68(1) restriction</strong></td>
</tr>
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<td></td>
<td>• Dossier preparation: more flexibility given to MS and ECHA for dossier preparation. In particular for complex cases (up to 18 months), instead of 12 months. There will still be 4 months consultation on the restriction proposal with a one month overlap with the opinion-making phase (i.e., comments arrive during the initial phase of drafting of the 1st draft opinion). Forum advice or opinion on all restriction options is conducted in parallel with the four month consultation.</td>
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<td></td>
<td>• Opinion making: commencing 1 month after the start of consultation. Separate opinions from RAC after six months and SEAC after 9 months, with possibility to extend it by 3 or 6 months in complex cases with the agreement of Committees’ chairs. Consultation on both RAC and SEAC draft opinions (not only SEAC) for 2 months from agreement of opinions in Committees, plus 3 months to take comments into account.</td>
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<td></td>
<td>• Decision making: extending the amount of time for the COM to prepare a proposal from 3 months to either 6 or 12 months to align it with actual time it takes for COM to present a proposal.</td>
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<td></td>
<td>• Safeguard clause: extending the deadline for the dossier preparation by MS to 6 months.</td>
</tr>
</tbody>
</table>

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Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction
6.8.2.2 Article 68(2)

As per the GRA, Article 68(2) would be modified to include into the Commission mandate additional hazard classes and professional uses. The Commission can include derogations from GRA restrictions in the decision and the burden of proof for such derogations will still lie on the European Commission, as currently. Under Option 2, a measure to introduce the possibility of derogation requests by industry under Article 68(2) restrictions for essential uses is being considered but could be combined with other measures in Option 1 if this was selected as the preferred option.

6.9 Option 2 measures: Merge the authorisation and restriction processes

6.9.1 Transitional measures

Transitional arrangements would be put into place to address requirements for users of SVHC currently subject to authorisation (Table 40).

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<tr>
<th>Ref no.</th>
<th>Detail</th>
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<tbody>
<tr>
<td>Op2 A1</td>
<td>Move the substances listed in Annex XIV to Annex XVII after the Sunset Date if the former has passed. This would mean a restriction (except for any exempted uses and for authorised uses, until the end of the review period). There would be a transition period where:</td>
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<td>1. parallel implementation of authorisation for new substances and those already in Annex XIV merged with Annex XVII</td>
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<td></td>
<td>2. authorisations granted under the existing REACH Regulation would remain valid until the end of the review period, but there would be no possibility to submit a review report.</td>
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</table>

6.9.2 Derogation from restrictions

Options for derogations for all types of restrictions (including SVHCs) are a key component of Option 2. As under the current system, derogations of general applicability for all types of restrictions could be included as part of the restriction as proposed and adopted by authorities and the European Commission. The burden of proof would rest with authorities, as now. However, there would be two new possibilities for derogations
from restrictions with the burden of proof on industry. As above, these would be granted based on “essential use” only or possibly (in exceptional circumstances) based on the “minimal exposure” route for non-essential uses. Note the scope is still to be decided upon. In other words:

- compared to the current authorisation regime, the range of tools to allow the use of listed SVHCs would be enlarged from individual authorisations (current Article 60) to derogations of general applicability (new). The conditions in Article 68(2) would be removed.
- compared to the current restrictions regime, there will be a formal possibility for authorities to set in the restriction the option for industry to submit applications for derogations of general or individual applicability.

### Table 41: Option 2 measures (Op2 A#)

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<th>Ref no.</th>
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<tr>
<td><strong>Op2 A2</strong></td>
<td>The European Commission could introduce the possibility for derogation requests (e.g., for specific uses) in the legal act introducing the restriction. This would be a case-by-case choice and applicable to both Article 68(1) and 68(2) restrictions. If there is the possibility indicated in the restriction, after inclusion of the restriction in Annex XVII, companies may apply for derogations. They would have several options on how to do this:</td>
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<td>- <strong>Joint derogations of general applicability</strong> (here the burden of proof to justify the derogation would be on industry).</td>
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<td>- The following procedure would apply:</td>
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<td>- The European Commission would set deadlines for submitting requests for derogations: the impact assessment has assumed an 18-month period from the date of inclusion of the restriction in Annex XVII to the latest request date. A possibility assessed in this impact assessment is that as for authorisation applications today, users can continue until European Commission takes a decision on the derogation request. This impact assessment does not examine the economic consequences of introducing a suspensive effect on continued use (as a result of the submission of the derogation request).</td>
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<tr>
<td></td>
<td>- Companies/groups of companies could apply jointly for a derogation of general applicability from the restriction. If specified in the restriction, such a request would be submitted after the adoption of the restriction by the latest request date. As above, a possibility assessed in this impact assessment is that this should not preclude later requests and would not have a suspensive effect, i.e., the same solution as currently applied under authorisation. The number of such requests is however extremely uncertain. The burden of proof for the justification of the derogation would be on industry. If no requests were submitted, the uses of the substance would be restricted from the application date of the restriction.</td>
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<td>- The criteria for assessing whether a derogation would be justified would be based on ESU and/or minimal exposure (see Table 53).</td>
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<td>- The assessment of requests for these joint and generally applicable derogations would be similar to the process for authorisation, with changes linked to the ESU concept.</td>
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<td></td>
<td>- After the evaluation of request(s), the European Commission would prepare a proposal for an amendment of Annex XVII concerning derogation.</td>
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Note: the time periods for such a decision have not been specified, but hypothetically any transitional period for operators requesting derogations would be reduced, if such a decision was determined fast.
6.10 Option 3 measures: Remove the authorisation title from REACH

This option proposes the removal of authorisation provisions from REACH, while keeping the SVHC identification and the Candidate List. Prioritisation of candidate listed substances for inclusion into Annex XIV/generic ban of those substances will be removed. Instead, uses of those substances would need to be addressed through restrictions (both, based on Articles 68(1) and 68(2) with an extended scope), non-REACH processes or national measures (falling under OSH and IED). Note that for the majority of all substances (those not in Annex XIV and those not belonging to the most harmful substances in consumer and some professional uses that are to be tackled via Article 68(2) restrictions), there would be no change to the current situation. The only difference to the baseline would be that instead of regularly including more substances in Annex XIV, these substances would still be covered by national rules under workers and environmental legislation or be restricted at EU level if needed.

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
6.10.1 Authorisation aspects

There would be a complete removal of the authorisation title within the legislation, but the candidate list would be maintained as a separate title to allow continued prioritisation of substances. Prioritisation would however not lead to authorisation, but rather to restrictions, non-REACH processes or national measures (falling under OSH and IED). As above, for the majority of all substances (those not in Annex XIV and those not belonging to the most harmful substances in consumer and professional uses that are to be tackled via Article 68(2) restrictions), there would be no change to the current situation. This option would include the following measures and process changes:

Table 42: Option 3 measures (Op3 A#)

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<tr>
<td><strong>Op3 A1</strong></td>
<td>If the authorisation title was removed, any authorisations already granted would remain valid until the end of the review period, without the possibility to submit a review report.</td>
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<tr>
<td><strong>Op3 A2</strong></td>
<td>Substances that are currently included in the Authorisation List of Annex XIV would be transferred to the Restriction List (Annex XIV) and restricted via Article 68(2) or 68(2), where relevant.</td>
</tr>
</tbody>
</table>

Not allowing the possibility of authorisations/derogations for industry in this type of restrictions would mean that authorities are responsible for all derogations (proposing, justifying, and introducing), increasing their administrative burden significantly.

Industry may still be able to make derogation proposals to authorities, but this would not be guided by a formal application process. As is the case today, opportunities may arise for industry during the call for evidence when authorities are preparing the restriction dossier or during the consultation on the Annex XV restriction dossier. While the burden of proof remains on authorities, during the call for evidence and the consultation on the Annex XV report, usually stakeholders are requested to provide supporting evidence for their proposals for derogations so would still have a say.

6.10.2 Non-REACH processes

Under Option 3, it is proposed that if all uses of the most hazardous substances by consumers and professionals are addressed in accordance with Article 68(2), industrial uses would remain under national jurisdiction in accordance with workers’ safety legislation and industrial emissions legislation, and any new concerns could be addressed under national legislation. It is important to note that there will be no change to the current
national responsibilities and these non-reach processes could also be applied as a horizontal measure in combination with the other options, if found to be preferable.

Table 43: Option 3 measures (Op3 #)

<table>
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<td><strong>Non-REACH processes</strong></td>
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<td>Op3 OSH</td>
<td>If the authorities identified concerns related to worker safety, actions under OSH could be initiated (non-binding recommendation to be followed up by DG EMPL). This would involve ECHA identifying and including substances of concern in the rolling plan for scientific assessment underpinning the development of GRLRs. ECHA would then prepare a scientific report for RAC based on the available scientific data and any relevant information collected through a 90-day call for evidence (if the requirements for data submission for SVHC will be imposed in REACH a 90-day call for evidence might not be needed as all information will be available already). Thus, the process could be speeded up. RAC would then develop an opinion based on the report and the information provided during the consultation. The adopted final RAC opinion is then forwarded to the Commission (DG EMPL) and the process proceeds further, as usual under OSH.</td>
</tr>
<tr>
<td>Op3 IED</td>
<td>RMMs could also be employed under IED instead of REACH to address hazardous substances (non-binding recommendation to be followed up by DG ENV). IED is key to the regulation of pollutant emissions from industrial installations and can enact a prohibition of substance use by defining the use of a substance (e.g., a SVHC) as not being Best Available Technique (BAT). Under Option 3, the measure would include more systematic use in BREFs of the possibility to declare the use of a substance as not being BAT - this would not be a risk assessment but a review of available alternatives that may better qualify as BAT. This would take place as part of the BAT Reference Document (BREF) review work programme under the IED. ECHA could also use information made available as part of the IED environmental management system.</td>
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Stying to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction.
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Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction.

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Study to support the impact assessment for potential amendments of the REACH Regulation to extend the use of the Generic Risk Management Approach to further hazard classes and uses, and to reform REACH authorisation and restriction.
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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs.
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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs.
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